greater weights can be used with practice.

Electrical stimulators are available in a range of devices that provide varying intensities and frequencies. Electrodes can be place vaginally or rectally. One prospective randomized masked trial showed that electrical stimulation was better than a sham device based on pad weigh testing improving by 50% in 62% of actively treated patients (Sand et al, 1995). Another non-randomized trial achieved cure in 50% and improvements in 72% at 3 months following cessation of treatment.

Bladder neck supports are devices that are inserted into the vagina to lift the bladder neck and so improve incontinence. These are useful in situations where incontinence is expected to be worse for short periods (e.g. sports) or when the other conservative measures are not suitable (e.g. the very elderly). Complications include mucosal erosion and UTI. Urethral plugs can help but are unacceptable to many and predispose to ascending infections.

Pharmacotherapy

Until recently, the role of medical treatment in SUI has remained limited. Various agents have been used 'off label', including oestrogen replacement, alpha-adrenergic agonists, beta-adrenergic antagonists and tricyclic antidepressants. However, none have demonstrated sufficient effect to justify widespread acceptance or approval (Viktrup and Bump, 2003).

Duloxetine, which is a selective serotonin and norepinephrine re-uptake inhibitor (SNRI), has been the focus of much recent attention as work indicates that it can significantly increase bladder capacity, and enhance external urethral sphincter activity (Thor and Katofiasc, 1995). Effects appear to be unique to the dual action of the drug, and cannot be readily reproduced by combined administration of selective serotonin and adrenergic reuptake inhibitors (Katofiasc et al, 2002).

In 2002, the first phase III study was published involving 683 women (Norton et al. 2002). Patients were randomly assigned to either a placebo, or to duloxetine 40 mg twice daily for 12 weeks. The primary outcome variables were incontinence episode frequency (IEF) and incontinence quality of life (I-QOL) scores, and the patient global impression of improvement (PGI-I) rating. The duloxetine group demonstrated a significant reduction in IEF, seven per week compared to three per week in the placebo group ($P<0.001$), the difference being unaffected by baseline incontinence severity. Using intention-to-treat analysis, 51.4% in the duloxetine group showed a 50–100% reduction in IEF compared to 33.5% in the placebo arm ($P<0.001$). These IEF improvements were demonstrable after 4 weeks treatment and persisted until the end of the study at 12 weeks.

Duloxetine was associated with significant improvements in I-QOL scores when compared to placebo, and PGI-I ratings paralleled this result. The most common adverse events noted in the treatment group were nausea (22.7%), fatigue (14.8%), insomnia (14.2%) and dry mouth (12.2%); Nausea was mild to moderate in 87% of the duloxetine group, and of these 74% completed the study, 81% of which had resolution of the nausea within 1 month.

Two other phase III studies involved 458 women (Millard et al, 2004), and 494 women (van Kerrebroeck et al, 2004). Subjects were randomized to placebo or Duloxetine. A significant decrease in IEF was described (an IEF reduction decrease 50% treatment *vs* 29% placebo) as well as parallel improvements in I-QOL and PGI-I. Significant increases in voiding intervals were observed with nausea once again being the most common adverse effect.

Tricyclic antidepressants have been used for SUI but no trials of quality substantiate the benefit of the drug class; and the side effect profile is often problematic. Oestrogens are also frequently used especially in the post-menopausal females, but hard evidence for their efficacy is scant. A Cochrane review found that, when combining subjective cure and improvement measures in women with stress incontinence, 46/107 (43%) *vs* 29/109 (27%) (treatment *vs* placebo) found improvement (Moehrer et al, 2003). Nonetheless, based on meta-analysis data, it is safe to say that there are significant subjective improvements with oestrogen, which do not necessarily translate into improvements in objective parameters.

Adrenergic agents (e.g. clenbuterol, phenylpropanolamine) for SUI have been shown to have a weak effect, with reductions in pad changes and incontinent episodes. The side effect profile is generally minor but is overshadowed by occasional serious cardiac arrhythmia or hypertension (Alhasso et al, 2003).

Surgical treatment

Surgical treatment aims to improve the support of urethro-vesical junction. There is no agreement as to the precise mechanism by which continence is achieved. A variety of surgical techniques have been described. Open retropubic colposuspension is considered the gold standard. This includes Burch, Marshall-

TABLE 1.
SURGICAL TREATMENTS AND OUTCOME RATES

Surgical treatment	Follow-up and outcome
Burch colposuspension[1]	■ 85–90% dry at 1 year ■ 69% cured at 13.8 years.
Marshall-Marchetti-Krantz[2]	■ 77% dry at 1 year ■ 61% cured at 22 years
Laparoscopic colposuspension[3]	■ 30% dry at 45 months ■ Rate of failure increases after 5 years
Anterior colporrhaphy[4]	■ 42% objective and 52% subjective cure rates at 14 years.

1. Alcalay et al, 1995; 2. Czaplicki et al, 1998; Hegarty et al, 2001; 3. Burton, 1999; McDougall et al, 1999; 4. Colombo et al, 2000

Marchetti-Krantz and vaginal shelf repair (*Table 1*).

Burch colposuspension is the most commonly utilized repair. The overall continence rate is 85–90% after 1 year and more than 70% can expect to be dry at 5 years (Lapitan et al, 2003) On longer term follow-up (mean 13.8 years) 69% subjective and objective cure rates were achieved with the Burch repair (Alcalay et al, 1995). Overall, with retro-pubic coloposuspension, one can expect a time-related decline of 'cure' of up to 15–20% beyond 5 years (Lapitan et al, 2003). Redo surgical rates also fair well with 71% subjective vs 80% objective cure rates at 4 years (Thakar et al, 2002).

Suburethral slings have been widely used in the treatment of SUI. However, other than the tension-free vaginal tape (TVT), which utilizes Prolene mesh tape, there is insufficient data to draw meaningful conclusions as to whether alternative slings (e.g. PTFE or rectus fascia) are as effective as open colposuspension in the management of SUI (Bezerra and Bruschini, 2001).

Two prospective randomized studies have compared cure rates of TVT and Burch colposuspension at 6 months (66% *vs* 57%) and at 2 years (84% *vs* 86%) in treatment of primary SUI (Liapis et al, 2002; Ward and Hilton, 2002). In a long-term, randomized controlled trial Culligan et al (2003) report better results with suburethral sling, compared to colposuspension (100% *vs* 84% dry at mean follow up 72.6 months) (*Table 2*).

TABLE 2.
SLING SURGERY AND OUTCOME RATES

Sling surgery	Follow-up and outcome
TVT[1]	■ 81.3% cured at 7.6 years
Suprapubic arch sling (SPARC)[2]	■ 72.4% objective cure at 2 years
Rectus fascia pubovaginal sling (PVS)[3]	■ Autograft : 77% cured at 2 years ■ Allograft : 71% cured at 2 years
TOT	■ As effective but safer than TVT at short term ■ Long term data awaited

TVT: tension free vaginal tape; TOT: trans obturator tape
1. Nilsson et al, 2004; 2. Lim et al, 2005; 3. Flynn and Yap, 2002

Similarly, compared to laparoscopic Burch colposuspension, TVT was found to be more cost effective with similar cure rates at 6 to 36 months follow-up (Cucinella et al, 2003). This could be explained by the fact that the hospital stay, and hence the cost, for TVT are about 25% lower (Bezerra and Bruschini, 2001). Nonetheless, significant and serious complications are seen with TVT. The overall rates of complications such as bladder injury (7.5–36.3%), significant bleeding (0.9%), nerve injury (0.9%) and urinary tract infection (6.1%) are not uncommon (Karram et al, 2003; Moran et al, 2000; Nilsson and Kuuva, 2001)

The transobturator-tape (TOT) is a relatively new procedure first described by Delorme (2001). It essentially uses a mesh sling to support the mid-urethra as in the TVT, but the approach avoids going near the retropubic space where the serious complications of the TVT procedure (vascular injury, bowel perforation) can occur.

Two randomized prospective trials exist comparing the TOT to the TVT, but both were underpowered for definitive comparisons to be made (de Tayrac et al, 2004; Mansoor et al, 2003). Data from these studies and from observational studies does support that the procedure is as effective in curing SUI as the TVT or colposuspension in the short term but both long-term success rates and complication rates will need more rigorous data. Complication rates appear to be low but trials have been underpowered to detect statistically significant differences.

The adjustable continence therapy implant (ACT implant; Uromedica, Plymouth, MN, USA) is a silicone balloon implant, which can be adjusted to achieve continence. It has been successfully used to achieve continence in post TVT recurrence. ACT may be the current alternative to therapy with injectable microballoons.

Periurethral injections have been used as a minimally invasive method. The randomized trials reported have used collagen, macroplastique, carbon particles and autologous fat. A recent review concluded that bulking agents may be used with limited benefit in the short term (1 year), but that results are still inferior to colposuspension (58% to 85%) (Pickard et al, 2003). There is no evidence that these agents should be used routinely as the first line of treat-

ment. However, in high-risk patients they may be a useful option for relief of symptoms in the short term, although multiple injections may be required to achieve desired results.

Needle suspensions (Pereyra , Stamey and Raz) have not stood the test of time. Trockman et al (1995) have reported only 20% patients cured at 10 years follow-up.

Lastly, the artificial urinary sphincter (AUS) has been used in cases refractory to the above methods. The success rate ranges from 91–99%, with an erosion rate of between 7 and 29%. It may be concluded that AUS is an acceptable method of managing SUI after the failure of other surgical options (Kowalczyk and Mulcahy, 2000).

In spite of high cure rates with surgical treatment there is a post-operative voiding dysfunction rate of 5–20% which may be successfully treated with urethrolysis (Dunn et al, 2004).

CONCLUSIONS

Stress incontinence constitutes an important issue for primary and secondary health-care providers. This article reinforces the need for health professionals to be proactive in questioning and educating patients about this common lower urinary tract symptom. A better understanding of the pathogenesis and risk factors, particularly in relation to pregnancy and childbirth, may help to prevent or minimize the risk of stress incontinence in later life.

In cases refractory to conservative measures, surgery has traditionally provided the next treatment option. Medical therapies up to now have been limited and mainly unproven. New medical advances, such as duloxetine, provide primary and secondary health-care providers with a safe and effective alternative first-line therapy, and challenge our traditional principles of the management of incontinence. More importantly, patients are provided with a greater choice as there appears to be additional benefit in administering duloxetine concomitantly with pelvic floor exercises. These new therapies prompt the need for new guidelines to be used in the management of incontinence. **HM**

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KEY POINTS

- Urinary incontinence is a significant clinical problem with prevalence of 10–40% and economic costs of treatment running up to $19.5 billion in the US.
- Nearly half of all the incontinent women have stress incontinence.
- Age, pregnancy, parity, obesity and previous surgery appear to be directly connected to causality of stress incontinence.
- Tension-free vaginal tape (TVT) is fast replacing the Burch colposuspension as the gold standard treatment with as good results over long term.
- Duloxetine has shown promise but long-term data are awaited.
- In combination with pelvic floor exercises duloxetine can be considered to be the first-line treatment in the community setting.