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ORIGINAL ARTICLE

Comparison of Mean Time Required to Achieve Sedation in Patients Undergoing Surgery in Spinal Anaesthesia Treated with Propofol vs. Midazolam

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ABSTRACT

Objective: To compare the mean time required to achieve sedation in patients undergoing surgery in spinal anaesthesia treated with propofol vs. midazolam.

Study Design: It was a randomized controlled trial

Setting: Research was conducted at Department of Anesthesiology Lahore General Hospital, Lahore from 12/03/2020 to 11/09/2020.

Materials and Methods: This study involved 60 patients of both genders aged between 18-60 years belonging to ASA class I and II undergoing spinal anesthesia for groin surgery which were randomly divided into two treatment groups. Patients in Group-P received propofol while those in Group-M received midazolam for sedation. Outcome variable was mean time to sedation which was noted in minutes from the moment of administration of drug till the patient achieved sedation score of 4.

Results: The mean time to sedation was significantly shorter in patients receiving propofol as compared to midazolam (4.30±1.24 vs. 7.57±2.19 minutes; p-value<0.001). Similar significant difference was observed between the groups across various subgroups based on patient's age, BMI, diabetic and ASA status.

Conclusion: In the present study, propofol was found superior to conventional practice of midazolam in terms of significantly shorter mean time to achieve sedation in patients undergoing groin surgery under spinal anesthesia which along with its well established safety profile advocates the preferred use of propofol to relieve patient's anxiety in future anesthetic practice.

Keywords: Propofol, Midazolam, Sedation, Spinal Anesthesia

INTRODUCTION

Spinal anesthesia is frequently performed anesthesia during various surgical procedures due to its safety and efficacy. During and after surgery the metabolic and inflammatory alterations are directly linked to the extent of tissue damage caused by surgery. These inflammatory stressors may be prevented or inhibited by blocking SA's sympathetic and somatic inhibition.[1,2] The lowest gauge needle available is recommended for all patients, including those at high risk of PDPH who need a non-cutting needle. Complications of spinal anaesthesia hypotension, vomiting and nausea, hematoma, hearing loss of low frequency, spinal hematoma, neurological injury, transient neurological syndrome, arachnoiditis and total spinal anaesthesia.[3,4]As a general rule, pre- and postoperative anxiety are exacerbated by concerns about surgery and anaesthesia. An overactive autonomic nervous system can cause hypertension, arrhythmias, and palpitations as symptoms. An increased risk of postoperative problems (nausea, vomiting and pain) has also been seen in patients who had more preoperative anxiety than those who had a lower level of worry.[5,6,7]

Patki et al. in 2011 conducted a study on comparison of mean time required to achieve sedation in patients undergoing surgery under spinal anaesthesia treated with propofol vs. midazolam was 6.62±1.091 minutes vs. 10.1±1.373 minutes respectively: p <0.001 8.

As certain drugs are used to cause transient loss of consciousness and anxiety to get rid of these obstacles, but they also have side effects. There is no local publish data present on this topic to the best of candidates knowledge and as proven in the study that propofol has shorter duration to reach desired sedation so there is a need to conduct this study in local population. If the result of present study also confirms that propofol reduces mean time required to achieve sedation in patients undergoing surgery in spinal anesthesia, it will enable us to use this drug regularly to reduce anxiety and physiological trauma in these patients.

MATERIAL AND METHODS

After taking permission from Institutional Review Board of the hospital this randomized controlled trial was conducted at Research was conducted at Department of Anesthesiology Lahore General Hospital, Lahore from 12/03/2020 to 11/09/2020. Informed written consent was obtained from the patients. Sample size of 60 patients was estimated with power of test 80% and confidence interval 95% while taking mean time to acquire sedation in patients undergoing surgery under spinal anesthesia treated with propofol vs. midazolam to be 6.62±1.091 minutes vs. 10.1±1.373 minutes respectively.[8] Patients with ages in the range of 18-60 years with ASA grades I-II undergoing surgery in spinal anesthesia were included in this study. Patients with bleeding disorder (INR >1.0), cardiac failure (ejection fraction <45%), pulmonary dysfunction (FEV1 <80% of normal), renal dysfunction (serum creatinine >1.2mg/dl) and TLC >13,000 were excluded. Propofol was administered to group-P, and midazolam was administered to group-M, all of the patients.

Ringer's lactate infusion was started with an intravenous cannula put into the patient's dorsum of the hand under aseptic conditions. To administer the research medicine, a second wide bore intravenous access was set up on the opposite limb's forearm. Using a 50-milliliter syringe filled with 5 percent dextrose and 1 milligramme of propofol or midazolam at an infusion rate of 6 milligrammes per kilogramme per hour, the drugs were administered. Time was calculated from the time of start of injection of the drugs till the sedation level 4 was achieved as per operational definition. Pulse and blood pressures were noted 5 minutes before starting this procedure and 15 minutes after the administrations of the drugs. An injection of bupivacaine 0.5 percent was administered via a 25-gauge spinal needle five minutes after starting the sedative infusion in order to create an appropriate sensory block for the planned procedure. Ten minutes following the spinal medication injection, the best amount of sensory block was determined. After completing the procedure, In order to facilitate recuperation, the patients were relocated to the recovery room and complaints of nausea and vomiting were recorded for next 2 hours.

SPSS 21.0 was used to enter and evaluate all of the gathered data. The mean±SD was used to present numerical data. The frequency and percentage of categorical variables were

calculated . For effect modifiers, data has been stratified by age, BMI, ASA (I/II) and diabetes status. The post-stratification t-test found that a p-value of 0.05 indicated statistical significance.

RESULTS

Patients ranged in age from 18 to 60 years old, with a mean age of 45.37 years old. With a mean BMI of 26.71 kg/m^2, these individuals had a BMI of 22.3 kg/m^2 to 34.0 kg/m^2. 11 (18.3%) patients were obese while 17 (28.3%) were diabetic. 37 (61.7%) patients belonged to ASA Class-I and 23 (38.3%) patients belonged to ASA Class-II as shown in Table 1. The mean time to sedation was significantly shorter in patients receiving propofol as compared to midazolam (4.30±1.24 vs. 7.57±2.19 minutes; p-value<0.001) as shown in Table 2. Table 3 shows that there was a significant difference between the groups depending on the patient's age, BMI, diabetes, and ASA status.

Table 1: Baseline Characteristics of Study Population

Parameters	Characteristics	Participants
Age (years)	Mean ±SD	45.37±13.32
	18-39 years	19 (31.7%)
	40-60 years	41 (68.3%)
Gender	Male	
	Female	
BMI	Mean BMI	26.71±3.24
	Non-obese	49 (81.7%)
	Obese	11 (18.3%)
ASA Class	Class-I	37 (61.7%)
	Class-II	23 (38.3%)
Diabetes	Yes	17 (28.3%)
	No	43 (71.7%)

Table 2: Comparison of mean time to sedation between the study groups

	Propofol (n=30)	Midazolam (n=30)	P-value
Mean Time to Sedation (minutes)	4.30±1.24	7.57±2.19	<0.001*

The observed difference, as determined by an independent sample t-test*, was statistically significant.

Table 3: Comparison of mean time to sedation between the study groups across various subgroups

Variables	Subgroups	Propofol (n=30)	Midazolam (n=30)	P-value
Age	18-39 years	4.20±0.92	7.33±2.78	0.004*
	40-60 years	4.35±1.39	7.67±1.96	<0.001*
BMI	Non-Obese	4.33±1.20	7.56±2.10	<0.001*
	Obese	4.17±1.47	7.60±2.88	0.031*
Diabetes	Yes	4.25±1.75	7.67±2.40	0.005*
	No	4.32±1.04	7.52±2.16	<0.001*
ASA Status	ASA-I	4.39±1.04	7.63±2.09	<0.001*
	ASA-II	4.17±1.53	7.45±2.46	0.001*

The observed difference, as determined by an independent sample t-test*, was statistically significant.

DISCUSSION

In the present study, a 45.37±13.32 year was the mean age of the patients undergoing surgery of hernia. A similar mean age 46.7±11.9 years has been described by Sandhya et al.[9] (2013) among such patients at Jinnah Postgraduate Medical Centre, Karachi. A restively higher mean age of 48.3±8.3 years has been observed by Marwat et al.[10] (2013) among patients undergoing inguinal hernia surgery at Gomal Medical College, DI Khan while Hanif et al.[11] (2014) reported a relatively younger mean age of 42.9±15.3 years among such patients presenting at Benazir Bhutto Hospital, Rawalpindi. Our results are also relate with Rao et al.[12] (2016) who reported similar mean age of 45.0±22.9 years among Indian patients undergoing inguinal hernia surgery. A similar mean age of 42.0±11.6 years has been reported by Hasan et al.[13] (2018) among Bangladeshi patients undergoing surgery for inguinal hernia. Ismail et al.[14] in 2009 (46.1±14.1 years) in Nepal and Ozgün et al.[15] in 2002 (46.9±19.8 years) in Turkey also reported similar mean age among such patients.

We observed that among patients with inguinal hernia 18.3% patients were obese. Safirullah[16] in a similar local study at Landikotal Khyber Agency reported that 16.6% of patients with inguinal hernia were obese. Pervaiz et al.[17] (2017) reported the frequency of obesity among hernia patients to be 18.2% in local population while Balamaddaiah et al.[18] (2016) reported it to be 17.9% in Indian such patients.

In the present study 28.3% of inguinal hernia patients were diabetic. A comparable frequency of diabetes among patients of inguinal hernia has been reported by Memon et al.[19] (2017) who reported it to be 20.7% at Peoples University of Medical & Health Sciences, Nawabshah. A relatively higher frequency of diabetes has been observed by Balamaddaiah et al.[20] (2016) who reported it to be 31.6% in Indian such patients. Much higher frequency of 43.2% and 64.0% has been reported by Hasan et al.[13] (2018) and Roy et al.[20] (2016) respectively in Bangladeshi such patients.

We observed that 61.7% of hernia patients belonged to ASA Class-I and 38.3% patients belonged to ASA Class-II. Our findings are consistent with those of Safirullah[16], who found that 58.3% and 41.7% of hernia patients in Landikotal Khyber Agency were ASA-I and ASA-II, respectively. Memon et al.[19] reported similar distribution of ASA-I (65.0%) and ASA-II (35.0%) patients presenting with inguinal hernia at PUMHS, Nawabshah.

Our findings are in agreement with Patki et al.[8] (2011) who also observed similar significantly shorter mean time to achieve sedation in patients undergoing surgery under spinal anesthesia treated with propofol vs. midazolam (6.62±1.091 vs. 10.1±1.373 minutes: p-value<0.001).

Ulmer et al.[21] (2003) in a similar trial in patients undergoing colonoscopy reported similar significantly shorter mean time to achieve sedation in patients treated with propofol vs. midazolam (2.1±0.7 vs. 6.1±3.0 minutes; p-value<0.0001) in line with the present study.

Similar results have also been reported by Kewon et al.[22] (1997) who compared mean time to achieve sedation between propofol and midazolam (194.5±34.0 vs. 277.0±51.2 sec; p-value≤0.05) in patients undergoing surgery under local anesthesia.

A very major limitation to this study was that we didn't assess the mean time required to full patient's recovery at the end of procedure as that would affect the patient's rehabilitation in the post-operative period.

CONCLUSION

Propofol was found superior to conventional practice of midazolam in terms of significantly shorter mean time to achieve sedation in patients undergoing groin surgery under spinal anesthesia which along with its well established safety profile advocates the preferred use of propofol to relieve patient's anxiety in future anesthetic practice.

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