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ABDOMINAL VS LAPAROSCOPIC SACROCOLPOPEXY: SUBGROUP ANALYSIS OF A PROSPECTIVE RANDOMIZED TRIAL

Hypothesis / aims of study

Abdominal sacrocolpopexy (AS) has been used extensively in patients with advanced-stage, mid-compartment pelvic organ prolapse (POP). We have recently performed a RCT comparing abdominal (AS) versus laparoscopic Sacrocolpopexy (LS) demonstrating that LS provides results as good as those of AS in terms of anatomical correction and functional outcomes. In the present study we performed a subgroup analysis in which enrolled patients were divided in 3 subgroups: Sacrocolpopexy (SC) for vaginal vault prolapse, Hysterectomy and SC for advanced utero-vaginal prolapse and Hysterosacropexy (HS) when uterus was preserved. The aim of this study is to compare AS vs LS in each of the subgroups

Study design, materials and methods

The RCT compared LS and AS in women referred to our tertiary Department of Urology for symptomatic stage >2 POP. The local ethics committee approved the study and the trial was registered at www.clinicaltrials.gov. All patients were assessed by means of a focused urogynaecologic history. Urinary symptoms were recorded according to the International Continence Society (ICS) criteria and categorized into urinary incontinence (stress, urgency, mixed UI), voiding and storage symptoms. Patients were assigned to one of the two groups (LS or AS) according to a computer generated block randomization sequence with randomization occurring at the time of surgical scheduling. Surgery was performed by two senior surgeons skilled in both procedures. The procedures were standardized as much as possible to ensure consistency. The primary outcome was the quantitative evaluation of the POP-Q system. Cure was defined as prolapse stage I or less, for the apex or point C/D \leq -5 for total vaginal length at least 7 cm. Secondary outcomes included complication rate, operating time, intra-operative blood loss, hospital-stay length, functional results and satisfaction (PGI-I scores). The analysis was performed in the 3 different surgical subgroups: SC for vaginal vault prolapse (group 1), Hysterectomy and SC for advanced utero-vaginal prolapse (group 2) and HS when uterus was preserved (group 3). The power calculation was performed using the PS Power and Sample Size ver.3.0, 2009. The Mann-Whitney, Wilcoxon, McNemar, X2 test with Yates' correction or Fisher's exact tests were used. Kruskal-Wallis test with post-hoc correction was used in comparisons among the 3 subgroups. A two-tailed p-value <0.05 was considered significant. All calculations were performed using IBM-SPSS® version 22.0 (IBM Corp., Armonk, NY, USA, 2013).

Results

200 consecutive patients affected by symptomatic stage >2 POP were considered for the main RTC. 79 were excluded and 121 patients participated in the RCT after giving informed consent. After randomization, 60 patients were allocated to the open approach (AS) and 61 to the laparoscopic one (LS). In this sub-analysis we compared 3 surgical subgroups: Group 1 (28): 14 AS, 14 LS; Group 2 (45): 24 AS, 21 LS; Group 3 (47): 22 AS, 25 LS. The statistical analysis showed the groups were comparable for demographic and clinical characteristics. As expected, women in group 3 (uterus preservation) were younger, with a lower number of menopause patients and lower previous surgery for urogynaecological reason. Table I reports perioperative details for each subgroup. Intra-operative median blood loss was higher in the abdominal approach ($p < 0.0001$) except for group 3 where no statistical difference was observed ($p = 0.166$). Hospital stay was longer in AS in all the 3 subgroups ($p \leq 0.005$) and median operating time was longer for laparoscopic approach in group 3 ($p < 0.0001$) and group 2 ($p \leq 0.022$) but not in group 1 ($p = 0.926$). No significant differences in the grade of complications were found among surgical subgroups in open ($p = 0.845$) as well as in the laparoscopic approach ($p = 0.250$). The majority of complications were observed in the patients who underwent hysterectomy plus SC (16/24 in AS and 9/21 in LS, $p = 0.193$). The 3 mesh exposures in LS included 2 patients in group 2 and 1 in group 1. The only exposure in the abdominal group appeared in group 2. Therefore exposure rate is higher when hysterectomy was performed. At a mean follow-up of 45.4 months anatomical results showed a statistical improvement for each POP-Q point in all subgroups. Pre and post-operative distribution of point C/D evaluation showed no statistically significant differences between laparoscopic and abdominal approach (Fig.1). However, considering any kind of POP (including stage I or II POP-q asymptomatic recurrences) in any compartment, an anterior compartment descensus was significantly more common in the laparoscopic group when uterus was preserved ($p = 0.015$). On the contrary a posterior compartment descensus was more frequently but not significantly present in the AS group (5 vs 3: $p = 0.736$). Functional improvement was statistically significant in all subgroups without significant difference in the post-operative assessment between AS and LS.

Interpretation of results

Primary objective of the study, the anatomical correction of apical prolapse, demonstrated both open and laparoscopic techniques are efficacious with no patients having apical prolapse recurrence in any of the subgroups. The presence of a post-operative anterior compartment descensus was more common in laparoscopic approach, especially when the uterus was preserved. On the contrary a posterior compartment descensus was more common in AS (5 vs 3: $p = 0.736$) although the difference was not significant both in the entire study population and the subgroups. These results could be explained by the differences in surgical approaches: to our experience the preparation of the posterior vaginal wall is easier by laparoscopy and anterior vaginal wall traction or preparations seem better for abdominal route. Despite differences in the presence of post-operative compartment descensus between groups, patient satisfaction was comparable: 57/60 in AS of patients and 55/60 in LS scored 1 in the PGI-I.

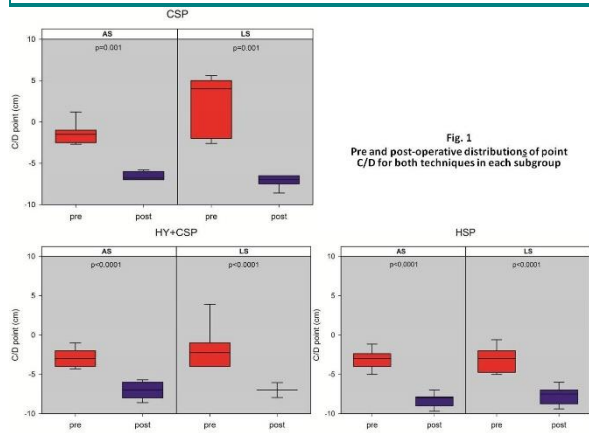
None of the patients was reoperated and no patient presented bulging symptoms or other disturbances related to POP, demonstrating that anatomical outcomes not always correlate with patient satisfaction.

Concluding message

Although the number of patients in the different subgroups is not large, this is the largest RCT comparing AS and LS in the above-mentioned subgroups and with the longer follow-up (median follow-up of 45.4 months; range 18-56 months). LS provides outcomes as good as AS with 100% anatomical correction of apical compartment in all the subgroups. Blood loss was less in LS in all except uterus preservation group. The Laparoscopic approach demonstrated shorter recovery times in all the subgroups and shorter operating time in group 2 and 3. Although the recurrence rate of anterior compartment is higher in LS especially when uterus is preserved, patients are equally satisfied with both procedures. These data allow us to state that LS can be considered the gold standard in the treatment of vault prolapse and an excellent option in patients with severe urogenital prolapse. Improvement in surgical techniques will probably improve the results in terms of anatomical outcomes on the different compartments and reduce the length of laparoscopic surgery as expertise of the surgeons and technical innovations accumulate.

Table I: perioperative details. Variable median and range were reported

	Hospital stay (days)			Blood loss (ml)			Operating time (min)		
	AS	LS	p	AS	LS	p	AS	LS	p
Overall	6 (4-9)	4 (3-10)	<0.0001	200 (0-1000)	100 (0-400)	<0.0001	180 (90-320)	215 (110-350)	<0.0001
Group 1	6 (4-8)	4 (3-6)	<0.0001	200 (0-400)	0 (0-200)	0.004	190 (95-255)	190 (110-260)	0.926
Group 2	6 (4-9)	4 (3-10)	<0.0001	250 (0-1000)	150 (0-400)	0.005	200 (120-320)	242 (160-290)	0.022
Group 3	6 (4-8)	4 (3-6)	0.005	100 (0-1000)	100 (0-300)	0.166	137 (90-240)	225 (140-350)	<0.0001



Disclosures

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