

CASE-CONTROL STUDY TO EVALUATE RISK FACTORS FOR PROLAPSE RELAPSE

Hypothesis / aims of study

Different surgical approaches and different philosophies for prolapse repair are described in the literature. Any of them carries a rate of relapse regardless the skills of the surgeon or the attention to specific defects repair. To improve success prosthetic material for reconstructive surgery has been proposed. However, despite the reported higher anatomical success rate compared to conventional surgery, prosthetic materials in some cases carry morbidity and increase costs. Therefore ideally prosthetic material should be used only in patients with risk factors for relapse. In the past different authors have tried to identify these risk factors but, apart from an increased risk in women with previous prolapse surgery, many other are purely anecdotal. The aim of this study is to evaluate the clinical importance of such risk factors in order to identify a population which could potentially be candidate for the use of mesh.

Study design, materials and methods

In this study we recruited women with symptomatic genital prolapse involving the anterior and/or posterior vaginal segments. Women were assessed for prolapse, urinary and bowel symptoms with specific questionnaires. Prolapse was evaluated in supine position, on the maximal exertion and classified according to the ICS POP-Q System. Women were divided in two groups depending on the presence of the following risk factors in their medical history: previous prolapse surgery, obesity (BMI > 29), chronic broncopneumoniae, chronic straining at defecation, history of hernia or collagen disease. These women were then compared in a case control study with women without such risk factors and matched for age, menopausal status, parity, severity of prolapse. Anterior and/or posterior repair was performed by three fully trained surgeons and involved a fascial plication both anteriorly and posteriorly without using any prosthetic material. The two groups were compared for anatomical restoration and recurrence was considered in case of descensus ≥ 2 Stage POP-Q in the treated vaginal segment. Urinary and bowel symptoms were also collected at follow-up. The data were stored onto a dedicated database and analysed with SPSS for statistical analysis. The Fisher's exact test was used for statistical analysis and a P value < .05 was considered significant. Logistic regression analysis was performed to calculate a likelihood of recurrence in between the two groups.

Results

Sixty-seven women were prospectively included in this study. Forty-eight of them underwent an anterior repair, while 19 a recto-vaginal septum reconstruction. The mean age was 65.8 (range 44-83), 88.1% of them were in menopause and mean parity was 2.4. Mean time at follow-up was 21.6 months (range 6-61).

In table 1 characteristics of the 46 women with risk factors and the 21 women without risk factors are reported

Table 1.: Characteristics of women with and without risk factors

| | Risk Group (46 p.ts) | No Risk Group (21 p.ts) | Statistical significance |
|-------------------------------------|-----------------------------|--------------------------------|---------------------------------|
| Age (mean / range) | 65.8 / 44-83 | 65.6 / 47-79 | <i>n.s.</i> |
| Menopause % | 89.1% | 85.7% | <i>n.s.</i> |
| Parity (mean) | 2.7 | 2.0 | <i>n.s.</i> |
| Preoperative Prolapse Stage (mean)§ | 2.7 | 2.5 | <i>n.s.</i> |

§ ICS POP-Q System;

Previous prolapse surgery was present in 9 over 46 women with risk factors.

Six out of the 46 women with risk factors (13%) showed a recurrence, while among the 21 patient without risk factors only one woman (4.8%) presented a recurrence (p= 0.288).

At logistic regression women with risk factors showed a likelihood for recurrence 3 times higher than women without risk factors (OR= 3.00; 95% CI 0.337-26.645) even if not statistically significant.

Interpretation of results

These data support the clinical relevance of the considered risk factors for prolapse relapse. In fact, despite a lack of statistical significance in terms of recurrence rate between the two groups, the logistic regression showed a risk three times higher in women with risk factors compared to controls. A bigger study would probably raise statistical significance although we believe that our results are already clinically relevant. This could potentially justify the use of prosthetic material in this selected population.

Concluding message

At our knowledge this is the first case-control which evaluate reported risk factors for prolapse recurrence and confirming their clinical relevance.