10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND 1996 – 2006

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Complete List of Authors: Mäkinen, Juha; University of Turku, Ob-Gyn
Brummer, Tea; University of Helsinki, Ob-Gyn
Jalkanen, Jyrki; Central Finland Hospital, Ob-Gyn
Heikkinen, Anna-Mari; University of Kuopio, Ob-Gyn
Fraser, Jaana; North Karelia Central Hospital, Ob-Gyn
Tomas, Eija; University of Tampere, Ob-Gyn
Härkki, Päivi; University of Helsinki, Ob-Gyn
Sjöberg, Jari; University of Helsinki, Ob-Gyn

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10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND

1996 – 2006

Juha Mäkinen a, M.D., Ph.D.
Tea Brummer b, M.D., Ph.D.
Jyrki Jalkanen c, M.D., Ph.D.
Anna-Mari Heikkinen d, M.D., Ph.D.
Jaana Fraser e, M.D.
Eija Tomás f, M.D., Ph.D.
Päivi Härkki b, M.D., Ph.D.
Jari Sjöberg b, M.D., Ph.D.

aDepartment of Obstetrics and Gynecology, Turku University and Turku University Hospital, P.O. Box 52, FI-20521 Turku, Finland
bDepartment of Obstetrics and Gynecology, Helsinki University Hospital, P.O. Box 140, FI-00029 HUS, Helsinki, Finland
cDepartment of Obstetrics and Gynecology, Central Finland (Jyväskylä) Central Hospital, Keskussairaantie 19, FI-40620 Jyväskylä, Finland
dDepartment of Obstetrics and Gynecology, Kuopio University Hospital, P.O. Box 1777, FI-70211 Kuopio, Finland
eDepartment of Obstetrics and Gynecology, North Karelia (Joensuu) Central Hospital, Tikkamäentie 16, FI-80210 Joensuu, Finland
fDepartment of Obstetrics and Gynecology, Tampere University Hospital, P.O.Box 2000, FI-33521 Tampere, Finland

Correspondence: Juha Mäkinen, Department of Obstetrics and Gynecology, Turku University and Turku University Hospital, P.O. Box 52, FI-20521 Turku, Finland.
E-mail juha.makinen@tyks.fi
Mobile +358400523529

Running title: Improved hysterectomy outcomes in Finland 1996 - 2006
Abstract

Objectives: To study the outcome of various hysterectomies in two years 1996 and 2006. The hypothesis was that the change in operative practices in ten years have resulted in improvements.

Design: Two prospective nationwide cohort evaluations with the same questionnaire.

Setting: All national operative hospitals in Finland.

Participants: Patients scheduled to either abdominal, vaginal or laparoscopic hysterectomy for benign disease.

Outcome measures: Patients characteristics, surgery related details and complications (organ injury, infection, VTE, haemorrhage).

Results: The overall complication rates fell 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 incidence 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.

Conclusions: The rate of postoperative complications fell markedly in the decade from 1996 to 2006. This parallels with the recommendation of the recent meta-analyses by Cochrane Collaboration; the order of preference of hysterectomies was first time precisely followed in this nationwide study.

Trial registration: In the clinical trials of protocol registration system data (NCT00744172).

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’s 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), but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in favor of VH and LH, which present themselves as 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. 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 LHs and RCTs have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate. 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. 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 with the results 10 years previously.
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. Data collection was nationwide and followed the same procedure as in the survey ten years previously, the FINHYST 1996 study. 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. 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 \( \chi^2 \)-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 rates of VH and LH in Finland increased markedly in the decade from 1996 to 2006, while the rate of AH fell to less than half (Figure 2). At the same time, the rate 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).

The overall 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 metronidazole 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. Furthermore 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. 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%) 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. In consequence, we have a much lower rate of AH (24%) compared to many other countries, e.g., the USA (68%) and the other Nordic countries Sweden (60%), Denmark (59%), Norway (78%). According to a recent meta-analysis by the Cochrane collaboration, the order of preference of hysterectomies should be VH and LH followed by AH. This 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 – 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. 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

National reports on the outcomes of surgical procedures need attention in terms of data
coverage. We believe that one of the main reasons for the fact that in the FINHYST 1996
study the cohort 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. The survey in 2006 was run according to new
regulations which require that each patient provides full disclosure of her dentity and 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.

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.). Furthermore, 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.26,27 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 severely affected than a decade earlier.

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.

References


Authors’ contributions

Authors: Juha Mäkinen (JM), Tea Brummer (TB), Jyrki Jalkanen (JJ), Anna-mari heikkinen (A-MH), Jaana Fraser (JF), Eija Tomas (ET), Päivi Härkki (PH) and Jari Sjöberg (JS)

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

Conflict of interest: No conflict of interest related to this article

Role of funding source: No source of funding

Ethics committee approval: 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 Gynaecology of the Helsinki University Hospital (Dnro 457/E8/04). The 2006 study was registered in the Clinical Trials of Protocol Registration System Data (NCT00744172).
Figure 1
Figure 2

![Bar chart showing the distribution of cases in 1996 and 2006.](chart.png)

- **1996**
  - VH: 18%
  - LH: 24%
  - AH: 58%

- **2006**
  - VH: 44%
  - LH: 32%
  - AH: 24%
Figure 3

- **ABDOMINAL**
  - 1996
  - 2006

- **VAGINAL**
  - 1996
  - 2006

- **LAPAROSCOPIC**
  - 1996
  - 2006

- **P<0.001**
- **P<0.005**
- **P<0.05**
- NS = not significant
Legends to the figures:

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

Footnote


Figure 2. Rate of hysterectomies by type in Finland in 1996 and 2006.

Footnote

AH = abdominal hysterectomy
VH = vaginal hysterectomy
LH = laparoscopic hysterectomy

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
Table 1. Patient characteristics and surgery-related details (mean +/- SD) by hysterectomy method in 1996 and 2006.

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<tbody>
<tr>
<td>Age</td>
<td>48.8 (8.7)</td>
<td>50.1 (8.8)</td>
<td>58.6 (13.2)</td>
<td>55.0 (11.8)</td>
<td>47.0 (7.5)</td>
<td>49.2 (8.5)</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>26.3 (4.5)</td>
<td>27.1 (5.3)</td>
<td>26.3 (3.9)</td>
<td>26.4 (4.4)</td>
<td>24.9 (3.9)</td>
<td>26.1 (4.6)</td>
</tr>
<tr>
<td>Oper time (min)</td>
<td>86 (31)</td>
<td>93 (37)</td>
<td>88 (32)</td>
<td>78 (33)</td>
<td>124 (48)</td>
<td>108 (43)</td>
</tr>
<tr>
<td>Hemorrhage (ml)</td>
<td>305 (312)</td>
<td>355 (360)</td>
<td>342 (353)</td>
<td>203 (269)</td>
<td>262 (271)</td>
<td>270 (669)</td>
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<tr>
<td>Uterine weight (g)</td>
<td>290 (302)</td>
<td>433 (425)</td>
<td>109 (84)</td>
<td>131 (110)</td>
<td>195 (108)</td>
<td>210 (146)</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>6.0 (2.2)</td>
<td>3.8 (1.8)</td>
<td>5.9 (2.7)</td>
<td>2.3 (1.5)</td>
<td>3.4 (2.0)</td>
<td>2.0 (1.4)</td>
</tr>
<tr>
<td>Convalescence (days)</td>
<td>34.4 (5.3)</td>
<td>32.3 (4.6)</td>
<td>34.0 (8.8)</td>
<td>29.4 (8.0)</td>
<td>21.5 (8.8)</td>
<td>22.0 (6.3)</td>
</tr>
</tbody>
</table>

All pairs (1996 vs. 2006) p<0.001, except in LH for hemorrhage (P=0.603) and in VH for BMI (P=0.484)
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

<table>
<thead>
<tr>
<th></th>
<th>ABDOMINAL</th>
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<tr>
<td></td>
<td>(N=5875)</td>
<td>(N=1255)</td>
<td>(N=1801)</td>
<td>(N=2345)</td>
<td>(N=2434)</td>
<td>(N=1679)</td>
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<td>%</td>
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<td>Ureter injury</td>
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<td>≤ 30</td>
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<td>1</td>
<td>-</td>
<td>2,2</td>
<td>20</td>
<td>0,3</td>
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<td>&gt; 30</td>
<td>0,2</td>
<td>9</td>
<td>0,3</td>
<td>3</td>
<td>0,04</td>
<td>1</td>
<td>0,5 **</td>
<td>7</td>
<td>0,2</td>
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<tr>
<td>Bladder injury</td>
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<td></td>
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<td>1,1</td>
<td>3</td>
<td>-</td>
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<td>0,5</td>
<td>28</td>
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<td>4</td>
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<td>Bowel injury</td>
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<td>3</td>
<td>0,3 *</td>
<td>4</td>
<td>0,06</td>
<td>1</td>
<td>0,3</td>
</tr>
</tbody>
</table>

* P = 0.05
** P < 0.001

Other comparisons (≤30 vs > 30): not significant
Patient Consent Form

The form was used only in Finnish (below).

The ethics committee in 1996 did not require us to collect the patients’ social security numbers or consent forms. The survey in 2006 was run according to new regulations which require that each patient provides full disclosure of her identity and written informed consent (in Finnish).

Potilastiedote Finhyst 2006 kohdunpoistotutkimuksesta

Olette tulossa kohdunpoistoleikkaukseen. Suomessa näitä leikkauksia tehdään vuosittain noin 10 000 ja se on yksi tavallisimmista naisille tehtävistä kirurgisista toimenpiteistä. Finhyst 2006 - tutkimuksen avulla haluamme selvittää koko maassa vuoden 2006 kohdunpoistoleikkauksien hoitotuloksia ja turvallisuutta.

Tietosuojan turvaamiseksi kohdunpoistoon liittyvät tiedot kerätään suljettuun tietokonerekisteriin ja ne käsitellään täysin luottamuksellisesti. Kerättyä tiedot rajoittuvat vain välittömästi kohdunpoistoleikkaukseen liittyviin seikkoihin. Tutkimuksen osallistumisen on teille täysin vapaaehtoista; siihen osallistuminen tai osallistumisesta kieltäytyminen ei vaikuta millään tavalla teille jo hoitopaikassanne suunniteltuun hoitoon, josta vastaa teidät leikkaava lääkäri.

Kotitueessanne saatte toipumistanne koskevan kyselylomakkeen ja toivomme teidän täyttävän ja postittavan ne 8 viikon kuluttua leikkauskestanne kirjekuorella, jonka saatte kyselylomakkeiden mukana.

Tutkijat:
LL Tea Brummer, HYKS Naistenklinikka, tea.brummer@hus.fi
LKT Päivi Härkki, HYKS Naistenklinikka, paivi.harkki@hus.fi
LKT Jyrki Jalkanen, HYKS Naistenklinikka, jyrki.jalkanen@hus.fi
Dos. Jari Sjöberg, HYKS Naistenklinikka, jari.sjoberg@hus.fi
LKT Minna Kauko, HUS Hyvinkään sairaala, minna.kauko@hus.fi
Prof. Juha Mäkinen, TYKS Naistenklinikka, juha.makinen@tyks.fi
LT Eija Tomás, TAYS Naistenklinikka, eija.tomas@uta.fi
LT Anna-Mari Heikkinen, KYS Naistenklinikka, anna-mari.heikkinen@kuh.fi
Dos. Ulla Puistola, OYS Naistenklinikka, ulla.puistola@oulu.fi
LL Jaana Fraser, Pohjois-Karjalan keskussairaala, jaana.fraser@pkshp.fi
Study protocol

The questionnaire sheets were used only in Finnish (below).

Data collection was nationwide and followed the same procedure in both annual cohorts of 1996 and 2006. The forms (FINHYST 1996 and 2006) were used to collect data on preoperative, peroperative and postoperative events and operation-related morbidity during the patients' hospital stay and convalescence.

FINHYST 2006 (Leikkaava lääkäri täyttää) Sivu 1

Rengasta oikea vaihtoehto. Lomake täytetään kaikista muista kohdunpoistoista paitsi syövistä, borderline munasarjakasvaimista ja synnytyksen jälkeisistä kohdunpoistoista

Potilaan nimi ja SOTU (mielellään tarra): __________________________________________

Sairaala __________________________________________________________

Toimenpidepäivä: _______________ Lomakkeen täyttöpäivä: _______________

Leikkaaja: 1. erikoislääkäri / 2. erikoistuva lääkäri

Leikkaajan kokemus ko. leikkauksessa: 1. alle 10 kpl / 2. 10-30 kpl / 3. yli 30 kpl

Kohdunpoisto:
1. a. Abdominaalinen totaali / b. abdominaalinen amputaatio
2. a. LH (uterinat yläkautta) / b. LAVH (uterinat alakautta) / c. laparoskooppinen amputaatio
3. Vaginaalinen
4. Konversio (mistä mihin __________________________________, syy ________________________)
5. Kohdun paloittelu sen ulos saamiseksi

TÄRKEIN preoperatiivinen syy miksi leikattiin (vain YKSI vaihtoehto): ICD-10 ___________

1. Myoma(t)
2. Menorrhagia
3. Dysmenorrhea
4. Endometrioosi
5. Laskeumat
6. Adnextuumori
7. Muu, mikä ________

Muuttuuuko tärkein diagnoosi leikkauksen jälkeen? 1. ei / 2. kyllä: uusi dg (ICD-10) ___________

Potilaan pituus ________ cm, paino ________ kg

Pariteetti: ________ joista alatiesynnytyksiä _______ kpl ja sektioita ________ kpl

Aikaisemmat muut vatsanalueen leikkaukset: laparoskopioita _______ kpl, laparotomioita _______ kpl

Antibioottiprofylaksia:
1. ei
2. kyllä: a. kefuroksiimi / b. metronidatsoli / c. muu, mikä ______________ + annos _______

Lääkkeellinen tromboosiprofylaksia:
1. ei
2. kyllä: a. minihepariini / b. muu, mikä ______________ + annos ______ + kesto (vrk) _______

Leikkauskseen kesto (min) (aika 1. viilosta sulkuun) ________________________________

Arvioitumitattu vuoto (ml) ________________________________

Uteruksen paino ilman adnexeja (g) ________________________________

Leikkaajan arvio leikkauskseen vaikeudesta:
1. erittäin helppo / 2. helppo / 3. tavallinen / 4 vaikea / 5. erittäin vaikea, miksi __________________
Hemostaasimenetelmät:
1. Ligatuurat
2. Bipolaaripoltto
3. Monopolaaripoltto
4. Ultraääniveitsi
5. Muu (Esim. Ligasure), mikä ____________________________

Liitännäistoimenpiteitä: Sivu 2
1. Ei
2. Kyllä
   A. toisen adnexin poisto / b. molemien adnexien poisto
   B. Vaginaaliset plastiat: a. KA / b. KP
   C. Inkontinenssin korjaus: a. TVT / b. TOT / c. muu ____________________________
   D. Enteroseelen korjaus
   E. Leikkausta hankaloittavien kiinnikkeiden irrottelu
   F. Muu, mikä ____________________________

Leikkauksen aikana havittu komplikaatio:
1. Ei
2. Kyllä
   A. Yli 1000ml leikkausvuoto
   B. Verisuonivaurio: a. epigastricasuonet / b. suuret suonet (aorta, v.cava, iliacat) / c. muu suoni, mikä ________
   C. Rakkovalvo
   D. Uretervalvo
   E. Suolivalvo
   F. Tekniset laiteongelmat, mikä ____________________________
   G. Muu, mikä ____________________________

Miten komplikaatio hoidettiin:

Leikkausen jälkeen osastolla todettu komplikaatio:
1. Ei
2. Kyllä
   A. Reoperaatio, syy ____________________________
   B. Postoperatiivinen vuoto/hematoma
   C. Haavainfektio (vaatinut antibiootin, punktion tai drenerauksen)
   D. Virtsaatievaltto (Uricult > 10s)
   E. Epäselvä kuumeilu (aksillaarinen lämpö ≥ 38°C)
   F. Syvä laskimotromboosi
   G. Keuhkoembolia
   H. Rakkovalvo
   I. Uretervalvo
   J. Suolenveto vaikeus
   K. Suolivalvo
   L. Hernia, mikä ____________________________

M. Muu ongelma, mikä ____________________________

Miten komplikaatio hoidettiin:

Potilas sai verensiirron
1. Ei
2. Kyllä
   a. ennen leikkausta _____ punasoluyksikkö/ b. leikkausen aikana _____ punasoluyksikkö/ c. leikkausen jälkeen _____ punasoluyksikkö

Kotiutuspäivämäärä ________________ Sairasloma (vrk) ___________ (sisältää sairaalassa oloajan)
FIN HYST 2006 JÄLKIKOMPLIKAATIOLOMAKE (Lääkäri täyttää)

Täytetään vain mikäli potilaas joutuu uudestaan sairaalaan komplikaation takia

Potilaan nimi ja SOTU (miehellään tarra): ________________________________
Sairaala: __________________________________________________________
Kohdunpoistopäivä: ________________________________
Lomakkeen täyttöpäivä: ________________________________
Komplikaation toteamispäivä: ________________________________
Havaittu komplikaatio:
1. Reoperaatio, syy __________________________________________
2. Verensiirtoon johtanut anemia
3. Haavainfektio (vaatinut antibiootin, punktion tai dreneerauksen)
4. Virtatieinfektio (Uricult > 105)
5. Epäselvä kuumeilu (Aksillaarin lämpö ≥ 38 °C)
6. Lantionpohjan infektio (hematoma ja/tai abskessi)
7. Syvä laskimotromboosi
8. Keuhkoembolia
9. Rakkovaurio
10. Uretervaurio
11. Suolenvetovoiteus
12. Suolivaario
13. Hernia, mikä __________________________________________
14. Muu ongelma, mikä __________________________________________
Miten komplikaatio hoidettiin
____________________________________________________________________
____________________________________________________________________
Sairaalassa oloaika (vrk) ________________________________
Uusi sairasloma (lisä vrk) ________________________________
Potilas 1. on työssä / 2. ei ole työssä
STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
</tr>
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</table>
| **Title and abstract** 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract.  
(b) Provide in the abstract an informative and balanced summary of what was done and what was found. |
| **Introduction** 2 | Explain the scientific background and rationale for the investigation being reported. |
| **Objectives** 3 | State specific objectives, including any prespecified hypotheses. |
| **Methods** 4 | Present key elements of study design early in the paper. |
| **Setting** 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. |
| **Participants** 6 | (a) **Cohort study**—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.  
(b) **Case-control study**—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls.  
**Cross-sectional study**—Give the eligibility criteria, and the sources and methods of selection of participants. |
| **Variables** 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. |
| **Data sources/measurement** 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. |
| **Bias** 9 | Describe any efforts to address potential sources of bias. |
| **Study size** 10 | Explain how the study size was arrived at. |
| **Quantitative variables** 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why. |
| **Statistical methods** 12 | (a) Describe all statistical methods, including those used to control for confounding.  
(b) Describe any methods used to examine subgroups and interactions.  
(c) Explain how missing data were addressed.  
(d) **Cohort study** If applicable, explain how loss to follow-up was addressed.  
**Case-control study**—If applicable, explain how matching of cases and controls was addressed.  
**Cross-sectional study**—If applicable, describe analytical methods taking account of sampling strategy.  
(e) Describe any sensitivity analyses. |

Continued on next page
Results

Participants 13* (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram

Descriptive data 14* (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Cohort study—Summarise follow-up time (eg, average and total amount)

Outcome data 15* Cohort study—Report numbers of outcome events or summary measures over time Case-control study—Report numbers in each exposure category, or summary measures of exposure Cross-sectional study—Report numbers of outcome events or summary measures

Main results 16 (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses 17 Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results 18 Summarise key results with reference to study objectives

Limitations 19 Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias

Interpretation 20 Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence

Generalisability 21 Discuss the generalisability (external validity) of the study results

Other information

Funding 22 Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Structured abstract

Objectives: To study the outcome of various hysterectomies in two years 1996 and 2006. The hypothesis was that the change in operative practices in ten years have resulted in improvements.

Design: Two prospective nationwide cohort evaluations with the same questionnaire.

Setting: All national operative hospitals in Finland.

Participants: Patients scheduled to either abdominal, vaginal or laparoscopic hysterectomy for benign disease.

Outcome measures: Patients characteristics, surgery related details and complications (organ injury, infection, VTE, haemorrhage).

Results: The overall complication rates fell 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 incidence 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.

Conclusions: The rate of postoperative complications fell markedly in the decade from 1996 to 2006. This parallels with the recommendation of the recent meta-analyses by Cochrane Collaboration; the order of preference of hysterectomies was first time precisely followed in this nationwide study.

Trial registration: In the clinical trials of protocol registration system data (NCT00744172).
# 10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND 1996 – 2006

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<td>Date Submitted by the Author:</td>
<td>13-Aug-2013</td>
</tr>
</tbody>
</table>

**Complete List of Authors:**
- Mäkinen, Juha; University of Turku, Ob-Gyn
- Brummer, Tea; University of Helsinki, Ob-Gyn
- Jalkanen, Jyrki; Central Finland Hospital, Ob-Gyn
- Heikkinen, Anna-Mari; University of Kuopio, Ob-Gyn
- Fraser, Jaana; North Karelia Central Hospital, Ob-Gyn
- Tomas, Eija; University of Tampere, Ob-Gyn
- Härkki, Päivi; University of Helsinki, Ob-Gyn
- Sjöberg, Jari; University of Helsinki, Ob-Gyn

**Primary Subject Heading:** Obstetrics and gynaecology

**Secondary Subject Heading:** Epidemiology, Surgery

**Keywords:**
- GYNAECOLOGY, Minimally invasive surgery
- GYNAECOLOGY, Clinical audit
- HEALTH SERVICES ADMINISTRATION & MANAGEMENT
SUMMARY

1. Article focus

- Morbidity related to any type of hysterectomy: differences and similarities in 1996 and 2006
- Evaluation of the perioperative factors related to the change in outcome from 1996 to 2006
- Outcome changes related to the experience of the gynecologic surgeon

2. Key messages

- Very significant decrease in overall complications between 1996 and 2006
- First study thus far where the order of preference of hysterectomies (in 2006) is precisely followed, as recommended by the Cochrane collaboration
- Severe organ injuries in laparoscopic hysterectomies in 1996 were overcome by 2006 and the incidence of ureteral injuries sank especially much

3. Strengths and limitations

- The strength of the study is that it is prospective and nationwide and spans a time frame of 10 years. Participation was anonymous and voluntary.

- The limitations are the difference of the background of the study populations in 1996 and 2006, and data coverage (79%) in 2006. Differences is study populations cannot be corrected for, but any selection bias in the population was checked by analysis of data in the national register of the Patient Insurance Center in Finland. This post-study evaluation showed that the complication rates were similar for non-participants and for participants.
Structured abstract

Objectives: To study the outcome of various hysterectomies in two years 1996 and 2006. The hypothesis was that the change in operative practices in ten years have resulted in improvements.

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10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND

1996 – 2006 A LONGITUDINAL OBSERVATION STUDY

Juha Mäkinen a, M.D., Ph.D.
Tea Brummer b, M.D., Ph.D.
Jyrki Jalkanen c, M.D., Ph.D.
Anna-Mari Heikkinen d, M.D., Ph.D.
Jaana Fraser e, M.D.
Eija Tomás f, M.D., Ph.D.
Päivi Härkki b, M.D., Ph.D.
Jari Sjöberg b, M.D., Ph.D.

a Department of Obstetrics and Gynecology, Turku University and Turku University Hospital, P.O. Box 52, FI-20521 Turku, Finland
b Department of Obstetrics and Gynecology, Helsinki University Hospital, P.O. Box 140, FI-00029 HUS, Helsinki, Finland
c Department of Obstetrics and Gynecology, Central Finland (Jyväskylä) Central Hospital, Keskussairaalan tie 19, FI-40620 Jyväskylä, Finland
d Department of Obstetrics and Gynecology, Kuopio University Hospital, P.O. Box 1777, FI-70211 Kuopio, Finland
e Department of Obstetrics and Gynecology, North Karelia (Joensuu) Central Hospital, Tikkaamäentie 16, FI-80210 Joensuu, Finland
f Department of Obstetrics and Gynecology, Tampere University Hospital, P.O.Box 2000, FI-33521 Tampere, Finland

Correspondence: Juha Mäkinen, Department of Obstetrics and Gynecology, Turku University and Turku University Hospital, P.O. Box 52, FI-20521 Turku, Finland.
E-mail juha.makinen@tyks.fi
Mobile +358400523529

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). The overall rate of complications declined from 17.5% in 1996 to 14.7% in 2006 (p<0.001). By operation type, a decrease was also observed in LH (from 17.0% to 15.5%, NS) 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 and appropriate use of prophylactic antibiotics and antithrombotics, and better targeting of patient selection for each specific type of hysterectomy. Furthermore, this study is the only nationwide, as recommended in a recent meta-analysis by the Cochrane collaboration.

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’s 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), but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in favor of VH and LH, which present themselves as 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. 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 LHs and RCTs have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate. 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. 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 with the results 10 years previously.
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. Data collection was nationwide and followed the same procedure as in the survey ten years previously, the FINHYST 1996 study. 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 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 the 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. 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 $\chi^2$-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).

The overall complication rate related to any type of hysterectomy 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 or table 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 metronidazole 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 or table 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. Furthemore 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. 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%) 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. In consequence, we have a much lower rate of AH (24%) compared to many other countries, e.g., the USA (68%) and the other Nordic countries Sweden (60%), Denmark (59%), Norway (78%). According to a recent meta-analysis by the Cochrane collaboration, the order of preference of hysterectomies should be VH and LH followed by AH. This 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 – 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. 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 (Figure 3 or table 3), 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. Of the other Scandinavian countries infectious morbidity related to hysterectomies in Sweden in 2003 - 2006 was 12.0% for AH, 15.0% for LH and 9.9% for VH. Much lower rates were entered into the Danish hysterectomy database: in 2006 there were postoperative infections (excluding urinary tract infections) in only 2% of all hysterectomies.

Data coverage is a limitation of our study. We believe that one of the main reasons for the fact that in the FINHYST 1996 study the cohort 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. The survey in 2006 was run according to new regulations which require that each patient provides full disclosure of her identity and 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. The lower recruitment in 2006 made us perform a type of data verification. We examined the data from the national register of the Patient Insurance Center, to which patients self-report complications, usually in pursuit of economical compensation. The rate of complications was similar...
among those who had been recruited to FINHYST 2006 and those who were unable to participate. This observation would exclude selection bias in our study cohort.

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. 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 severely affected than a decade earlier. Of course, it would have been ideal to adjust the complication rates of the different types of hysterectomy by the population difference because the patients in the three groups AH, VH and LH were very different in 1996 and 2006 but this was not possible. Consequently, a definite conclusion whether the improvements in some parameters are a result of 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 hysterectomies between 1996 and 2006 indicate that clinical improvement was real. Moreover, 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. 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.)

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.
References


Authors´ contributions

Authors: Juha Mäkinen (JM), Tea Brummer (TB), Jyrki Jalkanen (JJ), Anna-mari heikkinen (A-MH), Jaana Fraser (JF), Eija Tomas (ET), Päivi Härkki (PH) and Jari Sjöberg (JS)

- 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
Conflict of interest: No conflict of interest related to this article

Role of funding source. No source of funding

Ethics committee approval: 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 Gynaecology of the Helsinki University Hospital (Dnro 457/E8/04). The 2006 study was registered in the Clinical Trials of Protocol Registration System Data (NCT00744172).
Figure 1
Legends to the figures:

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

Footnote


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
Table 1. Patient characteristics and surgery-related details (mean +/- SD) by hysterectomy method in 1996 and 2006.

<table>
<thead>
<tr>
<th></th>
<th>ABDOMINAL</th>
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<th>VAGINAL</th>
<th></th>
<th>LAPAROSCOPIC</th>
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<tr>
<td></td>
<td>(N=5875)</td>
<td>(N=1255)</td>
<td>(N=1801)</td>
<td>(N=2345)</td>
<td>(N=2434)</td>
</tr>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Age</td>
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<td>BMI (kg/m^2)</td>
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<td>Oper time (min)</td>
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<td>93</td>
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<tr>
<td>Hemorrhage (ml)</td>
<td>305</td>
<td>312</td>
<td>355</td>
<td>360</td>
<td>342</td>
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<tr>
<td>Uterine weight (g)</td>
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<td>302</td>
<td>433</td>
<td>425</td>
<td>109</td>
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<tr>
<td>Hospital stay (days)</td>
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<td>3.8</td>
<td>1.8</td>
<td>5.9</td>
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<tr>
<td>Convalescence (days)</td>
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<td>5.3</td>
<td>32.3</td>
<td>4.6</td>
<td>34.0</td>
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</table>

All pairs (1996 vs. 2006) p<0.001, except in LH for hemorrhage (P=0.603) and in VH for BMI (P=0.484)
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

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<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>≤ 30</td>
<td>-</td>
<td>0.4 1</td>
<td>-</td>
<td>-</td>
<td>2.2 20</td>
<td>0.3 1</td>
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<td>&gt; 30</td>
<td>0.2 9</td>
<td>0.3 3</td>
<td>-</td>
<td>0.04 1</td>
<td>0.5 ** 7</td>
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<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>≤ 30</td>
<td>-</td>
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<td>-</td>
<td>0.6 3</td>
<td>2.0 18</td>
<td>1.3 5</td>
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<tr>
<td>&gt; 30</td>
<td>0.5 28</td>
<td>0.7 7</td>
<td>0.4 4</td>
<td>0.5 9</td>
<td>0.8 * 12</td>
<td>1.0 12</td>
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<tr>
<td>Bowel injury</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
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<td>n</td>
</tr>
<tr>
<td>≤ 30</td>
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<td>-</td>
<td>1.3 5</td>
<td>0.2 1</td>
<td>0.4 4</td>
<td>0.3 1</td>
</tr>
<tr>
<td>&gt; 30</td>
<td>0.2 12</td>
<td>0.3 3</td>
<td>0.3 * 4</td>
<td>0.06 1</td>
<td>0.3 5</td>
<td>0.4 5</td>
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</table>

* 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

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<td>n</td>
<td></td>
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<td>413</td>
<td>15.4</td>
<td>258</td>
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</tbody>
</table>

* 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.
STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| 1 | *(a)* Indicate the study's design with a commonly used term in the title or the abstract  
   *(b)* Provide in the abstract an informative and balanced summary of what was done and what was found |
| 2 | Introduc |
| 3 | Introduction |
| 4 | 2 Explain the scientific background and rationale for the investigation being reported |
| 5 | Objectives 3 State specific objectives, including any prespecified hypotheses |
| 6 | Methods |
| 7 | Study design 4 Present key elements of study design early in the paper |
| 8 | Setting 5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| 9 | Participants 6 *(a)* Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  
   *(b)* Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  
   Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants  
   *(b)* Cohort study—For matched studies, give matching criteria and number of exposed and unexposed  
   Case-control study—For matched studies, give matching criteria and the number of controls per case |
| 10 | Variables 7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| 11 | Data sources/ measurement 8* For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| 12 | Bias 9 Describe any efforts to address potential sources of bias |
| 13 | Study size 10 Explain how the study size was arrived at |
| 14 | Quantitative variables 11 Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| 15 | Statistical methods 12 *(a)* Describe all statistical methods, including those used to control for confounding  
   *(b)* Describe any methods used to examine subgroups and interactions  
   *(c)* Explain how missing data were addressed  
   *(d)* Cohort study—If applicable, explain how loss to follow-up was addressed  
   Case-control study—If applicable, explain how matching of cases and controls was addressed  
   Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy  
   *(e)* Describe any sensitivity analyses |

Continued on next page
Results

Participants 13* (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible,
examined for eligibility, confirmed eligible, included in the study, completing follow-up, and
analysed
(b) Give reasons for non-participation at each stage
(c) Consider use of a flow diagram

Descriptive data 14* (a) Give characteristics of study participants (eg demographic, clinical, social) and information
on exposures and potential confounders
(b) Indicate number of participants with missing data for each variable of interest
(c) Cohort study—Summarise follow-up time (eg, average and total amount)

Outcome data 15* Cohort study—Report numbers of outcome events or summary measures over time
Case-control study—Report numbers in each exposure category, or summary measures of exposure
Cross-sectional study—Report numbers of outcome events or summary measures

Main results 16 (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their
precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and
why they were included
(b) Report category boundaries when continuous variables were categorized
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful
time period

Other analyses 17 Report other analyses done—eg analyses of subgroups and interactions, and sensitivity
analyses

Discussion

Key results 18 Summarise key results with reference to study objectives

Limitations 19 Discuss limitations of the study, taking into account sources of potential bias or imprecision.
Discuss both direction and magnitude of any potential bias

Interpretation 20 Give a cautious overall interpretation of results considering objectives, limitations, multiplicity
of analyses, results from similar studies, and other relevant evidence

Generalisability 21 Discuss the generalisability (external validity) of the study results

Other information

Funding 22 Give the source of funding and the role of the funders for the present study and, if applicable, for the
original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and
unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and
published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is
Patient Consent Form

The form was used only in Finnish (below).

The ethics committee in 1996 did not require us to collect the patients’ social security numbers or consent forms. The survey in 2006 was run according to new regulations which require that each patient provides full disclosure of her identity and written informed consent (in Finnish).

Potilastiedote Finhyst 2006 kohdunpoistotutkimuksesta

Olette tulossa kohdunpoistoleikkaukseen. Suomessa näitä leikkauksia tehdään vuosittain noin 10 000 ja se on yksi tavallisimmista naisille tehtävistä kirurgisista toimenpiteistä. Finhyst 2006 - tutkimuksen avulla haluamme selvittää koko maassa vuoden 2006 kohdunpoistoleikkauksien hoitotuloksia ja turvallisuutta.

Tietosuojan turvaamiseksi kohdunpoistoon liittyvät tiedot kerätään suljettuun tietokonerekisteriin ja ne käsitellään täysin luottamuksellisesti. Kerättävät tiedot rajoittuvat vain välittömästi kohdunpoistoleikkaukseen liittyvien seikkoihin. Tutkimuksen osallistuminen on teille täysin vapaaehtoinen; siihen osallistumisen tai osallistumisesta kiellettyminen ei vaikuta millään tavalla teille jo hoitopaikan hoitoon, josta vastaa teidät leikkaava lääkäri.

Kotitutuessanne saatte toipumistanne koskevan kyselylomakkeen ja toivomme teidän täyttävän ja postittavan ne 8 viikon kuluttua leikkausksestanne kirjeen mukaan.

Tutkijat:
LL Tea Brummer, HYKS Naistenklinikka, tea.brummer@hus.fi
LKT Päivi Härkki, HYKS Naistenklinikka, paivi.harkki@hus.fi
LKT Jyrki Jalkanen, HYKS Naistenklinikka, jyrki.jalkanen@hus.fi
Dos. Jari Sjöberg, HYKS Naistenklinikka, jari.sjoberg@hus.fi
LKT Minna Kauko, HUS Hyvinkään sairaala, minna.kauko@hus.fi
Prof. Juha Mäkinen, TYKS Naistenklinikka, juha.makinen@tyks.fi
LT Eija Tomás, TAYS Naistenklinikka, eija.tomasiuta.fi
LT Anna-Mari Heikkinen, KYS Naistenklinikka, anna-mari.heikkinen@kuh.fi
Dos. Ulla Puistol, OYS Naistenklinikka, ulla.puistola@oulu.fi
LL Jaana Fraser, Pohjois-Karjalan keskussairaala, jaana.fraser@pkshp.fi
Study protocol

The questionnaire sheets were used only in Finnish (below).

Data collection was nationwide and followed the same procedure in both annual cohorts of 1996 and 2006. The forms (FINHYST 1996 and 2006) were used to collect data on preoperative, peroperative and postoperative events and operation-related morbidity during the patients' hospital stay and convalescence.
Hemostaasimenetelmät:
1. Ligatuurat
2. Bipolaaripoltto
3. Monopolaaripoltto
4. Ultraääniveitsi
5. Muu (Esim. Ligasure), mikä __________________________

Liitännäistoimenpiteitä: Sivu 2
1. Ei
2. Kyllä
A. a. toisen adnexin poisto / b. molempien adnexen poisto
B. Vaginaaliset plastiat: a. KA / b. KP
C. Inkontinenssin korjus: a. TVT / b. TOT / c. muu _______________________________
D. Enteroseelen korjus
E. Leikkausta hankaloittavien kiinnikkeiden irrottelu
F. Muu, mikä _________________________________

Leikkausen aikana havittu komplikaatio:
1. Ei
2. Kyllä
A. Yli 1000ml leikkausvuoto
B. Verisuonivaurio: a. epigastricasuonet / b. suuret suonet (aorta, v.cava, iliacat) /
   c. muu suoni, mikä __________
C. Rakkoavaario
D. Ureteravaario
E. Suolivaario
F. Tekniset laiteongelmat, mikä _________________________________
G. Muu, mikä _________________________________

Miten komplikaatio hoidettiin _________________________________

Leikkausen jälkeen osastolla todettu komplikaatio:
1. Ei
2. Kyllä
A. Reoperaatio, syy _________________________________
B. Postoperatiivinen vuoto/hematoma
C. Haavainfektio (vaatinut antibiootin, punktion tai drenerauksen)
D. Virtsetaineinfektio (Uricult > 10s)
E. Epäselvä kuumeilu (aksillaarinen lämpö ≥ 38°C)
F. Syvä laskimotromboosi
G. Keuhkoembolia
H. Rakkoavaario
I. Ureteravaario
J. Suolenvetovaikeus
K. Suolivaario
L. Hernia, mikä _________________________________
M. Muu ongelma, mikä _________________________________

Miten komplikaatio hoidettiin _________________________________

Potilas sai verensiirron
1. Ei
2. Kyllä a. ennen leikkausta ____ punasoluyksikkö/ b. leikkausen aikana ____ punasoluyksikkö/
c. leikkausen jälkeen______ punasoluyksikkö
Kotiutuspäivämäärä __________________ Sairasloma (vrk) ___________ (sisältää sairaalassa oloajan)
FINHYST 2006 JÄLKIKOMPLIKAATIOLOMAKE (Lääkäri täyttää)

Täytetään vain mikäli potilas joutuu uudestaan sairaalaan komplikaation takia

Potilaan nimi ja SOTU (mielellään tarra):______________________________
Sairaala: ______________________________________________________________________
Kohdunpoistopäivä: ________________
Lomakkeen täyttöpäivä: ________________
Komplikaation toteamispäivä: ______________________________________________________________________
Havaittu komplikaatio:

1. Reoperaatio, syy
2. Verensiirtoon johtanut anemia
3. Haavainfektsio (vaatinut antibiootin, punktion tai dreneerauksen)
4. Virtsatieinfektsio (Urict > 10^5)
5. Epäselvä kuumeilu (Aksillaarinen lämpö ≥ 38 °C)
6. Lantionpohjan infektsio (hematoma ja/tai abskessi)
7. Syvä laskimotromboosi
8. Keuhkoembolia
9. Rakkovaurio
10. Uretervaurio
11. Suolenvetovaikeus
12. Suolivaario
13. Hernia, mikä
14. Muu ongelma, mikä

Miten komplikaatio hoidettiin

________________________________________________________________________________

________________________________________________________________________________

________________________________________________________________________________

Sairaalassa oloaika (vrk) ____________________________
Uusi sairasloma (lisää vrk) ____________________________
Potilas 1. on työssä / 2. ei ole työssä
10 YEARS OF PROGRESS: IMPROVED HYSTERECTOMY OUTCOMES IN FINLAND
1996 – 2006

A LONGITUDINAL OBSERVATION STUDY

Juha Mäkinen a, M.D., Ph.D.
Tea Brummer b, M.D., Ph.D.
Jyrki Jalkanen c, M.D., Ph.D.
Anna-Mari Heikkinen d, M.D., Ph.D.
Jaana Fraser e, M.D.
Eija Tomás f, M.D., Ph.D.
Päivi Härkki b, M.D., Ph.D.
Jari Sjöberg b, M.D., Ph.D.

aDepartment of Obstetrics and Gynecology, Turku University and Turku University Hospital, P.O. Box 52, FI-20521 Turku, Finland
bDepartment of Obstetrics and Gynecology, Helsinki University Hospital, P.O. Box 140, FI-00029 HUS, Helsinki, Finland
cDepartment of Obstetrics and Gynecology, Central Finland (Jyväskylä) Central Hospital, Keskussairaalan tie 19, FI-40620 Jyväskylä, Finland
dDepartment of Obstetrics and Gynecology, Kuopio University Hospital, P.O. Box 1777, FI-70211 Kuopio, Finland
eDepartment of Obstetrics and Gynecology, North Karelia (Joensuu) Central Hospital, Tikkmäentie 16, FI-80210 Joensuu, Finland
fDepartment of Obstetrics and Gynecology, Tampere University Hospital, P.O.Box 2000, FI-33521 Tampere, Finland

Correspondence: Juha Mäkinen, Department of Obstetrics and Gynecology, Turku University and Turku University Hospital, P.O. Box 52, FI-20521 Turku, Finland.

E-mail juha.makinen@tyks.fi
Mobile +358400523529

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). The overall complication rates fell. The overall rate of complications declined from 17.5 % in 1996 to 14.7 % in 2006 (p<0.001). By operation type, a decrease was also observed in LH (from 17.0 % to 15.5, %, NS) 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 incidence 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 and appropriate 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’s 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) but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in favor of VH and LH, which present themselves as 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. 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 LHs and RCTs have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate. 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 understand what we have learned of the different approaches to hysterectomy during all these years. 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 with the results 10 years previously.
Methods

Information on all hysterectomies performed for benign conditions in Finland was prospectively registered from January 1st to December 31\textsuperscript{st}, 2006, by the operating gynecologist.\textsuperscript{6} Data collection was nationwide and followed the same procedure as in the survey ten years previously, the FINHYST 1996 study.\textsuperscript{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.\textsuperscript{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 $\chi^2$-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 rates proportions of VH and LH in Finland increased markedly in the decade from 1996 to 2006, while the rate proportion of AH fell to less than half (Figure 2). At the same time, the proportion rate 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).

The overall complication rate related to any type of hysterectomy declined very significantly from 17.5% in 1996 to 14.7% in 2006 (<0.001). The overall 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 or table 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 metronidazole 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 or table 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. Furthermore
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. 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%) 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. In consequence, we have a much lower rate of AH (24%) compared
to many other countries, e.g., the USA (68%) and the other Nordic countries Sweden
(60%) Denmark (59%), Norway (78%). According to a recent meta-analysis by the
Cochrane collaboration, the order of preference of hysterectomies should be VH and LH
followed by AH. This 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 – 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. 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 (Figure 3 or table 3), 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.

Of the other
Scandinavian countries infectious morbidity related to hysterectomies in Sweden in
2003 - 2006 was 12.0% for AH, 15.0% for LH and 9.9% for VH. Much lower rates were
entered into the Danish hysterectomy database; in 2006 there were postoperative
infections (excluding urinary tract infections) in only 2% of all hysterectomies.

Data coverage is a limitation of our study. National reports on the outcomes of surgical
procedures need attention in terms of data coverage. We believe that one of the main
reasons for the fact that in the FINHYST 1996 study the cohort 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. The survey in 2006
was run according to new regulations which require that each patient provides full disclosure
of her dentity and 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. The lower recruitment in 2006
made us perform a type of data verification. We examined the data from the national
register of the Patient Insurance Center, to which patients self-report complications,
usually in pursuit of economical compensation. The rate of complications was similar
among those who had been recruited to FINHYST 2006 and those who were unable to participate. This observation would exclude selection bias in our study cohort.

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. 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 severely affected than a decade earlier. Of course, it would have been ideal to adjust the complication rates of the different types of hysterectomy by the population difference because the patients in the three groups AH, VH and LH were very different in 1996 and 2006 but this was not possible. Consequently, a definite conclusion whether the improvements in some parameters are a result of 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 hysterectomies between 1996 and 2006 indicate that clinical improvement was real. Moreover, 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. 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.).

Furthermore, 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. 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 severely affected than a decade earlier.

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.

References


Authors’ contributions

Authors: Juha Mäkinen (JM), Tea Brummer (TB), Jyrki Jalkanen (JJ), Anna-mari heikkinen (A-MH), Jaana Fraser (JF), Eija Tomas (ET), Päivi Härkki (PH) and Jari Sjöberg (JS)

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

Conflict of interest: No conflict of interest related to this article

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Ethics committee approval: 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 Gynaecology of the Helsinki University Hospital (Dnro 457/E8/04). The 2006 study was registered in the Clinical Trials of Protocol Registration System Data (NCT00744172).
Ten years of progress—improved hysterectomy outcomes in Finland 1996–2006: a longitudinal observation study

Juha Mäkinen, Tea Brummer, Jyrki Jalkanen, Anna-Mari Heikkinen, Jaana Fraser, Eija Tomás, Päivi Härkki and Jari Sjöberg

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