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Original article:

Study of assessment haemodynamic stability of intravenous dexmedetomidine and intravenous midazolam in patients undergoing tympanoplasty under monitored anesthesia care

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Abstract:

Introduction: Midazolam is a potent in benzodiazepine which possesses typical benzodiazepine properties namely hypnotic, amnestic, anticonvulsant and anxiolytic activity.Midazolam has become the most frequently used medication given for sedation.

Material and methods: The present study was carried out in a tertiary health care centre. Sixty patients with American Society of Anesthesiologists (ASA) status I/ II undergoing tympanoplasty under monitored anesthesia care with local anesthesia and sedation were included in the study. A written informed valid consent was obtained from all patients. The study was prospective, randomized double blind trial. Randomization was done by card method. The anesthesiologist conducting the study, the patient and the anesthesiologist who followed up patient in postoperative period were all blinded to keep the study double blind.

Results : A total 60 patients of ASA grade I and II posted for tympanoplasty and MRM were randomly selected and divided into 2 equal groups. Group D received inj.dexmed 1µg/kg I.V. over 15 minutes followed by 0.5µg/kg/hr infusion till end of surgery.

Conclusion: Dexmedetomidine results in significant difference in bleeding score. Also better surgeon and patient satisfaction score which is statistically significant. Dexmedetomidine results in significant reduction in heart rate and mean arterial pressure as compare to midazolam.

Keywords : Dexmedetomidine, tympanoplasty, modified radical mastoidectomy

Introduction:

Midazolam is a potent in benzodiazepine which possesses typical benzodiazepine properties namely hypnotic, amnestic, anticonvulsant and anxiolytic activity.Midazolam has become the most frequently used medication given for sedation. Midazolam has a number of beneficial effects when used for sedation, fast onset and limited duration of action. [1,2] Despite having a number of beneficial effects it has side effects such as restlessness, paradoxical reaction, cognitive impairment, analgesis and respiratory depression. [1, 2] New drugs such as α-2 agonists, have emerged all alternatives for IV sedation during perioperative period. Dexmedetomidine is highly selective for α-2 receptors and has sedative and an analgesic effect. Among all milestones and achievements in medicine, conquering pain must be one of the very few that has potentially affected every human being in the world. It was in 1846 that one of mankind`s greatest fears, the pain of surgery, was eliminated. This historical review article describe how the various elements of anaesthesiology (gasses, laryngoscopes, endotracheal tubes,

intravenous medications, masks and delivery systems) were discovered and how some brilliant entrepreneurs and physicians of the past two centuries have delivered them to humanity.[3]

Material and methods:

The present study was carried out in a tertiary health care centre. Sixty patients with American Society of Anesthesiologists (ASA) status I/ II undergoing tympanoplasty under monitored anesthesia care with local anesthesia and sedation were included in the study. A written informed valid consent was obtained from all patients. The study was prospective, randomized double blind trial. Randomization was done by card method. The anesthesiologist conducting the study, the patient and the anesthesiologist who followed up patient in postoperative period were all blinded to keep the study double blind.

Inclusion Criteria :

1. Age 18-50 years
2. ASA I/II
3. Patients undergoing tympanoplasty.
4. Weight 35-70 Kg.
5. Duration.of.surgery.upto.90.minutes.

Exclusion Criteria:

1. Patients refusal
2. Patients with pre-existing cardiac, neurological or other illness
3. Known hypersensitivity to drugs.
4. History of taking sedative drugs.
5. Pregnant patients
6. Obese patients

Preanesthetic evaluation was done in all patients a day prior to surgery and all routine investigations like complete haemogram, Kidney function test, Liver function test, Random blood sugar and ECG (in patients with age > 40 years) were done.

Xylocaine sensitivity test was also performed.

Statistical analysis

Statistical analysis has been carried out in the present study. Results on continuous measurements were presented as Mean± SD. Unpaired T test (two tailed, independent samples) was used to find the significance of study parameters on continuous scale between two groups (inter group analysis) on metric parameters.

Results:

A total 60 patients of ASA grade I and II posted for tympanoplasty and MRM were randomly selected and divided into 2 equal groups. Group D received inj.dexmed 1µg/kg I.V. over 15 minutes followed by 0.5µg/kg/hr infusion till end of surgery.

In our study , the bleeding score was 1.58 in group D while it was 2.06 in group M .

Intraoperatively vitals were monitored for charts in mean arterial pressure and pulse rate. Values were recorded at various intervals of preoperative,at 10 mins, 15 mins, 30 mins, 45 mins, 60 mins, 90 mins, 120 mins, 150 mins, 180 mins.

The changes in pulse rate at various time intervals were as shown in table no.1

Pulse	**Group**	Mean	SD	t test	p value	Significance
PREOP	Dex	82.07	4.961	.108	.914	Not Significant
	Med	81.93	4.578			
@10MIN	Dex	76.93	4.863	-3.453	.001	Highly Significant
	Med	81.10	4.475			
@15MIN	Dex	75.87	4.725	-4.630	<0.001	Highly Significant
	Med	81.07	3.939			
@30MIN	Dex	74.47	4.629	-4.946	<0.001	Highly Significant
	Med	80.63	5.021			
@45MIN	Dex	73.40	4.709	-4.581	<0.001	Highly Significant
	Med	78.87	4.531			
@60MIN	Dex	72.27	5.298	-4.371	<0.001	Highly Significant
	Med	77.57	4.006			
@90MIN	Dex	70.53	5.309	-4.416	<0.001	Highly Significant
	Med	76.30	4.793			
@120MIN	Dex	69.20	5.910	-4.230	<0.001	Highly Significant
	Med	74.83	4.276			
@150MIN	Dex	67.90	4.780	-5.895	<0.001	Highly Significant
	Med	74.93	4.456			
@180MIN	Dex	68.17	4.549	-5.736	<0.001	Highly Significant
	Med	74.40	3.838			

In present study we observed that there was statistically significant difference in pulse rate between both the groups at various time intervals. We observed as p value < 0.05.

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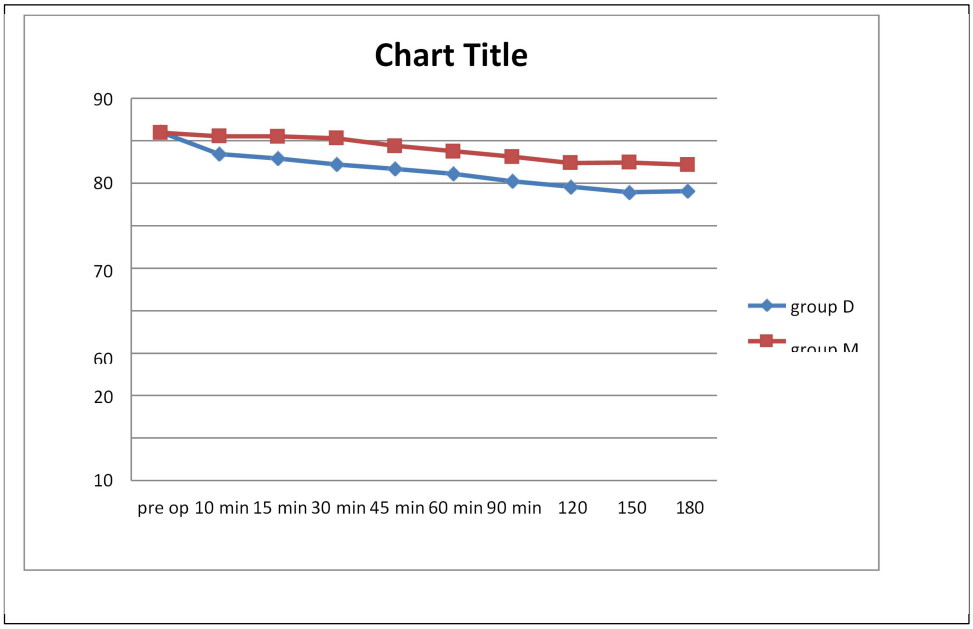
Table 2)

Mean Artial Pressure	Group	N	Mean	SD	t test	p value	Significance
PREOP	D	30	82.37	4.038	-.154	.878	Not Significant
	M	30	82.53	4.353			
10MIN	D	30	79.67	4.229	-.878	.383	Not Significant
	M	30	80.63	4.295			
15MIN	D	30	78.57	4.281	-1.451	.152	Not Significant
	M	30	80.20	4.437			
30MIN	D	30	76.93	4.160	-2.120	.038	Significant
	M	30	79.27	4.362			
45MIN	D	30	75.53	4.257	-2.985	.004	Highly Significant
	M	30	78.87	4.392			
60MIN	D	30	74.87	4.191	-2.881	.006	Highly Significant
	M	30	78.17	4.669			
90MIN	D	30	73.07	3.947	-3.545	.001	Highly Significant
	M	30	77.17	4.956			
120MIN	D	30	71.23	3.390	-4.716	.000	Highly Significant
	M	30	76.57	5.184			
150MIN	D	30	69.40	3.440	-6.134	.000	Highly Significant
	M	30	75.93	4.712			
180MIN	D	30	69.33	3.407	-6.344	.000	Highly Significant
	M	30	76.00	4.639			



Discussion:

Monitored anesthesia care is a technique of combining local anesthesia with parenteral drug for sedation and analgesis. A common practice with sedation is that the sedative drug is given in larger doses in an attempt to achieve calm, pain free patient . MAC is useful for various clinical fields such as minimal invasive surgery, gastrointestinal endoscopy and interventional or radiological procedures. It provides suitable intraoperative conditions as well as comfort for patients. The commonly used drugs are Midazolam, propofol and opioids, such as Fentanyl, Alfentanyl or Ramifentanyl.[4] Occasionally, the administration of sedatives or hypnotics in consumption with analgesics can cause significant respiratory depression or transient upper airway obstruction.

MAC may be applied for various ENT surgeries in which an adequate sedation and analgesis without respiratory depression are desirable for comfort of both patient and surgeon. In order to reduce the incidence of complications, it is important to have a bloodless surgical field as for as possible for better visibility.[5]

Bleeding control is usually attained with local application of Epinephrine. Pain during surgery may leads to sympathetic stimulation and restless patient may have tachycardia and hypotension, leading to increased bleeding in the surgical field. Several drugs have been used for sedation during surgery under local anesthetics with MAC including propofol, benzodiazepines, opioids . However, propofol may cause oversedation and disorientation, benzodiazepines may result in confusion, particularly in elderly and opioids are associated with increased risk of respiratory depression and oxygen desaturation. All of these effects may hamper patient's cooperation during surgery and would make these agents less than ideal for intra perative management of sedation in MAC. Midazolam is the most frequently used sedative and has been reported to be well tolerated when used in MAC

Dexmedetomidine is highly selective α2 adrenergic agonist with 8 time's higher specificity for the receptors compared to clonidine; it provides excellent sedation and analgesia with minimal respiratory depression. Recent multicenter trials indicates that it is an effective baseline sedative for patients undergoing broad range of surgical procedures under MAC, providing greater patient satisfaction, less opioid requirement and less respiratory depression , compared with the placebo. [6]Present prospective double blind controlled study was done in 60 patients of ASA gradeI − II, distributed equally in group D and group M. demographic charactristics of patients in terms of age, gender, weight, type of surgery and duration of surgery In both groups were statistically not significant and comparable with study of **Vyas D A et al 2013, Dr .Sangeeta Bansal Agarwal et .al 2017,Dr. Nazima menon et al 2015.**[8]

Group D received 1µg/kg of Dexmedetomidine a loading dose over 15 minutes followed by 0.5µg/kg/hras a infusion dose. Group M received inj. Midazolam 0.05mg/kg slowly followed by 0.01 mg/kg/hr infusion. Similar study was carried out by **Vyas D A etal**2013 and **Dr. Nazima Memon** 2017. But Dr. **Nazima Memon et al** used a combination of Midazolam and Pentazocine (0.5 mg/kg), instead of plain Midazolam in her study. Patients were observed for level of sedation bleeding score, mean arterial pressure, heart rate, patient satisfaction score and surgeon satisfaction score.[8] In our study dexmedetomidine infused patient produced reduction in blood pressure. In our study, the bleeding score was less in group D as compare to group M. which indicates that dexmedetomidine reduces blood loss and also provides better surgical condition compared to midazolam.

Conclusion:

Dexmedetomidine results in significant difference in bleeding score. Also better surgeon and patient satisfaction score which is statistically significant. Dexmedetomidine results in significant reduction in heart rate and mean arterial pressure as compare to midazolam.

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