SPECIAL ARTICLE

EAU guidelines on surgical treatment of urinary incontinence

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Mixed urinary incontinence;
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Sacral nerve stimulation;
Bulking agents;
Urinary incontinence;
Practice-based;
Surgical treatment;
Colposuspension;
Slings;
Compression devices;

Abstract
Context: The European Association of Urology (EAU) guidelines on urinary incontinence published in March 2012 have been rewritten based on an independent systematic review carried out by the EAU guidelines panel using a sustainable methodology.
Objective: We present a short version here of the full guidelines on the surgical treatment of patients with urinary incontinence, with the aim of dissemination to a wider audience.
Evidence acquisition: Evidence appraisal included a pragmatic review of existing systematic reviews and independent new literature searches based on Population, Intervention, Comparator, Outcome (PICO) questions. The appraisal of papers was carried out by an international panel of experts, who also collaborated in a series of consensus discussions, to develop concise structured evidence summaries and action-based recommendations using a modified Oxford system.
Evidence summary: The full version of the guidance is available online (www.uroweb.org/guidelines/online-guidelines/). The guidance includes algorithms that refer the reader back to the supporting evidence and have greater accessibility in daily clinical practice. Two original meta-analyses were carried out specifically for these guidelines and are included in this report.

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Introduction

This paper presents a shortened version of the European Association of Urology (EAU) guidelines on urinary incontinence (surgical management). Assessment of patients with urinary incontinence (UI) and nonsurgical management were summarised in a previous paper. Surgical treatment of UI is usually considered only after the failure of conservative therapy or drug treatment. This paper considers the treatment of women with uncomplicated and complicated stress urinary incontinence (SUI), men with SUI, and both men and women with urgency urinary incontinence (UUI) caused by refractory detrusor overactivity (DO). It does not consider patients with UI caused by neurologic disease, which is summarised in separate EAU guidelines.

The aim is to provide a concise but authoritative summary of the current state of evidence on clinical topics, complete with references to relevant literature together with clear recommendations on what to do or not to do in most clinical circumstances. These recommendations should be particularly helpful in those areas of practice for which there is little or no high-level published evidence. Fig. 1 shows algorithms for surgical management of UI in both men and women that are contiguous with those for nonsurgical management. The full-text guidelines do not review the management of fistula, a topic that will be addressed in future editions.

Methodology

The guidance was formulated using evidence-based medicine methodology. Every topic was defined as a precise clinical question, expressed in Population, Intervention, Comparator, Outcome (PICO) format, which formed the basis of the individual literature search strategies. Given the size of the task and our limited resources, we used the summarised evidence and identified literature from existing high-quality systematic reviews, evidence-based guidelines, and some extensive narrative reviews as primary sources of evidence up to the cut-off date for each individual review. Then, for each PICO, we performed our own tailor-made searches from the cut-off date of the most recent review forward to our own cut-off date of July 2010. We searched Medline, Embase, and the Cochrane Library and only considered English-language articles. This

Conclusions: These new guidelines present an up-to-date summary of the available evidence, together with clear clinical algorithms and action-based recommendations based on the best available evidence. Where high-level evidence is lacking, they present a consensus of expert panel opinion.

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Guía clínica de la Asociación Europea de Urología sobre el tratamiento quirúrgico de la incontinencia urinaria

Resumen

Contexto: Se ha vuelto a escribir la guía clínica de la Asociación Europea de Urología (EAU) sobre la incontinencia urinaria publicada en marzo de 2012, basándose en una revisión sistemática independiente llevada a cabo por el panel de guías clínicas de la EAU utilizando una metodología sostenible.

Objetivo: Presentamos una versión resumida de la guía clínica completa sobre el tratamiento quirúrgico de pacientes con incontinencia urinaria, con el objetivo de difundirla a un público más amplio.

Adquisición de la evidencia: La valoración de la evidencia incluyó una revisión pragmática de las revisiones sistemáticas existentes y nuevas búsquedas bibliográficas independientes, basadas en cuestiones sobre población, intervención, comparador, resultados (PICO). La evaluación de los trabajos fue realizada por un panel internacional de expertos, quienes también colaboraron en una serie de debates de consenso, para desarrollar breves resúmenes de evidencia estructurada y recomendaciones basadas en la acción utilizando un sistema modificado de Oxford.

Resumen de la evidencia: La versión completa de la guía clínica está disponible online (http://www.uroweb.org/guidelines/online-guidelines/). La guía clínica incluye algoritmos que remiten de nuevo al lector a la evidencia de apoyo, y son más inmediatamente utilizables en la práctica clínica diaria. Se llevaron a cabo 2 metaanálisis específicamente para esta guía clínica que se incluye en este informe.

Conclusiones: Esta nueva guía clínica presenta un resumen actualizado de la evidencia disponible, junto con claros algoritmos clínicos y recomendaciones basadas en la acción fundamentadas en la mejor evidencia disponible. Cuando dicha evidencia no existe, presentan un consenso de opiniones de expertos.

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Surgical treatment in women

Failed conservative or drug therapy

Stress incontinence

Mixed incontinence

Urgency incontinence

Stress predominant

Urgency predominant

Offer MUS consider peri-urethral injections for temporary relief of symptoms

Offer botulinum toxin A or the opportunity for SNS

Offer fascial sling or colposuspension if MUS unavailable

Discuss bladder augmentation or urinary diversion

Failure

Re-evaluate patient and consider second-line surgery - re-enter algorithm at appropriate stage

Surgical treatment in men

Failed conservative or drug therapy

Perform urodynamics and cystoscopy and consider imaging of lower urinary tract (ie: exclude bladder outlet obstruction)

Stress incontinence

Mixed incontinence

Urgency incontinence

Stress predominant

Urgency predominant

Consider peri-urethral injection for temporary relief, and minimally invasive compression devices

Offer Botulinum toxin A or the opportunity for treatment with SNS

Consider fixed slings for men with PRP/

Discuss bladder augmentation or urinary diversion

Offer AUS to men with persistent moderate to severe PP/

MUS = Mid-urethral sling

SNS = Sacral nerve stimulation

UT = Urinary tract

PRPI = Post radical prostatectomy incontinence

PPI = Post-prostatectomy incontinence

GA, GB, GC = Grades of recommendations

Figure 1 Surgical algorithms. GA = grade A; GB = grade B; GC = grade C; MUS = midurethral sling; PPI = postprostatectomy incontinence; PRPI = post-radical prostatectomy; SNS = sacral nerve stimulation; UT = urinary tract.
approach identified 2191 abstracts. The abstracts were then each independently assessed by two panel members, who selected relevant studies, 230 in total.

Each PICO was assigned to a panel member, who extracted the evidence from each selected full-text paper for incorporation into a dedicated database. Further panel discussion on each topic led to the development of summary statements that aimed to synthesise relevant clinical messages using level of evidence (LE) categories standardised by the EAU, leading to phrasing of action-based recommendations, again with strength graded according to EAU standards (see full-text guidelines in the methodological section). These make it clear what the clinician should or should not do in clinical practice and where further evidence is needed.

This guidance is based on the best evidence available to the expert panel up to July 2010, but adherence does not guarantee the best outcomes for individual patients. The need for clinical expertise when making treatment decisions for individual patients is paramount, taking into account the patient’s personal values, preferences, and specific circumstances.

Uncomplicated incontinence in women was defined as no history of previous incontinence surgery, no neurologic lower urinary tract symptoms, no bothersome genitourinary prolapse, and not considering further pregnancy.

Complicated incontinence refers to women where these criteria do not apply.

## Surgery of uncomplicated stress urinary incontinence in women

### Open colposuspension and autologous fascial sling

Systematic reviews have shown that open colposuspension and autologous fascial sling are similarly effective for the cure of SUI in women in the short term (LE: 1b).⁴,⁵ The effectiveness of colposuspension deteriorates over 5 yr, and there is a higher rate of genitourinary prolapse than with other operations.⁴ Autologous fascial sling has a higher risk of operative complications than open colposuspension, particularly voiding dysfunction and postoperative urinary tract infection (UTI) (LE: 1b).

### Anterior colporrhaphy

Anterior colporrhaphy has lower rates of cure for UI than colposuspension and a higher requirement for reoperation, especially in the longer term (LE: 1a).⁶

### Laparoscopic colposuspension

Laparoscopic colposuspension has similar efficacy to open colposuspension for the cure of SUI and a similar risk of voiding difficulty or de novo urgency (LE: 1a).⁷ Laparoscopic colposuspension has a lower risk of other complications and shorter hospital stay than open colposuspension (LE: 1a).

## Midurethral slings

There has been a rapid adoption of midurethral synthetic sling insertion as the first-line surgical option for SUI because it is effective, it is less invasive, and patients recover more quickly.

### Midurethral sling insertion compared with colposuspension

A systematic review compared midurethral slings with both open colposuspension (nine trials) and laparoscopic colposuspension (eight trials).³ Retropubic insertion of a synthetic midurethreale sling gave equivalent patient-reported and superior clinician-reported cure of SUI compared with colposuspension at 12 mo (LE: 1a); transobturator insertion gave equivalent patient-reported and clinician-reported cure of SUI at 12 mo (LE: 2). Midurethral sling insertion was associated with a lower rate of new symptoms of urgency and voiding dysfunction compared with colposuspension (LE: 1a). In meta-analysis, the overall patient-reported cure rate at 12 mo was 75%, longer term follow-up for up to 5 yr reported no difference versus colposuspension in effectiveness, although the number of participants lost to follow-up was high.⁹-¹¹ Voiding dysfunction was less likely for midurethreale slings compared with colposuspension (relative risk [RR]: 0.34; 95% confidence interval [CI]: 0.16–0.7).

Bladder perforation was more likely during midurethreale sling insertion (RR: 2.21; 95% CI, 0.82–5.95) favouring laparoscopic colposuspension (RR: 4.23; 95% CI, 1.83–9.75) favouring open colposuspension.¹²-¹⁶

### Transobturator versus retropubic route

Meta-analysis of 34 identified comparative randomised comparisons in 29 trials showed that transobturator insertion of a synthetic midurethreale sling gave equivalent patient-reported and clinician-reported cure rates at 12 mo compared with retropubic insertion (Fig. 2; LE: 1a).¹⁷-⁴⁶ Women undergoing transobturator insertion had a lower risk of bladder perforation and voiding dysfunction than those undergoing retropubic insertion (LE: 1a). Patients with a transobturator insertion had a higher risk of urethral perforation and of chronic perineal pain at 12 mo (LE: 1a).

### Insertion using a skin-to-vagina direction versus

The skin-to-vagina direction of retropubic insertion of the midurethreale sling appears less effective than a vagina-to-skin direction (LE: 1a).⁴⁷ The skin-to-vagina direction of both retropubic and transobturator insertion is associated with a higher risk of postoperative voiding dysfunction (LE: 1b).⁴⁷ However, a further systematic review and meta-analysis found that the skin-to-vagina direction of transobturator insertion of midurethreale slings was equally effective compared with the vagina-to-skin route using direct comparison. Indirect comparative analysis in this review gave weak evidence for a higher rate of voiding dysfunction and bladder injury for the skin-to-vagina direction.⁴⁸

### Single-incision slings

Less invasive forms of midurethreale sling insertion have been trialled, allowing routine placement under local anaesthesia. Most of the evidence concerns the TVT SECR device,
Table 1

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Retropubic</th>
<th>Transobturator</th>
<th>Odds ratio</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total Events</td>
<td>Weight</td>
<td>M-H, Fixed, 95% CI</td>
</tr>
<tr>
<td>Objective cure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>2014</td>
<td>2061</td>
<td>100.0%</td>
<td>1.12 [0.94–1.33]</td>
</tr>
<tr>
<td>Total events</td>
<td>1713</td>
<td>1734</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: chi-square = 13.11, df = 23 (p = 0.95); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.22 (p = 0.22)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Subjective cure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1068</td>
<td>1056</td>
<td>100.0%</td>
<td>1.10 [0.89–1.36]</td>
</tr>
<tr>
<td>Total events</td>
<td>813</td>
<td>785</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: chi-square = 4.87, df = 11 (p = 0.94); I² = 0%</td>
<td></td>
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</tr>
<tr>
<td>Test for overall effect: Z = 0.89 (p = 0.38)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder or urethral perforation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>2507</td>
<td>2535</td>
<td>100.0%</td>
<td>7.37 [4.48–12.12]</td>
</tr>
<tr>
<td>Total events</td>
<td>114</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: chi-square = 10.17, df = 28 (p = 1.00); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 7.86 (p &lt; 0.00001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voiding dysfunction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>2344</td>
<td>2322</td>
<td>100.0%</td>
<td>1.99 [1.53–2.59]</td>
</tr>
<tr>
<td>Total events</td>
<td>171</td>
<td>89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: chi-square = 23.63, df = 28 (p = 0.42); I² = 3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 5.12 (p &lt; 0.00001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic pain</td>
<td></td>
<td></td>
<td></td>
<td>0.34 [0.23–0.49]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1565</td>
<td>1554</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>35</td>
<td>103</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: chi-square = 17.94, df = 18 (p = 0.46); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 5.64 (p &lt; 0.00001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematoma</td>
<td></td>
<td></td>
<td></td>
<td>3.46 [1.60–7.47]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>995</td>
<td>948</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>25</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: chi-square = 3.53, df = 10 (p = 0.97); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 3.16 (p = 0.002)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2  Summary forest plot showing comparison between midurethral sling inserted by the retropubic route versus the transobturator route. Only the summaries have been included. CI = confidence interval; df = degrees of freedom; M-H = Mantel–Haenszel (test).

and this evidence may not be applicable to other conceptually similar devices. Single-incision midurethral slings appear equally effective for the cure of women with SUI at up to 12 mo compared with retropubic or transobturator midurethral slings (LE: 1b). This equivalence does not appear durable with single-incision slings being less effective than standard midurethral slings after >12 mo (LE: 1b).49 Blood loss and postoperative pain are lower for the insertion of single incision compared with standard midurethral slings (LE: 1b).

There is no evidence that other adverse outcomes from surgery are more or less likely with single-incision than standard midurethral slings (LE: 1b).

Adjustable slings
Adjustable slings were developed to overcome perceived problems of incorrect sling tensioning at implantation or subsequent displacement. There is weak evidence that synthetic adjustable midurethral slings are effective for the cure and improvement of SUI in women (LE: 3). There is no evidence that adjustable slings are superior to standard midurethral slings (LE: 4).

Bulking agents
A periurethral injection of a bulking agent may provide short-term improvement in symptoms for 3 mo, but not cure, in women with SUI40 (LE: 2a). There is less risk of harm using periurethral injection compared with colposuspension (LE: 2a). Repeat injections are frequently needed to gain benefit (LE: 2a). There is no evidence that one type of bulking agent is better than another (LE: 1b). Percutaneous access to the urethral submucosa appears to have a higher risk of urinary retention compared with the transurethral route (LE: 2b). For recommendations, see Table 1.
Table 1  Recommendations for surgery for uncomplicated stress urinary incontinence in women.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offer midurethral sling to women with uncomplicated stress urinary incontinence as the initial surgical intervention whenever available.</td>
<td>A</td>
</tr>
<tr>
<td>Offer colposuspension (open or laparoscopic) or autologous fascial sling to women with stress urinary incontinence if midurethral sling cannot be considered.</td>
<td>A</td>
</tr>
<tr>
<td>Warn women who are being offered a retropubic insertion synthetic sling about the relatively higher risk of perioperative complications compared with transobturator insertion.</td>
<td>A</td>
</tr>
<tr>
<td>Warn women who are being offered transobturator insertion of midurethral sling about the higher risk of pain and dyspareunia in the longer term.</td>
<td>A</td>
</tr>
<tr>
<td>Warn women undergoing autologous fascial sling that there is a high risk of voiding difficulty and the need to perform clean intermittent self-catheterisation; ensure they are willing and able to do so.</td>
<td>A</td>
</tr>
<tr>
<td>Do a cystoscopy as part of retropubic insertion of a midurethral sling, or if difficulty is encountered during transobturator sling insertion, or if there is a significant cystocele.</td>
<td>C</td>
</tr>
<tr>
<td>Women being offered a single-incision sling device, for which an evidence base exists, should be warned that they may be less effective than standard midurethral slings and that efficacy beyond 1yr remains uncertain.</td>
<td>C</td>
</tr>
<tr>
<td>Single-incision sling devices without level 1 evidence of effectiveness should only be implanted as part of a structured research programme.</td>
<td>A</td>
</tr>
<tr>
<td>Only offer adjustable midurethral sling as a primary surgical treatment for stress urinary incontinence within a structured research programme.</td>
<td>C</td>
</tr>
<tr>
<td>Do not offer periurethral bulking agents to women who are seeking a permanent cure for stress urinary incontinence.</td>
<td>A</td>
</tr>
</tbody>
</table>

GR = grade of recommendation.
Surgery for complicated stress urinary incontinence in women

We found one randomised controlled trial (RCT) comparing the outcome of surgical procedures in women who experience persistent or recurrent SUI after anterior colporrhaphy. Further evidence was available from a reanalysis of randomised comparative trials in which a proportion of participants had undergone previous surgery for SUI. Open colposuspension and autologous fascial sling appear equally effective as secondary surgery for women with recurrence of SUI after anterior colporrhaphy (LE: 1b). One reanalysis of RCT data found no statistically significant association between a history of previous UI surgery and the outcome of colposuspension or autologous sling insertion (LE: 2). In contrast, one systematic literature review suggested that the risk of treatment failure from surgery for SUI is higher in women who have had prior surgery for incontinence or prolapse (LE: 2). Implantation of a midurethral sling may be less effective as a second line procedure compared with its use as primary surgery (LE: 2).

External compression devices in women

Implantation of an artificial urinary sphincter (AUS) may cure or improve incontinence for women with complicated SUI (LE: 3). Mechanical failure and the need for device explantation and replacement are common adverse effects of AUS implantation (LE: 3). Older women and those who have had previous colposuspension or pelvic radiotherapy appear to have a higher risk of explantation (LE: 3). Implantation of the Adjustable Compression Therapy (ACT) device may cure or improve complicated SUI (LE: 3). Most patients required adjustment of the device to achieve continence, and the risk of explantation was high (LE: 3). For recommendations, see Table 2. Note that the midurethral sling, colposuspension, and fascial sling are all options for surgical treatment for women with persistent or recurrent SUI, and the choice among them will depend on previous surgery, patient or surgeon preference, and local availability of the procedure.

Surgery for stress incontinence for women with symptomatic mixed urinary incontinence

Preexisting urgency may improve, remain unchanged, or worsen after SUI surgery (LE: 3). Women with mixed urinary incontinence (MUI) and urodynamic DO have lower satisfaction rates following insertion of the midurethral sling compared with women with SUI alone. Women with stress-predominant MUI have significantly better overall outcomes following surgery for SUI than those with urgency-predominant MUI. For recommendation, see Table 3.

Men with stress urinary incontinence

Non-neurogenic SUI in men is mostly associated with prostatectomy. After urodynamic confirmation of SUI, several surgical options are available. Three recent literature reviews are available.

Bulking agents in men

No existing evidence indicates that bulking agents cure postprostatectomy incontinence (LE: 2a). There is weak evidence that bulking agents can offer temporary improvement in quality of life in men with postprostatectomy incontinence (LE: 3). There is no evidence that one bulking agent is superior to another (LE: 3).

Fixed male synthetic sling

Fixed slings are positioned under the bulbar urethra and fixed by a retropubic or transobturator approach. The tension is adjusted during surgery and cannot be readjusted postoperatively. For male synthetic slings, two therapeutic concepts are proposed: continence restoration by urethral compression (InVance, TOMS, Argus) and continence restoration by repositioning the urethral bulb (AdVance). There is low-level evidence that fixed male sling implantation results in cure or improves postprostatectomy incontinence at up to 3yr (LE: 3). Fixed male slings appear to be less effective for men with severe incontinence, previous radiotherapy, or previous urethral stricture surgery (LE: 3).
Table 4  Recommendations for surgery in men with stress urinary incontinence.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only offer bulking agents to men with mild postprostatectomy incontinence who desire temporary relief of urinary incontinence symptoms.</td>
<td>C</td>
</tr>
<tr>
<td>Do not offer bulking agents to men with severe postprostatectomy incontinence.</td>
<td>C</td>
</tr>
<tr>
<td>Offer fixed slings to men with persistent (&gt;6 mo) postprostatectomy incontinence who have not responded to conservative management.</td>
<td>B</td>
</tr>
<tr>
<td>Warn men that severe incontinence, prior pelvic radiotherapy, or urethral stricture may worsen outcome of fixed male sling implantation.</td>
<td>C</td>
</tr>
<tr>
<td>Offer AUS to men with persistent (&gt;6 mo) moderate-to-severe postprostatectomy incontinence who have not responded to conservative management.</td>
<td>B</td>
</tr>
<tr>
<td>Warn about the long-term risk of device failure and need for revision when counselling men for insertion of any implant for stress urinary incontinence.</td>
<td>C</td>
</tr>
<tr>
<td>Only offer a noncircumferential compression device to men with postprostatectomy incontinence if arrangements for monitoring of outcome are in place.</td>
<td>C</td>
</tr>
<tr>
<td>Warn men considering a noncircumferential compression device that there is a high risk of failure and subsequent explantation.</td>
<td>C</td>
</tr>
<tr>
<td>Do not offer a noncircumferential compression device to men who have had pelvic radiotherapy.</td>
<td>C</td>
</tr>
</tbody>
</table>

GR = grade of recommendation; AUS = artificial urinary sphincter.

3). Possible harms include voiding dysfunction, device erosion, and chronic pain. There is low-level evidence that the compressive sling (InVance) cures or improves postprostatectomy incontinence for up to 5 yr (LE: 3). It appears less effective in men who have had pelvic radiotherapy. Possible harms include infection and a new symptom of urgency. There is no evidence that one type of male sling is better than another.

Adjustable slings in men

Adjustable slings are composed of a suburethral synthetic sling whose tension can be adjusted postoperatively. Available devices are Remex and Argus. Evidence is restricted to small case series with short follow-up. There is no evidence that adjustability of the male sling offers additional benefit over other types of sling (LE: 3), and there is limited evidence that early explantation rates are high (LE: 3).

Compression devices in men

Implanted urethral compression devices can be divided into two types: circumferential (AUS) and noncircumferential (periurethral balloon devices).

Artificial urinary sphincter

Although the AUS is considered to be the standard treatment for men with SUI, the quantity and LE for effectiveness is low. Evidence from one low-quality RCT suggests that implantation of an AUS is more effective than injection of bulking agents for the cure and improvement of SUI in men. There have been no well-designed prospective RCTs.

Nonrandomised cohort studies suggest that primary AUS implantation is effective for cure and improvement of SUI in men (LE: 2b). Implantation of AUS may be less effective for men who have had pelvic radiotherapy (LE: 3). Long-term device failure is common in the longer term, although replacement can be performed (LE: 3). Men who develop cognitive impairment or lose manual dexterity are likely to have difficulty operating an AUS (LE: 4). There is no evidence that tandem cuff placement and insertion of the device through a single incision is superior to standard implantation (LE: 3). Prevention of device infection by meticulous antimicrobial precautions prior to and during implantation is mandatory (LE: 4).

Noncircumferential compression device (ProACT)

A quasi-randomised trial comparing a noncircumferential compression device (ProACT) with a bone-anchored male sling found that both devices improved SUI (LE: 3). Other nonrandomised cohort studies showed that repeated adjustment of balloon volume is required to achieve cure (LE: 3). The noncircumferential compression device is associated with a high failure and complication rate, leading to explantation (LE: 3). A questionnaire study showed that many men remained bothered by persistent incontinence after implantation (LE: 3). For recommendations, see Table 4.

Surgical interventions for detrusor overactivity

Intravesical injection of botulinum toxin A

Intravesical injection of botulinum toxin A (BoNTA) into the bladder wall is being increasingly used to treat UUI in adult women who have not responded to nonsurgical therapy. It is also being used for men with UUI, although there is less evidence for effectiveness. BoNTA is available as onabotulinumtoxin A (Botox), abobotulinumtoxin A (Dysport), and incobotulinumtoxin A (Xeomin), but potency varies, and an equivalent dosage cannot be calculated. Because of the high profile of this novel treatment, the expert panel have considered the most recent studies published beyond the cut-off date of July 2010 and obtained supplementary data from authors as well as carrying out specific metaanalyses (see Fig. 3).
<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>BoNTA Events</th>
<th>Control Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds ratio M-H, Fixed, 95% CI</th>
<th>Odds ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2.1 50 units</td>
<td>Denys 2011</td>
<td>3</td>
<td>16</td>
<td>23</td>
<td>3.9%</td>
<td>2.42 [0.36, 16.50]</td>
</tr>
<tr>
<td></td>
<td>Dmochowski 2010</td>
<td>17</td>
<td>57</td>
<td>74</td>
<td>16.2%</td>
<td>2.25 [0.84, 6.03]</td>
</tr>
<tr>
<td></td>
<td>Sahai 2007</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tincello 2011</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subtotal (95% CI)</td>
<td>73</td>
<td>0</td>
<td>73</td>
<td>20.1%</td>
<td>2.28 [0.99, 5.49]</td>
</tr>
</tbody>
</table>

Total events 20 9
Heterogeneity: $\chi^2 = 0.00$, $df = 1$ ($P = 0.95$); $I^2 = 0$
Test for overall effect: $Z = 1.84$ ($P = 0.07$)

| 1.2.2 100 units  | Denys 2011    | 10             | 19    | 29     | 2.5%                           | 11.67 [2.12, 64.33]            |
|                  | Dmochowski 2010 | 20             | 54    | 74     | 12.8%                          | 3.65 [1.36, 9.80]             |
|                  | Sahai 2007    | 0              | 0     | 0      | Not estimable                  |                               |
|                  | Tincello 2011 | 0              | 0     | 0      | Not estimable                  |                               |
|                  | Subtotal (95% CI) | 73         | 0     | 73     | 16.7%                          | 4.39 [1.91, 10.12]            |

Total events 30 9
Heterogeneity: $\chi^2 = 1.74$, $df = 1$ ($P = 0.19$); $I^2 = 42$
Test for overall effect: $Z = 3.48$ ($P = 0.0005$)

| 1.2.3 150 units  | Denys 2011    | 10             | 19    | 29     | 2.5%                           | 11.67 [2.12, 64.33]            |
|                  | Dmochowski 2010 | 20             | 49    | 74     | 12.8%                          | 3.65 [1.36, 9.80]             |
|                  | Sahai 2007    | 0              | 0     | 0      | Not estimable                  |                               |
|                  | Tincello 2011 | 0              | 0     | 0      | Not estimable                  |                               |
|                  | Subtotal (95% CI) | 68         | 67    | 135    | 15.3%                          | 4.96 [2.14, 11.53]            |

Total events 30 9
Heterogeneity: $\chi^2 = 1.34$, $df = 1$ ($P = 0.25$); $I^2 = 25$
Test for overall effect: $Z = 3.72$ ($P = 0.0002$)

| 1.2.4 200 units  | Denys 2011    | 0              | 0     | 0      | Not estimable                  |                               |
|                  | Dmochowski 2010 | 27             | 53    | 74     | 11.0%                          | 5.49 [2.08, 14.49]            |
|                  | Sahai 2007    | 8              | 16    | 24     | 0.7%                           | 37.00 [1.91, 717.99]          |
|                  | Tincello 2011 | 31             | 116   | 147    | 26.3%                          | 3.01 [1.45, 6.22]             |
|                  | Subtotal (95% CI) | 185        | 173   | 358    | 38.0%                          | 4.34 [2.49, 7.59]             |

Total events 66 19
Heterogeneity: $\chi^2 = 3.21$, $df = 2$ ($P = 0.20$); $I^2 = 38$
Test for overall effect: $Z = 5.16$ ($P < 0.00001$)

| 1.2.5 300 units  | Dmochowski 2010 | 32             | 56    | 88     | 9.8%                           | 7.05 [2.68, 18.51]            |
|                  | Sahai 2007    | 8              | 16    | 24     | 0.7%                           | 37.00 [1.91, 717.99]          |
|                  | Tincello 2011 | 0              | 0     | 0      | Not estimable                  |                               |
|                  | Subtotal (95% CI) | 56         | 44    | 100    | 9.8%                           | 7.05 [2.68, 18.51]            |

Total events 32 7
Heterogeneity: Not applicable
Test for overall effect: $Z = 3.96$ ($P < 0.00001$)

| Subtotal (95% CI) | 418             | 418   | 100.0% | 4.30 [3.05, 6.05] |

Total events 178 53
Heterogeneity: $\chi^2 = 9.36$, $df = 9$ ($P = 0.40$); $I^2 = 4$
Test for overall effect: $Z = 8.34$ ($P < 0.00001$)
Test for subgroup differences: $\chi^2 = 3.12$, $df = 4$ ($P = 0.54$); $I^2 = 0$

Figure 3 Summary forest plot showing comparison of cure/improvement between botulinum toxin A injection and sham injection or placebo injection. Only the summaries have been included. CI = confidence interval; df = degrees of freedom; M-H = Mantel-Haenszel (test).

A single treatment with intravesical onabotulinumtoxin A (100–300 U) is more effective than placebo at curing and improving UUI for up to 12 mo (LE: 1a). A single treatment with intravesical onabotulinumtoxin A (100–300 U) has a higher risk of increased postvoid residual urine, which is dose dependent (LE: 1a) and may require intermittent self-catheterisation (LE: 1b). There is also a higher risk of UTI after BoNTA therapy compared with placebo injection (LE: 1b). Following the recurrence of symptoms after initial successful treatment, a further injection of BoNTA appears effective (LE: 3a) (see Fig. 4).

There is no evidence that one technique of injection (site, volume, dose per millilitre) is more effective than another (LE: 3). For recommendations, see Table 5

Sacral nerve stimulation

Sacral nerve stimulation is a two-stage procedure: a test phase and full implantation if the test phase meets effectiveness criteria. Sacral nerve neuremodulation for patients meeting the criteria of a successful test phase
is more effective than continuation of failed conservative treatment for the cure of UUI (LE: 1b). No comparison against sham treatment has been performed.61,80 Cure and improvement of UUI appears durable for up to 5 yr (LE: 3).81 Adverse events are common, often requiring surgical revision (LE: 3).82 For the recommendation, see Table 6.

### Cystoplasty/urinary diversion

Augmentation of bladder capacity and disruption of coordinated detrusor contraction by means of enterocystoplasty or detrusor myectomy, together with urinary diversion by ileal conduit, are used for patients with UUI who do not respond to nonsurgical management. Use of these options

### Table 5  Recommendations for botulinum toxin A.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offer intravesical injection of botulinum toxin A to patients with urgency urinary incontinence in whom antimuscarinic therapy has failed.</td>
<td>A</td>
</tr>
<tr>
<td>Warn patients of the high risk of increased postvoid residual urine and the possible need to self-catheterise.</td>
<td>A</td>
</tr>
<tr>
<td>Warn patients of the risk of urinary tract infection. Patients should also be made aware of the local licensing status of botulinum toxin A and that the long-term harms remain uncertain.</td>
<td>A</td>
</tr>
</tbody>
</table>

GR = grade of recommendation.

### Table 6  Recommendation for sacral nerve stimulation.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>If available, offer patients with urgency urinary incontinence refractory to conservative therapy the opportunity to be treated by sacral nerve neuromodulation before bladder augmentation or urinary diversion is considered.</td>
<td>A</td>
</tr>
</tbody>
</table>

GR = grade of recommendation.
has decreased due to the high risk of long-term harms and the effectiveness of BoNTA and sacral neuromodulation.

There is limited evidence for the effectiveness and harms of augmentation cystoplasty and urinary diversion, either from cohort or comparative studies, for treatment of UUI caused by idiopathic DO. Augmentation cystoplasty is associated with high risks of short-term and long-term severe complications (LE: 3).\(^\text{83,84}\) The need to perform clean intermittent self-catheterisation is common amongst these patients (LE: 3). There is no evidence for long-term effectiveness of detrusor myectomy in adults with idiopathic DO (LE: 3). One nonrandomised study reported bladder augmentation with detrusor myectomy in adult patients with neurogenic and non-neurogenic bladder dysfunction demonstrated poor long-term results with myectomy (LE: 2).\(^\text{85}\)

Urinary diversion is rarely needed in the treatment of non-neurogenic UI, and there are no studies that have specifically examined this technique in non-neurogenic UI. For recommendations, see Table 7.

### Conclusions

When bothersome UI fails to improve with conservative therapy, surgery is usually considered. Given the wide range of surgical possibilities, there is a need for clarity in comparing the options so that patients can be offered the most effective and safest procedures. They need to be warned about the risks associated with the choice they make.

We have used the LE found by our review of the literature, together with the expert opinion of a panel of urologists, to appropriately weight the strength of practice recommendations contained in the guidelines. We hope this pragmatic approach will be useful for clinicians and patients in finding the best way for each individual to improve their UI and alleviate the distress that it causes. The present text represents a summary of the work; for more detailed information and a full list of references, please access the full-text version freely available on the EAU Web site (www.uroweb.org/guidelines/online-guidelines/; ISBN 978-90-79754-83-0). We believe the methodology we have used provides a robust and sustainable way to produce authoritative generalisable guidance that can be readily and regularly revised. In line with the policy of the EAU Guidelines Office, the guidelines on UI will be updated annually including the latest published evidence.

### Author contributions

Malcolm Lucas had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

- Study concept and design: Lucas.
- Acquisition of data: Lucas, Bosch, Cruz, Pickard, de Ridders, Tubaro, Neisius, Turner, Madden, Namibiar.
- Analysis and interpretation of data: Lucas, Bosch, Cruz, Pickard, de Ridders, Tubaro, Neisius, Turner, Madden, Namibiar.
- Drafting of the manuscript: Lucas, Bosch, Cruz, Pickard, de Ridders, Tubaro, Neisius, Turner.
- Critical revision of the manuscript for important intellectual content: Lucas, Bosch, Cruz, Pickard, de Ridders, Tubaro, Neisius, Turner, Burkhard.
- Statistical analysis: None.
- Obtaining funding: None.
- Administrative, technical, or material support: EAU Guidelines Office.
- Supervision: Lucas.
- Other (specify): None.

### Conflict of interest

The authors declare that they have no conflict of interest.

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