

# World Journal of *Clinical Cases*

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**OPINION REVIEW**

- 3920 Special features of SARS-CoV-2 in daily practice  
*Charitos IA, Ballini A, Bottalico L, Cantore S, Passarelli PC, Inchingolo F, D'Addona A, Santacroce L*

**EVIDENCE REVIEW**

- 3934 Gastrointestinal insights during the COVID-19 epidemic  
*Nie K, Yang YY, Deng MZ, Wang XY*

**REVIEW**

- 3942 From infections to autoimmunity: Diagnostic challenges in common variable immunodeficiency  
*Więsik-Szewczyk E, Jahnz-Różyk K*
- 3956 One disease, many faces-typical and atypical presentations of SARS-CoV-2 infection-related COVID-19 disease  
*Philips CA, Mohan N, Ahamed R, Kumbar S, Rajesh S, George T, Mohanan M, Augustine P*

**MINIREVIEWS**

- 3971 Application of artificial neural networks in detection and diagnosis of gastrointestinal and liver tumors  
*Mao WB, Lyu JY, Vaishnani DK, Lyu YM, Gong W, Xue XL, Shentu YP, Ma J*
- 3978 Hepatic epithelioid hemangioendothelioma: Update on diagnosis and therapy  
*Kou K, Chen YG, Zhou JP, Sun XD, Sun DW, Li SX, Lv GY*

**ORIGINAL ARTICLE****Clinical and Translational Research**

- 3988 *Streptococcus agalactiae*: Identification methods, antimicrobial susceptibility, and resistance genes in pregnant women  
*Santana FAF, de Oliveira TVL, Filho MBDS, da Silva LSC, de Brito BB, de Melo FF, Souza CL, Marques LM, Oliveira MV*
- 3999 Twelve-month evaluation of the atraumatic restorative treatment approach for class III restorations: An interventional study  
*Shivanna MM, Ganesh S, Khanagar SB, Naik S, Divakar DD, Al-Kheraif AA, Jhugroo C*

**Case Control Study**

- 4010 Effects of different doses of metformin on bone mineral density and bone metabolism in elderly male patients with type 2 diabetes mellitus  
*Wang LX, Wang GY, Su N, Ma J, Li YK*

- 4017 Relationship between granulomatous lobular mastitis and methylene tetrahydrofolate reductase gene polymorphism

*Lei QR, Yang X, Miao CM, Wang JC, Yang Y*

#### Retrospective Cohort Study

- 4022 First-line chemotherapy in very elderly patients with metastatic pancreatic cancer: Gemcitabine monotherapy *vs* combination chemotherapy

*Han SY, Kim DU, Seol YM, Kim S, Lee NK, Hong SB, Seo HI*

#### Retrospective Study

- 4034 Pre- and intraoperative predictors of acute kidney injury after liver transplantation

*Mrzljak A, Franusic L, Pavicic-Saric J, Kelava T, Jurekovic Z, Kocman B, Mikulic D, Budimir-Bekan I, Knotek M*

- 4043 Clinical value of needleless sling in treatment of female stress urinary incontinence

*Chen YG, Zhang YG, Zhang W, Li X, Wang X*

- 4051 Intratympanic dexamethasone injection for sudden sensorineural hearing loss in pregnancy

*Lyu YL, Zeng FQ, Zhou Z, Yan M, Zhang W, Liu M, Ke ZY*

- 4059 Research on the effect of health care integration on patients' negative emotions and satisfaction with lung cancer nursing activities

*Long FJ, Chen H, Wang YF, He LM, Chen L, Liang ZB, Chen YN, Gong XH*

- 4067 Comparison between computed tomography and magnetic resonance imaging in clinical diagnosis and treatment of tibial platform fractures

*Liu XD, Wang HB, Zhang TC, Wan Y, Zhang CZ*

#### SYSTEMATIC REVIEWS

- 4075 Primary sclerosing cholangitis and autoimmune hepatitis overlap syndrome associated with inflammatory bowel disease: A case report and systematic review

*Ballotin VR, Bigarella LG, Riva F, Onzi G, Balbinot RA, Balbinot SS, Soldera J*

#### CASE REPORT

- 4094 Epidermolytic acanthoma: A case report

*Ginsberg AS, Rajagopalan A, Terlizzi JP*

- 4100 Management of pembrolizumab-induced steroid refractory mucositis with infliximab: A case report

*Dang H, Sun J, Wang G, Renner G, Layfield L, Hilli J*

- 4109 Small bowel obstruction caused by a bezoar following an adult simultaneous liver-kidney transplantation: A case report

*Pan G, Kim RD, Campsen J, Rofaiel G*

- 4114 Laparoscopic resection of primary retroperitoneal schwannoma: A case report

*Ribeiro Jr MAF, Elias YGB, Augusto SDS, Néder PR, Costa CT, Maurício AD, Sampaio AP, Fonseca AZ*

- 4122** Sweet syndrome as a paraneoplastic manifestation of cholangiocarcinoma: A case report  
*Lemaire CC, Portilho ALC, Pinheiro LV, Vivas RA, Britto M, Montenegro M, Rodrigues LFDF, Arruda S, Lyra AC, Cavalcante LN*
- 4128** Multidisciplinary approach to suspected sudden unexpected infant death caused by milk-aspiration: A case report  
*Maiese A, La Russa R, Arcangeli M, Volonnino G, De Matteis A, Frati P, Fineschi V*
- 4135** Stress fractures in uncommon location: Six case reports and review of the literature  
*Ficek K, Cyganik P, Rajca J, Racut A, Kieltyka A, Grzywocz J, Hajduk G*
- 4151** Celiac disease and Sjögren's syndrome: A case report and review of literature  
*Balaban DV, Mihai A, Dima A, Popp A, Jinga M, Jurcut C*
- 4162** Nonasthmatic eosinophilic bronchitis in an ulcerative colitis patient – a putative adverse reaction to mesalazine: A case report and review of literature  
*Cernomaz AT, Bordeianu G, Terinte C, Gavrilescu CM*
- 4169** Insulinoma presenting with postprandial hypoglycemia and a low body mass index: A case report  
*Přidavková D, Samoš M, Kyčina R, Adamicová K, Kalman M, Belicová M, Mokáň M*
- 4177** Neoadjuvant chemoradiotherapy for locally advanced gastric cancer with bulky lymph node metastasis: Five case reports  
*Nomura E, Kayano H, Machida T, Izumi H, Yamamoto S, Sugawara A, Mukai M, Hasebe T*
- 4186** Unilateral pleuroparenchymal fibroelastosis as a rare form of idiopathic interstitial pneumonia: A case report  
*Lee JH, Jang HJ, Park JH, Kim HK, Lee S, Kim JY, Kim SH*
- 4193** Superior mesenteric vein thrombosis induced by influenza infection: A case report  
*Oh GM, Jung K, Kim JH, Kim SE, Moon W, Park MI, Park SJ*
- 4200** Mucinous adenocarcinoma of the buttock associated with hidradenitis: A case report  
*Kim SJ, Kim TG, Gu MJ, Kim S*
- 4207** TFE3-expressing malignant perivascular epithelioid cell tumor of the mesentery: A case report and review of literature  
*Kim NI, Lee JS, Choi YD, Ju UC, Nam JH*
- 4215** Robotic surgery in giant multilocular cystadenoma of the prostate: A rare case report  
*Fan LW, Chang YH, Shao IH, Wu KF, Pang ST*
- 4223** Multiple recurrent neurofibromas in the abdominal wall: A case report  
*Zhao XF, Shen YM, Chen J*
- 4228** Mine disaster survivor's pelvic floor hernia treated with laparoscopic surgery and a perineal approach: A case report  
*Chen K, Lan YZ, Li J, Xiang YY, Zeng DZ*

- 4234** Successful treatment of encrusted cystitis: A case report and review of literature  
*Fu JG, Xie KJ*
- 4245** Massive pulmonary haemorrhage due to severe trauma treated with repeated alveolar lavage combined with extracorporeal membrane oxygenation: A case report  
*Zhang BY, Chen XC, You Y, Chen M, Yu WK*
- 4252** Gitelman syndrome caused by a rare homozygous mutation in the *SLC12A3* gene: A case report  
*Yu RZ, Chen MS*
- 4259** Arterial embolism caused by a peripherally inserted central catheter in a very premature infant: A case report and literature review  
*Huang YF, Hu YL, Wan XL, Cheng H, Wu YH, Yang XY, Shi J*
- 4266** Left bundle branch pacing with optimization of cardiac resynchronization treatment: A case report  
*Zhang DH, Lang MJ, Tang G, Chen XX, Li HF*
- 4272** Lymphoplasmacyte-rich meningioma with atypical cystic-solid feature: A case report  
*Gu KC, Wan Y, Xiang L, Wang LS, Yao WJ*

**ABOUT COVER**

Editorial board member of *World Journal of Clinical Cases*, Dr. Li is a Professor at the Nanjing University Medical School in Nanjing, China. Having received his Bachelor's degree from Xuzhou Medical College in 1997, Dr. Li undertook his postgraduate training first at Nanjing Medical University, receiving his Master's degree in 2004, and then at Fudan University, receiving his PhD in 2007. He advanced to Chief Physician in the Department of Anesthesiology at The Affiliated Hospital of Nanjing University Medical School in 2017 and has held the position since. His ongoing research interests involve ultrasound (transthoracic echo and transesophageal echo) in clinical anesthesia and ultrasound-guided limb and trunk nerve block in postoperative pain management. (L-Editor: Filipodia)

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## Retrospective Study

# Clinical value of needleless sling in treatment of female stress urinary incontinence

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**Author contributions:** Chen YG and Zhang YG contributed equally to this work and should be considered as co-first authors; Zhang W and Zhang YG performed the operation; Chen YG and Li X designed this retrospective study; Chen YG wrote the paper; Zhang YG was responsible for sorting the data.

**Institutional review board**

**statement:** The study was reviewed and approved by the Beijing Hospital Institutional Review Board.

**Informed consent statement:**

Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

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## Abstract

### BACKGROUND

Stress urinary incontinence (SUI) is a common disease in women. The emergence of the needle-free sling has led to a new clinical treatment for SUI in women.

### AIM

To explore the clinical value of the needleless sling without acupuncture in the treatment of SUI in women.

### METHODS

From February 2017 to November 2018, according to the order of admission, 44 patients (mid-suspension group) were treated by tension-free transobturator urethral suspension, and 44 patients (non-acupuncture group) were treated with a needleless non-acupuncture band. The clinical effects of the two treatments were evaluated.

### RESULTS

There was no significant difference between the two groups in the total clinical effectiveness rate ( $P = 0.374$ ), but intraoperative blood loss and visual analogue scale score at postoperative day 1 were significantly lower in the non-acupuncture suspension group than in the middle urethral suspension group ( $P = 0.396$ ). The incidence of complications in the needle-free sling group was significantly lower

**Data sharing statement:** No additional data are available.

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than that in the middle urethral suspension group ( $P = 0.025$ ).

## CONCLUSION

The clinical effectiveness of acupuncture-free suspension in treating SUI in female patients is better than that of traditional tension-free transobturator mid-urethral suspension.

**Key Words:** No needle sling; Female stress urinary incontinence; Mid-urethral suspension; Controlled study; Complications; Application value

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**Core Tip:** Stress urinary incontinence (SUI) is mainly characterized by the involuntary overflow of urine when there is a sudden rise in abdominal pressure caused by actions such as coughing, laughing, and exertion, and it does not persist in daily life. At present, there are many methods available for SUI, such as life feedback training and pelvic floor muscle function exercises. However, these kinds of treatment are time-consuming and have highly variable curative effects. In this study, the clinical value of the needleless sling without acupuncture in the treatment of SUI in women was analyzed.

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## INTRODUCTION

Stress urinary incontinence (SUI) is a common disease in women<sup>[1,2]</sup>. It is mainly characterized by the involuntary overflow of urine when there is a sudden rise in abdominal pressure caused by actions such as coughing, laughing, and exertion, and it does not persist in daily life<sup>[3]</sup>. According to an epidemiological analysis, female SUI mainly occurs in middle-aged and elderly women. The current global incidence of female SUI is approximately 12.5%-22.5%, while the incidence of female SUI in China is 18.9-28.0%, which is higher than the international average<sup>[4]</sup>.

The severity of SUI varies; patients with mild cases only have very little urine overflow, which leads to a small impact on daily life, but some severe urinary incontinence cases lead to more urine overflow, which seriously affects patients' daily life. At present, there are many methods available for treating stress incontinence, such as life feedback training and pelvic floor muscle function exercises. However, these kinds of treatment are time-consuming and have highly variable curative effects<sup>[5]</sup>.

Tension-free mid-urethral suspension is a common surgical treatment, but some scholars have pointed out that there are some potential risks of the surgical treatment, such as puncture site injuries, hematomas, and long-lasting inguinal area pain; in addition, patients generally develop severe pain after the operation, and the clinical applications are also limited<sup>[6,7]</sup>. With advancements in medicine, the emergence of the needle-free sling has led to a new clinical treatment for SUI in women. However, there are relatively few clinical reports on this treatment. Thus, the clinical value of the needle-free sling is further analyzed in this paper.

## MATERIALS AND METHODS

### Basic information

Eighty-eight women with SUI were admitted to our hospital during the period from February 2017 to November 2018. All the patients were diagnosed with and treated for SUI in accordance with the guidelines (2017) formulated by the gynecological pelvic floor study group of the Chinese Medical Association. According to the standards for diagnosis and treatment, patients were listed in the order of admission, and patients receiving an even number were included in a needleless sling group. Forty-four patients who were treated by tension-free transobturator urethral suspension were

included in a mid-suspension group. The basic characteristics of the two groups were not significantly different, and the corresponding data and test values are shown in [Table 1](#). The study was approved by the Ethics Committee of our hospital.

### **Inclusion and exclusion criteria**

The inclusion criteria were as follows: (1) Cough, laughter, and other abdominal pressure rise leading to a large amount of urine leakage; (2) Positive finger pressure test result; (3) Urine blood test result confirming that bladder detrusor function is not abnormal; (4) Absence of urethral infection; and (5) Provision of informed consent for the treatment plan, with a form that was voluntarily signed.

The exclusion criteria were as follows: (1) Pelvic floor muscle function training was underway before admission; (2) History of vaginal surgery or pelvic surgery; (3) Urinary incontinence caused by bladder outlet obstruction; (4) Mixed urinary incontinence or neurogenic urinary incontinence; and (5) Incomplete baseline data.

### **Methods**

In the middle segment urethral suspension group, the patients were placed the lithotomy position, and general anesthesia or lumbar hard combined anesthesia was induced. The anterior vaginal wall was cut, tissue scissors were used to separate the vaginal wall to the side of the urethra, it was separated to the lower pubic branch, and a 0.5 cm incision was made at the inner angle of the closed hole on both sides. The wing guide was inserted at the upper part of the incision of the urethral orifice, and the puncture needle passed through the side space of the pubic branch-closed hole-inguinal incision. In the needleless sling group, the patients were placed in the lithotomy position, and general anesthesia or waist hard joint anesthesia was induced. An incision was made in the urethral mouth measuring 1 cm, the vaginal forearm was cut, the blunt separation was performed along the line at 10 o'clock and 12 o'clock, and the lower pubic branch was separated. The bending forceps were used to clamp the T-type pocket without the needle sling, passing through the completed separation gap from the 10 o'clock direction, reaching the posterior edge of the lower pubic branch. The bending forceps were opened to perform the T-type pocket position, and sling-tie fixation was completed in the internal closed hole muscle. The above operation was repeated along the side from the 2-o'clock direction. The position of the T-type pocket was adjusted on both sides, and the blue line of the middle sling was aligned with the middle line. After the calibration line was removed, the surgical incision was cleaned and sutured.

### **Curative effect evaluation and observation indexes**

The treatment was considered highly effective when the SUI symptoms basically disappeared and the cough-leak urine test result was negative. It was considered effective when pressure urinary incontinence symptoms were still present and the cough-leak urine test result was positive but the volume of urine leakage was reduced by less than 50% compared with before treatment. The treatment was considered invalid when the urinary incontinence symptoms were still present and the volume of urine leakage was reduced by < 50%. The total clinical effectiveness rate was calculated as (number of cured cases + number of valid cases)/total number of cases × 100%.

A one-year follow-up was conducted to assess the quality of life of the patients before and 12 mo after the operation. The evaluation tools used were the ICIQ-SF questionnaire and the IIQ-7 questionnaire.

The pain assessment was performed at postoperative day 1 by using the visual analogue scale (VAS) with a total score of 0 to 10 points, which was proportional to the degree of pain. The incidence of urinary retention, infection, hematomas, and other complications was calculated.

### **Statistical analysis**

SPSS 23.0 software was used to analyze the data. Continuous data ( $\pm$  SD) were analyzed using the *t* test, and count data (%) were analyzed using the chi-squared test. *P* < 0.05 indicated statistical significance.

**Table 1 Comparison of baseline data between the two groups**

Baseline data	Needle free sling group (n = 44)	Middle urethra suspension group (n = 44)	$\chi^2/t$	P value
Educational background, n (%)				
Junior middle school	3 (6.82)	4 (9.09)	0.352	0.553
High school	19 (43.18)	20 (45.45)	0.104	0.747
Junior college or above	22 (50.00)	20 (45.45)	0.415	0.519
Age (yr)	52.58 (5.96)	53.02 (6.02)	0.345	0.731
Course of disease (yr)	2.06 (0.26)	2.08 (0.28)	0.347	0.729
BMI (kg/m <sup>2</sup> )	24.51 (2.16)	24.86 (2.22)	0.750	0.456
Birth history (Times)	1.63 (0.28)	1.68 (0.31)	0.794	0.429
Residual urine volume (mL)	15.06 (3.54)	15.22 (3.41)	0.216	0.830

BMI: Body mass index.

## RESULTS

### **Comparison of clinical curative effect between the two groups**

There was no statistically significant difference in the total clinical efficiency between the needle-free sling group and the urethral mid-suspension group ( $P = 0.374$ ), and the data are shown in [Table 2](#).

### **Comparison of complications between the two groups**

The incidence of complications in the needle-free sling group was significantly lower than that in the middle segment of the urethra suspension group ( $P = 0.025$ ), as shown in [Table 3](#).

### **Comparison of perioperative observation indexes between the two groups**

The volume of blood loss was significantly smaller, the operative time was significantly shorter, and the 1 d VAS score was significantly lower in the needleless sling group than in the middle urethral suspension group ( $P = 0.001$ ,  $0.001$ , and  $0.001$ , respectively). However, the total length of stay was not statistically significant between the two groups ( $P = 0.225$ ), as detailed in [Table 4](#).

### **Comparison of quality of life scores between the two groups**

According to the data shown in [Table 5](#), at 12 mo after the operation, the ICIQ-SF and IIQ-7 scores decreased significantly in both groups compared with those before the operation, but the scores were not significantly different between the two groups ( $P = 0.713$ ,  $0.628$ ,  $0.859$ , and  $0.396$ , respectively).

## DISCUSSION

According to physiological anatomy, the female urethra is shorter than the male urethra and is more prone to SUI, which is mainly characterized by the uncontrolled overflow of urine under conditions such as coughing and laughing<sup>[8]</sup>. Clinical studies have suggested that related factors that can induce SUI include a decline in urethral sphincter function caused by aging, pelvic floor muscle group injury caused by fertility, and pelvic organ prolapse<sup>[9]</sup>. In view of the impact of this disease on women's daily life, there is no effective intervention, and long-term complications include lower abdomen pain, pudendal skin ulceration, bladder lithotomy, urinary system infection, and other serious complications; thus, timely and effective treatment is required<sup>[10]</sup>.

At present, the commonly used treatment methods include routine pelvic floor muscle rehabilitation exercises and biofeedback training, which can improve the symptoms of SUI by restoring pelvic floor muscle function. However, in clinical practice, these kinds of conservative treatment should be carried out for a long time, and some patients cannot continue to perform these exercises for a sufficiently long time for the treatment to be effective<sup>[11]</sup>. Surgical treatment is another common option

**Table 2 Comparison of therapeutic effect between the two groups, *n* (%)**

Curative effect	Needle free sling group ( <i>n</i> = 44)	Middle urethra suspension group ( <i>n</i> = 44)	$\chi^2$	<i>P</i> value
Cure	31 (70.45)	29 (65.91)	0.475	0.491
Effective	12 (27.27)	13 (29.55)	0.128	0.721
Invalid	1 (2.27)	2 (4.55)	0.789	0.374
Total clinical effective rate	43 (97.73)	42 (95.45)	0.789	0.374

**Table 3 Comparison of complications between the two groups, *n* (%)**

Complication	Needle free sling group ( <i>n</i> = 44)	Middle urethra suspension group ( <i>n</i> = 44)	$\chi^2$	<i>P</i> value
Infection	1 (2.27)	3 (6.82)	2.386	0.122
Hematoma	0 (0.00)	1 (2.27)	2.296	0.130
Urinary retention	1 (2.27)	2 (4.55)	0.789	0.374
Incidence of complications	2 (4.55)	6 (13.64)	4.997	0.025

**Table 4 Comparison of several perioperative observation indexes between the two groups**

Index	Needle free sling group ( <i>n</i> = 44)	Middle urethra suspension group ( <i>n</i> = 44)	<i>t</i>	<i>P</i> value
Total length of stay (d)	1.93 (0.56)	2.08 (0.59)	1.223	0.225
Operation time (min)	10.25 (2.01)	20.51 (3.95)	15.356	0.001
VAS score at 1 d after operation	3.48 (1.02)	5.63 (1.52)	7.791	0.001
Intraoperative blood loss (mL)	38.14 (5.22)	53.61 (8.94)	9.912	0.001

VAS: Visual analogue scale.

**Table 5 Comparison of quality of life scores between two groups**

Quality of life assessment	Needle free sling group ( <i>n</i> = 44)	Middle urethra suspension group ( <i>n</i> = 44)	<i>t</i>	<i>P</i> value
ICIQ-SF (sub)				
Preoperative	14.31 (3.14)	14.56 (3.21)	0.369	0.713
Postoperative	1.52 (0.36) <sup>a</sup>	1.48 (0.41) <sup>a</sup>	0.486	0.628
IIQ-7 (sub)				
Preoperative	9.61 (2.14)	9.53 (2.06)	0.179	0.859
Postoperative	0.93 (0.16) <sup>a</sup>	0.96 (0.17) <sup>a</sup>	0.852	0.396

<sup>a</sup>*P* < 0.05, 12 mo after operation in the group *v* that before operation.

for the clinical treatment of SUI in these patients.

Studies conducted outside of China have suggested that the pubic ligament and pubic tail muscle are similar to the hammocks in the female middle urethra. When the structure is destroyed, the abdominal pressure may rise, that is, urinary incontinence may occur. In clinical treatment, the reconstruction of a hammock structure can effectively treat urinary incontinence. Tension-free urethral mid-suspension (TVT) is based on this theory<sup>[12]</sup>. TVT has been used widely in clinical practice, with favorable curative effects, and the success rate of the operation is as high as 86%-99%. However, a follow-up study showed that patients need to undergo bladder examinations, which can easily cause bladder perforation, hematomas, and complications such as dysuria after the operation. The treatment has been improved to include an improved puncture path, and the improved treatment is referred to as tension-free

transobturator urethral suspension (TVT-O). Essentially, the puncture is performed through the obturator rather than the traditional puncture path, and the posterior pubic region is avoided. Compared with the TVT operation, TVT-O significantly reduces the risk of bladder perforation, but it can increase the severity of inguinal pain in patients during the puncture, and there are some limitations in the application<sup>[13]</sup>. Single incision slinging (SIMS) was developed to improve the TVT-O operation<sup>[14]</sup>. It does not require punctures through the posterior space or obturator, but the total area of the sling is 6.5 cm<sup>2</sup>, which is much lower than the area of the TVT and TVT-O slings (16.5 cm<sup>2</sup>). In clinical practice, there are limitations of using short slings and a relatively small area of support, which can easily lead to a decline in the sexual quality of life of patients and vaginal perforation<sup>[15,16]</sup>.

Needleless straps, as a product of modern medical advancements, have been designed by Spanish doctors to further improve the technique<sup>[17]</sup>. The two ends of a T-type bag are used for the needle-free sling and as a whole are considered a "worker" type; the length of the sling is 11.4 cm, the width of the pockets at both ends is 2.2 cm, and the width of the middle of the sling is 1.2 cm. The non-knot knitting technique used in the needleless sling can prevent the formation of a dead cavity after implantation with knots, as is common with the traditional sling, resulting in a large number of bacterial propagation and infection defects; in addition, the nonwoven structure gives the sling a certain degree of freedom inside the soft tissue of the patients, which can significantly reduce discomfort in patients after the sling is implanted and prevent a decline in their sexual quality of life<sup>[18]</sup>. In addition, the large aperture design used in sling knitting enables growth and fast recovery after implantation, and its contact area is 16.08 cm<sup>2</sup> larger than twice the support area of SIMS. In recent years, the needleless sling has gradually been accepted by patients, and the acceptance by clinicians is high<sup>[19]</sup>.

Overall, needleless straps have the advantages of SIMS and TVT-O, and the T-type pocket without needle straps can be directly fastened to the obturator muscle of the patient. The area of the straps is larger and the support effect is stronger with the needleless technique compared with SIMS, and the effect of urinary incontinence treatment is similar to that of TVT-O. The use of SIMS with the single-section approach can effectively prevent the occurrence of bladder perforation, nerve injury and other adverse events, and it can also effectively reduce the risk of postoperative dysuria, pain, decline in patients' sexual quality of life, and other complications<sup>[20]</sup>. In this study, there was no significant difference in the total effectiveness rate and the quality of life score on the questionnaire between the needleless and middle urethra suspension group at 12 mo after the operation. The results showed that the effect of needleless suspension and TVT-O in the treatment of female SUI was basically the same, but the VAS score at postoperative day 1, intraoperative blood loss, and postoperative complications were better than those in the middle urethra group. There was no significant difference in the total length of hospital stay between the two groups. The results showed that the two procedures were minor and the patients recovered rapidly, so the total length of hospital stay was not significantly different.

Chang *et al.*<sup>[19]</sup> compared the results of the clinical treatment of female SUI by the needleless sling and conventional TOT (TVT-O). The results of the perioperative time, VAS score at postoperative day 1, intraoperative blood loss, and hospitalization time were better in the needleless group than in the TOT group. There was no significant difference between the two groups in the ICIQ-SF scores or the average quality of life between the two groups. According to Xu *et al.*<sup>[2]</sup>, the results showed that the incidence of postoperative complications in the observation group was significantly lower than those in the control group (TVT-O), but there was no significant difference in the total clinical efficiency or quality of life scores between the two groups. However, the number of patients included in this study is small, and the results of the study may be affected by the small sample size; however, the differences were large, and future studies with larger sample sizes need to be conducted.

In summary, the clinical effectiveness of the two treatment options, TVT-O and the needleless sling, are basically the same in the clinical treatment of SUI in women, but the needleless sling has the advantages of fewer complications, shorter operative time, and milder postoperative pain in patients.

## ARTICLE HIGHLIGHTS

**Research background**

The emergence of the needle-free sling has led to a new clinical treatment for stress urinary incontinence in women.

**Research motivation**

Explore the new treat in stress urinary incontinence.

**Research objectives**

Analyzed the clinical value of the needle-free sling is further in this paper.

**Research methods**

Choose 44 patients in the mid-suspension group treated by tension-free transobturator urethral suspension, and 44 patients in the non-acupuncture group.

**Research results**

There was no significant difference between the two groups in the total clinical effectiveness rate, but the intraoperative blood loss and the postoperative 1 d visual analogue scale score were significantly lower in the non-acupuncture suspension group than in the middle urethral suspension group. The incidence of complications in the needle-free sling group was significantly lower than that in the middle urethral suspension group.

**Research conclusions**

The needleless sling had the advantages of fewer complications, a shorter operative time and milder postoperative pain in patients, which could be actively promoted.

**Research perspectives**

The concept of minimally invasive and people-oriented should be widely used in clinical nursing.

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