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RANDOMIZED PROSPECTIVE TRIAL COMPARING PROLIFT TOTAL AND SACROSPINOUS FIXATION WITH NATIVE TISSUE VAGINAL REPAIR IN THE MANAGEMENT OF VAGINAL VAULT PROLAPSE AFTER HYSTERECTOMY FOR PATIENTS WITH LEVATOR ANI AVULSION INJURY, WITH A 1-YEAR FOLLOW-UP

Hypothesis / aims of study

The primary aim was to compare, with a 1-year follow-up, the efficiency of two standard surgical procedures for vaginal vault prolapse - Prolift total and sacrospinous fixation with native tissue vaginal repair - for patients who have suffered at least two compartment prolapse after hysterectomy and been diagnosed with levator ani avulsion injury.

We have data going back to 2008 indicating that avulsion injury is closely associated with prolapse. We decided to define and diagnose - by means of 4D ultrasound - the high risk group of women and test whether they might benefit from one of those standard surgical techniques.

At present there is no clear indication whether or not to use mesh in patients with prolapse. There is no study available where the diagnosis of levator avulsion is a determining condition for a particular type of prolapse surgery.

Study design, materials and methods

This is a single-centre, prospective, randomised interventional trial of two standard surgical procedures for post-hysterectomy vaginal vault prolapse: Prolift total (Prolift) and sacrospinous vaginal fixation (Amreich-Richter procedure) with native tissue vaginal repair (SSF). All eligible patients had undergone hysterectomy and attended our urogynecological unit during the period from 5/2008 to 12/2010 with at least two compartment prolapse (POPQ ≥ II). They were diagnosed by 4D ultrasound with avulsion injury and then randomly divided into two groups. The POPQ classification for prolapse was used, and diagnosis of avulsion injury was performed by 4D ultrasound tomographic imaging using the levator urethra gap measurement in three axial slices (at minimal hiatal dimension and two above, 2.5 mm apart, during the pelvic floor muscle contraction - PFMC)

The randomisation process was carried out the night before surgery by email from a remote centre after sending the hospitalisation number of the patient. Both procedures were performed by experienced surgeons (KS, JM) who are familiar with both the procedures as standard procedures performed at the unit. The follow-up period was one year, with intermediate check-up after 3 month to diagnose any complications in the healing process, to plan subsequent anti-incontinence procedure in case of urinary incontinence (TVT-O), and to diagnose complications. The preoperative and postoperative assessment procedures were identical. (POPQ examination, 4D ultrasound with saving volumes: at rest, during PFMC and at Valsalva).

Preoperative levator assessment and avulsion diagnosis from 4D volume was performed at the time of diagnosis (2-3 months prior to surgery) to fulfil the main inclusion criteria. Other volume analysis was performed offline after completion of the study. The analysis was semi-blinded (the analysing doctor was not aware of the POPQ score and the procedure, but in most cases the implants were visible on ultrasound).

Prior to the study power analysis was performed; data was analysed using Statistica 10 – StatSoft.Inc software (Tulsa,USA). Descriptive analyses are provided, and comparisons between the groups were performed after normality testing by two-sample t-test. The failures were defined as any point at POPQ >-1, while the ultrasound criteria for failure was defined as urethra or bladder below the lower margin of the symphysis at maximal Valsalva more than 10 mm. The failures were analysed using Pearson Chi-Square test.

Results

During the study period there 592 patients underwent surgery for some sort of compartment prolapse in our unit: 132 were after hysterectomy and 72 of them had avulsion injury. They were randomised into two groups: 36 patients in the Prolift group and 34 patients in the SSF group. There were no drop-outs during the follow-up process. The reliability of the randomisation process and preoperative data is summarized in Table 1.

Table 1 Preoperative	Prolift N=36	SSF N=34	t	p	Prolift SD	SFF SD
Age	63.444	62.500	0.404	**0.687**	8.614	10858
Height (cm)	163.806	163.000	0.561	**0.576**	6.173	5.815
Weight (kg)	73.139	74.824	-0.688	**0.494**	9.894	10.602
BMI	27.230	28.210	-1.103	**0.274**	3.215	4.188
parity	2.139	2.176	-0.207	**0.837**	0.833	0.673
Aa	1.306	0.882	1.164	**0.248**	1.721	1.274
Ba	4.111	3.618	0.845	**0.401**	2.435	2.450
C	2.111	1.471	0.690	**0.492**	3.897	3.863

TVL	8.111	8.029	0.396	**0.693**	0.919	0.797
Ap	0.389	0.706	-0.807	**0.423**	1.761	1.508
Bp	2.417	2.441	-0.036	**0.971**	2.872	2.743
GH	4.778	4.559	0.886	**0.379**	0.989	1.078
PB	3.639	3.941	-1.179	**0.243**	1.150	0.983
Hiatal Area - Valsalva (cm^2)	43.522	43.117	0.137	**0.891**	12.491	12.223

The results at 1-year follow-up are summarized in Table 2

Table 2 1 year follow-up	Prolift N=36	SSF N=34	t	p	Prolift SD	SFF SD
Aa	-2.417	-0.853	-7.019	**0.000**	0.649	1.158
Ba	-2.389	-0.118	-7.533	**0.000**	0.645	1.684
C	-6.167	-3.235	-4.618	**0.000**	1.298	3.568
Ap	-2.333	-1.765	-2.278	**0.026**	0.717	1.304
Bp	-2.333	-1.353	-2.839	**0.006**	0.717	1.937
GH	3.333	3.500	-0.978	0.331	0.632	0.788
PB	4.556	4.794	-1.115	0.269	0.843	0.946
TVL	7.361	7.147	0.833	0.408	1.073	1.077
Hiatal Area Valsalva (cm^2)	29.576	36.992	-2.682	**0.009**	7.443	14.248
UVJ Valsalva (cm)	-1.163	-0.008	-6.415	**0.000**	0.744	0.762
Bladder Valsalva (cm)	-1.076	1.231	-10.365	**0.000**	0.721	1.111
The reference point for UVJ (uretro-vesical junction) and bladder measurement is the lower margin of symphysis						

There was one failure in the Prolift group (2.8%) and 22 failures in the SSF group (64.7%), (Pearson Chi-Square: 30.39; p<0,001), according to the POPQ examination and clinical failure definition. In addition, there was 1 failure in the Prolift group (2.8%) and 21 failures in the SSF group (61.7%) according to the ultrasound criteria. The protrusion rate in the Prolift group was 8.3% - 3 cases. The vaginal spotting rate in the SSF group was 14.7% - 5 cases. (Pearson Chi-Square:0.701; p=0.402). There were 3 cases in the SSF group who underwent re-operation for symptomatic prolapse diagnosed at the 3-month intermediate follow-up.

Interpretation of results

The classical Amreich-Richter procedure in patients with prolapse after hysterectomy and avulsion levator injury has a higher failure rate and was significantly inferior to the Prolift total procedure. Consequently the Prolift total procedure, with a failure rate of 2.8% at 1-year follow-up and a protrusion rate of 8.3%, is the method of choice for this type of prolapse.

Conclusion

This is the first prospective randomised study adopting the 4D ultrasound diagnosis of levator avulsion into the indication algorithm for prolapse surgery. This study shows a greatly superior effect of mesh implantation to native tissue repair in patients with levator avulsion injury.

Disclosures

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