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MONITORED ANAESTHESIA CARE: COMPARISON OF PROPOFOL-NALBUPHINE, PROPOFOL-FENTANYL AND PROPOFOL-DEXMEDETOMIDINE IN MIDDLE EAR SURGERY: A DOUBLE BLIND RANDOMIZED TRIAL

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Conflicts of Interest: Nil

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Abstract:

Subject and Methods: 90 patients, who belongs to American society of Anesthesiologist grade I & II of age 18-65 years randomized into three groups (n=30). All three groups received propofol bolus 0.75mg/kg IV followed by IV infusion at 0.025 mg/kg/min. group A received Nalbuphine 50 µg/kg IV bolus, group B fentanyl 1.5 µg/kg IV bolus and group C received Dexmedetomidine infusion 1 µg/kg given over 10 min as bolus followed by 0.1 mg/kg/hr IV infusion for maintenance. *Ramsay sedation score* and *Visual analogue scale* measured for sedation and analgesia respectively at 10 minute interval for 1st hour of surgery then every 30 minutes upto the end of surgery. Desired RSS was defined 3-5. Intraoperative hemodynamic variables viz. Heart Rate (HR), Respiratory Rate (RR), Mean Arterial Pressure (MAP) and SPO2 were recorded every 10 min till the end of surgery. Recovery was assessed using *Modified Aldrete Score* in the recovery room. Time to achieve Aldrete recovery score of 10 was recorded. Patient satisfaction score and Surgeon satisfaction score were noted using a 7-point *Likert verbal rating scale*.

Results: The groups were comparable with respect to demographic parameters. Ramsay sedation was significantly higher in Dexmedetomidine group (P<0.05) than Nalbuphine and fentalyl group, while Visual analogue score was comparable in all three study groups (p>0.05). Heart rate and Mean arterial pressure both significantly decreased in Dexmedetomidine group from the baseline during study period (p<0.05). Respiratory rate and SPO2 were comparable in all three groups. In this study MAP was never <60 mmhg, SPO2 was never <94% and Respiratory rate was never <12 bpm. Time to achieve modified alderate score in Dexmedetomidine (0.93±2.33 min) was significantly least as compare to Nalbuphine (1.80±2.65) & Fentanyl group (3.50±4.76) (p=0.016). Patient satisfaction score in Dexmedetomidine was significantly higher (6.53±0.44) (p=0.005). Surgeon satisfaction score in Dexmedetomidine was also significantly higher (6.73±0.52) (p=0.000). Two patients in Dexmedetomidine group had episode of bradycardia which was managed with injection Atropine 0.6 mg effectively

Conclusion: From these observations and analyses of the present study, it can be inferred that:

- ❖ Sedation in Dexmedetomidine was acceptable when used for MAC for middle ear surgeries.
- ❖ Visual analogue score was similar in all three study groups.
- ❖ Heart rate & Mean arterial pressure in Dexmedetomidine was lower than baseline value.
- ❖ Changes in Respiratory rate and SPO2 were similar in all three study groups.
- ❖ Time to achieve Modified alderate score of 10 in group Dexmedetomidine was least, suggesting quicker recovery from anesthesia.
- ❖ Patient and surgeon satisfaction score in Dexmedetomidine was significantly higher.

Keywords: Dexmedetomidine, Nalbuphine, Bupivacaine, Ropivacaine

Introduction:

Anesthesiology is one of the most fascinating and challenging branch of medical science. Since its first public demonstration by William Thomas Green Morton in October 1846, it has undergone tremendous advancement and has made it unimaginable for people to think about surgery without anesthesia [1] Today it not only meets all the requisites of any modern and sophisticated surgery but at the same time it assures a reasonable degree of safety to the life of patients. The period after 1846 witnessed the arrival of new inhalation agents, intravenous agents, local anesthetics, equipment, newer techniques and ultra-modern injection devices for administering anesthesia and a voluminous increased knowledge and understanding of body physiology, pharmacology of drugs, challenges of surgeries and strategies to decrease morbidity and mortality.

Like any other surgical procedures Middle Ear Surgeries are associated with anxiety and pain. The attending anesthesiologist face several challenges in safe conduction of anesthesia for middle ear surgeries viz. providing bloodless surgical field, head positioning, effect of nitrous oxide on middle ear, prevention and treatment of post-op nausea and vomiting and excellent analgesia. Most-middle ear procedures can be performed as outpatient surgery, thus rapid recovery, good analgesia, and avoidance of nausea and vomiting are essential.

These Middle ear surgeries can be done both under local or general anesthesia. Some surgeons prefer using local anesthesia for middle ear surgery owing to various advantages such as less bleeding and being able to test hearing during the surgery itself, early patient mobilization, post-op analgesia, reduced aspiration risk because of normal cough reflex. However, local anesthesia alone has been reported to be associated with anxiety, dizziness, claustrophobia, and earache [2, 3] Drilling and manipulation of instruments with long duration of the surgery raises the concern that the patient may not tolerate the noise and discomfort. Most of the patients prefer to have no memory of the surgical procedure, and some form of sedation is necessary. The ideal sedative medication for use during surgery would provide for an easily titratable level of sleepiness, predictable amnesia and decreased anxiety (anxiolysis), while providing for a rapid recovery with minimal side-effects. Hence, there is always a quest to find out an anesthetic drug, which can be used with local anesthetic block with maximum benefit and with minimum associated disadvantages. A variety of drugs are being used viz., Propofol, Benzodiazepines and Opioids for hypnosis, sedation and analgesia in the middle ear surgery in order to enhance the patient and surgical comfort [4, 5]. However, none has been completely complication free. Among various complications reported is oversedation, respiratory depression, disorientation and hampered patient's cooperation during surgery. [6]

Monitored Anesthesia Care (MAC) has been defined by the American Society of Anesthesiologist (ASA), as a specific anesthesia service, meant for diagnostic or therapeutic procedure done under local anesthesia along with sedation and analgesia[7]. This conscious sedation or twilight sleep [8] is a drug-induced depression of consciousness. The process puts the patient calm while remaining awake and responsive to follow commands, either alone or accompanied by light tactile stimulation.

Monitored Anesthesia Care (MAC), as per American Society of Anesthesiologists (ASA), includes the nature of procedure, clinical condition of the patient and/or the potential need to convert sedation to general or regional anesthesia. The vital signs and level of consciousness as required for surgical technique is monitored continuously by an anesthesiologist. The purpose and the three fundamental elements of a conscious sedation during a Monitored Anesthesia Care (MAC) are safe sedation, control of the patient's anxiety and pain [9] so that the patient remains motionless and can co-operate actively following verbal commands throughout the procedures. After the procedure is over, the anesthesiologist will discharge the patient fully awake.

The most commonly used medications for MAC are Midazolam, Propofol, and Fentanyl. Each of these drugs, however, causes respiratory depression. [10, 11] The most commonly reported adverse effects of Midazolam are variability of patient response and respiratory complications. [11] Combining Midazolam with Fentanyl or other Opioids for Monitored Anesthesia Care (MAC) increases the risk for hypoxemia and apnea. [10] The addition of Propofol may further exacerbate respiratory depression. [12]

Practicing combination of two agents can provide better patient control and allows the use of smaller doses of each single agent avoiding its undesirable effects. So this study was done with 3 different drug combinations, Propofol-Nalbuphine, Propofol-Fentanyl and Propofol-Dexmedetomidine. This study was designed to compare sedative as well as analgesic property along with better hemodynamic and respiratory control in middle ear surgery viz. Tympanoplasty, Mastoidectomy, Myringoplasty etc. [5]

Aim & Objectives

AIM

Aim of study was to compare analgesic and sedation efficacy of Propofol-Nalbuphine, propofol-Fentanyl and propofol-Dexmedetomidine combination

OBJECTIVES

Objective of study were:
1. Haemodynamics changes associated with study drugs.
2. Respiratory changes associated with study drugs.
3. Any associated adverse effect with study drugs.

MATERIAL AND METHODS

Study Design: Prospective randomized double blind study
Source of Data: Patients coming for elective middle ear surgery to UPUMS, Saifai, Etawah, India.
Sample Size: Sample size calculation was based on a population standard deviation of 1.1 with 80% power and 5% alpha error. Total sample size included 90 patients divided randomly in three groups.
Group 1 (n=30): Propofol (bolus 0.75mg/kg IV followed by IV infusion at 0.025 mg/kg/min.) + Nalbuphine (bolus 50 µg/kg IV) in vol. of 4 ml + Normal Saline 0.5 ml/kg over 10 mins followed by 0.2 ml/kg/hr.

Group 2 (n=30): Propofol (bolus 0.75mg/kg IV followed by IV infusion at 0.025 mg/kg/min.) + Fentanyl (1.5 mcg/kg IV) in a vol. of 4 ml + Normal Saline 0.5 ml/kg over 10 mins followed by 0.2 ml/kg/hr.
Group 3 (n=30): Propofol (bolus 0.75mg/kg IV followed by IV infusion at 0.025 mg/kg/min.) + Normal Saline 4 ml bolus + Dexmedetomidine infusion 2 µg/ml given at 0.5 ml/kg over 10 mins followed by 0.2 ml/kg/hr IV.

INCLUSION CRITERIA

After Institutional Ethics Committee approval, written informed consent was taken from all patients who were included in the study. 90 patients of either sex, aged between 18 and 65 years of ASA Grades I and II, undergoing Middle ear surgery like Tympanoplasty, Myringoplasty and modified radical Mastoidectomy etc. under local anaesthesia were included in the study.

EXCLUSION CRITERIA

1. Patients with known sensitivity to local anesthetics
2. Allergy to study drugs
3. II or III-degree heart block
4. Renal and hepatic insufficiency
5. Uncontrolled diabetes and hypertension,
[29]
6. Obesity (body mass index >30 kg/m2)
7. Pregnant and lactating females

Pre-anaesthetic check-up was conducted including detailed history, general and systemic examination of cardiovascular, respiratory and central nervous system and for any systemic illness. Patients were explained about the concerned technique and were instructed to keep fasting for 6 hrs for the day before surgery.
A random number table for 90 patients divided into three groups was generated and sequentially numbered opaque sealed envelopes were prepared. To maintain the blinding, an anaesthesiologist not involved in the study opened the envelope just before the premedication and prepared the appropriate drug filled syringe according to the code and did not take part in management and observations. The anaesthesiologist who administered the study drugs was not involved in uncoding the data and was also blind to groups assigned.
Routine non-invasive monitoring was applied to all patients with heart rate (HR), peripheral oxygen saturation (SpO2), electrocardiogram (ECG) and non-invasive blood pressure (NIBP). Intravenous (IV) cannula 18-gauge was secured.

Patients were placed supine on the operating table with the head turned opposite to the ear to be operated. Intraoperatively all patients received 2 L/min oxygen through nasal cannula. All the patients were premedicated with IV injection Glycopyrrolate 0.2 mg.

The level of sedation was assessed using Ramsay Sedation Score (RSS). [35]

1- Anxious, agitated, restless

2- Cooperative, oriented, tranquil

3- Responds to commands only

4- Brisk response to light glabellar tap or loud noise

5- Sluggish response to light glabellar tap or loud noise

6- No response.

Ramsay sedation score (RSS) was assessed each 10 mins for 1st hour of surgery then every 30 mins after 1st hours till the end of surgery. Desired sedation level will be defined as RSS ≥3. If RSS was <3, rescue sedation with a bolus of Midazolam 0.01 mg/kg was given. Patients with RSS >5 was considered as over sedated and was

planned to convert to standard General Anaesthesia. Patients who received rescue sedation and converted to General Anaesthesia were excluded from this study.

Simultaneously, the operating area was prepared and draped. Local anaesthetic infiltration was performed by the operating surgeon who was unaware of the group randomization, using lignocaine 2% with adrenaline 1:200,000 for blocking the tympanic branch of auriculotemporal nerve and great auricular nerve.

Intraoperative pain was assessed using Visual Analogue Scale (VAS) every 10 mins. If the patient complained of pain (VAS ≥3) during the surgery, IV Paracetamol 1 gm was planned to give as intraoperative rescue analgesia and the surgeon used an additional dose of Local Anaesthetics.

Heart Rate (beats per min.), Respiratory Rate (breaths per mins.), Mean Arterial Pressure (mmhg) and SPO2 was recorded every 10 min till the end of surgery and then every 15 min while the patient remained in post-anesthesia care unit (PACU) for 2 hr or achievement of desired Modified Aldrete Score.
Adverse events such as Bradycardia (HR <50 bpm or 20% decrease from the baseline value), Hypotension (fall in by 20% from the baseline or absolute Mean Arterial Pressure (MAP) <60 mmHg), Bradypnea (RR <8 breaths/min), Desaturation (SpO2 <94%), Nausea, Vomiting, dryness of mouth or any other events during or within 2 h after the procedure was noted.

Bradycardia was treated with increments of injection Atropine 0.6 mg IV, Hypotension was managed with a bolus of IV crystalloids or with increments of injection Mephentermine 6 mg IV. Desaturation was planned to treat with oxygen administration using face mask up to 6 L/min.

Statistical analysis

All data was recorded, summarized, tabulated and statistically analyzed using SPSS statistics program (Version 24.0). Demographic data was analyzed by using non-parametric test, chi- square test. Hemodynamic variables and pain scores were analyzed using analysis of variance (ANOVA) for three groups and independent t-test for two group's comparison. P value of <0.05 was considered as significant.

Results and Analysis

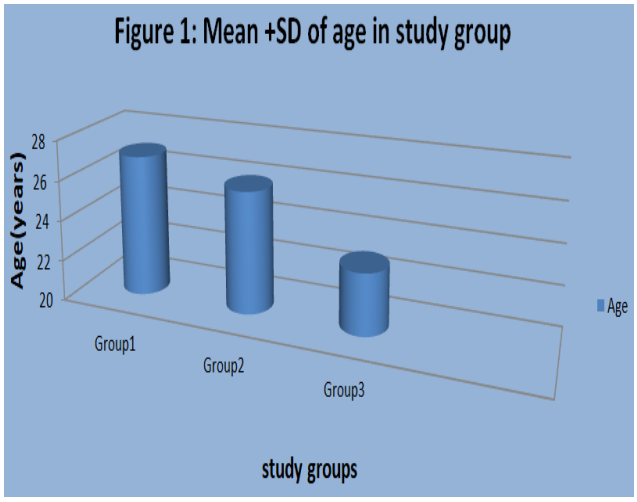
After ethical committee approval, this study was conducted in Uttar Pradesh University of Medical Sciences in 90 patients after written and informed consent. These patients were admitted in this institute for middle ear surgery. These were divided in 3 groups with 30 patients each.

DEMOGRAPHIC & OTHER BASIC DATA OF THE PATIENTS

Table 1: Group-wise distribution of samples across age and duration of surgery

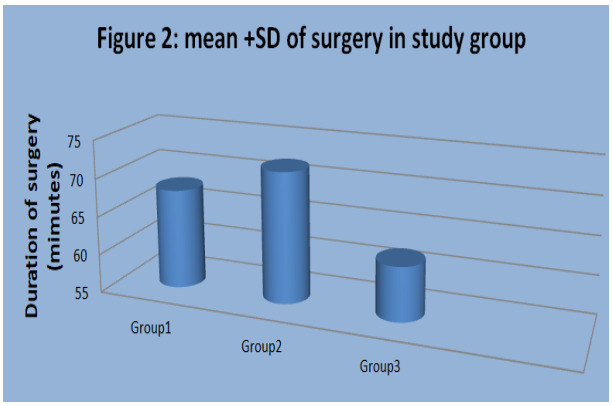
Variables	Group 1 (n=30) (Mean ± SD)	Group 2 (n=30) (Mean ± SD)	Group 3 (n=30) (Mean ± SD)	P-value
Age (years)	26.93±6.74	26.50±9.16	23.60±7.70	0.215(NS)
Duration of surg. (mins.)	68.26±12.76	72.90±13.60	66.80±12.35	0.168(NS)

(p<0.05 significant (S), p>0.05 non-significant (NS), Data expressed as Mean ± SD)



Mean age in group 1, 2 & 3 was 26.93±6.74, 26.50±9.16 & 23.60±7.70 years respectively [Table 1]. There was no significant difference between the groups with respect to age as their p-value is 0.215 (NS).

Mean



Mean duration of surgery in 1, 2 & 3 was 68.26±12.76, 72.90±13.60 & 66.80±12.35 minutes respectively [Table 1]. There was no significant difference between the groups with respect to duration of surgery as their p-value is 0.168 (NS).

Table 2: Proportion of males and females among the three groups

Sex	Group 1 (n = 30)	Group 2 (n = 30	Group 3 (n= 30)	P value
Male	12(40%)	10(33.3%)	11(36.7%)	0.866(NS)
Female	18(60%)	20(66.7%)	19(63.3%)	0.790(NS)

(p<0.05 significant (S), p>0.05 non-significant (NS), Data expressed as Mean ± SD)

In Group 1, the male: female ratio was 12:18, in Group 2, 10:20 and in group 3 was 11:19 [Table 2]. There was no significant difference between the groups with respect to sex of the patients (p-value>0.05)

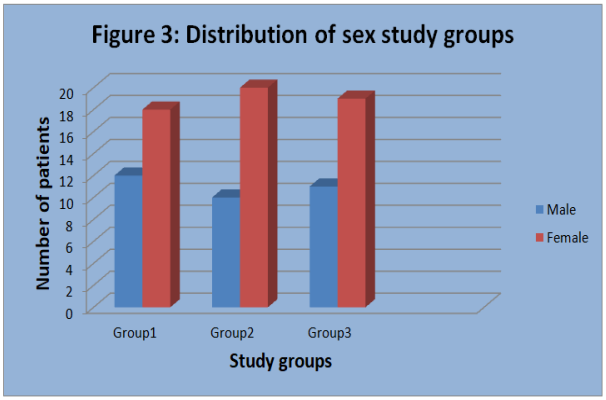


Table 3: Time to achieve Modified Aldrete Score of 10

	Group 1 (n = 30) Mean ± S.D.	Group 2 (n = 30) Mean ± S.D.	Group 3 (n = 30) Mean ± S.D.	Between group 1 and 2	P value Between group 1 and 3	Between group 2 and 3	Between group 1, 2 and 3
Time to achieve Aldrete recovery score of 10	1.80±2.65	3.50±4.76	0.93±2.33	0.93±2.33	0.185(NS)	0.010(S)	0.010(S)

(p<0.05=significant (S), p>0.05=non-significant (NS), Data expressed as Mean ± SD for time for recovery in minutes)

Mean time to achieve modified Aldrete score of 10 for group 1, 2 & 3 were 1.80±2.65, 3.50±4.76 and 0.93±2.33 minutes respectively [Table 12]. Mean time to achieve Modified Aldrete score of 10 in group 3 was 0.93±2.33 which was significantly less in comparison to group 1 and group 2 (p=0.016).

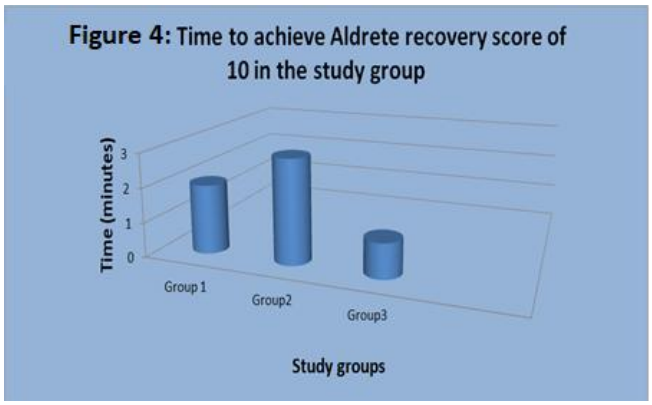


Table 4: Patient Satisfaction Score

	Group 1 (n = 30) Mean ± S.D.	Group 2 (n = 30) Mean ± S.D.	Group 3 (n = 30) Mean ± S.D.	P value			
				Between group 1 and 2	Between group 1 and 2	Between group 2 and 3	Between group 1, 2 and
Patient satisfaction score	6.06±0.44	6.36±0.55	6.53±0.62	0.025(S)	0.002(S)	0.281(NS	0.005(S)

(p<0.05=significant (S), p>0.05=non-significant (NS), Data expressed as Mean ± SD for patient satisfaction score)

Mean patient satisfaction score was 6.06±0.44, 6.36±0.55 and 6.53±0.62 for group 1, 2 & 3 respectively [Table 13]. Patient's satisfaction score in all three study groups were acceptable but group 3 have significantly higher satisfaction score (6.53±0.62) as compare to group 1 (6.06±0.44) & group 2 (6.36±0.55) (p=0.005).

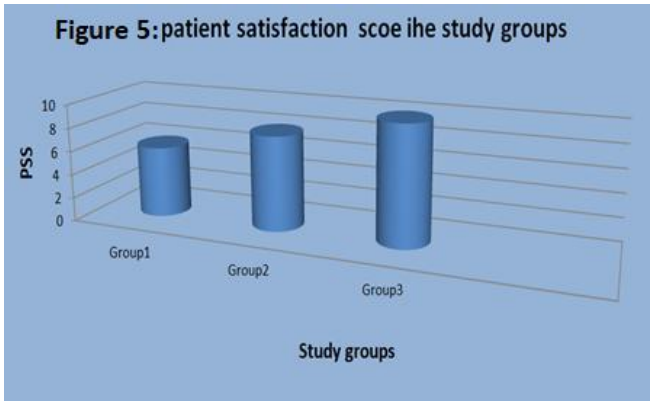


Table 5: Surgeon Satisfaction Score

	Group 1 (n = 30) Mean ± S.D.	Group 2 (n = 30) Mean ± S.D.	Group 2 (n = 30) Mean ± S.D.	P value			
				Between group 1 and 2	Between group 1 and 3	Between group 2 and 3	Between group 2 and 3
Surgeon Satisfaction score	5.90±0.66	6.26±0.44	6.73±0.52	0.015(S)	0.015(S)	0.000(S)	0.000(S)

(p<0.05=significant (S), p>0.05=non-significant (NS), Data expressed as Mean ± SD for surgeon satisfaction score)

Mean surgeon satisfaction score for group 1, 2 & 3 were 5.90±0.66, 6.26±0.44 and 6.73±0.52 respectively. surgeon's satisfaction score in all three study groups were acceptable but group 3 have significantly higher satisfaction score (6.73±0.52) as compare to group 1 (5.90±0.66) & group 2 (6.26±0.44) (p=0.000).

Discussion

Middle ear surgeries are usually performed under Monitored Anaesthesia Care (MAC), in which an adequate sedation and analgesia without respiratory depression are desirable for comfort of both surgeon and patient. Administration of single anaesthetic agent for MAC usually does not provide full control of the patient's status and almost always requires intraoperative intervention with rescue medications. Hence, combination of two anaesthetic agents from the beginning of the procedure, allows the use of lower dose of each agent and thereby decreasing its own undesired effects and gains the augmented desirable effects of each. Hence, present study was aimed to compare analgesic & sedation efficacy of Propofol-Nalbuphine Propofol-Fentanyl and Propofol-Dexmedetomidine combination.

All three groups were comparable with respect to demographic profile of the patients including mean age (p=0.215), Sex (p=0.866) and mean duration of surgery (p=0.168).

Nallam SR et al [35] compared Propofol-Nalbuphine with Dexmedetomidine-Nalbuphine in middle ear surgeries under MAC. One hundred adult patients undergoing middle ear surgeries were randomly allocated into two groups. All patients in both groups received injection Nalbuphine 50 µg/kg intravenously. Group D received Dexmedetomidine, while group P received Propofol. RSS was significantly higher in Group D (4.24±1.54) as compared to Group P (2.58 ± 0.95) (p=0.0001).

Harshbala et al [34] compared and evaluated the effects of Dexmedetomidine and midazolam for in patients

undergoing tympanoplasty and MRM under MAC. They includes eighty adult patients of ASA I & II. Group A received Dexmedetomidine and Group B received Midazolam. The mean RSS was significantly higher in Dexmedetomidine group (3.0±0.0 p<0.05). Similarly in our study RSS was higher in Dexmedetomidine group at all time intervals during study period. In our study, RSS in Dexmedetomidine group was significantly higher (3.90±0.80) than other study groups (p<0.000).

Reetu verma et al [38] in their study, evaluate Dexmedetomidine & Propofol for MAC for middle ear surgery. They include 80 ASA I & II patients which were randomly divided in two groups. Group A received Dexmedetomidine while Group B received propofol. Time to achieve RSS of 3 was 9.5±1.4 min in Propofol group, whereas in Dexmedetomidine group was 14.5±1.7 min thus showing a significant difference between two groups (p<0.001). But contrary to this, all patients in our study achieved RSS of 3 at 10 minutes in dexmedetomidine group. This could be explained by the reason that we used combination of dexmedetomidine and propofol in our study, while they used same drugs but separately for same surgery.

Hyo-seok Na et al [40] conducted study in which thirty-one eligible patients posted for cataract surgery were randomly divided into two groups. Group D received Dexmedetomidine and group P received propofol & alfentanil. MAP was significantly lower in group D from the beginning of the surgery (p<0.05).

Keith et al [41] in 2010 conducted study in which 326 patients were randomized 2: 2: 1 to Dexmedetomidine 0.5 µg/kg, Dexmedetomidine 1 µg/kg, or saline placebo initial loading dose, followed by a maintenance infusion of 0.2–1.0 µg/kg/hr of Dexmedetomidine. Midazolam was given if OAA/S≥4 and Fentanyl for intraoperative pain.

Review of Literature [12]

In this study significantly fewer patients in 0.5 and 1µg/kg Dexmedetomidine groups required supplemental Midazolam compared with placebo and at lower doses to achieve an OAA/S≤4. Both Dexmedetomidine groups required significantly less Fentanyl. Anesthesiologists indicated significantly increased sedation in both Dexmedetomidine groups compared with placebo. Patient satisfaction was significantly higher with Dexmedetomidine.

Kaygusuz et al [42] in 2008 conducted randomized control trial on comparison of sedation with Dexmedetomidine or Propofol during shockwave lithotripsy. Forty-six patients were randomly allocated into two groups to receive either Dexmedetomidine or Propofol for elective ESWL. Dexmedetomidine was infused at 6 µg/kg/hr for 10 min followed by an infusion rate of 0.2 µg/kg/hr. Propofol was infused at 6 mg/kg/hr for 10 min followed by an infusion of 2.4 mg/kg/hr. Fentanyl 1µg/kg/hr IV was given to all patients 10 min before ESWL. The Observer's Assessment of Alertness/ Sedation scores (OAA/S) and hemodynamic and respiratory variables were recorded regularly during ESWL. VAS values with Dexmedetomidine were significantly lower than those with Propofol only at the 25-35 min assessments. During sedation, the respiratory rate with Dexmedetomidine was significantly slower but SPO2 was significantly higher. Other clinical variables were similar. This study concluded that combination of Dexmedetomidine with Fentanyl can be used safely and effectively for sedation and analgesia.

Alhashemi et al [43] conducted study on forty-four patients undergoing cataract surgery under peribulbar anaesthesia. They were randomly received either Dexmedetomidine or Midazolam. In this study, Dexmedetomidine group had lower heart rate and mean arterial pressure from baseline (p<0.05).

Gaurav Singh et al [37] also noted fall in HR & MAP in dexmedetomidine group in their study. Fall in MAP was noted by 10% in Group D, but none of them required vasopressor and responded well to IV fluid boluses.

Ashraf Ghali et al [39] study Dexmedetomidine & Propofol for patients undergoing vitreoretinal surgery under sub-Tenon's anesthesia. Sixty patients were divided into two groups to receive either Dexmedetomidine or Propofol. SPO2 values in the dexmedetomidine group did not change from baseline (p>0.05). Reetu verma et al [38] in their study also finds similar respiratory rate and SPO2 in dexmedetomidine group with no incidence of respiratory depression in either of the two groups.

Gaurav Singh et al [37] conducted a study on 60 adult patients who belongs to ASA I & II. Patients were received randomly Dexmedetomidine or Midazolam & Propofol. In their study, Respiratory variables (RR & SPO2) were comparable to baseline in dexmedetomidine group during study period (p>0.05). Findings of these study was consistent with our study, as no significant changes in RR & SPO2 were recordable at all time interval during study period (P>0.05).

Kaygusuz et al [42] in their study include forty-six patients randomly allocated into two groups to receive either dexmedetomidine or propofol for elective ESWL. During sedation, the respiratory rate with dexmedetomidine was significantly low but SPO2 was higher (p<0.05). These findings were in contrast to findings of our study. This could be explainable because of higher dose of dexmedetomidine for bolus as infusion (6 µg/kg for 10 min) i.e. 6 times of dose used by Kaygusuz et al [42].

Gaurav Singh et al [37] in their study finds modified alderate score in between (9-10) just after and in the initial 5 min of procedure completion in dexmedetomidine group ($p<0.05$). These findings are consistent with findings of our study as in our study mean time to achieve modified Aldrete score of 10 in dexmedetomidine group was 0.93±2.33 min ($p=0.016$). [43] contrary to our study, conclude that time to achieve modified Aldrete score of 10 in Dexmedetomidine was significantly higher in comparison to Midazolam group.

Similarly Harshbala et al [34] in their study found significantly higher patient and surgeon satisfaction scores in Dexmedetomidine Group ($p<0.05$).

Hyo-seok Na et al [40] similarly founds higher patient and surgeon satisfaction score in Dexmedetomidine group ($p<0.001$). Findings of these study was consistent our study, as patient satisfaction score for Dexmedetomidine group in our study was 6.53±0.62 which was significantly better than of Nalbuphine (6.06±0.44) and Fentanyl (6.36±0.55) ($p=0.005$). Similarly surgeon satisfaction score for Dexmedetomidine group in our study was 6.73±0.52 which was significantly better than of Nalbuphine (5.90±0.66) and Fentanyl (6.26±0.44) ($p=0.000$). Two patients in Group 3 (Dexmedetomidine) had episode of bradycardia (HR <50/min), which was responded well with injection Atropine 0.6 mg IV. No other side effect likes hypotension, hypertension, dryness of mouth and postop nausea & vomiting were reported in any of the patients in all three groups.

Conclusion

On comparing Propofol-Dexmedetomidine combination with Propofol-Nalbuphine and Propofol-Fentanyl for monitored anaesthesia care for middle ear surgeries, it was clear that Propofol-Dexmedetomidine provide better sedation but almost similar analgesia. Heart rate and Mean arterial pressure was on lower side, which was advantageous to operating surgeon for middle ear surgeries, as it provides oligemic surgical field. Patients were more calm and co-operative in Propofol-Dexmedetomidine combination leading to better patient and surgeon satisfaction which is desirable for the surgeries to be done under MAC. Emergence from anaesthesia was also fastest in Propofol-Dexmedetomidine combination, supporting early discharge. Dexmedetomidine can be a useful adjuvant during minor surgeries. It can be opioid sparing in a multimodal analgesia technique for surgeries associated with mild to moderate pain or procedures of small duration From these observations and analyses of the present study, it can be inferred that Sedation in Dexmedetomidine was acceptable when used for MAC for middle ear surgeries. Visual analogue score was similar in all three study groups. Heart rate & Mean arterial pressure in Dexmedetomidine was lower than baseline value Changes in Respiratory rate and SPO2 were similar in all three study groups. Time to achieve Modified alderate score of 10 in group Dexmedetomidine was least, suggesting quicker recovery from anaesthesia. Patient and surgeon satisfaction score in Dexmedetomidine was significantly higher.

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