

Calistar A vs. Calistar S - Comparative Cohort Retrospective Analysis of Single Incision POP Systems

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Statistical Analysis Plan

EXPERIMENTAL DESIGN

HYPOTHESIS

The hypothesis is that the low weight Ca S mesh reduces complications while maintaining the therapeutic effectiveness of the high weight Ca A mesh.

STUDY ENDPOINTS

The primary outcome of this retrospective study is to evaluate the effectiveness of Calistar A or Calistar S pelvic floor repair systems. Cure is defined according to Barber criteria (1):

- Lowest point of POP-Q < 0 (no points beyond the hymen)
- No subjective bothersome symptoms (absence of vaginal bulge symptoms)
- No re-treatment/interventions on year post procedure.

The secondary outcomes of this retrospective study are the objective (anatomical) and subjective ([disease specific] quality of life) outcome of anterior and apical prolapses treated with Calistar A or Calistar S.

Other outcomes are follow-up time, blood loss during surgery, operating time, operative and post-operative complications, any recurrent prolapse according to the POP-Q classification, repeat surgery for prolapse, mesh erosion, mesh shrinkage, vaginal pain.

SAMPLE SIZE

For this retrospective study all patients who received a Calistar A or Calistar S implant between January 1st 2011 and April 30th 2017 and who meet all the inclusion criteria describe in 6.2.1 *Inclusion criteria* will be eligible for enrolment. Patients who meet at least one of the exclusion criteria listed in 6.2.2 *Exclusion criteria* will be excluded. A total of 200 subjects are planned to be included in this clinical study, distributed among research centres, gives the possibility of having results with a significance level of 0.05 (95%) with a minimum discriminant power of 80%. The multicenter aspect will guarantee a sufficient number of patients to be included in the study.

STATISTICAL ANALYSIS

Demographic and baseline characteristics will be summarized using standard descriptive methods.

The primary outcome is a compound score and will be reported as the percentage of patients that meet all 3 criteria (with the confidence interval around that percentage). Paired t-test for continuous variables and non-parametric (Wilcoxon or Mann-Whitney U) test for percentages differences between pre- and post-operative will be calculated. Sensitivity analysis will be performed for the primary endpoint.

Secondary outcomes will be presented as percentages with 95% CI for dichotomous outcomes, means with 95% confidence intervals for continuous normally distributed variables and medians

with interquartile ranges for non-normally distributed variables. Differences between baseline and post-operative follow-up for the questionnaire scores will be calculated. Comparison between Calistar A and Calistar S pelvic floor repair systems will be performed.

BIBLIOGRAPHY

1. Barber MD, Brubaker L, Nygaard I, Wheeler TL, Schaffer J, Chen Z, et al. Defining success after surgery for pelvic organ prolapse. *Obstet Gynecol.* 2009;114(3):600–9.