Choice of Surgery for Stress Incontinence

This guideline has been reviewed by the Urogynaecology Committee and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: To outline the evidence for the efficacy of surgical procedures used for the primary treatment of urinary incontinence.

Options: The range of surgical options available for the primary treatment of urinary incontinence in women.

Outcomes: The best possible outcomes for women undergoing primary surgery for urinary incontinence. To provide a current understanding of the evidence available as the basis of an informed discussion of the anticipated outcome of surgery.

Evidence: A systematic review of clinical trials of the outcomes of primary surgical treatment of urinary incontinence.

Values: The quality of the evidence is rated using the criteria described by the Canadian Task Force on periodic health examination (Table).

Benefits, Harms, and Costs: Careful consideration of the surgical options available will result in informed choice, which is essential to the process of determining the most appropriate surgery for a woman. Use of a range of surgeries that have the highest proven efficacy is most likely to result in long-term patient satisfaction.

Key Words: Urinary stress incontinence, urgency incontinence, cyfpopexy

Recommendations:

1. When considering a primary surgical correction of stress urinary incontinence women should be informed that, according to current available evidence, a retropubic procedure provides the best assurance of a durable cure (I-A).

2. Some surgeons offer laparoscopic Burch as an alternative to the open Burch. Currently available short-term evidence does not clearly demonstrate an advantage or disadvantage over the open Burch (I-A).

3. The tension-free vaginal tape procedure (TVT) has demonstrated short-term equivalency to retropubic procedures and may be offered as a primary surgery with the proviso that it has not been rigorously tested for long-term equivalency. There is insufficient evidence to permit informed recommendations concerning other sling procedures (I-A).

4. Anterior colporrhaphy should generally not be offered to women as a treatment for isolated primary stress urinary incontinence because of higher failure rates (I-A).

5. Needle suspensions should generally not be offered to women as a treatment for isolated primary stress urinary incontinence because of higher failure rates (I-A).

6. Periurethral injection of bulking agents should generally not be offered to women for the treatment of primary stress urinary incontinence because of anticipated high failure rates (III-C).

INTRODUCTION

In an era of evidence-based medicine, health care professionals are obliged to carefully evaluate the evidence supporting their practice. For many aspects of medical practice, evidence is scant and its quality is poor. The evidence guiding the choice of surgery for the correction of urinary incontinence in women is such a case in point. Over 200 procedures designed to cure urinary incontinence have been described in the medical literature, testifying to the dissatisfaction among surgeons with their surgical armamentarium.[1]

The range of treatments for stress urinary incontinence include pelvic floor retraining, vaginal pessaries, urethral plugs, pharmaco-therapy and surgical intervention for this problem.[2,3] While conservative options are effective for a significant number of women, many women will opt to undergo surgery.

Table. Criteria for quality of evidence assessment and classification of recommendations

Level of evidence*	Classification of recommendations†
I: Evidence obtained from at least one properly designed randomized controlled trial.	A. There is good evidence to support the recommendation for use of a diagnostic test, treatment, or intervention.
II-1: Evidence from well-designed controlled trials without randomization.	B. There is fair evidence to support the recommendation for use of a diagnostic test, treatment, or intervention.
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.	C. There is insufficient evidence to support the recommendation for use of a diagnostic test, treatment, or intervention.
II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.	D. There is fair evidence not to support the recommendation for a diagnostic test, treatment, or intervention.
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.	E. There is good evidence not to support the recommendation for use of a diagnostic test, treatment, or intervention.

*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on the Periodic Health Exam.[6]

†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on the Periodic Health Exam.[6]

The procedures most commonly utilized for surgical correction of stress incontinence include sub-urethral sling procedures, retropubic suspensions (open or laparoscopic), anterior colporrhaphy, needle suspension procedures, and periurethral injections.[3] This guideline will discuss the evidence for the choice of a primary surgery for urinary incontinence associated with urethral hypermobility. The appropriate investigation prior to performing primary surgery for urinary incontinence has been dealt with in a previous guideline.[4] It is not the intention of this guideline to examine the evidence about combined procedures for prolapse and incontinence or repeat surgeries for urinary incontinence. This guideline will focus on the outcomes of surgery (especially long term). In reviewing the literature, it is evident that there is a considerable heterogeneity of surgical methods, reporting of outcome measures, and duration of follow-up. This inconsistency makes comparisons between published reports more difficult. The recommendations from this review are based to a large extent upon the conclusions drawn by Cochrane reviewers.[5] The Cochrane Library was established in 1972 to encourage the promotion of medical evidence based upon the systematic review of comparative trials. The authors publishing in the Cochrane review use meta-analytic techniques, where possible, to draw conclusions which may guide clinical practice. The quality of evidence reported in these guidelines has been described using evaluation of evidence criteria outlined in the report of the Canadian Task Force on the Periodic Health Exam (Table).[6]

RETROPUBIC PROCEDURES

The most commonly performed retropubic procedures include the Burch retropubic urethropexy and the Marshall-Marchetti-Krantz procedure.[1] The Burch procedure has perhaps been the most carefully studied of all surgical procedures for urinary incontinence.[7]

Surgical technique

There have been many modifications to the suture placement, the type of suture material (absorbable versus permanent), and number of sutures. The Burch retropubic urethropexy is performed through a Pfannenstiel type incision with placement of sutures through the internal aspect of the vaginal wall lateral to the urethrovesical junction and the urethra. These sutures are attached to Cooper's ligament thereby suspending the vaginal wall and indirectly the urethra.[6]

Outcomes of retropubic urethropexy

A Cochrane review of the literature on retropubic procedures was published in November 2002 and updated in March 2003.[8] The authors included 33 trials involving 2403 women in their analysis.[9–42] The authors found that:

1. Six trials showed a lower failure rate of subjective cure (RR 0.49; 95% CI, 0.32–0.75) for a Burch procedure compared to an anterior colporrhaphy after 5 years.

2. There was a lower failure rate after Burch when compared to needle suspensions beyond 5 years (RR 0.32; 95% CI, 0.15–0.71).

3. Three trials found no significant difference between retropubic procedures and sling procedures.

4. Two trials found a lower failure rate for the Burch (RR 0.38; 95% CI, 0.18–0.76) compared to the Marshall-Marchetti-Krantz procedure.

The authors concluded that

> open retropubic colposuspension is the most effective treatment modality for stress urinary incontinence, especially in the long term. This is its main strength and the primary basis for considering it as the standard in the surgical treatment of urinary incontinence in women. After five years, approximately 70% of patients can expect to be dry.

Other Trials

Cohort studies of greater than 5 years reported success rates ranging from 79% to 94% (involving a total of 451 patients) when the retropubic procedure was used as the primary surgical intervention.[43–46]

Recommendation

1. When considering a primary surgical correction of urinary incontinence women should be informed that, according to current available evidence, a retropubic procedure provides the best assurance of a durable cure (I-A).

LAPAROSCOPIC COLPOSUSPENSION

Surgical technique

Laparoscopic colposuspension was introduced in the early 1990s. Many technical variations have been described including the use of different numbers of sutures, the use of mesh in place of sutures, and the location of anchor sites.[15,22,39,40,47–51] Usually, an effort is made to mimic the open colposuspension. Laparoscopic colposuspension has the advantage of being minimally invasive and has been shown to reduce the duration of postoperative recovery, hospitalization, and the degree of pain.[39,40] It is also well recognized that laparoscopic colposuspension is a technically difficult procedure which in most cases takes longer to perform than an open retropubic procedure.

Outcomes of laparoscopic colposuspension

A Cochrane review of the literature on laparoscopic colposuspension was published in May 2000 and updated in January 2002.[47] The authors included 8 studies in their analysis, 5 of which compared laparoscopic colposuspension with the open colposuspension and 3 of which compared different operative techniques or approaches for laparoscopic colposuspension (487 women).[15,22,40,48–51] Follow-up for these studies ranged between 6 and 18 months. While subjective cure rates were similar for open versus laparoscopic Burch, there was some evidence that objective cure rates were lower for laparoscopic Burch. One trial comparing the placement of 1 versus 2 sutures laparoscopically found higher subjective cure rates for the 2 suture technique (89% versus 65%).[49] The authors concluded that

> the long-term performance of laparoscopic colposuspension is uncertain. Currently available evidence suggests that it may be poorer than the open colposuspension. If it is performed, two paravaginal sutures appear to be more effective than one. The place of laparoscopic colposuspension in clinical practice should become clearer when ongoing trials are reported and when there are more data available describing long-term cure results.[47]

Other trials

In case series involving 484 women with less than 18 months follow-up, the success rate ranged from 87% to 100%.[52] One study with a follow-up of 3 years found a 69% success rate.[53]

Recommendation

2. Some surgeons offer laparoscopic Burch as an alternative to the open Burch. Currently available short-term evidence does not clearly demonstrate an advantage or disadvantage over the open Burch (I-A).

SUB-URETHRAL SLING PROCEDURES

Sub-urethral sling procedures were developed to treat patients who were experiencing either recurrent stress urinary incontinence or more severe types of stress urinary incontinence. Recently they have been advocated as the primary surgical treatment for stress urinary incontinence.[24]

Surgical technique

The operation involves the placement of a sling of either artificial or autologous tissue beneath the urethra and the suspension of the sling to various structures in the abdominal wall or retropubic space. The choice of material includes: autologous fascia (rectus or fascia lata), vaginal wall, exogenous natural tissues (bovine, porcine, or cadaveric) and synthetic materials (mersilene tape, polytetrafluoroethylene [gortex], marlex mesh, teflon, and silastic).[1] The large diversity of sling materials and surgical

techniques makes the analysis of the medical literature concerning this surgical technique extremely difficult.

A Cochrane review of the literature on the sub-urethral sling procedures was published in 2001 and updated in the same year.[55] The authors included 7 trials that involved a total of 682 women.[21,38,42,56–59] Four trials compared the sub-urethral sling to open retropubic procedures,[21,38,42,58] 1 compared it to a needle suspension,[59] and 2 trials compared 2 different types of sling procedures.[56,60] Six different types of slings were used. The authors found that short-term cure was no different from abdominal retropubic colposuspension although this finding was primarily the result of 1 large study comparing TVT to the Burch procedure.[42] Data were too few to give a reliable estimate of long-term results. Data were also too few to compare slings, other than the TVT, to the Burch. The authors concluded that

> preliminary results from a large trial provide reassuring evidence about the performance of the less invasive TVT sling procedure. Cure rates after TVT were similar to those following open abdominal retropubic suspension. The data were too few to address whether other types of sub-urethral slings were as effective as open abdominal retropubic suspension or needle suspension.[55]

Tension-free vaginal tape (TVT) procedure

The tension-free vaginal tape (TVT) procedure was developed as a minimally invasive sub-urethral sling procedure by Ulmsten and colleagues. There have been a number of observational trials of this surgical technique reporting cure rates of 74% to 85% in patients undergoing surgery for primary and secondary stress urinary incontinence.[60–63] A follow-up to the previously mentioned randomized trial comparing TVT to the Burch procedure found at 2 years that the cure rate using an intention to treat analysis was 63% for the TVT and 51% for the Burch procedure.[64]

Transobturator tape (TOT) procedure

The transobturator tape (TOT) procedure has recently been developed as a new minimally invasive sling procedure.[64] It is touted to have the benefits of easy performance and decreased risk of bladder and visceral injury. There are 2 published studies of the short-term outcomes of the TOT procedure. In one, a 94% success rate in 16 women was reported after a follow-up ranging from 3 to 12 months.[65] A second study found a 91% cure (29/32 women) after 1-year follow-up.[66] One randomized clinical trial of TVT versus TOT found comparable success rates at the first follow-up visit (84% vs. 90%).[67]

Other trials

The majority of the data on sling procedures involves case series. Differences in inclusion criteria, outcome measures, and surgical techniques makes pooling of these data inappropriate. Four trials have looked at the success of slings beyond 1 year.[68–71] Kaplan looked at the outcome for 183 patients with a vaginal wall sling after a mean follow-up of 40 months.[68] Fifty-one percent of patients were very satisfied with the procedure. Four percent failed, 7% developed overactive bladder, and 6% had persistent overactive bladder. Seven percent developed other organ prolapse. The 5-year success was quoted by the authors as 94%. Groutz studied 38 patients treated with a rectus fascia sling for primary surgery and reported a 67% cure rate.[69] Chaikin studied 47 women with mixed incontinence and after 5 years reported a 96% cure rate.[70] Chin followed 88 women who had a silastic sling procedure and reported a 71% cure rate over 5 years.[71]

Recommendation

3. The tension-free vaginal tape procedure (TVT) has demonstrated short-term equivalency to retropubic procedures and may be offered as a primary surgery with the proviso that it has not been rigorously tested for long-term equivalency. There is insufficient evidence to permit informed recommendation concerning other sling procedures (I-A).

ANTERIOR COLPORRHAPHY

Surgical technique

The anterior colporrhaphy is achieved by a transvaginal opening of the anterior vaginal wall below the bladder and urethra. Kelly plication stitches are then placed periurethrally and tied in the midline. There are a variety of modifications of this procedure including the Bologna procedure, Kelly-Kennedy, Marion-Kelly, and cystocele repair.[1]

Outcomes of anterior colporrhaphy

A Cochrane review of the literature on anterior colporrhaphy for the treatment of stress incontinence was published in 2001.[72] The authors found 9 trials involving 932 women.[13,18,30–32,73–76] Anterior repair was less effective than open retropubic suspension in 8 trials after the first year (failure rates 41% vs. 17%; RR, 2.5; 95% CI, 1.92–3.26). The authors concluded that

> open abdominal retropubic suspension appeared to be better than anterior repair judged on subjective cure rates in six trials, even in women who had prolapse in addition to stress incontinence. The need for repeat prolapse surgery was also less after an abdominal operation.[72]

Other trials

Long-term (4-year results) show a steady decrease in success over time. Cohort studies totalling 1088 patients report a mean cure rate of 61% (47%–72%).[77]

Recommendation

4. Anterior colporrhaphy should generally not be offered to women as a treatment for isolated primary stress urinary incontinence because of higher failure rates (I-A).

BLADDER NECK NEEDLE SUSPENSION PROCEDURES

Surgical technique

Needle suspensions are performed by attaching sutures to periurethral tissues or periurethral buttresses and suspending them to the anterior abdominal fascia. There are 3 principal types: Pereyra, Stamey, and Raz with many modifications.[1]

Outcomes of needle suspension procedures

A Cochrane review of the literature on bladder neck needle suspension for urinary incontinence in women was published in 2002 and updated in 2004.[78] The authors found 9 trials involving a total of 784 women.[9,13,23,24,79–81] They found that needle suspensions were more likely to fail after the first year when compared to open retropubic suspension (29% vs. 16%; RR, 2.1; 95% CI, 1.47–2.72) but that perioperative complication rates were not significantly different (23% versus 16%; RR, 1.44; 95% CI, 0.73–2.83). These data applied to women with primary urinary incontinence as well as women with recurrent incontinence following failed primary operations. Their findings suggested that needle suspensions may be as effective as anterior colporrhaphy. They concluded that

> bladder neck needle suspension surgery is probably not as good as open abdominal retropubic suspension for the treatment of primary and secondary urodynamic stress incontinence because the cure rates were lower in the trials reviewed.[78]

Recommendation

5. Needle suspensions should generally not be offered to women as a treatment for isolated primary stress urinary incontinence because of higher failure rates.

PERIURETHRAL BULKING AGENTS

Surgical technique

Periurethral injections of bulking agents are thought to promote continence by causing coaptation of the urethral mucosa[82] and by increasing functional urethral length.[83] Materials injected include autologous fat, teflon, collagen, and silicone.[84] Collagen is presently the most widely used

material.[82] Injections can be done on an outpatient basis. Most women require 2 or 3 injections.[85] There is a direct patient cost which may limit accessibility.[57] Four percent of women have allergic reactions.[82,86]

Outcomes of periurethral injections

There are no randomized studies comparing injectables with other procedures and there are no studies involving more than 100 women. The longest follow-up period is a mean of 46 months.[86] The published studies involve heterogenous patient populations and the majority of injection therapies have been reserved for women who have failed previous surgical treatment or who have so-called intrinsic sphincter deficiency. There are no studies of periurethral injection therapy used as the primary treatment for stress urinary incontinence. Cure rates in case series vary from 7% to 83%. Since there are no studies comparing the effectiveness of periurethral bulking agents to other surgical treatments, it is difficult to draw any conclusions concerning this therapy compared to other surgical therapies. Long-term cure rates are generally low and repeat treatment is common.

Recommendation

6. Periurethral injection of bulking agents should generally not be offered to women for the primary treatment of urinary incontinence because of anticipated high failure rates (III-C).

COMPLICATIONS OF PROCEDURES FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

Because of the heterogeneity of surgical procedures and poor reporting, it is very difficult to compare the complication rates of surgical procedures. The following general statements concerning complications are backed by some evidence:

1. Pelvic prolapse has been documented following surgical treatment of stress incontinence using the retropubic colposuspension.[64,88] Careful attention should be paid to pelvic support problems which may coexist with stress incontinence so that they may be corrected surgically at the same time.

2. While laparoscopic colposuspension permits more rapid recovery from surgery, it does not reduce the incidence of significant perioperative complications including detrusor instability, voiding dysfunction, and haematoma.[47]

3. Sub-urethral sling procedures do not involve higher rates of voiding dysfunction, urgency incontinence or detrusor instability when compared to the Burch procedure or the needle suspension procedure. While bladder perforation is a complication more commonly encoun-

tered with the TVT procedure, this has minimal significance over the long-term recovery.[55]

4. Anterior colporrhaphy is associated with similar rates of urgency incontinence, detrusor instability, and length of hospital stay when compared to the Burch procedure. It does not decrease the rates of voiding dysfunction but is associated with the higher need for repeat surgery for incontinence.[72]

CONCLUSION

The purpose of this guideline and review was to provide surgeons with some advice and guidance concerning the appropriate choice of surgical procedures for the treatment of urinary incontinence. This literature review has highlighted the shortcomings of the medical literature in this subject area. Future studies that involve properly designed randomized prospective studies with appropriate outcomes are necessary to provide high-quality evidence for interpretation.

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