

Research Article

A Clinical Study to Assess the Hypotensive Property of Dexmedetomidine and its Efficacy to Provide Oligemic Surgical Field in Middle Ear Surgery

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Abstract: Middle ear surgery is a type of microsurgery which requires minimum extravasation of blood into the surgical field for a better vision during surgery and hence a better outcome of surgery. The objective of the present study was to use dexmedetomidine an alpha-2 agonist to provide hypotensive anesthesia to minimize blood spillage during the middle ear surgeries. In this study the sample size was 25 subjects for each group at an alpha error 0.05 and power 80%. With written, informed consent, 50 patients of ASA grade I and II, aged 18-58 years, weight 40-70 kgs, undergoing elective surgeries under general anaesthesia, were randomly allocated into two groups. Group-A received Dexmedetomidine 1mcg/kg loading dose over 10 mins after premedication but before induction and a maintenance infusion of 0.4mcg/kg/hr which was stopped 20 mins before completion of surgery. Group-B received 10 ml normal saline as placebo. All the patients were observed intra operatively for vitals (HR, SBP, DBP, MAP, SPO₂), suction requirement every 15 minutes and post operatively for Ramsay sedation score. It was observed that patients in group – A had significantly lower HR, SBP, DBP, MAP as compared to group – B. Both the groups were comparable for demographics, SPO₂, suctioning requirement during surgery and post operative sedation. Our study concluded that Dexmedetomidine is effective in providing hypotensive anesthesia and can be used to provide oligemic surgical field without post operative sedation.

Keywords: Dexmedetomidine, middle ear, hypotensive anesthesia, Ramsay sedation, placebo, suction.

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INTRODUCTION

Hypotensive anesthesia is one of the most demanding techniques of anaesthesia, which results in a better surgical outcome. In this technique, the patient's mean blood pressure is reduced by approximately thirty percent⁽¹⁾. Maintaining patient's blood pressure within normal limits during the intra operative period is usually considered one of the markers of ideal and skillful anesthesia but a deliberately reduced and controlled blood pressure is advantageous because it reduces overall blood loss which provides the surgeon a clear surgical field. There are several surgeries which need a dry surgical field for a better outcome such as FESS (functional endoscopic sinus surgery), thyroid surgery, neurosurgery, hand surgery, spinal surgery etc. Middle ear is a delicate structure which requires not only a perfect hand in surgery but also an oligemic

surgical field for best vision. It also decreases the need of blood transfusion and hence it's complications too. There are numerous pharmacological agents which can be used for lowering systemic blood pressure to provide hypotensive anesthesia, like, nitroglycerine, calcium channel blockers, beta blockers, alpha-2 agonist, volatile inhalational agents and prostaglandin E1. Dexmedetomidine is one of the potent and selective alpha-2 agonist. It is used as an adjuvant agent to general anaesthesia before induction and as infusion during intra-operative period to provide hemodynamic stability. It is a valuable drug because of its anaesthetic effect and dose-dependent haemodynamic effects. The present hospital based interventional prospective randomized double blind study was aimed to evaluate the effect of dexmedetomidine in lowering the systemic

blood pressure, quality of oligemic surgical field and post-operative sedation.

MATERIAL AND METHOD

After approval from the institutional ethical committee (IEC) and review board, written informed patient consent was taken. A total of 50 adult patients of American Society of Anaesthesiologists (ASA) physical status I and II of both genders, aged 18-58 years, weighing 40-70 kg, scheduled for elective middle ear surgery for unilateral CSOM and ASOM, having no surgical complication leading to re-intervention and prolonged ventilation were included in the study.

Exclusion criteria include history of allergy to these drugs, patient with pre-existing bleeding and coagulation abnormalities and history of hypertension. Patients were randomly divided into two groups of 25 patients each by a simple random technique through chit in box method. All patients were visited on the day prior to surgery and explained about the anesthetic technique and peri-operative course. Each patient had a pre-anesthetic checkup. On arrival to the operation theatre, PAC and written informed consent was checked and patient was taken to OT. Pre operative HR, SBP, DBP, MAP and SPO₂ were noted down. Intravenous access achieved and Ringer Lactate started at 8 ml/kg/hr. Patients were premedicated with injection midazolam 1mg, injection glycopyrrolate 0.2 mg, injection ranitidine 50 mg, injection metoclopramide 10 mg, injection fentanyl (2 mcg/kg). Patients of Group-A received dexmedetomidine bolus of 1mcg/kg in 10 ml normal saline over 10 minutes followed by maintenance infusion at 0.4 mcg/kg/hr intra-operatively. Patients of Group-B received 10 ml normal saline over 10 minutes followed by infusion of normal saline intra-operatively. Preoxygenation done with 100% oxygen. Patients were induced with injection propofol 1- 2 mg/kg till loss of verbal command and muscle relaxation with succinylcholine 2 mg/kg. After intubation patients were maintained on oxygen and nitrous oxide with inhalational agent isoflurane and injection atracurium (0.5mg/kg) as needed. During intraoperative period observed parameters were heart rate, arterial blood pressure, ECG, and SpO₂, surgical site check for bleeding and need of suctioning, observed every 15 mins. The respective infusion was stopped 20 minutes before the completion of surgery. Assessment of intra-operative bleeding was done by surgeon after every 15

minutes as follows: no bleeding - no suction, minimum bleeding - spordiac suction, diffuse bleeding- repeated suction and troublesome bleeding- continue suction. After completion of surgery, neuromuscular reversal was achieved with injection neostigmine 0.05mg/kg and injection glycopyrrolate 0.4mg. Patients were extubated after observing adequate motor power and spontaneous breathing efforts. Assessment of post-operative sedation was done using Ramsay sedation score in recovery room. The sample size was calculated as 95% confidence level assuming proportion of diffuse bleeding in middle ear surgery in group-A receiving dexmedetomidine infusion and group -B receiving placebo infusion as 0.156 and 0.678 respectively. At alfa error of 0.05 and power of 80%, the sample size required to get detect difference was 17 in each group, which was further enhanced to 25 cases in present study. The demographic data for categorical variables were compared using student t-test and chi square test. Time statistical variables were compared using student t-test. Result was considered as statistically significant if p value <0.05. Study design is hospital based interventional prospective randomized double blind study and used simple random technique through chit in box method.

RESULTS

This study was done to assess the effect of dexmedetomidine on blood pressure. The study was successfully completed on 50 adult consenting patients and all patients under study were included in the data analysis. Groups were comparable for vitals, suctioning requirement and post-operative sedation. The mean arterial blood pressure 5 minutes after start of surgery in group-A and group-B was (88.4±7.5) and (94.5±6.9) respectively with *P* value < 0.05, after 30 min was (83.6±7.7) and (94.3±7.1) respectively with *P* value < 0.05. Heart rate after 5minutes in group-A and B was (65.8±13.5) and (106.9±13.7) respectively with *P* value < 0.05, after 30 min was (59.8±9.2) and (102.9±9.2) with *P* value< 0.05. Suctioning requirement was less in group-A as compared to group-B but the difference between the two groups was statistically not significant with *P* value >0.05. After recovery, all the patients were following commands and post-operative sedation between the two group was non-significant. No significant side effect of dexmedetomidine was seen during surgery and in the post-operative period.

Table-1. Showing demographic data between two groups

Parameters	Group-A	Group-B
Numbers (n)	25	25
Age (years)	39.68±11.92	36.12± 9.51
Weight(kg)	60.4 ±7.03	61.8±6.44
Gender(male/female)	16/9	16/9
ASA (I/II)	7/18	12/13
Mallampati grading (1/2)	2/23	16/9

Table 2: Change in heart rate during anesthesia

Heart rate	Group-A	Group-B
Baseline	77.8±15.4	84.2±12.9
After induction	61.5±8.0	108.4±3.8
After induction		
5mins	65.8±13.5	106.9±13.7
20mins	59±7.8	104±11.7
35mins	59.8±9.2	102.9±9.2
50mins	57.9±11	102±8.5
65mins	55.6±7.1	98.1±6.9
80mins	56.8±7.3	98.2±6.7
95mins	56.9±7.7	98.2±6.7
110mins	58.3±10	102.9±9.2
125mins	57.0±7.2	97.3± 7.7
140mins	57.0±6.1	98.2±6.7

Table 2. Showing comparison of dexmedetomidine and placebo on heart rate. Dexmedetomidine before intubation as compare to placebo blunt the effect of laryngoscopy and surgical stress on heart rate. Statistically difference between two group is significant throughout the surgery with p value <0.05

Table 3. Change in systolic blood pressure, diastolic blood pressure and mean arterial pressure.

Parameters	Group-A	Group-B
Baseline		
SBP	123.6±9.5	124.1±12.1
DBP	80.8 ±10.0	79.5±7.9
MAP	96.0±12.1	94.4±7.6
After induction		
SBP	121.2±11.1	132.6±10.6
DBP	74.6±6.9	81.±16.9
MAP	90.0±7.7	90.0±6.1
After induction		
5mins		
SBP	117.7±10.4	123.4±11.5
DBP	71.8±6.1	79.8±7.6
MAP	88.4±7.5	94.5±6.9
20mins		
SBP	111.6±10.2	124.1±12.1
DBP	70.4±6.5	79.5±7.9
MAP	83.8±7.5	94.4±7.6
35mins		
SBP	110.9±11.4	123.7±12.2
DBP	68.1±4.5	79.8±7.7
MAP	83.6±7.7	94.3±7.1
50mins		
SBP	110.8±11.4	123.7±12.2
DBP	68.4±6.0	79.5±7.9
MAP	82.3±7.3	94.7±7.6
65mins		
SBP	110.4 ±12.3	123.4±11.5
DBP	65.7±3.9	79.8±7.6
MAP	82.2±7.5	94.5±6.9
80mins		
SBP	112.2±12.1	123.7±11.2
DBP	66.0±4.3	79.6±7.7
MAP	81.4±6.7	94.3±7.2
95mins		
SBP	113.1±11.5	124.1±12.1

	DBP	68.2±5.3	79.5±7.9
	MAP	83.1 ±6.8	94.4±7.6
110mins			
	SBP	111.1±8.5	124.1±12.1
	DBP	66.5±5.2	79.5±7.9
	MAP	83.0±7.6	94.4±7.6
125mins			
	SBP	110.9±8.0	123.7±11.2
	DBP	70.7±9.9	79.6±7.7
	MAP	84.0±8.9	94.3±7.2
140mins			
	SBP	109.3±10.0	131.1±9.5
	DBP	65.8±4.8	81.0±6.7
	MAP	81.5±8.2	98.4±5.2

Table 3. Shows the distribution of patients according to systolic blood pressure, diastolic blood pressure and mean arterial pressure status in each

group. It was observed that there was statistically significant between each group ($p < 0.05$).

Table-4. Suctioning requirement assessment by surgeon during surgery

Grade	suctioning requirement	group-A	group-B
0:No bleeding	no suction	0	0
1:minimal bleeding	sporadic suction	21	16
2:diffuse bleeding	repeated suction	4	6
3:troublesome bleeding	continue suction	0	3

Table 4. Shows the distribution of patients according to suctioning requirement status in each group. Number of patients requiring continue and

repeated suction is less in group A as compare to group B but statistically not significant with P value >0.05 .

Table 5. Distribution of study subjects according to Ramsay grading

Ramsay grading	Dexmedetomidine group		Control group		Grand Total	
	N	%	N	%	N	%
1	0	0	3	12	3	6
2	21	84	20	80	41	82
3	4	16	2	8	6	12
Grand Total	25		25		50	

Table No 5. Shows the distribution of patients according to ramsay sedation grading status in each group. It was observed that there was no statistically significant difference regarding ramsay sedation grading status between each group ($p > 0.05$).

It is evident from the study that the patients receiving dexmedetomidine infusion have oligoemic surgical field and better visibility when compared to patients receiving placebo. These findings can be attributed to the fact that dexmedetomidine reduces sympathetic activity, resulting in lower blood pressure and reduced heart rate thereby decreasing blood loss at the surgical site to improve the quality of the surgical field.

DISCUSSION

A precise and smooth middle ear surgery requires a good surgical field visibility and causes minimum post-operative nausea and vomiting. Even a small amount of blood can obscure the microscopic operating field. Decreasing the extravasation of blood in the surgical field may improve the results of surgical procedures. In the present study, dexmedetomidine infusion was used to provide an oligoemic surgical field during middle ear surgery using operating microscope.

Our study shows that injection dexmedetomidine causes statistically significant lowering of systolic blood pressure and heart rate ($p < 0.001$). Bekker *et al* (2008) and Tanskanen *et al* (2006) observed the same in their respective studies. It is because dexmedetomidine regulates the autonomic and cardiovascular system. It inhibits norepinephrine

release at sympathetic nerve terminals, thereby attenuating the heart rate, blood pressure response to intraoperative stressful events of anesthesia and surgery. Hence confirming that dexmedetomidine is effective in providing hypotensive anesthesia. Our study does not show any significant effect on reducing amount of intraoperative bleeding ($p>0.05$) whereas Ayoglu *et al* (2008) observed a significant decrease in bleeding and bleeding scores. It was also observed that there was no statistically significant difference in suctioning requirement between the two groups ($p>0.05$) in our study. Gupta *et al* (2015) however observed a significantly lower suction requirement in dexmedetomidine group. It may be because a low dose of dexmedetomidine infusion was used in our study.

A significant decrease in systolic blood pressure, diastolic blood pressure, heart rate and attenuated pressor response to laryngoscopy and intubation was observed in the dexmedetomidine group in our study. Yildiz *et al.* also observed a similar significant blunting of the haemodynamic responses during laryngoscopy and a significant decrease in blood pressure and heart rate. In our study the comparison of sedation in post-operative period between two groups did not show any statistically significant difference (p value 0.158). Yidiz *et al* (2006) however observed a significantly higher sedation in dexmedetomidine group. This could possibly be because of use of dexmedetomidine bolus as premedication.

CONCLUSION

Our study concluded that dexmedetomidine is an effective drug in providing hypotensive anesthesia, resulting in a significant decrease in systolic, diastolic and mean blood pressure. Dexmedetomidine also decreases the suction requirement during surgery and thereby the blood loss, but the result was not statistically significant. Dexmedetomidine did not cause any statistically significant increase in post-operative sedation. The use of this drug did not cause any significant side effects like bradycardia, hypotension, nausea, vomiting, dry mouth etc during intraoperative or post-operative period.

Abbreviations

ASA	American society of Anesthesiologist
ASOM	Aute serous otitis media
CSOM	Chronic serour otitis media
bpm	beats per minute
ECG	Electrocardiography
ETT	Endotracheal tube
HR	Heart rate
MAP	Mean arterial pressure
SBP	Systolic blood pressure
DBP	Diastolic blood pressure

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