Implementing patient safety in laparoscopic surgery: quality assessment and process analysis

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IMPLEMENTING PATIENT SAFETY IN LAPAROSCOPIC SURGERY

Quality Assessment and Process Analysis

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Voor Cath, Mels, Tijn en mijn ouders

Contents

Chapter 1

General introduction

Due to the wide availability of therapeutic treatment options, nowadays it is not just the availability of care, but mainly the outcome of the care that has become important. To put it more strongly, it is particularly the prevention of suboptimal or undesired outcomes of care that has come to the fore [1]. This trend was first noted by the well-known report of the Institute of Medicine: To Err is Human [2]. At that time the world was first startled by the fact that in the USA alone annually between 44,000 and 98,000 patients die as a result of medical errors. Thus the term '*patient safety*', which is defined as reducing the risk of unnecessary harm associated with healthcare to an acceptable minimum, was born [3].

Quality is obtained by ensuring safety. Safety is ensured by guaranteeing in advance the frameworks in which care is provided. By measuring these processes and outcomes, the quality is determined afterwards [4]. With regard to the introduction of new surgical techniques and technologies (hereinafter referred to as '*new interventions*') it is conventionally recognized that efficacy and safety (i.e. major short-term safety issues) are assessed by means of Randomized Controlled Trials (RCT). To demonstrate long-term safety, cohort studies are the gold standard. The major disadvantage of RCTs is that they are not suitable for detecting complications with a low incidence. In addition, large numbers are required for both study designs, which means that in daily clinical practice such studies can be difficult to perform, for example, when there are rapid successive developments [5]. The question is: how can the quality of care be determined in such a situation?

In order to make quality comprehensible and transparent, quality indicators have been created [6]. Three different types of quality indicators can be distinguished: structure, process and outcome indicators [7]. Structure indicators assess the setting in which care takes place (e.g. the adequacy of facilities and equipment; the qualifications of medical staff). Process indicators examine the process of care itself (e.g. technical competence in the performance of surgical procedures; adherence to guidelines). Finally, outcome indicators (e.g. mortality, return to work) are the most frequently used by doctors as an indicator of the quality of healthcare. A major disadvantage of outcome indicators is that outcomes are influenced by many factors other than medical care itself. Using process indicators eliminates this problem as they focus on applying what is now known to be 'good' medical care. Although the estimates of quality that one obtains are less fixed/definite than those derived from the measurement of outcomes, they may be more relevant to the question at hand: whether medicine is properly practiced [7]. However, scientifically well-founded quality indicators are scarce.

Concerns with respect to potentially preventable damage are recognized in the field of minimally invasive surgery (MIS), especially in advanced laparoscopic procedures. These concerns are mainly due to two factors. The first factor is the use of advanced technology

in this surgical technique. This results in a high number of errors that are attributable to equipment [8, 9]. Secondly, MIS is already very safe in general. The introduction of a new intervention can thus potentially yield only marginal benefits, but unexpectedly could also entail new risks with possibly much greater consequences [10]. An example is the occurrence of capacitive coupling between an insulated electrode and a surrounding metal sleeve that has been suggested as the cause of unintended injury during laparoscopy [11, 12]. This pitfall was also emphasized in a report published by the Dutch Health Care Inspectorate (IGZ) in 2007 [13]. One of the suggested measures that had to be taken to prevent laparoscopic surgery from being unnecessarily risky was to guarantee patient safety by developing a quality-control system. Ideally, such a system should be based on clinically relevant indicators for quality.

Especially in MIS, new interventions are introduced in rapid succession or even simultaneously into the operating room (OR). To guarantee safety during this process, ideally, this implementation is preceded by performing a Prospective Risk Inventory (PRI) based on the Healthcare Failure Mode and Effect Analysis method (HFMEA) [14]. This approach has been promoted in the guideline 'New interventions into clinical practice' that was developed by the Dutch Order of Medical Specialists (OMS) in 2014 [15]. However, according to this guideline, an analysis of safety and effectiveness should be performed after 6 to 12 months *after* the actual introduction. Therefore safety *during* this first period of the introduction of new interventions is not completely ensured [10, 16]. Inherently, this causes a potential patient safety hazard that should be prevented.

Nevertheless, detection of safety issues during the introduction of new interventions is difficult [5]. One of the current theories about the origin of adverse events is the Swiss cheese model, which has been described by Reason [17]. Only in situations in which a variety of contributing factors combine to breach the many barriers and safeguards (i.e. when all holes are aligned) an adverse event may occur. The crux is therefore to find markers for the near misses and to learn from them so that they can be prevented in the future [18]. Clinicians must therefore actively seek other measuring instruments to continue to guarantee safety even during the introduction of new interventions.

Safety is monitored not only during a surgical procedure but also during the entire perioperative process. Technical solutions that autonomously ensure safety in the OR are being widely implemented. Well known are the systems that provide continuous monitoring of sterility, door movements, air temperature and air quality [19]. More recent developments are systems that report the location and maintenance status of the devices [20]. Both of these technical solutions constantly monitor factors that potentially affect the safety during the procedure and consequently lower the risks of adverse outcomes. However, monitoring of the progress of the surgical procedure is still depending almost completely on manpower.

A system that can automatically monitor the progress of the surgical procedure in real-time can offer many benefits. Due to increased efficiency of the OR schedule, more interventions will be ready during daytime instead of being delayed in after-hours. This is desirable, in particular with respect to the current staffing at all departments during after-hours [21]. Therefore, there are many initiatives worldwide to increase the efficiency of the OR [22]. This is typically attempted by better planning, i.e. better estimation in advance of the planned duration of the procedure [23]. However, the course of surgical procedures seems to be difficult to predict in practice [24]. Perioperative delays are very common in surgical procedures and moreover are hard to anticipate beforehand. Currently, any deviation from the planning must be recognized by the OR team and/or the OR manager. The OR schedule is therefore unreliable and not comprehensible for other participants throughout the process (patient ward, holding/recovery department, OR cleaning services, hospital transport, surgeon of next procedure etc.) [25, 26]. Allowing technical solutions to take over this task can support the clinicians better and more accurately so that they can engage in their primary task: to provide good care. This can potentially further improve the quality and safety of the surgical process [27].

To ensure patient safety during the introduction of new interventions in MIS, both the clinical questions and the technical process should be addressed. Therefore, the main objectives of this thesis are:

- To obtain clinically relevant tools to evaluate quality of minimally invasive surgical procedures, both in general as well as specifically regarding laparoscopic hysterectomy (LH), as the most frequently performed advanced gynecological MIS procedure; and
- To support clinicians to ensure surgical safety by means of process analysis.

Outline of this thesis

Conversion is suggested in the report of the Dutch Healthcare Inspectorate as a potential quality indicator [13]. The main reason for this is that a patient is exposed to the risks of complications specific to both surgical approaches if the laparoscopic procedure is converted to a laparotomy. Moreover, between different hospitals, a wide range of conversion rates are reported for the same procedures. However, these numbers cannot be used for reliable comparison at this time because very different definitions are used for what is referred to as conversion. Furthermore, in literature there is no consensus regarding an unambiguous definition and the same definitions are interpreted differently between different specialties. **Chapter 2** describes a study aimed at achieving multidisciplinary consensus on a generally applicable definition of conversion in laparoscopic surgery by means of the Delphi approach.

Furthermore, based on the results of a prospective cohort study and after obtaining systematic data on conversion rates, **Chapter 3** hypothesizes the extent to which conversion rate can act as a means of evaluation in an advanced MIS procedure. The LH was chosen as the procedure under research, requiring a wide array of endoscopic instruments and equipment.

A major complication after LH whose causation is sought in the applied technique and/or technology is the vaginal cuff dehiscence (VCD). The risk of VCD after an LH is higher than after vaginal or abdominal hysterectomy [28, 29]. The technology (e.g. type of electrosurgery used for the colpotomy) as well as the technique (type of suture and suturing technique) are thought to affect the risk of VCD. However, very few well-conducted RCTs or cohort studies are available, due to the rapid succession of new techniques and electrosurgical devices that are used. Since the facts have not been elucidated after all these years, a detailed analysis of occurred VCDs may further unravel the etiology of this major complication. **Chapter 4** compares the incidence of vaginal cuff dehiscence after different suturing methods of the vaginal vault after LH.

A group of patients that is a priori at risk for adverse events after surgery are the very obese and morbidly obese (BMI ≥ 35 kg/m^2). Undeniably, the prevalence of these patients has been rapidly increasing in Western countries in the past decades [30, 31]. Obesity can cause a number of gynecological diseases, such as abnormal uterine bleeding and endometrial hyperplasia [32]. As a result, a higher prevalence of enlarged uteri and especially a higher incidence of endometrial carcinoma are observed among these patients [33-35]. Inherently, the number for which hysterectomy is indicated has been rising over time. However, since this group of patients is almost always excluded from RCTs based on their BMI, no conclusive evidence on the preferred route of hysterectomy is available. In **Chapter 5** the outcomes of abdominal, laparoscopic and vaginal hysterectomy in very obese and morbidly obese patients (BMI ≥ 35 kg/m^2) are evaluated by means of a systematic review with cumulative analysis.

Currently, a measurement tool to monitor safety at the time of introduction of new interventions in MIS procedures does not exist. A novel method to evaluate safety is by observing the presence and effect of '*surgical flow disturbances*' during the course of a surgical procedure. These disturbances are defined as stimuli that distract one or more members of the sterile team and could potentially precede a safety issue (i.e. the Swiss cheese model) and are thus a good marker for measuring safety [36, 37]. Up till now, the most widely used method of assessing safety is analysis by a human observer in the OR. However, safety issues are complex and sometimes only noticeable afterwards. In addition, an observer in the OR influences the behavior of the team and/or the course of a procedure (Hawthorne effect) and can hardly identify real-time consequences of previous actions with subsequent effects [27, 38, 39]. Video observation

overcomes these shortcomings and is therefore acknowledged as the ultimate way to analyze the surgical workflow and assess safety in retrospect. Using video observation, in a prospective observational study, we compare a conventional OR with an integrated OR with regard to the incidence and effect of equipment-/instrument-related surgical flow disturbances during an advanced laparoscopic gynecological procedure (i.e. LH) (**Chapter 6**).

However, in daily clinical practice, extensive analysis of the entire procedure is difficult to perform. Firstly, it is time consuming and therefore expensive; at the same time, also privacy issues can be an obstacle. A specific questionnaire filled in by all members of the OR team (surgeon, scrub nurse, anesthetist(-assistant)) could possibly serve as a proxy for the presence of these surgical flow disturbances. Therefore, **Chapter 7** observes whether judgments of the surgical team are a reliable measure of surgical safety. A questionnaire that had to be filled out immediately after surgery was developed to measure surgical safety. Next, the validity of the questionnaire was assessed by comparison with the results from independent video analysis of these procedures.

Finally, **Chapter 8** describes a novel system for automated procedural progress monitoring that will be able to predict the remaining procedure duration. First, it is tested whether adaptation of the planned procedure duration with phase-specific reference data provides a reliable estimation of the actual procedure duration. Subsequently, the requirements for an automated real-time procedural progress monitoring system are described.

In **Chapter 9** the general discussion of the findings is provided and perspectives for future research will be given. **Chapter 10** gives a summary of this thesis.

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Chapter 2

Achieving consensus on the definition of conversion to laparotomy: a Delphi study among general surgeons, gynecologists, and urologists

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Abstract

Background: In laparoscopic surgery, conversion to laparotomy is associated with worse clinical outcomes, especially if the conversion is due to a complication. Although apparently important, no commonly used definition of conversion exists. The aim of this study was to achieve multidisciplinary consensus on a uniform definition of conversion.

Methods: On the basis of definitions currently used in the literature, a web-based Delphi consensus study was conducted among members of all four Dutch endoscopic societies. The rate of agreement (RoA) was calculated; a RoA of >70% suggested consensus.

Results: The survey was completed by 268 respondents in the first Delphi round (response rate, 45.6%); 43% were general surgeons, 49% gynecologists, and 8% urologists. Average ± standard deviation laparoscopic experience was 12.5 ± 7.2 years. On the basis of the results of round 1, a consensus definition was compiled. Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes: strategic conversion, a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically and because of anticipated operative difficulty or logistic considerations; and reactive conversion, the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e., >15 min in time). A laparotomy after a diagnostic laparoscopy (i.e., to assess the curability of the disease) should not be considered a conversion. In the second Delphi round, a RoA of 90% was achieved with this definition.

Conclusions: After two Delphi rounds, consensus on a uniform multidisciplinary definition of conversion was achieved within a representative group of general surgeons, gynecologists, and urologists. An unambiguous interpretation will result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a laparoscopic procedure.

Introduction

Inherent to laparoscopic surgery is a risk of conversion to conventional laparotomy. This risk depends on a combination of indication, disease and patient characteristics, and surgeon skill. In the past, the conversion rate was used to determine the feasibility of the laparoscopic approach [1, 2]. Nowadays, this rate could more specifically be used as a means of evaluation [3]. In general, compared to a procedure completed laparoscopically, a conversion is associated with worse outcomes, such as a longer length of surgery, more postoperative complications, and a longer hospital stay [4, 5]. The outcomes after a conversion due to a complication (reactive) are significantly worse in comparison to those after a strategic conversion in order to prevent an intraoperative complication in case of anticipated operative difficulty (e.g., dense adhesions, underlying or additional pathology) [6, 7].

To date, a uniform registration of conversions is not common practice. Moreover, some consider each laparotomy during a laparoscopic procedure a conversion [8], while others consider only a laparotomy due to an intraoperative complication [9, 10] or an incision larger than 7 cm to be a conversion [11, 12]. As a result of this inconsistency, comparison between centers, procedures, and the literature is not reliable, and any observed difference is likely to be explained by the lack of an unambiguous and generally accepted definition. This is increasingly recognized, and it is frequently stated that a unified and consistent definition of conversion must be obtained [4, 5, 13].

In general, a good definition has to be clear, easy to interpret, and complete, thereby covering every situation and even the (rare) exceptions. This can be obtained by stating the *genus* and *differentia* and by taking into account the five rules of Copi and Cohen [14]: focus on essential features, avoid circularity, capture the correct extension, avoid figurative or obscure language, and be affirmative rather than negative. Only when such a definition exists and is used consistently can conversion be a reliable means of evaluation, can it be used for reliable comparison between surgeons and/or clinics, and can it provide reliable grounds for the comparison of procedures that are performed now and in the future.

The goal of this study was to achieve multidisciplinary consensus on a generally applicable definition of conversion in laparoscopic surgery by means of the Delphi approach.

Materials and methods

Study design

On the basis of definitions of conversion that are currently used in the literature, a Delphi consensus study was conducted. The Delphi technique is a widely used consensus method that allows a large group of individuals to achieve consensus on a complex problem effectively by structuring the group communication process [15]. In repeated rounds, the respondents are polled individually and (quasi-)anonymously, with self-administered surveys [16, 17]. In each subsequent round, the results of the previous round are provided, thus enabling the range of answers to converge toward a consensus. This process is repeated until an acceptable level of consensus is reached. The data were collected between August 2011 and December 2012. An overview of the study design is presented in Figure 2.1.

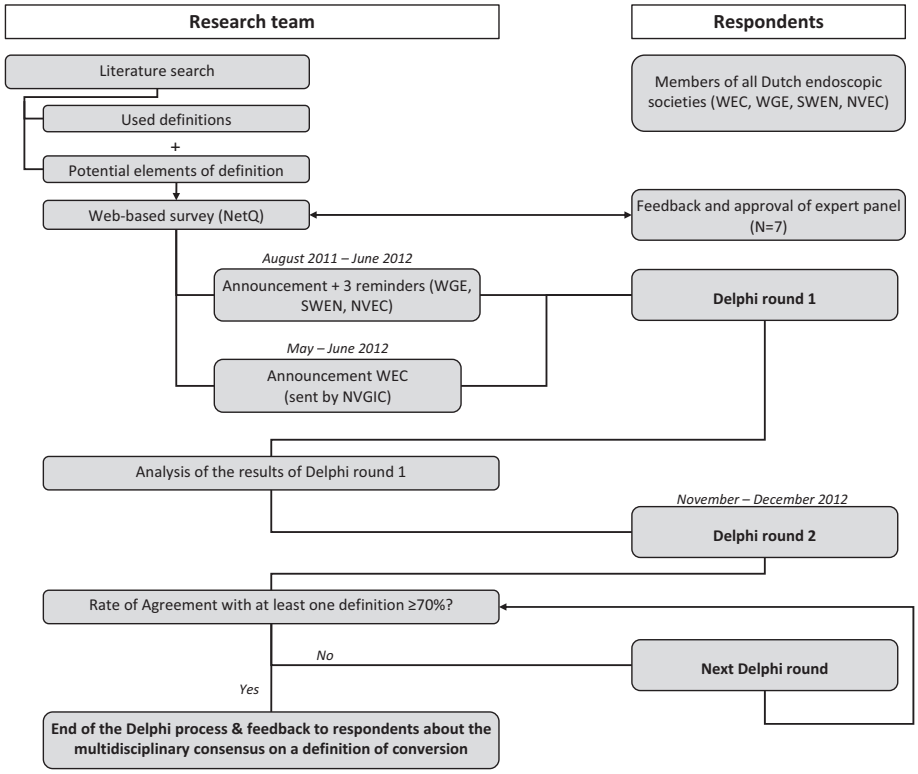

Figure 2.1 Flow chart of the Delhi technique used in this study to achieve multidisciplinary consensus on a generally applicable definition of conversion in laparoscopic surgery.
WEC = Working group Endoscopic Surgery, part of Dutch Society for Gastrointestinal Surgery, WGE = Working group Gynecologic Endoscopy, SWEN = Foundation Working group Endourology, NVEC = Dutch Society of Endoscopic Surgery, NVGIC = Dutch Society for Gastrointestinal Surgery.

Survey

Through the design of the web-based survey, the possible outcome was twofold. Ideally, an acceptable level of agreement with a definition that is currently used in the literature would already exist or would be established by the Delphi procedure. If not, on the basis of the (dis)agreement of the respondents with elements that could be present in a definition, a new definition could be compiled and introduced in the subsequent round or rounds. In this way, we tried to obtain an optimal balance between objectivity and the effectiveness of the Delphi process.

The survey consisted of four parts (see Appendix 2.1). Part I asked the respondents to state the definition of conversion they used in their daily practice (free text). These definitions were categorized on the basis of the presence of essential elements in the definition of conversion by two persons independently. Part II included the different elements that potentially could be present in a (new) definition of conversion. They were isolated from the definitions that are currently used in the literature. This part enquired after the current use of each specific element and provided some clinical scenarios. The scenarios had to be marked as a laparoscopic or laparoscopic-assisted procedure, or as a strategic or reactive conversion. The questions in this part were individually routed according to the answers provided. Part III consisted of definitions that are currently used in the literature. These were both definitions that were stated in studies covering the same topic and a selection of definitions used in recent observational studies with conversion or conversion rate as an outcome measure. The respondents were asked to state their agreement with each definition on a 5-point Likert scale, from -2 (strongly disagree) to +2 (strongly agree). Additionally, the respondents were able to indicate whether they were of the opinion that the definition would be useful in daily practice. To avoid bias, we did not provide any references of the definitions in the survey. The last part included physician demographics and characteristics of their surgical practices.

Selection of experts

A panel of senior laparoscopists with extensive experience in advanced procedures (three general surgeons, three gynecologists, and one urologist) was consulted beforehand to provide feedback on the survey. After incorporating their comments and obtaining their approval, we e-mailed the survey using an online survey tool (NetQ) to the members all four endoscopic societies: Working Group Endoscopic Surgery [WEC, part of the Dutch Society for Gastrointestinal Surgery (NVGIC); general surgeons], Working Group Gynecologic Endoscopy (WGE), Foundation Working group Endourology (SWEN), and the Dutch Society of Endoscopic Surgery (NVEC; multidisciplinary). Additionally, three reminders were sent to those who did not respond or who did not fully complete the survey. Double responses that were the result

of membership in multiple societies and data of partially completed surveys were discarded. The response rate was based on the number of fully completed surveys.

All answers were collected and analyzed by Microsoft Excel and SPSS software, version 20. A Pearson chi-square test was used to compare proportions, and p values of <.05 were considered statistically significant. The rate of agreement (RoA) was calculated by subtracting the number of respondents who (strongly) disagree from those who (strongly) agree and by dividing that by the total number of respondents:

$$\text{RoA} = \frac{(\text{strongly})\text{agree} - (\text{strongly})\text{disagree}}{(\text{strongly})\text{agree} + (\text{stronlgy})\text{disagree} + \text{indifferent}} \times 100\%$$

A RoA of >70% suggests consensus on the definition, and a RoA of ≤70% justifies rejection of the definition [18]. With respect to questions with dichotomous answers, 80% in one category was defined as the cutoff for consensus [19]. To avoid reduction in response rate with repeated questions due to respondent fatigue, in subsequent rounds, only questions were asked on which no consensus existed. The complete process ceased when consensus on a definition was obtained [18].

Results

Respondents

The response rate in the first round was 45.6% (268 completed surveys from 588 potential responders). Of the respondents, 43% were general surgeons (n = 116), 49% were gynecologists (n = 131), and 8% were urologists (n = 21). The denominator consisted of 275 general surgeons [member of WEC (approximation) and/or NVEC], 282 gynecologists (member of WGE and/or NVEC), and 31 urologists (member of SWEN and/or NVEC). Half of all respondents worked in a university-affiliated teaching hospital, 20% in a tertiary referral/university center, and 29% in a nonteaching hospital. The majority performed advanced laparoscopic procedures (general surgeons 94%, gynecologists 67%, urologists 95%). Over half of the respondents (53%) had performed laparoscopic procedures for >10 years; another 34% for 5–10 years (average ± standard deviation experience, 12.5 ± 7.2 years). Approximately two-thirds (64%) performed >50 laparoscopic procedures annually, and 24% performed 25–50 procedures per year. With respect to open procedures, 45% performed >50 annually, and another 28% performed 25–50 procedures annually. More than two-thirds (71%) used a conversion registration that is at least annually discussed or presented in a report.

Delphi round 1: elements potentially present in a definition of conversion

The definition of conversion that the respondents currently applied (answered as free text) were categorized on the presence of specific elements (Table 2.1). The most common element present in the definition was a deviation from the plan of the procedure: 51% stated a switch from laparoscopy to laparotomy has to be unplanned in order to be considered as a conversion. Furthermore, 45% responded that a conversion can be performed at any time during a laparoscopic procedure, while a minority (6%) was of the opinion at least some laparoscopic dissection had to be done before laparotomy. A reason for the conversion was

Table 2.1 Categorization of the presence of specific elements in the free-text definitions supplied by the respondents (part 1 of the survey, N = 267)

Characteristic	n (%)
Reason	108 (40)
Strategic and reactive	50 (19)
Only strategic	24 (9)
Only reactive	4 (1)
Any	29 (11)
No progression	1 (0)
Schedule	
Unplanned	137 (51)
Time	136 (51)
Intraoperative	120 (45)
Early vs. late	1 (0)
During the therapeutic part of the procedure	15 (6)
Incision	28 (10)
Standard	14 (5)
Any	8 (3)
Specific (midline, Pfannestiel, etc.)	5 (2)
Length	20 (7)
Larger than specimen	9 (3)
Larger than planned	6 (2)
Larger than trocar	1 (0)
Larger than hand-assistence	2 (1)
Larger than abdominal equivalent	1 (0)
Larger than 7 cm	1 (0)
Assisted	
Distinction between totally laparoscopic and laparoscopic-assisted or hand-assisted	10 (4)
Technique	9 (3)
No optics / no instruments	6 (2)
No pneumoperitoneum	2 (1)
No optics and no pneumoperitoneum	1 (0)

present in 40% of the supplied free-text definitions. Most frequently a subdivision between strategic and reactive (i.e., after an intraoperative complication) reasons for conversion was made (19%).

In the next part of the survey, when specifically asked, overall, 56% (n = 149) responded that they stated the reason for the conversion (reactive or strategic) in their registration of conversions (47% among general surgeons, 60% among gynecologists, and 71% among urologists, p = .04). The most common grounds for this subdivision were "additional insight in the indication" (74%) and "difference in morbidity" (54%). In five out of the seven clinical scenarios, between 93 and 97% of the respondents agreed on the type of conversion (either strategic or reactive) (Table 2.2). Only regarding a conversion due to anesthesiologic problems (42% reactive; 53% strategic) and a conversion due to technical failure of the equipment (50% reactive; 46% strategic) did no consensus exist on the type of conversion (equal among specialties, p = .892 and p = .835, respectively).

Table 2.2 Clinical scenarios regarding type of conversion (n = 149): a laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy if it was due to…

	Strategic		Reactive		No conversion	
	Round 1 (%)	Round 2 (%) [a]	Round 1 (%)	Round 2 (%) [a]	Round 1 (%)	Round 2 (%) [a]
… a large iatrogenic bleeding?	3		97		1	
… visibility / mobility problems?	97		1		2	
… an internal organ lesion?	3		93		4	
… extensive intra-abdominal adhesions?	95		3		3	
… underlying / additional pathology?	95		1		5	
… anesthesiologic problems?	53	49	42	50	5	1
… technical failure of the equipment?	46	35	50	64	3	1

[a] Only responses on which no consensus was achieved were asked again in the second round.

With respect to the moment of conversion, it seemed clear that if during the preoperative briefing it was decided to perform a standard laparotomy instead of a laparoscopic procedure, it was not considered a conversion (94%). Similarly, a planned switch to a laparotomy after a diagnostic laparoscopy (i.e., to assess the curability of the disease) was not considered a conversion (90%). On the other hand, an unplanned switch to a laparotomy directly after the assessment of the feasibility of completing the procedure laparoscopically (e.g., in case of underlying/additional pathology) was considered a conversion by 64% of the respondents (general surgeons 72%, gynecologists 59%, urologists 57%, p = .088).

Regarding the incision used, 66% responded that every type of abdominal incision potentially could be registered as a conversion. Among the others, 25% stated an incision for conversion should be similar to the incision required for the laparotomic equivalent of the same procedure.

With respect to the registration of an extension of a port site, overall, 17% (n = 46) indicated that they use the term *laparoscopic assisted* (general surgeons 31%, gynecologists 7%, and urologists 5%, p < .001). Among these respondents, a variation was observed within the presented clinical scenarios regarding the registration of an extended port site: ''an incision larger than usual,'' 41% laparoscopic, 48% laparoscopic assisted; ''any incision for specimen retrieval,'' 54% laparoscopic, 46% *laparoscopic assisted*; and ''an incision as large as the conventional open approach for retrieval of the specimen,'' 54% laparoscopic assisted, 35% conversion (n = 46 for all). Of those who did indicate that they did not use the term *laparoscopic assisted* (83%, n = 219), 94% did not consider an incision for specimen retrieval to be a conversion. However, an incision as large as the conventional open approach for retrieval of the specimen would be registered as a conversion by 52% of these respondents.

Delphi round 1: RoA with the definitions currently used in the literature

Although none of the definitions that were found in the literature was identical, we were able to group those that contained the same essential elements into nine different definitions (Table 2.3) [1, 8, 9, 12, 13, 20-23]. On the basis of the Likert scale, the calculated RoA for each definition ranged between -10 and +85% (Table 2.3). Two of these (Kolkman et al. [21] [75%] and Leonard et al. [1] [85%]) resulted in a RoA of >70%. Among the different specialties, both these RoAs did not differ (76% general surgeons, 72% gynecologists, 90% urologists, p = .614; 89% general surgeons, 82% gynecologists, 86% urologists, p = .564).

Delphi round 2

In concordance with the Delphi method, questions on which no consensus was achieved were asked again in the second round, together with a summary of the results of the first round. During the interim analysis of the results of round 1, it was found that both definitions that received a RoA of >70% were not able to discriminate indifferently in all situations between strategic or reactive conversion and no conversion. Because this was regarded as an important requirement for a uniform definition [14], a more specific definition, entirely based on the above-mentioned results of the first round, was compiled (Table 2.4). Because 17 respondents stated that they were not willing to participate in subsequent rounds, the second Delphi round was sent to 251 persons, of whom 191 fully completed the survey (response rate 76.1%).

Table 2.3 Different elements present in the definitions of conversion that we identified in the literature

Definition of conversion	Reason	Schedule / time	Type of incision	Length of incision	Specimen retrieval	RoA	
						Round 1 (N = 268)	Round 2 (N = 191)
Any incision made earlier than initially planned to complete the procedure [13]		X	X			-12%	
Open abdominal access through a more than 7-cm long skin incision [12]				X		-6%	
Any laparotomy other than extension of a port to remove the specimen [23]			X		X	15%	
A vertical incision greater than necessary for specimen retrieval [22]			X	X	X	10%	
Any laparotomy procedure performed for any reason [8]	X		X			16%	
A case that could not be completed endoscopically as planned [21]		X				75%	67%
The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties [1]	X	X	X			85%	91%
Failure of the planned procedure [20]		X				28%	
A substitution of laparoscopy by laparotomy for intraoperative complications [9]	X	X				61%	

In the last 2 columns, the rate of agreement (RoA) with each of these definitions is shown. RoA = [(Agreement - Disagreement)/(Agreement + Disagreement + Indifferent)] x 100%. A RoA of >70% allows acceptation of the recommendation, and a RoA of ≤70% justifies rejection of the recommendation [18].

The respondents were asked again to provide their agreement with the two definitions with the highest RoA from round 1 (respectively, 68 and 91% in round 2; Table 2.3). Additionally, the newly compiled definition was added. This definition resulted in a RoA of 90% (Table 2.4).

The latter was the preferred definition by 60% of the respondents, and in its current form, 93% considered this compiled definition applicable as a multidisciplinary definition. The definition of Leonard et al. [1] (Table 2.3) was preferred by 31% and was considered applicable by 87%. Therefore, after the second round, the compiled definition was adopted for consensus.

Within the 34% who did suggest the use of a separate definition for a laparoscopic-assisted procedure (n = 64), 53% preferred ‘‘any incision larger than required for laparoscopic

equipment and not being a conversion," while 42% suggested the definition used by Dindo et al. [7] ("a small-target incision for specimen retrieval").

The Delphi process was ceased after two rounds because consensus on a multidisciplinary applicable definition was achieved (Table 2.4).

Table 2.4 Definition of conversion that was compiled entirely based on the results of round 1 (RoA 90% in round 2)

Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of 1 of the 2 subtypes:
• Strategic conversion is a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically[a] and because of anticipated operative difficulty or logistic considerations
• Reactive conversion is the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e., >15 min in time)

[a] A laparotomy after a diagnostic laparoscopy (i.e., to assess the disease) should not be considered a conversion.

Discussion

Consensus on a uniform and multidisciplinary applicable definition was achieved after two Delphi rounds (Table 2.4). This definition received a very high RoA in Delphi round 2 (90%), was preferred by most respondents, and was considered applicable in its current form. The survey was performed within a representative group of laparoscopically experienced general surgeons, gynecologists, and urologists in the Netherlands (N = 268).

Because a converted laparoscopic procedure is associated with worse or similar outcomes compared to an initially primary laparotomy, conversion has received much attention as a means to evaluate the feasibility of newly introduced laparoscopic techniques. Nevertheless, most laparoscopic surgeons are of the opinion that conversion is inherent to laparoscopy and should not be regarded as a complication [6, 24, 25]. If laparoscopy fails, the surgeon always has the possibility to switch to the conventional abdominal approach. Still, the conversion rate can also be used as a means to evaluate indication, patient selection, and surgeon experience and skills [3, 13, 26]. However, proper evaluation and comparison is not possible until a clear, uniform, and generally accepted definition of conversion is used.

Only in the field of laparoscopic colorectal surgery have both the associated differences in morbidity and the definition of conversion been subject to research [4-7, 13, 27]. Gervaz et al. [5] found that only 30% of the studies stated the definition of conversion that was used. Shawki et al. [13] tried to obtain consensus on a definition within a group of laparoscopic

colorectal surgeons. In their survey, 68% agreed on the definition "any incision made earlier than initially planned to complete the procedure." However, in our opinion, although this definition is brief and concise, it leaves too much room for interpretation, lacks the differentiation between strategic and reactive conversions, and is only valid for colorectal procedures. In general, all these studies concluded that no consistent definition was currently used in the literature, and to our knowledge, in the international literature no uniform multidisciplinary definition of conversion has yet been obtained. These findings support the need to compile a uniform multidisciplinary applicable definition. This definition was entirely based on the results of round 1, which was completed by a large and broad group of experienced laparoscopists. Furthermore, the response rate of 46% was considered acceptable, both compared to the average response rate in other survey studies and especially compared to the response rate in the only other study on this subject (29%) [13, 28]. Therefore, the validity of the responses appears to be high, and the definition on which we achieved consensus seems widely supported.

Having taken into account the rules of Copi and Cohen [14], the first part of the consensus definition (Table 2.4) consists of the *genus*: the essence of each conversion is the switch from a laparoscopic to an open abdominal approach during the procedure. Then, because of the difference in morbidity, two subtypes with each a specific set of *differentia* are defined. In order to qualify as a strategic conversion, the laparotomy must be made before extensive dissection is done and before the decision is made that the procedure can be performed entirely laparoscopically. Furthermore, the laparotomy must be standard—that is, the type of incision that would be used for a conventional primary open abdominal approach. Reasons could be either anticipated operative difficulty (e.g., extensive adhesions, a large immobile structure) or logistic considerations (e.g., time constraints due to a busy operating schedule). This implies that a conversion performed at this stage of the procedure and because of a complication (e.g., a vessel or bowel injury) cannot be marked as strategic. It has to be noted that a laparotomy after a true diagnostic laparoscopy (i.e., to assess the curability of the disease, thereby preventing the patient from a laparotomy in case no therapeutic steps can/have to be performed) should not be registered as a conversion.

The first *differentium* of a reactive conversion is the need for a laparotomy. In other words, there is a necessity for the laparotomy, and it could be each type of abdominal incision. Second, one reason for this type of conversion could be the presence of a complication requiring laparotomy. In the absence of a complication, another reason could be either anticipated or experienced operative difficulty that is discovered after a considerable amount of dissection. Given the associated morbidity described in the literature, an evidence-based cutoff would be 15 min of dissection (starting after establishment of the pneumoperitoneum) [29]. This allows some dissection, thus enabling an optimal assessment of the feasibility of

completing the procedure laparoscopically. Although conversion should be regarded a safety step [26], a switch to laparotomy after a considerable amount of laparoscopic operating time because of a lack of progress indirectly implies that an inadequate judgment has been made during the assessment of the feasibility of completing the procedure laparoscopically, and that during some part of the procedure, an unnecessary combined risk of complications existed. It is important to realize that (extension of) an incision for specimen retrieval does not meet the criteria of either subtype and therefore should not be registered as a conversion. Importantly, because the researcher must maintain a subject-neutral role in the Delphi method, it was safeguarded that only elements on which already consensus existed after the first Delphi round were included in this compiled definition.

During Delphi round 1, in five out of the seven clinical scenarios, the type of conversion was already interpreted in concordance with the consensus definition (Table 2.2). Only the subdivisions of a conversion due to anesthesiologic problems and due to technical failure of the equipment were answered as ''indifferent.'' Applying the consensus definition to these scenarios, the differentiation between the type of conversion in case of anesthesiologic reasons depends entirely on the moment the decision is made. If the decision to convert is made during the assessment of the feasibility of completing the procedure laparoscopically, it should be regarded as a strategic conversion. However, if at first both the anesthetist and the surgeon judged a laparoscopic procedure to be feasible and after a considerable amount of dissection time (i.e., >15 min) ventilation problems and/or insufficient Trendelenburg or visualization of the operating field are experienced, it should be regarded as a reactive conversion. Similarly, because technical failure of the equipment that results in a conversion is regarded a complication [30], this should be interpreted as a reactive conversion.

The most important implication of a uniform and multidisciplinary used definition will be a more reliable comparison of (new) laparoscopic procedures. Additionally, given the differences in morbidity associated with the type of conversion, a subdivision into strategic and reactive conversions will provide detailed insight into the advantages or disadvantages of the procedure under research. Moreover, patient informed consent will improve as well.

Consensus on the registration of an incision for specimen retrieval and the definition of a laparoscopic-assisted procedure was not achieved. Although subject to debate, we are of the opinion that, in line with proper registration of converted procedures, laparoscopic procedures that require an incision for specimen retrieval should be adequately categorized. Most importantly, this will enable future research on technological developments that could make the (enlarged) incision for specimen retrieval superfluous. Only by adding a proper registration of laparoscopic-assisted procedures as well can the true morbidity associated with totally laparoscopic procedures be elucidated.

The size of the expert panel (N = 268) may be considered rather large, which is partially explained by the multidisciplinary design of the study. The reasons for approaching members of all endoscopic societies in the Netherlands were simultaneously to conduct this study and to create awareness among clinicians about this subject, as well as to create a final definition within an entire group of specialists performing (advanced) laparoscopic surgery. A panel consisting of 15–30 persons could have been prone to selection bias and would have resulted in a definition that should have been communicated to the entire field of laparoscopic surgeons as a top-down approach. A downside of a large panel is the fact that it is harder to reach consensus. The fact that we were able to reach consensus even within this large panel supports the proposed definition. On the other hand, it is stated that ''the output of the Delphi method is only as good as the experts selected for the panel.'' One could argue if every member of an endoscopic society should be considered an expert. However, the demographics show that this group is a rather experienced group, the majority of which performs advanced procedures. Furthermore, the compiled definition was preferred by 60% of the respondents, followed by the definition of Leonard et al. [1] (31%) (RoA 90 vs. 91%). Although only twice as many respondents preferred the compiled definition, in our opinion, these figures reflect a nuance in preference because these two definitions are very similar to each other, and both differentiate between a strategic and a reactive conversion. Therefore, we adopted the most preferred definition for consensus instead of performing a third Delphi round. Additionally, it was likely that the secondary questions on which no agreement of >80% was achieved would not converge significantly toward a consensus in subsequent rounds.

In conclusion, after two Delphi rounds, a high level of consensus within a representative group of general surgeons, gynecologists, and urologists was achieved on a uniform multidisciplinary definition differentiating between a strategic and a reactive conversion (Table 2.4). An unambiguous interpretation will consequently result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a surgical procedure, provided that this definition becomes obligatory to be adopted in laparoscopic surgery.

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Appendix 2.1

The original questions used for this manuscript were translated from Dutch. Included are all answers that were given (in percentages).

Round 1 (N = 268)

Part I:

Q1: What is the definition of conversion you are currently applying in your daily practice?
A: Free text (see Table 2.1)

Part II – Specific elements that could be present in a (new) definition of conversion (*some questions were individually routed according to the given answers*):

Q2: Regarding the registration of a conversion in the patient file: Do you differentiate between a laparotomy because of a complication ('reactive') and a laparotomy due to the inability to complete the procedure laparoscopically ('strategic')?
A:
- Yes (56%) →(routing to Q3)
- No (44%) →(routing to Q5)

Q3: "A laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy, in case it was due to …"
A:

	Strategic	Reactive	No conversion
… a large iatrogenic bleeding?	3%	97%	1%
… visibility / mobility problems?	97%	1%	2%
… an internal organ lesion?	3%	93%	4%
… extensive intra-abdominal adhesions?	95%	3%	3%
… underlying / additional pathology?	95%	1%	5%
… anesthesiologic problems?	53%	42%	5%
… technical failure of the equipment?	46%	50%	3%

Q4: Please mark why you differentiate between strategic and reactive conversion in your registration (multiple answers possible)

A:
- Difference in associated morbidity (54%)
- Recommendation in the multidisciplinary guideline Minimally Invasive Surgery (42%)
- Provides insight in the indication (74%)
- Provides insight in the skills of the surgeon (23%)
- Strategic conversion is a diagnostic laparoscopy followed by a laparotomy (21%)
- Means of evaluation / Quality indicator (31%)
- Other, …. (10%)

(*routing to Q7*)

Q5: "*A laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy, in case it was due to …*"

A:

	Conversion	No conversion
… a large iatrogenic bleeding?	98%	2%
… underlying / additional pathology?	84%	16%
… anesthesiologic problems?	93%	7%
… technical failure of the equipment?	97%	3%

Q6: Please mark why you don't differentiate between strategic and reactive conversion in your registration (multiple answers possible)

A:
- No difference in associated morbidity (21%)
- Superfluous (31%)
- Strategic conversion are a diagnostic laparoscopy followed by a laparotomy (26%)
- Other, …. (34%)

Q7: "How would you register a laparoscopically (planned) procedure, when …"

A:

	Conversion	No conversion
… during the preoperative briefing it is decided to perform a laparotomy?	6%	94%
… directly following the diagnostic laparoscopy a switch to laparotomy is made (as planned)?	10%	90%
… following the diagnostic laparoscopy a switch to laparotomy is made because of underlying / additional pathology (not as planned)?	64%	36%

Q8: Ihn what percentage of your laparoscopic procedures an extra incision or enlargement of an existing port site is made because of specimen retrieval?

A:
- Never (5%)
- 1–5% (27%)
- 5–10% (21%)
- 10–15% (12%)
- >15% (32%)
- Other, … (3%)

Q9: Do you use the term 'laparoscopic-assisted' with regard to the registration of an abdominal incision for specimen retrieval?

A:
- Yes (17%) →(*routing to Q10*)
- No (83%) →(*routing to Q11*)

Q10: Indicate how you would register the following clinical scenarios

A:

	Laparoscopic	Laparoscopic-assisted	(Strategic) conversion
If a larger then commonly used incision is necessary to complete this fully laparoscopic procedure	41%	48%	11%
If an incision for specimen retrieval is necessary	54%	46%	0%
If after the laparoscopic part of the procedure an incision as large as the conventional open approach for retrieval of the specimen is necessary	11%	54%	35%
If the specimen is morcellated	93%	4%	2%

(*routing to Q12*)

Q11: Indicate how you would register the following clinical scenarios

A:

	Conversion	No conversion
If an incision for specimen retrieval is necessary	6%	94%
If an incision as large as the conventional open approach for retrieval of the specimen is necessary	52%	48%

Q12: Which type of abdominal incision could potentially be registered as a conversion? (multiple answers possible)

A:
- Midline incision (15%)
- Pfannenstiel incision (12%)
- Lateral flank (McBurney, etc.) (9%)
- Every type of abdominal incision (66%)
- Similar to the incision required for the laparotomic equivalent of the same procedure (25%)
- Other, …. (3%)

Part III – Agreement with definitions currently used in the literature:

Q13: Please indicate to what extent you agree with the definitions of conversion used in the literature. Additionally, you can indicate if you are of the opinion that the definition could be useful in daily practice.

A:

	Strongly disagree	Disagree	Neither agree/ nor disagree	Agree	Strongly agree	Useful
Any incision made earlier than initially planned to complete the procedure	13%	35%	15%	19%	13%	14%
Open abdominal access through a more than 7-cm long skin incision	12%	32%	18%	26%	9%	6%
Any laparotomy other than extension of a port to remove the specimen	10%	28%	10%	30%	17%	15%
A vertical incision greater than necessary for specimen retrieval	10%	25%	19%	30%	12%	7%
Any laparotomy procedure performed for any reason	11%	22%	18%	26%	19%	12%
A case that could not be completed endoscopically as planned	3%	6%	7%	42%	35%	27%
The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties	2%	4%	3%	35%	42%	42%
Failure of the planned procedure	7%	18%	22%	31%	18%	12%
A substitution of laparoscopy by laparotomy for intraoperative complications	3%	9%	15%	39%	29%	13%

(*For calculated RoAs, please see Table 2.3 in the manuscript*)

Part IV – Demographics:

Q14: In what type of hospital are you currently working?

A:
- Non-teaching hospital (29%)
- University-affiliated teaching hospital (51%)
- Tertiary referral / university center (20%)

Q15: Which specialism do you perform?

A:
- General surgeon (43%)
- Gynecologist (49%)
- Urologist (8%)

Q16: Which procedures do you regularly perform laparoscopically?

A:

General surgeons		Gynecologists		Urologists	
Cholecystectomy	99%	Sterilization	98%	Varicocelectomy	25%
Appendectomy	99%	Cystectomy	91%	Ureterostomy	45%
Inguinal hernia repair	65%	Adnexectomy	98%	Pyelothomy	65%
Bariatric surgery	20%	Ectopic pregnancy	90%	Cystectomy	20%
Colorectal surgey	90%	Hysterectomy	66%	Adrenalectomy	40%
Nissen fundoplication	41%	Myomectomy	26%	(Radical) prostatectomy	60%
Adrenalectomy	22%	Endometriosis resection	46%	Nefrectomy	90%
Nefrectomy	5%	Other, …	16%	Other…	65%
Other, …	20%				

Q17: Are conversions centrally registered (on behalf of an annual discussion or report)?

A:
- Yes (71%)
- No (29%)

Q18: How many years are you currently working as a specialist?

A: Free text (0–5 years: 30%. 5–10 years: 24%. >10 years: 46%)

Q19: How many years of experience with laparoscopy do you have?

A: Free text (0–5 years: 13%. 5–10 years: 34%. >10 years: 53%)

Q20: How many laparoscopic procedures do you perform annually?

A:
- <10 (1%)
- 10–25 (11%)
- 25–50 (24%)
- 50–100 (29%)
- >100 (35%)
- Other, … (0%)

Q21: How many open abdominal procedures do you perform annually?

A:
- <10 (8%)
- 10–25 (19%)
- 25–50 (28%)
- 50–100 (30%)
- >100 (15%)
- Other, … (0%)

Round 2 (N = 191)

Part I:

Q1: The previous round resulted in two definitions with a very high Rate of Agreement (RoA). All other definitions resulted in a considerably lower RoA (-12% to 61%). Please indicate again to what extent you agree with these definitions.

A:

	Strongly disagree	Disagree	Neither agree/ nor disagree	Agree	Strongly agree
The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties (RoA 85%)	1%	4%	1%	31%	64%
A case that could not be completed endoscopically as planned (RoA 75%)	2%	10%	8%	51%	29%

(*For calculated RoAs, please see Table 2.3 in the manuscript*)

Q2: During the interim analysis of the results of Round 1 it was found that above mentioned definitions were not able to discriminate indifferently in all situations between '(strategic or reactive) conversion' and 'no conversion'. Since this is regarded an important requirement for a uniform definition, a more specific definition, entirely based on the results of the first round, was compiled. Please indicate to what extent you agree with this definition.

A:

	Strongly disagree	Disagree	Neither agree/ nor disagree	Agree	Strongly agree
Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes: • Strategic conversion: a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically* and because of anticipated operative difficulty or logistic considerations • Reactive conversion: the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e. in time >15 minutes) * A laparotomy after a diagnostic laparoscopy (i.e. to assess the curability of the disease) should not be considered as a conversion	1%	3%	4%	47%	46%

(*For calculated RoA, please see Table 2.3 in the manuscript*)

Q3: With which of the three above mentioned definitions you agree most?

A:
1 The need for a standard laparotomy at any time during the procedure, either because of complications or technical difficulties (31%)
2 A case that could not be completed endoscopically as planned (9%)
3 Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes: (60%)
   - Strategic conversion: a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically* and because of anticipated operative difficulty or logistic considerations
   - Reactive conversion: the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e. in time >15 minutes)

   * A laparotomy after a diagnostic laparoscopy (i.e. to assess the curability of the disease) should not be considered as a conversion

Q4: Concerning the definition with which you agree the most: Do you consider this definition in its current form to be applicable as a multidisciplinary definition? (if no, multiple answers possible)

A:	1. The need …	2. A case …	3. Conversion to …
• Yes	87%	76%	93%
• No, not specific enough	2%	12%	3%
• No, incomplete	3%	6%	2%
• No, too much room for interpretation	5%	12%	2%
• No, unclear	0%	0%	0%
• No, other …	3%	0%	2%

Q5: During the previous round, it seemed that consensus already existed on the registration of the type of conversion in five out of the seven clinical scenarios (strategic conversion: visibility / mobility problems (97%), extensive intra-abdominal adhesions (95%), underlying / additional pathology (95%); reactive conversion: a large iatrogenic bleeding (97%), an internal organ lesion (93%)).

"*A laparotomy is performed during a laparoscopic procedure. How would you register the laparotomy, in case it was due to …*"

A:

	Strategic	Reactive	No conversion
… anesthesiologic problems?	49%	50%	1%
… technical failure of the equipment?	35%	64%	1%

Q6: During the previous round, 30% of the respondents indicated they make an extra incision or enlargement of an existing port site because of specimen retrieval in 1–5% of their procedures and 61% in >5% of their procedures. Furthermore, 18% of the respondents indicated they register this type of procedures as 'laparosopic-assisted'.

Are you of the opinion that also for the registration of this type of procedures a (separate) definition is necessary?

A:
- Yes, this type should also be specified in the definition of conversion (4%)
- Yes, this type should be specified in a separate definition (34%)
  → (*routing to Q7*)
- No, this type is similar to 'conversion' (3%)
- No, this type is completely different from conversion (and its definition) (58%)
- No opinion (2%)

Q7: Which definition of 'laparosopic-assisted' procedures do you prefer?

A:
- Any incision larger than required for laparoscopic equipment and not being a conversion (53%)
- A small-target incision for specimen retrieval (Dindo, Surg Endosc, 2009) (42%)
- Other, … (5%)

Chapter 3

Clinical relevance of conversion rate and its evaluation in laparoscopic hysterectomy

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Abstract

Study objectives: To estimate the current conversion rate in laparoscopic hysterectomy (LH); to estimate the influence of patient, procedure, and performer characteristics on conversion; and to hypothesize the extent to which conversion rate can act as a means of evaluation in LH.

Design: Prospective cohort study (Canadian Task Force classification II-2).

Setting: The study included 79 gynecologists representing 42 hospitals throughout the Netherlands. This reflects 75% of all gynecologists performing LH in the Netherlands, and 68% of all hospitals.

Patients: Data from 1534 LH procedures were collected between 2008 and 2010.

Intervention: All participants in the nationwide LapTop registration study recorded each consecutive LH they performed during 1 year.

Measurements and main results: Conversion rate and odds ratios (OR) of risk factors for conversion were calculated. Conversions were described as reactive or strategic. The literature reported a conversion rate for LH of 0% to 19% (mean 3.5%). In our cohort, 70 LH procedures (4.6%) were converted. Using a mixed-effects logistic regression model, we estimated independent risk factors for conversion. Body mass index (BMI) ($p = .002$), uterus weight ($p < .001$), type of LH ($p = .004$), and age ($p = .02$) had a significant influence on conversion. The risk of conversion was increased at BMI >35 (OR 6.53; $p < .001$), age >65 years (OR 6.97; $p = .007$), and uterus weight 200 to 500 g (OR 4.05; $p < .001$) and especially >500 g (OR 30.90; $p < .001$). A variation that was not explained by the covariates included in our model was identified and referred to as the ''surgical skills factor'' (average OR 2.79; $p = .001$).

Conclusion: Use of estimated risk factors (BMI, age, uterus weight, and surgical skills) provides better insight into the risk of conversion. Conversion rate can be used as a means of evaluation to ensure better outcomes of LH in future patients.

Introduction

To spare women the customary abdominal incision, laparoscopic hysterectomy (LH) was adopted 20 years ago as a minimally invasive alternative to conventional abdominal surgery [1]. As a result, women are protected from the increased risk of blood loss, wound infection, and prolonged recovery [2]. If laparoscopy fails, the surgeon always has the possibility to "escape" by conversion to the conventional abdominal approach. Therefore, most gynecologists are of the opinion that conversion is inherent to laparoscopy and should not be regarded as an adverse event [3–5].

In previous publications, conversion rate was used to justify the feasibility of the laparoscopic approach [6]. However, to date, conversion rates in LH are still mentioned, yet no specific conclusions are drawn from these outcomes. As can be imagined, conversion that involves combined exposure to the general risk of the laparoscopic approach followed by an additional laparotomy is associated with substantially worse postoperative outcomes [7,8]. In addition, the indication for conversion is important. Several studies in the field of laparoscopic colorectal surgery have found that conversion because of an intraoperative adverse event ("reactive," e.g., a lesion of the ureter) is associated with higher postoperative morbidity than is conversion to prevent an adverse event in case of operative difficulties ("preemptive" or "strategic," e.g., adhesions) [9,10]. As a consequence, proper documentation of a conversion and its indication is essential.

In LH, strategic conversions can occur for a number of reasons. An enlarged immobile uterus and/or severe adhesions can obstruct sufficient visibility of the operative field. Furthermore, additional disease (e.g., a more advanced stage of cancer than expected) might dictate immediate conversion to the conventional approach. Also, patient risk factors such as (morbid) obesity might impede the laparoscopic approach; for example, the anesthesiologist is challenged to such an extent that conversion is required for patient safety. This subdivision into strategic and reactive conversions can provide information about indication, patient selection, and surgeon experience and skill. Therefore, we hypothesized that conversion rate may serve as a means of evaluation of the quality of a series of performed LH procedures.

In the past decade, quality assurance of the surgical process has been given increasing attention [11]. With the ultimate goal to improve quality of care, quality assurance enables evaluation and interpretation of variations in treatment, which in turn can be linked to treatment outcomes [12,13]. We believe that the importance of quality assurance in minimally invasive gynecology is currently underestimated. Given that in the near future an increasing number of LH procedures will be performed because of wider implementation of this surgical technique, the absolute number of conversions is likely to increase over time. To stay ahead of these developments and to answer the increasing demands of health inspectors,

professionals, and patients, it is essential to acquire better insight into conversion rate as a means of evaluation in LH.

The objective of the present study was 3-fold. First, on the basis of prospectively obtained data, we estimated the influence of patient, procedure, and performer characteristics on conversion in LH. Second, because no systematic data on conversion rates is available at present, we performed a systematic search of the literature to provide a basis for evaluation. Third, supported by these two results, we hypothesize the extent to which conversion rate can act as a means of evaluation in laparoscopic hysterectomy.

Materials and methods

To provide a current estimate of the conversion rate in LH, we searched the literature on PubMed using the following terms: "hysterectomy," "laparoscopy," and "conversion." We limited the results to original observational studies and randomized controlled trials published after 2000, written in English, and with an available abstract. We excluded all publications concerning robotic (assisted) hysterectomy, single-incision, and/or radical hysterectomy because of oncologic indications. We also excluded studies that did not report the actual percentage of procedures converted to laparotomy. In cases in which the indication for conversion was clearly mentioned, we calculated the percentage of strategic conversions.

To estimate independent risk factors for conversion in LH, we analyzed the data obtained from the LapTop study (2008–2010), a prospective nationwide cohort in which 79 gynecologists in the Netherlands who performed LH procedures were enrolled and for 1 year registered each LH that he or she performed as a primary surgeon. This represented 75% of all gynecologists performing LH in the Netherlands, and 68% of hospitals (n = 42). Potential risk factors for conversion were identified and consisted of patient, procedure, and performer characteristics. In addition to the age of the patient and the indication for LH, these characteristics included body mass index (BMI), previous abdominal surgery including cesarean section, and ASA (American Society of Anesthesiologists) classification. Procedure characteristics included the type of LH performed (i.e., laparoscopic-assisted vaginal hysterectomy, supracervical laparoscopic hysterectomy [SLH], or total laparoscopic hysterectomy [TLH]), accompanying salpingo-oophorectomy, and uterus weight (in grams, weighed in the operating room). Performer characteristics included the actual number of LH procedures performed including the procedure to be registered. To ensure that all LH procedures performed were submitted, we double-checked 10% of the cases with the actual operating room statistics for each clinic. Parts of the collected data related to patient and surgeon factors as predictors of blood loss, operative time, and adverse events have been published elsewhere [14].

Adverse events were registered for type, severity (i.e., requiring repeat intervention or not), and moment of onset, according to the definitions and regulations as determined by the guidelines for adverse events of the Dutch Society of Obstetricians and Gynecologists [15]. Conversion to laparotomy was defined as an abdominal incision made after the laparoscopic start-up. Strategic conversions (e.g., due to inadequate visibility, adhesions, or additional disease) were differentiated from conversions to laparotomy because of an adverse event (reactive conversion). Additional information on the indication for conversion was to be reported in the comment section.

The procedure and the patient and performer characteristics of this cohort were analyzed using statistical software (SPSS version 17.0; SPSS, Inc., Chicago, IL). The 95% confidence intervals (CIs) were calculated, and $p < .05$ was considered statistically significant. The distribution of continuous and ordinal variables was tested for normality using the Kolmogorov-Smirnov test. To describe non-normally distributed data the median, interquartile range (25^{th} and 75^{th} percentiles), and range (minimum and maximum values) were used. For the clinical relevance of the outcomes, we stratified a number of continuous variables: BMI (<25, 25–35, and >35), age (<45, 45–65, and >65 years), and uterus weight (<200, 200–500, and >500 g). As a reference category for categorical variables, we chose the most relevant category, preferably with the most cases. We used a mixed-effects logistic regression model to calculate the adjusted log odds ratio (OR) of each risk factor for conversion using statistical software (R-2 version 10.0) with the lme4-package [16]. In the case of a categorical variable, the OR was relative to the reference category. The variables included in the model had to either show a significant association in the univariable analysis or be marked as clinically important by the researchers.

The influence of surgical experience (number of LH procedures performed) was estimated in 2 ways. First, we estimated whether the risk of conversion is influenced by surgical experience, on a continuous scale per 10 consecutively performed procedures. Second, we estimated whether a dichotomous cutoff of >30 procedures influences the risk of conversion because this value is generally accepted as the individual learning curve [17,18].

We took into account that we observed multiple procedures for each surgeon [19]. Two procedures performed by the same surgeon tend to be “more similar” than 2 procedures performed by 2 different surgeons. We modeled this type of similarity by using a mixed-effects logistic regression model, thus including random contributions specific to each surgeon. The standard deviation (SD) of these random contributions (estimated at log odds of the exponent) capture differences between surgeons that are not explained by the included covariates of the model. Because our model corrects for all measurable patient and surgeon factors, this SD can be interpreted as an OR of factors that are not measurable as a number

with a unit such as the skills of the surgeon and the functionality of the complete operating team. Because the surgeon is ultimately responsible for the surgical procedure as a whole, we referred to this variation that is not explained by directly measurable factors as the "surgical skills factor." Using this approach, the calculated surgical skills factor can be used as an OR, describing the a priori difference in the risk of conversion between 2 randomly selected surgeons.

Results

From the literature search, we found a conversion rate in LH of 0% to 19% (Table 3.1) [20–52]. We found 33 relevant studies describing a total of 7827 procedures, of which 264 (3.5%) were converted to laparotomy. We calculated that 73% of conversions could be regarded as strategic in those studies that provided the reason for conversion.

A total of 1534 LH procedures were performed during the study (2008–2010). The mean experience (number of LH procedures performed) per gynecologist at the start of the study was 51 procedures (median, 28; range, 0–250). During the 12-month study, the mean (SD; range) number of LH procedures performed per year was 14.9 (10.7; 1–50).

A total of 70 LH procedures (4.6%; 95% CI, 4.3–4.9) were converted, of which 22 (31.4%; 95% CI, 22.9–40.0) were identified as a reactive conversion, and 48 (68.6%; 95% CI, 60.0–77.1) as a strategic conversion (Table 3.2). The primary reasons for a reactive conversion were uncontrollable bleeding (63.6%), internal organ lesions (13.6%), and technical failure of equipment (13.6%). Strategic conversions were primarily due to visibility or mobility problems as a result of altered anatomy (e.g., adhesions or myomas; 70.8%); a uterus too large to be removed in one piece in case of malignancy, and therefore contraindicated for morcellation; (14.6%); and anesthesiologic problems due to morbid obesity (BMI > 40; 10.4%).

In the course of the 1-year study, 42 gynecologists reported no conversions, whereas 46.8% of the performing surgeons had to convert to laparotomy at least once; their individual conversion rate ranged from 1.3% to 33.3%. Experience in more than 30 LH procedures did not correlate with the risk of conversion ($p = .73$). Moreover, the distribution between strategic and reactive conversions was not correlated with experience in more than 30 LH procedures ($p = .17$).

Overall patient and procedure characteristics are given in Table 3.3. The independent risk factors for conversion were BMI ($p = .002$), age ($p = .02$), uterus weight ($p < .001$), and type of LH ($p = .004$) (Table 3.4). Relative to the reference category of these risk factors, important categories were BMI >35 (OR, 6.53; $p < .001$), age >65 years (OR, 6.97; $p = .007$), uterus weight 200 to 500 g (OR, 4.05; $p < .001$), and uterus weight >500 g (OR, 30.90; $p < .001$). Compared

Table 3.1 Reported conversion rates in laparoscopic hysterectomy

Source, year	Type of LH	Study design	No. of procedures	No. of conversions	Conversion rate (%)	Strategic conversion (%)
Brummer et al [20], 2009	Mixed	Prospective cohort	1686	87	5.2	76
Candiani et al [21], 2009	TLH	Prospective cohort	30	0	0	NA
Chang et al [22], 2005	LAVH	Prospective cohort	225	2	0.9	0
Chen et al [23], 2008	LAVH	Prospective cohort	147	1	0.7	0
Daraï et al [24], 2001	LAVH	RCT	40	3	7.5	67
David-Montifiore et al [25], 2007	Mixed	Prospective cohort	121	23	19.0	65
Donnez and Donnez [26], 2010	Mixed	Prospective cohort	400	0	0	NA
Drahonovsky et al [27], 2010	Mixed	RCT	125	3	2.4	Unknown
Erian et al [28], 2005	SLH	Prospective cohort	100	0	0	NA
Garry et al [29], 2004	Mixed	RCT	920	32	3.5	72
Ghezzi et al [30], 2010	TLH	RCT	41	0	0	NA
Ghomi et al [31], 2007	SLH	Prospective cohort	60	1	1.7	0
Holub et al [32], 2001	LAVH	Prospective cohort	271	3	1.1	33
Johnston et al [33], 2007	Mixed	Prospective cohort	364	4	1.1	75
Karaman et al [34], 2007	Mixed	Prospective cohort	1120	26	2.3	92
Kluivers et al [35], 2007	Mixed	RCT	27	2	7.4	100
Kreiker et al [36], 2004	LAVH	Prospective cohort	160	5	3.1	100
Leung et al [37], 2007	Mixed	Prospective cohort	143	1	0.7	100
Lieng et al [38], 2005	SLH	Prospective cohort	43	1	2.3	0

Table 3.1 continues on next page

Table 3.1 ***Continued***

Source, year	Type of LH	Study design	No. of procedures	No. of conversions	Conversion rate (%)	Strategic conversion (%)
Long et al [39], 2002	Mixed	Prospective cohort	104	3	2.9	Unknown
Mourits et al [40], 2010	TLH	RCT	185	20	10.8	60
Mueller et al [41], 2011	TLH	Prospective cohort	567	1	0.2	100
Muzii et al [42], 2007	LAVH	RCT	40	2	5.0	0
Obermair et al [43], 2012	TLH	RCT	404	24	5.9	Unknown
Ottosen et al [44], 2000	LAVH	Prospective cohort	40	4	10.0	75
Pan et al [45], 2008	TLH	Prospective cohort	132	9	6.8	100
Persson et al [46], 2006	LAVH	RCT	63	3	4.8	33
Schütz et al [47], 2002	LAVH	Prospective cohort	28	0	0	NA
Seracchioli et al [48], 2002	TLH	RCT	60	1	1.7	0
Sesti et al [49], 2008	LAVH	RCT	50	0	0	NA
Shahid et al [50], 2011	SLH	Prospective cohort	29	0	0	NA
Soriano et al [51], 2001	LAVH	RCT	40	3	7.5	100
Wang et al [52], 2005	LAVH	Prospective cohort	62	0	0	NA
Total			**7827**	**264**	**3.5**	**73**[a]

LAVH = laparoscopic-assisted vaginal hysterectomy; LH = laparoscopic hysterectomy; NA = not applicable; RCT = randomized controlled trial; SLH = supracervical laparoscopic hysterectomy; TLH = total laparoscopic hysterectomy.

[a] Weighted average.

Table 3.2 Primary reason for strategic and reactive conversions (N = 1534)

Variable	n (%)	95% CI
Strategic conversion	48 (68.6)	60.0–77.1
Visibility/mobility problems	34 (70.8)	
Risk of spillage	7 (14.6)	
Anesthesiologic problems	5 (10.4)	
Reactive conversion	22 (31.4)	22.9–40.0
Uncontrollable bleeding	14 (63.6)	
Internal organ lesion	3 (13.6)	
Technical failure of equipment	3 (13.6)	
Total conversions	70 (4.6)	4.3–4.9

CI = confidence interval.

Table 3.3 Overview of primary patient and procedure characteristics and adverse events in total cohort (N = 1534)[a]

Patient characteristics	Median	IQR[b]	Minimum-Maximum
Age, yr	46.4	41.7–51.1	13.0–89.3
BMI	27.5	22.5–28.1	17.5–56
Parity	2	0–2	0–5
Uterus weight, g	150	97–285	14–1600
Indication for LH	No. (%)		
Dysfunctional uterine blood loss	762 (49.7)		
Uterus myomatosus	420 (27.4)		
(Pre)malignant endometrium or cervix	236 (15.4)		
Endometriosis	34 (2.2)		
Other (prophylaxis, sex change)	80 (5.2)		
Previous abdominal surgical procedure			
None	918 (59.9)		
1	397 (25.9)		
2	143 (9.3)		
>2	50 (3.3)		
Procedure characteristics	**Median**	**IQR[b]**	**Minimum-Maximum**
Operative time, min	110	90–134	32–344
Conversions (N = 70)	120	100–175	34–330
Blood loss, mL	100	50–200	0–2600
Conversions (N = 70)	500	300–950	10–2500

Table 3.3 continues on next page

Table 3.3 ***Continued***

Procedure characteristics	n (%)
Type of LH	
TLH	957 (62.4)
LAVH	185 (12.1)
SLH	391 (25.5)
Bilateral salpingo-oophorectomy	362 (23.6)
Adverse events	**n (%)**
Procedures with ≥1 adverse event	116 (7.6)
Infection	12 (0.8)
Internal organ lesion	29 (1.9)
Vessel lesion	8 (0.5)
Wound dehiscence	15 (1.0)
Blood loss >1000 mL	43 (2.8)
Venous thromboembolism	2 (0.1)
Other	21 (1.4)
Seriousness	
No (re)intervention needed	105 (6.8)
Intervention needed	25 (1.6)
Time of adverse event	
During procedure	67 (4.4)
On hospital ward	36 (2.3)
After hospital discharge	27 (1.8)

BMI = body mass index; IQR = interquartile range; LAVH = laparoscopic-assisted vaginal hysterectomy; LH = laparoscopic hysterectomy; SLH = supracervical laparoscopic hysterectomy; TLH = total laparoscopic hysterectomy.
[a] All continuous and ordinal variables given were not normally distributed.
[b] IQR (25th and 75th percentiles).

with TLH, performing SLH significantly decreased the risk of conversion (OR, 0.32; p = .02). History of abdominal surgery, ASA classification, accompanying salpingo-oophorectomy, and indication for LH were not associated with conversion. Furthermore, surgical experience, measured both per 10 procedures on a continuous scale (OR, 0.95; p = .09) and with a cutoff of >30 procedures (OR, 0.60; p = .25 (the latter not given in Table 3.4), was also not significantly associated with conversion. Although our model corrected for all of these (measurable) covariates, it repeatedly calculated an influence of the "variation not explained by the covariates" (the SD of the random contributions) on the risk of conversion. Some immeasurable "environmental" factors consisting of factors related to the surgeon, the operating room team, or organizational factors were accountable for this effect and were therefore referred to as the surgical skills factor. The SD of these random contributions was, independent of the included covariates, estimated at a log odds of 1.03 (p = .001) for the risk

of conversion. Therefore, between 2 randomly selected surgeons, on average, an intrinsic OR of 2.79 (Exp[1.03]) on the risk of conversion was present. The multivariable analysis was based on 1292 cases because 242 cases were excluded because of at least 1 missing parameter (15.7%). These excluded cases included 5 converted procedures.

Table 3.4 Risk factors and adjusted OR[a] for conversion to laparotomy in LH[b]

Variable	No. of procedures	Conversions (% of total)	Adjusted OR	95% CI	p value
Age, yr					.02
<45	528	16 (3.0)	1.0	Reference	
45–65	689	40 (5.8)	1.39	0.68–2.83	.37
>65	75	9 (12.0)	6.97	1.72–28.27	.007
Body mass index					.002
<25	531	13 (2.4)	1.0	Reference	
25–35	653	36 (5.5)	1.90	0.90–4.00	.09
>35	108	16 (14.8)	6.53	2.27–18.78	<.001
Uterus weight, g					<.001
<200	760	19 (2.5)	1.0	Reference	
200–500	408	24 (5.9)	4.05	1.87–8.79	<.001
>500	124	22 (17.7)	30.90	11.72–81.48	<.001
Previous abdominal surgical procedures					.54
None	773	38 (4.9)	1.0	Reference	
≥1	519	27 (5.2)	1.20	0.65–2.22	
ASA classification					.12
I	903	35 (3.9)	1.0	Reference	
II	357	24 (6.7)	1.4	0.68–2.72	
III/IV	32	6 (18.8)	5.39	1.12–25.84	
Type of LH					.004
TLH	787	42 (5.3)	1.0	Reference	
SLH	343	11 (3.2)	0.32	0.12–0.83	.02
LAVH	162	12 (7.4)	2.07	0.80–5.36	.13
Bilateral salpingo-oophorectomy					.07
No	1014	52 (5.1)	1.0	Reference	
Yes	278	13 (4.7)	0.39	0.13–1.16	
Indication					.79
Dysfunctional uterine bleeding	656	28 (4.3)	1.0	Reference	
Uterus myomatosus	361	23 (6.4)	0.83	0.39–1.75	
(Pre)malignancy, endometrium or cervix	176	13 (7.4)	1.61	0.51–5.06	
Endometriosis	31	1 (3.2)	1.01	0.09–10.83	

Table 3.4 continues on next page

Table 3.4 ***Continued***

Variable	No. of procedures	Conversions (% of total)	Adjusted OR	95% CI	p value
Other (e.g., sex change, prophylaxis)	68	0	NA[c]		
Surgical experience, continuous[d]			0.95	0.89–1.01	.09
Surgical skills factor			2.79[e]		.001

ASA = American Society of Anesthesiologists; CI = confidence interval; LAVH = laparoscopic-assisted vaginal hysterectomy; LH = laparoscopic hysterectomy; NA = not available; OR = odds ratio; SLH = supracervical laparoscopic hysterectomy; TLH = total laparoscopic hysterectomy.
[a] Relative to the reference category in case of a categorical variable.
[b] The mixed-effects logistic regression model was based on 1292 cases because 242 cases were excluded because of ≥1 missing parameter.
[c] Could not be calculated because there were no conversions. This did not affect the adjusted OR of all other covariates.
[d] Per 10 consecutive procedures performed.
[e] Average OR.

Discussion

In most cases (69%), strategic considerations are the reason for converting LH to the conventional abdominal approach. Visibility and/or mobility problems are the primary reason for this type of conversion, whereas uncontrollable bleeding is the primary adverse event leading to a reactive conversion. As reported in other studies, BMI and uterus weight have been confirmed as independent risk factors for conversion [53–55]. However, a new effect demonstrated in our study is that this risk increases with BMI > 35 (approximately 6.5-fold), age >65 years (approximately 7-fold), uterus weight 200 to 500 g (approximately 4-fold), and uterus weight >500 g (approximately 30-fold). However, performing SLH, compared with TLH, decreases the risk of conversion (approximately 3-fold). Surgical experience did not directly correlate with the conversion rate. However, we identified the presence of an intrinsic factor influencing the risk of conversion, which we referred to as the surgical skills factor.

Most LH procedures (>95%) are completed laparoscopically as planned. To facilitate an increase in this rate and further improvement of the quality assurance in LH, in our opinion, conversion rate can be considered a means of evaluation. In general, conversion should be viewed as a phenomenon inherent to laparoscopic surgery, being a calculated risk and a sign of good surgical judgment [56]. Nevertheless, from a quality control point of view, just as registration of adverse events is mandatory in every clinic, this registration should also include the number of conversions and their indication. A subdivision into strategic and reactive conversions will be helpful in daily practice because reactive conversion is associated with a higher risk of postoperative adverse events and prolonged hospital stay [9,10]. In

addition, while strategic conversions potentially are the result of suboptimal preoperative patient evaluation, an insufficiently trained surgeon and operating team might be the cause of either a strategic or reactive conversion. Such registration can be used as an additional means of evaluation of LH in which preeminently the rate of strategic conversions can provide information about patient selection, indication, and surgical skills of the gynecologist and the operating team.

Furthermore, each clinic should evaluate the ratio of vaginal hysterectomies, abdominal hysterectomies, and LH procedures performed over the years. Ideally, on hypothetical grounds, the rate of vaginal hysterectomies must remain steady while an optimum rate of LH should be reached, with subsequent low numbers of primary abdominal hysterectomy procedures [25,57–63]. To accomplish this, we must ensure and further improve the quality of the surgical procedure (in this case, LH) by using additional means of evaluation of the procedure such as the conversion rate and its subdivisions. It can be imagined that surgeons could fear such a measurement and therefore might refrain from the laparoscopic approach in some cases. However, this will deprive patients of the advantages of a minimally invasive approach, consequently obscuring the true indication for the abdominal approach. We would like to stress that the need to perform a conversion will always remain. Moreover, proper registration can be both a means of evaluation and a helpful tool for each surgeon. As a consequence, opportunities are provided that eventually might enable reduction in both the conversion rate in LH and the rate of abdominal hysterectomies as a whole.

With regard to the risk factors for conversion, a number of studies have reported a correlation between surgical experience and conversion rate [4,5,53,64]. However, in the present study we found no significant increase in the risk of (strategic or reactive) conversions in the group of less experienced gynecologists (<30 procedures). This is most probably the result of various teaching or mentorship programs that gynecologists who are novices to LH are now obliged to attend, thereby protecting patients from an increased risk of adverse outcomes and conversions [65].

We repeatedly found that the risk of conversion is significantly influenced (OR, 2.79; $p = .001$) by the presence of an intrinsic factor that, independent of experience, represents surgical skills and the functionality of the operating team. Although this assessment might be somewhat precarious, others have also stated that as a predictor for surgical outcome, surgical skills seem to have a more important role than surgical experience alone and that therefore should not be ignored [66]. Similarly, it has been argued that measuring structures and processes of care, which incorporate individual skills, may be a better means of evaluation than the conventional focus on outcome measurements [67,68]. If we compare testing proficiency in surgery with driving a car, we can state the following metaphor: Not only that the driver has

acquired a driver's license (i.e., completed a learning curve) and how many times he or she has driven a car before determine the outcome of the drive, but also the skills of the driver (or the instructor) and the functionality of the car influence the outcome of each ride. Thus, in our opinion, although easier to assess, surgical experience should not solely be used as a safeguard to prevent conversion. On the contrary, we should be aware of the presence of such an intrinsic surgical skills factor influencing the risk of conversion.

Although studies have been published on ORs that were adjusted for the influence of BMI on conversion rate, our study provides stratified groups rather than an OR per point increase, which makes it clinically more relevant [53,55]. This stratification is, in our opinion, more useful in daily practice and will enable better informed consent.

Some claim that conversion rate is related more to the shape of the uterus rather than its weight (e.g., myomas) [55]. Although we think that shape certainly may influence the outcome, our analysis showed a strong independent association between conversion and uterus weight. With respect to the influence of age on conversion, some studies state no correlation [53,55,69]. However, a recently published nationwide study showed an increasing conversion rate in elderly patients [70]. Furthermore, the significant influence of age >65 years can be explained by a relatively high conversion rate associated with premalignant indications within this subgroup (12.3%; data not shown). Although apparently this combination has an increased risk of (strategic) conversion, it is important to note that most patients in this subgroup can benefit from the advantages of the laparoscopic approach. Moreover, because the premalignant indication shows a trend toward a higher risk of conversion, this explains in part why performing SLH seems to be associated with a significantly lower risk of conversion. Furthermore, in theory, the lack of colpotomy in SLH, often regarded as a difficult surgical step, facilitates lower conversion rates. However, SLH should not be performed at the expense of a proper indication.

On the basis of our findings, we suggest when counseling about the laparoscopic approach that one should be aware of the aforementioned patient risk factors and evaluate one's personal (i.e., team) tendency to convert. When in doubt, one should ask for expert help or refer the patient. However, if past performance is reassuring, challenging patients should also be offered the laparoscopic approach.

The overall conversion rate of 4.6% in LH in our cohort is representative for the Netherlands: 75% of the Dutch gynecologists who perform LH fully participated in the study, and the patient and procedure characteristics were similar to the data we found in the literature [20,29]. However, this figure is somewhat higher than the 3.5% conversion rate identified in our literature review. This is probably because our cohort represents a country as a whole, reflecting daily practice rather than the specific experience of a single surgeon or

center. A limitation of the present study is the influence of possible selection bias because all gynecologists decided according to their individual criteria whether to perform the hysterectomy laparoscopically rather than abdominally or vaginally. However, this reflects the actual clinical situation in which all gynecologists try to use proper indication criteria to the extent of their surgical experience and skills. Furthermore, patient characteristics in our cohort are comparable with those of other large studies [20,29] (Table 3.3). In addition, in collecting our data, we had to rely on each individual gynecologist who submitted each performed procedure. We did not identify any missing procedures during the double-check. In our study design, registration of diagnostic laparoscopy followed by abdominal hysterectomy might potentially have led to underreporting of the number of conversions. However, we cannot think of any indication justifying this option as an optimal treatment, and, based on our definition for conversion (stated in the study protocol), even such a procedure should have been registered as a conversion.

In conclusion, because the present study provides data collected from many centers rather than a single (experienced) center, the results could be interpreted as applying nationwide. We therefore suggest that, supported by our literature review, a conversion rate of <5% can serve as a reference for future comparison. If a hospital exceeds this percentage, it should conduct an audit of its converted LH procedures. The questions to be asked would include the following: Did intraoperative adverse events occur? Were indications properly made? Were the skills of the surgeon and the functionality of the operating team adequate? In addition, the subdivision between strategic and reactive conversions enables better identification of conversions that could be avoided. Furthermore, the balance between strategic (70%) and reactive (30%) conversion provides information on the implementation of the above-mentioned risk factors in the indication for LH. Therefore, conversion rate in general, and the rate of strategic conversions in particular, represent a tool for evaluation of LH. Thus, additional insight into the indications for conversion can be acquired, enabling further improvement in the outcomes in LH and preventing unnecessary conversions in future patients.

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Chapter 4

Vaginal cuff dehiscence in laparoscopic hysterectomy: influence of various suturing methods of the vaginal vault

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Abstract

Vaginal cuff dehiscence (VCD) is a severe adverse event and occurs more frequently after total laparoscopic hysterectomy (TLH) compared with abdominal and vaginal hysterectomy. The aim of this study is to compare the incidence of VCD after various suturing methods to close the vaginal vault. We conducted a retrospective cohort study. Patients who underwent TLH between January 2004 and May 2011 were enrolled. We compared the incidence of VCD after closure with transvaginal interrupted sutures versus laparoscopic interrupted sutures versus a laparoscopic single-layer running suture. The latter was either bidirectional barbed or a running vicryl suture with clips placed at each end commonly used in transanal endoscopic microsurgery. Three hundred thirty-one TLHs were included. In 75 (22.7%), the vaginal vault was closed by transvaginal approach; in 90 (27.2%), by laparoscopic interrupted sutures; and in 166 (50.2%), by a laparoscopic running suture. Eight VCDs occurred: one (1.3%) after transvaginal interrupted closure, three (3.3%) after laparoscopic interrupted suturing and four (2.4%) after a laparoscopic running suture was used ($p = .707$). With regard to the incidence of VCD, based on our data, neither a superiority of single-layer laparoscopic closure of the vaginal cuff with an unknotted running suture nor of the transvaginal and the laparoscopic interrupted suturing techniques could be demonstrated. We hypothesize that besides the suturing technique, other causes, such as the type and amount of coagulation used for colpotomy, may play a role in the increased risk of VCD after TLH.

Introduction

Vaginal cuff dehiscence (VCD) after hysterectomy is an adverse event with potential severe morbidity. The incidence of VCD after total laparoscopic hysterectomy (TLH) varies between 0.3 and 3.1% [1-7]. This is higher compared with the abdominal (AH) and vaginal (VH) approach [1, 8]. Since the continuous increment in the number of hysterectomies performed laparoscopically, the etiology of VCD and explanations for its association with TLH have been subjected to research. Patient characteristics, such as smoking, diabetes, advanced age, radiation therapy and chronic steroid administration, next to precipitating factors such as sexual intercourse, postoperative cuff infection and/or hematoma and increased abdominal pressure (e.g. coughing, vomiting and straining at toilet) have been addressed with regard to their association with VCD [1, 9-10]. Nevertheless, none of these factors are unique for TLH. Therefore, an explanation could very well be found in some specific procedural steps used to achieve a hysterectomy by laparoscopic approach. Some authors state that electrosurgical colpotomy, often used in TLH, is responsible for suboptimal vaginal cuff healing, due to tissue necrosis and prolonged devascularisation [11]. Recently, several studies compared the influence of various vaginal vault closure techniques on the incidence of VCD after TLH. Jeung et al. conducted the only prospective study on this topic and found no difference between laparoscopically sutured interrupted figures-of-eight versus knotted double-layer running sutures (1.6 and 0.8%, respectively) [5]. On the other hand, Uccella et al. reported a threefold increased incidence associated with laparoscopic single-layer interrupted suturing compared with transvaginal closure with interrupted sutures (0.18 and 0.64%, respectively) [7]. However, Siedhoff et al. compared a barbed running suture with other laparoscopic suturing techniques and found no VCDs in the barbed suture group versus a VCD rate of 3.1% for other methods of closure [6]. Similarly, Einarsson et al. described a non-comparative cohort in which the vaginal cuff was closed with a barbed suture. An incidence of 0.6% of the patients requiring vaginal cuff re-suturing was found [3].

Internationally, the etiology of VCD is still a matter of concern. Either in its technique (TLH) as in the used technology (electrosurgical colpotomy and/or suturing method), an explanation could be found for the higher incidence of VCD. In our quest to further improve vaginal vault closure, we have been using various suturing methods. At first, we switched from transvaginal closure of the vaginal vault to laparoscopic closure with interrupted sutures. Thereafter, we started using running sutures: both barbed suturing and an unknotted running suturing technique with clips. To compare these methods, a power analysis indicated that we would have needed 1,349 cases in each arm to detect a desired reduction of 50% in the VCD rate of 3.4% [11] (80% power, type I error 0.05). Since we regarded an adequately powered prospective study to be impossible to perform and given the need for more information, we conducted a retrospective cohort study based on prospectively collected data on this subject.

This study aims to compare the incidence of vaginal cuff dehiscence with transvaginal closure of the vaginal vault versus laparoscopic closure with knotted interrupted sutures versus laparoscopic closure with two different unknotted single-layer running suturing methods.

Materials and methods

A university hospital (Leiden University Medical Centre, Leiden) and an affiliated teaching hospital (Bronovo Hospital, The Hague) participated in this study. All patients who underwent a TLH for benign and (pre)malignant indications between January 2004 and May 2011 were enrolled. Three gynecologists (JPTR, MJGHS and FWJ) performed all procedures and used similar techniques and instruments over time. According to the surgeon's preference and availability, the procedures were performed by one or two surgeons. At the start of the study, all surgeons were already experienced in advanced laparoscopic surgery.

TLH was carried out similar to a recently described technique [12]. Briefly, all classic surgical steps are carried out laparoscopically, using bipolar energy for dissection of the ligaments and coagulation of the vascular pedicles. The bladder peritoneum is dissected with ultrasonic energy and the cervico-vaginal fascia is identified anteriorly. Hereafter, the sacro-uterine ligament is dissected posteriorly and the vaginal fornix is opened circularly using ultrasonic energy, while cranial traction with the uterine manipulator is provided. To the surgeon's preference, during this step (additional), bipolar energy is used as well. The vaginal cuff is sutured transvaginally (interrupted sutures with Vicryl no. 0, Ethicon, Johnson & Johnson Medical GmbH, Norderstedt, Germany) or laparoscopically (interrupted sutures or a running suture, both single-layer). In every stitch, a full thickness bite of approximately 1 cm is obtained, containing recto-vaginal fascia and vaginal mucosa posteriorly and vaginal mucosa and pubo-cervical fascia anteriorly. In laparoscopic closure of the vaginal vault, Vicryl no. 0 is used for the interrupted sutures, which are secured with intracorporeal tied knots. In case of a running suture, two different suturing methods are used according to the surgeon's preference. In one method, a double-armed barbed suture (Quill™ Self-Retaining System; Angiotech Pharmaceuticals Inc., Vancouver, British Columbia, Canada) is used, in which the barbs change direction at mid-point. This suture is bidirectionally sutured from the midline to both lateral angles of the vaginal cuff [13]. In the other, we adopted (off label) a suturing technique commonly used in transanal endoscopic microsurgery (TEM). In this technique a regular Vicryl no. 0 with a suture staple placed at the distal end of the wire is sutured from the right to the left angle of the vaginal cuff, after which another suture staple is placed at the proximal end to secure the suture (suture clip forceps for TEM, Richard Wolf GmbH, Knittlingen, Germany). In all suturing methods, both utero-sacral ligaments are incorporated in the repair and the peritoneum is unclosed.

Patients were evaluated by anamnesis and physical examination 6 weeks postoperatively. Sexually active patients were instructed not to restart sexual intercourse until after this evaluation. All data were derived from a database supplemented by a chart review. For all patients, the type of suture (transvaginal interrupted, laparoscopic interrupted or laparoscopic running) was registered. Furthermore, patient characteristics (age, body mass index (BMI, in kilograms per square meter) and ASA classification) and procedure characteristics (operating time (in minutes, skin-to-skin), blood loss (in milliliter), uterus weight (in grams) and adverse outcomes) were obtained. Adverse events were registered for type of complication, severity (i.e. requiring re-intervention or not) and moment of onset, up to 6 weeks after discharge (i.e. marking the legitimate adverse event reporting period), according to the definitions and regulations as determined by the Guideline Adverse Events of the Dutch Society of Obstetricians and Gynecologists [14].

The primary outcome was the incidence of VCD by type of suture (transvaginal interrupted (group 1) versus laparoscopic interrupted (group 2) versus laparoscopic running (group 3)). According to literature, we defined VCD as a partial or complete separation of the vaginal cuff that required surgical intervention, regardless of the presence of an open peritoneum and/or evisceration [1]. As a secondary assessment, we collected additional data of all these patients to identify possible characteristics associated with this complication. This included the trigger event to onset of dehiscence, presenting symptoms at the time of dehiscence, presence of an open peritoneum, presence of evisceration, type of repair, the interval time (in days) between TLH and dehiscence, relevant comorbidities (i.e. smoking, diabetes, use of immune suppressing drugs and radiotherapy), relevant accompanying complications (i.e. vaginal cuff cellulitis, infection or hematoma), indication for surgery, menopausal status, type of energy used for colpotomy (bipolar, ultrasonic or a combination) and use of prophylactic antibiotics at the time of hysterectomy. All procedures in which the vaginal cuff was sutured by conventional open approach (i.e. after conversion to laparotomy or after a mini-laparotomy for specimen retrieval) were excluded.

To calculate differences between the groups, SPSS 17.0 statistical software (Chicago, IL, USA) was used. A Pearson chi-square test was used to compare proportions, and a one-way analysis of variance (ANOVA) was used for continuous variables. Pairwise t-tests with Bonferroni's correction were used for post hoc multiple comparison. If the condition of a normal distribution (kurtosis between -1 and +2) was not met, additionally a Kruskal–Wallis test was performed to confirm the p value calculated by the ANOVA. P values $< .05$ were considered statistically significant.

Table 4.1 Baseline characteristics of all procedures by suture method of the vaginal vault (transvaginal interrupted versus laparoscopic interrupted versus laparoscopic running) (N = 331)

	Group 1, transvaginal interrupted sutures (n = 75)		Group 2, laparoscopic interrupted sutures (n = 90)		Group 3, laparoscopic running sutures (n = 166)		ANOVA:	Bonferroni:		
							Overall	group 1 versus 2	group 1 versus 3	group 2 versus 3
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	p value	p value	p value	p value
Age (years)	47.2 ± 7.3	(32.5–66.1)	47.5 ± 8.5	(32.8–79.3)	49.0 ± 9.1	(29.0–78.3)	.230	–	–	–
BMI (kg/m^2)	25.3 ± 3.6	(18.1–35.0)	26.3 ± 5.2	(16.2–44.1)	27.5 ± 6.1	(17.5–48.0)	.013	NS	.014	NS
ASA classification[a]	1[b] ± 0.4	(1–2)	1[b] ± 0.5	(1–3)	1[b] ± 0.6	(1–3)	.018	.014	NS	NS
Length of surgery (min)[a]	141 ± 49	(60–335)	128 ± 32	(70–240)	129 ± 40.0	(50–260)	.082	–	–	–
Blood loss (mL)[a]	226 ± 312	(25–2,300)	129 ± 148	(25–1,000)	120 ± 122	(25–800)	< .001	.003	< .001	NS
Uterus weight (g)	283 ± 181	(35–822)	228 ± 163	(35–700)	249 ± 197	(31–950)	.202	–	–	–

SD = standard deviation; NS = not significant.

[a] P value was confirmed by Kruskal–Wallis test because of a non-normal distribution.

[b] Median.

Results

During the study period, a total of 333 TLHs were performed. Of these, two procedures were converted to laparotomy. These two procedures were excluded from further analysis (no VCD reported). Finally, 331 TLHs were included in the analysis. In 75 patients (22.7%), the vaginal vault was closed by transvaginal approach. Laparoscopic interrupted sutures were used for closure in 90 procedures (27.2%), and a laparoscopic running suture was used in 166 procedures (50.2%, 81 barbed sutures and 85 TEM sutures). The baseline characteristics of these three groups are detailed in Table 4.1. Compared with group 2, patients in group 1 had a lower ASA classification ($p = .014$), while blood loss was higher ($p = .003$). Compared with group 3, patients in group 1 had a lower BMI ($p = .014$), while blood loss was higher ($p \leq .001$). This difference in blood loss is partly caused by two procedures in group 1 with an estimated blood loss of 2,300 and 950 mL, respectively (uterus weight 880 and 650 g, respectively; length of surgery 335 and 160 min, respectively). Nevertheless, after exclusion of these two statistical outliers, the differences in blood loss remained significant (mean blood loss in group 1, 188 mL; SD ± 178 mL; $p = .028$ compared with group 2 and $p = .002$ compared with group 3). All other baseline characteristics were comparable between each group.

Overall, eight vaginal cuff dehiscences occurred: one (1.3%) after transvaginal interrupted closure, three (3.3%) after interrupted laparoscopic suturing and four (2.4%) after a laparoscopic running suture was used (Table 4.2). There was no statistical difference with regard to VCD between these three groups ($p = .707$). In addition, we plotted all procedures in a consecutive order—separately for each surgeon—and marked the cases complicated by a VCD. These graphs showed that the VCDs did not tend to occur more frequently within the beginning period of each suturing method (not shown). Furthermore, the overall complication rate (regarding all severities) (20.0 versus 17.8 versus 13.3%, $p = .373$) and the rate of complications requiring re-intervention (2.7 versus 3.3 versus 3.0%, $p = .773$) were similar between the groups as well. In all but three patient records (99.1%), both anamnesis and physical examination during the postoperative clinical evaluation after 6 weeks were

Table 4.2 Incidence of vaginal cuff dehiscence and other complications by type of suture (N = 331)

	Group 1, transvaginal interrupted sutures (n = 75)	Group 2, laparoscopic interrupted sutures (n = 90)	Group 3, laparoscopic running sutures (n = 166)	p value
Vaginal cuff dehiscence (%)	1 (1.3)	3 (3.3)	4 (2.4)	.707
Overall complications (%)	15 (20.0)	16 (17.8)	22 (13.3)	.373
Requiring (re)intervention (%)	2 (2.7)	3 (3.3)	5 (3.0)	.773

Table 4.3 Characteristics of all patients with a vaginal cuff dehiscence

Case	Age (years)	BMI (kg/m²)	ASA	Length of surgery (min)	Blood loss (mL)	Uterus weight (g)	Indication	Post-menopausal	Prophylactic antibiotics	Suture type	Energy used for colpotomy	Trigger event	Presenting symptoms	Time after hysterectomy (days)	Peritoneum open	Evisceration	Type of repair	Relevant comorbidities	Relevant accompanying complications
1	55	35	2	135	100	Unknown	EC	Yes	Yes	Transvaginal interrupted	Bipolar and ultrasonic	Spontaneous	VBL	13	No	No	Transvaginal resuturing	None	Vaginal vault haematoma
2	41	30	1	115	150	Unknown	DUB and UM	No	Yes	Laparoscopic interrupted	Bipolar and ultrasonic	Spontaneous	VBL	15	No	No	Transvaginal suturing	Smoking	None
3	49	25	2	120	155	Unknown	DUB	No	Yes	Laparoscopic interrupted	Bipolar and ultrasonic	Spontaneous	VBL	20	No	No	Transvaginal suturing	None	None
4	56	24	1	105	25	100	EC	Yes	Yes	Laparoscopic interrupted	Bipolar and ultrasonic	Spontaneous	VBL	28	No	No	Transvaginal suturing	None	Granulation
5	46	23	1	110	50	315	UM	Yes	Yes	Laparoscopic running (Quill™)	Bipolar and ultrasonic	Intercourse	VBL and pain	75	No	No	Transvaginal suturing	None	Granulation
6	40	26	1	125	25	360	UM	No	Yes	Laparoscopic running (Quill™)	Bipolar and ultrasonic	Intercourse	VBL and pain	71	Yes	No	Laparoscopic resuturing	None	Fallopian tube prolapse
7	50	25	1	105	200	150	UM	No	Yes	Laparoscopic running (TEM)	Bipolar and ultrasonic	Intercourse	VBL and pain	57	Yes	No	Transvaginal suturing	None	None
8	34	22	1	95	75	140	UM	No	Yes	Laparoscopic running (TEM)	Bipolar and ultrasonic	Intercourse	VBL and pain	41	No	No	Transvaginal suturing	None	Abscess (most likely[a])

EC = endometrial cancer; DUB = dysfunctional uterine bleeding; UM = uterine myomas; TEM = suture method adopted from transanal endoscopic microsurgery (see 'Methods' section); VBL = vaginal blood loss.
[a] Based on anamnesis and physical examination, this VCD most likely occurred after drainage of an abscess during sexual intercourse.

clearly registered. Table 4.3 represents the characteristics of all patients that presented with a vaginal cuff dehiscence. Within the patient and procedure characteristics, no obvious predisposing factors could be identified. All patients received prophylactic antibiotics at time of hysterectomy. During all the procedures, ultrasonic energy and bipolar coagulation were alternately used for colpotomy and hemostasis. All eight patients presented with (heavy) vaginal blood loss. Two cases were (most likely) accompanied by another complication. In the first, an old vaginal vault hematoma appeared to be present during exploration in the operating room. In the last case, based on anamnesis and physical examination, sexual intercourse most likely caused an abscess to 'spontaneously' drain. In at least half of the cases, the patient had marked intercourse as the trigger event for the complaint; all presented with abdominal pain. In two cases a small dehiscence of the peritoneum was present. However, no evisceration occurred. In three patients, a vaginal cuff dehiscence occurred after the 6 weeks follow-up examination, on the 57th, 71st and 75th day, respectively, all after sexual intercourse. Except for one of these patients in which some granulation tissue was treated with silver nitrate, anamnesis and physical examination during the regular follow-up examination did not reveal other abnormalities in the postoperative course. One case was complicated by a fallopian tube prolapse. In this case, both the prolapse and the vaginal cuff dehiscence could be managed laparoscopically. In all other cases, vaginal (re)suturing of the dehiscence was sufficient. After repair, further recovery was uneventful in all eight patients.

Discussion

VCD is a potentially severe adverse event. Internationally, the reason for the increased incidence of VCD after TLH is still a matter of concern. The used suturing method of the vaginal vault is mentioned as an etiological factor. In our comparison of laparoscopic suturing of the vaginal cuff with a single-layer unknotted running suture and both laparoscopic and transvaginal closure with knotted interrupted sutures, we found the lowest incidence of VCD after transvaginal suturing (1.3%). This was followed by both the barbed suture and the running vicryl suture with TEM clips (2.4%), which proved to be an easy to adopt alternative. However, based on our data, no statistical superiority of either of these suturing methods could be proven. Regardless of these suturing techniques, the incidence of VCD after TLH remains high compared with abdominal and vaginal hysterectomy. Therefore, other steps of the procedure unique to TLH, such as the amount and type of coagulation used for colpotomy, should be assessed in future research as possible determinants for the onset of VCD.

To our knowledge, the present study is the first to compare single-layer running suturing techniques with interrupted sutures for closure of the vaginal cuff. Additionally, cuff closure using a running vicryl suture with TEM clips is a newly introduced alternative to other suturing

techniques currently in use. The safety and effectiveness of barded sutures already has been demonstrated in two other studies [3, 6]. However, one was non-comparative and in the other a more time-consuming double-layer suturing method was used. Furthermore, the barbed suture proved to be relatively easy to learn [6]. In our experience as well, both the single-layer barbed suture and the single-layer running vicryl suture with TEM clips proved to be easy to adopt and as safe—regarding incidence of VCD—as transvaginal and laparoscopic closure of the vaginal cuff with interrupted sutures.

Both techniques allow laparoscopic closure of the vaginal vault to be less time-consuming, due to their unknotted fashion. However, some concern is expressed regarding adhesion formation of the intestine to the tail of the barbed suture, which in turn potentially could cause bowel obstruction [15-17].

As shown in Table 4.1, due to the retrospective design of our study, some differences in the baseline characteristics occurred. Especially with regard to the etiology of VCD, the observed differences in mean BMI and mean intraoperative blood loss are, however, not clinically relevant. Furthermore, the same counts for the difference in ASA classification between group 1 and group 2, since none of the patients presenting with a VCD suffered from a systemic disease which potentially could induce this complication (e.g. diabetes or chronic cough due to chronic obstructive pulmonary disease). Finally, given the relatively long study period (in which the same surgical techniques and instruments were used), we had to rule out a possible influence of surgical experience to explain these differences. However, near the end of the study period, VCD tended to occur as (in)frequent as at the beginning.

VCD is still a matter of concern to those who perform TLH. Although techniques for suturing of the vaginal cuff have changed rapidly over the past years, only one prospective study on this subject has been published [5]. It compared laparoscopic closure with interrupted and running sutures, however, with a double-layer suturing method and with an extracorporeal knotting technique. Recently, Uccella et al. advocated a superiority of transvaginal closure based on data of their own retrospective cohort and a review of literature in which they found a threefold increase in the incidence of VCD associated with laparoscopic closure [7]. Our study suggests a similar difference between transvaginal closure and laparoscopic closure with knotted interrupted sutures. However, they did not compare the use of laparoscopic running suturing methods. Given the fact that transvaginal closure cannot always be accomplished in all women, alternatives to this suturing method should be studied. Unfortunately, a prospective intention-to-treat study to test this superiority will be hard to perform. Based on a pooled incidence of 0.18% [7] (transvaginal closure) versus 2.4% (laparoscopic running unknotted suture, present study), we measured that at least 405 patients should be included in each arm to obtain adequate power (two-sided test for

independent samples with 80% power and 5% type I error). To ensure that the same surgical technique is applied in all procedures, ideally, a single-center study needs to be conducted. As a result, the conclusions drawn from the present study have to be strengthened by pooling of data with future publications on this topic.

Several explanations why hysterectomy by laparoscopic approach is prone to have a higher rate of VCD have been put forward. Firstly, regarding initial sexual intercourse as a precipitating event, it has been suggested that the rapid recovery after the laparoscopic approach, compared with the abdominal approach, facilitates swift return to everyday activities and early resumption of (sexual) activities, which could predispose rupture of the vaginal vault [10, 18]. On the other hand, this assertion does not seem to hold, whereas also in our study most VCDs related to intercourse occurred after the regular 6 weeks postoperative follow-up examination, which is considered to be sufficient time for primary wound healing [9-11, 18-20].

Secondly, several studies suggested that the amount and type of energy used for colpotomy could be predisposing for VCD [5, 18, 21-22]. Gruber et al. performed a histopathologic assessment to compare the thermal damage after the use of ultrasonic, monopolar and bipolar energy for colpotomy in swine. They concluded that ultrasonic energy causes the least and bipolar energy the greatest tissue damage [21]. In all our procedures, including those complicated by a VCD, ultrasonic energy was used for colpotomy and additional bipolar energy was used for hemostasis (Table 4.3). The amount of coagulation used in the cases in which a VCD occurred compared with the procedures after which no VCD occurred is, however, unclear. Nevertheless, in order to maintain sufficient vascularization, minimizing the use of bipolar energy for hemostasis seems advisable. Preferably, only arterial bleeders should be coagulated and one should rely on the sutures to control venous oozing. This recommendation is supported by the lower reported incidence of VCD after conventional abdominal approach to hysterectomy, in which the vaginal vault is clamped and sutured and no coagulation is used on a regular basis [23].

Furthermore, several studies did address the type and class of suture material as a possible cause for vaginal cuff dehiscence [11, 19, 22]. However, review of the literature yields neither evidence nor consensus on the preferred suture material, concerning monofilament versus multifilament and delayed absorbability of the thread.

Finally, surgical characteristics such as the technical difficulty of laparoscopic surgery, the high complexity of laparoscopic knot tying and insufficient amounts of tissue incorporated in the suture have been suggested as reasons for the increased incidence of VCD in LH [5-7, 13]. The placement of sutures in ‘big bites’ of viable tissue seems justified [5, 18].

It is more likely that a VCD occurs secondary to an underlying factor such as a hematoma or a primary healing defect as a result of excessive coagulation. Hypothetically, in these cases, the vaginal wall epithelium remains approximated only by the suture. Therefore, as soon as the suture loses most of its tensile strength, a (partial) separation of the vaginal cuff occurs. This hypothesis is supported by the difference in days between surgery and VCD, which we found in the present study (Table 4.3). With regard to the barbed suture (n = 2), the mean time to VCD was 73 days. For the other suturing methods (n = 6), in which regular Vicryl no. 0 was used, the mean time to VCD was 29 days. This difference can be explained by the fact that the tensile strength of Vicryl is 25% after 4 weeks (http://www.ecatalog.ethicon.com/sutures-absorbable), whereas the tensile strength of the barbed suture is still 80% [6]. Sexual intercourse might only trigger breakdown of a partially dissolved suture, which in case of such a primary healing defect, causes a (partial) separation of the vaginal wall epithelium that would have occurred sooner or later anyway. In our opinion, the advice to refrain from intercourse up to 3 months after TLH, as suggested by others, is neither based on the pathophysiological process of VCD nor based on evidence [2, 24]. Similarly, given the ambiguous relationship of intercourse and VCD, we thus tend to emphasize to our patients that from a clinical point of view they themselves are not to blame for this embarrassing event.

The VCD rate of 3.3% that we found for laparoscopic interrupted sutures was relatively high but was similar to the rate published by others before they started to use the barbed suture [6]. However, more importantly, in these cases the peritoneum remained closed and in none (of all our cases) an evisceration occurred. Especially the latter is important, since immediate reoperation is needed and its association with bowel perforation and/or necrosis, peritonitis and general sepsis [7, 9, 25].

Conclusion

In conclusion, based on our data, no superiority of one of the suturing methods over the other was found and the exact etiology of VCD still remains unclear. Regardless of the suturing method, we hypothesize that the surgical approach towards the colpotomy in TLH in comparison to the abdominal approach, with additional (extensive) application of coagulation, has inherent its specific side effects. To enable future scientific analysis of pooled data, we would like to challenge others to publish their data and opinion on this important subject.

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Chapter 5

Hysterectomy in very obese and morbidly obese patients: a systematic review with cumulative analysis of comparative studies

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Abstract

Purpose: Some studies suggest that also regarding the patient with a body mass index (BMI) ≥35 kg/m2 the minimally invasive approach to hysterectomy is superior. However, current practice and research on the preference of gynecologists still show that the rate of abdominal hysterectomy (AH) increases as the BMI increases. A systematic review with cumulative analysis of comparative studies was performed to evaluate the outcomes of AH, laparoscopic hysterectomy (LH) and vaginal hysterectomy (VH) in very obese and morbidly obese patients (BMI ≥35 kg/m^2).

Methods: PubMed and EMBASE were searched for records on AH, LH and VH for benign indications or (early stage) malignancy through October 2014. Included studies were graded on level of evidence. Studies with a comparative design were pooled in a cumulative analysis.

Results: Two randomized controlled trials, seven prospective studies and 14 retrospective studies were included (2232 patients; 1058 AHs, 959 LHs, and 215 VHs). The cumulative analysis identified that, compared to LH, AH was associated with more wound dehiscence [risk ratio (RR) 2.58, 95% confidence interval (CI) 1.71–3.90; $p < .001$], more wound infection (RR 4.36, 95% CI 2.79–6.80; $p < .001$), and longer hospital admission (mean difference 2.9 days, 95% CI 1.96–3.74; $p < .001$). The pooled conversion rate was 10.6%. Compared to AH, VH was associated with similar advantages as LH.

Conclusions: Compared to AH, both LH and VH are associated with fewer postoperative complications and shorter length of hospital stay. Therefore, the feasibility of LH and VH should be considered prior the abdominal approach to hysterectomy in very obese and morbidly obese patients.

Introduction

In general, the preferred surgical approach to hysterectomy is evident [1]. In case vaginal hysterectomy (VH) is not regarded possible or in case of early-stage endometrial cancer, laparoscopic hysterectomy (LH) is associated with clear advantages over abdominal hysterectomy (AH) [1- 5]. In obese patients (BMI 30.0–34.9 kg/m²), a similar approach to hysterectomy is considered to be best practice [6, 7]. However, no conclusive evidence exists regarding the preferred approach in the very obese and morbidly obese patients, i.e. a BMI ≥35 kg/m² [8-10]. Only one of the 34 randomized controlled trials (RCT) included in the most recent Cochrane review on the surgical approach to hysterectomy, described patients with a BMI ≥35 kg/m² [1, 11]. All other studies either excluded these patients from analysis or did not report the BMI.

Some non-randomized studies suggest that, compared to the AH, also this group of patients benefits most from the vaginal approach [12-15]. In daily practice, however, the VH frequently seems to be a less favorable approach due to large uterine size, (early stage) malignancy and/or expected intraoperative difficulties regarding exposure [16-18]. In more recent studies, LH was proven to be feasible and safe in these patients [2, 10, 19, 20]. Although, compared to the AH, fewer postoperative complications were found, an important point of concern is the report of a relatively high conversion rate and its suggested association with a higher postoperative morbidity [2, 8, 19, 21-24]. In contrast to these presumed better outcomes, research on the implementation and the preference of gynecologists show that that the rate of AH increases as the BMI increases [7, 25, 26].

These dilemmas have almost become daily practice due to rising prevalence of obesity over the past decades; in Europe fluctuating between 6 and 37% among its countries [27]. In the United States, the prevalence of BMI ≥35 kg/m² remained relatively stable around 15% [28]. Due to an increased unopposed estrogen effect in hormonally responsive tissues, obesity can promote a number of gynecological diseases, such as abnormal uterine bleeding and endometrial hyperplasia [29]. As a result, a higher prevalence of enlarged uteri and especially a higher incidence of endometrial carcinoma is observed among these patients [29-32]. Inherently, the number for which hysterectomy is indicated, is likely to rise over time.

Current practice shows that these controversies in literature cause diffusion in the approach to hysterectomy in these patients. To provide also the raising amount of these patients with optimal counselling and subsequent route of hysterectomy, it is necessary that conclusive evidence on this subject is obtained.

The objective of this study was to evaluate the outcomes of abdominal, laparoscopic and VH in very obese and morbidly obese patients (BMI ≥35 kg/m²) by means of a systematic review with cumulative analysis.

Materials and methods

The PubMed and EMBASE databases were systematically searched for records (last update October 9, 2014). We aimed to identify all studies on AH, LH and VH in patients with a BMI ≥35 kg/m^2. A clinical librarian was consulted, who assisted in composing a search string including the terms (and synonyms for) body mass index, obesity, laparoscopy, abdominal, laparotomy, vaginal and hysterectomy (Appendix 5.1). No limitations regarding publication date and language were applied. All titles and subsequently the abstracts of all relevant titles were screened on relevance by two authors individually (MB and ES). Exclusion criteria during the title and abstract screening were: conference abstracts, studies without abstract, non-clinical studies (e.g. review, case report, cadaver study), a mean/median BMI <35 kg/m^2 and studies involving extensive combined procedures (e.g. radical hysterectomy in combination with panniculectomy). Articles likely to be relevant were read in full text. Excluded were studies in which the BMI was not specified, the minimum BMI of the range was <35 kg/m^2 (or a mean BMI <40 kg/m^2 in case the range was not specified), multiple publications based on an overlapping cohort, studies that were not available in full text, and series of radical hysterectomies for cervical carcinoma. If the two independent reviewers did not achieve consensus on the inclusion or exclusion, a third reviewer (FWJ) was consulted.

Study selection

From each study that was included, a predefined set of data was extracted. This consisted of study design, inclusion period (years) and indication (malignant, benign or both). In case of malignancy, it was specified if the hysterectomy was performed with or without lymph node dissection (LND). Per approach (AH, LH and VH), the number of patients and in case of LH, the type of LH [laparoscopic-assisted vaginal hysterectomy (LAVH) or total laparoscopic hysterectomy (TLH; conventional, robotic(-assisted) or both)], along with the patient and procedure characteristics, were extracted. Patient characteristics included age, BMI and uterine weight. Procedure characteristics included operating time (in minutes, skin-to-skin), blood loss (in milliliters), length of hospital stay (in days, from day of procedure), complications and conversion to laparotomy. If possible, postoperative complications were separately labelled as wound problems, dehiscence (abdominal or vaginal cuff) or wound infection. Conversion to laparotomy was defined as an intraoperative switch from a laparoscopic to an open abdominal approach. Strategic conversion (e.g. due to inadequate visibility, adhesions or additional pathology) was distinguished from reactive conversion (i.e. because of a complication) [33].

Assessment of risk of bias

All studies were graded on the level of evidence (according to the Oxford Centre of Evidence-Based Medicine) [34]. From the highest to the lowest level, an adequately sampled (RCT) (level 1b), is followed by a low-quality RCT or observational/prospective cohort study (level 2b), an individual case–control study (3b) and a case series (and poor quality cohort or case–control study) (level 4).

Statistical analysis

A cumulative analysis (i.e. a meta-analysis on all types of comparative studies) was conducted due to the lack of randomized evidence [35, 36]. This analysis was based on the results of all comparative studies that were included in our systematic review and was conducted using Review Manager 5.3 (Cochrane Collaboration, Copenhagen, Denmark). The pooled results of these comparative studies were expressed as risk ratios (RR) with 95% confidence interval (CI) for dichotomous outcomes and as mean difference (MD) with 95% CI for continuous outcomes. Regarding the latter, only results that are presented as mean with standard deviation can be included in such an analysis. Since statistical heterogeneity between the studies was expected, random effects models were used. This resulted in de most 'conservative' estimation of the intervention effect. Only if two or more studies could be used to estimate the effect of the pooled outcome, this outcome was reported in the Results section. The guidelines for reporting of Meta-analysis Of Observational Studies in Epidemiology (MOOSE) were followed [37].

Hysterectomy in very obese and morbidly obese patients in our center

All patients with a BMI ≥35.0 kg/m² who underwent an elective AH, LH or VH at the Leiden University Medical Centre between January 2005 and September 2014 were also included in this study. All laparoscopic procedures were performed by two gynecologists with extensive experience in advanced laparoscopic surgery (>200 procedures). Patients who underwent radical hysterectomy or a combined procedure (such as prolapse surgery) were excluded. All above-mentioned patient and procedure characteristics were derived by retrospective chart review. Uterine weight was derived from the pathology report. In case an actual weight was missing, the uterine volume was calculated from the pathology report or preoperative ultrasound measurements and transformed to weight by a validated model [38]. Adverse events were registered for type of complication, severity (i.e. requiring re-operation or not) and moment of onset, up to 6 weeks after discharge (i.e. marking the legitimate adverse event reporting period), according to the definitions and regulations

as determined by the Guideline Adverse Events of the Dutch Society of Obstetricians and Gynecologists [39].

The data were analyzed using SPSS 20.0 statistical software (Chicago, IL, USA). A Pearson Chi square test was used to compare proportions and a student's t-test was used for continuous variables. To describe non-normally distributed data (kurtosis between -1 and +2) or in case Levene's test showed no homogeneity of variance, the median and interquartile range (IQR, 25^{th} and 75^{th} percentiles) were used and a Mann–Whitney test was performed. A $p < .05$ was considered statistically significant.

Results

The initial search yielded 3207 articles. After exclusion of conference abstracts (n = 1073), duplicates (n = 540), and irrelevant titles (n = 1052), the abstracts of 542 potentially relevant titles were screened. Based on the predefined exclusion criteria, 439 articles were excluded because no abstract was present (n = 30), the articles represented reviews, case reports, or cadaver studies (n = 104), the reported mean or median BMI of the study population was not ≥35 kg/m^2 (n = 296), or the studies involved combined procedures (such as hysterectomy and panniculectomy, n = 9). Of the remaining 103 articles that were subjected to a full-text review, another 81 studies were excluded because the minimum BMI of the range was <35 kg/m^2 or—in case the range was not reported—the mean BMI was <40 kg/m^2 (n = 44), the BMI was not specified (n = 24), overlap between study populations existed (n = 3), no full text was available (n = 9), or it concerned a study on the outcomes after hysterectomy for cervical carcinoma (n = 1). A total of 22 articles met all inclusion criteria. Figure 5.1 illustrates the search and exclusion algorithm.

Hysterectomy in very obese and morbidly obese patients in our center

During the study period, in our center a total of 27 AHs, 48 LHs, and five VHs were performed in patients with a BMI ≥35 kg/m^2. In 22% of AHs (n = 6) and 42% of LHs (n = 20) the BMI was ≥40 kg/m^2. Due to the low number of VHs, these procedures could not be used for further analysis.

Conversion to laparotomy was required in 12.5% of LHs (n = 6). Of these, five (83%) were for strategic considerations. The reactive conversion was performed in a patient with a BMI of 60 kg/m^2 because of inadequate visibility during the colpotomy combined with inability to maintain the Trendelenburg position because of hypercapnia.

Patient characteristics between the groups were comparable (Table 5.1). Compared to AH, LH is associated with less blood loss (mean 204 ± 181 vs. 575 ± 528 mL; p = .001) and a shorter

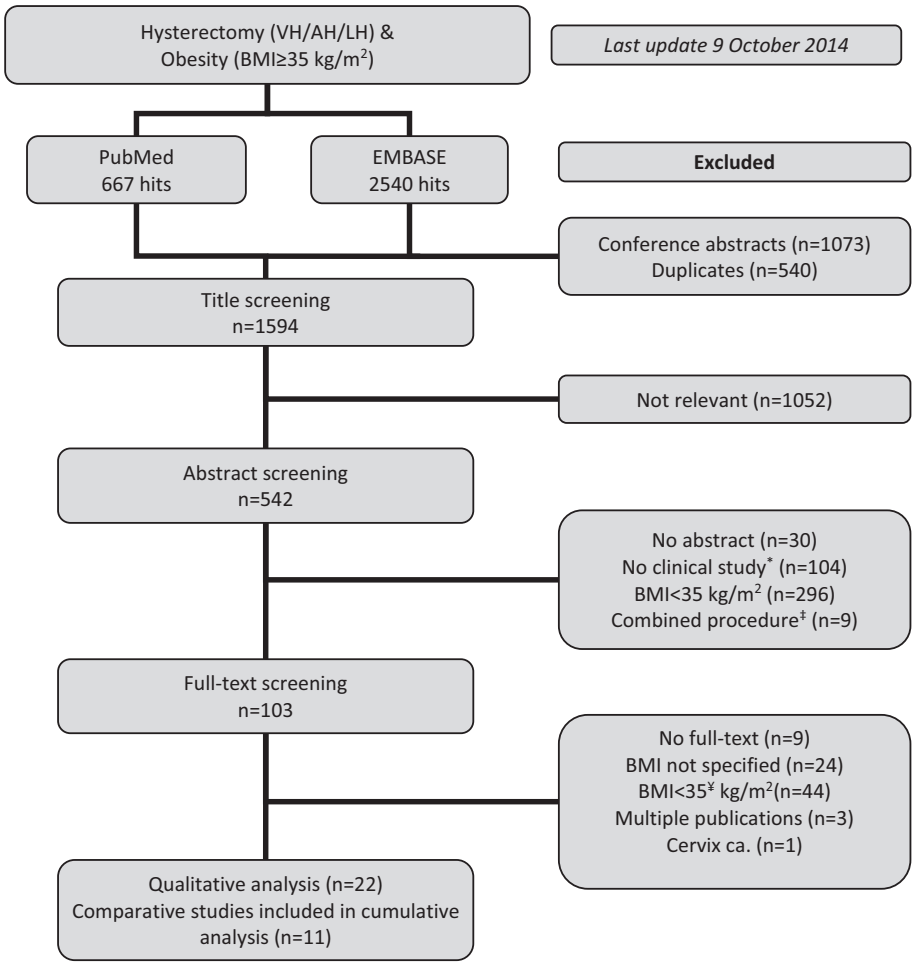

Figure 5.1 Flowchart of the search and exclusion algorithm.
* i.e. review, case report, cadaver studies.
‡ e.g. panniculectomy.
¥ including mean BMI <40 kg/m² if range not specified.
AH = abdominal hysterectomy; LH = laparoscopic hysterectomy; VH = vaginal hysterectomy.

length of hospital stay (mean 3.7 ± 1.7 vs. 6.0 ± 1.8 days; p < .001). No difference in operating time was detected (mean 138 ± 38 vs. 131 ± 47 min; p = .522).

All adverse events are listed in Table 5.2. In 18.5% of AHs (n = 5), intraoperative blood loss of >1 L was observed; all other adverse events were noted in the postoperative course. Two adverse events after LH required a re-operation (4.2%). Compared to LH, the overall complication rate after AH was higher (40.7 vs. 16.7%; p = .029). Among the six LHs that were converted to laparotomy, no complications were observed.

Table 5.1 Patient characteristics of all AHs and LHs performed in patients with a BMI ≥35 kg/m² in our hospital from 2005 until 2014

	AH (N = 27)		LH (N = 48)		
	Mean	± SD	Mean	± SD	p value
Age (years)	54.8	± 12.8	57.3	± 11.8	.404[a]
BMI (kg/m²)	37.0	36.0–39.7	38.5	36.1–44.8	.074[b]
Uterine weight (g)	140	102–365	150	104–250	.778[b]
Benign indication (%)	48.1%		41.7%		.678[c]

[a] Student's t-test.
[b] Median, interquartile range (25th and 75th percentiles) and Mann–Whitney test because of non-normal distribution.
[c] Pearson Chi square.
AH = abdominal hysterectomy; LH = laparoscopic hysterectomy; SD = standard deviation.

Table 5.2 Adverse events of all AHs and LHs

	AH (N = 27)	LH (N = 48)	Overall (N = 75)
Infection	3 (11.1%)[a]	3 (6.3%)[b]	6 (8.0%)
Organ lesion	0	1 (2.1%)[c]	1 (1.3%)
Wound dehiscence	0	1 (2.1%)[d]	1 (1.3%)
Intraoperative blood loss >1 L	5 (18.5%)	0	5 (6.7%)
Pulmonary embolism	2 (7.4%)	1 (2.1%)	3 (4.0%)
Others	1 (3.7%)	2 (4.2%)	3 (4.0%)
Total	11 (40.7%)	8 (16.7%)	19 (25.3%)

All adverse events did not require re-operation and occurred postoperatively, unless otherwise stated. All LHs that were converted to laparotomy were uneventful (n = 6).
[a] Three urinary tract infections.
[b] One urinary tract infection and one aspiration pneumonia, for which antibiotics were prescribed. The third 'infection' regarded one single measurement of fever (39.5 °C) without focus and that normalized within 6 h without specific treatment.
[c] Vesico-vaginal fistula, that needed a bladder catheter and re-operation by a urologist.
[d] Readmission because of vaginal cuff dehiscence that required resuturing in the OR.
AH = abdominal hysterectomy; LH = laparoscopic hysterectomy.

Summary of included studies

Including the data of our hysterectomies in patients with a BMI ≥35 kg/m², these 23 studies resulted in a total of 2232 hysterectomies, of which 1058 were AH (14 studies), 959 LH (18 studies), and 215 VH (3 studies) [8, 14, 15, 19-22, 40-54]. Of all LHs, 952 were TLH (of which 513 were performed robotically) and 7 were LAVH. The designs of the studies were 2 RCTs,

7 prospective studies, 1 case–control study, and 13 case series or retrospective studies. In 2 studies the level of evidence was graded as 2b, in 1 study as 3b and in the remaining 20 studies as 4.

All extracted data regarding AH, LH, and VH are summarized in Tables 5.3, 5.4, 5.5, respectively (see Appendix 5.2). The pooled conversion rate was 10.6% (95 out of 900). We calculated that 82% of conversions (18 out of 22) could be regarded as strategic. Except for one study [52], the outcomes of all converted cases were included in the LH group (intention-to-treat analysis).

Given the fact that only 2 RCTs were found, we performed a cumulative analysis based on the included studies that were performed in a comparative design (11 out of the 22 included studies) (Tables 5.3, 5.4, 5.5, Appendix 5.2). Among these, 10 compared AH with LH, 1 compared AH with VH and none compared LH with VH.

AH vs. LH

Compared to LH, AH was associated with a higher overall complication rate (RR 2.28, 95% CI 1.62–3.20; p < .001) (Figure 5.2). Intraoperative complications were rare and no difference was observed (RR 1.43, 95% CI 0.66–3.11; p = .36) (Figure 5.3). Regarding the postoperative

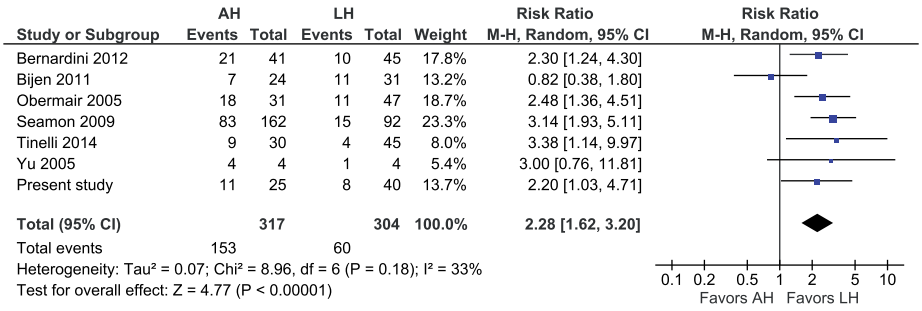

Figure 5.2 AH vs. LH, overall complication rate.

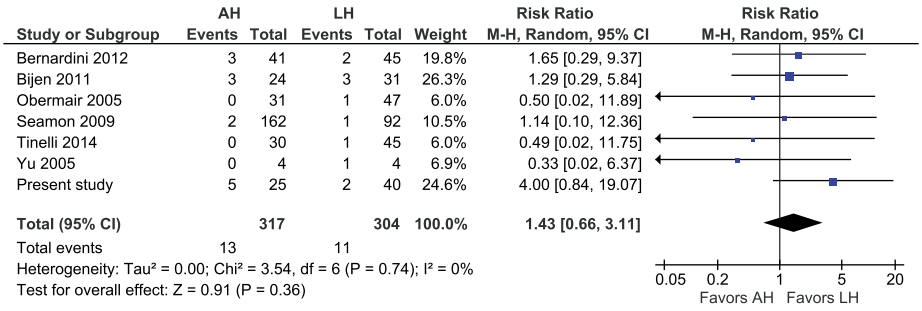

Figure 5.3 AH vs. LH, intraoperative complication rate.

complications, wound problems (RR 3.05, 95% CI 1.43–6.49; p = .004), wound dehiscence (RR 2.58, 95% CI 1.71–3.90; p < .001), and wound infection (RR 4.36, 95% CI 2.79–6.80; p < .001) all favored LH (Figures 5.4, 5.5, 5.6). No difference in operating time and estimated blood loss between AH and LH was detected (MD −33 min, 95% CI −72–7; p = .10 and MD 135 mL, 95% CI −30–301; p = .11, respectively) (Figures 5.7, 5.8). The length of hospital stay was longer after AH (MD 2.9 days, 95% CI 2.0–3.7; p < .001) (Figure 5.9). No separate analysis was performed to

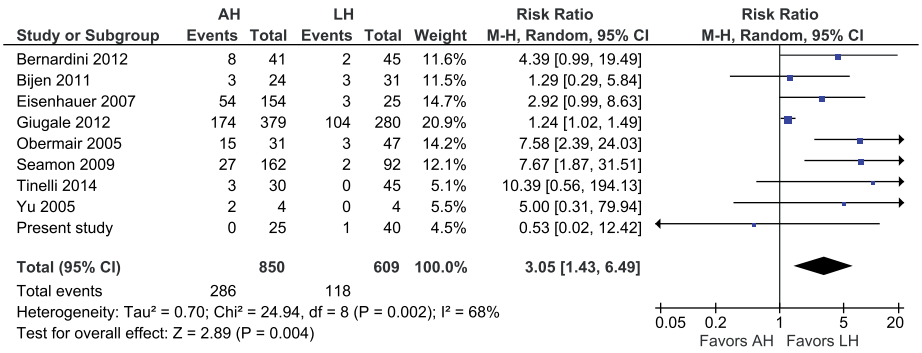

Figure 5.4 AH vs. LH, wound problem.

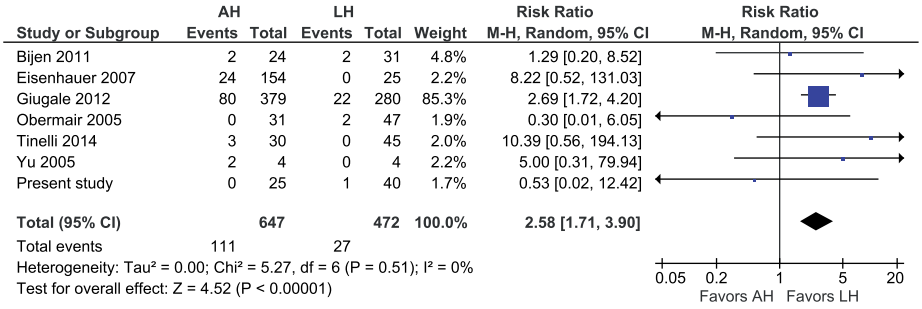

Figure 5.5 AH vs. LH, wound dehiscence (including vaginal cuff dehiscence).

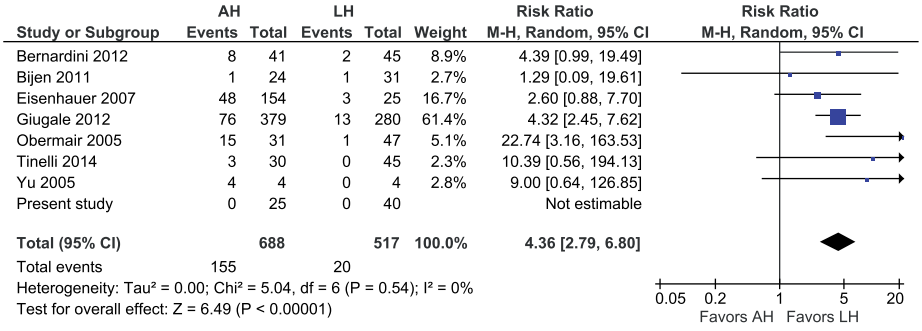

Figure 5.6 AH vs. LH, wound infection.

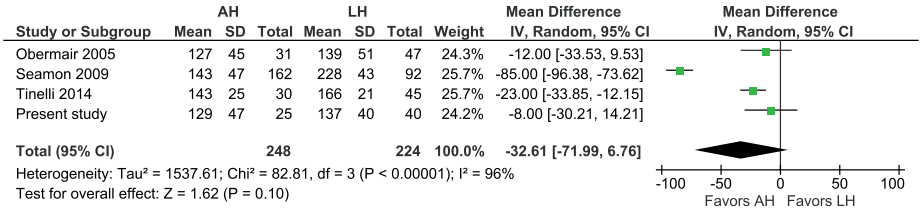

Figure 5.7 AH vs. LH, operating time.

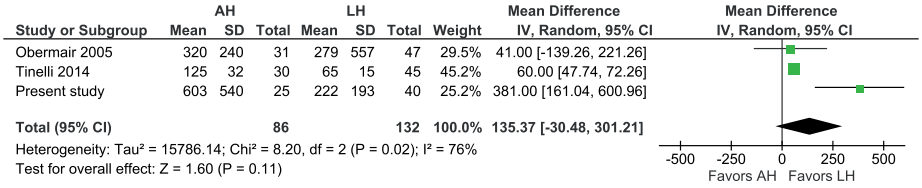

Figure 5.8 AH vs. LH, estimated blood loss.

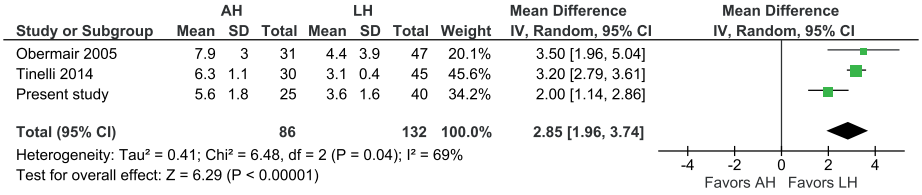

Figure 5.9 AH vs. LH, length of hospital stay.

compare benign indication and malignancy. All studies included in this cumulative analysis were for malignancy, except for one study and the hysterectomies performed in our center [21]. Excluding the studies on robotic hysterectomies [19, 21, 42, 52] from these analyses did not cause clinically relevant differences, except for wound dehiscence (RR 2.08, 95% CI 0.69–6.25; p = .19) and operating time (MD −19 min, 95% CI −28 to −10; p < .001) (not shown).

AH vs. VH

The results of one study showed more wound problems (18.0 vs. 0.0%), more wound dehiscence (8.0 vs. 0.0%) and a longer length of hospital stay after AH (5.3 vs. 2.6 days, Tables 5.3 and 5.5, Appendix 5.2) [15].

Discussion

Compared to both laparoscopic and VH, the abdominal approach in patients with a BMI ≥35 kg/m^2 is associated with more postoperative complications and longer length of hospital stay. The majority of LHs (89%) were completed laparoscopically. Due to better clinical outcomes, the feasibility of LH and VH should be considered prior to the abdominal approach to hysterectomy in these patients.

Although especially in patients with a BMI ≥35 kg/m^2 a restrictive policy to abdominal surgery is warranted, the rate of AH increases as the BMI increases [7, 25, 26]. This is also reflected by the VH rates that remain stable at around 20%, despite the fact that, in general, the vaginal approach is considered to be the preferred route to hysterectomy [1, 18]. Reasons could be a lack of experience, but also factors such as large uterine size and malignancy [55]. Since obesity is accountable for a higher incidence of both disorders, especially in the very obese and morbidly obese patients the laparoscopic approach could be the best alternative to bypass these contraindications, as confirmed by present study. Nonetheless, during laparoscopic surgery in this group of patients special considerations have to be taken into account and three-dimensional vision systems could make adequate visualization less difficult [13, 56].

Compared to AH, both the laparoscopic and vaginal approaches are associated with a significantly lower incidence of postoperative complications. This was mainly caused by the lower risk of wound problems, such as infection and dehiscence. However, not only the incidence, but also especially the severity of these complications is a matter of concern. Unfortunately, the identified studies did not provide sufficient data to assess the severity of these complications and also other studies on this subject (mainly regarding wound infections) did show contrasting results [57-60].

Another important advantage of the laparoscopic and vaginal approach over AH is the significantly shorter length of hospital stay. Similar to the results from our center, the cumulative analysis revealed a significant and clinically very relevant difference of approximately 3 days for the disadvantage of AH. Albeit differences in local recovery regimens and healthcare systems make comparison between studies difficult, this conclusion can be regarded valid. Firstly, it is based on differences that were found within multiple studies and secondly, they are also in line with the results of the non-comparative studies (Appendix 5.2).

Literature focusing on the outcomes of hysterectomy in patients with a BMI ≥35 kg/m^2 proved to be scant. Instead of a meta-analysis, a cumulative analysis had to be performed on the results from prospective, non-randomized and retrospective studies [35, 36]. Since this introduced heterogeneity in our analysis, we used a random effects model to correct

for the differences between studies, thereby providing the most conservative detection of differences between interventions. While these precautions have been taken into account, in our opinion, especially the major differences in complication rate and length of hospital stay cannot solely be explained by the limitations in the design of the included studies. Nonetheless, some precaution in the interpretation of our findings remains necessary. For example, the analyses on operating time, estimated blood loss and length of hospital stay are based on the results of three or four studies. Despite this, the results of these studies were similar to the outcomes of the non-comparative studies that could not be included in the cumulative analysis (Appendix 5.2).

The presumed higher conversion rate is most likely the main reason for the tendency to perform an AH instead of a LH in these patients. Conversion in general, and especially reactive conversion, is associated with more postoperative morbidity and a prolonged hospital stay [61, 62, 63]. Especially among very obese and morbidly obese patients, it is observed that conversion can result in high postoperative morbidity which has a significant impact on the quality of life, thereby obscuring the cost-effectiveness of LH over AH [8, 22, 64, 65]. The present cumulative analysis revealed a pooled conversion rate of 10.6% and although no cost-effectiveness analysis could be performed, in our opinion, this percentage is quite comparable to the 6.5% found in the only study that assessed cost-effectiveness with respect to conversion rate (versus a conversion rate of 32.3% that was found to be not cost-effective) [8]. This hypothesis is further supported by the fact that the far majority (82%) were strategic conversions. Although the risk for additional postoperative morbidity is thereby inherently minimized, further research is needed to draw more definite conclusions.

To determine superiority of VH over LH or vice versa with regard to postoperative complications, too little evidence was found. Most likely this is mainly due to the fact that VH is frequently (relatively) contraindicated due to either large uterine size or malignancy [55]. Additionally, LH was originally introduced as an alternative to AH in 1989, but at first was not accepted as an alternative for hysterectomy in very obese patients [66]. Although nowadays with the widespread implementation of LH potentially an adequately powered RCT could provide the answer, it is questionable if conducting such a study is still feasible from a methodological and ethical perspective.

The results of our systematic review with cumulative analysis finally provide sufficient evidence that also with regard to very obese and morbidly obese patients both the LH and VH result in better clinical outcomes, compared to the abdominal approach to hysterectomy. In contrast to VH, LH is considered standard of care in case of early-stage malignancy and it is less challenging to obtain adequate visualization. Therefore, in current perspectives, LH should become the most frequently performed approach to hysterectomy in the patients

with a BMI ≥35 kg/m^2. Although a reasonable rate of conversion to laparotomy (10.6%) was observed, hypothetically, increased experience and clustering of LH in high-volume centers might enable further improvement in the outcomes of this procedure in these patients.

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Appendix 5.1

Search string used for PubMed:

("Body Mass Index"[Mesh] OR BMI[All Fields] OR "Obesity"[MeSH Terms] OR "obesity"[All Fields] OR "obese"[All Fields] OR "overweight"[MeSH Terms] OR "overweight"[All Fields] OR Quetelet[All Fields]) AND ("laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields] OR "robotic"[all fields] OR "robot"[all fields] OR "robot-assisted"[all fields] OR "abdomen"[MeSH Terms] OR "abdomen"[All Fields] OR "abdominal"[All Fields] OR "laparotomy"[MeSH Terms] OR "laparotomy"[All Fields] OR "laparotomic"[all fields] OR "vagina"[MeSH Terms] OR "vagina"[All Fields] OR "vaginal"[All Fields]) AND ("hysterectomy"[MeSH Terms] OR "hysterectomy"[All Fields] OR (("uterus"[MeSH Terms] OR "uterus"[All Fields] OR "uterine"[all fields]) AND ("extirpation"[All Fields] OR "staging"[All Fields] OR "surgery"[All Fields]))).

Search string used for EMBASE:

(exp body mass/OR "body mass index".mp. OR BMI.mp. OR exp obesity/OR "obesity".mp. OR "obese".mp. OR "overweight".mp. OR "Quetelet".mp.) AND (exp laparoscopic surgery/OR exp laparoscopy/OR laparoscop*.mp. OR robot*.mp. OR exp abdomen/OR abdom*.mp. OR exp laparotomy/OR laparotom*.mp. OR exp vagina/OR "vagina".mp. OR "vaginal".mp.) AND (exp hysterectomy/OR "hysterectomy".mp. OR ((exp uterus/OR "uterus".mp. OR "uterine".mp.) AND ("extirpation".mp. OR "staging".mp. OR "surgery".mp.))).

Appendix 5.2

Table 5.3 Characteristics of the included studies concerning AHs. (part 1 of 2)

Author (year)	Design	Level of Evidence	Inclusion period	Indication	N	BMI		Age		OR time		Blood loss		Hospital stay		Uterus weight	
Bernardini et al. (2012)[a]	PS	4	2008-2010	Malign (mixed)	41	42,3	(36-66)	62	(31-86)	165	(75-295)	300	(100-3500)	4	(2-21)	NA	(-)
Bijen et al. (2011)[a]	RCT	2b	2007-2009	Malign (no LND)	24	NA	(35-48)	NA	(-)	NA	(-)	NA	(-)	NA	(-)	NA	(-)
Eisenhauer et al. (2007)[a]	RS	4	1993-2006	Malign (mixed)	154	41	(35-84)	60	(25-84)	164	(40-368)	200	(40-2200)	6	(4-56)	NA	(-)
Geppert et al. (2011)[a]	RS	4	2005-2009	Both (no LND)	13	NA	(35-51)	NA	(-)	128	(65-200)	300	(100-2300)	5,7	(2-17)	NA	(-)
Giugale et al. (2012)[a]	RS	4	2001-2011	Both (mixed LND)	379	44	±	57,8	±	NA	(-)	366	±	NA	(-)	NA	(-)
Krebs et al. (1984)	PS	4	1978-1982	Both (mixed LND)	21	40,3	(38-55)	52	(26-72)	195	±42	832,3	±246	12,8	±4	NA	(-)
Obermair et al. (2005)[a]	RS	4	1993-2001	Malign (mixed)	31	39,3	±[b]	56,9	±10	127	±45	320	±240	7,9	±3	NA	(-)
Santoso et al. (2012)	PS	4	2003-2009	Malign (+LND)	88	42,7	±7	57,9	±10	117	±43	346	±319	3,5	±2	NA	(-)
Seamon et al. (2009)[a]	CC	3b	1998-2008	Malign (+LND)	162	39,9	±7	62	±12	143	±47	394	±	3	±	NA	(-)
Sheth et al. (2010)[a]	PS	4	1997-2007	Both (no LND)	50	45,6	±	NA	(-)	102	±	NA	(-)	5,3	±	NA	(-)
Showstack et al. (2004)	RCT	2b	1998-2000	Benign	34	NA	(35-)	NA	(-)	NA	(-)	NA	(-)	NA	(-)	NA	(-)
Tinelli et al. (2014)[a]	RS	4	2004-2013	Malign (+LND)	30	39	±8	63	±14	143	±25	125	±32	6,3	±1	NA	(-)
Yu et al. (2005)[a]	PS	4	2002-2003	Malign (mixed)	4	44,8	±	56,5	(37-77)	142	±	700	±	11,5	(5-24)	NA	(-)
Present study[a]	RS	4	2005-2014	Both (no LND)	27	38,2	±4	54,8	±13	131,2	±47	575	±528	6	±2	140	(102-365)[c]
Total					1058												

[a] Included in cumulative analysis.
[b] BMI estimated based on average height of 1.70 meters.
[c] Interquartile range.
CS = Case-series; PS = Prospective cohort study; RCT = Randomized controlled trial; RS = Retrospective study; CC = Case-control study; LND = Lymph node dissection. Reported values are either mean ± SD or median (min-max).

Table 5.3 Characteristics of the included studies concerning AHs. (part 2 of 2)

	Overall complications		Intra-operative complications		Post-operative complications		Wound problem:		Dehiscence		Wound infection		
Author (year)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	General remarks
Bernardini et al. (2012)[a]	21	(51,2)	3	(7,3)	18	(43,9)	8	(19,5)	NA		8	(19,5)	
Bijen et al. (2011)[a]	7	(29,2)	3	(12,5)	4	(16,7)	3	(12,5)	2	(8,3)	1	(4,2)	
Eisenhauer et al. (2007)[a]	NA		NA		64	(41,6)	54	(35,1)	24	(15,6)	48	(31,2)	
Geppert et al. (2011)[a]	NA		NA		NA		NA		NA		NA		
Giugale et al. (2012)[a]	NA		NA		NA		174	(45,9)	80	(21,1)	76	(20,1)	
Krebs et al. (1984)	NA		NA		17	(81,0)	5	(23,8)	4	(19,0)	4	(19,0)	Peri-umbilical incision
Obermair et al. (2005)[a]	18	(58,1)	0		18	(58,1)	15	(48,4)	0		15	(48,4)	
Santoso et al. (2012)	11	(12,5)	2	(2,3)	9	(10,2)	1	(1,1)	1	(1,1)	0		
Seamon et al. (2009)[a]	83	(51,2)	2	(1,2)	81	(50,0)	27	(16,7)	NA		NA		
Sheth et al. (2010)[a]	NA		NA		NA		9	(18,0)	4	(8,0)	NA		Article is 'short report'
Showstack et al. (2004)	NA		NA		NA		NA		NA		NA		TOSH-trial, total vs. supracervical abdominal, subgroup analysis (17 vs 17)
Tinelli et al. (2014)[a]	9	(30,0)	0		9	(30,0)	3	(10,0)	3	(10,0)	3	(10,0)	
Yu et al. (2005)[a]	4	(100)	0		4	(100)	2	(50,0)	2	(50,0)	4	(100)	Article is 'short report'
Present study[a]	11	(40,7)	5	(18,5)	6	(22,2)	0		0		0		
Total	164	(40,3)	15	(3,7)	230	(39,5)	301	(29,8)	120	(14,9)	159	(19,9)	

[a] Included in cumulative analysis.

Table 5.4 Characteristics of the included studies concerning LHs. (part 1 of 2)

Author (year)	Design	Level of Evidence	Inclusion period	Indication	N	Type of LH	Techn	BMI		Age		OR time		Blood loss		Hospital stay		Uterus weight	
Almeida et al. (2004)	CS	4	2001-2003	Benign	7	LAVH	Conv.	45,8	(41-52)	36,9	(28-48)	109	±	207	(100-350)	1,4	±	141	±
Almeida et al. (2013)	PS	4	2011-2012	Benign	12	TLH	Robot	44,4	(40-59)	44,1	(28-67)	109,6	±	146,3	±	1	(1-2)	259	±
Bernardini et al. (2012)[a]	PS	4	2008-2010	Malign (mixed)	45	TLH	Robot	40,3	(35-75)	61	(36-87)	270	(135-470)	200	(50-1500)	2	(1-24)	NA	(-)
Bijen et al. (2011)[a]	RCT	2b	2007-2009	Malign (no LND)	31	TLH	Conv.	NA	(35-55)	NA	(-)	NA	(-)	NA	(-)	NA	(-)	NA	(-)
Eddib et al. (2014)	RS	4	2010-2012	Both (mixed LND)	84	TLH	Robot	42,5	±	50,4	±	215,1	±	79,3	±	1,43	±	222,7	±
Eisenhauer et al. (2007)[a]	RS	4	1993-2006	Malign (mixed)	25	TLH	Conv.	39	(35-49)	57	(35-79)	215	(94-330)	150	(50-500)	3	(2-7)	NA	(-)
Farthing et al. (2012)	RS	4	2003-2009	Malign (mixed)	45	TLH	Conv.	NA	(40-)	NA	(-)	75	(-)	50	(-)	2	(-)	NA	(-)
Gallo et al. (2012)	RS	4	2006-2010	Both (no LND)	101	TLH	Robot	44,3	(40-63)	54	(35-84)	124	(40-365)	100	(30-600)	1	(1-15)	156	(50-3543)
Geppert et al. (2011)[a]	RS	4	2005-2009	Both (no LND)	23	TLH	Robot	NA	(35-56)	NA	(-)	136	(100-183)	50	(25-200)	1,6	(1-2)	NA	(-)
Giugale et al. (2012)[a]	RS	4	2001-2011	Both (mixed LND)	280	TLH	Comb.	41,7	±	58,6	±	NA	(-)	174	±	NA	(-)	NA	(-)
Lau et al. (2011)	PS	4	2007-2009	Malign (+LND)	23	TLH	Robot	45,8	±5	54,7	±10	257	±39	94	±72	2	(1-6)	204	±89
Nawfal et al. (2011)	RS	4	2008-2010	Benign	36	TLH	Robot	NA	(35-56)	NA	(-)	196	(80-625)	100	(10-1000)	1	(1-5)	NA	(-)
Obermair et al. (2005)[a]	RS	4	1993-2001	Malign (mixed)	47	TLH	Conv.	42,1	±[b]	54,6	±13	139	±51	279	±557	4,4	±3,9	NA	(-)
Raiga et al. (2000)	RS	4	1999	Both (no LND)	3	TLH	Conv.	49,9	(40-51)	57	(51-74)	80	(70-85)	NA	(-)	3	(3-3)	NA	(-)
Seamon et al. (2009)[a]	CC	3b	1998-2008	Malign (+LND)	92	TLH	Robot	39,6	±7	58	±10	228	±43	109	±	1	±	NA	(-)
Tinelli et al. (2014)[a]	RS	4	2004-2013	Malign (+LND)	45	TLH	Conv.	38	±7	60	±11	166	±21	65	±15	3,1	±0,4	NA	(-)
Yu et al. (2005)[a]	PS	4	2002-2003	Malign (mixed)	4	TLH	Conv.	45	±	58	(52-64)	153,8	±	325	±	4	(2-5)	NA	(-)
Present study[a]	RS	4	2005-2014	Both (no LND)	48	TLH	Conv.	41	±6	57,3	±12	138	±38	204	±181	3,7	±1,7	150	(104-250)[c]
Total					959														

[a] Included in cumulative analysis.
[b] BMI estimated based on average height of 1.70 meters.
[c] Interquartile range.
CS = Case-series; PS = Prospective cohort study; RCT = Randomized controlled trial; RS = Retrospective study; CC = Case-control study; LND = Lymph node dissection; LAVH = Laparoscopic-assisted vaginal hysterectomy; TLH = Total laparoscopic hysterectomy; Technique = Conventional, robot or combined. Reported values are either mean ± SD or median (min-max).

Table 5.4 Characteristics of the included studies concerning LHs. (part 2 of 2)

	Overall complications		Intra-operative complications		Post-operative complications		Wound problem:		Dehis-cence		Wound infection		Conversion to laparotomy					
Author (year)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	Reason	# SC	(%)	General remarks
Almeida et al. (2004)	0		NA		NA		NA		NA		NA		0			0		
Almeida et al. (2013)	0		NA		NA		NA		NA		NA		1	(8,3)	Strategic	1	(100)	Conversion excluded in operating time
Bernardini et al. (2012)[a]	10	(22,2)	2	(4,4)	8	(17,8)	2	(4,4)	NA		2	(4,4)	4	(8,9)	Strategic	4	(100)	
Bijen et al. (2011)[a]	11	(35,5)	3	(9,7)	8	(25,8)	3	(9,7)	2	(6,5)	1	(3,2)	10	(32,3)	Unknown	NA		Performed by 16 different surgeons
Eddib et al. (2014)	5	(6,0)	1	(1,2)	4	(4,8)	0		0		0		1	(1,2)	Strategic	1	(100)	
Eisenhauer et al. (2007)[a]	NA		NA		3	(12,0)	3	(12,0)	0		3	(12,0)	4	(16,0)	Strategic	4	(100)	
Farthing et al. (2012)	5	(9,4)	3	(5,7)	2	(3,8)	1	(1,9)	0		1	(1,9)	1	(1,9)	Strategic	1	(100)	
Gallo et al. (2012)	13	(12,9)	3	(3,0)	10	(9,9)	3	(3,0)	0		3	(3,0)	1	(1,0)	Unknown	NA		
Geppert et al. (2011)[a]	NA		NA		NA		NA		NA		NA		NA			NA		
Giugale et al. (2012)[a]	NA		NA		NA		104	(37,1)	22	(7,9)	13	(4,6)	45	(16,1)	Unknown	NA		Converted cases: mean BMI 47.3 (vs 40.6 non-converted). BMI>60: conversion rate 38.5%
Lau et al. (2011)	3	(13,0)	0		3	(13,0)	2	(8,7)	0		1	(4,3)	0			0		Recovery: Hygiene regimens 3.9 days; Chores: 16.6 days, Physical activities: 18.3 days

Table 5.4 *Continued*

	Overall complications		Intra-operative complications		Post-operative complications		Wound problem:		Dehis-cence		Wound infection		Conversion to laparotomy					
Author (year)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	Reason	# SC	(%)	General remarks
Nawfal et al. (2011)	NA		NA		NA		NA		NA		NA		NA			NA		Subgroup (total cohort 135, median BMI 30,6)
Obermair et al. (2005)[a]	11	(23,4)	1	(2,1)	10	(21,3)	3	(6,4)	2	(4,3)	1	(2,1)	5	(10,6)	Both	2	(40,0)	Postoperative complications after conversion: 1 wound infection, 2 wound dehiscences, 1 atelectasis/chest infection, 1 atrial fibrillation
Raiga et al. (2000)	0		0		0		0		0		0		0			0		Article in French
Seamon et al. (2009)[a]	15	(16,3)	1	(1,1)	14	(15,2)	2	(2,2)	NA		NA		17	(18,5)	Unknown	NA		17 conversion excluded in further analysis; 92 Robot LHs matched to 162 laparotomies
Tinelli et al. (2014)[a]	4	(8,9)	1	(2,2)	3	(6,7)	0		0		0		0			0		
Yu et al. (2005)[a]	1	(25,0)	1	(25,0)	0		0		0		0		0			0		Article is 'short report'
Present study[a]	8	(16,7)	2	(4,2)	6	(12,5)	1	(2,1)	1	(2,1)	0		6	(12,5)	Both	5	(83,3)	
Total	86	(14,5)	18	(3,1)	71	(11,8)	124	(14,1)	27	(3,6)	25	(3,2)	95	(10,6)		18	(81,8)	

SC = Strategic conversion.
[a] Included in cumulative analysis.

Table 5.5 Characteristics of the included studies concerning VHs. (part 1 of 2)

Author (year)	Design	Level of Evidence	Inclusion period	Indication	N	BMI		Age		OR time		Blood loss		Hospital stay		Uterus weight	
Obermair et al. (2005)[a]	RS	4	1993-2001	Malign (mixed)	5	NA	(-)	NA	(-)	NA	(-)	NA	(-)	NA	(-)	NA	(-)
Pitkin et al. (1977)	RS	4	1948-1973	Benign	108	41,3	±5	46,2	±11	151	±41	NA	(-)	NA	(-)	NA	(-)
Sheth et al. (2010)[a]	PS	4	1997-2007	Both (no LND)	102	44	±	NA	(-)	80	±	NA	(-)	2,6	±	NA	(-)
Total					215												

[a] Included in cumulative analysis.
PS = Prospective cohort study; RS = Retrospective study; LND = Lymph node dissection. Reported values are either mean ± SD or median (min-max).

Table 5.5 Characteristics of the included studies concerning VHs. (part 2 of 2)

	Overall complications		Intra-operative complications		Post-operative complications		Wound problem:		Dehiscence		Wound infection		Conversion to laparotomy					
Author (year)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	Reason	# SC	(%)	General remarks
Obermair et al. (2005)[a]	NA		NA		NA		NA		NA		NA		NA			NA		Excluded 'for the aim of this analysis'
Pitkin et al. (1977)	NA		NA		113,4	(105,0)	NA		NA		NA		NA			NA		BMI according to Am J Public Health (suppl), 1973
Sheth et al. (2010)[a]	NA		NA		NA		0		0		NA		1	(1,0)	Reactive	0		Article is 'short report'
Total	0		0		113,4	(105,0)	0		0		0		1	(1,0)		0	(0,0)	

SC = Strategic conversion.
[a] Included in cumulative analysis.

Chapter 6

Surgical flow disturbances in dedicated minimally invasive surgery suites: an observational study to assess its supposed superiority over conventional suites

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Abstract

Background: Minimally invasive surgery (MIS) is frequently compromised by surgical flow disturbances due to technology- and equipment-related failures. Compared with MIS in a conventional cart-based OR, performing MIS in a dedicated integrated operating room (OR) is supposed to be beneficial to patient safety. The aim of this study was to compare a conventional OR with an integrated OR with regard to the incidence and effect of equipment related surgical flow disturbances during an advanced laparoscopic gynecological procedure [laparoscopic hysterectomy (LH)].

Methods: Using video recording, 40 LHs performed between November 2010 and April 2012 (20 in a conventional cart-based OR and 20 in an integrated OR) were analyzed by two different observers. Outcome measures were the number, duration and effect (on a seven-point ordinal scale) of the surgical flow disturbances (e.g., malfunctioning, intraoperative repositioning, setup device).

Results: A total of 103 h and 45 min was observed. The interobserver agreement was high (kappa .85, $p < .001$). Procedure time was not significantly different (NS) [conventional OR vs. integrated OR, minutes ± standard deviation (SD), mean 161 ± 27 vs. 150 ± 34]. A total of 1651 surgical flow disturbances were observed (mean ± SD per procedure 40.8 ± 19.4 vs. 41.8 ± 15.9, NS). The mean number of surgical flow disturbances per procedure with regard to equipment was 6.3 ± 3.7 versus 8.5 ± 4.0, NS. No clinically relevant differences in the mean effect of these disturbances on the surgical flow between the two OR setups were observed.

Conclusions: Performing LH in an integrated OR did not reduce the number of surgical flow disturbances nor the effect of these disturbances. Furthermore, in the integrated OR, repositioning of the monitors was a frequent and time consuming source of disturbance. In order to maintain the high standard of surgical safety, the entire surgical team has to be aware that by performing surgery in an integrated OR different potential sources for disruption arise.

Introduction

In the era of rapidly evolving surgical techniques and technology, the patient, hospital, health insurance and government demand transparency in surgical outcomes and desire the highest degree of patient safety. Merely a decade ago, we started to accept the idea that surgical outcome is affected by more than the patient characteristics and skills of the surgeon alone [1]. In fact, the combination of patient risk factors, task complexity, individual surgical factors, and above all team functioning, operative events and operative environment are responsible for the outcome [1–3]. Especially in minimally invasive surgery (MIS), patient safety has to rely on a smooth course of the procedure and is depending on proper functioning of the equipment and the working environment [4]. Secondly, compared with open surgery, MIS is more prone to disruptions due to problems with the extensive amount of equipment it relies on (either presence, position or functioning) [4–8]. A systematic review revealed that on average per procedure three equipment-/technology-related errors occur. This resembles 23.5% of the errors in the OR [9]. Additionally, they found that procedures that are more dependent on technology and/or equipment tended to show approximately three times higher equipment-related error rates [9]. Furthermore, during laparoscopic surgery, 47% of the communication is equipment related, compared with 39% during open surgery [10].

In order to guarantee an optimal working environment to perform MIS, the industry offers fully integrated surgical suites (e.g., ENDOALPHA by Olympus; iSuite by Stryker; OR1™ by Karl Storz). They state that—by their optimized design—these are the solution for efficient and safe surgical care by reducing operating room (OR) clutter and staff workload, increasing comfort and enhancing ergonomics and OR team performance [11–14]. Importantly, these statements are only describing potential benefits that are inherently biased by their manufactures and that are not based on objective research [12, 13, 15]. Regarding efficiency, only a couple of studies observed a small amount of time saving (i.e., ±4 min for setup and ±3 min for put away [13], ±6 min in 'preanesthesia time' [16] and 'potentially' ±6 min in overall OR time [11], respectively). Furthermore, a survey was performed under OR staff to investigate potential benefits of the integrated OR after 2 years of use. The results of the questionnaire showed a preference for the integrated OR; however, problems with staff education, integration and reliability were noted [17]. Another study explored the staff perceptions of the effects of an integrated OR on teamwork. The subjectively measured results of the nurses, consultants and trainees showed greater efficiency, better teamwork and reduced stress levels and therefore a strong preference for working in an integrated OR [18]. Although it is not clear whether an integrated OR is a useful, (cost-)effective and safe solution, globally many hospitals have invested or are investing in one or more integrated surgical suites [11, 17].

One could argue that an integrated OR facilitates such an improvement that patient safety is guaranteed and no extensive research is needed before applying this—expensive—technology [19]. However, it is well established that the failure of integrated devices also can lead to unforeseen problems, and from aviation technology, we know that even the smallest incidents can have catastrophic consequences [8, 20, 21]. One of the most striking examples is the crash of an airplane that, after a missed approach because of suspected gear nose malfunction, descended unnoticed because the entire flight crew became engrossed in the malfunction. Investigation revealed that only the nose landing gear position indicating system (i.e., the light bulb) was broken.

Therefore, quantitative research comparing equipment-related error rates in MIS performed in a conventional versus an integrated OR is desired. Studies describing surgical processes were generally based on live observation in the OR; video observation has only been used infrequently [6, 8, 22, 23]. Nevertheless, video registration is deemed superior since it is not limited by the capacity of an observer, cause-and-effect relationships are better analyzable, and the Hawthorne effect (i.e., the awareness of being observed alters the way a person behaves) is minimized [6, 7, 24, 25].

The aim of this prospective observational study was to compare a conventional OR with an integrated OR with regard to the incidence and effect of equipment-/instrument- related surgical flow disturbances during an advanced laparoscopic gynecological procedure (i.e., the laparoscopic hysterectomy (LH)).

Materials and methods

In a university-affiliated teaching hospital (Bronovo Hospital, The Hague), a prospective registration study was set up to record and analyze surgical flow disturbances during the same procedure in two different OR settings. The LH was chosen as procedure under research, because it is an advanced laparoscopic procedure, performed by a dedicated operating team and requiring a wide array of endoscopic instruments and equipment. The study started in November 2010 and all consecutive LHs that were performed in the conventional (cart-based) OR were registered until the start of the construction of the new integrated OR (Karl Storz OR1™ integrated OR system, September 2011). After construction of the integrated OR (October 2011), the same amount of eligible procedures were registered in this setting. Based on a power calculation, we needed 16 procedures in each OR (average 8 ± 3 equipment-/instrument-related surgical flow disturbances per procedure and a reduction to 5 regarded to be achievable by the introduction of the integrated OR (power 80%, type I error .05) [25]). The study design did not permit us to exactly determine the number of procedures beforehand, and furthermore, analysis of additional procedures would take an excessive

amount of time. Therefore, it was strived for to acquire at least 15 and a maximum of 20 eligible procedures. All procedures were performed by one out of two gynecologists with more than 10 years of experience in advanced gynecologic laparoscopy and were assisted by a person who conducted a fellowship in MIS; a group of five alternated in the position of either circulating or scrub nurse. To become acquainted with the integrated OR setting, the entire operating team received multiple training sessions that were provided by the vendor.

In the conventional OR, all standard laparoscopic equipment (insufflator, light source and camera control unit, all manufactured by Karl Storz) was placed on a cart with one flat-screen high-definition monitor on top and one on a swivel arm. The electrosurgical equipment was placed on separate cart(s). In the integrated OR, the standard laparoscopic and electrosurgical equipment (manufacturers identical to conventional OR) was placed on a ceiling-mounted boom arm and three flat-screen high-definition monitors (of which one touch screen) were attached to separate ceiling-mounted boom arms.

To minimize the impact on the environment under study, the study was performed with video observation. The researcher (M.D.B.) was present in the OR at the start of each registration, but did not participate in the procedure. All procedures were recorded on a personal computer using a quad-audiovisual recording system that synchronously recorded the input from three video signals and four audio signals (MPEG Recorder 2.1, Noldus Information Technologies, Wageningen, The Netherlands). The video signals captured the endoscopic image and the image from two dome cameras that provided a room overview from different angles (one placed in a corner and one opposite in the middle of the long side of the operating room) (see Figure 6.1). The audio signals were captured from two microphones placed on the ceiling next to the dome cameras and two wireless microphones placed on the surgical masks of the surgeon and scrub nurse, respectively. The recordings were started just before the time-out procedure and stopped after the skin of all port sites was sutured. In case technical problems related to the recording equipment were encountered, the procedure was excluded.

The study was approved by the Executive Board of the Bronovo Hospital. The recordings were only to be used for purpose of present study. Prior to the start of the study, all OR personnel was collectively informed about the study. They were told that the observations were performed to investigate the logistics of equipment and personnel during LH. From each patient, informed consent was obtained.

According to the methodology to analyze a peroperative surgical process described by Den Boer et al., all (potential) surgical steps that are commonly undertaken during LH were defined (Table 6.1) [26, 27]. The recordings were analyzed with The Observer© XT 11.5 software (Noldus Information Technologies, Wageningen, The Netherlands). Two residents in Obstetrics and Gynecology (M.D.B. and S.R.C.D.) observed the recordings. A random sample

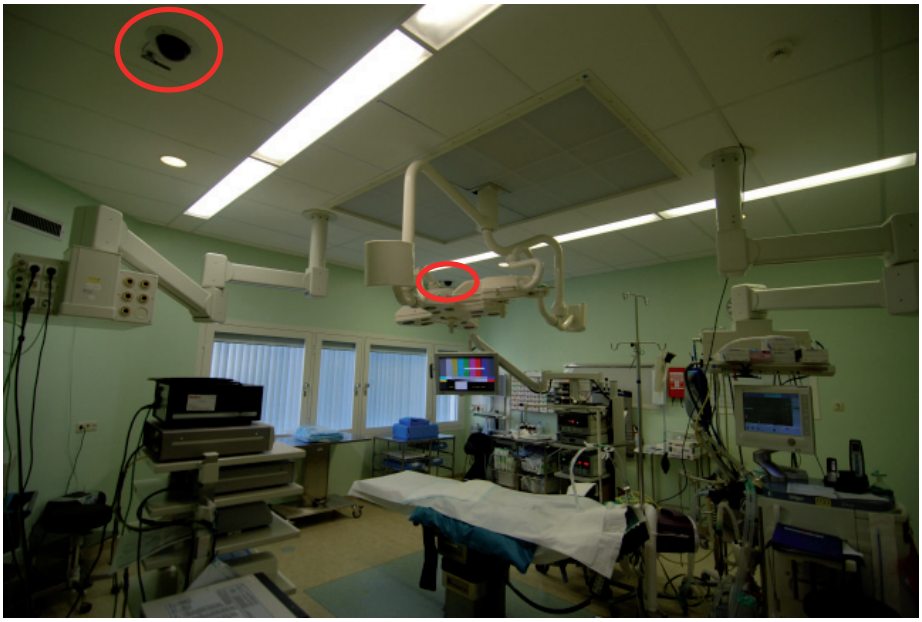

Figure 6.1 Conventional cart-based OR (dome cameras are circled).

of six recordings was scored by both observers. The findings of the two observers for these six procedures were compared, and the interobserver agreement was calculated (function incorporated in The Observer© XT 11.5 software). If satisfactory interobserver agreement would be achieved, the remaining procedures could be annotated by the two observers separately (randomly allocated and analyzed in a non-chronological random order) [5, 23].

Annotation and statistics

From each procedure, the predefined surgical steps and the presence and effect of predefined surgical flow disturbances were annotated (Table 6.1). Surgical flow disturbances were defined as stimuli (potentially) distracting one or more members of the sterile team (Table 6.2). To assess the (potential) severity, the effect on the sterile team members caused by each observed surgical flow disturbance was graded according to a seven-point ordinal scale modified by Persoon et al. (originally described by Healey et al.) (Table 6.3) [25, 28]. This scale ranges from '1' as a potentially distracting stimulus to '7' when the sterile team's work is completely interrupted. Primary outcome measures were the number of surgical flow disturbances per procedure. Secondary, a qualitative assessment was made comparing the types, effect and duration of these surgical flow disturbances for the two different OR settings.

Table 6.1 Surgical phases and (potential) surgical steps commonly undertaken during laparoscopic hysterectomy (adjusted from Den Boer et al. [26])

Surgical phases		Surgical steps	
1.	Pre-operative		
		1.1.	OR ready (clean, air quality, pressure)
		1.2.	Instruments & devices present and functioning
		1.3.	Patient to OR
		1.4.	Patient on OR table
		1.5.	Time-out procedure
		1.6.	Position patient on OR table
		1.7.	Team scrubs in washing room
		1.8.	Sterile preparation of instruments
2.	Anesthesia & surgical preparation		
		2.1.	Anesthesia & intubation
		2.2.	Sterilization operating area
		2.3.	Draping the patient
		2.4.	Insert urine catheter
		2.5.	Insert mobilizer in uterus
		2.6.	Install instruments
3.	Procedure		
	3.1. Create CO_2 pneumoperitoneum	3.1.1.	First incision & insert Veress or Hasson
		3.1.2.	Insufflate the abdomen
	3.2. Insert access ports	3.2.1.	Insert first (optical) port
		3.2.2.	Insert laparoscope
		3.2.3.	Inspect abdomen (active bleeding, 360 look, operability)
		3.2.4.	Insert second port under direct sight
		3.2.5.	Inspect and judge operability / unexpected pathology)
		3.2.6.	Insert third port under direct sight
		3.2.7.	Insert fourth port under direct sight
	3.3. Preparation operative area	3.3.1.	Dissect adhesions to uterus/ovaria/intestine in pelvis
		3.3.2.	Mobilize intestine out of pelvis
	3.4. Expose uterine arteries	3.4.1.	Dissect ligaments and mobilize uterus
		3.4.2.	Skeletize uterine arteries
		3.4.3.	Push off bladder
		3.4.4.	Identify location of ureters
	3.5. Transect uterine arteries	3.5.1.	Transect left uterine artery
		3.5.2.	Transect right uterine artery
		3.5.3.	Check color of uterus

Table 6.1 continues on next page

Table 6.1 ***Continued***

Surgical phases		Surgical steps	
		3.5.4.	Check if bladder and arteries are skeletized enough
3.6.	Separate uterus from vagina	3.6.1.	Colpotomy
		3.6.2.	Pneumoperitoneum is lost
3.7.	Specimen retrieval	3.7.1.	Morcellate uterus
		3.7.2.	Extract uterus through vagina
3.8.	Closure of the vaginal cuff	3.8.1.	Insert needle
		3.8.2.	Suture vaginal cuff
		3.8.3.	Extract needle
3.9.	Final check and irrigation	3.9.1.	Check hemostasis
		3.9.2.	Check vaginal cuff stump
3.10.	Close up patient	3.10.1.	Remove instruments
		3.10.2.	Remove accessory operating ports (under direct sight)
		3.10.3.	Check access wounds / bleeding
		3.10.4.	Release CO_2 from abdomen
		3.10.5.	Remove laparoscope and first trocar port
		3.10.6.	Suture port wounds
		3.10.7.	Remove draping
4. Extubation			
		4.1.	Patient awake
		4.2.	Extubation
5. Postoperative			
		5.1.	Patient from OR table to ward-bed
		5.2.	Sign-out procedure
		5.3.	Bring patient to recovery
6. Interoperative			
		6.1.	Cleaning of the OR

Patient and procedure characteristics were derived by chart review. For statistical analysis, The Observer® XT 11.5 software and SPSS 20.0 statistical software (Chicago, IL, USA) were used. A Pearson Chi-square test was used to compare proportions, and a Student's t-test was used for continuous variables. To describe non-normally distributed data (kurtosis between -1 and +2) or in case Levene's test showed no homogeneity of variance, the median and interquartile range (IQR, 25^{th} and 75^{th} percentiles) were used and a Mann–Whitney test was performed. A $p < .05$ was considered statistically significant.

Table 6.2 Observed types of surgical flow disturbances

Equipment-/instrument-related	Set-up device / connection
	Intraoperative repositioning
	Malfunctioning
	Not present
	Sterility
	Other / unclear
Environmental	Pager / telephone
	Door washing room
	Radio use
Personnel-related	Communication failure
	Irrelevant conversation
Procedure-related	Extra coagulation bleeding-site
	Unexpected adhesions
	Limited vision (condensation / smoke)
	Adverse event
	Conversion to laparotomy

Table 6.3 Effect of observed surgical flow disturbances (according to Persoon et al. [25])

1. Events with the potential to distract the sterile team
2. Sterile team member momentarily distracted: possible involvement of a single sterile member in an event not related to the primary task, e.g., a short head turn in response to a visual or auditory stimulus
3. Sterile team member engages in distraction: similar distraction in 2, but the sterile member engages with the source of distraction by verbally responding while maintaining primary task activity (multitasking)
4. Sterile team member's primary task interrupted: a single team member ceases his/her current tasks to engage entirely in the distracting stimulus
5. Sterile team momentarily distracted: two or more sterile team members respond to a stimulus with a short head turn, no verbal response
6. Sterile team engage in secondary tasks: two or more team members engage with the source of distraction by verbally responding while maintaining primary task activity
7. Sterile team's work interrupted—operation flow disrupted: interruption of the current primary task of the sterile team, the operation flow is disrupted

Results

During the study period, 46 LHs were performed in the conventional OR. Of those, 18 were not eligible (4 were not recorded because of no consent, 5 were excluded because of problems with the video recording, 6 due to audio problems and 3 for other reasons). In order to obtain the predefined 20 most recent procedures, first 8 procedures that were recorded

were not observed. During construction of the operating room that was equipped with the observation system, 11 LHs were performed in another integrated OR. Subsequently, in the observational integrated OR 27 LHs were performed until 20 LHs that were registered were eligible (3 were not recorded because of no consent, 2 were excluded because of technical problems and 2 for other reasons) (Figure 6.2).

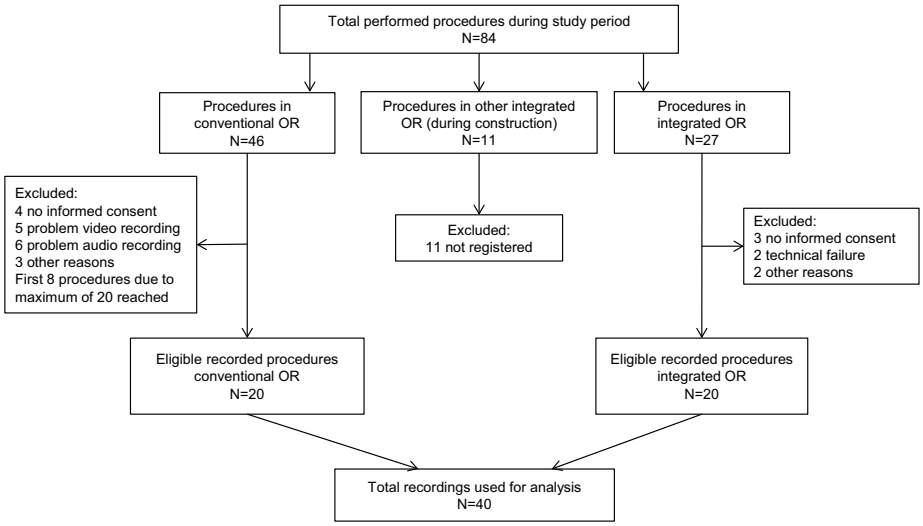

Figure 6.2 Inclusion of eligible procedures.

The overall observation duration of these 40 procedures was 103 h and 45 min. Patient and procedure characteristics were similar between the two OR settings (Table 6.4). Only 3 minor complications were noted, all postoperatively (Table 6.5). Procedure time (conventional OR vs. integrated OR, minutes ± standard deviation, mean 161 ± 28 vs. 150 ± 34) and operating time (skin to skin, mean 126 ± 27 vs. 116 ± 31) were not significantly different (NS) (Table 6.6).

In all six observations, both observers showed excellent agreement in their annotations (Cohen's kappa of .79–.98, all observations combined .85, $p < .001$). Therefore, the remaining procedures were annotated by the two observers separately (in total 36 observations by M.D.B. and 10 by S.R.C.D., respectively).

In total, during all 40 procedures, the researcher was present in the OR for 115 min (82 min in the conventional OR and 32 min in the integrated OR) [1.9% of total observation time, mean 4 min per procedure, 0–12 (min–max)]. The mean effect on the sterile team members of this presence was 1.7 (see Table 6.3). The mean effect of noticed study awareness was 3.6 (N = 52 in 40 procedures).

Table 6.4 Patient and procedure characteristics of analyzed LHs performed in the Bronovo Hospital, The Hague, between January 2011 and April 2012

	Conventional OR (N = 20)		Integrated OR (N = 20)		
	Median	IQR	Median	IQR	p value
Age (years)	48.2	43.9–55.2	47.1	43.5–56.0	.850[a]
BMI (kg/m^2)	24.9	22.7–27.3	25.3	22.5–28.9	.871[a]
Uterine weight (gram)	165	97–256	149	107–208	.643[a]
Operating time (minutes) [b]	122	± 31	124	± 36	.816[c]
Estimated Blood loss (mL)	100	50–175	75	50–150	.702[a]
Hospital stay (days)	2.0	1.1–2.1	1.9	1.3–2.0	.795[a]
Benign indication (%)	70.0%		55.0%		.514[d]

[a] Mann–Whitney test.
[b] Time according to medical file.
[c] Mean ± standard deviation and Student's t-test because of normal distribution.
[d] Pearson's Chi-square.
IQR = Inter quartile range (25th and 75th percentile); BMI = body mass index.

Table 6.5 Adverse events all analyzed LHs. All adverse events did not require reoperation and occurred postoperatively

	Conventional OR (N = 20)	Integrated OR (N = 20)	Overall (N = 40)
Infection	1[a] (5.0%)	0	1 (2.5%)
Blood loss > 1L	0 (0%)	1[b] (5.0%)	1 (2.5%)
Others	1[c] (5.0%)	0	1 (2.5%)
Total	2 (10.0%)	1 (5.0%)	3 (7.5%)

[a] Urinary tract infection.
[b] Postoperative drop in hemoglobin. CT scan showed approximately 1500 cc free fluid intraabdominally. Vital signs were stable, and after a blood transfusion with 2 packed cells, hemoglobin remained stable.
[c] Patient suffered from sensibility loss in her right hand. The neurologist diagnosed a neuropraxia of the median nerve. Conservative management resulted in almost complete recovery.

Incidence and effect of surgical flow disturbances

A total of 1651 surgical flow disturbances were scored (mean ± SD per procedure 40.8 ± 19.4 vs. 41.8 ± 15.9, NS) (unless otherwise specified, all comparisons are conventional vs. integrated OR). With regard to equipment, the mean number of surgical flow disturbances per procedure (setup of device, disturbance or problem regarding equipment, and intraoperative repositioning) was 6.3 ± 3.7 versus 8.5 ± 4.0, NS. More specifically, the mean duration of surgical flow disturbances regarding the setup of devices [n = 16 (total number

Table 6.6 Durations of all analyzed LHs (in minutes:seconds)

	Conventional OR (n = 20)					Integrated OR (n = 20)					Total (n = 40)
Observation duration	**53hours:42:55**					**50hours:02:38**					**103hours:45:33**
	Mean	**±SD**	**Min**	**-**	**Max**	**Mean**	**±SD**	**Min**	**-**	**Max**	**p value[c]**
Procedure time [a]	161:09	±27:38	107:37	-	210:24	150:08	±34:09	98:24	-	214:52	.269
Operating time [b]	126:17	±26:35	66:20	-	175:44	115:42	±30:38	71:48	-	174:58	.251

[a] Time between patient entering OR and leaving OR.
[b] Time between first incision and last suture (skin to skin).
[c] Unpaired t-test calculated using http://www.graphpad.com/quickcalcs/ttest1/?Format=SD.

of disturbances in 20 procedures), 1:16 ± 2:05 (mean ± SD in minutes:seconds) vs. n = 27, 1:57 ± 4:32, NS], disturbances or problems regarding equipment in general (n = 93, 2:19 ± 3:50 vs. n = 110, 1:54 ± 2:19, NS) and intraoperative repositioning (n = 16, 0:45 ± 0:37 vs. n = 33, 0:39 ± 0:32, NS) did not significantly differ either. Similarly, the mean effect of these disturbances did not show a clinically relevant difference (setup: 5.3 ± 1.6 vs. 4.2 ± 2.0, NS; disturbances regarding equipment in general: 5.8 ± 1.7 vs. 5.3 ± 1.8, p = .04; intraoperative repositioning: 4.6 ± 1.9 vs. 4.1 ± 1.7, NS).

The number and total duration of the different devices and instruments accountable for these disturbances are shown in Table 6.7. Particularly, the difference between the conventional OR and the integrated OR with respect to disturbances caused by 'monitor' is notable (n = 10, total duration 18 min vs. n = 46, 87 min; mean effect 4.7 ± 2.2 vs. 4.1 ± 1.7, NS). In the conventional OR one disturbance was caused by a failing connection of the second monitor (lasting 11 min). In the integrated OR during four procedures there were problems with activating the third monitor (which was eventually found out to be caused by a hardware

Table 6.7 Devices and instruments accountable for surgical flow disturbances with respect to setup of device, disturbance or problem in general, and intraoperative repositioning

	Conventional OR (N = 20)		Integrated OR (N = 20)	
Surgical flow disturbance regarding	n	Total duration (hour:min:sec)	n	Total duration (hour:min:sec)
Devices				
Diathermy	27	00:46:36	30	00:59:00
Endoscope	2	00:01:00	3	00:17:11[a]
Insufflator	19	00:21:07	21	00:17:34
Irrigation suction	7	00:09:15	9	00:05:44
Light source	3	00:00:50	4	00:02:24
Morcellation device	1	00:03:55	4	00:04:54
Pedals	-		6	00:04:33
Instruments				
Instruments - dismountable	25	01:52:38	20	00:45:06[b]
Instruments - non-dismountable	11	00:19:04	13	00:25:34
Trocar	3	00:01:39	1	00:00:53
Devices – OR-related				
Monitor	10	00:17:52	46	01:26:35[c]
Overhead light	3	00:00:52	2	00:00:49
Table	6	00:05:05	7	00:11:18
Tower	11	00:09:16	6	00:05:14

[a] Difference in total duration caused by one event lasting 16 min.
[b] Difference in total duration caused by a variety of non-OR-related problems.
[c] Mean degree of influence 4.7 ± 2.2 versus 4.1 ± 1.7, p = .37.

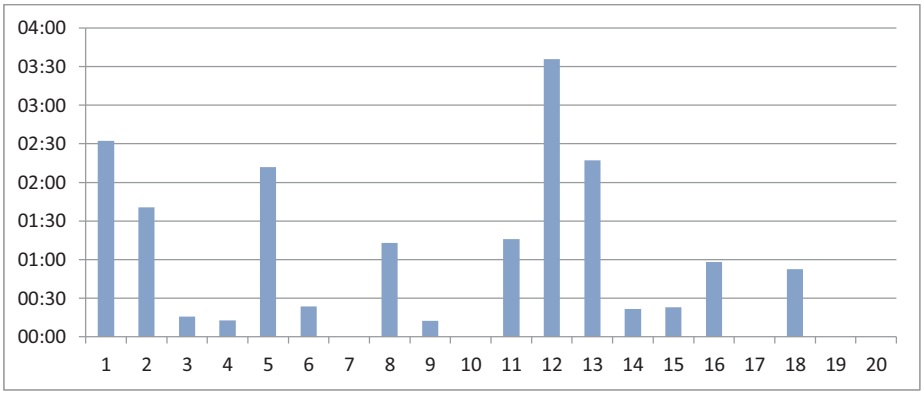

Figure 6.3 Duration (minutes:seconds) of intraoperative repositioning of a monitor in the integrated OR (per procedure, chronological order).

problem) (total duration 64 min). The majority of the remaining duration of the surgical flow disturbances regarding the monitor in the integrated OR were caused by intraoperative repositioning (n = 28, 18 min, mean effect 4.1). A chronological representation per procedure is shown in Figure 6.3.

The difference in total duration for surgical flow disturbances regarding 'instruments—dismountable' is caused by a variety of non-OR-related problems. No difference was found with regard to the number of surgical flow disturbances caused by devices that were not present in the OR [n = 12, 2:27 ± 2:00 (mean ± SD in minutes:seconds) vs. n = 16, 3:31 ± 2:37, NS].

Discussion

The number of equipment-related surgical flow disturbances is not reduced by performing laparoscopic hysterectomy in an integrated OR instead of a conventional cart-based OR. Similarly, regarding the effect of these disturbances on the sterile team members, no clinically relevant difference between the two types of OR was found. Moreover, in the integrated OR, intraoperative repositioning of the monitors is a frequent and time-consuming source of disturbance.

It has been stated that optimizing the operating environment potentially may have a more significant impact on overall surgical outcome than improving individual surgical skill [29]. Although our study was not designed to detect differences in surgical outcome, we found that an integrated OR, as one of the most promising solutions to improve the operating environment, did not result in a reduction in equipment-related surgical flow disturbances.

As a matter of fact, we even identified some potential hazards with the introduction of an integrated OR. The increased occupation that we observed with the repositioning of the monitors is important and has also been recognized by others [8]. Due to limitations in the degrees of freedom of the monitor and the ceiling-mounted boom arm, these disturbances were relatively time-consuming. Obviously, precise placement of the monitors can optimize the posture and improve ergonomics of all members of the surgical team [30]. However, apparently, the surgical team does not seem to be fully aware of the potential negative effect on the procedure during the repositioning. Having said this, the repositioning of the monitors fortunately did not have a direct effect on patient safety. However, what it does imply is that all implementations of either new technology, devices or instruments could potentially be hazardous in the chain of patient safety, because, especially during implementation of a new tool, one has to be aware that these are not always intuitive or straightforward in use [5]. Furthermore, the complete integration of the devices prevents easy (intraoperative) replacement in case of a dysfunctional device. Therefore, in an integrated OR, monitor positioning should be carefully planned and prepared preoperatively. This could be realized by the incorporating this as a mandatory item in a preoperative checklist [5, 31].

Previous research has demonstrated that surgical flow disturbances are directly related to surgical performance [25, 32, 33]. The number of surgical flow disturbances per procedure that we objectified was in line with similar studies. Persoon et al. [25] described surgical flow disturbances during endourological procedures (median operating time 35 min) and found a median of 20 disturbances per procedure of which 1.7 were equipment related. Moreover, also the effect of these disturbances on the sterile team was similar to our results (4.97 vs. 4.1–5.8). Furthermore, Verdaasdonk et al. [8] observed problems with equipment during laparoscopic cholecystectomy. In 30 procedures, they identified 58 disturbances. Since laparoscopic cholecystectomy is usually performed in approximately an hour and in general is being considered as one of the lesser advanced procedures in surgery, this rate seems also comparable to the 6.3–8.5 equipment-related disturbances we found. Nevertheless, although it is known that laparoscopic surgery is prone to instrument-related disturbances [9], this number leaves substantial room for improvement, and apparently this needs to be realized by other solutions than performing minimal invasive surgery in an integrated OR instead of a conventional OR.

As recommended by others, taking care of a structured implementation process is a key factor for an innovation to become a success [5, 34, 35]. During the construction period, the complete OR team received multiple training sessions by the vendor to become familiar with the new OR setting. Despite this, and beside the repositioning-related disturbances caused by the monitor, we incidentally observed some struggling with the new equipment. This finding could be attributable to the learning curve. Regardless of training, in daily practice

every new technique and technology comes along with a period a time during which one has to become completely familiar with the new environment. However, in our opinion, if the integrated OR really could reduce the number of surgical flow disturbances, that should—at least partially—be measurable from the first procedure performed in this OR, from both a patient safety and an ethical perspective. Moreover, observing 20 procedures in both types of OR should be sufficient to detect a clinically relevant difference, and graphical representations of our results did not show a learning curve (e.g., Figure 6.3).

One of the strengths of our study was the use of video observation making rewinding and playing again possible, in order to make sure all disturbances and their consequences are accurately interpreted. As a consequence, also the presence and influence of the researcher during the procedure and the awareness of the OR team on the study was reduced to a minimum, thereby making the interference of the study with its own results (the Hawthorne effect) negligible.

Despite this strength for research purposes, video observation is also limited by both the very time-consuming analysis and legal aspects. These downsides still have to be overcome, before it can become common practice for research as well as training and legal purposes [8, 24, 36]. In our opinion, a more widespread adoption of video recording has an enormous potential to improve quality and safety of surgery. It could be used for general reviewing of the procedural steps, but mainly for the analysis of (near) failures and (team) training purposes, thereby taking quality improvement to the next level [37]. Finally, also patients were positive about the idea of having their procedures recorded [38].

The presence of equipment-related surgical flow disturbances remains multifactorial. The proclaimed reduction in these disturbances during MIS in an integrated OR could not be shown. Especially with respect to MIS, a dedicated training has been proven to result in increased safety, shorted operating time and less conversions [39]. Also a dedicated (nurse) team is beneficial to patient safety [40]. Furthermore, of all types of disturbances, equipment problems have among the highest influence on the surgical flow and procedures during which disruptions occur take longer. Therefore, it may be assumed that a well-trained and dedicated surgical team will be more beneficial to patient safety than changing the OR setting, i.e., performing MIS in an integrated OR instead of a conventional cart-based OR [4, 41, 42].

Nevertheless, the integrated OR does have already proven advantages that we did not take into account in our study. Most importantly, for all team members the ergonomics are more favorable, thereby reducing physical complaints and eventually dropout [30]. Furthermore, also time saving in the preoperative setup has been observed [11, 13, 16]. Therefore, performing MIS in an integrated OR could be regarded an ergonomically responsible innovation for those who are frequently performing advanced MIS.

In conclusion, compared to a conventional OR, performing MIS in an integrated OR does not seem to increase patient safety either by a reduction in the number of surgical flow disturbances or by a reduction in the effect of these disturbances on the members of the sterile team. In order to maintain the high level of surgical safety that has been established by laparoscopic surgery, the entire surgical team has to be fully aware that by performing surgery in an integrated OR different potential sources for disruption arise.

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Chapter 7

Measuring surgical safety during minimally invasive surgical procedures: a validation study

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Abstract

Background: During the implementation of new interventions (i.e. surgical devices and technologies) in the operating room surgical safety might be compromised. Current safety measures are insufficient in detecting safety hazards during this process. The aim of the study was to observe whether surgical teams are capable of measuring surgical safety, especially with regard to the introduction of new interventions.

Methods: A Surgical Safety Questionnaire was developed that had to be filled out directly postoperative by three surgical team members. A potential safety concern was defined as at least one answer between (strongly) disagree and indifferent. The validity of the questionnaire was assessed by comparison with the results from video analysis. Two different observers annotated the presence and effect of surgical flow disturbances during 40 laparoscopic hysterectomies performed between November 2010 and April 2012.

Results: The surgeon reported a potential safety concern in 16% (85/520 questions). With respect to the scrub nurse and anesthesiologist this was both 9% (46/520). With respect to the preparation, functioning and ease of use of the devices in 37.5–47.5% (15–19/40 procedures) a potential safety concern was reported by one or more team members. During procedures after which a potential safety concern was reported, surgical flow disturbances lasted a higher percentage of the procedure duration (9.3% ± 6.2% versus 2.9% ± 3.7% (mean ± SD), $p < .001$). After procedures during which a new instrument or device was used, more potential safety concerns were reported (51.2% versus 23.1%, $p < .001$).

Conclusions: Potential safety concerns were especially reported during procedures in which a relatively high percentage of the duration consisted of surgical flow disturbances and during procedures in which a new instrument or device was used. The Surgical Safety Questionnaire can act as a validated tool to evaluate and maintain surgical safety during minimally invasive procedures, especially during the introduction of a new interventions.

Introduction

In the ongoing search for optimal patient outcomes, surgical procedures are continuously evolving [1]. As a result, maintaining the high level of patient safety has become a great challenge [2]. Implementing new techniques and / or technologies cause changes in standardized surgical procedures to which every surgical team member has to adapt [3, 4]. Monitoring surgical safety in the operating room (OR) is one of the most important issues to guarantee optimal surgical outcome. However, real-time monitoring of the surgical safety during a procedure is difficult. The question is: what and how should we monitor and who should do it?

Previous studies describing patient safety during minimally invasive surgery (MIS) have defined certain domains that are 'at risk' [5-8]. In daily practice the identification of these safety issues is often limited to observers that were physically present in the OR and retrospective interpretation of the obtained data [6, 9, 10]. Adequate interpretation is difficult and requires correct differentiation of errors (undesired actions) from events (consequence of undesired actions) [5]. Currently, patient safety indicators are frequently based on the occurrence of adverse events [11]. However, in general, intra-operative adverse events rarely occur. In theory, for an adverse event to occur several errors have to line up and slip through the holes of existing safety barriers [12]. Usually most errors that precede a potential adverse event are timely recognized and dealt with. However, these near-misses disturb the surgical flow to a greater or lesser extent and therefore interfere with surgical safety [3-5, 10, 13-16].

In daily practice, there is no external observer present during a procedure. The only 'real-time monitoring' of patient safety is done by the surgeon and / or the entire surgical team itself. However, from a psychological perspective it is known that an individuals' situational awareness is impaired when occupied with a (difficult) task [17]. Regarding this phenomenon, implementing new surgical devices and technologies in the OR puts more pressure on the responsibility of the surgeon to maintain surgical safety during the whole procedure [1, 15]. The only measures to enhance safety throughout a procedure that currently are – or at least should be – used, are the preoperative team briefings, the postoperative debriefings and, to a lesser extent, some preoperative checklists. In general, these safety instruments have proven to diminish preventable errors during the procedure and to safeguard open communication [18-21]. However, since these tools do not incorporate items to evaluate new surgical techniques or technologies, they are insufficient in detecting safety hazards during their introduction.

Therefore, the aim of this study was to observe whether surgical teams are capable of measuring surgical safety, especially with regard to the introduction of new techniques and technologies during a series of MIS procedures. A questionnaire that had to be filled

out directly postoperative was developed to measure surgical safety. Next, the validity of the questionnaire was assessed by comparison with the results from independent video analysis of these procedures.

Materials and methods

In a university affiliated teaching hospital (Haaglanden Medical Center, The Hague) a prospective registration study was set-up to record and analyze surgical flow disturbances. During a consecutive series of laparoscopic hysterectomies (LH) a questionnaire was filled out in the OR by the surgical team members. The surgical flow disturbances were scored by an independent observer. To minimize the interference of the study on its own results (the 'Hawthorne effect'), this observation was based on video registration of the procedures. Outcome measures were the number, types, effect and duration of surgical flow disturbances per procedure.

The LH was chosen as procedure of interest, because it is an advanced laparoscopic procedure, performed by a dedicated operating team and requiring a wide array of endoscopic instruments and equipment. The study started in November 2010 and all consecutive LHs that were performed in a conventional (cart-based) OR were registered until the start of the construction of the new integrated OR (Karl Storz OR1™ integrated OR system, September 2011). After construction of the integrated OR (October 2011), the same amount of eligible procedures was registered in this setting. Similarly, the occasional introduction of new devices in both the conventional and integrated OR was registered. In this manner, not only the transition to the integrated OR, but also the introduction of new devices was analyzed. All procedures were performed by either of the two gynecologists with more than 10 years of experience in advanced gynecologic laparoscopy and were assisted by one gynecologist who conducted a fellowship in MIS; a group of five alternated in the position of either circulating or scrub nurse.

The study was approved by the Executive Board of the Haaglanden Medical Center. Prior to the start of the study, all OR personnel was collectively informed about the study. From each patient informed consent was obtained. This design was adapted from another study [3].

Development of Surgical Safety Questionnaire

Patient safety risk factors that have been described by Rodrigues et al. were summarized in a questionnaire consisting of thirteen questions (i.e., time-out/sign-out, preparation and functioning of devices and instruments, functioning of the surgical team, distracting

stimuli and interference of the study on the procedure) [6]. Directly after each procedure the (assisting-)surgeon, scrub nurse and anesthetist(-assistant) filled out this short questionnaire. Answers were given on a 5-point Likert scale, ranging from (strongly) disagree to (strongly) agree. A potential safety concern was defined as an answer between (strongly) disagree and indifferent by at least one member of the surgical team. Additionally, several questions regarding experience (with the procedure, laparoscopy in general and the used instruments / devices) and the procedure (adhesions, adverse events) were stated (see Appendix 7.1).

Video analysis

The input from three video signals (endoscopic image and two dome cameras) and four audio signals (MPEG Recorder 2.1) was synchronously recorded during all procedures. The recordings were started just before the time-out procedure and stopped after suturing all port-sites. The procedure was excluded from analysis in case of technical problems related to the recording equipment. Two residents in Obstetrics & Gynecology (M.D.B. and S.R.C.D.) analyzed the presence and effect of predefined surgical flow disturbances. These surgical flow disturbances were defined as stimuli distracting one or more members of the surgical team (Table 7.1). To assess the severity, the effect of the surgical flow disturbance on the surgical team members was graded according to a seven-point scale. This scale ranges from 1 as a potentially distracting stimulus to 7 when the sterile team's work is completely interrupted (modified by Persoon et al., originally described by Healey et al.) (Table 7.2) [9, 22].

Table 7.1 Observed types of surgical flow disturbances

Equipment-/instrument-related	Set-up device / connection
	Intraoperative repositioning
	Malfunctioning
	Not present
	Sterility
	Other / unclear
Environmental	Pager / telephone
	Door washing room
	Radio use
Personnel-related	Communication failure
	Irrelevant conversation
Procedure-related	Extra coagulation bleeding-site
	Unexpected adhesions
	Limited vision (condensation / smoke)
	Adverse event
	Conversion to laparotomy

Table 7.2 Effect of observed surgical flow disturbances (according to Persoon et al. [9])

1.	Events with the potential to distract the sterile team
2.	Sterile team member momentarily distracted: possible involvement of a single sterile member in an event not related to the primary task, e.g., a short head turn in response to a visual or auditory stimulus
3.	Sterile team member engages in distraction: similar distraction in 2, but the sterile member engages with the source of distraction by verbally responding while maintaining primary task activity (multitasking)
4.	Sterile team member's primary task interrupted: a single team member ceases his/her current tasks to engage entirely in the distracting stimulus
5.	Sterile team momentarily distracted: two or more sterile team members respond to a stimulus with a short head turn, no verbal response
6.	Sterile team engage in secondary tasks: two or more team members engage with the source of distraction by verbally responding while maintaining primary task activity
7.	Sterile team's work interrupted—operation flow disrupted: interruption of the current primary task of the sterile team, the operation flow is disrupted

Statistics

To facilitate statistical analysis, the recordings were annotated with The Observer® XT 11.5 software (Noldus Information Technologies, Wageningen, The Netherlands). To assess the interobserver variability, a random sample of six recordings were scored by both observers. The findings of the two observers for these six procedures were compared and the interobserver agreement was calculated (compares events between two observations and takes the frequency and sequence into account; function incorporated in The Observer® XT 11.5 software). After satisfactory interobserver agreement was achieved, the remaining procedures were annotated by either one of the two observers (randomly allocated and analyzed in a non-chronological random order) [23, 24]. For statistical analysis, SPSS 23 statistical software was used. Intraclass Correlation Coefficient (ICC) was used to assess the inter-rater agreement. A two-way random effects model was used since both the procedures as well as the raters are a random sample from a larger pool of procedures and raters. We checked for consistency (i.e. raters have a similar pattern of scores). Outcomes are both Average Measures and Single Measures. Average Measures provide the reliability of the score being able to separate different levels of safety, despite differences in individual scoring. Single Measures represents the reliability you would get if one rater was used. Values between 0.4 and 0.75 were considered to represent "fair to good reliability" and >0.75 "excellent reliability" [25]. In case the kappa becomes negative (due to low variability and high agreement) the absolute agreement was described as a percentage [26]. A Pearson Chi square test was used

to compare proportions and a Mann-Whitney U test was used for continuous variables (non-normally distributed data). A $p < .05$ was considered statistically significant.

Results

During the study period, 84 LHs were performed of which 40 were eligible for inclusion in two studies [3]. For detailed information on the excluded procedures, see Figure 7.1. All procedures were successfully completed and 3 minor postoperative complications were noted (Table 7.3 and 7.4).

The (assisting-)surgeon answered 95% of all questions (494 out of total 520 questions (40 procedures, 13 questions per procedure)), the scrub nurse 89% (461 out of 520), and the anesthetist(-assistant) 86% of the questions (445 out of 520). Based on the questionnaire, all surgical team members were of the opinion that the study did not interfere with the procedure in 33 out of the 40 procedures (83%). In all cases one of the two experienced gynecologists (>100 LHs) attended the procedure. Nevertheless, the questionnaire was filled out in 58% of the cases by the assisting surgeon. As a result, reported experience of the surgeon with LH varied between ≤25 prior procedures (14%), 26–40 (30%), 41–100 (32%) and >100 prior LHs in 24% of the procedures. The surgeons reported in 41% of the cases to have used the same instruments and devices >100 times before in prior procedures. In 50% they reported to have experience with the equipment between 25–100 prior procedures and in 8% this was ≤25 procedures. Experience of the scrub nurse with MIS was in 37% of

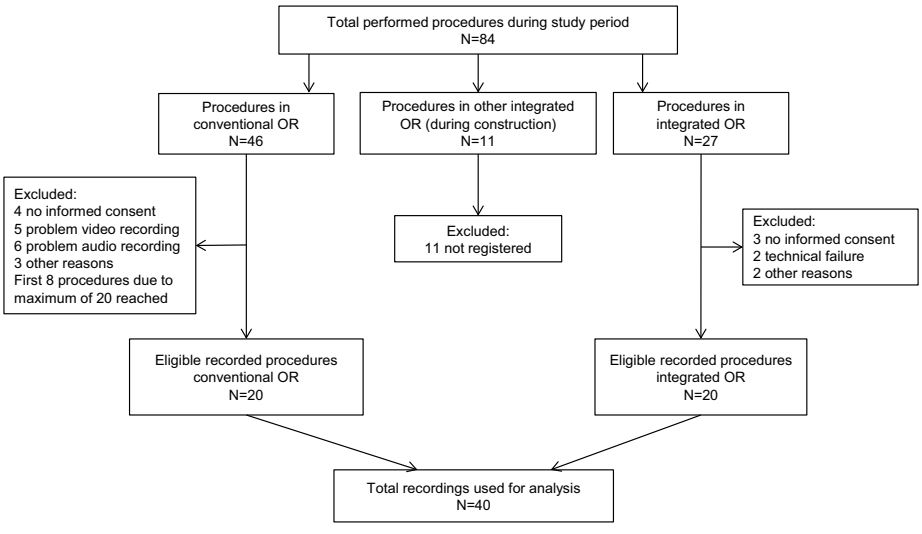

Figure 7.1 Inclusion of eligible procedures.

Table 7.3 Patient and procedure characteristics of analysed LHs performed in the Haaglanden Medical Center, The Hague between January 2011 and April 2012

	Overall (N = 40)		
	Median	IQR	Min–max
Age (years)	48.2	43.9–55.2	
BMI (kg/m^2)	24.9	22.7–27.3	
Uterine weight (gram)	165	97–256	
Operating time (minutes) [a]	121	± 29	66–176
Procedure time (minutes) [b]	156	± 31	98–215
Estimated Blood loss (mL)	100	50–175	
Hospital stay (days)	2.0	1.1–2.1	
Benign indication (%)	70.0%		

[a] Time between first incision and last suture (skin-to-skin) (based on video observation).
[b] Time between patient entering OR and leaving OR (based on video observation).
IQR = Inter Quartile Range (25th and 75th percentile); BMI = Body Mass Index.

Table 7.4 Adverse events all analysed LHs. All adverse events did not require re-operation and occurred postoperatively

	Overall (N = 40)
Infection	1[a] (2.5%)
Blood loss > 1L	1[b] (2.5%)
Others	1[c] (2.5%)
Total	3 (7.5%)

[a] Urinary tract infection.
[b] Postoperative drop in haemoglobin. CT-scan showed free fluid intra-abdominally. Vital signs were stable and after a blood transfusion with 2 packed cells haemoglobin levels remained stable.
[c] Patient suffered from sensibility loss in her right hand. The neurologist diagnosed a neuropraxia of the median nerve. Conservative management resulted in almost complete recovery.
LH = Laparoscopic hysterectomy.

the cases between 41–100 and in 53% >100 prior procedures. Despite this, experience with LH specifically was moderate; in 71% of the cases the scrub nurse had performed ≤25 prior LH procedures. Similarly, their experience with the equipment was moderate (in 43–47% of the cases ≤25 procedures).

Surgical Safety Questionnaire

The scores per question of the individual team members are summarized in Table 7.5. In 15% (6 out of 40) of the procedures potential safety concerns (i.e. answer 'indifferent' or '(strongly)

Table 7.5 Scores per question of the team members individually

	Surgeon					Scrub nurse					Anesthetist				
Question	N	Mean	SD	Range	n ≤3	N	Mean	SD	Range	n ≤3	N	Mean	SD	Range	n ≤3
1. Time-out	39	4.54	± 0.55	3 - 5	1	36	4.19	± 0.67	2 - 5	3	37	4.08	± 0.68	2 - 5	3
2. Sign-out	37	4.49	± 0.51	4 - 5	0	31	4.16	± 0.86	2 - 5	5	28	3.96	± 0.51	2 - 5	2
3. Preparation	39	3.97	± 1.06	1 - 5	11	36	4.14	± 0.72	2 - 5	5	34	3.88	± 0.81	2 - 5	7
4. Functioning	39	3.51	± 1.21	1 - 5	16	36	3.83	± 1.11	1 - 5	6	33	3.85	± 0.67	2 - 5	6
5. Ease of use	39	3.82	± 1.07	1 - 5	11	36	3.94	± 0.83	2 - 5	5	32	3.81	± 0.74	1 - 5	7
6. Communication	39	3.9	± 0.75	2 - 5	11	35	3.86	± 0.77	2 - 5	5	36	4.11	± 0.52	3 - 5	3
7. Collaboration	39	3.92	± 0.74	2 - 5	10	36	3.89	± 0.62	2 - 5	5	36	4.14	± 0.42	3 - 5	1
8. Disturbances	39	3.95	± 0.92	2 - 5	7	36	3.89	± 0.85	1 - 5	4	35	3.77	± 0.81	2 - 5	8
9. Surgeon	28	3.96	± 0.43	3 - 5	3	36	4.25	± 0.55	3 - 5	2	35	4.14	± 0.49	3 - 5	2
10. Scrub nurse	39	3.92	± 0.62	2 - 5	7	35	4	± 0.48	3 - 5	4	35	4.14	± 0.43	3 - 5	1
11. Anesthetist	39	4.18	± 0.51	3 - 5	2	36	4.19	± 0.47	3 - 5	1	32	4.41	± 0.5	4 - 5	0
12. Patient safety	39	4.21	± 0.7	3 - 5	4	36	4.08	± 0.5	2 - 5	1	36	4.42	± 0.5	4 - 5	0
13. Study influence	39	4.56	± 0.6	3 - 5	2	36	4.31	± 0.47	4 - 5	0	36	3.97	± 0.81	2 - 5	6

N ≤3: The number of questions to which a score ≤3 was given, which is defined as a safety concern.

disagree') were reported regarding the time-out and sign-out procedure. With respect to the preparation, functioning and ease of use of the devices in 37.5–47.5% (15–19 out of 40 procedures) a potential safety concern was reported by one or more team members. A strong disagreement to a flawless use of the devices was reported in seven procedures (17.5%). With respect to communication and collaboration in 30–35% (12–14 out of 40 procedures) concerns were reported, mostly by the surgeon.

In general, scores given by the surgeon were in 16% (85/520) regarded as a potential safety concern. With respect to the scrub nurse and anesthesiologist this was both 9% (46/520). Overall, 'strongly disagree' was reported in 2% (9/520), of which 8 were reported on questions 3, 4 or 5 (i.e. equipment related, see Appendix 7.1).

In 87% (452 of 520 questions) all members of the surgical team agreed in their answers (i.e. the maximum difference between the lowest and the highest was ≤ one point on the Likert scale). In 4% (22 of 520) the absolute difference between the members of the surgical team was high (≥3; for example, to the same question the surgeon reports 'disagree' and the scrub nurse reports 'strongly agree'). The ICC was 0.44 (average measures).

Validation of Surgical Safety Questionnaire by video analysis

The overall observation duration of these procedures was 103 hours and 45 minutes. Six randomly chosen observations were annotated by both observers and showed excellent agreement (Cohen's Kappa of 0.79–0.98, all observations combined 0.85, $p < .001$). Therefore, the remaining procedures were annotated by the two observers separately (in total 36 observations by M.D.B. and 10 by S.R.C.D., respectively). The duration and effect of disturbances during procedures in which a potential safety concern was reported with regard to the functioning of devices and instruments (question 4, see Appendix 7.1) were compared to the procedures in which no safety concern was reported (Table 7.6). In the procedures after which a potential safety concern was reported, a significantly higher percentage of the duration of the procedure consisted of surgical flow disturbances (9.3% ± 6.2% versus 2.9% ± 3.7% (mean ± SD), $p < .001$). Similarly, in these procedures, a significantly higher mean weighted effect (i.e. the mean effect of the disturbances corrected for the duration of the disturbances) was found (score 6.1 ± 1.9 versus 4.4 ± 2.4, $p = .020$; see Table 7.2 for the meaning of the scores).

In the group without any reported safety concerns, there were only two procedures during which a relatively high percentage of the procedure consisted of disturbances (10.0 and 15.4%, respectively). However, the mean weighted effect of these disturbances was low (1.9 and 3.0, respectively) and therefore can be regarded as adequately managed. All tests to assess

Table 7.6 Duration and effect of surgical flow disturbances with regard to functioning of devices and instruments (question 4 of questionnaire) separated between procedures with or without a safety concern reported by at least one member of the surgical team (N = 40 procedures)

	No safety concern[d] reported							Safety concern[d] reported							
	n	Mean	±	SD	Min	-	Max	n	Mean	±	SD	Min	-	Max	p[e]
Percentage of procedure[a]	21	2.9	±	3.7	0.0	-	15.4	19	9.3	±	6.2	1.6	-	21.7	< .001
Effect (weighted)[b]	21	4.4	±	2.4	0.0	-	7.0	19	6.1	±	1.9	3.0	-	7.0	.020
Impact[c]	21	13.2	±	12.0	0.0	-	47.1	19	56.2	±	38.7	11.5	-	145.7	< .001

[a] Total duration of the disturbance(s) defined as percentage of the total procedure time.
[b] Effect of the disturbance (based on Persoon et al. [9]) corrected by the duration of the disturbance(s).
[c] Percentage of procedure multiplied by weighted effect.
[d] Reported answer by at least one surgical team member was (strongly) disagree or indifferent.
[e] Mann-Whitney U test for independent samples.
SD = Standard Deviation.

whether using the questionnaire of one or two of the team members might be applicable as well, resulted in lower agreement with the video analysis (not shown).

Newly introduced devices and / or technology

During eight procedures (20%, 4 procedures in the conventional OR and 4 in the integrated OR) a new instrument and / or device was used. During these procedures, the surgical team members reported a potential safety concern in 51% (41 out of 80 questions regarding intraoperative aspects (question 3 till 12), see Appendix 7.1). In contrast, the prevalence of a potential safety concern during the other procedures was 23.1% (74 out of 320, $p < .001$).

The first 20 procedures were performed in a conventional cart-based OR. The last 20 procedures were performed in a new integrated OR. No difference in potential safety concerns was reported between the two OR set-ups (28 vs. 29%, $p = .740$). Furthermore, an employee of the medical industry was present during seven procedures (four in conventional OR, three in integrated OR), during which a newly introduced device was used. Additionally, in one procedure a new device was used without an employee of the industry being present (fourth consecutive procedure in which this instrument was used). The new equipment concerned a new bipolar sealing instrument (5 procedures), a new type of suture for the vaginal cuff (1 procedure), and multiple new devices/instruments (3 procedures).

Experience

Limited experience of the scrub nurse with the equipment (≤25 procedures) resulted in significantly more potential safety concerns reported by at least one member of the surgical team (30.7% versus 15.6%, $p = .002$). However, this did not result in a higher percentage of procedure time expended to surgical flow disturbances (7.3% ± 7.6 vs 5.0% ± 5.2, $p = .423$) and / or a higher effect of these disturbances (5.7 ± 1.4 versus 4.8 ± 2.3, $p = .275$) ($n = 30$ procedures). Experience of the surgeon with the used instruments did not have a significant influence on the potential safety concerns either (25.6% versus 23.8%, $p = .791$).

Discussion

The Surgical Safety Questionnaire filled out directly postoperative by all members of the surgical team proved to be a valid tool to adequately estimate surgical safety in MIS. Procedures during which a relatively high percentage of the duration consisted of surgical flow disturbances and / or with a relatively high mean weighted effect of these disturbances matched with the reported potential safety concerns. Furthermore, during procedures in

which a new instrument or device was used, significantly more potential safety concerns were reported by the surgical team. Therefore this could be a useful tool in the evaluation and maintenance of surgical safety during the introduction of new surgical equipment or technology.

The term patient safety is at risk to become an empty phrase by its broad interpretation. To define nuances in patient safety, the 'systems approach' is most commonly used [27, 28]. Based on this approach several studies introduced frameworks covering the risk domains relevant to surgical safety and patient outcomes [6, 7, 29]. The questionnaire validated in present study covers these risk domains and thereby provides a composite outcome for surgical safety.

A study conducted by Russ et al. had similar objectives and described the Metric for Evaluating Task Execution in the Operating Room (METEOR) as an easy to use tool to allow surgical teams to self-assess their performance, in order to track surgical hazards and to be able to evaluate safety [30]. However, their checklist is quite extensive (up to 80 items) and does not cover concerns regarding instruments and devices. Since the high dependency on technology in MIS, equipment-related disturbances are one of the well-known primary sources of disruption [3, 8, 31]. Additionally, during the introduction of a new technique and / or technology in the OR, disruptions are even more likely to occur [4, 7]. This hazard is also one of the main results in our study. Therefore, prior to the introduction of a new intervention in the OR, a prospective risk analysis should be performed to guarantee safe implementation (e.g. Healthcare Failure Mode and Effect Analysis) [32]. Nevertheless, in our opinion, methods currently used to monitor this implementation (i.e. evaluation after 6 and 12 months, adverse events registration, incident reporting system, etc.) fail to detect safety concerns in a timely manner. Similarly, our results rule out the widespread assumption that an employee of the medical industry being present can prevent safety hazards. Instead, the Surgical Safety questionnaire presented in this study could be a useful tool to systematically evaluate the surgical safety after each procedure, especially in case of the introduction of a new instrument or technology.

The main strength of our study is that by using video observation we were able to assess surgical flow disturbances without influencing the course of the procedure. In that way, we obtained very reliable quantitative results to serve as gold standard and thereby allowing validation of our Surgical Safety Questionnaire. This is in line with other studies recognizing the additional value of detailed analysis of video registration [33, 34]. A weakness could be that scoring on a 5-point Likert scale remains prone to subjectivity. What determines the difference between agree, neither agree nor disagree and disagreement? It was decided to place the cut-off for a potential safety concern at 'neither agree nor disagree'. By doing so,

every time at least one of the team members for any reason had a motive to not (fully) agree on a certain question in the questionnaire the item was marked as potential safety concern. Nevertheless, the results of our study indicate that by using this definition the potential safety concerns correlate very well with the observed surgical flow disturbances. Furthermore, in contrast to the high agreement (87%), the reported ICC (0.44) seems low. However, this discrepancy is explained by the low variability and high agreement in the reported answers. In those cases, kappa is not a reliable estimate for correlation [26]. Thirdly, the reported experience with the LH seems low. This is due to the system in The Netherlands, in which residents specializing in MIS are usually allowed to perform LH as 'primary' surgeon during the last year of their residency and therefore also filled out our scoring sheets. However, without exception, in these cases the senior consultant with extensive experience in advanced gynecologic endoscopy was always member of the sterile team as well.

Over the past decades patient outcomes regarding MIS have rapidly improved. Large leaps could be made in the early days of MIS, where measures taken to improve safety were highly effective. Currently, only smaller steps can be made with a higher risk of doing harm instead of good [1, 35]. Furthermore, the OR has become increasingly complex. As Sir Cyril Chantler said: "Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous" [36]. The common objective we are pursuing is to enable technology to assist the surgeon and its team in maintaining surgical safety. Similar to recent developments in the automotive industry to assist the driver on traffic safety (e.g. collision avoidance, blind spot detection and lane departure warning systems), some promising systems are currently tested in a few hospitals in The Netherlands. For example, the Digital Operating Room Assistant continuously monitors the location, status and (mal) functioning of devices [37, 38].

In conclusion, the results of our study demonstrate that the presented Surgical Safety Questionnaire can act as a validated tool to evaluate and maintain surgical safety during minimally invasive procedures. In daily practice, we recommend to fill out this questionnaire in case a new technique or technology is used during a procedure. By involving the complete surgical team with their individual knowledge, experience and opinions, this will provide the opportunity to constantly evaluate new equipment and techniques. As a consequence, in an early stage potential safety hazards will be prevented in future patients.

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Scoring sheet "postoperative evaluation"

Date: _____

Function: _____

IMPLEMENTATION OF A PATIENT SAFETY TOOL IN LAPAROSCOPIC SURGERY

	Strongly disagree	Disagree	Indifferent	Agree	Strongly agree
1. The time-out procedure was followed according to protocol (e.g.: completeness, presence, inaccuracies)	☐	☐	☐	☐	☐
2. The sign-out procedure was followed according to protocol (e.g.: completeness, presence, inaccuracies)	☐	☐	☐	☐	☐
3. The preparation of devices and instruments was optimal (e.g.: presence, checks passed, time-loss)	☐	☐	☐	☐	☐
4. The functioning of devices and instruments was optimal (e.g.: problems, complexity and time-loss in case of problem)	☐	☐	☐	☐	☐
5. The ease of use of devices and instruments was optimal (e.g.: ease of installation, intuitivity)	☐	☐	☐	☐	☐
6. The communication in the complete OR-team was optimal (e.g.: communication failures identified, time-loss, consequences)	☐	☐	☐	☐	☐
7. The collaboration within the complete OR-team was optimal (e.g.: possibilities for improvement)	☐	☐	☐	☐	☐
8. During the procedure no disturbing / distracting factors occurred (e.g.: unnecessary door movements, irrelevant conversations, pager / telephone)	☐	☐	☐	☐	☐
9. The surgeon had a professional attitude (e.g.: leadership, teacher, surgical skills, communication, collaboration, possibilities for improvement)	☐	☐	☐	☐	☐
10. The scrub nurse had a professional attitude (e.g.: preparation OR, communication, collaboration, active participation, takes responsibility)	☐	☐	☐	☐	☐
11. The anesthetist(-assistant) had a professional attitude (e.g.: preparation OR, adequate anesthesia, communication, collaboration)	☐	☐	☐	☐	☐
12. The patient safety during the whole procedure was optimal	☐	☐	☐	☐	☐
13. The IMPALA-study has no influence on the course of the procedure (e.g.: awareness presence camera / microphone, communication, atmosphere)	☐	☐	☐	☐	☐

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Appendix 7.1 *Continued*

Scoring sheet "postoperative evaluation"

Date: _____

Function: _____

IMPLEMENTATION OF A PATIENT SAFETY TOOL IN LAPAROSCOPIC SURGERY

How much experience do you have with:

This procedure	0-10	11-25	26-40	41-100	>100
Laparoscopy in general	0-10	11-25	26-40	41-100	>100
The used instruments	0-10	11-25	26-40	41-100	>100
The used devices	0-10	11-25	26-40	41-100	>100

Present procedure:

Adhesions: none few moderate extensive

Adverse events yes/no: _____

_____

Additional remarks: _____

_____

_____

Thank you for you co-operation!

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Chapter 8

Digital Operating Room Assistance: a novel system to predict the remaining procedure duration by automated procedural progress monitoring

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Submitted

Abstract

Background: To test whether transforming the planned procedure duration into a summation of the average historical durations for each surgical phase (i.e. reference data) provides a reliable estimation of the actual procedure duration and to describe the basic technical components of an automated real-time procedural progress monitoring system.

Methods: Historical operating procedure data were obtained from all OR procedures that were performed at the Leiden University Medical Center between May 2011 and December 2012. Reference data for the anesthesia induction and surgical preparation ($T_{preparation}$) and anesthesia emergence phase ($T_{emergence}$) specific to each surgeon were computed based on procedures performed in 2011. The transformed procedure duration (T_{DORA}) was computed by adding $T_{preparation}$ and $T_{emergence}$ to the planned procedure duration ($T_{planned}$) and corrected with the historical deviation specific to each surgeon (i.e. the Digital Operating Room Assistance (DORA) model). The reliability of the DORA model was tested by simulating the effect of T_{DORA} on procedures performed in 2012.

Results: Reference data were computed based on 3,515 procedures performed in 2011. T_{DORA} was computed for 6,712 procedures performed in 2012. Compared to $T_{planned}$, T_{DORA} was significantly more accurate (41 ± 49 versus 8 ± 47 minutes too short, $p < .001$).

Conclusions: Transforming the planned procedure duration into a summation of historical durations specific to each surgical phase results in a more accurate estimation of the actual procedure duration. Combining this approach with a system that is able to perform real-time phase detection of the operative procedure will enable dynamic prediction of the remaining duration of the surgical procedure.

Introduction

The adage "what happens in the operating room, stays in the operating room" was applicable until the end of the 20th century in terms of legal perspectives [1]. Nowadays, it is still applicable in terms of procedural progress monitoring. The operating room (OR) acts as a 'black box': patient, surgeon and OR staff enter the room at a certain point in time to perform an intended procedure and all come out when the procedure that they actually performed is finished [2]. Usually, the performed procedure goes as planned and approximately within the scheduled time. However, quite often procedures do not go as initially foreseen and take up either less but usually more time [3]. OR managers are still limited in their ability to monitor the progress of the procedure. For example, they can only call the OR or be physically present in the OR (creating a disturbance and sterility hazard), or peer through the small OR-window and/or look up some specific time notes (e.g. 'first incision') that are manually entered into the electronic patient record (EPR) (provided that this has been done immediately and correctly) [4].

Because the OR is one of the most expensive facilities of the hospital, it is important to optimize OR occupancy by accurate preoperative scheduling and thorough monitoring of the procedural progress [5]. Furthermore, in terms of process management, the complete perioperative process consists of multiple parts besides the procedure itself. Therefore, optimized OR efficiency also affects, for example, the patient ward, hospital transport, the holding unit, OR cleaning services, recovery unit and vice versa [5, 6]. Furthermore, optimizing OR occupancy decreases the number of procedures that have to be rescheduled to another day resulting in higher patient satisfaction and lower costs [7].

Currently, operative procedural progress monitoring in the OR resembles traffic control in the mid-20th century [8]. Without speedometers or real-time traffic information, the estimated time of arrival (ETA) was purely based on experience. Nowadays, by using the global positioning system, combined with both real-time and historical traffic data and the behavior of the driver, the ETA is very accurate and, moreover, real-time adjusted if unexpected events occur.

To facilitate a more modern procedural progress monitoring system for the OR, multiple methods have been described to divide the procedure into different phases by identifying unique 'landmarks'. The passing of these landmarks indicates the procedural progress. Table 8.1 shows a summary of the most useful methods. Guédon et al. used radiofrequency identification (RFID) to track the location of patients within the OR complex [9]. The patients' vital signs are also easily obtainable predictors of OR occupancy [10]. More detailed information on the procedural progress can be provided by continuous image analysis [4]. Bhatia et al. described several consecutive phases that are generic for every procedure: an

Table 8.1 Methods to determine procedural progress

Method	Sensor	'Landmark' during procedure
Patient identification	RFID	Position of patient on OR-complex / OR-occupancy [9]
Anesthesia vital signs	Pulse oximetry / Electrocardiography	OR-occupancy [10]
Double bed state	Image analysis	OR-occupancy [4]
Blue drape on/off	Image analysis	Surgery phase [4]
Activation pattern of electrosurgical device	Audio analysis	20–30 minutes before end surgery phase [11]
Segmentation & recognition of surgical workflow	Low-level sensors & video analysis	Intra-operative surgical phases [12]
Task recognition during laparoscopy	Video analysis	Intra-operative surgical phases [13-15]

RFID = radiofrequency identification; OR = Operating room.

empty OR bed, a patient on the OR bed, a patient covered in blue drapes (as start of the surgery phase), removal of the blue drapes (directly after last stitch) and an empty OR bed again. These four general states were detected with 99% accuracy. Additionally, Guédon et al. used the activation pattern of the electrosurgical device to predict 'if it was time to prepare the next patient'; optimally this is done 25 minutes before the last suture [11]. Furthermore, Dergachyova et al. have proven that automatic real-time segmentation and recognition of the surgical workflow is feasible [12]. Their combination of sensors and video analysis detected intraoperative surgical phases with a reliability of 91%. Last but not least, task recognition on laparoscopic video is rapidly advancing, allowing for accurate surgical phase recognition [13-15].

Presumably, the combination of the above-mentioned sensor methods will provide an automated and reliable real-time identification of the current phase within the surgical procedure. By linking this output to historical information on the duration of the procedure beyond this phase, the remaining duration of the procedure can be estimated. This estimation based on real-time data is the crucial parameter necessary to transform OR scheduling from a static to a dynamic process [6].

The aim of this study was to test whether transforming the planned procedure duration into a summation of historical durations for each surgical phase provides a reliable estimation of the actual procedure duration. Additionally, the basic technical components of an automated real-time procedural progress monitoring system are described.

Materials and methods

Historical operating procedure data were collected from all OR procedures that were performed by all surgical specialties at the Leiden University Medical Center, Leiden, the Netherlands between May 2011 and December 2012. All data were anonymously withdrawn from the EPR system and therefore are exempt from patient consent. Relevant perioperative phases were defined as shown in Figure 8.1. All stated timestamps had to be manually entered into the EPR during the operative process (see Figure 8.1).

Average historical duration of the surgical phases between the timestamps "patient on OR", "start surgery", "end surgery", and "patient leaving OR" were obtained to compute reference data. Thereby estimations for the average duration of the preparation phase ($T_{preparation}$) (i.e. anesthesia induction and surgical preparation combined), surgery phase ($T_{surgery}$), and anesthesia emergence phase ($T_{emergence}$) were acquired. Thus, the planned procedure duration is not a fixed time length, but a summation of these three phases marked by the four timestamps that are applicable to every procedure (underlined in Figure 8.1).

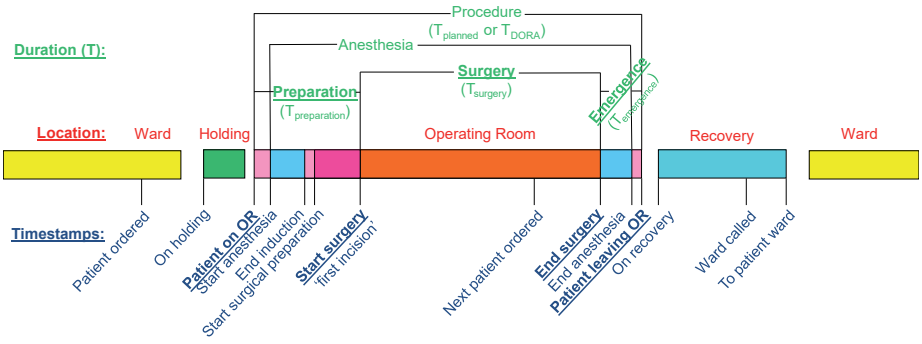

Figure 8.1 Schematic representation of the perioperative process.
DORA = Digital Operating Room Assistance.

Obtaining reference data

Operating procedure data were obtained from procedures performed between May and December 2011. Per surgeon and per specialty, $T_{preparation}$ and $T_{emergence}$ were computed. $T_{surgery}$ is obviously preoperatively estimated by the surgeon. However, at present, this estimation is used as the planned procedure duration ($T_{planned}$). Therefore, in order to correct for any consistent underestimation or overestimation of the surgeon, the average difference between $T_{planned}$ and $T_{surgery}$ (i.e. deviation) was computed. This computation was stratified into categories: $T_{planned}$ <60 minutes; 60–119 minutes; 120–180 minutes; and >180 minutes. To

allow transforming of $T_{planned}$ in case no reference data for that specific surgeon was available, reference data specific to each specialty were also computed.

Surgeons with ≤3 procedures per category were excluded. Similarly, prior to computation of the reference data, outliers were excluded (i.e. duration preparation phase <5 minutes or >105 minutes; duration anesthesia emergence phase 0 or >90 minutes; difference between planned and actual surgical duration <-90 minutes or >90 minutes, standard deviation (SD) of the average preparation phase >20 minutes or SD of the mean difference between planned and actual surgical duration >45 minutes).

T_{DORA} was computed by a model that was called "Digital Operating Room Assistance" (DORA). In this model, $T_{preparation}$ and $T_{emergence}$ were added to $T_{planned}$ and corrected for the deviation specific to the surgeon (stratified per 'planned procedure duration'-category). If no reference data for that specific surgeon were available, reference data for this surgeon's specific specialty were used.

Validation of the DORA model

The reliability of the DORA model was tested by simulating the effect of transforming $T_{planned}$. This simulation was based on procedures performed between January and December 2012. $T_{planned}$ and T_{DORA} were compared for individual procedures and for a series of procedures that were planned consecutively in a specific OR on a specific day (i.e. an OR session). Only sessions with ≥2 procedures and planned during the daytime (between 8:00am and 3:30pm) were simulated. The applied duration for OR cleaning between two procedures (i.e. turnover time) was 20 minutes.

Statistical analysis

Pivot tables in Microsoft Excel® 2010 were used for analysis and simulation. For statistical analysis, SPSS 23 statistical software was used. A paired samples T-test was used to compare differences between historical data and DORA. A $p < .05$ was considered statistically significant and a 95% confidence interval (CI) of the difference was provided.

Results

Obtaining reference data

Between May and December 2011 13,082 procedures were performed, of which the EPR of 3,515 procedures contained all data necessary to compute the reference data for all three phases. Incomplete operating procedure data were due to missing or invalid time stamps, most likely caused by incorrect manual data entry in the EPR system.

Validation of the DORA model

Between January and December 2012, 20,556 procedures were performed, of which the EPR of 6,712 procedures contained all data necessary to compute T_{DORA} and subsequently test its validity. The following were reason for exclusion: incomplete or invalid time stamps (n = 7,515); combined surgical procedures (n = 5,255); planned duration >300 minutes and emergency procedures outside office hours (n = 897); and missing reference data (n = 177).

$T_{planned}$ was 88 ± 55 (average ± SD) minutes and T_{actual} was 129 ± 84 minutes (average difference 41 ± 49 minutes too short). $T_{surgery}$ was 81 ± 70 minutes. T_{DORA} was 121 ± 62 minutes (average difference with T_{actual} 8 ± 47 minutes too short). Compared to $T_{planned}$, T_{DORA} was significantly more accurate (average difference 32.7 minutes, 95% CI 33.1–32.3, $p < .001$) (Table 8.2).

A total of 421 sessions (in total consisting of N = 1,312 procedures) were simulated. Mean actual turnover time was 21 minutes. Of all 421 sessions, 54% (N = 229 sessions) actually ended past 3:30pm. Based on the simulated durations of DORA, the overtime of 35% (n = 148 sessions was predicted, which means 65% (148 of 229 sessions) could have been anticipated. The overtime of the remaining 19% (n = 81 sessions) would not have been predicted preoperatively by DORA. Furthermore, DORA predicted incorrectly that 43 sessions would end past 3:30pm (10%, average overtime by DORA 49±41minutes; whereas actual end time of the sessions was on average 2:51pm ± 31 minutes).

Basic technical components of an automated real-time procedural progress monitoring system

Based on the results outlined above, the approach of the DORA model is a feasible basis for an automated real-time procedural progress monitoring system. This approach has to be implemented in a technical system that facilitates generic and reliable phase detection during any surgical procedure. Such systems have been described in the literature [4, 9, 11, 16].

Table 8.2 Average procedure and phase durations (in minutes) of the procedures performed in 2012 (N = 6,712)

	Average	±	SD	Min	–	Max
Procedure duration:						
$T_{planned}$	88	±	55	5	–	280
T_{actual}	129	±	84	8	–	830
T_{DORA}	121	±	62	12	–	331
Actual phase duration:						
$T_{preparation}$	36	±	18	2	–	177
$T_{surgery}$	81	±	70	1	–	733
$T_{emergence}$	12	±	10	0	–	137
Reference data:						
$T_{preparation}$	31	±	10	5	–	71
$T_{emergence}$	11	±	3	3	–	25
Deviation	10	±	10	-24	–	70

SD = standard deviation; $T_{planned}$ = originally planned procedure duration (estimation by surgeon); T_{actual} = actual procedure duration; T_{DORA} = transformed planned procedure duration based on Digital Operating Room Assistance (DORA) model (average $T_{preparation}$ and $T_{emergence}$ are added to $T_{planned}$ and corrected for the average historical deviation); $T_{preparation}$ = duration of anesthesia induction and surgical preparation combined; $T_{surgery}$ = duration of surgery; $T_{emergence}$ = duration of anesthesia emergence; Reference data = Average historical duration of the surgical phases; Deviation = historical difference between $T_{planned}$ and T_{actual} in order to correct for any consistent underestimation or overestimation of the surgeon.

Figure 8.2 provides a schematic outline of the basic technical components. A ceiling-mounted dome IP-camera, a microphone, and a RFID reader are examples of readily available sensors able to deliver relevant and reliable information from the OR. Algorithm-1 analyzes this raw sensor information and provides a binary output for registry in the 'current data' database. This algorithm replaces the manual entry of the timestamps, as shown in Figure 8.1. Since this algorithm directly analyzes the raw sensor information (e.g. it is constantly checking for the presence/absence of blue surgical drapes [4], 'listening' to the specific frequency of the coagulation device [11], etc.), no data are stored and privacy concerns are not an issue. See Figure 8.3 for an example of the binary output of these sensors that allow the algorithm to identify the current phase within the surgical procedure.

On a server, Algorithm-2 uses the reference data combined with the current data – consisting of general information from the EPR system (patient name, type of procedure, OR suite etc.) complemented with the timestamps – to compute the remaining time of the procedure. The remaining procedure duration is computed by subtracting the procedural progress from T_{DORA}. For example, a surgeon usually plans 120 minutes for a laparoscopic hysterectomy procedure. Including the $T_{preparation}$ (e.g. 15 minutes) and $T_{emergence}$ (e.g. 10 minutes) in total T_{DORA} becomes

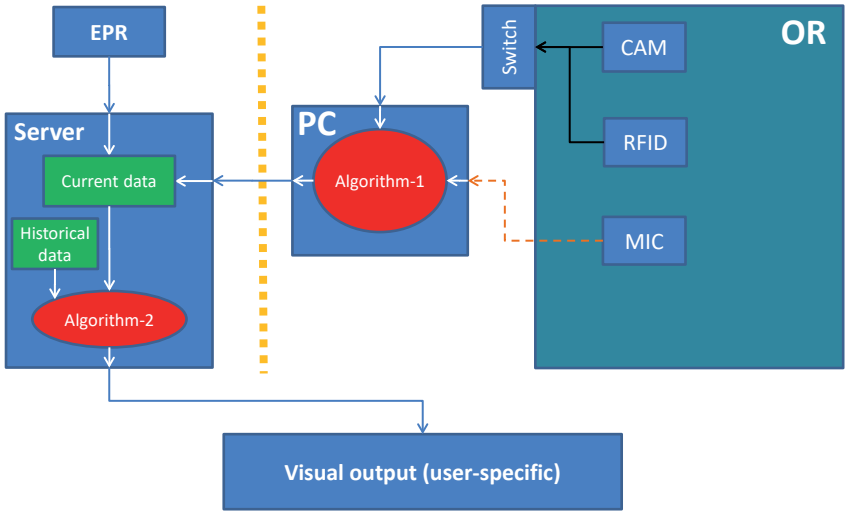

Figure 8.2 Schematic outline of the basic components required for an automated real-time procedural progress monitoring system.
OR = Operating room; CAM = IP-Camera (detecting patient on OR-bed / blue drapes etc.); RFID = Radiofrequency identification (detecting OR-occupancy by patient / personnel / devices); MIC = (Wireless) microphone (detecting electrocoagulation device activity); PC = Personal computer (containing Algorithm-1 that transforms sensor data real-time into timestamps); EPR = Electronic patient record system; Current data = Database containing all necessary information about the current operative procedures in the OR-complex (withdrawn from EPR) supplemented with the timestamps entered by Algorithm-1; Historical data = Phase specific reference data (surgeon & specialty specific); Server = Computer allowing the storage of the databases and containing Algorithm-2 that computes the transformed planned procedure duration and real-time adjusted remaining procedure duration. A visual output (user-specific) of all relevant information is made.

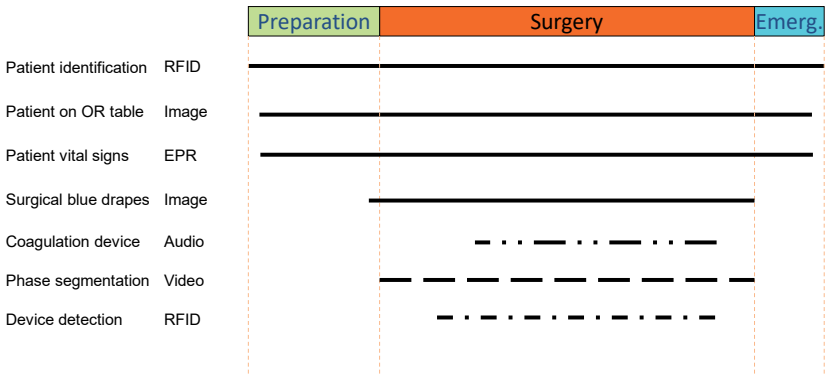

Figure 8.3 Example of the binary output of the different sensors allowing the algorithm to identify the current phase within the surgical procedure.
Emerg. = Anesthesia emergence phase; RFID = Radiofrequency identification (detecting OR-occupancy by patient / personnel / devices); EPR = Electronic patient record system.

145 minutes. However, in this case the uterus needs to be morcellated and therefore the surgeon adds 30 minutes to $T_{planned}$. At the start of this laparoscopic hysterectomy procedure the remaining procedure duration is 175 minutes. And at the start of the surgical phase the remaining procedure duration generally will be 160 minutes (175–15). However, in case of delay during the anesthesia preparation, from the minute this takes longer than $T_{preparation}$ the model will start adjusting the time that the procedure will end.

Discussion

The DORA model shows that transforming the planned procedure duration into a summation of historical durations specific to each surgical phase results in a reliable estimation of the actual procedure duration. Furthermore, the basic technical components required to perform real-time phase detection of the operative procedure have been highlighted. Combining these two features into one system will facilitate real-time prediction of the remaining duration of the procedure.

By transforming the planned procedure duration using historical deviation specific to the surgeon or his/her specialty and adding time for preparation and anesthesia emergence, the DORA model was able to show a significant reduction in the mean difference between the planned and actual duration of surgical procedures (8 ± 47 minutes). However, the SD of this difference (meaning 68% of the procedure durations are accurate within a window of 1.5 hours) is still high. No clinically relevant decline in this SD could be obtained by alterations to the DORA model. Additionally, in one in five sessions (19%) the overtime would not have been predicted by the DORA model either, resulting in procedure cancellations and overtime for OR personnel. We hypothesize this is due to the unpredictability that is intrinsic to surgery. Consequently, since the cause of this difference between the planned and the actual procedure duration cannot be prevented, this limitation can only be 'treated symptomatically'. This highlights the urgency to implement automated real-time procedural progress monitoring.

Procedural progress monitoring in the OR is still in its infancy. By showing the real-time adjusted remaining duration of a procedure, all participants involved in the perioperative process are able to plan their activities and react to ad hoc changes in the OR schedule immediately [6]. This could provide a boost in efficiency regarding workflow in the patient ward, holding department, hospital transport, OR cleaning services, surgeon for the next procedure, etc.

Based on the DORA model, every procedure can be divided into phases. Using a technical system, as described, every phase can be real-time identified and compared to the

historical duration, thereby allowing a dynamic estimation of the remaining procedure duration. Although more detailed surgical phase segmentation and identification is not yet incorporated, implementing the presented system would already be a major first step forward in automated procedural progress monitoring. To obtain more precise information on the procedural progress, large databases should be created containing all kinds of operative information (e.g. anesthesia machine settings, usage pattern of electrocoagulation and other devices, etc.). Additionally, analysis of the video image is a promising option to automatically detect surgical phases [4, 12-14, 17]. Based on this method, Malpani et al. were able to detect surgical phases with an accuracy of 74% in a series of robotic hysterectomies [18]. The integration of more advanced big data analysis and surgical phase detection by video will allow segmentation within the surgical phase of the procedure. This will be an important improvement, since unforeseen factors during the surgery phase are the main cause of the large standard deviation in the estimated procedure duration [6, 19].

Multiple methods of predicting the remaining intervention duration have been described in the literature. Based on a surgical process model, Franke et al. were able to provide an accurate estimation of the remaining procedure duration (mean absolute error between 13 and 29 minutes) [6]. However, they needed a human observer to record surgical tasks. Tran et al. were able to perform phase segmentation based on automatic surgical workflow analysis from video images [17]. They were able to divide the laparoscopic cholecystectomy procedure into phases of 12.8 minutes on average, thereby potentially allowing more precise monitoring of the progress. Although these phases were appropriately determined in 84% of the time, their model was only applicable to a single type of procedure that was simulated in a laboratory setting.

The strength of our approach is that it can be applied to every surgical procedure. Furthermore, reference data (based on procedures performed in 2011) proved to be valid in a simulation of procedures performed in the next year. However, this is still a rigid way of obtaining reference data. In future models, reference data could be based on a number of the most recent procedures instead of the average from the previous year. This will ensure that the reference data are constantly kept up to date. Another advantage of this approach is that it allows the surgeon to take patient and procedure characteristics into account while planning the initial duration of the surgical phase. Afterwards, to correct for historical underestimation or overestimation, the surgeon-specific deviation is applied. This method of preoperative planning of the procedure duration is supported by prior research [20, 21]. Similarly, Travis et al. demonstrated excellent predictions by orthopedic and plastic surgeons and an average underestimation of 35 minutes by anesthetists, thereby highlighting the potential differences between specialties and the importance of taking ‘anesthesia time’ into account [22].

The power of large data registries and big data analysis has been recognized before [23]. Although a major limitation of the present study was the amount of missing data in our historical data, due to the high number of procedures (N = 3,515 & N = 6,712) and the fact that the reference data could be validated, the results support the assumption that the missing data did not have a significant influence on the accuracy of the estimation. Currently, in our hospital, fourteen time stamps need to be manually entered into the EPR system during the complete perioperative process (Figure 8.1). This obviously causes delayed, incorrect and missing data. Automation of the entry of these (and other) timestamps would ensure more accurate and more precise reference data. Consequently, this will result in an even better estimation of the remaining procedure duration. Entering accurate and meaningful data into the EPR – without repetitive chart review or the need to enter data manually – supports the ultimate goal of having clinical support tools that provide real-time information about the patients, their outcomes, and the quality of care that is being delivered [23].

In conclusion, the implementation of automated procedural progress monitoring to predict the remaining procedure duration will facilitate a transition from static to dynamic OR scheduling. This will make the next generation of ORs truly intelligent and would support all participants involved in the perioperative process to better plan their tasks instead of acting in a reactive manner, thereby enhancing patient safety [12].

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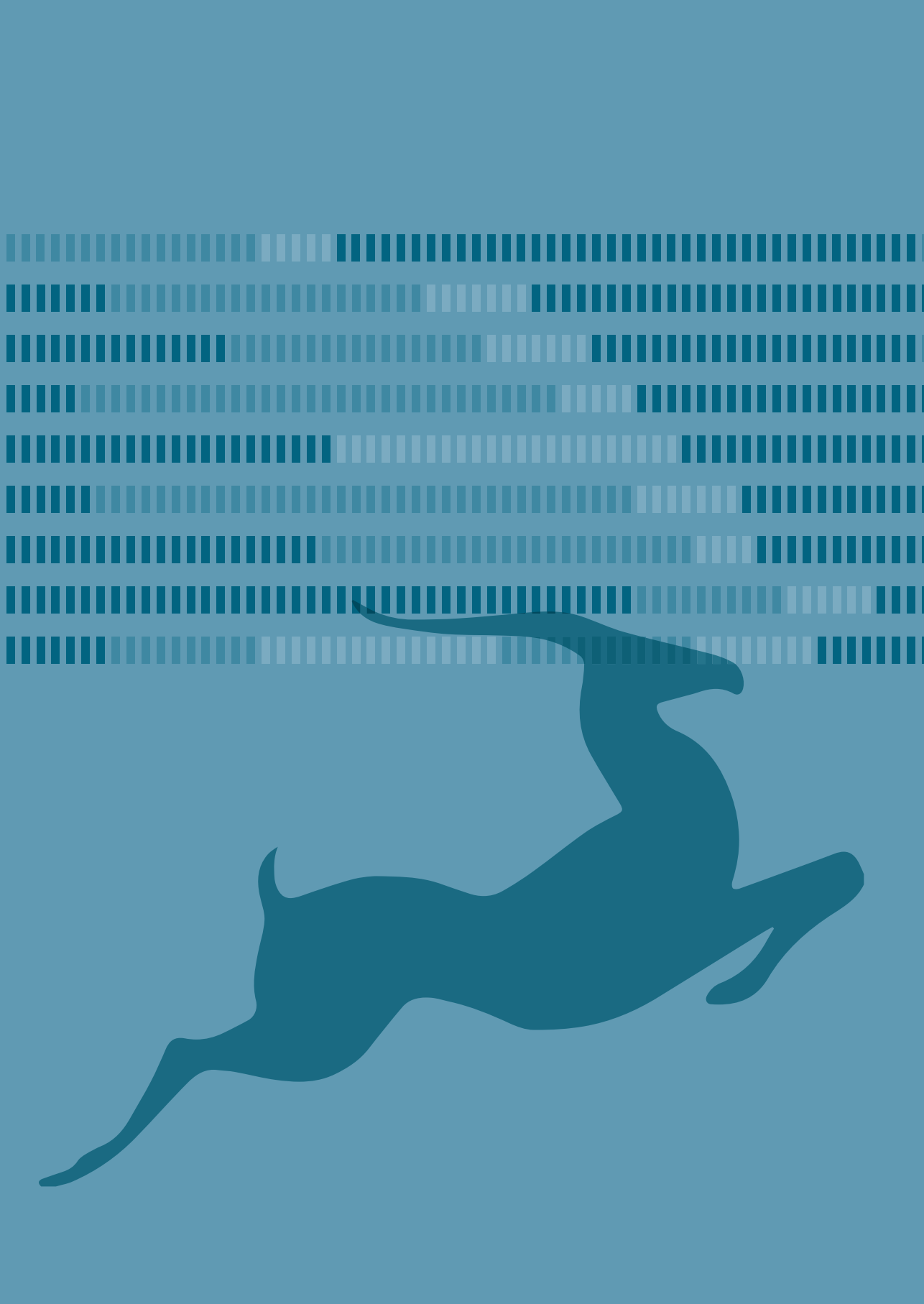

Chapter 9

General discussion

In the era of rapidly evolving surgical techniques and technology, the patient, hospital, health insurance companies and the government demand transparency in surgical outcomes and desire the highest degree of patient safety. Quality indicators are used to measure quality and ensure that patients receive the highest level of care. In this thesis, several process and outcome indicators are described that are clinically relevant in minimally invasive surgery (MIS). Furthermore, a new tool that evaluates the introduction of new interventions (i.e. both techniques and technologies) in MIS is validated. Finally, a technical solution is introduced to support clinicians during the operative process, thereby increasing both efficiency and patient safety.

Towards quality indicators for MIS that are clinically relevant

Many different outcomes and processes are currently used as quality indicators. Based on these indicators, hospitals are ranked, health insurance and government policies are made, and patients' preferences are determined. However, for most of the indicators that are used to 'measure' quality, the scientific basis or at least the clinical relevance is often lacking.

In general, and in particular to the LH, the minimal requirements for a quality indicator include (Table 9.1): relevance, evidence, feasibility (i.e. data easily available and reliable), controllability (i.e. can future outcomes be controlled?), and correction for case-mix [1]. Besides the mandatory registration of adverse events, other quality indicators that are suggested to be useful in MIS are conversion to laparotomy, hospital volume and the ratio between the minimally invasive and the conventional approach(es). Recently, the QUSUM was developed and tested as a dynamic quality assessment tool for measuring individual surgical outcomes for laparoscopic hysterectomy (LH) [2].

Table 9.1 Minimal requirements for quality indicators – particularly to the LH – per domain (adapted from Driessen et al. [1])

	Relevance	Evidence	Feasibility	Controllability	Case-mix
Structure indicator					
Volume	±	+	+	±	–
Process indicator					
Type of hysterectomy	±	+	+	+	–
Outcome indicator					
Conversion	+	+	±	±	±
Complications	+	+	±	–	–
QUSUM	+	+	±	+	+

+ present, ± partly present, – not present

In **Chapter 3**, the relevance, evidence and controllability of conversion rate as a means of evaluation in LH are described. Besides the predictors for conversion (BMI, uterus weight and surgical experience), we identified the presence of an intrinsic factor influencing the risk of conversion, which we referred to as the surgical skills factor. Virtually independent from patient and performer characteristics (i.e. experience), this factor therefore represents surgical skills including the functionality of the operating team. The presence of such a factor is confirmed by others who have stated that surgical skills seem to have a more important role than surgical experience [3]. Similarly, it has been argued that using structure and process indicators, which incorporate individual skills, may be a valuable additional means of evaluation than the conventional focus on outcome measurements alone [4-6]. For example, the implementation of mandatory and regularly scenario trainings of real-life complications (major bleedings, disfunctioning devices, etc.) will better prepare the entire surgical team to adequately manage these emergency situations laparoscopically. If we compare proficiency in surgery with driving a car, we can use the following metaphor: It is not only the possession of a driver's license (i.e., completed a learning curve) and how many times he/she has driven a car before that determines the outcome of the drive, but also the skills of the driver and the functionality of the car influence the outcome of each ride. Therefore, we should be aware of the presence of such an intrinsic surgical skills factor influencing the risk of conversion.

However, before conversion rate can be widely used as a quality indicator in MIS, it is important that a uniform and multidisciplinary applicable definition is available. Therefore, we performed a Delphi study in **Chapter 2**. The study was conducted among a representative group of laparoscopically experienced general surgeons, gynecologists, and urologists in the Netherlands. After two Delphi rounds, one definition received a very high rate of agreement (90 %), was preferred by most respondents, and was considered applicable in its current form. In order to facilitate a more detailed analysis of the reason for and outcome of the conversion, we introduced a differentiation between a *strategic* and a *reactive* conversion in the definition. This subdivision is important since reactive conversion is associated with a higher risk of postoperative adverse events and prolonged hospital stay [7, 8]. In addition, while strategic conversions mainly are the result of suboptimal indication and also low surgical volume [9], an insufficiently trained surgeon and operating team might be the cause of either a strategic or reactive conversion.

With this clear and concise definition being generally accepted and the influence of patient, procedure, and performer characteristics on conversion being known, a threshold for conversion rate in LH must be set. As demonstrated, > 95% of LH procedures are completed laparoscopically. We therefore suggest a conversion rate of < 5% to act as a future reference standard. In addition, the subdivision between *strategic* and *reactive* conversions enables better identification of conversions that are preventable. If a hospital exceeds these thresholds

(> 5% conversion in general and / or > 30% reactive conversions), we advise to conduct an audit of the converted LH procedures. The questions to be asked would include the following: Were indications properly made? Were the skills of the surgeon and the functionality of the operating team adequate? Thus, additional insight into the indications for conversion is acquired, which will enable further improvement in the outcomes in LH and will prevent unnecessary conversions in future patients.

Just as registration of adverse events is mandatory in every clinic, in order to allow for quality assessment, this registration should also include the number of conversions and their indication. Nevertheless, one has to remain aware that conversion is a phenomenon inherent to laparoscopic surgery, being a calculated risk and a sign of good surgical judgment [10]. Consequently, surgeons should not fear such a measurement and it should especially not deter them from applying the laparoscopic approach. This would deprive patients from the advantages of the minimally invasive approach and obscure the true indication for the abdominal approach. Ideally, on hypothetical grounds, an optimum rate of the laparoscopic approach should be reached, with subsequently low numbers of primary abdominal procedures. In this perspective, with respect to hysterectomy, the ratio of vaginal hysterectomies, abdominal hysterectomies, and LH procedures is another valid and clinically relevant quality indicator that should be evaluated by each clinic [11-14].

As shown in **Chapter 5**, this ratio is especially important in a group of patients inherently at risk because of their BMI ≥ 35 kg/m^2. Although morbidity is obviously the lowest in the minimally invasive approach, the surgeon's preference for the abdominal approach increases with the increase in BMI. Especially because in this group a higher conversion rate is also observed (up to 11%), in such cases the surgical skills and a well-functioning, experienced team are even more important (**Chapter 3**). Since obesity is accountable for a higher incidence of both large uterine size and malignancy [15], especially in the very obese and morbidly obese patients, the laparoscopic approach could be the best alternative to bypass these relative contraindications for the vaginal route. Nonetheless, during laparoscopic surgery in this group of patients special considerations have to be taken into account and it is argued that three-dimensional vision systems could make adequate visualization less difficult [16-18]. Together with increased experience and clustering of LH in high-volume centers, further improvement in the outcomes of hysterectomy in these patients could be achieved [9].

Thus, the analysis of complications is also a process that can ultimately improve outcomes. Especially in case of increased incidence of an adverse event after the introduction of a new intervention, the etiology has to become known. With regard to the LH, the vaginal cuff dehiscence (VCD) is such an adverse event, and the reason for the increased incidence of VCD after LH is internationally still a ground for debate. Since the suturing method used

for closure of the vaginal vault is mentioned as an etiological factor, we performed a study comparing different suturing techniques (**Chapter 4**). Laparoscopic interrupted suturing was associated with the highest incidence of VCD and should therefore – in our opinion – not be the preferred technique for closure of the vaginal cuff. In the absence of statistical superiority of vaginal versus laparoscopic closure with a running suture (e.g. Quill™, V-Loc™ or a regular Vicryl with a suture staple at both ends), the method can be based on the preference and experience of the surgeon. Nevertheless, the incidence of VCD after LH remains higher compared with abdominal or vaginal hysterectomy. Therefore, other steps of the procedure that are unique to LH, such as the amount and type of coagulation used for colpotomy, should be addressed in future research.

Measurement tool for introduction of new interventions in MIS

Innovation of new interventions is still particularly monodisciplinary and commercially driven rather than clinically driven. As stated by the IDEAL recommendations "no surgical innovation should come without evaluation" [19]. Nevertheless, new and expensive interventions are still implemented in surgery without proper evaluation. Good examples are robotic surgery [20-24] and the use of integrated operating rooms dedicated to MIS. With regard to the latter, the manufacturers state that – by their optimized design – these integrated ORs are the solution for safe surgical care by reducing OR clutter and staff workload, increasing comfort and enhancing ergonomics and OR team performance. Importantly, these statements are inherently biased and are only describing potential benefits that are not based on objective research [25-29]. Although it is not clear whether an integrated OR is a useful, cost-effective and safe solution, globally many hospitals have invested or are investing in integrated surgical suites [25, 30]. Therefore, in **Chapter 6** we performed a prospective observational study comparing a conventional versus an integrated OR with respect to equipment-related error rates. We found that the number and the effect of equipment-related surgical flow disturbances is not reduced by performing an advanced laparoscopic procedure in an integrated OR instead of a conventional cart-based OR. As a matter of fact, we observed that, in the integrated OR, intraoperative repositioning of the monitors is a frequent and time-consuming source of disturbance. Apparently, this potential hazard, which comes with the introduction of an integrated OR, is underestimated by the surgical team.

Nevertheless, performing surgery in the integrated OR does not affect outcomes in a negative way and provides some important advantages. Most importantly, for all team members the ergonomics are more favorable, thereby reducing physical complaints and eventually dropout [31]. Furthermore, time savings in the preoperative setup has also been observed [25, 27, 32]. Therefore, performing MIS in an integrated OR could be regarded as an ergonomically

responsible innovation for those who are frequently performing advanced MIS. However, in order to maintain the high level of surgical safety that has been established by laparoscopic surgery, the entire surgical team has to be fully aware that by performing surgery in an integrated OR different potential sources of disruption arise [33].

Therefore, it is important to encourage the surgeon and the entire team to continue to observe themselves critically when implementing new interventions. In any case, this can prevent following procedures from leading to the same safety hazard. To achieve this, we have developed and validated the Surgical Safety Questionnaire (**Chapter 7**). It appears that this short questionnaire filled in by all members of the OR team (surgeon, scrub nurse, anesthetist(-assistant) can demonstrate and in particular can exclude the presence of surgical flow disturbances. Despite the fact that its use takes time, this validated questionnaire potentially prevents future safety hazards. In our opinion, the potential damage that can be avoided is undoubtedly much greater than the short investment in time that is required to fill in the questionnaire thereby demonstrating that the surgical safety is ensured in most cases.

Regarding the application of this questionnaire, in daily clinical practice this would mean that during the introduction of a new intervention the Surgical Safety Questionnaire has to be filled out after each surgical procedure. Involving the complete surgical team with their individual knowledge, experience and opinions will provide the opportunity to constantly evaluate new interventions. Any safety hazards that arise from this can then be analyzed more extensively. If this shows that, for example, additional training, adaptation of the workflow or of the device are necessary, these can be implemented. As a consequence, in an early stage potential safety hazards will be prevented for future patients.

Towards a technical solution to automatically monitor the progress of the operative process

As Sir Cyril Chantler said: “Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous” [34]. To help surgeons and their teams maintain surgical safety, the power of technology is currently insufficiently harnessed in healthcare. This becomes even more clear when it is compared with the way technology is deployed to ensure safety for complex and high-risk processes in, for example, the petrochemical industry [35]. Clinicians know better than anyone where the needs and room for improvement are. With the development of the Digital Operating Room Assistance (DORA) model, we have shown that a cross-pollination between both worlds can contribute to a system that is clinically relevant and achievable with viable technology (**Chapter 8**).

Since the OR is regarded as one of the most expensive departments of the hospital, optimal efficiency also will result in reduced costs. However, improvements in the efficiency are hampered by the fact that the entire perioperative process can be considered a reactive process ("As soon as possible after you ask me, I will do that"). This is in contrast with having the ability to work proactively, which allows the participants to anticipate their work ("I know I should do this in 10 minutes"). This change of the perioperative process from a reactive to a proactive manner, could be achieved by means of a GPS-like system that automatically monitors and tracks the progress of procedures.

A system based on the DORA model should be developed in close cooperation with engineers and IT specialists. Privacy concerns regarding having a camera and microphone in the OR should be addressed and – at least at the beginning – will demand continuous explanation to all users of the OR [36]. However, the DORA system directly analyzes the video and audio streams using an algorithm that produces a binary output and no observational data have to be stored for the purpose of this system.

Moreover, there is a fear that ICT solutions will completely take over certain processes by making autonomous decisions which the clinician then can no longer affect. Health care is the epitome of a professional area that refuses to be limited to a fixed path. Instead, it is often through small adjustments to the standard that the best care is provided which is tailored to the patient [37]. The best of these two worlds comes together in a principle called "adaptive support" [38]. Hereby, clinical knowledge guides the process, but any bias that it may include is taken away by algorithms. In this way, processes are automated and standardized where possible, and information and flexibility is provided to professionals when needed.

In conclusion, measuring quality and safety during the introduction of new interventions is an important topic, yet also very difficult and often lacking clinical relevance. Clinicians strive to deliver the highest quality of care and patients demand the highest safety of care. With this thesis, regarding the operative process, the set of measurement tools that the clinician has available to achieve this goal is extended and validated from a clinical perspective.

Future perspectives

To take full advantage of the use of the conversion ratio, the Surgical Safety Checklist and the DORA system, further steps need to be taken.

Of course, during the introduction of new surgical interventions, the Randomized Controlled Trial will continue to be the gold standard for evaluating effectiveness. With regard to safety, a Prospective Risk Inventory is performed to prevent any problems *in advance* of its introduction. The current vacuum in the evaluation of safety *during* this introduction can be

covered by using the Surgical Safety Questionnaire. In future studies, it should be considered whether the questionnaire can be further shortened, considering that the answer to just one of the items "*The functioning of devices and instruments was optimal*" already proved to be highly correlated with surgical flow disturbances (as a surrogate measure for surgical safety). Thus, the use in daily clinical practice will be further improved. In addition, future research can also test the validity of our findings with regard to other new interventions and other medical specializations.

For good compliance regarding the use of the questionnaire, it should also be included in the next version of the "Guideline to New Interventions in the Clinical Practice" of the Dutch Order of Medical Specialists [39]. The same applies to the definition of conversion. Although, the current multidisciplinary Dutch guideline "Minimally Invasive Surgery" already advised to use a preliminary distinction between a strategic and reactive conversion, it lacks the nuances of our validated definition [40]. As a result, for example, currently the option of performing of a diagnostic laparoscopy in order to assess the operability still falls in a gray area.

Provided that it becomes obligatory to adopt this definition in laparoscopic surgery, an unambiguous interpretation of conversion will result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a surgical procedure. In order to allow conversion rate to act as a quality indicator with respect to other procedures, future studies should be performed to assess the predictors for conversion associated with this procedure and to set a cut-off percentage for reference. In this way, each surgeon or at least each clinic will similarly be able to evaluate their conversions for procedures other than LH and as a consequence will be able to prevent potentially unnecessary conversions for these future patients too. In the long term, with regard to these procedures, conversion rate should be included in the list "Basic Quality Indicators" of the Dutch Healthcare Inspectorate (IGZ) [41]. However, the field must prevent that the demand for registration does not unnecessarily increase. Nevertheless, in daily practice, this is already ensured as conversions are mandatory to be registered and conversion ratio as a quality indicator will have to replace indicators without or with less clinical relevance.

With regard to the increased incidence of VCD after LH, further research on the technique of the colpotomy may provide an answer. For example, the vaginal approach to the colpotomy is proposed to simplify this relatively difficult step within the LH [42]. This way, the colpotomy is performed more efficiently, thereby potentially reducing excessive coagulation to maintain adequate vascularization. Furthermore, we would like to challenge others to publish their data and opinion on this important subject, to enable future scientific analysis of pooled data.

The added value of video observation to systematically assess quality and safety of new interventions is becoming more and more recognized [43-45]. Our study shows that it offers

significant benefits for analyzing the surgical procedure in detail. However, full registration of procedures in the OR using cameras is rarely implemented yet. The main reason for this is that constant and complete analysis is expensive and time consuming. Nevertheless, video registration will take a more prominent role in the future because both for training purposes and error analysis it can be of great added value. Several centers do this already and several studies are investigating this [44-48]. In order not to impede further developments and broad application, it is important to better define the privacy and legal status of these data [44]. With regard to the Dutch situation, Blaauw et al. have created a framework for this [49]. However, they argue that according to Dutch law these data should also be available at all times in case of an adverse event. To prevent misinterpretation and to 'protect' the surgical teams, the hospital and the patients, the Academic Medical Center in Amsterdam has put this aside after correspondence with the IGZ and the Dutch Data Protection Authority (Autoriteit Persoonsgegevens) [46]. Further investigation by the Dutch Ministry of Health, Welfare and Sport is currently awaited. On the one hand innovations in video capture technology that automatically enable video data to be made anonymous can contribute to the protection of the privacy of all the participants involved [50]. On the other hand, the possibilities regarding this should be explored to make an agreement, similar to what has been done in the aviation industry, so that in case of a serious adverse event the data are only retrieved for analysis by an independent organization (and thus not the Public Prosecutor) [51].

Nevertheless, currently this type of video recording system is intended only for retrospective evaluation regarding safety assessment and/or (team) training purposes (i.e. a 'Closed' Black Box). Creating a system that focuses on active monitoring, constant support and, if necessary, adjustment of the process (i.e. 'To Open' the Black Box) offers additional opportunities to further exploit its capabilities.

Currently, IT solutions in the health care sector are not yet used to actively support clinicians in their work. This is the case despite the fact that the technology may well be capable of taking over secondary tasks so clinicians can focus more on the primary process (i.e. providing safe healthcare). The DORA system that we presented is a good example of this. The current study is primarily a proof of the principle that the sum of the historical duration of individual phases of the surgical procedure is reliable for predicting the duration of the entire procedure. Based on this, in a follow-up study, a system that is able to detect these phases can be transformed into a system that actually predicts the expected end time of the procedure. In addition, future studies should focus on the reliability, applicability and further expansion of these possibilities.

The increased demand for patient safety is often regarded as a sign of distrust. Essentially, however, providing the best care is an intrinsic driving force of every clinician. From this

perspective, health care should implement a different approach towards safety. This is since focusing on why the desired outcomes of healthcare are achieved in the great majority of the cases, can actually result in more room for educational reflection. This tendency is also the essence of the Safety II framework [37, 52]. As an example, although the practice during the introduction of new interventions may be characterized by frequent minimal hick-ups to near-misses, this does not result in an increase in adverse outcomes. The endorsement of factors because of which the surgical procedure nearly always goes well is a much stronger mechanism to ensure safety than focusing on problems and trying to overcome them in the future with all kinds of tricks. Following the examples of the petrochemical and aviation industries, according to the concept of High Reliability Organization, catastrophes are better avoided in an environment where accidents are normally expected as a result of risk factors and complexity [53-55]. This high level of safety is accomplished by commitment of the entire organization to the prevention of failure, early identification and mitigation of failure, and redesign of processes based on identifiable failures [56]. Thus, with respect to the introduction of new interventions in the OR, for example, more simulation training should be carried out, mandatory both before and during the implementation. This should be done both individually (by the surgeon, resident, scrub nurse, etc.) as well as in teams. This will further improve the skills of the team, will lead to better avoidance of problems or at least ensures that these near-misses are adequately solved by these dedicated OR teams before turning into adverse events. It is precisely here that feedback through video observation is of high added value. In this way, the competencies and capacities of all participants to the operative process will be better ensured. Consequently, this will lead to a further transformation from a reactive safety framework (20th century) to a proactive safety framework (currently) and then finally to a safety framework based on the concept of High Reliability Organization [57].

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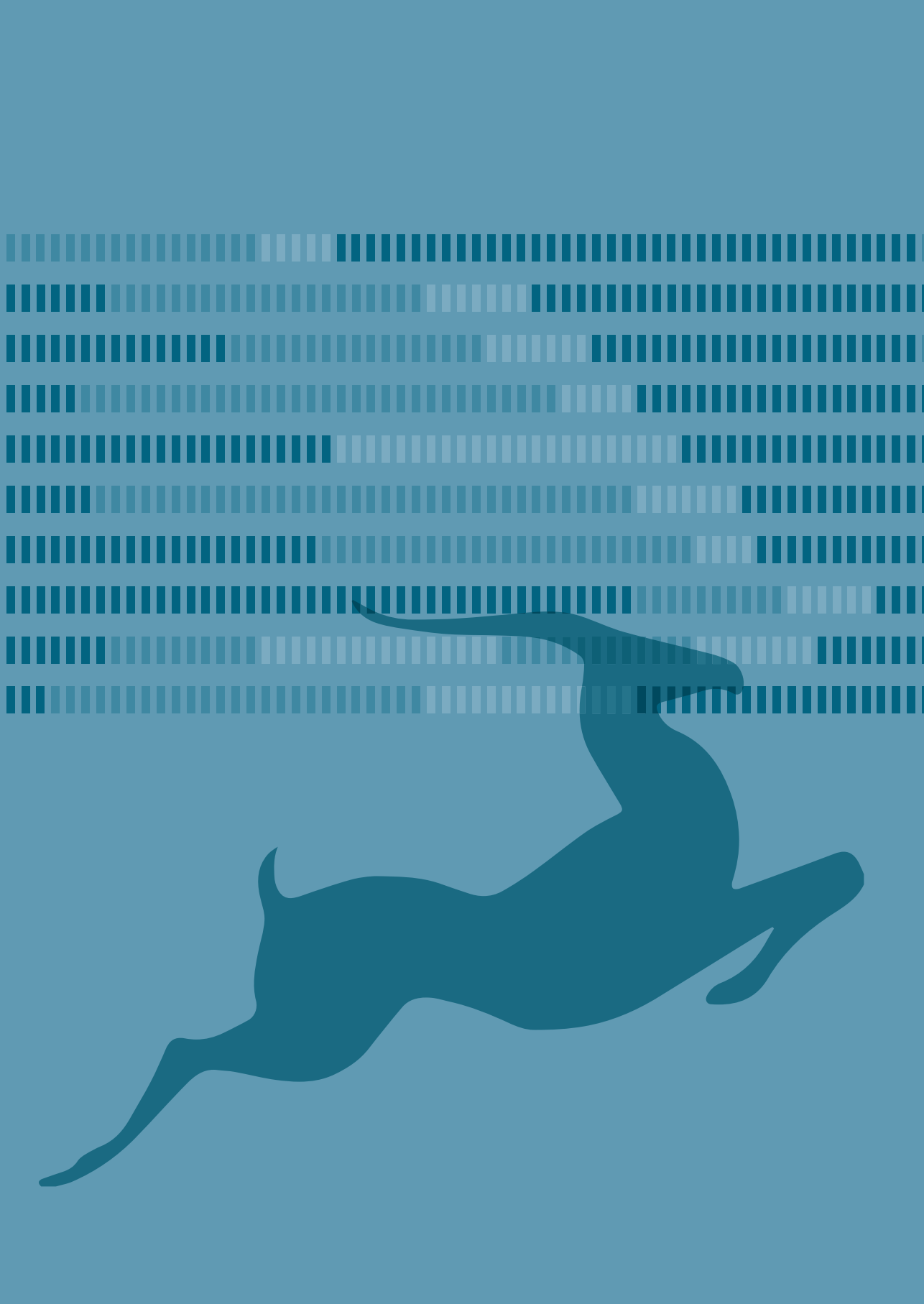


Chapter 10

Summary
Samenvatting

Summary

In the era of widely available therapeutic treatment options, patients as well as health care providers and the government desire the best care. As a consequence, the prevention of suboptimal or undesired outcomes of care that has also become more important. This common goal, to practice proper medicine, is also captured by the term *patient safety*, defined as reducing the risk of unnecessary harm associated with healthcare to an acceptable minimum.

It could be stated that *patient safety* is ensured by guaranteeing in advance the frameworks in which care is provided. Afterwards, by means of quality indicators, these processes and outcomes are measured and thus the quality of healthcare is determined. With regard to the introduction of new surgical techniques and technologies (referred to as *new interventions*) it is conventionally recognized that safety is assessed by means of Randomized Controlled Trials and/or cohort studies. However, when new interventions are introduced in rapid succession or even simultaneously into the operating room (OR), in daily practice both study designs are difficult to perform. This is especially the case in the field of Minimally Invasive Surgery (MIS) and consequently a relative high number of concerns with respect to potentially preventable damage are recognized. In that perspective, one has to realize that in general MIS has become already very safe and effective and that most introductions of a new intervention potentially yield only marginal benefits. Thus, the potential new risks could result in unexpected and undesired outcomes with possibly much greater consequences. Since scientifically well-founded quality indicators are scarce, the question is: how can the quality and safety of care in these situations be better ensured?

Therefore, the main objectives of this thesis are to obtain clinically relevant tools to evaluate quality of minimally invasive surgical procedures, both in general as well as specifically regarding laparoscopic hysterectomy (LH), as the most frequently performed advanced gynecological MIS procedure) and to support clinicians to ensure surgical safety by means of process analysis.

Some of the above described concerns with respect to patient safety in MIS were also stated in a report of the Dutch Health Care Inspectorate that was published in 2007. One of the suggested measures that had to be taken to prevent laparoscopic surgery from being unnecessarily risky was to guarantee patient safety by developing a quality-control system. Ideally, such a system would be based on clinically relevant quality indicators, of which conversion to laparotomy could be one. This is because after a conversion the patient is exposed to the risks of complications specific to both surgical approaches. Furthermore, between hospitals, a remarkable range of conversion rates are reported. Since it appeared that there is no consensus regarding an unambiguous definition and the same definitions

are interpreted differently between different specialties we performed a Delphi study to achieve consensus on a uniform and multidisciplinary applicable definition (**Chapter 2**). The study was conducted among a representative group of laparoscopically experienced general surgeons, gynecologists, and urologists in the Netherlands. After two Delphi rounds, one definition received a very high rate of agreement (90%). "Conversion to laparotomy is an intraoperative switch from a laparoscopic to an open abdominal approach that meets the criteria of one of the two subtypes: strategic conversion, a standard laparotomy that is made directly after the assessment of the feasibility of completing the procedure laparoscopically and because of anticipated operative difficulty or logistic considerations; and reactive conversion, the need for a laparotomy because of a complication or (extension of an incision) because of (anticipated) operative difficulty after a considerable amount of dissection (i.e., > 15 min in time). A laparotomy after a diagnostic laparoscopy (i.e., to assess the curability of the disease) should not be considered a conversion." This definition entails a differentiation between *strategic* and *reactive* conversions, in order to facilitate a more detailed analysis of the reason for and outcome of the conversion. Furthermore, an unambiguous interpretation will result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a laparoscopic procedure.

Based on this hypothesis, in **Chapter 3**, we described the relevance, evidence and controllability of conversion rate as a means of evaluation in LH. A systematic search of the literature provided the basis for evaluation, since no systematic data on conversion were available. We found that on average 3.5% of the procedures were converted to laparotomy, of which 73% could be regarded as strategic. Furthermore, we identified the predictors for conversion (BMI (mainly > 35 kg/m^2), uterus weight and surgical experience), as well as the presence of an intrinsic factor influencing the risk of conversion, which we referred to as the surgical skills factor. Virtually independent from patient and performer characteristics (i.e. experience), this factor therefore represents surgical skills including the functionality of the operating team. Based on these results, better insight into the risk of conversion is acquired. Consequently, conversion rate can be used as a means of evaluation to ensure better outcomes of LH in future patients.

Nevertheless, one has to remain aware that conversion is a phenomenon inherent to laparoscopic surgery, being a calculated risk and a sign of good surgical judgment. Consequently, surgeons should not fear such a measurement and it should especially not deter them from – at least initially – applying the laparoscopic approach. This would deprive patients from the advantages of the minimally invasive approach. This is especially the case in very obese and morbidly obese patients (BMI ≥ 35 kg/m^2); a group of patients that is a priori at risk for adverse events after surgery. The prevalence of these patients has been rapidly increasing in Western countries in the past decades. However, since this group of patients is almost always excluded from RCTs based on their BMI, no conclusive

evidence on the preferred route of hysterectomy is available. Therefore, in **Chapter 5**, we performed a systematic review with cumulative analysis to evaluate the outcomes of abdominal (AH), laparoscopic and vaginal hysterectomy (VH) in these patients. We showed that compared to LH, AH was associated with more postoperative complications (especially wound dehiscence (RR 2.6) and infection (RR 4.4)) and longer length of hospital stay (2.9 days). The pooled conversion rate of LH was 10.6%. Compared to AH, VH was associated with similar advantages as LH. As a consequence, we demonstrated that the feasibility of LH and VH should be considered prior the abdominal approach to hysterectomy in very obese and morbidly obese patients.

The analysis of complications is also a process that can ultimately improve outcomes. A major complication after LH whose causation is sought in the applied technique and/or technology is the vaginal cuff dehiscence (VCD). Therefore, in **Chapter 4**, we compared the incidence of VCD after different suturing methods of the vaginal vault after LH (transvaginal interrupted sutures versus laparoscopic interrupted sutures versus a laparoscopic single-layer running suture). With regard to the incidence of VCD, based on our data, neither a superiority of single-layer laparoscopic closure of the vaginal cuff with an unknotted running suture nor of the transvaginal and the laparoscopic interrupted suturing techniques could be demonstrated. Nevertheless, laparoscopic interrupted suturing was associated with the highest incidence of VCD and should therefore – in our opinion – not be the preferred technique for closure of the vaginal cuff. In the absence of statistical superiority of vaginal versus laparoscopic closure with a running suture, the method can be based on the preference and experience of the surgeon. We hypothesize that besides the suturing technique, other causes, such as the type and amount of coagulation used for colpotomy, may play a role in the increased risk of VCD after LH.

Nonetheless, a measurement tool to monitor safety at the time of introduction of new interventions in MIS procedures does currently not exist. In **Chapter 6**, we performed a prospective study using video observation, in which a conventional OR is compared with an integrated OR with regard to the incidence and effect of equipment-/instrument-related *surgical flow disturbances* during LH. Observing the presence and effect of surgical flow disturbances during the course of a surgical procedure is a novel method to evaluate safety. These disturbances are defined as stimuli that distract one or more members of the sterile team and could potentially precede a safety issue and are thus a good marker for measuring safety. The study was performed using video observation, since this is acknowledged as the ultimate way to analyze the surgical workflow and assess safety in retrospect. We found that the number and the effect of equipment-related surgical flow disturbances is not reduced by performing a laparoscopic procedure in an integrated OR instead of a conventional cart-based OR. As a matter of fact, we observed that, in the integrated OR, intraoperative repositioning of the monitors is a frequent and time-consuming source of disturbance.

Apparently, in order to maintain the high level of surgical safety that has been established by laparoscopic surgery, the entire surgical team has to be fully aware that by performing surgery in an integrated OR different potential sources of disruption arise.

Since, in daily clinical practice, extensive analysis of the entire procedure is difficult to perform, it is important to encourage the surgeon and the entire team to continue to observe themselves critically when implementing new interventions. In any case, this can prevent following procedures from leading to the same safety hazard. To achieve this, we assessed in **Chapter 7** if a specific questionnaire filled in by all members of the OR team (surgeon, scrub nurse, anesthetist) could possibly serve as a proxy for the presence of these surgical flow disturbances. We developed the Surgical Safety Questionnaire and validated its function to be a reliable measure of surgical safety by comparison with the results from independent video analysis. We found that potential safety concerns were especially reported during procedures in which a relatively high percentage of the duration consisted of surgical flow disturbances (9.3% versus 2.9%) and during procedures in which a new instrument or device was used (51% versus 23%). Therefore, it appears that this short questionnaire can demonstrate and in particular can exclude the presence of surgical flow disturbances. Any safety hazard that arises from this questionnaire can then be analyzed more extensively. As a consequence, in an early stage, potential safety hazards will be prevented for future patients.

To help surgeons and their teams maintain surgical safety, the power of technology is currently insufficiently harnessed in healthcare. Improvements in the efficiency of the perioperative process are hampered by the fact that this entire process can be considered reactive. This is in contrast with having the ability to work proactively, which allows the participants to anticipate their work. This change of the perioperative process from a reactive to a proactive manner, could be achieved by means of a GPS-like system that automatically monitors and tracks the progress of procedures. In **Chapter 8**, we presented the Digital Operating Room Assistance (DORA) model, which is a novel system for automated procedural progress monitoring that is able to predict the remaining procedure duration. First, it was tested whether adaptation of the planned procedure duration with phase-specific reference data provides a reliable estimation of the actual procedure duration. Subsequently, the requirements for an automated real-time procedural progress monitoring system were described. We have shown that a cross-pollination between both worlds can contribute to a system that is clinically relevant and achievable with viable technology.

In conclusion, measuring quality and safety during the introduction of new interventions is an important topic, yet also very difficult and often lacking clinical relevance. Clinicians strive to deliver the highest quality of care and patients demand the highest safety of care. With this thesis, regarding the operative process, the set of measurement tools that the clinician has available to achieve this goal is extended and validated from a clinical perspective.

Samenvatting

In het huidige tijdperk waarin vele behandelingsmogelijkheden ruimschoots beschikbaar en toegankelijk zijn, vereisen zowel patiënten, zorgverleners als de overheid de best mogelijke zorg. Ofwel: het voorkomen en signaleren van suboptimale of ongewenste uitkomsten van zorg is alsmaar belangrijker geworden. Het gezamenlijke doel om daarmee de best mogelijke zorg te bieden en te verlenen, wordt onderschreven door het begrip *patiëntveiligheid*; gedefinieerd als het risico op onbedoelde schade, geassocieerd met óf gerelateerd aan de te leveren zorg, te reduceren tot een acceptabel minimum.

Het kan worden gesteld dat – idealiter – de patiëntveiligheid gewaarborgd wordt door het vooraf zorgdragen voor goede kaders waarbinnen deze zorg geleverd wordt. Achteraf kunnen vervolgens door middel van kwaliteitsindicatoren deze processen en uitkomsten gemeten worden en kan daarmee een oordeel over de kwaliteit van zorg gegeven worden. Met betrekking tot de introductie van nieuwe chirurgische technieken en technologieën (verder benoemd als *nieuwe interventies*) wordt de effectiviteit en veiligheid bepaald door middel van wetenschappelijk onderzoek. Het liefst in *Randomized Controlled Trials* (*RCT's*), maar ook middels cohortstudies. Met name wanneer, zoals in de Minimaal Invasieve Chirurgie (MIC), de introductie van nieuwe interventies in de operatiekamer (OK) elkaar in snel tempo opvolgen, is dit echter niet altijd haalbaar. Tevens dient gerealiseerd te worden dat door de bank genomen met name MIC reeds als zeer veilig en effectief kan worden beschouwd en dat dientengevolge de introductie van een nieuwe interventie over het algemeen slechts marginale voordelen oplevert. Daartegenover staat dat potentiële nieuwe risico's juist kunnen resulteren in onverwachte en ongewenste uitkomsten met alle consequenties van dien. Dit wordt ook door de Inspectie voor Gezondheidszorg en Jeugd (IGJ, voorheen IGZ) onderkend. In 2007 heeft zij in het rapport *Risico's minimaal invasieve chirurgie onderschat* dan ook haar zorgen geuit ten aanzien van de patiëntveiligheid. De vraag is derhalve: hoe kan – in de afwezigheid van wetenschappelijk onderbouwde kwaliteitsindicatoren – de kwaliteit en veiligheid in dergelijke situaties beter gewaarborgd worden?

De belangrijkste doelstellingen van dit proefschrift zijn:

- Het verkrijgen van meetinstrumenten om de kwaliteit van minimaal invasieve chirurgische ingrepen te evalueren; zowel in het algemeen als specifiek voor de laparoscopische hysterectomie (LH, baarmoederverwijdering middels een kijkoperatie), als de meest frequent uitgevoerde geavanceerde MIC operatie in de gynaecologie.
- Het ondersteunen van clinici om de chirurgische veiligheid te waarborgen door middel van procesanalyses.

Een van de voorgestelde maatregelen uit het voornoemde rapport was het instellen van een kwaliteitssysteem om de patiëntveiligheid beter te kunnen waarborgen. Hierin zouden eenduidige, klinisch relevante en wetenschappelijk onderbouwde kwaliteitsindicatoren moeten worden opgenomen om een beter onderscheid te kunnen maken tussen hoogwaardige en suboptimale kwaliteit van zorg. Conversie naar laparotomie (het wisselen tijdens de operatie van kijkoperatie naar conventionele buiksnede) was een van de gesuggereerde kwaliteitsindicatoren. Enerzijds is na een conversie de patiënt aan de specifieke risico's van beide chirurgische technieken blootgesteld, anderzijds werd een opmerkelijk verschil in het conversiepercentage tussen de verschillende klinieken geconstateerd. Daarbij bleek dat er geen consensus bestond over wat wel en wat niet als conversie beschouwd diende te worden. In **Hoofdstuk 2** hebben wij daarom een Delphi-studie uitgevoerd om consensus omtrent een eenduidige en multidisciplinair toepasbare definitie van conversie te verkrijgen. De studie werd uitgevoerd onder een representatieve groep van chirurgen, gynaecologen en urologen uit Nederland. Na twee rondes werd een hoge mate van overeenstemming bereikt (90%) omtrent een definitie. In deze definitie werd onderscheid gemaakt tussen de reden van de conversie: strategisch (veelal uit voorzorg) of reactief (in de meeste gevallen 'gedwongen' na het optreden van een complicatie). Dit onderscheid maakt een gedetailleerde analyse van de oorzaken en uitkomsten van de conversie mogelijk. Tevens maakt deze eenduidige definitie een betrouwbaardere registratie en wetenschappelijke evaluatie van de haalbaarheid van (nieuwe) kijkoperaties mogelijk.

Gebaseerd op deze hypothese hebben wij in **Hoofdstuk 3** de relevantie, het bewijs en de mate van beïnvloedbaarheid van conversieratio als meetinstrument voor de LH onderzocht. Allereerst voerden wij een systematische zoektocht in de literatuur uit, waaruit bleek dat gemiddeld 3,5% van de in opzet laparoscopische ingrepen geconverteerd werden, 73% hiervan was vanwege strategische redenen. Daarnaast hebben wij voorspellers voor conversie van LH geïdentificeerd. Naast BMI (voornamelijk > 35kg/m^2, ernstige obesitas), baarmoedergewicht en de ervaring van de chirurg, werd onafhankelijk van deze voorspellers ook een intrinsieke factor gevonden die het risico op conversie beïnvloedt. Dit hebben wij de *surgical skills factor* genoemd en representeert de (onmeetbare) chirurgische vaardigheden inclusief het functioneren van het gehele OK-team. Met behulp van deze resultaten is beter inzicht in het risico op conversie verkregen. Conversieratio kan daarmee ook beschouwd worden als een instrument om de uitkomsten van LH bij (toekomstige) patiënten beter te meten en zodoende te borgen.

Desalniettemin dient men zich blijvend te realiseren dat conversie als een ingecalculeerd risico en teken van goede chirurgische afweging beschouwd wordt en zodoende inherent verbonden is aan een laparoscopische ingreep. Operateurs dienen daarom niet afgeschrikt te worden door een dergelijk meetinstrument of van het – tenminste initieel – laparoscopisch

opereren van patiënten. Want als dat gebeurt, zal een grote groep patiënten de vele voordelen van de laparoscopische benadering onthouden worden. Dit is voornamelijk het geval bij een groep patiënten die bij voorbaat al *at risk* is voor complicaties: de ernstig obese en morbide obese patiënt (BMI ≥ 35kg/m^2). De prevalentie van deze patiënten is snel gestegen gedurende de afgelopen decennia, alsmede de ziektes die direct geassocieerd zijn aan dit ernstig overgewicht. Gebaseerd op hun hoge BMI wordt deze groep patiënten veelal geëxcludeerd voor RCT's, waardoor geen wetenschappelijk bewijs beschikbaar is omtrent de voorkeursbenadering voor bijvoorbeeld de hysterectomie. In **Hoofdstuk 5** hebben wij een systematisch overzicht (*systematic review with cumulative analysis*) uitgevoerd om de uitkomsten van de abdominale (AH, conventionele buiksnede), laparoscopische en vaginale hysterectomie (VH) te evalueren. Wij hebben aangetoond dat, vergeleken met de LH, de AH geassocieerd is met meer postoperatieve complicaties (met name wondbreuk (relatief risico (RR) 2,6) en wondinfectie (RR 4,4)) en een langere opnameduur in het ziekenhuis (gemiddeld 2,9 dagen langer). Het conversiepercentage was 10,6%. Vergeleken met AH had de VH dezelfde voordelen als de LH. Hiermee werd aangetoond dat de haalbaarheid (*feasibility*) van de LH en VH dienen te worden overwogen alvorens ook bij patiënten met een BMI ≥ 35kg/m^2 te kiezen voor de abdominale benadering.

De analyse van complicaties is ook een proces dat kan bijdragen aan de verbetering van de operatieve uitkomsten. Een van de vervelende complicaties die na een LH kan optreden is die van een dehiscentie (wondbreuk) van de vaginatop (VTD). De oorzaak hiervan is tot op heden niet altijd duidelijk en wordt gezocht in de techniek en/of technologie die gebruikt wordt om de vagina tijdens de operatie te openen en na verwijdering van de baarmoeder weer te sluiten. In **Hoofdstuk 4** hebben wij de incidentie van VTD na verschillende hechttechnieken voor het sluiten van de vaginatop vergeleken. Transvaginaal losgeknoopte hechtingen werden vergeleken met laparoscopische losgeknoopte hechtingen en met een laparoscopische enkellaags doorlopende hechting. Wij vonden in onze studie geen statistisch verschil tussen deze hechttechnieken. De laparoscopisch losgeknoopte hechting was echter geassocieerd met het hoogste percentage VTD en heeft daarom, naar onze mening, niet de voorkeur. In de afwezigheid van wetenschappelijk bewijs dient de afweging tussen de vaginaal geknoopt of laparoscopisch doorlopende hechting gemaakt te worden op basis van de voorkeur en ervaring van de operateur. Onze hypothese is dat naast de hechttechniek ook andere oorzaken, zoals het type en de hoeveelheid (elektro)coagulatie die toegepast wordt bij het losmaken van de baarmoeder van de vaginawand, een belangrijke rol speelt in het postoperatief optreden van VTD na LH.

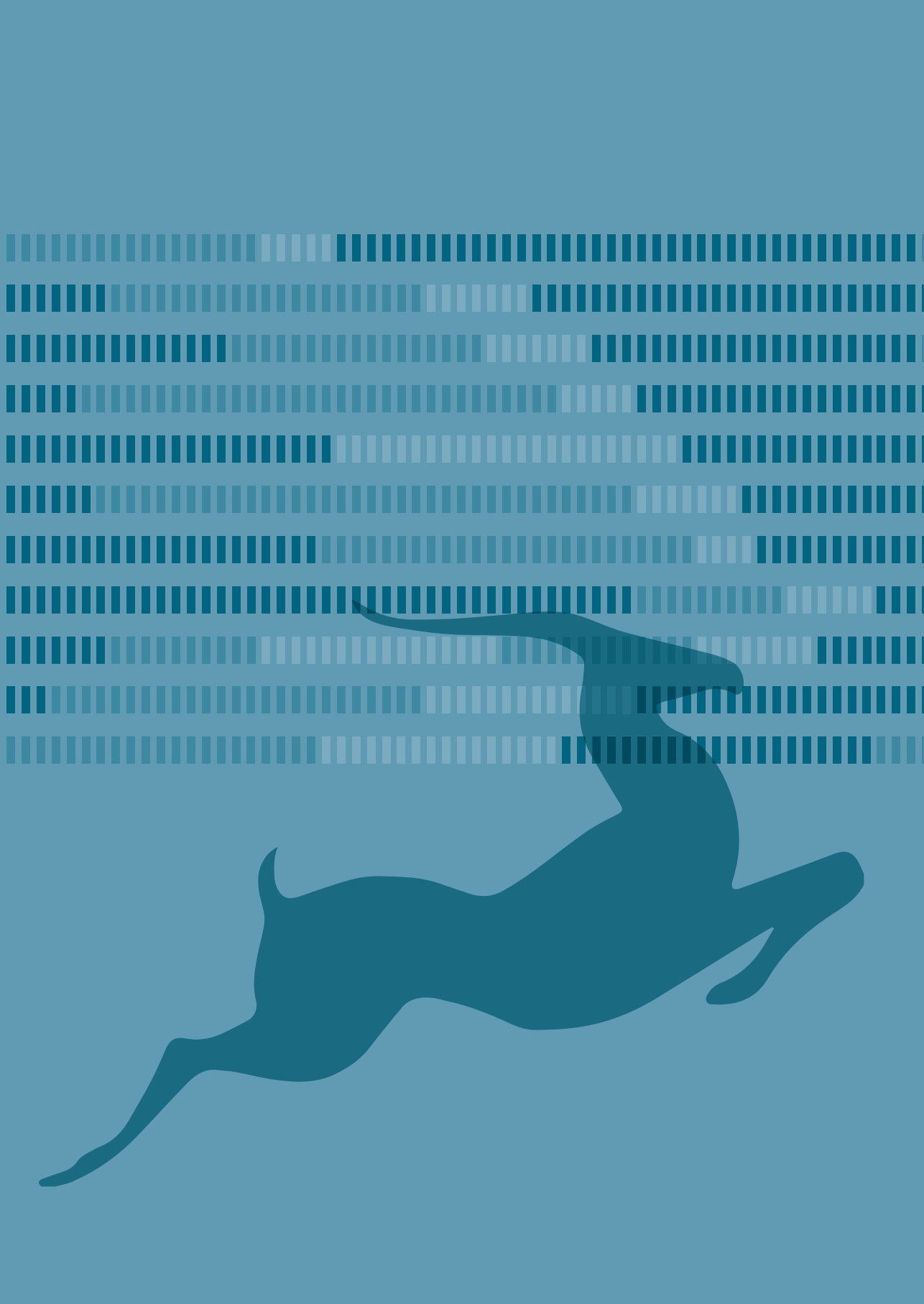
Een meetinstrument om tijdens de introductie van nieuwe interventies bij MIC procedures de veiligheid te monitoren bestaat momenteel niet. In **Hoofdstuk 6** beschrijven wij een prospectieve studie waarin met behulp van video-observatie de *conventionele OK* vergeleken

is met een *geïntegreerde OK* (volledig op laparoscopie gericht) ten aanzien van het optreden en het gevolg van apparatuur- en instrument-gerelateerde verstoringen van het chirurgisch proces (*surgical flow disturbances*) tijdens een LH. Het observeren van het optreden en het gevolg van *surgical flow disturbances* tijdens de procedure is een nieuwe methode om de veiligheid te evalueren. Dit soort verstoringen zijn gedefinieerd als stimuli die één of meerdere leden van het OK-team afleiden en die potentieel voorafgaan aan een veiligheidsincident. Hiermee zijn zij dus een goede afgeleide om veiligheid te meten. Wij hebben de studie uitgevoerd middels video-observatie, daar dit de beste manier is om operaties en veiligheid achteraf te beoordelen en de kans minimaliseert op beïnvloeding van de resultaten door de aanwezigheid van een observator die ter plaatse het onderzoek uitvoert (het *Hawthorne-effect*). Wij vonden dat het aantal en het gevolg van apparatuur-gerelateerde *surgical flow disturbances* niet verminderd is door het uitvoeren van een LH in een geïntegreerde OK. Daarentegen vonden wij dat in de geïntegreerde OK het herpositioneren van de monitoren een veel voorkomende en tijdrovende bron van verstoring tijdens de operatie was. Dit is tevens een goed voorbeeld van het feit dat tijdens het gebruik van een nieuwe interventie (in casu de geïntegreerde OK) andere potentiële bronnen van verstoring naar voren kunnen komen. Om het huidige hoge niveau van veiligheid tijdens MIC procedures te handhaven, dient het hele OK-team zich hiervan bewust te zijn.

Dit is tevens belangrijk aangezien in de dagelijkse praktijk uitgebreide analyses van de gehele procedure lastig realiseerbaar zijn. Wanneer een dergelijk bewustzijn om tijdens de introductie van nieuwe interventies extra kritisch te waken over de patiëntveiligheid structureel aanwezig is, kan het optreden van eventuele vergelijkbare incidenten tijdens een volgende operatie voorkomen worden. Om dit te bewerkstelligen hebben wij in **Hoofdstuk 7** bekeken of een korte vragenlijst – ingevuld door alle disciplines binnen het OK-team (operateur, instrumenterende, anesthesist) – kan fungeren als alternatief voor het detecteren van individuele *surgical flow disturbances*. Daartoe hebben wij de *Surgical Safety Questionnaire* ontwikkeld. Door vergelijking met de resultaten van de video-analyse uit **Hoofdstuk 6** kon deze vragenlijst gevalideerd worden als betrouwbaar meetinstrument voor de evaluatie van chirurgische veiligheid tijdens de procedure. Wij vonden dat potentiële veiligheidsincidenten voornamelijk werden gerapporteerd tijdens procedures waarbij een relatief groot percentage van de tijd opging aan *surgical flow disturbances* (9,3% versus 2,9%) en tijdens procedures waarin een nieuw instrument of apparaat gebruikt werd (51% versus 23%). Het lijkt daarom dat deze korte vragenlijst de aanwezigheid van *surgical flow disturbances* kan aantonen en met name kan uitsluiten. In de dagelijkse praktijk zullen de zorgen omtrent de veiligheid die uit deze vragenlijst gedestilleerd kunnen worden, uitgebreid geanalyseerd kunnen worden. Op deze manier kunnen potentiële veiligheidsincidenten in een vroeg stadium voorkomen worden.

De mogelijkheid om technologie aan te wenden om de operateur en het team te ondersteunen en daarmee de chirurgische veiligheid, in de breedste zin van het woord, te bewaken, wordt op dit moment nog maar nauwelijks toegepast. Ook worden verbeteringen in de efficiëntie van het hele peri-operatieve proces (afdeling, transport, holding, OK, verkoever, etc.) bemoeilijkt doordat het hele proces op dit moment *reactief* opgelijnd is. "Het volgende radartje komt pas in actie nadat het vorige radartje daar opdracht toe geeft". Beter is echter de mogelijkheid te creëren om een proactief proces op te zetten, waarin iedereen kan anticiperen op zijn eigen taak. Het neerzetten van een dergelijk peri-operatief proces kan worden bewerkstelligd door een GPS-achtig systeem te ontwikkelen, dat automatisch de voortgang van de procedure in de gaten houdt. Met dit doel voor ogen hebben wij in **Hoofdstuk 8**, in nauwe samenwerking met de TU Delft, het *Digital Operating Room Assistance* (DORA) model geïntroduceerd. De noviteit van dit systeem is dat het in staat is om de resterende duur van de procedure *real-time* te voorspellen. Allereerst hebben wij aangetoond dat aanpassing van de geplande operatieduur met fase-specifieke historische referentiedata een betrouwbare voorspelling kan geven van de daadwerkelijke operatieduur. Daarna hebben wij de technische benodigdheden beschreven voor een systeem dat automatisch de voortgang van de procedure kan monitoren. Wij hebben hiermee laten zien dat de kruisbestuiving tussen de technologie en de gezondheidszorg kan bijdragen aan een systeem dat klinisch relevant is en met betrekkelijk eenvoudige technologie te realiseren valt.

Concluderend: het meten van kwaliteit en veiligheid tijdens de introductie van nieuwe interventies is een belangrijk, maar desalniettemin moeilijk thema waarbij vaak de klinische relevantie gemist wordt. Clinici streven naar het leveren van de hoogste kwaliteit van zorg en patiënten vereisen de meest veilige zorg. In dit proefschrift zijn, met betrekking tot het operatieve proces en de introductie van nieuwe interventies, de meetinstrumenten die de clinicus voor handen heeft om dit te bereiken uitgebreid en gevalideerd vanuit een klinisch perspectief.



Chapter 11

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List of publications
Curriculum vitae
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Curriculum vitae

Mathijs Blikkendaal was born on March 20th 1984 in Haarlem. He grew up with his parents and sister in Aerdenhout and graduated in 2002 from secondary school at the Stedelijk Gymnasium Haarlem. Before starting University, he chose to spend a year abroad to study Pre-Med at Tarleton State University in Tarleton, Texas, United States of America. In 2003, he started with his curriculum Medicine at Leiden University. In 2005-2006, he interrupted his study to be treasurer of the Veerstichting. Directly after finishing his degree in Medicine, he started in January 2011 with his PhD under supervision of Prof.dr. F.W. Jansen. In October 2013, he started his official residency program in Obstetrics and Gynecology at the Haaglanden Medisch Centrum (former Bronovo Hospital), the Hague (Dr. C.A.G. Holleboom). After two years of residency in the Academic hospital (LUMC, Leiden, Prof.dr. J.M.M. van Lith), he is currently continuing his residency at the Haaglanden Medisch Centrum (Dr. M.J. Kagie & Dr. K.E. Boers).

Mathijs is married to Cathelijn and they live with their two sons Mels and Tijn in the Hague.

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