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EVALUATION OF THE SAFETY AND EFFICACY OF PELVIC ORGAN PROLAPSE REPAIR USING SURELIFT® SYSTEM – PRELIMINARY RESULTS

Introduction

Pelvic organ prolapse (POP) is a disorder that may have significant impact on pelvic organ function and quality of life. Though various surgical techniques and modifications have been proposed, surgical treatment of POP has yet been exposed to failure and re-operations. The use of synthetic implant materials in pelvic reconstructive surgery has increased considerably in recent years. Two new concepts: 6 points of fixation and special tissue anchors to attach the mesh to the sacrospinous ligament are presumed to decrease surgical failure. However, clinical efficacy and safety remain uncertain. The objective of the study is to evaluate the efficacy and safety of POP repair using the SURELIFT system.

Design

A prospective study was conducted between January and November, a total of 20 women with symptoms attributed to POP and the condition-specific POP quantification stage (POP-Q)≥II, underwent surgical repair using SURELIFT(Neomedic International, Spain) . Primary endpoint was objective cure rate after 6 months of operation based on POP-Q system. Other outcome measures were patients' satisfaction. An objective cure was defined as POP-Q stage 0, improvement as stage I. Failure was defined as stage II or greater. Adverse events during follow-up were also evaluated.

Results

Median age was 66.4 (range 49-75), median parity 2.6 (range 1-5), mean body mass index 26.3±2,9. I present preliminary results at median follow-up of 6 months (2-11). 70% of the cases were recurrent cases and the other 30% (obese ,<45 years old or Defect of the collagen).Both anterior and posterior meshes were used in 4 patients, an isolated anterior mesh (anterior&Apical) in 16 cases, no posterior mesh alone . Concomitant procedures were posterior colporrhaphy in 4 cases, and hysterectomy in 3 cases.. No patient is considered failure. Pre- and post-operative maximum flow rate and post-void residual were not different except 1 urinary retention. 20 (100%) of the women were satisfied with the operation. There was no bladder or rectal perforation during the procedure. One of the cases had a hematoma on the perivesical space solve without problems. One case of mild pain in one of the anchors. During the follow up period no cases of mesh erosion.

Conclusion

The POP repair using the SURELIFT® system seems to be effective in terms of objective and subjective assessments with no significant complications. This technique allows the surgeon to treat the Apical prolapsed solve by an anterior approach avoiding the posterior route. Further studies are need it to have a large number of cases and longer follow up period.

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Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**