IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 24, Issue 2, Series 1 (February. 2025), PP 71-77
www.iosrjournals.org

Infusion of Dexmedetomidine and Midazolam-Fentanyl combination for conscious sedation in middle ear surgeries

Dr. Noureen Bari[1], Dr. Shamsun Nahar Shanta[2], Dr. Sadia Afroz[3], Dr Shamima Akter[4], Dr. Hosne Ara[5], Dr. Snigdha Dey[6]

[1]*Anaesthesiologist, Department of Anaesthesia, Pain, Palliative and Intensive Care, Dhaka Medical College Hospital, Dhaka, Bangladesh.*
[2]*Junior consultant, department of Anesthesia, Shaheed Suhrawardy Medical College & Hospital.*
[3]*Junior Consultant, Pirojpur District Hospital, Pirojpur, Bangladesh.*
[4]*Associate Professor, Department of Anaesthesia, Pain, Palliative and Intensive Care, Dhaka Medical College Hospital, Dhaka, Bangladesh.*
[5]*Specialist, Department of Neuro ICU, Square Hospital Limited, Dhaka, Bangladesh.*
[6]*Anesthesiologist, Department of Anesthesia, pain, palliative and Intensive Care. Dhaka Medical College Hospital.*
Corresponding Author: *Dr Noureen Bari, Anaesthesiologist, Department of Anaesthesia, Pain, Palliative and Intensive Care, Dhaka Medical College Hospital.* ***Email:***

Abstract:
Background: *Analgesia and sedation are usually required for the comfort of the patient and surgeon during middle ear surgeries. Common middle ear surgery including tympanoplasty, mastoidectomy, myringotomy, grommet insertion and cochlear implantation can be performed under local anesthesia or general anaesthesia. As these cases may present with unique anaesthetic challenges, local anaesthetic may not be comfortable enough for the patients.* ***Objectives:*** *The aim of the study was to evaluate the effectiveness of Dexmedetomidine and Midazolam-Fentanyl combination was compared for conscious sedation in middle ear surgeries.* ***Methods:*** *This Prospective analytical study was carried out from July, 2022 to January, 2023 in the Department of Anaesthesia, Pain, Palliative care & Intensive Care, Dhaka Medical College. All patients were included according to the inclusion and exclusion criteria. A total of 100 patients were enrolled in the study. Statistical analyses were carried out by using the Statistical Package for Social Sciences version 26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). A "p" value <0.05 was considered as significant.* ***Results:*** *After comparing demographic characteristic between two groups, no statistical difference was found there. The mean heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean blood pressure (MAP) was lower in group D than group MF during intraoperative period and which were statistically significant (P value <0.05). The patient was receiving Midazolam plus Fentanyl during intraoperative period for sedation had higher RSS than the patients received Dexmedetomidine.* ***Conclusion:*** *Dexmedetomidine infusion was more effective than Midazolam-Fentanyl infusion for conscious sedation in middle ear surgeries under local anaesthesia.*

Keywords: *Analgesia, Tympanoplasty, Mastoidectomy, Myringotomy, Grommet insertion.*

Corresponding Author: Dr. Noureen Bari, Assistant professor, Department of Anaesthesia, Pain, Palliative & Intensive Care, Dhaka Medical College Hospital, Dhaka, Bangladesh.

Date of Submission: 01.02.2025 Date of Acceptance: 22.02.2025

I. Introduction

Common middle ear pathologic conditions requiring surgery in adult include tympanoplasty, stapedectomy or ossiculoplasty for otosclerosis and mastoidectomy. These surgeries can be performed under either local anaesthesia with or without sedation or general anesthesia. [1, 2] Many advantages have been reported with the local anesthetic techniques, as early recovery, less bleeding, less postoperative pain, and of great importance the surgeon's ability to test hearing while in surgery. However, during middle ear surgery under local anaesthesia, many patients experience various discomfort, a sensation of noise due to drilling and manipulation of instruments, anxiety, dizziness, backache, claustrophobia, or earache. [3] The attending Anesthesiologist faces several challenges in safe conduction of anesthesia for middle ear surgeries. Preoperative challenges include counseling the elderly patients with impaired hearing and counseling the parents of children with congenital ear anomalies, thorough evaluation of these patients with several comorbidities. [4] Most of the patients prefer to have no memory of the surgical procedure and some form of sedation is necessary for this. The ideal sedative

medication would provide an easily titratable level of sleepiness, predictable amnesia, and decreased anxiety (anxiolysis), while ensuring rapid recovery with minimal side-effects. [5] To reduce the discomforts and anxiety of patient and to provide favorable surgical environment, adequate sedation and analgesia is required.

There are various agents available to provide conscious sedation. Current drugs include benzodiazepine, most commonly Midazolam with an opioid usually Fentanyl with or without Propofol. Ketamine has also been used in lower doses. For moderate sedation, newer agents such as Dexmedetomidine and fosPropofol are also being used nowadays. Previous study noted that Dexmedetomidine, Midazolam and Fentanyl are established sedative agents for using intra-operatively and postoperative period. [6, 7]

Midazolam is most frequently used sedative and has been reported to be well tolerated in conscious sedation because of its fast onset, short duration of action and high amnesic property. Midazolam is water soluble agent that causes sedation, anxiolysis and amnesia. Despite having a number of benefits, it is far from being an ideal agent due to untoward effects like prolonged recovery after long-term or high dose use, hypotension, cognitive impairment, restlessness and respiratory depression. [8] The properties that make Midazolam suitable for use with local anesthesia are anxiolysis, sedation and antegrade amnesic action. [9] It was shown that Midazolam combination with others can be used safely for sedation in middle ear surgeries under local anaesthesia. [10] Combining Fentanyl with Midazolam provides effective analgesia but increases risk for respiratory depression and hypoxaemia. Fentanyl is a potent analgesic but may cause delayed recovery and postoperative nausea and vomiting. Fentanyl significantly improves sedation and provides better analgesia. Midazolam may suppress conditioned fear after an aversive event by disrupting the memory trace formed during conditioning, by altering the emotional part of the aversive event, or by the combination of both effects. [11] Therefore, the aim of the study will be to compare two techniques of conscious sedation, Dexmedetomidine and Midazolam Fentanyl infusion for middle ear surgery.

II. Methodology

This randomized control trial study was carried out in the Department of Anaesthesia, Pain, Palliative & Intensive Care Unit, Dhaka Medical College Hospital, Dhaka, during July 2022 to January 2023. A total of 100 patients were enrolled in the study. Patients' allocation was done randomly into two groups Group MF and Group D on the basis of a computer-generated randomization scheme. The anesthesiologist conducting the case, the patients and the anesthesiologist in the post anesthesia care unit (PACU) were all blinded to group assignment. Data were recorded by a blinded observer and the drugs were prepared by a senior anesthesiologist (co-guide of the research) who will not participate in patients' management or data collection. Two 50-ml syringes labeled as loading and maintenance were given to each group of patients and doses were calculated according to individual patient's weight. Group MF patients had received Midazolam 0.05mg kg-1 and Fentanyl 1µg kg-1 and Group D patients had received Dexmedetomidine 1µg kg-1 as loading dose, diluted with normal saline in respective syringes and administered over 10 min followed by continuous infusion. For maintenance infusion, Group MF had received Midazolam at a dose of 0.05 mg kg-1 hr-1 and Fentanyl at a dose of 1 µg kg-1 hr-1 diluted in normal saline to the concentration of 1mg ml-1 of Midazolam and 20µg ml-1 of Fentanyl respectively. In Group D, Dexmedetomidine was diluted in normal saline to the concentration of 4µg ml-1 and infused at a dose of 0.2µg kg-1 hr-1. According to the used concentration and dose range of either drug, infusion rate was 3ml hr-1 for both groups. Chi-square test (X2- test) was done for qualitative variables and a quantitative variable was tested by student's t-test. Statistical analyses were carried out by using the Statistical Package for Social Sciences version 26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). A "p" value <0.05 was considered as significant..

III. Result

Table I: Demographic characteristics of the patients of both groups. (n=100)

Characteristics		Group MF (n=50)	Group D (n=50)	P *value
Age(years)		34.7±6.2	31.6±5.5	0.723
Height(cm)		154.7±5.4	152.9±5.2	0.628
Weight(kg)		56.8±6.4	55.6±6.1	0.814
ASA	Class I	39(78%)	37(74%)	0.627

	Class Ⅱ	11(22%)	13(26%)	0.572
Gender	Male	22(44%)	19(38%)	0.463
	Female	28(56%)	31(62%)	0.482

On considering demographic characters of the patients of both groups (Table I), No statistical difference was observed in case of mean age between two groups. The mean height and weight were also well matched between the groups. As the p value was >0.05. Regarding ASA classification, 78% patient of group MF was in ASA class I and 74% patients of group D was ASA class I. That means patients of both groups had ASA class I. but there was no statistical difference between the groups as p>0.05.

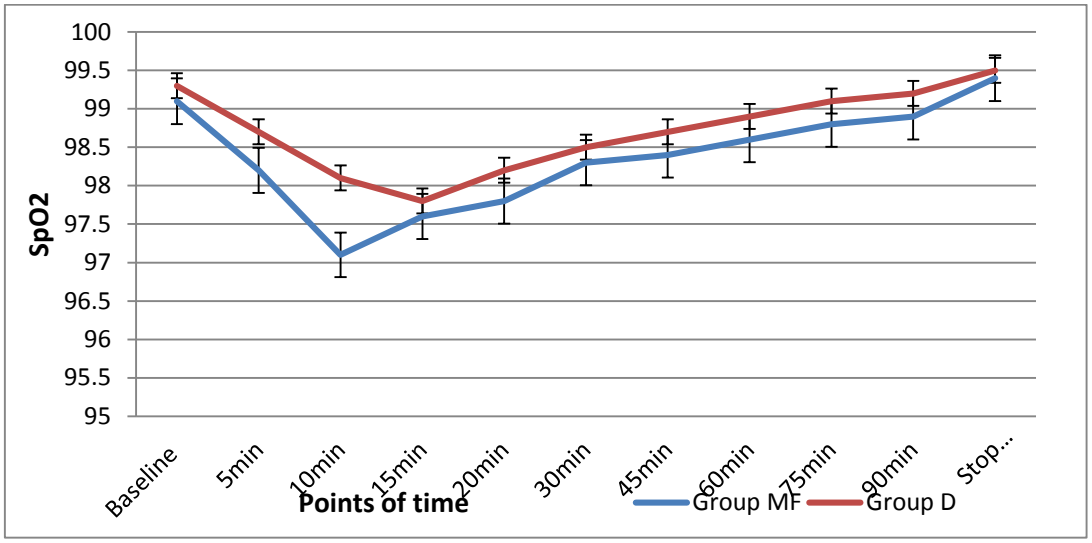

Figure I: Comparison of SpO2 during intraoperative period between two groups.

After comparing the SpO2 during intraoperative period between two groups (Figure I). No statistically significant was observed between the two groups. Intraoperative mean SpO2 was analyzed by Student t-test.

Table II: Comparison of Heart rate of the patients between two groups. (n=100)

Heart rate (beat/min)	Group MF (n=50)	Group D (n=50)	P value
Baseline	79.2±6.8	76.8±5.6	0.368
5min	75.8±5.5	69.3±5.3	0.028
10min	74.2±6.1	66.4±5.1	0.018
15min	73.8±5.6	67.3±5.8	0.023
20min	74.4±8.3	63.2±5.5	0.031
30min	73.5±6.9	64.3±6.2	0.023
45min	75.7±5.2	66.3±5.8	0.014
60min	77.1±5.9	68.5±6.3	0.025
75min	76.4±6.3	67.2±6.3	0.022
90min	78.5±6.3	71.2±6.3	0.034
5min after stop of infusion	81.5±6.3	78.8±6.3	0.241

The baseline mean heart rate was similar in between the groups. But the mean heart rate was lower in group D than group MF during intraoperative period. The p value was <0.05 at 5min to 90min during intraoperative period. But 5min after stop of study drug infusion, heart rate was increased in group D. Finally, there was no statistical difference was found in between the groups as p value as >0.05 (Table II).

Table III: Comparison of SBP during intraoperative period (n=100)

SBP (mmHg)	Group MF	Group D	P value
Baseline	125.8±9.6	123.7±9.5	0.590
5min*	121.5±6.7	115.3±6.1	0.018
10min*	120.7±5.8	113.1±5.3	0.011
15min*	121.1±6.3	112.9±5.7	0.014
20min*	120.3±5.5	114.2±4.9	0.022
30min*	117.9±6.4	111.4±4.6	0.015
45min*	119.6±6.2	112.5±4.8	0.019
60min*	118.9±6.5	113.7±5.1	0.029
75min	121.1±5.8	118.6±5.3	0.241
90min	122.7±5.6	121.3±4.8	0.317
Stop infusion	126.5±7.4	124.8±6.9	0.320

The mean SBP was well maintained between the groups during intraoperative period. There were statistical differences observed at 5min, 10min, 15min, 20min, 30min, 45min and 60min interval, during intraoperative period. The p value was <0.05 at this time of intervals. So, the patients received Dexmedetomidine infusion had lower SBP during intraoperative period (Table III).

Table IV: Comparison of DBP during intraoperative period (n=100)

DBP (mmHg)	Group MF	Group D	P value
Baseline	79.6±5.1	78.3±4.8	0.483
5min*	76.4±4.7	71.9±3.6	0.028
10min*	75.8±4.6	70.6±3.3	0.017
15min*	74.9±4.5	69.7±3.4	0.012
20min*	73.7±4.3	68.5±3.7	0.016
30min*	74.1±4.1	67.4±3.1	0.011
45min*	73.9±4.2	68.8±3.5	0.021
60min*	74.5±4.7	69.1±3.4	0.025
75min	73.8±4.9	72.6±3.9	0.261
90min	75.6±5.2	74.2±4.3	0.287
Stop infusion	76.8±5.3	77.5±4.8	0.331

During intraoperative period the mean DBP was lower in group D at 5min, 10min, 15min, 20min, 30min, 45min and 60min interval. There was statistical difference observed as Student t-test was performed to compare the mean DBP during intraoperative period (Table IV). The p value was <0.05 at that time of intervals. The patients received Dexmedetomidine infusion had lower DBP during intraoperative period.

Table V: Comparison of MAP during intraoperative period (n=100)

MAP (mmHg)	Group MF	Group D	p value
Baseline	95.8±5.4	93.6±5.1	0.415
5min*	91.9±5.7	86.4±4.7	0.032
10min*	90.5±5.3	85.2±4.3	0.013
15min*	88.7±5.6	83.3±4.5	0.019
20min*	87.5±5.8	82.1±4.4	0.014
30min*	86.9±5.2	81.2±4.1	0.008
45min*	84.6±4.9	78.5±3.8	0.005
60min*	85.8±5.1	79.6±3.9	0.007
75min	86.7±5.4	84.5±4.7	0.251
90min	88.6±5.5	87.2±4.9	0.211
Stop infusion	93.6±5.8	90.9±4.8	0.417

There had been a significant difference in mean arterial pressure (MAP) between two groups as p<0.05 during the intraoperative period at 5min, 10min, 15min, 20min, 30min, 45min and 60min interval.

Table-VI: Comparison of RSS scores of the patients between two groups. (n=100)

RSS score	Group MF (n=50)	Group D (n=50)	P value
0min	1.1±0.3	1.2±0.4	0.351
5min	2.8±0.9	3.1±0.4	0.237
10min	4.5±0.5	3.2±0.5	0.028
15min	4.6±1.2	3.4±0.6	0.022
20min	4.3±1.1	3.2±0.5	0.025
30min	4.4±0.9	3.15±0.6	0.021
45min	4.3±0.8	3.1±0.4	0.026
60min	4.1±0.7	3.09±0.5	0.039
75min	3.5±0.6	2.7±0.4	0.042
90min	3.1±0.7	2.3±0.3	0.032
5min after stop of infusion	2.5±0.4	1.1±0.12	0.014

No difference was found at base line and 5min after start of infusion between two groups. The p value was >0.05 at that point of time. After considering the RSS during intraoperative period, there had statistical significance were observed at 10min to up to after stop of drug infusion between the groups. The p value was <0.05 at this time of interval (Table- VI).

Table-VII: Assessment of Onset of sedation time, Duration of procedure and Recovery time of the patients. (n=100)

Variable	Group MF (n=50)	Group D (n=50)	P* value
On set of sedation time (RSS≥3) (min)	6.25±2.63	4.23±1.12	0.008
Recovery time after procedure(min)	11.85±2.49	6.48±1.5	0.011
Duration of procedure (min)	74.8±7.6	72.3±8.9	0.531

On set of sedation time (RSS≥3) was less in group D (4.23±1.12min) than the group MF (6.25±2.63min). On the other hand, recovery time after the procedure was more in group MF (11.85±2.49min) than group D (6.48±1.5min). Both were statistically significant as p value was less than 0.05 (Table-VII).

Table VIII: Assessment of Total Propofol consumption and total local anaesthetic requirement of the patients during intraoperative period. (n=100)

Variable	Group MF (n=50)	Group D (n=50)	P* value
Total Propofol consumption(mg/kg)	1.3±0.5	0.8±0.3	0.017
Total local anaesthetic agent (2% lignocaine with adrenaline) required for infiltration. (mg/kg)	1.8±0.6	1.2±0.4	0.021

Total Propofol consumption (mg) during intraoperative period for improvement of sedation were higher in group MF (1.3±0.5 mg/kg) and in group D (0.8±0.3mg/kg). Total local anaesthetic agent (mg/kg) required for surgical site infiltration was less in group D (1.2±0.4 mg/kg) and in group MF was more (1.8±0.6 mg/kg). Which was statistically significant as p<0.05 (Table VIII).

Table IX: The time for 1st demand of analgesia and total requirement of analgesics in 24hrs. (n=100)

Variable	Group MF (n=50)	Group D (n=50)	P* value
The time for 1st demand of analgesia(min)	32.7±5.8	15.3±4.7	0.016
Total requirement of analgesics (pethidine) in 24hrs (mg)	156.4±13.6	158.3±14.5	0.618

The time for 1st demand of analgesia (min) was longer in group MF (32.7±5.8min) than group D (15.3±4.7min). It was statistically significant as the p value <0.05.but there had no difference was found in case of Total requirement of analgesics in 24hrs (mg) between two groups as p value was >0.05 (Table IX).

Table X: Adverse events of the patients during peri-operative period. (n=100)

Adverse events	Group MF (n=50)	Group D (n=50)
Apnea	4(8%)	1(2%)
Bradycardia	3(6%)	8 (16%)
Hypotension	4(8%)	7(14%))

During intraoperative period bradycardia (16% vs 6%) and hypotension (14% vs 8%) were more in group D than group MF but apnea (8%) was more in group MF than group D (Table X).

IV. Discussion

For the conscious sedation; an ideal sedative agent should have rapid onset, easy titration, high clearance, and minimal side effects; particularly a lack of cardiovascular and respiratory depression. Due to unavailability of such an ideal sedative agent, techniques for conscious sedation often utilizes a combination of agents to provide analgesia, amnesia, and hypnosis with complete and rapid recovery that suits a particular operative procedure with minimum side effects. Dexmedetomidine has an arousal sedation property with analgesic effect. It also preserved airway reflexes and ventilator drive. As Midazolam has sedative effect but has no analgesic property. The injection Fentanyl was added as an analgesic with combination of Midazolam is conventionally used for conscious sedation. [12] In this prospective study, we compared the safety and efficacy of Dexmedetomidine with Midazolam plus Fentanyl in conscious sedation for middle ear surgery done under LA.

In this study it was observed that the mean heart rate was lower in group D than group MF during intraoperative period. The p value was <0.05 at 5min to 90min during intraoperative period. But 5min after stop of study drug infusion, heart rate was increased in group D. Which indicates patients were receiving Dexmedetomidine for intraoperative sedation had less heart rate during intraoperative peroid. Similarly, Parikh DA, et al., was showing that the variation of pulse rate during maintenance dose infusion among the study groups. They observed statistically significant fall of pulse rate at 120 min with mean of 75.09 and SD of 18.58 in the group that received Dexmedetomidine (p=0.003) [6]. On another study, Lavanya C, et al., observed that at 5 minutes interval itself, there was significant fall in heart rate (HR) resulting in fall in rate pressure product (RPP) in Dexmedetomidine group (mean HR < 80/min and mean RPP < 7000) from the baseline values and from corresponding values in Midazolam group (mean HR>80/min and mean RPP>7500) with P<0.05. This low HR and RPP continued till the end of the study in Dexmedetomidine group whereas in Midazolam group the HR and RPP showed a slow decrease up to 25 minutes interval followed by slow increase towards the end of their study. [13] These observations were similar with our study.

A study was conducted by Ramya, k., et al and they observed similar result with our study. They observed that That Systolic and Diastolic blood pressure decreased significantly in Dexmedetomidine group than in Midazolam group after the start of infusion (p<0.05). There was significant reduction in heart rate in Dexmedetomidine Group compared to group M (p<0.05) [8]. But Goyal, A., et al., found that intra-operative values of mean HR and RR were highly significantly lower from pre-operative value in both the groups throughout surgery. No statistically significant difference was present in mean intra-operative oxygen saturation as compared to the pre-op value in both the groups. [14] These findings were deviated from our findings.

In our study it was found that Propofol consumption (mg/kg) during intraoperative period for improvement of sedation were higher in group MF (65.8±9.9min) than in group D (35.8±6.3min) which is also observed by Parikh [6]. Like this observation Author's found that the requirement of additional sedation and local infiltration were lower in group D as compared to Group MF which were significant. In this study during intraoperative period patients of group MF required more local anaesthetic infiltration (1.8±0.6 mg/kg) than in patients of group D(1.2±0.4mg/kg) which were significant. But here in this study the time for 1st demand of analgesia (min) after surgery was longer in group MF (32.7±5.8min) than group D (15.3±4.7min).

Bradycardia (16% vs 6%) and hypotension (14% vs 8%) were more in group D than group MF. Other adverse events like apnea (8%) were more in group MF than group D. Nazima M., et al had found that the incidence of Complications: Patients in Group D had hypotension, bradycardia and dry mouth which were easily treatable whereas patients in Group MF had nausea, vomiting and pruritus [15].

In middle ear surgeries surgeon satisfaction score mainly depends on bloodless surgical field, and less intraoperative patient movement. Surgeons were asked about their satisfaction regarding the sedation technique after completion of surgery. Surgeon satisfaction score was higher in group D than in group MF. Surgeon was highly satisfied with the Dexmedetomidine sedation as it had bloodless surgical field and intra operative less

patient movement in group D as compared to group MF. Surgeon satisfaction score was statistically significant between group D and group MF P value = 0.001. [16] Similar results were also seen in this study.

On the basis of the findings of the present study, Dexmedetomidine seems to be better for conscious sedation when compared to Midazolam-Fentanyl combination. Dexmedetomidine provides a calm patient with better intraoperative analgesia, reducing need of rescue sedation and analgesic requirement in patients undergoing middle ear surgery under local anaesthesia leading to increased satisfaction of both patient and surgeon. However hemodynamic parameters and adverse effects like hypotension, bradycardia is needed to be closely monitored.

Limitations of the study

The present study was conducted in a very short period due to time constraints and funding limitations. The small sample size was also a limitation of the present study.

V. Conclusion

Intravenous Dexmedetomidine infusion provides better sedation and analgesia, good hemodynamic stability, better surgeon's satisfaction score with fewer side effects. It also reduces the requirement of rescue sedation and analgesia as compared to Midazolam with Fentanyl infusion in patients undergoing middle ear surgery under local anaesthesia. Thus, Dexmedetomidine is a better alternative to Midazolam with Fentanyl during conscious sedation for middle ear surgery.

VI. Recommendation

This study can serve as a pilot to much larger research involving multiple centers that can provide a nationwide picture, validate regression models proposed in this study for future use and emphasize points to ensure better management and adherence.

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