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COMPLICATIONS IN THE TREATMENT OF PELVIC ORGAN PROLAPSE THROUGH TRANSVAGINAL MESH WITH MINIMUM FOLLOW-UP OF 4 YEARS

Hypothesis / aims of study

Data are scarce in the literature with regard to complications beyond 2 years after pelvic organ prolapse (POP) surgery with transvaginal mesh (TVM). The FDA has raised safety concerns about the use of grafts for reconstructive pelvic surgery.
The aim of our study was to analyze the complications and time of appearance in the surgical treatment of POP with TVM.

Study design, materials and methods

A prospective observational study was performed. We studied 75 women, median age of 67 years (46–85), with POP grade ≥II in any compartment (Baden and Walker scale) who underwent surgery between November 2005 and December 2008 through TVM by the same surgeon (complete mesh: 70, anterior: 4, posterior: 1).
In our sample, there was 11% of obesity (BMI ≥ 30), 17% of smokers, 28% had previous vaginal surgery, 31% had previous abdominal surgery, 87% were menopausal, and 11% had diabetes. The median BMI was 26.3 (range 20.4-43). 30 patients (40%) underwent concomitant treatment of stress urinary incontinence through suburethral synthetic sling.
The average follow-up period was 60 month (SD 17.6) with a minimum of 48. They were reviewed at 1, 3, 6 and 12 months, and then annually (or as per patient requirement) recording: urogynecological examination, complications, urinary symptoms and sexual activity and dyspareunia data. Anatomical criterion for failure of POP correction was a prolapse grade >I in any compartment. Subjective evaluation was carried out with Visual Analogue Scale (VAS). Early complications (intraoperative and first month postoperative) and late complications (after the first month) are reported according to ICS and Clavien-Dindo classifications. Complications management is reported.
We studied with logistic regression the following risk factors: age, BMI, diabetes, tobacco usage, menopause, previous abdominal surgery, previous vaginal surgery and concomitant treatment of the IUE in the developing of failure of treatment and extrusion.
In the long-term follow up, we could not contact with 7 patients. A statistical analysis is carried out under SPSS 20.0, without considering the missing data.

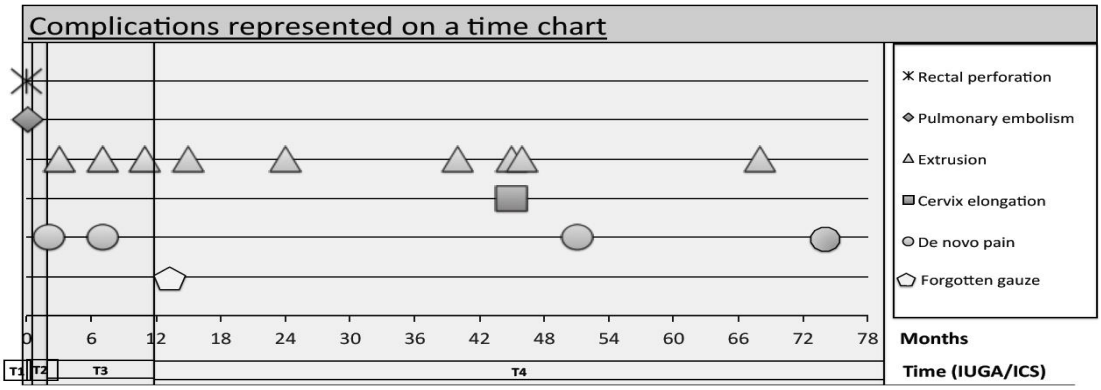
Results

-Anatomical results showed POP correction in 91.2% of the patients. The failure corresponded to middle compartment (4 grade II and 2 grade III), anterior compartment (1 stage II) and posterior compartment (1 stage II). No further surgery was required.
-Subjective VAS: median 9/10 (minimum of 2 in 1 patient, maximum of 10 in 27 patients).
Complications:

Early complications	N %	IUGA/ICS classification	Clavien-Dindo classification	Management
Rectal perforation	1(1.3%)	5BT1S2	III	Intraoperative reparation
Pulmonary embolism	1(1.3%)	7BT2S5	IV	Medical treatment
TOTAL	2(2.6%)	-	-	
- Average loss of haemoglobin: 1.91 g/dl (SD: 1.36). Transfusion rate: 0/75. - No visceral, vascular or nerve lesions. No infection complications related to mesh, fistula or abscess.				

Late complications	N %	IUGA/ICS classification	Clavien-Dindo classification	Management
Extrusion	9(13.2%)	3AT4S2 (3) 3BT4S2 (3) 3AT3S2 (3)	6 grade I 3 grade IIIa	Surveillance: 3 Local oestrogen: 4 Excision: 3 (4.4%)
Cervix elongation	1(1.5%)	1BT4S2	III	Reoperation: 1 (1.5%)
Forgotten gauze	1(1.5%)	6AT4S2	III	Reoperation: 1 (1.5%)
De novo pain	4(5.9%)	1BT3S2 (2) 1BT4S2 (2)	I	Surveillance: 4
TOTAL	15(22%)	-	-	Reoperation: 6 (8.9%)

Fig1. **Complications: moment of appearance**



There were 11(16.4%) patients with de novo constipation, but 8 (11.9%) patients who referred constipation before surgery improved. Presurgical dyspareunia was reported by 8 patients. The last evaluation showed 11 patients with dyspareunia, only 3 were de novo. There were no statistically significant differences in mean VAS in patients with and without complications.

Univariant regression analysis:

Factor	Failure of treatment		Extrusion	
	Odds ratio	p	Odds ratio	p
Age	1.022	0.649	1.019	0.636
Tobacco	2.437	0.509	2.057	0.456
BMI	1.143	0.569	1.191	0.199
Diabetes	5.6	0.105	0	0.143
Vaginal surgery	0.478	0.485	0.689	0.654
Abdominal surgery	1.105	0.913	1.111	0.890
Menopause	0.648	0.721	0.189	0.062
Concomitant treatment of the IUE	0.236	0.136	1.056	0.940

Interpretation of results

Surgical correction of POP through TVM showed good anatomical and subjective results with low complications rate. Remarkably, in our study 60% of late complications appeared 12 months or later after the surgery, and 40% of them occurred 3 years or later. Patients who presented complications were managed successfully and did not show worse subjective results.

We found no statistical association between any of the risk factors analysed (age, BMI, diabetes, tobacco usage, menopause, previous abdominal surgery, previous vaginal surgery and concomitant treatment of the IUE) and the development of extrusion or treatment failure. This could be due to the sample size and low complication rate.

Standardised systems for reporting and classification of surgical complications were described with IUGA/ICS and Clavien-Dindo classifications, but they do not take into account adequately the appearance of late complications.

We acknowledge some limitations of our study, being the most important the use of non-validated questionnaires to obtain data of functional and subjective results and the low number of cases included. We also have to consider missing data.

Concluding message

The rate of serious complications was low and similar to what is described in the literature. Subsequent management was effective when required.

There were many complications even after 3 years of surgery. For this reason we advice the importance of long-term follow-up of these patients.

Disclosures

Funding: NONE **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** When the study started, in 2005, this was not required by the Spanish law in observational studies. **Helsinki:** Yes **Informed Consent:** Yes