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# Comparative study of effect of clonidine with lignocaine and lignocaine alone infiltration in middle ear surgeries

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**Abstract:** *Background:* Middle ear surgeries are performed under either local or general anaesthesia. Many advantages have been reported with the local anaesthetic techniques. *Objectives:* To compare the effectiveness of clonidine with lignocaine and lignocaine alone infiltration for middle ear surgeries with respect to duration of analgesia, pain score & surgeon's satisfaction. *Methodology:* 66 adult patients undergoing elective middle ear surgeries were divided into two groups, study group A (n=33) and control group B (n=33). 15ml of local anaesthesia infiltrated at posterior auricular area and between tragus and helix using 2% lignocaine with 1 in 200000 dilution of adrenaline with 30mcg of clonidine hydrochloride for study group A and 15ml of 2% lignocaine with 1 in 200000 dilution of adrenaline with 0.2ml normal saline given for control group B by the surgeon, after confirming successful blockade, procedure started. Patients were asked to rate intraoperative pain using visual analogue scale consisting of scoring from 1 to 10. Surgeon satisfaction scores were assessed using Likert scale consisting of scoring from 1 to 7. *Results:* Demographic data were comparable in both the groups. Duration of analgesia was significantly higher in group A compared to group B. The surgeon satisfaction was better in group A than Group B. SBP and DBP found significantly higher in group B compared to group A. *Conclusion:* Duration of analgesia and surgeon satisfaction were better in clonidine as adjuvant compared with lignocaine with adrenaline alone infiltration, with well-maintained haemodynamic.

**Keywords:** Clonidine, Lignocaine, Adrenaline, Middle Ear Surgeries.

## Introduction

Middle ear surgeries (MES) like myringoplasty, tympanoplasty, mastoidectomy, stapedectomy etc., are performed under either local or general anaesthesia. Many advantages have been reported with the local anaesthetic (LA) techniques as it helps in early recovery, early ambulation, less postoperative pain, economical and the most important is the ability to test hearing of the patient during surgery [1].

An ideal anaesthetic technique for middle ear surgeries should produce adequate analgesia for surgical procedures, maximize patient comfort, reduce intra-operative bleeding, as well as provide good analgesia and reduce perioperative complications like nausea, vomiting etc [2]. General anaesthesia is associated with multi-pharmacy, postoperative nausea and vomiting, coughing or straining during extubation can dislodge implanted grafts, hospital stay and hence expenditure is increased in general anaesthesia for patients. These complications can be avoided using regional anaesthesia in middle ear surgeries [2-3]. Hence day care surgeries under regional anaesthesia is the preferred option and economical. Addition of adjuvants like clonidine has been proved to improve quality and duration of anaesthetic blocks. Clonidine is a mixed alpha 1 and alpha 2 adrenoreceptor agonist with predominant alpha 2 activity, used as an antihypertensive agent. By causing sympatholysis, it reduces peripheral norepinephrine release due to stimulation of prejunctional alpha 2

adrenoreceptors [3]. It has been found to decrease anaesthetic and analgesic requirement when given systematically [4-5]. Thus we have undertaken this study to see the effect of clonidine as an adjuvant to lignocaine with adrenaline and lignocaine with adrenaline alone in infiltration anaesthesia for middle ear surgery.

## Material and Methods

This Prospective, randomized, comparative study was conducted in 66 patients, after obtaining the approval of the institutional ethics committee. Patients aged between 18 and 60 years of either gender belonging to ASA physical status 1 and 2 scheduled for MES were enrolled in the study. Patients allergic to local anaesthetics, alpha 2 agonists, patients on pain perception modifying drugs, with impaired mental status, alcohol or drug abuse were excluded from the study.

All the patients who fulfilled the above-mentioned inclusion criteria were counselled and explained about the procedure, informed consent was obtained and a detailed pre-anaesthetic checkup done. All the patients were kept nil per oral for 8 hours. Tablet alprazolam 0.5mg, given orally the night before surgery. On shifting the patient to the operating room, IV cannula secured and IV fluids infusion ringer's lactate started. Standard monitors including pulse oximeter, non-invasive blood pressure monitoring, 3 lead ECG were connected and baseline readings were noted. All patients premedicated with inj. glycopyrrolate 0.2mg i.v and started on oxygen 2L/min via nasal prongs. All the patients were given with injection midazolam 0.03mg/kg over 10 minutes followed by maintenance dose of 0.02mg/kg/hour infusion using 0.9% normal saline for drug dilution. 1ml ampoule containing 5 mg of midazolam, diluted to 19 ml 0.9% normal saline and infusion started using syringe pump (AKAS syringe pump).

Patients randomly divided using a computer-generated random number table into two groups. Study group A (n=33) and control group B (n=33). Random number enclosed in a sealed opaque envelope and opened by one of the investigators to know the study drug combination to be administered. Observer anaesthesiologists blinded to the test drug combination. A standardized technique of local block, using 15ml of local anaesthesia infiltrated at posterior auricular area to block greater auricular nerve and lesser occipital nerve, between tragus and helix to block sensory branch of vagus and anterior to tragus blocking auriculotemporal nerve and between tragus and helix using 2% lignocaine with 1 in 200000 dilution of adrenaline with 30mcg of clonidine hydrochloride for study group A and 15ml of 2% lignocaine with 1 in 200000 dilution of adrenaline with 0.2ml normal saline given for control group B by the same surgeon, after confirming complete blockade the procedure started. When the surgeon starts closing the skin, infusion stopped. After the procedure the patient shifted to the recovery room and monitored for 2 hours.

Intraoperatively, duration of analgesia, the time from the administration of local anaesthesia to the time of the first analgesic request in the postoperative period is noted. Inj.paracetamol 1gram I.V. Infusion is given for postoperative analgesia. Patients were asked to rate intraoperative pain using Visual Analogue Scale scoring from 1-10-point Visual Analogue Scale (VAS) by asking patient (0-3 mild pain, 4-7 moderate pain, 8-10 severe intolerable pain). Surgeon satisfaction scores were assessed using Likert scale consisting of scoring from 1 to 7 (1- extremely dissatisfied, 2- dissatisfied, 3- somewhat dissatisfied, 4- undecided, 5- somewhat satisfied, 5- satisfied, 6- extremely satisfied). Side effects if any are treated and noted.

The sample size was calculated based on a study conducted by Raghuwansi SK et al [6]. The mean ± SD of total duration of analgesia was 177.13±48.90 in study group A and 53.66 ±7.7 in control group B. At 95% confidence level and 80% power considering the maximum clinical difference allowed for the study group to be considered non-inferior with the control group is 150. The estimated sample size n=27.3 that is 28 per group, considering dropout rates, 33 patients were enrolled in each group (Total 66).

*Statistical Analysis:* Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven`s

test for homogeneity of variance has been performed to assess the homogeneity of variance. A t-test is a statistical test that is used to compare the means of two groups. It is often used in hypothesis testing to determine whether a process or treatment actually has an effect on the population of interest or whether two groups are different from one another with the null hypothesis (H0) is that the true difference between these group means is zero and the alternate hypothesis (Ha) is that the true difference is different from zero. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small.

## Results

Demographic data (Table 1) were comparable in both the groups. Duration of analgesia (Table 2) in group A was more than 120minutes but in group B Only 21.9% of patients had duration of analgesia more than 120 minutes. P value was ≤0.001, which was significantly higher in group A.

**Table-1: Demographic data of patients of group A and group B**

| Parameter | Group A | Group B | P value |
|---|---|---|---|
| Age in Years | 38.44 ±9.35 | 36.03 ±7.97 | 0.272* |
| Sex (Male-Female) | 16 : 16 | 18:14 | 0.806* |
| Weight in kgs | 61.28 ±8.56 | 63.34 ±8.59 | 0.102* |
| ASA Grade (1/2) | 21/11 | 21/11 | 0.791* |
| *P value observed > 0.05 are found to be statistically not significant | | | |

**Table-2: Intra operative clinical data and measured parameter**

| Parameter | Group A | Group B | P value |
|---|---|---|---|
| Duration of Analgesia (mins) | 228.13 ±8.78 | 106.56 ±25.82 | <0.001 |
| Pain Score (VAS) | 1.3±0.3 | 2.0±0 | <0.001 |
| Surgeon's satisfaction score | 6.1±0.4 | 5.4±0.7 | 0.001 |
| *P value observed <0.001 are are found to be statistically significant | | | |

Pain score (figure 1) was assessed using visual analog scale, group A showed VAS 1 among 40.6%, VAS 2 among 59.4% and VAS 3 among 0% patients and in group D, VAS 1 among 12.5% patients, VAS 2 among 62.5% patients, VAS 3 among 25% patients, P value was <0.001 which is strongly significant. Surgeon's satisfaction (figure 2) assessed by Likerts scale, Group A showed 46.9% of patients in likert 6 and 53.1% patients in likert 7. Group B showed 71.9% patients in likert 5, 28.9% patients in likert 6. The P value was <0.001, significantly higher in Group A.

**Fig-1:** Graphical representation of Pain score

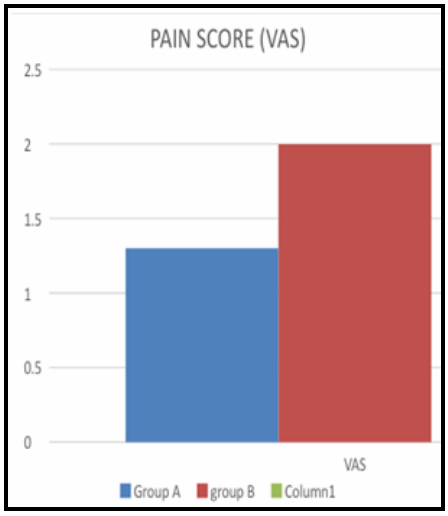
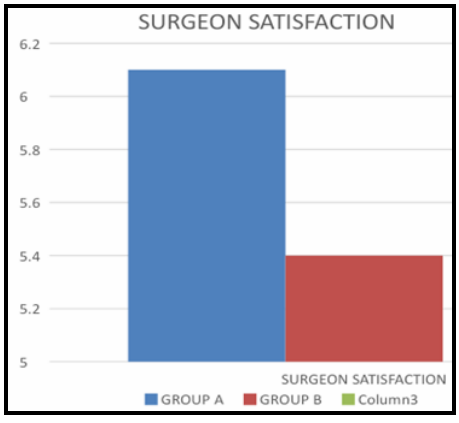



**Fig-2:** Graphical representation of surgeon's satisfaction score




## Discussion

Local anaesthesia for middle ear surgery achieves better compliance, avoids unwanted complications, adequate analgesia, sedation in intraoperative period and also gives adequate

postoperative analgesia [6]. Alpha agonist drugs when injected along axons had been shown to increase the efficacy of local anaesthetic drugs and thereby improving nerve block characteristics resulting in local vasoconstriction and facilitating C fibre block via local anaesthetic drug [7-8]. Alpha-2- agonists have been shown to be effective for their analgesic, sedative-hypnotic and as well as sympatholytic properties.

The benefit of adding clonidine to LAs for peripheral nerve blocks is less clear, although it is widely believed that clonidine improves quality as well as the duration of a LA block. The beneficial effect of clonidine in extending duration of peripheral nerve blocks is believed as a locally mediated effect, which is not reproduced by systemically administered clonidine [9-10]. In this study, we decided to see the effects of clonidine in the infiltration block.

In our study the demographic profile of the patients like age, gender, weight and ASA physical status were comparable between both the groups. In a study done on 20 volunteers by Pratap et al.,[10] and another study by Ashok Chaudhari et al., [11] also had similar demographic data compared to our study. We found all the patients of group A had duration of analgesia more than 120minutes, but in group B only 21.9% of patients had duration of analgesia more than 120 minutes which was significantly higher in group A. In a study conducted by Pratap et al.,[12]. Infiltration of 10mcg of clonidine with lidocaine abolished normal sensation at the site for up till 6 h, compared with plain lidocaine. In a study conducted by Ranganath A et al.,[4] 1 mcg/kg clonidine added to lidocaine 2% with 1:200000 epinephrine in ultrasound guided brachial plexus block has significantly higher duration of sensory and motor block compared to lidocaine 2% with 1:200000 epinephrine alone.

Hrishi AP et al.,[13] in studying the efficacy of clonidine as an additive in the duration action of brachial plexus perfomed under ultrasound guidance showed comparable results to our study. In a similar study conducted by Chaudhary A et al.,[12] administration of clonidine as adjuvant to infiltration anaesthesia for tympanoplasty surgeries. They found that addition of clonidine to lignocaine for post auricular block in patients posted for tympanoplasty, proved to be more effective in providing analgesia intra operatively and post operatively. Post operative nausea and vomiting incidence was also lower in clonidine group.

Daniel M et al.,[14] in their study of Clonidine as an adjuvant to local anaesthetics for peripheral nerve and plexus blocks concluded that, in patients undergoing surgery, clonidine when added to a LA for peripheral nerve or plexus block, prolongs the duration of post-operative analgesia by about 2 hours. In a similar study conducted by Chowda PM et al.,[15] comparing epinephrine 200mcg or clonidine 90mcg as adjuvants to local anaesthetic agent in brachial plexus block via supraclavicular approach found that 90mcg of clonidine was a better option as an additive than epinephrine 200mcg for hastening the onset of sensory and motor block with prolonged postoperative analgesia and sedation as the only adverse effect.

We assessed pain using visual analog scale. Group A showed VAS score 1, score 2, score 3 in 40.6%, 59.4%, 0% patients respectively. Group D showed VAS score 1, score 2, score 3 in 12.5%, 62.5%, 25% patients respectively. P value was <0.001 which was strongly significant. A study conducted by Chaudhari A et al.,[12] using administration of Clonidine as adjuvant to infiltration anaesthesia for tympanoplasty, 30mcg clonidine added to xylocaine for post auricular nerve block, pain scores reflected a significantly lower mean pain score in group having clonidine when compared to group without clonidine at second hour.

The Surgeon's satisfaction in our study was assessed by likert scale, In Group A, 46.9% of patients were in likert 6 and 53.1% patients in likert 7. In group B, 35.9% patients were in likert 5, 37.5% patients in likert 6 and 26.6% patients in likert 5. The P value was significantly higher in Group A. In a similar study conducted by Raghuwanshi SK et al., [6] with the use of Clonidine as an adjuvant to infiltration anaesthesia in tympanoplasty, and was found that 30 µg clonidine added to lidocaine 2 % showed higher surgeon satisfaction score compared to group without clonidine.

## Conclusion

Duration of analgesia was more with lignocaine with adrenaline and clonidine as an adjuvant compared with lignocaine with adrenaline alone infiltration, even pain score and surgeon's satisfaction were better with clonidine as an adjuvant with lignocaine for middle ear surgeries.

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