Original article

COMPARISON OF DEXMEDETOMIDINE INFUSION/ MIDAZOLAM-FENTANYL INFUSION IN MONITORED ANESTHESIA CARE FOR SEDATION & OLEGAMIC FIELD FOR TYMPANOPLASTY & MODIFIED MASTOIDECTOMY.

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Abstract :

Background:

Midazolam-fentanyl combination, has been used medication given for sedation in tympanoplasty and mastoidectomy because of a number of beneficial effects. However, Dexmedetomidine is a highly selective α2-adrenoceptor agonist is emerging as preferred choice present era..

Aims& objectives:

The aim of the study is to compare hemodynamic stability and sedation under Dexmedetomidine infusion vsersus Midazolam-fentanyl infusion during tympanoplasty and modified radical mastoidectomy done under monitored Anesthesia care

Material & Methods:

After proper councelling and written informed consent from patients, 60 patients of age group 18 to 60 years of ASA grade I & II were selected and divided in to two groups:

Group A : Inj. Dexmedetomidine 1µg/kg over 10 min bolus through infusion pump followed by infusion of 0.5µg/kg/hr (n= 30).

Group B: Inj. Midazolam 0.02 mg/kg & inj fentanyl 1 mcg/kg IV over 10 min bolus through infusion pump followed by infusion of inj.midazolam 0.02mg/kg/hr
& Inj fentanyl 1 mcg/kg/hour. (n= 30).
Noninvasive blood pressure, heart rate and sedation level were monitored.
The surgeons and patients were asked to rate their satisfaction, as poor, satisfactory, good, excellent.

OBSERVATIONS & RESULTS:

There was significant reduction in systolic blood pressure after bolus infusion of Dexmedetomidine in group A.($p<0.05$) between group Aand group B was not statistically significantt difference found in diastolic blood pressure of both the groups. There was a significant reduction in heart rate in group A as compared to group B Surgeon's satisfaction score and patient's satisfaction score both were high in group A compare to group B.

Conclusions:

For monitored anaesthesia care(MAC) in middle ear surgeries performed under local anaesthesia, inj. Dexmedetomidine is a good alternative over inj. Midazolam Fentanyl combination for sedation,& Olegamic field.

Key words:
Dexmedetomidine, Midazolam, ENT surgeries, Tympanoplasty ,mastoidectomy, Monitored anaesthesia care(MAC)

Introduction:

For middle ear surgeries typically involves administration of local regional anaesthesia with sedation & analgesia(1). Dexmedetomidine is α_2-adrenoceptor agonist that has sedative and analgesic effects(,2,3,4) Clinical investigations have demonstrated its sedative, analgesic and anxiolytic effects after IV administration's to volunteers and postsurgicalpatients.([5,6,7,8])
It is a novel analgesic agent that helps at preoperative state, postoperative period and during surgery especially for hemodynamic stability.(4,9).
In present study we have compared dexmedetomidine infusion with midazolam-fentanyl combination infusion which is commonly used for Monitored anaesthesia care for tympanoplasty & mastoidectomy.

Material & Methods

After proper councelling, 60 patients of physical status ASA grade 1-2 aged between 15-50 years undergoing ear surgery were randomly selected from NHLM Medical Collage, ENT OT. A Preoperative visit was made on the day prior to plan surgery. All routine investigations were done. Patients were explained about the concerned technique & informed consent taken. Patients were instructed to keep fasting for 6-8 hours. All the resuscitation and monitoring equipments kept ready in Operation theatre.
In the operation theatre Baseline Vitals HR,$SpO_2$and NIBP were recorded.. Premedication was given in the form of inj.

Glycopyrolate 0.04 mg/ kg and inj. Ondansatron 0.08 mg/kg IV. , 10 min before operative procedure were given.
Patients were randomly allocated in 2 groups by sealed opaque envelope method by odd& even number . Execution ofRandomisation at time of Premedication as follows:
Group A : Dexmedetomidine group (n= 30) - Inj. Dexmedetomidine 1µg/kg, bolus over 10 min through infusion pump followed by
0.5µg/kg/hr.
Group B : Midazolam group (n= 30) - Inj. Midazolam
0.02mg/kg diluted i.v. & inj fentanyl 1 mcg/kg slowly, bolus through infusion pump over 10 min followed by 0.02mg/kg/hr of midazolam & fentanyl of 1 mcg /kg/hour.
Both groups also received inj. Ondansetron 0.15 mg/kg i.v. and inj. DNS 1 litre started slowly.
Sedation level was measured by Ramsay sedation scale. As Ramsay score of 3 was achieved and hemodynamic and respiratory stability was ensured, operative procedure was started under Local anaesthesia was given by the operating surgeon, using xylocaine 2% with adrenaline1:200,000. SBP,DBP,HR,SPO2 were monitored periodically & data were noted in MS Excel .
Patients were allowed to breathe spontaneously without airway intervention during the operation. (6)
Intraoperative bleeding was assessed by bleeding scale of Bozzeart . (0-4)
0 - No bleeding,
1 - Slight bleeding; no suctioning of blood required
2 - Slight bleeding; occasional suctioning required. Surgical field not threatened
3 - Slight bleeding; frequent suctioning required. Bleeding threatened surgical field a few seconds after suction was removed
4 - Moderate bleeding; frequent suctioning required. Bleeding threatened surgical field directly after suction was removed.

patient satisfactionscore & surgeon satisfaction score
In terms of poor, satisfactory, good,& excellent.

Statastical Analysis:
Data were collected I. Ms Excel spreadsheet & analysed by SPSS software IBM Armonk NY USA.version 20.
Qualitative data were analysed by student unpaired T test
Categorical data were analysed by chi square test.

Results:

A study of 60 patients aged between 15-50 yrs undergoing tympanoplasty and mastoidectomy were randomized into 2 groups with 30 patients in Group A (Dexmedetomidine) and 30 patients in Group B (Midazolam& fentanyl). The study was undertaken to compare the sedative, analgesic and hemodynamic changes of Dexmedetomidine infusion vs Midazolam-fentanyl infusion.
Demographic data is shown in Table 1.

Dexmedetomidine group which was responsive to I.V. fluids. There was a significant reduction in heart rate in group A as compared to group B (Figure 4).

Table 1 Demographic parameters

Parameters(mean+/-SD)	Group A	Group B	Pvalue
Age(years)	30+/-8.2	29+/-7.8	>0.05
Sex(M/F)	(14/16)	(15/15)	-
Duration of surgery (mins)	120+/-20.5	122+/-18.5	>0.05

Table 2: Various monitoring scores of patients

Scores	Group A-	Group B-	Pvalue
Ramsey sedation score	3.64+/-0.84	2.86+/-0.72	<0.05
Bleeding scoreof Bozzeart	1.67+/-0.45	2.0+/-0.25	<0.05
Patients/surgeon satisaction score	Good/excellent	Satisfactory/good	-

Table3:Changes in Systolic blood pressure(SBP)& Diastolic blood pressure (DBP)

Time	Group A(SBP/DBP)	Group B(SBP/DBP)	P value

Baseline	(124+/-20) /(80+/-8)	(120+/-22) / (80+/-6)	>0.05
10 min	(100+/-16)/(70+/-10)	(118+/-12) / (78+/-2)	<0.05
20 min	(100+/-12)/ (70+/-8)	(118+/-14) / (78+/-4)	<0.05
30 min	(98+/-10)/ (72+/-8)	(116+/-16) / (76+/-4)	<0.05
45 min	(98+/-12)/(72+/-6)	(114+/-14) / (76+/-3)	<0.05
60 min	(100+/-14)/ (72+/-6)	(118+/-14) / (76+/-4)	<0.05
90 min	(100+/-12)/ (72+/-4)	(120+/-12) / (74+/-6)	<0.05
120 min	(104+/-12)/ (72+/-4)	(120+/-14) / (76+/-4)	<0.05

Table 4:Changes in Heart Rate

Time	Group A	Group B	P value
Baseline	84+/-10	82+/-10	>0.05
10 min	74+/-14	80+/-14	<0.05
20 min	70+/-14	78+-12	<0.05
30 min	68+/-12	78+/-14	<0.05
45 min	68+/+12	76+/-12	<0.05
60 min	68+/-10	78+/-14	<0.05
90 min	64+/-10	78+/-16	<0.05
120 min	64+/+10	78+/-14	<0.05

There was no. Significant change in Diastolic blood pressure (DBP),spo2, Respiratory Rate.

No patient in any group required airway intervention or desaturation.

Discussion and conclusion :

Monitored Anaesthesia Care (MAC) is a technique of combining local anaesthesia with parenteral drugs for sedation and analgesia.[10] A common practice with sedation is that the sedative drug is given in larger doses in an attempt to achieve a calm, pain free patient.[11] Monitored anesthesia care (MAC) is useful for various clinical fields such as minimally invasive surgery. Systolic Blood pressure (SBP) decreased significantly after

administration of the drug in group A than in group B . There was no statically significant difference found in diastolic blood pressure (DBP)of both the group.

Mild hypotension provides suitable intraoperative conditions as well as comfort for patients. The commonly used drugs are Midazolam, Propofol, and opioids such as Fentanyl, Alfentanil or Remifentanil.Occasionally, the administon of sedatives or hypnotics in conjunction with analgesics can cause significant respiratory depression and/or transient upper airwayObstruction.[12] Since the approval of Midazolam by FDA in 1985,[13] 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.

Monitored anaesthesia care (MAC) may be applied for various ENT surgeries in which an adequate sedation and analgesia without respiratory depression are desirable for comfort of both the patient and the surgeon.[11] In order to reduce the incidence of complications, it is important to have a bloodless surgical field as far as possible for better visibility. Bleeding control is usually attained with local application of epinephrine.(10) Pain during surgery may lead to sympathetic stimulation and a restless patient may have tachycardia and hypertension, leading to increased bleeding in the surgical field. Several drugs have been used for sedation during surgery under local anaesthesia with monitored anaesthesia care including Propofol, benzodiazepines and opioids. However, Propofol may cause over sedation 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 untoward effects may hamper patient's cooperation during surgery and would make these agents less than ideal for the intraoperative management of sedation in MAC. Midazolam-fentanyl combination is the most frequently used sedative and has been reported to be well tolerated when used in MAC.(1,2)

Dexmedetomidine is a highly selective α_2-adrenoceptor agonist with eight times higher specificity for the receptor compared to clonidine. It provides excellent sedation and analgesia with minimal respiratory depression. Recent multicenter trial indicated that it was an effective baseline sedative for patients undergoing a broad range of surgical procedures under MAC, providing greater patient satisfaction,less opioid requirements, and less respiratory depression compared with the placebo.(7) In patients undergoing diagnostic transesophageal echocardiography, the sedative effect of Dexmedetomidine proved to be equivalent to that of the standard therapy using Midazolam and Fentanyl without increasing the incidences of respiratory depression or oxygen desaturation. It also seemed to be better in terms of hemodynamic results.(6)

In our study when Dexmedetomidine was infused in patients it produced reduction in BP & pulse, 8.14% - 18.14% reduction in systolic blood pressure and in HR 20% reduction was seen. Midazolam fentanyl combination did not produced significant changes in BP & pulse,1.83%-9.61% reduction in systolic blood pressure, and 0.7%-12.3% decrease in HR is seen Oxygen saturation was maintained in both the groups.

Kumari I.et al,(3) done Comparison of clonidine versus Midazolam in monitored anesthesia care during ENT surgery. They evaluate intragroup variations, mean HR and MAP showed a significant fall from baseline in Clonidine Group, whereas they showed a significant rise from baseline in Midazolam Group. On intergroup comparison mean HR and MAP were significantly less in Group C as compared to Group M.[3]

Devangi A. Parikh et al., evaluate Dexmedetomidine vs Midazolam-Fentanyl in tympanoplasty, they said that lower HR and MAP in Dexmedetomidine group in comparison to the Midazolam(13)

-Fentanyl group could be explained by the markedly decreased sympathetic activity. There finding were similar to other studies where lower HR and MAP were observed in the Dexmedetomidine group. There result suggest that Dexmedetomidine has clinical advantage over Midazolam in providing a better operative field for microscopic surgery.[13] Danielson et al, have evaluated this property of Dexmedetomidine for providing controlled hypotension in general anaesthesia for tympanoplasty cases and concluded that it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required. (9)

Midazolam causes sedation by GABA receptor activation. α_2 receptors are found densely in the pontine locus ceruleus which is an important source of sympathetic nervous system innervations of the forebrain and a vital modulator of vigilance. The sedation effects evoked by α_2 agonists most likely reflects inhibition of this nucleus. In our study, sedation score was slightly higher in group A compare to group B, but $P>0.05$ indicate that statistically no significant difference found between group A and group B.

Devangi A. Parikh et al., evaluate Dexmedetomidine vs Midazolam Fentanyl in tympanoplasty, in there study both the drugs were comparable in terms of sedation as none of the patient in ether group required additional sedation with Propofol or any alternative anaesthesia technique, as in our study.(13)

In our study, bleeding score was less in group Acompares to group B, indicate that Dexmedetomidine reduces blood loss and provide better Olegamic surgical condition in comparison to Midazolam-fentanyl combination.
In our study Surgeon's satisfaction score and patient's satisfaction score both were high in group A compare to group B.
Na HS etal demonstrated Dexmedetomidine used significantly less rescue Tramadol in comparison to group Midazolam wh. Analgesic property of α_2 agonists like Dexmedetomidine with its opiate-sparing properties conducted in general anaesthesia with dexmeditomidine.(12)

Parikh DA et al., evaluate Dexmedetomidine vs Midazolam-Fentanyl in tympanoplasty, they demonstrated significantly higher patient and surgeon satisfaction scores with Dexmedetomidine. The lower HR and MAP in these patients could have probably resulted in a better surgical field thus attributing to better surgeon satisfaction.(13)

In nutshell it can be concluded that for monitored anaesthesia care for tympanoplasty& mastoidectomy surgeries performed under local anaesthesia, intravenous Dexmedetomidine could be a better alternative compared to conventional sedation with Midazolam, since it provides a calm patient with better intraoperative analgesia, and Olegamic surgical field leading to increased satisfaction of both patient and surgeon.
Limitations:
Unavailability of BIS monitor to measure proper sedation,& awareness was jimiting factor.

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