

Should an Anti-incontinence Procedure Be Routinely Performed at the Time of Pelvic Organ Prolapse Repair? An Evidence-based Review

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Published online: 19 June 2010
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Abstract The concept of prophylactic anti-incontinence surgery for women undergoing prolapse repair has been a popular and controversial debate in recent years. This article provides an evidence-based review of the current literature to determine the proper evaluation of the patient with prolapse, the predictive quality of preoperative urodynamics, and the selection of the appropriate anti-incontinence procedure. Based on this review, the midurethral sling predominates as the procedure of choice; however, there is poor evidence to suggest that routine usage of a prophylactic sling is warranted in treatment of the patient with pelvic organ prolapse.

Keywords Pelvic organ prolapse · Burch colposuspension · Midurethral sling · Urinary incontinence · Urodynamics · Pubovaginal sling

Clinical Trial Acronyms

CARE Colpopexy and Urinary Reduction Efforts
OPUS Outcomes Following Vaginal Prolapse Repair and Midurethral Sling
SISTEr Stress Incontinence Surgical Treatment Efficacy

Introduction

Pelvic organ prolapse (POP) and urinary incontinence are significant disease processes that affect women particularly within the 5th to 6th decades of life. The risk of surgery for

POP or urinary incontinence by age 80 is approximately 11.1%. Surgical intervention for POP with (22%) or without (41%) continence surgery was the attributed cause for 63% of this risk. This represents a lifetime risk of 7% [1]. The concept of anti-incontinence surgery at the time of POP repair has been a popular topic in recent years. Maybe the most prominent paper that brought this concept into the forefront was the CARE trial published in 2006 [2]. Members of the Pelvic Floor Disorders Network sought to determine if a standardized Burch colposuspension at the time of an abdominosacrocolpopexy (ASC) would reduce postoperative stress urinary incontinence (SUI) in patients without preoperative symptoms of SUI. The results were that women who did not receive the Burch procedure were more likely to report bothersome symptoms of stress incontinence than those in the Burch group (24.5% vs 6.1%; $P < 0.001$). For those patients without evidence of urodynamic stress incontinence with prolapse reduction, the Burch colposuspension reduced postoperative stress incontinence from 38.2% to 20.8% ($P = 0.007$). These results were so significant that enrollment was stopped after the first interim analysis because of a significantly lower frequency of stress incontinence in the group that underwent the Burch colposuspension. Conclusions from this study held that a prophylactic Burch procedure inferred protection from urinary incontinence that may be unmasked after repair of pelvic anatomy with the ASC procedure. Based on this study, arguments have been made to perform prophylactic anti-incontinence surgery at the time of prolapse repair. In this article, we will examine the role for anti-incontinence surgery at the time of POP repair. More specifically, should an anti-incontinence procedure be performed routinely during POP surgery in a prophylactic manner? If so, which procedures are to be performed, and are there any predictors of patient outcomes?

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Evaluation of Incontinence in the Patient with Pelvic Organ Prolapse

History and physical examination are the hallmarks for evaluation of any patient with complaints of POP or urinary incontinence. Dysfunction of the pelvic floor can manifest as uterine descensus, prolapse of the anterior (cystocele) or posterior (rectocele) wall of the vagina, and prolapse of the apex of the vagina with (enterocele) or without associated bowel protrusion, collectively identified as POP. POP may be independent of incontinence. The data on prevalence of POP is limited and highly variable. Increase in parity increases the risk of POP and the risk of surgery to correct POP. Parity alone appears to be the most significant variable related to surgery for POP. The risk of prolapse increases with each child but appears to level off after two children [3].

Currently, there are two methods for assessing the forms of POP that have been previously described: these are the Baden Walker system and the Pelvic Organ Quantification system (POPQ) [4, 5].

Following physical examination of the vaginal vault, demonstration of objective stress incontinence is essential for determining whether an anti-incontinence procedure is warranted. The most recent American Urological Association guidelines for management of SUI mandate that objective demonstration of involuntary loss of urine from the urethra with increased abdominal pressure is the *sine qua non* for diagnosis of stress incontinence. Other diagnostic testing includes a postvoid residual, urinalysis, and urine culture if indicated prior to anti-incontinence surgery. For patients with stage III POP, further diagnostic testing with either urodynamic evaluation or radiographic imaging is recommended [6]. Reduction of prolapse for evaluation of stress incontinence remains a controversy at this time. Though it seems to be highly beneficial, there is presently no standardized way to consistently perform prolapse reduction for purposes of evaluating stress incontinence. A sensible practice pattern would be to pursue a lower urinary tract investigation if there are clinical complaints of incontinence or obstructive voiding. My personal practice is to perform a fluorourodynamic test to look for occult urinary incontinence (urodynamic incontinence produced with reduction of the POP with and without a vaginal pessary). Formal pessaries can be obstructive; therefore, two 4×4 cm gauze pads are rolled into a ball and placed vaginally to provide support to the prolapsing vaginal vault (Figs. 1 and 2). The goal here is to mimic the support that would be obtained with a vault suspension to see if occult incontinence occurs with Valsalva maneuvers. Performing this exam can be cumbersome and it is not uncommon for the gauze pads to be expelled during the cough stress test.

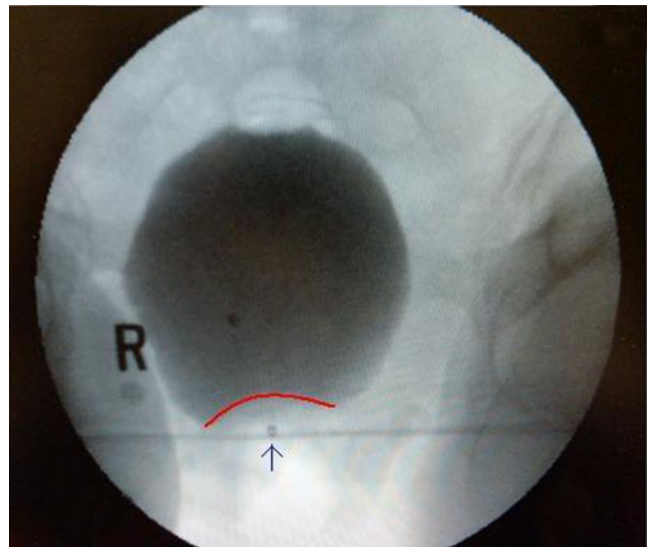


Fig. 1 Vaginal pessary or rolled gauze supporting the pelvic floor during urodynamic evaluation. Red semicircle depicts the area supported, allowing evaluation of the urethral sphincter (blue arrow) and stress incontinence

When evaluating stress incontinence in the patient with prolapse, the predictive quality of urodynamics on outcome after anti-incontinence surgery in published literature demonstrates inconsistent findings. In one of the earliest reports from Scandinavia, Borstad [7] reviewed the risk of developing SUI after vaginal repair of POP with a Manchester procedure. A 22% postoperative stress incontinence rate was identified; however, preoperative and postoperative urodynamics did not predict which patient would develop SUI after the repair. In a prospective study



Fig. 2 Unsupported vaginal vault with the location of the urethral sphincter unchanged (blue arrow). Prolapse of the vaginal vault and cystocele obscures fluorourodynamic evaluation for incontinence

by Chaikin [8], 24 continent women with POP underwent preoperative urodynamics with vaginal pessary placement. Occult urinary incontinence was identified in 14 (58%) of their patients. These patients underwent a pubovaginal (PV) sling and anterior colporrhaphy, while those without occult incontinence had anterior colporrhaphy only. Two patients with occult incontinence treated with a PV sling and anterior colporrhaphy developed postoperative incontinence, while none of the patients without occult incontinence developed postoperative incontinence. Due to the small sample size, statistical significance was not achieved. The authors concluded that a decision to perform concomitant prophylactic anti-incontinence surgery should be tailored to individual urodynamic findings [8]. In a follow-up study from the SISTEr trial, researchers sought to compare the predicative value to preoperative urodynamics for patients undergoing either a Burch procedure or a PV sling. This study, using a cohort of 655 patients, demonstrated that urodynamic parameters such as preoperative maximum flow rate (from pressure flow studies and noninstrumented flow studies), voiding pressures, and degree of abdominal straining were not associated with postoperative voiding dysfunction [9]. The summaries of the above studies and others indicate that there is a paucity of data to suggest that women with occult urinary incontinence are at risk for postoperative stress incontinence [10]. In addition, urodynamics alone seems a poor tool to assess if routine use of a prophylactic anti-incontinence surgery during prolapse surgery is warranted.

Choosing the Right Anti-incontinence Procedure

Once the decision has been made to perform an anti-incontinence procedure, the questions beckons, which one? Over the past 20 years, the treatment of female stress incontinence has been a moving target, with the newest and greatest treatment option seemingly right around the corner. Vaginal needle suspensions, bone anchored slings, Burch procedure, PV sling, the Gynecare tension-free vaginal tape (TVT) and TVT obturator (TVT-O; both by Ethicon, Inc., Somerville, NJ) systems, and Monarc Subfascial Hammock (American Medical Systems, Minnetonka, MN) are all procedures that have been touted to be the answer to female incontinence. Add this to the various types of prolapse repairs (eg, anterior colporrhaphy, posterior colporrhaphy, ASC, sacrospinous fixation, high utero-sacral vault suspension, and the various mesh procedures currently on the market for prolapse) and it can be quite perplexing to determine which anti-incontinence surgery would best fit a particular prolapse surgery. To determine the correct anti-incontinence procedure, certain criteria would have to be met. First, the procedure would have to be safe and

effective. Second, it should have low complication rates and have data demonstrating long-term effectiveness. Given these criteria and the most recent review of literature, the midurethral sling best fulfills these criteria.

Of all the previously mentioned anti-incontinence procedures, only the Burch procedure, traditional PV sling, and the midurethral sling (namely the TVT) have survived to be candidates for discussion. Though the TVT-O sling has gained significant popularity due to the ease of the procedure, few randomized studies in patients with prolapse and lack of long-term data make it unsuitable for discussion in this section. Previous studies have demonstrated an increased effectiveness of the PV sling over the Burch procedure for treatment of urinary incontinence [11]. However, a higher rate of postoperative voiding dysfunction and urinary urgency with the PV sling was noted. More recently, two studies have looked at the effectiveness of the Burch procedure and the midurethral sling with the ASC procedure. Costantini et al. [12] presented 47 women with preoperative urinary incontinence and randomized them to receive either a Burch procedure or no intervention for their urinary incontinence at the time of ASC procedure for clinical stage or grade prolapse greater than II (POPQ) or 2 (Baden Walker) based on their respective systems. Primary outcome measures for the two groups were a change in the incontinence rates as shown by bladder diary, number of daily pads, and stress test. Results were that significant incontinence occurred in 54% of the patients who underwent a Burch procedure at the time of ASC. These results were not significantly different from the group that did not receive the Burch procedure. In fact, 60.9% of patients with preoperative urinary incontinence who did not receive a Burch procedure achieved continence with the ASC procedure alone. The authors concluded that the Burch procedure did not provide any additional benefit for patients with urinary incontinence undergoing an ASC procedure for POP [12]. Earlier studies demonstrated that Burch colposuspension performed at the time of POP repair actually worsened continence rates [13, 14]. In accord with this finding, an internet survey of members of the American Urogynecological Society determined that 57% of respondents would not perform a prophylactic Burch procedure at the time of ASC. Reasons given for lack of compliance with the findings of the CARE trial included basing surgical intervention on preoperative barrier testing, preference of a prophylactic midurethral sling, and a staged (or “wait and see”) approach [15]. If the Burch procedure is not being used consistently as a prophylactic anti-incontinence procedure and fails to consistently provide protection against urinary incontinence in patients with POP undergoing ASC, what about the midurethral sling? An attempt was made to answer this question in a retrospective article comparing midurethral sling (TVT) and the Burch procedure. Patel et

al. [16] identified 150 women who had undergone an ASC with concomitant Burch or TVT procedure from January 2002 to December 2007. These women were randomized into three groups: genuine stress incontinence based on urodynamic testing or office cough stress test; potential stress incontinence based on lack of clinical symptoms but positive stress incontinence on urodynamics or office cough stress test; and no SUI with confirmation based on a negative office cough stress test and negative urodynamics. Outcomes were that subjects with preoperative stress incontinence who underwent a Burch procedure were more likely to have postoperative SUI compare to the TVT group (10 vs 0; $P=0.007$). The authors concluded that a midurethral sling (TVT) performed with an ASC procedure had lower rates of postoperative urinary incontinence, and that patients who underwent a Burch procedure were more likely to need repeat surgery for SUI [16].

Where then does the autologous fascial sling fit in this discussion? In terms of dryness, its outperformance of the Burch procedure has been demonstrated [11•]. But how does it compare to the midurethral sling? Unfortunately, there are no randomized head-to-head comparisons for these two treatment modalities with patients undergoing prolapse repair. However, there is new evidence demonstrating improved effectiveness of the midurethral sling over the rectus fascia sling. In a retrospective study by Trabuco [17], continence rates were compared after an autologous fascial sling procedure and midurethral sling using a polypropylene mesh kit (Uretex Urethral Support

System; Bard Urological, Covington, CA). Survival free of reoperation at 3 years was 94.4% in the autologous fascial group and 98% in the midurethral group. Survival free of any incontinence at 3 years was 52.3% in the autologous sling group and 66.4% in the midurethral sling group. These differences were not statistically different, but did demonstrate a 1.4-fold-greater relative risk for any incontinence in the autologous fascial sling group. Women in the autologous fascial sling group were more likely to require urethrolisis and were more likely to need intermittent self-catheterization. These results suggest that the midurethral sling may outperform the autologous fascial sling; however, longer-term studies would be needed to confirm this. Because none of these patients were also undergoing prolapse surgery, the outcome of this study may not apply to women undergoing prolapse repair.

Best Practice Policy

Understanding the role of prophylactic anti-incontinence surgery in patients undergoing POP surgery is a daunting task. The studies presented indicate that a clear consensus is lacking; yet, as practitioners, we must employ a safe practice pattern and remember to do no harm. Inherently, anything that is touted as prophylactic in the surgical arena seems to be fraught with controversy. Even when best intentions are desired, the outcomes can be very disappointing. The controversy with prophylactic sling procedures

Table 1 Outcomes of incontinence surgery with prolapse repair

Study	Study design	Patients, <i>n</i>	Prolapse repair	Anti-incontinence procedure	Mean or median follow-up, <i>mo</i>	Incontinence outcome with AIP	Incontinence outcome without AIP	<i>P</i> value
Patel et al. [16]	Retrospective	115	Sacrocolpopexy	Burch and TVT	8	Burch: 12% SUI; TVT: 0% SUI	N/A	$P<0.05^*$
Ballert et al. [18•]	Retrospective	105	Transvaginal prolapse repair with and without mesh	Synthetic midurethral sling	3	8.5% obstruction	8.3% de-novo SUI ^a	N/A
Constantini et al. [12]	Randomized prospective	47	Hysterocolposacropexy	Burch colposuspension	46	54.2% SUI	39.1% SUI	NS
Constantini et al. [13]	Randomized prospective	66	Colposacropexy	Burch colposuspension	38	36.4% SUI	9.37% SUI	$P<0.05$
Brubaker et al. [2]	Randomized prospective	322	Sacrocolpopexy	Burch colposuspension	3	23.6% SUI	44.1% SUI	$P<0.001$
Cosson et al. [14]	Retrospective	82	Sacrocolpopexy	Burch colposuspension	86	66% SUI (13% de novo)	N/A	N/A
Chaiken et al. [8]	Prospective nonrandomized	24	Anterior colporrhaphy	Pubovaginal sling	47	14% SUI	0% SUI	N/A

AIP anti-incontinence procedure; N/A not applicable; NS not significant; SUI stress urinary incontinence; TVT transvaginal tape

^a 30% incontinence in patients with pre-operative subjective SUI

* $P=0.007$ Burch compared to TVT

relates to the balance between unnecessary surgery and prevention of incontinence that is unmasked after repair of POP. In an attempt to properly select patients who would benefit from a sling at the time of prolapse repair, Ballert et al. [18•] developed a protocol whereby patients with stage II to IV POP would only receive an anti-incontinence procedure at the time of their prolapse repair if they demonstrated urodynamic or occult incontinence. Patients without urodynamic or occult incontinence did not have an anti-incontinence procedure performed. The anti-incontinence surgery performed in this study was either a retropubic midurethral sling or a transobturator sling. Outcomes were that patients with urodynamic or occult incontinence treated with a midurethral sling did not require intervention for further stress incontinence. However, the risk of intervention for urinary obstruction in this group was 8.5%. The risk of intervention for treatment of SUI (de novo) in the group without urodynamic or occult incontinence was 8.3%. Patients who reported clinical stress incontinence but lacked urodynamic or occult SUI had the highest chance for needing an intervention to treat urinary incontinence at 30%. Although the need for intervention was equivalent in both groups, it seems that the best practice policy for determining if a patient would benefit from anti-incontinence procedure at the time of prolapse repair would be the clinical symptom of SUI.

Conclusions

When treating non-life-threatening conditions such as incontinence, it should be argued that a staged approach may be prudent in patients undergoing prolapse repair. However, no study has looked at patient satisfaction or outcomes with a staged approach. Counseling regarding the risk of incontinence with surgical treatment of POP should dominate the decision making between the patient and physician. Based on all the studies presented, there is conflicting evidence to say that the Burch procedure is the best anti-incontinence procedure for patients undergoing prolapse surgery (Table 1). Best practice policy seems to identify the midurethral sling as the preferred anti-incontinence procedure when treating patients with prolapse based on its effectiveness, low morbidity and performance against comparable procedures such as the autologous fascial sling and the Burch procedure. However, strong evidence is lacking to suggest that routine prophylactic anti-incontinence surgery would provide any more benefit than a staged approach in those patients undergoing prolapse repair with no clinical or urodynamically proven incontinence. It is hopeful that the present debate will be answered with the upcoming OPUS trial [19••]. This study seeks to provide surgeons with information to better

counsel women on the benefits and risks of concomitant prophylactic anti-incontinence procedure at the time of vaginal surgery for prolapse.

Disclosure Dr. Humphrey Atiemo has served as a speaker for Astellas Pharma and holds stock in GMD Pharma Solutions.

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