On the measurement of recovery following hysterectomy

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Contents

1 Introduction

Introduction

Hysterectomy is the most frequently performed major gynaecologic 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). Hysterectomy can be performed by a vaginal, abdominal or laparoscopic approach. Vaginal hysterectomy is generally regarded as the first choice, although there is an overlap in indications for either approach. The decision is made in the light of the relative benefits and hazards of each approach (3). In health care, three levels of decision-making are generally distinguished: decisions on resource utilisation, decisions for groups of patients and decisions for individual patients (4). In the comparison of approaches to hysterectomy, the most important issues on these three levels need to be considered.

Significant blood loss, infections and injuries to adjacent organs are of concern in hysterectomy, and their rates of occurrence differ with various approaches to hysterectomy and surgical experience level (3). Ureteric injuries, for example, have been reported in 2.2% of laparoscopic hysterectomies and bladder injuries in 2.0% of laparoscopic hysterectomies during the learning curve (5), which is widely perceived as an unacceptable high rate. These rates decrease to 0.5% and 0.8% respectively after completion of a learning curve of 30 procedures, which is then comparable to the rates in abdominal hysterectomy.

In general, it is presumed that a quicker recovery is followed by the laparoscopic approach as compared with open surgery. However, post-operative recovery is ill defined. Although recovery is associated with the duration of hospital stay and the time taken to return to normal activities, their assessment provides no more than indirect measures of recovery. Local habits and social security matters have a major influence on the available time to recover, which disqualifies the assessment of duration of hospital stay and absence from work as objective recovery tools. Consequently, more reliable and valid instruments are needed to assess recovery.

An international consensus, based on available evidence on recovery following colonic surgery, has resulted in a post-operative recovery enhancement protocol (6). This protocol lists 21 elements on preoperative, intraoperative and post-operative patient care. The application of a similar protocol in patients undergoing colonic surgery has resulted in a reduction in hospital stay by over 50% (7), which has been considered as a major progress. However, the term recovery was used synonymous here with reduction of hospital stay, and it is not known whether the patients experienced the reduction in hospital stay as advantageous to their recovery. This example illustrates the importance of patients' judgement, when measuring a subjective matter, such as recovery.

As a consequence, more emphasis has been put on patient reported recovery instruments such as questionnaires in recent years (8). Both questionnaires assessing generic health-related quality of life or questionnaires assessing recovery specific quality of life are now available for this purpose. With regards to satisfactory measurement properties, these instruments offer a

less biased outcome measure with high relevance to the patient. These measurement properties include satisfactory validity and reproducibility, which ensure that the instrument measures what it is supposed to measure in a reproducible manner (9).

Laparoscopic surgery is likely to be associated with higher costs as compared with open surgery, due to longer operation times and the additional costs of the laparoscopic basic equipment and disposable materials. Whether reduced expenses associated with the recovery process and especially the absence from work, compensate these costs, remains unclear. Adequate recovery measurement tools will be helpful in future research on cost-effectiveness of surgical techniques, where the additional costs associated with a certain difference in recovery score can be established.

The choice of a laparoscopic approach instead of laparotomy, as well as the avoidance of complications are obvious elements in the improvement of recovery. These two issues are diametrically opposed in laparoscopic versus abdominal hysterectomy. In laparoscopic hysterectomy an extensive abdominal incision is avoided, but at the same time the operation bears an increased risk of major complications, such as injury to ureter and bladder (3), especially during the learning curve (5). These opposing effects are an important subject of discussion in the present thesis, where an evaluation of patients' preferences is included.

In addition to complication rates and the speed of recovery, long-term effects, such as effects on pelvic organ function, are likewise important in the choice for an approach to hysterectomy. Although hysterectomy for benign disease does not seem to have a major impact on pelvic floor function, it is not known until now, whether one of the approaches to hysterectomy is superior in that respect (10).

Thesis "On the measurement of recovery following hysterectomy"

This thesis studies the differences in various approaches to hysterectomy with emphasis on postoperative recovery. The available evidence on complications, costs and quality of life following hysterectomy is summarised and the results of a randomised controlled trial on laparoscopic versus abdominal hysterectomy are presented, in which quality of life and pelvic organ function are main outcome measures. In addition, a literature review on recovery specific instruments and their measurement properties is presented and the measurement properties of two recovery specific instruments and one generic health-related instrument are assessed in patients who underwent hysterectomy. Women's preferences are studied in patients and nurses to whom the benefits and disadvantages of laparoscopic and abdominal hysterectomy had been explained in a standardised manner.

The aims of this thesis are:

- to provide an overview on complications, recovery, quality of life, pelvic organ function, and costs associated with hysterectomy (Chapters 2 and 3).
- to compare laparoscopic and abdominal hysterectomy with regards to quality of life (Chapter 4) and pelvic organ function (Chapter 5).
- to provide an overview on available post-operative recovery instruments and their measurement properties (Chapter 6).
- to assess the relative measurement properties of two Dutch recovery instruments: Recovery index-10 and Quality of recovery-40, and a generic health-related instrument: RAND-36, in patients undergoing hysterectomy (Chapter 7).
- to assess women's preferences for laparoscopic or abdominal hysterectomy (Chapter 8)

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2 Comparison of hysterectomy techniques and cost-benefit analysis

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Introduction

The first descrixption of the removal of gangrenous and inverted uteri goes back to the third century A.D. (1). However, it was not until 1813 when a German surgeon Conrad Langenbeck described the first intentional complete vaginal hysterectomy in which the patient survived. In those days the operative mortality rate was close to 90%. The first reports of abdominal hysterectomies were accidental hysterectomies at the time of ovariectomy, mostly with conservation of the cervix. The first abdominal hysterectomy where the patient survived was reported by an American surgeon Walter Burnham in the American Lancet in 1854 (2). Another American surgeon Harry Reich has reported the first laparoscopic assisted vaginal hysterectomy in 1989 (3).

Hysterectomy is now the most frequently performed major gynaecologic operation, with millions of procedures annually performed throughout the world (4). Abdominal hysterectomy has traditionally been the surgical approach for gynaecological malignancy, in cases where pelvic pathology such as endometriosis or adhesions is suspected and in the presence of a large uterus. Abdominal hysterectomy remains the 'fallback option' if the uterus cannot be removed by another approach. The vaginal approach was originally used for prolapse, but has become more widely used for abnormal uterine bleeding when the uterus is of fairly normal size with or without a small degree of descent. Compared to abdominal hysterectomy, successful vaginal hysterectomy is considered as less invasive and can be performed under spinal anaesthesia, whereas abdominal and laparoscopic hysterectomy will mostly require general anaesthesia.

In women with an enlarged uterus, where vaginal hysterectomy is not feasible, laparotomy can be avoided by performing a laparoscopic hysterectomy. If oophorectomy is needed, a laparoscopic approach may also be preferred over the vaginal approach. Laparoscopic hysterectomy usually refers to a hysterectomy where at least part of the operation is undertaken laparoscopically. Laparoscopic hysterectomy (LH) is further classified in three categories: laparoscopic assisted vaginal hysterectomy (LAVH), where vaginal hysterectomy is assisted by prior laparoscopy and the laparoscopic procedure does not include the occlusion of the uterine arteries; laparoscopic hysterectomy (LH(a)), where the laparoscopic part of the hysterectomy includes the occlusion of the uterine arteries and total laparoscopic hysterectomy (TLH), where the vaginal part of the operation is restricted to the removal of the laparoscopically freed uterus and all other operative manipulations, including vaginal

Table 1. Categories of laparoscopic hysterectomy (5).

Category	Laparoscopic content
LAVH	Laparoscopic content does not involve division of the uterine vessels, which is performed vaginally
LH(a)	Laparoscopic content includes ligation of the uterine vessels, where there is a vaginal component in the procedure
TLH	Entire operation is performed laparoscopically, including suturing vaginal vault.

vault closure, are undertaken laparoscopically (5). This classification causes some confusion, as the term 'laparoscopic hysterectomy' is used for the overall laparoscopic hysterectomy (LH), as well as for LH(a), which refers to one of the three categories.

A total hysterectomy is the removal of the entire uterus and cervix. When the cervix is preserved, this is known as a subtotal hysterectomy. Other terms used for subtotal hysterectomy are supra-cervical and supra-vaginal hysterectomy. The procedure may be advantageous in case of dense pelvic adhesions or emergency obstetric hysterectomy for atonic bleeding.

Outcomes of hysterectomy

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. Each gynaecologist will have different indications for the approach to hysterectomy for benign disease, based largely on their own array of surgical skills and 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 (6). Previous caesarean section is often considered as a contraindication for vaginal hysterectomy. However, this is not supported by evidence, as the retrospective trials available have not reported a clinically relevant increase in complication rate in hysterectomy patients following caesarean section (7-10). 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 1980's. Following annual meetings on gynaecological surgery where vaginal and laparoscopic surgery was encouraged, the vaginal hysterectomy rate increased to 39% in 2004 (11).

Following the introduction of laparoscopic hysterectomy in 1989, research on hysterectomy received a new impetus. A systematic review summarizes the results of all randomized controlled trials on the subject, assessing the potential role of the three approaches to hysterectomy for benign indications (12). The meta-analysis provided adequate estimates on blood loss, operation times, complication rates and return to normal activities. However, estimates on post hysterectomy quality of life, pelvic organ function and psychosocial effects could still not be given due to lacking and heterogeneous data. Both LAVH and LH(a) are frequently evaluated in trials, whereas TLH is only studied in two randomized controlled trials.

Although much has been written in the scientific literature about various outcomes of hysterectomy, not discussion has been had over what outcomes are of key importance. Surgeons wish to minimise operative complications, health care managers wish to minimise costs, but

what do patients want? Complications are often uncommon and existing studies do not capture each one of them individually powerfully. So researchers tend to pool them 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 asymmetry in comparison. We have proposed that 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 patients' lives (13). The choice should therefore weigh this outcome when decision making.

In the following section the comparable oucomes of approaches to hysterectomy are described, mainly based on the results as achieved in the meta-analysis (12). Available quantitative data from the meta-analysis can be found in table 2.

Operating time

Operating time was longer for laparoscopic as compared to either abdominal or vaginal hysterectomy. However, LAVH had a significantly shorter operating time than both abdominal hysterectomy and LH(a), thus suggesting that the operating time is governed by the proportion of the surgery performed laparoscopically. The greater proportion performed laparoscopically, the lengthier the operation (12).

Haemorrhage

Although there was no significant difference in the need for blood transfusions between laparoscopic hysterectomy and abdominal hysterectomy, laparoscopic hysterectomy was associated with significantly less blood loss and a smaller drop in haemoglobin. The need

Table 2. Differences between approaches to hysterectomy (12).

	AH vs VH	LH vs AH	LH vs VH
Operating time (min)	NR	10.6 (7.4;13.8)	41.5 (33.7;49.4)
Blood loss (ml)	NR	-45.3 (-72.7;-17.9)	9.7 (-50.2;69.7)
Drop in haemoglobin (g/l)	NR	-0.6 (-0.8;-0.3)	0.2 (-0.3;0.6)
Infection unspecified	0.4 (0.2;0.8)*	0.7 (0.5;0.9)*	0.8 (0.5;1.3)*
Wound infections	NR	0.3 (0.1;0.9)*	3.1 (0.1;77.8)*
Urinary tract injury	NR	3.0 (1.3;6.9)*	1.0 (0.4;2.8)*
Hospital stay (days)	1.0 (0.7;1.2)	-2.0 (-2.2;-1.9)	0.3 (-0.1;0.8)
Return to normal activities (days)	12.3 (4.8;19.9)	-13.6 (-15.4;-11.8)	-1.1 (-4.2;2.1)

AH = abdominal hysterectomy, LH = laparoscopic hysterectomy, VH = vaginal hysterectomy, NR = not reported.
Data presented as weighted mean difference (95% confidence interval) or *odds ratio (95% confidence interval).

for blood transfusion, the mean blood loss and haemoglobin drop for comparisons between abdominal and vaginal hysterectomy, as well as between laparoscopic and vaginal hysterectomy were not significantly different (12).

Infections

There was significantly less infectious morbidity for vaginal hysterectomy as compared to abdominal hysterectomy. For laparoscopic hysterectomy versus abdominal hysterectomy, there were significantly fewer wound infections as well as other infectious morbidity. No significant differences were found between vaginal and laparoscopic hysterectomy. Thus, avoidance of abdominal hysterectomy appears to be important in the avoidance of postoperative infectious morbidity (12).

Urinary tract injury

A study amongst 37,295 women undergoing hysterectomy in the UK has shown that bladder injury was the most frequent visceral injury, with an incidence of one in 200 hysterectomies (14). Although no significant difference between the three different approaches has been found, the occurrence of ureteric injury remains the major concern in relation to the laparoscopic approach. Meta-analysis has shown that in laparoscopic hysterectomy the risk of urinary tract injury was 2.6 fold increased as compared to abdominal hysterectomy (12). Moreover, there was a tendency to increased ureteric injury, which occurred in 1 in 78 women having laparoscopic hysterectomy and 1 in 492 women having abdominal hysterectomy. Although it could be speculated that laparoscopic uterine artery ligation is the manoeuvre most likely to increase the risk of ureteric injury, this was not confirmed by evidence, as no statistically significant difference has been found in urinary tract injury for LH(a) versus LAVH.

Unintended laparotomy

As the abdominal approach is the 'fallback option' in case of difficult and complicated hysterectomies, unintended laparotomies or conversions are inherent to the laparoscopic and vaginal approach. Sometimes these conversions are prudent rather than the result of a complication. As calculated from randomised controlled trials, conversions occurred in 8.7% of laparoscopic hysterectomy patients and 2.6% of vaginal hysterectomy patients. The possibility of the need for conversion should be discussed with the patient prior to surgery (12).

Other complications

There were no significant differences in the occurrence of bowel injury between any of the approaches to hysterectomy, with an overall incidence of 0.2%. The same holds true for the occurrence of thrombo-embolic events, number of severe bleedings, blood transfusions and pelvic haematoma as well as for vaginal cuff infections, urinary tract infections and chest infections as separate entities (12).

Although it has been suggested that LAVH does little more than to combine the complications of laparoscopic surgery with those of vaginal surgery (15), this has not been supported by evidence. The concepts that laparoscopic hysterectomy allows identification of pelvic disease such as adhesions and endometriosis and that the meticulous haemostasis achievable with 'final-look' laparoscopy might reduce pelvic haematomas or vaginal cuff infections (16) have not been borne out by improved outcomes following laparoscopic versus abdominal hysterectomy in the meta-analysis of randomised trials (12).

Pain, hospital stay and return to normal activities

Avoidance of abdominal hysterectomy appears to be important to minimise postoperative pain. Recovery from surgery favoured vaginal hysterectomy and laparoscopic hysterectomy as compared to abdominal hysterectomy in terms of shorter hospital stay and return to normal activities. There were no significant differences in hospital stay and return to normal activities between laparoscopic hysterectomy and vaginal hysterectomy or between LH(a) and LAVH. Thus, the speed of postoperative recovery seems to be determined by the avoidance of an abdominal procedure; abdominal hysterectomy is associated with lengthier recovery as compared to the other approaches to hysterectomy (12).

Psychosocial effects and quality of life

A further report of the systematic review of randomised trials of surgical approach to hysterectomy arbitrarily identified three primary outcomes: time to return to normal activities, major operative complication and major lasting problem (17). As long term outcomes were not reported in any of the 27 randomised trials included in this review, no information was available for the latter outcome. Indeed, approximately 90% of hysterectomies are performed for benign indications, which are rarely life-threatening (18). Thus there is a strong argument that psychosocial effects and changes in quality of life should be considered as the outcomes of paramount importance in the comparison of techniques. Surprisingly, few studies assessing laparoscopic techniques address these issues. The available evidence does not support any broad adverse effects of hysterectomy on psychosocial functioning (19). As far as quality of life is concerned, there are various reports on the enhancement after hysterectomy (20). Randomised controlled trials using validated quality of life methods, have shown that the enhancement of quality of life is equal or greater in vaginal as well as laparoscopic hysterectomy when compared to abdominal hysterectomy (15;20-24), whereas no differences have been found amongst vaginal and laparoscopic hysterectomy (15;23).

Pelvic organ dysfunction

In the early 1980's advantages as far as postoperative urinary incontinence and sexuality were concerned, were claimed from a prospective observational study on subtotal hysterectomy and total abdominal hysterectomy (25;26). This has now been challenged by meta-analysis of three randomised controlled trials, where no advantages of subtotal hysterectomy were found (27).

In the short term there does not seem to be a negative effect from non-radical hysterectomy on the incidence of urinary, bowel and sexual dysfunctions (28). An improvement of urinary incontinence and sexual problems has even been found and de novo problems were rare. The roles of the different approaches still needs further establishment, but thus far there is no evidence of superiority of one of the approaches. No prospective long term data are available up to date, though large epidemiologic studies have shown an increased risk of urinary incontinence in post hysterectomy women (29).

Recource use in hysterectomy relative to outcome

There are several types of economic analysis available for the evaluation of health care technology (30). Costs or resource use for different treatment options can be compared without considering a (potential) difference in treatment outcome. In cost-effectiveness analysis however, costs are related to the effect of a particular treatment. A difference in effectiveness between two strategies is expected and the analysis aims to express additional costs of the additional health gain. Alternatives to cost-effectiveness analysis are cost-utility analysis and cost-benefit analysis. In cost-utility analysis, the outcome of medical interventions is expressed in utilities, for example life years that are adjusted for the quality of life of these years. In cost-benefit analysis, not only the costs, but also the potential benefits of interventions are expressed in financial terms. Since there is no uniform extrapolation of women having had hysterectomy into financial terms, cost-benefit analysis is only rarely applied. Where the difference in effectiveness or quality of life has not been assessed, and the analysis is limited to the difference in costs, assuming a similar medical outcome, the analysis is a cost-minimisation analysis.

When hysterectomy is compared to other interventions, such as ablation or a levonorgestrel intra-uterine device (IUD), a difference in effect on menorrhagia is expected, which makes a cost-effectiveness analysis appropriate. When comparing various approaches to hysterectomy, a difference in recovery can be expressed in quality adjusted life years (QALYs), making cost-utility analysis possible.

PubMed searches for economic analyses were performed using the key words 'cost$, combined with menorrhagia, uterine bleeding, hysterectomy, endometrial ablation, (fibroid or myom$ and emboli$) and myomectomy. Data on economic analyses from reviews and randomized controlled trials on comparisons of approaches to hysterectomy and comparisons of hysterectomy to other treatments were extracted.

Hysterectomy versus medical treatment as well as endometrial ablation has been subject to randomised studies comparing the costs or resource use (31-37). Formal cost-utility analysis has been performed for hysterectomy as compared to the levonorgestrel-IUD (38) and for laparoscopic hysterectomy as compared to both vaginal and abdominal hysterectomy (23).

The applicability of randomised studies on the economic impact of different treatment options for abnormal uterine bleeding is limited as endometrial ablation and hysterectomy are not

options for women wishing to retain their fertility, and as hormonal treatment is inappropriate for women wishing to become pregnant. Furthermore, a sufficiently long follow-up period is required to include all costs of re-treatments in the group where a less effective strategy has initially been applied. These costs will increase over time, whereas hysterectomy is more expensive on the short term, but has a long-lasting effect.

Resource use in different approaches to hysterectomy

Operating time, hospital stay and return to normal activities are obviously the most important factors in potential differences in resource use amongst approaches to hysterectomy. As derived from randomised controlled studies summarised in the meta-analysis (12), in laparoscopic hysterectomy the difference in operating time was 11 minutes as compared to abdominal hysterectomy and 42 minutes as compared to vaginal hysterectomy, both detrimetal to laparoscopic hysterectomy. On the other hand, hospital stay was two days longer in abdominal hysterectomy as compared to laparoscopic hysterectomy and one day longer in abdominal hysterectomy as compared to vaginal hysterectomy. Furthermore, in abdominal hysterectomy the difference in time taken until return to normal activities was 14 days as compared to laparoscopic hysterectomy and 12 days as compared to vaginal hysterectomy. There were no statistically significant difference amongst laparoscopic hysterectomy and vaginal hysterectomy as far as hospital stay and return to normal activities were concerned.

Six randomised controlled trials (21-23;39-41) have compared the resource use in laparoscopic versus abdominal hysterectomy, from which one performed a formal cost-utility analysis (23). None of the studies has found a significant difference in overall costs. However, hospital costs were significantly higher for the laparoscopic approach in two of these studies (21;22), caused by the longer operation times and higher costs of disposables in laparoscopic hysterectomy. When including society costs due to productivity loss, this difference was wiped out (21). Until now the resource use for basic equipment in laparoscopic hysterectomy, which is extremely variable, has not been taken into account. The least expensive will be a simple uterine manipulator and reusable bipolar coagulation forceps and scissors, although many surgeons regard an optimal vaginal delineator as an essential safety feature in total laparoscopic hysterectomy. However many varieties of more expensive equipment are now available for therapeutic laparoscopy. These costs should be carefully recorded in future studies to get a more thorough picture of comparable costs of laparoscopic and abdominal hysterectomy.

Resource use in hysterectomy as compared to alternative treatments

Medical treatment

Both endometrial ablation and hysterectomy have shown to be more effective in the resolution of abnormal uterine bleeding and the enhancement of quality of life, as compared to medical treatment (31;32). However, at the end of a two year follow-up period, the total resource use was significantly higher (51%) in women randomised to hysterectomy as compared to women

randomised to expanded medical treatment, i.e. combinations of prostaglandin synthetase inhibitors, tranexamic acid and hormonal treatment. Fifty-three percent of the women in the medical treatment group had undergone hysterectomy as a subsequent treatment within these two years.

Furthermore, in a randomized controlled trial comparing the levonorgestrel-IUD with hysterectomy, 42% of the women in the levonorgestrel-IUD eventually underwent hysterectomy in the five years follow-up period. Nonetheless, a cost-utility analysis at one-year follow-up and a cost comparison at five years follow-up both favoured the levonorgestrel-IUD group. Five years after randomization the resource use was 65% higher in the hysterectomy group (33;38).

Endometrial ablation

In three randomized controlled trials costs were calculated for endometrial ablation versus hysterectomy (34-37) and all have shown that the costs were lower in the endometrial ablation group. However, with longer-term follow-up periods this difference had narrowed due to the costs of further treatments in the endometrial ablation groups (37).

Myomectomy

Myomectomy is associated with a high recurrence rate. Following hysteroscopic myomectomy, 25% of the women had needed additional surgical treatment at the end of an eight year follow-up period (42). Comparable data have been reported following laparoscopic and abdominal myomectomy (43;44). Myomectomy may however bring relief to women suffering abnormal uterine bleeding due to myoma and wishing to preserve the uterus (45). Short-term costs of abdominal myomectomy will be comparable to those of hysterectomy, which makes cost-effectiveness of abdominal myomectomy less likely, although no studies are available to date.

Uterine artery embolization

In two randomised controlled trials uterine artery embolization was compared to hysterectomy, but costs were not considered as clinical endpoints (46;47). In a prospective observational study comparing hysterectomy to uterine artery embolization, women above the age of 40 were followed until menopause (48). This study suggested that the costs in the embolization group were lower.

Cost-utility analysis in hysterectomy

The first analysis in gynaecologic surgery on resource use in relation to outcome was published by Grover *et al.* in 1996 (49). They have reported positive cost-effectiveness of concomitant elective hysterectomy at the time of adnexectomy in women beyond 45 years of age.

In the cost-utility analysis published in 2004 by Sculpher et al., the costs for laparoscopic hysterectomy as compared to vaginal and abdominal hysterectomy were calculated in a secondary analysis of the eVALuate study data (23). One quality adjusted life year when performing a

laparoscopic hysterectomy instead of abdominal hysterectomy would cost the British National Health System (NHS) £26 571 ($46 893; €37 813). Provided that the outcome, including operation time, would not change when exchanging disposables for reusable instruments, these costs would decrease 2.5 fold. In the parallel trial on laparoscopic versus vaginal hysterectomy, it was shown that laparoscopic hysterectomy was not cost-effective (23). No other randomized studies have been performed on the financial implications of abdominal versus vaginal hysterectomy. However, as vaginal hysterectomy is associated with a shorter operation time and hospital stay, it is expected to be less expensive.

One randomised controlled study has reported a similar resource use over a two year period after subtotal abdominal hysterectomy as compared to total abdominal hysterectomy (50). Furthermore, the conclusion from a study on cost-effectiveness of the application of pre-operative GnRH agonists in women with fibroids undergoing hysterectomy was that the benefits do not justify the costs (51). A cost-effectiveness analysis of oophorectomy at the time of hysterectomy has not yet been undertaken.

As has already been remarked in the section on resource use, a cost-utility analysis at one-year follow-up favoured the levonorgestrel-IUD as compared to hysterectomy (38).

Other considerations on hysterectomy

Learning curve

Mäkinen *et al.* have reported a prospective study on the learning curve in 10,110 hysterectomies for benign indications of which 5,875 were abdominal, 1,801 were vaginal and 2,434 were laparoscopic hysterectomies (52). 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. Still, randomised controlled trials frequently do not report the experience of the surgeon(s), which hampers interpretation of the results. However, in the two largest trials incorporated in the meta-analysis on hysterectomy, thus having the highest impact on the outcome, surgeons had performed at least 25 respectively 50 interventions by either approach (15;22).

All 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 (53). Total laparoscopic hysterectomy requires the highest degree of surgical skill and currently only a very small proportion of newly trained gynaecologists will be able to perform this type of surgery. However, some gynaecologists who have not received specific training have acquired the skills to perform laparoscopic hysterectomy. One important benefit of introduction of laparoscopic hysterectomy into gynaecologic training has been to increase surgeons' confidence and skills with vaginal and overall laparoscopic surgery.

Conclusions

In conclusion, when technically feasible, vaginal hysterectomy should be performed in preference to laparoscopic and abdominal hysterectomy. There are no significant disadvantages of vaginal hysterectomy compared to any other surgical approach to hysterectomy, provided it can be accomplished safely. Compared to the abdominal approach, successful vaginal hysterectomy has a shorter operation time, is less painful and there are fewer febrile episodes postoperatively and it is associated with earlier discharge from hospital and return to normal activities. Where vaginal hysterectomy is not feasible, laparoscopic hysterectomy offers some benefits of avoiding abdominal hysterectomy, including less operative blood-loss, less pain and less infectious morbidity, as well as a shorter hospital stay and more rapid return to normal activities. These advantages are offset by longer operating time and more urinary tract injuries. No advantages of laparoscopic hysterectomy over vaginal hysterectomy could be found, whereas the disadvantages are a longer operating time, greater use of pain medication and higher cost.

In women undergoing hysterectomy, vaginal hysterectomy is cost-effective compared to laparoscopic hysterectomy and is likely to be cost-effective compared to abdominal hysterectomy. The difference in cost-effectiveness between laparoscopic and abdominal hysterectomy is more balanced, especially when avoiding the use of disposable instruments.

Cost-effectiveness of the levonorgestrel-IUD over hysterectomy has been reported in women suffering menorrhagia. Although other medical treatments are less expensive, cost-effectiveness is less likely, due to their lower effectiveness. The costs of endometrial ablation and uterine artery embolization are lower as compared to hysterectomy, although the difference decreases over time due to the higher costs of re-treatments in the non-hysterectomy groups.

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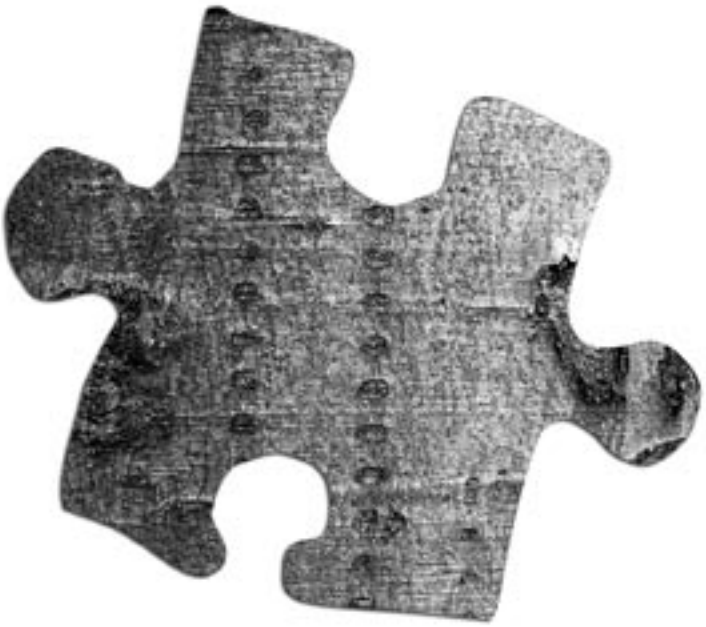
3 Comparison of laparoscopic and abdominal hysterectomy in terms of quality of life; a systematic review



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Abstract

The objective of this study was to investigate the randomized studies reporting on quality of life after laparoscopic hysterectomy as compared to abdominal hysterectomy.
A systematic qualitative review was performed on published studies identified by the databases PubMed and EMBASE, as well as cross-references. Randomized clinical trials on laparoscopic versus abdominal hysterectomy were assessed for the methods in which studies reported on postoperative health or quality of life as an outcome measure. Study results were described qualitatively. Thirty papers, published between 1994 and 2004 were identified. Only seven studies, incorporating data on 1,450 patients, reported on postoperative health or quality of life. Four of these studies used eight different validated quality of life questionnaires. Two of these four studies reported significant differences between the treatment groups, with better quality of life in the first six weeks after laparoscopic hysterectomy when compared to the abdominal approach.
Although the main reason for performing a laparoscopic hysterectomy instead of an abdominal hysterectomy is the improvement of quality of life, only few studies have used this as an outcome measure. The data available show that the laparoscopic hysterectomy performs equally or better in terms of postoperative health and quality of life in the first weeks after surgery. In the decision for an approach to hysterectomy, the advantage of better quality of life should be offset against the increased risk of complications in laparoscopic hysterectomy.

Introduction

For decades, abdominal hysterectomy has been the standard method for removal of the uterus for benign gynaecological disease, in cases where vaginal surgery was not possible. It is a safe and effective treatment, but has the disadvantage of morbidity, hospitalization and costs. Laparoscopic hysterectomy was introduced in 1989 as an alternative for hysterectomy by laparotomy (1). The laparoscopic approach aims to reach equal medical effectiveness for quicker recovery. As a consequence, studies evaluating laparoscopic hysterectomy should take into account measures for recovery as one of the key clinical outcomes. Recovery is frequently reported on in terms of pain scores, duration of hospital stay and return to normal activities or work. Although postoperative pain is an outcome of clinical interest, the duration of hospital stay or return to work is dependent on local culture and social security support and hence they cannot be used as rigorous scientific outcomes. A meta-analysis of the three approaches to hysterectomy has previously used three primary outcomes: time taken to return to normal activities, major adverse surgical complications and major long-term complications. Quantitative estimates of the effects on quality of life were not provided (2;3).

Quality of life instruments aim to measure the impact of surgery on the patient's life. They indirectly evaluate postoperative recovery by proxy, since there are at present no generally accepted postoperative recovery specific quality of life instruments. The purpose of the present study was to review randomized clinical trials comparing abdominal and laparoscopic hysterectomy on the approaches in which they have reported on postoperative health and quality of life. In view of the expected clinical and statistical heterogeneity with this outcome, our report will be qualitative rather than quantitative.

Materials and methods

A systematic literature search was performed, using both PubMed between January 1966 and January 2006 and EMBASE between January 1980 and January 2006. Keywords used were 'randomized' or 'randomised' and 'laparosc*' or 'abdominal' and ´hysterectomy'. Cross-references of the selected studies were checked to identify other studies. The studies had to be randomized clinical trials comparing laparoscopic and abdominal hysterectomy in humans. Both studies on benign and malignant disease were included.

All studies were scored methodologically. This was done independently by two of the authors (KBK and BWJM). In each study inclusion and exclusion criteria, method of randomization, type of surgery and outcome measures were documented. Depending on the extent of the laparoscopic and the vaginal part of the procedure, we categorized the laparoscopic hysterectomies as laparoscopically assisted vaginal hysterectomy (LAVH), laparoscopic hysterectomy (LH(a)), total laparoscopic hysterectomy (TLH) and laparoscopic subtotal hysterectomy (LSH). The LAVH was defined as procedures where the laparoscopic component of the surgery extended

only down to the level above the uterine arterial pedicles, whereas LH(a) were cases where the laparoscopic dissection was performed to the level at least below the uterine arterial pedicles. In the TLH there was no vaginal component of the procedure other then removal of the uterus. The LSH were cases of subtotal hysterectomy (i.e. cervix retained), which were performed entirely laparoscopically (4).

We checked whether there was concealment before randomization, and whether the study was performed according to the 'intention-to-treat' principle. We evaluated the primary outcome of the studies. For this purpose, trials having peri- and postoperative course, data of the surgical procedures, complications and morbidity, pain and medication use or duration of hospital stay as primary outcome, were categorized as reporting on short-term medical outcomes. We then evaluated on whether these studies reported on postoperative health or quality of life as an outcome measure. We recorded the methods used for measurement of postoperative health and quality of life. We also collected information on the prior validation of the instruments used, the postoperative time interval at which these instruments were used, the response rate, the completeness of reporting of the results of the quality of life instruments and conclusions generated.

Results

The PubMed-search revealed 670 studies, of which 29 fulfilled the inclusion criteria for this systematic review. The EMBASE search revealed 579 studies, of which 24 fulfilled the inclusion

Table 1. Characteristics of eight randomized studies reporting on postoperative health and quality of life.

First author	Year	Country	Number of centers	Inclusion criteria *	Randomisation
Raju (25)	1994	UK	1	B, uterine size < 14 wks	Y
Ellstrom (9)	1998	Sweden	NR	B, VH not suitable	Y
Falcone (11)	1999	USA	1	B, uterine fundus > 2 cm below umbilicus	Y
Lumsden (18)	2000	UK	3	B, uterine size > 14 wks or BSO	Y
Schutz (28)	2002	Germany	1	Estimated uterine size** > 200 g	Y
Ellstrom (10)	2003	Sweden	1	B, VH not suitable	NR
Garry (13), Sculpher (29)	2004	UK, South Africa	30	B, uterine size < 12 wks	Y

NR = not reported
Y = yes
N = no
B = benign disease
BSO = bilateral salpingo-oophorectomy
VH = vaginal hysterectomy
LH = laparoscopic hysterectomy
AH = abdominal hysterectomy
TAH = total abdominal hysterectomy
LAVH = laparoscopically assisted vaginal hysterectomy
LH(a) = laparoscopic hysterectomy
TLH = total laparoscopic hysterectomy
LSH = laparoscopic subtotal hysterectomy

criteria. Out of these 24 studies, one paper had not been detected in the PubMed-search (5). Checking of cross-references did not reveal further studies. Thus, 30 papers on randomized controlled trials comparing laparoscopic and abdominal hysterectomy were included in our study (5-34). The papers were published between 1994 and 2004 and reported on 3,016 women, of whom 876 women were included in the eVALuate trial which is the largest study on the topic (13;29). In 22 studies the primary outcome was a short-term medical measure. Other primary outcomes were costs (n=3) (9;21;29), tissue trauma or laboratory results (n=3) (6;7;34) and survival (n=1) (32). Only one study had disease specific quality of life as primary outcome (10).

Eight further studies reported on postoperative health and quality of life as a secondary outcome (9;11;13;18;21;25;28;29). One of these studies was presented as an abstract (21). As confirmed by the author, the abstract dealt with the same patients and methods as a later published paper (9) and for this reason only the latter paper was taken into account in our study. Two papers reported on different quality of life outcomes in the same patient group of 876 patients (13;29). These two papers were considered as a single study. Thus, seven randomized controlled trials comparing laparoscopic hysterectomy to abdominal hysterectomy studied postoperative health or quality of life. They reported on 1,450 patients, of which 874 were randomized to the laparoscopic procedure and 576 to the abdominal procedure. Nineteen patients (LH n=9, AH n=10) were recruited into two studies by Ellstrom et al., which reported on different clinical outcomes i.e. cost analysis and quality of life (9) versus psychological wellbeing and sexuality (10).

All patients were operated for benign disease. Further study characteristics and results of quality of life analysis are shown in Tables 1 and 2. In six studies (9;11;13;18;25;28), the randomization

Concealment	Blinding	Intention to treat analysis	Power analysis	Baseline characteristics	AH	LH
Y	NR	NR	Y	Y	TAH + BSO	LAVH+BSO
NR	NR	NR	Y	Y	TAH	LH(a)
Y	N	Y	Y	Y	AH***	LH(a)
Y	NR	Y	Y	Y	TAH***	LAVH, LH(a)
Y	NR	NR	Y	Y	TAH	LAVH, LH(a)
NR	NR	N	Y	Y	TAH	LH(a)
Y	NR	Y	Y	Y	AH***	LAVH, LH(a), TLH, LSH

* denotes inclusion criteria for indication and uterine size
** denotes sonographically estimated uterine weight
*** denotes no description of technique

Table 2. Data on the instruments used and the results of quality of life assessment.

First author	Number of patients	QoL instrument used	Prior instrument validation	Measurement interval	Response rate	Completeness of reporting of QoL results	Study group favoured
Raju (25)	LH n=40 AH n=40	Questioning	N	6 weeks	100%	NR	LH
Ellstrom (9)	LH n=38 * AH n=38 *	SF 36 health survey	Y	1,3,12 weeks	NR	Y	LH
Falcone (11)	LH n=24 AH n=24	Daily diary	N	6 weeks	NR	N	LH
Lumsden (18)	LH n=100 AH n=100	Achievement of milestones	N	4 weeks	87%	N	Equal
		VAS Euroqol 5D	Y	Baseline 1 month 6 month 12 month	95% 78% 64% 47%	Y	Equal
Schutz (28)	LH n=28 AH n=20	18 items questionnaire	N	12 month	NR	N	LH
Ellstrom (10)	LH n=36 AH n=38	Psychological General Well-Being Index	Y	Baseline 1 year	NR	Y	Equal
	LH n=29 AH n=33	Mc Coy Scale	Y	Baseline 1 year	NR	N	Equal
Garry (13)	LH n=584 AH n=292	SF 12 health survey	Y	Baseline 6 weeks 4 month 12 month	76% 50% 50% 50%	Y	LH
		Body Image Scale	Y	Baseline 6 weeks 4 month 12 month	92% 60% 55% 60%	Y	LH
		Sexual activity questionnaire	Y	Baseline 6 weeks 4 month 12 month	NR	N	LH
Sculpher (29)	LH n=573 AH n=286	Euroqol 5D and QALYs	Y	Baseline 6 weeks 4 month 12 month	NR	Y	Equal

N = no
Y = yes
NR = not reported

LH = laparoscopic hysterectomy
AH = abdominal hysterectomy
QoL = Quality of Life

QALYs = quality adjusted life years

*denotes undefined subgroup of trial population.

procedure was described adequately. However, in one of these studies only an undefined subset of 76 out of the 143 randomized patients was asked to fill out the SF 36 health survey without baseline measurement (9). Five (11;13;18;25;28) out of the six studies that described the randomization process reported adequate concealment by using a third party, sealed envelopes or telephone inquiry. None of the studies reported that they were set-up in a blinded fashion. Three studies were analyzed according the intention-to-treat principle (11;13;18). Two studies (25;28) did not provide information on the intention to treat analysis in spite of conversions from laparoscopic to abdominal hysterectomy in one of the studies (25). This leaves it unclear whether the patients with conversions were analyzed in the laparoscopic or abdominal hysterectomy group. Furthermore, one study neither provided information on intention to treat nor information on conversions (9). One study clearly did not follow the intention-to-treat principle (10). All studies presented a power analysis and patients' baseline characteristics.

Different approaches to laparoscopic surgery were used, ranging from LAVH to TLH and LSH. Although three studies used more then one laparoscopic approach, the quality of life data were not presented per subgroup (18;28;13). In four studies (9;10;25;28) the abdominal procedure was only described briefly whereas the other three studies (11;13;18) did not provide any information on the surgical technique.

The following eight validated quality of life questionnaires were used: the SF 36 health survey (9), the Euroqol Visual Analogue Scale (18), the Psychological General Well-Being Index (10), the Mc Coy Scale (10), the SF 12 health survey (13), the Body Image Scale (13), Sexual Activity Questionnaire (13) and the Euroqol 5D (29). The SF-36 and SF-12 health surveys are generic health related quality of life questionnaires measuring perceived health status in eight dimensions which are grouped into two components: the physical and mental health summary measure. The EuroQol 5D is another generic health related quality of life instrument with the potential to calculate quality adjusted life years, which can be used in economic evaluation. The EuroQol Visual Analogue Scale is a separately validated part of the EuroQol 5D and measures health status in one question, which is answered on a zero to 100 visual analogue scale. The Psychological General Well-Being Index was developed to measure self-perceived psychological well-being (anxiety, depression, positive well-being, vitality, self-control and general health) in the general population. The Body Image Scale is a questionnaire addressing satisfaction with bodily appearance and changes that may have resulted from disease or treatment. The McCoy Scale and Sexual Activity Questionnaire assess sexual functioning in terms of activity, pleasure and discomfort.

One study had a follow-up period of twelve weeks postoperatively (9), whereas the others included a measurement at one year postoperatively (10;13;18;29). Only two out of the four studies that used validated quality of life measurement resulted in significant differences between the treatment groups and showed better quality of life after laparoscopic hysterectomy in the early postoperative period, i.e. in the first six weeks (9;13). The first of these two studies, was by Ellstrom *et al.* on the SF 36 health survey. The study was powered to look for significant differences

in quality of life, and in two out of eight dimensions one week postoperatively and in four out of eight dimensions three weeks postoperatively the laparoscopic hysterectomy was favourable (9). However, the results were analyzed by unadjusted multiple testing for eight dimensions and three time points, which involves the risk of overestimation of the effects due to an increased type I error (9). The second study was the eVALuate study by Garry et al., in which laparoscopic hysterectomy was favourable at six weeks after surgery on all three questionnaires used (i.e. the Physical Component Summary of the SF 12 health survey, the Body Image Scale and the Sexual Activity Questionnaire), whereas no differences were found at one year after surgery (13). In this study the sample size calculation was based on the detection of differences in complications and not on differences in quality of life (13). This resulted in a large study population, where a clinically non-relevant difference in the secondary outcome became statistically significant. The follow up period was longer than six weeks in all studies, but no statistically significant differences between study groups were found beyond this time point.

Four studies (11;18;25;28), especially the older studies, made use of non-validated measurement methods to evaluate postoperative health and quality of life, of which one study used both a validated and a non-validated method (18). These studies failed to describe the methods used (11;18;25) or did not adequately present the results (28), thus hampering interpretation of the data. Nonetheless, three out of four studies concluded that laparoscopic hysterectomy was more favourable over abdominal hysterectomy (11;25;28).

Comment

This systematic review summarized the available evidence comparing the quality of life after hysterectomy by the laparoscopic and abdominal approach. Although we found 30 papers describing randomized trials on this topic, only seven studies reported on the assessment of some form of quality of life. The few data available indicate that the laparoscopic procedure performs better or equally as far as quality of life is concerned. In the two studies where significant differences between study groups were found, this was on the short term, i.e. in the first six weeks after surgery.

Either in their introduction or discussion sections of the manuscripts, the postoperative recovery was stated to be quicker after laparoscopic hysterectomy in 24 studies. However, most of them failed to measure quality of life and postoperative health in an adequate way or failed to make use of validated instruments. As a consequence the systematic review and meta-analysis on this subject only reported on complication rates and return to normal activities, but not on the primary aim of laparoscopic surgery, i.e. whether quality of life in the short and long term was better following laparoscopic surgery (2).

The same shortcoming came across in meta-analyses comparing other gynaecologic laparoscopic procedures, such as tubal sterilization, benign ovarian tumours, tubal ectopic

pregnancy and colposuspension, where data on quality of life where likewise lacking (35-38). Another issue of concern was the lack of uniformity on the use of the validated quality of life instruments amongst the few randomized trials that employed such outcome assessment. There is a necessity to standardize the quality of life instruments, which are suitable to measure postoperative recovery for studies comparing laparoscopic with conventional open surgery or other new surgical techniques. As postoperative differences in quality of life, disappeared in the longer term, a standard sequence of postoperative time intervals at which such instruments should be used would be helpful.

Laparoscopic hysterectomy is associated with quicker postoperative recovery and decrease of operative blood loss and febrile morbidity at the expense of an increased risk of urinary tract injuries (3). Whether these advantages can compensate for the extra risk of urinary tract injuries is an important issue. Data on quality of life can show the impact of surgery and complications on patient's lives and thus be a leading argument in the discussion about the best way to perform a hysterectomy. The effect of the uterine size on postoperative quality of life in hysterectomy patients is not known until now. Due to the limited number of studies, we were not able to compare subgroups of patients with normal and enlarged uteri. However, the largest study in our review excluded patients with enlarged uteri, which might have influenced the better postoperative quality of life after laparoscopic hysterectomy in this study (13).

Although the main reason to perform laparoscopic surgery is the enhanced postoperative quality of life due to less physical impact, our present study shows that this outcome is usually not considered in randomized controlled trials on laparoscopic hysterectomy. Data from the few studies that report on quality of life, indicate that postoperative quality of life after laparoscopic hysterectomy as compared to abdominal hysterectomy is better or equal in the first six weeks after surgery and equal subsequently. Women scheduled for hysterectomy, with a moderately enlarged and mobile uterus, should therefore be appropriately informed about the laparoscopic procedure and should have the opportunity to opt for this approach

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4 Quality of life and surgical outcome after total laparoscopic hysterectomy versus total abdominal hysterectomy for benign disease; a randomized controlled trial

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Abstract

Study objective

Minimal invasive surgery aims to achieve at least a similar clinical effectiveness with a quicker recovery. Although there have been numerous randomized clinical trials comparing laparoscopic hysterectomy with hysterectomy by laparotomy, only a few studies have compared quality of life after different types of hysterectomy. None of these studies evaluated total laparoscopic hysterectomy. In this paper we report on a randomized comparison of quality of life after total laparoscopic versus total abdominal hysterectomy.

Design

Randomized controlled trial (Canadian Task Force Classification I).

Setting

Single center teaching hospital in The Netherlands, experienced in gynecological minimal invasive surgery.

Methods

Patients scheduled for hysterectomy for a benign condition, in whom a vaginal hysterectomy was not possible and laparoscopic hysterectomy was feasible (mobile uterus not exceeding the size of 18 weeks' gestation).

Interventions

Abdominal versus laparoscopic hysterectomy.

Measurements and main results

Patients completed the Dutch version RAND-36 health survey pre-operatively as well as at five time points in the first 12 weeks after surgery. The primary outcome of the study was quality of life as measured by the RAND-36. A linear mixed model was used for statistical analysis while accounting for the baseline values. Secondary outcomes were hospital stay and complications. There were 88 patients eligible, of whom 59 gave consent for randomization. Twenty-seven women were allocated to the laparoscopic arm and 32 to the abdominal arm. We found a significant treatment effect favoring laparoscopic hysterectomy in the RAND-36 scale for vitality. Laparoscopic hysterectomy performed better on all other scales of the RAND-36, but these differences were not statistically significant.

Conclusions

Laparoscopic hysterectomy results in more postoperative vitality when compared with abdominal hysterectomy. For this reason, all women with a benign condition requiring abdominal hysterectomy, in whom the laparoscopic approach is feasible, should have the chance to choose laparoscopic hysterectomy.

Introduction

Hysterectomy is the most frequently performed gynecologic operation. In case of hysterectomy for benign gynecological disease, vaginal hysterectomy should, whenever possible, be the first procedure of choice (1;2). In 1989 a laparoscopic approach to hysterectomy, as an alternative for abdominal hysterectomy was described by Reich (3). Laparoscopic hysterectomy (LH) is further divided in three categories: laparoscopic assisted vaginal hysterectomy (LAVH), in which vaginal hysterectomy is assisted by prior laparoscopy and the laparoscopic procedure does not include the occlusion of the uterine arteries; LH(a), laparoscopic hysterectomy, in which the laparoscopic part of the hysterectomy includes the occlusion of the uterine arteries; and total laparoscopic hysterectomy (TLH), in which the vaginal part of the operation is restricted to the removal of the laparoscopically freed uterus (4,5).

In contrast to other implementations of laparoscopic interventions, laparoscopic hysterectomy is not well established (6). Laparoscopic hysterectomy has a longer learning curve, takes longer to perform and has a higher complication rate of urinary tract injury compared with abdominal hysterectomy, especially during the learning curve (7). On the other hand, there is less blood loss and febrile morbidity resulting in shorter hospital stay (2).

There have been 30 randomized trials published by now comparing laparoscopic and abdominal hysterectomy. However, in only five trials (8-12) were validated quality of life questionnaires used, of which two reported on the same patient group (10;12). Two trials (8;10) showed significantly better quality of life favoring laparoscopic hysterectomy, whereas the other three (9;11;12) did not show a difference. As different methods of quality of life assessment were used, the studies could not be pooled, as was demonstrated in a recent meta-analysis on the subject (2). In 2003, an expert committee on quality of life recommended use of the SF-36 health survey in trials comparing post-hysterectomy health status (13). The RAND-36 health survey used in the present study is identical to the SF-36 health survey (14). Until now there has been only one randomized trial using this instrument and showing better quality of life after laparoscopy (8). However that study was performed without baseline measurement and in an undefined subset of the randomized patients after LH(a), not TLH. The eVALuate study, the most extensive study on quality of life after laparoscopic hysterectomy, had major complications as its primary outcome (10). Quality of life as measured by the SF 12 and Body Image Scale was studied as one of the secondary outcomes. The SF-12 yields less precise scores than does the SF-36, although this becomes less important in a large study as confidence intervals for group averages are largely determined by sample size (15). The eVALuate study showed better quality of life in the SF-12 Physical Component Summary at six weeks after surgery in the laparoscopic group. But still, the conclusion of the authors was that future studies on hysterectomy incorporating quality of life measurement were needed, especially those on TLH (16), which was confirmed in the meta-analysis on the subject (5). Furthermore, there are at present only few data on the surgical outcomes of TLH (5).

In the present paper, we present the results of a randomized controlled trial comparing TLH and total abdominal hysterectomy (TAH). We studied postoperative quality of life as measured by the RAND-36 health survey and the surgical outcomes of the two interventions.

Methods

Participants

This randomized study was performed in the Máxima Medical Centre, a large teaching hospital with 865 beds in two locations in the south of The Netherlands, from August 2002 through January 2005. The gynecologic department is experienced in minimal invasive surgery, and the first laparoscopic hysterectomy was performed in 1992. In the year 2000, before the inclusion started, the distribution of the three different approaches to hysterectomy in our clinic was 50% vaginal hysterectomy, 25% abdominal hysterectomy and 25% 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, 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 ethics committee of the Máxima Medical Center.

Surgical procedures

All patients had general anesthesia and received preoperative antibiotic prophylaxis as well as anticoagulants during immobilization. Operations were either performed by gynecologists or residents in training supervised by gynecologists. The laparoscopic procedures were performed or supervised by three experienced gynecologists who were trained in Clermont-Ferrand, France and had performed at least 100 laparoscopic hysterectomies each before the start of the study. The laparoscopic procedures were intentionally TLH procedures. The performed procedures were subdivided in LAVH, LH(a) and TLH as described above (2). In addition to the port for the camera at the umbilicus or 10 cm above, three trocars were inserted for instrumentation. The uterus was manipulated by the Karl Storz Clermont-Ferrand manipulator (Karl Storz, Tuttlingen, Germany). All vascular pedicles were secured by bipolar coagulation and divided with the use of scissors. Scissors in combination with monopolar coagulation was used to open the bladder flap. The bladder was dissected with scissors as well as bluntly from the cervix and upper part of the vagina. The cervix was separated from the vagina making use of a monopolar needle over a rotating vaginal blade. Laparoscopic extracorporeal knots (vicryl) were used to close the vagina.

The abdominal hysterectomies were performed or supervised by 10 different experienced gynecologists. A transverse incision was made, and hysterectomy was performed using the extrafascial technique by means of clamps and suture ligation.

Quality of life

The primary outcome of this study was quality of life as measured by the Dutch version RAND-36 health survey until 12 weeks after surgery. The RAND-36 is a generic health related quality of life questionnaire, which is validated for the Dutch language. The questionnaire measures subjective health in eight scales, which range from 0-100. Thus the total score ranges from 0 to 800, where 0 is the poorest quality of life and 800 the best imaginable. Summated ratings and standardized scoring algorithms were used to assess the eight scales (17). Patients completed the baseline measurement after randomization. Postoperative measures were made at one, two, four, six and twelve weeks after surgery. Patients filled out the questionnaires without assistance of the researcher and returned the questionnaires by mail.

Secondary outcomes

The peri- and postoperative course, including surgical details, complications and duration of hospital stay, were secondary outcome measures of the study. Data were collected prospectively by completion of a standardized case record form by the surgeon and researchers. The anesthesiology team recorded the amount of blood loss and operation times. Conversions from laparoscopy to laparotomy were not seen as a complication and were described separately. We defined complications as adverse effects during and after surgery. All complications were collected prospectively in the first six weeks after surgery and according to a predefined list in case record forms. Complications were recorded ad hoc beyond these six weeks, and there had to be a reasonable relationship to the hysterectomy. Data on visceral damage, re-operations, major and minor anesthesia problems and trombembolism were collected. Complications of bleeding were split up in four groups: hemorrhage requiring transfusion, blood loss greater than 1000 mL without transfusion, major hematoma needing and major hematoma not needing surgery. We defined several categories of infections: urinary tract infections that had to be treated with antibiotics in hospital or by the general practitioner in the first six weeks; wound infections were infections with pus drainage; pelvic infections should have pus drainage or the combination of fever and ultrasound confirmation of an abscess; chest infections had to be confirmed by radiograph and there was a category of other infections (e.g. serious infection of the infusion site). Fever was defined as a temperature 38°C or higher on two time points at least 12 hours apart and had to occur beyond the first postoperative day to be regarded as a complication. Cervical stump problems were defined as unintended subtotal procedures. Wound dehiscence was defined as visceral herniation with and without restoration.

The postoperative care was administered according to local protocols, and the researchers did not interfere. The urinary catheter was removed on the morning after surgery. The hemoglobin

was measured prior to surgery and on day 1 after hysterectomy. Data on the use of medication in the first 3 postoperative days were collected from the nursing chart. Analgesics were given according to a standardized post-anesthesia protocol using a zero-to-10 visual analogue scale for pain, where patients were offered analgesics in case of a pain score at rest above three. Patients were discharged when they were free of fever; did not need systemic analgesics; had normal micturition and normal defecation; and were able to eat, drink and mobilize.

Sample size and randomization

Before the start of the study, the sample size was calculated for the quality of life as measured by the questionnaire RAND-36. A difference of 15 per scale (8) was considered as clinically relevant. With a standard deviation of 20, a type I error of 0,05, and 80% power, 28 patients were needed per arm.

After obtaining written informed consent, 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. The closed envelopes were shuffled before numbering. The patients and medical team were not blinded to the intervention.

Statistical methods

Analysis of the data was performed on intention-to-treat basis. Correlations among the patients' baseline characteristics (age, body mass index (BMI), parity, American society of Anesthesiologists (ASA) score, and uterus weight) were calculated using Spearman's correlation coefficient. Differences in medical outcome between the two treatment groups were tested for statistical significance using the t-test in case of normally distributed data, Mann Whitney U test in case of non-normally distributed data and the Fishers-exact test in case of two by two tables. The means and standard deviations are presented in case of normally distributed data, the medians with the range in case of non-normally distributed data and absolute numbers with percentages in case of dichotomous variables.

Cronbach's alpha of each scale of the RAND-36 at baseline was calculated to assess the internal consistency. A linear mixed model was used to study the differences in recovery from two to twelve weeks after surgery between the two groups while accounting for the baseline values, for each of the scales of RAND-36, separately (18). The dependent variable was the scale of RAND-36. The independent class variables were patient and treatment (laparoscopic and abdominal hysterectomy, respectively) and the independent regression variables were the RAND-36 baseline level and time in weeks after surgery. Both the intercept and the regression in time of each patient were treated as random variables in the model. This way differences between treatments are estimated given the baseline value, while differences in recovery among patients are allowed. Initially interaction terms and quadratic terms in time were included in the linear part of the model; but as the inclusion did not significantly (Likelihood-Ratio test) improve the fit to the data, these terms were not included in the final model used (18). Note that, excluding

the interaction term of group with time, results in a parallel line model, (i.e. the increase per week is estimated to be identical in both groups). The estimated regression parameters with standard errors of each RAND-36 score are used to calculate the average level per week of the patients in each group. These levels with confidence bands are further presented in figures.

The quality of life data were analyzed by SAS 10.0 software (SAS Institute, Inc., Chicago, IL), all other data in SPSS 13.0 software (SPSS, Inc., Chicago, IL), with p-values ≤ .05 considered statistically significant.

Results

The study population

A flowchart of the study is shown in Figure 1. We randomized 59 women, of which 27 were allocated to the laparoscopic arm and 32 were allocated to the abdominal arm. One woman allocated to the laparoscopic procedure refused the laparoscopy after randomization and an abdominal hysterectomy was performed. Her data were analyzed in the laparoscopy group according to the intention to treat principle. Patient characteristics and surgical indications are shown in Table 1. A statistically significant correlation was found between BMI and ASA score in both groups (LH .46, AH .62). All other correlations in the patients' characteristics were less than or equal to .34.

Quality of life

The overall return rate of the questionnaires was 91% in the laparoscopic group and 97% in the abdominal group. The Cronbach's alpha for the eight scales, two summary measures and total RAND-36 score at baseline were all high, ranging from .74 to .93.

In Figure 2 the observed and estimated scores from two to twelve weeks after surgery, as well as the observed baseline and one-week scores of the total RAND-36 score are presented. In both groups, a linear increase from two until twelve weeks after surgery was revealed. The estimated increase of RAND-36 level (95% confidence interval) by treatment group, by unit increase in baseline score and per week after surgery on the eight RAND-36 scales and total score are shown in Table 2. The presented difference between the treatment groups is after correction for differences in baseline values between the groups. For all items, the regression lines for the laparoscopic group (continuous line) were on a higher level as compared with the abdominal group (broken line) for all RAND-36 scales, indicating better quality of life. However, when accounting for differences at baseline, this difference is statistically significant only in the scale vitality, where the estimated difference over time measures 12.0 units on a scale of 100, with a 95% confidence interval of 4.7 to 19.3 units. The scores on the vitality scale are presented in Figure 3. As the difference exists over a period of 10 weeks, this may be seen as a clinically relevant difference. In the scales physical functioning and bodily pain, as well as in the

Figure 1. Flowchart of the trial population

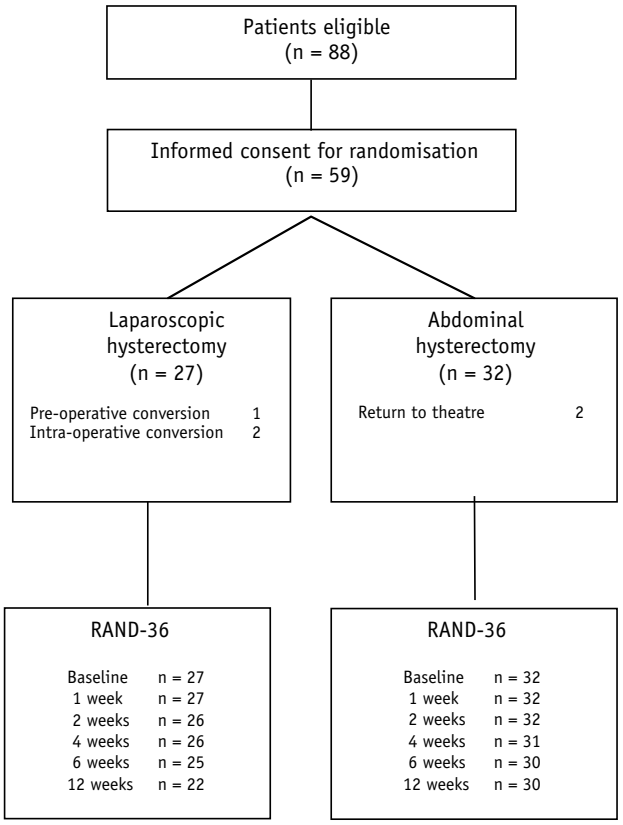


Table 1. Patient characteristics and surgical indications by treatment group.

	LH (n=27)	AH (n=32)
Age (yrs)	46.0 ± 7.3	45.2 ± 6.0
BMI (kg/m^2)	26.0 ± 4.5	26.5 ± 3.8
Parity	1.8 ± 1.1	1.4 ± 1.1
ASA score	1.4 ± 0.6	1.4 ± 0.6
Uterine weight (g)	281 [62-1066] *	173 [40-468] *
Primary indication for surgery		
Bleeding disorders	21 (78%) **	27 (84%) **
Dysmenorrhoea	4 (15%) **	5 (16%) **
Other	2 (7%) **	0

AH = abdominal hysterectomy; ASA = American society of Anesthesiologists;
BMI = body mass index; LH = laparoscopic hysterectomy.
Data shown as mean ± standard deviation, * median (range), ** absolute numbers (percentage).

Table 2. Estimated increase of RAND-36 level (95%confidence interval) by treatment group, by unit increase in baseline score and per week, using a linear mixed model.

RAND-36	Difference * in favor of LH	Baseline effect**	Increase per week after surgery in each group***
Physical functioning	7.8 (-0.3;15.9)	0.11 (-.07;.29)	4.1 (3.5;4.6)
Social functioning	7.0 (-1.8;15.7)	0.36 (.15;.57)	3.4 (2.7;4.1)
Role physical	1.7 (-7.7;11.1)	0.07 (-.04;.18)	4.6 (3.2;6.1)
Role emotional	1.5 (-13.4;16.5)	0.18 (.00;.36)	2.2 (1.1;3.4)
Mental health	3.6 (-2.8;9.9)	0.36 (.17;.56)	0.7 (0.3;1.2)
Vitality	12.0 (4.7;19.3)	0.27 (.10;.45)	2.1 (1.6;2.6)
Bodily pain	8.4 (-0.1;17.4)	0.39 (.18;.60)	3.4 (2.6;4.2)
General health	0.0 (-8.1;8.1)	0.49 (.27;.72)	0.23 (-.16;.62)
Total RAND-36	49.6 (-5.1 ; 104.2)	0.24 (0.05 ; 0.42)	20.8 (16.6 ; 24.9)

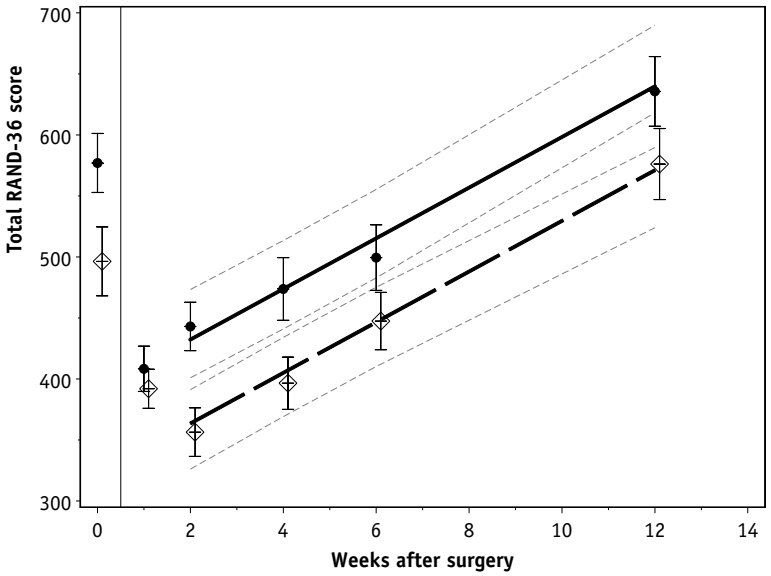
LH = Laparoscopic Hysterectomy; RAND-36 = RAND 36-Item Short Form Health Survey.
*Difference between groups after correction for baseline differences. **The baseline effect is the increase in postoperative score per unit increase at baseline. *** Because the data fit very well to the parallel-line model the increase per week is estimated to be identical in both groups (see also figure 2 and 3).
Example: On average the estimated level of the total RAND-36 score in the laparoscopic hysterectomy group was 49.6 units higher as compared with the abdominal hysterectomy group, at each time point from two until twelve weeks after surgery. The estimated increase per unit higher level in the total RAND-36 score at baseline between two patients was 0.24, this is independent of both time point and treatment group. Furthermore, the estimated increase in the total RAND-36 score per week in both groups was 20.8 units.

Table 3. Data on surgical procedures by treatment group.

	LH (n=27)	AH (n=32)	p
Laparoscopic procedures			
LAVH	1 (4%)	–	–
LH(a)	2 (7%)	–	–
TLH	21 (78 %)	–	–
Preoperative conversion	1 (4%)	–	–
Intra operative conversion	2 (7%)	–	–
Resident 1st surgeon	11 (39%)	28 (88%)	< 0.01
Readmissions	2 (7%)	2 (6%)	1.0
Return to theatre	0	2 (6%)	0.50
Operation time (min)	121 ±36 *	78 ±27 *	< 0.01
Operation time incl. re-operations (min)	121 ± 36 *	90 ± 60 *	0.02
Blood loss (mL)	200 [0-650] **	300 [100-1100] **	0.01
Patients receiving opoids	10 (37%)	22 (69%)	< 0.01
Patients receiving antiemetics	2 (7%)	8 (25%)	0.07
Hospitalization (days)	4.2 ± 1,3 *	5.4 ± 2,4 *	0.02
Hospitalization incl. readmissions (days)	4 [2-25] **	5 [3-34] **	0.02

AH=abdominal hysterectomy; LH=laparoscopic hysterectomy; LAVH=laparoscopic assisted vaginal hysterectomy, in which vaginal hysterectomy is assisted by prior laparoscopy and the laparoscopic procedure does not include the occlusion of the uterine arteries; LH(a)=laparoscopic hysterectomy, in which the laparoscopic part of the hysterectomy includes the occlusion of the uterine arteries; TLH=total laparoscopic hysterectomy, in which the vaginal part of the operation is restricted to the removal of the laparoscopically freed uterus; – =not applicable.
Data shown as absolute numbers (percentage), *mean ± standard deviation, ** median [range]. p=p-value for difference between groups using Fisher's exact test in cases of two-by-two tables, t-test in cases of normal distributed variables and Mann-Whitney test in cases of non-normal disrtibuted variables.

Figure 2. Observed total RAND-36 scores and estimated regression lines by treatment group, using a linear mixed model that accounts for the baseline value.



RAND-36 = RAND 36-Item Short Form Health Survey, Closed symbols = observed mean RAND-36 level ± one standard error in LH group, open symbols = observed mean RAND-36 level ± one standard error in AH group, continuous line = estimated regression lines in LH group, broken lines = estimated regression line in AH group, dotted lines = 95% confidence bands of regression lines, AH = abdominal hysterectomy, LH = laparoscopic hysterectomy. Note that the data fit very well to the parallel-line model.

Table 4. Number of complications by treatment group.

Complications	LH (n=27)	AH (n=32)	p
Ureteric injury	1 (4%)	0	0.46
Bladder injury	1 (4%)	2 (6%)	1.0
Anesthesia problems	0	1 (3%)	1.0
Hemorrhage (with transfusion)	0	2 (6%)	0.50
Blood loss >1000 cc (no transfusion)	0	1 (3%)	1.0
Hematoma (needing surgery)	0	0	–
Hematoma (resorption)	0	5 (15%)	0.06
Pulmonary embolus	0	1 (3%)	1.0
Infection or fever	3 (11%)	7 (21%)	0.32
Cervical stump problems	0	1 (3%)	1.0
Others	1 (4%) a	3 (9%) b	0.62
Total complications	6	23	–
No of patients with complications	6 (22%)	17 (53%)	0.02

AH = abdominal hysterectomy; LH = laparoscopic hysterectomy; -- = not applicable; a = local treatment of granulation tissue in the top of the vagina (n = 1); b = temporary lesion of the plexus lumbalis caused by an injury at the height of the m. psoas (n=1), dyspnoea and low oxygenation resolved with temporary oxygen therapy (n=1) and deterioration of colitis ulcerosa (n=1). Data shown as absolute numbers (percentage). p=p-value for difference between groups using Fisher's exact test.

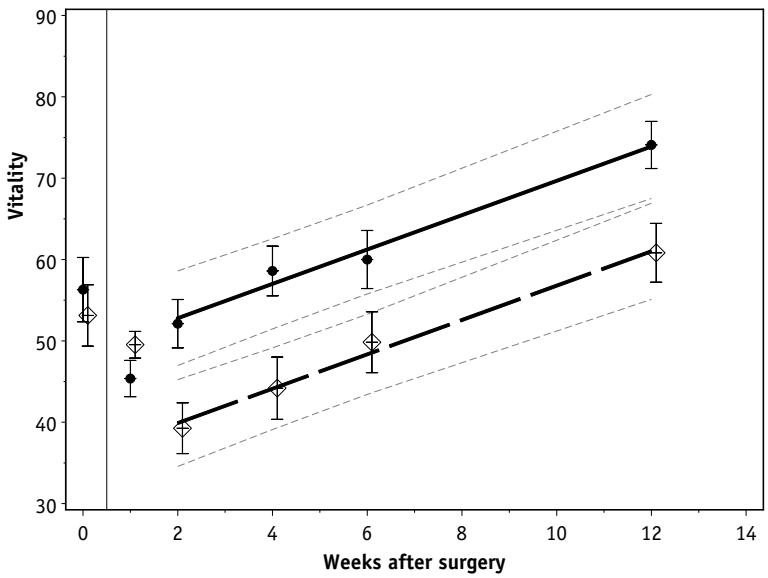
total RAND-36 score the lower limit of the 95% confidence interval is near zero, which shows borderline significance.

Quality of life as measured by the RAND-36 decreased after surgery in both groups. The RAND-36 baseline levels differed significantly, but the one-week levels in both treatment groups were remarkably similar. In the laparoscopic group, the RAND-36 levels started to increase beyond the first week, whereas in the abdominal group they started to increase only beyond the second week. This suggests a greater impact of surgery on the patient's quality of life in the abdominal group.

Secondary outcome - The surgical outcome

Data on the procedures are presented in Table 3. The two intraoperative conversions from laparoscopy to laparotomy were related to the size of the uterus in both patients. One of these patients suffered a urinary tract infection and no other complications occurred. In the abdominal group, one procedure was performed subtotal because of difficult access to the operation field.

Figure 3. Observed RAND-36 scores on the vitality scale and estimated regression lines by treatment group, using a linear mixed model that accounts for the baseline value.



RAND-36 = RAND 36-Item Short Form Health Survey, Closed symbols = observed mean RAND-36 level ± one standard error in LH group, open symbols = observed mean RAND-36 level ± one standard error in AH group, continuous line = estimated regression lines in LH group, broken lines=estimated regression line in AH group, dotted lines = 95% confidence bands of regression lines, AH = abdominal hysterectomy, LH = laparoscopic hysterectomy. Note that the data fit very well to the parallel-line model.

Intraoperative complications in the laparoscopic hysterectomy group consisted of a bladder lesion due to severe endometriotic scarring, which was treated by laparoscopic suturing. In the abdominal hysterectomy group one severe allergic reaction of unknown origin occurred. In both groups, there was an equal drop in hemoglobin and hematocrit. Significantly fewer patients in the laparoscopic group needed opoids in the first two postoperative days as compared with the abdominal group (37 vs 69%, p≤.01). Furthermore, fewer patients needed antiemetics (resp. 7% and 25%). On the third postoperative day none of the patients in either group needed any opoids or antiemetics. In the laparoscopic hysterectomy group, 59% of the patients versus 31% of the patients in the abdominal hysterectomy group were discharged on day two, three or four days after surgery (p=.03). Two patients in each treatment group were readmitted; these were the patients who had suffered urinary tract lesions.

The registration of complications is presented in Table 4. Within one-week postoperatively, one patient in the laparoscopic hysterectomy group presented with urinary loss through the vagina caused by a fistula of the right ureter. This was treated uneventfully with a double-J catheter for 4 weeks. Evaluation of the video of the procedure led to the conclusion that a coagulation lesion of the ureter must have occurred during bipolar coagulation of the uterine artery on the right side using the contra lateral (left) lateral port site. In the abdominal hysterectomy group two bladder fistulas occurred. One patient needed a relaparotomy, whereas the other needed two relaparotomies for repair. One patient in the laparoscopic group had a wound dehiscence of the 10 mm lateral port site, which was not repaired at the end of follow up. Histological findings of the uterus showed myoma or adenomyosis in 89% of patients after laparoscopic hysterectomy versus 87% after abdominal hysterectomy.

Discussion

We conducted a randomized controlled trial to establish the difference in quality of life after TLH and TAH in the patients suitable for both types of hysterectomy. After baseline correction, we report a significant difference in postoperative vitality favoring laparoscopic hysterectomy. This difference between the treatment groups was present all along the recovery period until twelve weeks after surgery. The vitality scale is composed of questions on fatigue and loss of energy. These are important factors in the post-hysterectomy period, as fatigue is known to occur more frequently and persist twice as long as compared with pain (19;20). Borderline significant differences, also favoring laparoscopic hysterectomy, were found in the RAND-36 scales of physical functioning and bodily pain, as well as in the total RAND-36 score. In agreement with previous reports, we found that the laparoscopic procedure took longer to perform, but was equal or favorable as compared with abdominal hysterectomy on all other parameters.

The RAND-36 is the most suitable instrument to measure post-hysterectomy quality of life (21), and our data are directly comparable to RAND-36 and SF-36 data from other studies (17;22).

Ellstrom *et al.* (8) studied the SF-36 in patients who had undergone hysterectomy, but analyzed the results by multiple statistical testing for the eight scales and for the three postoperative time points. This involved the risk of overestimation of the effects due to an increased type I error. Furthermore, they did not take baseline values into account. The present study shows better quality of life after laparoscopic hysterectomy even after correction for baseline measurement and multiple measure moments.

The vast majority of hysterectomy is performed for benign indications, which makes assessment of quality of life in research on hysterectomy an issue of utmost importance (20). It is surprising that so little studies on laparoscopic hysterectomy report on quality of life, as a better quality of life is the main reason for a laparoscopic approach. While our study was ongoing, the results of the eVALuate trial were published in 2004, and a meta-analysis on the subject was published in 2005 (2;10). As the eVALuate study was powered to find differences in complications, a large sample of over 800 women was studied. As a consequence, clinically irrelevant differences in the quality of life outcome became statistically significant. In the meta-analysis, the data on postoperative quality of life could not be presented due to missing and heterogeneous data. Thus our study can still fill the gap in published data on post-hysterectomy quality of life. The difference in quality of life all along a postoperative period of 10 weeks may be seen as a clinically relevant difference in a reasonable sample.

A disadvantage of our study is that the patients, who were not blinded to the procedure, completed the baseline measurement after hearing the result of the randomization. At this time point we found a statistically significant lower RAND-36 score in the abdominal hysterectomy group as compared with the laparoscopic hysterectomy group. There were no further differences in baseline characteristics that could account for the difference, including pre-existing psychopathology. Furthermore, we asked the patients whether they disliked the idea of the operation and found an equal percentage doing so in both groups. This indicates that the difference is not due to disappointment or fear of the abdominal procedure, which would be a treatment effect (23). To deal with the difference at baseline, we applied a statistical technique with a correction for the RAND-36 baseline level as described in the methods section. Still, we found a statistically significant treatment effect for patients with the same baseline levels in the different treatment groups.

The percentage of operations performed by a resident in training was significantly higher in the abdominal hysterectomy group, which will be a reflection of daily clinical practice in teaching hospitals. Furthermore, we could confirm most data on surgical outcome from earlier studies. The hospital stay was significantly shorter in the laparoscopic group. Conversions were not regarded as complication, because they are inherent to laparoscopic surgery (24). We had a large number of complications in our study, both minor and major complications. Because our study was prospective, under-reporting is less likely than in retrospective studies.

The finding that quality of life was better after laparoscopic hysterectomy goes hand in hand with a higher complication rate in laparoscopic hysterectomy. A meta-analysis reported a

significant 2.6-fold increased risk of urinary tract injury. Dependent on patient preference, this should be weighted against the improved quality of life in individual cases.

The lifetime risk of a woman to undergo hysterectomy ranges from 10% to 30% among different countries. The approach of hysterectomy is varying even more (1). This study suggests that in case of abdominal approach, patients may benefit from a total laparoscopic hysterectomy when feasible.

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5 Pelvic organ function in randomized laparoscopic and abdominal hysterectomy patients

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Abstract

Study objective

To assess the incidence of urinary incontinence, bowel dysfunction and sexual problems following laparoscopic hysterectomy as compared with abdominal hysterectomy.

Design

Randomized controlled trial (Canadian Task Force Classification I).

Setting

Single centre teaching hospital in The Netherlands, experienced in gynecological minimal access surgery.

Patients

Women with a benign or malignant condition scheduled for hysterectomy where vaginal hysterectomy was not feasible and laparoscopic hysterectomy was possible.

Interventions

Laparoscopic (n=38) and abdominal hysterectomy (n=38).

Measurements and main results

Patients were asked pre-operatively and three month after surgery whether they experienced urinary incontinence and completed the validated questionnaires Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ), Defecatory Distress Inventory (DDI) and the Questionnaire for screening Sexual Dysfunctions (QSD) one year after surgery. The incidence of urinary incontinence at three month after surgery decreased equally in both groups as compared with baseline. De novo urinary incontinence and sexual problems were rare. One year after surgery, a significant treatment effect favoring laparoscopic hysterectomy was found in the UDI and IIQ, whereas no differences were found in the DDI and QSD.

Conclusion

Laparoscopic hysterectomy is superior to abdominal hysterectomy with respect to postoperative symptoms of urinary dysfunction.

Introduction

Pelvic organ dysfunctions, such as urinary incontinence, bowel dysfunction and sexual problems, are a major health care problem with a large impact on the patients' quality of life (1). Because hysterectomy is the most frequently performed gynecologic operation, it is crucial to know the effects of various approaches to hysterectomy on pelvic organ function. Whether hysterectomy is a risk factor for pelvic organ dysfunction and particularly urinary incontinence has been a matter of debate (2-4). Large epidemiologic, cross sectional studies have shown an increased risk of urinary incontinence in women with previous hysterectomy (4). It is only since recently that data from large prospective studies have become available (3). They have shown that non-radical or simple hysterectomy, that is, hysterectomy performed for other reasons than cervical carcinoma, do not affect bowel function and sexual function. For urinary incontinence even a reduction was found (3-5). However, it is not known whether the route of hysterectomy is a factor in this.

Laparoscopic hysterectomy has been introduced as an alternative to abdominal hysterectomy in patients where vaginal hysterectomy is not feasible. Although many randomized controlled trials comparing laparoscopic and abdominal hysterectomy have been published, none of the studies reported on urinary and bowel dysfunctions. Two studies, however, considered questionnaires on sexual function as an outcome measure (6;7). Whereas the eVALuate trial showed a significant favorable sexual activity habit score at six weeks after laparoscopic hysterectomy as compared with abdominal hysterectomy in the Sexual Activity Questionnaire (7), no differences were found in either the Mc Coy Scale (6) or the Sexual Activity Questionnaire (7) at one year after surgery. Two prospective observational studies on pelvic organ function following hysterectomy have included laparoscopic hysterectomy patients (8;9). Whereas one study did not find differences between the abdominal, vaginal and laparoscopic hysterectomy groups (9), the other reported laparoscopic hysterectomy patients to be at a twofold increased risk of reporting severe urinary incontinence five years after surgery when compared with patients undergoing abdominal and vaginal hysterectomy (8). Furthermore, there is one report on factors influencing postoperative urinary function following laparoscopic hysterectomy. In a study by Long *et al.* patients undergoing laparoscopic hysterectomy were randomized to concomitant vaginal cuff suspension versus no suspension (10). In this study clamping the uterosacral ligament complex and closing the vagina was always performed vaginally. The intervention of the trial was the anchorage of the ligament complex to the vaginal cuff versus no anchorage. A positive effect on incidence of urinary incontinence was seen in the group with this cuff suspension.

The consequences for pelvic organ function of the different approaches to hysterectomy and especially laparoscopic hysterectomy are still under debate. In this article we present the results of a randomized controlled trial in which the effects of laparoscopic hysterectomy and abdominal hysterectomy on urinary function, bowel function and sexuality are compared.

Materials and methods:

Setting and patients

This randomized study was performed in the Máxima Medical Centre from August 2002 until January 2005. The local ethics committee approved the study. The Máxima Medical Centre is a large teaching hospital with 865 beds on two locations in the south of The Netherlands. The gynecologic department is experienced in minimally invasive surgery and the first laparoscopic hysterectomy was performed in 1992. Before the start of the study, the distribution of the three different approaches to hysterectomy in the department was 50% vaginal hysterectomies, 25% abdominal hysterectomies and 25% laparoscopic hysterectomies.

The criteria for the different approaches to hysterectomy were as follows: a vaginal hysterectomy was performed for benign indications in case the size of the uterus was not exceeding 12 weeks' gestation with the cervix descending until at least halfway the vagina under cervical traction with a tenaculum forceps. In case these conditions for vaginal hysterectomy were not met and, on the other hand, the uterus was not exceeding the size of 18 weeks' gestation, patients were scheduled for laparoscopic hysterectomy. In case the uterus was above this size an abdominal hysterectomy was performed. In case of atypical hyperplasia or endometrial carcinoma, patients were counseled for a laparoscopic hysterectomy, unless there was suspicion of advanced endometrial carcinoma beyond stage I.

All patients with benign and malignant disease, where vaginal hysterectomy was not possible and laparoscopic hysterectomy was feasible in terms of the criteria as mentioned above, were eligible for the study. Exclusion criteria were a previous lower midline incision, the need for simultaneous interventions such as anti incontinence procedures and prolapse repair and inability to understand Dutch. Written informed consent was obtained in every patient. No standardized information on pelvic floor alteration due to surgery was provided during consent for surgery. In case the issue was discussed pre-operatively, the patients were informed that no significant changes were to be expected.

The laparoscopic procedures were all intentionally total laparoscopic hysterectomies (TLH). The surgical technique has been described in detail before (11). The abdominal hysterectomies were performed through a transverse incision using the standard extrafascial technique. There was an equal dissection of pelvic tissues in the laparoscopic as compared with the open technique. No fixation of utero sacral ligaments or other form of vaginal cuff suspension was undertaken in either technique. Details on the procedures and short-term generic health related quality of life of the patients with benign indications for hysterectomy have been published previously (11).

Outcome measures

In this study we report on pelvic organ function as measured by the disease specific quality of life questionnaires Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ), Defecatory Distress Inventory (DDI) and the Questionnaire for the screening of Sexual

Dysfunctions (QSD) one year after surgery, of which the UDI was regarded as the primary outcome measure. The questionnaires were previously validated for the Dutch language (1;12;13).

The UDI consists of 11 items and five scales on bothersome urinary complaints. The IIQ consists of 13 items and measures the impact of urinary incontinence on quality of life in five scales. The DDI measures bothersome defecatory complaints, which consists of 10 items and four scales. The score on each scale of these questionnaires ranges from 0-100, where 0 indicates the best quality of life and 100 indicates the poorest quality of life.

Sexually active women were asked to complete the QSD. The QSD consists of 36 items, but in our study only 12 questions (14) concerning bothersome problems with lubrication, orgasm, pain or unpleasant sensations in the genital area and arousal were analyzed. Symptoms were considered to be bothersome when scored I am bothered, I am much bothered or I am severely bothered (14;15).

Furthermore, the women completed written questions on urinary incontinence and sexuality prior to surgery and 12 weeks post-operatively. Patients were asked whether they experienced urinary incontinence. In case urinary incontinence was present, they were asked whether this was related to physical effort such as coughing and sneezing (stress urinary incontinence) and/or when feeling the urge to void (urge urinary incontinence). Patients experiencing stress and urge incontinence were categorized as mixed incontinent. Furthermore, the patients were asked whether they were satisfied with their sexuality. In case a question was not completed at both time points, the data were excluded. Twelve weeks after surgery, the women were asked whether their sexuality had changed since the hysterectomy and in case it had, whether this was in a positive or a negative sense. Patients filled out the questionnaires without assistance of the researcher and returned them by mail.

Sample size and randomization

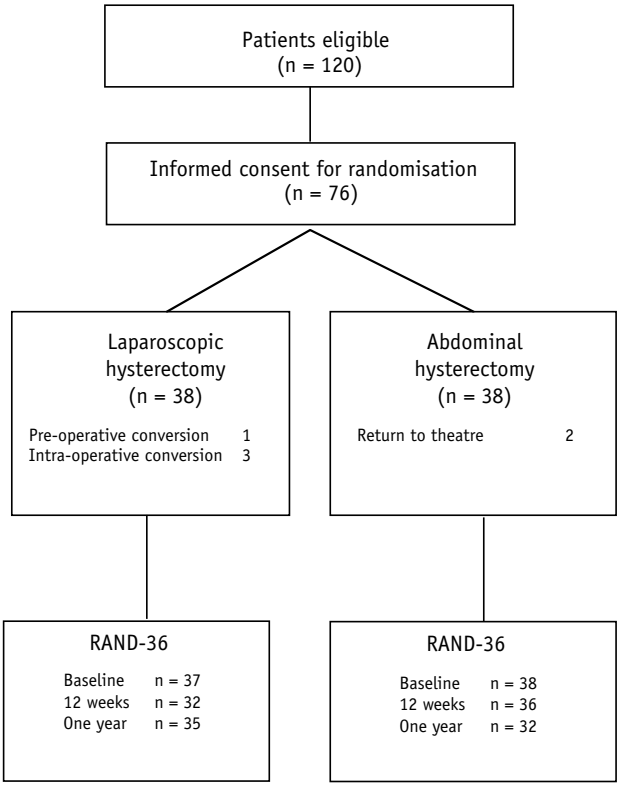
A difference of 15 units in each scale of the UDI, IIQ and DDI was considered as a clinical relevant difference (1;16). With standard deviation 20 units, a type I error of 0.05 and 90% power, 38 patients were needed per arm. The study was part of a study on generic health related quality of life after hysterectomy (11).

After obtaining written informed consent, randomization took place by opening numbered sealed opaque envelopes. It was not possible to blind the patients and medical team for the intervention.

Statistical methods

Analysis of the data was performed on intention to treat basis. Means, standard deviations and 95% confidence intervals are presented in case of normally distributed data, medians and range or means and 25^{th} and 75^{th} percentile in case of non-normally distributed data and absolute numbers and percentages in case of dichotomous variables. Differences between the treatment groups were tested for statistical significance using Mann Whitney test in case of non-normally

Figure 1. Flowchart of the trial population.



distributed data. Dichotomous data were analyzed by the Chi-square test (between groups) and the McNemar test (within groups). Software package SPSS 13.0 (SPSS, Inc., Chicago, IL) was used for statistical analysis. P-values < 0.05 were considered statistically significant.

Results

The study population

A flowchart of the study is shown in Figure 1. One hundred and twenty patients were eligible of which 76 gave informed consent for randomization. Thirty-eight patients were allocated to the laparoscopic arm and 38 to the abdominal arm. One woman allocated to the laparoscopic procedure refused the laparoscopy after randomization, and an abdominal hysterectomy was performed. Her data were analyzed in the laparoscopy group according to the intention to treat

principle. Patient characteristics and operation indications are shown in Table 1. Eleven patients in both groups (29%) had a fibroid uterus between 12 and 18 weeks' gestation.

There were three intra-operative conversions from laparoscopy to laparotomy, which were related to difficult access due to the uterine size twice and due to obesity once. In the laparoscopic group one patient had a bladder injury, which was sutured laparoscopically and one patient had a ureteric injury, which was treated with a double J catheter for six weeks. In the abdominal group two patients had vesicovaginal fistula. Repeat laparotomies were needed for repair. Although three patients required postoperative radiotherapy in each group, none of the patients with endometrial carcinoma required further surgical staging.

Pelvic Organ function

The response rate of the questionnaires one year after surgery was 92% in the laparoscopic group and 84% in the abdominal group (p=.46). The data from the quality of life questionnaires UDI, IIQ and DDI one year after surgery are presented in Table 2. A significant treatment effect favoring LH was found in the UDI scales Overactive Bladder, Incontinence and Obstructive Micturition, as well as in the IIQ scales Mobility, Social Functioning, Embarrassment and Emotional Health. After exclusion of the two patients in the abdominal hysterectomy group with previous incontinence surgery, the difference was still significant in two scales of the UDI, i.e. Overactive Bladder (p=0.01) and Obstructive Micturition (p=0.02) and three scales of the IIQ, i.e. Mobility (p=0.05), Social Functioning (p=0.05) and Embarrassment (p=0.01). No differences were found in the various scales of the DDI. There was a significant treatment effect favoring LH in the UDI total score (p=0.02), but not in the IIQ or DDI total scores (p=0.14 and p=0.09 respectively).

Table 1. Patient characteristics and operation indications by treatment group.

	LH (n=38)	AH (n=38)
Age (yr)	49.9 ± 9.1 (46.9;52.9)	48.1 ± 9.3 (45.1;51.2)
BMI (kg/m 2)	26.9 ± 5.9 (25.0;28.9)	26.4 ± 3.8 (25.2;27.7)
Parity	1.9 ± 1.1 (1.5;2.2)	1.6 ± 1.3 (1.2;2.0)
ASA score	1.5 ± 0.6 (1.3;1.7)	1.5 ± 0.6 (1.3;1.7)
Uterine weight (g)	187 [62-1066] *	168 [40-468] *
Urinary incontinence	16 (43%) **	21 (58%) **
Previous incontinence surgery	0	2 (5%) **
Indication for surgery		
Benign disease	27 (71%) **	32 (84%) **
Atypia /endometrial carcinoma (stage I)	11 (29%) **	6 (16%) **
Postoperative radio therapy	3 (8%) **	3 (8%) **

LH = Laparoscopic Hysterectomy, AH = Abdominal Hysterectomy.
Data shown as mean ± standard deviation (95% confidence interval) in case of normally distributed data,
* median [range] in case of non-normally distributed data,
** absolute numbers (percentage) in case of dichotomous variables.

Table 2. Urogenital Distress Inventory, Incontinence Impact Questionnaire and Defecatory Distress Inventory one year after laparoscopic and abdominal hysterectomy.

		LH (n=35)	AH (n=32)	P
UDI	Overactive bladder	0 [0-11]	11 [0-33]	0.01
	Urinary incontinence	0 [0-17]	17 [0-33]	0.05
	Obstructive micturition	0 [0-0]	0 [0-17]	0.01
	Discomfort/pain	0 [0-17]	17 [0-33]	0.21
	Genital prolapse	0 [0-0]	0 [0-0]	0.30
IIQ	Physical functioning	0 [0-0]	0 [0-0]	0.85
	Mobility	0 [0-6]	0 [0-22]	0.03
	Social functioning	0 [0-0]	0 [0-11]	0.03
	Embarrassment	0 [0-0]	0 [0-17]	0.00
	Emotional health	0 [0-0]	0 [0-22]	0.05
DDI	Constipation	0 [0-0]	0 [0-0]	0.32
	Obstructed defecation	0 [0-8]	8 [0-15]	0.07
	Pain	0 [0-0]	0 [0-0]	0.63
	Incontinence	0 [0-0]	0 [0-0]	0.14

LH = Laparoscopic Hysterectomy, AH = Abdominal Hysterectomy, UDI = Urogenital Distress Inventory, IIQ = Incontinence Impact Questionnaire, DDI = Defecatory Distress Inventory, p = p-value for difference between groups using Mann Whitney test. Data presented as median [p25-p75].
Note: three patients in the LH group and two patients in the AH group were lost to follow up.

Table 3. Urinary incontinence at baseline and 12 weeks after laparoscopic and abdominal hysterectomy.

		LH (n=32)	AH (n=36)	p
Urinary Incontinence	Baseline	16 (50%)	21 (58%)	0.49
	12 wks after surgery	9 (28%)	12 (33%)	0.64
	De novo complaints	0	3 (8%)	0.24
Stress Incontinence	Baseline	8 (25%)	9 (25%)	1.0
	12 wks after surgery	7 (22%)	4 (11%)	0.33
	De novo complaints	0	0	–
Mixed Incontinence	Baseline	7 (22%)	9 (25%)	0.76
	12 wks after surgery	2 (6%)	8 (22%)	0.09
	De novo complaints	0	3 (8%)	0.24
Urge Incontinence	Baseline	1 (3%)	3 (8%)	0.62
	12 wks after surgery	0	0	–
	De novo complaints	0	0	–

LH = Laparoscopic Hysterectomy, AH = Abdominal Hysterectomy, p = p-value for difference between groups using Chi square test. Data presented as absolute numbers (percentage).
Note: six patients in the LH group and two patients in the AH group were lost to follow up.

The incidence of urinary incontinence decreased in both treatment groups; in the laparoscopic hysterectomy group from 50% prior to surgery to 28% twelve weeks after surgery (p=0.02, McNemar test) and in the abdominal hysterectomy group from 58% to 33% respectively (p≤.01, McNemar test). There were no statistically significant differences between the treatment groups. The distribution amongst types of incontinence and the incidence of de novo incontinence by treatment group can be found in Table 3.

Data of the QSD are shown in Table 4 and Table 5, where the data on satisfaction with sexuality before and 12 weeks after surgery are presented including data on a possible change since the hysterectomy. As far as sexuality was concerned, there were no statistically significant differences between the groups. De novo dissatisfaction with sexuality at 12 weeks after surgery appeared in two patients undergoing laparoscopic hysterectomy (7%) and in one patient undergoing abdominal hysterectomy (3%) (p=0.60).

Table 4. Questionnaire for Screening of Sexual Dysfunctions one year after laparoscopic and abdominal hysterectomy.

	LH (n=23)	AH (n=23)	P
Any problem	11 (48%)	7 (30%)	0.37
Lubrication problem	5 (22 %)	4 (17 %)	1.0
Orgasm problem	7 (30 %)	3 (13 %)	0.28
Pain / unpleasant sensation	8 (35 %)	5 (22 %)	0.51
Arousal problem	7 (30 %)	3 (13 %)	0.28

LH = Laparoscopic Hysterectomy, AH = Abdominal Hysterectomy. p = p-value for difference between groups using Chi square test. Data presented as absolute number (percentage).
Note: only sexually active women completed the questionnaire.

Table 5. Sexuality at baseline and 12 weeks after laparoscopic and and abdominal hysterectomy.

	LH	AH	P
Satisfied with sexuality	**(n=27)**	**(n=30)**	
Baseline	19 (70%)	20 (67%)	0.78
12 wks after surgery	23 (85%)	26 (87%)	1.0
De novo complaints	2 (7%)	1 (3%)	0.60
Change in sexuality (12 wks)	**(n=27)**	**(n=32)**	
No change	15 (56%)	17 (53%)	1.0
Improvement	10 (37%)	11 (34%)	1.0
Deterioration	2 (7%)	4 (13%)	0.68

LH = Laparoscopic Hysterectomy, AH = Abdominal Hysterectomy, p = p-value for difference between groups using Chi square test. Data presented as absolute numbers (percentage).
Note: only sexually active women completed the questions.

Discussion

This randomized controlled study is to our knowledge the first that reports on urinary incontinence and other pelvic organ dysfunction after laparoscopic hysterectomy as compared with abdominal hysterectomy. Patients in whom a vaginal hysterectomy was not feasible, were suitable for both types of hysterectomy (maximum uterine size 18 weeks') and had benign and malignant disease. There was a significant difference between the groups in favor of the laparoscopic hysterectomy, in three scales of the questionnaire UDI and four scales of the IIQ at one year after surgery. No differences in bowel function and sexual problems as measured by the questionnaires DDI and QSD were found at one year after surgery. Furthermore, we found an equal and statistically significant decrease in urinary incontinence at 12 weeks after surgery as compared with baseline in both groups. There were only few patients suffering de novo urinary incontinence and de novo dissatisfaction with sexuality in both groups.

Our data on incidence of urinary incontinence before and after hysterectomy are comparable to those in other prospective non-comparative studies (3;4). This confirms, that on the short term there is a positive effect from hysterectomy on urinary function. However, the equal positive effect in both groups is in contrast with the increased risk of urinary incontinence after laparoscopic hysterectomy reported in a prospective cohort study by McPherson *et al.* (8). In a randomized controlled trial on the effects on urinary incontinence six months after laparoscopic hysterectomy of suspension of the utero-sacral ligament complex to the vaginal cuff, Long *et al.* found a positive effect from suspension (10). However, this treatment effect was largely caused by differences at baseline, whereas the postoperative incidences of urinary incontinence were remarkably similar in the two groups. The postoperative incidence of stress urinary incontinence following laparoscopic hysterectomy in the present study with no vaginal cuff suspension performed, was even less when compared with the incidence in the group with vaginal cuff suspension in the study by Long *et al.*.

The fact that laparoscopic hysterectomy results in less tissue trauma is a possible explanation for the better urinary incontinence – specific quality of life reported one year after surgery. Several studies show a difference in inflammatory response and tissue trauma when comparing laparoscopic and abdominal hysterectomy (17-20). However, it is unknown whether this difference in overall tissue trauma is also valid for a difference in bladder trauma, because the wound area will account for the majority of the observed difference in tissue trauma between laparoscopy and open surgery.

Bowel function is not influenced by non radical or simple abdominal hysterectomy or vaginal hysterectomy (3;21). Because we did not find differences in bowel function between the laparoscopic and abdominal hysterectomy, our data suggest that this holds true for the laparoscopic hysterectomy as well.

We showed that satisfaction with sexuality improves and that de novo sexual problems are rare after laparoscopic and abdominal hysterectomy, as has been reported previously by others

for the abdominal and vaginal hysterectomy (3;15). Our data confirm previously published data on sexuality at one year after surgery (6;7) and showed no difference between the laparoscopic and abdominal hysterectomy group as far as satisfaction with sexuality and change in sexuality following hysterectomy was concerned.

As the follow-up in our study is one year, the question whether these women are at an increased risk of suffering urinary incontinence at older age (>60 years) remains unanswered (2). Another limitation of our study is the lack of a baseline measurement of the quality of life questionnaires. However, this is overcome by the fact that the patients were randomized to the treatments and that there were no significant differences in the incidence of urinary incontinence and satisfaction with sexuality at baseline. Although the written questions on incidence of urinary incontinence and satisfaction with sexuality were not validated before the study, the questions were clear and unmistakable.

Regrettably, we had a large amount of complications in both groups. All four women suffering urinary tract injuries had a complete follow-up and were thus included in the analysis of the study. One-third of the patients in either group had a fibroid uterus of 12 to 18 weeks' gestation. In this respect, there was no difference between the groups. There was however a difference in number of patients with atypical hyperplasia or endometrial carcinoma, with eleven patients (29%) in the laparoscopic group and six patients (16%) in the abdominal group. Atypical hyperplasia and low stage endometrial carcinoma is not expected to have an influence on pelvic organ function. Therefore, the women with benign and malignant disease were included in the study. Because patients where a vaginal hysterectomy was feasible were excluded, as well as patients with a fibroid uterus beyond 18 weeks' gestation, our data may not be applicable to those patients.

Conclusion

Worldwide, hysterectomy and pelvic organ dysfunction are two major health care issues. As far as the combination of the two is concerned, there is still a lot to explore in the field. This study consolidates that on the short-term both laparoscopic and abdominal hysterectomy has a positive effect on symptoms of urinary incontinence. At one year after surgery this effect seems even more pronounced in laparoscopic hysterectomy as compared with abdominal hysterectomy. The effects on bowel function and sexuality after laparoscopic hysterectomy are comparable to those after abdominal hysterectomy.

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6 Systematic review on recovery specific quality of life instruments

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Abstract

Background

Postoperative recovery is a considerable issue in studies comparing surgical techniques of similar effectiveness. In recent years there has been a shift towards patient-centered study outcomes such as quality of life questionnaires. The objective of this report was to provide a systematic review of the literature on postoperative recovery specific quality of life instruments and their measurement properties.

Methods

We searched the databases EMBASE.com, Cinahl, PsycINFO and PubMed for papers reporting on postoperative recovery specific quality of life instruments. A checklist was used to assess the revealed studies and instruments. Existing quality criteria were applied to the measurement properties to enable comparison of the instruments.

Results

The search strategy identified 620 studies, of which 18 studies reported on 12 different postoperative recovery specific quality of life instruments. None of the instruments had been validated completely in line with the eight quality criteria, which were used to assess the measurement properties. However, two instruments were clearly superior, which were the Postdischarge surgical recovery scale and the Quality of recovery-40.

Conclusions

There is no fully validated instrument available for the assessment of postoperative recovery. We advise to use the Postdischarge surgical recovery scale and the Quality of recovery-40 in future validation and application studies on short-term postoperative recovery.

Introduction

When comparing surgical procedures, the postoperative recovery has traditionally been referred to in terms of pain scores, hospital stay and return to normal activities. However, these outcomes are much dependent on external factors, i.e. local habits and social security matters. Thus, the application of quality of life instruments, measuring recovery in a patient-centered manner, has become more popular in recent times and has more and more been accepted as a solid primary outcome measure in scientific studies (1). A number of recovery specific quality of life instruments is available by now. Since the awareness of the need to use valid measure instruments has been enhanced, the choice for one of these instruments has become a major challenge.

In 2007 Terwee *et al.* (2) have defined eight quality criteria on design and outcomes of studies describing the development and evaluation of quality of life instruments. These explicit criteria can be used to systematically assess the measurement properties of instruments, which facilitates the well-considered choice of the best measurement tool.

At present, an overview of the instruments used for the measurement of recovery is lacking. The purpose of the present report was to provide a systematic review of the literature on postoperative recovery specific quality of life instruments and their measurement properties, in order to enable an informed choice for appropriate instruments in future studies.

Methods

The databases EMBASE.com, PsycINFO, Cinahl and PubMed were searched until April 11, 2006; April 21, 2006; May 1, 2006; and May 11, 2006 respectively. The number of search terms was extensive and the complete search strategy can be obtained from the corresponding author. Search terms were adapted for each database accordingly and generally referred to the different terms for 'instrument', 'surgery' and 'recovery'. References of relevant retrieved studies were checked for additional studies.

We included all studies reporting on instruments evaluating general postsurgical recovery. There were no language restrictions. Studies were excluded in case the instruments were site specific, i.e. more than 10% of the items were only applicable to a limited number of diseases or surgical procedures. Instruments evaluating postsurgical cognitive function or functional outcome, e.g. range of joint movement or reduction of epileptic strokes, were also excluded. Furthermore, instruments limited to recovery in the recovery rooms were excluded. To differentiate between recovery from surgery and resumption of quality of life, we excluded studies in which the quality of life instrument was applied less than twice in the first six weeks after surgery.

All studies were scored independently by two of the authors (KK and HdV) and disagreement was resolved in consensus meetings. A checklist, based on the quality criteria for measurement

properties of health status instruments by Terwee *et al.* (2), was used. In each study data on the study design, i.e. population, sample size, characteristics of the instrument and points of measurements in time were documented. Furthermore, the availability of the questionnaire in the public domain as well as the respondent's burden (minutes to completion) were assessed.

Data on the measurement properties of the retrieved instruments, i.e. content validity, internal consistency, criterion validity, construct validity, floor and ceiling effects, reproducibility (reliability and agreement), longitudinal validity or responsiveness and interpretability, were collected. The quality criteria as proposed by Terwee *et al.* were used to rate each of the measurement properties (2). Possible ratings were positive, indeterminate, negative and no information available. The conditions for these ratings are described below. All publications on a specific instrument were used for completion of the checklist.

Content validity is the extent in which the items of the instrument cover the domain of interest. A positive rating was given in case a clear description of the measurement aim, the target population and the concepts being measured were given, as well as a description of the technique of the item selection in which, besides investigators or experts, the target population had to be involved.

Internal consistency is a measure for the homogeneity in which the items measure the same underlying concept (construct). A positive rating was given in studies where a factor analysis had been performed on a sample size of at least seven times the number of items, with a minimum sample size of 100, and the Cronbach's alphas per subscale were between 0.70 and 0.95.

Criterion validity is the degree to which scores on a particular instrument relate to a gold standard instrument and is not applicable in case such an instrument is not available. For a positive rating convincing arguments should be provided that the gold standard is gold and the correlation to this gold standard instrument should be a least 0.70.

Construct validity is the extent in which scores on an instrument correspond consistently to other measures and empirical findings. Hypotheses, defined prior to the study, on expected correlations to other instruments or expected score differences amongst defined groups should be tested. Since, the hypotheses had to be postulated before analysis of the data, we checked whether the hypotheses were already mentioned in the introduction or methods sections. For a positive rating specific hypotheses had to be formulated and at least 75% of the tested results had to be in accordance with these hypotheses.

Floor and ceiling effects are present in case more than 15% of respondents to a instrument achieved the lowest or highest possible score respectively, which limits the ability to distinguish differences among these respondents as well as changes in one direction. For a positive rating these effects had to be absent in a study with a sample size of at least 50 respondents.

Reproducibility is the extent in which stable scores over time are obtained. Reliability and agreement can be distinguished (3). Reliability is the ability to distinguish separate persons despite measurement error (relative measurement error), whereas agreement is a measure for absolute measurement error (scores on repeated measures). For a positive rating for reliability the intraclass correlation coefficient (ICC) or weighted Cohen's Kappa coefficient had to be at

least 0.70. For a positive rating for agreement, the minimally important change (MIC) had to be defined and had to be greater than the instruments smallest detectable change (SDC) or outside the limits of agreement in a Bland and Altman analysis. However, in case of other convincing arguments for acceptable agreement, the agreement was also rated as positive.

Responsiveness is a measure for the ability of an instrument to detect a clinically important change of health status and is also referred to as longitudinal validity. Responsiveness can be assessed and expressed in multiple ways and a positive rating was given in case, in a sample size of at least 50 subjects, the minimally important change (MIC) was greater than the instrument smallest detectable change (SDC) or was outside the limits of agreement in a Bland and Altman analysis. Positive rating were furthermore given, in case either the Guyatt's responsiveness ratio was above 1.96 or the area under the ROC-curve (AUC) for the diagnosis of an actual change was at least 0.70.

Interpretability is the extent in which qualitative meaning can be assigned to a score on an instrument. For a positive rating the mean scores with standard deviations had to be presented for at least four relevant subgroups of respondents as well as a presentation of the minimally important change (MIC).

Intermediate ratings were given in cases of a doubtful design, which was defined as follows: a sample size of less than 50 subjects; no clear description of measurement aim, target population, concepts being measured and item selection technique for content validity; no factor analysis for internal consistency; no convincing arguments for a gold standard instrument being gold for criterion validity; no hypotheses formulated for construct validity; no minimally important change defined and no convincing arguments for acceptable agreement for agreement; no mean scores with standard deviations provided for four subgroups and no minimally important change presented for interpretability.

Negative ratings were given in case the target population had not been involved in the item selection and in cases of an adequate design but unsatisfactory results for a measurement property. For interpretability a negative rating was not applicable.

Results

The EMBASE.com-search revealed 175 studies. The PsycINFO revealed 83 studies, of which three studies had already been detected in the EMBASE.com-search. The Cinahl search revealed 130 studies, of which one had already been detected in the previous databases. The PubMed search revealed 243 studies, of which seven had already been detected in the previous searches. Thus, a total of 621 studies were checked for eligibility, of which 480 studies were read by title and abstract only. Eighteen studies (4-21), published between 1970 and 2005, fulfilled the inclusion criteria, reporting on 12 different instruments. Two studies (4;22) were revealed by cross checking, of which one described the development and the other a translation of instruments, which both had been detected by the literature search.

The Quality of recovery–40 (5-7) was a self-completed instrument containing 40 closed questions on recovery, of which seven questions were double-barreled. The items were answered on a 5-point Likert scale and were grouped into five subjects, i.e. emotional state, physical comfort, psychological support, physical independence and pain. The Quality of recovery score (8-10) was a short form of the Quality of Recovery-40 and was a self completed and telephone interview instrument containing nine closed questions on recovery. The items were answered on a 3-point Likert scale and six out of nine questions were double-barreled. The Postdischarge surgical recovery scale (11) was a self completed instrument and consisted of 15 contrasting features, such as feeling alert versus feeling drowsy. These items on recovery, symptoms and functioning were answered on a 10-point semantic differential scale. According to factor analysis, the instrument was considered to be one scale. The Surgical recovery index (12) was a self-completed instrument with 24 closed questions on two subjects, i.e. pain and activity resumption. The Systemic symptom scale (13) was a Spanish instrument based on interviews. It measured symptoms and overall quality of life in 11 closed questions. The Biophysical health problems questionnaire (14) was a 27-item self completed Finnish instrument with closed questions on symptoms, functioning and wound healing. The Postoperative recovery scale (15) was a self completed instrument on symptoms, functioning and overall quality of life with a variable number of closed questions for pre-operative, hospitalized and recently discharged surgical patients (26, 21 and 31 items respectively). The Home recovery log (16) was an instrument consisting of 11 items on pain, fatigue and activities. The Postoperative symptoms diary (17;18) was a self completed and telephone interview instrument and consisted of 16 closed questions, of which eight items were on symptoms and eight items were on symptom management. The Baseline and transition index (19) was tested under interview conditions and consisted of three closed and five open-ended questions on postoperative functioning in relation to the pre-operative situation. The Inventory for postoperative recovery (20) was a French 25-item self completed or interview instrument with closed questions on symptoms and functioning. The Wolfer Davis recovery inventory (4;21) was a self completed instrument and consisted of eight closed questions on symptoms and functioning.

The time taken to complete the instruments ranged from one to seven minutes.

All questionnaires included items on physical aspects of recovery. Items referring to pain were included in all instruments, except for the Baseline and transition index (4;21) and the Wolfer Davis recovery inventory (19). In three instruments there was clear consideration of emotional aspects (5-10;19), whereas one item on emotions was included in two further instruments (4;11;19).

In six studies the scores from measurements prior to surgery were presented (5-10;15;19). In three studies (4;9;13) the instruments had been completed by hospitalized patients only, whereas in the majority of studies the instruments had been completed both by hospitalized and recently discharged patients (5-8;10;14;15;19;21). In four studies only discharged patients had completed the instruments (11;12;17;18) and two studies did not provide information on this issue (16;20).

In three studies (11;14;16) it was not clear to which time period the items referred, whereas one study referred to variable time periods (12). This variability was due to retrospective nature of the data collection, which was also remarked as a limitation in that study. The items in the other studies referred to the past hours (8-10), today (4;17;18;20;21), the past day (5-7), the past week (13;15) or the past one or two weeks (19).

Either a copy of the instruments or a link to a website where a copy could be obtained, was available on eight instruments (6;8;14;15;17;19-21). For the non-English instruments, these copies were in the original French language for the Inventory for postoperative recovery (20) and in English for the Finnish Biophysical health problems questionnaire (14). All other studies provided a list of the items' subjects, although this list seemed incomplete in case of the Surgical recovery index (12). Unfortunately, a request to the corresponding author was not answered. Furthermore, a slightly modified German translation of the nine item Quality of recovery score was available (22).

The data on study design, such as population and sample size, as well as the measurement properties of eligible instruments are shown in Table 1 and 2. In Table 3 data on the quality of measurement properties as assessed by the eight existing criteria are shown.

Content validity was rated positive in six instruments (5-12;14;20), which is the highest number of positive ratings on any of the eight quality criteria.

Only for the Postdischarge surgical recovery scale (11), data from factor analysis were presented and showed that the instrument consisted of a single scale with an acceptable Cronbach's alpha (0.88 and 0.91 in two samples). Cronbach's alpha has been presented in eight other instruments (5-10;12-14;16;17;21), which was either for the total scale or for subgroups of items on the same topic (e.g. pain), but in these cases prior factor analysis was lacking.

Although one study presented criterion validity (13), these data were regarded as construct validity, since no gold standard instrument was available for recovery measurement. For seven instruments (6;8;11;13;18;19), at least one with a maximum of nine predefined hypotheses were presented for construct validity testing In three instruments (6;8;11) at least 75% of these hypotheses were confirmed.

The Postdischarge surgical recovery scale (11) was the only instrument with satisfactory evidence for the absence of floor and ceiling effects. For the nine-item Quality of recovery score (9), floor effects seemed to be absent in hospitalized patients in the first six days after surgery, but not in ambulatory patients. Although Talamini *et al.* (12) stated the absence of floor and ceiling effects, both the actual scores and a definition for this absence was lacking. As a consequence, we were not able to apply the quality criterion of the absence of 15% lowest or highest scores to the Surgical recovery index.

The Quality of recovery-40 and the Postoperative recovery scale were the only instruments revealing satisfactory proof of reliability (6;15). For the Postoperative recovery scale, this was the only satisfactory property on this scale. None of the instruments was rated positively for either agreement, responsiveness or interpretability.

Table 1. Summary of the content validity and internal consistency of instruments measuring postoperative recovery.

Instrument	References	Total sample studied	Population(s)
Quality of recovery-40	Myles 2000; Myles 2001; Leslie 2003 (5-7)	465	surgery
Quality of recovery score	Myles 1999; Myles 2000; Wu 2005 (8-10)	6212	surgery
Postdischarge surgical recovery scale	Kleinbeck 2000 (11)	230	short stay surgery
Surgical recovery index	Talamini 2004 (12)	149	surgery
Systemic symptom scale	Prieto 2004 (13)	220	stemcell transplantation
Biophysical health problems questionnaire	Susilahti 2004 (14)	107	short stay surgery
Postoperative recovery scale	Pace 2003 (15)	71	surgery
Home recovery log	Horvath 2003 (16)	91	ambulatory surgery
Postoperative symptoms diary	Young 2000; Young 2001 (17;18)	252	surgery
Baseline and transition index	McKenzie 1986 (19)	83	surgery, internal medicine
Inventory for postoperative recovery	Grenier 1982 (20)	89	surgery
Wolfer Davis recovery inventory	Wolfer 1970; Daly 1992 (4;21)	172	surgery

Item selection = persons involved in item selection;
Item reduction = technique used for item reduction;
Reading skills = level of reading skills required;
– = no data available;
* = Cronbach's alpha for total scale;
** = split-half reliability.

Content validity			Internal consistency	
Item selection	**Item reduction**	**Reading skills required**	**Presentation factor analysis**	**Cronbach's alpha**
patients experts investigators	correlation item-total score>0.30	no	no	0.93 *
patients experts investigators	based on ranking importance	no	no	0.57-0.90 *
patients experts investigators	based on internal consistency and validity	no	yes, 1 scale	0.88-0.91 *
patients experts investigators	–	–	no	0.91-0.97
experts investigators	–	no	no	0.59-0.69 *
patients experts investigators	–	no	no	0.51-0.86
–	–	no	no	–
–	–	–	no	0.75-0.83 *
experts investigators	–	no	no	0.73-0.78 *
patients experts? investigators?	–	no	no	–
patients experts investigators	based on internal consistency	no	no	0.90-0.91 **
experts investigators	–	no	no	0.73-0.89 *

Table 2. Summary of the construct validity, reproducibility, responsiveness and interpretability of instruments measuring postoperative recovery.

	Construct validity	Floor and ceiling effects	Reproducibility reliability
Instrument	**Number of hypotheses confirmed**		**Method and result (time interval)**
Quality of recovery-40	5 out of 6	–	ICC 0.92 (same day) repeatability coefficient 24
Quality of recovery score	7 out of 9	ceiling in inpatients beyond day 6 and am bulatory patients	Spearman 0.62 (next day)
Postdischarge surgical recovery scale	3 out of 3	no floor or ceiling effects	–
Surgical recovery index	1 out of 2	ceiling effect in 7 out of 24 items	–
Systemic symptom scale	1 out of ?	–	Spearman 0.61-0.80 (one week)
Biophysical health problems questionnaire	–	–	–
Postoperative recovery scale	–	–	ICC 0.81 (2 weeks (before surgery))
Home recovery log	–	–	–
Postoperative symptoms diary	0 out of 1	–	–
Baseline and transition index	1 out of 2	–	–
Inventory for postoperative recovery	–	–	–
Wolfer Davis	–	–	–
recovery inventory			

ICC = intraclass correlation coefficient;
SRM = standardized response mean;
SD = standard deviation;
* = mean without SD presented for 2 groups;
Spearman = Spearman correlation coefficient;
MIC = minimal important change ;
– = no data available;
** = scores presented in percentage (incomplete).

Reproducibility agreement	Responsiveness		Interpretability	
Method and result	**Points of measure-ment following intervention**	**Method and result**	**Number of subgroups (mean and SD)**	**MIC**
test-retest bias 7.1, 1 and 3 months	first 3 days	SRM 0.65	6 groups	–
–	first 6 days and first 6 weeks	–	11 groups	–
–	day 2	–	2 groups	–
–	variable, retrospective completion	–	2 groups	–
–	first weeks, until discharge	score changes in separate groups	–	–
–	days 1 or 2 and 7	–	–	–
–	daily in hospital and at 2 weeks, 1,2,3,6 and 12 months	–	2 groups	–
–	first 6 days	–	1 groups	–
–	1-4 and 10 days	–	–*	–
subjective versus objective change; interviewer agreement	1,2,4 and 6 weeks	–	– **	–
–	first 2 days	–	–	–
–	first days until two weeks	–	6 groups	–

Table 3. Summary of the measurement quality of postoperative recovery instruments.

instrument	Content validity	Internal consistency	Construct validity	Floor and ceiling effect
Quality of recovery-40	+	?	+	0
Quality of recovery score	+	?	+	-
Postdischarge surgical recovery scale	+	+	+	+
Surgical recovery index	+	?	?	?
Systemic symptom scale	-	?	?	0
Biophysical health problems questionnaire	+	?	0	0
Postoperative recovery scale	0	0	0	0
Home recovery log	0	?	0	0
Postoperative symptoms diary	-	?	?	0
Baseline and transition index	?	0	?	0
Inventory for postoperative recovery	+	?	0	0
Wolfer Davis recovery inventory	-	?	0	0

+ = positive rating; ? = indeterminate rating; - = negative rating; 0 = no information available

Discussion

This systematic review summarizes the characteristics and measurement properties of twelve available instruments measuring postoperative recovery. Eighteen studies using these instruments were systematically scored and the available data were rated on the basis of eight clearly defined quality criteria. Five out of these twelve instruments did not fulfill any of the quality criteria, whereas four other instruments obtained only one positive rating. The maximum number of positive ratings was four for the Postdischarge surgical recovery scale (11), three for the Quality of recovery -40 (5-7) and two for the Quality of recovery score (8-10). The Postdischarge surgical recovery scale (11) and the Quality of recovery–40 (5-7) showed especially superior content validity and construct validity, and did not reveal any negative ratings which would have disqualified the instrument. The validation, however, has not been completed for either instrument.

The Quality of recovery-40 (40 items) (5-7) performed better in fulfilling quality criteria as compared with the Quality of recovery score (9 items) (8-10), which is the short form instrument. At the cost of a small increase in completion time, the Quality of recovery-40 appeared to be more valid and consisted of less double-barreled questions as compared with the short form.

The quality criterion, which was most frequently fulfilled, was the content validity in six instruments, showing that the target population had been involved in the selection of the items

Reproducibility reliability	Reproducibility agreement	Responsiveness	Interpretability
+	?	?	?
?	0	0	?
0	0	0	?
0	0	0	?
?	0	?	0
0	0	0	0
+	0	0	?
0	0	0	?
0	0	0	?
0	?	0	?
0	0	0	0
0	0	0	?

used. This involvement is crucial to avoid missing relevant items as well as the selection of non-relevant items (2). The number of items of the different instruments ranged from eight to 40 and the maximum completion time was seven minutes, which seems acceptable (26). There was clearly more consideration for physical as compared with emotional aspects in the recovery instruments. Only three instruments questioned the patients clearly on their emotions, which might be a reflection of the focus of surgical departments.

Cronbach's alpha is a measure for internal consistency and is known to be flattered when disregarding separate subscales as identified by factor analysis, especially in instruments with more than 19 items (23). Although a Cronbach's alpha for either the total scale or for groups of items on a certain subject were presented for the majority of instruments, only one study presented a prior factor analysis (11). When designing the recovery scales, developers probably included all items of potential importance to postoperative recovery, and did not aim at the measurement of one single construct. In that case it results in a more clinimetric scale without the need for determination of Cronbach's alpha (24).

In this review, it was not possible to check extensively whether the hypotheses on construct validity testing had been postulated prior to the data analysis. Although this is no guarantee, we demanded the hypotheses to be described in the introduction or methods sections of the study and not in the results or discussion sections only. More challenging hypotheses give more support

for good construct validity in case of confirmation. However, the specificity of hypotheses is difficult to judge. No obligatory number of hypotheses has been defined in the quality criteria, but the number of hypotheses tested in the instruments with a positive rating for construct validity ranged from three to nine, which seems reasonable.

Correct timing of measurements in the recovery process is essential, since incorrect timing can lead to floor and ceiling effects, causing difficulties in the measurement of actual differences and changes among and within respondents (2). A question aiming at recovery following discharge, e.g. resumption of work, should not be answered by a hospitalized patient and vise versa. Likewise, the extensiveness of surgery is an important factor in the correct timing. Consequently, instruments on symptoms typically concerning patients in the early postoperative period, such as nausea, seem more appropriate in the first days after major surgery and during hospitalization (5-10;13;14;17;18;20;21), whereas instruments focusing on daily life activities such as caring for a household and working, seem more appropriate in the first days after minor surgery and in the weeks or month following major surgery (11;12;15;16;19). Furthermore, the definition of standardized time intervals may enhance the comparability of studies.

There were only two instruments revealing a positive rating for reliability, which is an important issue, since it is a prerequisite for good construct validity and responsiveness (25). Satisfactory data on test-retest reliability were mostly lacking, which is probably due to the fact that recovery is a very dynamic process. A time interval between two measurements in which the situation of the patient does not change, is probably hard to find. The criteria for agreement, responsiveness and interpretability were not rated positive for any of the instruments. Nevertheless, responsiveness is an important issue in the evaluation of postoperative recovery, since the change at the time of surgery and the changes during the dynamic process of recovery have to be assessed in a valid manner. The same holds true for the interpretability. Only on three instruments the mean scores (and spread) of more than two separate groups of patients were available (5-10;21) and none of the studies described the minimally important change, which reflects the smallest difference in score, which patients perceive as beneficial.

The overview in Table 3 shows the measurement properties for which further validation is judged worthwhile. Properties rated as zero (i.e. no information available) or questionmarks (i.e. incomplete information or doubtful design), show issues, which need further assessment, whereas a negative rating disqualifies an instrument. The requirements for an instrument to comply with the eight strict quality criteria sets a high standard. However, these criteria are not unachievable and they can be a helpful guideline for future validation processes. For this reason, the present paper describes the criteria rather extensively.

On eight out of twelve instruments, only one publication has been found in the literature search and the maximum number of publications per instrument was three. The first paper, presenting a new instrument, usually describes the development and first steps in the validation. To obtain information on all measurement properties more studies are needed. For most recovery instruments further validation and consequent application in clinical studies was lacking. In view

of the enormous effort involved in the development process, this is rather surprising. Moreover, since the completion of questionnaires can place a load on patients, there is also an ethical obligation to avoid such aimless burden to postoperative patients. Using available instruments, more than developing new ones, would be helpful in solving this problem. This overview of available instruments, including a rating of their measurement properties, facilitates the choice of an appropriate measurement instrument.

The two instruments that we recommend for future use and validation are both available to researchers, including a description of the scoring system. Although a copy of the Postdischarge surgical recovery scale was lacking, the subject of the items was listed in the paper and the responses can be expressed on a 10-point semantic differential scale.

Besides on quality of measurement properties, the choice on an instrument for a future study should be based on the intended research questions, the study group and practical considerations, such as respondent burden and ease of scoring. None of the studies reported either on an acceptable level of missing data or provided information on the way they had dealt with missing data, let alone gave guidelines on that subject. Furthermore, this quality may vary among different settings, populations and languages. Until now, the Postdischarge surgical recovery scale, for example, has only been applied to short stay surgical patients and may not be as valid in other populations (11). Therefore the recommendations from this review are preliminary and do not relieve researchers from careful selection of their instruments. Moreover, testing of measurement properties needs to be repeated when using a translated version, since careful translation is no guarantee for maintenance of the properties.

The interest in using patient-based instruments for clinical assessment and treatment monitoring of individual patients is growing. Instruments used for clinical assessment of individuals demand higher quality of the instruments as compared with group comparisons (27). At this stage, none of the reviewed instruments showed sufficient quality of the measurement properties to justify their use in the assessment of individual patients.

Postoperative recovery measurement is not in sharp contrast with the measurement of resumption of quality of life or declining symptoms and return to normal functioning after surgery. In the present study, we tried to make the distinction on the basis of the timing of the postoperative measurements, which had to be at least twice within the first six weeks after surgery. Furthermore, the instruments had to be applicable to a wide range of postoperative patients, and we did not review studies focusing exclusively on recovery in the recovery rooms. Consequently, our study does not give a systematic review of instruments used in the very short term (i.e. recovery rooms) and longer-term postoperative period (i.e. beyond six weeks) or of more disease specific instruments.

In conclusion, we summarized the measurement properties of twelve instruments measuring postoperative recovery, which enables an informed choice for the use by future researchers. Although none of the instruments was validated completely in line with all eight quality criteria, two instruments appeared to be clearly superior. We advise to apply the Postdischarge surgical

recovery scale and the Quality of recovery-40 in future studies on postoperative recovery. Further validation of the instruments, with a focus on the responsiveness and the minimally important change, is required.

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Appendix: Search terms

Embase.com until 11th of April 2006

(('rating scale'/exp OR 'scoring system'/exp OR 'clinical assessment tool' OR 'summated rating scale'/exp OR 'visual analog scale'/exp OR 'questionnaire'/exp OR 'named inventories questionnaires and rating scales'/exp) AND 'Postoperative period'/exp AND (recovery OR convalescence OR Convalescence/exp OR reconvalescence OR recuperation OR return-to-normal-activities OR regain-of-health OR health-status/de OR quality-of-life) AND human/exp NOT ('case report'/exp OR [cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim OR [review]/lim OR [short survey]/lim OR [animal cell]/lim OR [animal experiment]/lim OR [animal model]/lim OR [animal tissue]/lim OR animal/exp)) AND ('psychometry'/exp OR 'correlation coefficient'/exp OR 'observer variation'/exp OR 'reliability'/exp OR 'reproducibility'/exp OR 'variance'/exp OR validity/exp OR 'instrument validation'/exp OR 'validation process'/exp OR 'Outcomes research'/exp OR 'accuracy'/exp OR 'intermethod comparison'/exp OR 'error'/exp OR 'sensitivity AND specificity'/exp) AND clinical-study/exp

Psycinfo until 21th of April 2006

kw=(postsurg* OR "post surg*" OR "after surg*" OR postoperat* OR "post operat*") OR de=surgery OR DE="surgical patients" OR DE="postsurgical complications"
AND
kw=(rating* OR scale* OR score* OR scoring OR assessment OR questionnaire* OR psychometr* OR correlat* OR observer OR reliab* OR reproduc* OR variance OR value OR valid* OR accura* OR intermethod OR error* OR sensitivity OR specificity) OR
de=test validity >
AND
kw=(recover* OR convalescence OR reconvalescence OR recuperation OR "return to normal activities" OR "regain of health" OR "health status" OR "quality of life") OR DE=("quality of life" or "quality of work life")
AND
de=Measurement+ OR cl=2200
OR de=("test interpretation" or "test standardization") OR DE=("test construction" or "content analysis test" or "difficulty level test" or "item analysis test" or "item content test" or "test bias" or "cultural test bias" or "test forms" or "test items" or "test reliability" or "test standardization" or "test validity")
Limits: human/inpatient/outpatient

Cinahl until 1st of May 2006

exp postoperative complications/ or exp "surgical recovery delay (saba ccc)"/ or exp postoperative period/
AND
exp Recovery/
AND
exp research measurement/ OR exp Outcome Assessment/ OR exp research methodology/
NOT
exp Case Studies/
limit : to research

PubMed until 11th of May 2006

Epidemiologic methods[mesh]
AND
measur*[ti] OR scale*[ti] OR subscale*[ti] OR rating*[ti] OR selfrating*[ti] OR rate[ti] OR rates[ti] OR selfrating*[ti] OR index[ti] OR indices[ti] OR score*[ti] OR scoring[ti] OR instrument[ti] OR instruments[ti] OR interview*[ti] OR questionnair*[ti] OR respondent*[ti] OR survey*[ti] OR inventory[ti] OR inventories[ti] OR assessment*[ti] OR assessing[ti] OR test[ti] OR tests[ti] OR testing[ti] OR self-report*[ti] OR selfreport*[ti]
AND
"Postoperative Period"[MeSH] OR "Postoperative Complications"[MeSH:noexp] OR "Pain, Postoperative"[MeSH]
AND
"Recovery of Function"[MeSH] OR "Convalescence"[MeSH] OR "Rehabilitation"[MeSH:NoExp] OR rehabilitation[sh] OR "Activities of Daily Living"[MeSH] OR "Disability Evaluation"[MeSH] OR "Quality of Life"[MeSH] OR recovery[ti] OR convalescence[ti] OR reconvalescence[ti] OR recuperation[ti] OR (return to normal activities) OR (regain of health) OR health-status/de OR (quality of life)
AND
"Sensitivity and specificity"[MeSH Terms] OR "Reference values"[mesh] OR "Evaluation studies"[mesh] OR "Reproducibility of results"[mesh] OR "Quality control"[mesh] OR Validation studies[pt] OR "Observer variation"[mesh] OR "Treatment Outcome"[mesh] OR "Comparative study"[mesh] OR sensitive[tiab] OR sensitivity[tiab] OR specificity[tiab] OR accurate[tiab] OR accuracy[tiab] OR (golden standard[tiab]) OR (gold standard[tiab]) OR (reference test[tiab]) OR (index test[tiab]) OR valid*[tiab] OR verif*[tiab] OR evaluat*[tiab] OR (false[tiab] AND (positive[tiab] OR negative[tiab])) OR pretest[tiab] OR pre-test[tiab] OR posttest[tiab] OR post-test[tiab] OR (predictive value[tiab]) OR predict*[tiab] OR roc[tiab] OR likelyhood[tiab] OR likelihood[tiab] OR value*[tiab] OR cutoff[tiab] OR cut-off[tiab] OR repeatab*[tiab] OR reproducib*[tiab] OR efficacy[tiab] OR reliab*[tiab] OR odds[tiab] OR error*[tiab] OR suitab*[tiab] OR utility[tiab] OR useful*[tiab] OR significance[tiab] OR clinimetr*[tw] OR psychometr*[tw]
NOT
(animals[mesh] NOT humans[mesh])
NOT
case reports[pt] OR review[pt] OR meta analysis[pt] OR clinical trial[pt] OR news[pt]

7 Clinimetric properties of three instruments measuring postoperative recovery in a gynecologic surgical population

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Abstract

Objective

Generic health related quality of life questionnaires and recovery specific questionnaires have been used to measure recovery in surgical patients. The aim of the present study was to evaluate the clinimetric properties of three recovery instruments and to examine whether recovery specific instruments are useful.

Methods

The Quality of Recovery-40 (QoR-40), Recovery Index-10 (RI-10) and RAND-36 health survey were used to measure recovery in patients undergoing different types of hysterectomy in the first 12 weeks after surgery. Construct validity was assessed by testing pre-defined hypotheses. The changes observed during the postoperative period were used as indicators for responsiveness.

Results

One hundred and sixty-one women were included. Response rate and internal consistency were found satisfactory. The highest number of hypotheses used for construct validity assessment was confirmed in the RI-10. The RI-10 was more responsive as compared to the QoR-40 and RAND-36.

Conclusion

Since construct validity and responsiveness were highest in the RI-10, we conclude that this short recovery specific instrument is useful in studies evaluating postoperative recovery. We recommend the use of the RI-10, unless the immediate postoperative days are of interest in which the QoR-40 was valid.

Introduction

Traditional evaluation of medical interventions considers clinical endpoints such as efficacy, effectiveness, mortality and occurrence of complications (1;2). In the last decade, there has been a shift from disease-orientated outcomes to patient orientated outcomes, such as patient preference and perceived health related quality of life.

This issue is of eminent importance in the evaluation of minimally invasive surgery. Non-invasive surgery as compared to conventional surgery is expected to obtain cure of the underlying disease at an equal effectiveness, however with less burden to the patient, and therefore quicker recovery after the operation and earlier resumption of daily activities and work. The evaluation of recovery from surgery requires instruments that specifically focus on recovery during the short-term postoperative period.

Although many researchers have developed ad hoc questionnaires for the postoperative period and even performed validation studies, none have given an answer to the question whether there is a necessity to use these recovery specific instruments. There is a wide range of well validated generic health related quality of life instruments available, like the SF-36 and RAND-36 health surveys, Nottingham Health Profile, Sickness Impact Profile and Euroqol 5D (3). A recovery specific quality of life instrument needs to show advantages over these widely known instruments before being recommended for use in clinical trials. Korijla *et al.* (4) advised to use the SF-36 health survey in the follow up of hysterectomy patients. However, they did not review studies that used this instrument or other recovery specific instruments. The SF-36 is identical to the RAND-36, which was used in the present study (5). Myles *et al.* have recently developed an instrument to measure quality of recovery (QoR-40) and tested the validity, reliability and responsiveness of the instrument in 160 patients after a wide range of surgical interventions. They concluded that the QoR-40 was a good objective measure of quality of recovery after anesthesia and surgery (6).

We translated the QoR-40 in Dutch, and developed a recovery specific instrument, the Recovery Index-10 (RI-10). The objective of the study was to compare these instruments with the RAND-36 health survey and to study their performance for the evaluation of recovery following gynecologic interventions.

Methods

Population

This clinimetric study was performed using the data from a randomized and parallel non-randomized study comparing the surgical outcomes of different types of hysterectomy (7;8). Patients were recruited from August 2002 until January 2005 in the Máxima Medical Centre, a large teaching hospital with 865 beds on two locations in the south of The Netherlands. Women

who underwent a hysterectomy with and without salpingo-oophorectomy for benign and malignant disease were asked to participate in the study. Patients who needed simultaneous interventions like vaginal repair or who were not fluently speaking Dutch were not eligible for the study. A vaginal hysterectomy was preferred unless there was suspicion of malignancy, the size of the uterus exceeded 12 weeks' gestation or the descent of the uterine cervix under traction was not reaching until halfway the length of the vagina. In case patients did not meet these criteria, either a laparoscopic or abdominal hysterectomy was performed for a mobile uterus not exceeding 18 weeks' gestation and in case there was no suspicion of endometrial carcinoma other than FIGO stage I. In case informed consent was given, those patients in whom a vaginal hysterectomy was not possible and a laparoscopic hysterectomy was feasible were randomized to either laparoscopic or abdominal hysterectomy. In case of a uterus exceeding 18 weeks' gestation and in case of suspicion of advanced cancer an abdominal hysterectomy was always preferred.

The patients were asked to complete the QoR-40, RI-10 and RAND-36 prior to surgery and postoperatively at five respectively eight points of measurement as shown in Table 1. The researchers did not assist the patients during completion of the questions. The questionnaires that were completed following discharge were returned by mail.

Instruments

The QoR-40 is a questionnaire containing 40 items on recovery, which consists of five subscales: emotional state, physical comfort, psychological support, physical independence and pain (9). A Dutch translation was used. Each item was answered on a five-point Likert scale, ranging from none of the time to all the time. The QoR-40 score was defined as the sum of the scores of all items. The QoR-40 score ranged from 40 to 200, in which 200 indicates a perfect recovery. The items referred to the past 24 hours and aimed at patients during hospital stay, but could be filled out at home as well.

Furthermore, we developed the Recovery Index-10 (RI-10), a 10-items questionnaire measuring postoperative recovery on five-point Likert scales ranging from full disagreement to full agreement. Two gynecologists developed the RI-10 in 1996. At that time no other recovery instruments, like the QoR-40, were available. The instrument was considered to be one scale and

Table1. Point of measurement of the three instruments.

	Baseline	1 dy	2 dy	3 dy	1 wk	2 wk	4 wk	6 wk	12 wk
QoR-40	X	X	X	X	X	X	X	X	X
RI-10					X	X	X	X	X
RAND-36	X				X	X	X	X	X

QoR-40 = Quality of Recovery-40, RI-10 = Recovery Index-10,
RAND-36 = RAND-36 health survey, X = measurement has been performed.

the score ranged from 10 to 50, where 50 indicates a perfect recovery. A translation of the RI-10 is shown in appendix-1. The items referred to the past week. Since most of the items in the RI-10 referred to the postoperative situation, no baseline measurement was available. The items suited best for recently discharged patients, but could be filled out in hospital as well.

The RAND-36 health survey is a widely known generic health-related quality of life instrument. We used the validated Dutch version (10). This instrument measured subjective health status in eight subscales. The range per subscale was 0-100 and thus the total score ranged from 0 to 800, where 0 was the poorest quality of life and 800 the best imaginable. The version referring to the past four weeks was used in this study.

Statistical analysis

The response rate and number of missing items were identified. In case items were missing and more than half of the items of the particular subscale was missing, the score of that subscale as well as the total scale were regarded as missing. In case half or less of the items of the subscale was missing, the average of the available items was used to complete the missings and determine the total score. Only the total scores, i.e. not the scores on subscales, were used in the study.

Cronbach's α was calculated at one week after surgery for each questionnaire to assess the internal consistency. The point of measurement at one week was used, as this was the first where data on all three instruments were available.

To assess the construct validity of the instruments in their use of post-operative recovery, hypothesis testing was used (11). The hypotheses were based on literature and defined prior to the study.

The six hypotheses tested on the three instruments were:

1. Patients younger than 45 years have a better recovery as compared to patients older than 60 years (12-14).
2. Patients with ASA score 1 do recover better as compared to patients with ASA 2 or more (15).
3. Patients with a total hospital stay of seven days or more have a worse recovery as compared to patients admitted for four days or less (9;13;16-18).
4. Patients with complications affecting recovery (i.e. all complications leading to readmission or re-operation, visceral lesions without re-admission or re-operation, neurological damage, exacerbation of pre-existing colitis, severe wound infection and pre-existing micturition problem) have a worse recovery as compared to patients without any complications (15-17).
5. Vaginal hysterectomy patients have a better recovery as compared to abdominal hysterectomy patients (19). Patients with peroperative conversions from laparoscopic hysterectomy to abdominal hysterectomy laparotomy due to complications in the days following laparoscopic hysterectomy and peroperative conversions from vaginal hysterectomy to abdominal hysterectomy were excluded from this hypothesis.
6. Patients with a hemoglobin decrease of less than 0.5 mmol/l have a better recovery as compared to patients with a hemoglobin decrease of more than 1.5 mmol/l (20). Patients who had received a blood transfusion were excluded from this hypothesis.

Differences between the groups, as defined in each of the six hypotheses of construct validity, were tested for statistical significance using the test of Mann-Whitney. The instrument for which most hypotheses were holding true was considered as having the highest construct validity. Again the data at one week after surgery were used. As the instruments referred to different time periods, i.e. the past 24 hours, past week and past four weeks, the testing of the aspects of validity as mentioned above was repeated making use of the four-week data.

Correlations among the three instruments at one week after surgery were calculated using Spearman's correlation coefficient.

Each instrument was assessed at several points in time. We assumed that the postoperative patients recovered continuously during at least six weeks. The responsive period of the instrument can be defined as the time period in which the score shows a change over time. The range of the mean scores over time as a percentage of the instruments total range was used as an indicator of responsiveness. A linear mixed model was used to study the mean levels in the quality of life score over time (21). The dependent variable was the quality of life score. The independent class variables were patient and time in weeks after surgery. The intercept of each patient was treated as random variable in the model. This way, random differences between patients are allowed. The estimated mean levels per week with 95% confidence bands were visualized in figures.

Recovery following hysterectomy as measured by the three instruments

Difference in recovery over time on the three instruments was studied in the RCT comparing the data of patients randomized to laparoscopic versus abdominal hysterectomy, who were not threatened by malignancy. The recovery scores during the suggested responsive time period of each instrument were used. The treatment effect was analyzed on an intention to treat basis.

A linear mixed model was used to study the increase in the quality of life score over time in the treatment groups (21). The dependent variable was the quality of life score. The independent class variables were patient, time in weeks after surgery and treatment group (laparoscopic and abdominal hysterectomy). In case of the RAND-36 and QoR-40 the baseline level was added to the model as an independent regression variable. The intercept of each patient was treated as random variable in the model. Initially the interaction term between time and group was added to the model. However, this term did never reach the level of statistical significance and was removed from the final model. The estimated regression parameters with standard errors of each score are used to calculate the average level per week in each treatment group. These levels with confidence bands are further presented in figures.

All data were analyzed using SAS 10.0 software (SAS Institute, Inc., Chicago, IL) and SPSS 13.0 software (SPSS, Inc., Chicago, IL). P-values below 0.05 were considered as statistically significant.

Results

We included a total of 161 hysterectomy patients in the clinimetric study. Twenty-one underwent vaginal hysterectomy, 76 abdominal hysterectomy and 64 laparoscopic hysterectomy. In the abdominal hysterectomy group, surgery had been started as vaginal hysterectomy twice and as laparoscopic hysterectomy in seven cases. Patient characteristics and indications for the intervention are shown in Table 2.

Clinimetrics

The overall response rate was 94%, ranging from 100% for the first days after surgery to 84% twelve weeks after surgery. The percentage of missing items ranged per point of measurement from 0.2 to 1.9% in the QoR-40, from 0.1 to 0.7% in the RI-10 and 0.1 to 0.6% in the RAND-36.

Cronbach's α at one week after surgery was 0.93 for the QoR-40, 0.81 for the RI-10 and 0.86 for the RAND-36, showing good internal consistency.

Table 3 shows the results of the construct validity assessment as measured by testing six pre-defined hypotheses at one week after surgery on all three instruments. Two hypotheses were confirmed in the QoR-40, three in the RI-10 and one in the RAND-36. In the hypothesis on difference in recovery amongst age groups, the QoR-40 and RI-10 were unexpectedly showing a significant better recovery in the older age group. A prolonged hospital stay and the occurrence

Table 2. Patient characteristics.

	Total (n=161)
Age (yr)	49.1 ± 9.1
BMI (kg/m 2)	26.9 ± 5.7
Parity	1.8 ± 1.2
ASA score	1 [1-3]
Employed women	106 (66)
Benign disease	127 (79)
Uterine weight (gr)	173 [30-1560]
No complication	89 (55)
Hb decrease (mmol/l)	1.1 ± 0.7
Hospitalization (dy)	5.8 ± 4.7
Readmissions	9 (6)
Return to theatre	7 (4)

BMI = body mass index; ASA score = physical status classification of the American Society of Anesthesiologists; Hb = hemoglobin; Hospitalisation (dy) = Hospitalisation incl readmissions in days.
Data shown as mean ± standard deviation, median [range] or absolute numbers (percentage).

of complications was significantly associated with a lower mean score in all questionnaires, although this difference was only borderline significant in the hypothesis on complications in the RAND-36. The results of the construct validity testing at four weeks after surgery were comparable to those at one week after surgery, although a slight reduction in the performance of the QoR-40 and a slight improvement in the performance of the RAND-36 has been found (data not shown).

Correlation at one week after surgery was high amongst the two recovery specific instruments (r=0.63), and moderate amongst each recovery specific instruments and the RAND-36 (r=0.37-0.38).

Observed mean scores at baseline and observed and estimated mean scores in the postoperative period of the 161 patients are shown in Figures 1 a, b and c.

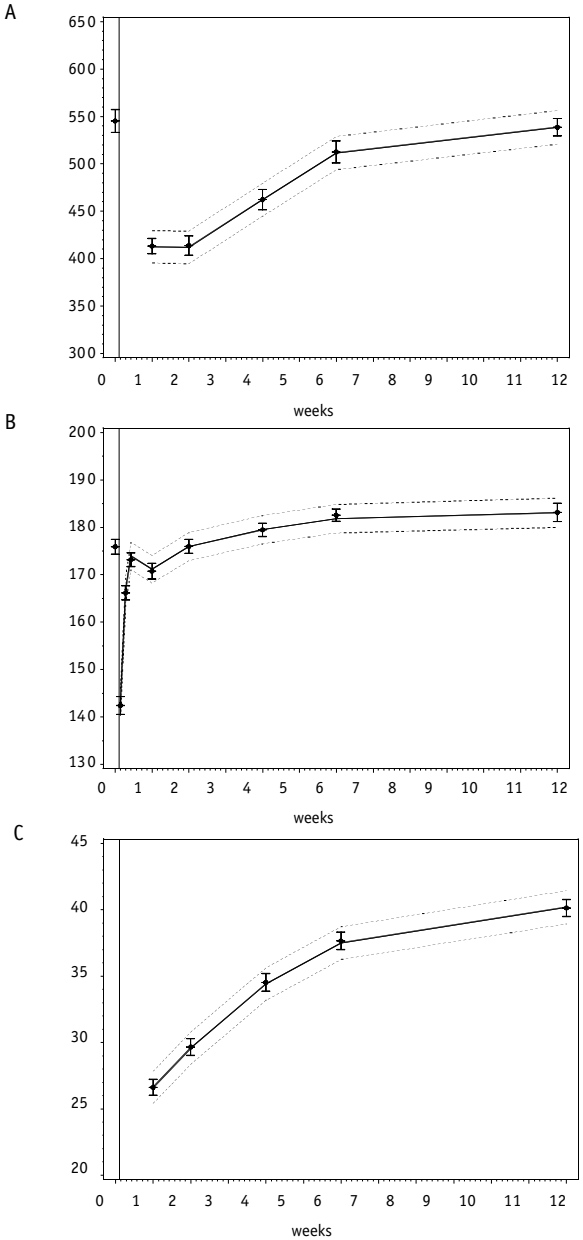
The range of the QoR-40 mean scores over time was 25% of the instruments total range, whereas the RI-10 scores ranged over 33% of the total range and the RAND-36 scores over 17% of the total range. Between two and twelve weeks after surgery the QoR-40 mean scores ranged over no more than 4% of the total range of the instrument, which shows that the QoR-40 was not responsive beyond two weeks after surgery. The RI-10 showed an increase and thus responsiveness during the entire twelve-week postoperative period, whereas the mean score on the RAND-36 did not change in the first two weeks after surgery and was not responsive in this time period.

Table 3. The mean scores (standard error) of the three instruments at one week after surgery by the groups as defined in the six hypotheses.

		QoR-40			RI-10			RAND-36		
Hypothesis	**Group**	*n*	**Mean (SE)**	**p**	*n*	**Mean (SE)**	**p**	*n*	**Mean (SE)**	**p**
1 Age	< 45 years	*48*	165 (3.3)	0.02	*49*	24.0 (1.0)	0.00	*49*	407 (13.6)	0.53
	> 60 years	*14*	180 (4.1)		*16*	32.5 (1.7)		*16*	389 (26.9)	
2 ASA score	ASA 1	*90*	173 (2.0)	0.09	*94*	27.3 (.7)	0.14	*94*	422 (10.0)	0.20
	ASA 2 + 3	*58*	167 (2.9)		*60*	25.5 (1.0)		*61*	401 (13.6)	
3 Hospital stay	≤ 4 days	*68*	176 (2.3)	0.00	*72*	29.4 (.9)	0.00	*72*	446 (10.5)	0.00
	≥ 7 days	*26*	159 (4.9)		*25*	23.3 (1.4)		*26*	379 (21.5)	
4 Complications	None	*79*	174 (2.0)	0.00	*86*	28.9 (.7)	0.00	*86*	421 (10.9)	0.07
	Major	*16*	151 (6.7)		*15*	20.3 (1.9)		*16*	370 (24.7)	
5 Treatment	VH	*19*	166 (6.2)	0.95	*20*	27.1 (1.7)	0.05	*20*	421 (25.6)	0.37
	AH	*59*	167 (2.2)		*62*	23.6 (.8)		*63*	397 (13.0)	
6 Hb-decrease	<0.5 $^{mmol}/_{l}$	*22*	175 (4.4)	0.07	*23*	27.1 (1.3)	0.25	*23*	421 (22.2)	0.38
	>1.5 $^{mmol}/_{l}$	*32*	163 (4.5)		*32*	24.6 (1.5)		*32*	394 (20.5)	

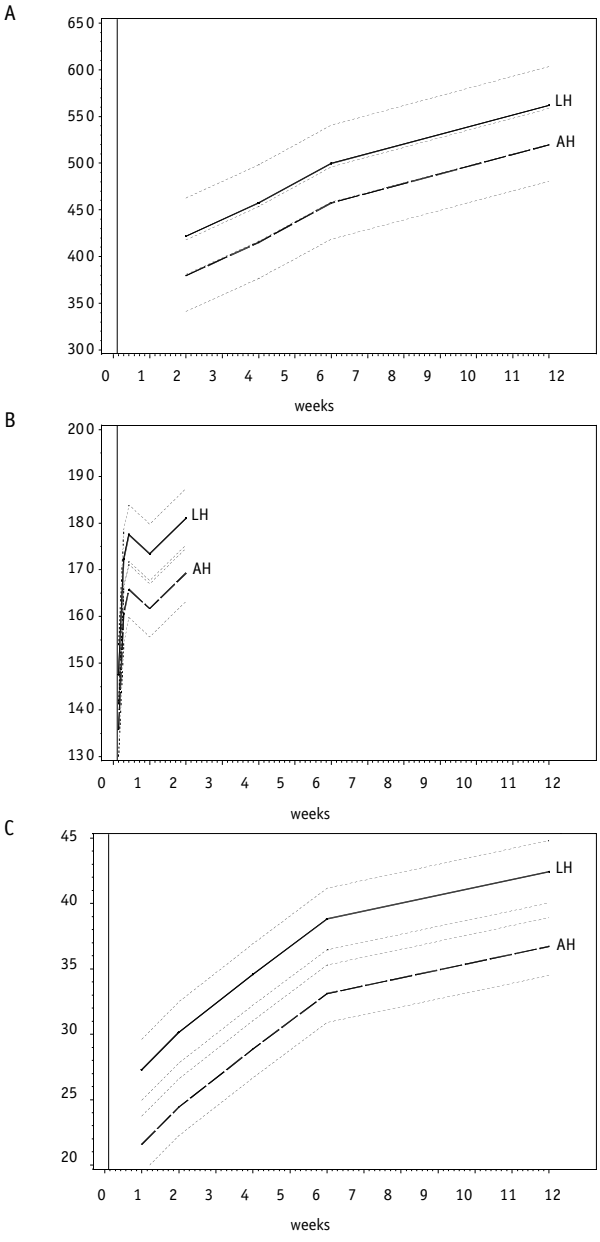
QoR-40 = Quality of Recovery-40, RI-10 = Recovery Index-10, RAND-36 = RAND-36 health survey, n = number op patients, SE = standard error, p = p-value for difference among groups using the test of Mann-Whitney,
ASA score = physical status classification of the American Society of Anesthesiologists,
VH = vaginal hysterectomy, AH = abdominal hysterectomy, Hb = Hemoglobin.

Figure 1 a,b,c. Observed scores and estimated mean scores with 95% confidence bands in 161 hysterectomy patients, using a linear mixed model.



RAND-36 = RAND-36 health survey, QoR-40 = Quality of Recovery-40, RI-10 = Recovery Index-10. Closed symbols = observed mean score with the vertical bar indicating one standard error, solid line = the line that joins the estimated mean scores, dotted lines = 95% confidence bands.

Figure 2 a,b,c. Estimated mean scores with 95% confidence bands by treatment group, using a linear mixed model.



RAND-36 = RAND-36 health survey, QoR-40 = Quality of Recovery-40, RI-10 = Recovery Index-10, AH = abdominal hysterectomy, LH = laparoscopic hysterectomy. Thick solid line = line that joins the estimated mean scores in LH group, dotted line = 95% confidence bands. Thick broken line = line that joins the estimated mean scores in AH group, dotted line = 95% confidence bands.

Table 4. Evaluation of three recovery questionnaires in randomized laparoscopic and abdominal hysterectomy patients, using a linear mixed model.

	QoR-40	p	RI-10	p	RAND-36	p
Score range	40 - 200	-	10 - 50	-	0 - 800	-
Postoperative time period	1day – 2 weeks	-	1week – 12 weeks	-	2 weeks – 12 weeks	-
Treatment effect *	11.7 (3.9)	< 0.01	5.72 (1.45)	< 0.01	42.3 (26.1)	0.11
Baseline effect	0.1 (0.1)	0.21	-	-	0.2 (0.1)	0.01
Time effect **	10.8 (1.6)	< 0.01	1.35 (0.08)	< 0.01	13.8 (1.4)	< 0.01
SDw	13.4	-	4.40	-	75.7	-
SDb	11.8	-	5.13	-	87.0	-

QoR-40 = Quality of Recovery-40, RI-10 = Recovery Index-10, RAND-36 = RAND-36 health survey, p = p-value for difference using a linear mixed model, treatment effect = estimated increase in score (standard error) by treatment group, baseline effect = estimated increase in score (standard error) by unit increase in baseline score, time effect = estimated increase in score (standard error) per week, SDw = standard deviation within patients, SDb = standard deviation between patients, - = not applicable.
Notes: *Treatment effect favors LH, **In the model different increments between the points of measurement were allowed, but for the ease of presentation the average increase per week was presented.

Recovery following hysterectomy: results on the three instruments

Fifty-nine patients with benign indications for surgery had been randomized to either laparoscopic (n=27) or abdominal hysterectomy (n=32). There was a statistically significant treatment effect of 11.7 (3.9) units in the QoR-40 and 5.72 (1.45) units in the RI-10 both favoring laparoscopic hysterectomy (Table 4). Figures 2 a,b and c show the estimated mean scores with 95% confidence bands by treatment group.

Discussion

This is, to our knowledge, the first study comparing postoperative recovery as measured by specific and generic instruments. The study was conducted to examine whether the application of a recovery specific quality of life instrument was more valid as compared to a generic health related quality of life instrument for the assessment of postoperative recovery. In other words, the objective of the study was to evaluate whether there is a need for recovery specific questionnaires. The QoR-40, RI-10 and RAND-36 showed good internal consistency. The three instruments showed comparable construct validity with the best performance in the RI-10. Moreover, the RI-10 showed the best responsiveness with an increase during the entire 12 weeks postoperative period, as well as the greatest score range over time in relation to the instruments score range.

At the start of this research project in 1996, there was no valid recovery specific instrument available to measure recovery from laparoscopy versus open surgery in gynecology. The number of items was an important issue in the development of the RI-10, as to cause as less trouble as possible to patients in their recovery period. Consequently, this instrument may be advantageous due to its limited number of questions. However, the validation process has only been performed for the Dutch language until now. A limitation of the questionnaire is that a baseline measurement is lacking, since most of the questions refer to the postoperative situation. Furthermore, the target population was not involved in the development and no item reduction techniques were applied, as has been recommended (22).

The QoR-40 has shown to be a valid and reliable tool for measurement of recovery in a wide range of surgical patients. In a cardiac surgical population, a poor QoR-40 score on day 3 was moderately correlated to a poor quality of life as measured by SF-36 at 3 month after the operation (17). Although Leslie *et al.* (16) have shown that the questionnaire did not discriminate between the recovery of cranial and spinal surgical patients, the conclusion of their study was that the QoR-40 had shown to be valid and reliable in a neurosurgical population as well. The mean score on day 1 in the adult cardiac surgical population as describes by Myles *et al.* (17) and the neurosurgical population as describes by Leslie *et al.* (16) was 163 and 160 respectively. Whereas baseline scores were comparable, our hysterectomy patients have a lower QoR-40 score with a mean score of 143 on day 1. Unfortunately, the QoR-40 has not been translated in accordance with prevailing rules of back and forward translations, but the Cronbach's α were comparable to those in the English version (17).

Although the RAND-36 is a more extensive instrument and was less responsive as compared to the RI-10, it has the advantage of being a more widely known questionnaire with well-validated subscales. In this study the total score of the instruments have been used for validation. Whether one of the eight subscales of the RAND-36 has better clinimetric properties for the measurement of postoperative recovery has not been studied.

Cronbach's α has been calculated for the three instruments and found satisfactory. However, in instruments focusing on evaluation of health status, responsiveness is more important than internal consistency (23;24). As recovery in the first weeks after surgery is expected to be a very dynamic process, we did not check for test-retest reliability in the present study.

It has been stated that at least 75% of pre-defined hypotheses should hold true on statistical testing to conclude that there is good validity (22). The instrument coming closest at one week after surgery was the RI-10 where three out of six hypotheses (50%) were confirmed. In the present study we were looking for the instrument where most hypotheses would hold true as compared to the others. This led to the formulation of quite challenging hypotheses, which were less likely to be confirmed in our population. This was probably the case for the difference between women with an ASA score 1 and women with an ASA score of at least 2, where none of the questionnaires could identify a difference between the groups. Since there were only six patients with an ASA score 3, we were practically testing for a difference between ASA score 1

and 2. From a clinical point of view a difference in recovery among these groups is not very likely. Lack of contrast was probably also the case for the hypothesis on hemoglobin decrease, as these two groups do not seem to be differing enough in relation to the sensitivity of the instruments used.

Although it has previously been shown that older patients have lower quality of life scores and poorer recovery (12-14), we were not able to confirm this in our population. In the RI-10 and QoR-40 the patients aged above 60 years had a significantly better recovery as compared to the women of less than 45 years of age. Moreover, as compared to the groups as defined in other hypotheses, the patient group aged above 60 years had a remarkable high quality of life score. This was in the exact opposite direction as defined in the hypothesis. Possibly, this difference in recovery was due to a difference in indications for surgery, since eleven women (65%) in the older age group were operated for endometrial carcinoma and another five women (29%) for atypical hyperplasia of the endometrium, which is a potentially malignant condition. Another possible explanation is that the older patients have corrected for their age their selves, and thus did not experience any mismatch between expectations and actual recovery.

Surprisingly, the hypothesis comparing vaginal and abdominal hysterectomy was only confirmed in the RI-10. Since it is widely accepted that vaginal hysterectomy is the first choice approach to hysterectomy, we would have expected to find differences in the other instruments as well (19).

The three instruments refer to different time periods after surgery, since the QoR-40 is referring to the past 24 hours, the RI-10 is referring to the past week and the RAND-36 is referring to the past four weeks. Furthermore, the questionnaires refer to different situations in the recovery process, i.e. in hospital for the QoR-40 and at home for RI-10 and RAND-36. This may have had an influence on the comparability of the instruments and might also be the explanation for the absence of change in the first two weeks in the RAND-36 and the weak correlation between the recovery specific instruments and the RAND-36 at one week after surgery. Furthermore, we did not apply the RI-10 and RAND-36 in the first days after surgery as we did for the QoR-40. The QoR-40 showed great changes in quality of life in these days. Whether this would also have been the case for the RI-10 and RAND-36 is less likely, although not proven at this stage. In retrospect, it would probably have been more appropriate to distribute all three questionnaires in the first days after surgery and to use the so-called acute-version of the RAND-36 referring to the past week (25). The pattern of score changes over time, imply that it is appropriate to use the QoR-40 on a daily basis in the first days after surgery and stop the application two weeks after surgery. Since the RAND-36 score does not change in the first two weeks after surgery, it is appropriate to await the application until this time point. The RI-10 can be applied for at least twelve weeks postoperatively as a change in score was seen along this time period.

Application of the instruments in the RCT, showed a statistically significant treatment effect in favor of the laparoscopic hysterectomy in the two recovery specific instruments. As this analysis was an evaluation over time, this is another indication for better responsiveness of

these instruments. The curve of the QoR-40 scores does not fit to a linear or parabolic model, which makes interpretation of the results over time more difficult. The decrease in mean score at one week after surgery might be caused by the discharge from hospital, as the laparoscopic hysterectomy patients returned home at a mean of 4.2 days and the abdominal hysterectomy patients at a mean of 5.4 days after surgery. Possibly, there are more or less two separate QoR-40 curves, i.e. one for hospitalized and one for discharged patients, which was not further evaluated in the present study.

In conclusion, the QoR-40, RI-10 and RAND-36 showed comparable internal consistency. With regard to construct validity, the RI-10 appeared to perform best and was more responsive as compared to the QoR-40 and RAND-36. Therefore we recommend the use of the short recovery specific questionnaire RI-10 in studies on postoperative recovery. However, in studies where the main interest is in hospitalized patients in their first postoperative days, the QoR-40 has likewise shown to be valid.

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Appendix 1. Quality of recovery - 40

Vragenlijst Kwaliteit van herstel - 40

Geachte mevrouw,

om inzicht te krijgen in het herstel na de operatie die u heeft ondergaan, vragen wij u deze vragenlijst in te vullen.

Geeft u daarvoor alstublieft bij elke vraag het antwoord dat het beste weergeeft hoe u zich de laatste 24 uur voelde. Dit gebeurt op een schaal van 1 tot 5. Boven de getallen staat de betekenis van de getallen.

Voorbeeld:

	helemaal niet waar				helemaal waar
Ik kan gemakkelijk ademhalen	1	2	3	4	(5)

Als u de laatste 24 uur steeds gemakkelijk kon ademhalen, omcirkelt u de 5.

Datum: _____

Hoe heeft u zich de laatste 24 uur gevoeld?

Welbevinden

	helemaal niet waar				helemaal waar
Ik kan gemakkelijk ademhalen	1	2	3	4	5
Ik heb goed geslapen	1	2	3	4	5
Het eten heeft me gesmaakt	1	2	3	4	5
Ik voel me uitgerust	1	2	3	4	5

Gevoelens

	helemaal niet waar				helemaal waar
Ik voel me over het algemeen goed	1	2	3	4	5
Ik heb de situatie / mezelf in de hand	1	2	3	4	5
Ik voel me op mijn gemak	1	2	3	4	5

Zelfredzaamheid

	helemaal niet waar				helemaal waar
Ik kan goed een gesprek voeren	1	2	3	4	5
Ik kan mezelf wassen en tandenpoetsen	1	2	3	4	5
Ik kan mezelf verzorgen	1	2	3	4	5
Ik kan schrijven	1	2	3	4	5
Ik kan werken / werkzaamheden thuis verrichten	1	2	3	4	5

Hoe heeft u zich de laatste 24 uur gevoeld?

Steun

	helemaal niet waar				helemaal waar
Het is mogelijk in het ziekenhuis met artsen en verpleegkundigen te spreken	1	2	3	4	5
Het is mogelijk met familie en vrienden te spreken	1	2	3	4	5
Ik word gesteund door de artsen in het ziekenhuis	1	2	3	4	5
Ik word gesteund door de verpleegkundigen in het ziekenhuis	1	2	3	4	5
Ik word gesteund door familie en vrienden	1	2	3	4	5
Ik begrijp uitleg en adviezen	1	2	3	4	5

Welbevinden

	helemaal niet waar				helemaal waar
Ik heb last van misselijkheid	5	4	3	2	1
Ik heb overgegeven	5	4	3	2	1
Ik moet kokhalzen	5	4	3	2	1
Ik voel me rusteloos	5	4	3	2	1
Ik heb last van trillen of beven	5	4	3	2	1
Ik heb last van rilligheid	5	4	3	2	1
Ik heb het te koud	5	4	3	2	1
Ik heb last van duizeligheid	5	4	3	2	1

Gevoelens

	helemaal niet waar				helemaal waar
Ik heb naar gedroomd	5	4	3	2	1
Ik voel me angstig	5	4	3	2	1
Ik ben boos	5	4	3	2	1
Ik voel me somber	5	4	3	2	1
Ik voel me alleen	5	4	3	2	1
Ik heb moeite om in slaap te komen	5	4	3	2	1
Ik voel me verward	5	4	3	2	1

Pijn en klachten

	helemaal niet waar				helemaal waar
Ik heb matige pijn	5	4	3	2	1
Ik heb ernstige pijn	5	4	3	2	1
Ik heb hoofdpijn	5	4	3	2	1
Ik heb spierpijn	5	4	3	2	1
Ik heb rugpijn	5	4	3	2	1
Ik heb een pijnlijke mond	5	4	3	2	1
Ik heb een pijnlijke keel	5	4	3	2	1

Appendix 2. Recovery index - 10

Vragenlijst Herstel index - 10

De volgende vragen hebben betrekking op hoe u zich de afgelopen week heeft gevoeld.
Er zijn geen foute antwoorden mogelijk. U kunt per vraag maar één cijfer aankruisen of omcircelen. De antwoorden staan op een vijfpuntenschaal. Als u het helemaal eens bent met de uitspraak omcirceld u een 1, als u het een beetje eens bent een 2, etc. Als u het er helemaal mee oneens bent omcircelt u een 5.

Hoe heeft u zich de afgelopen week gevoeld?	Helemaal eens				Helemaal oneens
1. Ik ben snel moe	1	2	3	4	5
2. Overdag moet ik regelmatig rusten	1	2	3	4	5
3. Ook als ik niets doe heb ik regelmatig last van buikpijn	1	2	3	4	5
4. Zelfs lichte inspanning (b.v. koffie zetten) kan ik nauwelijks doen	1	2	3	4	5
5. Ik voel me volledig hersteld na de operatie	1	2	3	4	5
6. Ik kan mijn normale dagelijkse bezigheden in huis helemaal doen	1	2	3	4	5
7. Sinds de operatie heb ik moeite met slapen	1	2	3	4	5
8. De operatie en het herstel daarna zijn minder goed verlopen dan ik mij had voorgesteld	1	2	3	4	5
9. Ik heb in het algemeen veel pijn gehad na de operatie	1	2	3	4	5
10. De klachten waarvoor ik ben geopereeerd zijn volledig verdwenen	1	2	3	4	5

Appendix 3. RAND - 36 health survey

Vragenlijst RAND - 36

Toelichting
In deze vragenlijst wordt naar uw gezondheid gevraagd.
Wilt U elke vraag beantwoorden door het juiste hokje aan te kruisen. Wanneer U twijfelt over het antwoord op een vraag, probeer dan het antwoord te geven dat het meest van toepassing is.

1. Wat vindt u, over het algemeen genomen, van uw gezondheid?

uitstekend	❒
zeer goed	❒
goed	❒
matig	❒
slecht	❒

2. *In vergelijking* met een jaar geleden, hoe zou u *nu* uw gezondheid in het algemeen beoordelen?

Veel beter dan een jaar geleden	❒
Iets beter dan een jaar geleden	❒
Ongeveer hetzelfde als een jaar geleden	❒
Iets slechter dan een jaar geleden	❒
Veel slechter dan een jaar geleden	❒

3. De volgende vragen gaan over dagelijkse bezigheden.
Wordt u door uw gezondheid *op dit moment* beperkt bij deze bezigheden? Zo ja, in welke mate?

		ja, ernstig beperkt	ja, een beetje beperkt	nee, helemaal niet beperkt
a.	*Forse inspanning* zoals hardlopen, zware voorwerpen tillen, inspannend sporten	❒	❒	❒
b.	*Matige inspanning* zoals het verplaatsen van een tafel, stofzuigen, fietsen	❒	❒	❒
c.	Tillen of boodschappen dragen	❒	❒	❒
d.	*Een paar* trappen oplopen	❒	❒	❒
e.	*Eén trap* oplopen	❒	❒	❒
f.	Buigen knielen of bukken	❒	❒	❒
g.	*Meer dan een kilometer* lopen	❒	❒	❒
h.	*Een have kilometer* lopen	❒	❒	❒
i.	*Honderd meter* lopen	❒	❒	❒
j.	Uzelf wassen of aankleden	❒	❒	❒

4. Had u, ten gevolge van uw lichamelijke gezondheid *de afgelopen 4 weken* één van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

		ja	nee
a.	U heeft *minder tijd* kunnen besteden aan werk of andere bezigheden	❒	❒
b.	U heeft *minder bereikt* dan u zou willen	❒	❒
c.	U was beperkt in het *soort* werk of het soort bezigheden	❒	❒
d.	U had moeite met het werk of andere bezigheden (het kostte u b.v. extra inspanning)	❒	❒

5. Had u, ten gevolge van een emotioneel probleem (bijvoorbeeld doordat u zich depressief of angstig voelde), *de afgelopen 4 weken* één van de volgende problemen bij uw werk of andere dagelijkse bezigheden?

		ja	nee
a.	U heeft *minder tijd* kunnen besteden aan werk of andere bezigheden	❒	❒
b.	U heeft *minder bereikt* dan u zou willen	❒	❒
c.	U heeft het werk of andere bezigheden niet zo zorgvuldig gedaan als u gewend bent	❒	❒

6. In hoeverre heeft uw lichamelijke gezondheid of hebben van emotionele problemen u *de afgelopen 4 weken* belemmerd in uw normale sociale bezigheden met gezin, vrienden, buren of anderen?

helemaal niet	❒
enigszins	❒
nogal	❒
veel	❒
heel erg veel	❒

7. Hoeveel pijn had u *de afgelopen 4 weken*?

geen	❒
heel licht	❒
licht	❒
nogal	❒
ernstig	❒
heel ernstig	❒

8. In welke mate heeft pijn u *de afgelopen vier weken* belemmerd bij uw normale werkzaamheden (zowel werk buitenshuis als huishoudelijk werk)?

helemaal niet	❒
een klein beetje	❒
nogal	❒
veel	❒
heel erg veel	❒

9. Deze vragen gaan over hoe u zich *de afgelopen 4 weken* heeft gevoeld. Wilt U bij elke vraag het antwoord aankruisen dat het beste aansluit bij hoe U zich heeft gevoeld.

Hoe vaak gedurende *de afgelopen 4 weken*:

		Voort-durend	meestal	vaak	soms	zelden	nooit
a.	voelde u zich levenslustig?	❒	❒	❒	❒	❒	❒
b.	voelde u zich erg zenuwachtig?	❒	❒	❒	❒	❒	❒
c.	zat u zo erg in de put dat niets u kon opvrolijken?	❒	❒	❒	❒	❒	❒
d.	voelde u zich kalm en rustig?	❒	❒	❒	❒	❒	❒
e.	voelde u zich erg energiek?	❒	❒	❒	❒	❒	❒
f.	voelde u zich neerslachtig en somber?	❒	❒	❒	❒	❒	❒
g.	voelde u zich uitgeblust?	❒	❒	❒	❒	❒	❒
h.	voelde u zich gelukkig?	❒	❒	❒	❒	❒	❒
i.	voelde u zich moe?	❒	❒	❒	❒	❒	❒

10. *Hoe vaak* hebben uw lichamelijke gezondheid of emotionele problemen *gedurende de afgelopen 4 weken* uw sociale activiteiten (zoals bezoek aan vrienden of naaste familieleden) belemmerd?

voordurend	❒
meestal	❒
soms	❒
zelden	❒
nooit	❒

11. Wilt U het antwoord kiezen dat het beste weergeeft hoe juist of onjuist u elke van de volgende uitspraken voor uzelf vindt.

		volkomen juist	groten-deels juist	weet ik niet	groten-deels onjuist	volkomen onjuist
a.	Ik lijk gemakkelijker ziek te worden dan andere mensen.	❒	❒	❒	❒	❒
b.	Ik ben net zo gezond als andere mensen die ik ken.	❒	❒	❒	❒	❒
c.	Ik verwacht dat mijn gezondheid achteruit zal gaan.	❒	❒	❒	❒	❒
d.	Mijn gezondheid is uitstekend.	❒	❒	❒	❒	❒

8 Women's preference for laparoscopic or abdominal hysterectomy

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Abstract

Objective

Laparoscopic hysterectomy and abdominal hysterectomy are alternative approaches for hysterectomy in women with a moderately enlarged uterus. This study was performed to elicit women's preferences on the subject.

Study design

Patients scheduled for hysterectomy and nurses were assessed in individual, structured interviews and a questionnaire identical to the interview respectively. Specific advantages and disadvantages of laparoscopic and abdominal hysterectomy were explained. In the interview we assessed patients' preferences for laparoscopic or abdominal hysterectomy. We asked for the maximum acceptable risk of major complications and the maximum acceptable risk of conversion from laparoscopic hysterectomy to abdominal hysterectomy.

Results

We interviewed 43 patients and 39 nurses. Eighty-four percent of patients and 74 percent of nurses preferred laparoscopic hysterectomy over abdominal hysterectomy. The avoidance of complications was indicated as the most important influencing factor. More than half of the women perceived 1% as the maximum acceptable major complication rate.

Conclusions

Women prefer laparoscopic hysterectomy over abdominal hysterectomy. The actual major complication rate in hysterectomy is perceived as high.

Introduction

Laparoscopic hysterectomy has been introduced in 1989 as an alternative to abdominal hysterectomy (1). Since then, both approaches have been compared in more than 30 randomised controlled trials. A meta-analysis of these trials demonstrated that laparoscopic hysterectomy was associated with less operative blood-loss, less post-operative pain and less infectious morbidity, as well as a shorter hospital stay and more rapid return to normal activities. On the other hand, longer operating times and more urinary tract injuries have been reported for laparoscopic hysterectomy (2;3), which seem partly due to the learning curve (4;5).

The introduction of laparoscopy in gynaecology develops at a slow pace. In 2002, only 4% of hysterectomies in the Netherlands was performed laparoscopically (6). The Council for Public Health and Health Care (Raad voor de Volksgezondheid en Zorg), an independent body that advises the Dutch government, supports the implementation of minimal access surgery in health care (7). Some gynaecologists are enthusiastic about the new technique and judge that the patients are better off with a quick recovery. Other gynaecologists, however, are reserved due to the higher major complication rate.

Although the choice for laparoscopic or abdominal hysterectomy can only be made after a weighing of the pros and cons of the procedure. At present, patients have not been involved systematically in the decision for the introduction of laparoscopic hysterectomy. The assessment of patient weighing of advantages and disadvantages could indicate the need for individualised treatment-decisions if patients make different trade-offs. On the other hand, if a large majority of patients clearly favours laparoscopic or abdominal hysterectomy, this could either stimulate the implementation of laparoscopic hysterectomy, or lead to an abandoning of the procedure.

Nowadays, the choice for a treatment option is more based on shared decision-making as compared with the past, although it is known that doctors still underestimate the patients' desire for the involvement in the decision-making (8). A recent survey in Scotland showed that half of the women with benign menstrual problems scheduled for either vaginal, abdominal or laparoscopic hysterectomy had not been informed on advantages and disadvantages of treatment options other than hysterectomy (9). Moreover, half of these women had not been informed on advantages and disadvantages of the different approaches to hysterectomy, and one in every five women did not even know which approach to hysterectomy was planned in her individual case (10).

Although both laparoscopic and abdominal hysterectomy are viable options in women with a moderately enlarged uterus, the preference of women has, to our knowledge, not been assessed systematically. The aim of the present paper was to investigate women's preferences for laparoscopic or abdominal hysterectomy, as well as the main factors underlying these preferences.

Material and Methods

We studied both patients scheduled for hysterectomy as well as nurses. Patients were recruited at the Máxima Medical Center between January 2005 and April 2007. The Máxima Medical Center is a teaching hospital with 865 beds on two locations in the south of The Netherlands. The gynaecology department of the Máxima Medical Center is experienced in minimally invasive surgery, and the first laparoscopic hysterectomy was performed in 1992.

Patients scheduled for hysterectomy for benign disease in whom vaginal surgery was not suitable, but in whom laparoscopic hysterectomy and/or abdominal hysterectomy were feasible, were included in the study. A laparoscopic hysterectomy and/or abdominal hysterectomy was indicated in case the size of the uterus was not beyond 18 weeks' gestation. In case the uterus was larger than 18 weeks' gestation, the patient was always scheduled for abdominal hysterectomy. The inclusion was not consecutive, but occurred arbitrarily depending on the presence of members of the study group and the availability of the research nurse who performed the interviews. Exclusion criteria were inability to speak Dutch and an expected endometrial carcinoma of stage II or higher. The study was exempt from Institutional Review Board approval.

Nurses were recruited from the departments for paediatrics, obstetrics, general surgery and internal medicine at the Radboud University Medical Centre, Nijmegen, The Netherlands. Inclusion criteria were being female, and not being involved in the care of hysterectomy patients. The nurses were asked to imagine that they were scheduled to undergo hysterectomy.

The patient group was assessed through a structured face-to-face interview taken by one research nurse. These interviews lasted for approximately one hour. Patients were invited for a second interview approximately six weeks after the procedure. The nurses completed the questionnaires without assistance of the researchers and returned them by mail.

The interview or questionnaire was introduced with the (hypothetical) situation that vaginal hysterectomy was not feasible, and that there were two alternative approaches to hysterectomy, of which none was superior; both having specific advantages and disadvantages.

The first two questions addressed the attitude of women to the decision-making process in general, including the amount of information the woman desired to receive on specific advantages and disadvantages of treatments, as well as the desired involvement in decision-making.

Subsequently, global information was provided on laparoscopic and abdominal hysterectomy, without explication of exact rates or figures. In short, abdominal hysterectomy was described as a procedure requiring an abdominal incision, associated with less major complications (e.g. injury to adjacent organs and major blood loss), and more minor complications (e.g. infections and wound healing problems). Laparoscopic hysterectomy was presented as a minimal access procedure, with a risk of conversion to laparotomy. However, a successful laparoscopic hysterectomy would result in a quicker recovery. Subsequently, women were asked for the first time whether they would prefer laparoscopic or abdominal hysterectomy.

Table 1. Detailed information on differences between laparoscopic and abdominal hysterectomy.

	LH	AH
Type of anesthesia	General	General
Removal uterus, cervix and ovaries	Identical to AH	Identical to LH
Incision	4 small incisions	Low transverse incision
Risk of conversion during surgery from LH to AH	10%	None
Operation time (minutes)	130	90
Major complications	More frequent as in AH	Less frequent as in LH
Injury to adjacent organs	1%	0.5%
Minor complications	Less frequent as in AH	More frequent as in LH
Hospital stay (days)	3 - 4	4 - 6
Pain in first 3 weeks after surgery	Less painful as in AH	More painful as in LH
Return normal activities (weeks)	3 - 6	5 – 8

LH = laparoscopic hysterectomy; AH = abdominal hysterectomy.

In the next part of the interview, the two approaches to hysterectomy and their advantages and disadvantages were explained in detail in a text of 600 words of which a summary is shown in Table 1. The presented complication rates, conversion rates, duration of hospital stay and duration of recovery were based on a recent randomized controlled trial from the local department (11), a meta-analysis on the subject (3), two prospective studies (4;12) and three retrospective case series (5;13;14) including over 10,000 laparoscopic hysterectomies. The figures and rates presented were mainly applicable to experienced surgeons beyond their learning curve.

When women indicated that they had read and understood the supplied detailed information, they were asked again to indicate a preference for laparoscopic or abdominal hysterectomy. Subsequently, the preference was assessed for the hypothetical situation of equal complication rates for both approaches to hysterectomy and no risk of conversion in laparoscopic hysterectomy. Women were furthermore asked whether they would accept a two-fold increased major complication rate in laparoscopic hysterectomy as compared with abdominal hysterectomy and whether they thought a possible conversion from laparoscopic hysterectomy to abdominal hysterectomy to be acceptable. Subsequently, women were asked to indicate the highest complication rate in laparoscopic hysterectomy and the highest conversion rate from laparoscopic hysterectomy to abdominal hysterectomy, that they still considered being acceptable.

Finally, the importance of individual advantages and disadvantages of laparoscopic and abdominal hysterectomy was rated on a five-point Likert scale (very unimportant until very important) for the following factors: avoidance of complications, avoidance of conversions, restriction of operation times, limitation of the recovery period and the avoidance of abdominal scars.

Statistical analysis

Normally distributed data were presented as mean and standard deviations, whereas skewed distributed data were presented as medians with a range. In case of dichotomous variables, data

were presented as absolute numbers with percentages. Differences between groups (patients versus nurses, laparoscopic hysterectomy versus abdominal hysterectomy and preoperative versus postoperative assessment) were tested with t-tests and non-parametric Wilcoxon-Mann-Whitney tests as appropriate. Chi-square tests were used for dichotomous data.

Thresholds for risk of complications and conversions were visually presented in cumulative distribution curves, reflecting the overall willingness to accept risks.

Data were analysed in SPSS 13.0 software (SPSS, Inc., Chicago, IL). P-values < 0.05 were considered to indicate statistical significance.

Results

We interviewed 43 patients, of whom 32 were scheduled for laparoscopic hysterectomy and 11 for abdominal hysterectomy. These groups are referred to as the laparoscopic hysterectomy group and abdominal hysterectomy group, respectively. The mean age was 46.6 (standard deviation 8.0) years in the laparoscopic hysterectomy group and 44.6 (standard deviation 5.4) years in the abdominal hysterectomy group. Five women, who were scheduled for abdominal hysterectomy, did not have an actual choice for laparoscopic hysterectomy, due to an enlarged uterus or endometriosis. One of the laparoscopic procedures was converted to an abdominal hysterectomy during the procedure, due to a bleeding that could not be controlled by laparoscopy. Twenty-six women (81%) in the laparoscopic hysterectomy group and ten women (91%) in the abdominal hysterectomy group returned for the post-operative interview.

Thirty-nine nurses completed the questionnaire, of whom six (15%) had undergone prior hysterectomy. The mean age of the nurses was 41.8 (standard deviation 10.5) years.

There was no difference in the desired amount of information on advantages and disadvantages of treatment options and the desired involvement in the decision-making between patients and nurses (Table 2). Overall, 81% of women preferred laparoscopic hysterectomy (Table 2). There was no difference in treatment preferences between the nurses and the patients ($p=0.38$).

At the post-operative interview, none of the women scheduled for laparoscopic hysterectomy had changed her preference for laparoscopic hysterectomy, whereas two women (18%), who had been scheduled and had undergone abdominal hysterectomy, changed their post-operative preference. One woman changed her preference from laparoscopic hysterectomy to abdominal hysterectomy, whereas the other switched from abdominal to laparoscopic hysterectomy.

Figure 1 shows the percentage of women in the laparoscopic hysterectomy group, abdominal hysterectomy group and nurses group who accepted a certain risk of major complications in hysterectomy. The median acceptable risk was 1.0% in the laparoscopic hysterectomy group, and 0.5% in the abdominal hysterectomy group and the nurses group. These percentages were significantly higher in the laparoscopic hysterectomy group versus the abdominal hysterectomy group ($p=0.001$) and in the patients versus the nurses ($p=0.004$). A major complication rate

Table 2. Women's preferences.

		Patients scheduled for LH (n=32)	Patients scheduled for AH (n=11)	Nurses (n=39)	Test for differences
Desired information		1 [1-8] *	1 [1-3] *	1 [1-10] *	a: p = 0.24 b: p = 0.76
Desired involvement		4 [1-9] *	3 [1-6] *	3 [1-10] *	a: p = 0.65 b: p = 0.67
Preferred approach (after global information)	LH ? AH	32 (100) 0 0	4 (36) 1 (9) 6 (55)	29 (74) 1 (3) 9 (23)	a: p < 0.01 b: p = 0.56
Preferred approach (after detailed information)	LH ? AH	32 (100) 0 0	5 (45) 0 6 (55)	29 (76 ‡) 1 (3) 8 (21)	a: p < 0.01 b: p = 0.38
Preferred approach (equal complications and no conversions)	LH ? AH	32 (100) 0 0	7 (64) 2 (18) 2 (18)	33 (92 ‡) 2 (6) 1 (3)	a: p < 0.01 b: p = 0.90
Accepts doubled major complication rate in LH	Yes Maybe No	28 (88) 2 (6) 2 (6)	3 (27) 4 (36) 4 (36)	17 (44) 16 (41) 6 (15)	a: p < 0.01 b: p = 0.04
Accepts conversion in LH in case needed	Yes Maybe No	32 (100) 0 0	7 (64) 1 (9) 3 (27)	31 (79) 5 (13) 3 (8)	a: p < 0.01 b: p = 0.18

AH = abdominal hysterectomy; LH = laparoscopic hysterectomy; Test for differences: a = LH vs AH; b = patients vs nurses; p = p-value for difference between groups using Chi-square tests; n.s. = difference not statistically significant; desired information = desired amount of information on advantages and disadvantages of treatment options on a 1 to 10 visual analogue scale, where 1 represents most information; desired involvement = desired level of involvement in medical decision -making on a 1 to 10 visual analogue scale, where 1 represents most involvement; ? = no preference.
Data shown as * median [range], absolute numbers (percentage). ‡ note: data from one and three nurses are missing respectively.

of 7.2%, such as reported in laparoscopic hysterectomy in the large eVALuate study, when disregarding the intraoperative conversions (15), was unacceptable to 96% of women.

Figure 2 shows the percentage of women in the laparoscopic hysterectomy group, abdominal hysterectomy group and nurses group who accepted a certain risk of conversion from laparoscopic hysterectomy to abdominal hysterectomy during surgery. The median acceptable conversion rate from laparoscopic hysterectomy to abdominal hysterectomy was 55%, 20% and 10% in the laparoscopic hysterectomy group, abdominal hysterectomy group and nurses group respectively. The difference between the laparoscopic hysterectomy group and abdominal hysterectomy group was not statistically significant (p=0.096), whereas the patients accepted a significantly higher conversion rate as compared to the nurses (p<0.001). A conversion rate from laparoscopic to

Figure 1. Women's acceptance of the risk of major complications.

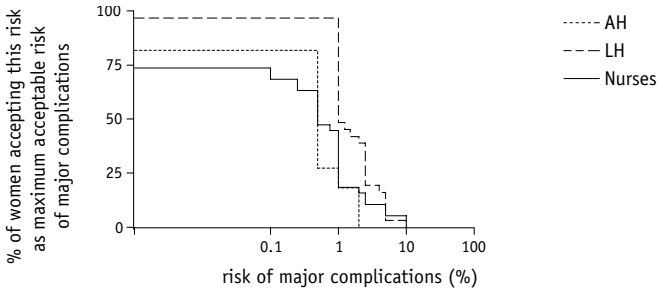
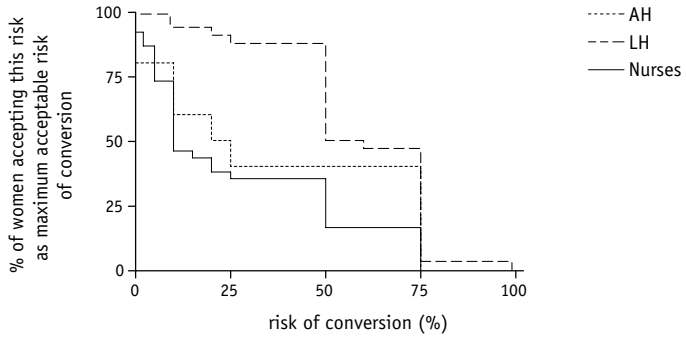


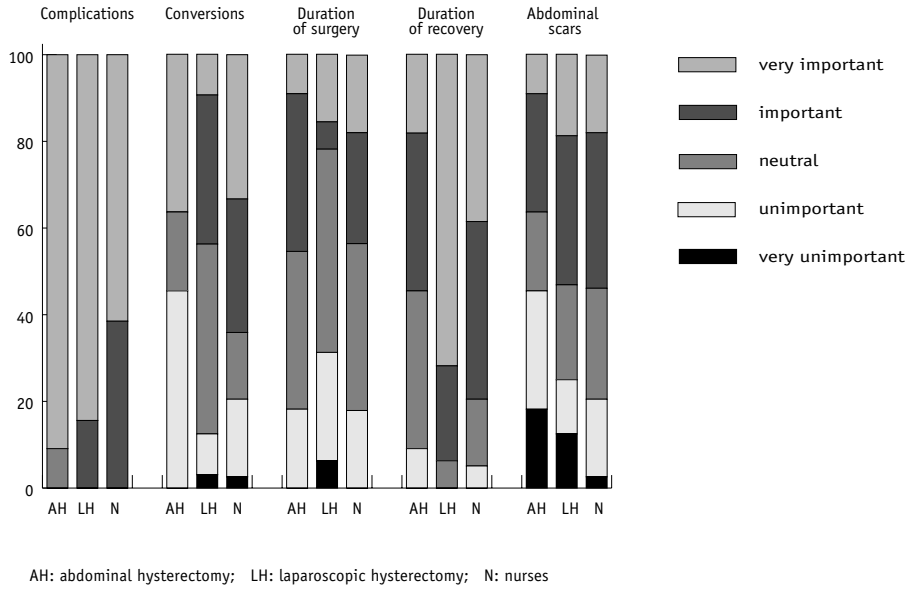
Figure 2. Women's acceptance of the risk of a conversion during surgery from laparoscopic to abdominal hysterectomy.



abdominal hysterectomy of 4%, such as reported in the eVALuate study (15), was unacceptable to 9% of women.

In Figure 3, the importance of treatment characteristics for women in the laparoscopic hysterectomy group, abdominal hysterectomy group and nurses group are presented as 100% stack bars. The avoidance of complications was ranked more important by the patients than by the nurses (p=0.015). The limitation of the recovery period was ranked more important in the laparoscopic hysterectomy group than in the abdominal hysterectomy group (p=0.002). Other comparisons were not significantly different.

Figure 3. Treatment characteristics.



AH: abdominal hysterectomy; LH: laparoscopic hysterectomy; N: nurses

Comment

This paper presents a study on women's preferences for laparoscopic or abdominal hysterectomy and the main treatment related factors influencing their preference. We found that 81% of the women preferred laparoscopic hysterectomy, in spite of disadvantages such as a higher risk of major complications in the laparoscopic approach. However, 4% of the women preferred abdominal hysterectomy even in case of a hypothetical situation of equal complication rates and no risk of conversion to laparoscopic hysterectomy. These preferences did not change following a more detailed explanation of the two procedures or after experiencing hysterectomy in the near past.

The main factor influencing the women's treatment preference was the avoidance of complications. More than half of the patients and three-quarters of the nurses experienced 1% as the maximum acceptable risk of major complications in hysterectomy, and none of the patients in the abdominal hysterectomy group accepted a major complication risk over 2%.

Considerable effort has been spent to obtain valid estimates for the figures and percentages on the differences between laparoscopic and abdominal hysterectomy in the detailed information of the interview. A difficulty in this respect, however, was that the meta-analysis of randomised controlled trials on laparoscopic versus abdominal hysterectomy (3) reported a much higher complication rate as compared with large prospective (4;12) and retrospective case series (5;13;14). This discrepancy might be explained by differences in learning curve in the various

studies (2;3;16-19). In the meta-analysis on hysterectomy, the cumulative risk of injury to urinary tract, bowels and blood vessels was 4.4% and 2.7% in laparoscopic and abdominal hysterectomy, respectively (3). This complication rate in laparoscopic hysterectomy was in agreement with the 4.6% injury rate to urinary tract or bowels as occurring during the learning curve of laparoscopic hysterectomy in a large prospective Finnish study (4). In the present study, less than 5% of women perceived this high complication rates as acceptable (Figure 1). Since more and more surgeons will be thoroughly trained in laparoscopic hysterectomy, we have presented the complication rates as achieved by experienced surgeons in the present study (i.e. 0.5% and 1% urinary tract injuries in abdominal and laparoscopic hysterectomy respectively). Consequently, the treatment preferences presented are mainly applicable to a wide range of surgeons who have finished their learning curve in laparoscopic hysterectomy.

The fact that women scheduled for hysterectomy considered a 1% probability of major complications as their maximum acceptable risk also indicates that other alternatives for hysterectomy should be considered prior to surgery. In a recent preference study among women suffering from dysfunctional uterine bleeding, we found that a majority of the patients scheduled for an endometrial ablation or a levonorgestrel-releasing IUD were inclined to take a risk of 50% likelihood of treatment failure to avoid a hysterectomy (20).

The risk of conversion in laparoscopic hysterectomy was less important to the women in the decision-making on approach to hysterectomy (Figures 3). There was, however, a minority of women who did not accept the risk of conversion and would prefer abdominal hysterectomy to avoid this uncertainty.

We have used face-to-face interviews to assess patients' preferences. Both strength and limitation of these personal interviews is the flexible nature (21). It allows tailoring information and explication to the need of the individual patient, whereas interviewers' influences make the technique prone to bias, and need to be minimised. Since the results from the questionnaires used in the nurses group were largely in line with the results from the interviews in the patients, this suggests absence of major bias in this respect.

Half of the women in the abdominal hysterectomy group did not have an actual choice for laparoscopic hysterectomy and all other patients had already made a personal decision on the desired approach to hysterectomy at the time of the first interview. Women could feel free to state their preference without consequences for their personal situation. It can be difficult, however, for women to reconsider the choices they have just made facing their own doctor. This might have caused some opportunistic answers in line with the planned approach, e.g. caused by a psychological mechanism called cognitive dissonance reduction (22). This might be the reason for (part of) the lower acceptance of complications and conversions, and the fact that the less importance was ascribed to the speed of recovery in the abdominal hysterectomy group as compared with the laparoscopic hysterectomy group. Another explanation for this phenomenon might be selection bias, as women with a lower acceptance of complications and conversions had opted already for abdominal hysterectomy.

We have included a group of nurses in the study, since, by virtue of their profession, we expected them to be more experienced in judging complex issues, such as complication rates, conversion rates, and post-operative recovery. Since treatment preferences in the nurses group were largely in line with the patients group, this consolidates our findings. The maximum acceptable rates of complications and conversions, however, were lower among nurses as among patients. Since the nurses did not experience the necessity for hysterectomy and are professionally involved in patients having complications, this might be the explanation for the difference in willingness to accept these adverse events.

Advantages and disadvantages of all feasible approaches to hysterectomy need to be discussed with each woman scheduled for hysterectomy, which may include the proposal of a laparoscopic hysterectomy as performed by a colleague. The fact that a recent study showed that half of the women was not informed on the pros and cons of different approaches and one in every five women did not even know which approach to hysterectomy was planned (10), indicates that there is a need for improvement in this perspective.

The evident preference for laparoscopic hysterectomy reported by patients in this study is conflicting with the slow implementation of laparoscopic hysterectomy in clinical practice. There is a strong call for laparoscopic hysterectomy from society to be heard and measures to stimulate the further implementation of laparoscopic hysterectomy are needed. This can be either by expansion of laparoscopic training to gynaecologists or the centralisation of laparoscopic hysterectomies in laparoscopic centres.

In conclusion, the majority of women prefers laparoscopic hysterectomy over abdominal hysterectomy, and accepts the risk of conversion to laparotomy. The complications, however, are a major issue of concern, and the actual major complication rate in hysterectomy is perceived as high.

Acknowledgement

We thank Mrs Marijne Bremer for interviewing all the patients.

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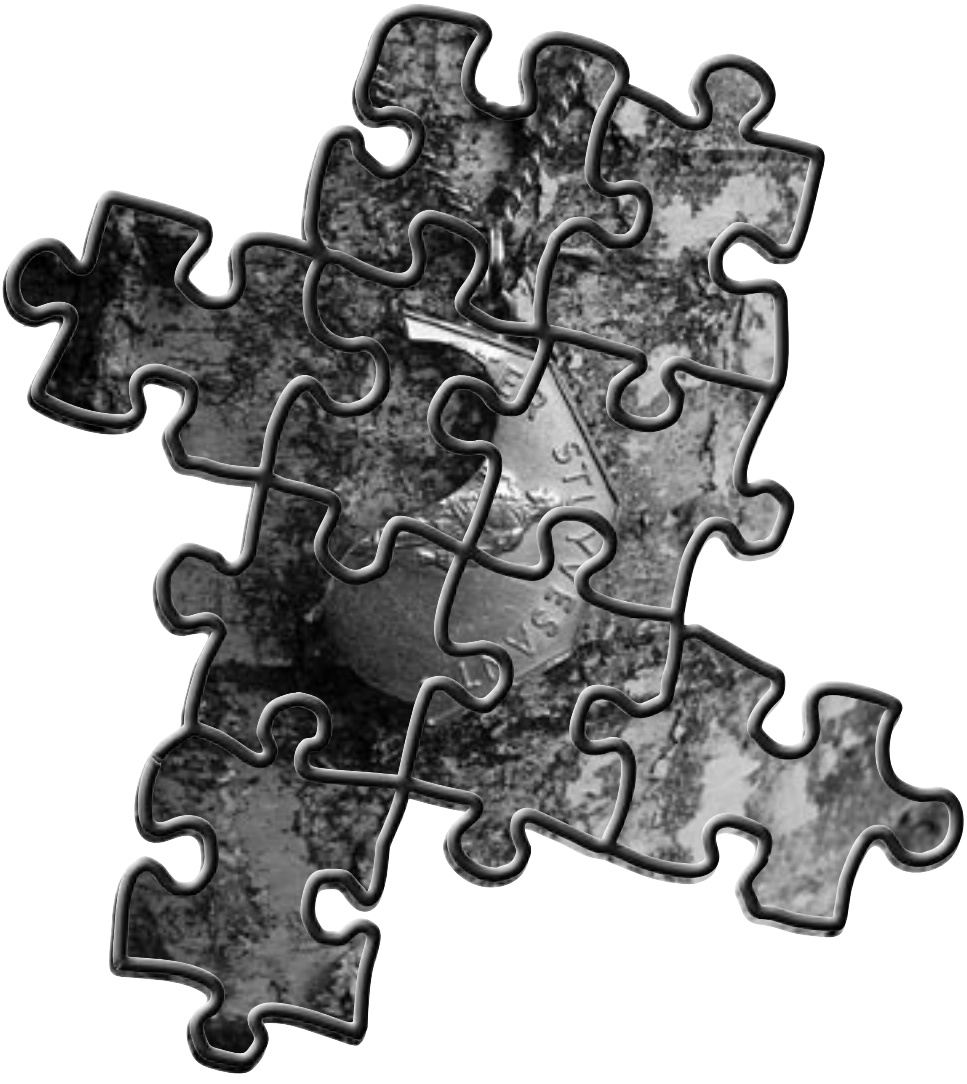
9 Discussion



This thesis describes various aspects of the three approaches to hysterectomy with emphasis on the measurement of quality of life and recovery following laparoscopic and abdominal hysterectomy.

The first chapters provide an overview of the available literature on hysterectomy. Since disadvantages from vaginal hysterectomy as compared with laparoscopic and abdominal hysterectomy have not been reported, there is a general consensus that vaginal hysterectomy is the first choice approach in women with no suspicion of gynaecological malignancy (1). Due to the limitation of access, however, the vaginal approach is impossible in women with more than moderately enlarged uteri. In these women, a decision for either laparoscopic or abdominal hysterectomy needs to be made. Laparoscopic hysterectomy is associated with a reduction in blood loss, infections, post-operative pain, hospital stay and time to resume normal activities, at the expense of longer surgical procedures and more urinary tract injuries as compared with abdominal hysterectomy. Although larger size uteri can be removed by laparoscopic approach as compared with the vaginal approach, the laparoscopic access is equally limited by uterine size. In abdominal hysterectomy, there is no uterine size limitation and this approach is applied where vaginal and laparoscopic hysterectomy is not feasible.

Laparoscopic hysterectomy has been introduced as an alternative for abdominal hysterectomy in 1989 by Reich (2). His introduction has given an impetus to research on the comparison of various approaches to hysterectomy, and more than 30 randomized controlled studies on laparoscopic versus abdominal hysterectomy have been published since. The main question on the relative complication rates in women undergoing hysterectomy by vaginal, laparoscopic and abdominal approach has now been answered by meta-analysis of these studies, which has shown a more than 2-fold increase in urinary tract lesions in laparoscopic hysterectomy as compared with abdominal hysterectomy (1). In spite of the large number of randomized controlled trials, however, the effects of the many other factors influencing complication rates remain obscure. It is still not known, for example, whether one of the subcategories of laparoscopic hysterectomy, such as laparoscopic assisted vaginal hysterectomy (LAVH) or total laparoscopic hysterectomy (TLH), is safer as compared with the others. It is equally not demonstrated as yet, how uterine size and the surgeons' experience influence complication rates. Due to the low major complication rate and the many influencing factors, large sample sizes are needed to allow various subgroup analyses. It is not very likely that more randomized controlled trials of a sample size comparable to the large eVALuate study (i.e. 1,346 women) (3) will be conducted in the near future. This emphasizes the importance of detailed descriptions of studies on new surgical procedures, since the detailed documentation of outcomes for which each individual study was underpowered, allows to draw conclusions in a subsequent meta-analysis (1). The sample size in our randomized controlled study was too small for proper analysis of complications (Chapters 4). Unfortunately, due to an accumulation of complications during the study period, there was a high complication rate.

A prospective observational study by Makinen *et al.* has shown that, with increasing experience in laparoscopic hysterectomy, the urinary tract injury rate decreases to a rate similar to abdominal hysterectomy (4). This is in agreement with results from large case series with

experienced surgeons, including over 6,000 laparoscopic hysterectomies (5-8). The urinary tract injury rate as reported in the meta-analysis of randomized controlled trials is comparable to the rate in surgeons during the learning curve in observational studies (1;4;6). Only few randomized controlled studies, however, have reported on the surgeons' experience or on experience in dealing with serious complications (Chapter 2). In the studies where experience of the surgeons has been reported, it has mainly been reported in terms of the numbers of previous laparoscopic hysterectomies, which is only one of the markers for competence (9). The learning curve of a surgeon without any laparoscopic experience will differ from the learning curve of a surgeon who is used to a wide range of other laparoscopic procedures. Analyses of complication rates are even more challenging with the assessment of the learning curve position of gynaecologists in training, supervised by a gynaecologist, both with a variable amount of experience. In the randomized controlled trial presented in this thesis, most abdominal procedures were performed by gynaecologists in training, whereas most laparoscopic hysterectomies were performed by gynaecologists. Although the gynaecologists had performed more than 100 procedures, it is not surprising, that the gynaecologists in training and the gynaecologists were equally involved in the urinary tract injuries in these procedures (Chapter 4). Obtaining more data on complication rates in relation to surgical experience level is an important, though complicated subject for future research, which would provide more insight in the need for future centralization of complex laparoscopic procedures.

Although the implementation of laparoscopic hysterectomy in clinical practice is slow (10), the procedure has not been abandoned since the publication of the meta-analysis with the report of higher urinary tract injury rates (11). Reasons for the laparoscopic hysterectomy to stay, may include the strong call from society for minimally invasive procedures (12), the patients' unawareness or acceptation of the risks (13), and the surgeons' believe of doing better than average and finding it hard to abandon the challenging procedure (14). It is not known which of these elements is the decisive factor. There is probably a wide believe among patients and doctors that a shorter recovery associated with laparoscopic hysterectomy can compensate for the extra complication risks.

The main objective of this thesis was to assess the post-operative recovery in hysterectomy patients. Post-operative recovery is the process of convalescence after surgery and involves physical and mental aspects. After successful recovery the patient will feel comfortable, free of symptoms such as pain and nausea, experience normal nutrition, micturition and defecation, and is able to fulfil normal activities. Recovery should be measured in an unbiased manner, which excludes the duration of hospital stay and time taken to resume work as measurement tools. Although these periods are related to recovery, they are influenced by local habits and protocols, and it is of more interest to know when the patient feels ready to go home and ready to resume normal activities. Consequently, patients' involvement in recovery assessment is essential, and in recent years, emphasis has been put on patient-reported post-operative quality of life measurement (15), where recovery is reflected in the time taken till resumption of preoperative quality of life.

In our studies, a modest advantage in favour of laparoscopic hysterectomy as compared with abdominal hysterectomy was found in three quality of life questionnaires (RAND-36, RI-10 and QoR-40) in the first twelve weeks after surgery (Chapters 4 and 7). Although clinicians would probably expect a more pronounced difference in recovery, the evidence in favour of laparoscopic hysterectomy is apparent, and in agreement with quality of life outcomes from other studies (Chapter 3).

Both generic health-related quality of life questionnaires and recovery specific quality of life questionnaires can be used as instruments for recovery assessment. The generic health-related instruments, such as RAND-36, have the advantage of being used more frequently as compared with recovery specific instruments, so that more data from other studies are available for comparison. Recovery specific instruments, however, are more valid for recovery measurement as compared with the RAND-36 (Chapter 7). The dilemma here is either more comparability or more validity, which can easily be solved by applying both types of instruments in future studies.

Unsatisfactory measurement properties of the instruments used, can lead to non-valid outcomes, which should be prevented at all times. Available recovery specific instruments with good measurement properties are the Postdischarge surgical recovery scale, the Quality of recovery-40 and the Recovery index-10 (Chapter 6 and 7). The latter two instruments are available in a Dutch version. The validation of none of the three instruments has been completed, and further validation is awaited with special regards to responsiveness and the minimally important change.

If the data from the Recovery index-10 (Chapter 7) had already been published at the time of our systematic review on available recovery specific instruments (Chapter 6), the instrument would have been included. This hampers the comparability of the Recovery index-10 to the other recovery instruments. When the eight quality criteria for measurement properties (16) are applied to the RI-10, it results in positive ratings for internal consistency and floor/ceiling effects, intermediate ratings for responsiveness and interpretability and negative ratings for content validity and construct validity, whereas no information is available for agreement and reliability. The two negative ratings are due to the lack of target population involvement and also to the fact that only two-thirds, instead of three-quarters, of predefined hypotheses held true on construct validity testing in hysterectomy patients. In our validation study (Chapter 7), however, the construct validity of the Recovery index-10 proofed superior to the Quality of recovery-40 and this instrument was rated positive for construct validity in the review (Chapter 6). This positive rating was based on the results of the original validation study of the Quality of Recovery-40 (17). As a consequence, it is not justified to disqualify the Recovery index-10 as a recovery specific instrument at this stage and a further validation study is needed.

The items in recovery instruments should correspond with the surgical procedure and the time period studied. Problems with mobility and emotional factors for example, are more likely in orthopaedic surgery and life-threatening diseases respectively. In addition, depending on the

extent of surgery and the time passed since surgery, there is a shift in the main topics with regards to recovery. Concerns about nausea, for example, are more prominent in the first days after surgery, whereas return to work plays a role at the end of the recovery period. With regards to the two Dutch recovery instruments, the application of the Quality of recovery-40 is more appropriate during hospitalization, whereas the Recovery index-10 is more suitable in recently discharged patients. The English version of the Quality of recovery-40 has shown to be valid in a wide range of surgical procedures (17), whereas the Recovery index-10 has only been studied in hysterectomy patients up until now.

In the study on women's preference for either approach to hysterectomy (Chapter 8), it is shown that over 80% of women would choose laparoscopic hysterectomy when counselled for abdominal and laparoscopic hysterectomy. Although 75% of women stated that the avoidance of complications is "very important", the majority of women accepted a doubled major complication rate in laparoscopic hysterectomy as compared with abdominal hysterectomy. A shorter recovery period was ranked as "very important" in only 50% of women. Apparently, complication rates in laparoscopic hysterectomy are perceived within acceptable limits and the controversy on complications versus recovery in abdominal and laparoscopic hysterectomy is settled in favour of laparoscopic hysterectomy.

It is assumed that laparoscopic hysterectomy is feasible in 25% of hysterectomies, although this rate will be reciprocal with the local vaginal hysterectomy rate. Since over 80% of patients would choose laparoscopic hysterectomy when offered and only 4% of hysterectomies in the Netherlands in 2002 were performed by laparoscopic approach (10), only a limited number of Dutch gynaecologists seem to offer this approach. In view of the patients' preference for the laparoscopic procedure, either more gynaecologists need to become familiar with laparoscopic hysterectomy or a referral system with centralization of the procedure is needed.

It is only since recently, that a causal relationship between hysterectomy and pelvic organ dysfunction has been refuted (18). Until now, however, little is known on the relative safety in this respect of either approach to hysterectomy. In our randomized controlled trial (Chapter 5), significantly less urinary problems have been found one year after surgery following laparoscopic hysterectomy as compared with abdominal hysterectomy. The reason for this remains hypothetical, but is possibly due to a less traumatic dissection of the bladder in laparoscopic hysterectomy. A potential difference in pelvic organ function following laparoscopic and abdominal hysterectomy is an important factor, since dysfunctions have a large and long-lasting impact on the patients' quality of life (19). Consequently, further investigation of urinary dysfunctions associated with hysterectomy is needed.

Increasing costs of medical care are a matter of political concern, since these costs are increasing relatively fast. Cost-utility analyses can be used to weigh benefits and costs of new techniques, and the assessment of costs for an additional quality adjusted life year has been mentioned as an appropriate outcome in this respect (20). In a cost-utility analysis of laparoscopic hysterectomy versus abdominal hysterectomy, no significant difference has been reported at the

end of one-year follow-up (21). In this cost-utility analysis, a generic health-related quality of life instrument was used to assess differences in quality of life. Since recovery specific instruments have superior properties for the assessment of these differences, a cost-utility analysis using a recovery specific instrument would be an interesting topic for future research. Differences in both quality of life as well as costs for the hysterectomy are visible on the short term, i.e. within the first three months after surgery (Chapter 3, 4 and 7). As a consequence, the cost-utility analysis can be performed in a study with this short follow-up, which avoids neutralization of the cost and quality of life differences when spread out over a year.

The three levels of decision-making in health care are decisions on resource utilisation, decisions for groups of patients and decisions for individual patients (22). As this thesis demonstrates, laparoscopic hysterectomy, particularly when performed by experienced surgeons, has shown to be a good alternative on all these three levels. It has even shown to be superior to abdominal hysterectomy on a considerable number of outcomes. This implies that laparoscopic hysterectomy deserves to be widely implemented in clinical practice.

Conclusions

When performing hysterectomy, vaginal hysterectomy is the first choice approach. When vaginal hysterectomy is not feasible, the individual choice for laparoscopic or abdominal hysterectomy should be balanced against the available evidence of benefits and hazards of the procedures, individual patients' characteristics, patients' and doctors' preferences, and surgical skills (Chapter 2).

Laparoscopic hysterectomy is associated with higher post-operative quality of life scores and enhanced post-operative recovery in the first twelve weeks after surgery as compared with abdominal hysterectomy (Chapters 3, 4 and 7).

Laparoscopic hysterectomy is associated with a better pelvic organ function one year after surgery as compared with abdominal hysterectomy (Chapter 5).

Recovery specific instruments assess post-operative recovery more validly as compared with a generic health-related instrument (Chapter 7).

Available English-version recovery specific instruments with superior measurement properties are the Postdischarge surgical recovery scale and the Quality of recovery-40 (Chapter 6 and 7).

Available Dutch-version recovery specific instruments with superior measurement properties are the Quality of recovery-40 and the Recovery index-10 (Chapter 6 and 7).

Women prefer laparoscopic hysterectomy to abdominal hysterectomy (Chapter 8).

Topics for future research

Further exploration of the impact of surgical experience level, uterine size and subcategory of laparoscopic hysterectomy on complication rates in hysterectomy.

Further exploration of the influences of surgical approach to hysterectomy on urinary symptoms.

Further validation of recovery specific instruments (Postdischarge surgical recovery scale, Recovery index-10 and Quality of recovery-40).

Cost-utility analysis of approaches to hysterectomy using a recovery specific instrument and short-term follow-up (i.e. three months).

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10 Summary

Summary

In **Chapter 2**, the available evidence on effectiveness, costs and cost-effectiveness of various hysterectomy techniques was compared.

Effectiveness

When technically feasible, vaginal hysterectomy is preferred over laparoscopic and abdominal hysterectomy. In case vaginal hysterectomy is not feasible, laparoscopic hysterectomy results in less operative blood-loss, less pain and less infectious morbidity, as well as a shorter hospital stay and more rapid return to normal activities as compared with abdominal hysterectomy. However, these benefits, need to be weighed against a longer operating time and a higher risk of urinary tract injuries in laparoscopic hysterectomy.

Costs

In the various randomised controlled studies on costs of different treatment options for menorrhagia, medical treatment, treatment with the levonorgestrel-IUD and endometrial ablation, were associated with lower costs as compared with randomisation for hysterectomy. Furthermore, the vaginal approach is the hysterectomy technique associated with the lowest costs. In studies on hospital costs in abdominal hysterectomy, these costs were either equal or lower, as compared with costs in laparoscopic hysterectomy. In case of differences among the hospital costs in the two techniques, these were neutralised by differences in societal costs, such as productivity loss.

Cost-effectiveness

A cost-utility analysis at one-year follow-up favoured randomisation for treatment with the levonorgestrel-IUD as compared with hysterectomy. In women undergoing hysterectomy, vaginal hysterectomy is cost-effective as compared with laparoscopic hysterectomy and is likely to be cost-effective as compared with abdominal hysterectomy. The difference in cost-effectiveness between laparoscopic and abdominal hysterectomy is more balanced, especially when avoiding the use of disposable instruments.

The objective of the study in **Chapter 3** was to investigate the results from randomised studies reporting on quality of life following laparoscopic hysterectomy as compared with abdominal hysterectomy. The studies were assessed for the methods in which they reported on postoperative quality of life as an outcome measure. We identified, thirty papers, published between 1994 and 2004. Only seven studies, incorporating data on 1,450 patients, reported on quality of life. In the four studies using validated instruments, eight different validated quality of life questionnaires were used. Two of these studies reported significant differences in quality of life in the first six weeks, favouring laparoscopic hysterectomy.

In **Chapter 4**, quality of life after total laparoscopic hysterectomy versus total abdominal hysterectomy was compared in a randomised controlled trial. Fifty-nine patients scheduled for

hysterectomy for a benign condition, in whom a vaginal hysterectomy was not possible and laparoscopic hysterectomy was feasible, were included. The primary outcome of the study was quality of life as measured by the RAND-36, whereas secondary outcomes were hospital stay and complications. Laparoscopic hysterectomy performed better as compared with abdominal hysterectomy, on all scales of the RAND-36, although these differences were only statistically significant in the scale for vitality. Overall complication rate (22% versus 53% of patients) and hospital stay (four versus five days) significantly favoured laparoscopic hysterectomy.

In **Chapter 5**, pelvic organ function was studied in seventy-six randomised hysterectomy patients. In contrast with Chapter 4, the women with both endometrial carcinoma and benign indications for hysterectomy, were included in the study. Data on the incidence of urinary incontinence and sexual problems were collected before and after surgery. Furthermore, the women completed the Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ), Defaecatory Distress Inventory (DDI) and the Questionnaire for screening Sexual Dysfunctions (QSD) one year after surgery. This study showed that the incidence of urinary incontinence at three month after surgery decreased equally in both groups as compared with baseline. Furthermore, de novo urinary incontinence and sexual problems were rare. One year after surgery, a significant treatment effect favouring laparoscopic hysterectomy was found in the UDI and IIQ, whereas no differences were found in the DDI and QSD.

Chapter 6 provides a systematic review of the literature on postoperative recovery specific quality of life instruments and their measurement properties. Existing quality criteria were applied to the measurement properties of 12 instruments detected by an extensive literature search. None of the instruments had been validated completely in line with the quality criteria. However, two instruments were superior, which were the Postdischarge surgical recovery scale and the Quality of recovery-40. We advise to use these two instruments in future studies on short-term postoperative recovery.

The aim of the study from **Chapter 7**, was to evaluate the relative quality of measurement properties of the Quality of Recovery-40 (QoR-40), Recovery Index-10 (RI-10) and RAND-36 health survey for the assessment of postoperative recovery. One hundred and sixty-one women completed the three questionnaires at several time points in the first 12 weeks after surgery. Both response rate and internal consistency were found satisfactory for all instruments. Construct validity was highest in the RI-10. Furthermore, the RI-10 showed the most marked change over time and was more responsive as compared to the QoR-40 and RAND-36. However, in hospitalised patients in their first days after surgery, validity and responsiveness of the QoR-40 were satisfactory as well. In conclusion, the RI-10, which is a recovery specific instrument, was most validly assessing postoperative recovery, although application of the QoR-40 is likewise appropriate in hospitalised patients in their first days after surgery

In **Chapter 8**, women's preference for laparoscopic or abdominal hysterectomy was assessed in standardised interviews and questionnaires. After explanation of the advantages and disadvantages of the two procedures, more than 80% of women preferred laparoscopic hysterectomy. Although the avoidance of complications was indicated as the most important treatment characteristic, only 15% of women regarded a two-fold increased risk of major complications in laparoscopic hysterectomy as unacceptable. More than half of the women perceived 1% as the maximum acceptable major complication rate. This rate can only be achieved by experienced surgeons. The slow implementation of laparoscopic hysterectomy in clinical practice is in contrast with women's preference for this approach.

11 Samenvatting

In **hoofdstuk 2**, werden de beschikbare gegevens over effectiviteit, kosten en kosteneffectiviteit van de verschillende technieken van hysterectomie (baarmoederverwijdering) met elkaar vergeleken.

Effectiviteit

Indien technisch mogelijk, is de vaginale hysterectomie te prefereren boven de laparoscopische en abdominale hysterectomie. Indien een vaginale hysterectomie niet mogelijk is, dan gaat de laparoscopische hysterectomie gepaard met voordelen van minder peroperatief bloedverlies, minder pijn, minder infecties, evenals een kortere opname duur en sneller hervatten van de dagelijkse bezigheden ten opzichte van de abdominale hysterectomie. Deze voordelen moeten echter afgewogen worden tegen een langere operatieduur en meer risico op laesies aan de urinewegen bij de laparoscopische hysterectomie.

Kosten

In verschillende gerandomiseerde studies waarin de kosten van verschillende opties voor de behandeling van menorragie werd vergeleken, gingen medicamenteuze behandeling, behandeling met het levonorgestrel-spiraal en ablatie van het endometrium gepaard met lagere kosten in vergelijking met hysterectomie. In geval van hysterectomie, is de vaginale hysterectomie de techniek met de laagste kosten. In studies naar de hoogte van ziekenhuiskosten bij abdominale hysterectomie, waren deze lager of gelijk in vergelijking met de kosten bij laparoscopische hysterectomie. Indien de ziekenhuiskosten verschilden, werd dit verschil opgeheven door een verschil in maatschappelijke kosten, zoals kosten van productiviteitsverlies.

Kosteneffectiviteit

In een kostenutiliteitsstudie met een follow-up van een jaar, werd een voordeel gevonden van randomisatie voor het levonorgestrel-spiraal in vergelijking met randomisatie voor hysterectomie. De vaginale hysterectomie is kosteneffectief in vergelijking met de laparoscopische hysterectomie en waarschijnlijk ook in vergelijking met de abdominale hysterectomie. Het verschil in kosteneffectiviteit tussen de laparoscopische hysterectomie en de abdominale hysterectomie is kleiner, vooral indien het gebruik van materiaal voor éénmalig gebruik wordt vermeden.

Het doel van de studie in **hoofdstuk 3** was om de resultaten van gerandomiseerde studies over kwaliteit van leven na laparoscopische en abdominale hysterectomie te evalueren. Van deze studies werd de methode in kaart gebracht die werd toegepast om de kwaliteit van leven te meten. We identificeerden dertig studies, gepubliceerd tussen 1994 and 2004. Slechts zeven studies, met data van 1450 patiënten, rapporteerden over kwaliteit van leven. In de vier studies die gebruik maakten van gevalideerde meetinstrumenten, werden acht verschillende gevalideerde kwaliteit van leven vragenlijsten toegepast. Twee van deze studies rapporteerden een significant verschil en wel een betere kwaliteit van leven in de eerste zes weken na laparoscopische hysterectomie in vergelijking met abdominale hysterectomie.

In **hoofdstuk 4** werd de kwaliteit van leven na totale laparoscopische hysterectomie in vergelijking met de abdominale hysterectomie in een gerandomiseerd onderzoek geëvalueerd. Negenenvijftig patiënten, gepland voor hysterectomie omwille van een goedaardige aandoening, waarbij een vaginale hysterectomie niet mogelijk was en een laparoscopische hysterectomie haalbaar leek, werden geïncludeerd. De primaire uitkomstmaat van de studie was kwaliteit van leven zoals gemeten met behulp van de vragenlijst RAND-36. De opnameduur en het complicatiepercentage waren de secundaire uitkomstmaten. Er was een significant betere kwaliteit van leven na de laparoscopische hysterectomie in vergelijking met abdominale hysterectomie in het RAND-36 domein Vitaliteit. De laparoscopische hysterectomie ging tevens gepaard met een betere kwaliteit van leven in alle overige domeinen, maar deze verschillen waren niet statistisch significant. Het totale complicatiepercentage (22% versus 53% van de vrouwen) en de opnameduur (vier versus vijf dagen) toonden een significant voordeel van de laparoscopische hysterectomie.

In **hoofdstuk 5,** werden problemen van urine incontinentie, verzakking, defaecatie en seksualiteit onder zesenzeventig gerandomiseerde vrouwen bestudeerd. In tegenstelling tot hoofdstuk 4, werden de vrouwen met zowel goedaardige als ook kwaadaardige aandoeningen geïncludeerd. De gegevens over het voorkomen van urine incontinentie en problemen met seksualiteit voor en na operatie werden opgenomen en de vrouwen vulden een jaar na de operatie de urogenitale klachtenlijst (UKL), incontinentie impact lijst (IIL), defaecatie klachtenlijst (DKL) en de vragenlijst voor het signaleren van seksuele dysfuncties (VSD) in. In deze studie toonden wij aan, dat de incidentie van urine incontinentie drie maanden na de operatie even veel gedaald was in de twee groepen ten opzichte van voor de operatie. Verder kwamen nieuwe klachten van urine incontinentie en seksuele problemen nauwelijks voor. Een jaar na de operatie werd een significant behandelingseffect in het voordeel van de laparoscopische hysterectomie gezien in de UKL en IIL, terwijl er geen verschillen in de DKL en VSD werden gevonden.

Hoofdstuk 6 geeft een systematisch overzicht van de literatuur over meetinstrumenten naar postoperatief herstel en hun meeteigenschappen. Bestaande kwaliteitscriteria werden toegepast op de meeteigenschappen van 12 instrumenten, die gevonden werden bij een uitgebreid literatuur onderzoek. Geen van de instrumenten was geheel in de lijn van de kwaliteitscriteria gevalideerd. Er waren echter twee instrumenten superieur: de Postdischarge surgical recovery scale and de Quality of recovery-40. Wij adviseren om één van deze twee instrumenten te gebruiken in toekomstige studies naar het postoperatieve herstel op de korte termijn.

Het doel van de studie beschreven in **hoofdstuk 7** was het evalueren van de relatieve kwaliteit van de meeteigenschappen van de Quality of Recovery-40 (QoR-40), Recovery Index-10 (RI-10) and RAND-36 voor wat betreft de postoperatieve herstelmeting. Honderdéénenzestig vrouwen vulden de drie vragenlijsten op meerdere tijdstippen gedurende de eerste twaalf weken na de

operatie in. Zowel het response percentage als ook de interne consistentie waren tevredenstellend. Construct validiteit was het hoogste voor de RI-10. Verder toonde de RI-10 de meest uitgebreide verandering van score door de tijd en was meer responsief dan de QoR-40 and RAND-36. Voor patiënten in het ziekenhuis in de eerste dagen na operatie, waren de validiteit en responsiviteit van de QoR-40 eveneens goed.

De conclusie was dat de RI-10, een herstelspecifiek instrument, het meest valide het postoperatieve herstel meet. Ook de QoR-40 is goed toepasbaar bij patiënten in het ziekenhuis in de eerste dagen na operatie.

In **hoofdstuk 8** werd de preferentie van vrouwen voor de laparoscopische of abdominale hysterectomie gemeten met behulp van interviews en vragenlijsten. Na uitleg over de voor en nadelen van de twee ingrepen, prefereerde meer dan 80% van de vrouwen de laparoscopische hysterectomie. Hoewel het vermijden van complicaties het meest belangrijk werd gevonden, was een verdubbeling van het risico op grote complicaties bij de laparoscopische hysterectomie maar voor 15% van de vrouwen onacceptabel. Voor meer dan de helft van de vrouwen was 1% het maximaal aanvaardbare complicatie risico. Dit percentage kan alleen behaald worden door ervaren operateurs. De trage implementatie van de laparoscopische hysterectomie staat in contrast met de voorkeur van vrouwen voor deze ingreep.

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Curriculum vitae

Kirsten Kluivers werd op 22 december 1969 te Arcadia, Ca, USA geboren. Na een jaar verhuisde haar gezin naar Zoetermeer. Op negen jarige leeftijd vertrokken zij voor zes jaar naar Curaçao. Zij haalde haar VWO-B diploma aan het Alfrink College te Zoetermeer en studeerde vervolgens eerst twee jaar Plantenveredeling aan de Landbouw Universiteit te Wageningen. Zij voltooide de medische opleiding aan de Justus von Liebig Universität, Giessen in Duitsland. Het laatste jaar van haar studie bracht zij door in USA, Nederland en Zwitserland. Na het behalen van haar artsexamen keerde zij terug naar Nederland en werkte anderhalf jaar als AGNIO in het Ziekenhuis Gelderse Vallei te Wageningen, het Bosch Medicentrum te Den Bosch en het Sint Lucas Andreas Ziekenhuis te Amsterdam. De opleiding tot gynaecoloog voltooide zij in het Academisch Ziekenhuis Maastricht onder leiding van Prof dr J.L.H. Evers en in het Máxima Medisch Centrum te Veldhoven onder leiding van Prof dr H.A.M. Brölmann en Prof dr S.G. Oei. In Veldhoven werd de basis gelegd voor het huidige proefschrift. Sinds het einde van de specialistische opleiding (31 maart 2005), volgt zij een fellowship algemene gynaecologie en urogynaecologie aan het Universitair Medisch Centrum St Radboud, Nijmegen onder leiding van Prof dr M.E. Vierhout. Zij is actief in de voortgangstoets commissie van de Nederlandse Vereniging voor Obstetrie en Gynaecologie en werkt mee aan verschillende onderzoeksprojecten op het gebied van de algemene gynaecologie en urogynaecologie.

Kirsten Kluivers was born on the 22nd of December 1969 in Arcadia, Ca, USA. One year later, her family moved to Zoetermeer, the Netherlands. From 1979 till 1985, the family lived on Curaçao (Netherlands Antilles). After the final exam of secondary schooling in 1988, she started agricultural studies at the University of Wageningen, the Netherlands. Two years later, she switched to medical studies at the Justus von Liebig University in Giessen, Germany, of which the last year was spent in the USA, the Netherlands and Switzerland. After her medical finals, she returned to the Netherlands and started the formal obstetrics and gynaecology training 18 months later at the Academic Medical Center, Maastricht, the Netherlands. The training was finished on the 31st March 2005 in the Máxima Medical Center, Veldhoven, the Netherlands, where the clinical studies included in this thesis have been conducted. Nowadays, she works as a gynaecologist in the field of benign gynaecology and urogynaecology at the Radboud University Medical Centre Nijmegen, the Netherlands.