A Comparative Study of Dexmedetomidine and Propofol for Sedation in Middle Ear Surgery under Monitored Anaesthesia Care at VIMSAR, Burla, Odisha

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ABSTRACT

BACKGROUND
Middle ear surgeries done under local anaesthesia require adequate patient sedation and analgesia to prevent patient anxiety and movement during surgical procedures. This study was undertaken to compare dexmedetomidine and propofol for their sedative and analgesic properties, safety profile, adverse events and recovery profile in patients undergoing middle ear surgery under monitored anaesthesia care.

METHODS
This is a prospective observational study. 96 patients of both sexes, of American society of anaesthesiologist (ASA) grade I or II, between 18 - 60 years of age were randomly divided into two groups; group D and group P consisting of 48 patients each. Patients in group D received a loading dose of injection dexmedetomidine 1 µg / kg I.V. over 10 minutes followed by an infusion at a rate of 0.5 µg / kg / hr. Patients in group P received a loading dose of injection propofol 75 µg / kg / min. I.V. over 10 min followed by an infusion at a rate of 50 µg / kg / min. Time taken to achieve the modified Aldrete score of 10 was compared between both the groups. Before discharge from post anaesthesia care unit (PACU), patient's satisfaction with sedation & surgeon satisfaction was recorded on Likert scale. Time to rescue analgesia was compared.

RESULTS
The Bi-Spectral Index values in intra-operative period were on the lower side in the group D as compared to the corresponding values in the group P, but P values were statistically insignificant suggesting that both dexmedetomidine and propofol produced similar sedation. Time to rescue analgesia was greater for group D.

CONCLUSIONS
Having similar sedation effect, dexmedetomidine was better than propofol for sedation in patients undergoing middle ear surgery under monitored anaesthesia care.

KEYWORDS
Dexmedetomidine, Propofol, Monitored Anaesthesia Care, Bi-spectral Index

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BACKGROUND

Most of the middle ear surgeries (like tympanoplasty, stapedectomy, mastoidectomy) are usually performed under local anaesthesia as a day-care procedure.[1,2]. Still many of them are performed under general anaesthesia due to patient anxiety, dizziness and discomfort due to positioning of head and neck during surgery, fear of sudden movement of the patient while crucial operative step being performed and advantages associated with hypotensive general anaesthetic techniques. But general anaesthesia has its own disadvantages like airway instrumentation with its complications and prolonged hospital stay.

Hence, there is always a quest to find out an anaesthetic drug that can be used safely during monitored anaesthesia care which comprises three basic components i) A safe conscious sedation ii) Measures of allaying patient's anxiety and iii) An effective pain control in both healthy and high-risk patients, with limited adverse effects. In monitored anaesthesia care (MAC), there is continuous communication with the patient and simultaneously observation of parameters such as oxygenation, ventilation, circulation, temperature, depth of sedation as well as vigilance for local anaesthesia toxicity (LAST).

Thus, the present study was planned to evaluate the efficacy of dexmedetomidine, a centrally acting α2 receptor agonist with analgesic and sedative effect without respiratory depression, as analgesic, sedative with its hemodynamic effects as compared to Propofol, a drug more commonly used and to find out which drug is better for monitored anaesthesia care. Patient satisfaction, surgeon satisfaction, time of recovery and side effects were the secondary outcome.

METHODS

After obtaining approval from the institutional ethical committee (ECR / 861 / Inst / OR / 2016), this prospective observational study was conducted from October 2016 to October 2018 at VIMSAR, Burla, Sambalpur, Odisha. Was carried out among 96 patients (with a confidence level of 95 % and power of the study 90 %, the sample size was calculated to be 96) of both sexes between the age of 18 - 60 years belonging to ASA physical status I and II, scheduled for undergoing elective middle ear surgery under local anaesthesia. Written informed consent was obtained from all the patients before the surgery. The patients were subjected to detailed clinical examination and routine investigations to exclude any systemic disorder. Patients with any systemic co-morbidity, history of allergy to the medications being used and pregnant patients were excluded from the study.

The venous access with a large bore I. V cannula was established and the crystalloid infusion was given as per holiday Segar formulae. The routine monitoring done with pulse-oximetry, electrocardiogram, Bi-Spectral Index (BIS) and non-invasive blood pressure was done. All required airway management equipment's, resuscitation drugs (like atropine, adrenaline, mephentermine, and succinylcholine) and anaesthesia machine were kept ready to counter any untoward events relating to hypoventilation and airway compromise. All patients received premedication with injection glycopyrrolate 0.2 mg IV. Inj. midazolam 0.05 mg / kg and Inj. nalbuphine 0.2 mg / kg body weight intravenously. The patients were randomly assigned into two groups (group D and group P) in equal numbers by simple randomisation.

Patients in group D received a loading dose of Inj. dexmedetomidine 1 µg / kg I.V over 10 minutes followed by an infusion at a rate of 0.5 µg / kg / hr. (dexmedetomidine was diluted in 0.9 % normal saline to a target concentration of 4 µg / ml in a 50 ml syringe).

Patients in group P received a loading dose of injection propofol 75 µg / kg / min I. V. given over 10 min followed by an infusion continued at a rate of 50 µg / kg / min.

After achieving a score of 3 on the Ramsay Sedation Scale (Table 1), the operative field was infiltrated with lignocaine (2 %) with adrenaline (1:200,000). Patient's response to local anaesthetic infiltration was evaluated by observing response to pain and body movement. Pain was recorded on 10-point verbal scale where, 0 indicated no discomfort and 10 indicated maximum discomfort.

All the patients were continuously monitored for hemodynamic parameters and electrocardiogram (ECG). Sedation scores were noted using bi-spectral index and Ramsay sedation scale (RSS) [Table 1]. All these parameters were recorded intra-operatively as well as post-operatively. Perioperative parameters viz., mean arterial pressure (MAP), heart rate (HR), BIS and peripheral oxygen saturation (SpO2) were recorded at 5 min intervals for the first 20 min and after that at every 10 min interval. During the procedure, study drug infusion rate was varied to maintain a deep level of sedation (RSS of 3, tested at 10 min intervals) and normal cardiovascular and respiratory variables (i.e., respiratory rate > 12 breaths / min, SpO2 > 94 %). Infusion of the study drug was stopped if the respiratory rate was less than 10 bpm or SPO2 < 90 %. If a patient was not adequately sedated through drug titration and complained pain, he / she was excluded from the study. MAP < 60 mm of Hg was considered as unwanted hypotension and supplemented with fluid boluses. If the patient did not respond to this then injection mephentermine 6 mg was given I. V, and infusion rate was reduced to half. HR < 50 beats per minute was considered as bradycardia and infusion rate was reduced to half and injection atropine 0.6 mg I. V was given as per requirement.

The study drug was stopped at the end of surgery and patients were shifted to PACU. Subjects remained in the PACU at least for 1h and discharged to postoperative ward ensuring that the patient had achieved a modified Aldrete score of 10, time taken to achieve the modified Aldrete score of 10 was noted and compared between both the groups. Vital signs were recorded every 10 min while the patient remained in PACU. The sedation was assessed in terms of BIS value every 10 min while the patient was in the PACU. Just before the discharge from PACU, patients were asked to rate their satisfaction with sedation on seven-point Likert like verbal rating scale [Figure 1] that was explained to patient on the preoperative visit. Surgeon satisfaction was

also recorded post-operatively as he was also asked to rate their experience with comfort during operation using a seven- point Likert like verbal rating scale. Time to rescue analgesia was noted in post-operative period for both the groups and was compared. Injection diclofenac 75 mg was used as rescue analgesic in post-operative period.

Adverse events like nausea, vomiting, dry mouth, hypotension (MAP < 60 mm Hg), bradycardia (HR < 50 bpm), and hypoventilation (SPO2 < 90 %) were noted. Nausea & vomiting were managed by giving injection ondansetron 4 mg I. V, hypotension was managed with injection mephentermine 6 mg I. V and bradycardia was managed with injection atropine 0.6 mg I. V, hypoventilation was managed with bag mask ventilation.

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

Table 1. Ramsay Sedation Scale

1	2	3	4	5	6	7
Extremely dissatisfied	Dissatisfied	Somewhat dissatisfied	Undecided	Somewhat satisfied	Satisfied	Extremely satisfied

Figure 1. Seven Point Likert like Verbal Rating Scale

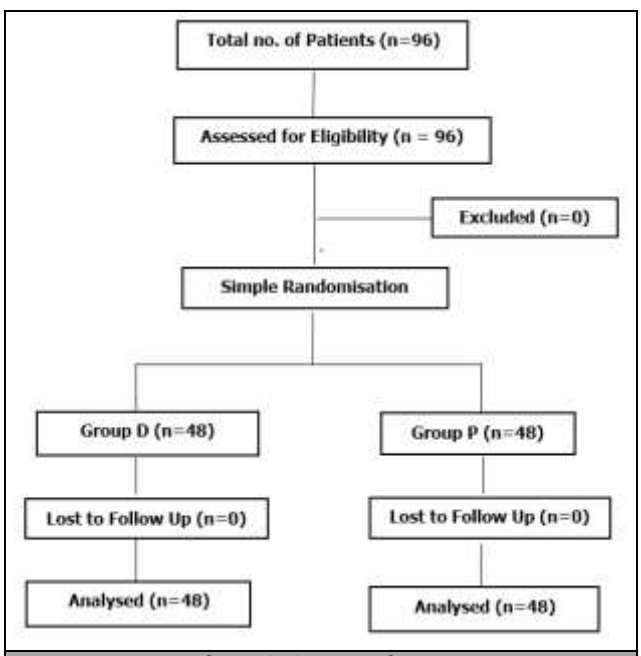

Figure 2. Consort Diagram

Statistical Analysis

According to statistical power analysis, 96 patients were needed to provide a study power of 90 % with a confidence level of 95 %. All data were collected in a pre-described proforma and tabulated using Microsoft Excel 2016. Data analysis was done by using SPSS software version 22. Independent sample's t-test was used to compare the parametric data, whereas categorical data were compared using chi-square test.

Fisher exact test was used wherever, the expected frequency of a cell was < 5. Confidence level of the study was kept at 95 %; hence P-value < 0.05 indicated a statistically significant association.

RESULTS

A total of 96 patients were included in this study with 48 patients each in group D and group P. All the patients completed the study and there were no dropouts and thus, all 96 patients were analysed for the final outcome of this study.

Demographic Profile	Group D	Group P	P-Value
Age in years (mean ± SD)	29.44 ± 8.79	29.04 ± 8.48	0.721
Sex (M: F)	25: 23	26: 22	0.500
Weight in kg (mean ± SD)	55.23 ± 5.19	53.44 ± 3.814	0.052
Height in cm (mean ± SD)	155.15 ± 5.67	154.98 ± 5.436	0.539
ASA PS (1: 2)	48:0	48:0	1.000
Duration of surgery in min (mean ± SD)	115.04 ± 3.798	114.73 ± 4.046	0.360

Table 2. Demographic Profile and Duration of Surgery

Both the groups were comparable with respect to age, sex, weight, height, ASA grade and duration of surgery (Table 2) as the individual P-value of all these parameters was statistically not significant.

The comparison of mean arterial pressure and heart rate between both the groups indicate decrease in the intra-operative and recovery period with statistically significant P-values (P-value < 0.05) from 10 min to 130 min, with more decrease in group D. MAP values become more comparable towards the discharge time in both the groups as the P-values from 140 min to 180 min were statistically not significant. SpO2 values of both the groups were comparable throughout the entire period of study and there was no significant change in SpO2 in both the groups.

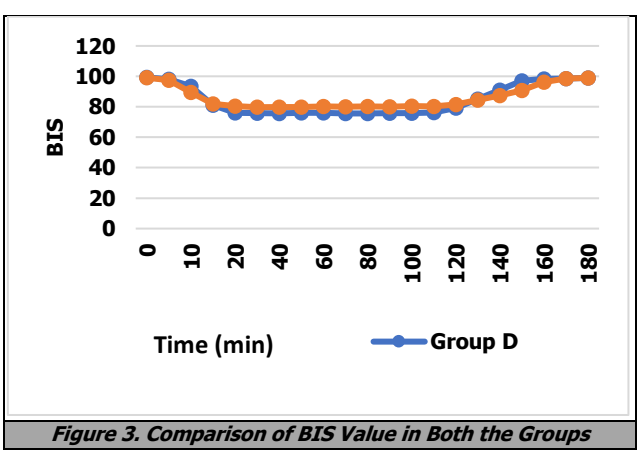

Figure 3. Comparison of BIS Value in Both the Groups

Figure 3 shows the comparison of the BIS values in both the groups which is somewhat on the lower side in the group D in the intra-operative period as compared to the corresponding values in the group P, but P-values were statistically not significant suggesting that both dexmedetomidine and propofol produced similar degree of sedation.

The mean time to achieve modified Aldrete score of 10 was 33.38 ± 2.972 min & 46.40 ± 1.932 min in group D &

group P respectively (P-value < 0.001). Time to rescue analgesia was 82.85 ± 4.603 min in group D & 48.96 ± 2.96 min in group P (P-value = 0.043). It indicates that the time to achieve a modified Aldrete score of 10 is less in group D as compared to group P & time to rescue analgesia was more in group D as compared to group P with a statistically significant P-value.

Satisfaction Score	Patient Satisfaction Score		Surgeon Satisfaction Score	
	Group D (No) %	Group P (No) %	Group D (No) %	Group P (No) %
1	0	0	0	0
2	0	0	0	0
3	0	3 (6.25)	0	0
4	0	23 (47.92)	0	8 (16.67)
5	0	19 (39.58)	0	22 (45.83)
6	20 (41.67)	3 (6.25)	20 (41.67)	18 (37.50)
7	28 (58.33)	0	28 (58.33)	0
P-value	< 0.001		< 0.001	

Table 3. Patient Satisfaction Score & Surgeon Satisfaction Score on Likert like Scale in Both the Groups

Table 3 shows the patient and surgeon satisfaction score in both the groups. In group D, the patient satisfaction score on 7 point Likert like scale was 6 in 41.67 % of patients, while it was 7 in rest 58.33 % patients. But in group P, the patient satisfaction score was 3 in 6.25 % patients, 4 in 47.92 % patients, 5 in 39.58 % patients and 6 in 6.25 % patients with statistically highly significant P-value of < 0.001. The surgeon satisfaction scores in group D were 6 in 41.67 % of patients & 7 in 58.33 % of patients, while in group P the scores were 4 in 16.67 % of patients, 5 in 45.83 % of patients & 6 in 35.5 % of patients. The P-value was < 0.001 which was highly significant. It indicates that both the scores were better in group D as compared to group P.

The incidence of side effects like hypotension, bradycardia, respiratory depression, dryness of mouth and post-operative nausea vomiting in either group was not significant.

DISCUSSION

Monitored anaesthesia care, as defined by the American Society of Anaesthesiologist, is nothing but a planned procedure during which the patient undergoes any procedure or any surgery under local anaesthesia together with sedation and analgesia. Monitored anaesthesia care uses similar medication used in general anaesthesia in lower doses to provide sedation and analgesia with spontaneous breathing and continuous monitoring of vital parameters.

Middle ear surgeries done under local anaesthesia require adequate patient sedation and analgesia to prevent patient anxiety and patient movement during important steps of microsurgical procedures. This requirement leads to the development of monitored anaesthesia care as a modality of anaesthesia in which a procedure or surgery is performed under local anaesthesia, sedation and analgesia under supervision of a trained anaesthesiologist.

Dexmedetomidine is a novel centrally acting α2 receptor agonist (·2:·1 = 1600:1) with analgesic and sedative effect without respiratory depression. It acts primarily on the sleep pathway and does not inhibit the activity of the orexinergic neurons, which is the basis of its arousable sedation. Its beneficial effects include its reduction in the opioid requirements both during and after surgery, in addition, it has a sympatholytic effect that can attenuate the stress response to surgery (tachycardia and hypertension) hence, maintaining the hemodynamic stability.[3]

Propofol is widely used as sedative-hypnotic with a rapid onset of action and short recovery time along with antiemetic and euphoric properties.[4] It is a well-known drug used for MAC because of easy titratability and rapid emergence. It has a short context-sensitive half-life even after prolonged infusions, and thus produces clear headed recovery.

In our study, we found that dexmedetomidine caused more decrease in the blood pressure and heart rate in intraoperative and post-operative period than propofol does. This finding of our study is similar to the finding by Dr. Harick Shah et al. (2016);[5] who conducted a comparative study between dexmedetomidine infusion & propofol infusion in patients undergoing functional endoscopic sinus surgery under general anaesthesia & Hong-mei Wang et al. (2017);[6] who carried out a comparison between dexmedetomidine and propofol for conscious sedation in inguinal hernia repair. Similar findings also found in various studies conducted by Leena Goel et al. (2016);[7] Amarjeet Kumar et al. (2017);[8] Kirti Kamal et al. (2017)[9] and Dr. Manoj Kamal et al. (2017).[10] The decrease in MAP and heart rate has a beneficial effect in the surgery as it decreases bleeding in the surgical field which is an essential prerequisite for the surgeon to perform the microsurgical procedures like tympanoplasty by providing a clear operative field.[11,12] As the decrease in the MAP and heart rate are more with dexmedetomidine so it is better than propofol in this regard. The decrease in mean arterial pressure & heart rate is not so alarming as to requiring any intervention. However, decrease in MAP & heart rate has a beneficial effect in surgery as it decreases bleeding in surgical field which is essential for the surgeon to perform the microsurgical procedures like tympanoplasty. Since dexmedetomidine decreases mean arterial pressure more than propofol, that may be the reason we are getting higher surgeon satisfaction score in group D compared to group P.

The BIS values throughout the surgery were comparable for both the groups suggesting that both dexmedetomidine and propofol produced similar sedation, similar to the finding of Shahbaz R. Arain et al. (2002);[13] Ashraf Ghali et al. (2011);[14] Ashraf Darwish et al. (2013);[15] Reetu Verma et al. (2014)[16] and Leena Goel et al. (2016)[7] though none of these investigators used BIS monitoring but the overall result was same based on Ramsay sedation score.

The difference in the recovery time is highly significant in both the groups, similar to the finding of Sumanth Samson et al. (2014);[17] Mostafa Eladany et al. (2015)[18] and Dr. Manoj Kamal et al. (2017).[10] Neither dexmedetomidine nor propofol caused respiratory depression during our study. This finding of our study is similar to the finding of Reetu Verma et al. (2014);[16] K. Ravi Kumar et al. (2016);[19] Leena Goel et al. (2016)[7] and Amarjeet Kumar et al. (2017).[8]

In our study, analgesic consumption was compared between the two groups in terms of the time elapsed in the

post-operative period before the first request for rescue analgesia was made by the patient, or in short time to rescue analgesia. There was low requirement of analgesia in the dexmedetomidine group as compared to the propofol group which indicates that dexmedetomidine has analgesic sparing effect. This was similar to the finding of Shahbaz R. Arain et al. (2002);[13] Reetu Verma et al. (2014);[16] Hong-mei Wang et al. (2017)[11] and Leena Goel et al. (2016).[14] The inherent analgesic property of dexmedetomidine which is mediated through stimulation of the α2C and α2A receptor in the dorsal horn, thus directly suppressing pain transmission by reducing the release of pro-nociceptive transmitters, substance P and glutamate, and hyperpolarization of interneurons, on the other hand propofol has minimal or no inherent analgesic activity of its own.

Patient satisfaction score was better in group D. The P value which is highly significant statistically, indicates that there was a significant difference between the patient satisfaction score of both the groups. This finding can be explained by the fact that dexmedetomidine produces sedation by effecting the natural sleep mechanism thus, causing a more pleasant sedation profile in contrast to propofol which acts on the $GABA_A$ receptor causing C.N.S depression, producing a somewhat unpleasant hypnosis. Secondly, the inherent analgesic property of dexmedetomidine decreases the analgesic requirement making it a comfortable affair for the patient, which is not the case with propofol.

Surgeon satisfaction score was better in group D due to lesser bleeding, clear operative field & more easily arousable sedation due to dexmedetomidine enabling easy access to patients hearing during surgery itself.

The most common adverse effects of dexmedetomidine are dryness of mouth, bradycardia and hypotension while those of propofol are respiratory depression, hypotension and pain on site of injection, but none of the patients showed any of the above-mentioned adverse effects in our study. Besides, no incidence of post-operative nausea or vomiting was seen in any case.

CONCLUSIONS

Both the drugs produced comparable sedation. Dexmedetomidine produced more significant fall in heart rate and MAP than propofol, thus, providing clearer operative field by decreasing bleeding in the operative field. Neither dexmedetomidine nor propofol caused respiratory depression in any of the patients. The recovery profile of dexmedetomidine was better than that of propofol. The analgesic requirement was less with dexmedetomidine. Both surgeon satisfaction and patient satisfaction were better with dexmedetomidine.

Hence, we conclude that though dexmedetomidine and propofol provide similar sedation, dexmedetomidine is better than propofol for sedation in patients undergoing middle ear surgery under monitored anaesthesia care.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

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