ORIGINAL RESEARCH

Comparative Study Between Dexmedetomidine and Midazolam in Monitored Anaesthesia Care During Ear Surgery

Sunil Chiruvella[1], Srinivasa Rao Nallam[2]

ABSTRACT

Introduction: Monitored anesthesia care (MAC) is the practice of administering local anesthesia in combination with IV sedatives, anxiolytics and/or analgesic drugs during certain surgical procedures. The aim of the study is to compare the effects of dexmedetomidine and midazolam in monitored anesthesia care during ear surgeries.

Material and method: Patients under American Society of Anesthesiologists I or II in age group 20-50 years were included in the study. The patients were randomly allocated into one of the two groups. Group D patients received dexmedetomidine 1 μg/kg IV over 10 min followed by 0.5 μg/kg/h and group M patients received midazolam 0.06 mg/kg diluted intravenously slowly, followed by 0.01 mg/kg/hr.

Results: There were no significant differences in demographic data between the two groups. Dexmedetomidine (D) group (4.50±1.05) showed more sedation than the midazolam (M) group (2.50± 0.85).Overall VAS was also significantly lower in group D (3.47 ±1.12) than group M (5.67± 1.84). Group D patients had significant fall in heart rate (30%)after start of infusion till the end of surgery compared to group M(6%). Patients in group D had a greater fall 20 out of 50(40%) in comparison to group M 7 out of 50 (14%) exhibited a minor fall in BP over a period of time.

Conclusion: Dexmedetomidine is superior to Midazolam in producing sedation and decreasing VAS in patients undergoing ear surgeries under MAC.

Keywords: Dexmedetomidine, Ear surgery, Midazolam, Monitored anesthesia care.

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INTRODUCTION

According to the American Society of Anesthesiologists (ASA), a monitored anesthesia care (MAC) is a planned surgical procedure during which surgery is performed under local anesthesia combined with sedation and analgesia under the supervision of Anaesthesiologist.[1] The three essential features and purposes of a conscious sedation during a MAC are as follows: safe sedation, control of the patient anxiety and analgesia.[2] Most of ear surgeries can be performed under monitored anesthesia care.

Drugs that can be used during monitored anesthesia care should be chosen according to the type and time of surgical procedure, patient's medical and psychological conditions and experience of the anesthetic team.[3] Various drugs can be used for sedation during surgery under local anesthesia with monitored anesthesia care including opioids, benzodiazepines and propofol.[4] Propofol may causeoversedation, disorientation and respiratory embarrassment.[5] Benzodiazepines may result in confusion and subsequent agitation, particularly in old age[6] and opioids are associated with increased risk of nausea, vomiting, respiratory depression and oxygen desaturation.[7]

Midazolam is a benzodiazepine which has sedative and anxiolytic properties, provides anterograde amnesia, and has anticonvulsant properties.[8] Alpha-2 adrenoreceptors agonists i.e. clonidine and Dexmedetomidine are increasingly used for their sedative, analgesic, sympatholytic and cardiovascular stabilizing effects.[9,10]

The present study was planned to evaluate the efficacy of dexmedetomidineas analgesic, sedative with its hemodynamic effects among patients undergoing ear surgeries under monitored anesthesia care. We have used midazolam as another drug for the comparison because it is the drug, which is widely used for monitored anesthesia care.

MATERIALS AND METHODS

One hundred patients aged between 20-50 years undergoing elective ear surgeries under local anesthesia like tympanoplasty, myringoplasty or stapedectomies were included in this study.The study protocol was approved by the Institutional Ethical Committee. Written Informed Consent was taken from each subject willing to enter the study. Preanaesthetic checkup and routine investigations like complete blood count, serum creatinine and ECG were done. Patients were kept nil by mouth for 6 hours. Intraoperative pain intensity was evaluated using visual analogue scale (VAS) (0-10, where 0 indicates no pain while 10 corresponded to maximum pain), was explained to the patient during the preoperative visit.

Patients with severe cardiac disease, 2nd or 3rd degree heart block, chronic obstructive lung disease, renal and hepatic insufficiency, uncontrolled diabetes and hypertension, metabolic or central nervous system disorders, pregnant and lactating female, any drug allergy, α2agonist or antagonist therapy taken, and active upper respiratory infection, were excluded from the study.

On arrival to operating room, an 18gauge intravenous (IV) catheter was inserted and 6 ml/kg/h crystalloid was infused. Non invasive monitors like electrocardiography, NIBP, oxygen saturation (SpO2) were attached and baseline parameters such as heart rate, systemic arterial pressure and peripheral oxygen saturation were noted down. Intraoperatively, all the patients received 2 L/min oxygen via nasal catheters. All the patients were premedicated with injection glycopyrrolate. Patients were randomly divided into two groups of 50 patients each to receive either dexmedetomidine (groupD) or midazolam (group M) for sedation and analgesia during surgery.Group D patients received dexmedetomidine 1 μg/kg IV over 10 min followed by 0.5μg/kg/h and group M patients received midazolam 0.06mg/kg diluted intravenously slowly, followed by 0.01 mg/kg/hr.

Local anesthetic infiltration was given by the operating surgeon, who was unaware of the group allocation, using lidocaine 1% with adrenaline 1:200,000. Paracetamol infusion 1gm was given to all patients. Surgery was confirmed after adequate analgesia. Intraoperative heart rate, mean blood pressure and oxygen saturation were recorded every 10 mins intervals till the end of surgery.

Level of sedation was assessed using Ramsay Sedation Score (RSS). The desired sedation level was definedas RSS =3 by the end of 10 mins. If RSS was less than 3, rescue sedation with propofol100–200 μg /kg/h IV was given. If the target end point was reached before completing the loading infusion, then the infusion was stopped and noted. The maintenance infusion in both the groups were commenced immediately, once the loading infusion was stopped.Then surgeon proceededto perform the surgery under local anesthesia.

Intraoperative pain intensity was evaluated using VAS. If the pain was persistent and the VAS 3, then rescue intra venous fentanyl in a dose of 1μg/kg was given. The number of rescue doses of fentanyl was recorded. Adverse events like bradycardia (15% reduction of the baseline heart rate), Hypotension(drop of mean arterial blood pressure 20% of baseline),nausea, vomiting, dry mouth or any other event during the procedures were noted. Bradycardia was treated with intravenous Atropine 0.01mg/kg and hypotension with fluid replacement. Hemodynamic and respiratory data were evaluated using unpaired t-test for inter group comparisionand paired t-test for with in the group comparision. Categorical data was analyzed using Chi square test. P value less than 0.05 was considered as significant.

STATISTICAL ANALYSIS

Results are based on descriptive statistics. Tables were generated with the help of SPSS version 21.

RESULTS

The demographic data of the two study groups are summarized in Table 2. Statistical analysis revealed non significant differences between the two study groups with regards to age, sex distribution, weight and duration of surgery. In the present study mean duration of surgery in group D was found to be 57.47±11.87 while in group M the mean duration of surgery is 59.6 ±12.46. As the p value is >0.05, duration of surgery was found to be an insignificant component.

The surgical procedure performed in patients was either: tympanoplasty, myringoplasty, or stapedectomy. The distribution of these procedures between the two study groups was found to be non-significant (p> 0.05) (Table 3).

Intraoperative sedation was measured by using Ramsay sedation score(Table 1). It revealed that there was statistically significant difference between the two studied groups, where the dexmedetomidine (D) group (4.50±1.05) showed more sedation than the midazolam (M) group (2.50± 0.85). This result led to statistically significant difference between the two groups as regards to the use of rescue sedation where in group (M) 27 patients (54%) while in group (D) 14 (28%) patients needed propofol infusion ($p< 0.05$). (Table 4)

Rescue analgesia was given in both the groups if VAS score is more than 3.Inj.fentanyl in the dose of 1μg/kg was given intravenously.Overall VAS was also significantly lower in group D (3.47 ±1.12) than group M (5.67± 1.84) (Table 4).In group M, significantly more number of patients (64%) required rescue fentanyl. In group D only 18(36%) patients required rescue fentanyl ($p<0.05$).Therefore on comparing both the groups rescue analgesia was found to be a statistically significant component.

There is no difference in baseline measurements of HR and MAP between the two groups, but group D had significant fall in heart rate (30%)after start of infusion till the end of surgery.Therefore there was statistically significant difference found in heart rate of both the groups(p value <0.05).Bradycardia in these patients was treated with intravenous Atropine sulphate 0.01mg/kg.Both the groups had significant reduction in MAP from the respective baseline values, however on analyzing the magnitude of decrease, patients in group D had a greater fall 20 out of 50(40%) in comparison to group M 7 out of 50 (14%) exhibited a minor fall in BP over a period of time.Hence there was statistical significance found in fall in MAP. ($p<0.05$) (Table 5).

DISCUSSION

The most valuable development in health care delivery is the shift from inpatient to outpatient surgery and the associated day-care anesthesia. The major benefit for this change is the economic savings afforded by not admitting patients the night before surgery or keeping them in hospital the night after surgery. Advantages of outpatient surgery include lower risk of nosocomial infection, earlier ambulation and better patient convenience.[11] Essential features for agents of day-care anesthesia are cost effectiveness and early discharge.[12] One of the methods of outpatient anesthesia is Monitored Anesthesia Care (MAC) which is a technique of combining local anesthesia with parenteral drugs for sedation and analgesia.

We compared the safety and efficiency of dexmedetomidine versus midazolam as intravenously administered agents for MAC during surgical ear procedures conducted under local anesthesia. We found that mean Ramsay Sedation Score (RSS) was significantly more in dexmedetomidine group (group D) than in midazolam group (group M).

Score	Response
1	Anxious or restless or both
2	Cooperative, oriented and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

Table-1: Ramsay sedation scale

	Group M (n=50)	Group D (n=50)
Age (year)	32.18±9.24	30.15 ±8.47
Sex M:F	30:20	28:22
Weight in Kgs	75.28±12.13	71.28±14.32
Duration of surgery in mins.	59.6 ±12.46	57.47±11.87

Table-2: Demographic data

	Group M (n=50) (%)	Group D (n=50) (%)
Tympanoplasty	22	23
Myringoplasty	16	14
Stapedectomy	12	13

Table-3: Type of surgery

	Group M (n=50)	Group D (n=50)
Sedation score	2.50± 0.85	4.50±1.05
VAS	5.67± 1.84	3.47 ±1.12
Intraoperative rescue sedation(if RSS=1, 2) n(%)	27(54%)	14(28%)
Rescue analgesia(if VAS>3) n(%)	32(64%)	18(36%)

Table-4: Intraoperative variables

	Group M (n=50) (%)	Group D (n=50) (%)
Mean Arterial BP	7/43(14%)	20/30(40%)
Heart Rate changes	3/47(6%)	15/35(30%)

Table-5: Intraoperative hemodynamics

	Group M (n=50) (%)	Group D (n=50) (%)
Nausea	4 (8)	5 (10)
Vomiting	1 (2)	3 (6)
Dry mouth	6 (12)	8 (20)
Hypotension	7 (14)	20 (40)
Bradycardia	3 (6)	15 (30)

Table-6: Complications

The sedative effects of midazolam are mediated through the activation GABAreceptor.Midazolam decreases pain perception by reducing the emotional component of pain through its anxiolytic and amnestic effects as anxiety and pain are intimately related so that anxiety leads to an exacerbation of pain.[13]

Dexmedetomidine is a selective alpha 2 (α2) adrenergic agonist with both analgesic and sedative properties. Dexmedetomidine is highly specific for α2receptors compared to the α1 receptor (200: 1 for clonidine and 1600: 1 for dex-medetomidine). Through presynaptic activation of the α2receptors, it inhibits the release of norepinephrine andsubsequently reduces sympathetic tone. It also decreasesthe neuroendocrine and hemodynamic responses to anesthesiaand surgery, leading to sedation and analgesia.[14] α2 receptors has been detected in highestdensity in the locus coeruleus,the predominant noradrenergic nucleus in the brain andan important modulator of vigilance. The sedative effects ofα2adrenoceptor activation have been attributed to this sitein the CNS, and this allows psychomotor function to be preservedwhile making the patient rest comfortably, so patientsare able to return to their baseline level of consciousness whenstimulated which is beneficial for MAC.[15] Both Clonidineand dexmedetomidine seem to offer these beneficial properties,but dexmedetomidine has a shorter half-life, which might bemore suitable for MAC.

Dexmedetomidine was used in many settings to provide sedation for surgeries performed under local anesthesia. For aesthetic facial surgery under local anesthesia, Taghinia et al. compared the addition of dexmedetomidine infusion to the usual sedative protocol (propofol, midazolam, fentanyl, and ketamine), they reported lower blood pressure values, but they did not comment on surgical field bleeding. They found that dexmedetomidineimproved the sedation safety as evidenced by the reported fewer incidences of oxygen desaturation, and the reduced need for the use of narcotics, and antiemetics.[16] Their results are consistent with the results of our study.

There are somestudies which reports that dexmedetomidine alone does not appear to be suitable for sedation in patients undergoing cataract surgery and midazolam is a better sedative agent. Though those reports shows that there was a slightly better subjective patient satisfaction with dexmedetomidine, it was found effective for sedation with vascular surgeries. Based on this pharmacologic background, our results may be explained on the fact that dexmedetomidine is a more effective sedative and analgesic agent with better preservation of psychomotor function in the given doses by its sympathetic attenuating effect, while midazolam has minimal analgesic effect (emotional component).

Dexmedetomidinewhen compared to midazolam to provide monitored anesthesia care for cataract surgery, Alhashemi found significantly better patient satisfaction scores indexmedetomidine group. Although he reported lower HR and MAP values in dexmedetomidine group, he did not find any difference in the incidence of hypotension, bradycardia or desaturation between both groups.[17] His previous results match well with the results of our study. But in contrast to our results, he reported earlier recovery and discharge times for midazolam group. This difference in results may be attributed to two factors; firstly, he used midazolam as a repeat bolus technique while dexmedetomidine as a continuous infusion. After an initial bolus of 20 µg/kg of midazolam, he used repeat boluses of 0.5 mg. According to his reports of mean total midazolam dose (1.5 mg) and mean body weight (70.6 kg), we can conclude that many of his patients might not have needed any repeat bolus. This could have allowed time for midazolam effect to fade whiledexmedetomidine was continuously infused in the other group. Secondly, he used Aldrete score of full 10 points to discharge patients from PACU which; in case of dexmedetomidine, might have delayed discharge due to the expected lower HR or blood pressure values.

Korogluet al.[18] compared dexmedetomidine versus propofol in children undergoing MRI examination, they foundthat dexmedetomidine preserved HR & MAP better than propofol. Also the incidence of oxygen desaturation was more with propofol, but the onset of sedation, recovery and discharge time were significantly shorter with propofol.[18] Another study by the same authors[19] Koroglu et al., compared dexmedetomidine versus midazolam in pediatrics undergoing MRI using a lower dose of dexmedetomidine, they found that the rate of adequate sedation was higher with dexmedetomidine associated with lower requirements of adjunct drugs. HR, MAP and RR were comparable between both groups but the onset of sedation was shorter with midazolam.

Midazolam sedation in our study was associated with lower patient satisfaction, higher pain scores and more use of rescue analgesic. Benedik and Manohin reported similar results when they compared midazolam during sedation in ear surgeries to propofol, the later provided significantly better patient and surgeon satisfaction scores, earlier recovery times.[20] In another study by Lee and Lee, the addition of remifentanil to midazolam was associated with less intraoperative anxiety and greater patient satisfaction than midazolam alone.[21]

CONCLUSION

On the basis of the findings of the present study, dexmedetomidine seems to be a better drug for monitored anesthesia care when compared to midazolam. The hypotensive effects of Dexmedetomidine on the cardiovascular system may be beneficial in high-risk patients and therebycauses decreased bleeding, thus providing a bloodless surgical field comfortable for the surgeon.

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