International Journal of Nursing Studies 89 (2019) 14–17

Contents lists available at ScienceDirect

International Journal of Nursing Studies

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

Bladder training prior to urinary catheter removal in total joint arthroplasty. A randomized controlled trial

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ARTICLE INFO

Keywords:
Bladder training
Foley catheter removal
Urinary retention
Total joint arthroplasty

ABSTRACT

Background: Urinary catheters are commonly used in patients undergoing total hip and knee arthroplasty. Bladder training before catheter removal is reported to shorten the time to return to normal bladder function and reduce the incidence of urinary retention.
Objective: To evaluate the results of bladder training in patients with total hip and knee arthroplasty.
Design: Randomized controlled trial.
Setting: Orthopaedic Department of a tertiary Military Hospital.
Participants: We enrolled consecutive patients undergoing total hip or knee arthroplasty during a period of 14 months.
Methods: We randomly allocated the participants into either a bladder training group, in which clamping was considered prior to catheter removal, or a free drainage removal group, using a computer-generated list and subsequently assessed their need for re-catheterization due to urinary retention. The primary outcome of this study was to evaluate if bladder training in patients with total hip and knee arthroplasty reduces the need for re-catheterization due to urinary retention. Multivariable logistic regression was used to model the association between postoperative urinary retention and independent variables (total hip or total knee arthroplasty, age, gender, and history of diabetes mellitus or prostatism). Secondary outcomes were the incidence of urinary tract infection, and subjective patients' symptoms.
Results: We included 218 patients in the study; 114 in the bladder training group and 104 in the free drainage removal group. All patients were over 50 years old with a mean age of 69.3 (SD = 8) years. We observed three cases of urinary retention in the bladder training and six in free drainage removal group, and the difference was not statistically significant (2.6% and 5.8% respectively, $p = 0.316$). We also observed increased odds of re-catheterization in patients with prostatism under medication (odds ratio was 26.42, $p < 0.001$). No infections or major subjective symptoms were noted.
Conclusion: This trial shows that bladder training by catheter clamping offers no advantage over free draining removal of short-term urinary catheters in patients with total hip and knee arthroplasty. Therefore, we conclude that the bladder training procedure is not indicated. However, healthcare providers should monitor patients' urination after removal of the catheter.

What is already known about the topic?

- Urinary catheters are commonly used in patients undergoing total hip and knee arthroplasty
- There is no consensus whether the use of bladder training by intermittent clamping before catheter removal reduces the incidence of urinary retention

What this paper adds

- Bladder training by catheter clamping has no advantage over free draining removal of short-term urinary catheters in patients with total hip and knee arthroplasty and is not indicated
- Patients with prostatism under medication are more likely to be re-catheterized

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https://doi.org/10.1016/j.ijnurstu.2018.09.007
Received 1 April 2018; Received in revised form 30 July 2018; Accepted 9 September 2018

1. Introduction

Patients undergoing total hip and knee arthroplasty may have difficulty or inability to urinate because of confinement in bed and postoperative pain. Male gender, intrathecal morphine and supplementary epidural anesthesia are additional risk factors, increasing the incidence of urinary retention up to 67% (Griesdale et al., 2011; Williams et al., 1995). Because of these difficulties, short-term urinary catheters are inserted before surgery and removed as soon as possible postoperatively.

Bladder training by intermittent clamping before catheter removal is reported to shorten the time to return to normal bladder function and reduce the incidence of urinary retention (Roe, 1990). However, there is no consensus on its use; a Cochrane review reported inconclusive evidence, and a more recent meta-analysis concluded that higher quality trials are needed to draw conclusions (Griffiths and Fernandez, 2007; Wang et al., 2016). Moreover, the effectiveness and safety of bladder training in total joint arthroplasty is not yet assessed.

The purpose of this randomized controlled trial was to evaluate the results of bladder training in patients with total hip and knee arthroplasty, evaluating the incidence of urinary retention after the removal of the catheter, and the occurrence of other adverse effects.

2. Material and methods

We conducted a prospective randomized controlled trial comparing bladder training by clamping before catheter removal, or free drainage removal. The study was approved by the institutional review board (IRB No 4337/424MGH).

2.1. Participants and randomization

We included consecutive adult patients undergoing total hip or knee arthroplasty from January 2015 to February 2016 in the Orthopaedic Department of a tertiary Military Hospital. Exclusion criteria were age under 50 years old, and known history of recurrent urinary tract infections, neurogenic bladder, previous urinary retention or voiding dysfunction, and diabetic cystopathy. The enrollment of the participants was made by two senior orthopaedic surgeons with respect to our pre-determined inclusion and exclusion criteria (i.e, the last two authors). All patients provided informed consent and were informed that they could withdraw from the study at any time. We randomized the patients either in the bladder training group of the free drainage group using a computer-generated list (www.randomizer.org). We ensured allocation concealment using sealed pre-numbered envelopes containing the assignments, which were kept and distributed by the departments' head nurse. Blinding of nurses and patients to the intervention was not possible.

2.2. Procedure

We inserted a Foley catheter to all patients prior to surgery, and we removed the catheter on postoperative day 2. In the bladder training group, we followed the protocol described by Williamson, by clamping the catheter for three hours and then unclamping for five minutes, to allow emptying of the bladder (Williamson, 1982). We started the procedure at 8 a.m. and repeated this procedure three times, for a total of nine hours and ten minutes, before removal. In the free drainage group, the catheter was removed without clamping at 8 a.m.

During the procedure of the bladder training, if a patient felt an urgent need to urinate, a drainage for five minutes was performed, to avoid discomfort. If the drained urine volume during bladder training did not exceed 300 ml, then we used an ultrasound examination of the bladder volume to exclude high residual urine volume and guide the treatment towards oliguria. If the drained urine volume exceeded 500 ml, we performed rapid decompression of the bladder and increased the frequency of the catheterization. Given the evidence from a clinical study demonstrating no significant difference in adverse effects between rapid and gradual decompression of the bladder in acute urinary retention, we considered rapid drainage of the bladder to be safe for the patients (Etafy et al., 2017). It is also documented by manometric studies that the removal of the first 100 ml of urine in cases with acute urinary retention decreases the intravesical pressure approximately 50%, and after this initial substantial decrease in pressure, the intravesical pressure declines only slightly (Christensen et al., 1987; Osius and Hinman, 1963).

All surgical procedures were performed under combined spinal and epidural anesthesia. The epidural catheter remained in place for postoperative analgesia until postoperative day 2 and was removed before the Foley catheter removal. Acetaminophen 1000 mg was administered intravenously every six hours and tramadol was administered for additional analgesia if the patient complained about severe pain. Subcutaneous low molecular weight heparin and intravenous cefuroxime were administered according to the department's protocol to all patients.

2.3. Outcomes

The primary outcome of the study was the need for re-catheterization due to urinary retention. We performed re-catheterization if the patient failed to urinate within 10 h of catheter removal, if the patient experienced discomfort or if marked distention of the bladder was apparent. Secondary outcomes were the occurrence of symptomatic urinary tract infection, as well as subjective symptoms during and beyond the clamping process, including pain.

2.4. Statistical analysis

The sample size calculation was based on a study which assessed the non-inferiority of bladder training in surgical patients (Fanfani et al., 2015). According to this study, for 80% power with a two-sided type I error of 0.05, a total of 110 patients would be necessary. For the primary outcome, we used Fisher's exact test to compare the incidence of re-catheterization between the groups. Multivariable logistic regression was used to model the association between postoperative urinary retention and independent variables. Independent variables were chosen a priori based on their potential association with the outcome variable. These variables were the procedure (total hip or total knee arthroplasty), age, gender, and history of diabetes mellitus or prostatism.

We used Chi-square or Fischer's exact test for nominal data and Mann-Whitney test for skewed continuous data for the comparison of baseline characteristics between groups. SPSS software version 24 was used.

3. Results

We included a total of 218 patients in the study; 114 in the bladder training group and 104 in the free drainage removal group. All patients fulfilled the inclusion and exclusion criteria, and there were no withdrawals from the study. All patients were over 50 years old with a mean age of 69.3 (SD 8) years. The baseline characteristics of the groups are presented in Table 1. No differences were found between the groups in preoperative demographic data. Of the 18 patients with prostatism, five were treated with tamsulosin 0.4 mg orally once a day, but they did not have symptoms at the preoperative assessment (two in bladder training group and three in free drainage group).

3.1. Primary outcome

We observed three cases of re-catheterization in the bladder training group (2.6%) and six in the free drainage removal group (5.8%). The difference between the groups was not statistically significant (Fisher's

Table 1
Patients' baseline characteristics.

	Bladder training group (N = 114)	Free drainage group (N = 104)	p
Gender (Male/female)	53/61	52/52	0.605[a]
Age	69 (8.7)	69.8 (7.3)	0.707[b]
Joint (Hip/knee)	56/57	55/49	0.733[c]
Diabetes	16 (14%)	11 (10.6%)	0.439[a]
Prostatism	7 (6.1%)	11 (10.6%)	0.235[a]

Age is expressed as mean (SD), and all other values are expressed as N. None of the differences was significant ($p > 0.05$).
[a] Chi-square test for between groups comparison.
[b] Mann-Whitney U test for between groups comparison.
[c] Fischer's exact test for between groups comparison.

Table 2
Need for re-catheterization.

Variable	OR_{unadj}	OR_{adj}	95% CI	p
Group (bladder training or not)	0.44		0.11–1.81	0.256
Gender (male/female)	0.45		0.11–1.85	0.268
Age	1.19	1.16	1–1.34	0.04
Joint (hip/knee)	0.29	0.39	0.06–2.57	0.327
Diabetes	3.85	1.77	0.28–11.22	0.544
Prostatism	32.83	26.42	5.08–137.39	< 0.001

OR_{adj}: adjusted odds ratio, OR_{unadj}: unadjusted odds ratio, CI: confidence interval.

exact test, $p = 0.316$).

The independent variables which correlated with re-catheterization ($p < 0.2$) and were inserted in the multivariate logistic regression model were age, joint (hip or knee), diabetes and prostatism (Table 2). Prostatism was associated with increased odds of re-catheterization (adjusted odds ratio: 26.42, $p < 0.001$). It is noted that seven of the nine patients with urinary retention were male, with history of prostatism under medication.

All patients subjected to re-catheterization returned to normal bladder function prior to the time of discharge.

3.2. Secondary outcomes

Most of the patients in the bladder training group stated the sensation of bladder filling during the clamping process, but the sensation was painless and none felt an urgent need to urinate. In all cases the drained urine volume exceeded 300 ml, and there was no need of urine culture tests because no patient complained of suspicious symptoms.

4. Discussion

We compared bladder training by intermittent clamping with free drainage removal of the Foley catheter in patients undergoing total hip or knee arthroplasty. Our study shows that bladder training has no effect on the need for re-catheterization in patients undergoing total hip or knee arthroplasty ($p = 0.316$). We observed normal bladder function in patients who were subjected to free drainage removal. We also observed increased odds of re-catheterization in patients with prostatism under medication (odds ratio: 26.42, $p < 0.001$). No infections or major subjective symptoms were noted.

Our results are consistent with other studies conducted in surgical patients, which showed no difference between these two types of catheter removal procedures in relation to re-catheterization. One study was performed in orthopaedic patients with hip fracture surgery (Nyman et al., 2010). Other studies concerned urogynecology-related surgery, colorectal surgery, and surgical patients in general (Bergman et al., 1987; Fanfani et al., 2015; Oberst et al., 1981; Ratnaval et al., 1996; Sun et al., 2004; Williamson, 1982).

We noticed a low frequency of postoperative urinary retention requiring re-catheterization in our patients (4.1%). Other studies in total hip and knee arthroplasty patients reported a higher incidence of urinary retention (David et al., 2015; Fernandez et al., 2014; Macdowell et al., 2004; O'Riordan et al., 2000; Tischler et al., 2016; Waterhouse et al., 1987; Williams et al., 1995). This could be explained by the occurrence of additional risk factors in these studies, including male gender, intrathecal morphine, and previous history of outflow symptoms.

There is a divergence in the literature in the use of the bladder training intervention. Williamson proposed the "Q3h" clamping protocol, which includes clamping of the catheter for three hours and unclamping for five minutes, repeated three times, for a total of nine hours and ten minutes (Williamson, 1982). Another proposed protocol, the "Q4h", includes clamping the catheter and when the patient needs to urinate, the catheter is removed clamped. Then, every fourth hour until normal bladder function resumed, the patients have their bladder scanned with an ultrasound device and if the bladder volume exceeds 450 ml, the patient is re-catheterized (Nyman et al., 2010). The progressive clamping protocol includes clamping the catheter for increasingly longer periods beginning with a one-hour interval until the maximum four-hour interval after two days; the clamping periods are alternated with drainage periods of 5–15 min (Bergman et al., 1987; Oberst et al., 1981; Sun et al., 2004). None of these protocols seems to have superior results (Wang et al., 2016). We utilized the "Q3h", which has been used in other studies, because it is faster than the other two, thus allowing the patients to be mobilized sooner and easier (Fanfani et al., 2015). Also, it does not require the use of an ultrasound device, thus being more flexible for daily practice.

It is well known that prostatism and diabetes mellitus predispose patients to voiding dysfunctions. Especially diabetes predisposes to a wide range of lower urinary tract dysfunction, from the classic diabetic cystopathy (the triad of decreased bladder sensation, increased bladder capacity, and poor bladder emptying) to urgency incontinence (Gomez et al., 2011). In the current study, we did not include patients with lower urinary tract complications. The 27 patients with diabetes presented with adequate blood glucose control (preoperative blood glucose between 100 and 180 mg/dL) and no history of urinary tract complications. It is our current practice to delay elective surgery until the blood glucose control improves (preoperative fasting blood glucose less than 200 mg/dL) and we temporarily introduce insulin treatment for better control of blood glucose. With proper management of the blood glucose, studies have found that the perioperative prognosis of patients with diabetes and no diabetic complications is similar to the prognosis in patients without diabetes (Gavin, 1989).

As life expectancy increases, an even larger number of patients will require total joint arthroplasty. Therefore, it is critical to optimize all aspects of treating such patients, one aspect being the strategy of removing the Foley catheter. Our study implies that bladder training by clamping is not necessary for returning to normal bladder function after catheter removal. The procedure of clamping, although not an expensive procedure, increases the workload of the nursing staff. Furthermore, it prolongs the duration of catheterization and the risk of related complications, such as infection or urinary tract injury (Colli et al., 2014).

The strong point of our study is that the anaesthetic, surgical, and nursing practices described are commonly performed in orthopaedic centres with large numbers of patients. Combined with the large sample size and the randomization process, our results can be generalized to the general population. Then again, our study has certain limitations. Firstly, blinding patients and nurses was not possible, introducing a possibility of observer bias. Secondly, the procedures were not performed by a single researcher, because nurses varied according to their shifts. Thirdly, although severe bladder dysfunction disorders can be safely diagnosed using ultrasound or urodynamic studies, we just relied

on patients' medical history to determine our exclusion criterion on severe bladder dysfunction, including diabetic cystopathy. The rationale behind this decision was that we aimed to have conclusions comparable and applicable by other orthopaedic centres and surgeons in the mainstream of the clinical practice. Finally, it is true that with current techniques the patients begin weight bearing as tolerated immediately. However, we currently use short-term Foley catheters, because patients undergoing total hip or knee arthroplasty experience significant perioperative pain, despite the use of a pre-emptive multimodal pain management approach (Gaffney et al., 2017). This pain may result in inability to properly urinate. All that, combined with the use of spinal with or without supplementary epidural anesthesia, increases the risk of urinary retention, especially in male patients (Griesdale et al., 2011). Such difficulties in urinating may result in decreasing the patient's satisfaction with the procedure. We also believe that our results may reflect on the need of bladder training in other types of surgery under combined spinal and epidural anesthesia or even in complex cases, monitoring the patient's urine flow may help in intraoperative and postoperative fluid management.

5. Conclusion

Our results show that bladder training by catheter clamping has no advantage over free draining removal of short-term urinary catheters in patients with total hip and knee arthroplasty. We observed normal bladder function in patients who were subjected to free drainage removal. We also observed increased odds of re-catheterization in patients with prostatism under medication. We conclude that the bladder training procedure is not indicated. However, healthcare providers should monitor patients' urination after removal of the catheter.

Funding

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

Conflict of interest

None.

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