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ORIGINAL ARTICLE

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Lower urinary tract symptoms after total and subtotal hysterectomy: results of a randomized controlled trial

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Abstract The aim of this Danish multicenter trial was to compare the proportion of women with lower urinary tract symptoms after total abdominal hysterectomy (TAH) and subtotal abdominal hysterectomy (SAH) for benign uterine disorders. A total of 319 women were randomized to TAH ($n = 158$) or SAH ($n = 161$). Women were followed up for 1 year by strict data collection procedures, including postal questionnaires. Results were analyzed by intention-to-treat analyses. Urinary incontinence was found less often among TAH women than among SAH women. This was due to a larger reduction of the number of women with stress and urinary incontinence in the TAH group. No other differences were found between the two operation methods. The number of women with urinary incontinence and frequency was reduced from study entry for follow-up, while double/triple voiding was increased. Incontinent women had significantly lower quality of life scores than continent women.

Keywords Lower urinary tract symptoms · Observational study · Questionnaire · Randomized clinical trial · Subtotal abdominal hysterectomy · Total abdominal hysterectomy

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Introduction

Over 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 incidence of total abdominal hysterectomy (TAH) by 38% as well as an increase in the incidence of subtotal abdominal hysterectomy (SAH) by 375% were observed in Denmark from 1988 through 1998 [1]. In 1998, the actual number of TAH performed for benign indications in Denmark was 2826 whereas the number of SAH was 1104; abdominal hysterectomy accounting for 80% of all hysterectomies was performed for benign indications [1].

Lower urinary tract symptoms (LUTS) in general and urinary incontinence (UI) in particular are prevalent

among women. The reported prevalence of LUTS varies from 5 to 22% [5, 6] and that of UI from 12 to 45% [5–8] depending on definitions, target populations, and study design. The observed risk factors for LUTS are muscular and/or neuromuscular pelvic injury during childbirth [9–11], diuretics [11], obesity [11–13], estrogen deficiency [9], age [9, 13], race [14], chronic obstructive pulmonary disease [13], and hysterectomy [5, 9, 11, 13]. A recent review on UI after hysterectomy supports the latter association [15].

Perimenopausal benign uterine diseases are known to affect quality of life [16, 17] and hysterectomy is known to improve quality of life, reaching values comparable to those of a reference population of similar age [16, 17]. UI is known to decrease women's quality of life [7, 18, 19] and may therefore influence the effect of hysterectomy on the overall quality of life. Particularly, if benign uterine diseases are treated in a way, which increases the risk of UI later in life, not much may be gained in terms of quality of life.

TAH and SAH have been compared regarding LUTS in randomized clinical trials (RCT) [20–22] and in observational studies (OS) [23–29]. This paper presents further analyses of the UI and other LUTS data from a previously published RCT [16].

Material and methods

The design of this RCT has been described previously [16]. The Research Ethics Committees at all of the participating centers as well as the Danish Data Protection Agency approved the trial, and informed consent was obtained from all women.

Women were recruited from 11 gynecology departments of public hospitals in Denmark if they were going to have a hysterectomy for benign diseases of the uterus. Those patients who met the inclusion criteria were approached and recruited into the study [16]. From 15 April 1996 until 30 June 2000, 319 women were randomized to either TAH ($n = 158$) or SAH ($n = 161$) via a central, computer-generated randomization procedure [16].

No instructions were given to the surgeons about the operation procedures apart from the instruction to electrocoagulate the cervical canal after removing the corpus uteri if the patients were randomized to the subtotal procedure.

Information about the preoperative gynecologic examination, the operation, the postoperative hospital stay, including its length, and pathology of the removed uterus was collected via case record forms filled out by the gynecologists. Information about deliveries, abortions, former diseases, admissions and operations, medication, tobacco and alcohol consumption, education, occupation, and outcome measures at entry were obtained by a tested questionnaire filled out by the patient before the operation. A validated questionnaire [29] concerning the outcome measures was filled out 2, 6, and 12 months after the operation. The questionnaire can be studied at http://www.gyncph.suite.dk/gimbel/praes/gi.htm.

All LUTS data were from the questionnaires except for postoperative urinary retention. This information was collected via case record forms filled out by the gynecologists. We defined UI as leakage of urine, which the woman suffered from "always" or "often." Frequency was defined as more than ten toilet visits per day. Nocturia was defined as more than two trips to the toilet per night. Urinary tract infection (UTI) was defined as an event, which the women suffered from "always," "often," or "every now and then." None of the patients were asked to do postoperative double/triple voiding unless incomplete bladder emptying was diagnosed.

The analyses of the outcome measures were prespecified [16]. UI was considered the primary outcome measure [16]. The level of significance was $p = 0.05$. "LUTS other than UI" encompassed frequency, nocturia, dysuria, UTI, incomplete bladder emptying, poor stream, straining at voiding, and a bother score for lower urinary tract symptoms. Due to the risk of mass significant findings, they were interpreted conservatively.

The outcome measurements were analyzed by intention to treat (ITT). The data shown in this paper as well as the conclusions were based on the ITT analysis. The analyses were carried out as comparisons of the two hysterectomy methods using chi-square tests and multiple logistic regression analyses.

Results

The response rate of the questionnaires at the 1-year follow-up was 86.8%. The total number of women experiencing frequency and nocturia decreased 1 year after the operation from 34 to 11 of 261 ($p < 0.001$) and

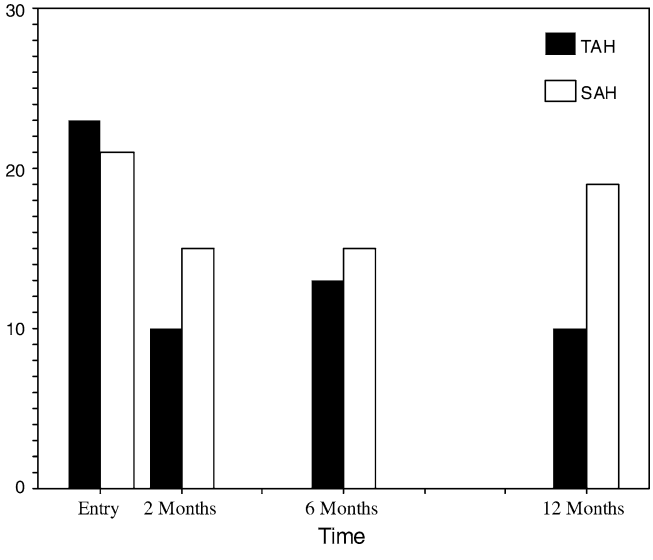

Fig. 1 Time-specific proportions of urinary incontinent women by operation method. *TAH* total abdominal hysterectomy, *SAH* subtotal abdominal hysterectomy

Table 1 Number (%) of women suffering from lower urinary tract symptoms distributed according to operation method. *TAH* total abdominal hysterectomy, *SAH* subtotal abdominal hysterectomy

	TAH, *n* (%)	SAH, *n* (%)	Statistics *p*
Urinary incontinence[a]			
0 month	35 (23)	33 (21)	0.78
12 months	13 (10)	25 (19)	0.030
Frequency			
0 month	23 (15)	18 (11)	0.82
12 months	4 (3)	7 (5)	0.15
Double/triple voiding			
0 month	3 (2)	16 (10)	0.002
12 months	10 (7)	13 (10)	0.52
Incomplete bladder emptying[b]			
0 month	13 (9)	20 (13)	0.20
12 months	14 (10)	15 (11)	0.87
Nocturia[c]			
0 month	8 (5)	4 (3)	0.22
12 months	1 (1)	4 (3)	0.21
Dysuria			
0 month	6 (4)	11 (7)	0.31
12 months	3 (2)	6 (5)	0.40
Urinary tract infections[d]			
0 month	4 (2)	12 (8)	0.78
12 months	7 (5)	3 (3)	0.34

[a]Previously reported in [16]
[b]Always or often
[c]More than twice a night
[d]Always, often, or every now and then

from 10 to 5 of 277 ($p = 0.01$), respectively). A decrease was also observed in the total number of UI women at the 1-year follow-up (from 56 to 37 of 268, $p < 0.001$). The decrease in UI was a result of a decrease in the patients reporting stress urinary incontinence (SUI) (from 26 to 11 of 277, $p = 0.002$) and mixed urinary incontinence (MUI) (23 to 14 of 277,$p < 0.001$). On the other hand, the number of women using double/triple voiding increased 1 year after the operation (18 to 22 of 265, $p < 0.001$).

The comparison of the two hysterectomy methods at the 1-year follow-up (the χ^2 analysis) showed a lower proportion of UI after TAH than after SAH ($p = 0.03$) (Tables 1, 2). The lower proportion of UI in the TAH group than in the SAH group was observed at 2, 6, and 12 months follow-up postoperatively but the difference was largest at the 1-year follow-up (Fig. 1). The difference between the two hysterectomy methods resulted from a larger decrease in the number of SUI and MUI women in the TAH group than in the SAH group and an increase in the number of urge urinary incontinence (UUI) women in the SAH group, while the number in the TAH group decreased.

No differences were observed between the TAH and SAH women regarding "LUTS other than UI" (Table 1) at the 1-year follow-up. The number of women suffering from UTI, incomplete bladder emptying, straining, and double/triple voiding from the TAH group increased from entry to 12 months, while the number of women suffering from UTI, incomplete bladder emptying, straining, and double/triple voiding from the SAH group decreased. The conclusions from the χ^2 tests did not change if a modified McNemar test was used considering entry results as well as 1-year follow-up results (UTI: $p = 0.43$, incomplete bladder emptying: $p = 0.63$, straining: $p = 0.79$, double/triple voiding: $p = 0.42$).

A multivariate analysis showed that urinary incontinence at study entry and the operation method were the most important variables for the presence of urinary incontinence at the 1-year follow-up (Table 3). The size of the uterus also seemed to influence the outcome but this variable did not reach statistical significance.

The question on the bother score of LUTS was not specifically related to UI in the questionnaire (http://www.gyncph.suite.dk/gimbel/praes/gi.htm). However, for 12 UI women from the TAH group and for 23 UI women from the SAH group, UI was correlated with "LUTS interfering with her daily life" (a small problem, a problem, or a big problem), while one and two women, respectively, had no problem at all. The two women

Table 2 Number (%) of stress, urge, mixed, and all urinary incontinent women at entry and 12 months after hysterectomy distributed according to operation method. Three women (2%) from the TAH group and zero women (0%) from the SAH group had urinary incontinence of unknown kind at 0 month, and two women (1%) from the TAH group and two women (1%) from the SAH group had urinary incontinence of unknown kind at the 12-month follow-up. *TAH* total abdominal hysterectomy, *SAH* subtotal abdominal hysterectomy, *OR* odds ratio, *CI* confidence interval

	TAH, *n* (%)	SAH, *n* (%)	Statistics: OR (95% CI) (*p*)
Stress urinary incontinence			
0 month	15 (9)	15 (9)	1.01 (0.48–2.17) (1.00)
12 months	3 (2)	8 (6)	0.35 (0.09–1.36) (0.12)
Urge urinary incontinence			
0 month	5 (3)	5 (3)	1.02 (0.29–3.59) (0.98)
12 months	2 (1)	7 (5)	0.27 (0.06–1.32) (0.084)
Mixed urinary incontinence			
0 month	12 (8)	13 (8)	0.94 (0.41–2.12) (0.87)
12 months	6 (4)	8 (6)	0.72 (0.24–2.14) (0.56)
All urinary incontinences[a]			
0 month	35 (23)	33 (21)	1.09 (0.63–1.86) (0.78)
12 months	13 (10)	25 (19)	0.46 (0.23–0.95) (0.03)

[a]Previously reported by Gimbel et al. [16]

Table 3 Predictors for outcomes at the 1-year follow-up. *CI* confidence interval

Outcome	Predictors[a]	Odds ratio (95% CI)	*p*
Urinary incontinence	**Preoperative incontinence**	**11.2 (5.1–25.9)**	**< 0.0001**
	Operation method (TAH/SAH)	**0.43 (0.18–0.96)**	**0.044**
	Size of the uterus (in cm^3)	**1.56 (1.00–2.49)**	**0.051**
	Menopause	0.57 (0.24–1.35)	0.20
	Body mass index	0.64 (0.26–1.53)	0.32
	Constipation	0.59 (0.18–2.11)	0.39
	Weight of heaviest child	0.78 (0.34–1.76)	0.55
	Bronchitis	0.97 (0.25–4.49)	0.96

[a]The multivariate logistic regression analyses were initially performed including all of the above-mentioned predictors in the models. Afterwards the analysis was performed in a reduced model, including only the predictors with $p \leq 0.05$. The predictors shown in boldface are results from the reduced model

Table 4 Results of the multivariate analysis of predictors for women bothered by lower urinary tract symptoms at 12 months after total and subtotal hysterectomy

Dependent variable	Predictor	Odds ratio (95% confidence interval)	Significance (*p*)
Bother score[a]	Urinary incontinence	463 (69–3109)	< 0.001
	Frequency	29.2 (4.1–211)	0.001
	Incomplete bladder emptying	20.0 (5.4–74.6)	< 0.001
	Nocturia	0.016 (1.67^{-17} –1.50^{13})	0.66
	Dysuria	9.3 (0.8–105.8)	0.09
	Urinary tract infection	1.9 (0.2–22.9)	0.61
	Straining	0.31 (0.03–3.0)	0.30
	Poor stream	1.9 (0.1–30.3)	0.64
	Double/triple voiding	0.60 (0.06–5.9)	0.67

[a]Women bothered: a big problem, a problem, only a minor problem. Women not bothered: no problem at all

from the SAH group who only suffered from UI "rarely" and who had "a big problem" or "a problem" also had nocturia ($n = 1$) and double/triple voiding, incomplete bladder emptying, and recurring UTI ($n = 1$). A multivariate analysis of 1-year follow-up data of the relation between bother score and each of the LUTS showed that UI is the best predictor of the bother score (Table 4).

Women suffering from UI had significantly lower scores of physical (PCS) as well as mental component (MCS) of quality of life (PCS: 50.60, MCS: 50.01) compared with women not suffering from UI (PCS: 53.82, MCS: 53.99; $p = 0.003$ and $p = 0.038$, respectively).

Discussion

In the present trial, the overall number of women suffering from UI and frequency were reduced from study entry to 1 year after hysterectomy, while the overall number of women using double/triple voiding was increased. As regards the type of hysterectomy, UI was found less often among the TAH women than among the SAH women at the 1-year follow-up. No other differences were found between the two operation methods regarding LUTS. The LUTS bother score was significantly related to UI, frequency, and incomplete bladder emptying, and we found significantly lower quality of life scores among the women suffering from UI than among women not suffering from UI.

The RCT could be criticized for not studying the criterion validity of the LUTS questions. The criterion validity of the questionnaire was not studied as we had difficulties finding the "gold standard" against which the results of the questionnaire could be tested. No obvious and valid method existed against which urinary incontinence could be measured [30–33]. A possible way to further validate our question could be to have our patients complete a 1-week voiding diary [34]. Further, it could be criticized that no objective measurements of urinary incontinence were performed. This might weaken the discrimination into different types of urinary incontinence. Further, lack of blinding and low recruitment to the trial could be criticized. These weaknesses have been discussed previously [16]. Finally, some of the LUTS and subdivisions of UI occur very rarely because of small sample sizes, which could result in type II errors.

An overall reduction of frequency of micturition has been reported previously by Kilkku [25, 26], Thakar et al. [21], Lalos and Bjerle [20], and Learman et al. [22], and an overall reduction of UI following hysterectomy was also found by Kilkku [25, 26], Thakar et al. [21], and Learman et al. [22]. Our finding of a reduction in UI resulting from a reduction of SUI has also been reported by Learman et al. [22]. To our knowledge, a reduction of

MUI has not been reported previously; neither has the overall increase in the number of women using double/triple voiding.

The finding that TAH was superior to SAH regarding UI has been discussed previously by Gimbel et al. [16]. This study elucidates the problem further by presenting analysis on SUI, UUI, and MUI. No statistically significant difference was found between the operation methods concerning the three forms of UI. However, the difference in UI could be explained by a larger reduction of SUI and MUI in the TAH group than in the SAH group as well as a small reduction in UUI in the TAH group and an increase in the SAH group. Kilkku [25, 26] did not distinguish between the different kinds of UI. Thakar et al. [21] and Learman et al. [22] found a decrease in SUI and UI in both hysterectomy groups. Learman et al.'s [22] findings were more pronounced in the TAH group. The reasons for the differences between our results and the results presented by Thakar et al. [21] and Learman et al. [22] seem to be due to the sample size of the RCT. Other reasons could be the different operation procedures of gynecological surgeons in Denmark and the United Kingdom/United States and differences in race of the women included in the trials [21], as the incidence of UI differs with race [14].

An explanation for a reduction in SUI and MUI could be the removal of a uterus with large fibroids in the TAH as well as the in SAH group. An explanation for the larger reduction in the TAH group than in the SAH group could be found in the etiology of SUI. There is a general consensus that abnormal urethral support plays some role in the etiology of SUI [35]. As part of the abnormal urethral support, SUI women have increased bladder neck mobility [36]. During the TAH procedure many gynecologists perform a suspension of the vaginal top as described in the literature [37]. A suspension of the cervical stump is not usually done in Denmark during the SAH procedure. The suspension during the TAH might serve as a minor bladder neck suspension procedure, thus decreasing/removing the problem of incontinence by decreasing the bladder neck mobility. A comparative study of 39 patients undergoing (total) abdominal hysterectomy and 30 controls [38] has shown that the TAH procedure decreases the bladder neck mobility. Procedures and devices often used to relieve UI symptoms in general and SUI in particular (Burch's procedure and application of vaginal devices) also decrease the bladder neck mobility [39, 40]. Therefore, the advantage of TAH compared to SAH may be due to the suspension associated with TAH. If the theory of suspension is correct, a suspension procedure of the cervical stump could be performed during SAH in cases where TAH is impossible to undertake. This needs to be tested in RCTs.

In agreement with other studies [7, 18, 19], as regards the quality of life, women suffering from UI at the 1-year follow-up in our trial scored significantly lower than continent women. Bother scores of LUTS were significantly related to UI and more so than with any other LUTS.

Our results primarily elucidate the reservoir function of the bladder. The complaints of double/triple voiding, incomplete bladder emptying, poor stream, and straining are all related to the emptying function of the bladder although not very specific. We found no significant difference between the two hysterectomy methods but an increase in the overall number of women using double/triple voiding after the operation. A study by Haylen [41] found that the emptying function of the bladder was disturbed after hysterectomy. As the latter study was not prospective and as our findings only suggest this relation, further studies have to be undertaken before a final conclusion may be drawn.

To elucidate the reasons for the differences of UI following total and subtotal hysterectomy, a 2×2 factorial design RCT of bladder neck mobility after the two operation methods and suspension versus no suspension of the vaginal top/cervical stump is needed.

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