Original Article

Intravesical bupivacaine in reducing catheter-related bladder discomfort and lower urinary tract symptoms after transurethral surgery: A randomized controlled trial

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ABSTRACT

Introduction: The objectives of this study were to investigate the efficacy and safety of intravesical bupivacaine instillation in reducing catheter-related bladder discomfort (CRBD) and lower urinary tract symptoms (LUTS) after transurethral surgery.

Methods: The study enrolled 100 American Society of Anesthesiologists (ASA) grade I–III patients aged ≥18 years undergoing transurethral resection of the prostate or transurethral resection of the bladder tumor, randomly assigned to Group B (intravesical bupivacaine) or Group S (saline). Double blinding was employed. Independent variables included demographics, surgery type, ASA grade, and intervention details. Dependent variables comprised CRBD severity, Patient Perception of Bladder Condition (PPBC), Pelvic Pain Urgency Frequency (PUF), Visual Analog Scale (VAS) for pain, need for additional analgesics, and International Prostate Symptom Score (IPSS). SPSS version 19 was used for analysis with a significance level of $P < 0.05$. Side effects such as hematuria were also recorded.

Results: Group B reported significantly lower "moderate" CRBD immediately (2% vs. 40%, $P < 0.001$) and at 12 h (0% vs. 18%, $P = 0.003$) post-instillation compared to Group S and also required fewer additional analgesics (4% vs. 46%). The PPBC at catheter removal also favored Group B ($P = 0.003$) and day 1 ($P < 0.001$). The PUF scores were also significantly lower in Group B at catheter removal ($P = 0.001$) and at day 1 ($P = 0.028$). The IPSS was also significantly lower in the Group B on day 1 ($P = 0.003$) and 7 ($P = 0.001$). The VAS scores also favored the Group B consistently and although the side effects were higher in Group B but this was not statistically significant.

Conclusion: Intravesical bupivacaine administration has the potential to alleviate CRBD and postoperative LUTS following lower urinary tract transurethral electrosurgery. The study's findings underscore the importance of personalized pain management strategies in optimizing the patient comfort during the postoperative recovery.

INTRODUCTION

Catheter-related bladder discomfort (CRBD) is a "distressing symptom complex characterized as a burning sensation or stabbing pain with an urge to void or as discomfort from the suprapubic area to the urethra,"[1] with an incidence ranging from 47% to 90%.[2] Urological surgeries of the lower urinary tract such as transurethral resection of the bladder tumor (TURBT) or transurethral resection of the prostate (TURP) are associated with a higher risk of CRBD when compared with

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surgeries that do not involve the lower urinary tract such as percutaneous nephrolithotomy and non-urologic surgeries.

Aside from CRBD, postoperative lower urinary tract symptoms (LUTS) are a significant problem in the early postoperative period following electrosurgery of the lower urinary tract after the catheter removal. A previous study had shown that intravesical application of bupivacaine is effective in the prevention and treatment of detrusor muscle hyperreflexia.[3] Since the symptoms of CRBD and LUTS are identical to those of detrusor hyperreflexia, the present study was conducted with the assumption that intravesical bupivacaine may prevent CRBD/LUTS. Patients undergoing surgery with spinal or general anesthesia usually exhibit a delayed return to full pain perception, which may take approximately 6 h. Hence, the subjective data collected within the 6 h of surgery are not reliable enough. This study was aimed at assessing the role of bupivacaine in reducing CRBD/LUTS after 6 h of transurethral electrosurgery.

MATERIALS AND METHODS

Trial design and oversight

This randomized controlled double-blinded study aimed to assess the impact of intravesical bupivacaine instillation after transurethral electrosurgery on the reduction of CRBD and LUTS during the postoperative period. This study was performed at a single center in the Southern part of India. The hospital's Research Ethics Committee approval (Ref: JIP/IEC/2021/032) and registration in Clinical Trials Registry-India (CTRI/2021/12/039020) were obtained. The study adhered to the principles of the Helsinki Declaration, and informed consent was obtained from the patients following a comprehensive explanation of the protocol. The authors vouch for the integrity and completeness of the data and the fidelity of the trial to the protocol, and the statisticians vouch for the accuracy of the data analysis.

Eligibility

This double-blind randomized clinical trial included 100 consecutive patients over the age of 18 years, with American Society of Anesthesiologists (ASA) physical status I to III, undergoing TURP and TURBT. Exclusion criteria encompassed residual tumor, bladder perforation, active hematuria, postoperative delirium, known allergy to bupivacaine/lidocaine, cardiac conduction block, hepatic/renal issues, Class III anti-arrhythmic drug usage, acute porphyria, corticosteroid administration, substance abuse, and uncooperativeness.

Sample size

The sample size for this study was determined based on the specific assumption that the estimated proportion of patients who experience CRBD in the intervention group was 50%, the estimated proportion of patients who experience CRBD in the control group was 80%, and the ratio of patients in the intervention group to the control group was 1:1. A confidence interval of 95% and a study power of 80% were used.

Using the Fleiss with continuity correction method in Epi Info version 7.2.4, by CDC (Centre for Disease Control and Prevention, USA) the calculated sample size was 90 cases. To account for a potential 10% dropout rate, the final corrected sample size was rounded up to 100 cases.

Randomization

Roughly 6 h post-anesthesia, patients were randomized into two groups in a 1:1 ratio by the technique of stratified block randomization with unequal block sizes of 2, 4, and 6. The randomization was performed using the Random Allocation software version 1.0.0.[4] Allocation concealment was done by the SNOSE method. The control group received intravesical normal saline (Group S) and the intervention group received intravesical bupivacaine group (Group B). The allocation of the patients in the respective groups is shown in the CONSORT diagram [Figure 1]. All surgeries were performed with a bipolar electrosurgical unit. Baseline assessments and scoring were conducted before installation. Using a sterile syringe, 40 mL of 0.5% bupivacaine (Group B) or 40 mL of normal saline (Group S) was instilled into the bladder via the Foley's catheter. Following instillation, bladder irrigation was halted, and catheters were clamped for 30 min to prevent outflow. Bladder irrigation was restarted after 30 min.

Primary and secondary end point assessment

Primary outcome

To study the efficacy of postoperative intravesical Bupivacaine administration in reducing the CRBD in patients undergoing lower urinary tract electrosurgery such as TURP and TURBT.

Secondary outcomes

To study the effect of postoperative intravesical bupivacaine administration in reducing LUTS such as dysuria, frequency, and urgency, after catheter removal in patients undergoing lower urinary tract electrosurgery such as TURP and TURBT.

Demographic data, clinical information, and the International Prostate Symptom Score (IPSS) were recorded before the surgery.

The incidence and severity of CRBD,[3] and the need for additional analgesia, were assessed at declamping, 12 h, and 24 h, primarily employing the CRBD Severity Grading Scale, enumerated as follows.

- Patients did not complain of any CRBD even on inquiring – None
- Reported by patients only on questioning – Mild
- Reported by patients on their own (without questioning) and not accompanied by any behavioral responses – Moderate
- Reported by patients on their own along with behavioral responses – Severe.

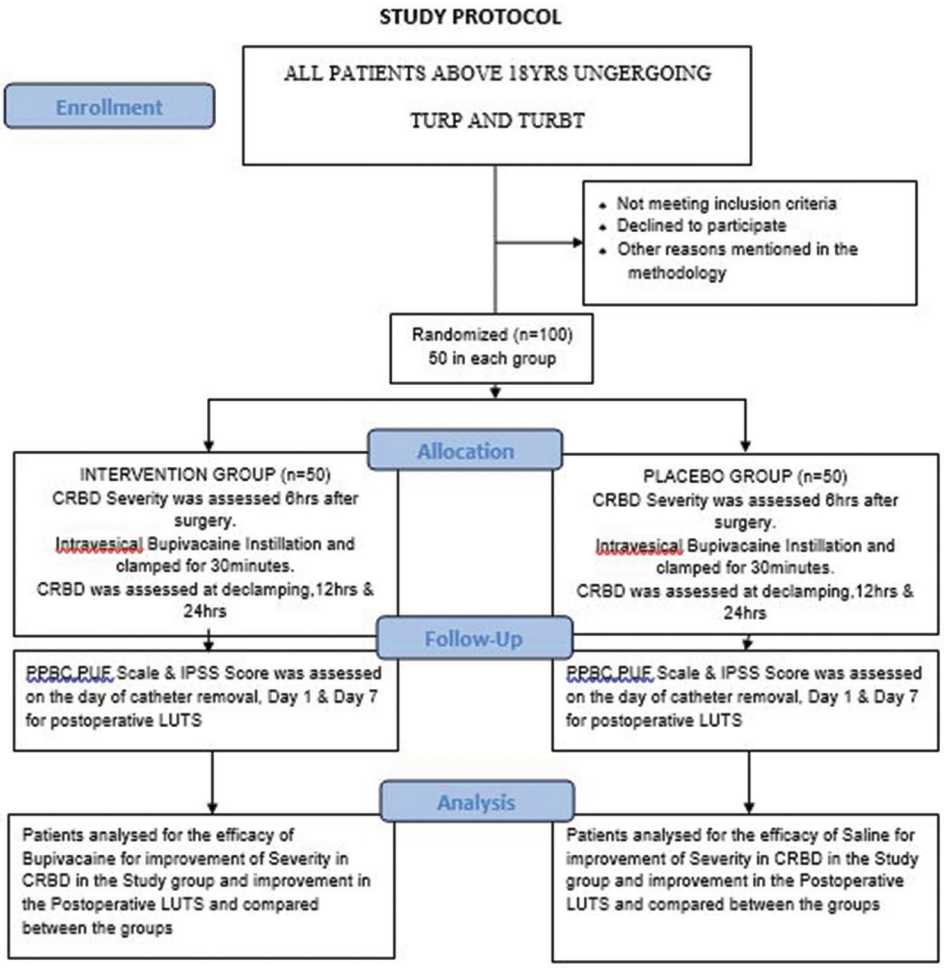

Figure 1: CONSORT diagram: Patient allocation and randomization. CRBD = Catheter-related bladder discomfort, PPBC = Patient Perception of Bladder Condition, PUF = Pelvic pain frequency urgency, VAS = Visual Analog Scale, IPSS = International Prostate Symptom Score, LUTS = Lower urinary tract symptoms, TURBT = Transurethral resection of the bladder tumor, TURP = Transurethral resection of the prostate

Patients experiencing moderate CRBD after declamping received the analgesic paracetamol. Pain was evaluated using the Visual Analog Scale (VAS) with scores ranging from 0 to 10. In addition, patients were evaluated for lower urinary symptoms on the 1st day after catheter removal and at 1 week. The secondary outcomes were assessed using the Pelvic Pain Urgency Frequency (PUF) Scale, the Patient Perception of Bladder Condition (PPBC) Scale, and the IPSS.

The PPBC[5] Scale, a validated tool, subjectively evaluated bladder state, categorized from none to severe (0 – none, 1 and 2 – mild, 3 – moderate, and 4 and 5 – severe). The PUF[13] Scale was administered as a questionnaire, with questions 3 and 8 excluded due to their non-applicability post-surgery. The questionnaire was then checked for its validity. The PUF scores were categorized as none (0), mild (1–9), moderate (10–18), and severe (19–29). The IPSS, a validated assessment tool in urology, categorized LUTS as mild, moderate, or severe.

Statistical analysis

The distribution of continuous variables such as age, VAS for pain, IPSS, size of bladder tumor, and data normality was determined using the Kolmogorov–Smirnov test. Prostate size was expressed as mean with standard deviation or median with range. The continuous variables were analyzed using the Student's *t*-test and Wilcoxon test. The severity of CRBD, PPBC, and PUF was comparatively analyzed between the two groups by using the Chi-square test or Fisher's exact test. The discrete variables, such as gender, ASA physical status, and side effects, were expressed in percentage or frequency and were analyzed using the Chi-square test. The *P* value was set at 0.05. All calculations were performed using the SPSS version 19 (IBM, SPSS Statistics for Windows, version 19. Armonk, NY: IBM Corp.).

RESULTS

The baseline demographic characteristics are represented in Table 1 and had a similar distribution across both the groups.

The primary outcome variable was CRBD after intravesical instillation of the drug. The results are depicted in Table 2. We compared the incidence of moderate CRBD among

the two treatment groups across different time points (at declamping the catheter, at 12 h, and at 24 h) to appreciate the treatment effects. The incidence of moderate CRBD was higher in Group S compared to Group B after the bladder declamping (40% vs. 2%, $P < 0.001$) and at 12 h (18% vs. 0%, $P = 0.003$). However, at 24 h, there was no statistically significant difference in the incidence of moderate CRBD between the two treatment groups. The need of additional analgesics was also significantly higher in Group S (46%) compared to Group B (4%), $P < 0.001$.

The pain assessment measures at various time points are presented in Table 3. Here, the medians are equal in both the groups; however, the test shows a statistically significant difference. When the two groups have the same median, it may indicate that the two groups are similar in terms of their central tendency. However, this does not necessarily mean that the two groups are not significantly different from each other. The Wilcoxon signed-rank test takes into account the entire distribution of the data, not just the central tendency, and can detect differences in the shape and spread of the data. Even if two groups have the same median, they may have different variances, skewness, or kurtosis, which may lead to a significant difference when using the Wilcoxon signed-rank test. Furthermore, outliers in one group, but not in the other, can also lead to a significant difference when using the Wilcoxon signed-rank test.

Table 1: Baseline characteristics

	Group B, *n* (%)	Group S, *n* (%)
Median age	61 (55.7–67.7)	61 (55.7–67.7)
Males	43 (86.0)	48 (96.0)
Females	7 (14.0)	2 (4.0)
TURBT	25 (50.0)	25 (50.0)
TURP	25 (50.0)	25 (50.0)
ASA 1	20 (40.0)	21 (42.0)
ASA 2	26 (52.0)	27 (54.0)
ASA 3	4 (8.0)	2 (4.0)
Preoperative IPSS	15.4±10.87	15.5±10.74
Size of bladder tumor (cm)	2.5 (1.72–3.12)	3 (2.25–3.75)
Volume of prostate resected (cc)	40 (30–50)	39 (30–50)
Presence of a preoperative catheter	17 (34)	15 (30)

IPSS=International Prostate Symptom Score, TURBT=Transurethral resection of the bladder tumor, TURP=Transurethral resection of the prostate, ASA=American Society of Anesthesiologists

Table 2: Catheter-related bladder discomfort at different time points among groups

Variable	Severity	Group B, *n* (%)	Group S, *n* (%)	Statistical significance
CRBD at 6 h of surgery	Mild	26 (52)	27 (54)	0.841
	Moderate	24 (48)	23 (46)	
CRBD at declamping of catheter	Mild	49 (98)	30 (60)	<0.001
	Moderate	1 (2)	20 (40)	
CRBD after 12 h of declamping	Mild	50 (100)	41 (82)	0.003
	Moderate	0	9 (18)	
CRBD after 24 h of declamping	Mild	50 (100)	47 (94)	0.242
	Moderate	0	3 (6)	

CRBD=Catheter-related bladder discomfort, Group B=Bupivacaine group, Group S=Saline group

The frequency of "moderate" PPBC was significantly higher in Group S compared to Group B at the catheter removal (46% vs. 18%, $P = 0.003$) and at day 1 after the catheter removal (17% vs. 3%, $P < 0.001$). However, with the progression of time, at day 7 after the catheter removal, the frequency of "moderate" PPBC was statistically similar in both the groups (7% vs. 1%, 0.059). The change in PPBC across different time points is represented in Table 4.

Similar to PPBC, the frequency of reporting of "moderate" PUF was statistically higher in Group S as compared to Group B on the day of the catheter removal (74% vs. 21%, $P = 0.001$) and at day 1 after the catheter removal (64% vs. 42%, $P = 0.028$). However, at day 7 of the catheter removal, both the groups had a similar incidence of moderate PUF (65% vs. 44%, $P = 0.23$). The PUF scores in both the groups across various time points is depicted in Table 4.

Both the groups had statistically similar IPSS immediately after the catheter removal. Both the groups showed a decrease in the IPSS with time [Table 3]. However, at day 1 and day 7, the IPSS was lower in Group B as compared to Group S, which was statistically significant.

Hematuria was more in Group B (14%) as compared to Group S (8%) however, it did not require any intervention. Fever was recorded in only 1 patient (2%) in Group B compared to 4 patients (8%) in Group S, however, the difference was found to be statistically non-significant.

DISCUSSION

Symptoms of CRBD are similar to those of an overactive bladder.[7] These symptoms often cause immense distress among the patients resulting in a typical behavioral response characterized by flailing limbs, a strong vocal response, and an attempt to pull out the urinary catheter. Such vehement behavioral response might amplify the perception of postoperative pain, cause undue anxiety among the family as well as the caregivers, and lengthens the hospital stay, which all culminate into an unpleasant postoperative experience for the patient. Patients undergoing transurethral procedures are especially at a higher risk of developing CRBD and LUTS, which is widely acknowledged in the literature.[8] CRBD and postoperative LUTS have been shown to have a negative impact on the patients' postoperative recovery.

For improved care and reduced morbidity, a sound knowledge of the mechanism and pathophysiology of CRBD is necessary. Urethral catheterization stimulates the sensory nerves of the bladder, which release acetylcholine from their nerve endings.[9] This brings about the parasympathetic-mediated involuntary contraction of the detrusor muscle. Based on this mechanism, different anticholinergic, opioid, and prostaglandin inhibitors are available with varying degrees of success for the management of CRBD.[10] Despite a multitude

Table 3: Visual Analog Scale and median International Prostate Symptom Score at different time points

Variable	Group B	Group S	Statistical significance
IPSS on the day of catheter removal	16 (15–19.25)	18 (15–20.5)	0.155
IPSS on day 1 of catheter removal	12 (10–15)	15 (12–18)	0.003
IPSS on day 7 of catheter removal	12 (10–12)	13 (11.5–16)	0.001
VAS score at declamping of catheter	4 (3.75–4)	4 (4–7)	0.006
VAS score after 12 h of declamping	3 (2–3.55)	3 (3–5)	0.003
VAS score after 24 h of declamping	2 (2–3)	3 (2–4)	0.003

IPSS=International Prostate Symptom Score, VAS=Visual Analog Scale, Group B=Bupivacaine group, Group S=Saline group

Table 4: Pelvic pain frequency urgency and Patient Perception of Bladder Condition score at different time points

Variable	Severity	Group B, *n* (%)	Group S, *n* (%)	Statistical significance
PUF on the day of catheter removal	Mild	29 (58)	13 (26)	0.001
	Moderate	21 (42)	37 (74)	
PUF on day 1 of catheter removal	Mild	29 (58)	18 (36)	0.028
	Moderate	21 (42)	32 (64)	
PUF at day 7 of catheter removal	Mild	28 (56)	22 (44)	0.23
	Moderate	22 (44)	28 (56)	
PPBC on the day of catheter removal	Mild	41 (82)	27 (54)	0.003
	Moderate	9 (18)	23 (46)	
PPBC on day 1 of catheter removal	Mild	47 (94)	33 (66)	<0.001
	Moderate	3 (6)	17 (34)	
PPBC at day 7 of catheter removal	Mild	49 (98)	43 (86)	0.059
	Moderate	1 (2)	7 (14)	

PUF=Pelvic pain frequency urgency, PPBC=Patient Perception of Bladder Condition, Group B=Bupivacaine group, Group S=Saline group

of proposed management options, there is a disagreement on the optimal management of CRBD/postoperative LUTS. Intravesical instillation of bupivacaine, a local anesthetic agent, has shown promising results in managing CRBD/postoperative LUTS. The drug blocks the sensory nerves from releasing acetylcholine. Studies on patients undergoing nonurological surgeries have shown good response to the treatment without any major adverse events.[11]

Patients undergoing endourological surgeries are at a higher risk of CRBD. Trauma to the urothelium exposes the subepithelial sensory nerve endings to the noxious stimuli causing the release of acetylcholine, resulting in detrusor overactivity. Few studies have reported on the efficacy of submucosal injection of bupivacaine after TURBT.[12] However, it carries the risk of drug intravasation and systemic reaction. Intravesical instillation of bupivacaine can be used for the management of CRBD thereby avoiding the side effect related to subepithelial injection.

Our study reveals intriguing patterns of CRBD between Group B (intravesical bupivacaine) and Group S (placebo). At the critical time points of declamping of the catheter and 12 h postoperatively, the higher incidence of moderate CRBD in Group S immediately after bladder declamping suggests a potential transient discomfort experienced by the patients in this group. This early divergence in CRBD underscores the intervention's immediate impact on the postoperative discomfort levels. The reduction of moderate CRBD to 0% in Group B at 12 h further highlights the potential efficacy of intravesical bupivacaine in alleviating bladder discomfort during this crucial phase of recovery. However, at the 24-h mark, the incidence of moderate CRBD in both the groups converges, and the difference becomes statistically nonsignificant. This trend indicates that the intervention's effects may diminish over time, resulting in a similar incidence of CRBD in both the groups. These results underscore the potential of intravesical bupivacaine to provide transient relief from moderate CRBD during the early period of recovery. The study's extended follow-up period of up to 24 h presents a unique strength, as it surpasses the durations typically assessed in similar studies.

None of the patients in the bupivacaine group encountered moderate CRBD and the saline group had 3 (0% vs. 6%) patients with moderate CRBD at 24 h and most of the patients of both the groups had only mild CRBD at 24 h (100 vs. 94). This mild CRBD may be attributed to the fact that additional analgesia was given to patients who complained of moderate CRBD after declamping. Another significant finding of the study is the substantial reduction in the sedative and analgesic requirements in the bupivacaine group compared with the saline group (4% vs. 46%), which further corroborates the positive effects of intravesical bupivacaine on pain and agitation.

The comparison of PPBC[5] between the two treatment groups, Group B (intravesical bupivacaine) and Group S (placebo), highlighted an initial disparity in the frequency of "moderate" PPBC. Group S exhibited a higher frequency of "moderate" PPBC at catheter removal and at day 1 after the catheter removal. However, this difference progressively diminished over time, with both the groups reporting similar frequencies by day 7. These results emphasize the dynamic nature of the postoperative recovery and the potential impact of interventions such as intravesical bupivacaine on the patients' perceived bladder discomfort.

Similarly, the examination of PUF scores[6] also revealed a consistent trend. Group S reported higher frequencies of "moderate" PUF on the day of the catheter removal and day 1 after the catheter removal. Yet, by day 7, both the groups converged toward similar frequencies, echoing the broader theme of normalized postoperative recovery

trajectories. This consistent pattern in PUF scores parallels the observations in the PPBC, suggesting that intravesical bupivacaine may alter the trajectory of urinary discomfort experienced by the patients in the post-operative period.

Both the groups exhibited comparable IPSS[14] immediately after the catheter removal, suggesting a shared baseline experience. However, over time, Group B consistently reported lower IPSS at day 1 and day 7 after the catheter removal compared to Group S. This divergence indicates the potential variations in urinary symptoms experienced by the two groups, which might be attributed to the effects of intravesical bupivacaine.

Among the adverse events examined, hematuria and fever were of particular interest. The marginally higher rate of hematuria in Group B as compared to the Group S might not be attributed to the potential effects of intravesical bupivacaine on the bladder tissues or its interaction with the catheter. However, the lack of statistical significance suggests that the observed difference could be well within the range of expected variability and may not necessarily be directly attributable to the intervention itself. It is also important to consider that the hematuria could be influenced by a variety of other factors, including surgical technique, individual patient characteristics, and postoperative care.

Limitations

The study does not delve into the specific mechanisms underlying bupivacaine's actions in the prostatic fossa, especially in the presence of a catheter. Although patients who underwent with preoperative catheters were included, a more comprehensive investigation into this subgroup could offer deeper insights into how the bupivacaine interacts in the prostatic fossa under these conditions. The study had an overwhelming majority of male subjects, thereby making the applicability of its results among the female patients somewhat limited.

CONCLUSION

This study provides compelling evidence that a single dose of intravesical bupivacaine administered 6 h after the surgery in patients undergoing TURP or TURBT is effective in reducing the postoperative CRBD and the effect lasts up to 24 h after the administration. It also helps in reducing the LUTS such as dysuria, frequency, and urgency on the 1st day after the catheter removal in these patients. It may, therefore, be useful to incorporate this technique in the postoperative management of patients undergoing TURP or TURBT.

Nevertheless, the efficacy of single dose of intravesical bupivacaine appears to diminish over time, leading to comparable experiences across the treatment groups after the first couple of days. It remains to be elicited whether additional intravesical doses would result in longer and more sustained benefits. The absence of statistically significant differences in the adverse events suggests that the intervention, intravesical bupivacaine, did not significantly elevate the risks in comparison to the placebo. This outcome enhances the overall confidence in the intervention's safety profile, supporting its potential role as a therapeutic option for the management of CRBD.

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