

# The argument for surgical therapy for stress urinary incontinence in females

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**S**tress urinary incontinence (SUI) affects 4% to 35% of women.<sup>1</sup> Many patients find it difficult to bring up the topic of incontinence, so it is imperative that when the complaint is brought forward, we deal with it swiftly and in the most effective manner possible. In 2007, Harris and colleagues published that only 45% of women and 22% of men with incontinence disclosed it to a health care provider; of those, only 60% received treatment. Furthermore, half of those 60% felt that they continued to have daily leakage and remained frustrated.<sup>2</sup> Surgery for SUI is fast and effective.

Once the SUI diagnosis has been made and other significant dysfunction has been ruled out, the patient and provider must agree on an initial therapeutic approach. Surgery should not be offered immediately to: (1) women of childbearing age who have not completed their family planning; (2) women with significant comorbidities and high surgical risk; and (3) women with overactive bladder (OAB) and mixed urinary incontinence, where the OAB has not been first addressed. Notwithstanding these contraindications, surgery for SUI is often straightforward and the best option. All incontinence surgeons love the words, “Can’t I just have surgery?”

Before we pour on the accolades for mid-urethral sling (MUS) surgery and declare it a winner (can you beat success rates of 77% cure rate at 11 years from Finland<sup>3</sup> or the 85% cure rate at 7 years from Greece<sup>4</sup>), we are obliged to look at the alternatives. We all attempt to modify our patient’s behaviours, such as reduce their coffee intake, increase weight loss and suggest pelvic floor physiotherapy. Yet each surgeon wonders: “When will this fail and when can I book her surgery?” Behaviour modification is not successful because patients need to understand, learn about their condition, perform regular and intentional physical exercises and consciously make challenging lifestyle adjustments. Most people are incapable of taking on this responsibility or are unwilling to pay for uninsured services.

## Weight loss

Let’s examine weight loss, reported to be successful as a treatment for SUI. One trial in the *New England Journal of Medicine* looked at one female group of 226 patients who underwent an “intensive 6 month weight loss program that included diet, exercise and behaviour modification,” and a control group of 112 female patients who entered a “structured education program.”<sup>5</sup> During the 6 months, the “intensive group” saw an 8% weight loss and a 47% reduction in incontinence episodes. The control group experienced a 1.6% weight loss and a 28% reduction in incontinence episodes.<sup>5</sup> This is fantastic as long as when you suggest to a woman that she “lose weight to help her leakage” you can offer her a program that is this intensive and worthy of publication in the *New England Journal of Medicine*. In 2010, MacFarlane and Thomas summarized it best when they said ... “in practice it is inordinately difficult and only a small percentage manage to maintain their weight loss over the long term.”<sup>6</sup> In another study, patients in an intensive lifestyle intervention lost 4.7% of their initial weight at 4 years, while only 1.1% in the diabetes support and education group lost weight.<sup>7</sup> Losing weight is very difficult so relying on it as a treatment for SUI is almost useless.

## Pelvic floor muscle training

Pelvic floor muscle training (PFMT), particularly under the direction of a dedicated pelvic floor physiotherapist or nurse continence advisor (NCA), can be successful about 40% of the time; however, at a considerable cost (time and money) to the patient.<sup>8</sup> In Dumoulin and Hay-Smith’s light reading 54-page Cochrane Review from 2010, they compare the results of PFMT to no treatment or inactive controls. They conclude that PFMT is better than no treatment. They felt PFMT should be offered as first-line treatment of SUI; however, they also conclude that there is no evidence that

PFMT is cost-effective in the short- or long-term.<sup>9</sup> In summary, PFMT is expensive to the patient (\$100 to \$175/hr), invasive to a point, time-consuming, and best completed in a supervised setting; however, it may not be cost-effective in the long-term and the success outside of a structured setting is unknown. Sign us up!

## Medical therapy

Is there a role for medical therapy for SUI? No. Duloxetine was never approved by the FDA or Health Canada for stress incontinence. Nausea rates of 23% and cure being similar to placebo stopped its progression.<sup>10</sup> Recently, several large studies have put the nail in the coffin for oral and topical estrogen therapy as treatments for incontinence; these studies showed that these therapies worsened incontinence!<sup>11-13</sup>

## The case for surgery

To this point, we've "poked holes" in the conservative treatments for SUI. We can now argue the benefits of SUI surgery and, especially in the modern era, the benefit of MUS, such as the tension-free vaginal tape (TFVT) devices and the trans-obturator tapes (TOT), which have quickly become the gold standard for surgical therapy of female SUI since its introduction in 1993.<sup>14</sup> Their high surgical cure rates (70% to 99%), minimally invasive nature, short length of stay and tolerable complication profile have established this reputation.<sup>15</sup> In our randomized comparative trial of TFVT versus TOT, at 12 months we witnessed a 77% and 81% cure rate as defined rigorously as <1 g of urine on defined pad test.<sup>16</sup> Others have reported similar cure rates, albeit with varying definitions of cure. Recently, Esin and colleagues reported excellent success with the TOT even in obese patients, with cure rates of 92% and 91.3% for obese and non-obese patients, respectively.<sup>17</sup> Additionally, complication rates were low and similar in both groups. Critics may argue that these trials suffer from short follow-up; however, the Finnish study shows the durability of surgical therapy for SUI.<sup>3</sup> In this study, 77% of the initial 90 women were available for follow-up at 11.5 years post-TFVT, with 90% having a negative stress test and negative pad test. Subjectively, only 3% regarded their operation as a failure, while 77% were cured and 20% improved. Furthermore, no late complications, such as tape erosion, were seen. If 77% of our patients still considered themselves cured at 11 years, we would be delighted.

Having established the high success rate and the durability of the MUS, we must examine its safety. In the right hands, the MUS are not too risky. Published complication rates of MUS include 4.7% bladder perforation, 6% de novo OAB and 4% to 10% new onset urinary retention.<sup>15</sup> In our TFVT versus TOT study, bladder perforation was 2.9% show-

ing that experienced surgeons can have lower complication rates (though they still occur). Surgeons using mesh should be aware of the advisories from the US Food and Drug Administration<sup>18</sup> and Health Canada<sup>19</sup> and respect the materials they are working with. Additionally, surgeons performing MUS should advise patients that on occasion a secondary procedure for recurrent stress incontinence, urinary retention, refractory OAB or mesh erosion or extrusion may be necessary. Importantly, surgery for SUI should be performed by specialists with an acceptable volume of cases and who can effectively recognize and treat potential complications.

## Conclusion

We have outlined the limitations of conservative treatments and highlighted the enormous success rates of surgical therapy with MUS, such as the TFVT and TOT. Ultimately, the choice will be with the patient, and many will select the fastest and most effective method to treat their stress incontinence, which is surgery.

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## POINT-COUNTERPOINT

# Conservative treatment for female stress urinary incontinence: simple, reasonable and safe

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**S**tress urinary incontinence (SUI) is common among women and has a significant negative impact on daily functioning and quality of life. SUI also has a large economic impact on health systems necessitating the implementation of simple and cost-effective management plans.<sup>1</sup> Although surgical treatments are widely used for SUI, many women prefer a self-managed conservative option to avoid long-term recurrence or possible devastating complications of surgical interventions. Moreover, some women are not eligible for surgery or prefer to defer it (i.e., women who plan to conceive). Pelvic floor muscle training (PFMT), vaginal devices, electrical stimulation and pharmacological agents (duloxetine) are conservative options for SUI.

### Pelvic floor muscle training

Urethral closure is maintained by an adequate support provided by the endopelvic fascia and the tonic contraction of the levator ani muscles. When properly carried out, PFMT restores the ability to contract these muscles in a timed and coordinated way and thus improves or restores continence.<sup>2</sup> A systematic review of 12 trials (involving 672 women) showed better continence-specific quality of life, fewer incontinence episodes per day and less leakage on pad test in women who practiced PFMT compared to controls.<sup>3</sup> A diligent physiotherapist and a motivated patient are needed to obtain good results with PFMT. PFMT could be taught in individual or in group sessions. Both methods yield similar improvement in clinical variables and in patient satisfaction.<sup>4</sup> A recently published Cochrane review which compared several PFMT approaches for SUI found

that regular supervision (e.g., weekly) combined with group sessions contribute to the success of PFMT; up to 90% of women reported improvement.<sup>5</sup>

Few studies reported the long-term results of PFMT. Bo and Talseth examined 23 women, 5 years after ceasing organized PFMT and found satisfaction rate of 70%. Seventy percent of women were exercising the pelvic floor muscles at least once a week, 75% showed no leakage during stress test and mean pelvic floor muscle strength was maintained.<sup>6</sup> Cammu et al showed that when PFMT is initially successful there is a 66% chance that the favourable result will persist for at least ten years.<sup>7</sup> A recent review of long term outcomes of PFMT supports these findings,<sup>8</sup> although other studies found lower success rates of PFMT.<sup>9</sup> PFMT is non-invasive with negligible side effects and low costs and should be suggested as a first line choice in SUI management.<sup>10</sup>

### Weighted vaginal cones

About 30% of women are unable to perform adequate voluntary muscle contractions.<sup>11</sup> Vaginal cones produce an involuntary contraction of pelvic floor musculature in reaction to the cone weight in the vagina, thus strengthening and synchronizing PFM and reducing SUI.<sup>12,13</sup> Cones are usually easy to insert, may be self-taught and used without supervision or vaginal examination. Women are instructed to insert the heaviest cone they can retain while standing and moving around; they can gradually increase cone weight as their muscle strength improves. Generally, the instructions are to carry the cone for two sessions of 15 minutes per day for one month or more,<sup>12</sup> but the duration of therapy is controversial. The effectiveness of vaginal cones is similar to that of PFMT.<sup>12,14</sup> Peattie and colleagues evaluated 30 patients who used vaginal cones, 70% of them were found to be completely dry or to have improved with respect to urinary loss after one month of treatment.<sup>15</sup> Side effects, such as vaginal pain and increased vaginal discharge, were reported in one study among 10% of the patients, although no treatment was required and there was no need to discontinue therapy.<sup>16</sup> A systematic review of 17 studies (involving 1484 women) on vaginal cone use for SUI treatment concluded that weighted vaginal cones are better than no active treatment and with similar effectiveness to PFMT. However, it pointed out that the drop-out rate in these studies was relatively high (average 25%), suggesting that this modality is not always well-accepted among patients.<sup>17</sup>

### Biofeedback

Both vaginal and anal surface electromyograms and urethral and vaginal squeeze pressure measurements have been used to make the patient more aware of muscle function and to enhance patient effort during PFMT.<sup>17</sup> Biofeedback is not a

treatment on its own, but an adjunct to training, measuring response while the patient is contracting. Several randomized controlled trials and systematic reviews, which compared PFMT with and without biofeedback, did not find significant benefit in adding biofeedback to PFMT.<sup>18,19</sup> A recent Cochrane systematic review, which included 24 trials involving 1584 women with urinary incontinence, evaluated the effectiveness of adding biofeedback to PFMT. Women who received biofeedback were significantly more likely to report that their urinary incontinence was cured or improved compared to those who received PFMT alone (risk ratio 0.75, 95% confidence interval 0.66 to 0.86). However, it was not clear whether this was the effect of the biofeedback device itself or the benefit from spending more time in clinic with the doctor, nurse or physiotherapist.<sup>20</sup>

### Electrical stimulation

Electrical stimulation either vaginal or extracorporeal is a modality which has been in clinical use in Europe and North America for three decades. Several early uncontrolled trials reported efficacy in urinary incontinence treatment, with improvement rates from 35% to 70%,<sup>21,22</sup> whereas in controlled trials the results were conflicting<sup>14,23</sup> and no additional benefit over PFMT was demonstrated.<sup>24,25</sup> The lack of evidence is compounded by differences in stimulation parameters and duration of treatment. Women with SUI who are having difficulties to correctly perform PFMT may benefit from a device which directly stimulates contraction of the pelvic floor.

### Incontinence pessary

Incontinence pessary is an intravaginal device with a knob that sits under the urethra to increase urethral support. It is an effective, self-managed option for SUI which is often underused due to a lack of knowledge regarding pessary fitting and its use in SUI.<sup>26,27</sup> A major limitation is the difficulty in inserting it properly and correctly positioning the device.<sup>27</sup> Nevertheless, more than half of the women who were successfully fitted with a pessary for SUI used it for the next 1 to 2 years.<sup>28</sup> A newly designed tampon-shaped device is available in different sizes. A recent pilot study found it to be effective and easy to manipulate, with a 76% satisfaction rate after one year of usage.<sup>27</sup>

### Pharmacological treatment

Different pharmacological agents, such as alpha adrenergic agonists, antidepressants and hormone replacement therapies, are not advocated for SUI due to the lack of significant benefit and high adverse effect profile.<sup>29</sup> Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor.

Serotonin and norepinephrine promote urine storage by relaxing the bladder and increasing sphincter resistance.<sup>30</sup> Three large multicentre, double-blind, placebo-controlled trials investigated the efficacy of duloxetine to treat SUI. More than 1635 women in five different continents were included in these trials. The trials demonstrated that duloxetine can decrease the frequency of incontinence episodes by up to 50% compared to placebo. However, the high rate of treatment discontinuation (up to 22%) due to adverse effects was consistent in all three trials; nausea was the most common adverse effect.<sup>30</sup> Duloxetine was approved by the European Union to treat SUI in 2004. Despite its demonstrated efficacy, the manufacturer decided to market duloxetine for depression rather than SUI and presently does not sell it in the dose shown to be effective for SUI (40 mg twice daily). Clinical studies done after the approval had conflicting results suggesting that more studies are required to evaluate the utility of duloxetine in SUI treatment.

## Conclusion

Conservative treatments for SUI are demonstrated to be beneficial, cost-effective and to have minimal side effects. Conservative management enables patients to be actively involved in the management of their SUI, while temporarily or permanently avoiding invasive procedures. According to current guidelines, lifestyle modifications (such as weight reduction) and conservative treatments should be advocated to all women with SUI as first-line treatment.<sup>10</sup>

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