ORIGINAL RESEARCH
Functional Urology

Doi: 10.4274/jus.galenos.2024.2024-10-9
J Urol Surg 2025;12(1):34-39

The Role of the Incontinence Severity Index in the Treatment of Stress Urinary Incontinence

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What's known on the subject? and What does the study add?

Urinary incontinence symptoms are quite common among women. It has a significant impact on quality of life and creates financial burdens on both personal and social levels. Stress urinary incontinence (SUI) is considered the most common type of transurethral urinary incontinence, especially in women of menopausal and reproductive age. Various quality of life questionnaires, such as the International Incontinence Consultation Questionnaire, the incontinence severity index (ISI), and the Incontinence Impact Questionnaire, have been developed to assess the impact of SUI on quality of life, but their results may vary. We believe that evaluating the effects of medical and surgical treatment of SUI on the ISI will offer valuable insights in monitoring the diagnosis and treatment response.

Abstract

Objective: To evaluate the effects of medical and surgical treatment of stress urinary incontinence (SUI) on incontinence severity index (ISI).

Materials and Methods: In our study, 64 patients aged 30-60 years, who were admitted to our hospital with symptoms of SUI between 2018 and 2023, underwent medical or surgical treatment for SUI, and met the inclusion criteria, were included. Women included in the study were divided into three groups: those who received medical treatment, those who underwent Burch colposuspension, and those who received tension-free obturator tape (TOT).

Results: When ISI measurements were categorized between the groups in the pre-treatment period, it was found that the rate of patients with slight and moderate SUI was significantly higher in the medical treatment group (p=0.018 and p=0.044, respectively). The rate of patients with severe SUI was found to be significantly lower in the medical treatment group (p=0.032). When the groups were evaluated individually, the post-treatment ISI score was found to be significantly lower than the pre-treatment ISI score in all groups (p<0.001). The difference between pre-treatment and post-treatment ISI scores (ΔISI) was found to be significantly higher in the TOT group and Burch colposuspension group compared to the medical treatment group (p<0.001).

Conclusion: ISI is useful in assessing the severity of incontinence in patients with SUI and the effectiveness of treatment after treatment. For ISI to be widely used as an alternative, prospective use with a larger number of patients and longer follow-up periods is needed.

Keywords: TOT, Burch colposuspension, incontinence severity index, stress urinary incontinence

Introduction

Urinary incontinence symptoms are quite common among women. It has a significant impact on quality of life and creates personal and social financial burdens. Urinary incontinence is evaluated in two groups (1). Stress urinary incontinence (SUI) is defined as the involuntary loss of urine during situations where bladder pressure exceeds the pressure at which the urethra can remain closed, and when intra-abdominal pressure is increased (e.g., coughing) (2). SUI is considered the most common type of urinary incontinence, especially in women of menopausal and reproductive age (3). The prevalence of SUI has a wide spectrum, ranging from 4% to 35% in the literature. Although the clinical definition of SUI has been established by the International

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Received: 23.10.2024 **Accepted:** 25.11.2024 **Publication Date:** 21.02.2025

Cite this article as: Öztürk B, Atlıhan U. The role of the incontinence severity index in the treatment of stress urinary incontinence. J Urol Surg. 2025;12(1):34-39.

Continence Society, its epidemiologic definition remains undefined, resulting in variable reported prevalence rates (4).

The occurrence and progression of SUI are associated with age, overweight, diabetes, and obstetric trauma (5). In addition, vaginal births, menopause, and hormone therapy are known to affect functionality at the lower urethral level (6). The multifactorial risk of SUI is evident, with different criteria shown to have a very complex effect on its development (7-9). Although urodynamic studies are useful in diagnosing SUI and excluding detrusor overactivity, they are not routinely recommended for all cases. They require expertise and have cost-related disadvantages (10-13). In patients with uncomplicated SUI, preoperative urodynamic evaluation has not been shown to improve the outcome of continence surgery. However, urodynamic testing provides additional information about lower urinary tract function that can guide physicians in making the right treatment choice (14,15).

Various quality of life questionnaires, such as the International Incontinence Consultation Questionnaire score, the incontinence severity index (ISI), and the Incontinence Impact Questionnaire, have been developed to assess the impact of SUI on quality of life, but their results may vary (16-18). ISI is a simple questionnaire with only two questions (frequency of urine leakage and its quantity). Its score is calculated, and patients are categorized as having slight (score 1-2), moderate (score 3-7), severe (score 8-9), and very severe (score 12) SUI (19). Although there are approaches that include treatment of mild-to-moderate SUI, lifestyle changes, pelvic floor exercises, and duloxetine therapy, surgical options are recommended as the gold standard of treatment, with Burch colposuspension or tension-free vaginal tapes or polypropylene tapes, including tension-free obturator tapes (TOT) (20-23). In addition, rectus fascial slings are used in the treatment of SUI (24). The aim of our study was to evaluate the effects of medical and surgical treatment of SUI on ISI scores.

Materials and Methods

This study was designed as a retrospective observational study. The study was initiated after receiving ethics committee approval (date: 09.10.2024, approval number: KA-24/338 - Başkent University Rectorate Medicine and Health Sciences Research Board) from the hospital. The study was designed according to the Helsinki Declaration, and informed consent was obtained from all patients.

In our study, 64 patients aged 30-60 years who were admitted to our hospital with symptoms of SUI between 2018 and 2023, who underwent medical or surgical treatment for SUI, and who met the inclusion criteria were included. Women included in the study were divided into three groups based on the type of treatment received: medical treatment, Burch colposuspension, and TOT. Patients in the medical treatment group were those who did not opt for surgical options. Pre-treatment and post-treatment ISI scores of all patients were compared. ISI scores of all patients were compared between groups according to treatment type. Women with urge urinary incontinence, overactive bladder diagnosis, neurogenic bladder diagnosis, other causes of incontinence, active urinary tract infection, total uterovaginal prolapse, and malignancy were excluded from the study.

Incontinence history, obstetric history, physical examination, and gynecologic examination findings of all patients were retrospectively reviewed from patient files. All patients suspected of having stress incontinence were questioned about their Bonney test results. ISI scores of all patients who were diagnosed as having stress incontinence and therefore started on medical treatment or underwent surgery were evaluated.

The ISI questionnaire seeks answers to two questions, asking how often patients experience urinary incontinence and how much urine they lose each time (19). In the ISI scoring, severity levels are defined as mild, moderate, severe, and very severe (19). ISI scoring was chosen because it is easy to apply and positive results regarding its effectiveness have been reported in previous studies. Inclusion criteria for the study were defined as being aged 30-60 years, having SUI confirmed through clinical examinations, Bonney tests, and voiding diaries. All patients diagnosed as having SUI and requesting medical treatment were advised to consume less fluids, lose weight, and do pelvic floor exercises, along with taking 20 mg duloxetine daily. Patients requesting surgery were subjected to Burch colposuspension or TOT after detailed evaluations. Routine examination records of all patients were reviewed at the end of the 3rd month and the 6th month. ISI scores of all patients at the end of the 6th month were evaluated retrospectively from the hospital database for each group.

Statistical Analysis

Statistical analysis was conducted using the SPSS 26.0 software package, (IBM Inc., Chicago, IL, USA). Descriptive statistics such as mean, standard deviation, and range values were computed from continuous variables. The normality of the data distribution was evaluated using the Kolmogorov-Smirnov and the Shapiro-Wilk tests. For the variables that showed approximately normal distribution, the independent Student's t-test was used to compare mean values of two groups. For the same group, pre- and post-values were compared using the paired t-test. Fisher's exact and chi-square tests were used in the categorical data analysis. To find correlations between two variable parameters, Pearson's correlation coefficient was

computed, and comparisons among subgroups were performed using analysis of variance.

Results

The mean age of the women included in the study was 40.25±9.64 years, and the mean body mass index score was 25.1±4.46 kg/m^2. The mean parity of the women was 2.16±1.18, and the mean gravidity was 2.81±1.34. Of the women included in the study, 30 (46.8%) were smokers and 40 (62.5%) were university graduates. No significant difference was found between the groups in terms of demographic characteristics (Table 1).

When ISI measurements were categorized in the pre-treatment period, it was found that the rate of patients with slight and moderate SUI was significantly higher in the medical treatment group (p=0.018 and p=0.044, respectively). The rate of patients with severe SUI was found to be significantly lower in the medical treatment group (p=0.032) (Table 2).

The overall pre-treatment ISI score of all participants was 7.78±2.86. The mean pre-treatment ISI score was 5.50±1.32 in the medical treatment group, 9.04±1.88 in the TOT group, and 8.38±1.76 in the Burch colposuspension group, with the medical treatment group having a significantly lower score (p<0.001). No significant difference was observed between the pre-treatment ISI scores of the TOT and Burch colposuspension groups (p>0.05). The mean post-treatment ISI score was 2.11±0.78. The mean post-treatment ISI score was 2.26±0.88 in the medical treatment group, 2.09±0.76 in the TOT group, and 2.05±0.79 in the Burch colposuspension group. No significant difference was observed between the groups (p=0.68). When the groups were evaluated within themselves, the post-treatment ISI score was found to be significantly lower than the pre-treatment ISI score in all groups (p<0.001). The difference between pre-treatment and post-treatment ISI score (ΔISI) in the TOT group and Burch colposuspension group was found to be significantly higher than in the medical treatment group (p<0.001) (Table 3).

Discussion

In our study, ISI scores were evaluated before and after treatment in different treatment modalities. A significant decrease in ISI scores was observed in all treatment groups compared with the pre-treatment period. However, when the patients in the surgical group were evaluated among themselves, no significant difference was found in terms of treatment response between the surgical methods.

Although the ISI score also decreased significantly in the medical treatment group in the post-treatment period, a more limited decrease was observed in ΔISI scores compared with the surgical groups. The ISI scoring system is important in evaluating the presence and severity of SUI before and after treatment because it is very cost-effective and can be easily performed even in small hospitals, unlike high-cost urodynamic studies (12,13).

Table 1. Comparison of demographic characteristics of participants

	All patients (n=64)	Medical treatment (n=22)	Tension-free obturator tape (n=21)	Burch colposuspension (n=21)	p-value
	Mean ± standard deviation				
Age (year)	40.25±9.64	40.1±9.76	39.95±9.52	40.42±9.68	0.78
Body mass index (kg/m^2)	25.1±4.46	25.2±4.62	25.3±4.36	24.9±4.51	0.28
Gravidity	2.81±1.34	2.76±1.30	2.86±1.38	2.82±1.37	0.42
Parity	2.16±1.18	2.12±1.22	2.19±1.16	2.13±1.19	0.56
Smoking n (%)	30 (46.8%)	10 (45.4%)	11 (52.3%)	9 (42.8%)	0.18
Education n (%)					
High school	24 (37.5%)	9 (40.9%)	8 (38%)	7 (33%)	0.11
University	40 (62.5%)	13 (59.1%)	13 (62%)	14 (67%)	

Table 2. Evaluation of pre-treatment incontinence severity index scores according to groups in patients with stress urinary incontinence

Incontinence severity index	All patients n (%)	Medical treatment n (%)	Tension-free obturator tape n (%)	Burch colposuspension n (%)	p-value
Slight (1-2)	2 (3.1%)	2 (9.1%)	-	-	0.018
Moderate (3-6)	18 (28.2%)	7 (31.9%)	5 (23.9%)	6 (28.6%)	0.044
Severe (8-9)	34 (53.1%)	10 (45.4%)	12 (57.1%)	12 (57.1%)	0.032
Very severe (12)	10 (15.6%)	3 (13.6%)	4 (19%)	3 (14.3%)	0.066

Table 3. Comparison of incontinence severity index scores within and between groups				
	Pre-treatment incontinence severity index score	Post-treatment incontinence severity index score	ΔISI score	p-value
	Mean ± standard deviation			
All patients	7.78±2.86	2.11±0.78	5.67±1.33	<0.001
Medical treatment	5.50±1.32	2.26±0.88	2.24±0.84	<0.001
Tension-free obturator tape	9.04±1.88	2.09±0.76	6.95±1.54	<0.001
Burch colposuspension	8.38±1.76	2.05±0.79	6.33±1.46	<0.001
p-value	<0.001	0.68	<0.001	
ISI: Incontinence severity index				

When all treatment modalities were evaluated in our study, there were two (3.1%) patients in the slight group, 18 (28.2%) patients in the moderate group, 34 (53.1%) patients in the severe group, and 10 (15.6%) patients in the very severe group. In the study conducted by Nygaard et al. (25), when ISI categories were evaluated, 9.2% were observed in the slight group, 37.8% in the moderate group, 64.6% in the severe group, and 85.3% in the very severe group. In evaluations made using ISI in women with SUI, mild incontinence was found at a rate of 64%, moderate incontinence was 13.25%, and severe incontinence was 22.75% (26). In the literature, a wide spectrum of results has been revealed in ISI assessments used for the evaluation of SUI. This difference in data may have occurred due to the different demographic and obstetric histories of the patients depending on the study inclusion criteria.

The review by Rodrigues-Amorim et al. (27) provided substantial evidence supporting duloxetine in the treatment of SUI. In the study conducted by Jost and Marsalek (28) duloxetine was shown to be effective in reducing incontinence attacks and improving quality of life in women with SUI. In our study, a significant decrease in the severity of incontinence was found in women with SUI who used duloxetine, consistent with the literature. In addition, the positive results of the treatment were clearly demonstrated in ISI evaluations, which was the main criterion of our study.

In the study conducted by Frick et al. (29), a significant improvement was found in ISI results in women who underwent TOT surgery for SUI in the post-treatment period. Therefore, it was stated that it could be preferred as the primary outcome measure in the evaluation of SUI treatment. Ye et al. (30) showed that Burch colposuspension was an effective procedure for SUI and the therapeutic effect was largely maintained during the long follow-up period. Similarly, in our study, significant improvement in incontinence symptoms was found in patients who underwent Burch colposuspension for SUI; the findings were confirmed by ISI evaluations.

To our knowledge, our study is the first in the literature to compare TOT surgery, Burch colposuspension surgery, and medical treatment through ISI evaluations between comparably sized patient populations. Surgery is generally preferred for successful improvement of symptoms in patients with moderate-to-severe SUI (3). Serati et al. (31) stated that "the best surgery includes retropubic urethropexy (Burch colposuspension) and pubovaginal slings". They were dismissive of midurethral slings, saying that they played a marginal and almost experimental role in the field However, there are studies in the literature evaluating the effectiveness of the Burch colposuspension and TOT operations, referring to the positive aspects of both methods (32-35). In our study, no significant difference was found in terms of the effect of TOT and Burch colposuspension surgeries on ISI measurements.

Study Limitations

The main limitation of our study is that it is retrospective, and only the data from the 6th month post-treatment of all patients in the medical and surgical treatment groups are available. Another limitation is that the data on the long-term effectiveness of the treatment methods, both individually and in comparison, with each other, have not yet been obtained. The strength of our study is that it is one of the few studies performing three different methods using equal numbers of patients, evaluating ISI scores. The evaluation of the effect of medical and surgical treatment on ISI can be considered another strength.

Conclusion

ISI is useful in assessing the severity of incontinence in patients with SUI and the effectiveness of treatment after SUI treatment. Considering the cost and difficulties in the applicability of urodynamic tests, prospective studies with larger patient numbers and longer follow-up periods are needed for ISI to be widely used as an alternative.

Ethics

Ethics Committee Approval: The study was initiated after receiving ethics committee approval (date: 09.10.2024, approval

number: KA-24/338 - Başkent University Rectorate Medicine and Health Sciences Research Board) from the hospital.

Informed Consent: Informed consent was obtained from all patients.

Footnotes

Authorship Contributions

Surgical and Medical Practices: B.Ö., Concept: U.A., Design: B.Ö., Data Collection or Processing: U.A., Analysis or Interpretation: B.Ö., Literature Search: U.A., Writing: B.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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