Published in final edited form as:

Obstet Gynecol. 2018 March ; 131(3): 475–483. doi:10.1097/AOG.0000000000002492.

Surgical Outcomes After Apical Repair for Vault Compared With Uterovaginal Prolapse

Rebecca G ROGERS, MD,

Albuquerque, New Mexico, University of New Mexico Department of Obstetrics and Gynecology and Austin, Texas, Department of Women's Health, Dell Medical School, University of Texas, Austin

Tracy L. NOLEN, DrPh,

Research Triangle Park, NC, RTI International

Alison C. WEIDNER, MD,

Durham, North Carolina, Department of Obstetrics and Gynecology, Duke University

Holly E RICHTER, PhD, MD,

Birmingham, Alabama, Department of Obstetrics and Gynecology, University of Alabama at Birmingham

J. Eric JELOVSEK, MD, MMed,

Cleveland, Ohio, Obstetrics, Gynecology & Women's Health Institute, Cleveland Clinic

Jonathan P SHEPHERD, MD, MSc,

Pittsburgh, Pennsylvania, Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh Medical Center

Heidi S HARVIE, MD,

Philadelphia, Pennsylvania, Department of Obstetrics and Gynecology, University of Pennsylvania

Linda BRUBAKER, MD, MS,

Maywood, Illinois, Departments of Obstetrics & Gynecology, and Urology Loyola University Chicago Stritch School of Medicine, and San Diego, California, Department of Obstetrics and Gynecology, University of California, San Diego

Shawn A. MENEFEY, MD,

San Diego, California, Department of Obstetrics and Gynecology, Kaiser Permanente

Deborah MYERS, MD,

Providence, Rhode Island, Department of Obstetrics and Gynecology, Brown University

Yvonne HSU, MD,

Corresponding author: Rebecca G Rogers, Dell Medical School, University of Texas, Austin, Department of Women's Health, 1501 Red River Street, Austin TX 78712; Phone: 505 272 9712; Rebecca.rogers@austin.utexas.edu.

Financial Disclosure: Rebecca G. Rogers has received royalties from UpToDate. Holly E. Richter has received a research grant from and been a consultant for Pelvalon. She has also received royalties from UpToDate. Linda Brubaker has received editorial revenue from UpToDate. Shawn A. Menefee has received royalties from UpToDate. Joseph I. Schaffer has received royalties from McGraw Hill, research funds from Boston Scientific, and has been a speaker for Astellas. The other authors did not report any potential conflicts of interest.

Presented at the annual meeting of the Society of Gynecologic Surgeons 2014, November 18, 2014, Orlando, Florida.

Salt Lake City, Utah, Department of Obstetrics and Gynecology, University of Utah

Joseph I SCHAFFER, MD,

Dallas Texas, Department of Obstetrics and Gynecology, University of Texas, Southwestern

Dennis WALLACE, PhD, and

Research Triangle Park, NC, RTI International

Susan F. MEIKLE, MD, MSPH

Northwest Texas Physician Group, Amarillo, TX, for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Pelvic Floor Disorders Network

Abstract

Objective—To retrospectively compare surgical success and complications between vaginal vault prolapse compared with uterovaginal prolapse in women who underwent apical prolapse repair for stage II–IV prolapse.

Methods—Women in one of three Pelvic Floor Disorders Network prolapse surgical trials were included. Absence of bothersome bulge symptoms, no prolapse beyond the hymen, and no subsequent prolapse treatment defined success and was our primary outcome. Secondary outcomes included comparison of quality of life measures, anatomical changes, and adverse events. Pelvic Organ Prolapse Quantification (POPQ) and quality-of-life measures were administered at baseline and 1–2 years postoperatively. Comparisons were controlled for study site, age, BMI, baseline POPQ, apical and anterior or posterior repair performed, and prior prolapse repair. Outcomes measured at multiple time points were analyzed using longitudinal models to assess whether differences existed across study follow-up.

Results—Four hundred and twenty-one women underwent vault prolapse (VP group) and 601 underwent uterovaginal prolapse apical repair. The VP group was older, more likely to be white, and to have prior urinary incontinence (UI) or prolapse repair, stage IV prolapse, and more prolapse bother on a validated scale (all $p < 0.034$). The VP group was more likely to undergo sacrocolpopexy (228/421 [54%] vs 93/601 [15%]); the UtVP group was more likely to undergo vaginal repair (508/601 [85%] vs 193/421 [46%] $p < 0.001$). There were no differences in success (OR 0.76 for vault prolapse vs. uterovaginal prolapse, 95% CI 0.51–1.15, $p = 0.20$), changes in Pelvic Organ Prolapse Distress Inventory (POPDI) scores (−79.4 vs −79.8, $p = 0.89$), postoperative POPQ point C measurements (−7.0 vs −7.1 cm, $p = 0.41$), or serious adverse events (86/421 [20%] vs 90/601 [15%], $p = 0.86$) between groups. Among women who received a vaginal approach for repair of vault prolapse ($N = 193$) or uterovaginal prolapse ($N = 508$), there was no differences in success rates (OR 0.67, 95% CI 0.43–1.04, $p = .09$) at 1–2 years postoperatively.

Conclusion—Surgical success of stage II–IV vault prolapse and uterovaginal prolapse apical repair was similar whether performed vaginally or abdominally at 1–2 years postoperatively.

Introduction

Over 225,000 surgeries for pelvic organ prolapse are performed annually in the US, and these include women with uterovaginal prolapse as well as post hysterectomy vault prolapse (1). Although the exact incidence of post-hysterectomy prolapse is unknown, estimates

ranged from 6–8% (2). In women planning to undergo surgery for apical pelvic organ prolapse, many surgeons elect to treat post-hysterectomy or vault prolapse differently than uterovaginal prolapse, believing that a previous hysterectomy increases both prolapse recurrence risk and adverse events. Adverse events are thought to be more common in vault prolapse than uterovaginal prolapse repairs secondary to scarring, loss of surgical landmarks and vaginal shortening related to the prior hysterectomy (3). On the other hand, many surgical trials for apical pelvic organ prolapse repair have included both women with uterovaginal prolapse and women with post-hysterectomy vault prolapse under the assumption that the surgical repairs are equally efficacious and risks are similar, limiting data available for clinicians to make evidenced based decisions regarding surgical approach (4, 5).

The objectives of this study were to compare outcomes (anatomical and functional) and adverse events between women undergoing surgical repair of uterovaginal prolapse (UtVP group) and women undergoing posthysterectomy vault prolapse (VP group). We hypothesized that surgical repair of women undergoing posthysterectomy vault prolapse results in increased risk of recurrence and of adverse events compared to women undergoing surgical repair of uterovaginal prolapse.

MATERIALS AND METHODS

A retrospective analysis was performed of women who participated in one of three Pelvic Floor Disorders' Network pelvic organ prolapse surgery trials: Operations and Pelvic Muscle Training in the Management of Apical Support Loss (OPTIMAL) (6), Colpopexy and Urinary Reduction Efforts (CARE) (7) or Outcomes following Vaginal Prolapse Repair and Midurethral Sling (OPUS) (8). All study sites had IRB approval and all women gave written informed consent. All participants underwent surgical correction of stage II–IV prolapse with apical repair by experienced pelvic surgeons at 17 study sites throughout the United States. We excluded patients who underwent transvaginal mesh procedures or colpocleisis and women whose only apical procedure was ligation of the peritoneal sac or trachelectomy. The cohort was divided into those women presenting with uterovaginal prolapse versus vault prolapse.

Women who underwent McCall's culdoplasty, sacrospinous ligament suspension, uterosacral ligament suspension, or ilioococcygeal repair were considered to have a vaginal apical suspension procedure. All women who underwent abdominal repair had an open sacral colpopexy with various mesh products as per study design. Vaginal approaches to repair of the anterior compartment including traditional anterior colporrhaphy and vaginal paravaginal repair; these approaches were grouped. Posterior repair included women who underwent traditional posterior colporrhaphy or perineorrhaphy. All women were followed for one year postoperatively and data were collected at 3, 6 and 12 months. For the CARE and OPTIMAL trials, data were also provided at 24 months after apical repair.

As determined previously in the three trials, success was defined as absence of all of the following: 1) bothersome bulge symptoms as measured by the Pelvic Floor Distress Inventory (PFDI) Question #5 (defined as a response of "Yes" to "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?", or "Not at all"

to “If yes, how much does it bother you”), 2) no prolapse beyond the hymen on Pelvic Organ Prolapse Quantification (POPQ) examination 3) no subsequent retreatment for prolapse. Women failing to meet any of these three were considered surgical failures. POPQ examinations and Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ) (9,10) and Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ-12) (11) measures were administered at baseline and each follow-up visit. Secondary efficacy endpoints include the calculated sub-scores for the PFDI, the POP Distress Inventory (POPDI), Urogenital Distress Inventory (UDI) and Colorectal Anal Distress Inventory (CRADI)) and the PFIQ, including the POP Impact Questionnaire (POPIQ), Urogenital Impact Questionnaire (UIQ) and Colorectal Anal Impact Questionnaire (CRAIQ) as well as the total PISQ-12 score. All surgical trials measured all these outcomes in a similar fashion with assessors who were masked to patient allocation in the parent trial.

Intraoperative and postoperative complications and serious adverse events (SAE) were recorded on standardized forms up to 6 weeks postoperatively and graded according to the Clavien-Dindo scale. The definition of a SAE for all studies included AEs that resulted in death, were life-threatening, required inpatient hospitalization (with the exception of hospitalization for stress incontinence surgery) or prolongation of existing hospitalization, resulted in persistent or significant disability or incapacity, resulted in a congenital anomaly/birth defect, or was another medically important condition. After 6 weeks, only SAEs were recorded and graded. Intraoperative and immediate postoperative complications up to 6 weeks postoperatively included blood transfusion, deep vein thrombosis, pulmonary embolus and surgical injuries including ureteral, bladder, urethral, bowel, vascular and nerve injuries.

We estimated that data from approximately 300 women who underwent vault prolapse repair and 600 women who underwent uterovaginal prolapse repair would be available for at least some follow-up visits. While longitudinal model-based approaches for analyses were planned, conservative estimates of power were calculated based on cross-sectional approaches at follow-up years 1 and 2. Based on the fact that at least 85% of the participants provided adequate data at one and two years to evaluate the primary outcome and the overall treatment success at one year was approximately 80%, we estimated that our sample size would provide over 90% power to detect any difference in our primary outcome as defined a priori to be 6% or greater. For the two year outcome, based on the finding that the overall treatment success at two years was approximately 60% for the vaginal surgery cohorts, the sample size provides over 90% power to detect a difference between the two groups of 10% or more in our primary outcome.

Participant baseline characteristics were compared between treatment groups using analysis of covariance or Kruskal-Wallis tests for continuous or interval measures, as appropriate,, Mantel-Haenszel mean score tests using modified ridit scores for ordinal categorical measures, and Cochran Mantel-Haenszel chi-square tests for general association for categorical measures. For outcomes obtained at multiple follow-up visits, proportion of participants considered a treatment success and change from baseline in QOL scores, analyses were conducted using extensions of generalized linear models with generalized estimating equations using empirical variance estimates to account for multiple time points

and longitudinal mixed effects models, respectively. These models included adjustments for center where possible as well as age, BMI, baseline POPQ stage, apical repair procedure performed, prior prolapse repair and performance of a concurrent anterior and posterior repair. Additionally, models for QOL scores controlled for the corresponding baseline QOL score. Interval estimates and p-values for these outcomes were obtained using contrast statements for assessing whether differences existed for the two groups across study follow-up and at each time point. Due to low rates of occurrence of specific complications, the percent of subjects experiencing those complications during the perioperative and six week postoperative period were compared between treatment groups using a Fisher's exact test without adjustments. Only the difference in the primary outcome at one-year was considered to be a formal hypothesis test and all other p-values are considered descriptive and hypothesis generating, so no formal adjustments were made for multiple testing. However, p-values should be interpreted cautiously given the number of comparisons presented.

Results

The methods and results of CARE, OPUS and OPTIMAL have been previously published (6-8). For the current analyses, 1022 women met inclusion criteria; 421 underwent vault prolapse and 601 uterovaginal prolapse repair. In the UtVP group, 585 (97%) of women underwent hysterectomy with or without oophorectomy. We included 321 women from CARE, 365 from OPTIMAL and 336 from OPUS. (Figure 1) By definition, no woman in the VP group underwent hysterectomy, but 85 (20%) underwent oophorectomy at the time of prolapse repair. The VP cohort was older ($p<0.001$), more likely to be white ($p<0.001$) and had lower mean BMIs ($p=0.034$). In addition, the VP group was more likely to have undergone prior UI or prolapse repair, had more advanced prolapse and reported more bother from their prolapse as measured by baseline POPDI scores when compared to the UtVP group (TABLES 1 and 2).

Surgical approaches varied between the VP and UtVP groups, depending on the protocol to which the patient was enrolled. The VP group was more likely to undergo sacrocolpopexy (54 vs 15%) while the UtVP group was more likely to undergo vaginal apical suspension (85 vs 46%), $p<0.001$. Women in the VP group were less likely to undergo anterior repair (45 vs 52%, $p<0.001$), but were equally likely to undergo posterior repair (43 vs 41%, $p=0.45$) as the UtVP group. Similarly, women in the VP group were more likely to undergo Burch retropubic urethropexy while women in the UtVP group were more likely to undergo a retropubic midurethral sling procedure, as a result of the parent study designs (TABLE 3).

Although success rates declined over time, we found no evidence of differences between the VP and UtVP groups after adjusting for differences between groups in baseline characteristics and surgical interventions performed. Similarly, results for points Bp, C, and bothersome bulge symptoms showed no differences between groups beyond the three-month timepoint. Point Ba was better supported in the UtVP group overall, but the difference of 0.4 cm was small. Few women in either group underwent retreatment for prolapse and most women in both groups had support of their prolapse above the hymen at 1–2 years postoperatively (TABLE 4). In order to more fully explore changes in pelvic floor function and quality of life, we compared change scores in PFDI and PFIQ subscales between groups

over time. Subscale scores did not vary between groups over time. Among women who reported sexual function, no difference was observed between groups (TABLE 5).

Because of the large differences in surgical approach between the two groups, we performed a sub-analysis of women who underwent apical repair only with a vaginal approach. For these analyses, 701 women were included; 193 underwent vault prolapse repair, and 508 underwent uterovaginal prolapse repair. Again, no differences in success rates were observed; few women underwent retreatment and most women reported absence of bothersome bulge symptoms and had support above the hymen at 1–2 years after surgery (Appendix 2, available online at <http://links.lww.com/xxx>).

Adverse events were rare and did not vary between groups (Appendixes 3 and 4, available online at <http://links.lww.com/xxx>).

Discussion

Data obtained from three large surgical trials performed in the Pelvic Floor Disorders Network provided us with a unique opportunity to compare outcomes in two cohorts of women undergoing apical prolapse surgery commonly encountered in clinical practice: women who had previously undergone a hysterectomy and those with uterovaginal prolapse. Using a multi-component outcome measure consisting of anatomic, symptom-specific distress and retreatment, we found no difference in success rates between groups at 1–2 years postoperatively. Similarly, when comparing surgical success in women undergoing a vaginal approach for these two conditions, no differences were noted in success rates. Furthermore, no significant differences were noted between groups in adverse events or serious adverse events reported including blood transfusion, cystotomy, deep vein thrombosis, pulmonary embolism, or visceral injuries between VP and UtVP groups. This is a robust comparison of surgical treatment outcomes between women undergoing vault prolapse versus uterovaginal prolapse repair. It provides reassurance to women who develop prolapse after hysterectomy that surgical interventions are likely to result in similar outcomes compared to women who undergo a hysterectomy as part of their prolapse repair. Our findings support that the outcomes after apical repair post-hysterectomy prolapse are not different from repair of uterovaginal prolapse repair in the hands of experienced surgeons 1–2 years postoperatively.

Post- vaginal vault prolapse repair has been thought to be a more difficult repair in a survey of pelvic surgeons (3). Direct comparisons of prolapse repair in women with vault and uterovaginal prolapse are lacking. Increasingly, pelvic reconstructive surgeons have recognized that suspension of the vaginal apex is critically important in optimizing overall vaginal prolapse treatment outcomes (12–15). Until now, very little was known about the differences in outcomes between women with uterovaginal prolapse and vault prolapse, particularly in regard to the success of repair and adverse events, to help guide these choices.

While not the primary focus of this investigation, the question of the optimal apical approach (abdominal versus transvaginal) for vault prolapse or uterovaginal prolapse is controversial and continues to evolve. Our study included women enrolled in three surgical trials, all of

which explored techniques of apical repair in the presence or absence of the uterus (6–8). In order to further explore whether sacrocolpopexy with graft significantly influenced our conclusions, a sensitivity analysis was performed of those women who underwent apical repair with a transvaginal approach only, excluding sacrocolpopexy patients. This analysis found that success and adverse event rates were similar to those reported for the entire cohort which further supports our conclusions.

The strengths of our study are the large, diverse and well-characterized patient population with standardized surgical interventions, outcome measures and adverse events. This is particularly important as women often weigh the risks of adverse events against the possible success of surgery when making decisions to undergo elective surgery. Limitations include the inherent risk of systematic bias of any retrospective analysis; surgical approach for an individual woman was guided by the protocol into which she was enrolled. In addition, our comparison focused on a comparison of vault versus uterovaginal prolapse repairs, and outcomes may have been influenced by surgeon experience, length of different surgical approaches, and performance of concomitant procedures, although these cases were performed by experienced surgeons and surgical approach was standardized between study sites. Most women enrolled in these trials were Caucasian which limits generalizability to other ethnicities. Our patient population differed significantly between groups, and although we controlled for baseline differences, there could still be significant biases that remain unmeasured including that the surgical intervention would be influenced by these baseline differences. We also did not correct for multiple comparisons. Other limitations include that the majority of women underwent vaginal approach to their repair, regardless of whether or not a uterus was present. These analyses did not directly compare abdominal versus vaginal approaches to repair, which is of clinical interest to the practicing gynecologist. Finally, there was attrition over time in all cohorts and we cannot account for the women who did not give data at all timepoints, and our study only includes outcomes up to 2 years after surgery, and many recurrences of prolapse occur outside of this timeframe. Although not a limitation of the study, these data do not inform the decision for women with uterovaginal prolapse whether or not a hysterectomy or uterine sparing procedure should be performed.

In summary, we found that neither prolapse success rates, quality of life, symptom scales nor adverse events varied between women undergoing vaginal vault or uterovaginal apical prolapse repair.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Supported by grants from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (2U01HD41249, 2U10 HD41250, 2U10 HD41261, 2U10 HD41267, 1U10 HD54136, 1U10 HD54214, 1U10 HD54215, 1U10 HD54241, U10 HD069013, U10 HD069025, U10 HD069010, U10 HD069010, and U01 HD069031) and the National Institutes of Health Office of Research on Women's Health.

For a list of acknowledgments pertaining to this study, see Appendix 1 online at <http://links.lww.com/xxx>.

References

1. Boyles SH, Weber AM, Meyn L. Procedures for pelvic organ prolapse in the United States, 1979-1997. *Am J Obstet Gynecol.* 2003; 188(1):108–15. [PubMed: 12548203]
2. Aigmueller T, Dungal A, Hinterholzer S, Geiss I, Riss P. An estimation of the frequency of surgery for posthysterectomy vault prolapse. In *J Urogynecol.* 2010; 2:299–302.
3. Yune JJ, Siddighi S. Perceptions and practice patterns of general gynecologists regarding urogynecology and pelvic reconstructive surgery. *Female Pelvic Med Reconstr Surg.* 2013; 19:225–9. [PubMed: 23797522]
4. Maher CF, Qatawneh AM, Dwyer PL, et al. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. *Am J Obstet Gynecol.* 2004; 190:20–26. [PubMed: 14749629]
5. Walters MD, Ridgeway BM. Surgical treatment of vaginal apex prolapse. *Obstet Gynecol.* 2013; 121(2):354–374. [PubMed: 23344287]
6. Barber MD, Brubaker L, Burgio KL, et al. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. *JAMA.* 2014; 311:1023–34. [PubMed: 24618964]
7. Brubaker L, Cundiff GW, Fine P, Nygaard I, Richter HE, Visco AG, Zyczynski H, Brown MB, Weber AM, Pelvic Floor Disorders Network. Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. *N Engl J Med.* 2006; 354:1557–1566. [PubMed: 16611949]
8. Wei JT, Nygaard I, Richter H, Nager CW, Barber MD, Kenton K, Amundsen CL, Schaffer J, Meikle SF, Spino C. A midurethral sling to reduce incontinence after vaginal prolapse repair. *NEJM.* 2012; 366(25):2358–2367. [PubMed: 22716974]
9. Barber MD. Symptoms and outcome measures of pelvic organ prolapse. *Clinical Obstetrics and Gynecology.* 2005; 48(3):648–661. [PubMed: 16012232]
10. Bump RC, Mattiasson A, Bo K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol.* 1996; 175(1):10–7. [PubMed: 8694033]
11. Rogers RG, Coates KW, Kammerer-Doak D, Khalsa S, Qualls C. A short form of the pelvic organ prolapse urinary incontinence sexual questionnaire (PISQ-12). *Int Urogynecol J Pelvic Floor Dys.* 2003; 14(3):164–8.
12. DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. *Am J Obstet Gynecol.* 1992; 166:1717–1724. [PubMed: 1615980]
13. Summers A, Winkel LA, Kussain H, DeLancey JOL. The relationship between anterior and apical compartment support. *Am J Obstet Gynecol.* 2006; 194:1438–1443. [PubMed: 16579933]
14. Brubaker, L., Bump, RC., Fynes, M., et al. Surgery for pelvic organ prolapse. In: Abrams, P.Cardozo, L.Khoury, S., Wein, A., editors. *International Consultation on Incontinence.* 3rd. Paris: Health Publication Ltd; 2005.
15. Eilber KS, Alperin M, Khan A, Wu N, Pashos CL, Clemens JQ, Anger JT. Outcomes of vaginal prolapse surgery among female medicare beneficiaries: The Role of apical support. *Obstet Gynecol.* 2013; 122(5):981–7. [PubMed: 24104778]

Figure 1.

Outline of participants. CARE, Colpopexy and Urinary Reduction Efforts; OPUS, Outcomes following Vaginal Prolapse Repair and Midurethral Sling; OPTIMAL, Operations and Pelvic Muscle Training in the Management of Apical Support Loss. *Of the 140 excluded participants, CARE: 1, OPUS: 130, and OPTIMAL: 9.

Table I

Baseline Characteristics

Characteristic	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	P-value*
Age at surgery, mean years $\pm$ SD [†]	63.9 $\pm$ 9.0	57.5 $\pm$ 10.4	<.001
Race(%)			
Black/African American	23 (5)	35 (6)	<.001
White	390 (93)	512 (85)	
Other	8 (2)	52 (9)	
Unknown	0	2 (0)	
Ethnicity(%)			
Hispanic/Latina	19 (5)	117 (19)	<.001
Not Hispanic/Latina	402 (95)	484 (81)	
Insurance(%)			
Medicaid/Medicare	81 (19)	142 (24)	0.206
Private/Health Maintenance Organization	332 (79)	443 (74)	
Self-Pay	5 (1)	13 (2)	
Other	3 (1)	3 (0)	
Vaginal deliveries, Median $\pm$ IQR [‡]	3 $\pm$ 2	3 $\pm$ 2	0.215
Caesarean delivery(%)	23 (5)	52 (9)	0.055
Post-Menopausal(%)	396 (94)	411 (68)	<.001
Currently using estrogen replacement therapy(%)	233 (55)	127 (21)	<.001
Current smoker(%)	25 (6)	49 (8)	0.179
Diabetes Mellitus(%)	40 (10)	60 (10)	0.780
BMI [‡] (mean kg/m ² $\pm$ SD [‡])	27.5 $\pm$ 4.9	28.2 $\pm$ 5.4	0.034
Cardiac impairment(%)	75 (18)	83 (14)	0.075
Sexually active (%)	197 (47)	290 (48)	0.286

* P-values based on comparing characteristics between groups while excluding responses of unknown

[†] SD; Standard Deviation, IQR: Interquartile Range

[‡] BMI ; Body mass Index

Table II**Baseline Prolapse and Quality of Life Characteristics**

Characteristic	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	P-value*
Prior urinary incontinence surgery(%)	40 (10)	5 (1)	<.001
Prior Prolapse surgery(%)	176 (42)	7 (1)	<.001
POPQ stage			<.001
II	95 (23)	176 (29)	
III	261 (62)	390 (65)	
IV	64 (15)	35 (6)	
POPQ Ba, cm, Median (IQR) [†]	3 (4)	2(2)	0.009
POPQ C, cm, Median (IQR) [†]	-2(8)	0 (6)	0.021
Missing, n	2	1	
POPQ BP, cm, Median +/- IQR [†]	0 (5)	-1 (2)	<.001
SF36 Physical component score, Mean +/- SD [†]	44.2 +/- 9.9	46.2 +/- 9.7	0.001
Missing, n	23	22	
UDI [‡] , Mean +/-SD [†]	80.9+/-55.5	82.9 +/-58.9	0.591
Missing, n	11	30	
POPDI [§] , Mean+/-SD [†]	119.9+/-70.8	100.4+/-63.6	<.001
Missing, n	10	31	
CRADI , Mean+/-SD [†]	87.2 +/-76.0	75.3 +/-75.2	0.016
Missing, n	14	32	
UIQ [¶] , Mean +/-SD [†]	78.0 +/-79.9	88.7 +/-94.4	0.063
Missing, n	13	35	
POPIQ [#] , Mean +/-SD [†]	60.5 +/-77.0	75.7 +/-94.1	0.008
Missing, n	13	33	
CRAIQ ^{**} , Mean +/-SD [†]	46.8 +/-70.1	44.7 +/-77.3	0.647
Missing, n	13	35	
	N =196	N =293	
PISQ-12 ^{††} , Mean +/- SD [†]	33.2 +/-7.3	32.8 +/-7.1	0.546
Missing, n			

* P-values based on comparing characteristics between groups while excluding responses of unknown, using ANOVA for measures with mean and Kruskal-Wallis test for measures with median given

[†] SD, Standard Deviation, IQR: Interquartile Range

[‡] Urinary Distress Inventory

[§] Pelvic Organ Prolapse Distress Inventory

^{||} Colorectal Anal Distress Inventory

[¶]Urinary Incontinence Impact Questionnaire

[#]Pelvic Organ Prolapse Impact Questionnaire

^{**}Colorectal Anal Impact Questionnaire

^{††}Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire cm, centimeter

If no values presented for missing, all 1022 participants had measures.

Table III**Surgical procedures**

Surgical Procedure	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	P-value *
Apex repair (%)			<.001
Sacrocolpopexy	228 (54)	93 (15)	
Illiococcygeal, McCall's culdoplasty, sacrospinous ligament or uterosacral ligament suspension	193 (46)	508 (85)	
Anterior Compartment Repair Procedures (%)			0.001
Anterior colporrhaphy with/without Paravaginal repair vaginal approach	155 (37)	287 (48)	
Paravaginal repair abdominal approach	33 (8)	26 (4)	
None of the above	233 (55)	288 (48)	
Posterior colporrhaphy and/or Perineorrhaphy (%)	183 (43)	247 (41)	0.450
Incontinence procedures (%)			<0.01
Burch	108 (26)	46 (8)	
Retropubic Midurethral Sling	148 (35)	378 (63)	
Anesthesia type (%)			0.842
General with/without regional	413 (98)	589 (98)	
Regional only	7 (2)	11 (2)	
Operating time, Mean +/- SD [†]	145.6 +/- 53.1	167.7 +/- 52.7	<.001

* P-values based on comparing characteristics between groups while excluding responses of unknown

[†] SD Standard Deviation

Table IV

Anatomical and functional outcomes at 3, 6, 12 and 24 months after surgery

Outcome	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	Adjusted difference or odds ratio(95% CI) ^{*,†}	Raw P-value [‡]	Adjusted P-value [§]
POPQ Ba (mean cm) Overall	-1.39	-1.60	0.20 (0.01,0.39)	0.005	0.041
Month 3	-1.59	-1.94	0.34 (0.12,0.57)	0.217	0.003
Month 6	-1.49	-1.67	0.18 (-0.10,0.46)	0.202	0.208
Month 12	-1.26	-1.43	0.17 (-0.04,0.38)	0.002	0.106
Month 24	-1.24	-1.35	0.11 (-0.12,0.34)	0.001	0.349
POPQ C (mean cm) Overall	-6.98	-7.11	0.13 (-0.18,0.44)	<.001	0.408
Month 3	-7.10	-7.26	0.16 (-0.25,0.57)	<.001	0.438
Month 6	-7.22	-7.41	0.18 (-0.38,0.75)	0.149	0.524
Month 12	-6.83	-6.93	0.10 (-0.26,0.46)	<.001	0.594
Month 24	-6.76	-6.84	0.08 (-0.35,0.51)	<.001	0.723
POPQ Bp (mean cm) Overall	-2.16	-2.21	0.05 (-0.10,0.19)	0.023	0.528
Month 3	-2.27	-2.35	0.08 (-0.11,0.26)	0.266	0.409
Month 6	-2.27	-2.26	-0.01 (-0.26,0.24)	0.086	0.941
Month 12	-2.07	-2.17	0.11 (-0.06,0.27)	0.275	0.196
Month 24	-2.04	-2.05	0.01 (-0.18,0.20)	0.044	0.914
Absence of bothersome bulge: n (%) Overall			0.53 (0.27,1.05)	0.537	0.077
Month 3	305/311 (98)	314/317 (99)	0.18 (0.04,0.89)	0.206	0.037
Month 6	80/86 (93)	229/244 (94)	0.57 (0.21,1.53)	0.841	0.334
Month 12	379/397 (95)	495/544 (91)	0.99 (0.51,1.91)	0.004	0.968
Month 24	271/288 (94)	269/303 (89)	0.78 (0.37,1.62)	0.021	0.515
Support above hymen: n (%) Overall			0.83 (0.53,1.29)	0.128	0.406
Month 3	294/310 (95)	285/313 (91)	0.91 (0.45,1.82)	0.142	0.781
Month 6	77/88 (88)	220/240 (92)	0.65 (0.30,1.40)	0.673	0.303
Month 12	333/376 (89)	439/527 (83)	0.94 (0.58,1.52)	0.027	0.793
Month 24	239/260 (92)	254/292 (87)	0.85 (0.45,1.61)	0.134	0.637
No report of retreatment: n (%)					

Outcome	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	Adjusted difference or odds ratio(95% CI) [†]	Raw P-value [‡]	Adjusted P-value [§]
Month 3	323/324 (100)	327/328 (100)		Not Estimated	
Month 6	92/92 (100)	250/252 (99)		Not Estimated	
Month 12	409/417 (98)	566/576 (98)		Not Estimated	
Month 24	313/321 (98)	331/348 (95)		Not Estimated	
Overall Success: n (%)			0.76 (0.51,1.15)	0.054	0.202
Month 3	280/300 (93)	273/303 (90)	0.79 (0.42,1.50)	0.209	0.477
Month 6	69/83 (83)	196/228 (86)	0.65 (0.34,1.25)	0.936	0.232
Month 12	310/369 (84)	395/512 (77)	0.86 (0.56,1.33)	0.009	0.503
Month 24	214/281 (85)	214/252 (76)	0.76 (0.45,1.28)	0.033	0.311

* CI Confidence interval

[†] For continuous outcomes, adjusted means and differences are presented based on repeated measure mixed models adjusting for center where possible as well as apical surgical type, occurrence of anterior or posterior surgeries, prior POP surgery, age, BMI and POP-q stage. For binary outcomes, proportions and adjusted odds ratios of vault vs. uterovaginal prolapse are presented based on subjects with available data at the visit.

[‡] Raw p-values based on analyses with no adjustments.

[§] Adjusted p-values based on repeated measure mixed models adjusting for center where possible as well as apical surgical type, occurrence of anterior or posterior surgeries, prior POP surgery, age, BMI and POP-q stage. Note that the p-values included in this table are considered to be descriptive, not inferential and should be interpreted cautiously given the number of comparisons, as 3 to 4 p-values of 0.05 or less would be expected simply by chance.

Table V

Quality of life and symptom distress outcome results

Outcome	Statistic/ Category	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	Adjusted difference or odds ratio(95% CI) [†]	Raw P-value [‡]	Adjusted P-value [‡]
UDI [§]	Overall	-59.38	-59.51	0.12 (-5.17,5.42)	0.471	0.963
	Month 3	-56.15	-59.69	3.53 (-2.65,9.72)	0.229	0.262
	Month 6	-64.35	-62.32	-2.04 (-9.80,5.72)	0.923	0.607
	Month 12	-60.96	-61.38	0.42 (-5.26,6.10)	0.405	0.885
POPDI	Month 24	-56.05	-54.64	-1.42 (-7.66,4.83)	0.461	0.656
	Overall	-79.35	-79.78	0.43 (-5.90,6.76)	<0.001	0.894
	Month 3	-78.85	-84.17	5.32 (-2.21,12.86)	0.003	0.166
	Month 6	-81.30	-80.87	-0.44 (-10.13,9.25)	0.002	0.930
CRADI [¶]	Month 12	-80.43	-81.82	1.39 (-5.48,8.26)	<0.001	0.692
	Month 24	-76.80	-72.25	-4.54 (-12.22,3.13)	<0.001	0.245
	Overall	-46.60	-48.16	1.56 (-4.85,7.98)	0.081	0.633
	Month 3	-44.39	-50.77	6.38 (-1.47,14.24)	0.353	0.111
UIQ [#]	Month 6	-51.86	-51.59	-0.27 (-10.52,9.99)	0.121	0.959
	Month 12	-48.53	-49.32	0.79 (-6.28,7.86)	0.092	0.826
	Month 24	-41.62	-40.97	-0.66 (-8.65,7.33)	0.108	0.872
	Overall	-56.29	-54.56	-1.73 (-9.98,6.52)	0.021	0.681
POPIQ ^{**}	Month 3	-50.13	-52.43	2.30 (-7.27,11.88)	0.010	0.637
	Month 6	-59.05	-58.73	-0.32 (-12.19,11.54)	0.093	0.957
	Month 12	-60.88	-58.48	-2.41 (-11.22,6.40)	0.031	0.592
	Month 24	-55.11	-48.62	-6.49 (-16.12,3.15)	0.083	0.187
POPIQ ^{**}	Overall	-50.93	-54.72	3.78 (-2.92,10.49)	0.002	0.268
	Month 3	-51.34	-54.20	2.85 (-5.18,10.89)	0.013	0.486
	Month 6	-48.04	-59.98	11.94 (1.64,22.25)	0.001	0.023
	Month 12	-56.40	-56.28	-0.11 (-7.41,7.18)	0.025	0.976
	Month 24	-47.96	-48.41	0.45 (-7.68,8.58)	0.013	0.914

Outcome	Statistic/ Category	Vault Prolapse (N=421)	Uterovaginal Prolapse (N=601)	Adjusted difference or odds ratio(95% CI) [†]	Raw P-value [‡]	Adjusted P-value [‡]
CRAIQ ^{††}	Overall	-31.28	-28.44	-2.84 (-9.37,3.69)	0.438	0.394
	Month 3	-26.08	-28.93	2.85 (-5.26,10.96)	0.749	0.490
	Month 6	-43.37	-33.85	-9.52 (-20.18,1.15)	0.055	0.080
	Month 12	-33.71	-31.49	-2.22 (-9.47,5.03)	0.632	0.548
	Month 24	-21.95	-19.49	-2.47 (-10.67,5.74)	0.871	0.556
PISQ 12 ^{‡‡}	Overall	4.76	3.98	0.77 (-0.33,1.88)	0.633	0.170
	Month 3	4.47	3.72	0.75 (-0.61,2.12)	0.619	0.280
	Month 6	5.91	4.25	1.66 (-0.11,3.43)	0.377	0.066
	Month 12	4.57	4.35	0.23 (-0.97,1.42)	0.155	0.712
	Month 24	4.08	3.63	0.45 (-0.91,1.81)	0.321	0.517

* CI Confidence Interval

[†] For continuous outcomes, adjusted means and differences are presented based on repeated measure mixed models adjusting for center where possible as well as baseline score for the QOL measure of interest, apical surgical type, occurrence of anterior or posterior surgeries, prior POP surgery, age, BMI and POP-q stage.

[‡] Raw p-values based on analyses with no adjustments. Adjusted p-values based on repeated measure mixed models adjusting for center where possible as well as baseline score for the QOL measure of interest, apical surgical type, occurrence of anterior or posterior surgeries, prior POP surgery, age, BMI and POP-q stage Note that the p-values included in this table are considered to be descriptive, not inferential and should be interpreted cautiously given the number of comparisons, as 3 to 4 p-values of 0.05 or less would be expected simply by chance.

[§] Urinary Distress Inventory Urinary Distress Inventory (UDI) (0–300) with higher scores indicating greater symptom bother.

^{||} Pelvic Organ Prolapse Distress Inventory Pelvic Organ Prolapse Distress Inventory (PODDI) (0–300), with higher scores indicating greater symptom bother.

[¶] Colorectal Anal Distress Inventory Patient reported outcome scale ranges Colorectal-anal Distress Inventory (CRADI) (0–400) with higher scores indicating greater symptom bother.

[#] Urinary Incontinence Impact Questionnaire - total scores ranging from 0 to 400; higher scores represent greater quality of life impact

^{**} Pelvic Organ Prolapse Impact Questionnaire - total scores ranging from 0 to 400; higher scores represent greater quality of life impact

^{††} Colorectal Anal Impact Questionnaire-total scores ranging from 0 to 400; higher scores represent greater quality of life impact

^{‡‡} Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire -12 PISQ-12 scores range from 0–48. Higher scores represent better sexual function