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Role of pudendal nerve block for prevention of catheter-related bladder discomfort in male pediatric patients undergoing hypospadias surgery: a prospective randomized control study

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Abstract

Background: Catheter-related bladder discomfort (CRBD) is a common distressing symptom complex during the postoperative period, especially after urologic procedures followed by urinary catheterization. The purpose of this study is to evaluate the efficacy of pudendal nerve block and compare it with intravenous butylscopolamine in CRBD prevention in pediatric male patients undergoing hypospadias surgery under general anesthesia.

Results: After getting ethical committee clearance and informed written consent, 60 male pediatric patients scheduled for hypospadias repair were enrolled for the study and were randomized using computer-generated random numbers in 2 groups of 30 each: group P (received bilateral pudendal nerve block using 0.25% ropivacaine) and group B (received intravenous butylscopolamine 0.3 mg/kg) 15 min before extubation. The primary outcome was the incidence and severity of CRBD. Visual analog scale (VAS) for postoperative pain, postoperative side effects, the postoperative requirement for tramadol as a rescue treatment for CRBD and fentanyl as rescue analgesia for postoperative pain, and VAS for acceptance of an indwelling urinary catheter were the secondary outcomes. The incidences of CRBD and side effects were analyzed by the chi-square test and severity by Fisher's exact test. The VAS scale was analyzed by the Mann-Whitney test. A p value of < 0.05 was considered significant.
Group P had significantly decreased incidence as well as severity of postoperative CRBD than group B with $p < 0.05$. The postoperative median VAS score and number of patients requiring fentanyl as rescue analgesics were significantly low in group P in comparison with group B ($p < 0.05$). The total tramadol requirement at the end of 6 h for CRBD management was also significantly reduced in group P ($p < 0.0001$).

Conclusions: Pudendal nerve block seems to be superior to intravenous butylscopolamine in reducing the incidence and severity of CRBD. This study can be extrapolated to other urogenital studies in pediatric patients.

Keywords: Anti-muscarinics, Butylscopolamine, CRBD, Hypospadias repair, Pediatric patients, Pudendal nerve block

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Background

Catheter-related bladder discomfort (CRBD) is defined as a burning sensation or stabbing pain or an increased urinary frequency or urgency or discomfort in the suprapubic region, postoperatively in patients who had urinary catheterization with an incidence ranging from 47 to 90% (Wilson, 2008; Bai et al., 2015). CRBD may aggravate postoperative pain, increase the incidence of postoperative complications, and cause prolongation in hospital stay (Binhas et al., 2011; Lepouse et al., 2006). It may manifest as an agitated patient presenting with flailing limbs, strong verbal response, and attempts to pull out the catheter (Wilson, 2008; Binhas et al., 2011).

CRBD is caused by catheter-induced bladder irritation leading to muscarinic (M3) receptor activation, causing increased acetylcholine release which in turn causes involuntary contractions of the detrusor muscles of the bladder (Andersson & Wein, 2004). It is supported by the fact that the drugs with anti-muscarinic effects have shown efficacy in CRBD prevention or management. The muscarinic receptor antagonists solifenacin, butylscopolamine, tolterodine, and oxybutynin have been reported to be effective in preventing CRBD (Agarwal et al., 2006; Ryu et al., 2013; Zhang et al., 2014). Other agents with anti-muscarinic effects like gabapentin, pregabalin, tramadol, and ketamine have also been studied for the same purpose and been found useful (Agarwal et al., 2007; Srivastava et al., 2015; Safavi et al., 2014; Agarwal et al., 2008a). However, most of these agents have been associated with systemic side effects like dry mouth, facial flushing, sedation, nausea, vomiting, dizziness, blurred vision, etc. (Agarwal et al., 2006; Ryu et al., 2013; Zhang et al., 2014; Agarwal et al., 2007; Srivastava et al., 2015; Safavi et al., 2014; Agarwal et al., 2008a).

The pudendal nerve is derived from the second, third, and fourth sacral nerves and innervates the urethral sphincter, perineal muscles, and pelvic floor and provides sensation to the penis, clitoris, urethra, and bladder triangle (Agur & Dailey 2nd, 2013; Shafik et al., 1995). Pudendal nerve block has been used to provide analgesia in pediatric hypospadias repair (Naja et al., 2013). So theoretically it should be effectively preventing CRBD in these patients. We performed this study to evaluate the efficacy of pudendal nerve block and compare it with intravenous butylscopolamine in CRBD prevention in pediatric male patients operated for hypospadias repair under general anesthesia.

Methods

After getting ethical committee clearance and written informed consents from patients' parents, the study was done in the pediatric surgery OT at IMS, BHU, Varanasi. Male children of age between 8 and 15 years, ASA I or II scheduled to undergo hypospadias repair under general anesthesia, were included in the study. Those with overactive/neurogenic bladder, history of previous urinary tract surgeries, presence of active urinary tract infection, CNS, CVS, renal, hepatic diseases, coagulation disorders, and known allergy to study drugs were excluded from the study. Randomization was done using Web-based randomization software into 2 groups of 30 each and allocation concealment was achieved using opaque sealed envelopes.

Group P received 0.1 mL/kg of 0.25% ropivacaine bilaterally for pudendal nerve block (PNB) under ultrasound guidance.

Group B received 0.3 mg/kg butylscopolamine intravenously (iv).

Both the study drugs were administered 15 min prior to extubation by the respective routes.

Anesthesia was induced as per institutional protocol. In the operation theater monitors like pulse oximeter, NIBP and electrocardiogram were applied and baseline values were recorded in all patients preoperatively. Intravenous cannulation was done with 20 or 22 G cannula and ringer lactate administered at the rate of 20 mL/kg. Patients were preoxygenated with 100% oxygen for 5 min, and premedication was done with iv midazolam 0.03 mg/kg and fentanyl 2 mcg/kg. Intravenous induction was done with propofol 2 mg/kg until loss of eyelash reflex, and after checking for adequate bag mask ventilation, iv vecuronium 0.1 mg/kg was given. Bag mask ventilation was done for 3 min after which appropriately sized i-Gel was introduced and its appropriate positioning was confirmed with capnography and bilateral chest auscultation. Anesthesia was maintained with isoflurane 1 MAC in O2:N2O (50:50 ratios) with intermittent top-ups of vecuronium. Patients were extubated after demonstrating adequate neuromuscular recovery with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. The study drugs were administered 15 min prior to extubation.

Technique of PNB (Long, 2019)

Patients were placed in lithotomy position with a towel or blanket under the hips, to rotate the pelvis anteriorly. The ischial tuberosity was palpated and a low-frequency curved transducer was placed in transverse orientation over the tuberosity. The transducer was moved posteriorly until the lesser sciatic notch was visualized as a curved hyperechoic line (an inverted "U" shape). The transducer was moved posteriorly until the ischial spine appeared as a flat hyperechoic line. Medial to the ischial spine were the superficial sacrotuberous ligament (STL) and deeper sacrospinous ligament (SSL). The pudendal canal lies between STL and SSL, adjacent to the ischial spine. The pudendal artery was located with visible pulsations. The pudendal nerve is usually located medial to

the artery. In the medial to lateral direction, in-plane with the probe, a 50- to 100-mm, short-bevel, 22-gauge needle was inserted. The needle was advanced until it penetrated the STL. After negative aspiration for blood, approximately 0.1 mL/kg of ropivacaine 0.25% was injected around the nerve. The procedure was done bilaterally.

After surgery, urinary catheterization was performed using a 10- or 12-Fr Foley catheter as per age and the catheter balloon was filled with 10 mL of normal saline or as per the recommendation. The catheter was fixed without traction in the suprapubic region. Patients were shifted to PACU after extubation and were assessed for outcomes at 0 h, 0.5 h, 1 h, 2 h, 4 h, and 6 h.

Primary outcome: Incidence of CRBD in both groups was the primary outcome.

Secondary outcomes were:

1) The severity of CRBD, assessed as a 4-point scale, follows: 0 = none, did not report any CRBD even when asked; 1 = mild, revealed only on questioning; 2 = moderate, complained on their own without questioning but not accompanied with any behavioral response; 3 = severe, stated on their own and followed by behavioral responses such as strong verbal response, flailing limbs, or even try to pull out the urinary catheter (Wilson, 2008). When the severity of CRBD was ≥ 2, the patient was administered intravenous tramadol 1.5 mg/kg as a rescue treatment for bladder discomfort reduction (Agarwal et al., 2008b), and total postoperative tramadol consumption at the end of 6 h was recorded and compared.
2) Pain in the postoperative period using VAS score: if VAS ≥ 30, intravenous fentanyl was given in boluses of 0.5–1 mcg/kg as rescue analgesics and total consumption at the end of 6 h was noted.
3) Adverse effects of drugs including dry mouth, facial flushing, sedation, nausea, or vomiting were noted.
4) Complications of PNB including bleeding, hematoma, and infection at the injection site or accidental systemic toxicity by intravascular ropivacaine administration were noted.

Statistical analysis

The primary outcome of this study was the incidence of CRBD. A difference of 30% between groups in the incidence of CRBD was considered significant (Li et al., 2016). Giving α = 0.05 and 1-β = 0.80, 24 patients in each group were required in this trial (Li et al., 2016). We included 30 patients in each group to counter the possibility of dropout. Demographic data was analyzed

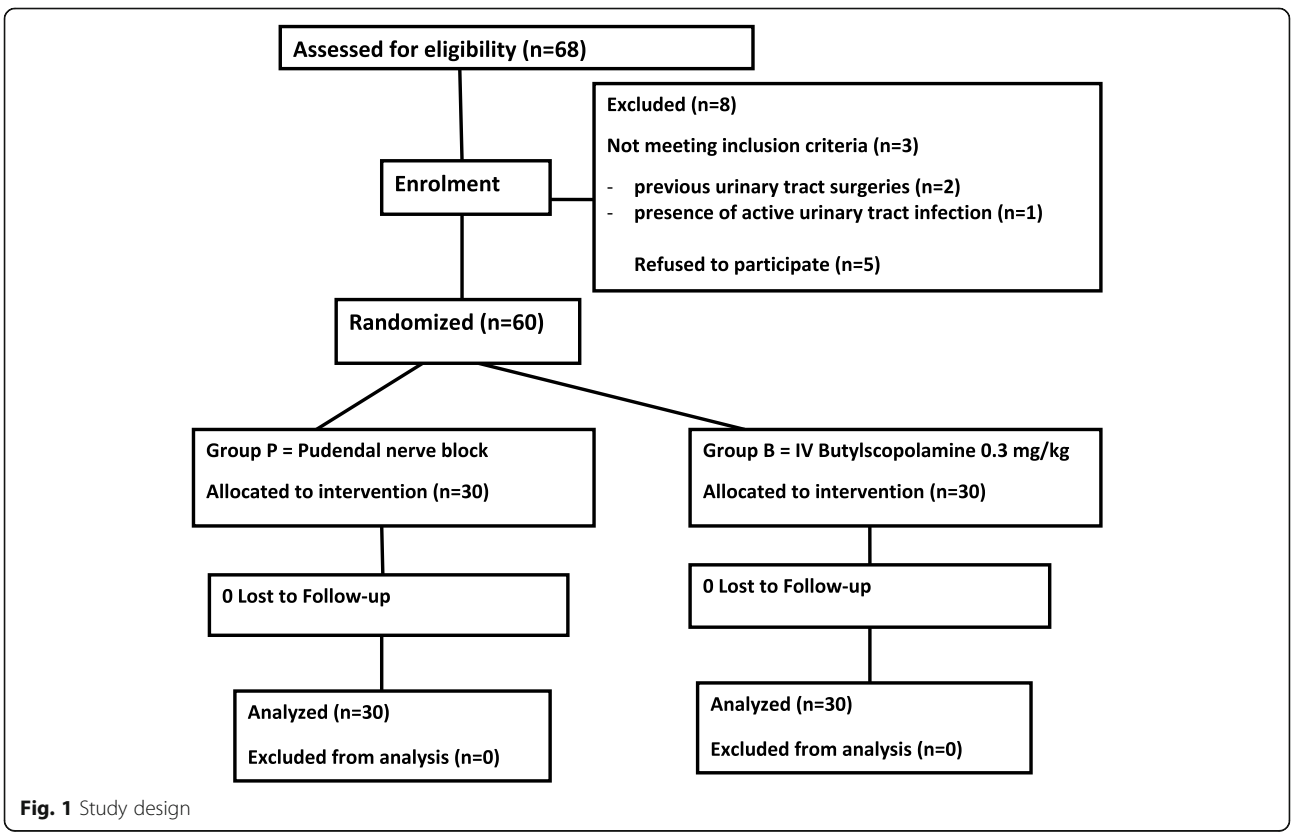

Fig. 1 Study design

Table 1 Demographic characteristics

	Group P (n = 30)	Group B (n = 30)	p value
Age (years) (mean ± SD)	10.5 (2.50)	11 (2.10)	0.4050
Weight (kg) (mean ± SD)	24.68 (6.10)	26.22 (5.33)	0.3021
Height (cm) (mean ± SD)	146.20 (12.86)	140.92 (15.26)	0.1527
ASA class (I/II) (no.)	22/8	23/7	0.5501
Duration of surgery (min) (mean ± SD)	124 (10.3)	122 (9.4)	0.4353
Duration of anesthesia (min) (mean ± SD)	140 (11.1)	143 (9.1)	0.2570
Size of the urinary catheter (10 Fr/12 Fr) (no.)	16/14	15/15	0.7100

$p > 0.05$ statistically not significant difference

using Student's *t*-test. Incidences of CRBD between the groups and side effects were analyzed by the chi-square test. The severity of CRBD was analyzed by Fisher's exact test. The Mann-Whitney test was used to assess VAS scores. Statistical package for social science SPSS 16.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. $p < 0.05$ was considered significant.

Results

In this study, a total of 68 patients were evaluated for inclusion. Eight patients were excluded from it, 5 from refusal to participate and 3 due to not meeting inclusion criteria (Fig. 1). Sixty patients were included and randomized into 2 study groups. There was no significant difference between the groups in terms of demographic profile, duration of anesthesia, or size of urinary catheters used (Table 1).

The incidence of CRBD was significantly lower in group P as compared to group B (13.3% vs 33.3% at 0 h, 10% vs 36.7% at 0.5 h and 1 h, 10% vs 40% at 2 h, 13.3% vs 43.3% at 4 h, and 13.3% vs 46.7% at 6 h respectively) in the PACU (Fig. 2). The severity of CRBD was also less in group P as evident by only 1 patient developing severe CRBD at 0 and 6 h in group P as compared to 5 patients in group B (Table 2) (Fig. 3). The postoperative median VAS score and the number of patients requiring fentanyl as rescue analgesics were significantly low in group P in comparison with group *B* ($p < 0.05$) (Fig. 4). The total fentanyl consumption at the end of 6 h was also significantly low in group P compared to group B [104.1 (12.7) vs 517.4 (23.3) respectively; $p < 0.0001$]. Total tramadol requirement at the end of 6 h for CRBD management was also significantly reduced in group P ($p < 0.0001$).

The incidence of dry mouth was significantly low in group P in comparison with group B (2 vs 22, $p < 0.0001$) while PONV developed in 2 patients in group P and 1 in group B (Table 3). None of the patients of either group developed facial flushing or sedation. In group P, none of the patients developed bleeding, hematoma, or infection at the PNB injection sites.

Discussion

CRBD is a major postoperative complication after urogenital surgeries as well as all surgeries requiring bladder catheterization in the perioperative period. A number of drugs have been evaluated in CRBD prevention and

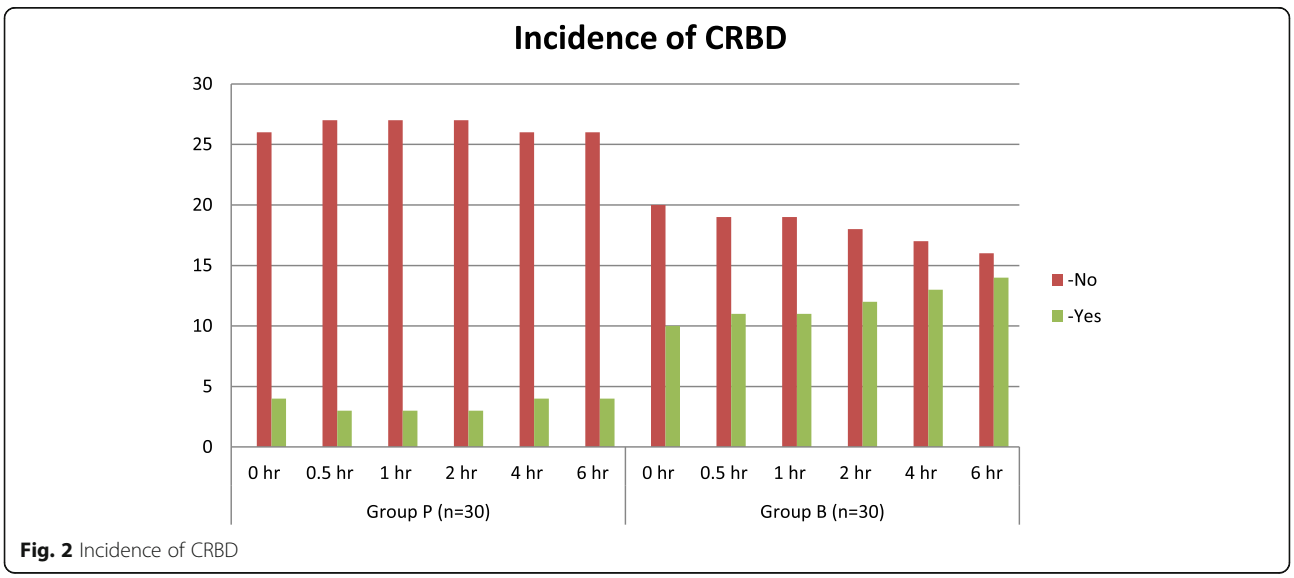

Fig. 2 Incidence of CRBD

Table 2 Incidence and severity of CRBD, VAS

	Group P ($n = 30$)						Group B ($n = 30$)						*P*- Value	
	0 hr	0.5 hr	1 hr	2 hr	4 hr	6 hr	0 hr	0.5 hr	1 hr	2 hr	4 hr	6 hr		
Incidence of CRBD (No.) (%)													0 hr	0.0013*
													0.5 hr	0.0001*
-No	26 (87)	27 (90)	27 (90)	27 (90)	26 (87)	26 (87)	20 (67)	19 (67)	19 (67)	18 (60)	17 (43)	16 (47)	1 hr	0.0001*
													2 hr	0.0001*
-Yes	4 (13)	3 (10)	3 (10)	3 (10)	4 (13)	4 (13)	10 (33)	11 (33)	11 (33)	12 (40)	13 (57)	14 (53)	4 hr	0.0001*
													6 hr	0.0001*
Severity of CRBD* (No.)	0 hr	0.5 hr	1 hr	2 hr	4 hr	6 hr	0 hr	0.5 hr	1 hr	2 hr	4 hr	6 hr	*P*- Value	
-Mild	2	2	2	2	3	2	2	4	4	5	5	6		Mild Mod Sev *
-Moderate	1	1	1	1	1	1	3	3	3	3	4	3	0 hr	1.000 0.08 0.0015
-Severe (No.) (%)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	5 (17)	4 (13)	4 (13)	4 (13)	4 (13)	5 (17)	0.5 hr	0.238 0.08 0.0002
													1 hr	0.238 0.08 0.0002
													2 hr	0.04* 0.08 0.0002
													4 hr	0.07 0.0165* 0.0002
													6 hr	0.119 0.08 0.0015
VAS score (median)	10	20	20	20	10	10	20	40	40	40	30	30	0.01046*	
No. of patients requiring fentanyl (%)	1 (3)	0 (0)	0 (0)	1 (3)	0 (0)	1 (3)	2 (7)	4 (13)	4 (13)	3 (10)	3 (10)	3 (10)	0 hr	0.3311
													0.5 hr	0.0002*
													1 hr	0.0002*
													2 hr	0.0818
													4 hr	0.0015*
													6 hr	0.0818
Total requirement of fentanyl (mcg) at the end of 6 hrs (mean+/− SD)					104.1 (12.7)						517.4 (23.3)		< 0.0001*	
No. of patients requiring tramadol for CRBD management	2 (7)	1 (3)	1 (3)	1 (3)	1 (3)	2 (7)	8 (27)	7 (23)	7 (23)	7 (23)	8 (27)	8 (27)	0 hr	0.003*
													0.5 hr	0.0001*
													1 hr	0.0001*
													2 hr	0.0001*
													4 hr	0.0001*
													6 hr	0.003*
Total requirement of tramadol (mg) at the end of 6 hrs (mean+/− SD)					331.6 (37.8)						1687.3 (51.7)		<0.0001*	

*$P < 0.05$

management, but mostly on adult patients. We evaluated the role of bilateral PNB using ropivacaine in pediatric patients undergoing hypospadias repair and found its superiority in reducing the incidence and severity of CRBD when compared to intravenous butylscopolamine.

Xiaoqiang et al. compared nerve stimulator-guided PNB versus no intervention in the control group in adult male patients undergoing lower urinary tract surgeries and found significantly lower incidence and severity of CRBD in the PNB group for the first 8 h postoperatively (Xiaoqiang et al., 2017). The pain relief was also better in the PNB group till 12 h postoperatively. In our study too, PNB proved to be associated with much lower incidence and severity of CRBD with greater pain relief in comparison with the butylscopolamine group. However, they found one patient complaining of levator ani muscle weakness which was not seen in any of our patients. This can be explained by the use of lower concentration of ropivacaine (0.25%) used in our study while 0.50% ropivacaine was used in the mentioned study.

Another block which has been studied in CRBD prevention is dorsal penile nerve block (DPNB) where Li

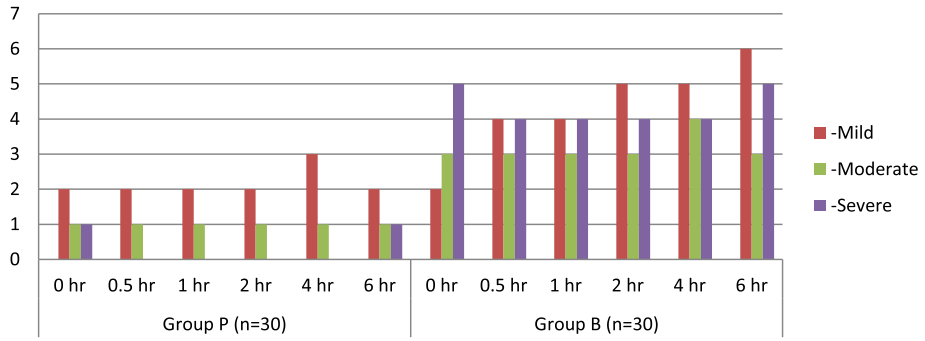

Fig. 3 Severity of CRBD

et al. found that DPNB though significantly reduced the incidence and severity of CRBD, 3 patients kept complaining of CRBD, so they concluded that though effective DPNB did not offer full CRBD prevention and further study could be focused on the efficacy of pudendal nerve block (Li et al., 2016).

PNB is a safe, effective, and easy to learn technique as per Aissaoui et al. which requires 10 cases for full command on the technique (Aissaoui et al., 2008). Ultrasonography has further improved its learning curve.

Preventive rather than therapeutic drugs for CRBD are essential to improve patient comfort in all surgery patients with a urinary catheter. Tolerance of the urinary catheter is at most needed in patients undergoing hypospadias surgery because any discomfort leading to pulling out the catheter will negate the surgical benefit. Pediatric patients are even much less cooperative than adult patients. Pudendal nerve block has been used in a wide variety of perineal, vaginal, and bladder surgeries. Also considering the neuroanatomy of the bladder and urethra, we hypothesized that it would reduce CRBD. Prophylactic use of PNB was found superior to iv butylscopolamine. The residual analgesic effect of PNB resulted in further comfort to the patients in the early postoperative period. The systemic side effects of the butylscopalamine could be avoided by the use of PNB.

There are several limitations of this study. First, with regard to the study design where different routes were used for study groups (nerve block and intravenous), double blinding could not be achieved in group allocation, so a potential bias was a possibility. Second, though we used ultrasound-guided PNB which made the block safer, the potential for neurovascular injury, bleeding, hematoma, infection, and local anesthetic toxicity cannot be ignored specially in the pediatric population. So risk-benefit analysis should be done before using it in non-surgical patients. In our study, we used it in patients undergoing hypospadias repair, where it offered analgesia as well as CRBD prevention without associated systemic side effects as seen with anti-muscarinics. Third, hypospadias being a urogenital surgery may itself be associated with bladder and urethral irritation and discomfort, and differentiating it from the surgical pain is also challenging. In addition, CRBD is a subjective feeling and its quantification partially depends on patient's ability to understand and physician's judgment. This may be the reason behind varied incidences of CRBD in different articles (Bai et al., 2015; Binhas et al., 2011).

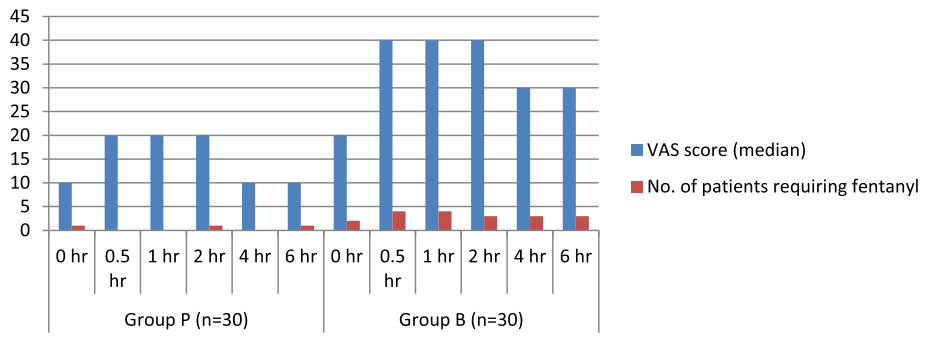

Fig. 4 VAS score (median) and number of patients requiring fentanyl

Table 3 Adverse effects

	Group P (n = 30)	Group B (n = 30)	p value
Dry mouth (no. (%))	2 (7)	22* (73)	< 0.0001*
Facial flushing (no. (%))	0 (0)	0 (0)	1.000
PONV (no. (%))	2 (7)	1 (3)	0.3311
Sedation (no. (%))	0 (0)	0 (0)	1.000
Bleeding (no. (%))	0 (0)	NA	NA
Infection at injection site (no. (%))	0 (0)	NA	NA

*p < 0.05. *NA* not applicable. All data presented in numbers and percentages

However, we strictly adhered to the study protocol to get more accurate data on its incidence and severity.

Conclusions

We conclude that prophylactic use of bilateral pudendal nerve block provides better control of symptoms of CRBD as well as better postoperative analgesia with least systemic side effects in pediatric patients undergoing hypospadias repair in comparison with intravenous butylscopolamine.

Abbreviations

CRBD: Catheter-related bladder discomfort; VAS: Visual analog scale; PNB: Pudendal nerve block; OT: Operation theater; ASA: American Society of Anesthesiologists; CNS: Central nervous system; CVS: Cardiovascular system; IV: Intravenous; NIBP: Non-invasive blood pressure; MAC: Minimum alveolar concentration; STL: Sacrotuberous ligament; SSL: Sacrospinous ligament; PONV: Postoperative nausea vomiting; PACU: Postanesthesia care unit; DPNB: Dorsal penile nerve block

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None.

Authors' contributions

AR: done the concepts, definition of intellectual content, literature search, clinical studies, experimental studies, data acquisition, statistical analysis, manuscript preparation, manuscript editing, and manuscript review. R: guarantor and done the concepts, definition of intellectual content, literature search, clinical studies, experimental studies, data analysis, statistical analysis, manuscript preparation, manuscript editing, and manuscript review. All the authors have reviewed and approved for submission.

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Availability of data and materials

The datasets during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Approval from the internal review board was taken for this study. Institutional ethical committee clearance was obtained from the IEC, IMS-BHU, Varanasi, India (BHU/2016-17/EC/142). The informed written consent to participate in the study was provided by parents or legal guardians of all the participants (male children between 8 and 15 years of age).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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