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Quality assessment of laparoscopic hysterectomy

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Chapter 2

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

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Abstract

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

Design: Observational multicenter study.

Design classification: Canadian Task Force classification II-2.

Setting: All hospitals in The Netherlands.

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

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

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

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

Introduction

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

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

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

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

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

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

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

Materials and methods

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

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

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

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

Results

Advanced laparoscopic procedures

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

The responding 86 hospitals performed a total of 4979 advanced laparoscopic procedures in 2012 (mean per hospital, 58; median 50.5; SD, 44.4). In 2007, 71 responding hospitals were included, performing a total number of 1657 advanced procedures (mean per hospital, 23; median, 15; SD, 29.7). All of these 71 hospitals provided data in both 2007 and 2012. A total of 4380 advanced procedures were performed in these 71 hospitals in 2012 (mean per hospital, 62; median, 53; SD 43.7), which is a significant increase over 2007 (95% CI, 30.3-46.5; *p* < .001).

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

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

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

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

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

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

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

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

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

Number of performing gynecologists and hospitals

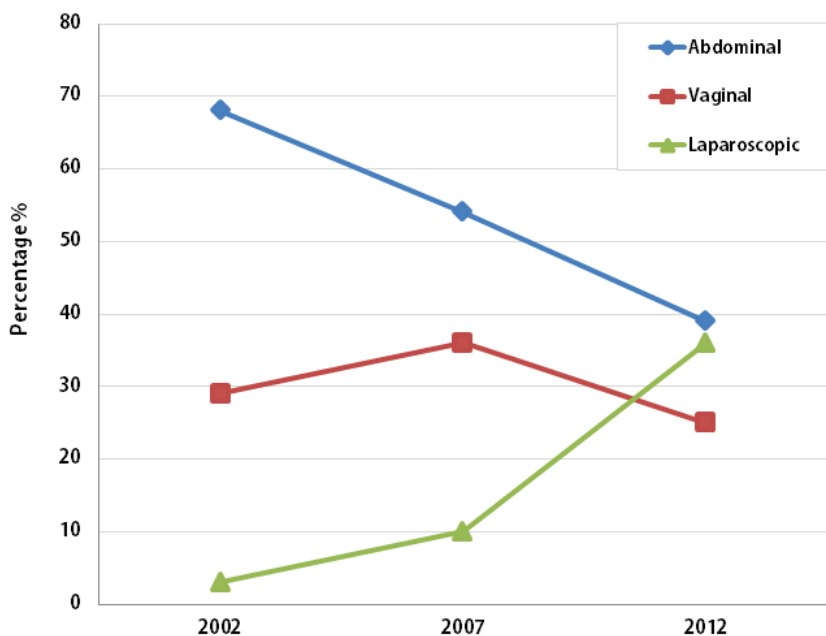
The number of advanced procedures performed per gynecologist and per hospital are presented in Table 3. The table shows that 37% of gynaecologists (n=76) and 12% of hospitals (n=9, including 3 teaching hospitals) perform fewer than 20 advanced procedures annually.

Surgical approaches to hysterectomy

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

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

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

**Figure 1** Trends in various types of hysterectomies.

Abdominal and vaginal approach decreased significantly, laparoscopic approach increased significantly ($p < 0.001$).

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

Discussion

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

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

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

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

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

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

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

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

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

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

Conclusion

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

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

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