Quality assessment of laparoscopic hysterectomy

Driessen, S.R.C.

Quality assessment of laparoscopic hysterectomy

Sara Driessen

Quality assessment of laparoscopic hysterectomy

Sara Driessen

This PhD thesis was partly funded by the Bronovo Research fund.

Cover	Marcel Schouwenaar
Layout	ProefschriftMaken | www.proefschriftmaken.nl
Printed by	ProefschriftMaken | www.proefschriftmaken.nl
ISBN	978-94-6295-570-7

Financial support for printing of this thesis was kindly provided by Skills Meducation, NVEC, ERBE, Chipsoft, Will Pharma, Walaeus bilbliotheek and Raad van Bestuur HMC Den Haag.

Quality assessment of laparoscopic hysterectomy

Proefschrift

ter verkrijging van
de graad van Doctor aan de Universiteit Leiden,
op gezag van Rector Magnificus prof. mr. C.J.J.M. Stolker,
volgens besluit van het College voor Promoties
te verdedigen op woensdag 29 maart 2017
klokke 16.15 uur

door

Sara Renée Charlotte Driessen

geboren te Utrecht
in 1985

Promotor	Prof. dr. F.W. Jansen
Copromotor	Dr. E.W. van Zwet
Leden promotiecommissie	Prof. dr. D. Oepkes Prof. dr. M.Y. Bongers (MUMC, Maastricht) Dr. M.W.J.M. Wouters (AVL, Amsterdam)

Contents

Chapter 1

General introduction and outline of this thesis

Transparency and measurement of quality of health care have received considerable attention worldwide in recent years. However, the assessment of quality of care is very complex. Quality indicators have been developed in an attempt to differentiate between high and low-quality of healthcare processes [1]. These indicators create the basis for quality improvement and transparency in the health care system [2]. Three different types of quality indicators, which are closely related to each other, are defined by Donabedian and generally adapted and used in medical care [3]: structure, process, and outcome indicators. Structure indicators reflect the setting in which the care is provided (e.g., case volume, access to specific technologies, etc.). Process indicators reflect the total care system (e.g., multidisciplinary team management, surgical approach, etc.). Finally, outcome indicators reflect direct clinical outcomes and are most commonly used by healthcare professionals to assess the quality of surgical care. Ideally, an optimal indicator of quality should support to measure, compare, monitor, and -most importantly- improve the quality of delivered care. Assessing quality is an indispensable step to ensure patient safety and maintain high quality of care, particularly for the field of surgery.

Since the introduction of minimally invasive surgery (MIS) in the past decades, some new and evolving technologies have been introduced without proper evidence regarding their benefits and safety (e.g. robotic surgery, LESS (laparoscopic endoscopic single-site surgery)). This can potentially lead to patient safety issues in daily clinical practice [4]. This observation was also emphasized by the report of the Dutch Health Care Inspectorate published in 2007, in which concerns were expressed regarding patient safety during MIS [5]. This report stated that specific quality measures are needed to develop a formal quality system for laparoscopic procedures to enhance patient safety.

Initially, the field of gynaecology remained reticent regarding the introduction of advanced laparoscopic procedures. However since the introduction of laparoscopic hysterectomy (LH) in 1989 [6] its implementation has significantly increased worldwide [7]. LH is nowadays even the most frequently performed advanced laparoscopic procedure in the field of gynaecology. As a result, it is particularly relevant to determine for this procedure a proper method to assess quality.

Three different surgical approaches of hysterectomy can be distinguished: laparoscopic hysterectomy (LH), abdominal hysterectomy (AH) and vaginal hysterectomy (VH) [8]. From an evidence-based perspective the VH remains the approach of first choice. When VH is technically not feasible, the laparoscopic approach may avoid a conventional AH [8]. However, since the introduction of MIS, a worldwide shift from VH towards LH is observed and the proportion of VH performed for benign gynaecologic conditions has decreased [9]. At the same time, the advantages of LH are getting more evident, and recently prospectively designed studies even

consider LH superior to VH (in the absence of prolapse) [10-12]. These results contribute to the current international debate regarding the position of the vaginal versus the laparoscopic approach. One of the biggest concerns is the growing lack of proficiency of gynaecologists to carry out a VH [9, 13]. To draw any conclusions about the position of VH versus LH, more insight is needed into the present (Dutch) distribution of hysterectomies per approach. Is the use of vaginal approach in hysterectomy indeed in decline? Are residents and gynaecologists less exposed to VH because of the implementation of the relatively newer technique of LH? And how is the implementation of these "newer" advanced laparoscopic procedures?

It is well established that new technology and advanced laparoscopic procedures such as LH require a more challenging work environment compared to conventional surgery. This can potentially lead to patient safety issues [4]. Therefore, in order to guarantee the highest level of (surgical) care, there is an urge to appropriately measure the quality of surgical care and the proficiency of the surgeon performing these advanced procedures.
In this context, since increased surgeon- and hospital volume seem to be directly related to improved outcomes [14-17], a mandatory case volume has been introduced for several high-risk low-volume procedures. This case volume has served as quality indicator for several years now and subsequently, a mandatory case volume as a proxy for quality has also entered the field of gynaecological surgery. For gynaecological oncology, an annual volume of 20 procedures is considered [18]. Also for the advanced gynaecological laparoscopic procedures (level 3 & 4 procedures according to the European Society for Gynaecological Endoscopy (ESGE)) [19] the Dutch Working Group Gynaecologic Endoscopy (WGE) opened the debate to define a minimum number of procedures per hospital/surgeon. Especially the number of LHs performed is still under debate, since there is no conclusive data on the association between a minimum case volume of 20 and improved surgical outcomes in the field of advanced laparoscopic gynaecologic surgery. This makes this "optimal" volume of 20 procedures only speculative [14, 20].
Insight is needed in the number of performed procedures and the number of practising gynaecologists in the Netherlands as this will help to assess the (logistical) consequences of a required case volume. Furthermore, case-volume alone is not sufficient to accurately measure quality of surgical care, and measuring individual surgeon's skills seem to be more relevant [21]. During the surgical training program of residency, (basic) laparoscopic skills are taught to future gynaecologists. However it is doubtful if residents are adequately trained to independently perform laparoscopic procedures directly after finishing residency. Furthermore, to monitor the individual surgical skills, an accurate quality assessment tool is required.

Unfortunately, most of these outcome quality indicators have specific limitations; they are usually not based on evidence, are not easily available, are not suitable for quality

improvement, and/or are not corrected for case-mix characteristics [2, 22-24]. Case-mix variables are defined as specific (patient) characteristics that affect (surgical) outcome. Quality assessment without correction for case-mix characteristics, will result in an invalid comparison of outcomes among healthcare providers [25, 26]. To illustrate; referral hospitals perform more complex procedures and treat more challenging cases (e.g. morbid obese patient, more co-morbidities, patients with prior surgery) which can potentially result in less optimal surgical outcomes. Therefore, case-mix correction is of highest importance and identification of relevant case-mix characteristics for LH is necessary when developing a reliable quality indicator.

Monitor tools based on cumulative sum (CUSUM) charts have already been used many decades to detect deteriorations in industrial processes [27-29], and also in healthcare processes recent research has shown that risk-adjusted CUSUM graphs can be used to continuously monitor individual surgical outcomes and to detect consistently suboptimal performance [30]. These CUSUM charts have been shown to be ideally suited to detect small persistent changes over time, and modified Observed minus Expected (O-E) CUSUM charts provide an easy to understand representation of feedback [31-33]. Benchmarking and providing the clinician with feedback appear to have positive effects on the quality of care, and these are recognized as important areas for quality improvement [34-36]. Therefore, for the development of a new outcome quality indicator, (O-E) CUSUM charts will be ideal to use. Furthermore, an important characteristic of a good quality indicator is the possibility to improve the quality of the delivered care. Therefore, consistently suboptimal performances should be detected and ideally be reflected on.

A next step in quality improvement is the identification of patient safety risk factors causing suboptimal performance (e.g., technological related problems, distractions of the surgical process). A recent study on this subject already showed a patient safety framework and prioritized various risk factors for MIS [37]. This framework should be evaluated into daily practice to find out which risk factors are important and clinically relevant in (gynaecological) surgery. Knowledge about and awareness of these patient safety risk factors are crucial to improve and enhance the surgical team, the environment and finally surgical quality.

The main objective of this thesis is to develop and test a unique dynamic quality assessment tool to correctly measure individual surgical performance of laparoscopic hysterectomy.
To substantiate the development of this new quality instrument, the implementation of LH in the Netherlands and in residency program was assessed, relevant case-mix characteristics for LH were explored, several ways to monitor surgical quality were analyzed and attempts were made to make quality registries less comprehensive for clinicians. Subsequently, patient safety risk factors in LH were identified to enhance patient safety and finally to improve the surgical quality of LH.

Outline of this thesis

Chapter 1: General introduction

Chapter 2: The implementation of advanced laparoscopic gynaecologic surgical procedures and the number of gynaecologists performing these procedures were assessed. Furthermore, the distribution of surgical approaches to hysterectomy was determined.

Chapter 3: The shift in indications in laparoscopic hysterectomy and the encountered "new" dilemmas were illustrated by using three case reports.

Chapter 4: By the use of an online survey the current state of laparoscopic gynaecologic surgery in the Dutch residency program, the level of competence among graduated residents, and whether they still perform these procedures were determined.

Chapter 5: A systematic review was conducted to determine case-mix variables and predictors for surgical outcomes of laparoscopic hysterectomy.

Chapter 6: The development and validation of a dynamic evidence-based quality assessment tool for measuring individual surgical outcomes for laparoscopic hysterectomy was described in a multicentre international study. This tool can serve as an outcome quality indicator for surgical procedures.

Chapter 7: The differences between monitoring outcome measures on hospital level versus individual surgeon's level for laparoscopic hysterectomy were analysed. Furthermore the relation between surgical experience and surgical outcomes was assessed.

Chapter 8: A multicentre study was conducted to identify and quantify patient safety risk factors in laparoscopic hysterectomy and their influence on surgical outcomes.

Chapter 9: In a randomized controlled trial, the effect of additional gamification elements in a registry system was evaluated in terms of engagement and involvement of gynaecologists to register their data.

Chapter 10: General discussion and future perspectives

Reference list

(1) Kotter T, Blozik E, Scherer M. Methods for the guideline-based development of quality indicators--a systematic review. Implement Sci 2012; 7:21.

(2) Mainz J. Defining and classifying clinical indicators for quality improvement. Int J Qual Health Care 2003; 15(6):523-530.

(3) Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q 1966; 44(3):Suppl-206.

(4) Rodrigues SP, Wever AM, Dankelman J, Jansen FW. Risk factors in patient safety: minimally invasive surgery versus conventional surgery. Surg Endosc 2012; 26(2):350-356.

(5) Inspectie voor de gezondheidszorg. Risico's minimaal invasieve chirurgie onderschat, kwaliteitssysteem voor laparoscopische operaties ontbreekt. http://www.igz.nl/zoeken/document.aspx?doc=Rapport+'Risico's+minimaal+invasieve+chirurgie+onderschat%2C+kwaliteitssysteem+voor+laparoscopische+operaties+ontbreekt'&docid=475. Den Haag, The Netherlands. 2007.

(6) Reich H, DeCaprio J, McGlynn F. Laparoscopic hysterectomy. J Gynaecol Surg 1989;(5):213-215.

(7) Makinen J, Brummer T, Jalkanen J, Heikkinen AM, Fraser J, Tomas E et al. Ten years of progress--improved hysterectomy outcomes in Finland 1996-2006: a longitudinal observation study. BMJ Open 2013; 3(10):e003169.

(8) Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BW et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2015; 8:CD003677.

(9) Moen M, Walter A, Harmanli O, Cornella J, Nihira M, Gala R et al. Considerations to improve the evidence-based use of vaginal hysterectomy in benign gynecology. Obstet Gynecol 2014; 124(3):585-588.

(10) Candiani M, Izzo S. Laparoscopic versus vaginal hysterectomy for benign pathology. Curr Opin Obstet Gynecol 2010; 22(4):304-308.

(11) Candiani M, Izzo S, Bulfoni A, Riparini J, Ronzoni S, Marconi A. Laparoscopic vs vaginal hysterectomy for benign pathology. Am J Obstet Gynecol 2009; 200(4):368-7.

(12) Ghezzi F, Uccella S, Cromi A, Siesto G, Serati M, Bogani G et al. Postoperative pain after laparoscopic and vaginal hysterectomy for benign gynecologic disease: a randomized trial. Am J Obstet Gynecol 2010; 203(2):118.

(13) Bongers M. Advances in laparoscopic surgery have made vaginal hysterectomy in the absence of prolapse obsolete: FOR: The laparoscopic approach is suitable for almost all hysterectomies. BJOG 2016; 123(4):633.

(14) Maruthappu M, Gilbert BJ, El-Harasis MA, Nagendran M, McCulloch P, Duclos A et al. The influence of volume and experience on individual surgical performance: a systematic review. Ann Surg 2015; 261(4):642-647.

(15) Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N Engl J Med 2003; 349(22):2117-2127.

(16) Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I et al. Hospital volume and surgical mortality in the United States. N Engl J Med 2002; 346(15):1128-1137.

(17) Dikken JL, Dassen AE, Lemmens VE, Putter H, Krijnen P, van der Geest L et al. Effect of hospital volume on postoperative mortality and survival after oesophageal and gastric cancer surgery in the Netherlands between 1989 and 2009. Eur J Cancer 2012; 48(7):1004-1013.

(18) NENI NVOG. http://nvog-documenten.nl/uploaded/docs/Nota%20NENI%201.0%20november%202014%20incl.%20aanvulling%2012-11-2015.pdf. November 2016. 2016.

(19) ESGE. European Society for Gynaecological Endoscopy (ESGE) classification laparoscopy; http://www.esge.org/education/endoscopic-training/esge-laparoscopy-standard. http://www.esge.org/education/endoscopic-training/esge-laparoscopy-standard. 2014.

(20) Doll KM, Milad MP, Gossett DR. Surgeon volume and outcomes in benign hysterectomy. J Minim Invasive Gynecol 2013; 20(5):554-561.

(21) Twijnstra AR, Blikkendaal MD, van Zwet EW, van Kesteren PJ, de Kroon CD, Jansen FW. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol 2012; 119(4):700-708.

(22) Rubin HR, Pronovost P, Diette GB. From a process of care to a measure: the development and testing of a quality indicator. Int J Qual Health Care 2001; 13(6):489-496.

(23) McGlynn EA, Asch SM. Developing a clinical performance measure. Am J Prev Med 1998; 14(3 Suppl):14-21.

(24) Wollersheim H, Hermens R, Hulscher M, Braspenning J, Ouwens M, Schouten J et al. Clinical indicators: development and applications. Neth J Med 2007; 65(1):15-22.

(25) Orchard C. Comparing healthcare outcomes. BMJ 1994; 308(6942):1493-1496.

(26) Wouters MW, Wijnhoven BP, Karim-Kos HE, Blaauwgeers HG, Stassen LP, Steup WH et al. High-volume versus low-volume for esophageal resections for cancer: the essential role of case-mix adjustments based on clinical data. Ann Surg Oncol 2008; 15(1):80-87.

(27) Biau DJ, Resche-Rigon M, Godiris-Petit G, Nizard RS, Porcher R. Quality control of surgical and interventional procedures: a review of the CUSUM. Qual Saf Health Care 2007; 16(3):203-207.

(28) Bolsin S, Colson M. The use of the Cusum technique in the assessment of trainee competence in new procedures. Int J Qual Health Care 2000; 12(5):433-438.

(29) Boulkedid R, Sibony O, Bossu-Salvador C, Oury JF, Alberti C. Monitoring healthcare quality in an obstetrics and gynaecology department using a CUSUM chart. BJOG 2010; 117(10):1225-1235.

(30) Twijnstra AR, Blikkendaal MD, Driessen SR, van Zwet EW, Kroon CD, Jansen FW. Tailor-made proficiency curves in laparoscopic hysterectomy: enhancing patient safety using CUSUM analysis. Gynecol Surg 2014; 11(4):235-240.

(31) Cockings JG, Cook DA, Iqbal RK. Process monitoring in intensive care with the use of cumulative expected minus observed mortality and risk-adjusted P charts. Crit Care 2006; 10(1):R28.

(32) Steiner SH, Cook RJ, Farewell VT, Treasure T. Monitoring surgical performance using risk-adjusted cumulative sum charts. Biostatistics 2000; 1(4):441-452.

(33) Grigg OA, Farewell VT, Spiegelhalter DJ. Use of risk-adjusted CUSUM and RSPRT charts for monitoring in medical contexts. Stat Methods Med Res 2003; 12(2):147-170.

(34) Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev 2012; 6:CD000259.

(35) van Leersum NJ, Snijders HS, Henneman D, Kolfschoten NE, Gooiker GA, Ten Berge MG et al. The Dutch surgical colorectal audit. Eur J Surg Oncol 2013; 39(10):1063-1070.

(36) Hattie J, Timperley H. The power of feedback. Review of Educational Research 2007; 77(1):81-112.

(37) Rodrigues SP, Ter KM, Dankelman J, Jansen FW. Patient safety risk factors in minimally invasive surgery: a validation study. Gynecol Surg 2012; 9(3):265-270.

Chapter 2

Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in The Netherlands

Sara R.C. Driessen
Niki L.M. Baden
Erik W. van Zwet
Andries R.H. Twijnstra
Frank Willem Jansen

Journal of Minimally Invasive Gynecology 2015 Jan; 22: 642-647

Abstract

Study objective: To assess the implementation of advanced laparoscopic gynecologic surgical procedures, assess the number of gynecologists performing these procedures and highlight the distribution of surgical approaches to hysterectomy.

Design: Observational multicenter study.

Design classification: Canadian Task Force classification II-2.

Setting: All hospitals in The Netherlands.

Sample: Minimally invasive surgical procedures in all 90 hospitals in the year 2012, and the number of gynecologists performing these procedures. Data were compared with national surveys conducted in 2002 and 2007.

Interventions: The number of advanced laparoscopic gynecologic procedures, the number of gynecologists performing these procedures, and the distribution of approaches to hysterectomy were collected through a Web-based questionnaire.

Measurements and main results: The response rate was 96% (86 of 90 hospitals). A total of 4979 advanced laparoscopic gynecologic procedures were performed in 2012 (mean per hospital, 58; median 50.5; SD, 44.4), which is a significant increase over 2007 (95% CI 30.3-46.5; $p < .001$). The proportion of laparoscopic hysterectomy increased from 3% in 2002 to 10% in 2007 and to 36% in 2012. The proportions of abdominal hysterectomy (68% in 2002, 54% in 2007 and 39% in 2012) and vaginal hysterectomy (29% in 2002, 36% in 2007 and 25% in 2012) decreased significantly. However, approximately 37% of gynaecologists (n=76) and 12% of hospitals (n=9), performed fewer than 20 advanced laparoscopic procedures (level 3 and level 4) annually.

Conclusions: Implementation of advanced laparoscopic gynecologic procedures has accelerated tremendously in the last decade, owing mainly to the increased number of laparoscopic hysterectomies. A significant shift has occurred from abdominal and vaginal hysterectomies toward a laparoscopic approach. The vaginal hysterectomy should be brought back in focus, to prevent the deterioration of skills needed to perform this least invasive approach. Furthermore, the introduction of case volume as quality assessment is sure to have consequences for daily gynecologic surgical practice in The Netherlands.

Introduction

Transparency and improvement of quality and safety in healthcare have generated considerable worldwide attention in recent years. To get insight into doctors' performance, a growing social demand has been observed from insurance companies and governmental associations, as well as from the patient's perspective.

Given that laparoscopy is being increasingly applied to a broader palette of gynecologic surgical procedures and thus is indispensable to the current daily practice of the gynecologic surgeon, growing emphasis is being placed on the quality assessment of these minimal invasive techniques.

In highly complex surgery, for example, patient safety issues and outcome measurements are directly connected to case volume and hospital volume. Furthermore, surgeon case volume has served as a quality measurement tool for several years now [1, 2]. The assumption that higher case volume is associated with better patient outcomes in a variety of complex surgical procedures is frequently supported in the literature [1, 3, 4]. In addition, the Dutch Health Care Inspectorate expressed concerns about low volume and highly complex procedures and urgently demanded case volume as quality assessment for these procedures [5].

As the laparoscopic approach gains popularity and gynecologic surgeons' laparoscopic skills improve, there is an ongoing shift in surgical indications in the minimally invasive approach. Therefore, the demand for volume has also entered the field of advanced laparoscopic gynecologic surgery. In this context, a minimum annual volume of 20 procedures is mentioned; however, there remain no conclusive data on the association between higher case volume and improved surgical outcomes in the field of advanced laparoscopic gynecologic surgery, an thus the optimal case volume is only speculative [6]. Furthermore, there is ongoing debate regarding centralization and the maximum possible number of gynecologists performing these advanced laparoscopic procedures to maintain their surgical skills with an adequate case volume.

To make valid decisions regarding this subject, reliable data are needed to provide insight into the current case volume and, not less importantly, the number of gynecologists performing these procedures. At the same time, there is growing international concern about an undesired shift in the approach of vaginal hysterectomy (VH) to laparoscopic hysterectomy (LH), because VH remains the first-choice method for benign indication [7, 8].

Currently, conclusions regarding the national exposure of advanced laparoscopy and the distribution of approaches to hysterectomy in The Netherlands are based on data from 2007 [9].

On these grounds, the aim of the present study was to assess the current state of advanced laparoscopic gynecologic surgery, the number of gynecologists and hospitals performing these laparoscopic procedures, and the distribution of the surgical approaches to hysterectomy, to analyze the possible practical consequences of an increasing demand for high-volume surgeons.

Materials and methods

In 2013, a Web-based questionnaire was sent to all hospitals in the Netherlands containing questions about the number of advanced laparoscopic procedures performed in 2012 and the number of gynecologists performing these procedures. The data were extracted from the local electronic database or from the theatre lists. In addition, the annual report of each hospital was obtained to double-check the provided data. The laparoscopic procedures were classified by the 4 levels of difficulty according to the internationally introduced classification [10]. Level 3 and 4 are considered advanced laparoscopic procedures (level 3: hysterectomy, myomectomy, extensive adhesiolysis, and severe endometriosis; level 4: sacrocolpopexy, lymphadenectomy, and recto-vaginal endometriosis). The questionnaire also included questions about the number of procedures performed using robotic surgery. Furthermore, the numbers of abdominal hysterectomies (AHs) and VHs for benign indications and endometrial cancer were collected to detect a possible shift in approach. VHs involving pelvic organ prolapse were excluded. In addition, the number of abdominal sacrocolpopexy procedures was requested as well.

To increase the response rate, 2 reminder e-mails were sent after 8 and 12 weeks, and follow-up calls were made. The collected data were compared with previous data obtained from 2002 and 2007 [9, 11].

The percentages of hospitals in which the different types of laparoscopic and robotic procedures are performed were determined. Subgroup analysis was performed with respect to teaching hospitals (both academic and nonacademic) and nonteaching hospitals. Furthermore, the mean numbers, median, minimum, maximum and standard deviation (SD) of procedures performed per hospital were determined, including only the hospitals in which procedures were performed. To compare the absolute total number of advanced procedures performed in 2007 and in 2012, a subcalculation was done including only the hospitals that provided data in both years. In addition, the number of gynecologists performing each procedure was collected, to calculate the mean number of annually performed advanced procedures per gynecologist and per hospital. The number of procedures were stratified by volume into 3 groups: low volume (< 20 procedures), medium volume (20 to 59 procedures) and high volume (≥ 60 procedures). The percentages of the different approaches to hysterectomy and sacrocolpopexy were determined.

Statistical analyses were performed using SPSS version 20.0 (IBM, Armonk, NY). The paired *t* test was used to assess the significance of differences in the total number of procedures for 2007 and 2012 and to calculate the 95% confidence intervals (CIs) of this difference. The χ^2 test and Fisher's exact test were used to calculate the differences in hysterectomy techniques between 2002, 2007 and 2012 and the differences between teaching and nonteaching hospitals. Here p values < .05 were considered statistically significant.

Results

Advanced laparoscopic procedures

Of the 90 hospitals in The Netherlands, 86 (96%) provided the requested data on the procedures performed in 2012 and the number of performing gynecologists. The distribution of the responding hospitals was 52% teaching (45 of 86) and 48% nonteaching (41 of 86), which reflects the national distribution in the Netherlands (50% teaching and 50% nonteaching).

The responding 86 hospitals performed a total of 4979 advanced laparoscopic procedures in 2012 (mean per hospital, 58; median 50.5; SD, 44.4). In 2007, 71 responding hospitals were included, performing a total number of 1657 advanced procedures (mean per hospital, 23; median, 15; SD, 29.7). All of these 71 hospitals provided data in both 2007 and 2012. A total of 4380 advanced procedures were performed in these 71 hospitals in 2012 (mean per hospital, 62; median, 53; SD 43,7), which is a significant increase over 2007 (95% CI, 30.3-46.5; p < .001).

The mean numbers of procedures performed per hospital in 2007 and 2012 are compared in Table 1. Significant increases were observed in the number of LHs (95% CI 24.4-34.8; p < .001), myomectomies (95% CI 0.4-1.9; p = .003), and lymphadenectomies (95% CI 0.4-3.1; p = .01).

Table 2 shows the percentage of hospitals where the different procedures were performed, along with the distribution among teaching and nonteaching hospitals. With the exception of the laparoscopic-assisted vaginal hysterectomy (LAVH), all advanced procedures were performed more frequently in teaching hospitals compared to nonteaching hospitals.

A total of 643 sacrocolpopexies were performed in 2012, with the abdominal approach used in 251 (39%) and the laparoscopic approach used in 392 (61%), of which 166 (42%) were performed using robotic surgery.

Table 1 Total and mean number of advanced laparoscopic procedures for 2007 and 2012

Procedure	2007			2012			95% CI of the difference	p value
	Total	Mean (SD)	Min-Max	Total	Mean (SD)	Min-Max		
Level 3								
LH	911	17.2 (15.5)	1-79	3518	45.1 (28.8)	2-156	(24.4 to 34.8)	<0.001
Myomectomy	34	2.4 (1.95)	1-8	128	3.8 (4.2)	1-21	(0.4 to 1.9)	0.003
Adhesiolysis	280	7.0 (10.9)	1-65	383	8.2 (7.0)	1-30	(-1.6 to 2.9)	0.576
Endometriosis	309	9.4 (12.1)	1-59	425	9.7 (9.2)	1-45	(-0.9 to 3.6)	0.221
Level 4								
Sacrocolpopexy	104	8.7 (8.9)	1-31	226	10.8 (9.4)	1-39	(-0.04 to 2.9)	0.055
Lymphadenectomy	9	3.0 (2.0)	1-5	135	11.3 (10.2)	1-29	(0.4 to 3.1)	0.010
Rv endometriosis	n.a.	n.a.	n.a.	164	9.1 (9.9)	1-34	n.a.	n.a.
Total								
Level 3	1544	24.5 (26.5)	1-150	4454	57 (36.0)	2-186	(25.7 to 39.9)	< 0.001
Level 4	113	8.7 (8.4)	1-31	525	15.9 (13.9)	1-56	(2.8 to 8.3)	< 0.001
Robot	n.a.	n.a.	n.a.	376	34.1 (29.3)	5-84	n.a.	n.a.

Mean is the calculated mean number of procedures per hospital, including only the hospitals in which this procedure is performed.
CI = confidence interval, n.a. = not applicable, Rv = rectovaginal, LH = laparoscopic hysterectomy.

Table 2 Percentage of teaching and nonteaching hospitals in which procedures are performed

Procedure	Hospitals			p value
	Total (n)	Non-teaching (n)	Teaching (n)	
Level 3				
LH total	91% (78)	80% (33)	100% (45)	0.002
TLH	78% (67)	61% (25)	93% (42)	< 0.001
LAVH	31% (27)	41% (17)	22% (10)	0.096
SLH	45% (39)	37% (15)	53% (24)	0.227
Myomectomy	40% (34)	32% (13)	47% (21)	0.116
Adhesiolysis	55% (47)	44% (18)	64% (29)	0.050
Endometriosis	51% (44)	39% (16)	62% (28)	0.074
Level 4				
Sacrocolpopexy	24% (21)	5% (2)	42% (19)	< 0.001
Lymphadenectomy	14% (12)	7% (3)	20% (9)	0.090
Rv endometriosis	21% (18)	5% (2)	36% (16)	< 0.001
Total				
Robotic	14% (12)	5% (2)	22 % (10)	0.020
Level 3	91% (78)	81% (33)	100% (45)	0.002
Level 4	38% (33)	10% (4)	64% (29)	< 0.001

Percentages were calculated using only the responding hospitals (n=86). Rv = rectovaginal; LH = laparoscopic hysterectomy; TLH = total laparoscopic hysterectomy; LAVH = laparoscopic assisted vaginal hysterectomy; SLH = supracervical laparoscopic hysterectomy. Teaching hospital include academic and nonacademic teaching hospitals.

Number of performing gynecologists and hospitals

The number of advanced procedures performed per gynecologist and per hospital are presented in Table 3. The table shows that 37% of gynaecologists (n=76) and 12% of hospitals (n=9, including 3 teaching hospitals) perform fewer than 20 advanced procedures annually.

Surgical approaches to hysterectomy

The contribution of LH increased significantly from 3% in 2002 to 10% in 2007 to 36% in 2012, including 1.5% using the robotic approach. The proportion of AHs (68% in 2002, 54% in 2007, and 39% in 2012) and VHs (29% in 2002, 36% in 2007, and 25% in 2012) decreased significantly (Figure 1). The proportion percentage of VHs was significantly higher in nonteaching hospitals than in teaching hospitals (29% vs. 23%; ($p < .001$). Of the various laparoscopic approaches

Table 3 Amount of performed advanced procedures in 2012 per number of gynecologist and hospital

	Number of gynecologists		Number of hospitals	
Volume of level 3 and 4 procedures	n (%)	Cumulative sum n (%)	n (%)	Cumulative sum n (%)
Low				
1-9	28 (14)	28 (14)	4 (5)	4 (5)
10-19	48 (23)	76 (37)	5 (7)	9 (12)
Medium				
20-29	64 (31)	140 (68)	7 (9)	16 (21)
30-39	35 (17)	175 (85)	8 (10)	24 (31)
40-59	27 (13)	202 (98)	18 (23)	42 (54)
High				
60-79	3(2)	205 (100)	11 (14)	53 (68)
80-99	-	-	12 (15)	65 (83)
100-149	-	-	9 (12)	74 (95)
>150	-	-	4 (5)	78 (100)

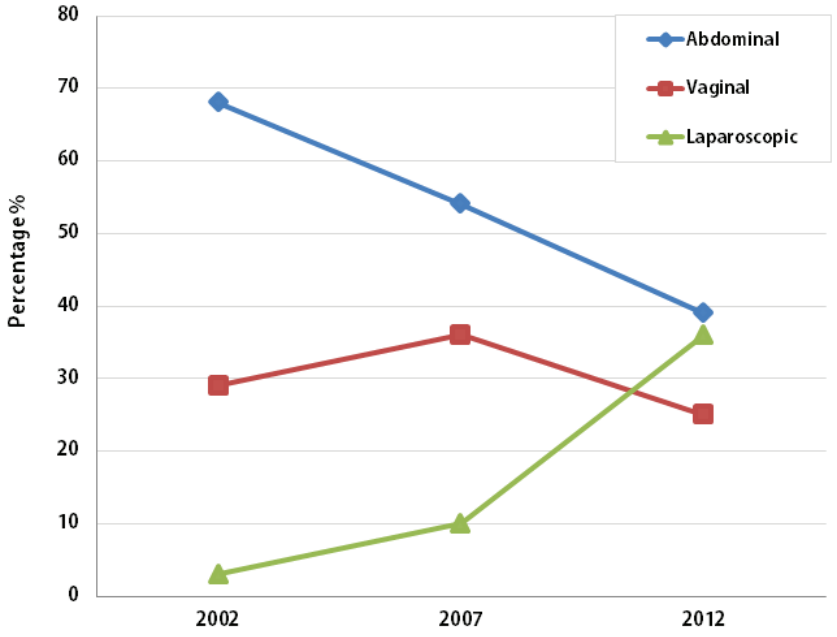


Figure 1 Trends in various types of hysterectomies.
Abdominal and vaginal approach decreased significantly, laparoscopic approach increased significantly ($p<0.001$).

to hysterectomy, total laparoscopic hysterectomy (TLH) was the most commonly performed, accounting for 70% of these procedures, followed by 17% for supracervical laparoscopic hysterectomy (SLH), 9% for LAVH, and 4% for the robotic approach.

Discussion

A significant increase has been observed in the implementation of advanced laparoscopic gynecologic procedures in the Netherlands. This is related especially to the enormous increase in the number of LHs performed, but a comparable trend is visible even for the less commonly performed myomectomy and lymphadenectomy procedures, demonstrating that laparoscopic surgery is being adapted in other fields of gynecologic surgery as well (e.g., fertility, oncology). Furthermore, an ongoing shift toward the laparoscopic approach can be expected, owing to the adoption of new technologies, increased surgical experience, and broader indications (e.g., oncology, performance of more complex procedures, removal of larger uteri) [12]. Moreover, the embedment of LH in residency programs has increased, with LH currently performed in all teaching hospitals and in 81% of nonteaching hospitals. Nonetheless, LAVH is performed more often in nonteaching hospitals. This is remarkable, given that TLH seems superior to LAVH with respect to significantly lower blood loss [13]. In addition, the proportion of VH was higher in nonteaching hospitals, indicating a slower rate of adaptation of LH in nonteaching hospitals, presumably owing to the established predominance of VH technique in these hospitals. LAVH may be the first choice for gynecologists with less laparoscopic experience and more vaginal surgery experience.

Our study demonstrates that a large proportion of gynecologists and 12% of the hospitals in The Netherlands perform fewer than 20 advanced procedures annually. Thus, acceptance of the aforementioned case volume of 20 procedures and implementation of the requirements of the Dutch Health Care Inspectorate is almost certain to have consequences for more than one-third of the gynecologists performing these procedures.

The main strength of this study is its highly representative picture of our country; 96% of all hospitals provided the requested data. In addition, the study included all types of hospitals: academic, teaching, and nonteaching; therefore, our results are also generalizable outside The Netherlands. This is the first study to provide data on the numbers of gynecologists and hospitals performing these procedures, thereby making an important contribution to our case volume analysis.

Most previous studies did not exclude the number of VHs regarding prolapse indications; therefore, comparing these studies with our data underestimates the VH rate in The Netherlands. However, we asked the same numbers and indications in our previous

studies, and thus we can observe a clear trend [9, 11]. Furthermore, one possible reason for the decrease in the vaginal approach is the reduced incidence of uterine prolapse and the upcoming uterine-sparing surgery for prolapse indications [14]; by excluding prolapse surgery from our study, we can eliminate this cause.

Preferably, additional data on clinical outcomes would even be more informative than the volume data alone. Unfortunately, we do not have access to these data and thus cannot draw any conclusions about clinical outcomes.

Although the significant decrease in the number of AHs is responsible for 58% of the tremendous increase of LHs (Figure 1), an undesirable decrease in the number of VHs was observed. This decrease is a matter of concern, given that VH is considered the approach of choice in hysterectomy [7, 15]. At the advent of LH a decade ago, an internationally stable or even increased percentage of the vaginal approach was observed [9, 16-20]. In this context, it might be necessary for training hospitals to bring the vaginal approach back in focus as the hysterectomy of first choice during residency, because the experience level of residents in VH seems relatively low [8, 21]. However, some argue that LH is superior to VH, and this issue is currently a matter of debate. Candiani and coworkers mentioned reductions in blood loss, operative pain and hospital stay in favor of the laparoscopic approach, but a reduced mean operating time as a clear advantage of the vaginal route [22, 23].

To enhance patient safety, case volume is considered of considerable value. A growing number of studies support the influence of surgeon and hospital volume on the clinical outcome of several high-risk procedures, such as esophageal cancer resection, colon cancer surgery, and abdominal aortic aneurysm repair [1, 3, 24]. Therefore, surgeons and hospital volume has become a mandatory aspect of maintaining certification for various surgical procedures [6]. Owing to the rapid increase in advanced laparoscopic surgical procedures within gynecology, the discussion on case volume has also entered our field. To supply all gynecologists who perform advanced laparoscopy with at least 20 advanced laparoscopic procedures, the total number needs to increase to at least 740 procedures yearly, an increase of 15%. Another solution, in this context, is centralization.

The question remains as to whether there is actually an optimal annual case volume for advanced laparoscopic procedures. Doll et al. [6] showed that composite morbidity for benign hysterectomy favored high-volume surgeons; however, there is a lack of prospective studies to confirm this statement, and no substantial evidence is available on recommendations about the optimal annual surgeon and hospital volumes in the field of gynecology. Other studies examining other fields of surgery noted that the optimal case volume is procedure-specific, ranging from 25 to 750 procedures, and the years of surgical practice seem to be relevant as well [6]. Introducing surgeon volume for advanced laparoscopic procedures as

measurement tool for quality will have considerable consequences for the daily practice. In addition, arbitrarily chosen volume criteria seem to be weak and ignore the fact that lower volumes do not exclude high-quality surgery, and that high volumes do not rule out suboptimal care [25].

Conclusion

Accelerated implementation of advanced laparoscopic gynecologic surgery in The Netherlands, particular LH, has been achieved. A significant shift in approach from AH and VH toward the laparoscopic approach was observed. Because VH remains the procedure of first choice, we should bring this approach back in focus to avoid the deterioration of skills needed to perform the vaginal approach.

Using case volume as a quality assessment tool has consequences for a reasonable number of gynecologists and should be introduced with more caution. To accurately measure quality, other aspects, such as case-mix, surgical skills, and experience, must be considered as well [26].

Acknowledgment

We thank all of the gynecologists who completed the survey and provided the requested data.

Reference list

(1) Dikken JL, Dassen AE, Lemmens VE et al. Effect of hospital volume on postoperative mortality and survival after oesophageal and gastric cancer surgery in the Netherlands between 1989 and 2009. Eur J Cancer. 2012; 48:1004-13.

(2) Mesman R, Faber MJ, Westert GP et al. [Volume standards: quality through quantity? relationship between treatment volume and outcomes not well founded]. Ned Tijdschr Geneeskd. 2013; 157:A5466.

(3) Birkmeyer JD, Stukel TA, Siewers AE et al. Surgeon volume and operative mortality in the United States. N Engl J Med. 2003; 349:2117-27.

(4) van Lanschot JJ, Hulscher JB, Buskens CJ et al. Hospital volume and hospital mortality for esophagectomy. Cancer. 2001; 91:1574-8.

(5) IGZ. Inspectie voor de gezondheidszorg; volumenormen beperken risico voor patiënt; http://www.igz.nl/actueel/nieuws/volumenormenbeperkenrisicovoordepatint.aspx. 2010.

(6) Doll KM, Milad MP, Gossett DR. Surgeon volume and outcomes in benign hysterectomy. J Minim Invasive Gynecol. 2013; 20:554-61.

(7) Nieboer TE, Johnson N, Lethaby A et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev. 2009;CD003677.

(8) Moen M, Walter A, Harmanli O et al. Considerations to improve the evidence-based use of vaginal hysterectomy in benign gynecology. Obstet Gynecol. 2014; 124:585-8.

(9) Twijnstra AR, Kolkman W, Trimbos-Kemper GC et al. Implementation of advanced laparoscopic surgery in gynecology: national overview of trends. J Minim Invasive Gynecol. 2010; 17:487-92.

(10) ESGE. European Society for Gynaecological Endoscopy (ESGE) classification laparoscopy . http://www.esge.org/education/endoscopic-training/esge-laparoscopy-standard. 2014.

(11) Kolkman W, Trimbos-Kemper TC, Jansen FW. Operative laparoscopy in The Netherlands: Diffusion and acceptance. Eur J Obstet Gynecol Reprod Biol. 2007; 130:245-8.

(12) Uccella S, Cromi A, Serati M et al. Laparoscopic Hysterectomy in Case of Uteri Weighing >/=1 Kilogram: A Series of 71 Cases and Review of the Literature. J Minim Invasive Gynecol. 2013; available online.

(13) Twijnstra AR, Kianmanesh Rad NA, Smeets MJ et al. Twenty-first century laparoscopic hysterectomy: should we not leave the vaginal step out? Gynecol Surg. 2009; 6:311-6.

(14) Wu MP, Huang KH, Long CY et al. Trends in various types of surgery for hysterectomy and distribution by patient age, surgeon age, and hospital accreditation: 10-year population-based study in Taiwan. J Minim Invasive Gynecol. 2010; 17:612-9.

(15) AAGL ADVANCING MINIMALLY INVASIVE GYNECOLOGY WORLDWIDE. AAGL Position Statement: Route of Hysterectomy to Treat Benign Uterine Disease. J Minim Invasive Gynecol. 2011; Jan-Feb:1-3.

(16) Makinen J, Brummer T, Jalkanen J et al. Ten years of progress--improved hysterectomy outcomes in Finland 1996-2006: a longitudinal observation study. BMJ Open. 2013; 3:e003169.

(17) Lykke R, Blaakaer J, Ottesen B et al. Hysterectomy in Denmark 1977-2011: changes in rate, indications, and hospitalization. Eur J Obstet Gynecol Reprod Biol. 2013; 171:333-8.

(18) Turner LC, Shepherd JP, Wang L et al. Hysterectomy surgical trends: a more accurate depiction of the last decade? Am J Obstet Gynecol. 2013; 208:277.

(19) Lee J, Jennings K, Borahay MA et al. Trends in the national distribution of laparoscopic hysterectomies from 2003 to 2010. J Minim Invasive Gynecol. 2014; 21:656-61.

(20) Schollmeyer T, Elessawy M, Chastamouratidhs B et al. Hysterectomy trends over a 9-year period in an endoscopic teaching center. Int J Gynaecol Obstet. 2014; 126:45-9.

(21) Miskry T, Magos A. A national survey of senior trainees surgical experience in hysterectomy and attitudes to the place of vaginal hysterectomy. BJOG. 2004; 111:877-9.

(22) Candiani M, Izzo S, Bulfoni A et al. Laparoscopic vs vaginal hysterectomy for benign pathology. Am J Obstet Gynecol. 2009; 200:368-7.

(23) Candiani M, Izzo S. Laparoscopic versus vaginal hysterectomy for benign pathology. Curr Opin Obstet Gynecol. 2010; 22:304-8.

(24) Birkmeyer JD, Siewers AE, Finlayson EV et al. Hospital volume and surgical mortality in the United States. N Engl J Med. 2002; 346:1128-37.

(25) Kolfschoten NE, Marang-van de Mheen PJ, Wouters MW et al. A combined measure of procedural volume and outcome to assess hospital quality of colorectal cancer surgery, a secondary analysis of clinical audit data. PLoS One. 2014; 9:e88737.

(26) Twijnstra AR, Blikkendaal MD, van Zwet EW et al. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol. 2012; 119:700-8.

Chapter 3

Steeds vaker laparoscopische hysterectomie
Verschuiving van indicatiegebied en dilemma's

Sara R.C. Driessen
Evelien M. Sandberg
Lukas van den Haak
Frank Willem Jansen

Ned Tijdschr Geneeskd 2015 dec;159:A9324
[Increase in laparoscopic hysterectomy: shift in indications and dilemmas]

Summary

Increase in laparoscopic hysterectomy: shift in indications and dilemmas

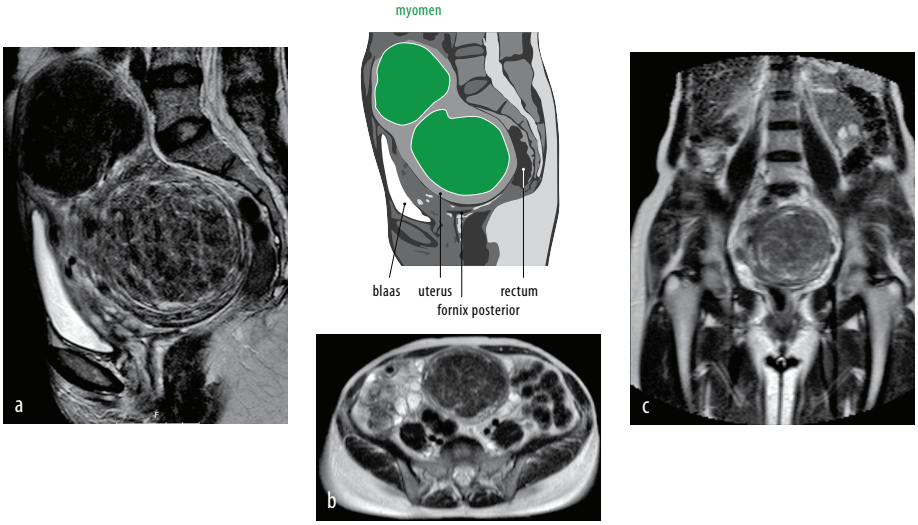
Hysterectomy is still one of the most frequently performed gynaecological procedures. The use of the laparoscopic approach has increased over recent years and a shift in indication has been observed. However, not every clinic or gynaecologist is able to provide laparoscopic hysterectomy for more challenging patients. Therefore, referral to an expert center is of the highest importance in order to offer the patient the least invasive approach to hysterectomy. The advantages of the laparoscopic approach have become more evident over recent years. The widespread introduction of minimally invasive surgery means that surgeons are encountering new challenges, such as the rapid introduction of new instruments, the absolute increased incidence of rare complications and the provision of post-operative counseling on recovery. Maintaining knowledge of these matters is essential in order to secure the quality of care.

Dames en heren,

Ondanks de introductie van meerdere medicamenteuze en hysteroscopische alternatieven, is de hysterectomie nog altijd één van de meest uitgevoerde grote ingrepen binnen de gynaecologische chirurgie. De laparoscopische uterusextirpatie, die in 1989 werd geïntroduceerd door Reich, werd begin jaren 90 voor het eerst uitgevoerd in Nederland. Sindsdien neemt de implementatie van deze nieuwe chirurgische techniek toe en breidt het indicatiegebied snel uit [1]. Aan de hand van 3 casussen illustreren wij de verschuiving van het indicatiegebied van de laparoscopische hysterectomie en een aantal dilemma's die daarbij een rol kunnen spelen.

Patiënte A, een 62-jarige vrouw, para 4, werd doorverwezen naar de polikliniek gynaecologie wegens postmenopauzaal bloedverlies. Patiënte had geen andere gynaecologische klachten. Wel had zij in de voorgeschiedenis morbide obesitas (BMI: 48 kg/m^2), diabetes mellitus type 2 en COPD. In speculo zagen we een gave cervix; het vaginaal toucher was illusoir door de obesitas. Transvaginale echografie toonde een uterus van 90x60x55mm en een verdikt endometrium van 18mm. Op basis van "endometriumsampling" werd een endometrioïdtype adenocarcinoom van het endometrium vastgesteld. Aanvullend werd een röntgenfoto van de thorax gemaakt, die geen bijzonderheden liet zien. Gezien de niet-afwijkende grootte van de uterus verrichtten we een totale laparoscopische hysterectomie met bilaterale salpingo-oöphorectomie, die ongecompliceerd verliep. De huidige richtlijn beschrijft dat een laparoscopische benadering bij patiënten die een endometriumcarcinoom met een laag stadium en laag risico hebben, in ervaren handen even effectief is als de klassieke open procedure [2]. Het postoperatieve beloop was ongecompliceerd. Pathologisch onderzoek toonde een adenocarcinoom van het endometrium graad 1 met >50% doorgroei in het myometrium. De ovaria en cervix waren niet afwijkend. Gezien de leeftijd van patiënte (≥ 60 jaar) werd zij behandeld met aanvullende brachytherapie van de vaginatop om zo het risico op een locoregionaal recidief te minimaliseren [3]. We controleerde patiënte poliklinisch; 2 jaar na de operatie was zij klachten- en ziektevrij.

Patiënte B, een 52-jarige vrouw, para 2 bezocht de polikliniek gynaecologie wegens een zeurende pijn in de onderbuik. Patiënte had bemerkt dat haar buik in omvang was toegenomen. Ze had een regulaire cyclus, waarbij de eerste 2 dagen van de menstruatie gepaard gingen met hevig vaginaal bloedverlies. In speculo zagen wij een gave cervix. Bij vaginaal toucher was de uterus palpabel tot navelhoogte. Transvaginale echografie toonde 2 vergrote structuren in de onderbuik, die het meest pasten bij een leio- of adenomyoom. Omdat er onzekerheid was over de oorsprong van de structuren werd een MRI scan verricht (Figuur 1). Deze toonde een uterus myomatosus met een beeld dat paste bij 2 grote myomen: 1 myoom craniaal van het corpus uteri met een afmeting van 75x95x90mm en 1 myoom dorsaal van 90x100x90mm.



Figuur 1 MRI-scan van patiënt B, met een myoom van 75 x 95 x 90 mm dat craniaal ligt en een myoom van 90 x 100 x 90 mm dat dorsaal ligt van het corpus uteri.
(a) Sagittaal, (b) transversaal en (c) coronaal vlak.

Bij aanvullend laboratorium onderzoek was de Hb-waarde 4.9mmol/l (*referentiewaarde 7.5-10.0mmol/L*). Gezien de hemoglobineondermijnende menorragie en mechanische klachten bij een uterus myomatosus bespraken we de verschillende behandelopties met patiënte, zoals hysterectomie of embolisatie. Patiënte koos voor een hysterectomie. We behandelden haar eerst met ijzersuppletie en een gonadotropine-'releasing' hormoon (GnRH)-agonist gedurende 3 maanden. Voorbehandeling met GnRH-agonist resulteert in een pre- en postoperatieve stijging van de Hb-waarde en in volumereductie van de myomen of uterus. Hierdoor is een minimaal invasieve benadering kansrijker. Hiertegenover staan echter de hoge kosten van behandeling met een GnRH-agonist en het optreden van post-menopauzale symptomen [4]. Na de voorbehandeling verrichtten we een totale laparoscopische hysterectomie, die ongecompliceerd verliep. We verwijderden de uterus door deze te fragmenteren (morcellatie); de uterus woog 930 gram. Het postoperatieve beloop was ongecompliceerd. Bij de controle 6 weken later was patiënte klachtenvrij.

Patiënte C, een 47-jarige vrouw, para 0, bezocht de polikliniek gynaecologie wegens hevig menstrueel bloedverlies en dysmenorroe. In het verleden had patiënte een hormoonhoudend spiraal en orale anticonceptie gebruikt, maar deze werkten onvoldoende en gaven bijwerkingen. Bij lichamelijk onderzoek vonden we geen bijzonderheden. Transvaginale echografie toonde een beeld dat paste bij een deels intramuraal, deels submuceus myoom van 34x25mm. Een vaginale hysterectomie zou de behandeling van eerste keus zijn, maar

deze benadering was niet mogelijk omdat patiënte een te nauwe vagina had. Patiënte wilde een definitieve oplossing en na voorlichting over de verschillende behandelopties, zoals endometriumablatie, hysteroscopische myoomresectie of hysterectomie, koos zij voor een totale laparoscopische hysterectomie, waarbij de adnexa in situ zouden blijven. Deze ingreep verliep ongecompliceerd; we sloten de vaginatop laparoscopisch met een doorlopende hechting met weerhaakjes. Op de tweede dag na de operatie was patiënte klachtenvrij en ontsloegen we haar uit het ziekenhuis. Na 6 weken zagen wij patiënte voor controle terug op de polikliniek; zij had geen klachten. Bij lichamelijk onderzoek waren er geen bijzonderheden; in speculo was de hechting van de vaginatop nog zichtbaar. Ruim 3 maanden later werd patiënte met spoed ingestuurd wegens acuut ontstane buikpijn na coïtus. In speculo zagen we een ruime hoeveelheid sereus vocht en een vaginatop dehiscentie van 2-3 cm met herniatie van de tuba. We verrichten daarom een laparoscopie. Omdat beide tubae niet vitaal waren verwijderden we deze; de ovaria waren niet-afwijkend. We sloten de vaginatop vaginaal gesloten en behandelden patiënte met intraveneuze antibiotica. We zagen patiënte hierna nog 2 keer op de polikliniek wegens zeurende buikpijn, waarvoor we geen oorzaak konden vinden. 3 maanden later was patiënte klachtenvrij en verwezen we haar terug naar de huisarts.

Beschouwing

Indicatiegebied

Aanvankelijk werd de laparoscopische hysterectomie geïntroduceerd als alternatief voor de abdominale benadering (wanneer de vaginale benadering niet mogelijk was) en werd deze alleen uitgevoerd bij de “ideale patiënt”. Zoals onze casussen illustreren worden de grenzen voor het uitvoeren van een laparoscopische hysterectomie echter steeds verder verlegd. Zo zijn tegenwoordig patiënten met een grote uterus, endometriumcarcinoom met een laag stadium en laag risico, of een hoge BMI eveneens geschikt voor de laparoscopische benadering.

Grote uterus. De ontwikkeling van het laparoscopisch verwijderen van een grote uterus, zoals bij patiënte B, komt door de verbetering van de laparoscopische vaardigheden van de huidige gynaecoloog maar ook door de introductie van nieuwe technologieën en instrumenten, zoals bijvoorbeeld de morcellator.

Endometriumcarcinoom. Bij patiënten met een endometrium carcinoom met een laag stadium en laag risico, zoals patiënte A, is de laparoscopische benadering inmiddels de eerstekeusbehandeling geworden. De opnameduur en complicatieratio zijn lager dan bij de

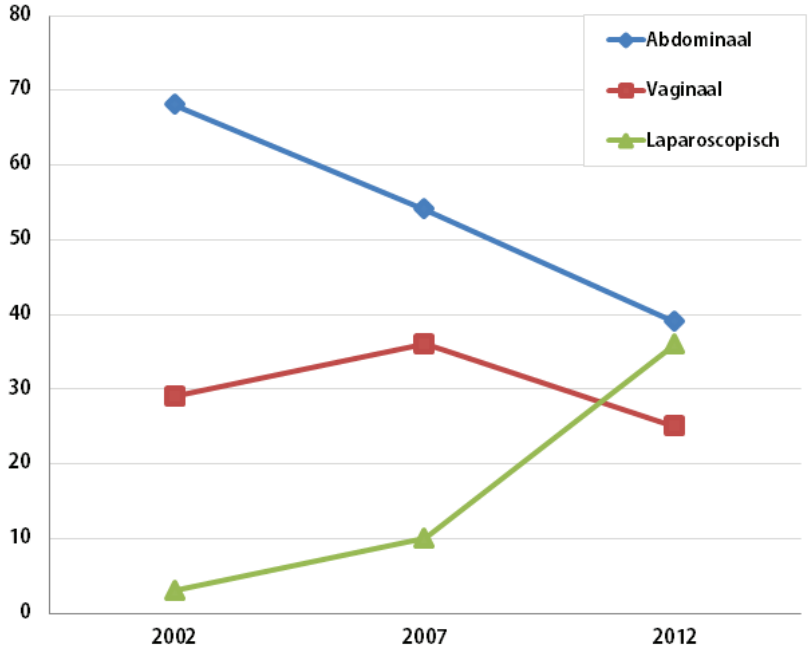
abdominale route en deze benadering is bewezen veilig [5]. Ook binnen de gynaecologische oncologie breidt de rol van minimaal invasieve chirurgie zich snel uit.

Hoge BMI. Zelfs morbide obesitas, zoals bij patiënte A, is geen belemmering om een ingreep succesvol laparoscopisch uit te voeren. Wel is bij patiënten met een hogere BMI of grotere uterus het risico op een complicatie of het converteren naar een abdominale benadering groter [6]. Een recente meta-analyse laat echter zien dat de laparoscopische benadering bij obese patiënten met een BMI ≥35kg/m^2 gepaard gaat met significant minder complicaties en een kortere opname duur, vergeleken met patiënten die een abdominale hysterectomie ondergingen [7].

Zoals beschreven lijken er nog maar weinig contra-indicaties om de hysterectomie via de laparoscopische route te verrichten. Niet elke kliniek beschikt over de praktische mogelijkheden om de hysterectomie laparoscopisch uit te voeren bij deze complexere patiënten. Om toch de juiste zorg te kunnen verlenen dienen gynaecologen zich te realiseren dat ze een patiënte kunnen doorverwijzen naar een expertisecentrum. Op deze manier wordt de patiënte de mogelijkheid geboden van de minst invasieve benadering van hysterectomie.

Voor patiënten met een benigne aandoening geldt de vaginale hysterectomie tot op heden nog altijd als gouden standaard en eerstekeuzebenadering, zoals ook beschreven wordt in een recente Cochrane-review [8, 9]. Wanneer deze chirurgisch technisch moeizaam uitvoerbaar lijkt, vanwege een te nauwe vagina, zoals bij patiënte C, of het ontbreken van descensus van de uterus, wordt gekozen voor een laparoscopische benadering voordat de conventionele abdominale hysterectomie wordt toegepast.

Uit recent onderzoek in Nederland is gebleken dat het aantal abdominale hysterectomieën afneemt (van 54% in 2007 naar 39% in 2012) ten gunste van het aantal laparoscopische (van 10% in 2007 naar 36% in 2012). Het aantal vaginale hysterectomieën lijkt echter ook af te nemen tijdens de implementatie van de laparoscopische hysterectomie (van 36% in 2007 naar 25% in 2012) (Figuur 2) [1]. Of dit een zorgelijke ontwikkeling is, is momenteel onderdeel van discussie. De voordelen van de laparoscopische benadering vergeleken met de vaginale hysterectomie lijken steeds duidelijker te worden, zoals een kortere opname duur, minder bloedverlies en minder postoperatieve pijn [10]. Daarentegen is de operatie duur van de vaginale benadering nog altijd sterk in het voordeel vergeleken met de laparoscopische ingreep. De voorkeur en ervaring van de gynaecoloog spelen een belangrijke rol in de keus voor het type benadering [11], maar de indicatie en de voorkeur van patiënte dienen hierin leidend te zijn.



Figuur 2 Trends in verschillende benaderingen van hysterectomie in Nederland in de periode 2002-2012 [1].

Dilemma's

Mede door de opkomst van de 'power morcellator' zijn de mogelijkheden van laparoscopie flink toegenomen en worden steeds grotere uteri en myomen met laparoscopie verwijderd. In tegenstelling tot de introductie van nieuwe medicijnen, worden nieuwe instrumenten relatief snel en vaak zonder eenduidig wetenschappelijk bewijs op de operatiekamer geïntroduceerd. Dit kan potentiële risico's met zich meebrengen.

Morcellatie. Zo is ook het gebruik van de morcellator in opspraak geraakt jaren na de introductie. Recent zijn casussen gepubliceerd waarbij onbedoeld uterussarcomen werden gemorcelleerd, wat de prognose negatief beïnvloedt. Er zijn echter geen eenduidige symptomen of diagnostische middelen die een uterussarcoom met 100% zekerheid kunnen aantonen of uitsluiten. Dit heeft ertoe geleid dat de Amerikaanse Food and Drug Administration (FDA) adviseert morcelleren te verlaten in bijna alle gevallen [12]. Als reactie hierop probeert men het morcelleren veiliger te maken. Eén van de ontwikkelingen is morcelleren in een zak. Op deze manier wordt weefseldisseminatie in de buikholte voorkomen. De langetermijnresultaten en mogelijke complicaties van deze methode zijn nog niet bekend en daarom moet ook deze techniek zorgvuldig worden geanalyseerd.

Recente studies tonen de grote voordelen van de laparoscopische benadering met morcellatie vergeleken met laparotomie met betrekking tot de morbiditeit, mortaliteit en kosteneffectiviteit. Het huidige standpunt van de Nederlandse beroepsvereniging over deze kwestie is dat alle voordelen en risico's uitgebreid met de patiënte besproken moeten worden voordat wordt overgegaan tot morcelleren.

Vaginatopdehiscentie. Naast de vele bekende voordelen van laparoscopische hysterectomie is het van belang te realiseren dat een vaginatopdehiscentie vaker voorkomt bij deze benadering, zoals bij patiënte C het geval was. Deze complicatie manifesteert zich meestal laat (>6 weken na de ingreep) en kan –zelden– tot zelfs 6 maanden na de ingreep optreden [13, 14]. De incidentie ervan varieert internationaal tussen de 0.3 en 3.1%; een Nederlandse studie vond een incidentie van 3.3% [14]. De meest voorkomende klachten zijn onderbuikspijn, bloed- en vochtverlies. Vaak volstaat het om de vaginatop vaginaal of laparoscopisch te overhechten. Hoewel een relatie wordt vermoed tussen coïtus en het optreden van dehiscentie, is er geen reden om coïtus af te raden na 6 weken na de operatie. Coïtus zou volgens de huidige zienswijze alleen een dehiscentie uitlokken die vroeg of laat toch al zou optreden, omdat er al eerder sprake lijkt te zijn van een primair genezingdefect van de vaginatop [14]. Het type hechtmateriaal (met weerhaakjes, mono- of multifilament) en type hechttechniek (doorlopend, enkellaags, dubbellaags) zijn regelmatig bestudeerd als mogelijke predisponerende factor voor het optreden van een dehiscentie, maar hierover geeft de literatuur geen eenduidige conclusie. Vaginatop dehiscentie blijft een zeldzame complicatie, maar door de stijging van het aantal laparoscopische hysterectomieën is kennis van deze complicatie steeds belangrijker. De klachten van de patiënten worden soms niet of niet meer direct gerelateerd aan de ingreep, waardoor er een vertraging in het stellen van de juist diagnose kan ontstaan.

Herstel. Patiënten die laparoscopisch geopereerd worden, hebben postoperatief een aanzienlijk kortere opnameduur. De veronderstelling dat laparoscopisch geopereerde patiënten ook sneller herstellen in de thuissituatie klopt echter regelmatig niet. Zo heerst er soms onduidelijkheid over wanneer en met welke dokter contact moeten worden opgenomen in het postoperatieve traject. Ook tijdens de thuissituatie blijft de medisch specialist verantwoordelijk voor de postoperatieve patiënte. Wanneer de patiënte zich bij de huisarts meldt met klachten, moet zij worden doorverwezen naar de medisch specialist, zodat de klachten in kaart kunnen worden gebracht in relatie tot de uitgevoerde ingreep.

Recent wetenschappelijk onderzoek in Nederland laat zien dat postoperatief advies op maat, bijvoorbeeld met een webbased e-healthprogramma, het postoperatieve herstel significant verkort en leidt tot minder postoperatieve pijn, snellere werkhervatting en een hogere kwaliteit van leven [15]. Mede door de komst van dit soort patiëntgerichte interventies

zal de laparoscopische benadering nog meer tot haar recht kunnen komen. Tevens zal dit de maatschappelijke kosten aanzienlijk reduceren en de patiënt tevredenheid vergroten.

Dames en Heren, de laparoscopische hysterectomie is momenteel niet meer weg te denken uit het chirurgische palet van de gynaecoloog. Er is verschuiving van het indicatiegebied voor deze operatie; in expertisecentra zijn er nog maar weinig contra-indicaties. De juiste chirurgische benadering van hysterectomie dient altijd gekozen te worden in nauw overleg met patiënte. De mogelijkheid tot doorverwijzing speelt hierbij een belangrijke rol, zodat de patiënte de minst invasieve behandeling kan krijgen.

Naast de vele voordelen van de minimaal invasieve chirurgie, worden gynaecologen maar ook andere specialisten geconfronteerd met nieuwe uitdagingen, zoals de snelle introductie van nieuwe instrumenten, de absolute toename van zeldzame (late) complicaties en de voorlichting bij het postoperatieve herstel. Het is zaak om hiervan kennis te hebben en te onderhouden, zodat de hoogste kwaliteit van zorg gewaarborgd blijft.

Leerpunten

- Door een verschuiving van het indicatiegebied wordt laparoscopische hysterectomie steeds vaker uitgevoerd.
- Patiënten met een hoge BMI, endometriumcarcinoom met een laag stadium en laag risico, of grote uterus komen tegenwoordig in aanmerking voor een laparoscopische hysterectomie.
- Vaginatopdehiscentie is een zeldzame, maar late complicatie, die vaker voorkomt bij patiënten die een laparoscopische hysterectomie ondergingen dan bij degenen die behandeld werden met een vaginale of abdominale hysterectomie.
- Voor patiënten met een benigne aandoening is vaginale hysterectomie de behandeling van eerste keus; hierna volgt de laparoscopische en daarna de abdominale hysterectomie.
- Als de gynaecoloog zelf niet beschikt over de praktische mogelijkheden voor de minst invasieve benadering van hysterectomie, kan hij of zij de patiënte doorverwijzen naar een expertisecentrum om zo de beste zorg te bieden.
- De veronderstelling dat laparoscopisch geopereerde patiënten sneller herstellen in de thuissituatie klopt regelmatig niet; goede, op maat gemaakte voorlichting kan het postoperatieve herstel wel aanzienlijk verkorten.
- Voordat wordt overgegaan tot het fragmenteren van de uterus (morcelleren) dienen alle voordelen en risico's hiervan uitgebreid besproken te worden met de patiënte.

Referentielijst

(1) Driessen SR, Baden NL, van Zwet EW, Twijnstra AR, Jansen FW. Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in the Netherlands. J Minim Invasive Gynecol 2015; 22(4):642-647.

(2) oncoline. http://www.oncoline.nl/endometriumcarcinoom; laatst geraadpleegd oktober 2015. 2015.

(3) Nout RA, Smit VT, Putter H, Jurgenliemk-Schulz IM, Jobsen JJ, Lutgens LC et al. Vaginal brachytherapy versus pelvic external beam radiotherapy for patients with endometrial cancer of high-intermediate risk (PORTEC-2): an open-label, non-inferiority, randomised trial. Lancet 2010; 375(9717):816-823.

(4) Lethaby A, Vollenhoven B, Sowter M. Pre-operative GnRH analogue therapy before hysterectomy or myomectomy for uterine fibroids. Cochrane Database Syst Rev 2001;(2):CD000547.

(5) Mourits MJ, Bijen CB, Arts HJ, ter Brugge HG, van der Sijde R, Paulsen L et al. Safety of laparoscopy versus laparotomy in early-stage endometrial cancer: a randomised trial. Lancet Oncol 2010; 11(8):763-771.

(6) Brummer TH, Jalkanen J, Fraser J, Heikkinen AM, Kauko M, Makinen J et al. FINHYST, a prospective study of 5279 hysterectomies: complications and their risk factors. Hum Reprod 2011; 26(7):1741-1751.

(7) Blikkendaal MD, Schepers EM, van Zwet EW, Twijnstra AR, Jansen FW. Hysterectomy in very obese and morbidly obese patients: a systematic review with cumulative analysis of comparative studies. Arch Gynecol Obstet 2015.

(8) Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.

(9) Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BW et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2015; 8:CD003677.

(10) Candiani M, Izzo S. Laparoscopic versus vaginal hysterectomy for benign pathology. Curr Opin Obstet Gynecol 2010; 22(4):304-308.

(11) Einarsson JI, Matteson KA, Schulkin J, Chavan NR, Sangi-Haghpeykar H. Minimally invasive hysterectomies-a survey on attitudes and barriers among practicing gynecologists. J Minim Invasive Gynecol 2010; 17(2):167-175.

(12) FDA. Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication; http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm. 2015.

(13) Janssen PF, Brolmann HA, Huirne JA. Causes and prevention of laparoscopic ureter injuries: an analysis of 31 cases during laparoscopic hysterectomy in the Netherlands. Surg Endosc 2013; 27(3):946-956.

(14) Blikkendaal MD, Twijnstra AR, Pacquee SC, Rhemrev JP, Smeets MJ, de Kroon CD et al. Vaginal cuff dehiscence in laparoscopic hysterectomy: influence of various suturing methods of the vaginal vault. Gynecol Surg 2012; 9(4):393-400.

(15) Vonk NA, Anema JR, van Mechelen W, Knol DL, van Baal WM, van Kesteren PJ et al. A personalised eHealth programme reduces the duration until return to work after gynaecological surgery: results of a multicentre randomised trial. BJOG 2014; 121(9):1127-1135.

Chapter 4

Proficiency for advanced laparoscopic procedures in gynecologic residency program: do all residents need to be trained?

Sara R.C. Driessen
Juliënne A. Janse
Henk W.R. Schreuder
Frank Willem Jansen

Journal of Surgical Education (J Surg Educ.) 2015 Apr; 72 (5): 942-948

Abstract

Objectives: To assess the current state of laparoscopic gynecologic surgery in the Dutch residency program, the level of competence among graduated residents, and whether they still perform these procedures. Furthermore, their current attitudes toward the implementation of minimally invasive surgery into residency training were assessed.

Design: An online survey (Canadian Task Force Classification III) regarding the level of competence, performance, training, and interest for gynecologic laparoscopic procedures.

Participants/Setting: Gynecologists who finished residency training between 2008 and 2013 in the Netherlands.

Results: Response rate was 73% (171/235). The scores for all basic and intermediate laparoscopic procedures performed immediately after residency showed the highest competence level (median 5, of scale 1-5). The competence level for advanced laparoscopic procedures was less at 3, indicating that the graduated residents are not able to perform these procedures without supervision. Overall, 56% of the gynecologists no longer perform any level 3 advanced procedures, and 86% do not perform level 4 advanced procedures. Gynecologists who still perform the inquired laparoscopic procedures scored a significantly higher competence level immediately after residency training for most of procedures compared with the gynecologists who do not perform these procedures.

Conclusion: Residents are sufficiently trained for basic and intermediate laparoscopic procedures during residency training. However, they are not sufficiently equipped to perform advanced laparoscopic procedures without supervision. We should consider training advanced procedures especially to a selected group of residents because most gynecologists do not perform these procedures after residency. The learning curve for advanced procedures continues to rise after finishing residency for those who keep on performing these procedures, therefore an additional fellowship is recommended for this group.

Introduction

In 2013, the Dutch gynecologic residency program implemented new guidelines, which also had surgical requirements [1]. Besides the quantity of performed procedures, the level of competence was introduced (Table 1). The requirements of laparoscopic procedures are mainly based on performing basic and intermediate (level 1 and 2) laparoscopic procedures without supervision, but performance of some advanced (level 3 and 4) procedures with supervision is also required (Table 1). Basic and intermediate laparoscopic procedures, according to the European Society for Gynaecological Endoscopy [2], are sufficiently taught during residency in the Netherlands [3]. However, advanced laparoscopic procedures are not formally embedded into this training program [3, 4].

The residency training program forms the basis for the gynecologist to obtain sufficient education and adequate proficiency in laparoscopic skills; however, many graduated residents do not think they are sufficiently prepared to perform all levels of laparoscopic procedures at the completion of their residency program [5-7]. Because laparoscopic approach is increasingly preferred to open surgery, there is a growing demand for an adequate and structured education program for all levels of laparoscopic procedures during residency. The latter is even more important because the Dutch Health Care Inspectorate showed concerns about patient safety regarding minimally invasive surgery (MIS) and stated a need for improved training in MIS [8]. Therefore, residency training programs are under pressure to incorporate both basic and advanced laparoscopic procedures. The question remains whether it is even necessary and required to train all residents in these more advanced procedures, as a large proportion of residents will potentially perform only basic laparoscopic procedures after residency in their daily practice.

Table 1 Dutch requirement of laparoscopic procedures during gynecological residency

Procedure	Required number	Level of competence*
Diagnostic laparoscopy	50	At least 10 on level 4
Laparoscopic adhesiolysis	10	Not specified
Salpingotomy/salpingectomy/ectopic pregnancy	20	Not specified
Cystectomy *(laparoscopic or abdominal)*	25	At least 5 on level 4
Myomectomy *(laparoscopic or abdominal)*	5	Not specified
Hysterectomy *(VH, AH or LH)*	40	Not specified

* *Level 1:* has theoretical knowledge, *level 2:* is able to perform under strict supervision, *level 3:* is able to perform under limited supervision, *level 4:* is able to perform without supervision, *level 5:* is able to supervise and educate others.
VH = vaginal hysterectomy, AH = abdominal hysterectomy, LH = laparoscopic hysterectomy.

The aim of this study is to assess the implementation of laparoscopic gynecologic surgery in daily residency training program, the level of competence among graduated residents, whether they still perform laparoscopic procedures, and at which level they currently perform these procedures. Furthermore, this study determines their current attitudes towards the implementation of MIS into residency program, to identify barriers and find practical ways to optimize the implementation of MIS into the gynecologic residency curriculum.

Materials and methods

A web-based survey (NetQ) was sent through e-mail to all gynecologists who finished residency within the previous 5 years (2008-2013) and were registered at the Dutch Society of Obstetricians and Gynecologists (NVOG). Names and e-mail addresses were obtained from the NVOG. To maximize the response rate, 3 reminder mails were sent.

The survey consisted of questions covering demographic characteristics, level of competence immediately after finishing residency, current level of competence, and whether the respondent still performs these procedures. The same questions were asked regarding abdominal and vaginal hysterectomy to compare the different surgical approaches to hysterectomy. In addition, the survey included questions about the interest of the respondents in performing the procedures and training acquired during residency. The last item of the survey was a request for possible solutions to optimize laparoscopic training during residency and was answered as free text. A 5-point Likert scale was used to measure the state of agreement and the degree of their interest: 1 (strongly disagree) to 5 (strongly agree); 1 (not interested) to 5 (very interested). Guidelines of the European Society for Gynaecological Endoscopy [2] were used to classify the requested laparoscopic procedures according to the 4 levels of difficulty- first level (*basic*): diagnostic laparoscopy and laparoscopic sterilisation; second level (*intermediate*): salpingotomy/salpingectomy/ectopic pregnancy, salpingo-oophorectomy, moderate adhesiolysis, and minimal endometriosis; third level (*advanced*): hysterectomy, myomectomy, extensive adhesiolysis, and severe endometriosis; and fourth level (*advanced*): sacrocolpopexy, lymphadenectomy, and recto-vaginal endometriosis. To indicate the level of competence, the Dutch residency curriculum uses 5 different competence levels to perform surgery, based on Miller's pyramid of clinical competence (Figure 1) [9] - *level 1:* has theoretical knowledge, *level 2:* is able to perform under strict supervision, *level 3:* is able to perform under limited supervision, *level 4:* is able to perform without supervision, and *level 5:* is able to supervise and educate others.

If the respondents did not answer every item of the questionnaire, subcalculations with different denominators were made. Teaching hospitals represent university and nonuniversity teaching hospitals.

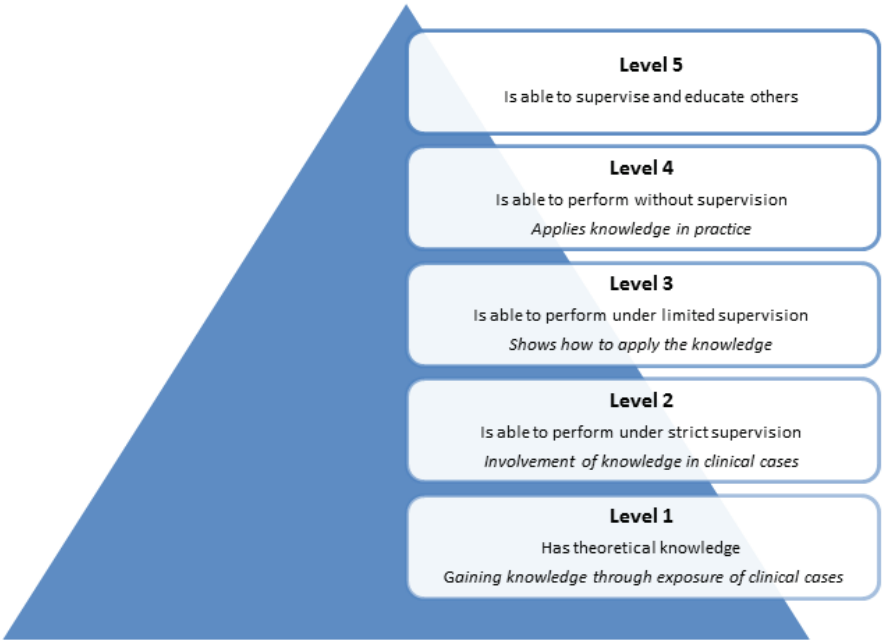


Figure 1 Competence levels used in the Dutch curriculum based on Miller's pyramid.

Subanalysis of the basic characteristics was performed for sex. Furthermore, the distribution of the different subspecialties was calculated. In addition, a subcalculation including the gynecologists who are and those who are not performing the surveyed procedures currently was performed. This subcalculation is necessary to avoid skewed data, because some respondents (e.g., subspecialists maternal-fetal medicine) do not practice any advanced laparoscopic procedures.

Data were analysed with SPSS version 20 (IBM SPSS Statistics, Chicago, IL). The *t* test and chi-square test were used to calculate the demographic differences between sexes. The paired and unpaired t tests were used to assess the difference between the levels of competence. Both mean and median levels of competence were calculated, as both provide useful information. A $p < 0.05$ was considered statistically significant.

Results

Of 235 surveyed gynecologists, 171 responded (73%). Table 2 shows the general characteristics of these participants. In total, 51 (30%) respondents were men. Most respondents worked

Table 2 Baseline characteristics of respondents

Variable	Men (n=51)	Women (n=120)	Total (n=171)	P value
Mean age *(range, median)*	38.5	38.0	38.2 *(33-49, 38)*	0.276
Currently working % *(n)*				
Non-teaching hospital	9.8 *(5)*	25.8 *(31)*	21.1 *(36)*	0.019
Teaching hospital*	90.2 *(46)*	74.2 *(89)*	78.9 *(135)*	0.019
Subspecialty % *(n)*				
General gynecology	27.5 *(14)*	25.8 *(31)*	26.3 *(45)*	0.854
Reproductive gynecology/infertility	17.6 *(9)*	19.2 *(23)*	18.7 *(32)*	0.816
Maternal-fetal medicine	41.2 *(21)*	35 *(42)*	37 *(63)*	0.444
Oncology	11.8 *(6)*	16.7 *(20)*	15.2 *(26)*	0.414
Urogynecology	17.6 *(9)*	16.7 *(20)*	17 *(29)*	0.876

* Teaching hospitals represent university and non-university teaching hospitals.

in a teaching hospital (n = 135, 78.9%), of which 51 (29.8%) worked in a university teaching hospital.

There was an equal distribution of the number of years after finishing residency between the respondents; 22% graduated less than one year ago, 24 % 1 to 2 years ago, 18% 2 to 3 years ago, 18% 3 to 4 years ago, and 18% finished their residency 4 to 5 years ago.

Level of competence

For the respondents who are still performing the procedures, the current level of competence is significantly higher for the majority of all procedures compared with their competence level immediately after residency (Table 3). Furthermore, comparing the competence level immediately after residency between performing and nonperforming gynecologists, a significantly higher competence level is observed for most of the procedures in favor of the respondents who still perform the procedures. Only basic laparoscopic procedures show similar competence levels for both groups (Table 3).

For all groups, basic and intermediate laparoscopic procedures scored a median and mean competence level between 4 and 5 (Table 3), immediately after residency as well as currently. All advanced laparoscopic procedures (level 3 and 4 procedures) were scored a competence level less than 3 after residency, indicating that the graduated residents were not able to perform these procedures under limited supervision. Furthermore, 56% of the gynecologists

Table 3 Percentage of respondents not performing the procedures currently and competence level of the respondents, divided between respondents performing and not performing the procedures currently

Procedure	Percentage of all respondent who not performing currently % (n)	Median level of competence [a] of respondents performing the procedure currently		P value	Median level of competence [a] of respondents not performing the procedure currently	P value [c]
		Immediately after residency *(mean, SD)*	Now *(mean, SD)*		Immediately after residency *(mean, SD)*	
Vaginal hysterectomy	43 (67)	4 *(4.41, 0.64)*	5 *(4.71, 0.53)*	<0.01	4 *(3.95, 0.81)*	<0.01
Abdominal hysterectomy	23 (35)	5 *(4.54, 0.63)*	5 *(4.81, 0.44)*	<0.01	4 *(4.12, 0.77)*	<0.01
First level laparoscopy *(basic)* [b]						
Diagnostic laparoscopy	17 (26)	5 *(4.85, 0.38)*	5 *(4.91, 0.28)*	0.05	5 *(4.77, 0.51)*	0.42
Laparoscopic sterilisation	30 (45)	5 *(4.83, 0.43)*	5 *(4.86, 0.52)*	0.22	5 *(4.84, 0.43)*	0.94
Second level laparoscopy *(intermediate)*						
Salpingotomy/salpingectomy/EP	16 (25)	5 *(4.60, 0.60)*	5 *(4.81, 0.45)*	<0.01	4 *(4.13, 0.74)*	<0.01
Salpingo-oophorectomy	23 (35)	5 *(4.62, 0.57)*	5 *(4.82, 0.41)*	<0.01	4 *(4.18, 0.76)*	<0.01
Moderated adhesiolysis	44 (66)	5 *(4.54, 0.66)*	5 *(4.79, 0.47)*	<0.01	4 *(4.18, 0.95)*	<0.01
Minimal/mild endometriosis	42 (64)	5 *(4.49, 0.65)*	5 *(4.81, 0.45)*	<0.01	4 *(3.85, 1.04)*	<0.01

Table 3 continues on next page

Table 3 *Continued*

Procedure	Percentage of all respondent who not performing currently % (n)	Median level of competence [a] of respondents performing the procedure currently		P value	Median level of competence [a] of respondents not performing the procedure currently	P value [c]
		Immediately after residency *(mean, SD)*	Now *(mean, SD)*		Immediately after residency *(mean, SD)*	
Third level laparoscopy *(advanced)*						
Laparoscopic hysterectomy	63 (97)	3 *(2.88, 0.99)*	4 *(4.06, 1.03)*	<0.01	2 *(2.31, 0.83)*	<0.01
Myomectomy	88 (133)	2 *(2.28, 0.90)*	3 *(3.00, 1.28)*	0.02	2 *(2.02, 0.82)*	0.21
Extensive adhesiolysis	77 (115)	2 *(2.67, 1.14)*	4 *(3.78, 0.94)*	<0.01	2 *(2.04, 0.79)*	<0.01
Severe endometriosis	88 (133)	2 *(2.39, 1.38)*	3 *(3.22, 1.35)*	<0.01	2 *(1.90, 0.74)*	0.02
Fourth level laparoscopy *(advanced)*						
Sacrocolpopexy	95 (145)	1 *(1.86, 1.22)*	2 *(2.29, 1.5)*	0.08	1 *(1.39, 0.65)*	0.08
Lymphadenectomy	94 (144)	2 *(2.11, 0.93)*	3 *(3.33, 1.12)*	0.04	1 *(1.28, 0.53)*	<0.01
Recto-vaginal endometriosis	96 (145)	2 *(2.00, 1.23)*	1 *(2.20, 1.64)*	0.66	1 *(1.31, 0.55)*	0.01

[a] Levels of competence: *Level 1:* has theoretical knowledge, *level 2:* is able to perform under strict supervision, *level 3:* is able to perform under limited supervision, *level 4:* is able to perform without supervision, *level 5:* is able to supervise and educate others.
[b] Classification of laparoscopic procedures according to the ESGE (European Society of Gynaecological Endoscopy).
[c] P value of level of competence directly after residency between respondents performing the procedures and respondents not performing the procedures currently.
EP = ectopic pregnancy.

no longer perform any level 3 procedure currently, and depending on the type of procedure, the response varied between 63 and 88% (Table 3). For level 4 procedures, the response was 86%, and depending on the type of procedures, it varied between 94 and 96% (Table 3).

Hysterectomy

A subcalculation including all respondents showed that performance of the vaginal hysterectomy scored a median level of competence of 4 (mean = 4.2) immediately after residency, which is significantly lower ($p < 0.001$) compared with abdominal hysterectomy (median = 5, mean = 4.4). The laparoscopic approach scored the lowest level of competence (median = 2, mean = 2.5, $p < 0.001$). On a Likert scale, the respondents are significantly less interested in performing a vaginal hysterectomy compared with performing an abdominal approach (mean = 3.7 vs. 4.2, $p < 0.001$).

Interest of respondents

Overall, 82% and 88% of the respondents are interested (Likert scale 4 and 5) in performing level 1 and level 2 laparoscopic procedures (basic and intermediate), respectively. For level 3 and 4 procedures, 58% and 39%, respectively, are interested in performing these advanced procedures.

Overall, 65% of the participants is satisfied (Likert scale 4 and 5) with their current laparoscopic skills, and all participants agreed that they were adequately trained to perform basic procedures during residency. However, for laparoscopic procedures levels 2, 3 and 4 this is 91%, 26% and 6.4 %, respectively.

Possible solutions

All respondents were asked to consider a solution to optimize laparoscopic training during residency. Table 4 shows the mentioned solutions. The 3 most mentioned solutions were more mandatory simulation training (66%), early differentiation during residency (19%), and a more structured laparoscopic curriculum (16%).

Table 4 Possible solutions mentioned by the respondents to optimize laparoscopic training during residency

Mentioned solution	Percentage of respondents %
More mandatory simulation training, including competition elements and a compulsory exam	66
Early differentiation during residency	19
A more structured laparoscopic curriculum with guidelines and protocols	16
More and sooner full responsibility for residents during surgical procedures	13
Surgical educators need more education and laparoscopic skills training in order to train their residents sufficiently	8
More scheduled operation time during residency	7

The requested possible solutions were not a mandatory item in the questionnaire and were answered as free text. Only the solutions that were mentioned by >5% of the respondents were included.

Discussion

The main findings of this study show that basic and intermediate laparoscopic surgical procedures are sufficiently taught and adequately implemented in the Dutch gynecologic residency program. However, the training and implementation of advanced procedures into the current residency program is not fully embedded. Furthermore, at the end of residency program, a significant higher competence level was found for those who keep on perform laparoscopic procedures compared with those who do not. A considerable number of gynecologists do not perform any level 3 or 4 laparoscopic procedures currently. Moreover, the respondents who keep on performing these procedures after residency are not able to do them without direct supervision, and their learning curve for advanced procedures continues to rise after finishing residency.

The scores for all basic and intermediate procedures represented the highest level of competence immediately after residency. This was already observed in 2003 [3], although the level of competence in the current study is even slightly higher. We therefore conclude that the implementation has been optimized during the past decade. The low competence level for advanced laparoscopic procedures is also observed in the United States and Spain [4, 5, 10, 11]. Einarsson et al. suggested the need to improve training for these advanced procedures. We consider that this is not feasible currently, and we plead for selection of certain residents to train them in these advanced laparoscopic procedures during residency, as most gynecologists will not even perform advanced laparoscopic procedures during their further career (Table 3). In addition, training programs are under pressure as work-hour

restrictions have affected the resident's case experience and a growing emphasis is placed on subspecialties [12-14]. At the same time, more complex surgical possibilities in MIS have emerged, and there is an increasing demand to measure quality and skills of residents and gynecologists [15]. In this context, we state that only to a selected group of residents who wish to specialize in the field of gynaecologic surgery should perform and be exposed to advanced procedures, and preliminary selection during residency could be an appropriate solution. To underline this idea, we found that 19% of the inquired gynecologists spontaneously gave the same solution and assume that early differentiation could be a realistic option to "optimize the implementation of MIS into residency". Consequently, this will increase the laparoscopic exposure to this selected group in daily practice [16, 17].

The question remains, however, how and when do we select these residents? First, we observed that 42% and 61% of the respondents are not interested in performing level 3 and level 4 procedures, respectively. Probably, based on their interests, we can already exclude a reasonable high number of residents. However, a remark has to be made. Because we surveyed postgraduates and not the residents themselves, this statement might be relative and, for example, their loss of interest could have occurred because of lack of training. Secondly, a significantly lower level of competence was observed immediately after residency for gynecologists who do not perform these procedures currently, compared with the gynecologists who do perform these procedures nowadays (Table 3). Therefore, on theoretical grounds, an early selection can be made during residency, as this variation of competence can be observed during surgical training by using Objective Structured Assessment of Technical Skills (OSATS). However, the use of OSATS alone will not be completely sufficient as there are some concerns about the objectivity of this tool [18, 19]. Furthermore, it should be emphasized that minimal knowledge of advanced laparoscopic procedures is still required for all residents.

Another possible solution for better laparoscopic training during residency is more mandatory simulation training as mentioned by two-third of respondents. This solution is already implemented, and all Dutch residents need to attend and succeed a mandatory basic surgical course, including laparoscopic training and examination. Furthermore, in 2013, 90% of the Dutch residents had free access to a skills laboratory in their clinic; whereas in 2003, this was only 35% [3, 20].

The strength of our study is the high response rate of our survey of 73%, which is higher than comparable published studies [6, 11]. Moreover, there is an equal distribution between the respondents in years after residency and subspecialties. Both suggest that our results demonstrate an accurate representation of the Dutch residency program. A potential weakness is that we asked competence levels in retrospect. As competence levels are self-rated and therefore subjective, this could make these data less reliable.

We observed that the learning curve of gynecologists who currently perform level 3 and 4 laparoscopic procedures continues to rise after residency and that they are not able to perform these procedures without supervision (Table 3). Therefore, additional training after residency, for example, a fellowship, is highly recommended for this group of gynecologist.

Since the implementation of the new guidelines for the Dutch gynecologic residency program in 2013, the residents are already challenged to choose a subspecialty after 4 years to practice this subspecialty during the last 2 years of the total residency training program of 6 years [21]. With these new guidelines, residents will be trained more extensively in their field of interest and subsequently finish residency at a higher competence level in this field.

A remarkable observation in our study is the lower competence level and the lower interest in performing the vaginal hysterectomy compared with abdominal approach. Miskry et al. observed similar results in the UK [22]. Because the vaginal approach remains the surgical method of choice for hysterectomy, this is a matter of concern [23]. In addition, recent research showed an undesirable decrease of the vaginal approach in the Netherlands (from 36% in 2007 to 25% in 2012) [24]. Therefore, the vaginal approach should be trained extensively during residency, and we have to ensure that this approach of hysterectomy will not disappear from the gynecological surgical palette [25].

Conclusion

Residents are sufficiently trained to perform basic and intermediate laparoscopic procedures (level 1 and 2) after residency training. For advanced procedures (level 3 and 4), residents are not sufficiently equipped to perform these procedures without direct supervision. Therefore, it is obvious that the learning curve for advanced procedures continues to rise after finishing residency. Additional training or a fellowship after residency to perform these procedures independently is recommended. Moreover, these advanced laparoscopic procedures should especially be taught to a selected group of residents, because most gynecologists will never perform these procedures after residency. This will also reduce the problem of the limited caseload of advanced procedures in residency program. An important area for future research will be the further development of selection tools and determination of how to identify residents who should or should not pursue advanced laparoscopic training.

Acknowledgment

We thank all gynecologists who filled out the survey for their cooperation and dr. E.W. van Zwet, associate professor medical statistics, for his statistical advice.

Reference list

(1) Nederlandse vereniging voor Obstetrie & Gynaecologie (NVOG) [Internet]. cJJJJ [updated 14 A.D. Jul 1; BOEG, opleidingsplan Obstetrie en Gynaecologie. http://www.nvog.nl/voorLeden/default.aspx. Accessed 1st of July 2014. Available from: http://www.nvog.nl/voorLeden/default.aspx.

(2) ESGE [Internet]. cXXXX [updated 2014; European Society for Gynaecological Endoscopy (ESGE) classification laparoscopy; Available from: http://www.esge.org/education/endoscopic-training/esge-laparoscopy-standard.

(3) Kolkman W, Wolterbeek R, Jansen FW. Implementation of advanced laparoscopy into daily gynecologic practice: difficulties and solutions. J Minim Invasive Gynecol 2006; 13(1):4-9.

(4) Pascual-Pedreno A, Perez-Medina T, Brouard U, I, Fernandez-Parra J, Sobreviela-Laserrada M. Practice of endoscopic gynecologic surgery: a survey of Spanish gynecologists. Eur J Obstet Gynecol Reprod Biol 2013; 169(1):64-68.

(5) Raymond E, Ternamian A, Leyland N, Tolomiczenko G. Endoscopy teaching in Canada: a survey of obstetrics and gynecology program directors and graduating residents. J Minim Invasive Gynecol 2006; 13(1):10-16.

(6) Chen I, Bajzak KI, Guo Y, Singh SS. A national survey of endoscopic practice among gynaecologists in Canada. J Obstet Gynaecol Can 2012; 34(3):257-263.

(7) Kolkman W, Wolterbeek R, Jansen FW. Gynecological laparoscopy in residency training program: Dutch perspectives. Surg Endosc 2005; 19(11):1498-1502.

(8) Stassen LP, Bemelman WA, Meijerink J. Risks of minimally invasive surgery underestimated: a report of the Dutch Health Care Inspectorate. Surg Endosc 2010; 24(3):495-498.

(9) Miller GE. The assessment of clinical skills/competence/performance. Acad Med 1990; 65(9 Suppl):S63-S67.

(10) Einarsson JI, Young A, Tsien L, Sangi-Haghpeykar H. Perceived proficiency in endoscopic techniques among senior obstetrics and gynecology residents. J Am Assoc Gynecol Laparosc 2002; 9(2):158-164.

(11) Einarsson JI, Sangi-Haghpeykar H. Perceived proficiency in minimally invasive surgery among senior OB/GYN residents. JSLS 2009; 13(4):473-478.

(12) Schreuder HW, Oei G, Maas M, Borleffs JC, Schijven MP. Implementation of simulation in surgical practice: minimally invasive surgery has taken the lead: the Dutch experience. Med Teach 2011; 33(2):105-115.

(13) Blanchard MH, Amini SB, Frank TM. Impact of work hour restrictions on resident case experience in an obstetrics and gynecology residency program. Am J Obstet Gynecol 2004; 191(5):1746-1751.

(14) Escobar MA, Jr., Hartin CW, Jr., McCullough LB. Should general surgery residents be taught laparoscopic pyloromyotomies? An ethical perspective. J Surg Educ 2014; 71(1):102-109.

(15) Singh SS, Marcoux V, Cheung V, Martin D, Ternamian AM. Core competencies for gynecologic endoscopy in residency training: a national consensus project. J Minim Invasive Gynecol 2009; 16(1):1-7.

(16) Doll KM, Milad MP, Gossett DR. Surgeon volume and outcomes in benign hysterectomy. J Minim Invasive Gynecol 2013; 20(5):554-561.

(17) Kroft J, Moody JR, Lee P. Canadian hysterectomy educational experience: survey of recent graduates in obstetrics and gynecology. J Minim Invasive Gynecol 2011; 18(4):438-444.

(18) Hiemstra E, Kolkman W, Wolterbeek R, Trimbos B, Jansen FW. Value of an objective assessment tool in the operating room. Can J Surg 2011; 54(2):116-122.

(19) Gibson KS, Muffly TM, Penick E, Barber MD. Factors used by program directors to select obstetrics and gynecology fellows. Obstet Gynecol 2012; 119(1):119-124.

(20) Janse JA, Driessen SR, Veersema S, Broekmans FJ, Jansen FW, Schreuder HW. Training of Hysteroscopic Skills in Residency Program: The Dutch Experience. J Surg Educ 2014.

(21) Schott S, Yaribakht S, Adams T, van dA, I. Four-country meeting on residency in France, Germany, The Netherlands and UK: 4 countries, 4 ways. Arch Gynecol Obstet 2014; 290(5):833-837.

(22) Miskry T, Magos A. A national survey of senior trainees surgical experience in hysterectomy and attitudes to the place of vaginal hysterectomy. BJOG 2004; 111(8):877-879.

(23) Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.

(24) Driessen SR, Baden NL, van Zwet EW, Twijnstra AR, Jansen FW. Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in the Netherlands. J Minim Invasive Gynecol 2015.

(25) Moen M, Walter A, Harmanli O, Cornella J, Nihira M, Gala R et al. Considerations to improve the evidence-based use of vaginal hysterectomy in benign gynecology. Obstet Gynecol 2014; 124(3):585-588.

Chapter 5

Case–mix variables and predictors for outcomes of laparoscopic hysterectomy: a systematic review

Sara R.C. Driessen
Evelien M. Sandberg
Claire F. la Chapelle
Andries R.H. Twijnstra
Johann P.T. Rhemrev
Frank Willem Jansen

Journal of Minimally Invasive Gynecology 2016 Mar-Apr; 23(3): 317-330

Abstract

The assessment of surgical quality is complex, and an adequate case-mix correction is missing in currently applied quality indicators. The purpose of this study is to give an overview of all studies mentioning statistically significant associations between patient characteristics and surgical outcomes for laparoscopic hysterectomy (LH). Additionally, we identified a set of potential case-mix characteristics for LH. This systematic review was conducted according to the Meta-Analysis of Observational Studies in Epidemiology guidelines. We searched PubMed and EMBASE from January 1, 2000 to August 1, 2015. All articles describing statistically significant associations between patient characteristics and adverse outcomes of LH for benign indications were included. Primary outcomes were blood loss, operative time, conversion and complications. The methodological quality of the included studies was assessed using the Newcastle-Ottawa Quality Assessment Scale. The included articles were summed per predictor and surgical outcome. Three sets of case-mix characteristics were determined, stratified by different levels of evidence. Eighty-five of 1549 identified studies were considered eligible. Uterine weight and Body mass index (BMI) were the most mentioned predictors (described, respectively, 83 and 45 times) in high quality studies. For longer operative time and higher blood loss, uterine weight ≥ 250 to 300g and ≥ 500g and BMI ≥30 kg/m^2 dominated as predictors. Previous operations, adhesions, and higher age were also considered as predictors for longer operative time. For complications and conversions, the patient characteristics varied widely, and uterine weight, BMI, previous operations, adhesions and age predominated. Studies of high methodological quality indicated uterine weight and BMI as relevant case-mix characteristics for all surgical outcomes. For future development of quality indicators of LH and to compare surgical outcomes adequately, a case-mix correction is suggested for at least uterine weight and BMI. A potential case-mix correction for adhesions and previous operations can be considered. For both surgeons and patients it is valuable to be aware of potential factors predicting adverse outcomes and to anticipate on this. Finally, to benchmark clinical outcomes at an international level, it is of the utmost importance to introduce uniform outcome definitions.

Introduction

Laparoscopic hysterectomy (LH) is the most performed advanced gynecologic laparoscopic procedure, and its implementation has increased worldwide [1]. Currently, there is a growing concern regarding patient safety during complex endoscopic surgical procedures, including LH [2]. This has led to increased efforts to measure and assess the quality of surgical procedures [3]. Quality indicators are widely accepted performance measures used to monitor, evaluate and improve the quality of care [4]. Three different types of indicators are outcome, process, and structural quality indicators [5]. Outcome indicators refer to direct clinical outcomes and are the most used indicators to assess quality of surgical care. Process indicators measure the complete care system (e.g., multidisciplinary meetings). Structural indicators reflect the setting in which the care is provided (e.g., case volume). The assessment of surgical quality is very complex, and one of the main problems of the introduced quality indicators is the lack of case-mix correction. Case-mix variables are defined as characteristics that influence surgical outcomes and could potentially explain the differences in outcome among hospitals and/or surgeons. Therefore, for a reliable interpretation of surgical outcomes, a correction for case-mix is of highest importance [6]. To develop an accurate quality indicator for LH, more insight is needed into the patient characteristics that influence surgical outcomes. Yet, no international consensus has been reached on this issue. A great variety of published studies mentioned 1 or more predicting patient characteristics for LH, but no accurate overview of these characteristics is available. This is a challenging topic because different outcome definitions are used in literature and also other factors than patient characteristics (e.g., surgeon volume, type of procedures etc.) could potentially influence surgical outcomes. However, a clear summary of patient characteristics associated with surgical outcomes is first needed in order to continue the discussion about the essence of case-mix adjustment for reliable quality assessment.

The objective of this study is to identify patient characteristics that significantly influence the surgical outcome of LH. Additionally, we aim to compose a minimal set of potential case-mix variables for LH. This set should preferably be used in the development of (new) quality assessment tools and is the first step required to develop a valid and accurate quality indicator for LH.

Materials and methods

Data sources

This systematic review was performed according to the Meta-Analysis of Observational Studies in Epidemiology guidelines [7]. A search of the literature in PubMed and EMBASE was

performed from January 1, 2000 to August 1, 2015 to identify articles describing a statistically significant association between patient characteristics and surgical outcomes of LH.

A clinical librarian was consulted to define the search strategy, together with the primary researcher (S.R.C.D.). The exact search string is shown in Supplemental Appendix 1. All duplicate articles were removed. All references of selected articles were reviewed to identify other relevant articles. If additional eligible articles were identified, a new search string was composed by the research librarian to include these extra references as well. This was repeated until no new cross-references were found. At this point the search was considered as definitive (see Supplemental Appendix 1). We limited the results to human studies and studies written in English.

Study selection

The literature selection was performed independently by 2 authors (S.R.C.D. and E.M.S.). In case of uncertainty, a third author (F.W.J.) was contacted. After a first selection on titles and abstracts, the full text of the remaining articles were reviewed using the following exclusion criteria: LHs for oncologic indications, studies reporting no association between predictors and clinical outcomes, nonclinical studies (e.g., review, case report), and conference abstracts. If unexpected oncologic cases were included in the study population, only those studies with less than 5% oncologic cases were included.

Equal data from multiple publications based on the same cohort were only used once in the final analysis.

Predictors were defined as patient characteristics that were statistical significantly associated with adverse surgical outcomes. Our study focused only on patient characteristics as predictors, because these variables cannot be influenced in any way during the (pre)surgical process and are therefore suitable as case-mix characteristics. For this reason the type of LH, the use of different technical instruments (e.g., monopolar, bipolar, ultrasound, use of mobilizer etc.), preoperative medical treatment, surgeon's volume, and the number of surgeons performing the procedure were not included in our study.

Surgical outcomes included intraoperative blood loss, operative time, conversion to laparotomy, and complications. The definition of the surgical outcomes as mentioned by the authors in the included paper was applied. Hospital stay was not considered as a surgical outcome, because hospital discharge mainly depends on the (local) guidelines.

The included articles were summed per predictor and surgical outcome (Table 1). The surgical outcomes were depicted in 4 separated tables, including all selected articles with

the detailed predictor, the (detailed) outcome, the study population, the study design and the methodological quality (Table 2, 3, 4, 5).

This systematic review did not involve human subjects and was exempt from institutional board review.

Quality assessment

The methodological quality of the included studies was assessed according to the Newcastle-Ottawa Quality Assessment Scale (NO-QAS) [8]. This assessment scale assigns a specific study up to a maximum of 9 points, to include points for selection of the study groups, comparability of the groups and the ascertainment of outcome or exposure of the study. For example, a study was higher rated when correction for confounders or regression analysis was performed. The rating was done independently by the 2 review authors (S.R.C.D. and E.M.S.). Furthermore, the different study designs were reported: randomised controlled trial, prospective cohort study, retrospective cohort study, and case-control study.

Selection of case–mix variables

Per surgical outcome, 3 sets of case-mix characteristics were composed according to defined criteria of levels of evidence (Table 6; low, medium, and high). These criteria were based on the number of high quality studies (NO-QAS 9) and considerable quality studies (NO-QAS 8 or 7) as modified from Courrech Staal et al. [9]. Case-mix selection set 1 (low): all characteristics mentioned in ≥1 study with NO-QAS of 9 or ≥2 studies with NO-QAS 8 or 7; set 2 (medium): characteristics identified in ≥1 study with NO-QAS of 9 and ≥1 study with NO-QAS 8 or 7, set 3 (high): characteristics mentioned in ≥2 studies with NO-QAS of 9 or ≥4 studies with NO-QAS 8 or 7 (Table 6).

Results

Overview of studies

An overview of the literature selection is shown in Figure 1. The literature search yielded 1549 unique articles. After selection, 85 articles met the inclusion criteria and reported a significant association between specific patient characteristics and surgical outcomes. Of these 85 articles, 4 were randomized controlled trials, 29 prospective cohort studies, 47 retrospective cohort studies and 5 case-control studies (Table 2, 3, 4 and 5).

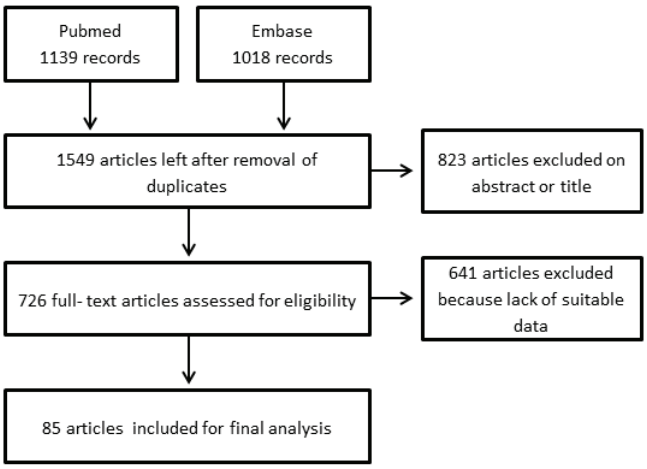


Figure 1 Flowchart of reviewed and selected studies.

Table 1 Number of found articles that showed a statistical significant association between the patient characteristics and surgical outcome

OUTCOME / PATIENT CHARACTERISTIC *(Predictor)*	Longer operative time	More blood loss	Increased complication rate	Increased conversion rate	Total
Uterine weight	47	21	7	8	83
BMI	21	11	8	5	45
Previous operations	3	na	7	6	16
Adhesions	3	3	4	2	12
Endometriosis	1	na	2	na	3
Age	3	1	4	1	9
Uterine descent	na	na	1	na	1
Menopause	1	na	na	na	1
Parity	1	1	2	na	4
Fibroid	na	na	na	1	1
Comorbidity *(previous stroke/TIA, DM, creatinine or platelet count, ASA score, hypertension)*	1	na	6	na	7
Smoking	na	na	2	na	2
Ethnicity	na	na	1	na	1
Total	81	37	44	23	185

DM = diabetes mellitus, na = not applicable.

The number of included articles per patient characteristic and surgical outcome is depicted in Table 1. Figure 2 demonstrates a graphical representation of the number of articles where a significant association between the patient characteristic (predictor) and surgical outcome was identified.

Uterine weight and body mass index (BMI) are by far the most mentioned patient characteristics influencing all surgical outcomes and described, respectively 83 and 45 times in the selected articles (Table 1 and Figure 2). Subsequently, previous operations, adhesions, and age were mentioned 16, 12, and 9 times, respectively, as predictor (Table 1).

Several other patient characteristics were only mentioned once or a few times in the selected articles: parity, endometriosis, uterine descent, menopause, presence of fibroids, ethnicity, previous stroke, smoking, diabetes mellitus, American Society of Anesthesiologists (ASA) score, hypertension, creatinine serum, and platelet count (Table 1).

The selected articles and predictors are shown in detail per surgical outcome (blood loss, operative time, conversion and complications) in Table 2, 3, 4 and 5.

Predictors for longer operative time

Respectively, 47 and 21 studies reported a significant association between prolonged operative time and high uterine weight and high BMI.

The most mentioned detailed associations for prolonged operative time were uterine weight ≥ 250 to 300 grams and ≥ 500 grams and BMI ≥ 30 kg/m^2. Previous operations and adhesions

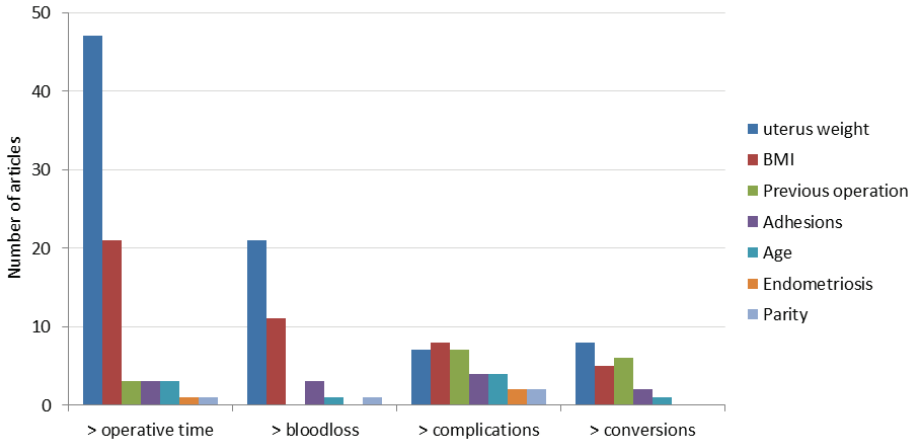


Figure 2 Number of selected articles that showed a statistical significant association between the patient characteristic and outcome *(including only the characteristics which are mentioned more than twice).*

were also considered as relevant predictors, both mentioned in 3 studies (Table 2). Three studies found older age to be associated with prolonged operative time.

Predictors for increased blood loss

For the outcome increased blood loss, 21 articles observed a significant association with larger uterus and 11 articles with higher BMI (Table 1), whereas uterine weight ≥ 500 g and BMI ≥ 30 kg/m^2 were mentioned the most (Table 3). In addition, 3 different studies found that the presence of adhesions also had an impact on blood loss.

Predictors for increased complication rate

For complications, patient characteristics varied widely, but uterine weight, BMI, previous operations and adhesions predominated (Table 4). Also, the predictor age was mentioned in 4 different studies. A considerable difference was found among described ages, and no consistent cutoff value could be found. Endometriosis was mentioned as a significant predictor in 2 studies. Furthermore, comorbidity (e.g., diabetes mellitus, previous stroke, ASA score), smoking, ethnicity, and uterine descent were mentioned in 1 or 2 studies rated as high quality (NO-QAS 8-9).

Predictors for increased conversion rate

For conversion (Table 5), the least studies showing a significant association with patient characteristics were found (a total of 23 studies, Table 1). Uterine weight, BMI and previous operations were the most mentioned significant predictors. Adhesion, age, and presence of fibroids were also found in 1 or 2 studies.

Selection of case–mix characteristics

Three different sets of case-mix variables per surgical outcome are depicted in Table 6.
The number of case-mix variables depends on the preferred level of evidence criteria. Looking at the lowest level of evidence criteria (set 1), a great variety of case-mix characteristics can be selected: uterine weight, BMI, adhesions, previous operations, age, endometriosis, uterine descent, smoking, transient ischemic attack/stroke, diabetes mellitus, and ASA score. When selecting the highest composed level of evidence criteria (set 3), less case-mix characteristics were observed: uterine weight, BMI, previous operations, and adhesions.
In all defined levels of evidence (low, medium, and high; Table 6), uterine weight and BMI remained selected as relevant case-mix characteristics for all surgical outcomes.

Table 2 Longer operative time: predictors in detail

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	≥ 250-300g	Giep, 2010 [14]	589 RALH, LAVH and LSH	[C]	9
		Kondo, 2011 [15]	2092 TLH and LAVH	[C]	6
		Boggess, 2009 [16]	152 RALH	[B]	8
		Kriplani, 2012 [17]	110 TLH	[C]	6
		Surgit, 2012 [18]	68 TLH	[B]	7
		Hussain, 2012 [19]	85 LSH	[B]	7
		Wong, 2011 [20]	97 LAVH	[C]	6
		Wattiez, 2002 [21]	240 TLH	[D]	7
		Mebes, 2012 [22]	52 LH	[C]	7
		Dassel, 2015 [23]	1004 LH	[C]	8
		Catanzarite, 2015 [24]	7630 LH	[C]	8
	≥500g	Payne, 2010 [25]	256 RALH	[C]	8
		Ark, 2009 [26]	367 LAVH	[C]	7
		Chang, 2005 [27]	225 LAVH	[B]	8
		Fiaccavento, 2007 [28]	684 TLH	[C]	7
		Shahid, 2011 [29]	29 LASH	[B]	7
		Wang, 2004 [30]	189 LAVH	[B]	7
		Ferrari, 2000 [31]	31 LAVH	[B]	6
		Wong, 2010 [32]	588 LAVH	[C]	7
	≥750-800g	Shiota, 2011 [33]	629 LAVH	[C]	6
		Chang, 2008 [34]	181 LAVH	[B]	7
	Increase/100g	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Longitudinal >9cm or uterine volume >370ml on ultrasound	Carugno, 2014 [36]	558 RTH	[C]	9

Table 2 continues on next page

Table 2 ***Continued***

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
	Not defined	Uccella, 2013 [11]	712 TLH	[C]	7
		Condous, 2007 [37]	75 TLH	[B]	7
		Shashoua, 2009 [38]	70 TLH and RATLH	[C]	8
		Song, 2010 [39]	15 SPA-LAVH	[B]	6
		Chou, 2011 [40]	56 LAVH	[B]	6
		Paek, 2011 [41]	100 SPA-TLH	[C]	7
		Lin, 2014 [42]	100 RATLH	[C]	8
		Bojahr, 2006 [43]	1692 LASH	[C]	6
		Payne, 2010 [44]	100 RALH	[C]	8
		Gyr, 2001 [45]	48 TLH	[D]	6
		Shin, 2011 [46]	168 TLH and LAVH	[C]	6
		Ghomi, 2007 [47]	59 LSH	[B]	6
		Tu, 2005 [48]	167 LAVH	[C]	8
		McClellan, 2007 [49]	100 LSH	[B]	8
		Song, 2013 [50]	21 SPA-TLH	[B]	6
		Erian, 2008 [51]	400 LSH	[B]	7
		Göçmen, 2012 [52]	60 TLH	[C]	6
		Heaton, 2010 [53]	379 TLH	[D]	6
		Jahan, 2015 [54]	100 LAVH	[C]	7
		Mueller, 2012 [55]	567 TLH	[B]	6
		Paraiso, 2013 [56]	52 LH and RALH	[A]	9
		Sendag, 2014 [57]	36 RALH	[C]	7
		Wang, 2015 [58]	512 tVNOTEH and LAVH	[C]	7
		Estrade, 2015 [59]	40 SPA-LSH	[B]	6

Table 2 continues on next page

Table 2 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
BMI	BMI ≥ 30 kg/m^2	Chopin, 2009 [60]	1460 TLH	[C]	9
		Giep, 2010 [14]	589 RALH, LAVH and LSH	[C]	9
		Morgan-Ortiz, 2013 [61]	209 TLH	[B]	7
		Carugno, 2014 [36]	1290 TLH and RALH	[C]	9
		Morsi, 2013 [62]	186 LAVH and LH	[C]	7
		Harmanli, 2013 [63]	970 LSH and TLH	[C]	7
		Surgit, 2012 [18]	68 TLH	[B]	7
		Heinberg, 2004 [64]	270 TLH	[C]	8
		Mikhail, 2015 [65]	3812 LAVH and TLH	[C]	7
	Not defined	Siedhoff, 2012 [66]	834 TLH and LSH	[C]	8
		Shashoua, 2009 [38]	70 TLH and RALH	[C]	8
		Bardens, 2014 [67]	194 LH	[C]	8
		Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
		Brummer, 2011 [69]	1679 LH	[B]	8
		Payne, 2010 [44]	100 RALH	[C]	8
		Kriplani, 2012 [17]	110 TLH	[C]	6
		Göçmen, 2012 [52]	120 TLH and RALH	[C]	6
		Heaton, 2010 [53]	379 TLH	[D]	6
		Shah, 2015 [70]	26609 LH	[C]	9
		Dassel, 2015 [23]	1004 LH	[C]	8
		Catanzarite, 2015 [24]	7630 LH	[C]	8
Adhesions	Adhesion score (adhesion severity combined with extent of adhesions)	Chiu, 2015 [71]	216 RLH and TLH	[C]	8
	Dense adhesions	Paek, 2011 [41]	100 SPA-TLH	[C]	7
	Extensive pelvic adhesions	Hsu, 2007 [72]	236 LAVH	[C]	6

Table 2 continues on next page

Table 2 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Previous operations	Previous history of myomectomy	Carugno, 2014 [36]	2580 LH, TLH and RALH	[C]	9
	Previous laparotomy	Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
	Not defined	Shin, 2011 [46]	168 TLH and LAVH	[C]	6
Age	≥41 years	Giep, 2010 [14]	589 RALH, LAVH and LSH	[C]	9
	Not defined	Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
	>50 years	Catanzarite, 2015 [24]	7630 LH	[C]	8
Endometriosis	Pelvic endometriosis	Song, 2012 [73]	2012 LAVH	[C]	8
Menopause	Premenopausal women	Yavuzcan, 2013 [74]	87 LH	[B]	7
Parity	Nullipara	Wong, 2011 [20]	297 LAVH	[C]	6
Comorbidity	Diabetes Mellitus	Catanzarite, 2015 [24]	7630 LH	[C]	8
	Hypertension	Catanzarite, 2015 [24]	7630 LH	[C]	8
	ASA score 3-4	Catanzarite, 2015 [24]	7630 LH	[C]	8

RALH = robot-assisted total laparoscopic hysterectomy, LAVH = laparoscopic assisted vaginal hysterectomy, LSH = laparoscopic supracervical hysterectomy, TLH = total laparoscopic hysterectomy, LASH = laparoscopic subtotal hysterectomy, SPA = single-port access, tVNOTEH = transvaginal natural orifice transluminal endoscopic hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study.
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 3 More blood loss: predictors in detail

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	≥250-300g	Hussain, 2012 [19]	85 LSH	[B]	7
		Kriplani, 2012 [17]	110 TLH	[C]	6
		Surgit, 2012 [18]	68 TLH	[B]	7
		Dassel, 2015[23]	1004 LH	[C]	8
	≥500g	Payne, 2010 [25]	256 RALH	[C]	8
		Ark, 2009 [26]	367 LAVH	[C]	7
		Chang, 2005 [27]	225 LAVH	[B]	8
		Fiaccavento, 2007 [28]	684 TLH	[C]	7
		Huang, 2014 [75]	109 SPA-LH	[B]	7
		Wang, 2004 [30]	189 LAVH	[B]	7
		Wong, 2010 [32]	588 LAVH	[C]	7
	≥750-800g	Shiota, 2011 [33]	629 LAVH	[C]	6
		Chang, 2008 [34]	181 LAVH	[B]	7
	Increase/100g	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Not defined	Uccella, 2013[11]	712 TLH	[C]	7
		Condous, 2007 [37]	75 TLH	[B]	7
		Chou, 2011 [40]	56 LAVH	[B]	6
		Yen, 2002 [76]	61 LAVH	[B]	6
		Song, 2013 [50]	21 SPA-TLH	[B]	6
		Jahan, 2015 [54]	100 LAVH	[C]	7
		Wang, 2015 [58]	512 tVNOTEH and LAVH	[C]	7

Table 3 continues on next page

Table 3 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
BMI	BMI ≥ 30 kg/m^2	Shen, 2002 [77]	670 LAVH	[C]	7
		Harmanli, 2013 [63]	970 LSH and TLH	[C]	7
		Morgan-Ortiz, 2013 [61]	209 TLH	[B]	7
		Surgit, 2012 [18]	68 TLH	[B]	7
		Heinberg, 2004 [64]	270 TLH	[B]	8
	Not defined	Siedhoff, 2012[66]	834 TLH and LSH	[C]	8
		Twijnstra, 2012 [35]	1534 LH	[B]	9
		Bardens, 2014 [67]	194 LH	[C]	8
		Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
		Brummer, 2012 [78]	1679 LH	[B]	9
		Dassel, 2015[23]	1004 LH	[C]	8
Adhesions	Adhesion score (adhesion severity combined with extent of adhesions)	Chiu, 2015 [71]	216 RALH and TLH	[C]	8
	Extensive pelvic adhesions	Hsu, 2007 [72]	236 LAVH	[C]	6
	Vesicouterine peritoneum adhesions	Lee, 2000 [79]	50 LAVH	[B]	6
Age	Not defined	Lin, 2014 [42]	100 RATLH	[C]	8
Parity	Nullipara	Wong, 2011 [20]	297 LAVH	[C]	6

RALH = robot-assisted total laparoscopic hysterectomy, LAVH = laparoscopic assisted vaginal hysterectomy, LSH = laparoscopic supracervical hysterectomy, TLH= total laparoscopic hysterectomy, SPA= single-port access, tVNOTEH = transvaginal natural orifice transluminal endoscopic hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study.
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 4 Increased complication rate: predictors and outcome in detail

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	>250 g	Urinary tract infection and blood transfusions	Catanzarite, 2015 [24]	7630 LH	[C]	8
	≥500g	Total complications and intra-operative haemorrhage ≥1000mL	Brummer, 2011 [69]	1679 LH	[B]	8
		Events requiring active treatment or prolonged hospital stay	Chang, 2005 [27]	225 LAVH	[B]	8
		Postoperative minor complications	Fiaccavento, 2007 [28]	684 TLH	[C]	7
	≥750-800g	Intraoperative complications	Shiota, 2011 [33]	629 LAVH	[C]	6
	Increase/100g	Adverse events defined by the Dutch Society of Obs and Gyn.	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Not defined	Secondary haemorrhage	Paul, 2014 [80]	1613 TLH	[C]	6
BMI	BMI < 20 kg/m^2	Infection (urinary, wound of intra-abdominal)	Osler, 2011 [81]	1331 LH	[B]	9
		Vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
	BMI ≥ 30 kg/m^2	Major complications	Morgan-Ortiz, 2013 [61]	209 TLH	[B]	7
		Febrile event (not defined)	Brummer, 2011 [69]	1679 LH	[B]	8
		vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
		Minor intraoperative complication; vaginal or uterine perforation	Kondo, 2012 [83]	2271 LAVH, TLH and SLH	[C]	7

Table 4 continues on next page

Table 4 ***Continued***

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
	Not defined	Complication severity; Dindo-Clavien grade 1 or 2 vs grade 3 or higher	Siedhoff, 2012 [66]	834 TLH and LSH	[C]	8
		Postoperative complications	Bardens, 2014 [67]	194 LH	[C]	8
		Overall complications	Catanzarite, 2015 [24]	7630 LH	[C]	8
Previous operations	≥2 caesarean sections	Bladder injury	Song, 2012 [73]	2012 LAVH	[C]	8
	1 vs none and ≥3 vs none	Adverse events defined by the Dutch Society of Obs and Gyn.	Twijnstra, 2012 [35]	1534 LH	[B]	9
	Previous caesarean section	Bladder injury	Brummer, 2011 [69]	1679 LH	[B]	8
		Cystomy	Rooney, 2005 [84]	433 LAVH	[D]	6
		Major complication particular cystotomy	Wang, 2010 [85]	574 LH	[B]	8
	Previous laparotomy or caeseran section	Bladder injury	Lafay Pitter, 2009 [86]	1501 LH	[C]	7
	Not defined	Fever (undefined)	Ghomi, 2010 [68]	421 LAVH and LSH	[C]	8
Adhesions	Extensive vs none	Short-term post-operative complications (requiring re-operation)	Wallwiener, 2013 [87]	1952 TLH and LSH	[B]	9
	Adhesiolysis	Bowel injury	Brummer, 2011 [69]	1679 LH	[B]	8

Table 4 continues on next page

Table 4 *Continued*

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
	Moderate or severe adhesions	vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
	Severe adhesions	Pelvic cellulitis	Chang, 2011 [88]	195 LAVH	[D]	7
Age	Younger patient	Short-term post-operative complications (requiring re-operation)	Wallwiener, 2013 [87]	1952 TLH and LSH	[B]	9
	<55 years	Pelvic infection, haematoma or abscess	Brummer, 2011 [69]	1679 LH	[B]	8
	>60 years	Medical complications	Hanwright, 2013 [89]	6190 LAVH and TLH	[C]	8
	Younger age	Overall complications	Catanzarite, 2015 [24]	7630 LH	[C]	8
Endometriosis	Severity of endometrioses (highest incidence stage III/IV)	Vaginal cuff abscess	Patzkowsky, 2013 [90]	545 LH and RALH	[C]	8
	Not defined	Major complication	Brummer, 2011 [69]	1679 LH	[B]	8
Parity	Nullipara	Not defined	Wong, 2011 [20]	297 LAVH	[C]	6
	No previous vaginal delivery	Bladder injury	Lafay Pitter, 2009 [86]	1501 LH	[C]	7
Uterus descent	No descent (vs first degree)	Major complications	Garry, 2004 [91],	920 LH	[A]	9

Table 4 continues on next page

Table 4 *Continued*

Predictor	Detailed predictor	Detailed outcome	Reference, Year	Study population	Study design	NO-QAS
Smoking	Active smoker	Medical complications	Hanwright, 2013 [89]	6190 LAVH and TLH	[C]	8
	History of smoking	vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
Comorbidity	Previous stroke/TIA	Medical complications	Hanwright, 2013 [89]	6190 LAVH and TLH	[C]	8
	Diabetes mellitus	vaginal spotting, major complications and vaginal bleeding	Jeung, 2010 [82]	248 TLH	[A]	9
	Diabetes mellitus	Postoperative urinary retention	Liang, 2009 [92]	150 LAVH	[A]	8
	Higher serum creatinine or platelet count	Surgical site infection	Mahdi, 2014 [93]	15549 LH	[C]	8
	ASA score 2	Pelvic cellulitis	Chang, 2011 [88]	195 LAVH	[D]	7
	ASA score 3-4	Overall complications and blood transfusions	Catanzarite, 2015 [24]	7630 LH	[C]	8
	Previous stroke/ TIA	Overall complications	Catanzarite, 2015 [24]	7630 LH	[C]	8
Ethnicity	Non-white ethnicity	Deep or organ/space surgical site infection	Mahdi, 2014 [93]	15549 LH	[C]	8

LAVH = laparoscopic assisted vaginal hysterectomy, TLH = total laparoscopic hysterectomy, LSH = laparoscopic supracervical hysterectomy, RALH = robot-assisted total laparoscopic hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study.
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 5 Increased conversion rate: predictors in detail

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
Uterine weight	≥500g	Kondo, 2011 [15]	2092 TLH and LAVH	[C]	6
		Song, 2012/2011 [73,94]	2012 LAVH	[C]	8
		Twijnstra, 2013 [95]	1534 LH	[B]	9
		Ferrari, 2000 [31]	31 LAVH	[B]	6
	≥750-800g	Shiota, 2011 [33]	629 LAVH	[C]	6
	Uterus width on ultrasound 8-10cm	Leonard, 2005 [96]	416 TLH	[C]	8
	Not defined	Park, 2011 [97]	288 TLH	[C]	7
		Wallwiener, 2013 [87]	1956 LSH and TLH	[B]	9
BMI	BMI ≥ 30 kg/m^2	Shen, 2002 [77]	670 LAVH	[C]	7
		Song, 2012 [73]	2012 LAVH	[C]	8
		Harmanli, 2013 [63]	970 LSH and TLH	[C]	7
		Twijnstra, 2013 [95]	1534 LH	[B]	9
	Not defined	Leonard, 2005 [96]	416 TLH	[C]	8
Previous operations	Previous history of myomectomy	Song, 2012/2011 [73,94]	2012 LAVH	[C]	8
	Caesarean section	Song, 2011 [94]	2012 LAVH	[C]	8
		Wang, 2010 [85]	574 LH	[B]	8
		Jo, 2013 [98]	300 LESS (LAVH and TLH)	[C]	6
	3 laparotomies	Lafay Pitter, 2009 [86]	1501 LH	[C]	7

Table 5 continues on next page

Table 5 *Continued*

Predictor	Detailed predictor	Reference, Year	Study population	Study design	NO-QAS
	History of adhesion-causing abdominopelvic surgery	Leonard, 2005 [96]	416 TLH	[C]	8
Adhesions	Pelvic adhesions	Park, 2011 [97]	288 TLH	[C]	7
	Minor vs none and extensive vs none	Wallwiener, 2013 [87]	1952 LSH and TLH	[B]	9
Age	>65 years	Twijnstra, 2013 [95]	1534 LH	[B]	9
Fibroids	Lateral fibroid measuring > 5cm	Leonard, 2005 [96]	416 TLH	[C]	8

TLH = total laparoscopic hysterectomy, LAVH = laparoscopic assisted vaginal hysterectomy, LSH = laparoscopic supracervical hysterectomy, LESS = laparoendoscopic single-site hysterectomy.
[A] = randomized controlled trial, [B] = prospective cohort study, [C] = retrospective cohort study, [D] = case-control study
NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Table 6 Selection of case-mix variables per surgical outcome; stratified per level of evidence criteria

	Sets of case-mix characteristics		
	Set 1 (Low) *Level of evidence criteria:* **≥1 study with NO-QAS 9 or ≥2 studies with NO-QAS 8 or 7**	**Set 2 (Medium)** *Level of evidence criteria:* **≥1 study with NO-QAS 9 and ≥1 study with NO-QAS 8 or 7**	**Set 3 (High)** *Level of evidence criteria:* **≥2 study with NO-QAS 9 or ≥4 studies with NO-QAS 8 or 7**
Operative time	Uterine weight BMI Adhesions Previous operations Age	Uterine weight BMI - Previous operations Age	Uterine weight BMI - - -
Bloodloss	Uterine weight BMI	Uterine weight BMI	Uterine weight BMI
Complication	Uterine weight BMI Previous operations Adhesions Age Endometriosis Uterus descent Smoking TIA/Stroke Diabetes Mellitus ASA score	Uterine weight BMI Previous operations Adhesions Age - - Smoking - Diabetes Mellitus -	Uterine weight BMI Previous operations Adhesions - - - - - - -
Conversion	Uterine weight BMI Previous operations Adhesions Age	Uterine weight BMI - Adhesions -	Uterine weight BMI Previous operations - -

NO-QAS = Newcastle-Ottawa Quality Assessment Scale.

Discussion

In this review we aimed to identify predictors for surgical outcomes of LH. These predictors can be used as case-mix correctors for quality assessment and serve to correctly compare the outcomes of clinicians. We observed that most studies of high quality described a statistically significant association between higher BMI, high uterine weight, and less favorable surgical outcomes. Also, adhesions and previous operations seemed to be important predictors for the outcome of LH. These 2 characteristics are closely linked to each other, because previous operations are obviously associated with pelvic adhesions [10]. The strong association between larger uterine weight and all surgical outcomes for LH can inherently be explained by a larger blood supply in large uteri, the need of morcellation, and inadequate visibility

during surgery, which can also lead to prolonged surgery and more complications [11]. Higher BMI was found to be a predictor for longer operative time, more blood loss, and higher risk for complications and conversion. The laparoscopic entry and actual procedure can be more difficult in obese women. However, as has been shown in different studies, LH in obese women and for large uteri is still a safe and feasible approach and should be considered before the abdominal approach [11, 12].

Based on our search, a case-mix correction for at least uterine weight and BMI is strongly recommended when assessing surgical quality of LH. It remains debatable which level of evidence criteria a patient characteristic should meet before being selected as valid case-mix characteristic. However, even when we consider the highest level of evidence (Table 6), BMI and uterine weight remain relevant predictors for all surgical outcomes.

Previous operations and adhesions can also be considered as potential case-mix factors. However, the difference in severity of adhesions makes it more complex to use for a quality assessment tool and quality indicator. Age is also mentioned as predictor in a number of high quality studies for the outcomes complications, operative time, and conversion. However, both younger and older ages are observed as predictors, and no specific cut-off point is observed, which makes a case-mix correction difficult. Furthermore, comorbidity characteristics (e.g., diabetes mellitus, ASA score, transient ischemic attach/stroke), smoking, and uterine descent should be further explored, as only 1 or 2 studies did mentioned these factors, however these are studies of high quality.

Pelvic endometriosis is often mentioned as a level of difficulty of LH and therefore expected to be highly associated with worse surgical outcomes. However, unexpectedly, the appearance of endometriosis did not seem to be an important predictor in the literature, because only 3 articles showed a significant association with longer operative time and more complications. A possible explanation is the difficulty in consistently determining the stage of endometriosis and therefore was not included as a registered patient characteristic in the studies. In addition, LH alone is generally not the primary treatment for (deep infiltrating) endometriosis (e.g., in case of bowel or bladder involvement), and therefore a large proportion of endometriosis cases were probably excluded in the study population of the eligible articles. Furthermore, it is well known that the appearance of endometriosis is closely correlated with pelvic adhesions, which is more often found to be a predictor.

Strengths and limitations

The major weakness of our study is the fact that our conclusions are only based on the number and quality of identified articles and that a more in-depth analysis of the data was

not possible. Our intended design was to pool the results with meta-analysis to determine strong evidence. Most included studies are studies had a different main objective from our search query, and therefore only very limited data for analysis were available (e.g., no means, no standard deviations) and an enormous heterogeneity in outcomes was observed. For this reason it was also not possible to identify all studies that did not find a significant difference between patient characteristics and outcome, because most articles only described the statistically significant data in the results section. However, because we were able to select more than 80 articles, our data do give a clear overview of the importance of certain patient characteristics in the outcome of LH. In addition, it is clear that a case-mix correction for some patient characteristics is indispensable to compare surgical outcomes correctly. We are also aware that reporting bias may play a role in the interpretation of our results. Our selected list of patient characteristics includes only those characteristics that have been reported in literature, and possibly also other characteristics not mentioned in literature, are associated with certain surgical outcomes. In addition, other well-known factors or diseases are inherently associated with our found characteristics (e.g., hypothyroidism with BMI).

A subject for future debate is how to apply case-mix adjustment for quality assessment tools. Several issues need to be taken into account as cut-off values of certain characteristics and how to weight these case-mix variables.

Another important issue regards the problem in the definitions of clinical outcome in literature. For example, the definition of a complication varies per study. This inconsistency makes it more difficult to properly compare clinical outcomes and thus surgical quality, and therefore we mentioned all used definitions for complications in our results (Table 5). In our opinion it is of the utmost importance to achieve an international consensus on uniform outcome definitions and to implement them worldwide. An attempt was made in a recently published study that gives a multidisciplinary consensus on the definition of conversion [13].

Measuring quality of healthcare interventions is a complex and difficult issue. To obtain and develop a validated and accurate quality assessment tool for LH, our study is the first necessary step, and case-mix adjustment is indispensable [6]. At the current time, quality assessment is a much-discussed issue and ranking lists of “best hospital” and “top surgeons”

are available to everyone. These data are widely interpreted by the media and patients as reliable quality measurements of performance data of hospitals and surgeons. However, the differences in patient population between hospitals and surgeons are usually ignored. Therefore, these quality-ranking lists provide the clinician, the insurance company, and the patient with a certain false sense of security. This is especially important for teaching and referral hospitals, because more challenging and more complex patients are treated in these clinics.

Our study gives an overview of all patient characteristics that influence the surgical outcome of LH. This is an important issue, not only for quality assessment but also for patient counselling and surgical scheduling. Based on these results surgeons will be able to better predict operative time, blood loss and risk for complications or conversion and anticipate on those issues. Furthermore, evidence-based knowledge of case-mix characteristics can be important considering medicolegal issues.

In conclusion, BMI, uterine weight, adhesions and/or previous surgery are the main predictors for surgical outcomes of LH. For future development of outcome quality indicators of LH and to correctly compare surgical outcomes, a case-mix correction is suggested for at least uterine weight and BMI. For both surgeons and patients it is of great value to be aware of potential factors predicting worse clinical outcomes and to anticipate on them. Finally, to benchmark clinical outcomes, it is of highest importance that similar (international) definitions are developed.

Acknowledgment

We thank J.W. Schoones, specialized librarian, for his extensive assistance with the literature search and Dr. E.W. van Zwet, associate professor medical statistics, for his statistical advice, both from Leiden University Medical Centre.

Reference list

(1) Makinen J, Brummer T, Jalkanen J et al. Ten years of progress--improved hysterectomy outcomes in Finland 1996-2006: a longitudinal observation study. BMJ Open. 2013; 3:e003169.

(2) Stassen LP, Bemelman WA, Meijerink J. Risks of minimally invasive surgery underestimated: a report of the Dutch Health Care Inspectorate. Surg Endosc. 2010; 24:495-8.

(3) Wright JD. Measuring what matters: quality in gynecologic surgery. Am J Obstet Gynecol. 2015; 212:257-8.

(4) Wollersheim H, Hermens R, Hulscher M et al. Clinical indicators: development and applications. Neth J Med. 2007; 65:15-22.

(5) Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1966; 44:Suppl-206.

(6) Orchard C. Comparing healthcare outcomes. BMJ. 1994; 308:1493-6.

(7) Stroup DF, Berlin JA, Morton SC et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA. 2000; 283:2008-12.

(8) Deeks JJ, Dinnes J, D'amico R et al. Evaluating non-randomised intervention studies. Health Technol Assess Rep. 2003; 7:1-173.

(9) Courrech Staal EF, Wouters MW, Boot H et al. Quality-of-care indicators for oesophageal cancer surgery: A review. Eur J Surg Oncol. 2010; 36:1035-43.

(10) Brill AI, Nezhat F, Nezhat CH et al. The incidence of adhesions after prior laparotomy: a laparoscopic appraisal. Obstet Gynecol. 1995; 85:269-72.

(11) Uccella S, Cromi A, Bogani G et al. Systematic implementation of laparoscopic hysterectomy independent of uterus size: clinical effect. J Minim Invasive Gynecol. 2013; 20:505-16.

(12) Blikkendaal MD, Schepers EM, van Zwet EW et al. Hysterectomy in very obese and morbidly obese patients: a systematic review with cumulative analysis of comparative studies. Arch Gynecol Obstet. 2015.

(13) Blikkendaal MD, Twijnstra AR, Stiggelbout AM et al. Achieving consensus on the definition of conversion to laparotomy: a Delphi study among general surgeons, gynecologists, and urologists. Surg Endosc. 2013; 27:4631-9.

(14) Giep BN, Giep HN, Hubert HB. Comparison of minimally invasive surgical approaches for hysterectomy at a community hospital: robotic-assisted laparoscopic hysterectomy, laparoscopic-assisted vaginal hysterectomy and laparoscopic supracervical hysterectomy. J Robot Surg. 2010; 4:167-75.

(15) Kondo W, Bourdel N, Marengo F et al. Surgical outcomes of laparoscopic hysterectomy for enlarged uteri. J Minim Invasive Gynecol. 2011; 18:310-3.

(16) Boggess JF, Gehrig PA, Cantrell L et al. Perioperative outcomes of robotically assisted hysterectomy for benign cases with complex pathology. Obstet Gynecol. 2009; 114:585-93.

(17) Kriplani A, Garg P, Sharma M et al. A review of total laparoscopic hysterectomy using LigaSure uterine artery-sealing device: AIIMS experience. J Laparoendosc Adv Surg Tech A. 2008; 18:825-9.

(18) Surgit O, Gumus II, Derbent A et al. Laparoscopic type 7 total hysterectomy and adnexectomy with or without Burch colposuspension: Operative technique with the LigaSure device and results. Archives of Gynecology and Obstetrics. 2012; 285:1287-94.

(19) Hussain M, Odejinmi F. Laparoscopic supracervical hysterectomy: Impact of body mass index and uterine weight. Gynecological Surgery. 2012; 9:351-5.

(20) Wong WS, Lee TC, Lim CE. A retrospective study of laparoscopic-assisted vaginal hysterectomy (LAVH) in virgins and nulliparae. Eur J Obstet Gynecol Reprod Biol. 2011; 157:217-21.

(21) Wattiez A, Soriano D, Fiaccavento A et al. Total laparoscopic hysterectomy for very enlarged uteri. Journal of the American Association of Gynecologic Laparoscopists. 2002; 9:125-30.

(22) Mebes I, Diedrich K, Banz-Jansen C. Total laparoscopic hysterectomy without uterine manipulator at big uterus weight (>280 g). Arch Gynecol Obstet. 2012; 286:131-4.

(23) Dassel MW, O'Hanlan KA, Shwayder JM. Ultrasonographically calculated uterine mass as a predictor for surgical outcomes in total laparoscopic hysterectomy. Journal of Gynecologic Surgery. 2015; 31:128-34.

(24) Catanzarite T, Saha S, Pilecki MA et al. Longer operative time during benign laparoscopic and robotic hysterectomy is associated with increased 30-day perioperative complications. J Minim Invasive Gynecol. 2015.

(25) Payne TN, Dauterive FR, Pitter MC et al. Robotically assisted hysterectomy in patients with large uteri: outcomes in five community practices. Obstet Gynecol. 2010; 115:535-42.

(26) Ark C, Gungorduk K, Celebi I et al. Experience with laparoscopic-assisted vaginal hysterectomy for the enlarged uterus. Archives of Gynecology and Obstetrics. 2009; 280:425-30.

(27) Chang W-C, Torng P-L, Huang S-C et al. Laparoscopic-assisted vaginal hysterectomy with uterine artery ligation through retrograde umbilical ligament tracking. Journal of Minimally Invasive Gynecology. 2005; 12:336-42.

(28) Fiaccavento A, Landi S, Barbieri F et al. Total laparoscopic hysterectomy in cases of very large uteri: a retrospective comparative study. J Minim Invasive Gynecol. 2007; 14:559-63.

(29) Shahid A, Sankaran S, Odejinmi F. Laparoscopic subtotal hysterectomy for large uteri using modified five port technique. Arch Gynecol Obstet. 2011; 283:79-81.

(30) Wang CJ, Yen CF, Lee CL et al. Laparoscopically assisted vaginal hysterectomy for large uterus: a comparative study. Eur J Obstet Gynecol Reprod Biol. 2004; 115:219-23.

(31) Ferrari MM, Berlanda N, Mezzopane R et al. Identifying the indications for laparoscopically assisted vaginal hysterectomy: A prospective, randomised comparison with abdominal hysterectomy in patients with symptomatic uterine fibroids. British Journal of Obstetrics and Gynaecology. 2000; 107:620-5.

(32) Wong WS, Lee TC, Lim CE. Novel Vaginal “paper roll” uterine morcellation technique for removal of large (>500 g) uterus. J Minim Invasive Gynecol. 2010; 17:374-8.

(33) Shiota M, Kotani Y, Umemoto M et al. Indication for laparoscopically assisted vaginal hysterectomy. JSLS. 2011; 15:343-5.

(34) Chang W-C, Huang S-C, Sheu B-C et al. Successful laparoscopically assisted vaginal hysterectomies for large uteri of various sizes. Acta Obstetricia et Gynecologica Scandinavica. 2008; 87:558-63.

(35) Twijnstra AR, Blikkendaal MD, van Zwet EW et al. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol. 2012; 119:700-8.

(36) Carugno J, Gyang A, Hoover F et al. Physician risk estimation of operative time: A comparison of risk factors for prolonged operative time in robotic and conventional Laparoscopic Hysterectomy. Journal of Gynecologic Surgery. 2014; 30:15-9.

(37) Condous G, Van CB, Van HS et al. What is the value of preoperative bimanual pelvic examination in women undergoing laparoscopic total hysterectomy? J Minim Invasive Gynecol. 2007; 14:334-8.

(38) Shashoua AR, Gill D, Locher SR. Robotic-assisted total laparoscopic hysterectomy versus conventional total laparoscopic hysterectomy. JSLS. 2009; 13:364-9.

(39) Song T, Kim TJ, Kim MK et al. Single port access laparoscopic-assisted vaginal hysterectomy for large uterus weighing exceeding 500 grams: technique and initial report. J Minim Invasive Gynecol. 2010; 17:456-60.

(40) Chou LY, Sheu BC, Chang DY et al. Operating time and blood loss during laparoscopic-assisted vaginal hysterectomy with in situ morcellation. Acta Obstet Gynecol Scand. 2011; 90:985-9.

(41) Paek J, Kim SW, Lee SH et al. Learning curve and surgical outcome for single-port access total laparoscopic hysterectomy in 100 consecutive cases. Gynecol Obstet Invest. 2011; 72:227-33.

(42) Lin JF, Frey M, Huang JQ. Learning curve analysis of the first 100 robotic-assisted laparoscopic hysterectomies performed by a single surgeon. Int J Gynaecol Obstet. 2014; 124:88-91.

(43) Bojahr B, Raatz D, Schonleber G et al. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. J Minim Invasive Gynecol. 2006; 13:183-9.

(44) Payne TN, Dauterive FR. Robotically assisted hysterectomy: 100 cases after the learning curve. Journal of robotic surgery. 2010; 4:11-7.

(45) Gyr T, Ghezzi F, Arslanagic S et al. Minimal invasive laparoscopic hysterectomy with ultrasonic scalpel. Am J Surg. 2001; 181:516-9.

(46) Shin JW, Lee HH, Lee SP et al. Total laparoscopic hysterectomy and laparoscopy-assisted vaginal hysterectomy. JSLS. 2011; 15:218-21.

(47) Ghomi A, Littman P, Prasad A et al. Assessing the learning curve for laparoscopic supracervical hysterectomy. JSLS. 2007; 11:190-4.

(48) Tu FF, Feinglass J, Milad MP. Does physician benchmarking improve performance of laparoscopically assisted vaginal hysterectomy? South Med J. 2005; 98:883-7.

(49) McClellan SN, Hamilton B, Rettenmaier MA et al. Individual physician experience with laparoscopic supracervical hysterectomy in a single outpatient setting. Surg Innov. 2007; 14:102-6.

(50) Song T, Lee Y, Kim ML et al. Single-port access total laparoscopic hysterectomy for large uterus. Gynecol Obstet Invest. 2013; 75:16-20.

(51) Erian J, Hassan M, Pachydakis A et al. Efficacy of laparoscopic subtotal hysterectomy in the management of menorrhagia: 400 consecutive cases. BJOG. 2008; 115:742-8.

(52) Gocmen A, Sanlikan F, Ucar MG. Robot-assisted hysterectomy vs total laparoscopic hysterectomy: a comparison of short-term surgical outcomes. Int J Med Robot. 2012; 8:453-7.

(53) Heaton RL, Walid MS. An intention-to-treat study of total laparoscopic hysterectomy. Int J Gynaecol Obstet. 2010; 111:57-61.

(54) Jahan S, Jahan A, Joarder M et al. Laparoscopic hysterectomy in large uteri: Experience from a tertiary care hospital in Bangladesh. Asian J Endosc Surg. 2015.

(55) Mueller A, Boosz A, Koch M et al. The Hohl instrument for optimizing total laparoscopic hysterectomy: results of more than 500 procedures in a university training center. Arch Gynecol Obstet. 2012; 285:123-7.

(56) Paraiso MF, Ridgeway B, Park AJ et al. A randomized trial comparing conventional and robotically assisted total laparoscopic hysterectomy. Am J Obstet Gynecol. 2013; 208:368-7.

(57) Sendag F, Zeybek B, Akdemir A et al. Analysis of the learning curve for robotic hysterectomy for benign gynaecological disease. Int J Med Robot. 2014; 10:275-9.

(58) Wang CJ, Huang HY, Huang CY et al. Hysterectomy via transvaginal natural orifice transluminal endoscopic surgery for nonprolapsed uteri. Surg Endosc. 2015; 29:100-7.

(59) Estrade JP, Crochet P, Aumiphin J et al. Supracervical hysterectomy by laparoendoscopic single site surgery. Arch Gynecol Obstet. 2014; 290:1169-72.

(60) Chopin N, Malaret JM, Lafay-Pillet MC et al. Total laparoscopic hysterectomy for benign uterine pathologies: obesity does not increase the risk of complications. Hum Reprod. 2009; 24:3057-62.

(61) Morgan-Ortiz F, Soto-Pineda JM, Lopez-Zepeda MA et al. Effect of body mass index on clinical outcomes of patients undergoing total laparoscopic hysterectomy. International Journal of Gynecology and Obstetrics. 2013; 120:61-4.

(62) Morsi H, Nightingale P, De Silva MS. Obesity does not increase rates of major complications or conversion in minimally invasive hysterectomy. Journal of Gynecologic Surgery. 2013; 29:190-5.

(63) Harmanli O, Esin S, Knee A et al. Effect of obesity on perioperative outcomes of laparoscopic hysterectomy. J Reprod Med. 2013; 58:497-503.

(64) Heinberg EM, Crawford BL, III, Weitzen SH et al. Total laparoscopic hysterectomy in obese versus nonobese patients. Obstet Gynecol. 2004; 103:674-80.

(65) Mikhail E, Miladinovic B, Velanovich V et al. Association between obesity and the trends of routes of hysterectomy performed for benign indications. Obstet Gynecol. 2015; 125:912-8.

(66) Siedhoff MT, Carey ET, Findley AD et al. Effect of extreme obesity on outcomes in laparoscopic hysterectomy. J Minim Invasive Gynecol. 2012; 19:701-7.

(67) Bardens D, Solomayer E, Baum S et al. The impact of the body mass index (BMI) on laparoscopic hysterectomy for benign disease. Archives of Gynecology and Obstetrics. 2014; 289:803-7.

(68) Ghomi A, Cohen SL, Chavan N et al. Laparoscopic-assisted vaginal hysterectomy vs laparoscopic supracervical hysterectomy for treatment of nonprolapsed uterus. J Minim Invasive Gynecol. 2011; 18:205-10.

(69) Brummer TH, Jalkanen J, Fraser J et al. FINHYST, a prospective study of 5279 hysterectomies: complications and their risk factors. Hum Reprod. 2011; 26:1741-51.

(70) Shah DK, Vitonis AF, Missmer SA. Association of body mass index and morbidity after abdominal, vaginal, and laparoscopic hysterectomy. Obstet Gynecol. 2015; 125:589-98.

(71) Chiu LH, Chen CH, Tu PC et al. Comparison of robotic surgery and laparoscopy to perform total hysterectomy with pelvic adhesions or large uterus. J Minim Access Surg. 2015; 11:87-93.

(72) Hsu WC, Chang WC, Huang SC et al. Laparoscopic-assisted vaginal hysterectomy for patients with extensive pelvic adhesions: a strategy to minimise conversion to laparotomy. Aust N Z J Obstet Gynaecol. 2007; 47:230-4.

(73) Song T, Kim TJ, Kang H et al. Factors associated with complications and conversion to laparotomy in women undergoing laparoscopically assisted vaginal hysterectomy. Acta Obstet Gynecol Scand. 2012; 91:620-4.

(74) Yavuzcan A, Caglar M, Ustun Y et al. The effects of age, parity, menopause and previous pelvic surgery on the outcomes of laparoscopic hysterectomy. Duzce Medical Journal. 2013; 15:22-5.

(75) Huang C-Y, Wu K-Y, Su H et al. Accessibility and surgical outcomes of transumbilical single-port laparoscopy using straight instruments for hysterectomy in difficult conditions. Taiwanese Journal of Obstetrics and Gynecology. 2014; 53:471-5.

(76) Yen YK, Liu WM, Yuan CC et al. Comparison of two procedures for laparoscopic-assisted vaginal hysterectomy of large myomatous uteri. J Am Assoc Gynecol Laparosc. 2002; 9:63-9.

(77) Shen CC, Hsu TY, Huang FJ et al. Laparoscopic-assisted vaginal hysterectomy in women of all weights and the effects of weight on complications. J Am Assoc Gynecol Laparosc. 2002; 9:468-73.

(78) Brummer TH, Heikkinen A, Jalkanen J et al. Pharmaceutical thrombosis prophylaxis, bleeding complications and thromboembolism in a national cohort of hysterectomy for benign disease. Hum Reprod. 2012; 27:1628-36.

(79) Lee JN, Tsai EM. Laparoscopically assisted vaginal hysterectomy using the light-endorsed transvaginal section technique versus the conventional method: a preliminary study. Gynecol Obstet Invest. 2000; 50:50-3.

(80) Paul PG, Prathap T, Kaur H et al. Secondary hemorrhage after total laparoscopic hysterectomy. JSLS. 2014; 18.

(81) Osler M, Daugbjerg S, Frederiksen BL et al. Body mass and risk of complications after hysterectomy on benign indications. Hum Reprod. 2011; 26:1512-8.

(82) Jeung IC, Baek JM, Park EK et al. A prospective comparison of vaginal stump suturing techniques during total laparoscopic hysterectomy. Arch Gynecol Obstet. 2010; 282:631-8.

(83) Kondo W, Bourdel N, Marengo F et al. What's the impact of the obesity on the safety of laparoscopic hysterectomy techniques? J Laparoendosc Adv Surg Tech A. 2012; 22:949-53.

(84) Rooney CM, Crawford AT, Vassallo BJ et al. Is previous cesarean section a risk for incidental cystotomy at the time of hysterectomy? A case-controlled study. Am J Obstet Gynecol. 2005; 193:2041-4.

(85) Wang L, Merkur H, Hardas G et al. Laparoscopic hysterectomy in the presence of previous caesarean section: a review of one hundred forty-one cases in the Sydney West Advanced Pelvic Surgery Unit. J Minim Invasive Gynecol. 2010; 17:186-91.

(86) Lafay Pillet MC, Leonard F, Chopin N et al. Incidence and risk factors of bladder injuries during laparoscopic hysterectomy indicated for benign uterine pathologies: a 14.5 years experience in a continuous series of 1501 procedures. Hum Reprod. 2009; 24:842-9.

(87) Wallwiener M, Taran FA, Rothmund R et al. Laparoscopic supracervical hysterectomy (LSH) versus total laparoscopic hysterectomy (TLH): an implementation study in 1,952 patients with an analysis of risk factors for conversion to laparotomy and complications, and of procedure-specific re-operations. Arch Gynecol Obstet. 2013; 288:1329-39.

(88) Chang WC, Hsieh CH, Lin CC et al. An analysis of risk factors for postoperative pelvic cellulitis after laparoscopic-assisted vaginal hysterectomy. Taiwan J Obstet Gynecol. 2011; 50:463-7.

(89) Hanwright PJ, Mioton LM, Thomassee MS et al. Risk profiles and outcomes of total laparoscopic hysterectomy compared with laparoscopically assisted vaginal hysterectomy. Obstet Gynecol. 2013; 121:781-7.

(90) Patzkowsky KE, As-Sanie S, Smorgick N et al. Perioperative outcomes of robotic versus laparoscopic hysterectomy for benign disease. JSLS. 2013; 17:100-6.

(91) Garry R, Fountain J, Mason S et al. The eVALuate study: two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy. BMJ. 2004; 328:129.

(92) Liang CC, Lee C-L, Chang TC et al. Postoperative urinary outcomes in catheterized and non-catheterized patients undergoing laparoscopic-assisted vaginal hysterectomy—a randomized controlled trial. Int Urogynecol J Pelvic Floor Dysfunct. 2009; 20:295-300.

(93) Mahdi H, Goodrich S, Lockhart D et al. Predictors of surgical site infection in women undergoing hysterectomy for benign gynecologic disease: a multicenter analysis using the national surgical quality improvement program data. J Minim Invasive Gynecol. 2014; 21:901-9.

(94) Song T, Kim TJ, Kang H et al. A review of the technique and complications from 2,012 cases of laparoscopically assisted vaginal hysterectomy at a single institution. Aust N Z J Obstet Gynaecol. 2011; 51:239-43.

(95) Twijnstra AR, Blikkendaal MD, van Zwet EW et al. Clinical relevance of conversion rate and its evaluation in laparoscopic hysterectomy. J Minim Invasive Gynecol. 2013; 20:64-72.

(96) Leonard F, Chopin N, Borghese B et al. Total laparoscopic hysterectomy: preoperative risk factors for conversion to laparotomy. J Minim Invasive Gynecol. 2005; 12:312-7.

(97) Park SH, Cho HY, Kim HB. Factors determining conversion to laparotomy in patients undergoing total laparoscopic hysterectomy. Gynecol Obstet Invest. 2011; 71:193-7.

(98) Jo EJ, Kim TJ, Lee YY et al. Laparoendoscopic single-site surgery with hysterectomy in patients with prior cesarean section: comparison of surgical outcomes with bladder dissection techniques. J Minim Invasive Gynecol. 2013; 20:160-5.

Supplemental Appendix 1

Complete search strategy

Pubmed

((“laparoscopic hysterectomies”[tw] OR “laparoscopic hysterectomy”[tw] OR “laparoscopically assisted hysterectomies”[tw] OR “laparoscopically assisted hysterectomy”[tw] OR “laparoscopically assisted vaginal hysterectomies”[tw] OR “laparoscopically assisted vaginal hysterectomy”[tw] OR “laparoscopically assisted vaginal radical hysterectomy”[tw] OR “laparoscopical hysterectomy”[tw] OR ((“Laparoscopy”[mesh] OR “laparoscopy”[tw] OR “laparoscopic”[tw] OR laparoscop*[tw]) AND (“Hysterectomy”[mesh] OR “hysterectomy”[tw] OR “hysterectomic”[tw] OR hysterectom*[tw])) OR “robotic hysterectomies”[tw] OR “robotic hysterectomy”[tw] OR “robotic assisted hysterectomies”[tw] OR “robotic assisted hysterectomy”[tw] OR “robot assisted hysterectomies”[tw] OR “robot assisted hysterectomy”[tw] OR “robotically assisted hysterectomy”[tw]) AND (“predictor”[tw] OR “predictors”[tw] OR predict*[tw] OR “Forecasting”[Mesh] OR “Time factors”[mesh] OR “learning curve”[tw] OR “Learning Curve”[mesh] OR ((“Blood Loss, Surgical”[majr] OR “blood loss”[ti] OR “blood losses”[ti] OR “mean estimated blood loss”[tw] OR “Intraoperative Complications”[majr] OR “Postoperative Complications”[majr:noexp] OR “Pain, Postoperative”[majr] OR “Postoperative Hemorrhage”[majr] OR “Shock, Surgical”[majr] OR “Surgical Wound Dehiscence”[majr] OR “complication”[ti] OR “complication severity”[tw] OR “complications”[ti] OR “conversion”[ti] OR “conversion rate”[tw] OR “conversion rates”[tw] OR “Conversion to Open Surgery”[majr] OR “hospital discharge”[ti] OR “Patient Discharge”[majr] OR “Patient Discharge”[ti] OR “hospital stay”[ti] OR “Length of Stay”[majr] OR “Length of Stay”[ti] OR “Operative Time”[majr] OR “operative time”[ti] OR “Surgical Time”[ti] OR “Surgery Time”[ti] OR “Surgical volume”[ti] OR “high volume”[ti] OR “low volume”[ti] OR “hospital volume”[ti] OR “Hospitals, Low-Volume”[majr] OR “Hospitals, High-Volume”[majr] OR “Reoperation”[majr] OR “reoperation”[ti] OR “re-operation”[ti] OR “Surgical Revision”[ti] OR “revision surgery”[ti] OR “Repeat Surgery”[ti] OR “surgical site infection”[ti] OR “surgical site infections”[ti] OR “Surgical Wound Infection”[majr] OR “Surgical Wound Infection”[ti] OR “Surgical Wound Infections”[ti] OR “uterine weight”[tw] OR “uterus weight”[tw] OR “uterine size”[tw] OR “uterus size”[tw] OR “Organ Size”[mesh] OR “large uterus”[tw] OR “large uteri”[tw] OR “small uterus”[tw] OR “small uteri”[tw] OR “large uterus”[tw] OR ((“large”[ti] OR “small”[ti] OR “size”[ti] OR “weight”[ti]) AND (“uterus”[ti] OR “uteri”[ti])) OR “Uterus/anatomy and histology”[Majr:NoExp] OR “Risk Factors”[Majr] OR “Risk Factors”[ti] OR “Risk Factor”[ti] OR “BMI”[ti] OR “Body mass index”[ti] OR “Body Mass

Index"[Majr] OR (("Uterus"[ti] OR "uterine"[ti]) AND descen*[ti]) OR "Age"[ti] OR "age factors"[majr] OR "Previous"[ti] OR adhesion*[ti] OR "Tissue Adhesions"[majr] OR "Parity"[ti] OR "Parity"[majr] OR "abdominal surgery"[ti] OR "abdomen surgery"[ti] OR "Abdomen/surgery"[Majr] OR "endometriosis"[ti] OR "Endometriosis"[majr] OR "smoker"[ti] OR "smoking"[ti] OR "Smoking"[majr]) AND ("Outcome Assessment (Health Care)"[Mesh] OR "outcome"[tw] OR "outcomes"[tw] OR "Risk"[mesh] OR "risk factor"[tw] OR "risk factors"[tw] OR "safe"[tw] OR "unsafe"[tw] OR "safety"[tw] OR "Medical Errors"[mesh] OR "injury"[tw] OR "injuries"[tw]))) AND ("2000/01/01"[PDAT] : "3000/12/31"[PDAT]) NOT ("Animals"[mesh] NOT "Humans"[mesh]) AND english[la]) OR (("laparoscopic hysterectomies"[ti] OR "laparoscopic hysterectomy"[ti] OR "laparoscopically assisted hysterectomies"[ti] OR "laparoscopically assisted hysterectomy"[ti] OR "laparoscopically assisted vaginal hysterectomies"[ti] OR "laparoscopically assisted vaginal hysterectomy"[ti] OR "laparoscopically assisted vaginal radical hysterectomy"[ti] OR "laparoscopical hysterectomy"[ti] OR (("Laparoscopy"[majr] OR "laparoscopy"[ti] OR "laparoscopic"[ti] OR laparoscop*[ti]) AND ("Hysterectomy"[majr] OR "hysterectomy"[ti] OR "hysterectomic"[ti] OR hysterectom*[ti])) OR "robotic hysterectomies"[ti] OR "robotic hysterectomy"[ti] OR "robotic assisted hysterectomies"[ti] OR "robotic assisted hysterectomy"[ti] OR "robot assisted hysterectomies"[ti] OR "robot assisted hysterectomy"[ti] OR "robotically assisted hysterectomy"[ti]) AND ("predictor"[tw] OR "predictors"[tw] OR predict*[tw] OR "Forecasting"[Mesh] OR "Time factors"[mesh] OR "learning curve"[tw] OR "Learning Curve"[mesh] OR (("Blood Loss, Surgical"[majr] OR "blood loss"[ti] OR "blood losses"[ti] OR "mean estimated blood loss"[tw] OR "Intraoperative Complications"[majr] OR "Postoperative Complications"[majr:noexp] OR "Pain, Postoperative"[majr] OR "Postoperative Hemorrhage"[majr] OR "Shock, Surgical"[majr] OR "Surgical Wound Dehiscence"[majr] OR "complication"[tiab] OR "complication severity"[tw] OR "complications"[tiab] OR "conversion"[ti] OR "conversion rate"[tw] OR "conversion rates"[tw] OR "Conversion to Open Surgery"[majr] OR "hospital discharge"[ti] OR "Patient Discharge"[majr] OR "Patient Discharge"[ti] OR "hospital stay"[ti] OR "Length of Stay"[majr] OR "Length of Stay"[ti] OR "Operative Time"[majr] OR "operative time"[ti] OR "Surgical Time"[ti] OR "Surgery Time"[ti] OR "Surgical volume"[ti] OR "high volume"[ti] OR "low volume"[ti] OR "hospital volume"[ti] OR "Hospitals, Low-Volume"[majr] OR "Hospitals, High-Volume"[majr] OR "Reoperation"[majr] OR "reoperation"[ti] OR "re-operation"[ti] OR "Surgical Revision"[ti] OR "revision surgery"[ti] OR "Repeat Surgery"[ti] OR "surgical site infection"[ti] OR "surgical site infections"[ti] OR "Surgical Wound Infection"[majr] OR "Surgical Wound Infection"[ti] OR "Surgical Wound Infections"[ti] OR "uterine weight"[tw] OR "uterus weight"[tw] OR "uterine size"[tw] OR "uterus size"[tw] OR "Organ Size"[mesh] OR "large uterus"[tw] OR "large uteri"[tw] OR "small uterus"[tw] OR "small uteri"[tw] OR "large uterus"[tw] OR (("large"[ti] OR "small"[ti] OR "size"[ti] OR "weight"[ti]) AND "uterus"[ti]) OR "Uterus/anatomy and histology"[Majr:NoExp] OR "Risk Factors"[Majr] OR "Risk Factors"[ti] OR "Risk Factor"[ti] OR "BMI"[ti] OR "Body mass index"[ti]

OR "Body Mass Index"[Majr] OR (("Uterus"[ti] OR "uterine"[ti]) AND descen*[ti]) OR "Age"[ti] OR "age factors"[majr] OR "Previous"[ti] OR adhesion*[ti] OR "Tissue Adhesions"[majr] OR "Parity"[ti] OR "Parity"[majr] OR "abdominal surgery"[ti] OR "abdomen surgery"[ti] OR "Abdomen/surgery"[Majr] OR "endometriosis"[ti] OR "Endometriosis"[majr] OR "smoker"[ti] OR "smoking"[ti] OR "Smoking"[majr]) AND ("Outcome Assessment (Health Care)"[Mesh] OR "outcome"[tw] OR "outcomes"[tw] OR "Risk"[mesh] OR "risk factor"[tw] OR "risk factors"[tw] OR "safe"[tw] OR "unsafe"[tw] OR "safety"[tw] OR "Medical Errors"[mesh] OR "injury"[tw] OR "injuries"[tw])))) AND ("2000/01/01"[PDAT] : "3000/12/31"[PDAT]) NOT ("Animals"[mesh] NOT "Humans"[mesh]) AND english[la]) OR ((((laparoscopic*[ti] OR robotic*[ti]) AND hysterectom*[ti]) OR "laparoscopic hysterectomies"[ti] OR "laparoscopic hysterectomy"[ti] OR "laparoscopically assisted hysterectomies"[ti] OR "laparoscopically assisted hysterectomy"[ti] OR "laparoscopically assisted vaginal hysterectomies"[ti] OR "laparoscopically assisted vaginal hysterectomy"[ti] OR "laparoscopically assisted vaginal radical hysterectomy"[ti] OR "laparoscopical hysterectomy"[ti] OR (("Laparoscopy"[majr] OR "laparoscopy"[ti] OR "laparoscopic"[ti] OR laparoscop*[ti]) AND ("Hysterectomy"[majr] OR "hysterectomy"[ti] OR "hysterectomic"[ti] OR hysterectom*[ti])) OR "robotic hysterectomies"[ti] OR "robotic hysterectomy"[ti] OR "robotic assisted hysterectomies"[ti] OR "robotic assisted hysterectomy"[ti] OR "robot assisted hysterectomies"[ti] OR "robot assisted hysterectomy"[ti] OR "robotically assisted hysterectomy"[ti]) AND ("predictor"[tw] OR "predictors"[tw] OR predict*[tw] OR "Forecasting"[Mesh] OR "Time factors"[mesh] OR "learning curve"[tw] OR "Learning Curve"[mesh] OR "Blood Loss, Surgical"[majr] OR "blood loss"[ti] OR "blood losses"[ti] OR "mean estimated blood loss"[tw] OR "Intraoperative Complications"[majr] OR "Postoperative Complications"[majr:noexp] OR "Pain, Postoperative"[majr] OR "Postoperative Hemorrhage"[majr] OR "Shock, Surgical"[majr] OR "Surgical Wound Dehiscence"[majr] OR "complication"[tiab] OR "complication severity"[tw] OR "complications"[tiab] OR "conversion"[ti] OR "conversion rate"[tw] OR "conversion rates"[tw] OR "Conversion to Open Surgery"[majr] OR "hospital discharge"[ti] OR "Patient Discharge"[majr] OR "Patient Discharge"[ti] OR "hospital stay"[ti] OR "Length of Stay"[majr] OR "Length of Stay"[ti] OR "Operative Time"[majr] OR "operative time"[ti] OR "Surgical Time"[ti] OR "Surgery Time"[ti] OR "Surgical volume"[ti] OR "high volume"[ti] OR "low volume"[ti] OR "hospital volume"[ti] OR "Hospitals, Low-Volume"[majr] OR "Hospitals, High-Volume"[majr] OR "Reoperation"[majr] OR "reoperation"[ti] OR "re-operation"[ti] OR "Surgical Revision"[ti] OR "revision surgery"[ti] OR "Repeat Surgery"[ti] OR "surgical site infection"[ti] OR "surgical site infections"[ti] OR "Surgical Wound Infection"[majr] OR "Surgical Wound Infection"[ti] OR "Surgical Wound Infections"[ti] OR "uterine weight"[tw] OR "uterus weight"[tw] OR "uterine size"[tw] OR "uterus size"[tw] OR "Organ Size"[mesh] OR "large uterus"[tw] OR "large uteri"[tw] OR "small uterus"[tw] OR "small uteri"[tw] OR "large uterus"[tw] OR (("large"[ti] OR "small"[ti] OR "size"[ti] OR "weight"[ti]) AND ("uterus"[ti] OR "uteri"[ti])) OR "Uterus/anatomy and histology"[Majr:NoExp]

OR “Risk Factors”[Majr] OR “Risk Factors”[ti] OR “Risk Factor”[ti] OR “BMI”[ti] OR “Body mass index”[ti] OR “Body Mass Index”[Majr] OR ((“Uterus”[ti] OR “uterine”[ti]) AND descen*[ti]) OR “Age”[ti] OR “age factors”[majr] OR “Previous”[ti] OR adhesion*[ti] OR “Tissue Adhesions”[majr] OR “Parity”[ti] OR “Parity”[majr] OR “abdominal surgery”[ti] OR “abdomen surgery”[ti] OR “Abdomen/surgery”[Majr] OR “endometriosis”[ti] OR “Endometriosis”[majr] OR “smoker”[ti] OR “smoking”[ti] OR “Smoking”[majr]) AND “Randomized Controlled Trial”[Publication Type] AND (“2000/01/01”[PDAT] : “3000/12/31”[PDAT]) NOT (“Animals”[mesh] NOT “Humans”[mesh]) AND english[la])

Embase (OVID version)

((“laparoscopic hysterectomies”.mp OR “laparoscopic hysterectomy”.mp OR “laparoscopically assisted hysterectomies”.mp OR “laparoscopically assisted hysterectomy”.mp OR “laparoscopically assisted vaginal hysterectomies”.mp OR “laparoscopically assisted vaginal hysterectomy”.mp OR “laparoscopically assisted vaginal radical hysterectomy”.mp OR “laparoscopical hysterectomy”.mp OR ((exp laparoscopic surgery/ OR “laparoscopy”.mp OR “laparoscopic”.mp OR laparoscop*.mp) AND (exp Hysterectomy/ OR “hysterectomy”.mp OR “hysterectomic”.mp OR hysterectom*.mp)) OR “robotic hysterectomies”.mp OR “robotic hysterectomy”.mp OR “robotic assisted hysterectomies”.mp OR “robotic assisted hysterectomy”.mp OR “robot assisted hysterectomies”.mp OR “robot assisted hysterectomy”.mp OR “robotically assisted hysterectomy”.mp) AND (“predictor”.mp OR “predictors”.mp OR predict*.mp OR forecasting/ OR prediction/ OR learning curve.mp OR learning curve/ OR ((*operative blood loss/ OR “blood loss”.ti OR “blood losses”.ti OR “mean estimated blood loss”.mp OR *complication/ or *peroperative complication/ or *postoperative complication/ or *preoperative complication/ or *wound complication/ OR “complication”.ti OR “complication severity”.mp OR “complications”.ti OR “conversion”.ti OR “conversion rate”.mp OR “conversion rates”.mp OR *”conversion to open surgery”/ OR “hospital discharge”.ti OR *hospital discharge/ OR “Patient Discharge”.ti OR “hospital stay”.ti OR *”Length of Stay”/ OR “Length of Stay”.ti OR *operation duration/ OR “operative time”.ti OR “Surgical Time”.ti OR “Surgery Time”.ti OR “Surgical volume”.ti OR “high volume”.ti OR “low volume”.ti OR “hospital volume”.ti OR * Low Volume hospital/ OR *High Volume Hospital/ OR *Reoperation/ OR “reoperation”.ti OR “re-operation”.ti OR “Surgical Revision”.ti OR “revision surgery”.ti OR “Repeat Surgery”.ti OR “surgical site infection”.ti OR “surgical site infections”.ti OR *Surgical Infection/ OR “Surgical Wound Infection”.ti OR “Surgical Wound Infections”.ti OR uterus weight/ OR “uterine weight”.mp OR “uterus weight”.mp OR “uterine size”.mp OR “uterus size”.mp OR “large uterus”.mp OR “large uteri”.mp OR “small uterus”.mp OR “small uteri”.mp OR “large uterus”.mp OR *Organ Weight/ OR ((“large”.ti OR “small”.ti OR “size”.ti OR “weight”.ti) AND (“uterus”.ti OR “uteri”.ti)) OR *risk factor/ OR risk factor.ti OR risk factors.ti OR “BMI”.ti OR

"Body mass index".ti OR *"Body Mass"/ OR (("Uterus".ti OR "uterine".ti) AND descen*.ti) OR "Age".ti OR exp *"Age"/ OR "Previous".ti OR exp * "patient history of surgery"/ OR adhesion*.ti OR *"Tissue Adhesion"/ OR "Parity".ti OR *"Parity"/ OR "abdominal surgery".ti OR "abdomen surgery".ti OR *"Abdominal surgery"/ OR "endometriosis".ti OR exp *"Endometriosis"/ OR "smoker".ti OR "smoking".ti OR exp *"Smoking"/) AND (adverse outcome/ OR exp Outcome Assessment/ OR "outcome".mp OR "outcomes".mp OR *"Risk Factor"/ OR "risk factor".ti,ab OR "risk factors".ti,ab OR "safe".ti OR "unsafe".ti OR "safety".ti OR "injury".ti OR "injuries".ti))) AND 20*.yr AND exp Humans/ AND english.la) OR ((((laparoscop* OR robotic*) AND hysterectom*).ti OR "laparoscopic hysterectomies".ti OR "laparoscopic hysterectomy".ti OR "laparoscopically assisted hysterectomies".ti OR "laparoscopically assisted hysterectomy".ti OR "laparoscopically assisted vaginal hysterectomies".ti OR "laparoscopically assisted vaginal hysterectomy".ti OR "laparoscopically assisted vaginal radical hysterectomy".ti OR "laparoscopical hysterectomy".ti OR ((exp *laparoscopic surgery/ OR "laparoscopy".ti OR "laparoscopic".ti OR laparoscop*.ti) AND (exp *Hysterectomy/ OR "hysterectomy".ti OR "hysterectomic".ti OR hysterectom*.ti))) AND ("predictor".mp OR "predictors".mp OR predict*.mp OR forecasting/ or prediction/ OR learning curve.mp OR learning curve/ OR ((*operative blood loss/ OR "blood loss".ti OR "blood losses".ti OR "mean estimated blood loss".mp OR *complication/ or *peroperative complication/ or *postoperative complication/ or *preoperative complication/ or *wound complication/ OR "complication".ti,ab OR "complication severity".mp OR "complications".ti,ab OR "conversion".ti OR "conversion rate".mp OR "conversion rates".mp OR *"conversion to open surgery"/ OR "hospital discharge".ti OR *hospital discharge/ OR "Patient Discharge".ti OR "hospital stay".ti OR *"Length of Stay"/ OR "Length of Stay".ti OR *operation duration/ OR "operative time".ti OR "Surgical Time".ti OR "Surgery Time".ti OR "Surgical volume".ti OR "high volume".ti OR "low volume".ti OR "hospital volume".ti OR * Low Volume hospital/ OR *High Volume Hospital/ OR *Reoperation/ OR "reoperation".ti OR "re-operation".ti OR "Surgical Revision".ti OR "revision surgery".ti OR "Repeat Surgery".ti OR "surgical site infection".ti OR "surgical site infections".ti OR *Surgical Infection/ OR "Surgical Wound Infection".ti OR "Surgical Wound Infections".ti OR uterus weight/ OR "uterine weight".mp OR "uterus weight".mp OR "uterine size".mp OR "uterus size".mp OR "large uterus".mp OR "large uteri".mp OR "small uterus".mp OR "small uteri".mp OR "large uterus".mp OR *Organ Weight/ OR (("large".ti OR "small".ti OR "size".ti OR "weight".ti) AND ("uterus".ti OR "uteri".ti)) OR *risk factor/ OR risk factor.ti OR risk factors.ti OR "BMI".ti OR "Body mass index".ti OR *"Body Mass"/ OR (("Uterus".ti OR "uterine".ti) AND descen*.ti) OR "Age".ti OR exp *"Age"/ OR "Previous".ti OR exp * "patient history of surgery"/ OR adhesion*.ti OR *"Tissue Adhesion/" OR "Parity".ti OR *"Parity"/ OR "abdominal surgery".ti OR "abdomen surgery".ti OR *"Abdominal surgery"/ OR "endometriosis".ti OR exp *"Endometriosis"/ OR "smoker".ti OR "smoking".ti OR exp *"Smoking"/) AND (adverse outcome/ OR exp Outcome Assessment/ OR "outcome".mp OR "outcomes".mp OR *"Risk factor"/ OR "risk factor".ti,ab

OR “risk factors”.ti,ab OR “safe”.ti OR “unsafe”.ti OR “safety”.ti OR “injury”.ti OR “injuries”.ti))) AND 20*.yr AND exp Humans/ AND english.la) OR ((((laparoscop* OR robotic*) AND hysterectom*).ti OR “laparoscopic hysterectomies”.ti OR “laparoscopic hysterectomy”.ti OR “laparoscopically assisted hysterectomies”.ti OR “laparoscopically assisted hysterectomy”.ti OR “laparoscopically assisted vaginal hysterectomies”.ti OR “laparoscopically assisted vaginal hysterectomy”.ti OR “laparoscopically assisted vaginal radical hysterectomy”.ti OR “laparoscopical hysterectomy”.ti OR ((exp *laparoscopic surgery/ OR “laparoscopy”.ti OR “laparoscopic”.ti OR laparoscop*.ti) AND (exp *Hysterectomy/ OR “hysterectomy”.ti OR “hysterectomic”.ti OR hysterectom*.ti))) AND (“predictor”.mp OR “predictors”.mp OR predict*.mp OR forecasting/ or prediction/ OR learning curve.mp OR learning curve/ OR *operative blood loss/ OR “blood loss”.ti OR “blood losses”.ti OR “mean estimated blood loss”.mp OR *complication/ or *peroperative complication/ or *postoperative complication/ or *preoperative complication/ or *wound complication/ OR “complication”.ti OR “complication severity”.mp OR “complications”.ti OR “conversion”.ti OR “conversion rate”.mp OR “conversion rates”.mp OR *”conversion to open surgery”/ OR “hospital discharge”.ti OR *hospital discharge/ OR “Patient Discharge”.ti OR “hospital stay”.ti OR *”Length of Stay”/ OR “Length of Stay”.ti OR *operation duration/ OR “operative time”.ti OR “Surgical Time”.ti OR “Surgery Time”.ti OR “Surgical volume”.ti OR “high volume”.ti OR “low volume”.ti OR “hospital volume”.ti OR * Low Volume hospital/ OR *High Volume Hospital/ OR *Reoperation/ OR “reoperation”.ti OR “re-operation”.ti OR “Surgical Revision”.ti OR “revision surgery”.ti OR “Repeat Surgery”.ti OR “surgical site infection”.ti OR “surgical site infections”.ti OR *Surgical Infection/ OR “Surgical Wound Infection”.ti OR “Surgical Wound Infections”.ti OR uterus weight/ OR “uterine weight”.ti OR “uterus weight”.ti OR “uterine size”.ti OR “uterus size”.ti OR “large uterus”.ti OR “large uteri”.ti OR “small uterus”.ti OR “small uteri”.ti OR “large uterus”.ti OR *Organ Weight/ OR *risk factor/ OR risk factor.ti OR risk factors.ti OR “BMI”.ti OR “Body mass index”.ti OR *”Body Mass”/ OR (((“Uterus”.ti OR “uterine”.ti) AND descen*.ti) OR “Age”.ti OR exp *”Age”/ OR “Previous”.ti OR exp * “patient history of surgery”/ OR adhesion*.ti OR *”Tissue Adhesion/” OR “Parity”.ti OR *”Parity”/ OR “abdominal surgery”.ti OR “abdomen surgery”.ti OR *”Abdominal surgery”/ OR “endometriosis”.ti OR exp *”Endometriosis”/ OR “smoker”.ti OR “smoking”.ti OR exp *”Smoking”/) AND randomized controlled trial/ AND 20*.yr AND exp Humans/ AND english.la)

Chapter 6

A dynamic quality assessment tool for laparoscopic hysterectomy to measure surgical outcomes

Sara R.C. Driessen
Erik W. van Zwet
Pascal Haazebroek
Evelien M. Sandberg
Mathijs D. Blikkendaal
Andries R.H. Twijnstra
Frank Willem Jansen

American Journal of Obstet & Gynecol. 2016 Jul 9. S0002-9378(16)30437-9

Abstract

Background: The current healthcare system has an urgent need for tools to measure quality. A wide range of quality indicators have been developed in an attempt to differentiate between high-quality and low-quality healthcare processes. However, one of the main issues of currently used indicators is the lack of case-mix correction and improvement possibilities. Case-mix is defined as specific (patient) characteristics that are known to potentially affect (surgical) outcome. If these characteristics are not taken into consideration, comparisons of outcome among healthcare providers may not be valid.

Objective: The objective of the study was to develop and test a quality assessment tool for laparoscopic hysterectomy, which can serve as a new outcome quality indicator.

Study design: This is a prospective, international, multicenter implementation study. A web-based application (https://www.qusum.org) was developed with 3 main goals: (1) to measure the surgeon's performance using 3 primary outcomes (blood loss, operative time, and complications); (2) to provide immediate individual feedback using cumulative observed-minus-expected graphs; and (3) to detect consistently suboptimal performance after correcting for case-mix characteristics. All gynecologists who perform laparoscopic hysterectomies were requested to register their procedures in the application. A patient safety risk factor checklist was used by the surgeon for reflection. Thereafter a prospective implementation study was performed, and the application was tested using a survey that included the System Usability Scale.

Results: A total of 2066 laparoscopic hysterectomies were registered by 81 gynecologists. Mean operative time was 100±39 minutes, blood loss 127±163 mL, and the complication rate 6.1%. The overall survey response rate was 75%, and the mean System Usability Scale was 76.5±13.6, which indicates that the application was good to excellent. The majority of surgeons reported that the application made them more aware of their performance, the outcomes, and patient safety, and they noted that the application provided motivation for improving future performance.

Conclusions: We report the development and test of a real-time, dynamic, quality assessment tool for measuring individual surgical outcome for laparoscopic hysterectomy. Importantly, this tool provides opportunities for improving surgical performance. Our study provides a foundation for helping clinicians develop evidence-based quality indicators for other surgical procedures.

Introduction

To ensure that patients receive the highest level of care, the healthcare system needs reliable tools for assessing quality; indeed, measuring outcome values is an essential principle [1, 2]. A wide range of quality indicators have been developed in an attempt to differentiate between high-quality and low-quality health care processes. Nearly 2 decades ago, Donabedian defined 3 categories of quality indicators: structure indicators, process indicators, and outcome indicators [3]. Structure indicators reflect the setting in which the care is provided (e.g., case volume, access to specific technologies, etc.). Process indicators reflect the total care system (e.g., multidisciplinary team management). Finally, outcome indicators reflect direct clinical outcomes and are most commonly used by healthcare professionals to assess the quality of surgical care [3]. Ideally, an optimum indicator of quality should measure, compare, monitor, and -most importantly- improve the quality of delivered care. Thus, suboptimal performance relative to an established standard can be recognized and, ideally, corrected. Therefore, a quality indicator must be included in an improvement strategy. In this context, because benchmarking and providing the physician with instant feedback can have positive effects on the quality of surgical care, they are recognized as important areas for improvement [4-6]. However, developing and selecting quality indicators are complex tasks [7]. The majority of quality indicators have limitations because they usually are not evidence-based are not easily available, and/or are not suitable for quality improvement [8-11].

The principal shortcoming of most currently used outcome indicators is their low applicability due to a lack of case-mix adjustment. In the context of health care, case-mix is defined as specific (patient) characteristics that are known to potentially affect (surgical) outcome. If these characteristics are not taken into consideration, comparisons of outcome among healthcare providers may not be valid, and patients, clinicians, insurance companies, and government organizations may develop a false sense of security and/or insecurity.

Assessing quality is an indispensable step in ensuring patient safety, particularly with respect to the field of surgery, in which evaluating surgical performance is essential for maintaining high quality. Because emerging surgical technologies are frequently introduced, particularly with respect to minimally invasive surgery, this field is highly prone to factors that compromise patient safety [12]. However, no tested quality assessment tool is currently available to measure individual surgical performance and provide the surgeon with direct feedback while adjusting for case-mix characteristics.

To address this need, we developed and tested an evidence-based quality assessment tool that can serve as an indicator of outcome quality for surgical procedures. For this study, we focused on laparoscopic hysterectomy (LH) because it is an advanced and technically complex procedure that is performed relatively frequently [13].

Materials and methods

We developed a real-time, web-based quality measurement tool called QUSUM (**QU**ality indicator of **SU**rgical performance in **M**inimally invasive surgery). The primary function of this tool is to measure the surgeon's performance, provide immediate individual feedback and to detect consistently suboptimal performance after correcting for case-mix characteristics. To assess the general usability of this tool, it was tested by a prospective multicenter study using the System Usability Scale (SUS) score as reported by Bangor et al. [14] The QUSUM tool was developed in four phases.

Phase 1: Determination of the benchmark and case–mix characteristics

Operative time, intraoperative blood loss, and complications were selected as primary outcomes. Operative time was defined as the number of minutes between the first incision and insertion of the final stitch and blood loss measured in milliliters directly after the procedure. Complications included infection (local, organ, and/or systemic); injury (vascular, bowel, bladder, and/or ureter); wound dehiscence; hemorrhage (defined as >1000 mL or post-operative bleeding); thromboembolism formation; organ dysfunction (e.g., urinary retention or incontinence, ileus, liver or kidney dysfunction, etc.); systemic events (e.g., medication error, adverse drug reaction. etc.); technical complications (e.g., failed procedure, corpus alienum, etc.); reactive conversion (as defined by Blikkendaal et al. [15]); and other (i.e., not specified). Complications were classified in four levels based on severity: level A, recovery without re(operation); level B, reoperation indicated; level C, permanent injury and/or loss of function; level D, death [16].

The benchmark data and case-mix characteristics specific to laparoscopic hysterectomy were calculated based on a multicenter prospective cohort study that included 1534 laparoscopic hysterectomy procedures [17]. Using these data, regression models were fitted to the primary outcomes as follows: blood loss (numerical), operative time (numerical), and complication (categorical). Because blood loss and operative time had severely right-skewed distributions, a gamma regression model with the logarithmic link function was used. The independent variables (case-mix) included the logarithm of uterine weight and BMI for the outcome blood loss, and the logarithm uterine weight for the outcome operative time. For complications, a multinomial regression model with the cumulative logistic link function was used; the logarithm of uterine weight and the number of previous abdominal surgeries were used as independent variables.

Phase 2: Development of the type of individual feedback: O–E cumulative graphs

The regression models were used to compute the expected value (E) of each outcome after correcting for the case-mix variables. The difference between the observed outcome (O) and (E) was calculated (O–E), and the cumulative sum of O-E was plotted as a time series. A graph depicting the performance of the three outcomes over time is shown in Figure 1. An out-of-control signal was generated when cumulative blood loss exceeded 2000 mL after correcting for the benchmark and case-mix values, and this was defined as consistently suboptimal performance. For operative time this applies for 180 minutes, and for complication score when this value exceeded 2, these cutoff values were calculated based on an out-of-control signal rate of 10-20% of the benchmark data [17]. The complication score was weighted according to the severity: level A was rated as 1 point, whereas levels B, C, and D were each rated as 2 points. The application instantly calculated updated graphs (including out-of-control signals) when the surgeon entered new data. For example, when a reoperation was needed and this was retrospectively entered in the application, the application instantly updated the graphs (including out-of-control signals). In the event of an out-of-control signal, the surgeon was asked to reflect upon the underperformance by completing a validated patient safety risk factor checklist; each surgeon also had the option to complete this checklist after each procedure (Table 1) [18].

Phase 3: Development and testing of the application

The following key requirements were used in the development of the QUSUM application: web-based, immediate feedback, platform independent, user friendly, and privacy secured. The QUSUM application (https://www.QUSUM.org) was developed in collaboration with experts from the Faculty of Social and Behavioral Sciences at Leiden University. The application complied with NEN 7510 standards (Dutch certification regarding informatics and security in the healthcare field) and was approved by the privacy officer at Leiden University Medical Center. Because the requested patient data were anonymous, this study was exempt for approval by our Institutional Review Board (C14.002).

Phase 4: Multicenter implementation

A prospective multicenter study was conducted using the QUSUM application. Gynecologists who performed laparoscopic hysterectomy procedures were requested to register their consecutive laparoscopic hysterectomies performed from April 2014 through November 2015 at our website (https://www.QUSUM.org). A personal email invitation was send to all Dutch gynecologists performing laparoscopic hysterectomies, and gynecologists were

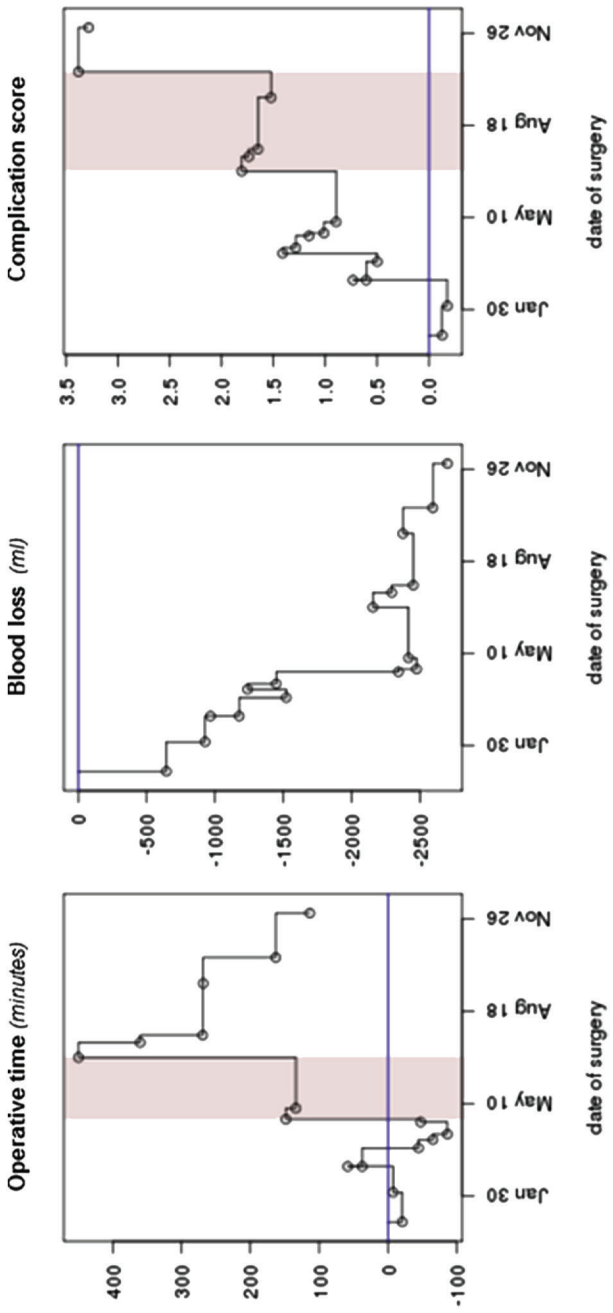


Figure 1 Observed minus expected graphs.
Example of cumulative observed minus expected graphs as used in the QUSUM application. Explanation of graphs is as follows: for each surgical procedure, the expected outcome was calculated based on the provided case-mix characteristics. If a surgeon performed better than expected, the line drops. If a surgeon performed worse than expected, the line rises. The y-axis shows the cumulative difference of the surgical performance compared with the benchmark and corrected for the case-mix. The *red shaded area* represents an out-of-control signal (see *Materials and methods*). This surgeon registered 16 procedures over a period of 11 months. At the last procedure performed, the cumulative operative time was 115 minutes longer than expected, blood loss was 2800 mL less than expected, and the total complication score was 3.3.

Table 1 The validated patient safety risk factor checklist used in the QUSUM application to evaluate of surgical performance

Domain *(detailed description)*	Detailed risk factors per domain
Surgeon *(functioning of the surgeon)*	Lack of experience *(of surgeon or resident)* Lack of technical skills *(of surgeon or resident)* Lack of leadership
Surgical team *(functioning of the scrub or circulating nurse)*	No qualified staffing *(e.g. student/pupil because of shortage of staff or unqualified staffing)* Lack of experience of the scrub nurse *(concerning this procedure)* Lack of knowledge of the procedure of scrub nurse Lack of experience of circulating nurse
Technology *(availability and functioning of equipment and instruments)*	Instrument(s) not present or available Instrument(s) do(es) not work properly It is not known how to handle instruments *(either surgeon or scrub nurse)* Equipment is not present Equipment doesn't work properly Limited vision *(e.g. because of condensation and/or smoke)* It is not known how to handle equipment *(either surgeon or scrub nurse)*
Social interaction *(teamwork and communication)*	Poor communication between OR team members *(e.g. misunderstandings)* Failure of professional communication *(either verbal or non-verbal)* Poor collaboration between OR team members
Environment *(potentially cause distraction or disruptions of the surgical process)*	Distractions *(e.g. telephone calls, case irrelevant conversations, door movements)* Disruption of the surgical process *(surgical process has to be interrupted because of distractions)* Too many people in the OR
Patient *(patient-related risk factors)*	Severe adhesions Unexpected comorbidity, please specify *(e.g. unknown bleeding disorder (e.g. v Willebrand disease, hemophilia))*
Fallibility *(factors that influence the fallibility of the surgeon)*	Moment of day surgery takes place *(e.g. during evening or night shifts)* Perceived high workload Fatigue of the surgeon
Safety *(Compliance or safety protocols)*	Poor compliance of briefing procedure Poor compliance of debriefing procedure Poor compliance of (surpass) checklist (if applicable)
Anesthesiology	Anesthesiology-related problems
Other	Free text option, please specify

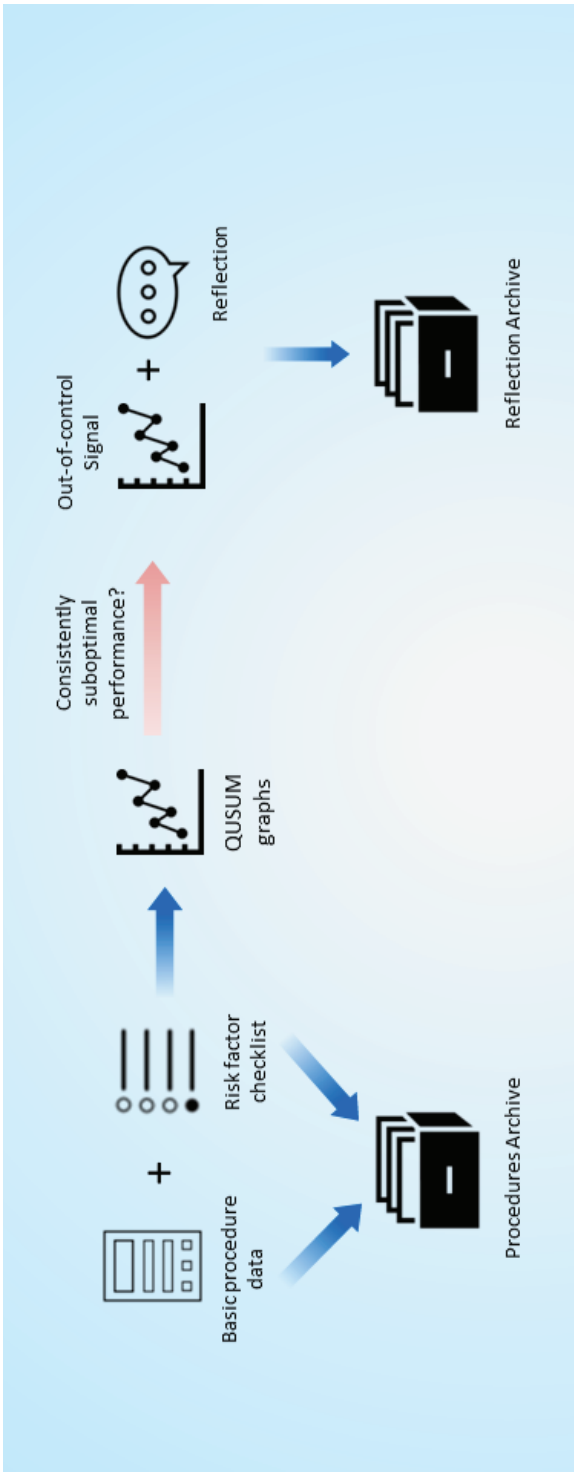


Figure 2 QUSUM application flow chart of registration of procedures.

recruited through conferences and meetings. The following patient characteristics were registered: age; BMI (kg/m^2); number of previous abdominal procedures; date the current hysterectomy was performed; type of hysterectomy (total laparoscopic hysterectomy, supracervical laparoscopic hysterectomy, laparoscopic assisted vaginal hysterectomy, or robotic-assisted hysterectomy); uterine weight (in grams); and the 3 primary outcomes (blood loss, operative time, and complications). Follow-up for complications lasted up to 6 weeks postoperatively, and gynecologists were automatically reminded to fill in the complication form using an automatic pop-up function.

Participants could register immediately postoperatively or at any given moment after surgery.

Directly after entering the data, a risk-adjusted O-E cumulative graph was generated for each primary outcome (Figure 1). This graph provided the surgeon with immediate individual feedback. A flow chart depicting the entire QUSUM application and data registration is showed in Figure 2 (also see Video, Supplemental Digital Content 1, which demonstrates and explains the QUSUM application).

Determine usability of the application

At the end of the prospective registration period, all users received a validated survey that was developed by the Faculty of Social and Behavioral Sciences at Leiden University and included the System Usability Scale and questions regarding the surgeon's awareness, motivation, and ease of use of the application (Table 2).

Statistical analysis

The mean and standard deviation of the System Usability Scale scores were calculated using SPSS version 22 (IBM Corp., Armonk, NY). A System Usability Scale score >70 (of 100) was considered to be good to excellent [14]. A 5 point and 7 point Likert scale was used to measure the awareness and motivation of the users and the ease of use of the application. For these scales, the median and interquartile ranges were calculated. Patient characteristics and surgical outcome variables between benchmark data and newly registered data were compared using the independent Student *t*-test or the chi-square test. Differences were statistically significant at $p<0.05$.

Table 2 Awareness, motivation and ease of use; results of final survey to all users

Questions User awareness	(Strongly) Disagree %	Neutral %	(Strongly) Agree %	Median, *(IQR)**
Because of the QUSUM application I am generally more aware of:				
▪ My performance during an LH procedure	20.9	35.8	43.3	3.0 *(1)*
▪ My surgical outcomes during an LH procedure	17.8	28.4	53.8	3.5 *(1)*
▪ The patient safety risk factors during an LH procedure	14.9	37.3	47.8	3.0 *(1)*
Questions User motivation	**(Strongly) demotivating %**	**Neutral %**	**(Strongly) motivating %**	**Median, (IQR)†**
How would you describe the effect of seeing the QUSUM graphs on your subsequent LH performance?	10.4	41.8	47.7	4.0, (2)
How would you describe the effect of seeing the QUSUM graphs on registering your subsequent LHs in the QUSUM application?	9.0	43.3	47.7	4.0 (2)
Question Easiness application	**(Very) difficult %**	**Neutral %**	**(Very) easy %**	**Median, (IQR)***
Registering LHs in the QUSUM application is	1.5	4.4	94.1	5.0 *(1)*

* Likert scale 1 to 5.
† Likert scale 1 to 7.
IQR = interquartile range.

Results

Procedure data

A total of 2066 LH procedures were entered by 81 gynecologists. Mean (±SD) uncorrected operative time was 100±39 minutes, blood loss was 127±163mL, and the overall complication rate was 6.1%. The majority of procedures performed were total laparoscopic hysterectomies (91.4% of all procedures registered, Table 3).

Procedure data for the benchmark and QUSUM cohort are summarized in Table 3. Comparing these data revealed significant improvement over the last five years with respect to operative time (from 116±42 to 100±39 minutes; p<0.001) and blood loss (from 185±247 to 127±163 ml; p<0.001); in contrast, the number of complications did not change significantly (7.7% vs. 6.1%; p=0.068).

Table 3 Procedure data of used benchmark and new registered QUSUM study data of all entered laparoscopic hysterectomies

	Benchmark data 2009/2010 N=1534	*QUSUM* data 2014/2015 N=2066	P value	95% CI of the difference
Operative time (min), mean ±SD	116±42	100±39	0.001	-13.3, -18.7
Blood loss (mL), mean±SD	185±247	127±163	0.001	-43.9, -72.5
Uterus weight (g), mean±SD	227±199	217±204	NS*	5.9, -21.7
Age (y), mean±SD	47.8±10.2	48.6±11.4	0.038	1.5, -0.4
BMI (kg/m^2), mean±SD	27.2±5.3	28.3±6.1	0.001	1.5, -0.7
Complications	118 (7.7%)	127 (6.1%)	NS*	NA†
Previous procedures			0.001	NA†
▪ none	918 (60.9%)	1128 (56.1%)		
▪ one	397 (26.3%)	520 (25.9%)		
▪ two	143 (9.5%)	223 (11.1%)		
▪ > two	50 (3.3%)	136 (6.9%)		
Reactive conversion to laparotomy	32 (2.1%)	9 (0.4%)	0.001	NA†
Procedure type			0.001	NA†
▪ TLH	957 (62.4%)	1888 (91.4%)		
▪ SLH	391 (25.5%)	89 (4.3%)		
▪ LAVH	185 (12.1%)	68 (3.3%)		
▪ Robotic	0 (0%)	21 (1.0%)		

* NS = not significant.
† NA = not applicable.

QUSUM application data

Sixty-one of the 81 participating gynecologists (75.3%) completed the survey at the end of the study period. There were no differences in outcomes between the gynecologists who completed the survey and who did not completed the survey. The mean System Usability Scale score was 76.5±13.6 (range, 47.5-100), which represents a good to excellent score [14]. The majority of respondents indicated that using the QUSUM application made them more aware of their performance, the surgical outcomes, and patient safety. Moreover, the surgeons reported that using the application motivated them to focus on their performance in the future. Ninety-four percent of the users reported that they found it either easy or very easy to register their procedures in the QUSUM application (Table 2).

Comment

Here we report the development and test of a real-time, dynamic, quality assessment tool used to reflect upon individual surgical performance. To date, many tools have been developed for monitoring surgical outcome. However, we consider our QUSUM application to be a unique tool because the application is easy to use, provides immediate feedback to the surgeon, and includes case-mix correction. In addition, the opportunity for reflection is incorporated into this tool through the use of a risk factor checklist (Table 2). Thus, we believe that our application provides an accurate indicator of quality with respect to laparoscopic hysterectomy. Importantly, the QUSUM application is a dynamic tool because it can be adjusted to an established benchmark, can incorporate case-mix correction, and can accommodate out-of-control values when required. With respect to quality assessment, this is an essential factor, given that benchmark criteria can change over time, particularly with relatively new surgical procedures that are still evolving and become optimized over time. This notion is illustrated in our data because the benchmark for the surgical outcomes changed significant during the last five years (Table 3) (which partly can be due to increased experience [19]). To ensure that a quality indicator is up to date, periodic reevaluations are essential.

This is the first study to test a quality assessment tool using the System Usability Scale, a highly robust and validated survey scale that allows users to assess an application's usability [14]. The high mean System Usability Scale score for our QUSUM application is rather exceptional, given that this was the first use of this application, this suggesting that the application has good to excellent usability and that the features selected were appropriate for our group of participants. We believe that the key to creating a successful registration tool lies in achieving high usability. Clinicians are increasingly required by government agencies to register a wide variety of clinical data for quality control purposes. However, whether the data collected truly reflects the quality of the care provided remains an open question. Therefore, case-mix adjustment is an essential step to successfully implement a tool that can accurately and transparently measure quality [20, 21]. Indeed, if individual performance reports are not corrected for case-mix variables, surgeons may decline to provide care for high-risk patients because of fear of negative ratings [22]. Therefore, case-mix correction is increasingly important in order to succeed with a quality indicator regarding the uptake of surgeons. Although a quality indicator should not have a punitive goal, without good quality indicators, undesirable suboptimal outcomes can go undetected for extended lengths of time.

This study has several strengths, including a carefully chosen design and key features of the application, which include the use of immediate feedback. This latter feature is particularly important because it facilitates the engagement of users, improves registration behavior,

and increases the user's intrinsic motivation for personal improvement [6]. The majority of users reported that the application provided motivation with respect to their performance and registration behavior (Table 2), which is an important finding, given the increasing administrative burden that most clinicians face. Moreover, 94% of users reported that registering a procedure in the application was easy or very easy, a crucial factor for keeping users engaged. An additional strength of our approach is that we used validated benchmark values and case-mix characteristics that were based on a previous prospective cohort study.[17] Using accurate values is considered to be a basic criterion when developing an evidence-based quality indicator. In particular, the selection of case-mix characteristics is incredibly important, which should be evidence based [20]. Lastly, we tested our application in a large, multicenter, prospective study.

On the other hand, the reliability of the data that were entered into the application was dependent on the integrity of the participating surgeons. However, this potential limitation would apply to all forms of quality assessment tools, and previous studies have shown that the overall accuracy of data entered by clinicians is high [5, 17].

It is also important to note that data measured using a quality indicator are generally a close approximation of reality but may not necessarily reflect the true situation precisely. Therefore, penalizing surgeons and/or hospitals based only on the raw data obtained using a quality indicator may not necessarily be appropriate. When a specific indicator provides a less favorable outcome, this should be considered a first sign to reflect on the below-average outcome. We have taken the first step towards addressing this issue by using an out-of-control signal and by evaluating key features in our application (Table 2). In addition, the majority of participants reported that using the QUSUM application increased their awareness regarding their performance, surgical outcome, and patient risk factors during the procedure (Table 2). This awareness automatically leads to self-evaluation and control of individual outcomes, thereby inherently improving surgical outcome.

This study may serve as a foundation for developing quality indicators for use in other surgical procedures. An important prerequisite when developing a new quality indicator is to define and select clinically relevant outcomes that can be measured instantly and that reflect performance quality. With respect to oncological procedures, long-term outcomes (for example, five-year survival and the recurrence of disease) will be less suitable for the QUSUM application because direct feedback cannot be provided. However, other outcomes such as radicality of resection and the number of resected lymph nodes are potentially suitable, provided that benchmark and case-mix values are determined first. Furthermore, for future development of quality assessment tools and internationally benchmark comparisons, we advocate for the use of similar accepted definitions of clinical outcomes. This will allow

quality comparisons on international level. Thus, the QUSUM application can be adapted for use in a variety of surgical procedures. Although we do not necessarily advocate using quality assessment for every type of surgical procedure, quality assessment is particularly recommended for high-risk and/or high-volume procedures [23].

In this study, we focused on surgical outcomes. However, one may question whether a slightly longer operative time or 50mL more blood loss is truly relevant to the patient and the patient's ultimate recovery, which is obviously the ultimate goal in healthcare. Nevertheless, recent studies reported a direct relationship between longer operative time and increased risk of complications, reoperations, and higher hospital costs [24, 25]. Moreover, in addition to assessing surgical outcomes, patient-reported outcome measures (PROMs) should also be taken into consideration when evaluating quality of care.

In conclusion, we recognize that most quality indicators have specific limitations, and the challenge is to develop an indicator that provides the most accurate overview of the current quality of care. As summarized by Porter; "the absence of comprehensive and rigorous outcome and cost measurement is arguably the biggest weakness standing in the way of health care improvement" [26].

In developing the QUSUM application, we attempted to overcome the limitations of currently used quality indicators. However, in this context, a quality indicator has little value if the performance being measured cannot be improved (e.g., by providing feedback or the opportunity for reflection). Therefore, we recommend that surgeons and other health care providers take the lead in developing suitable evidence-based quality indicators using our study as a starting point.

Acknowledgement

The authors thank all the participating gynecologists who registered their procedures during the study period and Wikanand Basropansingh, BSc at Institute of Psychology, Leiden University, for helping develop the survey. All participating gynecologists and BSc Basropansingh received no compensation for their contributions.

Reference list

(1) Porter ME. Value-based health care delivery. Ann Surg 2008; 248(4):503-509.

(2) Porter ME. A strategy for health care reform--toward a value-based system. N Engl J Med 2009; 361(2):109-112.

(3) Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q 1966; 44(3):Suppl-206.

(4) Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev 2012; 6:CD000259.

(5) van Leersum NJ, Snijders HS, Henneman D, Kolfschoten NE, Gooiker GA, Ten Berge MG et al. The Dutch surgical colorectal audit. Eur J Surg Oncol 2013; 39(10):1063-1070.

(6) Hattie J, Timperley H. The power of feedback. Review of Educational Research 2007; 77(1):81-112.

(7) Kotter T, Blozik E, Scherer M. Methods for the guideline-based development of quality indicators--a systematic review. Implement Sci 2012; 7:21.

(8) Rubin HR, Pronovost P, Diette GB. From a process of care to a measure: the development and testing of a quality indicator. Int J Qual Health Care 2001; 13(6):489-496.

(9) McGlynn EA, Asch SM. Developing a clinical performance measure. Am J Prev Med 1998; 14(3 Suppl):14-21.

(10) Wollersheim H, Hermens R, Hulscher M, Braspenning J, Ouwens M, Schouten J et al. Clinical indicators: development and applications. Neth J Med 2007; 65(1):15-22.

(11) Mainz J. Defining and classifying clinical indicators for quality improvement. Int J Qual Health Care 2003; 15(6):523-530.

(12) Rodrigues SP, Wever AM, Dankelman J, Jansen FW. Risk factors in patient safety: minimally invasive surgery versus conventional surgery. Surg Endosc 2012; 26(2):350-356.

(13) Driessen SR, Baden NL, van Zwet EW, Twijnstra AR, Jansen FW. Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in the Netherlands. J Minim Invasive Gynecol 2015; 22(4):642-647.

(14) Bangor A., Kortum P.T., Miller J.T. An Empirical Evaluation of the System Usability Scale. Intl Journal of Human-computer interaction 2008; 24(6):574-594.

(15) Blikkendaal MD, Twijnstra AR, Stiggelbout AM, Beerlage HP, Bemelman WA, Jansen FW. Achieving consensus on the definition of conversion to laparotomy: a Delphi study among general surgeons, gynecologists, and urologists. Surg Endosc 2013; 27(12):4631-4639.

(16) Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. Qual Saf Health Care 2010; 19(2):132-137.

(17) Twijnstra AR, Blikkendaal MD, van Zwet EW, van Kesteren PJ, de Kroon CD, Jansen FW. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol 2012; 119(4):700-708.

(18) Rodrigues SP, Ter KM, Dankelman J, Jansen FW. Patient safety risk factors in minimally invasive surgery: a validation study. Gynecol Surg 2012; 9(3):265-270.

(19) Maruthappu M, Gilbert BJ, El-Harasis MA, Nagendran M, McCulloch P, Duclos A et al. The influence of volume and experience on individual surgical performance: a systematic review. Ann Surg 2015; 261(4):642-647.

(20) Driessen SR, Sandberg EM, la Chapelle CF, Twijnstra AR, Rhemrev JP, Jansen FW. Case-Mix Variables and Predictors for Outcomes of Laparoscopic Hysterectomy: A Systematic Review. J Minim Invasive Gynecol 2016; 23(3):317-330.

(21) Orchard C. Comparing healthcare outcomes. BMJ 1994; 308(6942):1493-1496.

(22) Schneider EC, Epstein AM. Influence of cardiac-surgery performance reports on referral practices and access to care. A survey of cardiovascular specialists. N Engl J Med 1996; 335(4):251-256.

(23) Rose G. Strategy of prevention: lessons from cardiovascular disease. Br Med J (Clin Res Ed) 1981; 282(6279):1847-1851.

(24) Hanwright PJ, Mioton LM, Thomassee MS, Bilimoria KY, Van AJ, Brill E et al. Risk profiles and outcomes of total laparoscopic hysterectomy compared with laparoscopically assisted vaginal hysterectomy. Obstet Gynecol 2013; 121(4):781-787.

(25) Matteson KA, Peipert JF, Hirway P, Cotter K, DiLuigi AJ, Jamshidi RM. Factors associated with increased charges for hysterectomy. Obstet Gynecol 2006; 107(5):1057-1063.

(26) Porter ME. What is value in health care? Supplementary Appendix 1. N Engl J Med 2010; 363(26):2477-2481.

Chapter 7

Hospital versus individual surgeon's performance in laparoscopic hysterectomy

Sara R.C. Driessen
Markus Wallwiener
Florin-Andrei Taran
Sarah L. Cohen
Bernhard Kraemer
Christian W. Wallwiener
Erik W. van Zwet
Sara Y. Brucker
Frank Willem Jansen

Archives of Gynecol and Obstet. 2016 Sep 15. doi:10.1007/s00404-016-4199-2

Abstract

Purpose: To compare hospital versus individual surgeon's perioperative outcomes for laparoscopic hysterectomy (LH), and to assess the relationship between surgeon experience and perioperative outcomes.

Methods: A retrospective analysis of all prospective collected LHs performed from 2003 to 2010 at one medical center was performed. Perioperative outcomes (operative time, blood loss, complication rate) were assessed on both a hospital level and surgeon level using Cumulative Observed minus Expected performance graphs.

Results: A total of 1618 LHs were performed, 16% total laparoscopic hysterectomies and 84% laparoscopic supracervical hysterectomies. Overall outcomes included mean (SD±) blood loss 108.9±69.2 mL, mean operative time 95.4±39.7 minutes and a complication occurred in 76 (4.7%) of cases. Suboptimal perioperative outcomes of an individual surgeon were not always detected on a hospital level. However, collective suboptimal outcomes were faster detected on a hospital level compared to individual surgeon's level. Evidence of a learning curve is seen; for the first 100 procedures, a decrease in operative time is observed as individual surgeon experience increases. Similarly, the risk of conversion decreases up to the first 50 procedures.

Conclusion: An individual outlier (i.e., surgeon with consistently suboptimal performance) will not always be detected when monitoring outcome measures only on a hospital level. However, monitoring outcome measures on a hospital level will detect suboptimal performance earlier compared to monitoring only on an individual surgeon's level. To detect performance outliers timely, insight into an individual surgeon's outcome and skills is recommended. Furthermore, an experienced surgeon is no guarantee for acceptable surgical outcomes.

Introduction

In an effort to improve patient safety in gynecologic surgery, there has been an increasing focus on measures of perioperative outcomes. As the field of minimally invasive surgery involves new and evolving technology, these procedures may be particularly vulnerable to adverse incidents [1]. Individual surgeon outcomes as well as hospital-wide complication rates have been reported; possible uses for this information vary from quality improvement projects, credentialing, ranking list and reimbursement profiles [2]. One of the main problems of this widely released data is the lack of an accurate case-mix correction (patient characteristics that could influence outcomes). As referral hospitals perform more complex procedures and treat more challenging patients, this can potentially result in less optimal surgical outcomes [3]. This case-mix correction may be appropriate when analyzing data on a surgeon level as well, and has been recommended for parameters including uterine weight and BMI regarding laparoscopic hysterectomy (LH) [3]. In addition, many of the quality assessment registries focus only solely on hospital outcome measures, merging all individual surgeon outcomes. This can result in lack of detection of lesser-skilled surgeons who may exhibit suboptimal performance. Furthermore, the experience of a surgeon is increasingly being used as a component in assessment of surgical quality [4-8], and it is important to determine the value of an individual surgical skills factor [9].

The aim of this study is to compare hospital outcome measures versus individual surgeon outcomes for LH. Further, we aim to assess the relationship between surgeon experience and perioperative outcomes once corrected for case-mix characteristics.

Materials and methods

In this retrospective study, all consecutive cases of laparoscopic hysterectomy (laparoscopic supracervical hysterectomy (LSH) and total laparoscopic hysterectomy (TLH)) performed for benign uterine disease between January 2003 to December 2010 at the Department of Obstetrics and Gynecology of the University of Tübingen, Germany were collected. Exclusion criteria included indication of malignancy, deep infiltrating endometriosis or urogenital prolapse in order to limit confounding factors which may be attributed to more complex operations.

The primary outcome measures included: operative time (minutes from first incision to skin closure), estimated blood loss (milliliters) and complications. The blood loss was calculated using the following formula: ((Hemoglobin concentration preoperative (g/l))-(Hemoglobin 1st day postoperative (g/l))) / ((Hemoglobin preopoperative (g/l))-(Hemoglobin 1st day postoperative (g/l))) /2)*1000 [10]. Complications included infection (local, organ and/or

systemic), injury (vascular, bowel, bladder and/or ureter), wound dehiscence, hemorrhage (defined as >1000mL or post-operative bleeding), thromboembolism formation, organ dysfunction (e.g., urinary retention or incontinence, ileus, liver or kidney dysfunction), systemic events (e.g., medication error, adverse drug reaction, etc.), technical complications (e.g., failed procedure, corpus alienum, etc.), and other (i.e., not specified) [11]. For this study, complications were classified by two levels of severity: level 1 (recovery without (re)operation) and level 2 (reoperation indicated, permanent injury and/or function loss or death). Additional data, which was abstracted from the medical record, included: conversion to laparotomy, BMI (kg/m^2), uterus weight (gram), number of previous abdominal surgery and age.
The Ethics Committee of the Medical Faculty of the University of Tübingen approved this study.

Data analysis

Statistical analyses were performed using R statistical software, version 20 for Windows and SPSS version 22 (IBM Corp., Armonk, NY). In addition to descriptive statistics, we fitted regression models for the primary outcomes measures. For the numerical outcomes of blood loss and operative time, a gamma regression model with the logarithmic link function was used. For the categorical outcome of perioperative complications (defined as none, level 1 or level 2) a multinomial regression model with cumulative logistic link function was used. Adjustment factors were adapted from previous research [9]; all outcomes were adjusted for uterine weight. In addition, blood loss was adjusted for BMI and complication was adjusted for the number of previous abdominal surgeries. We computed a numerical complication score by rating a level 1 complication at 1 point and a level 2 at 2 points.

Upon fitting the regression models, we obtained expected outcomes (given the relevant patient characteristics) for each surgery. From these, we constructed individual performance graphs (cumulative Observed minus Expected (O-E)) for every surgeon per surgical outcome (operative time, blood loss and complication score). These individual O-E graphs provided an intuitive representation of the performance in risk-adjusted outcomes over time. Furthermore, we combined the results of all surgeons into a single O-E graph to show the performance at the hospital level. It should be noted, that since we determined the expected performance on the same data, the perceived performance will be exactly according to the benchmark. However, the combined graph shows the progression over time.

Furthermore, we studied the learning effect by regressing the three outcomes on each surgeon's experience (i.e. number of previous LH performed) in addition to the above-mentioned patient characteristics. We modelled the effect of experience by using penalised regression splines as implemented in the R package mgcv [12].

Results

A total of 1618 LHs were performed by 12 gynecologists over the study period. Overall mean (±SD, range) blood loss was 108.9 (±69, 709)mL, mean operative time 95.4 (±39.7, 390) minutes and there was a 4.7% complication rate. The surgical experience of the 12 gynecologists ranged between 18 and 202 procedures at the end of the study period. Table 1 outlines the perioperative characteristics of the LH cases by individual surgeon.

Figures 1, 2, 3 show the cumulative Observed minus Expected Graphs for the individual surgical outcome of blood loss, operative time and complication score on both the hospital level (Figure 1a, 2a, 3a) and the individual surgeon's level (Figure 1b, 2b, 3b).

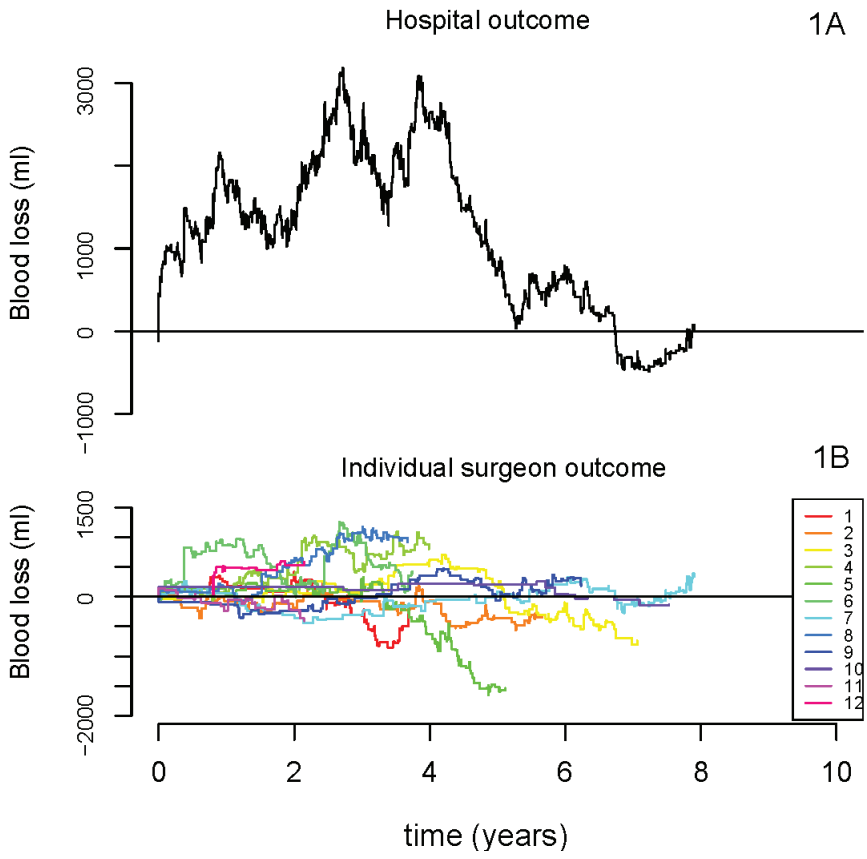


Figure 1 Observed-minus-Expected (O-E) graphs for outcome blood loss.
Explanation of the graphs: when the line drops, the surgeon/hospital performed better than expected. When the line rises, the surgeon/hospital performed less optimal than expected.

Table 1 Surgical data of total performed laparoscopic hysterectomies and procedure data per individual surgeon

	Total LHs (n=1618)	Surgeon #1 (n=113)	Surgeon #2 (n=181)	Surgeon #3 (n=202)	Surgeon #4 (n=187)	Surgeon #5 (n=195)	Surgeon #6 (n=184)
BMI, kg/m^2 (SD)	25.4 (5.0)	25.9 (4.9)	25.7 (5.3)	25.1 (4.8)	25.9 (5.4)	25.6 (5.4)	25.2 (4.8)
Age, years (SD)	53 (6.9)	52 (5.5)	54.4 (6.8)	54.1 (6.5)	52.1 (5.8)	52.5 (6.2)	52.6 (6.1)
Uterus weight, gram (SD)	217.6 (91.0)	212 (178)	200.8 (155.8)	187.5 (134.6)	226.5 (180.6)	233.4 (212.5)	232.7 (194.2)
Previous surgery %							
▪ None	35.6	34.9	32.4	34.9	38.1	35.5	37.2
▪ One	31.3	34.8	35.8	38.5	25.4	29.6	22.1
▪ Two	19.0	21.1	19.9	13.3	16.6	23.8	21.5
▪ > two	14.1	9.2	11.9	13.3	19.9	11.1	19.2
Blood loss, mL (SD, range)	108.9 (69.2, 709)	106.6 (67.3, 309)	105.9 (61.9, 338)	103.7 (60.0, 352)	113.8 (70.1, 462)	99.0 (68.5, 457)	111.7 (93.5, 709)
Operative time, min (SD, range)	95.4 (39.7, 390)	74.7 (31.8, 181)	93.7 (35.9, 210)	94.8 (30.0, 170)	93.7 (39.6, 240)	86.5 (38.7, 290)	99.2 (39.5, 221)
Complications %	4.7	1.8	2.8	3.0	4.8	3.1	4.4
Conversion rate %	2.9	1.8	1.7	2.5	1.6	3.1	2.2
Type hysterectomy %							
▪ LSH	84	77.9	87.3	91.1	75.9	79.5	84.2
▪ TLH	16	22.1	12.7	8.9	24.1	20.5	15.8

Table 1 continues on next page

Table 1 ***Continued***

	Surgeon #7 (n=197)	Surgeon #8 (n=146)	Surgeon #9 (n=132)	Surgeon #10 (n=18)	Surgeon #11 (n=42)	Surgeon #12 (n=21)
BMI, kg/m^2 (SD)	24.6 (4.2)	26.1 (5.3)	25.2 (4.6)	25.6 (4.1)	25.8 (6.7)	23.3 (3.2)
Age, years (SD)	54.3 (7.6)	52.2 (7.6)	54.7 (7.2)	56.3 (8.6)	55.6 (6.2)	60.3 (10.6)
Uterus weight , gram (SD)	221.3 (225.7)	217.2 (173.0)	246.5 (235.8)	179.8 (112.1)	203.4 (142.8)	177 (149.9)
Previous surgery %						
▪ None	39.4	36.2	37.2	37.5	31.7	28.6
▪ One	32.1	29.8	28.7	18.8	34.1	38.1
▪ Two	17.1	17.0	18.6	31.3	24.4	23.8
▪ > two	11.4	17.0	15.5	12.4	9.8	9.5
Blood loss ,mL (SD, range)	111.7 (63.9, 342)	114.9 (59.6, 378)	110.7 (62.3, 313)	98.4 (76.6, 270)	97.0 (80.8, 342)	142.8 (99.4, 454)
Operative time, min (SD, range)	102.9 (44.3, 228)	111.1 (51.3, 350)	95.6 (36.2, 285)	123.6 (58.3, 243)	89.8 (42.7, 211)	105.0 (37.6, 161)
Complications %	6.1	2.8	4.6	0.0	7.1	0.0
Conversion rate %	5.1	1.4	3.8	0.0	2.4	28.6
Type hysterectomy %						
▪ LSH	91.4	71.9	84.1	100	83.3	90.5
▪ TLH	8.6	28.1	15.9	0	16.7	9.5

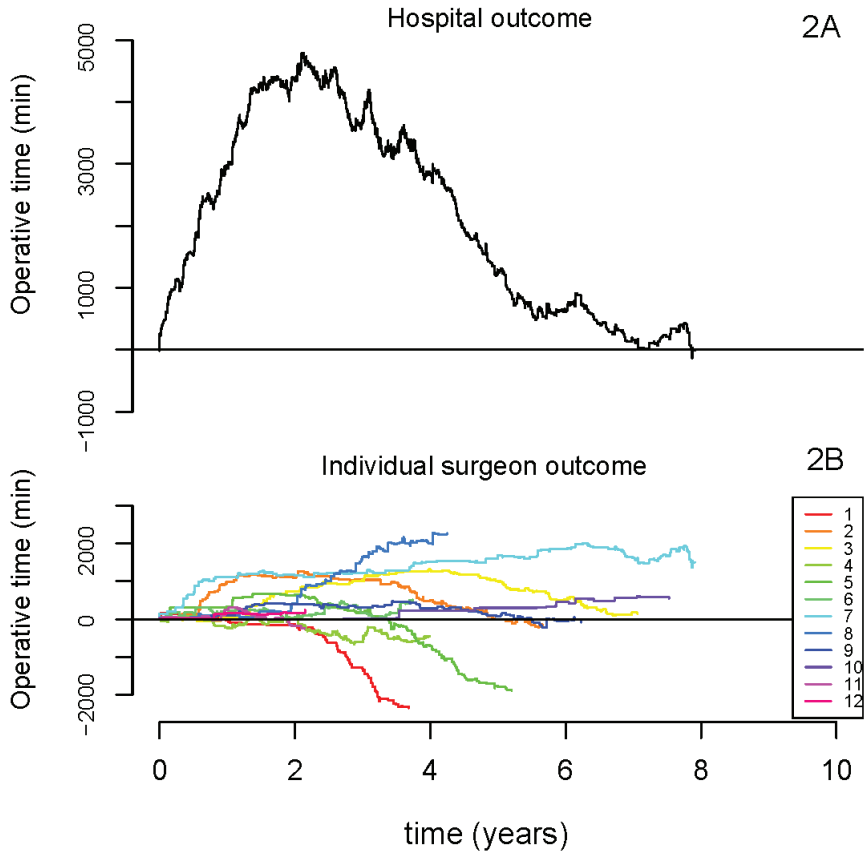


Figure 2 Observed-minus-Expected (O-E) graphs for outcome operative time.
Explanation of the graphs: when the line drops, the surgeon/hospital performed better than expected. When the line rises, the surgeon/hospital performed less optimal than expected.

Hospital–level outcome measures (Figure 1a, 2a and 3a)

For blood loss (Figure 1a), the outcome measures were diverse and the graph line alternately moved downward and upward. The downward part of the graph line indicated a cumulative better outcome than expected; the upward part of the graph line indicated a cumulative less optimal outcome than expected.

For operative time (Figure 2a), less optimal outcomes were observed for the first two years, indicating a learning curve. After two years a cumulative operative time of 4900 minutes more than expected was observed. Thereafter, the graph line continued to move downward, indicated that cumulative better outcomes for this hospital was observed than expected.

For complications (i.e., level 1 and level 2 complications) (Figure 3a), in the first year there was an upward trend in the graph, which indicated less optimal outcomes, with cumulative 3.9 complications more than expected. Thereafter, the graph line moved downward and the complication outcome measure for the hospital continued below zero, indicated that the complication score for the hospital was better than expected.

Comparing individual versus hospital outcome measures, a more rapid detection of suboptimal outcomes was detected for all three outcomes on hospital level (Fig, 1, 2 and 3).

Individual outcome measures (Figure 1b, 2b, 3b)

For blood loss (Figure 1b), a considerable difference between all individual outcome measures was observed. Surgeon 8 can be considered an outlier, since the graph of this

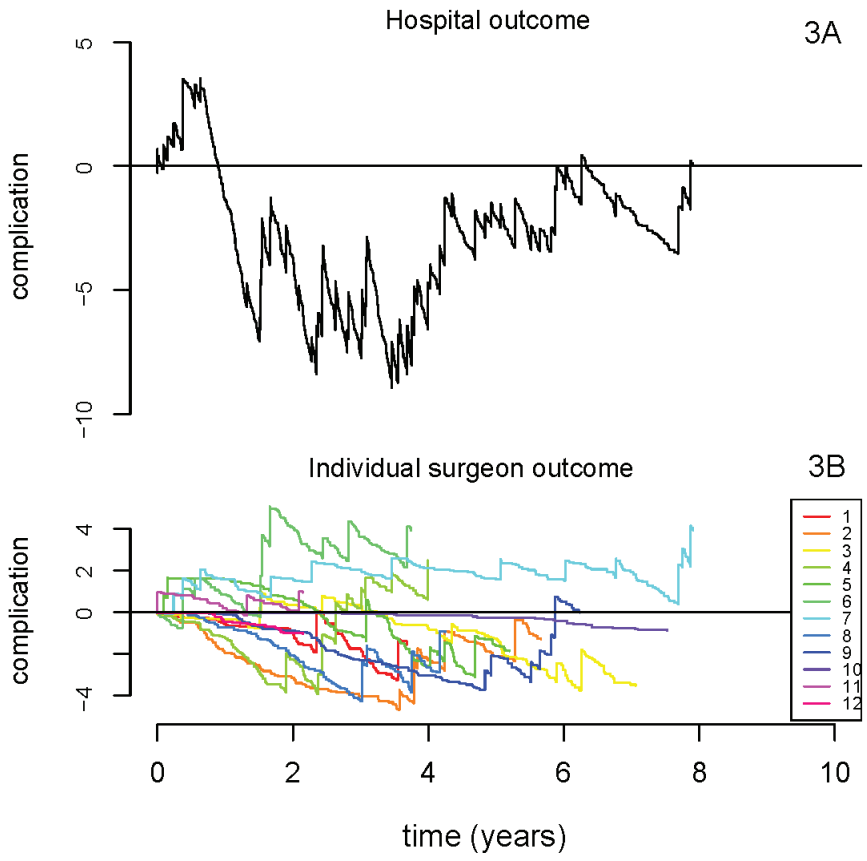


Figure 3 Observed-minus-Expected (O-E) graphs for outcome complication score.
Explanation of the graphs: when the line drops, the surgeon/hospital performed better than expected. When the line rises, the surgeon/hospital performed less optimal than expected.

surgeon continued to move upward (ended with cumulative 915 mL more blood loss than expected). The same applied for surgeon 4 (ended with cumulative 873mL more blood loss than expected). The best individual outcome measure for blood loss was observed for surgeon 5 (cumulative 1537mL blood loss less than expected).

With regards to operative time (Figure 2b), an upward trend in the graphs of almost all individual surgeons was observed for the first two years, indicated less optimal performance. Thereafter, most of the surgeons performed better than expected, indicated by a descending graph line. However, surgeon 8 was observed as an outlier, as the graph of this surgeon continued to move upward (ended with cumulative 2267 minutes more operative time than expected). Surgeon 1 and surgeon 5 can be considered as better skilled surgeon of this hospital, and these outcomes compensated the suboptimal outcome of surgeon 8 (resulting in good outcome measures on a hospital-level; i.e., descending graph, Figure 2a).

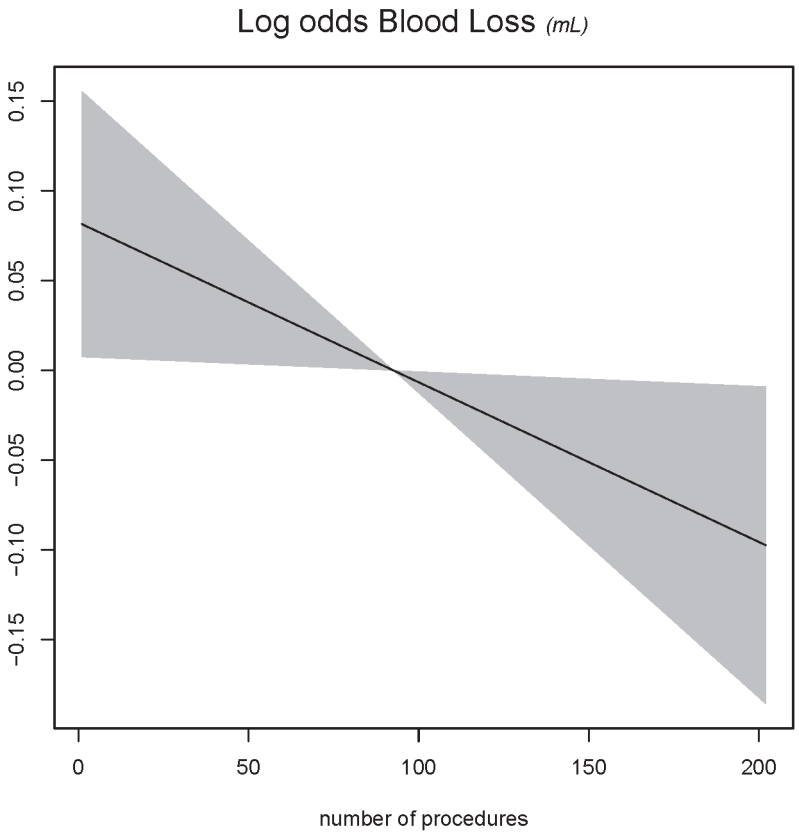


Figure 4 Log odds of Blood loss and surgeons experience.
The grey shaded area represents the Standard Deviation (SD).

For complication score (Figure 3b), three inferior outliers were observed (surgeon 4, surgeon 6 and surgeon 7) with a score of respectively, 2.5, 3.9 and 3.92 more complications than expected. The graph line of these surgeons continued to move upward.

Surgeon's experience

Figures 4, 5, 6, and 7 showed the log odds graphs of surgeon's experience per surgical outcome, corrected for case-mix characteristics. For blood loss, an association was observed between increasing surgical experience and decreased blood loss, however this should be interpreted with caution given the large standard deviation observed (Figure 4).

For operative time, up to 100 procedures a clear decrease was observed as experience increased (Figure 5). A higher complication rate was found when experience increased;

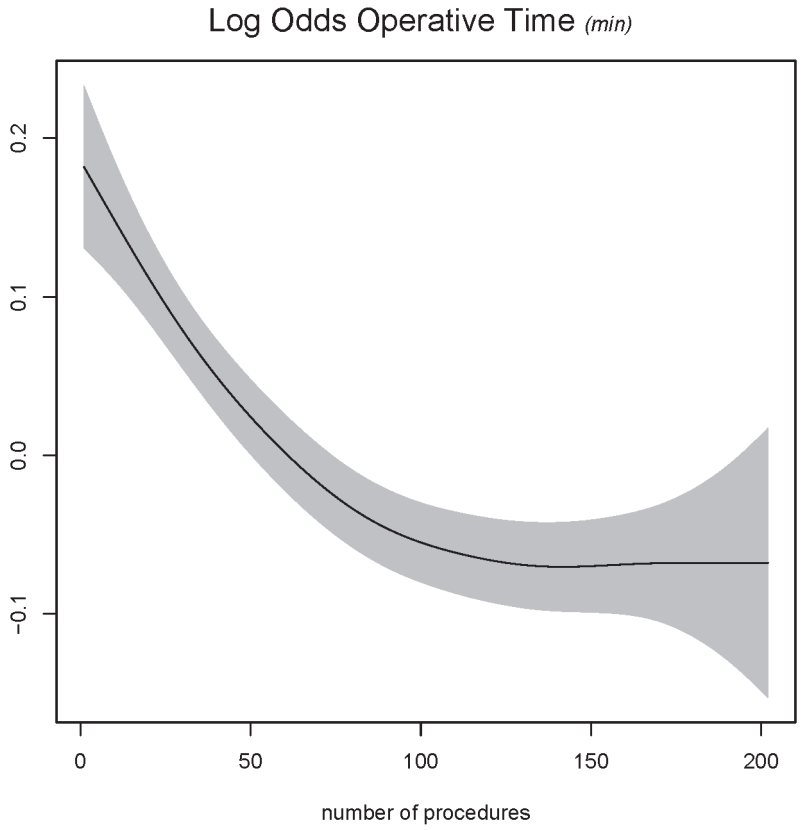


Figure 5 Log odds of Operative time and surgeons experience.
The grey shaded area represents the Standard Deviation (SD).

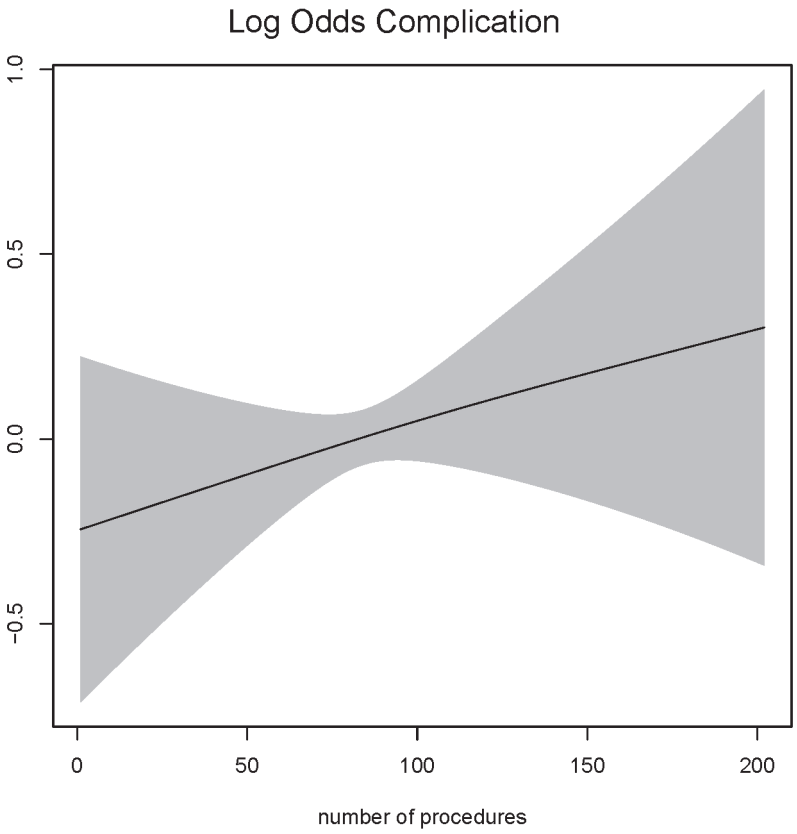


Figure 6 Log odds of Complication score and surgeons experience.
The grey shaded area represents the Standard Deviation (SD).

however this was not statistically significant (Figure 6). Up to 50 procedures a clear decrease was observed for conversion rate, with a plateau thereafter (Figure 7).

Discussion

Surgeons and hospitals may be expected to provide evidence of the quality of care which they deliver by documenting outcome measures [13]. To date, most of the publically reported quality indicators are based on hospital-level outcome measures, such as complication and reoperation rates. As demonstrated in our results, monitoring outcome measures exclusively on the hospital level will not always detect individual surgeon with extreme outcomes. We have demonstrated that suboptimal outcomes of a lesser-skilled surgeon will

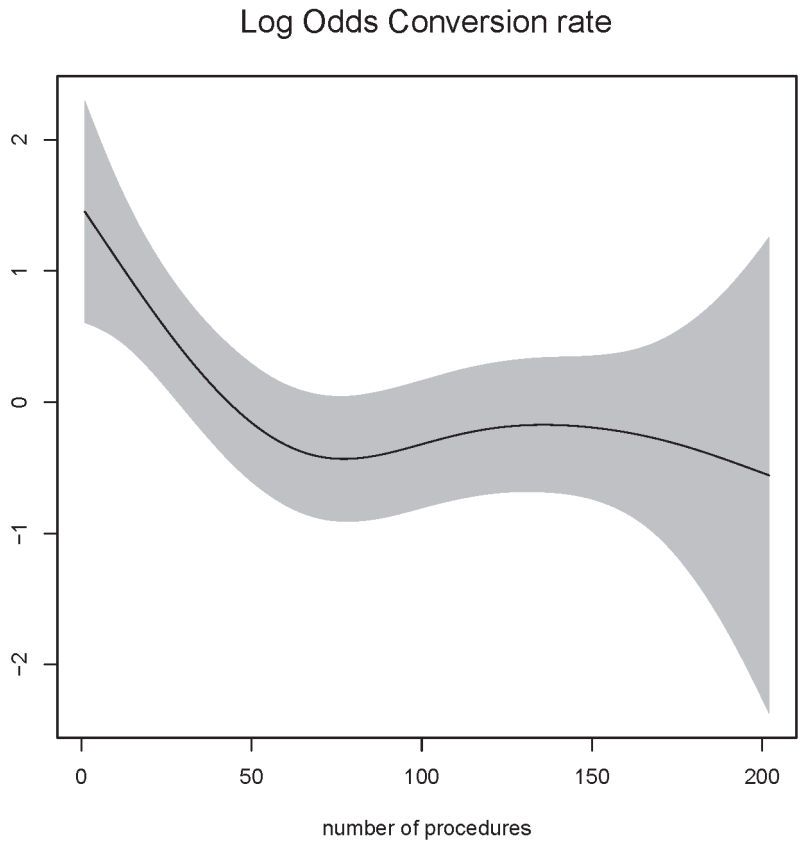


Figure 7 Log odds of Conversion rate and surgeons experience.
The grey shaded area represents the Standard Deviation (SD).

be compensated by the superior skills of other surgeons in the same hospital, resulting in a normal or good quality outcome measure for the hospital (Figure 2 and Figure 3, e.g. surgeon 8 is compensated by surgeon 1 and surgeon 5). Therefore, in order to evaluate quality of care accurately, outcome measures should also be assessed on individual surgeon's level.

As we observed, good hospital outcome measures do not necessarily reflect good surgeon outcome measures and vice versa. However, when all surgeons of one hospital perform less optimal, this will be detected quicker on a hospital level (Figure 2). This can be considered as strength of monitoring outcome measures on a hospital level instead of individual.

Surgical experience is often discussed as a proxy for quality assessment measurement [4-8]. Our data also showed a clear association between increased surgical experience and both a

decreased operative time (after 100 procedures) and conversion rate (after 50 procedures). Compared to previous literature which has suggested a learning curve of 30 cases for LH, this demonstrates a slower rate of improvement [5, 14]. One possible explanation for the longer learning curve found in this study is that a more experienced surgeon may take on more complex procedures, which can consequently cause more complications and less optimal outcomes [4]. The outcomes in this study were corrected for case-mix characteristics such as uterine weight, BMI and previous abdominal surgery, although there may be unknown variables for which no correction was applied such as severe endometriosis, age and other comorbidities [3]. Hence, our data suggest that experience alone is not sufficient to assure the quality of surgical care; individual skills may provide more information about the actual quality of individual surgical performance.

Strengths of this study include the correction for case-mix characteristics in all performed analyses, which makes the comparison of surgical outcomes more precise. Additionally, we were able to longitudinally follow all 12 surgeons and record all their consecutive procedures from the beginning of their (laparoscopic) career. A potential limitation of our study was the necessity to calculate blood loss using the value of Hemoglobin drop, as opposed to surgeons estimated blood loss or a different objective marker. Furthermore, it is difficult to confirm external validity of the complication rates as our chosen definition of complications differs from the more frequently reported Clavien Dindo scale. Other limitations inherent to the study of quality and performance include the issues of rare outcomes and small case numbers. For example, if the incidence of a particular adverse outcome is relatively low, one can not presume that the absence of a complication in a small series of patients implies optimal care [15]. This phenomenon occurred in our results; two surgeons had a complication rate of 0% (surgeon 10 and 12), which was based on only a few procedures (18 and 21 procedures, respectively). Additionally, if we look closer to the surgeon with the highest mean operative time (surgeon 10), this was based on 18 procedures and the high mean was only due to one single procedure with an operative time of 284 minutes. Therefore, small sample sizes should always be taken into account when measuring surgical quality [15]. Small sample sizes is in general a problem in (advanced) gynecologic surgery [16]. Therefore, surgical outcomes with a low incidence should be measured on both hospital level and individual level in an effort to detect consistently suboptimal performance timely.

An important subject for future research is the definition of a performance outlier. Different methods are defined to determine an outlier [17]. In our study we choose to define the outliers as the best and worst performers, compared to their own benchmark. However, this does not necessarily mean these surgeons are also superior or inferior skilled compared to the national or worldwide benchmark. Therefore, before drawing any conclusion of quality assessment outcomes, benchmark and outlier definition should be defined first, and we urge

that international definitions should be adopted. In addition, it is also important to define clinically relevant quality outcomes since, for example, blood loss of 50-100mL more or less is not always clinically relevant for the patient, and the same applies for operative time. However, recent studies have shown significant associations between increased operative time and complication rates or reoperations [18].

Although performance ratings may be useful, there is potential for falsely low or high ratings both on the surgeon and hospital level. For this reason, reliable case-mix adjustment is of major importance to benchmark surgical outcomes correctly. Our study showed that measurement of quality on a hospital level would detect suboptimal performances quicker and in a more consistent fashion. However, it is still possible to misidentify an individual surgeon who is either a high or low performer. Further insight into the individual surgeon's outcome measures and skills is required to detect suboptimal performances timely. Furthermore, experience alone is not a sufficient measurement assessment to assure surgical quality and a very experienced surgeon is unfortunately no guarantee for acceptable surgical outcomes.

Reference list

(1) Rodrigues SP, Wever AM, Dankelman J et al. Risk factors in patient safety: minimally invasive surgery versus conventional surgery. Surg Endosc. 2012; 26:350-6.

(2) Nederlandse vereniging van ziekenhuizen. Kwaliteitvenster, https://www.nvz-kwaliteitsvenster.nl/. 2015.

(3) Driessen SR, Sandberg EM, la Chapelle CF et al. Case-mix variables and predictors for outcomes of laparoscopic hysterectomy: a systematic review. J Minim Invasive Gynecol. 2015.

(4) Maruthappu M, Gilbert BJ, El-Harasis MA et al. The influence of volume and experience on individual surgical performance: a systematic review. Ann Surg. 2015; 261:642-7.

(5) Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. Obstet Gynecol. 2004; 104:308-13.

(6) Ghomi A, Littman P, Prasad A et al. Assessing the learning curve for laparoscopic supracervical hysterectomy. JSLS. 2007; 11:190-4.

(7) Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod. 2008; 23:840-5.

(8) Wattiez A, Soriano D, Cohen SB et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc. 2002; 9:339-45.

(9) Twijnstra AR, Blikkendaal MD, van Zwet EW et al. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol. 2012; 119:700-8.

(10) Palmer T, Wahr JA, O'Reilly M et al. Reducing unnecessary cross-matching: a patient-specific blood ordering system is more accurate in predicting who will receive a blood transfusion than the maximum blood ordering system. Anesth Analg. 2003; 96:369-75, table.

(11) Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. Qual Saf Health Care. 2010; 19:132-7.

(12) Wood S.N. Generalized Additive Models: An Introduction with R. In: Chapman and Hall, CRC, eds. 16 ed. Florida: 2006.

(13) Birkmeyer JD, Dimick JB, Birkmeyer NJ. Measuring the quality of surgical care: structure, process, or outcomes? J Am Coll Surg. 2004; 198:626-32.

(14) Tunitsky E, Citil A, Ayaz R et al. Does surgical volume influence short-term outcomes of laparoscopic hysterectomy? Am J Obstet Gynecol. 2010; 203:24-6.

(15) Dimick JB, Welch HG, Birkmeyer JD. Surgical mortality as an indicator of hospital quality: the problem with small sample size. JAMA. 2004; 292:847-51.

(16) Driessen SR, Baden NL, van Zwet EW et al. Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in the Netherlands. J Minim Invasive Gynecol. 2015; 22:642-7.

(17) Shahian DM, Normand SL. What is a performance outlier? BMJ Qual Saf. 2015; 24:95-9.

(18) Hanwright PJ, Mioton LM, Thomassee MS et al. Risk profiles and outcomes of total laparoscopic hysterectomy compared with laparoscopically assisted vaginal hysterectomy. Obstet Gynecol. 2013; 121:781-7.

Chapter 8

Identification of risk factors in minimally invasive surgery: a prospective multicenter study

Sara R.C. Driessen
Evelien M. Sandberg
Sharon P. Rodrigues
Erik W. van Zwet
Frank Willem Jansen

Surg Endosc. 2016 Oct 31. DOI: 10.1007/s00464-016-5248-4

Abstract

Background: Since the introduction of minimally invasive surgery (MIS), concerns for patient safety are more often brought to the attention. Knowledge about and awareness of patient safety risk factors are crucial in order to improve and enhance the surgical team, the environment, and finally surgical performance. The aim of this study was to identify and quantify patient safety risk factors in laparoscopic hysterectomy and to determine their influence on surgical outcomes.

Methods: A prospective multicenter study was conducted from April 2014 to January 2016, participating gynecologists registered their performed laparoscopic hysterectomies (LHs). If deemed necessary, gynecologists could fill out a checklist with validated patient safety risk factors. Association between procedures with and without an occurred risk factor(s) and the surgical outcomes (blood loss, operative time, and complications) were assessed, using multivariate logistic regression and generalized estimation equations.

Results: Eighty-five gynecologists participated in the study, registering total 2237 LHs. For 627(28%) procedures, the checklist was entered (in total 920 items). The most reported risk factors were related to the surgeon (19.6%), the surgical team (14.4%), technology (16.6%) and the patient (26.8%). The procedures where a risk factor was registered had significantly less favorable outcomes, higher complication rate (10.5 vs. 4.8% ($p=0.002$), longer operative time (114 vs. 95 minutes ($p<0.001$)), and more blood loss (110 vs. 168 mL ($p=0.047$)), which was mainly due to the technological and patient-related risk factors.

Conclusion: Technological incidents are the most important and clinically relevant risk factors affecting surgical outcomes of LH. Future improvements of MIS need to focus on this. As awareness of safety risk factors in MIS is important, embedding of a safety risk factor checklist in registration systems will help surgeons to evaluate and improve their individual performance. This will inherently improve the surgical outcomes and thus patient safety.

Introduction

Since the introduction of minimally invasive surgery (MIS) in daily surgical practice, patient safety issues have increasingly received attention. Implementation of new technologies in surgery is a challenge for practicing surgeons, especially when it comes to complex procedures such as MIS. In general, MIS requires a more demanding work environment compared to conventional surgery, and in order to facilitate the surgeon in this, a fast development of new medical devices is observed [1]. In contrast to the introduction of newly developed drugs, new devices are mostly introduced into the operating room without proper evidence regarding their benefit and safety. This can potentially lead to patient safety issues in daily clinical practice, as also seen after the wide introduction of the laparoscopic power morcellator; years after this introduction, the U.S. Food and Drug Administration (FDA) issued a statement discouraging the use of power morcellation in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids due to the potential risk of upstaging of uterine sarcoma [2].

Besides improper introduction of new technologies, limited experience and skills of the surgeon are considered to be important risk factors in MIS [3]. In addition, also communication and environmental failures occur commonly during surgical procedures and are recognized as risk factors regarding patient safety [1, 4]. Knowledge about and awareness of these patient safety risk factors are crucial to improve and enhance the surgical team, the environment, and finally surgical performance. However, it is not known whether and how these validated risk factors directly affect surgical outcome. In order to improve the surgical process, insight into the occurrence of events as potential risk factors and their consequences is required. Laparoscopic hysterectomy (LH) is the most performed advanced laparoscopic procedure in gynecological surgery [5]; therefore this procedure is ideal for further analyses. The aim of this multicenter prospective study was to identify and quantify patient safety risk factors in LH and to assess their influence on surgical outcomes.

Materials and methods

During this prospective multicenter study, all gynecologists performing advanced MIS (regarding the ESGE classification [6]) were asked to register their consecutive LHs from April 2014 to January 2016 in a secured web-based application.

During initial registration, gynecologists were asked to enter the number of LHs performed yearly (their annual surgical volume), the total amount of LH performed during their career (their experience) and the number of years they were performing LHs. After initial registration, the application was available 24/7 for the registration of all consecutive performed LHs.

After entering the procedure data, the gynecologist could optionally enter a checklist with validated patient safety risk factors and observations, which could have potentially influenced the outcome of the procedure (Table 1). The risk factor checklist was developed based upon previous research [3]. A brief description of every domain and risk factor was easily available by the use of information pop-ups. A free text option was available to write additional comments.

The following patient characteristics were registered: age, BMI (kg/m^2), uterine weight, number of previous abdominal surgeries defined as laparotomy (including cesarean section) or therapeutic laparoscopy, and the presence and stage of endometrioses (stage 1 minimal, stage 2 mild, stage 3 moderate and stage 4 severe, as defined by the American Society for Reproductive Medicine [7]). Additionally, the surgical outcomes collected included the type of hysterectomy (total laparoscopic hysterectomy (TLH), supracervical laparoscopic hysterectomy (SLH), laparoscopic-assisted vaginal hysterectomy (LAVH), and robotic hysterectomy), intra-operative blood loss (millilitres, collected in containers and directly measured after surgery), operative time, and complications. Operative time was defined as the number of minutes between first incision and the final stitch. Complications were registered according to the classification of the Dutch Society of Obstetrics and Gynecology [8], including infection (local, organ and systemic), injury (vascular, bowel, bladder and ureter), wound dehiscence, hemorrhage (>1000mL, postoperative bleeding), thromboembolism, dysfunction (urinary retention, incontinence, ileus, liver, kidney), systemic (medication error, adverse drug reaction), technical (failed procedure, corpus alienum), reactive conversions (as defined by Blikkendaal et al. [9]), and other (not specified). The postsurgical follow-up period lasted for 6 weeks after discharge. After the 6 weeks, gynecologists received an automatic reminder from the application to register any possible postoperative complication. All surgical outcome data were mandatory items to register in the web-based application.

Since only limited anonymous patient data were requested, our Institutional Review Board at Leiden University Medical Center exempted this study (C14.002) from approval.

Data analysis

For the statistical analysis, SPSS version 20.0 (SPSS Inc, Chicago, IL) was used. The number of entered risk factor was summed per domain and per detailed risk factor (Table 1). Mean values were calculated and shown with their standard deviation (SD). Patient characteristics and surgical outcomes were compared between two groups: LHs with entered risk factor(s) and LHs without entered risk factor(s) (Table 2). Multivariate logistic regression was used for risk adjustment in assessing associations between procedures with and without an entered risk factor checklist and surgical outcomes. Variables used in this model included BMI, previous

abdominal operations, the presence of endometriosis, type of LH, uterine weight, operative time, blood loss and complications (Table 2). A sub-analysis was performed comparing entered risk factor per domain and surgical outcomes (Table 3). The influence of surgeon's volume, experience, and years of experience on the entering of a risk factor checklist were calculated using binary logistic regression analysis.

To account for the clustering of data from multiple entered procedures and risk factor checklists by a single surgeon, generalized estimation equations were used for all analyses. Ninety-five percent confidence intervals were calculated of all odd ratios. Statistical significance was defined as a p-value <0.05.

Results

During the study period, a total of 85 gynecologists participated and entered their performed LHs. Mean (SD) LH experience (total amount of performed LH during their career) of the surgeons was 177 (173), with a range of 800 procedures. A total number of 2237 LH procedures were entered and for 627 (28%) procedures, the risk factor checklist was filled in. Because more than one risk factor could be entered per procedure, a total of 920 patient safety risk factors were registered. All entered risk factor are depicted in Table 1, subdivided by domain. The most frequently reported risk factor domains were surgeon (19.6% and in 7.3% of all procedures), surgical team (14.4% and in 5.4% of all procedures), technology (16.6 % and in 6.2% of all procedures), and patient-related risk factors (26.8% and in 10% of all procedures) (Table 1). Regarding the domain 'surgeon', lack of experience (of surgeon or resident) was mainly reported, i.e., 141 times (15.3% of all entered items). Furthermore, lack of experience/knowledge of the scrub/circulating nurse was also considered one of the main potential risk factors, reported in total 141 times (15.3% of all entered items). Registered technology-related events included mainly the improper functioning of instrument(s) and/or equipment, and were reported in total 94 times (10.2% of all entered items). Patient-related factors such as unexpected severe adhesions were mentioned 182 times (19.8% of all entered items). Social interaction including teamwork and professional communication was entered 9 times (1% of all entered items). Other patient safety risk factors with low count of events were environment (2.2%), fallibility of the surgeon (0.5%), and lack of compliance to the safety protocols (1.2%). Anesthesiological-related issues were reported in 30 of the procedures (3.2% of all entered items).

In 116 procedures the free text option was filled out. The main issues reported were patient-related issues (e.g., morbid obesity, adhesions, previous operations, endometriosis, large uterus, fibroids, etc.), together with logistical and setup problems (e.g., "had to wait for assistance", "testing new equipment in new theater", "procedure was part of a training course").

Table 1 Used patient safety risk factor checklist with number and percentage of entered items per domain

Domain *(detailed description)*	Number of entered domains (%; and % of total procedures N=2237)	Detailed risk factors per domain	Number of entered detailed options
Surgeon *(functioning of the surgeon)*	164 (19.6; 7.3)	Lack of experience *(of surgeon or resident)*	141
		Lack of technical skills *(of surgeon or resident)*	27
		Lack of leadership	2
Surgical team *(functioning of the scrub or circulating nurse)*	120 (14.4; 5.4)	No qualified staffing *(e.g., student/ pupil because of shortage of staff or unqualified staffing)*	25
		Lack of experience of the scrub nurse *(concerning this procedure)*	78
		Lack of knowledge of the procedure of scrub nurse	26
		Lack of experience of circulating nurse	37
Technology *(availability and functioning of equipment and instruments)*	139 (16.6; 6.2)	Instrument(s) not present or available	18
		Instrument(s) do(es)n't work properly	75
		It is not known how to handle instruments *(either surgeon or scrub nurse)*	5
		Equipment is not present	4
		Equipment does not work properly	19
		Limited vision *(e.g. because of condensation and/or smoke)*	31
		It is not known how to handle equipment *(either surgeon or scrub nurse)*	5
Social interaction *(teamwork and communication)*	9 (1.1; 0.4)	Poor communication between OR team members *(e.g., misunderstandings)*	5
		Failure of professional communication *(either verbal or nonverbal)*	1
		Poor collaboration between OR team members	3

Table 1 continues on next page

Table 1 ***Continued***

Domain *(detailed description)*	Number of entered domains (%; and % of total procedures N=2237)	Detailed risk factors per domain	Number of entered detailed options
Environment *(potentially cause distraction or disruptions of the surgical process)*	21 (2.5; 0.9)	Distractions *(e.g., telephone calls, case irrelevant conversations, door movements)*	10
		Disruption of the surgical process *(surgical process has to be interrupted because of distractions)*	7
		Too many people in the OR	4
Patient *(patient-related risk factors)*	224 (26.8; 10)	Severe adhesions	182
		Unexpected co-morbidity, please specify *(e.g., unknown bleeding disorder (e.g., v Willebrand disease, hemophilia))*	57
Fallibility *(factors that influence the fallibility of the surgeon)*	11 (1.3; 0.5)	Moment of day surgery takes place *(e.g., during evening or night shifts)*	1
		Perceived high workload	3
		Fatigue of the surgeon	7
Safety *(compliance or safety protocols)*	1 (0.1; 0.04)	Poor compliance of briefing procedure	0
		Poor compliance of debriefing procedure	1
		Poor compliance of (surpass) checklist (if applicable)	0
Anesthesiology	30 (3.6; 1.3)	Anesthesiology-related problems	30
Other	116 (13.9; 5.1)	Free text option, please specify	116
Total	835		920

Table 2 shows patient characteristics and surgical outcomes of entered procedures and the differences between procedures with (n=627) and without (n=1610) an entered risk factor checklist. There were no significant differences in patient characteristics between the two groups with the exception of previous abdominal surgery (p<0.001), with a higher rate in the LH group where a risk factor checklist was entered. For all reported surgical outcomes, a significant difference was observed in favor of the procedures where no risk factors occurred: complications 10.5 versus 4.8% (p=0.002), blood loss 110.1 versus 167.6 mL (p=0.047), and operative time 114.3 versus 95.3 minutes (p<0.001).

Table 2 Patient characteristics and surgical outcomes for LHs with entered risk factor and without entered risk factor

Variable	Total N=2237	LHs with entered risk factor N=627	LHs without entered risk factor N=1610	p-value	Odds ratio (95% CI)
Age ±SD	48.8 ±11.6	48.6 ±11.4	48.9 ±11.6	0.749	1.002 (0.991-1.012)
BMI kg/m^2 ±SD	28.3 ±6.1	29.0 ±6.3	28.0 ±6.02	0.249	1.010 (0.993-1.026)
Previous abdominal surgery				<0.001	-
▪ None %	56.0	49.4	58.5		
▪ One %	25.8	26.7	25.5		
▪ Two %	11.3	13.3	10.5		
▪ > two %	6.9	10.5	5.5		
Type LH				0.449	-
▪ TLH %	91.2	91.1	91.3		
▪ SLH %	4.5	4.8	4.3		
▪ LAVH %	3.2	3.0	3.3		
▪ Robotic %	1.1	1.1	1.1		
Uterus weight gr ±SD	217.3 ±206.3	240.5 ±234.7	209.1 ±193.2	0.079	0.999 (0.999-1.000)
Endometriosis %	15.3	19.9	13.5	0.562	0.915 (0.667-1.236)
Blood loss mL ±SD	126.2 ±164.0	167.6 ±201.6	110.1 ±143.7	0.047	1.001 (1.000-1.002)
Operative time min ±SD	100.6 ±39.0	114.3 ±41.6	95.3 ±36.6	<0.001	1.014 (1.009-1.019)
Complication %	6.4	10.5	4.8	0.002	0.548 (0.376-0.797)

LH = laparoscopic hysterectomy.
TLH = total laparoscopic hysterectomy.
SLH = supracervical laparoscopic hysterectomy.
LAVH = laparoscopic-assisted vaginal hysterectomy.
RALH = robotic-assisted laparoscopic hysterectomy.

Table 3 Difference in surgical outcomes of LHs with and without an entered risk factor checklist stratified per safety domain

Safety Domain Entered checklist?	Blood loss ml ± SD	p-value	Operative time min ± SD	p-value	Compli-cations	p-value
Surgeon						
Yes (n=164)	135.0 ± 156.5	0.879	109.8 ± 26.7	0.408	8.5%	0.445
No (n=2073)	125.5 ± 164.6		99.8 ± 39.7		6.3%	
Surgical team						
Yes (n=120)	148.8 ± 203.3	<0.001	107.4 ± 37.8	<0.001	6.7%	0.032
No (n=2117)	124.9 ± 161.5		100.2 ± 39.0		6.4%	
Technology						
Yes (n=139)	202.6 ± 286.3	<0.001	126.9 ± 53.1	<0.001	12.2%	<0.001
No (n=2098)	121.1 ± 151.3		98.9 ± 37.2		6.1%	
Social interaction						
Yes (n=9)	141.7 ± 106.1	0.428	129.6 ± 30.8	<0.001	11.1%	0.242
No (n=2228)	126.1 ± 164.2		100.5 ± 39.0		6.4%	
Environment						
Yes (n=21)	200.5 ± 206.6	0.005	126.7 ± 48.1	<0.001	9.5%	0.554
No (n=2216)	125.5 ± 163.5		100.3 ± 38.8		6.4%	
Patient						
Yes (n=224)	213.5 ± 244.9	<0.001	120.6 ± 48.7	<0.001	14.3%	<0.001
No (n=2013)	116.5 ± 149.4		98.4 ± 37.1		5.6%	
Fallibility						
Yes (n=11)	101.8 ± 72.2	0.531	113.5 ± 38.5	0.034	9.1%	0.358
No (n=2226)	126.3 ± 164.4		100.5 ± 39.0		6.4%	
Safety						
Yes (n=1)	na		na		na	
No (n=2236)	na		na		na	
Anesthesiology						
Yes (n=30)	154.7 ± 149.4	0.293	114.5 ± 39.0	0.001	10.0%	0.357
No (n=2207)	125.8 ± 164.2		100.4 ± 39.0		6.4%	

Na = not applicable.

Table 3 shows the difference in surgical outcomes stratified per entered risk factor domain. When technological-related risk factors were registered, all surgical outcomes were significantly less favorable (p<0.001 for blood loss, operative time, and complications). This also was found for the procedures with risk factors related to the surgical team (e.g., no qualified staffing, lack of experience/knowledge of the scrub/circulating nurse) and to patient-related issues (especially adhesions). It appeared that for procedures where surgeon-related risk factors occurred (e.g., lack of experience and/or lack of technical skills),

no significant difference was observed in surgical outcomes compared to procedures where no risk factor occurred.

The experience of the surgeon was not correlated to the number of registered risk factor checklist of the surgeon, p=0.425 (95% CI = 0.998-1.001). A similar result was seen for surgeon's volume and years of experience, respectively p=0.936, (95% CI = 0.987-1.014) and p=0.085 (95% CI = 0.999-1.015).

Discussion

In this prospective cohort study, 85 gynecologists entered their LHs, and when deemed necessary, they could additionally fill in a risk factor checklist. In 28% of LHs, surgeons entered at least one patient safety risk factor. We observed less favorable surgical outcomes in the group LHs where a risk factor checklist was registered (Table 2). Patient-related risk factors and technological-related problems were listed as most important risk factor during LH, affecting negatively all surgical outcomes (Table 3). The lack of proper functioning equipment and instruments in the surgical field is well known to be associated with an increased risk of incidents [10]. In our study, 6.2% of all registered procedures encountered technological problems. This percentage is considerably lower compared to previously studies, as Wubben et al. [11] found equipment-related incidents in 16% of observed surgeries and Verdaasdonk et al. [12] observed technical incidents in 87% of recorded laparoscopic cholecystectomies. However, these percentages are not comparable with our study, as they focused on technological incidents counted by direct observations or video observations. In our study, the registered events were entered by the surgeon him/herself, which makes these events clinically more relevant, and the event had to be serious enough for the surgeon to remember and register it afterward, especially since it might influence their surgical outcomes. Therefore, our number could be an underestimation of the actual percentage of occurred risk factors.

We observed that the occurrence of patient-related risk factors, such as adhesions, are of significant influence on all surgical outcomes (Table 3). We consider patient-related risk factors of a different nature compared to the other registered risk factors; for example, as doctors cannot influence comorbidity of a patient (e.g., extent of adhesions, obesity etc.) [13]; however we do have a responsibility for technological issues or surgical team-related problems, and these are therefore important targets for future improvements regarding patient safety.

It is notable that surgeons criticized their selves (i.e., "functioning of the surgeon") in 20% of the registered risk factors. Surprisingly though, our data showed that the occurrence of these surgeon-related risk factors did not affect any surgical outcomes (Table 3). Yet, the occurrence of risk factors relating to the surgical team (i.e., lack of experience/knowledge

of scrub/circulating nurse) did significantly affect surgical outcomes. Although, it can be questionable whether a difference of 20-30mL blood loss truly is clinically relevant (Table 3), it could indicate that the surgical team in its entirety is more important to surgical outcomes than previously thought [3]. Therefore, it seems obvious to assume that a dedicated and experienced surgical team will lead to increased efficiency, better communication, and inherently enhance patient safety. Still, we need to emphasize that the primary responsibility for a procedure and its outcomes lies in the hands of the (primary) surgeon and not the other members of the surgical team.

It has been shown that when a laparoscopic procedure is performed under distracting conditions, performance could be directly affected [14]. Our results showed that the effect of environmental events seems to be a minor subject since this domain was only entered 21 times, corresponding with less than 1% of all procedures (Table 1). However, the occurrence of environmental risk factors adversely affected the outcomes blood loss and operative time (Table 3). This suggests, that when an environmental event is clinically relevant and significant enough to be noticed, it could negatively influence outcomes. This observation emphasizes the clinical impact of the environment as also shown in previous studies [1, 4].

Since the development of the time-out protocol by the World Health Organization (WHO) [15], multiple publications demonstrated that the use of this protocol improves patient outcomes, teamwork, and communication [16]. In our study, the domain of safety (e.g. poor compliance of safety protocols) is only mentioned once. Therefore we can conclude that the implementation of this briefing is well established and (inter) nationally accepted.

A potential limitation of our study is that it is conceivable that surgeons will enter more risk factor items when they performed a procedure with unfortunate outcomes, in order to justify their suboptimal performances. This could potentially lead to reporting bias. To correct for these limitation, we used generalized estimation equation to account for the clustering of data by a single surgeon.

Technological problems are the most relevant and important patient safety risk factors, and future improvements need to focus on this to enhance quality and safety of MIS. It is not acceptable that nowadays technological problems are still such a major patient safety issue in these modern times, and a concise training and/or briefing for the entire surgical team should be mandatory when new devices are introduced. Evidence showed that most technological issues can be solved with decent preparation and more attention to technology during briefing [1, 10]. Our risk factor checklist can be seen as an individual guidance tool, for instance when the performance of a surgeon is consistently suboptimal. The use of the current checklist allows individual reflection and will potentially help to improve individual performance [16], this will inherently increase awareness and insight in risk factors in MIS.

Acknowledgement

The authors thank all the participating gynecologists who registered their procedures during the study period.

Reference list

(1) Rodrigues SP, Wever AM, Dankelman J, Jansen FW (2012) Risk factors in patient safety: minimally invasive surgery versus conventional surgery. Surg Endosc 26:350-356

(2) FDA (2015) Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication; http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm. Available at.

(3) Rodrigues SP, Ter KM, Dankelman J, Jansen FW (2012) Patient safety risk factors in minimally invasive surgery: a validation study. Gynecol Surg 9:265-270

(4) Lingard L, Espin S, Whyte S, Regehr G, Baker GR, Reznick R, Bohnen J, Orser B, Doran D, Grober E (2004) Communication failures in the operating room: an observational classification of recurrent types and effects. Qual Saf Health Care 13:330-334

(5) Driessen SR, Baden NL, van Zwet EW, Twijnstra AR, Jansen FW (2015) Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in the Netherlands. J Minim Invasive Gynecol 22:642-647

(6) ESGE (2014) European Society for Gynaecological Endoscopy (ESGE) classification laparoscopy . Available at.

(7) American Society for Reproductive Medicine (1997) Revised American Society for Reproductive Medicine classification of endometriosis: 1996. Fertil Steril 67:817-821

(8) Twijnstra AR, Zeeman GG, Jansen FW (2010) A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. Qual Saf Health Care 19:132-137

(9) Blikkendaal MD, Twijnstra AR, Stiggelbout AM, Beerlage HP, Bemelman WA, Jansen FW (2013) Achieving consensus on the definition of conversion to laparotomy: a Delphi study among general surgeons, gynecologists, and urologists. Surg Endosc 27:4631-4639

(10) Verdaasdonk EG, Stassen LP, Hoffmann WF, van der Elst M, Dankelman J (2008) Can a structured checklist prevent problems with laparoscopic equipment? Surg Endosc 22:2238-2243

(11) Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH (2010) Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. Qual Saf Health Care 19:e64

(12) Verdaasdonk EG, Stassen LP, van der Elst M, Karsten TM, Dankelman J (2007) Problems with technical equipment during laparoscopic surgery. An observational study. Surg Endosc 21:275-279

(13) Driessen SR, Sandberg EM, la Chapelle CF, Twijnstra AR, Rhemrev JP, Jansen FW (2015) Case-Mix Variables and Predictors for Outcomes of Laparoscopic Hysterectomy: A Systematic Review. J Minim Invasive Gynecol

(14) Pluyter JR, Buzink SN, Rutkowski AF, Jakimowicz JJ (2010) Do absorption and realistic distraction influence performance of component task surgical procedure? Surg Endosc 24:902-907

(15) Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA (2009) A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 360:491-499

(16) Russ S, Rout S, Sevdalis N, Moorthy K, Darzi A, Vincent C (2013) Do safety checklists improve teamwork and communication in the operating room? A systematic review. Ann Surg 258:856-871

Chapter 9

Gamification to engage clinicians in registering data: a randomized trial

Sara R.C. Driessen
Pascal Haazebroek
Wikanand Basropansingh
Erik W. van Zwet
Frank Willem Jansen

Global Journal of Health Science, Vol 9, No 4 (2017)
DOI: http://dx.doi.org/10.5539/gjhs.v9n4p240

Abstract

Objective: To determine the effect of additional gamification elements in a web-based registry system in terms of engagement and involvement to register outcome data, and to determine if gamification elements have any effect on clinical outcomes.

Methods: Randomized controlled trial for gynecologists to register their performed laparoscopic hysterectomies (LH) in an online application. Gynecologists were randomized for two types of registries. Both groups received access to the online application; after registering a procedure, direct individual feedback on surgical outcomes was provided by showing three proficiency graphs. In the intervention group, additionally gamification elements were shown. These gamification elements consisted of points and achievements that could be earned, and insight in monthly collective scores. All gamification elements were based on positive enforcement.

Results: A total of 71 gynecologists were randomized and entered a total of 1833 LH procedures. No significant difference was found between the groups in terms of engagement and involvement on a 5-point Likert scale, respectively 2.34±0.87 versus 2.56±1.05 and 3.63±0.57 versus 3.33±1.03 for the intervention versus the control group ($p>0.05$). The intervention group showed longer operative time than the control group (108±42 vs. 101±34 minutes, $p=0.04$), no other differences were found in terms of surgical outcomes.

Conclusions: The addition of gamification elements in a registry system did not enhance the engagement and involvement of clinicians to register their clinical data. Based on our results, we advise that registry systems for clinical data should be as simple as possible with the focus on the main goal of the registry.

Trial registration: The study was registered in www.trialregister.nl (NTR 5040).

Introduction

The administrative responsibilities of clinicians are currently much to complain about and the struggle to balance this "paperwork" burden with the clinical care is cumbersome. Clinicians are increasingly imposed to register a wide range of data that is intended to use for quality assessment. It is shown that on average a doctor spends around 17% of working hours on his/her administrative responsibilities only, and this percentage is even increasing (Woolhandler & Himmelstein, 2014).

However, the use of registered clinical data for auditing is recognized as an important tool for quality improvement (van Leersum et al., 2013; Maruthappu, Trehan, Barnett-Vanes, McCulloch, & Carty, 2015; Ivers et al., 2012). Therefore, since the improvement of patient safety and quality of care are both high on the international political agenda, the registration of clinical data is indispensable in the current duties of a clinician(Dreyer & Garner, 2009). Besides, this data collection is also needed to support the possibility to conduct clinical research studies. As incomplete or incorrect data is not usable for the assessment of quality or for conducting clinical research, it is essential to engage and motivate clinicians to register.

In this context, gamification elements may offer opportunities to motivate and engage doctors to participate in medical registries. Gamification can be explained as the use of game elements and techniques in existing applications or in nongame contexts, to motivate and engage users with a system (Morris, Croker, Zimmerman, Gill, & Romig, 2013). Gamification focuses on making necessary and annoying tasks more enjoyable through a positive approach (Dithmer et al., 2015). During the last few years gamification is used within a broad variety of domains, such as finance, health, education, news and entertainment, for example by the earning of badges, points and achievements when completing specific tasks (Deterding S, Dixon D, Khaled R, & Nacke L, 2011). In a similar vein, serious gaming is increasingly used to train doctors technical and non-technical skills relevant to the surgical field (Graafland, Schraagen, & Schijven, 2012). To note, gamification and serious gaming are two different concepts, but show many similarities. Serious gaming refers to games for non-entertainment purposes whereas gamification refers to the use of elements from games in non-game contexts (Deterding S et al., 2011).

Despite the increased popularity of gamification, to the best of our knowledge, this strategy had not been used yet in the context of medical research to motivate an engage physicians participating in medical studies, and even more interesting, on the impact on clinical outcomes. However, recent studies showed that the use of gamification impacted residents' engagement in simulation training, and motivated heart patients as a part of a rehabilitation program (Kerfoot & Kissane, 2014; Dithmer et al., 2015). Furthermore, it is noted that the impact of gamification in health-related contexts has achieved significant results (Pereira,

Duarte, Rebelo, & Noriega, 2014). Therefore, the introduction of gamification elements could potentially be helpful to motivate clinicians to register their data completely and correctly. In this light, it is well known that providing audit and feedback to the clinician leads to improvements in professional practice. Audit and feedback is defined as a summary of clinical performance over a specified period of time preferably leading to clinical actions (Ivers et al., 2012). However, there is lack of knowledge about what kind of feedback is most effective to increase insight in personal performance and to increase engagement to register medical data (Ivers et al., 2012; Maruthappu et al., 2015). The high workload of surgeons is a main reason for non-participation in medical registries and aspects such as lack of support and feedback, but also lack of rewards and recognition are cited as reasons to not participate in medical registries (Albers & Sedler, 2004; Rahman et al., 2011). Hypothetically, the addition of gamification elements in the provision of feedback could enhance the effect of feedback because of the positive enforcement of gamification.

The aim of this study is to determine the effect of additional gamification elements in a web-based registry system for laparoscopic hysterectomy (LH) in terms of engagement and involvement of gynecologists to register their outcome data and to determine if gamification elements have any effect on clinical outcomes.

Methods

Design and participants

The CONsolidated Standards Of Reporting Trials (CONSORT) statement was followed to describe the design of the study (Schulz, Altman, & Moher, 2010). All Dutch gynecologists who perform laparoscopic hysterectomy (LH) were eligible for participation and were asked to register all their consecutive LHs between April 2014 and November 2015 at a newly introduced web-based application, https://www.QUSUM.org (**QU**ality indicator of **SU**rgical performance in **M**inimally invasive surgery).

Gynaecologists were recruited by a personal email invitation. A study notification in the NTOG (Dutch Journal of obstetrics and gynaecology) and an email newsletter through the WGE (Working Group Gynecologic Endoscopy) were published to increase the number of participants.

Interventions

Control group

Participants assigned to the control group received access to the web-based application. Directly after entering a LH procedure, feedback on surgical outcomes was provided by showing three cumulative Observed minus Expected proficiency graphs for three surgical outcomes (blood loss, operative time and complications) (Figure 1). These graphs provided the surgeon with immediate individual feedback.

Intervention group

The intervention group also received access to the web-based application. Besides the individual, immediate feedback graphs as well gamification elements were shown (Figure 2 and Figure 3A, 3B, 3C, 3D, 3E).

The gamification elements were developed by experts from the Institute of Psychology, Leiden University, and were selected to induce competition, motivation and collaboration based on positive enforcement. They consisted of three key components; 1. points that could be earned when there was registered procedure had less blood loss and/or less operative time than what could be expected based on the case mix, and points for the contribution of knowledge to the study (i.e., by providing additional information concerning the procedure, Figure 3A, 3B and 3C), 2. participants could earn individual achievement badges for their general contribution by registering procedures (Figure 3D) and, 3. insight in a monthly collective score which represented the aggregate scores of all registered procedures per month of all participants in the intervention group. Each month the scores of the QUSUM collective were compared with existing national benchmark data (Figure 3C and 3E). In addition to these key components, an activity tracker showing the latest contributions of all participants was visible at the homepage (Figure 3A). Also, after entering a procedure, a message popped-up showing how many points the participant had earned (Figure 3B).

The application complied with NEN 7510 standards (Dutch certification regarding informatics and security in the healthcare field) and was approved by the privacy officer at Leiden University Medical Center. Since no identifiable patient data was requested, this study was exempted from approval by our Institutional Review Board at Leiden University Medical Center.

Outcome measure

The primary outcomes of this study were engagement and involvement of participants to register their procedures, which were assessed by the use of a web-based survey. This survey was developed by the Institute of Psychology at Leiden University and was send to all

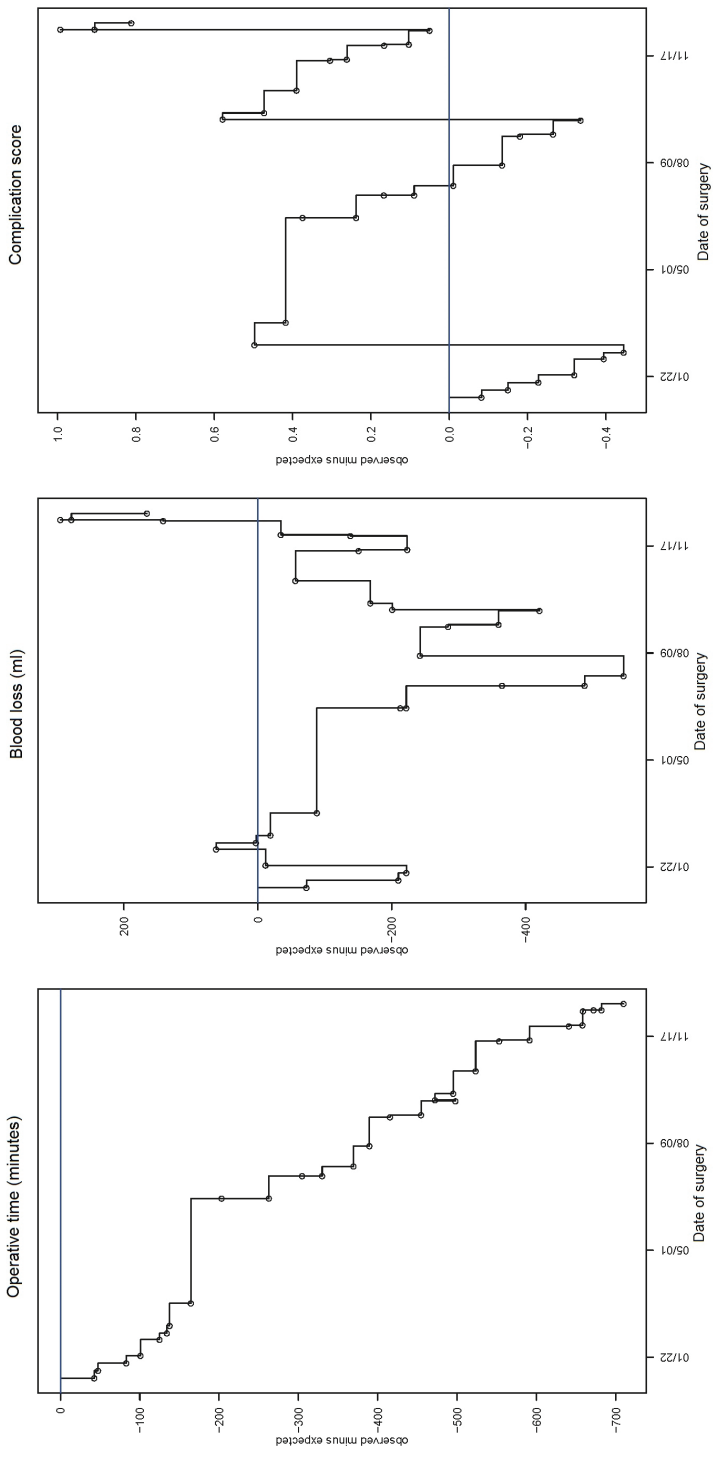


Figure 1 The individual, direct feedback graphs as provided to participants from both groups in the study.
Explanation of graphs: If a surgeon performed better than expected, the line drops. If a surgeon performed worse than expected, the line rises. The y-axis shows the cumulative difference of the surgical performance compared to the benchmark.

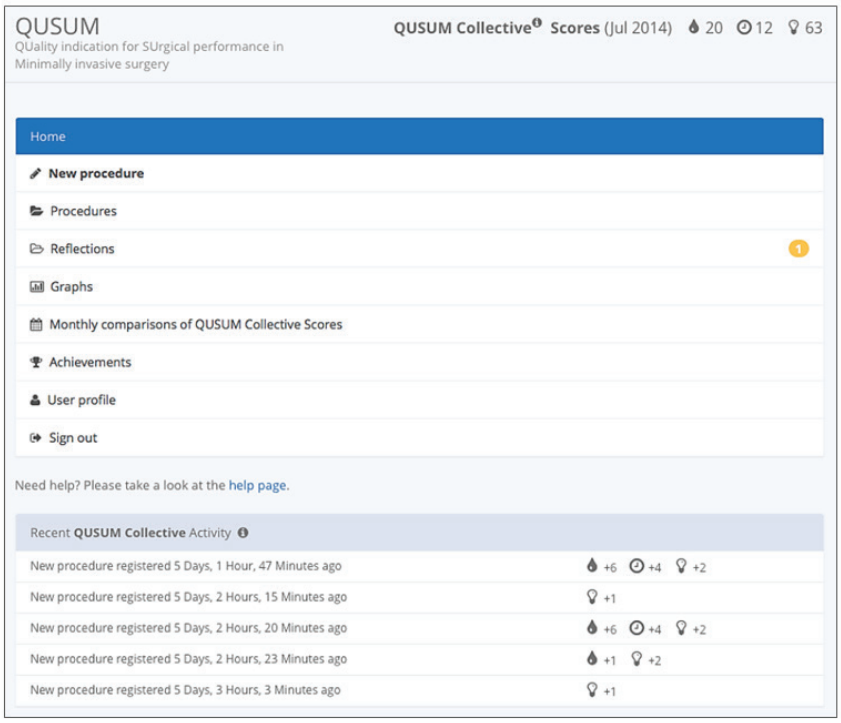


Figure 2 Homepage QUSUM application (https://www.QUSUM.org) as seen by users randomized in the intervention group.
All gamification elements are explained in Figure 3. Participants randomized in the control group had no access to these gamification elements: *QUSUM collective scores, monthly comparisons of QUSUM Collective Scores, Achievements, Recent QUSUM Collective Activities (Activity tracker).*

participants at the end of the study period (November 2015). A Likert scale of 1 to 5 was used (never to always, never to a great deal, not at all to very, not at all to always). It is shown that different types of motivation can be most objectively answered using Likert-scales (Ryan & Connell, 1989). Furthermore, involvement and engagement were assessed by the behavior of users as logged by the application (e.g., number of login sessions, number of active views of features of the application). Furthermore, during initial registration, the users were asked to rate their motivation to participate in this study on a Likert scale 1 to 5 (e.g., very low to very high), to enter the number of LHs performed yearly (their annual surgical volume), to enter the total amount of LH performed during their career (their experience) and to enter the number of years they were performing LHs (Table 1).

As secondary outcome was selected; the effect of the gamification elements on the surgical performance, which was defined as operative time, intraoperative blood loss, and complications. Operative time was described as the number of minutes between the

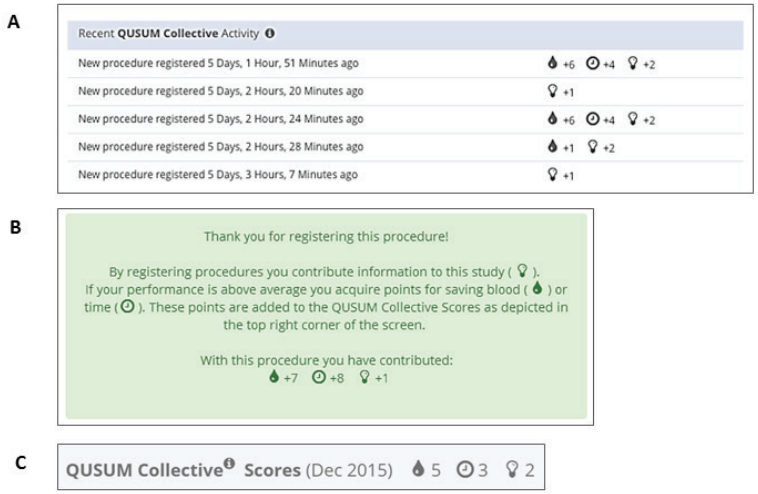


Figure 3 Gamification elements used in QUSUM application.
A. Activity tracker, showing the latest contributions to the QUSUM study by the participants in the intervention group. Here, participants are able to see that other participants (from the intervention group) are contributing to the total score.
B. After register a new procedure, a message pops-up that shows how many points the participant had earned by registering this very procedure.
C. The user is part of the QUSUM collective (represents the scores of all registered procedures of all participants). When the user performs better than expected, a contribution is made to the collective scores.

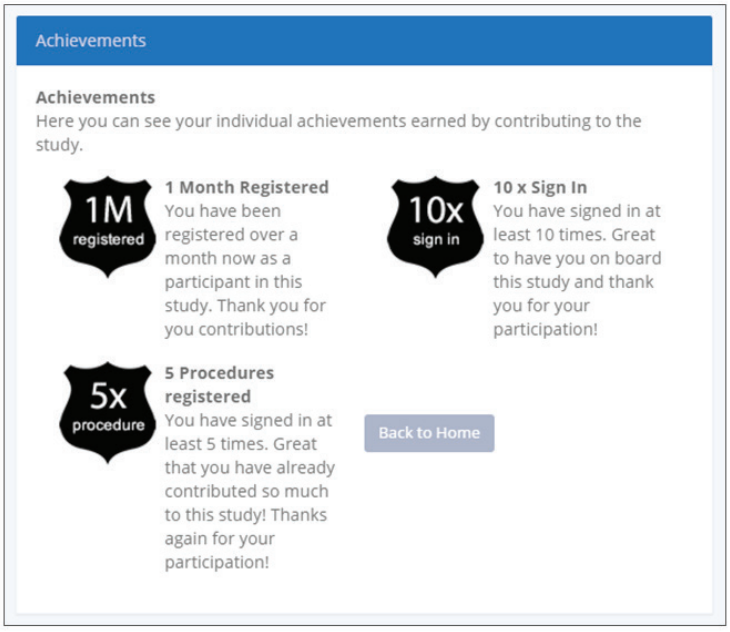


Figure 3 Gamification elements used in QUSUM application.
D. Overview of personal achievements.

E

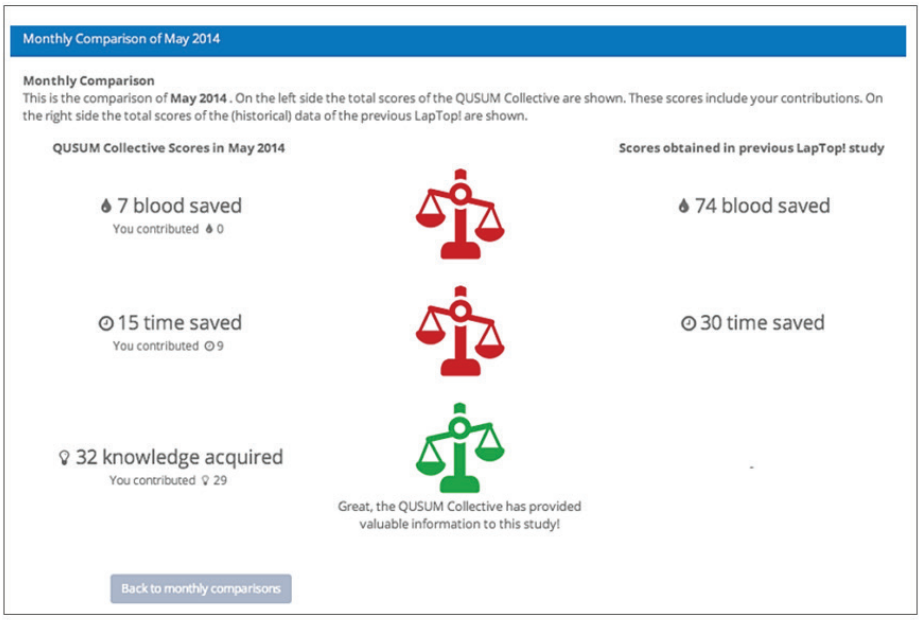


Figure 3 Gamification elements used in QUSUM application.
E. Monthly comparison of QUSUM Collective Score; when the QUSUM collective (i.e., all participants in the intervention group) performs better than the national benchmark this is indicated by a green scale, when the collective performs worse this is indicated by a red scale.

Table 1 Baseline characteristics of participants

	All participants N=71, Mean (SD)	Gamification group N=37, Mean (SD)	Control group N=34, Mean (SD)	P value
Total number of entered procedures	27.5 (23.1)	27.4 (18.2)	27.6 (27.5)	0.98
Initial study motivation of users [a]	3.9 (0.7)	4.0 (0.83)	3.9 (0.92)	0.22
Years of experience [b]	6.0 (4.3)	5.3 (3.6)	6.8 (4.9)	0.15
Surgeon's annual volume [c]	28.7 (10.7)	27.2 (11.2)	30.4 (10.1)	0.21
Surgeon's experience [d]	150.9 (137.3)	129.7 (108.4)	173.9 (161.6)	0.18

[a] Likert scale 1 to 5 (very low to very high).
[b] The number of years performing laparoscopic hysterectomies.
[c] The number of laparoscopic hysterectomies performed yearly.
[d] The total amount of laparoscopic hysterectomies performed during their career.

first incision and insertion of the final stitch, blood loss was measured in millilitres, and complications were registered as determined by the Dutch Society of Obstetricians and Gynecologists (Twijnstra, Zeeman, & Jansen, 2010).

Sample size

A prospective sample size calculation was not applicable for this study, since the intent was to include as many gynecologists as possible. We consider a retrospective sample size calculation as arbitrary.

Randomization

During initial registration participants were randomly assigned to either the control or the intervention group using computer-generated randomization. Block center randomization was applied, meaning that gynecologists from the same center were allocated in the same group, in order to avoid notification of the other study condition when discussing results with direct colleagues. Participants were included for analysis when at least one procedure was entered in the application.

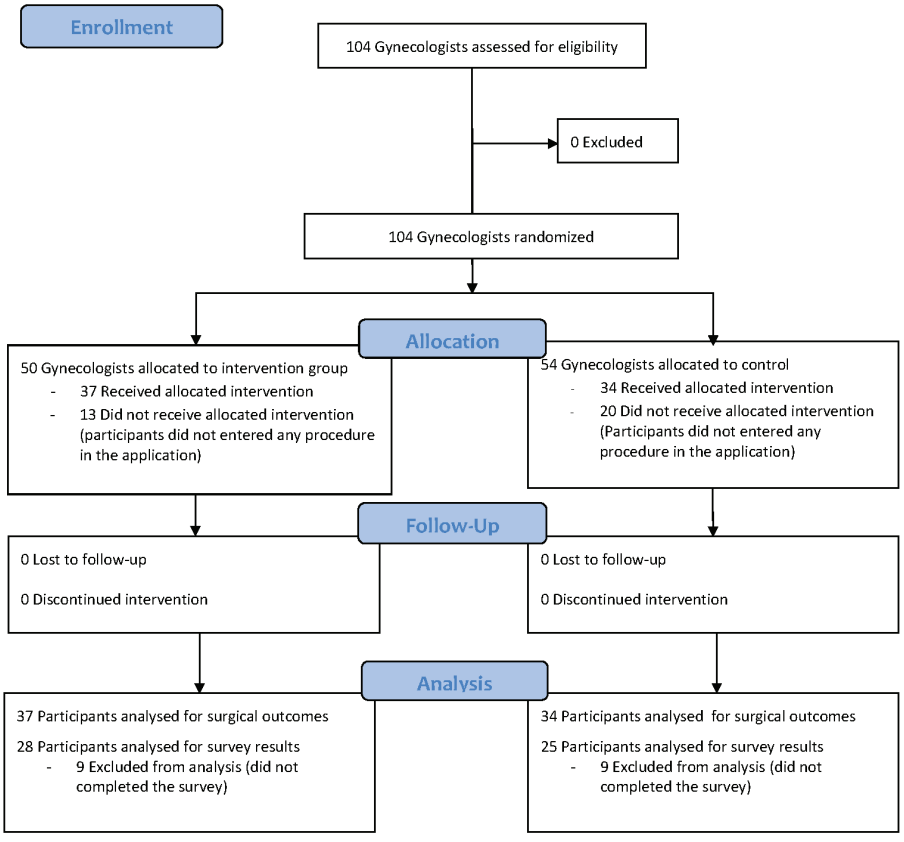


Figure 4 Flowdiagram of participants.

Statistical methods

For the statistical analysis, SPSS version 22 (IBM Corp., Armonk, NY) was used. Mean values of surgical outcomes were calculated with their standard deviation (SD). Differences were statistically significant at $p<0.05$.

To account for clustering of data from multiple entered procedures by a single surgeon, generalized estimation equations were used for the analyses of differences of surgical outcome between the two groups. Logistic regression was used to analyse the difference between the groups with respect to their activity on the application. Dependent variables used in this model included total number of entered procedures and study motivation of users. The questionnaire regarding engagement and involvement consisted of multiple subscales, measured on a 5-point Likert scale. For each subscale the Kaiser-Meyer-Olkin (KMO) measure was used to assess the general factor structure. Then, for each subscale that met the KMO criterion of > 0.5, a factor analysis was performed to assess which items to include in the subscale. Items with factor load < .30 were removed. Finally, the reliability of each subscale was calculated using Cronbach's Alpha. We adopted the threshold value of .70 or above to consider the subscale as reliable. In order to assess the influence of condition on the various subscales, a MANOVA was conducted.

Results

From April 2014 to November 2015, a total of 71 Dutch gynecologists enrolled in the study and entered one or more LH procedures. Of the participants, 37 gynecologists were randomized in the gamification group and 34 participants in the control group. A total of 53 participants (75%) completed the survey, of which 28 of the gamification group and 25 of the control group (Figure 4).

A total of 1833 LHs were registered. The mean ±SD number of entered procedures of participants was 27.5±23.1 (Table 1). Surgical volume and experience of both groups is shown in Table 1.

Engagement

The observed mean (±SD) for the engagement subscale was 2.44±0.96 for all participants combined (Table 2). No significant difference was found between the two groups; 2.34±0.87 for the intervention group versus 2.56±1.05 for the control group (p=0.41).

Table 2 Engagement and Involvement outcomes

Survey question per domain	All participants, Mean (SD)	Gamification group, Mean (SD)	Control group, Mean (SD)	p-value
Domain engagement	2.44 (0.96)	2.34 (0.87)	2.56 (1.05)	0.41
How often, while performing a LH, do you think about the outcomes shown in the QUSUM graphs? [a]	1.91 (1.2)	1.58 (0.96)	2.19 (1.3)	
How often, while registering a LH into the QUSUM application, do you think about the QUSUM graphs? [a]	3.25 (1.5)	3.06 (1.4)	3.41 (1.5)	
Outside of performing and registering LHs, how often do you think about the QUSUM graphs? [a]	2.07 (1.1)	1.68 (0.9)	2.41 (1.1)	
In general, during your participation in the QUSUM study, how much have you talked about the QUSUM study with your colleagues? [b]	3.09 (1.1)	3.10 (1.0)	3.08 (1.2)	
Domain involvement	3.49 (0.8)	3.63 (0.57)	3.33 (1.03)	0.19
Do you think that the QUSUM study will improve the surgical outcomes for LH in general? [c]	3.26 (1.0)	3.26 (0.9)	3.27 (1.7)	
Do you think it is important to contribute to the QUSUM study?	3.96 (1.0)	4.16 (0.8)	3.78 (1.1)	
Do you strive to score above average on the surgical outcomes as shown in the QUSUM graphs (operative time, blood loss, and complications)? [d]	3.54 (1.2)	3.65 (0.9)	3.46 (1.5)	

[a] Likert scale 1 to 5 (never to always, [b] never to a great deal, [c] not at all to very, [d] not at all to always.

Involvement

For the involvement subscale a score of 3.49±0.83 was observed for all participants combined (Table 2). No significant difference was found between the two groups, respectively 3.63±0.57 versus 3.33±1.03 for the intervention and the control group (p=0.19). The majority of both groups considered the contribution to the QUSUM study as (very) important (Likert scale of 3.96±1.0).

Activity on application

No significant difference for any activity on the application was observed between the two groups (Table 3). A mean of 22.2±18.8 login sessions was observed for all participants combined.

Table 3 Activity on application

	All participants N=71, Mean (SD)	Gamification group N=37, Mean (SD)	Control group N=34, Mean (SD)	p-value	95% confidence interval of the difference
Number of login sessions	22.2 (18.8)	22.9 (18.2)	21.5 (19.8)	0.53	-7.6 – 10.4
Number of active views of individual feedback graphs	3.1 (4.0)	2.5 (2.4)	3.8 (5.3)	0.59	-3-3 – 0.64
Number of active views of list of entered procedures	22.6 (30.1)	19.4 (20.0)	26.1 (38.2)	0.96	-21.5 – 8.0

Surgical outcomes

A significant difference was observed for mean (±SD) operative time. The intervention group showed longer operative time (108±42 minutes) than the control group (101±34 minutes) (p=0.039). For blood loss and complications no significant difference was observed between the two groups, 122±164 vs. 144±173 mL and 4.8 vs. 8.7%, for respectively the intervention and control group (Table 4).

Table 4 Surgical outcomes of entered procedures per randomized group

	All procedures N=1833	Gamification group, N=922	Control group, N=911	p-value
Operative time min, mean (SD)	104.4 (38.5)	107.8 (42.1)	101.0 (34.0)	0.04
Blood loss mL, mean (SD)	132.8 (172.9)	122.1 (164.0)	143.6 (172.8)	0.27
Complication rate	6.7%	4.8%	8.7%	0.29
BMI, mean (SD)	28.5 (11.6)	28.4 (12.8)	28.5 (10.1)	0.82
Uterine weight gram, mean (SD)	214.9 (205.5)	220 (201.8)	209 (208)	0.46

Ease of use of application

A significant difference was observed regarding the clearness of the possibilities of the QUSUM application. Participants in the intervention group, who used the application with gamification elements showed lower scores (3.65±1.2) than the control group (4.24±0.7) (p=0.019) (Table 5). Overall, registering procedures in the applications is considered for the majority of users as (very) easy (4.46±0.7). The individual, direct feedback graphs for surgical outcomes (Figure 1), which are provided in both groups, are considered clear (overall score of 3.56±1.2) and useful (overall score 3.79±1.1).

Table 5 Ease of use of application

Survey questions	All participants, Mean (SD)	Gamification group, Mean (SD)	Control group, mean (SD)	p-value
Have the possibilities of the QUSUM application (registering, reviewing own procedures, etc.) been clear to you? [a]	3.97 (1.0)	3.65 (1.2)	4.24 (0.7)	0.02
Registering LHs in the QUSUM application is (very difficult to very easy) [b]	4.46 (0.7)	4.48 (0.7)	4.43 (0.6)	0.75
Has it been clear to you how to interpret the QUSUM graphs of surgical outcomes (operative time, blood loss, and complications)? [a]	3.56 (1.2)	3.39 (1.3)	3.70 (1.2)	0.30
Do you consider the QUSUM graphs of surgical outcomes (operative time, blood loss, and complications) as provided by the QUSUM application useful? [c]	3.79 (1.1)	3.62 (1.2)	3.95 (1.0)	0.22

[a] Likert scale 1 to 5 (not at all to completely, [b] very difficult to very easy, [c] not at all to very much.

Conclusions

The addition of gamification elements in a registry system did not enhance the engagement and involvement of clinicians to register their clinical data. In addition, our results showed that the features of the application were significantly less clear for the users in the gamification group, which can be explained by the fact that this version of the application consisted of many more elements that need to be understood. This may suggest that easiness and simplicity of an application is more important to engage users. Furthermore, if we look at surgical outcomes, we observed a significant difference in operative time in favor of the group without gamification elements. Therefore, our results demonstrated that the addition of gamification elements did not show any advantages and may even imply that the gamification elements could distract users from the primary goal of the application, which is the provision of direct feedback to the surgeon.

In general, the application introduced in this study was rated as very useful and (very) easy to use by the majority of participants (Table 4). Therefore, we recommend that registries should be simple and exclusively collect data that is truly relevant and usable. In addition, we assume that gamification elements will also be distracting in more comprehensive registry systems.

Another important result is that the majority of users believe it is important to contribute to a study and consider that the registration of procedures in the application has positive impact on their clinical performances (Table 2). This suggests that the participating clinicians are already aware about the necessity of registering clinical data, and therefore, the focus should

be placed on making this easier and less comprehensive for them. Furthermore, to reduce the extensive administrative workload of clinicians, a future development of new registries should be the possibility to implement these in existing data systems.

A strength of our study is the fact that this is, in our knowledge, the first study that determined the effect of gamification elements in a randomized control design study. Considering the current extensive administrative workload for clinicians this is an interesting topic (Woolhandler & Himmelstein, 2014) and attempts to make registries more fun and more easy for clinicians are increasingly relevant. Although we conducted our study with the use of a registry application for laparoscopic hysterectomy, we consider our results to be generalizable to registries of other kinds of procedures and specialties.

The benefits of additional gamification elements are previously demonstrated in other domains of healthcare (e.g., simulation training for residents and patient engagement to rehabilitation) (Kerfoot & Kissane, 2014; Dithmer et al., 2015). However, unexpectedly, our study did not show any benefits from the applied gamification elements in the domain of doctor's engagement and involvement to register clinical data. In comparison to other fields, the use of gamification elements in medical (research) registries has several limitations regarding the choice of elements. As privacy issues limits the boundaries of possibilities in gamification, we also must be careful with the use of elements, which are considered to be fun respecting patient related outcomes. Furthermore, in many cases the financial resources are limited to properly design a registry system and their gamification elements.

A possible limitation of our study could be the fact that the used gamification elements were not intuitive enough for users to understand, which could result in the opposite effect of their initial goal. A potential solution for this problem is to instruct all users first about the exact meaning of the gamification elements. However, this will shift the accent to games instead of registration. And in daily practice this is probably a mission impossible, since we will all recognize the fact that reading of a detailed guideline and/or instruction is cumbersome and annoying for clinicians. Therefore, we consider that gamification elements can only have a chance of success, when the meaning is completely intuitive and no detailed explanation required. Another potential weakness is the relatively low number of participants, however since the participants entered more than 1800 procedures they were sufficiently exposed to the gamification elements.

Much research has demonstrated the positive impact of feedback on clinical outcomes and professional practice (Ivers et al., 2012; Maruthappu et al., 2015; Foy et al., 2005; Trehan, Barnett-Vanes, Carty, McCulloch, & Maruthappu, 2015). Therefore, another possible explanation of our results might be the following: the individual, immediate feedback graphs on surgical outcomes, which were shown in both groups (Figure 1), may already have

provided enough positive enforcement to involve users. As a consequence, no difference between the groups was observed.

With this study we investigated the question, how to make a registry system more attractive for clinicians to register data. To conclude, our study showed that the addition of gamification elements in a registry did not affect engagement and involvement of clinicians. Based on our results, we advise that registry systems for clinical data should be as simple as possible with the focus on the main goal of the registry. This is especially true considering the increased pressure to register a large amount of (clinical) data currently; irrelevant features, which can distract users from the primary task, should therefore be minimized.

Acknowledgements

The authors thank all the participating gynecologists who registered their procedures during the study period and Alexander Verhaar, MSc for helping develop the gamification elements. All participating gynecologists and MSc Verhaar received no compensation for their contributions.

Reference list

Albers, L. L. & Sedler, K. D. (2004). Clinician perspectives on participation in research. J.Midwifery Womens Health, 49, 47-50.

Deterding S, Dixon D, Khaled R, & Nacke L. (2011). From game design elements to gamefulness: defining "gamification". MindTrek September[11], 28-30.

Dithmer, M., Rasmussen, J. O., Gronvall, E., Spindler, H., Hansen, J., Nielsen, G. et al. (2015). "The Heart Game": Using Gamification as Part of a Telerehabilitation Program for Heart Patients. Games.Health J, 5, 1-7.

Dreyer, N. A. & Garner, S. (2009). Registries for robust evidence. JAMA., 302, 790-791.

Foy, R., Eccles, M. P., Jamtvedt, G., Young, J., Grimshaw, J. M., & Baker, R. (2005). What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review. BMC.Health Serv. Res., 5, 50.

Graafland, M., Schraagen, J. M., & Schijven, M. P. (2012). Systematic review of serious games for medical education and surgical skills training. Br.J Surg, 99, 1322-1330.

Ivers, N., Jamtvedt, G., Flottorp, S., Young, J. M., Odgaard-Jensen, J., French, S. D. et al. (2012). Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane.Database.Syst.Rev., 6, CD000259.

Kerfoot, B. P. & Kissane, N. (2014). The use of gamification to boost residents' engagement in simulation training. JAMA.Surg, 149, 1208-1209.

Maruthappu, M., Trehan, A., Barnett-Vanes, A., McCulloch, P., & Carty, M. J. (2015). The impact of feedback of surgical outcome data on surgical performance: a systematic review. World.J Surg, 39, 879-889.

Morris, B. J., Croker, S., Zimmerman, C., Gill, D., & Romig, C. (2013). Gaming science: the "Gamification" of scientific thinking. Front Psychol., 4, 1-16.

Pereira, P., Duarte, E., Rebelo, F., & Noriega, P. (2014). A Review of Gamification for Health-Related Contexts. Design, User Experience, and Usability 8518, 742-753.

Rahman, S., Majumder, M. A., Shaban, S. F., Rahman, N., Ahmed, M., Abdulrahman, K. B. et al. (2011). Physician participation in clinical research and trials: issues and approaches. Adv.Med.Educ.Pract., 2, 85-93.

Ryan, R. M. & Connell, J. P. (1989). Perceived locus of causality and internalization: Examing reasons for acting in two domains. Journal of Personality and Social Psychology 57, 749-761.

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ., 340, c332.

Trehan, A., Barnett-Vanes, A., Carty, M. J., McCulloch, P., & Maruthappu, M. (2015). The impact of feedback of intraoperative technical performance in surgery: a systematic review. BMJ.Open., 5, e006759.

Twijnstra, A. R., Zeeman, G. G., & Jansen, F. W. (2010). A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. Qual.Saf Health Care, 19, 132-137.

van Leersum, N. J., Snijders, H. S., Henneman, D., Kolfschoten, N. E., Gooiker, G. A., Ten Berge, M. G. et al. (2013). The Dutch surgical colorectal audit. Eur.J Surg Oncol., 39, 1063-1070.

Woolhandler, S. & Himmelstein, D. U. (2014). Administrative work consumes one-sixth of U.S. physicians' working hours and lowers their career satisfaction. Int J Health Serv., 44, 635-642.

Chapter 10

General discussion

Quality assessments of surgical care and patient safety issues have become increasingly important in health care. To ensure that patients receive the highest level of care, the healthcare system needs reliable tools for assessing quality. In this thesis, we developed a new quality assessment tool for laparoscopic hysterectomy (LH) and explored new methods to correctly measure, compare and improve the quality of surgical care. Furthermore, the implementation of advanced laparoscopic procedures in gynaecology in the Netherlands and in residency is described.

Quality assessment of surgical care is especially important when new technologies are being introduced or complex surgical techniques such as minimally invasive surgery (MIS) are being performed. Currently, a worldwide on-going shift towards surgical indications in the minimally invasive approach is observed. First, we determined how advanced laparoscopy was implemented in gynaecology in The Netherlands (**Chapter 2**), and observed a significant increase in the total number of laparoscopically performed procedures (three times as high as 5 years ago). The tremendous increase was mainly due to the major increase of the number of LHs performed. This was especially caused by a shift in indications, which we discussed in **Chapter 3**; a large uterus, oncology and high BMI are nowadays also appropriate indications for LH. However, since not every clinic or gynaecologist has the resources or skills to provide LH for these more challenging cases, the possibility for referral is of highest importance to offer the patient the most minimally invasive approach of hysterectomy.

We observed that surgeons encounter new dilemmas because of the wide introduction of MIS and the rapid introduction of new technologies (**Chapter 3**). New devices could potentially be introduced into the operating room without proper evidence of their benefit and safety [1], which could lead to patient safety issues in daily clinical practice. This was also observed after the wide introduction of the laparoscopic power morcellator. Years after its introduction, the U.S. Food and Drug Administration (FDA) issued a statement discouraging the use of power morcellation in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids due to the potential risk of upstaging of an occult uterine sarcoma [2]. Maintaining knowledge of these matters and knowledge of new introduced instruments is essential to assure the quality of care.

Case volume and experience as quality assessment measurement?

Nowadays, case volume and surgical experience is often discussed as a proxy for quality assessment measurement [3-9]. In **Chapter 2**, we showed that introducing an annually case volume of 20 advanced procedures will have considerable consequences for daily practice. Almost 40% of the practicing gynaecologists and 12% of the hospitals in the Netherlands would not meet this requirement. To supply all gynaecologists who perform advanced

laparoscopic procedures with at least 20 advanced laparoscopic procedures, the total number of laparoscopic procedures needs to rise annually with 15% (740 procedures). We consider that centralization of certain high-complex laparoscopic procedures is inevitable to accomplish a required case volume and to maintain individual surgical skills to perform these. However, case volume as quality assessment measurement should be introduced with caution. No firm evidence is available regarding the optimal case volume in the field of (advanced) laparoscopic gynaecology [10]. Furthermore, volume seems to be an indirect indicator for other important aspects of health care providers, such as process and/or structural aspects, potentially explaining the positive volume-outcome association [11]. In addition, arbitrarily chosen volume criteria seem to be weak and ignore the fact that high volumes do not rule out suboptimal care, and lower volumes do not exclude high-quality surgery [12]. The same applies for surgical experience, as described in **Chapter 7**; here we observed a decrease in operative time and conversion rate until 100 and 50 LH procedures respectively. However we also found that a very experienced surgeon is not necessarily a guarantee for the best surgical outcome, and experience alone is not sufficient to assure the quality of surgical care. Therefore, case volume and/or experience is not a sufficient measurement assessment to assure surgical quality, and we consider that other factors such as individual surgical skills will provide more relevant information on the actual quality of surgical performance.

Trends in type of hysterectomy

In **Chapter 2** we described trends in the distribution of hysterectomies. A significant and preferable decrease in abdominal hysterectomy (AH) is observed, and is responsible for 58% of the increase in LH. However, an undesirable decrease in the number of vaginal hysterectomies (VHs) was also observed, which is a matter of concern, given that VH is still considered the approach of first choice for hysterectomy [13, 14]. The observations from **Chapter 2** are rather paradoxical; on the one hand, a preferred increase of advanced laparoscopic procedures is observed, however, on the other hand, this increase is mainly caused by the expansion of LH, which is partially at the expense of the VH. Therefore, we need to scrutinize if this shift in hysterectomy (i.e., VH to LH) is actually unwanted. Since the advantages of the laparoscopic approach become more apparent, the *gold standard* for hysterectomy is currently a matter of debate; patient related outcomes such as pain and hospital stay seem to be in favour of the laparoscopic approach. However, operative time and costs are still in clear advantage of VH [13, 15-18]. We do not exclude that in the future LH may be comparable to VH in terms of clinical outcomes and costs, however for now VH should be brought back in focus, and we need to ensure that this approach of hysterectomy

does not disappear from the gynaecologic surgical palette. This is especially important during residency; in **Chapter 4** we observed that residents are less interested in performing VH compared to AH. Furthermore, residents' experience in VH seems relatively low, and studies have shown that the majority of residents perform less than 20 VHs during residency [19-21]. As a result, graduating residents expressed a lack of confidence in performing VH, and these concerns are widely recognized in the literature [22].

This matter brought us to the question, how proficient are residents actually to perform the different approaches of hysterectomy and to perform (advanced) laparoscopic procedures? In **Chapter 4** we explored this question. We concluded that residents are perfectly trained for basic and intermediate laparoscopic surgical procedures (**Chapter 4**, Table 3), but not sufficiently trained to perform advanced laparoscopic procedures without supervision. This includes the lack of proficiency to perform LH after residency, and additional training (in the form of a fellowship) is required after residency to perform these procedures without supervision. In addition, we observed that 42% to 61% of the gynaecologists were not even interested in performing advanced procedures, and 63% to 96% of gynaecologists no longer perform any advanced laparoscopic procedures after graduating (**Chapter 4**).

Training programs are under pressure as work-hour restrictions have affected the resident's case experience and a growing emphasis is placed on subspecialties [23-25]. Therefore, we advocate that training of advanced laparoscopic procedures should only be reserved to a selected group of residents, and preliminary selection during residency is recommended (to note, minimal knowledge of advanced laparoscopic procedures is still required for all residents). This selection of residents can be conducted by means of interests of residents to perform advanced procedures as well as their variation in competence level (**Chapter 4**). However, the use of Objective Structures Assessment of Technical Skills (OSATS) to measure proficiency of residents is not regarded as completely sufficient and objective [26, 27]. Therefore, reliable quality assessment tools to measure the quality and skills of both residents and gynaecologists are needed. This is particularly relevant for more complex and frequently performed procedures such as LH.

Requirements of a Quality assessment tool

A first essential step towards reliable quality assessment of surgical performance is insight into case-mix variables (i.e., patient characteristics that influence surgical outcomes). The differences in case-mix variables between hospitals and surgeons are often ignored in used quality indicators, and this provides the clinician, the insurance company, and the patient with a certain false sense of (in)security. For a reliable interpretation and comparison of surgical outcomes, a correction for case-mix is of highest importance.

To identify all relevant case-mix characteristics for surgical outcomes of LH, we conducted a systematic review as described in **Chapter 5**. We observed that most studies of high quality described a statistically significant association between higher BMI, high uterine weight, and less favourable surgical outcomes for LH such as blood loss, operative time, conversion to laparotomy and complications. Also, adhesions and previous operations seemed to be important predictors for the outcomes of LH. Based on our search, we found that a case-mix correction for at least uterine weight and BMI is strongly recommended when assessing and comparing surgical quality of LH. Besides, evidence-based knowledge of case-mix characteristics is important considering patient counselling, surgical scheduling and medico-legal issues. This is especially relevant for clinics such as referral hospitals that are treating more complex patients.

New Quality Indicator for LH

Taken into account the aforementioned requirements to measure surgical quality, we developed and validated a web-based quality measurement tool for LH called QUSUM (**QU**ality indicator of **SU**rgical performance in **M**inimally invasive surgery). This was performed in collaboration with the department of Medical Statistics and the Institute of Psychology, as described in **Chapter 6**. This online and real-time application was (inter)nationally launched in a prospective study (www.qusum.org), and used by gynaecologists all over the world that registered in total more than 2000 LHs. The primary functions of this tool were to measure surgeon's performance, to provide immediate individual feedback, and to detect consistently suboptimal performance, all corrected for case-mix characteristics. Directly after registering a new LH procedure, three risk-adjusted Observed minus Expected (O-E) cumulative graphs were shown to the surgeon; one graph for each primary outcome (i.e., blood loss, operative time and complication score). The difference between the observed outcome (O) and expected outcome (E) was calculated (O–E), and the cumulative sum of O-E was plotted as a time series (**Chapter 6**).

To test the application, we used the System Usability Scale (SUS), a highly robust and validated survey scale that allows users to assess the usability of an application [28]. The mean SUS score for our QUSUM application was 76.5, suggesting that the application has good to excellent usability and that the features selected were appropriate for our group of participants. In addition, the majority of participants reported that using the QUSUM application increased their awareness regarding their performance, surgical outcomes, and patient risk factors during the procedure. This will lead to self-evaluation and control of individual outcomes, thereby inherently improving surgical outcome. We consider our developed QUSUM application to be a unique tool as it is easy to use, provides immediate feedback to the surgeon, and includes a case-mix correction.

We observed that quality assessment is a dynamic process, as our study showed that the benchmark for surgical outcomes changed significantly over time (**Chapter 6**). The QUSUM application is developed to be dynamic and established benchmark data can be adjusted when required. Furthermore, our used benchmark values and case-mix characteristics were based on a previous prospective multicenter cohort study [29]. These are important prerequisites when developing an evidence-based quality indicator.

Another important issue regarding quality assessment is that most of the published quality indicators are based on hospital outcomes and not on individual surgeon's outcome measures as the QUSUM application. With a retrospective analysis of 1618 LHs we demonstrated in **Chapter 7** that monitoring outcome measures exclusively on hospital level would not always detect an individual outlying surgeon (i.e., surgeon with consistently suboptimal performance). We observed that suboptimal outcomes of a lesser-skilled surgeon were masked by the superior skills of other surgeons in the same hospital, resulting in average quality outcome measure for the hospital. As a result, suboptimal care could potentially be delivered for an undue length of time, without the possibility to detect this. Therefore, we concluded that quality assessment should also be monitored on individual surgeon's level.

It is important to note that the reliability of entered data for registries and quality indicators is always dependent upon the integrity of the clinician. Previous studies have shown that this accuracy is generally high [29, 30]. In addition, in the future the application might be implemented into the electronic patient record and, outcome data will be transferred automatically, which makes incorrect registration difficult. However, we want to emphasize that a quality indicator should not have a punitive goal. Data measured by a quality indicator are generally a close approximation of reality, but may not always reflect the true situation precisely. Therefore, penalizing surgeons and/or hospitals based only on the raw data of quality indicators may not necessarily be appropriate. When a specific indicator provides a less favourable outcome, this should be considered as first sign to reflect on the below average outcome.

With our developed QUSUM application we created the possibility for clinicians to reflect and evaluate their individual performances. In the same application, we also implemented a patient safety risk factor checklist based upon previous research [31]. This checklist consisted of an adapted framework of risk factors in MIS and was composed of 10 different domains; surgeon related, surgical team, technology, social interaction, environment, patient, fallibility, safety, anaesthesiology and other. If any risk factors were observed during the procedure, which potentially could have influenced the clinical outcomes, the participating gynaecologist could optionally enter this information into the checklist when registering the procedure. We consider that the embedding of a patient safety risk factor checklist in used and new registries help surgeons to evaluate, reflect and improve their individual performance.

In **Chapter 8** we identified and quantified all entered patient safety risk factors in LH and determined their influence on surgical outcomes. We observed that in 28% of LHs a risk factor checklist was entered. The most reported risk factor domains were surgeon related risk factors (19.6%), surgical team risk factors (14.4%) and technology related risk factors (16.6%, e.g., availability and functioning of equipment and instruments).

We observed significantly less favorable surgical outcomes in the group of LHs where a risk factor checklist was registered. Technological incidents are the most significant and important risk factors influencing surgical outcomes of LH. Implementation of new technologies in surgery is challenging for practicing surgeons, especially when it comes to complex procedures such as MIS. As technology evolves rapidly over time, we should no longer accept technological failures. Therefore, future changes in MIS need to focus on these technological incidents and errors. General knowledge of technical issues and knowledge on how to handle instruments and errors should be mandatory before participating in MIS and the introduction of new instruments brings a responsibility to the whole surgical team.

Risk factors regarding the surgical team (e.g. lack of experience/knowledge of scrub/circulating nurse) seem to be relevant as well with respect to surgical outcomes. A dedicated and skilled surgical team will be more efficient, will better communicate with each other and will potentially enhance patient safety. Yet, the main responsibility for a procedure always lies primarily in the hands of the surgeon and not in the first place of the other members of the surgical team. The same applies to the participation of a resident, which is frequently mentioned as justification for less optimal surgical outcome. However, recent research showed that trainee involvement was not associated with adverse patient safety or a higher overall complication rate [32, 33]. In addition, the primary surgeon, in this case the teacher remains responsible for achieving favorable surgical outcomes

Since the improvement of patient safety and the quality of care are both high on the international political agenda [34], the registration of clinical data is indispensable in the current duties of a clinician. Consequently, it is not surprising that the engagement and motivation of clinicians to register their data is essentially for the success of a quality assessment registry.

In this context, we hypothesized that gamification elements may offer opportunities to motivate and engage doctors to participate in medical registries. Gamification can be explained as the use of game elements and techniques in existing applications or in nongame contexts, to motivate and engage users with a system [35]. Gamification focuses on making necessary and annoying tasks more enjoyable through a positive approach [36]. During the last few years gamification is used within a broad variety of domains, such as finance, health, education, news and entertainment, by earning badges, point and achievements when completing specific tasks [37].

In **Chapter 9** we explored, in collaboration with the Institute of Psychology, the additional value of gamification elements in a registry system for LH in terms of engagement and involvement of gynaecologists to register their outcome data. In a randomized control trial we observed that gamification elements did not show any advantages, and that it may even distract users from the primary goal of the application. Therefore, we recommend that new and existing registries should be simple, and exclusively collect data that are truly relevant and usable. This is especially true considering the increased pressure to register a large amount of (clinical data) currently, and irrelevant features, which can distract users from the primary task, should therefore be reduced.

In this context, we should ask ourselves which data is truly relevant? In this thesis we focused on (surgical) outcome measures. However, one may question whether a slightly longer operative time is truly clinically relevant to the patient and her recovery? Still, recent studies reported a direct relationship between a longer operative time and an increased risk of complications, reoperations, and higher hospital costs [38, 39]. Moreover, it is increasingly important to take into consideration patient's perspectives on their health status, also known as the patient-reported outcomes measures (PROMs). In the near future, we expect that PROMs and Value Based Health Care as defined by Porter et al. will become and adopt an important position when assessing quality of care [40].

To conclude, quality assessment in surgical care is very important, though very difficult. With this thesis we attempted to overcome the limitations of currently used quality indicators and developed a dynamic, unique quality assessment tool to reflect upon individual surgical performance with case-mix correction.

Future perspectives

To enhance patient safety, monitoring quality of health care is indispensable. In this thesis we described different possibilities and requirements in the domain of quality assessment for surgical procedures. We consider this as a foundation for the development of new quality indicators for other surgical procedures, and recommend that surgeons and other healthcare providers take the lead in developing suitable evidence-based quality indicators using this thesis as a starting point. Our developed QUSUM application can therefore easily be adapted to other procedures. An important prerequisite is first to define and select clinically relevant outcomes, that can be measured instantly and that reflect performance quality for that specific procedure. Thereafter, it is necessary to determine benchmark data and case-mix characteristics for the selected procedure, preferable by performing a prospective study. A correct case-mix adjustment is of major importance to correctly benchmark surgical outcomes, especially because the concern of surgeons for incorrect

negative performance ratings is a great problem in the field of quality assessment and transparency.

Looking at quality improvement of surgical care, Geoffrey Rose has stated the famous prevention paradox [41]: for high-risk procedures much individual gain can be achieved, while on the other hand, when in a large number of procedures (high-volume) a relatively small improvement can be achieved, this will eventually result great benefits of quality of surgical care. In this light, we do not necessarily argue for the development of quality assessment tools for every type of surgical procedure but we believe this should be particularly recommended for certain high-risk and/or high-volume procedures.

A quality indicator has little value if the performance being measured cannot be improved (e.g., by providing feedback, detection of suboptimal performance or the opportunity for reflection). Therefore, the possibility to improve is key issue to enhance the quality of care, and future research should focus on it. For example, as this thesis showed, there is considerable room for improvement in the area of technological problems in MIS and attempts to enhance the currently used instruments and equipment should be encouraged.

Furthermore, to correctly benchmark surgical outcomes, we recommend that at an international level the same definitions of clinical outcomes are adopted and used. This will allow quality comparisons at an international level.

Another important aspect for future research is the definition of an outlier (i.e., clinician with consistently suboptimal performances) [42]. Definitions of suboptimal performances may be different between national and international societies. These differences will depend on (inter)national benchmark values but also on cultural diversity. Awareness of these differences is important.

A next step for the QUSUM project and a key issue for new registries is the possibility to implement these in an existing data system (e.g. electronic patient records). Currently, the merge of multiple registry systems is highly cumbersome and a struggle in the present registration climate. Logically, duplicate and inconvenient registries are extremely annoying for clinicians and increase their administrative workload.

Clinicians themselves should take the lead in the development of quality registries and how to (publicly) release their data. We should be aware of the fact that media and/or governmental agencies could interpret certain quality measures incorrectly, and given the current (social) media possibilities these inaccuracies can be directly widely spread. Therefore, an active participation of the clinician is extremely important for the development of quality registries and for a correct interpretation of measured outcome data.

Reference list

(1) Rodrigues SP, Wever AM, Dankelman J, Jansen FW. Risk factors in patient safety: minimally invasive surgery versus conventional surgery. Surg Endosc 2012; 26(2):350-356.

(2) FDA. Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication; http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm. 2015.

(3) Maruthappu M, Gilbert BJ, El-Harasis MA, Nagendran M, McCulloch P, Duclos A et al. The influence of volume and experience on individual surgical performance: a systematic review. Ann Surg 2015; 261(4):642-647.

(4) Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N Engl J Med 2003; 349(22):2117-2127.

(5) Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I et al. Hospital volume and surgical mortality in the United States. N Engl J Med 2002; 346(15):1128-1137.

(6) Dikken JL, Dassen AE, Lemmens VE, Putter H, Krijnen P, van der Geest L et al. Effect of hospital volume on postoperative mortality and survival after oesophageal and gastric cancer surgery in the Netherlands between 1989 and 2009. Eur J Cancer 2012; 48(7):1004-1013.

(7) Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. Obstet Gynecol 2004; 104(2):308-313.

(8) Ghomi A, Littman P, Prasad A, Einarsson JI. Assessing the learning curve for laparoscopic supracervical hysterectomy. JSLS 2007; 11(2):190-194.

(9) Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008; 23(4):840-845.

(10) Doll KM, Milad MP, Gossett DR. Surgeon volume and outcomes in benign hysterectomy. J Minim Invasive Gynecol 2013; 20(5):554-561.

(11) Mesman R, Faber MJ, Westert GP, Berden B. [Volume standards: quality through quantity? relationship between treatment volume and outcomes not well founded]. Ned Tijdschr Geneeskd 2013; 157(33):A5466.

(12) Kolfschoten NE, Marang-van de Mheen PJ, Wouters MW, Eddes EH, Tollenaar RA, Stijnen T et al. A combined measure of procedural volume and outcome to assess hospital quality of colorectal cancer surgery, a secondary analysis of clinical audit data. PLoS One 2014; 9(2):e88737.

(13) Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BW et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2015; 8:CD003677.

(14) Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.

(15) Ghezzi F, Uccella S, Cromi A, Siesto G, Serati M, Bogani G et al. Postoperative pain after laparoscopic and vaginal hysterectomy for benign gynecologic disease: a randomized trial. Am J Obstet Gynecol 2010; 203(2):118.

(16) Wright KN, Jonsdottir GM, Jorgensen S, Shah N, Einarsson JI. Costs and outcomes of abdominal, vaginal, laparoscopic and robotic hysterectomies. JSLS 2012; 16(4):519-524.

(17) Schindlbeck C, Klauser K, Dian D, Janni W, Friese K. Comparison of total laparoscopic, vaginal and abdominal hysterectomy. Arch Gynecol Obstet 2008; 277(4):331-337.

(18) Candiani M, Izzo S, Bulfoni A, Riparini J, Ronzoni S, Marconi A. Laparoscopic vs vaginal hysterectomy for benign pathology. Am J Obstet Gynecol 2009; 200(4):368-7.

(19) Miskry T, Magos A. A national survey of senior trainees surgical experience in hysterectomy and attitudes to the place of vaginal hysterectomy. BJOG 2004; 111(8):877-879.

(20) Moen M, Walter A, Harmanli O, Cornella J, Nihira M, Gala R et al. Considerations to improve the evidence-based use of vaginal hysterectomy in benign gynecology. Obstet Gynecol 2014; 124(3):585-588.

(21) Greer JA, Segal S, Salva CR, Arya LA. Development and validation of simulation training for vaginal hysterectomy. J Minim Invasive Gynecol 2014; 21(1):74-82.

(22) Burkett D, Horwitz J, Kennedy V, Murphy D, Graziano S, Kenton K. Assessing current trends in resident hysterectomy training. Female Pelvic Med Reconstr Surg 2011; 17(5):210-214.

(23) Schreuder HW, Oei G, Maas M, Borleffs JC, Schijven MP. Implementation of simulation in surgical practice: minimally invasive surgery has taken the lead: the Dutch experience. Med Teach 2011; 33(2):105-115.

(24) Blanchard MH, Amini SB, Frank TM. Impact of work hour restrictions on resident case experience in an obstetrics and gynecology residency program. Am J Obstet Gynecol 2004; 191(5):1746-1751.

(25) Escobar MA, Jr., Hartin CW, Jr., McCullough LB. Should general surgery residents be taught laparoscopic pyloromyotomies? An ethical perspective. J Surg Educ 2014; 71(1):102-109.

(26) Hiemstra E, Kolkman W, Wolterbeek R, Trimbos B, Jansen FW. Value of an objective assessment tool in the operating room. Can J Surg 2011; 54(2):116-122.

(27) Gibson KS, Muffly TM, Penick E, Barber MD. Factors used by program directors to select obstetrics and gynecology fellows. Obstet Gynecol 2012; 119(1):119-124.

(28) Bangor A., Kortum P.T., Miller J.T. An Empirical Evaluation of the System Usability Scale. Intl Journal of Human-computer interaction 2008; 24(6):574-594.

(29) Twijnstra AR, Blikkendaal MD, van Zwet EW, van Kesteren PJ, de Kroon CD, Jansen FW. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol 2012; 119(4):700-708.

(30) van Leersum NJ, Snijders HS, Henneman D, Kolfschoten NE, Gooiker GA, Ten Berge MG et al. The Dutch surgical colorectal audit. Eur J Surg Oncol 2013; 39(10):1063-1070.

(31) Rodrigues SP, Ter KM, Dankelman J, Jansen FW. Patient safety risk factors in minimally invasive surgery: a validation study. Gynecol Surg 2012; 9(3):265-270.

(32) Igwe E, Hernandez E, Rose S, Uppal S. Resident participation in laparoscopic hysterectomy: impact of trainee involvement on operative times and surgical outcomes. Am J Obstet Gynecol 2014; 211(5):484-487.

(33) Nijhof HW, Silvis R, Vuylsteke RC, Oosterling SJ, Rijna H, Stockmann HB. Training residents in laparoscopic colorectal surgery: is supervised surgery safe? Surg Endosc 2016.

(34) Nederlandse vereniging van ziekenhuizen. Kwaliteitvenster, https://www.nvz-kwaliteitsvenster.nl/. 2015.

(35) Morris BJ, Croker S, Zimmerman C, Gill D, Romig C. Gaming science: the “Gamification” of scientific thinking. Front Psychol 2013; 4(607):1-16.

(36) Dithmer M, Rasmussen JO, Gronvall E, Spindler H, Hansen J, Nielsen G et al. “The Heart Game”: Using Gamification as Part of a Telerehabilitation Program for Heart Patients. Games Health J 2015; 5(1):1-7.

(37) Deterding S, Dixon D, Khaled R, Nacke L. From game design elements to gamefulness: defining “gamification”. MindTrek September[11], 28-30. 2011.

(38) Hanwright PJ, Mioton LM, Thomassee MS, Bilimoria KY, Van AJ, Brill E et al. Risk profiles and outcomes of total laparoscopic hysterectomy compared with laparoscopically assisted vaginal hysterectomy. Obstet Gynecol 2013; 121(4):781-787.

(39) Matteson KA, Peipert JF, Hirway P, Cotter K, DiLuigi AJ, Jamshidi RM. Factors associated with increased charges for hysterectomy. Obstet Gynecol 2006; 107(5):1057-1063.

(40) Porter ME. What is value in health care? N Engl J Med 2010; 363(26):2477-2481.

(41) Rose G. Strategy of prevention: lessons from cardiovascular disease. Br Med J (Clin Res Ed) 1981; 282(6279):1847-1851.

(42) Shahian DM, Normand SL. What is a performance outlier? BMJ Qual Saf 2015; 24(2):95-99.

Chapter 11

Summary

Transparency and measurement of quality of health care have received considerable attention in recent years. Quality indicators have been developed in an attempt to differentiate between high and low quality of healthcare processes. Assessing quality is an indispensable step to ensure patient safety, particularly in the field of minimally invasive surgery (MIS). In 2007 the report of the Dutch Health Care Inspectorate was published, in which concern was expressed regarding patient safety during MIS. This report stated that specific quality measures are needed to develop a formal quality system for laparoscopic procedures to enhance patient safety. However, most of the currently applied quality indicators are not corrected for case-mix characteristics; these are patient characteristics that affect (surgical) outcome (e.g., high BMI, enlarged uterus). Quality assessment without correction for case-mix characteristics will result in an invalid comparison of outcomes among healthcare providers

In this thesis, we developed a new quality assessment tool for laparoscopic hysterectomy (LH) and explored new methods to correctly measure, compare and improve the quality of surgical care.

First, we observed in **Chapter 2** a significant increase in the total number of advanced laparoscopically performed procedures in the Netherlands. The tremendous increase was mainly due to the major increase of the number of LHs performed. This was especially caused by a shift in indications, which we discussed in **Chapter 3**; a large uterus, low risk oncology and high BMI are nowadays also appropriate indications for LH.

Nowadays, case volume and surgical experience is often discussed as a proxy for quality assessment measurement. In **Chapter 2**, we showed that introducing an annually case volume of 20 advanced laparoscopic procedures would have considerable consequences for daily practice. Almost 40% of the practicing gynaecologists and 12% of the hospitals in the Netherlands would not meet this requirement. We consider that centralization of certain high-complex laparoscopic procedures is inevitable to accomplish a required case volume and to maintain individual surgical skills to perform these. However, case volume as quality assessment measurement should be introduced with caution. High volumes do not rule out suboptimal care, and lower volumes do not exclude high-quality surgery.

In **Chapter 2** we also described trends in the distribution of hysterectomies. A significant and preferable decrease in abdominal hysterectomy (AH) is observed in favour of the LH. However, an undesirable decrease in the number of vaginal hysterectomies (VHs) was also observed, which is a matter of concern, given that VH is still considered the approach of first choice for hysterectomy. In **Chapter 4** we observed that residents are even less interested in performing VH compared to AH. Furthermore, we found that residents are not sufficiently trained to perform advanced laparoscopic procedures without supervision. This includes the lack of proficiency to perform LH after residency, and additional training (in the form of

a fellowship) is required to perform these procedures without supervision. In addition, we observed that 63% to 96% of gynaecologists no longer perform any advanced laparoscopic procedures after graduating. Therefore, we advocate that training of advanced laparoscopic procedures should only be reserved to a selected group of residents, and preliminary selection during residency is recommended. Reliable quality assessment tools to measure the quality and skills of both residents and gynaecologists are therefore needed.

A first essential step towards reliable quality assessment of surgical performance is to get insight in case-mix variables. For a reliable interpretation and comparison of surgical outcomes, a correction for case-mix is of highest importance. To identify all relevant case-mix characteristics for surgical outcomes of LH, we conducted a systematic review as described in **Chapter 5**. We observed that higher BMI and high uterine weight are associated with less favourable surgical outcomes for LH such as blood loss, operative time, conversion and complications. Also, adhesions and previous operations seemed to be important predictors for the outcomes of LH.

In **Chapter 6** we describe the development and validation of a web-based real-time quality measurement tool for LH (www.qusum.org). This online application was (inter)nationally launched and more than 2000 LHs were registered by more than 80 gynaecologists. The primary function of this tool was to measure surgeon's performance, to provide immediate individual feedback, and to detect consistently suboptimal performance, all corrected for case-mix characteristics. The usability of the application was good to excellent. And the majority of participants reported that using the QUSUM application increased their awareness regarding their performance, surgical outcomes, and patient risk factors during the procedure.

Another important issue regarding quality assessment is that most of the published quality indicators are based on hospital outcomes and not on individual surgeon's outcome measures as the QUSUM application. In **Chapter 7** we observed that suboptimal outcomes of a lesser-skilled surgeon were masked by the superior skills of other surgeons in the same hospital, resulting in average quality outcome measure for the hospital. As a result, suboptimal care could potentially be delivered for an undue length of time, without the possibility to detect this. Therefore, we concluded that quality assessment should also be monitored on individual surgeon's level.

With our developed QUSUM application we created the possibility for clinicians to reflect and evaluate their individual performances by the implementation of a validated patient safety risk factor checklist. This list consisted of an adapted framework of risk factors in MIS, which could be entered by the surgeon (e.g., technical failures, communication problem). We observed that in 28% of LHs a risk factor checklist was entered and technology related risk factors were most important considering patient safety **(Chapter 8)**.

Currently, the registration of clinical data is indispensable in the current duties of a clinician, which can be annoying and cumbersome. In this context, we hypothesized that gamification elements may offer opportunities to motivate and engage doctors to participate in medical registries. Gamification can be explained as the use of game elements in existing applications to motivate and engage users with a system. In a randomized control trial **(Chapter 9)** we observed that gamification elements did not show any advantages, and that it may even distract users from the primary goal of the application. Therefore, we recommend that new and existing registries should be simple, and exclusively collect data that are truly relevant and usable.

To conclude, quality assessment in surgical care is very important, though very difficult. With this thesis we attempted to overcome the limitations of currently used quality indicators and developed a dynamic, unique quality assessment tool to reflect upon individual surgical performance with case-mix correction.

Chapter 12

Nederlandse samenvatting
Author affiliations
List of publications
Curriculum Vitae
Dankwoord

Nederlandse samenvatting

Transparantie en het meten van de kwaliteit van (chirurgische) zorg heeft de afgelopen jaren toenemende aandacht gekregen. Momenteel worden hiervoor kwaliteitsindicatoren gebruikt, die idealiter onderscheid kunnen maken tussen suboptimale zorg en hoogwaardige zorg. Het beoordelen van de kwaliteit van zorg is een belangrijk aspect om de patiëntveiligheid en hoge kwaliteit van zorg te waarborgen. De minimaal invasieve chirurgie (MIC) is een voorbeeld van hoogcomplexe chirurgische zorg daar met name hoogwaardige technologie bij de operatie wordt geïntroduceerd en waar een (aanstaande) chirurg een leercurve voor moet doorlopen. Deze MIC techniek werd, gezien de technologische mogelijkheden (video-laparsocopisch opereren, introductie elektrochirurgie, verbeterde instrumenten etc.) aan het eind van de vorige eeuw plots massaal geïntroduceerd in het chirurgische pallet. In 2007 werden de beoefenaars van die MIC echter opgeschrikt door een zeer kritisch rapport vanuit de Inspectie voor de Gezondheidszorg (IGZ) over de toepassing en introductie van deze relatief nieuwe vorm van chirurgie. De implementatie zou tot meer complicaties leiden en bracht de patiëntveiligheid in gevaar. Dit leidde tot de vraag naar eenduidige kwaliteitsindicatoren binnen de MIC. Echter, het correct meten van de kwaliteit van zorg is zeer complex en het grootste probleem van de meest gebruikte kwaliteitsindicatoren is dat er niet gecorrigeerd wordt voor *case-mix*; dit zijn patiënt karakteristieken die de klinische uitkomsten kunnen beïnvloeden (bijv. een hoge BMI, comorbiditeit, grote tumoren, eerdere operaties etc.). Zonder te corrigeren voor deze karakteristieken is een eerlijke vergelijking van de chirurgische uitkomstmaten en dus de kwaliteit tussen ziekenhuizen en/of behandelaars niet goed mogelijk.

In dit proefschrift beschrijven wij de ontwikkeling en valorisatie van een nieuw uniek kwaliteitsinstrument voor de laparoscopische uterusextirpatie (baarmoeder verwijdering middels kijkoperatie). Ook onderzoeken wij hoe de kwaliteit van chirurgische zorg correct gemeten, vergeleken en verbeterd kan worden.

In **hoofdstuk 2** hebben wij de implementatie van complexe laparoscopisch ingrepen bestudeerd en zien wij dat deze aantallen binnen de gynaecologie enorm gestegen zijn in de afgelopen jaren. Deze stijging wordt met name veroorzaakt door de forse toename van het aantal laparoscopische uterusextirpaties (ook laparoscopische hysterectomie (LH) genoemd). In **hoofdstuk 3** beschrijven wij dat dit vooral komt doordat de indicaties voor het uitvoeren van een laparoscopische uterusextirpatie steeds verder verlegd worden. Tegenwoordig komen ook patiënten met een grote uterus, laag stadium- en laag risico oncologische aandoening en een hoge BMI in aanmerking om een uterusextirpatie laparoscopisch uit te voeren.

Een hoger volume van complexe chirurgische ingrepen wordt tegenwoordig steeds vaker gehanteerd als maat voor kwaliteit. Een minimaal behandelvolume van 20 ingrepen per jaar wordt hierbij als passend beschouwd. In **hoofdstuk 2** laten we zien dat het instellen van

volumenormen voor complexe laparoscopische ingrepen in de gynaecologie grote consequenties kan hebben voor de dagelijkse praktijkvoering: 40% van de gynaecologen en 12% van de ziekenhuizen voeren minder dan 20 van deze ingrepen per jaar uit. Centralisatie van bepaalde hoog complexe ingrepen is dan onvermijdelijk om zo aan een gesteld volume te komen en om de vaardigheden te behouden om deze ingrepen veilig uit te kunnen voeren. Doch, men moet voorzichtig zijn deze normen in te stellen. Het excluderen van laagvolume klinieken zal niet automatisch leiden tot het uitsluiten van ondermaatse zorg, daarnaast spelen factoren als chirurgische *skills* en ervaring ook een belangrijke rol in de uitkomsten.

Tevens zagen wij dat er een verschuiving in benadering van de uterusextirpatie in Nederland in de afgelopen vijf jaar plaatsvond. De abdominale benadering (via een buiksnede) nam significant af ten gunste van de laparoscopische benadering, Dit is een gewenste verschuiving, daar de laparoscopische benadering duidelijk voordelen heeft ten opzichte van de open abdominale chirurgie (sneller herstel, minder peroperatief bloedverlies, minder infecties, cosmetiek). Echter, ook een significante afname van de vaginale uterusextirpatie (via de schede) ten gunste van de laparoscopische benadering werd geobserveerd. Dit is een minder gewenste verschuiving, omdat de vaginale uterusextirpatie tot op heden gezien alle voordelen voor de patiënt (geen uitwendige littekens, kortere operatietijd, minder kosten) beschouwd wordt als de benadering van eerste keus.

Oorzaken van deze verschuiving onderzochten wij verder in **hoofdstuk 4**, waarin we de bekwaamheid niveaus van *jonge klaren* (gynaecologen die ≤ 5 jaar geleden de opleiding tot gynaecoloog hebben afgerond) in het uitvoeren van (laparoscopische) ingrepen analyseerden. Geconcludeerd kan worden dat *jonge klaren* minder interesse hebben om de vaginale uterusextirpatie uit te voeren ten opzichte van de abdominale hysterectomie. Verder blijkt dat *jonge klaren* onvoldoende getraind worden tijdens de opleiding om complexe laparoscopische ingrepen, zoals de LH, na het afronden van de opleiding zonder supervisie uit te kunnen voeren. Derhalve is extra training na de opleiding (bijv. een fellowship) noodzakelijk alvorens complexe laparoscopische ingrepen bekwaam uitgevoerd kunnen worden. Ook werd gezien dat een groot deel van de gynaecologen (63 tot 96%) deze ingrepen nooit meer uitvoert na het afronden van de opleiding. Zodoende pleiten wij ervoor dat alleen een geselecteerde groep assistenten bepaalde complexe laparoscopische ingrepen getraind krijgt in de opleiding. Ook voor deze selectie is een betrouwbaar kwaliteitsinstrument zeer gewenst om zo de chirurgische vaardigheden correct te kunnen meten.

Een eerste stap naar de ontwikkeling van een kwaliteitsinstrument om de chirurgische bekwaamheid correct te meten is inzicht in case-mix karakteristieken (patiënt karakteristieken die klinische uitkomsten kunnen beïnvloeden). Betrouwbare onderlinge vergelijkingen van de kwaliteit van chirurgische zorg is niet mogelijk zonder deze case-mix correctie.

Met behulp van een systematische review **(hoofdstuk 5)** hebben wij die case-mix karakteristieken kunnen identificeren voor chirurgische uitkomsten van de laparoscopische uterusextirpatie. Zo blijkt dat een hoger BMI en een vergrote uterus gerelateerd zijn aan minder goede chirurgische uitkomsten (meer bloedverlies, langere operatie tijd en meer complicaties). Ook zijn verklevingen in de buik en eerdere buikoperaties in de voorgeschiedenis nauw gerelateerd aan minder succesvolle uitkomsten.

Met het in acht nemen van bovenstaande vereisten, hebben wij een uniek web-based, real-time kwaliteitsinstrument ontwikkeld (www.QUSUM.org). Dit instrument meet individuele chirurgische prestaties bij de LH, met een correctie voor case-mix **(hoofdstuk 6)**. De online applicatie is (inter)nationaal geïntroduceerd en meer dan 2000 LH's zijn geregistreerd door ruim 80 gynaecologen. Het doel van de applicatie is drievoudig: 1. het correct meten van individuele chirurgische prestaties, 2. de chirurg voorzien van directe individuele feedback, en 3. het detecteren en signaleren van (opeenvolgende) suboptimale prestaties. In **hoofdstuk 6** werd onderzocht hoe de bruikbaarheid van de applicatie is. Deze bleek aan de hand van een referentiemeting (de SUS score) goed tot uitstekend te zijn. Daarnaast bleek de bewustwording van de individuele prestaties, de chirurgische uitkomsten en de patiënt veiligheid toe te nemen bij de gebruiker. Dit zijn belangrijke punten in het kader van kwaliteitsverbetering.

Veel kwaliteit uitkomsten worden momenteel gebaseerd en openbaar gemaakt op basis van uitkomsten op ziekenhuis niveau. In **hoofdstuk 7** laten we zien dat het van belang is om de kwaliteit van chirurgische zorg ook op het individuele niveau van de operateur te meten. Zo blijkt dat de operateurs met minder optimale uitkomsten gecompenseerd worden door collega operateurs met (boven) gemiddeld goede uitkomsten. Dit resulteert weer in een gemiddeld tot goede kwaliteit uitkomst op ziekenhuisniveau. Zonder zicht op de kwaliteit van de individuele operateur is het mogelijk dat er suboptimale zorg geleverd wordt voor een onnodig lange tijdsduur. Kwaliteit moet bij voorkeur dus ook op individueel niveau gemeten worden, zoals wij laten zien in de QUSUM applicatie.

Een kwaliteitsinstrument is van weinig waarde wanneer er geen verbetering mogelijkheden zijn. Om deze reden ontwikkelden wij een gevalideerde *patiëntveiligheid risico checklist*, welke geïmplementeerd werd in de QUSUM applicatie. Hierdoor hadden operateurs de mogelijkheid om na elke ingreep aan te geven wat voor risico factoren een rol hebben gespeeld tijdens het uitvoeren van de operatie (bijv. technische problemen, communicatieve problemen ect). Deze risicofactoren hebben we geanalyseerd en gekwantificeerd in **hoofdstuk 8**. Het blijkt dat bij ruim een kwart van de ingrepen een risico factor aanwezig was, en dat technologische incidenten de grootste rol speelden bij de patiëntveiligheid tijdens een laparoscopische uterusextirpatie.

Door de toenemende vraag naar transparantie in de zorg, wordt van artsen verwacht dat zij steeds meer registraties invullen. Dit is een tijdrovend proces, wordt vaak als hinderlijk ervaren en kan ten koste te gaan van de patiëntenzorg, Door middel van een gerandomiseerde trial hebben we onderzocht of *gamification* elementen van toegevoegde waarde zijn om operateurs te motiveren en te betrekken bij het registreren van data **(hoofdstuk 9)**. *Gamification* is het gebruik maken van bepaalde spelelementen in een bestaand systeem. Via een positieve benadering zouden deze elementen gebruikers kunnen motiveren de applicatie in te vullen. Het bleek dat de toevoeging van dit soort elementen geen enkel voordeel heeft en de gebruikers zelfs kan afleiden van het primaire doel van registratie. Derhalve concluderen wij dat bestaande en nieuwe registratie systemen zo simpel mogelijk moeten zijn, en alleen relevante data geregistreerd dienen te worden.

Concluderend, om de patiëntveiligheid te waarborgen is het monitoren van de kwaliteit van zorg onmisbaar geworden. In dit proefschrift worden de knelpunten beschreven, oplossingen en aanbevelingen gegeven hoe de kwaliteit van de laparoscopische hysterectomie (als complexe minimaal invasieve chirurgische ingreep) kan worden gemeten en de ontwikkeling van een nieuw uniek kwaliteitsinstrument beschreven. Met een goede kwaliteitsindicator zou men idealiter suboptimale zorg kunnen onderscheiden van kwalitatief hoogwaardige zorg. Daarnaast is het van belang dat met behulp van een kwaliteitsindicator de mogelijkheid tot kwaliteitsverbetering bestaat. Hierin speelt individuele feedback en reflectie van en naar de operateur toe een belangrijke rol. De taak voor het ontwikkelen en definiëren van accurate kwaliteitsindicatoren ligt bij de beroepsgroepen en het gebruik van case-mix correctie is hierbij van essentieel belang gebleken.

Author affiliations

Haaglanden Medisch Centrum, Bronovo, the Hague, the Netherlands
Department of Obstetrics and Gynaecology
Johann Rhemrev

Leiden University Medical Center, Leiden, the Netherlands
Department of Gynaecology
Mathijs Blikkendaal, Claire la Chapelle, Frank Willem Jansen, Lukas van den Haak, Sharon Rodrigues, Evelien Sandberg, Dries Twijnstra

Leiden University Medical Center, Leiden, the Netherlands
Department of Medical Statistics
Erik van Zwet

Delft University of Technology, Delft, The Netherlands
Department BioMechanical Engineering
Frank Willem Jansen

St Antonius Hospital, Nieuwegein, the Netherlands
Department of Gynaecology and Obstetrics
Juliënne Janse

University Medical Center Utrecht, Utrecht, the Netherlands
Department of Reproductive Medicine and Gynecology
Henk Schreuder

Institute of Psychology, Leiden, The Netherlands
Pascal Haazebroek, Wikanand Basropansingh

University of Heidelberg, Heidelberg, Germany
Department of Obstetrics and Gynaecology
Markus Wallwiener

University of Tübingen, Tübingen, Germany
Department of Obstetrics and Gynaecology
Sara Brucker, Bernhard Kraemer, Florin-Andrei Taran, Christian Wallwiener

Brigham and Women's Hospital, Boston, USA
Division of Minimally Invasive Gynaecologic Surgery
Sarah Cohen

Former Medical Student
Leiden University Medical Center, Leiden, the Netherlands
Niki Baden

List of publications

Sandberg EM, **Driessen SRC**, Bak EAT, van Geloven N, Berger JP, Smeets MJGH, Rhemrev JPT, Jansen FW.
The impact of endometriosis on surgical outcomes of laparoscopic hysterectomy.
Submitted

Sandberg EM, Bordewijk EM, Klemann D, **Driessen SRC**, Twijnstra ARH, Jansen FW.
Medical claims in laparoscopic gynaecologic surgery: national overview over 20 years.
Submitted

Driessen SR, Haazebroek P, Basropansingh W, van Zwet EW, Jansen FW.
Gamification to engage clinicians in registering data: a randomized trial. Global Journal of Health Science, 2017, Vol. 9, No.4; 240-250

Sandberg EM, Twijnstra AR, **Driessen SR**, Jansen FW.
Total laparoscopic hysterectomy versus vaginal hysterectomy: a systematic review and meta-analysis. J Minim Invasive Gynecol. 2016 Nov 17. pii: S1553-4650(16)31167-0. PMID: 27867051

Driessen SR, Sandberg EM, Rodrigues SP, van Zwet EW, Jansen FW.
Identification of risk factors in minimally invasive surgery: a prospective multicenter study. Surg Endosc. 2016 Oct 31. PMID: 27800588

Driessen SR, Wallwiener M, Taran FA, Cohen SL, Kraemer B, Wallwiener CW, van Zwet EW, Brucker SY, Jansen FW.
Hospital versus individual surgeon's performance in laparoscopic hysterectomy.Arch Gynecol Obstet. 2016 Sep 15. PMID: 27628752

Driessen SR, Van Zwet EW, Haazebroek P, Sandberg EM, Blikkendaal MD, Twijnstra AR, Jansen FW.
A dynamic quality assessment tool for laparoscopic hysterectomy to measure surgical outcomes. Am J Obstet Gynecol. 2016 Jul 9. pii: S0002-9378(16)30437-9.PMID: 27403847

Blikkendaal MD, **Driessen SR**, Rodrigues SP, Rhemrev JP, Smeets MJ, Dankelman J, van den Dobbelsteen JJ, Jansen FW.
Surgical flow disturbances in dedicated minimally invasive surgery suites: an observational study to assess its supposed superiority over conventional suites. Surg Endosc. 2016 May 20. [PMID: 27198548

van den Haak L, Rhemrev JP, Blikkendaal MD, Luteijn AC, van den Dobbelsteen JJ, **Driessen SR**, Jansen FW.
A new approach to simplify surgical colpotomy in laparoscopic hysterectomy. Gynecol Surg. 2016;13:63-69. PMID: 26918004

Driessen SR, Sandberg EM, van den Haak L, Jansen FW.
[Increase in laparoscopic hysterectomy: shift in indications and dilemmas]. Ned Tijdschr Geneeskd 2015;159:A9324. PMID: 26732209

Driessen SR, Sandberg EM, la Chapelle CF, Twijnstra AR, Rhemrev JP, Jansen FW.
Case-Mix Variables and Predictors for Outcomes of Laparoscopic Hysterectomy: A Systematic Review. J Minim Invasive Gynecol 2015. Mar-Apr;23(3):317-30.PMID: 26611613

Driessen SRC, Blikkendaal MD, Twijnstra ARH, Jansen FW.
Een kwestie van een goede keuze; kwaliteitsindicatoren voor laparoscopische hysterectomie. Nederlands Tijdschrift voor Obstetrie & Gynaecologie 2015; 128(mei):140-145.

Driessen SR, Janse JA, Schreuder HW, Jansen FW.
Proficiency for Advanced Laparoscopic Procedures in Gynecologic Residency Program: Do all Residents Need to be Trained? J Surg Educ 2015;72(5):942-948. PMID: 25921187

Driessen SR, Baden NL, van Zwet EW, Twijnstra AR, Jansen FW.
Trends in the implementation of advanced minimally invasive gynecologic surgical procedures in the Netherlands. J Minim Invasive Gynecol 2015;22(4):642-647. PMID: 25655043

Arkenbout EA, van den Haak L, **Driessen SR**, Thurkow AL, Jansen FW.
Assessing basic “physiology” of the morcellation process and tissue spread: a time-action analysis. J Minim Invasive Gynecol 2015;22(2):255-260. PMID: 25460321

Janse JA, **Driessen SR**, Veersema S, Broekmans FJ, Jansen FW, Schreuder HW.
Training of hysteroscopic skills in residency program: the Dutch experience. J Surg Educ 2015;72(2):345-350. PMID: 25439181

Driessen SR, Arkenbout EA, Thurkow AL, Jansen FW.
Electromechanical morcellators in minimally invasive gynecologic surgery: an update. J Minim Invasive Gynecol 2014;21(3):377-383. PMID: 24462590

Bogaerts-Samama MJW, **Driessen SRC**, Jenninga E, Delemarre JBVM, Trimbos JB, Westerweel ME.
Outcome and medium-term functional results of anterior rectopexy for rectocele repair. Gynecol Surg 2014; 11:257-260

Twijnstra AR, Blikkendaal MD, **Driessen SR**, van Zwet EW, Kroon CD, Jansen FW.
Tailor-made proficiency curves in laparoscopic hysterectomy: enhancing patient safety using CUSUM analysis. Gynecol Surg 2014;(11):235-240.

Peters AAW, **Driessen SRC**.
Ineens onduldbare buikpijn. In: Bohn, Stafleu, van Loghum, editors. Gynaecologie praktische huisarts geneeskunde. 2013:37-49.

Driessen SR, Haans LC, Puylaert JB.
[Uterine fibroids complicated by haematometra]. Ned Tijdschr Geneeskd 2012;156(47):A5398. PMID: 23171564

Driessen SR, den Hartog WC, Peters AA.
[Actinomycosis resembling an ovarian malignancy]. Ned Tijdschr Geneeskd 2012;156(16):A4511. PMID: 22510419

Curriculum Vitae

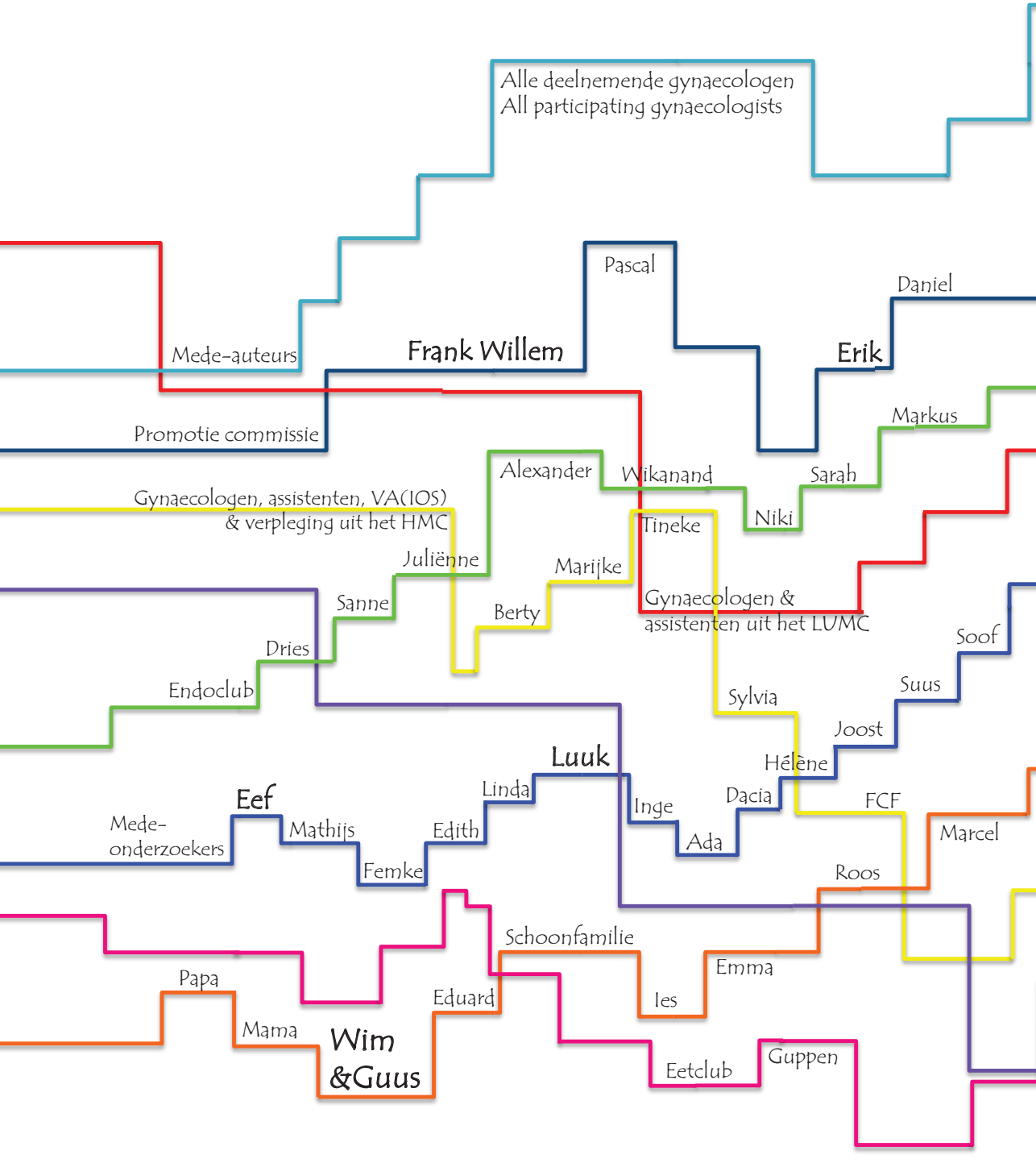
Sara Driessen was born on the 25th of September 1985 in Utrecht. In 2003 she graduated from secondary school at the Christelijk Gymnasium in Utrecht.

After her graduation she first took a year off to backpack in Central America before she started medical school at the Leiden University in 2004. After obtaining her bachelor's degree she went on a public health exchange to the regional hospital of Mangochi in Malawi. In 2009 she started her regular internships for which she also went to Suriname to attend her internship of Pediatrics. In 2011 she attained her medical degree and started to work as a physician (ANOIS) at the department of Obstetrics and Gynaecology at Haaglanden Medisch Centrum, the Hague (Dr. M.J. Kagie).

In March 2013 she started her PhD program as an AIOSKO (PhD candidate and resident OBS/GYN) at the department of Gynaecology (section Minimally Invasive Surgery) at the LUMC under supervisor of Prof. Dr. F.W. Jansen. In March 2016 she returned to Haaglanden Medisch Centrum to start her residency (Dr. M.J. Kagie), which she will continue at the LUMC (Prof. Dr. J.M. van Lith) in 2017.

Sara lives together with Wim de Jong and their son Guus (2014) in the Hague and expecting a daughter in May 2017.

DANK!


Alle deelnemende gynaecologen
All participating gynaecologists
Mede-auteurs
Frank Willem
Pascal
Daniel
Erik
Promotie commissie
Markus
Alexander
Wikanand
Sarah
Gynaecologen, assistenten, VA(IOS)
& verpleging uit het HMC
Niki
Tineke
Juliënne
Marijke
Sanne
Berty
Gynaecologen &
assistenten uit het LUMC
Dries
Soof
Endoclub
Sylvia
Suus
Joost
Luuk
Hélène
Linda
Eef
Inge
Dacia
FCF
Mede-
onderzoekers
Mathijs
Edith
Ada
Marcel
Femke
Roos
Schoonfamilie
Papa
Emma
Eduard
Ies
Mama
Wim
&Guus
Eetclub
Guppen