

Department of Obstetrics and Gynecology
Helsinki University Hospital and University of Helsinki
Helsinki, Finland

TRAINING LAPAROSCOPIC SKILLS - CHANGES IN GYNECOLOGICAL SURGERY

Ewa Jokinen

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Supervised by: Docent Päivi Härkki, MD, PhD
Department of Obstetrics and Gynecology
Helsinki University Hospital
University of Helsinki
Helsinki, Finland

Docent Tomi Mikkola, MD, PhD
Department of Obstetrics and Gynecology
Helsinki University Hospital
University of Helsinki
Helsinki, Finland

Reviewed by: Docent Pauliina Aukee, MD, PhD
Department of Obstetrics and Gynecology
Central Finland Central Hospital
University of Eastern Finland
Jyväskylä, Finland

Docent Jaana Vironen, MD, PhD
Department of Gastrointestinal Surgery
Helsinki University Hospital
University of Helsinki
Espoo, Finland

Official opponent: Docent Jyrki Kössi, MD, PhD
Department of Surgery
Päijät-Häme Central Hospital
University of Turku
Lahti, Finland

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ABSTRACT

During recent decades, gynecological surgery has changed considerably, and this development affects surgical training. In Finland, the total number of gynecological procedures has decreased by 30% during the last ten years. An increasing number of basic procedures are now done under local anesthesia at outpatient clinics where training is much more demanding than in the operating room. Laparotomies are frequently replaced by laparoscopic procedures that require more complex skills than open surgery. Furthermore, operating room efficiency causes time constraints, while patients in general have more co-morbidities and the surgical procedures needed are more complex. Thus, for trainees all these factors make training more challenging, and the traditional apprenticeship model alone no longer ensures that trainees learn the needed skills.

In this dissertation study our aim was to assess developments in gynecological surgery in Finland and other Nordic countries by evaluating trends in hysterectomies. In addition, we investigated outcomes of traditional surgical training, as compared to systematic cognitive and manual pre-training on laparoscopic skills. We assessed separately the effect of pretraining on the trainee's first operative laparoscopy, and on the other hand, on laparoscopic hysterectomy, which is the most demanding laparoscopic procedure trainees perform.

In Study I, we assessed the numbers of different hysterectomies from the Nordic Medico-Statistical Committee and Finnish Institute for Health and Welfare databases. We compared outcomes of different hysterectomy methods between trainees and specialists collected from the FINHYST 2006 survey. In Finland, hysterectomy rates started to decline in 2003 and reached the rate of other Nordic countries in 2008. The rate of hysterectomy in Finland declined until 2017, and the laparoscopic method has been the most common method since 2013. In the outcome comparison, it was noted that the overall operative time was longer in trainees' operations. In the vaginal method, blood loss was higher in the trainees' group whereas in other hysterectomy methods or in total complication rates there were no differences between the groups.

In Study II, we evaluated the effectiveness of a cognitive web-course '*Basics in Gynecological Laparoscopy*' for trainees at various levels of experience. All trainees in Finland were invited to participate in this web-based anonymous study where the level of knowledge was evaluated before and after taking the course. Participants were allocated into three groups according to their experience. After the course, improvement in knowledge gain was detected in all three groups; the less experienced group reached the starting level of the middle group and the middle group reached the starting level of the most experienced group.

Abstract

In Studies III and IV, the effect of simulator training on operative skills was evaluated. Trainees with no experience in operative laparoscopy were recruited for Study III. Half of the group comprised the intervention group. They did the web-based course '*Basics in Gynecological Laparoscopy*' and trained basic skills with a virtual reality simulator. The control group took part in the traditional training only. The first live laparoscopic salpingectomy was video-recorded and evaluated. We found no differences in the surgical outcomes between the groups. In Study IV, the participants recruited were more experienced, but had not done laparoscopic hysterectomy as a first surgeon. All participants did the basic training as the intervention group in Study III. Furthermore, the intervention group trained with the hysterectomy module in a virtual reality simulator. The intervention group performed significantly better as evaluated by the Objective Assessment of Technical Skills and Visual Analog scale.

Our findings indicate that the traditional apprentice model alone is no longer sufficient in trainee education due to changes in gynecological surgery. In Study III, we did not detect differences in outcomes between the groups. However, in Study IV evaluating learning of a more advanced procedure, we demonstrated better performance after training with the procedural module in a simulator. Based on these studies, we suggest that simulator training should be mandatory, with allocated training time for the trainee and supervision time for the trainer for providing feedback. As innate skills are different, a proficiency-based curriculum results in more homogeneous skills. Less experienced trainees seem to benefit the most from simulator training, thus the training should be started in the earliest stage of training.

FINNISH SUMMARY

Gynekologinen kirurgia on muuttunut huomattavasti viimeisinä vuosikymmeninä, ja nämä muutokset vaikuttavat gynekologiaan erikoistuvien lääkäreiden kirurgiseen koulutukseen. Gynekologisten toimenpiteiden kokonaismäärä on vähentynyt Suomessa 30% viimeisen kymmenen vuoden aikana. Yhä enenevässä määrin monia perusleikkauksia tehdään paikallispuudutuksessa poliklinikalla, jossa uuden toimenpiteen oppiminen on vaativampaa kuin leikkaussalissa. Avoleikkaukset ovat pääosin korvattu tähytysleikkauksilla, joissa tarvittavat taidot ovat vaativampia. Nykyään leikkaussalissa pyritään myös entistä tehokkaampaan ajankäyttöön, samalla kun potilaat ovat keskimäärin sairaampia ja leikkaukset vaativampia kuin ennen. Kaikki nämä muutokset vaikeuttavat erikoistuvan vaiheen lääkärin koulutusta eikä perinteinen oppipoikamalli ainoana koulutusmuotona enää ole riittävä.

Tässä väitöskirjatutkimuksessa selvitimme gynekologisen kirurgian muutoksia Suomessa sekä muissa Pohjoismaissa käyttäen esimerkkinä kohdunpoistoleikkausten suuntauksia. Arvioimme perinteisen leikkauskoulutuksen onnistumista ja toisaalta ennen leikkaussalityöskentelyä tapahtuvan systemaattisen tiedollisen ja taidollisen koulutuksen vaikutusta tähytysleikkauksen oppimiseen. Arvioimme erikseen uuden koulutuksen vaikutusta erikoistuvan lääkärin ensimmäiseen toimenpiteelliseen tähytysleikkaukseen sekä toisaalta tähytysteitse tehtyyn kohdunpoistoleikkaukseen, joka on yksi vaativammista erikoistuvan lääkärin tekemistä leikkauksista.

Ensimmäisessä osatyössä keräsimme pohjoismaisesta Nordic Medico-Statistical Committee (NOMESCO) -rekisteristä sekä Terveyden ja hyvinvoinnin laitoksen rekistereistä kohdunpoistoluvut sekä eri leikkausmenetelmien osuudet. Vertasimme lisäksi erikoistuvien ja erikoislääkäreiden tekemien kohdunpoistoleikkausten tuloksia käyttäen FINHYST 2006 -aineistoa. Suomessa kohdunpoistomäärät alkoivat vähentyä vuoden 2003 jälkeen ja määrät saavuttivat pohjoismaisen tason vuonna 2008. Suomessa kohdunpoistojen vuosittainen kokonaismäärä pieneni vuoteen 2017 asti, ja vuoden 2013 jälkeen laparoskooppinen leikkaustapa on ollut yleisin. Erikoistuvien ja erikoislääkäreiden tekemien kohdunpoistoleikkausten vertailututkimuksessa todettiin, että erikoistuvien lääkäreiden tekemät leikkaukset kestivät pidempään. Emättimen kautta tehdyissä leikkauksissa oli enemmän verenvuotoa erikoistuvien lääkäreiden ryhmässä, kun taas muissa kohdunpoistotavoissa tai komplikaatioiden kokonaismäärissä ei ollut eroja ryhmien välillä.

Toisessa osatyössä selvitimme 'Gynekologisen laparoskopian perusteet' - verkkokurssin vaikuttavuutta eri kokemustason omaaville erikoistuville lääkäreille. Tähän sähköpostipohjaiseen nimettömään tutkimukseen kutsuttiin kaikki gynekologiaan erikoistumassa olevat lääkärit. Tietotaso tutkittiin ennen ja jälkeen kurssin läpikäymisen. Osallistujat jaettiin kolmeen ryhmään kokemustason

mukaisesti, ja kaikissa kolmessa ryhmässä tietotaso nousi merkittävästi. Kurssin käytyään kokemattomin ryhmä saavutti samat pisteet kuin keskiryhmä tutkimuksen alussa. Vastaavasti keskiryhmä saavutti kokeneiden ryhmän lähtötason.

Sekä kolmannessa että neljännessä osatyössä tutkimme simulaattoriharjoittelun vaikutusta leikkaustaitojen oppimiseen. Kolmanteen tutkimukseen osallistuvat olivat kokemattomia erikoistuvia lääkäreitä, jotka eivät vielä olleet tehneet itse toimenpiteellisiä tähytysleikkauksia. Puolet osallistujista muodostivat interventioryhmän, jotka tekivät 'Gynekologisen laparoskopian perusteet' - verkkokurssin sekä perusharjoitteita virtuaalisella simulaattorilla. Kontrolliryhmä osallistui ainoastaan perinteiseen koulutukseen. Ensimmäinen oma laparoskooppinen munanjohtimen poistoleikkaus videoitiin ja arvioitiin. Tässä tutkimuksessa interventioryhmän ja kontrolliryhmän tekemien leikkausten tuloksissa ei todettu eroja. Neljänteen tutkimukseen otetut erikoistuvat lääkärit olivat kokeneempia, mutta he eivät vielä olleet itse tehneet laparoskooppisia kohdunpoistoleikkauksia. Kaikki osallistujat suorittivat saman harjoitusohjelman kuin interventioryhmä kolmannessa osatyössä. Tämän tutkimuksen interventioryhmä harjoitteli lisäksi virtuaalisen simulaattorin kohdunpoisto-ohjelmalla. Interventioryhmän tekemät kohdunpoistoleikkaukset sujuivat paremmin, kun ne arvioitiin leikkaustaitojen arviointilomakkeita käyttäen.

Tutkimustuloksemme mukaan oppipoikamalli yksistään ei enää turvaa riittävää koulutusta johtuen gynekologisessa kirurgiassa tapahtuneista muutoksista. Kolmannessa osatyössä emme saaneet eroja tutkimusryhmien leikkaustulosten välille. Sen sijaan neljännessä osatyössä vaativan toimenpiteen harjoittelu virtuaalisen simulaattorin toimenpideohjelmalla tuotti paremman leikkaustuloksen kuin ilman simulaatioharjoitusta.

Simulaattoriharjoittelun pitäisi olla pakollista, ja siihen pitäisi varata työaika sekä erikoistuvalla lääkärillä että ohjaajalla palautteen antamisen mahdollistamiseksi. Koska synnynnäiset taidot ovat erilaiset yksilöiden välillä, osaamisperustainen harjoitteluohjelma johtaa tasalaatuisempiin taitoihin. Kokemattomammat erikoistuvat lääkärit tuntuivat hyötävän simulaattoriharjoittelusta eniten, joten systemaattinen harjoittelu pitäisi aloittaa heti erikoistumisvaiheen alussa.

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications:

- I Jokinen E, Brummer T, Jalkanen J, Fraser J, Heikkinen AM, Mäkinen J, Sjöberg J, Tomàs E, Mikkola TS, Härkki P. Hysterectomies in Finland in 1990-2012: comparison of outcomes between trainees and specialists. *Acta Obstet Gynecol Scand*. 2015 Jul;94(7):701-707.
- II Jokinen E, Mikkola TS, Härkki P. Evaluation of a Web Course on the Basics of Gynecological Laparoscopy in Resident Training. *J Surg Educ*. 2017 Jul - Aug;74(4):717-723.
- III Jokinen E, Mikkola TS, Härkki P. Effect of structural training on surgical outcomes of residents' first operative laparoscopy: a randomized controlled trial. *Surg Endosc*. 2019;33(11):3688-95.
- IV Jokinen E, Mikkola TS, Härkki P. Simulator training and residents' first laparoscopic hysterectomy: a randomized controlled trial. *Surg Endosc*. 2019. Doi 10.1007/s00464-019-07270-3. Epub ahead of print.

The publications are referred to in the text by their roman numerals. The original publications are reprinted with permission of the copyright holders. In addition, some unpublished material is presented.

ABBREVIATIONS

AH	Abdominal hysterectomy
FLS	Fundamentals of Laparoscopic Surgery
GESEA	Gynecological Endoscopic Surgical Education and Assessment
GRS	Global rating scale
LH	Laparoscopic hysterectomy
LH-OSATS	Hysterectomy specific form for objective structured assessment for technical skills
NOMESCO	the Nordic Medico-Statistical Committee
NRS	Numeric rating scale
OR	Operating room
OSA-LS	Salpingectomy specific form for objective structured assessment for technical skills
OSATS	Objective Assessment of Technical Skills
PBA	Procedure-based assessment
SD	Standard deviation
THL	the Finnish Institute for Health and Welfare (Terveyden ja hyvinvoinnin laitos)
VAS	Visual Analog scale
VH	Vaginal hysterectomy
VR	Virtual reality

INTRODUCTION

The first diagnostic laparoscopy was done at the beginning of the 20th century, followed by the first operative laparoscopy in 1933 (1). Alongside new technological inventions during the 40s to 60s, gynecologists and surgeons developed laparoscopic surgery further. The first trainer to teach hand-eye coordination and suture-tying techniques was introduced in 1982. After the video-guided laparoscopic technique was invented in 1986, more advanced surgical procedures were described (1), and laparoscopic methods started to challenge open techniques in all specialties.

Advantages of laparoscopic surgery include less surgical trauma, shorter hospital stay and recovery, better operative visibility, and better cosmetic outcome (2). Learning the laparoscopic method is different from open surgery, operational time is longer than in open surgery (2) and the beginning of the learning curve is often associated with an increased complication rate (3).

Trainees and the entire surgical education are under several simultaneous pressure factors (4). The traditional way of teaching surgical skills, where the trainee learns in the operating room (OR) under the guidance of a senior surgeon, has been questioned due to patient safety and ethical concerns (5). In the Netherlands, the Dutch Health Care Inspectorate has evaluated risks of minimally invasive surgery and demanded training to be improved (6). Furthermore, reforms in specialist training in the United Kingdom and the European Working Time Directive have reduced working hours and shortened the training period, thus decreasing opportunities for live surgery for trainees (7). In Finland, the total number of gynecological operations has also been declining (thl.fi). In the US, where the number of procedures for the trainees is sufficient, it is necessary to prove the competence in credentialing programs before working in the OR (8, 9). Currently, patients in the teaching hospitals have more co-morbidities, the surgery needed is more complex, and there are increased demands for OR efficiency (10, 11). Some of these issues are global, while others depend on the local practice and resources. All training programs, however, face these challenges.

To resolve the demands for surgical training, medical educators followed the example of e.g. aviation (12). The use of simulators and training outside the OR prior to live surgery, became part of the solution. In the past two decades, the number of publications on validation studies of different simulators, training programs, and learning and teaching surgical skills has gradually increased (13, 14). Implementation of training programs with simulator training have been surprisingly difficult, as the contents of an adequate training program has not been defined (13, 15).

The objective of this dissertation study was to evaluate developments in hysterectomy methods and most importantly, trainees' surgical education in

Introduction

gynecological laparoscopy in Finland. We compared hysterectomy outcomes between trainees and specialists to assess how effective the education has been before. In addition, we conducted an effectiveness study on national cognitive e-learning material. This course was then combined with the simulator training program to evaluate the effect of pre-training on learning laparoscopic procedures. We assessed the impact of the training curriculum on one of the basic adnexal procedures, but also on hysterectomy, being one of the most difficult procedures trainees perform.

REVIEW OF THE LITERATURE

Developments in gynecological surgical practice

In Finland, the total number of periods of care with gynecological surgical procedures in the OR has reduced by 40% between 2006-2018 (thl.fi) (Figure 1). The NOMESCO procedure group L (Female genital organs) includes abdominal, vaginal and laparoscopic procedures concerning uterus, adnexa, vagina, and vulva due to both benign and malignant indications. The number of operations has declined due to a broader selection of conservative treatments and alternative outpatient procedures. Annual hysterectomy numbers have decreased (16) because of effective medications like the levonorgestrel releasing intrauterine device (17) and ulipristalasetat, and the number of female sterilizations have diminished by more than 80% between 1999-2018 (thl.fi). In addition, Finnish guidelines for operative treatment in gynecology were released in 2005, setting clear indications for various surgical procedures, thus, decreasing their numbers.

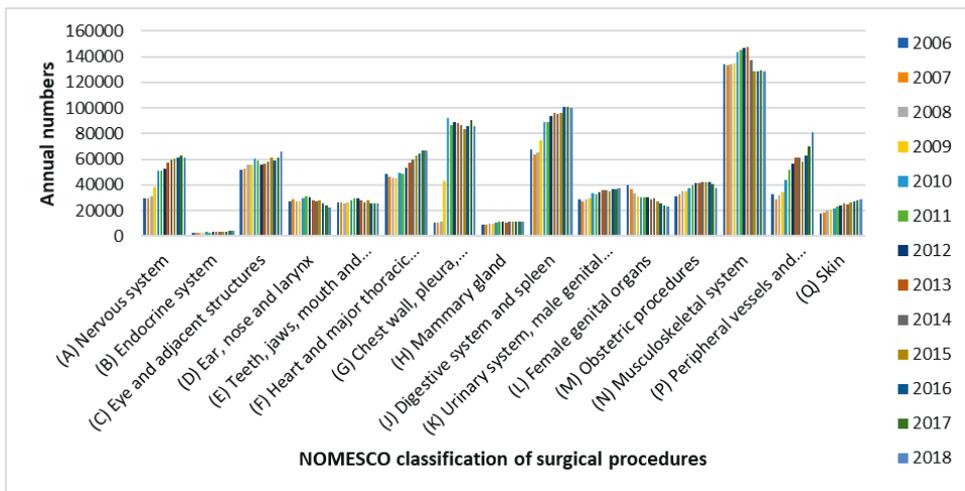


Figure 1. Annual numbers of periods of care with surgical procedures including day surgery according to NOMESCO classification of surgical procedures in Finland (thl.fi).

Similar changes are also seen in some other surgical specialties. In the NOMESCO procedure groups D (Ear, nose and larynx), E (Teeth, jaws, mouth and pharynx), and N (Musculoskeletal system), procedure numbers have been slightly declining (Figure 1). In some conditions, operative treatments are now replaced by more conservative alternatives, resulting in declining numbers, e.g., of operative arthroscopies (18, 19).

Thus, these developments in surgery may also affect training and learning operative skills in other specialities.

Outpatient surgery has increased, and training a new procedure is much more demanding there as compared to the same procedure in the OR, because the procedure is done under local anesthesia. In Finland in 2017, about 60% of operative hysteroscopies were done in outpatient clinics (thl.fi). The respective number was around 10% for anterior colporrhaphies and 25% for vaginal stress urinary incontinence sling procedures.

Surgical techniques have changed with the increasing number of alternative procedures. Mini-invasive surgery is recommended, but the learning period is often longer in these delicate procedures (3). In hysterectomies, both vaginal, laparoscopic, and abdominal methods are used, and in addition to vaginal and abdominal methods, trainees are assumed to learn the demanding laparoscopic technique as well. In Finland, the laparoscopic method is the first option in benign adnexal surgery.

The effectiveness and productivity in the OR have become highly important (5) generating time constraints in training. At the same time, safety aspects are essential (9), patients have more co-morbidities, and surgeries performed are more complex (5, 10). Thus, the OR is hardly the optimal place for training basic operative skills.

For trainees, all these changes mean fewer patients in the OR and challenges in gaining operative experience. Thus, the case numbers in the OR are often too few for sufficient learning using solely the traditional apprentice model. Basic surgical skills should be learned outside the OR and operative outpatient clinics before live surgery.

Surgical skills and learning

Surgical skills consist of cognitive, technical and non-technical skills (9) (Figure 2). Technical skills needed in laparoscopic surgery differ from open surgery in several aspects. Laparoscopic surgery with long instruments through fixed ports cause the fulcrum effect and limitations to degrees of freedom. The two-dimensional picture of the three-dimensional surgical field require hand-eye-coordination, and the depth dimension needs practice. In addition, during laparoscopic surgery, the use of both the dominant and the non-dominant hand is needed, while the haptic feedback, e.g. the sense of touch, is deficient. Thus, learning these skills requires specific and different training methods compared to open or vaginal surgery.

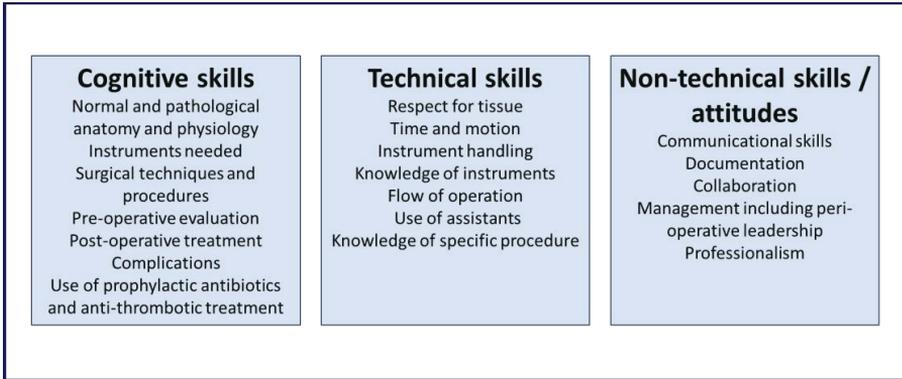


Figure 2. Contents of cognitive skills (20), technical skills (21), and non-technical skills (22) comprising surgical skills.

As the learning curve in laparoscopic surgery is thought to be longer than in open surgery, the basic training should be started before live operations (23). The basic psychomotoric skills and techniques needed in laparoscopic surgery can be acquired in training with models (24), like simulators. Skills acquisition is characterized by two main principles (12). The first is that the performance is progressed in a non-linear manner, meaning that at first the rate of learning is fast and slowing thereafter (Figure 3).

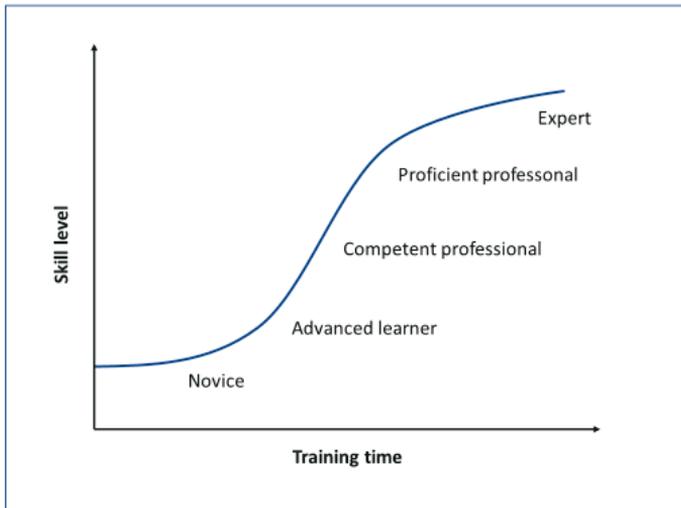


Figure 3. Increase in skill level according to training time from novice to expert. Modified from White et al (12).

The second principle is that during skill progression the performance is first conducted by explicit rules, and the performance becomes step by step more automatic. Learning complex manual skills can be divided to three stages: cognitive, associative, and autonomous stage (11). At the first stage, the trainee understands the task at the cognitive level. At the associative stage, the trainee learns how to perform the task, and gradually the performance becomes effortless. At the final stage, the movements become automated. This automatization differentiates a novice from an expert. A novice focuses on the usage of instruments and hand movements, while an expert focuses on the outcome of the surgical step and on the environment (12). Unlike the expert, background noise like music disturbs the novice from concentrating on the task. On the contrary, concentrating, e.g., on movement details may even worsen the performance of an expert because of disturbance in the automatization (20).

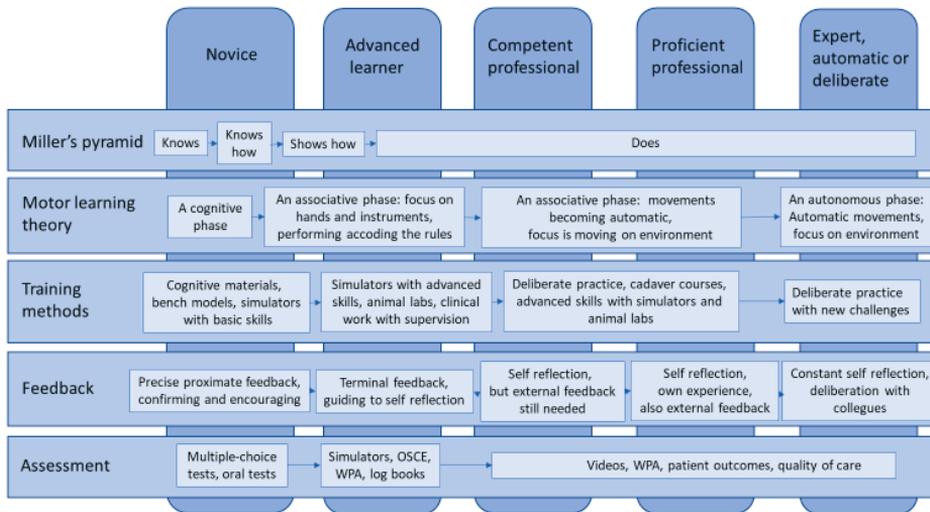
Simulator training offers almost an optimal learning environment. It is possible to train a certain skill or procedure repeatedly until the movements are smooth and the performance becomes automatic. In simulator training the basic objective for trainees is to achieve these automatic movements (20). Another objective for simulator training is to learn what not to do (20). Making errors while training with simulators is almost recommended, because then the trainee is forced to discontinue and reflect and learn from these mistakes. Simulator training enables the learner to observe the whole surgical environment, understand the reason for the error and what is needed for a better outcome (12).

Pre-training before working in the OR enables the trainee to focus on a distinct case while operating; in pathological anatomy, advanced surgical techniques and in the procedure itself (20). The effect of pre-training in cognitive skills while doing an open fascial closure was evaluated (25). An assistant read an article on wound complications for both the intervention and control groups, and after the operation, a multiple choice test was carried out. In this study, the pre-trained group had significantly better results in the theoretical test, being in concordance with the theories of motor learning (12). Thus, with automatic movements, attention may be paid elsewhere, for instance, on a cognitive task. This is important particularly for novices, since diverse information on several topics is transmitted while operating. When trainees are pre-trained with basic technical skills, they are able to concentrate on learning cognitive and non-technical skills, along with more advanced technical skills (20, 25).

The theoretical basis for learning surgical skills is best explained by constructive and experimental learning theories (26). An example of adult learning theories is Miller's pyramid (27), where the base of the skill is the theoretical knowledge and how the skill is performed (Figure 4). At that level, the trainee comprehends the action and can explain it (28). In the next level, the trainee performs the task and is able to show how the action is done. Only in the fourth level is the trainee able to do the task

independently. Miller’s pyramid is actually well in concordance with the motor learning theories.

When training a new task, regular feedback and self-reflection are essential for achieving a good performance and for reducing anxiety (28). This has been shown to result in better skills and their recollection (11). For novices, correcting feedback should be given immediately when training a new task (12). As the performance progresses, the feedback should be given as summative after training the task (11). Feedback changes from external to self-reflecting, as the performance becomes more independent. Theoretical tests can be used in the levels of ‘knows’ and ‘knows how’, whereas in the level of ‘shows how’ simulated environments or simulators can be used (29). Live surgery may be assessed by workplace-based assessment tools (Figure 4).



OSCE Objective Structured Clinical Examination
WPA Workplace-based assessment

Figure 4. Development of operative skills, training methods, feedback, and assessment according to level of expertise. Modified from Miller et al. (27) , White et al. (12), Stefanidis et al. (11), and Wragg et al.(29)

Learning of cognitive skills

The foundation of learning a new skill lies on theoretical knowledge and how the skill is performed (11, 27). This theoretical content is diverse starting with the meaning of this new skill and ending with complications associated with it.

The traditional way of transmitting information includes lectures and books along with clinical work, where the learner is a relatively passive receiver of information. The new generation of trainees is active in their learning (30), and they prefer to use new medical technologies (31). Consequently, medical teachers have started to use new learning strategies like a flipped classroom, and blended or spaced learning (30, 32). With these new learning modalities, the information also needs to be offered so that the learner can be active.

Computer technology offers multi-functional platforms for delivering information (32) called e-learning in education (33). E-learning contents are diverse: it comprises all instructional material, lessons, modules or complete courses, portals, repositories and ePortfolios, but also chat forums and learning assessment (30). Advantages of e-learning include the possibility for learners to choose where, when and how to study, as well as materials that are easily accessible and easy to update (32, 33). The course content is also standardized (30). On the other hand, in e-learning the initial costs are high. Special technical support may be needed, and studying on-line may limit social connections (32, 33).

Many universities and organizations offer students modular learning possibilities and large quantities of on-line materials (33, 34). Certification programs, like Fundamentals of Laparoscopic Surgery (FLS) in the United States and Gynecological Endoscopic Surgical Education and Assessment (GESEA) in Europe, have their own theoretical materials on-line. These materials consist of lectures, files with texts, diagrams and photos, and surgical videos. In the GESEA program each topic is followed by a test to ensure learning.

In gaining knowledge the effectiveness between internet based and non-internet based material did not differ in a meta-analysis (35). In knot-tying skills, watching a video is superior compared to reading a text with pictures in order to understand this new skill (36). Thus, e-learning is adding new possibilities for teaching surgical skills (32) and therefore, the traditional model and e-learning should not be seen as alternative, but rather as complementary (33).

Training of manual skills

After understanding the theoretical base of a new skill, the trainee begins to train the action. Besides clinical work, human cadavers, animal models, and various simulators provide training environments for training manual skills.

Clinical practice

In the traditional apprenticeship model, the trainer first shows how a specific task is done. Then the trainee does part of the task under guidance. Step by step, the trainee takes more responsibility for the task, and finally the trainee is able to do the task independently.

In order to progress, the training period should be continued with focus oriented and repeated practice of a certain activity with the intention of improving the performance, i.e. deliberate practice (11). This requires time, energy, and motivation (37), since plain repetition does not ensure that the performance is improved. Either external or self-reflecting immediate feedback is essential for skill development (9). Mentoring programs provide feedback and coaching that are based on deliberate practice (38), allowing the accomplishment of true expertise (10). Even experts may improve their performance by monitoring their colleagues' manners and innovating new ones and thus, there is no limit for a maximal performance (37).

The apprenticeship model does not solely ensure learning required operative skills, since the exposure on live patients has diminished. This has created a need to move part of the training to skill laboratories (10). Basic surgical skills can be acquired outside the OR, but the final mastering of a new skill is reached only in live surgery. When the basic skills have been acquired in advance, the trainee is able to more quickly focus on advanced topics, like pathological anatomy, advanced surgical techniques, and non-technical skills (10). This is likely to shorten the learning curve in the OR and expedite the objectives set for the trainee education.

Human cadavers

Cadavers offer an almost complete model for learning anatomy and training surgical skills and procedures. Using the same equipment as in the OR, it is possible to perform surgical laparoscopic procedures starting from the insufflation and setting the primary trocar, ending with closing the wounds. The preservation method has an impact on tissue handling and simulation fidelity (39, 40) and in medical education, cadavers used are fresh, fresh frozen, or embalmed with different kinds of fixation methods (41). The main difference compared to real operations is that with cadavers it is not possible to demonstrate bleeding. Reperfused cadavers offer high fidelity models for training vascular procedures in plastic surgery (42, 43).

Cadavers are found to be superior in teaching surgical anatomy compared to other modalities (44, 45). Cadaver training improves self-confidence in manual skills and increases satisfaction with training curriculum among residents (46-48). Residents in the intervention group were more satisfied with their anatomic training, when evaluating the effectiveness of a one-day laparoscopic cadaveric dissection on basic

anatomical knowledge among residents in obstetrics and gynecology (49). In final anatomical tests, there was no difference between the intervention and control groups, although the intervention seemed to improve three-dimensional understanding of anatomy. This may be important, because visuo-spatial ability has a clear impact on learning minimally invasive surgery and surgical procedures (50).

Though cadaveric dissections offer advantages to surgical education, there are ethical concerns about their use, and their effectiveness is poorly demonstrated (51) as many studies focus on participants' self-confidence and satisfaction. Not in every country or in every hospital are human cadavers available for postgraduate training. With procedural modules, virtual reality (VR) simulators may be the most cost-effective alternative (52).

Animal models

In surgical education, animal models offer an opportunity to train management of bleeding tissue. The porcine model is most often used, but different training programs include also rabbit, canine and chicken models (53, 54). Animals are anesthetized and euthanized after the training, but models without sacrificing the animals have also been described (54).

In training laparoscopic surgery, the main object with the animal models, is to train advanced surgical skills like dissection, suturing and use of energy sources (53), to develop new surgical techniques (55) and to train complex procedures (53, 56, 57). The effectiveness studies are few (58), but some studies show subjective satisfaction (56).

Animal labs are not available in every teaching hospital due to cost and also ethical issues, and the effectiveness remains unproven. Basic laparoscopic skills and techniques can be learned by using box trainers, and VR simulators produce realistic models for procedural training (56, 57).

Bench models

A bench model consists of a platform with different training materials for different tasks (Figure 5). This is often used for training skills needed in open surgery since the trainee has a direct view of the training board. Training material may be artificial like silicon or plastic, organic like fruits, or parts of non-live animal like skin, tongue and bowel (8, 59). These models may be used to train skin incision, different sutures, knots, biopsy techniques, skin grafts, and surgical flaps (59). Pulsatile, tissue based models have been developed for training skills needed in vascular surgery (60). Bench models also enable to train vaginal hysterectomy (61), bowel anastomosis and anal sphincter repair (8).

The effectiveness of training in bench models has been proven in many studies (8). It appears that the inexperienced residents benefit more from basic exercises than the more experienced ones. It has been shown that skills gained in the artificial bench model are transferred to the OR, e.g., on fascial closure (25). In addition, advantages of the bench models includes inexpensiveness and the possibility to use artificial materials and the same equipment as in the OR (8).

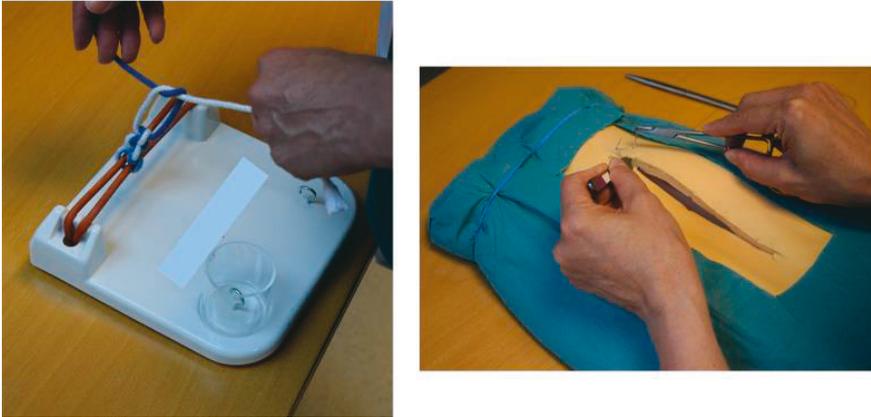


Figure 5. Bench models for training knot tying and suturing.

Box trainers

Box trainers, or video trainers, ('black boxes'), consist of two main components: a box or a covered training platform and an image transmission chain (Figure 6). They are suitable for training endoscopic skills since the trainee has only an indirect view of the training board. The platform allows the use of physical training objects, like pins, beads and threads, but also biological material and even anatomical models in a 3-dimensional environment. The image transmission chain converts this 3-dimensional picture to 2-dimensional on the chosen monitor. This may be done by conventional laparoscopic cameras, but also with web-cameras, or with smartphones and tablets by using the video function. The training is done by typical laparoscopic instruments, being one of the main advantages of this training model. In addition, box trainers are inexpensive, as it is possible to use just a cardboard box and a tablet (62), but commercial units are also available.

The training is typically initiated by practicing basic psychomotor skills, such as hand-eye coordination and bi-manual dexterity needed when working simultaneously with two hands. Some models allow the trainee to insert the trocars and to perform a procedure with an anatomical artificial model or even with a pulsatile organ perfusion model of animal origin (24, 63) or with 3D-printed patient-specific organs

and vasculature (52). In addition, box trainers are very useful for training more advanced skills, like laparoscopic suturing (64).



Figure 6. Examples of a box trainer and a virtual reality simulator.

The effectiveness of learning basic operative skills with a box trainer has been demonstrated in many studies (65-68). Skills acquired with a box trainer have been proven to be transferred to the OR (66, 68-76) (Table 1). In a Cochrane review, the box model training appears to improve technical skills for trainees with no laparoscopic experience (77), and there appears to be no significant differences between the different methods of box model training. However, another Cochrane review on box model training among trainees with limited laparoscopic experience (78) revealed that when the assessment was made in a single operative procedure, the box training could decrease the operative time, while there is only very low quality evidence on skills improvement.

Box trainer models possess unique benefits in addition to common advantages of simulator training; they allow the trainee to use the same instruments as in the OR and the training objects give haptic feedback. Furthermore, the models are simple, and trainees may perform exercises even at home. The main problem with box trainers concerns assessment. An assessor is needed to evaluate the performance, and some of the metrics are difficult to assess objectively. Validation of a testing protocol is complicated, but this has been done with the Laparoscopic Skills Testing and Training (LASTT) model (79) and the Suturing and knot tying Training and Testing (SUTT) method (64) used in the European GESEA program (80). The validated form

Table 1. Published studies on evaluating the effect of box trainer on human operations.

The study	Participants and their number	Intervention	Controls	Assessed procedure	Outcome measures	Results
Scott et al. 2000 (68)	27 surgical residents (PGY 2-3)	Box trainer Basic skills and suturing 10 x 30min	No formal training	LCC	OSATS-GRS	Intervention group performed better (p=0.007)
Hamilton et al. 2001 (65)	21 surgical residents (PGY 1,3 and 4)	Instructional video and interactive CD-ROM Box trainer with procedural module 10 x 30min sessions	No additional training	Laparoscopic total extraperitoneal hernia repair	OSATS-GRS Knowledge of the procedure Ability for the procedure	Intervention group performed better (p<0.05), cognitive test better (p=0.01) and they felt their ability improved (p=0.01) compared to controls
Coleman et al. 2002 (69)	18 gynecological residents (PGY 3-4)	Orientation week Video trainer 5 basic drills 10 x 30min	Orientation week, then no formal practice sessions	Partial salpingectomy	Global Skill Assessment: Tool Operative time	In intervention group the performance score improved (p=0.015) and operative time reduced more (p<0.0001)
Banks et al. 2007 (70)	20 gynecological residents (PGY 1)	1 hour session of didactics and 2 hours session of box trainer and bench model	Traditional teaching	Bilateral tubal ligation	Task-specific checklist OSATS-GRS Pass/fail -rate	Intervention group performed better in checklist (p=0.002), in global score (p=0.003), in pass rate (p=0.003)
Stroka et al. 2010 (71)	17 junior residents	Box trainer FLS basic skill tasks until proficiency	No additional training	LCC	GOALS	Intervention group performed better (p=0.004), they improved their performance more (p=0.0005)
Gala et al. 2013 (67)	102 gynecological residents	Box trainer FLS tasks until proficiency	Traditional teaching	Bilateral tubal ligation	OSATS-GRS	Intervention group performed better (p=0.03)
Bansal et al. 2014 (72)	17 general surgery residents	Porcine phantom model 10 x LCC	Standard training	LCC	GOALS, task-specific checklist, VAS, overall competence, operation time	In intervention group statistically better outcomes in GOALS, checklist, VAS, and operation time
Akdemir et al. 2014 (73)	40 gynecological residents (PGY 1-2), 20 senior residents as controls	LapSim VR simulator 8 basic skills or box trainer 7 basic skills 1 h/week for 4 week	Controls were senior residents (PGY5) with no simulator training	Bilateral tubal ligation	OSATS-GRS, operating time	No difference between VR and box-trainer groups. Simulator groups performed better (p<0.01) and faster (p<0.01-0.03)
Patel et al. 2016 (74)	22 gynecological residents (PGY 1-4)	Theoretical material and educational session 3h, porcine cadaver single session	Traditional training	Salpingectomy	OSATS-GRS for laparoscopic skills, comfort levels	Intervention group performed better (p=0.01), comfort level increased in the intervention group (p=0.02), while no change in controls
Sleiman et al. 2019 (75)	39 gynecologists novices in hysteroscopy	Box trainer 1 training session with basic hysteroscopic skills	No training	Diagnostic hysteroscopy with punch biopsy	Check-list Grading in taking the biopsy poor/good/excellent/failed	Intervention group performed better (p<0.001) and rated higher in taking the biopsy (p<0.001)

PGY Postgraduate year

LCC Laparoscopic cholecystectomy

OSATS-GRS Objective structured assessment for technical skills form for global rating skills

FLS Fundamentals of Laparoscopic Surgery

GOALS Global Operative Assessment of Laparoscopic Skills

VAS Visual analog scale

VR Virtual reality

of Objective Assessment of Technical Skills (OSATS) (21) has been used to assess suturing skills in simulator models (81), although the use of such a form is to some extent subjective.

Virtual reality simulators

The VR simulator consists of a console with two instrumental handpieces and optics, and a computer with a monitor (Figure 6). These simulators offer relatively realistic anatomical models for procedural training, and it is even possible to create anatomically accurate virtual reality environment based on patient imaging data (52). Some, but not all, models possess haptic feedback. With these training tools, it is possible to train endoscopic basic psychomotor and suturing skills, endoscopies like colonoscopies and bronchoscopies, and laparoscopic procedures like cholecystectomies and salpingectomies.

The main advantage with the VR simulators is automatic feedback after every training session. These include total time, accuracy, path length and economy of the instruments, and number of movements. The programs have guided rehearsals, and the feedback also includes idle time, noted and suspected organ injuries, and minor injuries in form of respect for tissue. The training sessions are stored, and they serve as a baseline for later sessions. The trainee may set personal objectives for each training session and after the introduction to the training model, the presence of a trainer is not required. Proficiency based training programs are easy to build up. The main disadvantages are the lack of true haptic feedback and the high price.

Laparoscopic skills improve with VR basic skill training (65, 82, 83), and a virtual reality based training curriculum may promote residents' participation in live operations as the primary surgeon (84). Skills are transferred to the OR (2, 66, 74, 85-94) (Table 2), however, there are no studies on more advanced procedures than cholecystectomies and tubal surgeries (95). In the Cochrane review 'Virtual reality training for surgical trainees in laparoscopic surgery' (96) suggest that VR simulators are better than box trainers in shortening the operative time and improving the operative performance. However, in other studies (97, 98) the superiority of the VR simulator over the box trainer is not fully defined.

Table 2. Published studies on evaluating the effect of virtual reality simulator on human operations.

The study	Participants and their number	Intervention	Controls	Assessed procedure	Outcome measures	Results
Seymour et al. 2002 (83)	16 surgical residents (PGY 1-4)	MIST-VR Basic skills tasks until expert criterion level	No additional training	LCC	Operative time Error definition	Intervention group 29% faster Mean errors were six times less likely to occur in intervention group, p<0.008
Hamilton et al. 2002 (65)	19 surgical residents (PGY 2)	MIST-VR Basic skills 10 x 30min	Box trainer Basic skills 10 x 30min	LCC	OSATS-GRS	Only in VR-group the performance improved, p<0.01
Grantcharov et al. 2004 (84)	16 surgical trainees with limited experience in laparoscopy	MIST-VR 6 basic skills tasks x 10	No additional training	LCC	Operative time Error score Economy of movement score	In the intervention group the second operation was faster (p=0.021), with less errors (p=0.003), better economy of movements (p=0.003)
Mcclusky et al. 2004 (85)	12 surgical residents (PGY 1-2)	MIST-VR 1 basic skill until proficiency	Standard training	LCC	Error rate Operative time	Controls made 40% more errors Intervention group 20% faster
Chaer et al. 2006 (86)	20 general surgery residents	Procedicus VIST VR simulator Iliofemoral angioplasty/stenting model until proficiency	No additional training	Two catheter-based interventions for lower extremity occlusive disease	Task-specific checklist OSATS-GRS for Endovascular performance	Intervention group scored higher in procedural steps (p=0.0015-0.0006) and performed better (p=0.0052-0.0015)
Cosman et al. 2007 (87)	10 surgical residents	LapSim Basic skills until proficiency	No additional training	LCC partially	OSATS-GRS Operative time	Intervention group performed better and operative time 46% reduced
Ahlberg et al. 2007 (88)	13 surgical inexperienced	VR training until proficiency	No additional training	10 x LCC	Error rate Operative time	Intervention group made fewer errors (p=0.0037), control group used 58% longer time
Hogle et al. 2009 (89)	12 surgical residents (PGY 1)	LapSim Basic skill tasks until proficiency	No additional training	LCC	GOALS	No difference in performances between study groups (p=0.55-0.99)
Larssen et al. 2009 (2)	24 gynecological registrars (first and second year)	LapSim 2 basic skills and salpingectomy module until proficiency	Standard training	Salpingectomy	OSATS-GRS + OSA-LS operating time	Intervention group performed better (p<0.001) and operative time was shorter (p<0.001)
Ahlborg et al. 2013 (90)	23 gynecological trainees (12 performed also the 3rd operation)	LapSimGyn, additional structured mentorship 3 basic skill tasks and tubal occlusion and salpingectomy modules until proficiency	Traditional training	Three tubal occlusions	Operative time Self-efficacy Flow score	In the intervention group operative time was shorter in 2nd and 3rd operation (p<0.01), before the 3rd operation self-efficacy was better (p<0.05), flow score was higher after the 3rd operation (p<0.05)
Akdemir et al. 2014 (73)	40 gynecological residents as controls	PGY 1- LapSim VR simulator 8 basic skills or 20 senior box trainer 7 basic skills 1 h/week for 4 weeks	Controls were senior residents (PGY5) with no simulator training	Bilateral tubal ligation	OSATS-GRS, operating time	No difference between VR and box-trainer groups. Simulator groups performed better (p<0.01) and faster (p<0.01-0.03)
Shore et al. 2016 (91)	21 gynecological residents (PGY 1-2)	cognitive sessions, box-trainer and VR simulator, team simulation	Conventional teaching	Salpingectomy	OSATS-GRS + OSA-LS multiple-choice questionnaire nontechnical skills questions	Intervention group performed better (p=0.043), also cognitive (p<0.001) and nontechnical (p=0.016) test better
Thomsen et al. 2017 (92)	18 cataract surgeon with different levels of experience	EyeSI VR simulator Cataract module until proficiency	No controls	Cataract surgery	Procedure specific OSATS	Improvement in novices of 32 % (p=0.008), in surgeons <75 cataract surgeries 38% (p=0.018)

PGY Postgraduate year

LCC Laparoscopic cholecystectomy

OSATS-GRS Objective structured assessment for technical skills form for global rating skills

VR Virtual reality

GOALS Global Operative Assessment of Laparoscopic Skills

OSA-LS Salpingectomy specific form for objective structured assessment for technical skills

OSATS Objective structured assessment for technical skills

Laparoscopic certification programs

Certification programs have been created to ensure skills and to offer training for young colleagues. Development of these programs started in the US, as the national system requires demonstration of the competence before clinical work. Europe has followed the practice.

The Society of American Gastrointestinal Endoscopic Surgery started to develop a comprehensive program to educate and assess basic laparoscopic skills at the end of the 1990s (99). The European certification program GESEA (80) was created at the end of the first decade of the 2000s. The program was launched in 2012 (websurg.com), but not all parts are available yet. The program is divided into three levels of progression; Bachelor in endoscopy, Minimal invasive gynecological surgeon and Laparoscopic pelvic surgeon. The theoretical part consists of web-based lectures on several topics accompanied by quizzes before taking the theoretical test. The practical part comprises of three validated tests measuring psychomotor skills in laparoscopy and hysteroscopy, and the suturing test (64, 79, 100). At the moment, the certification program is not obligatory in Europe. Urologists also have their own European Basic Laparoscopic Urological Skills (EBLUS) program (101, 102). The EBLUS-program includes an online theoretical course and hands-on training of four exercises with tests.

Some of these programs are freely available, while many are only for certain University or society members. Furthermore concerning theoretical knowledge, global materials for training are difficult to produce, as every nation has partly different health care systems and their own customs.

Assessment of training outcome and surgical operations

The ultimate goal for surgical training program is to improve patient safety and surgical outcomes in the OR. Hence, the training outcomes and skills should also be assessed in the typical working environment. This is called work-based assessment (28).

Effectiveness of medical education is divided into four levels in Kirkpatrick's model (103) (Figure 7). Evaluation methods may be subjective or objective, qualitative or quantitative (28). The benefits for patients can be measured by quantitative measures like operating time, blood loss, and complications, or with qualitative instruments like a 15D evaluating health-related quality of life. Behavior in the OR can be evaluated with forms measuring general skills like instrument handling and non-technical skills, or steps in a certain procedure.

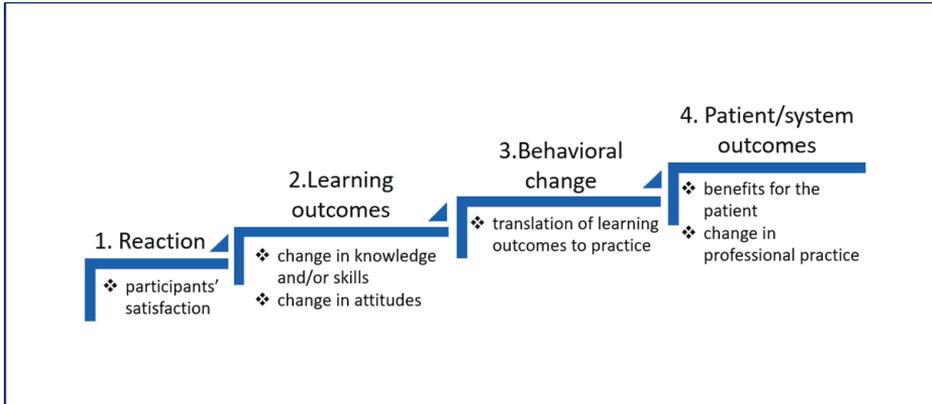


Figure 7. Four levels of evaluating effect of educational events. Modified from Issenberg et al. (103)

Numerous forms have been developed for assessing surgical skills in the OR (104) (Figure 8). Most of the forms include assessment of generic skills with a binary or 5-point Likert scale. A specific procedure can be assessed with a checklist or with an error rating scale (105), and the assessment can involve only the procedure or start with preoperative planning and end with postoperative aspects. In competence-based curricula, the global competence level is also assessed. In addition to summative assessment, formative feedback may also be given, and it is important to separate assessment from feedback. For following skills progression and giving feedback, the use of global rating scales seems sufficient together with formative feedback. In educational studies and in mentoring or credentialing programs, more detailed assessment with procedural checklists may be needed. There is no consensus of when and how often to use them in trainee education (104).

In assessing technical skills, OSATS is considered the 'gold standard' (106). Validation studies of different assessment tools are controversial, and most of the tools are suitable for giving feedback and following skills progression, but not for credentialing (106). When comparing OSATS and PBA assessment tools, both seem to be reliable but PBA possesses better validity and higher overall usefulness and satisfaction among users (107). Although OSATS may be partly subjective, due to its general acceptance, it seems to be the best available tool for assessing performances in the OR (108).

In the future, new tools are available to assess objectively the performed procedures (9). Data obtained from the OR could be modelled by using different computer algorithms to provide objective feedback. This data includes preoperative patient data, surgical videos and audio recordings, instrument and hand movements, eye and head movements, patient monitoring, and postoperative outcomes. The feedback data may be used for skills assessment and automated coaching, but also for improving the patient safety and quality of surgical care (9).

Review of the literature

Assessment forms and scales used	OSATS original	OCRS 'new OSATS'	GOALS	DOPS	PBA	VAS / NRS
Global rating scale 5-point Likert scale	✓	✓				
Laparoscopic specific global rating scale 5-point Likert scale			✓			
Task-specific checklist Binary scale	✓					
Procedure-specific checklist 5-point Likert scale		✓				
Pre-, per- and postoperative checklist Competence levels (1-3)				✓		
Pre-, per- and postoperative checklist with generic skills Binary					✓	
Global summary Competence level (1 to 5)				✓	✓	
Global summary Scale 1-10 / 1-100						✓
Formative assessment				✓		
OSATS Objective Assessment of Technical Skills						
OCRS Operative Component Rating Scale						
GOALS Global Operative Assessment of Laparoscopic Skill						
DOPS Direct Observation of Procedural Skills						
PBA Procedure-based assessment						
VAS Visual Analog scale						
NRS Numeric rating scale						

Figure 8. Workplace-based assessment tools (21, 29, 109-111).

AIMS OF THE STUDY

This dissertation study was carried out to evaluate developments in gynecological surgery in Finland and to assess the effect of systematic cognitive and manual pre-training on laparoscopic skills. The specific aims of individual studies were to evaluate

1. trends in rates and methods of hysterectomies in Finland and to compare those to numbers in other Nordic countries, and to compare outcomes of different hysterectomy methods in Finland between the trainees and specialists (Study I)
2. the effectiveness of a cognitive web-course '*Basics in Gynecological Laparoscopy*' for trainees at various levels of experience (Study II)
3. the effectiveness of a simple training curriculum containing both a cognitive and practical part on trainees' first laparoscopic salpingectomy (Study III)
4. the effectiveness of a hysterectomy module in virtual reality simulator on trainees' first laparoscopic hysterectomy (Study IV)

MATERIALS AND METHODS

Trends in hysterectomies (Study I)

Nordic hysterectomy data were collected from the Nomesco database (Nordic Medico-Statistical Committee, available at www.nowbase.org). Numbers of hysterectomies in the Nordic countries were initially available from 1995 to 2011, but were later collected until 2016. The data from Iceland are missing before year 2000 and between 2010 to 2012. These Nordic numbers include both benign and malignant cases, and they are reported per 100 000 women. The data do not include open radical hysterectomy due to ovarian malignancy, and from 2007 onward pelvic exenterations and colpoperineoplasties with vaginal hysterectomy. The proportions of the laparoscopic method were reported separately only in the years 2008 - 2011.

The numbers of hysterectomies and proportion of different hysterectomy methods due to benign reasons in Finland were collected from the Hospital Discharge Register of the Finnish Institute for Health and Welfare between the years 2007 - 2012. Numbers concerning the years 1990 - 2006 have been published previously (16, 112, 113). Numbers of different hysterectomy methods concerning both benign and malignant cases were here obtained from the statistics of the Finnish Institute for Health and Welfare (thl.fi) in the years 2006 - 2018.

Hysterectomy outcome comparison (Study I)

Data from the FINHYST 2006 survey were used to compare the operative outcome between trainees and specialists (113). Data were collected from 5279 hysterectomies (79.4 % of all hysterectomies) carried out in Finland in year 2006. These data included surgeon status (trainee or specialist) and experience, patient and operation related data, and post-operative complications.

In operations done by trainees versus specialists, we compared hysterectomy methods used, the patients' age and BMI, operating time, blood loss, uterus weight, and complications. Complication variables included blood loss of 1000ml or more, postoperative hemorrhage or hematoma, organ injuries, deep vein thrombosis or pulmonary embolism, or other complications requiring re-operation.

Effect of the web-course ‘Basics in gynecological laparoscopy’ (Study II)

The Finnish Society of Gynecological Surgery (GKS) in collaboration with the Finnish Medical Society Duodecim started to develop a web-based course ‘Basics in Gynecological Laparoscopy’ in Spring 2010. This course includes information on pelvic anatomy, instrumentation, operative phases, gynecological operations, complications, and training possibilities. In addition, the course contains a large number of photos and videos, along with written texts, and also has a web-based test. The course was available on-line in February 2012.

In Autumn 2011, all trainees in obstetrics and gynecology were invited to participate in this web-based study. Participants were subdivided into three groups according to their experience in obstetrics and gynecology (<18 months, 18-36 months, and >38 months) for comparison. Participation in the study was voluntary and anonymous. The level of knowledge was evaluated before and after taking the course with two equally difficult web-based questionnaires with multiple-choice questions. Both questionnaires were graded from 0 to 110. Demographics were collected with the first questionnaire. Working history in a surgical unit during the study period and satisfaction with the course were collected with the second questionnaire.

Simulator studies (Studies III and IV)

Both simulator studies were randomized, interventional, and blinded trials with two parallel study groups with a 1:1 allocation rate. We recruited 20 trainees for each study between June 2013 and December 2016 from Helsinki University Hospital and Hyvinkää Hospital. In the first simulator study (Study III), we included trainees with no experience in operative laparoscopies as a first surgeon, but diagnostic laparoscopies and laparoscopic clip sterilizations were allowed, as well as assisting in more advanced laparoscopies. The aim of this study was to evaluate the effect of systematic training in learning laparoscopic salpingectomy. For the second simulator study (Study IV), we included trainees with experience in laparoscopic adnexal procedures, but no laparoscopic hysterectomy (LH) as a first surgeon was allowed. The aim of this study was to evaluate the effect of simulator training on learning LH. For the salpingectomy study we excluded trainees with experience in training with a VR simulator. For the hysterectomy study, training in basic skill tasks with a VR simulator was permitted, but not training in the LH module. In both studies, ten of the participants were randomized to the intervention group, while the rest served as controls.

In the salpingectomy study, the intervention comprised of the web-course ‘Basics in Gynecological Laparoscopy’ and a training program with the nine basic skill tasks in a Lap Mentor VR simulator (Simbionix Corporation, Cleveland, Ohio, USA). These

basic skill tasks included camera navigation, eye-hand coordination, clip application, clipping and grasping, two-handed maneuvers, cutting, electro-surgery, and translocation of objects, and tasks were practiced five times each. Every practice session was recorded for later evaluation. These recordings included parameters describing each skill and of the parameters. 32 were chosen for the learning curve evaluations. The control group underwent a traditional training without a web-course or simulator training.

In the hysterectomy study, all participants did the web-course and training program with the nine basic skill tasks in a VR simulator described above. The same 32 parameters were used to compare the basic skills between to the study groups at the beginning of the study. Composite scores were calculated for each task (114). In addition, participants in the intervention group trained ten times with the hysterectomy module with the same simulator. The hysterectomy module recordings included parameters like total procedure time, idle time (time when a moving instrument is not touching the tissue), total path length of the instruments, total number of movements of the instruments, respect for tissue, and vascular and organ injuries. Composite scores were calculated for each participant.

In the first simulator study (III), the trainee performed salpingectomy of the right side, and this was the first operative laparoscopy by the trainee as a first surgeon. The operation was video recorded for later evaluation. In the second simulator study (IV), the trainee performed the first LH in a similar study setting as in the Study III. In the salpingectomy study, the video recordings were assessed by three blinded assessors, while in the hysterectomy trial, this was done by two blinded assessors. The assessment was done by using the OSATS form for Global rating Skills (GRS) (21) and procedure specific forms. In the salpingectomy trial, we used a salpingectomy specific form (OSA-LS) (115), and for the hysterectomy trial we developed a new hysterectomy specific form (LH-OSATS). In the salpingectomy trial, we used the Numeric Rating Scale (NRS) and the expert level as a reference, while in the hysterectomy trial we used the Visual Analog Scale (VAS) and the young specialist's level as a reference. Demographics of the participants were collected by questionnaires, and patient and surgery-related data were collected in medical records.

We used OSATS- and NRS/VAS scores as the primary outcome measures. In Study III, the OSATS scores were rated from 10 to 50, and NRS scores from 0 to 10. In Study IV the OSATS scores were rated from 13 to 65 and VAS scores from 0 to 100. Secondary outcome measures in both studies included operating time, blood loss, and direct complications.

Power calculations and statistical analyses

Power calculations for Studies III and IV were based on OSATS scores. Based on a previous study assessing salpingectomy (2), to detect a 6-scores difference in OSA-LS, using type 1 error 0.05 and power of 0.80, the required number of participants was 18. For the hysterectomy study, we assumed that the effect size on training would be at the same level as in the salpingectomy module. Thus, we recruited 20 participants for Studies III and IV.

The statistics were done by using SPSS 21.0-24.0 statistical software (Chicago, IL, USA). The continuous parametric variables were tested with Independent samples T-test, and non-parametric with the Mann-Whitney U Test. The categorial variables were tested with Pearson Chi-Square Tests. The reliability analyses were done by the Intraclass Correlation Coefficient test, and correlations with the Pearson Correlation test for the parametric variables and with the Spearman's rho for the non-parametric variables. In the learning curve analysis, the Friedman test and the Wilcoxon Signed Rank test were used. In the LH-OSATS form validation study, we used the Kruskal-Wallis test, and in post-hoc analysis the Mann-Whitney test with Bonferroni adjustment.

Ethics and permissions

The study plan was approved by the Helsinki University Hospital Ethics Committee (Dnro 390/13/03/03/2012) and by the Hospital District of Helsinki and Uusimaa.

RESULTS

Trends in hysterectomy numbers and methods (Study I)

Hysterectomy rate in Finland was slightly below 400 per 100 000 women annually between years 1995-2002, while in Denmark, Norway and Sweden the respective number was 200-250 per 100 000 women (Figure 9). From 2003 the hysterectomy rate in Finland started to decrease and reached other Nordic countries in 2008. The hysterectomy rate has been decreasing in all Nordic countries excluding Iceland until the end of our evaluating period of 2016. In 2016 the hysterectomy rate in Finland was 165 per 100 000 women, while in Denmark and in Sweden it was slightly less 136-148 per 100 000 women.

During the study period, the proportion of the laparoscopic method was higher in Finland than in other Nordic countries. During the years 2008-2011 the rate of LH increased in Finland from 36 % to 43%, while in Denmark and in Norway the rate in 2011 was about 20%.

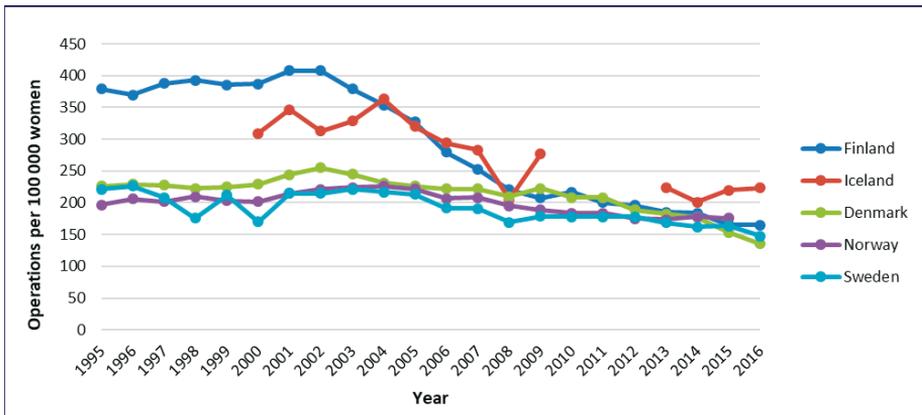


Figure 9. Hysterectomy rates in the Nordic countries in 1995-2016 (NOMESCO database). E.J. et al. unpublished data.

In Finland, the abdominal method has been the most common hysterectomy method for benign reasons since 1990 until 2002, when the vaginal method became the most common method. The laparoscopic method exceeded the abdominal hysterectomy (AH) in 2005. The laparoscopic method exceeded the vaginal hysterectomy (VH) in 2013. In 2018, 52% of all hysterectomies were performed laparoscopically, 32 % vaginally and 15% abdominally. When evaluating both benign and malignant cases, the total number of hysterectomies has decreased by 17% between the years 2006 - 2018 (Figure 10).

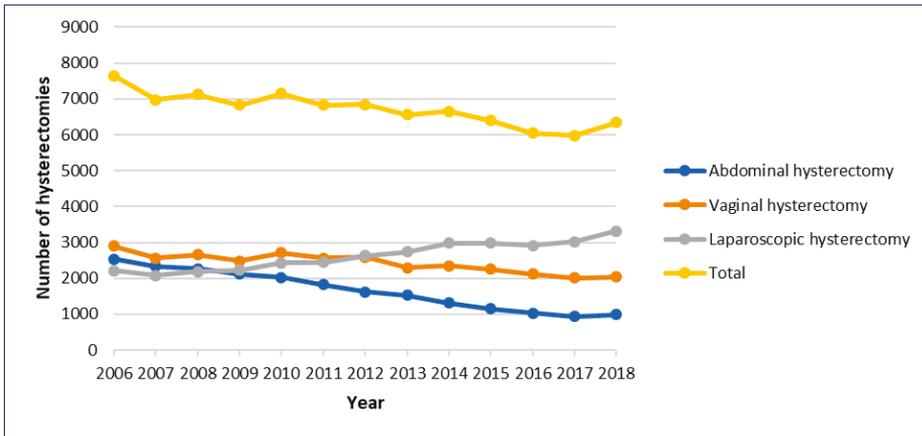


Figure 10. Numbers of different hysterectomies methods in Finland in 2006-2018 (thl.fi). E.J. et al. unpublished data.

Hysterectomy outcomes (Study I)

In the FINHYST 2006 survey, from the 5279 hysterectomies 3832 (77%) were done by a specialist, while 1145 (23%) were done by a trainee. From the operations by trainee, 51% were VH, 25% LH and 24% AH. The numbers for specialists were 42%, 34%, and 24%, respectively.

Operative time was longer by trainees: 16% longer in AH ($p < 0.001$), 26% longer in VH ($p < 0.001$), and 25% longer in LH ($p < 0.001$). In the AH and LH groups, there were no differences in blood loss or weight of the uteri. However, in the VH group, blood loss was higher in operations performed by trainees ($p = 0.03$), while the mean uteri weight was higher in operations done by specialists ($p < 0.001$).

No differences were detected in any complication variables in AH or LH when compared between trainees and specialists. In VH, blood loss of 1000ml or more was more frequent ($p = 0.037$) in operations by trainees, whereas in total complication rates there were no differences between the groups.

Web-course (Study II)

From the 154 trainees invited, 38% (58) filled in the first questionnaire. 33 of those (57%) filled in the second questionnaire as well. Answers came from all University districts.

In every experience group, the scores between the first and second questionnaire increased significantly (Table 3). After the course, the less experienced group

reached the starting level of the middle group, and the middle group reached the starting level of the most experienced group.

Table 3. The mean scores in the first and second questionnaires according the experience in obstetrics and gynecology.

Experience in months	1. questionnaire / before			2. questionnaire / after			p value
	n	Mean score	SD	n	Mean score	SD	
<18	23	81.9	6.8	12	89.3	8.6	0.009
18-36	19	90.4	6.9	12	97.9	5.2	0.003
>36	16	94.8	4.8	9	100.0	6.2	0.017

Participants rated the usefulness of the web-course at 4.8 when using the Likert scale. 100% of participants agreed to repeat the course.

Simulator studies

Salpingectomy study (Study III)

There were no differences in baseline data between the intervention and control groups concerning patient or surgery related data. Participants in the control group had longer experience in general surgery (3 vs. 5.9 months, $p=0.034$), but neither experience in obstetrics and gynecology nor numbers of performed basic laparoscopies differed between the groups.

Visual plateaus in learning curves were reached only in two of the nine basic skill tasks with the VR simulator; in cutting and in translocating of objects. In the practice sessions the two weakest ones started the first sessions at 0.7% and 16.5% below the average mean, while the best started at 14.5% and 15.1% above (Figure 11). While practicing, the two weakest participants improved their performances 31.6% and 29.2%, while the two best participants improved their performances less (23.3% and 21.1%, respectively). At the end of the program, the performance of the best performed participants still exceeded the performances of the weakest participants.

Based on video recordings, there were no differences in OSATS or NRS-scores, nor in surgery related measures between the groups (Table 4).

Results

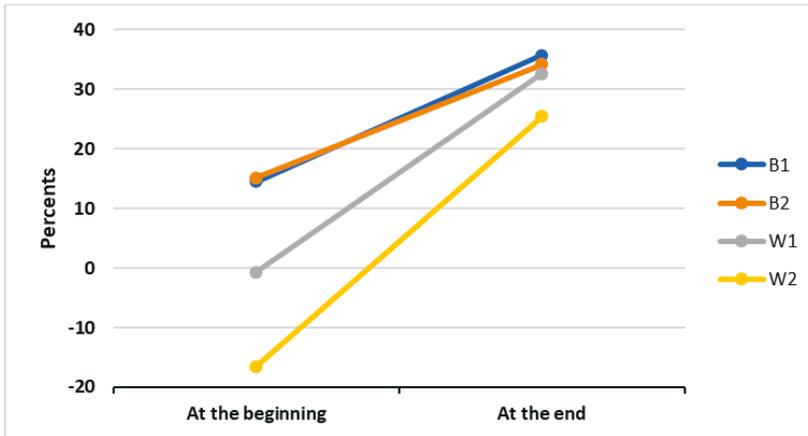


Figure 11. Skill level progression of two of the best (B1 and 2) and two of weakest (W1 and 2) during the practice program. The skill levels are compared in percent to the average at the beginning of the practice program.

Table 4. OSATS- and NRS-scores, and surgery related measures in the salpingectomy study.

Outcome measure	min-max score	Intervention group		Control group		p-value
		Mean	SD	Mean	SD	
OSATS-GRS	6-30	9.7	3.5	9.3	3.4	0.712
OSA-LS	4-20	6.7	1.9	6.9	2.3	0.824
OSATS total	10-50	16.4	5.3	16.2	5.7	0.947
NRS	0-10	2.9	1.9	3.1	1.7	0.879
Operative time (min)		14.6	4.7	12.6	4.0	0.349
Blood loss (stage 0-3)		0.8	1.0	0.3	0.7	0.515
Direct complications (n)		0	0	0	0	1.0

OSATS-GRS Objective structured assessment for technical skills form for global rating skills

OSA-LS Salpingectomy specific form for objective structured assessment for technical skills

OSATS total Combination of objective structured assessment for technical skills forms for global rating skills and for salpingectomy

NRS Numeric rating scale

Hysterectomy study (Study IV)

The participants in the intervention group compared to the controls were more experienced in obstetrics and gynecology (mean 38.0 vs. 27.1 months, $p=0.003$) and had done more laparoscopies as a first surgeon (mean number 25.6 vs. 11.8, $p=0.027$). However, in basic skills tasks the composite score was higher in the control group than in the intervention group (101.4 vs 98.7, $p=0.033$). In patient related data, there were no differences between the groups.

The learning curve plateaus were statistically detected after the third practice session in total procedure time, in total movements of the instruments, and in total path length of the instruments. In idle time, in respect for tissue, or in vascular or organ injuries plateaus were not detected.

We developed a procedure-specific OSATS-form with seven operational core steps to evaluate LHs (LH-OSATS) (Table 5). To validate the LH-OSATS form, 27 procedures done by trainees, young specialists, and experts, were video recorded and rated by assessors blinded for the operator. The mean score for trainees was 20.8 (SD 2.6), for young specialists 25.0 (SD 3.3) and for experts 27.6 (SD 6.3) ($p=0.01$) showing construct validity of the form.

Table 5. Seven core steps of laparoscopic hysterectomy included in procedure specific assessment form (LH-OSATS).

Core steps in laparoscopic hysterectomy

1. Exposure
2. Division of adnexa
3. Division of round ligament
4. Opening of vesico-vaginal space
5. Division of uterosacral ligaments and posterior leaflets of broad ligament
6. Division of uterine pedicles
7. Hemostasis and final inspection

The intervention group rated significantly better using both OSATS- and VAS-scores compared to the control group (Table 6). Operative time in the intervention group was 20 minutes shorter, but this did not reach statistical significance. There were no differences between the groups in blood loss or in direct complications.

Results

Table 6. OSATS- and VAS-scores, and surgery related measures in the hysterectomy study. Statistically significant values are highlighted in bold ($p < 0.05$).

Outcome measure	min-max score	Intervention group		Control group		p-value
		Mean	SD	Mean	SD	
OSATS-GRS	6-30	17.0	3.1	11.2	2.4	0.002
LH-OSATS	7-35	20.0	3.3	16.0	2.8	0.012
OSATS total	13-65	37.0	6.2	27.5	5.2	0.002
VAS	0-100	55.0	14.8	29.9	14.9	0.001
Operative time (min)		144.0	20.8	164.9	44.9	0.205
Blood loss (ml)		130.5	129.0	120.5	113.0	0.907
Direct complications (n)		1	0.3	0	0	1.0

OSATS-GRS Objective structured assessment for technical skills form for global rating skills

LH-OSATS Hysterectomy specific form for objective structured assessment for technical skills

OSATS total Combination of objective structured assessment for technical skills forms for global rating skills and for hysterectomy

VAS Visual analog scale

DISCUSSION

We evaluated the trends in hysterectomy numbers and methods and compared the outcomes in the operations done by trainees versus specialists. In addition, we evaluated the impact of pretraining, using both the web-course and VR simulator on trainees' first laparoscopic salpingectomy, as well as trainees' first LH, being one of the most demanding procedures during residency.

Changes in gynecological surgery

In Finland, the decrease in total number of gynecological operations and the frequent use of the laparoscopic method have had a strong impact on surgical training. In 2006, when the FINHYST study was carried out, besides the longer operative time, there were no major differences between the outcomes in hysterectomies done by trainees and specialists. This indicates good preoperative patient selection for trainees and an adequate senior support during the operations. However, thereafter the number of hysterectomies has decreased.

Since 2008 - 2009, the hysterectomy rate has been decreasing in every Nordic country, except in Iceland. The hysterectomy rate in Finland has decreased by 25%, but the decrease is even more distinct in Denmark (by 39%). In Finland, the laparoscopic method in hysterectomy has been the most frequent method since 2013, and in 2018 52% of hysterectomies were done laparoscopically. It is used more often in Finland than in other Nordic countries. The laparoscopic method has also become more frequent globally; in the US in 2003 the laparoscopic method was used in 11.8% of hysterectomies, while in 20.4% of the cases in 2009 (116). Due to these changes, new methods for trainees' operative education are needed.

Training models and programs

The VR simulator was used as a training model in our studies. Several studies have suggested that with laparoscopic simulators basic and suturing skills can be acquired (59, 77, 96). They allow the trainee to train independently according to objectives set. Despite that, the VR simulator is not superior to some other training methods (74, 117-119). The VR explicit advances include automated objective feedback, easiness to follow skills development, and procedure modules with or without guidance mode. Furthermore, the use of the VR simulator allowed us to detect the learning curves and use of a procedural module (Study IV).

We showed construct validity of the web course (Study II) that increased the theoretical knowledge of a novice to the level of a more experienced trainee. This indicates that the course is suitable for novices as a part of the basic training program. As the course includes information on basic gynecological laparoscopic procedures and complications, more experienced trainees can also gain new knowledge, as shown in our study (Study II). In addition, participants' satisfaction with the course was high.

A combination of cognitive web-course 'Basics in Gynecological Laparoscopy' and a training program with a fixed number of basic skill tasks in a simulator was used in Study III. A successful training program includes both cognitive material and practical skills tasks, as learning of a new skill is based on theoretical knowledge (27). The objective of the cognitive part of the program is to ensure that the trainee has sufficient knowledge on what to do, why, when, and where to do it (20). In addition, it is important to learn what not to do.

As a practical part of the training program, we included basic skill tasks only (Study III). Our intention was to evaluate the effect of basic pretraining in readiness to perform a basic laparoscopic procedure. Combining the cognitive web course with this training program of five repetition times each of nine basic skill tasks in VR simulator, however, did not seem to improve significantly the operative outcome compared to the control group. However, in the hysterectomy study (Study IV), all participants did the basic training program described above, but additionally the intervention group trained the hysterectomy module 10 times in the VR simulator. The operations done by the intervention group were rated better with OSATS and VAS scores than those in the control group, indicating better laparoscopic performance after the training procedural module in the simulator. Procedural modules in the VR simulator have been shown to result in better procedural outcomes in salpingectomy (2), tubal occlusion (92), and cataract surgery (94), which is in line with our findings. However, there are no previous data on VR simulator use in more advanced procedures. Thus, our novel findings support the VR simulator use also in more advanced surgery training.

Training objective

Training programs in the simulator studies (Studies III, IV) were repetition based. Criteria for basic skills (clipping and grasping, and two-handed maneuver) and procedural metrics were set in a study on the VR simulator curriculum for LH (120). Concerning the intervention group in Study IV, only one participant out of ten fulfilled these criteria for basic skills and six for procedural skills. Thus, it appears that five-time repetition rate in basic skills and ten-time in procedural skills are not enough in the majority of the tasks and for a majority of the trainees. Proficiency based programs seem to provide more uniform and better skills when compared with training programs based on time or repetitions (11, 121).

There is a wide variability in starting levels of the participants (122) and thus, differences in innate skills, abilities, and motivation among trainees (20). This was distinct also in our studies. However, when the training program proceeds this variability rapidly decreases and skill levels are leveled (123). However, training time and the number of repetitions needed varies between individuals due to different starting levels. When innate operative skills with the VR simulator were evaluated among 155 medical students, 5.8% of the participants had good innate talents, while 11.0% had low innate skills (124). Thus, the VR simulator could be used to measure applicant's innate ability.

Besides innate operative skills, the way we learn is also different between individuals. The learning curve represents the difficulty of the task, but also the individual's learning ability; i.e. in what time or repetition rate the trainee has acquired the skill and how deep the curve is (20). When analyzing the learning curve of a certain group, general information on the difficulty of the task may be obtained and these curves can be used to define the average number of task repetitions needed to acquire a certain skill (125). However, the significance of learning curve plateaus is controversial, as we lack a common definition to measure plateaus and even several plateaus are possible to detect (122). In addition, reaching a plateau is dependent on several factors, e.g. on motivation and attentiveness, which may vary in different situations or points of time (11).

When learning curves were evaluated in Study III, basic skills improved while practicing, but a plateau was reached only in two of the nine tasks. However, when training with the procedural module (Study IV), plateaus in three of the four core metrics were detected after the third practice session. In a study evaluating the learning curve in VR simulator basic skills, in 10 skills out of 12 a plateau was reached in 11-20 repetition times, and a slope plateau at the 8th training session (122). However, after reaching this plateau, the performance still improved, and the ultimate plateau was reached after 27-30 training times in 11 out of 12 tasks. This performance improvement after the plateaus was also noted in our studies. Interestingly, in studies assessing laparoscopic salpingectomy and cholecystectomy after procedure module training, plateaus were detected in a majority of skills after the 7th or 8th repetition time (5, 126). In some skills, even ten sessions were not enough to reach the plateau. However, it seems that more repetitions are needed for acquiring basic skills than procedural skills. This means that probably basic skills are more difficult to acquire than procedural skills once the trainee has already acquired the basic skills. Thus, it seems that inexperienced trainees benefit even more than experienced ones from simulator training.

In proficiency based programs, the objectives for training are often set to meet the level of experts in the clinic (127), and thus, the criteria may vary (128). Instead of using the performance of one or two experts as a reference, criteria could be based on performances of several proficient experts (20). Nevertheless, after training the

skills until the expert level, learning is still ongoing e.g. in the form of automatization. Thus, the training should be continued to take further advantage from the simulator (129). To what extent this further training is beneficial likely depends on the task and needs further studies.

Implementing of simulator training

There are no clear recommendations how to use simulators in trainee education that at least in part, delay the incorporation of simulators into national training programs. In addition, many teaching hospitals lack the equipment needed, or a trainer familiar with their use.

It has been shown that one of the main barriers to implement a VR simulation program into trainee education was a time restriction (130). Suggested improvements include a written instructions on simulator use, and scheduled supervision. The training should be a mandatory part of the training program, with dedicated time for training. Importantly, by only providing the simulators does not ensure that they are used in training (13, 131).

With simulator training, skills are gained at various levels of experience, but less experienced participants seem to benefit the most (132-134). This is in accordance with our studies, as we noted that skill levels of each participant increased with practice. The increase was higher in participants with lower starting levels than those with higher starting levels. However, the trainees with lower starting levels did not reach the level of the ones with higher starting levels. This indicate that simulator training should be started in the very early stages of specialty training. Initiating specialty training often occurs in small local hospitals where a surgical trainer is rarely provided. Thus, pre-designed surgery training programs with guidance should be provided at national levels (15).

Cost effectiveness

Studies focusing on cost effectiveness of simulator training are still lacking. However, reduced operative time in the VR training group compared to the control group has been shown in many studies (2, 74, 86). We show similar results, as in the hysterectomy study (Study IV) operative time in the intervention group was 21 min shorter than in the control group. The fact that this difference did not reach statistical significance is probably due to the small participant number. Investment costs are relatively high with the VR simulator, but with reduced operative time simulator training clearly has an impact on OR efficiency.

Strengths and limitations of the study

In the present study, we used reliable Finnish and Nordic registries and the FINHYST 2006 -study (Study I) to explore the trends in operative treatments. Secondly, rather than medical students as in many previous studies (119, 135), our participants were trainees in obstetrics and gynecology (Studies II-IV). This is important since our focus is in specialty training. Thirdly, we used live operations to assess the operative outcomes after simulator training. Our aim was to assess the training outcomes in the typical daily OR work. Fourthly, the assessors were blinded for the operator and the study group. Reliability between the assessors was good.

Our studies have several limitations. One of the main concerns is the limited number of participants (Studies II-IV). However, the numbers are similar or even higher than in other studies assessing VR training. Despite randomization we noted baseline differences in the VR study (IV) that could be due to the limited participant number. Secondly, Study II was conducted by internet questionnaires anonymously, thus it is not possible to determine if participants used outside help when answering the questionnaires. Thirdly, we recruited participants in Studies III and IV in two hospitals, and the recruitment time was long, although every suitable trainee agreed to participate. There were no changes in training programs in either of the hospitals during the study period. In addition, it needs to be noted that in the live surgery, the impact of first and second assistant is crucial. However, this concerns equally both the intervention and control groups, and therefore it is unlikely to cause bias.

SUMMARY AND FUTURE ASPECTS

Due to the declining numbers of operative cases, the apprenticeship model alone does not ensure sufficient learning of operative skills. In addition, medico-legal and productivity pressure in the OR mandate developments in surgical education.

Basic operative skills should be learned before live operations outside the OR in order to benefit most from the OR training. E-learning offers various possibilities to teach cognitive skills especially for young generations. Since the laparoscopic method is mainstream in gynecological surgery, the VR simulator is the most feasible training method for manual skills. To ensure the learning outcomes, skills should be assessed before permitting OR work.

Between individuals, there are considerable differences in innate skills needed in laparoscopy. Almost all individuals learn the skills, although some need more training than others. This can be managed with proficiency-based training programs, instead of time or repetition based. In learning basic skills, the VR simulator is effective.

It seems that skills learned in a VR simulator are transferred to the OR, but further studies are needed to evaluate how the entire curriculum should be built up. It is not clear how to define proficiency levels required, and how to ensure learning outcomes before permitting OR work.

Since not all teaching hospitals have VR simulators, it would also be important to evaluate the use of box trainers in both basic and more advanced procedures in gynecological surgery. The use of box trainers as part of the training curriculum is likely to be beneficial, but how to use them needs further evaluations. Nevertheless, teaching hospitals need guidelines how to implement the use of simulators in an early stage of a specialist training.

CONCLUSIONS

To summarize our studies on gynecological surgery developments and effectiveness of a comprehensive web-course and simulator pre-training in learning laparoscopic procedures:

1. The total number of hysterectomies incidence has declined since 2002. The hysterectomy rate is similar in other Nordic countries, but the laparoscopic method is more common in Finland. The laparoscopic method has been the most often used hysterectomy method since 2013.

Compared to specialists, trainees needed more time to operate in all three methods, but the outcomes did not differ in abdominal or in laparoscopic hysterectomies. In the vaginal method blood loss was higher in operations done by trainees.

2. Improvement in knowledge gain was noted among trainees at every three levels of experience after studying the web-course '*Basics in Gynecological Laparoscopy*'.
3. A basic training curriculum did not improve the trainees' first laparoscopic salpingectomy performance. However, the participants with low innate skills appeared to benefit most from the training.
4. Training with a hysterectomy module in a virtual reality simulator improved the trainees' first laparoscopic hysterectomy performance when evaluated with work-based assessment tools.

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