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Laparoscopic Hysterectomy: Predictors of Quality of Surgery

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Laparoscopic Hysterectomy: Predictors of Quality of Surgery

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in 1981

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Ter nagedachtenis aan mijn ouders
Voor Marlies

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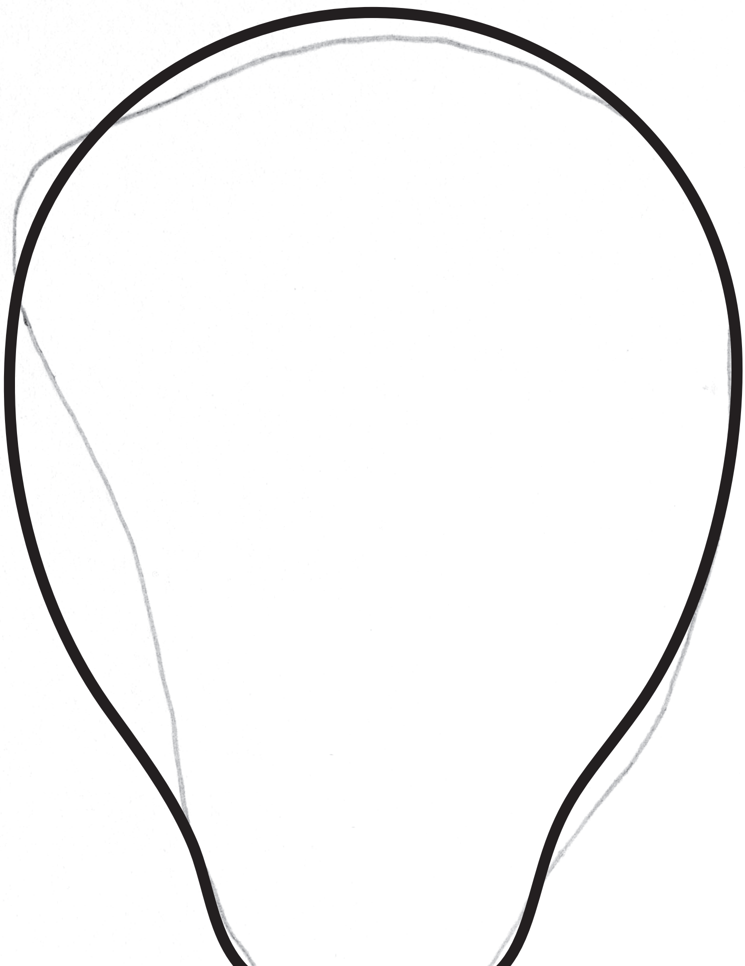
Chapter one

Introduction and outline of this thesis



Introduction

Hysterectomy is the most frequently performed major gynecological surgical procedure with millions of procedures performed annually throughout the world.[1] The vast majority of hysterectomies are performed for benign conditions, including fibroids and dysfunctional uterine bleeding. We distinguish three approaches in hysterectomy; abdominal, vaginal and laparoscopic.[2] It is well known that, due to equal or significantly better outcomes, vaginal hysterectomy (VH) should be performed in preference to abdominal hysterectomy (AH) where possible.[3] Where VH is not possible, laparoscopic hysterectomy (LH) shows several, well researched advantages over the abdominal approach. However, despite these advantages, still a wide diversity in implementation of the three approaches is observed (Figure 1).[1;4;5]

History of hysterectomy: struggle for implementation

A glance at the early history of hysterectomy teaches us that all three approaches were challenged at their origination. Charles Clay, reared in Manchester in the early nineteenth century, gained a reputation for his surgical work and was considered a 'great ovariotomist'. By accident he performed the first (subtotal) hysterectomy in 1843, as after making a massive incision in suspecting an ovarian tumor the patient coughed and extruded a huge uterine fibroid, which Clay was unable to replace. He therefore had no choice but to continue with a

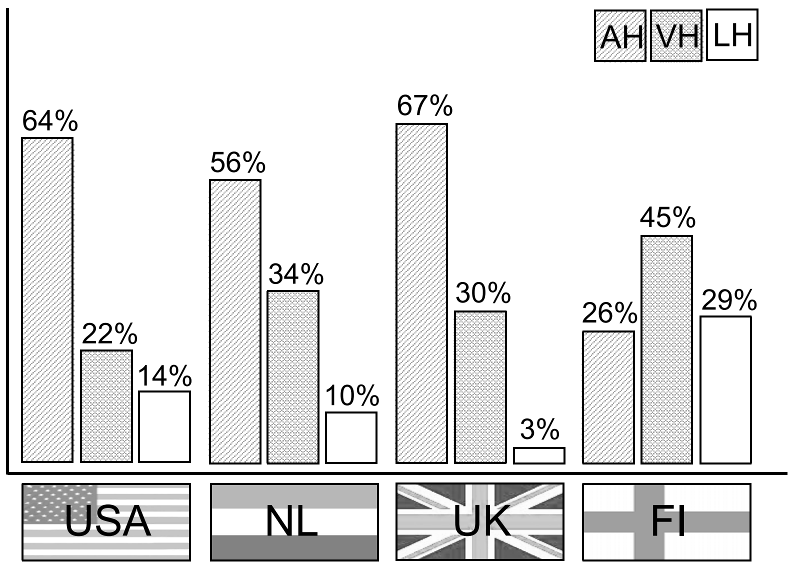


Figure 1 Global diversity in implementation rates. (USA = United States of America (source: Jacoby et al. 2009), UK = United Kingdom (source: Garry et al. 2005), NL = The Netherlands (source: this thesis), FI = Finland (source: Brummer et al. 2008)) AH = abdominal hysterectomy, VH = vaginal hysterectomy, LH = laparoscopic hysterectomy.

subtotal hysterectomy.[6] Sadly, the patient died soon afterwards from massive hemorrhage. Due to this demise and recalling the agonies his colleague Ephraim McDowell suffered during the first abdominal procedure ever performed (several of his townsfolk were erecting a gallows for him, should the patient die at the hands of 'the dreadful doctor'), Clay decided not to report this hysterectomy until years later.[6]

Similar to the numerous (self) claimed inventors of the art of printing ('*boekdrukkunst*', i.e. Johannes Gutenberg (Germany), William Caxton (Great Britain) or Laurens Janszoon Coster (The Netherlands)), the first vaginal hysterectomy was performed either in Greece (Soranus, 120 AD), Italy (Berengarius da Carpi, 1507) France (Baudelocque, 1800) or Germany (Osiander of Gottingen, 1801), depending on the nationality of the reporting source. Most of these procedures were performed on externally prolapsed and or puerperal uteri and were performed on emergency basis. Again, publication on this 'founding' procedure is scarce. It was Conrad Langenbeck, who severely regretted reporting on his first vaginal hysterectomy performed in 1813. None of his colleagues would believe the report of his operation, the specimen never reached the pathology department and the assistant surgeon died two weeks after the procedure, so there was no one to testify that the procedure had in fact taken place. The patient herself was demented and therefore an unreliable witness and died of senility 26 years later and only then could Langenbeck prove by post-mortem examination that he had performed the operation. During those 26 years he was ridiculed and none if his colleagues gave him credit at the time for this achievement.[7] Only decades afterwards, when the procedure is gaining popularity, one sees several originators of vaginal hysterectomy popping up in Europe, resembling the various inventors of the printing press. History repeats when the American Harry Reich publicizes on his first laparoscopic hysterectomy in 1989.[8] His article and subsequent live demonstrations throughout the world were met with varying degrees of amazement and skepticism.[9] Critics claimed that it took too long and would not be suitable for busy operating schedules in most countries and was a luxury peculiarly suited to the cosseted US health system, where the average gynecologist only performs one or two procedures a week.[10] Surprisingly, it was the Laparoscopic Assisted Vaginal Hysterectomy (LAVH), which was implemented in most countries, although the inventor did not recommend this subtype.[11] Again, in retrospect, others claim to have performed laparoscopic hysterectomies in the same decade.[12] Hypothetically, some synchronicity can explain these simultaneous innovations. Additionally, when it comes to innovations in general and in surgery in particular, colleagues perhaps tend to fear these 'novelties' at first instant, and then adept cautiously and then spread the word enthusiastically. However, this behavior can partially explain the hampered implementation of laparoscopic hysterectomy in most countries, almost two decades after its introduction. Perhaps in twenty years, in retrospect this period will be regarded as a 'fearful' period. Parallel to this phenomenon in surgical innovations, novelties in other fields regularly tend to be received with skepticism. Although he never admitted it, it was Bill Gates himself in 1981 who thought that 640K of RAM *'ought to be enough for everyone'*.[13] Also in the field of (pop) music, skepticism can be swiftly passed by as an US centered major record label rejected a young Liverpool based band saying *'we don't like their sound, and guitar music is on their way out'*.[14] Most of us will remember the Beatles by now.

Preferences, predicting factors and patient safety

Laparoscopy was introduced into continental Europe in the 1940s with the pioneering surgery of Hans Frangenheim from Konstanz and Raoul Palmer from Paris.[15] Gynecologists instantly understood the opportunities of laparoscopy as a diagnostic tool in gynecology. It even allowed the performance of relatively simple procedures, such as female sterilization and puncture or fenestration of ovarian cysts. Although currently laparoscopy is increasingly practiced by gynecologists throughout the world for ever evolving and challenging indications,[16-18] it was shown at the dawn of the twenty-first century that in several countries acceptance of advanced laparoscopic gynecological surgery is still limited.[1;5] Although surgeons at first instant were less keen on laparoscopy in general, the implementation of for example laparoscopic cholecystectomy shows to be much more of a success compared to gynecologic laparoscopic surgery.[5;19;20] Why is this acceptance of gynecological advanced laparoscopic surgery still limited and why seems overall preference nevertheless hampered?

Besides preference factors, performance challenges, unique to laparoscopic surgery, are likely to contribute to the hampered implementation of laparoscopic hysterectomy.[4;21] As yet no conclusive data are available with respect to predictive factors (both patient characteristics as well as surgeon's skills), its influence on surgical outcome and preference tendencies. Insight into the relevance and impact of these factors on the current hampered implementation should provide useful tools for improvement.

When it comes to basic procedures in gynecology, the advantages of the laparoscopic approach are nationwide recognized and implemented. Ectopic pregnancy and adnexal surgery by laparoscopic approach seems even almost optimal.[5] These surgical procedures are also, to a certain level of performance, mandatory in the training program during residency. However, on the contrary, the more advanced procedures (e.g. the laparoscopic approach in hysterectomy- myomectomy- and sacro-colpopexy) are scarcely implemented. Imaginably, partly due to the complexity of the technique and initial lack of skills will likely hamper the shift from conventional to laparoscopic approach, however, (i.e. with respect to laparoscopic hysterectomy,) little is known about efficient methods of safe apprenticeship. Maintenance of skills after acquiring initial experience with a new technique should be paramount in choosing a learning method.

In the Netherlands in 2007, the Health Inspectorate demanded well-defined training and registered maintenance of performance in laparoscopy, in order to enhance patient safety.[22] This report increased the urgency of matters to gain evidence on predictors of quality of surgery. Additionally, along with these recent calls for continuous quality assessments in (minimally invasive) healthcare, a validated task for testing experienced surgeons' skills outside the operating theatre is wanted.[23]

If implementation, quality of surgery, patient safety and learning curves in laparoscopy should be addressed, laparoscopic hysterectomy is the preferred advanced laparoscopic procedure to be studied. This is because this laparoscopic procedure is the most frequent performed advanced level procedure, practiced by many surgeons and is more prone to complications, compared to basic level laparoscopic procedures.[19] Laparoscopic hysterectomy is therefore an exponent to all advanced and even basic level laparoscopies.

In order to predict the quality of surgery in laparoscopic hysterectomy a nationwide prospective study, larded with several related studies was designed in order to gain evidence with respect to these predictors. Therefore, the following questions were formulated. Firstly, to which extend is laparoscopic hysterectomy implemented in the Netherlands, compared to other countries? Secondly, how preferred is laparoscopic hysterectomy by its performers as well as (potential) referring colleagues? Thirdly, is a mentorship a safe and durable tool in order to implement the techniques of laparoscopic hysterectomy? Fourthly, can we identify risk factors in laparoscopic hysterectomy, both with respect to patient and surgeon make-up? Fifthly, how can I define whether a surgeon is skilled and/or proficient enough, to perform laparoscopic hysterectomy? This thesis will provide answers to aforementioned questions and directs tools in order to assess and maintain a controllable environment in order to predict quality of surgery and to strive after patient safety.

Outline of this thesis

In **Chapter two** the implementation of laparoscopic surgery in operative gynecology, especially for laparoscopic hysterectomy, will be described. By using questionnaires similar to earlier surveys[5;19] implementation tendencies of laparoscopy and its conventional counterpart shall be outlined.

In **Chapter three** two techniques in laparoscopic hysterectomy, TLH and LAVH, will be compared, with respect to blood loss and adverse events.

In **Chapter four** we aim to explore preference boundaries and patient factors, both for gynecologists who perform laparoscopic hysterectomy, their colleagues and gynecologists employed by a hospital that does not provide laparoscopic hysterectomy. Additionally, referral tendencies will be compared.

In **Chapter five** the results of a prospective multicenter cohort study in laparoscopic hysterectomy will be presented (LapTop! study). Patient factors (such as body mass index, uterus weight, previous abdominal surgeries) as well as primary outcomes and surgeon's experience will be recorded.

In **Chapter six** all conversions registered in the aforementioned LapTop! study will be analyzed. Possible risk factors will be researched, as well as the influence of experience and skills on conversion rates.

In **Chapter seven** the influences of abdominal, vaginal and laparoscopic hysterectomy on pre-, intra- en postoperative endocrine responses and intraoperative nociceptive stress state will be studied. In addition, baseline characteristics, including anxiety factors and pain scores will be recorded.

In **Chapter eight** the influence of implementation and maintenance of advanced laparoscopic skills after a structured mentorship program in laparoscopic hysterectomy in a teaching hospital will be measured.

In **Chapter nine** the performance of gynecologists during an intracorporeal knot tying task will be researched, to which we will compare the risk adjusted surgical performance as registered in the LapTop! study.

In **Chapter ten** we will study the development of a risk adjusted CUSUM score for laparoscopic hysterectomy, based on risk adjusted patient characteristics and average national outcomes.

Finally, in the general discussion a summary of the most important findings of this thesis will be outlined and perspectives for future research will be given. Eventually, based on the assessed predictors, directives for safe implementation and maintenance of quality of surgery in laparoscopic hysterectomy will be set.

References

1. Garry R. The future of hysterectomy. BJOG 2005; 112(2):133-139.
2. Garry R, Reich H, Liu CY. Laparoscopic hysterectomy - definitions and indications. Gynaecol Endosc 1994; 3:1-3.
3. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
4. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.
5. Kolkman W, Trimbos-Kemper TC, Jansen FW. Operative laparoscopy in The Netherlands: Diffusion and acceptance. Eur J Obstet Gynecol Reprod Biol 2007; 130(2):245-248.
6. Sutton C. Hysterectomy: a historical perspective. Baillieres Clin Obstet Gynaecol 1997; 11(1):1-22.
7. Benrubi GI. History of hysterectomy. J Fla Med Assoc 1988; 75(8):533-538.
8. Reich H, Decaprio J, McGlynn F. Laparoscopic hysterectomy. J Gynaecol Surg 1989; 5:213-216.
9. Sutton CJ. Whither hysterectomy? Curr Opin Obstet Gynecol 1994; 6(3):203-205.
10. Richardson RE, Bournas N, Magos AL. Is laparoscopic hysterectomy a waste of time? Lancet 1995; 345(8941):36-41.
11. Reich H. Total laparoscopic hysterectomy: indications, techniques and outcomes. Curr Opin Obstet Gynecol 2007; 19(4):337-344.
12. Mettler L, Semm K. Endoscopic classic intrafascial supracervical hysterectomy without colpotomy. Baillieres Clin Obstet Gynaecol 1994; 8(4):817-829.
13. [http://quoteinvestigator.com/2011/09/08/640k-enough/]. 1-7-2012.
14. Decca Records. 1962.
15. PALMER R. Gynecol Obstet (Paris) 1947; 46(4):420-431.
16. Darzi A, Mackay S. Recent advances in minimal access surgery. BMJ 2002; 324(7328):31-34.
17. Schreuder HW, Verheijen RH. Robotic surgery. BJOG 2009; 116(2):198-213.
18. Holloway RW, Ahmad S, Denardis SA, Peterson LB, Sultana N, Bigsby GE et al. Robotic-assisted laparoscopic hysterectomy and lymphadenectomy for endometrial cancer: Analysis of surgical performance. Gynecol Oncol 2009.
19. Jansen FW, Kapiteyn K, Trimbos-Kemper T, Hermans J, Trimbos JB. Complications of laparoscopy: a prospective multicentre observational study. Br J Obstet Gynaecol 1997; 104(5):595-600.
20. Keus F, de Jong JA, Gooszen HG, van Laarhoven CJ. Laparoscopic versus open cholecystectomy for patients with symptomatic cholecystolithiasis. Cochrane Database Syst Rev 2006;(4):CD006231.
21. Aggarwal R, Moorthy K, Darzi A. Laparoscopic skills training and assessment. Br J Surg 2004; 91(12):1549-1558.
22. IGZ Rapport 'Risico's minimaal invasieve chirurgie onderschat'. 1-11-2007.
23. Feldman LS, Sherman V, Fried GM. Using simulators to assess laparoscopic competence: ready for widespread use? Surgery 2004; 135(1):28-42.

Chapter two

Implementation of advanced laparoscopic surgery in gynecology: national overview of trends

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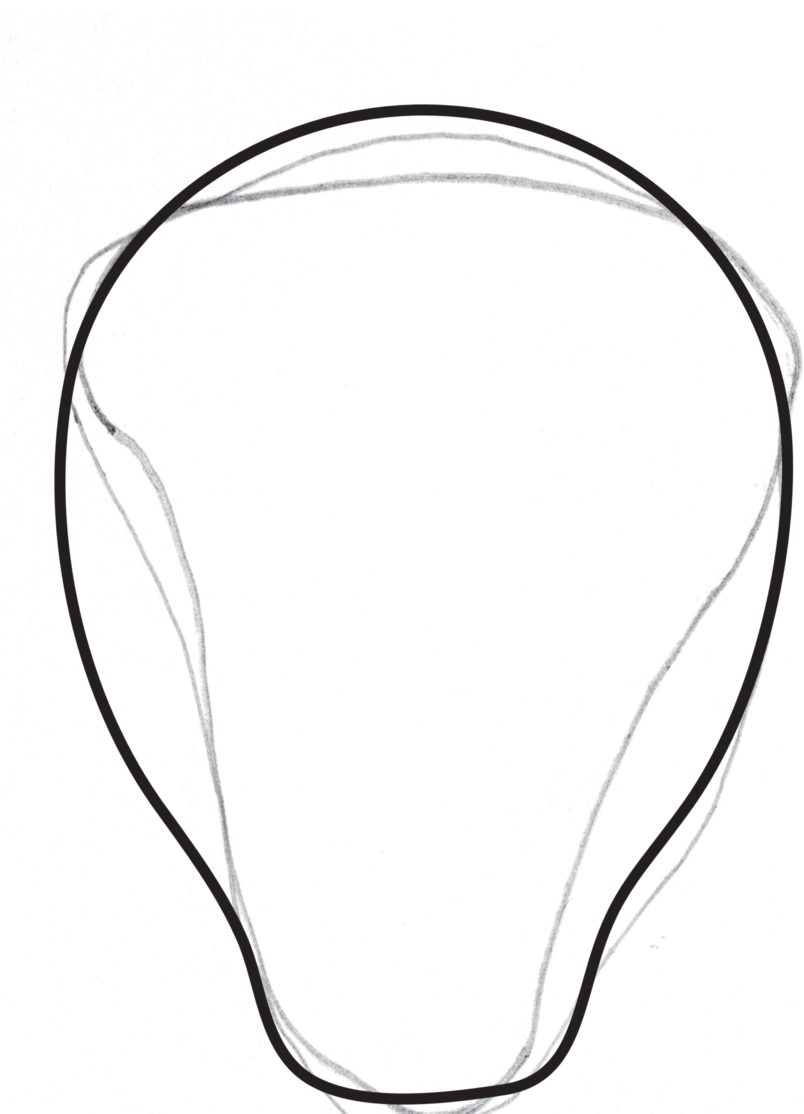
Kolkman W

Trimbos-Kemper GC

Jansen FW



J Minim Invasive Gynecol. 2010 Jul-Aug;17(4):487-92

Abstract

Aim

To estimate the implementation of laparoscopic surgery in operative gynecology.

Materials and Methods

Observational multicenter study in hospitals in the Netherlands. Nationwide annual statistics for 2002 and 2007. A national survey of the number of performed laparoscopic and conventional procedures was performed. Laparoscopy was categorized for complexity in level 1, 2, and 3 procedures. Outcomes were compared with results from 2002 to evaluate trends.

Results

In 2002, 21 414 laparoscopic and 9325 conventional procedures were performed in 74 hospitals (response rate, 74%), and in 2007, 16 863 laparoscopic and 10 973 conventional procedures were performed in 80 hospitals (response rate, 80%). Compared with 2002, in 2007, level 1 procedures were performed significantly less often and level 2 and level 3 procedures were performed significantly more often. The mean number of performed laparoscopic procedures per hospital decreased from 289 to 211 procedures. Teaching hospitals performed more than twice as many therapeutic laparoscopic procedures as nonteaching hospitals do. Cystectomy, oophorectomy, and ectopic pregnancy surgery were preferably performed using the laparoscopic approach. Laparoscopic hysterectomy was performed significantly more often, accounting for 10% of all hysterectomies. Annually, 20% of hospitals in which laparoscopic hysterectomy was implemented performed 50% of all laparoscopic hysterectomies, and 50% of the hospitals performed 20% of laparoscopic hysterectomies.

Conclusion

This study describes increasing implementation of therapeutic laparoscopic gynecologic surgery. Clinics increasingly opt to perform laparoscopic surgery rather than conventional surgery. However, implementation of advanced procedures such as laparoscopic hysterectomy seems to be hampered.

Introduction

When the laparoscopic approach was introduced as a novel minimally invasive diagnostic tool in gynecology by pioneer Raoul Palmer in the late 1940s, one could not envision the vast array of indications in which laparoscopy is used today.[1] Currently, laparoscopy is increasingly practiced by gynecologists throughout the world for ever evolving and challenging indications.[2-4] However, few data are available about the number of laparoscopic procedures performed annually, their distribution among hospitals, and their influence on the number of procedures performed using the conventional approach. Especially for providing accurate training programs, a nationwide insight into distribution between diagnostic and (advanced) therapeutic laparoscopy is useful. Tailor-made skills-training programs during residency and after completing specialty training will enhance patient safety and eventually improve surgical efficiency.[5]

To map these developments accurately, frequent national surveys are necessary.[6-8] Such surveys can detect a possible shift in surgical approach used, and adverse results can be traced. As a result, laparoscopic skills-training programs can be adjusted, and certain procedures can be regulated to be performed only in authorized centers. If most hospitals do not perform the complete array of (advanced) laparoscopic procedures, specific expertise must be optimized, and consequently, patient safety will be enhanced. Currently, validation for a minimal number of procedures performed to accomplish the learning curve of advanced laparoscopic surgery such as laparoscopic hysterectomy (LH) is not available.[9] However, certain studies suggest that, on average, 30 of these procedures must be performed to accomplish the learning curve.[10;11]

The objectives of this study were to inventory the implementation of gynecological laparoscopic surgery in the Netherlands and to detect and clarify a possible shift in approach from conventional to laparoscopic surgery.

Material and Methods

Each hospital in the Netherlands was asked to complete an electronic mail-based questionnaire about the number of laparoscopic procedures performed in 2007. The questionnaire was subdivided for 15 specific procedures according to the 3-level classification for laparoscopic procedures as given in the guidelines of the Royal College of Obstetricians and Gynaecologists.[12] In addition, the number of procedures performed using the conventional approach was determined. Acquired data were compared with outcomes of a previous national survey published in 2002.[7] In both surveys, the same set of hospitals was provided with an unaltered questionnaire.

First, for each specific laparoscopic procedure, the mean number of performed procedures was determined and compared with previous outcomes. Second, for hospitals that provided data in 2002 and 2007, an extra analysis was performed to compare implementation tendencies between teaching and nonteaching hospitals. Third, for procedures eligible to be performed using the conventional or laparoscopic approach (e.g., cystectomy, oophorectomy, ectopic pregnancy surgery, and hysterectomy), the percentage of procedures performed conventionally was compared with those performed laparoscopically, and compared with previous outcomes. Fourth, for LH, the percentages of the 3 most common procedures, that is, laparoscopy–assisted vaginal hysterectomy (LAVH), supracervical laparoscopic hysterectomy (SLH), and total laparoscopic hysterectomy (TLH), were compared. Vaginal hysterectomy with accompanying prolapse surgery and radical oncologic abdominal hysterectomy were excluded from the analysis. In addition, to determine any possible variations between hospitals insofar as implementation of LH, we classified hospitals that performed 1 to 10 such procedures annually as low-volume hospitals, those that performed 11 to 20 such procedures as intermediate-volume hospitals, and those that performed more than 30 such procedures as high-volume hospitals.[10]

Analysis was performed using commercially available software (SPSS 16.0 statistical software; SPSS, Inc., Chicago, IL). In an attempt to censor any incorrect data, only fully completed questionnaires were included, and when in doubt, accuracy of data was verified with the responding hospital. Differences in mean numbers and percentages between 2002 and 2007 were assessed using linear mixed models to account for possible clustering of hospital responses. We calculated 95% confidence intervals. $P < .05$ was considered significant.

Results

Eighty hospitals (response rate, 80%) provided a complete overview of the number of procedures performed in 2007. The remaining 20 hospitals were unable to gather and supply reliable data because of an inaccurate data recording system. The 80 responding hospitals reflected the national distribution of teaching (44%) and nonteaching (56%) hospitals.

Data for 16 863 laparoscopic and 10 973 conventional procedures were collected in 2007 and compared with the outcomes in 2002 (21 414 laparoscopic and 9325 conventional procedures performed in 74 hospitals). Compared with 2002, in 2007, level 1 procedures were performed significantly less often (mean, 106 procedures per hospital; $P < .001$), and level 2 and level 3 procedures (i.e., therapeutic laparoscopy) were performed significantly more often (mean, +28 procedures; $P < .001$, and mean +9 procedures; $P < .001$, respectively). The number of laparoscopic procedures performed per hospital decreased from 228 procedures in 2002 to 117 procedures in 2007 (mean, −64 procedures; $P < .001$) (Table 1).

A subgroup analysis of the 62 hospitals that provided data in both 2002 and 2007 yielded a significantly greater decrease in level 1 procedures in teaching hospitals compared with

Table 1 Number of laparoscopic procedures per hospital per level of complexity for 2002 and 2007

	2002	2007			
	Mean (SD)	**Mean (SD)**	**Difference**	**95%-CI**	**P-value**
Level 1					
Diagnostic laparoscopy	78.3 (61.1)	48.3 (41.1)	- 30.0	(-46.7 to -13.4)	< .001
Sterilization	102.3 (63.1)	40.8 (32.1)	- 57.4	(-68.8 to - 46.0)	< .001
Chromopertubation	47.1 (40.9)	30.4 (25.2)	- 16.0	(-24.6 to - 7.7)	< .001
Level 2					
Cystectomy	8.4 (13.6)	15.2 (15.8)	7.0	(3.5 to 10.5)	< .001
Oophorectomy	24.6 (26.4)	41.1 (28.0)	17.8	(10.3 to 25.3)	<.001
Ectopic pregnancy surgery	11.0 (8.9)	13.8 (9.6)	3.7	(1.7 to 5.8)	.001
Endometriosis	3.1 (8.8)	4.1 (9.1)	0.9	(-2.0 to 3.8)	0.53
Adhesiolysis	6.4 (8.4)	4.1 (8.7)	-2.0	(-4.0 to 0.0)	.046
Tubal surgery	2.1 (5.4)	1.9 (5.9)	-0.2	(-1.9 to 1.4)	.79
LAVH	1.9 (7.0)	2.0 (3.9)	0.1	(-1.7 to 1.9)	.89
Level 3					
Laparoscopic myomectomy	0.3 (0.7)	0.4 (1.2)	0.2	(-0.1 to 0.5)	.24
TLH	NA	7.4 (13.4)			
SLH	1.2 (4.0)	2.1 (5.2)	0.9	(-0.4 to 2.2)	.16
Sacropexy	0.9 (3.9)	1.4 (4.5)	0.5	(-0.9 to 1.8)	.50
Lymphadenectomy	0.3 (2.1)	0.1 (0.7)	-0.2	(-0.7 to 0.3)	.52
Total					
Level 1	227.8 (130.6)	116.6 (77.3)	-106.2	(-135.0 to -77.4)	< .001
Level 2	58.9 (54.8)	82.8 (48.7)	28.5	(16.7 to 40.3)	< .001
Level 3	2.7 (7.0)	11.4 (18.4)	9.0	(4.7 to 13.2)	< .001
Total	289.4 (162.5)	210.8 (120.3)	-63.6	(-95.4 to -31.8)	< .001

IC = confidence interval; NA = not applicable; EP = Ectopic Pregnancy; LAVH = Laparoscopic Assisted Vaginal Hysterectomy; TLH = Total Laparoscopic Hysterectomy; SLH = Supracervical Laparoscopic Hysterectomy.

nonteaching hospitals (−44% and −36%, respectively; $P < .05$). Furthermore, teaching hospitals performed more than twice as many therapeutic laparoscopic procedures annually as nonteaching hospitals (mean, 139 procedures and 61 procedures, respectively).

Nationwide, the number of cystectomies and oophorectomies performed using the laparoscopic approach during the last 5 years remained stable (83% and 60%, respectively), whereas ectopic pregnancy surgery was performed significantly more often using the laparoscopic approach, and today is performed in 86% of cases (Figure 1). A significant increase in LH (from 3% in 2002 to 10% in 2007) was observed (Table 2).

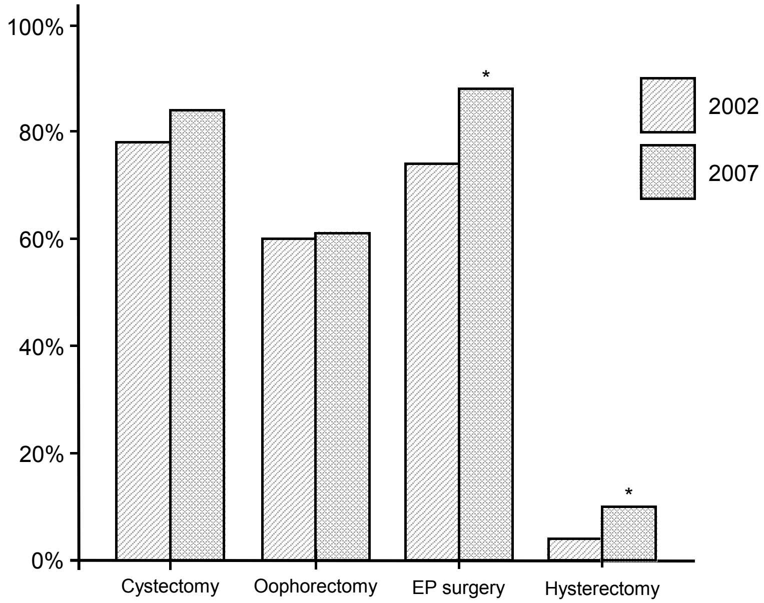


Figure 1 Trends in proportions of laparoscopic approach to cystectomy, oophorectomy, EP surgery and hysterectomy (* = significant increase; P value < 0.05. EP = Ectopic Pregnancy)

Table 2 Distribution of various methods of hysterectomy in 2002 and 2007

	2002	2007	Difference,		
	Mean% (SD)	Mean% (SD)	mean %	95%-CI	*P*-value
Total number of clinics	65	80			
Total number of procedures	8 004	9 476			
Abdominal hysterectomy	68.3% (14.1)	56.2% (15.4)	-12.3	(-16.5 to -8.1)	< 0.001
Vaginal hysterectomy	29.4% (14.1)	34.1% (16.6)	4.8	(0.8 to 8.8)	0.02
Laparoscopic hysterectomy	2.4% (6.3)	9.7% (10.9)	7.6	(5.0 to 10.1)	< 0.001
Number of 'non-LH clinics'	47	24			
Number of procedures	5 469	2 741			
Abdominal hysterectomy	70.4% (14.2)	58.1% (17.8)	-12.3	(-19.9 to -4.6)	0.002
Vaginal hysterectomy	26.6% (14.2)	41.9% (17.8)	12.3	(4.6 to 19.9)	0.002
Number of 'LH clinics'	18	56			
Number of procedures	2 535	6 735			
Abdominal hysterectomy	62.6% (12.7)	55.4% (14.3)	-11.5	(-17.6 to -5.3)	.001
Vaginal hysterectomy	28.9% (14.3)	30.8% (15.1)	4.5	(-2.3 to 11.3)	.19
Laparoscopic hysterectomy	8.5% (9.6)	13.8% (10.6)	6.5	(2.5 to 10.6)	.003

LH = Laparoscopic Hysterectomy

In the Netherlands, 56 of 80 (70%) responding hospitals perform LH. Annually, 20% of hospitals in which LH is implemented perform almost 50% of total LH procedures (high-volume hospitals), and 50% of hospitals perform 20% of LH procedures (low-volume hospitals) (Figure 2). Insofar as the various methods of LH, TLH is generally preferred, and is performed in 64% of registered procedures. In low-volume hospitals, LAVH is preferred, and is the method of choice in 44% of registered LH procedures. However, LAVH accounts for only 12% of the total number of LH procedures in hospitals that annually perform more than 10 hysterectomies, compared with 18% for supracervical laparoscopic hysterectomies and 69% for TLHs. Total laparoscopic hysterectomy is performed significantly more often in teaching hospitals compared with nonteaching hospitals (65% vs 23%; $P < .001$).

Discussion

This study demonstrates increasing implementation of therapeutic laparoscopic gynecologic surgery in the Netherlands. Clinics increasingly opt for laparoscopy over the conventional approach. However, implementation of advanced procedures such as LH seems to be hampered. Insofar as implementation of laparoscopy in gynecology in general, there has been

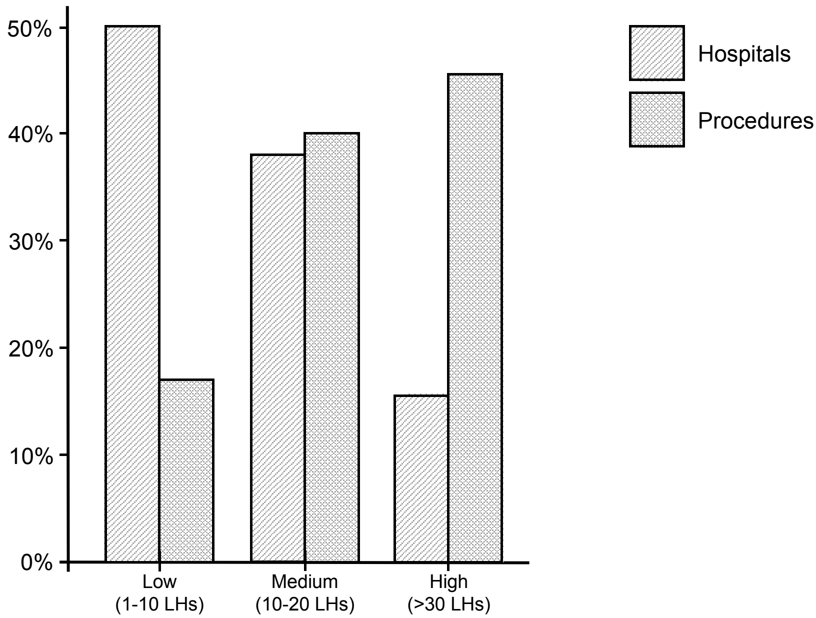


Figure 2 In 2007, less than a fifth of hospitals in which laparoscopic hysterectomy (LH) is implemented perform almost 50% of total LH procedures (high-volume hospitals), and half of hospitals perform less than 20% of LH procedures (low-volume hospitals).

a distinct shift from primarily diagnostic laparoscopy in the late 1990s toward an increasing number of therapeutic procedures currently.[6]

The decrease in the number of performed diagnostic laparoscopies (Table 1) may have been caused by the decline in belief that laparoscopy is a useful tool in the diagnostic workup of, for example, pelvic pain (accompanied with the increased use of improved noninvasive diagnostic tools) in combination with a growing number of "see and treat" laparoscopies (e.g., for diagnosis of ovarian cysts).[13] Furthermore, the decrease in the number of performed laparoscopic sterilizations during the last 5 years is likely caused by development of less invasive alternatives such as hysteroscopic sterilization and the levonorgestrel-releasing intrauterine device, as well as changed insurance coverage in the Netherlands. We hypothesize that the significant decrease in the number of performed chromopertubations is probably the result of speedier referral to in vitro fertilization clinics in combination with nationwide implementation of a less invasive strategy in the diagnostic workup to assess tubal status, hence offering laparoscopy exclusively to patients who test positive for Chlamydia antibody and, consequently, decreasing the number of laparoscopic procedures performed.[14]

This shift from diagnostic to therapeutic laparoscopy largely facilitates evolving endoscopic devices combined with an increasing number of training facilities. The latter development is also triggered because minimally invasive surgery is increasingly incorporated in residency training. Perhaps the teach-the-teacher phase for level 2 laparoscopic surgery has been accomplished already.[15] This development is also observed in other areas such as general surgery.[16;17] Although a variable that is difficult to measure, the influence of surgical companies, with the objective to sell more (nonreusable) instrumentation and, consequently, to increase promotion of laparoscopy rather than conventional surgery, should not be underestimated.

Therapeutic laparoscopy in general, and advanced (level 3) laparoscopy in particular, is still more frequently performed in teaching hospitals. However, nonteaching hospitals seem to be increasingly implementing these techniques as well. The growing applicability of therapeutic procedures explains the preference of gynecologic surgeons for laparoscopy over the conventional approach for cystectomy, oophorectomy, and ectopic pregnancy surgery. However, the hampered implementation of LH seems to be in striking contrast with the increasing growth of these laparoscopic procedures.

Reasons for the hampered implementation of advanced laparoscopic procedures such as LH are many. Whereas most hospitals perform a few LH procedures annually, only a few hospitals perform most of these procedures. A number of reasons could explain this phenomenon. First, because LH, among other level 3 laparoscopic procedures, is not included on the list of compulsory procedures to be acquired during residency training, gynecologists must acquire these skills by themselves, and only after completing their registration. Second, no nationwide standardized guidelines for training in LH are available. Therefore, acquiring the necessary skills is free of obligations, yet cumbersome. Third, possibly in part because of omission of level 3 laparoscopy from the residency program, gynecologists who are willing to implement LH in their hospital need not only acquire the skills themselves but must also convince their colleagues to refer patients eligible for LH or at least tolerate the addition of LH, with its accompanying novel endoscopic instruments, in the operating room. These restrictions are likely to "condemn" novice LH surgeons to "hobbyism" and to adopt traditional laparoscopic techniques such as LAVH and to perform few LH procedures annually. Overrepresentation of the percentage of performed LAVHs (49%) in low-volume hospitals, as demonstrated by our data, supports this assumption.

Furthermore, there is concern about another development in the field of LH: implementation of LH seems to hamper the number of vaginal hysterectomies performed. This development is undesirable because vaginal hysterectomy is the method of choice in hysterectomies performed because of benign indications.[18] Inasmuch as LH originally was introduced as an alternative to the abdominal approach, a larger decrease in the number of abdominal hysterectomies would be expected.[19;20] However, in our study, we observed only a minor difference in the percentage of abdominal hysterectomies performed (55% vs 58% for clinics that do or do not perform LH).

Hypothetically, because of the learning curve of LH during the implementation phase, surgeons perhaps continue to select candidates for abdominal hysterectomy while also performing LH in patients who are candidates for vaginal hysterectomy. However, comparison of distribution of the various methods of hysterectomy between high- and low-volume hospitals does not support this assumption. Our data reflect only the number of hysterectomies per hospital and do not provide information per individual surgeon, and in addition, our data do not take into account the possible number of external referred candidates for LH. Nevertheless, the unexpected influence of LH on its conventional counterparts (i.e., abdominal hysterectomy and vaginal hysterectomy) is indisputable. In our opinion, a restructured residency training program with optimized training in both vaginal and laparoscopic surgical techniques, accompanied by increased awareness of the advantages of these minimally invasive techniques, could effectively reduce the number of abdominal hysterectomies. Thus, we stress that LH is not the criterion standard and that not every patient is a candidate for TLH. Appropriate case selection will, it is hoped, more often offer patients access to vaginal hysterectomy before LH is considered.

A shortcoming of the present study might be the guaranteed reliability of the provided data. In contrast with countries such as Finland, gynecologists in the Netherlands do not have yet a national standardized registration system for operative procedures.[9] Therefore, retrieval of data for this study depended on the willingness and dedication of colleague gynecologists to gather and supply the requested data. Another limitation of this study might be its retrospective design. However, because no national prospective registration system is yet available, retrospective studies such as this are needed to gain insight into implementation tendencies. We would like to encourage other countries to frequently retrieve and publish national data on laparoscopic procedures as well, to monitor possible developments in this field.

It might be argued that the reported decreasing influence of LH on the number of vaginal hysterectomies performed is caused by concurrently evolving novel prolapse surgery techniques such as tension-free vaginal tape surgery. However, similar to 2002, in 2007, vaginal hysterectomies with accompanying prolapse surgery were excluded from analysis. Therefore, a reliable representation of tendencies was established.

In conclusion, the present study describes current tendencies in gynecologic laparoscopic surgery. Therapeutic laparoscopy seems to be readily implemented. However, there is concern about certain developments in the field of advanced laparoscopy. Permanent prospective research of gynecologists performing advanced laparoscopic procedures such as LH is needed to gain insight into indications, patient characteristics, procedure-related outcomes, and surgeon characteristics. With use of these data, evidence-based guidelines can be established for certification and accreditation of surgeons to perform advanced laparoscopic procedures. Before options such as centralizing certain advanced laparoscopic procedures can be outlined, a patient-centered optimum for operative gynecologic laparoscopic surgery must be assessed.

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References

1. Palmer R. Gynecol Obstet (Paris) 1947; 46(4):420-431.
2. Schreuder HW, Verheijen RH. Robotic surgery. BJOG 2009; 116(2):198-213.
3. Holloway RW, Ahmad S, Denardis SA, Peterson LB, Sultana N, Bigsby GE et al. Robotic-assisted laparoscopic hysterectomy and lymphadenectomy for endometrial cancer: Analysis of surgical performance. Gynecol Oncol 2009.
4. Darzi A, Mackay S. Recent advances in minimal access surgery. BMJ 2002; 324(7328):31-34.
5. Kolkman W, Wolterbeek R, Jansen FW. Gynecological laparoscopy in residency training program: Dutch perspectives. Surg Endosc 2005; 19(11):1498-1502.
6. Brolmann HA, Vervest HA, Heineman MJ. Declining trend in major gynaecological surgery in The Netherlands during 1991-1998. Is there an impact on surgical skills and innovative ability? BJOG 2001; 108(7):743-748.
7. Kolkman W, Trimbos-Kemper TC, Jansen FW. Operative laparoscopy in The Netherlands: Diffusion and acceptance. Eur J Obstet Gynecol Reprod Biol 2007; 130(2):245-248.
8. Tu FF, Beaumont JL. Outpatient laparoscopy for abdominal and pelvic pain in the United States 1994 through 1996. Am J Obstet Gynecol 2006; 194(3):699-703.
9. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.
10. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
11. Twijnstra AR, Blikkendaal MD, Kolkman W, Smeets MJ, Rhemrev JP, Jansen FW. Implementation of Laparoscopic Hysterectomy: Maintenance of Skills after a Mentorship Program. Gynecol Obstet Invest 2010; 70(3):173-178.
12. Royal College of Obstetricians and Gynaecologists (RCOG). Classification of Laparoscopic Procedures per Level of Difficulty. 2001.
13. Cox L, Ayers S, Nala K, Penny J. Chronic pelvic pain and quality of life after laparoscopy. Eur J Obstet Gynecol Reprod Biol 2007; 132(2):214-219.
14. Perquin DA, Beersma MF, de Craen AJ, Helmerhorst FM. The value of Chlamydia trachomatis-specific IgG antibody testing and hysterosalpingography for predicting tubal pathology and occurrence of pregnancy. Fertil Steril 2007; 88(1):224-226.
15. Kolkman W, Engels LE, Smeets MJ, Jansen FW. Teach the teachers: an observational study on mentor traineeship in gynecological laparoscopic surgery. Gynecol Obstet Invest 2007; 64(1):1-7.
16. Vidovszky TJ, Smith W, Ghosh J, Ali MR. Robotic cholecystectomy: learning curve, advantages, and limitations. J Surg Res 2006; 136(2):172-178.
17. Schijven MP, Jakimowicz JJ, Broeders IA, Tseng LN. The Eindhoven laparoscopic cholecystectomy training course--improving operating room performance using virtual reality training: results from the first E.A.E.S. accredited virtual reality trainings curriculum. Surg Endosc 2005; 19(9):1220-1226.
18. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
19. Reich H, Decaprio J, McGlynn F. Laparoscopic hysterectomy. J Gynaecol Surg 1989; 5:213-216.
20. Reich H. Total laparoscopic hysterectomy: indications, techniques and outcomes. Curr Opin Obstet Gynecol 2007; 19(4):337-344.

Chapter three

Twenty-first century laparoscopic hysterectomy: should we not leave the vaginal step out?

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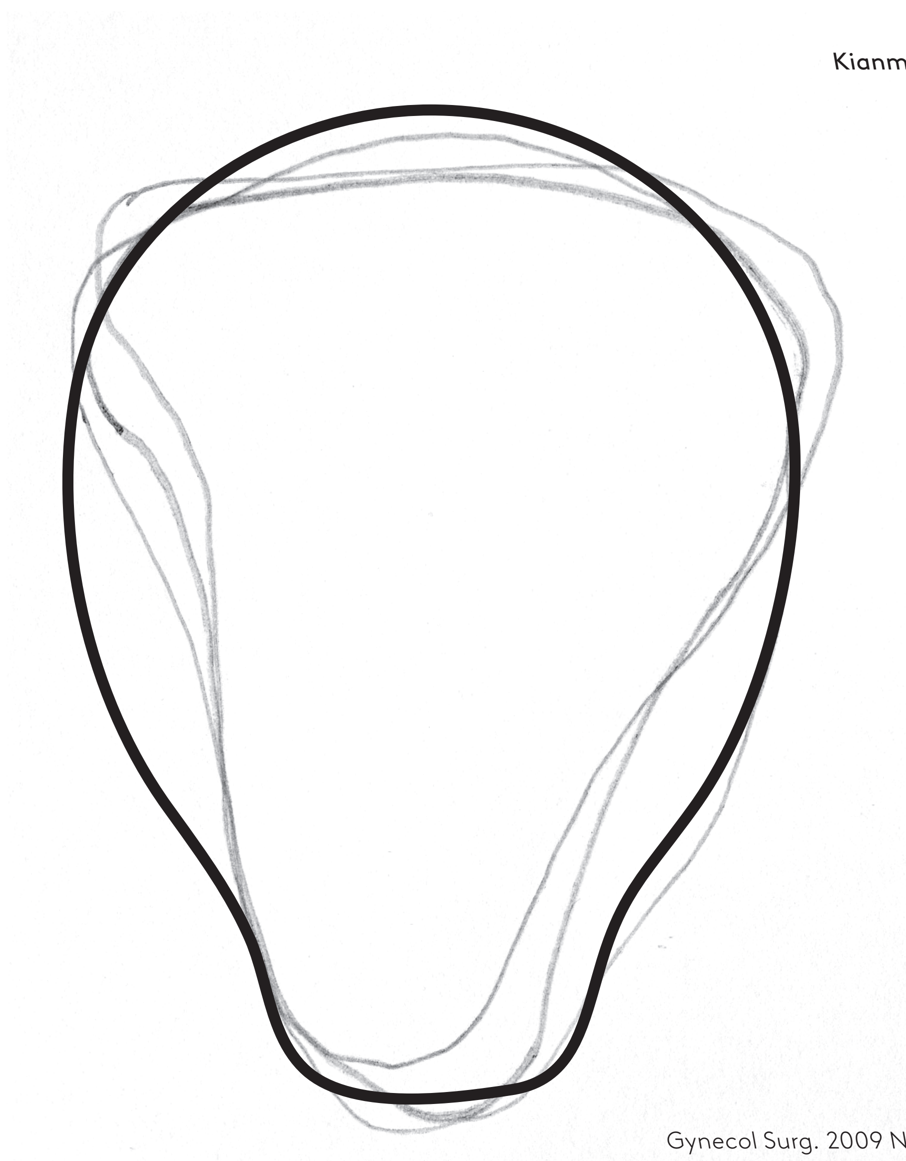

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Abstract

Background

The objective of this study was to compare surgical outcomes for laparoscopically assisted vaginal hysterectomy (LAVH) with total laparoscopic hysterectomy (TLH) in three teaching hospitals in the Netherlands.

Materials and Methods

Multicenter cohort retrospective analysis of consecutive cases.

Results

One hundred and four women underwent a laparoscopic hysterectomy between March 1995 and March 2005 at one of three teaching hospitals. This included 37 women who underwent LAVH and 67 who underwent TLH. Blood loss, operating time, and intraoperative complications such as bladder or ureteric injury as well as conversion to an open procedure were recorded. In the TLH group, average age was statistically significant lower, as well as the mean parity, whereas estimated uterus size was statistically significant larger, compared to the LAVH group. Main indication in both groups was dysfunctional uterine bleeding. In the TLH group, mean blood loss (173 mL) was significant lower compared to the LAVH group (457 mL), whereas length of surgery, uterus weight, and complication rates were comparable between the two groups. The method of choice at the start of the study period was LAVH, and by the end of the study period, it had been superseded by TLH.

Discussion

LAVH should not be regarded as the novice's laparoscopic hysterectomy. Moreover, with regard blood loss, TLH shows advantages above LAVH. This might be due to the influence of the altered anatomy in the vaginal stage of the LAVH procedure. Therefore, when a vaginal hysterectomy is contraindicated, TLH is the procedure of choice. LAVH remains indicated in case of vaginal hysterectomy with accompanying adnexal surgery.

Introduction

Hysterectomy is the most frequently performed major gynecologic surgical procedure annually throughout the world.[1] The most common indication for hysterectomy is uterine fibroids, followed by dysfunctional uterine bleeding.[2] Regarding the procedure, three different approaches can be distinguished—abdominal, vaginal, and laparoscopic. Traditionally, abdominal hysterectomy (AH) has been used for Gynecological malignancy or if the uterus is enlarged. Vaginal hysterectomy (VH) was originally used only for prolapse, but it is now also used for dysfunctional uterine bleeding when the uterus is of fairly normal size.[3] Laparoscopic hysterectomy (LH) was introduced in 1988 and published in 1989 by Harry Reich as an alternative to abdominal hysterectomy. The first LH was set up as LH, as both uterine arteries were ligated laparoscopically, and most of the vagina opened laparoscopically. In 1992, already Reich described his foremost total laparoscopic hysterectomy (TLH).[4] However, in the 1990s, most gynecologists "adopted" the alternative laparoscopic-assisted vaginal hysterectomy (LAVH), an operation in which the upper blood supply to the uterus was ligated laparoscopically followed by a vaginal hysterectomy. Laparoscopic hysterectomy in general requires other technical skills than the vaginal or abdominal method.[5] A recent meta-analysis compared the three methods stated above in detail.[3] Significantly improved outcomes already confirmed that VH should be performed in preference to AH whenever possible. LH (in general) can avoid the abdominal approach and shows benefits in lower intraoperative blood loss, smaller drop in hemoglobin level, shorter duration of hospital stay, speedier return to normal activities, fewer wound, or abdominal wall infections, fewer unspecified infections, however, at the cost of longer operating time and more urinary tract (bladder or ureter) injuries[3;6-10]

When it comes to laparoscopic hysterectomy, a variety of associated operations can be distinguished. Garry et al. delineated this evolution of different LH procedures in Table 1.[11] Whereas several prospective studies already thoroughly compared the LH in general versus conventional hysterectomy methods, unfortunately, no proper randomized controlled trial comparing LAVH

Table 1 Laparoscopic associated hysterectomy classification

1	Diagnostic laparoscopy with vaginal hysterectomy
2	Laparoscopic Assisted Vaginal Hysterectomy
3	Laparoscopic hysterectomy
4	Total Laparoscopic Hysterectomy
5	Laparoscopic supracervical hysterectomy including classical interstitial Semm hysterectomy
6	Vaginal hysterectomy with laparoscopic vault suspension or laparoscopic pelvic reconstruction
7	Laparoscopic hysterectomy with lymphadenectomy
8	Laparoscopic hysterectomy with lymphadenectomy and omentectomy
9	Laparoscopic radical hysterectomy with lymphadenectomy

Source: Garry R, Reich H, Liu CY. Laparoscopic hysterectomy - definitions and indications. Gynaecol Endosc. 1994;3:1-3.

versus TLH has been set up yet. Until now, only expert's opinions are available.[5] Therefore, this retrospective study aims to compare recorded data on two types of LH, i.e., LAVH and TLH, with respect to indication, operative characteristics, and adverse outcomes. The results could indicate whether a prospective study should be designed or not.

LAVH, introduced as a "prototype" of laparoscopic hysterectomy in the early 1990s of the last century, has a reputation for its easy implementation into daily practice as well as being an often overused expensive procedure.[5] The latter can be explained as skilled vaginal surgeons rarely find the addition of a laparoscope necessary. TLH, on the other hand, faces a slow implementation rate in many clinics due to required new and complex laparoscopic skills and extensive length of surgery.[12] Especially in the Netherlands, LH knows a slow implementation rate (4% of all hysterectomies) possibly because of a tradition in vaginal hysterectomy.

Since the introduction of LH in the Netherlands, AH shows a declining trend.[13] Both LH and VH are practiced more often, the latter demonstrating a steeper implementation curve. With the slow but significant move from LAVH to TLH, this study aims to analyze these two procedures in order to highlight possible differences.

Materials and methods

Three teaching hospitals (of which one is a university hospital) in the west urban area of the Netherlands, which introduced LH in the same era, participated in this retrospective study. Each teaching hospital practiced identical techniques (regarding LAVH, TLH, and supracervical laparoscopic subtotal hysterectomy (SLH)). From the beginning, Harmonic Scalpel hook and bipolar forceps were used for ligation. Except for closure and suspension of the vaginal cuff, no sutures were applied. In LAVH, the vaginal cuff was closed vaginally with interrupted sutures. In TLH, the vaginal cuff was closed laparoscopically with interrupted figures-of-eight, herewith suspending the sacro-uterine ligaments. Participating gynecologists were thoroughly trained vaginal surgeons with special interests in advanced laparoscopic gynecological surgery.

One hundred and four consecutive cases of women who underwent a laparoscopic hysterectomy between March 1995 and March 2005 were analyzed. This included 37 LAVHs and 67 TLHs. Three laparoscopic hysterectomies were converted intraoperatively. SLHs were excluded in order to compare the remaining two groups. As a frame of reference, the majority (90%) of hysterectomies performed during this study period were either vaginal or abdominal (equally distributed).

The case history notes were manually reviewed, and epidemiological data were extracted including age, parity, estimated uterus size, and main indication. Blood loss was determined by the surgeon and recorded in the operative notes. Blood loss was invariably estimated by subtracting the applied irrigation fluid from the postoperative fluid level in the suction bottle. Possible vaginal blood loss was estimated and added to the total blood loss. The time taken to complete the procedure (skin-to-skin) was recorded from the anesthetic chart. Uterus weight was determined postoperatively. Length of stay was measured by available hospital files. Hospital stay was calculated taking day 1 as the first day following hysterectomy. Complication rates were extracted from medical charts and the weekly post surgery conferences, in which eventual adverse outcomes were discussed. Major complications (i.e., adverse outcomes demanding further treatment) were defined as blood loss exceeding 1,000 mL, a blood transfusion due to a postoperative clinical relevant drop in Hemoglobin or bladder/ureteric injury. Minor complications (i.e., adverse outcomes recovering in absence of further treatment) were defined as occurrence of postoperative vault abscess or hematoma, urinary tract infection, or fever. Analysis was performed using SPSS 16.0 statistical software (Chicago, IL, USA). Differences between groups were assessed with the Chi-square test for proportions in independent samples and t tests for continuous variables, nonparametric Kolmogorov–Smirnov Z tests and Wilcoxon rank sum tests were used to asses normal distribution and to assess differences if parameters lacked a normal distribution (e.g., blood loss), 95% confidence intervals (95% CI) were calculated, $P < 0.05$ were considered statistically significant.

Results

Women in the TLH group were statistically significant younger and had a lower parity compared to the women in the LAVH group (Table 2). In the latter group the main indication for hysterectomy was significantly more frequently the existence of a (pre) malignancy, whereas in the TLH group statistically significant more frequently the main indication was dysfunctional uterine bleeding.

Table 2 Patient characteristics

	LAVH (n =37)			TLH (n =67)			
	Mean	SD	range	Mean	SD	range	P value
Age (years)	50,5	10,3	(30,2 to 77,8)	45,7	5,8	(32,6 – 64,8)	< .05
Parity	2,2	1,1	(0 to 5)	1,4	1,3	(0 to 5)	< .05
Estimated uterus size (weeks)	9,5	3,5	(6 to 16)	11,7	3,6	(6 to 16)	< .05
Main indication	**N**	**%**		**N**	**%**		**P value**
Dysfunctional uterine bleeding	19	51,4		55	82,1		< .05
(pre)malignancy/ prophylaxis	14	37,8		7	10,4		< .05
Pelvic discomfort	2	5,4		5	7,5		N.S.
Prolapse	2	5,4		0	0		N.S.

Table 3 details the intraoperative and postoperative parameters in the LAVH and TLH groups. Mean estimated blood loss (± SD) was 456.8 mL (±893.7) and 173.1 mL (±188.2) in LAVH and TLH groups, respectively ($P < 0.05$). In the LAVH and TLH groups, mean length of surgery was 144.3 min (±40.0; range 90–255) and 150.7 min (±47.7; range 60–320), respectively. Mean uterus weight was 165.3 g (±120.7) and 207.2 g (±120.7), respectively. These differences are not statistically significant. Length of patient stay was 6.1 days (±2.1) and 4.3 days (±2.0), respectively ($P < 0.05$). As a frame of reference, in The Netherlands, as in many neighboring countries, "overnight" stay for a L(AV)H is highly unusual. One woman in the LAVH group as well as one woman in the TLH group sustained a blood loss in excess of 1,000 mL. Three women in the LAVH group and two women in the TLH group needed a blood transfusion due to a postoperative clinical relevant drop in hemoglobin. After excluding the patients with blood loss in excess of 1,000 mL, analysis still yielded a significantly higher mean estimated blood loss in the LAVH group (312.5 ± 171.7 mL) versus the TLH group (157.6 ± 139.6 mL; $P < .05$). Linear regression revealed no statistically significant association between uterine weight and estimated blood loss or length of surgery in both groups.

Major and minor complications are detailed in Table 4. Almost 22% of LAVH cases were associated with a complication compared to 28% of TLH cases ($P = .45$). Regarding major complications exclusively, 10.8% of LAVH cases were complicated compared to 7.5% of TLH cases. Regarding minor complications exclusively, 10.8% of LAVH cases were complicated versus 20.1% of TLH cases. Both morbidity subgroups yielded no statistically significant differences.

Three laparoscopic hysterectomies were converted intraoperatively due to a complication (twice due to insufficient hemostasis, once due to a profuse bleeding of the uterine artery which failed to be sutured laparoscopically). Without exception, the conversions took place in the TLH group.

Discussion

In this study, TLH shows considerable advantages over LAVH with respect to blood loss, with comparable length of surgery and complication rates.

Table 3 Intraoperative and postoperative parameters

	LAVH (n=37)			TLH (n=67)			
	Mean	SD	range	Mean	SD	range	P value
Blood loss (mL)	457	894	(100 to 5.650)	173	188	(0 to 1.200)	< .05
Length of surgery (min)	144	40	(90 to 255)	151	48	(60 to 320)	N.S.
Uterus weight (g)	165	121	(40 to 560)	207	121	(50 to 620)	N.S.
Length of patient stay (days)	6	2	(3 to 12)	4	2	(2 to 12)	< .05

Table 4 Major and minor complications

	LAVH (n=37)		TLH (n=67)		
	N	%	N	%	*P* value
Major complications					
Blood loss > 1000mL	1	2.7	1	1.5	N.S.
Blood transfusion[a]	3	8.1	2	3.0	N.S.
Ureteric injury	0	0	2	3.0	N.S.
Minor complications					
Vault abcess/haematoma	1	2.7	3	4.5	N.S.
Urinary tract infection	1	2.7	4	6.0	N.S.
Fever	2	5.4	4	6.0	N.S.
Technical failure[b]	0	0	3	4.5	N.S.
Total	8	21.6	19	28.4	N.S.

[a] with blood loss <1.000 mL

[b]unable to ligate the a. uterine laparoscopically (1), needle lost and found (2)

Several possible explanations for these differences should be stated. First of all, it must be considered that participating surgeons during this study period were still in their learning curve. Furthermore, during the transition period from LAVH to TLH (range period of LAVH expertise, 28–106 months) laparoscopic skills of the surgeons were already more refined, which may contribute to more favorable outcomes in the TLH group. However, the initial experience with TLH was achieved with a major adjustment to technique and, thus, represents a learning curve of its own, as has been verified in similar studies.[14;15] In contrast with the general opinion that TLH is characterized as a procedure rather challenging to acquire, several studies show a reasonable learning curve not seldom similar to conventional open methods.[16-19] Concerning the evolvement of instrumentation, we would like to notify that every LH in this study was performed with the use of ultrasonic and bipolar energy. In contrast with other publications, no suture ligation (except for vaginal cuff closure) was applied.[20]

Moreover, it is recognized that the groups vary in terms of patient characteristics and main indication. Women who underwent LAVH were prone to be older and above all, more multiparous at the time of the intervention compared to women who underwent TLH. Taking into account the extension of indications in the field of laparoscopic hysterectomy during this study period, in which time for example fewer enlarged uteri were removed conventionally, meanwhile a decline in age (accompanied with an on average bigger uterus) is shown. The latter might explain the found differences.

In addition, the most remarkable finding in this study is the striking higher mean blood loss in the LAVH group, which is confirmed by other studies.[14;15] As stated above, position of the surgeon in her/his learning curve and ongoing technical innovations do partially explain this difference. However, in addition to this, we would like to mention the possible influence of the altered anatomy of the corpus uteri and surroundings in the vaginal stage of the LAVH procedure, inflicting the surgeon's familiar sight of anatomical landmarks. On the other hand, when it comes to uteri without descensus, some surgeons claim to create descensus by applying LAVH. However, their line of thought that disconnecting the pedicles of the round ligament as well as the cardinal ligament will facilitate descensus laparoscopically does not hold. In our opinion, descensus is directly related to the firmness of the uterosacral ligaments.[21-23] In the classical LAVH, these ligaments are clamped vaginally. Therefore, being developed as an alternative to abdominal hysterectomy the laparovaginal approach should be regarded as rather illogical.

The arguments stated above contribute to our opinion that LAVH nowadays knows fewer indications compared to the era of its introduction. In fact, in presence of sufficient descensus and an introitus wide enough to have the operation field exposed, both needed to perform LAVH, a vaginal hysterectomy is proved to be preferable regardless of estimated uterus size.[3;20;24] The LAVH (levels 1–3 in the Garry classification, Table 1) remains solely indicated in case of vaginal hysterectomy, with expected adhesions or endometriosis hindering vaginal surgery or planned accompanying adnexal surgery.

At this point in history, at which every comparison study concerning the putative advantages of one form of surgery over another preferably is designed as a randomized clinical trial, we strongly recommend to keep in mind the outcomes of retrospective studies like this.[10;25;26] Although we confirm the advantages of a prospective comparison between these two types of surgery, we must be taken aware of distinct differences as observed in this study. Of course, the improved global experience with LH in general does add to better outcomes in the TLH group in comparison with the "historical" LAVH group. However, as TLH now proves to be a safe procedure that can be achieved with low blood loss, LAVH still happens to know a higher mean blood loss due to the earlier mentioned altered anatomy.[14;15]

Concerning observed complications, even with improved techniques, this study shows a ureteric injury rate of 3% in the TLH group, which is comparable with other complication studies.[7;8] However, as is confirmed by a recent study, we expect this rate to decline to a rate comparable with the abdominal approach after completing the learning curve for this procedure.[27] Both ureter lesions during this study were recognized postoperatively and before discharge. Both patients required repair by laparotomy.

In conclusion, the results from our study show that LAVH should not be regarded as the novice's laparoscopic hysterectomy. The LAVH should be considered as an specific surgical approach with its own distinctive indication. Vaginal hysterectomy should remain "no. 1" in the domain the gynecological surgeon. VH should, therefore, remain incorporated in the arsenal of the gynecologist-in-training, apart from training in laparoscopy. Expert vaginal surgeons need to train laparoscopic skills in a safe environment (skills lab, assisting salpingo ophorectomies, etc.) before one can start doing the incidental LAVH. Surgeons who are well trained in VH and consider acquiring skills in LH should keep in mind the flow chart as depicted in Figure 1. If gynaecologists receive appropriate surgical training in laparoscopic techniques, TLH is a recommended option in case of a vaginally inapproachable uterus. In our opinion laparoscopic hysterectomy should not assist vaginal surgery when no additional (adnexal) pathology is present.

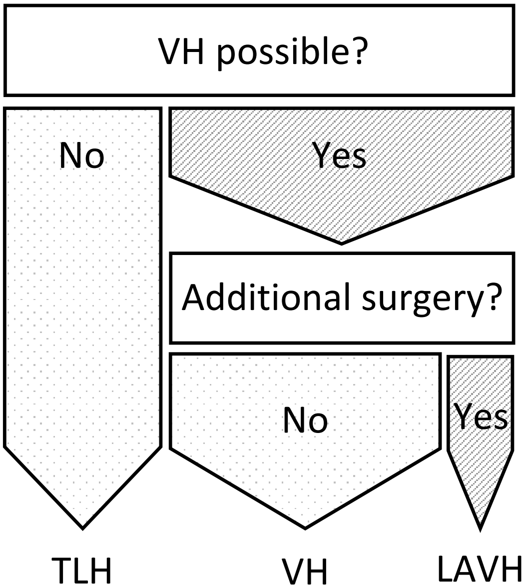

Figure 1 Flow chart indicating method of choice in laparovaginal hysterectomy. Additional surgery indicates expected adhesions, endometriosis or adnexal pathology. (VH = Vaginal Hysterectomy, TLH = Total Laparoscopic Hysterectomy, LAVH = Laparoscopic Assisted Vaginal Hysterectomy).

References

1. Garry R. Health economics of hysterectomy. Best Pract Res Clin Obstet Gynaecol 2005; 19(3):451-465.
2. Garry R. The future of hysterectomy. BJOG 2005; 112(2):133-139.
3. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
4. Reich H. Laparoscopic hysterectomy. Surg Laparosc Endosc 1992; 2(1):85-88.
5. Reich H. Total laparoscopic hysterectomy: indications, techniques and outcomes. Curr Opin Obstet Gynecol 2007; 19(4):337-344.
6. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Health Technol Assess 2004; 8(26):1-154.
7. Harkki P, Kurki T, Sjoberg J, Tiitinen A. Safety aspects of laparoscopic hysterectomy. Acta Obstet Gynecol Scand 2001; 80(5):383-391.
8. Makinen J, Johansson J, Tomas C, Tomas E, Heinonen PK, Laatikainen T et al. Morbidity of 10 110 hysterectomies by type of approach. Hum Reprod 2001; 16(7):1473-1478.
9. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. J Minim Invasive Gynecol 2006; 13(3):183-189.
10. Sarmini OR, Lefholz K, Froeschke HP. A comparison of laparoscopic supracervical hysterectomy and total abdominal hysterectomy outcomes. J Minim Invasive Gynecol 2005; 12(2):121-124.
11. Garry R, Reich H, Liu CY. Laparoscopic hysterectomy - definitions and indications. Gynaecol Endosc 1994; 3:1-3.
12. Kolkman W, Trimbos-Kemper TC, Jansen FW. Operative laparoscopy in The Netherlands: Diffusion and acceptance. Eur J Obstet Gynecol Reprod Biol 2007; 130(2):245-248.
13. Brolmann HA, Vervest HA, Heineman MJ. Declining trend in major gynaecological surgery in The Netherlands during 1991-1998. Is there an impact on surgical skills and innovative ability? BJOG 2001; 108(7):743-748.
14. Cook JR, O'Shea RT, Seman EI. Laparovaginal hysterectomy: a decade of evolution. Aust N Z J Obstet Gynaecol 2004; 44(2):111-116.
15. Long CY, Fang JH, Chen WC, Su JH, Hsu SC. Comparison of total laparoscopic hysterectomy and laparoscopically assisted vaginal hysterectomy. Gynecol Obstet Invest 2002; 53(4):214-219.
16. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
17. Leminen A. Comparison between personal learning curves for abdominal and laparoscopic hysterectomy. Acta Obstet Gynecol Scand 2000; 79(12):1100-1104.
18. Malzoni M, Perniola G, Perniola F, Imperato F. Optimizing the total laparoscopic hysterectomy procedure for benign uterine pathology. J Am Assoc Gynecol Laparosc 2004; 11(2):211-218.
19. Kolkman W, Engels LE, Smeets MJ, Jansen FW. Teach the teachers: an observational study on mentor traineeship in gynecological laparoscopic surgery. Gynecol Obstet Invest 2007; 64(1):1-7.
20. Garry R, Fountain J, Mason S, Hawe J, Napp V, Abbott J et al. The eVALuate study: two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy. BMJ 2004; 328(7432):129.
21. Possover M, Krause N, Kuhne-Heid R, Schneider A. Laparoscopic assistance for extended radicality of radical vaginal hysterectomy: description of a technique. Gynecol Oncol 1998; 70(1):94-99.
22. Buller JL, Thompson JR, Cundiff GW, Krueger SL, Schon Ybarra MA, Bent AE. Uterosacral ligament: description of anatomic relationships to optimize surgical safety. Obstet Gynecol 2001; 97(6):873-879.
23. Schwartz M, Abbott KR, Glazerman L, Sobolewski C, Jarnagin B, Ailawadi R et al. Positive symptom improvement with laparoscopic uterosacral ligament repair for uterine or vaginal vault prolapse: interim results from an active multicenter trial. J Minim Invasive Gynecol 2007; 14(5):570-576.
24. Darai E, Soriano D, Kimata P, Laplace C, Lecuru F. Vaginal hysterectomy for enlarged uteri, with or without laparoscopic assistance: randomized study. Obstet Gynecol 2001; 97(5 Pt 1):712-716.
25. Taylor SM, Romero AA, Kammerer-Doak DN, Qualls C, Rogers RG. Abdominal hysterectomy for the enlarged myomatous uterus compared with vaginal hysterectomy with morcellation. Am J Obstet Gynecol 2003; 189(6):1579-1582.
26. Lenihan JP, Jr., Kovanda C, Cammarano C. Comparison of laparoscopic-assisted vaginal

hysterectomy with traditional hysterectomy for cost-effectiveness to employers. Am J Obstet Gynecol 2004; 190(6):1714-1720.

27. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.

Chapter four

Laparoscopic hysterectomy: eliciting preference of performers and colleagues via conjoint analysis

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Abstract

Background

Aim of this study is to compare preferences for laparoscopic hysterectomy (LH) over abdominal hysterectomy (AH) by gynecologists who perform LH (group 1), their colleagues (group 2), and gynecologists employed by a hospital that does not provide LH (group 3), and to estimate boundary values of patient characteristics that influence preference for mode of hysterectomy. Differences in referral tendencies between groups 2 and 3 are compared.

Materials and Methods

Group comparison study (Canadian Task Force classification II-2). Nationwide conjoint preference study in groups 1, 2, and 3 by a web-based choice-based conjoint analysis questionnaire.

Results

In general, group 1 preferred LH significantly more often (86.3%; 95% confidence interval [CI], 81.6–91.0) than did group 2 (70.9%; 95% CI, 63.4–78.4). Group 3 preferred LH significantly less frequently (50.3%; 95% CI, 35.7–64.9). Increases in body mass index, estimated uterus size, and number of previous abdominal surgeries caused a significant drop in shares of preferences in all groups.

Discussion

The presence of a gynecologist who performs LH positively influences the referral behavior of colleagues. The effect of an increased body mass index seems to be a restrictive parameter for choosing LH according to both referring gynecologists and those who perform LH. Level of experience does not influence preference of laparoscopists. The observed discrepancy between reported and simulated referral behavior in group 3 demonstrates that practical impediments significantly decrease referral tendencies, consequently hampering implementation of this minimally invasive approach.

Introduction

Despite the introduction of alternative nonsurgical therapies, hysterectomy for benign indication remains the number one major surgery in gynecology, preferably, but not actually, via the vaginal approach.[1;2] If vaginal hysterectomy (VH) is not achievable, laparoscopic hysterectomy (LH) has several advantages over conventional abdominal hysterectomy (AH).[3;4] Potential disadvantages of LH such as higher rates of urinary tract lesions and a supposedly longer learning curve have been studied thoroughly.[5-9] These studies have demonstrated that the aforementioned disadvantages of LH are absent in skilled hands. Other studies disprove possible limitations of LH with regard to body mass index (BMI) and uterine size.[10-13] Notwithstanding this evidence, AH still prevails as the approach of choice, in some countries.[14-16] These findings are in striking contrast with the distinct preference of optimally counseled patients, who strongly prefer LH over AH.[17]

Dutch gynecologists mention insufficient laparoscopic skills training during residency as a major obstacle to mastering advanced laparoscopic procedures such as LH.[18] In the Netherlands, standardized teaching in LH during residency is not provided. Gynecologists willing to master LH must learn the techniques during a fellowship or a mentored traineeship.[6] Candidate patients for LH must be referred by colleagues from the same hospital or by gynecologists employed in a hospital that does not provide the option of LH. It is conceivable that despite knowledge of the advantages of LH over AH, there exists a discrepancy between this knowledge and daily practice in preference for LH and referral of candidate patients.

Only a few studies have been performed that elicited clinician preference for mode of hysterectomy. A recent US survey revealed that most gynecologists would prefer VH or LH for themselves or their spouse.[19] Yet US gynecologists, as well as Danish gynecologists, seem to opt for AH in most hysterectomy candidates, and Australian colleagues, willing to increase the percentage of LH procedures, report lack of hospital equipment and lack of support from colleagues as major limiting factors.[15;20-22] Other studies have discussed teaching hospital status as affecting gynecologist preference.[23;24] However, all of these studies failed to explore preference boundaries, and did not properly assess various patient factors. In addition, referral tendencies for LH have not been investigated. Exploration of preference boundaries and patient factors, combined with referral tendencies, will likely provide answers to the origin of the observed hampered implementation of LH.

With the introduction of choice-based conjoint analysis techniques, it is possible to obtain an accurate view of preference boundaries over multiple patient factors while applying a concise set of cases. The main characteristic differentiating choice-based conjoint analysis from other types of conjoint analysis is that the respondent expresses preferences by choosing concepts (ie, mode of hysterectomy) from sets of concepts rather than by rating or ranking them. Choice-based conjoint analysis is a well-established web-based analytic tool used for learning about respondent preferences for the combinations of features that compose products or therapies. Market simulators that result from choice-based conjoint analysis enable researchers to test numerous product formulations and competitive scenarios. Use of this innovative and sophisticated technique enables assessment of the preference for LH by gynecologists who perform the procedure vs those who do not. A secondary objective of the present study was to estimate boundary values of patient characteristics that influence preference for mode of hysterectomy. Differences in referral tendencies are compared and discussed.

Materials and Methods

To define a realistic set of patient characteristics, a panel of 6 gynecologists consisting of 3 experienced laparoscopists and 3 gynecologists who do not perform advanced laparoscopy was provided with a list of the top 10 discriminating factors for choice of mode of hysterectomy, based on a search of the literature. This list included estimated uterus size, uterine prolapse, number of vaginal deliveries, number of previous laparoscopic abdominal surgeries, obesity, procedure cost, risk of urinary tract injury, duration of surgery, recovery time, and cosmetic aesthetics. Consensus was reached on 3 factors: estimated uterine size, previous abdominal surgery (either via laparotomy or laparoscopy), and BMI. These 3 characteristics were presumed to have a major effect on the choice of mode of hysterectomy. Each parameter, hereafter called "attribute," was assigned a distinct set of levels (Table 1). With respect to risk of adhesion formation, laparotomy, and major laparoscopy were considered trigger events.[25]

To provide a limited number of hypothetical cases while gaining sufficient information to precisely assess each respondent's preference, choice-based conjoint analysis (Sawtooth Software, Sequim, WA) was used. In the present study, 18 hypothetical pair wise choices, each consisting of variants of all 3 attributes, were needed to assess preference. Each pair wise choice represented a hysterectomy candidate for AH on the left side of the screen and a different hysterectomy candidate for LH on the right side (Fig. 1). Because VH is the criterion standard, each respondent was told that in the hypothetical cases, VH was contraindicated because of insufficient descensus or accompanying adnexal disease, and consequently was excluded as a surgical treatment option in each pair wise choice. Responding gynecologists who did not perform LH were asked to opt for the LH alternative in the choice task if they preferred referring this case to an LH-performing colleague rather than performing AH on the other patient. Consequently, referral tendencies could be measured.

Next to the 18 pair wise choices, a concise number of demographic questions was introduced including sex, number of years as a specialist, performing LH or not, working in a hospital where LH is performed or not, experience with laparoscopy in general, and, if applicable, total number of LH procedures performed as the primary surgeon. To evaluate possible learning curve bias, gynecologists who perform LH were subdivided for overall number of LH procedures performed. Although hard evidence on completion of the LH learning curve is still lacking, it was decided to

Which of the two subsequent cases do you prefer? Please make a choice by picking one case	
An indication for hysterectomy is assessed in a 45-years old woman with a **BMI of 20** and an estimated uterus size of **16 weeks.** Her medical history reveals **no previous (laparo)abdominal surgery**. An **abdominal hysterectomy** is planned.	An indication for hysterectomy is assessed in a 45-years old woman with a **BMI of 35** and an estimated uterus size of **10 weeks**. Her medical history reveals **one previous (laparo)abdominal surgery.** A **laparoscopic hysterectomy** is planned.

Figure 1 Example of a pairwise choice-based conjoint case.

use a cut-point of 30 LH procedures, as reported in the literature.[6;7;26;27] Therefore, gynecologists were classified into subgroups of those who were progressing along the learning curve (<30 LH procedures performed), those who had accomplished the learning curve (>30 LH procedures), and those who had mastered the learning curve twice (>60 LH procedures).

Insofar as preferred LH techniques, 3 subtypes were identified: laparoscopic-assisted vaginal hysterectomy (LAVH), supracervical laparoscopic hysterectomy (SLH), and total laparoscopic hysterectomy (TLH).[28] In addition, for gynecologists not performing LH, 1 multiple-choice question assessed preference insofar as possible referral for LH to determine self perception of referral behavior.

Each gynecologist in the Netherlands who performed LH (n = 110 laparoscopists, group 1) was asked to fill out the web-based CBC questionnaire. For each laparoscopist, a colleague employed in the same hospital and who performed only AH and VH was asked to fill out the questionnaire as well (n = 115, group 2). At each hospital where LH was not provided (n = 22), 2 randomly assigned gynecologists were requested to fill out the questionnaire (group 3). In the Netherlands, during residency, all gynecologists are trained in both AH and VH.

The local institutional review board exempted the study from review because the survey was executed by physicians.

Global analysis was performed using commercially available software (SPSS version 16.0; SPSS, Inc, Chicago, IL). Differences between groups were assessed using the $\chi 2$ test for proportions and the t test for continuous variables. One-way analysis of variance was used to assess differences between the 3 groups, and 95% confidence interval (CI) and standard deviation were calculated. Statistical significance was considered at $p < .05$. Choice-based conjoint analysis was performed using Sawtooth software, in which Market simulations were run with choice-based conjoint–hierarchical Bayes (www.sawtoothsoftware.com/education/techpap.shtml).

Market simulations provide mean utility values and importances. Mean utility values quantify respondent preferences for each level of each attribute. The importance of an attribute was defined as its weight, or the maximum influence it can have on product levels as defined in the study. Shares of preferences were calculated using SMRT analysis (Sawtooth Software, Inc), thus providing proportions of preferences (for LH) for each conceivable hypothetical patient. To estimate part-worth utility coefficients per subgroup for each level, hierarchical Bayes analysis was performed. Differences in decline of shares of preferences between groups for optimal vs worst case scenario were calculated using multivariate analysis of variance (SPSS, Inc).

Results

Two hundred of 268 gynecologists (response rate, 75%) completed the web-based questionnaire. Response rates for the subgroups (groups 1, 2, and 3) were 89%, 60%, and 77%, respectively, with no significant differences. Responses were obtained from 77 of 78 LH-performing hospitals (99%) and 19 of 22 conventional hospitals (86%). Mean (SD) duration after registration was 12.6 (9.4) years and did not differ between groups (p = .19). Eleven respondents (5%) did not complete the questionnaire after starting, and were, therefore, excluded from choice-based conjoint analysis. Thus, 189 questionnaires were available for evaluation. The choice-based conjoint questionnaire was conducted over 3 months, launched in August 2009 and closed in November 2009, after sending 2 reminder e-mails.

In group 1, nearly 43% of gynecologists were still progressing along the learning curve (<30 LH procedures performed). The remaining gynecologists had accomplished the learning curve once (27%) or twice (30%). Approximately half of the responding laparoscopists had been practicing LH for less than 5 years. An increasing trend was observed (Figure 2).

Insofar as the various LH techniques, TLH was performed in 50% of cases, followed by LAVH in 23% and SLH in 17%. Ten percent of laparoscopists stated they performed TLH, SLH, and LAVH equally. Experienced laparoscopists tended to perform TLH more often than LAVH, compared with laparoscopists who were still progressing along the learning curve (p = .001) (Figure 3).

Market simulation analysis provided mean utility values for each attribute and level (Table 1). In the "Total" column, representing mean utility values for all respondents together, there was a tendency toward preference for LH in patients with BMI 20 kg/m2, normal uterine size, and no previous laparoscopic abdominal surgery. Insofar as mean importances of the given attributes, all gynecologists seemed to consider uterine size and BMI as factors with major effect on decision making about mode of hysterectomy (Table 2).

In all 3 groups, market simulation revealed a preference for LH over AH in identical cases (mean share of preference, 75.6%; 95% CI, 71.2–80.0). Group 1 opted significantly more often for LH (86.3%; 95% CI, 81.6–91.0) in comparison with group 2 (70.9%; 95% CI, 63.4–78.4), and group

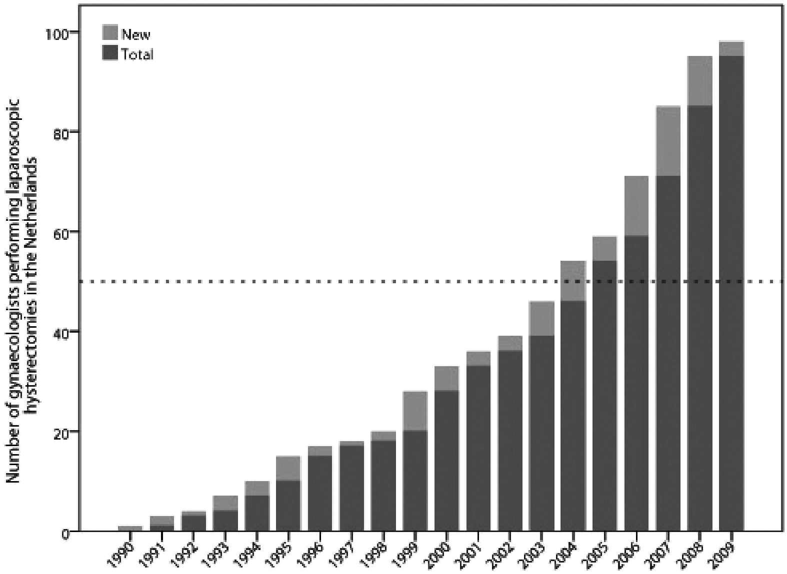

Figure 2 Trend in number of gynecologists performing laparoscopic hysterectomies in the Netherlands, 1990 – 2009.

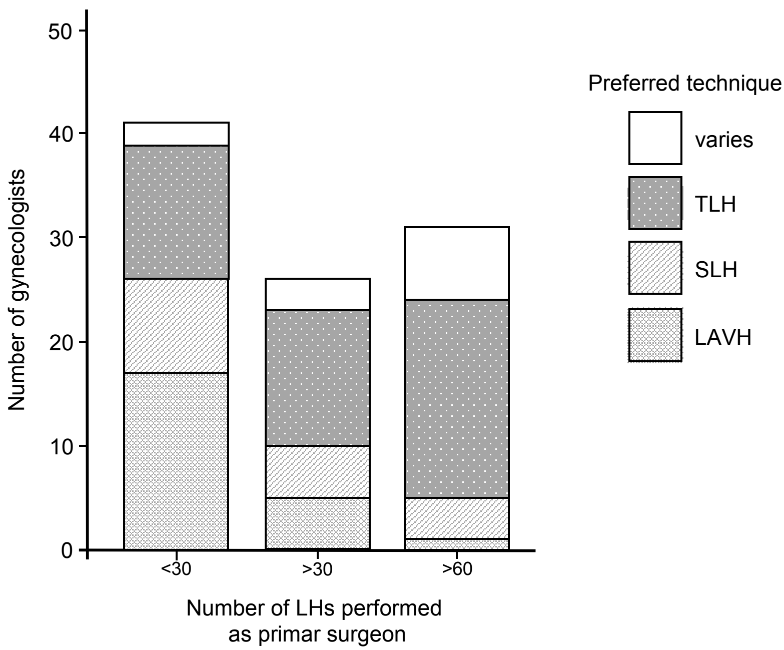

Figure 3 Distribution of preferred laparoscopic hysterectomy (LH) techniques for laparoscopists progressing along the learning curve (<30 LH procedures) and those who completed the learning curve once (>30 procedures) or twice (>60 procedures). (TLH = Total Laparoscopic Hysterectomy; SLH = Supracervical Laparoscopic Hysterectoy; LAVH = Laparoscopic Assisted Vaginal Hysterectomy).

Table 1 Average utility values for each attribute and level, for all respondents and subdivided per group.

Attribute	Level	Total	Group 1	Group 2	Group 3
BMI	20	23.35	21.86	29.01	16.38
(kg/m²)	25	18.11	14.36	20.26	24.30
	30	1.86	2.47	-0.54	3.82
	35	3.64	5.95	1.53	1.25
	40	-46.96	-44.62	-50.27	-45.75
Uterus size	normal	7.65	17.86	4.89	-19.48
(weeks	10 wks	12.67	22.71	3.56	-2.05
gestation)	12 wks	5.81	5.58	2.08	13.40
	14 wks	1.57	-8.43	9.62	18.85
	16 wks	-27.70	-37.72	-20.14	-10.72
Surgery	none	12.20	7.24	23.60	1.29
	1 procedure	9.10	7.41	7.62	18.19
	2 procedures	-21.30	-14.65	-31.22	-19.48
Modus	AH	-52.04	-79.75	-35.71	2.68
	LH	52.04	79.75	35.71	-2.68

AH = abdominal hysterectomy; LH = laparoscopic hysterectomy; Group 1= LH-performers; Group 2 = colleagues of LH-performers; Group 3 = gynecologists employed in a hospital where LH is not provided.

Table 2 Average importances of each attribute by group.

Attribute	Total	Group 1	Group 2	Group 3
BMI	25.17	22.18	28.99	25.99
Uterine size	24.74	22.51	26.30	28.51
Previous surgery	15.68	12.44	19.60	17.18
Mode of hysterectomy	34.42	42.87	25.11	28.33

Group 1 = LH performers; Group 2 = colleagues of LH performers; Group 3 = gynecologists employed in a hospital where LH is not provided.

2 significantly more frequently chose LH in comparison with group 3 (50.3%; 95% CI, 35.7–64.9). This finding was confirmed in that, with respect to reported referral behavior based on the multiple-choice task in the questionnaire, group 2 claimed to more often refer candidates for LH in comparison with group 3 (Figure 4).

Increased BMI, estimated uterine size, or number of previous abdominal surgeries caused a drop in shares of preferences for LH in the Market simulator in all 3 groups (Figure 5). Multivariative analysis of variance yielded a significant difference in decline in shares of preference for LH between the 3 groups when comparing the optimal scenario with scenarios with the highest BMI, largest estimated uterine size, and greatest number of previous abdominal surgeries (3 times; p <.001). Post hoc analysis revealed that the shares of preferences in group 1 were significantly less affected by decreasing BMI, uterine size, or number of previous abdominal surgeries, compared with both groups 2 and 3. The preference of referring gynecologists is primarily influenced by increase in BMI, and much less by increase in uterine size.

In group 1, no significant differences in change in shares of preferences for LH were observed between the subgroups of laparoscopists who were progressing along the learning curve (<30 LH procedures performed), had accomplished the learning curve (>30 LH procedures), or mastered the learning curve twice (>60 LH procedures).

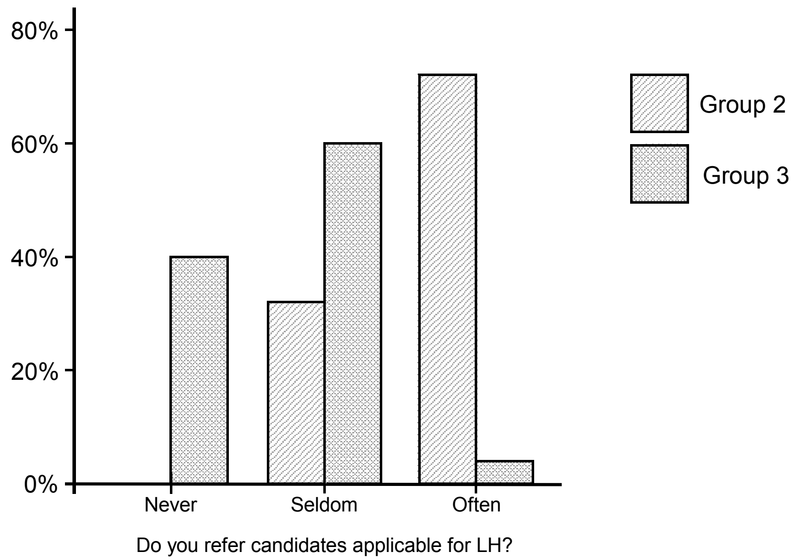

Figure 4 Reported actual referral behavior among gynecologists employed in hospitals that provide laparoscopic hysterectomy (LH) (group 2) and gynecologists employed in hospitals that do not provide LH (group 3).

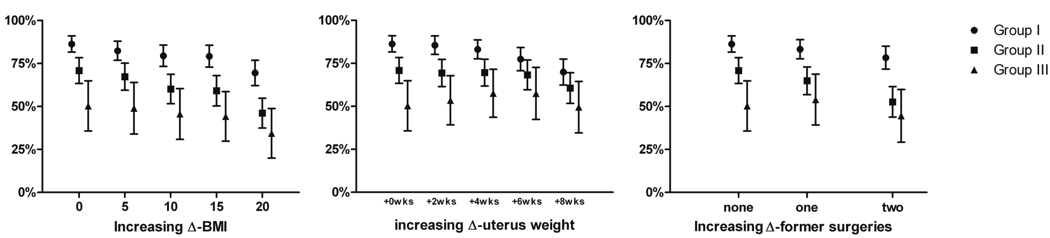

Figure 5 Differences in shares of preferences for laparoscopic hysterectomy (LH). Group 1 = gynecologists who perform LH; group 2 = colleagues of group 1; and group 3 = gynecologists employed in hospitals that do not provide LH, plotted for different scenarios.

Discussion

The present study demonstrates that preference for the minimally invasive approach in hysterectomy depends heavily on its availability and knowledge about the advantages of this approach. Using conjoint analysis, we observed that the presence of a gynecologist who performs LH significantly improves referral behavior of colleagues. In addition, it was observed that LH seems to be increasingly adopted by gynecologists in the Netherlands. Furthermore, more than half of the laparoscopists stated that they had been performing LH for less than 5 years, with 40% claiming to be still progressing along the learning curve of 30 procedures. These data demonstrate that with growing popularity of this procedure, a steady state of implementation of this advanced laparoscopic procedure has yet not been reached. However, the level of experience (expressed in number of LH procedures performed) does not significantly influence LH performers' opinion of BMI, estimated uterus size, and previous abdominal surgery as restrictive characteristics for the laparoscopic approach.

The finding of increased BMI as a restrictive factor for choosing LH, according to both referring gynecologists (groups 2 and 3) and performers (group 1) at CBC analysis, is intriguing. From evidence-based data, it has been proved that obesity is not a contraindication for the laparoscopic approach.[10-13] Minimally invasive techniques facilitate a more rapid recovery and a shorter hospitalization, both advantageous aspects of major importance, especially in the high-risk obese patient. Assuming proper knowledge of the literature regarding high-risk obese patients, it is worrisome that gynecologists apparently would rather continue to perform hysterectomy using the conventional approach than change their practice according to the evidence. Possible explanations may be fear of litigation, difficulties in performing laparoscopy in obese women, or perverse reimbursement incentives.[15;23;24] Apparently, estimated uterine size affects the referring gynecologist's preference much less than does change in BMI.

Gynecologists who do not have a colleague who performs LH stated that they still prefer to refer a problematic candidate patient (i.e., BMI 40 kg/m2, estimated uterus size 16 weeks' gestation, and 2 previous abdominal surgeries) for LH in nearly 40% of cases. This is in striking contrast with their self-perceived referral behavior because all of these gynecologists claim to seldom refer candidate patients for LH in daily practice. Other researchers have also observed this attitude.[20;22-24] The observed discrepancy between reported (ie, daily practice) and simulated (ie, this choice-based conjoint study) referral behavior in group 3 is interesting. Apparently, striving to provide the minimally invasive approach seems to be present in gynecologists employed in hospitals that do not provide LH. However, possibly because of practical impediments, honorary consequences, or long-lasting physician-patient relationships, gynecologists in group 3 tends to not refer patients in daily practice. In the Netherlands, gynecologists are salaried and not paid for number of performed surgical procedures on an individual basis. However, at the department level, income and reimbursement depend highly on annual surgical volume contracted for by the insurance companies. This volume-dependent compensation at the department level may hamper referral to other gynecologic departments. An alternative explanation for this discrepancy could be that although group 3 claims to be willing to refer candidate patients, covertly they prefer AH. A third possible explanation for the observed discrepancy between simulated and actual referral behavior could have its origin in the extensive process of decision making involved in the many (benign) indications for hysterectomy. After having tried many (outpatient department) alternatives, patients probably prefer to undergo surgery performed by someone they know and trust rather than being referred to someone who may perform a more ideal surgical procedure but whom they do not know. In this light, we are convinced that patient preference is heavily influenced by completeness of information about all alternatives. Although we did not assess actual decision making by both physician and patient, we deduce from the outcomes that suboptimal counseling results in suboptimal implementation of LH.

We stress that the mentioned impediments and explanations are not solely applicable to the Netherlands. Hampered implementation of LH is a global problem, and many countries have far too many gynecologists without the inclination or ability to practice at the highest level and would rather continue to perform procedures that are less than ideal.[14-16;19-24] Compared with similar studies, the present study has a high response rate (75%). Still, the outcomes of preference studies in general remain a rough estimate of actual decision making.[19-23] In addition, our choice-based conjoint analysis of LH-performing gynecologists and referral behavior of their colleagues has shortcomings. First, the concise set of 18 pair wise choices might seem insufficient to rely on. Nevertheless, after applying the choice-based conjoint analysis market simulator to the raw data, a complete spectrum of scenarios was provided (5760 simulated pair wise scenarios). Therefore, solid preference estimates of every imaginable scenario could be calculated. Second, the limited set of 3 patient characteristics (BMI, estimated uterus size, and previous abdominal surgery) covers only partially the complex patient in daily practice. However, the selection of discriminating factors by the expert panel seemed to be proper because each selected attribute significantly influenced the responding gynecologist's preference.

In conclusion, preference for the minimally invasive approach in hysterectomy depends heavily on its availability and on knowledge about the advantages of this approach. Assuming that the evidence about indication is well known by laparoscopists, more in-depth analysis is necessary to evaluate why their preferences for LH does not correspond to this evidence. Consequently, most patients who do not qualify for the vaginal approach are still offered AH despite its many disadvantages.[2] We believe that improvement in compliance with the indication for LH and correcting the applicability of the procedure, in addition to improved laparoscopic training during residency and a regional referral system, will optimize patient access to a minimally invasive approach in hysterectomy. Work is still needed to properly implement LH as a preferred procedure for surgical gynecologic indications when VH, the criterion standard, is not applicable.

Acknowledgements

We thank our colleague gynecologists in the Netherlands who participated in this preference study.

Reference

1. van Dongen H ,van de Merwe AG, de Kroon CD, Jansen FW. The impact of alternative treatment for abnormal uterine bleeding on hysterectomy rates in a tertiary referral center. J Minim Invasive Gynecol 2009; 16(1):47-51.
2. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
3. Kluivers KB, Johnson NP, Chien P, Vierhout ME, Bongers M, Mol BW. Comparison of laparoscopic and abdominal hysterectomy in terms of quality of life: a systematic review. Eur J Obstet Gynecol Reprod Biol 2008; 136(1):3-8.
4. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Health Technol Assess 2004; 8(26):1-154.
5. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.
6. Twijnstra AR, Blikkendaal MD, Kolkman W, Smeets MJ, Rhemrev JP, Jansen FW. Implementation of Laparoscopic Hysterectomy: Maintenance of Skills after a Mentorship Program. Gynecol Obstet Invest 2010; 70(3):173-178.
7. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
8. Leonard F, Fotso A, Borghese B, Chopin N, Foulot H, Chapron C. Ureteral complications from laparoscopic hysterectomy indicated for benign uterine pathologies: a 13-year experience in a continuous series of 1300 patients. Hum Reprod 2007; 22(7):2006-2011.
9. Donnez O, Jadoul P, Squifflet J, Donnez J. A series of 3190 laparoscopic hysterectomies for benign disease from 1990 to 2006: evaluation of complications compared with vaginal and abdominal procedures. BJOG 2009; 116(4):492-500.
10. O'Hanlan KA, Dibble SL, Fisher DT. Total laparoscopic hysterectomy for uterine pathology: impact of body mass index on outcomes. Gynecol Oncol 2006; 103(3):938-941.
11. Chopin N, Malaret JM, Lafay-Pillet MC, Fotso A, Foulot H, Chapron C. Total laparoscopic hysterectomy for benign uterine pathologies: obesity does not increase the risk of complications. Hum Reprod 2009; 24(12):3057-3062.
12. Heinberg EM, Crawford BL, III, Weitzen SH, Bonilla DJ. Total laparoscopic hysterectomy in obese versus nonobese patients. Obstet Gynecol 2004; 103(4):674-680.
13. Brezina PR, Beste TM, Nelson KH. Does route of hysterectomy affect outcome in obese and nonobese women? JSLS 2009; 13(3):358-363.
14. Garry R. The future of hysterectomy. BJOG 2005; 112(2):133-139.
15. Jacoby VL, Autry A, Jacobson G, Domush R, Nakagawa S, Jacoby A. Nationwide use of laparoscopic hysterectomy compared with abdominal and vaginal approaches. Obstet Gynecol 2009; 114(5):1041-1048.
16. Twijnstra AR, Kolkman W, Trimbos-Kemper GC, Jansen FW. Implementation of Advanced Laparoscopic Surgery in Gynecology: National Overview of Trends. J Minim Invasive Gynecol 2010.
17. Kluivers KB, Opmeer BC, Geomini PM, Bongers MY, Vierhout ME, Bremer GL et al. Women's preference for laparoscopic or abdominal hysterectomy. Gynecol Surg 2009; 6(3):223-228.
18. Kolkman W, Wolterbeek R, Jansen FW. Implementation of advanced laparoscopy into daily gynecologic practice: difficulties and solutions. J Minim Invasive Gynecol 2006; 13(1):4-9.
19. Einarsson JI, Matteson KA, Schulkin J, Chavan NR, Sangi-Haghpeykar H. Minimally invasive hysterectomies-a survey on attitudes and barriers among practicing gynecologists. J Minim Invasive Gynecol 2010; 17(2):167-175.
20. Gimbel H, Ottesen B, Tabor A. Danish gynecologists' opinion about hysterectomy on benign indication: results of a survey. Acta Obstet Gynecol Scand 2002; 81(12):1123-1131.
21. Bickell NA, Earp J, Evans AT, Bernstein SJ. A matter of opinion about hysterectomies: experts' and practicing community gynecologists' ratings of appropriateness. Am J Public Health 1995; 85(8 Pt 1):1125-1128.
22. Englund M, Robson S. Why has the acceptance of laparoscopic hysterectomy been slow? Results of an anonymous survey of Australian gynecologists. J Minim Invasive Gynecol 2007; 14(6):724-728.
23. Persson P, Hellborg T, Brynhildsen J, Fredrikson M, Kjolhede P. Attitudes to mode of hysterectomy--a survey-based study among Swedish gynecologists. Acta Obstet Gynecol Scand 2009; 88(3):267-274.
24. Tu FF, Beaumont JL, Senapati S, Gordon TE. Route of hysterectomy influence and teaching hospital status. Obstet Gynecol 2009; 114(1):73-78.

25. Audebert A.J. The role of microlaparoscopy for safer wall entry, incidence of umbilical adhesions according to past surgical history. Modifications of the closed technique. Gynaecol Endosc [8], 363-367. 1999.
26. Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. Obstet Gynecol 2004; 104(2):308-313.
27. Tunitsky E, Citil A, Ayaz R, Esin S, Knee A, Harmanli O. Does surgical volume influence short-term outcomes of laparoscopic hysterectomy? Am J Obstet Gynecol 2010.
28. Garry R, Reich H, Liu CY. Laparoscopic hysterectomy - definitions and indications. Gynaecol Endosc 1994; 3:1-3.

Chapter five

Predictors of successful surgical outcome in laparoscopic hysterectomy

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Obstet Gynecol. 2012;119:700-8

Abstract

Objective

To estimate, after correction for patient factors, to what extent blood loss, operative time, and adverse events are decisive factors for the successful outcome of laparoscopic hysterectomy. A secondary objective was to estimate to what extent a successful outcome can be predicted from surgical experience or other measures of surgical skill.

Materials and Methods

A nationwide multivariate 1-year cohort analysis was conducted with gynecologists who perform laparoscopic hysterectomy. The primary outcomes were blood loss, operative time, and adverse events. The procedures were corrected for multiple covariates in a mixed-effects logistic regression model. Furthermore, all primary outcomes were related to experience and the influence of individual surgical skills factors.

Results

One thousand five hundred thirty-four laparoscopic hysterectomies were analyzed for 79 surgeons. The success of the surgical outcome was significantly influenced by uterus weight, body mass index, American Society of Anesthesiologists Physical Status Classification, previous abdominal surgeries, and the type of laparoscopic hysterectomy. Surgical experience also predicted the successful outcome of laparoscopic hysterectomy with respect to blood loss and adverse events (P=.048 and .036, respectively). A significant improvement in surgical outcomes tends to continue up to approximately 125 procedures. Independently from surgical experience, an individual surgical skills factor was identified as odds ratio 1.67 and 3.60 for blood loss and operative time, respectively.

Conclusion

After adjusting for risk factors, it was shown that an increase in experience positively predicted a successful outcome in laparoscopic hysterectomy with respect to blood loss and adverse events. However, the independent surgical skills factor shows a large variation in proficiency between individuals. The fact that a surgeon has performed many laparoscopic hysterectomies does not necessarily guarantee good surgical outcome.

Introduction

Laparoscopic hysterectomy has consistently gained in popularity since its worldwide introduction to the surgical palette in the early 1990s.[1-3] Today, it is common knowledge that in cases of benign diseases, if the gold standard (ie, vaginal hysterectomy) is for some reason not feasible, the laparoscopic approach is superior to abdominal hysterectomy with respect to blood loss, wound infection, hospital stay, and recovery period.[4] In addition, patients claim to prefer this minimally invasive approach over abdominal hysterectomy for esthetical reasons and because of recovery considerations.[5]

However, the implementation of laparoscopic hysterectomy is slow and diffuse in the majority of countries, accounting for only 6–16% of all hysterectomies.[6;7] This hampered implementation is assumed to be caused by a number of factors. Firstly, laparoscopic hysterectomy is considered to be an advanced laparoscopic procedure, which is thought to be characterized by a long learning curve.[8;9] However, the few studies that have attempted to describe this learning curve in laparoscopic hysterectomy have all been hampered by their retrospective design and other methodological flaws.[10-14] Chiefly based on complication rates or operative time, these studies state that the learning curve for laparoscopic hysterectomy is completed after approximately 30 procedures.[12;14;15] As a result, the (end of the) learning curve in laparoscopic hysterectomy is not well-defined, whereas a clear definition is important both for training and for reasons relating to ethical and medical–legal issues. Second, probably partly because of the lack of consistent laparoscopic hysterectomy guidelines, performers, and their referring colleagues tend to disagree on the risk factors of laparoscopic hysterectomy.[16-19] Regarding these risk factors (ie, patient characteristics), we identified an ongoing debate in the literature on how the surgical outcome in laparoscopic hysterectomy is influenced by uterus weight, body mass index (BMI, calculated as weight (kg)/[height (m)]2), and the number of previous abdominal surgeries.[20-24] Clearly, more evidence is needed to identify the risk factors that predict successful surgical outcome in laparoscopic hysterectomy and to assist gynecologists in selecting and counseling patients who will benefit from the laparoscopic approach. Applying the data from our nationwide prospective cohort of gynecologists who performed laparoscopic hysterectomies, we tried to estimate which patient and surgeon factors predict surgical outcome in laparoscopic hysterectomy.

Materials and Methods

Every gynecologist in the Netherlands who performed laparoscopic hysterectomies was requested to enroll in this study and to register every laparoscopic hysterectomy performed as a primary surgeon for a period of 12 consecutive months. Before the start of this LapTop! study (Laparoscopic Advanced Procedures, Testing Overall Parameters), every participant was provided with a short questionnaire to assess years of experience with laparoscopic surgery in general and laparoscopic hysterectomy in particular. A concise set of patient and procedure characteristics was defined in a consensus meeting of six gynecologists who had extensive expertise in advanced laparoscopic surgery. At this meeting, the results of a literature search on relevant procedure and patient characteristics were also discussed. In addition to date of birth and indication for laparoscopic hysterectomy, patient characteristics consisted of BMI, age, American Society of Anesthesiologists Physical Status Classification,[25] number of previous abdominal surgeries, and uterus weight (measured in grams, weighed in the operating room). Procedure characteristics included surgery outcomes such as blood loss measured in milliliters, operative time measured in minutes from first incision until final stitch, adverse events, and whether conversion to laparotomy was performed. Performer characteristics included actual number of laparoscopic hysterectomies performed, including the procedure to be registered. Furthermore, the surgeon was asked to register whether the procedure was performed by one or by two gynecologists. If surgery was performed by two surgeons, then the experience of the primary surgeon was registered.

Because of its observational and anonymous character, this study was exempted from approval by our Institutional Review Board. The electronic study record form was designed as an interactive PDF to facilitate swift registration in the operating room. Data were automatically sent to a central study data server. In the event of adverse events observed after sending the record form, a new form could be forwarded. Adverse events were registered by type of complication, severity (ie, requiring re-intervention or not), and moment of onset for a period of up to 6 weeks after discharge (ie, marking the end of the legitimate adverse event reporting period) according to the definitions and regulations as determined by the Guideline on Adverse Events of the Dutch Society of Obstetricians and Gynecologists.[26] Conversion to laparotomy was defined as a switch to an open procedure after laparoscopic start-up.

We aimed to minimize the possibility of incomplete participation because registration was voluntary and participants could hypothetically omit less successful procedures from registration. Therefore, in return for the efforts made, a periodic electronic personal outcomes overview was provided to motivate participation. Furthermore, complete participation was assured by the guaranteed anonymity of the results of each participant, by double-checking the numbers of laparoscopic hysterectomies received with publicly accessible year reports, and, finally, by randomly visiting 10% of the participating centers for a double-check of the surgeons' reports.

We considered blood loss, operative time, and an adverse event to be decisive factors for the successful outcome of laparoscopic hysterectomy, and these outcomes were related to surgeon experience corrected for uterus weight, BMI, age, American Society of Anesthesiologists classification, previous abdominal surgeries, type of laparoscopic hysterectomy (laparoscopically assisted vaginal hysterectomy, supracervical laparoscopic hysterectomy, total laparoscopic hysterectomy) and the number of surgeons performing hysterectomy.

For the statistical analysis, we used SPSS 17.0 and R 2.10.1. Differences between groups were assessed with the [chi]2 test for proportions and Student independent samples t test, or by using the one-way analysis of variance for continuous variables. We calculated standard deviations and odds ratios (ORs). As explained in more detail, we used multivariate mixed-effects logistic regressions to estimate the effects (in terms of log OR) of the relevant risk factors on our outcome variables. A log odds can be converted to an OR by raising e to the power of the log odds.

We used 95% confidence intervals (CIs) and considered $P<.05$ to be statistically significant. We did not correct for multiple comparisons but did report all the tests we performed.

The two numeric outcomes (blood loss and operative time) were dichotomized by setting threshold values to distinguish a successful procedure from an unsuccessful one. For operative time and blood loss, we decided to set the threshold at the rounded mean observed. The third primary end point, adverse event, was already binary. Thus, for all three primary end points, the outcome was binary: success or failure. As a result, in our analysis we did not take into account the raw linear data of blood loss and operative time but applied the binary outcomes to differentiate between successful and unsuccessful procedures (as compared with the mean observed).

We used logistic regression to estimate the influence of various patient characteristics on the outcome. As covariates, we included: BMI, age, American Society of Anesthesiologists classification, previous abdominal surgeries, uterus weight, applied laparoscopic hysterectomy technique (laparoscopically assisted vaginal hysterectomy, supracervical laparoscopic hysterectomy, or total laparoscopic hysterectomy), and whether the surgery was performed by one or two surgeons.

We had to take into account the fact that we observed multiple procedures for each surgeon. Two procedures performed by the same surgeon tend to be “more similar” than two procedures performed by two different surgeons. We modeled this type of similarity by using a mixed-effects logistic regression, thus including random contributions specific to each surgeon. This resulted in the calculation of an individual surgical skills factor. There was no restriction on the type of relation brought about by the effect of experience because a mixture of splines was used. Moreover, in this way, the standard deviation of the random contributions (estimated at log odds of the exponent) demonstrated the size of the surgical skills factor with regard to each primary outcome. Using this approach, the surgical skills factor calculated could be used as an average OR for a successful procedure between two randomly selected surgeons.

Because our model corrects for all measurable patient and surgeon factors, this standard deviation can be interpreted as an OR of surgical factors that are not measurable as a number with a unit, such as the surgical skills and the functionality of the complete operating team.

Because the latter is also the responsibility of the surgeon, we referred to this as the surgical skills factor. To fit this generalized additive mixed model, we used the function gamm in the R package mgcv by Simon Wood.[27]

Results

Seventy-nine out of a total number of 106 gynecologists performing laparoscopic hysterectomy in the Netherlands registered every laparoscopic hysterectomy over a consecutive period of 1 year (response rate 75%). Participants were recruited by 42 out of the 62 gynecology departments performing laparoscopic hysterectomies (laparoscopic hysterectomy hospital cover factor 68%).

The distribution of experience at the start of the study is shown in Figure 1. Approximately 29% of the participating gynecologists had performed 10 or fewer laparoscopic hysterectomies at the beginning of the study, and 50% had performed 30 or fewer laparoscopic hysterectomies at the moment of inclusion. The median number of previously performed laparoscopic hysterectomies was 28 (range 0–250). During the study period of 12 months, the mean number of performed laparoscopic hysterectomies was 14.9 per year (SD 10.7, range 1–50), 43% of the participants performed 10 or fewer laparoscopic hysterectomies per year during the study period, 34% performed between 10 and 20 laparoscopic hysterectomies per year, and 23% performed more than 20 laparoscopic hysterectomies per year.

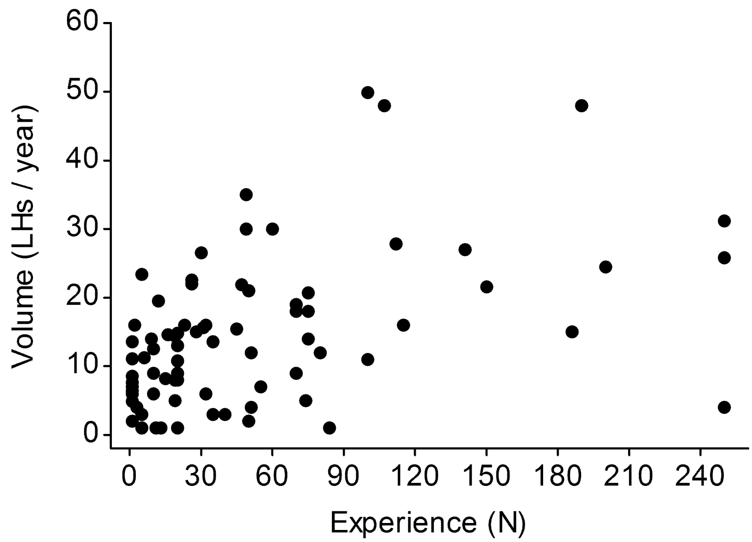

Figure 1 Scatterplot representing experience (number of previously performed LHs) at inclusion plotted against surgical volume (numbers of LHs performed during the study period of one year). R=0.46, P < 0.001. N= 79 gynecologists. (LH= Laparoscopic Hysterectomy).

A total of 1,585 laparoscopic hysterectomies were registered. Twenty-nine robot laparoscopic hysterectomies, 16 conventional radical laparoscopic hysterectomies, and six laparoscopic hysterectomies with accompanying stage 3 or 4 endometriosis were excluded from analysis to enhance comparability between laparoscopic hysterectomies. A double-check of the number of procedures performed in publicly accessible year reports and by means of a random visit to 10% of the participating centers confirmed the quoted number of procedures registered per center.

The final analysis included 1,534 laparoscopic hysterectomies. The procedure and patient characteristics, together with adverse events and conversion statistics for each type of laparoscopic hysterectomy, are outlined in Table 1. Mean operative time was 116 minutes (SD 42, median 110, range 32–344), mean blood loss was 185 mL (SD 247, median 100, range 0–2,600), and adverse event rate was 7.6%. Procedure characteristics and patient characteristics varied significantly between the three types of laparoscopic hysterectomy. Supracervical laparoscopic hysterectomy was associated with the shortest mean operative time and the highest mean uterus weight. Blood loss was significantly higher in laparoscopically assisted vaginal hysterectomy compared with the other laparoscopic hysterectomy types ($P=.002$). Patients in the supracervical laparoscopic hysterectomy group were significantly younger, less obese, and had a lower American Society of Anesthesiologists classification ($P<.001$, .009, and .007, respectively). General adverse events did not differ significantly between types of laparoscopic hysterectomy (adverse event rate 7.6%). Regarding specific adverse outcomes, blood loss more than 1 L was observed significantly more often in laparoscopically assisted vaginal hysterectomy compared with supracervical laparoscopic hysterectomy and total laparoscopic hysterectomy combined (OR 2.46, 95% CI 1.18–5.11), whereas bladder lesions (n=13, 0.9%) were observed exclusively in the total laparoscopic hysterectomy group. The aforementioned calculations were based on pure observation, without correction for patient and surgeon characteristics.

Adverse events and rounded mean values of operative time and blood loss were used as cut-off points for our definition of successful surgery (blood loss less than 200 mL: n=996, operative time less than 120 minutes, n=852). Other more extreme cut-offs (blood loss 500 mL, operative time 150 minutes) did not significantly affect outcomes as presented. The distribution of operative time and blood loss were skewed (1.1 and 4.4, respectively), justifying dichotomization of these outcomes, as described in the Materials and Methods section.

Tables 2, 3, and 4 show all patient and procedure characteristics (ie, BMI, age, American Society of Anesthesiologists classification, previous abdominal surgery, uterus weight, applied type of laparoscopic hysterectomy, and one or two surgeons present at hysterectomy) identifying the influence of each covariate for successful surgery with respect to blood loss less than 200 mL, operative time less than 120 minutes, and no adverse event. Significant covariates that decreased the chance of lower than average blood loss (blood loss less than 200 mL) were an increase in uterus weight (OR 0.70, 95% CI 0.65–0.75), an increase in BMI (OR 0.77, 95% CI 0.68–0.89), and laparoscopically assisted vaginal hysterectomy instead of total laparoscopic hysterectomy (OR 0.46, 95% CI 0.29–0.74). Significant covariates decreasing the chance of lower than average operative time (operative time less than 120 minutes) were an increase in uterus weight (OR 0.66, 95% CI 0.60–0.72) and laparoscopic hysterectomy being performed by two surgeons instead of

Table 1 Procedure and patient characteristics for each type of laparoscopic hysterectomy

	Total n = 1.534	LAVH n = 183 (12%)	SLH n = 391 (25%)	TLH n = 960 (63%)	*P* value*
Procedure characteristics					
Operative time (min)	116 ± 42	114 ± 35	112 ± 49	118 ± 40	.021
Blood loss (mL)	185 ± 247	238 ± 302	195 ± 266	170 ± 226	.002
Uterus weight (g)	227 ± 199	165 ± 131	280 ± 221	217 ± 196	<.001
Patient characteristics					
Age (years)	47.8 ± 10.2	47.1 ± 10.4	45.9 ± 6.0	48.8 ± 11.3	<.001
BMI (kg/m2)	27.2 ± 5.3	27.3 ± 4.8	26.5 ± 4.8	27.5 ± 5.7	.009
No former abdominal surgery	24.6	30.1	26.6	22.8	.066
ASA classification 1	66.9	63.9	73.4	55.9	.007
Main indications					
Dysfunctional uterine bleeding	50	62	55	45	
Myomata	27	14	40	25	
(Pre)malignancy	15	14	0.5	22	
Pelvic pain	2	1.5	1.5	2.5	
Complicated procedures	116 (7.6)	19 (10.4)	22 (5.6)	75 (7.8)	.119
Requiring re-intervention (%)	23 (1.5)	5 (2.7)	3 (0.8)	15 (1.6)	.189
Top five complications					
Lesion	31 (2.0)	5 (2.7)	2 (0.5)	23 (2.4)	.142
Bladder	13 (0.9)	-	-	1.4 (13)	.020
Ureter	7 (0.5)	2 (1.1)	-	4 (0.4)	.366
Vessel	3 (0.2)	2 (1.1)	-	1 (0.1)	.224
Intestine	8 (0.5)	1 (0.6)	2 (0.5)	5 (0.5)	.999
Blood loss > 1L	43 (2.8)	10 (5.5)	11 (2.8)	22 (2.3)	.033
Infection	12 (0.8)	1 (0.6)	1 (0.3)	10 (1.0)	.480
Wound dehiscence	15 (1.0)	2 (1.1)	3 (0.8)	10 (1.0)	.688
Technical failure	6 (0.4)	1 (0.6)	2 (0.5)	3 (0.3)	.815
Conversions to laparotomy	71 (4.6)	12 (6.6)	13 (3.3)	46 (4.8)	.221
Proportion due to complication (%)	31	42	54	22	.178

Data are mean +/- standard deviation, %, or n (%) unless otherwise specified.

* ANOVA test was used for continuous variables; Chi-square test was used for proportions.

Table 2 Influence of each covariate on successful surgical outcome with respect to blood loss less than 200 mL

	Odds Ratio	95%-CI		*P* value
		Lower	Upper	
Procedure characteristics				
LAVH (compared to TLH)	0.46	0.29	0.74	.001
SLH (compared to TLH)	1.04	0.73	1.49	.810
Two surgeons (compared to one)	1.21	0.77	1.92	.413
Patient characteristics				
Age (increase per year)	1.00	0.99	1.02	.599
Uterus weight (increase per 100 gr)	0.70	0.65	0.75	<.001
BMI (increase per 1 kg/m^2)	0.77	0.68	0.89	<.001
ASA 2 (compared to ASA 1)	0.84	0.60	1.16	.291
ASA 3 (compared to ASA 1)	0.52	0.21	1.28	.156
Numbers of prior abdominal surgeries				
One (versus none)	0.93	0.68	1.26	.616
Two (versus none)	0.80	0.50	1.27	.345
Three or more (versus none)	0.75	0.36	1.53	.424

Table 3 Influence of each covariate on successful surgical outcome with respect to operative time less than 120 minutes

	Odds Ratio	95%-CI		*P* value
		Lower	Upper	
Procedure characteristics				
LAVH (versus TLH)	0.81	0.44	1.47	.483
SLH (versus TLH)	1.58	1.04	2.41	.032
Two surgeons (versus one)	0.55	0.30	0.99	.045
Patient characteristics				
Age (increase per year)	0.99	0.97	1.01	.201
Uterus weight (increase per 100 gr)	0.66	0.60	0.72	<.001
BMI (increase per 1 kg/m^2)	0.92	0.79	1.06	.242
ASA 2 (versus ASA 1)	0.95	0.67	1.35	.792
ASA 3 (versus ASA 1)	0.40	0.15	1.11	.078
Numbers of prior abdominal surgeries				
One (versus none)	0,90	0,65	1,25	.538
Two (versus none)	0,94	0,57	1,55	.798
Three or more (versus none)	0,55	0,26	1,17	.122

Table 4 Influence of each covariate on successful surgical outcome with respect to no adverse event

	Odds Ratio	95%-CI		P value
		Lower	Upper	
Procedure characteristics				
LAVH (versus TLH)	0.88	0.46	1.70	.705
SLH (versus TLH)	1.67	0.93	3.01	.089
Two surgeons (versus one)	1.08	0.55	2.15	.820
Patient characteristics				
Age (increase per year)	1.00	0.98	1.03	.772
Uterus weight (increase per 100 gr)	0.84	0.76	0.92	<.001
BMI (increase per 1 kg/m^2)	1.08	0.85	1.39	.522
ASA 2 (versus ASA 1)	0.97	0.54	1.72	.911
ASA 3 (versus ASA 1)	0.31	0.08	1.21	.092
Numbers of prior abdominal surgeries				
One (versus none)	0.55	0.33	0.91	.020
Two (versus none)	1.21	0.45	3.26	.704
Three or more (versus none)	0.30	0.11	0,81	.017

one (OR 0.55, 95% CI 0.30–0.99). However, performing supracervical laparoscopic hysterectomy instead of total laparoscopic hysterectomy increased the probability of operative time less than 120 minutes (OR 1.58, 95% CI 1.04–2.41). Significant covariates decreasing the chance of an uneventful procedure were increased uterus weight (OR 0.84, 95% CI 0.76–0.92) and previous abdominal surgeries (one previous abdominal surgery: OR 0.55, 95% CI 0.33–0.91; more than two previous abdominal surgeries: OR 0.30, 95% CI 0.11–0.81).

Figure 2 shows the influence of experience (ie, previous numbers of performed laparoscopic hysterectomies) on the log odds (ie, probability) of a successful laparoscopic hysterectomy with respect to blood loss less than 200 mL, operative time less than 120 minutes, and no adverse event. We found a significant effect of experience on both blood loss (P=.048) and an adverse event (P=.036). The effect of experience on operative time was not significant (P=.2). Additionally, surgical volume (numbers of performed laparoscopic hysterectomies per surgeon during the study period) did not significantly predict successful outcomes in laparoscopic hysterectomy with respect to blood loss less than 200 mL, operative time less than 120 minutes, and an adverse event (P=.20, .85, and .49, respectively). Surgical volume and experience were moderately correlated (R=0.46, P<.001; Fig. 1).

The random contributions specific to each surgeon and used in our mixed-effects logistic regression model captured the fact that some surgeons appeared to be intrinsically more skilled than others; we defined this as the surgical skills factor. The surgical skills factor varied between the three assessed outcomes. The standard deviation of this random effect was estimated at a log

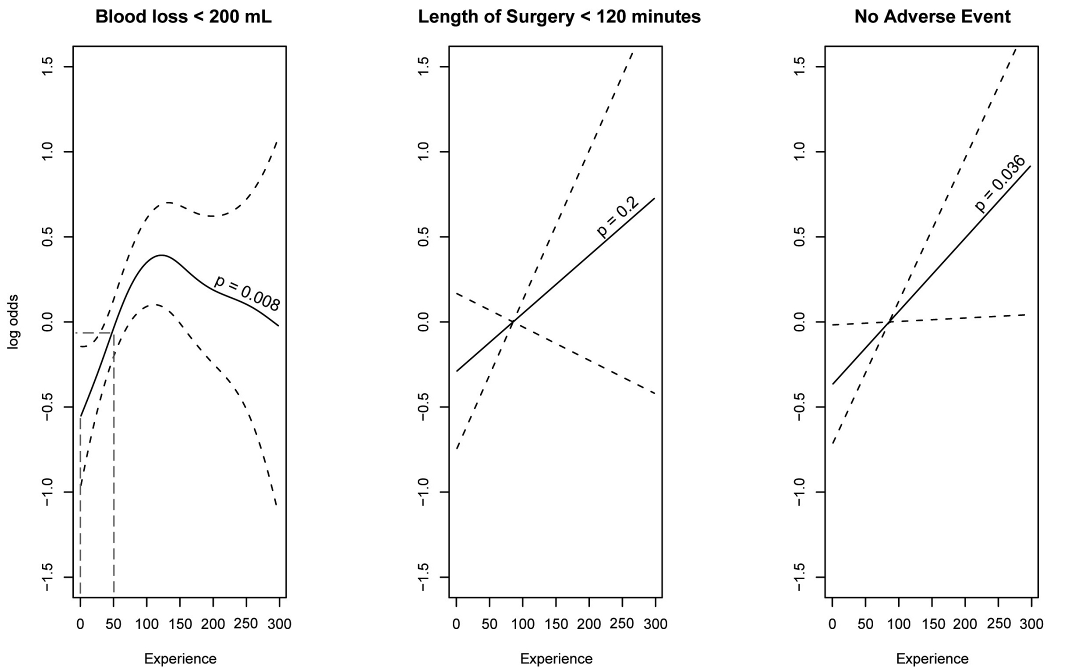

Figure 2 Graphic representation of the increasing probability of performing a successful LH with an increase in experience (numbers of performed LHs); with respect to blood loss < 200 milliliters (P = .008), operative time < 120 minutes (P = .2) and no adverse event (P = .036). The dotted black lines represent 95% confidence intervals. (LH= Laparoscopic Hysterectomy)

odds of 0.51 for blood loss less than 200 mL. This means that for two randomly selected surgeons, we calculated an average OR of 1.67 for blood loss less than 200 mL (exp (0.51)), comparable to a difference in success probability for a difference in experience between 0 and 50 procedures (dotted lines in left graph of Fig. 2). For operative time, this surgical skills factor OR was 3.60 (exp (1.28)). For adverse event, the surgical skills factor OR was 1.00 (exp (less than 0.001), ie, we detected no significant surgical skills factor for adverse event).

In the standard logistic regression model, the effect of a covariate on the log odds was assumed to be linear. For the outcome blood loss less than 200 mL, there was evidence of a nonlinear effect. After adjusting for all other covariates, success probability increased up to approximately 125 procedures. Beyond 125 procedures, no further gain was detected. With respect to operative time and adverse event, this cohort did not provide enough evidence for a departure from a linear effect.

Discussion

Our nationwide, prospective, multivariate cohort analysis of gynecologists performing laparoscopic hysterectomy shows that surgical experience predicts successful outcome in laparoscopic hysterectomy with respect to blood loss and adverse events. Surprisingly, a successful outcome in laparoscopic hysterectomy does not depend on surgical volume (expressed in the numbers of procedures performed during the study period).

This study provides us with risk-adjusted predictors for successful laparoscopic hysterectomy. Multiple risk factors such as uterus weight, BMI, previous abdominal surgery, type of laparoscopic hysterectomy, and one compared with two surgeons were identified. With respect to these factors, the present study confirms the findings in the literature.[20;28-30] Increased uterus weight, increased BMI, and performing a laparoscopic assisted vaginal hysterectomy (instead of supracervical laparoscopic hysterectomy or total laparoscopic hysterectomy) increased the amount of blood loss, performing laparoscopic hysterectomy with two surgeons seemed to slow down the procedure, and the risk of an adverse event increased in cases involving a history of abdominal surgeries.

Furthermore, the number of procedures required to acquire a steady rate of successful surgical outcomes in laparoscopic hysterectomy differed considerably from former (retrospective) learning curve studies that reported that 30 procedures were needed to reach proficiency.[10-14] The present study showed, however, that a significant improvement with respect to blood loss and adverse events could still be observed far beyond the aforementioned thirty procedures. With respect to the entire cohort, we identified a significant improvement up to approximately 125 procedures for blood loss less than 200 mL. This gain in experience did not decrease with respect to adverse events. Furthermore, we observed an intrinsic surgical skills factor independent from experience. This finding indicates that skills vary significantly among surgeons. It is therefore reasonable to assume that proficiency in laparoscopic hysterectomy should not be based solely on the number of procedures performed. Moreover, although experience did not predict a decline in operative time, we detected a significant variation in surgical skills factor with respect to this factor, ie, independently from experience, some surgeons tended to operate significantly faster than others. However, as the risk of causing an adverse event significantly declined with increasing experience, we detected no significant variation in surgical skills factor with respect to this factor, ie, two randomly selected gynecologists with the same amount of experience will have a comparable chance of an adverse event occurring.

We observed that experience significantly influenced outcomes with regard to blood loss and adverse events. Operative time was not significantly influenced by experience. These outcomes differ greatly from those of former studies.[31] This might be attributable to the fact that the present study prospectively investigated an entire cohort of gynecologists performing laparoscopic hysterectomy, each with their own level of experience. Previous studies mainly consisted of retrospective reports of a single surgeon's experiences with a newly acclaimed technique, without correcting for patient characteristics.[10-14;32] Our results call into question the definition of proficiency with respect to a given surgical technique.[15] We might follow the aforementioned single-surgeon studies in defining proficiency in terms of the number of procedures performed, which might then reach a plateau after a certain number of procedures. Alternatively, we suggest that proficiency can be defined as a level of performance that is as successful as the average measured for the entire cohort. We are convinced that this allows for a much better estimate of surgical expertise than only taking into account the number of procedures performed.

One might say that the cut-off values for unsuccessful procedures as defined by the median observed operative time (less than 120 minutes) and blood loss (less than 200 mL) are rather low. However, the same significant associations were found in analyses with other cut-off values, such as operative time less than 150 minutes and blood loss less than 500 mL. The probability of an operative time less than 120 minutes was significantly decreased if two surgeons performed the surgery. Hypothetically, this might be attributable to the fact that these laparoscopic hysterectomies were performed in a mentorship setting. Compared with other studies, the mean estimated blood loss observed is rather high. Hypothetically, this might be attributable to the fact that most other studies were single-center or single-surgeon–based reports. The results of the present study, however, reflect actual population-based estimated blood loss levels.

The substantial variation in surgical skills factors observed between individuals raises the question of whether it is possible for any individual to learn to perform a laparoscopic hysterectomy properly. A study on basic laparoscopic skills training outside the operating theater showed that up to 20% of trainees failed to become adequately proficient in minimally invasive surgery, which seems to support this hypothesis.[33] In our study, despite correction for risk factors, type of laparoscopic hysterectomy applied, and whether surgery was performed by one or two surgeons, a significant surgical skills factor for successful surgery still remained with respect to blood loss (OR 1.67) and operative time (OR 3.6).

Because we have identified a wide variation in proficiency in laparoscopic hysterectomy, we would like to continue to find tools to identify individual skills factors after correction for patient and procedure characteristics based on national or even international averages. To meet the persistent call for continuous quality assessments in surgery, we feel that there is a need for an ongoing proficiency check in laparoscopic hysterectomy.[34] We hope that future research will, for instance, assess the usefulness of cumulative summation analysis for determining a proficiency range in laparoscopic hysterectomy and distinguish adequate performers from less competent surgeons.[35-37] Because ultimate proficiency in advanced laparoscopic surgery might be regarded as a rather unrealistic goal, the maintenance of operative skills should become the real measure of this lifetime learning curve.[38]

Apart from the expected finding that successful surgical outcome depends on experience, our results show that successful laparoscopic hysterectomy also depends on an individual surgical skills factor and that this success rate varies significantly among individuals. According to our results, one should be cautious in adopting a general 30-procedure mantra for the learning curve involved in surgery. Instead, one should try to estimate individual learning curves by regularly comparing individual outcomes and adverse events with a national or even international cohort. This will inevitably result in a focus on the maintenance of individual surgical skills that will enhance and guarantee the patient-safe performance of laparoscopic hysterectomy.

References

1. Reich H, Decaprio J, McGlynn F. Laparoscopic hysterectomy. J Gynaecol Surg 1989; 5:213-216.
2. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.
3. Jacoby VL, Autry A, Jacobson G, Domush R, Nakagawa S, Jacoby A. Nationwide use of laparoscopic hysterectomy compared with abdominal and vaginal approaches. Obstet Gynecol 2009; 114(5):1041-1048.
4. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
5. Kluivers KB, Opmeer BC, Geomini PM, Bongers MY, Vierhout ME, Bremer GL et al. Women's preference for laparoscopic or abdominal hysterectomy. Gynecol Surg 2009; 6(3):223-228.
6. Twijnstra AR, Kolkman W, Trimbos-Kemper GC, Jansen FW. Implementation of Advanced Laparoscopic Surgery in Gynecology: National Overview of Trends. J Minim Invasive Gynecol 2010.
7. Garry R. The future of hysterectomy. BJOG 2005; 112(2):133-139.
8. Royal College of Obstetricians and Gynaecologists (RCOG). Classification of Laparoscopic Procedures per Level of Difficulty. 2001.
9. Aggarwal R, Moorthy K, Darzi A. Laparoscopic skills training and assessment. Br J Surg 2004; 91(12):1549-1558.
10. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
11. Perino A, Cucinella G, Venezia R, Castelli A, Cittadini E. Total laparoscopic hysterectomy versus total abdominal hysterectomy: an assessment of the learning curve in a prospective randomized study. Hum Reprod 1999; 14(12):2996-2999.
12. Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. Obstet Gynecol 2004; 104(2):308-313.
13. Twijnstra AR, Blikkendaal MD, Kolkman W, Smeets MJ, Rhemrev JP, Jansen FW. Implementation of Laparoscopic Hysterectomy: Maintenance of Skills after a Mentorship Program. Gynecol Obstet Invest 2010; 70(3):173-178.
14. Tunitsky E, Citil A, Ayaz R, Esin S, Knee A, Harmanli O. Does surgical volume influence short-term outcomes of laparoscopic hysterectomy? Am J Obstet Gynecol 2010.
15. Dagash H, Chowdhury M, Pierro A. When can I be proficient in laparoscopic surgery? A systematic review of the evidence. J Pediatr Surg 2003; 38(5):720-724.
16. Einarsson JI, Matteson KA, Schulkin J, Chavan NR, Sangi-Haghpeykar H. Minimally invasive hysterectomies-a survey on attitudes and barriers among practicing gynecologists. J Minim Invasive Gynecol 2010; 17(2):167-175.
17. Gimbel H, Ottesen B, Tabor A. Danish gynecologists' opinion about hysterectomy on benign indication: results of a survey. Acta Obstet Gynecol Scand 2002; 81(12):1123-1131.
18. Englund M, Robson S. Why has the acceptance of laparoscopic hysterectomy been slow? Results of an anonymous survey of Australian gynecologists. J Minim Invasive Gynecol 2007; 14(6):724-728.
19. Persson P, Hellborg T, Brynhildsen J, Fredrikson M, Kjolhede P. Attitudes to mode of hysterectomy--a survey-based study among Swedish gynecologists. Acta Obstet Gynecol Scand 2009; 88(3):267-274.
20. Heinberg EM, Crawford BL, III, Weitzen SH, Bonilla DJ. Total laparoscopic hysterectomy in obese versus nonobese patients. Obstet Gynecol 2004; 103(4):674-680.
21. O'Hanlan KA, Dibble SL, Fisher DT. Total laparoscopic hysterectomy for uterine pathology: impact of body mass index on outcomes. Gynecol Oncol 2006; 103(3):938-941.
22. Chopin N, Malaret JM, Lafay-Pillet MC, Fotso A, Foulot H, Chapron C. Total laparoscopic hysterectomy for benign uterine pathologies: obesity does not increase the risk of complications. Hum Reprod 2009; 24(12):3057-3062.
23. Brezina PR, Beste TM, Nelson KH. Does route of hysterectomy affect outcome in obese and nonobese women? JSLS 2009; 13(3):358-363.
24. Twijnstra AR, Stiggelbout AM, de Kroon CD, Jansen FW. Laparoscopic hysterectomy: eliciting preference of performers and colleagues via conjoint analysis. J Minim Invasive Gynecol 2011; 18(5):582-588.
25. Pasternak RL. Prenaesthesia evaluation of the surgical patient. ASA Refresher Courses Anesth 1996; 24:205-219.
26. Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. Qual Saf Health Care 2010; 19(2):132-137.
27. Wood SN. Fast stable direct fitting and smoothness selection for generalized additive models. J R Stat Soc B 2008; 70:495-518.

28. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Health Technol Assess 2004; 8(26):1-154.
29. Brummer TH, Jalkanen J, Fraser J, Heikkinen AM, Kauko M, Makinen J et al. FINHYST 2006--national prospective 1-year survey of 5,279 hysterectomies. Hum Reprod 2009; 24(10):2515-2522.
30. Twijnstra AR, Kianmanesh Rad NA, Smeets MJ, Admiraal JF, Jansen FW. Twenty-first century laparoscopic hysterectomy: should we not leave the vaginal step out? Gynecol Surg 2009; 6(4):311-316.
31. Kreiker GL, Bertoldi A, Larcher JS, Orrico GR, Chapron C. Prospective evaluation of the learning curve of laparoscopic-assisted vaginal hysterectomy in a university hospital. J Am Assoc Gynecol Laparosc 2004; 11(2):229-235.
32. Leminen A. Comparison between personal learning curves for abdominal and laparoscopic hysterectomy. Acta Obstet Gynecol Scand 2000; 79(12):1100-1104.
33. Schijven MP, Jakimowicz J. The learning curve on the Xitact LS 500 laparoscopy simulator: profiles of performance. Surg Endosc 2004; 18(1):121-127.
34. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Institute of Medicine, National Academy of Sciences, 2000.
35. Biau DJ, Resche-Rigon M, Godiris-Petit G, Nizard RS, Porcher R. Quality control of surgical and interventional procedures: a review of the CUSUM. Qual Saf Health Care 2007; 16(3):203-207.
36. Bolsin S, Colson M. The use of the Cusum technique in the assessment of trainee competence in new procedures. Int J Qual Health Care 2000; 12(5):433-438.
37. Steiner SH, Cook RJ, Farewell VT, Treasure T. Monitoring surgical performance using risk-adjusted cumulative sum charts. Biostatistics 2000; 1(4):441-452.
38. Park IJ, Choi GS, Lim KH, Kang BM, Jun SH. Multidimensional analysis of the learning curve for laparoscopic colorectal surgery: lessons from 1,000 cases of laparoscopic colorectal surgery. Surg Endosc 2009; 23(4):839-846.

Chapter six

Clinical relevance of conversion rate and its evaluation in laparoscopic hysterectomy

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Abstract

Background

Objective of is study is 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.

Materials and Methods

Prospective cohort study in 79 gynecologists representing 42 hospitals throughout the Netherlands. This reflects 75% out of all gynecologists performing LH in the Netherlands (and 68% of the hospitals). Data from 1.534 LHs were collected between 2008 and 2010.

Results

Conversion rate, odds ratios (OR) of risk factors for conversion and conversion as a means of evaluation. Conversions were discriminated as reactive or strategic. The literature reported a conversion rate in LH of 0-19% (mean 3.5%). In our cohort, 70 LHs were converted (4.6%). Using a mixed effects logistic regression model we estimated independent risk factors for conversion. BMI (p=.002), uterus weight (p<.001), type of LH (p=.004) and age (p=.023) had a significant influence on conversion. The risk of conversion was increased at BMI >35 kg/m^2 (OR 6.53, p<.001), age >65 years (OR 6.97, p=.007), uterus weight 200-500 grams (OR 4.05, p<.001) and especially >500 grams (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 odds ratio 2.79, p=.001).

Conclusion

By means of the estimated risk factors (BMI, uterus weight, age and surgical skills), better insight is acquired into the risk of conversion. Conversion rate can be used as a means of evaluation to ensure better outcomes of LH for future patients.

Introduction

In order to spare women the customary and inevitable abdominal incision, laparoscopic hysterectomy (LH) was adopted twenty 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 period.[2] Yet, if laparoscopy fails, the surgeon apparently always has the possibility to 'escape' by conversion to the conventional abdominal approach. Therefore, most gynecologists are at the opinion that conversion is inherent to laparoscopy and should not be regarded as an adverse event.[3-5]

In former 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 one could imagine, conversion, that involves a combined exposure to the general risk of the laparoscopic approach followed by an additional laparotomy, is associated with significantly worse post-operative outcomes.[7,8] Additionally, also the indication for conversion matters. Several studies within the field of laparoscopic colorectal surgery showed that a conversion due to an intra-operative adverse event ('reactive', e.g. due to a lesion of the ureter) is associated with higher post-operative morbidity than a conversion in order to prevent an adverse event in case of operative difficulties ('preemptive' or 'strategic', e.g. due to 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 proficient visibility of the operating field. Furthermore, additional pathology (e.g. a more advanced stage of cancer than expected) might dictate immediate conversion to the conventional approach. Finally, patient risk factors, such as (morbid) obesity, might impede the laparoscopic approach; e.g. the anesthesiologist is challenged to such an extent that conversion is required for patient safety reasons.

Interestingly, especially this subdivision into strategic and reactive conversions can provide information on indication, patient selection and the experience and skill of the surgeon. Therefore, we hypothesize that the conversion rate may act as a means of evaluation of the 'quality' of a series of performed LHs.

Since the past decade quality assurance of the surgical process is under increasing attention. [11] With the ultimate goal to improve the 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 are at the opinion that the importance of quality assurance in minimally invasive gynecology is currently underestimated. Given the fact that in the near future an increasing number of LHs will be performed due to the wider implementation of this surgical technique, the absolute number of conversions is likely to rise over time. To stay ahead of these developments and to answer the increasing demands of Health Inspectorates, professionals and patients, it is essential to acquire better insight into conversion rate as a means of evaluation in LH.

The aim of this study was threefold. Firstly, based on prospectively obtained data, we estimated the influence of patient, procedure and performer characteristics on conversion in LH. Secondly, while no systematic data on conversion rates is available at present, we performed a systematic search of the literature to provide a basis for evaluation. Thirdly, 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

In order 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 (RCTs) published after the year 2000, written in English and with an available abstract. We excluded all publications concerning robotic (assisted) hysterectomy, single incision and/or radical hysterectomy for oncological indications. We also excluded studies that did not report the actual percentage of procedures converted to laparotomy. In cases where the indication for conversion was clearly mentioned, we calculated the proportion 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 LHs were enrolled and registered for a period of one year every LH that he/she performed as a primary surgeon. Out off all gynecologists performing LH in the Netherlands, this reflects 75% (and 68% of the hospitals (N=42)). Potential risk factors for conversion were identified and consisted of patient, procedure, and performer characteristics. Besides the age of the patient and the indication for LH, these characteristics included body mass index (BMI, kg/m^2), prior abdominal surgery (including Caesarean sections), and ASA classification. Procedure characteristics included the type of LH performed [i.e. laparoscopic assisted vaginal hysterectomy (LAVH), supracervical laparoscopic hysterectomy (SLH) or total laparoscopic hysterectomy (TLH)], the accompanying salpingo-oophorectomy and uterus weight (in grams, weighed in the operating room). Performer characteristics included the actual number of LHs performed, including the procedure to be registered. To be sure that all LHs performed were submitted, we double-checked 10% of the cases with the actual operating room statistics of each clinic. Parts of the collected data with regard to patient and surgeon factors as predictors for blood loss, operative time and adverse events have been published elsewhere.[14]

Adverse events were registered for type, severity (i.e. requiring re-intervention or not) and moment of onset, according to the definitions and regulations as determined by the Guideline 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 pathology) were distinguished from forced conversions to laparotomy due to an adverse event (reactive conversion). Additional information on the indication for conversion was to be reported in the comment section.

The procedure, patient and performer characteristics of this cohort were analyzed using SPSS 17.0 statistical software (Chicago, IL, USA) and p-values <.05 were considered to be statistically significant. The normality distribution of continuous and ordinal variables was tested using the Kolmogorov-Smirnov test. To describe non-normally distributed data the median and interquartile range (25^{th} and 75^{th} percentile, IQR) was used. For the clinical relevance of the outcomes, we stratified a number of continuous variables: BMI (<25, 25-35 and >35 kg/m^2), age (<45, 45-65, >65 years) and uterus weight (<200, 200-500, >500 grams). As a reference category for categorical variables, we chose the most relevant category, preferably with the highest number of cases. We used a mixed effects logistic regression model to calculate the 'adjusted' log odds ratio (OR) and the 95%-confidence intervals (95% CI) of each risk factor for conversion using R-2 10.0 statistical software (Vienna, Austria) 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 either had to show a significant association in the univariable analysis or otherwise had to be marked as clinically important by the researchers.

The influence of surgical experience (number of LHs performed) was estimated in two ways. Firstly, we estimated whether the risk of conversion is influenced by surgical experience, on a continuous scale per 10 consecutively performed procedures. Secondly, we estimated whether a dichotomous cut-off of >30 procedures influences the risk of conversion, since this value is generally accepted as the individual learning curve.[17,18]

We had to take into account the fact that we observed multiple procedures for each surgeon.[19] Two procedures performed by the same surgeon tend to be "more similar" than two procedures performed by two 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 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 standard deviation 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, in the end, the surgeon is 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' (SSF). Using this approach, the calculated SSF can be used as an OR, describing the a priori difference in the risk of conversion between two randomly selected surgeons.

Results

From the literature search, we found a conversion rate in LH of 0-19% (Table 1).[20-52] We found 33 relevant studies, describing a total of 7827 procedures, of which 264 were converted to laparotomy (3.5%). We calculated that 73% of conversions could be regarded as strategic, in those studies that provided information on the reason for conversion.

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

A total of 70 LHs (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 2). The main 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 mainly due to visibility or mobility problems as a result of altered anatomy (e.g. adhesions, myomata) (70.8%), a too large uterus to be removed in one piece in case of malignancy (and therefore contra-indicated for morcellation) (14.6%) and anesthesiological problems due to morbid obesity (BMI>40 kg/m^2)(10.4%).

In the course of the one-year study period, 42 gynecologists reported no conversions, while 46.8% of the performers had to convert to laparotomy at least once; their individual conversion rate ranged from 1.3% to 33.3%. Experience of more than 30 LHs did not correlate with the risk of conversion (p=.734). Moreover, also the distribution between strategic and reactive conversions was not correlated with experience of more than 30 LHs (p=.168).

Overall patient and procedure characteristics are shown in Table 3. The independent risk factors for conversion were BMI (p=.002), age (p=.023), uterus weight (p<.001) and type of LH (p=.004) (Table 4). Relative to the reference category of these risk factors, significant categories were BMI >35 kg/m^2 (OR 6.53, p<.001), age >65 years (OR 6.97, p=.007), uterus weight between 200-500 gram (OR 4.05, p<.001) and uterus weight >500 grams (OR 30.90, p<.001). Compared to TLH, performing SLH significantly decreased the risk of conversion (OR .32, p=.02). History of prior abdominal surgery, ASA classification, accompanying salpingo-oophorectomy and indication for LH were not associated with conversion. Furthermore, surgical experience – both measured per 10 procedures on a continuous scale (OR 0.95, p=.090) and with a cut-off of >30 procedures (OR 0.60, p=.253 (the latter not shown in Table 4)) – was also not significantly associated with conversion. Although our model corrected for all these (measurable) covariates, it repeatedly calculated an influence of the 'variation not explained by the covariates' (the standard deviation of the random contributions) on the risk of conversion. Some immeasurable 'environmental' factors, consisting of factors related to the surgeon, the OR team or organizational factors, were accountable for this effect and were therefore referred to as the 'Surgical Skills Factor' (SSF). The standard deviation

Table 1 Reported conversion rates in laparoscopic hysterectomy

Author (year)	Type of LH	Design	n	Converted	Conversion rate	Strategic conversion
Brummer *et al.*(2009)	Mixed	Prospective cohort	1686	87	5,2%	76%
Candiani *et al.*(2009)	TLH	Prospective cohort	30	0	0,0%	-
Chang *et al.*(2005)	LAVH	Prospective cohort	225	2	0,9%	0%
Chen *et al.*(2008)	LAVH	Prospective cohort	147	1	0,7%	0%
Daraï *et al.*(2001)	LAVH	Randomized Controlled Trial	40	3	7,5%	67%
David-Montfiore *et al.*(2007)	Mixed	Prospective cohort	121	23	19,0%	65%
Donnez *et al.*(2010)	Mixed	Prospective cohort	400	0	0,0%	-
Drahonovsky *et al.*(2010)	Mixed	Randomized Controlled Trial	125	3	2,4%	unknown
Erian *et el.*(2005)	SLH	Prospective cohort	100	0	0,0%	-
Garry *et al.*(2004)	Mixed	Randomized Controlled Trial	920	32	3,5%	72%
Ghezzi *et al.*(2010)	TLH	Randomized Controlled Trial	41	0	0,0%	-
Ghomi *et al.*(2007)	SLH	Prospective cohort	60	1	1,7%	0%
Holub *et al.*(2001)	LAVH	Prospective cohort	271	3	1,1%	33%
Johnston *et al.*(2007)	Mixed	Prospective cohort	364	4	1,1%	75%
Karaman *et al.*(2007)	Mixed	Prospective cohort	1120	26	2,3%	92%
Kluivers *et al.*(2007)	Mixed	Randomized Controlled Trial	27	2	7,4%	100%
Kreiker *et al.*(2004)	LAVH	Prospective cohort	160	5	3,1%	100%
Leung *et al.*(2007)	Mixed	Prospective cohort	143	1	0,7%	100%
Lieng *et al.*(2005)	SLH	Prospective cohort	43	1	2,3%	0%
Long *et al.*(2002)	Mixed	Prospective cohort	104	3	2,9%	unknown
Mourits *et al.*(2010)	TLH	Randomized Controlled Trial	185	20	10,8%	60%
Mueller *et al.*(2011)	TLH	Prospective cohort	567	1	0,2%	100%
Muzii *et al.*(2007)	LAVH	Randomized Controlled Trial	40	2	5,0%	0%
Obermair *et al.*(2012)	TLH	Randomized Controlled Trial	404	24	5,9%	unknown
Ottosen *et al.*(2000)	LAVH	Prospective cohort	40	4	10,0%	75%
Pan *et al.*(2008)	TLH	Prospective cohort	132	9	6,8%	100%
Persson *et al.*(2006)	LAVH	Randomized Controlled Trial	63	3	4,8%	33%
Schütz *et al.*(2002)	LAVH	Prospective cohort	28	0	0,0%	-
Seracchioli *et al.*(2002)	TLH	Randomized Controlled Trial	60	1	1,7%	0%
Sesti *et al.*(2008)	LAVH	Randomized Controlled Trial	50	0	0,0%	-
Shahid *et al.*(2009)	SLH	Prospective cohort	29	0	0,0%	-
Soriano *et al.*(2001)	LAVH	Randomized Controlled Trial	40	3	7,5%	100%
Wang *et al.*(2005)	LAVH	Prospective cohort	62	0	0,0%	-
Total			7827	264	3,5%	73%[a]

[a] weighted average

Table 2 Main reasons for strategic and reactive conversion (*n* = 1.534)

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

Table 3 An overview of the main patient and procedure characteristics and adverse events of the total cohort (*n* = 1.534)

I Patient characteristics	**median**	**IQR[a]**			**min**	**-**	**max**
Age (years)	46.4	41.7	-	51.1	13.0	-	89.3
BMI (kg/m²)	27.5	22.5	-	28.1	17.5	-	56
Parity	2	0	-	2	0	-	5
Uterus weight (grams)	150	97	-	285	14	-	1600
Indication to LH	*n* (%)						
Dysfunctional uterine bloodloss	762 (49.7)						
Uterus myomatosus	420 (27.4)						
(Pre)malignancy endometrium or cervix	236 (15.4)						
Endometriosis	34 (2.2)						
Others (profylactic, gender change)	80 (5.2)						
Previous abdominal surgeries							
No	918 (59.9)						
1	397 (25.9)						
2	143 (9.3)						
> 2	50 (3.3)						

Table 3 Continued from previous page

II Procedure characteristics	**median**	**IQR[a]**			**min**	**-**	**max**
Operative time (min)	110	90	-	135	32	-	344
Converted cases (*n* = 70)	120	100	-	175	34	-	330
Blood loss (mL)	100	50	-	200	0	-	2600
Converted cases (*n* = 70)	500	300	-	950	10	-	2500
Type of LH	*n* (%)						
TLH	957 (62.4)						
LAVH	185 (12.1)						
SLH	391 (25.5)						
BSO performed	362 (23.6)						
III Adverse events	***n* (%)**						
Procedures with ≥ 1 adverse event(s)	116 (7.6)						
Infection	12 (0.8)						
Lesion internal organ	29 (1.9)						
Lesion vessel	8 (0.5)						
Wound dehiscence	15 (1.0)						
Blood loss > 1000mL	43 (2.8)						
Venous thromboembolism	2 (0.1)						
Others	21 (1.4)						
No (re)intervention needed	105 (6.8)						
Intervention needed	25 (1.6)						
Moment of adverse event							
During procedure	67 (4.4)						
On hospital ward	36 (2.3)						
After hospital discharge	27 (1.8)						

All continuous and ordinal variables shown were not normally distributed (Kolmogorov-Smirnov test)

[a] Interquartile range (25^{th} and 75^{th} percentile)

Table 4 Risk factors and adjusted odds ratios[a] for conversion to laparotomy in LH

	n	Conversions (% of total)	aOR	95% CI	P value
Age (years)					.023
<45	528	16 (3.0)	1.0	(reference)	
45-65	689	40 (5.8)	1.39	.68 - 2.83	.366
>65	75	9 (12.0)	6.97	1.72 - 28.27	.007
BMI (kg/m²)					.002
<25	531	13 (2.4)	1.0	(reference)	
25-35	653	36 (5.5)	1.90	.90 - 4.00	.093
>35	108	16 (14.8)	6.53	2.27 - 18.78	<.001
Uterusweight (grams)					<.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
History of prior abdominal surgery					.544
No	773	38 (4.9)	1.0	(reference)	
≥1 procedures	519	27 (5.2)	1.20	.65 - 2.22	
ASA classification					.118
ASA I	903	35 (3.9)	1.0	(reference)	
ASA II	357	24 (6.7)	1.36	.68 - 2.72	
ASA 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)	.32	.12 - .83	.019
LAVH	162	12 (7.4)	2.07	.80 - 5.36	.132
BSO performed					.069
No	1014	52 (5.1)	1.0	(reference)	
Yes	278	13 (4.7)	.39	.13 - 1.16	
Indication					.785
Dysfunctional uterine bleeding	656	28 (4.3)	1.0	(reference)	
Uterus myomatosus	361	23 (6.4)	.83	.39 - 1.75	
(Pre)malignancy (endometrium or cervix)	176	13 (7.4)	1.61	.51 - 5.06	
Endometriosis	31	1 (3.2)	1.01	.09 - 10.83	
Other (e.g. gender change, prophylaxis)	68	0	N/A[b]		

Table 4 Continued from previous page

	n	Conversions (% of total)	aOR	95% CI	P value
Surgical experience (continuous)[c]			.95	.89 - 1.01	.09
Surgical Skills Factor			2.79[d]		.001

The mixed effects logistic regression model was based on 1292 cases, since 242 cases were excluded due to at least one missing parameter.

[a] Relative to the reference category in case of a categorical variable

[b] Could not be calculated, since no conversions occurred. This did not affect the aORs of all other covariates

[c] per 10 consecutive procedures performed

[d] average odds ratio

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. This means that between two 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 due to at least one missing parameter (15.7%). These excluded cases contained 5 converted procedures.

Discussion

Strategic considerations are in the majority of cases (69%) the reason for converting laparoscopic hysterectomy to the conventional abdominal approach. Visibility and/or mobility problems are the main reason for this type of conversion, while uncontrollable bleeding is the main adverse event leading to a reactive conversion. As reported in other studies, BMI and uterus weight are confirmed to be independent risk factors for conversion.[53-55] However, a new effect shown in our study is that this risk increases with a BMI >35 kg/m^2 (approximately 6.5-fold), an age >65 years (approximately 7-fold), a uterus weight between 200-500 grams (approximately 4-fold) and a uterus weight >500 grams (approximately 30-fold). On the other hand, performing SLH, compared to 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 (SSF).

The majority of the LHs (>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 as 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 numbers of conversions and its indication. A subdivision into strategic and reactive conversions will be helpful in daily practice, since a reactive conversion is associated with a higher risk of post-operative adverse events and a prolonged hospital stay.[9,10] Additionally, while strategic conversions potentially are the result of suboptimal pre-operative patient evaluation, an insufficiently trained surgeon and operating team might cause either a strategic or a reactive conversion. In the end, such a registration can be used as an additional means of evaluation of LH, in which pre-eminently the rate of strategic conversions can provide information about patient selection, indication and the surgical skills of the gynecologist and the operating team.

Furthermore, each clinic should evaluate the ratio of vaginal hysterectomies (VH), abdominal hysterectomies (AH) and LHs performed over the years. Ideally, on hypothetical grounds the rate of VH has to remain steady, while an optimum rate of LH should be reached, with subsequent low numbers of primary AHs.[25,57-63] In order to accomplish this we have to assure 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 subdivision. Imaginably, surgeons could fear such a measurement and therefore might refrain from the laparoscopic approach in some cases. However, this will deprive patients from 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, a proper registration can be both a means of evaluation as well as a helpful tool for each surgeon. As a consequence, opportunities are provided that eventually might be able to reduce both the conversion rate in LH and the rate of abdominal hysterectomy as a whole.

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

On the other hand, we repeatedly found that the risk of conversion is substantially influenced (OR 2.79, p=.001) by the presence of an intrinsic factor that - independently of experience - represents surgical skills and the functionality of the operating team. Although this assessment might be somewhat precarious, others also stated that, as a predictor for surgical outcome, surgical skills seem to play a more important role than surgical experience alone and therefore it 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, rather than the conventional focus on outcome measurements.[67,68] If we compare testing proficiency in surgery to driving a car, we can state the following metaphor. Not only the fact that the driver has acquired its driver's license (i.e. a completed learning curve) and how many times he or she has driven a car before determine the outcome of the drive, 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 SSF influencing the risk of conversion.

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

Some claim that conversion rate is more related to the shape of the uterus rather than its weight (e.g. myomata).[55] Although we think that the shape certainly may influence the outcome, our analysis showed a very 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 on this matter showed an increasing conversion rate in elder patients.[70] Furthermore, the significant influence of age >65 years can be explained by a relatively high conversion rate associated with (pre)malignant indications within this subgroup (12.3%, not shown). Although apparently this combination has an increased risk of (strategic) conversion, it is important to note that still the vast majority of this subgroup can benefit from the advantages of the laparoscopic approach. Moreover, since (pre)malignant indication shows a trend towards a higher risk of conversion, this partly explains why performing SLH seems to be associated with a significantly lower risk of conversion. Furthermore, on theoretical grounds, the lack of colpotomy in SLH, often regarded a difficult surgical step, facilitates lower conversion rates. However, SLH should not be performed at the expense of a proper indication.

From our findings we suggest when counseling the laparoscopic approach 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 this patient. However, if past performances are reassuring, also challenging patients should 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 we identified in our literature review. This is probably due to the fact that our cohort represents a country as a whole, reflecting daily practice instead of the specific experience of a single surgeon or center. A drawback of this study is the influence of a possible selection bias because all gynecologists worked by their individual criteria whether to perform the hysterectomy laparoscopically instead of abdominally or vaginally. However, this reflects the actual clinical situation in which all gynecologists try to use proper indication criteria to the extent of his/her surgical experience and skills. Furthermore, as shown in Table 3, patient characteristics in our cohort are comparable to other large studies.[20,29] 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, the registration of a diagnostic laparoscopy followed by an 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.

Conclusion

In conclusion, since this study presents data collected from many centers, rather than a single (experienced) centre, the results could be interpreted as applying nationwide. We therefore suggest that, supported by our literature review, a conversion rate of <5% can act as a reference for future comparison. If a hospital exceeds this percentage, they should conduct an audit of their converted LHs. The questions to be asked would include: did intra-operative 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 allows better identification of conversions that could be avoided. Furthermore, the balance between strategic (70%) and reactive conversion (30%) 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 the evaluation of LH. In this way, additional insight in the indications for conversion can be acquired, allowing further improvement of the outcomes in LH and preventing future patients from unnecessary conversions.

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References

1. Reich H, Decaprio J, McGlynn F. Laparoscopic hysterectomy. *J Gynaecol Surg*. 1989; 5:213-6.
2. Nieboer TE, Johnson N, Lethaby A et al. Surgical approach to hysterectomy for benign gynaecological disease. *Cochrane Database Syst Rev*. 2009;CD003677.
3. Atkinson SW. Results of eVALuate study of hysterectomy techniques: conversion to open surgery should not be regarded as major complication. *BMJ*. 2004; 328:642.
4. Visco AG, Barber MD, Myers ER. Early physician experience with laparoscopically assisted vaginal hysterectomy and rates of surgical complications and conversion to laparotomy. *Am J Obstet Gynecol*. 2002; 187:1008-12.
5. Chapron C, Querleu D, Bruhat MA et al. Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases. *Hum Reprod*. 1998; 13:867-72.
6. Hunter RW, McCartney AJ. Can laparoscopic assisted hysterectomy safely replace abdominal hysterectomy? *Br J Obstet Gynaecol*. 1993; 100:932-4.
7. Chew MH, Ng KH, Fook-Chong MC et al. Redefining conversion in laparoscopic colectomy and its influence on outcomes: analysis of 418 cases from a single institution. *World J Surg*. 2011; 35:178-85.
8. Gervaz P, Pikarsky A, Utech M et al. Converted laparoscopic colorectal surgery. *Surg Endosc*. 2001; 15:827-32.
9. Yang C, Wexner SD, Safar B et al. Conversion in laparoscopic surgery: does intraoperative complication influence outcome? *Surg Endosc*. 2009; 23:2454-8.
10. Dindo D, Schafer M, Muller MK et al. Laparoscopy for small bowel obstruction: the reason for conversion matters. *Surg Endosc*. 2010;792-7.
11. Landheer ML, Therasse P, van de Velde CJ. The importance of quality assurance in surgical oncology. *Eur J Surg Oncol*. 2002; 28:571-602.
12. Peeters KC, van de Velde CJ. Surgical quality assurance in breast, gastric and rectal cancer. *J Surg Oncol*. 2003; 84:107-12.
13. Verleye L, Vergote I, Reed N et al. Quality assurance for radical hysterectomy for cervical cancer: the view of the European Organization for Research and Treatment of Cancer--Gynecological Cancer Group (EORTC-GCG). *Ann Oncol*. 2009; 20:1631-8.
14. Twijnstra AR, Blikkendaal MD, van Zwet EW et al. Predictors of Successful Surgical Outcome in Laparoscopic Hysterectomy. *Obstet Gynecol*. 2012; 119:700-8.
15. Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. *Qual Saf Health Care*. 2010; 19:132-7.
16. Bates D, Maechler M, Bolker B. lme4: Linear mixed-effects models using S4 classes. R package version 0.999375-35. 2011.
17. Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. *Obstet Gynecol*. 2004; 104:308-13.
18. Makinen J, Johansson J, Tomas C et al. Morbidity of 10 110 hysterectomies by type of approach. *Hum Reprod*. 2001; 16:1473-8.
19. Urbach DR, Austin PC. Conventional models overestimate the statistical significance of volume-outcome associations, compared with multilevel models. *J Clin Epidemiol*. 2005; 58:391-400.
20. Brummer TH, Jalkanen J, Fraser J et al. FINHYST 2006--national prospective 1-year survey of 5,279 hysterectomies. *Hum Reprod*. 2009; 24:2515-22.
21. Candiani M, Izzo S, Bulfoni A et al. Laparoscopic vs vaginal hysterectomy for benign pathology. *Am J Obstet Gynecol*. 2009; 200:368-7.
22. Chang WC, Torng PL, Huang SC et al. Laparoscopic-assisted vaginal hysterectomy with uterine artery ligation through retrograde umbilical ligament tracking. *J Minim Invasive Gynecol*. 2005; 12:336-42.
23. Chen SY, Chang DY, Sheu BC et al. Laparoscopic-assisted vaginal hysterectomy with in situ morcellation for large uteri. *J Minim Invasive Gynecol*. 2008; 15:559-65.
24. Darai E, Soriano D, Kimata P et al. Vaginal hysterectomy for enlarged uteri, with or without laparoscopic assistance: randomized study. *Obstet Gynecol*. 2001; 97:712-6.
25. David-Montefiore E, Rouzier R, Chapron C et al. Surgical routes and complications of hysterectomy for benign disorders: a prospective observational study in French university hospitals. *Hum Reprod*. 2007; 22:260-5.
26. Donnez O, Donnez J. A series of 400 laparoscopic hysterectomies for benign disease: a single centre, single surgeon prospective study of complications confirming previous retrospective study. *BJOG*. 2010; 117:752-5.
27. Drahonovsky J, Haakova L, Otcenasek M et al. A prospective randomized comparison of vaginal hysterectomy, laparoscopically assisted vaginal hysterectomy, and total laparoscopic hysterectomy in women with benign uterine disease. *Eur J Obstet Gynecol Reprod Biol*. 2010; 148:172-6.
28. Erian J, El-Toukhy T, Chandakas S et al. One hundred cases of laparoscopic subtotal hysterectomy using the PK and Lap Loop systems. *J Minim Invasive Gynecol*. 2005; 12:365-9.

29. Garry R, Fountain J, Brown J et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. *Health Technol Assess*. 2004; 8:1-154.
30. Ghezzi F, Uccella S, Cromi A et al. Postoperative pain after laparoscopic and vaginal hysterectomy for benign gynecologic disease: a randomized trial. *Am J Obstet Gynecol*. 2010; 203:118.
31. Ghomi A, Littman P, Prasad A et al. Assessing the learning curve for laparoscopic supracervical hysterectomy. *JSLS*. 2007; 11:190-4.
32. Holub Z, Jabor A, Kliment L et al. Laparoscopic hysterectomy in obese women: a clinical prospective study. *Eur J Obstet Gynecol Reprod Biol*. 2001; 98:77-82.
33. Johnston K, Rosen D, Cario G et al. Major complications arising from 1265 operative laparoscopic cases: a prospective review from a single center. *J Minim Invasive Gynecol*. 2007; 14:339-44.
34. Karaman Y, Bingol B, Gunenc Z. Prevention of complications in laparoscopic hysterectomy: experience with 1120 cases performed by a single surgeon. *J Minim Invasive Gynecol*. 2007; 14:78-84.
35. Kluivers KB, Hendriks JC, Mol BW et al. Quality of life and surgical outcome after total laparoscopic hysterectomy versus total abdominal hysterectomy for benign disease: a randomized, controlled trial. *J Minim Invasive Gynecol*. 2007; 14:145-52.
36. Kreiker GL, Bertoldi A, Larcher JS et al. Prospective evaluation of the learning curve of laparoscopic-assisted vaginal hysterectomy in a university hospital. *J Am Assoc Gynecol Laparosc*. 2004; 11:229-35.
37. Leung SW, Chan CS, Lo SF et al. Comparison of the different types of "laparoscopic total hysterectomy". *J Minim Invasive Gynecol*. 2007; 14:91-6.
38. Lieng M, Istre O, Langebrekke A et al. Outpatient laparoscopic supracervical hysterectomy with assistance of the lap loop. *J Minim Invasive Gynecol*. 2005; 12:290-4.
39. Long CY, Fang JH, Chen WC et al. Comparison of total laparoscopic hysterectomy and laparoscopically assisted vaginal hysterectomy. *Gynecol Obstet Invest*. 2002; 53:214-9.
40. Mourits MJ, Bijen CB, Arts HJ et al. Safety of laparoscopy versus laparotomy in early-stage endometrial cancer: a randomised trial. *Lancet Oncol*. 2010; 11:763-71.
41. Mueller A, Boosz A, Koch M et al. The Hohl instrument for optimizing total laparoscopic hysterectomy: results of more than 500 procedures in a university training center. *Arch Gynecol Obstet*. 2011.
42. Muzii L, Basile S, Zupi E et al. Laparoscopic-assisted vaginal hysterectomy versus minilaparotomy hysterectomy: a prospective, randomized, multicenter study. *J Minim Invasive Gynecol*. 2007; 14:610-5.
43. Obermair A, Janda M, Baker J et al. Improved surgical safety after laparoscopic compared to open surgery for apparent early stage endometrial cancer: Results from a randomised controlled trial. *Eur J Cancer*. 2012; 48:1147-53.
44. Ottosen C, Lingman G, Ottosen L. Three methods for hysterectomy: a randomised, prospective study of short term outcome. *BJOG*. 2000; 107:1380-5.
45. Pan HS, Ko ML, Huang LW et al. Total laparoscopic hysterectomy (TLH) versus coagulation of uterine arteries (CUA) at their origin plus total laparoscopic hysterectomy (TLH) for the management of myoma and adenomyosis. *Minim Invasive Ther Allied Technol*. 2008; 17:318-22.
46. Persson P, Wijma K, Hammar M et al. Psychological wellbeing after laparoscopic and abdominal hysterectomy--a randomised controlled multicentre study. *BJOG*. 2006; 113:1023-30.
47. Schutz K, Possover M, Merker A et al. Prospective randomized comparison of laparoscopic-assisted vaginal hysterectomy (LAVH) with abdominal hysterectomy (AH) for the treatment of the uterus weighing >200 g. *Surg Endosc*. 2002; 16:121-5.
48. Seracchioli R, Venturoli S, Vianello F et al. Total laparoscopic hysterectomy compared with abdominal hysterectomy in the presence of a large uterus. *J Am Assoc Gynecol Laparosc*. 2002; 9:333-8.
49. Sesti F, Calonzi F, Ruggeri V et al. A comparison of vaginal, laparoscopic-assisted vaginal, and minilaparotomy hysterectomies for enlarged myomatous uteri. *Int J Gynaecol Obstet*. 2008; 103:227-31.
50. Shahid A, Sankaran S, Odejinmi F. Laparoscopic subtotal hysterectomy for large uteri using modified five port technique. *Arch Gynecol Obstet*. 2011; 283:79-81.
51. Soriano D, Goldstein A, Lecuru F et al. Recovery from vaginal hysterectomy compared with laparoscopy-assisted vaginal hysterectomy: a prospective, randomized, multicenter study. *Acta Obstet Gynecol Scand*. 2001; 80:337-41.
52. Wang CJ, Yuen LT, Yen CF et al. Comparison of the efficacy of the pulsed bipolar system and conventional bipolar electrosurgery in laparoscopically assisted vaginal hysterectomy. *J Laparoendosc Adv Surg Tech A*. 2005; 15:361-4.
53. Sokol AI, Chuang K, Milad MP. Risk factors for conversion to laparotomy during gynecologic laparoscopy. *J Am Assoc Gynecol Laparosc*. 2003; 10:469-73.
54. Kondo W, Bourdel N, Marengo F et al. Surgical outcomes of laparoscopic hysterectomy for enlarged uteri. *J Minim Invasive Gynecol*. 2011; 18:310-3.

55. Leonard F, Chopin N, Borghese B et al. Total laparoscopic hysterectomy: preoperative risk factors for conversion to laparotomy. *J Minim Invasive Gynecol*. 2005; 12:312-7.
56. Lengyel BI, Azagury D, Varban O et al. Laparoscopic cholecystectomy after a quarter century: why do we still convert? *Surg Endosc*. 2012; 26:508-13.
57. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. *Hum Reprod*. 2008; 23:840-5.
58. Twijnstra AR, Kolkman W, Trimbos-Kemper GC et al. Implementation of advanced laparoscopic surgery in gynecology: national overview of trends. *J Minim Invasive Gynecol*. 2010; 17:487-92.
59. van der Wat J. When will laparoscopy totally replace laparotomy? *J Minim Invasive Gynecol*. 2012; 19:236-7.
60. Kluivers KB, Opmeer BC, Geomini PM et al. Women's preference for laparoscopic or abdominal hysterectomy. *Gynecol Surg*. 2009; 6:223-8.
61. Nieboer TE, Hendriks JC, Bongers MY et al. Quality of life after laparoscopic and abdominal hysterectomy: a randomized controlled trial. *Obstet Gynecol*. 2012; 119:85-91.
62. Kluivers KB, Johnson NP, Chien P et al. Comparison of laparoscopic and abdominal hysterectomy in terms of quality of life: a systematic review. *Eur J Obstet Gynecol Reprod Biol*. 2008; 136:3-8.
63. Bijen CB, Vermeulen KM, Mourits MJ et al. Costs and effects of abdominal versus laparoscopic hysterectomy: systematic review of controlled trials. *PLoS One*. 2009; 4:e7340.
64. Heinberg EM, Crawford BL, III, Weitzen SH et al. Total laparoscopic hysterectomy in obese versus nonobese patients. *Obstet Gynecol*. 2004; 103:674-80.
65. Twijnstra AR, Blikkendaal MD, Kolkman W et al. Implementation of Laparoscopic Hysterectomy: Maintenance of Skills after a Mentorship Program. *Gynecol Obstet Invest*. 2010; 70:173-8.
66. Sarker SK, Kumar I, Delaney C. Assessing operative performance in advanced laparoscopic colorectal surgery. *World J Surg*. 2010; 34:1594-603.
67. Leake PA, Urbach DR. Measuring processes of care in general surgery: assessment of technical and nontechnical skills. *Surg Innov*. 2010; 17:332-9.
68. Fink AS, Itani KM, Campbell DC, Jr. Assessing the quality of surgical care. *Surg Clin North Am*. 2007; 87:837-52, vi.
69. Bijen CB, de Bock GH, Vermeulen KM et al. Laparoscopic hysterectomy is preferred over laparotomy in early endometrial cancer patients, however not cost effective in the very obese. *Eur J Cancer*. 2011.
70. Stang A, Merrill RM, Kuss O. Nationwide rates of conversion from laparoscopic or vaginal hysterectomy to open abdominal hysterectomy in Germany. *Eur J Epidemiol*. 2011.

Chapter seven

Nociceptive and stress hormonal state during abdominal, laparoscopic and vaginal hysterectomy as predictors of postoperative pain perception

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Abstract

Background

Primary objective is to compare pain perception during and after surgery between abdominal hysterectomy (AH), laparoscopic hysterectomy (LH), and vaginal hysterectomy (VH). Secondary objective of this study is to investigate whether pain indicators during surgery predict pain perception and demand for analgesics postoperatively.

Methods

Prospective observational analysis of intraoperative nociceptive state (by means of pulse transit time; PTT), heart rate (HR) and stress hormone levels (adrenalin and noradrenalin) were correlated with postoperative pain scores and stress hormone levels and demand for postoperative analgesics such as morphine.

Results

Intraoperative PTT levels and perioperative and postoperative stress hormone levels did not differ significantly between AH, LH and VH. During the first hours postoperatively, LH patients showed non-significant lower pain scores, compared to AH and VH. One day postoperatively, LH patients reported significantly lower pain scores. High intraoperative stress hormone levels predicted a significant higher demand for morphine postoperatively, accompanied with significant higher pain scores.

Conclusions

No differences were found, with respect to intraoperative pain indicators well as pain perception during the first hours after surgery between AH, LH and VH. If VH is not applicable, LH proves to be advantageous over AH with respect to a faster decline in pain scores.

Introduction

Almost without exception, surgery is associated with postoperative pain. Also in hysterectomy, women experience postoperative pain to some degree, despite adequate general and or locoregional anesthesia.[1]

Among other superior characteristics, vaginal hysterectomy (VH) is particularly known for its short period of postoperative pain and quick recovery, and also therefore considered the *gold standard* in hysterectomy.[2] Over the recent years, some studies stated that LH is preferred over VH with respect to lower postoperative pain scores. However, these studies are underpowered.[3-5] When VH is not applicable, laparoscopic hysterectomy (LH) shows several advantages over abdominal hysterectomy (AH). Firstly, it is generally known that, compared to the abdominal approach, LH is characterized by less intraoperative blood loss, shorter duration of hospital stay, speedier return to normal activities and fewer wound or abdominal wall infections. [2;6-8;8] Secondly, relatively elevated IL-6 and CRP serum levels found in AH, suggests that this approach is associated with inclined tissue damage, compared to LH.[9-13] Thirdly, patients claim to prefer LH over AH, probably because of the aforementioned findings, combined with esthetical considerations.[14] Lastly, LH patients report to become pain free in a significantly shorter period of time, compared to women operated by laparotomy. [1;2;8;15]

Surprisingly, a recent study observed that laparoscopic surgery is associated with higher pain scores in the first hours postoperatively.[16] Others described higher nociceptive pain scores during laparoscopic procedures, compared to conventional open surgery.[17] These findings are in contrast with the rationale that minimally invasive surgery (MIS), with accompanying less tissue damage, would result in declined perceived pain. Hypothetically, the observed higher pain perception when applying the laparoscopic approach could be the result of peritoneal absorption of insufflated carbon dioxide in laparoscopy, which can cause referred shoulder pain. Another explanation to the reported higher pain scores could be due to a suboptimal analgesic regimen, because anesthesiologists assume MIS to be minimally painful as well. Consequently, because of applying thrifty amounts of analgesics patients could experience more physical stress during and after laparoscopic surgery. However, previous research indicated that MIS is connected with lower intraoperative stress hormone levels.[18;19]

In conclusion, recent research found conventional surgery not superior to MIS with respect to pain perception during surgery and during the first hours postoperatively. These findings cannot be satisfactorily explained yet.

Objective of this study is to compare pain perception during and after surgery between LH, AH and VH, and whether pain indicators during surgery (nociceptive state, stress hormones) predict pain perception as well as demand for analgesics (e.g. morphine) postoperatively.

Materials and Methods

Each consecutive patient scheduled for either AH, LH or VH at our department was requested to participate in the study. Informed consent was required as several blood samples were to be collected and participation of the patient was needed, with respect to completing the questionnaires and assessing pain intensities postoperatively. Exclusion criteria included disturbances of the central nervous system or psychiatric diseases, chemical substance abuse, chronic use of analgesics, chronic pain, cardiovascular, hepatic or renal insufficiency, pregnancy, extended accompanying prolapse or oncologic surgery, and age less than 18 years. In addition, supracervical hysterectomies were excluded from the study as well. The protocol was approved by the local Human Ethics Committee (protocol number P08.100).

After inclusion, plasma catecholamine concentrations (CAMI; norepinephrine and epinephrine levels in nmol/L) were measured at our outpatient department in order to obtain baseline levels. Three more CAMI samples were obtained during surgery (i.e. instantly after intubation, after ligation of the second uterine artery and after closing the vaginal cuff) and two more samples four and eight hours postoperatively, respectively. Each obtained sample consisted of 4 ml venous blood in an EDTA-fuse, instantly stored in a minus 20 degrees Celsius environment and analyzed according to protocol within 60 minutes.

Each patient was asked to assess her pain level using a Visual Analogue Scale meter (VAS, ranging from zero for no pain at all to ten for intolerable pain) preoperatively (before pre-medication had been administered) and four, eight and 24 hours postoperatively, provided she self-rated herself awake (>4 VAS).

In order to correct for catastrophation of pain (exaggerated or extreme negative conception of pain) each patient was provided with a concise validated questionnaire, which was to be filled out on the day prior to surgery.[20;21] This base line questionnaire aimed to assess actual pain experience, possible fear of the upcoming surgery as well as expectations about pain during the first hours after surgery.

A validated mode to assess nociceptive state in patients was by means of measuring the pulse transit time (PTT). Pulse Transit Time was defined as the interval from the ECG R-wave to the upstroke of the waveform of the pulse oximeter of the same cardiac cycle. Elevation in PTT levels were associated with a low nociceptive stress response, while lowering of PTT indicated elevation in nociceptive stress state.

Pain perception during surgery was measured by continuously assessing nociceptive state as well as by determining stress hormonal levels (i.e. catecholamines, also known as 'fight or flight' stress hormones). Perceived pain were assessed during the first 24 hours postoperatively.

During surgery, continuous 3-lead ECG and infrared pulse oximeter waveforms were obtained from a Cardiocap II and a Capnomac Ultima device (Datex, Helsinki, Finland). These signals were linked to a custom made analogue computer (Marc Geerts, Leiden University Medical Center, The Netherlands), which calculated the PTT for each heart beat. The pulse oximeter was attached to the index fingertip of the left arm. PTT and heart rate (HR) values were measured continuously. General anesthesia was induced according to the following guideline: remifentanil at 10 µg.kg-1.h-1, followed by an induction dose of propofol (2 mg/kg) and atracurium (0.5 mg/kg). The trachea of all patients was subsequently intubated (tube sizes 8-9) and propofol was continued at an infusion rate of 6 – 10 µg.kg-1.h-1. Since this was an observational study, the attending anesthesiologist was allowed to change the drug doses and infusion rates according to his or her own discretion. His or her decisions were based on the routine parameters used to guide anesthesia (heart rate, blood pressure, patient movement, sudomotor responses).

If patients received general anesthesia combined with epidural anesthesia, epidural anesthesia was continued up to the second day after surgery. Postoperatively, every patient was provided with patient controlled analgesia (PCA, an electronically controlled infusion pump, delivering a prescribed amount of intravenous analgesic when activating the button). The amount of peri- and postoperatively provided analgesics were recorded.

Provided patients undergoing LH experienced more pain during surgery and during the first eight hours postoperatively, compared to AH, we aimed to assess a 30% mean difference (alpha = 0.05) in PTT during surgery, with SD 0.2. Based on results from former research with PTT comparing laparoscopy with laparotomy, 15 patients in each group were needed to achieve a power of 0.90. The VH group primarily acted as a control group, as no adequate comparable research on pain perception in vaginal surgery was available.

Data was analyzed using SPSS 17.0 statistical software (Chicago, IL, USA). Variables were tested for normal distribution using the Kolmogorov Smirnov test. If variables lacked a normal distribution, Spearman's rank correlation coefficients where calculated. Differences between groups, were assessed with the Chi-square test for proportions and, if normally distributed, Student Indepent Samples *t*-test for continuous variables. One-way analysis of variance (ANOVA) was used to assess differences between the three groups. 95%-confidence intervals (95% CI) and standard deviations (SD) were calculated, *P*-values < 0.05 were considered statistically significant.

Results

Patient characteristics were comparable between groups, with respect to indication, age, BMI, ASA classification and preoperative pain perception (*Table 1*). Perioperative blood loss and amounts of anesthetics administered did not differ between groups, while length of surgery was significantly higher in LH and uterus weight was significantly higher in AH. Patients receiving

Table 1 Study group characteristics

	Total (n = 45)	95%-CI	P value	AH (n = 15)	LH (n = 15)	VH (n = 15)
Age (years)	48.2	45.9 to 50.4	.129	51.4 (8.5)	46.6 (5.6)	46.7 (7.2)
BMI (kg/m²)	26.9	25.1 to 28.7	.165	28.3 (7.1)	24.5 (4.6)	27.8 (4.7)
Preoperative pain score (VAS)	0.9	0.41 to 1.35	.964	0.9 (1.4)	0.9 (1.8)	0.8 (1.5)
ASA I (%)	55.6		.181	73.3	53.3	40.0
General anesthesia and epidural (%)	40.4		.027	53.3	53.3	6.7
Length of surgery (min)	107	95 to 120	.005	99 (37)	134 (45)	89 (31)
Blood loss (mL)	196	132 to 260	.308	231 (246)	126 (151)	231 (230)
Uterus weight (g)	291	203 to 380	.017	447 (447)	280 (136)	147 (82)
BIS (mean values)	39.9	37.3 to 42.5	.213	40.1 (4.5)	37.8 (4.9)	43.3 (8.3)
Atracurium dose (mg)	46.8	40.6 to 53.1	.084	55.7 (25.6)	42.5 (14.0)	40.5 (8.0)
Remifentanil dose (microg/kg/hr)	12.1	9.2 to 15.1	.736	5.4 (3.1)	7.4 (4.2)	4.7 (3.9)
Propofol dose (mg/kg/hr)	5.9	4.6 to 7.2	.187	5.4 (3.1)	7.4 (5.3)	4.7 (4.4)

AH = abdominal hysterectomy, LH = laparoscopic hysterectomy, VH = vaginal hysterectomy. Values between brackets are standard deviations. Differences between groups were calculated using One-way ANOVA for continuous variables and Chi-square for proportions.

general anesthesia combined with epidural analgesics were equally distributed in LH and AH. However, VH significantly more often received general anesthesia exclusively.

During the first 90 minutes of surgery, PTT and HR levels did not differ significantly between AH, LH and VH (*Figure 1*). Perioperative and postoperative stress hormone levels did not differ significantly between groups (*Table 2*). However, subgroup analysis in patients receiving general anesthesia exclusively showed significant lower Noradrenalin levels in LH patients during the first hours after surgery, compared to AH.

Analysis of the preoperatively completed questionnaire yielded no differences with respect to actual pain experience, fear of having surgery and expectations about pain during the first hours after surgery. Preoperative pain scores were comparable between groups (*Figure 2*). During the first hours after surgery, LH patients showed non-significant lower pain scores, compared to AH and VH (VAS_{delta} -1.57 (-3.41 to 0.29) and VAS_{delta} -1.66 (-3.54 to 0.23) respectively). About half of the

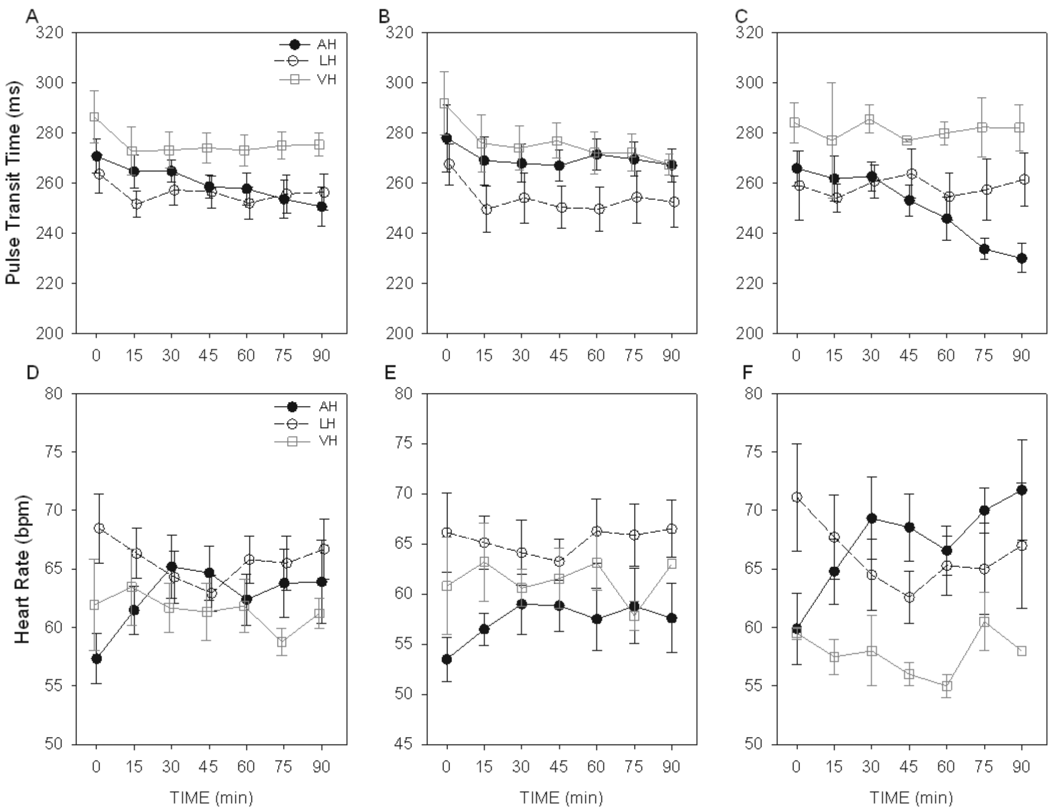

Figure 1 Intraoperative PTT and HR levels in total (A and D), in general anesthesia (B and E) and general and epidural anesthesia combined (C and F). PTT = Pulse Transit Time (ms), HR = heart rate (bpm), AH = abdominal hysterectomy, LH = laparoscopic hysterectomy, VH = vaginal hysterectomy. Differences between groups were calculated using One-way ANOVA for continuous variables. Error bars represent Standard Errors of the Means.

Table 2 Mean catecholamine (CAMI) levels during and after surgery.

		Total (n = 45)	95% CI	P value	AH (n = 15)	LH (n = 15)	VH (n = 15)
Total	Noradrenalin during surgery (nmol/L)	1.66	1.26 to 2.07	.658	1.53 (0.88)	1.52 (1.00)	1.92 (1.95)
	Noradrenalin after surgery (nmol/L)	1.05	0.82 to 1.28	.517	1.10 (0.75)	0.86 (0.27)	1.17 (0.28)
	Adrenalin during surgery (nmol/L)	0.18	0.09 to 0.27	.413	0.12 (0.16)	0.16 (0.30)	0.26 (0.42)
	Adrenalin after surgery (nmol/L)	0.08	0.06 to 0.09	.286	0.07 (0.03)	0.07 (0.05)	0.10 (0.09)
					AH (n = 6)	LH (n = 7)	
No epidural	Noradrenalin during surgery (nmol/L)	1.75	1.16 to 2.34	.392	2.01 (1.09)	1.53 (0.87)	
	Noradrenalin after surgery (nmol/L)	1.11	0.67 to 1.56	.013	1.62 (0.82)	0.67 (0.20)	
	Adrenalin during surgery (nmol/L)	0.27	0.07 to 0.46	.636	0.22 (0.21)	0.31 (0.40)	
	Adrenalin after surgery (nmol/L)	0.09	0.06 to 0.12	.355	0.07 (0.03)	0.10 (0.06)	
					AH (n = 9)	LH (n = 8)	
With epidural	Noradrenalin during surgery (nmol/L)	1.36	0.90 to 1.82	.527	1.22 (0.58)	1.51 (1.17)	
	Noradrenalin after surgery (nmol/L)	0.89	0.68 to 1.10	.186	0.76 (0.49)	1.03 (0.21)	
	Adrenalin during surgery (nmol/L)	0.04	0.02 to 0.06	.355	0.05 (0.04)	0.03 (0.04)	
	Adrenalin after surgery (nmol/L)	0.06	0.04 to 0.07	.690	0.06 (0.02)	0.05 (0.04)	

AH = abdominal hysterectomy, LH = laparoscopic hysterectomy, VH = vaginal hysterectomy. Values between brackets are standard deviations. Differences between groups were calculated using One-way ANOVA for continuous variables, Independent Samples T-tests were applied to calculate differences between two subgroups.

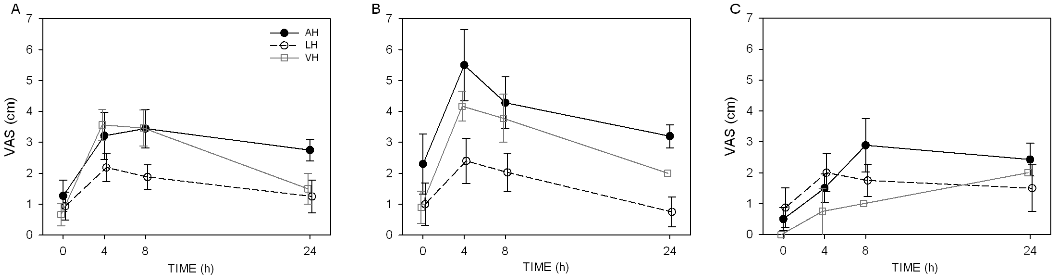

Figure 2 Baseline and postoperative pain scores in AH, LH and VH in total (A), after general anesthesia (B) and general and epidural anesthesia combined (C). Preoperative pain scores were comparable between groups. During the first hours after surgery, LH patients showed non-significant lower pain scores, compared to AH and VH (VAS_{delta} -1.57 (-3.41 to 0.29) and VAS_{delta} -1.66 (-3.54 to 0.23) respectively). In general, patients with postoperative epidural analgesics showed significantly lower pain scores in the first four hours postoperatively, compared to patients without epidural analgesics (VAS_{delta} -2.17 (-3.32 to -1.02)). However, subgroup analysis of LH patients yielded no difference in pain scores between LH patients with postoperative epidural analgesics compared to LH patients without epidural analgesics (VAS_{delta} -0.40 (-1,66 to 2,44)). One day postoperatively, LH patients reported significantly lower pain scores, compared to AH patients (VAS_{delta} -1.50 (-3.06 to -0.01)) AH: abdominal hysterectomy, LH: laparoscopic hysterectomy, VH: vaginal hysterectomy. Differences between groups were calculated using One-way ANOVA for continuous variables. *: significant differences (P <.05). Error bars represent Standard Errors of the Means.

Table 3 Correlations between intraoperative and postoperative stress indicators.

	r_s	***P*-value**
PTT and mean postoperative pain VAS	0.04	.776
PTT and postoperative analgesics use	0.29	.27
PTT and intraoperative Propofol dose	0.44	.038
HR and mean postoperative pain VAS	-0.21	.162
HR and call for postoperative analgesics use	0.13	.62
Intraoperative NOR and postoperative NOR	0.37	.005
Intraoperative ADR and postoperative ADR	0.42	.001
Intraoperative NOR and postoperative pain VAS	0.30	.046
Intraoperative ADR and postoperative pain VAS	0.37	.012
Postoperative pain VAS and postoperative analgesics use	0.72	.029

AH = abdominal hysterectomy, LH = laparoscopic hysterectomy, VH = vaginal hysterectomy, PTT = Pulse Transit Time, VAS = Visual Analogue Scale, HR = Heart rate, NOR = Noradrenalin, ADR = Adrenalin. As parameters lacked a Normal distribution, The Spearman's rank correlation coefficient (rs) was applied to provide a measure of association between principal stress indicators.

AH and LH patients opted for general anesthesia combined with regional (epidural) anesthesia. In general, patients with postoperative epidural analgesics showed significantly lower pain scores in the first four hours postoperatively, compared to patients without epidural analgesics (VAS_{delta} -2.17 (-3.32 to -1.02)). However, subgroup analysis of LH patients yielded no difference in pain scores between LH patients with postoperative epidural analgesics compared to LH patients without epidural analgesics (VAS_{delta} -0.40 (-1,66 to 2,44)). One day postoperatively, LH patients reported significantly lower pain scores, compared to AH patients (VAS_{delta} -1.50 (-3.06 to -0.01)). Observed differences in the general anesthesia group mainly contributed to this finding.

High intraoperative CAMI levels predicted a significant higher demand for morphine postoperatively, accompanied with significant higher pain scores (*Table 3*). Low mean PTT and high HR levels did not predict a higher demand for postoperative analgesics or pain scores. However, high PTT levels were associated with elevated intraoperative Propofol use.

Discussion

Pain perception during the first hours after surgery and intraoperative pain indicators are comparable between abdominal, laparoscopic and vaginal hysterectomy. These outcomes suggest that an unambiguous anesthetic protocol for both conventional as well as laparoscopic surgery is justified. Minimally invasive surgery is not associated with a minimum of pain perception. This is in contrast with the previously observed minimal tissue damage in MIS. Therefore, MIS patients should be offered a 'conventional' anesthetic regime. However, addition of epidural analgesics did not significantly lower postoperative pain scores in MIS patients.

On a patient level, we observed that elevated intraoperative noradrenalin levels predicted elevated postoperative pain scores, accompanied with an increased demand for postoperative rescue analgesia. These findings are solely applicable in a research setting and not clinically relevant, as determination of noradrenalin values is time consuming and rather expensive.

The intraoperative PTT values in our study did not show a significant difference between conventional and MIS procedures, which was observed in other research. [17] Perhaps, minor heterogeneity in indication for surgery in that former study was causing selection bias. Hypothetically, homogeneity of the patient sample in our study reproduces PTT levels more accurately.

From a scientific perspective, a randomized controlled trial would provide optimal reliable outcomes indicating which approach in hysterectomy is associated with the lowest pain perception. However, from both practical as well as ethical perspective this design is not feasible anymore, due to two reasons. Firstly, former research provided evidence that VH is superior over AH and LH with respect to many aspects, and consequently patients should be offered the best available option.[2;3] Secondly, with respect to applied amounts of analgesics, no ethical committee would allow a protocol that would not take into account patient specific demand for supplementary analgesics. Therefore, we consider an observational cohort study to be the best available option.

Analysis of intraoperatively administered analgesics yielded no statistically significant differences between groups. Besides, postoperative calls for rescue analgesics were recorded and therefore appropriate for analysis. Furthermore, the observational design of this study facilitates instant applicability in daily practice.

Each previous study on pain perception after hysterectomy mainly focused on the time needed to become pain free.[1-3;8;22] One recent study concentrated on pain scores during the first hours after surgery and found higher scores in laparoscopic procedures, compared to the conventional approach.[16] However, that study did not take into account the intention to treat principle with respect to assessment of pain-VAS scores, consequently overrating conscious 'laparoscopic' patients while excluding uncooperative, drowsy 'abdominal' patients. Also, no correction for amount of administered analgesics was made. In our study, both corrections for consciousness as well as administered analgesics were taken into account.

The few articles, that studied stress hormonal values as an outcome in comparisons between minimally invasive and conventional surgery, found lower values in the minimally invasive group.[18;19] Similar to our study, relatively elevated intraoperative noradrenalin levels were found in the conventional group. The only study researching postoperative hormonal state did determine serum cortisol, a circadian hormone with a long half-life.[18] Our study assessed catecholamines (120 seconds half-life) at specific time points during and after surgery.

VH and LH, both regarded as true exponents of minimally invasive surgery, are often considered to be minimally painful as well. However, with respect to nociceptive and stress hormonal intraoperative pain indicators, no significant lower values in this study were found, compared to the abdominal approach. These outcomes were confirmed with observed comparable pain scores during the first hours after surgery. As intraoperative and postoperative administered analgesics were corrected, these outcomes are likely to be reliable.

Although not a primary outcome of this study, the added value of epidural analgesics to general anesthesia, with respect to postoperative pain perception in LH patients is questionable. Probably traction on tissue during VH and peritoneal wound healing in AH might explain the differences compared with LH. Also others found lower postoperative pain scores in MIS.[3;4] This study states that, although LH is preferred over AH with respect to postoperative pain perception, this minimally invasive approach in hysterectomy remains a major surgical procedure. However, perhaps MIS patients are better served in a fast track system without accompanying epidural analgesics, consequently enhancing a quicker recovery[23].

References

1. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Health Technol Assess 2004; 8(26):1-154.
2. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
3. Ghezzi F, Uccella S, Cromi A, Siesto G, Serati M, Bogani G et al. Postoperative pain after laparoscopic and vaginal hysterectomy for benign gynecologic disease: a randomized trial. Am J Obstet Gynecol 2010; 203(2):118.
4. Candiani M, Izzo S, Bulfoni A, Riparini J, Ronzoni S, Marconi A. Laparoscopic vs vaginal hysterectomy for benign pathology. Am J Obstet Gynecol 2009; 200(4):368-7.
5. Gendy R, Walsh CA, Walsh SR, Karantanis E. Vaginal hysterectomy versus total laparoscopic hysterectomy for benign disease: a metaanalysis of randomized controlled trials. Am J Obstet Gynecol 2011; 204(5):388.
6. Harkki P, Kurki T, Sjoberg J, Tiitinen A. Safety aspects of laparoscopic hysterectomy. Acta Obstet Gynecol Scand 2001; 80(5):383-391.
7. Makinen J, Johansson J, Tomas C, Tomas E, Heinonen PK, Laatikainen T et al. Morbidity of 10 110 hysterectomies by type of approach. Hum Reprod 2001; 16(7):1473-1478.
8. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. J Minim Invasive Gynecol 2006; 13(3):183-189.
9. Malik E, Buchweitz O, Muller-Steinhardt M, Kressin P, Meyhofer-Malik A, Diedrich K. Prospective evaluation of the systemic immune response following abdominal, vaginal, and laparoscopically assisted vaginal hysterectomy. Surg Endosc 2001; 15(5):463-466.
10. Ellstrom M, Bengtsson A, Tylman M, Haeger M, Olsson JH, Hahlin M. Evaluation of tissue trauma after laparoscopic and abdominal hysterectomy: measurements of neutrophil activation and release of interleukin-6, cortisol, and C-reactive protein. J Am Coll Surg 1996; 182(5):423-430.
11. Demir A, Bige O, Saatli B, Solak A, Saygili U, Onvural A. Prospective comparison of tissue trauma after laparoscopic hysterectomy types with retroperitoneal lateral transsection of uterine vessels using ligasure and abdominal hysterectomy. Arch Gynecol Obstet 2007.
12. Ribeiro SC, Ribeiro RM, Santos NC, Pinotti JA. A randomized study of total abdominal, vaginal and laparoscopic hysterectomy. Int J Gynaecol Obstet 2003; 83(1):37-43.
13. Atabekoglu C, Sonmezer M, Gungor M, Aytac R, Ortac F, Unlu C. Tissue trauma in abdominal and laparoscopic-assisted vaginal hysterectomy. J Am Assoc Gynecol Laparosc 2004; 11(4):467-472.
14. Kluivers KB, Opmeer BC, Geomini PM, Bongers MY, Vierhout ME, Bremer GL et al. Women's preference for laparoscopic or abdominal hysterectomy. Gynecol Surg 2009; 6(3):223-228.
15. Perino A, Cucinella G, Venezia R, Castelli A, Cittadini E. Total laparoscopic hysterectomy versus total abdominal hysterectomy: an assessment of the learning curve in a prospective randomized study. Hum Reprod 1999; 14(12):2996-2999.
16. Ekstein P, Szold A, Sagie B, Werbin N, Klausner JM, Weinbroum AA. Laparoscopic surgery may be associated with severe pain and high analgesia requirements in the immediate postoperative period. Ann Surg 2006; 243(1):41-46.
17. Sigtermans MJ, Looijestijn J, Olofsen E, Dahan A. Pulse Transit Time (PTT) measurements during laparoscopic and open abdominal surgery: a pilot study in ASA I-II female patients. The Open Anesthesiology Journal [2], 20-25. 2008.
18. Kataja J, Chrapek W, Kaukinen S, Pimenoff G, Salenius JP. Hormonal stress response and hemodynamic stability in patients undergoing endovascular vs. conventional abdominal aortic aneurysm repair. Scand J Surg 2007; 96(3):236-242.
19. Thompson JP, Boyle JR, Thompson MM, Strupish J, Bell PR, Smith G. Cardiovascular and catecholamine responses during endovascular and conventional abdominal aortic aneurysm repair. Eur J Vasc Endovasc Surg 1999; 17(4):326-333.
20. Peters ML, Sommer M, de Rijke JM, Kessels F, Heineman E, Patijn J et al. Somatic and psychologic predictors of long-term unfavorable outcome after surgical intervention. Ann Surg 2007; 245(3):487-494.
21. Kalkman CJ, Visser K, Moen J, Bonsel GJ, Grobbee DE, Moons KG. Preoperative prediction of severe postoperative pain. Pain 2003; 105(3):415-423.
22. Lieng M, Lomo AB, Qvigstad E. Long-term outcomes following laparoscopic and abdominal supracervical hysterectomies. Obstet Gynecol Int 2010; 2010:989127.
23. Lindsetmo RO, Champagne B, Delaney CP. Laparoscopic rectal resections and fast-track surgery: what can be expected? Am J Surg 2009; 197(3):408-412.

Chapter eight

Implementation of laparoscopic hysterectomy: maintenance of skills after a mentorship program

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Abstract

Objective

To evaluate the implementation and maintenance of advanced laparoscopic skills after a structured mentorship program in laparoscopic hysterectomy (LH).

Methods

Cohort retrospective analysis of 104 successive LHs performed by two gynecologists during and after a mentorship program. LHs were compared for indication, patient characteristics and intraoperative characteristics. As a frame of reference, 94 LHs performed by the mentor were analyzed.

Results

With regard to indication, blood loss and adverse outcomes, both trainees performed LHs during their mentorship program comparable with the LHs performed by the mentor. The difference in mean operating time between trainees and mentor was not clinically significant. Both trainees progressed along a learning curve, while operating time remained statistically constant and comparable to that of the mentor. After completing the mentorship program, both gynecologists maintained their acquired skills as blood loss, adverse outcome rates and operating time were comparable with the results during their traineeship.

Conclusion

A mentorship program is an effective and durable tool for implementing a new surgical procedure in a teaching hospital with respect to patient safety aspects, as indications, operating time and adverse outcome rates are comparable to those of the mentor in his own hospital during and after completing the mentorship program.

Introduction

Hysterectomy is the most frequently performed major gynecological surgical procedure worldwide.[1] The most common indication for hysterectomy is uterine fibroids, followed by dysfunctional uterine bleeding.[1;2] Regarding the procedure, three different approaches can be distinguished: abdominal, vaginal and laparoscopic. Meta-analysis yielded that vaginal hysterectomy is the method of choice.[3] Prerequisites for this approach are a uterus of fairly normal size with sufficient descensus and no additional adnexal pathology to be expected. In 1989, laparoscopic hysterectomy (LH) was introduced as an alternative to abdominal hysterectomy (AH).[4] Compared to the abdominal approach, this procedure showed benefits of lower intraoperative blood loss, a smaller drop in hemoglobin level, shorter duration of hospital stay, speedier return to normal activities, fewer wound or abdominal wall infections, and fewer unspecified infections. However, due to a long learning curve for surgeons and longer operating time, accompanied by reports of possible higher risks of bladder and ureteric injury, the popularity of LH has been hampered.[5-8] Regarding the latter, recent research has revealed a decline in bladder and ureteric injury rates in LH to percentages comparable to AH after completing the learning curve.[9] Despite advantages for the patient and promising developments as stated above, implementation of LH in the Netherlands (among other countries) is proving to be rather slow.[1;10] A plausible cause for this situation is the absence of training in LH [as well as other advanced level (level 3) gynecological laparoscopic procedures, according to the RCOG-classification] during residency.[11;12] Gynecologist trainees, therefore, would be willing to perform LHs after specialization, but hesitate to do so, as they consider themselves as rather untrained.[13]

Other specialties researched and demonstrated that recruitment of an advanced laparoscopic surgeon positively influences the number of procedures and learning curve of the trainee, as well as the resulting increased transfer of skills to its residents.[14;15] To measure the possible effect of a mentorship program in general, a research group studied data before and during implementation of advanced laparoscopic gynecological surgery in a teaching hospital. Its observations showed that a mentorship program facilitated the implementation of advanced laparoscopic surgery, which resulted in an increase in advanced procedures, while no increase in conversion and complication rates were observed.[16] As mentioned above, although LH already has proven to be a valuable addition to the surgical palette of modes in hysterectomy, its implementation remains to be rather slow. This study aims to evaluate the implementation and maintenance of advanced laparoscopic skills after a structured mentorship program in LH in a teaching hospital.

Materials and Methods

In 2001, the obstetrics and gynecology department in a Dutch teaching hospital decided to implement the technique of LH with the use of a structured mentorship program. Two gynecologists with a special interest in gynecological laparoscopy and several years of experience in level 2 laparoscopic procedures were assigned to be trained. As a mentor, an advanced laparoscopic gynecological surgeon from an affiliated university hospital was

hired. LHs (i.e. total laparoscopic hysterectomies) were planned on a biweekly basis. During every procedure the trainee was the primary surgeon. The mentor acted as the assisting surgeon. His position could be compared with the role of a driving instructor: he taught, guided, advised and intervened if necessary. This way the trainee was instantly able to perform the full procedure while patient safety was guarded. The trainees were trained subsequently and on an individual basis. The end of the mentorship program was determined as the moment the trainee as well as the mentor judged the newly acquired technique to be accomplished adequately and safely with minimum transfer of skills from mentor to trainee during the procedure. A series of independently performed procedures by the trainee up to June 2008 were analyzed or evaluating the maintenance of the acquired skills. As a frame of reference, the series of successive procedures during the study period performed by the mentor in his own hospital were analyzed.

Data for this study was collected retrospectively via a prospectively kept database. Patient and intraoperative characteristics (length of surgery, blood loss, uterus weight, length of hospital stay and morcellation), as well as adverse outcomes, were extracted from medical charts. Both hospitals register adverse outcomes as defined by the Dutch Society of Obstetricians and Gynecologists.[17]

Primary outcomes were length of surgery, blood loss and adverse outcomes. In addition, patient characteristics and indication for surgery were recorded in order to assess similarity between groups. A method to construct a learning curve per trainee was adapted from Rogers et al.[18] and was defined as the relation between length of surgery and the successive procedures. This curve was determined during and after the mentorship program to check for maintenance of the acquired skills. The effect of the mentorship program was determined by comparing length of surgery, blood loss and adverse outcome rates of both trainees with the performance of the mentor during and after the mentorship program. During the study period, annual hysterectomy rates for every approach were recorded. Indications for LH were categorized as uterine fibroids, dysfunctional uterine bleeding, endometriosis/abdominal pain and endometrial/cervical (pre) malignancy.[2] Analysis was performed using SPSS 16.0 statistical software (Chicago, Ill., USA). Differences between groups were assessed with the Chi square test for proportions in independent samples and t tests for continuous variables with a normal distribution. Trends for length of surgery were assessed with singular linear regression. R values (correlation coefficients) and 95% CI were calculated; p values < 0.05 were considered statistically significant.

Results

The first trainee performed 25 LHs over a period of 48 months before completion of the traineeship was reached. After completion, she performed 33 procedures in 33 months. The second trainee needed 22 LHs to be performed under supervision over a period of 30 months. After completion, he performed 24 LHs in 20 months. During the integral study period, the mentor performed 94 LHs in his own hospital. Patient characteristics (age: mean 45.9 years, 95% CI 44.5–47.4, SD 8 7.1, range 30.2–64.2; parity: mean 1.7, 95% CI 1.4–1.9, SD 8 1.2, range 0–5; BMI: mean 25.2, 95% CI 24.4–25.9, SD 8 3.9, range 16–37) were comparable between hospitals during and after the mentorship program ($p = 0.059$, 0.278 and 0.077, respectively). Dysfunctional uterine bleeding (45%) and uterine fibroids (35%) were the main indications for surgery in both hospitals. Intraoperative characteristics between both trainees and their mentor were comparable during as well as after the mentorship program (table 1). Although the mean length of surgery for the procedures performed by the second trainee during his mentorship program was longer compared to his mentor, the mean length of surgery between the trainees during the mentorship program was equal ($p = 0.647$). Intraoperative characteristics of the procedures performed by the mentor remain constant during both mentorship programs. Adverse outcome rates [e.g. (bladder) infection, fever, blood loss more than 1 liter, blood transfusion] were comparable during and after completing the mentorship program between mentor and trainees together (19 and 16%, respectively), as well as among the trainees themselves ($p = 0.611$, $p = 0.188$, respectively). Severity of adverse outcomes is also comparable ($p = 0.229$, $p = 0.245$, respectively; table 2). A graphical representation of the learning curves of both trainees during and after completing their mentorship program is shown in figures 1 and 2. For both trainees, singular linear regression demonstrates a constant trend in length of surgery during the mentorship program ($R = 0.184$ and $p = 0.844$, $R = 0.144$ and $p = 0.180$, respectively), as well as a constant trend after completing the mentorship program ($R = 0.235$ and $p = 0.876$, $R = 0.069$ and $p = 0.572$, respectively). The dashed line in the charts represents the mean length of surgery of the mentor. Figure 3 demonstrates the annual trend in hysterectomies (subdivided by approach) in the trainee hospital during the study period. The total annual number of hysterectomies remains constant ($p = 0.398$), whereas the proportion of LHs has an increase which is statistically significant ($p = 0.001$) at the expense of AHs ($p = 0.002$).

Discussion

A mentorship program in LH is an effective and durable tool in order to implement a new surgical technique in a teaching hospital with respect to patient safety. Indications, operating time and adverse outcome rates were comparable to those of the mentor in his own hospital, both during and after completing the mentorship program. By consulting the mentor (regarding the

Table 1 Intraoperative characteristics during and after mentor-traineeship

	I: During mentor-traineeship			II: After mentor-traineeship			III: Reference outcomes					
	1st trainee (n=25)			1st trainee (n=33)			Mentor (n=94)			*P* value		
	Mean	**SD**	**Range**	**Mean**	**SD**	**Range**	**Mean**	**SD**	**Range**	**I vs II**	**I vs III**	**II vs III**
Length of surgery (min)	139	± 55	(60-320)	150	± 49	(70-290)	127	± 32	(60-240)	N.S.	N.S.	.003
Blood loss (mL)	318	± 451	(25-2200)	169	± 199	(25-900)	187	± 260	(25-2000)	N.S.	N.S.	N.S.
Uterus weight (grams)	302,6	± 200	(60-775)	247	± 200	(35-830)	211	± 145	(35-630)	N.S.	.020	N.S.
	2nd trainee (n=22)			2nd trainee (n=24)			Mentor (n=75)					
	Mean	**SD**	**Range**	**Mean**	**SD**	**Range**	**Mean**	**SD**	**Range**	**I vs II**	**I vs III**	**II vs III**
Length of surgery (min)	146	± 37	(75-235)	176	± 58	(85-335)	125	± 31	(60-240)	N.S.	.003	.0001
Blood loss (mL)	142	± 101	(25-400)	246	± 470	(25-2300)	168	± 274	(25-2000)	N.S.	N.S.	N.S.
Uterus weight (grams)	206	± 133	(36-492)	279	± 238	(64-850)	216	± 154	(35-630)	N.S.	N.S.	N.S.

T-test was used for analysis of continuous variables

Table 2 Adverse events during and after mentor-traineeship

	I: During mentor-traineeship		II: After mentor-traineeship		
	AE / total	**%**	**AE / total**	**%**	***P* value**
Trainee-hospital	9/47	19.1	9/57	15.8	N.S.
Mentor-hospital	12/52	23.1	7/42	16.7	N.S.

Chi square test was used for proportions. AE = adverse event.

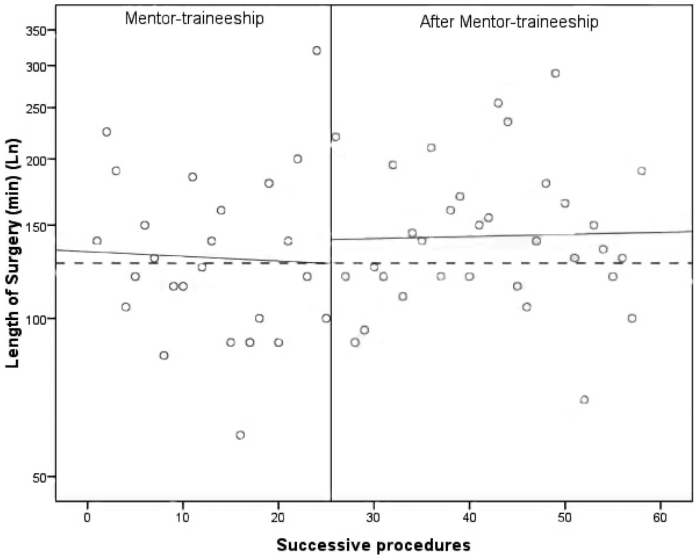

Figure 1 Learning curve of the first trainee during and after accomplishing her mentor-traineeship. The y-axis represents length of surgery (measured on a logarithmic scale), as the x-axis represents the successive procedures during mentor-traineeship. Singular linear regression demonstrates a statistic non-significant decline in length of surgery during mentor-traineeship (P= .844) as well as a constant trend after completing mentor-traineeship (P= .876). The interrupted line represents the mean length of surgery of the mentor.

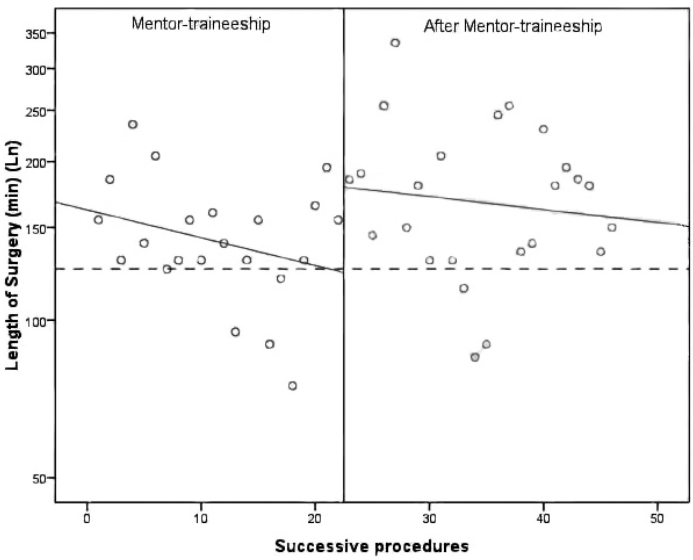

Figure 2 Learning curve of the second trainee during and after accomplishing his mentor-traineeship. The y-axis represents length of surgery (measured on a logarithmic scale), as the x-axis represents the successive procedures during mentor-traineeship. Singular linear regression demonstrates a statistic non-significant decline in length of surgery during mentor-traineeship (P= .180) as well as a constant trend after completing mentor-traineeship (P= .572). The interrupted line represents the mean length of surgery of the mentor.

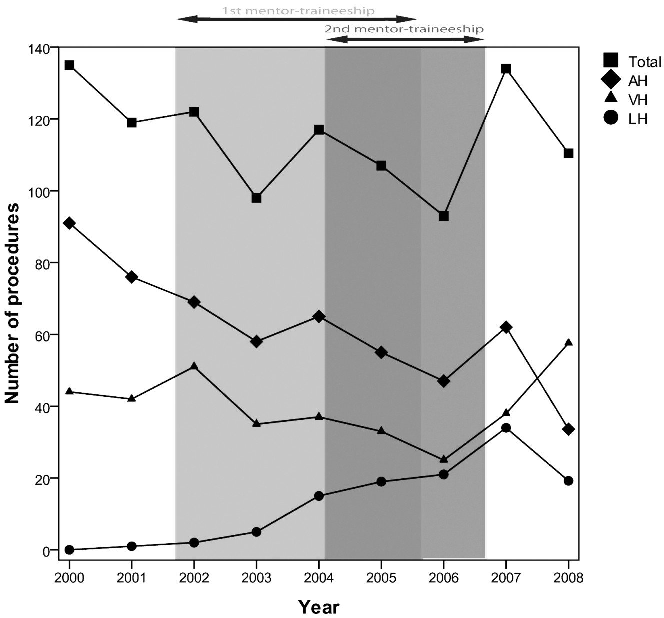

Figure 3 The annual trend in hysterectomies (subdivided by approach) in the trainee hospital during the study period is shown. The total annual number of hysterectomies remains constant (P= .398), whereas the number of LHs increase statistically significant (P= .001), at the expense of AHs (P= .002).

assessment of accurate indications) on a frequent basis, patient characteristics as well as indication proportions were found to be transferable. Studies in the fields of urology and surgery confirm our finding of maintenance of newly acquired laparoscopic skills.[14;15] While length of surgery remained statistically constant, both trainees progressed along a learning curve as the mentor's role was gradually phased out. It is important to be aware of the fact that the mentor dosed the amount of knowledge per session. In this way, trainees could experience tailor-made learning moments, while length of surgery was guarded. Consequently, no redundant lengthy procedure was performed with the accompanying raised risk of adverse outcomes, which is known to be present especially at the beginning of an autodidactic learning process.[9] After completing the mentorship program, both trainees maintained the same tempo as compared with the mentor. Comparable outcomes were also found in another study: procedures performed by residents in a teaching setting can be accomplished with low risk of adverse outcomes and a clinically nonsignificant lengthier procedure.[19] In the presence of the mentor, the trainee was able to become familiar with the new procedure and its instruments, thereby creating a safe environment. Additionally, the mentor had the opportunity to coach the operating room team with respect to adaption to the new set-up. After all, availability and knowledge of material by the entire operating room team is paramount when we aim for safe implementation of minimally invasive surgery.[20]

A prerequisite for a successful mentorship program as introduced in this model is that the trainee consults the mentor on a frequent basis to discuss patients and their possible indication for LH. Consequently, a comparable collection of patients can be selected from the very beginning.

As a major limitation, apart from its expense, we consider this method of mentorship program to be time-consuming. Acceleration of the traineeship could be achieved by raising the caseload via a fellowship or by centering multiple sessions for several trainees in one hospital. Other alternatives such as training in skills labs and plenary training weekends will possibly offer the essential techniques but leave out the 'total package' of performing LHs on personally selected patients in a familiar operating room.

Implementation of new surgical techniques needs time to habituate. This is illustrated by the fact that it took the second trainee almost half of the time necessary to complete his mentorship program, compared with the first trainee (30 vs. 48 months). This initial delay is explained by the need of the trainees as well as their referring colleagues to grow accustomed to the indication for LH. A distinct fall in the number of performed AHs after introducing LH confirms an accurate selection of patients and emphasizes this procedure to be a valuable addition to the surgical palette of modes in hysterectomy.

By gradually applying newly acquired skills in a controlled environment, both trainees succeeded in operating with adverse outcome rates comparable to their mentor.

Our research suggests 22–25 LHs need to be performed under supervision until one has gained sufficient experience to operate independently. Similar numbers are suggested by others.[6;21] However, in order to objectify the endpoint of the mentorship program more accurately, we suggest considering measuring tools like OSATS in future research, though, until now, OSATS is only validated as an 'in vitro' skills assessment tool.[22] A warranted transfer of skills is important where advanced laparoscopic skills need to be obtained after completing basic surgical specialization.[11] The mentorship program, as depicted in this article, proved to be a safe method. When applying this method of transfer, the supplementary advantage of the 'next generation' becoming familiar with the above mentioned procedure should not be underestimated. In this way, assisting residents will already be conversant with the new instruments, the procedure and the correct indication for LH during their specialization. With this in mind, a deliberate choice to use LH techniques might be considered later on. The advantages mentioned above will improve the current slow implementation in concerned countries. Whereas minimal invasive surgery does not answer the old adage 'see one, do one, teach one', our method of mentorship has been proven to be a safe, effective and durable tool for acquiring advanced laparoscopic skills. In this way we will be able to offer more patients the profits of minimally invasive hysterectomy in the very near future.

References

1. Garry R. The future of hysterectomy. BJOG 2005; 112(2):133-139.
2. Reich H. Total laparoscopic hysterectomy: indications, techniques and outcomes. Curr Opin Obstet Gynecol 2007; 19(4):337-344.
3. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
4. Reich H, Decaprio J, McGlynn F. Laparoscopic hysterectomy. J Gynaecol Surg 1989; 5:213-216.
5. Harkki P, Kurki T, Sjoberg J, Tiitinen A. Safety aspects of laparoscopic hysterectomy. Acta Obstet Gynecol Scand 2001; 80(5):383-391.
6. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Health Technol Assess 2004; 8(26):1-154.
7. Makinen J, Johansson J, Tomas C, Tomas E, Heinonen PK, Laatikainen T et al. Morbidity of 10 110 hysterectomies by type of approach. Hum Reprod 2001; 16(7):1473-1478.
8. Sarmini OR, Lefholz K, Froeschke HP. A comparison of laparoscopic supracervical hysterectomy and total abdominal hysterectomy outcomes. J Minim Invasive Gynecol 2005; 12(2):121-124.
9. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.
10. Kolkman W, Trimbos-Kemper TC, Jansen FW. Operative laparoscopy in The Netherlands: Diffusion and acceptance. Eur J Obstet Gynecol Reprod Biol 2007; 130(2):245-248.
11. Kolkman W, Wolterbeek R, Jansen FW. Implementation of advanced laparoscopy into daily gynecologic practice: difficulties and solutions. J Minim Invasive Gynecol 2006; 13(1):4-9.
12. Royal College of Obstetricians and Gynaecologists (RCOG). Classification of Laparoscopic Procedures per Level of Difficulty. 2001.
13. Kolkman W, Wolterbeek R, Jansen FW. Gynecological laparoscopy in residency training program: Dutch perspectives. Surg Endosc 2005; 19(11):1498-1502.
14. Fowler DL, Hogle N. The impact of a full-time director of minimally invasive surgery: clinical practice, education, and research. Surg Endosc 2000; 14(5):444-447.
15. Fabrizio MD, Tuerk I, Schellhammer PF. Laparoscopic radical prostatectomy: decreasing the learning curve using a mentor initiated approach. J Urol 2003; 169(6):2063-2065.
16. Kolkman W, Engels LE, Smeets MJ, Jansen FW. Teach the teachers: an observational study on mentor traineeship in gynecological laparoscopic surgery. Gynecol Obstet Invest 2007; 64(1):1-7.
17. Twijnstra AR, Zeeman GG, Jansen FW. A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study. Qual Saf Health Care 2010; 19(2):132-137.
18. Rogers DA, Elstein AS, Bordage G. Improving continuing medical education for surgical techniques: applying the lessons learned in the first decade of minimal access surgery. Ann Surg 2001; 233(2):159-166.
19. Akingba DH, iseiko-Sanses TV, Melick CF, Ellerkmann RM, Matsuo K. Outcomes of hysterectomies performed by supervised residents vs those performed by attendings alone. Am J Obstet Gynecol 2008; 199(6):673-676.
20. van Det MJ, Meijerink WJ, Hoff C, Totte ER, Pierie JP. Optimal ergonomics for laparoscopic surgery in minimally invasive surgery suites: a review and guidelines. Surg Endosc 2008.
21. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
22. Martin JA, Regehr G, Reznick R, MacRae H, Murnaghan J, Hutchison C et al. Objective structured assessment of technical skill (OSATS) for surgical residents. Br J Surg 1997; 84(2):273-278.

Chapter nine

Intracorporeal knot tying in a box trainer: how proficient is in vitro evaluation in laparoscopic experts?

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Abstract

Background

Motion analysis of intracorporeal knot tying in laparoscopic box trainers can differentiate between novices, intermediates and experts. In search of predictive models for quality of care we researched the applicability of motion-analysis parameters of intracorporeal knot tying in box trainers in experts as predictors for surgical outcome.

Methods

Time, path length and motion in depth of a standardized intracorporeal knot tying task were compared to average risk-adjusted primary clinical outcomes for each participant; the Operative Time Index and Blood Loss Index as obtained from 1.534 laparoscopic hysterectomies.

Results

Although a large variety in proficient knot tying and surgical skills factors was observed; after correction for patient mix in 50 expert surgeons, motion-analysis of intracorporeal knot tying could not significantly discriminate surgical outcome skills in advanced laparoscopic surgery.

Conclusion

Levels of proficiency in advanced laparoscopic surgery cannot be appropriately discriminated by motion analysis in box trainers. Therefore, box trainer assessments do not adequately distinguish proficient from suboptimal clinical performance.

Introduction

Laparoscopy is characterized by unique operative skills.[1] Especially, lack of a directly visible three dimensional operating field, limited tactile feedback and the 'fulcrum' effect due to the long shafted instruments used, are challenging surgeon's skills. As a result, it became clear that obtaining laparoscopic skills needed attention.[2] Initial laparoscopic training should be practiced outside the operating theatre and therefore basic skills needed to be acquired in laparoscopic box trainers and/or Virtual Reality (VR) simulators.[3]

Nowadays, in several countries sufficient basic skills training in laparoscopy is mandatory before residents are allowed to enter the minimally invasive OR.[5] Numerous laparoscopic tasks in box trainers and VR trainers are validated for residents.[6;7]

Within these tasks the Intracorporeal Knot Tying (IKT) task is considered one of the most difficult basic maneuvers and comprises all skills characteristic for laparoscopy.[8] Moreover, all basic laparoscopic skills are incorporated in this task, i.e. ambidexterity, judging depths, handling materials, manipulating instruments, and the need to apply fluent movements.[9] Additionally, being proficient in suturing, including IKT, is a prerequisite to perform advanced laparoscopic surgical procedures.[1] Suturing skills are needed if a complication occurs (e.g. a bleeding, a lesion in the urinary tract or the intestine), or in case of a dysfunction of conventional suturing devices.

In former research we validated this task in the TrEndo, with addition of economy of movement to time, consequently adding the potential to refine acquisition of skills of residents.[4] All residents showed a rapid improvement of proficiency until achieving expert level performance.

Nevertheless, should the "experts" meet certain preconditions at regular time intervals? Unlike residents, laparoscopic surgeons who already perform advanced laparoscopic procedures lack validated box trainer tasks in order to measure their skills.[10] Additionally, until now, no 'gold standard' of surgical competency against which the validity of a skills task can be judged, is available.[11] With recent calls for continuous quality assessments in (minimally invasive) healthcare, a validated task for testing experienced surgeons' skills outside the operating theatre is wanted.[12] Since residents have to proof their psychomotor skills in a skills lab prior to commencement of endoscopic surgery on the OR, both government/insurance companies and patients now demand a reliable quality and proficiency control for experts. [IGZ rapport 2007]

From former research we learned that with time, path length and motion in depth analysis we are able to discriminate between groups with different levels of experience during an IKT task in a physical box trainer.[13] This indicates the construct validity of these objective assessment parameters for psychomotor skills for IKT. With respect to the group of experts, no significant improvement over three attempts was measured; confirming the expert status of this group.

The aim of this study is to quantify and qualify correlations between IKT-skills in the box trainer and proficiency in advanced laparoscopic surgery. Does swift and efficient IKT predict surgical skills of an expert in advanced laparoscopic surgery?

Materials and methods

In order to define good surgical outcomes, a one-year consecutive series of performed advanced laparoscopic procedures (in this case laparoscopic hysterectomies; LHs) was registered. Risk adjustment for several patient and procedure characteristics was executed.

Every gynecologist participating in this one-year prospective observational study on laparoscopic hysterectomy (LH) outcomes was requested to perform an IKT task in the TrEndo box trainer. The department of Biomechanical Engineering from the Technical University of Delft developed this tracking system, in order to provide reliable motion analysis in laparoscopic box trainers.[4]

Historically, gynecologists performing laparoscopic hysterectomies (i.e. advanced level laparoscopies) are considered to be experts in this field. Prior to the IKT task, a videotaped example of the procedure was displayed and an animated instruction was provided. In this way, every participant was informed about the IKT technique to be applied. This technique, also known as the 'C-method', consisted of a series of knots, starting with a double loop around the needle holder of the dominant hand, followed by a single loop around the contra lateral needle holder, followed by a final single loop around the needle holder of the dominant hand. Every knot was judged for firmness and stability. Starting position of the needle was at the tip of the needle holder of the dominant hand. Both needle holders were set up on standardized marked starting points. The knotting area was indicated by a vertical line on the artificial soft tissue pad, exactly in the middle front of both needle holders. Applied suture material was a 3-0 polyglactine thread of 7.5 cm, with a taper point ¾ needle.[13]

The movements of the laparoscopic instruments were recorded with the TrEndo tracking device in four degrees of freedom (DOF): an up-down translation (1^{st} DOF), a forward-backward translation (2^{nd} DOF), and a left-right (3^{rd} DOF) ration around the incision point, and the rotation of the instruments around its longitudinal axis (4^{th} DOF).[4] The three recorded motion-analysis parameters were time (s), defined as the total time taken to perform the task, and the following three motion analysis parameters; path length (mm), defined as the average path length of the right and the left instrument tip during the task; motion in depth (mm) defined as the average of the distance travelled by right and left instrument along its axis.

Each participant was explained that swiftness and efficiency of IKT would be studied and the best attempt out of two was included for analysis.

From previous prospective clinical research, we learned that patient factors (i.e. uterus weight, body mass index, ASA status, numbers of previous abdominal procedures) as well as type of laparoscopic hysterectomy predicted surgical outcome with respect to blood loss, operative time and adverse events.[14] After correction for these multiple covariates in a mixed-effects logistic regression model, this model showed an independent surgical skills factor. This factor largely varied between individuals.

Based on the provided surgical outcomes over the study period, for each participant an Operative Time Index and Blood Loss Index were constructed. An Index of 0 indicated moderate skills, an SSF of + 4 indicated superb skills, and an SSF of -4 indicated (relatively) very poor skills.

The Operative Time Index and Blood Loss Index of each participant were plotted with the three IKT motion-analysis results of the best attempt. Data were analyzed using SPSS 17.0 statistical software (Chicago, IL, USA).

Results

Fifty gynecologists volunteered for tying an intracorporeal knot in the TrEndo box trainer. Additionally, of each participant we already obtained an Operative Time Index and Blood Loss Index, as described in the Materials and Methods section. Surgeon's characteristics are shown in Table 1. Less than half of participants applied IKT in daily practice (38.5%). The remaining group applied extracorporeal knot tying, barbed wire suturing and/or used a knot pusher.

Experience (expressed in numbers of laparoscopic hysterectomies performed) could not be predicted with knotting time, path length and motion in depth in the box trainer (Figure 1).

Participants in the left upper quadrant (A) of Figure 1 showed both suboptimal performance on the box trainer as well as less than average experience, while participants in the upper right quadrant (B) also showed suboptimal performance on the box trainer, however with more than average experience. Participants in the lower left quadrant (C) showed proficient performance on the box trainer with less than average experience and participants in the lower right quadrant were both beyond average proficient on the box trainer as well as more than average experienced with LH.

Figure 2 shows the distribution of performance in the box trainer, compared to risk adjusted clinical performance, by means of the Operative Time Index and Blood Loss Index. A wide dispersion of outcomes over the previously described four quadrants is seen. A filled circle depicts extreme outliers in performance on the box trainer. Also without taking these outliers into account, an almost even distribution between the four quadrants can be observed.

Table 1 Surgeon's characteristics (n = 50)

	Median	Interquartile range
Baseline characteristics		
Experience with LH (years)	6.0	3 – 10
Total numbers of performed LHs	37.5	16 – 75
Volume during study period (LHs/year)	14	10 – 24
Unadjusted operative characteristics		
Blood loss (mL)	181	122 – 235
Operative time (min)	118	100 – 135
Motion analysis characteristics		
Knotting time (s)	133	104 – 177
Path length (mm)	3060	2410 – 4420
Motion in depth (mm)	1380	1060 – 2080

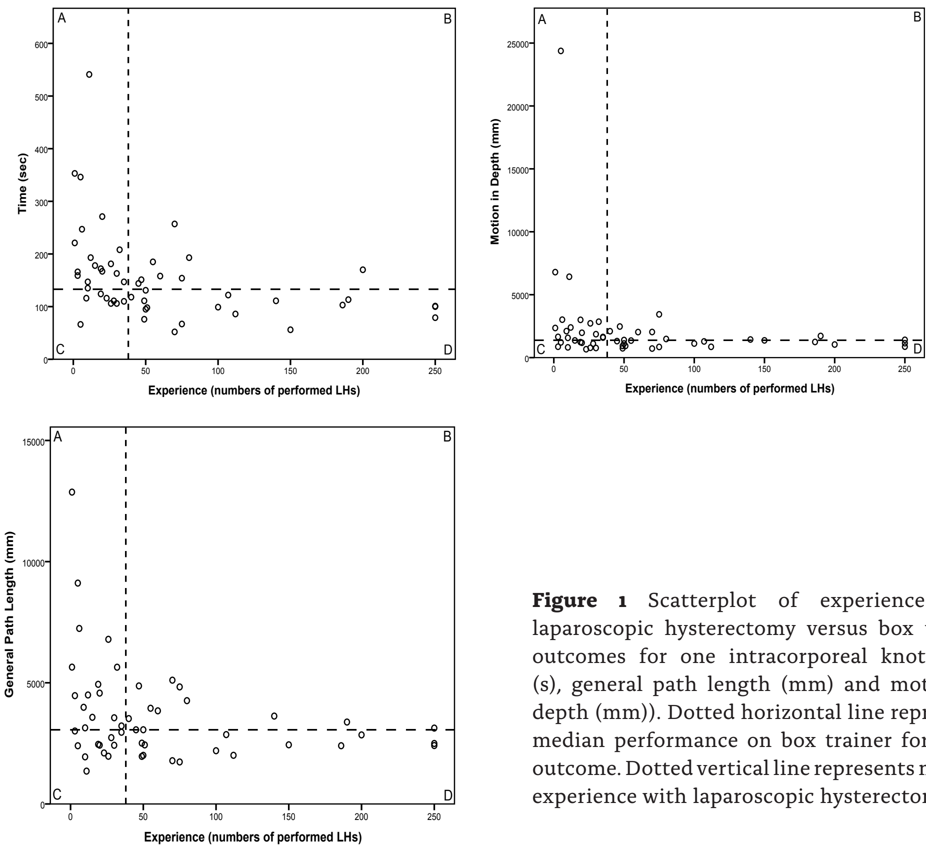

Figure 1 Scatterplot of experience with laparoscopic hysterectomy versus box trainer outcomes for one intracorporeal knot (time (s), general path length (mm) and motion in depth (mm)). Dotted horizontal line represents median performance on box trainer for given outcome. Dotted vertical line represents median experience with laparoscopic hysterectomy.

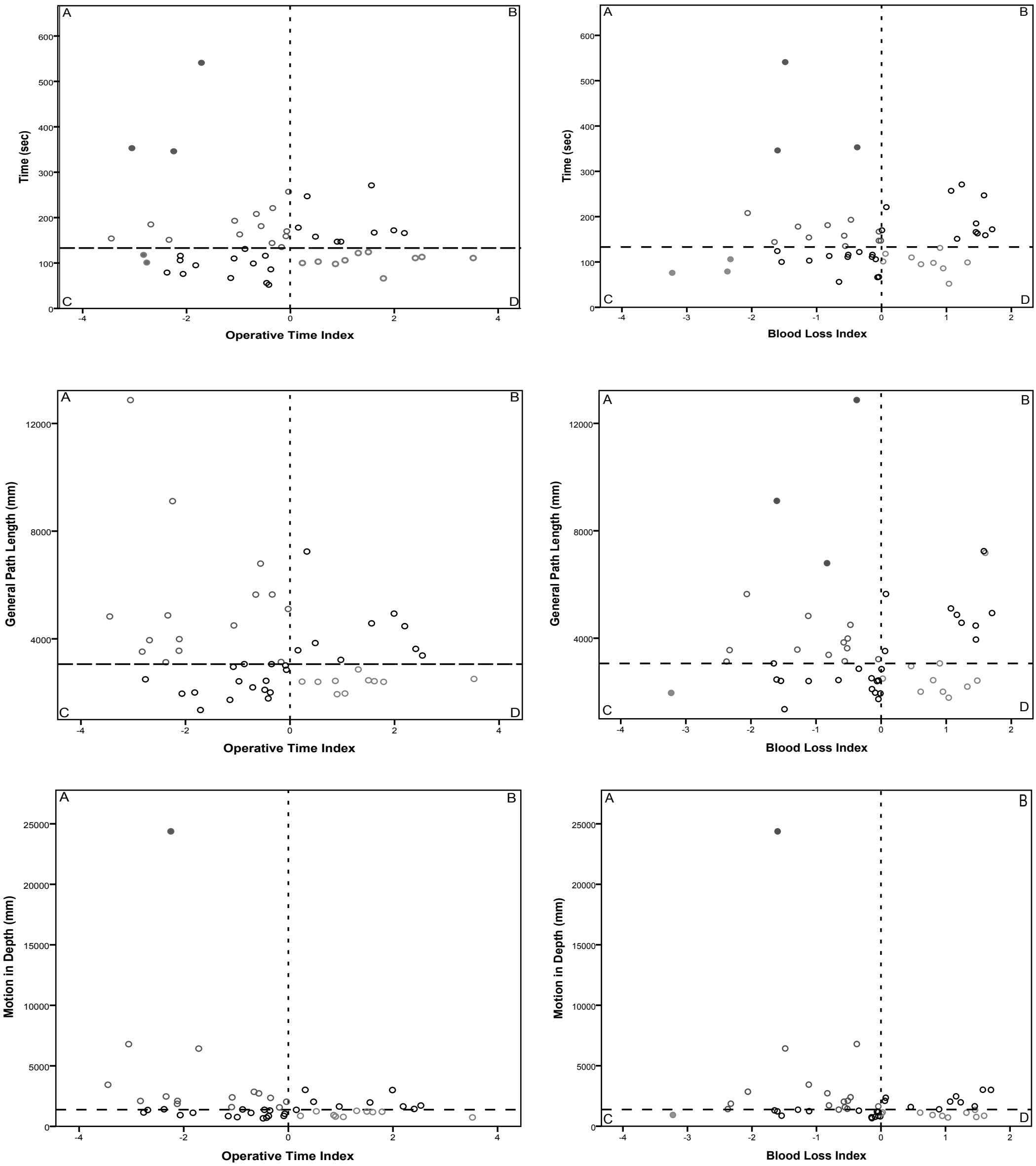

Figure 2 Left column: Operative Time Index versus box trainer outcomes (time (s), general path length (mm) and motion in depth (mm), respectively. Right column: Blood Loss Index versus box trainer outcomes (time (s), general path length (mm) and motion in depth (mm), respectively. Dotted horizontal line represents median performance on box trainer for given outcome. Dotted vertical line represents average clinical performance index. Positive indices represent superior clinical performance; negative indices represent inferior clinical performance. Outcomes of extreme outliers are depicted by filled dots. Quadrant A represents both suboptimal clinical as well as box trainer performance.

Discussion

Surgical outcome in the operating room does not sufficiently correlate with motion-analysis of intracorporeal knot tying in a box trainer. Surgical experience and surgical volume positively influences IKT skills in the box trainer in some subjects, however no predictive value can be derived from these outcomes. Furthermore, with respect to proficiency in the operating room (by means of Operative Time Index and Blood Loss Index) of laparoscopic experts, no predictive value with respect to the studied surgical outcomes can be derived from performance on the box trainer. Only a minority of participants showed relatively poor results in the box trainer with respect to time, path length and motion in depth, combined with suboptimal Operative Time Index and Blood Loss Index.

Based on our results we would like to state a number of possible explanations. Firstly, during acquiring the first competencies in (laparoscopic) surgical skills, monitoring of VR or box trainer results provides useful information regarding the proficiency-gaining curve and discriminates skillful novices from less competent residents. However, after reaching the nebulous-termed and ill-defined 'expert level', surgeons tend not to show significant improvement over multiple attempts on a box trainer.[13] Secondly, we imply that in experts, single task observations in box trainers lack the complexity of 'real' advanced laparoscopic surgery and therefore fail to mimic results from these complex procedures. Perhaps, with the evolution of VR trainers, comprising of realistic full procedure tasks including augmented and force feedback, a more predictive outcome measurement tool will become available. Until then, a more pragmatic approach should be applied.

Unfortunately, proficiency in advanced laparoscopy cannot be predicted with an in vitro evaluation tool such as the box trainer, because the same proportion of 'clumsy' knot tiers happen to operate as swift and bloodless as their handy counterparts. Furthermore, a good score on the box trainer will not guarantee swift and bloodless surgery. Therefore, the proposed task is not reliable and therefore not applicable by means of evaluation of clinical proficiency. Also in this light, perhaps a more 'real-time' monitoring tool should be considered.

It is conceivable that the outliers we depicted in Figure 2 (filled red dots) should reconsider their initial (knot tying) skills, however, the same number of participants with swift and efficient knot tying performance did show comparable suboptimal clinical performance (filled orange dots) by means of a negative Operative Time Index and Blood Loss Index.

This study reflects performance of an unique large group of gynecologists with a wide diversity on the OR as well as in the box trainer. As a result, we consider the outcomes representative for an even larger cohort of surgeons that perform advanced level laparoscopic surgery. In this light, we should reconsider the limited additive value of testing basic laparoscopic skills in experts, and search for alternative monitoring tools.

At this point we suggest that a continuous risk adjusted and comparative monitoring of advanced laparoscopic tasks can assist in signal derailing surgical competence. Examples with cumulative summation analysis can be found in the field of minimally invasive obstetrics and laparoscopic colorectal surgery.[15;16] In conclusion, the novice and intermediate are well served in using box trainers with motion analysis. This provides them with usable tools in order to optimize their proficiency gaining curve prior to performing minimally invasive surgery on patients. Once surgeons have achieved this level of competence, they face advanced level 'tasks' in real patients, of which each requires a multidimensional approach. Exclusively dexterity with basic box trainer tasks will not guarantee good surgical outcome. Definition of the 'real' expert requires a yet to be revealed palette of skills, indication strategies and patient outcome measures.

References

1. Aggarwal R, Moorthy K, Darzi A. Laparoscopic skills training and assessment. Br J Surg 2004; 91(12):1549-1558.
2. Dankelman J, Chmarra MK, Verdaasdonk EG, Stassen LP, Grimbergen CA. Fundamental aspects of learning minimally invasive surgical skills. Minim Invasive Ther Allied Technol 2005; 14(4):247-256.
3. Hiemstra E, Kolkman W, van de Put MA, Jansen FW. Retention of basic laparoscopic skills after a structured training program. Gynecol Surg 2009; 6(3):229-235.
4. Chmarra MK, Bakker NH, Grimbergen CA, Dankelman J. TrEndo, a device for tracking minimally invasive surgical instruments in training setups. Sensors and Actuators A-Physical 2006; 126(2):328-334.
5. Vassiliou MC, Dunkin BJ, Marks JM, Fried GM. FLS and FES: comprehensive models of training and assessment. Surg Clin North Am 2010; 90(3):535-558.
6. Kolkman W, van de Put MAJ, Jansen FW. Laparoscopic simulator: construct validity and establishing performance standards for residency training. Gynecol Surg 2008;(5):109-114.
7. Schreuder HW, van den Berg CB, Hazebroek EJ, Verheijen RH, Schijven MP. Laparoscopic skills training using inexpensive box trainers: which exercises to choose when constructing a validated training course. BJOG 2011; 118(13):1576-1584.
8. Schaafsma BE, Hiemstra E, Dankelman J, Jansen FW. Feedback in laparoscopic skills acquisition: an observational study during a basic skills training course. Gynecol Surg 2009; 6(4):339-343.
9. Rosser JC, Rosser LE, Savalgi RS. Skill acquisition and assessment for laparoscopic surgery. Arch Surg 1997; 132(2):200-204.
10. Chmarra MK, Klein S, de Winter JC, Jansen FW, Dankelman J. Objective classification of residents based on their psychomotor laparoscopic skills. Surg Endosc 2010; 24(5):1031-1039.
11. Feldman LS, Sherman V, Fried GM. Using simulators to assess laparoscopic competence: ready for widespread use? Surgery 2004; 135(1):28-42.
12. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Institute of Medicine, National Academy of Sciences, 2000.
13. Hiemstra E, Chmarra MK, Dankelman J, Jansen FW. Intracorporeal suturing: economy of instrument movements using a box trainer model. J Minim Invasive Gynecol 2011; 18(4):494-499.
14. Twijnstra AR, Blikkendaal MD, van Zwet EW, van Kesteren PJ, de Kroon CD, Jansen FW. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol 2012; 119(4):700-708.
15. Lindenburg IT, Wolterbeek R, Oepkes D, Klumper FJ, Vandenbussche FP, van Kamp IL. Quality control for intravascular intrauterine transfusion using cumulative sum (CUSUM) analysis for the monitoring of individual performance. Fetal Diagn Ther 2011; 29(4):307-314.
16. Park IJ, Choi GS, Lim KH, Kang BM, Jun SH. Multidimensional analysis of the learning curve for laparoscopic colorectal surgery: lessons from 1,000 cases of laparoscopic colorectal surgery. Surg Endosc 2009; 23(4):839-846.

Chapter ten

Tailor made proficiency curves in laparoscopic hysterectomy: enhancing patient safety using cumulative summation analysis

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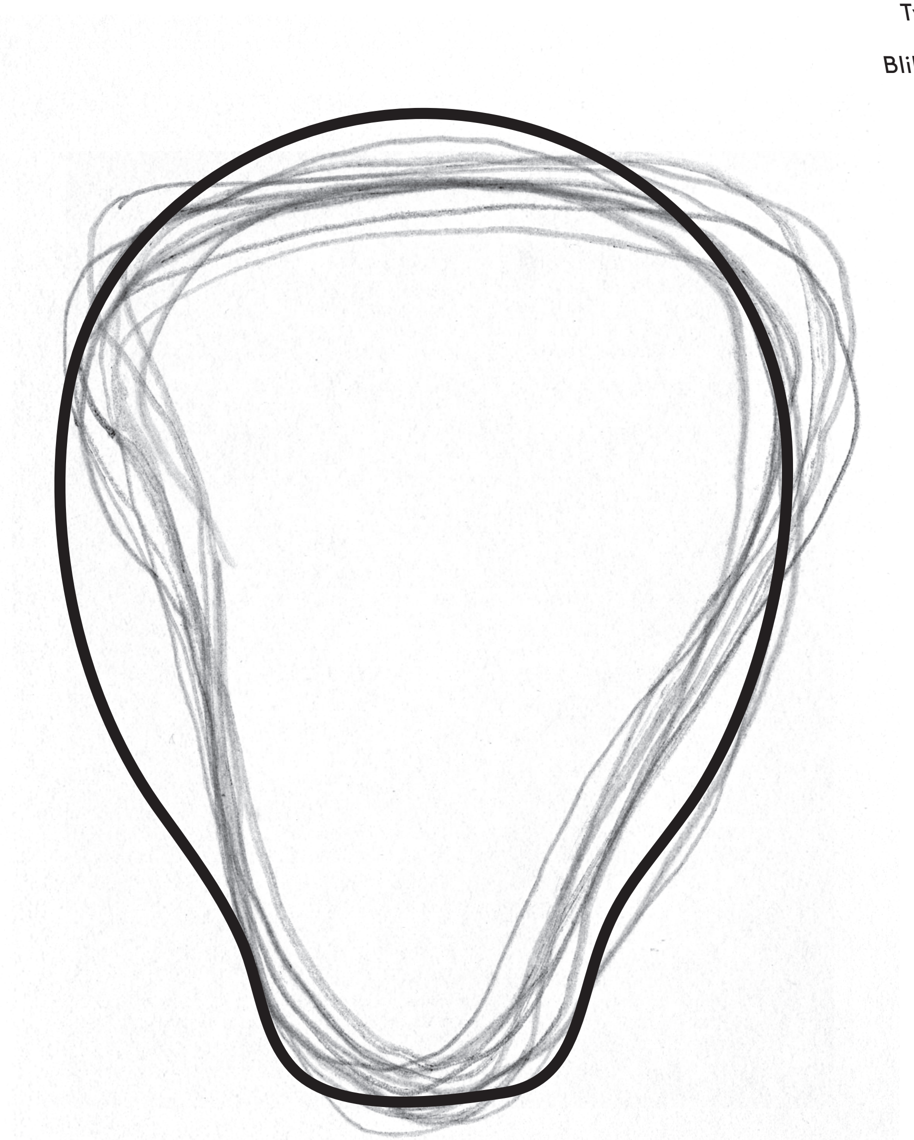


Submitted.

Abstract

Background

Aim of this study is to develop a risk adjusted real-time quality control system in laparoscopic hysterectomy with respect to blood loss, operative time and adverse events in order to signal derailing surgical performance in a timely fashion.

Methods

Based on prior research uterus weight, body mass index, number of surgeons, prior abdominal surgery and type of laparoscopic hysterectomy were identified as significant covariates predicting successful surgical outcome. Cumulative sum (CUSUM) analysis, a model based on dichotomous input (success or 'failure') was selected as a predictive tool for performance analysis. Cut-off values were set at blood loss <200 mL and operative time <120 minutes and no adverse event.

Results

Risk adjusted CUSUM graphs were constructed. In order to detect progressive failure rates (odds ratio 2.0 compared to average) in surgical performance (for blood loss, operative time and adverse events) within 20 procedures; as a result surgeons with average clinical outcomes will be flagged once in every 70-75 procedures (median) without justified derailing performance.

Conclusion

With proposed validated and risk adjusted CUSUM graphs gynecologists are able to continuously monitor their surgical performance in laparoscopic hysterectomy. Consequently this identifies suboptimal factors, which allows improvement of their surgical outcomes (by means of adjustment) and further enhancement of patient safety.

Introduction

In order to enhance patient safety, it has become increasingly important to measure outcome in health care. Surgical outcomes such as blood loss, operative time and the occurrence of adverse events are widespread applied instant measures. These measures, as well as skills and experience of the surgeon (usually expressed by the number of performed cases) are currently still used as quality predictors.[1] However, it is also established that surgical outcome, apart from surgical experience, is influenced by co-factors such as the make-up of the OR-team and (inherently) patient factors (i.e. the case mix). These factors are not taken into account when the aforementioned crude and unadjusted parameters are used to measure and present the actual surgical outcome.[2;3]

With respect to patient related factors, recent research in laparoscopic hysterectomy (LH) demonstrated five significant covariates predicting successful outcome: uterus weight, body mass index, number of surgeons present at surgery, prior abdominal surgery and type of laparoscopic hysterectomy (i.e. Total Laparoscopic Hysterectomy, Supracervical Laparoscopic Hysterectomy or Laparoscopic Assisted Vaginal Hysterectomy).[4] Moreover, experience is predicting successful surgical outcome in LH, with respect to blood loss and adverse events, up to at least a hundred procedures. This finding was also observed in the field of advanced colorectal laparoscopic surgery.[5;6] Finally, recent research demonstrated a significant experience independent and case mix adjusted surgical skills factor (SSF) with regard to successful outcome in LH.[4]

The afore mentioned findings support that surgical outcomes in laparoscopic hysterectomy should be monitored consecutively, as both case mix and surgeon's skills may vary over time, and experience alone is not sufficiently predicting these outcomes. Parallel to the traditional outcome measures, the traditional single outcome learning curves in surgery which were applied in order to assess surgical proficiency, do not take these findings into account.[7-10] Monitoring tools based on cumulative sum (CUSUM) analysis, already used in obstetrics and general surgery, overcome these shortcomings.[11-16] In the industrial setting, since 1974, CUSUM charts have been shown to be ideally suited to detect relatively small persistent changes in the event rates over time.[3] Traditional CUSUM approaches, however, make no adjustment for different risk profiles because machine inputs are usually relatively homogeneous. In contrast, patients undergoing a particular surgical intervention are often very heterogeneous in their clinical presentation. Additionally, the surgical approach may vary considerably, due to the clinical presentation as well as the preference of the surgeon. As a result, the probability of successful outcome may vary considerably between patients. By using a likelihood-based scoring method, the cumulative sum procedure is adapted so that it adjusts for the surgical risk of each patient estimated preoperatively.[2;17;18]

In gynecology, nowadays a shift in implementing more advanced surgical procedures is observed. However, several studies suggest that these advanced laparoscopic surgical procedures are characterized by a specific proficiency gaining curve, due to the acquirement of unique operative skills.[19] Consequently, this learning curve is considered a barrier for widespread implementation of advanced laparoscopic surgery.[5] Other research already revealed that even in basic laparoscopy nearly a fifth of surgeons never gain proficient skills to perform laparoscopic surgery adequately.[20] These insights, combined with the call for constant monitoring of patient safety, make us strive for risk adjusted continuous quality assessments during mentorships and beyond in order to adjust performance when quality of surgery is at risk.

The aim of this study is to develop such a tool. In order to signal derailing surgical performance in a timely fashion, a risk adjusted real-time quality control system for laparoscopic hysterectomy is analysed, inquired and launched.

Methods

A previously described data set of 1.534 LHs, performed by 79 surgeons, was used to validate and compose a risk adjusted CUSUM graph in LH.[4] Significant predicting covariates were included. These consisted of uterus weight, body mass index, number of surgeons present at surgery, prior abdominal surgery and type of laparoscopic hysterectomy. (Table 1)

The CUSUM score depends on four factors; the current average level of surgical performance, a chosen level of surgical performance deemed undesirable, the patient's surgical risk estimated preoperatively, and the actual surgical outcome in this patient. With respect to the continuous surgical outcomes; blood loss and operative time, these were dichotomized using the rounded mean observed value. Consequently, successful surgical outcome was determined as blood loss <200 mL, operative time <120 minutes, and no adverse event. Because incidences of these outcomes varied, with accompanying varying influences of covariates, we applied three risk adjusted CUSUM graphs, one for each outcome.

With the chosen level of surgical performance deemed undesirable, we aimed to minimize the number of procedures before possible derailing performance is signaled, while minimizing 'false alarms'. For quality control, a lower boundary line is not used. To allow a sensitive and timely detection of 'eventful' procedures, this model resets itself to 0, each time the x-axis is hit.[18] As a consequence, the median number of procedures needed to detect an unacceptable failure rate (in case a surgeon performs below an acceptable level) is based on the upper boundary ('out of control', odds ratio of 2 compared to average performance). Nevertheless, this model cannot prevent that also average clinical performance every once in a while is 'flagged' as derailing (Figure 2). The primary outcome of this study is the number of procedures after which surgeons are flagged, both true positive and false positive.

To apply a risk adjusted (i.e. based on the patient's surgical risk estimated preoperatively) CUSUM analysis we have to estimate the logistic regression model as described earlier.[4] Based on this model we can compute for each procedure the probability of an unfavorable outcome (failure). For ease of notation, suppose we use only uterus weight '*Ut*' as a predictor. Then, provided the surgeon is performing exactly on the national average (i.e. is in control) the probability of failure in procedure 'i' is:

$p0(i) = 1 / (1 + \exp(-\beta 0 - \beta 1 * Ut(i)))$
$\beta 0$ = the intercept in the logistic regression model
$\beta 1$ = log odds ratio for uterus weight.

If the surgeon performs worse than average (OR = 2 compared to the national average) the probability of failure becomes larger and is given by:

$p1(i) = p0 = 1 / (1+ \exp(-\beta 0 - \beta 1 * Ut(i) - \log(2)))$

Given the outcome of procedure i, we can compute the log likelihood ratio as

$$W(i) = \begin{cases} \log(p0/p1) & \textit{if failure} \\ \log((1-p0)/(1-p1)) & \textit{if success} \end{cases}$$

Now we construct the CUSUM graph by plotting X (i) = max(0, X(i-1) +W(i))

This 'X' will provide the actual direction and weight of the outcome of procedure 'i' on the CUSUM graph, corrected for uterus weight. In our model we included all covariates (uterus weight increase per 100 grams, BMI increase per 5 points, numbers of prior abdominal surgeries, 1 or 2 performing surgeons, type of laparoscopic hysterectomy)

Results

Figure 1 provides an example of the principle of a risk adjusted CUSUM graph of 21 consecutive LHs in one surgeon with respect to the outcome of blood loss <200 mL. The horizontal axis represents the numbers of consecutive procedures. The vertical axis represents the cumulative sum of the risk adjusted scores per procedure. As can be seen at no. 1, the fourth procedure was complicated by blood loss > 200 mL in a regular patient, followed by three regular procedures with blood loss <200 mL. The eighth procedure (no. 2) was performed uneventful in a 'challenging patient' (e.g. high BMI, large uterus weight). Then, at the thirteenth procedure (no. 3), blood loss >200 mL occurred, however this occurred in a challenging case (high BMI, large uterus weight; compare to no. 1). At the fifteenth procedure another failure (no. 4), however, because of average patient characteristics (see also Table 1) this procure was expected to be performed uneventful; a steep rise on the curve represents this disconcordance between observed and expected outcome. At attempt number 21 (no. 5) the CUSUM graph goes out of control and the chart signals.

For the defined outcomes of LH, respectively blood loss, operative time and adverse events separate risk adjusted CUSUM graphs were constructed. In order to detect unacceptable failure rates (clinical performance OR 2.0 compared to average clinical performance) in surgical performance within 20 procedures, as a result a surgeon with average surgical outcomes will be flagged without justified bad performance once in approximately every 70-75 procedures,

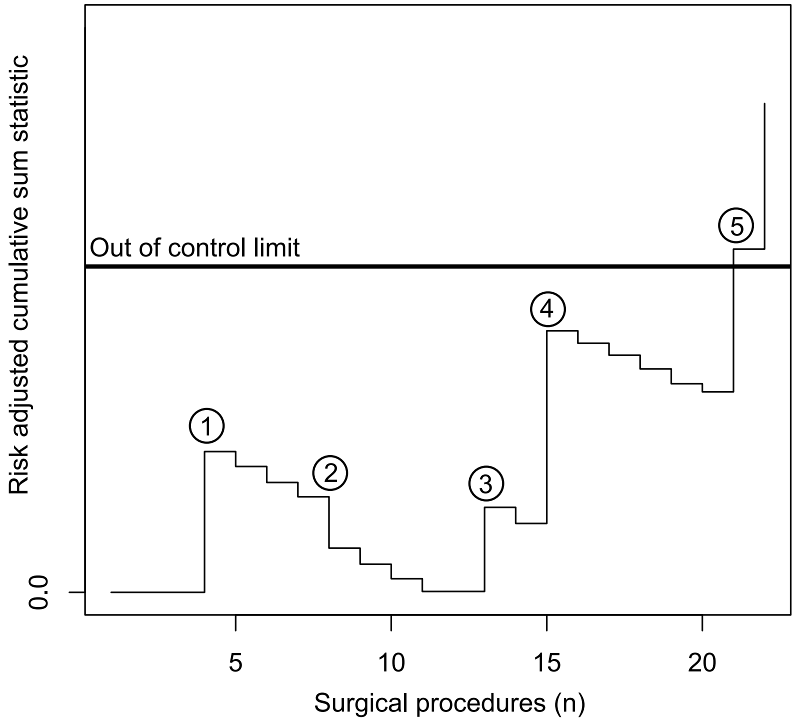


Figure 1 Example of the principle of a risk adjusted CUSUM graph of 21 consecutive laparoscopic hysterectomies in one surgeon with respect to blood loss <200 mL. See Results section for detailed clarification.

respectively (Figure 2). Reference values are based on the previously described cohort of 1.534 procedures, performed by 79 gynecologists.

Once one of the three CUSUM graphs signal, one should analyze at least twenty of its past performed procedures using a concise checklist as depicted in Table 2. Five fields address possible causes. If one or more fields are ticked once ore more times; this field should be studied and addressed in particular. This check list is not validated yet.

At the moment, stand alone software is being developed in order to process the proposed CUSUM graphs in the field of LH in order to provide the surgeon his/her performance statistics at a glance. This software should be easily integrated with (existing) data recording systems. The five characteristics (uterus weight in grams, body mass index (kg/m^2), number of previous abdominal surgeries, one or two surgeons, type of LH) and the three primary outcomes (operative time in minutes, blood loss in milliliters, adverse event) can be entered immediately postoperatively or at any given moment. The authors can be contacted about the (non commercial) dispense of the CUSUM software.

Table 1 Association between predictors and primary outcomes in laparoscopic hysterectomy

	Blood loss > 200 mL	Operative time > 120 min	Adverse event yes
Uterus weight increase per 100 grams	**0.33 (*P* < .0001)**	**0.40 (*P* < .0001)**	**0.18 (*P* = .0002)**
Body Mass Index increase per 1 point (kg/m^2)	**0.28 (*P* < .0001)**	0.18 (*P* = .0841)	0.02 (*P* = .221)
Numbers of previous abdominal surgeries	0.19 (*P* = .54)	0.78 (*P* = .782)	**0.48 (*P* = .048)**
Two surgeons (vs. one)	- 0.47(*P* = .072)	**0.64 (*P* = .028)**	0.05 (*P* = .811)
LAVH vs. TLH	**0.91 (P = .0274)**	0.04 (*P* = .915)	0.33 (*P* = .306)
SLH vs. TLH	-0.14 (*P* = .482)	**-0.47 (*P* = .032)**	-0.52 (*P* = .079)

Positive predictors represent higher chance of suboptimal primary outcome, negative predictors represent lower chance of suboptimal primary outcome. Bold numbers are significant predictors. LAVH = Laparoscopic Assisted Vaginal Hysterectomy, TLH = Total Laparoscopic Hysterectomy, SLH = Supracervical Laparoscopic Hysterectomy.

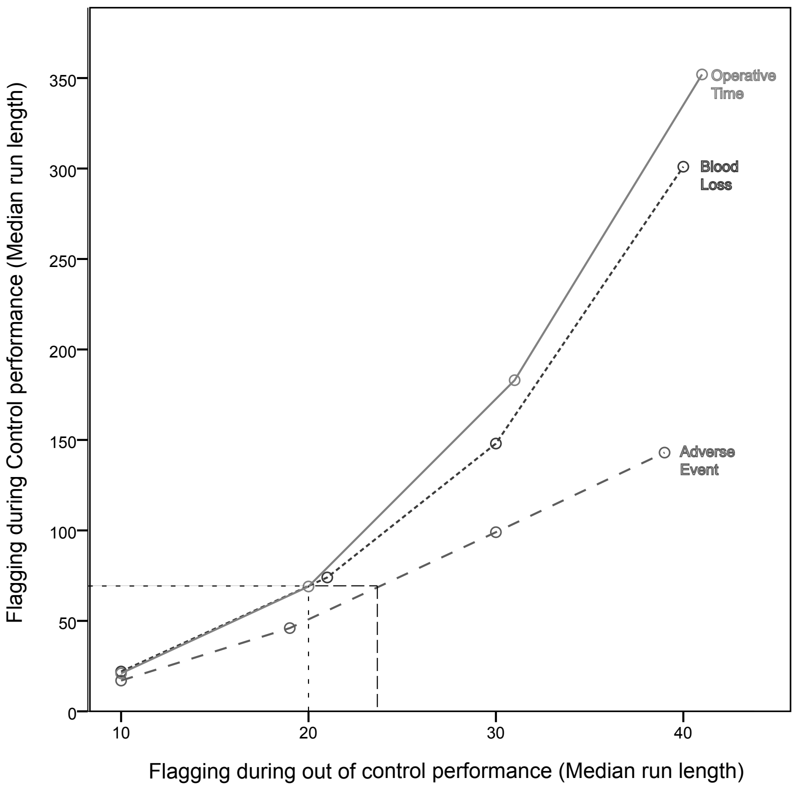


Figure 2 Threshold curves for blood loss, operative time and adverse events. Horizontal axis represents amount procedures before flagging in case of out-of-control performance (OR 2.0 compared to average performance). When performing exactly on average, flagging will occur as frequent as depicted on the vertical axis.

Table 2 Check list after signalling of CUSUM graph

Factor	
Patient	e.g. unexpected co-morbidity
Surgeon	e.g. fatigue, stress, inaccurate indication
Team	e.g. communication, staff's experience
Equipment	e.g. altered vision, new coagulation device
Logistic	e.g. tight scheduled operation programmes

Discussion

With proposed validated and risk adjusted CUSUM graphs, gynecologists have the ability to continuously monitor their surgical performance in laparoscopic hysterectomy, consequently identifying suboptimal factors with respect to operative time, blood loss and adverse events. As a result, they are able to enhance patient safety.

Despite correction for patient case mix (i.e. identified risk factors), this analysis model still inevitably yields flagging of surgeons with average clinical performance. This is due to the sensitivity of the model. If the CUSUM analysis has to identify derailing performance (OR 2 compared to average performance) in surgeons within a reasonable number of procedures (i.e. 20 laparoscopic hysterectomies), occasional flagging of surgeons with average clinical performance is inevitable. These proposed cut-off limits are set primarily to identify possible suboptimal situations and to enhance patient safety. The goal is twofold. Firstly, by alarming "out of control" limits in a timely fashion the surgeon can evaluate his/her performance as well as of its surgical team and even its equipment and act if necessary. Secondly, by providing (national) averages as a standard of care, hypothetically at long-term also suboptimal performing surgeons that do not cross the out-of-control line will improve their outcomes.

Although this proposed CUSUM system for laparoscopic hysterectomy is based on national averages of Dutch cohort in 2009, we suggest that the references values are applicable to every gynecologist. The proposed cut off values might appear 'mild'. However, if these values are raised, as a consequence signaling will be delayed. This will result in less adequate flagging of potentially derailing performance.

If implemented in a straightforward digital registry tool (or stand alone computer program), this CUSUM for LH provides easy to understand and swift to apply insight into tailor-made proficiency curves. We suggest, that out-of-control signaling should primarily be discussed internally, and only after a certain acclimatizing period should be discussed with expert peers, in order to identify suboptimal care and to provide 'Best Practices'.

A number of aspects of the proposed model should be addressed. Firstly, is the average signaling rate of one in 75 procedures in surgeons with average clinical performance acceptable? Yes, however, proper information and efficient evaluation is a prerequisite. Time-consuming evaluation will harm initial motivation. When a CUSUM chart goes out of control, one should be provided with a concise check-box based questionnaire, in order to signal the origin of derailing performance (Table 2). This could be due to skills, technical issues, misjudging of a series of cases, problems with the OR team, et cetera. These issues should be directed. Secondly, ideally, the CUSUM chart (and preferably also its evaluation system) should be integrated and implemented in an already existing electronic patient file system. Registration of patient data in multiple sources will affect quality and quantity of data. Thirdly, the national averages set in this tool should be updated on a frequent basis, preferably every five years. Hypothetically, the cohort will improve its surgical outcomes over time. As a result, averages and out-of-control limits should be fine tuned as well.

An example is found in the field of (surgical) oncology, in which the value of continuous quality assurance is well studied.[21-23] However, these examples use evaluation of care on a yearly basis and often lack correction for patient case mix. Furthermore, most of these registries use adverse events as sole primary outcome and direct hospitals rather than surgeons personally. Some registries reflect hospital outcomes to national averages, however, most systems compare to (outdated) literature. CUSUM analysis addresses all above mentioned points of interest.

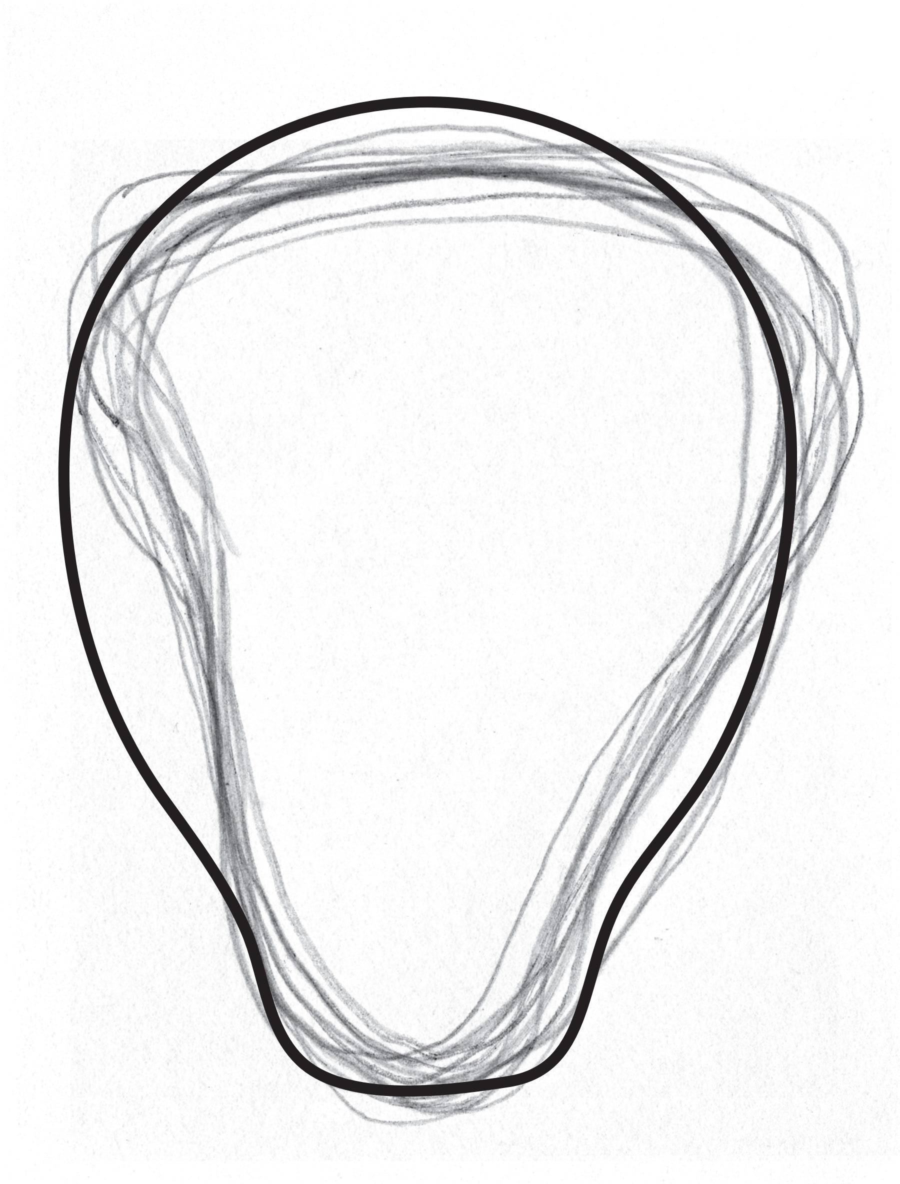
For a start, the CUSUM should be applied and compared indoors only. In conclusion, applying CUSUM charts as quality assurance for the surgical performance and clinical outcome measure of LH potentially enhances patient safety.

References

1. Hopper AN, Jamison MH, Lewis WG. Learning curves in surgical practice. Postgrad Med J 2007; 83(986):777-779.
2. Steiner SH, Cook RJ, Farewell VT, Treasure T. Monitoring surgical performance using risk-adjusted cumulative sum charts. Biostatistics 2000; 1(4):441-452.
3. Biau DJ, Resche-Rigon M, Godiris-Petit G, Nizard RS, Porcher R. Quality control of surgical and interventional procedures: a review of the CUSUM. Qual Saf Health Care 2007; 16(3):203-207.
4. Twijnstra AR, Blikkendaal MD, van Zwet EW, van Kesteren PJ, de Kroon CD, Jansen FW. Predictors of successful surgical outcome in laparoscopic hysterectomy. Obstet Gynecol 2012; 119(4):700-708.
5. Park IJ, Choi GS, Lim KH, Kang BM, Jun SH. Multidimensional analysis of the learning curve for laparoscopic colorectal surgery: lessons from 1,000 cases of laparoscopic colorectal surgery. Surg Endosc 2009; 23(4):839-846.
6. Cheng JM, Duan H, Wang JJ, Zhang HT, Liu Y. [Clinical analysis of conversion from gynecological laparoscopic surgery to laparotomy]. Zhonghua Fu Chan Ke Za Zhi 2007; 42(3):173-175.
7. Perino A, Cucinella G, Venezia R, Castelli A, Cittadini E. Total laparoscopic hysterectomy versus total abdominal hysterectomy: an assessment of the learning curve in a prospective randomized study. Hum Reprod 1999; 14(12):2996-2999.
8. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
9. Leminen A. Comparison between personal learning curves for abdominal and laparoscopic hysterectomy. Acta Obstet Gynecol Scand 2000; 79(12):1100-1104.
10. Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. Obstet Gynecol 2004; 104(2):308-313.
11. de Saintonge DM, Vere Dw. Why don't doctors use CUSUMs? Lancet 1, 120-121. 1974.
12. Schlachta CM, Mamazza J, Seshadri PA, Cadeddu M, Gregoire R, Poulin EC. Defining a learning curve for laparoscopic colorectal resections. Dis Colon Rectum 2001; 44(2):217-222.
13. Bolsin S, Colson M. The use of the Cusum technique in the assessment of trainee competence in new procedures. Int J Qual Health Care 2000; 12(5):433-438.
14. Weerasinghe S, Mirghani H, Revel A, bu-Zidan FM. Cumulative sum (CUSUM) analysis in the assessment of trainee competence in fetal biometry measurement. Ultrasound Obstet Gynecol 2006; 28(2):199-203.
15. Boulkedid R, Sibony O, Bossu-Salvador C, Oury JF, Alberti C. Monitoring healthcare quality in an obstetrics and gynaecology department using a CUSUM chart. BJOG 2010.
16. Lindenburg IT, Wolterbeek R, Oepkes D, Klumper FJ, Vandenbussche FP, van Kamp IL. Quality control for intravascular intrauterine transfusion using cumulative sum (CUSUM) analysis for the monitoring of individual performance. Fetal Diagn Ther 2011; 29(4):307-314.
17. Steiner SH, Cook RJ, Farewell VT. Risk-adjusted monitoring of binary surgical outcomes. Med Decis Making 2001; 21(3):163-169.
18. Grigg OA, Farewell VT, Spiegelhalter DJ. Use of risk-adjusted CUSUM and RSPRT charts for monitoring in medical contexts. Stat Methods Med Res 2003; 12(2):147-170.
19. Aggarwal R, Moorthy K, Darzi A. Laparoscopic skills training and assessment. Br J Surg 2004; 91(12):1549-1558.
20. Schijven MP, Jakimowicz J. The learning curve on the Xitact LS 500 laparoscopy simulator: profiles of performance. Surg Endosc 2004; 18(1):121-127.
21. Landheer ML, Therasse P, van de Velde CJ. The importance of quality assurance in surgical oncology. Eur J Surg Oncol 2002; 28(6):571-602.
22. Peeters KC, van de Velde CJ. Surgical quality assurance in breast, gastric and rectal cancer. J Surg Oncol 2003; 84(3):107-112.
23. Verleye L, Vergote I, Reed N, Ottevanger PB. Quality assurance for radical hysterectomy for cervical cancer: the view of the European Organization for Research and Treatment of Cancer--Gynecological Cancer Group (EORTC-GCG). Ann Oncol 2009; 20(10):1631-1638.

Chapter eleven

General discussion and summary



General Discussion

This thesis describes the current implementation of laparoscopic hysterectomy, identifies several predicting factors for surgical outcome and addresses monitoring devices in order to enhance patient safety and quality of care during acquisition and maintenance of skills.

The implementation of gynecologic laparoscopic surgery in general and of laparoscopic hysterectomy in particular is characterized by a varying intensity throughout the world.[1-3] In **Chapter 2** we demonstrate an increasing implementation of therapeutic laparoscopic gynecologic surgery in the Netherlands. Hospitals increasingly opt for the laparoscopic over the conventional approach and the decline in diagnostic procedures is well compensated by an increase in numbers of therapeutic procedures. However, implementation of advanced procedures such as laparoscopic hysterectomy seems to be hampered. Furthermore, regarding laparoscopic hysterectomy, a scattered implementation is seen. The majority of hospitals that applied this procedure to their surgical palette perform only a minority of the total volume of procedures, whereas a minority of hospitals provides a high volume annual caseload, taking charge of the majority of procedures. In other words; a lot perform a few while a few perform a lot. From these numbers we can hypothesize a number of explanations. Firstly, this distribution pattern might be due to the 'learning curve' of certain adopters. Secondly, referral tendencies between and in hospitals might be a cause. We researched this matter in **Chapter 4** and found that laparoscopists reported lack of support of referring colleagues. This is confirmed with referral tendencies in other countries.[4-6] Gynecologists employed in a hospital that did not perform laparoscopic hysterectomies were much less likely to refer candidates for this procedure, despite basic knowledge about the indication and limitations of the approach. Furthermore, patient related factors, such as body mass index and uterus weight, might play a role in this tendency. Also others already published on the impact of these patient factors on surgical outcome.[7-12] In skilled hands these factors seem not to impede application of the laparoscopic approach. However, it is shown that obesity is in fact correlated with less favorable outcomes, including a higher risk of conversion to laparotomy.[13] One might say that these discrepancies in literature reporting might be caused by difference in patient mix, surgical experience and surgical skills. However, we found that the level of experience (expressed in number of laparoscopic hysterectomies performed) did not significantly influence the laparoscopist's opinion on body mass index, uterus weight and previous abdominal surgery as restrictive characteristics for the laparoscopic approach. Both, performers as well as referring colleagues regarded a high body mass index, big uterus weight and previous abdominal surgery as restricting parameters for the laparoscopic approach. This is worrisome, as we know from **Chapter 5**, that although these patient characteristics are correlated with increased blood loss, longer operative time and higher risk of adverse events, the majority of patients (>85%) have an uneventful procedure. Other research confirms these outcomes.[9;10;13] Especially the obese patient is better served by a laparoscopic approach than by conventional abdominal surgery.

Furthermore, it was shown that with growing popularity of this procedure (half of laparoscopic hysterectomy performing gynecologists had less than five years experience), a steady state of implementation of this advanced laparoscopic surgical procedure has yet not been reached.

However, the vaginal approach to hysterectomy is still considered the gold standard.[14] This approach appears to increase in hospitals that do not provide laparoscopic hysterectomy, however, this seems to be relatively hampered in those hospitals that perform these procedures (**Chapter 2**). Abdominal hysterectomy, for which the laparoscopic approach originally was intended an alternative, is performed approximately as much in hospitals that do perform laparoscopic hysterectomies as in hospitals that do not (55 versus 58%). Regarding different types of laparoscopic hysterectomy we found that Laparoscopic Assisted Vaginal Hysterectomy (LAVH) was prominent in low volume (1-10 laparoscopic hysterectomies per year) hospitals, whereas the majority of Total Laparoscopic Hysterectomy (TLH) and Supracervical Laparoscopic Hysterectomy (SLH) were performed in medium (11-20) and high volume (>20 laparoscopic hysterectomies per year) hospitals. Again, this is a worrisome finding, as we identified in **Chapter 3** in a retrospective multicenter cohort study that LAVH is associated with higher blood loss, compared to TLH. Also in the light of apprenticeship in laparoscopic hysterectomy, we would like to stress, that LAVH is by no means a 'beginners' technique to be taught/acquired, because of its higher blood loss and risk of adverse events, compared to TLH and SLH. This finding is confirmed in our national prospective multicenter cohort study in **Chapter 5**. In this study we observed that the success of the surgical outcomes was significantly influenced by uterus weight, body mass index, ASA classification and previous abdominal surgeries. Surgical experience also predicted the successful outcome of laparoscopic hysterectomy with respect to blood loss and adverse events. This proficiency gaining curve, which was an average based on 79 surgeons, showed to be increasing over a larger number of procedures, than was previously assumed (i.e. over a hundred versus 30 procedures).[15-17] Independently from surgical experience, an individual surgical skills factor was identified for blood loss and operative time. This skills factor showed a large variation in proficiency between individuals. Therefore, the fact that a surgeon has performed many laparoscopic hysterectomies does not necessarily guarantee good surgical outcome.

This means that experience alone is insufficiently sanctifying, when it comes to predicting surgical outcome. Moreover, the individual skills factor is a crucial determinant in measuring quality of surgery. What about these considerations with respect to conversion to laparotomy? As described in **Chapter 6,** the majority of conversions are performed because of strategic considerations. Visibility and/or mobility problems were the main reason for a conversion, while uncontrollable bleeding was the main adverse event leading to a reactive conversion. As reported by others, BMI and uterus weight were confirmed to be independent risk factors for conversion.[18-20] A new explored effect from our study shows, however, that this risk increases with a BMI >35 kg/m^2 (5-fold), a uterus weight between 200-500 grams (4.5-fold) and a uterus weight >500 grams (37.5-fold). Furthermore, surgical experience did not correlate with the conversion rate. However, also with respect to the risk of conversion, we identified again the presence of an intrinsic surgical skills factor. This factor means that independent of experience, the tendency to convert varies between surgeons. Apparently, similar to the skills factor with respect to operative time and blood loss, some surgeons tend to decide to convert sooner than equally experienced surgeons. More research is needed to gain insight in exact motivations and/or trigger points to decide to convert.

Minimally invasive surgery is not necessarily minimally painful. Despite esthetic favorable outcomes on the outside, the laparoscopic approach imaginably takes account of similar damage intraperitoneally. However, relatively elevated IL-6 and CRP serum levels found in abdominal hysterectomy patients, suggests that this approach is associated with inclined tissue damage, compared to laparoscopic hysterectomy.[21-25] In contrast, others described higher nociceptive pain scores during laparoscopic procedures, compared to conventional open surgery. These findings are in contrast with the rationale that minimally invasive surgery, with accompanying less tissue damage, would result in declined perceived pain. This is controversial, as laparoscopic hysterectomy patients report to become pain free in a significantly shorter period of time, compared to women operated by laparotomy.[26-28] In **Chapter 7** we observed that pain perception during the first hours after surgery and intra-operative pain indicators are comparable between abdominal, laparoscopic and vaginal hysterectomy. Minimally invasive surgery is not associated with a minimum of pain perception. However, addition of epidural analgesics did not significantly lower postoperative scores in minimally invasive surgery. Therefore, based on these data, we suggest that laparoscopic hysterectomy should be performed under general anesthesia preferably without accompanying (postoperative) epidural analgesia. Secondly, this study confirms earlier findings that laparoscopic hysterectomy is associated with an earlier decline in pain scores, compared to abdominal hysterectomy, and even vaginal hysterectomy. However, our study might be underpowered to make such a statement. Comparative follow up studies on long term pain perception, prolapse incidences and quality of life between laparoscopic and vaginal hysterectomy patients might shed new lights on the sheen of the present *'no scar'* gold standard in hysterectomy.

Proficiency in laparoscopic hysterectomy by means of a mentorship program described in **Chapter 8** is effective and durable. For two gynecologists, this tool for implementing a new surgical procedure in a teaching hospital showed to be successful with respect to patient safety aspects. Indication, operative time and adverse event rates were comparable to those of the mentor in his own hospital during and after completing the mentorship program. While length of surgery remained statistically constant, both trainees progressed along a learning curve as the mentor's role was gradually phased out. The mentor dosed the amount of knowledge per session. In this way, trainees could experience *tailor-made learning moments*, while length of surgery was guarded. We stress that when applying this method of transfer; the supplementary advantage of the 'next generation' becoming familiar with the above mentioned procedure should not be underestimated. In this way assisting residents will already be conversant with the new instruments, the procedure and the correct indication for laparoscopic hysterectomy during their specialization. With this in mind, a deliberate choice to use this technique might be considered later on. Of course, before getting the opportunity of assisting during (advanced level) laparoscopic procedures, residents in OB/GYN need to attain and sustain basic laparoscopic skills in a skills lab in a box trainer or Virtual Reality simulator.[29;30] We know that the majority of residents show to attain and to sustain proficiency in basic laparoscopic skills in a limited amount of procedures.[30-32] Residents showed a (rapid) improvement of proficiency until achieving expert level performance.

Nowadays, in several countries sufficient basic skills training in laparoscopy is mandatory before residents are allowed to enter the minimally invasive OR.[33]

Nevertheless, what about the experts? No box trainer tasks in order to proof surgical skills or surgical competency against which the validity of a skills task can be judged exists.[34;35] In **Chapter 9** we showed in 50 surgeons who perform laparoscopic hysterectomy in daily practice, surgical experience proofed to be positively influencing economy of movement parameters during an intracorporeal knot-tying task in a box trainer. However, if correlated with risk adjusted surgical skills with respect to operative time and blood loss, no direct correlation between surgical outcome and economy of movement parameters in the box trainer were found. This implicates that regular monitoring of surgical skills by means of a basic laparoscopic task in a box trainer is not efficient in order to signal less skillful surgeons. Therefore, the call of Health Inspectorates to develop such an ‘in vitro’ measuring tool is not realistic and other, ‘real time’ clinical monitoring tools in order to measure surgical performance in experts in the operating room should be considered instead. From the classical point of view, a learning rate and a learning plateau characterize the learning curve, assuming stable performance after a certain amount of procedures.[36] Others described that surgical performance can deteriorate also in surgeons with substantial experience.[37;38] In order to correct for patient case mix, one should address clinical meaningful predictors, while refrain from registering useless parameters. In **Chapter 10** we applied cumulative sum (CUSUM) analysis on the one-year analyses of the LapTop study as described in **Chapter 5**. Because we already identified and validated several clinical significant covariates influencing surgical outcome, we could construct a concise risk adjusted proficiency curve. Difficult cases gone wrong would result in a slight deterioration of the curve, while an adverse outcome in hysterectomy with normal patient characteristics would lead to a more severe ‘punishment’. This analysis showed that by using CUSUM graphs surgeons are able to continuously monitor their quality in surgical performance in laparoscopic hysterectomy, consequently identifying suboptimal factors, which allows improvement of their surgical outcomes and further enhancement of patient safety. We aimed to detect unacceptable failure rates in surgical performance (for blood loss, operative time and adverse events) within 20 procedures. As a consequence, on average the CUSUM model will flag competent surgeons once in approximately every 70-75 procedures, without justified bad performance. Signaling of the graph must primarily result in thorough analysis of recent ‘failed’ procedures and to reevaluate indication, patient characteristics, operative skills, instrumentation and operating team factors. Traditional quality assurance tools in other fields are mainly based on a yearly-based evaluation, without correction for case mix, regarding only adverse events and direct clinics and not surgeons.[39-41] As a consequence, individual underperformance is not registered. CUSUM analysis provides continuous information on performance in relation to actual (national) averages and corrects for patient factors.

Learning curves in surgery

The classic learning curve in surgery is often characterized by three phases, in which at start up the curve ascends. This part of the curve may be a stepwise ascent as individuals learn and master stages of a complex procedure.[42] Improvements tend to be most rapid at first and then tail off, as the degree of improvement attained with each case reduces, as technique is refined. Secondly, assuming adequate aptitude, a point is reached when the procedure can be performed independently and competently. Additional experience improves outcomes by small amounts, until a plateau, or asymptote is reached. Several researchers question this last phase of the learning curve and postulate that the proficiency can be reached but should be monitored also afterwards, because surgical outcomes can deteriorate due to patient case mix, applying new techniques or overconfident behavior.[43]

Consequently, a graphical representation of the learning curve is demanded, which allows both for risk adjustment as well as comparing to the national average.

As a reaction, observed-expected (O-E) curves were applied in surgery, in order to provide visual aids in order to show how the current surgical performance compares with past performance.[44] However, these charts do not specify how much variation in the curve is expected under good surgical performance and hence, from which point a deviation from the expected outcomes should be a cause for concern. In the field of surgery and obstetrics, an alternative surgical monitoring tool is proposed, based on a cumulative sum (CUSUM) chart that uses a methodology borrowed from an industrial context.[37;38;45]In the industrial setting, since 1974 CUSUM charts have been shown to be ideally suited to detect relatively small persistent changes in the event rates over time.[46] Traditional CUSUM approaches, however, make no adjustment for different risk profiles because machine inputs are usually relatively homogeneous. In contrast, patients undergoing a particular surgical intervention are often very heterogeneous in their clinical presentation. Additionally, the surgical approach may vary considerably, due to the clinical presentation as well as the preference of the surgeon. As a result, the probability of a successful outcome may vary considerably between patients. By using a likelihood-based scoring method, the cumulative sum procedure is adapted so that it adjusts for the surgical risk of each patient estimated preoperatively (Figure 1).

For those who already practice laparoscopic hysterectomy, no reliable training or benchmarking tool is yet available. From research in novices in laparoscopy we know that nearly one fifth never reaches sufficient skills to perform endoscopy at a proficient level.[31] One could state, that gynecologists performing laparoscopic hysterectomy are sufficiently enthusiastically to perform safe surgery.

Since its early implementation, early adopters and pioneers in laparoscopic hysterectomy recorded and published their primary outcomes such as blood loss, adverse events and operative time.[15-17;47] With these results an average learning curve of 30 procedures before reaching proficiency was estimated. A number of limitations concerning these studies must be stated. First of all, most of these studies were single center or even single surgeon based, used single outcome measures, did not research and or applied risk adjustment, and often had a retrospective design. Secondly, when it comes to learning of skills, one should define outcome, possible covariates and the level at which competency is reached.[42] As a result a learning curve can be drawn, in which experience as a predicting factor can be visualized. Perhaps, also other intrinsic skills factors in surgeons might attribute to variation in the subsequent learning curve in primary outcomes such as blood loss, operative time and adverse events. Additionally, the tendency to decide to convert to laparotomy should be researched as well.

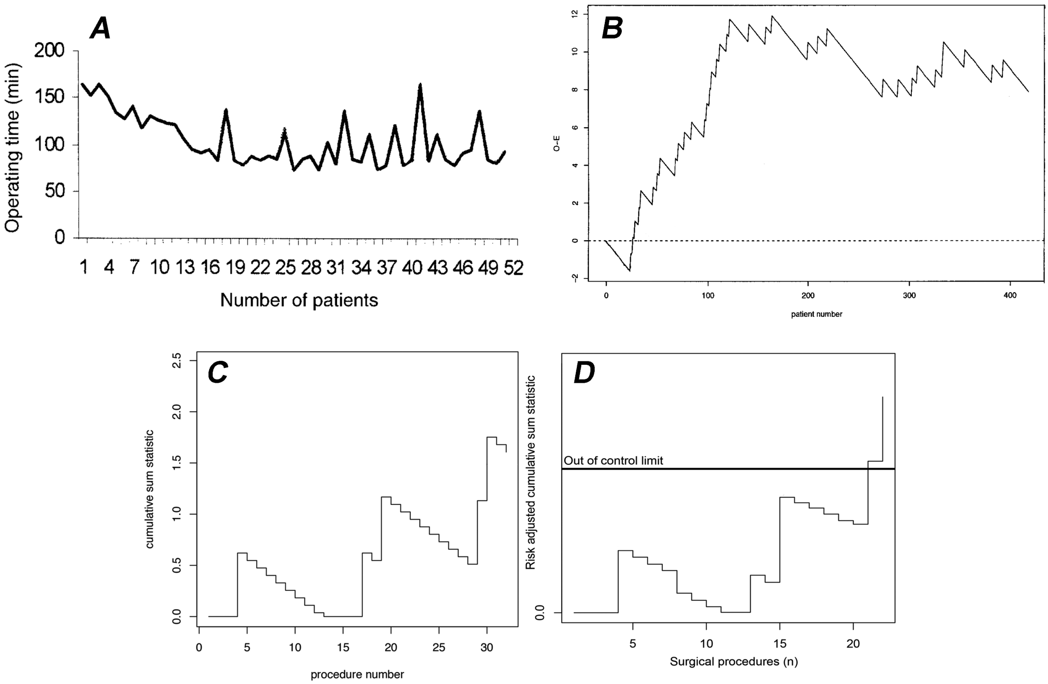


Figure 1 Evolution in learning curves. A = Classical, unadjusted, single outcome learning curve, B = Unadjusted Observed – Expected learning curve, without chart signalling, C = unadjusted CUSUM learning curve, D = Risk adjusted CUSUM learning curve.

Until now, in laparoscopic surgery in general and in laparoscopic hysterectomy in particular, little consensus exists on the definition of conversion.[48] As a consequence, no distinct data on conversion rates are available yet. Additionally, one can convert to an abdominal approach due to an adverse event, which cannot be controlled by laparoscopy. However, surgeons can also decide to convert because of 'strategic' considerations. Both sub groups can possibly provide information on indication and skills of the surgeon.

Future perspectives

In this thesis, we show that in the Netherlands implementation of laparoscopic hysterectomy is scattered and many surgeons are yet still gaining experience and/or perform few procedures per year. Furthermore, referral tendencies are still far from optimal, contributing to the aforementioned hampered implementation.

From our data, we learned that experience counts. However, also an independent skills factor contributes to surgical outcome. Furthermore, having performed many laparoscopic hysterectomies does not necessarily guarantee good surgical outcome. Therefore, no general advice on a minimum number of performed laparoscopic hysterectomies can be provided. However, if we want to ascertain patient safety and detect derailing performance within one year, using risk adjusted CUSUM analysis based on our LapTop! study data, the recommended volume should be around twenty laparoscopic hysterectomies per year. Continuation of nationwide monitoring in laparoscopic hysterectomy will provide changes in actual average performance parameters and as a result hypothetically the recommended volume can be adjusted because of improvement in average national outcomes. If a gynecologist performed fifteen procedures over the last twelve months, should he or she refrain from performing laparoscopic hysterectomies from now on? If the CUSUM graph 'signals' after twenty procedures; should the relevant gynecologist cancel its next hysterectomy? Not necessarily. However, low surgical volumes could indicate suboptimal referral tendencies in colleagues and signaling of the CUSUM graph could reflect difficulties with (a combination of) indication, instrumentation, skills and perhaps lack of a dedicated OR team. One could imagine that the set 'national average' in the proposed CUSUM graph could likely be subject to changes in accordance with the changes measured in each surgeon individually. Therefore we suggest a periodic calibration (in conformity with all medical regulations set on a 5-yearly basis) of risk factors and mean surgical outcomes (i.e. blood loss, operative time, adverse event). This will attribute to 'updated' standards of care.[49]

Furthermore, with respect to advanced level laparoscopy, what is the true definition of an expert? From the literature, several recommendations concerning experience (i.e. numbers of performed procedures or years of experience) are made.[43;50;51] However, no validation with respect to surgical outcome could be performed until so far. From a pragmatic point of view one should consider everyone who performs advanced laparoscopic surgery (e.g. laparoscopic hysterectomy) an expert. From this point on, this 'expert' can prove his or her expertise and skills by continuous monitoring of (risk adjusted) surgical outcomes. Hypothetically, only when technology succeeds in constructing a haptic perfect augmented reality simulation of the entire procedure, in vitro training and testing of the aforementioned experts can take place.[52] Before such a device is available we should focus on in vivo assessments of skills in advanced laparoscopic surgery.

Within a reasonable amount of time, commencement of advanced level laparoscopic surgery will also apply to residents, as during residency one is increasingly put in touch with laparoscopic hysterectomy, its indications and techniques. In the Netherlands, officially the surgical curriculum in gynecology does not contain yet laparoscopic hysterectomy. However, others already describe curricula including laparoscopic hysterectomy.[53]

Regarding this development we should perhaps reconsider the rationale of a required minimum numbers of vaginal and abdominal hysterectomies performed during residency and incorporate laparoscopic hysterectomies and perhaps downsize the required numbers of abdominal hysterectomies. Assisting laparoscopic hysterectomies will likely result in knowledge of basic principles and proper indication.[54] Consequently, referral tendencies and performance might improve.

Directives

In order to enhance patient safety and to guarantee a standard quality of care in laparoscopic hysterectomy, we suggest the following guidelines:

Laparoscopic hysterectomy should preferably be adapted in a teacher controlled environment (i.e. via fellowship/mentorship).

Simultaneously, referral tendencies of colleagues should be optimized, by lecturing about indication and agreements on reimbursement. This accounts for direct colleagues, as well as colleagues in neighboring hospitals. As a result, a proper analysis on expected caseload (concerning abdominal, vaginal and laparoscopic hysterectomy candidates) prior to implementation of laparoscopic hysterectomy should be accomplished.

Every gynecologist performing laparoscopic hysterectomy should continuously monitor its risk adjusted surgical outcomes.

After signaling of possible derailing performance, an analysis of skills, indication, instrumentation and OR team should be executed.

Minimum numbers of performed procedures per year should be around 20 laparoscopic hysterectomies, based on a safe fitting of performance monitoring tools, i.e. the proposed risk adjusted CUSUM graph (based on data from the LapTop! study cohort).

Continuity of care should be guaranteed. Therefore, one should consider training of at least two gynecologists per hospital who perform laparoscopic hysterectomies.

Future research

Firstly, a five yearly update of national data with respect to predictors of outcomes in laparoscopic hysterectomy must be performed in order to reassess and, if necessary, adjust averages and cutoff values. Secondly, studies on determinants of the surgical skills factor, as found in our research should demonstrate in detail the contribution of each factor (instrumentation, anesthesia, OR-team, dexterity). Thirdly, reimbursement studies will likely shed a light on the financial impact on preference and referral tendencies. Fourthly, once indication and techniques in (laparoscopic) hysterectomy are defined in national protocols/guidelines, comparative studies on patient outcomes between the vaginal, laparoscopic and abdominal approach will be conclusive with respect to advantages and relevance of each technique.

Summary

Although hospitals increasingly opt for the laparoscopic over the conventional approach and the decline in diagnostic procedures is well compensated by an increase in numbers of all types of therapeutic procedures, the implementation of laparoscopic hysterectomy in the Netherlands seems to be hampered and scattered (**chapter 2**). The majority of hospitals that apply laparoscopic hysterectomy perform only a minority of the total volume of procedures, whereas the minority of hospitals performs a high annual caseload of procedures.

From our studies, preference and referral tendencies seem to be suboptimal, despite knowledge indication and advantages of this minimally invasive technique (**chapter 4**). Gynecologists employed in a hospital that did not perform laparoscopic hysterectomies were much less likely to refer candidates for this procedure, despite basic knowledge about the indication and limitations of the approach. Furthermore, patient related factors, such as body mass index and uterus weight, might play a role in this tendency. The level of experience (expressed in number of laparoscopic hysterectomies performed) did not significantly influence the laparoscopist's opinion on body mass index, uterus weight and previous abdominal surgery as restrictive characteristics for the laparoscopic approach. Both, performers as well as referring colleagues regarded a high body mass index, big uterus weight and previous abdominal surgery as restricting parameters for the laparoscopic approach. This is worrisome, as we know that the majority of these 'challenging' patients have an uneventful procedure (85%) and especially since there is evidence that the obese patient is better served by a laparoscopic approach than by conventional abdominal surgery. Furthermore, it was shown that with growing popularity of this procedure (half of laparoscopic hysterectomy performing gynecologists had less than five years experience), a steady state of implementation of this advanced laparoscopic surgical procedure has yet not been reached.

The Laparoscopic Assisted Vaginal Hysterectomy (LAVH), a variant of laparoscopic hysterectomy, showed to be generally performed by inexperienced surgeons in low volume hospitals, while adverse events and blood loss were increased compared to Total Laparoscopic Hysterectomy (**chapter 3** and **chapter 5**). In our prospective study in 79 surgeons (the LapTop! study), we observed that the success of surgical outcomes was significantly influenced by uterus weight, body mass index, ASA classification and previous abdominal surgeries, next to the type of laparoscopic hysterectomy (**chapter 5**). Surgical experience also predicted the successful outcome of laparoscopic hysterectomy with respect to blood loss and adverse events. However, also an experience independent surgical skills factor was identified, representing a crucial determinant in measuring quality of surgery. This skills factor was also present in the probability of conversion to laparotomy in the same cohort (**chapter 6**). The majority of conversions were performed because of strategic considerations, while uncontrollable bleeding was the main adverse event leading to a reactive conversion. A high body mass index and increased uterus weight predicted conversion probability, while experience did not.

No differences in nociceptive and hormonal pain perception were found between laparoscopic, vaginal and abdominal hysterectomy (**chapter 7**). Therefore, minimally invasive surgery is not necessarily minimally painful. However, patients in the minimally invasive group reported a steeper decline in pain scores postoperatively.

Acquiring and maintaining skills in laparoscopic hysterectomy by mentorship showed to be effective, safe and durable, as indication, operative time and adverse event rates were comparable to those of the mentor in his own hospital during and after completing the mentorship program (**chapter 8**). Assessment of skills in advanced laparoscopic surgery is increasingly demanded. Prediction of surgical skills based on 'in vitro' box trainers outcomes was not conclusive as surgeons with suboptimal average clinical outcomes could not be indicated by means of a box trainer task (**chapter 9**). However, 'real time' risk-adjusted clinical monitoring of performance by means of cumulative sum (CUSUM) analysis appeared to be a valuable tool in order to signal derailing performance in a timely fashion (**chapter 10**). This is paramount, as in laparoscopic hysterectomy no definitive accomplishment of the proficiency curve is foreseen and applying relevant predictors of quality of surgery should guard patient safety.

References

1. Garry R. The future of hysterectomy. BJOG 2005; 112(2):133-139.
2. Brummer TH, Seppala TT, Harkki PS. National learning curve for laparoscopic hysterectomy and trends in hysterectomy in Finland 2000-2005. Hum Reprod 2008.
3. Jacoby VL, Autry A, Jacobson G, Domush R, Nakagawa S, Jacoby A. Nationwide use of laparoscopic hysterectomy compared with abdominal and vaginal approaches. Obstet Gynecol 2009; 114(5):1041-1048.
4. Gimbel H, Ottesen B, Tabor A. Danish gynecologists' opinion about hysterectomy on benign indication: results of a survey. Acta Obstet Gynecol Scand 2002; 81(12):1123-1131.
5. Englund M, Robson S. Why has the acceptance of laparoscopic hysterectomy been slow? Results of an anonymous survey of Australian gynecologists. J Minim Invasive Gynecol 2007; 14(6):724-728.
6. Bickell NA, Earp J, Evans AT, Bernstein SJ. A matter of opinion about hysterectomies: experts' and practicing community gynecologists' ratings of appropriateness. Am J Public Health 1995; 85(8 Pt 1):1125-1128.
7. O'Hanlan KA, Dibble SL, Fisher DT. Total laparoscopic hysterectomy for uterine pathology: impact of body mass index on outcomes. Gynecol Oncol 2006; 103(3):938-941.
8. O'Hanlan KA, McCutcheon SP, McCutcheon JG. Laparoscopic hysterectomy: impact of uterine size. J Minim Invasive Gynecol 2011; 18(1):85-91.
9. Chopin N, Malaret JM, Lafay-Pillet MC, Fotso A, Foulot H, Chapron C. Total laparoscopic hysterectomy for benign uterine pathologies: obesity does not increase the risk of complications. Hum Reprod 2009; 24(12):3057-3062.
10. Heinberg EM, Crawford BL, III, Weitzen SH, Bonilla DJ. Total laparoscopic hysterectomy in obese versus nonobese patients. Obstet Gynecol 2004; 103(4):674-680.
11. Brezina PR, Beste TM, Nelson KH. Does route of hysterectomy affect outcome in obese and nonobese women? JSLS 2009; 13(3):358-363.
12. Mebes I, Diedrich K, Banz-Jansen C. Total laparoscopic hysterectomy without uterine manipulator at big uterus weight (>280 g). Arch Gynecol Obstet 2012.
13. Bijen CB, de Bock GH, Vermeulen KM, Arts HJ, Ter Brugge HG, van der Sijde R et al. Laparoscopic hysterectomy is preferred over laparotomy in early endometrial cancer patients, however not cost effective in the very obese. Eur J Cancer 2011; 47(14):2158-2165.
14. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009;(3):CD003677.
15. Wattiez A, Soriano D, Cohen SB, Nervo P, Canis M, Botchorishvili R et al. The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. J Am Assoc Gynecol Laparosc 2002; 9(3):339-345.
16. Altgassen C, Michels W, Schneider A. Learning laparoscopic-assisted hysterectomy. Obstet Gynecol 2004; 104(2):308-313.
17. Perino A, Cucinella G, Venezia R, Castelli A, Cittadini E. Total laparoscopic hysterectomy versus total abdominal hysterectomy: an assessment of the learning curve in a prospective randomized study. Hum Reprod 1999; 14(12):2996-2999.
18. Sokol AI, Chuang K, Milad MP. Risk factors for conversion to laparotomy during gynecologic laparoscopy. J Am Assoc Gynecol Laparosc 2003; 10(4):469-473.
19. Kondo W, Bourdel N, Marengo F, Azuar AS, Tran-ba-Vang X, Roman H et al. Surgical outcomes of laparoscopic hysterectomy for enlarged uteri. J Minim Invasive Gynecol 2011; 18(3):310-313.
20. Leonard F, Chopin N, Borghese B, Fotso A, Foulot H, Coste J et al. Total laparoscopic hysterectomy: preoperative risk factors for conversion to laparotomy. J Minim Invasive Gynecol 2005; 12(4):312-317.
21. Malik E, Buchweitz O, Muller-Steinhardt M, Kressin P, Meyhofer-Malik A, Diedrich K. Prospective evaluation of the systemic immune response following abdominal, vaginal, and laparoscopically assisted vaginal hysterectomy. Surg Endosc 2001; 15(5):463-466.
22. Ellstrom M, Bengtsson A, Tylman M, Haeger M, Olsson JH, Hahlin M. Evaluation of tissue trauma after laparoscopic and abdominal hysterectomy: measurements of neutrophil activation and release of interleukin-6, cortisol, and C-reactive protein. J Am Coll Surg 1996; 182(5):423-430.
23. Demir A, Bige O, Saatli B, Solak A, Saygili U, Onvural A. Prospective comparison of tissue trauma after laparoscopic hysterectomy types with retroperitoneal lateral transsection of uterine vessels using ligasure and abdominal hysterectomy. Arch Gynecol Obstet 2007.
24. Ribeiro SC, Ribeiro RM, Santos NC, Pinotti JA. A randomized study of total abdominal, vaginal and laparoscopic hysterectomy. Int J Gynaecol Obstet 2003; 83(1):37-43.
25. Atabekoglu C, Sonmezer M, Gungor M, Aytac R, Ortac F, Unlu C. Tissue trauma in abdominal and

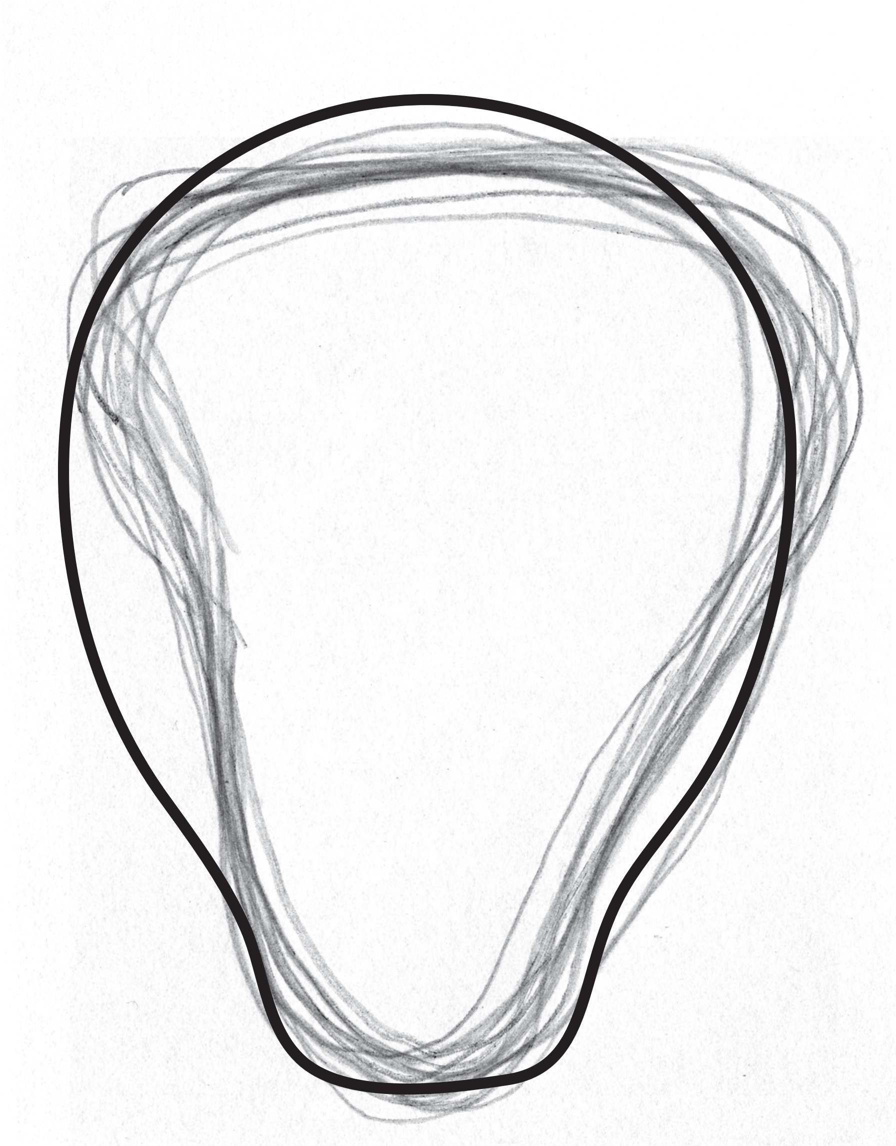
laparoscopic-assisted vaginal hysterectomy. J Am Assoc Gynecol Laparosc 2004; 11(4):467-472.

26. Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M et al. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Health Technol Assess 2004; 8(26):1-154.
27. Nieboer TE, Hendriks JC, Bongers MY, Vierhout ME, Kluivers KB. Quality of life after laparoscopic and abdominal hysterectomy: a randomized controlled trial. Obstet Gynecol 2012; 119(1):85-91.
28. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. J Minim Invasive Gynecol 2006; 13(3):183-189.
29. Kolkman W, van de Put MAJ, Jansen FW. Laparoscopic simulator: construct validity and establishing performance standards for residency training. Gynecol Surg 2008;(5):109-114.
30. Hiemstra E, Kolkman W, van de Put MA, Jansen FW. Retention of basic laparoscopic skills after a structured training program. Gynecol Surg 2009; 6(3):229-235.
31. Schijven MP, Jakimowicz J. The learning curve on the Xitact LS 500 laparoscopy simulator: profiles of performance. Surg Endosc 2004; 18(1):121-127.
32. Schaafsma BE, Hiemstra E, Dankelman J, Jansen FW. Feedback in laparoscopic skills acquisition: an observational study during a basic skills training course. Gynecol Surg 2009; 6(4):339-343.
33. Vassiliou MC, Feldman LS, Andrew CG, Bergman S, Leffondre K, Stanbridge D et al. A global assessment tool for evaluation of intraoperative laparoscopic skills. Am J Surg 2005; 190(1):107-113.
34. Chmarra MK, Klein S, de Winter JC, Jansen FW, Dankelman J. Objective classification of residents based on their psychomotor laparoscopic skills. Surg Endosc 2010; 24(5):1031-1039.
35. Feldman LS, Sherman V, Fried GM. Using simulators to assess laparoscopic competence: ready for widespread use? Surgery 2004; 135(1):28-42.
36. Feldman LS, Cao J, Andalib A, Fraser S, Fried GM. A method to characterize the learning curve for performance of a fundamental laparoscopic simulator task: defining "learning plateau" and "learning rate". Surgery 2009; 146(2):381-386.
37. Bolsin S, Colson M. The use of the Cusum technique in the assessment of trainee competence in new procedures. Int J Qual Health Care 2000; 12(5):433-438.
38. Lindenburg IT, Wolterbeek R, Oepkes D, Klumper FJ, Vandenbussche FP, van Kamp IL. Quality control for intravascular intrauterine transfusion using cumulative sum (CUSUM) analysis for the monitoring of individual performance. Fetal Diagn Ther 2011; 29(4):307-314.
39. Landheer ML, Therasse P, van de Velde CJ. The importance of quality assurance in surgical oncology. Eur J Surg Oncol 2002; 28(6):571-602.
40. Verleye L, Vergote I, Reed N, Ottevanger PB. Quality assurance for radical hysterectomy for cervical cancer: the view of the European Organization for Research and Treatment of Cancer--Gynecological Cancer Group (EORTC-GCG). Ann Oncol 2009; 20(10):1631-1638.
41. Peeters KC, van de Velde CJ. Surgical quality assurance in breast, gastric and rectal cancer. J Surg Oncol 2003; 84(3):107-112.
42. Hopper AN, Jamison MH, Lewis WG. Learning curves in surgical practice. Postgrad Med J 2007; 83(986):777-779.
43. Park IJ, Choi GS, Lim KH, Kang BM, Jun SH. Multidimensional analysis of the learning curve for laparoscopic colorectal surgery: lessons from 1,000 cases of laparoscopic colorectal surgery. Surg Endosc 2009; 23(4):839-846.
44. Axelrod DA, Kalbfleisch JD, Sun RJ, Guidinger MK, Biswas P, Levine GN et al. Innovations in the assessment of transplant center performance: implications for quality improvement. Am J Transplant 2009; 9(4 Pt 2):959-969.
45. Boulkedid R, Sibony O, Bossu-Salvador C, Oury JF, Alberti C. Monitoring healthcare quality in an obstetrics and gynaecology department using a CUSUM chart. BJOG 2010.
46. Biau DJ, Resche-Rigon M, Godiris-Petit G, Nizard RS, Porcher R. Quality control of surgical and interventional procedures: a review of the CUSUM. Qual Saf Health Care 2007; 16(3):203-207.
47. Tunitsky E, Citil A, Ayaz R, Esin S, Knee A, Harmanli O. Does surgical volume influence short-term outcomes of laparoscopic hysterectomy? Am J Obstet Gynecol 2010.
48. Shawki S, Bashankaev B, Denoya P, Seo C, Weiss EG, Wexner SD. What is the definition of "conversion" in laparoscopic colorectal surgery? Surg Endosc 2009; 23(10):2321-2326.
49. http://www.clinicalaudit.nl/. 1-7-2012.
50. Hiemstra E, Chmarra MK, Dankelman J, Jansen FW. Intracorporeal suturing: economy of instrument movements using a box trainer model. J Minim Invasive Gynecol 2011; 18(4):494-499.
51. Schreuder HW, van Hove PD, Janse JA, Verheijen RR, Stassen LP, Dankelman J. An "intermediate curriculum" for advanced laparoscopic skills training with virtual reality simulation. J Minim Invasive Gynecol 2011; 18(5):597-606.
52. Larsen CR, Soerensen JL, Grantcharov TP, Dalsgaard T, Schouenborg L, Ottosen C et al. Effect of virtual reality training on laparoscopic surgery: randomised controlled trial. BMJ 2009; 338:b1802.
53. Burkett D, Horwitz J, Kennedy V, Murphy D, Graziano S, Kenton K. Assessing current trends in resident hysterectomy training. Female Pelvic Med Reconstr Surg 2011; 17(5):210-214.

54. Pijnenborg JM, ter Haar JF. Innovations in surgery: the role of residents in the implementation of laparoscopic hysterectomy. J Laparoendosc Adv Surg Tech A 2011; 21(7):615-619.

Chapter twelve

Samenvatting, Acknowledgements, Authors and affiliations, List of publications, Curriculum Vitae, Dankwoord



Samenvatting

Voor de uterusextirpatie (baarmoederverwijdering) bestaan drie verschillende benaderingen; vaginaal, abdominaal (buiksnede) en laparoscopisch (sleutelgatoperatie). De vaginale uterusextirpatie geldt als de goud standaard, daar deze operatie over het algemeen het kortst duurt, gepaard gaat met weinig bloedverlies, geen uitwendige littekens geeft, relatief goedkoop is en een korte opnameduur en herstelperiode kent. Bij een onmogelijkheid om de uterus vaginaal te benaderen, bestaat er sinds 1989 het alternatief om de uterus laparoscopisch te verwijderen, naast de al veel langer bestaande abdominale uterusextirpatie. De laparoscopische methode kent voordelen ten aanzien van bloedverlies, infectierisico, herstelperiode en cosmetisch-esthetische overwegingen. Deze ‘minimaal invasieve’ benadering is echter duurder dan de buiksnede, kent een langere operatieduur en wordt als complex gekenmerkt met een langere leercurve voor de operateur.

In Nederland blijkt uit **hoofdstuk 2** de laparoscopische uterusextirpatie diffuus en matig geïmplementeerd te zijn in het gynaecologisch-chirurgische palet. Hoewel ziekenhuizen in het algemeen vaker kiezen voor de minimaal invasieve benadering, waar het bijvoorbeeld de buitenbaarmoederlijke zwangerschap of eierstokoperaties betreft, lijken de meer complexere ingrepen (met als exponent de laparoscopische uterusextirpatie) hierin achter te lopen. In veel ziekenhuizen worden weinig van deze operaties uitgevoerd, terwijl weinig ziekenhuizen veel van deze ingrepen voor hun rekening nemen.

Naast de complexiteit van de ingreep, lijken voorkeur en verwijs-gedrag van zowel operateurs als verwijzende collega’s van invloed te zijn op deze matige implementatie. Uit ons onderzoek zoals beschreven in **hoofdstuk 4** komt naar voren, dat ondanks basiskennis van de voordelen van de laparoscopische uterusextirpatie ten opzichte van de abdominale benadering, en er in hypothetische casuïstiek zelfs in de moeilijkere gevallen een voorkeur voor minimaal invasief benaderen bestaat, er in de praktijk zelden of nooit wordt doorverwezen. De operateurs zelf lijken soms afgeschrikt te worden door een hoge body mass index van de patiënt of preoperatief groot geschat uterusgewicht, terwijl we uit de literatuur weten, dat juist de adipeuze patiënt meer voordeel van de laparoscopische benadering ondervindt en dat de meerderheid van de adipeuze patiënten (>85%) ongecompliceerd laparoscopisch geopereerd kan worden. Uit ons onderzoek bleek tevens, dat er in Nederland een sterke groei is in het aantal gynaecologen dat de laparoscopische uterusextirpatie verricht. Op dit moment zegt 1 op de 9 gynaecologen deze verrichting uit te voeren. De helft van deze gynaecologen heeft minder dan 5 jaar ervaring. Van een stabiele implementatie kan tot dusver niet gesproken worden.

De laparoscopische uterusextirpatie kent drie verschillende subtypen; de totaal laparoscopische uterextirpatie (TLH, waarbij de gehele uterus met baarmoedermond en eventueel meenemen van de eierstokken laparoscopisch wordt verricht en hetzij vaginaal hetzij, na morcellatie via de insteekopening verwijderd wordt), de supracervicale laparoscopische uterusextirpatie (SLH, waarbij de baarmoedermond in het lichaam blijft en aldus de uterus (met eventueel de eierstokken) na verkleinen laparoscopisch verwijderd wordt) en de laparoscopisch geassisteerde vaginale uterusextirpatie (LAVH, waarbij een deel van de baarmoederverwijdering via de kijkbuis en een deel via de schede geschiedt). De TLH wordt het meest uitgevoerd in Nederland. De LAVH blijkt vooral bij 'beginnende' gynaecologen en bij gynaecologen die weinig laparoscopische uterusextirpaties uitvoeren populair (**hoofdstuk 2**). Onafhankelijk van ervaring blijkt juist deze techniek gepaard te gaan met meer bloedverlies en meer complicaties ten opzichte van de TLH en SLH en zou daarom bij voorkeur verlaten moeten worden (**hoofdstuk 3 en 5**).

In een grote prospectieve studie (de LapTop! studie), waarin 79 gynaecologen een jaar lang al hun laparoscopische uterusextirpaties registreerden, werd gekeken naar voorspellers van een goede uitkomst van de ingreep (**hoofdstuk 5**). Het uterusgewicht, de body mass index, preoperatieve gezondheid van de patient en het aantal buikoperaties in de voorgeschiedenis bepaalden naast het type laparoscopische uterusextirpatie de succeskans van de ingreep met betrekking tot bloedverlies, operatietijd en complicatierisico. Wanneer gecorrigeerd werd voor deze factoren, bleek ervaring van de operateur met deze ingreep een onafhankelijke voorspeller voor een goede klinische uitkomst. Deze leercurve bleek door te lopen tot ver voorbij de honderd ingrepen, veel verder dan de 30 ingrepen die eerder in andere (retrospectieve) studies werd verondersteld. Naast de leercurve bleek er ook een onafhankelijke 'operateursfactor' te bestaan. Dat wil zeggen, dat een operateur met twintig ingrepen ervaring, na correctie voor de moeilijkheid van de ingreep, soms beter kon presteren dan een collega met zestig ingrepen ervaring.

In de 1534 ingrepen, die tijdens deze LapTop! studie werden verzameld, werd ook gekeken naar de kans op een conversie (dat is het besluit tijdens de laparoscopische ingreep alsnog over te gaan tot het verrichten van een buiksnede). In **hoofdstuk 6** staat beschreven, dat de meerderheid van de 70 conversies (4.6%) werd verricht op basis van strategische overwegingen (vaak door bemoeilijkt zicht en/of een immobiele uterus door verklevingen met de buikwand). Van de 'reactieve' conversies was het merendeel het gevolg van een laparoscopisch niet te verhelpen bloeding. Een hoge body mass index of een groot uterusgewicht waren voorspellers voor een conversie, terwijl ervaring hierin niet een voorspeller bleek. Wel bleek er weer sprake van een onafhankelijke 'operateursfactor' in de besluitvorming tot een conversie; sommige operateurs kozen onafhankelijk van ervaring en gecorrigeerd voor de complexiteit van de patiënt vaker voor een conversie, dan andere operateurs.

Uit onze klinische studie naar nociceptieve en endocriene factoren in pijnperceptie bij de drie benaderingen van de uterusextirpatie, zoals beschreven in **hoofdstuk 7**, bleek dat de laparoscopische variant niet 'minimaal pijnlijk' bleek ten opzichte van de vaginale en abdominale tegenhanger, maar wel een snel(ler)e daling van de pijnscores postoperatief gevonden. Tevens bleek weinig toegevoegde waarde van een ruggeprik naast de conventionele narcose bij een laparoscopische uterusextirpatie.

In **hoofdstuk 8** beschrijven we, dat het aanleren en beklijven van de techniek van de laparoscopische uterusextirpatie door middel van een mentorship of fellowship effectief, veilig en duurzaam blijkt. In deze studie, waarin twee gynaecologen gedurende 20-30 ingrepen werden begeleid door een ervaren mentor bleken de operatieduur, indicatie en complicatierisico tijdens en na afsluiten van het 'meester-gezel'-trainingsprogramma vergelijkbaar tussen de lerende gynaecologen en hun mentor.

Onder andere vanuit de Inspectie voor de Gezondheidszorg is er een groeiende vraag naar indicatoren voor goede operateurs. In ons onderzoek in **hoofdstuk 9**, waarin 50 operateurs (die ook deelnamen aan de LapTop! studie) een laparoscopische knoop moesten leggen in een box trainer, bleek ervaring niet een discriminerende voorspeller voor een snelle en efficiënt gelegde knoop. Wanneer werd vergeleken met klinische uitkomsten zoals bloedverlies en operatieduur (na correctie voor voornoemde patiënt karakteristieken), bleek er tevens geen discriminerend verband te bestaan tussen deze klinische uitkomstmaten en de uitkomsten op de boxtrainer. Het 'op het droge' testen van operateurs heeft dus geen voorspellende waarde voor klinische uitkomsten op de operatiekamer. Het continu registreren van klinische uitkomsten, gecorrigeerd voor de 'complexiteit' van de patiënt en in vergelijking tot de gemiddelde operatie uitkomsten van alle operateurs bleek daarentegen wel degelijk zin te hebben, zo bleek uit ons onderzoek met behulp van 'cumulative summation', CUSUM analyse, beschreven in **hoofdstuk 10**. Op deze wijze kan binnen een beperkt aantal ingrepen gesignaleerd worden of een operateur sterk afwijkend van het gemiddelde opereert. Aldus kunnen (tijdig) risicofactoren geïdentificeerd worden (die mogelijk in de vaardigheid van de operateur, het team of het instrumentarium liggen) en op maat verbeterd.

Dit is noodzakelijk, aangezien in dit proefschrift is aangetoond, dat er een variatie in vaardigheid ten opzichte van de techniek bestaat waarbij de leercurve binnen de laparoscopische hysterectomie niet eindig blijkt. Daarom is het continu registreren van voorspellers van de kwaliteit van de ingreep alsmede haar uitkomsten van groot belang teneinde de patiëntveiligheid te kunnen waarborgen.

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List of publications

Twijnstra AR, Blikkendaal MD, van Zwet EW, de Kroon CD, Jansen FW.
Tailor made proficiency curves in laparoscopic hysterectomy: enhancing patient safety using cumulative sum analysis.
Submitted

Twijnstra AR, Hiemstra E, van Zwet EW, Balkema EI, Dankelman J, Jansen FW.
Intracorporeal knot tying in a box trainer as predictor of surgical outcome in advanced laparoscopy: how proficient is in vitro evaluation in experts?
Submitted

Twijnstra AR, Blikkendaal MD, van Zwet EW, Jansen FW.
Clinical relevance of conversion rate and its evaluation in laparoscopic hysterectomy.
Accepted in J Minim Invasive Gyn. 2012.

Twijnstra AR, Dahan A, ter Kuile MM, Jansen FW.
Nociceptive and stress hormonal state during abdominal, laparoscopic and vaginal hysterectomy as predictors of postoperative pain perception.
Gynecol Surg. 2012 September. Epub ahead of print

Blikkendaal MD, **Twijnstra AR**, Pacquee SC, Rhemrev JP, Smeets MJ, de Kroon CD, Jansen FW.
Vaginal cuff dehiscence in laparoscopic hysterectomy: influence of various suturing methods of the vaginal vault.
Gynecol Surg. 2012 Nov;9(4):393-400. (PMID: 23144640)

Twijnstra AR, Blikkendaal MD, van Zwet EW, van Kesteren PJ, de Kroon CD, Jansen FW.
Predictors of successful surgical outcome in laparoscopic hysterectomy.
Obstet Gynecol. 2012 Apr;119(4)700-8 (PMID: 22395145)

Rodrigues SP, de Burlet KJ, Hiemstra E, **Twijnstra AR**, van Zwet EW, Trimbos-Kemper TC, Jansen FW.
Ectopic pregnancy: when is expectant management safe?
Gynecol Surg. 22012 Nov;9(4):421-426. (PMID: 23144641)

Twijnstra AR, Stiggelbout AM, de Kroon CD, Jansen FW.
Laparoscopic hysterectomy: eliciting preferences of performers and colleagues via conjoint analysis.
J Minim Invasive Gynecol. 2011 Sep-Oct;18(5):582-8 (PMID: 21803663)

Twijnstra AR, Leenders SJ, Zeeman GG, Jansen FW.
Implementatie van de NVOG-complicatieregistratie: een schijnbaar ongecompliceerde exercitie?
Ned Tijdschr Obst Gyn 2010; 8:270-4.

Twijnstra AR, Blikkendaal MD, Kolkman W, Smeets MJ, Rhemrev JP, Jansen FW.
Implementation of laparoscopic hysterectomy: maintenance of skills after a mentorship program.
Gynecol Obstet Invest. 2010 Jun 16;70(3):173-178 (PMID: 20558991)

Einarsson JI, Vellinga TT, **Twijnstra AR**, Chavan NR, Suzuki Y, Greenberg JA.
Bidirectional barbed suture: an evaluation of safety and clinical outcomes.
JSLS. 2010 Jul-Sep;14(3):381-5. (PMID 21333192)

Twijnstra AR, Kolkman W, Trimbos-Kemper GCM, Jansen FW.
Implementation of advanced laparoscopic surgery in gynecology: national overview of trends.
J Minim Invasive Gynecol. 2010 May 13. (PMID: 20471917)

Twijnstra AR, Zeeman GG, Jansen FW.
A novel approach to registration of adverse outcomes in obstetrics and gynaecology: a feasibility study.
Qual Saf Health Care. 2010 Apr;19(2):132-7. (PMID: 20351161)

Twijnstra AR, Kianmanesh Rad NA, Smeets MJ, Admiraal JF, Jansen FW.
Twenty-first century laparoscopic hysterectomy: should we not leave the vaginal step out?
Gynecol Surg. 2009 Nov;6(4):311-316. (PMID 20234845)

Blikkendaal MD, **Twijnstra ARH**, Smeets MJ, Rhemrev JPT, Jansen FW.
Laparoscopische hysterectomie: veilige introductie van een nieuwe operatietechniek.
Ned Tijdschr Geneeskd. 2009;153:A255.

Twijnstra ARH, Jansen FW.
Hoe implementeer ik veilig de laparoscopische hysterectomie in mijn kliniek?
Reproductieve geneeskunde, gynaecologie en obstetrie anno 2009: 455-457.(ISBN 978-90-811646-5-8)

Jansen FW, **Twijnstra ARH**, NVOG Commissie Complicatieregistratie.
Complicatieregistratie voor Obstetrie & Gynaecologie van de NVOG; verslag van een pilotstudy.
Ned Tijdschr Obst Gyn 2007; 120: 35-40

Jansen FW, **Twijnstra ARH**.
Complicatieregistratie als kwaliteitsinstrument.
Ned Tijdschr Obst Gyn 2007; 120: 32-34.

Curriculum vitae

Dries Twijnstra werd op 14 december 1981 geboren in het Geertruide Ziekenhuis te Deventer. Hij groeide op in Diepenveen en voltooide in 2000 het Gymnasium Bèta aan het Geert Groote College te Deventer. Na uitloten werd hij in Leiden in dat zelfde jaar alsnog decentraal voor de studie Geneeskunde geselecteerd, welke hij in 2007 afrondde. Onder leiding van prof. dr. F.W. Jansen startte hij als student met landelijk onderzoek naar complicatieregistratie in de gynaecologie en verloskunde, waarna hij de kans kreeg in een AIOSKO constructie promotieonderzoek naar de implementatie van de laparoscopische hysterectomie te verrichten, waarvan de resultaten in dit proefschrift zijn beschreven.

Vanaf oktober 2010 is hij in opleiding tot gynaecoloog in het Bronovo Ziekenhuis te Den Haag (opleider Dr. C.A.G. Holleboom) en sinds oktober 2012 vervolgt hij deze in het Leids Universitair Medisch Centrum te Leiden (opleider Prof. Dr. J.M.M. van Lith).

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