ORIGINAL RESEARCH PAPER

Volume-9 | Issue-3 | March-2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A RANDOMIZED DOUBLE BLIND STUDY FOR COMPARISION OF DEXMEDETOMIDINE VERSUS CLONIDINE AS A PREMEDICATION FOR OLIGEMIC FIELD IN MIDDILE EAR SURGERY

Anaesthesiology

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ABSTRACT

Aims; The aim of this study was to compare the efficacy of pre operative use of dexmedetomidine and clonidine for producing quality of surgical field visualization during middle ear surgery. Secondary goal was to compare the two agents in regards to satisfaction of surgeon, adverse effects and post op need of analgesia.

Method; This prospective study was conducted on 60 patients of either sex belonging to American Society of Anaesthesiologists (ASA) physical status I-II, aged 18 to 60 years, scheduled for elective microscopic operation in middle ear. **Group D :** Patient received iv dexmedetomidine 1 mcg/kg diluted in 100 ml saline solution 15 mint before anaesthesia induction. **Group C :** Patients received iv clonidine 1.5 mcg/kg diluted in 100 ml saline solution 15 min before anaesthesia induction. Isoflurane %was titrated to maintain mean blood pressure around 30% descent in blood pressure. isoflurane percentage was recorded every 15 mint until extubation. bleeding at the surgical field and quality of vision under the operating microscope were evaluated by same surgeon every 15 min in the first hour and then every 30 min according to the intraoperative Surgical field Evaluation (IOSFE) Boezart scale.

Result; Main outcome in this study depends on the IOSFE scale score , which was statistically significantly lower (better quality of vision of the surgical field) in the **Group D** than in the **Group C** in all study times. Surgeon's satisfaction score was significantly better in **Group D**. The amount of blood loss was significantly lower in the **Group D** (61.86 ± 3.87 ml) than in the **Group C** (84.7 ± 10.03 ml), At the end of surgery the mean VAS in **Group D** was significantly lower as compared to **Group C** at admission, 15, and 30 mint after admission in PACU.

Conclusion; Preinduction bolus dexmedetomidine 1 µg/kg is more effective than bolus clonidine 1.5 µg/kg; for providing controlled hypotension, lesser bleeding at the surgical site and lesser requirement of isoflurane concentration.

KEYWORDS

INTRODUCTION

Middle ear surgeries have made a significant progress with the use of the operating microscope, which magnifies the surgical field many times; however, it also magnifies the blood droplets and thus a small amount of blood can obscure the surgical field.

The practice of middle ear surgery under anesthesia has undergone a revolution with the introduction of hypotensive anesthesia to provide a relatively bloodless field while using an operating microscope.Use of inhalational agents such as halothane, isoflurane, intravenous (IV) propofol infusion, vasodilators like sodium nitroprusside, glyceryl trinitrate (GTN), prostaglandin E1, remifentanil, magnesium sulphate, beta-adrenergic blocker like esmolol, labetalol, metoprolol to alpha adrenergic agonist like clonidine and dexmedetomidine. Dexmedetomidine is highly selective alpha2 adrenergic agonists having several beneficial actions during the perioperative period. In addition to central sympatholytic action, dexmedetomidine also decreases the requirement of opioids and anaesthetic drugs and provides adequate sedation, analgesia as well as vasoconstrictive effect.

Clonidine is an alpha -2 agonist that has been used for premedication in adult and pediatric patient. Clonidine is effective by stimulation of pre and post synaptic alpha -2 agonist in many area of central nervous system leading to sedation, analgesia and reduction of sympathetic tone. single preoperative administration of clonidine can reduce surgical time and improve surgical result through a less bloody field**.**

This prospective, randomoised double blinded study was designed to compare the efficacy of preoperative iv bolus dexmedetomidine 1 mcg/kg and clonidine 1.5 mcg/kg for producing controlled hypotension as well as on visibility of surgical field,

satisfaction of surgeon and postoperative need of analgesia.

Material and Methods

After approval from ethical committee, the study was conducted at S.R.N. Hospital over a period of one year. All patients were visited the day before surgery and all patients were explained the purpose of the study along with the procedure and thereafter a valid, informed and written consent was taken from all the patients undergoing study. This prospective study was conducted on 60 adult patients (Thirty patients in each group) of either sex belonging to American Society of Anaesthesiologists (ASA) physical status I-II, aged 18 to 60 years, scheduled for elective microscopic operation in middle ear.

INCLUSION CRITERIA

1) Patients of ASA I and ASA II
2) Patients with age 18 to 60 years.
3) Patients with written valid consent.
4) Patients undergoing elective microscopic middle ear surgery.

Patient eligible for the study (60 patient) were randomly allocated in to the two study group of 30 patient each using the random allocation software. The allocation ratio was 1:1, and group identification paper was put in a sealed and opaque envelopes to hide allocation.

Group D : Patient received iv dexmedetomidine 1 mcg/kg diluted in 100 ml saline solution 15 mint before anaesthesia induction.

Group C : Patient received iv clonidine 1.5 mcg/kg diluted in 100 ml saline solution 15 mint before anaesthesia induction.

Study drug was diluted in equal amount of normal saline in both group and transfuse over similarly, time for blinding purpose.

IV line was secured when they entered operation room, preoxygenation for 3 mint followed by induction of anaesthesia with 2 mg /kg propofol was carried out until loss of verbal communication. There after .1 mg/kg vecuronium followed by positive pressure ventilation with face mask delivering isoflurane administered until adequate relaxation and intubation was performed with suitable size endotracheal tube. Anaesthesia were maintained with isoflurane and

vecuronium, patient were under controlled ventilation at respiratory rate 12 cycle per minute and tidal volume 6 ml/kg. isoflurane %was titrated to maintain mean blood pressure around 30% descent in blood pressure. isoflurane percentage was recorded every 15 mint until extubation. Blood pressure, oxygen saturation, and HR were recorded at the following time : before intubation baseline, 1, 5, 15, 30, 60, 90, 120, 150, and 180 mint. A volume of 5 ml/kg/h of.9% saline was given during the operation. bleeding at the surgical field and quality of vision under the operating microscope were evaluated by same surgeon every 15 min in the first hour and then every 30 min according to the intraoperative Surgical field Evaluation (IOSFE) Boezart scale.[table 1]

Table 1 : (IOSFE) Boezart scale

Degree of bleeding	Grade
No bleeding	0
Slight bleeding: no suctioning of blood required	1
Slight bleeding: occasional suctioning required, surgical field not threatened	2
Slight bleeding: frequent suctioning required, surgical field threatened a few seconds after suction removal	3
Moderate bleeding: frequent suctioning required, threat of bleeding in surgical field directly after suction removal	4
Severe bleeding: constant suctioning required, bleeding appears faster than can be removed by suction. Surgical field severely threatened and surgery not possible	5

At the end of surgery surgeon was asked to score according to Surgeon satisfaction Criteria Score (4-Excellent; 3-Good; 2-Fair; 1-Poor).

The amount of blood loss was calculated as follows volume of bloody fluid in the suction container -volume of irrigating fluid**.** At the end of the surgery, anesthesia was discontinued and muscle relaxation was reversed with intravenous 0.01 mg/kg atropine followed by 0.05 mg/kg neostigmine. patients were transferred to the PACU Visual analogue scale was recorded every 15 min in the PACU; if patients suffered from pain (visual analogue scale more than 4), they were given diclofenac 75 mg intravenously. If they suffered from vomiting they were treated with ondansetron 4 mg intravenously.Patient's sedation scores were noted according to Ramsay Sedation Score during postoperative period. Ramsay Sedation Scale is as given below

1. Anxious and agitated or restless or both.
2. Cooperative oriented and tranquil.
3. Drowsy but respond to commands.
4. Asleep, brisk response to light glabellar tap or loud auditory stimulus.
5. Asleep, sluggish response to light glabellar tap or loud auditory stimulus.
6. Asleep or unarousable.

Statistical Analysis

Statistical analysis was performed using Microsoft Excel 2010 and statistical software plug-ins. Student t test (paired and unpaired) test. Data are being represented as mean ± SD. A $P < 0.05$ was considered statistically significant and $p < 0.001$ was considered statistically highly significant.

Result and Observation

A total of 60 patients of ASA physical status I or II undergoing middle ear surgery were enrolled in the study and analyzed. They were randomized into two groups of 30 each: the dexmedetomidine (D) group and the clonidine (C) group. There was no statistically significant difference between the two groups as regards demographic data such as age, weight, height, sex of patients, and type of surgery [Table 2].

Table 2: Demographic Data

Item	Group-D [Dexmedetomidine]	Group-C [Clonidine]	P value
No. of Patients	30	30	
Age [in years]	34.03 ±9.7	36.4±11.2	.386
Sex [Male/Female]	22/8	21/9	
Weight [kg]	62.83±8.93	64.86±10.25	.4161
Height[cms]	166.03	167.06	.5735
TYPE OF OPERATION			
Mastoid Exploration	21	25	
Myringoplasty	9	5	

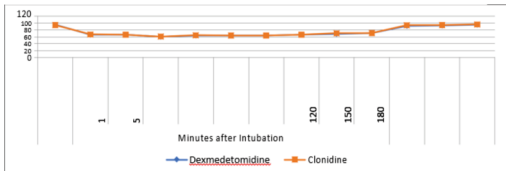

Fig.-1: Comparison of Mean Arterial Pressure between group D and Group C

As regards mean blood pressure, it was lower in the dexmedetomidine group when compared with the clonidine group.

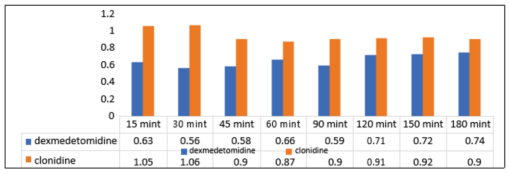

Fig.-2: Comparison of required Isoflurane concentration between group D and group C

The required percentage of isoflurane concentration was significantly less ($P < 0.05$) to maintain the desired mean blood pressure in patient of group dexmedetomidine than clonidine group.

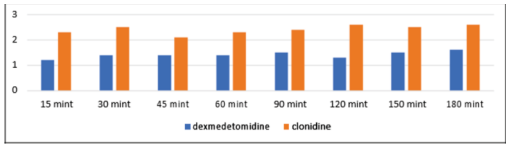

Fig.- 3 : Intraoperative Surgical Field Evaluation Score

Main outcome in this study is the IOSFE scale score [figure 3], which was statistically significantly lower (better quality of vision of the surgical field) in the dexmedetomidine group than in the clonidine group in all study times..

Table-3: Surgeon satisfaction score

	Group D	Group C
1=Bad	1(3.3%)	3 (10%)
2=Moderate	2 (6.6%)	9 (30%)
3=Good	9 (30%)	10 (33.3%)
4=Excellent	18 (60%)	8 (26.60%)

Surgeon's satisfaction score was significantly better in dexmedetomidine pretreated group than clonidine pretreated group [Table 3]

TABLE 4: Comparison of studied variable in PACU

Parameter	Group dexmedetomidine	Group clonidine	P value
Requirement of post-operative analgesia ime(mint)	24.8 ±4.08	8.23±2.4	<.0001
Vomiting	3(10%)	8(26%)	.1097
Hypotension	4 (13.3%)	5 (19.9%)	.4597
Bradycardia	3 (10%)	4 (13.3%)	.6928

There were no patients suffering from respiratory depression (SpO 2 <90%) in both groups during the postoperative period. Only four (13.3) %patients in the dexmedetomidine group and five (19.9%) patients in the clonidine group suffered from hypotension statically insignificant. and three (10%) patient in dexmedetomidine group four (13.3%) patient in clonidine group suffered from bradycardia statically insignificant. 3(10%) patient in group D and 8 (26%) patient in group C suffered from vomiting statically insignificant.

VAS (visual Analogue Scale)

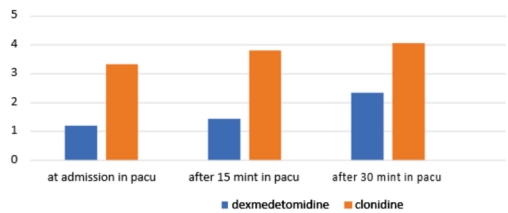

Fig.-4: Comparison of mean VAS score between two group

At the end of surgery the mean VAS in group dexmedetomidine lowered significantly as compared to group clonidine at admission, 15, and 30 mint after admission in pacu. (figure 4)

DISCUSSION

In this study, we had chosen a target MAP (reduction of 30% of baseline mean blood pressure) to provide the best surgical conditions without the risk of tissue hypoperfusion depending on a review of study conducted by Barak *et al*.[1] with a MAP of 50-65 mm Hg during major maxillofacial surgeries. Hypotensive anesthesia induced by using sodium nitroprusside or nitroglycerine in mandibular osteotomy to achieve MAP 60-70 mm Hg was found to be absolutely safe. [2] .

C.N. Navya1 et al [3] 2018 conducted a study Dexmedetomidine over Labetalol for oligemic surgical field in middle ear microsurgeries the result of this study was the Patients receiving dexmedetomidine had significantly lesser bleeding at surgical field and better surgeon satisfaction score ($P < 0.05$). Mean time required for postoperative analgesia was significantly higher with dexmedetomidine group.

Ahmed Z Mohamed**,** Usama G Abd-Elnaby [4] 2015 conducted a study To compare between the effects of dexmedetomidine and magnesium sulphate on quality of surgical field visualization in middle ear surgery .The result of this study was Dexmedetomidine provided better quality of surgical field vision and less bleeding when compared to magnesium sulphate without any side effects in middle ear surgery.

Kumkum Gupta, Manoranjan Bansal, Prashant K Gupta et al 2015. [5], conducted a study Dexmedetomidine infusion during middle ear surgery under general anaesthesia to provide oligemic surgical field**:** The result of this study was Patients receiving dexmedetomidine infusion had statistically significant lesser bleeding at surgical field ($P < 0.05$).

Malla Sadiq M, Junaida S, Mir Younus M 2017 [6] conducted a study to see the Efficacy of dexmedetomidine infusion as an anesthetic adjuvant to provide oligemic surgical field in middle ear surgeries The result of this study was the *Dexmedetomidine was found to significantly reduce intra operative bleeding. This, in turn, improves operative field visibility and increases surgeon's satisfaction during middle-ear surgery under general anesthesia.*

A Das, A Mukherje, S Chhaule, S Chattopadhyay et al [7] 2016 to Induced hypotension in ambulatory functional endoscopic sinus surgery: A comparison between dexmedetomidine and clonidine as premedication The result of this study was Dexmedetomidine found to be providing more effectively controlled hypotension and analgesia, and thus, allowing less nasal bleeding as well as more surgeons' satisfaction score.

The results of our study are consistent with these above mentioned studies, as the main outcome in this study is the IOSFE scale score (intraoperative surgical field evaluation scale) [table1] [figure 3], which was statistically significantly lower (better quality of vision of the surgical field) in the dexmedetomidine group than in the clonidine group. Patients receiving dexmedetomidine had significantly better surgeon satisfaction score ($P < 0.05$) [table 3]. Mean time required for postoperative analgesia was significantly higher with dexmedetomidine group. [table 4] At the end of surgery, the mean VAS in group dexmedetomidine lowered significantly as compared to group clonidine. [figure 4]

As regards isoflurane concentration this study show the required percentage of isoflurane concentration was significantly less to maintain the desired mean blood pressure in patient of group dexmedetomidine than group clonidine.[table 5] The same result is found in C.N.Navya at al[3].

In our study, nausea, vomiting, and bradycardia, hypotension were comparable among two groups. But, the bradycardia was more in the clonidine group in a in significant manner than dexmedetomidine group. Again, hypotension was more in clonidine group than dexmedetomidine group but the result is insignificant. Both drug are hemodynamically stable. the same result found C.N. Navya1 et al[3] 2018 in their study.

CONCLUSION

On the basis of finding of our study we conclude that preinduction bolus dexmedetomidine is more effective than clonidine for providing controlled hypotension with smaller need of an additional hypotensive agent isoflurane and rendering an excellent surgical field with higher surgeon's satisfaction score and lesser post-operative analgesic requirement without major hemodynamic alteration.

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