Original Article

Effect of bilateral intranasal transmucosal sphenopalatine ganglion block on intraoperative fentanyl requirement in children undergoing palatoplasty under general anaesthesia – A randomised, double-blinded, comparative study

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ABSTRACT

Background and Aims: Palatoplasties are extremely painful surgeries commonly performed in children; hence, providing excellent analgesia for these surgeries is crucial. This study aims to evaluate the effect of bilateral intranasal transmucosal sphenopalatine ganglion (SPG) block on intraoperative fentanyl requirement in children undergoing palatoplasty under general anaesthesia (GA). **Methods:** Thirty American Society of Anesthesiologists physical status (PS) I and II patients, aged 6 months–12 years, scheduled to undergo palatoplasty, were randomised to two groups. After induction of anaesthesia, patients in Group T received bilateral SPG block using 0.5% bupivacaine-soaked cotton-tip applicators, while patients in Group C received standard anaesthesia care. The primary outcome was intraoperative fentanyl requirement, and secondary outcomes were intraoperative haemodynamics and post-extubation Paediatric Anaesthesia Emergence Delirium (PAED) scale scores at 5 and 10 min, respectively. **Results:** The mean intraoperative fentanyl consumption was 26.73 [standard deviation (SD): 10.19)] [95% confidence interval (CI): 20.38, 33.08] μg in Group T compared to 34.47 (SD: 12.73) (95% CI: 27.20, 41.74) μg in Group C ($P = 0.008$). Heart rate and mean arterial pressure were lower in Group T as compared to that in Group C ($P < 0.05$). PAED scale scores were recorded to be 7.33 (SD: 1.50) (95% CI: 6.47, 8.19) and 6.00 (SD: 1.31) (95% CI: 5.30, 6.70) for Group T, and 15.53 (SD: 0.74) (95% CI: 15.13, 15.93) and 14.07 (SD: 0.59) (95% CI: 13.75, 14.39) for Group C at 5 and 10 min, respectively ($P < 0.001$). **Conclusion:** SPG block causes a significant reduction in intraoperative fentanyl consumption, stabilises haemodynamics, and facilitates smoother recovery of children undergoing palatoplasty under GA.

Keywords: Airway extubation, analgesia, anaesthesia, bupivacaine, emergence delirium, fentanyl, palatoplasty, sphenopalatine ganglion block

INTRODUCTION

Palatoplasty is a commonly performed surgery in children with cleft palate. The palate has a rich sensory nerve supply; consequently, surgeries in this area are extremely painful. This warrants the administration of excellent perioperative analgesia for palatoplasties.[1] IV opioids are the first line of analgesics, but their use poses significant risks. The liberal use of opioids may lead to sedation and respiratory depression, which is a

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grave concern, especially in children with cleft palate,[2] where the airway is challenging and postoperative airway obstruction is a concern. Underdosing, on the contrary, may lead to inadequate analgesia, causing postoperative agitation and increased risk of complications such as bleeding. Postoperative bleeding in children undergoing palatoplasty is particularly concerning, as it may lead to blood aspiration, thereby limiting the role of non-steroidal anti-inflammatory drugs (NSAID) in providing analgesia for such patients.

Peripheral nerve blocks, such as suprazygomatic nerve blocks and greater and lesser palatine nerve blocks, have been shown to provide excellent perioperative analgesia while minimising the adverse effects in patients undergoing palatoplasty.[3] Ultrasonographic guidance has further improved the success rate and efficacy of these blocks. Blocking of the sphenopalatine ganglion (SPG), an extracranial ganglion that provides extensive sensory innervation to the palate and surrounding nasopharyngeal structures, is a relatively new addition to nerve block techniques. Bilateral SPG block, administered through the intranasal transmucosal approach, has been shown to provide good postoperative analgesia after palatoplasty.[4] However, the specific impact of this block on the intraoperative fentanyl requirement remains underexplored.

This study was conducted in children scheduled for elective palatoplasty under general anaesthesia (GA), with the primary objective of comparing the total intraoperative fentanyl consumption in those receiving bilateral intranasal transmucosal SPG block and those who did not. The secondary objectives included evaluating intraoperative haemodynamics and postoperative recovery, as assessed by the Paediatric Anaesthesia Emergence Delirium (PAED) scale score at 5 and 10 min after tracheal extubation. We hypothesised that bilateral intranasal transmucosal SPG block reduces intraoperative fentanyl requirement in children undergoing palatoplasty under GA.

METHODS

This randomised, double-blinded, comparative study was conducted from April 2023 to June 2024. Ethical clearance for conducting the study was obtained from the Institutional Ethics Committee [vide approval number F. No. TP (MD/MS) 118/2022/IEC/ABVIMS/RMLH/1284, dated 14 March 2023], and the trial was registered with Clinical Trials Registry – India (vide registration number: CTRI/2023/05/052315, accessible at: https://www.ctri.nic.in/). Informed assent was obtained from all patients aged 6 years and above, and written informed consent was obtained from the guardians of all the enroled patients for both participation in the trial and subsequent publication in a scientific journal. Principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines were adhered to while conducting the trial.

Thirty American Society of Anesthesiologists (ASA) physical status (PS) I and II patients, aged 6 months–12 years and scheduled for elective palatoplasty under GA, were included in the study. Exclusion criteria were upper airway abnormality, including collapsed nostrils and significant nasal obstruction, upper respiratory tract infection, cardiac, pulmonary, hepatic, or renal disorders, bleeding diathesis, and allergy to the local anaesthetic agent. The selected patients were randomly divided into two groups of 15 patients each, using a computer-generated random number sequence. Patients in Group T received bilateral intranasal transmucosal SPG block using 0.5% bupivacaine, and patients in Group C received standard anaesthesia care with no nerve block.

On the morning of surgery, the patients were reassessed, and nil per oral status was confirmed. The patients were taken to the operation theatre (OT), and standard ASA monitors were attached. One parent was permitted to accompany the child into the OT to help alleviate preoperative anxiety. After preoxygenation, inhalation induction was performed using sevoflurane. Once the child was sedated and IV access secured, IV fentanyl 2 μg/kg, propofol 1 mg/kg, and atracurium 0.5 mg/kg were administered. The airway was secured using an appropriately sized oral Ring, Adair and Elwyn tube, which was fixed in the midline. Anaesthesia was maintained using sevoflurane, at an end-tidal concentration of 1.5%–2.0%, in a 50:50 oxygen/air mixture to maintain a minimum alveolar concentration of 1.0, and intermittent maintenance doses of IV atracurium were used for neuromuscular blockade.

After tracheal intubation, patients in Group T received bilateral SPG block by intranasal transmucosal approach, and patients in Group C received standard anaesthesia care without any nerve block. To administer the block, the patient was placed in a supine position with the neck extended. Each nostril was cleansed with an antiseptic solution and sterile

cotton swabs. A sterile 10-cm cotton-tipped applicator soaked in 1 mL of 0.5% bupivacaine was inserted into each nostril and advanced along the superior border of the middle turbinate until resistance was met, where it was left in place for 5 min. To ensure blinding, the anaesthesiologist administering the block was blinded to the subsequent intraoperative proceedings, while the anaesthesiologist responsible for intraoperative management and data collection was blinded to the block status.

Heart rate (HR) and mean arterial pressure (MAP) of all the patients were noted immediately after tracheal intubation (baseline) and every 15 min thereafter. Any increase in HR or MAP > 20% was managed by administering IV fentanyl 0.5 μg/kg, not exceeding a cumulative dose of 1 μg/kg/h. The total fentanyl consumption was also noted for all the patients. Patients in both groups received IV paracetamol 15 mg/kg 30 min before the end of surgery for postoperative analgesia. After the procedure was completed, residual neuromuscular blockade was antagonised, and the trachea was extubated. The PAED scale score at 5 and 10 min after extubation was also calculated and noted.

The sample size was calculated based on data from a study by Rajan *et al.*[5] The mean difference in intraoperative fentanyl consumption between the two groups was assumed to be 1 μg/kg, with a 95% confidence interval (CI). Using the formula by Snedecor and Cochran (1989), with a pooled standard deviation (SD) of 0.55, a power of 99%, and an alpha error of 0.05, the sample size was calculated to be 12.2 patients per group. To account for any potential dropouts, a total of 30 patients were enroled in the study.

Data entry and coding were performed using MS Excel (v. 2021, Microsoft Corp., Redmond, WA, USA), and all statistical analyses were conducted using SPSS software (v. 21, IBM Corp., NY, USA). The collected data are presented as mean (SD) (95% CI) for quantitative variables (age, weight, total fentanyl consumption, HR, MAP, and PAED score) and as frequencies (*n*) [percentages (%)] for categorical variables (gender, ASA PS, and requirement of rescue IV fentanyl). Normality of continuous data was assessed, and accordingly, age and weight were analysed using the Wilcoxon-Mann-Whitney U test, while total fentanyl consumption, HR, MAP, and PAED scores were analysed using an independent *t*-test. Categorical variables were compared using the Chi-squared test. A *P* value of less than 0.05 was considered statistically significant.

RESULTS

All the 30 patients enroled completed the study, and observations were analysed [Figure 1]. There was no statistically significant difference between the demographic parameters of the two groups [Table 1]. Both HR [Figure 2] and MAP [Figure 3] were lower in Group T patients compared to patients in Group C, with the difference being statistically significant from 30 min to 2 h 30 min. The requirement of rescue fentanyl and total fentanyl consumed were both significantly lower in Group T than in Group C, as was the PAED scale score at both 5-min and 10-min intervals [Table 2].

DISCUSSION

The present study demonstrates a statistically significant reduction in intraoperative fentanyl consumption in children who received a bilateral intranasal transmucosal SPG block with 0.5% bupivacaine during elective palatoplasty under GA compared to those who did not. Additionally, the study reveals a significant decrease in HR, MAP, and PAED scale scores at 5 and 10 min post-extubation in children receiving the block. These findings validate the study hypotheses, supporting the efficacy of SPG block in reducing intraoperative fentanyl consumption in children undergoing elective palatoplasties under GA.

The total intraoperative fentanyl consumption was lower in group T compared to group C, indicating the beneficial opioid-sparing effect of SPG block. Similar findings were obtained by Rajan *et al.*,[5] who administered bilateral SPG block using cotton-tipped applicators soaked in 2% lignocaine solution in children undergoing cleft palate repair. They reported a statistically significant reduction in the intraoperative requirement of fentanyl in

Table 1: Comparison of demographic parameters between the groups

Parameter	Group T (*n*=15)	Group C (*n*=15)
Age (months) Mean (SD)	38.34 (30.80)	30.92 (33.55)
Weight (kg) Mean (SD)	12.51 (4.95)	11.33 (4.22)
Gender (Female/Male) (*n*)	7/8	7/8
ASA PS (I/II) (*n*)	15/0	15/0

Data expressed as mean (standard deviation) or number of patients, SD=Standard Deviation, IQR=Interquartile Range, *n*=Frequency, ASA PS=American Society of Anesthesiologists Physical Status

Table 2: Comparison of fentanyl consumption and PAED scale score between the groups

Parameter	Group T (*n*=15)	Group C (*n*=15)	*P*
Requirement of rescue fentanyl (Yes/No) (*n*)	1/14	15/0	<0.001
Total fentanyl consumption (μg) Mean (SD) (95% CI)	26.73 (10.19) (20.38, 33.08)	34.47 (12.73) (27.20, 41.74)	0.008
PAED scale score (5 min) Mean (SD) (95% CI)	7.33 (1.50) (6.47, 8.19)	15.53 (0.74) (15.13, 15.93)	<0.001
PAED scale score (10 min) Mean (SD) (95% CI)	6.00 (1.31) (5.30, 6.70)	14.07 (0.59) (13.75, 14.39)	<0.001

Data expressed as mean (standard deviation) (95% confidence interval) or number of patients. PAED scale score=Paediatric Anaesthesia Emergence Delirium scale score, *n*=Frequency, SD=Standard Deviation, 95%CI=95% Confidence Interval

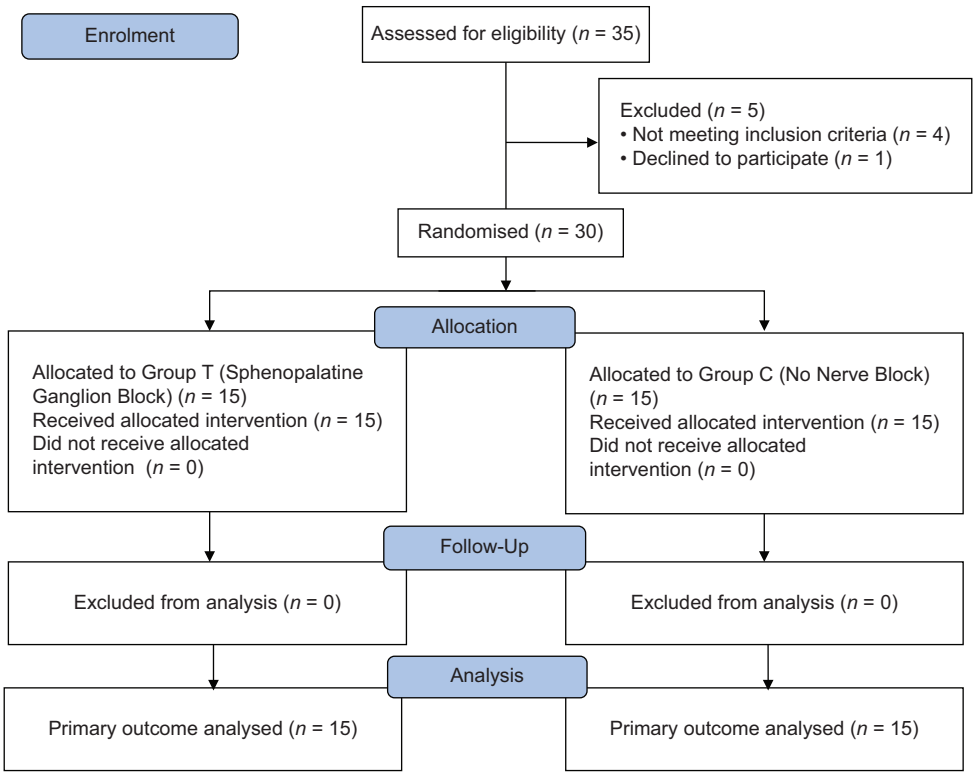

Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram. *n* = number of patients

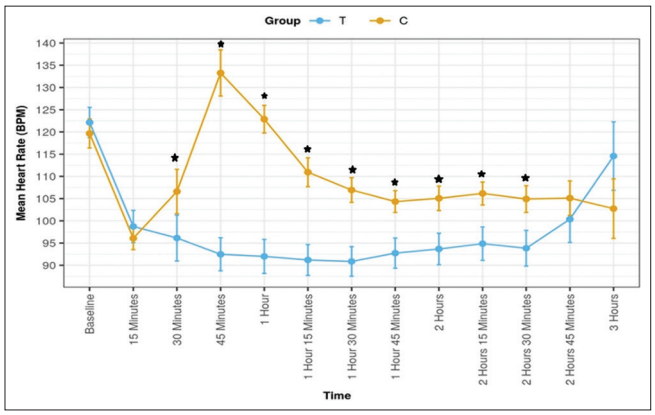

Figure 2: Comparison of heart rate (HR) between the groups. BPM = beats/min, * denotes $P < 0.05$

the SPG block group. Mostafa *et al.*[6] administered bilateral SPG block in patients undergoing functional endoscopic sinus surgery (FESS) using 2.0 mL of 0.5% bupivacaine (Group B) and 1.5 mL of 0.5% bupivacaine + 0.5 mL of 10% magnesium sulphate (Group M) and compared them to a control group (Group C). They observed a significant reduction in the requirement of intraoperative fentanyl in Group B and Group M, compared to Group C. Ismail *et al.*[7] and Bhattacharyya *et al.*[8] evaluated the effect of bilateral SPG block using 0.75% ropivacaine and 0.25% levobupivacaine, respectively, against control groups in FESS patients. Both studies noted a statistically significant lowering of intraoperative fentanyl requirement in the SPG block group.

The reduction in fentanyl consumption may be attributed to the blocking of parasympathetic and somatosensory afferent fibres, which innervate the palate and adjacent structures, by the SPG block.[9] By blocking the nociceptive inputs to the central nervous system via the maxillary division of the trigeminal nerve, SPG block mitigates pain perception during the palatal surgical procedure, thus decreasing the necessity for intraoperative opioids.

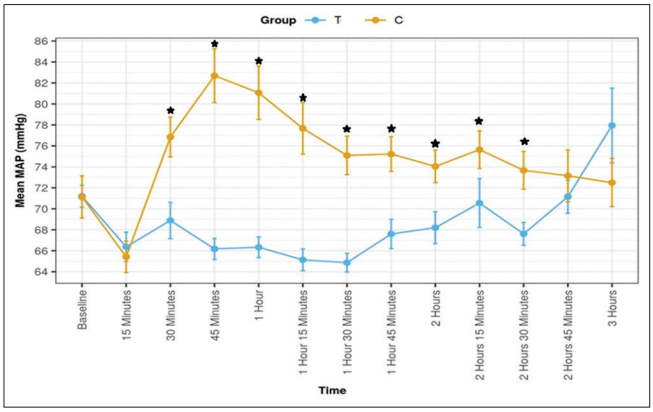

Figure 3: Comparison of mean arterial pressure (MAP) between the groups. * denotes $P < 0.05$

In the current study, intraoperative HR and MAP were consistently lower in Group T compared to Group C, from 30 min to 2 h 30 min after intubation. Lower HR and MAP values indicate reduced autonomic responses to surgical stress, likely due to the localised analgesic effect of the SPG block in inhibiting nociceptive transmission through the maxillary nerve pathway. Rajan *et al.*[5] found similar results, with HR being consistently lower throughout the intraoperative period and MAP being lower at 15, 60, and 75 min intervals in the SPG block group. Both Ismail *et al.*[7] and Bhattacharyya *et al.*[8] also documented lower HR and MAP in patients receiving SPG block. Ali *et al.*[10] administered bilateral SPG block using 0.5% bupivacaine to patients undergoing transnasal resection of pituitary adenoma and compared the findings to a control group. Although no statistically significant differences in HR or MAP were reported between the groups, there was a statistically significant reduction in the intraoperative requirements of propranolol and nitroglycerine in patients who received SPG block. A similar lowering of intraoperative requirements of propranolol and nitroglycerine was also observed by Mostafa *et al.*[6] Parameswaran *et al.*[4] administered bilateral SPG block using 0.75% ropivacaine in children undergoing palatoplasty and compared the findings to a control group. However, they observed no significant difference in the intraoperative HR and MAP values between the two groups. This discrepancy may be attributed to the differences in the anaesthetic protocols between the two studies.

The current study also revealed lower PAED scale scores at 5 and 10 min post-extubation in Group T compared to Group C. The PAED scale is a validated tool used to assess and quantify the emergence of delirium in paediatric patients in the immediate postoperative period. Lower PAED scale scores in Group T indicate that children who received SPG block experienced a smoother emergence from anaesthesia with less agitation and discomfort. Rajan *et al.*[5] also reported similar results with PAED scale scores at 5 and 10 min, showing a statistically significant reduction in the SPG block group. Emergence delirium in paediatric patients is not only distressful for both children and their parents but may also negatively impact recovery by causing accidental self-injury or disruption of surgical repair.

While this study provides valuable insights, a few limitations need to be acknowledged. The blind technique, while simple and time-efficient, can be challenging to administer in the presence of anatomical variations in the upper airway. This is particularly relevant in patients with concomitant cleft lip. The sample size, although sufficient to provide statistical significance, was relatively small. Additionally, postoperative pain was not assessed. Larger, multicentric studies evaluating both intraoperative and postoperative analgesia following SPG block are needed.

CONCLUSION

The study demonstrates a statistically significant reduction in intraoperative fentanyl consumption, stabilisation of haemodynamic parameters (lowered HR and MAP), and smoother recovery (reduced PAED scale scores at 5 and 10 min post-extubation) in children who received bilateral intranasal transmucosal SPG block while undergoing palatoplasty under GA.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

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Conflicts of interest

There are no conflicts of interest.

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