

Effectiveness of a Pre-emptive Preoperative Belladonna and Opium Suppository on Postoperative Urgency and Pain After Ureteroscopy

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Purpose: Postoperative ureteroscopy patients can develop bladder spasms, complaints of pain, and the urgent need to void during emergence from anesthesia. Discomfort leads to patient agitation, resulting in a risk to patient safety. The purpose of this study was to determine the effectiveness of a preemptive preoperative belladonna and opium (B + O) suppository on postoperative bladder comfort, narcotic requirements, and length of stay of ureteroscopy patients.

Design: A prospective double-blind study was conducted.

Methods: Fifty adult outpatients scheduled for ureteroscopy were assigned to routine care or a B + O suppository immediately after anesthesia induction. Urinary urgency and pain were assessed every 15 minutes.

Findings: Urgency significantly decreased in the B+O group, with less than half reporting urgency at discharge.

Conclusions: Pre-emptive preoperative administration of a B + O suppository before ureteroscopy results in decreased urinary urgency during the postoperative recovery. Pre-emptive preoperative interventions can result in positive outcomes before discharge.

Keywords: ureteroscopy, postoperative period, urinary bladder, suppositories.

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POSTOPERATIVE RECOVERY is characterized as painful or extremely discomforting after the manipulation of a cystoscope or ureteroscope placed in the bladder for diagnostic or treatment purposes.¹ Voiding urgency is a major contributing painful complaint of postoperative ureteroscopy patients.^{2,3} Feelings of urgency leads to postanesthesia emergence agitation in 1 of every 10 urological surgery patients.⁴ This agitation leads to tachycardia, hypertension, and the de-

mand or attempt to go to the bathroom even if not fully recovered from anesthesia; such behaviors create safety risks. The treatment of postoperative voiding urgency, a precursor of agitation and safety risks, has the potential to improve patient outcomes.

Voiding urgency, the urgent need to void despite an empty bladder, arises from the bladder detrusor muscle. Normally, the bladder urothelium releases

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nitrous oxide and adenosine triphosphate (ATP) during bladder stretch resulting in afferent nerve transmission to the brain signaling the need to void. It is possible that mechanical stimulation of the urological scope or stents may cause similar afferent signals. The goal of pharmacologic intervention is to inhibit the detrusor muscle by anticholinergic pharmacology. Belladonna and opium (B + O) suppositories contain the naturally occurring muscarinic antagonists atropine and scopolamine. Postanesthesia care unit (PACU) nurses routinely implement postoperative order sets for cystoscopy and ureteroscopy patients, routinely administering a B + O suppository to patients complaining of postoperative bladder pain or urgency. However, the onset of action of the drug is 15 to 30 minutes for opium and 1 to 2 hours for belladonna. If a B + O was administered preoperatively, bladder spasms could be pre-empted, thus improving pain and urgency symptoms in the immediate postoperative period and before discharge.

Background

A thorough search for evidence on the effectiveness of B + O suppositories for postoperative urological symptoms identified three studies. Preoperative pre-emptive administration of a B + O suppository was reported by Lukasewycz et al⁵ in a prospective randomized control trial of patients undergoing robotic-assisted laparoscopic radical prostatectomy (RALP). Compared with a control group, patients receiving a B + O suppository had significantly less postoperative pain and less 24-hour narcotic consumption. However, in a later retrospective study, Scavonetto et al⁶ found no difference between patients who received a B + O suppository and those in the control group. However, their patients received the suppository at the end of the RALP procedure. In a recent study of preoperative B + O suppositories for ureteral stent pain, Lee et al¹ reported that quality of life increased when urinary pain decreased at postoperative day 3 for patients receiving the drug. However, there is a paucity of research on interventions to decrease the immediate postoperative voiding urgency of urology patients. The effect of preoperative pre-emptive muscarinic antagonists on bladder comfort after ureteroscopy has not been studied. It was hypothesized that urological patients receiving a B + O suppository preopera-

tively would report decreased urgency and pain sensations postoperatively compared to urological patients who received routine care.

Methods

Design, Subjects, and Procedures

A prospective double-blind study was conducted to determine the effectiveness of a preoperative B + O suppository on postoperative bladder comfort, narcotic requirements, and length of stay of outpatient urological patients. After obtaining full approval from the Institutional Review Board, adult patients scheduled for diagnostic or therapeutic outpatient cystoscopy or ureteroscopy were approached during their admission to the day surgery unit. Patients with a preoperative indwelling catheter, stent, or reported allergy to belladonna or opium were excluded. Patients were provided a verbal explanation of the study by the preoperative nurse and written informed consent was obtained.

Consecutive patients were assigned to the intervention (B + O) or control group using year of birth to facilitate communication and preoperative administration by the urologist. Power analysis calculation for an α of 0.05 and power of 0.80 required 22 subjects per group. Data collection occurred from October 2015 to February 2016.

After general anesthesia was induced and before insertion of the surgical scope, the urologist administered a rectal B + O suppository (16.2 mg belladonna and 60 mg opium) to subjects born in even years. Only the consenting preoperative nurse, pharmacy, and the urologist were aware of the assignment decision. Four PACU nurses, who had received a course in the responsible conduct of research, were blind to the assignment decision. PACU nurse blinding was promoted by the absence of B + O administration documentation in the patient's electronic health record. Medication administration was documented by the pharmacy. There was no added cost for drug administration for patients in the intervention group.

Postoperatively on arrival to the PACU, subjects in both groups received routine care from a PACU nurse who was blind to the group assignment but aware that a B + O suppository may have been administered. Education was provided to

the PACU nurses to ensure understanding and consistency when completing the data collection tool. Routine postoperative care included administering “rescue medications” to treat symptoms such as narcotics, antispasmodics, or urinary anesthetics under routine postoperative orders and observing for any complications of a B + O suppository. Routine postoperative orders included administering a B + O suppository.

Variables and Measurement

The primary end point, bladder comfort during the postoperative stay, was defined as the patient’s report of the intensity of urgency or pain. Bladder comfort was recorded on admission, every 15 minutes for 1 hour and at discharge from the PACU. Bladder urgency was rated on a 5-point Likert scale from 0 (no desire to void) to 4 (must void now).⁷ Pain was rated using a 0 to 10 verbal rating scale with 0 equal to no pain and 10 the most pain possible. As patients’ recovery from anesthetics differs, mean urgency and pain scores were calculated for the length of PACU stay using the five data collection points. Secondary end points included PACU length of stay and time from PACU admission to outpatient discharge. Perioperative and post-anesthesia narcotic administration was recorded and converted into morphine equivalents using a standard conversion chart. Postoperative rescue medications for the immediate relief of breakthrough pain or urgency symptoms were administered by the PACU nurse based on clinical judgment using existing standard order sets.

Data Analysis

An independent *t* test was used to test for differences between groups as appropriate with a significance level set at $P < .05$. Confidence intervals (CIs) were calculated for a difference between the means for sample size of 30 or less. SPSS version 21 was used for analysis.

Results

Fifty-three patients agreed to participate in the study. The surgical procedures of two subjects were canceled after consent had been obtained. One subject was excluded because of inadvertent disclosure of preoperative B + O to the PACU nurse. Fifty subjects provided data, an equal num-

ber assigned to the control and intervention groups (Figure 1). Thirty patients of one urologist and 20 patients of a second urologist participated. The mean age was 54 years (SD = 14.6) and 27 (54%) subjects were male. There was no difference between the groups on gender, mean age, or duration of surgery ($X = 46$ minutes \pm 20.6, range 20 to 105 minutes). All the patients underwent ureteroscopy with most having one stent placed during the procedure ($n = 43$, 86%); two subjects received two stents. There was no difference in the administration of morphine equivalent narcotics between the groups (control = 15.4 ± 8.6 ; intervention = 17.1 ± 9.9). On the basis of nursing clinical judgment, subjects in both groups were administered postoperative rescue drugs for relief of bladder pain and urgency (Table 1). However, subjects in the control group required 43 additional doses of rescue medications compared with 31 additional doses in the intervention group. Eight subjects in the intervention group received an additional B + O suppository whereas 10 subjects in the control group received a B + O suppository. The number needed to treat (NNT = 5) reflected that for every five patients given a B + O suppository preoperatively, one patient would have a decreased need for rescue medications.

Urgency

The mean urgency score of the preoperatively administered B + O group (1.4 ± 0.8) was significantly less ($P = .018$) than the mean urgency score of the control group (2.0 ± 0.9 ; CI = 0.34 to 0.86, $df = 48$; NNT = 4.1). During the postoperative period all 25 subjects in the control group expressed a feeling of urgency whereas 22 (84%) of the subjects in the intervention group reported urgency. At discharge, less than half of the patient in the intervention group reported urgency compared with the control group (11/25, 44% vs 21/25, 84%; NNT = 2.5).

Pain

There was no difference between the groups on mean pain score (control = 2.2 ± 2.3 , intervention = 1.5 ± 1.9) (CI = -2.8 to 1.4 , $df = 48$). As might be expected there was a significant positive relationship between the mean pain score and narcotic equivalence

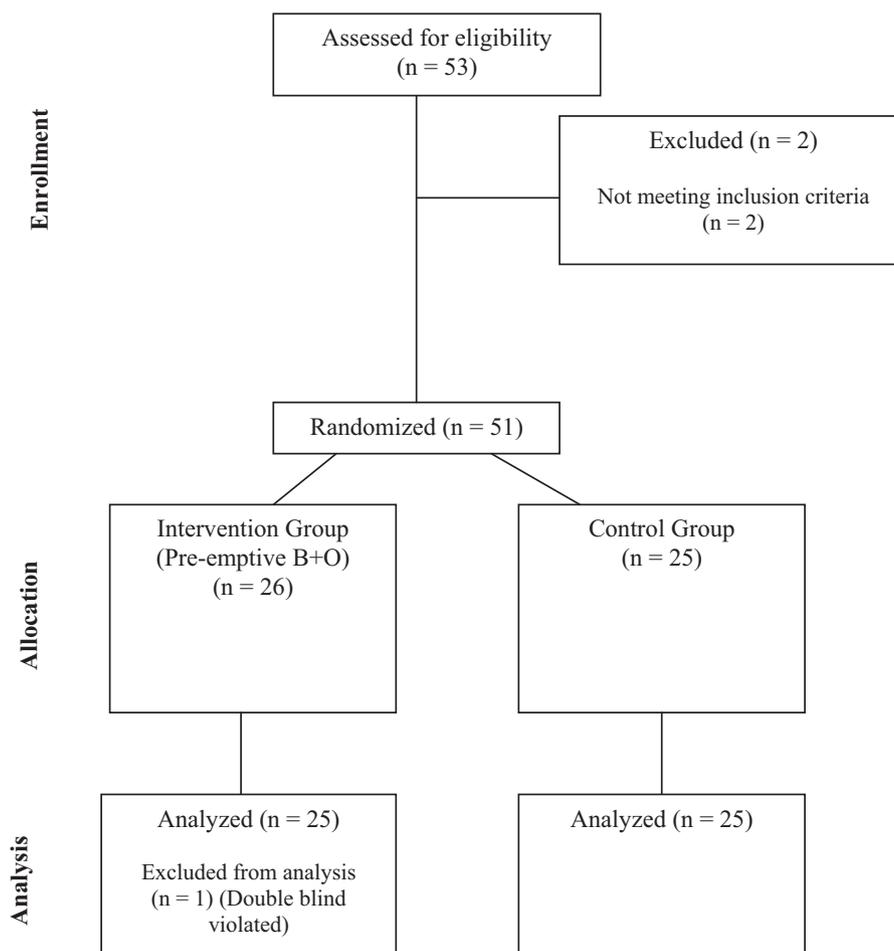


Figure 1. Flow of subjects through the study. B + O, belladonna and opium.

($r = 0.584$, $P = .001$). There was no difference in the administration of morphine equivalent narcotics between the groups (control = 15.4 ± 8.6 ; intervention = 17.1 ± 9.9).

Length of Stay

The mean PACU length of stay, from admission to transfer to Phase 2 care, was 76 ± 25.5 minutes. The total postoperative stay, from PACU admission to discharge from the facility, was 134 ± 37 minutes. There was no difference in the length of stay between the groups.

Discussion

The B + O suppository has been a first line agent in the treatment of bladder discomfort and has been widely administered, especially during the postoperative period.⁸ Historically the B + O suppository

was available and marketed before the Food, Drug, and Cosmetic Act of 1938 and is considered, even today, an “unapproved drug,” although exempt and grandfathered by the US Food and Drug Administration (FDA). Thus, there have been few clinical trials to determine efficacy. This is the first study to test the effectiveness of pre-emptive preoperative B + O administration on the immediate postoperative care of outpatient urological patients.

Nearly all ($n = 47$, 94%) the subjects in this study experienced urgency during the postoperative period. Comparatively, Yates et al⁹ reported that only 5% of cystoscopy patients reported bladder spasms. However, Yates et al⁹ defined bladder spasms using patient’s report of pain after medication administration. The subjects in the present study were able to differentiate urgency from

Table 1. Postoperative Interventions Administered to Ureteroscopy Patients by PACU Nurses

Intervention	Control Group (n = 25)	Experimental Group (n = 25)
Fentanyl IV	8	7
Oxycodone/acetaminophen oral	8	6
Hydrocodone/acetaminophen oral	5	3
Total pain interventions	21	16
B + O rectal	10	8
Tolterodine oral	6	4
Oxybutynin oral	4	3
Lorazepam	2	0
Total urgency interventions	22	15

B + O, belladonna and opium; IV, intravenous; PACU, postanesthesia care unit.

pain. In addition, all the subjects in the present study underwent procedures requiring a ureteroscope. Although the ureteroscope is a smaller diameter instrument than a cystoscope, the longer duration of the procedure may result in more bladder contact, creating a greater likelihood of detrusor spasm.

The use of pre-emptive preoperative B + O suppositories in this study was associated with a reduction in bladder spasms as reflected in patients' reports of urgency. For every four patients receiving a pre-emptive preoperative B + O suppository, one patient will experience a decrease in urgency in the PACU. The decrease in urgency has the potential to reduce agitation and improve patient safety. Further study on the effect of a B + O suppository on patient outcomes and satisfaction is needed.

Patients in this study were able to discriminate urgency from postoperative pain, an indication that the constructs differ. In addition, the treatment for urgency did not influence the treatment for pain. Nearly twice as many subjects who received a pre-emptive preoperative B + O suppository were discharged without urgency compared with the control group. The pre-emptive preoperative administration allows time for the onset of the drug effect to reduce the likelihood of detrusor spasm and combat urgency.

Although there was no difference in mean pain scores, there was a trend toward less postoperative pain with pre-emptive B + O administration; however, this did not meet the level of statistical significance. A finding of no difference in pain was also reported by Butler et al⁸ administering

B + O suppositories to women after vaginal surgery. The randomized control trial detected no differences between women's pain in those that received a placebo or B + O suppository at 2, 4, or 12 hours after surgery.

The study found no difference in postoperative narcotic requirements between subjects who received a B + O suppository and those that did not. This finding supports Lukasewycz et al⁵ who found no significant difference in narcotic administration in the immediate postoperative period between patients after RALP who received preoperative B + O suppository and those who did not. Unfortunately, the researchers only assessed pain and did not assess urgency. Similar pain and narcotic equivalence between B + O and control group patients with stents were reported by Lee et al¹ on postoperative days 1 and 3. Future research on the effect of B + O suppositories requires outcome assessment of urgency.

Postanesthesia length of stay for outpatients is a multifactorial variable. Thus, it was not surprising that there was no difference between the B + O and control groups in the present study. The presence of nausea, hypothermia, sedation, and lack of on-time discharge transportation likely contributed variability to this end point.

A variety of rescue pain and antispasmodic medications were administered by PACU nurses in this study. Yet, despite the variety of interventions, patients in the control group received more doses and types of rescue medications than the B + O group. The polypharmacy approach reflects the nurse's desire to manage symptoms and improve ureteroscopy patient comfort.

Limitations

The study findings are limited to the patients of one urology practice and may not be representative of all ureteroscopy patients. Assignment by year of birth was used for urologist convenience and is not a conventional method. The use of postoperative rescue medications was based on the judgment of experienced PACU nurses using standard order sets, which may be different in other facilities.

Conclusions

Pre-emptive preoperative administration of a B + O suppository for patients about to undergo an ureteroscopy can decrease urinary urgency during the postoperative period. Urinary urgency can be discriminated from surgical pain and should be included in a postoperative nursing assessment. A

pre-emptive preoperative B + O suppository has the potential to improve comfort at discharge of one of every two ureteroscopy patients. Nurses have successfully advocated for pre-emptive preoperative medications for nausea and postoperative pain. The addition of a pre-emptive preoperative B + O suppository for ureteroscopy patients has the potential to improve patient outcomes and satisfaction. Further research on postoperative outcomes and the pre-emptive preoperative use of B + O suppositories for other urological procedures is warranted.

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