GYNECOLOGY

Subtotal versus total abdominal hysterectomy: randomized clinical trial with 14-year questionnaire follow-up

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OBJECTIVE: The objective of the study was to compare long-term results of subtotal vs total abdominal hysterectomy for benign uterine diseases 14 years after hysterectomy, with urinary incontinence as the primary outcome measure.

STUDY DESIGN: This was a long-term follow-up of a multicenter, randomized clinical trial without blinding. Eleven gynecological departments in Denmark contributed participants to the trial. Women referred for benign uterine diseases who did not have contraindications to subtotal abdominal hysterectomy were randomized to subtotal (n = 161) vs total (n = 158) abdominal hysterectomy. All women enrolled in the trial from 1996 to 2000 who were still alive and living in Denmark (n = 304) were invited to answer the validated questionnaire used in prior 1 and 5 year follow-ups. Hospital contacts possibly related to hysterectomy from 5 to 14 years postoperatively were registered from discharge summaries from all public hospitals in Denmark. The results were analyzed as intention to treat and per protocol. Possible bias caused by missing data was handled by multiple imputation. The primary outcome was urinary incontinence; the secondary outcomes were pelvic organ prolapse, constipation, pain, sexuality, quality of life (Short Form-36 questionnaire), hospital contacts, and vaginal bleeding.

RESULTS: The questionnaire was answered by 197 of 304 women (64.8%) (subtotal hysterectomy [n = 97] [63.4%]; total hysterectomy [n = 100] [66.2%]). Mean follow-up time was 14 years and mean age at follow-up was 60.1 years. After subtotal abdominal hysterectomy, 32 of 97 women (33%) complained of urinary incontinence compared with 20 of 100 women (20%) after total abdominal hysterectomy 14 years after hysterectomy (relative risk, 1.67; 95% confidence interval, 1.02–2.70; $P = .035$). After a multiple imputation analysis, this difference disappeared (relative risk, 1.36; 95% confidence interval, 0.86–2.13; $P = .19$). No differences were seen in any of the secondary outcomes.

CONCLUSION: Subtotal abdominal hysterectomy was not superior to total abdominal hysterectomy on any outcomes. More women seem to have subjective urinary incontinence 14 years after subtotal abdominal hysterectomy. This result was not confirmed by multiple imputation analysis and should be interpreted cautiously.

Key words: hysterectomy, long-term follow-up, pelvic organ prolapse, quality of life, urinary incontinence

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Approximately 4500 benign hysterectomies are performed yearly in Denmark.[1] Although the use of the less invasive laparoscopic mode of hysterectomy is rising, 32% of Danish hysterectomies in 2012 were abdominal,[2] and more than 50% of hysterectomies in the United States were abdominal in 2010.[3]

Of abdominal hysterectomies, 10% were subtotal, and of laparoscopic hysterectomies, 20% were subtotal in Denmark in 2011.[1] In some hospitals in Germany, subtotal laparoscopic hysterectomy is the standard and accounts for more than 80% of laparoscopic hysterectomies.[4] The background for preferring subtotal hysterectomy is that it is simpler and quicker and may result in

fewer complications.[5] However, morcellation is part of this mode of hysterectomy, and because leiomyosarcomas are sometimes mistaken for fibromas, morcellation is no longer recommended by the Food and Drug Administration[6]; consequently, one may assume, in the future, large uteri will more often be removed by abdominal hysterectomy.

Studies in the 1980s[7-9] suggested that subtotal abdominal hysterectomy (SAH) was superior to total abdominal hysterectomy (TAH) regarding sexual function. This finding was not reproduced in randomized clinical trials (RCTs).[10-12] The risk of cervical cancer in the remaining cervix is another important issue. Nevertheless, if a Papanicolaou smear is normal prior to surgery and the woman continues to participate in cervical cancer screening, the risk of cervical cancer is only approximately 0.03%.[14,15]

Three RCTs comparable with our Danish trial[15,16] comparing SAH with TAH[16-18] have performed long-term follow-up and found no significant differences between SAH and TAH on clinical outcomes. Few data on long-term outcomes after subtotal vs total laparoscopic hysterectomy are available.[19] Although open abdominal and laparoscopic surgery differ in many ways, the most recent Cochrane systematic review[20] on the topic included both methods and stated that there was no evidence to support the shift toward subtotal hysterectomy seen in laparoscopy. The authors of the review conclude that more long-term follow-up is needed because urogenital problems may occur years after surgery, especially in postmenopausal women.[20]

We aimed to compare 14-year outcomes after SAH vs TAH in women included in a randomized clinical trial for benign uterine diseases.[14,15] The primary outcome is urinary incontinence (UI) 14 years after hysterectomy.

Materials and Methods

In 1996–2000, 319 women from 11 gynecological departments in Denmark were randomized to SAH vs TAH.[14] Details about eligibility criteria, consent, inclusion, randomization, and surgical procedures have been published.[14] The sample size of the original trial was calculated based on an assumed prevalence of the primary outcome, UI, 1 year after TAH of approximately 23%.[21,22] With a power of 0.80, a type I error of 5%, and a 15% absolute difference in UI between the surgical groups, 160 participants had to be included in each intervention group.[14]

Results from 1 year of follow-up[14] showed that significantly more women in the SAH group were urinary incontinent compared with the TAH group. A decrease in UI after hysterectomy was seen in both surgical groups. The secondary outcomes postoperative complications, quality of life (Short Form-36 [SF-36]), constipation, pelvic organ prolapse, satisfaction with sexual life, and pelvic pain did not show any difference between surgical groups. Neither did the further analyses of lower urinary tract symptoms[23] and sexuality.[13] At 1 year, 20% of the SAH group still experienced vaginal bleeding. At 5 years,[15] the significant difference between SAH and TAH regarding UI was reproduced. The number of incontinent women was higher than at 1 year. In the SAH group, 11% still experienced vaginal bleeding.

All participants still alive and living in Denmark in September 2012 were contacted by letter, and it contained the validated questionnaire[24] (Appendix; Supplemental Material) used in prior follow-ups.[14,15] The questionnaire assessed primary and secondary outcomes (presented in the following text). Reminders were sent 2 and 7 months later to nonresponders. Participants were encouraged to return the questionnaire unanswered if they did not wish to participate, thus avoiding reminders. Age at follow-up and follow-up time was calculated with January 2013 as the cutoff point.

The primary outcome, UI, was defined as a subjective complaint of involuntary loss of urine often or always (question 35 in the questionnaire). Because this result could reflect a difference in treatment-seeking behavior between surgical groups rather than in the occurrence of UI, we also analyzed the number of women who reported UI at any time since hysterectomy including prior follow-ups.[14,15]

Secondary outcomes were hospital contacts, pelvic organ prolapse (POP), pelvic pain, satisfaction with sex life, constipation, quality of life (QoL), and vaginal bleeding after SAH. All outcomes, except QoL, were dichotomized, and the SAH and TAH groups were compared using a χ^2 test. Analyses were conducted as intention to treat as well as per protocol excluding participants that did not receive the allocated intervention (Figure 1). As in prior follow-ups,[14,15] the conclusions are based on the intention-to-treat analyses. Additionally, satisfaction with sex life was analyzed separately for those stating they had a partner and those who did not.

QoL was assessed by the validated SF-36 questionnaire[25] included in our questionnaire (Supplemental Material). SF-36 was scored according to the specifications by Quality Metric using the official scoring software. For each participant a physical component score (PCS) and a mental component score (MCS) were calculated. These scores are validated and a norms based mean of 50 is interpreted as average QoL. Means were compared between surgical groups using the Wilcoxon rank sum test because the scores were not normally distributed.

Some women did not answer all questions resulting in different totals for each analysis. The number in each group for the particular analysis is stated in Table 1. To account for possible bias caused by missing data because of the loss to follow-up and incomplete questionnaires, multiple imputation (MI) was carried out using the FCS method in SAS (version 9.3; SAS Institute, Cary, NC) using the PROC MI and MIANALYZE functions. The 14-year outcomes imputed were UI, pelvic pain, POP, satisfaction with sex life, QoL, and constipation.

The following variables were included in the imputation model because they were associated with ($P < .1$) one or more of the outcomes in the multivariate logistic regression: baseline variables included type of surgery, number of