Annals of Medicine and Surgery 62 (2021) 415–418

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Randomised Controlled Trial

Prophylactic postoperative condom sheet placement: A randomized clinical trial to test a new concept

Hadi Ahmadi Amoli [c], Farzad Vaghef Davari [b,*], Bahare Rahmanian [a], Amirsina Sharifi [b], Reza Shariat Moharari [c], Ehsan Rahimpour [c], Mahmoud Rahmanian [d], Shahram Gooran [c]

[a] Tehran University of Medical Sciences, Tehran, Iran
[b] Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Tehran, Iran
[c] Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran
[d] Tehran University, Tehran, Iran

ARTICLE INFO

Keywords:
Condom sheet
Postoperative urinary retention
Preventive measurement
Anorectal surgery
Surgical complications

ABSTRACT

Objective: Postoperative urinary retention (POUR) is one of the most common complications after surgery with several risk factors. However, its precise etiology is not completely understood. So far, the effect of prophylactic condom sheet placement on the prevention of POUR has not been addressed. This study was designed to understand whether preventive condom sheet decreases the rate of POUR.

Materials and methods: This randomized clinical trial was carried out in an educational hospital during 2018–2019. All male patients, who underwent anorectal surgery with spinal anesthesia, were included and randomly allocated into two groups (with and without postoperative condom sheet placement).

Results: A total of 172 patients were included in this study (86 patients per group). Twenty-three (13.4%) patients developed POUR. The incidence of POUR was 15.1% among patients with condom sheets and 11.6% in patients without condom sheets, which was not significantly different ($P > 0.5$). POUR development had a significant correlation with the use of morphine and history of hypertension in both univariate and multivariate analyses.

Conclusion: Based on the present results, it seems that condom sheet placement did not effectively prevent POUR in patients; therefore, ambulation of patients after surgery is a more effective strategy for these patients.

1. Introduction

Postoperative urinary retention (POUR) is defined as one's inability to void in spite of full bladder following surgery under anesthesia. POUR affects both male and female patients and is one of the most common complications following surgeries with anesthesia, as reported in up to 76% of surgeries [1–4]. Although the exact etiology of POUR has not been identified, various studies suggest a multifactorial etiology, with several risk factors including age, gender, type of surgery, and anesthesia. The most important risk factors include comorbidities, preexisting urinary pathologies, duration of surgery, and intravenous fluids [1,4–6].

The main mechanism of retention after benign anorectal surgeries is adrenergic stimulation after postoperative pain, which inhibits detrusor muscle contraction and bladder outlet relaxation [7]. Regional anesthesia is an important risk factor for POUR, and surgeries performed under this type of anesthesia are associated with a greater risk of POUR [8]. POUR is most commonly characterized by inability to void, abdominal pain, and lower abdominal discomfort [1,9,10]. There are several methods for diagnosis of POUR, such as physical examination (either palpation or percussion in the suprapubic region), bladder catheterization for both treatment and diagnosis, and ultrasound assessment, which is not necessary for all patients [1,11,12].

Considering the critical and emergent nature of POUR, it should be treated immediately. It is an unpleasant postoperative complication, which needs to be evaluated and treated accordingly. We hypothesized that the psychological factor is one of the important factors responsible for this complication, as it prevents urination before complete ambulation or while sleeping. Therefore, placement of a prophylactic condom sheet may have preventing effects on this complication.

2. Material and methods

This randomized controlled clinical trial was conducted during

* Corresponding author. Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Sina Hospital, Hassan Abad Sq. Tehran, Iran.
E-mail address: fvdavari@sina.tums.ac.ir (F. Vaghef Davari).

https://doi.org/10.1016/j.amsu.2021.01.018
Received 10 December 2020; Received in revised form 2 January 2021; Accepted 12 January 2021
Available online 19 January 2021

2017–2018 in Sina Hospital, a tertiary referral hospital, affiliated to Tehran University of Medical Sciences (TUMS), Tehran, Iran. This study was approved by the ethics committee of TUMS (IR.TUMS.MEDICINE.REC.1397.315) and was registered by Iranian Registry of Clinical Trials (IRCT20180720040533N1). All of the participants were completely informed about the study before surgery, and all possible complications and problems were discussed with the patients; finally, a written consent form was signed by each patient.

All male patients aged ≥18 years, who were candidates for anorectal surgery due to a benign disease, were included in the study after obtaining written consent forms. Patients with a history of urethral stricture, neurological diseases, renal stone, urinary incontinence, current urogenital infections, and history of urogenital surgery were excluded from the study.

Sample size was computed by related formula and a total of 172 patients were randomly allocated to two groups via block randomization (1:1 allocation ratio) by statistician who was unaware of patient's condition.; each group consisted of 86 patients. Patients in group A underwent postoperative condom sheet placement, while patients in group B did not. All of the patients underwent spinal anesthesia (4 cc of Ropivacaine 0.5%) and received equal volume of intravenous (IV) fluids after surgery, as well as 30 mg of ketorolac after surgery. In the postoperative period of both groups, if the patient's pain persisted (visual pain score was >5), 3 mg of IV morphine was injected, which could increase to 5 mg if necessary. In both groups patients were encouraged to urinate as soon as they had urine sensation, in the intervention group surgical nurse explained that they have condom sheet and can urinate while sleeping in the bed but in the second group they were encouraged to ambulate as soon as possible (after returning sensation and movement of lower extremities) and make the urination in the toilet. Variables including demographic characteristics, preexisting diseases with possible effects on the outcomes (ischemic heart disease, diabetes mellitus, and hypertension), use of morphine for pain alleviation, and its total injected dose, type of surgery, POUR, and need for therapeutic urinary catheterization were recorded in a data sheet. POUR was excluded by the first urination, and catheterization was considered for patients without urination with clinical symptoms suggestive of POUR. After catheterization if the urine volume exceeded 200 cc, diagnosis of POUR was established. All of the patient were followed for at least 12 hrs after surgery after which they were discharged when they had tolerated food and had normal urination. If the diagnosis of POUR was confirmed, hospitalization time was extended to 18 and up to 24 h after resolution of POUR. Postoperative data recording was performed by an experienced surgery nurse in research team and was supervised by project manager.

Analysis of data was carried out using SPSS version 16 (SPSS Inc., Chicago, USA). Chi-Square, mann-whitney and logistic regression statistical tests were used and test P-value less than 0.05 was considered statistically significant. Variables are expressed as number (%) or mean ± standard deviation (SD).

3. Results

A total of 172 patients were enrolled in this study, with the mean age of 41.35 ± 12.1 years. Overall, 116 (67.4%), 24 (14%), 20 (11.6%), 7 (4.1%), and 5 (2.9%) patients underwent hemorrhoidectomy, examination under anesthesia (EUA), sphincterotomy, and abscess drainage, respectively (Table 1). The results showed no significant relationship between the type of surgery and POUR ($P < 0.05$).

Seventeen (9.9%) patients received IV morphine to relieve their pain. In this group, 7 (41%) patients had urinary retention, while the rate of retention was 10.3% ($n = 16$) in patients who did not receive morphine ($n = 155$); this is indicative of a significant relationship ($P < 0.05$). Twenty-three (13.4%) patients developed POUR. The incidence of POUR was estimated at 15.1% among patients with condom sheet placement and 11.6% in patients without condom sheets; the difference was not significant ($P > 0.05$). Moreover, 6 (3.5%), 8 (4.7%), and 3 (1.7%) patients had diabetes mellitus (DM), hypertension (HTN), and ischemic heart disease (IHD), respectively (Table 1).

Table 1
Outlines relation of type of surgery and comorbidities and presence of POUR.

		Patients with POUR	Patients without POUR	P-value
IHD		0 (0%)	3 (100%)	0.491
HTN		5 (62.5%)	3 (37.5%)	0.001
DM		2 (33.3%)	4 (66.6%)	0.144
Type of Surgery	Sphincterotomy	0 (0%)	7 (100%)	0.333
	Hemorhoidectomy	4 (16.7%)	20 (83.3%)	
	Fistulotomy	14 (12.1%)	102 (87.9%)	
	Abscess drainage	2 (40%)	3 (60%)	
	EUA	3 (15%)	17 (85%)	

Among comorbidities, there was no significant relationship between POUR and DM or IHD ($P > 0.05$), while the relationship between HTN and POUR was significant ($P < 0.05$) (Table 1).

Logistic regression analysis was carried out by considering age, type of surgery, condom sheet placement, DM, HTN, IHD, and morphine administration as independent variables and POUR as the outcome. In this model, only IHD and morphine administration were significantly associated with POUR ($P < 0.05$; 95% CI).

4. Discussion

The exact pathophysiology of POUR following anorectal surgeries is not completely understood. However, the most possible causes include bladder outlet obstruction or inhibition of the detrusor muscle [13,14]. The incidence rate of POUR was 13.4% in the present study, and most cases occurred due to abscess drainage (40%) and hemorrhoidectomy (16.7%). In this regard, a study by Toyonaga T et al. reported an incidence rate of 16.7%, while fistulectomy was the main surgery leading to the development of POUR [12].

Moreover, Kunitake H et al., in their review study, showed that the incidence of POUR ranges from 3% to 50%, although the most common incidence rate was around 15% [15]. Zaheer S et al. concluded that POUR is the most common complication after hemorrhoidectomy and reported an overall incidence of 16% [16]. In addition, Baldini G et al. in their review study reported an incidence of 5%–70% [1]. They retrospectively reviewed patients undergoing arthroplasty and concluded that the incidence of POUR was nearly 17% [17]; these results are compatible with our findings.

The current study revealed that use of IV opioid (morphine) and HTN are risk factors for POUR. We believe that the main contributing factor for POUR is pain, while opium only plays an intermediate role. It has been also reported that pain is a major risk factor for POUR by inhibiting the detrusor muscle [9,14]. In this regard, Toyonaga T et al. concluded that postoperative pain and excessive amounts of IV fluids are the most important risk factors for POUR, which should be considered [14]. Kunitake H et al. revealed that the IV fluid is the most important risk factor [15]. Moreover, Zaheer S et al. concluded that older age and perioperative IV fluids may be important risk factors for POUR [16].

A study by Baldini G et al. on POUR showed that risk factors, such as comorbidities, type of surgery, and type of anesthesia, influence the development of POUR [1]. Pertek JP et al. concluded that besides age, long-acting agents in spinal anesthesia are more likely to increase the incidence of POUR [18]. Choi S et al. concluded that several factors, such as comorbidities, type of surgery, anesthetic type, and anesthetic agents (such as long-acting neuraxial opioids), play important roles in the development of POUR [19]. Balderi T et al. recommended that epidural analgesia has the greatest effect on developing POUR [17]. Moreover, Petros JG and Bradley TM concluded that use of long-acting anesthetic agents and preoperative administration of IV fluids have significant effects on the development of POUR [20]. Bowers FJ et al.

also concluded that the volume of IV fluids significantly affects the incidence of POUR [21].

Additionally, Sung KH et al. reported that DM, HTN, type of surgery, male sex, and age were the risk factors for POUR [22]. As previously discussed, the mean age of the participants in our study was 41.35 years; therefore, we cannot report the actual effects of old age on POUR in this study. According to our inclusion criteria, only male patients were included in the study, while the effect of sex on POUR remains controversial. Some studies have reported that male sex is a risk factor for POUR [16,22,23], while others have reported no significant difference between males and females [20,21,24].

Based on our study, there was no significant difference between patients with and without condom sheets. Also, it was found that patients with condom sheets were more prone to POUR than their peers without the sheets. This finding was somehow expected, as the most important factor in the prevention of POUR seems to be ambulation, not psychological factors, such as inability to void while sleeping on the bed. Therefore, placement of a condom sheet not only is not preventive in this regard but also may act as an aggravating factor by encouraging the patient to void during sleeping on the bed. There were some limitations in this study. First of all, we injected a single dose of ketorolac to all patients after surgery which decreased and sometimes omitted their need to the morphine and made comparison of two groups somehow difficult. Second we chose a disease with special age range of involvement and patients without previous history of urologic disorders so the results are not generalizable to the other groups.

5. Conclusion

Using condom sheets is not effective in preventing POUR. Therefore, its routine prophylactic use is not recommended and immediate ambulation of patients seems to be the best strategy. Our future recommendation is to extend this experiment to the patients with other types of surgeries and other age groups that may benefit from this noninvasive intervention.

Provenance and peer review

Not commissioned, externally peer reviewed.

Ethical approval

Ethic committee of Tehran University of Medical Sciences approved study protocol.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contribution

Hadi Ahmadi Amoli: Conception and design of the study, writing the paper.

Farzad Vaghef Davari: Conception, Design of Study, Supervision, writing the paper.

Bahare Rahmanian: Data collection, supervision and writing the paper.

Amirsina Sharifi: Writing the paper, critical review and analysis and/or interpretation.

Reza Shariat Moharari: Design of Study and Writing the paper.

Ehsan Rahimpour: Data collection and/or processing.

Mahmoud Rahmanian: Data processing and analysis.

Shahram Gooran: design of the study.

Registration of research studies

1. Name of the registry:Iranian Registry of Clinical Trials

2. Unique Identifying number or registration ID: IRCT20180720040533N1

3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://en.irct.ir/trial/33980

Guarantor

Dr.Farzad Vaghef Davari.

Consent

In every step of running this research current ethical considerations were noticed and the study protocol conforms to the ethical guidelines of the Declaration of Helsinki 2013.

Declaration of competing interest

There is no conflict of interest to disclose.

Acknowledgment

The authors would like to express their gratitude to Ms. Samaneh Eskandari for her diligence and effort in data registration. Indeed we wish to acknowledge Tehran University of Medical Scienses as the funding source of this project.

References

[1] G. Baldini, H. Bagry, A. Aprikian, F. Carli, Postoperative urinary retention anesthetic and perioperative considerations, Anesthesiology: J. Am. Soc. Anesthesiol. 110 (2009) 1139–1157.

[2] T. Feliciano, J. Montero, M. McCarthy, M. Priester, A retrospective, descriptive, exploratory study evaluating incidence of postoperative urinary retention after spinal anesthesia and its effect on PACU discharge, J. PeriAnesthesia Nurs. 23 (2008) 394–400.

[3] D. Altschul, A. Kobets, J. Nakhla, A. Jada, R. Nasser, M.D. Kinon, R. Yassari, J. Houten, Postoperative urinary retention in patients undergoing elective spinal surgery, J. Neurosurg. Spine 26 (2017) 229–234.

[4] C. Kin, K.F. Rhoads, M. Jalali, A.A. Shelton, M.L. Welton, Predictors of postoperative urinary retention after colorectal surgery, Dis. Colon Rectum 56 (2013) 738–746.

[5] F. Grass, J. Slieker, P. Frauche, J. Solà, C. Blanc, N. Demartines, M. Hübner, Postoperative urinary retention in colorectal surgery within an enhanced recovery pathway, J. Surg. Res. 207 (2017) 70–76.

[6] K. Lingaraj, M. Ruben, Y. Chan, S.D. Das, Identification of risk factors for urinary retention following total knee arthroplasty: a Singapore hospital experience, Singap. Med. J. 48 (2007) 213.

[7] L. McLeod, K. Southerland, J. Bond, A clinical audit of postoperative urinary retention in the postanesthesia care unit, J. PeriAnesthesia Nurs. 28 (2013) 210–216.

[8] A.A. aziz Niazi, M.A. aziz Taha, Postoperative urinary retention after general and spinal anesthesia in orthopedic surgical patients, Egypt. J. Anaesth. 31 (2015) 65–69.

[9] S. Choong, M. Emberton, Acute urinary retention, BJU Int. 85 (2000) 186–201.

[10] K. Thomas, G. Oades, C. Taylor-Hay, R.S. Kirby, Acute urinary retention: what is the impact on patients' quality of life? BJU Int. 95 (2005) 72–76.

[11] F. Hollman, N. Wolterbeek, R. Veen, Risk factors for postoperative urinary retention in men undergoing total hip arthroplasty, Orthopedics 38 (2015) e507–e511.

[12] L. Lamonerie, E. Marret, A. Deleuze, N. Lembert, M. Dupont, F. Bonnet, Prevalence of postoperative bladder distension and urinary retention detected by ultrasound measurement, Br. J. Anaesth. 92 (2004) 544–546.

[13] H.D. de Boer, O. Detriche, P. Forget, Opioid-related side effects: postoperative ileus, urinary retention, nausea and vomiting, and shivering. A review of the literature, Best Pract. Res. Clin. Anaesthesiol. 31 (2017) 499–504.

[14] T. Toyonaga, M. Matsushima, N. Sogawa, S.F. Jiang, N. Matsumura, Y. Shimojima, Y. Tanaka, K. Suzuki, J. Masuda, M. Tanaka, Postoperative urinary retention after surgery for benign anorectal disease: potential risk factors and strategy for prevention, Int. J. Colorectal Dis. 21 (2006) 676–682.

[15] H. Kunitake, V. Poylin, Complications following anorectal surgery, Clin. Colon Rectal Surg. 29 (2016) 14.

[16] S. Zaheer, W.T. Reilly, J.H. Pemberton, D. Ilstrup, Urinary retention after operations for benign anorectal diseases, Dis. Colon Rectum 41 (1998) 696–704.

[17] T. Balderi, G. Mistraletti, E. D'Angelo, F. Carli, Incidence of postoperative urinary retention (POUR) after joint arthroplasty and management using ultra-sound-guided bladder catheterization, Minerva Anestesiol. 77 (2011) 1050.
[18] J. Pertek, J. Haberer, Effects of Anesthesia on Postoperative Micturition and Urinary Retention, Publisher, 1995.
[19] S. Choi, I. Awad, Maintaining micturition in the perioperative period: strategies to avoid urinary retention, Curr. Opin. Anesthesiol. 26 (2013) 361–367.
[20] J.G. Petros, T.M. Bradley, Factors influencing postoperative urinary retention in patients undergoing surgery for benign anorectal disease, Am. J. Surg. 159 (1990) 374–376.
[21] F.J. Bowers, R. Hartmann, K.S. Khanduja, T.G. Hardy, P.S. Aguilar, W.R.C. Stewart, Urecholine® prophylaxis for urinary retention in anorectal surgery, Dis. Colon Rectum 30 (1987) 41–42.
[22] K.H. Sung, K.M. Lee, C.Y. Chung, S.-S. Kwon, S.Y. Lee, Y.S. Ban, M.S. Park, What are the risk factors associated with urinary retention after orthopaedic surgery? BioMed Res. Int. 2015 (2015).
[23] R. Janković, M. Stošić, Specific aspects OF anesthesia IN proctology, Facta Univ. – Ser. Med. Biol. (2019) 21–24.
[24] C. Clancy, J.C. Coffey, M.G. O'Riordain, J.P. Burke, A meta-analysis of the efficacy of prophylactic alpha-blockade for the prevention of urinary retention following primary unilateral inguinal hernia repair, Am. J. Surg. 216 (2018) 337–341.