Original Article

A Clinical Comparative Study of Total Intravenous Anaesthesia with Propofol-Fentanyl Versus Dexmedetomidine-Fentanyl for Tympanoplasty Surgery in Adults

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Abstract

Background: Total intravenous anaesthesia (TIVA) avoids the drawbacks of inhalational agents and nitrous oxide. Propofol enables rapid induction and recovery, while dexmedetomidine offers sedation, analgesia, and hemodynamic stability without respiratory depression. This study compares the efficacy and hemodynamic effects of dexmedetomidine versus propofol in patients undergoing tympanoplasty under TIVA. The study aimed to evaluate dexmedetomidine as a TIVA agent for tympanoplasty surgeries compared to propofol. It focused on comparing induction and recovery characteristics, analgesic properties, cardiovascular effects, and adverse events associated with both agents. **Material and Methods:** This randomized controlled trial, conducted at Kempegowda Institute of Medical Sciences from December 2014 to April 2016, compared total intravenous anaesthesia using Propofol-Fentanyl (Group P) versus Dexmedetomidine-Fentanyl (Group D) in 60 ASA I and II patients aged 18–60 undergoing tympanoplasty under 60 minutes. Patients were randomized via sealed envelopes. Group P received propofol 2 mg/kg induction and 6 mg/kg/hr infusion; Group D received dexmedetomidine 1 µg/kg over 10 minutes, then 0.6 µg/kg/hr. Both groups received fentanyl at 0.5 µg/kg/hr. **Results:** Propofol enabled faster induction (29.67±1.81 sec) than dexmedetomidine (583.97±59.16 sec), while dexmedetomidine provided better analgesia. Both agents maintained hemodynamic stability despite reducing SBP, DBP, MAP, and HR. Recovery was quicker with dexmedetomidine (6.70±1.09 min) versus propofol (7.93±1.39 min), but PACU discharge was faster with propofol (25.67±4.69 min vs 45.67±5.37 min). **Conclusion:** Dexmedetomidine offers effective sedation, analgesia, and stable hemodynamics, making it a suitable alternative to propofol for total intravenous anaesthesia.

Keywords: Propofol, Dexmedetomidine, Total Intravenous Anaesthesia (TIVA).

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Introduction

Inhalational anaesthetics, though widely used, pose concerns like environmental pollution and side effects. Total intravenous anaesthesia (TIVA) offers a viable alternative, especially with agents like propofol and dexmedetomidine.[1,2] Propofol provides rapid onset and recovery, mimicking inhalational agents without their drawbacks. Dexmedetomidine, an α2-agonist, offers sedation, analgesia, and haemodynamic stability without respiratory depression.[3,4] Tympanoplasty, often performed under general anaesthesia, requires agents that ensure patient comfort and minimal side effects. This study compares the safety and efficacy of dexmedetomidine versus propofol in TIVA for tympanoplasty, aiming to determine the better alternative in terms of sedation, recovery, and haemodynamic outcomes.

Materials and Methods

This randomized clinical trial titled "A Clinical Comparative Study of Total Intravenous Anaesthesia with Propofol-Fentanyl Versus Dexmedetomidine-Fentanyl for Tympanoplasty Surgery in Adults" was conducted in the Department of Anaesthesiology and Critical Care at a tertiary health centre, from December 2014 to April 2016. Sixty adult patients, aged 18 to 60 years and classified as American Society of Anesthesiologists (ASA) physical status I or II, undergoing tympanoplasty surgery of less than 60 minutes' duration, were included after obtaining institutional ethical clearance and informed written consent.

Patients were randomized into two equal groups of 30 using the sealed envelope method. Group P received propofol 2 mg/kg as an induction dose followed by an infusion of 6 mg/kg/hr and fentanyl 0.5 µg/kg/hr. Group D received a loading dose of dexmedetomidine 1 µg/kg over 10 minutes followed by an

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infusion of 0.6 µg/kg/hr along with fentanyl 0.5 µg/kg/hr. Preoperative evaluation included history, physical examination, and routine investigations (CBC, blood sugar, BT/CT, chest X-ray, ECG, renal function tests). Patients were premedicated with pantoprazole 40 mg and alprazolam 0.5 mg the night before and on the morning of surgery.

Upon arrival in the operating room, IV access was secured, and Lactated Ringer's solution was started. Patients were connected to monitors for ECG, non-invasive blood pressure, SpO_2, and heart rate. All patients received glycopyrrolate 0.2 mg, midazolam 1 mg, and fentanyl 2 µg/kg intravenously. Oxygen at 2 L/min via nasal prongs was administered throughout.

The assigned anaesthetic agents were given, and parameters such as time to loss of verbal response, induction time (loss of eyelash reflex), sedation (Ramsay Sedation Scale, score ≥5), and intraoperative hemodynamics were recorded. Local anaesthesia was achieved using 5 mL of 0.5% bupivacaine and 5 mL of 2% lignocaine with adrenaline. Analgesia to infiltration was assessed using Cameron's four-point scale. Infusions were stopped at skin closure, and the response time (time to verbal response and orientation) was recorded. Postoperatively, patients were monitored every 15 minutes for one hour, and side effects such as nausea, vomiting, and dry mouth were documented. Recovery was assessed using the Modified Aldrete Score, with a score ≥10 indicating readiness for discharge.

For statistical analysis, data were compiled and analyzed using SPSS software version 20. Quantitative variables such as induction time, sedation time, and recovery time were expressed as mean ± standard deviation and compared using the unpaired Student's T-test. Qualitative variables such as incidence of bradycardia, hypotension, and postoperative side effects were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value of <0.05 was considered statistically significant.

Results

A total of 60 patients aged between 18 and 60 years, demographic profile shown in [Table 1].

Table 1: Demographic profile – Age, weight, BMI of patients expressed as a mean ± standard deviation and gender & American Society of Anesthesiologists (ASA) physical status as actual numbers.

Sl. No	Variable		Group P	Group D	p-value
1.	Age (in years)		30.40±10.03	28.60±6.86	0.421
2.	Weight (kg)		57.97±5.88	56.23±4.97	0.222
3.	BMI (kg/m2)		23.02±1.89	22.24±1.23	0.064
4.	Gender	Male (No.)	15	15	
		Female (No.)	15	15	1
5.	ASA Physical Status	ASA- 1 (No.)	26	26	1
		ASA- 2 (No.)	4	4	

The mean age of patients in Group P was 30.40 ± 10.03 years, and in Group D was 28.60 ± 6.86 years, with no statistically significant difference between the groups (p = 0.421. Most patients in both groups were aged 20–30 years (Group P: 56.7%, Group D: 60%). Gender distribution was equal in both groups (15 males and 15 females in each group) and statistically comparable (p = 1).

The mean weight was 57.97 ± 5.88 kg in Group P and 56.23 ± 4.97 kg in Group D, with no significant difference (p = 0.222) and the mean height was 158.30 ± 6.11 cm (Group P) and 158.97 ± 7.54 cm (Group D), again with no significant difference (p = 0.708). The mean BMI was 23.02 ± 1.89 kg/m² in Group P and 22.24 ± 1.23 kg/m² in Group D, which was statistically comparable (p = 0.064).

In terms of ASA physical status, 26 patients (86.7%) were ASA I and 4 patients (13.3%) were ASA II in both groups, with no significant difference (p = 1).

The mean duration of infusion was 53.50 ± 6.18 minutes in Group P and 53.83 ± 6.25 minutes in Group D (p = 0.836). The mean duration of surgery was also comparable between Group P (60.97 ± 5.42 minutes) and Group D (60.77 ± 6.16 minutes) (p = 0.894).

The mean time to loss of verbal response, loss of eyelash reflex and the mean time to achieve a Ramsay Sedation Score was significantly shorter in Group P than in Group D as show in in [Table 2].

Table 2: Observation; loss of verbal response, loss of eyelash reflex and time taken to reach RSS ≥5.

Variables	Group P	Group D	P Value
Onset of induction loss of verbal response	28.67±1.81	582.00±59.27	<0.001
Onset of induction loss of eyelash reflex	29.67±1.81	583.97±59.16	<0.001
Time taken to get RSS of ≥ 5	29.67±1.81	583.97±59.16	<0.001

Evaluation using the Cameron four-point pain scale showed that 26.7% of patients in Group P and 3.3% in Group D scored 1, indicating a statistically significant difference in pain perception between the groups (p = 0.026) [Tables 6 & 7, Figures 19 & 20].

Apnea following induction occurred in 4 patients (13.3%) in Group P, whereas no patients in Group D experienced apnea. However, this difference was not statistically significant (p = 0.112).

Group D exhibited significantly lower Heart Rate compared to Group P at multiple intraoperative time points including 1 minute after induction, start of surgery, and at 10, 30, 35, 40, 45, 55, and 60 minutes. HR was also significantly lower in Group D from drug discontinuation through recovery. Postoperatively, HR

remained significantly lower in Group D at all measured intervals (t0 to 60 minutes) shown in [Figure 1].

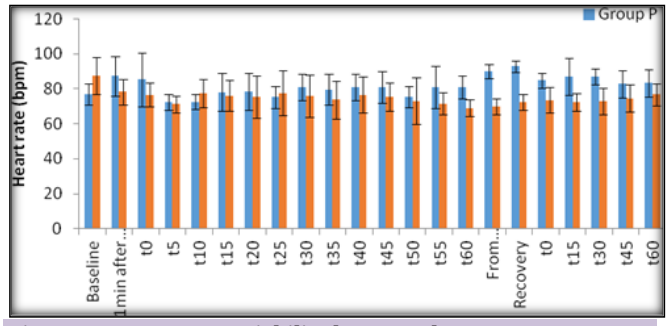

Figure 1: Heart rate variability between the two groups

Systolic Blood Pressure was significantly lower in Group D at 1-minute post-induction, start of surgery, and at 5, 10, and 15 minutes intraoperatively. It also remained lower at drug discontinuation and throughout the recovery phase. Postoperatively, SBP was consistently and significantly lower in Group D as show in figure 2.

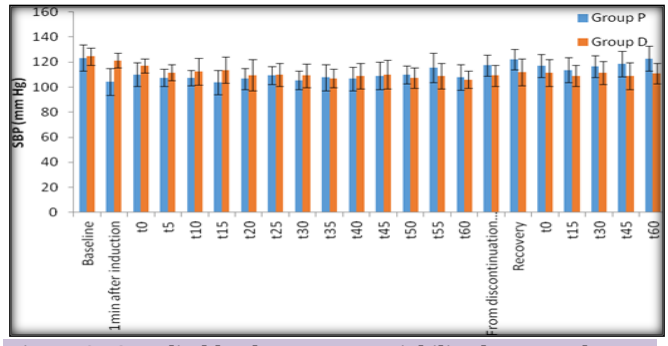

Figure 2: Systolic blood pressure variability between the two groups

Diastolic Blood Pressure was significantly lower in Group D at 1 minute post-induction, start of surgery, and at 10, 15, 20, 35, and 50 minutes. It remained significantly lower from drug discontinuation through recovery. Postoperatively, DBP was significantly lower in Group D at 30, 45, and 60 minutes as show in [Figure 3].

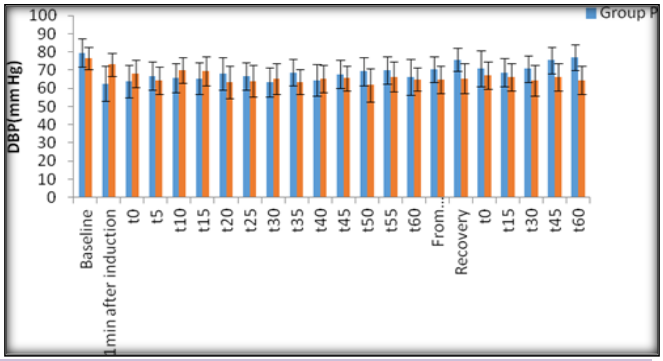

Figure 3: Diastolic blood pressure variability between two groups

Mean Arterial Pressure was significantly lower in Group D at 1-minute post-induction, start of surgery, and at 5, 10, 15, 20, 25, 35, 50, 55, and 60 minutes intraoperatively. It was also significantly lower at discontinuation and during recovery. Postoperatively, MAP was consistently lower in Group D at all time points as show in [Figure 4].

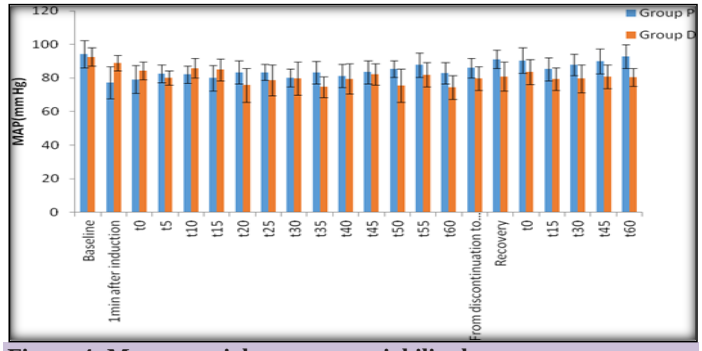

Figure 4: Mean arterial pressure variability between two groups

SpO_2 levels were significantly higher in Group D at 1-minute post-induction, and at several intraoperative time points including start of surgery, 5, 10, 15, 20, 30, 40, 45, 55, and 60 minutes. This trend continued into the recovery phase. Postoperatively, SpO_2 remained significantly higher in Group D throughout as show in [Figure 5].

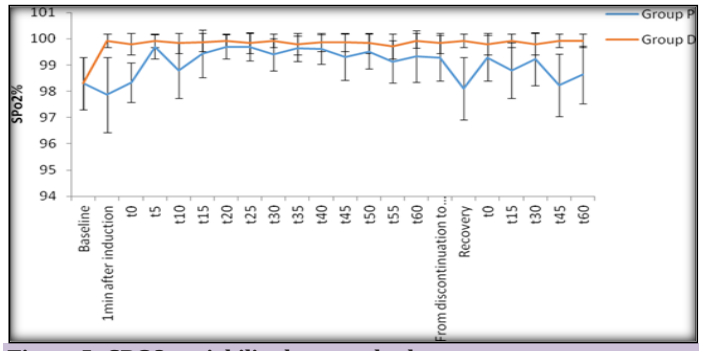

Figure 5: SPO2 variability between both groups

Respiratory Rate was significantly lower in Group D throughout the intraoperative period. Postoperatively, RR was significantly lower in Group D at t0, 30 minutes, and 60 minutes as show in [Figure 6].

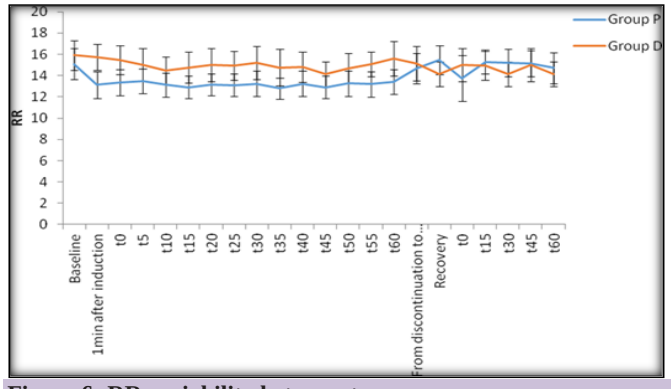

Figure 6: RR variability between two groups

The mean response time was significantly shorter in Group D (6.70 ± 1.09 minutes) compared to Group P (7.93 ± 1.39 minutes)

($p < 0.001$) as show in [Figure 7].

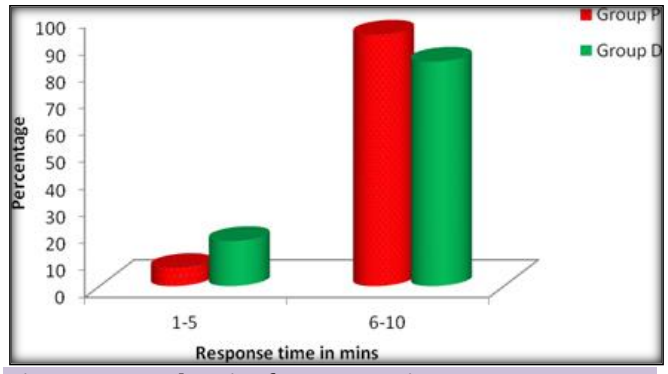

Figure 7: Mean duration for response time

The time to achieve a Modified Aldrete Score ≥10 was significantly shorter in Group P (25.67 ± 4.69 minutes) compared to Group D (45.67 ± 5.37 minutes) ($p < 0.001$) as show in [Figure 8].

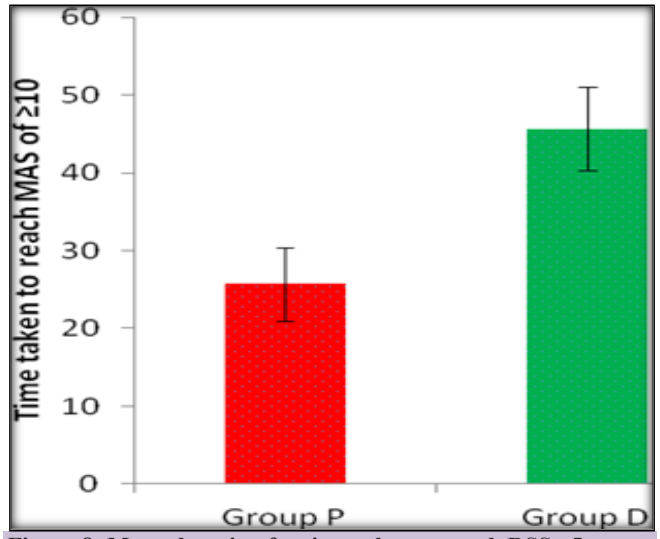

Figure 8: Mean duration for time taken to reach RSS ≥5

The postoperative complications varied between the two groups. Nausea and vomiting were observed only in the propofol group, with 6.7% of patients experiencing nausea and 3.3% vomiting, while none of the patients in the dexmedetomidine group reported these symptoms. Dry mouth was a notable complication in the dexmedetomidine group, affecting 16.7% of patients, whereas it was absent in the propofol group. Hypotension was more commonly observed in the propofol group (16.7%) compared to the dexmedetomidine group (6.7%). On the other hand, bradycardia was reported in 13.3% of patients receiving dexmedetomidine, while none of the patients in the propofol group developed bradycardia.

Discussion

Total Intravenous Anaesthesia (TIVA) involves induction and maintenance of anaesthesia using only intravenous agents, avoiding volatile agents and nitrous oxide. It allows independent control over unconsciousness, analgesia, muscle relaxation, and autonomic stability through specific IV agents. Earlier, high doses of single agents were used to achieve deep anaesthesia, but modern balanced anaesthesia, often combining IV and inhalational agents, offers greater flexibility. Gray and Rees initially defined the triad of anaesthesia as narcosis, analgesia, and muscle relaxation, later expanded to include autonomic reflex control by Woodbridge in 1957.[5]

TIVA differs from balanced anaesthesia by eliminating inhalational agents and nitrous oxide, which are associated with hepatic/renal toxicity, operating room pollution, and contraindications in certain surgeries like tympanoplasty. Nitrous oxide, in particular, causes middle ear pressure changes and postoperative nausea. These limitations propelled the development of TIVA.[6]

The ideal TIVA agent should be water-soluble, rapidly acting, non-cumulative, non-irritant, and analgesic. Continuous infusion and Target-Controlled Infusion (TCI) help maintain stable drug levels, avoiding fluctuations seen with intermittent injections. In our study, due to unavailability of plasma drug monitoring, we used continuous infusion via programmable pumps.

Propofol is the most widely used agent for TIVA due to its rapid onset and recovery. Dexmedetomidine, an α-2 agonist, offers sedation, analgesia, and sympatholysis without respiratory depression and reduces perioperative opioid use.

This randomized trial compared propofol-fentanyl (Group P) versus dexmedetomidine-fentanyl (Group D) for tympanoplasty under TIVA in 60 ASA I–II patients. The groups were comparable demographically.

Loss of verbal response was significantly faster with propofol (28.7±1.8s) vs. dexmedetomidine (582.0±59.3s), consistent with Lal et al,[7] and Verma et al.[8] Loss of eyelash reflex also occurred more rapidly in Group P (29.7±1.8s vs. 584.0±59.2s), in line with Doze et al,[9] and Mirakhur et al.[10]

The time to achieve Ramsay Sedation Score ≥5 was much shorter in Group P (29.7s) than Group D (584.0s), echoing findings by Verma et al,[8] Ghali et al,[11] and Shaaban et al.[12] Apnoea occurred in 13.3% of Group P and none in Group D, though this was not statistically significant—similar to Verma et al[31] and Kaygusuz et al.[13]

Pain incidence was significantly higher in Group P (26.7%) vs. Group D (3.3%) per Cameron scale. Verma et al,[8] and Ghali et al,[11] reported similar findings, with dexmedetomidine showing lower pain scores.

Heart rate, SBP, DBP, and MAP were significantly lower in Group D at various intraoperative intervals and during recovery, suggesting superior hemodynamic stability. Four patients in Group D developed bradycardia, but all were managed conservatively. This profile supports dexmedetomidine's sympatholytic action, corroborated by earlier findings.[8,11,12]

The postoperative complications varied between the two groups. These findings suggest that while propofol is associated with higher rates of hypotension and gastrointestinal symptoms, dexmedetomidine tends to cause more bradycardia and dry mouth.

Conclusion

Based on the findings of this study, it can be concluded that

dexmedetomidine, when administered at a loading dose of 1 µg/kg over 10 minutes followed by an infusion, offers smooth but slower induction compared to the rapid onset seen with propofol at 2 mg/kg. Despite the delayed onset, dexmedetomidine provides a comparable depth of anaesthesia during total intravenous anaesthesia (TIVA) and has superior analgesic properties, reducing the need for postoperative opioids. Hemodynamic stability was effectively maintained in both groups, although dexmedetomidine resulted in significantly lower heart rate and mean arterial pressure. Additionally, it preserved respiratory function better than propofol and enabled smoother, earlier recovery. However, discharge from the post-anaesthesia care unit (PACU) was slightly delayed with dexmedetomidine. Overall, dexmedetomidine demonstrates potential as an effective alternative to propofol for TIVA in tympanoplasty surgeries, offering enhanced analgesia, stable hemodynamics, and a favourable recovery profile.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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