

## OPEN AND LAPAROSCOPIC SACROCOLPOPEXY DEMONSTRATE CLINICAL EQUIVALENCE: ONE YEAR RESULTS FROM THE LAS TRIAL, AN RCT COMPARING THE TWO APPROACHES FOR TREATING POST HYSTERECTOMY VAULT PROLAPSE

### Hypothesis / aims of study

Post-hysterectomy vaginal vault prolapse (PHVP) has a reported incidence of 3.6 per 1,000 woman years. While various procedures have been tried to correct PHVP, until now the most successful has been the abdominal sacrocolpopexy (ASCP) with mesh (1). The laparoscopic approach (LSCP) is claimed to be equally effective with ASCP, while having the advantage of reduced morbidity, shorter hospital stay and convalescence.

There has as yet been no randomised controlled trial (RCT) to compare the 2 procedures. The aim of this study is to test the clinical equivalence of the two procedures in terms of subjective and objective outcome.

### Study design, materials and methods

The study is a multicentre true (2-sided) equivalence trial. The null hypothesis is that the two forms of surgery are different for the two primary outcome measures: 1. quantitative description of pelvic organ prolapse (point C in POPQ) and 2. subjective patient global impression of improvement (PGI-I) for prolapse, both within pre-defined tolerances (2). Secondary to this the LSCP is tested for superiority over ASCP in terms of morbidity, symptom specific and generic quality of life, hospital discharge, convalescence and return to work/usual activities.

The study included patients referred with symptomatic Grade 2 or more PHVP (i.e. vaginal angles / "dimples" seen 1cm above the hymeneal remnants or lower) who wished to retain sexual function. The patients were randomised by procedure not by surgeon but the randomisation was blocked to ensure similar numbers of patients for each surgeon/procedure. All the surgeons performing study operations, were experienced in this type of surgery.

A sample size calculation was performed by interim analysis of the first 30 cases, considering there was no previous RCT comparing the two procedures (3). Based on these initial data a sample size of 25 for a two group 0.05 one-sided t-test was estimated to have 80% power to reject the null hypothesis that the laparoscopic and open are not equivalent (with a pre-specified margin of 1 cm for equivalence) in favour of the alternative hypothesis that the means of the two groups are equivalent, assuming that the expected difference in means is 0.0 and the common standard deviation is 1.4.

### Results

Twenty seven women underwent an open sacrocolpopexy (ASCP) and 26 women underwent a laparoscopic sacrocolpopexy (LSCP). The mean age in ASCP group was 60.67 years and 63.16 years in LSCP (SD 8.1 and 6.6). The mean BMI in ASCP group was 27.46kg/m<sup>2</sup> and 27.26kg/m<sup>2</sup> in LSCP group (SD 4.65 and 3.46). Seventy six percent in group 1 and 88% in group 2 had given birth to at least 2 children.

The mean pre-operative value for point C on POPQ was 0.12 cm in ASCP group and 0.28cm in ASCP group (SD 1.79 and 1.54), The mean point C height at 12 weeks was -6.65 cm and -6.48 cm respectively with mean difference -0.17 (95% CI -0.95 to 0.59). The mean point C height at 12 months was -6.63 cm and -6.65 cm for ASCP and LSCP respectively with mean difference 0.02 cm (95% CI -0.67 to 0.74).

Sixty-nine point six percent of women in ASCP group vs 64.0% in LSCP group, scored 1 (very much better), 26.1% vs 36% scored 2 (much better) and 4.3% vs none scored 4 (no change) on PGI-I at 12 weeks. Sixty six point seven percent of women in ASCP group vs 54.2% in LSCP group scored 1 (very much better), 25% vs 29.2% scored 2 (much better), none vs 12.5% scored 3 (a little better), 4.2% vs 4.2% scored 4 (no change) and 4.2% vs none scored 5 (a little worse) on PGI-I at 12 months. Differences were not statistically significant.

The mean haemoglobin drop in ASCP group was 2.33 mg/dl (SD 1.24) vs 1.12 mg/dl in LSCP group (SD 0.84), the difference being significant (p<0.01). The mean estimated blood loss in ASCP group was 240.41 ml (SD 231.7) vs 56.15 ml in LSCP group (SD 34.30), the difference being significant (p<0.01). The mean operating time in ASCP group was 131.16 min (SD 44.19) vs 143.6 min in ASCP group (SD 28.28). The mean post-operative 3-day morphine use through patient controlled analgesia (PCA) was 32.22 ml (SD 33.9) of the standard solution in ASCP group vs 16 ml (SD 29.1) in LSCP group. Differences were not statistically significant. Twice daily self-reported pain as a visual analogue score for pain was similar between the two groups during hospital stay.

Women in both groups scored similarly on all domains of PQoL at 12 weeks and 12 months

### Interpretation of results

The one year results of the trial suggest clinical equivalence of open and laparoscopic sacrocolpopexy with mesh particularly regarding point C on POPQ and PGI -I score for prolapse. Estimated blood loss, post-operative haemoglobin drop and PCA use appear less in the laparoscopic group. The operating time in both groups but predominantly in LSCP group might be exaggerated in the trial because during the proportionately large 30 case pilot phase the surgical procedure was delayed by the persisting efforts to standardise the techniques and apply similar standard operating procedures in both arms. A large number of peri-operative and post-operative morbidity and quality of life indices appear similar in the two groups. Further data on return to work and activities will be analysed.

### Concluding message

Where adequate experience and patient numbers are available, laparoscopic sacrocolpopexy with mesh is equivalent to open sacrocolpopexy with regards to vaginal vault correction. The laparoscopic approach might have the advantages over open surgery as seen in other types of surgery but further studies are required to confirm this.

### References

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<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>Yes</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Devon and Cornwall Research Ethics Committee</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>