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Comparison ropivacaine and bupivacaine in sphenopalatine ganglion block for postoperative analgesia after functional endoscopic sinus surgery : a randomized controlled trial

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Abstract : *Objective:* In this study the efficacy of sphenopalatine ganglion (SPG) block will be evaluated using bupivacaine or ropivacaine in adult patients undergoing functional endoscopic sinus surgery (FESS) under general anesthesia.

Methods : Sixty adult patients undergoing FESS under general anesthesia has been randomized in three groups to receive bupivacaine, ropivacaine or normal saline in SPG block before surgery.

Results : Time to recovery from anesthesia was significantly higher in patients who received normal saline than bupivacaine or ropivacaine. VAS scores were significantly lower in both bupivacaine and ropivacaine groups at all recorded time points when compared to saline group. Five patients in the bupivacaine group (25%) and six patients in the ropivacaine group (30%) required rescue analgesia whereas fifteen patients (75%) in the saline group required rescue analgesia.

Conclusion : Preoperative SPG with either bupivacaine or ropivacaine is an effective method of postoperative analgesia after FESS in adult patients up to 8 hours post-surgery.

Keywords : sphenopalatine ganglion block, endoscopic sinus surgery, postoperative analgesia, ropivacaine, bupivacaine.

Introduction

Functional endoscopic sinus surgery (FESS) is a minimally invasive and safe technique for the treatment of sinonasal disease. Although it is a minimally invasive and less traumatic procedure (1) it is usually associated with pain of mild to moderate intensity which reaches its maximum level in the first few postoperative hours (2, 3). However, even low-level postoperative pain may be associated with delayed functional recovery and it frequently contributes to dissatisfaction with the procedure (4, 5), delay in return to work and readmission after surgery (6-9). Postoperative analgesia after FESS can be achieved through opioids, NSAIDs, topical or infiltration of local anesthetic and regional techniques like sphenopalatine ganglion (SPG) block, infraorbital nerve block and nasociliary block (10). As the sensory innervations of the SPG supplies the nasal turbinates, nasopharynx and palate (11), SPG block is expected to provide perioperative analgesia after FESS. Integration of regional anesthesia with general anesthesia technique can provide a better hemodynamic control, less perioperative opioid use, less bleeding and higher level of patients' satisfaction (12). Reduction in surgical bleeding in FESS can improve surgical field and also surgeons' satisfaction and a reduced opioid use may be translated into a less postoperative nausea & vomiting, rapid recovery and early hospital discharge. But, the current evidences regarding the benefit of SPG block after FESS is controversial (13,14). In this randomized controlled trial, efficacy of sphenopalatine ganglion block will be evaluated using bupivacaine or ropivacaine as local anesthetic in adult patients undergoing FESS under general anesthesia.

Methods

This prospective randomized controlled trial was registered with ClinicalTrials.gov PRS with Unique Protocol ID : 9157/PG2Trg/2012/15727 after obtaining Institute Ethics Committee approval (NK/997/MD/13472-473) and was performed at

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This study was conducted after approval of the Institutional Ethics Committee of the Post Graduate Institute of Medical Education and Research (NK/997/MD/13472-473) and was registered with the Clinical Trials.gov PRS with Unique Protocol ID: 9157/PG2Trg/2012/15727.

Post Graduate Institute of Medical Education and Research, Chandigarh, India. After obtaining informed written consent from the participants, 60 American Society of Anesthesiologists (ASA) physical status I and II patients aged 18-60 years scheduled to undergo FESS for disease which is limited only to ethmoid, maxillary, frontal and sphenoid sinuses were enrolled in this prospective randomized placebo controlled trial. Pansinusotomy was done in all cases and a single experienced surgeon operated on all patients. In patients requiring additional procedures involving septum, rhino or turbinate were excluded from this study. Patients were randomly allocated to one of three groups of 20 each after picking a sealed envelope generated by randomized computer sequence. The block was given bilaterally after induction of general anesthesia to minimize patient discomfort by a single surgeon. Both the patients and surgeon were blinded to the drug used for the block.

Group B (n = 20): The patients in this group were infiltrated with 3 ml of 0.5% bupivacaine; Group R (n = 20): The patients in this group were infiltrated with 3 ml of 0.5% ropivacaine and Group S (n = 20, Control): The patients in this group were infiltrated with 3 ml of normal saline.

Anesthesia technique

Patients were evaluated on the day before surgery and checked for the presence of predefined exclusion criteria of this study. ASA fasting guidelines were followed in all patients and they were pre-medicated with oral alprazolam 0.5 mg a night prior to and on the morning of surgery. I n the operating room, standard monitors for continuous electrocardiography (ECG), noninvasive arterial blood pressure (NIBP) and pulse oximetry (SpO_2) were attached and baseline heart rate (HR) and mean arterial pressure (MAP) were recorded. After placing an intravenous (IV) cannula, infusion of normal saline was started. All patients received intravenous fentanyl 2 μg/kg for analgesia and to prevent the intubation response. Anesthesia was induced with propofol 1.5-2.5 mg/kg and tracheal intubation was facilitated with vecuronium 0.1 mg/kg. Mechanical ventilation was initiated to maintain an end tidal carbon dioxide level of 35-40 mm Hg. Patients were placed in 15-degree reverse Trendelenburg position to facilitate venous drainage. Anesthesia was maintained with oxygen- nitrous oxide (40%- 60%) and propofol infusion at 100-150 μg/kg/min, titrated to maintain MAP within 60-70 mm Hg range. If required, esmolol and/or nitroglycerin infusion was used to control mean arterial pressure and obtain a satisfactory surgical field. Muscle relaxation was maintained with boluses of IV vecuronium 0.02 mg/kg as required.

Following induction of general anesthetic, the surgeon administered sphenopalatine block bilaterally using a 3.5 inch 22G needle bent at the distal end at a 45-degree angle using the transnasal endoscopic approach. The medication was injected into the mucosa behind the middle turbinate after negative aspiration of blood. In all groups, pellets soaked in a mixture of epinephrine 1:2,00,000 in 4% lidocaine was inserted in the nasal cavity to induce vasoconstriction and local anesthesia around the incisional area prior to the block. Following parameters were recorded in all patients by a blinded observer:

I. VAS scores were noted upon transfer to PACU when the patient was able to communicate and at 30 minutes, 1 hour, 2 hours, 4 hours, 6 hours and 8 hours thereafter.

II. For VAS score> 3 during any of the assessments, rescue analgesia in the form of IV acetaminophen 15 mg/kg mg was given. If no improvement was seen during a pain assessment 30 minutes later, IV diclofenac 75 mg was given. Rescue analgesia was also given if the patient requested analgesia in the period between recordings of pain scores. Time to first administration of rescue analgesia was recorded.

III. Recovery time: Time from discontinuation of general anesthetic to eye opening and/or obeying commands was recorded.

IV. Postoperative hemodynamic parameters like heart rate and mean arterial pressure were recorded.

V. Patient satisfaction score: The overall quality of treatment, as reported by the patient, was recorded at the end of 8 hours using a four-point scale of 1 = poor, 2 = fair, 3 = good and 4 = excellent.

STATISTICAL ANALYSIS

Sample size was estimated based on the effect size of 0.47 for 3 groups on the basis of previous study by Kesimci et al (14). Sample size came out to be 14 subjects per group at a power of 80% & confidence interval of 95%. Considering possible dropouts, it was decided to include 20 patients per group. The *continuous data were presented as mean ± standard deviation or median and* interquartile range, as appropriate. Normality of quantitative data was checked by measures of Kolmogorov Smirnov tests of normality. For normally distributed

Table 1

Demographic Parameters and Clinical Outcome of the patients in three groups
[Data expressed as mean ± SD, median (IQR) or proportions as applicable]

	Group B	Group R	Group S	p value
Age (years)	31.60 ± 13.03	29.70 ± 12.36	30.25 ± 13.34	p = 0.89
Weight (kg)	64.50 ± 8.25	64.55 ± 9.45	63.95 ± 9.24	p = 0.97
Male/Female	14/6	15/5	13/7	p = 0.78[y]
DOS (min)	69.35 ± 11.22	69.30 ± 11.60	70.30 ± 12.69	p = 0.95
DOA (min)	89.10 ± 12.88	88.50 ± 12.43	89.10 ± 13.36	p = 0.98
ASA PS (I/II)	17/3	18/2	17/3	p = 0.86[y]
Time to recovery (minutes)	10.95 ± 0.76	11.05 ± 1.05	13.10 ± 0.91	p <0.001
Time to request rescue analgesia (minutes)	68.40 ± 46.69	47.33 ± 17.86	49.53 ± 26.15	p = 0.421
No. of patients requiring rescue analgesic (yes/ no)	5/15	6/14	15/5	p = 0.002[y]
Patients satisfaction score	3.00 (2.00-3.00)	2.50 (2.00-3.00)	1.50 (1.00-2.00)	p <0.001[z]

Oneway ANOVA ; y Chi-square test ; z Kruskal- Wallis test
DOS: Duration of surgery, DOA: Duration of anaesthesia, ASA PS: American Society of Anesthesiologists Physical Status

Table 2

Postoperative VAS Scores

VAS	Group B	Group R	Group S	p1	p2	p3
t0	1.50 (0.25-2.00)	2.00 (1.00-2.00)	2.00 (2.00-3.00)	0.001*	0.005*	0.230
t1	2.00 (1.00-2.00)	2.00 (2.00-3.00)	3.00 (2.25-3.00)	0.001*	0.006*	0.146
t2	2.00 (2.00-3.00)	3.00 (2.00-3.00)	3.00 (3.00-4.00)	0.001*	0.014*	0.064
t3	2.00 (1.00-2.00)	2.00 (2.00-3.00)	3.00 (2.00-3.00)	0.002*	0.013*	0.168
t4	1.00 (1.00-2.00)	2.00 (1.00-2.00)	2.00 (2.00-2.75)	0.001*	0.001*	0.312
t5	1.00 (0.00-2.00)	1.00 (1.00-1.75)	2.00 (2.00-2.00)	0.001*	0.001*	0.293
t6	1.00 (0.00-1.00)	1.00 (0.00-1.00)	2.00 (1.00-2.00)	0.001*	0.001*	0.551

Values expressed as median (25^{th}-75^{th} percentile); *: statistically significant; p1, p2 and p3 denote p values derived from comparison of groups B and S, R and S, and B and R respectively. VAS scores were noted when patient was able to communicate after extubation (t0) and at 30 minutes (t1), 1 hour (t2), 2 hours (t3), 4 hours (t4), 6 hours (t5) and 8 hours (t6) thereafter

data, means of the 3 groups were compared using One Way Analysis of Variance (ANOVA) followed by post-hoc multiple comparisons. For skewed data or ordinal data, Kruskal-Wallis test followed by Mann-Whitney test for two groups was applied. For time-related scores, Wilcoxon signed rank test was applied. For repeated measures of hemodynamics, ANOVA followed by Bonferroni's correction for multiple comparisons was used. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using Chi square or Fisher's exact test whichever was applicable. A two-tailed p value of <0.05 was considered to indicate statistical significance. All calculations were performed using SPSS® version 17 (Statistical Packages for the *Social Sciences, Chicago, IL).*

Results

A total of 60 patients have been recruited in this study and data from all of them have been included for statistical analysis (Fig. 1). All three groups were comparable in terms of demographic parameters (age, sex, body weight), ASA physical status, duration of surgery and anesthesia (Table 1). However, recovery time from anesthesia was significantly higher in patients who received NS than bupivacaine or ropivacaine. VAS scores were significantly shorter in both bupivacaine and ropivacaine groups at all recorded time points when compared to saline group whereas they were comparable in bupivacaine and ropivacaine groups at all recorded time points (Table 2) (Fig. 2). Number of patients requiring rescue analgesia

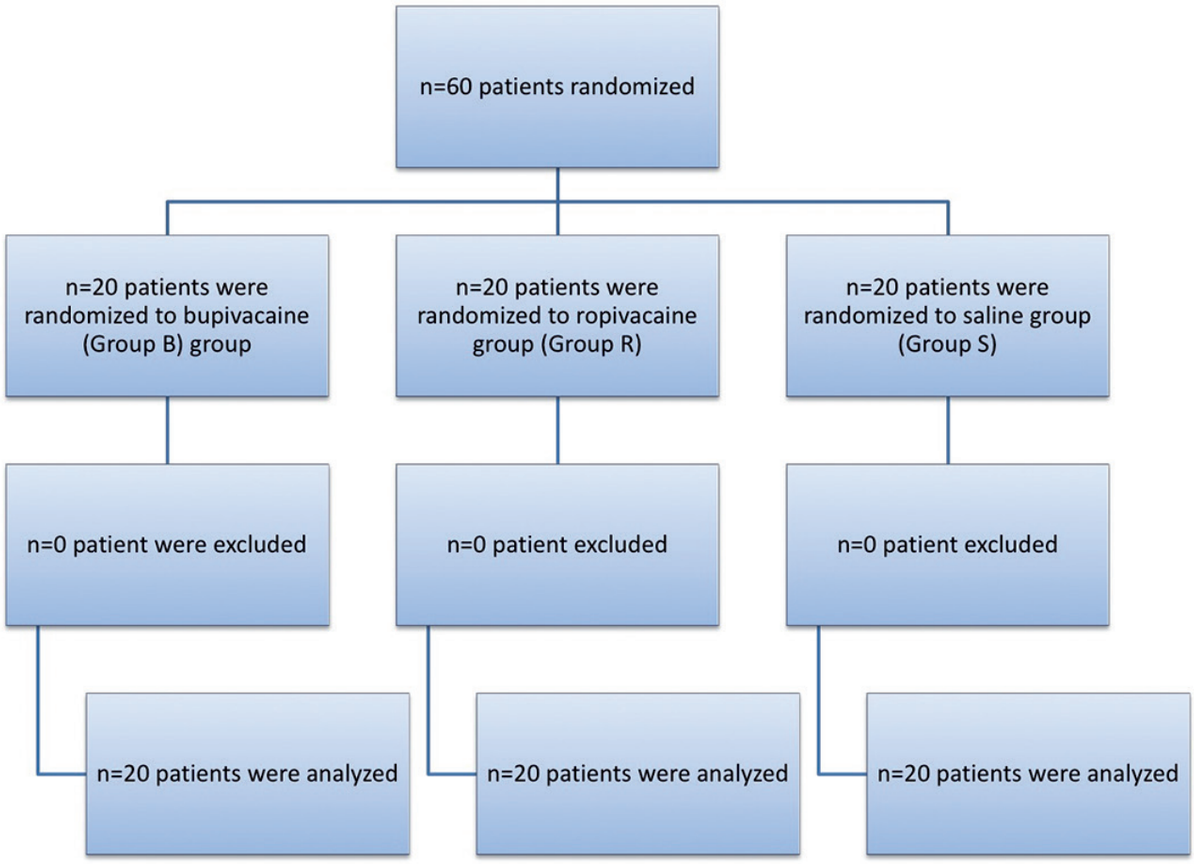

Fig. 1. — Consort Diagram.

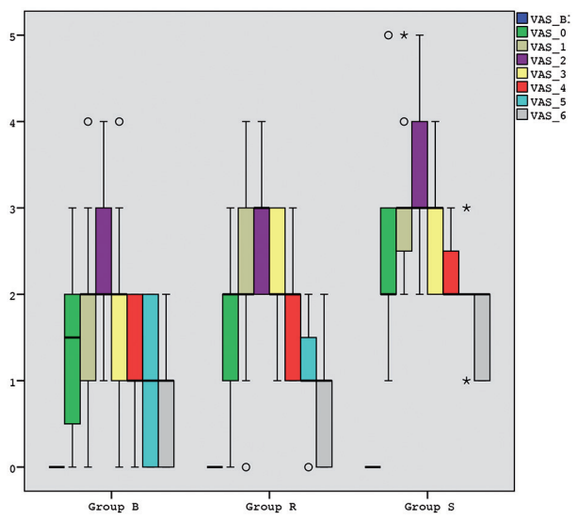

Fig. 2. — Box-plot showing median (IQR] of VAS score in three groups in the postoperative period (at 30 minutes, 1 hour, 2 hours, 4 hours, 6 hours and 8 hours].

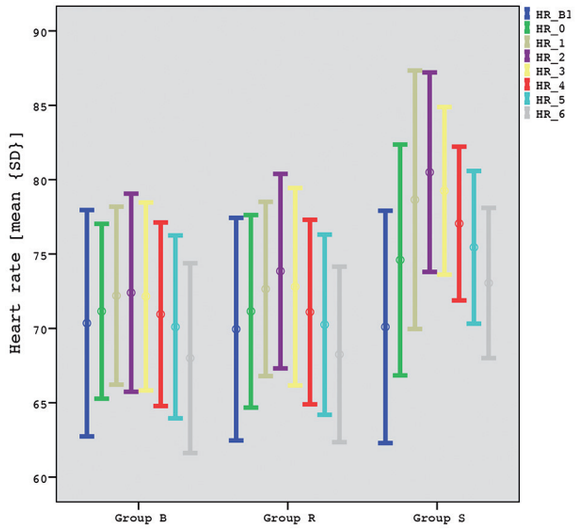

Fig. 3. — Error bar diagram showing mean {SD} of heart rate in three groups in the postoperative period (at 30 minutes, 1 hour, 2 hours, 4 hours, 6 hours and 8 hours].

was also comparable between bupivacaine and ropivacaine groups and was statistically significant when compared to saline group. Five patients in the bupivacaine group (25%) and six patients in the ropivacaine group (30%) required rescue analgesia whereas fifteen patients (75%) in the saline group required rescue analgesia. However, time to administer rescue analgesia was similar in

all three groups (Table 1). Postoperative heart rate was significantly higher in saline group compared to bupivacaine or ropivacaine from 30 min postoperative period onwards (Fig. 3) but mean arterial pressure was similar in the postoperative period all recorded time period.

Patient satisfaction score was significantly higher in the bupivacaine and ropivacaine groups compared to the saline groups ($p = 0.00$), but there was no statistically significant difference between bupivacaine and ropivacaine groups ($p = 0.426$) (Table 1).

Discussion

FESS is usually associated with pain of mild-to-moderate intensity, which reaches its maximum level in the first few postoperative hours (2, 3). Even low-level postoperative pain may be associated with delayed functional recovery and it frequently contributes to dissatisfaction with the procedure, (4, 5) delay in return to work and readmission after surgery (7). Postoperative pain after FESS is mainly due to surgical wound and postoperative nasal packing for prevention of bleeding (15).

Quality of recovery and pain management in the immediate postoperative period after FESS is of utmost importance as a smooth recovery and properly managed pain is associated with a stable hemodynamic parameters. Various methods of pain management have been used in such patients with variable success. Al-Qudah reported that simple 2% lignocaine injection at the end of surgery is an effective and safe method of postoperative analgesia (16). Intravenous dexamethasone has also been used for postoperative pain management in these patients with limited success (17). In this randomized controlled trial, we have found that SPG block with either bupivacaine or ropivacaine is comparable and provides a better quality of analgesia and less requirement of rescue analgesia in the post-operative period when compared to saline group. A few previous studies evaluated SPG for perioperative analgesia after FESS. Cho et al in 2011 reported that SPG block has limited utility for postoperative analgesia in patients undergoing FESS (13). On the contrary, Kesimci et al in 2012 reported that either bupivacaine or levobupivacaine provided effective postoperative analgesia after FESS (12). Though FESS is associated with mild to moderate pain, an effective postoperative analgesia is very important in these patients as elevation of blood pressure from sympathetic stimulation due to pain can cause postoperative bleeding. Though we have not evaluated intraoperative bleeding & surgeons' satisfaction, a pre-emptive SPG block is also expected to provide better intraoperative hemodynamic control and less surgical bleeding. Postoperative bleeding is an important cause of delayed hospital discharge, re-admission and higher cost of medical care. We have found that patients who received SPG block with either drug had better heart rate control in the postoperative period, which also indicates a reduced sympathetic tone.

Our study has several limitations, such as, intraoperative hemodynamic changes and analgesic consumptions, quality of the surgical field and surgeons satisfaction were not measured in our study. However mean blood pressure was maintained within 60-70 mm Hg range. All patients received intravenous fentanyl 2 μg/kg for analgesia and since the average duration of procedure is 70 min, no analgesic was repeated intraoperatively. VAS scores and postoperative hemodynamic parameters were not measured beyond the 8-hour period and analgesic effect of local anesthetics may continue long after the period of sensory or motor blockade. (11) A larger sample size could have brought out significant differences in outcomes in cases where the actual difference among groups could be low.

So, we conclude that preoperative SPG block with bupivacaine is comparable to ropivacaine and is an effective method of postoperative analgesia after FESS in adult patients up to 8 hours post-surgery.

Acknowledgements

Trial registration site : ClinicalTrials.gov PRS with Unique Protocol ID: 9157/PG2Trg/2012/15727

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