

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

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Preamble

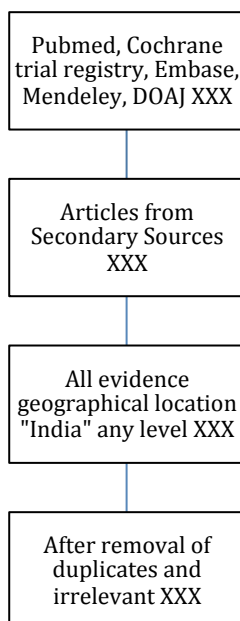
These guidelines have been drafted by the USI Urinary Incontinence Guidelines Panel and address "Non-neurogenic urinary incontinence in adults". The guidelines are targeted at health professionals and the recommendations are updated till October 2018. These will remain valid until the next update or for a maximum period of five years.

Material 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 1, 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.^[1] 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.

Abbreviations

BTX-A	Onabotulinum toxin A
GR	Grade of recommendation
ICS	International Continence Society
IUGA	International Urogynecology Association
LE	Level of evidence
LR	Likelihood ratio
LUTS	Lower urinary tract symptoms
MUS	Midurethral sling
ORC	Open retropubic colposuspension
PFMT	Pelvic floor muscle training
PPI	Post-prostatectomy incontinence
PTNS	Percutaneous tibial nerve stimulation
PVR	Postvoid residual
PVS	Pubovaginal sling
RPT	Retropubic tape
SNM	Sacral neuromodulation
TOT	Transobturator tape
UI	Urinary incontinence



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

Figure 1. Flow chart of literature search

1 loss of urine associated with urgency”. **Mixed UI** is “complaint of involuntary loss of urine with
 2 urgency and also with effort or physical exertion or on sneezing or coughing”
 3

4 **Urinary Incontinence In India**

5
 6 UI has been noted in 25% to 45% of adult women in global studies.^[3] Studies from India show a
 7 prevalence of 10-42% in nine population-based door-to-door epidemiological studies with stress UI
 8 being the commonest type (Table 1).^[4-12] Age-adjusted prevalence progressively increased from the
 9 3rd to 7th decade (5.6%, 14.2%, 27.3%, 34.3% and 39.0% respectively). This finding has important
 10 implications for health planning since the population of Indians older than 60 years is set to double
 11 from 117 million in 2015 to 246 million by 2040.^[13]
 12

13 Two noteworthy risk factors were delivery at home and pregnancy at young age.^[4,7,9] About 40% of
 14 women attributed incontinence to a natural consequence of ageing.^[4,6,9] Social embarrassment
 15 (about 25%) was possibly more important than financial constraint (3-14%) in determining help-
 16 seeking behavior.^[4,8,9]
 17

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

Geographical location, state [citation]	Age group	Total sample	Number consented (%)	Number incontinent (%)	Type of Incontinence (SUI, UUI, MUI)	Other findings
1. Bareilly, Uttar Pradesh[4]	>30y	464	236 (50.8%)	28 (12%)	22%, 38%, 38%	Increased risk if 1 st delivery <18y, with age, more parous, home delivery
2. Delhi* (Abstract)[5]	>18y	NA	245	37 (15.1%)	44%, 32%, 24%	Increased risk with age and BMI (multivariate)
3. Khardi, Maharashtra [6]	>20y	442	353 (79.9%)	90 (25.5%)	56%, 32%, 12%	Increased risk with age, parity and diabetes
4. Coimbatore, Tamil Nadu[7]	20-60y	NA	598	202 (33.8%)	Not assessed	Increased risk if 1 st delivery <20y, with age
5. Chandigarh[8]	>18y	1989#	1979 (99.5%)	220 (11.6%)	46%, 26%, 28%	Increased risk with age
6. Karimnagar, Telangana[9]	>35y	NA	552	53 (10%)	57%, 23%, 20%	Increased risk if 1 st delivery <18y, with age, more parous. Not with SES
7. Udipi, Karnataka[10]	18-70y	NA	1256 Stratified sample	239 (19%)	Not assessed	Increased risk with age
8. Aligarh, UP[11]	>41**		530 Systematic random sampling	219 (41.3%)	UUI 22%, SUI 46%, MUI 33%	Increase with age, urban, obesity, smoking (but not oral tobacco)
9. Allahabad, UP[12]	>40**		400 stratified Random sampling	38 (9.5%)##	Only SUI recorded	10.5% urban women and 9.5% rural

20 *The studies aimed to survey all eligible women living in a specified area except No. 7, 8 and 9 which surveyed a sample*

21 **International Continence Society 2017 abstract*

***postmenopausal women only*

22 *# back-calculated from given information*

Urgency recorded separately but no data on urgency UI or mixed UI.

23

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

6 The committee examined the issue of access and usage of toilets in India. Inability to access a toilet
7 facility in time can convert urgency in an individual with limited ambulation into UI.^[15] Women in
8 rural India unable to access a toilet facility until twilight affords privacy may be similarly
9 disadvantaged. Conversely, perceived ability to void on the street-side might render urgency less
10 bothersome to some Indian men. Although there has been a dramatic increase in toilet availability
11 under the Swachh Bharat Mission.^[16] Usage remains clouded by misplaced beliefs regarding
12 personal hygiene and household sanctity.^[17]
13

14 Historical reports of PPI after radical prostatectomy ranging from 2.5-87% have improved with
15 refinements in technology and technique. Currently, about 6-9% of men undergoing radical
16 prostatectomy are expected to require surgery for incontinence.^[18,19] In contrast the risk of
17 incontinence after benign prostate surgery is 1% or less. Urinary incontinence has also been noted
18 after radiation therapy, hormonal ablation and watchful waiting in 12%, 11% and 3%
19 respectively.^[19] The number of radical prostatectomies in India has increased rapidly as more cases
20 are diagnosed early and robot-assisted surgery becomes increasingly available.
21

22 **Evaluation of Urinary Incontinence**

23
24 **1.1 Carry out a clinical evaluation to categorize the type of urinary incontinence (stress,**
25 **urgency, mixed or incontinence associated with chronic retention). (Clinical Principle)**
26

27 **1.2 Baseline clinical evaluation should include clinical history, physical examination and**
28 **degree of bother (Clinical Principle), complete urine examination (LE-3, GR-Strong), voiding**
29 **diary (LE-2, GR-Strong) and post-void residual urine measurement. (Expert Opinion)**
30

31 Clinical categorization of UI is important and guides subsequent decisions. A broad range of
32 conditions can present with UI. Search for associated LUTS, hematuria, dysuria, prolapse, abnormal
33 vaginal bleeding, history of pelvic surgery, medication history, bowel and neurological symptoms
34 any of which could lead to an alternative diagnosis. Clinical examination includes general,
35 abdominal, vaginal, rectal and a focused neuro-urological examination (for S2-S4 segments). The
36 cough stress test, preferably the ICS uniform cough stress test should be performed to assess for
37 stress UI.^[20] Visual assessment of urethral mobility rather than Q-tip test is adequate and
38 recommended for stress UI.^[21] A complete clinical evaluation can diagnose or exclude stress UI with
39 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
40 corresponding figures are positive LR 2.2 (95% CI 0.55-8.7) and negative LR 0.63 (95% CI 0.34-
41 1.17).^[22]
42

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

1 Elevated PVR is not uncommon in women presenting with stress UI^[30] and overactive bladder.^[31]
2 Absence of voiding difficulty is not a good predictor of elevated PVR in women.^[32] While there is
3 lack of evidence in men with UI, PVR may help identify patients who are more likely to
4 deteriorate.^[33] PVR is best measured by ultrasound scan. Ultrasonography is universally and
5 promptly available across India for about INR300-1000 (4-15\$) Since the test is performed by a
6 radiologist with standard machine (not a hand-held bladder scanner) and given the high prevalence
7 of calculus-induced chronic kidney disease in India, the entire urinary tract should be screened. In
8 the USI survey, 86% of the 468 respondents would check PVR.
9

10 Uroflow is recommended for men and women in whom voiding dysfunction is suspected. Results
11 should be compared with PGIMER nomograms.^[34,35]
12

13 Clinicians must ascertain the degree of bother and desire for treatment for what is a quality of life
14 problem.^[36] A validated questionnaire such as the ICIQ-UI SF that has been translated into multiple
15 Indian languages is preferable.^[37]
16

17 Pad test is not recommended for routine clinical practice in women. However, a surrogate of the
18 pad test i.e. the number of pads per day is widely used in men with PPI for guiding therapy.^[38]
19

20 Complete urine examination should be performed to exclude infection, hematuria and to screen for
21 diabetes mellitus that is often undiagnosed in India.^[39] Antimicrobial treatment of asymptomatic
22 pyuria or bacteriuria for improving continence is not recommended.
23

24 Caution is advised when patient and physician are gender-discordant. Just 15 of 2109 full members
25 of the USI are female making the odds overwhelmingly high that a male urologist will evaluate a
26 woman with UI. Currently, 28% of Indian urologists reported not performing a routine stress test in
27 women presenting with UI.^[26] Lack of clinical examination can significantly compromise care.
28 Urologists should be alert to the possibility of an unsatisfactory clinical examination and develop
29 protocols to address this.
30

31 **1.3 Do not perform invasive urodynamics testing prior to initiating non-invasive treatment.**
32 **(LE-1 GR-Strong)**
33

34 **1.4 Invasive urodynamics may be omitted before surgery in women with uncomplicated**
35 **stress UI. (LE-1, GR-Moderate) All other women should undergo urodynamics prior to stress**
36 **UI surgery. (LE-3, GR-Strong)**
37

38 **1.5 Invasive urodynamics is recommended in men and women with urgency UI prior to**
39 **invasive therapies (LE-3, GR-Weak).**
40

41 **1.6 Invasive urodynamics is recommended in men with post-prostatectomy incontinence**
42 **prior to surgical therapy (LE-4, GR-Moderate).**
43

44 **1.7 A diagnostic cystoscopy is not recommended in the evaluation of urinary incontinence in**
45 **women. (LE-4, GR-Moderate) In men with PPI, a diagnostic cystoscopy should be performed**
46 **prior to surgical intervention. (LE-4, GR-Moderate)**
47

48 *The panel defines uncomplicated stress UI as that which occurs in an adult woman under 65 years*
49 *with a history of stress-induced leak without urgency or voiding symptoms who has not undergone*
50 *pelvic surgery or radiation therapy. The uncomplicated patient has demonstrable stress UI with*

1 *urethral hypermobility, no pelvic organ prolapse beyond the introitus, low post-void residual urine*
2 *and a normal uroflow.*

3
4 In women with uncomplicated stress UI urodynamics may be omitted prior to surgery for stress UI.
5 The defined criteria should be applied scrupulously and a uroflowmetry must be performed prior
6 to surgery. [40] Patients with complicated presentations should undergo urodynamics prior to
7 surgery. Testing after reduction of prolapse should be a part of protocol. Any appropriate method
8 (manual, packing, pessary, sponge stick or split speculum) could be used in view of the lack of clear
9 superiority of any method.[41] Identification and classification of any cough associated detrusor
10 overactivity is recommended.[42]

11
12 A meta-analysis in 2015 concluded lack of benefit of urodynamics in clinical outcomes of stress UI
13 surgery.[43] This conclusion is based on highly select patients and centers and the external validity
14 of this conclusion in the average Indian center remains uncertain.[44,45] The panel found one new
15 randomized trial of 72 women of whom 60 were randomized 1:1 to either office evaluation or
16 urodynamics before transobturator tape surgery. This Indian study concluded that outcomes were
17 superior in the group undergoing preoperative urodynamics. However, the study suffers from
18 critical flaws in patient allocation and in excluding patients from the urodynamics arm after
19 randomization based on unfavorable characteristics.[46]

20
21 Although reviews have concluded that urodynamics findings do not impact the outcome of
22 treatment for urgency UI, the underlying studies are few and of moderate quality.[47,48] Limited
23 recent evidence suggests that women with urgency UI have better outcomes when the treatment is
24 concordant with their urodynamics findings.[49] Given the possibility of alternate diagnoses
25 especially bladder outlet obstruction and stress incontinence in patients referred as “urgency UI”[50-
26 52], a urodynamics is recommended prior to invasive treatment.

27
28 Urodynamics is widely available in India with 84% urologists having easy access.[26] The test can
29 usually be scheduled promptly at a typical cost of about Rs 2200-8500 (30-116\$ US).

30
31 There is scant evidence with regard to urodynamics in men with PPI. Bladder dysfunction including
32 detrusor overactivity (30-40%), reduced compliance (5%) or underactive detrusor (30-40%) can
33 potentially influence decisions. 15% men with PPI show exclusive abnormality of bladder.[53]
34 Urodynamics findings may prognosticate the outcome of PPI surgery.[54,55] However, in persistent
35 severe PPI, urodynamics may not alter outcomes. Currently there are no high volume centers
36 performing surgery for PPI in India. Given this background and the significant cost of therapy, the
37 panel recommends urodynamics in men with PPI prior to invasive treatment.

38
39 A diagnostic cystoscopy is not recommended in initial evaluation of UI in women. However 35% of
40 Indian urologists continue to offer cystoscopy routinely to women.[26] In contrast, men with PPI may
41 benefit from cystoscopy since anatomical narrowing can co-exist or even be responsible for the
42 symptoms.[56]

43 44 **Conservative Therapies**

45 **2.1 Patient education regarding lower urinary tract function and implications of UI should** 46 **be an integral part of management. (Clinical Principle)**

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

4
5 **2.3 Comorbid conditions and medications that may influence UI should be addressed as**
6 **appropriate (Clinical Principle)**

7
8 Misconceptions regarding UI are common^[57] and available public information is often inadequate
9 or misleading.^[58] Education, group-based or individualized, can improve the outcome of subsequent
10 interventions and reduces anxiety.^[59-63] Hence, patient education is recommended.

11
12 Weight loss improves UI in obese individuals. Weight loss was associated with a sustained
13 reduction in UI in women (RR 1.40, 95% CI 1.14 to 1.71).^[64] Benefits have also been noted after
14 bariatric surgery in both women and men (RR 1.08 and RR 1.07 per 5% weight loss
15 respectively).^[65] Obese men with PPI may also benefit from weight loss.^[66]

16
17 Low quality evidence suggests benefits from fluid restriction.^[64] Improvement in urgency UI has
18 been noted with reduction in caffeine intake.^[67,68] Beneficial effects of smoking cessation have also
19 been noted in a small trial.^[69]

20
21 **2.4 Pelvic floor muscle training (PFMT) is recommended for women with UI as initial**
22 **treatment or in combination with other treatments (LE-1, GR-Strong).**

23
24 **2.5 Routine use of biofeedback, pelvic floor stimulation therapy, vaginal cones or continence**
25 **pessary is not recommended (LE-2, GR-moderate).**

26
27 **2.6 PFMT is effective in the prevention and treatment of UI during pregnancy and**
28 **postpartum (LE-2, GR-moderate).**

29
30 **2.7 Bladder training is effective in women with UI (LE-1, GR-strong).**

31
32 *The panel defines PFMT as training of pelvic floor muscles with intent to improve the strength and*
33 *endurance of contractions and ensure appropriate relaxation verified by clinical examination.*

34
35 In addition, knack maneuver (voluntary contraction of the pelvic floor timed in anticipation of a rise
36 in intra-abdominal pressure) is a useful adjunct for stress incontinence. PFMT is effective in women
37 with UI with cure or improvement noted in 67% versus 29% controls (RR 2.39, 95% CI 1.64-3.47).
38 One prospective, randomized Indian study compared combination of herbal products *B. serrata* and
39 *C. scariosus* and PFMT with PFMT and placebo in a prospective randomized trial of 60 women (1:1).
40 Women in both arms experienced improvement although the improvement with the herbal product
41 was superior. The authors postulated a serotonin-norepinephrine uptake inhibition pathway for
42 the herbs.^[70] There is wide variation in protocol of PFMT; however, none has proven superiority
43 over others.^[71]

44
45 Biofeedback devices may be useful for patients unable to contract pelvic floor muscles in
46 isolation.^[72-75] Pelvic floor stimulation should be reserved for patients unable to contract their
47 pelvic floor.^[76,77] Acupuncture has been found to be useful in management of overactive bladder
48 symptoms and urge incontinence.^[78]

1 Postpartum stress UI is common. 23% of 222 Indian women were noted to have stress UI with
2 greater odds for those who underwent vaginal rather than LSCS delivery (OR 2.23, 95% CI 1.03-
3 5.03, P=0.032).^[79] The beneficial effect of supervised PFMT during pregnancy or postpartum period
4 is well documented.^[80,81]

5
6 Behavioral therapy including PFMT for UI has been studied in a randomized trial of 198 Indian
7 women. This study showed that the therapy was superior to controls (pad-weight difference -9.3g,
8 IIQ7 difference -5.5; p=0.001). [8] Establishment of a separately demarcated facility may help.^[82]

9
10 *The panel defines bladder training as a scheduled regimen of voiding and maneuvers to suppress urge*
11 *with incremental increases in inter-void interval till a socially acceptable goal is attained.*

12
13 A commonly used urge inhibition technique consists of rapid sequence pelvic floor squeeze without
14 full relaxation in between.

15
16 Only about one-fourth of Indian urologists use conservative treatments regularly.^[26]

17 18 **2.8 Percutaneous tibial nerve stimulation (PTNS) is effective for the short-term treatment of** 19 **women with urgency UI. (LE-2, GR-moderate).**

20
21 PTNS is more effective in urgency UI in adults than sham treatment. Limited data suggests that it is
22 as effective as antimuscarinics with lesser side effects.^[83,84] Limited evidence supports its use in
23 conjunction with drug therapy.^[84,85] Repeated sessions, typically weekly, are necessary and there is
24 little long-term data. Data with regard to transcutaneous tibial nerve stimulation is insufficient to
25 make a recommendation.

26 27 **2.9 PFMT is recommended for men with PPI for more rapidly attaining their final continence** 28 **status (LE-1, GR-strong). Routine use of biofeedback or pelvic floor stimulation therapy is** 29 **not recommended (LE-2, GR-moderate).**

30
31 PFMT has been noted to be beneficial in men with urgency UI as well as PPI.^[86,87] Supervised
32 instruction with digital rectal examination is preferable to verbal or written instruction alone.^[88]
33 Preoperative PFMT before radical prostatectomy may not confer significant benefit.^[89] There is
34 little evidence to support the use of pelvic floor stimulation for men with PPI. A recent randomized
35 trial showed no benefit with either PFMT or stimulation.^[90]

36 37 **Pharmacotherapy**

38
39 **3.1. Antimuscarinics (darifenacin, oxybutynin, solifenacin, tolterodine, trospium,**
40 **fesoterodine, propiverine) are appropriate for patients with urgency UI. (LE-1, GR-Strong)**

41
42 **3.2 Exercise caution while prescribing antimuscarinics in the elderly. (LE-1, GR-Strong)**

43
44 **3.3 Mirabegron is appropriate for patients with urgency UI. (LE-1, GR-Strong)**

45
46 **3.4 Combination of mirabegron with antimuscarinics is more efficacious than either drug**
47 **alone. (LE-1, GR-Strong)**

48
49 **3.5 Consider propanthelin in patients with financial constraint. (LE-2, GR-conditional)**

50

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

9
10 The panel recommends caution in elderly patients who might be taking co-medication that can
11 augment, undermine or alter the response to therapy and are in general more susceptible to
12 adverse events.^[97] Cognitive dysfunction is a concern. Darifenacin, trospium and solifenacin have
13 not shown propensity to impact cognitive function in the short term unlike oxybutynin.^[98-103] Long
14 term dementia remains a concern.^[104]

15
16 The panel specifically examined propanthelin an older and cheaper quaternary non-selective
17 antimuscarinic. The drug has been studied in small trials against placebo and oxybutynin and has
18 been found to be effective.^[92] The panel recommends consideration of propanthelin for patients
19 with financial constraint.

20
21 Mirabegron, a beta 3 adrenergic agonist, is effective for urgency UI with low propensity for dry
22 mouth, constipation and urinary retention similar to placebo.^[105,106] Improvement has been found
23 in patients exposed to antimuscarinics as well as the treatment-naïve. Mirabegron is preferred
24 when antimuscarinics are contraindicated e.g. narrow angle glaucoma, delayed gastric emptying
25 and urinary retention. Uncontrolled hypertension is a contraindication. Effect of digoxin effect is
26 potentiated, hence it must be started in lower doses.

27
28 Patients are more likely to persist with mirabegron than with antimuscarinics in the long-term but
29 the reasons have not been studied thoroughly.^[107]

30
31 Mirabegron has been evaluated in Indian patients. A large Asian study randomized 1126 patients to
32 mirabegron, tolterodine or placebo (1:1:1) and noted that mirabegron was more effective than
33 placebo at 12 weeks with no difference between the two treatment arms and minimal adverse
34 effects.^[108]

35
36 Combination therapy of solifenacin (5mg) with mirabegron (50mg) has been shown to have
37 superior efficacy when compared to either drug alone and is well tolerated. ^[97] In a recent meta-
38 analysis, the combination was noted to be more efficacious both for achieving dryness as well as a
39 50% reduction in incontinence episodes. ^[98] Combining the two drugs maybe a more effective
40 strategy than enhancing the dose of solifenacin to 10mg.^[99,109-111]

41
42 **3.6 Duloxetine may offer some benefit in the treatment of stress UI in women and PPI in men**
43 **(LE-1, GR-Moderate) but caution is advised in view of the potential for serious side effects.**
44 **(LE-2, GR-Strong)**

45
46 In the short-term duloxetine improves stress UI with slight improvement in quality of life. Counsel
47 patients regarding behavioral changes and rarely suicidal tendencies^[112] In men with PPI trials
48 show an earlier recovery of continence with duloxetine without any impact on the final continence
49 rates. While the drug was effective and well tolerated in a small randomized trial^[113], others have
50 noted issues with tolerance.^[114]

1 **Invasive Therapy for Urgency UI**

2
3 **4.1 Offer Onabotulinum Toxin A (BTX-A) (LE-1, GR-strong) or sacral neuromodulation (SNM)**
4 **(LE-2, GR-moderate) in patients with refractory urgency UI or when drug therapy is**
5 **contraindicated or not tolerated.**

6
7 *The panel defines refractory urgency UI as a patient with unsatisfactory response to drug therapy*
8 *(including combination therapy) and conservative management at 12 weeks in whom a voiding diary*
9 *has been examined.*

10
11 100 units injection of BTX-A in the bladder wall is the recommended initial dose.^[115,116] A meta-
12 analysis showed mean change of -2.06 (95%CI -2.60, - 1.52, p<0.0001) in UI episodes.^[117] BTX-A
13 was studied in 39 Indian women (mean 52y) with refractory overactive bladder. A satisfactory
14 clinical response (median 7 months) was noted in 86% without any retentions despite the 200U
15 dose.^[118] Counsel patients regarding the need for and continued efficacy with re-injections (not
16 before 12 weeks), dose-dependent transient urinary retention (5% with 100U) best managed by
17 intermittent catheterization, and the need for monitoring.

18
19 BTX-A may be preferred over SNM in India on account of cost, availability and expertise. A large
20 randomized comparative trial found that 200 units of BTX-A was more effective than SNM at
21 reducing urgency UI episodes (3.9 vs 3.3; mean difference 0.63; 95% CI 0.13–1.14; p=0.01) at 6
22 months.^[119] SNM may be preferred in those with indicators of poor voiding (elevated residuals,
23 detrusor underactivity, history of retention) or associated bowel symptoms. Patients offered SNM
24 should be counseled regarding the need for a two-step procedure, device adjustments, revisions
25 and replacement and the prohibition of whole body MRI. About three-quarter of patients show
26 long-term sustained benefit.

27
28 **Invasive Therapy for Stress UI**

29 **5.1 Mid-urethral slings (MUS), autologous pubovaginal slings (PVS) and the open retropubic**
30 **colposuspension (ORC) are standard surgical options for a woman with uncomplicated**
31 **stress UI. (LE-1, GR-strong) Both transobturator (TOT) and retropubic (RPT) tapes using**
32 **macroporous polypropylene mesh are appropriate. (LE-1, GR-strong)**

33
34 **5.2 In women with mixed UI, initial treatment should be conservative with or without**
35 **pharmacotherapy for urgency component. (LE-1, GR-strong) Stress UI surgery is appropriate**
36 **treatment in women with stress-predominant mixed UI. (LE-1; GR-strong). Counsel**
37 **regarding unpredictable resolution or worsening of urgency.**

38
39 **5.3 Single incision slings are a less invasive but less effective alternative to MUS. (LE-2, GR-**
40 **Moderate)**

41
42 For women with uncomplicated stress UI, PVS is more efficacious than ORC (47% versus 38%,
43 p=0.01) but with greater propensity for voiding dysfunction (14% versus 2%) and urgency (27% vs
44 20%).^[120] ORC and MUS are equally efficacious but there are more urinary tract injuries with the
45 latter 0.9% versus 6.3% and more posterior compartment prolapse (33.9% vs 20.1%) with the
46 former.^[121] MUS and PVS are equally effective but bladder injury is commoner with MUS.^[122] These
47 comparisons mostly included MUS patients who underwent RPT.

1 Robust short-term data shows equivalent efficacy of TOT and RPT (40 trials, 6145 women). TOT
2 has lower morbidity with less bladder injury (0.6% versus 4.5%), less voiding dysfunction (RR 0.53,
3 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
4 similar at just over 2%.^[123] Most evidence shows the medial-to-lateral approach for TOT is similar
5 in efficacy and safety to the lateral-to-medial approach.
6

7 Data with regard to stress UI surgery in presentations complicated by obesity, intrinsic sphincter
8 deficiency, recurrence or associated voiding dysfunction is inadequate^[123] Obese women^[124,125] and
9 those with recurrent stress UI^[126,127] may have inferior outcomes. Elderly women are more likely to
10 have voiding dysfunction and urgency.^[128] RPT may be more likely than TOT to aggravate pre-
11 existent voiding dysfunction.^[129]
12

**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.

13
14
15 Women with intrinsic sphincter deficiency have inferior outcomes regardless of the surgical option
16 chosen. A meta-analysis showed no difference in objective outcome but the largest trial of 164
17 women showed lower need for repeat surgery in the RPT group compared with the TOT group
18 (1.4% versus 20%, $p < 0.001$).^[130,131] Another trial showed much lower success rate with a bulking
19 agent as compared with PVS (9% versus 81%, $p < 0.001$).^[132] Lack of hypermobility is a marker for
20 inferior prognosis^[133] and may be a more important factor than presence of intrinsic sphincter
21 deficiency.^[134]
22

23 In women with concomitant pelvic organ prolapse consideration for stress UI surgery is only
24 appropriate if there is demonstrable stress UI (overt or occult). Discuss the reduced odds of
25 postoperative stress UI with concomitant stress UI surgery (RR 0.30, 95% CI 0.19 to 0.48) but 8-
26 19% risk of failed resolution of stress UI^[135,136] and possibility of new-onset voiding dysfunction.
27 Sequencing stress UI surgery following prolapse surgery might avoid surgery in some and reduce
28 morbidity.^[136] Not all women with preoperative occult stress UI develop clinical stress UI. Overt
29 stress UI became manifest in about two-third of the 68% women with occult stress UI in a
30 prospective study of 78 Indian women.^[137]
31

32 **5.4 Consider use of customized mesh using established surgical principle in patients with**
33 **financial constraint who desire MUS. (LE-3, GR-conditional)**
34

35 **5.5 Bulking agents are weakly effective in women with stress UI (LE-1, GR-moderate) and**
36 **should be considered only when surgery is inappropriate or refused.**
37

38 **5.6 Laser therapies are not recommended for the treatment of stress UI in women outside a**
39 **research protocol. (LE-2, GR-Strong)**
40

1 Customised macroporous polypropylene mesh slings have been performed in India and elsewhere
2 observing principles similar to the MUS.^[138-143] One study followed 53 women who underwent
3 retropubic suburethral mesh for 46 months and noted 85% complete dry rate and low
4 complications.^[138] A 24-month comparative study of 57 women from Brazil found no difference in
5 outcome between commercial and custom-made slings.^[144] One randomized trial (156 patients)
6 compared customized mesh with standard TOT and found equivalent outcomes. However, the trial
7 examined only 1-month outcomes by subjective measures.^[138] Tapes manufactured by Indian
8 industry have shown acceptable outcomes without any major red flags but the studies have
9 generally been of low quality. The panel recommends an informed decision-making process
10 discussing all the available options.^[145,146]

11
12 For single incision slings^[147], adjustable slings, minimally invasive retropubic colposuspension and
13 bulking agents; the panel recommends a discussion that includes the lack of robust data
14 demonstrating long-term efficacy, safety or both.^[148,149]

15
16 There are sporadic reports of intravaginal laser therapy for stress UI but the quality of these studies
17 is low and the numbers are small. One small randomized trial showed benefit but had significant
18 limitations in terms of design and outcome parameters. Accordingly, while clinical research may be
19 appropriate, management of patients cannot be currently recommended.^[150,151]

21 **Surgery for post prostatectomy incontinence**

22
23 **6.1 Surgery should be offered after a minimum interval of 6 months following the initial**
24 **prostate surgery. (LE-4, GR-Moderate) Confirm stable patency of any anatomical narrowing**
25 **before offering PPI surgery (Clinical Principle).**

26
27 **6.2 For mild to moderate PPI artificial urinary sphincter (LE-2, GR-Moderate) and slings (LE-**
28 **3, GR-Moderate) are appropriate surgeries.**

29
30 **6.3 For severe PPI artificial urinary sphincter is appropriate. (LE-2, GR-Strong)**

31
32 **6.4 Inform patients that reoperation rates are significant with all the current surgical**
33 **options for PPI. (LE-3, GR-Moderate)**

34
35 **6.5 Bulking agents are appropriate for short term relief in men with mild PPI. (LE-3, GR-**
36 **Weak)**

37
38 After prostatectomy for benign or malignant disease patients may show improvement with
39 conservative treatment up to 2 years^[152] and in most patients, surgery is inappropriate before 6
40 months. Progressive improvement till one year with 6% incontinence rate at 12 months was noted
41 in a series of 52 Indian men following open radical retropubic prostatectomy.^[18]

42
43 While both sphincter and slings are appropriate in patients with mild-moderate PPI data suggests
44 that slings may be associated with lower rate of major complications. Slings should not be offered in
45 patients recurrent PPI following radiation therapy. Infection, erosion, pain and retention are some
46 complications reported and may lead to explantation in upwards of 10%.^[19] Adjustable slings have
47 shown equivalent efficacy. A large multi-institutional study (n=287; mean 31mo follow up; 22%
48 severe PPI) across high volume centers using the ATOMS sling showed a dry rate of 64% with
49 median of 3 adjustments and 20% explantation rate.^[153]

50

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

6 In an online survey of Indian urologists, self-designed synthetic meshes and autologous slings
7 accounted for 10.2% and 1.5% of all PPI surgeries. Such slings have shown acceptable medium
8 term success in non-irradiated patients but results cannot be generalized due to heterogeneity. A
9 small Indian study showed complete continence in four of six patients (follow up 6-22 months)
10 operated using a self-designed polypropylene mesh fixed by retropubic route. Of note, these
11 patients had severe incontinence (6.4 pads/day) for 2.1y before surgery. One patient needed self-
12 catheterization for retention.^[155]
13

14 Detrusor underactivity does not necessarily predict postoperative voiding difficulty following sling
15 surgery as long as post-void residuals are low.^[156] Patients with elevated PVR may fail to void
16 spontaneously following a sling procedure.
17

18 Bulking agents are minimally invasive but have poor long-term efficacy despite multiple
19 sittings.^[157,158] The agent used (bovine collagen, dextranomer hyaluronic acid, silicone
20 macroparticles or others), location of injection (bladder neck or proximal urethra) or the injection
21 technique (periurethral or transurethral) does not seem to materially affect these outcomes.
22 Bulking agents are typically appropriate in men with mild PPI who are unfit or refuse more
23 effective surgery.
24
25

26 **Health care in India with regard to urinary incontinence**

27

28 India has traditionally presented a unique healthcare situation that can be summarized as
29 inadequate public health infrastructure, (resultant) reliance on private health care, low penetration
30 of insurance and a safety net primarily for families of individuals employed in the structured
31 economy (both private and public). The year 2018 marked a watershed when the Indian
32 government launched the ambitious “Ayushman Bharat” program, one of the largest attempts by
33 any country to provide universal healthcare (with caveats) to a large section of its population.^[159]
34

35 Most Indian healthcare plans fail to cover evaluation and treatment of UI that does not lead to a
36 surgical procedure. Since few with UI will require surgery, patients need to fund their evaluation
37 and medical treatment. UI often requires long term therapy and cost can be critical. (Table 2) The
38 “National List of Essential Medicines” subject to price control from the Ministry of Health does not
39 include any drugs used for UI.^[160] Fortunately strong domestic manufacturing and intense
40 competition have kept prices of drugs drastically lower than that in most other countries.
41

42 There is limited literature on the costing of various surgical procedures for UI in India. Low cost
43 surgeries have been performed in India observing principles similar to the MUS with macroporous
44 polypropylene mesh using two distinct approaches. Self-fashioned slings made from polypropylene
45 hernia mesh and use of economical tapes made by Indian manufacturers. Both of these approaches
46 have the potential for significant cost benefits with an estimated cost that is one-fifth to one-sixth of
47 that incurred by using imported mesh kits without any major red flags. A similar low-cost approach
48 for PPI yielded all-inclusive hospital cost equivalent to \$350 in a public hospital.^[155]
49

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

Molecule	Range of cost INR/10 tabs (number of common brands)*	Median cost INR/10 tabs	Frequency per day	Estimated cost INR per month (30 days)	Estimated cost (US\$) per month (30 days)
Oxybutynin 2.5	39-80.85[4]	74.25	3	668	9.4
Oxybutynin ER 2.5	340[1]	340.00	2	2040	28.6
Oxybutynin 5	75-149.6[4]	125.00	3	1125	15.8
Oxybutynin ER 5	144[1]	144.00	2	864	12.1
Oxybutynin ER 10	152.36[1]	152.36	2	914	12.8
Tolterodine 1	35.03-89[4]	55.35	2	332	4.7
Tolterodine 2	65-351.4[8]	91.00	2	546	7.6
Tolterodine ER 2	98.16-146.3[4]	115.00	1	345	4.8
Tolterodine ER 4	65-414.2[12]	162.00	1	486	6.8
Solifenacin 5	163-296[12]	239.00	1	717	10.0
Solifenacin 10	285-417[9]	360.00	1	1080	15.1
Darifenacin 7.5	226.75-339[5]	235.00	1	705	9.9
Darifenacin 15	220-395[5]	347.00	1	1041	14.6
Trospium 20	141.3-198.97[2]	170.14	2	1021	14.3
Trospium ER 60	211.72-263[3]	263.00	1	789	11.1
Propanthelin 15	4-15[2]	9.5	3	86	1.2
Mirabegron 25	192-290[13]	202.50	1	608	8.5
Mirabegron 50	299-390[13]	299.00	1	897	12.6

2
3 Surgical procedures for UI under the newly launched Ayushman Bharat program (that subsumes
4 several state-level health plans) has three surgical packages for stress incontinence under
5 “Urology” with a prescribed tariff of INR 20,000 (\$275), 30,000 (\$412) and 35,000 (\$480) for open,
6 laparoscopic and sling procedures (procedure codes 130-132). Paradoxically, procedure code 4
7 under “Gynecology” lists Burch colposuspension tariff as INR 35,000 (\$480). Apparently, urologists
8 will be reimbursed less than gynecologists for the same procedure! There are no packages
9 mentioned for botulinum toxin, artificial sphincter and bulking agents but there is provision for
10 special permission for such procedures.^[159] Of note, all tariffs include diagnostic investigations,
11 medication, consultation, bed charges as well as meals for the patient. The guidelines panel notes
12 that despite significant innovation hospitals will struggle to deliver on these tariffs.

13
14 **Appendix 1. Search strategy**

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