

PROSPECTIVE-RANDOMIZED STUDY COMPARING HIGH UTEROSACRAL VAULT SUSPENSION VS. ABDOMINAL SACROCOLPOPEXY FOR THE REPAIR OF APICAL DEFECTS AND VAGINAL VAULT PROLAPSE.

Aims of study: To compare apical suspension success and complication rates between abdominal sacrocolpopexy (SCP) and high uterosacral vault suspension (HUVS) at 18 months follow up.

Material and methods: We ran a prospective randomized study to demonstrate a 20% difference in cure rates between two surgical techniques (HUVS & SCP) in patients with a severe apical defect defined as POP Q point C greater than or equal to stage 2. The number of patients needed to demonstrate this difference with a significance of 0.05 and a power of 80% is 124. The primary outcome is to evaluate surgical success defined as POP Q point C less than stage 2. Secondary objectives were to compare surgical time, intra and post surgical complications, anterior compartment defects and hospital stay between both surgical techniques. All patients were asked to sign informed consent and the protocol was approved by the Institutional Ethics Committee. The current data is a preliminary report of the first 81 (65%) randomized patients with a mean follow-up of 18 months. Success is shown as survival curves using the Kaplan Meier method.

Results: 42 patients who underwent SCP and 39 who underwent HUVS were compared with a mean follow-up of 18 months. Both groups had similar epidemiologic features. SCP vs HUVS: Age: 57.3±10.1 v/s 57.1±10.4. p= 0,60; Parity 3,8 ±1.8 v/s 4,0±2.0, p=0.60; Body Mass Index 29.0 ±4.4 v/s 31.0±5.7 , p=0,07. Previous POP Surgery 7.1% v/s 10.3 p=0.60; Previous Hysterectomy 21.4% v/s 15.4% p=0.40; Stage 4 POP: 23.8% v/s 30.8 p=0.40.

Our success rate for apical suspension at 18 months follow up was 100% for SCP and 87,2% for HUVS (log rank p 0.017). Success of surgery for anterior and posterior compartment defined as POP Q Ba and Bp points less than stage 2 at 18 months was 97.6% for SCP vs 71.8% for HUVS (p < 0.01) and 100% for SCP v/s 85,3% for HUVS (p=0,02). Hospital stay and surgical times were significantly lower in the HUVS group: 3.0±0.5, v/s 2,2±0,7 days p<0,01 and 105.5+28 v/s 82.8+25 minutes p<0.001. Intra-surgical complications rate were 2.4% for SCP v/s 0.0 % for HUVS groups (p=0.33). Post-surgical complications were 16.7% for SCP and 2.6% for HUVS groups (p=0.03).

Interpretations of the results: Sacrocolpopexy had lower failure rates than HUVS for correction of apical defects as well as anterior and posterior compartments. However, High Uterosacral Vault Suspension had shorter hospital stay and a lower post-surgical complications rate. There was no difference in intra-surgical complications between both techniques. We must conclude our study to confirm our preliminary results.

Conclusion: Sacrocolpopexy has lower failure rates than High Uterosacral Vault Suspension in severe apical defects correction.

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Comite de Etica Hospital Padre Hurtado
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes