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LAPAROSCOPIC AND ROBOTIC ASSISTED LAPAROSCOPIC SACROCOLPOPEXY: A RANDOMIZED CONTROLLED TRIAL IN THE ERA OF MINIMALLY INVASIVE SURGERY

Hypothesis / aims of study
The abdominal sacrocolpopexy is considered to be a gold standard in surgical treatment of apical vaginal prolapse. Minimally invasive approaches specifically reduce morbidity associated with open sacrocolpopexy. Laparoscopic sacrocolpopexy has similar outcomes to abdominal sacrocolpopexy (1). When compared to open techniques, robotic abdominal sacrocolpopexy is associated with less blood loss, shorter lengths of stay, and longer operative times. The present randomized study compares laparoscopic sacropexy (LSC) and robotic assisted sacropexy (RASC) in women with advanced pelvic organ prolapse (POP) to demonstrate the equivalence between the two techniques

Study design, materials and methods
Consecutive patients referred to our tertiary Department of Urology for symptomatic stage >II POP according to the POP-Q classification were prospectively randomized to test the clinical equivalence of RASC and LS, using a predetermined computer-generated randomization code. The local ethics committee approved the study . All patients signed an informed consent. Preoperative evaluation included detailed medical and urogynaecological surgery history, evaluation of storage symptoms, voiding symptoms, urinary incontinence (ICS standardization) and sexual activity, clinical examination, urodynamic study. Patients completed self-administered Urinary Distress Inventory Short Form (UDI-6), Incontinence Impact Questionnaire–Short Form (IIQ-7), Female Sexual Function Index questionnaire (FSFI). All procedures were performed by 2 senior surgeons, with standardized technique. Surgical technique in laparoscopic and robotic-assisted is the same. Patients were followed up at 1, 3, 6, and 12 months after surgery, and then annually. At each visit, patients underwent clinical examination, evaluation of urinary and sexual symptoms, uroflowmetry with PVR measurement and Patient Global Impression of Improvement (PGI) questionnaire. Furthermore patients completed self-administered UDI-6 and IIQ-7 questionnaires annually and FSFI at 1 and 2 years. All the data present in our database were collected and recorded along the follow up period.The following outcomes were recorded: a) anatomic outcomes, b) functional outcomes c) complications d) global patient perceptions. Then we evaluated the difference between the two groups in terms of hospital stay length, blood loss, operating time. Statistical analysis was performed by using the non parametric Mann-Whitney U test was used for analysis of continuous variables and the categorical data were analyzed by using X2 test. All calculations were performed using IBM-SPSS® version 22.0 (IBM Corp., Armonk, NY, USA, 2013). A two-sided p-value <0.05 was considered significant

Results
From May 2013 to April 2016, 21 women have been randomized to RASC and 19 to LSC. The mean follow-up was 15,5 months for RASC and 32.05 for LSC. No significant inter-group differences emerged in the pre-operative evaluations of age (mean 63.5 vs 58.82 yrs for RASC and LSC respectively, p=0.06) and BMI (mean 24.59 vs 25.41 kg/m2 for RASC and LSC respectively, p=0.55).The objective success rate was 81% for RASC vs 78,9% for LSC (p=0,6), 85% for RASC vs 79% for LSC (p=0,8) and 100% for RASC vs 94,7% for LSC (p=0,57) for cystocele, rectocele and point c/D repair respectively. Although not significant, operating time was longer for RASC (mean 213 min for RASC vs 184 min for LSC, p=0.11) and intra-operative blood loss was higher in RASC (mean 32 ml for RASC vs 47 ml for LSC, p=0.014). No difference emerged in hospital stays (mean 3.8 days for LSC vs 3.9 days for RASC, p=0.76). Functional results are reported in table 1. No major complications were detected, only 2 grade III complication according to Clavien-Dindo classification has been reported in the LSC group (1 bladder injury and 1 mesh exposure). The subjective success rate was very high, 100% of patients of both groups reported to be “much satisfied” and “very much satisfied” at the PGI-I questionnaire.

Interpretation of results
Anatomic success rate was high in both groups, with more improvement in RASC group probably for the best technical characteristics of robotic procedures. Functional outcomes were comparable. These results were confirmed by PGI-I. Our work showed a relatively small increase in operative time in the robotic group, but it was not statistically significant, probably because the operating time in robotic procedure included docking and undocking time. Intraoperative blood loss was low in both groups mostly for RASC, however the statistical difference was not clinically significant. Mean hospital stay was about 4 days in both groups, this result is included in benefits of minimally invasive surgery.

Concluding message
RASC aims at providing a similar excellent outcome as LSC in terms of anatomical results, satisfaction rate, complications, sexual function and voiding and storage symptoms relief.

Tab 1. Evolution of urinary symptoms and sexual function after surgery

	RASC			LSC		
	Pre-operative	Post operative	P	Pre operative	Post operative	p
Voiding Symptoms	19 (90.5%)	0	<0.01*	16 (94.1%)	1(5.9%)	<0.01
Storage Symptoms	16 (76.2%)	6 (28.6%)	0.013	10 (52.6%)	5 (26.3%)	0.12
Stress urinary incontinence	2 (9.5%)	3 (14.3%)	0.1	2 (10.5%)	1 (5.3%)	0.1
Urge urinary incontinence	3 (14.3%)	2 (9.5%)	0.1	3 (16.7%)	1 (5.3%)	0.6
Mixed urinary incontinence	3 (14.3%)	0	<0.01	4 (22.2%)	2 (11.1%)	0.68
Sexual intercourse	20 (95.2%)	12 (57.1%)	0.008	15 (83.3%)	16 (88.3%)	0.1
Sexual dysfunctions	8 (38.1%)	1 (4.8%)	0.016	4 (22.2%)	1 (5.6%)	0.3

* Significant p-value <0.05

References

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