ARAŞTIRMA / RESEARCH

Investigation of Optimal Solution Type and Volume for Inflation of Foley Catheter Balloon in Indwelling Urethral Catheterization

Kalıcı Üretral Kateterizasyonda Foley Kateter Balonunun Şişirilmesi İçin Optimal Solüsyon Tipi ve Hacminin İncelenmesi

Ayşe AKBIYIK[1], Ebru ÖZEL[2], Perihan ÇETİN[3], Leyla KHORSHID[4]

[1]*Izmir Katip Çelebi University, Faculty of Health Sciences, Department of Nursing*
[2]*Ege University Faculty of Medicine Hospital Neurology Intensive Care Unit*
[3]*Izmir Katip Çelebi University, Vocational School of Health Services*
[4]*Ege University, Faculty of Nursing, Department of Fundamentals of Nursing*

Geliş tarihi/Received: 26.06.2021
Kabul tarihi/Accepted: 19.04.2022

Sorumlu Yazar/Corresponding Author:

Ayşe AKBIYIK, Assistant Professor
Izmir Katip Çelebi University, Faculty of Health Sciences, Department of Nursing
E-posta: ayseakbyk@hotmail.com
ORCID: 0000-0003-0513-5433

Ebru ÖZEL, Clinical Specialist Nurse
ORCID: 0000-0003-0405-6370

Perihan ÇETİN, Assistant Professor
ORCID: 0000-0002-9626-9420

Leyla KHORSHID, Professor
ORCID: 0000-0001-7101-9014

Abstract

Objective: In this study investigates the effect of the type and volume of solution used in inflation of the foley catheter balloon on the development of urine leakage around the catheter during indwelling urethral catheterization.

Material and Method: This randomized controlled experimental study was conducted with 128 patients hospitalized in the intensive care unit and carried out between 2015 and 2019. In each study group, different types and volumes of the solution including 10 mL 0.9% sodium chloride, 15 mL 0.9% sodium chloride, 10 mL sterile distilled water, and 15 mL sterile distilled water were used to inflate the foley balloon.

Results: In the study, 7% of the patients who underwent indwelling urinary catheterization had urine leakage around the catheter. Urine leakage occurred on a mean of 11.33±8.22 days of catheterization. The urine leakage rate was calculated as 7.22/1000 catheterization days. Urine leakage rates of 10 mL 0.9% sodium chloride, 15 mL 0.9% sodium chloride, 10 mL sterile distilled water, and 15 mL sterile distilled water on the day of 1000 catheterization were 7.72, 5.60, 13.25, and 3.01 catheterization days, respectively. The most frequent urine leakage was in catheterizations using 10 mL sterile distilled water. Urine leakage was lower in catheterizations using 15 mL sterile distilled water compared to other groups.

Conclusion: Using 15 mL of sterile distilled water to inflate the balloon can minimize urine leakage to ensure that the catheterization continues safely.

Keywords: Indwelling urethral catheter, saline, balloon, urine leakage, sterile distilled water.

Öz

Amaç: Bu çalışma foley kateter balonunun şişirilmesinde kullanılan solüsyon tipi ve hacminin kalıcı üretral kataterizasyon sırasında kateter etrafından idrar sızıntısı gelişimi üzerindeki etkisini incelemektedir. Foley balonun şişirilmesi için her bir çalışma grubunda 10 mL %0,9 sodyum klorür, 15 mL %0,9 sodyum klorür, 10 mL steril distile su ve 15 mL steril distile su olmak üzere farklı tip ve hacimLerde solüsyon kullanıldı.

Gereç ve Yöntem: Bu randomize kontrollü deneysel çalışma, yoğun bakım ünitesinde yatan 128 hasta ile 2015-2019 yılları arasında yürütüldü.

Bulgular: Çalışmada kalıcı üriner kateterizasyon uygulanan hastaların %7'sinde kateter çevresinde idrar sızıntısı gelişti. Kateterizasyonun ortalama 11,33±8,22 gününde idrar sızıntı meydana geldi. 1000 kateterizasyon gününde 10 mL %0.9 sodyum klorür, 15 mL %0,9 sodyum klorür, 10 mL steril distile su ve 15 mL steril distile su için idrar sızıntısı oranları sırasıyla 7,72, 5,60, 13,25 ve 3,01 gündü. En sık idrar sızıntı 10 mL steril distile suyun kullanıldığı kateterizasyonlarda gelişti. 15 mL steril distile su kullanılan kateterizasyonlarda idrar sızıntısı oranı diğer gruplara göre daha düşüktü.

Sonuç: Balonu şişirmek için 15 mL steril distile su kullanmak, kateterizasyonun güvenli bir şekilde devam etmesini sağlamak için idrar sızıntısını en aza indirebilir.

Anahtar Kelimeler: Kalıcı üretral kateter, salin, balon, idrar kaçağı, steril distile su.

1. Introduction

Indwelling urinary catheterization (IUC) is one of the most common invasive procedures in hospitals. About a quarter of patients are exposed to IUC at least once during hospitalization (1,2). In Foley catheter balloons, the volume of solution used to inflate the balloon is usually indicated on the catheter and ranges from 30 to 60 mL. For maintaining the continuity of catheterization, the volume of fluid in the balloon should be optimal. In maintaining the continuity of catheterization, it is extremely important that the volume of solution in the balloon is optimal. In catheterization, the foley catheter balloon is placed in the bladder neck. Inflating the balloon to an appropriate amount will close the bladder neck and prevent urine leakage from around the catheter. In one study, urine leakage was shown in low-volume balloons due to failure of the bladder neck to close (3).

10 mL 0.9% sodium chloride (NaCl) or sterile distilled water (SDW) are generally used for inflating foley catheter balloons in clinics (2–4). However, it is experienced by clinical nurses that urine leakage occurs around the catheter in mid and long-term urinary catheterizations. The literature has attributed the volume declines to three possible causes. The first reason is that the balloon is semi-permeable. This feature allows fluid movement between sections easily in case of an osmotic pressure difference between the solution in the balloon and the urine. The second reason is an accumulation of the liquid in the hydrophilic balloon inflation channel. The third is a decrease in liquid volume due to crystallization of 0.9% NaCl solution or other ionic-containing liquids (2–6).

Urine leakage around the catheter interrupts catheterization continuation as well as causes unpleasant odor and skin maceration as a result of contact with the skin. In this study, we aimed to determine the development of urine leakage in the IUCs, and the effect of the type and amount of solution used to inflate the foley catheter balloon on the development of urine leakage.

2. Materials and Methods

This randomized controlled experimental study was conducted between 2015 and 2019. The study was registered in http://clinicaltrials.gov/(clinicalTrials gov ID: NCT04103229).

2.1. Participants

In the study, the number of people in the sample was determined by using the small effect size suggested by Cohen (7). The result of the power analysis was determined as follows: It was calculated with 128 patients in total by taking effect size = 0.15, type 1 error = 0.05, power = 0.90, number of groups = 4. 128 patients who met the inclusion criteria were included in the study sample.

Inclusion criteria:

- Being over 18 years old.
- Having an indication for IUC intervention.
- Using an 18 Fr silicone foley catheter.

Exclusion criteria:

- Having prostate hypertrophy.
- Having a problem that may affect the urinary system.

2.2. Data Collection

In the implementation of the study, the patients were evaluated in terms of diagnosis, age, gender, and inclusion criteria from the follow-up and patient registration forms. Written informed consent was obtained from the relatives of the patients who met the inclusion criteria. Patients were assigned to the groups by block randomization to take into account the patient variables.

IUC was performed under surgical aseptic conditions. In the catheterization procedure, the catheter balloon was inflated according to the type and amount of solution appropriate to the group to which the patient was assigned.

2.3. Study Groups

Although the study group is shown in Table 1, the experiment consisted of the following groups.

- Group 1: The IUC was inflated with 10 mL 0.9% NaCl of the balloon.
- Group 2: The IUC was inflated with 15 mL 0.9% NaCl of the balloon.
- Group 3: The IUC was inflated with 10 mL SDW of the balloon.
- Group 4: The IUC was inflated with 15 mL SDW of the balloon.

The date of the day of catheterization was recorded. In addition, urine osmolarity was determined at the beginning of catheterization. Furthermore, the presence of a disease or infusion therapy that had an effect on urine osmolarity was evaluated. Patients were followed up every 12 hours for the presence of urine leakage around the catheter. The presence of urine leakage was monitored by observation, wetting of the diaper, and pH meter strip wrapped around the catheter. In addition, urine samples of the urine leakage were collected, and urine pH and leakage pH were compared.

Table 1. Research Groups

Range of year	Application groups							
	10 mL sterile distilled water		15mL sterile distilled water		10 mL 0.9% sodium chloride (NaCl)		15 mL 0.9% sodium chloride (NaCl)	
	Female	Male	Female	Male	Female	Male	Female	Male
18-64 years	8	8	8	8	8	8	8	8
65 years and older	8	8	8	8	8	8	8	8
Total	16	16	16	16	16	16	16	16

Participation of the patients in the study groups continued until one or more of the following criteria met:

- Development of urine leakage around the catheter,
- Termination of catheterization,
- Transfer of the patient to another unit,
- Development of Exitus.

In the study, if urine leakage occurred within 12 hours after catheterization, it was assumed that the leakage was caused by the size of the catheter, and these patients were excluded from the study.

2.4. Validity and Reliability

In this study, urine leakage around the foley catheter was detected as follows: Visible wetness was detected in the diapers of patients with leakage. The pH of this fluid that caused wetness in the patient's diaper and the urine pH of the patient were also determined at the same time. In addition, when the fluid in the balloon in the foley catheter was withdrawn, patients with urine leakage had a fluid loss of more than 4 mL compared to the initial fluid.

2.5. Ethical Considerations

Oral and written approval was obtained from the patient's relatives who agreed to take part in the study, and their identities were kept confidential. In addition, permission was obtained from the institution. Ethical approval was obtained from the Ethical Committee of the University (June 02, 2015, Number:0.20.05.00/OY/784/313).

2.6. Data Analysis

SPSS 15.0 was used in the analysis of data. Means and percentages of the variables were evaluated. The chi-square test (Fisher's Exact Test) and Mann-Whitney U test were used to examine the change in the dependent variable according to independent variables. In the comparisons, $p<0.05$ was interpreted as a statistically significant difference.

3. Results

The mean age of 128 patients included in the study was 64.80±12.71 (Min:26; Max:98) years. The mean length of stay in the intensive care unit was 9.51±8.99 (Min:2; Max:63) days. 83.4% of the patients had cerebral hemorrhage (Table 2).

Table 2. Reasons for Hospitalization of Intensive Care Units in Patients Undergoing Urethral Catheterization

Diagnosis	n	%
Cerebral vascular diseases	107	83.40
Encephalopathy	6	4.70
Myasthenia gravis	6	4.70
Carotid artery stenosis	2	1.60
Polyneuropathy	2	1.60
Acute Lymphoblastic Leukemia	2	1.60
Parkinson	2	1.60
Guillain-Barre syndrome	1	0.80
Total	128	100

The mean urine osmolarity at the beginning of urinary catheterization was 1013.93±5.12 (Min:1005; Max:1030) mOsm/kg. 39.1% of the patients had diabetes mellitus. None of the patients had a disease such as diabetes insipidus, which reduced urine osmolarity. 4.7% of the patients were receiving hypertonic fluid (3% NaCl) infusion. None of the patient received hypotonic fluid during IUC. The mean duration of IUC was 62.21±12.91 (Min: 26; Max: 98) days. 71.1% of the patients who were followed up for leakage around the catheter were transferred to the ward, 22.7% were discharged and 6.2% developed exitus.

Urine leakage occurred in 7% of urinary catheterization patients. Urine leakage around the catheter developed on the mean day of catheterization of 11.33±8.22 (Min:2; Max:28). Of the IUCs with urine leakage, 22.2% were in the "10 mL 0.9% NaCl" or "15 mL 0.9% NaCl" groups, 44.5% in the "10 mL SDW" group, and 11.1% in the 15 mL SDW group.

Urine leakage rate was calculated as 7.22/1000 catheterization days. Urine leakage rates of 10 mL 0.9% NaCl, 15 mL 0.9% NaCl, 10 mL SDW, and 15 mL SDW on the day of 1000 catheterization were 7.72, 5.60, 13.25, and 3.01 catheterization days, respectively.

The development of urine leakage around the catheter did not differ significantly according to the type and volume of solution used to inflate the balloon (X^2=2.078; p=0.500). 66.7% of patients who developed urine leakage in the catheter were female. There was no significant difference between men and women in urine leakage (X^2=1.095; p=0.246). 44.4% of patients with urine leakage of the IUC also had diabetes mellitus. There was no statistically significant difference between patients with and without diabetes mellitus in the rate of urine leakage through catheters (X^2=0.153; p=0.475). 11.1% of patients with urine leakage of the IUC had hypertonic infusion during IUC. There was no significant relationship between the use of hypertonic infusion and urine leakage (X^2=0.476; p=0.407) (Table 3). The mean urine osmolarity of the patients who developed urine leakage around the catheter during catheterization was 1013.44 mOsm/kg (Min:1007; Max:1025). There was no significant relationship between urine leakage and urine osmolarity (Mann-Whitney-U =474.000; p=0.566). It was determined that 66.6% of urine leakage occurred between 7 and 28 days of urethral catheterization (mid-term catheterization process).

4. Discussion

In this study, the incidence of urine leakage around the catheter during the IUC and the change of urine leakage according to the type and amount of solution used to inflate the catheter balloon were investigated. Urine leakage around the catheter, especially in the course of medium and long-term urinary catheterization, has been a problem with which clinical nurses have been familiar. However, few studies have mentioned this problem (8,9). In a study that examined the complications of IUC, the majority of patients (89%) reported urine leakage around the catheter (8). In the present study, urine leakage around the catheter in 7% of the IUCs developed on the mean catheterization day of 11.33±8.22 (Min:2; Max:28). It has been reported that the development of urine leakage around the catheter may be related to the size of the catheter, design errors of the catheter, urethral structure

Table 3. Variation of Urine Leakage Around Urethral Catheter According to Patient Variables

Variables		Development of urine leakage			
		Yes		No	
		n	%	n	%
Applications groups	10 mL %0.9 NaCl	2	22.2	30	25.2
	15 mL %0.9 NaCl	2	22.2	30	25.2
	10 mL sterile distilled water	4	44.5	28	23.5
	15 mL sterile distilled water	1	11.1	31	26.1
		Fisher's Exact Test (2.078; p=0.500)			
Range of year	18-64 years	6	66.7	58	48.7
	65years and older	3	33.3	61	51.3
		Fisher's Exact Test (1.095; p=0.246)			
Gender	Male	3	33.3	61	51.3
	Female	6	66.7	58	48.7
		Fisher's Exact Test (1.095; p=0.246)			
Presence of diseases that may affect urine osmolarity	Yes*	4	44.4	45	37.8
	No	5	55.6	74	62.2
		Fisher's Exact Test (0.153; p=0.475)			
Use of hypertonic infusion	Yes**	1	11.1	6	5.0
	No	8	88.9	113	95.0
		Fisher's Exact Test (0.476; p=0.407)			

*Diabetes mellitus; ** 3% NaCl infusion

anomalies, and the volume of the catheter balloon (9,10). Maintaining the initial volume of the catheter balloon which is designed to keep the catheter in the bladder and to prevent urine output by closing the urethral neck (10), is important to maintain catheterization, especially in long-term catheterization without any problem. However, in the IUC, the volume of solution in the balloons is reduced for some reasons including the osmolarity difference between the balloon solution and urine, crystallization of saline, or other ionic compound containing solution over time (2–6). In this study, although there was no significant relationship between the type and amount of solution used to inflate the balloon and urine leakage ($p>0.05$), there was more urine leakage in the NaCl group in IUCs and 10 mL fluid volume groups. Thus, in 12.5% of catheters using 10 mL SDW, 6.2% of catheters using 10 mL or 15 mL 0.9% NaCl developed urine leakage and in the catheters using 15 mL SDW, urine leakage rate was 3.1% (data not shown). In this study, less urine leakage in the 15 mL SDW group compared to the 15 mL 0.9% NaCl group may be related to the crystallization of the ions in the liquid content, as mentioned above. Urine leakage was observed in catheterizations (44.4%) using 10 mL SDW. The rise of the rate can be explained by the movement of the balloon fluid into the bladder due to the difference between balloon solution and urine osmolarity. Sharpe et al. (2011)'s in vitro study was sufficient to support the consistency of the results we found in our study. SDW and 0.9% NaCl were used to inflate the balloon, while the diameter of both catheters decreased in the first five days compared to the initial diameter (SDW: 15.66±6.320; 0.9% NaCl: 15.5 6±0.452), whereas balloon diameters with 0.9% NaCl at day 10 were significantly reduced compared to SDW (SDW: 10.06 ± 5.693; 0.9% NaCL:4.00±7.505) (3). In the present study, no statistically significant relationship was found between urine osmolarity and catheter leakage ($p<0.05$). In the literature, it was mentioned that urine osmolarity affects the movement of fluid in the permeable balloon (3,11). On the other hand, the fact that leakage development did not differ according to urine osmolarity may be caused by the narrow range of urine osmolality values (Min: 1007; Max: 1025) in our study.

5. Conclusion

In this study, the effect of fluid type and volume used in inflating foley catheter balloons on urine leakage development was investigated. Urine leakage was relatively high in catheters using 10 mL volumes of solution compared to other groups. The most frequent urine leakage was in catheterizations using 10 mL 0.9% NaCl. Urine leakage was lower in catheterizations using 15 mL SDW compared to other groups. Although there has been a need to repeat randomized controlled clinical trials that support our results, using 15 mL SDW in the application of silicone IUC may be appropriate for the continuity of catheterization.

6. Contribution to the Field

The development of urine leakage around the catheter during IUC may be related to the volume of solution used to inflate the catheter balloon. In the IUC, using 15 mL of SDW to inflate the catheter balloon may minimize urine leakage around the catheter.

Ethical Aspect of the Research

Oral and written approval was obtained from the patient's relatives who agreed to take part in the study, and their identities were kept confidential. In addition, permission was obtained from the institution. Ethical approval was obtained from the Ethical Committee of the University (June 02, 2015, Number:0.20.05.00/OY/784/313).

Conflict of Interest

This article did not receive any financial fund. There is no conflict of interest regarding any person and/or institution.

Authorship Contribution

Concept: AA; **Design:** AA, LK; **Supervision:** AA, EÖ, PÇ; **Funding:** AA, EÖ; **Materials:** AA, EÖ; **Data Collection/ Processing:** AA, EÖ; **Analysis/Interpretation:** AA, LK; **Literature Review:** AA; **Manuscript Writing:** AA, PÇ; **Critical Review:** AA, EÖ, PÇ, LK.

Kaynaklar

1. Wu AK, Blaschko SD, Garcia M, McAninch JW, Aaronson DS. Safer urethral catheters: How study of catheter balloon pressure and force can guide design. BJU Int. 2012;109(7):1110–4.

2. Huang JG, Ooi J, Lawrentschuk N, Chan STF, Travis D, Wong LM. Urinary catheter balloons should only be filled with water: Testing the myth. BJU Int. 2009;104(11):1693–5.

3. Sharpe SJ, Mann FA, Wiedmeyer CE, Wagner-Mann C, Thomovsky EJ. Optimal filling solution for silicone Foley catheter balloons. Can Vet J. 2011;52(10):1111–4.

4. Hui J, Ng CF, Chan LW, Chan PSF. Can normal saline be used to fill the balloon of a Foley catheter? The experience of a prospective randomized study in China. Int J Urol. 2004;11(10):845–7.

5. Daneshmand S, Youssefzadeh D, Skinner EC. Review of techniques to remove a Foley catheter when the balloon does not deflate. Urology. 2002;59(1):127–9.

6. Gonzalgo ML, Walsh PC. Balloon cuffing and management of the entrapped Foley catheter. Urology. 2003;61(4):825–7.

7. Cohen, J. Statistical Power Analysis for the Behavioral Sciences. Hillsdale (NJ): Lawrence Erlbaum Associates (1988): 18-74.

8. Roe BH, Brocklehurst JC. Study of patients with indwelling catheters. J Adv Nurs. 1987;12(6):713–8.

9. Theriault R, Ward-Smith P, Soper C. Leakage associated with urinary catheter usage: a design challenge. Urol Nurs [Internet]. 2012;32(6):307–12.

10. Smith J. Indwelling catheter management: from habit-based to evidence-based practice. Ostomy Wound Manag. 2003;49(12):34–45.

11. Studer UE, Bishop MC, Zingg EJ. How to fill silicone catheter balloon. Urology. 1983;22(3):300–2.