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Effects of Lower Doses of Dexmedetomidine on Controlled Hypotension During Middle Ear Surgery

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Abstract

Context: Controlled hypotension is required for middle ear surgery to achieve a bloodless operative field which is achieved by dexmedetomidine. *Aims:* To study and assess the efficacy of dexmedetomidine infusion in lower doses i.e., 0.25 mcg/kg/hr to lower systolic blood pressure below 30% of baseline values, quality of oligaemic surgical field to achieve the targeted SBP in patients undergoing middle ear surgery. *Settings and Design:* Double blinded Randomised Control Prospective Study. *Methods and Material:* After obtaining ethical committee permission and patient consent, the study was conducted on 50 patients aged 18 to 60 years belonging to ASA-PS I and II undergoing middle ear surgery, were randomly divided into 2 groups. Group A received dexmedetomidine 0.25 µg/kg/hr as continuous IV infusion. Group B received dexmedetomidine 0.5 µg/kg/hr as continuous IV infusion. Exclusion criteria included cardiovascular disease, hypovolemia, bradycardia, hepatic impairment, pregnancy and lactating mothers, on sedatives and hypnotics, known allergy to dexmedetomidine. *Statistical analysis used:* Data analyzed- SPSS 22.0 software. Categorical data: frequencies, proportions. Test of significance: Chi-square test. Continuous data: Mean standard deviation. Test of significance: Independent t test. p value: < 0.05- statistically significant. *Results:* There was insignificant difference in mean HR, mean SBP, mean DBP among both groups. Both groups had excellent surgical field favourable to operating surgeons with similar grading of surgical bleed. *Conclusions:* Dexmedetomidine at lower doses i.e., 0.25 µg/kg/hr can be used safely to yield blood less surgical field in middle ear surgeries by allowing the hemodynamic variations within the physiological range.

Keywords: dexmedetomidine; middle ear surgery; oligaemic surgical field.

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Introduction

In middle ear surgery, a surgical field free of bleeding is very essential [1]. Even a very minimal bleed under the operating microscope appear like a major one and having bloodless field favours surgeons during middle ear surgeries. It provides more visibility and simplifies the procedure, also reduces time required for the procedure. It is challenging for the anaesthesiologist to maintain bleeding free environment. So, controlled hypotension came as rescue in decreasing intra operative bleeding.

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The main techniques to reduce blood loss during middle ear procedures were mild head end elevation of 15°, and topical application or infiltration of adrenaline (1: 50,000 or 1: 200,000). A mild head end elevation acts by reducing the arterial and venous pressures in head and neck but in turn increases the chance of air embolism. In case of such hypotension, head end elevation would furthermore compromise vascular supply to head and neck [1,2,3].

Several intravenous and inhalational anaesthetic methods have been studied to offer best intra operative conditions for middle ear procedures with their pros and cons [4,5].

Dexmedetomidine, a highly selective α2 adreno-receptor agonist [6]. It has dose dependent and predictable hemodynamic effects. It is useful in blunting the hemodynamic response during perioperative period due to its central sympatholytic effect [7,8,9]. It has been utilised with success intravenously with doses ranging from 0.25 to 1 µg/kg in attenuating intubation response [10,11,12].

This study purpose is to assess the efficacy of dexmedetomidine infusion in lower doses than previous studies, to reduce systolic blood pressure by 30% below baseline values, hence its effects on the quality of an oligaemic surgical field and the dose requirement of Isoflurane to achieve the targeted SBP in patients undergoing middle ear surgery.

Objectives

To assess effects of lower doses of dexmedetomidine on the following parameters.

1. Hemodynamic parameters like Blood Pressure and Heart Rate
2. Bleeding in surgical field
3. Surgeon satisfaction

Also, the percentage of Isoflurane concentration required to maintain targeted Systolic Blood Pressure, safety of the drug and adverse effects to be assessed.

Materials and Methods

After obtaining institutional ethical committee approval and informed consent from patient, a double blinded randomized control prospective study was conducted at tertiary care level. Fifty patients belonging to ASA Grade I and II of both genders, aged between 18 to 60 years, weighing more than 45 kgs scheduled for elective middle ear surgical procedures. Exclusion criteria included patients suffering from cardiovascular disease, hypovolemia, bradycardia, hepatic impairment, diabetes mellitus, pregnancy and lactating mothers, patients who are on sedatives and hypnotics, patients with known allergy to dexmedetomidine.

An elaborated clinical examination was conducted and necessary investigations sent and reviewed before surgery. Fasting of 6 hours was ensured. After securing a venous access using a 18G cannula, patient was preloaded with Ringer's Lactate infusion at a rate of 5 ml/kg/hr.

Patients were randomly allocated into two groups of 25 each. Randomization was done by computer generated table.

Group A (Dex-0.25): received dexmedetomidine 0.25 µg/kg/hr as continuous IV infusion.

Group B (Dex-0.5): received dexmedetomidine 0.5 µg/kg/hr as continuous IV infusion.

On arrival to the operation room, baseline heart rate, non invasive blood pressure, ECG, SpO_2 were recorded and monitoring was started. All patients were premedicated with Inj.Glycopyrollate 0.005 mg/kg, Inj. Fentanyl citrate 2 µg/kg and Inj. ondansetron 4 mg, 10 minutes before induction of anaesthesia. After preoxygenation for 3 minutes, patient was induced with Inj. Propofol 2 mg/kg till verbal command is lost and tracheal intubation with appropriate size oral endo tracheal tube was advanced with Inj. Succinyl choline 2 mg/kg.

Dexmedetomidine infusion was started after induction of anaesthesia upto 20 mins prior to completion of surgery.

Anaesthesia was maintained with 60% nitrous oxide in oxygen, inhalational anaesthetic Isoflurane and Inj.vecuronium, loading dose of 0.1 mg/kg as muscle relaxant. Isoflurane concentration was gradually titrated to achieve a SBP of 30% below the preoperative values. The patient was mechanically ventilated to maintain $ETCO_2$ between 30 – 35 mmHg. Monitoring was recorded every 5 minutes.

Hypotension was managed by reducing the dial concentration of Isoflurane or the infusion rate of IV fluids and bradycardia was managed with IV atropine.

The quality of hypotensive anaesthesia was determined by the operating surgeon based on the blood loss at the surgical site.

Grade 0: Nil bleed, excellent surgical condition, no suction needed.

Grade 1: Minimal bleed, sporadic suction needed.

Grade 2: Diffuse bleed, repeated suction needed.

Grade 3: Troublesome bleed, continuous suction needed.

After completion of surgery, the residual neuromuscular blockade was reversed with Inj. Neostigmine 0.05 mg/kg and Inj. Glycopyrollate 0.008 mg/kg.

Extubation was done after adequate motor recovery and spontaneous breathing efforts. The awakening time following reversal of neuromuscular blockade was recorded. Patient was later transferred to PACU to be observed for respiratory depression, sedation score, VAS score, hahemodynamic changes, nausea, vomiting or any other drug induced adverse effects or complications.

Sample size was estimated based on the difference in proportion of bleeding assessed by surgeon in two groups, from the study by Gupta K et al. diffuse bleeding in group 1 was proportion in cases is 15.6%, proportion in controls is 68.75% at 95% confidence level and 90% power, with equal ratio in two groups a sample size of 20 was obtained in each group. Considering non response rate of 20%, 20 + 4 = 24. Rounding it up, 25 patients were included in each group.

The recorded data was entered in Ms Excel and analyzed using SPSS 22 version software. Qualitative data is presented in the form of proportions and pie diagrams, bar charts is used to represent graphically. Quantitative data is presented as mean, standard deviation. Student's t test is the test of significance for quantitative data and chi-square test is the test of significance for qualitative data. p value <0.05 has been considered as statistically significant.

Results

The present study evaluated the clinical effects of dexmedetomidine infusion during middle ear surgery using operating microscope under general anaesthesia. It was successfully completed on 64 adult consenting patients, and all patients were included in the data analysis. The demographic data of age, sex, weight, ASA physical status and duration of surgery were comparable between the groups (Table 1).

Table 1: Patient Demographic Characteristics.

Parameters	Group A	Group B
Number (n)	25	25
Age (years)	34.12 ± 9.54	33.16 ± 8.54
Weight (kg)	62.4 ± 7.22	60.48 ± 6.61
Gender (male/female)	13/12	11/14
ASA status (I/II)	18/7	16/9
Surgical time (mins)	186.2 ± 67.22	159 ± 54.25

The baseline values of mean heart rate and systolic blood pressure were comparable between the groups with no statistical significance. Though mean heart rate values are comparable during intra-operative period between the groups but bradycardia was recorded in three patients of Group B which responded to intravenous atropine. There was insignificant difference in mean arterial pressure between two groups at any intervals except at 45th minute. (Figs. 1 and 2).

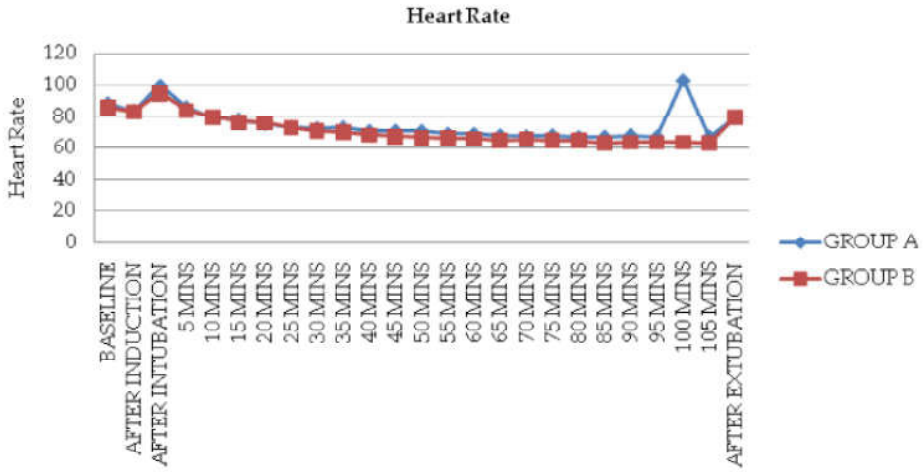

Fig. 1: Line Diagram Showing Heart Rate Comparison between Two Groups

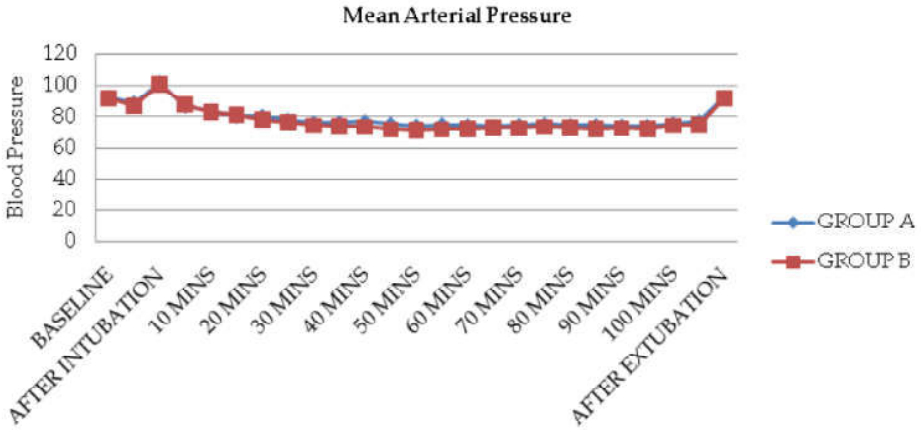

Fig. 2: Line Diagram Showing Mean Arterial Blood Pressure Comparison Between Two Groups

Table 2: Surgical Field Bleed Grading by Operating Surgeon

Surgical Field Bleed Grading	Group A	Group B	Total	Percentage
Grade 0	3	3	6	12
Grade 1	22	22	44	88

Surgeons graded bleeding at the surgical field. 88% of both groups were graded as 1 and 12% of both groups had grade Zero. None in both groups had grade 2 or 3 suggestive of major bleed. Thus suggesting that both groups had excellent surgical field favourable to operating surgeons. There was no significant difference in SpO_2 and $ETCO_2$ among two groups at any intervals. Sedation status of the patients were acceptable in both groups in the post operative period.

Quality of extubation was extremely satisfying with stable hemodynamics in both the groups. All patients were able to obey the commands, and the duration of awakening time and recovery were comparable between the groups. Post-operative respiratory rate and peripheral SpO_2 were comparable at any time. No drug related complications or side effects was seen in any patients during both intra operative period and post operative period.

Discussion

During middle ear surgeries, a good surgical field visualisation is essential while operating under the microscope. Under the microscope, even a very small amount of blood appear like a major one and thus obscure the microscopic operating field. Decreasing the extravasation of blood helps the surgeons to have better visibility and help in ease of operation and thus reduces the operating time.

Controlled hypotension helps in improving the surgical field by decreasing the intraoperative bleeding.

Many inhalational or intravenous anaesthetics have been evaluated to offer better intra operative conditions for middle ear surgical procedures with their own pros and cons. Dexmedetomidine is being most commonly used in day to day practice in anaesthesia.

Dexmedetomidine is a highly selective agonist of α2 adreno-receptor and this high selective action to α-2a receptors mediates sedation and analgesia [13]. Course of its action is predictable and has dose dependent hahemodynamic effects. Dexmedetomidine is helpful in attenuating hahemodynamic response during peri-operative period because of its central sympatholytic effect. It has been used with success intravenously with doses ranging from 0.25 to 1 µg/kg in attenuating intubation response [7]. The major side effects noted following dexmedetomidine infusion are hypotension and bradycardia [7].

This was a double blinded randomized control prospective study carried out at tertiary care centre during the period of Jan 2017 to June 2018. Fifty patients of age group 18 – 60 years with ASA grade I, II of either sex undergoing elective middle ear surgical procedures under general anaesthesia were included. After obtaining informed written consent, patients were randomly allocated into two groups of 25 each. Baseline HR, NIBP, ECG, SpO_2 were recorded. Preoxygenation was done for 3 minutes and premedicated with glycopyrollate, fentanyl and ondansetron and induced with propofol. After tracheal intubation with appropriate size oral endotracheal tube, dexmedetomidine infusion was started. Group A (Dex-0.25) received dexmedetomidine 0.25 µg/kg/hr as continuous

iv infusion and Group B (Dex-0.5) received dexmedetomidine 0.5 µg/kg/hr as continuous iv infusion. Parameters like HR, SBP, DBP, MAP SPO_2, $ETCO_2$, Isoflurane concentration were recorded till the end of surgery and dexmedetomidine infusion was stopped 20 mins prior to completion of surgery. Awakening time during extubation was noted. Sedation scores, VAS scores were assessed in the post operative period. In this study group, the drug dosage was fixed based on previous studies.

In our study, both the groups were comparable with respect to age, sex, weight and ASA physical status grading. Mean duration of surgery taken in group A is 186.2 ± 67.2 minutes and 159 ± 54.25 minutes in group B. Both groups were comparable without statistical difference. There was insignificant difference in mean heart rate between two groups at any intervals. Though mean heart rate values were comparable during intra-operative period between the two groups, episodes of bradycardia was recorded in three patients of Group B which responded to intravenous atropine. There was insignificant difference in mean systolic blood pressure among two groups at any intervals. There was insignificant difference in mean diastolic blood pressure between two groups at any intervals. There was insignificant difference in mean arterial pressure among two groups at any intervals except at 45^{th} minute with p value of 0.049. These observations showed us that 0.25 µg/kg/hr of dexmedetomidine (Group A) is sufficient to achieve targeted hemodynamic parameters without any episodes of bradycardia in any of the patients. There was insignificant difference in SpO_2 and $ETCO_2$ among two groups at any intervals. Surgeons graded bleeding at the surgical field. 88% of both groups were graded as 1 and 12% of both groups had Grade Zero. None in both groups had grade 2 or 3 suggestive of major bleed. Thus suggesting that both groups had excellent surgical field favourable to operating surgeons. Sedation status of the patients were acceptable in both groups in the post operative period.

Our study shows that the use of dexmedetomidine infusion decreased Isoflurane requirement to sustain systolic blood pressure 30% below baseline values, but more reduction of percentage of Isoflurane concentration was seen in group B than in group A. Previous studies conducted by Khan et al., Aho et al. and Aantaa et al. confirmed that dexmedetomidine usage reduces inhalational anaesthetics requirement and also proved synergism between Isoflurane and dexmedetomidine [14,15,16].

Average awakening time in group A was 182.4 ± 56.07 seconds and 177.6 ± 100.965 seconds in group B. There was insignificant difference in mean awakening time between two groups. Quality of extubation was extremely satisfying with stable hemodynamics in both the groups. This corresponded with the study conducted by Guler et al. [17] who showed the increase in heart rate and blood pressure during extubation is decreased.

No drug related complications or side effects was seen in any patients during both intra operative period and post operative period. In our study, no patients developed respiratory depression in the post operative period as dexmedetomidine was used in smaller doses.

Dexmedetomidine infusion at both 0.25 µg/kg/hr and 0.5 µg/kg/hr provided oligaemic field required for surgeries of middle ear and satisfactorily grading by operating surgeons for both groups. Though there was insignificant statistical difference seen between two groups, few episodes of bradycardia was recorded in group of patients who received 0.5 µg/kg/hr of dexmedetomidine infusion, which responded prompting to few doses of atropine. No events of bradycardia was observed in group which received 0.25 µg/kg/hr of dexmedetomidine.

To conclude, dexmedetomidine infusion at 0.25 µg/kg/hr can safely be used to yield blood less surgical field for middle ear surgical procedures allowing the hemodynamic variations within the physiological limits.

Conclusion

From our study, we hereby conclude that dexmedetomidine at lower doses i.e., 0.25 µg/kg/hr can be used safely to yield blood less surgical field in middle ear surgeries by allowing the hemodynamic variations within the physiological range.

Acknowledgement

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Key Messages

In middle ear surgeries, bloodless field is necessary under the microscope and the same can be achieved with controlled hypotension. The

use of dexmedetomidine provides hypotensive anaesthesia. It can be achieved through lower doses thereby avoiding undue side effects like bradycardia and over sedation.

Conflict of Interest: Nil

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