Minimally invasive surgery: patients’ and doctors’ perspectives

Theodoor Elbert Nieboer
Minimally invasive surgery: patients' and doctors' perspectives

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Chapter 1

General introduction and outline of the thesis
General introduction and outline of the thesis

The word laparoscopy is derived from the Greek *lapara*, meaning flank or loin, and *skopein*; to view or to examine. It is also known as minimal access surgery, minimally invasive surgery or keyhole surgery. After initial reports of peritoneoscopy in 1948, usage of laparoscopy extended into the field of general surgery, gynaecology and urology. In gynaecology it was the occlusion of the fallopian tubes which caused the widespread introduction of laparoscopic surgery. Over the last two decades, laparoscopic surgery has become more and more implemented. Currently in arthroscopy, thoracoscopy and oesophagoscopy, endoscopic surgery is implemented in the whole surgical spectrum. With over 78,000 PubMed citations for laparoscopy, its presence in current day medical science is extensive.

The patient’s perspective

The advantages of laparoscopy versus conventional (open) surgery have extensively been studied in randomized controlled trials. In general, laparoscopic surgery is accompanied with less postoperative pain, shorter hospital stay, quicker return to normal activities, higher quality of life and better cosmetic results. However, for the greater part, laparoscopic surgery requires more time and is accompanied with higher costs, the latter mainly due to expensive disposables. Despite these disadvantages, meta-analyses have shown that the laparoscopic approach has become the first choice in adnexal surgery, appendectomy and cholecystectomy. Hysterectomy is the most frequently performed major gynaecological procedure. More than 550,000 hysterectomies are performed annually in the USA. In the Netherlands, almost 15,000 hysterectomies have been performed in 2012 (data from Kiwa Prismant; www.prismant.nl). The vast majority of hysterectomies is performed for benign conditions, mainly heavy menstrual bleeding. The first laparoscopic hysterectomy was performed by Harry Reich in 1989. Compared to abdominal hysterectomy, the laparoscopic approach has a longer learning curve, requires longer surgery time and has a higher rate of urinary tract injuries. In contrast, laparoscopic hysterectomy is associated with less blood loss, less febrile morbidity and requires shorter hospital stay. However, there are no long-term follow-up data (longer than 12 months) from any randomized controlled trial on hysterectomy. Furthermore, only a minority of studies on hysterectomy for benign gynaecological disease reported quality of life as outcome measure.

The doctor’s perspective

Already in 1955, it was observed that laparoscopic surgery required specific skills and that surgeons had to be aware of specific complications. Studies were reported and awareness arose on air embolism and mediastinal emphysema, severe
internal hemorrhage, ureteral injury, and gastrointestinal complications. In 1973 Dr. Patrick Steptoe considered none of the laparoscopic instruments to be "nurse-proof" and mentioned that every working part of each instrument should be checked at the beginning of each laparoscopy by the operator. Furthermore, from an anesthesiologic point of view, it was recognized that laparoscopic surgery required some adaptations in anaesthesiology. Due to the raised intra-abdominal pressure, caused by the continuous insufflation of CO₂ and Trendelenburg position, artificial respiration may be arduous.

One underexposed matter is the physical impact of laparoscopy on surgeons. There are several important limitations or drawbacks of endoscopic surgery: the surgeon’s vision is restricted by an optic system and camera system, 3-dimensional organs in the abdomen are presented on a monitor (2-dimensional), the degrees of freedom for camera and instruments are restricted at the level of the abdominal wall and tactile feedback is limited. Furthermore, the typical design of instrument handles leads to high pressure at hand areas and may even cause nerve injuries. Most instruments come with a “one size fits all” handle, although glove size of surgeons vary from size 6.5 to 9. These aspects together force the surgeon into unnatural and uncomfortable postures. These restrictions of surgery itself, added to sub-optimal ergonomic circumstances in a large proportion of operation rooms, may negatively influence the surgeons’ physical condition. Chronic injuries due to laparoscopic surgery are not uncommon. Reyes et al. first described these injuries as Minimal Access Surgery (MAS)-related surgeon morbidity syndromes. Not only do these syndromes impair the surgeon’s physical condition, they also have a negative impact on the outcome of the operation. Hypothetically, physical fatigue and other complaints during surgery may lead to less controlled movements with a higher risk of complications.

The patient’s versus the doctor’s perspective
A valid comparison of the advantages for the patients against the aforementioned limitations of laparoscopy for surgeons is impossible. The patient undergoes one or only a few laparoscopies during lifetime, whereas the surgeon may perform laparoscopies on a daily basis. The type of inconvenience for the patient and the doctor are incomparable as well. There are no guidelines on decisions that need to be made in this respect. For example, one may argue the standard introduction of an additional trocar in laparoscopy in order to enhance the ergonomic circumstances for the surgeon. Additionally, surgeons could benefit from more awareness of ergonomic guidelines regarding trocar placement, since trocar placement presently is mostly empiric. Furthermore, it has been shown in several studies that physical strain for surgeons is higher in laparoscopy compared to laparotomy, but it is not clear whether this leads to a higher complication rate due to surgeons’ fatigue.

Some professionals might consider the high physical load in laparoscopy as “part of the job” and will not recognize physical fatigue as a possible cause of complications. Due to these limitations, other surgeons may consider the laparoscopic approach to prolonged operations as hysterectomy or colectomy “a bridge too far” and prefer the less physically challenging open abdominal approach. In the latter case, patients are withheld less invasive surgery. In The Netherlands, the implementation of operative gynaecological laparoscopy seems to develop at a slow pace. However, the role of ergonomics in this matter has not been studied in detail, but could be of significance.

In this thesis, the long-term advantages of laparoscopy for patients are assessed and balanced against the disadvantages for laparoscopic surgeons. In the view of the aforementioned limitations of endoscopy in terms of ergonomics and physical strain for the surgeon, one may discuss to what extent it is justifiable that patients benefit while doctors are at risk, added to the doctor’s discomfort as a risk for the quality of the surgery.

The aims of this thesis are:
- To specify the medical advantages of laparoscopy in gynaecological surgery for benign disease by performing a systematic review and meta-analysis of randomized controlled trials of vaginal, abdominal and laparoscopic hysterectomy (Chapter 2)
- To evaluate long-term effects of laparoscopic surgery on patients’ condition by evaluating the long-term effect of laparoscopic and abdominal hysterectomy in terms of quality of life (Chapter 3)
- To study the perceptions that gynaecologists have of the difficulty of laparoscopic and abdominal hysterectomy by evaluating the expected and experienced difficulty in a randomized controlled trial on laparoscopic versus abdominal hysterectomy (Chapter 4)
- To investigate the extent of surgeons’ physical complaints due to laparoscopic surgery by performing a questionnaire study in surgeons performing laparoscopy (Chapter 5)
- To evaluate the effect of training on muscle strain and skills during laparoscopic surgery by performing a randomized controlled trial of training the non-dominant upper extremity (Chapters 6 and 7)
- To balance the patients’ advantages of laparoscopy against the disadvantages for laparoscopic surgeons (Chapter 8)
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Part 1

The patient’s perspective
Chapter 2

Surgical approach to hysterectomy for benign gynaecological disease

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The full version is available online on www.cochrane.org.
Abstract

Background: The three approaches to hysterectomy for benign disease are abdominal hysterectomy (AH), vaginal hysterectomy (VH), and laparoscopic hysterectomy (LH). Laparoscopic hysterectomy has three further subdivisions depending on the part of the procedure performed laparoscopically.

Objectives: To assess the most beneficial and least harmful surgical approach to hysterectomy for women with benign gynaecological conditions.

Search methods: We searched the Cochrane Menstrual Disorders and Subfertility Group Specialised Register of controlled trials (15 August 2008), CENTRAL (The Cochrane Library 2008, Issue 3), MEDLINE (1950 to August 2008), EMBASE (1980 to August 2008), Biological Abstracts (1969 to August 2008), the National Research Register, and relevant citation lists.

Selection criteria: Only randomised controlled trials comparing one surgical approach to hysterectomy with another were included.

Data collection and analysis: Independent selection of trials and data extraction were employed following Cochrane guidelines.

Main results: There were 33 included studies with 4095 women. The benefits of VH versus AH were speedier return to normal activities (mean difference (MD) 9.5 days), fewer febrile episodes or unspecified infections (odds ratio (OR) 0.42), and shorter duration of hospital stay (MD 1.1 days). The benefits of LH versus AH were speedier return to normal activities (MD 13.6 days), lower intraoperative blood loss (MD 45 cc), a smaller drop in haemoglobin (MD 0.55 g/dl), shorter hospital stay (MD 2.0 days), and fewer wound or abdominal wall infections (OR 0.31) at the cost of more urinary tract (bladder or ureter) injuries (OR 2.41) and longer operation time (MD 20.3 minutes). There was no evidence of benefits of LH versus VH and the operation time (MD 37.4 minutes) was increased in LH. For some important outcomes, the analyses were underpowered to detect important differences or they were simply not reported in trials. Data were absent for many important long-term outcome measures.

Conclusions: Because of equal or significantly better outcomes on all parameters, VH should be performed in preference to AH where possible. Where VH is not possible, LH may avoid the need for AH however the length of the surgery increases as the extent of the surgery performed laparoscopically increases. The surgical approach to hysterectomy should be decided by the woman in discussion with her surgeon in light of the relative benefits and hazards.

Description of the condition

Hysterectomy is the most frequently performed major gynaecological surgical procedure with millions of procedures performed annually throughout the world.1 Approximately 90% of hysterectomies are performed for benign conditions, such as fibroids causing abnormal uterine bleeding.2 The first reported elective hysterectomy was performed through a vaginal approach by Conrad Langenbeck in 1813. The first elective abdominal hysterectomy, a subtotal operation (where the cervix was conserved), was performed by Charles Clay of Manchester in 1863.3 These approaches remained the only two options until the latter part of the 20th century. The first laparoscopic-assisted vaginal hysterectomy (LAVH) was performed by Harry Reich in 1989.4 He also reported the first total laparoscopic hysterectomy (TLH) in 1993.

Description of the intervention

Approaches to hysterectomy may be broadly categorised into three options, abdominal hysterectomy (AH); vaginal hysterectomy (VH); and laparoscopic hysterectomy (LH) where at least some of the operation is conducted laparoscopically.5 The AH has traditionally been the surgical approach for gynaecological malignancy, when other pelvic pathology is present such as endometriosis or adhesions, and in the context of an enlarged uterus. It remains the ‘fallback option’ if the uterus cannot be removed by another approach. The VH was originally used only for prolapse but has become more widely utilised for menstrual abnormalities such as dysfunctional uterine bleeding (DUB), when the uterus is a fairly normal size. Compared to AH, VH was (and still is) regarded as less invasive and seemed to have the advantages of fewer blood transfusions, less febrile morbidity (fever), and less risk of injury to the ureter, but the disadvantages are more bleeding complications and greater risk of bladder injury.6 The term ‘laparoscopic hysterectomy’ (LH) usually refers to a hysterectomy where at least part of the operation is undertaken laparoscopically.7 This approach requires general laparoscopic surgical expertise. The proportion of hysterectomies performed by LH has gradually increased and, although the surgery tends to take longer, its proponents argue that the main advantages are the possibility to diagnose and treat other pelvic diseases such as endometriosis, to carry out adnexal surgery including the removal of the ovaries, the ability to secure thorough intraperitoneal haemostasis (direct laparoscopic vision enables careful sealing of bleeding vessels at the end of the procedure), and a more rapid recovery time from surgery compared to AH.7 More recently, three subcategorisations of LH have been described:8

- Laparoscopic assisted vaginal hysterectomy (LAVH) is where part of the hysterectomy is performed by laparoscopic surgery and part vaginally, but the laparoscopic component of the operation does not involve division of the uterine vessels.
Laparoscopic hysterectomy (which we will abbreviate to LH(a)) is where the uterine vessels are ligated laparoscopically but part of the operation is performed vaginally.

Total laparoscopic hysterectomy (TLH) is where the entire operation (including suturing of the vaginal vault) is performed laparoscopically and there is no vaginal component except for the removal of the uterus. TLH requires the highest degree of laparoscopic surgical skill.

It has been unclear whether TLH offers any benefit over other forms of laparoscopic hysterectomy. A total hysterectomy is the removal of the entire uterus including the cervix. When the cervix is not removed this is known as a subtotal or supracervical hysterectomy. Subtotal hysterectomies are most easily performed abdominally or laparoscopically, although it is possible to conserve the cervix in a VH or LAVH. In common with the overall hysterectomy rate, the proportion of hysterectomies currently being performed by different approaches varies markedly across countries, within countries, and even between individual surgeons working within the same unit. The surgical approach taken at hysterectomy continues to depend upon the experience and biases of the surgeon. Each gynaecologist will have different indications for the approach to hysterectomy for benign disease, based largely on their own array of surgical skills and the patient characteristics such as uterine size and descent, extra-uterine pelvic pathology, previous pelvic surgery, and other features such as obesity, nulliparity, and the need for oophorectomy. Even though vaginal hysterectomy has been widely considered to be the operation of choice for abnormal uterine bleeding, the VALUE study has shown that, in 1995 in the UK, 67% of the hysterectomies performed for this indication were abdominal hysterectomies. Previous caesarean section, for example, is often considered to be a contraindication for vaginal hysterectomy. However, this is not supported by evidence as analysis of cumulative data of four studies available on the subject did not find a significant difference in complication rates in hysterectomy patients following caesarean section. Mäkinen et al. reported a prospective study on the learning curve in 10,110 hysterectomies for benign indications, of which 5875 were abdominal, 1801 were vaginal, and 2434 were laparoscopic hysterectomies. As far as injuries to adjacent organs were concerned, the surgeons’ experience significantly correlated inversely with the occurrence of urinary tract injuries in laparoscopic hysterectomy and the occurrence of bowel injuries in vaginal hysterectomy. Encouraging vaginal surgery amongst gynaecologists has been shown to be an effective method of increasing vaginal hysterectomy rates. Finland had a vaginal hysterectomy rate as low as 7% in the 1980s. Following annual meetings on gynaecological surgery where vaginal and laparoscopic surgery were encouraged, and individual training provided, the vaginal hysterectomy rate increased to 39% in 2004. In the same period of time, ureter injuries decreased, which represents an impressive national learning curve.

How the intervention might work
Injuries to adjacent organs are of concern in hysterectomy and their rates of occurrence differ with the various approaches to hysterectomy and surgical experience level. Furthermore, operation times differ with the different approaches to hysterectomy. In general it is presumed that the laparoscopic approach is followed by a quicker recovery compared with open surgery. Apart from the surgical approach to hysterectomy, other aspects of the surgical technique may have an effect on the outcome of surgery. Examples of this include total versus subtotal (where the cervix is not removed) hysterectomy, Doderlein VH or LAVH versus standard VH or LAVH, techniques to support the vaginal vault; bilateral elective oophorectomy versus ovarian conservation, and other strategies used mainly by those conducting laparoscopic surgery with the aim of reducing the likelihood of complications, including the use of vaginal delineators, rectal probes, and illuminated ureteric stents. These other aspects are not be within the scope of this review (other than for assessing trial quality), which will focus simply on benefits and harms of the different surgical approaches.

Why it is important to do this review
It was interesting to note that in 1998 there was not a single randomised controlled trial (RCT) comparing AH and VH. The introduction of the newer approaches to hysterectomy (LAVH, LH(a) and TLH) has stimulated a much greater interest in the proper scientific evaluation of all forms of hysterectomy. The findings of various randomised controlled trials are summarised in this systematic review.

Objectives
The aim of the review was to assess the most beneficial and least harmful surgical approach to hysterectomy when considering AH, VH and LH for women with benign gynaecological conditions.
Methods

Criteria for considering studies for this review

Types of studies
Randomised controlled trials (RCTs) where one surgical approach to hysterectomy was compared with another.

Types of interventions
The surgical approach to removal of the uterus where at least one approach was compared with another. Approaches were, for example, AH, VH, and LH. AH involves removal of the uterus through an incision on the lower abdomen. VH involves removal of the uterus via the vagina, with no abdominal incision. The distinction between the subcategories of LH was made based on whether ligation of the uterine vessels was undertaken laparoscopically and whether suturing of the vaginal vault was undertaken vaginally. Thus LH was further subdivided in the analysis into LAVH (where the laparoscopic component did not involve ligation of the uterine vessels), LH(a) (where the uterine vessels were ligated laparoscopically but there was still some vaginal component), TLH (where the entire hysterectomy was completed laparoscopically with no vaginal component other than the removal of the uterus), and non-categorisable LH (where there was insufficient information or the types of LH were too heterogeneous to otherwise subcategorise). Subtotal versus total hysterectomy is the scope of another Cochrane review and trials making this comparison were excluded from the present review. Trials evaluating different surgical approaches to subtotal hysterectomy were also excluded. However, if a minority of the trial women had a subtotal hysterectomy and the comparison was made between any of the three approaches outlined above then the trial was included.

Types of outcome measures
The following outcome measures were defined as the primary outcomes:

Primary outcomes
- Return to normal activities
- Satisfaction and quality of life
- Intra-operative visceral injury
  - Bladder injury
  - Ureter injury
  - Urinary tract (bladder or ureter) injury
- Bowel injury
- Vascular injury

Secondary outcomes
- Operation time
- Other intra-operative complication
  - (Sequelaes of) bleeding
  - Substantial bleeding
  - Haemoglobin or haematocrit drop
  - Transfusion
  - Pelvic haematoma
  - Unintended laparotomy for approaches not involving routine laparotomy
- Short-term outcomes and complications
  - Length of hospital stay
  - Infections
    - Vaginal cuff
    - Abdominal wall or wound
    - Urinary tract infection
    - Febrile episodes or unspecified infections
  - Thromboembolism
  - Costs

Note: data on the cost of treatment were sought but it was intended to describe these data qualitatively and not to include the information in the meta-analysis, since ‘cost’ could be defined differently in different studies depending upon whether studies incorporate the cost of sequelaes. Different healthcare systems could produce markedly different results.

Measures of treatment effect
Statistical analysis was performed in accordance with the guidelines from the Cochrane Handbook for Systematic Reviews of Interventions. The data were analysed using an intention-to-treat model, where data were available. Dichotomous data were expressed as odds ratios with 95% confidence intervals and combined for meta-analysis with RevMan software using the Peto-modified Mantel-Haenszel method. Continuous data were combined for meta-analysis with RevMan software using the mean difference (MD) with 95% confidence interval (CI). The mean and
standard deviation (SD) were used when available or calculated from 95% CIs. When only the median and (interquartile) ranges were reported, or when measures of variation were missing, these results were presented as descriptive data. Outcome variables that were reported only graphically were not included in the study. Statistical heterogeneity between the results of different studies was examined by inspecting the scatter in the data points on the graphs, the overlap in their CI and, more formally, by checking the results of Chi^2 tests and I^2 statistics. The outcomes were pooled statistically where no clinical heterogeneity was apparent. A fixed-effect model was used where statistical heterogeneity was absent. Where statistical heterogeneity was apparent following pooling of data, this was noted and statistically significant results interpreted cautiously after further analysis using a random-effects statistical model.

Data synthesis
A fixed-effect model was used to calculate a pooled estimate of effect in meta-analyses. If significant statistical heterogeneity was confirmed by the Chi^2 test (P < 0.1) and the I^2 statistic (I^2 > 50%) it was planned to use a random-effects model.

Results
Fifty-five trials were identified. Nine of these were initially identified as published abstracts from conference proceedings. The first authors of these studies were contacted in an attempt to obtain details that were not reported; two studies were included and two excluded. Five studies that had been listed as ‘Studies awaiting assessment’ in the first publication of the review have been included in the present update. Either no replies from the authors were received to our repeated request for more information or the women had already been included in another study. One study was excluded because of scientific felony. Fourteen further studies were excluded from the review; the reasons for their exclusion are listed in the ‘Characteristics of excluded studies’ table of the online version. The authors were able to extract data from the remaining 33 trials of which three compared VH versus AH; 19 compared LH versus AH (including one LH-BSO versus AH-BSO and one LAVH versus minilaparotomy AH); five compared LH versus VH; two compared LAVH versus TLH; one compared both LH versus AH and LH versus VH; and three compared LH versus AH versus VH.

Interventions
Surgical procedures
**VH versus AH**
Four trials compared VH with AH; one included a laparoscopic arm as well. Hysterectomies were performed by standard technique for each route.

**LH versus AH**
Twenty-three trials included a comparison of LH with AH. These included four trials that randomised women to LH, AH, and VH. Raju et al. compared LH and bilateral salpingo-oophorectomy (LH-BSO) with AH-BSO. Ellstrom et al. stratified the two randomised groups (LH and AH) into total and subtotal hysterectomies. Muzii et al. performed minilaparotomy for AH (with a moving surgical field or window and three separate retractors).

**LH versus VH**
Nine trials included a comparison of laparoscopic hysterectomy (LH) with vaginal hysterectomy (VH), including the four trials randomising women to LH, AH, and VH. Garry et al. performed a very large RCT comparing LH (called vLH in the trial) with VH and LH (called aLH in the trial) with AH; it was essentially two concurrent RCTs as part of the same study.

**Blinding**
One trial reported sham abdominal dressings until discharge in VH. One trial reported blinding of the interviewer one month after surgery.

**Intention-to-treat**
Twenty-five trials reported no dropouts. Of the eight RCTs reporting dropouts, three reported analysis by intention to treat (ITT), defined as all randomised women reported upon according to the group of randomised allocation. Five RCTs reporting dropouts did not report ITT analysis of all randomised women. Five RCTs reporting dropouts did not report ITT analysis of all randomised women.

**Primary outcomes**
Return to normal activities
**VH versus AH**
For VH versus AH, patients returned to normal activities sooner after VH (MD 9.5 days, 95% CI 6.4 to 12.6 days; 176 women, 3 trials) although statistical heterogeneity was present (Chi^2 P value 0.02, I^2 = 75.3%); similar results were obtained with a random-effects model.

**LH versus AH**
Return to normal activities was quicker after LH than after AH (MD 13.6 days, 95% CI 11.8 to 15.4 days; 520 women, 6 trials) although statistical heterogeneity was present (Chi^2 P value 0.004, I^2 = 71.2%); similar results were obtained with a random-effects model.
LH versus VH
For LH versus VH there was no difference in return to normal activities (140 women, 2 trials).
See also Figure 1.

Figure 1 Forest plot of Return to normal activities after different types of hysterectomy.

Intra-operative visceral injury
VH versus AH
There were no statistically significant differences in bladder, ureter, or urinary tract injuries for the comparison VH versus AH (239 women, 3 trials). No bowel or vascular injuries occurred in either group.
LH versus AH
Where bladder and ureter injuries were pooled as ‘urinary tract injury’, there was a significant increase in urinary tract injury for LH versus AH (OR 2.41, 95% CI 1.21 to 4.82; 2090 women, 12 trials). There were no statistically significant differences in bladder, ureter, bowel, or vascular injuries for the comparison LH versus AH.
LH versus VH
There were no significant differences in urinary tract injuries between LH and VH (805 women, 6 trials). Furthermore, there were no statistically significant differences in bowel or vascular injuries for the comparison LH versus VH.

Major long-term complications
VH versus AH
No urinary dysfunction occurred in either group (80 women, 1 trial).
LH versus AH
No significant differences were found in the following long-term complications: fistula formation (245 women, 2 trials), and urinary dysfunction (246 women, 2 trials).
LH versus VH
No significant differences were found in the following long-term complications: fistula formation (56 women, 1 trial), and urinary dysfunction (80 women, 1 trial).

Secondary outcomes
Satisfaction and quality of life
VH versus AH
For VH versus AH, Silva Filho et al. found significantly better quality of life after VH in the SF-36 domains for functional capacity, physical aspects, and pain; furthermore, a higher rate of patients in VH who would choose the same treatment again. There were no significant differences in patient satisfaction between VH versus AH in the study by Benassi et al.
LH versus AH
For LH versus AH, Garry et al. demonstrated that quality of life (measured by the SF-12 scoring system) was significantly better for LH at six weeks; body image was significantly improved for LH versus AH at six weeks and four months, but not at 12 months; and sexual frequency was significantly higher at six weeks following LH. Kluivers et al. found a significant treatment effect favouring LH in the SF-36 domain for vitality in the first 12 weeks postoperatively. Lumsden et al. found no significant differences in patient satisfaction between LH and AH.
LH versus VH
Data on the quality of life and satisfaction were absent for LH versus VH.

Operation time
VH versus AH
Three trials in the meta-analysis of VH versus AH showed a significant difference, two in favour of VH (259 women, 3 trials). Because the direction of the treatment effect differed amongst studies, the results were not pooled.
LH versus AH
AH had a significantly shorter operation time than LH (MD 11.8 minutes, 95% CI 8.6 to 14.9 minutes; 1047 women, 11 trials). In the subcategory of trials where LAVH was compared with AH, one trial showed a significantly shorter operation time in LAVH, whilst other subcategories of LH took significantly longer than AH operations (LH(a) versus AH: MD 30.6 minutes, 95% CI 25.6 to 35.7 minutes; 420 women, 5
occurrence of pelvic haematoma, vaginal cuff infection, UTI, chest infection, and thromboembolic events.

**LH versus VH**

There were no significant differences in hospital stay for LH versus VH (685 women, 5 trials, Analysis 5.12). There were no significant differences in the need for blood transfusion, occurrence of pelvic haematoma, vaginal cuff infection, UTI, chest infection, febrile episodes or unspecified infection, and thromboembolic events.

### Data from included trials that were not in the meta-analysis

Only outcomes reaching statistical significance will be mentioned below.

#### Primary outcomes

**Return to normal activities**

**LH versus AH**

Median duration of return to normal activities was significantly shorter for LH in three trials.32,48,52

**Secondary outcomes**

**Operation time**

**VH versus AH**

Hwang et al.41 found a significantly shorter median operating time for VH (74 minutes) versus AH (98 minutes).

**LH versus AH**

In five trials, AH had a significantly shorter median operation time than LH.32,33,45,48,53 Dranonovsky et al.38 reported a significantly shorter median operating time for LAVH (85 minutes) versus TLH (111 minutes).

**LH versus VH**

Hwang et al.41 found a significantly shorter median operating time for VH (74 minutes) versus LH (109 minutes).

#### Intraoperative complications (other than visceral injury)

**VH versus AH**

No significant differences in mean blood loss were found between VH and AH (140 women, 2 trials).

**LH versus AH**

No significant differences were found in the number of women with substantial bleeding between LH and AH (1266 women, 5 trials).

**LH versus VH**

There was no difference in substantial bleeding (504 women, 1 trial). There were no differences in the number of unintended laparotomies (1290 women, 8 trials).

### Short-term outcomes and complications

**VH versus AH**

Hospital stay was significantly shorter in VH compared to AH (MD 1.1 day, 95% CI 0.9 to 1.2 days; 295 women, 4 trials) although statistical heterogeneity was present (Chi² P value < 0.00001, I² = 95.0%); similar results were obtained for these outcomes using a random-effects model. For VH versus AH, there were significantly fewer febrile episodes or unspecified infections in VH (OR 0.42, 95% CI 0.21 to 0.83; 295 women, 4 trials). There were no significant differences in the need for blood transfusion, mean blood loss, haemoglobin drop, occurrence of pelvic haematoma, or vaginal cuff infection, UTI and chest infection for VH versus AH.

**LH versus AH**

Hospital stay was significantly shorter in LH compared to AH (hospital stay MD 2.0 days, 95% CI 1.9 to 2.2 days; 1007 women, 10 trials) although statistical heterogeneity was present (Chi² P value < 0.00001, I² = 95.0%); similar results were obtained for these outcomes using a random-effects model. For LH versus AH, there were significantly fewer wound or abdominal wall infections in LH (OR 0.31, 95% CI 0.12 to 0.77; 530 women, 6 trials) and significantly fewer febrile episodes or unspecified infections (OR 0.67, 95% CI 0.51 to 0.88; 2138 women, 15 trials). Although LH and AH showed no significant difference in the need for blood transfusion, LH was associated with a significantly lower mean blood loss (MD 45.3 ml, 95% CI 17.9 to 72.7 ml; 693 women, 7 trials) and smaller drop in haemoglobin (MD 0.55 g/L, 95% CI 0.28 to 0.82 gm/L; 288 women, 3 trials). There were no significant differences in the occurrence of pelvic haematoma, vaginal cuff infection, UTI, chest infection, and thromboembolic events.

**LH versus VH**

There were no significant differences in hospital stay for LH versus VH (685 women, 5 trials, Analysis 5.12). There were no significant differences in the need for blood transfusion, occurrence of pelvic haematoma, vaginal cuff infection, UTI, chest infection, febrile episodes or unspecified infection, and thromboembolic events.
**Chapter 2** Surgical approach to hysterectomy for benign gynaecological disease

**Short term outcomes**

**VH versus AH**

Benassi et al.\(^{30}\) found a significant lower percentage of patients demanding analgesics after VH.

**LH versus AH**

For LH versus AH, LH was associated with significantly lower pain scores in a number of trials: on post-operative days 0, 1, 2 and 3,\(^{35}\) day 1 and 2,\(^{33}\) day 2,\(^{36}\) day 4,\(^{54}\) and on coughing.\(^{37}\) LH was associated with significantly less severe post-operative pain than AH.\(^{58}\) Recovery from pain was significantly faster for LH.\(^{32}\) Concerning analgesic use, LH was associated with: significantly less opiate use\(^{40,46}\) and oral and rectal analgesia;\(^{32}\) shorter duration of analgesic use overall\(^{32}\) and of patient-controlled analgesic use;\(^{45}\) fewer patients requiring intramuscular narcotics on the day of surgery;\(^{49}\) and less analgesic use after the first 24 hours.\(^{53}\) Median duration of hospital stay was significantly shorter for LH in six trials.\(^{32,45,48,50,52,53}\)

**LH versus VH**

In one study, LH was associated with significantly greater use of oral pain tablets on post-operative day two.\(^{37}\)

**TLH versus LAVH**

For TLH versus LAVH, TLH was associated with significantly greater use of tramadol during hospitalization.\(^{38}\)

**Cost**

**LH versus AH**

No trial found a significant difference in the overall cost of LH versus AH, but only five RCTs examined comparative cost in any detail.\(^{32,44,45,47,49}\)

**LH versus VH**

The mean total hospital cost was significantly higher for LH than for VH.\(^{17}\)

**Discussion**

**Summary of main results**

Our review found a number of statistically significant advantages of VH over AH. VH was associated with quicker return to normal activities, earlier discharge from hospital, and VH was less painful. There were conflicting data on which was the quickest operation to perform and this presumably relates to the prior experience with these procedures of the surgeons involved in the trials. LH offered a number of statistically significant advantages over AH. These were quicker return to normal activities, less post-operative pain, fewer wound or abdominal wall infections, fewer febrile episodes or unspecified infections, smaller drop in haemoglobin, earlier discharge from hospital, and improved quality of life at six weeks and four months after surgery; the cost was more urinary tract injuries and longer operating time. LH had a number of statistically significant disadvantages compared to VH. These were longer operating time, greater use of oral pain tablets on day two, and a higher hospital cost. TLH was associated with statistically significantly more urinary tract injuries compared to VH. TLH was associated with significantly more febrile episodes or unspecified infections and longer operation time compared to LAVH. Speed of recovery is determined by the avoidance of an abdominal procedure; AH is associated with lengthier recovery than all other approaches to hysterectomy. Avoidance of AH appears to be important to minimise post-operative pain and to avoid abdominal wall infections and infections of unspecified origin or general apyrexial illness post-operatively. Although regarded as very important, the quality of life data do not lend themselves easily to meta-analysis (due to the use of diverse tools, time frames, and statistical analysis). Data on quality of life can show the impact of surgery and complications on patients’ lives, and thus can be a leading argument in the discussion about the best way to perform a hysterectomy.\(^{17}\) Only a few studies in the meta-analysis have used quality of life as an outcome measure. The available data indicate that the laparoscopic and vaginal procedures performed better or equally compared with AH as far as the quality of life in the first weeks after the procedure was concerned. In the decision on an approach to hysterectomy, the advantage of better quality of life should be offset against disadvantages. Meta-analysis of quality of life data would benefit from the use of well validated instruments applied in a standardised manner in future studies.\(^{59,60}\)

Urinary tract damage, in particular ureteric injury, remains the major concern related to the laparoscopic approach.\(^{40,61,62}\) However, this meta-analysis of RCTs was underpowered to detect a clinically significant increase in the incidence of bladder and ureter damage from a laparoscopic approach. Much of the data for an increased incidence of urinary tract injury has come from non-randomised studies. Only large case series usually have the power to detect such a rare complication, but RCTs remain the least biased way to assess the benefits and harms of an intervention. When bladder and ureter injuries in our meta-analysis were pooled under a single category ‘urinary tract injury’, a significant increase in urinary tract injury was detected for LH versus AH (OR 2.4, 95% CI 1.2 to 4.8) and TLH versus VH (OR 3.7, 95% CI 1.1 to 12.2). Operating time is overall longer for LH versus AH, and LH versus VH. However, LAVH had a significantly shorter operating time than TLH. This suggests that operating time seems to be governed by the proportion of the surgery performed laparoscopically and the greater proportion performed laparoscopically, the lengthier the operation.
Overall completeness and applicability of evidence

It is particularly difficult to address the issues surrounding effectiveness and complications in surgical procedures where the skill base of surgeons is not only variable but different between surgeon experience of ‘traditional’ operations and ‘laparoscopic’ operations. This is likely to be especially relevant to the rates at which complications, such as ureteric damage, occur. There is no good way of taking into account the risk of such rare complications in surgeons who are beyond their learning curve. This is not just a hysterectomy issue but pervades many aspects of surgical therapy and surgical innovations. It does not apply to the same extent where drug therapy interventions are being studied, in which the efficacy is much less dependent on the skill of the investigator providing the treatment. Much of the Cochrane methodology is developed based on the medical model of intervention. Until the last few years, the vast majority of hysterectomies were performed abdominally,\textsuperscript{5,6} although in some countries there is a tendency to perform fewer abdominal hysterectomies.\textsuperscript{14,64} In the current state of gynaecological practice and training, all training gynaecologists tend to become thoroughly trained in abdominal hysterectomy techniques but there is huge variation in their learning curve position in relation to vaginal and laparoscopic hysterectomy techniques. In clinical practice as well as in the trials included in this review, VHs will be mostly performed under optimum conditions only, whereas AH remains the default intervention for all more difficult cases. Each gynaecologist (as has been the case since AH became the alternative to VH, in 1863)\textsuperscript{15} will have his or her own indications for the choice of approach to hysterectomy for benign disease. These choices may be influenced to some extent by the results from scientific evidence (for example this review) but the decisions will also be largely based on their own array of surgical skills and the patient characteristics. Whether there will be more of a consensus in the future than there has been to date, regarding these indications for route of hysterectomy, is less certain. To reach this consensus, however, should probably not be the ultimate goal since the prudent decision for one approach to hysterectomy over the other may be very justified and may lead to better outcomes after all. One concern is the statistical heterogeneity of the trials included in this review. The heterogeneity in such outcomes as operating time, even when the ‘traditional’ hysterectomy techniques VH versus AH are compared, directly relates to the fact that some surgeons are better trained in and thus perform faster either type of hysterectomy. This heterogeneity might be expected to be even more apparent when LH is compared with either AH or VH. Concerning the heterogeneity in recovery time, hospital policies on post-operative stay and advice regarding when to resume work can differ, hence the observed differences.

Although much has been written in the scientific literature about various outcomes of hysterectomy, there has been no discussion on what outcomes are of key importance. Surgeons wish to minimise operative complications, healthcare managers wish to minimise costs, but what do patients want? Quality of life is likely to be the most key outcome as it captures the benefit the patient experiences from treatment and takes into account the effects of complications on women’s lives.\textsuperscript{16,17,65} Consequently, the most plausible primary measure of effectiveness is ‘return to normal activity’ (where VH and LH fare most favourably). ‘Major lasting problem’ could be considered as the primary adverse event, but data on all long-term outcomes are sparse in these RCTs. Whether it is reasonable to prioritise outcomes as primary or secondary in advance is controversial. Usual Cochrane policy is to term the most clinically relevant outcome as ‘primary’ rather than the one most obviously affected by the treatments under comparison. There is certainly scope for the authors of individual RCTs to report only the outcomes that they consider to have produced interesting results, resulting in reporting bias.

Each single complication is rare and thus a large sample size is needed to capture each one of them individually and powerfully. So researchers tend to pool complications together into composite outcomes, an approach that is not scientifically sound. More importantly, when comparing different types of hysterectomies laparotomy cannot be a complication of abdominal hysterectomy, leading to asymmetry of comparison. There is currently a much larger database of trial experience involving LAVH than for TLH and this undermines the extent to which conclusions may be drawn about TLH currently.

One vital conclusion from our review must be that VH remains a very good option when it is feasible, since we have not shown any significant disadvantages of VH versus any other approach. In selected cases, even in patients without previous vaginal delivery, VH can be performed.\textsuperscript{66} The concept that LH allows identification of pelvic disease (such as adhesions and endometriosis) which could otherwise lead to complications with VH, and that the meticulous haemostasis achievable with ‘final look’ laparoscopy during LH might reduce pelvic haematomas or vaginal cuff infections, have not been borne out in the outcomes in this review. It is uncertain whether the increased detection of unexpected pathology at LH versus VH affects subsequent clinical outcomes.\textsuperscript{60} Although it has been suggested that LAVH does little more than to combine the complications of laparoscopic surgery with those of vaginal surgery,\textsuperscript{14} this has not been supported in our review. Where oophorectomy is desired, a laparoscopic approach may facilitate this.
Surgical approach to hysterectomy for benign gynaecological disease

Authors’ conclusions

Implications for practice

When technically feasible, VH should be performed in preference to AH because of more rapid recovery and fewer febrile episodes post-operatively. Where VH is not possible, LH has some advantages over AH (including less operative blood loss, more rapid recovery, fewer febrile episodes, and wound or abdominal wall infections) but these are offset by longer operating time and more urinary tract (bladder or ureter) injuries. No advantages of LH over VH could be found; LH had a longer operation time. The surgical approach to hysterectomy should be decided by a woman in discussion with her surgeon in light of the relative benefits and hazards. These benefits and hazards seem dependent of surgical expertise and may influence the decision.

Implications for research

The various subcategories of LH should be further evaluated against each other. For example, whether TLH has any benefits or harms in comparison to other forms of LH (including LH(a) and LAVH). The increase in the rate of ureteric injury resulting from LH, suggested by very large observational studies, remains to be conclusively proven by RCT data. In recent years, robot-assisted hysterectomy has come into practice, but RCTs are lacking, until now. Although it is important that RCTs should have the same surgeon (or group of surgeons) carrying out each of the approaches being compared, different levels of expertise with each approach means that such RCTs are always likely to be statistically heterogeneous when considered for pooling in meta-analyses. We strongly encourage trial authors to report their laparoscopic approach to hysterectomy according to defined subcategories: LAVH, LH(a), TLH, and LSH (laparoscopic supracervical hysterectomy). This should minimise the confusion that has prevailed in the first published literature on LH.

There is an absence of data for long-term outcomes in RCTs comparing surgical approaches to hysterectomy. RCTs should aim to report long-term outcomes, including urinary, bowel, and sexual function, along with occurrence of fistulae. Quality of life may be regarded as a key outcome in trials on the approaches to hysterectomy for benign disease. To enable meta-analysis of quality of life data, well validated instruments should be applied in a standardised manner.

References

Chapter 2

Surgical approach to hysterectomy for benign gynaecological disease


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Chapter 3

Quality of life after laparoscopic and abdominal hysterectomy: a randomized controlled trial

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Abstract

Objective: To report the 4-year follow-up quality-of-life data of a randomized controlled trial between abdominal and laparoscopic hysterectomy and to investigate whether any difference in quality of life would remain long-term.

Methods: Patients scheduled for hysterectomy for benign indications were randomized and received the Dutch version of the Short Form 36 questionnaire. The Short Form 36 consists of eight domains in which 100 points can be obtained. Higher scores denote a higher quality of life. A linear mixed model was used to study the differences between the two groups up to 4 years after surgery for each of the domains and the total Short Form 36 score separately.

Results: Fifty-nine patients were randomized (27 to laparoscopic hysterectomy and 32 to abdominal hysterectomy). Median follow-up after surgery was 243 weeks (range, 188–303 weeks). The overall response rate on the Short Form 36 questionnaire after 4 years was 83% (49 of 59 patients). Total Short Form 36 questionnaire scores were significantly higher in patients after laparoscopic compared with abdominal hysterectomy up to 4 years after surgery (overall mean difference 50.4 points [95% confidence interval 1.0–99.7] in favor of laparoscopic hysterectomy). Higher scores were also found on the domains physical role functioning, social role functioning, and vitality.

Conclusion: With a follow-up of 4 years, patients who underwent laparoscopic hysterectomy reported a better quality of life compared with abdominal hysterectomy. Therefore, patients in whom vaginal hysterectomy is not possible should be able to have a laparoscopic hysterectomy, if feasible, in terms of uterine size.


Introduction

In studies reporting on surgical procedures, emphasis often lies on outcome measures such as operation time, surgical complications, hospital stay and recurrence rate. From the patients point of view, however, results such as symptom resolution, return to normal activities and patient satisfaction are at least as important as the classical outcomes. These patient-centered outcomes may well be summarized in the measurement of quality of life with validated questionnaires. Especially in surgery for benign diseases, quality of life may be one of the most important outcome measures and should be utilized more systematically in trials, as it is now only reported in up to 5% of randomized trials. In cancer studies, the importance of patient-centered outcomes are likewise emphasized and reported.

More than 500,000 hysterectomies for benign pelvic diseases are performed in the United States each year. In spite of this high number of hysterectomies, a small minority of studies on hysterectomy have evaluated quality of life after different types of surgical approaches. A recent review and meta-analysis of randomized trials reported that, compared to abdominal hysterectomy, women who received laparoscopic hysterectomy had a lower intra-operative blood loss, lower drop in hemoglobin, lower percentage of wound infections and quicker return to normal activities, but a higher rate of urinary tract injuries. A large observational study from Finland has shown that the risk of urinary tract injuries in laparoscopic hysterectomy decreases with surgical experience. Only 2 studies reported quality of life as primary outcome measure, whereas an additional 7 mentioned quality of life as secondary outcome measure. Conclusions from 2 of these studies were that, up to 12 weeks postoperatively, quality of life was higher after laparoscopic hysterectomy as compared to abdominal hysterectomy. However, as the longest follow up was 1 year, no conclusions could be drawn on any long term effect.

In the present study we report the long term follow-up (4 years) from a randomized controlled trial between laparoscopic and abdominal hysterectomy for benign gynaecologic disease. The goal of this study was to investigate whether any difference in quality of life would remain long time after surgery.

Methods

Between August 2002 and January 2005, patients scheduled for hysterectomy for a benign condition, in whom vaginal hysterectomy was not possible, were randomized between laparoscopic and abdominal hysterectomy. Exclusion criteria were size of the uterus greater than 18 weeks gestation, a suspicion of malignancy, a previous lower midline incision, the need for simultaneous interventions like...
prolapse repair and inability to speak Dutch. Furthermore, patients using anti-depressant drugs or with a history of psychiatric disease or other severe medical issues were excluded. Randomization took place by opening numbered, sealed opaque envelopes. For concealment an independent person had randomly assigned an equal number of 38 papers with either intervention to the envelopes. Closed envelopes were randomly drawn at each new inclusion. Neither the patients nor the medical team were blinded to the intervention.

The study was conducted in the Máxima Medical Centre, a large teaching hospital in the south of The Netherlands. The gynecology department is experienced in minimal access surgery and the first laparoscopic hysterectomy was performed in 1992. Laparoscopic hysterectomies were all intentionally total laparoscopic hysterectomies and abdominal hysterectomy was performed by the standard extrafascial technique. Laparoscopic hysterectomies were performed by 3 experienced gynaecologists. There was a standard operative procedure which has been described in detail before. Approval from the local medical ethical committee (METC-MMC) was acquired and informed consent from each participant was obtained.

Short term quality of life was the primary outcome measure of the trial and these results have been published before. After a median follow-up of 4 years, the participants from the primary study were sent the Dutch version of the Short Form 36 questionnaire (similar as used in the first study) by regular mail. The SF-36 is a general health-based survey of quality of life. It has been validated, is used widely across medical disciplines, and can be self-administered by the patient with reliability. The SF-36 consist of 8 domains (vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health) and on each domain, 100 points can be obtained. As a consequence, the total SF-36 score may range from 0 to 800 points. Higher scores denote a better quality of life. In a previous study, the SF-36 has been identified as the superior questionnaire to assess quality of life after hysterectomy. Furthermore, the patients were asked if any adverse health event had occurred since last follow up.

Sample size was calculated for quality of life as measured by the Medical Outcome Trust 36-item Short Form Health Survey questionnaire (SF-36). A difference of 15 points per scale was considered clinically relevant. With a standard deviation of 20, a type I error of 0.05 and 80 % power, 28 patients were needed per arm. A linear mixed model was used to study the differences between the two groups up to 4 years after surgery, while accounting for the baseline values, for each of the domains and for the total SF-36 score separately. The dependent variable was a SF-36 (domain) score. The independent continuous variable was the baseline value of the dependent variable. The independent class variables were group (laparoscopic and abdominal hysterectomy) and weeks post surgery (2, 4, 6, 12 and 212). The interaction-term between these two variables was also included in the model. The intercept of each patient was treated as random variable in the model. This technique allows us to estimate differences between treatments given the baseline value, while differences in recovery among patients are allowed.

Initially, the actual time at the last follow-up and the interaction term with group were included in the model, to study the effect of the variation in time of the last follow-up (range 3.6 to 5.8 years) on the outcome. However, these terms were omitted from the final model, since these never reached the level of statistical significance. The estimated regression parameters with standard errors of the final model of the SF-36 (domain) score were used to calculate the average level with confidence interval per week of the patients in each group. These levels with confidence interval bands are further presented in figures.

The data were analyzed using SAS 9.2 (SAS Institute Inc., Cary, NC, USA) and SPSS 16.0 (SPSS Inc., Chicago, USA). P-values < 0.05 were considered statistically significant.

Results

Fifty-nine patients were randomized (27 to laparoscopic and 32 to abdominal hysterectomy). After 4 years, 49 patients (83%) returned the SF-36 questionnaire. Median follow-up after surgery was 243 weeks (range 188 to 303 weeks). Patient and surgical characteristics at baseline are summarized in table 1. These results are

| Table 1 Baseline patient and surgical characteristics of participants. |
|-----------------|-----------------|-----------------|-----------------|
|                 | Laparoscopic hysterectomy | Abdominal hysterectomy | P      |
| Age (years)    | Median (range)     | Median (range)     |       |
|                | 46 (30 – 62)       | 43 (30 – 55)       | 0.51  |
| BMI (kg/m²)    | 25.8 (19.2 – 34.9) | 26.9 (19.1 – 34.9) | 0.82  |
| Operation time (min) | 116 (62 – 205) | 77 (32 – 149)      | < 0.01|
| Blood loss (mL)| 200 (50 – 900)     | 275 (100 – 1100)   | 0.01  |
| Uterine weight (g)| 300 (62 – 1066)  | 177 (40 – 458)     | 0.02  |
| Hospital stay (days)| 5 (3 – 10)      | 6 (4 – 9)          | 0.02  |

P-values from a non-parametric test (Mann-Whitney U)
consistent with the short term outcomes, except for the observed difference in uterine weight. Table 2 shows the estimated mean difference of the SF-36 domains post-surgery between the laparoscopic hysterectomy group and the abdominal hysterectomy group, using a linear mixed model. The second column of table 2 shows that on average the total SF-36 score, after correction for baseline values, was statistically significant higher in the laparoscopic hysterectomy group compared to the abdominal hysterectomy group up to 4 years (i.e. 212 weeks) post surgery. In other words, the mean total SF-36 score was estimated to be 50.4 points (95% CI: 1.0 - 99.7) higher in the laparoscopic hysterectomy group at each point of measurement up to 4 years post surgery, in case the mean values pre-surgery would have been identical. Similarly, higher scores for laparoscopic hysterectomy were also found on the domains vitality (12.8; 95% CI: 5.9 - 19.8), physical functioning (8.5; 95% CI: 0.6 - 16.4) and social functioning (8.4; 95% CI: 0.7 - 16.2). Regarding the domains general health, physical role functioning, emotional role functioning, social functioning and mental health, the differences between the two groups never reached the level of statistical significance. Note that the 95% CI of the adjusted overall mean difference between the groups of these domains included (easily) the value zero (i.e. no difference). Consistent with the short term outcomes, except for the observed difference in uterine weight.

Table 2 shows the estimated mean difference of the SF-36 domains post-surgery between the laparoscopic hysterectomy group and the abdominal hysterectomy group, using a linear mixed model. The second column of table 2 shows that on average the total SF-36 score, after correction for baseline values, was statistically significant higher in the laparoscopic hysterectomy group compared to the abdominal hysterectomy group up to 4 years (i.e. 212 weeks) post surgery. In other words, the mean total SF-36 score was estimated to be 50.4 points (95% CI: 1.0 - 99.7) higher in the laparoscopic hysterectomy group at each point of measurement up to 4 years post surgery, in case the mean values pre-surgery would have been identical. Similarly, higher scores for laparoscopic hysterectomy were also found on the domains vitality (12.8; 95% CI: 5.9 - 19.8), physical functioning (8.5; 95% CI: 0.6 - 16.4) and social functioning (8.4; 95% CI: 0.7 - 16.2). Regarding the domains general health, physical role functioning, emotional role functioning, social functioning and mental health, the differences between the two groups never reached the level of statistical significance. Note that the 95% CI of the adjusted overall mean difference between the groups of these domains included (easily) the value zero (i.e. no difference).

<table>
<thead>
<tr>
<th>Domain of SF-36</th>
<th>Difference in favor of LH</th>
<th>Difference compared to the reference</th>
<th>Difference compared to the reference</th>
<th>Increase per unit domain score at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted overall mean (95% CI)</td>
<td>2 weeks mean (95% CI)</td>
<td>4 weeks mean (95% CI)</td>
<td>6 weeks mean (95% CI)</td>
</tr>
<tr>
<td>Total SF-36</td>
<td>50.4 (1.0; 99.7)</td>
<td>181.4 (145.1; 217.0)</td>
<td>141.8 (105.4; 178.1)</td>
<td>104.6 (67.9; 141.3)</td>
</tr>
<tr>
<td>Vitality</td>
<td>12.8 (5.9; 19.8)</td>
<td>15.9 (11.0; 20.9)</td>
<td>10.3 (5.3; 15.3)</td>
<td>6.9 (1.9; 11.9)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>8.5 (0.6; 16.4)</td>
<td>41.4 (35.7; 47.2)</td>
<td>26.5 (20.7; 32.3)</td>
<td>10.0 (4.5; 15.9)</td>
</tr>
<tr>
<td>General health</td>
<td>0.9 (-6.4; 8.3)</td>
<td>-7.1 (-11.9; -2.3)</td>
<td>-6.9 (-11.7; -2.2)</td>
<td>-7.1 (-12.0; -2.3)</td>
</tr>
<tr>
<td>Role (physical)</td>
<td>4.1 (-5.2; 13.4)</td>
<td>66.3 (54.6; 77.9)</td>
<td>66.6 (54.9; 78.3)</td>
<td>61.7 (50.0; 73.5)</td>
</tr>
<tr>
<td>Role (emotional)</td>
<td>2.4 (-10.9; 15.6)</td>
<td>19.3 (7.1; 31.5)</td>
<td>14.0 (1.7; 26.3)</td>
<td>19.8 (7.4; 32.2)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>8.4 (0.7; 16.2)</td>
<td>37.2 (30.8; 43.6)</td>
<td>32.9 (26.5; 39.3)</td>
<td>21.8 (15.3; 28.3)</td>
</tr>
<tr>
<td>Mental health</td>
<td>3.8 (-1.8; 9.3)</td>
<td>0.5 (-4.7; 3.7)</td>
<td>-3.8 (-8.1; 0.4)</td>
<td>-4.7 (-9.0; 0.4)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

SF-36 = 36 Item Short Form Health Survey; LH = Laparoscopic Hysterectomy, AH = Abdominal Hysterectomy, CI= Confidence Interval, NA = Not Applicable. Note that the differences between LH and AH are estimated to be identical at all points of measurement post surgery (a parallel line model) for all the domains except for Bodily pain. For example, the mean Total SF-36 score in the LH group is 50.4 (95% CI: 1.0; 99.7) higher compared to the AH group at each time point post surgery (2 weeks, 4 weeks, 6 weeks, 12 weeks and 212 weeks, respectively). In contrast, the mean difference in Bodily pain between LH and AH that is present in the first weeks post surgery has diminished at 12 and 212 weeks post surgery (-0.4, 95% CI: -12.0; 11.0 and 5.2, 95% CI: -6.5; 16.8, respectively).
Table 2 shows that regarding the bodily pain, on average the score in the laparoscopic hysterectomy group was statistically significant higher compared to the abdominal hysterectomy group in the early weeks post surgery. However, this difference was found to be not statistically significant at 12 weeks and 212 weeks (i.e. 4 years) post surgery. Figure 1 and 2 visualize the agreement of the observed data with the estimated mean profiles in both groups. Specifically, the observed means of the total SF-36 score, the domains vitality, physical functioning and social functioning are in agreement with the estimated means, using a model of equal differences at each point of measurement up to 4 years post surgery (i.e. the parallel-line model).

Figure 1 The estimated mean profiles of the total SF-36 score, given the mean baseline score, up to 4 years post surgery in the laparoscopic hysterectomy group (thick solid line) and abdominal hysterectomy group (thick broken line).

The mean profiles are estimated using a linear mixed model with adjustment for baseline values. The short dashed lines indicate the appropriate 95% confidence bands and the vertical bars indicate the observed mean with one standard deviation. Note that for all domains except the Bodily pain a parallel-line model was used to estimate the mean profiles.

Figure 2 The estimated mean profiles of four domains of the SF-36, given the mean baseline score, up to 4 years post surgery in the laparoscopic hysterectomy group (thick solid line) and abdominal hysterectomy group (thick broken line).

Table 2 shows that regarding the bodily pain, on average the score in the laparoscopic hysterectomy group was statistically significant higher compared to the abdominal hysterectomy group in the early weeks post surgery. However, this difference was found to be not statistically significant at 12 weeks and 212 weeks (i.e. 4 years) post surgery.
surgery. Figure 2 also visualizes the agreement of the observed data and the non parallel-line model of the bodily pain post surgery. Note that the differences between both groups in the Figures 1 and 2 are larger compared to the estimated differences in Table 2, because Table 2 shows the estimated differences adjusted for the baseline values. In other words, Table 2 shows the difference one may expect given equal baseline values.

One patient (laparoscopic hysterectomy) reported loss of sensation during intercourse, what she attributed to the removal of her cervix. Besides this case, no specific surgery-related long term complications were reported. One patient (abdominal hysterectomy) had developed rheumatism in the upper extremities, one patient (laparoscopic hysterectomy) had developed fibromyalgia, one patient (abdominal hysterectomy) was treated for pulmonary carcinoma and one patient (abdominal hysterectomy) had cardiac problems (not otherwise specified).

Discussion

In this study, quality of life data at 4 years follow-up in a randomized controlled trial between laparoscopic and abdominal are presented. It was observed that 4 years after surgery, laparoscopic hysterectomy still offers advantages over abdominal hysterectomy in terms of quality of life, as measured with the SF-36 questionnaire.

The finding that quality of life is still better 4 years after laparoscopic hysterectomy is striking. The benefits of avoiding a laparotomy seem to work through after several years. Until now, laparoscopic hysterectomy has only proven to result in better quality of life until 6 and 12 weeks after surgery. There are several possible explanations for the long term effect on quality of life. The ongoing advantages of laparoscopic hysterectomy may be related to the higher scores on the Body Image Scale, as observed by Garry et al.26 Laparoscopic hysterectomy patients may be influenced positively by the fact that they underwent what in layman press is known as the “minimally invasive method” (e.g. on www.hysterectomyoptions.com).

Chronic abdominal pain may also contribute to less quality of life. In their review of chronic pain after surgery, Perkins et al.36 state that chronic abdominal pain is common after cholecystectomy (range 3-56 %).21 Nerve injury as well as psychological vulnerability and anxiety were mentioned as risk factors for developing chronic pain. In a prospective cohort study of patients having gastrointestinal surgery, Bruce et al. reported that 4 years after laparotomy the prevalence of chronic pain was 18 %.22 In their cohort, risk factors for chronic post surgical pain included female gender, younger age and surgery for benign disease. This quite resembles the characteristics of patients having hysterectomy for benign gynaecologic disease, as described in our study. Crombie et al. described their experience with patients attending specialist chronic pain clinics.23 In their survey among 5,130 patients with chronic pain, 22.5% implicated surgery as the cause of their pain and was particularly associated with the development of abdominal pain. Furthermore, there is evidence that formation of peritoneal adhesions may play a role in the development and persistence of chronic abdominal complaints.24,25

The fact that laparoscopy is superior to laparotomy in terms of hospital stay, pain and convalescence has been proven for inflammatory bowel disease,26-27 pancreatic surgery,28 cholecystectomy,29 appendectomy,30 inguinal hernia repair,31 benign ovarian tumour32 and hysterectomy.17 However, searching for randomized trials with quality of life as outcome measure only revealed superiority of laparoscopy in acute appendicitis30 and hysterectomy.11 In the era of enhancing patient-centredness, quality of life may well be the superior outcome measure comprising elements of surgery that patients find most important. As such, quality of life should be studied more often, especially in studies for benign indications.

The superiority of laparoscopic hysterectomy in terms of quality of life was consistent with better secondary outcomes such as hospital stay, use of analgesics and convalescence. Contoupoulos et al. performed a systematic review on reporting and interpretation of SF-36 outcomes in randomized trials published in 2005 in 22 journals with a high impact factor.7 Over 1,000 papers were screened of which 52 were identified as randomized trials using SF-36. They concluded that although SF-36 measurements sometimes produce different results from those of the primary efficacy outcomes, it rarely modifies the overall interpretation of randomized trials. Our findings are consistent with this.

This study has some limitations. First of all, there is a small sample size and not all patients returned the questionnaires after 4 years. However, a response rate of 83 % after 4 years is still acceptable. As in the initial study, a sample size calculation was performed to detect a difference of 15 points per scale of the SF-36.11 In this way, 28 patients were needed per arm. Although the current number of participants failed to reach the acquired 56 patients, we still observed significant differences in the total SF-36 score and in 3 out of 8 domains. Furthermore, note that at baseline there were some significant differences in quality of life data. These might be due to the fact that patients completed the questionnaire after randomization. Corrections for this difference have however been made in the linear mixed model.

Concerning the somewhat skewed diversion of patients in the laparoscopic and abdominal hysterectomy groups, this is probably due to the exclusion of patients which appeared to have endometrial carcinoma and who were analyzed separately. With regard to the length of hospital stay, discharge did not occur on predefined criteria and, as a consequence, hospital stay in laparoscopic hysterectomy patients was longer compared to some other studies on this subject. Another limitation was the matter of patients self-reporting their newly diagnosed conditions.
no certainty on International Classification of Diseases (ICD) diagnosis could be acquired. Other non-surgical factors that may have influenced quality of life, e.g., death of a spouse, have not been taken into account. As a consequence, these matters may have been a possible cofounder. Finally, in our study, laparoscopic hysterectomy reported better quality of life compared to abdominal hysterectomy patients. Therefore, all patients listed for hysterectomy in whom vaginal hysterectomy is not possible and with a moderately enlarged uterus should be able to opt for laparoscopic hysterectomy.

References


Part 2
The doctor’s perspective
Gynaecologists estimate and experience laparoscopic hysterectomy as more difficult compared with abdominal hysterectomy

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**Abstract**

**Introduction:** The level of difficulty of various types of hysterectomy differs and may influence the choice of either approach. When surgeons consider one specific approach to hysterectomy more difficult, they may be reluctant to perform this type of hysterectomy. The main objective of this study was to investigate the potential different levels of difficulty for laparoscopic and abdominal hysterectomy. Furthermore, the accuracy of estimating the level of difficulty was examined.

**Materials and Methods:** In a randomized controlled trial between laparoscopic hysterectomy (LH) and abdominal hysterectomy (AH), gynaecologists were asked to record the preoperatively estimated and postoperatively experienced level of difficulty on a Visual Analogue Scale (VAS). Differences between LH and AH were examined and the correlation between the estimated uterine weight on bimanual palpation and the actual uterine weight was calculated. A difference on the VAS of 3 points or more (ΔVAS ≥ 3) was considered clinically relevant.

**Results:** In 72 out of 76 cases, both VAS scores were recorded. LH was estimated and experienced as significantly more difficult as compared with AH. In 13 (18%) cases ΔVAS was ≥ 3, equally distributed between LH (n = 6) and AH (n = 7). Eleven of these 13 cases had a positive ΔVAS ≥ 3, meaning surgery was experienced as more difficult than it was estimated. Surgeon’s estimation of uterine size correlated well with the actual uterine weight.

**Conclusion:** LH is considered as more difficult than AH, which might be a reason for its slow implementation. In a large proportion of cases, gynaecologists seem to be able to estimate the level of difficulty of hysterectomy accurately.

**Introduction**

Hysterectomy is the most frequently performed major gynaecological surgical procedure. Vaginal hysterectomy (VH) is considered the least invasive approach. However, if VH hysterectomy is not possible, laparoscopic hysterectomy (LH) may avoid the need of a laparotomy in a large proportion of cases. Since the first description of LH by Reich et al. in 1989, this procedure has been implemented worldwide. In the Netherlands, however, the implementation of laparoscopic hysterectomy seems to develop at a slow pace. Kolkmann et al. reported that laparoscopic assisted vaginal hysterectomy (LAVH) was performed in only 58% of hospitals and only 4% of hysterectomies were LAVHs. Lack of laparoscopic training and experience during residency could be a factor of importance in this matter. With less experience, gynaecologists who plan hysterectomies may judge LH as too difficult and therefore may have a tendency to perform an abdominal hysterectomy when vaginal hysterectomy is not possible. Several factors may influence the estimated level of difficulty of hysterectomy: uterine size on bimanual palpation, patients weight and BMI, previous abdominal surgery and surgeon’s experience with the planned approach to hysterectomy. Furthermore, the estimated level of difficulty itself may have an impact on the scheduled amount of time for surgery. In order to optimize logistic patterns of operating theatre, next to accurate day case management, it is mandatory that surgeons planning hysterectomy make adequate estimations of the difficulty of surgery.

Until now, it is not known whether surgeons experience abdominal and laparoscopic hysterectomy equally difficult. The main objective of this study was to assess whether there was a difference in estimated and experienced difficulty between abdominal and laparoscopic hysterectomy.

**Materials and methods**

Between August 2002 and January 2005 a randomized controlled trial was conducted, in which women were randomized to either abdominal or laparoscopic hysterectomy. For benign indications, a vaginal hysterectomy was performed when the size of the uterus did not exceed 12 weeks’ gestation with the cervix descending until at least halfway the vagina under cervical traction with a tenaculum forceps. In cases in which these conditions for vaginal hysterectomy were not met and the size of the uterus did not exceed 18 weeks’ gestation, patients were eligible for the study. Exclusion criteria were suspicion of malignancy other than endometrial carcinoma, a previous lower midline incision, the need for simultaneous interventions like...
prolapse repair, and inability to speak Dutch. Written informed consent was required. We obtained approval for the study from the hospital Medical Ethical Committee.

We recorded body mass index (BMI), uterine size on bimanual palpation, the surgeon’s number of previously performed hysterectomies, operation time, conversions in case of LHs and per- and postoperative complication rate. The laparoscopic procedures were all intentionally total laparoscopic hysterectomies (TLH). The surgical technique has been described in detail before\(^9\). The abdominal hysterectomies were performed through a transverse incision using the standard extrafascial technique. The surgeon’s number of previously performed hysterectomies were used as a measure of surgical experience. Preoperatively, all gynaecologists were asked to rate the estimated level of difficulty on a 1-10 visual analogue scale (VAS) with the patient under anaesthesia. Postoperatively, the same was done for the experienced level of difficulty. Higher scores denote a higher difficulty level. A difference of 3 or more points between the estimated and experienced score (\(\Delta\)VAS \(\geq 3\)) was considered clinically relevant. Furthermore, we analyzed factors that could possibly be related to these cases of \(\Delta\)VAS \(\geq 3\) and factors related to cases in which a complication occurred. As a measure of the surgeon’s ability to perform accurate estimations, we analyzed the correlation between the estimated uterine size on bimanual palpation and the actual uterine weight on pathological examination.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) 16.0. Data are detailed as mean and standard deviation or median and inter quartile range and analysed by Mann Whitney test or Chi square test whenever applicable. Spearman’s Rho analysis was used to determine potential correlations. P-values below 0.05 were considered statistically significant.

**Results**

Out of 76 patients randomised, both pre- and postoperative VAS scores were recorded by gynaecologists in 72 patients (95%). Table 1 shows baseline patient characteristics and surgical parameters. As expected, LH required longer surgery time and was accompanied with less blood loss. Compared with AH, LH was estimated and experienced as more difficult. Subgroup analysis revealed that surgical experience (number of previous hysterectomies) was inversely related to the estimated level of difficulty in AH (Spearman’s rho -0.365; \(p = 0.031\)), but not in LH.

In 13 patients (18%), there was a \(\Delta\)VAS \(\geq 3\) (surgery was estimated significantly less or more difficult compared to the actual experienced difficulty; see figure 1).

### Table 1 Baseline patient characteristics and surgical parameters.

<table>
<thead>
<tr>
<th></th>
<th>AH (n = 35)</th>
<th>LH (n = 37)</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>48.1 ± 9.5</td>
<td>50.0 ± 9.2</td>
<td>0.208</td>
</tr>
<tr>
<td>Parity</td>
<td>1.5 ± 1.3</td>
<td>1.9 ± 1.2</td>
<td>0.137</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>26.4 ± 3.9</td>
<td>26.7 ± 5.8</td>
<td>0.774</td>
</tr>
<tr>
<td>Uterine size (weeks)</td>
<td>9.2 ± 4.2</td>
<td>9.7 ± 5.2</td>
<td>0.875</td>
</tr>
<tr>
<td>Estimated difficulty(^#)</td>
<td>3.0 ± 1.6</td>
<td>4.3 ± 2.4</td>
<td>0.023</td>
</tr>
<tr>
<td>Experienced difficulty(^#)</td>
<td>3.4 ± 2.2</td>
<td>4.8 ± 2.5</td>
<td>0.018</td>
</tr>
<tr>
<td>Surgery time (min)</td>
<td>82 ± 32</td>
<td>121 ± 31</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Blood loss (ml)</td>
<td>402 ± 299</td>
<td>204 ± 172</td>
<td>&lt; 0.01</td>
</tr>
</tbody>
</table>

Data are presented as mean ± standard deviation. AH = abdominal hysterectomy; LH = laparoscopic hysterectomy. \(^\#\)Estimated and experienced difficulty rated on a 0-10 Visual Analogue Scale, where a higher score denotes a higher difficulty level.

### Figure 1 Difference between estimated and experienced difficulty level in laparoscopic (LH) and abdominal hysterectomy (AH).

VAS: Visual Analogue Scale. A positive difference indicates that surgery was experienced as more difficult than it was estimated.
These 13 cases were equally divided between the laparoscopic (n = 6) and abdominal (n = 7) approach. In 11 out of 13 (85%) cases there was a positive ΔVAS ≥ 3 [surgery was experienced more difficult than it was estimated]. The 2 patients in whom experienced difficulty was significantly lower compared to estimated difficulty, were both AHs. Conversion from laparoscopy to laparotomy did not occur in these 11 patients.

Table 2 shows the cases of positive ΔVAS ≥ 3 in relation to BMI, operation time, intubation time, total time in operating room, blood loss, uterine weight, surgeons’ number of previously performed hysterectomies and complication rate. Surgery time, intubation time and total time in operating room were longer in more difficult cases (with positive ΔVAS ≥ 3), although 95% confidence intervals crossed zero.

Table 2 Factors possibly related to ΔVAS.

<table>
<thead>
<tr>
<th></th>
<th>ΔVAS &lt; 3 (n = 59)</th>
<th>ΔVAS ≥ 3 (n = 11)</th>
<th>Mean difference (95 % CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>26.5 ± 5.2</td>
<td>26.7 ± 4.4</td>
<td>NA</td>
</tr>
<tr>
<td>Time of surgery (min)</td>
<td>99 ± 37</td>
<td>119 ± 35</td>
<td>20 (-5 to 44)</td>
</tr>
<tr>
<td>Time of intubation (min)</td>
<td>120 ± 40</td>
<td>142 ± 34</td>
<td>22 (-4 to 47)</td>
</tr>
<tr>
<td>Time on OR (min)</td>
<td>129 ± 43</td>
<td>150 ± 31</td>
<td>21 (-2 to 44)</td>
</tr>
<tr>
<td>Blood loss (cc)</td>
<td>288 ± 269</td>
<td>382 ± 227</td>
<td>94 (-70 to 257)</td>
</tr>
<tr>
<td>Uterine weight (gram)</td>
<td>220 ± 182</td>
<td>215 ± 154</td>
<td>NA</td>
</tr>
<tr>
<td>Surgeon’s experience</td>
<td>30 (9-100)</td>
<td>30 (13-100)</td>
<td>NA</td>
</tr>
<tr>
<td>Complications (%)</td>
<td>8 (13.6)</td>
<td>1 (9.1)</td>
<td>NA</td>
</tr>
</tbody>
</table>

Data presented as mean ± standard deviation or # median (range) or * number (percentage).

† Only 11 cases with a positive ΔVAS ≥ 3 were used for this analysis (cases where experienced difficulty was higher than estimated difficulty).

¥ 95 % Confidence intervals of the mean difference (independent sample t-test)

Surgeon’s experience = surgeon’s number of previously performed hysterectomies.

Figure 2 shows the correlation between the estimated uterine size on bimanual palpation and the actual uterine weight on pathological examination. With Spearman’s rho = 0.702 (p < 0.001), the estimated size of the uterus correlated well with the actual weight.

In 9 patients (12.5%) a complication occurred (4 conversions and 1 bladder lesion in LH; 2 bleedings > 1000 cc, 1 severe allergic reaction and 1 unintentionally subtotal hysterectomy in AH). In these cases, BMI and both the estimated and experienced difficulty was higher (table 3).

Table 3 Factors possibly related to surgical complications.

<table>
<thead>
<tr>
<th></th>
<th>Complication (n = 9)</th>
<th>No complication (n = 63)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative VAS score</td>
<td>6.9 ± 2.8</td>
<td>3.2 ± 1.6</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Postoperative VAS score</td>
<td>7.3 ± 2.7</td>
<td>3.6 ± 2.1</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.4 ± 8.4</td>
<td>26.0 ± 4.1</td>
<td>0.014</td>
</tr>
<tr>
<td>Size of uterus (gr)</td>
<td>316 ± 368</td>
<td>205 ± 123</td>
<td>0.812</td>
</tr>
<tr>
<td>Surgeon’s experience</td>
<td>9 (3-100)</td>
<td>20 (0-100)</td>
<td>0.315</td>
</tr>
</tbody>
</table>

Data presented as mean ± standard deviation or # median (range)

VAS = 1-10 Visual Analogue Scale, where higher scores denote a higher difficulty level.

Surgeon’s experience = surgeon’s number of previously performed hysterectomies.
Discussion

To our knowledge, this is the first study in which estimated and experienced level of difficulty of hysterectomy have been compared. We have found that laparoscopic hysterectomy is estimated and experienced as more difficult compared to abdominal hysterectomy. We also observed that the level of difficulty in about one out of five operations is not correctly estimated. The subjective higher level of difficulty of LH versus AH may have a substantial role in the slow implementation of laparoscopic hysterectomy in The Netherlands. As mentioned by Koliman et al, in 2002 laparoscopic assisted vaginal hysterectomy (LAVH) was performed in only 58% of hospitals and only 4% of hysterectomies were LAVHs. Total laparoscopic hysterectomy (TLH) was not reported to be performed. More laparoscopic training and experience during residency may partly melt away this subjective higher level of difficulty. Many initiatives have already been taken to enhance the practise hours on virtual reality and box trainers. Results from a Dutch nationwide study on laparoscopic hysterectomy will soon reveal its current implementation.

More surgical experience with AH seems to be associated with a lower estimated level of difficulty. This association was not observed in LH, which might be due to the fact that all LHs were performed by experienced laparoscopic surgeons, whereas AHs were also performed by residents in training. Many authors have reported on the learning curve for LH and, in general, concluded that with increasing experience, operation time and complication rate decreased. In literature, data on the learning curve for AH are scarce. Yagasaki et al. concluded that from 25 AHs and onwards blood loss is reduced and surgical time reduces from 75 AHs and onwards. Leminen et al. stated that increased experience had no effect on complication rates in AHs, but a decrease of 44% was seen in LHs. Previous studies have reported on factors that may influence operating room planning. Although adequate estimation of surgery time for a specific procedure is frequently mentioned as an important factor, refinement of OR allocations a few months before the day of surgery as well as management decisions on the day of surgery appear to be more relevant in preventing over- or underutilization of operating rooms. In a large observational study, average underestimation of required surgery time by surgeons and schedulers was 22 minutes for each 8 hours of OR time. In our study, patients in which surgery was estimated less difficult than it was experienced (positive AVAS ≥ 3) required on average 21 minutes longer OR time. However, as confidence intervals just crossed zero and this short overutilization of an operating room is likely to be levelled by underutilization of other ORs and up-to-date day case management, no strict conclusions can be drawn from this result. Furthermore, as our study concerned a randomized trial in which the scheduler was not necessarily the surgeon, reticence on extrapolating these findings to everyday practice seems argumentative.

Interestingly, we found higher estimated difficulty levels in cases where a complication occurred. This might be an indication for surgeons being capable of predicting the risk of complications. Others have studied the possibility of predicting the risk of complications in gynecologic (laparoscopic) surgery. Mirashemi et al. found that, besides type of laparoscopic surgery, increasing age was the most important predictor of complications. In our study, age was not related to the occurrence of complications (data not shown). Myers et al. developed a model to predict medical and surgical complications of hysterectomy; they incorporated demographic, diagnostic, and procedural data. However, they concluded that use of routinely collected administrative data for risk adjustment of hysterectomy complication rates cannot be recommended. Dean et al. concluded that the mean length of hospital stay was longer and complication rate was higher in patients with 2 or more co-morbidities, age above 60 and higher ASA (American Society of Anesthesiologists) classification score. Several other groups tried to predict which patients were at risk for postoperative infection in AH; they concluded that bacterial vaginosis and trichomoniasis vaginitis are risk factors for the development of post hysterectomy cuff cellulitis. All mentioned factors can be used to coordinate pre-, intra- and postoperative care.

There are some possible limitations of our study. First of all, the preoperative estimation of level of difficulty was performed with the patient under anaesthesia. This may have led to a slightly different estimation as compared to judgement in the outpatient setting. Secondly, the scheduler was not necessarily the surgeon who performed the hysterectomy and multiple surgeons scheduled and performed the hysterectomies. Furthermore, in cases with high estimated and experienced VAS scores, the reason for these high scores were not reported by surgeons. Finally, the difference in VAS score of 3 units is a chosen cut off point.

In conclusion, we have found that laparoscopic hysterectomy was estimated and experienced as more difficult compared to abdominal hysterectomy. This may be a matter of importance in the slow implementation of LH in The Netherlands. Further studies on the effect of enhancing laparoscopic training and experience are needed.
References


Chapter 4 Gynaecologists estimate and experience LH as more difficult compared with AH
Chapter 5

The operation room as a hostile environment for surgeons: physical complaints during and after laparoscopy

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Dick F. Stegeman
Kirsten B. Kluivers

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Introduction

Since the late eighties, laparoscopy has been widely implemented in medicine. Patients experience less postoperative pain\(^1\)\(^-\)\(^3\), shorter hospital stay\(^1\)\(^,\)\(^4\) and better cosmetic results\(^5\)\(^,\)\(^6\). In contrast, there is more burden for the surgeon due to longer surgery time\(^1\)\(^,\)\(^4\)\(^,\)\(^7\), less ergonomic positioning\(^8\)\(^,\)\(^9\) and the use of non-ergonomic instruments.\(^10\)\(^-\)\(^12\) Guidelines have been developed to improve ergonomic circumstances during laparoscopic procedures which deal with the optimal table height, monitor placement, foot pedal positioning and instruments’ handle design.\(^10\)\(^,\)\(^13\)\(^-\)\(^17\) Despite these guidelines, some limitations of laparoscopy, leading to suboptimal ergonomic conditions, will remain. The loss of binocular vision, limited degrees of freedom, the limited ergonomic design of instruments and longer operation time demand more physical effort from the laparoscopic surgeons compared to open surgery. These conditions result in more awkward movements and positioning of the upper extremity and greater muscle strain on arm and hand. Physical complaints such as fatigue, pain, stiffness and numbness of the upper extremity have previously been reported.\(^11\)\(^,\)\(^18\)\(^-\)\(^20\) This may dispose surgeons to musculoskeletal or arthritic injuries of the upper extremity, known as “minimal access surgery (MAS)-related surgeon morbidity syndromes”.\(^21\) Furthermore, this may also decrease the patients’ safety during laparoscopic surgery.

In a clinical review on ergonomics in medicine and surgery, Stone et al.\(^22\) concluded that despite the success in many areas, ergonomics still has to make a major contribution to health care. Since ergonomics is celebrating its 60\(^{th}\) anniversary this year (http://ergonomics.org.uk/page.php?s=6&p=193), we aimed to measure the present-day prevalence of physical strain and complaints among surgeons during or after laparoscopic procedures. One of the objectives of this study was to determine the possible difference between the dominant and non-dominant upper extremity. Furthermore, the possible causes of physical complaints were evaluated.

Methods

The study was conducted at the Radboud University Nijmegen Medical Centre, The Netherlands. In this centre, 16,000 elective operations are performed each year, of which approximately 800 are laparoscopic procedures. A questionnaire with 16 items was developed for the purpose of this study, and included questions on years of laparoscopic experience, type of laparoscopic procedures performed and handedness. The participants were asked to describe physical complaints during or after laparoscopic procedures, as well as the possible causes. The frequency of

Abstract

**Background:** Due to suboptimal ergonomic conditions during laparoscopic procedures, surgeons are disposed to physical strain on the upper extremity. The primary objective of this study was to assess the prevalence of physical complaints among laparoscopic surgeons and to assess the factors that influence these complaints.

**Methods:** A questionnaire was distributed in a university hospital to all surgeons who perform laparoscopic procedures. Participants were asked to answer questions related to experience, physical complaints during or after laparoscopic procedures and the possible causes of their complaints.

**Results:** Fifty-five out of 92 (60%) surgeons completed the questionnaire. In this group, 40 surgeons (73%) reported physical complaints during or after laparoscopic procedures, mainly involving neck, lower back, shoulders and thumbs. Significantly more surgeons reported complaints in the dominant upper extremity compared to the non-dominant side. Poor table height adjustment, bad monitor positioning and suboptimal design of instrument handles were reported as important causes of complaints.

**Conclusion:** Physical complaints of the dominant upper extremity are common among laparoscopic surgeons, especially less experienced surgeons. The dominant upper extremity appears to be more involved than the non-dominant side. More awareness and implementation of ergonomic guidelines is needed.
Fourteen (25%) surgeons had previously performed less than 50 laparoscopic procedures whereas 41 (75%) surgeons had performed more than 50 procedures. In the group with less experience, 12 (86%) surgeons had physical complaints, whereas physical complaints were rated on a Likert scale (rarely, occasionally, frequently, always). Surgeons were furthermore asked whether they themselves or colleagues had ever had surgical complications due to physical complaints or fatigue. Out of the 16 questions, four questions were open ended. One included an anatomical figure of a human body (front and back side) on which the areas of physical complaints could be indicated. The questionnaire was covered by an explanation of the study and a return envelope was included. To prevent under-reporting of physical complaints, the questionnaire had to be returned anonymously. After 4 weeks, a reminder to return the questionnaire was sent out. To test whether surgical experience had an impact on physical complaints, a cut off of 50 previously performed laparoscopic procedures was used to divide the surgeons into two groups with different experience levels.

Statistical analysis was performed using the Statistical Package for the Social Sciences version 16.0 (SPSS, Inc., Chicago, IL). Chi-square analysis was used in case of two by two tables. Numerical data were analysed with the Kruskal Wallis test. A $p$ value of less than .05 was considered statistically significant.

**Results**

One hundred and six surgeons and surgical trainees (gynaecologists, general surgeons and urologists) work at our centre. Fourteen surgeons from the department of Trauma and Vascular Surgery never performed laparoscopic procedures and were excluded. Consequently, 92 questionnaires were posted to 52 surgeons and 40 surgical trainees. Fifty-five participants (60%) returned the questionnaire. The response rate among surgeons and trainees was 67% and 50%, respectively. The characteristics of the study population are presented in Table 1. Only 2 (4%) respondents were left-handed. The most frequently performed types of laparoscopic surgery were diagnostic laparoscopy (58%), cholecystectomy (29%), ovarian surgery (29%), sterilisation (27%) and appendectomy (26%). Forty (73%) of the responding laparoscopic surgeons reported physical complaints during or after laparoscopic procedures. Forty-five percent rated their complaints as occurring rarely, 45% occasionally, 10% frequently and none as always. Figure 1 shows the involvement of the dominant and non-dominant upper extremity during or after laparoscopic procedures. These data illustrate that statistically significant more physical complaints were experienced at the dominant side compared to the non-dominant side ($p = 0.012$). The number of surgeons reporting physical complaints in none, one and in two upper extremities was equally divided (35%, 29% and 36% respectively, $p = 0.505$). The most frequently affected body areas were shoulders, low back and neck (45%, 26% and 15%, respectively).

![Figure 1](image1.png)

**Table 1** Characteristics of the study population.

<table>
<thead>
<tr>
<th></th>
<th>Urology</th>
<th>Surgery</th>
<th>Gynaecology</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of respondents (%)</td>
<td>9 (50)</td>
<td>20 (57)</td>
<td>26 (67)</td>
<td>0.017</td>
</tr>
<tr>
<td>Age (years)*</td>
<td>40.0 ± 5.8</td>
<td>38.2 ± 6.3</td>
<td>40.4 ± 9.8</td>
<td>0.756</td>
</tr>
<tr>
<td>Number of females (%)</td>
<td>3 (33)</td>
<td>4 (20)</td>
<td>12 (46)</td>
<td>0.021</td>
</tr>
<tr>
<td>Number of residents (%)</td>
<td>3 (33)</td>
<td>6 (30)</td>
<td>11 (42)</td>
<td>0.086</td>
</tr>
<tr>
<td>Years of experience*</td>
<td>6.2 ± 4.4</td>
<td>7.5 ± 4.3</td>
<td>10.6 ± 9.5</td>
<td>0.522</td>
</tr>
<tr>
<td>Hours of surgery time/week#</td>
<td>5.0 (1.0-16.0)</td>
<td>7.0 (1.0-15.0)</td>
<td>6.0 (0.0-30.0)</td>
<td>0.209</td>
</tr>
</tbody>
</table>

Experience in years and hours of surgery time are presented for laparoscopic procedures only. Data presented as *mean ± standard deviation or #median (range). P-values were calculated using the Kruskal Wallis test.

Fourteen (25%) surgeons had previously performed less than 50 laparoscopic procedures whereas 41 (75%) surgeons had performed more than 50 procedures. In the group with less experience, 12 (86%) surgeons had physical complaints, whereas
in the more experienced group 28 (68%) surgeons reported complaints (p = 0.011).
In analogy with this finding, respondents with physical complaints were younger than respondents without complaints (38.0 ± 6.5 versus 43.5 ± 10.3 years, p = 0.022). No statistically significant differences between specialist surgeons and trainees, males and females or between the three specialities in the experience of physical complaints could be detected.
Regarding the possible causes of physical complaints, 35 (64%) respondents reported the poor positioning (inadequate table height, position and height of the screen, and limited freedom of movement) during a laparoscopic procedure as the main cause. Less frequently reported causes were the limited ergonomic instrumentation, such as the design of the handle (49%), longer operation time (40%), physical strain on the upper extremity (28%) and type of laparoscopic procedure (18%) (mainly pelvic lymph node dissection and prostatectomy). None of the respondents reported occurrence of surgical complications due to fatigue or physical complaints.

Discussion

This study reports on the prevalence of physical complaints among laparoscopic surgeons and causes of this burden. We found that physical complaints during or after laparoscopic procedures are common, especially in the shoulders and neck. The dominant upper extremity seems to be more prone to physical complaints compared to the non-dominant side. Complaints decreased with laparoscopic experience.
Although, to our knowledge, the differences between dominant and non-dominant side have not been studied before, the prevalence of overall complaints is in analogy with earlier reports. In a study by Wauben et al,23 out of 284 surgeons and residents, almost 80% experienced discomfort in neck, shoulders and back. Berguer et al,24 found a lower prevalence; they collected 149 questionnaires and concluded that 12% of respondents reported frequent pain or numbness in the neck, shoulder, arm or wrist, whereas 18% reported stiffness in these areas. Objective discomfort has been assessed by others with electromyography (EMG), as a measure for the workload of muscles. A significant higher muscle strain on the upper extremity has been found during laparoscopic surgical tasks compared with open surgical tasks.8,9,23-25

As to the reported causes of physical complaints, a high percentage reported poor positioning due to suboptimal table height and monitor positioning. As early as 1998, Hanna et al,26 provided guidelines for the optimum position of video monitor during laparoscopy. They concluded that task performance improves when the

image display is placed in front of the surgeon, at a level below the head and close to the hands. The ideal view angle is reported to be approximately 15° below the horizontal line of sight.27-29 Several others investigated the optimal table height for laparoscopic surgery.14,15 In general, they recommended that the preferable table height for laparoscopic surgery ranges between a factor 0.7 to 0.8 of the surgeons’ elbow height, thus allowing instruments to rotate around elbow level. This corresponds with approximately 64 to 77 cm above floor level. In a large proportion of current operating rooms, this is beyond the range of the table height. Furthermore, about half of respondents still consider the limited ergonomic design of instrument handles as a cause of physical complaints. Although several studies have been published about this predicament in laparoscopy,12,27,28 we conclude that little progress has been made so far. Medical and industrial engineers, ergonomic specialists and surgeons should cooperate better to improve the design of these handles.
The significant higher percentage of complaints among the group with less experience compared with the more experienced group, may be explained by the fact that the group with less experience have less laparoscopic skills and, as a consequence, will have higher muscle tension. Better insight into the optimal placement of instruments introduction in the patients abdomen and options to improve ergonomics could also be a factor of importance. Our findings are consistent with the results by Hemal et al,20 who illustrated that surgeons with less than 2 years of laparoscopic surgical experience experienced more discomfort. Furthermore, higher EMG-amplitudes were found among residents compared with attending surgeons, which is a sign for more muscle strain as well.25 Ergonomic education and training early in medical career is desirable to optimize positioning of both surgeon and devices and, hopefully, prevent long lasting injuries.
A possible limitation of our study was that we only assessed the subjective complaints on the dominant and non-dominant extremity due to laparoscopic procedures. This may lead to underreporting of physical complaints, because surgeons may regard these complaints as “part of the job.” We have tried to bypass this effect by allowing the respondents to return the questionnaire anonymously. Furthermore, none of the respondents reported complications in their patients due to own physical complaints. Reluctance to admit this might have happened may play a role in this matter. As the response rate of subjects was only 60%, we have to be careful with statements regarding the total percentage of laparoscopic surgeons with physical inconvenience. However, if all the non-responders in this study would never have any complaints, still 43% of laparoscopic surgeons experience physical complaints. Finally, we did not correct for hand size, although from previous studies this is known to be a significant determinant of difficulty using laparoscopic instruments.29,30
In conclusion, a high percentage of the laparoscopic surgeons experience physical complaints during or after a laparoscopic procedure. The dominant upper extremity is more prone to physical complaints and physical complaints seem to decrease with increasing laparoscopic experience. Positioning of monitor, adjustment of table height and instruments design remain major bottlenecks. More awareness and better implementation of ergonomic guidelines is required to reduce surgeons’ burden and prevent long-lasting injuries to the upper extremities due to laparoscopy.
Chapter 5

Chapter 6

A randomized trial of training the non-dominant upper extremity to enhance laparoscopic performance

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Dick F. Stegeman

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Abstract

Introduction: In laparoscopy, the surgeon’s dominant arm will execute difficult tasks with less effort compared to the non-dominant arm. This leads to a relative overuse of muscles on this side. We hypothesized that training the non-dominant arm would improve laparoscopic skills.

Material and methods: At baseline, all participants performed three validated tasks on a virtual reality simulator. After randomization, subjects in the intervention group were assigned training tasks. All these tasks had to be performed with the non-dominant hand. Within a week after a three-week study period, participants performed the same three tasks as before.

Results: Twenty-six participants were included, 13 in each group. At baseline, there were no differences between groups on all tested parameters. Compliance to training tasks was good. At the end of three weeks, subjects in both groups showed similar improvement of skills on the non-dominant side. On the dominant side, however, subjects in the training group showed significant better improvement of skills on four out of eight parameters.

Conclusion: Specific training of the non-dominant upper extremity appears to lead to improvement of skills on the dominant side, a phenomenon known in literature as intermanual transfer of skill learning. To improve laparoscopic skills, bimanual training is recommended.

Introduction

Handedness, also known as lateralization or hand dominance, is one of the most frequently occurring functional asymmetries present in approximately 96% of the human population. This asymmetry could well have consequences for surgical skills, when these are predominantly performed by the dominant hand. Obviously, complex tasks are executed with less effort by the dominant side. As a consequence, a relative overuse of the dominant upper extremity is expected. Especially laparoscopic surgeons will be prone to this overuse, as laparoscopy often involves more complex tasks than open surgery. Gupta et al. reported in their study that physical fatigue and lack of synchronized movements of the non-dominant hand were the most noted deficiencies in residents compared to experienced laparoscopic urologists.

Training in box trainers and Virtual Reality (VR) simulators has been shown to enhance laparoscopic skills. A study by Larsen et al. furthermore underscored that VR simulator training resulted in better technical performance and less operation time in laparoscopic salpingectomy. However, some trainees may never reach proficient psychomotor skills relevant for laparoscopy. The possible limitations of VR training are the availability of trainers and the troublesome implementation of VR training in a busy residency program. Our previous study among residents and clinical consultants performing laparoscopic surgery showed a significant larger proportion of physical complaints in the dominant upper extremity compared to the non-dominant side. This may be due to the fact that surgeons are inclined to perform complex tasks with their dominant arm. Enhancement of skills of the non-dominant upper extremity may result in a more equal distribution of tasks and, as a consequence, decrease work load and subsequent physical complaints of the dominant extremity. In this study, the effect of training the non-dominant upper extremity in everyday activities on virtual reality trainer performance is described. We hypothesized that specific training of the non-dominant hand and arm would result in improved skills on this side and, consequently, equip one better for laparoscopy.

Methods

Subjects

The study was conducted in the Radboud University Nijmegen Medical Center, which is a tertiary medical center. Residents and clinical consultants from surgical departments in our centre were recruited by mass e-mailing. True ambidexter persons were excluded. Subjects were told they had to be prepared to spend
approximately 15 minutes a day on training the non-dominant upper extremity in
everyday activities for 3 weeks. Right handedness was assessed using the
(translated) ten item Edinburgh Handedness Inventory (Oldfield 1971). Experienced
in laparoscopy was defined as having performed (i.e. being the primary surgeon)
more than 50 laparoscopic procedures. Subjects were randomized between a 3
week training schedule or no training.

Training
We specifically choose training tasks that could be performed in private time at any
location. For the purpose of this study, a diary was developed in which subjects in
the training group had to record or perform the tasks (hand writing, drawing lines
in labyrinths, cutting specific forms of paper and painting of drawn pictures). For an
example of completed tasks (drawing line in labyrinth and handwriting), see figures
1 and 2. Also, subjects in the training group were asked to brush teeth at least once
a day for 2 minutes with the non-dominant hand. Cutlery had to be changed from
left to right and vice versa with every dinner. Subjects in the intervention group
were provided with all the required material (diary, glue, scissors, pencils and
manual tooth brush). To measure the compliance of participants in the training
group, all task were assigned a specific score and with all tasks being performed, a
total of 100 points could be collected. The effect of training was compared to
subjects in a control group without specific training of the non-dominant hand and
arm. All participants were asked not to train on box trainers or Virtual Reality
trainers for the period of 3 weeks. Furthermore, subjects in the control group were
asked not to perform any of the tasks mentioned above with their non-dominant
hand. Testing at baseline and after 3 weeks was performed on a non-surgical day
for participants.

Virtual Reality Simulator
For objective assessment of the effect of training the non-dominant hand,
evaluation on a virtual reality simulator was performed. In this way, skill acquisition
and individual hand performance was assessed objectively. At baseline and
after 3 weeks, all subjects performed 3 tasks on a laparoscopic virtual reality (VR) simulator for laparoscopy (LapSim Virtual Reality Trainer, Skills Meducation, The Netherlands). Subjects were able to adjust the position of the simulator to their own optimal height. The 3 validated basic skill tasks were navigation, grasping and lifting & grasping, which provide specific parameters per hand. The parameters used were time in seconds, path length in meters (total distance covered with trocart) and angular path in degrees (measure for internal rotation of trocart). These variables signify efficiency and economy of movement. All 3 tasks generate these parameters separately for each hand, except “time” in the lifting & grasping task. For both groups, the percentage change was calculated and compared between the two groups; a negative value implies improvement whereas a positive value implies deterioration. This calculation was performed for the dominant and non-dominant upper extremity separately.

Power analysis and randomization
No previous studies reported on the expected difference after specific training the non-dominant hand in everyday activities. Hence, no sample size calculations could be performed. We aimed at a minimum of 10 subjects in each group. After completion of the tasks at baseline, randomization was performed using sealed opaque envelopes. These sealed envelopes contained papers with “intervention” or “control”, were shuffled and an envelope was drawn by each participant. All participants knew the goals of the study. Blinding was not performed. It was intended to analyze only cases that were available after the study period.

Statistics
Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 16.0 (Chicago, Illinois). For normally distributed data, student t-test was performed. For non-parametric testing, Mann Whitney U was performed. In all analysis, p < 0.05 was considered statistically significant.

Results
Twenty-six subjects were included and performed the tasks at baseline. One person in the control group was excluded from analysis because measurements after three weeks study period were not possible. Thus, a total of 13 subjects in the training group and 12 in the control group could be analyzed.

Out of 25 participants, 24 reported to be right handed. This was analogous to the results from the Edinburgh Handedness Inventory, where median score for right handedness was 9 (range 8-10; 10 is the score for strict right handedness). There were no differences in baseline characteristics for age, gender and experience in laparoscopy. None of the variables of baseline VR tasks showed a significant difference between groups (data not shown).

The diaries showed that there had been a good “compliance” in the intervention group (mean 88 points; range 69 to 100). During or after the performance of tasks, 6 out of 13 (46%) subjects in the intervention group experienced physical complaints in their non-dominant hand or arm, mainly after hand writing and brushing teeth. Performance of the non-dominant hand after 3 weeks revealed no significant change compared to the controls (see table 1). On 4 parameters, however, the dominant hand showed significant improvement of skills in the intervention group, whereas there was less improvement or even deterioration in controls (see table 2).

### Table 1 Change in task variables after 3 weeks of the non-dominant hand.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 13)</th>
<th>Control group (n = 12)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navigation: time</td>
<td>-8</td>
<td>-5</td>
<td>0.594</td>
</tr>
<tr>
<td>Navigation: path length</td>
<td>0</td>
<td>0</td>
<td>0.635</td>
</tr>
<tr>
<td>Navigation: angular path</td>
<td>-13</td>
<td>-8</td>
<td>0.307</td>
</tr>
<tr>
<td>Grasping: time</td>
<td>-21</td>
<td>-23</td>
<td>0.583</td>
</tr>
<tr>
<td>Grasping: path length</td>
<td>-25</td>
<td>-22</td>
<td>0.421</td>
</tr>
<tr>
<td>Grasping: angular path</td>
<td>-29</td>
<td>-38</td>
<td>0.516</td>
</tr>
<tr>
<td>Lifting &amp; grasping: path length</td>
<td>-18</td>
<td>-16</td>
<td>0.241</td>
</tr>
<tr>
<td>Lifting &amp; grasping: angular path</td>
<td>-17</td>
<td>-17</td>
<td>0.689</td>
</tr>
</tbody>
</table>

Data reported as median percentage of change between baseline and 3 weeks. A negative value denotes an improvement, whereas a positive value implies a deterioration.
In these experimental studies, the dominant limb system area may play a role in intermanual transfer of acquired skills. Furthermore, an intermanual transfer, several studies have been published.16-20 Functional Magnetic Resonance imaging and Positron Emission Tomography (PET)-Computed Tomography scanning showed that the cerebellum, prefrontal cortex and supplementary motor area may play a role in intermanual transfer of acquired skills. Furthermore, an intact posterior part of the corpus callosum is required for this transfer.20,25-27

Previously, a rather stringent distinction was made between dominant and non-dominant hand function. Recent studies, however, provide evidence for various degrees of handedness with both sides having specific advantages in movement tasks.1,28-30 In these experimental studies, the dominant limb system shows specialization for controlling limb trajectory (movements from one fixed point to different targets), whereas the non-dominant system appears more specialized for controlling limb position (movements from different points to one fixed target). In everyday activities, this is for example observed in cutting bread and hitting a nail with a hammer. In interlimb transfer of motor learning it was, furthermore, concluded that different features of movement transferred in different directions. It has been shown that opposite arm training improves only the initial direction of dominant arm movements, whereas it improves only the final position of non-dominant arm movements.1 In our study, all parameters that improved on the dominant side after training the opposite side are considered to be parameters for trajectory control. These findings are analogous with the aforementioned studies.

Some authors have reported on the relationship between the degree of handedness and its effect on intermanual transfer of skill learning.31,32 For example, less strongly right handed individuals exhibited better intermanual transfer of sequence learning. To correct for this possible confounder, we compared the self-reported handedness with the results from the Edinburgh Handedness Inventory and found that these were consistent in 24 out of 25 cases. Only one subject in the training group scored 6 items on right handedness and 4 items on ambidexterity. Therefore, no corrections for true ambidextrous subjects were necessary. Exclusion of the one left-handed subject did not alter the results.

Interestingly, we found that subjects in both intervention and control group showed improvement of skills with their non-dominant hand on all parameters. This may be due to the fact that at baseline, non-dominant hand performance was less compared to the dominant side. Consequently, a better score after 3 weeks is easier accomplished. Regarding the dominant side, we observed that on all but two parameters, all subjects in the control group decreased their skills compared to their initial measurement. We were not able to find a satisfactory explanation for this finding. Hypothetically, this may be due to the possibility that they were more tense/competitive compared to subjects in the intervention group and, consequently, showed less skill. It is known that stress impairs the performance of laparoscopic tasks.33 Furthermore, this may be an unexpected side effect of not having performed blinding.

Our study has possible limitations for the extrapolation of the results. Firstly, although the groups showed no differences in baseline characteristics, a variety of

### Table 2 Change in task variables after 3 weeks of the dominant hand.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 13)</th>
<th>Control group (n = 12)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navigation: time</td>
<td>-3</td>
<td>+8</td>
<td>0.273</td>
</tr>
<tr>
<td>Navigation: path length</td>
<td>0</td>
<td>+10</td>
<td>0.080</td>
</tr>
<tr>
<td>Navigation: angular path</td>
<td>-12</td>
<td>+6</td>
<td>0.025</td>
</tr>
<tr>
<td>Grasping: time</td>
<td>-14</td>
<td>+7</td>
<td>0.038</td>
</tr>
<tr>
<td>Grasping: path length</td>
<td>-10</td>
<td>+10</td>
<td>0.038</td>
</tr>
<tr>
<td>Grasping: angular path</td>
<td>-22</td>
<td>+9</td>
<td>0.016</td>
</tr>
<tr>
<td>Lifting &amp; grasping: path length</td>
<td>-13</td>
<td>-14</td>
<td>0.375</td>
</tr>
<tr>
<td>Lifting &amp; grasping: angular path</td>
<td>-13</td>
<td>-11</td>
<td>0.238</td>
</tr>
</tbody>
</table>

Data reported as median percentage of change between baseline and 3 weeks. A negative value denotes an improvement, whereas a positive value implies a deterioration.

### Discussion

To our knowledge, this is the first study in which specific training of the non-dominant upper extremity was examined in a randomized controlled trial. We hypothesized that training of the non-dominant upper extremity would result in improvement of skills on that side. However, our study could not show a significant improvement of skills on the trained non-dominant side compared to controls. Instead, we observed a significant improvement of the contra-lateral dominant extremity after training the non-dominant side.

It has been shown that practice of some novel tasks with one arm can improve performance of the other arm doing the same task. In literature, this phenomenon is known as “intermanual transfer of motor skills”.16-20 In studies examining this phenomenon, subjects are trained unilaterally in specific tasks. Subsequently, the same series of tasks has to be performed using the opposite hand and/or arm (unexposed side) and the time to accomplish task and accuracy were then compared. With different tasks, intermanual transfer can occur from the dominant to the non-dominant side and vice versa. Regarding the neural correlates associated with intermanual transfer, several studies have been published.21-24 Functional Magnetic Resonance imaging and Positron Emission Tomography (PET)-Computed Tomography scanning showed that the cerebellum, prefrontal cortex and supplementary motor area may play a role in intermanual transfer of acquired skills. Furthermore, an agreement that opposite arm training improves only the initial direction of dominant arm movements, whereas it improves only the final position of non-dominant arm movements.1 In our study, all parameters that improved on the dominant side after training the opposite side are considered to be parameters for trajectory control. These findings are analogous with the aforementioned studies.

Some authors have reported on the relationship between the degree of handedness and its effect on intermanual transfer of skill learning.31,32 For example, less strongly right handed individuals exhibited better intermanual transfer of sequence learning. To correct for this possible confounder, we compared the self-reported handedness with the results from the Edinburgh Handedness Inventory and found that these were consistent in 24 out of 25 cases. Only one subject in the training group scored 6 items on right handedness and 4 items on ambidexterity. Therefore, no corrections for true ambidextrous subjects were necessary. Exclusion of the one left-handed subject did not alter the results.

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Our study has possible limitations for the extrapolation of the results. Firstly, although the groups showed no differences in baseline characteristics, a variety of
medical doctors with different experience in surgery and laparoscopy were included. We therefore have to be cautious to extrapolate these findings to the group of residents in which training studies are mostly performed. Another matter is the small sample size of our study. For reliable sub group analysis to be performed, more participants are required. One participant was lost to follow-up. Since this was only one person on a total sample size of 26 and all but one parameters showed the same direction of effect, no effect on the final results is expected. Furthermore, as skills were tested on a VR trainer, it has to be seen what the actual effect on surgical skills will be. Finally, at baseline, we did not correct for previous experience in video gaming. Video game skills have been shown to correlate with laparoscopic skills. However, as the setting of the current study was a randomized controlled trial, we do not think this may have altered our results. In conclusion, our study demonstrates that training of the non-dominant upper extremity in everyday activities seems to improve laparoscopic skills on the dominant side. Larger studies are needed to confirm these findings. In view of the intermanual transfer of motor skills, we recommend bimanual training for improving bimanual skills and ambidexterity.

References

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Chapter 7

Does training of the non-dominant upper extremity reduce surgeons’ muscular strain during laparoscopy? Results from a randomized controlled trial

Theodoor E. Nieboer
Mark Massa
Martin J.N. Weinans
Mark E. Vierhout
Kirsten B. Kluivers
Dick F. Stegeman

Surgical Innovation (in press)
Abstract

Introduction: In laparoscopy, suboptimal ergonomics frequently lead to morbidity for surgeons. Physical complaints are more commonly reported on the dominant upper extremity. This may be the consequence of challenging laparoscopic tasks being easier performed by the dominant side. We hypothesized that specific training of the non-dominant upper extremity may equip this side better and lead to a more equal distribution of physical load.

Materials and methods: Participants (medical doctors) were randomized to a 3 week training schedule or no training. The training program consisted of training the non-dominant upper extremity. Participants were not allowed to train on a laparoscopic box or virtual reality trainer during the study period. Baseline and outcome measurements after three weeks were examined with the use of EMG measurements during a validated task on a laparoscopic box trainer (beads placing alternately with the right and left hand, with the non-active side holding as loose as possible). Muscle strain of the trapezius and deltoid muscles and effective alternation of brachioradial and abductor pollicis brevis muscles were used as outcome variables.

Results: Twenty-six subjects were included. EMG analysis revealed that subjects in both intervention and control group showed a decrease in muscle strain of trapezius and deltoid muscles. However, there were no significant differences between groups. Subjects in the intervention group showed significantly better alternation in brachioradial muscle (improvement of 19% in the invention group and deterioration of 18% in the control group; p = 0.039).

Conclusion: Training the non-dominant upper extremity leads to better alternated use of lower arm muscles during a validated box trainer task. Repeating the task after 3 weeks led to less muscle tension in trapezius and deltoid muscles.

Introduction

Compared to open surgery, patients benefit from laparoscopy in terms of pain, convalescence time, hospital stay and cosmetic results.1-3 However, as there is a reverse to every medal, laparoscopy comprises greater physical strains for the surgeon. Up to 87% of surgeons report physical complaints during or after laparoscopy.4-7 Frequently mentioned injuries are located in shoulder, neck, upper extremities and thumb. These have been described as Minimal Access Surgery (MAS) related surgeon morbidity syndromes.5 The injuries concerned may result from factors that are inherent to laparoscopy, such as longer surgery time, more awkward body positioning, suboptimal design of instruments and lack of implementation of ergonomic guidelines. The fact that physical problems however are not confined to laparoscopic surgeons was demonstrated by Dolan et al.8 In their survey among gynaecologist, 72% reported back pain and 8% required surgery for this condition.

Studies on surgical ergonomics, including electromyography (EMG) measurements have shown that compared to open surgery, laparoscopy requires higher muscular load to the surgeon’s upper extremity.9-12 It has been shown that continuous strain in a static posture builds up lactic acid and toxins.11-13 Therefore, ergonomic guidelines have been developed which should be widely implemented. Wauben et al. however reported that, although 100% of interviewed surgeons stated that ergonomics were important, 89% was unaware of ergonomic guidelines.16 Training of laparoscopic skills in vitro may play a role in preventing physical injuries. It has been shown that training leads to better operating room performance and that effectiveness levels of experienced surgeons can be achieved early in residency.17-19 Furthermore, compared to novices experienced surgeons seem to have less physical complaints after laparoscopic surgery.5 It was also observed that physical complaints were significantly more often reported in the dominant upper extremity compared to the non-dominant side.6 This may be the result of the fact that complex tasks are easier accomplished with the dominant upper extremity, which may lead to a relative overuse of the dominant side.

In the present study, the effect of training of the non-dominant upper extremity on physical strain and alternation during a box trainer exercise was evaluated. We hypothesized that such specific training equips this non-dominant side better and leads to a more equal distribution of physical strain as measured with EMG.
Materials and methods

Subjects and randomization
The study was conducted in the Radboud University Nijmegen Medical Center. All residents and clinical consultants from surgical departments in this center were informed and recruited by e-mail. Right handedness was assessed using the ten item Edinburgh Handedness Inventory (Oldfield 1971). True ambidexterity was an exclusion criterion. Experienced in laparoscopy was defined as having performed (i.e. being the primary surgeon) more than 50 laparoscopic procedures. Subjects were randomized between a 3 week training schedule or no training. Randomization was performed using sealed opaque envelopes. These sealed envelopes contained papers with “intervention” or “control”, were shuffled and randomly drawn by the participants. The randomization was performed by the research assistant directly after the individual participant perform the task at baseline. The exercise accompanists were not blinded to the randomization. It was intended to analyze the cases with available data at both baseline and follow-up. Medical ethical approval was not applicable.

Training
The training tasks were performed during 15 minutes daily private time at any location. For the purpose of this study, a diary was developed in which subjects in the training group had to record or perform the tasks. All these tasks had to be performed by the non-dominant arm and hand and comprised non-dominant hand writing, drawing lines in labyrinths, cutting specific forms of paper and painting of drawn pictures (examples in figures 1 and 2, overview of training schedule in Table 1). Cutlery had to be changed from left to right and vice versa with every evening meal, and the tooth brush had to be utilized at least once a day for 2 minutes with the non-dominant hand. The main reasons for choosing every-day activities were that it is known that implementing a specific in-hospital training schedule is likely to reduce study compliance. Furthermore, our university hospital was unable to supply a sufficient amount of box trainers for use at home. The intensity of the tasks increased over the weeks. The compliance of participants in the training group was assessed on a scale of 0-100, where 100 points denoted that all tasks were performed correctly. Physical complaints during or after training had to be noted by the participants in the training group. The effect of training was compared to subjects in a control group. All participants (both intervention and control group) were not allowed to train on box trainers or Virtual Reality trainers for the period of 3 weeks. Furthermore, subjects in the control group were asked not to perform any of the tasks mentioned above with their non-dominant hand.

EMG measurements
Measurements of the trapezius, deltoid, brachioradial and abductor pollicis brevis muscles were performed by means of surface EMG electrodes (3M Red Dot 2271.
AG/AGCl). Surface EMG has the advantage of a more global view on muscle activity compared to fine-wire EMG for evaluation of muscle fatigue and force.\textsuperscript{1,2} A 32-channel EMG system was used to acquire bipolar surface EMG data (Porti 32, TMS International, The Netherlands). The sample rate was 2048 Hz, data were filtered with a digital FIR filter in the ADC (low pass, cut-off frequency 550 Hz). The EMG measurements were normalized for each participant by means of lifting a 2.5 kilograms weight while spreading arms laterally in the horizontal plane with hand palms facing down. Isometric muscle contractions were recorded during 3 seconds.

**EMG data analysis**

Data were analyzed in Matlab\textsuperscript{7} (Version 7.6.0.324, R2008a, the MathWorks\textsuperscript{™}). The raw bipolar surface EMG were high pass filtered (4th order Butterworth filter, with a cut-off frequency of 15 Hz). The RMS (Root Mean Square) amplitude was calculated for subsequent intervals of 100 ms. The resulting amplitude envelopes were used to calculate the relative activation time (RAT) for the trapezius and deltoid muscles. The mean EMG amplitude during the lifting was used as reference. RAT expresses the relative time during which the EMG amplitude exceeds 10% of that reference amplitude. Furthermore, the coefficient of variation (CoV) was calculated from the summed and smoothed (0.1 Hz, 4\textsuperscript{th} order Butterworth) activity of corresponding left and right brachioradial and abductor pollicis brevis muscles. Corresponding left and right activity was transformed into a comparable range by normalizing each with the 90\textsuperscript{th} percentile of the overall amplitude distribution. This variable uses the fact that better alternation in a task lowers the CoV of the summed signals compared with the independent left/right activity.

**Table 1 Overview of training tasks in the intervention group.\textsuperscript{*}**

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>3 labyrinth practices</td>
<td>Cutting 5 square pieces of paper</td>
<td>Hand writing exercise (40 words)</td>
<td>Random exercise#</td>
<td>No additional exercise</td>
<td>No additional exercise</td>
</tr>
<tr>
<td>Week 2</td>
<td>3 labyrinth practices</td>
<td>Cutting 8 pieces of square and round pieces of paper</td>
<td>Hand writing exercise (70 words)</td>
<td>Random exercise</td>
<td>No additional exercise</td>
<td>No additional exercise</td>
</tr>
<tr>
<td>Week 3</td>
<td>Cutting 3 pieces of randomly angled paper</td>
<td>Painting exercise</td>
<td>Hand writing exercise (105 words)</td>
<td>90 minutes of bowling</td>
<td>Random exercise</td>
<td>No additional exercise</td>
</tr>
</tbody>
</table>

\* During the 3 week training period, participants were asked to brush their teeth minimally 2 minutes per day with a provided non-electric tooth brush. Furthermore, participants were instructed to change cutlery from left to right and vice versa and control the computer mouse with their non-dominant hand for 5 days per week.

\# One of the previous 4 exercises (personal choice of the individual participant) had to be repeated.
Outcome measures and statistical analysis

For the trapezius and deltoid muscles, the RAT was the main outcome whereas the CoV was the main outcome for the brachioradial and abductor pollicis brevis muscles. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 16.0 (Chicago, Illinois). Differences between groups were tested with the use of student t-test (normally distributed data) or Mann Whitney U (non-parametric testing). In all analysis, p < 0.05 was considered statistically significant.

Results

Twenty-six participants were included and performed the task at baseline, 13 in each group. After 3 weeks, 1 participant was lost to follow-up. Characteristics of participants are shown in table 2. Only 1 participant was left-handed (intervention group). The “compliance” in the intervention group was good (mean 88 points; range 69 to 100). During or after the daily practice of training, 6 out of 13 (46 %) subjects in the intervention group experienced physical complaints in their non-dominant hand or arm, mainly after hand writing and brushing teeth.

At baseline and after 3 weeks, there were no statistically significant differences between groups in time required to perform the exercise (mean time in the intervention group 523 and 405 seconds; mean time in the control group 496 and 363 seconds). Participants in the intervention and control group performed the task significantly faster after 3 weeks (23% and 26% decrease in required time, respectively). Compared to novices, experienced laparoscopic surgeons performed the exercise significantly faster at baseline (mean 444 versus 581 seconds; p = 0.046) and after the study period of 3 weeks (mean 345 versus 428 seconds; p = 0.046).

Table 3 shows the difference in RAT for the dominant and non-dominant trapezius and deltoid muscles before and after the study period. It was observed that the dominant and non-dominant trapezius muscles and the dominant deltoid muscle showed a decrease in RAT after 3 weeks compared to baseline measurements. However, the decrease in RAT did not differ between groups. Furthermore, the non-dominant deltoid muscle was not different from baseline measurements in the intervention group, while there was a increase in RAT in the control group.

Table 4 shows the results of the CoV for the brachioradial muscles. These data show that after the training period, subjects in the intervention group performed better with respect to alternation in the brachioradial muscles, as compared to controls. EMG data for the abductor pollicis brevis muscle showed a wide range and there were artifacts in the measurements in 6 out of 26 participants, which made these measurements inappropriate for analysis.

Table 2 Baseline characteristics of study participants.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 13)</th>
<th>Control group (n = 12)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age^a</td>
<td>32 (28-59)</td>
<td>31 (23-37)</td>
<td>0.492</td>
</tr>
<tr>
<td>Females (%)</td>
<td>7 (54)</td>
<td>7 (58)</td>
<td>0.825</td>
</tr>
<tr>
<td>Experienced in laparoscopy (%)</td>
<td>6 (46)</td>
<td>7 (58)</td>
<td>0.683</td>
</tr>
</tbody>
</table>

Table 3 Difference in relative activation time (RAT) for trapezius and deltoid muscles.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 13)</th>
<th>Control group (n = 12)</th>
<th>P-value^*</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRAP non-dominant pre</td>
<td>16.6 ± 7.6</td>
<td>16.9 ± 8.7</td>
<td>0.922</td>
</tr>
<tr>
<td>TRAP non-dominant post</td>
<td>11.3 ± 9.0</td>
<td>13.5 ± 8.8</td>
<td>0.546</td>
</tr>
<tr>
<td>TRAP non-dominant Δ (%)</td>
<td>-32</td>
<td>-20</td>
<td>0.639</td>
</tr>
<tr>
<td>TRAP dominant pre</td>
<td>21.2 ± 9.4</td>
<td>18.0 ± 8.2</td>
<td>0.378</td>
</tr>
<tr>
<td>TRAP dominant post</td>
<td>16.1 ± 10.3</td>
<td>11.2 ± 6.2</td>
<td>0.169</td>
</tr>
<tr>
<td>TRAP dominant Δ (%)</td>
<td>-24</td>
<td>-38</td>
<td>0.342</td>
</tr>
<tr>
<td>DELT non-dominant pre</td>
<td>6.4 ± 4.1</td>
<td>7.9 ± 6.3</td>
<td>0.510</td>
</tr>
<tr>
<td>DELT non-dominant post</td>
<td>6.4 ± 3.7</td>
<td>9.9 ± 9.4</td>
<td>0.222</td>
</tr>
<tr>
<td>DELT non-dominant Δ (%)</td>
<td>0</td>
<td>+25</td>
<td>0.642</td>
</tr>
<tr>
<td>DELT dominant pre</td>
<td>8.0 ± 4.2</td>
<td>9.6 ± 6.4</td>
<td>0.476</td>
</tr>
<tr>
<td>DELT dominant post</td>
<td>6.2 ± 2.8</td>
<td>6.2 ± 2.9</td>
<td>0.954</td>
</tr>
<tr>
<td>DELT dominant Δ (%)</td>
<td>-23</td>
<td>-35</td>
<td>0.877</td>
</tr>
</tbody>
</table>

^aData reported as median (range). Experienced in laparoscopy was defined by > 50 laparoscopic procedures performed.

\[ ^{*} \text{P-values from non-parametric Mann Whitney test, considering differences between intervention and control group.} \]
Healthy adults are able to perform unilateral movements, although a slight, involuntary mirroring can often be observed on EMG. Recently, it has been demonstrated that this activity can be modulated by higher order cognitive control with directed attention. Furthermore, unwanted mirror activity may be potentially harmful in influencing the final outcome. A more customized training schedule, where specific outcomes and artifacts due to technical difficulties. Finally, as 6 of the 13 subjects in the intervention group developed physical complaints during the training period, they were more able to relax their non-active arm when transferring a bead in the box trainer. This may well be an important finding, since continuous contraction has proven to build up lactic acid and toxins in muscles. Studies have shown that the amount of mirror EMG activity increases with more demanding motor tasks, fatigue, cognitive distraction and age. However, it has been demonstrated that this activity can be modulated by higher order cognitive control with directed attention. Furthermore, unwanted mirror activity may be potentially harmful when moving a laparoscopic instrument out of view of the camera.

Bilateral trapezius and right deltoid muscle tension was decreased after the study period in participants in the intervention group, as well as in controls. This may be a result of the repetition itself, as participants were already familiar with the task. Regular training on box or Virtual Reality trainers as a whole may therefore be advisable. The well-known Hawthorne-effect (phenomenon that an individual performs a task better and with more caution when he has the knowledge that he is under observation and assessment) may have also been a matter of relevance. The observation however that muscle tension in the non-dominant deltoid muscle did not differ (intervention group) or was even raised (controls) is not quite consistent with the Hawthorne-effect. The lack of significant difference after the training period between the groups may well be a consequence of an inappropriate training schedule. After all, subjects were trained in everyday activities and tested on a laparoscopic box trainer. Future studies on training the non-dominant upper extremity specifically in laparoscopic tasks will have to reveal whether that would improve laparoscopic skills on that side. In a separate part of this randomized study, it was observed that participants showed improvement of the dominant side on a virtual reality trainer after training the non-dominant upper extremity. In literature, this phenomenon is known as intermanual transfer of motor learning. Surgeon’s knowledge of basis ergonomic principles will become more and more important in the near future, since an increase in laparoscopic surgery can be expected. Furthermore, with a trend to increasing sub-specialization, as also stimulated by the Dutch Health Care Council, more laparoscopies will be performed by less surgeons. As a result of this increase in case load, more physical injuries are expected. Emerging techniques such as Natural Orifice Transluminal Endoscopic Surgery (NOTES) and Single Incision Laparoscopic Surgery (SILS) are likely to be even significantly more challenging than conventional laparoscopy in terms of required muscular exertion.

This study has some limitations. First of all, no power analysis was performed prior to the study because reference data were lacking. Furthermore, it not known in detail what amount of decrease in muscular strain would be of clinical importance in preventing injuries in the surgeon. Since performing post-hoc power analysis remains very controversial, it was chosen not to perform this. In all, the results have to be interpreted with the necessary reservation. The number of participants was small, which hampered subgroup analysis. For example, one participant in the intervention group was left handed and we assumed that the left hand was directly comparable to the right hand of the other participants. It would however be interesting to analyze whether this assumption was true. Analysis of the 24 right handed individuals did however not change any of the outcomes and conclusions. Moreover, although muscles of the thenar compartment have frequently been reported as being involved in laparoscopy-related injuries, we were not able to test the abductor pollicis brevis muscle appropriately. Small surface EMG electrodes proved to be inadequate to produce data for analysis due to a wide range of the outcomes and artifacts due to technical difficulties. Finally, as 6 of the 13 subjects in the intervention group developed physical complaints during the training period, the intensity of training everyday activities might have been too high and may have influenced the final outcome. A more customized training schedule, where specific

Table 4 Difference in CoV for the brachioradial muscle.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 13)</th>
<th>Control group (n = 12)</th>
<th>P-value *</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRACH pre</td>
<td>0.081 ± 0.048</td>
<td>0.094 ± 0.052</td>
<td>0.497</td>
</tr>
<tr>
<td>BRACH post</td>
<td>0.101 ± 0.057</td>
<td>0.077 ± 0.064</td>
<td>0.333</td>
</tr>
<tr>
<td>BRACH Δ</td>
<td>-0.021 (-0.007 – 0.048)</td>
<td>-0.017 (-0.046 – 0.012)</td>
<td>0.039</td>
</tr>
</tbody>
</table>

CoV: Coefficient of Variation; the higher the CoV, the better the alternation in the box trainer exercise.
BRACH = brachioradial muscle.
Δ Mean change (95% confidence intervals) between CoV at baseline and after the study period. An increase implies better alternation, a decrease worsening.
* P-values from non-parametric Mann Whitney test, considering differences between intervention and control group.
characteristics of the individual participant are taken into account, may be superior. In conclusion, in this study it was observed that training the non-dominant upper extremity in everyday activities leads to better control in terms of alternation for the brachioradial muscle. However, our training regime did not lead to less physical strain on shoulder and upper arm muscle activity compared to controls. Future studies have to reveal what specific training types are useful to decrease or prevent physical complaints resulting from laparoscopic surgery.

References


(33) Obayashi S. Possible mechanism for transfer of motor skill learning: implication of the cerebellum. Cerebellum. 2004; 3(4):204-211.


Part 3

The patient’s perspective versus the doctor’s perspective
Chapter 8

General discussion and conclusions
General discussion

In this thesis, the advantages for patients in laparoscopic surgery are balanced against the (mainly ergonomic) disadvantages for surgeons. This is a new approach of interpreting the relevance of laparoscopy. To improve patient care as a whole, all preconditions, including ergonomic circumstances for surgeons, have to be considered and optimized where possible.

The patient’s perspective of minimally invasive surgery

In recent decades, the old adage “big surgeons, big incisions” has fortunately been increasingly abandoned. Since the first laparoscopy by Georg Kelling in a dog in 1901, this approach to surgery has been widely implemented in gynaecology, general surgery, urology and thoracic surgery. Compared to conventional open surgery, patients benefit with less pain, shorter hospital stay, earlier return to normal daily activities and better cosmetic results. Therefore, laparoscopic surgery is frequently denoted as minimally invasive surgery. Based on meta-analyses of randomized controlled trials, the laparoscopic approach has become the first choice in adnexal surgery, appendectomy and cholecystectomy.¹⁻⁴

As described in Chapter 2, the vaginal approach to hysterectomy is the first choice for women without suspicion of malignancy. In the meta-analysis of randomized controlled trials, laparoscopic hysterectomy offered no advantages over vaginal hysterectomy and laparoscopic hysterectomy took longer to perform. In 2010, in the Netherlands 14,930 hysterectomies for benign indications have been performed (data from KiwaPrismant; www.prismant.nl). Of these, 46% were vaginal hysterectomies, 41% abdominal hysterectomies and 13% laparoscopic hysterectomies. In 2008, these percentages were 51, 44 and 5, respectively. As it seems, the higher percentage of laparoscopic hysterectomies has risen partially at the cost of vaginal hysterectomy. This may be caused by gynaecologists who have embraced the relatively new technology of laparoscopic hysterectomy and started to perform this on patients with small uteri. Small uteri, even without reasonable descent, may well be removed vaginally. Recently, the old technique of uterosacral-cardinal ligament stretching during vaginal hysterectomy has been proven to increase uterine descent.⁵ Furthermore, a laparoscopic bipolar cutting forceps may be helpful in difficult cases of vaginal hysterectomy.⁶⁻⁷ Even the moderately enlarged uteri could be removed vaginally as concluded in several studies.⁸⁻¹² Residents in obstetrics and gynaecology should be thoroughly trained in vaginal hysterectomies, since the vaginal approach to hysterectomy remains the first choice of approach to hysterectomy.

Important studies on the Dutch rates of laparoscopic hysterectomy have been performed by Twijnstra et al.¹³ In 2007, 70% of the Dutch hospitals performed
Laparoscopic hysterectomies. Annually, 20% of Dutch hospitals where laparoscopic hysterectomy was implemented performed 50% of all laparoscopic hysterectomies, and 50% of the hospitals performed 20% of laparoscopic hysterectomies. These findings (“a few perform a lot, a lot perform a few”), and a critical report on laparoscopy in general by the Dutch Health Care Inspectorate, have been reasons for the Dutch Society for Obstetrics and Gynaecology to make new guidelines. It is advised that gynaecologists should perform at least 30 level III or IV (according to the classification of the Royal College of Obstetrics and Gynaecology, including laparoscopic hysterectomy) laparoscopic procedures annually. Future nationwide observational studies will be needed to observe the effects on trends in hysterectomy rates. Ideally, we should observe a rise in laparoscopic hysterectomies but not at the cost of the vaginal approach.

Studies on surgical procedures frequently report on traditional outcomes such as surgery time, blood loss and length of hospital stay. Only since the recent decade, the measurement of patient-centred outcomes has become more and more apparent. Quality of life is an important outcome in studies measuring the effect of surgical procedures. Well validated questionnaires represent and summarize various aspects that are relevant to patients. Especially in surgery for benign diseases, quality of life is expected to be one of the most important outcome measures. It should be used more systematically in trials, since now it is only reported in up to 5% of all randomized trials.\textsuperscript{14,15} Similarly, only a minority of randomized controlled trials on various types of hysterectomy reported on quality of life. We were able to report on the long-term (4 years) follow-up from a randomized trial on laparoscopic versus abdominal hysterectomy (Chapter 3). It was observed that compared to abdominal hysterectomy, quality of life after laparoscopic hysterectomy is still higher 4 years after surgery. One year was the longest follow-up in previous randomized hysterectomy trials and studies only reported a better quality of life at 6\textsuperscript{16} and 12\textsuperscript{17} weeks after laparoscopic hysterectomy. The benefits of avoiding a laparotomy persisted after several years in the present study. The ongoing advantages of laparoscopic hysterectomy may be related to a better Body Image Scale, as observed by Garry et al.\textsuperscript{16} Laparoscopic hysterectomy patients may be influenced purely by the awareness that they underwent what in layman press is known as the “minimally invasive method.” Chronic abdominal pain may also contribute to less quality of life.\textsuperscript{18,19} The difference in quality of life in favour of laparoscopic hysterectomy should serve as an incentive to further implement the laparoscopic approach in daily practise. As discussed above, this should however not be at the cost of vaginal hysterectomy, as this remains the first choice of approach.

The doctor’s perspective of minimally invasive surgery

Laparoscopic surgery is considered technically more difficult to perform compared to the conventional abdominal approach. There are less degrees of freedom, hand movements are contrary to the movement of instruments (fulcrum effect) and 3D-images are projected on a 2-dimensional screen. Consequently, the learning curve is longer and some surgeons may never reach proficiency.\textsuperscript{20} In Chapter 4, we concluded that gynaecologists estimated and experienced laparoscopic hysterectomy more difficult than abdominal hysterectomy. The subjectively higher difficulty of laparoscopic versus abdominal hysterectomy may have a substantial role in the slow implementation of laparoscopic hysterectomy in the Netherlands. Recently, Twijnstra et al. analyzed the preference of performers of laparoscopic hysterectomy and their referring colleagues over abdominal hysterectomy.\textsuperscript{21} They found that the immediate presence of a gynaecologist who performs laparoscopic hysterectomy influences the referral behavior of colleagues. Furthermore, they concluded that overweight was considered an unfavourable factor for choosing laparoscopic hysterectomy according to both referring gynaecologists and those who perform laparoscopic hysterectomies. In a study by Kolkman et al. in 2006, Dutch gynaecologists stated that insufficient laparoscopic skills training is an important obstacle to master advanced laparoscopic procedures such as laparoscopic hysterectomy.\textsuperscript{22} More recently, laparoscopic box trainers and virtual reality trainers have become more available in teaching hospitals. This may have consequences for the learning curves of laparoscopic surgery, as studied by Hiemstra et al.\textsuperscript{23} These authors evaluated the learning curve of residents for laparoscopic and abdominal hysterectomy by means of OSATS (Objective Structured Assessment of Surgical Skills). More than 300 OSATS were collected during a 27 months investigation period. Learning curves were defined as OSATS scores plotted against procedure-specific caseload and were compared for minimally invasive surgery and conventional surgery. It was concluded that basic minimally invasive surgery procedures are not harder to acquire during residency than conventional surgical procedures. A better incorporation of structured minimally invasive surgery training programs in residency during the recent years probably has played a significant role in this matter.\textsuperscript{24,25}

Ergonomics have been somewhat ignored in the first decades of laparoscopic surgery. It was not until the mid-nineties that studies arose on the high physical impact for surgeons in laparoscopy.\textsuperscript{26} In the following decade, there was an increasing recognition of the laparoscopy-specific injuries surgeons were prone to acquire. Ergonomic guidelines were developed, but implementation of these guidelines hampered.\textsuperscript{27} In the nearby future, a rise of caseload in laparoscopic surgery is to be expected.\textsuperscript{28,29} Added to the trend of further differentiation of tasks, surgeons will be exposed to more physical effort since it is known that laparoscopy
is physically more challenging than open surgery. In the study presented in Chapter 5, we observed a high prevalence (73%) of physical complaints in surgeons performing laparoscopic surgery. Neck, lower back, shoulders and thumbs were mainly mentioned. Surgeons indicated poor table height adjustment, bad monitor positioning and suboptimal design of instrument handles as important causes of complaints. These restrictions of operating theatres and instrument design have been described by others as well. Several laparoscopy-specific injuries to surgeons have already been described such as finger numbness, cervical hernia and shoulder pain. In a recent study, Rodrigues et al. found that in minimally invasive surgery, significantly more adverse technical events occurred compared to conventional surgery. Added to the suboptimal ergonomic conditions of laparoscopy, these adverse technical events provide additional risks for patients undergoing laparoscopic surgery. Further collaboration in the field of designing, developing and testing of laparoscopic instruments is expected to lead to a reduction of physical strain and injuries for surgeons and improve patients' safety in the operating room.

Handedness or hand dominance is present in approximately 96% of the human population, with 88% being right-handed. In laparoscopy, complex tasks are easier accomplished with the dominant side. Consequently, the prevalence of physical complaints in the dominant upper extremity was higher than in the non-dominant side (Chapter 5). In gynaecological laparoscopy, where surgical sites are located deep in the pelvis, one of the main factors of relevance may be the positioning of trocars. With the mostly right-handed gynaecologist positioned left of the patient and additional trocars being placed on the left and right side, the dominant upper extremity has to be stretched over the patient’s body when working with two instruments. Physical strain on the dominant upper extremity will, consequently, be higher compared to the non-dominant side. In addition, complex tasks are easier accomplished with the dominant extremity. More insight in ergonomic placement of trocars, e.g. two on the surgeon’s side of the abdomen to prevent high strain on the dominant side, will be of key importance in the prevention of minimal access surgery related morbidity in surgeons. Training the non-dominant upper extremity could lead to enhancing skills on that side and, consequently, a more equal distribution of physical strain during laparoscopic surgery. Gupta et al. suggested that hand writing with the non-dominant hand improved non-dominant hand functioning and reduced physical fatigue on that side. However, their conclusion was based on a study with only 1 participant. As described in Chapter 6, for the purpose of our study, we developed a specific training schedule for the non-dominant upper extremity of three weeks. In order to prevent a low participation rate, specific everyday tasks such as hand writing and using cutlery were chosen for the training period. Three validated tasks (Navigation, Lifting and Lifting & Grasping) on the LapSim virtual reality trainer were performed by the participants. After the study period, participants in both the control and the intervention group showed an increase in the non-dominant hand performance in 7 out of 8 parameters. And what is more, it was observed that in the parameters time, path length and angular path in Grasping and angular path in Navigation, subjects in the training group showed a significantly bigger improvement of skills on the dominant side compared to controls. This surprising effect, in literature referred to as intermanual transfer of motor skills, is important in the development of a training program for box or virtual reality trainers. In addition, surgeons may benefit from the knowledge that the dominant limb system shows specialization for controlling limb trajectory (movements from one fixed point to different targets), whereas the non-dominant system appears more specialized for controlling limb position (movements from different points to one fixed target). As mentioned earlier, muscular strain in laparoscopy has been proven to be significantly higher than in open surgery. According to the so-called “Cinderella hypothesis”, work-related muscular disorders are caused by the overuse of the low-threshold motor units (MUs, the muscle’s functional building blocks) as a consequence of long-time low-level contractions. These low-threshold MUs are the first recruited and are also the first ones to be at risk for selective fiber injuries in a sustained activation of the muscle (like in the tale where Cinderella had to work continuously). Intermittent muscle relaxation may therefore be of key importance. In a recent study by Szeto et al. long durations of static postures in laparoscopic surgery were strongly associated with continuous low-level muscle tension. As concluded in Chapter 7, training the non-dominant upper extremity leads to a better alternation in muscle activation of the brachioradial muscle in a box trainer exercise. Healthy adults are usually able to perform unilateral movements (as was the order in our box trainer exercise). However, a slight unintended mirror activity can often be observed and this mirror activity increases with more demanding motor tasks and fatigue. The latter occur frequently in laparoscopy and surgeons have to be aware of these involuntary mirror movements and especially avoid unintended tissue damage due to movements of the instrument out of sight of the camera. Specific attention has to be paid to residents, since novices in laparoscopy are inclined to use excessive forces in grip handling. The prevalence of physical complaints in less experienced laparoscopic surgeons was also higher compared to the more experienced surgeons (Chapter 5). Ideally, ergonomic guidelines are widely available and residents should be aware of these from the beginning of their participation in laparoscopy. In general, from the doctor’s perspective, laparoscopy as a minimally invasive way of surgery is not so harmless at all.
The patient’s perspective versus the doctor’s perspective

One could state that what is minimally invasive for the patient is maximally burdensome for the doctor. However, one may question whether it is altogether appropriate to compare the patients’ benefits from laparoscopic surgery to disadvantages for the doctors. All items in the Hippocratic oath are paraphrased from the patients’ point of view. Therefore, doctors may be inclined to consider negative side effects of treatments that are advantageous for patients as “part of the job.”

There are several arguments, however, to take the doctor’s perspective in laparoscopic surgery seriously into account. First of all, when experienced laparoscopic surgeons will develop minimal access surgery related morbidity and renounce from the operating theatre for a period of time, patients will potentially encounter longer waiting lists for surgery or maybe have to settle for a less experienced surgeon. Secondly, physical complaints of surgeons during laparoscopy may lead to a decrease in performance. Furthermore, the total costs of laparoscopic surgery compared to open surgery may further increase in case of a doctor’s sick leave and the associated costs for health insurance and these indirect costs will have to be taken into account when evaluating the cost-effectiveness of laparoscopic surgery.

Although it was not specifically studied in this thesis, some words will follow on robotic surgery. This latest development in surgery may present itself as the approach which comprises “the best of both worlds.” Meta-analyses of studies performed so far, have shown that compared to conventional laparoscopic surgery, robot-assisted surgery results in similar patient-related outcomes in hysterectomy, myomectomy, adnexectomy and fallopian tube reanastomosis. In a recent meta-analysis of non-randomized studies on robot-assisted laparoscopic hysterectomy versus traditional laparoscopic hysterectomy, it was concluded that robot-assisted hysterectomy was associated with shorter hospital stay, fewer postoperative complications and less conversions to laparotomy. Another meta-analysis showed that robot-assisted surgery provides certain advantages with respect to Heller myotomy, gastrectomy, and cholecystectomy. However, these meta-analyses include mostly non-randomized studies often with questionable methodological quality. Furthermore, almost all studies report higher costs for robot-assisted surgery. To date there is a lack of randomized trials that compare laparoscopic versus robot-assisted hysterectomy for benign indications.

The learning curve for robotic surgery is found to be shorter compared to laparoscopic surgery. In a study by Mucksavage et al., it was concluded that the Da Vinci (Intuitive Surgical) system overcomes innate hand dominance among novice surgical trainees. Additionally, recent studies have shown that robotic surgery is physically less demanding and decreases operator workload. As a consequence, proficiency in robot-assisted surgery is expected to be achievable for more surgeons compared to laparoscopy and physical complaints will be lower in surgeons performing robotic surgery. Therefore, when incorporating robot-assisted surgery in everyday practice, minimal access surgery may be available for a larger proportion of patients.

The ergonomic circumstances for surgeons in open, laparoscopic and robot-assisted surgery to date have not been taken into account in (randomized) trials, although from a macro-economical perspective this may well be justifiable. Ergonomic analyses of the surgeons’ posture during vaginal hysterectomy are also entirely. Future studies will have to demonstrate whether robot-assisted surgery is the abdominal approach from which both patients and surgeons benefit.

Conclusions

The vaginal approach to hysterectomy for benign gynaecological disease is the first choice. When vaginal hysterectomy is not possible, a laparoscopic approach may avoid the need for an abdominal hysterectomy. Risks and benefits of different approaches may be influenced by the surgeon’s experience (Chapter 2).

Compared to abdominal hysterectomy, laparoscopic hysterectomy provides advantages in terms of quality of life. These advantages are present up until 4 years after surgery (Chapter 3).

Gynaecologists estimate and experience laparoscopic hysterectomy as more difficult compared to abdominal hysterectomy (Chapter 4).

The prevalence of physical complaints in surgeons performing laparoscopic surgery is high and requires further attention (Chapter 5).

The dominant upper extremity appears to be more involved in physical complaints compared to the non-dominant side (Chapter 5).

Training the non-dominant upper extremity in everyday activities leads to enhanced performance of the dominant side during a validated box trainer exercise. Training did not lead to a decrease in muscular strain. (Chapters 6 and 7).

Training the non-dominant upper extremity leads to better control in terms of alternated use of lower arm muscles during a validated box trainer task. A decrease in involuntary mirror movements is of importance in preventing physical complaints and unintended tissue damage during laparoscopic surgery; training the non-dominant upper extremity may play a beneficial role in this matter (Chapter 7).
Chapter 8

Topics for future research

On the basis of this thesis, the following topics for further research are suggested:

Studies on the long-term results of vaginal hysterectomy in terms of quality of life, as compared to other forms of hysterectomy.

Further exploration of the surgeon’s and assistant’s ergonomic circumstances in all types of hysterectomy.

Randomized trials comparing conventional open and laparoscopic surgery to robot-assisted surgery in order to define the role of robot-assisted surgery in benign gynaecological disease, with both patient-centered and doctor-centered outcomes.

Studies on ergonomic guidelines in laparoscopic surgery and prevent minimal access surgery related surgeon morbidity syndromes.

Developing accurate training schedules to equip both the dominant and non-dominant upper extremity for laparoscopic surgery.

References

Chapter 8

General discussion and conclusions


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Chapter 9

Summary & Samenvatting
Summary

After initial reports of peritoneoscopy in the late 1940’s, laparoscopic surgery has been implemented worldwide and is currently covered in the whole surgical spectrum. In Chapter 1, a general introduction on this thesis is provided. It is explained that the advantages of laparoscopy versus conventional (open) surgery for patients have widely been documented. In general, laparoscopic surgery is accompanied by less postoperative pain, shorter hospital stay, quicker return to normal activities, better quality of life and superior cosmetic results. For the surgeon however, laparoscopic surgery has much more physical impact and chronic injuries are not uncommon. As it seems, the ergonomic circumstances for doctors during laparoscopic surgery are an underexposed matter. Hypothetically, physical fatigue and complaints during surgery may lead to uncontrolled movements with a higher risk of tissue damage and complications. In this thesis, an attempt is made to compare patients’ benefits of laparoscopic surgery to the limitations and physical impact of laparoscopy for surgeons.

Chapter 2 presents a review and meta-analysis of studies on various forms of hysterectomy for benign gynaecological disease. All randomized controlled trials including vaginal and/or abdominal and/or laparoscopic hysterectomy were included. Thirty-three studies with a total of 4,095 patients were included. The benefits of vaginal hysterectomy versus abdominal hysterectomy were a speedier return to normal activities (mean difference (MD) 9.5 days), fewer febrile episodes or unspecified infections (odds ratio (OR) 0.42), and a shorter duration of hospital stay (MD 1.1 days). The benefits of laparoscopic hysterectomy versus abdominal hysterectomy were a speedier return to normal activities (MD 13.6 days), lower intra operative blood loss (MD 45 cc), a smaller drop in hemoglobin (MD 0.55 g/dl), a shorter hospital stay (MD 2.0 days), and fewer wound or abdominal wall infections (OR 0.31) at the cost of more urinary tract (bladder or ureter) injuries (OR 2.41) and a longer operation time (MD 20.3 minutes). There was no evidence of benefits of laparoscopic hysterectomy versus vaginal hysterectomy and the operation time (MD 37.4 minutes) was increased in laparoscopic hysterectomy. From this meta-analysis it is concluded that vaginal hysterectomy is the first choice of approach in case of hysterectomy for benign gynaecological disease.

The long term quality of life (4 years follow-up) from a randomized controlled trial between laparoscopic and abdominal hysterectomy is presented in Chapter 3. Quality of life was measured with the Dutch version of the Short Form 36 questionnaire; higher scores denote better quality of life. Fifty-nine patients were randomized and the median follow-up after surgery was 243 weeks. The response
rate was 83% (49 out of 59 patients). Total Short Form 36 questionnaire scores were significantly higher in patients after laparoscopic hysterectomy compared with abdominal hysterectomy up to 4 years after surgery. Higher scores were also found on the domains physical role functioning, social role functioning and vitality. Based on these results, it was suggested that patients in whom a vaginal hysterectomy is not possible should have a laparoscopic hysterectomy if feasible in terms of uterine mobility and size.

The gynaecologists’ perception of the level of difficulty of hysterectomy is described in Chapter 4. In a randomized controlled trial on laparoscopic versus abdominal hysterectomy, gynaecologists were asked to score the (preoperatively) estimated and (postoperatively) experienced level of difficulty on a Visual Analogue Scale (VAS). A difference on the VAS of 3 points or more was considered clinically relevant and this was noted in 13 out of 72 (18%) cases, equally distributed between laparoscopic and abdominal hysterectomy. In eleven of these 13 cases, surgery was experienced as more difficult than it was estimated. Furthermore, it was observed that, even among experienced surgeons, on average laparoscopic hysterectomy was estimated and experienced significantly more difficult compared to abdominal hysterectomy. This experienced higher level of difficulty may well be one of the reasons for the slow implementation of laparoscopic hysterectomy in the Netherlands.

The operation room as a hostile environment for surgeons, is the subject of Chapter 5. In the Radboud University Nijmegen Medical Center, a questionnaire was distributed among all surgeons and surgical residents who perform laparoscopy. Fifty-five subjects completed the questionnaire and from these respondents, 40 (73%) reported physical complaints during or after laparoscopic surgery. Most frequently mentioned areas of physical discomfort were the neck, lower back, shoulders and thumbs. Furthermore, significantly more surgeons reported complaints in the dominant upper extremity compared to the non-dominant side. This is probably a result of complex tasks are more frequently and easier performed with the dominant side and consequently, a relative overuse might occur of the dominant upper extremity. Poor table height adjustment, bad monitor positioning and suboptimal design of instrument handles were reported as important causes of complaints. More awareness of ergonomic guidelines seems needed to prevent long lasting injuries in surgeons performing laparoscopic surgery.

In Chapter 6, the results of a randomized controlled trial on training of the non-dominant upper extremity are presented. We hypothesized, inspired by the findings in Chapter 5, that enhancing laparoscopic performance of the non-dominant upper extremity would equip this side better for laparoscopic surgery. For the purpose of this study, a three weeks training schedule was developed and comprised of every-day activities such as hand writing, tooth brushing and using cutlery. Before and after the training period subjects in both the intervention group and control (no training) group performed three validated tasks on a virtual reality simulator. After the training period, subjects in both groups showed improvement of skills on the non-dominant side. On the dominant side, however, subjects in the training group showed a significant stronger improvement on four out of eight parameters. In literature, this phenomenon is known as intermanual transfer of motor skills. From this study it is concluded that in order to improve laparoscopic skills, bimanual training is recommended.

The effects of training the non-dominant upper extremity on surgeons’ muscular strain, as measured with surface electromyography (EMG), are provided in Chapter 7. Participants in the intervention group of this randomized controlled study were trained as described in Chapter 6. The exercise on a laparoscopic box trainer was to place beads alternately with the right and left hand, with the instruction to hold the non-active side as relaxed as possible. Muscle strain and effective alternation were used as outcome variables. EMG analysis revealed that subjects in both intervention and control group showed a decrease in muscle strain of trapezius and deltoid muscles. However, there were no significant differences between groups. Subjects in the intervention group showed significantly better alternation in brachioradial muscle. It was concluded that training the non-dominant upper extremity leads to better control in terms of alternated use of lower arm muscles during a validated box trainer task. This may well be an important finding, since continuous contraction is known to build up lactic acid and metabolic stress in muscles. Furthermore, so-called unwanted mirror activity may be potentially harmful with regard to unintended tissue damage, especially when unnoticed due to moving a laparoscopic instrument out of view of the camera.

In Chapter 8, the advantages for patients in laparoscopic surgery are balanced against the (mainly ergonomic) disadvantages for surgeons. As described in Chapter 2 and 3, the laparoscopic approach to hysterectomy has several advantages over the open abdominal approach. Even 4 years after surgery, laparoscopic hysterectomy appears to be advantageous in terms of quality of life. However, from the doctors’ perspective, laparoscopic surgery results in higher physical strain and inures a risk of neuromuscular injuries. In the view of the benefits for patients, it is the question whether doctors have to consider the ergonomic disadvantages as “part of the job?” More awareness of ergonomic guidelines and optimal trocar positioning may well improve the circumstances for doctors and, hypothetically, patients will also...
Samenvatting

Laparoscopie, in de jaren ’40 begonnen onder de naam peritoneoscopie, is inmiddels wereldwijd geïmplementeerd en wordt heden ten dage toegepend in vrijwel het gehele chirurgische spectrum. In Hoofdstuk 1 wordt een algemene introductie op het proefschrift gegeven. De voordelen van laparoscopie ten opzichte van conventionele (open) chirurgie zijn uitgebreid onderzocht en beschreven in de literatuur. In het algemeen is laparoscopie geassocieerd met minder postoperatieve pijn, een korter ziekenhuisverblijf, snellere werkhervatting, betere kwaliteit van leven en fraaiere cosmetische resultaten. Echter, de fysieke belasting voor de operateur is tijdens laparoscopische chirurgie veel hoger en chronische blessures komen bij artsen regelmatig voor. Het blijkt dat de ergonomische omstandigheden waaronder artsen werken een onderbelicht thema is. Hypothetisch kunnen fysieke vermoeidheid en lichamelijke klachten van de operateur tot ongecontroleerde bewegingen leiden met dientengevolge een hogere kans op weefselschade en complicaties bij de patiënt. In dit proefschrift worden de voordelen voor de patiënt van laparoscopie afgezet tegen de ergonomische beperkingen en de fysieke impact voor de operateur.

In Hoofdstuk 2 wordt een review en meta-analyse van studies naar verschillende vormen van hysterectomie voor benigne aandoeningen beschreven. Alle gerandomiseerde studies omtrent vaginale en/of abdominale en/of laparoscopische hysterectomie werden onderzocht. Drieërtwintig studies konden worden geïncludeerd met in totaal 4095 patiënten. De voordelen van vaginale versus abdominale hysterectomie waren een snellere hervatting van dagelijkse activiteiten (mean difference (MD) 9,5 dagen), minder koorts of niet nader gespecificeerde infecties (odds ratio (OR) 0,42) en een korter ziekenhuisverblijf (MD 1,1 dag). De voordelen van laparoscopische versus abdominale hysterectomie waren een snellere hervatting van dagelijkse activiteiten (MD 13,6 dagen), minder bloedverlies (MD 45 cc), een minder grote daling in het hemoglobinegehalte (MD 0,55 g/dl), een korter ziekenhuisverblijf (MD 2,0 dagen) en minder wond- of buikwandinfecties (OR0,31), terwijl er meer letse aan blaas of urineweg waren (OR 2,41) en een langere operatietijd (MD 20,3 minuten). Er was geen bewijs dat laparoscopische hysterectomie voordelen biedt boven vaginale hysterectomie, terwijl de operatietijd bij laparoscopische hysterectomie langer was (MD 37,4 minuten). De conclusie van deze meta-analyse was dat de vaginale benadering de eerste keus is in het geval van een hysterectomie voor goedaardige aandoeningen.

De langetermijn follow-up (4 jaar) van een gerandomiseerde studie tussen laparoscopische en abdominale hysterectomie wordt beschreven in Hoofdstuk 3. Kwaliteit benefit from such adjustments. Furthermore, the role of robotic surgery is discussed. To date, studies fail to demonstrate advantages for patients in robotic surgery over laparoscopic surgery. Future studies will have to demonstrate whether the superior ergonomic circumstances in robot-assisted surgery justify the significantly higher direct costs.
van leven werd gemeten met de Nederlandse versie van de Short Form-36 vragenlijst; een hogere score op deze vragenlijst impliceert een betere kwaliteit van leven. Negenvijftig patiënten werden gerandomiseerd en de mediane follow-up na chirurgie was 24,3 weken (4,7 jaar). De respons was 83% (49 van de 59 patiënten). De totale score op de vragenlijst 4 jaar na de operatie was hoger bij patiënten die een laparoscopische hysterectomie ondergingen. Hogere scores werden ook gevonden op de domeinen fysiek functioneren, sociaal functioneren en vitaliteit. Op basis van deze resultaten wordt voorgesteld om bij patiënten bij wie vaginale hysterectomie niet mogelijk is, een laparoscopische hysterectomie te verrichten (indien mogelijk met betrekking tot de grootte en mobiliteit van de uterus).

In Hoofdstuk 4 worden de percepties van gynaecologen over de moeilijkheidsgraad van hysterectomie beschreven. In een gerandomiseerd onderzoek over laparoscopische versus abdominale hysterectomie werden gynaecologen gevraagd om de moeilijkheidsgraad van de ingreep preoperatief in te schatten en postoperatief te evalueren op een Visueel Analoge Schaal (VAS). Een verschil van 3 of meer punten tussen de ingeschatte en ervaren moeilijkheidsgraad werd als klinisch relevant beschouwd en werd geconstateerd in 13 van de 72 gevallen (18%). Deze 13 ingrepen waren gelijk verdeeld over beide operatietypen. In 11 van deze 13 gevallen (85%) werd de ingreep als moeilijker ervaren dan dat deze tevoren was ingeschat. Verder werd gezien dat de laparoscopische hysterectomie moeilijker werd ingeschat en ervaren op de domeinen fysiek functioneren, sociaal functioneren en vitaliteit. Deze hogere subjectieve moeilijkheidsgraad kan een van de redenen zijn voor de langzame implementatie van de laparoscopische hysterectomie in Nederland.

De operatiekamer is in feite een oncomfortabele omgeving voor operateurs, zoals beschreven in Hoofdstuk 5. In het UMC St Radboud te Nijmegen werd een vragenlijst verspreid onder alle snijdende specialisten (in opleiding) die laparosco pieën verrichten. Vijfenvijftig personen retourneerden de ingevulde vragenlijst en van deze groep rapporteerden 40 (73%) fysieke klachten tijdens en na laparoscopische chirurgie. De meest genoemde locaties waarin de klachten voorkwamen waren de nek, onderrug, schouders en duimen. Verder kwamen er significant meer klachten voor aan de dominante zijde versus de niet-dominante zijde van het lichaam. Dit komt meest waarschijnlijk door het feit dat complexe taken makkelijker uitgevoerd worden met de dominante zijde en dat er dientengevolge een relatieve overbelasting van deze zijde optreedt. Als meest belangrijke oorzaken van klachten werden genoemd een slecht te stellen hoogte van de operatietafel, slechte positionering van de monitor en suboptimal ontwerp van de handvatten van de instrumenten. Meer kennis en implementatie van ergonomische richtlijnen zijn nodig om chronische blessures bij laparoscopisch opererende specialisten te voorkomen.

In Hoofdstuk 6 worden de resultaten van een gerandomiseerde studie naar het effect van training van de niet-dominante bovenste extremiteit beschreven. Geïnspireerd door de bevindingen in Hoofdstuk 5 stelden wij de hypothese op dat door verbetering van de vaardigheden van de niet-dominante extremiteit deze zijde meer gebruikt zou kunnen worden tijdens laparoscopische ingrepen. Voor deze studie werd een trainingsschema van 3 weken opgesteld, waarin alledaagse activiteiten zoals schrijven, tanden poetsen en het gebruik van bestek gecoördineerd moesten worden met de niet-dominante zijde. Voor en na de studieperiode verrichten deelnemers in zowel de interventiegroep als de controlegroep (geen training) 3 gevalideerde oefeningen op een virtual reality simulator. Na de trainingseffecten van de niet-dominante extremiteit werden gynaecologen gevraagd om de ingreep als moeilijker ervaren dan dat deze tevoren was ingeschat. Verder werden de effecten van training van de niet-dominante bovenste extremiteit op de spierspanning van chirurgen, gemeten met oppervlakte-electromyografie (EMG), worden beschreven in Hoofdstuk 7. Personen in de interventiegroep werden getraind zoals beschreven in Hoofdstuk 6. Als oefening op een laparoscopische box-trainer werd een gevalideerde oefening gekozen; deelnemers moesten afwisselend met links en rechts krantjes plaatsen in een vooraf bepaalde vorm. Als instructie kregen de deelnemers om de niet-actieve zijde zo ontspannen mogelijk te houden. Spierspanning en effectieve alternatie werden de uitkomstparameters, waarbij alternatie werd gedefinieerd als de mate waarin het de deelnemer lukt om de niet-actieve zijde ook daadwerkelijk ontspannen te houden. EMG-analyse toonde dat deelnemers in zowel interventie- als controlegroep een afname in spierspanning vertoonden in de musculus trapezius en deltoideus. Er waren echter geen significant verschillen tussen beide groepen. Deelnemers in de interventiegroep vertoonden na de studieperiode significante verbeterde alternatie in de musculus brachioradialis. Er werd geconcludeerd dat training van de niet-dominante bovenste extremiteit leidt tot een betere alternatie van de onderarmspieren tijdens een gevalideerde box-traineroefening. Omdat het bekend is dat een continue spiercontractie leidt tot stapeling van melkzuur en metabole stress, kan deze uitkomst een belangrijke bevinding zijn. Zogeheten onvrijwillige spiegelbewegingen van spieren (ongewilde bewegingen van de spieren...
aan de zijde die op dat moment niet actief is) kunnen potentiële weefselsschade veroorzaken tijdens een laparoscopische operatie, met name wanneer een instrument zich buiten het gezichtsveld van de camera bevindt.

In **Hoofdstuk 8** worden de voordelen voor de patiënt van laparoscopische chirurgie afgezet tegen de (met name ergonomische) nadelen voor de operateur. Zoals beschreven in Hoofdstuk 2 en 3 biedt de laparoscopische benadering van hysterectomie diverse voordelen ten opzichte van de open abdominale procedure. Zelfs 4 jaar na de operatie zijn er nog verschillen in kwaliteit van leven zichtbaar. Vanuit het perspectief van de operateur daarentegen resulteert laparoscopische chirurgie in hogere fysieke spanning en bestaat er een verhoogd risico op neuromusculaire schade. Meer bewustwording van ergonomische richtlijnen, adequate training en optimale positionering van trocars kunnen de omstandigheden voor operateurs beduidend verbeteren. Ook patiënten kunnen hier (indirect) voordelen van ondervinden. Tevens wordt in dit hoofdstuk de rol van robotchirurgie besproken. Tot nu toe zijn er nog geen evidente bewijzen dat patiënten voordelen ondervinden van robotchirurgie vergeleken met laparoscopische chirurgie. Toekomstige studies moeten onderzoeken of de superieure ergonomische omstandigheden in robotchirurgie de significant hogere kosten rechtvaardigen.

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**Chapter 9 Summary & Samenvatting**

Chapter 9

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9
Addendum

Bibliografie
Dankwoord
Curriculum Vitae
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Dankwoord

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\[
\text{Cov}_{12} = \frac{\sqrt{\text{Var}(N_1 + N_2)}}{M_1 + M_2} = \frac{\sqrt{\text{Var}(N_1) + \text{Var}(N_2)}}{M_1 + M_2}
\]

op tafel kwamen, moest ik regelmatig alle zelen bijzetten. Fijn dat u uiteindelijk mede-promotor bent geworden.

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Ik hoop op toekomstige samenwerking op ergonomisch gebied. Beste professor

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Dankwoord

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“Sorry, even mijn dankwoord gaan aanpassen” zit er niet meer in na vandaag; ik hoop dat het traject Arnhem-Haarlem nog vaak afgelegd gaat worden. Beste Arrien, wij zijn het levende bewijs dat een goede vriendschap kan ontstaan tijdens een nageboortetijdsperk van een bevalling. Wat geniet ik van de momenten samen met onze gezinnen, onze sushi-avonden, retraiteweekenden of bezoekjes aan het Gelredome voor wederom een verliespartij van de lokale FC. Dat we hetzelfde geloof delen is een mooi vertrekpunt voor veel van onze gesprekken. Op nog ontelbare momenten samen; FFL!

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Addendum

Lieve Cathelijne, wat ben ik gelukkig met je! Dank voor alle steun rondom dit boekje en de dagelijkse vreugde die je me geeft; je bent een fantastische vrouw en moeder. Ik kijk er naar uit om de rest van dit leven met je te delen.

Horeca est!

Dankwoord
Curriculum Vitae