**284**

Halaska M[1], Sottner O[2], Maxova K[2], Hurt K[2], Vlacil J[2], Kolarik D[2], Mala I[3]
***1.*** *Dept. of Obstetrics and Gynecology, Charles University in Prague, 1st Medical Faculty and Faculty Hospital Bulovka and Faculty Hospital Bulovka,* ***2.*** *Dept. of Obstetrics and Gynecology, Charles University in Prague, 1st Medical Faculty and Faculty Hospital Bulovka,* ***3.*** *Faculty of Statistics, University of Economics, Prague*

# A RANDOMIZED MULTICENTRIC PROSPECTIVE COMPARISON OF PROLENE MESHES AND SACROSPINOUS FIXATION IN THE TREATMENT OF PELVIC ORGANS PROLAPSE.

Hypothesis / aims of study
The primary objective of our study was the comparison of success rate of prolene surgical kits and of sacrospinous fixation on a large randomized cohort. As secondary objectives we evaluated the complications of the methods used, operation time and quality of life changes before and after operations.

Study design, materials and methods
We performed a 3-year open multicenter prospective randomized comparative study running in 5 centers, approved by the Ethics committee and registered at FDA. We were able to include the population of 469 patients divided into 3 groups (A- 150 - anterior defect=anterior Prolift, B- posthysterectomy vaginal vault prolapse randomized by the computer into subgroup BA - 74 treated with sacrospinous fixation = Amreich procedure and subgroup BPT - 104 = total Prolift, C-141 - posterior defect = Prolift posterior). Examination comprised of history, urodynamics (ICS standards) and ultrasound. MRI was used in group B. All patients filled out QoL questionnaires (PISQ, UIQ, CRAIQ, POPIQ, ICIQ, UDI, CRADI, POPDI), first four were included into the analysis. These methods were performed before and 3 months after the surgery. We documented frequency and relevance of peri- and postoperative complications. Parametric tests (ANOVA and t-tests) and the analysis in contingency tables were used for statistical analysis (performed in SAS v.9.2). MRI parameters are the subject of the next publication.
Statistics included the process of contingent squares, parametrical analysis for quantitative magnitude levels, classic regression analysis and logistic regression- SAS 9 pack (ANOVA and t-tests).

Results
At the end of the trial we haven't reached planned numbers (469 vs. 500) but all the groups including randomized ones reached statistical significance.

Table 1: Demography

| | mean (SD) | | | | P |
|---|---|---|---|---|---|
| | A | BA | BPT | C | |
| age | 65.7 (9.3) | 66.41 (9.62) | 63.37(10.12) | 64.37 (10.28) | 0.48 |
| BMI | 27.42(3.73) | 27.62 (3.80) | 26.81 (3.73) | 28.00 (4.10) | 0.15 |
| parity | 2.08 (0.89) | 2.32 (0.68) | 2.08 (0.71) | 2.12 (0.79) | 0.37 |

Table 2: Patients distribution in groups

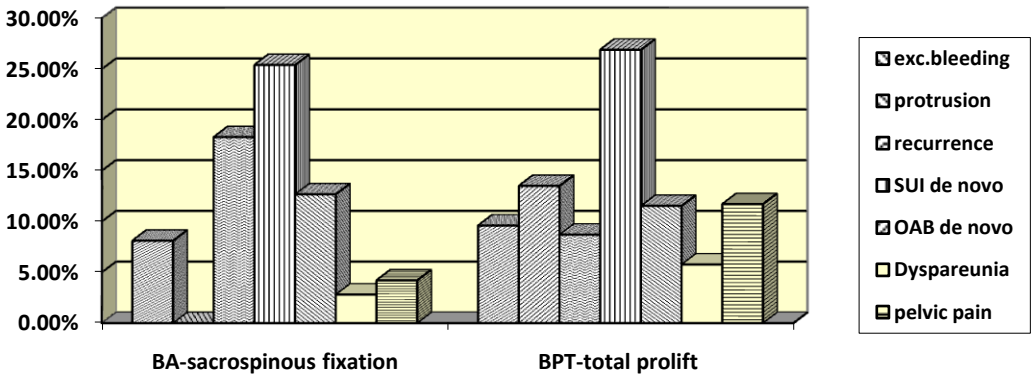
| A | BA | BPT | C | Total |
|---|---|---|---|---|
| 150 | 74 | 104 | 141 | 469 |

Table 3: Complications rate in the groups

| | A | BA | BPT | C | P |
|---|---|---|---|---|---|
| Severe bleeding | 9 (6%) | 6 (8.1%) | 11 (9.6%) | 2 (1.5%) | 0.80 |
| Bladder injury | 3 (2.01%) | 1 (1.3%) | 4 (3.81%) | 0 | 0.41 |
| Bowel injury | 0 | 0 | 0 | 1 (0.74%) | 1 |
| Protrusion | 10 (9.7%) | NA | 14 (13.5%) | 6 (5.4%) | 0,11 |
| Prolapse recurrence | 3 (3.3%) | 13 (18.3%) | 9 (8.7%) | 5 (4.5%) | 0.07 |
| De novo SUI | 33 (25.4%) | 18 (25.4%) | 28 (26.9%) | 11 (9.9%) | 0.86 |
| De novo urgency | 7 (5.4%) | 9 (12.6%) | 12 (11.5%) | 11 (9.9%) | 0.81 |
| Pelvic pain | 6 (8.6%) | 3 (4.2%) | 12 (11.7%) | 2 (1.8%) | 0.11 |
| Dyspareunia | 4 (3.1%) | 2 (2.8%) | 6 (5.7%) | 2 (1.8%) | 0.47 |

Statistical significance P for BA vs. BPT

Graph 1: Comparison of the most frequent complications rate between randomized groups




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 after the operation with no difference between the groups.

Interpretation of results
Table 1: Demographic data in all the groups is comparable.
Table 2: Computerized randomization procedure included into this particular group smaller number of patients with no other factor influence
Table 3: No difference between the groups; only the SUI de novo incidence was low in C Group. The reason of lower SUI de novo frequency in C group is due to the fact, the method doesn't influence the anterior compartment structures responsible for continence.
The only statistically difference between most important randomized groups was nonexistence of protrusion in the group without heterologous mesh implants (BA).
Questionnaires:
The comfort of all small pelvis organs function increased in all the groups including the sexual function.

Concluding message
1. 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 quality of life.
2. Randomized comparison of two techniques without and with the use of prolene meshes proved the acceptable rate of complications of vaginal meshes with better
fixation ability of this material in the short term follow up.
3. The comfort of all small pelvic organ functions including the sexual function increased in all the groups.

References
1. Maher C,et al.: Surgical management of pelvic organ prolapse in women. Neurourol Urodyn, 2008, 27: 3-12
2. Wetta, LA, et al.: Synthetic graft use in vaginal prolapsed surgery: objective and subjective outcomes. Int Urogynecol J, 2009, 20: 1307-1312


| | |
|---|---|
| ***Specify source of funding or grant*** | **Grant of the Ministry of Health Care of the Czech Republic, number NS 10453-3/2009** |
| ***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).** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **Yes** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |
| ***Specify Name of Ethics Committee*** | **Local Ethical Committee University Hospital Na Bulovce** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |