PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND 1996 – 2006
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VERSION 1 - REVIEW

REVIEWER	Øjvind Lidegaard Professor Department of Gynaecology Rigshospitalet University of Copenhagen Denmark No conflict of interest with this review.
REVIEW RETURNED	21-May-2013

GENERAL COMMENTS	This observational case-only study assessed complication rates in different types of hysterectomies on benign indication in Finland in 1996 and 2006, and demonstrated an almost halving in number of hysterectomies and an increasing proportion of vaginal and laparoscopic hysterectomies from 1996 to 2006. Main results: The rate of complications changed from 1996 to 2006 from 16.2% to 19.2% for AH, from 22.2% to 11.7% for VH and from 17.0% to 15.5% for LH. Bowel injuries in 2006 compared to 1996 were less common in the VH group and unchanged in the AH and LH groups, and ureter lesions decreased in the LH group. General comments This type of quality control is today routinely conducted in several Scandinavian countries. A critical parameter in assessing complications in hysterectomies is an almost complete coverage. This coverage was in this study 92% in 1996 but only 79% in 2006. This is critical, because we know that complicated hysterectomies are less likely to be reported to quality databases than uncomplicated hysterectomies. With one fifth of all hysterectomies lacking in 2006, the complication rates could be underestimated. No discussion about this important issue is given in the discussion section. The next problem is that the patients in the three groups AH, VH and LH were very different in 1996 and in 2006. Therefore, the complication rates for the different types of hysterectomy should ideally be adjusted for this change in patients undergoing each type of hysterectomy, an adjustment which, however, will be difficult to realise. The first thing to be done is to add an extra column in Table 1 and Table 2 and an extra row in Fig. 3 indicating the overall

	complication rates for all hysterectomies. Thereby it is possible to see whether the change in surgical practice actually improved the overall hysterectomy complication rates. Similarly, each of the organ complications in Table 2 should have a "total" row, adding the complication among the non-skilled and skilled surgeons. In the abstract all abbreviations should be defined (AH, VH, LH). The result section in the abstract should be focused the overall complication rates rather than the stratified results for each operation type. Throughout the paper, the figures in Fig. 1 and Fig. 2 are referred to as "rates". The correct expression here is however "proportion". Rates indicate a number of events per a certain population per year. For example the authors indicate that the rate of LH has increased from 24% to 32%. But 24% of 10,110 is 2,426 while 32% of 5,279 is 1,689, indicating a significant fall in the rate of VH from 1996 to 2006. The proportion of LH of all hysterectomies on the other hand increased from 24% to 32%. In the discussion, the first paragraph is good and valid, as randomised studies in this scale are very difficult to realise. But it is important to focus on the limitations of the observational design, e.g. the changed patient populations for the three hysterectomy groups from 1996 to 2006, and thereby the difficulties to assess whether the improvement in some parameters are a result of a real clinical improvement, rather than just a change in the population undergoing a certain type of hysterectomy. The complication rates should be compared with similar complication rates indicated in for example the Danish hysterectomy database or corresponding database in Sweden, in order to compare the incidence rates of complications in Finland with the corresponding rates in Denmark. Conclusion The most important limitation of this study is the low coverage in 2006 of less than 80%. One possible option is to make an assessment of complications in the National Hospital Discharge Register among the missing 20%. Such an assessment will probably underestimate the occurrence of complications, but it would be possible to compare the complication rates among those being reported to FINHYST study with those not being reported, and thereby providing a suggestion about the importance of the missing data on 20% of the patients.

REVIEWER	Professor Dr. Arnd Hönig Vice director University of Wuerzburg Dep. of OB/GYN Josef-Schneider Str. 4 Germany
REVIEW RETURNED	01-Jun-2013

GENERAL COMMENTS	Review Line scheduled not schedued Line 111 perioperative not perooperative There are very investigations analyzing hysterectomies in such a

	relevant way. Although the procedures analyzed are very frequently performed data is scarce. The study is scientifically interesting and of relevance for daily practice. It shows that first of all the experience of the surgeon is crucial. If a surgeon performs a technique frequently complications decrease. To some degree a certain technique/approach (LH,VH, AH) might have less impact on outcome and the varying experiences of surgeons could be a bias for the analysis of techniques. Of note the rate of VH increased from 18% to 44% in Finnland, which is remarkable. The authors conlude that the vaginal approach should be used whenever possible. Beneficial for patiens is that the complication rate significantly decreased in the latter analysis of 2006. As AH is used in “more severe and advanced cases” results dealing with complications should rated with caution. Of note is that overregulation (asking for the social security number within the study) leads to lower study participation and is not beneficial for research. Overregulation is not only be found in Finnland. Finnland seems to be recommendable in terms of collaboration with regard to clinical practice and training. One of the very few countries with data collection for research and quality control. Conclusion: The paper definitely needs to be published. There are always some weaknesses in observational studies which are outweighed by far by its strengths considering the enormous clinical relevance of the paper.

VERSION 1 – AUTHOR RESPONSE

By thanking the reviewers, we respond to their fruitful comments with the following replies numbered 1 - 2a to 2h. Corrections are given as bold in the text.

1. Limitation of the study

We agree that the most important limitation of the study is the coverage of data in 2006, representing 79.4% of annual hysterectomies. We have discussed this problem in the section of discussion (6th paragraph). We had also discussed the (additional) assessment of possible complications in missing cases from our national register of the Patient Insurance Center (in the same paragraph). This register based evaluation of major complications resulted in much lower rates as it is register-based, retrospective, and concentrated only to major complications. This is exactly why we have performed our prospective evaluation in the first place: to collect every complication. Furthermore

2. Other comments (a- h)

a. We also agree that the problem is that the patients in various hysterectomy groups were different in 1996 and in 2006. However, it was not possible (realistic) to adjust the complications rates for this change. This matter is also discussed in the section of discussion (paragraph 7). We have also added a sentence about the “common” limitation in the observational studies whether the improvements in some parameters are result of real clinical improvement rather than just a change in the population undergoing certain type of hysterectomy (in the same paragraph).

b. Regarding the table 1 (indicating the patient characteristics of both study years) it was not possible (and logical) to add the overall complication rates analyzed for all hysterectomies in both study years.

However, we have added this very important information as pointed by the reviewers in the text in the section of results and also in the abstract.

c. Instead of adding the total rate of different organ injuries for non-skilled and skilled surgeons in the table 2 they are given in the (suggested) table 3 (see below).

d. Regarding the figure 3, three rows have been added indicating the total complications for each hysterectomy type (AH, VH and LH) in both study years 1996 and 2006. - If the reviewers and the editorial board agree, we suggested to use an additional table (numbered table 3; attached) instead of the figure 3. This table would also give additionally the numbers for each parameter with the existing percentages.

e. The abbreviations of AH, VH and LH have been more clearly defined in the section of abstract.

f. The ”rates” referred in figures 1 and 2 and also in the text have been changed into the correct expression ”proportion”.

g. Instead of the expression of perioperative events we had used in the text the expressions preoperative, peroperative and postoperative (1st paragraph in section of methods)

h. We have also added in the section of discussion short comment for the comparison of available (infectious) rates of complications from Sweden and Denmark (paragraph 8).

10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND 1996 – 2006. A LONGITUDINAL OBSERVATION STUDY

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Running title: Improved hysterectomy outcomes in Finland 1996 - 2006

Abstract

Background The morbidity associated with hysterectomy has been studied cross-sectionally in observational studies, case-controlled and randomized trials, large hospital based series and meta-analyses but never longitudinally. We compared hysterectomy practices and patient outcomes of cohorts operated in 1996 and 2006.

Methods A nationwide, prospective evaluation of women undergoing abdominal hysterectomy (AH), vaginal hysterectomy (VH) or laparoscopic hysterectomy (LH) for benign conditions was made in 1996 (N=10110) and was followed by this trial in 2006 (N=5276). All hospitals in Finland participated. Patient characteristics, surgery-related outcomes and complications were analyzed.

Findings In 1996, AH was the main approach (58%), but was surpassed within a decade by VH and LH (together, 76% of all hysterectomies in 2006). Analysing all hysterectomies together the rate of overall complication declined from 17.5 % in 1996 to 14.7 % in 2006 ($p<0.001$). Stratifying the results for each operation type a decrease was also observed in LH, and markedly in VH (from 22.2% to 11.7%, $p<0.001$). The overall surgery-related infectious morbidity decreased in all groups and significantly in VH (from 12.3% to 5.2%, $p<0.001$) and AH (from 9.9% to 7.7%, $p<0.05$). The rate of bowel lesions in VH sank from 0.5% to 0.1% and of ureter lesions in LH from 1.1% to 0.3%. In 2006 there were no deaths compared to three in 1996.

Interpretation The rate of postoperative complications fell markedly from 1996 to 2006. This seems to be associated with better training of gynecological surgeons, more widespread use of prophylactic antibiotics and antithrombotics, and better targeting of patient selection for each specific type of hysterectomy. Furthermore, this study is the only one thus far where the order of preference of hysterectomies is precisely followed nationwide, as recommended in a recent meta-analysis by the Cochrane collaboration.

Funding: No funding

Keywords: Hysterectomy, complications, longitudinal cohort study

The 2006 study was registered in the Clinical Trials of Protocol Registration System Data (NCT00744172).

Introduction

With the advent of laparoscopic hysterectomy (LH) in the late 1980's1 the role of vaginal (VH) and abdominal hysterectomies (AH) has been a matter of re-evaluation. The rate of abdominal hysterectomies (AH) has subsequently fallen in some countries (Figure 1),2-6 but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in favour of VH and LH, which are less traumatizing procedures than AH.

More than twenty years ago a systematic follow-up of the advantages and disadvantages of the then novel laparoscopic method for performing hysterectomy would have been scientifically and clinically very much in order. However, the opportunity of collecting valuable pioneering data on the benefits

and disadvantages of LH in comparison to the established methods (VH and AH) was never grasped. In Finland, a nationwide study on the morbidity related to AH, VH and LH for benign conditions was conducted in 1996.8 Not surprisingly, the most modern method, LH, was, at that time, associated with more severe complications than the other methods. The rate of complications stood also in proportion to the experience of the surgeons – the more experienced the surgeon, the less LH-associated complications.

Since the beginning of the 2000's, several smaller studies, hospital-based series of LHs2 and RCTs18-19 have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate.20-21 There are, however, no longitudinal follow-up studies on the results of hospital-based or nationwide studies on patients undergoing hysterectomy. Such studies are not only scientifically important but they also constitute important measures of quality control and are, as such, badly needed to help us to understand what we have learned of the different approaches to hysterectomy during all these years.22 We conducted a nationwide survey on the outcomes of hysterectomies of two cohorts first in 1996 and second in 2006. In this paper we compare the results after AH, VH and LH for benign conditions in 2006 6 with the results 10 years previously. 8

Methods

Information on all hysterectomies performed for benign conditions in Finland was prospectively registered from January 1st to December 31st, 2006, by the operating gynecologist.6 Data collection was nationwide and followed the same procedure as in the survey ten years previously, the FINHYST 1996 study. 8 A dedicated form (FINHYST 2006) was used to collect data on preoperative, peroperative and postoperative events and operation-related morbidity during the patients' hospital stay and convalescence. Severe organ complications were defined as injuries to bladder, ureter and/or bowel. All Finnish 53 hospitals participated and produced 5324 forms, 45 of which were censored, usually because the final diagnosis was a malignant condition. The final data set consisted thus of 5279 hysterectomies; this covers 79.4% of all hysterectomies for a benign condition (5279 / 6645) reported to national Hospital Discharge Register. In the FINHYST 1996 study, the cohort coverage was higher (92.1%, N=10110) and the number of participating hospitals was 60 at that time. The FINHYST 2006 study was approved by the Ministry of Social Affairs and Health (Dnro STM/606/2005), by the Helsinki University Hospital Institutional Review Board (IRB) and by the Ethics Committee of the Department of Obstetrics and Gynecology of the Helsinki University Hospital (Dnro 457/E8/04). The 2006 study was registered in the Clinical Trials of Protocol Registration System Data (NCT00744172).

Consistency of the data and missing information were thoroughly reviewed. The hysterectomies were divided into three groups: AH, VH, and LH.23 To facilitate comparisons between the data sets in 1996 and 2006, each patient was defined as having had a complication or not. Categorical data were analyzed by the χ^2-test or Fisher's exact probability test, and the means of continuous variables were analyzed pair wise with Student's t-test. Statistical significance was set at $p<0.05$. All calculations were performed with the SPSS 17.0 software.

Results

The proportions of VH and LH in Finland increased markedly in the decade from 1996 to 2006, while the proportion of AH fell to less than half (Figure 2). At the same time, the proportion of the less invasive hysterectomies, LH and VH, had surpassed AH in all hospitals and the overall number of hysterectomies dwindled from 10,110 to 5,279 (reduction of 47.8%). In 2006, 1.7% of all hysterectomies were subtotal, in 1996 7.3%. In 2006, the most common indication for AH was fibroids 58% (in 1996 67%), for VH uterine prolapse 61% (in 1996 83%) and for LH fibroids 39% (in 1996 56%) and menorrhagia 30% (in 1996 47%).

In 2006 hysterectomy was performed on significantly older patients in the AH and LH groups but younger in the VH group compared to 1996 (Table 1). Also, the mean BMI had increased significantly in the AH and LH groups but not in the VH group. The average uterine weight had risen significantly in all groups, most in the AH group, while the duration of the operation decreased significantly for LH and for VH, but increased for AH. Perioperative hemorrhage in VH decreased significantly and increased in AH and in LH but not significantly in LH. In all groups the duration of the hospital stay was significantly reduced, mostly in the VH group. The convalescence period decreased significantly in the AH and VH groups but increased slightly in the LH group (Table 1).

Analysing all hysterecomies together the overall complication rates declined very significantly from 17.5 % in 1996 to 14.7 % in 2006 (<0.001). The rate of complications in 1996 was 16.2% for AH, 22.2% for VH and 17.0% for LH. Ten years later there was a slight increase to 19.2% in complications among AH-patients ($p<0.05$) but a significant decrease to 11.7% in the VH ($p<0.001$) and a non-significant decrease to 15.5% in LH. The overall occurrence of organ injuries was significantly reduced only in the LH group from 2.8% to 1.7% ($p<0.05$). Of the severe organ complications bowel injuries were significantly less common only in the VH group in 2006 compared to 1996 and there was no difference in this respect in the AH and LH groups (Figure 3). Similarly, ureter lesions occurred significantly less often only in the LH group in 2006 than in 1996.

The use antibiotic prophylaxis increased from 82.1% to 97.5% ($p<0.001$) in a decade, and also the selection of antibiotics changed. In 1996 metronidazole was given as a single prophylactic agent to 66.7% of all patients, but in 2006 to only 9.9%. In 2006 cefuroxime was the primary choice of antimicrobial agent alone or in combination with metrionidazole for 82.1% but in 1996 only for 15.3%. There were concomitantly significant reductions in the overall rate of infections; in the AH group from 9.9% to 7.7.% ($p<0.05$), in the VH group from 12.3% to 5.2% ($p<0.001$) but a non-significant change from 17.0% to 15.4% in the LH group.

Also, the use of pharmacological thrombosis prophylaxis had risen from 35.4% in 1996 to 64.8% in 2006 ($p<0.001$) and there was a concomitant reduction in VTEs in all groups, which was significant in the LH group (Figure 3). In 2006, there were no surgery-related deaths, whereas in 1996 there was one death in each hysterectomy group. The occurrence of postoperative hemorrhage in the LH group increased significantly from 1996 to 2006 (Figure 3).

The intraoperative detection of organ injuries in LH increased from 60% in 1996 to 75% in 2006. Postoperative ileus occurred at a similar rate in 1996 and 2006: AH 1.0% vs. 0.6%, LH 0.3% vs. 0.2%, and VH 0.1% vs. 0.2%. The incidence of urinary retention was significantly higher ($p<0.001$) in the VH group in 1996 (3.1%) than in 2006 (1.6%) while in the AH group it was 0.5% both in 1996 and 2006 and in the LH group 0.9% and 0.5% in 1996 and 2006, respectively.

By 2006 the percentage of surgeons with experience of more than 30 hysterectomies had risen most markedly among surgeons performing LH: from 62% in 1996 to 73% in 2006 while there was no change for VH (78% in 1996, 76% in 2006) but for AH there was a sinking trend from 91% in 1996 to 75 % in 2006. The experience of the surgeons was associated to the occurrence of organ injuries.

Surgeons who had performed more than 30 hysterectomies in 1996, had significantly fewer ureter and bladder injuries, especially in the LH group, than the less experienced surgeons (Table 2). The same was the case for bowel injuries in 1996 in the VH group. In 2006, these differences were no longer present.

Discussion

The role of laparoscopic hysterectomy (LH) compared to the traditional abdominal (AH) and vaginal hysterectomy (VH) has been debated ever since the laparoscopic technique was introduced. It has been argued that LH is associated with higher expenses, longer operation times and a higher rate of complications. Large and comprehensive RCT-studies have been badly needed to give answers to these questions. Such studies need to be very large, even to the point of being unfeasible, if they are to have sufficient statistical power.22 Furhermore they would also need to be set up so that they discount the effect of the individual surgeon, the surgeon's experience and the effect of sophisticated surgical centres compared to ordinary hospitals. National registry-based observational surveys on large numbers of consecutive patients with prospective data collection are an alternative to cumbersome and, maybe, unrealistic RCT's and document effectiveness because they reflect clinical reality in the hands of the "average" gynecological surgeon.22 This alternative was chosen for the present nationwide study, which compares some clinical determinants related to hysterectomies (AH, VH and LH) and hysterectomy-related morbidity in 2006 with 1996 in Finland.

In the present study the growth of the popularity of VH was especially gratifying: the rate of VH increased from 18% in 1996 to 44% in 2006 (Figure 2), while the total number of complications, operation time, hemorrhage and bowel lesions related to VH decreased. All this took place despite the fact that the patients in 2006 were younger and were operated on for uterine descent less frequently – circumstances claimed to pose more operative challenges and yield complications. We believe that the vaginal approach should be used whenever possible.

The rate of LH increased also (from 24% to 36%). The current rate of LHs in Finland is high compared to our neighbouring Nordic countries (4-7%)4,12,15 and globally (Figure 1). Worldwide, only Taiwan has a higher rate of LH, where the rate of LH has soared from 5 % in 1996 to 40 % in 2005.5 In consequence, we have a much lower rate of AH (24%) compared to many other countries, e.g., the USA (68%)13 and the other Nordic countries Sweden (60%)15, Denmark (59%),4 Norway (78%).12 According to a recent meta-analysis by the Cochrane collaboration, the order of preference of hysterectomies should be VH and LH followed by AH .21This study shows that this is precisely the sequence of preferences followed in Finland.

The main finding of this study is that the overall complication rates related to VH and LH have decreased in Finland. Another important observation was that, of the severe organ lesions, ureter complications related to LH – one of the main concerns in 1996 8– have decreased highly significantly (from 1.1% to 0.3%). This finding is in accordance with a retrospective nationwide registry study on the complications of LH, which reported a continuously decreasing trend from 1993 to 2005 in ureter injuries in Finland.24 Also, the fact that LH-related bladder complications sank from 1.3% to 1.0% supports the notion that surgeons doing this operation have steadily gained experience and are better aware of the need to avoid harming the bladder and ureters. The rate of VH-associated bowel complications sank also significantly (Figure 3). For AH there was a slight increase in the occurrence of total complications (from 16% in 1996 to 19% in 2006), but this only reflects the fact that more severe and advanced cases required the abdominal approach in 2006.

The reduction in the number of infections, especially urinary tract infections, was probably due to the increased prophylactic use of antibiotics. The reduction of thromboembolic events is most likely due to

a consequence of increased and appropriate use of thromboprophylaxis. The aim to reduce both of these complications was discussed already some ten years ago at a consensus meeting with the members of the Society of Gynecological Surgery in Finland, and a unified, common prophylaxis management system with antibiotics and antithrombotics was introduced and implemented.25

Data coverage is a limitation of our study. We believe that one of the main reasons for the fact that in 1996 study the coverage was higher (92%) than in 2006 (79%) is related to the circumstance that the approval of the ethics committee in 1996 did not require us to collect the patients' social security numbers. In 2006, the survey was run according to new regulations which require that each patient provides full disclosure of her identity and a written informed consent. Since all other facets of the studies and the data collection were identical between the two studies, these requirements remain the only explanatory variable for the reduced participation coverage in 2006. This lower recruitment of hysterectomy forced us to perform a verification from the national register of the Patient Insurance Center, to which patients themselves report complications in seek of economical compensation. Among those who had been recruited to FINHYST 2006t and those who were unable to particpiate the rate of complications appeared similarly. Consequently, no selection bias was observed.

In 2006, compared to 1996, our patients were proportionately older, more obese and had a higher uterine weight, but still the duration of hospital stay in all hysterectomy types and the operation time for LH and VH was reduced (Table 1). Evidently, the need for hysterectomy will persist, but it will not be as high as in the late 1990's.27-28 The outlook is that hysterectomies will be safer than before. Recent indications for hysterectomies in Finland were more properly scrutinized and patients undergoing these procedures were more severly affected than a decade earlier. Of course, it would have been ideal to adjust the complications rates for the different types of hysterectomy because the patients in the three groups AH, VH and LH were very different in 1996 and 2006 byt unfortunately, this was not possible and realistic. Consequently, an absolute conclusion whether the improvements in some parameters are a result of a real clinical improvement rather than just a change in the populations cannot be drawn. However, the very significant decrease in overall complication rate in all hysterecomies between 1996 and 2006 support the clinical improvement.

The overall maximum rates of the most severe organ injuries (bladder, ureter, bowel) in all types of hysterectomies in Finland were 0.7% - 2.8% in 1996 and 0.7 - 1.7% in 2006. This improvement is encouraging and similar trends have been reported in other countries.2 This positive development has taken place in a time of a markedly decreasing need for hysterectomies mostly as a consequence of many new and effective conservative treatments of various bleeding problems (hormonal IUD, thermoablation etc.). Comparing the rates between other scandinavian countries (available only asinfectious morbidity) it shows that the Swedish national register for gynecological surgery in 2003 - 2006 reported postoperative infections with AH in 12.0 %, with LH in 15.0 % and with VH in 9.9 %. 26 Much lower results appeared in the Danish hysterectomy database which in 2006 reported postoperative infections (excl. urinary tract infections) only in 2 % of hysterecomies together. 4

Since the introduction of laparoscopic hysterectomy in Finland in the 1990's, gynecological surgeons have collaborated actively in clinical practice and training. This has resulted in a unified system of data collection for research and quality control. With the first FINHYST study in 1996 we identified matters needing improvement, after which practices were changed, training was increased and collaboration on a national level was implemented. As a consequence of this fruitful and collegial collaboration, hysterectomy-associated morbidity has decreased and patients are selected more appropriately for the traditional abdominal, vaginal or endoscopic route.

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Literature search: TB, PH and JM.

Figures: TB and JM.

Tables: TB and JM

Study design: all authors

Permissions: TB, PH, JS and JM

Data collection: TB and PH

Data analysis: TB, PH and JM

Data interpretation: all authors

Writing: all authors

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Table 1. Patient characteristics and surgery-related details (mean +/- SD) by hysterectomy method in 1996 and 2006.
ABDOMINAL VAGINAL LAPAROSCOPIC
1996
(N=5875) 2006
(N=1255) 1996
(N=1801) 2006
(N=2345) 1996
(N=2434) 2006
(N=1679)
Mean SD Mean SD Mean SD Mean SD Mean SD Mean SD
Age 48,8 8,7 50,1 8,8 58,6 13,2 55,0 11,8 47,0 7,5 49,2 8,5
BMI (kg/m2) 26,3 4,5 27,1 5,3 26,3 3,9 26,4 4,4 24,9 3,9 26,1 4,6
Oper time (min) 86 31 93 37 88 32 78 33 124 48 108 43
Hemorrhage (ml) 305 312 355 360 342 353 203 269 262 271 270 669
Uterine weight (g) 290 302 433 425 109 84 131 110 195 108 210 146
Hospital stay (days) 6.0 2,2 3,8 1,8 5,9 2,7 2,3 1,5 3,4 2,0 2,0 1,4
Convalescence (days) 34.4 5.3 32,3 4,6 34.0 8.8 29,4 8,0 21.5 8.8 22,0 6,3

All pairs (1996 vs. 2006) p<0.001, except in LH for hemorrhage (P=0.603) and in VH for BMI (P=0.48
Table 2. Rate and number of ureter, bladder and bowel injuries in various hysterectomies in Finland in relation to surgeon’s experience (more than 30 vs 30 or less than 30 hysterectomies) in 1996 and 2006
ABDOMINAL VAGINAL LAPAROSCOPIC
1996

(N=5875) 2006
(N=1255) 1996
(N=1801) 2006 (N=2345) 1996 (N=2434) 2006 (N=1679)
% n % n % n % n % n % n
Ureter injury
≤ 30 - 0,4 1 - - 2,2 20 0,3 1
> 30 0,2 9 0,3 3 - 0,04 1 0,5 ** 7 0,2 3
Bladder injury
≤ 30 - 1,1 3 - 0,6 3 2,0 18 1,3 5
> 30 0,5 28 0,7 7 0,4 4 0,5 9 0,8 * 12 1,0 12
Bowel injury
≤ 30 - - 1,3 5 0,2 1 0,4 4 0,3 1
> 30 0,2 12 0,3 3 0,3 * 4 0,06 1 0,3 5 0,4 5

* P = 0.05
** P < 0.001
Other comparisons (≤30 vs > 30): not significant

Table 3. The rate and number of complications in various hysterectomies in 1996 and 2006

ABDOMINAL

1996 2006
N=5875 N=1255
% n % N P
VAGINAL

1996 2006
N=1801 N=2345
% n % n P
LAPAROSCOPIC

1996 2006
(N=2434) (N=1679)
% n % n P
ORGAN INJURY
Ureter 0.2 9 0.3 4 0.212 - 0 0.04 1 0.381 1.1 27 0.3 5 0.004
Bladder 0.5 29 0.9 11 0.099 0.2 4 0.6 14 0.069 1.3 31 1.0 17 0.443
Bowel 0.2 12 0.2 3 0.807 0.5 9 0.1 2 0.010 0.4 9 0.4 7 0.811
Total/patient 0.9 50 1.4 18 0.054 0.7 13 0.7 17 0.991 2.8 67 1.7 29 0.032
INFECTION
Wound 3.1 180 2.4 30 0.200 0.9 20 <0.001 0.7 17 1.5 25 0.013
Urinary 4.2 245 2.2 28 0.001 7.3 129 1.5 36 <0.001 2.6 63 0.7 11 <0.001
Unknown fever 2.6 152 2.5 32 0.939 3.4 62 0.9 22 <0.001 3.2 79 1.4 23 <0.001
Pelvic * 0.3 19 0.8 10 0.017 2.0 36 2.2 51 0.695 1.9 47 3.2 54 0.009
Total /patient ** 9.9 583 7.7 97 0.016 12.3 222 5.2 122 <0.001 8.3 201 6.7 113 0.070
TROMBOEMB. 0.2 9 0.1 1 0.528 0.2 4 0.04 1 0.099 0.3 7 - 0 0.028
HEMORRHAGE 3.8 221 3.3 42 0.479 4.4 79 4.9 114 0.472 4.4 107 6.4 108 0.004
TOTAL /PATIENT ** 16.2 952 19.2 241 0.010 22.2 400 11.7 275 <0.001 17.0 413 15.4 258 0.172

* Pelvic infection data from 1996 comprise all intra-abdominal and vaginal infections, whereas in 2006 was defined as abscess or hematoma

** N of patients. A patient may have had more than one complication.
Figure 1
Figure 2
Legends to the figures:

Figure 1. PROPORTIONS of abdominal, vaginal and laparoscopic hysterectomies in various countries from 1994 to 2006.

Footnote
_____
Figures from France represent samples from University clinics only, otherwise national data are presented, apart from the UK, which excludes Wales, and represents 45% of national hysterectomies. References: UK 1994-1995, 7 Finland 1996, 8 France 1996, 9 Taiwan1996,5 USA 1997,10 Denmark 1998-2000, 11 Norway 2000-2001, 12 USA 2000,2004, 13 Netherlands 2002,14 France 2004, 9 Sweden 2004,15 Denmark 2004, 4 Australia 2005-2005, 16 Taiwan 2005,5 Germany,17 Denmark 2006, 4 and Finland 2006, 6
Figure 2. PROPORTION of hysterectomies by type in Finland in 1996 and 2006.
Footnote
_____
AH = abdominal hysterectomy
VH = vaginal hysterectomy
LH = laparoscopic hysterectomy
Figure 3
Figure 3. Complications related to abdominal, vaginal and laparoscopic hysterectomies in 1996 and 2006
Footnote
_____
VTE, venous tromboembolism.
* Pelvic infection data from 1996 comprise all intra-abdominal and vaginal infections,
whereas in 2006 was late onset of pelvic infection was defined as pelvic abscess or hematoma
** N of patients. A patient may have had more than one complication.
*) including vaginal cuff infection

VERSION 2 – REVIEW

REVIEWER	Øjvind Lidegaard, Professor, Department of Gynaecology and Obstetrics, Rigshospitalet, University of Copehnagen, Denmark. Conflicts of interest: None.
REVIEW RETURNED	28-Aug-2013

GENERAL COMMENTS	This prospective study planned to assess complication rates to different types of hysterectomies in 1996 and 2006 in Finland, and demonstrated both a major change between the different types of hysterectomies by time, and fewer complications in 2006 as compared with 1996. The most important limitation was the inclusion rate of 92.1% in 1996 but of only 79.4% in 2006. Non included women in 2006 were, however, traced in the Patient Insurance Center, and the same claimed complication rate was found among those who participated and did not, respectively. The claim figures were not given, however. I think it is acceptable that one compares the complication rates in

	these two years despite important changes had taken place in the type of hysterectomies between the two study years. Table 2 and Table 3 should be switched according to the succession they are mentioned in the text. Line 272: Should be changed to: “This observation suggests selection bias to be of little significance”