### SEXUAL MEDICINE

#### EPIDEMIOLOGY & RISK FACTORS

# The Impact of Sacrospinous Hysteropexy and Vaginal Hysterectomy With Suspension of the Uterosacral Ligaments on Sexual Function in Women With Uterine Prolapse: A Secondary Analysis of a Randomized Comparative Study



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#### **ABSTRACT**

**Introduction:** Studies on pelvic organ prolapse (POP) surgery show conflicting evidence regarding the impact of uterus preservation and hysterectomy on sexual function and no large randomized trials with long-term follow-up have been published on this topic.

Aims: The aim of this secondary analysis was to evaluate and compare sexual function after sacrospinous hyster-opexy and vaginal hysterectomy with suspension of the uterosacral ligaments in women with uterine prolapse.

Methods: This is a secondary analysis of the SAVE U trial data, a multicenter trial in 4 nonuniversity hospitals in the Netherlands comparing sacrospinous hysteropexy and vaginal hysterectomy with suspension of the uterosacral ligaments in primary surgery of uterine prolapse stage II or higher. Primary outcome of the original study was recurrent prolapse stage II or higher of the uterus or vaginal vault (apical compartment) evaluated by POP-Q examination in combination with bothersome bulge symptoms or repeat surgery for recurrent apical prolapse at 12 months follow-up. Secondary outcomes were overall anatomical recurrences, functional outcome, complications, hospital stay, postoperative recovery, and sexual functioning. Data from patients who had completed the POP/urinary incontinence sexual questionnaire (PISQ-12) at baseline and 24 months after surgery were used in the present trial. Total, subscale, and individual question analyses were performed. The SAVE U trial is registered in the Dutch trial registry, number NTR1866.

**Main Outcome Measures:** Differences and changes in sexual function 24 months after surgery, measured by the PISQ-12 questionnaire.

**Results:** Between November 2009 and March 2012, 208 women were randomized between sacrospinous hysteropexy (n = 103) and vaginal hysterectomy with suspension of the uterosacral ligaments (n = 105). Of these, 99 women completed questionnaires at baseline and after 24 months follow-up and were included in the present study. During a follow-up period of 24 months, no significant differences in total PISQ-12 scores were observed between the groups. After both interventions the item "avoidance of intercourse due to prolapse" significantly improved, as did the physical subscale of the PISQ-12 questionnaire.

**Conclusion:** There was no statistically significant difference in overall sexual functioning (total PISQ-12 scores) between uterus-preserving sacrospinous hysteropexy and vaginal hysterectomy with suspension of the uterosacral ligaments after a follow-up period of 24 months.

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Key Words: Hysterectomy; Uterus Preservation; Sexual function; Hysteropexy; PISQ-12

#### INTRODUCTION

Pelvic organ prolapse (POP) is one of the most common benign gynecological disorders, with an increasing incidence due to increased life expectancy. The lifetime risk for POP surgery is up to 20% and approximately 16% to 30% of patients need repeat surgery because of recurrent POP or urinary incontinence. <sup>1–5</sup> Up to 60% of sexually active women with POP

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214 Detollenaere et al

awaiting pelvic reconstructive surgery reported that their sex life was negatively affected by their prolapse and 1 cohort study that included 1267 sexually active women reported that women with POP had lower scores on the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire short form (PISQ-12) than woman without POP.<sup>6,7</sup>

In general sexual function improves after POP surgery, although there are some studies that have shown conflicting evidence. <sup>8–10</sup> POP has anatomical, functional, and psychological aspects. The physical and anatomical cure of POP may result in less physical bother during sexual intercourse. On the other hand, POP surgery may be accompanied by negative side effects. Vaginal narrowing and scarring as well as damage to vascularization and innervation can lead to sexual dysfunction including dyspareunia, vaginal dryness, and/or orgasmic problems, and therefore diminished satisfaction and frequency of intercourse. Associated dysfunctions such as stress urinary incontinence during intercourse may change after surgery and thus also may change the perception of sexuality. Surgical repair of POP may relieve symptoms by improvement of women's body image. <sup>11,12</sup>

It is known that the type or route of hysterectomy (abdominal vs vaginal hysterectomy) does not play a role in sexual function after hysterectomy. 13 Controversy exists regarding the effect of uterus preservation vs hysterectomy in POP repair on sexual function. Two randomized controlled trials measured sexual function after sacrospinous hysteropexy vs vaginal hysterectomy and found no differences between the 2 groups. 14,15 However, no validated questionnaires were used in these studies and follow-up was only performed after 6 and 12 month follow-up with limited sample size. Another prospective cohort study by Constantini et al assessing uterus-sparing surgery vs hysterectomy with sacrocolpopexy showed that 12 months after surgery, uterus preservation was associated with a greater improvement in the desire, arousal, and orgasm sexual domains. 16 No large randomized trials with longterm follow-up are available evaluating sexual functioning after uterus preservation vs hysterectomy in treatment of uterine prolapse. This is the report on a secondary analysis of a large randomized clinical trial comparing sexual function after sacrospinous hysteropexy and vaginal hysterectomy with suspension of the uterosacral ligaments in treatment of uterine prolapse.

#### **AIMS**

The aim of this secondary analysis was to evaluate and compare sexual function in women who were randomized between sacrospinous hysteropexy vs vaginal hysterectomy with suspension of the uterosacral ligaments in treatment of uterine prolapse stage II or higher.

#### **METHODS**

The SAVE U trial was designed to compare surgical failure after 12 months follow-up between sacrospinous hysteropexy and vaginal hysterectomy with suspension of the uterosacral ligaments. These

results have been published previously.<sup>17</sup> In short, women with symptomatic uterine prolapse POP-Q stage II or higher (uterine prolapse 1 cm above the hymen or beyond) requiring surgery were randomly assigned to sacrospinous hysteropexy and vaginal hysterectomy in an open-label multicenter non-inferiority trial.<sup>18</sup> The surgical procedures were performed according to guidelines described in previous trials.<sup>17,18</sup> Patients with previous pelvic floor or POP surgery, known malignancy or abnormal cervical smears, a wish to preserve fertility, language barriers, presence of immunological or hematological disorders interfering with recovery after surgery, abnormal ultrasound findings of the uterus or ovaries or abnormal uterine bleeding, and those who were unwilling to return for follow-up were excluded from the study.

Gynecological consultation prior to surgery included pelvic ultrasonography to exclude uterine or ovarian disease, a cervical smear test and vaginal inspection in 45° semi-upright position for staging uterovaginal prolapse by POP-Q examination. Preoperative urodynamic evaluation was only performed when indicated. During the first 6 weeks after surgery, patients kept a diary to evaluate postoperative pain measured by the Visual Analogue Scale (VAS) score. All patients consulted the hospital for follow-up/ POP-Q examination at 12 months after surgery and annually thereafter. At baseline and at the follow-up visit all patients completed the validated disease-specific quality of life questionnaires: Short Form-36 (SF-36), Urogenital Distress Inventory (UDI), Defecatory Distress Inventory (DDI), and Incontinence Impact Questionnaire (IIQ). 19-21 Patients were considered to be sexually active if they responded "yes" to the question "are you having sexual contact with your partner?" To assess sexual functioning, the PISQ-12, translated from the validated questionnaire but not validated for Dutch language, was used. Data from patients who had completed the PISQ-12 at baseline and 24 months after surgery were used in the present trial. This PISQ-12 questionnaire is a shorter version of the original PISQ questionnaire and is validated for assessment of sexual function in women with POP. <sup>22,23</sup> PISQ-12 individual question scores range from 0 to 4. Total PISQ-12 scores range from 0, which represents poorest sexual function, to 48, best sexual function. A questionnaire was considered valid if there were no more than 2 missing items and total scores were corrected for the number of answered questions. The behavioral/emotive subscale was calculated using questions 1, 2, 3, 4, and 9 (desire, arousal, emotions), the physical subscale by questions 5, 6, 7, and 8 (pain, urinary and/or fecal incontinence, and bulge symptoms) and the partner-related subscale by questions 10, 11, and 12 (erection, premature ejaculation, and intensity of orgasm).

Data were entered and registered using a web-based application facilitated by the Dutch consortium for studies in women's health and reproductivity (www.studies-obsgyn.nl). The trial was approved by the medical ethical committee of Isala hospital (MEC 09-625) and the local ethical committees of the participating centers. The trial was registered: trialregister.nl, number NTR1866.

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