The Urological Society of India Guidelines for Evaluation and Management of Non-Neurogenic Urinary Incontinence in Adults.


Preamble

These guidelines have been drafted by the USI Urinary Incontinence Guidelines Panel and address "Non-neurogenic urinary incontinence in adults". The guidelines are intended for urologists and the recommendations are updated till October 2018. These will remain valid until the next update or for a maximum period of five years. The guidelines should not be regarded as a rigid clinical pathway for every patient and are not intended to replace clinical judgment. (Appendix 1. Disclaimer)

Materials and Methods

Literature search was conducted on Pubmed, Cochrane Central Register of Controlled Trials (including randomized and quasi-randomized trials from Embase and Pubmed), Mendeley and Directory of Open Access Journals (Figure 1; Appendix 2, Search Strategy). Each set of search was conducted twice, once for high level evidence (randomized trials and systematic reviews) and another time for all levels of evidence with geographical area restricted to "India". Secondary evidence sources included citations from all published English language guidelines and reviews. Level of evidence was evaluated by the Center for Evidence Based Medicine method.[2] References were collated on the Zotero reference manager and irrelevant and duplicate references were eliminated. Each search was assessed by two individuals with reconciliation of any discordance.

The guidelines panel based its final recommendations on the best available global evidence, Indian data as well as the socioeconomics of health care in India. Grades of recommendation (strong/moderate/weak) are the strength of mandate based on the extent of risk-benefit ratio of either taking or not taking an action. Clinical principle is a statement that is widely agreed upon by clinicians for which there may or may not be evidence in medical literature. Expert opinion is a statement agreed upon by the guidelines panel in the absence of evidence.
Definitions

This guideline follows the joint IUGA-ICS terminology document of 2010.\[2\] Urinary incontinence (UI) is defined as “the complaint of any involuntary leakage of urine”. Stress UI is “complaint of involuntary loss of urine with effort or physical exertion, or on sneezing or coughing”. Urgency UI is “complaint of involuntary loss of urine associated with urgency”. Mixed UI is “complaint of involuntary loss of urine with urgency and also with effort or physical exertion or on sneezing or coughing”

Urinary Incontinence In India

UI has been noted in 25-45% of adult women in global studies,\[3\] Studies from India show a prevalence of 10-42% in nine population-based door-to-door epidemiological studies with stress UI being the commonest type (Table 1).\[4-12\] Age-adjusted prevalence progressively increased from the 3rd to 7th decade (5.6%, 14.2%, 27.3%, 34.3% and 39.0% respectively). This finding has important implications for health planning since the population of Indians older than 60 years is set to double from 117 million in 2015 to 246 million by 2040,\[13\]

Two noteworthy risk factors were childbirth at home and pregnancy at young age.\[4,7,9\] About 40% of women attributed their UI to a natural consequence of ageing,\[4,6,9\] Social embarrassment

Table 1. Prevalence of urinary incontinence in Indian women in population-based door-to-door direct-interview community studies

<table>
<thead>
<tr>
<th>Geographical location, state [citation]</th>
<th>Age group</th>
<th>Total sample</th>
<th>Number consented (%)</th>
<th>Number incontinent (%)</th>
<th>Type of Incontinence (SUI, UUI, MUI)</th>
<th>Other findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Bareilly, Uttar Pradesh[4]</td>
<td>&gt;30y</td>
<td>464</td>
<td>236 (50.8%)</td>
<td>28 (12%)</td>
<td>22%, 38%, 38%</td>
<td>Increased risk if 1st delivery &lt;18y, with age, parity, childbirth at home</td>
</tr>
<tr>
<td>2. Delhi* (Abstract)[5]</td>
<td>&gt;10y</td>
<td>NA</td>
<td>245</td>
<td>37 (15.1%)</td>
<td>44%, 32%, 24%</td>
<td>Increased risk with age and BMI (multivariate)</td>
</tr>
<tr>
<td>3. Khadri, Maharashtra [6]</td>
<td>&gt;20y</td>
<td>442</td>
<td>353 (79.9%)</td>
<td>90 (25.5%)</td>
<td>56%, 32%, 12%</td>
<td>Increased risk with age, parity and diabetes</td>
</tr>
<tr>
<td>4. Coimbatore, Tamil Nadu[7]</td>
<td>20-60y</td>
<td>NA</td>
<td>598</td>
<td>202 (33.8%)</td>
<td>Not assessed</td>
<td>Increased risk if 1st delivery &lt;20y, with age</td>
</tr>
<tr>
<td>5. Chandigarh[8]</td>
<td>&gt;10y</td>
<td>1989*</td>
<td>1979</td>
<td>220 (11.6%)</td>
<td>46%, 26%, 28%</td>
<td>Risk increased with age</td>
</tr>
<tr>
<td>6. Karimnagar, Telangana[9]</td>
<td>&gt;35y</td>
<td>NA</td>
<td>552</td>
<td>53 (10%)</td>
<td>57%, 23%, 20%</td>
<td>Increased risk if 1st delivery &lt;18y, with age, parity. Not with socioeconomic status</td>
</tr>
<tr>
<td>7. Udupi, Karnatala[10]</td>
<td>18-70y</td>
<td>NA</td>
<td>1256</td>
<td>239 (19%)</td>
<td>Not assessed</td>
<td>Increased risk with age</td>
</tr>
<tr>
<td>8. Aligarh, UP[11]</td>
<td>&gt;41**</td>
<td>NA</td>
<td>530</td>
<td>219 (41.3%)</td>
<td>46%, 22%, 33%</td>
<td>Increase with age, urban, obesity, smoking (but not oral tobacco)</td>
</tr>
<tr>
<td>9. Allahabad, UP[12]</td>
<td>&gt;40**</td>
<td>NA</td>
<td>400</td>
<td>38 (9.5%)**</td>
<td>Only SUI recorded</td>
<td>10.5% urban women and 9.5% rural</td>
</tr>
</tbody>
</table>

The studies aimed to survey all eligible women living in a specified area except No. 7, 8 and 9 which surveyed a sample
*International Continence Society 2017 abstract  **postmenopausal women only
# back-calculated from given information  ## Urgency recorded separately but no data on urgency UI or mixed UI.
(about 25%) was possibly more important than financial constraint (3-14%) in determining help-seeking behavior.[8,9]

In general, the prevalence of UI in men has been noted to be lower than women; however, the age-related trend is similar. A systematic review of 21 studies showed a prevalence of 3-5% in young and middle-age men and 11-34% in older men.[14] The guidelines committee could not find any study that looked at prevalence in Indian men.

The committee examined the issue of access and usage of toilets in India. Inability to access a toilet facility in time can convert urgency in an individual with limited ambulation into UI.[15] Women in rural India unable to access a toilet facility until twilight affords privacy may be similarly disadvantaged. Conversely, perceived ability to void on the street-side might render urgency less bothersome to some Indian men. Although there has been a dramatic increase in toilet availability under the Swachh Bharat Mission,[16] usage remains clouded by misplaced beliefs regarding personal hygiene and household sanctity.[17]

Historical reports of PPI after radical prostatectomy ranging from 2.5-87% have improved with refinements in technology and technique. Currently, about 6-9% of men undergoing radical prostatectomy are expected to require surgery for incontinence.[18,19] In contrast the risk of incontinence after benign prostate surgery is 1% or less. Urinary incontinence has also been noted after radiation therapy, hormonal ablation and watchful waiting in 12%, 11% and 3%, respectively.[19] The number of radical prostatectomies in India has increased rapidly as more cases are diagnosed early and robot-assisted surgery becomes increasingly available.

**Evaluation of Urinary Incontinence**

1.1 Carry out a clinical evaluation to categorize the type of urinary incontinence (stress, urgency, mixed or associated with chronic retention). (Clinical Principle)

1.2 Baseline clinical evaluation should include clinical history, physical examination and degree of bother (Clinical Principle), complete urine examination (LE-3, GR-Strong), voiding diary (LE-2, GR-Strong) and post-void residual urine measurement. (Expert Opinion)

Clinical categorization of UI is important and guides subsequent decisions. A broad range of conditions can present with UI. Search for associated LUTS, hematuria, dysuria, prolapse, abnormal vaginal bleeding, history of pelvic surgery, medication history, bowel and neurological symptoms any of which could lead to an alternative diagnosis. Clinical examination includes general, abdominal, vaginal, rectal and a focused neuro-urological examination (for S2-S4 segments). The cough stress test, preferably the ICS uniform cough stress test should be performed to assess for stress UI.[20] Visual assessment of urethral mobility rather than Q-tip test is adequate and recommended for stress UI.[21] A complete clinical evaluation can diagnose or exclude stress UI with positive LR 3.7 (95% CI 2.6-5.2) and negative LR 0.20 (95% CI 0.08-0.51). For urgency UI the corresponding figures are positive LR 2.2 (95% CI 0.55-8.7) and negative LR 0.63 (95% CI 0.34-1.17).[22]

Voiding diary is recommended in initial evaluation.[23,24] Comprehensive 3-day bladder diary is desirable[25] but at the minimum this should be a one-day record of micturition time and volume including leak episodes. Diary record is a pre-requisite for making a diagnosis of refractory urgency UI (vide infra). Current practice patterns suggest an encouraging use of voiding diary amongst Indian urologists.[26] The rapid increase in smartphone usage across India, 28% in 2018 with a 16% growth rate, opens the possibility of adopting multilingual electronic voiding
Electronic diaries have been shown to be reliable.\textsuperscript{[27,28]} Innovative diary records may be useful in patients who are illiterate.\textsuperscript{[29]}

Elevated PVR is not uncommon in women presenting with stress UI\textsuperscript{[30]} and overactive bladder.\textsuperscript{[31]} Absence of voiding difficulty is not a good predictor of low PVR in women.\textsuperscript{[32]} While there is lack of evidence in men with UI, PVR may help identify patients who are more likely to deteriorate.\textsuperscript{[33]} PVR is best measured by ultrasound scan. Ultrasonography is universally and promptly available across India for about 150-1000 INR (2-14 USD). Since the test is performed by a radiologist with standard machine (not a hand-held bladder scanner) the entire urinary tract should be screened. In the USI survey, 86% of the 468 respondents would check PVR.

Uroflow is recommended for men and women in whom voiding dysfunction is suspected. Results should be compared with PGIMER nomograms validated for the Indian population.\textsuperscript{[34,35]}

Clinicians must ascertain the degree of bother and desire for treatment for what is a quality-of-life problem.\textsuperscript{[36]} A validated questionnaire such as the ICIQ-UI SF that has been translated into multiple Indian languages is preferable.\textsuperscript{[37]}

Pad test is not recommended for routine clinical practice in women. However in men with PPI, the number of pads per day is widely used for guiding therapy.\textsuperscript{[38]}

Complete urine examination should be performed to exclude infection, hematuria and to screen for diabetes mellitus that is often undiagnosed in India.\textsuperscript{[39]} Antimicrobial treatment of asymptomatic pyuria or bacteriuria for improving continence is not recommended.

Caution is advised when patient and physician are gender-discordant. Just 15 of 2109 full members of the USI are female making the odds overwhelmingly high that a male urologist will evaluate a woman with UI. Currently, 28% of Indian urologists reported not performing a routine stress test in women presenting with UI.\textsuperscript{[26]} Lack of clinical examination can significantly compromise care. Urologists should be alert to the possibility of an unsatisfactory clinical examination and develop protocols to address this.

1.3 Do not perform invasive urodynamics testing prior to initiating non-invasive treatment. (LE-1 GR-Strong)

1.4 Invasive urodynamics may be omitted before surgery in women with uncomplicated stress UI. (LE-1, GR-Moderate) All other women should undergo urodynamics prior to stress UI surgery. (LE-3, GR-Strong)

1.5 Invasive urodynamics is recommended in men and women with urgency UI prior to invasive therapies (LE-3, GR-Weak).

1.6 Invasive urodynamics is recommended in men with post-prostatectomy incontinence prior to surgical therapy (LE-3, GR-Moderate).

1.7 A diagnostic cystoscopy is not recommended in the evaluation of urinary incontinence in women. (LE-4, GR-Moderate) In men with PPI, a diagnostic cystoscopy should be performed prior to surgical intervention. (LE-4, GR-Moderate)

The panel defines uncomplicated stress UI as that which occurs in an adult woman under 65 years with a history of stress-induced leak without urgency or voiding symptoms who has not undergone pelvic surgery or radiation therapy. The uncomplicated patient has demonstrable stress UI with urethral hypermobility, no pelvic organ prolapse beyond the introitus, low post-void residual urine and a normal uroflow.
In women with uncomplicated stress UI urodynamics may be omitted prior to surgery for stress UI. The defined criteria should be applied scrupulously and a uroflowmetry must be performed prior to surgery. Patients with complicated presentations should undergo urodynamics prior to surgery. Testing after reduction of prolapse should be a part of protocol. Any appropriate method (manual, packing, pessary, sponge stick or split speculum) could be used in view of the lack of clear superiority of any method. Identification and classification of any cough associated detrusor overactivity is recommended.

A meta-analysis in 2015 concluded lack of benefit of urodynamics in clinical outcomes of stress UI surgery. This conclusion is based on highly select patients and centers and the external validity of this conclusion in the average urology unit remains uncertain. The panel found one new randomized trial of 72 women of whom 60 were randomized 1:1 to either office evaluation or urodynamics before transobturator tape surgery. This Indian study concluded that outcomes were superior in the group undergoing preoperative urodynamics. However, the study suffers from critical flaws in patient allocation and in excluding patients from the urodynamics arm after randomization based on unfavorable characteristics.

Although reviews have concluded that urodynamics findings do not impact the outcome of treatment for urgency UI, the underlying studies are few and of moderate quality. Limited recent evidence suggests that women with urgency UI have better outcomes when the treatment is concordant with their urodynamics findings. Given the possibility of alternate diagnoses especially bladder outlet obstruction and stress incontinence in patients referred as “urgency UI”, a urodynamics is recommended prior to invasive treatment.

Urodynamics is widely available in India with 84% urologists having easy access. The test can usually be scheduled promptly at a typical cost of 500-8500 INR (7-123 USD). Adherence to quality standards and supervision by the physician is recommended.

There is scant evidence with regard to urodynamics in men with PPI. Bladder dysfunction including detrusor overactivity (30-40%), reduced compliance (5%) or underactive detrusor (30-40%) can potentially influence decisions. Fifteen percent of men with PPI show exclusive abnormality of bladder. Urodynamics findings may prognosticate the outcome of PPI surgery. However, in persistent severe PPI, urodynamics may not alter outcomes. Currently there are no high volume centers performing surgery for PPI in India. Given this background and the significant cost of therapy, the panel recommends urodynamics in men with PPI prior to invasive treatment.

A diagnostic cystoscopy is not recommended in initial evaluation of UI in women. However, 35% of Indian urologists continue to offer cystoscopy routinely to women. In contrast, men with PPI may benefit from cystoscopy since anatomical narrowing can co-exist or even be responsible for the symptoms.

**Conservative Therapies**

2.1 Patient education regarding lower urinary tract function and implications of UI should be an integral part of management. (Clinical Principle)

2.2 Counsel patients that moderation of caffeine consumption (LE-2, GR-moderate), modification of fluid intake (LE-2, GR-moderate), treatment of constipation (LE-3, GR-Moderate) and reduction of obesity (LE-1, GR-strong) can benefit patients with UI.

2.3 Comorbid conditions and medications that may influence UI should be addressed as appropriate. (Clinical Principle)
Misconceptions regarding UI are common and available public information is often inadequate or misleading. Education, group-based or individualized, can improve the outcome of subsequent interventions and reduces anxiety. Hence, patient education is recommended.

Weight loss improves UI in obese individuals. Weight loss has been associated with a sustained reduction in UI in women (RR 1.40, 95% CI 1.14 to 1.71). Benefits have also been noted after bariatric surgery in both women and men (RR 1.08 and RR 1.07 per 5% weight loss respectively). Obese men with PPI may also benefit from weight loss.

Low quality evidence suggests benefits from fluid restriction. Improvement in urgency UI has been noted with reduction in caffeine intake. Beneficial effects of smoking cessation have also been noted in a small trial.

2.4 Pelvic floor muscle training (PFMT) is recommended for women with UI as initial treatment or in combination with other treatments (LE-1, GR-Strong).

2.5 Routine use of biofeedback, pelvic floor stimulation therapy, vaginal cones or continence pessary is not recommended (LE-2, GR-moderate).

2.6 PFMT is effective in the prevention and treatment of UI during pregnancy and postpartum (LE-2, GR-moderate).

2.7 Bladder training is effective in women with UI (LE-1, GR-strong).

The panel defines PFMT as training of pelvic floor muscles with intent to improve the strength and endurance of contractions and ensure appropriate relaxation verified by clinical examination.

In addition, knack maneuver (voluntary contraction of the pelvic floor timed in anticipation of a rise in intra-abdominal pressure) is a useful adjunct for stress incontinence. PFMT is effective in women with UI with cure or improvement noted in 67% versus 29% controls (RR 2.39, 95% CI 1.64-3.47). One prospective, randomized Indian study compared combination of PFMT and herbal products B. serrata and C. scariosus with PFMT and placebo in a prospective randomized trial of 60 women (1:1). Women in both arms experienced improvement although the improvement with the herbal product was superior. The authors postulated a serotonin-norepinephrine uptake inhibition pathway for the herbs. There is wide variation in protocol of PFMT; however, none has proven superiority over others.

Biofeedback devices may be useful for patients unable to contract pelvic floor muscles in isolation. Pelvic floor stimulation should be reserved for patients unable to contract their pelvic floor. Acupuncture has been found to be useful in management of overactive bladder symptoms and urge incontinence.

Postpartum stress UI is common. 23% of 222 Indian women were noted to have stress UI with greater odds for those who underwent vaginal rather than LSCS delivery (OR 2.23, 95% CI 1.03-5.03, P=0.032). The beneficial effect of supervised PFMT during pregnancy or postpartum period is well documented.

Behavioral therapy including PFMT for UI has been studied in a randomized trial of 198 Indian women. This study showed that the therapy was superior to controls (pad-weight difference -9.3g, I1Q7 difference -5.5; p=0.001). Establishment of a separately demarcated facility may help.
The panel defines bladder training as a scheduled regimen of voiding and maneuvers to suppress urge with incremental increases in inter-void interval till a socially acceptable goal is attained.

A commonly used urge inhibition technique consists of rapid sequence pelvic floor squeeze without full relaxation in between.

Only about one-fourth of Indian urologists use conservative treatments regularly.[26]

2.8 Percutaneous tibial nerve stimulation (PTNS) is effective for the short-term treatment of women with urgency UI. (LE-2, GR-moderate).

In adults PTNS is more effective in urgency UI than sham treatment. Limited data suggests that it is as effective as antimuscarinics with lesser side effects.[83,84] Limited evidence supports it use in conjunction with drug therapy.[84,85] Repeated sessions, typically weekly, are necessary and there is little long-term data. Data with regard to transcutaneous tibial nerve stimulation is insufficient to make a recommendation.

2.9 PFMT is recommended for men with PPI for more rapidly attaining their final continence status (LE-1, GR-strong). Routine use of biofeedback or pelvic floor stimulation therapy is not recommended (LE-2, GR-moderate).

PFMT has been noted to be beneficial in men with urgency UI as well as PPI.[86,87] Supervised instruction with digital rectal examination is preferable to verbal or written instruction alone.[88] Preoperative PFMT before radical prostatectomy may not confer significant benefit.[89] There is little evidence to support the use of pelvic floor stimulation for men with PPI. A recent randomized trial showed no benefit with either PFMT or stimulation.[90]

Pharmacotherapy

3.1. Antimuscarinics (darifenacin, oxybutynin, solifenacin, tolterodine, trospium, fesoterodine, propiverine) are appropriate for patients with urgency UI. (LE-1, GR-Strong)

3.2 Exercise caution while prescribing antimuscarinics in the elderly. (LE-1, GR-Strong)

3.3 Mirabegron is appropriate for patients with urgency UI. (LE-1, GR-Strong)

3.4 Combination of mirabegron with antimuscarinics is more efficacious than either drug alone. (LE-1, GR-Strong)

3.5 Consider propanthelin in patients with financial constraint. (LE-2, GR-Weak)

All the commonly used antimuscarinics have been shown to alleviate symptoms of urgency UI.[91-93] Solifenacin and fesoterodine may be more effective than tolterodine.[93] However, there is no conclusive evidence to recommend a specific drug for specific presentations. There is good evidence that higher doses are more effective but with more side effects and sustained release preparations have lower side effects.[93-95] Combining two antimuscarinics increases the adverse effects without commensurate benefit.[96] A minimum trial of 3 weeks is recommended along with conservative treatment as above. Current prescribing patterns show that Indian urologists most often choose solifenacin (47%) or tolterodine (29%).[26]

The panel recommends caution in elderly patients who might be taking co-medication(s) that can augment, undermine or alter the response to therapy and are in general more susceptible to adverse events.[97] Cognitive dysfunction is a concern. Darifenacin, trospium and solifenacin
have not shown propensity to impact cognitive function in the short term unlike oxybutynin.[98-103] Long term dementia remains a concern.[104]

The panel specifically examined propanthelin, an older and cheaper quaternary non-selective antimuscarinic. The drug has been studied in small trials against placebo and oxybutynin and has been found to be effective.[92] The panel recommends consideration of propanthelin for patients with financial constraint.

Mirabegron, a beta 3 adrenergic agonist, is effective for urgency UI with low propensity for dry mouth, constipation and urinary retention similar to placebo.[105,106] Improvement has been found in patients exposed to antimuscarinics as well as the treatment-naive. Mirabegron is preferred when antimuscarinics are contraindicated e.g. narrow angle glaucoma, delayed gastric emptying and urinary retention. Uncontrolled hypertension is a contraindication. Effect of digoxin is potentiated, hence it must be started in lower doses.

Patients are more likely to persist with mirabegron than with antimuscarinics in the long-term, but the reasons have not been studied thoroughly.[107]

Mirabegron has been evaluated in Indian patients. A large Asian study randomized 1126 patients to mirabegron, tolterodine or placebo (1:1:1) and noted that mirabegron was more effective than placebo at 12 weeks with no difference between the two treatment arms and minimal adverse effects.[108]

Combination therapy of solifenacin (5mg) with mirabegron (50mg) has been shown to have superior efficacy when compared to either drug alone and is well tolerated. [97] In a recent meta-analysis, the combination was noted to be more efficacious both for achieving dryness as well as a 50% reduction in incontinence episodes. [98] Combining the two drugs maybe a more effective strategy than enhancing the dose of solifenacin to 10mg.[99,109-111]

3.6 Duloxetine may offer some benefit in the treatment of stress UI in women and PPI in men (LE-1, GR-Moderate) but caution is advised in view of the potential for serious side effects. (LE-2, GR-Strong)

In the short-term duloxetine improves stress UI with slight improvement in quality of life. Counsel patients regarding behavioral changes and rarely suicidal tendencies[112] In men with PPI trials show an earlier recovery of continence with duloxetine without any impact on the final continence rates. While the drug was effective and well tolerated in a small randomized trial[113], others have noted issues with tolerance.[114]

**Invasive Therapy for Urgency UI**

4.1 Offer Onabotulinum Toxin A (BTX-A) (LE-1, GR-strong) or sacral neuromodulation (SNM) (LE-2, GR-moderate) in patients with refractory urgency UI or when drug therapy is contraindicated or not tolerated.

The panel defines refractory urgency UI as a patient with unsatisfactory response to drug therapy (including combination therapy) and conservative management at 12 weeks in whom a voiding diary has been examined.

100 units injection of BTX-A in the bladder wall is the recommended initial dose.[115,116] A meta-analysis showed mean change of -2.06 (95%CI -2.60, -1.52, p<0.0001) in UI episodes.[117] BTX-A was studied in 39 Indian women (mean 52y) with refractory overactive bladder. A satisfactory clinical response (median 7 months) was noted in 86% without any retentions despite the 200U dose.[118] Counsel patients regarding the need for and continued efficacy with re-injections (not
before 12 weeks), dose-dependent transient urinary retention (5% with 100U) best managed by intermittent catheterization, and the need for monitoring.

BTX-A may be preferred over SNM in India on account of cost, availability and expertise. A large randomized comparative trial found that 200 units of BTX-A was more effective than SNM at reducing urgency UI episodes (3.9 versus 3.3; mean difference 0.63; 95% CI 0.13–1.14; p=0.01) at 6 months. SNM may be preferred in those with indicators of poor voiding (elevated residuals, detrusor underactivity, history of retention) or associated bowel symptoms. Patients offered SNM should be counseled regarding the need for a two-step procedure, device adjustments, revisions and replacement and the prohibition of whole body MRI. About three-quarter of patients show long-term sustained benefit.

**Invasive Therapy for Stress UI**

5.1 Mid-urethral slings (MUS), autologous pubovaginal slings (PVS) and the open retropubic colposuspension (ORC) are standard surgical options for a woman with uncomplicated stress UI. (LE-1, GR-strong) Both transobturator (TOT) and retropubic (RPT) tapes using macroporous polypropylene mesh are appropriate. (LE-1, GR-strong)

5.2 In women with mixed UI, initial treatment should be conservative with or without pharmacotherapy for urgency component. (LE-1, GR-strong) Stress UI surgery is appropriate treatment in women with stress-predominant mixed UI. (LE-1; GR-strong). Counsel regarding unpredictable resolution or worsening of urgency.

5.3 Single incision slings are a less invasive but less effective alternative to MUS. (LE-2, GR-Moderate)

For women with uncomplicated stress UI, PVS is more efficacious than ORC (47% versus 38%, p=0.01) but with greater propensity for voiding dysfunction (14% versus 2%) and urgency (27% versus 20%). ORC and MUS are equally efficacious but there are more urinary tract injuries with the latter 0.9% versus 6.3% and more posterior compartment prolapse (33.9% versus 20.1%) with the former. MUS and PVS are equally effective but bladder injury is commoner with MUS. These comparisons mostly included MUS patients who underwent RPT.

### Position Statement of the USI Guidelines Panel on Synthetic Tapes for Stress Urinary Incontinence:

The use of macroporous polypropylene mesh for minimally invasive stress incontinence surgery (distinct from other uses of vaginal mesh) is backed by robust data that demonstrates efficacy and a low rate of complications. A small minority of women can suffer from complications that are difficult to reverse even after surgical take-down. Use of strict asepsis as for all implants, careful technique and long term follow up are critical. Detailed pre-operative counseling is recommended.

Robust short-term data shows equivalent efficacy of TOT and RPT (40 trials, 6145 women). TOT has lower morbidity with less bladder injury (0.6% versus 4.5%), less voiding dysfunction (RR 0.53, 95% CI 0.43 to 0.65) but more groin pain (RR 4.12, 95% CI 2.71 to 6.27). Tape exposure rate is similar at just over 2%. Most evidence shows the medial-to-lateral approach for TOT is similar in efficacy and safety to the lateral-to-medial approach.
Data with regard to stress UI surgery in presentations complicated by obesity, intrinsic sphincter deficiency, recurrence or associated voiding dysfunction is inadequate. Obese women and those with recurrent stress UI may have inferior outcomes. Elderly women are more likely to have voiding dysfunction and urgency. RPT may be more likely than TOT to aggravate pre-existent voiding dysfunction.

Women with intrinsic sphincter deficiency have inferior outcomes regardless of the surgical option chosen. A meta-analysis showed no difference in objective outcome but the largest trial of 164 women showed lower need for repeat surgery in the RPT group compared with the TOT group (1.4% versus 20%, p<0.001). Another trial showed much lower success rate with a bulking agent as compared with PVS (9% versus 81%, p<0.001). Lack of hypermobility is a marker for inferior prognosis and may be a more important factor than presence of intrinsic sphincter deficiency.

When surgery for pelvic organ prolapse is planned, concomitant stress UI surgery is only appropriate if it is demonstrable (overt or occult). Discuss the reduced odds of postoperative stress UI with concomitant stress UI surgery (RR 0.30, 95% CI 0.19 to 0.48) but 8-19% risk of failed resolution of stress UI and possibility of new-onset voiding dysfunction. Sequencing stress UI surgery following prolapse surgery might avoid surgery in some and reduce morbidity. Not all women with preoperative occult stress UI develop clinical stress UI. Overt stress UI became manifest in about two-third of the 68% women with occult stress UI in a prospective study of 78 Indian women.

5.4 Consider use of customized mesh using established surgical principle in patients with financial constraint who desire MUS. (LE-3, GR-Weak)

5.5 Bulking agents are weakly effective in women with stress UI (LE-1, GR-Moderate) and should be considered only when surgery is inappropriate or refused.

5.6 Laser therapies are not recommended for the treatment of stress UI in women outside a research protocol. (LE-2, GR-Strong)

Customised macroporous polypropylene mesh slings have been performed in India and elsewhere observing principles similar to the MUS. One study followed 53 women who underwent retropubic suburethral mesh for 46 months and noted 85% complete dry rate and low complications. A 24-month comparative study of 57 women from Brazil found no difference in outcome between commercial and custom-made slings. One randomized trial (156 patients) compared customized mesh with standard TOT and found equivalent outcomes. However, the trial examined only 1-month outcomes by subjective measures. Tapes manufactured by Indian industry have shown acceptable outcomes without any major red flags but the studies have generally been of low quality. The panel recommends an informed decision-making process discussing all the available options.

For single incision slings, adjustable slings, minimally invasive retropubic colposuspension and bulking agents, the panel recommends a discussion that includes the lack of robust data demonstrating long-term efficacy, safety or both.

There are sporadic reports of intravaginal laser therapy for stress UI but the quality of these studies is low and the numbers are small. One small randomized trial showed benefit but had significant limitations in terms of design and outcome parameters. Accordingly, while clinical research may be appropriate, management of patients cannot be currently recommended.
Surgery for post prostatectomy incontinence

6.1 Surgery should be offered after a minimum interval of 6 months following the initial prostate surgery. (LE-4, GR-Moderate) Confirm stable patency of any anatomical narrowing before offering PPI surgery. (Clinical Principle)

6.2 For mild to moderate PPI artificial urinary sphincter (LE-2, GR-Moderate) and slings (LE-3, GR-Moderate) are appropriate surgeries.

6.3 For severe PPI artificial urinary sphincter is appropriate. (LE-2, GR-Strong)

6.4 Inform patients that reoperation rates are significant with all the current surgical options for PPI. (LE-3, GR-Weak)

6.5 Bulking agents are appropriate for short term relief in men with mild PPI. (LE-3, GR-Weak)

After prostatectomy for benign or malignant disease patients may show improvement with conservative treatment up to 2 years\textsuperscript{[152]} and in most patients, surgery is inappropriate before 6 months. Progressive improvement till one year with 6\% incontinence rate at 12 months was noted in a series of 52 Indian men following open radical retropubic prostatectomy.\textsuperscript{[158]}

While both artificial sphincter and slings are appropriate in patients with mild-moderate PPI, data suggests that slings may be associated with lower rate of major complications. Slings should not be offered in patients recurrent PPI following radiation therapy. Infection, erosion, pain and retention are some complications reported and may lead to explantation in upwards of 10\%.\textsuperscript{[159]} Adjustable slings have shown equivalent efficacy. A large multi-institutional study (n=287; mean 31mo follow up; 22\% severe PPI) across high volume centers using the ATOMS sling showed a dry rate of 64\% with median of 3 adjustments and 20\% explantation rate.\textsuperscript{[153]}

Artificial urinary sphincter has the largest body of evidence and has shown reliable efficacy in severe incontinence. Patients offered artificial sphincter must demonstrate adequate cognitive function and manual dexterity. Counseling should include information regarding a median sphincter survival rate of 5-7 years and a 26\% all-cause reoperation rate in high volume centers.\textsuperscript{[154]}

In an online survey of Indian urologists, self-designed synthetic meshes and autologous slings accounted for 10.2\% and 1.5\% of all PPI surgeries.\textsuperscript{[24]} Such slings have shown acceptable medium term success in non-irradiated patients but results cannot be generalized due to heterogeneity. A small Indian study (follow up 6-22 months) showed complete continence in four of six patients operated using a self-designed polypropylene mesh fixed by retropubic route. Of note, these patients had severe incontinence (6.4 pads/day) for 2.1y before surgery. One patient needed self-catheterization for retention.\textsuperscript{[155]}

Detrusor underactivity does not necessarily predict postoperative voiding difficulty following sling surgery as long as post-void residuals are low.\textsuperscript{[156]} Patients with elevated PVR may fail to void spontaneously following a sling procedure.

Bulking agents are minimally invasive but have poor long-term efficacy despite multiple sittings.\textsuperscript{[157,158]} The agent used (bovine collagen, dextranomer hyaluronic acid, silicone macroparticles or others), location of injection (bladder neck or proximal urethra) or the injection technique (periurethral or transurethral) does not seem to materially affect these outcomes. Bulking agents are typically appropriate in men with mild PPI who are unfit or refuse more effective surgery.
Health care in India with regard to urinary incontinence

India has traditionally presented a unique healthcare situation that can be summarized as inadequate public health infrastructure, (resultant) reliance on private health care, low penetration of insurance and a safety net primarily for families of individuals employed in the structured economy (both private and public). The year 2018 marked a watershed when the Indian government launched the ambitious “Ayushman Bharat” program, one of the largest attempts to provide universal healthcare (with caveats) to a large section of its population.\textsuperscript{[159]}

Most Indian healthcare plans fail to cover evaluation and treatment of UI that does not lead to a surgical procedure. Since few with UI will require surgery, patients need to fund their evaluation and medical treatment. UI often requires long term therapy and cost can be critical. (Table 2) The “National List of Essential Medicines” subject to price control from the Ministry of Health does not include any drugs used for UI.\textsuperscript{[160]} Fortunately strong domestic manufacturing and intense competition have kept prices of drugs drastically lower than that in other countries.

Table 2. Cost of commonly used drugs for urgency urinary incontinence in India

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Range of cost INR/10 tabs (number of common brands)*</th>
<th>Median cost INR/10 tabs</th>
<th>Frequency per day</th>
<th>Estimated cost INR per month (30 days)</th>
<th>Estimated cost (USD) per month (30 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxybutynin 2.5</td>
<td>39-80.85[4]</td>
<td>74.25</td>
<td>3</td>
<td>668</td>
<td>9.4</td>
</tr>
<tr>
<td>Oxybutynin ER 2.5</td>
<td>340[1]</td>
<td>340.00</td>
<td>2</td>
<td>2040</td>
<td>28.6</td>
</tr>
<tr>
<td>Oxybutynin 5</td>
<td>75-149.6[4]</td>
<td>125.00</td>
<td>3</td>
<td>1125</td>
<td>15.8</td>
</tr>
<tr>
<td>Oxybutynin ER 5</td>
<td>144[1]</td>
<td>144.00</td>
<td>2</td>
<td>864</td>
<td>12.1</td>
</tr>
<tr>
<td>Oxybutynin ER 10</td>
<td>152.36[1]</td>
<td>152.36</td>
<td>2</td>
<td>914</td>
<td>12.8</td>
</tr>
<tr>
<td>Tolterodine 1</td>
<td>35.03-89[4]</td>
<td>55.35</td>
<td>2</td>
<td>332</td>
<td>4.7</td>
</tr>
<tr>
<td>Tolterodine 2</td>
<td>65-351.4[8]</td>
<td>91.00</td>
<td>2</td>
<td>546</td>
<td>7.6</td>
</tr>
<tr>
<td>Tolterodine ER 2</td>
<td>98.16-146.3[4]</td>
<td>115.00</td>
<td>1</td>
<td>345</td>
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<tr>
<td>Tolterodine ER 4</td>
<td>65-414.2[12]</td>
<td>162.00</td>
<td>1</td>
<td>486</td>
<td>6.8</td>
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<tr>
<td>Solifenacin 5</td>
<td>163-296[12]</td>
<td>239.00</td>
<td>1</td>
<td>717</td>
<td>10.0</td>
</tr>
<tr>
<td>Solifenacin 10</td>
<td>285-417[9]</td>
<td>360.00</td>
<td>1</td>
<td>1080</td>
<td>15.1</td>
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<tr>
<td>Darifenacin 7.5</td>
<td>226.75-339[5]</td>
<td>235.00</td>
<td>1</td>
<td>705</td>
<td>9.9</td>
</tr>
<tr>
<td>Darifenacin 15</td>
<td>220-395[5]</td>
<td>347.00</td>
<td>1</td>
<td>1041</td>
<td>14.6</td>
</tr>
<tr>
<td>Trospium ER 60</td>
<td>211.72-263[3]</td>
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<td>Propanthelin 15</td>
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<td>9.5</td>
<td>3</td>
<td>86</td>
<td>1.2</td>
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<tr>
<td>Mirabegron 50</td>
<td>299-390[13]</td>
<td>299.00</td>
<td>1</td>
<td>897</td>
<td>12.6</td>
</tr>
</tbody>
</table>
There is limited literature on the costing of various surgical procedures for UI in India. Low cost surgeries have been performed in India observing principles similar to the MUS with macroporous polypropylene mesh using two distinct approaches. Self-fashioned slings made from polypropylene hernia mesh and use of economical tapes made by Indian manufacturers. Both of these approaches have the potential for significant cost benefits with an estimated cost that is one-fifth to one-sixth of that incurred by using imported mesh kits without any major red flags. A similar low-cost approach for PPI yielded all-inclusive hospital cost equivalent to 350 USD in a public hospital.[155]

Surgical procedures for UI under the newly launched Ayushmaan Bharat program (that subsumes several state-level health plans) has three surgical packages for stress incontinence under “Urology” with a prescribed tariff of 20,000 INR (289 USD), 30,000 INR (433 USD) and 35,000 INR (506 USD) for open, laparoscopic and sling procedures (procedure codes 130-132). Paradoxically, procedure code 4 under “Gynecology” lists Burch colposuspension tariff as 35,000 INR (506 USD). Apparently, urologists will be reimbursed less than gynecologists for the same procedure! There are no packages mentioned for botulinum toxin, artificial sphincter and bulking agents but there is provision for special permission for such procedures.[159] Of note, all tariffs include diagnostic investigations, medication, consultation, bed charges as well as meals for the patient. The guidelines panel notes that despite significant innovation hospitals will struggle to deliver on these tariffs.

Appendix 1. Disclaimer
Appendix 2. Timelines and search strategy

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