

CONTROLLED HYPOTENSION WITH DESFLURANE COMBINED WITH ESMOLOL OR DEXMEDETOMIDINE DURING MASTOIDECTOMY IN ADULTS: A RANDOMISED CONTROLLED TRIAL

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Abstract

Background: Controlled hypotension is a technique that is used to limit intraoperative blood loss to provide the best possible surgical field during surgery. The present study compared the efficacy of Desflurane combined with Dexmedetomidine or Esmolol in achieving controlled hypotension during mastoidectomy surgeries. **Materials and Methods:** A total of 52 patients enrolled for the study were randomly divided into the Esmolol and Dexmedetomidine groups. Esmolol infusion was initiated at a rate of 1mg/kg. A loading dose of dexmedetomidine was infused intravenously over 10 minutes at one mcg/kg. General Anaesthesia was maintained with 4-6% end-tidal concentrations of Desflurane. At the end of the surgery, parameters such as the amount of bleeding, time is taken for total recovery from anaesthesia using Modified Aldrete Score, sedation scores at 15, 30 and 60 minutes after tracheal extubation, intraoperative Fentanyl consumption, hypotension and bradycardia were analysed. **Result:** The observation of mean SBP, DBP and MAP were comparable for the initial 15 minutes of surgery. Almost all patients in both groups had a 6-point bleeding scale less than or equal to 2. In the present study, none of the patients in Group E had hypotension. No patient in Group D had bradycardia, whereas 15.4% of patients in Group E had bradycardia. Group D patients reported higher incidents of nausea and vomiting at 15 and 30 minutes. Sedation was higher in Group E patients at 30 and 60 minutes. Group D patients required less additional fentanyl supplementation. **Conclusion:** The study concluded that controlled hypotension was better achieved with Desflurane and dexmedetomidine.

INTRODUCTION

The middle ear is a closed air-filled cavity between the tympanic membrane and the oval window. Surgeries performed under the operating microscope need a bloodless field for better visualisation of important structures to avoid the risk of complications.^[1] During these surgeries, the slightest bleeding in the surgical area would look larger due to the microscope's magnifying effect, which could upset surgical comfort and lead to incomplete surgical procedures, thereby increasing further bleeding and recurrence of the disease.^[2,3]

Anaesthesiologists have devised various techniques to prevent this bleeding, of which induced hypotension has stood the test of time. Controlled or deliberate or induced hypotension is a technique used to limit intraoperative blood loss to provide the best possible field for surgery, which can be achieved through multiple modalities.^[4,5] Pharmacological and

non-pharmacological methods can achieve controlled hypotension.^[6] Non-pharmacological methods include arteriotomy, positioning the surgical site higher than the heart's, and positive pressure ventilation. Pharmacological means can be through intravenous or inhalational agents.

The ideal hypotensive agent should be nontoxic, maintain cerebrovascular auto-regulation, produce no change in cardiac function, have short-term effects and be easily titrated.^[7] Pharmacological agents which can be used include vasodilators, beta-adrenergic antagonists, centrally acting alpha 2 agonists, calcium channel blockers and various inhalational agents like Sevoflurane, Isoflurane and Desflurane. Each drug has drawbacks like delayed recovery, drug resistance, tachyphylaxis, hemodynamic instability and Cyanide toxicity (e.g., Nitroprusside).^[1,8] Esmolol is an ultra-short acting β 1-cardioselective adrenergic receptor blocker that provides a stable course of controlled hypotension

and produces beneficial effects in the surgical field and blood conservation.^[9]

Dexmedetomidine is a recently introduced highly selective centrally acting α -2-adrenoreceptor agonist that can be used for a better quality surgical field without additional hypotensive agents. Various studies have compared the efficacy of Esmolol or Dexmedetomidine with other drugs during middle ear surgeries.^[8,10] Very few studies have compared Esmolol with Dexmedetomidine during middle ear surgeries. Hence, we compare the efficacy of Desflurane combined with Dexmedetomidine or Esmolol on achieving controlled hypotension during mastoidectomy surgeries.

MATERIALS AND METHODS

This clinical study was conducted in the Department of Anaesthesiology, Thanjavur medical college. Clearance was obtained from the hospital's ethical committee for the study. Written informed consent was obtained from all the study participants before study initiation.

Inclusion Criteria

Patients aged 18 to 60 years of either sex with ASA physical class I or II enrolled for mastoidectomy were included.

Exclusion Criteria

Patients with significant dysrhythmias, ASA physical class greater than II, uncontrolled hypertension, cardiovascular disease, cerebrovascular disease and bleeding disorder were excluded.

A total of 52 patients were allocated into two groups of 26 each, Group E - Patients received Esmolol, and Group D - Patients received dexmedetomidine. All patients were hospitalised the day before surgery and fasted for more than 8 hours before surgery. All patients received Midazolam 0.07 mg/kg intramuscularly as premedication 30 minutes before surgery.

On arrival in the operating room, two cannulae were inserted, one for infusion of Esmolol or Dexmedetomidine and the other for administering fluids and other drugs. Before induction of anaesthesia, baseline measurements of heart rate, non-invasive blood pressure, mean arterial pressure and saturation were made with a Datex Ohmeda monitor. Premedication was done with Glycopyrrolate 0.2 mg i.v and Fentanyl 2 μ g/kg i.v. Preoxygenation was done with 100% oxygen for 3 minutes. Induction was performed with Propofol 2 mg/kg i.v, and endotracheal intubation was facilitated with Vecuronium 0.1mg/kg i.v. Mechanical ventilation was adjusted to provide an end-tidal carbon dioxide (ETCO₂) level of 30 to 35 mmHg and a SpO₂ level >97% with 66% N₂O in oxygen. After tracheal intubation, Esmolol infusion was initiated at 1mg/kg as a loading dose over 1 minute, followed by a maintenance infusion rate of 0.4 to 0.8 mg/kg/hr to achieve controlled hypotension in Group E. In group D, a loading dose of dexmedetomidine was infused

intravenously over 10 minutes at 1 mcg/kg, followed by a maintenance infusion rate of 0.4 to 0.8 mcg/kg/hr. The infusion rates were then titrated to maintain mean arterial pressure between 65 to 75 mmHg. General Anaesthesia was maintained with 4 – 6% end-tidal concentrations of Desflurane. Both groups treated signs of inadequate anaesthesia (e.g., increase in arterial pressure greater than the targeted mean arterial pressure) or somatic responses (e.g., movement, tearing or sweating) with additional titrated doses of fentanyl. At the end of the surgery, the amount of blood in the surgical field was assessed using the following six-point scale. The scale ranges from no bleeding (1) to massive bleeding that was uncontrollable and made dissection impossible (6).

A local vasoconstrictor was not used to control bleeding during the surgery. Infusion of the study drugs was stopped 5 minutes before the anticipated end of the surgery, and Desflurane was stopped after skin closure. At the end of the surgery, any residual neuromuscular blockade was antagonised with Neostigmine 0.05mg/kg i.v and Glycopyrrolate 0.01mg/kg i.v. Time taken for total recovery from anaesthesia was recorded using the Modified Aldrete Score.

Sedation score was determined at 15, 30 and 60 minutes after tracheal extubation by using Ramsay Sedation Score. After total recovery from anaesthesia, patients were transferred to the recovery room, and SpO₂ was monitored up to 1 hour after extubation. Intraoperative hypotension [Mean Arterial Pressure <65 mm Hg], bradycardia [HR <50 beats/ min], intraoperative. Fentanyl consumption and postoperative nausea and vomiting were recorded. The same attending surgeon and Anaesthesiologist evaluated all patients.

The parameters such as the amount of bleeding in the operative field, time taken for total recovery from anaesthesia using Modified Aldrete Score, sedation scores at 15,30 and 60 minutes after tracheal extubation, intraoperative Fentanyl consumption, hypotension and bradycardia were analysed.

Statistical Analysis

The data were entered into Microsoft Excel and analysed using SPSS-16 software. Discrete variables were presented as frequencies and percentages. Chi-square and Fisher's exact tests measured associations between variables such as gender, blood loss, postoperative nausea, vomiting, hypotension, bradycardia, Aldrete scores, and sedation scores at different intervals. The Student T-test assessed associations between age, weight, heart rate, blood pressure, mean arterial pressures at various intervals, and additional Fentanyl administration. A p-value less than 0.05 was considered statistically significant.

RESULTS

The gender distribution, mean age, and weight in both groups and mean age and weight were comparable between groups [Table 1].

Table 1: Observation of demographic and other evaluation parameters of patients

Parameters	Observation N (%)		P-value
	Group D (N=26)	Group E ((N=26)	
Gender			
Male	15 (57.7%)	15 (57.7%)	1
Female	11 (42.3%)	11 (42.3%)	
Age Groups			
≤ 30 years	18 (34.6%)		-
31-40 years	17 (32.7%)		
41-50 years	11 (21.2%)		
51-60 years	6 (11.5%)		
Mean Age years ±SD	36.192 ±10.87	35.615 10.63	0.847
Mean Weight Kg± SD	56.79 ±8.41	56.96 6.43	0.927
Amount of blood loss (6-point scale)			
1	20 (76.9%)	16 (61.5%)	0.368
2	6 (23.1%)	10 (38.5%)	
Hypotension			
Present	2 (7.7%)	0 (0%)	0.490
Absent	24 (92.3%)	26 (100%)	
Bradycardia			
Present	0 (0%)	4 (15.4%)	0.110
Absent	26 (100%)	22 (84.6%)	
Nausea and vomiting at 15 mins			
Present	7 (26.9%)	3 (11.5%)	0.291
Absent	19 (73.1%)	23 (88.5%)	
Sedation score at 15 mins			
1	0 (0%)	21 (80.8%)	<0.001
2	9 (34.6%)	5 (19.2%)	
3	14 (53.8%)	0 (0%)	
4	3 (11.6%)	0 (0%)	
Aldrete score at 15 mins			
9	8 (30.8%)	0 (0%)	0.004
10	18 (69.2%)	26 (100%)	
Nausea and vomiting at 30 mins			
Present	3 (11.5%)	0 (0%)	0.235
Absent	23 (88.5%)	26 (100%)	
Sedation score at 30 mins			
1	0 (0%)	24 (92.3%)	0.00
2	17 (65.4%)	2 (7.7%)	
3	9 (34.6%)	0 (0%)	
Sedation score at 60 mins			
1	15 (57.7%)	26 (100%)	0.00
2	11 (42.3%)	0 (0%)	

Table 2:

Mean heart rate (bpm)	Observation N (%)		P-value
	Group D (N=26)	Group E ((N=26)	
Time			
0	84.346 ±12.98%	83.692 ±12.61%	0.855
5	83 ±13.67%	85.192±12.28%	0.546
10	79.192±13.16%	78.731±11.90%	0.895
15	88.269 ±14.47%	86.385 ±12.97%	0.623
20	79.462±11.54%	78.731±11.39%	0.819
30	74.192±9.95%	72.923 ±10.71%	0.660
40	71.269 ±8.52%	68.192±9.17%	0.216
50	69.154±8.70%	64.5±7.79%	0.048
60	66.8±8.22%	61.308±7.33%	0.014
80	65.846±8.65%	59.615±7.16%	0.007
100	64.423±8.01%	57.269±6.85%	0.001
120	62±6.78%	55.5±6.05%	0.002
150	60±5.76%	53.75±2.49%	0.011
180	62.25±6.02%	51 ±1	0.026

Table 3: Comparison of additional Fentanyl administration in both groups

	Observation N (%)	
	Group D (N=26)	Group E ((N=26)
Number of patients requiring fentanyl supplementation	1	20
Mean ± SD	0.03± 0.147	1± 0.735
Mean Difference	0.97	
p-value	<0.001	

The mean heart rate was comparable in both groups till 40 minutes of surgery, and after that, a statistically significant difference ($p < 0.05$) in mean heart rate was reported [Table 2]. The mean SBP, DBP and MAP were comparable in Group D and Group E for the initial 15 minutes of surgery. In contrast, a significant difference ($p < 0.05$) was reported after 15 minutes till the end of surgery (180 minutes) [Figure 1].

Almost all patients in both groups had a 6-point bleeding scale less than or equal to 2, considered optimal for surgical conditions, and the results were not statistically significant ($p = 0.368$). In our study, 2 (7.7%) patients in Group D had hypotension, whereas none in Group E had hypotension. In our study, no patient in Group D had bradycardia, whereas 4 (15.4%) patients in Group E had bradycardia. Total of 7 (26.9%) patients in Group D had nausea and vomiting at 15 mins compared to 3 patients (11.5%) in Group E. At 15 minutes, around 17 (65.38%) of the study population in Group D had a sedation score of more than 2, while everyone in Group E had a sedation score of less than or equal to 2. At 15 minutes, all the study population in Group E had an Aldrete score of 10, while only 18 (69.23%) of the patients in Group D had an Aldrete score of 10. The effect was statistically significant ($p < 0.05$) in both groups [Table 1].

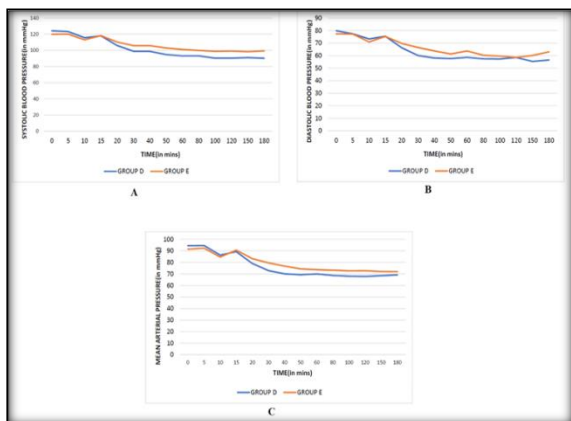


Figure 1: Observation of MSPB, MDBP and MAP among patients of both groups

A total of 3 (11.5%) patients in Group D had nausea and vomiting at 30 minutes compared to none in Group E. At 30 minutes, 24 (92.3 %) of the study population in Group E had a sedation score of 1 compared to none in Group D. The results were statistically significant ($p < 0.05$) in both groups. However, at 60 minutes, all the participants in Group E had a sedation score of 1 compared to 15 (57.7%) patients in Group D. The results were statistically significant ($p < 0.05$) [Table 2, Figure 2].

In the present study, 1 (3.84%) patient in Group D required additional fentanyl supplementation of 0.75mcg/kg. In contrast, in Group E, 6 (23.07%) patients required 2mcg/kg, three patients required 1.5mcg/kg, eight patients required 1mcg/kg, and three patients required 0.5mcg/kg and the difference was statistically significant ($p < 0.05$) [Table 3].

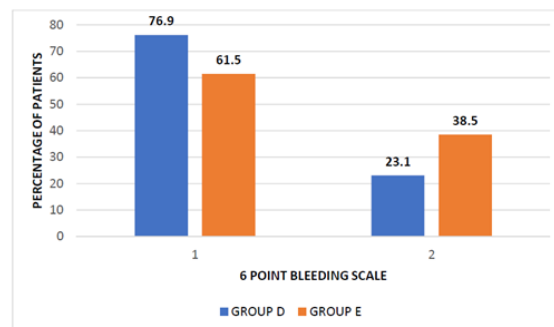


Figure 2: Observation of 6-point bleeding scale of patients in both groups

DISCUSSION

Most of our study population (above 65%) were below 40, and 57.7% were males. Males and females were also equally distributed in both groups. There was no significant difference in demographic parameters between the groups in our study, similar to most of the studies mentioned in the literature.^[10,11] Hence we ensured that the demographic parameters did not confound our results.

Our study found that administration of loading dose and maintenance infusion of Esmolol and Dexmedetomidine decreased heart rate intraoperatively, at the end of surgery and after extubation. There was no significant difference in heart rate between both the groups till 40 minutes, but after 40 min, a significant difference was observed. The Esmolol group's heart rate was less than the Dexmedetomidine group's. This result was comparable to a study by Shams T et al. which showed a significant difference in heart rate following a loading dose of Dexmedetomidine and Esmolol.^[11] But this result was contrary to Malhotra et al., where heart rate was significantly lower in the Dexmedetomidine group than in the Esmolol group.^[12]

In our study, the SBP, DBP and MAP were more or less similar in both groups during the initial 15 minutes. After that, the measurements in Group D were significantly lesser till the end of the surgery compared to those in Group E. Target MAP in our study was 65 to 75 mmHg. Shams et al., in their research, had a target MAP of 55 to 65 mmHg.^[11] Guney et al., in their study, had a target MAP of 60 to 65 mmHg.^[13] MAP reached target values within 15 minutes after infusion of Dexmedetomidine in Group D. Still, it took 35 minutes after infusion of Esmolol in Group E. From 40 minutes onwards, MAP values were almost similar with an average difference of 3 to 6 mmHg at each time interval recorded with lower values in Group D than Group E, which was statistically significant ($p < 0.05$). Both the groups achieved target MAP with 76% of patients in Group E requiring additional intravenous fentanyl at 0.5 to 2 mcg/kg to achieve controlled hypotension. The results of our study were similar to those obtained by Erbesler et al., who found comparable MAP values with minimal differences in Dexmedetomidine and

Esmolol groups.^[14] This result was contrary to Kakati et al., where Esmolol showed lower MAP as compared to Dexmedetomidine.^[15]

In our study, the quality of the surgical field was assessed using a 6-point bleeding scale. We considered a score less than or equal to 2 optimal for surgical conditions. We found that Esmolol and Dexmedetomidine effectively produced a surgical field with improved visibility (average score less than or equal to 2). The results were not statistically significant. This result was supported by Shams et al., who showed that 6-point scale values were comparable in both the groups receiving Dexmedetomidine and Esmolol.^[11]

When target MAP was not achieved using the upper limit of infusion of study drugs, we administered an additional dose of intravenous fentanyl in titrated doses. Out of 26 patients in Group D, 25 achieved target MAP with an infusion of dexmedetomidine, except one who required an additional dose of intravenous fentanyl at 0.75mcg/kg. Nearly 76 % of patients needed an additional dose of intravenous fentanyl at 0.5-2mcg/kg in Group E to attain a statistically significant target MAP ($p < 0.001$). Results of our study were comparable with those by Kol et al., where the need for additional hypotensive agents like intravenous Fentanyl, Nitroglycerin, and higher concentrations of inhalational agents was higher in those who received Esmolol than those who received Dexmedetomidine.^[16]

In the present study, we compared the incidence of hypotension and bradycardia in both groups, and the results showed no statistical significance. 7.7% of patients in Group D had hypotension, whereas none in Group E had hypotension. No patient in Group D had bradycardia, whereas 15.4% of patients in Group E had bradycardia. These were consistent with the results produced by Bajwa et al., where both Dexmedetomidine and Esmolol achieved controlled hypotension with no adverse effects.^[17]

Our study assessed post anaesthesia recovery score using Modified Aldrete Score at 15, 30 and 60 minutes after tracheal extubation. A score greater than 9 (out of 15) was required to confirm recovery. At 15 minutes after tracheal extubation, the study population in Group E had an Aldrete score of 10, while only 69% of the patients in Group D had an Aldrete score of 10. The results were statistically significant ($p=0.004$). Saturation was monitored up to 1 hour after tracheal extubation and was in the range of 98 to 99% in both groups, which was statistically insignificant. Kol et al., in their investigation, found that time to Aldrete score >9 was longer in the Dexmedetomidine group (7.9 min) than in the Esmolol group (5.9 min).¹⁶ Similar results were obtained with Shams T et al., where dexmedetomidine had a longer recovery time than Esmolol or Remifentanyl.^[11]

We found that sedation scores were higher in the Dexmedetomidine group than in the Esmolol group at 15, 30 and 60 minutes after extubation. This was consistent with the results obtained by Kol et al.,

where the mean sedation score was 3.5 in the Dexmedetomidine group and 2.5 in the Esmolol group.^[16]

In the current study, we compared the incidence of postoperative nausea and vomiting in both groups at 15, 30 and 60 minutes after surgery. At 15 minutes, 26.9% of patients in Group D had nausea and vomiting compared to 11.5% in Group E; the difference was not statistically significant. At 30 minutes, 11.5% of patients in Group D had nausea and vomiting compared to none in Group E. At 60 minutes, none of the patients in either group had nausea and vomiting. This result was supported by Das et al., who found that three patients complained of nausea and 1 of vomiting in Group D as compared to 6 patients with nausea and three patients having vomiting in Group E.^[18]

CONCLUSION

Controlled hypotension using Desflurane combined with dexmedetomidine was more effective than Desflurane combined with Esmolol for mastoidectomy surgeries, achieving target mean arterial pressure earlier and reducing intraoperative anaesthetic requirements. Dexmedetomidine better maintained intraoperative mean arterial pressure. Although postoperative sedation scores were higher, saturation remained normal. Postoperative recovery was slightly delayed with dexmedetomidine, while Esmolol required additional doses of intravenous fentanyl to reach the target mean arterial pressure. However, Esmolol resulted in a significantly shorter recovery time and less postoperative sedation than dexmedetomidine. Both groups demonstrated equal effectiveness in ensuring a high-quality surgical field.

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