Clinical and Experimental Obstetrics & Gynecology

Clin. Exp. Obstet. Gynecol. **2022**; 49(9): 193
https://doi.org/10.31083/j.ceog4909193

Original Research

The Effects of Suburethral Tension Adjustable Sling (Remeex system) for Female Urinary Incontinence between Pure Intrinsic Sphincter Deficiency and Intrinsic Sphincter Deficiency with Overactive Bladder: Initial Experience with Propensity Score Matching

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Academic Editor: Ambrogio Pietro Londero
Submitted: 4 March 2022 Revised: 25 April 2022 Accepted: 26 April 2022 Published: 24 August 2022

Abstract

Objective: To compare the therapeutic efficacy after suburethral adjustable sling (Remeex system) for female stress urinary incontinence (SUI) between pure intrinsic s phincter deficiency (ISD) and ISD with overactive bladder (OAB) group. **Methods**: The study subjects were 86 female patients with ISD who underwent Remeex system to treat female SUI and who were available for 12 months follow-up. We retrospectively studied both patients who underwent Remeex system due to pure ISD (group I) and those who underwent Remeex system due to ISD with OAB (group II). Improvement in objective and subjective symptoms were retrospectively evaluated using a 1hr pad weight test, global response assessment (GRA) and overactive bladder symptom score (OABSS). **Results**: Group I included 43 patients and group II included 43 patients of mean ages 56.8 $\pm$ 7.5 and 57.4 $\pm$ 6.6 years, respectively. Use of 1 hr pad weight test showed that incontinence decreased after the procedures in both groups, and that of group I patients was significantly lower than that of group II patients. The mean GRA score was significant a higher score in group I. The OABSS of patients in group II were 8.2 $\pm$ 1.1 and 7.2 $\pm$ 1.1, respectively, before and at 12 months after operation, did differ significantly. The mean change of OABSS of group II patients was significantly more decreased than that of group I patients. **Conclusions**: The Remeex system showed a greater patient satisfaction and a higher cure rate in pure ISD than ISD with OAB in female patients with urinary incontinence.

Keywords: suburethral slings; urinary incontinence; urinary sphincter; overactive bladder; female

1. Introduction

A tension-free midurethral sling procedure, via the retropubic or transobturator pathway, is the standard surgical treatment for stress urinary incontinence (SUI). However, the majority of these procedures are less effective for the treatment of SUI due to intrinsic sphincter deficiency (ISD) [1]. Guerette *et al*. [2] reported that the surgical failure rate is 4–6 times higher in patients with ISD than in those with normal urethral function.

Compared with the tension-free midurethral sling, the suburethral tension-adjustable sling (Remeex system) is less invasive and has a higher surgical success rate in patients with ISD. In their study with 125 patients and a mean follow-up of 38 months, Errando *et al*. [3] reported that 109 patients (87%) treated with the Remeex procedure were cured based on the results of a 1-hr pad weight test and urodynamic criteria. However, some patients in that study reported less satisfaction, due to persistent urgency symptoms and urgency urinary incontinence. Additionally, the tension-free midurethral sling procedure led to lower surgical success rates and patient treatment satisfaction among patients with mixed urinary incontinence (MUI) accompanied by urgency urinary incontinence than among those with pure SUI [4]. However, a comparison with the Remeex system has yet to be reported.

Overactive bladder (OAB) has been defined as urgency, with or without urge incontinence, usually with frequency and nocturia [5]. Although ISD is addressed by the Remeex system, treatment may be less effective in patients with ISD accompanied by OAB due to the symptoms of urgency, urge incontinence, etc. Thus, this study investigated the differences in treatment efficacy and patient satisfaction in patients with or without OAB accompanied by urgency and urgency urinary incontinence in female patients with urinary incontinence due to ISD.

2. Materials and Methods

2.1 Patients

From January 2012 to January 2015, 158 patients underwent Remeex system implantation for SUI due to ISD at three different university hospitals. From this group, 131 patients were included in this retrospective analysis. Patients who underwent previous anti-incontinence surgery, those who had urethral hypermobility demonstrated by the Q-tip test, and those who received conservative treatments, such as anticholinergic medication, before or after surgery were excluded from the study.

The preoperative evaluation consisted of a medical history, routine laboratory tests, physical examination, rigid cystoscopy, multichannel urodynamic study, Q-tip test, 1-hr pad test, and overactive bladder symptom score (OABSS).

All patients had urodynamically proven SUI with ISD. The latter was defined as a maximal urethral closure pressure and abdominal leak point pressure of $<$20 cm H20 and $<$60 cm H20, respectively.

Patients in group I were those with pure ISD, an OABSS $<$3 at the preoperative evaluation, and no evidence of a urinary tract infection or other obvious pathology. Group II patients had SUI and an OABSS $>$3, i.e., urinary urgency, usually accompanied by frequency and nocturia, with or without urinary urgency incontinence.

2.2 Surgical Procedure

The patients received general anesthesia and were positioned in the dorsal lithotomy position. An 18 French Foley catheter was passed and inflated. An incision was made in the anterior vaginal wall from the mid urethra to the urethrovesical junction for about 2 cm and dissected from the underlying tissues. In the region superior to the pubic symphysis, a 3- to 4-cm incision was made in the transverse direction and the fascia of the rectus muscles was exposed. Traction needles (threads) were inserted to pass two non-absorbable prolene sutures through the retropubic space from the anterior vaginal wall through the rectus fascia of the abdominal incision. Cystoscopy was performed to ensure the absence of bladder perforation. The threads passing the inferior abdominal line penetrated the varitensor bilaterally. The varitensor was positioned and then fixed 10 cm above the fascia of the abdominal rectus. The manipulator was rotated clockwise until the varitensor was positioned at a distance of approximately two fingertips (~3 cm) above the rectus fascia. The anterior vaginal wall and the inferior abdominal area were sutured using general methods.

The day after surgery, the bladder was filled with 300 mL of normal saline and the Foley catheter was removed. The patient was asked to cough in a standing position in order to allow the sling support to be adjusted with the manipulator until there was no leakage. The amount of residual urine was measured: if the amount was $>$100 mL, the manipulator was adjusted to decrease the tension of the sling; if the amount was $<$100 mL, the manipulator was disconnected from the varitensor.

2.3 Postoperative Management and Evaluation

A follow-up examination consisting of a medical history, physical examination with stress tests, and abdominal ultrasonography for the evaluation of postvoiding residual urine was performed 1–2 weeks after surgery and then every 3 months thereafter on an outpatient basis. At 12 months after surgery, a 1-hr pad test was performed in all patients. Changes in incontinence before and after surgery and in OAB symptoms based on the preoperative and 12-month postoperative OABSS were compared in groups I and II. Treatment satisfaction after surgery was also assessed and compared in the two groups based on the results of a Global Response Assessment (GRA) test conducted 12 months after surgery. The OABSS consists of four questions. OABSS1 is frequency, OABSS2 is nocturia, OABSS3 is urgency, and OABSS4 is urge incontinence. The sum of the scores for each item is OABSS-T. If OABSS1 is 2 or more and OABSS-T is 3 or more, it is possible to diagnose as OAB. According to the severity, a score of less than 5 is defined as mild, a score of 6 to 11 is defined as moderate, and a score of 12 or more is defined as severe. A GRA symptom score of –3 indicated markedly worse, –2 moderately worse, –1 slightly worse, 0 no change, 1 slightly improved, 2 moderately improved, and 3 markedly improved. A score $\geq$1 indicated symptom improvement.

2.4 Statistical Analysis

The characteristics of the two study groups as determined by the GRA at 12 months postoperatively are reported as the frequency (percentage), and the results for the other variables as the mean $\pm$ standard deviation. Before the two groups were compared, propensity score matching (PSM) was performed to minimize the effect of potential confounders on selection bias between the ISD patients with or without OAB. PSM accounted for the baseline characteristics including age, body mass index (BMI), parity, and the result of the Q-tip test. One-to-one matching was accomplished by the nearest-neighbor matching method. Data from the two groups were compared using Student's *t*-test or the Mann-Whitney U-test for continuous variables after normality and variance-equivalence were tested using the Shapiro-Wilk test and Levene's test, respectively. The GRA scores of the two groups at 12 months postoperatively were compared using Mantel-Haenszel's linear trend test. All statistical analyses were conducted using R (version 3.1.3, The R Foundation for Statistical Computing, Vienna, Austria). A p-value < 0.05 was considered to indicate statistical significance.

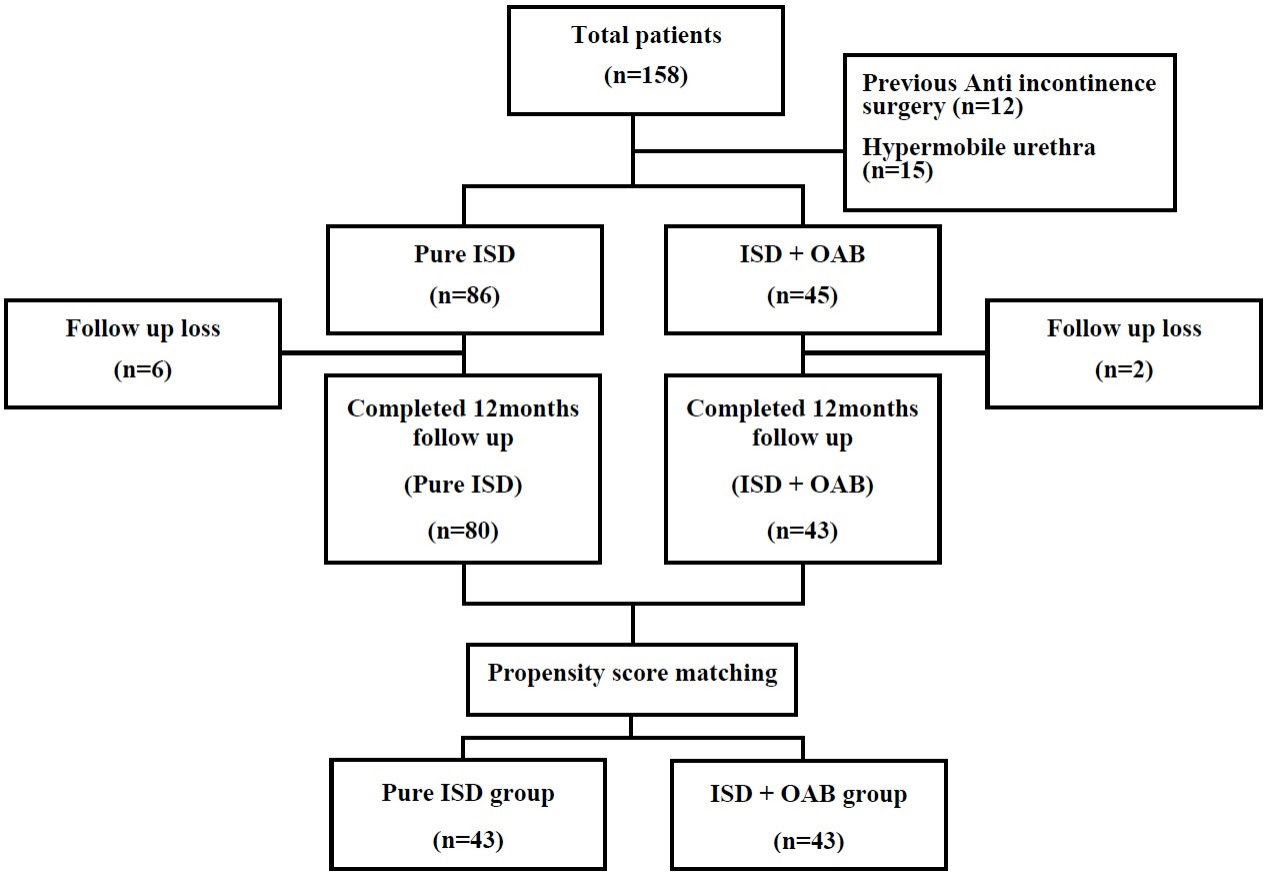


Fig. 1. Consolidated standards of reporting trials diagram.

3. Results

Among the 131 patients, 86 had pure ISD and 45 had ISD with OAB. Six patients with pure ISD and two patient with ISD and OAB were excluded from the study due to follow-up loss. PSM was then performed for 123 patients: 80 patients with pure ISD and 43 patients with ISD and OAB (Fig. 1).

After PSM, each group included 43 patients, and thus no significant loss of group II patients after matching. The mean age of group I and group II patients was 56.8 $\pm$ 7.5 and 57.4 $\pm$ 6.6 years, respectively, and the mean BMI was 29.7 $\pm$ 36 and 28.6 $\pm$ 5.3 kg/m^2, respectively. The differences in age and BMI between the two groups were not significant. Parity in groups I and II (2.6 $\pm$ 0.8 and 2.5 $\pm$ 0.7, respectively) also did not differ significantly ($p = 0.81$; Table 1). The results of the Q-tip test in groups I and II were 14.7 $\pm$ 4.5 and 15.3 $\pm$ 3.8, respectively, thus indicating a fixed urethra in both. Among the urodynamic parameters, the maximal urethral closure pressure was 15.4 $\pm$ 2.5 cmH20 in group I and 16.2 $\pm$ 3.5 cmH20 in group II and the abdominal leak point pressures were 41.4 $\pm$ 10.7 and 42.7 $\pm$ 11.8 cmH20, respectively, with no significant difference between groups. Detrusor overactivity in group I and group II patients was 0 (0%) and 10 (23.3%), respectively. The OABSS was significantly higher ($p < 0.001$) in group II (8.2 $\pm$ 1.1) than in group I (1.1 $\pm$ 0.8) patients (Table 1).

Comparison of the results of the 1-hr pad weight test preoperatively and 12 months postoperatively revealed significant decreases in group I and group II, from 40.1 $\pm$ 9.1 g to 1.5 $\pm$ 3.1 g and from 37.5 $\pm$ 11.5 g to 8.0 $\pm$ 10.3 g, respectively. The preoperative difference between the two groups was not significant, but at 12 months postoperatively the 1-hr pad weight test of group I patients was significantly ($p = 0.008$) lower than that of group II. There was also a significant difference in the amount of change in the 1-hr pad weigtht test before and after surgery ($p = 0.01$) (Table 2).

The mean GRA score for group I patients 12 months after surgery was 2.2 $\pm$ 1.0. The score distribution was as follows: a score of 1 was assigned to 3 patients (7%), a score of 2 to 14 patients (33%), and a score of 3 to 21 patients (49%). The overall improvement rate of group I was 88% (38 of 43 patients). The mean GRA score for group II patients 12 months after surgery was 1.2 $\pm$ 1.7, with the following distribution: a score of 1 was assigned to 5 patients (12%), a score of 2 to 9 patients (21%), and a score of 3 to 14 patients (33%). The improvement rate of group II was 65% (28 of 43 patients). The mean GRA scores of group I and group II patients 12 months after surgery differed significantly ($p = 0.048$), and were higher in group I (Table 2).

Table 1. Baseline characteristics per group.

Variable	Before matching			After matching		
	ISD	ISD with OAB		ISD	ISD with OAB	
	(N = 80)	(N = 43)	*p*-value	(N = 43)	(N = 43)	*p*-value
Age (year)	55.7 ± 8.2	57.4 ± 5.6	0.374	56.8 ± 7.5	57.4 ± 6.6	0.77
BMI (kg/m^2)	30.5 ± 4.7	28.6 ± 5.3	0.133	29.7 ± 3.6	28.6 ± 5.3	0.535
Parity	2.8 ± 0.8	2.5 ± 0.7	0.269	2.6 ± 0.8	2.5 ± 0.7	0.81
Q-tip test	14.3 ± 4.2	15.3 ± 3.8	0.23	14.7 ± 4.5	15.3 ± 3.8	0.597
Urodynamic parameters						
MUCP (cmH20)	14.9 ± 2.9	16.2 ± 3.5	0.092	15.4 ± 2.5	16.2 ± 3.5	0.438
ALPP (cmH20)	39.5 ± 13.2	42.7 ± 11.8	0.178	41.4 ± 10.7	42.7 ± 11.8	0.623
DO	0/80 (0%)	10/43 (23.3%)		0/43 (0%)	10/43 (23.3%)	
OABSS Total	1.1 ± 0.7	8.2 ± 1.1	<**0.001**	1.1 ± 0.8	8.2 ± 1.1	<**0.001**

ISD, intrinsic sphincter deficiency; OAB, overactive bladder; BMI, body mass index; MUCP, maximal urethral closure pressure; ALPP, Abdominal leak point pressure; OABSS, overactive bladder symptom score; DO, detrusor overactivity. Data were presented as mean ± standard deviation. *p*-values were calcuated by Student's *t*-test or Mann-Whitney U test.

Table 2. Outcomes of the Remeex in patients with ISD divided by OAB (After matching).

Variable	ISD	ISD with OAB	Comparison
	(N = 43)	(N = 43)	(*p*-value)
1 hr pad weight test (g)			
Pre	40.1 ± 9.1	37.5 ± 11.5	0.38
Post	1.5 ± 3.1	8.0 ± 10.3	**0.008**
Δ (Post–Pre)	–38.6 ± 9.0***	–29.4 ± 14.2***	**0.01**
GRA at 12 months	2.2 ± 1.0	1.2 ± 1.7	**0.048**
OABSS Total			
Pre	1.1 ± 0.8	8.2 ± 1.1	<**0.001**
Post	0.8 ± 0.6	7.2 ± 1.1	<**0.001**
Δ (Post–Pre)	–0.3 ± 0.7	–1.1 ± 1.2***	**0.009**
p for (pre vs. post)	0.138	<**0.001**	

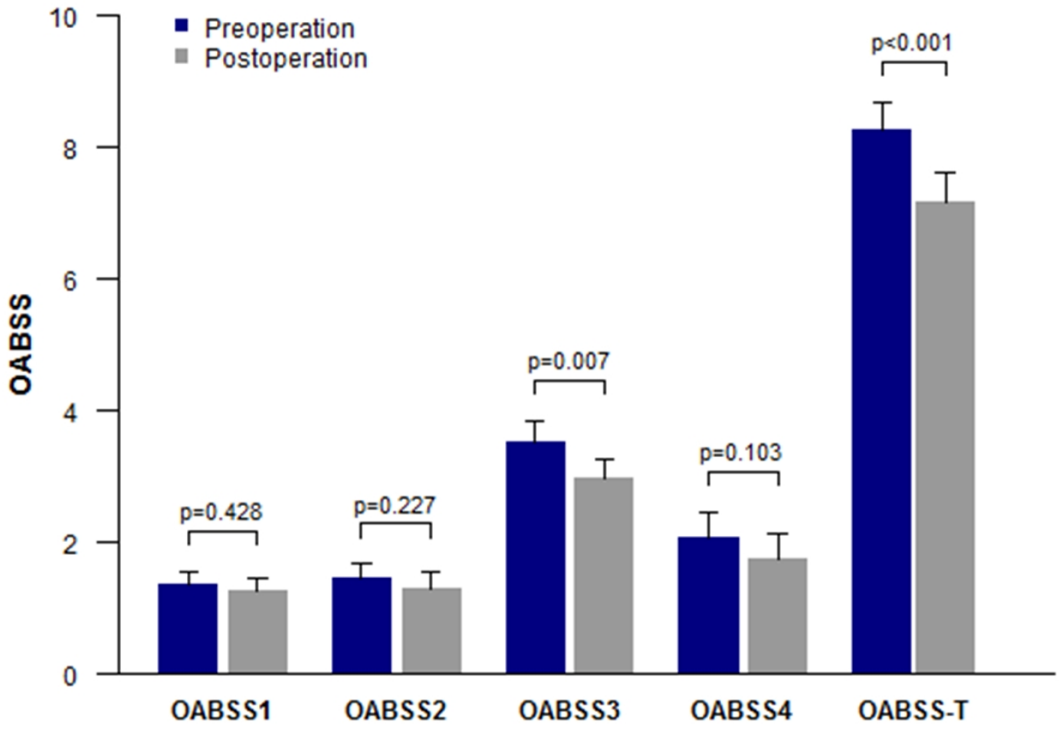
ISD, intrinsic sphincter deficiency; OAB, overactive bladder; GRA, global response assessment; OABSS, overactive bladder symptom score. Data were presented as mean±standard deviation. *p*-values were calcuated by Student's *t*-test or Mann-Whitney U test. ***, $p < 0.001$; there was statistically significant difference between pre and post operation by Wilcoxon's signed rank test.

The OABSS of group I patients decreased from 1.1 ± 0.8 preoperatively to 0.8 ± 0.6 at 12 months postoperatively; the difference was not significant ($p = 0.138$). The OABSS1, OABSS2, and OABSS4 of group II patients did not differ significantly preoperatively vs. 12 months postoperatively, but the OABSS3 of group II patients decreased significantly, from 3.52 ± 0.82 preoperatively to 2.96 ± 0.73 at 12 months postoperatively ($p = 0.007$) (Fig. 2). The total OABSS of group II patients decreased significantly, from 8.2 ± 1.1 preoperatively to 7.2 ± 1.1 12 months postoperatively ($p < 0.001$) (Table 2, Fig. 2). The OABSS of group II patients was significantly higher than that of group I patients both before and 12 months after surgery ($p < 0.001$). The drop in the OABSS of group II patients was significantly larger than that of group I patients ($p = 0.009$) (Table 2).

Three patients in group I and 1 patient in group II developed skin wound infection, but their varitensors were not removed. In all four of these patients, the infections resolved after 1 week of oral antibiotics and wound dressing.

4. Discussion

A variety of sling materials and surgical techniques have been used to minimize complications in the treatment of female patients with urinary incontinence. The midurethral sling procedure using tension-free vaginal tape is considered the standard treatment for female SUI. Ghezzi *et al.* [6] reported a 91.4% cure rate in their series of patients treated with this procedure. However, the outcomes of patients with ISD differ from those with pure SUI. In ISD, the urethral closure mechanism is ineffective, possibly as a



Variable	OABSS1	OABSS2	OABSS3	OABSS4	OABSS-T
Pre	1.36 ± 0.49	1.44 ± 0.58	3.52 ± 0.82	2.04 ± 1.06	8.24 ± 1.13
Post	1.24 ± 0.52	1.28 ± 0.68	2.96 ± 0.73	1.72 ± 0.98	7.16 ± 1.14
p-value	0.428	0.227	**0.007**	0.103	**<0.001**

Fig. 2. Preoperative and postoperative changes of OABSS in patients with ISD with OAB (N = 25). ISD, intrinsic sphincter deficiency; OAB, overactive bladder; OABSS, overactive bladder symptom score. Value were mean ± 1.96*standard error of mean (SEM). *p*-value were calculated by Wilcoxon's signed-rank test.

result of aging, neurological etiology, or previous surgery. Schierlitz *et al*. [7] reported that patients with ISD have more severe incontinence and a lower surgical success rate than patients with SUI and normal urethral function.

The tension-free midurethral sling procedure has been less effective in patients with ISD and has a higher surgical failure rate. This is in part due to the difficulty in achieving the appropriate tension, as a sophisticated adjustment is needed between incontinence, continence, and obstruction after implantation of the sling. While good results have been reported in patients with ISD and urethral hypermobility after undergoing a tension-free midurethral sling procedure [8], patients with ISD and a fixed urethra, like those in our study, require other treatments [9]. The Remeex system, in which a tension-controlling device is permanently positioned in the lower abdomen, may be considered in such cases, as it yields better results and is less invasive [10]. In addition to the increased surgical success rate, it involves fewer complications, including obstruction due to inappropriate tension, because the suburethral tension can be adjusted after surgery [11].

Previous studies have reported good cure rates with the Remeex system based on long-term follow-up examination. Giberti *et al*. [12] treated 30 patients who had SUI with ISD with the Remeex system. After an average of 60.6 months (range, 22–96 months), cure or improvement was reported in 28 (93%) patients and treatment failure was reported in only 2 (7.0%) patients. Moreno Sierra *et al*. [13] conducted a follow-up study of 683 female patients at 23 months (range, 6–93 months) after treatment using the Remeex system. The reported cure rate was 92.2%, with 6.9% improvement and 0.9% treatment failure. The success rate in the present study was comparable with the results of that and other studies of the Remeex system in women with ISD [3,14].

Despite the good surgical rate achieved with the Remeex system in patients with pure ISD, few studies have examined its therapeutic effect in ISD patients with OAB

or MUI accompanied by urgency and urgency urinary incontinence. However, ~50% of women suffering from SUI also have symptoms of OAB [15]. SUI with OAB is associated with a worse quality of life than is the case with pure SUI [16]. It is therefore important to assess the effect of Remeex system surgery for SUI on the symptoms of OAB.

Several studies have examined the cure rate achieved with the tension-free midurethral sling procedure in patients with preoperative urgency or urgency urinary incontinence. Sinha *et al*. [4] reported a success rate of 75% in patients with MUI, which was lower than in patients with pure SUI. However, Rezapour and Ulmsten reported that the tension-free midurethral sling procedure was effective in treating not only SUI but also urgency or urgency urinary incontinence in patients with MUI [17]. Choe *et al*. [18] also reported that the tension-free midurethral sling procedure was effective in the treatment of MUI.

In our ISD patients with OAB treated with the Remeex system, a 65% improvement in the GRA was achieved together with significant decreases in the total urgency score and OABSS. However, surgical treatment of this group was not completely effective because they had lower overall improvement rates and improvements in OAB symptoms compared with patients with pure ISD, as determined by the 1-hr pad weight test. The reasons for this difference are unclear. Athanasiou *et al*. [19] reported persistent symptoms or the occurrence of new symptoms in patients with urinary incontinence treated with the midurethal sling procedure, consistent with the findings of Barber *et al*. [20]. It may be that OAB symptoms develop in SUI patients after midurethral sling surgery. Therefore, the low improvement rate in ISD patients with OAB can perhaps be attributed to OAB symptoms that occurred after the adjustment procedure with the Remeex system. However, this was not the case in our study because our patients with pure ISD did not have aggravated OAB symptoms. Further studies are needed to elucidate the cause of the lower improvement rate in patients with ISD and OAB symptoms.

Our study had several limitations. First, In this study, patients had a relatively short follow up period. This is mainly related to follow up loss in patients. Patients who underwent this surgery showed dramatic improvement in SUI symptoms and had high satisfaction, although there was a difference in degree depending on the group. As such, these patients often do not feel the need for follow-up because they are satisfied with the improvement of symptoms after surgery. Because this tendency affects high follow up loss rate, the follow up period in our study was relatively short. Also, Although ISD patients with OAB were informed before the procedure that with the exception of stress incontinence, other voiding symptoms may not be improved by surgery, their complaints about urgency and urge incontinence intensified after their stress incontinence improved postoperatively. In these patients, urgency and urge incontinence were treated conservatively, including with anticholinergics, after completion of the 1-year follow-up. Because these treatments could have created bias in the study, this extended follow-up was not included. Second, this study had a small sample. Since the subjects of this study were ISD patients who underwent the Remeex system, there were not many patients. To compensate for these limitations, in dividing patients into those with ISD and those with ISD and OAB, PSM was performed to reduce the statistical errors because the latter group was small. However, in order to prove the results, a multi-center study with a larger number of patients in cooperation with other institutions is needed.

5. Conclusions

Among female patients with urinary incontinence treated with the Remeex system, greater satisfaction and a higher cure rate, assessed using the 1-hr pad weight test, were obtained in patients with pure ISD than in those with ISD and OAB. While the Remeex system improves OAB symptoms in ISD patients, larger and well-designed studies are still needed to fully evaluate the applications of this treatment.

Author Contributions

SWL and YHK designed the research study. WBK, KWL, JMK, JJP performed the research. JHK and SHK provided help and advice on mehodology. JEM and SHK analyzed the data. SWL and YHK wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

All patients received written informed consent for publication of this study and any accompanying images and agreed prior to the procedure. All procedures in this study were performed in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration.

Acknowledgment

This manuscript was prepared with the assistance of Textcheck, an English-language scientific editing company.

Funding

This study was supported by “Soonchunhyang University Research Fund”.

Conflict of Interest

The authors declare no conflict of interest.

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