ORIGINAL RESEARCH

The effects of dexmedetomidine vs magnesium sulphate on intraoperative heart rate changes in adult patients undergoing maxillectomy/mandibulectomy surgery

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ABSTRACT
Oral and maxillofacial surgeries involve surgical manipulation of facial skeletal elements and thus have marked impact on the cardiovascular stress response, which can result in a significant increase in the MAP and HR. After obtaining approval from the ethics committee, data was collected from patients coming to Institute of Oncology for elective mandibulectomy/maxillectomy surgeries performed under General Anaesthesia. Patients fulfilling the inclusion criteria were briefed about the procedure and written informed consenttaken. Patient demographic details noted. Difference in HR between BL, BI shows no statistical significance difference at $p > 0.05$ level, whereas in 15 AI, 30AI,45AI,60AI,90AI,120 AI,150AI, 180 AI,5BE shows highly statistical significance difference at $p<0.01$ level respectively.
Key words: Dexmedetomidine, magnesium sulphate, intraoperative heart rate changes

INTRODUCTION

Mandibulectomy/Maxillectomy surgeries are commonly performed for tumour excision and these surgeries are associated with wide fluctuations in hemodynamic parameter such as hypertension and also associated with massive bleeding.Challenges for anaesthetist is to provide hypotensive anaesthesia and there by minimise blood loss and maintain clear surgical field.[1]

Oral and maxillofacial surgeries involve surgical manipulation of facial skeletal elements and thus have marked impact on the cardiovascular stress response, which can result in a significant increase in the MAP and HR. To blunt such haemodynamic stress response, frequent adjustments in the depth of anaesthesia and analgesia are required [1]. Controlled hypotension is of utmost importance in such surgeries to reduce bleeding in the surgical field and thereby facilitate the surgery [2]. Surgical stimulus like hemi-mandibulectomy which is commonly performed in surgeries involving buccal mucosa cancer results in an intense surge in stress response.[3] Dexmedetomidine and magnesium sulphate is considered as a near-ideal hypotensive agents due to the ease of its

administration, predictable interaction with anaesthetic agents and lack of major side effects while maintaining adequate perfusion of the vital organs[2,4].

METHODOLOGY

INCLUSION CRITERIA

- Patients aged > 18 and <65years.
- ASA class I and II
- Patients undergoing electivemandibulectomy/maxillectomy surgeries.

EXCLUSION CRITERIA

- Patient refusal.
- History of Allergy to study drug.
- Patients on calcium channel blockers, beta Blockers, ACE inhibitors, anticoagulants.
- H/O cerebrovascular accident, ischemic heart disease, chronic obstructive lung disease.
- Impaired renal function test, Impaired liver function test.
- Preoperative heart rate of <45 beats/min, second or third degree heart block.

SAMPLE SIZE

The sample size and power were calculated based on the following formulae,

$n=(z\alpha/2+z\beta)2 \times z\sigma2/d2$

Where,

- n is sample size.
- σ2 is population variance.
- zα/2 is the critical value at normal distribution α/2.

zβ is the critical value at normal distribution at β.

By considering 80% power and 5% level of significance (α), the sample size 30 in each group is enough to compare two means i.e. 60.

STUDY DESIGN: A Prospective Randomized Comparative study.

METHODS

After obtaining approval from the ethics committee, data was collected from patients coming to Institute of Oncology for elective mandibulectomy/maxillectomy surgeriesperformed under General Anaesthesia. Patients fulfilling the inclusion criteria were briefed about the procedure and written informed consenttaken. Patient demographic details noted.

- Patients were kept nil per oral 8 hours prior to the surgery, premedicated with Tab Pantoprazole 40 mg and Tab Alprazolam 0.5 mg on the night prior to the surgery.
- All the patients were then randomly allocated to one of the following two groups using computer generated random sequence.

GROUP D: Patients were given IV Dexmedetomidine 1mcg/kg as loading dose over 10 mins before induction, and maintained as an IV Infusion at 0.5mcg/kg/hr till the end of the surgery.

GROUP M: Patients were given IV Magnesium sulphate 50mg/kg IV over 10mins before induction and maintained as an IV Infusion at 15mg/kg/hr till the end of the surgery.

- In the operation theatre, patients were connected to monitors and baseline hemodynamic parameters such as Electrocardiography, pulse oximetry and non-invasive blood pressure were noted. An intravenous line secured and patients were given intravenous Fluids, and infusion of study drugs started.
- Group D patients were given IV Dexmedetomidine 1mcg/kg over 10mins as loading dose and IV dexmedetomidine infusion continued at 0.5mcg/kg/hr.
- Group M patients were given IV Magnesium sulphate 50mg/kg over 10mins as loading dose and IV Magnesium sulphate infusion continued at 15mg/kg/hr.
- Patient were then preoxygenated with 100% oxygen with O2 flow rate at 5L/min for a period of 3 mins.
- Patients were then induced with intravenous Fentanyl 1mcg/kg and Propofol 1-1.5 mg/kg. Patients once check ventilated and confirmed HR then muscle relaxant Succinylcholine 2mg/kg was given prior to laryngoscopy and intubation for muscle relaxation. patients were intubated with appropriate sized cuffed endotracheal tube. Bilateral equal air entry checked and endotracheal tube placement was confirmed by capnography. The endotracheal tube is then fixed, and then patients were connected to a closed-circuit system. The mechanical ventilator set to achieve an end tidal CO_2 of 35-45 mm Hg.
- Maintenance was by 40% O_2, 60% N_2O and Isoflurane (0.8 to 1 MAC). 0.02 mg/kg Vecuronium bromide every 30 to 40 mins administered to maintain surgical relaxation. During the maintenance of anaesthesia study drug infusion was continued.
- Intraoperativelyhemodynamicswere assessed at regular time intervals.
- Patients with heart rate below 50bpm (i.e. decrease in HR more than 20%of baseline)was managed with Inj. Glycopyrrolate 0.01mg/kg.
- If Mean Arterial Blood pressure (MAP) decreased below 50mmHg, it was managed with IV fluids bolus over 5-10min according to response and a bolus dose of inj. Ephedrine (5-10mg) if needed. Inotropes (NorAdrenaline 0.1-3mcg/kg/min) was added in cases where hypotension not managed by IV fluids and inj Ephedrine.
- Inj. Nitroglycerin (5mcg/min max upto 20mcg/min) was added if Diastolic Blood

Pressure above 100mmHg, to control hypertension.

- The secondary outcome, Adverse effects of the study drug such as bradycardia, hypotension and the postoperative sedation assessment done using Ramsay sedation score.
- At the end of surgery study medications stopped and neuromuscular blockade was reversed with injection Neostigmine 0.04mg/kg and injection Glycopyrollate 0.01mg/kg. All patients were shifted to post-anaesthesia care unit with Endotracheal tube *in situ*.
- In post operative unit patients were assessed for sedation according to Ramsay sedation score.
- Adverse effects of the study drugs such as bradycardia, hypotension, respiratory depression and hyporeflexia were assessed perioperatively.

RESULTS

Table 1: Comparison of ASA between Groups by Fisher's Exact test

			Groups		Total	□2 - value	p-value
			Group D	Group M			
ASA	I	Count	1	2	3	0.351	1.000 #
		%	3.3%	6.7%	5.0%		
	II	Count	29	28	57		
		%	96.7%	93.3%	95.0%		
Total		Count	30	30	60		
		%	100.0%	100.0%	100.0%		
# No Statistical Significance at p > 0.05 level							

The above table shows comparison of ASA between Groups by Fisher's Exact test were, p=1.000>0.05 there was no statistically significant difference seen in the ASA grading among the two groups.

Table 2: Comparison of HR between the Groups by Unpaired sample t-test

HR	Groups	N	Mean	SD	t-value	p-value
BL	Group D	30	89.33	10.36	0.674	0.503 #
	Group M	30	91.03	9.13		
BI	Group D	30	76.53	9.75	1.610	0.113 #
	Group M	30	80.80	10.75		
15 AI	Group D	30	69.73	9.35	2.485	0.016 *
	Group M	30	76.37	11.23		
30 AI	Group D	30	66.53	8.82	2.763	0.008 **
	Group M	30	77.07	18.93		
45 AI	Group D	30	64.83	9.22	3.442	0.001 **
	Group M	30	73.03	9.23		
60 AI	Group D	30	62.97	9.11	2.994	0.004 **
	Group M	30	69.90	8.82		
90 AI	Group D	30	61.73	8.54	3.118	0.003 **
	Group M	30	68.50	8.27		
120 AI	Group D	30	62.57	9.63	2.155	0.035 *
	Group M	29	67.52	7.90		
150 AI	Group D	30	62.33	8.77	2.954	0.005 **
	Group M	30	68.97	8.63		
180 AI	Group D	30	62.23	9.75	2.300	0.025 *
	Group M	30	67.93	9.45		
5BE	Group D	28	70.61	9.15	3.547	0.001 **
	Group M	28	79.32	9.23		
** Highly Statistical Significance at p < 0.01 ,* Significant at p < 0.05 and # No Statistical Significance at p > 0.05						

Difference in baseline Heart rate was not statistically significant. Hence the groups were comparable with regards to Baseline Heart rate.
Difference in HR between BL, BI shows no statistical significance difference at p > 0.05 level, whereas in 15 AI, 30AI,45AI,60AI,90AI,120 AI,150AI, 180AI,5BE shows highly statistical significance difference at $p<0.01$ level respectively.

Table 3: Comparison of Bradycardia between Groups by Fisher's Exact test

			Groups		Total	χ 2 - value	p-value
			Group D	Group M			
Bradycardia	Present	Count	11	4	15	4.356	0.072 #
		%	36.7%	13.3%	25.0%		
	Absent	Count	19	26	45		
		%	63.3%	86.7%	75.0%		
Total		Count	30	30	60		
		%	100.0%	100.0%	100.0%		
# No Statistical Significance at p > 0.05 level							

Comparison of Bradycardia between Groups by Fisher's Exact test were, p=0.072>0.05 which shows no statistical significance between Bradycardia among the two Groups.

DISCUSSION

In a study done by Mallick *et al.* [15] on the comparison of infusion of Dexmedetomidine and infusion of Magnesium sulphate on attenuation of blood pressure surge in laparoscopic surgery under general anaesthesia, it was found that Dexmedetomidine infusion 0.5mcg/kg more effective than Magnesium sulphate infusion 10mg/kg in attenuating cardiovascular effects of pneumoperitoneum, similar observations were noted in our study as dexmedetomidine provided better hemodynamic stability than magnesium sulphate in maxillectomy or mandibulectomy surgery.
Zarif *et al.* [6] conducted study on Dexmedetomidine versus Magnesium sulphate as adjunct during anaesthesia for laparoscopic colectomy concluded that either intraoperative infusion of Dexmedetomidine 1mcg/kg or Magnesium sulphate infusion 15mg/kg/hr could ameliorate the pressor response to anaesthetic and surgical manipulations during laparoscopic colectomy under pneumoperitoneum in 30degree Trendelenburg position. our study concluded that dexmedetomidine is better in attenuating hemodynamic stress response to surgery than magnesium sulphate.
Rabie Soliman, Eman Fouad[7]. conducted study comparing "the effects of dexmedetomidine and magnesium sulphate in adult patients undergoing endoscopic transnasaltranssphenoidal resection of pituitary adenoma". They conducted the study in 152 patients and concluded that during transsphenoidal pituitary resection, dexmedetomidine, compared to magnesium sulfate is associated with lower blood loss and better operating conditions but with more hypotension and bradycardia in dexmedetomidine group. In our study we noted dexmedetomidine provided better hemodynamics compared to magnesium sulphate group.
Comparative study between magnesium sulfate and dexmedetomidine in controlled hypotension during functional endoscopic sinus surgery done by Bayoumy*et al.* [8] using 1mcg/kg loading dose and 0.5 to 1mcg/kg/hr infusion of dexmedetomidine and IV mgso4 40mg/kg as loading dose and 10 to 15mg/kg as maintenance dose found that dexmedetomidine was more effective than magnesium sulfate to achieve controlled hypotension in patients undergoing FESS.in our study we found that dexmedetomidine group had better intraoperative hemodynamics than magnesium sulphate group.

CONCLUSION

Heart rate was significantly lower in Group D than Group M at all points after induction and intubation ($p<0.05$).

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