WHICH IS THE MOST APPROPRIATE OPERATION FOR GENUINE STRESS INCONTINENCE (GSI)?

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Definitions of urinary incontinence and genuine stress incontinence (GSI).

Urinary incontinence was defined by Bates[1] as a condition in which involuntary loss of urine is a social or hygienic problem, and is objectively demonstrable. Genuine stress incontinence (GSI) is defined as the involuntary loss of urine when the intravesical pressure exceeds the maximum urethral pressure, but in the absence of detrusor activity[2]. This is a urodynamic diagnosis obtained by filling cystometry. If the diagnosis is assumed clinically, without urodynamics, the term stress urinary incontinence should be used instead.

Prevalence of urinary incontinence and GSI

Fourteen percent and 6.6% of British women and men respectively, aged > 30 years, were incontinent of urine at some time[3]. The prevalence of urinary incontinence occurring at least twice in the previous month in the elderly Singaporean 65 years and above was 4.6%[4]. Nearly 10% of healthy Singaporean nurses aged between 24 and 59 years suffered from troublesome urinary incontinence[5], the term "troublesome" was coined from the nurses' confession of frequent incontinence (rather than occasional), incontinence occurring at least twice per month and the need to wear protective pads for their incontinence. GSI is the commonest cause of urinary incontinence in women, comprising 40% to 60% of female urinary incontinence[6-8]. Stress urinary incontinence has been reported to occur between 51% and 57% of young, healthy, nulliparous women, of whom between 4% and 16% confessed to leaking urine frequently or on a daily basis respectively[9,10]. The incidence of GSI, detrusor instability (DI) and mixed GSI and DI has been reported as 47.5%, 37.7% and 5.2% respectively[11], these represent the main causes of urinary incontinence in women.

Aetiology of GSI

The common aetiological and associated factors of GSI include the anatomy of the female genito-urinary tract, pregnancy and delivery[12-14], denervation of the pelvic floor musculature[15,16], genital tract prolapse, previous vaginal surgery to cure prolapse or previous bladder neck surgery, ageing, menopause[13,17], obesity, chronic bronchitis, constipation and occupations requiring heavy lifting.

Management of GSI

The management of GSI is either conservative[18] or

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surgical[19]. The mainstay of conservative treatment is physiotherapy [pelvic floor exercises[20-22], cones[23,24] and electrical stimulation[25-28]]. The other conservative methods of treatment include drug treatment [alpha-adrenergic agonist, eg phenylpropanolamine[29,30] or oestrogens alone[31,32] or in combination[33]] and devices [sanitary tampons, ring and shelf pessary].

When conservative measures have failed to give a satisfactory result, surgery should be offered. However, the patient must make the final decision; it is unwise to persuade a patient to have an operation if she is not keen. This is because GSI surgery gives only a 80% to 90% cure or improvement rate with the possibility of immediate failure and late recurrences. As with any surgery, there is a mortality and a morbidity rate and there may be intra-operative and post-operative complications like haemorrhage, bladder and urethral injuries, voiding difficulties, urinary tract and wound infections and detrusor instability. A patient will usually give her informed consent for surgery if her GSI is severe enough to incapacitate her domestic and social life.

Pre-operative assessment of GSI

The key to a successful surgical outcome for GSI lies in making an accurate pre-operative diagnosis and then choosing the appropriate operation for each patient. Pre-operative assessment should include a detailed urogynaecological and medical history, physical examination with special emphasis on the genito-urinary and neurological systems.

In the examination of the genito-urinary system the sign stress incontinence should be demonstrated in the erect posture with the legs apart, the labia parted and the patient asked to cough as hard as possible and repeatedly, if necessary, with a comfortably full bladder. The patient should then be examined with a Sim's speculum in the left lateral position to specifically look for atrophic changes, the angulation of the urethro-vesical junction (bladder neck), cystourethrocele, uterine prolapse, enterocele or rectocele at rest and on straining or coughing. If the sign stress incontinence is demonstrated in the left lateral position, during a Sim's speculum examination, it is extremely important to determine whether the patient has a hypermobile urethra (stress incontinence accompanied by descent of the bladder neck/ base) or proximal urethral dysfunction (stress incontinence accompanied by a rigid urethra, ie without descent of the bladder neck/base). Finally the patient is examined in the dorsal position by a vaginal and bimanual pelvic examination to assess the capacity and mobility of the vagina, the strength of the pelvic floor contractions and the size of the pelvic organs and to exclude other pelvic pathology.

The choice of operation depends largely on the above-mentioned findings. If GSI is diagnosed in the presence of a hypermobile urethra with a normal capacity and mobile vagina, then the best type of operation to perform is a bladder

neck suspension operation such as a Burch colposuspension (in the presence or absence of a cystocele), Marshall-Marchetti-Krantz (only in the absence of a cystocele) or endoscopic bladder neck suspension procedures (plus an anterior colporrhaphy in the presence of a cystocele). On the other hand, if the diagnosis is GSI with proximal urethral dysfunction, usually accompanied by a narrow and scarred vagina, most probably from previous failed incontinence surgery, then there is no point performing a bladder neck suspension operation. In such patients injection of implants, a Stamey-Martius procedure, sling or insertion of artificial sphincter should be performed instead.

Pre-urodynamic assessment should include pad test[34,35] to qualify and quantify the severity of urinary incontinence, uroflowmetry to screen for voiding disorders and urine for bacteriological examination to exclude a urinary tract infection.

Pre-operative urodynamics should be performed to diagnose GSI and voiding disorders and to exclude detrusor instability. This is because the results of surgery are jeopardised by pre-existing detrusor instability[7]. Previously some authors had advocated that urodynamics were not necessary in patients presenting solely or mainly with stress incontinence but without urge incontinence, and especially if the sign stress incontinence was demonstrated[8,36,37]. More recently, the general consensus of opinion has been in favour of pre-operative urodynamics[11,38-42].

Urodynamics must be performed prior to primary suprapubic bladder neck suspension operations even in patients presenting solely with stress incontinence. This is because the latter history is very rare indeed. Haylen et al[40] reported a series of 494 patients complaining of stress incontinence, none of whom had any previous surgery for urinary incontinence; only 12 (2.4%) of these 494 women had stress incontinence as their only symptom, and only 6 of these 12 patients (50%) also had the sign stress incontinence as well as the final diagnosis of GSI alone. Even when stress incontinence is truly the only symptom or the main complaint detrusor instability was variously diagnosed in 7%[42], 10%[11], 12%[39] and 21%[40] of cases. As a result of urodynamics the management was changed or significantly altered in 21%[42] and 31%[11] of cases!

There is no doubt that urodynamics should be performed in previous failed surgery for GSI or stress urinary incontinence. Some authors have even advised that in this group of patients videocystourethrography (VCU)[43] must be substituted for conventional urodynamics. VCU is the combined synchronous recording of bladder function measured by urodynamic techniques together with the visual image of the lower urinary tract using radiological screening. However, the equipment is extremely expensive; fortunately there are cheaper alternatives to visualise the lower urinary tract, eg screening cystourethrography[44] and vaginal ultrasound scan[45], but conventional urodynamics cannot be performed synchronously. In another group of patients in whom previous GSI surgery have failed, conventional urodynamics may fail to give a diagnosis of detrusor instability in about 5%, perhaps because of the clinical environment of urodynamics. Recently ambulatory urodynamics[46] have been used to achieve greater sensitivity by allowing the bladder to fill naturally. The disadvantage of this technique is that it is time-consuming (2-4 hours). Hence, if ambulatory urodynamics is not available, conventional urodynamics may have to be repeated more than once to try and diagnose detrusor instability in this group of patients with symptoms strongly suggestive of mixed GSI with detrusor instability.

Relative contraindications for GSI
Mixed GSI and detrusor instability
Detrusor instability should be treated before surgery, because the cure of stress incontinence due to urethral sphincter incompetence is compromised by the presence of detrusor instability and urge incontinence is particularly likely to deteriorate. Only when a reasonable trial of medical treatment for detrusor instability has been attempted and the patient believes that stress incontinence is still a major symptom, should continence surgery be carried out. However she should be forewarned that the cure rate of GSI is much lower [only 30%[47] -60%[48-51] compared to 85% with GSI alone[48]] and she may have residual frequency and urgency requiring indefinite medical treatment for detrusor instability.

Neurological lesion
Spinal cord injury patients with reflex neuropathic bladders and massive urethral dilatation associated with urinary leakage around their Foley urethral catheters can be cured of their incontinence by combining endoscopic suspension of the vesical neck with suprapubic catheter drainage[52]. Women with acontractile, neuropathic bladders, and large residual volume - when accompanied by demonstrable stress urinary incontinence - can also be cured of their incontinence by an endoscopic suspension or sling procedure, but they must accept a permanent programme of clean intermittent self-catheterisation.

Recurrent failed previous surgery
An appropriate operation may still be carefully selected with its inherent poorer success and higher complication rate, as discussed later under, "Which is the best operation for GSI?"

Chronic medical condition
The patient has to be managed jointly with the appropriate specialists before, during and after surgery.

Family incomplete
A subsequent pregnancy, even if delivered by elective Caesarean section, may 'undo' the operation; and a subsequent vaginal delivery will most probably cause the condition to recur.

The aims of GSI surgery
1. To elevate the bladder neck and proximal urethra to an intra-abdominal position where intra-abdominal pressure will act as an additional closure force.
2. To support the bladder neck and align it to the postero-superior surface of the symphysis pubis.
3. To increase outflow resistance.

Which is the best operation for GSI?
Hodgkinson (1970) stated that the first operation had the best chance of success and was the easiest to perform[53]. Hence, one must always remember the importance of performing the best operation the first time although the choice of operation is usually decided by the experience and preference of the operator.

There is overwhelming evidence from the literature that suprapubic operations rather than vaginal offer the best and most permanent chance of cure[53-56]. However, there is still a place for anterior colporrhaphy with bladder neck buttress in patients with mild to moderate cystourethrocele associated with minimal genuine stress incontinence. The advantage of

this operation is that it can be combined with a vaginal hysterectomy and posterior colporrperineorrhapy in such patients with accompanying uterine prolapse, enterocoele and/or rectocele. Another benefit of bladder neck buttress is its negligible complication rate of post-operative voiding dysfunction and detrusor instability, 0% of both in Stanton and Cardozo's series[45]. Hence, this operation may be preferred in this group of patients presenting with pre-existing (pre-operative) detrusor instability or voiding dysfunction. However, one must be aware of its lower continence rate as a trade-off. The objective cure rate from vaginal repair in patients with detrusor instability alone or combined with genuine stress incontinence is only 30%[47]. The success rate for primary bladder neck buttress varies from 38% to 90%[56,57]; however, most of these studies were subjective and the length of follow-up short. It must be emphasised that there is no place for a second vaginal approach as the cure rate will be less than 30%.

The key to a successful bladder neck buttress is the accurate identification of the bladder neck by the balloon (filled with 30ml of H_2O) of a size 16 Foley catheter. (In fact this should also be used in all suprapubic operations for genuine stress incontinence). The bladder neck is elevated by approximating the pubocervical fascia in the region of the trigone, bladder neck and proximal urethra using three to four number 0 polyglycolic acid sutures (Dexon/Vicryl) or non-absorbable polyester (Mersilene). The choice of suture material is of utmost importance as fibroblasts take 3 to 4 months to mature and hence a suture like chromic catgut (still commonly used for this procedure) which looses its tensile strength retention in-vivo within 21 to 28 days would contribute to poorer results. Beck and McCormick have achieved an 80% 2-year cure rate with Dexon[58] and Warrell has reported a 6-month cure rate of 80%-90% (150 patients) and a 3-year cure rate of 80% (20 patients) using Mersilene[57].

The colposuspension operation was originally described by Burch[59] and has since been modified by many surgeons. Usually, two to three long-term absorbable polyglycolic acid sutures (Dexon or Vicryl) or non-absorbable polyester (Ethibond) are inserted from the paravaginal fascia to the ipsilateral ileo-pectineal ligament on each side. A colposuspension is most likely to produce a lasting cure for primary or recurrent genuine stress incontinence and will correct a cystocele at the same time. A coincidental uterine pathology like uterine fibroids, dysfunctional uterine bleeding or uterine prolapse can be corrected by an abdominal hysterectomy, and an enterocoele by the closure of the pouch of Douglas (Moschowitz procedure). If there is a rectocele, this will usually become more pronounced after a colposuspension and may need a posterior repair at the same time.

In all reported series the cure rate of colposuspension is greater than the procedure with which it was compared and range between 73% and 98%[56,60-63]. The colposuspension has a relatively low recurrence rate; 71% (n = 76 patients) remained cured after being followed-up for 5 years[64].

Various authors have audited failed colposuspension and reported on its associated factors:
(i) Pre-operative co-existent detrusor instability, especially if the detrusor contractions > 25 cm H_2O[65] [43% as against 85% in GSI alone[48]].
(ii) Older women [74% success in those > 65 years of age[66]].
(iii) Previous incontinence surgery [67% success at 5 years[67]].
(iv) Low maximum urethral closure pressure [< 25 cm H_2O[67]].

Thus, patients with any of the above factors should be forewarned of the poorer results before colposuspension and should be strongly advised to consider alternative treatment before surgery. For example, a patient with genuine stress incontinence and co-existent detrusor instability should be offered medical treatment and/or electrical stimulation for detrusor instability and pelvic floor exercises, electrical stimulation or cones for genuine stress incontinence respectively. Another example is the patient with low maximum urethral closure pressure who should be offered a Stamey-Martius[78] procedure instead of colposuspension.

The two major complications of colposuspension include voiding difficulty and detrusor instability. Immediate voiding difficulties occur in 25% of patients and is usually transient, resolving in one to two weeks. It is most probably secondary to surgically induced inflammation and oedema, perhaps combined with the effects of anaesthesia and pain, which further inhibits normal voiding. However, if the pre-operative maximum flow rate is < 15 ml/sec or the maximum voiding pressure < 15 cm H_2O, the post-voiding residual urine volume is > 100 ml, early voiding difficulties can be as high as 40%. Such patients (preferably all patients having a suprapubic operation for GSI) are best managed by the intra-operative placement of a suprapubic catheter, which also allows measurement of post-voiding residual volumes. Late voiding difficulties persist in about 20% which may be due to overcorrection of the bladder neck and proximal urethra which may also cause obstruction-induced detrusor instability. Detrusor instability has been shown to occur in 18.5% of women at 3 months after colposuspension[68] and 12% of these women were still symptomatic at 5 years[69]. Hence, it is extremely important not to tie the sutures too tightly to try to achieve complete approximation of the paravaginal fascia to the ipsilateral ilio-pectineal ligament with the absence of any 'bow-stringing'.

Table I - Operations for GSI

Vaginal	Anterior colporrhaphy with bladder neck buttress
Suprapubic	Burch colposuspension Marshall-Marchetti-Krantz
Combined Suprapubic and Vaginal	Endoscopic bladder neck suspension (Modified Pereyra, Raz, Stamey) Modified Pereyra/Stamey with Anterior colporrhaphy/Vaginal hysterectomy Stamey with Martius procedure Sling
Injectables	Teflon, collagen, macroplastique
Complex	Artificial sphincter

This author recommends a double throw on the first knot, to prevent knot-slippage, and firm digital pressure to tighten the subsequent reef knots; allowing some degree of taut 'bow-stringing' as the final result - as an effective prophylaxis against voiding difficulty and perhaps obstruction-induced detrusor instability.

Vancaillie and Schuessler (1991)[70] were the first to describe laparoscopic bladder neck suspension for the treatment of urinary stress incontinence. However, their procedure resemble the Marshall-Marchetti-Krantz and not the Burch colposuspension. Since then there have been successful attempts to perform laparoscopic colposuspension by the traditional laparoscopic transperitoneal and newer extraperitoneal routes. The latter route mimics the open colposuspension approach without the inherent risks of a

laparoscopic intraperitoneal procedure. Obviously, if laparoscopic colposuspension were to be performed after another laparoscopic procedure, eg laparoscopic assisted vaginal hysterectomy, the intraperitoneal approach should be used.

Initially, most laparoscopic surgeons have aimed to substitute the open colposuspension in its entity with the laparoscopic approach; with all the advantages of a minimally invasive procedure. However, there is an extremely steep learning curve, even in very experienced laparoscopists. Hence, very few have been able to accurately approximate the paravaginal fascia, just lateral to the bladder neck, to the ipsilateral ileopectineal ligament by suturing; either by using the more difficult intra-corporeal or the easier extra-corporeal knot-tying techniques. Even if they have succeeded, they would inevitably have compromised on the number of sutures. Furthermore, they might not have been able to achieve the same degree of accuracy and elevation of the bladder neck as compared to the open approach. Hence, some laparoscopic surgeons have attempted to take short cuts by simplifying the procedure. They justify their course of action by arguing that they wish to make laparoscopic colposuspension more widely acceptable. Recently Ou et al (1993)[71] have advocated the use of Prolene hernia mesh and titanium hernia staples to approximate the paravaginal fascia to the ipsilateral ileopectineal ligament. A single 1 cm wide strip of Prolene hernia mesh is used on each side, held by two staples at each end of the Prolene mesh. They argue that the apparent lack of elevation of the bladder neck compared to the original suturing method might be offset by the formation of fibroblasts on the Prolene mesh which would strengthen the support and improve long-term results. However, their series is modest (n = 40 patients) and follow-up short (mean = 6 months).

To date (from 1986 to March 1993 Medline Search) there are no other publications on laparoscopic Burch colposuspension apart from presentations at scientific meetings. However, their numbers are small and follow-up short. We have to await larger numbers and longer follow-up, preferably randomised controlled trials between the open and laparoscopic colposuspension procedures and between the laparoscopic suturing and stapling colposuspension techniques, before drawing any conclusions.

In the meantime, it is this author's opinion that if a surgeon wishes to perform a laparoscopic colposuspension, he/she should incorporate the general principles and methodology of an open colposuspension, ie the accurate and adequate placement of at least two sutures between the paravaginal fascia and the ileopectineal ligament on each side to elevate the bladder neck effectively and satisfactorily.

The Marshall-Marchetti-Krantz (MMK)[72] procedure has slowly but surely been surpassed by the Burch colposuspension for the surgical treatment of primary or recurrent genuine stress incontinence. The operative technique is very similar to colposuspension except that the paravaginal fascia is sutured to the periosteum on the posterior surface of the symphysis pubis instead of the ipsilateral ileopectineal ligament. The former tissue can sometimes tear-through leading to failure or if too deep a bite is taken, especially with a cutting needle, give rise to the complication of osteitis pubis (5%). Furthermore, this procedure cannot correct an existing cystocele. However, it has 96%[73] success rate in Krantz's hands but other authors have not been able to reproduce his results.

Endoscopic bladder neck suspension procedures like modified Pereyra[74,75], Raz[76] or Stamey[77] are easy and quick to perform with lower morbidity when compared to

colposuspension. Hence, they are ideal for the older patient and the frail. They can be combined with an anterior colporrhaphy to reduce a cystocele. A Stamey procedure can be combined with a vaginal hysterectomy, pelvic floor repair together with a bladder neck buttress in a patient with significant uterine prolapse, cystourethrocele, enterocele and/ or rectocele together with moderately severe genuine stress incontinence (a 'belt and braces' combination).

The latter surgical combination is argued to be more logical than performing a Burch colposuspension, Moschowitz procedure and posterior repair in a similar patient. The choice is usually decided by the operator's preference and experience. The success rate of endoscopic bladder neck suspension procedures (modified Pereyra and Stamey) are lower when compared to colposuspension[60-63].

The Stamey procedure can also be combined with the Martius procedure in women with poor urethral function as demonstrated by severe genuine stress incontinence or gross leakage on videocystourethrography (VCU) and/or low maximum urethral pressures (<20 cm H_2O); in those with previous incontinence surgery with varying degrees of scarring on the anterior vaginal wall[78]. In this Stamey-Martius procedure a standard Stamey procedure is performed without tying of the sutures. A vertical incision is made over a labium majus and the fat pad is harvested; its postero-lateral blood supply is carefully preserved. The fat pedicle is then sutured across the bladder base and proximal urethra after bringing it through a tunnel created alongside the vagina. The anterior vaginal wall is reconstructed, the Stamey sutures tied and the labium majus closed. In this small series (n = 40 patients) with short follow-up (mean 13 months) a subjective cure of stress incontinence occurred in 89% although 40% of such asymptomatic patients had minor leaks on VCU. This simple operation with low morbidity and short hospital stay should be considered before a sling operation or even the insertion of an artificial sphincter in this difficult group of patients.

Sling operations should be reserved for recurrent genuine stress incontinence after failed surgery when the vagina is narrowed and scarred. A sling, either organic (bovine or patient's own rectus sheath) or inorganic (Marlex, Mersilene, GORE-TEX or Silastic), is inserted around the vesical neck and the base of the urethra by a combined suprapubic and vaginal approach with retropubic dissection. Slings function by causing outflow obstruction and may fail if there is too little tension of the sling on the urethra, especially organic slings. On the other hand, if the tension is excessive, especially inorganic slings, a patient may require clean intermittent self-catheterisation, possibly indefinitely. Slings have a high complication rate and apart from failure and voiding difficulty, they include haemorrhage, injury to the bladder and urethra, infection, erosion of the sling into the urethra and detrusor instability.

In the near future injectables may replace the sling but their long-term result await evaluation and their cost must be significantly reduced before they become more widely acceptable.

The various types of injectable implants available include:
(i) Polytetrafluoroethylene or Teflon (Polytef™)
(ii) Gluteraldehyde cross-linked bovine collagen or GAX-Collagen (Contigen™ Bard[R])
(iii) Polydimethylsiloxane particles suspended in plasdone hydogel (Macroplastique™ Uroplasty[R])

Injectable implants are basically bulk-enhancing substances which increase urethral resistance by increasing pressure on the urethra and decreasing lumen size. Such an

implant is injected submucosally at or near the bladder neck until tissue bulking closes the lumen across the midline of the urethral opening. Usually four to five injection sites are required to produce this final result. The implant can be injected either by the transurethral (Collagen, Macroplastique) or periurethral (Teflon, Collagen) routes, both conducted under direct cystoscopic or video vision. Injection of implants is a minimally invasive procedure and can be performed as a day surgery or day case or even as an outpatient procedure under local anaesthesia (periurethral route).

However their long-term results await further evaluation. Teflon's use has gone into disrepute despite its initial encouraging results (1974)[79] after it was reported that it migrated to the lungs and brain (1989)[80]. Collagen has gained recent popularity but there may be a 3% incidence of allergic reaction from bovine collagen and an intradermal skin test has to be performed and monitored upto a month (product information). Collagen is supposedly replaced by natural collagen in three to six months and hence the initial amount injected, even if adequate initially, may require topping up. Macroplastique does not change appreciably over time and hence maintains its bulk-enhancing properties. It is more expensive than Collagen but may require less injections. However, it is also more difficult to inject compared to Collagen and can only be delivered transurethrally. The success rate for both Collagen and Macroplastique is about 80%[81,82] but the follow-up is short.

Artificial sphincters should be the last resort in one's armamentarium of genuine stress incontinence operations. However, its high cost, complication rate and mechanical failure rate have to be improved to benefit more of these patients.

CONCLUSION
Finally, it is important to remember that surgery carries a mortality and morbidity rate whereas urinary incontinence does not. I would like to conclude by stressing again that the first operation is the most likely to cure the condition hence the best operation should be chosen for the first attempt. It is equally important that every patient should be assessed accurately preoperatively and followed-up subjectively and objectively for at least five years if we want to sincerely audit the results of our surgery.

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