Adverse events following transvaginal mesh surgery for stress urinary incontinence and pelvic organ prolapse in women

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Introduction

The use of polypropylene mesh devices during surgical procedures to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP) in women has been the subject of scrutiny by healthcare regulators and intervention by governments(1). Results of the largest cohort study of these procedures were published in December 2016 (2), however, it was limited by the lack of details regarding the severity of complications. Our study differs as it delves into these complications in more detail, and looks at follow up over a longer time frame.

Methods

A cohort study was conducted to determine and analyse complications following mid-urethral tape (MUT) procedures for SUI and POP performed within one surgeon's team during the 5-year period (February 2009 – June 2014 when procedures were suspended). Abdominal procedures were excluded as well as the previous mesh procedures performed by a different surgeon. Data linkage has combined records from the national database of the British Society of Urogynaecologists (BSUG) and Scottish Morbidity Records allowing follow up in both an inpatient and outpatient setting.

Results

Figure 1 – Cohort data

	Average	Median	Minimum	Maximum	% patients	data from % of cohort
Age (all)	56	55	27	85		100%
Age (at index procedure)	55	54	27	85		100%
Parity	0.5	0	0	6		41.8%
BMI	29.7	29.4	18	48		43.1%
Previous Hysterectomy (index)					14.5%	100%
Previous Hysterectomy (patients)					14.9%	100%
Consultant Operation					71.3%	42.8%

Figure 2 – Index procedures – with mesh only

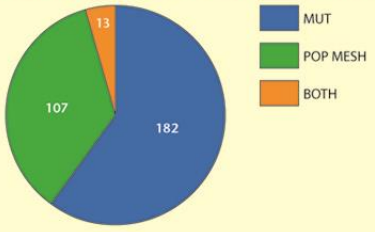

Figure 3 - Dindo scores

	OVERALL	MUT	POP MESH	BOTH
0	256	161	84	11
1	43	19	23	1
2	57	30	24	3
3	96	33	52	11
4	4	2	2	0

Figure 4 - ICS/IUGA scores

Classification		Total Complication's Classified	Index Incontinence	Index Prolapse	Both
Category	1. Vaginal: no epithelial separation	73	31	32	10
	2. Vaginal: smaller =< 1cm exposure	22	11	7	4
	3. Vaginal: larger >1cm exposure (or any extrusion)	10	3	6	1
	4. Urinary tract: Compromise or perforation. Including prosthesis (graft) perforation, fistula and calculus	53	29	22	2
	5. Rectum or bowel: Compromise or perforation. Including prosthesis (graft) perforation and fistula	1	0	0	1
	6. Skin or musculoskeletal: complications including discharge pain lump or sinus tract formation	13	6	5	2
	7. Patient compromise: including haematoma or systemic compromise	8	4	4	0
Time (Clinical Diagnosed)	T1: Intraoperative to 48 hours	15	9	4	2
	T2: 48 hours to 2 months	34	14	17	3
	T3: 2 months to 12 months	63	25	25	9
	T4: over 12 months	72	35	28	4
Site	S0: No site applicable				
	S1: Vaginal: area of suture line	76	33	30	12
	S2: Vaginal: away from suture line	40	14	18	3
	S3: Trocar passage	0	0	0	0
	S4: Other skin or musculoskeletal site	16	8	5	2
	S5: Intra-abdominal	52	27	22	2

Figure 5 - Excision of vaginal mesh exposure (partial mesh excision)

	MUT	POP mesh	Both	Total
No. of patients	7 (3.8%)	8 (7.4%)	4 (30.8%)	19
No. of removal procedures	9	13	4	26

Figure 6 - Number of infection-related hospital admissions

	MUT	POP mesh	Both	Total
No. of patients	8 (4.3%)	0	1 (7.7%)	9
No. of hospital admissions	13	0	1	14

Discussion

295 patients underwent 302 index mesh procedures.

140 women underwent a first single MUT procedure and 42 women underwent a concomitant native tissue POP procedure. 107 underwent a single first POP mesh procedure and 13 women underwent concomitant MUT and POP mesh procedures.

65 patients had a total of 105 hospital re-admissions for a mesh-related adverse event. The average duration from the index procedure to the first hospital re-admission was 1 year and 7 months (range: 1-day to 7 years and 8 months).

30 (16.4%) women who underwent MUT surgery (with and without concomitant non-mesh POP surgery) have suffered a mesh-related adverse event that required a total of 45 hospital re-admissions.

30% women who underwent POP mesh surgery (with and without concomitant non-mesh surgery in a different compartment) have suffered a mesh-related adverse event that required a total of 56 hospital re-admissions.

6/13 (46%) women who underwent concomitant MUT and POP mesh surgery have suffered a mesh-related adverse event that required a total of 8 hospital re-admission.

Patients who underwent a POP mesh procedures where twice more likely to require a hospital admission for a mesh-related adverse event compared to those who underwent a mid-urethral tape procedure. Vaginal mesh exposure requiring surgical removal was twice more prevalent following POP mesh surgery compared to MUT surgery (3.8% and 7.4%).

The majority of women suffering mesh-related adverse events requiring hospital admission fell in the Clavien – Dindo category IIIb (surgery under general anaesthesia) and one patient required ICU admission for a non-mesh related incident.

Conclusion

Our real-world data confirms that mesh-related adverse events in urogynaecological surgery are very common and are related to the amount of implanted material. 1:3 women who underwent MUT or POP surgery, and 1:2 women who underwent concomitant MUT and POP surgery, have suffered a mesh-related adverse event that required at least one hospital re-admission. Further analysis at mesh device-level and on impact of adverse events on quality of life is planned.