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PROSPECTIVE RANDOMIZED CONTROLLED STUDY BETWEEN TWO DIFFERENT PROCEDURES TO SUSPEND THE VAGINAL VAULT: HIGH LEVATOR MYORRAPHY AND UTEROSACRAL VAGINAL VAULT SUSPENSION.

Hypothesis / aims of study

The primary objective of this prospective randomized study is to evaluate the anatomical efficacy and the safety of two different transvaginal techniques for suspension of the superior vaginal segment in patients with Pelvic Organ Prolapse (POP) ≥ stage 2: High Levator Myorraphy (HLM) (1) and Uterosacral Vaginal Vault Suspension (UVVS) (2). The secondary objective is to define the impact of these procedures on anorectal function, sexuality and Quality of Life (QoL).

Study design, materials and methods

Between September 2005 and December 2006, 116 female patients were enrolled. The pre-operative work-up included: history, POP-Q score, Q-Tip test, conventional urodynamic studies and questionnaires (King's Health Questionnaire, Wexner score for constipation, and a Sexuality score). The patients were randomized into two groups: in the first group we used the HLM procedure for vaginal vault suspension; in the second group the UVVS was performed. All the patients underwent correction of cystocele with a Polypropylene mesh applied "tension-free" and vaginal hysterectomy. The results were analyzed using: T-test, McNemar Chi-squared test and Mann-Whitney U test. We considered $p<0.05$ as statistically significant.

Results

The groups were matched for demographic characteristics as reported in Table 1.

Table 1

	HLM	**UVVS**	**P***
Patients (#)	58	58	0.18
Age	50-78 years (mean 66.3),	45-78 years (mean 60.2),	0.25
Parity	0-4 (median 2)	1-8 (median 2)	0.97
Menopause	54 patients (93.1%)	48 patients (82.8%)	0.08
Body Mass Index	20.31-35.56 (mean 26.2)	20-34.25 (mean 25.98)	0.49

* Mann Whitney U test

There were no significant pre-operative differences between the two groups regarding storage and voiding symptoms, urodynamic parameters and grade of prolapse.
Pre and post-operative symptoms are reported in Table 2 for HLM and UVVS groups.

Table 2

	LM # (%)	**UVVS # (%)**	**P***
Increased daytime frequency	13 (22.4%)	23 (39.7%)	0.18
Urgency	21 (36.2%)	25 (43.1%)	0.57
Urge urinary incontinence	18 (31.1%)	25 (43.1%)	0.38
Nocturia	12 (20.7%)	17 (12.1%)	0.57
Hesitancy	4 (6.9%)	6 (10.3%)	0.61
Slow stream	17 (29.3%)	14 (24.1%)	0.75
Feeling of incomplete emptying	3 (5.2%)	9 (15.5%)	0.37
Dyspareunia	13 (22.4%)	16 (27.6%)	0.13
Constipation	15 (25.9%)	13 (22.4%)	1
Heaviness	4 (6.9%)	5 (8.6%)	0.61

* McNemar Chi-square test

In Table 3 anatomical results for HLM and UVVS groups are reported.

Table 3

	LM	**UVVS**	**P***
Point Aa ≥ 2	33 (56.9%)	32 (55.2%)	1
Point Ba ≥ 2	20 (34.5%)	23 (39.7%)	1
Point C ≥ 2	2 (3.4%)	15 (25.95)	0.47
Point Bp ≥ 2	5 (8.6%)	2 (3.5%)	1
Total Vaginal Length	Mean 7.2 cm	Mean 8.9 cm	0.04

* McNemar Chi-square test

Post operative Urodymanics data are reported in Table 4

Table 4

	HLM	**UVVS**	**P**
First desire to void	46-232 ml (mean 120.1, SD 72.21)	30-347 ml (mean 136.69, SD 71.91)	0.29*

Maximum Bladder capacity	250-644 ml (mean 378.4, SD 78.87)	191-481 ml (mean 360.76, SD 72.31)	0.33*
Pressure at Maximum flow	12-60 cmH_20 (mean 25.2, SD 13.22)	69.60 cmH_20 (mean 25.24, SD 811-92)	0.99*
Maximum flow	4-25 ml/sec (mean 13.8,SD 4.52)	1-40 ml/sec (mean 14.75, SD 9.18)	0.64*
Detrusor overactivity	17 patients(29.3%)	22 patients (37.9%)	0.05**
Urodynamic SUI	4 patients (6.9%)	7 patients (12.1%)	1**

* Mc Nemar Chi-square test ** T test

"De novo" Symptoms are reported in Table 5

Table 5

	HLM	**UVVS**
Stress urinary incontinence	5 (8.6%)	8 (13.8%)
Urge incontinence	0	7 (12.1%)
Urgency	2 (3.3%)	5 (8.6%)
Increased daytime frequency	3 (5.2%)	9 (15.5%)
Nocturia	6 (10.3%)	7 (12.1%)
Slow stream	11 (18.9%)	5 (8.6%)
Dyspareunia	5 (8.6%)	5 (8.6%)
Constipation	7 (12.1%)	8 (13.8%)

Quality of life was significantly improved in almost all domains according to the King's Health Questionnaire, with the exception of Personal Relationships in HLM group, and General Health Perception, Sleep and Severity Measures in UVVS group.

In the UVVS procedure, angulation of the left ureter with hydronephrosis was observed in 5 patients (8.6%) which was diagnosed in the immediate post-operative period and resolved after removal of the suture. No intra-operative complications occurred in the HLM group. Vaginal mesh erosions were present in 12% of HLM group and 17% in UVVS group (p 0.34)

Interpretation of results

Both procedures provide significant anatomical correction of all vaginal segments. However the correction of the anterior segment was less effective. A possible explanation for this finding could be that the vaginal axis is displaced caudally by vault suspension. An additional aggravating factor could be the tension free application of the mesh anteriorly without anchoring sutures which does not provide adequate contrast to the tension resulting from the central segment suspension. The mean Total Vaginal Length is 7.2 cm in HLM and 8.9 cm in UVVS group (p 0.04), but this does not coincide with an improvement in sexuality, as demonstrated by incidence of post-operative dyspareunia. There is a statistically significant improvement of the voiding symptoms and prolapse-related symptoms, with a good impact on the quality of life.

Concluding message

This study demonstates that the two vaginal vault suspension techniques are equivalent regarding anatomy, function and QoL. UVVS has a higher incidence of major complications involving the higher urinary tract, which, in our opinion, is an important factor to consider when selecting the appropriate surgical procedure.

The recent introduction of trans-perineal techniques for the correction of central vaginal prolapse seems promising, and results of ongoing trials are eagerly awaited.

References

1. Urology (2000) 56 (suppl 6A); 50- 54.
2. Am J Obstet Gynecol (1993) 168; 1669-74

FUNDING: None

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the San Carlo-IDI Sanità Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.