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The effect of intravesical stent length and Propiverine on ureteral stent related symptoms - Prospective controlled trial

Üreteral stent ilişkili semptomlara intravezikal stent uzunluğunun ve Propiverin'in etkisi- Prospektif kontrollü çalışma

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ÖZET

Amaç: Üreteral double J stentler taş hastalıklarında sıklıkla kullanılmaktadır. Stent normal lokalizasyonunda iken stent ilişkili rahatsız edici sempomlara neden olabilmektedir. Bu problem için çeşitli medikal ajanlar ve stent ilişkili çözümler araştırılmıştır. Ancak hala kesin bir ilaç bulunamamıştır. Biz stent ilişkili semptomlar üzerinde propiverinin etkisini araştırmayı amaçladık.

Gereç ve Yöntemler: Çalışmaya haziran 2020 ile mayıs 2022 tarihleri arasında üreteroskopik taş cerrahisi yapılan hastalar dahil edildi. Kontrol grubu tedavi almaz iken tedavi grubu operasyonun 1. haftasından sonra günlük 45 mg propiverin aldı. 1. ve 3. haftanın sonunda stent ilişkili semptomlar üreteral stent semptom anketi (USSQ) ile değerlendirildi. Ek olarak tüm hastaların 3. Hafta sonunda stent alınması sırasında intravezikal stent kısımları cetvel ile ölçüldü.

Bulgular: Çalışmada toplamda 177 hasta değerlendirildi. Bunlardan 87si kontrol grubunu oluştururken 90 hasta tedavi grubunu oluşturdu. USSQ skorlarına göre, üriner semptom skorları, vücut ağrı skorları, genel sağlık skorları, iş performansı skorları, cinsel sağlık skorları, ek problemler skoru ve global hayat kalitesi skoru tedavi gruplarında azalmış bulundu ($p<0,001$ tüm alanlarda). Tüm hastalarda intravezikal stent uzunluğu 1. hafta sonundaki üriner semptom skoru ile pozitif korele olarak bulundu.

Sonuç: Stent ilişkili semptomlar intravezikal stent boyu daha uzun olanlarda daha fazladır. Propiverin stent ilişkili semptomları başarılı şekilde rahatlatmaktadır.

Anahtar Kelimeler: Propiverin, Stent ilişkili semptom, Double J stent, USSQ

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This study was approved by the Ethics Committee of Okmeydanı Training and Research Hospital (Approval Number: KAEK-2020-01-21/22, Date: 2020-01-21). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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ABSTRACT

Objective: Ureteral double J stents are widely utilized in urolithiasis. Disturbing stent-related symptoms may occur while the stent is in location. Various medical agents and stent-related solutions were examined for this problem. However, a definite drug has still not been found. We aimed to research the effect of propiverine on stent-related symptoms.

Material and Methods: Patients who underwent ureteroscopic stone surgery between June 2020 and May 2022 were included in the study. While the control group was untreated, the treatment group received 45 mg of propiverine daily after 1 week of the operation. Stent-related symptoms were assessed by ureteral stent symptom questionnaire (USSQ) at the end of 1st week and 3rd week of surgery. In addition, the intravesical stent parts of all patients were quantitatively measured with a ruler during stent removal at the end of 3 weeks.

Results: A total of 177 patients were assessed in the study. Eighty-seven patients were control and 90 patients of them were treatment group. According to USSQ, urinary symptoms scores, body pain scores, general health scores, work performance scores, sexual health scores, additional problem scores, and global quality of life (QoL) scores were found to decrease in the treatment group ($p<0.001$ All domains). Intravesical stent length was found positive correlation with the urinary symptom score (1st week) of all patients.

Conclusion: Stent-related symptoms are more likely in patients with longer intravesical stent length. Propiverine successfully relieves stent-related symptoms.

Keywords: Propiverine; Stent related symptom; Double J stent; USSQ

INTRODUCTION

Ureteral stents were first defined in 1967 and they are widely utilized for upper urinary tract dilatation, drainage of urine, and relief of obstruction (1). One of the most important usage areas is urolithiasis. However, these stents cause discomfort to the patient and reduce the quality of life by 45-80% (2). The exact mechanism of stent-related symptom is unknown. However, the consensus is that the symptoms are caused by mechanical irritation of the bladder and neck, trigone, and reflux of urine into the kidney (3). In addition, the length of the stent in the bladder may also be an important factor. Ureteral stent-related symptoms may include dysuria, frequency, flank pain, urgency, and haematuria through these possible mechanisms.

Although there are some attempts at stent material and design to reduce symptoms, there is still no optimal ureteral stent (4). Some pharmacotherapies such as alpha-blockers, anticholinergics, and special stents containing analgesics are used. There are some studies in the literature showing that antimuscarinics such as solifenacin and tolterodine have positive effects on stent-related symptoms (5,6).

To the best of our knowledge, the effect of propiverine has not yet been studied in ureteral stent symptoms. Propiverine is one of the most used antimuscarinic drugs for overactive bladder (7,8). According to a recent study, propiverine shows its effect with a mixed effect. It blocks muscarinic receptors in the detrusor muscle and alleviates muscle spasms by inhibition of calcium influx (9,10). This possible different mechanism encouraged us to evaluate the effect of propiverine on stent-related symptoms.

The ureteral stent symptom questionnaire (USSQ) has been developed to describe and categorize these symptoms (2). This validated form includes main 6 main domains about ureteral stent symptoms. Many studies of ureteral stent-related symptoms usually consist of small patient groups or unvalidated questionnaires. We designed a randomized controlled trial to evaluate the effect of propiverine on stent-related symptoms and quality of life using the USSQ. Also, we aimed to evaluate the effect of intravesical stent length on stent related symptoms.

MATERIAL AND METHODS

This prospective randomized controlled trial was carried out after approving the local ethical committee. (Approval No: 2020/20) Patients who underwent ureteroscopic lithotripsy with ureteral stent place-

ment between June 2020 and May 2022 were evaluated prospectively. Informed consent was obtained from the included patients.

Postoperative stone-free patients aged 18-50 years were included in to study. Patients with ureteral stent history, lower urinary tract symptoms (LUTS) related to benign prostate hyperplasia, urethral stricture, active urinary tract infection, anticholinergic drug use, pregnancy, and cognitive disorder were excluded from the study. Ureteral access sheath was not used in any patients.

Patients were randomized into two groups a control group and a treatment group, and simple randomization was used by flipping a coin while dividing the patients. All demographic and clinical data were enrolled postoperatively. The treatment group received 45 mg of propiverine once a day since the first week after surgery. They continued receiving 45 mg of propiverine for two more weeks. The control group did not receive treatment.

Patients received perioperative similar intravenous fluid and antibiotic treatments. 4.8 Fr Cook C-Flex® Double pigtail ureteral stents of 26 cm were placed in all patients. All stent tethers were removed before the placement of the stent to prevent tether-related irritation. Stent-related symptoms have increased after 1 week in patients with ureteral stent (11,12). Therefore, treatment and control groups were assessed at the end of the 1st and 3rd week after surgery with the Turkish version of USSQ (13).

Ureteral stents were removed at the end of the 3rd week after surgery. During stent removal, the intravesical stent portion was held from the level of ureteral orifice insertion by forceps. After stent removal, intravesical stent lengths were measured from this holding level. Intravesical stent lengths of all patients were measured with this technique (Figure 1).

Statistical results were analyzed using the Statistical Package for the Social Sciences version 21.0 (SPSS Inc, Chicago, IL, USA). The data were stated as mean ± standard error of the mean (SEM). The Shapiro–Wilk test was used to test the normal distribution of the variables. The Wilcoxon test was used to compare USSQ scores in the control and treatment groups. Independent samples t-test was used for assessment between groups. The Spearman correlation test was used to evaluate the correlation between urinary symptom score (1st week) and intravesical stent length in all patients. P value <0.05 was accepted as statistically significant.

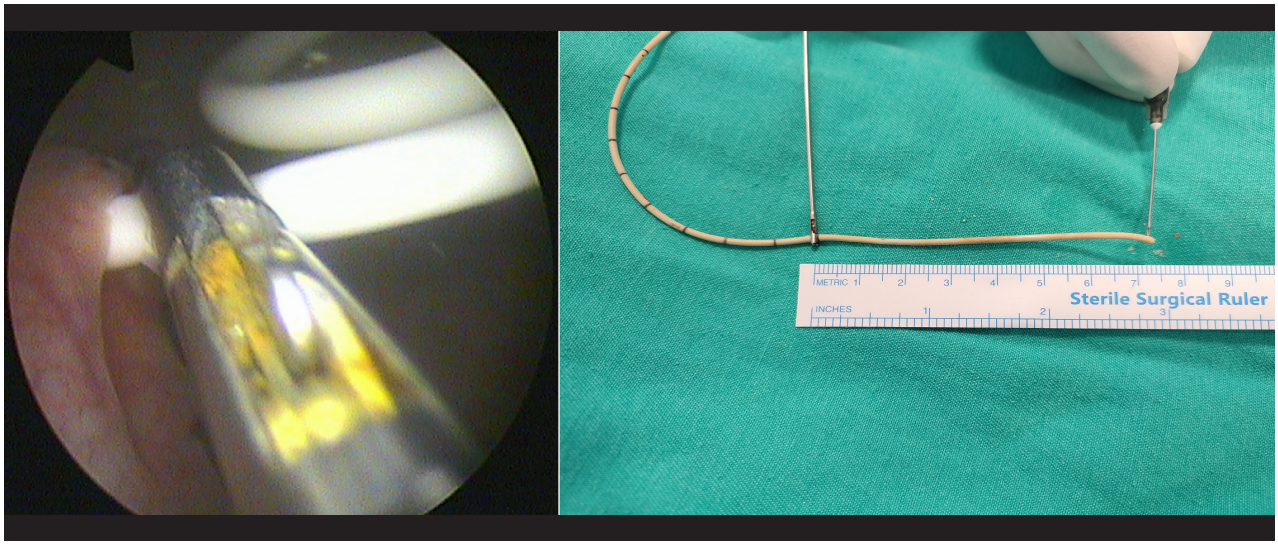

Figure 1: Measurement technique of intravesical stent length

RESULTS

A total of 177 patients were included in to present study. Ninety of them constituted the treatment group and 87 of them were the control group. Adverse events such as slight dry mouth developed in 6 patients in the treatment group but they did not discontinue the drug. The demographic and clinical data

of the groups were presented in Table 1. The mean age of the control and treatment groups were respectively 46.3±1.4 and 44.4±1.2 (p=0.31). The mean height of the control group was 170±0.8 and the treatment group was 169.1±0.8 (p=0.09). The mean body mass index (BMI) of the control and treatment groups were respectively 27.9±0.4 and 28.2±0.5 (p=0.67). There were 47 males and 43 females in the treatment group. While the control group consisted of 57 males and 30 females (p=0.07). The number of analgesics requirement patients was 51 of 87 patients in the control group. However, only 10 of 90 patients needed analgesics in the treatment group (p<0.001). This difference was statistically significant between groups. Intravesical stent lengths of the control and treatment group were respectively 7.9±0.1 cm and 8.2±0.1 cm (p=0.08). A correlation was found between the lengthening of the intravesical stent as the patient got shorter in all patients (p<0.001). There was no statistically significant difference between groups except for analgesic requirements. In addition, a positive correlation was found between urinary symptom score (1st week) and intravesical stent length (r=0.317; p<0.001). According to this result, intravesical stent length was correlated with stent-related symptoms.

USSQ scores of the control group were presented in Table 2. USSQ scores on the 7th day of surgery and before stent removal (3rd week) were respectively urinary symptoms scores 24.3±0.6 and 23.7±0.7 (p=0.07). The mean body pain scores were 13.9±0.3 and 14.1±0.3 (p=0.13); the mean general health scores were 10.9±0.2 and 11±0.3 (p=0.40); the mean work performance scores were 7.4±0.2 and 7.5±0.2 (p=0.21); the mean sexual health scores were 3.8±0.1 and 4±0.1 (p=0.06); the mean additional problem scores were 6.8±0.2 and 6.9±0.2 (p=0.79); the mean global QoL scores were 3.4±0.1 and 3.5±0.1 (p=0.18).

USSQ scores of the treatment group were presented in Table 3. USSQ scores on the 7th day of surgery and before stent removal (3rd week) were respectively urinary symptoms scores 24.9±0.7 and 21.1±0.6 (p<0.001). The mean body pain scores were 14.2±0.4 and 12.6±0.4 (p<0.001); the mean general health scores were 11.6±0.3 and 11±0.4 (p<0.001); the mean work performance scores were 8±0.2 and 7±0.3 (p<0.001); the mean sexual health scores were 5±0.2 and 4.5±0.1 (p<0.001); the mean additional problem scores were 7±0.2 and 6.3±0.2 (p<0.001); the mean global QoL scores were 4.4±0.1 and 3.5±0.1 (p<0.001).

There was no obvious difference between the groups in USSQ scores on the 7th day of surgery stent in situ. However, a significant decrease was observed in the treatment group.

Table 1. Demographic features of control and treatment groups

	Control n=87	Propiverine n=90	p value
Age (Mean±SEM)	46.3±1.4	44.4±1.2	0.31
Height (cm) (Mean±SEM)	170±0.8	169.1±0.8	0.09
BMI (kg/m²) (Mean±SEM)	27.9±0.4	28.2±0.5	0.67
Gender (Male/Female)	57/30	47/43	0.07
Side (Right/Left)	36/51	46/44	0.19
Comorbidities			
HT (n)	6	12	
DM (n)	6	6	0.06
Others (n)	3	9	
None (n)	72	63	
Analgesic requirement (Yes/No)	51/36	10/80	**<0.001**
Intravesical stent length (cm) (Mean±SEM)	7.9±0.1	8.2±0.1	0.08

SEM: *Standard Error of the Mean,* ***BMI:*** *Body Mass Index,* ***HT:*** *Hypertension,* ***DM:*** *Diabetes Mellitus*

Table 2. USSQ scores in the control group

USSQ	7th day of surgery stent in situ	Before stent removal	p value
Urinary symptoms score (mean ± SEM)	24.3±0.6	23.7±0.7	0.07
Body pain score (mean ± SEM)	13.9±0.3	14.1±0.3	0.13
General health score (mean ± SEM)	10.9±0.2	11±0.3	0.40
Work performance score (mean ± SEM)	7.4±0.2	7.5±0.2	0.21
Sexual health score (mean ± SEM)	3.8±0.1	4±0.1	0.06
Additional problems (mean ± SEM)	6.8±0.2	6.9±0.2	0.79
Global QoL (mean ± SEM)	3.4±0.1	3.5±0.1	0.18

SEM: *Standard Error of the Mean,* ***USSQ:*** *Ureteral stent symptom questionnaire,* ***QoL:*** *Quality of life*

Table 3. USSQ scores in the treatment group

USSQ	7th day of surgery stent in situ	Before stent removal	p value
Urinary symptoms score (mean ± SEM)	24.9±0.7	21.1±0.6	**<0.001**
Body pain score (mean ± SEM)	14.2±0.4	12.6±0.4	**<0.001**
General health score (mean ± SEM)	11.6±0.3	11±0.4	**<0.001**
Work performance score (mean ± SEM)	8±0.2	7±0.3	**<0.001**
Sexual health score (mean ± SEM)	5±0.2	4.5±0.1	**<0.001**
Additional problems (mean ± SEM)	7±0.2	6.3±0.2	**<0.001**
Global QoL (mean ± SEM)	4.4±0.1	3.5±0.1	**<0.001**

USSQ, *Ureteral stent symptom questionnaire,* ***SEM:*** *Standard Error of the Mean,* ***QoL,*** *Quality of life*

DISCUSSION

Ureteral stents may be used after ureteral intervention or to prevent upper urinary tract obstruction and urinary leakage. Thus, ureteral stents prevent complications such as kidney failure and death by protecting kidney function. Nevertheless, it may also cause annoying symptoms. According to previous studies, these symptoms have been reported as 76% residual urine feeling, 40-60% dysuria, irritative symptoms such as frequency and urgency, 20-30% haematuria, incontinence, suprapubic and flank pain (14,15).

The general opinion is that stent-related symptoms are the result of mechanical irritation of the bladder trigone, impaired ureteral peristalsis, stent position, bacterial colonization of the stent, and vesicoureteral reflux (16). Although various drugs have been studied to reduce stent-related symptoms, their definite superiority to each other still has not been demonstrated. We showed that Propiverine has beneficial effects on stent-related symptoms in the present study by using USSQ. Many studies have examined stent-related symptoms with the International Prostate Symptom Score (IPSS) questionnaire in the literature. While IPSS only questions lower urinary tract symptoms, USSQ is a more comprehensive questioning form that also includes quality of life. USSQ is the only validated scoring system for the evaluation of stent-related symptoms, and it is more appropriate to use it for the standardization of symptoms and contribute to the literature.

Even though routine ureteral stent placement is not recommended after uncomplicated ureteroscopy, it is widely used to reduce postoperative ureteral oedema, and prevent colic pain and hydronephrosis. A

recent systematic review reported that re-admissions to the hospital increased due to not using a ureteral stent after a ureteroscopy (17). Therefore, it may be reasonable that be in search to find the correct medical agent for stent-related symptoms. Alpha-blockers, antimuscarinics, and a combination of these were used to decrease stent-related symptoms in the literature. Although some studies reported inconsistent data, meta-analyses have demonstrated that alpha-blockers are beneficial in the treatment of stent-related symptoms (18,19). Urine reflux to the kidney and flank pain may develop as a result of bladder outlet resistance and increased pressure. Alpha-blockers may decrease pain and other symptoms by reducing bladder outlet resistance. Similarly, current studies in the combination of alpha-blockers and antimuscarinics have controversial results. A multicentre prospective randomized study showed that the combination of tamsulosin and solifenacin was superior to monotherapy in stent-related symptoms (20). Another study showed that there was no difference between USSQ scores of monotherapy and combination treatment (21). Combination therapy, such as alpha-blockers and anticholinergics, has been shown to be superior to monotherapy only for the first few days (22). Co-inhibition of alpha receptors and muscarinic receptors may have shown a synergistic effect in the improvement of bladder irritative symptoms within the first days.

The bladder detrusor has muscarinic receptors including M1-5 subtypes and these receptors are responsible for involuntary contractions of the bladder. Joshi et al. reported that ureteral stents may induce or worsen subclinical detrusor overactivity (23). Anticholinergic drugs are thought to relieve symptoms by reducing bladder overactivity and contractions by blocking muscarinic receptors. Solifenacin has been examined many times to alleviate stent-related symptoms due to the feature of a selective M3 receptor blocker. However, symptoms may persist through other receptors or mechanisms. In addition, the superiority of antimuscarinics over each other has not been proven yet (24). When considering the possible adverse effects of combination therapy due to using more than one drug, the different antimuscarinic molecules may be examined for stent-related symptoms. Propiverine shows its effect on both muscarinic receptor blockade and calcium blockade. Since haematuria may occur due to mechanical irritation of the stent to the bladder mucosa, its symptoms may be greatly affected by routine activities, occupations, and daily exercises. Haematuria may be associated with ureteral spasms in addition to physical activity. Activation of the muscarinic receptor causes an increase in the amplitude of ureteric contractions (25). During ureteral contraction, it may cause muscle spasms and pain with the stent inside. Due to the different action mechanisms of propiverine, stent-related symptoms may be alleviated effectively.

During the Double-J stent is in a normal position, the stent tips make 1 loop in the renal pelvis and bladder to prevent proximal or distal migration due to ureteral peristalsis or patient movements. As a result of mechanical friction of the stent to the bladder mucosa, acetylcholine is released, the muscarinic receptors are stimulated and the detrusor is contracted. Some studies have shown that ureteral stent position was associated with stent-related symptoms according to whether the intravesical stent crosses the midline of the bladder on X-ray images (12,26). Some studies with similar measure techniques showed that there was no relationship (27). However, we think that stent localization may change depending on the bladder fullness in this measurement method. Therefore, we measured the intravesical stent portions quantitatively. According to our results, intravesical stent length has a statistically significant effect on stent-related symptoms. In addition, shorter patients were found risky for more bothersome stent-related symptoms.

Patients who suffer from ureteral stent-related pain often use drugs such as non-steroidal anti-inflammatory drugs (NSAIDs). It may diminish pain by reducing ureteral contractility and inflammation. In addition, NSAIDs reduce renal prostaglandin levels and cause a decrease in renal blood flow. Thus, kidney and ureteral pressure decreases, and symptoms may be alleviated (28). However, against these beneficial effects, NSAIDs are not innocent drugs. In our daily practice, we see that the eGFR levels of patients who have undergone ureteral stone operation are mostly reduced, even though the other kidney is normal. Therefore, it is extremely important to reduce the use of analgesics, especially in risky patients. This study showed that Propiverine reduced the use of analgesics for stent-related symptoms.

Our study is not impeccable. Firstly, there was no placebo arm. Second, we did not define a cut-off value of intravesical stent length for stent-related symptom development.

CONCLUSION

Although stent-related symptoms are considered to be related to stent material, location and length, the optimal ureteral stent could not develop so far. A longer intravesical stent length portion is risky for stent-related symptoms. Propiverine reduces ureteral stent-related symptoms and the use of analgesics. Future studies with various antimuscarinic and placebo agents may better demonstrate this association.

Conflict of Interest: The authors have no conflicts of interest to declare.

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Ethical Approval: Okmeydanı Training and Research Hospital Local Ethical Committee approved the study in 21/01/2020. Approval no is 22.

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