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Original

Effect of spinal anesthesia with and without addition of fentanyl on the occurrence of urinary retention after knee replacement in patients with class III obesity: A randomized clinical trial

Amin Moradi, Naghi Abedini*

Abstract

Introduction: Fentanyl is a short-acting lipophilic opioid. Given the increased volume of distribution in people with a very high body mass index (BMI), fentanyl appears to act more effectively in obese people compared with normal-weight people.

Objectives: This study aimed to evaluate effect of spinal anesthesia with and without addition of fentanyl on the occurrence of urinary retention after knee replacement in patients with class III obesity.

Patient and Methods: This randomized single-blind clinical trial was conducted with the participation of 80 patients with a BMI >40 kg/m² who were candidates for unilateral knee replacement with spinal anesthesia in 2019–20. The patients were randomly assigned to the intervention group (bupivacaine 15–20 mg + 25-µg fentanyl) and control group (bupivacaine (15–20 mg)) and compared in terms of urinary retention.

Results: There was no statistically significant difference between the groups in the time of first postoperative urination ($P=0.706$). In fentanyl group, twenty patients needed catheterization after surgery, while this was reported in 13 patients in the opioid-less spinal anesthesia group, which was not statistically significant ($P=0.115$).

Conclusion: Addition of 25 µg fentanyl to bupivacaine in spinal anesthesia can lead to a brief increase in the probability of urinary retention after surgery.

Keywords: Spinal anesthesia, Fentanyl, urinary retention, Knee replacement, Class III obesity

Trial Registration: The trial protocol was approved by the Iranian Registry of Clinical Trials (identifier: IRCT20160202026328N7; https://www.irct.ir/trial/61035, ethical code; IR.TBZMED.REC.1400.820).

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Introduction

Postoperative urinary retention (POUR) is one of the common complaints and complications after surgeries and procedures with local anesthesia (1). Since the bladder is innervated via pelvic plexuses, the risk of urinary retention (UR) is higher in pelvic- and perineal-area surgeries and orthopedic surgeries such as hip replacement (hip arthroplasty) (2, 3), Although cases of this complication have been reported in many abdominal, thoracic, and head and neck surgeries. The prevalence of POUR ranges from 5% to 70% in different studies (4,5).

Much research has been done on the risk factors of POUR and various results have been reported (6). According to studies, increased risk of POUR has been associated with the volume of received intraoperative fluids, patient age and gender, and background diseases like renal disorders, benign prostatic hyperplasia (BPH), diabetes, and hypertension (7, 8). Duration of operation has been considered an independent variable in some studies and a confounding variable in some others for the direct relationship with the volume of received fluids and the dose of anesthetic drugs (9).

Studies have shown that lowering the dose of local anesthetics in spinal anesthesia reduces occurrence of UR and the need for urinary catheterization. Along with lowering the dose of local anesthetic, addition of supplementary drugs and using multi-drug combination are needed for improving the quality of spinal anesthesia (10,11). Topical or systemic administration of opioid drugs such as morphine or fentanyl can cause risk of UR (12,13). This might be because of the combination of topical and systemic effects of these drugs. These drugs both inhibit detrusor tone and the pontine micturition center (PMC) and cause inhibitory block with epidural injection. With

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Clinical Research Development Unit, Shohada Hospital, Tabriz University of Medical Sciences, Tabriz, Iran.
***Corresponding Author:** Naghi Abedini, Email: naghi26@tbzmed.ac.ir

Implication for health policy/practice/research/ medical education

The 80 patients with a BMI >40 kg/m² who were candidates for unilateral knee replacement were randomly assigned to the intervention group (bupivacaine 15–20 mg + 25 µg fentanyl) and control group (bupivacaine (15–20 mg)) and compared in terms of urinary retention. Results show addition of 25 µg fentanyl to bupivacaine in spinal anesthesia can lead to a brief increase in the probability of urinary retention after surgery.

usually longer acting effects than local anesthetics, they can lead to longer UR (14, 15).

Fentanyl is a short-acting lipophilic opioid. Given the increased volume of distribution in people with very high BMI, fentanyl appears to act more effectively in obese people compared with normal-weight people.

Objectives

This study aimed to evaluate effect of spinal anesthesia with and without addition of fentanyl on the occurrence of UR after knee replacement in patients with Class III Obesity.

Patients and Methods

Study design

A total of 80 over 18-year-old patients with class III obesity (BMI >40) who were candidates for lower limb orthopedic surgery and spinal anesthesia were enrolled in this clinical trial conducted in Shohada Hospital affiliated with Tabriz University of Medical Sciences, Tabriz, Iran in 2019–2020. The patients were enrolled in the study according to inclusion and exclusion criteria through convenience sampling. Based on the results of a similar study (15) and a type I error of 0.05 and power of 80%, the sample size was determined 80.

Inclusion and exclusion criteria

The inclusion criteria were being over 18 years old, being a candidate for unilateral knee replacement, having a BMI greater than 40, and willingness to participate in the study. Patients who reported any urinary problems including UR, past trauma, or recent urinary tract infection (UTI) were excluded from the study. Patients who needed catheterization, had intraoperative urinary system trauma, needed alteration of anesthetic method during surgery were excluded from the study.

Randomization and blinding

The participants were assigned into the intervention and control groups through block randomization (20 four-person blocks) by the statistical consultant. The outcome analyst was blinded to the grouping, making this study a single-blind clinical trial.

Methodology

The patients were hydrated with 300 cc isotonic solution. In fentanyl group, the patients received bupivacaine (15–20 mg) in addition to 25-µg fentanyl in sitting position on midline at L3/L4 or L4/L5. In control group, the patients received only bupivacaine (15–20 mg) in a similar way as the fentanyl group. The patients were positioned flat to maximum T12 spinal level, which was checked by pinprick test. The patients in both groups were followed up after surgery for different urinary outcomes. The outcomes included the following: The time need for the first postoperative urination, patient's complaint about incomplete bladder emptying, patient's complaint about difficulty and problem in urination, and the need for postoperative catheterization. The demographic information of the patients such as age and gender were documented on forms prepared by the researcher. Moreover, other needed information including duration of operation, the volume of received intraoperative fluids, the need for catheterization after surgery, and the time of first postoperative urination were recorded by the researcher.

Statistical analysis

The demographic and background information of the patients such as age and gender were reported using frequency, mean, and standard deviation. Student's *t* test was used to compare the time needed for first postoperative urination, the duration of operation, and the volume of received intraoperative fluids between the two groups. Chi-square test was used to examined the relationship between the type of spinal anesthesia (with or without opioid) and urinary complaints after surgery including incomplete bladder emptying, difficulty in urination, and the need for catheterization. Binary logistic regression was used to examine the effect of different variables on the occurrence of complaints about difficulty in urination, as the dependent variable, and other variables such as age, gender, duration of operation, the volume of received intraoperative fluids, and the type of spinal anesthesia. *P* value less than 0.05 was considered significant.

Results

In the mentioned time frame (study period) there were 113 participants, of which 80 participants met the inclusion criteria and entered the study. These 80 participants received the intervention after being randomly assigned to the two groups and were present until the end of the study (the sample drop was 0) (Figure 1).

The mean age of participants was 42.59 ± 3.89 years with mean BMI of 41.09±3.03 kg/m². There was no significant difference between the two groups in the distribution of age, gender, duration of operation, and received intraoperative fluids (Table 1).

The time of first postoperative urination ranged from 2 hours to 10 hours in the patients. The mean time of first postoperative urination was 4.11 ± 1.49 hours in the fentanyl group and 4.49 ± 1.83 in the control group. There was no statistically significant difference between

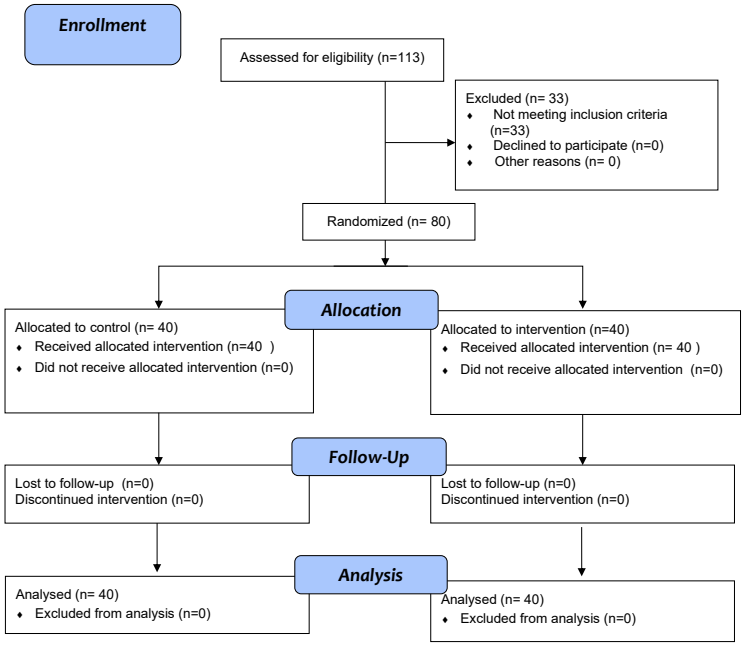

Figure 1. The Study Consort Flowchart.

the groups in the time of first postoperative urination ($P=0.706$). In fentanyl group, twenty patients needed catheterization after surgery, while this was reported in 13 patients in the opioid-less spinal anesthesia group, which was not statistically significant ($P=0.115$). Twenty patients in the fentanyl group complained about incomplete bladder emptying after surgery and twelve patients complained about incomplete bladder emptying after surgery, indicating a significant relationship ($P=0.05$). Sixteen patients in the fentanyl group and eight patients in the control group complained about difficulty in urination, indicating a significant relationship ($P=0.05$). Logistic regression analysis demonstrated that only age, BMI, and the volume of received intraoperative fluids (from the variables age, gender, duration of operation, volume of received intraoperative fluids, and the type of spinal anesthesia) independently affected difficulty in bladder emptying (Table 2).

Table 1. Comparison of participants' basic information

Variable	Study groups (N = 80)		*P* value
	Control group (n = 40)	Intervention group (n = 40)	
Male gender	29 - 72.5%	29 - 72.5%	0.999*
Age (year)	43.3 ± 03.59	42.3 ± 11.29	0.775**
BMI (kg/m²)	41.3 ± 95.45	40.3 ± 42.56	0.665**
Duration of operation (min)	125.10 ± 33.49	123.10 ± 96.59	0.749**
Duration of anesthesia (min)	155.19 ± 30.63	150.15 ± 32.85	0.885**
Received fluids (cc)	1230.150 ± 41.29	1245.175 ± 59.37	0.691**

BMI: body mass index. [a] Chi-square; [b] T test.

Table 2. Logistic regression analysis to determine independent predicting factors of occurrence of difficulty in bladder emptying after surgery

Variable	B	*P* value	Exp(B)	95% CI for Exp(B)	
				Upper	Lower
Male gender	-0.888	0.185	0.439	0.556	0.253
Age (year)	-0.843	0.003	1.562	2.01	0.958
BMI (kg/m²)	-0.002	0.852	2.223	2.885	1.112
Duration of operation (min)	-0.002	0.003	0.559	0.751	0.359
Duration of anesthesia (min)	0.559	0.313	0.859	0.956	0.635
Received fluids (cc)	0.002	0.004	1.359	2.003	0.995

Discussion

Micturition involves two phases of bladder filling and bladder emptying via the coordination of the autonomic, somatic, and parasympathetic nervous systems. The process of POUR, particularly after surgeries with spinal anesthesia, is a common, unpleasant outcome caused by changes taking place mainly through opioid and non-opioid drugs. It can lead to longer hospitalization and more systematic costs. A meta-analysis has identified different risk factors for UR, categorized into three groups (preoperative, intraoperative, and postoperative) to facilitate research (16). For example, age, gender, and presence of background diseases such as BPH are among the preoperative risk factors, type and duration of operation, high BMI, and the volume of received fluids during anesthesia are among the intraoperative risk factors. Analgesic drugs administered to patients after surgery are categorized among postoperative risk factors. A total of 80 patients participated in this study. The intervention group (n = 40) received local anesthesia and narcotic (Marcaine and fentanyl) and the control group (n = 40) received only local anesthesia (Marcaine). The groups had a similar age and gender distribution. The occurrence of UR was more frequent in men than in women (17). The prevalence of UR in men, particularly in over-35 years age range, has been confirmed in other studies. In this study, logistic regression analysis showed that age and BMI independently had a relationship with the occurrence of POUR. Given the physiological and anatomical changes and prostate enlargement in men as they get older, this was not a far-fetched finding (18).

Previous studies have shown that opioids affect POUR (19, 20). This is explained by their effect on the PMC and the autonomic parts of the peripheral nervous system. Morphine is the most important known narcotic with UR effect (21). Intrarectal, intradural, and even intravenous morphine injection increases bladder capacity and inhibits its contractions, disrupting the coordination between the detrusor muscle and the internal urethral sphincter (22). This finally leads to more UR in obese people. A few studies have examined the effect of epidural, local, or systemic fentanyl on UR, but the effect of intrarectal fentanyl has not been studied (23). The dose of local anesthetics in spinal anesthesia is another unstudied influential factor on the occurrence of UR. Studies have shown that lowering the dose of local anesthetics reduces the occurrence of UR and the need for catheterization after surgery (24). Along with lowering the dose of local anesthetics, addition of supplementary drugs and using multi-drug combination are needed for improving the quality of spinal anesthesia. In this study, Marcaine alone was administered in the control group and a lower dose of Marcaine in addition to fentanyl was administered in the intervention group (25). The patients who had received fentanyl complained more about UR, incomplete bladder emptying, and problems in urination compared with the patients in the control group. Although there was no significant difference between the groups in the need for urinary catheterization, lower dose of fentanyl in spinal anesthesia may show better results in future studies (26). One of the risk factors for POUR is the duration of operation. Studies have reported contradictory results in this regard. Multiple regression analysis did not prove the duration of operation as an independent factor in the occurrence of UR in this study. It seems that duration of operation is influenced by several other variables such as type of surgery, the volume of received intraoperative fluids, and the dose of local anesthetics and narcotics, all of which are independently connected with the increased risk of POUR (27,28).

Conclusion

Addition of 25-µg fentanyl to bupivacaine in spinal anesthesia can lead to a brief increase in the probability of urinary retention after surgery. From the UR risk factors reported in previous studies including male gender, age, duration of operation, and the volume of received intraoperative fluids, only the last factor affected UR in this study. Furthermore, the state of health and presence of background diseases such as BPH, diabetes, and renal disorders can dispose patients to UR.

Limitations of the study

The limitations of this study due to insufficient funds were absence of urodynamic testing and indices to examine UR in patients and absence of accurate determination of the volume of remaining urine using pre- and postoperative ultrasonography.

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Authors' contribution

Conceptualization; AM and NA, Methodology; AM, Validation; NA, Formal Analysis; NA, Investigation; AM and NA, Resources; AM and NA, Data Curation; AM and NA, Writing—Original Draft Preparation; AM and NA, Writing—Review and Editing; AM and NA, Visualization; NA, Supervision; NA, Project Administration; NA, Funding Acquisition; NA.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical issues

The research conducted in accordance with the tenets of the Declaration of Helsinki. The Ethics Committee of Tabriz University of Medical Sciences approved this study (IR.TBZMED.REC.140.82). Accordingly, written informed consent was taken from all participants before any intervention. The trial protocol was approved by the Iranian Registry of Clinical Trials (identifier: IRCT20160202026328N7; https://www.irct.ir/trial/61035). Besides, ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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