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OBJECTIVE AND SUBJECTIVE RESULTS ON TENSION FREE VAGINAL MESH PROCEDURE (PROLIFT®) FOR PELVIC ORGAN PROLAPSE.

Hypothesis / aims of study

The aim of this study is to evaluate the Prolift® (Tension free Vaginal Mesh) procedure in two centres. We want to determine effectiveness, subjective satisfaction and safety of the procedure.

Study design, materials and methods

It is a prospective cohort study. In two centres, specialised in pelvic organ dysfunction, prolapse surgery with the Prolift® system was undertaken from September 2005 onward. Preoperatively all patients underwent a pelvic organ prolapse quantification (POP-Q) assessment and filled in a disease-specific quality of life questionnaire (Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ) and the Defecatory Distress Inventory (DDI))[1]. Surgery was performed by four gynaecologists, trained for the Prolift procedure. Complications were registered. Patients were examined six months and one year after surgery. (POP-Q and disease-specific quality of life questionnaires and Patient Global Impression of Improvement (PGI-I)[2] questionnaire) Data were analysed with SPSS, version 12.0.1, Wilcoxon Signed Rank test was used.

Results

118 patients underwent prolapse surgery with a Prolift® procedure. 21 patients had a Prolift® anterior, 52 had a Prolift® posterior, 22 had a Prolift® totalis and 23 had Prolift® anterior+posterior. Median age was 66 years (range 19-86). One patient was only 19 years old, she had had multiple operations before due to bladder extrophia. 78% was postmenopausal and 51% had co-morbidity. 64% of the patients underwent a previous prolapse operation. Six month follow-up was available in 60 patients, twelve month follow-up in 31 patients. Follow-up is still going on.

Median operating time was 58 minutes (range 30-150). Median blood loss 100 ml (range 50-1200). Complications occurred in 7 cases (5.9%) during operation, 3 bladder lesions, 2 serosa lesions of the rectum , 2 haemorrhage over 500 ml. Median hospital stay was 4 days (range 2-11 days). Relevant POP-Q scores (most distal point anterior wall, most distal point posterior wall and most distal point cervix or vaginal cuff) are shown in table 1. One patient had a Prolift® posterior despite point Bp -3. This was to treat the prolapse of the middle compartment. Subjective improvement is shown in table 2 and table 3 shows disease-specific quality of life.

Table 1. POP-Q.

	Before operation Median cm (range)	After 6 months Median cm (range)	After 12 months Median cm (range)
Ba	n=42 3 (-2 /+9)	n=28 -2 (-3 /0)	n=17 -3 (-3 /–1)
Bp	n=73 1 (-3 /+9)	n=38 -3 (-3 /+4)	n=21 -2 (-3 /+3)
C	n=44 2 (-7 /+9)	n=25 -7 (-9 /+3)	n=16 -6 (-8 /+6)

Ba in all patients with a Prolift® anterior or a Prolift® anterior+posterior, Bp in all patients with a Prolift® posterior or a Prolift® anterior+posterior, C in all patient with a Prolift® totalis or a Prolift® anterior+posterior

Table 2. Patient Global impression of Improvement.

	After 6 months (n=58)	After 12 months (n=30)
Very much better	13 (22%)	11 (37%)
Much better	30 (52%)	16 (53%)
A little better	9 (15%)	2 (7%)
No change	4 (7%)	0
A little worse	1 (2%)	1 (3%)
Much worse	1 (2%)	0
Very much worse	0	0

Results is numbers (%)

Table 3. UDI, DDI and IIQ score.

	Pre-operative Median (range)	After 6 months Median (range)	P value	After 12 months Median (range)	P value
	n= 106	n=60		n=31	
UDI overactive bladder	33 (0-100)	11 (0-78)	0.00	6 (0-67)	0.00
UDI incontinence	17 (0-100)	17 (0-83)	0.74	17 (0-67)	0.65
UDI obstructive micturation	33 (0-100)	0 (0-67)	0.00	0 (0-67)	0.00

UDI discomfort/pain	33 (0-100)	0 (0-100)	0.00	0 (0-67)	0.00
UDI genital prolapse	67 (0-100)	0 (0-83)	0.00	0 (0-50)	0.00
DDI constipation	0 (0-83)	0 (0-50)	0.18	0 (0-33)	0.03
DDI obstructed defecation	8 (0-75)	0 (0-67)	0.05	0 (0-50)	0.51
DDI pain	0 (0-83)	0 (0-67)	0.83	0 (0-33)	0.04
DDI incontinence	0 (0-83)	0 (0-100)	0.52	0 (0-67)	0.27
IIQ physical functioning	33 (0-100)	0 (0-100)	0.00	0 (0-67)	0.01
IIQ mobility	22 (0-100)	11 (0-89)	0.00	0 (0-89)	0.00
IIQ social functioning	11 (0-100)	0 (0-67)	0.00	0 (0-33)	0.11
IIQ embarassment	0 (0-100)	0 (0-100)	0.12	0 (0-33)	0.30
IIQ emotional health	22 (0-100)	0 (0-89)	0.00	0 (0-56)	0.03

Score range 0-100, a high score means more bother.

Erosion was seen in 5 patients (8%) after 6 months, two had surgical excision. After 12 months 2 patients still had an erosion and they also had a surgical excision.

Interpretation of results

POP-Q scores improved after surgery with Tension free Vaginal Mesh. Subjective improvement was reached in 89% of the patients after 6 months and in 97% of the patients after 12 months. There is a significant improvement in bother of overactive bladder, obstructive micturation, discomfort/pain, genital prolapse. Less improvement of bother of defecatory problems is seen. Overall quality of life is significantly improved.
No major complications occurred. Five erosions of the mesh were seen.

Concluding message

Tension free Vaginal Mesh (Prolift®) seems an effective and safe treatment for pelvic organ prolapse. Randomised controlled trials are necessary to compare effectivity and safety of this new technique with classic techniques.

References

1. Measuring health-related quality of life in women with urogenital dysfunction: the urogenital distress inventory and incontinence impact questionnaire revisited. Neurol Urodyn 2003;22:97-104.
2. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003;189:98-101.

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