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PROSPECTIVE RANDOMIZED CONTROLLED STUDY OF THE USE OF A SYNTHETIC MESH (GYNEMESH®) VERSUS A BIOLOGICAL MESH (PELVICOL®) IN RECURRENT CYSTOCELE

Hypothesis / aims of study

Aim of the study is to evaluate the surgical correction of recurrent cystocele using two different prosthetic materials : Gynemesh® (synthetic) and Pelvicol® (biological), both applied with an identical tension free technique, with particular attention to the incidence of erosions and the impact of this surgical approach on the quality of life and sexuality.

Study design, materials and methods

Between September 2003 to July 2005, 118 female patients with recurrent Pelvic Organ Prolapse (POP) stage $\geq$ 2 were enrolled. The pre-operative work up included: history, clinical examination with vaginal profile using POP-Q score, Q-Tip test for urethral hypermobility, conventional urodynamic studies and completion of questionnaires (King's Health Questionnaire[1], Wexner score[2] for anal incontinence and constipation, and a Sexuality score). All patients signed a detailed informed consent form before participating in the study.

The patients were randomized into two groups (computer generated randomization list): in the first group the cystocele was corrected with a Prolene soft® synthetic mesh; in the second group a biological mesh was used made of acellular porcine dermis (Pelvicol®). All the patients underwent Tension-free Cystocele Repair (TCR) [3] and High Levator Myorraphy (HLM).

The results were analyzed using three statistical tests: T-test, McNemar Chi squared test and Wilcoxon test. We considered $p<0.05$ as statistically significant.

Results

The mean age was 64.35 years (range 49-79), median parity was 2 (range 0-5); 168 patients (93.3%) were post-menopausal. Follow up ranged from 6 to 28 months. The groups were matched for age, parity and menopausal status. There were no significant differences between the two groups regarding storage and voiding symptoms, urodynamic parameters and grade of prolapse. Pre and post-op symptoms are reported in Table 1 and 2 for Gynemesh and Pelvicol group. In Table 2 the anatomical results of Gynemesh® and Pelvicol® group are reported. Post op Urodynamic data of both groups are reported in Table 3

Table 1 – Pre and post-op symptoms Gynemesh®

	Gynemesh® # (%)	Pelvicol®	P*
Increased Day time frequency	27(29,03)	6(6,89)	0.72
Urgency	12(12,9)	21(24,13)	0.42
Urge Urinary Incontinence	12(12,9)	21(24,13	0.267
Nocturia	15(16,12)	24(27,58)	1
Hesitancy	12(12,9)	0(0)	1
Slow stream	15(16,12)	6(6,89)	0.54
Felling of Incomplete emptying	12(12,9)	9(10,34)	0.68
Perineal pain	0(0)	0(0)	0.47
Dyspareunia	12(12,9)	12(13,79)	0.72
Constipation	9(9,67)	6(6,89)	0.72
Heaviness	3(3,22)	3(3,44)	1

* McNemar Chi-square test

Table 2

	Gynemesh® # (%)	Pelvicol® # (%)	P*
Urethrocele $\geq$ 0	36(38,7)	27(31,03)	0.45
Cystocele $\geq$ 0	27(29,03)	39(44,82)	0.38
Rectocele $\geq$ 0	6(6,45)	3(3,44)	0.61

* McNemar Chi-square test

Table 3

	Gynemesh®	Pelvicol®	P
First desire to void	56-344 ml (mean 190.46 ml SD 71.06)	45-450 ml (mean 189.83 SD 86.87)	0.97*
Maximum Bladder capacity	209-548 ml (mean 384.5 ml SD 73.69)	150-655 ml (mean 405.58 ml SD 102.32)	0.27*
Detrusor	18	27	0.55**

overactivity			
Pressure at Maximum flow	8-57cm H2O (mean 31.75 cm H2O SD 24.62)	4-54 cm H2O (mean 25.70 cm H2O SD 13.53)	0.58*
Maximum flow	5-25 ml/sec (mean 13.59 ml/sec SD 6.15)	7-21 ml/sec (mean 13.83 ml/sec SD 4.78)	0.72*

* Wilcoxon
** McNemar Chi-square test

Interpretation of results

The analysis of the results shows no statistically significant differences in anatomical correction of POP; with an identical impact on symptomatology and on functional data.
Quality of life was significantly improved according to the King's Health Questionnaire both globally (mean sum of all the domains) and in the specific areas of limitations of everyday activities, physical-social limitations, personal relationships and emotions (Wilcoxon test; $p<0.05$). There was a statistically significant variation in sexuality (frequency of intercourse, libido, satisfaction during intercourse, dyspareunia) in the Pelvicol® group respect to the Gynemesh® group (p 0.01). An absence of erosions was observed in the Pelvicol® Group and 6 cases in the Gynemesh® group (p 0.02)

Concluding message

Both materials provide a satisfactory anatomical correction of the anterior segment, with a statistically significant improvement of prolapse-related symptoms and voiding symptoms and with a positive impact on the quality of life. In addition, the Pelvicol® mesh has a greater effect with regards to improvement of sexuality and, of fundamental importance, there is an absence of erosions in the post-operative follow up, which leads us to suggest that this material could be a safer option for surgical correction of recurrent POP.

References

1. Int Urogynecol J (2005) 16: 176-181.
2. BJOG. 2001 oct; 108(10): 1057-67
3. J Urol 2004;171: 305.

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