

PELVIC FLOOR SURGERY WITH MESH (ELEVATE ANTERIOR/APICAL AND POSTERIOR/APICAL) CAN CURE SYMPTOMS OF URINARY FREQUENCY, URGENCY, URGENCY INCONTINENCE AND NOCTURIA OVER LONG TIME

Hypothesis / aims of study

The „Integral theory“ (Petros and Ulmsten 1993) states that over-active-bladder (OAB)-symptoms can be caused by vaginal prolapse at different zones of the pelvic floor by activating stretch receptors at the bladder base. So pelvic floor reconstruction should improve these symptoms. Based on data gained by patients who underwent a pelvic floor surgery with Mesh and answered the PFDI (Pelvic Floor Distress Inventory) questions at baseline, 6, 12 and 24 months after operation we pursued the question, whether and to which extent OAB-symptoms occur in patients with vaginal prolapse and have been improved after surgery and how long the improvements have been lasted.

Study design, materials and methods

To prove time and efficacy effects of surgical reconstruction with Elevate anterior/apical and posterior/apical the prospective multicentre Propel-study (10 US & 6 EU, IRB/EC approved protocol and ICF) on the various pelvic floor symptoms 277 women with cystocele stage II-IV (N=142) or rectocele stage II-IV (N=135) with or without apical prolapse were observed and interrogated before and 6, 12 and 24 months after pelvic floor reconstruction. Focusing our interest on the PVDI questions 17 (urination frequency), 18 (urgency), 19 (urgency incontinence, OAB wet) and 27 (nocturia) and considering for each of these symptoms only three categories “no symptoms or not at all”, “somewhat or moderately” and “quite a bit” we evaluated statistically the significance of the interesting effects by applying the nonparametric tests of Cochran (Cochran's Q-tests) and McNemar. The Cochran's Q-tests were firstly applied to test about significance the global time effects of surgery on the prevalence rates (rel. frequencies) of each of the single symptom categories, whereas the McNemar tests were performed only by significant global time effects to localize significant differences in the investigated prevalence rates between pairs of phases. As nominal level of significance (type I Error) were $\alpha=0.05$ accepted.

Results

For all investigated symptoms the prevalence rates of the outcome “no symptoms or not at all” in the total population significantly increased during the time from 32 - 43 % in the baseline to 57-74 % 24 months after surgery, whereas the prevalence rate of the symptom outcome “quite a bit” was significantly reduced from 25–29 % in the baseline to ca. 2 - 7 % at the end of the observation period. The improvement effects even appeared 6 months after surgery and lasted to 2 years (table). Further analyses revealed similar significant time and efficacy effects on all symptom categories when considering the subpopulations defined by the cystocele (N=142) or rectocele (N=135) repair (data not shown). Moreover, it is to remark, that the same results have also been obtained, when evaluated the intent to treat (ITT) population after replacing missing values according to the LOCF (last observation carried forward) method.

Urgency, urge incontinence and nocturia									Cochran's Q-tests for testing global time effects (p-values)	McNemar - tests for testing simple effects (pairs of phases with significant differences)
Total- population (n=277)	baseline		6 m after OP		12 m after OP		24 m after OP			
	(0)		(1)		(2)		(3)			
	abs. freq.	rel. freq.	abs. freq.	rel. freq.	abs. freq.	rel. freq.	abs. freq.	rel. freq.		
PFDI 17 (urination frequency)										
symptom free	91	32,90%	186	72,40%	180	72,60%	138	74,60%	p < 0.00001	0/1, 0/2, 0/3
somewhat or. moderat.	105	37,90%	58	22,60%	55	22,20%	44	23,80%	p < 0.00001	0/1, 0/2, 0/3
quite a bit	81	29,20%	13	5,10%	13	5,20%	3	1,60%	p < 0.00001	0/1, 0/2, 0/3
<i>observed cases</i>	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 18 (urgency)										
symptom free	99	35,70%	181	70,40%	176	71,00%	131	70,80%	p < 0.00001	0/1, 0/2, 0/3
somewhat or. moderat.	93	33,60%	60	23,30%	58	23,40%	47	25,40%	p = 0.00247	0/1, 0/2
quite a bit	85	30,70%	16	6,20%	14	5,60%	7	3,80%	p < 0.00001	0/1, 0/2, 0/3
<i>observed cases</i>	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 19 (OAB wet)										
symptom free	119	43,00%	189	73,50%	187	75,40%	137	74,10%	p < 0.00001	0/1, 0/2, 0/3
somewhat or. moderat.	87	31,40%	51	19,80%	50	20,20%	41	22,20%	p = 0.0012	0/1, 0/2
quite a bit	71	25,60%	17	6,60%	11	4,40%	7	3,80%	p < 0.00001	0/1, 0/2, 0/3
<i>observed cases</i>	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 27 (nocturia)										
symptom free	90	32,50%	155	60,30%	149	60,10%	104	56,20%	p < 0.00001	0/1, 0/2, 0/3
somewhat or. moderat.	110	39,70%	91	35,40%	82	33,10%	71	38,40%	n.s.	n.s.
quite a bit	77	27,80%	11	4,30%	17	6,90%	10	5,40%	p < 0.00001	0/1, 0/2, 0/3
<i>observed cases</i>	277	100,00%	257	100,00%	248	100,00%	185	100,00%		

Table: Absolute und relative frequencies of the three symptom outcomes before (baseline) and 6, 12 and 24 months after surgery for the PFDI symptoms 17, 18, 19 and 27 in the total sample population (n=277). The frequencies at each observation time point (phase) refer to the number of subjects observed at that phase. Global time effects on the prevalence rates of the single outcomes were tested about significance with the Cochran's Q-tests. Whenever a global effect was significant, differences in the prevalence rates between phase pairs were tested about significance with the McNemar tests. Red colored p-values and phase pair numbers indicate statistical significances at a Bonferroni corrected level of significance (say α^* , where $\alpha^* < \alpha = 0.05$).

Interpretation of results

This study gives high evidence that OAB symptoms often occurs in patients with cystoceles and rectoceles and that many patients can be permanently cured by pelvic floor surgery with Mesh (Elevate anterior/apical and posterior/apical). Even for those patients with quite a bit OAB symptoms significant improvements emerge in about 80 % of the cases with long lasting effects (at least over 2 years).

Concluding message

Over active bladder symptoms can be caused by cystoceles and rectoceles and be cured by pelvic floor surgery. Women with OAB-symptoms should be adviced to have vaginal examination to seek for a curable cause of OAB.

Disclosures

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