

COMPARISON OF TENSION-FREE VAGINAL TAPE AND BURCH COLPOSUSPENSION FOR SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

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SUMMARY – During 2001 and 2002, 15 women hospitalized in Požega County General Hospital underwent the tension-free vaginal tape (TVT) procedure, and 21 women had Burch colposuspension for stress urinary incontinence. The mean age of the patients treated by the TVT method and Burch colposuspension was 50.3 (range 38-72) and 48.6 (range 39-66) years, respectively. Among the 15 women who underwent TVT, ten (66.7%) were less than 50 years old, two (13.3%) were in the 51-60 age group, and three (20.0%) were aged >60. Among 21 women who underwent Burch procedure, 11 (52.4%) were aged <50, nine (42.9%) were in the 51-60 age group, and one (4.7%) patient was aged >60 years ($\chi^2=4.6$; $p=NS$). The mean duration of TVT operation was 38 (range 30-47) minutes, and of Burch operation 49 (range 43-65) minutes. The mean duration of hospitalization was 5.0 (range 3-14) days in patients treated with TVT method, and 15.0 (range 10-18) days in those treated with Burch colposuspension. Of 15 patients treated with TVT method, 12 (80.0%) were hospitalized for less than 7 days, and three (20.0%) for 8-14 days. Of 21 patients treated with Burch colposuspension, ten (47.6%) were hospitalized for 8-14 days, and 11 (52.4%) for more than 14 days ($p<0.001$). Irrespective of the treatment chosen, the correction of stress urinary incontinence was successful in all patients. During the follow-up, stress urinary incontinence was significantly decreased or completely eliminated in all patients. So, we concluded that both operative procedures for stress urinary incontinence correction were equally effective. Despite our relatively short experience with the TVT method, it is surely appropriate for patients with normal gynecologic findings, however, Burch colposuspension is more appropriate in patients with genital prolapse or other benign uterine or adnexal pathology.

Key words: *Urinary incontinence – stress, surgery; Vagina, surgery; Urological surgical procedures, methods; Urodynamics; Female*

Introduction

Urinary incontinence is defined by the International Continence Society (ICS) as a condition in which objectively proven involuntary leakage of urine represents a social and hygienic problem for the patient. Urinary incontinence is divided into two major groups: urethral and

extraurethral¹. Stress incontinence (urethral sphincter incontinence, anatomic stress incontinence) belongs to urethral incontinence. It is defined as a condition in which involuntary leakage of urine through the urethra occurs when intravesical pressure is higher than intraurethral pressure in the absence of detrusor activity. Symptomatically, it is seen as an involuntary leakage of urine on some physical activity, *e.g.*, coughing, sneezing, load lifting, etc. Objectively, there is flow of urine through the urethra due to the increase of intra-abdominal pressure. According to ICS definition, genuine stress incontinence is a urodynamically proven condition consisting of involuntary leakage

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of urine through the urethra when intravesical pressure becomes higher than the maximal intraurethral pressure due to the increase in intra-abdominal pressure in the absence of detrusor contractions¹.

The right choice of treatment, especially surgical, depends on the type and degree of urinary incontinence, the general condition and concomitant diseases of the patient, local findings, the experience of the physician, and the technical equipment of the hospital. Surgical methods are generally used for the correction of stress urinary incontinence (SUI), except when there is a need of bladder denervation¹. As in all correction procedures, indications for surgical treatment of stress incontinence are very complex and should be considered individually. Factors that have to be taken into consideration include the type and degree of stress incontinence, and the parity and age of the female patient¹.

It is important to insist on the key fact, well known but little respected. Namely, it is obvious that the first surgical procedure for the correction of stress incontinence offers the best chance for successful treatment. On any subsequent operation, the operator comes across adhesions, scars, denervation and iatrogenic movement of urinary and genital organs, etc. Therefore, the cure rate of the second, third and any following operation is progressively lower. In order to avoid this, every patient with SUI should undergo all the available preoperative examinations in order to give maximum tactical and technical indications for surgical therapy, so the correction will have the best chance of success^{1,2}.

About 100 procedures have been proposed for the surgical treatment of SUI to date, this *ipse facto* indicating that there are differences in the understanding of its etiopathogenesis and in the principles of surgical treatment for these patients. Such a large number of proposed procedures, which are performed in daily routine and the results of which are often difficult to compare and are differently presented, obviously prove that there are differences in their efficacy, which varies from 60% to 98%².

All surgical procedures in treating SUI can be divided into several groups according to their effect on the urethrovesical complex. Procedures with several effects are classified according to the most important one. The choice of surgical treatment is also complex. There are generally three classical approaches: vaginal, abdominal, and mixed. They all have the common objective to form an active suburethral support. This can be achieved by the modified Marshall-Marchetti or Burch procedure *via* abdominal approach; the May or Bagovic procedure *via* vaginal

approach, or the 'sling' operation *via* a mixed approach. Nowadays, the most widely spread is the laparoscopic approach, *e.g.*, Burch procedure, while one of the most promising sling operations is 'tension-free vaginal tape' (TVT)¹⁻³.

Minimally invasive methods of surgical therapy, such as TVT, are nowadays ever more used in all fields of medicine. The objective of these methods is to avoid long operations and to achieve faster, easier and complete post-operative recovery. SUI caused by weakness of the muscles and connective supporting system of the pelvic floor is a constant challenge for the gynecologist and urologist. Minimally invasive methods have also found their place in surgical therapy for SUI, but classical methods such as the Burch colposuspension have not, in the least, lost their value and importance. On the contrary, they are successfully used along with modern modifications, *e.g.*, development of the laparoscopic approach^{1,2,4-8}.

Patients and Methods

During 2001 and 2002, 36 women hospitalized at the Požega County General Hospital underwent the operation for SUI, following preoperative diagnosis including urodynamic evaluation and transvaginal ultrasound examination for the evaluation of bladder neck mobility (hypermobility). Fifteen of 36 women underwent the TVT procedure and 21 women had retropubic approach according to Burch.

Urine culture was obtained from all patients prior to the operation, together with complete urodynamic evaluation and transvaginal ultrasound examination for the evaluation of bladder neck mobility. Twelve (80.0%) of the 15 women submitted to TVT procedure had normal gynecologic findings, and three women had previously undergone unsuccessful vaginal or abdominal correction of SUI. Of the 21 women submitted to Burch colposuspension, normal histologic findings were recorded in four (19.0%), adenomyosis uteri in five (23.8), myoma uteri in eight (38.1%), ovarian cysts in two (9.5%) patients, and sarcoma uteri and chronic cervicitis in one (4.7%) patient each.

Tension-free vaginal tape (TVT) is a minimally invasive operation for genuine stress urinary incontinence (GSI, SUI), and possibly for mixed incontinence, during which the patient can be informed on the expected effect of the surgical treatment⁷⁻⁹. During the operation, a Prolen tape (Gynecare) is inserted through the vagina with the help of an inductor and needles in order to elevate the middle and distal parts of the urethra. In this way, the

posterior angulation of the urethra towards the bladder is formed. The Prolen tape is fastened on two steel needles and wrapped with a plastic protection, which prevents early fixation of the tape to the surrounding tissue. The equipment needed is an inductor (Gynecare) onto which the needles are fastened enabling easier insertion behind the symphysis, and an internal catheter guide for the Foley catheter (Gynecare) which is inserted into the bladder to enable lateral movement of the bladder while inserting the needles and the tape^{4,6,10-14}.

Local anesthetic (2% lidocaine) is first used to infiltrate the skin above the symphysis where later the needles will be pulled out with a Prolen tape. Infiltration with the anesthetic continues deeper behind the symphysis along the path where the needles with the tape are passing, thus forming a 'water pillow'. After that the vaginal mucosa is infiltrated suburethrally and on both sides laterally of the midline. A midline incision, 10 mm long, is made through which the urethra is visible, and then the channel for the insertion of the needles and the tape is prepared¹⁰⁻¹⁴.

Upon moving the bladder to the side, the needle is inserted suburethrally by means of an inductor just behind the symphysis ('shaving symphysis') towards the abdominal incision infiltrated with the anesthetic, where sometimes an incision is made earlier, 5 mm in length. After that, cystoscopy is necessary in order to exclude the probable perforation of the bladder. In case of perforation, the needle is moved more laterally and the injury heals spontaneously with the internal catheter (10 to 14 days) and prophylactic antibiotics. The same procedure is done on the other side, and after cystoscopy one half of the Prolen protection wrapper is removed, which allows fixation of the tape to the surrounding tissue. Lifting of the urethra angulation and an increase of its functional length is achieved by traction of the other half of the tape^{4,6,10-14}.

The benefit of local anesthesia is apparent in this step of the operation, when the surgeon in collaboration with the patient can check the degree of incontinence correction. Namely, as the patient is able willingly to contract the abdominal muscles, *e.g.*, by coughing, it is possible to check immediately the effect of tape traction. After that, the rest of the protection wrapper is removed, and the tape is spontaneously fixed to the surrounding tissue. No extrafixation with sutures is necessary, and sutures are placed only on the suprapubic abdominal incisions of the skin and vagina^{3,4,26}.

Voiding should occur spontaneously 4 hours after the operation, and upon discharge from the hospital (on the same or the next day) the patient should rest for 2-3 weeks.

As the operation is performed under local anesthesia, it is considered an ambulatory procedure, after which the patient can be discharged on the same day, which significantly reduces hospital costs^{10,11,13,16,27}. The operation can also be performed under spinal or general anesthesia, but then it is much more difficult to assess the degree of Prolen tape traction. The procedure can also be coupled with abdominal or vaginal hysterectomy. Cure rate, according to some follow-up studies, is up to 90%, which makes this method comparable with, up to now, the most successful operation techniques for stress urinary incontinence^{4,6,10-14}.

Burch colposuspension uses the anterior vaginal wall as a temporary suspensor. It is not sutured to the posterior wall of the symphysis but on each side to the ligamentum iliopectineum (lig. pubicum Cooperi). The approach for entry into the space of Retzius is the same as in the Marschal-Marchetti-Kranz method, and it can be coupled with hysterectomy and adnexectomy^{15,24}. Besides the preparation of the bladder neck and urethra, it is necessary to identify the fascia of lateral roofs. The surgeon, therefore, inserts the finger of the left hand into the vagina, elevating by turns the left and the right lateral roof in order to separate the vagina and to allow for sight of the perivaginal fascia, which is easily recognizable by its whitish color. During this procedure, the bladder is gradually moved medially, whilst special attention is needed so as not to damage the broad veins of the perivesical plexus. Bleeding from the perivesical veins can be considerable and should be controlled with electrocoagulation, placing sutures or, sometimes, by means of Fibrospuma or similar material (Surgicel)^{1,2,28-30}.

When the perivaginal wall is visible, 4 Dexone sutures are placed on both sides with a middle size needle. Each suture placed on the perivaginal fascia is tied down on each side to the ligamentum iliopectineum (lig. pubicum Cooperi). When all the sutures have passed through Cooper's ligament, they are tied down, so that the assistant's fingers, inserted into the vagina, move closer to the lateral roofs of the vagina^{2,21-23}.

Stanton²¹⁻²³ recommends that on each side of the urethra the first suture is placed at the level of the bladder neck, after that the second suture is placed more distally, whilst its placement is made easier by gentle traction of the first suture. Another two sutures should be placed nearer to the margin of the bladder. This is the way to decrease the formation of not only urethrocele but also of cystocele.

The vagina is sometimes not long enough or flexible enough for the lateral walls to be pulled towards the Coo-

per's ligament, so for disburdening it is necessary to make an incision *via* the vagina, longitudinally on the lateral vaginal wall. Such elevation of lateral roofs enables transverse traction and at the end of the operation it is sutured along that axis^{1,2,28-30}.

Aims of the study

The main aims of the study were comparing the efficacy of both operative techniques in the treatment of SUI, defining their advantages and disadvantages, and finding out some criteria for patient selection for either operative procedure. With this prospective, comparative study of the efficacy of the TVT procedure and Burch colposuspension we wanted to achieve the following:

1. to investigate the efficacy of the TVT procedure in the treatment of SUI;
2. to study the efficacy of Burch colposuspension in the treatment of SUI;
3. to objectively compare the efficacy, advantages and disadvantages of these operative procedures for SUI;
4. to set clear guidelines for proper patient selection for either procedure for SUI; and
5. to objectively and critically assess the postoperative follow-up results over measured time intervals.

Results

From a total of 36 patients with SUI, 15 (41.7%) women underwent the TVT operation, and 21 (58.3%) women had Burch colposuspension (Fig. 1). The mean age of patients submitted to TVT and Burch procedure was 50.3 (range 38-72) and 48.6 (range 39-66) years, respectively.

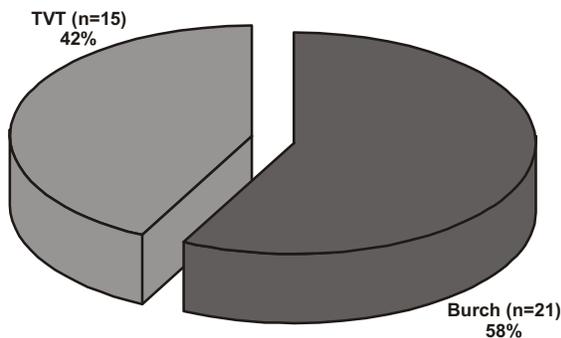


Fig. 1. Distribution of patients by the kind of surgical operation (N=36)

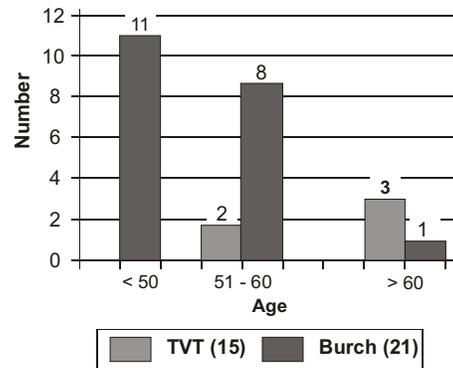


Fig. 2. Distribution of patients by age

Among the 15 women who underwent TVT, 10 (66.7%) were aged <50, two (13.3%) were in the 51-60 age group, and three (20.0%) were aged >60. Among the 21 women who underwent Burch procedure 11 (52.4%) were aged <50, nine (42.9%) were in the 51-60 age group, and one (4.7%) patient was older than 60 ($\chi^2=4.6$; $p=NS$) (Fig. 2).

The mean duration of TVT and Burch operation was 38 (range 30-47) and 49 (range 43-65) minutes, respectively. One of 15 (6.67%) patients submitted to TVT operation had perforation of the bladder, which healed *per primam* with an internal catheter and prophylactic antibiotics (cefuroxime 1.0 g *per* day for 10 days). In 1/21 (4.7%) patient who underwent Burch operation, deserozation of the sigmoid colon, 5 cm long, occurred during adhesiolysis and was managed with atraumatic sutures.

The length of hospital stay after TVT procedure was 5.0 (range 3-14) days, and after Burch procedure 15.0 (range 10-18) days. Of the total of 15 patients who underwent TVT operation, 12 (80%) stayed at the hospital for less than 7 days and three (29%) for 8-14 days. Of the to-

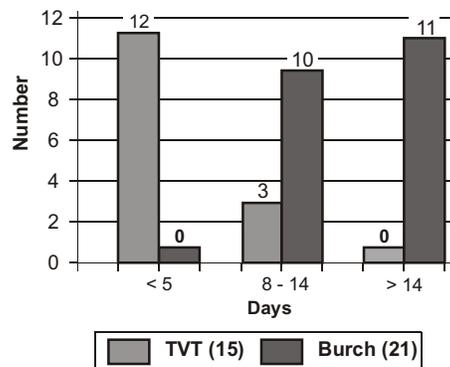


Fig. 3. Distribution of patients duration of hospital stay

tal of 21 patients who underwent Burch operation, ten (47.6%) patients were hospitalized for 8-14 days and 11 (52.4%) patients for more than 14 days ($\chi^2=26.5$; $p<0.001$) (Fig. 3).

Urine culture was obtained prior to the operation in all patients from both groups, along with urodynamic evaluation and transvaginal ultrasound for the assessment of bladder neck mobility. Of the 15 patients submitted to TVT procedure, 12 (80%) had normal gynecologic findings, and three had previously undergone unsuccessful vaginal or abdominal correction of SUI. Of the 21 patients submitted to Burch operation, four had normal gynecologic findings, five (23.5%) had adenomyosis uteri, eight (38.%) had myoma uteri, two (9.5%) had ovarian cysts, and one had sarcoma uteri and chronic cervicitis each.

The success of treatment was evaluated according to urinary continence confirmed by negative Boney test, decreased residual urine volume, and bladder neck stability verified by transvaginal ultrasound. In spite of the lack of longterm follow-up so far, control checkups (Boney, residual urine) at 1, 3, 6 and 12 months from the operation showed that a significant reduction or absence of the symptoms was achieved in all patients.

Discussion

Minimally invasive operations for SUI are nowadays the most desirable and justified methods, not only for medical reasons but also for social and economic reasons. The TVT procedure is a quick, low risk and minimally invasive operation in which the genital organs are not extirpated. This means that the human body integrity is preserved, which is exceptionally important not only for medical and psychological reasons but for reproductive reasons as well. The surgical instruments are simple and lasting (except for the Prolen tape), and are easily sterilized and maintained^{17,31-36}.

Local anesthesia considerably reduces the risk of anesthesiologic complications, including fatality. In addition, the ability to communicate with the patient during the operation leads to maximal cooperation in each phase of the operation, especially during the traction of the Prolen tape when the patients can contract the abdominal wall themselves (by coughing instead of Valsalva maneuver), enabling the surgeon to check the effect of the correction. It is obvious that local anesthesia requires careful selection of psychologically well-prepared patients for the TVT procedure^{3,18-20,25,26}.

Quick mobilization of the patient, only a few hours after the operation, along with spontaneous voiding without

catheterization and prophylactic antibiotics, decreases the risk of postoperative complications (thromboembolic disease, urinary infection). The short hospital stay or discharge on the very same day, faster rehabilitation and shorter sick-leave obviously represent a number of advantages, social, medical and economic. Expensive Prolen tape is compensated with savings achieved at all other levels of surgical treatment by TVT operation¹⁶.

The TVT operation has objectively become the method of choice in patients with genuine or mixed SUI, in whom there is no need of an operation of the uterus or/and adnexa, as well as in patients who have previously undergone unsuccessful SUI correction, including a possible previous TVT operation^{27,37-39}.

Burch colposuspension is a classical operation for SUI and has a notable role in the treatment of these patients. Longterm results surely prove its unquestionable reliability and efficacy, and it is the reason why it is a standard procedure in the treatment of SUI. In our study, we preferred Burch procedure in patients with genital descensus or prolapsus uteri, and in patients with benign changes of the uterus and/or ovaries. In other patients, the TVT procedure was performed in those with previous failed SUI correction, vaginal or abdominal, including Burch colposuspension.

Comparison of the TVT operation and Burch colposuspension confirmed that both methods are of high quality as indicated earlier by numerous references in recent scientific publications^{10-14,27-31,37-40}.

Although we performed TVT more often in women under 50 years of age (2/3 *versus* 1/2 in Burch procedure), there was no reason not to perform TVT in older patients, especially because of the advantage of local anesthesia (Fig. 2). Although, for example, the patients who underwent TVT operation were on an average by 8 years younger than those who underwent Burch operation, the oldest patient submitted to TVT operation was 72 years old, and the oldest patient submitted to Burch colposuspension was 68 years old ($p=NS$).

The mean duration of TVT operation was by 11 minutes shorter than Burch operation and there were no severe intraoperative complications. While the TVT was inserted, bladder perforation occurred in one patient, and healed *per primam* with internal catheterization and prophylactic antibiotics (cefuroxime 1.0 g/day for 10 days). Deserozation of the sigmoid colon, 5 cm long, occurred in one patient and was sutured with atraumatic sutures. Both patients were discharged as cured.

The mean length of hospital stay in the patients submitted to TVT operation was by 10 days shorter than the hospital stay in patients who underwent Burch operation. Namely, 40% of those who underwent TVT operation had a hospital stay of up to 3 days, and hospitalization longer than 8 days, maximum 14 days, was recorded in only 20% of these patients. In the patients who underwent Burch operation there was no hospital stay under 8 days and more than a half of these hospital stays were longer than 14 days, maximum 18 days ($p < 0.001$) (Fig. 3). Taking into consideration that we have only recently introduced the TVT procedure, patients were hospitalized for longer time than objectively needed, so short hospital stay information is still lacking. However, based on the experience gained so far and good results achieved, we intend to reduce hospitalization in the future to a maximum of 48-72 hours, until we reach the one-day hospital stay (one-day surgery). In patients who undergo Burch operation, however, we would not be able to shorten hospitalization significantly because of the suprapubic incision required and the need of internal catheterization and prophylactic antibiotics postoperatively. Laparoscopic modification of Burch procedure is the future, although it requires more sophisticated technical equipment and specially educated medical staff.

Generally, for the success of both surgical therapies for SUI, along with good equipment and operative technique, proper patient selection is needed. This requires preoperative gynecologic examination, Papa smear, Boney test, urine culture, complete urodynamic evaluation, and transvaginal ultrasound assessment of inner genital organs and bladder neck mobility. Out of 15 patients who underwent TVT operation, 80.0% had normal gynecologic findings, and 20.0% had previously undergone unsuccessful correction of SUI. Of 21 patients who underwent Burch operation, 19.0% had normal histologic findings, 23.8% had adenomyosis uteri, 38.1% had myoma uteri, 9.5% had ovarian cysts, and 4.7% had sarcoma uteri and chronic cervicitis each.

Irrespective of the method chosen, the correction of SUI was successful in all patients, which means that outpatient checkups after the operation showed significant improvement or absence of previous symptoms. So, we conclude that both surgical methods for the correction of SUI are equally effective. Although there are no longterm results on the efficacy of TVT procedure to date, the method is definitely appropriate for patients with normal gynecologic findings. The Burch procedure, on the other hand, is the method of choice in patients with descensus or prolapsus uteri and with benign changes of the inner genital organs.

Conclusions

We have come to the following conclusions based on the results of our prospective comparative study of the efficacy of TVT procedure *versus* Burch colposuspension:

1. TVT procedure for surgical therapy of SUI proved successful and effective in well selected patients (SUI with normal gynecologic findings).
2. Burch colposuspension for SUI proved successful and effective in well selected patients (SUI with descensus or prolapsus uteri, and with benign changes of inner genital organs).
3. Both surgical methods for the correction of SUI are equally effective, and there are no drawbacks in well selected patients.
4. Proper selection of patients for surgical therapy of SUI is based on clinical assessment and appropriate diagnostic procedure (ultrasound, urodynamic evaluation).

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Sažetak

USPOREDBA TVT I KOLPOSUSPENZIJE PO BURCHU U KIRURŠK OM LIJEČENJU STRESNE INKONTINENCIJE MOKRAĆE U ŽENA

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Od 2001. do 2002. godine u Općoj županijskoj bolnici P ožega 15 bolesnica sa stresnom inkontinencijom mokraće (SIM) liječeno je primjenom tzv. *tension-free vaginal tape* (TVT), dok je u 21 bolesnice učinjena kolposuspenzija po Burchu. Srednja dob bolesnica operiranih metodom TVT bila je 50,3 (raspon 38-72) godine, a onih operiranih metodom po Burchu 48,6 (raspon 39-66) godina. Od 15 bolesnica operiranih metodom TVT deset (66,7%) ih je bilo mlađih od 50 godina, dvije (13,3%) su bile u dobi od 51-60 godina, a tri (20,0%) su bile starije od 60 godina. Od 21 bolesnice operirane metodom po Burchu 11 (52,4%) ih je bilo mlađih od 50 godina, devet (42,9%) ih je bilo u dobi od 51-60 godina, a jedna (4,7%) je bolesnica bila starija od 60 godina ($p=n.s.$). Prosječno trajanje operacije metodom TVT bilo je 38 (raspon 30-47) minuta, a operacije po Burchu 49 (raspon 43-65) minuta. Prosječno trajanje bolničkog liječenja bolesnica operiranih metodom TVT bilo je 5,0 (raspon 3-14) dana, a bolesnica operiranih metodom po Burchu 15,0 (raspon 10-18) dana. Od 15 bolesnica operiranih metodom TVT 12 (80,0%) ih je hospitalizirano kraće od 7 dana, a tri (20,0%) 8-14 dana. Od 21 bolesnice operirane metodom po Burchu deset (47,6%) ih je hospitalizirano 8-14 dana, a 11 (52,4%) dulje od 14 dana ($p<0,001$). Neovisno o odabiru metode u svih je operiranih bolesnica SIM uspješno ispravljena, tj. na redovnim kontrolnim pregledima u svih je ustanovljeno značajno smanjenje ili potpuno uklanjanje ranijih tegoba. Stoga je zaključeno kako su obje primijenjene operacijske metode ispravljanja SIM jednako učinkovite. Iako zasad nema dugoročnih rezultata učinkovitosti TVT, ova je metoda neupitno primjerena za bolesnice s urednim ginekološkim nalazom, dok je operacija po Burchu metoda izbora u bolesnica s genitalnim descenzusom ili prolapsom, te u onih s dobroćudnim promjenama unutarnjih genitalnih organa.

Ključne riječi: *Inkontinencija mokraće – stresna, kirurgija; Vagina, kirurgija; Urološki kirurški zahvati, metode; Undinamiki; Ženski spol*