Int J Clin Exp Med 2017;10(4):7084-7090
www.ijcem.com /ISSN:1940-5901/IJCEM0049755

Original Article

The clinical efficacy of needleless sling technique and TOT in the treatment of female stress urinary incontinence: a prospective randomized controlled trial

Qibo Fu[1], Jianwei Lv[1], Weilin Fang[1], Chen Jiang[1], Yinjun Gu[1], Jing Leng[2], Wei Xue[2]

[1]Department of Urology, South Campus, Renji Hospital, School of Medicine, Shanghai Jiaotong University, Shanghai, P. R. China; [2]Department of Urology, Renji Hospital, School of Medicine, Shanghai Jiaotong University, Shanghai, P. R. China

Received January 27, 2017; Accepted February 17, 2017; Epub April 15, 2017; Published April 30, 2017

Abstract: Objective: To evaluate the efficacy and safety of the single-incision Needleless sling technique in the treatment of female stress urinary incontinence. Methods: From Sept. 2014 to Sept. 2015, 164 consecutive subjects were enrolled in the study and were randomized by envelope technique at the time of surgery to either a trans-obturator vaginal tape (TOT) or Needleless anti-incontinence procedure. Parameters in perioperative period such as operating time, intraoperative hemorrhage volume, length of stay in hospital, intraoperative complications, and postoperative pain of each patient were recorded. In the follow-up visits, the parameters of operation cure rate, stress urinary incontinence score and groin pain/femoribus internus pain were also recorded and the incontinence questionnaire-short form (ICIQ-SF) was completed. Results: A total of 164 patients assessed for eligibility were randomized into Needleless groups (n=78) and TOT (n=86). There were no significant differences in age, body mass index, process, parity, pad test or the assessment of preoperative quality of life between the two groups. In the perioperative period, statistically significant differences between the two groups were found in operating time, intraoperative hemorrhage volume, groin pain scores at 24 h after operation and length of stay in hospital ($P<0.001$). After two weeks of follow-up, a statistically significant difference between the two groups was found in groin pain/femoribus internus pain scores, but there were no significant differences in cure rates, pad test, complications or ICIQ-SF. After 1 year, there were no significant differences between the Needleless and TOT groups in cure rates, pad test, groin pain or ICIQ-SF ($P>0.05$). Both groups registered a significant improvement in the quality of life ($P<0.001$), but there were no significant differences between the two groups ($P>0.05$). Conclusion: Comparing with TOT, the single incision Needleless sling technique was a safe, effective treatment with fewer side effects and less complications.

Keywords: Needleless, single incision, stress urinary incontinence, surgery

Introduction

Midurethral tension free vaginal tape (TVT) and trans-obturator vaginal tape (TOT) are the golden standard of surgery in the treatment of female stress urinary incontinence now. But both of them can cause intraoperative complications such as vascular injury, vesical perforation, groin pain or femoribus internus pain [1, 2]. Preliminary studies abroad have suggested that Needleless slings technique, as a form of single incision mini slings (SIMS), may have a better clinical efficacy. To further investigate its safety and efficacy in clinical applications, we conducted randomized controlled trials to study the clinical efficacy of needleless sling technique and TOT in the treatment of female stress urinary incontinence. The research procedure and results were as follows.

Materials and methods

Subjects

Approved by Ethics Committee, female patients, who were diagnosed as having stress urinary incontinence and required surgery from Sept. 2014 to Sept. 2015, were enrolled in this study. The major clinical manifestation of these female patients was the leakage of urine while coughing or running. According to the 1 h-pad test, all of the patients could be classified into

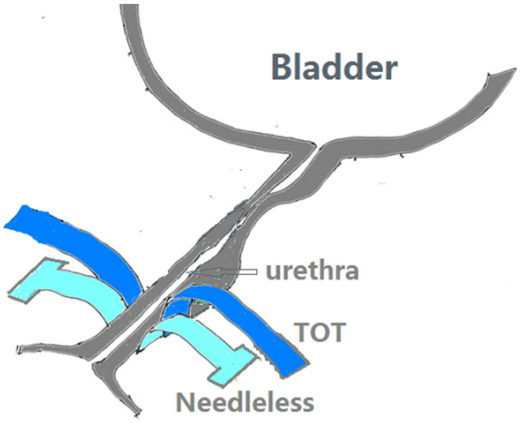

Figure 1. TOT sling penetrated through the incision of anterior vaginal wall, traversed obturator membrane and out of both sides of the incision in the root of the thigh. Needleless sling penetrated through the incision of anterior vaginal wall, the T sling was expanded and fixed after breaking through the obturator membrane.

mild or moderate urinary incontinence (leakage of urine ≤10 g/h).

Inclusion criteria

Simple stress urinary incontinence patients, aged from 35 to 70 years old, underwent urodynamic studies before operation. Cough stress tests (CST) were performed when patients were in lithotomy position and bladder capacities were 250 ml and the result was positive. Exclusion criteria: abdominal pressure <60 cmH_2O, leak point pressure <60 cmH_2O; Patients with urge urinary incontinence (UUI), urethral sphincter injury (maximal urethral closure pressure <20 cmH_2O), or pelvic organ prolapse. And patients who had a history of urge urinary incontinence (UUI) or pelvic organ prolapse operation, pelvic organ disease such as terine fibromyomata and so on. (Loss to follow-up was the problem happened in procedure, which should not be listed in exclusion criteria).

Preoperative evaluation

Baseline assessments included patient's age, body mass index (BMI), childbearing history, 1 h-pad test, post-void residual urine volume (PVR), incontinence questionnaire-short form (ICIQ-SF).

Grouping

Having all the patients who met the criteria signed informed consent, group assignments were made and the surgical methods were selected via random selection of opaque labelingenvelope by lab assistant (a total of 200 envelopes, 100 for group A, 100 for group B, group A performing needleless surgery, group B performing TOT surgery). Those lab assistants were non-surgical staff and perioperative management staff. In view of the specificity of surgical treatment, patients and their families were informed of surgical methods and related surgical risks before operation and signed the consent of the surgery; and the surgeon was informed of the surgical approach at the beginning of surgery.

Introduction of surgical approaches

Patients were given general anesthesia or continuous epidural anesthesia (CEA) with lithotomy position and an incision was made on the anterior vaginal wall, which was separated from both sides of urethra to inferior ramus of pubis by using tissue scissors. TOT surgery: longitudinal skin incisions about 0.5 cm were made in both sides of the obturator foramen, pass spiral puncture needle was inserted into the incision in the root of the thigh and handle was rotated to make puncture needle penetrate the obturator membrane and occlusor. Then, inserted the middle finger or the index finger into the incision of anterior vaginal wall to guide puncture needle out of the incision and rotated the needle handle reversely to pull out the sling from the incision of skin in the root of the thigh and adjusted the position between the sling and the urethra. At last, plastic sleeve was drawn out and incision was sutured. Needleless sling surgery: the T-pocket of Needleless sling was clipped with a special curved forceps and reached the posterior margin of the inferior ramus of pubis from the 10 o'clock direction bypass. After breaking through the obturator membrane, the T sling was inserted into it and the head of T sling was completely opened in the internal muscle of obturator foramen. Then, the curved forceps withdrew at the state of half-closed. Afterwards, the head of the Tsling was inserted into the other side along the 2 o'clock direction with the same method, tension control was used to make the sling could fully fit the urethra and in the end, the incision was sutured. After operation, the vagina was packed with iodophors gauze for 1 day. Urinary catheter was indwelled in TOT group for 2 days and in Needleless group, for 1 day (**Figure 1**).

Table 1. Comparison of preoperative clinical data of patients in two groups

Items	Needleless group (n=78)	TOT group (n=86)	*P* value
Age/y	52.35±10.02	52.43±10.86	0.96
BMI/kg·m^{-2}	26.04±3.46	25.85±3.71	0.74
Course of Desease/m	24.82±13.04	26.81±12.10	0.31
Pad test/g	6.04±2.28	6.55±2.55	0.18
Childbearing History/times	1.64±0.64	1.64±0.72	1.00
PVR/ml	14.81±8.88	12.79±9.26	0.16
ICIQ-SF	13.96±2.74	13.98±2.42	0.96

Evaluation and standard of the efficacy

(1) Perioperative periodassessment: Main outcome measurements included operating time, intraoperative hemorrhage volume and visual analog scale (VAS) pain scores at 24 h after operation; secondary outcome measurements included residual urine volume, length of stay (in hospital), the incidence of urinary retention, recent onset frequent urination, urinary urgency, infection and so on. (2) The assessment of postoperative curative effect and safety: the curative effect in patients was evaluated at 2 weeks, 6 months and 12 months after operation, the main index was Patient Global Impression of Improvement (PGI-I), 1 h-pad test and ICIQ-SF scores, secondaryindex included pain scores in VAS of groin and femoribus internus and the symptoms of residual urine and frequent urination.

Statistical analysis

SPSS19.0 software was adopted for statistical analysis, quantitative count data were expressed by mean ± standard deviation (x±s) and t test was used for the group comparison; qualitative data were examined by χ^2 test and the grade grouping data were demonstrated by Ridit and P<0.05 was considered statistically significant.

Results

Grouping and clinical data

Among 179 cases of patients enrolled, 15 cases were lost to follow up. Therefore, 164 cases of patients were enrolled in this research actually. These patients were divided into two groups: 78 cases in Needleless surgery group and 86 cases in TOT surgery group. Before operation, no significant difference existed in the general data of two groups (P<0.05). Besides, the scoring data of ICIQ-SF (Incontinence Questionnaire-short Form) revealed no difference in severity degrees of urinary incontinence and its influence on the life qualities of patients (P<0.05) (**Table 1**).

The conditions of two groups in perioperative period

Needless group was superior to TOT group in operating time, pain in 24 h after operation and length of stay in hospital (P<0.001). No difference existed in post-void residual urine volume (PVR) of two groups (P>0.05). In Needleless group after operations, 6 cases of recent onset urinary frequency and urgency occurred, but there was no intraoperative complication, such as urinary retention, postoperative infection. While in TOT group, 8 cases of recent onset urinary frequency and urgency occurred, two of which had the symptom of urge urinary incontinence, and there were 2 cases of urinary retention and 1 case of postoperative infection (**Table 2**). There was no difference in intraoperative complications above of two groups. All the patients got better after symptomatic treatments (patients of urinary frequency and urgency were treated with oral M receptor blocker, the patients of urinary retention, with indwelling catheterizations, and the patients of postoperative infection, with anti-infective therapy and incision nursing).

The follow-up results of two groups at 2 weeks after operations

No obvious difference was found in subjective cure rate, 1 h-pad test, ICIQ-SF scoring, residual urine volume and the incidence of frequent urination between two groups (P>0.05). Needleless group was superior to TOT group in VAS pain scores of groin and femoribus internus (P<0.001). Biofeedback pelvic floor rehabilitation therapy was performed on the patients who had symptoms of leakage of urine after moving (the condition of these patients, getting better or not being healed yet, was revealed by PGI-I) (**Table 3**). All the patients had no symptoms of hematuria or fever.

Table 2. Comparison of patients' conditions in the peroperative period in two groups

Items	Needleless group (n=78)	TOT group (n=86)	*P* value
Operating time/min	11.67±2.78	20.29±3.04	P<0.001
Intraoperativehemorrhage volume/ml	17.55±7.54	22.70±4.67	P<0.001
VAS (24 h after operation)	0.92±0.79	3.56±2.48	P<0.001
PVR/ml	16.60±10.43	19.04±37.64	0.58
Urinary retention	0% (0/78)	2.33% (2/86)	0.52
Frequent urination	7.69% (6/78)	9.30% (8/86)	0.93
Length of stay/d	1.49±0.50	3.05±0.95	P<0.001

Table 3. Comparison of follow-up conditions and effects at 2 weeks after operations

Items	Needleless group (n=78)	TOT group (n=86)	*P* value
PGI-I (recovered)	80.77% (63/78)	81.40% (70/86)	0.97
PGI-I (improved)	12.82% (10/78)	10.4% (9/86)	0.97
PGI-I (not improved)	6.41% (5/78)	8.14% (7/86)	0.97
1 h-pad test/g	1.56±2.53	1.69±2.68	0.75
ICIQ-SF	2.49±3.32	3.05±3.67	0.31
VAS	0.36±0.48	1.88±2.05	P<0.001
Residual urine volume/ml	10.83±5.83	15.87±27.46	0.14
Frequent urination	5.13% (4/78)	7.00% (6/86)	0.87

Table 4. Comparison of follow-up conditions and curative effects at 6 months after operations

Items	Needleless group (n=78)	TOT group (n=86)	*P* value
PGI-I (recovered)	91.03% (71/78)	90.70% (78/86)	0.94
PGI-I (improved)	8.97% (7/78)	9.30% (8/86)	0.94
PGI-I (not improved)	0% (0/78)	0% (0/86)	0.94
1 h-pad test/g	0.97±1.26	0.87±1.20	0.65
ICIQ-SF	1.37±1.50	1.48±1.61	0.31
VAS	0	0.14±0.77	0.11
Residual urine volume/ml	11.41±7.16	12.26±8.53	0.49
Frequent urination	0	2.33% (2/86)	0.52

The follow-up results of two groups at the 6th and 12th month after operations

The patients of two groups were evaluated at the 6th and 12th month after operations. There were no differences in subjective cure rate, 1 h-pad test, ICIQ-SF rating, residual urine volume and the incidence of frequent urination between two groups (P>0.05). The incidence of pain of groin/femoribus internus in Needleless group was slightly lower than TOT group, but no significant difference existed in the pain scores of two groups (P=0.17) (as shown in **Tables 4**, **5**). All the patients of two groups had no symptoms of infection and sling exposed.

Discussion

Stress urinary incontinence (SUI) is a common disease of middle and old aged women. In China, its prevalence rate in adult female is about 18.9% while the highest prevalence, occurring in their 50 s, is 28% [3]. TVT proposed by Ulmsten and other doctors [4] as well as TOT proposed by Delorme [5] are considered as standard midurethral slings (SMUS). However, having been considered to have the advantages of smaller wounds, less pains, shorter length of stay and more rapid postoperative recovery, the recent single incision mini slings (SIMS) is getting its popularity gradually. As a branch of SIMS, Needleless slings implantation technique applies the approach of single-incision to anterior vaginal wall and midurethral, theoretically avoiding the intestine of bladder and perforation in TVT and obturator nerve injury in TOT. But it lacks defined supporting clinical data. A multi-center study [6] in Spain in 2007 showed that among 230 patients, who were performed Needleless slings implantation, 86% of them were cured while 6% of them had symptomatic improvement. Rogersiv [7] compared the curative effect of Needleless slings implantation and TVT-O as well as followed up the patients for 24 months. The result turned out to be the same between the two types of operation. And patients who were performed Needleless slings implantation showed a higher degree of surgi-

Table 5. The comparison of curative efficacy between two groups of patients at 12 months after operations

Items	Needleless group (n=78)	TOT group (n=86)	*P* value
PGI-I (cured)	94.87% (74/78)	93.02% (80/86)	0.62
PGI-I (improved)	5.13% (4/78)	6.98% (6/86)	0.62
PGI-I (uncured)	0% (0/78)	0% (0/86)	0.62
1 h-pad test/g	0.85±1.15	0.80±1.09	0.76
ICIQ-SF	1.32±1.43	1.24±1.15	0.69
VAS	0	0.12±0.76	0.17
PVR/ml	11.15±7.89	10.35±7.15	0.50
Frequent urination	0	0	1.00

cal satisfaction. Karateke and other doctors [8] performed Needleless slings implantation on 50 patients with SUI and followed them up with an average period of 433.5 days. 96% of the patients showed a higher satisfaction in quality of life. It was found in this paper that Needleless slings implantation obviously outperformed TOT in length of surgery, intraoperative hemorrhage volume and length of stay. There was no statistical difference between two groups in the comparison of complications such as fever, infection, frequent urination, urge urinary incontinence, and urinary retention as well as in the comparison of short-term curative effect which respectively accounted for 88.46% and 89.53%. The result of study was consistent to the studies abroad [9-12]. The result of long-period follow-up of this study indicated that there was no obvious statistical difference between the two types of slings operation in long-term subjective cure rate, respectively accounting for 92.30% and 93.02%, which also consistent to the result of studies abroad [13, 14].

The design of SIMS slings, featuring shorter puncture approach, avoids the loss of thigh adductor muscles so that postoperative pain of groin/femoribus internus can be reduced. Therefore, the incidence of inguina/femoribus internus pains in SIMS is lower than in TOT surgery. This is in agreement with report in related literature [15, 16]. Also, the result of Meta-analysis of a prospective study showed that SIMS outperformed TOT/TVT-O in postoperative inguinal region pains and intensity of the pain shared no obvious statistical difference between the two operations at twelve months after surgery [17]. Studies performed by Martinez et al. [18] showed that postoperative pain of Needleless operation was significantly lower than that of TVT-O, which was similar to the results of this study. In terms of the pain scores at 24 h after operation, the outcome of the Needleless group was greatly superior to that of the TOT group (P<0.001). Patients in the TOT group were mainly characterized by inguinal region pains and the pain would get worse after exercise, and the puncture might cause the adductor muscles injuries; while patients in the Needleless group mainly manifested as the pain and discomfort of vaginal incisions as the puncture was confined to obturator membrane and did not penetrate obturator externus, thus there was no injury of tendon and no obvious pain in inguinal region/femoribus internus. During the long-term follow-up, none of the patients in Needleless group had the pain in inguinal region/femoribus internus while there were two cases in the TOT group having recalcitrant pain in inguinal region/femoribus internus. However, there was no statistic difference in VAS scores between two groups. The above proved that Needleless surgery owned obvious advantage in reducing postoperative pain.

In theory, due to the design of two-piece T sling, Needleless sling is able to be fixed into the obturator internus, and the contact area of the sling in midurethral is similar to TOT surgery. As a consequence, its long-term curative effect can be similar to TOT. In this study, there showed no statistic difference in ICIQ-SF scores of patients in both groups after surgery, but there were significant differences compared to the preoperative data. For patients of both groups, the ICIQ-SF showed that their life quality was greatly improved after operation, the result of which was similar to the reports of related literature [19, 20].

The design of Needleless sling makes it impossible to adjust the tension of the sling after implantation, like TOT sling or TVT sling. So in order to achieve the satisfactory treatment effects, the operators are required to precisely control the depth of puncture to adjust the tension of it, according to the degree of severity of the patient's incontinence. Therefore, the procedural difficulty in Needleless sling surgery is relatively large for the beginners. Moreover, at present, there are no relevant literature and

reports at broad and home about the therapeutic effects of treating severe stress urinary incontinence by using the Needleless sling. In our opinion, the reason why this happens is that the Needleless sling fails to adjust the tension. The tension of the Needleless sling is not able to meet the requirement to treat severe stress urinary incontinence. Therefore, this study did not try it out in that the therapeutic effects of treating severe stress urinary incontinence by using the Needleless sling may not be favorable.

This study is a single-center one with small sample capacity. The follow-up time so far is only one year, which means that the study still lacks long-term follow-up results such as results of 3 or 5 years after surgery. During the later period, the study will continue to expand the amount of samples and meanwhile, further research about the long-term therapeutic effects of the single-incision Needleless sling will be done.

From this study, we conclude that compared with the TOT surgery, single-incision Needleless sling in the treatment of female stress urinary incontinence is simpler and quicker and has less hemorrhage during surgery as well as faster recovery and it also can obviously reduce the inguinal region pains after operation and shorten hospital stays. In summary, single-incision Needleless sling is a kind of convenient, safe and effective minimally invasive surgery for urinary incontinence.

Acknowledgements

This work is supported by SHDC12015911.

Disclosure of conflict of interest

None.

Address correspondence to: Jianwei Lv, Department of Urology, South Campus, Renji Hospital, School of Medicine, Shanghai Jiaotong University, Shanghai 201112, P. R. China. Tel: +86-021-34506563; Fax: +86-021-54435631; E-mail: jianweilv1@126.com

References

[1] Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V, Hilton P, Nilsson CG and Waltregny D. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol 2010; 58: 218-238.

[2] Hazewinkel MH, Hinoul P and Roovers JP. Persistent groin pain following a trans-obturator sling procedure for stress urinary incontinence: a diagnostic and therapeutic challenge. Int Urogynecol J Pelvic Floor Dysfunct 2009; 20: 363-365.

[3] Ostle Z. Assessment, diagnosis and treatment of urinary incontinence in women. Br J Nurs 2016; 25: 84-91.

[4] Ulmsten U, Henriksson L, Johnson P and Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996; 7: 81-85; discussion 85-86.

[5] Delorme E. [Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women]. Prog Urol 2001; 11: 1306-1313.

[6] Cabrera J, Puyol M, Sousa A, Amat L, Baya G. Minimum invasive surgical technique without needle (contasure needleless) for the surgical treatment of stress urinary incontinence: a multicentric trial. European Urology Supplements 2008; 7: 147.

[7] Rogersiv M. A retrospective review of surgical morbidity and long term patient satisfaction with two suburethral slings for stress urinary incontinence: TVT-O versus contasure needleless (single incision TOT). 36th Annual IUGA Meeting, Abstract.

[8] Karateke A, Cam C, Ince SB, Tug N, Selcuk S, Asoglu MR and Vatansever D. Effects of single vaginal incision technique on quality of life in women with stress urinary incontinence. J Minim Invasive Gynecol 2011; 18: 634-639.

[9] Navazo R, Moreno J, Hidalgo C, Herraiz MA, Vidart JA, Salinas J and Silmi A. [Contasure Needleless: a single incision tot for the surgical treatment of stress urinary incontinence]. Arch Esp Urol 2009; 62: 719-723.

[10] ElSheemy MS, Fathy H, Hussein HA, Hussein EA and Hassan SM. Surgeon-tailored polypropylene mesh as a needleless single-incision sling versus TVT-O for the treatment of female stress urinary incontinence: a comparative study. Int Urol Nephrol 2015; 47: 937-944.

[11] Chang CP, Chang WH, Hsu YM, Chen YJ, Wen KC, Chao KC, Yen MS, Horng HC and Wang PH. Comparison of single-incision mini-slings (Ajust) and standard transobturator midurethral slings (Align) in the management of female stress urinary incontinence: a 1-year follow-up. Taiwan J Obstet Gynecol 2015; 54: 726-730.

[12] Jiang T, Xia Z, Cheng D, Song Y, Guo Z, Hu Q, Zhao Y and Yin Y. Short-term outcomes of adjustable single-incision sling (Ajust) procedure for stress urinary incontinence: a prospective single-center study. Eur J Obstet Gynecol Reprod Biol 2015; 186: 59-62.

[13] Gaber ME, Borg T, Samour H, Nawara M and Reda A. Two new mini-slings compared with transobturator tension-free vaginal tape for treatment of stress urinary incontinence: a 1-year follow-up randomized controlled trial. J Obstet Gynaecol Res 2016; 42: 1773-1781.

[14] Amat I Tardiu L, Martinez Franco E and Lailla Vicens JM. Contasure-needleless compared with transobturator-TVT for the treatment of stress urinary incontinence. Int Urogynecol J 2011; 22: 827-833.

[15] Djehdian LM, Araujo MP, Takano CC, Del-Roy CA, Sartori MG, Girao MJ and Castro RA. Transobturator sling compared with single-incision mini-sling for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2014; 123: 553-561.

[16] Nambiar A, Cody JD and Jeffery ST. Single-incision sling operations for urinary incontinence in women. Cochrane Database Syst Rev 2014; CD008709.

[17] Zhang P, Fan B, Han H, Xu Y, Wang B and Zhang X. Meta-analysis of female stress urinary incontinence treatments with adjustable single-incision mini-slings and transobturator tension-free vaginal tape surgeries. BMC Urol 2015; 15: 64.

[18] Martinez Franco E and Amat Tardiu L. Contasure-needleless(R) single incision sling compared with transobturator TVT-O(R) for the treatment of stress urinary incontinence: long-term results. Int Urogynecol J 2015; 26: 213-218.

[19] Navalon V, Navalon P, Pallas Y, Ordono F and Monllor E. Outpatient surgical treatment of female stress urinary incontinence under local anesthesia-sedation with contrasure needleless incision. Actas Urol Esp 2014; 38: 49-54.

[20] Texl J, Huser M, Belkov I, Jurakova M, Hudecek R, Janku P, Rejdova I and Ventruba P. [Efficacy of surgical treatment of stress urinary incontinence with mini-invasive single incision sling]. Ceska Gynekol 2015; 80: 345-350.