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2009
Annual Evidence Update
Urinary Incontinence

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1. Introduction

Urinary Incontinence

By Alison Brading, Emeritus professor of Pharmacology, University Department of Pharmacology, Mansfield Road, Oxford OX1 3QT

Urinary incontinence is normally not life-threatening, and yet may have a greater detrimental effect on the quality of life of those suffering from it than many more serious conditions. A great deal of literature is published yearly, and the aim of this annual evidence update is to direct attention to the relevant information gleaned from papers published about male and female urinary incontinence in recent years.

We have considered the more traditional pharmacological and surgical treatment of adult male and female stress and urge incontinence, including post-prostatectomy incontinence in men, and, as well as more conservative approaches now cover the rapidly growing use of botulinum toxin injected into the bladder wall as a treatment for urge incontinence.

We hope that this will provide a useful source for busy clinicians, and will help to improve treatment of this devastating condition.

2. Methodology

The NICE guideline Urinary incontinence: the management of urinary incontinence in women published in 2006 was identified. The aim of this AEU is to update the evidence from 2006-2008.

The original NICE search strategies were obtained and we devised our own search strategies using both these strategies and the involvement of the clinicians in our expert panel. Databases searched included Cochrane Database of Systematic Reviews, OVID Medline, OVID Embase and EBSCOHOST CINAHL. Systematic reviews, meta-analyses and randomised controlled trials (RCTs) were specifically targeted, using a combination of the SIGN Embase Systematic Review filter, the SIGN Embase RCT filter, the Medline Systematic Review CRD filter, the Medline SIGN RCT filter and the CINAHL SIGN Systematic Review and SIGN RCT filters. The search terms used included urinary incontinence; stress incontinence; overactive bladder; urge incontinence; Botulinum; sacral nerve stimulation; conservative management; quality of life. These were combined with sub-headings including: drug therapy; surgery. Limits such as 'English in language', adult and female were applied and the search was also restricted to the date range 2006 to 2008.

The retrieved references were sifted by members of the expert panel to identify all the good quality papers. These papers were then manually inspected to determine their relevance and appropriateness for inclusion in this document. Articles included were good systematic reviews and randomised controlled trials, and less robust studies where they were considered to illustrate a point of controversy or indicate a possible future direction for the management of the condition. When a paper was to be included, or where doubt existed over the appropriateness of the data, the full-text was obtained. Summaries were then written based on the NICE guideline to which has been added any new evidence where this has become available.

3. Drug therapy in the management of overactive bladder syndrome

Dr Natalia Price, Subspecialty trainee in urogynaecology,
Mr Simon R Jackson, Consultant Urogynaecologist,
Department of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford.

Background

Overactive bladder syndrome (OAB) is a condition defined as urinary urgency, with or without urge incontinence and usually with frequency and nocturia [1]. Pharmacological suppression of detrusor overactivity with anticholinergics (antimuscarinics) is the most widely used treatment for this condition. Anticholinergic drugs block the muscarinic receptors that mediate detrusor smooth-muscle contraction and have a direct, relaxing effect on the detrusor muscle. There are a number of drug treatments available. They differ in their selectivity for various muscarinic receptors and some drugs have additional actions, such as direct smooth muscle effects. There is no evidence of any clinically important difference in efficacy between these antimuscarinic drugs. Based on a cost minimisation analysis, non-proprietary immediate-release oxybutynin is the most cost effective antimuscarinic drug [2]. Adverse effects are common with all antimuscarinic drugs and, therefore, early review of treatment is good practice. Oestrogen replacement has been promoted as a solution to urinary incontinence in postmenopausal women. Oestrogens help to maintain the health of tissues that are essential for normal pressure transmission in the urethra.

NICE guideline recommendations 2006

Recommendations for anticholinergic drugs

Immediate release non-proprietary oxybutynin should be offered to women with OAB or mixed urinary incontinence (UI) as first-line antimuscarinic drug treatment, if bladder training has been ineffective. If immediate-release oxybutynin is not well tolerated, darifenacin, solifenacin, tolterodine, trospium or an extended release or transdermal formulation of oxybutynin should be considered as alternatives. Women should be counselled about the adverse effects of antimuscarinic drugs.

An early treatment review should be undertaken following any change in antimuscarinic drug therapy. Propiverine should be considered as an option to treat frequency of urination in women with OAB, but is not recommended for the treatment of UI. Flavoxate, propantheline and imipramine should not be used for the treatment of UI or OAB in women.

Recommendations for oestrogens

Systemic hormone replacement therapy is not recommended for the treatment of UI. Intravaginal oestrogens are recommended for the treatment of OAB symptoms in postmenopausal women with vaginal atrophy.

New evidence for anticholinergic preparations

Pharmacological suppression of detrusor overactivity with anticholinergics is the mainstay of OAB pharmacotherapy. There have been number of placebo-controlled randomised studies of antimuscarinic drugs and comparison RCTs of these drugs in recent years, as well as systematic reviews of available preparations [3,4,5].

Oxybutynin, propiverine, tolterodine and trospium chloride have been used for many years to treat OAB symptoms. Sustained release oxybutynin transdermal patches, which release 3.9mg every 24 hours, have recently been launched in the UK [5,6,7].

Solifenacin and darifenacin are newer bladder-selective anticholinergic preparations. They are more recent useful additions to the list of available drugs and may possibly have a lower incidence of adverse effects. Solifenacin is a long-acting muscarinic antagonist. At 5mg and 10mg daily dosing it reduces the frequency of daily voids and number of urge and incontinence episodes. Efficacy has been observed as early as within one week of starting treatment. Darifenacin is a highly selective M3 receptor antagonist available in 7.5 or 15 mg once-daily sustained-release form [8,9].

Fesoterodine is the latest addition to the available list of drugs. It is a nonselective oral antimuscarinic agent that exerts its pharmacologic effects as a competitive muscarinic receptor antagonist. Fesoterodine acts as a prodrug; when administered, it is rapidly hydrolysed by nonspecific esterases to the active metabolite, 5-hydroxymethyl tolterodine (5-HMT). After oral dosing, the parent compound is not detectable in plasma. The main active metabolite of fesoterodine, 5-HMT, is identical to the active metabolite of tolterodine; 5-HMT is formed from tolterodine by cytochrome P450 2D6-mediated oxidation in the liver. Clinical trials have demonstrated that treatment with fesoterodine 4 and 8 mg resulted in statistically significant and clinically relevant improvements in bothersome OAB symptoms compared with placebo. Treatment effects appeared to be more pronounced with fesoterodine 8 mg than with tolterodine ER 4 mg or fesoterodine 4 mg, especially regarding urge incontinence episodes and volume voided per micturition. Fesoterodine 4 and 8 mg were generally well tolerated and discontinuations because of an adverse effect (AE) were low. Observed AEs were low and similar to those of a placebo, except for dry mouth, which occurred at a higher rate with fesoterodine 8 mg. The availability of two doses of fesoterodine presents an additional clinical benefit, in that dose flexibility allows OAB treatment to be tailored to individual subject needs [10,11].

Many new promising compounds are emerging, which target key molecular pathways involved in micturition control but effective nonantimuscarinic treatments for OAB are currently scarce [12]. The most promising potential therapeutic targets include: nervous GABAergic, glycinergic, dopaminergic, and serotonergic systems; b-drenoceptors and cAMP metabolism; nonadrenergic–noncholinergic mechanisms such as purinergic and neuropeptidergic systems; vanilloid receptors; bladder afferent nerves; nonneuronal bladder signaling systems including urothelium and interstitial cells; prostanoids; Rho-kinase; and different subtypes of potassium and calcium different subtypes of potassium and calcium channels. Despite the enormous amount of new biologic insight, very few drugs with mechanism of action other than antimuscarinics have passed as yet the proof-of-concept stage. Further preclinical and clinical studies are urgently needed in this rapidly moving field.

New evidence for oestrogens

Very little further evidence has become available since publication of the NICE guideline, Urinary incontinence in women (2006). Short-term studies of intravaginal oestrogens suggest some improvement in symptoms of incontinence and frequency in postmenopausal women who have urogenital symptoms secondary to vaginal atrophy.

Systemic oestrogen treatment does not confer any benefit in women with UI and there is evidence that it may increase the likelihood of developing incontinence in postmenopausal women.

Conclusions

Antimuscarinics remain the mainstay of medical therapy for overactive bladder. Intravaginal oestrogens provide some improvement in symptoms of incontinence and frequency in postmenopausal women who have urogenital symptoms secondary to vaginal atrophy. Despite the enormous amount of new biologic insight, very few drugs with mechanism of action other than antimuscarinics have passed as yet the proof-of-concept stage. Further preclinical and clinical studies are urgently needed in this rapidly moving field.

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4. Sacral nerve stimulation in the management of overactive bladder syndrome

Dr Natalia Price, Subspecialty trainee in Urogynaecology,
Mr Simon R Jackson, Consultant Urogynaecologist,
Department of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford.

Background

Overactive bladder syndrome (OAB) is a common condition with a significant negative impact on quality of life. Currently accepted practice is to offer lifestyle or behavioural modifications or antimuscarinic medications as initial treatments.

Where these are unsuccessful, a range of surgical interventions may be considered. These aim to increase the capacity of the bladder, alter or modulate its nerve supply and contractility, or to bypass the lower urinary tract completely.

Sacral nerve modulation (SNS) is a least invasive surgical procedure used in management of overactive bladder syndrome. The principle of neuromodulation is that appropriate electrical stimulation of the sacral reflex pathway will inhibit the reflex behaviour of the bladder.

Permanently implantable sacral root stimulators have been developed to provide chronic stimulation directly to the S3 nerve roots. Patients first undergo a percutaneous nerve evaluation (PNE) in which a needle is inserted through the sacral foramina under local anaesthetic. This is connected to an external stimulation source and left in place for a few days. Those who show satisfactory response to the PNE may then proceed to a permanent implant.

NICE guideline 2006 recommendations on use of sacral nerve stimulation

Sacral nerve stimulation is recommended for the treatment of urinary incontinence due to detrusor overactivity in women who have not responded to conservative treatments. Women should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation. Life-long follow-up is recommended.

New evidence

Two systematic reviews and several randomised controlled trials (RCTs) published recently showed that complete continence (completely dry with no incontinent episodes) or improvement of more than 50% in incontinence symptoms was observed in 50% and 80% of patients, respectively, following the procedure. This compared with 5% of patients in the control groups, who were receiving conservative treatments while waiting for an implant. All studies considered SNS in the S3 foramen via an implanted device. Most studies included men and women [1,2,3,4,5,6,7].

In the one RCT that reported on patients with urgency-frequency, an improvement of more than 50% in incontinence symptoms was observed in 56% of patients, compared with 4% in the control group [4]. More evidence is available for patients with urge incontinence than for those with urgency-frequency.

The results of the case series studies included in the systematic review showed similar results, with complete continence and improvement in symptoms being reported in 39% (139/361) and 67% (338/501) of patients with urge incontinence, respectively, and 41% (22/54) and 65% (75/116) of patients with urgency-frequency, respectively. The benefits of sacral nerve stimulation were reported to persist for at least 3-5 years after implantation.

In the RCT of patients with urgency-frequency, after 6 months' treatment, frequency was significantly reduced, and mean voided volume and bladder volume at first sensation to void were significantly increased in the SNS group compared with control, with improvements in several SF-36 domains in the active treatment group (n = 51; 90% women). At 2 years follow-up of 21 patients, 43% had a reduction in frequency of at least 50% and 62% had an increase in voided volume of at least 50% [3].

A satisfaction rate of 68% was reported at mean follow-up of 2 years in one study. Three studies found significant improvement in quality of life (QOL) at 18 months.

Complications

Most complications observed in the studies were the result of technical problems related to implantation of the device. The results of the systematic review showed that, overall, the re-operation rate for patients with implants was 33% (283/860). The most common reasons for surgical revision were to replace or reposition implants due to pain or infection at the implant site, or to adjust and modify the lead system to correct breakage or migration.

Pain at the site of the pulse generator or at the site of stimulation was reported in 24% (162/663) of patients, sometimes requiring replacement and repositioning of the pulse generator. Other complications included lead-related problems such as migration (16%), wound problems (7%), adverse effects on bowel function (6%), and infection (5%). Surgical intervention for these complications was reported in between 7% and 66% (median 22%) of patients. Removal of the implant was required in 4-11% (median 7%). Other adverse effects were cases of seroma formation, disturbed bowel function (1-7%), wound dehiscence or infection (3-15%), infection (2-9%), toe flexion (8%) and pain (abdominal, leg, pelvis and gluteal incision) (2-20%). No cases of long-lasting neurological complications were identified.

Conclusions

Recent evidence continues to support SNS therapy as a safe and effective long-term treatment for OAB in appropriately selected cases refractory to other forms of treatment. Up to two-thirds of patients achieve continence or substantial improvement in symptoms after SNS, and the available data show that beneficial effects appear to persist for up to 3-5 years after implantation. Around one-third of patients may require re-operation, most often owing to pain at the implant site, infection, or the need for adjustment and modification of the lead system. Permanent removal of the electrodes may be required in one in ten patients. The treatment options for women who have not responded to conservative treatments are all costly and associated with significant morbidity. There is a stronger body of evidence to support the use of sacral nerve stimulation than augmentation cystoplasty, urinary diversion or botulinum toxin A.

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5. Intravesical Botulinum toxin injections in the management of Overactive Bladder (OAB) syndrome

Dr Natalia Price, Subspecialty trainee in Urogynaecology
Mr Simon R Jackson, Consultant Urogynaecologist.
Department of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford.

Background

Overactive bladder syndrome is a common condition with a significant negative impact on quality of life. Intravesical injection of botulinum toxin is increasingly used as a treatment for refractory overactive bladder, with case reports and series in the literature suggesting beneficial effects.

NICE guideline 2006 recommendations on the use of botulinum toxin

Bladder wall injection with botulinum toxin A should be used in the treatment of idiopathic detrusor overactivity only in women who have not responded to conservative treatments and who are willing and able to self-catheterise. Women should be informed about the lack of long-term data.

Botulinum toxin B is not recommended for the treatment of women with idiopathic OAB.

New evidence

Data on the use of botulinum toxin A in the management of idiopathic detrusor overactivity is still limited. The available data show cure or improvement of up to 90%, with duration of benefit between 3 and 12 months. Botulinum toxin B appears to be effective only in the short term (up to 6 weeks).

Botulinum toxin A (BTX-A)

Since the publication of the NICE guideline, several randomised controlled trials [7,8,11] evaluated BTX-A for the treatment of OAB refractory to conservative treatment. Patient numbers in these studies were small and included men and women. Duration of follow-up ranged from 3 to 12 months. The doses injected varied, ranging from 100 to 300 units (BOTOX) and 500 to 1000iu (DYSPOORT) into 10–40 sites in the bladder wall. Intravesical BTX-A does appear to reduce incontinence when compared with placebo, with results reported:

- cure or improvement rates of 60–93% at 3 weeks to 12 months follow-up [3,7,8,11]
- duration of response to a single dose of a mean of 24 weeks (range 10–52 weeks).

Intravesical BTX-A injections ameliorates all OAB symptoms within the first week after treatment, but urgency is most rapidly and consistently affected, suggesting an early effect on bladder afferent pathways [12]. The most common complication reported were voiding dysfunction and urinary retention (up to 43%), which usually resolved by 9 months [5,9,11]. Other complications reported were haematuria, pelvic pain, transient dysuria and UTI.

Use of low doses of BTX-A (100U BOTOX) appeared to have a similar rate of improvement and were associated with significantly fewer adverse events (eg. urinary retention) compared with 150 or 200 U. However, the duration of therapeutic effectiveness was significantly shorter for the patients treated with 100 U compared with that for those treated with 150 or 200 U of BTX-A. [5]

One study looked at the additional injection of low doses of BTX-A into the external sphincter muscle and concluded that for patients who are at high risk of post-treatment urinary retention this could be one option in reducing the risk [3].

Injections of BTX-A into detrusor muscle and suburothelial injections achieve a similar therapeutic effect on idiopathic detrusor overactivity. One RCT compared injections of 100 U BTX-A into detrusor muscle with suburothelial injections. A successful result at 3 months was achieved in 93% in the detrusor group and 80% in the suburothelial injection group. [8]

Increasing evidence suggests that sensory nerve dysfunction contributes to the pathophysiology of OAB and, for this reason, targeting the afferent innervation of the bladder trigone during injection may provide clinical benefit. One study compared trigone or trigone-sparing injection of BTX-A. No significant difference in symptom score or treatment response was noted between the trigone and trigone-sparing groups. Further studies are needed to evaluate possible benefit of trigonal injection. [4]

Botulinum toxin B (BTX-B)

Efficacy of BTX-B in the treatment of refractory idiopathic DO in men and women was evaluated in one placebo-controlled RCT [2]. BTX-B was found to have a limited duration of action, with most of its symptomatically beneficial effects wearing off by 10 weeks in most patients. Transient adverse effects were urinary retention, constipation and dry mouth [2,6]. The short duration of action for BTX-B suggests it is unlikely to gain widespread use in the treatment of OAB. Its use will presumably be limited to patients who have experienced tachyphylaxis with botulinum toxin A.

Conclusion

Intravesical botulinum toxin shows promise as a therapy for overactive bladder symptoms, but as yet too little controlled trial data exist on benefits and safety. Furthermore, the optimal dose of botulinum toxin for efficacy and safety has not yet been established. It must be recognised that the therapeutic use of intravesical BTX is relatively recent and the longterm effects are unknown at this stage.

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6. Pharmacotherapy for stress urinary incontinence

Dr Natalia Price, Subspecialty trainee in urogynaecology,
Mr Simon R Jackson, Consultant Urogynaecologist,
Department of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford.

Background

Stress urinary incontinence (stress UI) is a common, distressing condition known adversely to affect quality of life. Until recently the only available treatments were conservative measures, lifestyle modification and a variety of surgical procedures.

Duloxetine is the first drug to be licensed for the treatment of stress UI. It is a potent balanced serotonin noradrenaline reuptake inhibitor. The inhibition of serotonin and noradrenaline reuptake during bladder storage is thought to increase pudendal nerve output, resulting in increased tone of the rhabdosphincter and subsequently improved urethral closure. Duloxetine has been evaluated in phase II and phase III clinical trials and was found to be efficacious and safe in the treatment of women with moderate to severe stress UI symptoms.

Oestrogen replacement has been promoted as a solution to UI in postmenopausal women, although its chief mode of action is unclear. Oestrogens help to maintain the health of tissues that are essential for normal pressure transmission in the urethra. These include the sphincter muscles, urothelium and vascular tissues, as well as the urethral secretions that may help to create a 'seal'.

NICE guideline recommendations 2006

Recommendations for duloxetine

Duloxetine is not recommended as a first-line treatment for women with predominant stress UI.

Duloxetine should not routinely be used as a second-line treatment for women with stress UI, although it may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. If duloxetine is prescribed, women should be counselled about its adverse effects.

Recommendations for oestrogens

Systemic hormone replacement therapy is not recommended for the treatment of UI.

Intravaginal oestrogens are recommended for the treatment of overactive bladder (OAB) symptoms in postmenopausal women with vaginal atrophy.

New evidence

Evidence for duloxetine

There have been further studies evaluating the efficacy and safety of duloxetine but there is still a lack of long-term safety data. Recent evidence from randomized placebo controlled trials have shown it to be significantly more effective than placebo in reducing incontinence episode frequency and improving quality of life scores [1-4].

However, adverse effects, particularly nausea, and discontinuation rates are very common. Sixty-eight percent of patients discontinued duloxetine within the first 4 weeks of commencing treatment because of the adverse effects [5]. In one cohort study only 9% of patients were still taking duloxetine one year later [6]. The main reasons for discontinuation were intolerance of duloxetine's side effects and perceived lack of efficacy.

The data also suggest that the 20 mg BID dose escalation regimen may contribute to a decrease in the adverse event related discontinuation rate for women taking duloxetine. The results of one trial demonstrate that starting duloxetine treatment at a dose of 20 mg BID for 2 weeks before increasing the dose to the optimally effective 40 mg BID dose significantly reduced the risk of nausea and dizziness [7].

In conclusion, the available evidence suggests that duloxetine treatment can improve the quality of life of patients with stress urinary incontinence but it is unclear whether or not the benefits are sustainable. The commonest adverse effect was nausea and many women stopped the treatment as a consequence. Treatment with duloxetine can be considered in women not suitable for surgical treatment or awaiting surgery. If duloxetine is prescribed, women should be counselled about its adverse effects.

Evidence for oestrogens

Very little further evidence has become available since publication of the NICE guideline, Urinary incontinence in women (2006). Short-term studies of intravaginal oestrogens suggest some improvement in symptoms of incontinence and frequency in postmenopausal women who have urogenital symptoms secondary to vaginal atrophy. There is a lack of evidence to support the use of intravaginal oestrogens for the treatment of stress UI.

Systemic oestrogen treatment does not confer any benefit in women with UI and there is evidence that it may increase the likelihood of developing incontinence in postmenopausal women. Systemic oestrogens are also associated with increased risk of thromboembolism.

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7. Surgical management of stress urinary incontinence

Dr Natalia Price, Subspecialty trainee in urogynaecology,
Mr Simon R Jackson, Consultant Urogynaecologist,
Department of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxford.

Background

The large number of different procedures described for the surgical management of stress urinary incontinence (stress UI) reflects the numerous theories proposed to explain the pathophysiology of the condition and the continuing search for a procedure that can successfully deal with all cases. Although the range of procedures described is bewildering, a recent surgical classification simplifies them into those that aim to augment urethral closure and those that aim to support the bladder neck or urethra.

In 1997-98 approximately 8000 operations for stress UI were carried out in England over a 12-month period. By 2004-05 the annual number had increased by 16%, despite an approximately 90% reduction in the numbers of colposuspension and needle suspension procedures and a 30-50% reduction in bladder neck buttress, sling and periurethral injection procedures. This increase was entirely due to the rapid introduction of tension-free vaginal tape and similar mid-urethral tape procedures.

NICE (2006) recommendations on surgical management of stress UI

Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI if conservative management has failed. Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options, provided women are made aware of the lack of long-term outcome data.

Intramural bulking agents should be considered for the management of stress UI if conservative management has failed. Women should be made aware that repeat injections may be required to achieve efficacy, efficacy diminishes with time and efficacy is inferior to that of a retropubic suspension or sling.

Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate. Laparoscopic colposuspension is not recommended as a routine procedure for the treatment of stress UI in women. The procedure should be performed only by an experienced laparoscopic surgeon working in a multidisciplinary team with expertise in the assessment and treatment of UI.

New evidence

Laparoscopic colposuspension

Currently available evidence suggests that laparoscopic colposuspension may be as good as open colposuspension at two years postsurgery. There have been ten trials in which laparoscopic was compared with open colposuspension. All the trials concluded that the advantages of laparoscopy included decreases in blood loss, postoperative pain, hospital stay and duration of catheterisation. However, laparoscopy did increase operative times by a mean of 13.7 minutes. There were no statistically significant differences in objective cure, de-novo detrusor overactivity and voiding dysfunction between laparoscopy and laparotomy. Subjective cure rates ranged from 58-96% in the laparotomy group and 62-100% in the laparoscopy group [1,2]. Significantly higher subjective and objective one-year cure rates were found for women randomised to two paravaginal sutures compared with one suture in a single trial [3].

With the advent of polypropylene mid-urethral slings for stress UI, the purpose of laparoscopy for continence procedures has been questioned. In eight studies laparoscopic colposuspension has been compared with suburethral polypropylene vaginal slings [4,5]. There were no significant differences in the reported subjective cure rates of the two procedures but objective cure rates at 18 months favoured slings. No significant differences were observed for postoperative voiding dysfunction and perioperative complications. Laparoscopic colposuspension had a significantly longer operation time and hospital stay.

In conclusion, short-term results favour mid-urethral slings over laparoscopic colposuspension. If laparoscopic colposuspension is performed, the use of two paravaginal sutures appears to be the most effective method.

Retrobubic versus transobturator tapes

Various types of suburethral tapes inserted via the transobturator route (tension-free vaginal tape obturator route (TVTO) and transobturator tape (TOT)) have been widely adopted for treatment of stress urinary incontinence (SUI). There were five randomised controlled trials (RCT) that compared TVTO with TVT and six RCTs that compared TOT with TVT. When compared by subjective cure, TVTO and TOT at 2-12 months were no better than TVT (OR 0.85; 95% CI 0.60-1.21). Adverse events such as bladder injuries and voiding difficulties were less common, whereas groin/thigh pain, vaginal injuries or erosion of mesh were more common after tape insertion by the transobturator route. The evidence for short-term superiority of effectiveness of TOT is currently limited. Bladder injuries and voiding difficulties are lower but the risk of vaginal erosions and groin pain is higher with TVTO/TOT. Methodologically sound and sufficiently powered RCTs with long-term follow-up are needed and the results of continuing trials are awaited.

Single-incision sub-urethral short tape (TVT-secur)

The first single-incision mini sling has been introduced recently (TVT Secur (Ethicon)). Few data are available regarding the safety and efficacy of this new type of sling. Its short-term success rate appears comparable with that of traditional midurethral slings [7-9]. However, long-term follow-up is warranted and comparative studies are needed to determine its true safety and efficacy.

Use of adult muscle derived stem cells

Preclinical studies have suggested that transurethral injections of autologous myoblasts can assist in regeneration of the rhabdosphincter, and fibroblasts in reconstruction of the urethral submucosa.

In one clinical study the efficacy and safety of the application of autologous myoblasts and fibroblasts for treating female stress UI were assessed. One hundred and twenty three women with stress UI (aged 36-84 years) were treated with transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts obtained from skeletal muscle biopsies. One year after implanting the cells, 79% of the women were completely continent, 13% had a substantial improvement in continence and 8% a slight improvement. The thickness of urethra and rhabdosphincter, as well as the contractility of the rhabdosphincter, were improved postoperatively [10].

The same authors conducted a RCT comparing transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts obtained from skeletal muscle biopsies with standard transurethral endoscopic injections of collagen and found treatment with autologous stem cell effective and safe [11].

This novel treatment appears promising but more substantial data are required before it can be implemented into clinical practice.

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8. Conservative Management of Stress Urinary Incontinence in Women

Jane E P Newman

Clinical Specialist Physiotherapist in Women's and Men's Health, Oxford Radcliffe Hospitals, Oxford.

Conservative management is recommended as a first line treatment for stress urinary incontinence and mixed urinary incontinence in women. International studies have shown an approximate 66% improvement rate with these patients provided they are given appropriate supervision. This has been evident across the age ranges. There is evidence that women do better in a regime of exercise supervised by specialist physiotherapists and specialist continence nurses in preference to unsupervised or leaflet provided care. The reasons for this may be that in addition to exercise, specialists are likely to cover numerous other areas which may also impact on the pelvic floor such as occupation, respiratory status, lifestyle issues, overall muscle fitness, diet and general health. There is also likely to be better compliance with exercise regimes in the long term if the woman fully understands how she can help herself and if she has had adequate time to address the problem with professional support.

Other studies have suggested that supervised specialist physiotherapy by members of the Association of Chartered Physiotherapists in Women's Health (ACPWH) or ACPWH's 'sister' organisations internationally, linked as part of a multidisciplinary team are more effective than community stand alone physiotherapy in reducing the workload and operating time of surgeons.

Some studies have shown a link between low back pain in women and urinary incontinence and suggest the need to include core stability exercises for the low back when teaching a pelvic floor regime.

Criteria for inclusion in a conservative management regime:

- Compliant well motivated women
- Suggestion of a weak pelvic floor on vaginal assessment with evidence that there is adequate muscle tissue to develop
- Suggestion on history taking of lifestyle issues which may be impacting on the pelvic floor
- Symptomatic young women who are of child bearing age who may get pregnant in the future
- Women where surgery is inappropriate for medical reasons
- Women with multiple problems in the pelvis where the pelvic floor may be having an impact on function e.g. pelvic pain and Dyspareunia

Assessment should include:

- Detailed history of the ongoing nature of the urinary problem, previous treatment, frequency, urgency and function
- Detailed assessment of bowel habits and function to establish possible links between the anterior and posterior compartments of the pelvic floor and the possible need to liaise with the colo-rectal team
- Detailed assessment of the woman's respiratory status and the need to liaise with the woman's GP if care is required as for example in the case of a chronic cough aggravating symptoms in the pelvic floor
- Detailed vaginal and pelvic assessment to establish the impact of the pelvic muscles in the mid line, the strength and endurance of these muscles, the impact and strength of the deep abdominal muscles (Transversus Abdominus)
- Assessment of the woman's lifestyle, working patterns and dietary patterns to establish whether any of these are impacting adversely on the pelvic floor

Treatment may include:

- An explanation of the function and anatomy of the pelvic floor

- An intensive regime of supervised pelvic floor exercise
- An 'outcome diary' linking pain, function, diet and leakage with lifestyle and activities to try to educate the woman in how best to help herself
- Liaison with the others in the multi disciplinary team whether in the community or hospital setting to ensure contributing factors are addressed adequately. This may include discussion regarding medical management of mixed incontinence in relation to medication as there is evidence that these patients do best on a combined approach of conservative and drug regimes
- A supporting 'hand out' as an exercise and lifestyle reminder
- Various biofeedback regimes – these may include electrical stimulation
- Supporting exercise regimes for the core trunk stability muscle groups where these are also affected
- Advice on avoiding increasing symptoms, by poor bowel function e.g. constipation or straining, lifting or moving excessive weights and chronic respiratory conditions
- Education of the woman in bladder regulating patterns to try to re-establish a normal bladder pattern
- An explanation of why conservative management is not effective and why an exercise regime has failed to cure the urinary problem

Follow on care:

- Evidence suggests that women need to be encouraged to continue with a long term program of pelvic floor exercises for the benefits to be maintained
 - There needs to be close liaison between those providing conservative management and providers of more interventionist treatments such as surgery and medical management, to provide a seamless progression if the conservative treatments do not work.
- Additional note on mixed urinary incontinence:
- Many of the patients with mixed stress and urge incontinence will also benefit through the above conservative management. Numbers vary in different studies but good practice suggests that a multi-disciplinary approach of combined medication and conservative care may be beneficial.

Useful links:

www.acpwh.org.uk (Membership is by examination as a post graduate branch of the Chartered Society of Physiotherapy)

www.csp.org.uk

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9. Urinary incontinence and quality of life scores

Mrs Alison Bardsley MSc, RGN, DN and Mrs Jo Turner BSc,RGN.

Urinary incontinence

Symptoms of urinary incontinence are common particularly in the older population. The estimated prevalence of urinary incontinence varies considerably between studies, mainly due to methodological issues and under-reporting due to embarrassment. Urinary symptoms can include frequency and urgency with or without incontinence, stress incontinence, urinary retention (complete and partial) and reflex incontinence. Urinary incontinence can have a severe impact on employment, social interactions and emotional well-being (1). High levels of depression and low quality of life have been reported in men and women with overactive bladder symptoms (2). The treatments currently available for incontinence are aimed at reducing the number of incontinent episodes and limit the impact on everyday life.

From a review of the evidence in the literature over the last 5 years the use of patient completed methods (including voiding diaries and questionnaires) for measuring the impact of incontinence on quality of life are becoming increasingly common both clinically and within research (3-12) .

The International Consultation on Incontinence (ICI) uses a grading system for recommendation of symptom scoring and quality of life scales based on validity, reliability and responsive to support their use and recommends the following validated tools for use in clinical practice and research:

ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISS, ICS male (ISCmale SF) and KHQ.

Quality of life

The term quality of life is widely used in research. The World Health Organisation offers a definition which includes physical, emotional and social well-being, not just the absence of disease (13) "Health related quality of life" (HRQL) refers to attributes valued by patients to have a sense of well-being: the extent to which they were able to maintain physical, emotional and intellectual function and ability to participate in valued activities within a community such as family and work. This highlights the multidimensional nature of quality of life and the individual's perception in the context of their circumstances (14).

Measurement of quality of life and symptom scores

The symptoms of incontinence and their impact on an individual's quality of life can be assessed in a number of ways. However the only valid way to measure the patient's personal perspective is by using self completion questionnaires (15). Quality of life and symptom scoring tools are useful in clinical settings to standardise the measurement of severity of incontinence which can help to determine required care and to evaluate the effectiveness of care provided.

Patient completed questionnaires are used to record the presence and severity of urinary symptoms including incontinence as well as the impact on quality of life and everyday activities. Although questionnaires used in clinical research can be long and detailed, those used for clinical practice need to be short and easy to complete.

Conclusion

The experience for people of the symptoms of incontinence, its impact on their quality of life and the outcomes of healthcare desired by patients is uniquely individual and multifaceted. Measuring quality of life and symptoms in a way that reflects the patient's voice presents a challenge to healthcare professionals. However, identifying patient outcomes is the most credible method of assessment and can be achieved in a number of ways. The scoring of symptoms and quality of life in urinary incontinence provides a method of quantifying the

impact of urinary symptoms for patients and can be used as a measure to assess outcomes of treatment at various stages. Evaluation and outcome measures should be built into all clinical assessment and research projects.

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10. Validated and disease specific incontinence quality of life questionnaires

The main resource for validated questionnaires and disease-specific questionnaires about urinary incontinence is the ProQolid Patient-Reported Outcome and Quality of Life Instruments Database [\[link\]](#), which lists the following questionnaires:

Lower urinary tract symptoms (LUTS)

1. DAN-PSS-1: Danish Prostatic Symptom Score. Andersen J T, Bilde T, Hald T, et al.
2. ICIQ-FLUTS: International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms. Abrams P.
3. ICSmale: ICSmale. Donovan J L.
4. ICSQoL: International Continence Society-Benign Prostatic Hyperplasia study quality-of-life. Donovan J L.
5. MSHQ: Male Sexual Health Questionnaire. Althof S E, Catania J, O'Leary M et al.
6. UROLIFETM/BPHQoL9: Benign Prostatic Hypertrophy Health-Related Quality of Life Questionnaire. Lukacs B, Sanofi A.

Urinary Bladder, Overactive

1. OAB-q: Overactive Bladder symptom and health-related quality of life questionnaire. Coyne K, Hunt T, Revicki D A.

Urinary incontinence

1. Contilife®: Quality of Life Assessment Questionnaire Concerning Urinary Incontinence. Amarenco G, Haab F, Labat JJ, et al.
2. DIS: Detrusor Instability Score. Kauppila A, Kujansuu E.
3. I-QOL: Urinary Incontinence-Specific Quality of Life Instrument. Bushnell D M, Martin M L, Patrick D L, PhD, MSPH.
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5. ICIQ-UI Short Form: International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form. Avery K, ICIQ Group.
6. ISI: Incontinence Stress Index. Yu L C.
7. KHQ: King's Health Questionnaire. Cardozo L, Kelleher C J, Khullar V, et al.
8. MUDI: Male Urogenital Distress Inventory. Robinson J P, Shea J A.
9. MUSIQ: Male Urinary Symptom Impact Questionnaire. Robinson J P, Shea J A.
10. N-QoL: Nocturia Quality of Life Questionnaire. Abraham L, Abrams P, Hareendran A, et al.
11. PMSES: Broome Pelvic Muscle Exercise Self-Efficacy Scale. Broome B S.
12. SSI and SII: Symptom Severity Index and Symptom Impact Index for stress incontinence in women. Black N.
13. UIHI: Urinary Incontinence Handicap Inventory. Rai GS.

14. YIPS: York Incontinence Perceptions Scale. Lee P S, MA, Linton L, RN, MHA, Reid D W, PhD, et al.

Urination disorders

1. SF-QUALIVEEN: QUALIVEEN Short Form. Bonniaud V.

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Research

2008

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