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Original Research Paper

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"EFFECT OF DEXMEDETOMIDINE INFUSION IN MIDDLE EAR SURGERY UNDER GENERAL ANAESTHESIA TO PROVIDE OLIGAEMIC FIELD"

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ABSTRACT

Introduction: Common middle ear pathologic conditions requiring surgery include tympanoplasty (reconstructive surgery for the tympanic membrane, or eardrum), stapedectomy or ossiculoplasty for otosclerosis, mastoidectomy for removal of infected air cells within the mastoid bone, and removal of cholesteoma. A bloodless surgical field is ideal, as even small amounts of blood will obscure the surgeon's view in microsurgery. Hypotensive anaesthesia is a technique that is achieved by maintaining controlled hypotension which is used to limit intraoperative blood loss to provide the best possible field for surgery. Many pharmacological agents have been used for induction of controlled hypotension such as inhalational anesthetic agents (isoflurane,sevoflurane), vasodilators(sodium nitroprusside and nitroglycerine), beta adrenoceptor blockers(esmolol), opioids(remifentanyl), alpha-2 adrenergic blockers (clonidine, dexmeditomidine) and magnesium sulphate. Some of the disadvantages associated with these drugs include resistance, tachyphylaxis, cyanide toxicity with nitroprusside, myocardial depression and long post anesthetic recovery period with inhalational anesthetic. Recently, the role of dexmedetomidine has been evaluated for different purposes in anaesthesia. Dexmedetomidine is a potent, highly selective α2 adrenoreceptor agonist. It has sedative, analgesic, and anxiolytic effects after intravenous administration.It also has sympatholytic properties that blunt many of the cardiovascularresponses during intraoperative period. It has the advantages of absence of reflex tachycardia, the suppression of sympathetic nervous system allowing for not having rebound hypertension and has good hemodynamic control.Its onset of action is rapid following intravenous administration. It is 94% protein bound. Here in this study, we are evaluating the effect of dexmeditomidine in inducing controlled hypotension in middle ear surgery for providing an oligaemic surgical field.

Objectives: The primary aim of the study is to evaluate the effect of dexmedetomidine infusion

- In providing a controlled hypotension
- In providing oligaemic surgical field
- In maintaining the hemodynamic stability

Methods: A study of 60 patients of either sex, ASA-I/II of age group 18 to 60 years was conducted in patients undergoing middle ear surgery under General Anesthesia in Civil Hospital, Ahmedabad during a period from July 2020 to July 2021. **Result:** VAS score at rest and at movement at 15 minutes in femoral nerve block group was 2.37 +/- 1.45 and 3.37+/- 1.55 in intravenous fentanyl group was 4.94+/- 0.98 and 5.55+/- 0.88.Patient satisfaction score was higher in femoral nerve block group. **Conclusion:** From our results we conclude that dexmedetomidine is having advantage of causing controlled hypotension and providing a good blood less surgical field with minimal blood loss and also maintaining the stable hemodynamcis throughout the intraoperative period. Dexmedetomidine is safe in middle ear surgery.

KEYWORDS :

INTRODUCTION

The development of induced hypotension as an adjuvant to surgery is an excellent example of this interdependence. Fundamentally unrelated to anaesthesia, the techniques have been evolved almost exclusively by anaesthetists, who must be prepared to accept responsibility for the management of such cases[27].

Middle ear disease affects patients of all ages. Common middle ear pathologic conditions requiring surgery include tympanoplasty (reconstructive surgery for the tympanic membrane, or eardrum), stapedectomy or ossiculoplasty for otosclerosis, mastoidectomy for removal of infected air cells within the mastoid bone, and removal of cholesteoma. The practice of middle ear surgery under general anaesthesia has undergone a revolution with introduction of hypotensive anaesthesia to provide a relatively bloodless field while using an operating microscope or endoscope. A bloodless surgical field is ideal, as even small amounts of blood will obscure the surgeon's view in microsurgery. A combination of physical and pharmacologic techniques is used to minimize bleeding. With the usage of the operating microscope, that magnifies the surgical field many times and also the blood droplets and thus a small amount of blood can obscure the surgical field and lengthens the time of surgery.

To reduce bleeding during middle ear surgery, maintaining deliberate hypotension has been a popular technique. So hypotensive anaesthesia is a technique that is achieved by maintaining controlled hypotension which is used to limit intraoperative blood loss to provide the best possible field for surgery.

The various methods to minimize blood loss during middle ear surgery included mild head elevation of 15^0 and infiltration or topical application of epinephrine. Many pharmacological

agents have been used for induction of controlled hypotension such as inhalational anesthetic agents

(isoflurane, sevoflurane), vasodilators (sodium nitroprusside and nitroglycerine), beta adrenoceptor blockers (esmolol), opioids (remifentanyl), alpha-2 adrenergic blockers (clonidine, dexmeditomidine) and magnesium sulphate.

Each drug has its own advantages and disadvantages in providing controlled hypotension. Some of the disadvantages associated with these drugs include resistance, tachyphylaxis, cyanide toxicity with nitroprusside, myocardial depression and long post anesthetic recovery period with inhalational anesthetic.

Ideally, hypotensive agents should be easy to administer, to have a short durationof onset, effects that disappear quickly, and negligible effects on vital organs. Recently, the role of dexmedetomidine has been evaluated for different purposes in anaesthesia.

Dexmedetomidine is a potent, highly selective α_2 adrenoreceptor agonist. It has sedative, analgesic, and anxiolytic effects after intravenous administration.It also has sympatholytic properties that blunt many of the cardiovascularresponses during intraoperative period. It has the advantages of absence of reflex tachycardia, the suppression of sympathetic nervous system allowing for not having rebound hypertension and has good hemodynamic control. Its onset of action is rapid following intravenous administration. It is 94% protein bound.

Here in this study, we are evaluating the effect of dexmeditomidine in inducing controlled hypotension in middle ear surgery for providing an oligaemic surgical field.

A. Methodology

After obtaining institutional ethical committee approval and written informed valid consent, a study of 60 patients of either sex, ASA-I/II of age group 18 to 60 years was conducted in patients undergoing middle ear surgery under General Anesthesia in Civil Hospital, Ahmedabad during a period from July 2020 to July 2021.

Study Design:

Prospective, randomized controlled, double blinded interventional study was done at civil hospital Ahmedabad from July 2020 to July 2021.The study involved use of Dexmedetomidine which is available in government supply at Civil Hospital.

Subject/Patient Selection:

Inclusion Criteria:

- ASA grade I and II physical status
- Patient scheduled for elective middle ear surgery under general anaesthesia
- Age between 18-60yrs, belonging to both sexes
- Weight 50-100 kg

Exclusion Criteria:

- Age < 18yrs
- ASA-PS grade 3,4,5
- Patients' refusal to give consent
- Known Hypertensives or unstable blood pressure SBP<70 or > 150
- Cardiac or respiratory diseases
- Emergency Surgery
- Diabetics
- Patient with history of anticipated Difficult Airway
- Impaired renal function and electrolyte imbalance
- Bleeding or coagulation disorder
- Patients having hypersensitive reactions to anaesthetic drugs

Source of Data:

Patients were screened for eligibility to participate in the study. Written informed consent was obtained from patients, who would be scheduled for middle ear surgeries under general anaesthesia in Civil Hospital, Ahmedabad attached to B.J Medical College, Ahmedabad, Gujarat.

Pre-operative evaluation was carried out a day before the surgery. A thorough history was taken, and detailed examinations were carried out in all patients. Patients advised for routine and relevant investigations like random blood sugar, CBC, renal and liver function tests, Chest X-Ray, 12 lead ECG. All reports were reviewed on the day of surgery. Patients were kept nil per oral for 6hrs before surgery.

Procedure:

After getting informed written consent, patients were taken on OT table and all the minimum mandatory monitors like non-invasive blood pressure (NIBP), heart rate (HR), pulse oximetry, end tidal CO2, were applied. Baseline hemodynamics were recorded and two iv lines were secured with 20G cannula at different sites, one for the study drug administration and other for fluid and other drugs administration.

Randomization were performed using a coin toss method to allocate patientsto various groups. Patients were randomly divided into two groups.

Group 1 - Inj. Dexmedetomidine infusion iv was given at a dose of 0.5μg/kg/hr

Group 2 - received normal saline infusion

In both the group infusion was started after the induction of anaesthesia and continued till 20 mins before completion of surgery.

General anaesthesia was standardized for all patients in both groups.

- Premedicated with glycopyrrolate 4 microgram/kg, fentanyl 2 microgram/kg and ondansetron 0.15 mg/kg IV.
- Preoxygenated for 3 mins with Bains circuit with 100% O2 at 6-8 l/min and induced with Inj. Propofol 2-2.5 mg/kg iv and Inj.Succinylcholine 2 mg/kg iv mg/kg to facilitate tracheal intubation with properendotracheal tube size.
- For maintainanceO2, N2O, Sevoflurane(concentration was titrated to achieve a systolic blood pressure 30% below the baseline) and Inj. Vecuronium 0.080.12mg/kg iv followed by 0.01-0.015 mg/kg iv were given.Discontinued N2O at the time of graft insertion.
- Bleeding at surgical site was assessed by the surgeons as grade 0 – no bleeding excellent surgical conditions, grade 1 – minimum bleeding, sporadic suction needed, grade 2 - diffuse bleeding, repeated suction needed, grade 3 – continuous troublesome bleeding and continuous suction needed.
- The infusion rates were then titrated to maintain MAP between 60 to 70 mm of Hg (systolic 80-90 mm of Hg). If MAP increased then maintained with increased concentration of sevoflurane and or additional dose of dexmedetomidine.
- Infusion was stopped 20 minutes before completion of surgery.
- On completion of surgical procedure, the patients were extubated after reversal of neuromuscular blockade by neostigmine 0.05mg/kg and glycopyrrolate 8 microgram/kg intravenously.
- Patients were transferred to post anaesthesia care unit (PACU).
- Throughout the procedure heart rate (HR), blood pressure, SPO2, ETCO2 were observed.

RESULTS

The observations and results of this study which was conducted at B.J. Medical college among 60 patients have been summarized in tabulated form. The patients have been divided into two groups with 30 patients in each group.

Group 1 –Inj.Dexmedetomidine 0.5μg/kg/hrinfusion
Group 2 –Inj. Normal saline(placebo)

Table 1: Demographic data

Parameters	Group I (dexmed)		Group II (placebo)		P - value
	Mean	Std. Deviation	Mean	Std. Deviation	
Age(in years)	30.53	7.49	29.7	10.00	0.7173
Weight(in kilograms)	60.16	6.62	59.9	6.48	0.8784

Test applied:
Student t-test; Significant ($p<0.05$); Not Significant ($p \geq 0.05$)

Parameters	Group I (Dexmed)	Group II (Placebo)	P–value
ASA Grade I	18	19	0.7898
ASA Grade II	12	11	
Sex (M:F)	1:1(Group I)	1:1(GROUP II)	

Test Applied:
Chi square test; Significant ($p<0.05$); Not Significant ($p \geq 0.05$)

As shown in above tables both the groups are comparable in baseline characteristics such as age, weight, sex ratio and ASA Grading. No significant differences have been found in those parameters.

Table 2: Comparison of Heart Rate

Heart Rate	Group I		Group Ii		P – Value
	Mean	Std. Deviation	Mean	Std. Deviation	
Baseline	79.13	8.21	78.93	9.11	0.9292
At Induction	83.23	9.06	83.86	10.88	0.8074
15 Mins	76.26	7.39	87.2	12.60	0.0001
30 Mins	74	9.54	90.03	10.87	0.0001
45 Mins	70.13	7.91	90.63	11.86	0.0001
60 Mins	69	8.08	87.43	10.35	0.0001
75 Mins	67.73	6.82	86.86	9.19	0.0001
90 Mins	68.66	5.82	86.10	8.75	0.0001
105 Mins	69	6.53	84.66	7.72	0.0001
120 Mins	69.7	6.85	84.40	7.79	0.0001
Pacu	72.06	7.38	86.36	7.30	0.0001

Test Applied:
Student t-test; Significant ($p<0.05$); Not Significant ($p \geq 0.05$)

Table 5: Comparison Of Mean Arterial Blood Pressure

Mean Arterial Pressure	Group I		Group Ii		P-Value
	Mean	Std. Deviation	Mean	Std. Deviation	
Baseline	83.04	4.76	82.78	3.86	0.8197
At Induction	77.61	4.16	81.26	6.25	0.0100
15mins	72.71	3.51	81.02	7.39	0.0001
30mins	68.53	2.92	85.93	7.09	0.0001
45mins	66.98	2.19	88.1	6.42	0.0001
60mins	68.85	2.53	85.85	4.13	0.0001
75mins	69	1.90	85.9	5.97	0.0001
90mins	67.8	2.30	85.63	4.71	0.0001
105mins	70.62	2.28	84.57	4.14	0.0001
120mins	72.93	1.56	85.2	3.99	0.0001
Pacu	78.04	3.74	85.81	4.12	0.0001

Test Applied:
Student t-test, Significant ($p<0.05$); Not Significant ($p \geq 0.05$)

Table 5 shows mean blood pressure in mm of Hg at different time intervals. There was statistically significant difference in the mean blood pressure between both the groups. Drop in mean arterial pressure was more in Group I as compared to Group II

Graphical presentation of MEAN ARTERIAL PRESSURE

Table 6: Comparison Of Mean Percentage Of Sevoflurane Used

Groups	Percentage Of Sevoflurane (Mean ± S.D)	P-Value
I (Dexmed)	0.7±0.12	0.0001
Ii (Placebo)	1.24±0.18	

Test Applied:
Student t-test, Significant ($p<0.05$); Not Significant ($p \geq 0.05$)
Table 6 shows mean percentage of sevoflurane used in both the groups. There was statistically significant difference between both the groups. The required percentage of sevoflurane was significantly less to maintain the mean systolic blood pressure below 30% in Group I when compared to Group II.

Table 8: Comparison of surgical site bleeding

Grade		Group I	Group Ii	P-Value
0	No Bleeding	2	0	<0.0001
1	Minimal Bleeding, Occasional Suction Needed	24	3	
2	Diffuse Bleeding, Repeated Suction Needed	4	16	
3	Considerable Troublesome Bleeding, Continuous Suction Needed	0	11	
Total		30	30	

DISCUSSION:

The middleear space is small, with an estimated volume of 2 cm^3. The field of view, obtained via an operating microscope or rigid endoscope is always a challenge, as procedures are performed down the limited space of the ear canal and via the mastoid. Even a very small quantity of active bleeding can severely hamper the surgeon's ability to safely operate in this region. Great care must be taken to prevent inadvertent damage to the delicate hearing structures, balance system and facial nerve. A clear view is of paramount importance. Reducing the bleeding is the primary goal of the bloodless-field anaesthesia.[14] The special requirements for middle ear surgery are a still operative field, minimal bleeding, and a smooth recovery without coughing or straining.

Controlled or deliberate hypotension has been used for many years as a means of reducing intraoperative blood loss and facilitating surgical exposure. Reduced intraoperative blood pressure leads to a direct reduction in bleeding from surgically injured arteries and arterioles. Decreased bleeding improves surgical visualization of the wound, resulting in faster surgeries and thus, there have been a number of prospective trials demonstrating the efficacy of deliberate hypotension, alone or in combination with other techniques, at reducing the blood loss and providing a good bloodless surgical field which helps in reducing the duration of surgery and in turn reduces exposure to anaesthesia.

We have conducted this prospective randomized double-blind study in an attempt to examine effect of dexmedetomidine and in providing an oligaemic surgical field and good hemodynamic stability.

CONCLUSION

Effects of dexmedetomidine on heart rate, mean blood pressure and in providing surgical bloodless field using surgical site bleeding grade have been compared.

From our results we conclude that dexmedetomidine is having advantage of causing controlled hypotension and providing a good blood less surgical field with minimal blood loss and also maintaining the stable hemodynamcis throughout the intraoperative period. Dexmedetomidine is safe in middle ear surgery.

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