ORIJINAL ARAŞTIRMA ORIGINAL RESEARCH

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Effects of Urinary Catheter Clamping After Cesarean Section on Urinary Retention and Urinary Tract Infection

Sezaryen Sonrası Üriner Kateter Klemplemenin Üriner Retansiyon ve İdrar Yolu Enfeksiyonu Üzerine Etkileri

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ABSTRACT Objective: This study was planned to investigate the effect of intermittent clamping of the urinary catheter after cesarean section and exercising the detrusor muscle on the post-void residual urine volume and reduction of the risk of urinary tract infection in the early stage. Material and Methods: This randomized controlled study was carried out with 100 primiparous pregnant women who were to undergo elective cesarean section between January 2019 and January 2020. The participants were randomly assigned into 2 groups: the experimental group including 50 patients who underwent urinary catheter clamping 3 times after the postoperative 3rd hour, by turning off the urinary catheter for 3 hours, and then turning it on for 5 minutes and the control group including 50 patients who did not undergo urinary catheter clamping. The study data were collected with the maternal information form and Urinary Distress Inventory (UDI-6). The UDI-6 was used to assess the subjective voiding difficulty. The primary outcome of the present study was to determine whether exercising the detrusor muscle decreased post-void residual urine volume in patients having undergone cesarean section. The secondary results were the incidence of urinary tract infections and subjective symptoms experienced by the patients. Results: According to the comparison of the post-void residual urine volume in the experimental (E) and control (C) groups, no significant difference was observed between the groups on the first day [E=10 (20%), C=12 (24%) (p=0.629)] and in the first week [E=2 (4%), C=3 (6%) (p=1.000)]. In the sixth week, no post-void residual urine volume was observed in any patient in either group. There was no statistical difference between the groups in percentage change values in time dependent intragroup UDI-6 scores (p=0.453). While the median change in the experimental group was 50.60%, this value was obtained as 58.93% in the control group. While the rate of the participants with positive urine culture in the experimental group was 6%, it was 4% in the control group, and there was no significant difference between the groups (p=1.000). Conclusion: In our study, urinary catheter clamping has no reducing effect on post-void residual urine volume, urinary tract infection and subjective voiding difficulty.

Keywords: Bladder exercising; urinary catheter clamping; urinary retention; cesarean section

ÖZET Amaç: Bu çalışma, sezaryen sonrası idrar sondasının aralıklı olarak klemplenmesi ve detrusor kasının egzersizinin rezidüel idrar hacmi üzerine ve erken evrede idrar yolu enfeksiyonu riskini azaltmada etkisini arastırmak için planlandı. Gerec ve Yöntemler: Bu randomize kontrollü çalışma, Ocak 2019-Ocak 2020 tarihleri arasında elektif sezaryen ameliyatı geçirecek olan 100 primipar gebe kadınla gerçekleştirildi. Katılımcılar rastgele 2 gruba ayrıldı: Üriner kateter klempleme uygulanan 50 hastadan oluşan deney grubu (ameliyat sonrası 3. saatten sonra 3 kez, idrar sondasını 3 saat boyunca kapatarak ve sonra 5 dk boyunca açacak şekilde) ve idrar sondası klemplenmemiş 50 hastadan oluşan kontrol grubu. Çalışma verileri, maternal bilgi formu ve Üriner Sıkıntı Envanteri [Urinary Distress Inventory (UDI-6)] ile toplanmıştır. UDI-6, subjektif işeme zorluğunu değerlendirmek için kullanıldı. Bu çalışmanın birincil sonucu, sezaryen uygulanan hastalarda detrusor kas egzersizi ile rezidüel idrar hacminde azalma olup olmadığını belirlemekti. İkincil sonuçlar, idrar yolu enfeksiyonu insidansı ve hastaların yaşadığı öznel semptomlardı. Bulgular: Deney (D) ve kontrol (K) gruplarında bosluk sonrası rezidüel idrar hacminin karşılaştırılmasına göre, ilk gün gruplar arasında anlamlı bir fark gözlenmedi [D=10 (%20), K=12 (%24), (p=0,629)]. İlk haftada [D=2 (%4), K=3 (%6), (p=1,000)] ve 6. haftada, her iki grupta da hiçbir hastada rezidüel idrar hacmi gözlenmedi. Gruplar arasında, zamana bağlı grup içi UDI-6 skorlarında yüzde değişim değerleri açısından istatistiksel fark yoktu (p=0,453). Deney grubundaki ortalama değişim %50,60 iken, kontrol grubunda bu değer %58,93 olarak elde edildi. Deney grubunda pozitif idrar kültürü olan katılımcıların oranı %6 iken, kontrol grubunda %4 olup, gruplar arasında anlamlı fark yoktu (p=1,000). Sonuç: Çalışmamızda, idrar sondası klempinin rezidüel idrar hacmi, idrar yolu enfeksiyonu ve subjektif idrar yapma zorluğu üzerinde azaltıcı etkisi yoktur.

Anahtar Kelimeler: Mesane egzersizi; idrar sondası klempleme; idrar retansiyonu; sezaryen

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One of the most common surgical procedures that women undergo throughout their life is cesarean section. During the postoperative period after cesarean section, women can experience not only the effects of surgery and anesthesia but also urinary retention. In most patients, urinary retention is asymptomatic. While the incidence of postpartum urinary retention (PUR) ranges from 1.70 to 17.90% after vaginal delivery, it varies between 3.20 and 24.20% after caesarean section. 2-4

In the literature, urinary retention is defined as the amount of residual urine greater than 150 ml after the first spontaneous voiding.⁵ Different treatments are performed to reduce voiding difficulty and urinary retention after cesarean section. One of them is the intermittent clamping of the urinary catheter before it is removed, which was first proposed by Ross in 1936.6 Urinary catheter clamping strengthens the bladder muscle tone and sensation of the bladder, and as a result, the bladder returns to its normal function. However, long-term clamping of the urinary catheter can lead to negative effects such as an increase in urinary tract infections and the rate of re-catheterization.⁷⁻⁹ There is no clear consensus on this issue. For instance, while in a review performed by Cochrane, inconclusive evidence is reported, in a more recent meta-analysis, it has been concluded that to achieve acceptable results, more studies should be conducted. 10,11

This randomized controlled experimental study was planned to investigate the effect of intermittent clamping of the urinary catheter after cesarean section and exercising the detrusor muscle on the postvoid residual urine volume and reduction of the risk of urinary tract infection in the early stage.

MATERIAL AND METHODS

The Clinical Research Ethics Committee of Medipol University approved the study. The management of Private Nisa Hospital where the study was to be conducted gave its written permission to conduct the study before the data collection phase (Reference number: 10840098-604.01.01-E14126). All the procedures were performed in accordance with the rules regarding studies involving human participants by

taking into account the ethical standards of the institutional and/or national research committee and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

One thousand pregnant women presented to the Obstetrics Outpatient Clinics of Private Nisa Hospital between January 2019 and January 2020. Of them, 520 presented to have an elective cesarean delivery. While some of those pregnant women (n=320) gave birth under general anesthesia, the remaining (n=200) gave birth under spinal anesthesia. Of the pregnant women who had caesarean section under spinal anesthesia, 120 were primiparae and 100 were multiparae. The G*Power (version 3.1) was used to calculate the sample size of the study. The study was designed to detect the 20% difference in UDI-6 scores representing a clinically significant difference between women with and without urinary clamping. According to the results of the literature review, and the relevant scientific literature, the minimum sample size was calculated as 100 (n= 50 for each group) taking the type 1 error as 0.05 and the power of the test as 0.90 (α = 0.05, $1-\beta = 0.90$). However, considering the possibility that there might be losses during the study, it was decided to include 55 participants in each group (Figure 1).

Before the surgery, the participants were assigned into intervention and control groups based on the patient protocol number. Of the patients, those with an even protocol number and clamping were assigned to the intervention group and those with an odd protocol number and without clamping were assigned to the control group considering the number of the participants to be included in each group determined by the power analysis. Randomization sequence was created using the computer-based random number generator with a 1:1 allocation (https://stattrek.com/statistics/random-number-generator.aspx#error) (Figure 1). These intervention and control groups were enrolled into a list by the researchers. To avoid bias and to standardize the surgical procedure, all the participants were operated by the same surgeon (Figure 1).

Inclusion criteria: Being between 20-40 years of age, being at the 37th-42nd weeks of gestation with

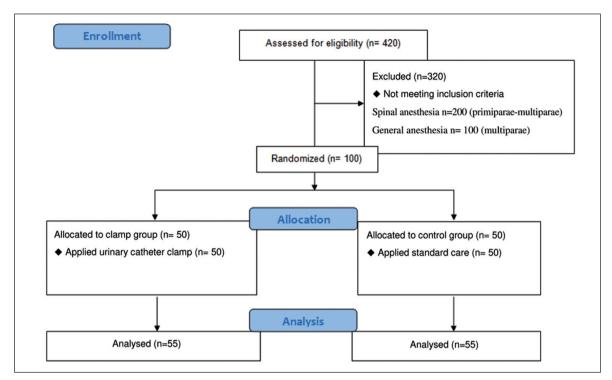


FIGURE 1: Diagram showing the recruitment of postpartum women and progression throughout the trial.

a singleton pregnancy, being primipara, having undergone caesarean section and spinal anesthesia.

Exclusion criteria: Having a chronic disease (diabetes, hypertension, etc.), having prenatal urinary tract infection, taking medication regularly, having a problem preventing the person from communicating, and having psychiatric treatment (pharmacotherapy or psychotherapy) having undergone laparotomy previously, having to undergo urgent cesarean section (detachment placenta, placenta previa, etc.)

Maternal Information Form: The form developed by the researchers in accordance with the pertinent literature includes 34 items questioning the participants' socio-demographic characteristics, residual urine volume, ultrasonography measurements, urine culture, hematuria, pre- and post-operative hemoglobin and hematocrit values.

Urogenital Distress Inventory (UDI-6): It was developed by Vassalo et al. to assess the effect of urinary incontinence on daily (quality of) life of women. 12 The inventory has three subscales. The irritative symptoms subscale questions urgency, frequency, and pain (items 1 and 2), stress symptoms

subscale (items 3 and 4), and obstructive / discomfort or voiding difficulty symptoms subscale (items 5 and 6). As the score obtained from the scale increases, so does urinary incontinence. The Turkish validity-reliability study of the scale was conducted by Cam et al.¹³

DATA COLLECTION PROCEDURE

Surgical Procedure

All the surgical procedures were performed under spinal anesthesia. Surgical steps up to the point of bladder flap formation were performed in a standard manner. Pfannenstiel skin incision was performed and subcutaneous tissues were opened by blunt dissection. The fascia was laterally opened with sharp dissection. The parietal peritoneum was opened by blunt dissection and then the abdominal cavity was entered A transverse incision was made 1 cm above the peritoneal layer of vesicouterine and no bladder flap was formed. The uterine cavity was entered with a blunt fingertip and a 1-2 cm space was formed. The space was then widened slightly laterally with the index fingers. After the delivery of the fetus, the pla-

centa was spontaneously separated (placental separation occurred spontaneously). Uterine incisions were closed with a single suture (For the closure of the uterine incision, one single suture was performed / Single layer closure of the uterine incision was performed). Parietal peritoneum was sutured. The fascia was closed with a continuous non-locking suture. The skin was closed intracutaneously. To prevent uterine atony after delivery, 30 units of oxytocin were administered in 1,000 mL saline solution.

Post-surgery

In line with the routine hospital protocol, 20 IU of oxytocin in 500 mL of 5% dextrose saline was infused to each participant at a flow rate of 20 drops per min for 4 hours after surgery. The postoperative analgesic protocol was the same for all the patients. According to the hospital protocol, in the postoperative period, to relive pain, the participants were administered 75 mg/3 ml diclofenac sodium, a nonsteroidal anti-inflammatory drug, intramuscularly twice a day, and 500 mg paracetamol orally twice a day.

While the participants in the experimental group underwent urinary catheter clamping 3 times after the postoperative 3rd hour, by turning off the urinary catheter for 3 hours, and then turning it on for 5 minutes (Q3h procedure). ¹⁴ The participants in the control group underwent the routine care implemented in the hospital in the same environment together with the participants in the experimental group.

During urinary clamping, if the patient needed to urinate urgently, drainage was performed for five minutes to prevent discomfort. If the volume of urine drained during urinary clamping did not exceed 300 ml, we performed the ultrasound scanning of the bladder to exclude high residual urine volume and started the oliguria treatment. If the volume of urine drained exceeded 500 ml, we performed rapid decompression of the bladder and increased the frequency of catheterization. Considering the evidence obtained from a clinical study indicating that there was no significant difference between the negative effects of rapid and gradual decompression of the bladder in acute urinary retention, we thought that the rapid drainage of the bladder would be safer for pa-

tients.¹⁵ In the literature, it has been reported that in cases of acute urinary retention, the removal of the first 100 ml of urine decreased intravesical pressure by approximately 50%, and after this first significant decrease in pressure, intravesical pressure decreased only slightly.^{16,17}

The urinary catheter was removed from the participants in the experimental and control groups after the post-operative 12th hour. Then the puerperae were expected to urinate spontaneously. After they urinated, urine samples were taken from them and the residual urine volume was measured through routine ultrasonography using the 3D portable ultrasound device (Verathon Bladder Scan BVI 9400). Of the participants, those with a residual urine volume of 150 ml or more were considered to have urinary retention. The participants with urinary retention underwent a urinary re-catheterization, and they were observed for 24 hours. Residual urine volumes of the participants were reassessed at the postoperative 1st and 6th weeks through ultrasonography. Then, their subjective urinary complaints at the postoperative 1st and 6th weeks were assessed based on the UDI-6 score. After the removal of the urinary catheter, the first urine sample was analyzed by the urine culture test. After the intervention, the data on the participants in the experimental and control groups were recorded in the checklist by the researchers. Then, the intergroup results were analyzed statistically.

The primary outcome of the present study was to determine whether exercising the detrusor muscle decreased post-void residual urine volume in patients having undergone cesarean section. The secondary results were the incidence of urinary tract infections and subjective symptoms experienced by the patients.

STATISTICAL ANALYSIS

For statistical analysis, IBM SPSS version 23.00 for Windows was used. Compatibility of variables to normal distribution was evaluated with the Kolmogorov-Smirnov test. Categorical variables were evaluated by Fisher exact test and Pearson chi-square test and in comparison of quantitative variables according to the binary group, two independent sample t tests were used for normally distributed data and

Mann-Whitney U test was used for non-normally distributed data. The difference between the residual urine volumes (categorical data, intra-group difference) obtained from three repetitive measurements of the patients in the experimental and control groups was compared using Cochran's Q test (post hoc analysis) and Bonferroni-corrected McNemar test. In the comparison of the intra-group differences the mean UDI-6 scores obtained from the two repeated measurements, the paired samples t-test was used. Mann-Whitney U test was used to detect the difference between the changes in the UDI-6 scores according to the groups. Descriptive statistics were presented as n (%) and mean \pm standard deviation if the variable is normally distributed, and median (minimum-maximum) if not, p values less than 0.05 was taken as the level of significance.

RESULTS

DESCRIPTIVE CHARACTERISTICS OF THE PARTICIPANTS

No significant differences were determined between the participants in the experimental and control groups in terms of their age, body mass index (BMI), education level, perception of income (Table 1).

EFFECTS OF CLAMPING OF THE URINARY CATHETER ON URINARY TRACT INFECTION, HEMATURIA AND BLADDER INJURY

While the urine culture was positive in 3 (6%) of the participants in the experimental group, it was 2 (4%) in the control group, and the difference between the groups was not significant (p=1.000). While the incidence of hematuria was 10 (20%) in the participants in the experimental group, it was 12 (24%) in the participants in the control group, and the difference between the groups was not significant (p=0.629). Bladder injury occurred in none of the participants in both groups (Table 2).

EFFECTS OF CLAMPING OF THE URINARY CATHETER ON POST-VOID RESIDUAL URINE VOLUME

The inter- and intra-group comparisons of the presence of post-void residual urine on the first day, and in the first and sixth weeks after the cesarean section in the participants in the experimental and control groups are given in Table 3.

TABLE 1: Descriptive characteristics of patients by study group.

Characteristics	Experimental group (n=50)	Control group (n=50)	2	
maternal	n (%)	n (%)	χ^2	р
Level of education				
Primary education*	15 (30)	16 (32)	1.504	.471
High school	29 (58)	24 (48)		
University	6 (12)	10 (20)		
Income perception				
Income less than expenses	34 (68)	42 (84)	3.509	.061
Income more than expenses	16 (3)	8 (16)		
			t	р
Mean age±SD year	32.32±5.30	31.68±5.44	.596	.553
Mean BMI±SD	29.48±3.46	29.23±3.63	.357	.722

χ2: Pearson Chi-square analysis

TABLE 2: Comparison of urinary tract infection, hematuria and bladder injury in patients in the experimental and control groups.

	Experimental Group (n=50)	Control Groups (n=50)	Test	
	n (%)	n (%)	χ²: .233	р
Urine culture				
Positive	3 (6)	2 (4)		1.000F
Negative	47 (94)	48 (96)		
Hematuria				
Yes	10 (20)	12 (24)		.629
No	40 (80)	38 (76)		
Bladder injury	1			
Yes	-	-		AY
No	50 (100)	50 (100)		

F: (Fisher's Exact test)

INTERGROUP COMPARISON OF RESIDUAL URINE IN THE PARTICIPANTS

The analysis of the incidence rates of residual urine performed in the experimental and control groups at three measurement times demonstrated that there was no significant difference between the groups both on the first day [E: 10 (20%), C: 12 (24%), p=0.629] and in the first week [E: 2 (4%), C: 3 (6%), p=1.000]. In

t: Independent sample t- tests

^{*} In the control group, only one person was illiterate. The others had primary education.

 $[\]chi^2$: Pearson chi-square test

AY: Analysis was not possible in some sections since the sample size was not available (expected number <1).

	Experimental group (n=50)	Control group (n=50)		
	n (%)	n (%)	Test	р
1st day residual urine volume> 150 m	nl			
Yes	10 (20)	12 (24)	χ ²: .233	.629
No	40 (80)	38 (76)		
1st week residual urine volume> 150	ml			
Yes	2 (4)	3 (6)		1.000F
No	48 (96)	47 (94)		
6th week residual urine volume> 150	ml			
Yes	-	•		
No	50 (100)	50 (100)		AY
Intra-group difference test	16.800 / .000	19.500 /.000		
C-Q/p	Day 1st> Week1st and Week 6th	Day 1st> Week 1st and Week 6th		
	р	р		
1st day and 1st week	.006	.004		
1st day and 6th week	<.001	<.001		
1st week and 6th week	1000.	.867		

γ²: Pearson chi-square test

the sixth week, no residual urine was observed in any patient in both groups (Table 3).

COMPARISON OF THE PRESENCE OF RESIDUAL URINE IN THE PARTICIPANTS OVER TIME (INTRA-GROUP DIFFERENCE)

In the further analysis (Bonferroni corrected McNemar test), the incidence rate of residual urine on the first day was significantly higher than that in the first weeks in both groups (E: p=0.006, C: p=0.004); the incidence rate of residual urine on the first day was significantly higher than that in the sixth weeks in both groups (E: p<0.001, C: p<0.001); however, the difference between the first and sixth week measurements was not significant (E: p=1.000, C: p=0.867).

EFFECTS OF CLAMPING OF THE URINARY CATHETER ON THE UDI-6 SCORE

The intra-group comparisons of the UDI-6 scores determined 1st and 6th weeks after the cesarean section in the participants in the experimental and control groups are given in Table 4. The intragroup comparison of the mean UDI-6 scores obtained by the par-

ticipants in the first and sixth weeks after cesarean section revealed that in the experimental group, the mean UDI-6 score determined in the sixth week (10.00±7.21) was lower than was that determined in the first week (25.22±16.35), and that the difference was significant (p<0.001). As for the control group, the mean UDI-6 score determined in the sixth week (11.11±6.92) was lower than was that determined in the first week (29.33±19.28), and that the difference was significant (p<0.001, Table 4). There is no statistical difference between the groups in percentage change values in time dependent intragroup UDI-6 scores (p=0.453). While the percentage median change (%) in the experimental group was 50.60, this value was obtained as 58.93 in the control group (Table 4).

DISCUSSION

In our study, there was no statistically significant difference in the clamping (experimental) group and in the non-clamping (control) group in terms of postvoid residual urine volume, urinary tract infection and subjective voiding difficulty. The differences be-

F: Fisher exact test

AY: Since there is no sample number in some regions (expected number <1), analysis could not be performed.

C-Q: Cochran's Q test, post hoc analysis: Bonferroni-corrected McNemar test

TABLE 4: Comparison of patients' UDI-6 mean score by group and time. p** Measuring time Experimental Groups (n=50) Control Groups (n=50) Mean first week UDI-6 total score±SD 25 22+16 35 29.33±19.28 Mean sixth week UDI -6 total score±SD 10.00±5.02 11.11±6.92 Difference in the group t* 6.543 8.328 <.001 <.001 Percentage changes % in the UDI-6 scores (st-6th weeks) Median (min-max) 50.60 (-51-100) 58.93 (0-100) .453**

tween the two groups in terms of age, body mass index (BMI), education level, perception of income, hematuria, and bladder injury were not significant either.

Postpartum urinary retention (PUR) is one of the leading causes of maternal morbidity. In numerous studies, it has been asserted that urinary retention occurs after vaginal delivery. 5,18,19 While the incidence of postpartum urinary retention (PUR) after vaginal delivery ranges from 1.70% to 17.90%, it varies between 3.20% and 24.20% after caesarean section. Therefore, inexpensive, easy-to-apply diagnostic treatment strategies (e.g. clamping of the urinary catheter and detrusor muscle exercises) should be developed to reduce the development of postoperative urinary retention.

The review of the literature demonstrated that there are different opinions about the clamping procedure before removing the catheter in the short-term urinary catheter. While some studies emphasize that clamping of the urinary catheter can strengthen the detrusor muscle, increase the muscle tone and sensitivity, and return the bladder to its normal function in a shorter time, some other studies put forth that clamping of the urinary catheter had no effect on the development of postoperative urinary retention and re-catheterization. 7,10,11,20-26 In our study, the analysis of the incidence rates of residual urine performed in the experimental and control groups at three measurement times demonstrated that there was no significant difference between the groups both on the first day [E: 10 (20%), C: 12 (24%)] and in the first week [E: 2 (4%), C: 3 (6%)]. In the sixth week, no residual urine was observed in any patient in both groups. Our study was performed with patients undergoing cesarean section under spinal anesthesia, which is a regional anesthesia. There may be a decrease in detrusor contraction in the early period (such as the first 12 hours) due to spinal anesthesia. This result may have been due to the lack of sufficient time for 12-hour bladder training detrusor motivation after cesarean section.

In Wang et al.'s review including 2515 patients, postoperative short-time urinary catheter clamping did not lead to a difference between the groups in terms of postoperative urinary retention, urinary tract infection, and patients' subjective complaints. However, it was emphasized that there might be a risk of urinary tract injury due to the presence of long-term catheter. 11 In their review including 2933 patients, Griffiths et al., reported that the benefit of short-term urinary catheter clamping on postoperative urinary retention was not certain, and that the patients whose catheters were removed late stayed in the hospital shorter than did the patients whose catheters were removed early.¹⁰ In another review involving 3 studies, it was found that clamping before the removal of the urinary catheter had no effect on urinary tract infection, urinary retention, the need for re-catheterization, and the length of hospital stays in patients with shortterm catheters.²² According to our study, no difference was found in the group with and without clamps in terms of urinary tract infection, bladder injury and subjective voiding difficulty.

In parallel with the increase in the world population, the number of cesarean sections is increasing too. Therefore, it is important to optimize all aspects of the postoperative treatment in such patients: One of these options is the development of treatment strategies to reduce postoperative urinary retention

^{*} t: paired samples t-test

^{**}Mann Whitney U testi

and urinary infection. The review of the literature revealed that there is a study emphasizing that initiative bladder function training given on how to exercise abdominal muscles and levator ani muscle after cesarean section can improve the function of the bladder and reduce urinary tract infections.²⁷ However, there is no study investigating the effect of the intermittent clamping of the urinary catheter and exercising of the detrusor muscle on the reduction of residual urine volume in the early period and the prevention of urinary tract infection associated with this.

The study had some limitations. Firstly, neither the patients nor the nurses were blinded; therefore, there is a possibility of observer bias. Secondly, the procedures were not performed by a single researcher because nurses varied according to their shifts. Thirdly, the urinary clamping procedure was performed with a few repetitions in a short time.

CONCLUSION

In our study, urinary catheter clamping has no reducing effect in terms of the postoperative residual urine volume, urinary tract infection and subjective voiding difficulty. Therefore, it is recommended that in the future, more research with higher quality methodologies designed with the clamping method that is repeated more frequently in patients with residual urinary volume undergoing catheterization for a long time should be conducted.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

This study is entirely author's own work and no other author contribution.

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