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Original Article

Therapeutic effect of autologous fascia urethral suspension on female stress urinary incontinence and analysis of risk factors affecting the efficacy

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Abstract: Objective: To observe the therapeutic effect of autologous fascial urethral suspension on female stress urinary incontinence and analyze the risk factors affecting the therapeutic effect. Method: The clinical data of 89 female patients with stress urinary incontinence treated in our hospital from February 2018 to February 2020 were retrospectively analyzed (training group). Another cohort of 45 patients treated in Xi'an Gaoxin Hospital from March 2020 to March 2021 were retrospectively enrolled as the validation group. Surgery-related parameters (including operation time, intraoperative blood loss, indwelling time of catheter, and hospital stay) were recorded. The scores of the urinary incontinence questionnaire short form (IC-IQ-SF), urinary incontinence quality of life questionnaire (I-QOL), and pelvic organ prolapse/urinary incontinence sexual function questionnaire (PISQ-12) were compared before and after the operation. The clinical efficacy of the treatment was counted. The risk factors affecting the treatment efficacy were analyzed. The efficacy prediction model was established by logistics regression equation and verified by the data from the validation group. Results: After the treatment, the urine leakage score, urine leakage score quality of life score, and the total score were evidently reduced compared with those before the treatment ($P < 0.05$). Patients' I-QOL score and PISQ-12 score increased significantly after the treatment ($P < 0.05$). Multivariate logistics regression analysis revealed that age, BMI, history of pelvic surgery, and length of hospital stay were risk factors affecting the outcome of patients ($P < 0.05$). The ROC curve analysis revealed that the area under the curve of the efficacy score in predicting the treatment efficacy was 0.828, and that in the validation group was 0.895. Conclusion: The treatment effect of autologous fascia urethral suspension in female patients with stress urinary incontinence was significant. It improved the quality of life of patients. The risk factor analysis showed that age, BMI, history of pelvic surgery, and length of hospital stay were risk factors affecting the treatment outcome of patients.

Keywords: Autologous fascia urethral suspension, female stress urinary incontinence, clinical efficacy, risk factors

Introduction

Female pelvic floor dysfunction is a disease that poses the greatest impact on the life quality of middle-aged and elderly women in recent years. It includes pelvic organ prolapse, urinary incontinence, fecal incontinence, and sexual dysfunction [1]. Stress urinary incontinence (SUI) is most commonly seen in clinical practice [2]. It refers to the involuntary overflow of urine when the abdominal pressure suddenly increases. SUI is a common disease that significantly affects the normal social interaction of patients and leads to a decrease in life quality [3, 4]. Data statistics show that SUI exists in 8.2% of women worldwide. It can occur at any age, with an incidence of 13% at 18 to 20 years of age, 35% at 40 to 49, and 36% at 70 to 74 [5]. In China, the incidence in women aged 15-64 years fluctuates between 12% and 34%. Women aged 45-55 years-old are a cohort of high incidence [6]. Some scholars believe that trophic vaginitis and inflammation lead to vaginal microecological imbalance and will increase the incidence of female SUI [7]. The rate of SUI visits in China is significantly lower than it real incidence because of the limitation of living conditions and medical conditions and the lack of understanding of the disease [8]. In a statistic, it was found that 66.5% of female patients

believed that the disease is merely a normal aging manifestation and 21.5% believed that SUI is incurable [9].

The clinical treatment options for SUI are surgical and conservative treatment [10]. Conservative treatment is suggested for patients with mild to moderate female SUI, but only half of them have achieved significant results with it [11]. It has the limitation of a slow effect and a long treatment cycle compared with surgical treatment. More patients prefer surgical treatment due to its quick results and immediately improved quality of life [12]. With the continuous progress in medicine, midurethral suspension with artificial material sling has become the main method for the treatment of female SUI [13]. Artificial materials are easily complicated by serious contaminant such as infection and pain. Erosion of the genitourinary system of patients have a great impact on the quality of life of patients [14]. Recent studies have found that autologous tissue materials, with the advantage of small rejection, have been developed and applied. This has comforted patients who worried about long-term complications and were afraid of erosion of the vagina caused by artificial materials [15].

In this study, we aimed to analyze the risk factors affecting the efficacy of autologous fascial urethral suspension surgery, and to provide reference for clinical prognosis observation.

Methods and materials

Clinical information

A total of 89 female patients with stress urinary incontinence treated in our hospital from February 2018 to February 2020 were retrospectively analyzed (training group). Another cohort of 45 patients treated in Xi'an Gaoxin Hospital from March 2020 to March 2021 were collected as the validation group. This study was approved by the Medical Ethics Committee of Department of Gynaecology, Xi'an Gaoxin Hospital. Ethical batch number: LWFB2022010-01.

Inclusion and exclusion criteria

Inclusion criteria: Female patients who meet the diagnostic criteria for SUI [16] and have normal bladder sensation and capacity; patients with complete medical records and laboratory examination data.

Exclusion criteria: Patients with severe gynecologic comorbidities; patients with preoperative urinary tract infection; patients with concomitant urinary disorders; patients with pathological bladder disease; pregnant and lactating patients; patients with severe cardiovascular and cerebrovascular diseases.

Treatment regimen

Epidural anesthesia was conducted and patients were placed in the lithotomy position. The anterior rectus sheath strip with 2 cm superior pubic margin, 4 cm in length and 1 cm in width, was selected from the transverse incision position. The appropriate length of No. 7 nylon suture was selected to fix the four corners. An appropriate longitudinal incision was made in the proximal direction 1 cm away from the urethra on the anterior vaginal wall. The vaginal mucosa on both sides was slightly separated using scissors to expose the middle urethra. A disposable catheter was inserted into the patient. After emptying the bladder, the cystoscope sheath was punctured and the needle was inserted through the lateral urethra through the anterior vaginal wall incision. The needle was guided through the pelvic floor fascia through the incision and punctured out the anterior incision. A total of 250 ml normal saline was injected after bladder emptying. A 70° cystoscope was used to observe and determine that there was no perforation of the bladder. The needle position was appropriate to thread the fascial suspension line from the tip into an arcuate pinhole after determining that there was no injury to the bladder and urethra. While threading the fascial suspension line, the suspension line was threaded out of the anterior vaginal wall. The needle was withdrawn from the abdominal wall after emptying the bladder and determining that the bladder was not injured. The fascial strip was brought out of the abdominal wall from the anterior vaginal wall and bypassed the middle urethra in a "U" shape. When wrapping around the transurethral tract, attention was paid to the fascial strip flat. The tightness of the fascial suspension was adjusted using scissors (based on the cough test with 1-2 drops of normal saline leakage). The fascial strip suspension line was fixed on the muscle sheath. The vaginal incision was closed, 3-0 absorbable suture was applied, and iodophor gauze was used to pack the vagina for hemostasis by compression. At the end of the operation, a urinary catheter was placed in the

patient and removed 24 h after the operation. Antibiotics were applied 1 to 3 d after the operation for anti-infection.

Outcome measures

Main outcome measures: Clinical efficacy after the treatment was statistically analyzed. According to the efficacy after the treatment, patients were divided into the recovered group (n = 58) and the unrecovered group (n = 31). The risk factors affecting the treatment efficacy were analyzed. The logistics regression equation was used to establish the efficiency prediction model. Data validation was performed.

Secondary outcome measures: Surgery-related parameters (including operation time, intraoperative blood loss, indwelling time of urinary catheter, and length of hospital stay) were recorded. The Incontinence Questionnaire Short Form (IC-IQ-SF) score was used to analyze the degree of urinary incontinence in patients [17]. The IC-IQ-SF includes a total of six items: age, gender, number of urine leaks, urine leakage, impact of urine leakage on daily life, and urine leakage scenario. The total score is 21 points, with a higher score indicating more severe urinary incontinence. Life quality of patients was assessed using the Incontinence Quality of Life Questionnaire (I-QOL) score [18]. It contains three dimensions with a total of 22 items: behavioral limitations (8 items), psychological impact (9 items), and social function (5 items). Each item counts 1 to 5 points from "completely", "often", "sometimes", "rarely", and "never", respectively. The higher the score, the better the quality of life. Pelvic floor function was assessed using the Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire (PISQ-12) score [19]. The PISQ-12 includes 12 evaluation items. Each item is scored on a 5-level scale of 0 to 4, of which 1/2/3/4 items have the opposite score. The total score ranges 0 to 48 points, with a higher scores indicating better sexual function.

Criteria for response assessment

"Cured" was defined as no involuntary leakage symptoms and no residual urine volume were recovered when the abdominal pressure increased after the treatment. "Improved" was defined as involuntary leakage ≤ 10 g and frequency of urinary incontinence significantly decreased ≥ 50% when the abdominal pressure increased after the treatment. "Ineffective" was defined as: the degree and frequency of urinary incontinence were not significantly improved or aggravated when the abdominal pressure increased after the treatment.

Statistical analysis

In this study, SPSS 20.0 was used for statistical analysis of the collected data. GraphPad 7 was used to draw the required pictures. K-S test was used to analyze the distribution of dose data. Normally distributed data were expressed as mean ± standard deviation (Means ± SD). Inter-group and intra-group comparison were conducted with the Student t-test and the paired t-test, respectively. The enumeration data was expressed as use rate (%) and compared using the chi-square test. The logistics regression analysis was used to analyze the risk factors affecting the efficacy of patients. The receiver operating curve (ROC) was used to analyze the clinical value of the factors in predicting the efficacy of patients. $P < 0.05$ indicated that there was a statistical difference.

Results

Patient clinical data

In the training group, the mean age of patients was (57.6±9.03) years old. The mean Body Mass Index (BMI) was (23.64±3.62) kg/m^2. The mean disease duration was (4.91±2.80) years. A total of 46 patients had a history of diabetes.

Comparison of IC-IQ-SF scores before and after the operation

The comparison of IC-IQ-SF scores before and after the operation showed that there were significant reductions in the number of urine leaks, urine leakage score, and quality of life score of the patients after the treatment ($P < 0.05$). The total score after the treatment was significantly reduced compared with that before the treatment ($P < 0.05$, **Figure 1**).

Comparison of I-QOL score and PISQ-12 score of patients before and after the surgery

When comparing the I-QOL score and the PISQ-12 score of patients before and after the surgery, it was found that the I-QOL score and the PISQ-12 score of patients after the treatment

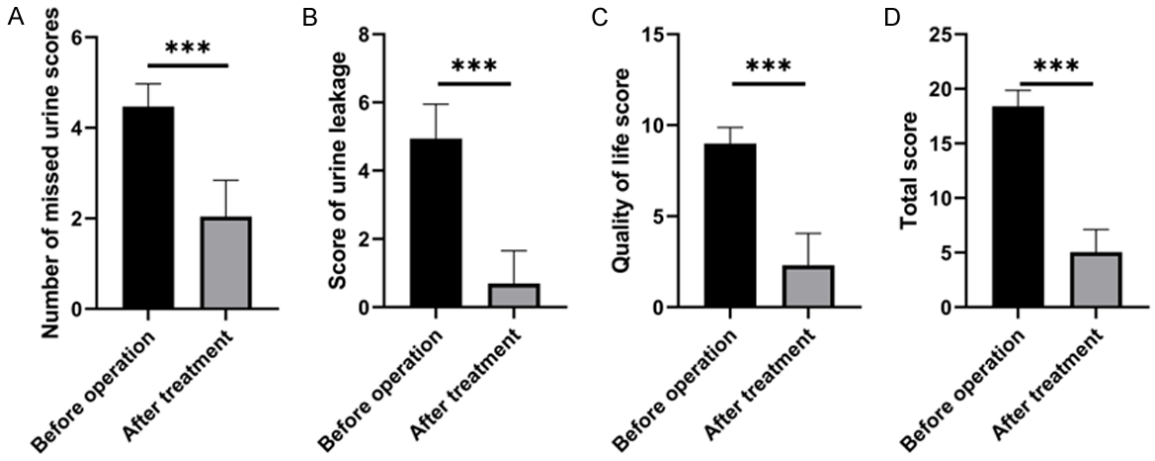

Figure 1. Comparison of IC-IQ-SF scores of patients before and after the treatment. A. Changes in the score of urinary leakage frequency of patients before and after the treatment. B. Changes in urine leakage scores of patients before and after the treatment. C. Changes in quality of life scores of patients before and after the treatment. D. Changes in the total score of patients before and after the treatment. Note: IC-IQ-SF: Urinary Incontinence Questionnaire Short Form, *** means P < 0.001.

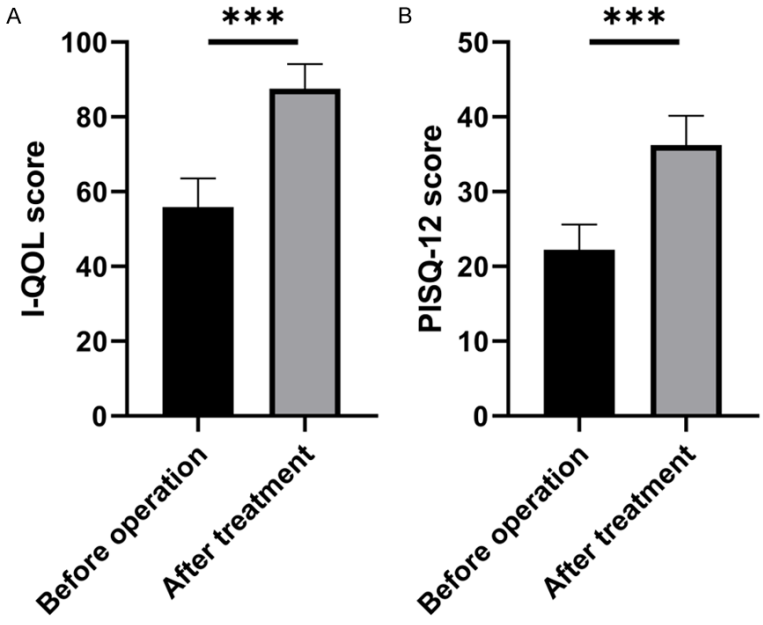

Figure 2. Comparison of I-QOL score and PISQ-12 score of patients before and after the treatment. A. Changes in I-QOL score of patients before and after the treatment. B. Changes in PISQ-12 score of patients before and after the treatment. Note: Urinary Incontinence Quality of Life Questionnaire (I-QOL) score, Pelvic Organ Prolapse/Urinary Incontinence Questionnaire (PISQ-12) score, *** means P < 0.001.

increased significantly (both P < 0.05, **Figure 2**).

Analysis of risk factors affecting the treatment effect of patients

In this study, 58 patients were cured, 31 were improved and none were ineffective after the treatment. We divided the patients into a recovered group and a non-recovery group according to their treatment efficacy. Univariate analysis revealed that age, BMI, fertility, history of pelvic surgery, and length of hospital stay were risk factors affecting the efficacy of patients (**Table 1**, all P < 0.05). To identify the contributing factors, we assigned values to each variable (**Table 2**). Amultivariate logistics regression analysis revealed that age, BMI, history of pelvic surgery, and length of hospital stay were independent risk factors affecting the efficacy of patients (**Table 3**, P < 0.05).

Establishment and validation of the efficacy model

In the above study, we identified the risk factors affecting the efficacy of patients. To predict the efficacy of patients, we constructed the efficacy prediction formula according to the return model: efficacy score = -7.053 + 1.453* age + 1.174 BMI + 1.479* pelvic surgery history + 0.741* length of hospital stay. When comparing the efficacy score between the recovery group and the non-recovery group, it was found that the efficacy

Table 1. Univariate analysis of the factors affecting treatment efficacy

Variable	Recovery Group (n = 58)	Non-recovery Group (n = 31)	x^2/t value	*P* value
Age			8.995	0.003
≥ 55 years old	20	21		
< 55 years old	38	10		
BMI			7.614	0.006
≥ 25 kg/m^2	18	19		
< 25 kg/m^2	40	12		
Course of disease			0.078	0.779
≥ 5 years	30	17		
< 5 years	28	14		
Fertility status			11.871	0.001
≥ 2 times	19	22		
< 2 times	39	9		
History of pelvic surgery			9.651	0.002
Yes	23	23		
No	35	8		
IC-IQ-SF score	18.43±1.45	18.35±1.27	0.245	0.806
I-QOL score	55.87±7.51	55.80±8.05	0.042	0.966
PISQ-12 Score	22.15±3.18	22.41±3.69	0.352	0.725
Operation time (min)	46.70±4.93	48.22±4.18	1.456	0.149
Intraoperative blood loss (mL)	58.81±5.09	60.68±4.48	1.716	0.089
Urinary catheter indwelling time (d)	5.18±0.73	5.38±0.55	1.304	0.196
Length of hospital stay (d)	5.58±0.87	6.09±0.70	2.792	0.006

Note: BMI: Body Mass Index; IC-IQ-SF: Urinary Incontinence Questionnaire Short Form; I-QOL: Urinary Incontinence Quality of Life Questionnaire; PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Questionnaire .

Table 2. Assignment

Variable	Assign
Age	≥ 55 years old = 1, < 55 years old = 0
BMI	≥ 25 kg/m^2 = 1, < 25 kg/m^2 = 0
Fertility status	≥ 2 times = 1, < 2 times = 0
History of pelvic surgery	Presence = 1, Absence = 0
Hospital stay	Belong to continuous variables using raw data analysis
Curative effect	Healed = 0, not healed = 1

Note: BMI: Body Mass Index.

Table 3. Multivariate analysis of the factors affecting the treatment efficacy

Variable	B	S.E	Wals	Sig.	Exp (B)	95% C.I.	
						Lower limit	Upper limit
Age	1.453	0.546	7.08	0.008	4.275	1.466	12.463
BMI	1.174	0.538	4.765	0.029	3.235	1.127	9.281
History of pelvic surgery	1.479	0.553	7.147	0.008	4.389	1.484	12.981
Hospital stay	0.741	0.371	3.989	0.046	2.098	1.014	4.342

Note: BMI: Body Mass Index.

score of the recovered group was significantly lower than that of the non-recovery group (**Figure 3A**, P < 0.001). The efficacy score was found to have an area under the curve (AUC)

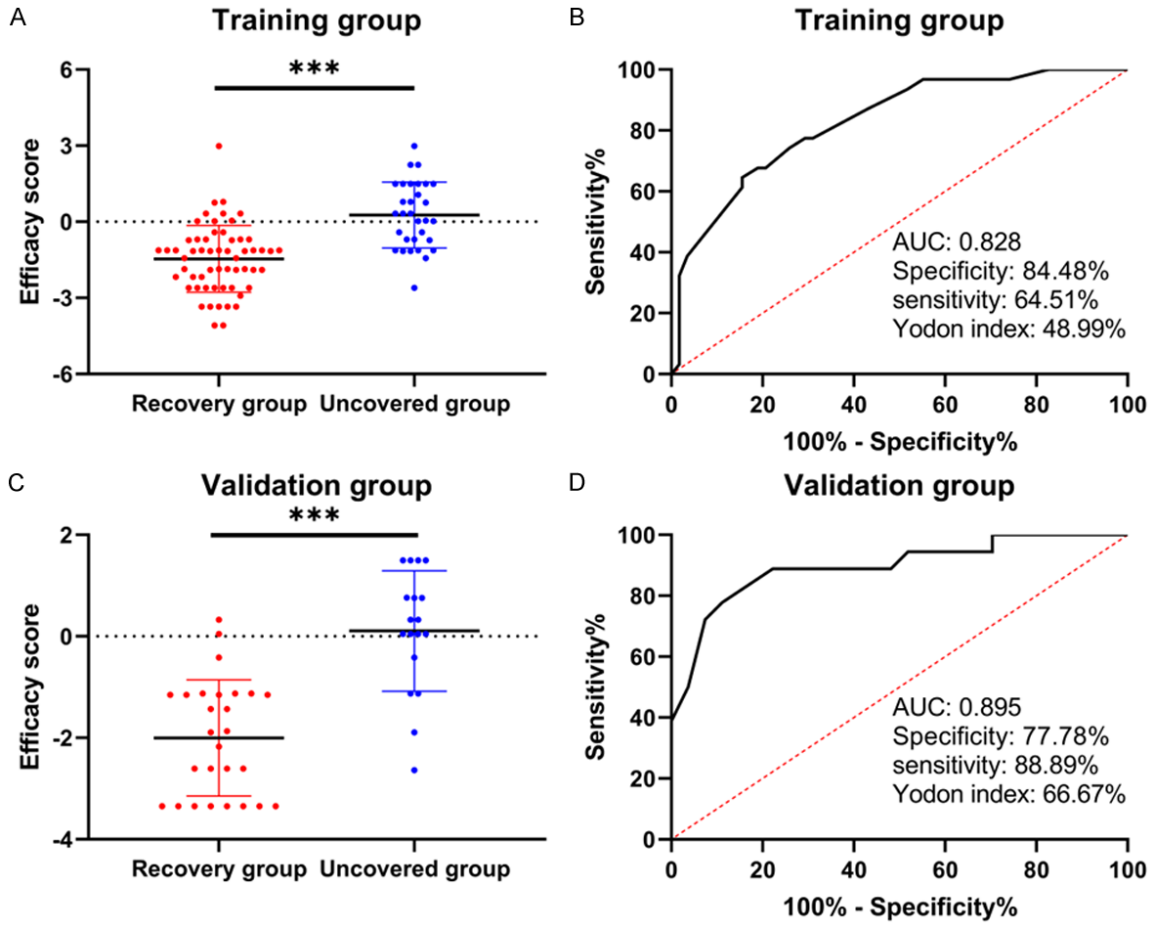

Figure 3. Construction and validation of the efficacy model. A. Expression of efficacy score in patients in the training group. B. ROC curve of training group efficacy score in predicting patient efficacy. C. Expression of efficacy score in the validation group of patients. D. The ROC curve of the efficacy score of the validation group in predicting the efficacy of the patients. Note: ROC: Receiver Operating Curve, *** means $P < 0.001$.

of 0.828 to predict the efficacy of patients (**Figure 3B**). To verify the validity of our prediction model, we included 45 female SUI patients treated with autologous fasciourethral suspension as the validation group. There were 89 patients included as the training group during the same period. Through comparison, it was found that there was no significant difference in other clinical data between the training group and the verification group, except the operation time ($P > 0.05$, **Table 4**). We substituted the data according to the efficacy score formula to obtain the efficacy score of the verification set. Through comparison, it was found that the efficacy score was significantly lower in the recovery group than that in the non-recovery group (**Figure 3C**, $P < 0.05$) in the verification set. The ROC curve analysis revealed that the AUC of the efficacy score in the validation group in predicting the efficacy of patients was 0.895 (**Figure 3D**).

Discussion

Female SUI occurs frequently in middle-aged and elderly women. It is mostly caused by pelvic floor muscle relaxation after delivery and changes in the anatomical position of the bladder, neck, and urethra [20]. With the acceleration of the aging process, the disease has gradually increased and has seriously affected the life quality of middle-aged and elderly women [4]. Surgical treatment of SUI is effective. Surgical methods are varied and optional. The basic principle is to provide the necessary support for the bladder, neck, and proximal urethra to establish a framework for adequate urethral closure when abdominal pressure increases [21].

Table 4. Comparison of clinical data between training group and validation group

Variable	Training Group (n = 89)	Validation Group (n = 45)	x^2/t value	*P* value
Age			0.178	0.672
≥ 55 years old	41	19		
< 55 years old	48	26		
BMI			0.854	0.355
≥ 25 kg/m^2	37	15		
< 25 kg/m^2	52	30		
Course of disease			0.836	0.360
≥ 5 years	47	20		
< 5 years	42	25		
Fertility status			0.304	0.580
≥ 2 times	41	23		
< 2 times	48	22		
History of pelvic surgery			0.179	0.671
Yes	46	25		
No	43	20		
Efficacy assessment			0.254	0.614
recovered	58	27		
unrecovered	32	18		
IC-IQ-SF score	22.53±3.60	22.67±3.10	0.222	0.824
I-QOL score	55.85±7.65	57.04±4.79	0.952	0.342
PISQ-12 Score	22.24±3.35	22.02±3.02	0.711	0.370
Operation time (min)	47.23±4.71	49.11±3.73	2.332	0.021
Intraoperative blood loss (ml)	59.46±4.94	60.28±4.43	0.938	0.349
Urinary catheter indwelling time (d)	5.25±0.68	5.40±0.61	1.247	0.214
Length of hospital stay (d)	5.76±0.85	5.53±0.66	1.588	0.114

Note: BMI: Body Mass Index; IC-IQ-SF: Urinary Incontinence Questionnaire Short Form; I-QOL: Urinary Incontinence Quality of Life Questionnaire; PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Questionnaire.

Urethral suspension is currently the main treatment for SUI in clinical practice [4]. Tension-free mid-urethral slings have achieved some therapeutic effect in early clinical treatment. Artificial materials are expensive. The body rejection of implanted materials can cause local pain or mesh erosion and mesh exposure defects in patients [22]. This has led to the necessity of seeking new materials as replacements. The new treatment modifies autologous fascia into autologous fascia sling according to the principle of tension-free suspension of the middle urethra. It uses autologous fascia sling as urethral reinforcement material, which fully avoids body rejection. Using autologous and synthetic materials is a better choice for female patients worried about long-term complications [23]. In this study, we identified the therapeutic effect of autologous fascial urethral suspension in female patients with SUI. IC-IQ-SF scores were found to be significantly lower in patients treated by autologous fascial urethral suspension. The patients' surgical I-QOL score and PISQ-12 score were improved significantly compared with those before the treatment. In a previous study by Wu et al. [24], it was found that the ICI-Q-SF score was much lower and the I-QOL score was significantly higher in postmenopausal patients with mild to moderate SUI treated with fractional carbon dioxide laser. Lumen et al. [25] found that SUI patients treated by urethral suspension had significantly decreased ICI-Q-SF scores. This was consistent with our findings, indicating that autologous fascial urethral suspension can significantly improve SUI patients' condition.

A clinical efficacy evaluation is a critical evaluation criterion to assess their recovery condition after the treatment. Many reports focused on the analysis of the therapeutic effect of SUI in clinical practice. There is a lack of efficacy pre-

diction model construction and effective guidance. In this study, we analyzed the risk factors affecting the clinical efficacy of SUI, which included age, BMI, history of pelvic surgery, and length of hospital stay. With the rise of age and the arrival of menopause, estrogen in women will show a substantial decrease that causes deficiency of nutritional support for the pelvic organs and muscles, which is more likely to induce SUI [26, 27]. One statistic found [28] that, by analyzing 4804 women, the prevalence of SUI was 16.7%. This was found to be positively correlated with the age. Obesity, more commonly seen these days worldwide, has a great impact on people's work, life, health, and elevated BMI. This is an inevitable consequence led by obesity. It is an important factor leading to pelvic organ prolapse [29]. It leads to increased intra-abdominal pressure and diminished pelvic floor nerve and muscle system function, which are pathophysiological causes of SUI [30]. Due to the history of pelvic surgery, there is some damage to both sides of the upper vagina and the parametrial connective tissue. The pelvic diaphragm is thin. The cardinal ligament and uterosacral ligament complex are not complete enough. This results in an increased risk of SUI, affecting the efficacy of the patient [31]. A lengthy hospital stay can become a risk factor affecting the efficacy of patients because patients with poor efficacy require further treatment. It has been found that the length of hospital stay after midurethral sling incontinence surgery is a risk factor for urinary tract infection [32]. Preoperative understanding of patient age, weight and surgical history, postoperative acceleration of patient rehabilitation, and reduction of hospital stay can significantly control the clinical efficacy of patients.

At the end of the study, we constructed the efficacy prediction model according to the logistics regression model. Through the regression equation (-7.053 + 1.453* age + 1.174 BMI + 1.479* history of pelvic surgery + 0.741* length of hospital stay), we obtained an efficacy score. By comparing the efficacy score of recovered patients with that of unrecovered patients, it was found that the score was much lower in recovered patients than in unrecovered patients. The ROC curve analysis found that the area under the curve of efficacy score in predicting the efficacy of patients was 0.828, indicating the model was ideal. To validate our conclusions, we collected data from a group of women with SUI treated with autologous fasciourethral suspension as the validation group for this study. By importing the data into the equation, we learned the efficacy score of recovered patients in the validation group was significantly lower than those non-recovered patients. This was consistent with the results of our training set. The area under the ROC curve for predicting efficacy was 0.895, indicating that our efficacy assessment model had some generalization.

This study had certain limitations. It remains unclear whether patients with SUI have recurrence in the long term due to the nature of retrospective study. The samples collected in this study was quite limited, which may have led to bias in the equation model results. We hope to carry out more clinical studies in future studies to refine our conclusions.

In summary, the use of autologous fascial urethral suspension has a significant therapeutic effect and improves life quality of female SUI patients. A risk factor analysis concluded that age, BMI, pelvic surgery history, and length of hospital stay are risk factors affecting the therapeutic effect of patients.

Disclosure of conflict of interest

None.

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