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Efficacy of Nalbuphine as an Adjunct To 0.5% Bupivacaine in Ultrasound Guided Suprazygomatic Maxillary Nerve Block in Patients Undergoing Nasal and Maxillofacial Surgery – A Randomized Clinical Comparative Study

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ABSTRACT

Background & Aims

The ultrasound guided suprazygomatoic maxillary nerve block (MNB) is safe and efficacious in nasal and maxillofacial surgeries. The analgesic effect of nalbuphine has been found to be equal to the analgesic effect of morphine with a ceiling effect on respiration. Therefore this study aims to evaluate the efficacy of 0.2mg/kg nalbuphine as an adjuvant to 0.5% bupivacaine compared to plain 0.5% bupivacaine in maxillary nerve block.

Material & Methods

This randomized controlled trial included 100 ASA I-II patients of either sex scheduled for elective nasal and maxillofacial surgeries under general anaesthesia. The patients were randomly allocated in to Group A and Group B (n=50) to receive USG guided suprazygomatic MNB. Group A and Group B received 0.5% bupivacaine with 0.2mg/kg of nalbuphine and 0.5% bupivacaine respectively. The mean duration of analgesia , the total consumption of opioids , intraoperative hemodynamics and 24 hr postoperative side effects were recorded in both groups. The data was compared using Student's *t*-test,

Chi-square test, and Mann–Whitney U-test. $P < 0.05$ was considered as statistically significant.

Results

The mean duration of postoperative analgesia was significantly prolonged in nalbuphine group (769.2±117 vs 559.2±75 minutes ;(p=0.002). There was significant reduction in total consumption of nalbuphine (26.4±5.06 vs 52.77. ±7.46 mg; p=0.007) . There was no significant difference in intraoperative and postoperative parameters.

Conclusion

0.2mg/kg nalbuphine can be effective as an adjuvant to local anesthetic in MNB to prolong the postoperative duration of analgesia without significant side effects.

Keywords

Analgesia, Nalbuphine, suprazygomatic MNB

INTRODUCTION

Nasal surgeries done under general anaesthesia generally produce mild to moderate postoperative pain, but there can be suddenly high situations of postoperative pain in some cases.[1] General anesthesia has been used routinely for maxillofacial surgery with nasotracheal intubation to ensure airway patency and reduce the risk of aspiration. Being an invasive and painful procedure, pain control is obligatory in this type of operation. [2] Also the procedures involving nasal sinuses and maxillofacial surgery are painful and postoperatively the cases are obliged to breathe through their mouth, therefore providing acceptable postoperative analgesia is pivotal in these cases. Maxillary nerve provides sensory innervations to hard and soft palate, maxillary air sinus, posterior nasal cavity, upper lip and upper dental arch.[3] In adults, , suprazygomatic maxillary nerve block(MNB) is shown to produce reliable and effective anaesthesia of the entire sensory area of the maxillary nerve and its terminal branches.[4] Lately, the ultrasound guided MNB has revolutionized the management of perioperative pain in upper limb, lower limb and abdominal surgeries. On the contray, the facial blocks haven't endured the same. Numerous adjuvants have been used with local anesthetics to prolong the postoperative duration of analgesia including alpha- 2 agonists, corticosteroids, and opioids. Nalbuphine is a derivative of 14-hydroxymorphine which is a strong analgesic with kappa agonist and μ antagonist activity. The analgesic effect of nalbuphine has been set up to be equal to the analgesic effect of morphine but unlike it has a ceiling effect on respiration. Nalbuphine has the implicit to maintain or indeed enhance μ- opioid grounded analgesic effect while contemporaneously mitigating the μ- opioid side effects. . The efficacy of Nalbuphine as adjuvant to local anesthetics in spinal, epidural and brachial plexus block has been proved.[5] Still, till date no study is available in the literature that had used nalbuphine as an adjuvant in maxillary nerve block for nasal and maxillofacial surgeries. Hence we plan to conduct this study with the primary objective of assessing the effectiveness of the bilateral ultrasound guided suprazygomatic MNB with nalbuphine as an adjuvant to Bupivacaine compared to plain bupivacaine, in terms of the mean duration of analgesia and consumption of opioids for control of pain in postoperative period (2 hours postoperatively up to 24 hr).

METHODOLOGY

This randomisedc controlled clinical study was started after obtaining institutional ethical committee

clearance with CTRI registration (CTRI/ 2022/ 11/ 047436). Informed written consent was documented from the cases undergoing the procedure in the study. One hundred cases belonging to ASA grade I- II of either sex between 18- 50 years posted for functional endoscopic sinus surgery, septoplasy, rhinoplasty, osteotomy and Le Fortes fracture- I (uncomplicated), under general anaesthesia were included in the study. Exclusion criteria included Patient refusal, infection at point of injection, history of allergy to local anaesthetic, deformities of maxillofacial anatomy, bleeding disorders and cardiac, hepatic and renal failure. All cases enrolled in the study were randomized by a computer generated table of arbitrary figures and numbered sealed opaque envelopes containing group. Cases were allocated into group A and group B containing 50 cases in each group. The study drug was prepared by the anaesthesiologist who was not involved in the study. In both groups ultrasound guided suprazygomatic MNB was performed by an anaesthesiologist who was blinded for the study drug. Group A received MNB with 5 ml of 0.5% bupivacaine with 0.2 mg/ kg of nalbuphine and Group B received MNB with 5 ml of plain 0.5% Bupivacaine. The primary objective was to compare the Mean Duration of postoperative analgesia in both groups, defined as, time from the initiation of MNB till the time of first rescue analgesia used and to record the mean consumption of opioids in 24hr postoperative period. The secondary objectives included The Number of rescue analgesic used during 24 hrs postoperative period , the intraoperative hemodynamics , side effects like postoperative nausea, vomitting and pruritus up to 24h postoperative period in both groups. Preoperatively, all the cases underwent thorough preanesthetic evaluation with general examination and laboratory investigation. The cases were kept nil by mouth for solids for 6 hrs. Visual analogue pain scale(VAS) was explained to all cases in the preoperative visit. The standard institutional anaesthetic protocol was used in all the cases. On the day of surgery appropriate intravenous access was established in all cases. Intraoperatively the monitoring included electrocardiogram(ECG), noninvasive blood pressure(NIBP), oxygen saturation (SpO2) and End tidal carbon dioxide(ETCO2). General Anaesthesia was induced as per the institutional protocol. After intubation, under aseptic precaution ultrasound guided suprazygomatic MNB was performed by the anaesthesiologist who was not involved in the study . The block was performed using 12 MHz high frequency linear ultrasound transducer (Mindray DC 60). The probe was placed in the infrazygomatic area with an approximate inclination of 45° in the transverse plane. A 25-Gauge spinal needle was located at an angle formed by the superior edge of the zygomatic arch below and the posterior orbital rim anterior. The needle was introduced perpendicular to the skin and advanced up to 20mm depth slowly to reach the greater wing of the sphenoid . The needle was then reoriented and advanced 35-45 mm deep to the pterygopalatine fossa (fig 1). The needle was advanced using the out of-plane approach, and the needle tip was identified carefully multiple times during movements. Pulsations of maxillary artery was not consistent, hence multiple aspirations and careful needle movements were monitored at all the time to avoid intravascular injection. After needle placement the study drugs were injected according to the protocol after careful negative aspiration The

Heart rate, Mean arterial blood pressure, SpO2 and End Tidal Carbon Dioxide(EtCo2)) were recorded immediately after the block and every 15 min throughout the first hour of surgery and every 30 min till the end of surgery. All cases were extubated after reversal with neostigmine(0.05 mg/ kg) and glycopyrollate(0.2 mg) using the standard criteria of extubation. Postoperatively, all cases received standard postoperative analgesia with IV paracetamol 15mg/ kg every 6 hr with additional boluses of 0.1 mg/ kg IV nalbuphine if VAS ≥ 4. The following data were recorded in post anaesthesia care unit(PACU) : The time of first request for rescue analgesia; number of rescue analgesia used during 24 hr postoperative period; the total consumption of nalbuphine in 24 hr postoperative period; the hemodynamic parameters HR, NIBP and SPO2 and side effects including nausea, vomitting and pruritus at 1h, 2h, 6h, 12h, 18h and 24h.

Sample size computation was based on our pilot study. Our pilot study included ten cases with 5 cases in each group and with the help of computer programmes it was calculated that a sample size of 45 cases in each group would be required to see clinically significant difference(> 20%) in duration of block and postoperative analgesia between the groups with nascence error of 0.05 with 80 power and 95 % confidence limit. Assuming a 5 % drop rate, the final sample size was determined to retain a aggregate of hundred cases for better confirmation of results. The attained data were expressed as mean ± standard deviation or number and chance. Statistical analysis was performed using statistical program SPSS20.0 Software for social wisdom (SPSS 20) for comparing observed data by Student's t test, Chi square test, and Mann – Whitney U test. $P<0.05$ was considered as statistically significant.

RESULTS

All the hundred patients enrolled for the study completed the study. The demographic data was comparable in both groups (Table 1). The mean duration of postoperative analgesia, total number of rescue analgesia in 24hr postoperative and total consumption of nalbuphine is depicted in table 2. The mean duration of postoperative analgesia was 769.2±117 minutes in group A and 559.2±75 minutes in group B which was statistically significant with p value 0.002. In group A , 5 (10%) patients requested rescue analgesic once in 24hr postoperative period while in group B 16 patients (32%) required 3 times rescue analgesia which was statistically significant with $p<0.001$. The mean consumption of nalbuphine was 26.4±5.06mg and 52.77. ±7.46 mg in Group A and Group B respectively which was statistically significant with p value 0.007.

DISCUSSION

The maxillary nerve (V2) is purely a sensory division of the trigeminal nerve. The V2 gives innervation to all structures in and around the maxillary bone and the midfacial region, including the skin of the midfacial regions, the lower eyelid, side of the nose, and upper lip; nasopharyngeal mucosa, maxillary sinus, soft and hard palate, palatine tonsil, maxillary teeth, and periodontal tissues .[6] Hence the MNB can be effectively used to provide prolonged postoperative analgesia for Nasal surgeries like FESS, septoplasty, rhinoplasty and maxillofacial surgeries. These surgeries are associated with a risk of postoperative upper airway obstruction and intravenous use of opioids for postoperative pain can further exaggerate

the respiratory complications. Hence multimodal analgesia has been practiced by most of the anaesthesiologists to limit the postoperative pain and enhance postoperative recovery in patients undergoing such surgeries. . MNB can be employed as a part of these multimodal analgesic regimens to provide effective postoperative analgesia and also to minimize the need for intravenous opioids in postoperative period. Numerous approaches have been described for maxillary nerve block and among all , the suprazygomatic approach to maxillary nerve block is safest in both children and adult patients . Recent studies quoted Suprazygomatic approach to be safe and efficacious in maxillofacial surgeries like osteotomy. [7-10] Furthermore Ultrasound guided MNB provides high success rate compared to traditional landmark guided techniques.[11] Since plain local anaesthetic can limit the duration of analgesia , various adjuvant have been used to prolong the duration of analgesia. Nalbuphine is an opioid which has both μ-antagonist and κ-agonist activities with strong analgesic effect, which can reduce μ receptor-mediated related complications, such as respiratory depression, itching, nausea, and vomiting.[12] Nalbuphine is used as an adjuvant to local anaesthetics in epidural, caudal, brachial plexus block and intrathecal

anaesthesia.[13] One of the meta analysis on perineural nalbuphine , the authors studied the efficacy of nalbphine in different blocks with different doses reported that 10-20mg of nalbuphine when used as an adjuvant significantly prolonged duration of analgesia in upper limb surgeries in adults with no significant side effects.[14] Another study by Kabade et al,[15] compared nalbuphine at a dose of 0.1 mg/kg and 0.2 mg/kg as an adjuvant to brachial plexus block and reported that 0.2mg/kg nalbuphine was associated with significant prolongation of postoperative analgesia with significant reduction in the requirement of rescue analgesics. Therefore 0.2 mg/kg of nalbuphine was used as an adjuvant in our study. Another anatomical study on ultrasound guided suprazygomatic approach for MNB recommended 1ml of local anaesthetic to be sufficient enough to produce efficacious and safer block. However the authors also claimed that, 5 mL of local anesthetic volume exceeded the capacity of pterygopalatine fossa and there was no significant spread to off target sites like orbit and cranial fossa and yet a volume slightly over 1 mL might be needed to ensure efficacious analgesia . Since the MNB complications are directly related to the volume of the drug , we limited our volume of local anaeshetic to 5ml..[11]

Our randomized double blind study demonstrated that bilateral suprazygomatic MNB in patients undergoing nasal and maxillofacial surgeries produced a significant prolongation in the postoperative analgesia when nalbuphine is used as adjuvant to bupivacaine. The mean duration of analgesia was approximately 12hr in nalbuphine group compared to 9 hr in plain bupivacaine group, which was statistically significant. In accordance to our study , Gupta et al [16]

and Vengadessane et al,[17] compared the efficacy of 10 mg of nalbuphine in supraclavicular brachial plexus block and reported the duration of analgesia to be about 7–9 h and 7-11 hr respectively . Another study compared the efficacy of 0.2mg/kg nalbuphine and magnesium sulphate in serratus anterior palne block for breast surgeries and found that nalbuphine

significantly prolonged the duration of analgesia and reduced the use of rescue analgesics.[18] Jain et al[19] also reported that 10mg of nalbuphine produced significant prolongation in analgesia (502.60 ± 22.751; P < 0.0001) which was in accordance to our study.

Our study also demonstrated a significant reduction in the mean dose of opioid consumption and number of rescue analgesics in 24hr postoperative period. Similar to our study Rao et al. compared nalbuphine and dexmedetomidine as an adjuvant to erector spinae block and reported 14hr of sensory block in nalbuphine group. The authors also reported that the first patient controlled analgesia was requested at 21hr postoperatively. However the longer duration of analgesia may be attributed to the use of higher dose(20mg) of nalbuphine.. [20]

In our study the intraoperative hemodynamics were comparable in both groups. There were no significant side effects noted in any of the group. Nalbuphine produced prolonged duration of analgesia without significant side effects like nausea vomiting and pruritus. In accordance to our study various studies reported that 10 and 20mg nalbuphine did not cause significant side effects when used as an adjuvant to regional anaesthesia technique. [21, 16,18]

Limitations of our study include the lack of specific reference article related to our study . Since , our study is unique in using nalbuphine as an adjuvant in ultrasound guided suprazygomatic maxillary nerve block , we have quoted the available references where nalbuphine has produced significant prolongation of analgesia in different regional anaesthesia techniques. Secondly nalbuphine has never been used an adjuvant in maxillary nerve block, hence we recommend further studies on the dose of nalbuphine and volume of local anesthetic for MNB.

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