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A Comparitive Study of Dexmedetomidine Vs Midazolam for Monitored Anaesthesia Care during ENT Surgical Procedures

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Abstract:
Aims And Objectives: *Comparison of the efficacy of Dexmedetomidine vs Midazolam during monitored anaesthesia care in minor ENT surgical procedures with special emphasis on the sedative properties and the effectiveness of sedation, the number of doses of rescue analgesics given and the haemodynamic properties measured.*
Materials And Methods: *40 patients aged between 15-50 years undergoing ear surgeries under local anaesthesia randomly received Inj. Dexmeditomidine 1µg/kg intravenously, over 10 mins followed by 0.5µg/kg/hr(Group D) or Inj. Midazolam 0.06mg/kg diluted intravenously slowly, followed by 0.01 mg/kg/hr(Group M) followed by dextrose normal saline infusion at 0.2 ml/kg/hr. Sedation was titrated to Ramsay sedation score (RSS) of three. Vital parameters, intraoperative pain intensity by visual analogue scale (VAS)>3,no of rescue analgesics doses with fentanyl 1µg/kg was recorded.*
Results: *The mean sedation score in group D is 3.18± 0.19 and in group M is 3.03±0.21.(p>0.05).Intra operative heart rate and mean arterial pressure in group D were lower than the base line values and the corresponding values in group M (p<0.05).No of patients receiving rescue fentanyl were more in group M(2 patients 1dose,5 patients 2 doses),in group D only 2 patients required single dose of rescue analgesic fentanyl(p<0.05).*
Conclusion: *Dexmedetomidine and Midazolam were equally comparable in the effectiveness of sedation. The lesser requirement of rescue analgesics and decrease in MAP facilitating improved surgical field makes Dexmedetomidine a better choice in ENT surgical procedures.*
Keywords: *Dexmedetomidine, sedation, Midazolam, Monitored Anaesthesia Care*

I. Introduction

Monitored anaesthesia care involves administering a combination of drugs for anxiolytic, hypnotic, amnestic, and analgesic effect. Ideally it should result in less physiological disturbance and allow for more rapid recovery than general anaesthesia. It typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and analgesic drugs which is a common practice during various ENT surgical procedures. Tympanoplasty in ENT surgical procedures involves reconstruction of perforated tympanic membrane with or without ossiculoplasty. It is usually done under local anaesthesia with sedation under monitored anaesthesia care(MAC) or general anaesthesia. Patients may feel discomfort due to pain, noisy suction, manipulation of instruments and head and neck position. 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 intraoperatively.

Commonly used medication forMAC are benzodiazepines, opioids and propofol. Midazolam with its quick onset, but a relatively long half life can cause prolonged sedation after repeated administration. Dexmedetomidine is a selective α2 receptor agonist with properities of analgesia, sympatholysis and titrating sedation without major respiratory depression. It reduces opioid requirements and stress response to surgery ensuring a stable hemodynamic state. Dexmeditomidine is increasingly being used as a sedative for MAC for various surgical procedures. Dexmeditomidine is a novel analgesic agent that helps at preoperative, intraoperative and postoperative periods especially for hemodynamic stability.

Hence in the present study comparison of Dexmedetomidine with Midazolam is undertaken in patients admitted in the hospital for minor ENT surgical procedures under local anaesthesia (LA)Inj. Fentanyl used asrescue analgesic is common to both the groups when necessary depending on the pain exhibited by the patient which was evaluated using the Visual Analogue Scale (VAS).

II. Materials And Methods

After ethical committee approval 40 patients aged between 15-50 years undergoing ear surgery under local anaesthesia were included and written informed consent was obtained from all the participants. All routine investigations were done. Patients were explained about the concerned technique and informed consent taken.

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 were then randomly allocated in 2 groups as follows:

GROUP D: Dexmedetomidine group (n=20)- Inj. Dexmedetomidine 1µg/kg intravenously, over 10 minutes followed by 0.5µg/kg/hr.GROUP M: Midazolam group(n=20) - Inj. Midazolam 0.06mg/kg diluted intravenously slowly, followed by 0.01 mg/kg/hr.

During this period the patients were assessed using Ramsay sedation score (RSS) (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 by the end of 10 mins. 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 infusions were stopped.

Local anaesthesia was given by the operating surgeon, using 30ml of Inj. Xylocaine 2% with Inj. Adrenaline 1:200,000. 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.

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 (HR,15% OF BASELINE BPM), Hypotension(drop of mean arterial blood pressure .20% of baseline),desaturation (SPO2<90%),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 and 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.

III. Results

A study of 40 patients aged between 15-50 years undergoing minor ENT surgical procedures were randomized into two groups with 20 patients in group D(Dexmeditomidine) and 20 patients in group M(Midazolam). The study was undertaken to compare the effectiveness of sedation and hemodynamic changes of Dexmeditomidine vs Midazolam. In group D, median dose of Dexmeditomidine given was 115µg whereas those in group M received 5.06mg of Midazolam as the mean dose. The patient characteristics and demographic data were comparable in both the groups(table1).

Table_1

±PARAMETER	DEXMEDETOMIDINE (n=20)	MIDAZOLAM (n=20)	PVALUE
Age in Years (Mean±SD)	26.15±4.3	26.7±2.8	>0.05
Sex M:F	15/5	13/7	>0.05
Weight in Kgs	64.2±8.1	67.3±7.8	>0.05
Duration of surgery in mins.	107.4±6.2	105±7.6	>0.05

In the present study Mean age In group D was found to be mean=26.15±4.3 and in group M Mean 26.7±2.8 (P>0.05) stastically insignificant parameter.In the present study group D had 15 male patients and 5 female patients whereas in group M there were 13 male patients and 5 female patients.Since p>0.05 sex of the patients is found to be an insignificant variable.Mean weight of patient in group D is 64.2±8.1 while mean weight in group M was found to be 67.3±7.8. As p>0.05,weight of the patients is found to be insignificant parameter.

In the present study mean duration of surgery in group D was found to be 107.4±6.2 while in group M the mean duration of surgery is 105±7.6.As the p value is >0.05 , duration of surgery was found to be an insignificant component.

Table 2 - Sedation score: The mean sedation score in group D is found to be mean = 3.18±0.19 and in group M is 3.03±0.21. Since the p value observed was >0.05 sedation score is found to be statistically not significant.

Table 2

PARAMETER	DEXMEDETOMIDINE (n=20)	MIDAZOLAM (n=20)	P VALUE
Ramsay Sedation Score	3.18±0.19	3.03±0.21	>0.05

Table 3 shows changes in heart rate and mean arterial pressure over a period of time. There is no difference in baseline measurements of HR and MAP between the two groups, but group D had significant fall in heart rate (15-20%)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.

Table 3

PARAMETER	DEXMEDETOMIDINE (n=20)	MIDAZOLAM (n=20)	P VALUE
Mean Arterial BP	8/12(40%)	2/18(15%)	<0.05
Heart Rate changes	6/14(30%)	1/19(5%)	<0.05

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 8 out of 20(15-20%) in comparison to group M 2 out of 20 (5-10%) exhibited a minor fall in BP over a period of time..Hence there was statistical significance found in fall in MAP (p<0.05) as shown in table 3 and figure 3.

Table 4 shows the requirement of rescue analgesic in both the groups if VAS score is more than 3 Inj.fentanyl in the dose of 1µg/kg was given intravenously.In group M, significantly more number of patients required rescue fentanyl with 2 patients requiring one dose, and five patients requiring two doses. In group D only 2 patients required a single dose(p<0.05).Therefore on comparing both the groups rescue analgesia was found to be a statistically significant component.The median dose of Inj.fentanyl used in group M was 86µgm compared to only 70µgm in group D.

Table 4

PARAMETER	DEXMEDETOMIDINE (n=20)	MIDAZOLAM (n=20)	P VALUE
Rescue Analgesia	2/18(10%)	7/13(35%)	<0.05

Monitored anesthesia are (MAC) is useful for various clinical fields such as minimally invasive surgery, gastrointestinal endoscopy, and interventional or radiological procedures. It provides suitable intra operative conditions as well as comfort for patients.

Dexmedetomidine is a highly selective α2-adrenoceptor agonist with eight times higher specificity for the receptor compared to clonidine.[1] It provides excellent sedation and analgesia with minimal respiratory depression.[2] Dexmedetomidine can be safely and effectively used for procedural sedation and surgeries done under MAC[3]. Since the approval of Midazolam by FDA in 1985, [4] practitioners of all medical disciplines embraced the versatility provided by Midazolam though the risk of losing airway control, hypoxia and hypotension with higher doses of Midazolam has also been recognized. Midazolam is the most frequently used sedative and has been reported to be well tolerated when used in MAC.[5] Dexmedetomidine has both sedative and analgesic properties and has been used as a single agent in many painful procedures.[6] In the present study we chose a loading dose 1 mcg/kg of Dexmedetomidine . In view of its short distribution half life of 5 min Dexmedetomidine necessitates that it be given as a maintenance infusion. The dose of midazolam in our study was 0.06 mg kg -1 for the first ten minutes followed by a maintenance infusion of 0.01mg/kg/hour till the end of surgery. This dose is chosen as it is comparable to dexmedetomidine 1 µg kg -1 in terms of sedation.

In the present study, sedation score was slightly higher in group D (Mean = 3.18 ± 0.19) compared to group M (Mean = 3.03 ± 0.21) (P>0.05)and this indicates that statistically no significant difference was found between group D and group M. Similar findings were found in studies carried by Vyas DA et al.,11 where sedation score in Group D (3.64±0.86) and Group M (3.32±0.63) were also found to be statistically insignificant. Hence in spite of good sedation levels and lesser use of analgesics in the dexmedetomidine group, both the drugs were comparable in terms of sedation as none of the patients in either group required any additional sedation with propofol or any other alternative anesthesia technique.

In the present study percentage of patients requiring rescue fentanyl was higher in Group M than Group D (10% vs. 35% , P >0.05). Hence rescue analgesia was found to be a statistically significant parameter. Similar findings have also been reported by a study carried by K. Karaaslan et al., [7] where Group dexmedetomidine used significantly less rescue tramadol in comparison to Group midazolam when both the drugs were compared in FESS and nasal septoplasties. Analgesic property of α2 agonists like dexmedetomidine with its opiate-sparing properties has been documented by studies carried by Smith H et al.,[8] and has also been reported in studies conducted in general anesthesia with dexmedetomidine by Keniya VM et al.[9] In the present study when Dexmedetomidine was infused in patients it produced reduction in mean arterial pressure (15-20%) in 40% of the subjects and pulse rate (5-10%) in 30% when compared to midazolam.

However midazolam did not produce significant changes in mean arterial pressure, where 15-20% of the reduction is seen in only 15% of the subjects (P >0.05) and 5-10% decrease in heart rate in only 5% of the subjects(P >0.05). Hence fall in the mean arterial pressure (MAP) and heart rate was noted to be a statistically significant component in our study. This similar lower HR and MAP in Group D in comparison to the midazolam-fentanyl group could be explained by the markedly decreased sympathetic activity as seen in the study carried by Kamibayashi et al. [11]

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 and hence considered to be a statistically insignificant component . Cheung et al, [11] and Na et al, [12] has 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 is no evidence of bradypnea in either of the groups. Hence saturation was not a statistically significant component. Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by the Ỳ aminobutyric system.[13]However, Alhashemi et al.,[14] 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 with the use of lesser opiod requirements and this is similar to other studies conducted by Na HS et al., [12] Alhashemi et al.[14], and Candiotti et al. [15] However, Zeyneloglu et al.,[16] have reported better sedation scores with midazolam-fentanyl combination as compared to dexmedetomidine in extracorporeal shock wave lithotripsy (ESWL) when used alone.

Summary

In a prospective randomized study carried out on 40 adult patients, both male and female between ages of 15-50 which we divided into 2 groups of 20 each. Group D patients were given Inj. Dexmedetomidine 1 µgm / kg body weight over 10 minutes followed by 0.5 micro gram / kg / hour. Group M patients received Inj Midazolam 0.06 mg/ kg body weight over 10 minutes followed by 0.01mgm / kg / hour.

The effectiveness of sedation, rescue opioid requirements and haemodynamic parameters (MAP and HR) were measured in both the groups. The sedation score was found to be a statistically insignificant component.

There was a lesser dose of opioid requirement or rescue analgesic found in the patients who received Inj. Dexmedetomidine when compared to the Midazolam group(Group D and Group M = 10% vs 35%) (P<0.05). Hence rescue analgesics was a statistically significant component.

Fall in the Mean arterial pressure was more in Group D compared to Group M(Group D and Group M = 40% vs 15%) (P>0.05). Also fall in theheart rate more I Group D than in Group M (Group D and Group M = 30% vs5%) (P>0.05). Hence the comparision of the haemodynamics like blood pressure and heart rate was found to be a statistically significant component.

IV. Conclusion

Sedation with Dexmedetomidine seems to be a better alternative to Midazolam in Monitored Anaesthesia Care performed in minor ENT surgical procedures as it provides a calm sedated patient, with lesser opioid requirements. The hypotensive effects of Dexmedetomidine on the cardiovascular system may be beneficial in high-risk patients, and also causes decreased bleeding thus providing a bloodless surgical field comfortable for the surgeon.

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