GYNECOLOGY

Recurrence of vaginal prolapse after total vaginal hysterectomy with concurrent vaginal uterosacral ligament suspension: comparison between normal-weight and overweight women

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BACKGROUND: Obesity is one of the most important risk factors for the development and progression of the pelvic organ prolapse. However, data regarding whether obesity is a risk factor for recurrence after pelvic organ prolapse surgery are controversial.

OBJECTIVE: The aim of this study was to estimate the risk of recurrent prolapse in any vaginal compartment after total vaginal hysterectomy with concurrent uterosacral ligament vaginal vault suspension among normal-weight women compared with either overweight or obese women.

STUDY DESIGN: This is a 5-year retrospective cohort study of women who underwent total vaginal hysterectomy with concurrent vaginal uterosacral ligament suspension at one referral center for pelvic organ prolapse in Italy from January 2010 to January 2015. All women who underwent total vaginal hysterectomy with concurrent uterosacral ligament suspension were included in the analysis. Laparoscopic approach was excluded. Women were classified according to the body mass index of 2 groups: (1) normal weight (body mass index, 18.5—24.9 kg/m^2) and (2) either overweight (body mass index, 25.0—29.9 kg/m^2) or obese (body mass index, $\geq$30.0 kg/m^2). The primary outcome was the incidence of recurrent prolapse in any vaginal compartment (anterior, posterior, or apical). *Recurrent prolapse* was defined as prolapse extending beyond the hymen with straining (pelvic organ prolapse quantification points Ba, C, Bp $\geq$0) or repeat treatment for prolapse with either pessary or surgery. Uterosacral ligament suspensions were performed with a vaginal approach with the use of sutures placed in the intermediate uterosacral ligament, at or above the ischial spine, and affixed to the vaginal apex. Delayed absorbable sutures were used, with 2 sutures per side.

RESULTS: Three hundred sixty women who underwent total vaginal hysterectomy with concurrent uterosacral ligament suspension with at least 6 months of follow up after surgery were included in the study. The overall incidence of recurrent prolapse in any vaginal compartment was 19.7% (71/360 women). The risk of recurrent prolapse in any vaginal compartment (ie, primary outcome) was similar in the normal-weight compared with the overweight or obese group (16.7% vs 21.3%; *P*=.30). Women in the normal-weight group had a lower risk of recurrent anterior vaginal prolapse (10.8% vs 20.0%; adjusted odds ratio, 0.49; 95% confidence interval, 0.25—0.94) and of multiple compartment prolapse (8.3% vs 14.6%; adjusted odds ratio, 0.53; 95% confidence interval, 0.31—0.83).

CONCLUSION: After total vaginal hysterectomy with concurrent uterosacral ligament suspension, the risk of recurrent vaginal prolapse was 20% based on a composite outcome definition of any anatomic prolapse beyond the hymen or pessary or repeat surgery. The most common site of recurrence was the anterior compartment. The risk of recurrent surgery was 10%. Our study showed that women with normal-weight had similar risk of recurrent prolapse compared with the overweight or obese group. In subgroup analyses, women with normal-weight had one-half the odds of recurrent anterior vaginal wall prolapse compared with those who were overweight or obese.

Key words: cistoscopy, incontinence, mesh, prolapse, urology

Hysterectomy for benign gynecologic disease, which includes prolapse, is 1 of the most frequent gynecologic procedures performed in the United States.[1,2] The vaginal route is the most cost-effective approach for a hysterectomy performed for uterovaginal prolapse.[1] Vaginal hysterectomy with concurrent uterosacral ligament

suspension is a common, safe, and cost-effective procedure for prolapse.[3] A recent systematic review with meta-analysis showed that uterosacral ligament suspension is a highly effective procedure for the restoration of apical vaginal support, with a successful rate of approximately 80%.[4]

Obesity is 1 of the most important risk factors for the development and progression of pelvic organ prolapse.[5] However, data regarding whether obesity is a risk factor for recurrence after pelvic organ prolapse surgery are controversial.[6–11]

Therefore, the aim of this study was to estimate the risk of recurrent prolapse in any vaginal compartment after total vaginal hysterectomy with concurrent

uterosacral ligament vaginal vault suspension among normal-weight women compared with overweight or obese women.

Materials and Methods

This was a 5-year retrospective cohort study of women who underwent total vaginal hysterectomy with concurrent uterosacral ligament suspension at 1 referral center in Naples, Italy (Department of Obstetrics and Gynecology, Ospedale Buon Consiglio Fatebenefratelli) from January 2010 to January 2015. In this center, vaginal hysterectomy with concurrent uterosacral ligament suspension is the preferred approach in cases of pelvic organ prolapse.

Study design that included exclusion criteria, primary outcome, and sample size calculations were based on a similar previously published study.[6]

Clinical records of women who were referred for uterovaginal prolapse were collected prospectively in a dedicated database. All charts that were recorded in the database were reviewed carefully by the 2 authors. All variables that were reported were collected on all of the patients who were included in this study. The study was approved by the local institutional review board, which also checked the quality of the dataset. Data were anonymized before analysis.

All women who underwent total vaginal hysterectomy with concurrent vaginal uterosacral ligament suspension were included in the analysis. Women with history of previous vault suspension and those with <6 months of follow up were excluded. Laparoscopic approach and women with previous hysterectomy were also excluded.

Women were classified in 2 groups according to the body mass index (BMI; calculated as weight [kg]/height [m²]): normal weight (BMI, 18.5—24.9 kg/m²) and either overweight (BMI, 25.0-29.9 kg/m²) or obese (BMI, ≥30.0 kg/m²).

We planned to assess the primary outcome in a subanalysis across all 3 BMI groups. Only the primary outcome was assessed in the subanalysis.

Primary and secondary outcomes were designed a priori. The primary outcome was the incidence of recurrent prolapse in any vaginal compartment (anterior, posterior, or apical). *Recurrent prolapse* was defined as prolapse that extended beyond the hymen with straining (pelvic organ prolapse quantification points Ba, C, Bp ≥0) or repeat treatment for prolapse with either pessary or surgery. The secondary outcomes were incidence of anterior prolapse, posterior prolapse, and apical prolapse. Incidence of multiple compartment prolapse, defined as a combination of recurrent prolapse in >1 compartment, was also assessed.

During this 5-year period, all total hysterectomies and uterosacral ligament suspensions were performed with a vaginal approach with the use of sutures

that were placed in the intermediate uterosacral ligament, at or above the ischial spine, and affixed to the vaginal apex as previously described by Shull et al.[12] In all the procedures, delayed absorbable sutures were used, with 2 sutures per side.

Statistical analysis was performed with Statistical Package for Social Sciences (SPSS) software (version 19.0; IBM Inc, Armonk, NY). Data were shown as means±standard deviation or as number (percentage). Categoric variables were compared with the use of the chi-square or Fisher's exact test. Continuous variables were compared with the use of Wilcoxon and Mann-Whitney tests for nonparametric data. Parametric analysis was assessed to test group means with standard deviation for parametric data. Probability values of <.05 was considered statistically significant. Logistic regression, presented as adjusted odds ratio (aOR) with the 95% of confidence interval (CI), was performed to correct data for those variables significantly different between the 2 groups.

Sample size calculations were assessed a priori and were based on previously published data.[6] We observed that with an α of .05 and 80% power, a sample size of approximately 360 women (120 normal-weight and 240 either overweight or obese women) was required to detect a 30% difference in the recurrence of prolapse.

The study was performed according to the strengthening the reporting of the observational studies in epidemiology (STROBE) guidelines.[13]

Results
Data for 360 women who underwent total vaginal hysterectomy with concurrent vaginal uterosacral ligament suspension with at least 6 months follow-up after surgery were analyzed (Figure). Table 1 shows the characteristics of the women who were included. Of the 360 women, 120 had normal weight (mean BMI, 22.1±1.2 kg/m²), and 240 were overweight or obese (mean BMI, 30.7±4.4 kg/m²). Compared with the overweight or obese group, the normal-weight cohort had less incidence of smoking (10.0% vs
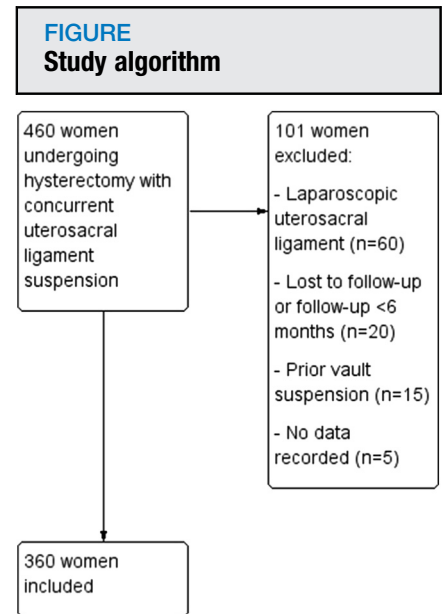
30.0%; P=.02) and constipation (27.5% vs 40.0%; P=.03). The follow-up interval was similar. Forty-two women in the normal-weight group and 79 in the overweight or obese group received a concomitant stress urinary incontinence procedure.[14] Regarding the intraoperative and postoperative complications, among the total cohort, there were 5 urinary tract injuries (1.4%; 2 cystotomies [0.6%] and 3 ureteral injuries [0.8%]). No women required blood transfusion. One women in the normal-weight group reported neuropathic pain 8 months after the procedure.

Regarding the primary outcome, the overall incidence of recurrent prolapse in any vaginal compartment (anterior, posterior, or apical) was 19.7% (71/360 women). The risk of recurrent prolapse in any vaginal compartment was similar in the normal-weight group compared with the overweight or obese group (16.7% vs 21.3%; P=.30). The risk of repeat surgery was 10.0% (36/360 women). The risk among normal-weight (10/120 women; 8.3%) was similar compared with the risk in the overweight or obese group (26/240 women; 10.8%; P=.11).

Table 2 shows the site of recurrences in both groups. The anterior compartment was the 1 compartment at most risk of recurrent prolapse. After adjusting for confounders that were proved statistically (ie, smoking and constipation), we found that women in the normal-weight cohort had a lower risk of recurrent anterior vaginal prolapse (10.8% vs 20.0%; aOR, 0.49; 95% CI, 0.25—0.94) and of multiple compartment prolapse (8.3% vs 14.6%; aOR, 0.53; 95% CI, 0.31—0.83); no differences were found in the risk of overall recurrence (16.7% vs 21.3%; aOR, 0.78; 95% CI, 0.49—1.25), apical (8.3% vs 9.6%; aOR, 0.87; 95% CI, 0.43—1.77), and posterior prolapse (5.8% vs 6.3%; aOR, 0.93; 95% CI, 0.39—2.23). Subanalysis across all 3 BMI cohorts showed no differences in the risk of recurrent prolapse in any vaginal compartment (anterior, posterior, or apical) comparing the normal-weight group (20/120 women; 16.7%) with the overweight (28/140 women; 20.0%) and the obese group (23/100 women; 23.0%; $P=.27$).

Comment

This retrospective cohort study showed that, with at least 6 months of follow up after total vaginal hysterectomy with concurrent vaginal uterosacral ligament suspension, the risk of recurrent vaginal prolapse was 20%, based on a composite outcome definition of any anatomic prolapse beyond the hymen or pessary or repeat surgery. The most common site of recurrence was the anterior compartment. The risk of recurrent surgery was 10%. Our study showed that women in the normal-weight group had similar risk of recurrent prolapse compared with the overweight or obese group. However, subgroup analyses showed that women with normal weight had a lower risk of anterior vaginal prolapse of approximately 51% compared with overweight or obese women.

Our study has several strengths. This is a large 5-year study. The number of the included women was very high. To our knowledge, no previous study on this issue is as large or comprehensive. Logistic regression was performed to correct data for those variables that

were significantly different between the 2 groups. Strengthening the reporting of the observational studies in

Epidemiology (STROBE) guidelines were followed strictly.[13] Subgroup analyses were established a priori. These are

TABLE 1
Characteristics of the included women

Variables	Normal-weight (n=120; 33.3%)	Overweight or obese (n=240; 66.7%)	P value
Body mass index group, n (%)			—
Normal weight	120 (100)	—	
Overweight	—	140 (58.3)	
Obese	—	100 (41.7)	
Mean body mass index, kg/m^2±SD	22.1±1.2	30.7±4.4	<.01[a]
Mean age, y±SD	69.1±5.7	69.5±11.4	.14[b]
Ethnicity, n (%)			.33[b]
White	115 (95.8)	236 (98.3)	
Non-white[c]	5 (4.2)	4 (1.7)	
Nulliparous, n (%)	37 (30.8)	70 (29.2)	.77[b]
Multiparous, n (%)	83 (69.2)	170 (70.8)	.77[b]
Current tobacco use, n (%)	12 (10.0)	72 (30.0)	.02[a]
Chronic hypertension, n (%)	15 (12.5)	31 (12.9)	.81[b]
Diabetes mellitus, n (%)	9 (7.5)	17 (7.1)	.69[b]
Constipation, n (%)	33 (27.5)	96 (40.0)	.03[a]
Pulmonary disease, n (%)	7 (5.8)	13 (5.4)	.90[b]
Previous pelvic organ prolapse surgery, n (%)	6 (5.0)	11 (4.6)	.77[b]
Preoperative pelvic organ prolapse quantification stage, n (%)			.22[b]
1	0	2 (0.8)	
2	42 (35.0)	80 (33.3)	
3	75 (62.5)	150 (62.5)	
4	3 (2.5)	8 (3.4)	
Concurrent anterior repair, n (%)	90 (75.0)	187 (77.9)	.12[b]
Concurrent posterior repair, n (%)	66 (55.0)	131 (54.6)	.34[b]
Concurrent stress urinary continence procedure, n (%)	42 (35.0)	79 (32.9)	.17[b]
Estimated blood loss, mL			.41[b]
Mean±SD	131 ± 77	121 ± 61	
Median (interquartile range)	100 (100—200)	100 (100—200)	
Operative time, min			.07[b]
Mean±SD	83.3±14.5	94.7±11.2	
Median (interquartile range)	85 (60—110)	91 (68—121)	
Median follow-up time, mo (interquartile range)	13 (7.5—25.5)	12 (8.0—28.0)	.94[b]

[a] Statistically significant; [b] Not significant; [c] Non-white ethnicity, including Hispanic, Asiatic, and Black African.

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TABLE 2
Primary and secondary outcomes

Site of recurrence	Normal-weight (n=120; 33.3%), n (%)	Overweight or obese (n=240; 66.7%), n (%)	P value
Overall recurrence[a]	20 (16.7)	51 (21.3)	.30[b]
Apical	10 (8.3)	23 (9.6)	.24[b]
Anterior	13 (10.8)	48 (20.0)	.03[c]
Posterior	7 (5.8)	15 (6.3)	.15[b]
Multiple compartment	10 (8.3)	35 (14.6)	.01[c]

Recurrent prolapse was defined as prolapse extending beyond the hymen with straining (pelvic organ prolapse quantification points Ba, C, Bp $\geq$0) or repeat treatment for prolapse with either pessary or surgery.

[a] Primary outcome; [b] Not significant; [c] Statistically significant.

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key elements that are needed to evaluate the reliability of a study.[15]

The most important limitation of our study is that this is a retrospective, nonrandomized comparison. We do acknowledge that the subgroup analysis was underpowered, which is a major weakness of this study; however, this is indeed an uncommon cohort of women. Our outcomes did not include an assessment of prolapse symptoms. No subjective outcomes were reported; anatomic findings and retreatment were used to define recurrent prolapse. All procedures were performed with the use of 2 delayed absorbable sutures per side; therefore, assessment of the risk of recurrent prolapse according to the type of sutures (eg, delayed absorbable vs permanent suture) or to the number of suture (eg, 1 per side, 2 per side, or another combination) was not feasible.

Edenfield et al[6] showed that, after uterosacral ligament suspension, normal-weight women had similar anterior prolapse recurrence compared with overweight or obese women. They found a nonsignificant reduction in the normal-weight group regarding the anterior compartment prolapse. However, their data probably did not reach statistical significance because of a type II error (number of women included, 219).[6] Conversely, Diez-Itza et al[9] showed an increased risk of anterior prolapse recurrence after vaginal surgery with increase bodyweight. Our findings add to the literature because previous studies did not investigate specifically total vaginal hysterectomy with concurrent vaginal uterosacral ligament suspension, included also women without hysterectomy, and the sample size were smaller.[6-11]

In conclusion, after uterosacral ligament suspension, overweight or obese women have a similar overall risk of prolapse recurrence but may be more prone to recurrence in the anterior wall compared with normal-weight women. ∎

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Received April 22, 2016; revised June 9, 2016; accepted June 13, 2016.

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