

Role of Incontinence Severity Index in Evaluating Severity and Impact of Treatment of Stress Urinary Incontinence

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ABSTRACT

Background: Stress urinary incontinence (SUI) is a common ailment in affecting quality of life. This study was performed to see role of incontinence severity index (ISI) in evaluating severity of SUI and to see the impact of treatment of SUI. **Materials and Methods:** A total of 40 women with the diagnosis of SUI on history and clinical examination were enrolled. ISI was calculated on all the women before treatment. All women were treated with either conservative treatment (pelvic floor exercises, life style modification, and duloxetine therapy) (4, 10%) or Burch's colposuspension (18, 45%) or tension-free obturator tape (18, 45%) as per clinical situation after discussion with patients. ISI was again calculated 6 months after treatment. **Results:** Mean age, parity, body mass index in the study were 41.60 years, 2.73, and 24.2 kg/m², respectively. All 40 (100%) patients had SUI with the mean duration of symptoms being 4.04 years. A total of 11 (27.5%) had moderate SUI (ISI 3–6), while 24 (60%) had severe SUI (ISI 8–9), while 5 (12.5%) had very severe SUI (ISI 12). Range of pretreatment ISI was 3–12 with mean being 8.8 ± 3.2. Posttreatment ISI reduced significantly with range of 1–4 and mean of 1.3 ± 0.4 ($P < 0.001$). The reduction was significant for all the groups, but there was no significant difference in efficacy of three treatment groups. Statistical analysis was done using SPSS IBM Version 2-1-0 using Chi-square test, Fisher's Extract test, and ANOVA test as appropriate. **Conclusion:** ISI is a useful modality to evaluate the severity of SUI and to see the impact of treatment modalities on SUI.

KEYWORDS: Burch's colposuspension, conservative treatment, incontinence severity index, stress urinary incontinence, tension-free obturator tape

INTRODUCTION

Urinary incontinence is the involuntary loss of urine which is a social or hygienic problem.^[1,2] Stress urinary incontinence (SUI) is defined as leakage of urine in condition of raised intraabdominal pressure such as coughing, sneezing, laughing, walking, climbing stairs, and sneezing.^[1-3] SUI is the most common type of transurethral urinary incontinence, especially in menopausal and reproductive age group women.^[1,2] The prevalence of SUI is different in different countries but about 26.4% have SUI in the USA, 44% in Europe while in India, 21.8% had urinary incontinence out of which 73.8% had SUI.^[4-6] We have observed a high prevalence of SUI during pregnancy.^[7] The causative factors are advanced age, increasing parity, and obesity,^[1,2] which

thereby causes weakness of pelvic floor structure and cause hypermobility.^[1,2] Childbirth trauma causes injury to pelvic floor as well as to bladder and urethral innervations through stretching and compression of nerves during passage of fetus through the birth canal.^[1,2] SUI is diagnosed from good history taking and clinical examination with demonstration of SUI with Bonney's test and by use of 24 h urine pad test (amount of soakage of pads in 24 h).^[1,2] Urodynamic studies are also useful in the diagnosis of SUI and to rule out

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detrusor overactivity but are not routinely recommended for all cases and need expertise and high cost.^[8,9]

Various quality of life questionnaires have also been devised to see the impact of SUI on quality of life including the International Consultation on Incontinence Questionnaire (ICIQ) Score, Incontinence Severity Index (ISI), and incontinence impact questionnaire with varying results.^[10-12]

ISI is a simple questionnaire with only 2 questions (frequency of urine leakage and its quantity) and calculate the score and categorize patients into slight (score 1–2), moderate (score 3–6), severe (scores 8–9), and very severe (score 12) SUI.^[11]

Treatment of mild-to-moderate SUI can be conservative which includes lifestyle changes, pelvic floor exercises, and duloxetine therapy while it is usually surgery in the form of gold standard Burch's colposuspension or polypropylene tapes including tension-free vaginal tapes or tension-free obturator tapes.^[13-17] Rectus fascial slings have also been used.^[18-20]

In the present study, we calculated ISI score before and after treatment and observed the impact of conservative (medical) and surgical treatment (Burch's colposuspension or tension-free obturator tape) of SUI on the ISI.

MATERIALS AND METHODS

It was a prospective study conducted over 4 years in a tertiary referral center over 40 women between 35 and 65 years of age presenting with SUI who were attending Gynaecology outpatient department and were willing to participate in the study. Women with urge incontinence, overactive bladder, neurogenic bladder or other causes of incontinence, urinary tract infections, 3rd and 4th degree uterovaginal prolapse, women with coexisting factors such as malignancy and who were not willing to participate were excluded from the study. Written informed consent was taken from all the participants. A detailed history of the symptoms, menstrual history, detailed incontinence history, obstetrics history was taken and complete clinical examination was conducted which included general physical examination, per abdomen examination, local examination, per speculum, and vaginal examination. Bonney's test was done in all the cases. As a baseline procedure, all patients were asked to keep a 3 day voiding diary to confirm the diagnosis. Those who were drinking too much water were advised to decrease fluid intake and were not included in the study. All patients were asked about details of urinary leakage and ISI was calculated for all patients as follows;

ISI simple questionnaire with only 2 questions (frequency of urine leakage and its quantity).

- I. How often do you experience urinary leakage? (Please check one)
 1. Never, I do not leak urine
 2. Less than once a month
 3. A few times a month
 4. A few times a week
 5. Every day and/or night
- II. How much urine do you lose each time? (Please check one)
 1. None, I do not leak urine
 2. Drops
 3. Small Splashes
 4. More

ISI Score = 1 × 11

ISI category (circle):

Slight,^[1-2] Moderate,^[3-6] Severe,^[8-9] Very severe.^[12]

ISI was chosen as it is a very simple and inexpensive way of calculating the severity of SUI which has been well validated by previous studies.^[11,12] Furthermore, it can be done even in smaller places without the need of expensive investigations.

Inclusion criteria

Inclusion criteria were 35–65 years age, SUI on history and confirmed by clinical examinations, Bonney's test and voiding diary and those willing to participate in the study.

Exclusion criteria

Exclusion criteria were patients not willing to participate, other types or causes of urinary in continence.

As per policy of our hospital, all patients of SUI were first treated using conservative treatment for 6 weeks like lifestyle changes – reducing weight, drinking less fluids, perineal floor exercises, and taking duloxetine 20 mg once daily. After 6 weeks, they were investigated. Those willing to continue conservative treatment were continued while others were equally randomized into 2 groups, Burch's Colposuspension and Tension-free Obturator tape using computer generated number. All patients were followed up at 3 months and at the end of 6 months. Detailed history was again taken, ISI was again performed on all women at 6 months and impact of treatment of SUI on ISI and symptomatic relief of SUI was calculated again.

Sample size calculation

Using previous studies on the subject and taking alpha and beta error into consideration, a sample size

of 36 samples was calculated. To take care of loss to follow-up, a total of 40 cases were taken into study.

Statistical analysis

Data were computed using Excel spreadsheet. Data analysis was carried out using statistical package SPSS IBM Version 21.0 IBM corporation, ARMONK K, New York, USA, 2012. Descriptive statistics such as mean, standard deviation, and range values were computed with continuous variable. Normality of data was tested using appropriate statistical tests. For the variables which showed approximate to normal distribution, Student's *t* independent test was used to compare mean values of two Groups. For the same group, pre and postvalues were compared with paired *t*-test. Frequency distribution by categories was compared using Chi-square or Fischer exact test as appropriate. To find the correlation between two variable parameters, Pearson's Correlation Coefficient was computed, comparison among subgroups done by ANOVA. For all statistical tests, $P < 0.05$ was considered statistically significant.

RESULTS

The characteristics of the women in the present study are shown in Table 1. Mean age, parity, and body mass index were 41.60 ± 8.43 years, 2.73 ± 1.13 , and 24.2 ± 2.18 kg/m², respectively, with most patients (65%) being from lower socioeconomic status. The symptoms and their duration are shown in Table 2 with all (100%) patients having SUI with mean duration being 4.04 ± 3.58 years. The pretreatment grading of SUI was done as per ISI which is shown in Table 3 with 11 (27.5%) women with moderate SUI, 24 (60%) women with severe SUI, and 5 (12.5%) women with very severe SUI.

Various treatment modalities given to patients are shown in Table 4. Conservative treatment with perineal exercises, life style change, and duloxetine tablets (20 mg once daily) was given to only 4 women with mild SUI. Rest 36 women with moderate and severe SUI underwent surgical procedure as most patients demanded surgery due to failure of conservative treatment after 6 weeks to us. A total of 18 (45%) women underwent Burch's colposuspension operation while another 18 (45%) underwent tension-free obturator tape procedure.

Postoperatively after 6 months of surgery, all patients underwent history taking, clinical examination, Bonney's test, and ISI. The effects of various treatment modalities of SUI on ISI are shown in Table 5. Pretreatment mean ISI was 8.8 ± 3.2 . Mean pretreatment ISI was 4.5 in conservative treatment, 9.2 in Burch's colposuspension group, and 9.0 in tension-free obturator

Table 1: Characteristics of women of stress urinary incontinence (n=40)

Characteristics	n (%)
Age (years)	
Range	30-65
Mean±SD	41.60±8.43
Parity	
Range	0-6
Mean±SD	2.73±1.13
BMI (kg/m ²)	
Range	18.5-31.8
Mean±SD	24.2±2.18
Socioeconomic status	
Lower	26 (65)
Moderate	12 (30)
Upper	2 (5)

SD: Standard deviation, BMI: Body mass index

Table 2: Symptoms and duration of stress urinary incontinence (n=40)

Symptoms	n (%)
Stress urinary incontinence	40 (100)
Duration (years)	
Range	0.6-6.5
Mean±SD	4.04±3.58
Urge incontinence	0

SD: Standard deviation

Table 3: Pretreatment grading of stress urinary incontinence as per incontinence severity index in stress urinary incontinence patients (n=40)

ISI	Grading of SUI	n (%)
1-2	Slight	0
3-6	Moderate	11 (27.5)
8-9	Severe	24 (60)
12	Very severe	5 (12.5)

ISI: Incontinence severity index, SUI: Stress urinary incontinence

Table 4: Treatment of stress urinary incontinence given to patients (n=40)

Treatment given	n (%)
Conservative treatment (Kegel's exercise, lifestyle modification, duloxetine)	4 (10)
Burch's colposuspension	18 (45)
Tension-free obturator tape	18 (45)

tape ($P = 0.04$, significant in conservative versus Burch's colposuspension group and conservative versus tension free obturator tape but was 0.08, not significant between Burch's colposuspension group and Tension free tape-obturator (TVT-Obturator group). There was a significant reduction in ISI after all treatments with mean being 1.3 ± 0.4 ($P < 0.001$, pretreatment versus posttreatment). The mean posttreatment ISI was

Table 5: Effect of various treatment of stress urinary incontinence on incontinence severity index (n=40)

	Pretreatment ISI	Posttreatment ISI	P	Significance
Range	3-12	1-4		
Overall	8.8	1.3	<0.001	S
Standard deviation	3.2	0.4		
	Mean Pretreatment ISI	Mean Posttreatment ISI	P	Significance
Conservative treatment (n=4)	4.5	2.2	0.04	S
Burch's colposuspension (n=18)	9.2	1.1	0.001	HS
Tension free Obturator tape (n=18)	9.0	1.3	0.001	HS

Pretreatment: Conservative versus Burch's: 0.04, significant, Burch's versus TVT-O: 0.08, NS, Posttreatment: Conservative versus Burch's versus TVT-O: 0.18-0.28 (range), NS. TVT-O: Tension-free vaginal tape-obturator, NS: Not significant, S: Significant, HS: Highly significant, ISI: Incontinence severity index

2.2 in conservative treatment group, 1.1 in Burch's colposuspension group, and 1.3 in tension-free obturator tape group ($P = 0.18-0.28$, not significant). Hence, all the three treatments were equally effective modality in significantly reducing the symptoms of SUI.

Both Burch's colposuspension and tension-free obturator tape were equally successful in reducing the ISI from the pretreatment mean ISI of 9.2 to posttreatment mean ISI of 1.1 ($P = 0.001$) in Burch's colposuspension group and from mean ISI of 9 (pretreatment) to 1.3 (posttreatment) ($P = 0.001$) in tension-free obturator tape group. There was no difference in the two groups ($P = 0.18$).

Hence, both Burch's colposuspension and tension-free obturator tape were equally effective in reducing ISI in moderate-to-severe SUI.

DISCUSSION

SUI is defined as the involuntary leakage of urine with raised intraabdominal pressure such as coughing and sneezing and is a social and hygienic problem.^[1,2] Its prevalence varies from 21% to 44% in different countries.^[4,6] The predisposing factors are repeated childbirth, obesity, smoking, chronic obstructive pulmonary disease, and chronic constipation.^[1-4] The diagnosis of SUI is made from the history of SUI and clinical examination of patient in dorsal position with full bladder when on coughing leakage of urine can be observed and a Bonney's test can also be done.^[1] Urodynamics can help but are mainly useful to rule out detrusor overactivity and are expensive and not routinely available in all hospitals and are not recommended for all patients.^[1,8,9]

Various questionnaires such as ICIQ Score, ISI, and Incontinence Impact Questionnaire have been used and validated in many countries with robust results.^[10-12] ISI is a very simple questionnaire with only two questions about frequency and quantity of urinary leakage and can stage the SUI into slight (score 1-2), moderate (score

3-6), severe (score 8-9), and very severe (score 12) SUI. It can be used before and after treatment of SUI and can detect the impact of medical or surgical treatment on urinary incontinence.^[11]

In the present study, ISI was calculated on all 40 women of SUI before treatment. We observed a range of ISI of 3-12 with mean score of 8.8 ± 3.2 before treatment being 4.5 in conservative (medical treatment group), 9.2 in Burch's colposuspension group, and 9.0 in tension-free obturator tape group. Out of 40 patients, 4 (10%) patients underwent conservative treatment (pelvic floor exercises, life style changes, and duloxetine therapy) while 18 (45%) patients underwent open Burch's colposuspension and another 18 (45%) underwent tension-free obturator tape operation. 6-month posttreatment ISI was calculated on all patients. There was a significant decrease in ISI in all the patients with treatment with range of 1-4 and mean of 1.3 ± 0.4 ($P < 0.001$). Although the decrease was more (mean 1.1) in Burch's colposuspension group and tension-free obturator tape group (mean score 1.3) than in conservative treatment group (mean score 2.2), the difference in three groups was not significantly different (p range 0.18-0.28). Thus, all three treatments were effective in improving quality of life and reducing frequency and quantity of urinary leakage in SUI.

We observed ISI to be a very easy and relatively accurate method to grade the SUI before and after treatment and very cost effective and can be easily done even at small peripheral hospitals in contrast to urodynamic studies which are expensive and not easily available.^[1,8,9] Our results are similar to Elks *et al.*^[21] who also used ISI in their study on women with SUI in two groups of women either using CrossFit classes or not using CrossFit classes. They observed slight incontinence in 44% cases, moderate incontinence in 38% cases, and severe incontinence in just 2% cases on ISI in their study in contrast to 27.5%, 60%, and 12.5% in our study. Yang *et al.*^[22] from California, USA, also

used ISI to assess the efficacy of high impact CrossFit exercises on SUI. They observed prevalence of mild SUI in 64% cases, moderate SUI in 13.25% cases, and severe SUI in 22.64% cases using ISI and observed ISI to be useful in evaluating women with SUI. Sandvik *et al.*^[23] validated severity index in female urinary incontinence and observed it to be useful in the evaluation of SUI. They observed prevalence of mild, moderate, and severe SUI to be 47%, 27%, and 27%, respectively, in contrast to 27.5%, 60%, and 12.5%, respectively, in our study. Murphy *et al.*^[24] also found ISI to be highly valid in the evaluation of SUI and observed it to be highly correlated with (Urogenital Distress Inventory -6) and concluded that ISI is a useful modality to evaluate SUI, an observation similar to us.

Treatment of SUI can be conservative in the form of pelvic floor exercises (Kegel's exercises), life style changes, and duloxetine therapy which should be the first-line treatment and should be tried for at least 3 months before planning surgical treatment.^[13] However, most patients of SUI, especially with moderate to severe and very severe SUI, usually require surgery for successful amelioration of symptoms.^[1,2] The gold standard in treatment is Burch's colposuspension in which vagina at bladder neck is suspended to ipsilateral Cooper's ligaments through laparoscopy or laparotomy.^[1,2,14] It has very high success rate of 85%–90% but is a major operation and needs expertise and can cause *de novo* detrusor instability.^[14] Tension-free vaginal tape and obturator tapes are made up of polypropylene mesh and are minimally invasive, short procedures with high success rate.^[15-17] However, due to cases of mesh erosion and adverse publicity and their nonavailability in some countries, natural rectus fascial slings are becoming popular.^[18-20,25,26] However, rectus fascial sling is a bigger operation than artificial tape and is associated with larger operation time and increased immediate morbidity.^[18-20] Large systemic review and meta-analysis and of surgical treatment of SUI found Burch's colposuspension, rectus fascia sling, and tension-free tapes to be equally effective and safe.^[27] Other large studies also found the tapes and other treatments effective.^[28,29] However, mesh erosion is seen with artificial tapes, though the incidence is very low.^[17,25,30]

The strength of the study are use of validated ISI, a tool for evaluation of SUI in Indian condition on confirmed cases of SUI and to evaluate the impact of medical and surgical treatment on ISI. All patients were first given 6 weeks course of conservative treatment and then were given surgical treatment. The limitations of the study are lesser number of cases, inability to perform

Urodynamic studies to confirm diagnosis of SUI, shorter follow up and inclusion of mild, moderate, and severe SUI which may need different treatment and are often not comparable.

CONCLUSION

ISI appears to be useful in evaluating severity of SUI and to assess the impact of treatment of SUI. However, larger Indian studies are recommended to validate ISI in India before its routine use.

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Conflicts of interest

There are no conflicts of interest.

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