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ABDOMINAL INTEGRAL PELVIC RECONSTRUCTION PLUS OR MINUS BURCH COLPOSUSPENSION IN THE TREATMENT OF SEVERE URO-GENITAL PROLAPSE ASSOCIATED TO URINARY INCONTINENCE. A RCT WITH A MID-TERM FOLLOW-UP

Hypothesis / aims of study
This study assessed the efficacy of Burch colposuspension combined with integral pelvic floor reconstruction in patients with severe Pelvic Organ Prolapse (POP).
Study design, materials and methods
We prospectively enrolled 47 patients with severe urogenital prolapse and urinary incontinence due to urethral hypermobility. They underwent POP reconstruction and they were randomly assigned to receive a Burch colposuspension or not to correct incontinence. 24 underwent colposuspension and 23 did not undergo any type of incontinence correction. The uro-gynaecological work-up included clinical assessment, the Urogenital Distress Inventory (UDI) and Impact Incontinence Quality of life (IIQ) questionnaires, urological and gynaecological ultrasound scans, a complete urodynamic test with the urethral pressure profile and Valsalva leak point pressure (VLPP) with reduced prolapse. Methods and terms complied with International Continence Society Standards. Follow-ups were scheduled for 3, 6 and 12 months after surgery and then yearly.
Statistical analysis: Non parametric Mann-Whitney test for continuous data. X2 and Fisher exact tests for categorical data were used. The sample size of 47 patients provides a statistical power (1-ß) of 80% at a=0.05 for detecting 40% difference in proportion of any condition in the two groups when the lower frequency of condition equals 50%
Results
Mean age was 60±12 S.D (range 27-76 years) with a median parity of 2. Mean follow-up is 32 months (range 12-60). All patients presented with severe POP (>stage II on the basis of POP-q classification) and underwent abdominal integral pelvic floor reconstruction with Burch colposuspension (#24) or without (#23). Our technique is a so-called colposacropexy, with or without hysterectomy. After wide preparation of the anterior and posterior vaginal walls, two polypropylene meshes are fixed to the sacrum. The Burch colposuspension was performed in accordance with the standard technique. The two groups were well balanced in terms of preoperative clinical data, demographic characteristics and urodynamic results. Preoperative IIQ score was of 16±9.5 and UDI score was of 17.5±10 in the Burch group and 21.6±14.7 and 19.6±11.3, respectively, in the other group. Voiding symptoms and storage symptoms were cured in 100% and 83% respectively in the Burch group. They resolved in 91% and 87% in the group without colposuspension. Interesting data emerged on incontinence results. In the Burch group 14/24 (58%) are completely dry after surgery and incontinence persists in 10 (3 stress incontinence G1, 4 G2: 2 stress, 1 mixed and 1 urge incontinence, 3 stress G3). In the group without Burch 15/23 (65%) are dry. In the 8 patients with persistent incontinence 5 referred slight stress incontinence and only 2/5 used pads. Another 3 patients referred moderate or severe incontinence (2 stress incontinence G2 ed 1 G3). The inter-group difference is not significant ($p>0.05$) probably because of the few patients in each group. Post-operative IIQ score was of 3.6±3.5 and UDI score was of 4±3.5 in the Burch group and 5±4 and 4,5±4, respectively, in the other group.
Interpretation of results
Since the term sacropexy covers a series of different surgical techniques, they might play a role in accounting for differences in outcome not only with regards to prolapse correction but also incontinence resolution. As our approach not only corrects vaginal vault prolapse but also repairs anterior and posterior prolapse as well as urethral hypermobility, it provides excellent results in terms of POP and incontinence which is resolved in 65% of cases without Burch.
Concluding message
These preliminary data cast doubts on whether Burch colposuspension should be performed during sacropexy.

References

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the University of Perugia EC and followed the Declaration of Helsinki Informed consent was obtained from the patients.