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PROLIFT(MESH (GYNECARE) FOR PELVIC ORGAN PROLAPSE SURGICAL TREATMENT USING THE TVM GROUP TECHNIQUE: A RETROSPECTIVE STUDY OF 96 WOMEN OF LESS THAN 50 YEARS OLD.

Hypothesis / aims of study

The new Prolift® mesh (Gynecare) is now available to augment surgery for pelvic organ prolapse. To date, little data is available on its effectiveness and possible complications, even less in women of less than 50 years old. The aim of this study was to state efficiency, and also intra-operative, short and medium-term post-operative complications of the technique. Those results were subsequently compared to the all population of the study (687 patients). The average follow-up was 3.6 months and patients were from seven centers of gynaecologic surgery.

Study design, materials and methods

Since november 2002, 96 women of less than 50 years old were included in a retrospective multicentric study. All of them did benefit from a vaginal cure of genital prolapse by the use of Prolift® mesh. Surgical protocol was standardized according to an original technique designed by surgeons of the TVM group: cystocele repair used anterior mesh anchored transversally between arcus tendineus with two arms each side through obturator foramen. Rectocele repair used posterior mesh anchored transversally between sacro-spinal ligaments. Mean age was 44.9 years old. 12.5% had previous hysterectomy, 12.5% previous prolapse surgery. Simultaneous hysterectomy (SH) was performed in 53.1% patients (Table 1). Intra-operative and short-term post-operative complications were reported. Vaginal erosion (GF&VE), clinically estimated mesh shrinkage (MS), recurrent organ prolapse and de novo stress urinary incontinence (SUI) incidences were noticed at about 3.6 months after surgery.

Results

The results are summarized in tables 2 and 3. Intra-operative complications are quite rare (2.1%), but not significantly higher than in the all population of the study (1.32%) ($p>0.05$): 1 hemorrhage and 1 vesical injuries were reported. Short-term post-operative complications are more common (5.2%), but not significantly higher than in the all population (P0) of the study (2.49%) ($p>0.05$). Most of them are benign, with 4 haematomas (4.1%), and 1 perineal abscess (1.0%). Recurrent organ prolapse incidence ranged between 0.0% and 100.0% (mean of 8.3%): 91.7% of prolapse were considered as cured, which is not different to P0 (5.3%) ($p>0.05$). De novo SUI incidence ranged between 0.0% and 25.0% (mean of 3.1%), which is not different to P0 (5.4%) ($p>0.05$). Surgically treated GF&VE incidence ranged between 0.0% and 50.0% (mean of 6.3%); this rate is higher in the "SH" group with 6.3%, than in the other group (0.0%) ($p<0.05$), which is not different to P0 ($p>0.05$). Surgically treated MS incidence ranged between 0.0% and 25.0% (mean of 4.2%), which is not different to P0 ($p>0.05$).

Interpretation of results

The results of this multicentric study confirm the technique is safety for women of less than 50 years old, with low rates of benign intra-operative and short-term post-operative complications (2.1% and 5.2% respectively), which are not significantly different to P0 ($p>0.05$). Functional results are less satisfying with rates of recurrent organ prolapse and de novo SUI of 8.3% and 3.1% respectively. High rates of OPR are all the more so worrting as follow-up is rather short (mean of 3.6 months). Large variations between centers in incidences of medium-term post-operative complications are noticed. Considering GF&VE, high incidence reported at the beginning of the study was subsequently decreased thanks to technical improvements, consisting in short incisions of vagina and avoiding simultaneous hysterectomy ($p<0.05$). But

despite these advances, the rate of 6.3% remains high regarding the impairment GF&VE would cause to young patients.

Concluding message

Prolift® mesh is obviously an interesting improvement in organ prolapse surgery, even for women of less than 50 years of old. Intra-operative, short and medium-term complications are not significantly higher in this population. Durability of anatomical results should be assessed during a longer period. But medium-term outcome is more dissapointing. At first, GF&VE rates remain significant, despite technical improvements due to the TVM group. Secondly, high rates of OPR at only 3.6 months make us wonder what long-term anatomical result would be.

Table 1: Operative data in each center (B,CF,N, D, JDF-R, S, R).

=< 50 years old		B	CF	N	D	JDF-R	S	R	Total
n		4	2	4	8	49	3	26	96
Mean age (years)		45.3	45.5	47.5	46	44.6	47.3	44.4	44.9
Previous hysterectomy	%	0,0%	50,0%	0,0%	12,5%	10,2%	33,3%	15,4%	12,5%
Previous prolapse surgery	%	25,0%	50,0%	0,0%	0,0%	14,3%	0,0%	11,5%	12,5%
Simultaneous hysterectomy	%	100,0%	0,0%	100,0%	62,5%	51,0%	66,7%	42,3%	53,1%

Table 2 : Intra-operative and short-term post-operative complication rates.

=< 50 years old		B	CF	N	D	JDF-R	S	R	Total
Intra-operative complications	n	0	0	0	1 vesical injury	1 intra-operative haemorrhage	0	0	2
	%	0,0%	0,0%	0,0%	12,5%	2,0%	0,0%	0,0%	2,1%
Short-term post-operative complications	n	0	0	1 haematoma	0	3 haematomas 1 perineal abscess	0	0	5
	%	0,0%	0,0%	25,0%	0,0%	8,2%	0,0%	0,0%	5,2%

Table 3: Medium-term post-operative complications.

=< 50 years old		B	CF	N	D	JDF-R	S	R	Total
n		4	2	4	8	49	3	26	96
Surgically treated GF&VE									
%		25,0%	0,0%	50,0%	0,0%	6,1%	0,0%	0,0%	6,3%
Surgically treated GF&VE + SH									
%		25,0%	0,0%	50,0%	0,0%	6,1%	0,0%	0,0%	6,3%
Surgically treated GF&VE without SH									
%		0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
Surgically treated mesh shrinkages									

%	25.0%	0.0%	25.0%	0.0%	0.0%	0.0%	7.7%	4.2%
Recurrent organ prolapse								
%	0.0%	100.0%	25.0%	25.0%	6.1%	0.0%	0.0%	8.3%
De novo SUI								
%	0.0%	0.0%	25.0%	0.0%	4.1%	0.0%	0.0%	3.1%