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Full length article

Laparoscopic sacrocolpopexy with or without midurethral sling insertion: Is a two- step approach justified? A prospective study

Corina Christmann-Schmid[a,*], Esther Bruehlmann[a], Isabell Koerting[a], Joerg. Krebs[b]

[a] Department of Urogynaecology, Cantonal Hospital of Lucerne, Switzerland
[b] Clinical Trial Unit, Swiss Paraplegic Centre, Nottwil, Switzerland

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ABSTRACT

Objective: Most data support the fact that women with symptomatic pelvic organ prolapse (POP) with concomitant symptomatic or occult stress urinary incontinence (SUI) benefit from concurrent POP and anti-incontinence procedure. However some data support a delayed or 2-step approach.
The aim of this study was to demonstrate the effectiveness and safety of laparoscopic sacrocolpopexy (SCP) alone with a delayed approach for SUI to prove the justification of a 2-step approach.
Study design: A prospective study from 2014 to 2016 including women with symptomatic POP ≥ stage 2 prolapse and concomitant SUI or occult SUI.
Laparoscopic SCP for apical or multi-compartment POP with or without concomitant MUS insertion was performed.
Primary outcome measures were asymptomatic regarding SUI after prolapse surgery alone, persisting SUI with or without subsequent anti-incontinence surgery.
Results: A SCP alone was performed on 62 women. Stress urinary incontinence was seen in 31% with SCP alone and a third of those women needed an additional midurethral sling for persisting SUI. Women who chose a combined surgery for POP and incontinence with SCP and a suburethral sling the postoperative success rate regarding SUI was 100% with two women needing a sling release.
Conclusion: We showed that women with POP with concomitant stress urinary incontinence undergoing sacrocolpopexy benefitted from a two-step approach as only 11% needed an additional incontinence procedure. This study highlights the importance of pre-operative counselling. It should be tailored to the individual woman.

Introduction

Stress urinary incontinence (SUI) and occult SUI (oSUI) are common and frequently debilitating concomitant conditions in women undergoing prolapse surgery for pelvic organ prolapse (POP) [1–4]. By the age of 80 years, 11% of women require surgery for these conditions [5].

Stress urinary incontinence and pelvic organ prolapse share similar pathophysiological and etiological mechanisms [6–8], and both arise from failure of the pelvic floor support [6].

To date there are conflicting data available whether combined POP and anti-incontinence surgery should be performed concurrently, or a two-step approach in women with POP and symptomatic SUI or oSUI can be justified. On the one hand, there is strong evidence that postoperative SUI is less frequent after the combination of prolapse and anti-incontinence surgery compared to prolapse surgery alone [9–12]. However, it is reported that combination therapy results in more intraoperative complications and voiding dysfunction and less satisfaction with the surgery, may justify a two-step approach [4,13–16]. Furthermore, a two-step approach may be chosen and justified because a great percentage of women undergoing vaginal prolapse repair did not need any further anti-incontinence surgery or were cured of SUI by prolapse surgery alone [4,17].

Until 1996, the Burch uretheropexy, an abdominal procedure which can be performed by laparotomy or laparoscopically, was regarded as the gold standard operation to treat SUI with reported success rates up to 88% [18,19]. Ever since the introduction of the minimal invasive tension free vaginal tape (TVT), the midurethral sling (MUS) has become the new gold standard incontinence surgery [20,21].

For that reason a concomitant abdominal incontinence procedure like the Burch colposuspension was commonly chosen, if an

* Corresponding author at: Department for Urogynecology, Cantonal Hospital of Lucerne, 6000 Lucerne, Switzerland.
E-mail address: corina.christmann@luks.ch (C. Christmann-Schmid).

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abdominal prolapse surgery was performed, rather than changing to a vaginal approach.

To date there is a lack of data on the outcome of laparoscopic sacrocolpopexy (SCP) with concomitant or delayed midurethral sling (MUS) insertion in women with POP and symptomatic SUI or oSUI.

Is it possible that a delayed approach may also be justified after an abdominal POP repair as compared to a vaginal approach, as demonstrated by Borstad et al? [4]

The aim of this study was therefore to investigate the effectiveness and complications of laparoscopic SCP with delayed incontinence surgery (if necessary) using a MUS for women with POP and preoperatively diagnosed SUI or oSUI and to demonstrate the justification of a two-step approach.

Materials and methods

Patients and assessments

This prospective study (2014–2016) was performed at the Cantonal Hospital of Lucerne, Switzerland (tertiary referral hospital) on women with apical or multi-compartment POP ≥ stage II (Pelvic Organ Prolapse Quantification system points Aa, Ba or C/ D −1 cm or greater) [22] who with concomitant symptomatic SUI, stress-predominant mixed urinary incontinence (UI) or oSUI, underwent a combination of laparoscopic SCP and MUS insertion or SCP alone. The study was approved by the local ethics committee, Ethikkommission Nordwest- und Zentralschweiz, Switzerland. (01676). All women were provided with an informed consens. Women were operated with combined SCP and MUS or SCP alone based on published criteria, data and after extensive counselling to Borstad et al, van der Ploeg et al and Trabuco et al. [4,10–13,23,24].

The women were informed about the postoperative success rates, intra- and postoperative complications and the possibility of resolution of the stress incontinence symptoms if a combined procedure or a SCP alone will be performed according to latest data [4,10–13,23,24].

Women with pre-existing subjective and/ or objective voiding dysfunction, elevated post residual volume >100 ml or under clean intermittent catheterisation were advised to undergo SCP alone as this is a commonly accepted exclusion criteria to have a anti-incontinence procedure.

All other women with POP and concurrent symptomatic SUI or oSUI on examination were given the choice between the one- or the two-step approach as above mentioned.

Women who were not eligible for an abdominal procedure and who were excluded were those with a history of radiation therapy or with vesico-vaginal fistula or urethral diverticula. Women who have had a hysterectomy were not excluded.

The primary outcome measure was the presence of SUI after surgery.

Pre-operatively, all women underwent general gynaecological and specific urogynaecological examination as follows:

Women with objective and subjective symptomatic POP ≥ stage II, who were going to receive SCP were evaluated. All these women were asked for symptoms of SUI like urinary leakage on physical exertion, coughing, laughing or sneezing.

Furthermore, all women underwent multichannel urodynamic studies in order to objectify the symptoms. Urodynamic studies included a conventional filling-cystometry (with maximal bladder filling up to 500 ml) and a pressure-flow-study according to the recommendations of the International Continence Society (ICS) [25]. Residual urine was measured utilising clean intermittent catheterisation. An increased post-void residual (PVR) volume was defined as ≥100 ml [26].

Clinical cough stress tests in the lithotomy and standing position with a minimal bladder filling of 300 ml and/or pad-weight-tests were performed in order to assess overt SUI. Occult SUI (oSUI) was defined as clinically proven urinary leakage after prolapse reduction. A sponge holder was used to reduce the prolapse.

The Pelvic Organ Prolapse Quantification system (POP Q) was performed according to ICS in order to assess the degree of pelvic organ prolapse [22].

Pre-operatively concomitant OAB symptoms as defined by the IUGA/ ICS terminology with urgency, frequency, nocturia and with or without urge incontinence were recorded [25].

Recurrent UTI was defined as $\geq 10^5$ bacterial count in mid stream urine and at least 2 episodes per 6 months or 3 episodes per 12months.

After a follow-up period of 6–10 weeks post-operatively, women were asked for POP symptoms like for example “do you feel a bulge in the vagina” and for symptoms of SUI like “do you lose urine when coughing, sneezing, laughing or during physical exertion”.

Post-operatively women underwent a urognyaecological examination including performing the POP-Q, the cough test at full bladder capacity (at least 300 ml) in the lithotomy and standing position, and the evaluation of the PVR with clean intermittent catheterisation.

Women were asked for concomitant OAB symptoms as above mentioned (pre-operatively).

Post-operative increased frequency of UTI was defined as > 2 proven UTI.

Furthermore, women were examined regarding mesh extrusion and mesh-related pain.

Successful POP surgery was defined as POP-Q < stage II at any site and POP-Q points Aa, Ba ≥−1, C/D > 6. Success regarding SUI was defined as no subjective SUI symptoms present and no leakage on physical examination as described above.

All women with persisting SUI after SCP alone required longer follow-up or time to undergo subsequent anti-incontinence surgery, were still included in the post-operative analysis.

The head Urogynaecologist (CC) and two Urogynaecology fellows (EB, IF) of our Urogynaecology unit performed the pre- and post-operative examination.

Surgical procedures

The SCP was performed as described previously [27,28]. In women with a uterus, a subtotal or a total laparoscopic assisted vaginal hysterectomy was performed concomitantly. The anterior part of the mesh was placed at the level of the bladder neck. Posteriorly, the mesh was placed at the level of the perineal body. The mesh was attached with multiple 2-0 PDS (Ethicon) sutures. The cranial part of the Y-shape EndoGynious mesh (A.M.I GmbH, Austria) was attached to the longitudinal ligament of the sacral promontory with three staples (ProTack 5 mm; Tyco Healthcare, Mansfield, MA).

The TVT procedure was performed according to Ulmsten et al [20] using the TVT-exact device (Gynecare Ethicon).

Pre-operatively, all women received a single dose of prophylactic antibiotic treatment (Co-Amoxicillin 2.2 g), an in-dwelling catheter and a vaginal pack for 48 h.

The head surgeon, a Urogynaecology specialist (CC) performed all procedures using standard techniques.

Statistical analyses

The median and the lower and upper quartiles or proportions and 95% confidence intervals (CI) using the Clopper-Pearson exact