

## ADVERSE EVENTS ASSOCIATED WITH VAGINAL HYSTERECTOMY WITH HIGH UTEROSACRAL COLPOPEXY FOR UTEROVAGINAL PROLAPSE

### Hypothesis / aims of study

To determine the rate and risk factors of adverse events in women undergoing vaginal hysterectomy with high uterosacral colpopexy (UC) for uterovaginal prolapse.

### Study design, materials and methods

All women who underwent a vaginal hysterectomy with UC for pelvic organ prolapse (POP) between 2006 and 2011 at a single tertiary care referral center were identified by their *Current Procedural Terminology* code for intraperitoneal colpopexy (57283). Subjects were included if they underwent concomitant POP procedures or anti-incontinence surgery with midurethral sling placement. Subjects were excluded if they underwent extraperitoneal colpopexy (i.e. sacrospinous colpopexy), or if they had concomitant procedures unrelated to the repair of POP. The health system-wide electronic medical record was queried for demographic, intra- and postoperative data. Adverse events included intraoperative events, events that occurred in the immediate 30 day-postoperative period, and up to 12 months after the index surgery. Strict definitions for each adverse event were created prior to data collection. Ureteral kinking was defined as transient obstruction of the ureter, relieved with removal of suspension sutures; and, ureteral injury was defined as transection or injury requiring urologic repair. Postoperative ureteral obstruction was defined as patients who were determined to have hydro- ureter or nephrosis on imaging, attributed to undiagnosed obstruction at the time of surgery. Univariate analyses were performed with adjustment for variables found to be associated with adverse events. Multivariate analyses were not possible due to our low adverse event rates.

### Results

1,038 subjects were identified and 868 met study inclusion criteria. Mean age was 60 ( $\pm 11$ ) years and BMI 28.1 ( $\pm 5.2$ ) kg/m<sup>2</sup>; median (range) vaginal parity was 3 (0-10) and preoperative POP-Q stage was 3 (2-4). Table 1 displays the rates of adverse events as % (95%CI). The overall adverse event rate was 32.7%, which included 19.8% of subjects who were treated postoperatively for culture-proven urinary tract infections (UTI). The overall adverse event rate excluding UTI was 12.1%. Transient intraoperative ureteral kinking was noted in 4.7% of cases, which resolved in all patients with intraoperative removal/replacement of the vault suspension stitches. No patients required additional intraoperative treatment beyond this for ureteral injury (ureteral injury rate 0%). However, the rate of postoperative ureteral obstruction was 0.6%. The bladder injury rate was 0.8%. 1.6% of subjects had EBL >500cc, 2.7% of subjects were found to have a postoperative hematoma, and 1.7% underwent postoperative transfusion. Vaginal cuff cellulitis and pelvic abscess occurred in 1.7% and 0.5% of subjects, respectively. Bowel obstruction occurred at a rate of 0.9%, and ileus at 0.1%. The rate of neurologic injury/neuropathic pain was 1.3%. The majority of injuries were localized to the femoral or sciatic nerve, and there was a combination of pain, weakness, and sensory deficits. All patients were successfully treated with either expectant or conservative management. The rates of pulmonary and cardiac complications were 2.4% and 0.8%, respectively. Age was not determined to be a risk factor for these complications. Subjects with chronic obstructive pulmonary disease (COPD) were more likely to experience postoperative pulmonary (23.0% v. 2.2%, Adj OR 14.8 {95%CI 2.8,77.9}, p<0.001) and cardiac (14.3% v. 0.7%, Adj OR 20.3 {95%CI 2.2,191.2}, p<0.001) complications. Similarly, subjects with cardiovascular disease (CVD) were more likely to experience postoperative pulmonary (19.4% v. 0.5%, Adj OR 14.1 {95%CI 5.3,37.6}, p<0.001) and cardiac (11.1% v. 0.6%, Adj OR 34.5 {95%CI 7.4,160.8}, p<0.001) complications. Known abdominal and pelvic adhesive disease was associated with a higher likelihood of postoperative small bowel obstruction (7.7% v. 0.8%, p=0.01, OR 10.0 {95%CI 1.2,88.5}). UTI alone was not found to be associated with any preoperative risk factors. Subjects with obstructive sleep apnea (OSA) were more likely to experience any adverse event including UTI (adjusted OR 7.2 (95%CI 2.0,45.5), p=0.0009). The following variables were associated with any adverse event excluding UTI: OSA (adjusted OR 3.3 (95%CI 1.3,8.2), p=0.008), CVD (adjusted OR 3.0 (95%CI 1.5,5.9), p=0.0008), and concomitant midurethral sling placement (adjusted OR 1.4 (95%CI 1.1,2.0), p=0.02).

**Table 1. Peri- and Postoperative Adverse Events for all subjects, N=868**

	<b>Adverse Event</b>	<b>n/N</b>	<b>% (95%CI)</b>
<b>Intraoperative Events</b>	Bladder Injury	7	0.8 (0.4,1.7)
	Ureteral Kinking	41	4.7 (2.6,5.2)
	Ureteral Injury	0	--
	Bowel Injury	1	0.1 (0.02,0.6)
	EBL >500cc	14	1.6 (1.0,2.7)
<b>Postoperative Events</b>	Reoperation <30 days	3	0.3 (0.1,1.0)
	Transfusion	15	1.7 (1.0,2.8)
	Hematoma	23	2.7 (1.8,3.9)
	Vaginal Cuff Cellulitis	15	1.7 (1.0,2.8)
	Pelvic Abscess	5	0.5 (0.2,1.3)
	Ileus	1	0.1 (0.02,0.6)
	Small Bowel Obstruction	8	0.9 (0.5,1.8)
	Pulmonary	21	2.4 (1.6,3.7)
	Cardiac	7	0.8 (0.4,1.7)
	DVT/PE	2	0.2 (0.06,0.8)

	Neurologic Injury	11	1.3 (0.7,2.3)
	Postoperative Ureteral Injury/Obstruction	5	0.6 (0.2,1.3)
	Culture-Proven UTI	172	19.8 (17.3,22.6)
	Pyelonephritis	8	0.9 (0.5,1.8)
<b>Any Adverse Event</b>	With Culture-Proven UTI	284	32.7 (29.2, 38.6)
	Without Culture-Proven UTI	112	12.1 (10.1,14.4)
	≤ Grade 3 Dindo Complication	263	30.3 (27.3,33.4)

EBL = Estimated blood loss

DVT/PE = Deep vein thrombosis/pulmonary embolus

UTI = Urinary tract infection

≤ Grade 3 Dindo Complication = Requiring surgical, endoscopic, or radiologic intervention

#### Interpretation of results

The rate of adverse events including UTI was 32.7% and without UTI was 12.1%. Our high rate of postoperative UTI was higher than rates reported in 2 recently published clinical trials [1,2]. Conversely, our rate of intraoperative ureteral kinking was similar to the rates previously reported [1,3]. Certain variables such as OSA, CVD and concomitant midurethral sling were associated with the overall adverse event rate. Postoperative pulmonary and cardiac complications were more common in patients with COPD and cardiovascular disease, and abdominal and pelvic adhesive disease was a risk factor for postoperative small bowel obstruction. The major limitation to this study is its retrospective design and the biases that are inherent to this type of design. Additionally, because our adverse event rates were low, interpretation of risk factors associated with these events should be done with caution. Despite these limitations, this is one of the largest retrospective cohort studies looking at adverse events related to uterosacral colpopexy to date, and our findings may be useful for counselling patients during the preoperative period.

#### Concluding message

In this retrospective analysis, urinary tract infection occurred in approximately 20% of patients undergoing vaginal hysterectomy with UC. The overall adverse event rate after this procedure was approximately 12% and the rates of events leading to severe morbidity were low. Certain patient characteristics increased the risk of some adverse events. While the intraoperative ureteral kinking rate was 4.7%, there were no intraoperative ureteral injuries.

#### References

1. 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(10):1023-1034.
2. Brubaker L, Norton PA, Albo ME, et al. Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the TOMUS study. Am J Obstet Gynecol 2011;205(5):498-500.
3. Gustilo-Ashby AM, Jelovsek JE, Barber MD, et al. The incidence of ureteral obstruction and the value of intraoperative cystoscopy during vaginal surgery for pelvic organ prolapse. Am J Obstet Gynecol 2006;194(5):1478-1485.

#### Disclosures

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