

PROLIFT (MESH (GYNECARE) FOR PELVIC ORGAN PROLAPSE SURGICAL TREATMENT USING THE TVM GROUP TECHNIQUE: A RETROSPECTIVE STUDY OF 687 PATIENTS.

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, often related to mesh intolerance. The aim of this study was to state its efficiency, but also intra-operative, short and medium terms post-operative complications (such as granuloma formations and vaginal erosions (GF&VE) requiring surgical treatment, mesh shrinkages (MS), organ prolapse recurrences (OPR) and de novo stress urinary incontinences(SUI)) at 3.6 months of follow up in seven centers of gynaecologic surgery.

Study design, materials and methods

Since November 2002, 687 patients 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 63.8 years old. 84.3% were menopausal. 24.3% had previous hysterectomy, 16.7% previous prolapse surgery and 11.1% previous SUI surgery. Simultaneous hysterectomy was performed in 50.3% patients. Simultaneous SUI surgery was performed in 40.9% patients (Table 1). Intra-operative and short-term post-operative complications were reported. OPR, de novo SUI, GF&VE requiring surgical treatment and clinically estimated MS incidences were noticed at about 3.6 months after surgery.

Results

Results are summarized in tables 2 and 3. Intra-operative complications are quite rare (1.32%): haemorrhages, vesical and rectal injuries were reported. Short-term post-operative complications are also uncommon (2.49%) and only 1.32% required surgical treatment. Most of them are benign with 1.75% haematomas and 0.29% perineal abscess. Fortunately, more serious complications, such as perineal cellulitis, vesico-vaginal or recto-vaginal fistulas, have very low incidences with 0.15% for each one. OPR incidence ranged between 0% and 10.9% (mean of 5.3%): 94.7% of prolapses were considered cured. De novo SUI incidence ranged between 0% and 10.3% (mean of 5.4%). GF&VE incidence ranged between 0% and 13.3% (mean of 6.7%). MS incidence ranged between 0% and 8% (mean of 2.8%).

Interpretation of results

The results of this multicentric study confirm the technique is safe with low rates of intra-operative and short-term post-operative complications (1.32% and 2.49% respectively). However, the serious complications reported for TVM technique were also noticed for older techniques, using autologous tissues. Functional results are ambivalent, with low rates of OPR and de novo SUI (5.3% and 5.4% respectively). De novo SUI are explained by a vesical destabilization due the technique and can be subsequently treated by sub-urethral slings. More worrying are high rates of OPR, all the more so 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. But despite these advances, the rate of 6.7% remains high regarding the impairment GF&VE would cause.

Concluding message

Prolift® mesh is obviously an interesting improvement in organ prolapse surgery. This study confirms its feasibility and short-term safety. But medium-term outcome is more disappointing. 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 results would be.

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

	B	CF	N	D	JDF-R	S	R	Total
Patients	77	75	39	55	239	35	164	684
Follow-up (Months)	3	4.1	4.4	10	3	4.1	2	3.6
Mean age (years)	65.9	68.2	67.1	63.6	62.1	60.6	63.3	63.8
Menopausal	96.8%	89.6%	86.6%	81.8%	82.4%	85.7%	78.7%	84.3%
Previous hysterectomy	19,5%	34,7%	23,1%	7,3%	26,8%	28,6%	23,2%	24,3%
Previous prolapse surgery	13,0%	24,0%	2,6%	9,1%	20,1%	20,0%	15,2%	16,7%
Previous stress urinary incontinence surgery	10,4%	18,7%	0,0%	9,1%	13,8%	14,3%	6,7%	11,1%
Simultaneous hysterectomy	50,6%	28,0%	71,8%	56,4%	41,4%	57,1%	64,6%	50,3%
Simultaneous stress urinary incontinence surgery	41,6%	54,7%	2,6%	72,7%	42,3%	28,6%	33,5%	40,9%

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

				Total		
Intra-operative complications	Vesical injuries	4	0,58%	1,32%		
	Rectal injuries	1	0,15%			
	Rectal erosion	1	0,15%			
	Intra-operative haemorrhages	3	0,44%			
				Total	Surgically treated	
Short-term post-operative complications	Perineal cellulitis	1	0,15%	Σ%94,2=	0,15%	Σ%23,1=
	Perineal abscess	2	0,29%		0,29%	
	Pelvic haematoma	12	1,75%		0,58%	
	Recto-vaginal fistula	1	0,15%		0,15%	
	Vesico-vaginal fistula	1	0,15%		0,15%	

Table 3: Medium-term post-operative complication rates (centers B,CF,N, D, JDF-R, S, R).

	B	CF	N	D	JDF-R	S	R	Total
Surgically treated granuloma formation or vaginal erosion (n=)	8	10	5	4	14	0	5	46
(%)	10,4%	13,3%	12,8%	7,3%	5,9%	0,0%	3,0%	6,7%
Surgically treated mesh shrinkages (n=)	4	6	2	0	1	0	6	19
(%)	5,2%	8,0%	5,1%	0,0%	0,4%	0,0%	3,7%	2,8%
Organ prolapse recurrence (n=)	2	8	2	6	17	1	0	36
(%)	2,6%	10,7%	5,1%	10,9%	7,1%	2,9%	0,0%	5,3%
De novo stress urinary incontinence (n=)	3	6	4	0	17	2	5	37
(%)	3,9%	8,0%	10,3%	0,0%	7,1%	5,7%	3,0%	5,4%