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ADVERSE EVENTS FOLLOWING TRANSVAGINAL MESH SURGERY FOR STRESS URINARY INCONTINENCE AND PELVIC ORGAN PROLAPSE IN WOMEN

Hypothesis / aims of study

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.

Study design, materials and 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.

Primary outcomes were immediate postoperative complications, subsequent readmissions for later postoperative complications, mesh removal surgery (partial and complete), further incontinence surgery, or further prolapse surgery. There were no time limitations. Individual patient records were searched for details of any subsequent hospital treatment (both in local hospital or any other hospital in the country). The severity assessed by the Clavien - Dindo classification of surgical complications - contracted form. Where a patient had more than one admission, the higher classification score was taken into account.

Results

298 women underwent 301 transvaginal procedures using mesh to treat SUI and POP over a period of 5 years (March 2009 - May 2014) and women were followed up for an average of 5.5 years (till March 2017). The average age was 56.5 years (53 years for women undergoing MUT and 60 years for women undergoing POP mesh surgery. The average BMI was 30 (calculated for 140 women, 47% of the cohort).

141 women underwent a first single MUT procedure and 42 women underwent a concomitant native tissue POP procedure. 105 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. Of these, 20 required 1 re-admission, 7 required 2, 2 required 3 and 1 required 5 readmissions

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. Of these, 17 women required 1 readmission, 10 required 2, 3 required 3, 1 required 4 and 1 required 6 hospital 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 (4 had one readmission and two had 2 re-admissions.

Table 1: 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

Table 2: 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

Table 3: Clavien - Dindo classification of surgical complications (for 135 patients

Score	No of patients
0	70
1	12
2	16
3	36
4	1

Interpretation of results

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.

A small number of patients, 3 (1.6%) following MUT and 2 (1.6%) following POP mesh procedures required repeat hospital readmissions and continue to suffer ongoing problems.

Concluding message

The use of vaginal implants during POP repair is associated with higher risks of mesh-related adverse event while efficacy in comparison to native tissue repair remains uncertain. The risks associated with midurethral tape procedures are comparable to the national figures. Larger studies are required to identify the risk factors that predisposes women to suffer repeat and ongoing mesh complications.

References

1. www.gov.scot/Publications/2017/03/3336
2. The Lancet 2016, 389, Issue 10069: 629 – 640.

Disclosures

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