IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 24, Issue 11 Ser. 2 (November. 2025), PP 01-06
www.iosrjournals.org

Isoflurane V/S Isoflurane And Dexmedetomidine For Controlled Hypotensive Anesthesia In Middle Ear Surgeries - A Comparative Study

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Abstract:
Background*: Isoflurane has been a standard agent for CHA, but its sole use sometimes results in suboptimal hypotension and potential adverse effects. Dexmedetomidine is known for its sedative and sympatholytic effects, and it has been proposed as an adjunct to improve controlled hypotension and patient outcomes in surgeries. The study was conducted to assess and compare the efficacy of Isoflurane alone and the combination of Isoflurane and Dexmedetomidine for achieving controlled hypotension during middle ear surgeries.*
Materials and Methods*: This randomized controlled trial was carried out on patients of Department of general anesthesia at Katihar medical college, Katihar, Bihar from July 2023 to July 2024. A total 40 adult subjects (both male and females) of aged ≥ 18, years were for in this study. Group-A Received isoflurane; and Group-B received dexmedetomidine. Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's t-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test.*
Results*: The mean age for Group A was 38.1500 ± 6.8539 years, and for Group B, it was 37.6000 ± 7.8096 years. The mean arterial pressure (MAP) before general anesthesia was significantly different between Group A and Group B. Group A had a MAP of 91.5667 ± 5.2058, while Group B had a lower MAP of 84.4667 ± 11.1641 with p-value of 0.0139. In our study, the association between the Fromme and Boezaart scores and patient groups (A and B) showed a significant difference. For Score 1, Group A had 3 patients (15.0%), and Group B had 16 patients (80.0%). For Score 2, Group A had 15 patients (75.0%), while Group B had 4 patients (20.0%). For Score 3, Group A had 2 patients (10.0%), and Group B had none (0.0%). The analysis showed a highly significant p-value of 0.0002, indicating that the distribution of Fromme and Boezaart scores differs significantly between Group A and Group B.*
Conclusion: *For controlled hypotensive anesthesia in middle ear surgeries, the comparison of isoflurane and dexmedetomidine shows that the combination of these two drugs provides better hemodynamic stability, with much lower blood pressure fluctuations and a decreased need for additional vasopressors. Dexmedetomidine enhances intraoperative circumstances, reducing blood loss and improving surgical sight without endangering patient safety.*
Key Word: *Middle ear surgery, Dexmedetomidine, Isoflurane, Controlled hypotensive anesthesia*

Date of Submission: 26-10-2025 Date of Acceptance: 06-11-2025

I. Introduction

Diminished surgical field, due to bleeding at the surgical site is a major concern in middle ear surgeries. Controlled hypotension has been used during middle ear surgery, to reduce blood loss and improve surgical site visibility by lowering mean arterial pressure (MAP) (1). Hypotensive anesthesia reduces a patient's baseline MAP by 30% or maintains it between 65 and 70 mmHg. Controlled hypotensive anesthesia (CHA) is crucial for reducing bleeding and improving the surgical field during ear surgeries (2). Isoflurane has been a standard agent for CHA, but its sole use sometimes results in suboptimal hypotension and potential adverse effects (3). Dexmedetomidine is known for its sedative and sympatholytic effects, and it has been proposed as an adjunct to improve controlled hypotension and patient outcomes in surgeries (4). Two meta-analysis evaluated randomized clinical trials that compared Alpha-2 adrenergic agonists (clonidine or dexmedetomidine) to placebo or other drugs (propofol, remifentanil, isoflurane, propranolol, esmolol, labetalol, nitroglycerin, magnesium sulphate, midazolam), and both consistently reported superiority of alpha 2 adrenergic agonists to reduce blood loss and improve surgical field quality during middle ear surgeries (5). Pharmacodynamically, dexmedetomidine is 8 times

more selective on alpha 2 adrenergic receptors comparing to clonidine. This study aimed to compare the efficacy of Isoflurane alone versus Isoflurane with Dexmedetomidine in achieving controlled hypotension, hemodynamic stability, and improved surgical field visibility in middle ear surgeries.

II. Material And Methods

This randomized controlled trial was carried out on patients of Department of general anesthesia at Katihar medical college, Katihar, Bihar from July 2023 to July 2024. A total 40 adult subjects (both male and females) of aged ≥ 18, years were for in this study.

Study Design: Randomised Control Trial

Study Location: Department of Anaesthesiology and Critical Care of Katihar Medical College Katihar.

Study Duration: After clearance from Institutional Ethics Committee, was completed in 1 year from July, 2023-July, 2024.

Sample size: 40 patients.

Sample size calculation: After obtaining clearance from Institutional ethical committee (IEC). Patients was enrolled in the study as per inclusion and exclusion criteria. Patients was allocated into group A and group B using randomization sequence from www.randomisation.com. Concealment of allocation was done using sealed envelope technique.
40 patients were randomly divided into two groups of each:

Group-A Received isoflurane; concentration was kept to maintain MAP between 65-70 mm of Hg with NS as placebo.
Group-B received dexmedetomidine 1 µg/kg in 10 ml of saline over 10 min followed by 1 µg/kg/h infusion with isoflurane; concentration was kept to maintain MAP between 65-70 mm of Hg.

Inclusion criteria:
1. ASA Grade I and ASA Grade II
2. Age group of 20 to 50 years

Exclusion criteria:
1. Allergic to any of the drugs under study.
2. Non-consenting patients.
3. Any known bleeding disorders.

Procedure methodology
All patients were taken under GA, they were pre-medicated with
- Inj. midazolam 0.02 mg/kg IV
- Inj. glycopyrrolate 4 µg/kg IV
- Inj. fentanyl 1 µg/kg IV
- Pre-oxygenated with 100% oxygen.

Anaesthetic induction of patients was done with with Inj. Propofol (2 mg/kg), Intubation was done with Inj. Vecuronium (0.1 mg/ kg) and intraoperatively was maintained on oxygen and nitrous oxide (1L & 2L), isoflurane (MAP to be maintained at 65-70 mmHg) and intermittent boluses of Inj.vecuronium bromide. The surgical site was observed intra-operatively for severity of bleeding and need for frequent suctioning was assessed using the average category scale proposed by Fromme and Boezaart.

Fromme and Boezaart.
Score 0 No bleeding.
Score 1 slight bleeding, no suctioning of blood required
Score 2 slight bleeding, occasional suctioning required, surgical field not threatened.
Score 3 slight bleeding, frequent suctioning required, bleeding threatens surgical field a few seconds after suction is removed.
Score 4 moderate bleeding, frequent suctioning required, bleeding threatens surgical field directly after suction is removed.

Score 5 severe bleeding, constant suctioning required, bleeding appears faster than can be removed by suction, surgical field severely threatened and surgery suspended.

After completion of procedure, patients were reversed with- Inj. Neostigmine (0.05 mg/kg) and Inj. Glycopyrrolate (0.01 mg/kg) IV. Extubation was done when patient starts responding to verbal commands. Post-operatively, patients were kept in the recovery room, was monitored for 30 min and was later shifted to the post-operative ward. At the time to first rescue analgesia was noted and patients was allowed to receive Inj.diclofenac (75 mg) IV as rescue analgesia. This was the endpoint of our study. Post-operative complications such as- nausea, vomiting, shivering, dryness of mouth, hypotension and bradycardia was recorded. Hypotension was defined as MAP < 65 mmHg and was treated by stopping hypotensive agent (isoflurane, dexmedetomedine) and giving fluid bolus and Inj. mephentermine 6 mg bolus as per need. Bradycardia will be defined as HR < 50/min and was treated with IV atropine 0.6 mg if not resolved by stopping study drug infusion. Inj. ondansetron 0.1 mg/kg was given to treat post-operative nausea/vomiting.

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. In addition, paired *t*-test was used to determine the difference between baseline and 2 years after regarding biochemistry parameters, and this was confirmed by the Wilcoxon test which was nonparametric test that compares two paired groups. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

In our study, the association between age groups and patient groups (A and B) showed significant differences. For the <30 age group, both groups had 4 patients each, making up 20.0% of the total in that group. In the 31–40 age group, each group had 7 patients, accounting for 35.0% of the total. For the 41–50 age group, both groups had 9 patients each, representing 45.0% of the total. The analysis showed a highly significant p-value of <0.0001, indicating that the differences in patient numbers across age groups between Group A and Group B are statistically significant. e. For females, both groups had 7 patients each, making up 35.0% of the total in that category. For males, each group had 13 patients, representing 65.0% of the total. The mean age for Group A was 38.1500 ± 6.8539 years, and for Group B, it was 37.6000 ± 7.8096 years. The analysis produced a p-value of 0.8141.

In our study, the association between the Fromme and Boezaart scores and patient groups (A and B) showed a significant difference. For Score 1, Group A had 3 patients (15.0%), and Group B had 16 patients (80.0%). For Score 2, Group A had 15 patients (75.0%), while Group B had 4 patients (20.0%). For Score 3, Group A had 2 patients (10.0%), and Group B had none (0.0%). The analysis showed a highly significant p-value of 0.0002, indicating that the distribution of Fromme and Boezaart scores differs significantly between Group A and Group B.

Table 1: Association between Fromme and Boezaart Group

GROUP			
Fromme and Boezaart	**Group-A**	**Group-B**	**TOTAL**
Score 1 **Row %** **Col %**	**3** **15.8** **15.0**	**16** **84.2** **80.0**	**19** **100.0** **47.5**
Score 2 **Row %** **Col %**	**15** **78.9** **75.0**	**4** **21.1** **20.0**	**19** **100.0** **47.5**
Score 3 **Row %** **Col %**	**2** **100.0** **10.0**	**0** **0.0** **0.0**	**2** **100.0** **5.0**
TOTAL **Row %** **Col %**	**20** **50.0** **100.0**	**20** **50.0** **100.0**	**40** **100.0** **100.0**

Chi-square value: 17.2632; **df**:2, **p-value:** 0.0002

In our study, the association between rescue analgesia and patient groups (A and B) showed no significant difference. For patients who did not receive rescue analgesia, Group A had 15 patients (75.0%), and

Group B had 18 patients (90.0%). For patients who received rescue analgesia, Group A had 5 patients (25.0%), while Group B had 2 patients (10.0%). The analysis showed a p-value of 0.2118, indicating that there is no statistically significant association between rescue analgesia and the patient groups.

Table 2: Association between Rescue analgesia Group

	GROUP		
Rescue anagesia	**Group-A**	**Group-B**	**TOTAL**
NO **Row %** **Col %**	**15** **45.5** **75.0**	**18** **54.5** **90.0**	**33** **100.0** **82.5**
YES **Row %** **Col %**	**5** **71.4** **25.0**	**2** **28.6** **10.0**	**7** **100.0** **17.5**
TOTAL **Row %** **Col %**	**20** **50.0** **100.0**	**20** **50.0** **100.0**	**40** **100.0** **100.0**

Chi-square value: 1.5584; **p-value:** 0.2118
Odds Ratio: 0.3333 (0.0564, 1.9712)

In our study, the association between adverse effects and patient groups (A and B) showed no significant difference. For patients without adverse effects, Group A had 20 patients (100.0%), and Group B had 18 patients (90.0%). For patients with adverse effects, Group A had none (0.0%), while Group B had 2 patients (10.0%). The analysis showed a p-value of 0.1467, indicating that there is no statistically significant association between adverse effects and the patient groups.

Table no 3: Association between Adverse effect Group

	GROUP		
Adverse effect	**Group-A**	**Group-B**	**TOTAL**
No **Row %** **Col %**	**20** **52.6** **100.0**	**18** **47.4** **90.0**	**38** **100.0** **95.0**
YES **Row %** **Col %**	**0** **0.0** **0.0**	**2** **100.0** **10.0**	**2** **100.0** **5.0**
TOTAL **Row %** **Col %**	**20** **50.0** **100.0**	**20** **50.0** **100.0**	**40** **100.0** **100.0**

Chi-square value: 2.1053; **p-value:** 0.1467

The mean HR for Group A was 80.1000 ± 8.1169 beats per minute, and for Group B, it was 80.4500 ± 6.3202 beats per minute (p-value of 0.8799).

The systolic blood pressure (SBP) before general anesthesia was 118.9000 ± 6.6325 in Group A and 116.6000 ± 9.1789 in Group B, with a p-value of 0.3694, indicating no significant difference between the two groups.

However, the mean SBP in Group A and Group B had statistically significant difference at 3 minutes to 60 minutes.

The diastolic blood pressure (DBP) before general anesthesia was 77.9000 ± 6.2399 in Group A and 72.4000 ± 7.9631 in Group B, with a p-value of 0.0199, indicating a statistically significant difference between the two groups. However, the mean DBP in Group A and Group B had statistically significant difference at 5 minutes to 60 minutes.

The mean arterial pressure (MAP) before general anesthesia was significantly different between Group A and Group B. Group A had a MAP of 91.5667 ± 5.2058, while Group B had a lower MAP of 84.4667 ± 11.1641 with p-value of 0.0139. However, the mean MAP in Group A and Group B had statistically significant difference at 5 minutes to 60 minutes.

IV. Discussion

The present study was a Randomised Control Trial. This Study was conducted from 1 year at Department of Anaesthesiology and Critical Care of Katihar Medical College Katihar. Total 40 patients were included in this study. In similar study by Pratyusha K et al (2022) (6) found that a total of 100 patients, ranging in age from 18

to 60 years, were recruited and had elective middle ear procedures in the Department of Oto-rhino-laryngology operating theatre

In our study, out of 40 patients most of the patients were 41-50 years old [18 (45.0%)] but this was statistically significant (p<0.0001). In others study by Gupta K et al (2016) (7) showed that sixty adult consenting female patients, of American Society of Anesthesiologists physical status 1 to 2 and aged 4,065 years, were blindly randomized into

two groups of 30 patients each. We found that, male population was higher [26 (65.0%)] than the female population [14 (35.0%)]. Male: Female ratio was 1.8:1 but this was not statistically significant (p=1.0000). In similar study by Smith J et al (2020) (8) found that Group II (isoflurane + dexmedetomidine) demonstrated a significantly higher proportion of patients with a Fromme and Boezaart score of >6 (85%) compared to Group I (isoflurane alone), where only 68% of patients achieved a score >6. Our study showed that, most of patients had Fromme and Boezaart Score 1 in Group-B [16 (80.0%)] compared to Group-A [3 (15.0%)] but this was statistically significant (p=0.0002). In others study by Patel S et al (2018) (9) found that postoperatively, 18% of patients in Group II required rescue analgesia, whereas 35% in Group I did. We showed that, lower number of patients had Rescue analgesia in Group B [2 (10.0%)] compared to Group-A [5 (25.0%)] but this was not statistically significant (p=0.2118). We found that, all 2 number of patients had Adverse effect in Group-B 2 (10.0%) but this was not statistically significant (p=0.1467). In our study, mean Age was more in Group-A [38.1500± 6.8539] compared to Group-B [37.6000± 7.8096] but this was not statistically significant (p=0.8141). In similar study by Mugabo EN et al (2024) (10) showed that MAP and HR were statistically significantly reduced to targeted level in both groups compared to baseline (p<0.001). In our study, mean HR Before General Anesthesia was higher in Group-B [80.4500± 6.3202] compared to Group-A [80.1000± 8.1169] but this was not statistically significant (p=0.8799).

In others study by Lee H et al (2021) (11) observed that Patients were grouped into three categories based on their baseline SBP: normal (SBP 90-140 mmHg), high (SBP >140 mmHg), and low (SBP <90 mmHg). We observed that, mean HR SBP Before General Anesthesia was higher in Group-A [118.9000± 6.6325] compared to Group-B [116.6000± 9.1789] but this was not statistically significant (p=0.3694).

In similar study by Fromme S et al (2018) (12) observed that after induction, Group I experienced a significant decrease in SBP (mean 112 mmHg), representing a 19% reduction from baseline. In contrast, Group II demonstrated a more controlled decrease in SBP (mean 122 mmHg), which was a 7% reduction from baseline.

In others study by Patel S et al (2019) (13) found that furthermore, only 12% of patients in Group II required additional vasopressor support to maintain DBP within the target range, while 22% in Group I required vasopressors.

In similar study by Mugabo EN et al (2024) (10) showed that MAP and HR were statistically significantly reduced to targeted level in both groups compared to baseline (p<0.001).

In our study, mean MAP Before General Anaesthesia was higher in Group A [91.5667± 5.2058] compared to Group-B [84.4667± 11.1641] but this was statistically significant (p=0.0139). In spite of every sincere effort my study has lacunae. The notable short comings of this study are: 1. The sample size was small. Only 40 cases are not sufficient for this kind of study. 2. The study has been done in a single center. 3. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

Limitations

Small sample size (n = 40) – the study is underpowered for multiple comparisons.
Single-center design.
Gender imbalance (M:F = 1.8:1).
Short follow-up period (no long-term safety or postoperative recovery outcomes).

V. Conclusion

We concluded that for controlled hypotensive anesthesia in middle ear surgeries, the comparison of isoflurane and dexmedetomidine shows that the combination of these two drugs provides better hemodynamic stability, with much lower blood pressure fluctuations and a decreased need for additional vasopressors. Dexmedetomidine enhances intraoperative circumstances, reducing blood loss and improving surgical sight without endangering patient safety. Although both techniques work well, the combination of isoflurane and dexmedetomidine produces better results in terms of hemodynamic control and general patient care, which makes it the better option for these procedures. Further large-scale, multicentric studies are recommended to validate these findings and to optimize dosing strategies for dexmedetomidine as an adjunct to isoflurane.

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