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Evaluation of hyoscine *N*-butyl bromide efficacy on the prevention of catheter-related bladder discomfort after transurethral resection of prostate: a randomized, double-blind control trial

Golnar Sabetian[1] · Farid Zand[2] · Elham Asadpour[2] · Mohammad Ghorbani[3] · Pourya Adibi[2] · Mohammad Mehdi Hosseini[4] · Shahryar Zeyghami[4] · Farzaneh Masihi[2]

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Abstract

Background Transurethral resection of prostate (TURP) is the most common treatment for benign prostatic hyperplasia (BPH). Urinary tract catheter is inserted post-operatively which results in catheter-related bladder discomfort (CRBD) in many patients. The purpose of this study was to assess the preventive effect of hyoscine *N*-butyl bromide on CRBD caused by a urinary tract catheter after TURP surgery in patients with BPH.

Methods Twenty-four and twenty-six patients in the treatment and control groups were enrolled, respectively. At the end of the surgery, slow intravenous injection of 20 mg hyoscine *N*-butyl bromide was administered to the patients of treatment group. The severity of CRBD was followed up at five different time periods and up to 2 h after surgery.

Results On arrival to PACU and after 30 min of injection, statistically significant less CRBD was seen in the treatment group comparing to the control group ($P \leq 0.05$ and $P \leq 0.007$). The total utilized meperidine dose during PACU stay and the time to discharge for the intervention group were significantly lower than those for the control group ($P \leq 0.0001$) with no significant difference in adverse effects ($P > 0.05$).

Conclusions Hyoscine *N*-butyl bromide could reduce the severity of CRBD related to TURP in patients with BPH and their need for analgesic consumption either. It shortened the length of stay in the recovery room. Regarding its availability and low cost, it can be an effective pain relief drug for CRBD discomfort related to TURP in BPH patients.

Keywords Benign prostatic hyperplasia · Catheter-related bladder discomfort · Butylscopolammonium bromide · Transurethral prostate resection

✉ Elham Asadpour
asadpoure@sums.ac.ir

[1] Trauma Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

[2] Anaesthesiology and Critical Care Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

[3] Torbat Heydarieh University of Medical Sciences, Torbat Heydarieh, Iran

[4] Department of Urology, Shiraz University of Medical Sciences, Shiraz, Iran

Introduction

Benign prostatic hyperplasia (BPH) is the most common benign tumour found in men with the ages over 50 years old [1, 2]. BPH causes are not clear completely, but the symptoms of the BPH would be presented in the men over 35 years old. In people who are symptomatic and when the routine medical approaches do not work for them, surgical intervention would be the choice of the treatment [3]. BPH is developed as the consequence of obstruction or the reactions secondary to obstruction which can terminate to serious complications like hypertrophy, hyperplasia, collagen sedimentation, thickness of bladder, trabeculation of bladder wall, polyuria, burning sensation, hesitancy and urinary retention [1, 4, 5]. It has been shown that histological BPH prevalence in men rises typically by age, so that it is reported as high as 50% by the age of 60 years old [6]. The most common treatment for BPH is transurethral resection of the prostate (TURP) as a urology surgery which still is considered as the gold standard treatment for BPH treatment [2, 3]. Studies on TURP have reported morbidities as high as 18% including bleeding, transurethral resection

syndrome (TURS), bladder neck perforation caused by TURP and hypothermia [7, 8].

General or regional anaesthesia is used to facilitate this surgery [7, 9, 10]. Although regional anaesthesia and postoperative regional anaesthetic pain control strategies are the preferred methods of care [11], they are not always feasible due to patient or surgical considerations. Most of the patients need a urinary bladder catheter for postoperative bladder irrigation and drainage. Those who got urinary bladder catheterization complain of discomfort related to involuntary contraction of the bladder, directed by muscarinic receptors in the early period of post-TURP surgery [12, 13], which concludes in urge to void, burning sensation, suprapubic discomfort and poor quality of recovery [4, 12–14]. According to the previous studies, it is reported that muscarinic receptors' antagonists like oxybutynin and tolterodine can alleviate the incidence and severity of catheter-related bladder discomfort (CRBD) in almost half of patients in a successful way [15, 16]. Furthermore, in some other researches, ketamine, opioids and resiniferatoxin were used to prevent the initiation of this bothering sensation [13, 17–20]. It is also reported that hyoscine *N*-butyl bromide can reduce the CRBD during recovery of various urologic and non-urologic surgeries [12]. Nevertheless, up to now no specific and effective medication to reduce these side effects after TURP surgery is introduced.

Hyoscine *N*-butyl bromide also known as scopolamine is a drug with anticholinergic effects which exerts its effects by inhibiting the acetylcholine effects in parasympathetic receptors of smooth muscle cells, secretory glands and central nervous system [21]. It is not categorized as an analgesic drug for pain relief in the ordinary state, as it does not directly influence the pain pathway and, however, may stop painful cramps and spasms [22]. Pharmacodynamics' properties for hyoscine such as onset of action of 10 min for intravenous form, time to peak of about 20–60 min and duration of action of around 2 h are identified. It has a hepatic metabolism and is excreted through urine [42–61% (half as parent drug)], faeces (28–37%) [23]. Hyoscine as injection is contraindicated in some conditions like hypersensitivity to the drug, untreated narrow-angle glaucoma, active haemorrhage, paralytic ileus, myasthenia gravis, chronic lung disease (repeated administration) and tachycardia secondary to cardiac insufficiency [24, 25]. Since in the previous studies that evaluated the effect of hyoscine *N*-butyl bromide in urologic patients the TURP surgeries were excluded [12, 26], we decided to investigate the efficacy of intra-vascular hyoscine for alleviation of CRBD and analgesic requirements in the post-surgery period of TURP approach for patients with BPH after general anaesthesia.

Methods

This double-blind randomized controlled trial (IRCT No.: 2013071013934N1) was performed in a sample population of patients with benign prostatic hyperplasia who underwent prostate surgery (TURP) in three hospitals affiliated to Shiraz University of Medical Sciences, Shiraz, Iran. The sample size was calculated as 50 patients based on the obtained results of similar studies with the $p1 = 0.15$, $p2 = 0.5$, $\alpha = 5\%$ and the power of 80%. After receiving approval from the ethics committee of Shiraz University of Medical Sciences, 50 patients out of the 86 screened patients were enrolled. In the preoperative examination, the patients were informed of the method and goals of the investigation and written informed consent was obtained. Inclusion criteria covered all the BPH patients with urethral resection of the prostate (TURP) with an ASA physical status I and II who requested or needed general anaesthesia. Patients with uncontrolled underlying diseases (ASA III or IV), chronic pelvic pain, drug abuse, myasthenia gravis, bleeding tendency, renal or liver failure, tachycardia and heart failure were excluded from the study. Simple randomization technique was used to assign the patients into the treatment and control groups. Random numbers were generated after referring to the http://www.randomizer.org/ and two customized sets of random numbers were produced which named 1 and 2. Based on these two sets, the patients were allocated in two groups.

All patients were premedicated intravenously with 0.03 mg/kg midazolam and 2 mcg/kg fentanyl. Morphine 0.1 mg/kg was given intravenously before the induction of anaesthesia. Anaesthesia was induced with sodium thiopental 3–5 mg/kg, and orotracheal intubation was facilitated by atracurium 0.5 mg/kg. Anaesthesia was maintained using 70% nitrous oxide in oxygen and adjusted concentration of isoflurane to provide acceptable hemodynamic parameters. Monitoring consisted of five-lead ECG, non-invasive blood pressure, pulse oximetry, temperature and end-tidal carbon dioxide (kept between 30 and 40 mmHg). At the end of the surgery, neuromuscular blockade was antagonized with neostigmine (0.06 mg/kg) and atropine (0.03 mg/kg). After reliable recovery, the patients were tracheally extubated and transferred to the post-anaesthesia care unit (PACU). Anaesthesia protocol did not contain antiemetic medications. On the terminal part of the surgery, the urinary bladder was catheterized using a size 22-French Foley catheter, lubricated with plain lubricating jelly (Lubri-Jell, Shafa Co., Iran) followed with injection of 10 mL distilled water to inflate the balloon and then was fixed with adhesive tape on the suprapubic area with no traction. The amount of irrigation fluid used by surgeons during the operation was recorded.

Just before the extubation, slow intravenous injection of 20 mg hyoscine *N*-butyl bromide was administered to 24

patients of the treatment group over 1 min and 1 mL of normal saline was injected similarly to 26 patients of the second group and all the patients were followed for the next 2 h. The injections were prepared in similar appearances, and the subject and monitoring staff were unaware of which injection contains either medication or normal saline. During next 2 h, the CRBD feeling of the patients was graded into four degrees as: no distress (zero), mild discomfort expression after interviewing the patient but no complain automatically (one), moderate pain including urination desire, dysuria, or suprapubic discomfort feeling with no emotional distress (two) and severe pain including agitated behaviours such as restlessness and muscle tension, shouting for help and trying to remove the urinary tract catheter (three) [27].

The primary end point was described as rescue analgesic consumption amount. Secondary end points were reduction in pain related to TURP and PACU length of stay. Drug side effects including post-operative vomiting, dry mouth, blurred vision and tachycardia were recorded. In the PACU, all the patients were checked every 30 min regarding the discomfort intensity caused by the urinary tract catheter and every 15 min for discharge criteria (Aldrete score ≥ 9 [28]). We have recorded the time of discharge early when the patients got the discharge criteria, but still we kept them in the recovery for 2 h to complete their data collection. The patients with severe discomfort feeling caused by the catheter, including the grade 2 or 3, received a slow intravenous injection of 25 mg meperidine (conventional therapy) every 10 min, and this trend was continued to control the discomfort of the patient in PACU. The data collected from the study groups were analysed by SPSS 16 software (SPSS Inc., Chicago, IL). Obtained quantitative data were analysed using Mann–Whitney and repeated measurement test, and the qualitative data analysis was done by Chi-square and Fisher exact test.

Results

Out of 86 patients who were screened for enrolment, 36 patients were excluded. Four patients were a probable candidate for conversion to open prostatectomy, 16 because of drug abuse and 16 patients did not fulfil the inclusion criteria. Therefore, 50 patients participated in the study, 24 patients were in the treatment group and 26 patients in the control group, (among which 17 patients operated in Nemazee Hospital, 22 in Faghihi Hospital and 11 patients in Ali-Asghar Hospital) (Fig. 1). The mean age of the patients in this study was 66.12 ± 8.55 years. No significant differences were detected regarding demographic data of patients including age, weight, operation length, required irrigation volume and type of the catheters ($P > 0.05$) (Table 1).

The incidence of CRBD in the treatment group on arrival to PACU and after 30 min of infusion was significantly less than the control group ($P = 0.0001$ and $P = 0.007$, respectively). For the subsequent time intervals, this difference disappeared and there was no significant difference between two groups ($P > 0.05$); however, the total utilized meperidine dose and the time to discharge of intervention group were significantly lower than those of the control group ($P \leq 0.05$) (Table 2). There were no statistically detectable differences in adverse effects prevalence including dry mouth and tachycardia between treatment and control groups at the PACU ($P > 0.05$) (Table 3). Furthermore, none of the patients experienced any vomiting or blurred vision episode. Mean pain score of treatment group was increased during the time into plateau state, and oppositely the control group showed a reduction into the plateau state in a way that there was no difference in mean pain scores between two groups 1 h after intervention (Fig. 2).

Discussion

TURP remains the gold standard for obstructive prostatic hypertrophy management and is both the regular care and the optimal surgical action when other methods miss the mark [6, 29]. A great population of these patients confront with CRBD as the most usual complication in the PACU, and the incidence of this complication in male patients after 60 min of surgery has been reported about 55–63% [16, 30]. It is presented in the Agarwal et al. study that tolterodine as a pure muscarinic receptor antagonist could inhibit the catheter-related discomfort related to urinary catheterization in patients who are experiencing urological interventions. Tolterodine 2 mg was administered orally for fifty patients 1 h prior to the operation, and the rate of post-operative pain in the intervention group was significantly reduced comparing with the control group [16]. Moreover, it is shown that tolterodine, oxybutynin or gabapentin could decrease the CRBD incidence and severity in the post-operative period. Ketamine was compared with the placebo in 44 patients undergoing percutaneous nephrolithotomy, and the results indicated that the intensity of CRBD was significantly lower in the ketamine group [15, 31].

Our results showed that lower amount of rescue analgesic was demanded by the patients who have received the intervention comparing to the patients of control group. This effect is somehow similar to the effect of agents with analgesic properties like tramadol and gabapentin in reduction the CRBD pain, post-operatively [18, 32]. However, these medications had shown complications such as sedation, dizziness or potential risks of drug abuse which are not expected in use of hyoscine *N*-butyl bromide.

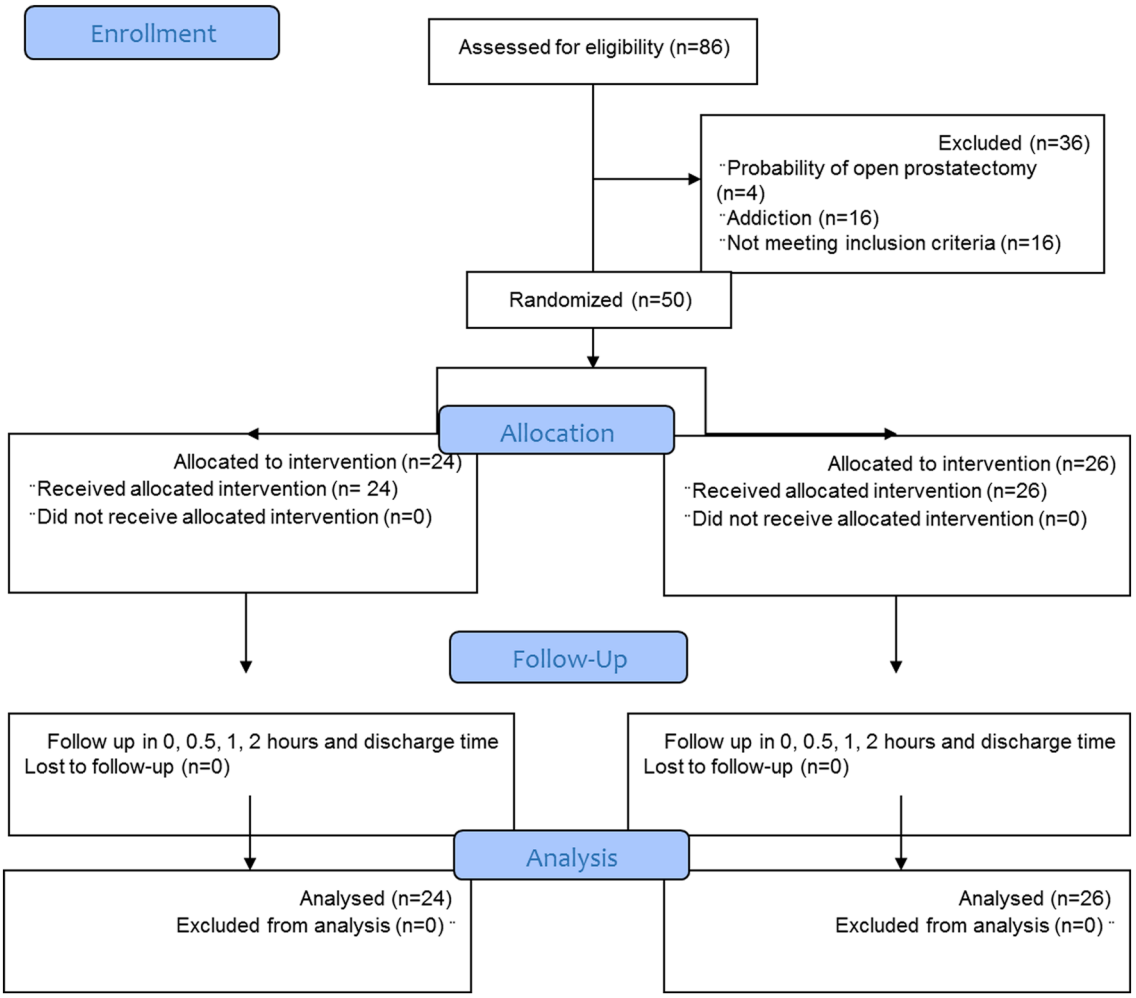

Fig. 1 CONSORT flow diagram

Table 1 Baseline characteristics of the patients and operations

Variables	Group		*P* value
	Treatment ($n = 24$)	Control ($n = 26$)	
Age (years)	64.95 ± 7.88	63.34 ± 9.22	0.511
Weight (kg)	66.29 ± 6.77	65.61 ± 7.21	0.735
Operation length (min)	73.12 ± 20.42	76.34 ± 23.64	0.62
Irrigation volume (L)	13 ± 3.58	12.53 ± 3.20	0.96
Silicone catheters	17 (70.8%)	20 (76.9%)	0.62
Latex catheters	7 (29.2%)	6 (23.1%)	

Data are presented as mean ± SD or patients' numbers (percentage)

About 77% of control group patients experienced pain on the arrival to PACU implying the lack or inadequate analgesic effect of the morphine which they have received during the surgery. We have shown that the severity of CRBD is downturned due to hyoscine *N*-butyl bromide on arrival to PACU and 30 min after injection. This finding is consistent with Ryu et al. [12] and Nam et al. [26] findings on the effect of butyl scopolamine in the prevention of CRBD [18]. However, in those studies this statistically significant difference has been observed even after an hour of drug injection, and we recorded this difference only up to 30 min after injection. This difference could be explained by use of rescue medication in our study. The patients in the control group received meperidine as a rescue analgesic to treat the pain in the first 30 min. Since the intravenous meperidine's onset of action is within few minutes, its analgesic properties could be the reason for non-significant difference between two groups after 60 min of injection. Here, the patients who received hyoscine *N*-butyl bromide as an intervention reached the discharge Aldrete scale of 9–10 in a shorter period of time comparing to the control group that could be either a direct effect of hyoscine *N*-butyl bromide on respiratory, cardiovascular and oxygen saturation system or could be the consequence of

Table 2 Catheter-related bladder discomfort (CRBD), analgesic consumption amount and time to PACU discharge in two studied groups

Variables	Pain score	Treatment group	Control group	*P* value
PACU entrance	0	23 (95.8%)	7 (26.9%)	0.0001
	1	1 (4.2%)	7 (26.9%)	
	2	0 (0%)	12 (46.2%)	
After 30 min	0	16 (66.7%)	11 (42.3%)	0.007
	1	7 (29.2%)	4 (15.4%)	
	2	1 (4.2%)	11 (42.3%)	
After 60 min	0	11 (45.8%)	16 (61.5%)	0.22
	1	11 (45.8%)	6 (23.1%)	
	2	2 (8.3%)	4 (15.4%)	
After 90 min	0	9 (37.5%)	14 (53.8%)	0.50
	1	14 (58.3%)	11 (42.3%)	
	2	1 (4.2%)	1 (3.8%)	
After 120 min	0	7 (29.2%)	10 (38.5%)	0.55
	1	17 (70.8%)	16 (61.5%)	
At discharge	0	7 (29.2%)	10 (38.5%)	0.55
	1	17 (70.8%)	16 (61.5%)	
Meperidine dose (mg)	Median (IQR) 0 (0–0)		Median (IQR) 20 (20–21.25)	0.0001
Time to Aldrete score ≥9 (min)	37.8 ± 11.87		60 ± 14.07	0.0001

Data are presented as mean ± SD, median (IQR) or patients' numbers (percentage)

Table 3 Prevalence of side effects in two studied groups

Variables	Grading	Treatment group	Control group	*P* value	RR	Confidence interval (95%)
Dry mouth	No	16 (66.7%)	20 (76.9%)	0.42	1.44	0.61–1.23
	Yes	8 (33.3%)	6 (23.1%)			
Tachycardia	No	24 (100%)	25 (96.2%)	0.33	1.04	0.96–1.12
	Yes	0 (0%)	1 (3.8%)			

Data are presented as patients' numbers (percentage)

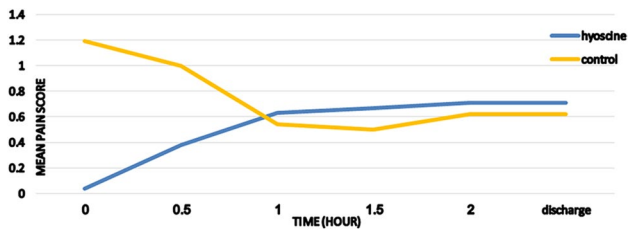

Fig. 2 Mean pain score variation of control and treatment groups in different follow-up periods in post-anaesthesia care unit

lower amount of analgesic consumption in the intervention group which probably led to quicker recovery.

The most frequently reported adverse events in clinical studies of antimuscarinic drugs are dry mouth, vomiting, tachycardia and blurred vision; few patients withdraw from clinical trials because of these adverse events. Anticholinergic central side effects like blurred vision, dry mouth, post-operative vomiting or tachycardia were not enhanced after the intervention which is in accordance to the findings of Ryu et al. [12] and Schafer et al. [33]. These outcomes were explainable, because hyoscine *N*-butyl bromide is a quaternary ammonium derivative and a peripheral anticholinergic drug which the attachment of the butyl bromide moiety efficiently inhibits the movement of this medicine through the blood–brain barrier, contributing to minimized undesirable central nervous system side effects [12]. Hyoscine *N*-butyl bromide is not centrally active and has a little incidence of abuse.

In the present study, we have evaluated only the response of a single dose of hyoscine *N*-butyl bromide without a dose–response titration on the prevention of CRBD and analgesic consumption in patients undergoing TURP surgery. Also, the pain could get worsen during 8 h later, but since we have followed the patients only up to the end of the recovery, we did not access to the data related to their pain

severity at the ward. So, further studies are warranted in this area. Moreover, we did not have access to any drug as a standard treatment of CRBD to compare the results with a positive control, and finally possible direct effect of this drug on Aldrete score factors was not investigated in this study. For the future investigations, other existing pathways responsible for CRBD and the therapeutic impending of several other agents, such as phosphodiesterase inhibitors, neurokinin-1 receptor antagonists, purinergic receptor antagonists, alpha (3)-adrenoceptor agonists and Rho-kinase inhibitors, could also help to find a standard remedy for treatment of CRBD.

Conclusion

In the present study, we have shown that hyoscine *N*-butyl bromide could reduce the severity of CRBD related to TURP surgery due to BPH and more importantly the need for analgesic consumption. In addition, length of stay in the PACU was shorter in the post-operative patients. According to the availability, low cost and minimum side effects of hyoscine *N*-butyl bromide, it can be an effective modality to relief the CRBD feeling related to TURP surgery in BPH patients.

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Compliance with ethical standards

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Conflict of interest All authors declare that they have no conflict of interest.

Ethical approval IRCT No.: 2013071013934N1.

Informed consent Informed consent was obtained from all individual participants included in the study.

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