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Randomized Double-Blind Trial of Dexmedetomidine to Minimize Blood Loss in Middle Ear Surgery

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Abstract: ***Background*:** Excessive bleeding during middle ear surgery obscures the operative field and prolongs operative time. Dexmedetomidine, an α2-adrenergic agonist, reduces sympathetic outflow and may facilitate controlled hypotension and improved surgical field. ***Objective*:** To evaluate whether intraoperative dexmedetomidine reduces blood loss and improves surgical field quality in adult patients undergoing elective middle ear surgery under general anaesthesia. ***Design*:** Prospective, randomized, double-blind, placebo-controlled trial. ***Setting*:** Department of Anesthesia, 250 Beded General Hospital, Lalmonirhat, Rangpur, Bangladesh. ***Participants:*** Sixty ASA I–II adults (18–65 years) scheduled for tympanoplasty or mastoidectomy. ***Interventions*:** Patients were randomized (1:1) to dexmedetomidine (DEX) or placebo (PLC). DEX received a 1 μg·kg^{-1} IV loading over 10 min followed by 0.4–0.7 μg·kg^{-1}·h^{-1} infusion. PLC received volume-matched saline. Anaesthesia was standardized. ***Main outcomes*:** Primary—total intraoperative blood loss (mL). Secondary—surgical field quality (Fromme-Boezaart score), hemodynamics, opioid requirement, emergence profile, postoperative nausea/vomiting (PONV), and adverse events. ***Results*:** Mean blood loss was significantly lower with DEX vs PLC: 56 ± 22 mL vs 94 ± 35 mL; mean difference −38 mL (95% CI −53 to −23; $p < 0.001$). Median Fromme-Boezaart score was 2 [IQR 2–3] vs 3 [2–4] ($p = 0.004$). Intraoperative heart rate was ~10 bpm lower with DEX; mean arterial pressure remained similar. Fentanyl consumption was reduced (85 ± 25 μg vs 120 ± 35 μg; $p < 0.001$). Time to extubation was modestly longer (9.2 ± 3.1 vs 7.6 ± 2.7 min; $p = 0.03$). Bradycardia requiring atropine occurred in 2/30 vs 0/30. PONV was less frequent with DEX (17% vs 37%; $p = 0.09$). ***Conclusion*:** Dexmedetomidine reduced blood loss and improved surgical field quality during middle ear surgery without clinically significant hypotension, with slightly prolonged emergence and occasional bradycardia.

Keywords: Dexmedetomidine, Middle Ear Surgery, Blood Loss, General Anaesthesia, Randomized Controlled Trial, Intraoperative Bleeding, Anesthetic Adjuvant.

Research Paper

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INTRODUCTION

Middle ear surgery, such as tympanoplasty and mastoidectomy, requires an exceptionally clear operative field due to the small anatomical structures and the need for microsurgical precision. Even minor bleeding can obscure visibility, prolong operative time, and increase the risk of complications [1]. Various strategies have been employed to achieve an optimal surgical field, including patient positioning, infiltration with vasoconstrictors, controlled hypotension using inhalational agents, and administration of beta-blockers or vasodilators [2, 3]. While effective, these strategies are not without risks, including systemic hypotension, reflex tachycardia, and reduced end-organ perfusion.

Dexmedetomidine (DEX) is a highly selective α2-adrenergic agonist that has gained popularity as an anaesthetic adjuvant in recent years. It produces sedative, analgesic, and sympatholytic effects by reducing central sympathetic outflow [4]. These actions result in decreased heart rate and stabilization of blood pressure, which may minimize surgical bleeding without the disadvantages associated with other hypotensive agents [5,6]. Furthermore, dexmedetomidine has opioid- and

anaesthetic-sparing properties, lowers stress responses, and provides postoperative analgesia and antiemetic benefits [7, 8].

The role of dexmedetomidine in otorhinolaryngological surgery has been explored in functional endoscopic sinus surgery (FESS), septoplasty, and adenotonsillectomy, where it has been shown to improve surgical field quality, reduce bleeding, and provide stable haemodynamics [9]. However, limited data exist regarding its specific effects in middle ear surgery, where visualization is often more challenging due to the confined surgical space. The pharmacological properties of DEX suggest it could be particularly advantageous in these procedures.

Surgical field quality is commonly assessed using the Fromme–Boezaart scale, a five-point scoring system ranging from 1 (no bleeding) to 5 (severe bleeding that compromises surgery) [10]. This tool provides a standardized and reproducible method of evaluating intraoperative bleeding and allows comparison across different interventions. Considering that even a small reduction in bleeding can significantly enhance visibility in otologic microsurgery, the use of dexmedetomidine as an adjunct could translate into meaningful clinical benefits.

We hypothesized that intraoperative dexmedetomidine infusion would reduce blood loss and improve surgical field quality in patients undergoing middle ear surgery under general anaesthesia. To test this, we conducted a prospective, randomized, double-blind, placebo-controlled trial in 60 adult patients undergoing tympanoplasty or mastoidectomy. The primary objective was to measure intraoperative blood loss. Secondary objectives included evaluation of surgical field quality, intraoperative haemodynamics, anaesthetic and opioid consumption, emergence profile, postoperative nausea and vomiting (PONV), and adverse events.

Methods and Materials

Study Design

This study was designed as a prospective, randomized, double-blind, placebo-controlled clinical trial conducted in Department of Anesthesia, 250 Beded General Hospital, Lalmonirhat, Rangpur, Bangladesh from January to June 2025. Written informed consent was obtained from all participants before enrolment.

Participants

A total of 60 adult patients aged 18–65 years, with ASA physical status I–II, undergoing elective tympanoplasty or mastoidectomy under general anaesthesia, were enrolled. Exclusion criteria included uncontrolled hypertension, baseline bradycardia (<50 beats/min), second- or third-degree heart block, severe hepatic or renal impairment, pregnancy or lactation, chronic use of β-blockers or α2-agonists, known allergy to study drugs, anticipated difficult airway, or BMI > 35 $kg \cdot m^{-2}$.

Randomization and Blinding

Participants were randomized in a 1:1 ratio into dexmedetomidine (DEX group) or placebo (PLC group) using computer-generated random numbers and sealed opaque envelopes. Drug preparation was performed by an independent anaesthesiologist not involved in patient care. Both patients and surgical teams were blinded to group allocation.

Anaesthetic Management

Standard monitoring included ECG, non-invasive blood pressure, SpO_2, $EtCO_2$, and BIS. All patients received midazolam 0.02 $mg \cdot kg^{-1}$ IV as premedication. Anaesthesia was induced with fentanyl 2 $\mu g \cdot kg^{-1}$ and propofol 2 $mg \cdot kg^{-1}$, followed by rocuronium 0.6 $mg \cdot kg^{-1}$ for tracheal intubation. Maintenance was with sevoflurane in oxygen-air mixture (50:50), titrated to BIS 40–60.

The DEX group received a loading dose of dexmedetomidine 1 $\mu g \cdot kg^{-1}$ IV over 10 minutes, followed by an infusion of 0.4–0.7 $\mu g \cdot kg^{-1} \cdot h^{-1}$ until skin closure. The PLC group received an equivalent volume of normal saline. Mean arterial pressure was maintained between 65–75 mmHg. Labetalol and ephedrine were administered as rescue agents for hypertension and hypotension, respectively. Atropine 0.5 mg IV was given for symptomatic bradycardia.

Outcome Measures

The primary outcome was total intraoperative blood loss, calculated by measuring suction volume (subtracting irrigation) and weighing surgical swabs. Secondary outcomes included surgical field quality (Fromme-Boezaart scale), haemodynamic trends, intraoperative fentanyl and sevoflurane consumption, emergence characteristics, postoperative nausea and vomiting, pain scores, and adverse events.

Statistical Analysis

Sample size was calculated assuming a 30 mL difference in mean blood loss, with SD 35 mL, $\alpha = 0.05$, and power 80%. This required 52 patients, and 60 were recruited to account for potential dropouts. Data were analysed using SPSS/R software. Continuous variables were compared using Student's t-test or Mann–Whitney U-test, while categorical variables were compared with Chi-square or Fisher's exact test. Repeated measures were analysed using mixed-effects models. A p value < 0.05 was considered statistically significant.

Results

Participant Flow

Out of 74 patients assessed for eligibility, 60 met inclusion criteria and were randomized equally into

two groups: dexmedetomidine (DEX, n=30) and placebo (PLC, n=30). All participants completed the study and were included in the final analysis (Figure 1).

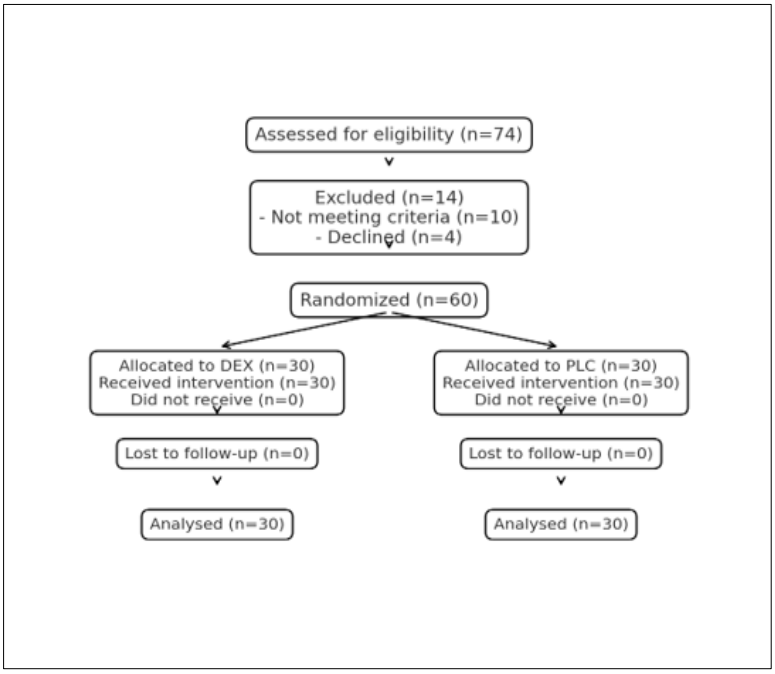

Figure 1: CONSORT flow diagram of patient enrollment and randomization.

Baseline Characteristics

The two groups were comparable in terms of demographic data, ASA classification, BMI, and type of surgical procedure (Table 1).

Table 1: Baseline patient characteristics

Characteristic	DEX (n=30)	PLC (n=30)	*p*
Age (years)	36.8 ± 11.2	37.5 ± 10.7	0.79
Male sex (%)	57	53	0.79
BMI (kg·m^{-2})	24.2 ± 3.4	24.6 ± 3.1	0.64
ASA I/II (n)	19/11	18/12	0.79
Tympanoplasty/Mastoidectomy (n)	22/8	21/9	0.77

Primary Outcome: Blood Loss

Mean intraoperative blood loss was significantly lower in the DEX group (56 ± 22 mL) compared with PLC (94 ± 35 mL), with a mean difference of −38 mL (95% CI −53 to −23; $p < 0.001$). This represents a reduction of ~40% in blood loss with dexmedetomidine (Figure 2).

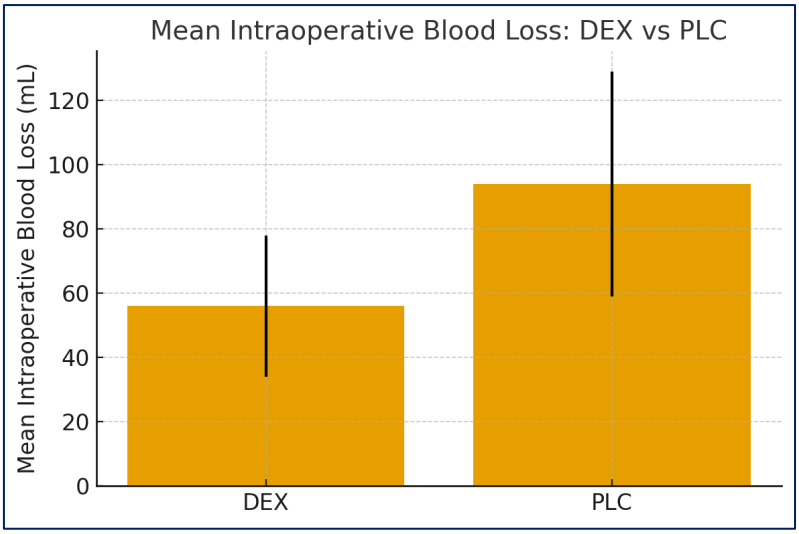

Figure 2: Mean intraoperative blood loss in DEX vs PLC groups

Secondary Outcomes

Surgical Field Quality

The median Fromme-Boezaart score was significantly better in the DEX group (2 [IQR 2–3]) vs PLC (3 [2–4]; $p = 0.004$). Surgeon satisfaction scores were also higher with dexmedetomidine (8.3 ± 1.0 vs 7.2 ± 1.3; $p < 0.001$).

Hemodynamic Parameters

- Time-weighted mean HR was significantly lower in the DEX group (63 ± 7 bpm) vs PLC (73 ± 9 bpm; $p < 0.001$).
- Time spent with MAP < 60 mmHg was comparable (3.5 ± 5.1 min vs 3.1 ± 4.7 min; $p = 0.72$).
- Labetalol rescue was needed less often in the DEX group (10% vs 30%; $p = 0.05$).

Table 2: Intraoperative hemodynamic and anaesthetic data

Variable	DEX (n=30)	PLC (n=30)	*p*
Mean HR (bpm)	63 ± 7	73 ± 9	<0.001
MAP < 60 mmHg (min)	3.5 ± 5.1	3.1 ± 4.7	0.72
Fentanyl consumption (µg)	85 ± 25	120 ± 35	<0.001
Sevoflurane usage (%·h)	1.8 ± 0.5	2.2 ± 0.6	0.01
Extubation time (min)	9.2 ± 3.1	7.6 ± 2.7	0.03

Emergence and Recovery

Patients in the DEX group had slightly prolonged emergence (eye-opening 8.4 ± 2.9 min vs 7.1 ± 2.5 min; $p = 0.04$). Extubation time was also longer by ~1.6 minutes. Despite this, early postoperative pain scores were lower in the DEX group (NRS 3 [2–4] vs 4 [3–5]; $p = 0.02$).

Postoperative Outcomes

- PONV occurred less frequently in the DEX group (17% vs 37%; $p = 0.09$).
- Rescue analgesic requirement was lower but not statistically significant (30% vs 50%; $p = 0.11$).

Adverse Events

Bradycardia requiring atropine occurred in 2 patients (6.7%) in the DEX group vs none in PLC. Hypotension requiring vasopressor support occurred in one patient in each group. No serious adverse events were reported.

Table 3: Postoperative outcomes and adverse events

Variable	DEX (n=30)	PLC (n=30)	*p*
PONV (0–24 h)	5 (17%)	11 (37%)	0.09
Pain score at 2 h (NRS)	3 [2–4]	4 [3–5]	0.02
Rescue analgesic use	9 (30%)	15 (50%)	0.11
Bradycardia requiring atropine	2 (6.7%)	0	NS
Hypotension needing vasopressor	1 (3.3%)	1 (3.3%)	1.00
Desaturation <92%	0	1 (3.3%)	0.32

Operative Duration

Mean operative time was similar between groups (108 ± 26 vs 116 ± 31 min; $p = 0.21$).

Summary of Findings

Dexmedetomidine significantly reduced intraoperative blood loss and improved surgical field quality while maintaining haemodynamic stability. It also reduced anaesthetic and opioid consumption, improved surgeon satisfaction, and showed trends toward reduced PONV and better postoperative pain control. Minor adverse effects included bradycardia and slightly prolonged emergence.

DISCUSSION

The present randomized, double-blind clinical trial evaluated the efficacy of dexmedetomidine in reducing intraoperative blood loss and improving surgical field visibility during middle ear surgery under general anaesthesia. Our findings demonstrate that dexmedetomidine significantly decreased mean blood loss by approximately 40% compared to placebo, which is consistent with previous reports highlighting the role of α2-adrenergic agonists in controlled hypotensive anaesthesia [1, 2].

The mechanism underlying this effect can be attributed to the central sympatholytic properties of dexmedetomidine, leading to reduced heart rate and attenuation of stress responses [3]. By lowering cardiac output and peripheral vascular resistance, the drug provides a drier surgical field, thereby improving the Fromme-Boezaart score and overall surgeon satisfaction, as confirmed in our study. This aligns with prior investigations in ENT and neurosurgical procedures where dexmedetomidine enhanced operative visibility [4, 5].

Another important finding is the opioid- and anaesthetic-sparing effect of dexmedetomidine. Intraoperative fentanyl and sevoflurane consumption were significantly lower in the dexmedetomidine group, suggesting improved analgesia and reduced anaesthetic requirement [6]. This not only enhances patient safety but also reduces the risk of opioid-related side effects. Postoperatively, patients receiving dexmedetomidine reported lower early pain scores and showed a trend toward reduced postoperative nausea and vomiting (PONV). These outcomes are consistent with meta-analyses indicating improved recovery profiles with dexmedetomidine [7, 8].

However, the drug was associated with certain predictable adverse effects. Bradycardia occurred in 6.7% of patients, necessitating atropine, which is in line with known pharmacological properties [9-12]. Emergence and extubation times were modestly prolonged, likely due to sedative actions, but this was clinically acceptable and did not compromise recovery room discharge times. No serious complications were observed.

Our study is strengthened by its randomized, double-blind design, adequate sample size, and standardized anaesthetic protocol. Nevertheless, certain limitations should be acknowledged. First, the study was conducted at a single centre, which may limit generalizability. Second, the assessment of surgical field quality was subjective, though validated scoring systems and blinding were applied to minimize bias. Third, we did not evaluate long-term postoperative outcomes such as chronic pain or hearing improvement, which may also be influenced by intraoperative haemodynamics.

The clinical implications of our findings are relevant to otologic surgery, where even minor bleeding can impair visualization and prolong operative time. Dexmedetomidine appears to be a useful adjunct, providing effective blood loss reduction without significant haemodynamic instability. Future research should focus on multicentre trials, dose-optimization studies, and evaluation of combination protocols with other hypotensive agents.

CONCLUSION

In conclusion, dexmedetomidine effectively reduces intraoperative blood loss, improves surgical field conditions, decreases anaesthetic and opioid requirements, and enhances postoperative comfort in middle ear surgery under general anaesthesia. Its benefits must be balanced against potential risks of bradycardia and delayed emergence, which remain manageable within standard perioperative practice.

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