*ORIGINAL ARTICLE*

Annals of Agricultural and Environmental Medicine 2015, Vol 22, No 2, 293–296
www.aaem.pl

# Standardized modified colposuspension – mid-term results of prospective studies in one centre

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Surkont G, Wlaźlak E, Petri E, Suzin J. Standardized modified colposuspension – mid-term results of prospective studies in one centre. Ann Agric Environ Med. 2015; 22(2): 293–296. doi: 10.5604/12321966.1152082

## Abstract

**Introduction.** Burch colposuspension is still estimated as a 'gold standard' by the Cochrane Collaboration Group in the treatment of operative stress urinary incontinence (SUI) Some urogynecologists agree with this statement, some argue that Burch colposuspension should no longer be used.

**Objective.** The aim of this study was to evaluate mid-term effects and patient's satisfaction with standardized modified colposuspension performed in one centre.

**Material and methods.** Modified colposuspension was performed after standardization by 2 trained gynaecologists in 354 women. Data collected from 227 women were added to the final analysis of mid-term results. Average time from the operation to mid-term visit was 19 months (range 9–36 months).

**Results.** At mid-term visit, 86.3% of patients were cured. There was no case of post-void urine residual over 100 ml. Pain near the operated region was reported by 1 woman from agricultural region. No one reported negative impact of modified colposuspension on sexual activity or dyspareunia.

**Conclusions.** Modified colposuspension according to the E. Petri technique seems to be an operation that is safe and well-tolerated by women with preoperative stress urinary incontinence and paravaginal defect without urodynamic signs of ISD in mid-term observation.

## Key words

stress urinary incontinence, Burch colposuspension, success rates, complications

## INTRODUCTION

Considering the variety of causes of SUI, there are many surgical methods for treating this symptom; however, the Burch and sling procedures are the most frequently used [1, 2]. Burch colposuspension is still estimated as a 'gold standard' by the Cochrane Collaboration Group in operative stress urinary incontinence (SUI) treatment [3]. Some urogynecologists agree with this statement [3, 4], some argue that the Burch colposuspension should no longer be used [5]. The latter argue that alloplastic slings have taken over completely and there is no longer any indication for using other procedures [5]. During the last decade, there have been more publications on the higher rate of complications and lower cure rate after different tension-free slings than previously expected [3, 4, 6, 7]. Comparison studies TVT vs. Burch colposuspension showed a similar success rate and complication rate [8, 9].

Ulmsten and Petros introduced TVT procedure with detailed instruction for the technique called 'cook-book' [10]. Burch colposuspension was described in 1961 [11] and there are many modifications of the procedure and no one unified technique.

Burch colposuspension was evaluated in many studies but most of them were performed many years ago [3, 4]. In those times, different methods of evaluation were used and requirements of organizing urogynecological studies were also different. This often makes the comparison with newer studies on alloplastic slings not so easy and objective.

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Received: 15 May 2013; accepted: 21 June 2013

## OBJECTIVE

The aim of this study was to evaluate mid-term effects and patients' satisfaction with standardized modified colposuspension performed in one centre.

## MATERIAL AND METHODS

Data of patients who underwent modified colposuspension were analysed and the study subsequently conducted in the Clinic of Operative and Oncologic Gynaecology in the 1st Department of Obstetrics and Gynaecology at the Medical University in Lodz, Poland. Two gynaecologists who had undergone unified training in performing modified colposuspension, led by E. Petri, a world famous urogynecologist from Germany, operated on the women. Continuous exchange of experience and ideas has led to the design of a unified technique [3]. For years, Dr. Petri has been using standardized technique of colposuspension, and in last 30 years more than 5,000 procedures were performed in his departments.

According to the method used by Petri, modified colposuspension starts with a Pfannenestiel incision 5–10 cm long incision and the rectus muscles are carefully separated from the underlying transverse fascia. The pelvic side walls are opened by blunt finger dissection, staying strictly to the side wall, guided by Cooper's ligament and the obturator

fascia, completely avoiding the space of Retzius with its delicate neural and vascular supply. Pulling aside the rectus muscles in a v-shape with retractors, the surgeon places his index and middle fingers in the vagina to elevate the vaginal fornix. The perivesical and paraurethral fat is bluntly wiped off from the vaginal wall with a swab. A white tissue and the veins compressible help to confirm the paravaginal fascia by the vaginal finger (impossible if only the bladder wall is visualized). Two sutures are inserted through all layers of the tissue, except the vaginal epithelium, and laterally as far as possible in the vaginal wall. The first stitch is inserted at the level of the lower pole of the catheter balloon, and then to the nearest point on the ipsilateral iliopectineal ligament. The assistant ties the knots while trying not to elevate vagina too much, to avoid overcorrection. As described by Burch, complete apposition of the vaginal fascia and the ligament should be avoided. In most cases, there is at least 1.5 – 2 cm between the tissues, which is why permanent sutures are preferred (e.g. Ethibond® 0 with a strong MOX needle).

Excluded from this analysis were women after previous anti-incontinence procedures, e.g. an M-M-K operation and sub-urethral sling procedures. The women included were those who had undergone previous vaginal surgery to treat pelvic organ prolapse (POP). Also not included in this analysis were women with urodynamic signs of intrinsic sphincter deficiency (ISD), defined as maximal urethral closure pressure (MUCP) ≤ 25cm H2O evaluated during profilometry. Patients with combined procedures: modified colposuspension, POP procedures (with the exception of anterior repair) and hysterectomy for benign disease but not for malignant gynaecological diseases were included.

Stress urinary incontinence (SUI) was verified by a clinical examination, a one-hour pad test, urodynamic testing. Patients rated their subjective distress related to SUI on a visual analogue scale (VAS) ranging from 0 – 10, with 0 being 'no incontinence-related distress' and 10 being 'unbearable distress related to incontinence'.

Modified colposuspension was offered to women with SUI and paravaginal defect (type II Blaivais). Mixed incontinence – SUI and urge incontinence – with predominant SUI, was not a contraindication for anti-incontinence operative procedure. Anti-incontinence operations were not performed on patients with preoperative post-void volume above 100 ml, with neurological disease, which could have an influence on SUI symptoms, and mixed incontinence with urge incontinence being predominant.

Postoperative evaluation of the clinical effectiveness of the procedure was performed during mid-term visits. This included patients' reports, clinical findings and pad test results. The residual post-void bladder volume was sonographically determined. A post- micturition residual volume greater than 100 ml was defined as significant. Patients rated their subjective distress related to SUI on a visual analogue scale (VAS).

Patients with no symptoms of SUI, a negative cough test, a negative one-hour pad test (< 2 g difference) at the time of the postoperative match criteria for the cure group. Groups with improvement and failures were not selected, but all patients were combined who did not match the criteria for cure in one group – failures.

On mid-term visit, patients answered the question concerning the operation: 'Would you agree to have modified colposuspension again?' Patients were also asked to answer questions concerning pain in the operated region, dyspareunia and negative impact of operation on sexual function in a unified manner.

During the period 2001–2008, 2 trained gynaecologists performed modified colposuspension in 354 women. To the final analysis were included data collected from 227 women (64.1%), which was the percentage of women that took part in the mid-term visit (after a minimum of 9 months post-operation). The average time from the operation to the mid-term visit was 19 months (range 9–36 months).

## RESULTS

The median age of the study participants was 53.1 years (range 32–81). The group had a mean body mass index (BMI) of 28.6 (range 20–41); the median number of spontaneous deliveries was 2 (range 0–5), and 46 patients had a history of caesarean sections. Forty-one women had in operations performed previously to correct pelvic organ prolapse (POP).

The perioperative period, from the beginning of the operation until discharge from hospital, was analysed in all operated patients and separately in all patients who completed a 12-month visit.

In 354 patients, the mean pre-operative VSC was 8.4 (between 8 – 10). In 67 of 354 women (18.9%), combined procedures were performed:

- abdominal hysterectomy (partial or total) with or without adnexectomy – 19 (5.4%);
- transvaginal sacrospinous fixation Amreich-Richter – 31 (8.8%);
- vaginal hysterectomy – 4 (1.1%);
- posterior repair – 48 (13,6%).

Complications in the perioperative time are summarized in Table 1.

**Table 1.** Complications in perioperative time (n=354)

| Complication | No. of patients (%) |
|---|---|
| Infection in lower urinary tract | 38 (10.7%) |
| Post-void urine residual over 100 ml (1–6 days) | 4 (1.1%) |
| Post-void urine residual over 100 ml (>6 days) | 0 (0%) |
| Haematoma needed evacuation | 2 (0.6%) |
| Haematoma without evacuation | 1 (0.3%) |
| Intraoperative blood loss > 200 ml | 3 (0.8%) |
| Blood transfusion | 0 (0%) |
| Blood in urine | 3 (0.8%) |

After the operation, 9.6% (n=38) of the patients had symptoms of infection in the lower urinary tract. No difference was noted between combined and not-combined procedures.

During the first 50 procedures performed by both of surgeons, there were 4 cases of transient post-void urine residual lasting longer than 24 hours after removal of the Foley catheter. The problem lasted a mean of 3.7 days (1 – 4 days). There was no case of post-void residual lasting longer than 4 days. During the subsequent procedures (more than 50) there was no case of post-void residual lasting over

24 hours. No influence was observed of combined procedures on post-void residual problems.

All major complications, presented below, occurred in women who had modified colposuspension performed as the only procedure.

Haematoma in the retroperitoneal space was evacuated in 2 patients during the first 20 procedures. Haematoma in pelvic floor muscles, without signs of haematoma in the Retzius space, was diagnosed in one women (between 101 – 200 operations). It resolved non-operatively after 2 weeks. Blood loss over 200 ml was noticed in 3 cases during the first 50 operations. Bleeding stopped after tightening the colposuspension sutures, without addition sutures. The retroperitoneal space was drained 11 times during the first 100 procedures performed by both surgeons. There was no need for blood transfusion in any case.

In 3 cases, transient blood in urine was noticed. This occurred during the first 50 procedures by one gynaecologist, and lasted from 1 – 4 days. In the first case there was cystoscopy control which showed superficial bladder damage, and occurred in a patient after previous POP procedure. Foley catheter was left in place for 2 weeks, after which cystoscopy control showed no bladder damage. The remaining 2 patients had also previously had a POP operation. There was no case of intraoperative bladder perforation.

Among the women who attended mid-term visits there were patients who had complications in the peri-operative time:
– 2 women with transient post-void urine residual;
– 1 patient with haematoma needing evacuation;
– 3 patients with transient blood in urine.

In those 227 patients the mean pre-operative VSC was 9.2 (between 8–10).

Mid-term visit was completed 227 patients, 41 of whom were after combined procedure. Telephone was contact lost with 136 women; 1 woman refused to attend, but without giving a reason. She telephoned to inform that she was cured. The big drop-out by patients was due to population changes: at that time many people had moved to different districts and out of the city; others had changed their home telephones to mobile ones.

At mid-term visit, 86.3% (n=196) of patients were cured. According to ITT (intention to treat) analysis, assuming that all patients lost from post-op follow-up were failures, 55.4% of patients were cured. There was no case of post-void urine residual over 100 ml. Three patients reported symptomatic recto/enterocele. In 7 cases asymptomatic recto/enterocele >1 were noticed. There was no case where there were clinical signs of disruption of colposuspension sutures. Symptoms of *de novo* urge were reported by 2 women. One woman from an agricultural region reported pain near the operated area; she felt this pain during work but reported that there was no need for treatment.

From 104 women after only colposuspension and who answered questions concerning sexual activity, none of them reported any negative impact of the modified colposuspension on this aspect. In this group of patients, all of them reported that they would decide to have the operation again. VAC ranged from 0 – 3 (mean 0.9).

At mid-term visit, 13.7% (n=31) of patients were not cured. There was no case of post-void urine residual over 100 ml in this group of patients. One patients reported symptomatic recto/enterocele. In 2 cases, asymptomatic recto/enterocele >1 was observed. In 2 cases, signs of disruption of the colposuspension sutures were seen. Two women reported *de novo* urge.

Out of 18 women after colposuspension only who answered questions concerning sexual activity, none of them reported any negative impact of the modified colposuspension on this aspect.

In this group of patients, 29% of them (n=9) reported that they would decide against repeating this operation. VAC ranged from 3–10 (mean 7.2).

Mid-term results after colposuspension are summarized in Table 2.

**Table 2.** Mid-term results after colposuspension

| Symptom | No. of patients from cured group (%) (n=196, 86.3%) | No. of patients from failure group (%) (n=31, 13.7%) | Total (%) (n=227, 100%) |
|---|---|---|---|
| Post-void urine residual | 0 | 0 | 0 |
| Asymptomatic recto/enterocele | 7 (3.6%) | 1 (3.2%) | 8 (3.5%) |
| Symptomatic recto/enterocele | 3 (1.5%) | 1 (3.2%) | 4 (1.8%) |
| Disruption of colposuspension sutures | 0 | 2 (6.5%) | 2 (0.9%) |
| Pain in the operated region | 1 (0.5%) | 0 | 1 (0.4%) |
| Negative impact of modified colposuspension on sexual activity | 0 | 0 | 0 |
| Dyspareunia | 0 | 0 | 0 |
| Mid-term VAS for SUI | 0–3 (mean 0.9) | 3–10 (mean 7.2) | 0–10 (mean 1.8) |
| *De novo* urge | 2 (1%) | 2 (6.5%) | 4 (1.8%) |

## DISCUSSION

In 2007, Paulo Palma wrote an editorial with the title *'A requiem for the Burch'* [5]. The Cochrane Collaboration Group evaluated 33 trials involving a total of 2,403 women after Burch colposuspension, for which the cure rates were 68.9 – 88.0%. The benefit was maintained over time (RR of failure 0.51; 95% CI 0.34 – 0.76 before the first year, RR 0.43; 95% CI 0.32 – 0.57 at 1 – 5 years, RR 0.49; 95% CI.0.32 – 0.75 in periods beyond 5 years). Within the first year of treatment, the overall continence rate was approximately 85–90% [3, 8, 9]. Most studies comparing TVT with colposuspension summarise a comparable success rate [8, 9]. This means that the evidence available indicates that open colposuspension is an effective treatment modality for stress urinary incontinence especially. There are long-term (10–15 years) observations of Burch colposuspension available in the literature. There is no information about any reactions to the non-absorbable suture used in this procedure, no matter which kind was used [3, 4, 12].

In a review of the literature on Burch colposuspension there are numerous typical complications noted: intraoperative bleeding, bladder injuries, ureteral kinking or injury, voiding dysfunction and urinary tract infections. The main source of controversy is the incidence of complications which differ greatly depending on the author: between 0 – 21 %. This might be caused by different definitions of complications, operative techniques, or patient material. Some authors suggest that

the complications rate for Burch operation complications is too high, while others find colposuspension the optimal procedure for many patients [3, 4, 8, 9]. In a prospective randomised comparison of colposuspension and TVT, direct perioperative complications were different but comparable in their frequency [8, 9]. Obstructed voiding and secondary recto-enterocele are the clinically relevant complications after colposuspension, apparently correlating with the extent of elevation, thus overcorrection [3].

In the opinion of the authors of the presented study, in the population of operated women the risk of perioperative and mid-term complications was low, and the tolerance by the patients was good. There was no case of voiding dysfunction lasting longer than 4 days. Post-void residual lasting longer that 1 day happened occasionally, after the first 50 procedures by both gynaecologists. This was probably due to overcorrection and the learning curve. There was no case of dyspareunia in the evaluated group of patients. One woman from an agricultural region noticed pain during work, which occurred near the place where sutures were inserted into Cooper's ligament. Most of the major complications occurred during the first 50 procedures by both gynaecologists, probably as the consequence of the learning curve. In the authors' opinion, the correct indication for using the open anatomical spaces and reducing the extent of procedure, can reduce complications of colposuspension. Also, using the standardized optimal technique of operation introduced under the supervision of an experienced surgeon may have an influence on the percentage and types of complications.

Inclusion and exclusion criteria may always be a source of controversy. To minimize bias, in the presented study an attempt was made to avoid exclusions as often as possible. It was decided to include patients after combined procedures because it presented the possibility to make analysis, which was closer to everyday life in the authors' clinic. Only those women were excluded in whom colposuspension was combined with anterior repair, because in these cases, the Foley catheter was kept longer in the bladder than in women after colposuspension alone. This may have an impact on patients' perception of the procedure, as well as on the risk of urinary tract infection.

The unique aspect of this study is that the analysis was made on patients who were operated in the department where colposuspension was introduced for the first time, and with the use of the unified technique proposed by a world expert on this procedure. The learning curve was not excluded in order to make the presented results closer to real life. Patients with ISD were excluded from the analysis because it was not clear whether colposuspension should be offered in this group of women. Patients after previous anti-incontinence procedure were not included in the study since this may have had an important impact on the cure rate and patients' opinion about colposuspension. Also excluded were patients who had colposuspension performed together with an operation on a malignant gynaecologic disease, because extensive hysterectomy, as well as radio- and chemotherapy, may have had an impact on the patients' opinion and complaints.

Sexual satisfaction was evaluated only in the group of patients after colposuspension alone, as hysterectomy and POP operations may have had an additional impact on sexual satisfaction. The obtained results showed no negative impact of the procedure on sexual function. Patients noticed no dyspareunia.

There is no doubt that the TVT-concept as developed by Ulmsten and Petros is an excellent and successful option for the treatment of genuine stress incontinence. In the opinion of the authors, compared with the tension-free vaginal tapes, colposuspension remains the first choice in cases with marked paravaginal defects, and for women with unstable bladders caused by anatomical defects. Besides, colposuspension should be offered as an addition to all laparotomies necessitated by other pathologies in patients with SUI and paravaginal defect. In such cases, there appears to be no data proving that colposuspension produces worse results than suburethral slings, not only in complication rates, but also in the success rates.

The presented data confirms that modified colposuspension characterizes low risk of complications with a high rate of success, and is well tolerated by patients in mid-term prospective observations. The authors will continue thir observations in the future.

## CONCLUSIONS

Modified colposuspension according to the E. Petri technique seems to be a safe operation, well-tolerated by women with preoperative stress urinary incontinence and paravaginal defect without urodynamic signs of ISD in mid-term observation.

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