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COMPARATIVE ESTIMATES OF LONG-TERM EFFECTIVENESS OF TRANSVAGINAL UTEROSACRAL COLPOPEXY VERSUS MINIMALLY INVASIVE SACRAL COLPOPEXY FOR THE TREATMENT OF PELVIC ORGAN PROLAPSE

Hypothesis / aims of study: To compare the estimated long-term rates of recurrent pelvic organ prolapse (POP) between patients who underwent transvaginal uterosacral colpopexy (UC), laparoscopic sacral colpopexy (LSC), and robotic-assisted laparoscopic sacral colpopexy (RASC).

Study design, materials and methods:
All women who underwent UC, LSC, or RASC for treatment of POP between 2006 and 2012 at a single tertiary care center were identified using *Current Procedural Terminology* codes for intraperitoneal (57283) and sacral (57425) colpopexy. Sacral colpopexy was performed with or without hysterectomy whereas all subjects in the UC cohort underwent concomitant hysterectomy. Subjects were included if they underwent concomitant POP repair or anti-incontinence procedures and were excluded for non-gynecologic procedures. The system-wide electronic medical record was queried for baseline patient characteristics, intra- and postoperative data. Follow-up was defined as the last visit each subject was evaluated. The primary outcome was defined as recurrent POP using a composite definition: symptomatic vaginal bulge, any prolapse to or beyond the hymen, or any retreatment (reoperation or pessary) for POP. Kaplan-Meier survival curves were generated. Parametric survival models were used to control for baseline risk factors significant on univariate analysis or those likely to contribute to our outcomes (age, vaginal parity, previous POP surgery, POPQ C point, and concomitant posterior colporrhaphy) in order to estimate recurrence rates for each group using the composite and each individual definition of recurrent POP over a 6-year period.

Results:
1,266 subjects met inclusion criteria including 868 UC, 256 LSC, and 142 RASC. Follow-up ranged from 0 to 91 months [UC median 6.2 (range 0.2-90.5), LSC 5.8 (0.2-70.9), RASC 5.8 (0-63.9) months]. By year 6 (Table 1), the estimated composite recurrence rates for the UC, LSC and RASC groups were 41%, 52%, and 60%, respectively [treatment difference (95%CI) between UC and LSC =11% (5.9,16), UC and RASC = 19% (13,25), and LSC and RASC = 8.4% (6.9,9)]. Rates of symptomatic bulge were 34%, 48%, and 54% [treatment difference between UC and LSC = 15% (9.4,19.9), UC and RASC = 21% (13,27), and LSC and RASC = 5.7% (3.8,6.9)]. Rates of POP to or beyond the hymen were 32%, 12%, and 24% [treatment difference between UC and LSC = -20% (-20,-14), UC and RASC = -8.2% (-14,3.4) and LSC and RASC = 12% (5.9,18)]. Rates of retreatment for POP were 12%, 7.7%, and 40.8% [treatment difference between UC and LSC = -4.5% (-4.9,5.9), UC and RASC = 29% (10,56), and LSC and RASC = 33% (15,50)]. Survival curves for composite recurrence are shown in Figure 1.

Figure 1. Survival curves for the composite definition of recurrent pelvic organ prolapse up to 6 years after transvaginal uterosacral colpopexy and minimally invasive sacral colpopexy

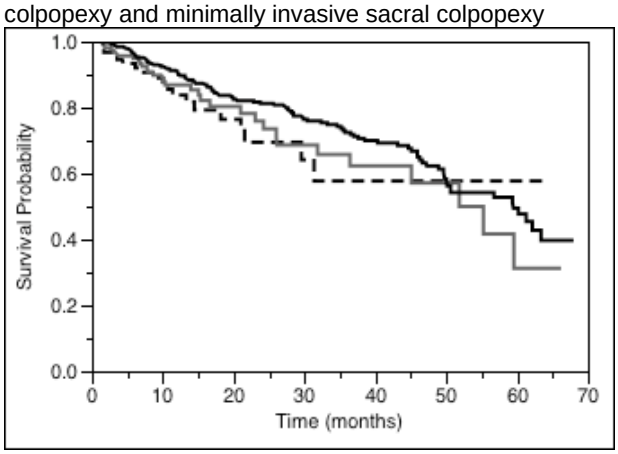

Table 1. Estimated probability of recurrent POP after transvaginal colpopexy and minimally invasive sacral colpopexy using composite and individual definitions*

Recurrent POP Definition		UC % (95%CI)	LSC % (95%CI)	RASC % (95%CI)
Bulge Symptoms	1 Year	5.6 (3.8,8.1)	11.5 (6.8,18.0)	14.5 (8.3,23.1)
	2 Years	12.8 (9.4,16.9)	22.6 (14.9,32.2)	27.1 (17.3,39.0)
	3 Years	19.1 (14.6,24.4)	31.3 (21.6,42.4)	36.4 (24.7,49.7)
	4 Years	24.6 (19.2,30.8)	38.2 (27.3,50.1)	43.7 (30.7,57.4)
	5 Years	29.4 (23.2,36.2)	43.8 (32.1,56.1)	49.4 (35.7,63.2)
	6 Years	33.6 (26.8, 41.0)	48.5 (36.2,60.9)	54.1 (40.0,67.7)
Prolapse Beyond Hymen	1 Year	4.1 (2.5,6.4)	0.7 (0.2,2.7)	2.4 (0.6,7.2)
	2 Years	10.6 (7.4,14.8)	2.6 (0.7,7.6)	6.8 (2.2,16.8)
	3 Years	16.9 (12.3,22.5)	4.9 (1.5,12.6)	11.5 (4.2,25.3)
	4 Years	22.7 (16.9,29.3)	7.3 (2.5,17.5)	16.0 (6.3, 32.5)
	5 Years	27.8 (21.1,35.3)	9.8 (3.5,22.0)	20.2 (8.4,38.6)

	6 Years	32.3 (24.8,40.5)	12.3 (4.6,26.2)	24.1 (10.5,43.9)
Retreatment	1 Year	0.7 (0.3,1.6)	0.4 (0.1,1.8)	2.8 (1.0,7.3)
	2 Years	2.1 (1.1,4.1)	1.3 (0.3,5.0)	8.4 (3.3,20.2)
	3 Years	4.1 (2.3,7.3)	2.5 (0.7,9.4)	15.6 (6.3,35.8)
	4 Years	6.5 (3.7,11.2)	4.0 (1.1,14.6)	23.7 (9.6,51.5)
	5 Years	9.2 (5.3,15.7)	5.7 (1.5,20.4)	32.3 (13.2,65.6)
	6 Years	12.2 (7.0,20.8)	7.7 (2.0,26.7)	40.8 (17.0,77.1)
Composite	1 Year	6.9 (4.8,9.6)	11.4 (6.8,17.8)	16.1 (9.5,25.0)
	2 Years	15.9 (12.1,20.3)	23.6 (15.7,33.2)	30.6 (20.3,42.7)
	3 Years	23.7 (18.8,29.3)	33.2 (23.4,44.3)	41.2 (29.1,54.3)
	4 Years	30.4 (24.5,36.8)	40.8 (29.8,52.5)	49.2 (36.1,62.4)
	5 Years	36.1 (29.5,43.0)	46.9 (35.2,58.9)	55.4 (41.8,68.4)
	6 Years	40.9 (33.9,48.3)	52.0 (39.8,64.0)	60.4 (46.7,73.0)

*Rates adjusted using survival models to control for age, vaginal parity, previous POP surgery, POPQ C point, and concomitant posterior colporrhaphy

Interpretation of results:

Real-world comparisons between surgical techniques for POP are difficult to perform in randomized controlled trials (RCTs) due to surgeon proficiency in one technique and approach preference. Moreover, RCTs for prolapse surgery rarely follow patients beyond 1-2 years. This observational comparative effectiveness study is the largest study to date that compares these 3 procedures with expert surgeons performing the approach deemed best for each patient with patient follow-up to 6 years. The survival models allow us to provide estimated recurrence rates after controlling for baseline risk factors, and to account for different follow up times and for the differential slopes of failure over time for each definition of recurrence; an improvement over point estimate rates. Using a strict composite definition, these estimated recurrence rates may be as high as 40-60% 6 years after surgery. When baseline risk factors for recurrent POP were controlled for, transvaginal uterosacral colpopexy appears to have higher risk of recurrent POP to or beyond the hymen but a lower risk of symptomatic bulge and need for retreatment for POP. These findings may be counterintuitive and may result from not accounting for unmeasured risk factors leading to selection bias. Additional limitations include the inability to control for unmeasured confounders such as surgeon, as not all surgeons performed all 3 operations, Also, follow-up was not prospectively determined which may bias towards those subjects who returned for evaluation of recurrent POP or with other complaints. Despite these limitations, these findings demonstrate that patient-centered outcomes maintain different recurrence rates from anatomic outcomes among the three approaches. Moreover, comparisons of recurrence should be substantially longer than 1 or 2 years since there are differential rates of recurrence between approaches depending on which definition is used.

Concluding message:

In this retrospective analysis, transvaginal uterosacral colpopexy appears to have a higher risk of anatomic recurrent POP to or beyond the hymen but a lower risk of patient-centered recurrent POP such as symptomatic bulge and need for retreatment for POP, resulting in an overall lower risk of recurrent POP compared to minimally invasive sacral colpopexy up to 6 years after surgery. Future prospective trials should use patient-centered outcomes with longer follow-up time to confirm these findings and make valid comparisons.

Disclosures

Funding: We have no disclosures and no source of funding for this project **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Cleveland Clinic Institutional Review Board **Helsinki:** Yes **Informed Consent:** No