

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb



Full length article

No evidence of association between native tissue vault suspension and risk of pelvic pain or sexual dysfunction



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ARTICLE INFO

Article history: Received 26 January 2018 Received in revised form 10 April 2018 Accepted 16 April 2018 Available online xxx

Keywords: Hysterectomy Benign indication Vaginal vault suspension Pelvic pain Sexual dysfunction

ABSTRACT

vaginal vault suspension.

Objective: Hysterectomy is suspected of increasing risk of subsequent pelvic organ prolapse (POP). In attempt to prevent this, several suspension methods during hysterectomy on benign indication are used as a prophylactic procedure. However, possible complications to the use of prophylactic vaginal vault suspension to prevent POP are not fully investigated. We aimed to elucidate prophylactic vaginal vault suspension as a possible cause for pelvic pain and sexual dysfunction.

Study design: We included all women registered with a total hysterectomy on benign indication and registered with a suspension method or specifically no suspension in the nationwide Danish Hysterectomy and Hysteroscopy Database (DHHD) between 10 May 2012 and 4 September 2013 (N = 3999). A postal questionnaire on pelvic pain and sexual dysfunction was sent to women 25.8 (range 23.8-28.4) months after hysterectomy. Questions were selected from a previous study as well as from the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). We used independent samples t-tests and χ 2-tests for univariate analyses. In multivariable analyses, we used log-binomial – and linear regression models adjusted for risk factors of pelvic pain and sexual dysfunction, respectively. Results: The response rate was 60.3% (N = 2412). Of the respondents, 88.8% (N = 2143) were registered with a suspension method and 11.2% (N = 269) were registered with specifically no suspension. Overall, pelvic pain of any kind was reported in 24.3% (N = 576) of the respondents. In adjusted log-binomial regression, suspension did not increase risk of pelvic pain compared to no suspension (RR 0.92; 95% CI 0.75 to 1.14; p-value 0.45). In adjusted linear regression, suspension was significantly associated with less degree of sexual dysfunction (regression coefficient -0.92; 95% CI -1.70 to -0.14; p-value 0.02). Conclusions: In women undergoing prophylactic vaginal vault suspension during hysterectomy, we found less sexual dysfunction and no evidence of increased risk of pelvic pain compared to women with no

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Introduction

Suspension of the vaginal vault during hysterectomy on benign indication is used in treatment of pelvic organ prolapse (POP) [1]. Gynecologists, however, also apply suspension methods during hysterectomies for indications other than POP in order to prevent development of POP [2]. Little is known regarding possible side effect to prophylactic vault suspension.

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Studies on native tissue suspension involving the apical compartment have shown associations between transabdominal sacrocolpopexy, transvaginal ilioccocygeus fixation and sacrospinous ligament suspension and postoperative pain [3,4]. Moreover in the recent OPTIMAL study, Barber et al. showed that women undergoing transvaginal sacrospinous ligament suspension sought treatment because of persistent pain more frequently than women undergoing suspension to the uterosacral ligament, 4.5% and 0.5% respectively [5]. In the sub study, authors reported improvement in sexual function after both procedures; however, de novo dyspareunia appeared in 10% of the participants [6]. In these studies, the different suspension methods were applied in order to treat women with POP.

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If vaginal vault suspension is performed as a prophylactic procedure to prevent POP, it is important to elucidate whether gynecologists inflict postoperative complications like pelvic pain and sexual dysfunction/dyspareunia. To address this, we investigated the hypotheses of an association between prophylactic vaginal vault suspension during hysterectomy on benign indication and pelvic pain and sexual dysfunction, respectively.

Materials and methods

The Danish Hysterectomy and Hysteroscopy Database (DHHD), which is part of the National Patient Registry (NPR), holds prospectively registered data on all hysterectomies on benign indication performed in Denmark since 2003. Registration of all operations in the NPR is compulsory by law. Previous studies of the DHHD and NPR have shown high completeness [7] and good reliability of hysterectomy codes [8].

In 2011 the DHHD trial group discussed preferences and used suspension methods on their affiliated departments and decided on five different individual suspension methods and one related procedure to be included in the DHHD [9]. The procedures are listed in Fig. 1.

From the DHHD, we collected data on date and geographical site of hysterectomy, body mass index, method of hysterectomy, indication of hysterectomy, method of suspension and postoperative complications.

Two pre-specified main outcomes were assessed through a questionnaire: pelvic pain and sexual dysfunction. We included 24 questions on pelvic pain from a previously published questionnaire by Brandsborg et al. [10]. We also included 10 questions about sexual function from the Danish Urogynecological Society's translation [11] of the validated Pelvic Organ prolapse/urinary incontinence Sexual Questionnaire — 12 (PISQ-12) [12]. In addition, frequency of intercourse was included. For an English translation of the questionnaire, see Supplementary material S2.

Reliability of the questionnaire was investigated within a twoweek period in 23 women with simple or weighted kappa according to the nature of questions. Mean kappa value was 0.68 (range 0.29–1.00.)

All women undergoing hysterectomy on benign indication between 10 May 2012 and 4 September 2013 and registered with a suspension method (N = 3999) received a questionnaire by letter to be answered by letter or electronically. The questionnaires were sent 25.8 (range 23.8–28.4) months after hysterectomy. Three weeks later, we sent a reminder.

Questionnaire analysis

Pelvic pain was defined as pain in the pelvic region within 3 months prior to responding to the questionnaire 2 years after hysterectomy [13]. Pelvic pain corresponded to a 'yes' in question 13: 'Have you within the past 3 months had pain in the pelvic region?'

Sexual dysfunction was recorded as a summed score of 10 questions (questions 25, 27–34 and 22c) regarding behavioral, emotive, physical and partner related factors as suggested by Rogers et al. [12]. The lower the score the better the sexual function. Range of the score was 0 to 40.

Additionally, the questionnaire included descriptive questions on pain (Questionnaire, Supplementary Table 4) Women having pain outside of the pelvic region before the operation (question 10) as well as within the past 3 months (question 24a) were categorized as having other pain problems.

Statistical analyses

When this study was initiated, the prevalence of pelvic pain or sexual dysfunction in relation to prophylactic vaginal vault

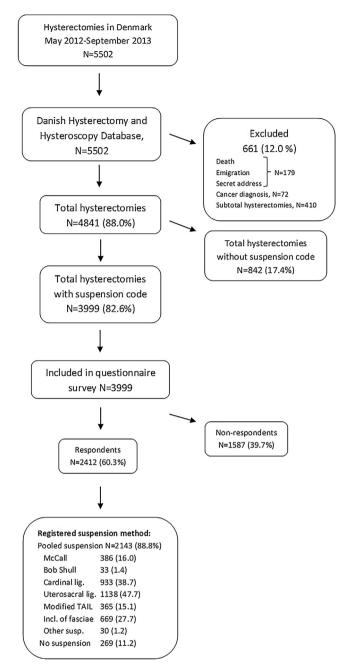


Fig. 1. Study population of hysterectomies in Denmark, $10\,$ May $2012\,$ to $4\,$ September 2013.

suspension had not yet been studied and was thereby not available for use in sample size estimation. Maher et al. reported buttocks pain in 19% and 14% of two groups undergoing two different apical suspension methods [4]. Based on this, we hypothesized a 15% probability of pain after prophylactic suspension and defined a 10% difference to be of clinical interest. With a power of 90% and significance level of 0.05, the calculated sample size per group was 182 women. With eight different groups, an expected response rate of 50% and unknown distribution of the individual suspension methods within the cohort, we included 4000 women.

All univariate analyses were performed as to whether any suspension was registered (*pooled suspension*) or not (*no suspension*) [9]. We used independent samples t-tests for continuous variables and Pearson's X^2 tests for dichotomous variables.

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