

Original Research Article

Comparison between Dexmedetomidine and Fentanyl Infusion for Short-Term Sedation in Mechanically Ventilated Patients in Intensive Care Unit

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ABSTRACT

Background: Sedation and analgesia are essential components of care for mechanically ventilated patients in the ICU (Intensive Care Unit). Conventional sedative and opioid agents may be associated with prolonged sedation, respiratory depression and haemodynamic effects. Dexmedetomidine, a selective α_2 -adrenergic agonist, provides sedation and analgesia with preservation of arousability and minimal respiratory depression. This study compared dexmedetomidine with fentanyl for short-term sedation in mechanically ventilated ICU patients.

Methods: A prospective, randomized, double-blind study was conducted in a Tertiary Care Centre, South India for a period of one and half years. Sixty-two mechanically ventilated patients aged 20-60 years were enrolled and randomly allocated into two groups of 31 each. Group I received dexmedetomidine infusion and Group II received fentanyl infusion. Sedation was assessed using the RASS (Richmond Agitation-Sedation Scale), with haemodynamic parameters and 24-hour rescue midazolam requirements recorded. Statistical analysis was performed using the chi-square test and Student's unpaired *t* test.

Results: The mean time to achieve RASS -1 was significantly shorter with dexmedetomidine than fentanyl (2.97 ± 1.278 vs. 6.29 ± 3.388 hours; $p < 0.001$). The mean rescue midazolam requirement was also significantly lower with dexmedetomidine (0.39 ± 1.202 vs. 2.29 ± 1.657 mg/24 hours; $p < 0.001$), representing an 87% reduction. The mean dexmedetomidine infusion rate required for effective sedation was 0.5 ± 0.1 $\mu\text{g/kg/hour}$. No significant differences in heart rate or mean arterial pressure were observed between the groups.

Conclusion: Dexmedetomidine provided faster and effective sedation with significantly lower rescue midazolam requirements compared with fentanyl, while maintaining a comparable haemodynamic profile. It may therefore be considered an effective sedative for short-term sedation during the first 24 hours of mechanical ventilation in ICU patients.

Keywords: Dexmedetomidine, Fentanyl, Sedation, Mechanical Ventilation, Intensive Care Unit, RASS, Midazolam.

INTRODUCTION

The majority of patients admitted to the ICU (Intensive Care Unit) require sedation at some point during their stay, particularly those undergoing mechanical ventilation. Appropriate sedation is essential to suppress coughing, provide comfort, prevent patient-ventilator asynchrony, and facilitate procedures such as tracheal aspiration, physiotherapy, and catheter placement.^[1] Critically ill patients frequently experience pain due to underlying disease or invasive

procedures. Inadequate sedation and analgesia may result in agitation, accidental removal of essential tubes and vascular catheters, aggressive behaviour, and poor patient-ventilator synchrony. Thus, sedation and analgesia are integral components of modern ICU care.^[2]

An ideal sedative should be easily titratable, provide predictable sedation, have a rapid onset and short duration of action, and allow prompt recovery of spontaneous respiration without significant cardiovascular or

respiratory depression.^[3] However, the diverse clinical conditions, severity of illness, haemodynamic instability, and pharmacodynamic variability among critically ill patients make it difficult to establish a uniform sedation protocol.^[4] Both inadequate sedation and oversedation can adversely affect outcomes. Inadequate sedation may contribute to psychological and physiological complications, whereas excessive sedation can prolong mechanical ventilation and increase the risk of ventilator-associated pneumonia and respiratory depression.^[5]

Commonly used sedative and analgesic agents include benzodiazepines, opioids, and propofol. Although midazolam has a relatively short half-life, its elimination may be prolonged in critically ill patients.^[3] Opioids such as fentanyl provide rapid onset and ease of titration but may cause respiratory depression, hypotension, bradycardia, ileus, histamine release, and depression of consciousness. Fentanyl is widely used in ICU practice, but its context-sensitive half-life may vary considerably depending on the clinical setting.^[6]

Dexmedetomidine, a highly selective α_2 -adrenoceptor agonist, offers several desirable properties, including sedation with preserved arousability, analgesic and anxiolytic effects, predictable haemodynamic effects, and minimal respiratory depression.^[7]

Aims and Objectives

The present study aimed to evaluate the efficacy of dexmedetomidine infusion in mechanically ventilated patients admitted to the ICU. The objectives were to assess the requirement of dexmedetomidine and fentanyl infusions for achieving adequate sedation, determine the 24-hour requirement of midazolam, and evaluate the effects of dexmedetomidine and fentanyl infusions on the haemodynamic profile of mechanically ventilated ICU patients.

MATERIALS AND METHODS

Study Design

This was a prospective, randomized, double-blind study conducted among patients admitted to the ICU of Tertiary Care Centre, South India for a period of one and half years.

Inclusion and Exclusion Criteria

The study included a total of 62 patients. The inclusion criteria comprised patients aged 20–60 years who were mechanically ventilated,

had a SAPS-II (Simplified Acute Physiology Score II) of less than 59, and had a RASS (Richmond Agitation-Sedation Scale) score ranging from +4 to 0. Patients were excluded if they had a SAPS-II score greater than 60, a RASS score greater than –4, current or recent treatment (within the preceding 30 days) with any of the study drugs, contraindications or known allergies to any study drug, gross obesity (more than 60% above ideal body weight), or were receiving inotropic or vasopressor support.

Sample Size Calculation

With confidence level of 95% and power of 80%, taking reference value our sample size (n) was 62.

Data Collection Procedure

Patients admitted to the ICU who fulfilled the predefined inclusion and exclusion criteria were enrolled after obtaining informed consent from their relatives or bystanders. The critical status of each patient was assessed on admission, and the SAPS-II score was calculated on the same day. Baseline parameters including blood pressure, heart rate, respiratory rate, peripheral oxygen saturation, RASS score, and ventilatory settings were recorded. Patients were randomly allocated using the sealed-envelope technique to receive either dexmedetomidine or fentanyl by intravenous infusion. The study drugs were prepared in patient-specific syringe pumps by an anaesthesiologist who was not involved in the study, ensuring double blinding. Sedation was assessed using the RASS, with the target maintained between –1 and –3. RASS and vital parameters were recorded hourly for the first 6 hours and subsequently every 6 hours for the next 24 hours, as well as before each change in infusion rate. The infusion rates were adjusted according to the RASS score, and midazolam was administered as rescue sedation when adequate sedation was not achieved at the maximum study-drug dose. The total dose of study drug and rescue midazolam required over 24 hours, along with cardiovascular adverse events and the requirement for rescue treatment, were recorded in the study proforma.

Statistical Analysis

Statistical analysis was performed using the chi-square test for comparison of the distribution of sex between the two study

groups. Student's unpaired *t*-test was used to compare the mean age, height, weight, SAPS-II score, time required to achieve a RASS score of -1, infusion rate of the individual study drug required to achieve a RASS score of -1, and total dose of midazolam required during the 24-hour study period. A *P* value

<0.05 was considered statistically significant, *P* <0.01 was considered highly significant, and *P* <0.001 was considered very highly significant; *P* >0.05 was considered statistically not significant. The two groups compared were Group I (dexmedetomidine) and Group II (fentanyl).

RESULTS

Sex	Group I – Dexmedetomidine n (%)	Group II – Fentanyl n (%)	Total n (%)
Male	25 (80.6%)	21 (67.7%)	46 (74.2%)
Female	6 (19.4%)	10 (32.3%)	16 (25.8%)
Total	31 (100%)	31 (100%)	62 (100%)

Table 1. Sex Distribution among the Two Groups

Table 1 illustrates the sex distribution among the two study groups. Group I consisted of 25 males and 6 females, whereas Group II consisted of 21 males and 10 females. Overall, 46 (74.2%) patients were male and 16

(25.8%) were female. The study reported no statistically significant difference in the demographic distribution of sex between the two groups.

Variable	Group I – Dexmedetomidine (n=31) Mean ± SD	Group II – Fentanyl (n=31) Mean ± SD	t value	p value	Significance
Age (years)	42.42 ± 12.336	51.81 ± 8.972	3.426	<0.001	Very highly significant
Weight (kg)	55.39 ± 6.190	56.03 ± 4.476	0.470	0.64	Not significant

Table 2. Age and Weight Distribution among the Two Groups

Table 2 observes the age and weight distribution among the two groups. The mean age was 42.42 ± 12.336 years in Group I and 51.81 ± 8.972 years in Group II, showing a statistically very highly significant difference.

The mean body weight was 55.39 ± 6.190 kg in Group I and 56.03 ± 4.476 kg in Group II, with no statistically significant difference between the groups.

Variable	Group I – Dexmedetomidine (n=31) Mean ± SD	Group II – Fentanyl (n=31) Mean ± SD	t value	p value	Significance
SAPS-II score	26.52 ± 4.830	27.84 ± 5.040	1.055	0.296	Not significant
RASS-0 score	1.94 ± 0.680	1.94 ± 0.727	0.000	1.000	Not significant

Table 3. Baseline SAPS-II and RASS Scores among the Two Groups

Table 3 illustrates the baseline severity of illness and sedation status in the two groups. The mean SAPS-II score was 26.52 ± 4.830 in Group I and 27.84 ± 5.040 in Group II, with

no statistically significant difference. Similarly, the mean RASS score at baseline was 1.94 in both groups, with no significant difference between them.

Variable	Group I – Dexmedetomidine (n=31) Mean ± SD	Group II – Fentanyl (n=31) Mean ± SD	t value	p value	Significance
Time to achieve RASS -1 (hours)	2.97 ± 1.278	6.29 ± 3.388	5.109	<0.001	Very highly significant
Infusion rate to achieve RASS -1 (mcg/kg/hr)	0.500 ± 0.1000	2.700 ± 0.8266	14.7110	<0.001	Very highly significant

Table 4. Sedation Characteristics among the Two Groups

Table 4 illustrates the sedation characteristics of the two groups. The mean time required to achieve a RASS score of -1 was 2.97 ± 1.278 hours in Group I compared with 6.29 ± 3.388 hours in Group II, demonstrating a statistically

very highly significant difference. The mean infusion rate required to achieve RASS -1 was 0.500 ± 0.1000 mcg/kg/hr in Group I and 2.700 ± 0.8266 mcg/kg/hr in Group II, which was also statistically very highly significant.

Time interval	Group I – Dexmedetomidine Mean $\pm$ SD	Group II – Fentanyl Mean $\pm$ SD	p value	Significance
Baseline	88.68 $\pm$ 12.608	90.42 $\pm$ 13.507	0.602	Not significant
1 hour	85.35 $\pm$ 10.815	89.32 $\pm$ 12.831	0.193	Not significant
2 hours	84.26 $\pm$ 11.281	85.81 $\pm$ 17.034	0.675	Not significant
3 hours	83.94 $\pm$ 10.237	88.32 $\pm$ 11.757	0.122	Not significant
4 hours	84.13 $\pm$ 9.538	86.35 $\pm$ 11.786	0.417	Not significant
5 hours	84.61 $\pm$ 9.653	86.29 $\pm$ 10.543	0.516	Not significant
6 hours	84.77 $\pm$ 9.244	86.06 $\pm$ 10.020	0.600	Not significant
12 hours	84.29 $\pm$ 8.088	87.23 $\pm$ 9.787	0.203	Not significant
18 hours	85.19 $\pm$ 8.308	86.71 $\pm$ 9.617	0.509	Not significant
24 hours	85.06 $\pm$ 7.164	87.81 $\pm$ 9.460	0.203	Not significant

Table 5. Mean Arterial Blood Pressure at Different Time Intervals

Table 5 illustrates the mean arterial blood pressure (MAP) at different time intervals following initiation of sedation. No statistically significant differences were observed between Group I and Group II at baseline or at any of

the assessed time intervals from 1 to 24 hours. The results reported in the study also indicate that MAP showed variations over time within the groups, with a fall during the initial hours following initiation of sedation.

Time interval	Group I – Dexmedetomidine Mean $\pm$ SD	Group II – Fentanyl Mean $\pm$ SD	p value	Significance
Baseline	92.19 $\pm$ 14.425	90.94 $\pm$ 7.771	0.671	Not significant
1 hour	95.23 $\pm$ 14.350	92.45 $\pm$ 7.814	0.348	Not significant
2 hours	91.58 $\pm$ 14.075	93.48 $\pm$ 6.999	0.503	Not significant
3 hours	92.55 $\pm$ 13.147	92.81 $\pm$ 7.825	0.925	Not significant
4 hours	93.74 $\pm$ 13.317	91.42 $\pm$ 6.937	0.393	Not significant
5 hours	93.23 $\pm$ 13.601	93.03 $\pm$ 7.246	0.944	Not significant
6 hours	93.71 $\pm$ 14.584	95.26 $\pm$ 10.589	0.634	Not significant
12 hours	92.71 $\pm$ 15.619	92.19 $\pm$ 6.300	0.865	Not significant
18 hours	91.52 $\pm$ 14.635	92.42 $\pm$ 6.308	0.753	Not significant
24 hours	92.84 $\pm$ 12.453	92.48 $\pm$ 6.382	0.888	Not significant

Table 6. Heart Rate at Different Time Intervals

Table 6 observes the heart rate recorded at different time intervals in the two study groups. The mean heart rate remained comparable between Group I and Group II

throughout the observation period. None of the comparisons from baseline through 24 hours demonstrated a statistically significant difference between the two groups.

Variable	Group I – Dexmedetomidine (n=31) Mean $\pm$ SD	Group II – Fentanyl (n=31) Mean $\pm$ SD	t value	p value	Significance
Midazolam dose/24 hours (mg)	0.39 $\pm$ 1.202	2.29 $\pm$ 1.657	5.176	<0.001	Very highly significant

Table 7. Rescue Sedation Requirement: Midazolam Dose in 24 Hours

Table 7 illustrates the requirement for rescue sedation with midazolam during the 24-hour observation period. The mean dose of midazolam required was 0.39 ± 1.202 mg in

Group I and 2.29 ± 1.657 mg in Group II. The difference between the two groups was statistically very highly significant.

DISCUSSION

Dexmedetomidine is a highly selective α_2 -adrenergic agonist with an $\alpha_2:\alpha_1$ affinity ratio of 1600:1. Its action on presynaptic α_2 receptors inhibits noradrenaline release, while central α_2 -receptor activation decreases sympathetic activity, producing sedation, reduced heart rate and blood pressure, with additional analgesic effects. Compared with conventional sedatives and opioids, dexmedetomidine is associated with sedation and analgesia, minimal respiratory depression, and reduced agitation and delirium.^[1]

In the present comparative study conducted among mechanically ventilated ICU patients in a tertiary care centre, south India, patients were randomly assigned to receive either dexmedetomidine or fentanyl infusion. The principal objectives were to compare the 24-hour requirement of midazolam for rescue sedation and the time required to achieve effective sedation, defined as a RASS score of 0 or -1. Both groups achieved an equivalent depth of sedation; however, the dexmedetomidine group required less rescue midazolam.

The demographic characteristics were comparable between the two groups, although a statistically significant difference in age was observed. The mean age was 42.42 ± 12.336 years in the dexmedetomidine group and 51.81 ± 8.972 years in the fentanyl group ($p < 0.001$). Mean body weight was comparable between the groups (55.39 ± 6.190 kg vs. 56.03 ± 4.476 kg, $p = 0.64$). Baseline SAPS-II scores were also comparable, with mean scores of 26.52 ± 4.83 and 27.84 ± 5.04 in the dexmedetomidine and fentanyl groups, respectively ($p = 0.296$).

RASS was used to assess sedation because of its simple single-item numerical structure and good inter-rater reliability and validity across adult ICU patients.^[2] In the present study, the baseline RASS score was 1.94 ± 0.680 in the dexmedetomidine group and 1.94 ± 0.727 in the fentanyl group ($p = 1$), indicating comparable initial sedation status.

The RASS score of -1 was achieved with dexmedetomidine at an infusion rate of 0.5–0.6 $\mu\text{g/kg/hr}$ and with fentanyl at 1.5–3 $\mu\text{g/kg/hr}$. The mean infusion rate of dexmedetomidine required to achieve effective sedation was 0.5 ± 0.1 $\mu\text{g/kg/hr}$. This finding was consistent with Tobias et al., who reported that dexmedetomidine at 0.5 $\mu\text{g/kg/hr}$ provided effective sedation and reduced rescue morphine requirements.^[8]

Similarly, Samia Elbaradie et al., comparing dexmedetomidine with propofol for short-term sedation in mechanically ventilated postoperative patients, reported Ramsay sedation scores of 4.1 ± 1 and 4.0 ± 0.9 , respectively ($p = 0.59$).^[9]

The present study demonstrated a significant difference in the time required to achieve RASS -1. The mean time was 2.97 ± 1.278 hours in the dexmedetomidine group compared with 6.29 ± 3.388 hours in the fentanyl group ($p < 0.001$). The corresponding mean infusion rates were 0.500 ± 0.1000 and 2.700 ± 0.8266 $\mu\text{g/kg/hr}$, respectively ($p < 0.001$). Thus, effective sedation was achieved more rapidly with dexmedetomidine in this study.

The haemodynamic findings showed no statistically significant differences in mean arterial pressure between the two groups at baseline or at 1, 2, 3, 4, 5, 6, 12, 18 and 24 hours. Although MAP decreased during the initial hours following sedation, the haemodynamic effects were clinically minimal and did not require intervention. The findings are consistent with the observations of Venn et al., who reported hypotension or bradycardia in 18 of 66 patients, particularly during bolus administration.^[1] Bloor et al. and Tobias et al. similarly reported that bradycardia, sinus arrhythmia and hypotension were mainly associated with the initial loading dose.^[8,10] In the present study, the limited haemodynamic effects may have been related to administration of the bolus dose slowly over 15 minutes and subsequent careful titration according to RASS.

Heart rate also remained comparable between the two groups throughout the 24-hour observation period. No statistically significant difference was observed at any measured time point. Petroz et al., in a two-centre pharmacokinetic and pharmacodynamic study in children, reported modest reductions in heart rate and systolic blood pressure during the first hour of dexmedetomidine infusion, with greater changes at higher doses.^[11]

A major finding of the present study was the reduced requirement for rescue sedation. Patients receiving dexmedetomidine required 0.39 ± 1.202 mg of midazolam over 24 hours compared with 2.29 ± 1.657 mg in the fentanyl group ($p < 0.001$). The study reports this as an 87% reduction in midazolam requirement. The finding is concordant with Venn et al., who reported 80% less midazolam requirement in intubated patients receiving

dexmedetomidine compared with controls (4.9 [5.8] $\mu\text{g/kg/hr}$ vs. 23.7 [27.5] $\mu\text{g/kg/hr}$, $p < 0.0001$), along with a 50% reduction in morphine requirement (11.2 [13.4] $\mu\text{g/kg/hr}$ vs. 21.5 [19.4] $\mu\text{g/kg/hr}$, $p = 0.0006$).^[1]

The present study demonstrates that dexmedetomidine provided effective sedation in mechanically ventilated ICU patients, with a mean time of 2.97 ± 1.278 hours to achieve RASS -1 and substantially lower rescue midazolam requirements compared with fentanyl. The haemodynamic parameters, including MAP and heart rate, remained statistically comparable between the two groups during the observation period. These findings support the sedative and opioid-sparing properties of dexmedetomidine demonstrated in the present study and in the studies cited above.

Limitations

Cardiac output, systemic vascular resistance, pulmonary vascular resistance and pulmonary artery pressure were not assessed, which could have provided more definitive information regarding the cardiovascular effects of the drugs. The sample size was small, and because of the diversity of cases, the two groups were not comparable with respect to age. In addition, plasma drug concentrations were not measured; therefore, kinetic homogeneity between the groups could not be assumed.

CONCLUSION

This study concludes that dexmedetomidine is an effective short-term sedative for mechanically ventilated patients in the ICU, providing a faster achievement of adequate sedation within the prescribed clinical dose range and requiring significantly less rescue midazolam over the first 24 hours compared with fentanyl. Despite its sedative advantages, dexmedetomidine demonstrated a comparable haemodynamic profile to fentanyl, with no significant differences in mean arterial pressure or heart rate during the observation period. Therefore, dexmedetomidine may be considered an effective and safe option for routine sedation during the first 24 hours following initiation of mechanical ventilation in ICU patients.

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