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FINHYST, a prospective study of 5279 hysterectomies: complications and their risk factors

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BACKGROUND: Hysterectomy guidelines highlight an increase in urinary tract injuries with laparoscopic hysterectomy (LH). This national survey analyses complications of LH, abdominal hysterectomy (AH) and vaginal hysterectomy (VH).

METHODS: A prospective cohort undergoing hysterectomy for benign indications during 2006 was drawn from 53 hospitals in Finland; all communal hospitals participated. Detailed questionnaires covered surgical data and intra- and post-operative major and minor complications, for which risk factors were analysed by a multivariate logistic regression model adjusted for surgical data and patient characteristics.

RESULTS: Major complications rates in AH ($n = 1255$, 24%), LH (1679, 32%) and VH (2345, 44%) were 4.0, 4.3 and 2.6%, and total complications rates were 19.2, 15.4 and 11.7%, respectively. Logistic regression showed no statistically significant differences between approaches for any organ injuries or other major complications. Most bladder and bowel injuries (88 and 83%), but not ureter injuries (10%), were recognized intra-operatively. The ureter injury rate was low after LH (0.3%), as it was after other types of hysterectomy. Compared with LH, AH increased the odds of wound infection, and was an independent risk factor for urinary infections and febrile events. Compared with AH, LH and VH both presented a higher risk for pelvic infection; surgically treated equally often regardless of the type of hysterectomy. No differences in complications emerged between LH and VH. Obesity was a risk factor for many infections. Surgical adhesiolysis [odds ratio (OR) 2.41, 95% confidence interval (CI) 1.38–4.21] was the strongest single risk factor for major complications as a whole. Bladder injury was associated with a history of caesarean section (OR 4.01, 95% CI 2.06–7.83) and with a large uterus $\geq$500 g (OR 2.88, 95% CI 1.05–7.90), while bowel injury was associated with adhesiolysis (OR 29.07, 95% CI 7.17–117.88).

CONCLUSIONS: FINHYST is a large prospective hysterectomy study illustrating actual complications. Whenever possible, hysterectomy should be minimally invasive.

Key words: adhesiolysis / complications / hysterectomy / ureter injury / bowel injury

Introduction

The national quality assessment tradition concerning hysterectomy in Finland began a year after introduction of the laparoscopic hysterectomy (LH) in 1992 (Mäkinen and Sjöberg, 1994), and data on 1165 operations revealed a high incidence of ureter injuries (1.3%) (Härkki-Sirén *et al.*, 1997). Prospective data on 10 110 operations, including all approaches, were collected in 1996, with vaginal hysterectomy (VH) predominating in the number of complications, in particularly infections. (Mäkinen *et al.*, 2001). The overall complication rate for VH in Finland in 1996 was similar to a rate from a large series published much earlier (Dicker *et al.*, 1982). Dicker *et al.* observed a rate, which for its era was much lower than for abdominal hysterectomy (AH). Thus, the superiority of the vaginal approach was already being considered. A large American observation later discovered no differences in surgical complications among the

three approaches, but VH was recommended because of its low cost (Campbell et al., 2003). Only a recent meta-analysis on randomized studies was able to confirm these conclusions; it stated that VH should be performed in preference to AH if possible, and if not, avoidance of AH could be through performing LH; these guidelines state, however, that after LH, urinary tract injuries are increased (Johnson et al., 2005, 2006; updated by Nieboer et al., 2010). Using Finnish retrospective data, complications have been analysed with a focus on urinary tract injuries (Härkki-Sirén et al., 1998) and major complications of LH (Härkki et al., 2001; Brummer et al., 2008). However, a prospective multi-centre study is the best approach to obtain relative complication rates. The aim of FINHYST was to observe complications, and their determining factors, after hysterectomy for benign causes, in a prospective real-life national setting.

Materials and Methods

Data on 5279 hysterectomies, all performed for benign causes, were prospectively collected from 1 January to 31 December 2006. All 46 municipal (public) hospitals where hysterectomies are performed in Finland collaborated, comprising 5 university clinics (one containing 3 different units), 16 central hospitals and 23 local hospitals. In addition, seven private clinics collaborated. The study plan was approved by the Ministry of Social Affairs and Health in Finland and by the ethics committees at the hospitals and was included in the ClinicalTrials.gov protocol. Written consent was obtained from each patient. The data were collected prospectively by the performing gynaecological surgeons, identifying themselves as either specialists (73%) or residents (22%). Complications were categorized by the time of their appearance: detected intra-operatively or post-operatively. Late-onset post-operative complications, detected after discharge when a patient visited an outpatient clinic or was re-admitted to the hospital, were collected on another specific form. In the absence of such a form, the patient was assumed not to have a late complication. Any omission of essential information led to a request for it. Conversions to laparotomy were not calculated as complications, whereas complications responsible for conversions (such as haemorrhage or organ injuries) were.

Intra-operative complications were defined as haemorrhage $\geq$1000 ml, bladder, ureter or bowel injuries, vascular injuries (epigastric vessels and major vessels such as the aorta, vena cava or iliac vessels) or other complications (with description) resulting in additive procedures or treatment during surgery. Post-operative complications were defined as haemorrhage or haematoma, wound infection, urinary tract infection (UTI), febrile event, deep vein thrombosis (DVT), pulmonary embolism (PE), ileus, hernia (with description) and other complications (with description). The causes of each re-operation were collected. Post-operatively detected organ injuries (bladder, ureter or bowel) were handled as post-operative complications. Wound infection was defined as those requiring antibiotic treatment or drainage, UTI was defined as a single bacterial growth exceeding 10^5/ml and a febrile event was defined as a clinically relevant fever of an unknown reason with axillary temperature $\geq$38.0°C. Late-onset post-operative complications were defined similarly to those detected during the initial hospitalization, and also included pelvic infection, defined by a haematoma or abscess. Data on the need for and duration of re-admittance to hospital, as well as re-operations occurring, and data on other types of treatment were collected.

The definition of major complications in FINHYST was chosen to resemble that of the severe complications reported to the Finnish Patient Insurance Centre: Death, PE or DVT, all injuries to bladder, ureter or bowel, or to vascular structures such as the aorta, vena cava or iliac vessels or any other reason making a re-operation necessary (either during the initial hospitalization or at late-onset appearance). The Finnish Patient Insurance Centre handles the compensation procedures for patient injuries occurring in Finland. All patients are insured during their hospitalization; their insurance covers bodily injuries that patients have sustained in connection with health care, and patients seeking financial compensation can file claims free of charge. Retrospective data from the Centre for 2006 were analysed as a quality assessment of the prospective FINHYST 2006 data (see Discussion section).

Univariate Chi-square (χ^2) or Fisher's exact test analyses preceded adjustments for the multivariate logistic regression model for risk analysis. The choice of confounding covariates was guided by clinical interests and prior research. Risk factors for each complication or group of complications were analysed for all the types of hysterectomy together; then the comparison of the three approaches was performed first with AH as the reference, then VH, in order to represent all pairs (Table I). Furthermore, logistic regression analyses of risk factors were then performed separately for each type of hysterectomy (AH $n = 1255$, LH $n = 1679$, VH $n = 2345$). The prior experience of 30 operations or fewer ever performed of that particular type of hysterectomy by the gynaecological surgeon was compared with the experience exceeding 30 operations. Patient age was classified to match the pre-, peri- and post-menopausal age groups of under 45, 45–54 and 55 or over, with the youngest age group as the reference. A standard classification of BMI (kilogram per square metre) classed patients as overweight (25.0–29.9), obese (30.0–34.9) or extremely obese (35.0 or over), with normal weight (under 25.0) as the reference. The surgeons were requested to report a single main indication for hysterectomy: myomas (33%), menorrhagia (21%), dysmenorrhoea (3%), endometriosis (2%), uterine prolapse (28%), adnexal mass (6%) or other (7%), with myomas as the reference, except for VH, for which the reference was uterine prolapse (61% of VHs). A large uterus was classified with a chosen cut-off point of 500 g, with lower than 500 g as the reference. Prior caesarean section (CS), prior laparotomy (other than CS), prior laparoscopy, adhesiolysis during surgery, and concomitant surgery (any) were applied as a categorical variables (yes or no).

The logistic regression model is presented in Table II; the data were also adjusted for antibiotic and thrombosis prophylaxis. In the analyses by the type of hysterectomy, in VH (where adnexal mass as indication was non-existent), the three patients with the indication endometriosis were excluded, while in the analysis of AH, a single patient with uterine prolapse was excluded. Within certain rare complications, no event appeared in the context of some of the covariates. When this occurred for a certain indication, a forced exclusion of cases with such an indication was necessary. Otherwise a covariate with no effect was simply not applied; the configuration of each analysis is presented within the tables. A CI of 95% and a P-value <0.05 was considered significant. All calculations were performed with SPSS 17.0.

Results

The cohort representing 79% of benign hysterectomies in Finland in 2006 has been described in detail elsewhere (Brummer et al., 2009). Briefly, the number of hysterectomies reported was 5279, of which 44% were VH ($n = 2345$), 32% LH ($n = 1679$) and 24% AH ($n = 1255$). The conversion rate in LH was 5.2%, and in VH 0.6% (χ^2 $P < 0.001$).

A multivariate logistic regression model adjusted for important confounders showed no statistically significant differences in ureter injuries between the types of hysterectomy. Similarly, differences in any other organ injury, post-operative haemorrhage or major complications as a

Table I Complications of hysterectomy, with comparison of approaches. Organ injuries (bladder, ureter, bowel) comprise both intra- and post-operatively recognized complications.

				AH as the reference group to LH and VH				VH as the reference group to LH and AH				Variables
Complication		***n***	**%**	**Adjusted OR**	**95% CI**		***P***	**Adjusted OR**	**95% CI**		***P***	**NA to model**
Operative haemorrhage ≥1000 ml	AH	72	5.7	1.00				1.36	0.77	2.41	0.289	[a]
	LH	50	3.0	0.77	0.50	1.17	0.222	1.04	0.61	1.79	0.875	
	VH	37	1.6	0.73	0.41	1.30	0.289	1.00				
Bladder injury	AH	11	0.9	1.00				0.69	0.24	1.96	0.486	[a]
	LH	17	1.0	1.60	0.66	3.87	0.298	1.10	0.47	2.61	0.823	
	VH	14	0.6	1.45	0.51	4.13	0.486	1.00				
Ureter injury	AH	4	0.3	1.00				9.77	0.25	377.15	0.221	6[a†]
	LH	5	0.3	1.32	0.29	6.15	0.720	12.94	0.41	410.77	0.147	
	VH	1	0.04	0.10	0.00	3.95	0.221	1.00				
Bowel injury	AH	3	0.2	1.00				1.21	0.07	19.60	0.894	1, 6, 12[a†]
	LH	7	0.4	2.94	0.66	13.09	0.157	3.55	0.29	43.10	0.319	
	VH	2	0.1	0.83	0.05	13.40	0.894	1.00				
Pulmonary embolism	AH	1	0.1									
	LH	0										
	VH	1	0.04									
Post-operative haemorrhage or haematoma	AH	33	2.6	1.00				0.79	0.44	1.40	0.413	
	LH	45	2.7	0.87	0.52	1.44	0.577	0.68	0.42	1.10	0.118	
	VH	65	2.8	1.27	0.72	2.26	0.413	1.00				
Ileus	AH	13	1.0	1.00				6.74	0.42	109.22	0.179	[a†]
	LH	5	0.3	0.06	0.33	0.11	1.044	2.25	0.15	34.00	0.559	
	VH	3	0.1	0.18	0.15	0.01	2.405	1.00				
Urinary retention	AH	6	0.5	1.00				0.90	0.23	3.60	0.883	[a]
	LH	9	0.5	1.10	0.34	3.57	0.871	0.99	0.34	2.93	0.991	
	VH	37	1.6	1.11	0.28	4.43	0.883	1.00				
Urinary infection	AH	28	2.2	1.00				1.47	0.66	3.27	0.345	
	LH	11	0.7	**0.33**	**0.15**	**0.70**	0.004	0.48	0.21	1.12	0.090	
	VH	36	1.5	0.68	0.31	1.51	0.345	1.00				
Wound infection	AH	30	2.4	1.00				**3.81**	**1.60**	**9.10**	0.003	
	LH	25	1.5	**0.46**	**0.25**	**0.86**	0.014	1.77	0.78	4.03	0.172	
	VH	20	0.9	**0.26**	**0.11**	**0.63**	0.003	1.00				
Febrile event	AH	32	2.5	1.00				1.51	0.74	3.07	0.258	
	LH	23	1.4	**0.50**	**0.27**	**0.91**	0.023	0.75	0.38	1.49	0.407	
	VH	22	0.9	0.66	0.33	1.35	0.258	1.00				
Pelvic infection, haematoma or abscess	AH	10	0.8	1.00				**0.19**	**0.08**	**0.41**	<0.001	
	LH	54	3.2	**5.08**	**2.45**	**10.54**	<0.001	0.94	0.59	1.50	0.799	
	VH	51	2.2	**5.40**	**2.46**	**11.89**	<0.001	1.00				
Complication groups												
Infections total[b]	AH	97	7.7	1.00				1.14	0.78	1.66	0.493	
	LH	113	6.7	0.84	0.61	1.16	0.287	0.96	0.69	1.34	0.812	
	VH	122	5.2	0.88	0.60	1.28	0.493	1.00				
Major complications total[b]	AH	50	4.0	1.00				0.93	0.55	1.55	0.775	[a]
	LH	72	4.3	1.13	0.75	1.70	0.571	1.05	0.67	1.62	0.844	
	VH	61	2.6	1.08	0.64	1.81	0.775	1.00				
Complications total[b]	AH	241	19.2	1.00				1.20	0.92	1.57	0.179	
	LH	258	15.4	0.86	0.69	1.07	0.169	1.03	0.81	1.31	0.799	
	VH	275	11.7	0.83	0.64	1.09	0.179	1.00				

Post-operative haemorrhage or haematoma represent rates from index admission to hospital (early), comprising both operatively and conservatively treated cases. *Pelvic infection, haematoma or abscess* represents only complications discovered after discharge (late). All other post-operative complications comprise those both early and late. AH, abdominal hysterectomy ($n = 1255$); LH, laparoscopic hysterectomy ($n = 1679$); VH, vaginal hysterectomy ($n = 2345$); NA, not applicable. Multivariate logistic regression model adjusted for variables: 1, hospital type; 2, surgeon's experience; 3, patients' age; 4, BMI; 5, indication for hysterectomy; 6, prior cesarian section; 7, prior laparotomy; 8, prior laparoscopy; 9, adhesiolysis; 10, concomitant surgery; 11, uterine size; 12, antibiotic; 13, thrombosis prophylaxis. In VH, adnexal mass was not an indication ($n = 0$), and endometriosis ($n = 3$) was excluded from the analyses, as was uterine prolapse ($n = 1$) in AH.

[a]Patients who underwent surgery in private hospitals ($n = 49$) were excluded, due to lack of events.

[b]A patient may have had more than one complication. *Infections total* comprise urinary infections, wound infections, febrile events, pelvic infections; or a combination of these. *Major complications total* includes thromboses, organ injuries and re-operations for other cause.

[†]Patients with the indication dysmenorrhoea ($n = 145$) were excluded due to lack of events.

Table II Multivariate logistic regression analysis on predisposing factors of occurrence of total complications, presented by the type of hysterectomy.

	AH				LH				VH			
	Adjusted OR	95%	CI	P	Adjusted OR	95%	CI	P	Adjusted OR	95%	CI	P
Type of hospital												
University	1.00				1.00				1.00			
Central	**0.67**	**0.47**	**0.96**	**0.028**	1.11	0.80	1.56	0.528	0.77	0.56	1.05	0.097
Local	**0.63**	**0.41**	**0.98**	**0.038**	1.12	0.77	1.63	0.557	**0.69**	**0.48**	**0.97**	**0.036**
Private	0.90	0.10	8.09	0.923	0.76	0.22	2.62	0.667	0.39	0.05	3.11	0.377
Experience of the gynaecological surgeon												
More than 30 operations ever performed	1.00				1.00				1.00			
Less or equal to 30 operations ever performed	0.81	0.55	1.19	0.284	1.04	0.74	1.45	0.839	0.74	0.52	1.06	0.099
Patient age												
Under 45	1.00				1.00				1.00			
45–54	0.86	0.58	1.27	0.458	1.08	0.78	1.49	0.633	**0.66**	**0.47**	**0.93**	**0.017**
55 or over	0.85	0.52	1.41	0.537	0.65	0.39	1.07	0.093	**0.45**	**0.30**	**0.68**	**<0.001**
BMI												
Normal weight (under 25.0)	1.00				1.00				1.00			
Overweight (25.0–29.9)	1.21	0.86	1.70	0.282	0.98	0.72	1.34	0.915	1.15	0.85	1.55	0.357
Obese (30.0–34.9)	1.05	0.69	1.62	0.811	1.15	0.77	1.71	0.504	1.28	0.87	1.87	0.209
Extremely Obese (35.0 or over)	1.01	0.59	1.75	0.958	1.18	0.59	2.36	0.638	**2.12**	**1.22**	**3.70**	**0.008**
Indication for hysterectomy												
Myomas	1.00				1.00				1.03	0.65	1.65	0.885
Menorrhagia	1.41	0.90	2.19	0.131	0.99	0.71	1.38	0.955	1.36	0.89	2.08	0.151
Dysmenorrhoea	1.15	0.37	3.61	0.813	0.82	0.40	1.67	0.584	1.95	0.89	4.30	0.096
Endometriosis	0.81	0.40	1.64	0.561	1.99	0.99	4.00	0.053	NA			
Uterine prolapse	NA				0.87	0.35	2.19	0.773	1.00			
Adnexal mass	1.30	0.80	2.13	0.289	0.97	0.54	1.73	0.911	NA			
Other	1.60	0.90	2.85	0.110	0.81	0.49	1.32	0.397	1.42	0.72	2.78	0.310
Prior CS												
None	1.00				1.00				1.00			
One or more	0.74	0.49	1.12	0.155	1.02	0.70	1.47	0.924	1.11	0.72	1.72	0.628
Prior laparotomy (other than CS)												
None	1.00				1.00				1.00			
One or more	1.11	0.81	1.54	0.513	1.04	0.76	1.43	0.796	0.99	0.71	1.37	0.941
Prior laparoscopy												
None	1.00				1.00				1.00			
One or more	0.84	0.56	1.25	0.384	1.08	0.80	1.45	0.609	0.91	0.65	1.26	0.562
Adhesiolysis												
No	1.00				1.00				1.00			
Yes	**4.45**	**2.58**	**7.67**	**<0.001**	**1.69**	**1.00**	**2.84**	**0.049**	0.71	0.09	5.78	0.748
Concomitant surgery												
No	1.00				1.00				1.00			
Yes	**1.54**	**1.07**	**2.21**	**0.019**	1.01	0.73	1.41	0.941	**1.44**	**1.01**	**2.06**	**0.046**
Uterine size												
Under 500 g	1.00				1.00				1.00			
More than 500 g	**1.60**	**1.12**	**2.28**	**0.009**	**1.83**	**1.06**	**3.16**	**0.030**	0.53	0.16	1.80	0.311

The model is adjusted also for the use of prophylaxis. Adjusted odds ratios (OR) are presented by category, along with the corresponding confidence interval (CI) and statistical significance (*P*). OR for reference groups are indicated by 1.00. Statistically significant results in bold. NA, not applicable.

whole were non-existent. Women who underwent AH were at a higher risk for wound infections compared with those with LH and VH. AH was also an independent risk factor for urinary infections and febrile events compared with LH (Table I).

No significant differences arose between the minimally invasive approaches LH and VH (Table I). The only category in which the minimally invasive methods presented an increased risk compared with AH was pelvic infection (Table I).

Intra-operative complications

Major intra-operative complications comprised visceral damage; most bladder (88%) and bowel (83%) injuries were detected intra-operatively, whereas only a single ureter injury (10%) was detected during AH in a case with retrocervical endometriosis, and treated with end-to-end anastomosis. In VH, all 17 bladder perforations (Table I) were detected and repaired intra-operatively, likewise in 9 of 11 bladder injuries in AH, and in 14 of 17 bladder injuries in LH. Of the 14 bladder injuries detected and repaired during LH, 6 were sutured laparoscopically. In VH, vaginal repair of the bladder was most common, but one case of perforation was treated laparoscopically, and once a perforation led to laparo-conversion. All bowel injuries in AH and VH (Table I) were intra-operatively detected and repaired, as were five of seven bowel injuries in LH; in total laparo-conversion for bowel injury repair was necessary twice. A single major vessel injury also occurred: a Veress-needle injury of the left communal iliac artery and vein.

Other intra-operative complications comprised four cases (0.24%) of epigastric inferior artery injury, and one case of vaginal rupture to a virgin in LH. Moreover, in AH and VH, a few cardiac arrhythmias and unintended unilateral salpingo-oophorectomies occurred due to bleeding.

Post-operative complications

Major post-operative complications comprised PEs (Table I), organ injuries detected post-operatively, and re-operations for another cause. No deaths occurred. Two bladder injuries were discovered early post-operatively, at index admission, both were after LH and both were sutured laparoscopically. Three bladder injuries had a late-onset appearance: one patient was re-admitted after LH and treated by insertion of a suprapubic catheter, and two were re-admitted after AH and treated by laparotomy to repair vesicovaginal fistulas (VVFs). Three ureter injuries were discovered early post-operatively, two after AH and one after VH. Six ureter injuries were late-onset, with an average diagnostic delay of 14 days (range 6–22): one arose after AH, and five after LH, of which four occurred on the right side. Ureter injuries were most commonly treated with ureteroneocystotomy in six of nine cases, whereas two were treated by stenting and one was treated by end-to-end anastomosis. The two post-operatively detected bowel injuries were both perforations of the rectosigmoid colon after LH, with sigmoideostomy performed on the fourth post-operative day. One had a Hartmann operation with stoma closure within 3 months. The other case with deep endometriosis was complicated by a rectovaginal fistula. An attempt to close the sigmoideostomy at 3 months was unsuccessful, resulting in resection of the rectosigmoid. Furthermore, due to an infection, after 9 days a third re-operation was performed resulting in a transversostomy; finally, stoma closure at 7 months was successful.

Other major post-operative complications comprised re-operations, most commonly due to secure intra-abdominal or vaginal haemostasis: in AH 21 (1.7%), in LH 35 (2.0%) and in VH 36 (1.5%) cases. Late-onset pelvic infection with haematoma or abscess was surgically treated equally often (0.4%) regardless of the type of hysterectomy. Other re-operations comprised four cases of dehiscent laparotomy wounds, a wound infection, an adherent drain and a retained sponge after AH; and a single case of suspicion of haemorrhage after LH.

Other sporadic post-operative complications reported comprised anaemia requiring blood transfusion, angina pectoris, bulla on one diabetic patient's foot, cardiac arythmia, clostridium difficile diarrhoea, colpitis, delirium, dyspnoea, erysipelas, haematoma of the abdominal wall, impaired analgesia, nausea and vomiting, nerve distension of the upper extremity, opioid-induced drowsiness, pneumonia, pneumothorax, postdural puncture headache, a retained vaginal sponge, ruptured posterior colporrhaphy, severe hyponatraemia and urticaria. These miscellaneous complications are under 'complications, total' in Table I.

Patients in whom a major post-operative complication occurred had a mean post-operative hospital stay of 6 days (SD 5, range 1–34). The mean number of sick-leave days for working patients for whom a major post-operative complication occurred was 34 days (SD 16, range 14–145). Patients with a major late-onset complication were always re-admitted. Overall, re-admittance occurred for 54% of those with any reported late-onset complication: for 23 (1.8%) after AH, for 60 (3.6%) after LH and for 42 (1.8%) after VH.

Risk factors for complications

Surgical removal of adhesions was reported in 6.6% of AHs and in 5.9% of LHs, but very rarely in VH (0.6%). For total complications of LH, only adhesiolysis and a large uterus emerged as statistically significant risk factors, and endometriosis was close to significance (Table II). In a secondary analysis with adhesiolysis removed from the model, endometriosis [odds ratio (OR) 2.27, 95% confidence interval (CI) 1.15–4.50, $P = 0.018$], along with a large uterus, arose as sole risk factors. Almost one-third (30.6%) of the endometriosis patients undergoing LH had a complication, while in AH the total complication rate in endometriosis patients (19.2%) was the same as the average (Table I).

Major complications by indication were most common with endometriosis in LH (12.2%), with an adnexal mass in AH (7.2%) and with menorrhagia in VH (5.3%), but none reached significance. Major complications occurred commonly in cases with adhesiolysis, in 10.1% in LH and in 13.3% in AH. In AH, adhesiolysis was the sole significant risk factor for major complications (Table III). In LH, no variables reached significance, but in a secondary analysis with adhesiolysis removed, the sole risk factor emerging for major complications was endometriosis (OR 2.87, 95% CI 1.02–8.03, $P = 0.045$). In VH, the risk was reduced for local and central hospitals (OR 0.46, 95% CI 0.22–0.94, $P = 0.032$ and OR 0.37, 95% CI 0.19–0.70, $P = 0.002$, respectively). With all hysterectomies analysed together, obesity was not a risk factor for major complications, neither was age nor a large uterus of importance. Cases operated on for an

Table III Effect of a history of CS, large uterus, adhesiolysis during surgery and concomitant surgery (any) on the risk for various individual complications or group of complications.

	Complication	Adjusted OR	95%	CI	P	Variables NA
Prior CS						
	Bladder injury					
	In all	4.01	2.06	7.83	<0.001	[a]
	In LH	5.39	1.87	15.55	0.002	[a,c]
	In VH	7.89	2.50	24.85	<0.001	9, 11, 12[a]
Uterine size ≥500 g						
	Intra-operative haemorrhage ≥1000 ml					
	In all	2.93	1.88	4.58	<0.001	[a]
	In AH	2.76	1.52	5.02	<0.001	[a,b]
	In LH	5.47	2.51	11.95	<0.001	12[a]
	Bladder injury					
	In all	2.88	1.05	7.90	0.040	[a]
	Complications total					
	In all	1.44	1.10	1.89	0.008	
Adhesiolysis						
	Intra-operative haemorrhage ≥1000 ml					
	In all	3.56	1.95	6.51	<0.001	[a]
	In AH	5.80	2.53	13.27	<0.001	[a,b]
	Bowel injury					
	In all	29.07	7.17	117.88	<0.001	1, 6, 12[a,b]
	In LH	56.45	5.96	534.82	<0.001	1, 6, 11, 12[a,b,c]
	In AH	113.79	3.85	3366.03	0.006	1, 2, 6, 8, 12[a,b,d]
	Ileus					
	In all	19.22	1.78	207.24	0.015	[a,b]
	Febrile event					
	In all	3.16	1.37	7.31	0.007	
	In AH	4.28	1.38	13.27	0.012	[a]
	Infections total					
	In AH	3.61	1.67	7.82	0.001	
	Major complications total					
	In all	2.41	1.38	4.21	0.002	[a]
	In AH	4.02	1.63	9.94	0.003	[a]
	Complications total					
	In all	2.48	1.75	3.52	<0.001	
Concomitant surgery						
	Intra-operative haemorrhage ≥1000 ml					
	In all	1.91	1.28	2.85	0.002	[a]
	In AH	2.14	1.13	4.06	0.020	[a,b]
	Ileus					
	In all	8.96	1.05	76.43	0.045	[a,b]
	Urinary retention					
	In all	2.73	1.08	6.87	0.033	[a]
	Infections total					
	In AH	1.72	1.01	2.95	0.047	
	Complications total					
	In all	1.28	1.05	1.56	0.014	

Data were analysed as all approaches together (in all, $n = 5279$) and separately for abdominal (AH), laparoscopic (LH) and vaginal hysterectomy (VH). Multivariate logistic regression model adjusted for: 1, hospital type; 2, surgeon's experience; 3, patients' age; 4, BMI; 5, indication for hysterectomy; 6, prior cesarian section; 7, prior laparotomy; 8, prior laparoscopy; 9, adhesiolysis; 10, concomitant surgery; 11, uterine size; 12, antibiotic; 13, thrombosis prophylaxis. In addition, analysis with all hysterectomies together is adjusted for the type of hysterectomy (AH, LH or VH). NA, not applicable to model.

[a]Patients who underwent surgery in private hospitals NA (in AH $n = 6$, in LH $n = 26$, in VH $n = 17$) were excluded due to lack of events.

[b]Patients with the indication dysmenorrhoea were excluded due to lack of events (in AH $n = 26$, in LH $n = 73$, in VH $n = 46$).

[c]Patients with the indications uterine prolapse and adnexal mass were excluded due to lack of events in LH (n=52 and $n = 141$, respectively).

[d]Patients with the indications menorrhagia and endometriosis were excluded due to lack of events in AH (n=185 and $n = 78$, respectively).

adnexal mass were at risk (OR 2.30, 95% CI 1.25–4.22, $P = 0.007$), but overall the strongest risk factor for major complications was adhesiolysis (Table III); and if adhesiolysis was removed from the model, adnexal mass persisted, with prior laparotomy emerging as a new risk factor (not shown). Bowel injury occurred more commonly in cases with adhesiolysis: in 5.1% in LH and in 2.4% in AH, both in comparison with cases without adhesions at 0.1% (Fisher's exact test, $P < 0.001$ for LH, $P = 0.012$ for AH) (Table III).

Complications were not associated with hospitals outside university clinics. With a more experienced LH surgeon, a febrile event was less common (1.1 versus 2.4%, univariate χ^2 test, $P = 0.056$) and the operation time was faster (101 versus 130 min, $P < 0.001$). In the logistic regression analysis, the experience of the gynaecological surgeon being 30 or fewer LHs was an independent risk factor for febrile events (OR 2.66, 95% CI 1.06–6.69, $P = 0.038$). Taking all the types of hysterectomy together, for surgeons with experience amounting to more than 30 operations, pelvic infection was significantly more common (2.4 versus 1.3%, χ^2, $P = 0.028$), and in logistic regression, having experience of 30 or fewer hysterectomies emerged as risk reductive (OR 0.53, 95% CI 0.30–0.93, $P = 0.028$).

The removed uterus weighed 500 g or more in 29% of the AHs, but only in 5% of the LHs and 2% of the VHs. A large uterus emerged as a risk for excessive operative bleeding (Table III), and was also significant for bladder injuries, in which a history of CS was the most important independent risk factor (Table III); bladder injuries occurred more frequently among patients with a history of CS in LH (2.6 versus 0.7%, χ^2, $P = 0.012$) and in VH (2.9 versus 0.4%, χ^2 test, $P = 0.001$).

Concomitant surgery differed by the type of hysterectomy, and therefore was applied as a categorical variable (yes or no, Table III); but additional analyses were performed. Concomitant surgery and adhesiolysis were both associated with infections in AH, but concomitant surgery did not increase operation times significantly, while adhesions did (by 34 min, $P < 0.001$). Haemorrhage $\geq$1000 ml in AH (Table III) was, in a closer evaluation, associated with adnexal surgery (OR 2.53, 95% CI 1.36–4.71, $P = 0.003$). In the analysis of all hysterectomies together, uterine prolapse emerged as an independent risk factor for urinary retention, and VH itself was not a risk factor (Table I), but in fact this complication was associated with concomitant colporrhaphy. In VH with anterior colporrhaphy (AC, $n = 1145$), 3.2% suffered from urinary retention, which occurred even more often if posterior colporrhaphy (PC, $n = 830$) was also performed: 4.2% with, and 2.0% without (χ^2, $P = 0.037$). In a multivariate analysis, AC (OR 18.38, 95% CI 2.75–122.92, $P = 0.003$) and PC (OR 2.25, 95% CI 1.03–4.90, $P = 0.042$) were the risk factors for retention, not uterine prolapse. For total complications of VH, PC, not AC, posed a risk (OR 1.50, 95% CI 1.08–2.09, $P = 0.015$); but individual complications, other than urinary retention, failed to reach significance for PC.

Lower risk for infections was associated with older age (Table IV). Descending trends by age groups—pre-, peri- and post-menopausal—were observable in pelvic infections in LH (4.5, 3.6, 0.6%) and in VH (4.0, 2.3, 1.2%). In VH, pelvic infection occurred less commonly with uterine prolapse, in comparison with all other indications together (1.2 versus 3.7%, χ^2, $P < 0.001$); and also in a multivariate re-analysis, adjusted for any uterine weight (linear variable), uterine prolapse was associated with a lowered risk for pelvic infection (OR 0.31, 95% CI 0.14–0.70, $P = 0.004$).

The overweight and obese patient was at a greater risk for infections, in particularly in AH and VH (Table IV). The greater the BMI, the longer the mean operation time (this trend occurred in all approaches) but obesity persisted as an independent risk factor for total infections in re-analyses adjusted for duration (not shown). The series included 267 extremely obese (BMI $\geq$35) patients. The proportion of extremely obese patients affected by any complication was high in VH (22.0%) (Table II), whereas in AH and LH (20.4 and 16.2%), it resembled the average (Table I).

Discussion

FINHYST is a large prospective study on hysterectomy for benign indications and involves unselected cases. Minimally invasive hysterectomy is preferred in Finland, as AH represented only 24% of hysterectomies, with a trend towards reserving it for large uteri. VH was the most commonly performed, at 44%. LH was widely performed in all hospital groups, representing 24% of hysterectomies in local, 25% in central and 44% in university hospitals (Brummer *et al.*, 2009). These data thus represent a real-life view of the complications of hysterectomy, in a situation where also laparoscopic surgery is widely implemented throughout the whole nation, in contrast to studies from specialized centres.

In the recently updated Cochrane review of 34 randomized trials, similar to our results, LH led to significantly fewer wound infections and febrile episodes, but in contrast to our results, to more urinary tract injuries (Johnson *et al.*, 2006; Nieboer *et al.*, 2010). Training and education have produced positive developments; in FINHYST no significant differences occurred in major complications between approaches (4.0% in AH, 4.3% in LH and 2.6% in VH). An earlier national prospective survey took place in 1996, with a higher (1.1%) incidence of ureter injuries in LH (Mäkinen *et al.*, 2001). Retrospective analyses have showed a constant decrease since then, reaching a national learning-curve plateau of 0.3% at the millennium (Härkki *et al.*, 2001; Brummer *et al.*, 2008). Similar incidences (0.3–0.4%) occur in large single-centre reports (Wattiez *et al.*, 2002; Léonard *et al.*, 2007; Donnez *et al.*, 2009). The current prospective FINHYST resulted in a risk for ureter injury with LH being similar to that associated with other approaches to hysterectomy.

In a Canadian national retrospective register study, only 18% of urinary tract injuries were discovered intra-operatively: none of the ureter injuries or fistulas and a third of the bladder injuries were detected (Gilmour and Baskett, 2005). In the USA, in laparoscopically assisted VH (LAVH) no ureter injuries were recognized intra-operatively (Frankman *et al.*, 2010), and many large studies have reported it as rare: 5% (Härkki-Sirén *et al.*, 1998), 9% (Donnez *et al.*, 2009) and 12.5% (Daahlgard Hove *et al.*, 2010). Unfortunately, this phenomenon persists in FINHYST, 9 of 10 ureter injuries were diagnosed outside the index surgery, showing that this complication, often caused by coagulation injury, should still be feared. In contrast, 88% of the bladder injuries were detected during the primary operation, including all those which occurred during VH, and 82% of those occurring in either AH or in LH. In addition, 83% of the bowel injuries were intra-operatively detected, all of those in AH and VH, and five of seven occurring in LH. It is highly beneficial to

Table IV Effect of patient characteristics, age or BMI, on the risk for various complications.

	Complication	Adjusted OR	95%	CI	P	Variables NA
Age of the patient						
	Pelvic infection, haematoma or abscess					
55 or over	In all	0.46	0.23	0.92	0.027	
	In LH	0.20	0.04	0.97	0.046	[c]
	Infections total					
55 or over	In all	0.66	0.45	0.98	0.037	
	Complications total					
55 or over	In all	0.61	0.47	0.79	<0.001	
BMI						
	Wound infection					
Overweight	In all	2.36	1.37	4.09	0.002	
	In AH	5.49	1.74	17.30	0.004	[a,b]
Obese	In AH	5.04	1.44	17.64	0.011	[a,b]
	Febrile event					
Overweight	In all	3.02	1.66	5.50	<0.001	
	In AH	2.83	1.10	7.30	0.032	[a]
	In LH	5.49	1.51	19.91	0.010	11[a,c]
Obese	In all	3.64	1.84	7.20	<0.001	
	In LH	7.70	1.83	32.43	0.005	11[a,c]
	In VH	4.57	1.37	15.31	0.014	9, 11[d]
	Infections total					
Overweight	In all	1.61	1.23	2.09	<0.001	
	In AH	2.79	1.61	4.81	<0.001	
Obese	In all	1.67	1.20	2.33	0.002	
	In AH	2.41	1.27	4.56	0.007	
	In VH	1.77	1.03	3.05	0.040	9, 11
Extremely obese	In all	1.82	1.13	2.95	0.014	
	In VH	2.68	1.26	5.71	0.010	9, 11

Data were analysed as all approaches together (in all, $n = 5279$) and separately for abdominal (AH), laparoscopic (LH) and vaginal hysterectomy (VH). The reference group for age is age under 45, and for BMI normal weight (<25.0). The BMI categories are overweight (25.0–29.9), obese (30.0–34.9) and extremely obese (35.0 or over). Multivariate logistic regression model adjusted for variables: 1, hospital type; 2, surgeon's experience; 3, patients' age; 4, BMI; 5, indication for hysterectomy; 6, prior CS; 7, prior laparotomy; 8, prior laparoscopy; 9, adhesiolysis; 10, concomitant surgery; 11, uterine size; 12, antibiotic; 13, thrombosis prophylaxis. In addition, analysis with all hysterectomies together is adjusted for the type of hysterectomy (AH, LH or VH). NA, not applicable to model.

[a]Patients who underwent surgery in private hospitals were excluded (in AH $n = 6$, in LH $n = 26$ and in VH $n = 17$) due to lack of events.

[b]Patients with the indications dysmenorrhoea and endometriosis were excluded due to lack of events in AH ($n = 26$ and $n = 78$, respectively).

[c]Patients with the indication uterine prolapse were excluded due to lack of events in LH ($n = 52$), for the analysis for febrile event also patients with the indication adnexal mass ($n = 141$).

[d]Patients with the indication "other" were excluded due to lack of events in VH ($n = 88$).

have damage repaired instantly, and the patient saved from excessive re-operations. Nevertheless, it should be noted that all severe injuries with a self-evident risk for surgically induced mortality, a major vascular injury and both post-operatively detected bowel injuries, occurred with LH. Although sporadic events can occur even to the experienced surgeon, here two of three were related with an experience of <30 operations; only the LH case for severe endometriosis complicated by a late-onset bowel injury was performed by an experienced gynaecologist.

To assess the quality of our collection of major complications, we analysed the data from the Patient Insurance Centre in Finland for hysterectomies for benign disease in 2006. Not surprisingly, this being retrospective, lower rates of severe complications from the centre database were observed: 1.0% for AH, 1.1% for LH and 0.4% for VH. The most common complication was re-operation due to haemorrhage or haematoma. There were only four bladder injuries reported. Injuries by far subjectively most harmful were each reported: the single major vessel injury, both post-operatively detected bowel injuries, and all VVFs and ureter injuries. Apparently intra-operative detection and repair of the majority of organ injuries had made any desire to seek compensation unnecessary.

Mortality rates from hysterectomy are 0.03% in Finland (Mäkinen *et al.*, 2001), 0.04% in the UK (McPherson *et al.*, 2004) and 0.06% in Denmark and Australia (Møller *et al.*, 2002; Spilsbury *et al.*, 2009). The most recent national study, the Danish hysterectomy database (DHD), had no deaths, similar to our results (Hansen *et al.*, 2008). A large series of 4505 women from a single clinic presented markedly low major complication rates: in AH 0.49%, in LH 0.51% and in VH 0.33%; but here the definition of major complications omitted bladder perforations and all internal medicine morbidity (Donnez *et al.*, 2009). The overall re-operation rate from the DHD data in 2006 was 4%. The Australian retrospective data of over 78 000 hysterectomies used no classification based on severity, but gave overall complication rates of 8.3% for AH, 9.8% for LH and 9.1% for VH. In the UK, over 37 000 hysterectomies involved severe operative complications in 3.6% in AH, in 6.1% in LAVH and in 3.1% in VH, with 0.9, 1.2 and 1.7% being post-operative severe complications, respectively, defined again somewhat differently from ours. Whereas major complication rates are difficult to compare directly with rates in other national non-randomized studies, we can attempt a comparison with the eVALuate study (Garry *et al.*, 2004), a precise and important large randomized trial from 30 centres in the UK and South Africa. If major complications of eVALuate were calculated by definitions similar to those of FINHYST, they would result in 4.1% for AH, 4.5–4.6% for LH and 3.0% for VH—remarkably similar to our figures. In fact, had patients exposed to conversions been excluded from the eVALuate study, significant differences for major complications within the type of hysterectomy would have disappeared (Garry, 2009). Nevertheless, they chose the intention-to-treat principle to avoid bias, and included all patients, and they calculated conversions as complications. In FINHYST, all patients undergoing conversion were included as in the approach with which surgery began, but with a conversion itself not considered a complication. Despite similar complication rates, conversion rates for LH were lower, and the mean operation time of all approaches was faster in the eVALuate trial, which may result from its exclusion criteria. The complication incidences of FINHYST are modern multi-centre data, useful for informing patients as to actual risks.

A simple crude comparison of the three approaches to hysterectomy would have been impossible due to the non-randomized character of our study. Logistic regression was the means of controlling for various confounding factors. Analysis of hysterectomies overall did not seem sufficient, even if adjusted for type. Hysterectomy, despite a common end point, comprises differing surgeries in a variety of patients. Additional analysis by approach splits the results into four: all, AH, LH and VH. The initial model was kept the same, to aim for a coherent and comparable result. As a reverse effect, not all covariates were applicable to each analysis, usually due to the non-existence of complications within a certain variable, for example, adhesions and large uteri were sparse in VH. Although it is difficult to build a uniform model feasible for all, the strength of the national FINHYST is the large number of complications and confounders collected, due to its prospective approach. Strict exclusion criteria such as uterine size (Garry *et al.*, 2004; McPherson *et al.*, 2004) were absent; real-life practice was the focus. Nevertheless, serious illness of the patient as a risk factor for complications (McPherson *et al.*, 2004) was not taken into account, and FINHYST also has another important limitation familiar in many studies: it neglects the effect of complications upon each other. Severe operative complications have been the most important risk factor for post-operative complications (McPherson *et al.*, 2004). Therefore, the totals for major infection and all complications (Table I) are presented as the number of patients experiencing various adverse effects of surgery, in order to give a clinically relevant view of overall morbidity.

In LH, surgeons' inexperience constituted a risk for febrile events, presumably because of the longer duration of surgery. Surprisingly, experience of more than 30 operations emerged as a risk factor for late-onset pelvic infection, a complication associated with LH and VH. In fact, this excess occurrence of pelvic infections is the reason why the total infection difference in comparison with AH was non-significant, even if AH posed an independent risk for many other infections. A vaginal approach may predispose to infection; a common practice in Finland also in LH is to close the vaginal vault vaginally. Indication also has an effect: in VH, indications other than prolapse raised the odds for pelvic infection over 3-fold. This complication, defined as haematoma or abscess, more precisely represents the difficulty of haemostasis of the non-prolapsed vaginal vault. Nevertheless, generally most common after LH and VH, the incidence of a haematoma or abscess in need of a re-operation was, for all hysterectomy types, the same (0.4%).

FINHYST serves as a reminder of the particular care required in opening the anterior peritoneal cul-de-sac of patients who have undergone CS. In a case-controlled study, the significant odds for incidental cystotomy was doubled with a history of CS comprising all hysterectomies, and in LAVH it was more than 7-fold (Rooney *et al.*, 2005). In a study investigating LH, a history of CS was the most important factor influencing the onset of bladder injury, and the risk also increased with the number of CSs (Lafay Pillet *et al.*, 2009). A 2855-patient study analysing AH and VH revealed two predisposing risk factors for bladder injury: previous CS and vaginal approach (Neumann *et al.*, 2004). Another VH study showed a history of CS as a risk for bladder injury (Boukerrou *et al.*, 2003, 2004). One prospective multi-centre study revealed a history of CS, and obesity in the case of AH, to be associated with a higher risk for complications (David-Montefiore *et al.*, 2007). In a Swedish register study of 3267 hysterectomies, obesity was also a risk factor for post-operative infection, and similar to our findings, independent of antibiotic prophylaxis (Löfgren *et al.*, 2004). Both the Swedish and the large Australian study, like ours, had older patient age associated with reduced risk for post-operative infection (Löfgren *et al.*, 2004; Spilsbury *et al.*, 2008). FINHYST associations of obesity with infections were notably many, in particular for AH and VH (Table IV).

Post-operative adhesions are a natural consequence of tissue trauma and healing. Because one-fifth of our patients with adhesiolysis had neither endometriosis nor any surgery in their past, inclusion of the entity of adhesiolysis separately in the model was necessary. Incidence of intestinal adhesions after a history of only a single operation is higher after laparotomy (9.0%) than after laparoscopy (1.6%) (Dubuisson *et al.*, 2010). Adhesions cause long-term adverse effects such as pain and small bowel obstruction, which, if arising from AH, occur after a median of 4 years (Al-Sunaidi and Tulandi, 2006). Short-term effects arise again with subsequent surgery: adhesiolysis, often non-avoidable, elevates the risk for bowel injury (van Goor, 2007). In one series of over 2700 laparoscopic operations, trocar injury was a

minor cause, and bowel injury was, for 90%, preceded by adhesiolysis (Binenbaum and Goldfarb, 2006). In FINHYST, risk factors for organ injuries seemed to directly and indirectly emerge from a history of open surgery, as prior CS was associated with bladder injuries, and adhesiolysis was associated with bowel injuries. Adhesiolysis emerged in the context of many complications, and was the most important risk factor for major and total complications as a whole. Adhesions arising from clinical pathology, such as endometriosis, cannot be avoided, but to prevent iatrogenic adhesions, the least invasive methods, LH and VH, are preferable to AH (Robertson *et al.*, 2010).

In Finland, LH and VH comprised 76% of national operations. Statistically significant differences in major complications between the approaches were non-existent. Most bladder and bowel injuries were diagnosed intra-operatively, meaning excessive surgery could be avoided. FINHYST in 2006 is a national quality assessment revealing a suitable choice of approach and a generally expected level of complications. In conclusion, a major complication will occur in 3–4% of patients. If abdominal hysterectomy is performed, 20% will suffer from some complication; if not, 12–15%. Whenever possible, hysterectomy should be minimally invasive.

Authors' roles

The conception of the study was by T.B., J.F., A.H., J.J., M.K., J.M., J.S., E.T. and P.H., all of whom also participated in the acquisition of the data. Advice on the statistical design and analysis was provided by T.S., and the analyses were conducted by T.B. and T.S. All authors contributed to the critical revision of the paper drafted by T.B. and P.H. The final version was approved by all authors.

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