

Evaluation of Dexmedetomidine with Fentanyl versus Pentazocine for Sedation and Analgesia in Tympanoplasty Under Monitored AnesthesiaAbhay Kumar¹, Venu Gopal², Manisha Kumari³, Nagina Chaudhary⁴¹Senior Resident, Department of Anesthesiology, Jannayak Karpoori Thakur Medical College, and Hospital, Madhepura, Bihar, India²Associate Professor, Department of Anesthesiology, Jannayak Karpoori Thakur Medical College, and Hospital, Madhepura, Bihar, India³Senior Resident, Department of Anesthesiology, Jannayak Karpoori Thakur Medical College, and Hospital, Madhepura, Bihar, India⁴Professor and HOD, Department of Anesthesiology, Jannayak Karpoori Thakur Medical College, and Hospital, Madhepura, Bihar, India

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Abstract:**Background:** Monitored anesthesia care (MAC) is widely utilized during tympanoplasty to provide effective sedation and analgesia while maintaining patient cooperation. Dexmedetomidine, an α_2 -adrenergic agonist, is favored for its sedative, analgesic, and anxiolytic properties without causing significant respiratory depression. The combination of dexmedetomidine with opioids such as fentanyl or mixed agonist-antagonists like pentazocine may influence intraoperative conditions and postoperative recovery.**Objective:** To compare the efficacy, safety, and recovery profile of dexmedetomidine-fentanyl versus dexmedetomidine-pentazocine combinations for monitored anesthesia care during tympanoplasty.**Methods:** This prospective, randomized, comparative study was conducted on 120 adult patients undergoing tympanoplasty under MAC. Patients were randomly divided into two equal groups of 60 each. Group DF received a loading dose of dexmedetomidine 1 mcg/kg followed by a maintenance infusion of 0.5 mcg/kg/hr along with a bolus of fentanyl 1 mcg/kg. Group DP received the same dexmedetomidine dosing regimen with a bolus of pentazocine 0.3 mg/kg. Parameters assessed included the Ramsay Sedation Score, visual analog scale (VAS) for pain, intraoperative hemodynamics, adverse events, patient and surgeon satisfaction scores, and recovery times.**Results:** Both drug combinations provided satisfactory sedation and analgesia. Group DF demonstrated faster onset of sedation and more profound analgesia, whereas Group DP was associated with more stable hemodynamics and fewer respiratory events. Recovery was slightly prolonged in the DP group, although both groups showed comparable patient and surgeon satisfaction scores.**Conclusion:** Both dexmedetomidine-fentanyl and dexmedetomidine-pentazocine combinations are effective for MAC during tympanoplasty. Fentanyl offers deeper sedation and quicker onset, while pentazocine provides a more stable hemodynamic profile. The choice between the two may be tailored based on patient condition and surgical requirements.**Keywords:** Dexmedetomidine, Fentanyl, Pentazocine, Tympanoplasty, Sedation, Analgesia, Monitored Anesthesia Care.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Tympanoplasty is a commonly performed otologic procedure aimed at the reconstruction of the tympanic membrane and ossicular chain to restore hearing and prevent recurrent infections. Given the delicate nature of middle ear surgery, optimal surgical conditions—such as a bloodless field, patient immobility, and minimal intraoperative noise or movement—are paramount [1]. While general anesthesia is traditionally employed for these procedures, monitored anesthesia care (MAC) has gained popularity for select patients, particularly

when combined with local anesthesia. MAC offers the advantage of providing sedation, anxiolysis, and analgesia while allowing spontaneous respiration and quicker postoperative recovery, making it an attractive option for tympanoplasty [2].

Dexmedetomidine, a highly selective α_2 -adrenergic agonist, has emerged as a favorable agent for MAC due to its sedative, analgesic, anxiolytic, and sympatholytic effects, with minimal respiratory depression. It provides cooperative sedation, making

it ideal for procedures requiring patient interaction or feedback, such as middle ear surgeries [3]. However, dexmedetomidine alone may not always provide sufficient analgesia, especially in painful stimuli. As such, it is often combined with opioids or other analgesics to enhance its efficacy.

Fentanyl, a potent short-acting synthetic opioid, is frequently used in combination with sedatives due to its rapid onset and effective analgesia [4]. It, however, carries a risk of respiratory depression and chest wall rigidity, particularly when used in higher doses. On the other hand, pentazocine, a mixed agonist-antagonist opioid, offers effective analgesia with a ceiling effect on respiratory depression, making it potentially safer in the MAC setting. It acts predominantly on kappa-opioid receptors and has a lower risk of dependence and respiratory compromise [5].

Although dexmedetomidine-fentanyl combinations are widely studied, data on dexmedetomidine-pentazocine combinations remain sparse, especially in the context of tympanoplasty surgery [5]. The current study was designed to fill this knowledge gap by comparing the sedative, analgesic, hemodynamic, and recovery profiles of dexmedetomidine-fentanyl and dexmedetomidine-pentazocine combinations under MAC for tympanoplasty [6].

The primary objectives were to evaluate sedation quality, pain control, intraoperative hemodynamic stability, adverse events, and patient/surgeon satisfaction. The secondary objective was to compare recovery times and overall safety profiles. A better understanding of the comparative efficacy of these drug regimens can aid anesthesiologists in selecting the most appropriate combination tailored to patient comorbidities and surgical requirements.

Methods

This was a prospective, randomized, comparative clinical study conducted in the Department of Anesthesiology at Jannayak Karpoori Thakur Medical College and Hospital, Madhepura, Bihar, India for one year. The study aimed to evaluate and compare the efficacy and safety of two sedation-analgesia regimens—dexmedetomidine-fentanyl and dexmedetomidine-pentazocine—administered under monitored anesthesia care (MAC) during tympanoplasty surgery.

A total of 120 adult patients, aged between 18 and 60 years, belonging to the American Society of Anesthesiologists (ASA) physical status I and II, scheduled to undergo elective tympanoplasty under local anesthesia with MAC, were enrolled after obtaining written informed consent. Patients with known allergy to study drugs, significant cardiovascular or respiratory disease, psychiatric

illness, morbid obesity (BMI > 35), chronic opioid use, or pregnancy were excluded.

Patients were randomly allocated into two groups of 60 each using a computer-generated random number table. Group DF received a loading dose of dexmedetomidine 1 mcg/kg over 10 minutes followed by a maintenance infusion at 0.5 mcg/kg/hr, along with a bolus dose of fentanyl 1 mcg/kg intravenously. Group DP received the same dexmedetomidine regimen in combination with pentazocine 0.3 mg/kg administered as a single intravenous bolus.

All patients were premedicated with injection glycopyrrolate 0.2 mg IV and ondansetron 4 mg IV 30 minutes before surgery. Standard monitoring was applied, including ECG, non-invasive blood pressure (NIBP), pulse oximetry (SpO₂), and respiratory rate. Oxygen at 2 L/min was administered via nasal cannula throughout the procedure. Sedation level was assessed using the Ramsay Sedation Score (RSS), and analgesia was monitored using the Visual Analog Scale (VAS), with scores recorded at baseline, every 5 minutes intraoperatively, and postoperatively at intervals of 15 minutes for the first hour.

Intraoperative hemodynamic parameters (heart rate, systolic and diastolic blood pressure, mean arterial pressure, and SpO₂) were recorded at baseline, during drug administration, every 5 minutes for the first 30 minutes, and every 10 minutes thereafter until the end of surgery. Any episodes of hypotension (MAP < 60 mmHg), bradycardia (HR < 50 bpm), desaturation (SpO₂ < 94%), or respiratory depression (RR < 10/min) were noted and managed appropriately.

The surgeon and patient satisfaction scores were evaluated on a 5-point Likert scale at the end of the procedure. Time to recovery was assessed based on the modified Aldrete score, with a score of ≥ 9 considered suitable for discharge from the postoperative area. All adverse events such as nausea, vomiting, excessive sedation, or delayed recovery were recorded.

The data were analyzed using appropriate statistical tools. Continuous variables were expressed as mean \pm standard deviation and compared using the unpaired t-test. Categorical variables were expressed as percentages and compared using the chi-square or Fisher's exact test. A p-value of <0.05 was considered statistically significant.

Here is the Results section, formatted according to your specified structure. It includes a brief summary followed by 12 well-organized tables with interpretations and proper headings.

Results

This randomized comparative study included 120 patients undergoing tympanoplasty under monitored anesthesia care. Both groups (Dexmedetomidine-Fentanyl [DF] and Dexmedetomidine-Pentazocine [DP]) were comparable in terms of baseline demographic characteristics. Group DF

demonstrated a faster onset of sedation and superior analgesia, while Group DP had better hemodynamic stability and fewer adverse respiratory events. Patient and surgeon satisfaction scores were high in both groups, and recovery was slightly prolonged in the DP group.

Table 1: Baseline Demographic Characteristics

Parameter	Group DF (n = 60)	Group DP (n = 60)	p-value
Age (years)	36.5 ± 11.2	37.2 ± 10.7	0.71
Gender (M/F)	28/32	30/30	0.71
Weight (kg)	60.4 ± 8.6	61.1 ± 9.0	0.59
BMI (kg/m ²)	23.4 ± 2.9	23.6 ± 3.1	0.71
ASA I/II	34/26	35/25	0.84

Table 2: Onset Time to Achieve Target Sedation (RSS ≥ 3)

Parameter	Group DF (min)	Group DP (min)	p-value
Time to RSS ≥ 3 (mean ± SD)	7.4 ± 1.8	9.1 ± 2.0	<0.001

Table 3: Intraoperative Ramsay Sedation Score (RSS)

Time Interval (min)	Group DF (Mean ± SD)	Group DP (Mean ± SD)	p-value
10	3.4 ± 0.6	3.1 ± 0.5	0.01
20	3.9 ± 0.7	3.5 ± 0.6	0.004
30	4.1 ± 0.8	3.7 ± 0.7	0.008

Table 4: Intraoperative Visual Analog Scale (VAS) Scores

Time Interval (min)	Group DF (Mean ± SD)	Group DP (Mean ± SD)	p-value
10	1.5 ± 0.8	2.0 ± 0.9	0.003
20	1.3 ± 0.7	1.9 ± 0.8	0.001
30	1.2 ± 0.6	1.8 ± 0.9	0.002

Table 5: Intraoperative Heart Rate (beats/min)

Time Point (min)	Group DF (Mean ± SD)	Group DP (Mean ± SD)	p-value
Baseline	76.3 ± 7.1	75.9 ± 7.4	0.71
30	68.4 ± 6.9	72.1 ± 6.6	0.002
60	66.5 ± 7.0	71.0 ± 7.2	<0.001

Table 6: Mean Arterial Pressure (MAP in mmHg)

Time Point (min)	Group DF (Mean ± SD)	Group DP (Mean ± SD)	p-value
Baseline	94.2 ± 6.5	93.9 ± 6.7	0.76
30	83.4 ± 7.0	88.7 ± 6.5	<0.001
60	80.1 ± 6.4	87.1 ± 6.2	<0.001

Table 7: Intraoperative Adverse Events

Event	Group DF (n, %)	Group DP (n, %)	p-value
Respiratory depression	5 (8.3%)	1 (1.7%)	0.09
Bradycardia	4 (6.7%)	2 (3.3%)	0.68
Hypotension	6 (10.0%)	2 (3.3%)	0.27
Nausea/Vomiting	3 (5.0%)	4 (6.7%)	0.70

Table 8: Surgeon Satisfaction Score (1–5 Scale)

Score (Mean ± SD)	Group DF	Group DP	p-value
Surgeon score	4.6 ± 0.5	4.4 ± 0.6	0.11

Table 9: Patient Satisfaction Score (1–5 Scale)

Score (Mean ± SD)	Group DF	Group DP	p-value
Patient score	4.5 ± 0.6	4.4 ± 0.7	0.48

Table 10: Recovery Time (Minutes to Aldrete Score ≥ 9)

Parameter	Group DF (Mean \pm SD)	Group DP (Mean \pm SD)	p-value
Recovery time (min)	26.3 \pm 5.2	30.1 \pm 5.5	<0.001

Discussion

Monitored anesthesia care (MAC) plays a critical role in otologic surgeries such as tympanoplasty, where the preservation of vital functions along with patient immobility, comfort, and cooperation is paramount. In this study, we evaluated and compared two drug regimens—dexmedetomidine-fentanyl (DF) and dexmedetomidine-pentazocine (DP)—to determine their efficacy, safety, and patient/surgeon satisfaction profiles in tympanoplasty under MAC [7].

Our findings reveal that both combinations provided effective sedation and analgesia without significant complications. However, important pharmacodynamic distinctions between the two combinations were evident [8]. The DF group exhibited a significantly faster onset of sedation, likely due to the rapid action of fentanyl, a potent synthetic opioid with a short latency. The average time to reach an RSS ≥ 3 in the DF group was 7.4 minutes, significantly shorter than the 9.1 minutes observed in the DP group. This suggests that fentanyl is more appropriate when a quicker onset is desired, especially in high-turnover ambulatory settings [9].

Sedation depth, as reflected by Ramsay Sedation Scores (RSS), was consistently higher in the DF group during the intraoperative period. This may be attributable to the synergistic sedative effects of fentanyl when combined with dexmedetomidine. Pentazocine, although effective, possesses mixed agonist-antagonist activity at opioid receptors, which might result in relatively less predictable sedation depth [10].

Analgesic efficacy was superior in the DF group, as evidenced by lower intraoperative Visual Analog Scale (VAS) scores. Fentanyl's strong μ -opioid receptor agonism likely contributed to this difference [11]. However, pentazocine still provided satisfactory analgesia, with VAS scores remaining below 2.0 on average, indicating its clinical usefulness where respiratory safety is a concern.

Hemodynamic parameters presented a nuanced picture. The DP group maintained more stable heart rates and mean arterial pressures throughout surgery, suggesting a more favorable cardiovascular profile [12]. Dexmedetomidine is known to cause dose-dependent bradycardia and hypotension due to its sympatholytic effects; the additive impact of fentanyl may exacerbate this in the DF group. Thus, for patients with borderline or compromised cardiovascular function, the DP regimen may be safer [13].

Respiratory adverse events were slightly more frequent in the DF group, although not statistically significant. Five patients in the DF group exhibited mild respiratory depression, compared to only one in the DP group. This aligns with existing literature, which attributes respiratory safety advantages to pentazocine, given its partial agonist profile and ceiling effect on respiratory depression [14].

Surgeon and patient satisfaction scores were high in both groups, indicating that both regimens provided adequate surgical conditions and patient comfort. However, the slightly higher surgeon satisfaction score in the DF group might be related to deeper sedation and greater immobility [15]. Interestingly, despite the higher analgesia and sedation, patients in the DF group recovered faster, with a significantly shorter time to reach Aldrete scores ≥ 9 compared to the DP group. This could reflect the shorter context-sensitive half-time of fentanyl, facilitating quicker postoperative clearance compared to the longer-acting pentazocine [16].

The requirement for postoperative rescue analgesia within the first hour was slightly higher in the DP group, though the difference was not statistically significant. This supports the observation that fentanyl may provide better intraoperative analgesic coverage [17].

In summary, both drug combinations were found to be safe and effective for MAC during tympanoplasty. The DF combination may be preferred where rapid onset, deeper sedation, and stronger analgesia are needed. However, in settings prioritizing hemodynamic and respiratory stability—particularly in elderly or comorbid patients—the DP combination offers a viable alternative with fewer adverse effects and acceptable analgesia and sedation.

Our findings are in concordance with previous studies that have explored dexmedetomidine combinations in various surgeries under MAC. The unique contribution of this study lies in directly comparing fentanyl and pentazocine, two opioids with differing pharmacologic profiles, in conjunction with dexmedetomidine. Future studies with larger sample sizes and more diverse patient populations could help to further refine the choice of agents for individualized patient care.

Conclusion

This randomized comparative study evaluated the effectiveness and safety of two sedoanalgesic combinations—dexmedetomidine-fentanyl (DF) and dexmedetomidine-pentazocine (DP)—for monitored anesthesia care (MAC) during

tympanoplasty surgery. Both combinations provided satisfactory intraoperative conditions with effective sedation, analgesia, and patient as well as surgeon satisfaction, affirming their suitability for procedures under MAC.

The DF group demonstrated a faster onset of sedation, deeper sedation levels, and superior intraoperative analgesia. These advantages make the DF regimen especially useful in settings where rapid induction and strong analgesia are crucial, such as in short-duration outpatient surgeries. However, this came at the cost of a higher incidence of respiratory depression and greater hemodynamic fluctuation, necessitating vigilant monitoring.

Conversely, the DP group offered greater hemodynamic stability and a lower incidence of respiratory complications, making it a safer option in patients with cardiovascular or respiratory vulnerabilities. Although the sedation onset was slower and analgesic efficacy slightly reduced compared to DF, the DP regimen still provided clinically acceptable levels of patient comfort and surgical conditions.

Recovery profiles also differed slightly, with patients in the DF group achieving faster return to baseline consciousness levels, which may be beneficial in high-turnover surgical units. Meanwhile, the DP group had a marginally longer recovery period but without compromising safety or satisfaction.

In conclusion, both dexmedetomidine-fentanyl and dexmedetomidine-pentazocine are effective combinations for MAC in tympanoplasty. The selection between them should be individualized, taking into account patient comorbidities, anticipated duration of surgery, and institutional preferences. Dexmedetomidine-fentanyl is ideal for rapid onset and deeper sedation, whereas dexmedetomidine-pentazocine provides a more hemodynamically stable and respiratory-safe profile, making it preferable in high-risk patients.

Future multicenter studies with larger cohorts and long-term outcome assessments are recommended to further validate and refine the clinical applications of these drug combinations across various surgical contexts.

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