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A MID URETHRAL SLING PREVENTS INCONTINENCE AMONG WOMEN UNDERGOING VAGINAL PROLAPSE REPAIR– THE OPUS TRIAL

Hypothesis / aims of study

Stress continent women undergoing surgery for pelvic organ prolapse (POP) may develop de-novo urinary incontinence (UI) post-operatively. The Colpopexy and Urinary Reduction Efforts (CARE) trial [1] found that continent women who underwent a concomitant abdominal Burch procedure at the time of abdominal sacrocolpopexy had approximately half the rate of stress UI as women who did not undergo the Burch procedure. The aims of the Outcomes Following Vaginal Prolapse Repair and Midurethral Sling (OPUS) Trial [2] were to examine urinary incontinence and adverse events at 3 months for a prophylactic mid-urethral sling in stress continent women undergoing vaginal surgery for prolapse and to determine if prophylactic vs delayed SUI treatment resulted in differential outcomes 12 months after surgery.

Study design, materials and methods

Women enrolled in this multicenter masked randomized clinical trial planned vaginal surgery for symptomatic ≥ Stage 2 anterior POP and reported no SUI symptoms. Intraoperatively, women were randomized to sham incisions or retropubic TVT. The 3 month postoperative UI endpoint (Table 1[†]) was met if any of the following were present: positive cough stress test, bothersome UI symptoms ("moderately or quite a bit"), or treatment for UI (pharmacologic or surgical). The 12 month endpoint (Table 1[‡]) examining the role of prophylactic vs delayed treatment was met if women had a positive stress test and/or bothersome UI symptoms at 12 months. Analysis was by intention to treat.

Results

337 women with a mean age of 63 years were randomized; 96% completed 1-year followup. Baseline POP-Q stages were: II, 28%; III, 63%; IV, 9%. 34% had a positive reduced stress test pre-operatively. 11% underwent anterior repair, 82% apical suspension +/- anterior repair, and 7% colpocleisis. At 3 months, UI was lower in the TVT arm (24% vs 49%, p<0.0001). At 12 months, the prophylactic TVT arm had a lower rate of UI even after allowing for additional UI postoperative treatment (Table 1). The number needed to treat to prevent an additional case of symptomatic UI was 3.9 (95%CI 2.8, 6.5) at 3 months and 6.3 (95% CI 3.9, 18) at 12 months in favor of prophylactic TVT. While there were no significant differences in serious and unexpected adverse events, there was a higher rate of bladder perforations, UTI, bleeding complications and incomplete bladder emptying in the TVT arm (Table 2).

Interpretation of results

Consistent with the CARE trial, the addition of a prophylactic anti-incontinence procedure during POP repair resulted in a lower rate of postoperative UI at 3 months. When comparing the prophylactic approach to the delayed SUI treatment approach, the prophylactic approach yielded a lower rate of postoperative UI at 12 months. From a safety perspective, the addition of a TVT during POP repair was associated with more bladder and bleeding events though serious adverse events did not differ significantly.

Concluding message

A prophylactic TVT during vaginal POP surgery resulted in superior continence rates at 3 and 12 months. On average, 6 women would have to undergo a prophylactic sling to prevent one additional case of UI at 12 months. These benefits are tempered by a higher rate of perioperative complications.

Table 1 – Efficacy of mid urethral sling during vaginal prolapse surgery

	Treatment Group Vaginal prolapse repair plus		Adjusted Odds Ratio* (95% CI)	p-value*
	TVT N=165	Sham incision N=172		
3 month UI failure[†]	39/165 (23.6%)	85/172 (49.4%)	3.22 (1.99, 5.22)	<0.0001
12 month UI failure[‡]	45/165 (27.3%)	74/172 (43.0%)	2.08 (1.30, 3.34)	0.0024

*based on multivariate conditional logistic regression model controlling for surgeon and type of prolapse repair procedure [colpocleisis, anterior repair, apical repair or both].

Table 2 – Safety of mid urethral sling during vaginal prolapse surgery

	Treatment Group Vaginal prolapse repair plus		Difference in Proportions (95% CI)	p-value*
	TVT N=165	Sham incision N=172		
3 month additional UI treatment**	11/164 (6.7%)	13/172 (7.6%)	-0.9% (-6.45, 4.7%)	0.76

12 month additional UI treatment**	12/164 (7.3%)	19/172 (11.1%)	-3.7% (-9.9%, 2.5%)	0.24
Bladder Perforation during TVT	11/164 (6.7%)	0/172 (0%)	6.7% (2.9%, 10.5%)	0.0006
UTI 1st 3 months	49/158 (31.0%)	30/174 (17.2%)	13.8% (4.6%, 22.9%)	0.008
Major Bleeding / Vascular Complications	5/164 (3.0%)	0/172 (0%)	3.0% (0.5%, 15.6%)	0.03
Incomplete Bladder Emptying at 6 Weeks	6/162 (3.7%)	0/170 (0%)	3.7% (0.8%, 6.6%)	0.01
Sling release/urethrolysis	2/165 (1.2%)	0/172 (0%)	1.2% (-0.4%, 2.9%)	0.24

*based on chi-square or Fisher's exact test

**additional UI treatment includes surgery, medication, pelvic muscle exercise, timed voids, periurethral injection, botox injection

References

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2. Wei J, Nygaard I, Richter H, Brown M, Barber M, Xiao X, Kenton K, Nager C, Schaffer J, Visco A, Weber A, Pelvic Floor Disorders N. Outcomes following vaginal prolapse repair and mid urethral sling (OPUS) trial--design and methods. Clinical Trials2009 Apr;6(2):162-71

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Is this a clinical trial?	**Yes**
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Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Michigan IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**