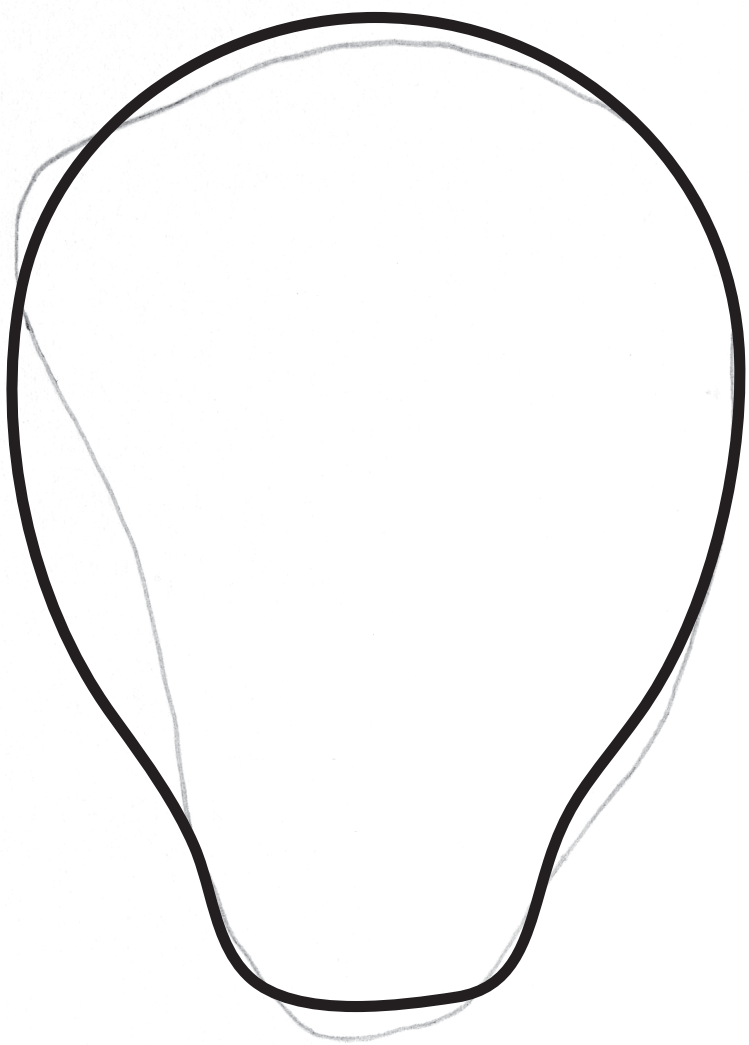
Chapter one

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

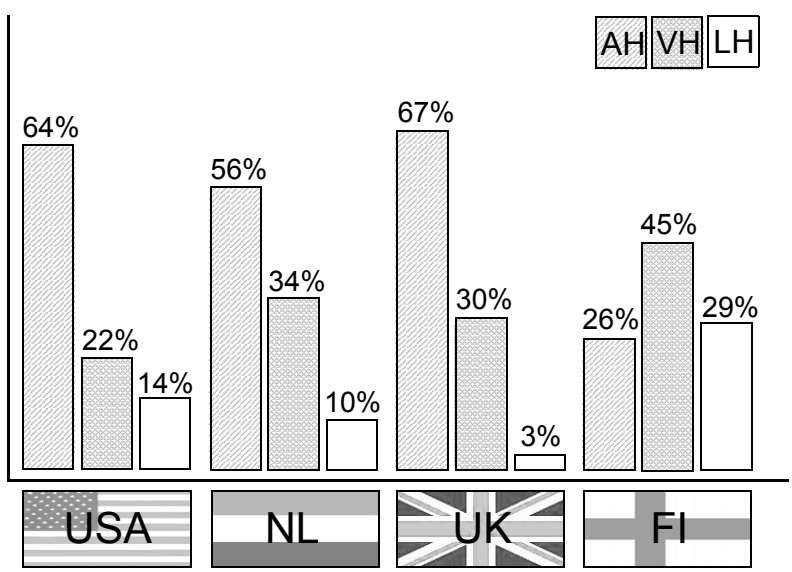


Figure 1 Global diversity in implementation rates. (USA = United States of America (source: Jacoby et al. 2009), UK = United Kingdom (source: Garry et al. 2005), NL = The Netherlands (source: this thesis), FI = Finland (source: Brummer et al. 2008)) AH = abdominal hysterectomy, VH = vaginal hysterectomy,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

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