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

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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 nationawide cohort evaluations with the same questionnaire.

Setting: All national operative hospitals in Finland.

Participants: Patients schedued 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 paralles 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).

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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[1] the role of vaginal (VH) and abdominal hysterectomies (AH) has beeen a matter of re-evaluation. The rate of abdominal hysterectomies (AH) has subsequently fallen in some countries (Figure 1),[2,3,4,5,6] but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in 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.[8] Not surprisingly, the most modern method, LH, was, at that time, associated with more severe complications than the other methods. The rate of complications stood also in proportion to the experience of the surgeons – the more experienced the surgeon, the less LH-associated complications.

Since the beginning of the 2000's, several smaller studies, hospital-based series of LHs[2] and RCTs[18-19] have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate.[20-21] There are, however, no longitudinal follow-up studies on the results of hospital-based or nationwide studies on patients undergoing hysterectomy. Such studies are not only scientifically important but they also constitute important measures of quality control and are, as such, badly needed to help us to understand what we have learned of the different approaches to hysterectomy during all these years.[22] We conducted a nationwide survey on the outcomes of hysterectomies of two cohorts first in 1996 and second in 2006. In this paper we compare the results after AH, VH and LH for benign conditions in 2006[6] with the results 10 years previously. [8]

Methods

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

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

Results

The 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 metrionidazole for 82.1% but in 1996 only for 15.3%. There were concomitantly significant reductions in the overall rate of infections; in the AH group from 9.9% to 7.7.% ($p<0.05$), in the VH group from 12.3% to 5.2% ($p<0.001$) but a non-significant change from 17.0% to 15.4% in the LH group.

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

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

By 2006 the percentage of surgeons with experience of more than 30 hysterectomies had risen most markedly among surgeons performing LH: from 62% in 1996 to 73% in 2006 while there was no change for VH (78% in 1996, 76% in 2006) but for AH there was a sinking trend from 91% in 1996 to 75 % in 2006. The experience of the surgeons was associated to the occurrence of organ injuries. Surgeons who had performed more than 30 hysterectomies in 1996, had significantly fewer ureter and bladder injuries, especially in the LH group, than the less experienced surgeons (Table 2). The same was the case for bowel injuries in 1996 in the VH group. In 2006, these differences were no longer present.

Discussion

The role of laparoscopic hysterectomy (LH) compared to the traditional abdominal (AH) and vaginal hysterectomy (VH) has been debated ever since the laparoscopic technique was introduced. It has been argued that LH is associated with higher expenses, longer operation times and a higher rate of complications. Large and comprehensive RCT-studies have been badly needed to give answers to these questions. Such studies need to be very large, even to the point of being unfeasible, if they are to have sufficient statistical power.[22] Furhermore they would also need to be set up so that they discount the effect of the individual surgeon,

the surgeon's experience and the effect of sophisticated surgical centres compared to ordinary hospitals. National registry-based observational surveys on large numbers of consecutive patients with prospective data collection are an alternative to cumbersome and, maybe, unrealistic RCT's and document effectiveness because they reflect clinical reality in the hands of the "average" gynecological surgeon.[22] This alternative was chosen for the present nationwide study, which compares some clinical determinants related to hysterectomies (AH, VH and LH) and hysterectomy-related morbidity in 2006 with 1996 in Finland.

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

The rate of LH increased also (from 24% to 36%). The current rate of LHs in Finland is high compared to our neighbouring Nordic countries (4-7%)[4,12,15] and globally (Figure 1). Worldwide, only Taiwan has a higher rate of LH, where the rate of LH has soared from 5 % in 1996 to 40 % in 2005.[5] In consequence, we have a much lower rate of AH (24%) compared to many other countries, e.g., the USA (68%)[13] and the other Nordic countries Sweden (60%)[15], Denmark (59%),[4] Norway (78%).[12] According to a recent meta-analysis by the Cochrane collaboration, the order of preference of hysterectomies should be VH and LH followed by AH .[21]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 [8]– have decreased highly significantly (from 1.1% to 0.3%). This finding is in accordance with a retrospective nationwide registry study on the complications of LH, which reported a continuously decreasing trend from 1993 to 2005 in ureter injuries in Finland.[24] Also, the fact that LH-related bladder complications sank from 1.3% to 1.0% supports the notion that surgeons

doing this operation have steadily gained experience and are better aware of the need to avoid harming the bladder and ureters. The rate of VH-associated bowel complications sank also significantly (Figure 3). For AH there was a slight increase in the occurrence of total complications (from 16% in 1996 to 19% in 2006), but this only reflects the fact that more severe and advanced cases required the abdominal approach in 2006.

The reduction in the number of infections, especially urinary tract infections, was probably due to the increased prophylactic use of antibiotics. The reduction of thromboembolic events is most likely due to a consequence of increased and appropriate use of thromboprophylaxis. The aim to reduce both of these complications was discussed already some ten years ago at a consensus meeting with the members of the Society of Gynecological Surgery in Finland, and a unified, common prophylaxis management system with antibiotics and antithrombotics was introduced and implemented.[25]

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 severly 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.

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Literature search: TB, PH and JM.

Figures: TB and JM.

Tables: TB and JM

Study design: all authors

Permissions: TB, PH, JS and JM

Data collection: TB and PH

Data analysis: TB, PH and JM

Data interpretation: all authors

Writing: all authors

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Figure 1

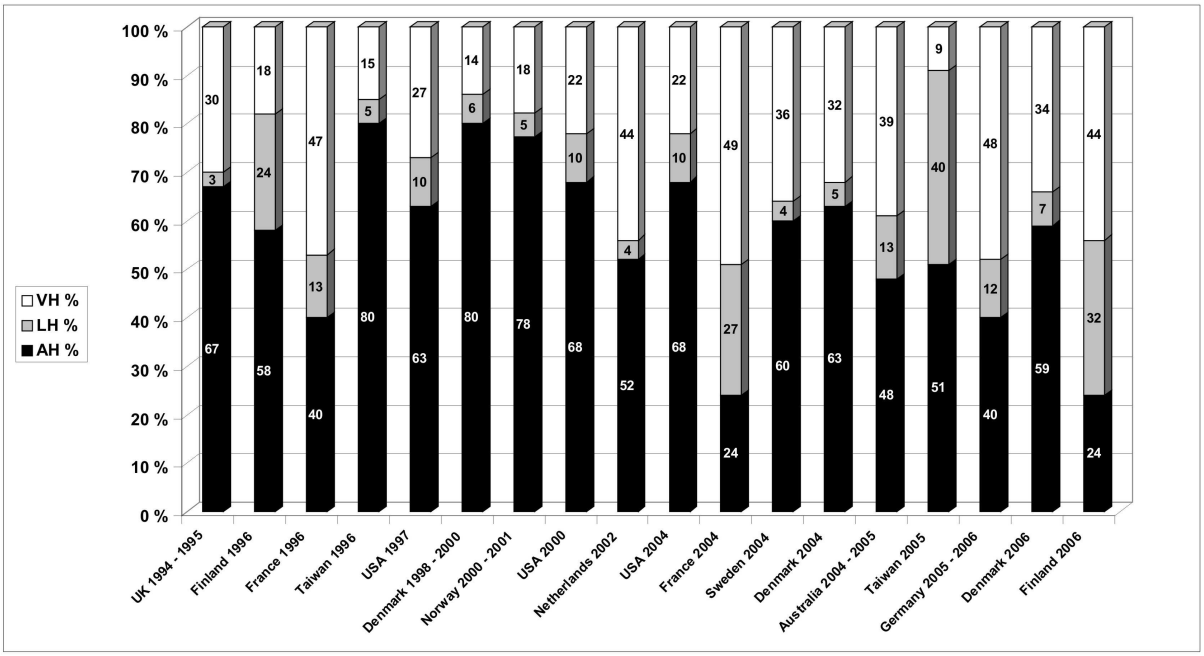


Figure 2

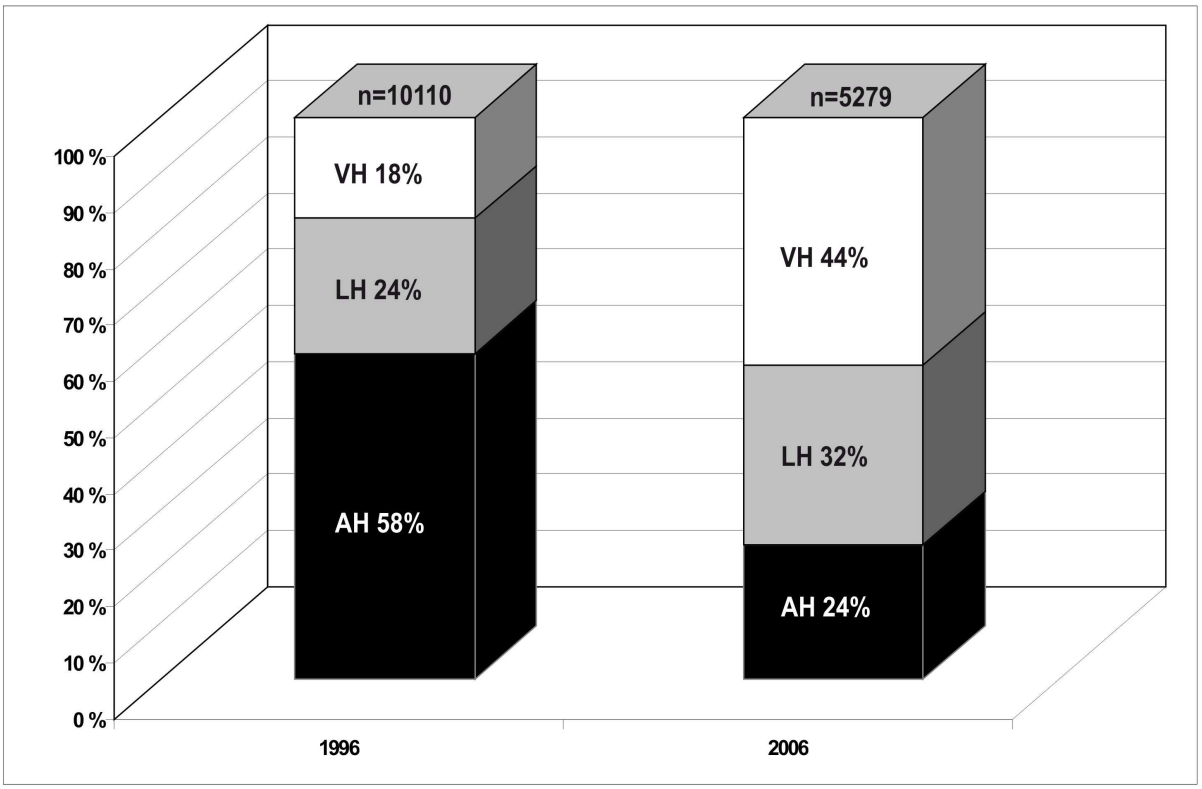
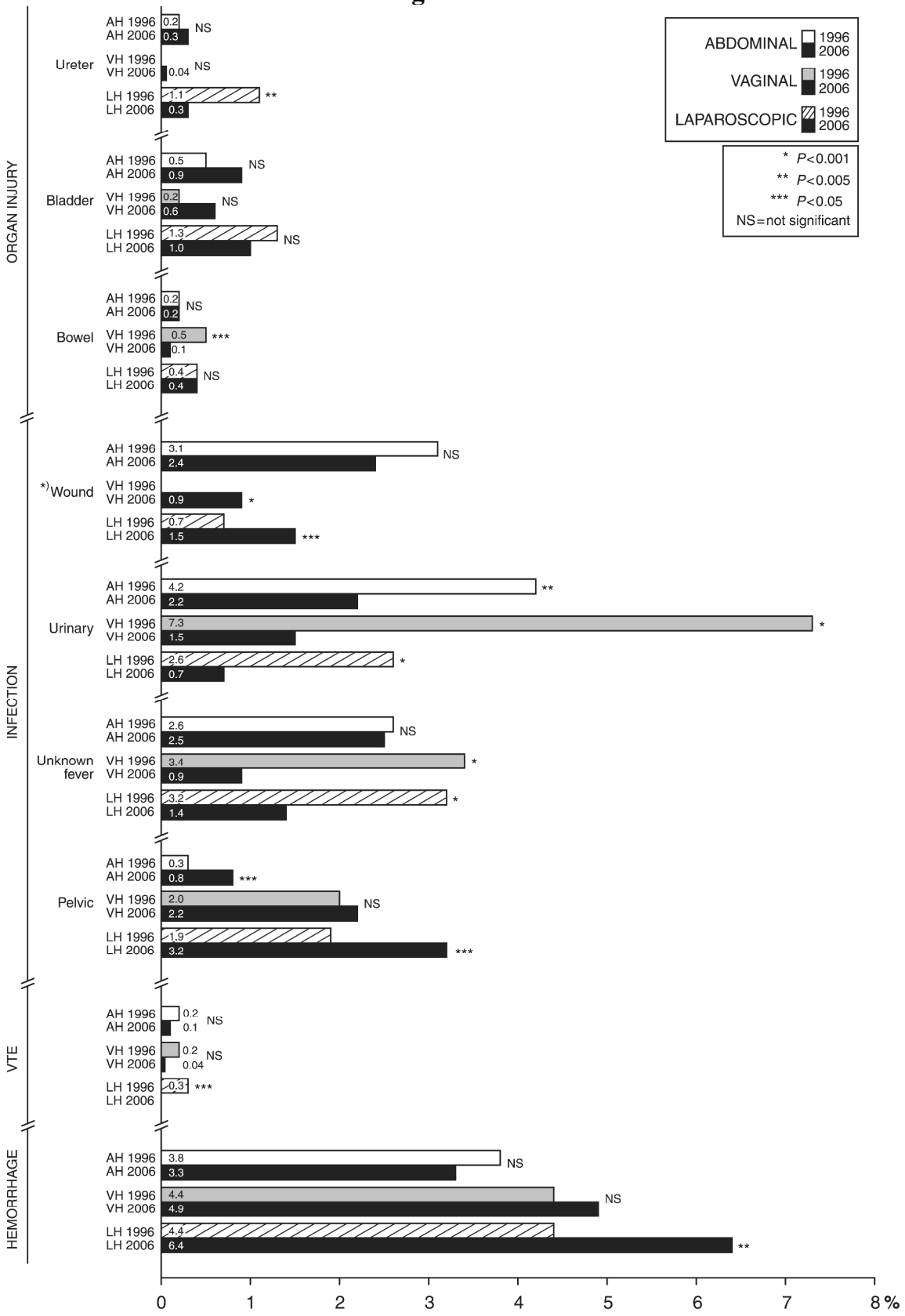


Figure 3


ABDOMINAL 1996 2006
VAGINAL 1996 2006
LAPAROSCOPIC 1996 2006
* P<0.001
** P<0.005
*** P<0.05
NS=not significant
ORGAN INJURY
INFECTION
VTE
HEMORRHAGE
Ureter
Bladder
Bowel
*)Wound
Urinary
Unknown fever
Pelvic
AH 1996 0.2
AH 2006 0.3 NS
VH 1996
VH 2006 0.04 NS
LH 1996 1.1
LH 2006 0.3 **
AH 1996 0.5
AH 2006 0.9 NS
VH 1996 0.2
VH 2006 0.6 NS
LH 1996 1.3
LH 2006 1.0 NS
AH 1996 0.2
AH 2006 0.2 NS
VH 1996 0.5
VH 2006 0.1 ***
LH 1996 0.4
LH 2006 0.4 NS
AH 1996 3.1
AH 2006 2.4 NS
VH 1996
VH 2006 0.9 *
LH 1996 0.7
LH 2006 1.5 ***
AH 1996 4.2
AH 2006 2.2 **
VH 1996 7.3
VH 2006 1.5 *
LH 1996 2.6
LH 2006 0.7 *
AH 1996 2.6
AH 2006 2.5 NS
VH 1996 3.4
VH 2006 0.9 *
LH 1996 3.2
LH 2006 1.4 *
AH 1996 0.3
AH 2006 0.8 ***
VH 1996 2.0
VH 2006 2.2 NS
LH 1996 1.9
LH 2006 3.2 ***
AH 1996 0.2
AH 2006 0.1 NS
VH 1996 0.2
VH 2006 0.04 NS
LH 1996 0.3
LH 2006 ***
AH 1996 3.8
AH 2006 3.3 NS
VH 1996 4.4
VH 2006 4.9 NS
LH 1996 4.4
LH 2006 6.4 **
0 1 2 3 4 5 6 7 8 %

Legends to the figures:

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

Footnote

Figures from France represent samples from University clinics only, otherwise national data are presented, apart from the UK, which excludes Wales, and represents 45% of national hysterectomies. References: UK 1994-1995, [7] Finland 1996, [8] France 1996, [9] Taiwan1996,[5] USA 1997,[10] Denmark 1998-2000, [11] Norway 2000-2001, [12] USA 2000,2004, [13] Netherlands 2002,[14] France 2004, [9] Sweden 2004,[15] Denmark 2004, [4] Australia 2005-2005, [16] Taiwan 2005,[5] Germany,[17] Denmark 2006, [4] and Finland 2006, [6]

Figure 2. 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.

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

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

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

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

* P = 0.05

** P < 0.001

Other comparisons (≤30 vs > 30): not significant

Patient Consent Form

The form was used only in Finnish (belowe).

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 liittyviin seikkoihin. Tutkimukseen osallistuminen on teille täysin vapaaehtoista; siihen osallistuminen tai osallistumisesta kieltäytyminen ei vaikuta millään tavalla teille jo hoitopaikassanne suunniteltuun hoitoon, josta vastaa teidät leikkaava lääkäri.

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

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Study protocol

The qestoinnaire sheets were used only in Finnish (belowe).

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_____
Muuttuiko 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.** miniheparіini / **b.** muu, mikä _____ + annos _____+ kesto (vrk) _____
Leikkauksen kesto (min) (aika 1. viillosta sulkuun) _____
Arvioitu/mitattu vuoto (ml) _____
Uteruksen paino ilman adnexeja (g) _____
Leikkaajan arvio leikkauksen vaikeudesta:
1. erittäin helppo/ **2**. helppo/ **3.** tavallinen/ **4** vaikea/ **5.** erittäin vaikea, miksi _____

Hemostaasimenetelmä(t):
1. Ligatuurat
2. Bipolaaripoltto
3. Monopolaaripoltto
4. Ultraääniveitsi
5. Muu (Esim. Ligasure), mikä _____

Liitännäistoimenpiteitä: Sivu 2
1. Ei
2. Kyllä
A. a. toisen adneksin poisto / **b** .molempien 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** havaittu 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. Rakkovaurio
D. Uretervaurio
E. Suolivaurio
F. Tekniset laiteongelmat, mikä _____
G. Muu, mikä _____
Miten komplikaatio hoidettiin _____
Leikkauksen **jälkeen** osastolla todettu komplikaatio:
1. Ei
2. Kyllä
A. Reoperaatio, syy_____
B. Postoperatiivinen vuoto/hematoma
C. Haavainfektio (vaatinut antibiootin, punktion tai dreneerauksen)
D. Virtsatieinfektio (Uricult > 10^5)
E. Epäselvä kuumeilu (aksillaarinen lämpö ≥ 38°C)
F. Syvä laskimotromboosi
G. Keuhkoembolia
H. Rakkovaurio
I. Uretervaurio
J. Suolenvetovaikeus
K. Suolivaurio
L. Hernia, mikä _____
M. Muu ongelma, mikä _____
Miten komplikaatio hoidettiin_____
Potilas sai verensiirron
1. Ei
2. Kyllä **a.** ennen leikkausta ____ punasoluyksikkö/ **b**. leikkauksen aikana ____ punasoluyksikköä/
c. leikkauksen jälkeen _____ punasoluyksikköä
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. Haavainfektio (vaatinut antibiootin, punktion tai dreneerauksen)
4. Virtsatieinfektio (Uricult > 10^5)
5. Epäselvä kuumeilu (Aksillaarinen lämpö ≥ 38 °C)
6. Lantionpohjan infektio (hematoma ja/tai abskessi)
7. Syvä laskimotromboosi
8. Keuhkoembolia
9. Rakkovaurio
10. Uretervaurio
11. Suolenvetovaikeus
12. Suolivaurio
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

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	p 2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	p 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	p 3
Objectives	3	State specific objectives, including any prespecified hypotheses	p 3
Methods			
Study design	4	Present key elements of study design early in the paper	p 4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p 4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *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	p 4
		(*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	p 4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p 4
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	p 4
Bias	9	Describe any efforts to address potential sources of bias	p 4
Study size	10	Explain how the study size was arrived at	p 4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p 4
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	p 4
		(*b*) Describe any methods used to examine subgroups and interactions	p 4
		(*c*) Explain how missing data were addressed	p 4
		(*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	p 4
		(*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 F2 P4
		(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 T1
		(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) P4
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time F3 T2
		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 P5-6 T2 F3
		(*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 P7
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 P8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence P8
Generalisability	21	Discuss the generalisability (external validity) of the study results P8-9
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 available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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 nationawide cohort evaluations with the same questionnaire.

Setting: All national operative hospitals in Finland.

Participants: Patients schedued 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 paralles 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).

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

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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 hysterctomies (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.

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

Setting: All national operative hospitals in Finland.

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Conclusions: The rate of postoperative complications fell markedly in the decade from 1996 to 2006. This paralles 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 **A LONGITUDINAL OBSERVATION STUDY**

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Running title: Improved hysterectomy outcomes in Finland 1996 - 2006

Abstract

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

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

Findings In 1996, AH was the main approach (58%), but was surpassed within a decade by VH and LH (together, 76% of all hysterectomies in 2006). **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, t**his s 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[1] the role of vaginal (VH) and abdominal hysterectomies (AH) has beeen a matter of re-evaluation. The rate of abdominal hysterectomies (AH) has subsequently fallen in some countries (Figure 1),[2,3,4,5,6] but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in 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.[8] Not surprisingly, the most modern method, LH, was, at that time, associated with more severe complications than the other methods. The rate of complications stood also in proportion to the experience of the surgeons – the more experienced the surgeon, the less LH-associated complications.

Since the beginning of the 2000's, several smaller studies, hospital-based series of LHs[2] and RCTs[18-19] have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate.[20-21] There are, however, no longitudinal follow-up studies on the results of hospital-based or nationwide studies on patients undergoing hysterectomy. Such studies are not only scientifically important but they also constitute important measures of quality control and are, as such, badly needed to help us to understand what we have learned of the different approaches to hysterectomy during all these years.[22] We conducted a nationwide survey on the outcomes of hysterectomies of two cohorts first in 1996 and second in 2006. In this paper we compare the results after AH, VH and LH for benign conditions in 2006[6] with the results 10 years previously. [8]

Methods

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

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

Results

The **proportions** of VH and LH in Finland increased markedly in the decade from 1996 to 2006, while the **proportion o**f 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 metrionidazole for

82.1% but in 1996 only for 15.3%. There were concomitantly significant reductions in the overall rate of infections; in the AH group from 9.9% to 7.7.% ($p<0.05$), in the VH group from 12.3% to 5.2% ($p<0.001$) but a non-significant change from 17.0% to 15.4% in the LH group.

Also, the use of pharmacological thrombosis prophylaxis had risen from 35.4% in 1996 to 64.8% in 2006 ($p<0.001$) and there was a concomitant reduction in VTEs in all groups, which was significant in the LH group (Figure 3 **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.[22] Furhermore they would also need to be set up so that they discount the effect of the individual surgeon, the surgeon's experience and the effect of sophisticated surgical centres compared to ordinary hospitals. National registry-based observational surveys on large numbers of consecutive patients with prospective data collection are an alternative to cumbersome and, maybe, unrealistic RCT's and document effectiveness because they reflect clinical reality in the hands of the "average" gynecological surgeon.[22] This alternative was chosen for the present nationwide study, which compares some clinical determinants related to hysterectomies (AH, VH and LH) and hysterectomy-related morbidity in 2006 with 1996 in Finland.

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

The rate of LH increased also (from 24% to 36%). The current rate of LHs in Finland is high compared to our neighbouring Nordic countries (4-7%)[4,12,15] and globally (Figure 1). Worldwide, only Taiwan has a higher rate of LH, where the rate of LH has soared from 5 % in 1996 to 40 % in 2005.[5] In consequence, we have a much lower rate of AH (24%) compared to many other countries, e.g., the USA (68%)[13] and the other Nordic countries Sweden (60%)[15], Denmark (59%),[4] Norway (78%).[12] According to a recent meta-analysis by the Cochrane collaboration, the order of preference of hysterectomies should be VH and LH followed by AH .[21]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 [8]– have decreased highly significantly (from 1.1% to 0.3%). This finding is in accordance with a retrospective

nationwide registry study on the complications of LH, which reported a continuously decreasing trend from 1993 to 2005 in ureter injuries in Finland.[24] Also, the fact that LH-related bladder complications sank from 1.3% to 1.0% supports the notion that surgeons doing this operation have steadily gained experience and are better aware of the need to avoid harming the bladder and ureters. The rate of VH-associated bowel complications sank also significantly (Figure 3). For AH there was a slight increase in the occurrence of total complications (from 16% in 1996 to 19% in 2006), but this only reflects the fact that more severe and advanced cases required the abdominal approach in 2006.

The reduction in the number of infections **(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.[25] **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. [26] 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 hysterecomies. [4]**

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 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 particpiate. 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.[27,28] The outlook is that hysterectomies will be safer than before. Recent indications for hysterectomies in Finland were more properly scrutinized and patients undergoing these procedures were more severly affected than a decade earlier. . **Of course, it would have been ideal to adjust the 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 hysterecomies between 1996 and 2006 indicate that clinical improvement was real. Moreover, t**he 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.)

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

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Authors´ contributions

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Literature search: TB, PH and JM.

Figures: TB and JM.

Tables: TB and JM

Study design: all authors

Permissions: TB, PH, JS and JM

Data collection: TB and PH

Data analysis: TB, PH and JM

Data interpretation: all authors

Writing: all authors

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

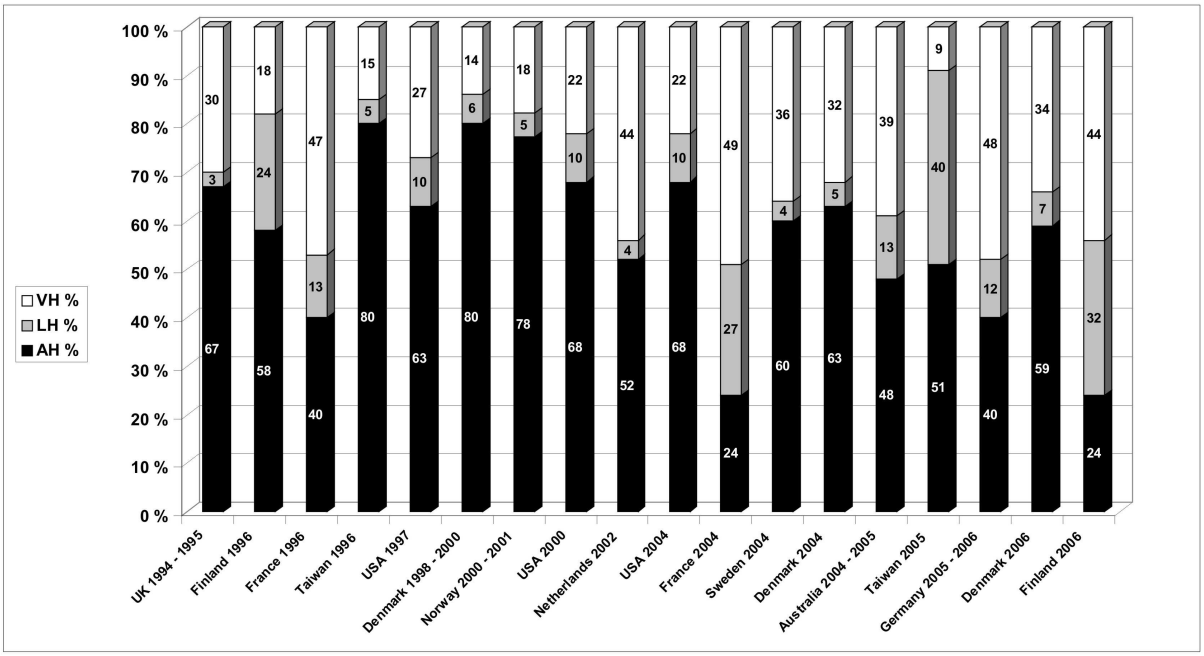
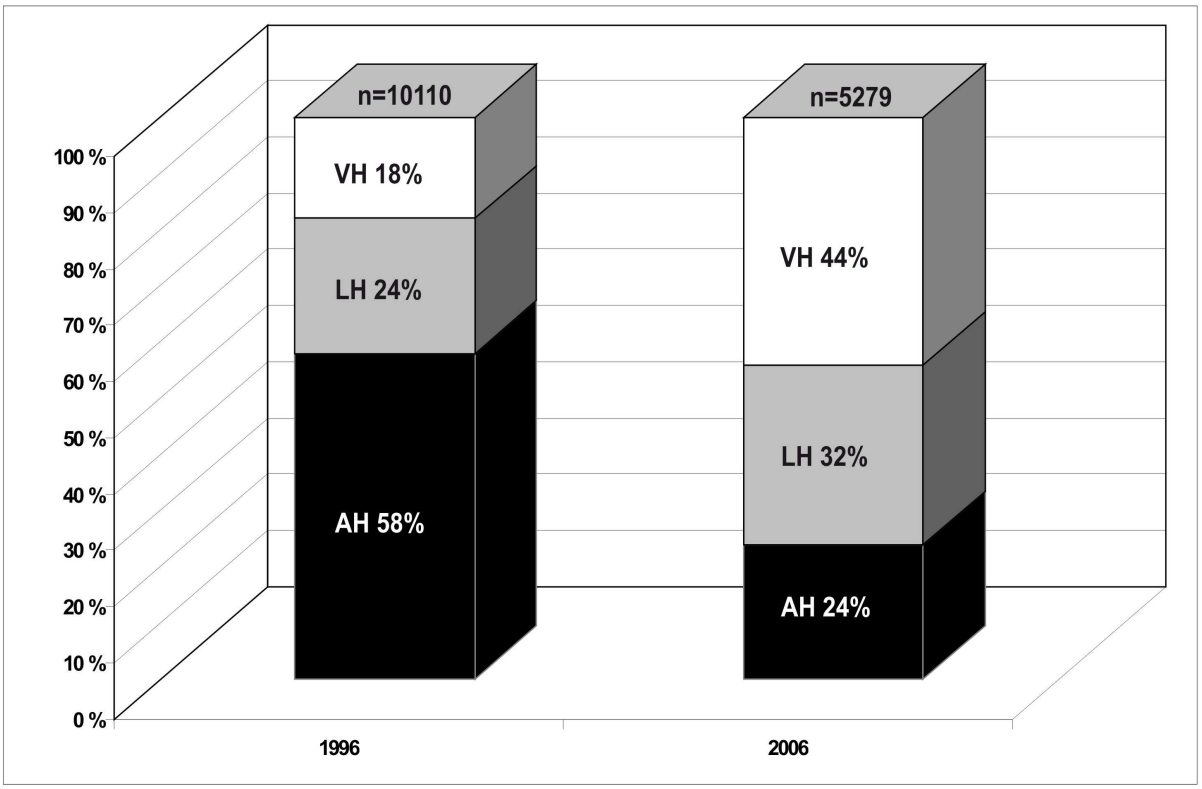


Figure 2



Legends to the figures:

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

Footnote

Figures from France represent samples from University clinics only, otherwise national data are presented, apart from the UK, which excludes Wales, and represents 45% of national hysterectomies. References: UK 1994-1995, [7] Finland 1996, [8] France 1996, [9] Taiwan1996,[5] USA 1997,[10] Denmark 1998-2000, [11] Norway 2000-2001, [12] USA 2000,2004, [13] Netherlands 2002,[14] France 2004, [9] Sweden 2004,[15] Denmark 2004, [4] Australia 2005-2005, [16] Taiwan 2005,[5] Germany,[17] Denmark 2006, [4] and Finland 2006, [6]

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

Footnote

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

Figure 3

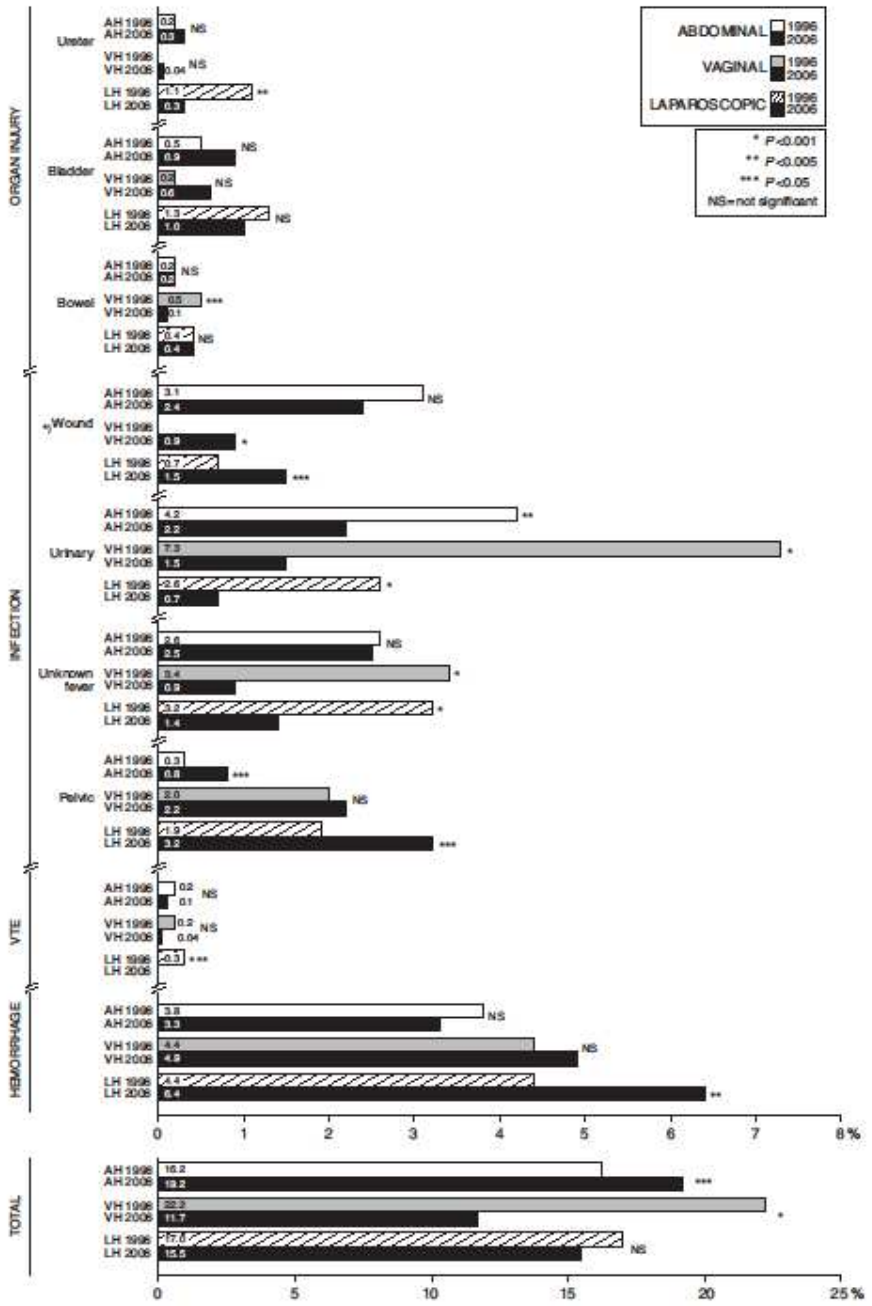

ABDOMINAL 1996 2006
VAGINAL 1996 2006
LAPAROSCOPIC 1996 2006
* P<0.001
** P<0.005
*** P<0.05
NS=not significant
ORGAN INJURY
Ureter
Bladder
Bowel
INFECTION
Wound
Urinary
Unknown fever
Pelvic
VTE
HEMORRHAGE
TOTAL
AH 1996 AH 2006
VH 1996 VH 2006
LH 1996 LH 2006
0 1 2 3 4 5 6 7 8 %
0 5 10 15 20 25 %

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.

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

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

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

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

* P = 0.05

** P < 0.001

Other comparisons (≤30 vs > 30): not significant

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

	ABDOMINAL					VAGINAL					LAPAROSCOPIC				
	1996 N=5875		2006 N=1255			1996 N=1801		2006 N=2345			1996 (N=2434)		2006 (N=1679)		
	%	n	%	N	P	%	n	%	n	P	%	n	%	n	P
ORGAN INJURY															
Ureter	0.2	9	0.3	4	0.212	-	0	0.04	1	0.381	1.1	27	0.3	5	**0.004**
Bladder	0.5	29	0.9	11	0.099	0.2	4	0.6	14	0.069	1.3	31	1.0	17	0.443
Bowel	0.2	12	0.2	3	0.807	0.5	9	0.1	2	**0.010**	0.4	9	0.4	7	0.811
Total/patient	0.9	50	1.4	18	0.054	0.7	13	0.7	17	0.991	2.8	67	1.7	29	**0.032**
INFECTION															
Wound	3.1	180	2.4	30	0.200			0.9	20	**<0.001**	0.7	17	1.5	25	**0.013**
Urinary	4.2	245	2.2	28	**0.001**	7.3	129	1.5	36	**<0.001**	2.6	63	0.7	11	**<0.001**
Unknown fever	2.6	152	2.5	32	0.939	3.4	62	0.9	22	**<0.001**	3.2	79	1.4	23	**<0.001**
Pelvic *	0.3	19	0.8	10	**0.017**	2.0	36	2.2	51	0.695	1.9	47	3.2	54	**0.009**
Total /patient **	9.9	583	7.7	97	**0.016**	12.3	222	5.2	122	**<0.001**	8.3	201	6.7	113	0.070
TROMBOEMB.	0.2	9	0.1	1	0.528	0.2	4	0.04	1	0.099	0.3	7	-	0	**0.028**
HEMORRHAGE	3.8	221	3.3	42	0.479	4.4	79	4.9	114	0.472	4.4	107	6.4	108	**0.004**
TOTAL /PATIENT **	16.2	952	19.2	241	0.010	22.2	400	11.7	275	**<0.001**	17.0	413	15.4	258	0.172

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

** N of patients. A patient may have had more than one complication.

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

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	p 2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	p 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	p 3
Objectives	3	State specific objectives, including any prespecified hypotheses	p 3
Methods			
Study design	4	Present key elements of study design early in the paper	p 4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p 4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *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	p 4
		(*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	p 4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p 4
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	p 4
Bias	9	Describe any efforts to address potential sources of bias	p 4
Study size	10	Explain how the study size was arrived at	p 4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p 4
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	p 4
		(*b*) Describe any methods used to examine subgroups and interactions	p 4
		(*c*) Explain how missing data were addressed	p 4
		(*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	p 4
		(*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 F2 P4
		(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 T1
		(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) P4
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time F3 T2
		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 P5-6 T2 F3
		(*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 P7
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 P8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence P8
Generalisability	21	Discuss the generalisability (external validity) of the study results P8-9
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 available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Patient Consent Form

The form was used only in Finnish (belowe).

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 liittyviin seikkoihin. Tutkimukseen osallistuminen on teille täysin vapaaehtoista; siihen osallistuminen tai osallistumisesta kieltäytyminen ei vaikuta millään tavalla teille jo hoitopaikassanne suunniteltuun hoitoon, josta vastaa teidät leikkaava lääkäri.

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

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Study protocol

The qestoinnaire sheets were used only in Finnish (belowe).

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_____
Muuttuiko 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) _____
Leikkauksen kesto (min) (aika 1. viillosta sulkuun) _____
Arvioitu/mitattu vuoto (ml) _____
Uteruksen paino ilman adnexeja (g) _____
Leikkaajan arvio leikkauksen vaikeudesta:
1. erittäin helppo/ **2**. helppo/ **3.** tavallinen/ **4** vaikea/ **5.** erittäin vaikea, miksi _____

Hemostaasimenetelmä(t):
1. Ligatuurat
2. Bipolaaripoltto
3. Monopolaaripoltto
4. Ultraääniveitsi
5. Muu (Esim. Ligasure), mikä _____

Liitännäistoimenpiteitä: Sivu 2
1. Ei
2. Kyllä
A. a. toisen adneksin poisto / **b** .molempien 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** havaittu 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. Rakkovaurio
D. Uretervaurio
E. Suolivaurio
F. Tekniset laiteongelmat, mikä _____
G. Muu, mikä _____
Miten komplikaatio hoidettiin _____
Leikkauksen **jälkeen** osastolla todettu komplikaatio:
1. Ei
2. Kyllä
A. Reoperaatio, syy_____
B. Postoperatiivinen vuoto/hematoma
C. Haavainfektio (vaatinut antibiootin, punktion tai dreneerauksen)
D. Virtsatieinfektio (Uricult > 10^5)
E. Epäselvä kuumeilu (aksillaarinen lämpö ≥ 38°C)
F. Syvä laskimotromboosi
G. Keuhkoembolia
H. Rakkovaurio
I. Uretervaurio
J. Suolenvetovaikeus
K. Suolivaurio
L. Hernia, mikä _____
M. Muu ongelma, mikä _____
Miten komplikaatio hoidettiin_____
Potilas sai verensiirron
1. Ei
2. Kyllä **a.** ennen leikkausta ____ punasoluyksikkö/ **b**. leikkauksen aikana ____ punasoluyksikköä/
c. leikkauksen jälkeen _____ punasoluyksikköä
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. Haavainfektio (vaatinut antibiootin, punktion tai dreneerauksen)
4. Virtsatieinfektio (Uricult > 10^5)
5. Epäselvä kuumeilu (Aksillaarinen lämpö ≥ 38 °C)
6. Lantionpohjan infektio (hematoma ja/tai abskessi)
7. Syvä laskimotromboosi
8. Keuhkoembolia
9. Rakkovaurio
10. Uretervaurio
11. Suolenvetovaikeus
12. Suolivaurio
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

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

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Running title: Improved hysterectomy outcomes in Finland 1996 - 2006

Abstract

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

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

Findings In 1996, AH was the main approach (58%), but was surpassed within a decade by VH and LH (together, 76% of all hysterectomies in 2006). ~~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, t**his s 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[1] the role of vaginal (VH) and abdominal hysterectomies (AH) has beeen a matter of re-evaluation. The rate of abdominal hysterectomies (AH) has subsequently fallen in some countries (Figure 1),[2,3,4,5,6] but AH still predominates in many countries as the main method for hysterectomy. Along with these changes, the attitudes have, however, gradually changed in 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.[8] Not surprisingly, the most modern method, LH, was, at that time, associated with more severe complications than the other methods. The rate of complications stood also in proportion to the experience of the surgeons – the more experienced the surgeon, the less LH-associated complications.

Since the beginning of the 2000's, several smaller studies, hospital-based series of LHs[2] and RCTs[18-19] have been published. Cochrane meta-analysis recommended VH as the primary technique for hysterectomy, followed by LH when appropriate.[20-21] There are, however, no longitudinal follow-up studies on the results of hospital-based or nationwide studies on patients undergoing hysterectomy. Such studies are not only scientifically important but they also constitute important measures of quality control and are, as such, badly needed to help us to understand what we have learned of the different approaches to hysterectomy during all these years.[22] We conducted a nationwide survey on the outcomes of hysterectomies of two cohorts first in 1996 and second in 2006. In this paper we compare the results after AH, VH and LH for benign conditions in 2006[6] with the results 10 years previously. [8]

Methods

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

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

Results

The ~~rates~~ **proportions** of VH and LH in Finland increased markedly in the decade from 1996 to 2006, while the ~~rate~~ **proportion o**f 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 metrionidazole for

82.1% but in 1996 only for 15.3%. There were concomitantly significant reductions in the overall rate of infections; in the AH group from 9.9% to 7.7.% ($p<0.05$), in the VH group from 12.3% to 5.2% ($p<0.001$) but a non-significant change from 17.0% to 15.4% in the LH group.

Also, the use of pharmacological thrombosis prophylaxis had risen from 35.4% in 1996 to 64.8% in 2006 ($p<0.001$) and there was a concomitant reduction in VTEs in all groups, which was significant in the LH group (Figure 3 **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.[22] Furhermore they would also need to be set up so that they discount the effect of the individual surgeon, the surgeon's experience and the effect of sophisticated surgical centres compared to ordinary hospitals. National registry-based observational surveys on large numbers of consecutive patients with prospective data collection are an alternative to cumbersome and, maybe, unrealistic RCT's and document effectiveness because they reflect clinical reality in the hands of the "average" gynecological surgeon.[22] This alternative was chosen for the present nationwide study, which compares some clinical determinants related to hysterectomies (AH, VH and LH) and hysterectomy-related morbidity in 2006 with 1996 in Finland.

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

The rate of LH increased also (from 24% to 36%). The current rate of LHs in Finland is high compared to our neighbouring Nordic countries (4-7%)[4,12,15] and globally (Figure 1). Worldwide, only Taiwan has a higher rate of LH, where the rate of LH has soared from 5 % in 1996 to 40 % in 2005.[5] In consequence, we have a much lower rate of AH (24%) compared to many other countries, e.g., the USA (68%)[13] and the other Nordic countries Sweden (60%)[15], Denmark (59%),[4] Norway (78%).[12] According to a recent meta-analysis by the Cochrane collaboration, the order of preference of hysterectomies should be VH and LH followed by AH .[21]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 [8]– have decreased highly significantly (from 1.1% to 0.3%). This finding is in accordance with a retrospective

nationwide registry study on the complications of LH, which reported a continuously decreasing trend from 1993 to 2005 in ureter injuries in Finland.[24] Also, the fact that LH-related bladder complications sank from 1.3% to 1.0% supports the notion that surgeons doing this operation have steadily gained experience and are better aware of the need to avoid harming the bladder and ureters. The rate of VH-associated bowel complications sank also significantly (Figure 3). For AH there was a slight increase in the occurrence of total complications (from 16% in 1996 to 19% in 2006), but this only reflects the fact that more severe and advanced cases required the abdominal approach in 2006.

The reduction in the number of infections **(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.[25] **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. [26] 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 hysterecomies. [4]**

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**

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among those who had been recruited to FINHYST 2006 and those who were unable to particpiate. This observation would exclude selection bias in our study cohort.

2006, compared to 1996, our patients were proportionately older, more obese and had a higher uterine weight, but still the duration of hospital stay in all hysterectomy types and the operation time for LH and VH was reduced (Table 1). Evidently, the need for hysterectomy will persist, but it will not be as high as in the late 1990's.[27,28] The outlook is that hysterectomies will be safer than before. Recent indications for hysterectomies in Finland were more properly scrutinized and patients undergoing these procedures were more severly affected than a decade earlier. . **Of course, it would have been ideal to adjust the 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 hysterecomies between 1996 and 2006 indicate that clinical improvement was real. Moreover, t**

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~~T~~he 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 severly 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.

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