e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(7); 258-270

Original Research Article

Comparison Between Propofol and Midazolam as Sedatives in Mechanically Ventilated Patients in ICU

Gouri Diwan[1], Akshay Raut[2], Bhavyaa Ranawat[3], Teesta Sen[4], Jeetendra Singh[5], Amruta Pingale[6]

[1]Associate Professor, Department of Anaesthesia, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, 422003, Maharashtra, India.
[2]JR-3, Department of Anaesthesia, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, 422003, Maharashtra, India.
[3]Phase III MBBS, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, 422003, Maharashtra, India.
[4]Phase III MBBS, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, 422003, Maharashtra, India.
[5]Jeetendra Singh, Professor and Head, Department of Pharmacology, Nashik, 422003, Maharashtra, India.
[6]Assistant Professor, Department of Anaesthesia, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, 422003, Maharashtra, India.

Received: 24-04-2023 / Revised: 28-05-2023 / Accepted: 30-06-2023
Corresponding author: Dr. Amruta Pingale
Conflict of interest: Nil

Introduction: The management of critically ill patients often requires invasive and uncomfortable procedures such as Tracheal intubation, Central line insertion, Arterial line catheterization, chest tubes and physical restraint. Furthermore, the intensive care unit (ICU) environment is filled with noise which greatly exaggerates the stress and anxiety of conscious patients. There is evidence that prevention of exposure to environmental noise, stress, anxiety can help improve outcome of patients. An important modality is the use of sedatives to prevent critically ill patients from being exposed to hazardous physical and psychological stimulus.

Method: The study commenced after receiving approval from the institutional ethics committee and taking informed consent from the patients. A total of 60 patients were divided into the two groups of 30 each using computer generated random numbers.

Result: This was a hospital based randomized control study conducted in the ICU of a tertiary care centre.

A total of 60 patients were divided into following two groups of 30 each using computer generated random numbers. In **Group 'P'** patients randomized to the Propofol group received a loading dose of 0.5-1 mg/kg then an infusion of 25-75 mcg/kg/min adjusted to achieved the target Ramsay sedation score. In **Group 'M'** Patients randomized in Midazolam group received loading dose 0.03 to 0.3 mg/kg then an infusion of 0.012-0.024 mg/kg/h adjusted to achieved the target Ramsay sedation score.

Conclusion: We were summarized from the current study that Propofol had a shorter mean recovery time than Midazolam. When compared to Midazolam, the Propofol group had a shorter mean extubation time and sedation time. In addition, the Propofol group spent less time on a mechanical ventilator in an intensive care unit than the midazolam group did. In comparison to the midazolam group, the propofol group had a lower percentage of side effects. The Ramsay sedation score did not differ significantly between the two groups.

Introduction

The management of critically ill patients often requires invasive and uncomfortable procedures such as Tracheal intubation, Central line insertion, Arterial line catheterization, chest tubes and physical restraint. Furthermore, the intensive care unit (ICU) environment is filled with noise which greatly exaggerates the stress and anxiety of conscious patients. There is evidence that prevention of exposure to environmental noise, stress, anxiety can help improve outcome of patients. An important modality is the use of sedatives to prevent critically ill patients from being exposed to hazardous physical and psychological stimulus.

Mechanical ventilation (MV) is commonly used in the ICU. Due of its invasiveness, mechanical ventilation usually brings a stressful, uncomfortable and even painful experience to ICU patients. Mechanically ventilated patients are at an increased risk of developing delirium. Therefore, international guidelines recommend routine use of sedation to prevent patients from exposure to these adverse stimuli. However, there is a variety of sedatives that are available for clinical use, including midazolam, dexmedetomidine, propofol, combination of midazolam & opioids, lorazepam. They have different advantages and limitations in clinical use, due to their distinct pharmacological properties.

Recent surveys showed that midazolam and propofol remain the dominant medications used for ICU sedation [1-3]. Midazolam is a fast-acting benzodiazepine and has been used for sedation and as an anticonvulsant. Propofol has been used extensively as an anaesthetic agent and as a sedative in the ICU. It produces sedation and hypnosis in a dose-dependent manner [4]. The pharmacokinetic properties of propofol are characterized by a rapid onset and short duration of action. The two drugs are equally safe and effective for short-term sedation. However, each drug is associated with adverse effects when used for long-term sedation. Treatment with midazolam may cause acute withdrawal syndrome and delayed recovery from drug accumulation, especially in patients with chronic renal failure. Propofol treatment causes dose-dependent effects and faster recovery with no accumulation. However, propofol may cause hypertriglyceridemia and cardiovascular depression, and is associated with the risk of propofol infusion syndrome and a high pharmaceutical cost [5]. In this clinical study, we aimed to compare these two commonly used sedative agents in mechanically ventilated patients admitted in the ICU in terms of quality of sedation, hemodynamic effects, recovery time, extubation time , presence & absence of agitation , incidence of occurrence of hypotension and adverse reaction profile.

Aim & Objectives

Aim of the Study

To compare the efficacy of propofol and midazolam as a sedative agent in mechanically ventilated patients in the ICU.

Objectives of the Study

To compare the efficacy of propofol and midazolam as a sedative agent in mechanically ventilated patients in the ICU, in terms of :

1. Quality of sedation
2. Duration of sedation
3. Hemodynamic stability
4. Adverse reaction
5. Occurrence of hypotension
6. Presence or absence of agitation
7. Recovery time
8. Extubation time

Materials & Methods

Study Area: Medical and Surgical ICU of a tertiary health care centre.

Study Population: Adult patients who required mechanical ventilation for Medical reason or post-operative cases.

Sample Size: The sample size was calculated using following formulae:

$$n \geq \frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2 (\sigma_1^2+\sigma_2^2/r)}{(\mu_1-\mu_2)^2}$$

$\alpha = 0.0001$
$\beta = 0.001$
$\mu_1 = 23$
$\sigma_1 = 3.04$
$\mu_2 = 34$
$\sigma_2 = 3.93$
Ratio (group 2/ group 1) = 1
n- Sample size
Minimum sample size needed for group 1 = 12
Minimum sample size needed for group 2 = 12
Minimum total sample size needed = 24
But we are taking 30 in each group = Total 60

Study Design

Hospital based randomized control study

Inclusion Criteria

1. Patients >18 years of age.
2. Patients of either gender.
3. Patients who require immediate sedation as to permit the initiation and tolerance of mechanical ventilation.

Exclusion Criteria

1. Known or suspected allergy or intolerance to propofol or midazolam.
2. Pregnancy.
3. Head injury.
4. Coma due to cerebrovascular accidents or unknown etiology.

Study Methodology

The study commenced after receiving approval from the institutional ethics committee and taking informed consent from the patients. A total of 60 patients were divided into the following two groups of 30 each using computer generated random numbers:

Group P: Patients randomized to the **Propofol group** received a loading dose of 0.5-1 mg/kg. Before giving loading dose, all parameters were recorded with GCS score, then an infusion of 25-75

mcg/kg/min was adjusted to achieve the target Ramsay sedation score.

Group M: Patients randomized in **Midazolam group** received loading dose of 0.03 to 0.3 mg/kg and an infusion of 0.012-0.024 mg/kg/h adjusted to achieve the target Ramsay sedation score. Before starting midazolam all parameters were recorded with GCS score.

Only Tramadol 1 mg/kg was given to patients of both groups as analgesic agent. The Ramsay sedation score was used to quantitate the desired degree of sedation, specified at the regular intervals and adjusted as per the patient's condition (i.e., recovery or deterioration)[6]. Patients were maintained at Ramsay sedation score of >2 by adjustments to the sedative regimens.

Parameters Monitored

- Ramsay Sedation Score recorded every 20 min, 40 min, 1 hr then every 4 hourly after loading dose up to 72 hrs.
- Blood pressure
- Pulse rate
- SPO2

Awake

1. Anxious and/or agitated
2. Cooperative, oriented and tranquil
3. Response to command.

Asleep

1. Quiescent with brisk response to light glabellar tap or loud auditory stimulus
2. Sluggish response to light glabellar tap or loud auditory stimulus
3. No response.

The Ramsay sedation score was recorded at 20 min., 40 min., 1 hr., then every 4 hourly. A record of vital signs (Blood pressure, Respiratory Rate and SpO_2, Pulse rate) was maintained till extubation. Sedation was stopped before weaning. Decision to wean the patient from the ventilator was taken once the patient fit into weaning criteria, both clinically and other in accordance with other weaning parameters like ABG (Arterial Blood Gas), Rapid Shallow Breathing Index (RSBI) .

Outcome measurements

The outcome measures included the recovery and extubation time, defined as the time from the cessation of sedation until awakening and extubation, respectively. The data was also collected for the Quality of sedation, duration of sedation, Pulse rate, Blood Pressure, SpO2, occurrence of hypotension (decrease in systolic blood pressure >20%) during the sedation period, presence or absence of agitation.

Statistical Methods

All the data was noted down in a pre-designed study Proforma. Qualitative data was represented in the form of frequency and percentage. Association between qualitative variables was assessed by Chi-Square test with Continuity Correction for all 2 X 2 tables and Fisher's exact test for all 2 X 2 tables. Quantitative data was represented using Mean ± SD and Median & IQR (Inter quartile range). Analysis of Quantitative data between the two groups was done using unpaired t-test if data passed 'Normality test' and by Mann-Whitney Test if data failed 'Normality test. A p-value < 0.05 was taken as level of significance. Results were graphically represented. SPSS Version 25.0 was used for most analysis and Microsoft Excel 2010 for graphical representation.

Results & Observations

This was a hospital based randomized control study conducted in the ICU of a tertiary care centre.

A total of 60 patients were divided into following two groups of 30 each using computer generated random numbers.

In **Group 'P'** patients randomized to the Propofol group received a loading dose of 0.5-1 mg/kg then an infusion of 25-75 mcg/kg/min adjusted to achieved the target Ramsay sedation score.

In **Group 'M'** Patients randomized in Midazolam group received loading dose 0.03 to 0.3 mg/kg then an infusion of 0.012-0.024 mg/kg/h adjusted to achieved the target Ramsay sedation score.

All the data was systematically noted in the excel spread sheet. The data was analysed using SPSS 25 software in which the frequency, mean, standard deviation, p-value were calculated to study the findings. A P- value < 0.005 was considered as statistically significant.

Table 1: Age distribution

Age in years	Group P		Group M		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
18 - 20	2	6.67	1	3.33	0.734
21 – 40	10	33.33	14	46.67	
41 – 60	13	43.33	11	36.67	
61 - 80	5	16.67	4	13.33	
Total	30	100	30	100	

Mean	44.2 years	42.63	
SD	± 15.66	± 16.25	

Table 1 represents the age distribution of 30 patients in each group. Group P had a maximum 13 (43.33 %) patients in age group of 41 – 60 years with mean age of 44.2 years with SD ± 15.66. In Group M maximum 14 (46.67%) patients in age group 21-40 years with mean age of 42.63 years with SD ± 16.25.

The age distribution in the two groups was statistically insignificant with p-value of 0.734.

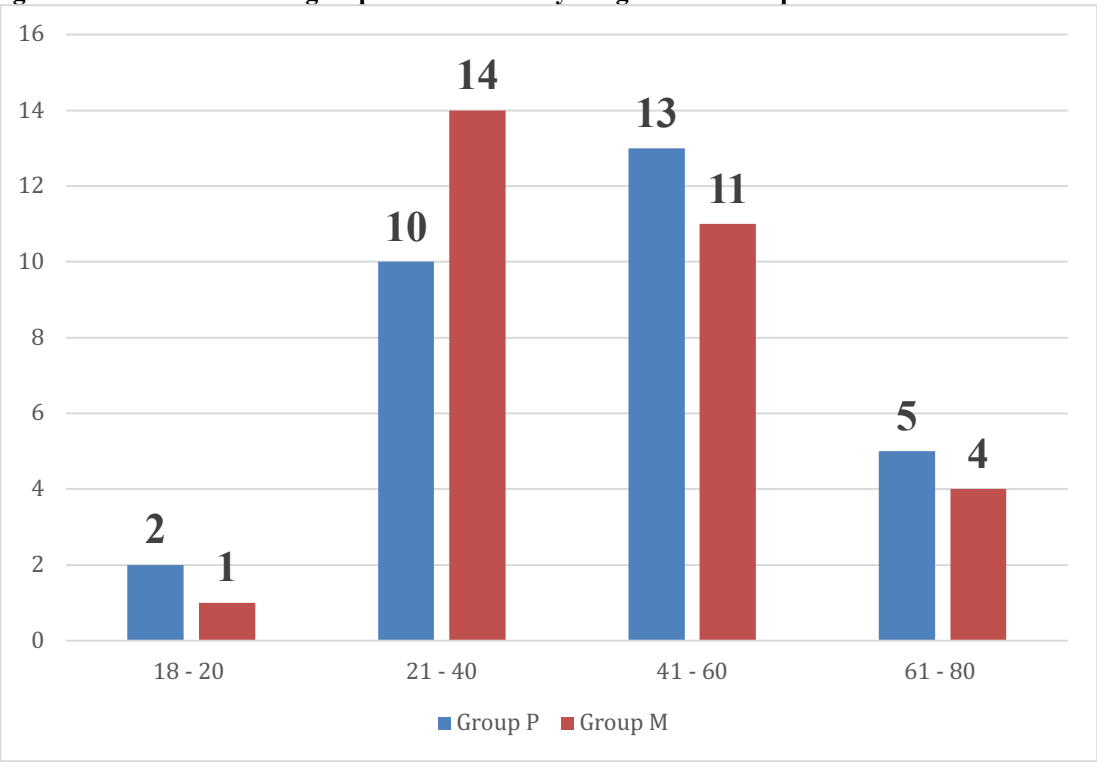

Figure 1: Age distribution

Table 2: Gender distribution

Gender distribution	Group P		Group M		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Female	9	30	5	16.67	0.222
Male	21	70	25	83.33	
Total	30	100	30	100	

Table 2 represents the gender study in which Group P had 9 (30 %) females patients and 21 (70 %) females patients with male : female ratio of 2.33 :1. Group M had 5 (16.67 %) female patients and 25 (83.33 %) male patients with Male : female ratio of 5 :1.

The age distribution between the two groups was statistically insignificant with p-value of 0.222.

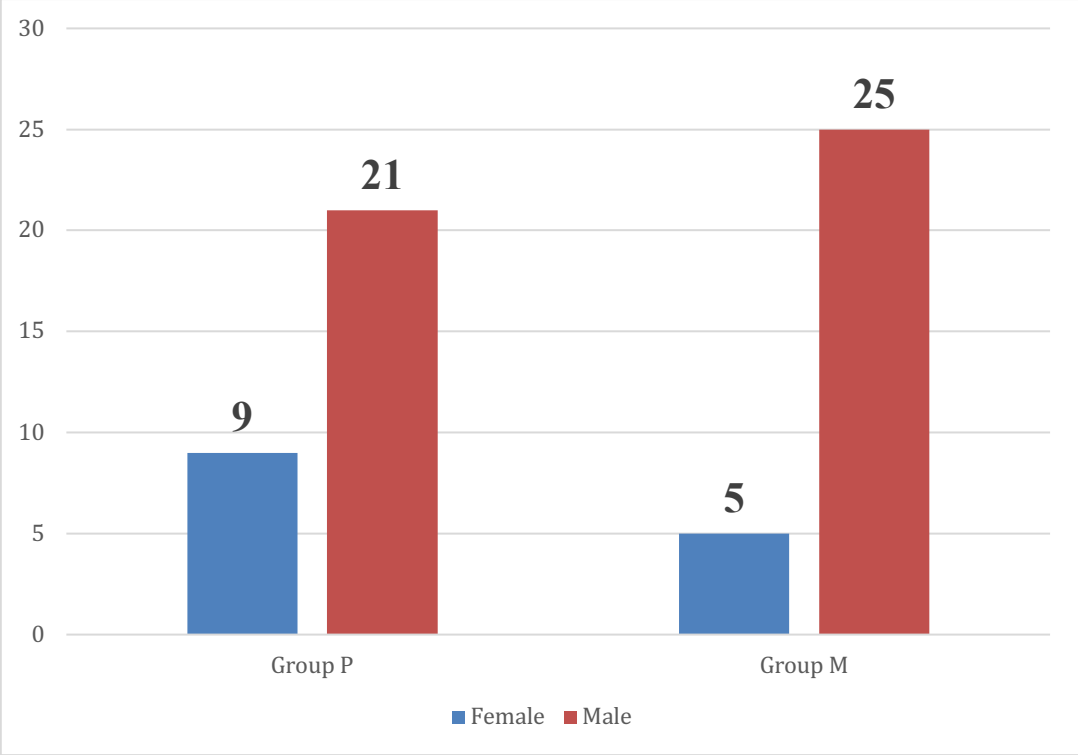

Figure 2: Gender distribution

Table 3: ASA classification study

ASA classification	Group P		Group M		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Class I	8	26.67	10	33.33	0.573
Class II	22	73.33	20	66.67	
Total	30	100	30	100	

Table 3 represents the American society of anaesthesiologist classification (ASA) between the two groups. In Group P 8 (26.67 %) patients were in ASA class I and 22 (73.33 %) patients in ASA class II . In Group M 10 (33.33 %) patients were in ASA class I and 20 (66.67 %) patients in ASA class II.

Table 4: Recovery time in minutes

Recovery Time (mints)	Group P	Group M	P-value
Mean	92.17	156	0.0003
Standard deviation	±31.48	± 84.3	

Table 4 represents the mean recovery time needed in both the groups. Group P needed 92.17 minutes mean recovery time with SD ±31.48 and Group M needed 156 minutes mean recovery time with SD ± 84.30.

The ASA classification in two groups was statistically insignificant with p-value of 0.573.

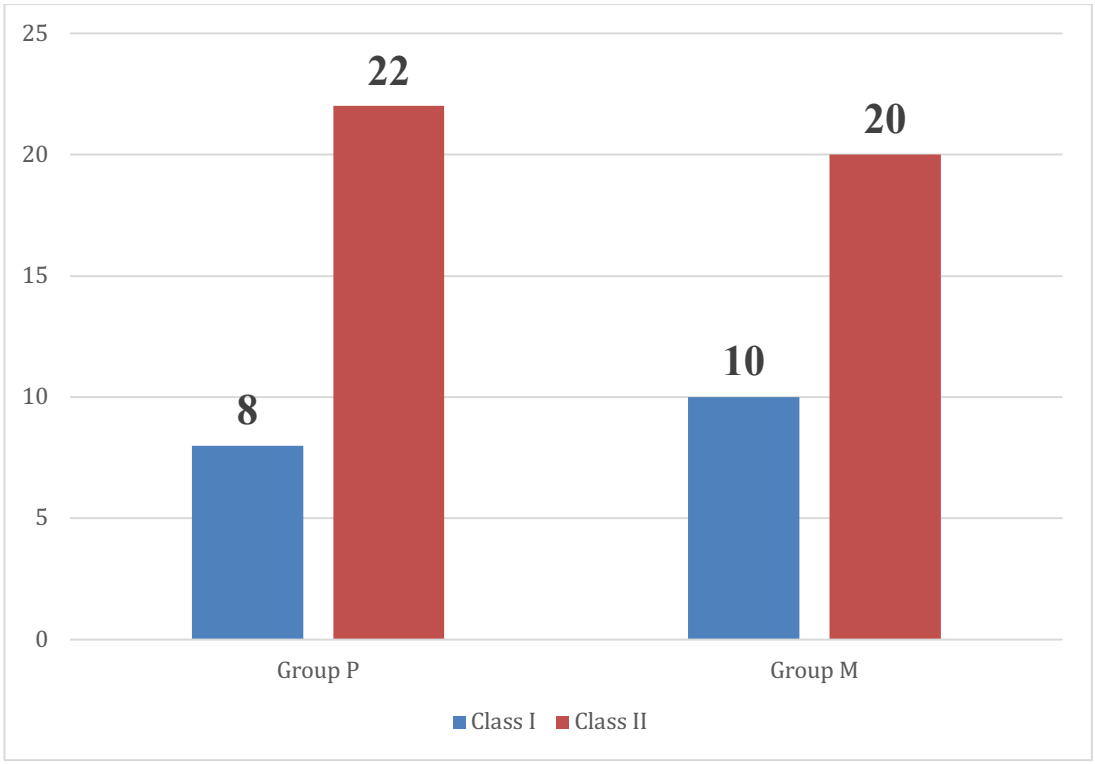

Figure 3: ASA classification

The recovery time between the two groups was statistically significant with p-value of 0.0003

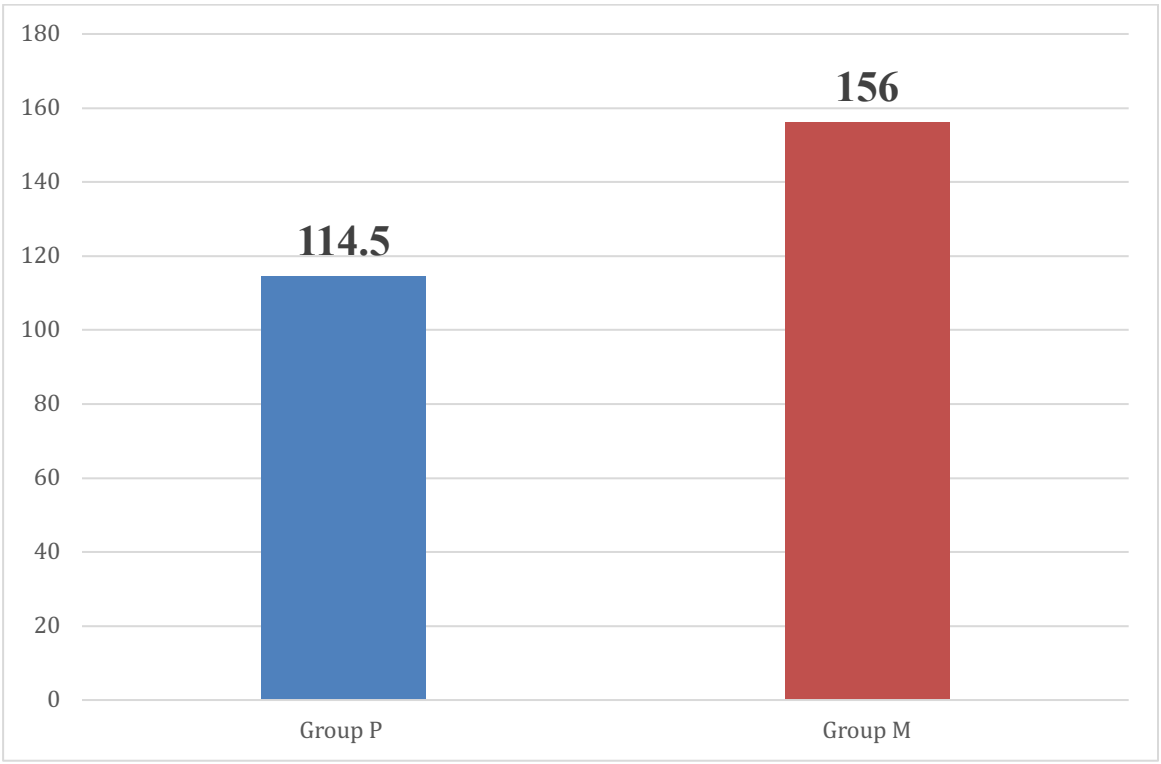

Figure 4: Recovery time

Table 5: Extubation time in minutes

Exudation Time (mints)	Group P	Group M	P-value
Mean	117.33	267.17	**< 0.001**
Standard deviation	±47.73	±94.81	

Table 5 represents the mean extubation time required in two groups. The mean extubation time in Group P needed 117.33 minutes with SD ± 47.73 and Group M required 267.17 minutes mean exudation time with SD ± 94.81.

The extubation time between the two groups was statistically significant with p-value of < 0.001

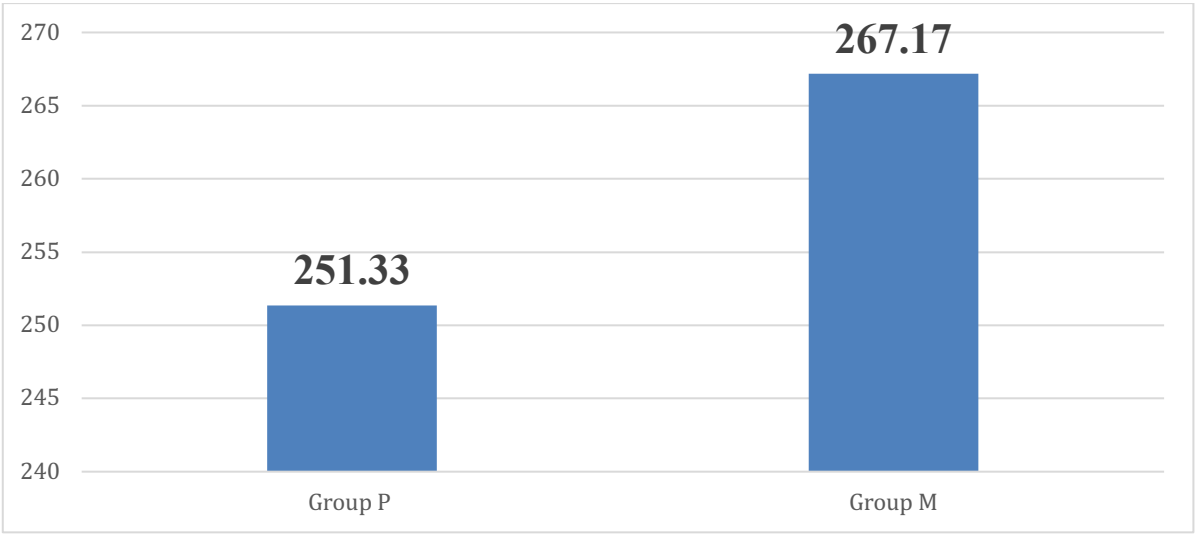

Table 5: Extubation time

Table 6: Duration of sedation study

Duration of Sedation (hrs)	Group P	Group M	P-value
Mean	29.83	31.6	0.558
Standard deviation	12.36	10.88	

Table 6 represents the duration of mean sedation in two groups. Group P had a mean sedation of 29.83 minutes with SD ± 12.36. Group M had a mean sedation of 31.60 minutes with SD ± 10.88.

The duration of sedation in the two groups was statistically insignificant with p-value of 0.558.

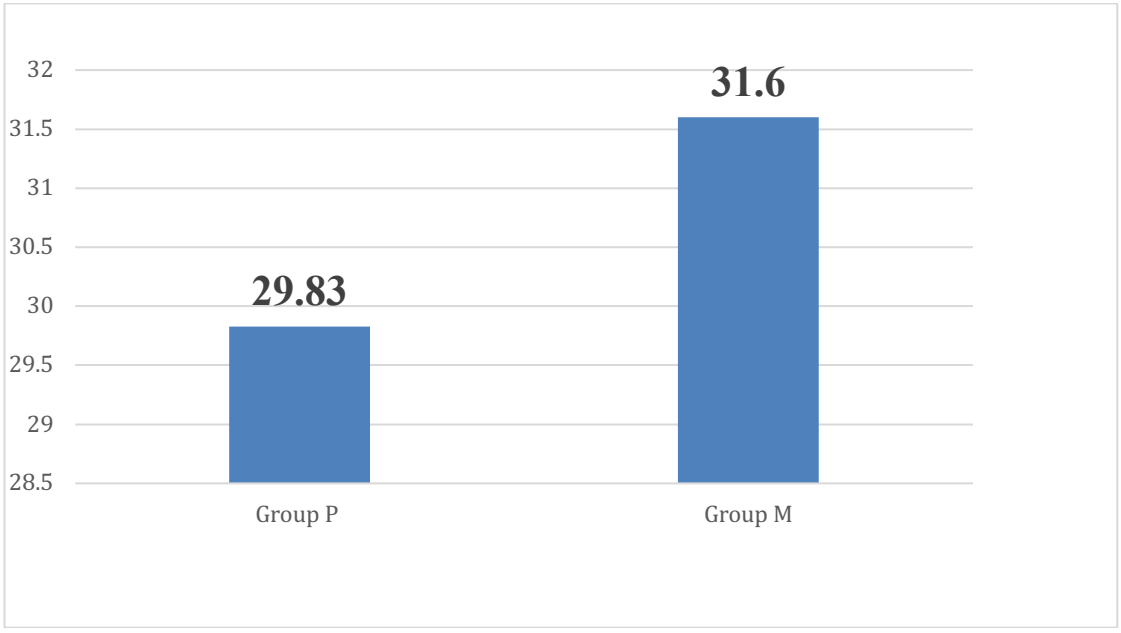

Figure 6: Duration of sedation

Table 7: Duration of time on mechanical ventilator

Duration of time in MV (hrs)	Group P	Group M	P-value
Mean	30.63	31.6	0.752
Standard deviation	12.74	10.88	

Table 7 represents the duration of time on mechanical ventilator. Group P had a mean time of 30.63 hours with SD ± 12.74 on mechanical ventilator and Group M had a mean of 31.60 hours with SD ± 10.88 mean time on mechanical ventilator.

The duration of time on mechanical ventilator in two groups was statistically insignificant with p-value of 0.752.

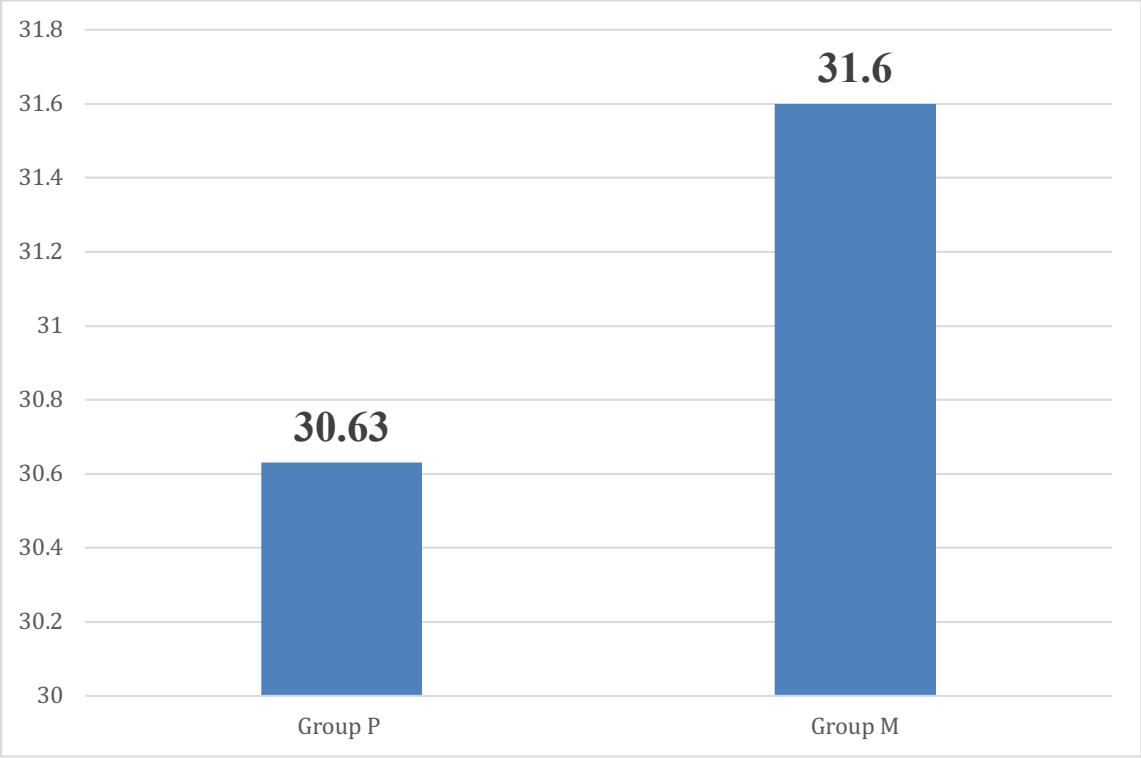

Figure 7: Duration of time on mechanical ventilator

Table 8: Study of mortality in Intensive care unit .

Mortality	Group P	Group M
ICU Mortality	0	0

Table 8 represents the study of mortality in ICU. No mortality in both the groups was reported in ICU.

Table 9: Study of side effects

Side effects	Group P		Group M		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Occurrence of Hypotension	03	10	05	16.66	0.872
Presence & Absence of Agitation	02	6.66	04	13.33	
Total	05	16.66	09	30.00	

Table 9 represents the side effects in the two groups. In group P 3 (10 %) patients reported hypotension, 2 (6.66 %) patients had presence of agitation. Group M reported 5 (16.66 %) cases of hypotension, 4 (13.33 %) cases had agitation.

The side effect in the two groups was statistically insignificant with p-value of 0.872.

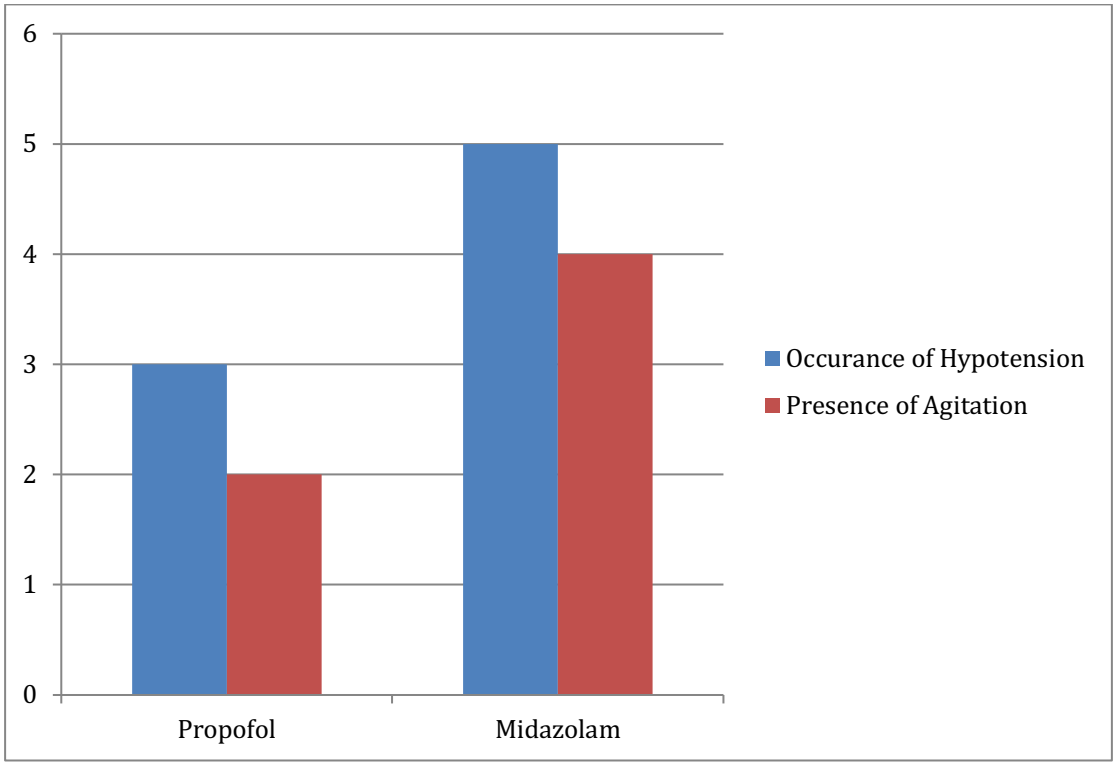

Figure 9: Study of side effects

Table 10: Study of Ramsay sedation score

Ramsay sedation score	Group P		Group M		P-value
	Mean	Standard deviation	Mean	Standard deviation	
0 hours	3.73	0.69	3.31	0.71	0.023
1 hours	4.27	0.64	3.77	0.77	0.008
12 hours	5.23	0.68	4.17	0.79	< 0.001
24 hours	6.20	0.76	5.00	0.64	< 0.001
48 hours	6.60	0.77	5.50	0.78	< 0.001
72 hours	6.80	0.71	5.87	0.96	0.0001

Table 10 represents the study of Ramsay sedation score in 6 intervals. The group P had a mean score of 3.73 at 0 hours and at the end of 72 hours it was 6.80. In group M the mean score at 0 minute was 3.31 and at end of 72 hours it was 5.87.

The Ramsay sedation score in the two groups was statistically significant in all the 6 intervals.

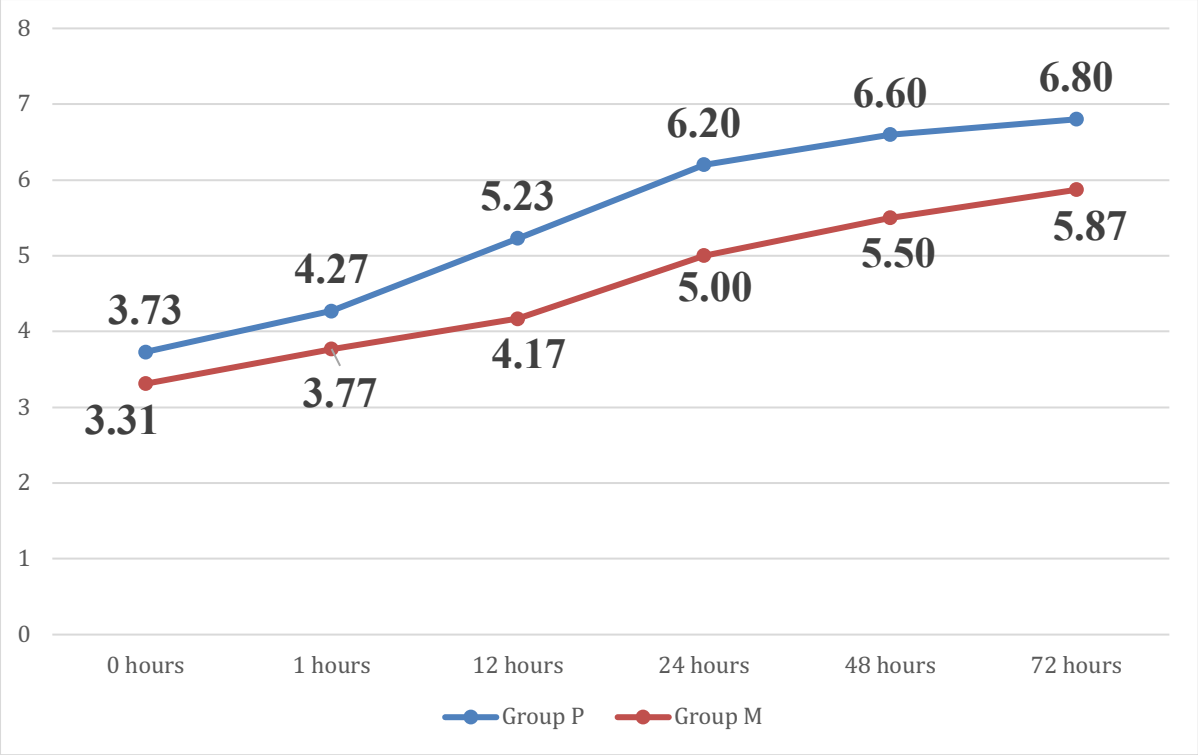

Figure 10: Study of Ramsay sedation score

Discussion

The present comparative hospital-based randomized control study was conducted at the ICU of a tertiary care center. 30 patients in each group satisfying the inclusion criteria were selected and divided into two equal groups Group P & Group M.

Group P: Patients randomized to the Propofol group received a loading dose of 0.5-1 mg/kg and then an infusion of 25-75 mcg/kg/min adjusted to achieved the target Ramsay sedation score.

Group M: Patients randomized in the Midazolam group was received loading dose of 0.03 to 0.3 mg/kg then an infusion of 0.012-0.024 mg/kg/h adjusted to achieved the target Ramsay sedation score.

Sedation was given to mechanically ventilated patients to minimize their anxiety, to make certain interventions easier, such as tracheal suctioning, central line insertion , Arterial line catheterization, frequent venipuncture and to prevent problems like unintended self-extubation. An ideal sedative should not cause cardiovascular or respiratory depression and should have a quick onset, brief duration of action, lack of accumulation, ease of titration and administration.

Thus this study aimed to compare the efficacy of propofol and midazolam as a sedative agents in a mechanically ventilated patients in the CU.

The observation of both groups are reported in an excel spreadsheet and the results are analyzed and discussed below.

Age distribution

The age distribution of 30 patients in each group.

Group P had a maximum of 13 (43.33%) patients in the age group of 41 – 60 years with a mean age of 44.2 years with SD ± 15.66.

In Group M maximum of 14 (46.67%) patients in the age group 21 – 40 years with a mean age of 42.63 years with SD ± 16.25. The age distribution in the two groups is statistically insignificant with a p-value of 0.734.

The comparable study conducted by Suresh Chandra Dulara[8] et al reported the mean age in Group M as 35.96±2.29 and Group P as 38.76±2.522. The finding is similar to the present study.

Another study conducted by P. Hari Keerthy[9] et al reported the mean age of the patients in the Group propofol group was 26.15 ± 4.45 years and in the midazolam group the mean age of the patients was 26.70 ± 6.74 years. This study also had no statistically significant differences between the two groups in terms of basic characteristics.

Gender distribution

In the present study of gender distribution in which Group P had 9 (30%) females patients and 21 (70%) females patients with a male: female ratio of 2.33 :1. Group M had 5 (16.67%) female patients

and 25 (83.33%) male patients with Male: female ratio of 5:1. The age distribution between the two groups is statistically insignificant with a p-value of 0.222.

In a comparable study conducted by Noriko Miyagawa[10], et al reported in Group M reported 31 (60.78%) male patients and 20 (39.21%) female patients. In Group P the study reported 39 (59.09%) male patients and 27 (40.90%) female patients. This study also showed no statistical significance in the group based on gender distribution.

Another comparable study conducted by P. Hari Keerthy[9] et al reported that the propofol group had 14 males and 6 females and the midazolam group there 12 male and 8 female patients. This study also had no statistically significant differences between the two groups in terms of basic characteristics

ASA classification study

In the present study of ASA classification in Group P 8 (26.67%) patients were in ASA class I and 22 (73.33%) patients in ASA class II. In Group M 10 (33.33%) patients were in ASA class I and 20 (66.67%) patients were in ASA class II. The ASA classification in the two groups is statistically insignificant with a p-value of 0.573.

Recovery time in minutes

In the present study, the mean recovery time is needed in both groups. Group P needed 92.17 minutes of mean recovery time with SD ±31.48 and Group M needed 156 minutes of mean recovery time with SD ± 84.30. The recovery time between the two groups is statistically significant with a p-value of 0.0003

A comparable study conducted by Yongfang Zhou[11] et al reported the recovery time as 54.7 and 1.8 hours respectively for both groups.

In another comparable study done by P. Hari Keerthy[9] recovery time (Mean ± SD) in the propofol group was 22.50 ± 3.04 (range 15–25 min) and that of midazolam group was 33.75 ± 3.93 (range 30–40 min), which was statistically significant.

Recovery is rapid with propofol sedation. This quick recovery is facilitated by a high clearance rate and a low potential for drug build-up. When compared to propofol, midazolam often causes a longer recovery period for cognitive function, which may be exacerbated by excessive postoperative sedation and amnesia.

Extubation time in minutes

In the present study, the mean extubation time in Group P needed 117.33 minutes with SD ± 47.73, and Group M required 267.17 minutes with a mean exudation time of SD ± 94.81. The extubation time between the two groups is statistically significant with a p-value of < 0.001.

The comparable study conducted by Yongfang Zhou[5] et al reported a mean extubation time of 180 minutes in Group P and 2000 minutes in group M. The findings are too high compared with other studies but Group P needed less extubation time than Group M in both the studies.

Duration of sedation study

Group P had a mean sedation of 29.83 minutes with SD ± 12.36. Group M had a mean sedation of 31.60 minutes with SD ± 10.88. **The duration of sedation in the two groups is statistically insignificant with a p-value of 0.558.**

Many studies demonstrated the use of propofol for long-term sedation in the ICU. In the study conducted by Saito et al [12] and colleagues, 13 patients with midazolam were switched to propofol approximately 24 hours before the expected cessation of sedation. When patients were sedated with midazolam for a longer time, extubation delays of up to 49 hours or even longer were reported.

In the present study, the mean sedation in both the group did not have much difference the similar findings were reported in the study conducted by Yongfang Zhou[5] et al.

Duration of time on a mechanical ventilator

Group P had a mean time of 30.63 hours with SD ± 12.74 on the mechanical ventilator and Group M had a mean of 31.60 hours with SD ± 10.88 meantime on the mechanical ventilator. The duration of time on the mechanical ventilator in the two groups is statistically insignificant with a p-value of 0.752.

The comparable study conducted by Yongfang Zhouet al reported that in group P the mean duration of time on a mechanical ventilator was 126.0 hours and SD ± 71.1 and in group M it is 192 hours and SD ± 124. The present study had similar finding in which Group P had less duration of time on the mechanical ventilator when compared with Group M.

Study of mortality in Intensive care unit

In the present study, no mortality in either group was reported both in ICU and during a hospital stay. Different studies have reported different findings. The study conducted by Yongfang Zhou et al reported 17% mortality in Group P and 20% in Group M. This finding is different from the present study findings.

Study of side effects

In group P3 (10%) patients reported hypotension, and 2 (6.66%) patients had the presence of agitation. Group M reported 5 (16.66%) cases of hypotension, and 4 (13.33%) cases had agitation. The side effect in the two groups is statistically insignificant with a p-value of 0.999. In Group P the total percentage of side effects is 16.66% and in Group M it is 30%. The side effects in both groups are statistically insignificant.

Study of Ramsay sedation score

In the present study, Ramsay's sedation score was in 6 intervals.

Group P had a mean score of 3.73 at 0 hours and at the end of 72 hours, it was 6.80.

In group M the mean score at 0 minutes was 3.31 and at end of 72 hours, it was 5.87. The Ramsay sedation score in the two groups is statistically significant in all 6 intervals. The RSS in the present study did not show much difference than the comparable study conducted by Saito et al [12] which also reported that the efficacy of the percentage of assessment as similar between the groups in Ramsay sedation score.

Summary

The present comparative hospital-based randomized control study was conducted at the ICU of a tertiary care center. A total of 60 patients attending the ICU were grouped into two parts with 30 patients in each group.

Group P patients randomized to the Propofol group received a loading dose of 0.5-1 mg/kg then an infusion of 25-75 mcg/kg/min.

Group M Patients randomized in the Midazolam group received loading dose of 0.03 to 0.3mg/kg then an infusion of 0.012-0.024 mg/kg/hr. In the present study, various factors were studied to compare the efficacy of both drugs.

The result and discussion are summarised below.

- In the present study of age group, Group P had a maximum of 13 (43.33%) patients in the age group of 41 – 60 years with a mean age of 44.2 years with a SD ± 15.66. In Group M maximum of 14 (46.67%) patients in the age group 21 – 40 years with a mean age of 42.63 years with a SD ± 16.25. The age distribution in the two groups was statistically insignificant with a p-value of 0.734.
- In the gender distribution study, Group P had 9 (30 %) females patients and 21 (70 %) females patients with a male: female ratio of 2.33 :1. Group M had 5 (16.67%) female patients and 25 (83.33%) male patients with Male: female ratio of 5:1. The gender distribution between the two groups was statistically insignificant with a p-value of 0.222.
- In the ASA classification, in Group P 8 (26.67%) patients were in ASA class I, and 22 (73.33%) patients were in ASA class II. In Group M 10 (33.33%) patients were in ASA class I and 20 (66.67%) patients were in ASA class II. The ASA classification in the two groups was statistically insignificant with a p-value of 0.573.
- In the present study the mean recovery time in Group P was 92.17 minutes with a SD ± of 31.48 and Group M reported 156 minutes as the mean recovery time with a SD of ± 84.30. The recovery time between the two groups was statistically significant with a p-value of 0.0003.
- The mean extubation time in Group P was 117.33 minutes with a SD of ± 47.73 and in Group M it was 267.17 minutes mean extubation time with a SD of ± 94.81. The extubation time between the two groups was statistically significant with a p-value of < 0.001.
- The mean sedation time in Group P was 29.83 minutes with a SD ± 12.36 & in Group M it was 31.60 minutes with a SD ± 10.88. The duration of sedation in the two groups was statistically insignificant with a p-value of 0.558.
- The mean time on the mechanical ventilator in Group P was 30.63 hours with a SD of ± 12.74 and Group M had a mean time of 31.60 hours with a SD ± 10.88. The duration of time on the mechanical ventilator in the two groups was statistically insignificant with a p-value of 0.752.
- No mortality was reported in ICU from both the groups.
- The side effect in group P was that 3 (10%) patients suffered from hypotension, and 2 (6.66%) patients had the presence of agitation. In Group M 5 (16.66%) cases of hypotension and 4 (13.33%) cases of agitation were seen. The side effect in the two groups was statistically insignificant with a p-value of 0.999.
- In the study of Ramsay's sedation score in 6 intervals. Group P had a mean score of 3.73 at 0 hours and at the end of 72 hours, it was 6.80. In group M the mean score at 0 minutes was 3.31 and at end of 72 hours, it was 5.87. The Ramsay sedation score in the two groups was statistically significant in all 6 intervals.

We were summarized from the current study that Propofol had a shorter mean recovery time than Midazolam. When compared to Midazolam, the Propofol group had a shorter mean extubation time and sedation time. In addition, the Propofol group spent less time on a mechanical ventilator in an intensive care unit than the midazolam group

did. In comparison to the midazolam group, the propofol group had a lower percentage of side effects. The Ramsay sedation score did not differ significantly between the two groups**.**

Bibliography

1. Soliman HM, Mélot C, Vincent JL. Sedative and analgesic practice in the intensive care unit: the results of a European survey. Br J Anaesth. 2001;87:186–192.
2. Payen JF, Chanques G, Mantz J, Hercule C, Auriant I, Leguillou JL, Binhas M, Genty C, Rolland C, Bosson JL. Current practices in sedation and analgesia for mechanically ventilated critically ill patients: a prospective multicenter patient-based study. Anesthesiology. 2007;106:687–695.
3. Wunsch H, Kahn JM, Kramer AA, Rubenfeld GD. Use of intravenous infusion sedation among mechanically ventilated patients in the United States. Crit Care Med. 2009;37:3031–3039.
4. Fulton B, Sorkin EM. Propofol. An overview of its pharmacology and a review of its clinical efficacy in intensive care sedation. Drugs. 1995 Oct;50(4):636-57.
5. Zhou Y, Jin X, Kang Y, Liang G, Liu T, Deng N. Midazolam and propofol used alone or sequentially for long-term sedation in critically ill, mechanically ventilated patients: a prospective, randomized study. Crit Care. 2014 Jun 16;18(3):R122.
6. Singh G, Srinivas K. Comparison of Intensive Care Unit Sedation Using Dexmedetomidine, Propofol, and midazolam. Int J Sci Stud 2017;4(10):115-124.
7. Jayashree Raikhelkar, Peter J. Papadakos, in Mechanical Ventilation, 2008.
8. Suresh Chandra Dulara, Pooja Jangid, Ashish Kumar JangirA Comparative Study of Midazolam, Propofol and Dexmedetomidine Infusions For Sedation in Mechanically Ventilated Patients in ICU Natl J Med Res. 2015; 5(3): 234-239.
9. Keerthy PH, Balakrishna R, Srungeri KM, Singhvi N, John J, Islam M. Comparative evaluation of propofol and midazolam as conscious sedatives in minor oral surgery. Journal of maxillofacial and oral surgery. 2015 Sep;14(3):773-83.
10. Noriko Miyagawa, Yu Kawazoe, Tetsuya Sato, Shigeki Kushimoto, Kyohei Miyamoto et al Comparison between midazolam and propofol in acute phase for ventilated patients with sepsis: a post-hoc analysis of the DESIRE trial, Acute Medicine & Surgery2022;9:e746
11. Zhou Y, Jin X, Kang Y, Liang G, Liu T, Deng NI. Midazolam and propofol used alone or sequentially for long-term sedation in critically ill, mechanically ventilated patients: a prospective, randomized study. Critical Care. 2014 Jun;18(3):1-9.
12. Saito Masataka, Terao Yoshiaki, Fukusaki Makoto, Makita Tetsuji, Shibata Osamu, Sumikawa Koji. Sequential Use of Midazolam and Propofol for Long-Term Sedation in Postoperative Mechanically Ventilated Patients. Anesthesia & Analgesia March 2003; 96(3): 834-838,.