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Laso-García I M[1], Rodriguez-Cabello M A[1], Orosa-Andrada A[1], Carracedo-Calvo D[1], Gomez-de-Vicente J M[1], Lopez-Fando L[1], Jimenez Cidre M A[1]

1. *Ramon y Cajal University Hospital. Madrid. Spain*

ANALYSIS OF COMPLICATIONS AND RISK FACTORS IN THE TREATMENT OF PELVIC ORGAN PROLAPSE WITH TENSION-FREE VAGINAL MESH

Hypothesis / aims of study

The aim of the present study is to assess the early and medium-long term (minimum follow up of 48 months) complications of the treatment of pelvic organ prolapse with transvaginal mesh and also to analyze some risk factors for treatment failure or extrusion.

Study design, materials and methods

Prospective observational analysis of 75 women with pelvic organ prolapse grade ≥ II in any compartment, under Baden and Walker scale, who underwent surgery between November 2005 and December 2008 with the tension-free vaginal mesh Prolift®, by the same surgeon (complete mesh:70, anterior:4, posterior:1). 30 (40%) patients underwent concomitant treatment of stress incontinence.

In our sample, there was a 16,7% of smokers, 28% had previous vaginal surgery, 30,7% had previous abdominal surgery, 86,7% were menopausal, and 10,7% had diabetes. The median of BMI was 26,3 (range 20,4-43)

The average follow up was 60 months (SD 17.6) and the minimum follow up was 48 months. The schedule of follow up was at one month, 3 months, 6 months, one year, and then annually or under patient requirement.

An analysis of the early complications (intraoperative and first month postoperative) and late complications (after the first month) is carried out, following the classification and terminology of the IUGA/ICS.

We also study 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

Complications:

-Early complications (intraoperative and first month postoperative):

	N (%)	Code (IUGA/ICS)	
Pulmonary embolism	1 (1,3%)	7BT2S5	Resolution with medical treatment
Rectal perforation	1 (1,3%)	5BT1S5	Intraoperative reparation
Subcutaneous hematoma	10 (13,3%)	7AT1S3	Treatment not required
TOTAL	12 (16%)		1 serious (1,3%), 11 mild (14,6%)

The average loss of hemoglobin the day after the surgery was 1,91 g/dL (SD 1,36) Transfusion rate was 0/75

-Late complications (after the first month postoperative):

	N (%)	Code (IUGA/ICS)	Reintervention (%)
Extrusion	9 (13,2%)	3AT4S2 (4) 3AT3S2 (1) 3AT3S2 (1) 3BT4S2 (1) 3BT4S2 (2)	3 (4,4%), one twice
Mesh contraction	1 (1,5%)	1AT4S1	0 (0%)
Cervix elongation	1 (1,5%)	1BT4S2	1 (1,5%)
Forgotten gauze	1 (1,5%)	6AT4S2	1 (1,5%)
De novo pain	4 (5,9%)	1AT3S2 1AT4S2	0 (0%)
TOTAL	16 (23,5%)		7 (10,3%)

Analysis of risk factors for failure of treatment and extrusion:

There were 6 failures of treatment

Univariant regression:

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

There were 12 early complications, one of which was serious (pulmonary embolism). None of them required reoperation. There was not any bladder perforation or wound infection. No visceral, vascular or nerve lesions in the follow up were observed.

There were 16 further late complications, being extrusion the most frequent. The reoperation was effective when it was required. There was not any severe late complication. There were not infectious complications related to the mesh, fistula or abscess.

We did not find a statistical association between any of the risk factors analyzed (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.

Concluding message

The rate of complications was relatively low, being the reoperation effective when it was required. In our series of data analyzed, none of the factors studied was associated to failure of treatment or extrusion.

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