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Randomised controlled trial of total compared with subtotal hysterectomy with one-year follow up results

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Objective To compare total abdominal hysterectomy and subtotal abdominal hysterectomy performed for benign uterine diseases.

Design Randomised, controlled, unblinded trial with central, computer-generated randomisation.

Setting Danish trial performed in 11 departments of gynaecology.

Population Women referred for benign uterine diseases were randomised to total abdominal hysterectomy ($n = 158$) or subtotal abdominal hysterectomy ($n = 161$). One-year follow up questionnaires had a response rate of 87%.

Methods Patients were followed by strict data collection procedures, including postal questionnaires. The results after one year of follow up were analysed by intention-to-treat analyses.

Main outcome measures (1) Primary: urinary incontinence and (2) secondary: post-operative complications, quality of life (SF-36), constipation, prolapse of the vaginal vault/cervical stump, satisfaction with sexual life, pelvic pain and vaginal bleeding.

Results A significantly ($P = 0.043$) smaller proportion of women had urinary incontinence one year after total abdominal hysterectomy compared with subtotal abdominal hysterectomy [9% *vs* 18% (OR 2.08, 95% CI 1.01–4.29)]. The lower proportion of incontinent women in the total abdominal hysterectomy group was a result of a higher proportion of symptom relief (total abdominal hysterectomy: 20/140, subtotal abdominal hysterectomy: 14/136) as well as a lower proportion of women with new symptoms (total abdominal hysterectomy: 3/140, subtotal abdominal hysterectomy: 10/137). Twenty-seven women (20%) from the subtotal abdominal hysterectomy group had vaginal bleeding and two of them had to have their cervix removed. No other clinically important differences were found between the two hysterectomy methods.

Conclusions A smaller proportion of women suffered from urinary incontinence after total abdominal hysterectomy than after subtotal abdominal hysterectomy one year post-operatively.

INTRODUCTION

During the past 20 years, the treatment of benign uterine disorders has changed in Denmark[1] as well as in other Western countries[2–4]. A decrease in the rate of total abdominal hysterectomy by 38% from 173 total abdominal hysterectomies per 100,000 women per year in 1988 to 107 total abdominal hysterectomies per 100,000 women per year in 1998 has taken place[1]. During the same period, the number of subtotal abdominal hysterectomies had increased by 375% from 7.5 subtotal abdominal hysterectomies per 100,000 women in 1988 to 41.5 subtotal abdominal hysterectomies per 100,000 women in 1998[1]. In 1998, the actual number of total abdominal hysterectomies performed on benign indications in Denmark was 2826, whereas the number of subtotal abdominal hysterectomy was 1104, abdominal hysterectomy accounting for 80% of all the hysterectomies performed[1].

Hysterectomy may cause lower urinary tract symptoms[5,6]. A recent review on urinary incontinence after hysterectomy supports this association[7]. In addition to immediate post-operative complications[8], other sequelae of hysterectomy have been described. These are improvement in quality of life[9,10], deterioration or improvement of bowel function[11,12], prolapse of the vaginal vault/cervical stump[8,13], deterioration or improvement in sexual function[8,11,14] and no change or improvement of pelvic pain[10,15].

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Total abdominal hysterectomy and subtotal abdominal hysterectomy have been compared in observational studies[8,14,16]. Despite the superiority of the randomised clinical trial in the evaluation of the treatment effects[17], only two randomised clinical trials have been published[11,18]. The small size of both randomised clinical trials makes the conclusions questionable. Therefore, we performed a randomised clinical trial of total abdominal hysterectomy *versus* subtotal abdominal hysterectomy considering urinary incontinence, post-operative complications, quality of life, constipation, prolapse of the vaginal top/cervical stump, satisfaction with sexual life and pelvic pain as outcome measures. Vaginal bleeding after subtotal abdominal hysterectomy was also evaluated.

METHODS

All the 33 departments of obstetrics and gynaecology in Denmark were invited to participate in the trial. From April 15, 1996 until June 30, 2000 eleven departments contributed randomised patients to the trial. Five were situated in Copenhagen and six in the province. Not all of the departments were actively recruiting patients during the whole period.

Women were eligible for the trial if they were going to have a hysterectomy for benign diseases of the uterus unless they were formally ineligible (Fig. 1). In some centres, the physician who met the patient in the outpatient clinic enrolled and randomised the patient, while in others, this procedure was undertaken by the local project representative. Informed consent was obtained either in the outpatient clinic at the time of referral or at admission on the day before the operation.

Informed consent was obtained from those who accepted participation in the trial and they were centrally randomised. Information regarding the woman's identity (number in The Central Registry of Persons), expected status of the ovaries after the operation (preserved, removed or unknown) and the centre concerned was transferred via a press-button, voice response telephone system. Restricted, computer-generated block randomisation (1:1, individual-based) was employed within strata defined by cross tabulating clinical centres against the three clinical groups (i.e. the status of the ovaries). Within each stratum, block sizes of 2, 4 and 6 occurred in random order. Randomisation identified one of the two interventions: total abdominal hysterectomy or subtotal abdominal hysterectomy.

The randomisation office was central and located outside the participating centres. Details of the generation and the generated randomisation were concealed from the Steering Committee as well as the participating centres until after the recruitment period ended.

Each operation was carried out using the clamp–cut–ligate method[19], polyglycolic sutures and antibiotic prophylaxis. No detailed instructions were given to the surgeon about the operation procedures apart from the instruction to electrocoagulate the cervical canal after removing the uterus in the subtotal abdominal hysterectomy.

The surgeons, patients and Steering Committee were not blinded to the treatment.

Information about the gynaecologic examination was collected via a case record form filled out by the gynaecologists. Baseline information about deliveries, abortions, former diseases, admissions, operations, medication, tobacco and alcohol consumption, education and occupation was obtained by a questionnaire completed by the patient before the operation pre-operatively.

Urinary incontinence was prespecified as the *primary outcome measure*. The secondary outcome measures were: post-operative complications, quality of life, constipation, prolapse of the cervical stump/vaginal vault, sexual function, pelvic pain after both hysterectomy methods and vaginal bleeding after subtotal abdominal hysterectomy. All outcome measures were obtained through the validated, self-administered, postal questionnaire consisting of 67 questions[20], which was filled out at entry and 2, 6, 12 months post-operatively. The SF-36 questionnaire (physical and mental components)[21] was used as a generic quality of life measure. An English translation of the entire questionnaire can be studied at http://www.gyncph.suite.dk/praes/gimbel/gi.htm.

Information on post-operative complications was obtained from case records filled out by the gynaecologists and from the self-administered postal questionnaires. Information about re-hospitalisation was checked via a central data registry of admissions and patient records requested from the department concerned.

The analyses of the outcome measures were prespecified.

The significance level for the primary outcome measure, urinary incontinence, was set at $P = 0.05$. The significance level for the secondary outcome measures, post-operative complications, quality of life, constipation, prolapse of the vaginal vault/cervix uteri, satisfaction with sexual life and pelvic pain was $P = 0.0073$. These levels of significance were calculated to take the problem of multiple tests into consideration. The outcome measurements were analysed by intention to treat and per protocol. The per-protocol analyses excluded patients for whom the operation method had been changed pre- or per-operatively. The conclusions were based on the regular intention-to-treat analyses.

We defined urinary incontinence as a subjective complaint from which the woman suffered 'always' or 'often' (question 38 in the one-year follow up questionnaire). Subjective complaints of incontinence being present 'rare' and 'never' were defined as no incontinence. The outcome measure was analysed as +/− success with the operation. Operative success (incontinence 'rare' or 'never') was attributed to scores obtained directly from the questionnaires. We performed four intention-to-treat analyses of the primary outcome. 'Regular' intention to treat was based on

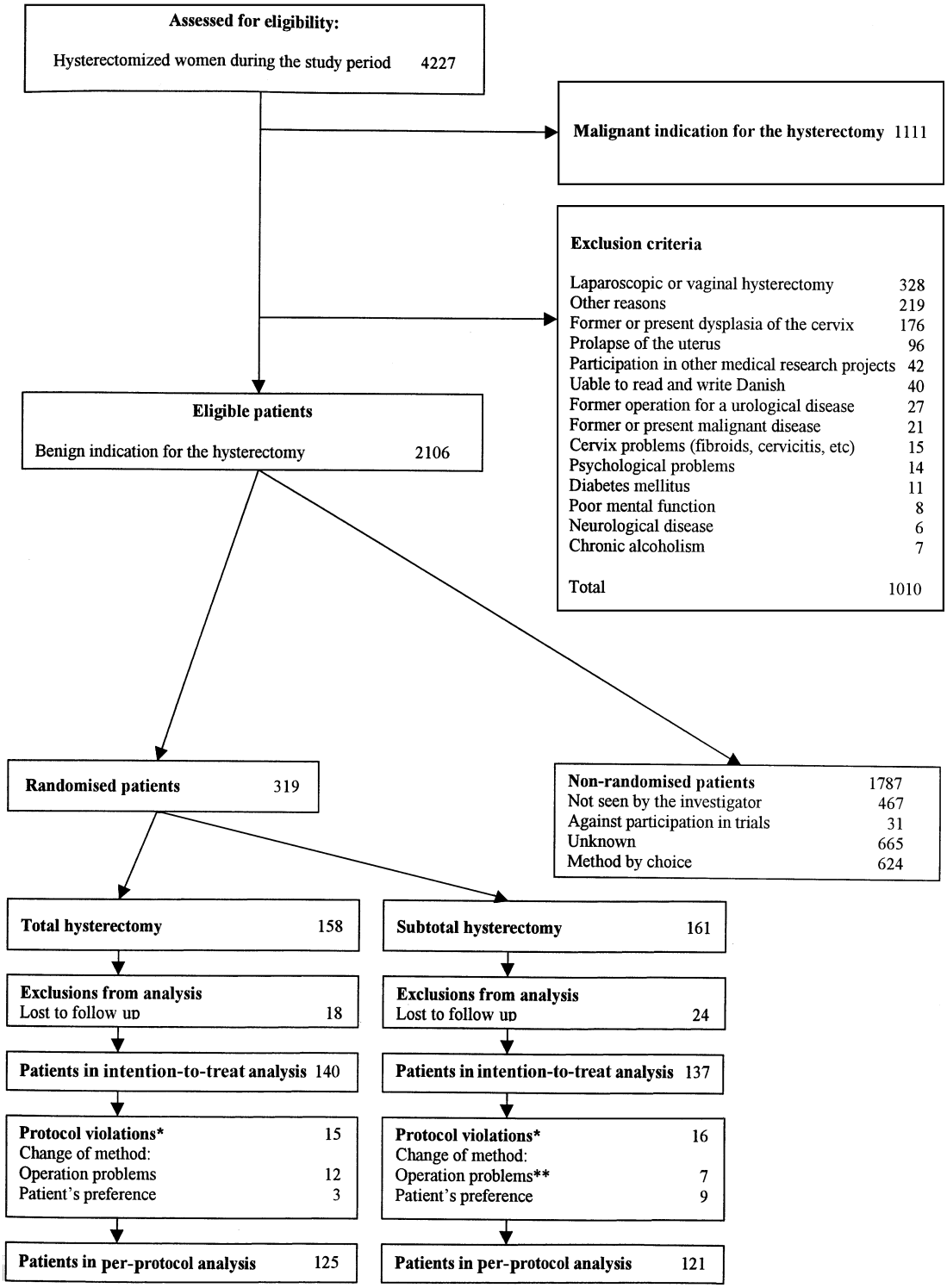

Fig. 1. Flow of participants through each stage of the trial to one-year follow up. (Number of women). Exclusion by 'Other reasons' comprised cases of extreme obesity or refusal of blood transfusion (including Jehovah's Witness), and cases in which another operation than hysterectomy was originally planned. The intention-to-treat analysis mentioned is 'regular' intention to treat. *Four women from the total abdominal hysterectomy group and eight women from the subtotal abdominal hysterectomy group had protocol violations but were also lost to follow up. They are categorised as 'lost to follow up'. From the total abdominal hysterectomy group, they were not hysterectomised because of no diseases of the uterus (an ovarian cyst misinterpreted as a fibroid) ($n = 1$) and had changed the operation method because of 'patient's choice' ($n = 3$). From the subtotal abdominal hysterectomy group, they were not hysterectomised because of extensive adhesions ($n = 1$), and had changed the operation method because of 'operation problems' ($n = 1$) and 'patient's choice' ($n = 6$). **The subtotal abdominal hysterectomy group of women with 'operation problems' could be subdivided into three groups. Pre-operative problems: one woman had human papilloma virus in pre-operative smear and had to have the operation method changed. Per-operative problems: four women. Post-operative problems: two women had to have their cervical stump removed because of unacceptable vaginal bleeding after the operation.

outcome data only for those patients whose results were known. 'Best case scenario' intention to treat considered all randomised patients and estimated dropouts as having no urinary incontinence. 'Worst case scenario' intention to treat considered all randomised patients and estimated dropouts as having urinary incontinence. 'Carry forward' intention to treat considered the last registered information on urinary incontinence among those dropping out as being the result at 12 months. The conclusions were based on the 'regular' intention-to-treat analysis. The comparisons of the two hysterectomy methods were undertaken using the χ^2 test.

Post-operative complications were categorised into four severity classes by two independent gynaecologists: (1) serious adverse event (causing death, being life threatening, causing hospitalisation or prolonging present hospitalisation, causing lifelong or significant reduction regarding function/invalidity), (2) severe, non-serious adverse event (intolerable symptoms having significant effect on the patients daily activities), (3) moderate, non-serious adverse event (tolerable symptoms having a moderate effect on the patients daily activities) or (4) mild, non-serious adverse event (transient symptoms having no influence on the patients daily activities).

The result of the categorisation was analysed as all adverse events *versus* none using the χ^2 test.

Regarding quality of life, the answers were scored according to the specifications[21]. The results of the scores were analysed using Wilcoxon's test corrected for ties.

Comparisons of the two hysterectomy methods were also undertaken using the χ^2 tests for the analyses of constipation, prolapse of the vaginal vault/cervix uteri, satisfaction with sexual life and pelvic pain.

The statistician performing the analyses was blinded to the allocation.

Calculation of the sample size was based on information on the prevalence of the primary outcome (urinary incontinence) among hysterectomised women—approximately 23%[5,16].

The calculation had a power of 0.80 to detect a significant difference of 5% (two-sided). We expected urinary incontinence in 23% of the total abdominal hysterectomy group and wanted to be able to detect a difference between the two operations of 15%. From these basic figures, a total of 320 patients were required, 160 in each study group. However, the inclusion was stopped July 1, 2000, when 319 out of 320 planned patients were included, because of very low recruitment during the previous half year and because we knew that recruitment would fall dramatically during the summer period.

The size of the sample was also expected to be able to detect a significant difference regarding categorised post-operative complications (incidence rate 20–40%[10,22–24]), sexual life (significant difference in an observational study among 212 total abdominal hysterectomy and subtotal abdominal hysterectomy women[14]) and prolapse (significant difference between 200 total abdominal hysterectomy and subtotal abdominal hysterectomy women[25]). Quality of

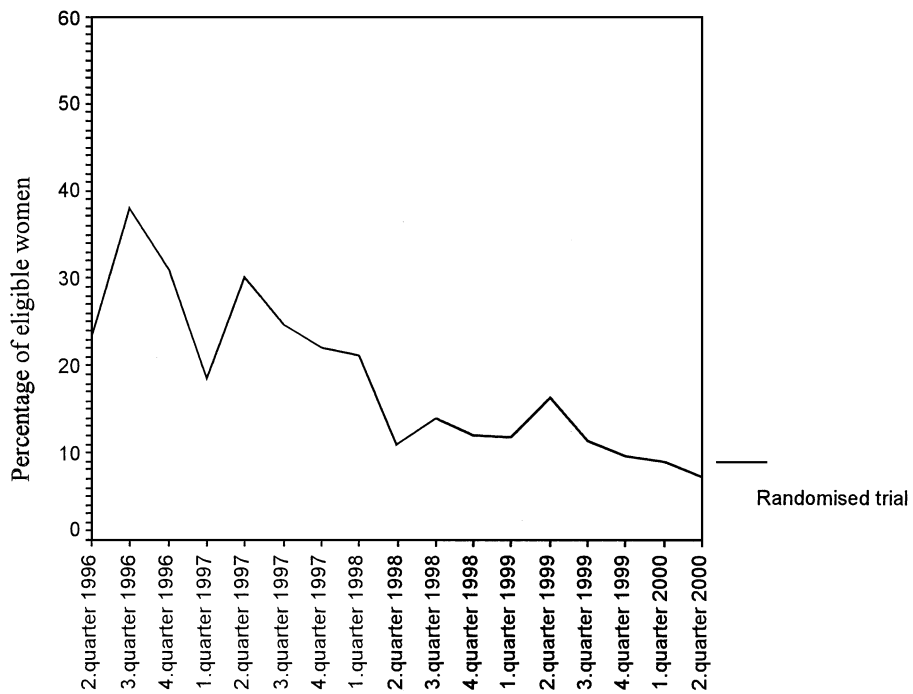

Fig. 2. Time dependent recruitment rate. The recruitment rate: the number of randomised trial patients is the numerator. The number of eligible patients is the denominator.

life, constipation and pelvic pain had either divergent, inconclusive results or no results from previous studies.

An independent Data Monitoring and Safety Committee consisting of a medical doctor specialised in trials, a gynaecologist, and a statistician performed three interim analyses during the inclusion period. The prespecified stopping rules were based on the Peto–Haybittle rule[26]. The success of the hysterectomy concerning urinary incontinence was analysed as the main outcome and the categorised post-operative complications were also taken into consideration. The P values for stopping the trial were specified to be 0.001 for all the interim analyses.

The Data Monitoring and Safety Committee was blinded to the treatment allocation. Only a statistically significant difference between the two treatments would result in a break of the allocation concealment. The results of the analyses were only accessible to the Data Monitoring and Safety Committee, which reported the results of the analyses to favour a continuation of the trial or not. None of the interim analyses resulted in a discontinuation of the trial.

The local ethics committees of the participating centres and the Danish Data Protection Agency had accepted the design of the randomised clinical trial before recruitment of the patients was started.

RESULTS

Although the mean recruitment rate was 15.1% (range of mean department recruitment rates: 7% to 24%), a large variation was found during the recruitment period (Fig. 2). The highest recruitment rate (38%) was found in the beginning and the lowest recruitment rate (7%) at the end of the inclusion period.

The response rate for the questionnaires at one-year follow up was 86.8%: 140 women from the total abdominal hysterectomy group and 136 from the subtotal abdominal hysterectomy group answered the questionnaires at entry and at 12 months follow up. Only these were included in the analyses. No difference was found regarding the experience of the surgeons performing the two operation methods.

The patients in the two intervention groups were similar regarding the baseline characteristics (Table 1).

At entry, a higher percentage of low quality-of-life scores was found in the subtotal abdominal hysterectomy group than in the total abdominal hysterectomy group in both physical and mental components.

A significantly lower proportion of women were incontinent after total abdominal hysterectomy than after subtotal abdominal hysterectomy ($P = 0.043$) (Table 2). The results of 'best case scenario' intention to treat (total abdominal hysterectomy: 13, subtotal abdominal hysterectomy: 25, $P = 0.044$), 'worst case scenario' intention to treat (total abdominal hysterectomy: 31, subtotal abdominal hysterectomy: 49, $P = 0.026$), 'carry forward' intention to treat (total abdominal hysterectomy: 16, subtotal abdominal hysterectomy: 27, $P = 0.082$) and per-protocol analyses (total abdominal hysterectomy: 10, subtotal abdominal hysterectomy: 23, $P = 0.011$) supported this finding. However, the results of the 'carry forward' intention to treat was not significant. The lower proportion of incontinent women after total abdominal hysterectomy was a result of a higher proportion of symptom relief (total abdominal hysterectomy: 20/140, subtotal abdominal hysterectomy: 14/136) as well as a lower proportion of women with new symptoms (total abdominal hysterectomy: 3/140, subtotal abdominal hysterectomy: 10/136).

Table 1. Baseline demographics and other characteristics of the patients distributed on hysterectomy methods. The values are expressed in n (%), mean [SD] and mean (range). % = The number of patients in the group is the numerator while the total number of patients having a total abdominal hysterectomy or a subtotal abdominal hysterectomy is the denominator.

Hysterectomy method	Total abdominal hysterectomy ($n = 140$)	Subtotal abdominal hysterectomy ($n = 136$)
Age (years)	47.6 [15.1]	46.6 [6.4]
No. of deliveries	1.7 (0–4)	1.8 (0–5)
Indication for hysterectomy		
Fibroids	90 (57)	93 (58)
Dysfunctional uterine bleeding	53 (38)	52 (38)
Dysmenorrhoea	6 (4)	6 (4)
Pelvic pain	5 (3)	8 (5)
Endometriosis	1 (1)	0 (0)
Other	2 (1)	1 (1)
Smoking >5 cigarettes per day	56 (35)	47 (29)
Alcohol consumption >14 units alcohol per week	13 (8)	15 (9)
Body mass index >25 kg/m^2	66 (42)	76 (47)
Education		
Going to school	2 (1)	3 (2)
7 years of schooling	11 (7)	18 (12)
8–9 years of schooling	30 (20)	27 (18)
10 years of schooling	68 (44)	57 (37)
High school certificate	34 (22)	38 (25)
Other (foreign school)	9 (6)	19 (6)
Vocational training	114 (76)	114 (76)
Occupation		
Salaried employee group I	7 (5)	11 (7)
Salaried employee group II	36 (25)	42 (29)
Salaried employee group III	65 (44)	55 (37)
Skilled worker	2 (1)	1 (1)
Unskilled worker	21 (14)	19 (13)
Unemployed	4 (3)	5 (3)
Student	4 (3)	3 (2)
Independent businesswoman	2 (1)	2 (1)
Old-age pensioner	1 (1)	3 (2)
On job release scheme	0 (0)	1 (1)
Other pensioner	3 (2)	2 (1)
Housewife	0 (0)	1 (1)
Assistant wife	1 (1)	1 (1)
Sick leave, rehabilitation	0 (0)	1 (1)

No other significant differences between the two hysterectomy methods were found regarding the outcomes at one-year follow up (Table 2).

Subtotal abdominal hysterectomy had a shorter operation time and less per-operative bleeding than total abdominal hysterectomy [median operation time was 70 minutes (range: 34–165 minutes) for the subtotal abdominal hysterectomy group and 85 minutes (range: 35–255 minutes) for the total abdominal hysterectomy group, $P < 0.0001$]. The median per-operative bleeding was 250 mL (range: 10–2500 mL) for the subtotal abdominal hysterectomy group and 400 mL (range: 25–4500 mL) for the total abdominal hysterectomy group ($P < 0.0001$).

The intention-to-treat analysis revealed that 64 (46%) women from the total abdominal hysterectomy group and 54 (40%) women from the subtotal abdominal hysterectomy group had a hysterectomy with complication (Table 3). Altogether 32 women, 16 from the total abdominal hysterectomy group and 16 from the subtotal abdominal hysterectomy group, had to be readmitted because of the complication, and one woman from the total abdominal hysterectomy group was admitted twice after the hysterectomy. Analyses of the post-operative complications grouped into four categories according to severity showed no significant differences between the two hysterectomy methods (Table 3). The per-protocol analysis of the categorised post-operative complications did not contradict this finding ($P > 0.20$). An insignificant trend was found concerning per-operative bleeding above 1000 mL, post-operative bleeding and intra-abdominal abscesses/haematomas being detected more often in the total abdominal hysterectomy group (Table 3). In the subtotal abdominal hysterectomy group, rupture of

Table 2. Main clinical outcomes distributed on hysterectomy method at study entry and one year post-operatively. Intention-to-treat analyses. Values are expressed as *n* (%) or mean [SD].

Outcome	Total abdominal hysterectomy ($n = 140$)	Subtotal abdominal hysterectomy ($n = 136$)	Odds ratio	95% confidence intervals	Significance test* (P)
Urinary incontinence					
0 month	30 (21)	28 (21)			
12 months	13 (9)	24 (18)	2.08	1.01–4.29	0.043
Quality of life					
Physical score					
0 month	48.58 [9.04]	47.77 [8.69]			
12 months	53.78 [8.81]	52.92 [8.81]			0.09**
Mental score					
0 month	49.67 [9.45]	48.76 [10.71]			
12 months	53.78 [7.73]	53.03 [8.74]			0.75**
Constipation					
0 month	26 (19)	30 (22)			
12 months	25 (18)	27 (20)	1.13	0.62–2.07	0.69
Prolapse of the vaginal top/cervical stump					
0 month	0 (0)	0 (0)			
12 months	0 (0)	3 (2)	0.14	0.01–2.67	0.12***
Satisfaction with sexual life					
0 month	95 (68)	87 (64)			
12 months	95 (68)	85 (63)	0.60	0.31–1.16	0.13
Pelvic pain					
0 month	109 (78)	103 (76)			
12 months	32 (23)	31 (23)	1.01	0.57–1.78	0.98
Vaginal bleeding					
0 month	135 (96)	129 (95)			
12 months	0 (0)	27 (20)****	–	–	–

* χ^2 tests are performed for all outcomes except for quality of life, where a Wilcoxon test is performed, and prolapse of the vaginal top/cervical top, where a Fisher's exact test is performed.

** Wilcoxon's test.

*** Fisher's exact test as several frequencies were less than 10.

**** Thirty women (21.6%) of all the women who had a subtotal abdominal hysterectomy, whether randomised to the operation method or changed to the operation method later, had vaginal bleeding.

Table 3. Per- and post-operative complications distributed on hysterectomy method.

Complication	Total abdominal hysterectomy, *n* (%)	Subtotal abdominal hysterectomy, *n* (%)	Odds ratio	95% confidence intervals	Significance test (*P*)
All postoperative complications	64 (46)	54 (40)	1.02	0.55–1.88	0.95
Serious adverse events	22 (16)	21 (15)			
Intra-abdominal haematoma/abscess	7	0			
Temperature >38°C > 2 days	0	2			
Abdominal pain	2	1			
Per-operative blood loss during the operation >1000 mL	1	2			
Wound infection/haematoma	2	4			
Lesion of the bladder	2	1			
Removal of cervical stump	0	2			
Post-operative bleeding	5	2			
Hernia of the wound	1	1			
Rupture of the fascia	0	3			
Rupture of the wound	2	0			
Serious vasovagal attack	0	1			
Ileus	0	1			
Deep venous trombosis	0	1			
Depression*	0	1			
Urinary retention*	1	0			
Severe, non-serious adverse events	7 (5)	8 (6)			
Intra-abdominal haematoma/abscess	0	2			
Temperature >38°C > 2 days	0	1			
Per-operative blood loss >1000 mL	2	0			
Urinary retention	1	0			
Wound haematoma/infection	1	2			
Post-operative bleeding	1	1			
Urinary tract infection during hospital stay	1	0			
Candida vaginitis	0	1			
Depression	1	1			
Moderate, non-serious adverse events	19 (14)	12 (9)			
Abdominal pain	1	1			
Per-operative blood loss >1000 ml	8	3			
Wound haematoma/infection	3	1			
Anaemia post-operatively	3	0			
Abdominal pain	3	4			
Cicatricial pain	1	2			
Cough after anaesthesia	0	1			
Mild, non-serious adverse events	16 (11)	13 (10)			
Intra-abdominal haematoma/infection	1	0			
Abdominal pain	0	1			
Per-operative blood loss >1000 mL	1	0			
Wound haematoma/infection	1	1			
Urinary tract infection during hospital stay	1	4			
Vaginal bleeding	2	0			
Dysuria	1	1			
From the wound	0	1			
Post-operative macroscopic haematuria	1	0			
Candida vaginitis	5	2			
Per-operative ECG changes	0	1			
Bleeding from surface of wound	1	0			
Cicatricial pain	0	1			
Skin problems around the wound	1	0			
Cosmetic problems regarding the wound	0	1			
Problems from cervix uteri	1	0			

n = number of patients.

Serious adverse events = causes death, is life threatening, causes hospitalisation or prolongs present hospitalisation, causes lifelong or significant reduced function/invalidity.

Severe, non-serious adverse events = Intolerable symptoms which have significant effect on the patients daily activities.

Moderate, non-serious adverse events = Symptoms which are tolerable and which have a moderate effect on the patients daily activities.

Mild, non-serious adverse events = Transient symptoms which do not have any influence on the patients daily activities.

* The patient is registered two times.

the fascia (total abdominal hysterectomy: 0, subtotal abdominal hysterectomy: 3) was found more often (Table 3).

Overall, a statistically significant increase in the quality of life after operation for the physical (total abdominal hysterectomy: from 48.58 to 53.78, subtotal abdominal hysterectomy: from 47.77 to 52.92, $P = 0.0001$), as well as the mental score (total abdominal hysterectomy: from 49.67 to 53.78, subtotal abdominal hysterectomy: from 48.76 to 53.03, $P = 0.0001$) (Table 2), was seen but not between groups.

Twenty-seven women (20%) randomised to the subtotal abdominal hysterectomy group continued to have vaginal bleeding after the hysterectomy. Out of these women, 9 had experienced regular, 10 irregular and 8 both regular and irregular vaginal bleeding. Two women described the quality of the vaginal bleeding as normal, 8 women as weak and 17 women as very weak. For 25 women, the bleeding did not interfere with their daily activities, but most of them would have preferred to be without it. In two women, the problem exceeded acceptability and they had their cervical stump removed less than 3 months after the hysterectomy.

DISCUSSION

In this trial urinary incontinence was seen more often after subtotal abdominal hysterectomy than after total abdominal hysterectomy. The operation method was found not to be significantly important for any of the other outcome one year after the operation. One out of five women in the subtotal abdominal hysterectomy group, however, continued to have vaginal bleeding, and two women had to undergo re-operation.

The superiority of total abdominal hysterectomy *versus* subtotal abdominal hysterectomy regarding urinary incontinence has not previously been documented. Previous studies[8,11,14,16,18,27] observed no significant difference between the two operations. The trend in three studies[11,14,16] was in favour of subtotal abdominal hysterectomy, while the trend in three other studies[8,18,27] was in favour of total abdominal hysterectomy. The difference in the results of the present trial compared with previous studies may be explained by small samples[14]. The difference between two treatments in small studies might not be apparent because they are swamped by random errors. The difference between the present trial and previous studies could also be explained study design[8,14,16,18], Iosif *et al.*'s[16] being a cross sectional study and Lauridsen and Jensen[8], Kilkku[14] and Roovers *et al.*'s[27] being prospective cohort studies. It has previously been demonstrated that the results from cross sectional and cohort studies differ from the results of randomised clinical trials in an unpredictable way[17]. Non-randomised studies tend to over-estimate the treatment effect of a new treatment (i.e. subtotal abdominal hysterectomy).

The difference between our trial and the randomised clinical trials by Lalos and Bjerle[18] and Thakar *et al.*[11] could be due to the sample size. The sample sizes in the two randomised clinical trials[11,18] were smaller in absolute figures, but apart from that 35% of the randomised women in the randomised clinical trial by Thakar *et al.*[11] were Afro-Caribbean. It has been reported previously[28] that such women have a much lower incidence rate of stress incontinence than Caucasian women. This means that the sample size in a population of mixed races should be larger to be able to detect a difference. Another potential explanation for the differences could be methodological quality. Inadequate generation of the allocation sequence and allocation concealment may affect the results of randomised clinical trials[17,29–32]. No description regarding these components was given by Lalos and Bjerle[18]. Thakar *et al.*'s[11] allocation sequence was computer-generated random numbers and the concealment of allocation was performed using sealed envelopes, which one knows can be broken[31,32]. Further, Thakar *et al.*[11] used subjective (questionnaire) as well as objective assessment (urodynamics) of incontinence, whereas we based our findings on subjective assessments (questionnaire) only. It does not seem likely, however, that this is the explanation for the differences between the results of the studies. First, the analyses of the data on stress incontinence from the questionnaire in the randomised clinical trial by Thakar *et al.*[11] are carried out as analyses of numerical data. In fact they are true categorical data. Second, most studies[33] of incontinence agree that subjective and objective assessments of urinary incontinence do not necessary give the same result. Some patients are asymptomatic but are found to be urinary incontinent according to objective measurements and *vice versa*. The randomised clinical trial by Thakar *et al.*[11] confirmed this paradox.

Finally, the differences could be explained by our results being false. Such an error could arise due to chance (type I error) or due to lack of internal validity of the study.

A considerable number of perimenopausal women might suffer from incontinence[16,33,34] as well as prolapse[35,36] due to childbirth and age[5,36], which is also the case in our trial. The relief of urinary incontinence in both treatment groups could be explained by the removal of a heavy uterus due to fibroids. Although the surgical procedures of both operations may vary, most gynaecologists perform a suspension of the vaginal top during the total abdominal hysterectomy, while a suspension is seldom made during the subtotal abdominal hysterectomy. The higher cure rate of urinary incontinence in the total abdominal hysterectomy group might be explained by the difference in the suspension of the distal remnants of the female sexual organ. Further analyses and discussions of the lower urinary tract symptoms will be published later.

Our randomised clinical trial could be criticised of lack of criterion validity [e.g. comparing subjective assessment of urinary incontinence with an objective measurement ('golden standard')][20], lack of blinding and low recruitment to the study.

If the outcomes of the questions on urinary incontinence did not correspond with outcomes of 'the gold standard', which we however have been unable to identify, it could

introduce systematic error and affect the internal validity of the trial. We find, however, that this is not likely to be the explanation of the difference of our findings from other studies. This problem would affect both hysterectomy groups.

The lack of blinding might impair[29,30] our results compared with those of Thakar *et al.*[11]. We do not believe, however, that the lack of blinding is the correct explanation in this case, as the lack of blinding would be expected to result in an exaggerated effect of the new treatment method (i.e. subtotal abdominal hysterectomy)[29,30].

The low recruitment in our randomised clinical trial might give rise to a selected population of the randomised clinical trial, potentially affecting the external validity. Danish as well as international randomised clinical trials with recruitment rates higher than ours could be found[37,38], but lower recruitment rates are also observed[39,40]. However, in many randomised clinical trials, recruitment rates are not reported and there is a lack of information about assessed and eligible patients[11,18,41,42]. Nevertheless, a low recruitment rate might impoverish the generalisability of our results (the external validity) as the studied population might not be representative. The low recruitment rate in our randomised clinical trial resulted from factors, which could be attributed to the patients, the physicians and the departments. The low recruitment rate of the randomised patients arose from the fact that many patients wanted to choose the treatment method themselves (Fig. 1). This was also found in a German trial on mastectomy *versus* tumorectomy against malignant breast disease[43] and in a systematic review on the topic[44]. Physicians might have contributed to the low recruitment rate because of time constraint, lack of staff and training, worry on the impact on the physician–patient relationship, concern for patients, loss of professional autonomy, difficulty with the consent procedure, lack of rewards and recognition and an insufficiently interesting research question[44]. The departments might have affected the recruitment rate as only 11 departments (one-third of those in Denmark) contributed to the randomisation. Out of these 11 departments, two departments only contributed with two and three randomised patients, respectively, and one department was closed for inclusion due to the conduct of other studies. This resulted in only 4000 patients being assessed for eligibility out of the approximately 20,000 patients undergoing hysterectomy during the years of recruitment.

Spontaneous remission of incontinence[33,45] does not seem a likely explanation for the difference between the groups either. The randomisation seems to have been successful evidenced by the baseline characteristics. Therefore, spontaneous remission should occur equally in both groups.

We did not observe any significant difference regarding post-operative complications. More injuries to the bladder and ureter are thought to occur during the total abdominal hysterectomy[46]. We have not been able to identify studies comparing the two hysterectomy methods that showed this difference or other differences regarding post-operative complication. The overall complication rate observed in this trial was 41%. This is higher than in some reports[10,22], but similar rates have also been reported[23,24]. The reasons for the differences could be the length of follow up or the source of the data.

Post-operatively, we found an increase in quality of life, physically as well as mentally for all patients, but no significant difference between groups. An increase in quality of life after hysterectomy[9,10] to scores similar to an age-matched norm group of women[9] has been observed previously.

The operation time and the blood loss were significantly less in the subtotal abdominal hysterectomy group compared with total abdominal hysterectomy. However, the actual differences were not large and are unlikely to be clinically significant except for difficult operations, where one might decide to perform subtotal abdominal hysterectomy instead of total abdominal hysterectomy.

Unlike Kilkku[14], but like the randomised clinical trial by Thakar *et al.*[11], we did not find any difference between the two hysterectomy methods regarding sexual life. This could be explained by the differences of the study by Kilkku[14] and ours as already described. Further analyses of the data on sexuality will be published elsewhere[47].

One out of five subtotal abdominal hysterectomy operated women continued to have vaginal bleeding after the hysterectomy. A similar proportion of vaginal bleeding after subtotal abdominal hysterectomy was found in some studies[8,48], while other studies[11,49] observed a lower proportion. Even when the cervical canal is electrocoagulated, this complication is not negligible.

The present randomised clinical trial suggests that the shift towards the subtotal abdominal hysterectomy seems unwarranted. Before the final conclusion on this topic can be drawn, more randomised clinical trials and a systematic review of these trials according to the guidelines of The Cochrane Collaboration[50] should be performed.

CONCLUSION

A smaller proportion of women had urinary incontinence after total abdominal hysterectomy than after subtotal abdominal hysterectomy. No significant difference between the operation methods was found regarding post-operative complications and quality of life. However, the quality of life increased significantly after both operation methods to a level expected from Danish norm data. A non-negligible proportion of women experiences regular or irregular vaginal bleeding after subtotal abdominal hysterectomy.

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