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PROLENE MESHES AND SACROSPINOUS FIXATION IN THE TREATMENT OF FORESEEN 500 PATIENTS WITH PROLAPSE; OUTCOMES, COMPLICATIONS, QOL AND ANATOMICAL CHANGES EVALUATION

Hypothesis / aims of study

Objective evaluation of the success rate of new techniques (Prolift) in comparison with sacrospinous fixation on a large population and QoL assesment before and after operations. (1)

Study design, materials and methods

A 3-year open multicenter prospective randomized comparative study running in 5 centres. Our aim was to operate on the population of 500 patients divided into 3 groups (A-150 –anterior defect=anterior Prolift, B- 200 posthysterectomy vaginal vault prolapse divided randomly by the computer into subgroup BA - treated with sacrospinous fixation=Amreich procedure and subgroup BPT = total Prolift, C-150- posterior defect= Prolift posterior). Examination comprises of history, urodynamics (ICS standards) and ultrasound. MRI is used in group B. All patients fill out QoL questionnaires (PISQ, UIQ, CRAIQ, POPIQ, ICIQ, UDI, CRADI, POPDI), first four were analyzed. (2) These methods were used again in 3 to 6 months after the operation. Type, frequency and relevance of peri- and postoperative complications were documented. Statistics include the process of contingent squares, parametrical analysis for quantitative magnitude levels, classic regression analysis and logistic regression- SAS 9 pack (ANOVA and t-tests). MRI parameters are the subject of the next publication.

Results

Until now, 361 patients underwent the surgery and the planned figures will be reached in 6 months. Still, subject of evaluation are those who passed follow up terms - 225 women.

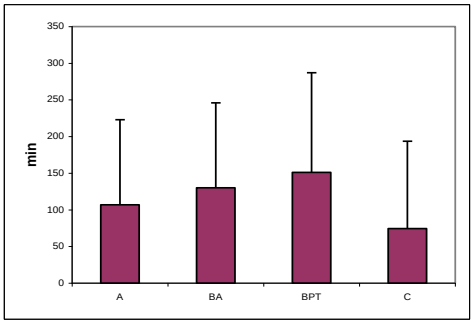
Table 1: Demography

	mean (SD)				P
	A	**BA**	**BPT**	**C**	
age	64.5 (10.9)	64.1 (8.41)	64.0 (9.3)	62.6 (9.6)	0.672
BMI	27.9 (3.8)	28.0 (3.9)	26.1 (3.6)	28.2 (4.4)	**0.025**
parity	2.1 (0.8)	2.5 (0.7)	2.1 (0.7)	2.2 (0.7)	0.090

Table 2: Patients distribution in groups (361 cases until now)

A	**BA**	**BPT**	**C**	**Total**
125	40	83	113	361

Graph 1: Operation time



Graph 2: Blood loss during operation

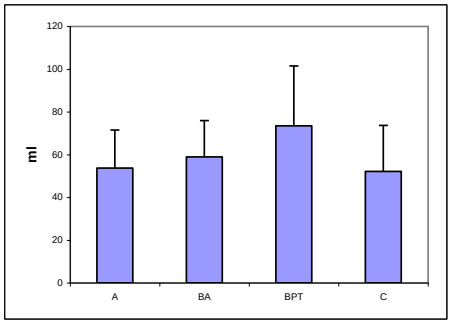


Table 3: Complications rate in the groups

	A (*n*=70)	**BA (*n*=25)**	**BPT (*n*=50)**	**C (*n*=80)**	**P**
Severe bleeding	6	4	4	2	0,09
Bladder injury	0	0	1	0	0,33
Bowel injury	0	0	0	1	1
Protrusion	6	0	8	6	0,14
Prolapse recurrence	6	6	3	8	0,13
De novo SUI	22	6	11	6	**0,001**

De novo urgency	3	7	4	8	**0,02**
Pelvic pain	3	0	5	1	0,08
Dyspareunia	3	1	3	1	0,43

Table 4: POPQ staging changes after the operations

	A	**BA**	**BPT**	**C**
Aa	**0.000**	**0.003**	**0.000**	0.32
Ba	**0.000**	**0.000**	**0.000**	0.53
C	**0.000**	**0.000**	**0.000**	**0.000**
Ap	0.42	**0.030**	**0.001**	**0.000**
Bp	0.23	**0.000**	**0.000**	**0.000**
tvl	**0.016**	**0.002**	0.26	0.46

Questionnaires: UIQ, POPIQ and CRAIQ were analyzed exhaustively; we found significant improvement in all the domains of UIQ and POPIQ with no difference between the groups. Only the bowel symptoms limitations of CRAIQ haven't improved in SSF group. PISQ – statistical improvement in all the parameters with no difference between the groups.

Interpretation of results

Table 1: Demographic data in all the groups is comparable.

Table 2: Unbalanced figures in Group B are due to the planning of controls in study centres; this insufficiency will be corrected before ICS meeting.

Graphs: High statistical significance for both parameters in favour of sacrospinous fixation = shorter operation time ($p < 0,0001$), smaller blood loss ($p<0,0004$), probably due to several cases of greater bleeding in the BTP group during the learning curve.

Table 3: No difference between the groups; only he SUI de novo incidence was low in C group and de novo urgency most frequent with SSF. It seems the reason of lower SUI frequency in C group is due to the fact that method doesn't influence the anterior compartment structures responsible for continence, whereas definitive evaluation of de novo urgency in group BA is to be done after it is completed.

Table 4: Upwards lifting of monitored points is highly statistically significant with relevant exceptions in respective areas of anterior and posterior meshes repair. That means all the techniques used delivered satisfactory results concerning the prolapse treatment.

Questionnaires: The lack of positive influence of sacrospinous fixation on the bowel function can be possibly explained by the interference of fixation stitches in the immediate vicinity of bowel and nervous plexi. Surprisingly, the sexual function was improved in all the techniques including SSF.

Concluding message

The surgical techniques under discussion revealed to be suitable instruments for pelvic organ prolapse repair with comparable outcomes, acceptable complications rates and sufficient influence on the subjective perception of the patient including her quality of life.

References

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Specify source of funding or grant	**This project was supported by the Grant IGA of The Ministry of Health of the Czech Republic No. 9309-3.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Our study was registered at FDA (evidence number NCT00572702, www.clinicaltrials.gov).**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of the University Hospital Na Bulovce, Prague, Czech Republic.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**