

## A randomized controlled clinical trial to compare intraoperative hemodynamics and postoperative nausea and vomiting in Middle Ear Surgeries with Sevoflurane and Desflurane

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### Abstract

**Introduction:** Ideal anaesthetic technique for middle ear surgeries is one which maintains hemodynamic stability, optimizes surgical field, minimizes coughing on emergence from anaesthesia and avoids postoperative nausea and vomiting. **Aim of the study:** To compare Hemodynamics (Heart rate, Systolic blood pressure, Diastolic blood pressure) and postoperative nausea and vomiting (PONV) in middle ear surgeries done under general anesthesia with Sevoflurane and Desflurane. **Materials and Methods:** After institutional ethics approval the study was conducted at Govt. ENT Hospital, Koti, Hyderabad, Telangana state during 2016-2018. Study included patients in age group 12-60 years belonging to ASA I,II of both genders scheduled for elective middle ear surgeries under general anaesthesia, randomly divided into two equal groups-Group S (n=30), Group D(n=30) based on inhalation anaesthetic used. Intraoperatively hemodynamics were recorded at predetermined intervals, after extubation and recovery, postoperatively patients were transferred to post anesthesia care unit and incidence of PONV within first 23hrs were recorded. **Results:** Intraoperatively hemodynamics mean values between two groups were as Group S - Systolic, Diastolic blood pressure -118.85±9.72 and 77.01±6.93 (p value 0.481), Group D - Systolic, Diastolic blood pressure-119.16±10.80 and 77.02±6.84 (p value 0.485) respectively, mean heart rates in Group S-86.00±12.09, Group D-84.75±11.50 (p value 0.337), incidence of PONV in Group S (23.33%) and Group D (26.66%). Intraoperative hemodynamics and incidence of postoperative nausea and vomiting between study groups were comparable and statistically insignificant. **Conclusion:** Sevoflurane and Desflurane showed no significant difference in intra operative hemodynamics and incidence of postoperative nausea and vomiting when used for anesthesia maintenance in middle ear surgeries.

**Keywords:** Desflurane, Middle ear surgeries, Postoperative nausea and vomiting (PONV), Sevoflurane

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### Introduction

Middle ear is an air-filled space between tympanic membrane and oval window traversed by facial nerve before it exits the skull via stylomastoid foramen[1,2].

Middle ear surgeries are strongly influenced by anatomical and functional characteristics. Given the unique location, size, and delicate content of middle ear, great care must be executed during perioperative period. Special considerations include: provision of a bloodless surgical field, attention to patient's head positioning, airway management, the effect of nitrous oxide on the middle ear, no intratympanic pressure fluctuations, a smooth and fast emergence and calm recovery and prevention of postoperative nausea and vomiting (PONV)[3-6].

The introduction of newer inhalational agents Sevoflurane and Desflurane into anesthesia marked the start of new era of fast tracking and have gained popularity and convenience in terms of maintenance of hemodynamic stability, emergence and recovery when compared to older agents. Middle ear surgery is associated with a high incidence of postoperative nausea and vomiting (PONV), contributory factors include surgery in younger patients, stimulation of vestibular system and suction irrigation (a caloric vestibular stimulant), incidence of PNOV may vary with use of inhalation anesthetics. PONV is a major contributor to increasing health care costs for hospital and patient[7] resulting from longer recovery, as well as unanticipated admissions following procedures, achieving a more effective outcome with respect to PONV is desirable, as it can potentially affect surgical repair and will become increasingly important in future as a result of increasing pressure to decrease discharge times. In this study, effects of desflurane and sevoflurane as inhalation agents on intraoperative hemodynamics and postoperative nausea and vomiting in Middle ear surgeries is comparatively investigated.

### Materials and methods

The present study was a prospective, randomized, comparative clinical study approved by the Institutional Ethics Committee conducted at Government ENT Hospital, Koti, Hyderabad, T.S. during 2016-2018. Patients in the age group 12 to 60 years belonging to both

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genders who were scheduled for Elective Middle ear surgeries (Tympanoplasty, Mastoidectomy, Ossicular chain reconstruction, Stapedectomy, Cochlear implants etc.) under General anesthesia were included in the study. All the study patients were informed in detail about surgery, written and informed consent was obtained. Patients were randomly divided in two groups – Group S (n=30) and Group D (n=30) by simple randomization method based on inhalation agent used for maintenance of anesthesia.

#### Inclusion Criteria

ASA Class I & II, Age 12 to 60years with Elective Middle ear surgeries lasting 60mins to 2hours

#### Exclusion Criteria

H/o General Anesthesia in past 1week, H/o Neuropsychiatric disorders, Pregnancy and Lactation, Baseline Heart rate <60beats/min, Baseline Blood pressure <100/50mmHg, BMI >30 and Patients with Impaired Hearing

All study participants were assessed evaluated and thoroughly investigated preoperatively, explained in detail about surgery, written and informed consent was obtained. On the day of surgery anesthesia workstation, airway equipment, suction apparatus and emergency crash trolley were kept ready in the operating room. On receiving patient in operating room ECG, NIBP and Pulse oximeter were connected and baseline vitals were recorded, an iv access was secured on left forearm with 18G iv cannula, Ringers Lactate infusion was started @3mlkg<sup>-1</sup>. Both study groups received Standard General Anesthesia -Glycopyrrolate 0.2mg, Fentanyl 2 µgkg<sup>-1</sup>, Ondansetron 4mg, Propofol induction@2 mgkg<sup>-1</sup>, Endotracheal intubation facilitated with Suxamethonium (1.5 mg/kg) and

appropriate sized oral cuffed endotracheal tube passed and lungs ventilated mechanically with 33:66 O<sub>2</sub>/N<sub>2</sub>O using a closed circle system, FGF @ 5L/min, vecuronium for muscle relaxation, maintenance Group S received Sevoflurane1-2% and group D received Desflurane of 4-6%. Inhalational anesthetic was discontinued at end of procedure, N<sub>2</sub>O was discontinued after the last skin suture was placed. After completion of surgery, residual neuromuscular blockade antagonized with Neostigmine 60 µgkg<sup>-1</sup>, glycopyrrolate10 µgkg<sup>-1</sup>iv. Intraoperative monitoring included NIBP Heart Rate, oxygen saturation recorded at predetermined time intervals preoperatively (baseline), at intubation 5min,10min, 15min,30min and every 30 min thereafter, until completion of surgery. After extubation and full recovery, postoperatively patients were transferred to post anesthesia care unit (PACU) incidences of PONV were recorded within first 24 hours after surgery. Episodes of PONV were identified by patients complaints or questionnaire. No distinction between nausea, vomiting and retching.

Statistical analysis: The data was collected in Excel sheet and statistical analysis was done with statistical package for social sciences version 1.6. Qualitative data was expressed in frequencies and percentages, Quantitative data expressed in Mean± SD. Unpaired 't' test was used for comparing the trends of all parameters between two groups.

#### Results and observations

Sixty patients undergoing Middle Ear surgery, were selected for the study and were randomly divided into two groups of 30 patients each. Group S-patients who received Sevoflurane and Group D - patients received Desflurane intraoperatively for maintenance of anesthesia.

**Table 1: Comparison of age distribution of groups S & D**

Age in years	Group S		Group D	
	No.	%	No.	%
12-20	2	6.66	2	6.66
21-30	5	16.66	7	23.33
31-40	6	20	9	30
41-50	11	36.66	8	25.66
51-60	6	20	4	13.33
Total	30	100	30	100
Mean ±SD	40.0312.04		37.36±11.74	
'p' Value- 0.388				

The difference in age group of the study participants are comparable and statistically insignificant.

**Table 2: Comparison of Systolic BP of between Group S & Group D**

Systolic BP	Group S	Group D	'p' value
Pre-op	118.33±11.13	118.40±9.84	0.980
Intubation	121.06±11.91	120.43±9.22	0.818
5mins	120.03±9.16	120.86±11.95	0.763
10mins	120.3±8.79	119.2±10.54	0.662
15mins	118.3±8.80	114.9310.25±	0.177
30mins	116.4±9.51	119.80±11.85	0.225
60mins	118.20±9.98	120.13±10.75	0.473
90mins	114.44±7.17	120.4±10.60	0.068
End of surgery	122.60±11.04	118.36±12.17	0.163

**Table 3: Comparison of Diastolic BP of between Group S & Group D**

Diastolic BP	Group S	Group D	'p' value
Pre-op	73.93±6.79	77.13±6.14	0.0605
Intubation	76.16±7.28	77.03±7.23	0.645
5mins	77.73±6.64	79.06±7.38	0.465
10mins	79.06±6.57	77.13±7.68	0.299
15mins	77.60±6.79	77.26±6.25	0.843
30mins	77.30±7.35	76.16±5.93	0.513
60mins	77.13±6.60	76.63±7.29	0.781
90mins	77.22±7.31	78.6±6.24	0.618
End of surgery	77.03±7.08	74.26±7.45	0.146

**Table 4: Comparison of Heart rates between Group S & Group D**

Heart rate (mins)	Group S	Group D	'p' value
Pre-op	84.8±13.39	88.66±13.55	0.271
Intubation	81.70±14.50	87.30±14.31	0.137
5mins	86.63±12.13	87.30±11.70	0.829

10mins	83.96±11.78	81.20±11.42	0.359
15mins	85.13±10.27	81.90±11.04	0.245
30mins	86.13±11.04	84.70±10.01	0.600
60mins	88.16±10.70	83.86±11.58	0.140
90mins	89.33±11.06	82.80±9.84	0.137
End of surgery	88.20±13.94	85.06±10.10	0.323

The difference in intraoperative hemodynamics in terms of Systolic Blood Pressure , Diastolic Blood Pressure and Heart rate were comparable between the two groups and statistically no significance 'p' value >0.05 from preoperative period to end of surgery.

**Table 5: Duration of anesthesia and surgery**

	Group S	Group D	'p' value
Duration of Surgery (mins)	82.7±10.69	85.43±11.16	0.3368
Duration of Anesthesia (mins)	105.06±10.21	104.66±9.97	0.8765

The mean duration of surgery and anesthesia in group S and group D were 82.7±10.69mins, 105.06±10.21mins and 85.43±11.16mins , 104.66±9.97mins respectively , the difference were comparable and statistically insignificant p value 0.3368 and 0.8765 .

**Table 6: Comparison of PONV in first 24 hrs. in groups S & D**

Incidence of Post-operative nausea and vomiting			
Group S		Group D	
No. of patients	% of patients	No. of patients	% of patients
7 / 30	23.33%	8 / 30	26.66%

There was no statistically significant difference ( $p > 0.05$ ) between the two groups with respect to PONV as Fisher exact test statistic value is 1.

### Discussion

Middle ear surgeries requires a bloodless, motionless operative field, non-fluctuant hemodynamics, no increase in middle ear pressures and a reduced incidence of postoperative morbidities especially nausea and vomiting (PONV). PONV is a common problem after middle ear surgery that can be minimized by appropriate choice of anesthetic technique and antiemetic prophylaxis[3-5]. Most middle ear procedures can be performed as outpatient surgery; thus rapid recovery, good analgesia, and avoidance of nausea and vomiting are essential[6]. Sevoflurane produces its hypotensive effect by direct vasodilatation without modifying cochlear blood flow[9,10]. Middle ear surgery is associated with a high incidence of PONV. Middle ear surgery is associated with a high incidence of PONV. The etiology of PONV is multifactorial and depends on various factors, including patient demographics, history of PONV, anesthetic technique, use of nitrous oxide, duration of anesthesia and operation, and even surgical experience[11,12,13]. This study assesses intraoperative and perioperative outcomes (PONV) using Sevoflurane and Desflurane as anesthetic agents for middle ear surgeries. The ideal anesthetic for middle ear surgery is one that optimizes the surgical field without excessive arterial hypotension. The search for an ideal anesthetic agent which serve intraoperative anesthesia goals in middle ear surgeries were answered by sevoflurane and desflurane . This study was undertaken to compare effects of sevoflurane and desflurane on intraoperative hemodynamic and post-operative profile (ponv) in middle ear surgeries in terms of systolic blood pressure , diastolic blood pressure , heart rate and ponv. Patients were randomly divided into two groups of 30 each Group S (sevoflurane) and Group D (desflurane). The two anesthetic groups were also comparable with respect to demographic variables like, gender, ASA grade , durations of anesthesia and surgery, as well as doses of medications used for premedication, Propofol induction dose , intra op analgesic requirement. Group S received 1-2% sevoflurane ,Group D received 4-6% as inhalational anesthetics. For assessing intraoperative hemodynamic status - heart rate ,systolic and diastolic blood pressure were recorded before induction (pre op) and at time of intubation, at 5min , 10 min,15mins,30 min and every 30 min till end of surgery. All study patients were in age group of 12yrs to 60yrs ,the Mean age (Mean±SD) in Group S was 40.03±12.04 and Group D was 37.36±11.74 , the difference between both study groups was statistically insignificant 'p' value -0.38 .The two anesthetic agents used in our study appeared to achieve objectives of maintaining intraoperative hemodynamic stability and providing optimal surgical conditions. The preoperative mean pulse rate in Group S and Group D are 84.8 ± 13.39 and 88.66± 13.55 the difference is comparable but statistically insignificant 'p' value 0.27, preoperative mean systolic blood pressure in Group S and in Group D - 118.33±11.13,

118.4±9.84 and differences observed are statistically insignificant 'p' value 0.98, Diastolic blood pressure in Group S and Group D 73.93±6.79 and 77.13±6.14, differences observed are statistically insignificant 'p' value 0.06. Intraoperatively all study patients hemodynamics (HR, SBP & DBP) were recorded. Intraoperative mean heart rates of patients in Group S (81.7±14.50, 86.63±12.13 , 83.96±11.78, 85.13±10.27, 86.13±11.04, 88.16±10.70, 89.33±11.06) was compared with Group D (87.3±14.31, 87.3±11.70, 81.2±11.42, 81.9±11.04, 84.7±10.01, 83.86±11.58, 82.8±9.84)at all time intervals are found to be statistically insignificant  $p > 0.05$ . SBP intraoperatively for Group S (Mean±SD) (121.06±11.91, 120.03±9.16, 120.3±8.79, 118.3±8.80, 116.4±9.51, 118.2±9.98 ,114.44 ±7.17) was compared with Group D (120.43±9.22, 120.86±11.95, 119.2±10.54, 114.93±10.25, 119.8±11.85, 120.13±10.75, 120.4±10.68), it was observed that the difference in intraoperative systolic blood pressure were comparable and statistically insignificant at all time intervals  $p > 0.05$ . Intraoperatively DBP for Group S (Mean±SD) (76.16±7.28, 77.73±6.64, 79.06±6.57, 77.6±6.79, 77.3±7.35, 77.13±6.60, 77.22±7.31) was compared with Group D (77.03 ± 7.23,79.06±7.38, 77.13±7.68 ,77.26±6.25, 76.16±5.93,76.63±7.29, 78.6±6.24), the observation was diastolic blood pressure at all time intervals intraoperatively between study groups is comparable and statistically insignificant 'p' value > 0.05 . Mean heart rate postoperatively for Group S and Group D are (88.2±13.94) and (85.06±10.10) difference was statistically insignificant 'p' value >0.05 , postoperative SBP and DBP in Group S -122.6±11.04 and 77.03±7.08 and Group D is 118.36±12.17and 74.26±7.45 were comparable and statistically insignificant p value 0.35 and 0.34 respectively. Mayur Patel et al[14]. compared intraoperative hemodynamic profile of desflurane, sevoflurane for anesthesia maintenance in day care laparoscopic gynecological surgeries . A prospective randomized single-blind study was conducted in 100 female patients belonging to ASA grade I or II patients randomized into two groups to receive either desflurane (group D; n = 50) or sevoflurane (group S; n = 50) for maintenance of anesthesia and reported that intraoperative hemodynamic parameters are similar in both desflurane and sevoflurane anesthesia which is in concordance with our study. Fraga et al[15]. compared the MAP, ICP, and cerebral perfusion pressure (CPP) using 1 MAC of either isoflurane or desflurane (with 60% N2O) in normocapnic patients undergoing craniotomy for supratentorial brain tumors. The ICP measurements throughout the study did not change within each group compared with baseline values and they did not find any significant difference of MAP, ICP, and CPP between the two groups. Our study results have shown comparable hemodynamic parameters in both groups similar to results of above study and we did not include measurement of ICP in this study. Sponheim et al.[16] reported a

dose-dependent and clinically similar increase ICP and reduced MAP with  $P < 0.001$  and CPP at 0.5 and 1.0 MAC of isoflurane, sevoflurane and desflurane in  $N_2O$  (60%) in hypercapnic children of study population of 36 divided into 3 groups of 12 each. They concluded that 0.5 and 1.0 MAC of isoflurane, sevoflurane and desflurane in  $N_2O$  all increased ICP and reduced MAP and CPP in a dose dependent manner. In our study, SBP and DBP values (indicating MAP) are in line with this study statistically insignificant and we did not compare effect on ICP. White et al[17] studied hemodynamics, emergence, and recovery characteristics of sevoflurane with those of desflurane in nitrous oxide anesthesia and concluded that the groups did not differ in these hemodynamic measures. Findings in our study are consistent with this study[15]. The current findings are consistent with comparative study conducted by Heavner et al[18] demonstrating that sevoflurane and desflurane provided similar intraoperative conditions during maintenance period. The study by Nathanson[19] suggested that sevoflurane and desflurane provided similar intraoperative conditions during maintenance period. Although early recovery was faster with desflurane, there was no difference in intermediate recovery end points. S Gergin, B Cervik, G B yildrium[20] concluded intraoperative cardiovascular stability was easily achieved with both sevoflurane and desflurane, with MAP and HR maintained at  $\pm 20\%$  baseline values intraoperatively during maintenance although HR reduced below baseline values, blood pressure fall was less in desflurane group. In conclusion, desflurane like sevoflurane maintains hemodynamic stability during intraoperative period. Although duration of anesthesia was longer early recovery profile was rapid in desflurane group. In our study, though a fall in heart rate with desflurane was not much appreciable, heart rate between group S and group D remained comparable. SBP and DBP (indicating MAP) values along with HR showed no statistical significance. All patients were followed postoperatively for PONV during first 24 hrs. and the difference is statistically insignificant ( $p > 0.05$ ) between the two groups. as Fisher exact test statistic value is 1. Gupta et al.[21] did systemic analysis of recovery after ambulatory surgery comparing isoflurane, sevoflurane, and desflurane with a conclusion that early recovery and time to obey was significantly less with desflurane when compared to sevoflurane and isoflurane. They also observed that time to home readiness was 5 min earlier with sevoflurane as compared to isoflurane and other parameters such as pain, nausea and vomiting were comparable. Our study showed similar results, except that we did not compare recovery parameters. The incidence of postoperative nausea and vomiting was similar in both the groups, consistent with the study by Kim et al[22] who also found that late recovery profiles and incidences of postoperative side effects were similar after desflurane and sevoflurane. Our study results are in concordance with this study.

#### Conclusion

Sevoflurane and Desflurane used as maintenance agents in middle ear surgeries equally maintained a stable intraoperative hemodynamics and the incidence of post-operative nausea and vomiting is of no significant difference.

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