Original Article

Evaluation of USG-guided novel sacral erector spinae block for postoperative analgesia in pediatric patients undergoing hypospadias repair: A randomized controlled trial

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Abstract

Background and Aims: Erector spinae plane block (ESPB) has been found to be simple, safe, and effective at thoracic and lumbar levels. There is no randomized controlled trial evaluating its effectiveness at sacral level. The present study was conducted to evaluate its effectiveness at sacral level for postoperative analgesia in pediatric patients undergoing hypospadias repair.

Material and Methods: Forty children of 2–7 years with ASA grade I or II were included. They were randomly allocated to one of the two groups of 20 patients each. After induction of general anesthesia, patients of group I were given ultrasound-guided sacral ESPB with 1 ml/kg of 0.25% bupivacaine, and patients of group II were not given block. Postoperatively, pain was assessed using face, legs, activity, cry, consolability (FLACC) scale at 0 hour, every 15 min up to 1 hour, every half an hour up to 2 hours, 2 hourly up to 12 hours, and at 18th hour and 24th hour postoperatively. At FLACC score ≥4, rescue analgesia was given using 15 mg/kg paracetamol infusion. Primary objective was to compare postoperative analgesic (paracetamol) consumption, and secondary objective was time to first rescue analgesia.

Results: Mean postoperative paracetamol consumption was 360 ± 156.60 mg in group I and 997.50 ± 310.87 mg in group II (P = 0.001). Time to first rescue analgesia was 906 ± 224.51 min in group I and 205.00 ± 254.92 min in group II (P = 0.001).

Conclusion: Sacral ESPB has been found to be effective in reducing postoperative analgesic consumption in pediatric patients undergoing hypospadias repair.

Keywords: Erector spinae block, hypospadias, pediatric, postoperative analgesia, sacral, ultrasound

Introduction

Caudal block is the most frequently used regional technique in children undergoing hypospadias repair for management of postoperative pain. However, its main disadvantage is its short duration, and this may lead to inadequate postoperative pain control and further administration of postoperative analgesics.[1]

Various additive drugs have been combined with the local anesthetic injected into the caudal space in an attempt to prolong the duration of block. Opioids have been used successfully for this purpose, but they were observed to cause undesirable side effects, most serious of which is delayed respiratory depression. Other non-opioid additives such as such as epinephrine, ketamine, midazolam, neostigmine, clonidine, and dexmedetomidine have all been used but with different resulting side effects.[2]

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Erector spinae plane block (ESPB) is an interfascial plane block which has been found to be simple, safe, and effective with longer duration at thoracic and lumbar levels in various studies.[3,4] The sacral ESPB was first performed by Tulgar *et al.*[5] in 2019 to provide analgesia to sacral dermatomes for pilonidal sinus surgery. Aksu *et al.*[6] used sacral ESPB for hypospadias repair.

In caudal block, drug is injected into the sacral epidural space through sacral hiatus. In sacral ESPB, drug is injected below the erector spinae muscle in sacral region. Though there are few case reports to assess effectiveness of ESPB at sacral level, but there is no randomized controlled trial evaluating its effectiveness. ESPB at sacral level can potentially block the pudendal nerve and may prove as an alternative to caudal block for hypospadias repair. So we decided to evaluate effectiveness of sacral ESPB before comparing it with standard caudal block. Hence, the present study was conducted to evaluate the effectiveness of ultrasound-guided sacral ESPB for postoperative analgesia in pediatric patients undergoing hypospadias repair.

The hypothesis was that sacral erector spinal block may be effective in reducing postoperative analgesic consumption in pediatric patients undergoing surgery for hypospadias repair. The primary objective was postoperative analgesic (paracetamol) consumption in 24 hours. The secondary objective was intraoperative fentanyl consumption, postoperative pain score, and time to first rescue analgesic.

Material and Methods

The present study was conducted in a prospective, randomized, and double-blind manner after obtaining approval from institutional ethical committee. The study was registered in the Clinical Trial Registry of India (CTRI/2022/03/041052). Forty pediatric male patients aged 2–7 years with American Society of Anesthesiologist (ASA) physical status I or II scheduled to undergo elective surgery for hypospadias repair under general anesthesia were included in the study. Patients with history of developmental delay, allergic reactions to local anesthetic, infection at the puncture site, and parental refusal were excluded from the study.

All children were evaluated one day prior to surgery. A detailed clinical history was taken, and complete general physical and systemic examination of all the patients was done. All routine investigations including hemoglobin (Hb), bleeding time (BT), clotting time (CT) and complete urine examination were carried out. The purpose and protocol of the study were explained to the parents in detail. An informed and written consent of the parents was taken for participation in the study.

Patients were kept nil per oral 6 hours before surgery for solids, 4 hours for mother's milk, and 2 hours for clear fluids. Oral midazolam 0.5 $mgkg^{-1}$ was given 30 mins prior to surgery. After shifting the patient to the operating room, standard monitors were attached including heart rate (HR), electrocardiogram (ECG), non-invasive blood pressure (NIBP), and oxygen saturation (SpO_2). Patients were randomly allocated to one of the two groups comprising of twenty patients each using computer generated random number table. Group I (n = 20) was given USG-guided sacral erector spinae plane block with 1 $mlkg^{-1}$ of 0.25% bupivacaine, and group II (n = 20) was not given any block.

Inhalational induction of anesthesia was done in a standardized manner by using 6–8% sevoflurane in 100% oxygen. An intravenous cannulation was done with appropriate size cannula. Intravenous glycopyrrolate 0.005 $mgkg^{-1}$ and fentanyl 2 μkg^{-1} were given. After checking adequacy of ventilation atracurium 0.5 $mgkg^{-1}$ was given to facilitate the placement of supraglottic airway device. Maintenance of anesthesia was done with MAC 1 of sevoflurane and 50% nitrous oxide in oxygen.

In group I, before the start of surgery, patient was turned to right lateral position for performing block. Aseptic preparation of block site and ultrasound probe was done. Linear ultrasound probe was placed longitudinally to midline just above the sacrum using Sonosite M-Turbo ultrasound machine with linear array probe. Median sacral crests and erector spinae muscle were identified. A 21 G, 38 mm needle was inserted from the edge of the probe using in-plane technique. Needle was advanced with a cranial to caudal direction until its tip touched to the top of the 4th median sacral crest [Figure 1]. Following negative aspiration, 1 ml/kg of 0.25% bupivacaine was injected. Then the patient was turned to supine position. In group II, no block was given.

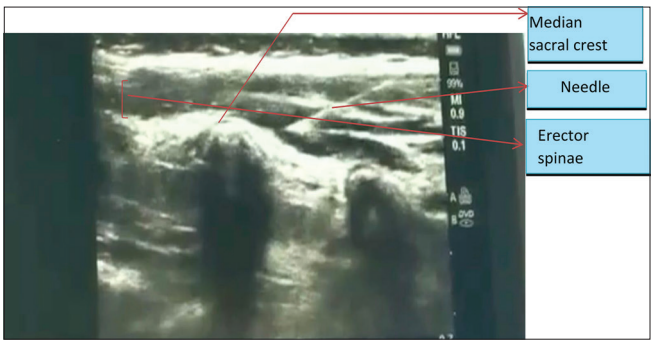

Figure 1: Showing sacral erector spinae block

In both the groups, increase in heart rate of more than 20% above the baseline values at any time during the surgery was considered as insufficient analgesia, and fentanyl 1 μgkg^{-1} was given. Further maintenance of anesthesia was done as per requirement of the case. After conclusion of surgery, the residual neuromuscular blockade was reversed by administering intravenous neostigmine 0.05 $mgkg^{-1}$ and glycopyrrolate 0.01 $mgkg^{-1}$, and supraglottic device was removed. After regaining consciousness, patients were shifted to postanesthesia care unit (PACU). Pain assessment was done postoperatively using FLACC score at 0 hr, every 15 mins up to 1 hr postoperatively, every half an hour up to 2 hours postoperatively, 2 hourly up to 12 hours postoperatively, and then at 18th hour and 24th hour, postoperatively.[7]

Rescue analgesic was given at FLACC score ≥4. Patient was given 15 $mgkg^{-1}$ paracetamol infusion but not more frequently than 6 hours. If pain persisted after paracetamol administration, oral ibuprofen 10 $mgkg^{-1}$ was given but not more frequently than 8 hrs. At the time of pain assessment, if child was sleeping comfortably, he was not disturbed and was assumed as pain free.

Intraoperative HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), and SpO_2 were recorded before induction of general anesthesia, before the block, after the block, prior to incision, immediately after the incision and then every 10 minutes till the end of surgery. Additional fentanyl consumption was also recorded. Postoperatively FLACC score, time for requirement of first rescue analgesic, and analgesic consumption in 24 hrs were recorded.

As per pilot study of 10 cases (5 cases in each group), mean dose of postoperative analgesic (paracetamol) consumption was 17.5 mg/kg in case group and 45 mg/kg in control group. For sample size calculation, we defined mean difference of 27.5 with 25.0 standard deviation. We calculated sample size with 95% confidence interval, 80% power, and alpha level of. 05. Thus, sample size was calculated as 15 in each group. To counteract any dropout, sample size was taken as 20 in each group.

At the end of the study, all data were compiled and analyzed using Statistical Package for the Social Sciences (SPSS) version 17.0 (International Business Machines Corporation, Armonk, New York, United States). Quantitative variables were presented as mean ± standard deviation, and unpaired *t*-test was used for comparison between the groups. Qualitative variables were presented in the form of frequencies/percentages, and Chi-square test was used for comparison. A P value < 0.05 was considered as statistically significant.

Results

Forty patients were recruited, and all the patients completed the study [Figure 2]. Both the groups were comparable with respect to demographic profile and duration of surgery [Table 1]. Mean HR, SBP, DBP, and SpO_2 were comparable between the two groups at different timelines. The mean postoperative analgesic consumption in group I was 360.0 ± 156.60 mg and 997.50 ± 310.87 mg in group II (P = 0.001) [Table 2]. The FLACC score was significantly higher (P > 0.05) postoperatively at 0 min, 15 min, 4 hr, 6 hr, 18 hr, and 24 hr in group II. The mean time to first rescue analgesic in group I was 906.00 ± 282 min and in group II was 63.6 ± 100.2 min (P = 0.001) [Table 3]. The total intraoperative fentanyl consumption in group I was 0 and in group II was 24.75 ± 5.31 µg. In group I, 18 patients required only one dose of analgesic, and only one patient required two doses of analgesic postoperatively. In group II, four patients required two doses of analgesic while 16 patients required three doses of analgesic postoperatively (P < .001) [Table 4].

Table 1: Comparison of demographic profile and duration of surgery

	Group I (n=20) Mean±SD	Group II (n=20) Mean±SD	P
Age (Years)	4.90±1.74	5.45±1.43	0.283
Weight (kg)	23.65±8.54	23.75±6.07	0.966
Height (cms)	108.15±11.15	110.45±9.83	0.493
BMI (kgm^{-2})	19.6±4.56	19.1±2.59	0.673
Duration of surgery (min)	49.60±11.37	42.50±12.08	0.063

Table 2: Comparison of analgesic dose between the two groups

Analgesic dose (mg)	Group I (n=20) Mean±S.D	Group II (n=20) Mean±S.D	P
	360.00±156.60	997.50±310.87	0.001

Table 3: Comparison of time to first rescue analgesia between the two groups

Time to rescue analgesia (min)	Group I (n=20) Mean±S.D	Group II (n=20) Mean±S.D	P
	906.00±282	63.6±100.2	0.001

Table 4: Comparison of number of analgesic doses between the two groups over 24 h

Number of dose	Group 1 (n=20)	Group II (n=20)	P
One	18	0	
Two	1	4	<0.001
Three	0	16	
Total doses in group	20	56	

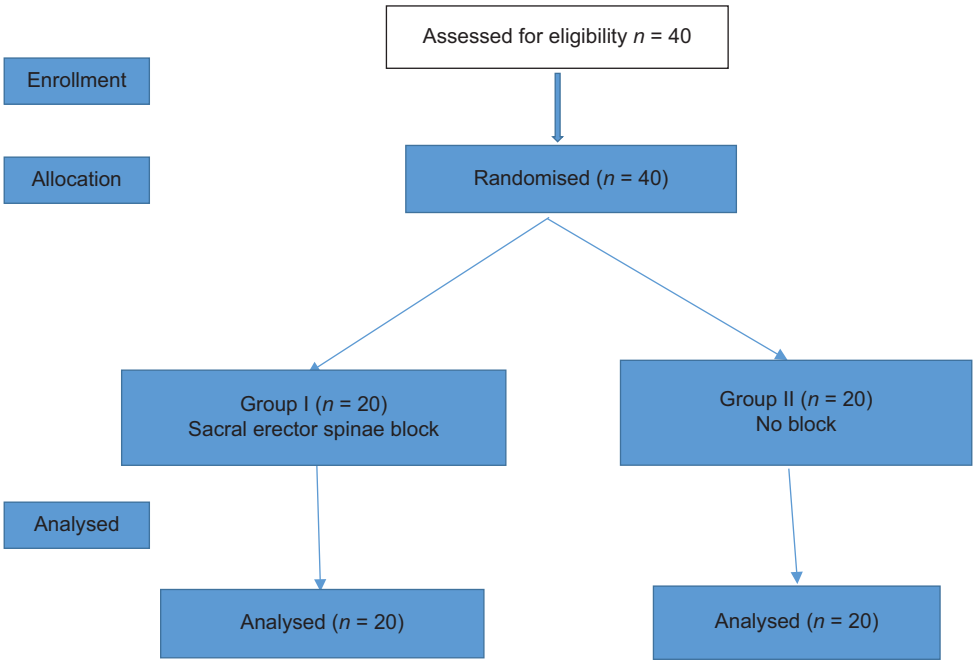

Figure 2: Consort flow diagram

Discussion

Primary objective of the study was to compare postoperative analgesic consumption in 24 hrs in the two groups. In present study, mean postoperative analgesic (paracetamol) consumption was 360 ± 156.60 mg in group I and 997.50 ± 310.87 mg in group II ($P = 0.001$) [Table 2]. There is no study in literature evaluating the sacral ESPB. Only few case reports have shown that it is useful in various types of surgeries.[5,6,8,9] ESPB is an interfascial plane block that provides somatic and visceral analgesia blocking the dorsal and ventral rami of spinal nerves along with rami communicantes that transmit autonomic fibers to and from the sympathetic ganglia. ESPB has extensive cranio-caudal spread of local anesthetic and helpful in blocking multiple dermatomes. In the present study, we used sacral ESPB which is a relatively new interfascial block. ESPB at sacral level can potentially block pudendal nerve.

Tulgar *et al.*[5] first performed sacral ESPB in a 28-yr-old male scheduled to undergo surgery for pilonidal cyst under general anesthesia. After completion of surgery, bilateral sacral ESPB was given. The authors observed that postoperative Numerical Rating Scale (NRS) was <3/10 for first 13 hr with no additional analgesic requirement. These authors described that mechanism of action of sacral ESPB is sensory blockage of posterior branches of spinal nerves. These authors used parasagittal approach and administered local anesthetic between erector spinae muscle and intermediate sacral crest at S2 level.

Aksu *et al.* performed sacral ESPB with longitudinal midline approach in 6-month-old infant weighing 8 kg, scheduled for hypospadias repair. After induction of anesthesia, 8 ml of 0.25% bupivacaine was given. The authors observed that postoperative Face, Leg, Activity, Cry, and Consolability (FLACC) score was 0 or 1 for 24 hrs postoperatively, and no additional analgesic was required. These authors suggested epidural spread of local anesthetic agent. This new technique described by Aksu *et al.*[6] is advantageous for having bilateral effect with single injection from midline.

Oksuz *et al.*[9] administered USG-guided sacral ESPB for postoperative analgesia in 7-month-old boy weighing 10 kg who was scheduled for anoplasty. These authors observed FLACC score of 0 during 24 hrs postoperative period. In addition, they also observed that there was no muscle weakness in lower limbs. Piraccini *et al.*[10] performed USG-guided sacral ESPB for L5 radicular pain in 67-yr-old male and observed that NRS decreased to 0 after 20 mins, and it was 4 after 7 days. These authors concluded that a sacral ESPB performed with adequate volume and clear view of cranial spread of injectate may reach the anterior branches of spinal nerves as well. Kukreja *et al.*[11] performed sacral ESPB for gender reassignment surgery to manage perioperative pain at two levels (S4 and S2 levels) with the aim of covering the pudendal innervation from S4 injection and to cover lower lumbar levels from S2 injection and recorded very minimal requirement of opioids intraoperatively as well as postoperatively.

In the present study, FLACC score was used to assess severity of pain. FLACC score was low in the group that received sacral ESPB as compared to control group. There was significant difference in FLACC score between the two groups at 0 and 15 mins postoperatively, which signifies the effectivity of sacral ESPB. When FLACC score was further compared between the two groups at different time interval, the difference was found to be statistically significant at 4 hr, 6 hr, and 18 hr. The mean postoperative analgesic consumption in group I was 360.0 ± 156.60 mg and 997.50 ± 310.87 mg in group II ($P = 0.001$) [Table 2], and it was administered for more number of times in group II than group I ($P < 0.001$) [Table 4] which might have led to comparable pain scores at remaining timelines.

Kilicaslan *et al.*[8] used sacral ESPB in two cases. First case was 69-yr-old male patient with bilateral pubic rami and right sacrum fracture. USG-guided sacral ESPB was given at S1 level for postoperative analgesia after completion of surgery, and the authors observed sensory blockade between T1 and S3 dermatomes, and VAS score was <3/10 up to 14th hr postoperatively. Second case was 29-yr-old male scheduled for posterior sacroiliac fixation surgery, and sacral ESPB was given before surgery. The authors observed that the postoperative 30 min, 1 hr, 2 hr, 4 hr, 6 hr VAS scores were 1/10, and it was 4/10 at 24 hr. Bilge *et al.*[12] also used sacral ESPB in two cases. First case was 71-yr-old female scheduled to undergo intramedullary nail treatment under spinal anesthesia. After completion of surgery, sacral ESPB was given and postoperatively the pain severity with joint motion was scored as 2/10, and VAS score was 2/10 at the end of 24 hrs. No additional analgesic was required for 48 hrs. Second case was 83-yr-old female scheduled for total hip replacement with congestive heart failure with 40% ejection fraction. After completion of surgery and extubation, VAS score was 9/10 at the end of first postoperative hour. Sacral ESPB was given, and 15 min after injection, VAS score was 1/10, and no additional analgesic was required for 24 hrs. Kaya *et al.*[13] used sacral ESPB as sole anesthetic technique. The authors conducted two case studies. First case was 52-yr-old man scheduled for anal fistulectomy, and second case was 46-yr-old man scheduled for perianal fistulectomy. In both patients, bilevel (at S2 and S4 levels), bilateral sacral ESPB given, and sensory blockade was achieved at S2–S5 dermatomes within 30 mins after block. Both patients were hemodynamically stable throughout the surgery, and no analgesic was needed for 24 hrs postoperatively.

In the present study, time to first rescue analgesic was 906.00 ± 282 min in group I and 63.6 ± 100.2 min in group II ($P = 0.001$) [Table 3]. Mostafa *et al.*[3] evaluated USG-guided ESPB at T7 level for postoperative analgesia in pediatric patients undergoing splenectomy and observed that the time to first rescue analgesic was 508 ± 194 mins in ESPB group and 33.6 ± 31.8 mins in control group ($P < 0.001$). Singh *et al.*[4] evaluated analgesic effect of bilateral USG-guided ESPB at L1 level in pediatric patients posted for lower abdominal surgeries and reported that time to first rescue analgesic was 360 ± 30 mins in ESPB group and 160 ± 25 mins in control group and ($P = 0.00$). El Emam *et al.*[14] evaluated USG-guided ESPB at L1 level vs ilioinguinal nerve (IIN) block for postoperative analgesia in pediatric patients undergoing inguinal hernia surgery and observed that ESPB group resulted in significantly longer time to rescue analgesic compared to IIN block group.

In the present study, sacral ESPB was successful in all the patients. No bradycardia or hypotension was observed in sacral ESPB group and patients remained hemodynamically stable intraoperatively. No motor blockade was observed in any patient postoperatively.

The sacral ESPB offers many advantages. It is easy to perform under USG guidance because it is applied relatively more superficially and injection site is not close to major vascular and neural structure. It can widely spread under the muscle depending on the volume applied and allows long-term analgesia without any motor block. In addition, it provides coverage of multiple dermatomal levels by a longitudinal midline technique and patient remains hemodynamically stable.

To conclude, sacral ESPB has been found to be effective in reducing postoperative analgesic consumption in patients undergoing hypospadias repair. The mean FLACC score was significantly lower in sacral ESPB group than control group. Time to first rescue analgesic was observed to be significantly longer in sacral ESPB group. No complication of sacral ESPB group was observed in any patient.

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Conflicts of interest
There are no conflicts of interest.

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