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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/m² (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.

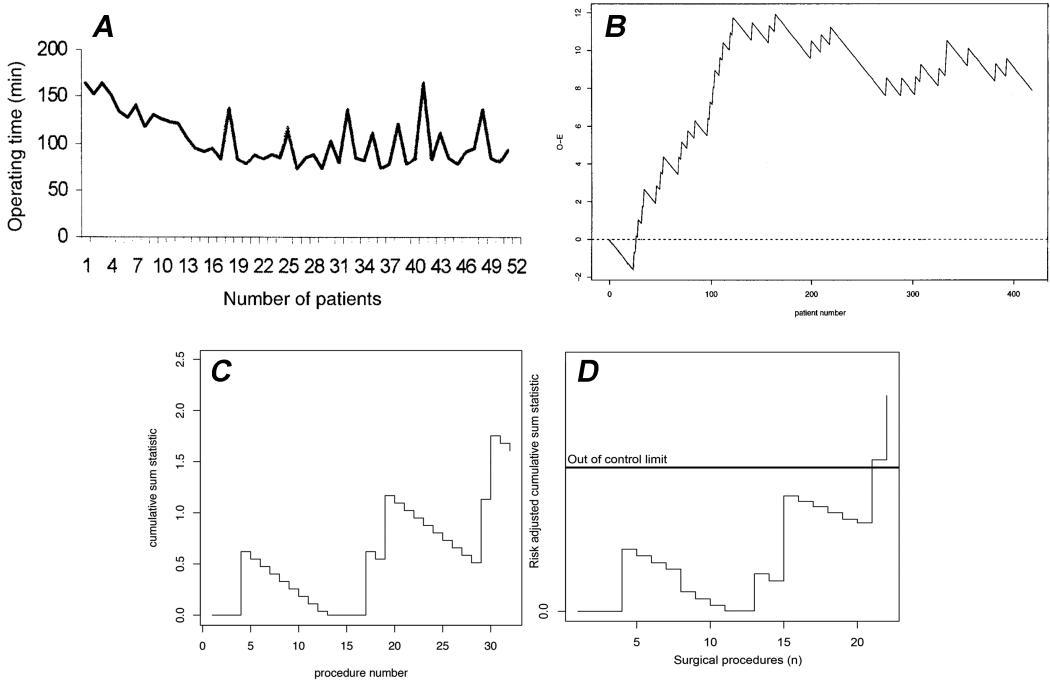


Figure 1 Evolution in learning curves. A = Classical, unadjusted, single outcome learning curve, B = Unadjusted Observed – Expected learning curve, without chart signalling, C = unadjusted CUSUM learning curve, D = Risk adjusted CUSUM learning curve.

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.

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