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Analgesic Efficacy of Dexmedetomidine as an Adjunct in Ultrasound-Guided Supraclavicular Block for Pediatric Upper Limb Surgeries: A Randomised Double Blind Controlled Study

Sargam Goel[1], Bhumika Kalra[2], Aikta Gupta[2], Geeta Kamal[2], Shilpa Agarwal[2]

[1]DNB, Department of Anaesthesia, Chacha Nehru Bal Chikitsalaya, Delhi, India
[2]MD, Department of Anaesthesia, Chacha Nehru Bal Chikitsalaya, Delhi, India

ABSTRACT

Background and Aims: Dexmedetomidine has been studied extensively in peripheral nerve blocks in adults. However, a literature search revealed no study regarding its use in the ultrasound-guided supraclavicular block in pediatrics. Hence, the present study evaluated the analgesic efficacy of dexmedetomidine in combination with bupivacaine in the ultrasound-guided supraclavicular block in pediatric patients undergoing upper limb surgeries. **Material and Methods**: This prospective randomized, double-blind study was conducted in fifty patients of American Society of Anesthesiologists (ASA) physical status grade I and II, aged 3-12 years, undergoing elective upper limb surgeries. Patients were divided into two groups of 25 each. Group A received general anesthesia (GA) and ultrasound(USG)- guided supraclavicular brachial plexus block with 0.25% bupivacaine 0.3ml/kg, and 0.5ml normal saline. Group B patients received GA and USG guided supraclavicular block with 0.25% bupivacaine 0.3ml/kg and dexmedetomidine 1 µg/kg in a volume of 0.5 ml. The time to first rescue analgesic request, pain scores, consumption of postoperative rescue analgesics, hemodynamics, patient satisfaction and adverse effects were noted. For normally distributed variables, Unpaired Student's t test and Chi-square test were used. Mann Whitney Test was used for variables that were not normally distributed. **Results**: Patients receiving dexmedetomidine had a longer time to the first analgesic request in the postoperative period (p-value:0.004),reduced consumption of rescue analgesics (p-value: 0.002), and better satisfaction scores (p-value: 0.003). **Conclusion**: USG-guided supraclavicular block with bupivacaine and dexmedetomidinein pediatric patients provides superior analgesia in terms of the longer time to the first rescue analgesic request, reduced requirement of rescue analgesics, and stable hemodynamics. In addition, the use of dexmedetomidine results in better patient satisfaction as compared to bupivacaine alone, without any significant adverse effects.

Key Words: *Anesthesia; Analgesia; Bupivacaine; Dexmedetomidine; Pediatric; Ultrasound;Upper extremity*

***Corresponding Author**
Bhumika Kalra
MD, Department of Anaesthesia, Chacha Nehru Bal Chikitsalaya, Delhi, India

INTRODUCTION

For decades, upper limb surgeries have been performed safely in adults, using supraclavicular block as the sole anesthetic technique or with sedation and general anesthesia. Upper limb peripheral nerve blocks have gained popularity in adults due to furtherance in block administration techniques, newer local anesthetics, and adjuvant drugs. However, they are not very common in children due to the risk of pneumothorax. Ultrasound has improved the success rate of the block with excellent visualization of pleura, subclavian artery and vein, and needle movements, thus reducing the risk of pneumothorax and improving the safety margin in pediatric patients[1].

Various adjuvants like fentanyl, morphine, clonidine, dexamethasone, dexmedetomidine, etc., have been added to local anesthetics to prolong the duration of analgesia[2,3]. The effect of adding dexmedetomidine has been studied in pediatrics in central neuraxial and peripheral nerve blocks like ilioinguinal/iliohypogastric nerve block, greater palatine nerve block, infraorbital block, maxillary nerve block, transversus abdominis plane (TAP) block, and caudal epidurals [3-9]. These studies concluded that the addition of dexmedetomidine improved the quality of post-operative analgesia without increasing any unwanted side effects.

An extensive search of the literature revealed no study with regard to the use of dexmedetomidine in ultrasound-guided supraclavicular block in pediatric patients. Hence, the study was undertaken with an aim to evaluate the analgesic efficacy of dexmedetomidine in ultrasound-guided supraclavicular block in terms of the time to first rescue analgesic request, pain scores, consumption of post-operative rescue analgesics, the incidence of complications (procedure

complications, inadvertent motor blockade, and sedation, hypotension, bradycardia, nausea, and vomiting), and patient satisfaction.

Materials and methods

This prospective, randomized controlled, double-blinded study was registered with CTRI (CTRI/2020/05/025284) and approved by the Institutional Human Ethics Committee(F.1/IEC/CNBC/05/01/2020/4223). This study was carried out in 50 patients with American Society of Anesthesiologists (ASA) physical status grade I and II patients, aged 3-12 years, who were electively scheduled for upper limb surgeries between March 2020 to October 2020. Pre-anesthetic evaluation of all patients was done a day prior to the scheduled surgery. Patients were enrolled and assessed for eligibility. Patients with a contraindication to supraclavicular block, receiving chronic analgesics, and posted for bilateral surgery on the upper limb in the same setting were excluded from the study. A patient information sheet was provided and written informed consent was obtained from the parents of all the patients. Assent of the patient was taken if the child was seven years or more in age.

The eligible participants were randomly assigned to groups A and B.

Group A(n=25) received USG-guided Supraclavicular block with 0.3ml/kg of 0.25% bupivacaine and 0.5ml normal saline.

Group B (n=25) received USG-guided Supraclavicular block with 0.3ml/kg of 0.25% bupivacaine and dexmedetomidine 1µg/kg in a volume of 0.5ml (Figure 1).

Randomization was done by an independent statistician not involved in the study using permuted blocks of varying sizes from http://www.randomization.com. After enrolment, group assignments were determined by a computer-generated number sequence and were contained in sequentially numbered opaque envelopes to ensure blinding.

Two anesthesiologists were involved in the study.

Anesthesiologist 1: Opened the opaque envelope and asked for the drug injection as per the envelope. The drugs were prepared by an anesthesiologist who was not involved in the study.

Anesthesiologist 2: Performed the block, administered GA, and performed post-operative monitoring for 24 hours. Along with the surgeon, the anaesthesiologist was also blinded to the drug used in the block. Both the drug injections were of the same volume and colour.

In case of an emergency (cardiac arrest/refractory bradycardia not responding to atropine; refractory hypotension not responding to fluid boluses), the investigator would break the blinding of single patients, and the study would then be open labelled.

In the preoperative holding area, oral midazolam 0.4 mg/kg was administered40 min before the procedure. In the operation theatre, the following monitors were attached – non-invasive blood pressure (NIBP), pulse oximetry (SpO2), and electrocardiography (ECG). Baseline vital parameters were recorded. Inhalational induction was done for all patients using oxygen and 8% sevoflurane. After securing intravenous access to the non-operative arm, ringer lactate was started. Injection fentanyl 1 µg/kg and propofol 1 mg/kg were given intravenously (iv), and the airway was secured with an appropriate size proseal laryngeal mask airway (LMA).

An experienced anesthesiologist performed the blocks under ultrasound (USG) guidance (Sonosite machine), using a 7–13 MHz 35 mm linear probe, short bevel needle (22– 25 G, 35–50 mm, Stimuplex needle), and extension tubing. Aseptic preparation of the puncture site and USG probe was carried out. The probe was placed in a coronal-oblique plane in the supraclavicular fossa, with the needle being introduced using an in-plane technique[10].

Anesthesia was maintained by sevoflurane to attain a minimum alveolar concentration (MAC) value between 1-1.5 in a 40% air/oxygen mixture. Tourniquet was used on all the patients. The vitals were recorded intraoperatively at regular intervals, including HR, NIBP, SpO2, and end-tidal carbon dioxide levels (EtCO2). Hypotension was defined as a 20% decrease relative to baseline mean arterial pressure (MAP)and was treated with a rapid infusion of intravenous fluids. Hypotension persisting despite fluid administration was treated with ephedrine 0.1-0.2 mg/kg IV. Bradycardia was defined as a 20%decrease from baseline heart rate (HR) and was treated by inj. atropine 0.02mg/kg IV. Any intra operative increase in MAP and HR above 20% of the baseline values after 15 minutes of block administration, with sevoflurane exceeding 1.5 MAC, was regarded as pain and hence block failure. Such patients were to be excluded from the study after giving additional fentanyl 1µg/kg iv. All patients received injection ondansetron 0.1mg/kg iv 30 minutes before the end of surgery. At the end of the surgical procedure, LMA was removed after suctioning. On arrival in the

post-operative care unit (PACU), NIBP, HR, respiratory rate, and SpO2 were monitored at regular intervals. Post-operative pain monitoring was done by Wong-Baker (FACES) pain scale[11].

Patient demographics (age, weight, and gender), ASA physical status, intra operative vitals at the time of induction at 5, 10, 15, 20, 25, 30, 45minutes (mins), 1 hour, and then after every 15 mins till the end of the surgery, were noted. Postoperative vitals, motor score, sedation score, FACES score, time of first rescue analgesic, number of rescue analgesics, and side effects were noted at 0 mins, 30 mins, 1 hour, 1.5, 2, 4, 8 and 24 hours. Satisfaction scores and complications were noted for all patients at the end of the study duration.

The duration from the time of block administration till the first request for rescue analgesia was noted. Oral paracetamol 15 mg/kg was given when the FACES score was ≥ 4. Following this, if the pain persisted for an hour after the administration of paracetamol, oral ibuprofen was given in a dose of 6 mg/kg. Further pain episodes were similarly treated, but the next dose of paracetamol was not repeated within six hours of the previous dose. If the patient experienced pain before being allowed orally (1.5- 2 hours postoperatively), intravenous paracetamol was given in a dose of 15 mg/kg.

Motor block was assessed by the modified Bromage scale for upper limb as follows: 0 - normal motor function with full extension and flexion of the elbow, wrist and fingers; 1 - decreased motor strength with the ability to move only fingers; 2 - complete motor block with the inability to move elbow, wrist, and fingers[12]. The level of sedation was assessed by the modified Ramsay Sedation scale (RSS) from 1-6 as follows: 1 = anxious, agitated, restless; 2 = cooperative, oriented, tranquil; 3 = responds to commands only; 4 = brisk response to a light glabellar tap or loud noise; 5 = sluggish response to a light glabellar tap or loud noise; 6 = no response[13].

Complications related to the block technique like pneumothorax, bleeding, and horner's syndrome were noted. Adverse effects of dexmedetomidine like hypotension, bradycardia, nausea, vomiting, and sedation were monitored. Any episode of vomiting postoperatively was treated with inj. dexamethasone 0.1 mg/kg i.v. The satisfaction score was graded on a 5-point scale from 1 to 5 as follows: 5-very satisfied;4 – satisfied; 3 – neutral; 2 – unsatisfied; 1 – very unsatisfied, and was obtained from the parents of the patients. The primary and secondary outcomes were as followed:

Primary outcome:

1. Time to first analgesic request in the postoperative period

Secondary outcomes:

1. Total consumption of analgesics in postoperative period for 24 hours
2. Pain scores in the postoperative period for 24 hours
3. Satisfaction score
4. Untoward effects, if any

The sample size estimation was based on the anticipated duration of analgesia. A previous study indicated that the mean duration of analgesia was 9.76 hours with a standard deviation (SD) of 2.57 hours[14]. Considering a 25% increase in the duration of analgesia to be clinically significant, the sample size required to detect this reduction at a 5% level of significance and 90% power was 23 patients in each group. Thus, 25 patients were included in each group. Data were entered in MS Excel, and analysis was done using the social science system version (SPSS) 21.0 version. Mann Whitney test was used for variables that were not normally distributed like FACES score, motor score, sedation score, time first to rescue analgesia, number of rescue analgesics, and satisfaction scores. For these outcomes, data were presented as the median and interquartile range (IQR). All the other outcomes were normally distributed and were presented as mean and SD for continuous variables and as percentages for categorical variables. Unpaired t-test was done to compare two group means for variables like age, weight, intraoperative and postoperative vitals (heart rate, systolic and diastolic pressures, respiratory rate, oxygen saturation, end-tidal carbon dioxide concentration), and duration of anaesthesia between the two groups. Chi-square test was done to find out the association between categorical variables such as gender, ASA physical status grade, and complications between the two groups. A p-value of less than 0.05 was considered significant.

RESULTS

There was no statistically significant difference among the patients in the two groups with regard to age, weight, sex, ASA grade, duration of anesthesia, and baseline vital parameters(Table 1). The median value for time to first rescue analgesia in group A was 10.00 hours, with an IQR of 3.00, and the median time in group B was 12.00 hours, with an IQR of 13.50, which was statistically significant with a p-value of 0.044. The number of rescue analgesics required in group A had a median value of 3.00 with an IQR of 1.00, and group B had a median value of 1.00 with an IQR of 1.00. This difference was found to be statistically significant, with a p-value of 0.002. The 5-point satisfaction score was also statistically significant (p-value was 0.003) between the two groups. In group A, the median was 4.00, and IQR was 2.00. Group B had a median and IQR of 5.00 and 1.00 respectively (Table 2).

Table 1: Patient demographics (age, weight, gender and ASA grade), dose of fentanyl required, duration of anaesthesia and baseline vitals. Data is presented as absolute numbers and percentages for gender and ASA grade and as mean and standard deviation with 95% confidence interval (CI) for other variables. (age in years, weight in kilograms, DOA in minutes, HR in beats per minute, SBP and DBP in millimeter mercury)

Variables	GROUP A (N=25)				GROUP B (N=25)				
	Mean ± S.D	S.E.M	95% C.I		Mean ± S.D	S.E.M	95% C.I		p-value
			L	U			L	U	
Age	6.64 ± 2.486	0.49	5.62	7.66	7.00 ± 2.24	0.45	6.08	7.92	0.592
Weight	20.38± 8.27	1.65	16.97	23.80	19.33 ± 5.64	1.13	17.00	21.66	0.602
Dose	1.08 ± 0.19	0.042	1.00	1.16	1.08 ± 0.19	0.04	1.00	1.16	0.773
DOA	1.41± 0.24	0.049	1.31	1.51	1.38 ± 0.22	0.044	1.29	1.48	0.689
Baseline HR	103.68 ± 13.34	2.67	98.17	109.19	101.64 ±14.28	2.86	95.74	107.54	0.604
Baseline SBP	94.08 ± 11.99	2.40	89.13	99.03	94.08 ±11.99	2.40	89.13	99.03	0.557
Baseline DBP	54.64 ± 9.88	1.98	50.57	58.72	58.84 ± 8.42	1.68	55.36	58.84	0.122
Gender M:F	14:11				19:6				0.136
ASA I:II	23:2				25:0				0.149

ASA- American Society of Anesthesiologists, C.I- confidence interval, DBP- diastolic blood pressure, DOA- duration of anesthesia, Dose- intraoperative fentanyl dose administered, F- female, HR- heart rate, L- lower, M- male, N- Number, SBP- systolic blood pressure, S.D- standard deviation, S.E.M- standard error of mean, U- upper.

Table 2: Time to first rescue analgesic(hours), number of rescue analgesics and satisfaction score. Non parametric test (Mann Whitney) was used for statistical analysis. Data is presented as median and interquartile range

	STUDY GROUP						Independent Samples Mann Whitney U- Test
	Group A			Group B			
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	p-value
1) Time to first rescue analgesic	10.00	9.00	12.00	12.00	10.50	24.00	0.044
2) Number of rescue analgesics	3.00	2.00	3.00	1.00	1.00	2.00	0.002
3) Satisfaction score	4.00	3.00	5.00	5.00	4.00	5.00	0.003

The type of surgery, intraoperative fentanyl requirements, intraoperative and postoperative vitals (heart rate, systolic and diastolic blood pressure, SpO2, EtCO2, respiratory rate), motor scores, sedation scores (Table 3), and FACES scores (Figure 4) were comparable in the two groups at all the time intervals. There were nine patients in group B who did not require any rescue analgesia during the postoperative period for 24 hours, as compared to only 4 patients in group A, although this difference was not statistically significant (p-value was 0.107). None of the patients in group A had any complications related to the anesthetic technique. One patient in group B had a pleural puncture during block administration, with an uneventful intraoperative and postoperative period.

Table 3: Comparison of sedation scores between the groups. Non parametric test (Mann Whitney) was used for statistical analysis. Data is presented as median and interquartile range**.**

Sedation score	STUDY GROUP						Independent Samples Mann Whitney U- Test
	Group A			Group B			
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	p- value
At 0 MIN	3.00	3.00	4.00	4.00	3.00	4.00	0.094
At 30 MIN	3.00	2.00	3.00	3.00	3.00	4.00	0.162
At 1 HR	2.00	2.00	3.00	2.00	2.00	3.00	0.227
At 1.5 HR	2.00	2.00	2.00	2.00	2.00	2.00	0.259
At 2 HR	2.00	2.00	2.00	2.00	2.00	2.00	0.389
At 4 HR	2.00	2.00	2.00	2.00	2.00	2.00	0.735
At 8 HR	2.00	2.00	2.00	2.00	2.00	2.00	0.716
At 24 HR	2.00	1.00	2.00	2.00	1.00	2.00	0.634

HR- hour**,** MIN- minutes

DISCUSSION

The present study has demonstrated that a combination of dexmedetomidine and bupivacaine in ultrasound-guided supraclavicular nerve block in pediatric patientsprovides better analgesia in terms of the longer time to first rescue analgesic, reduced requirement of rescue analgesics, and better satisfaction scores as compared to bupivacaine alone.

Upper limb surgeries are commonly performed in the pediatric age group for various conditions, such as supracondylar fractures, forearm fractures, implant removals, cross-finger flaps, etc. Sensory blockade of the brachial plexus in upper limb procedures leads to stable intraoperative and postoperative vitals; reduces the dose of inhalational and intravenous anesthetics required; provides smoother emergence; decreases the need for supplemental analgesics in the postoperative period[2]. Ultrasound has transformed regional anesthesia and analgesia, especially in pediatrics, where the landmark technique may not be very dependable due to the variability of age and size. The use of ultrasound technology has thus improved the block success rate and reduced the local anesthesia dose requirements[15].

Dexmedetomidine is an imidazole derivative and a highly selective α2 adrenergic receptor agonist with a receptor selectivity (α2: α1) of 1620:1. It has broad application prospects in clinical anesthesia and has emerged as a potent local anesthetic adjuvant. It has peripheral as well as central actions. Centrally it exerts its analgesic action by inhibiting the release of substance P at the dorsal root neuron and activating alpha-2 receptors in locus coeruleus. Peripherally, it produces analgesia by reducing the release of norepinephrine and inhibiting nerve fibre action potentials [16,17].

Dexmedetomidine has numerous applications. It is used as an intravenous sedative and analgesic for mechanically ventilated patients in intensive care units (ICUs) and for procedural sedation in non-intubated pediatric patients. It has been reported to improve the quality of anesthesia and analgesia in peripheral and central neuraxialblocks by hastening the onset of sensory block and prolonging the time to the first analgesic request in the postoperative period[16,18,19,20,21,22]. The bulk of the published data ondexmedetomidine use is in adults [23-26], and there are fewer studies of its use as a perineural adjuvant in pediatric patients[3-8]. These studies done in children concluded that the addition of dexmedetomidine improved the quality of postoperative analgesia without increasing any unwanted side effects. The dose of dexmedetomidine used in the present study was inferred from previous studies on adults[24-26].

In the present study, no additional fentanyl was required after block administration in any group, indicating block success and adequate intraoperative analgesia produced by the block injections. The time to first analgesic request (TFR) was longer in the dexmedetomidine group with a reduced need for rescue analgesia. The pain scores in both the study groups were comparable (Figure 4), which can be attributed to the control group's statistically higher rescue analgesic consumption (p-value of 0.002).The study by Lundblad M et al. on ultrasound-guided ilioinguinal/iliohypogastric nerve block in children observed a significantly less number of total analgesic doses administered in the ropivacaine and dexmedetomidine group as compared to the ropivacaine group[3]. Bielka et al. reported that dexmedetomidine provided satisfactory postoperative analgesia and thus reduced the need for administration of opioids and NSAIDs (non-steroidal anti-inflammatory drugs), which might lead to nausea, vomiting, and sedation[27].

Hypotension and bradycardia are the known side effects of dexmedetomidine administration. In the present study, the intraoperative and postoperative HR and BP values were comparable in the two groups (Figure 2,3).No patient in group A had any drug-related complications, whereas one patient in group Bdeveloped bradycardia intraoperatively,

which was treated with a single dose of intravenous atropine. These results of the present study were in accordance with the results of other studies [2,22,28].

Sedation in the postoperative period maybe associated with the use of dexmedetomidine[18,19]. However, in the present study, the sedation scores recorded in the postoperative period were comparable in both the groups as the p-value was >0.05 at all the time intervals (Table 3). Most of the patients were arousable within 30 minutes of shifting to PACU (post-anaesthesia care unit) from the operation theatre. These results were comparable to the results of the study by Karan D et al., who concluded that dexmedetomidine at 1µg/kg when given perineurally in ultrasound-guided ilioinguinal/iliohypogastric nerve block, does not result in significant sedation [4].

The duration of sensory and motor blockade was defined as the time interval between the completion of block injection and the complete resolution of sensory and motor block. In the postoperative period, the skin dermatomes covered by the surgical dressing were not accessible to pinprick testing to assess sensory block; hence, complete scoring could not be performed in such a scenario. The time for the first request of rescue analgesia in the postoperative period was used as a proxy end-point for the duration of sensory block, which was significantly prolonged in the present study. Motor scores recorded in the postoperative period were comparable in both groups; the motor block duration was not prolonged by dexmedetomidine in the dosage used in the present study. This is desirable, as early mobilization enhances postoperative recovery and shortens the hospitalization period. However, in the study by Agarwal S et al. in adults, the duration of motor block was significantly longer in the group that received dexmedetomidine with bupivacaine for supraclavicular nerve block compared to the group that received bupivacaine alone (p-value of <0.001). The reason for this difference could be the use of a fixed dose of dexmedetomidine (100 µg) in this study [22].

The 5-point satisfaction score was significantly better in group B in the present study, indicating superior analgesic efficacy of dexmedetomidine (p-value of 0.003). These findings were similar to those observed by El-Emam EM et al., who compared dexamethasone and dexmedetomidine as adjuvants to bupivacaine for infraorbital nerve block[6].

In the present study, one patient in group B had an accidental pleural puncture during block administration, which was visualized under ultrasound. The patient was followed up with a chest x-ray, and his postoperative period was uneventful, with no episode of respiratory distress or hypoxia. However, this was statistically insignificant, with a p-value of 0.312. No patient in either group had any episode of nausea or vomiting. The results of this study were at par with other studies, with no significant complications either because of the block procedure or drugs in either group [2-4,22].

The present study has a few limitations. The FACES score is subjective, hence challenging to evaluate in pediatric patients. The sensory and motor block onset could not be assessed as the nerve block was administered under general anesthesia. The sample size calculation in the study was not based on the incidence of side effects like hypotension, bradycardia, postoperative nausea, and vomiting. Larger sample size would probably be required to find statistical significance, if any, for these parameters.

To conclude, the addition of dexmedetomidine 1 µg/kg to 0.25% bupivacaine 0.3ml/kg in ultrasound-guided supraclavicular block in pediatrics, has superior analgesic efficacy during the postoperative period; provides stable hemodynamics intraoperatively and postoperatively; does not cause nausea, vomiting, inadvertent sedation, and motor blockade; provides better patient satisfaction.

Author contributions:

- **Sargam Goel**- conception and design; acquisition and interpretation of data; writing – original draft, review & editing; final approval of the article.
- **Bhumika Kalra**– conception and design; acquisition and interpretation of data; writing – review & editing; final approval of the article.
- **Aikta Gupta**– conception and design; acquisition and interpretation of data; editing and final approval of the article.
- **Geeta Kamal**– conception and design; acquisition and interpretation of data; final approval of the article.
- **Shilpa Agarwal**- conception and design; acquisition and interpretation of data; final approval of the article.

The manuscript has been read and approved by all the authors, the requirements for authorship as stated have been met, each author believes that the manuscript represents honest work and have agreed to be accountable for all aspects of the work.

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Figure legends:

Figure 1: Consort flow diagram – flow of patients during the study.

Figure 2 : Comparison of intraoperative and postoperative heart rates between the two groups. (HR – hour, MIN- minutes)

Figure 3 : Comparison of intraoperative and postoperative systolic blood pressures between the two groups. (HR – hour, MIN- minutes)

Figure 4 : Comparison of FACES score between the two groups(HR – hour, MIN- minutes)