ORIGINAL RESEARCH PAPER

Volume-8 | Issue-1 | January-2019 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

MIDAZOLAM VERSUS DEXMEDETOMIDINE FOR SEDATION IN ENT SURGERIES UNDER LOCAL ANAESTHESIA. A PROSPECTIVE RANDOMISED DOUBLE BLIND STUDY.

Anesthesiology

Dr. Ritu Pauranik (MD,FIPM) Assistant Professor Department of Anesthesia and Intensive care Shri Aurbindo Institue of Medical Sciences Indore

Dr. Sohail Sachdeva* (MBBS) PG Sudent Department of Anesthesia and Intensive care Shri Aurbindo Institue of Medical Sciences Indore *Corresponding Author

ABSTRACT

BACKGROUND: Minor ENT surgeries are usually performed under local anesthesia and sedation. In this study sedation scores and peri-operative haemodynamics were compared when pre-medicated with intravenous midazolam (0.05mg/kg) or dexmedetomidine (1µg/kg) infusion.

MATERIAL AND METHODS: Sixty patients undergoing ENT surgeries under local anesthesia randomly received either IV dexmedetomidine 1 µg kg -1 over 10 min (Group D) or IV midazolam 0.05 mg kg -1 over 10 min (Group M) . Sedation score was assessed using Ramsay sedation score (RSS). Vital parameters, rescue sedatives (midazolam 1 mg intravenous) and any perioperative complications were recorded.

RESULTS: The mean sedation score in group D was found to be 4.33±0.76 and in group M was 2.83±0.46 which was statistically significant (p value <0.05). Rescue sedation was required in 13 patients in the midazolam group whereas no patient needed rescue sedation in the dexmedetomidine group. There was no complication in any of the groups.

CONCLUSION: Dexmedetomidine given in a single loading dose of 1mcg/kg could be a better alternative compared to conventional sedation with Midazolam for minor ENT procedures, since it provides a calm patient with better intraoperative haemodynamics without any complications.

KEYWORDS

Dexmedetomidine, sedation, midazolam sedation, monitored anesthesia care, ENT surgery

INTRODUCTION

ENT surgeries viz tympanoplasty, septoplasty, functional endoscopic sinus surgery (FESS) and dacrocystorhinostomy (DCR) are superficial, less invasive and can be done under local anaesthesia or local with sedation in co-operative and well counselled patients.[1] Tympanoplasty in ENT surgical procedures involves reconstruction of perforated tympanic membrane with or without ossiculoplasty[2]. Patients may feel discomfort due to pain, noisy suction, manipulation of instruments and head and neck position[3].

There are many advantages of local anaesthesia supplemented with intravenous sedation, such as less bleeding, cost effectiveness, postoperative analgesia, faster mobilisation of the patient, and the ability to test hearing [4]. Local anesthesia is cost effective but better preoperative counselling is needed and at times may cause patient discomfort if it is used as sole technique.

Monitored anaesthesia care (MAC) typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and/or analgesic drugs which is a common practice during various ENT surgical procedures[4]. Therefore MAC is an attractive option as it invokes less physiological disturbance, allows a more rapid recovery than general anesthesia and is cost effective. Thus the primary objective in providing MAC is to ensure patient comfort, safety, and satisfaction during surgery[5].

This study was done to compare sedation scores according to Ramsay sedation score and peri-operative haemodynamics when pre-medicated with midazolam (0.05mg/kg) or dexmedetomidine (1µg/kg) for patients undergoing ENT surgeries under local anesthesia.

MATERIALS AND METHODS

This prospective, randomized, double blind study was conducted at a tertiary care hospital after approval from the hospital Ethics Committee. A total of sixty patients in the age group between 20-40 years, , belonging to American society of Anesthesiologists (ASA) physical status I or II, undergoing various ENT surgeries like tympanoplasty, septoplasty, Functional endoscopic sinus surgery were included in the study after taking informed and written consent.

Patient not fulfilling inclusion criteria, allergic to local anesthetics, patients with severe bradycardia and heart blocks, history of allergy to medication, active CNS disease, patients with acute narrow angle glaucoma, not willing to undergo local anaesthesia were excluded from the study.

All patients were given a pre-operative visit and a detailed general physical examination, systemic examination including airway examination was done. As per institutional protocol Laboratory investigations like routine blood and urine examinations, bleeding time and clotting time, chest x-ray if required, serum serology for HIV and HBsAg was done in all patients.

In the operating room, fasting status, consent, PAC were checked, and intravenous access was secured. Baseline values of pulse oximetry (SpO_2), noninvasive BP, heart rate and electrocardiogram were recorded and intravenous Ringer lactate started. Oxygen supplementation was done using a venturi mask at flow rate of 4-6 litre per min. Patients were randomly allocated into two groups (30 in each group) using sealed envelope technique.

- Group D : 1mcg/kg dexmedetomidine over 10 minutes before surgery
- Group M : 50 mcg/kg midazolam over 10 min before surgery

Base line vitals were recorded. Group D patients were given dexmedetomidine 1mcg/kg over 10 minutes as an intravenous infusion and group M were given midazolam 50mcg/kg intravenous infusion over 10 minutes.

After an interval of 10 minutes their sedation score was assessed using Ramsay sedation score (1 = agitated, restless; 2 = cooperative, tranquil; 3 = responds to verbal command while sleeping; 4 = brisk response to glabellar tap or loud voice while sleeping; 5 = sluggish response to glabellar tap or loud voice; 6 = no response to glabellar tap or loud voice). The target end point was a patient having RSS = 3. Patient was administered local anaesthesia by the surgeon only when the sedation score was at least 2/3. Intraoperative haemodynamics were recorded every 5 minutes for half an hour and at an interval of 10 minutes thereafter. Oxygen administered via venture mask at flow rate of 4-6 litre per min. Patients who got awake or conscious during the procedure were given midazolam 1mg intravenously as a rescue drug to maintain sedation.

After the procedure patients were shifted to recovery room for monitoring. The number of rescue doses of midazolam were recorded and a maximum of three rescue doses of midazolam were given. At any time, if clinically indicated or if maximum amounts of rescue drugs were reached, the sedation technique was converted to any alternative sedative or anesthetic technique and the study drug was discontinued. Adverse events like bradycardia (HR <45 bpm), hypotension (drop in systolic blood pressure >20% of baseline or MAP <60 mmHg), hypertension (an increase in systolic blood pressure or MAP >20%of

baseline), bradypnea (RR <8 breaths/min), desaturation (SpO_2 < 90%), nausea, vomiting, dry mouth or any other event during or within two hours of the procedure were noted. Bradycardia was treated with intravenous atropine sulphate 0.6 mg , hypotension with fluid replacement and if needed, intravenous ephedrine hydrochloride 5 mg in incremental doses was administered. In case of bradypnea, patient was asked to take deep breaths. Desaturation was treated by increasing O_2 flow up to 6 litres and if needed, using bag mask ventilation with 10 litres of oxygen. After the completion of surgery patients were shifted to the PACU and were monitored for hemodynamic parameters and adverse events, if any for 2 hours.

STATISTICALANALYSIS

Data analysis was done using Statistical Package Mini-Tab version 17.0. Sample size calculation was based on a population standard deviation of 1.1 with 80% power and 5% alpha error. Hemodynamic and respiratory data were evaluated using unpaired t test for intergroup and paired t-test for within group comparisons. P value less than 0.05 was considered as significant.

RESULTS

There was no statistically significant difference between dexmeditomidine and midazolam groups (P>0.05) in the age, sex, weight , ASA grade, duration of surgery (Table 1).

There was no difference in baseline measurements of mean and systolic blood pressure between the two groups, but group D had significant fall in systolic blood pressure 15 minutes after the start of surgery till the end. In the midazolam group there was a fall in blood pressure initially for 20 minutes which again started rising towards baseline.(Fig.1) There was statistically significant difference (p value <0.05) in systolic blood pressure and mean arterial pressure with a lower blood pressure in the dexmedetomidine group. There was no statistically significant difference found in diastolic blood pressure between both the groups.

There was no difference in baseline measurements of HR, but group D had significant fall in heart rate after start of surgery till the end. Statistically significant difference was found in heart rate of both the groups with a lower heart rate in group D (p value <0.05)(Table 2).

There was no statistically significant change in respiratory rate initially, but upto 20 minutes of the commencement of surgery respiratory rate was statistically significant between the groups with a lower respiratory rate in group D (Table No. 3) The mean sedation score in group D was found to be 4.33±0.76 and in group M was 2.83±0.46 which was statistically significant (p value <0.05) (Figure2).

Rescue sedation was required in 13 patients in the midazolam group whereas no patient needed rescue sedation in the dexmedetomidine group. There was no complication in any of the groups.

TABLE NO. 1 DEMOGRAPHIC DISTRIBUTION OF PATIENTS

Study variables	Dexmedetomidine n=30	Midazolam N=30	P value
Age (years)	28.97(5.92)	29.50(6)36	0.738
Sex- M:F	11/19	14/16	0.643
Weight (kg)	52.8(9.2)	54.3(10.2)	0.155
ASA Grade (I/II)	30/0	29/1	0.53
Duration of surgery (min)	78.9(11.6)	79.6(10.9)	0.63

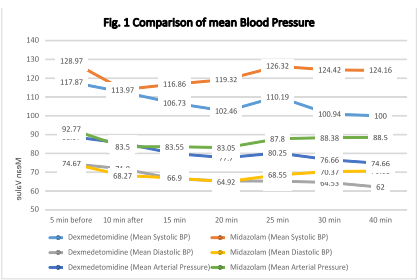


TABLE NO. 2 COMPARISON OF HEART RATE BETWEEN DEXMEDETOMIDINE AND MIDAZOLAM GROUPS

(N=60)

Time Intervals	Dexmedetomidine (n=30)		Midazolam (n=30)		't' Value	P Value
	n	Mean ± SD	n	Mean ± SD		
5 min before	30	85.00 ± 15.50	30	122.00 ± 177.99	1.134, df=58	0.261
10 min after	30	78.07 ± 9.79	30	91.13 ± 12.84	4.432, df=58	0.000*
15 min	30	73.67 ± 8.49	29	91.55 ± 15.12	5.625, df=57	0.000*
20 min	28	69.96 ± 5.41	24	94.33 ± 16.48	7.386, df=50	0.000*
25 min	21	69.62 ± 5.51	22	91.45 ± 12.93	7.141, df=41	0.000*
30 min	17	68.76 ± 5.87	19	89.05 ± 12.29	6.197, df=34	0.000*
40 min	4	68.50 ± 10.79	19	89.79 ± 13.38	2.968, df=21	0.007*

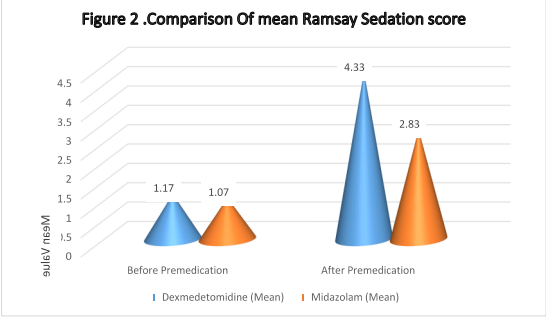
Unpaired 't' test applied. P value < 0.05 was taken as statistically significant

TABLE NO.3COMPARISON OF MEAN RESPIRATORY RATE BETWEEN DEXMEDETOMIDINE AND MIDAZOLAM GROUPS

(N=60)

Time Intervals	Dexmedetomidine (n=30)		Midazolam (n=30)		't' Value	P Value
	n	Mean ± SD	n	Mean ± SD		
5 min before	30	17.47 ± 2.59	30	18.67 ± 2.99	1.657, df=58	0.103, NS
10 min after	30	16.50 ± 1.78	30	19.67 ± 4.77	3.410, df=58	0.001*
15 min	30	16.43 ± 2.19	29	19.66 ± 5.06	3.193, df=57	0.002*
20 min	29	16.48 ± 1.79	25	18.80 ± 4.05	2.785, df=52	0.007*
25 min	26	16.85 ± 2.49	23	17.96 ± 3.78	1.226, df=47	0.226, NS
30 min	22	16.68 ± 2.34	22	17.36 ± 3.69	0.731, df=42	0.469, NS
40 min	2	21.50 ± 6.36	21	18.81 ± 4.39	-0.807, df=21	0.428, NS
50 min	0	-	4	18.00 ± 3.37	-	-

Unpaired 't' test applied. P value < 0.05 was taken as statistically significant



DISCUSSION

Monitored Anesthesia Care is emerging as a special modality by virtue of which, procedures that required patients to stay overnight in a hospital are now performed safely in outpatient suites. It combines intravenous sedation, anxiolysis and analgesia with local anaesthetic infiltration or nerve blocks[6].

Dexmedetomidine can be safely and effectively used for procedural sedation and surgeries done under MAC[7,8,9]. It's use in other ENT surgeries like functional endoscopic sinus surgery (FESS), septoplasty, and thyroplasty under MAC has also been

documented[10,11,12]. Middle-ear surgeries pose a different set of challenges for the patient, surgeons and anesthesiologists. Sympathetic stimulation and movements of an anxious patient cause increased bleeding and disturb the fine microscopic nature of the surgery which may even lead to graft failure. The advantages of local anesthesia include testing hearing intraoperatively, immediately detecting complications and a truncated postsurgical emergence. Good patient selection, preoperative counselling and use of appropriate sedation are important factors for success of this surgery under local anesthesia. [13,14]

In our study dexmedetomidine was given in a bolus of 1mcg/kg based on previous literature[15,16]. The dose of midazolam in our study was 0.05 mg kg[17]. This dose is chosen as it is comparable to loading dose of dexmedetomidine 1 µg kg -1 in terms of sedation. Both the groups attained a minimum required level of sedation but dexmedetomidine proved better in terms of quality of sedation, lesser rescue sedatives and better patient satisfaction. Since, operating site was infiltrated thoroughly with local anaesthetic, analgesia was not a concern, so rescue sedation chosen was midazolam for both the groups.

Dexmedetomidine provides sedation and analgesia without respiratory depression. It has a novel property of providing " conscious sedation", i.e. patient can be aroused any time during the procedure only to go to sleep again. The sleep produced by dexmedetomidine mimics natural sleep. Moreover it has an impressive pharmacological profile with a shorter half life (2hrs) as compared to midazolam(3-4hrs) and a wider margin of safety. Besides sedation, it also produces analgesia via acting on substantia nigra and locus ceruleus[6].

Koroglu A et al[18] studied and compared the sedative, hemodynamic and respiratory effects of dexmedetomidine with midazolam in children undergoing MRI examination. They found the quality of MRI was significantly better and the rate of adequate sedation was higher in group D than in group M (P<0.001). In group D, the requirement for rescue drugs was lower and the onset of sedation time was shorter than in group M (P<0.001). This study is in accordance with ours in relation to sedation scores.

Devangi A. Parikh[19] et al., evaluated Dexmedetomidine vs Midazolam Fentanyl in tympanoplasty, in their study both the drugs were comparable in terms of sedation as none of the patient in either group required additional sedation with Propofol or any alternative anaesthesia technique, as in our study.

Durmus et al.,[20] have evaluated this property of dexmedetomidine for providing controlled hypotension in general anesthesia for tympanoplasty cases and concluded that it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required which was similar to the finding of lower mean arterial pressure in the dexmedetomidine group in the present study.

Alhashemi JA et al[21] in the year 2006 compared the use of dexmedetomidine and midazolam for monitored anaesthesia care in patients undergoing cataract surgery. He found that Group D patients had slightly higher satisfaction with sedation, but delayed readiness for discharge (P<0.01)compared with patients in Group M. In this study dexmedetomidine was given as infusion like our study but midazolam was given as intermittent boluses as and when required. This explained the delayed recovery in the Group D. Since in our study both the drugs were given as bolus injection and rescue sedative used was midazolam 1mg which is just an anti-anxiety dose, so delayed recovery was not found in any of the group .

Comparing the HR between the two groups, in Group D overall HR was maintained on lower side than the pre-operative value. Whereas in Group M, the HR almost remained same throughout and the difference was statistically significant. Ustün Y et al[22] also compared dexmedetomidine versus midazolam in outpatient third molar surgery. They observed that mean heart rate and blood pressure measurements were significantly lower in group D.

In the present study respiratory rate in group D (Mean = 15.01) and in group M (Mean = 16.5) (P >0.05) was found to be normal in both the groups. Cheung et al[23] and Na et al[24], had similar findings. Saturation of oxygen (Spo2) was also found to be normal in group D (Mean = 98.89%) and group M (Mean = 99.25%) (P > 0.05). And there was no evidence of bradypnea in either of the groups. Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by the Ỳ aminobutyric system[25]. However, Alhashemi et al.,[21] in their comparative study of dexmedetomidine with midazolam for cataract had observed a higher ventilatory frequency in patients receiving midazolam. They attributed the increased respiratory rate to midazolam causing decreased tidal volume and an increase in the respiratory rate as a compensation to maintain minute ventilation. Overall our study showed that dexmedetomidine could be a better alternative compared to conventional sedation with midazolam in view of providing an equal sedation compared to midazolam.

However, Zeyneloglu et al[26] have reported better satisfaction scores with midazolam-fentanyl combination as compared to dexmedetomidine in extracorporeal shock wave lithotripsy (ESWL) when used alone. The authors also concluded that probably it was not effective as a sole agent in ESWL.

CONCLUSION

Dexmedetomidine given in a single loading dose of 1mcg/kg could be a better alternative compared to conventional sedation with Midazolam for minor ENT procedures, since it provides a calm patient with better intraoperative haemodynamics without any complications. The hypotensive effects of Dexmedetomidine on the cardiovascular system may be beneficial in high-risk patients as well.

REFERENCES

1. Delmade MA, Parikh DA. A prospective randomized double blind study to compare dexmedetomidine and midazolam in ear nose and throat surgery for monitored anesthesia care. Int J Res Med Sci 2016;4:3159-63
2. Jackson CG. Principles of Temporal bone and Skull Base Surgery. In: Glasscock,editor. Surgery of the Ear. 5thed. New Delhi: Elsevier India;2003.p.264-6.
3. Yung MW. Local anaesthesia in middle ear surgery: Survey of patients and surgeons. Clin Otolaryngol Allied Sci 1996;21:404-8.
4. Dr. Padmaja A, Dr. Tars Varma, et al.A Comparitive Study of Dexmedetomidine Vs Midazolam for Monitored Anaesthesia Care during ENT Surgical Procedures. Int. J Sci Res Apr 2015;4:100-104 Vol 14.
5. Stovner J, Endresen R: Diazepam in intravenous anesthesia. Lancet 1965; 2:1298-1299.
6. Priyamvada Gupta, Durga Jethava, Samrat Joshi, Ankit Kumar: Dexmedetomidine ameliorates monitored anaesthesia care. Indian Journal of Anaesthesia, Vol. 58, No. 2, March-April, 2014, pp. 154-159
7. Abdalla MI, Mansouri FA, Bener A. Dexmedetomidine during local anesthesia. J Anesth 2006;20:54-6.
8. Alhashemi JA. Dexmedetomidine vs. Midazolam for monitored anaesthesia care during cataract surgery. Br J Anaesth 2006;96:722-6.
9. Cheung CW, Ying CL, Chiu WK, Wong GT, Ng KF, Irwin MG. A comparison of Dexmedetomidine and Midazolam for sedation in third molar surgery. Anaesthesia 2007;62:1132-8.
10. Goksu S, Arik H, Demiryurek S, Mumbuc S, Oner U, Demiryurek AT. Effects of Dexmedetomidine infusion in patients undergoing functional endoscopic sinus surgery under local anaesthesia. Eur J Anaesthesiol 2008;25:22-8.
11. Dogan R, Erbek S, Gonencer HH, Erbek HS, Isbilen C, Arslan G. Comparison of local anaesthesia with Dexmedetomidine sedation and general anaesthesia during septoplasty. Eur J Anaesthesiol 2010;27:960-4.
12. Busick T, Kussman M, Scheidt T, Tobias JD. Preliminary experience with dexmedetomidine for monitored anesthesia care during ENT surgical procedures. Am J Ther 2008;15:520-7.
13. Sarmento Jr KM, Tomita S. Retroauricular tympanoplasty and tympanomastoidectomy under local anesthesia and sedation. Acta Otolaryngol 2009;129:726- 8.
14. Yung MW. Local anaesthesia in middle ear surgery: Survey of patients and surgeons. Clin Otolaryngol Allied Sci 1996;21:404-8.
15. Bhana N, Goa KL, McClellan KJ. Dexmedetomidine. Drugs 2000;59:263-8.
16. Kamibayashi T, Maze M. Clinical uses of alpha2- adrenergic agonists. Anesthesiology 2000;93:1345-9.
17. Eren G, Cukurova Z, Demir G, Hergunsel O, Kozanhan B, Emir NS. Comparison of Dexmedetomidine and three different doses of Midazolam in preoperative sedation. J Anaesthesiol Clin Pharmacol 2011;27:367-72.
18. Koroglu A, Demirbilek S, Teksan H. Sedative, hemodynamic and respiratory effects of dexmeditomidine in children undergoing magnetic resonance imaging examination: preliminary results. Br J Anaesth. 2005;94:821-4
19. Parikh DA, Kolli SN, Karnik HS, Lele SS, Tendolkar BA. A prospective randomized double-blind study comparing dexmedetomidine vs. combination of midazolam-fentanyl for tympanoplasty surgery under monitored anesthesia care. J Anaesthesiol Clin Pharmacol. 2013 Apr;29(2):173-8.
20. Durmus M, But AK, Dogan Z, Yucel A, Miman MC, Ersoy MO. Effect of Dexmedetomidine on bleeding during tympanoplasty or septorhinoplasty. Eur J Anaesthesiol 2007;24:447-53.
21. Alhashemi JA. Dexmedetomidine vs. Midazolam for monitored anaesthesia car during cataract surgery. Br J Anaesth 2006;96:722-6.
22. Ustün Y, Gündüz M, Erdogan O, Bendlidayi ME. Dexmedetomidine versus midazolam in outpatient third molar surgery. J Oral Maxillofac Surg. 2006;64:1353-8.
23. Cheung CW, Ying CL, Chiu WK, Wong GT, Ng KF, Irwin MG. A comparison of Dexmedetomidine and Midazolam for sedation in third molar surgery. Anaesthesia 2007;62:1132-8.
24. Na HS, Song IA, Park HS, Hwang JW, Do SH, Kim CS. Dexmedetomidine is effective for monitored anesthesia care in outpatients undergoing cataract surgery. Korean J Anesthesiol 2011;61:453-9
25. Gerlach AT, Dasta JF. Dexmedetomidine: An updated review. Ann Pharmacother 2007;41:245-52.
26. Zeyneloglu P, Pirat A, Candan S, Kuyumcu S, Tekin I, Arslan G. Dexmedetomidine causes prolonged recovery when compared with Midazolam/fentanyl combination in outpatient shock wave lithotripsy. Eur J Anaesthesiol 2008;25:961-7.