A Comparative Study of Propofol Vs Midazolam for Sedation and Anti Emetic Effect in Spinal Anesthesia

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Abstract: <u>Background and objective</u>: To compare Propofol and Midazolam for sedation and anti - emetic effect in spinal anesthesia. <u>Methods and materials</u>: This study was conducted in 130 patients of ASA grade I and II of both sexes in the age group of 18 - 60 years who were scheduled for various elective surgeries under spinal anesthesia. They were randomly allocated into 2 groups. Propofol group received Propofol in the dose of 0.75 - 1mg/kg body weight to maintain a sedation level 3 and repeated as necessary at a dose of 0.25 mg/kg and in midazolam group, Midazolam in the dose of 0.02mg/kg intravenous was given and repeated at a dose of 0.005mg/kg body as per requirement to maintain a sedation level 3. At the same time, the incidence of nausea and vomiting was alsoevaluated. Nausea and vomiting were evaluated using Bellville score. <u>Results</u>: Propofol appears to have a very rapid onset of sedation when compared to Midazolam. In this study, time of recovery in Propofol (78.46%) was faster when compared to Midazolam (53.8%) i. e,. within 2 - 3 minutes. Percentage of amnesia is more in Midazolam (61.5%) when compared to Propofol (41.5%) with p=0.023. Incidence of intraoperative nausea was less with Propofol group than Midazolam group. There is no significant difference in postoperative nausea in both groups at 30 mins intervals. The incidence of postoperative nausea was less with the propofol group than the midazolam group after 1 hour. <u>Conclusion</u>: Propofol gives rapid onset of sedation and faster recovery, while midazolam provides more hemodynamic stability in regional anesthesia. Propofol has lesser incidence of nausea and vomiting compared to midazolam

Keywords: sedation, antiemetic, propofol, midazolam

1. Introduction

Patients undergoing surgery tend to be anxious, although anxiety exists long before the patient is brought to the operative room, so the reduction of anxiety to a tolerable level is a human goal and should be attempted for every patient undergoing surgery.

Sedation is defined as "a state of reduced excitement or anxiety that is induced by administration of a sedative agent".1 Sedation in another words is also defined as the "depression of a patient's awareness of the environment and reduction of patient's responsiveness to external stimulation".²

Preoperative anxiety about anesthesia remains for many patients a major subject of concern. Anxiety is defined as "an unpleasant state of uneasiness or tension, which may be associated with abnormal hemodynamics as a result of sympathetic, parasympathetic and endocrine stimulation".

Anxiety is associated with significant adverse physiological responses like hypertension, tachycardia, increased myocardial oxygen consumption, gastric erosion, intracranial hypertension, and persistent catabolism that may affect postoperative recovery. Therefore, anxiolysis is a must for patients undergoing surgery under regional anesthesia.

The most common and distressing symptoms following surgery and anesthesia are pain, nausea, and vomiting. Post Operative Nausea and Vomiting (PONV) has been associated with various complications ranging from minor incision pain to more severe hematoma, wound dehiscence, oesophageal rupture, bilateral pneumothorax, and increased risk for aspiration. So, reduction of nausea and vomiting to a tolerable level is another goal of this study and should be attempted for the patient undergoing surgery.

The method of relieving anxiety includes Nonpharmacological and pharmacological.

1) Non - pharmacological methods:

These are very effective in reducing anxiety. It is found that a preoperative visit by the anesthesiologist is more effective in decreasing anxiety than the administration of drugs. Other methods include a detailed explanation of the operative procedure with the help of booklets by non - anesthesia personnel or by the anaesthesiologists themselves. And also audio - visual instruction reduces preoperative anxiety.

2) Pharmacological methods:

There are different types of drugs used for sedation

- Non barbiturates like propofol and etomidate
- Benzodiazepines like midazolam, lorazepam and diazepam
- Opioids like fentanyl and meperidine
- Non opioids like ketamine

There are different classes of drugs used for antiemetic ${\rm effect}^3$

- Anticholinergics like atropine, hyoscine and scopolamine
- Benzamides like metoclopramide

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• Benzodiazepines like midazolam

In this context two types of drugs are considered, these are:

- **Propofol** possesses an antiemetic effect, possibly via antagonism of the dopamine D2 receptor. Propofol in sub hypnotic doses is effective against nausea and vomiting⁴
- **Midazolam** reduces the incidence of PONV. Unlike propofol, these benzodiazepines have no direct antiemetic effect, but controls anxiety and accompanying anticipatory nausea5, 6

Aims and Objectives

To compare Propofol and Midazolam for sedation and anti emetic effect in spinal anesthesia about their attributes like:

- Sedative and amnesic effects.
- Induction and recovery parameters.
- Antiemetic effect and control of nausea
- Effects on cardiovascular and respiratory systems.
- Cumulative and adverse effects.

2. Materials and Methods

This study was conducted in 130 patients, after approval of institute ethics committee, of ASA grade I and II of both sexes in the age group of 18 - 60 years who were scheduled for various elective surgeries under spinal anesthesia, randomly allocated into 2 groups. Propofol group received Propofol in the dose of 0.75mg/kg to 1mg/kg to maintain a sedation level 3 and in midazolam group, Midazolam in the dose of 0.02mg/kg intravenous was given and repeated as necessary in the dose of 0.005mg/kg body weight to maintain a sedation level 3. At the same time, the incidence of nausea and vomiting was also evaluated. Nausea and vomiting were evaluated using Bellville score.

Inclusion criteria

- Males and females aged between 18 60 years.
- Patients scheduled for various elective surgeries under spinal anesthesia
- ASA grade I and ASA grade II.

Exclusion criteria

- Patient refusal
- Patients with known hypersensitivity to Propofol and Midazolam.
- Patients with ASA grade III, IV of either gender
- Obstetrics & Gynaecology cases.

Statistical Analysis

Collected data were entered into a Microsoft Excel datasheet and were analysed by using SPSS 22 version software. Categorical collected data was represented in the form of Frequencies and proportions. Chi - square test, independent t - test or Mann Whitney U test was calculated and Graphical representation of data was done.

3. Results

In propofol group majority 28 (43.1%%) patients in age group of 21 - 30 years while in Midazolam group majority 21 (32.3%) belonging in age of 31 - 40 years and also Mean

age (SD) was $33.3.7\pm11.98$ in propofol group and 36.09 ± 11.089 years in midazolam group. (Table 1). For onset of action in propofol group, 30 (46.15%) patients had taken less than 60 seconds to reach target sedation and 35 (53.85%) patients achieved desirable level of sedative effects within 90 seconds of drug administered, while inmidazolam group 54 (83.07%) patients required more than90 seconds to reach at same level of sedation as per target set. The difference between two group was statistically significant (p<0.05) (Table 2). In propofol group 4 (6.15%) had nausea and 3hhad vomited while in midazolam 7 (10.77%) had nausea and 8 (12.31%) had vomited. (Table 3). The incidence of nausea and vomiting between two was not statistically significant.

Base line values taken for hemodynamic stability and compare change during surgery, for mean heart rate, systolic blood pressure, diastolic - blood pressure, mean arterial blood pressure, SpO2 and respiratory rate. (Table 4)

 Table 1: Patient's characteristic and Age wise distribution in Propofol group vs. Midazolam group

		Group			
		Propofol		Midazolam	
		Count	%	Count	%
Age group	≤20 years	6	9.2%	5	7.7%
	21 - 30 years	28	43.1	20	30.8%
	31 - 40 years	14	21.5%	21	32.3%
	41 - 50 years	10	15.4%	10	15.4%
	>50 years	7	10.8%	9	13.8%

 Table 2: Onset of action at target level of sedation in

 Propofol group and Midazolam group

		Group				
		Propofol		Midazolam		
		Count	%	Count	%	
Time of onset of sedation (in Sec)	No	61	93.85%	58	89.23%	
	Yes	4	6.15%	7	10.77%	
	No	62	95.38%	57	87.69%	
	Yes	3	4.62%	8	12.31%	

Table 3: Nausea and Vomiting distribution in Propofol and Midazolam group

		Group				
		Propofol		Midazolam		
		Count	%	Count	%	
Nausea	<60	30	46.15%	0	0.00%	
	60-90	35	53.85%	11	16.92%	
Vomiting	90-120	0	0.00%	44	67.69%	
	> 120	0	0.00%	10	15.38%	

Table 4: Expressing the level of baseline value in P group	
vs. M group	

Vs. M group						
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Indicators monitored	Propofol	Midazolam	P value			
	$(\text{mean} \pm \text{SD})$	(mean \pm SD)				
Heart rate	79.15 ±13.54	82.7 ±8.6	0.234			
Systolic blood pressure	118.6 ± 10.7	115 ±8.1	0.246			
Diastolic blood pressure	74.7 ±7.19	78.1 ±6.2	0.048			
Mean arterial pressure	83.9 ± 7.63	89.9 ±7.3	0.065			
Spo2	98.3 ±1.65	98.6 ±1.2	0.645			
Respiratory rate	16.1 ±2.04	18.1 ±1.3	0.061			

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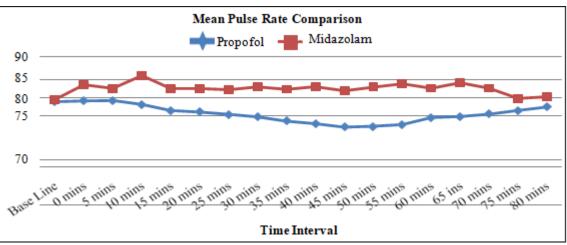


Figure 1: Expressing pulse rate changes between Propofol group and Midazolam gr

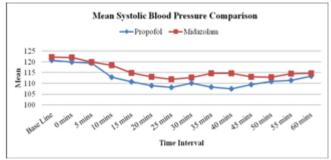


Figure 2: Expressing changes in SBP (MmHg) and comparison during surgery in Propofol and Midazolam Group

4. Discussion

Regulation and maintenance of sedative effect is important aspect which helps in minimizing complication in spinal anaesthesia. In order to improve patient's co - operation and compliance it is necessary to provide some sedative medication during procedure. Incidence of nausea and vomiting varies in incidence rate depending on patient groups, the type of surgery and type of anaesthetic used.

There are many pharmacological methods in practicewhich are useful in decreasing apprehension to various degrees. Both propofol and midazolam have almost all properties which provide advantage over other agents especially in subarachnoid block like rapid onset of action and maintenance. Propofol has a good antiemetic effect and less incidence of nausea for the procedures carried out under regional anesthesia both intraoperatively and postoperatively.

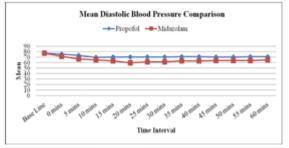


Figure 3: Expressing changes in DBP (MmHg) and comparison between Propofol and Midazolam group

Chamorro et al (1993) ⁷concluded that Propofol is an effective and safe alternative for sedation, with some advantages, such as a short duration of action and high effectiveness over the conventional regimen with benzodiazepines and opiates.

Wilson et al (1990)⁸ found that amnesia for the immediate postoperative period was significantly greater after Midazolam.

Sousan Rasooli et al (2014) ⁹ concluded that Sub - hypnotic doses of midazolam and/or propofol are effective in the prevention of incidence of vomiting and nausea during and after caesarean section with spinal anesthesia and does not significantly influence hemodynamic of the patients.

Monika Danielak et al (2016)¹⁰ studied the sub hypnotic dose of propofol and midazolam during spinal anesthesia for elective caesarian section and observed good sedative effects for both agents and also rapid onset and fast recovery with propofol.

5. Conclusion

We concluded that propofol has rapid onset and recovery of sedation and less incidence of nausea and vomiting compared to midazolam.

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