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KEYWORDS: Deliberate hypotension, dexmedetomidine, tympanoplasty , FESS.

EFFECTIVENESS OF DEXMEDETOMIDINE TO REDUCE BLEEDING DURING TYMPANOPLASTY & FUNCTIONAL ENDOSCOPIC SINUS SURGERY (FESS) ; AN INTERVENTIONAL STUDY

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Abstract

BACKGROUND AND OBJECTIVE: The aim of this study was to evaluate the efficacy of dexmedetomidine, an alpha(2)-adrenoceptor agonist, on intraoperative bleeding and duration of the surgery. This study shows the improvement of the efficacy of surgery with minimum bleeding, at the same time not compromising the hemodynamic stability of the patient.

METHODS: sixty patients scheduled for elective tympanoplasty and FESS operations under general anaesthesia were included in the study. The patients were randomly assigned to receive either a dexmedetomidine 1 mcg/kg bolus 10mins before is given to Group (D) and a bolus dose of 10ml normal saline will be given to Group (P). After intubation in Group (D) maintenance dose of dexmedetomidine 0.5 to 0.8 mcg/kg/hr is started and the dose is titrated in between 0.5 to 0.8 mcg/kg/hr on the bases of MAP, maintaining at 70mmHg. Normal saline infusion 8 to 10 ml/kg/hr is continued in Group (P).The Heart Rate, Blood Pressure and MAP is measured every 5min throughout the surgery Bleeding during surgery was assessed by the surgeon, blinded to the study drugs intraoperatively and a bleeding severity score is given by the surgeon as a final personal opinion about the whole surgical process.

RESULTS: Bleeding graded on the basis of the severity score was found to be higher in the placebo group than dexmedetomidine group. hemodynamic stability is also well maintained in dexmedetomidine group when compared with placebo group. The mean duration of surgery is also more in placebo group than dexmedetomidine group. Thus indicating that bleeding was less in the dexmedetomidine group with good hemodynamic stability and with decreased duration of surgery.

CONCLUSION: This study concluded that intraoperative dexmedetomidine infusion provides a considerable reduction in bleeding, relatively dry operative filed , controlled hypotension improves visualization and allows the accurate delineation of lesions during FESS & Tympanoplasty under general anaesthesia.

INTRODUCTION

Creating a blood less field during Tympanoplasty & Functional endoscopic sinus surgery is challenging to the Anaesthesiologist and here we are exploring a way of achieving a safer technique of controlled hypotension.

Controlled Hypotension by i.v Dexmedetomidine infusion is used in order to provide a better vision and create a surgical field free of bleeding during Tympanoplasty or FEES. Hypotensive Anaesthesia is a technique in which the blood pressure is deliberately reduced by using pharmacological agent or volatile anesthetic or combination of both, to reduce the MAP, thereby minimizing the blood loss and comparatively a blood less field for the surgeon for better vision of the operative field. In the present study the goal is to reduce MAP to around 70mmHg to achieve the above mentioned purpose.

Dexmedetomidine is a selective α2 receptor agonist which is being used as a antihypertensive agent, it has additional properties of analgesia, sympatholysis and sedation without major respiratory depression. It has also been used to suppress sympathetic responses. It also reduces opioid requirement , stress responses to surgery and post operative shivering. Dexmedetomidine is increasingly used as sedation agent in monitored anaesthesia care surgeries.

MATERIALS AND METHODS

Sixty ASA class I and II patients of both sexes between the age of 18 to 40 years, who were scheduled for elective endoscopic nasal sinus surgery and tympanoplasty under general anesthesia at PES Institute of Medical sciences and Resarch were selected for this study.After receiving the institutional ethical committee approval and informed consent, the patients were allocated into two groups, the dexmedetomidine group (D) and the placebo group(P), each group comprising of thirty patients respectively.

INCLUSION CRITERIA:

1.Age group 18-40 years of either sex.
2.patients of ASA physical status Grade I & II
3.Weight between 40-85 Kgs
4. patient undergoing tympanoplasty or FEES under General anaesthesia

EXCLUSION CRITERIA:

1.Patients more than 40 years of age, less than 18yrs age.
2.Patients of ASA physical status Grade III & IV.
3.Pregnant women.
4.patients with bleeding disorders.
5.Patients with Sinus Bradycardia / Heart Block / Conduction defects
6.Patients with Ischemic Heart Diseases (IHD) /Rheumatic Heart Disease.
7.Patients with Chronic Renal Diseases with increased renal parameters.
8.Preoperative hypotension.
9. Patient refusal.

All the patients were informed about the procedure and written consent obtained.Prof. of ENT Department was informed about the study and his prior permission was obtained. This study was carried

out in the theatre where facilities for Induced Hypotension and Resuscitation were available.

PROCEDURE:

All the patients were examined prior to surgery. Routine Clinical Examination, Biochemistry Tests, Electrocardiogram and Chest X-Ray were examined thoroughly for the conduct of anaesthesia. Only those patients in the ASA Class I were taken into this study. NPO duration was eight hours and fluid replacement during Infra operative period was according to the 4 — 2 —1 rule.

After routine pre-anaesthetic evaluation, explaining the procedure and taking informed consent, patients will be shifted to operation theatre, and an 18G/20G IV cannula will be secured, normal saline infusion will be started. Patients will be connected to the monitor which records heart rate, non-invasive blood pressure, ECG, O2 saturation, end-tidal carbon dioxide.

Pre- induction Heart rate, Blood Pressure both Systolic & Diastolic and MAP will be recorded. Bolus dose of dexmedetomidine 1mcg/kg over 10mins will be given to Group (D) and a bolus dose of 10ml normal saline will be given to Group (P).

Premedication with Inj. Glycopyrrolate 0.2 mg IV, inj. Fentanyl 1.5 µg/kg will be given. After pre-oxygenation with 100% oxygen for 3 minutes, anaesthesia will be induced with sleep dose of inj. Propofol, endotracheal intubation will be facilitated with inj.succinylcholine 1.5mg/kg or inj. Vecuronium bromide 0.1 mg/kg. Then laryngoscopy will be performed and trachea will be intubated after 3minutes of mask ventilation with 100% oxygen. In all patients anaesthesia will be maintained with nitrous oxide and oxygen (2:1ratio) , isoflurane and vecuronium as on required basis.

To maintain hypotension for producing a bloodless surgical field, mean arterial pressure will be maintained around 70 mm Hg. After intubation in Group (D) maintenance dose of dexmedetomidine 0.5 to 0.8 mcg/kg/hr is started and the dose is titrated in between 0.5 to 0.8 mcg/kg/hr on the bases of MAP, maintaining at 70mmHg. Normal saline infusion 8 to 10 ml/kg/hr is continued in Group (P). The Heart Rate, Blood Pressure and MAP will be measured every 5min throughout the surgery. If the heart rate is below 50 beats per minute, rescue medication 0.6mg of atropine will be given.

Dexmedetomidine infusion is continued till the end of the operation, I.v Ondansetron 4 mg will be administered as a routine antiemetic 30 min prior to end of surgery, oxygen 100% will be administered and residual neuromuscular block will be antagonized with inj. Glycopyrolate 0.01 mg/kg and neostigmine 0.05 mg/kg in all patients. Oral suctioning will be done gently just before extubation only. The trachea

will be extubated after deflating the cuff when patient fulfils the standard criteria for extubation. All patients will receive oxygen by a facemask after operation.

Intra-operative bleeding and surgeons opinion on this will be confirmed by the following questionnaire to the operative surgeon and graded accordingly.

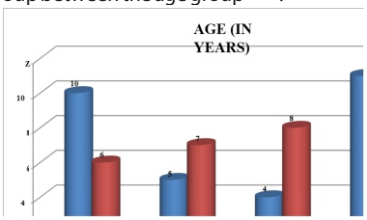
1 - No bleeding , a virtually blood less field.
2 - Bleeding that was so mild that it was not a surgical nuisance.
3 - Moderate bleeding that was a nuisance but did not interfere with accurate dissection.
4 - Moderate bleeding that moderately compromised surgical dissection .
5 - Bleeding that was heavy but controllable and that significantly interfered with surgical dissection .
6 - Massive bleeding that was uncontrollable and made dissection impossible.

All the patients were observed for 24hours after surgery in the post operative period for any side effects in the form of hypotension and bradycardia will be recorded and treated.

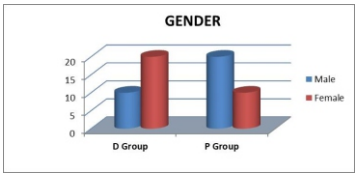
STATISTICAL ANALYSIS:

Distribution Of Age: Out of sixty cases, there were 10 cases in the Dexmedetomidine group and 06 cases in the placebo group under the age 25 .There were 05 cases in the Dexmedetomidine group and 07 cases in the Placebo group between the age group 26-30. There were 04 cases in the Dexmedetomidine group and 98 cases in the Placebo group between the age group [31-35].

There were 11 cases in the Dexmedetomidine group and 09 cases in the placebo group between the age group [36-40].



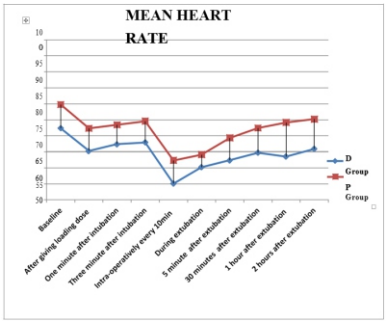
Distribution Of Gender: Out of sixty there were 10 males in Dexmedetomidine group and 20 males in placebo group .There were 20 females in Dexmedetomidine group and 10 females in the placebo group .



Heart rate: Mean value of heart rate were taken at baseline , at scopy , at loading dose , One minute after intubation ,three minutes after intubation ,every 10 min on average , during extubation , 30 minutes after extubation , 1 hour after extubation ,2 hours after extubation.

The P values are calculated on comparing both groups at each stage and the results are significant except during extubation and 30 minutes after extubation .

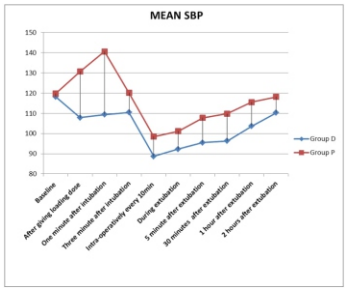
This shows that Dexmedetomidine drug is highly effective when compared with Placebo drug .



Systolic Blood Pressure (SBP): Interpretation:
Mean value of systolic Blood pressure were taken at baseline , at scopy , at loading dose , One minute after intubation ,three minutes after intubation ,every 10 min on average , during extubation ,1 minute after extubation, 30 minutes after extubation , 1 hour after extubation ,2 hours after extubation.

The P value have been calculated on comparing both the groups at each stage and the results are significant except 1 minutes and 30 minutes after extubation .

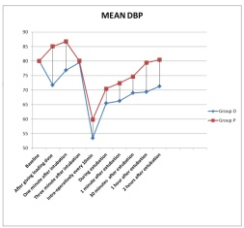
This shows that Dexmedetomidine drug is highly effective when compared with Placebo group.



DIASTOLIC BLOOD PRESSURE (DBP): Mean value of Diastolic blood pressure were taken atbaseline , at scopy , at loading dose , One minute after intubation ,three minutes after intubation ,every 10 min on average , during extubation ,1 minute after extubation, 30 minutes after extubation , 1 hour after extubation ,2 hours after extubation.

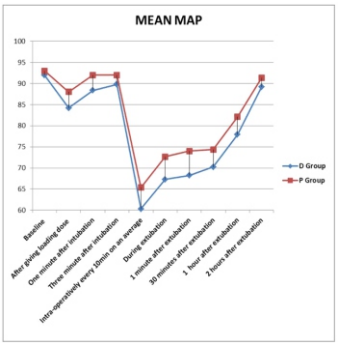
Mean value of Diastolic blood pressure were taken atbaseline , at scopy , at loading dose , One minute after intubation ,three minutes after intubation ,every 10 min on average , during extubation ,1 minute after extubation, 30 minutes after extubation , 1 hour after extubation ,2 hours after extubation.

The P value have been calculated on comparing both the groups at each stage and the results are significant except 1 minute and 30 minutes after extubation. This shows that Dexmedetomidine drug is highly effective when compared to placebo group.



Mean Arterial Pressure (MAP): Mean value of arterial pressure were taken at baseline , at scopy , at loading dose , One minute after intubation ,three minutes after intubation ,every 10 min on average , during extubation ,1 minute after extubation, 30 minutes after extubation , 1 hour after extubation ,2 hours after extubation.

The P value have been calculated on comparing both the groups at each stage and the results are significant in all the stages .



MEAN DURATION OF SURGERY:

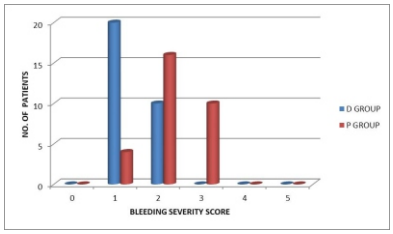
Group	Minutes	SD
Dexmedetomidine	50.43	± 2.3487
Placebo	55.39	± 4.3897

P = 0.458 (NS)

Interpretation: The duration of surgery for the dexmedetomidine group is less when compared to placebo group.

Bleeding Severity Score: Interpretation:

Bleeding graded on the basis of the severity score 2 & 3 was found to be higher in the placebo Group (16 patients with a score of 2and 10 patients with a score of 3).Frequency of bleeding severity score of 1in the dexmedetomidine group was significantly greater than that of placebo group, thus indicating that bleeding was less in the dexmedetomidine group.



DISCUSSION

Controlled hypotension is a technique used to reduce bleeding in patients undergoing middle ear surgery, nasal surgery, neurosurgery, orthopaedic surgery, head and neck surgery. During FESS & tympanoplasty surgery the single and most common complication is excessive bleeding[18].

In this study, the effects of iv dexmedetomidine (1mcg/kg as a loading dose and 0.5 to 0.8mcg/kg/hr as a maintenance dose) was studied in 30 patients who underwent FESS & tympanoplasty. Bleeding severity score of 2 and 3 was seen to be higher in the Placebo Group and score 1 & 2 was seen to be higher in dexmedetomidine Group.

Controlled hypotension is used for reducing bleeding as an aid to surgery in patients undergoing middle ear or nasal surgery, neurosurgical operations, major orthopaedic procedures, head and neck surgery, and different procedures in plastic surgery . Although the approach is multifactorial, the principal mechanism employed is to reduction of the vascular tone. Nitroglycerin, hydralazine, Sodium nitroprusside, phentolamine ,trimethaphan, urapidil, esmolol, and labetalol are Common drugs used in combination with volatile anesthetic agents[24]. In this study dexmedetomidine, a Potent suppressor of sympathoadrenal activity, has been given i.v before operation.

In the present study, we also found that patients in the dexmedetomidine group scored significantly lower in the intraoperative bleeding assessment than patients given placebo. For surgeons, what is really disturbing is to have bleeding scores of 2 or higher, at any time. Dexmedetomidine has been shown to suppress central noradrenergic hyperactivity with secondary attenuation of perioperative hemodynamic lability[15]. In our study, a more favorable hemodynamic stability in patients treated with dexmedetomidine than in placebo was also observed. Various studies have been done to enable a reduction in bleeding during FESS and tympanoplasty surgeries by using various vasoconstriction agents like Oxymetazoline Hcl (0.05%), Phenylephrine Hcl (0.25%) and cocaine 4%[23] and by the use of Isoflurane[30]. SNP and Esmolol were also experimented as primary hypotensive agents[2].

In this study, the effects of i.v dexmedetomidine on intraoperative bleeding in Endoscopic Nasal Sinus surgery and middle ear surgeries was studied. Bleeding severity score of 2 and 3 was seen to be higher in the Placebo Group

The Induced Hypotension effect by i.v dexmedetomidine directly attributed to reduced bleeding and a good surgical field. Hypotension was produced in the Placebo Group using NTG and Sevoflurane infusion on surgeons demand. There was a statistically significant difference in the Sevoflurane requirement of both the dexmedetomidine and Placebo Group. With dexmedetomidine , Fentanyl requirement was also significantly reduced when compared with the Placebo Group. This is attributed to the

Pharmacological properties of dexmedetomidine which includes analgesia.

Extubation was smooth in all the patients of the dexmedetomidine group who were sedated but arousable. patients in the placebo group were sedated and drowsy in the post-operative period thereby requiring a longer observation in the recovery room.

CONCLUSION

The present interventional study shows that i.v dexmedetomidine1mcg/kg as loading dose and 0.5to 0.8mcg/kg/hr as maintenance dose provides a considerable reduction in bleeding during Functional Endoscopic Sinus Surgery and tympanoplasty under General Anaesthesia. It also reduces the need for other hypotensive drugs to provide a clear field for surgery. Therefore i.v dexmedetomidine a drug of choice in our setup, can be used as a hypotensive agent for FESS and tympanoplasty

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