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Effectiveness of Endoscopist-Directed Nurse-Administered Propofol Sedation (EDNAPS) for EGD, Colonoscopy and MRCP: A Prospective Study in 929 Patients

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ABSTRACT

Background/objectives: *The aim of our study was to review the safety and effectiveness of Endoscopist-directed nurse-administered propofol sedation (EDNAPS) during GIT endoscopic procedures, occurrence of major and minor adverse events followed by propofol sedation, level of patient satisfaction and possible choice of propofol as sedative agent in their future endoscopic procedures in Pakistani population.* ***Materials and methods:*** *Prospective data were collected from patients receiving diagnostic AGD, colonoscopy or ERCP. Subjects who stopped the emergency procedure or both EGD and colonoscopy were excluded on the same date. Other exclusions include over 20 years of age, pregnancy, the American society of associate psychologists (ASA) Class III or IV, overweight (body weight>100kg), or drugs or its components or components (Soybean or egg) allergies included.* ***Result:*** *In our study a total of 929 patients comprising 520 males (56%) and 409 females (44%) with mean age of 46.19 ± 15.3years, mean MBI 24.27 ± 2.7. Age-specific propofol dosage was similar across gender except for age group 60 years and above where higher mean propofol dosage was required for females as compared to males for EGD and Colonoscopy (82.8 ± 32.2 vs. 63.5 ± 29.8; p-value 0.005; 81.1 ± 26.1 vs. 75.3 ± 25.0; p-value 0.03). The required examination was completed in all cases. There was no major adverse event. Majority of the patients rated the procedure satisfactory and agreed to undergo same sedative for next time.* ***Conclusion****: Endoscopist-directed nurse-administered propofol sedation (EDNAPS) during GIT endoscopic procedures is safe and effective in selected patients.*

Keywords: Propofol sedation, Endoscopy, Blood, Cardiopulmonary

INTRODUCTION

Nowadays, sedation is being used during most of the GIT endoscopic procedures. Old traditional agents like benzodiazepines and opioids were used for this purpose but now the trend has been changed in most of the countries where propofol is becoming popular for short term procedures like GIT endoscopy because of unique pharmacokinetic properties of propofol [1,2].

Propofol (2,6-diisopropyl phenol) is the substituted alkyl phenol derivative that potentiates the activity of GABA-A receptor in the brain. Its onset of action is very instantaneous (0.5-1 min) because it is highly lipid-soluble and readily cross the blood-brain barrier. To induce sedation, propofol serum level should be greater than 1 mg. It is rapidly metabolized in the liver via conjugation and hydroxylation. Its metabolites are excreted through kidneys. Half-life of propofol is 2-4 minutes and there is rapid recovery after interruption of its infusion as its effects are dose-dependent [3-5].

Propofol has its narrow therapeutic window and larger doses when used alone may produce cardiopulmonary complications like respiratory depression, apnea, and clinically significant hypotension. Furthermore, there is no clinical antagonist available until present. Therefore, it is highly recommended that propofol administration should be done by trained anesthetics and staff nurse with cardiopulmonary support available [6,7].

However, if overdosage occurs, the patient can recover easily by simply dose reductions by interruption of dose infu-

sion. Moreover, dose should be reduced in elderly patients. Thus, instantaneous onset of action and very rapid and predictable recovery period of propofol has very good impacts on satisfaction of patients, generally follow of endoscopy unit and post-procedure education. All these features make propofol popular for use for short term procedures like GIT endoscopy [8]. Met analysis in 2005 and 2013 provides a shorter recovery time and better sedation compared traditional sedative agents without increasing the risks of cardiopulmonary complications [9,10].

The aim of our study was to review the safety and effectiveness of propofol during GIT endoscopic procedures in the Pakistani population. We also compared the level of patient satisfaction and a possible choice of propofol as a sedative agent in their future endoscopic procedures. In this study, we also collated the occurrence of major and minor adverse events followed by propofol sedation. We also demonstrated the possible effects of propofol on respiratory rate, pulse rate, systolic and diastolic blood pressure, partial oxygen saturation and recovery time.

MATERIALS AND METHODS

Study Design

The hospital policy of regular discharge is a regular activity one hour after propofol monosedation for EGD the colonoscopy was approved by the Ethics Committee of Lahore General Hospital, Lahore, Pakistan. Based on many studies, the upper limit of 200 mg was set for these patients for early exit allowed. Prospective data were collected from patients receiving diagnostic AGD or colonoscopy. Verbal or written informed consent for endoscopic procedures.

Study Population

The study was performed at the Lahore General Hospital, Lahore, Pakistan and included patients who underwent EGD or colonoscopy. Subjects who stopped the emergency procedure or both EGD and colonoscopy were excluded on the same date. Other exclusions include over 20 years of age, pregnancy, the American society of associate psychologists (ASA) Class III or IV, overweight (body weight>100 kg), or drugs or its components or components (Soybean or egg) allergies included.

Procedure of Study

EGD or colonoscopy was performed in the left restorative decubitus position. Propofol administered by a nurse by butterfly needle injection using standard protocol adjusted from 60 mg to 80 mg for subjects younger than 70 years, 70 to 89 years for 40 mg to 60 mg and 20 mg for older than 90 years or more. The depth of the sedation was considered as moderate, as follows: (1) the subject is fully responded to with verbal injunctions; (2) the airway is patented, and sudden ventilation is appropriate, and (3) Cardiovascular function is unaffected. When the target level was not achieved or subjects were pending, an additional injection of 20 mg propofol was added up to 200 mg.

Heart rate, respiratory rate, the partial pressure of oxygen (SpO_2), systolic and diastolic blood pressure and temperature were measured before, during and after the procedure and maintained throughout the procedure. After monotherapy endoscopic procedure, the subject was moved to the recovery room. Full recovery was assessed by evaluating using 2 criteria: level of consciousness (complete awareness and answering questions asked by nurse in recovery room), and the ability to walk in a straight line without instability for up to 5 m. Subjects were discharged after 1 hour of procedure.

Materials

All EGDs and colonoscopies were performed by one of 3 endoscopists, each performing more than 500 procedures each year. An Olympus GIF-XP240, GIF-XQ260, or GIF-H260 Videocope (Olympics Medical System, Tokyo, Japan) was used for EGD. The diameters of the entries were 7.7 mm, 9.0 mm, or 9.5 mm. All the clips have a static channel diameter of 2.8 mm, a length of 1335 mm, and a length of 1030 mm. The Olympus PCF-Q260AI or PCF-Q260AZI video capsules were used for colonoscopy and had an insertion diameter of 11.3 or 11.8 mm, instrument channel of 2.8 or 3.2 mm, and a working length of 1330 mm.

Outcomes

The primary outcome was the occurrence of any adverse event occurring within 24 hours after EGD or colonoscopy. Secondary outcome measures included successful procedures, respiratory depression, and other adverse event rates during the execution.

Statistical Analysis

Statistical package of social sciences (SPSS version 22) for windows was used to analyze data. Mean ± Standard deviation were calculated for quantitative variables like age and propofol dose. Frequency and percentages were calculated for qualitative variables like gender, the satisfaction of patients and adverse events. Stratification was done on gender, age, and type and duration of procedure to control the bias in study. Chi-square was applied to find out any association between different variables. A p-value ≤ 0.05 will be considered statistically significant.

RESULTS

In our study, a total of 929 patients comprising 520 males (56%) and 409 females (44%) with mean age of 46.19 ± 15.3 years, mean MBI 24.27 ± 2.7, mean propofol dose used 87.19 ± 39.98. Mean systolic blood pressure, mean diastolic blood pressure, SpO_2, Pulse rate before, during and after the procedure are given in Table 1 along with Mean procedure time and recovery period.

Table 1 Mean systolic blood pressure, mean diastolic blood pressure, SpO_2, Pulse rate before, during and after the procedure with Mean procedure time and recovery period

Variables	Mean	Std. Deviation
Age	46.1938	15.30456
BMI	24.278	2.7056
Propofol Dose	87.19	39.986
Systolic Blood Pressure Before Procedure	130.33	20.82
Diastolic Blood Pressure Before Procedure	76.0614	11.03011
Systolic Blood Pressure During Procedure	124.6265	20.37978
Diastolic Blood Pressure During Procedure	72.62	9.84
Systolic Blood Pressure During Procedure	121.21	19.064
Diastolic Blood Pressure After Procedure	71.79	10.819
SpO_2 before Procedure	97.84	1.433
SpO_2 during Procedure	96.62	5.058
SpO_2 after Procedure	96.5	4.969
Pulse Rate before Procedure	88.47	13.553
Pulse Rate during Procedure	84.68	13.328
Pulse Rate after Procedure	84.2	13.518
Respiratory Rate before Procedure	20.34	3.014
Respiratory Rate during Procedure	18.86	2.254
Respiratory Rate after Procedure	18.93	2.547
Recovery Time	1.49	0.5
Procedure Time	15.18	9.289

Out of 929 patients, 340 (36.6%) patients fall in ASA-I, 420 (45.2%) in ASA-II and 169 (18.2%) patients in ASA-III. Most common procedures performed were EGD 725 (78%), Colonoscopy 158 (17%), ERCP 43 (4.6%) and EUS 3 (0.3%) patients as indicated in Bar chart 1.

Bar Chart 1 Showing the Types of Procedures Performed

Most of the endoscopy procedures were indicated for UGIB 312 (33.6%), Follow up EGD 184 (19.8%), Epigastric pain 178 (19.2%), Dysphagia 42 (4.5%), Obstructive jaundice 31 (3.3%), S.EGD 4 (0.4%) and others indications were 178 (19.2%) to the patients included in our study as indicated in Bar chart 2.

Bar Chart 2 Showing the Indications of Procedures Performed

Level of sedation (MOAA/S) was mild in 106 (11.4%) patients, moderate in 665 (71.6%) patients and deep in 158 (17%) patients undergoing different endoscopic procedures and interventions. No adverse events were noted in 839 (90.3%) of the patients. Minor adverse events (BP<100 mmHg and Hypoxia) were seen in 82 (8.8%) patients while major adverse effects (Bradycardia<50 b/min, BP<90 mmHg, SpO_2<85% and Need for ETT) were seen in 8 (0.9%) patients.

No intervention was taken in 258 (27.8%) patients due to either reason, Biopsy was performed in 233 (25.1%) pa-

tients, Banding in 382 (41.1%), Stenting in 35 (3.8%), Dilatation in 14 (1.5%) and others interventions were 7 (0.8%) patients. The procedure was completed in 921 (99.1%) of the patients while it remained incomplete in 8 (0.9%) of the patients. Mask ventilation was required by only 6 (0.6%) patients while remaining 923 (99.4%) patients remained stable during the procedure and they did not require mask ventilation 923 (99.4%) patients were satisfied with propofol sedation for endoscopy procedures and they while 6 (0.6%) patient remained unsatisfied and they refused to have propofol sedation in future, 10 (1.1%) patients had adverse effects within 24 hours of the procedure while majority of the patients 919 (98.9%) did not have adverse events within 24 hours.

833 (89.7%) patients face no complication during the procedure while minor complications including BP<100 mmHg and Hypoxia occurred in 62 (6.7%) and 15 (1.6%) patients respectively. Major complications including Bradycardia<50 b/min, BP<90 mmHg, SpO_2<85% and Need for ETT occurred in 3 (0.3%), 8 (0.8%), 2 (0.2%) and 6 (0.6%) patients respectively (Table 2).

Table 2 Complications during the procedure

	Frequency	Percent (%)	Valid Percent (%)	Cumulative Percent (%)
No Complication	833	89.7%	89.7%	89.7%
BP<100 mmHg	62	6.7%	6.7%	96.3%
Hypoxia	15	1.6%	1.6%	98.0%
Bradycardia<50 b/min	3	0.3%	0.3%	98.3%
BP<90 mmHg	8	0.9%	0.9%	99.1%
SpO_2<85%	2	0.2%	0.2%	99.4%
Need for ETT	6	0.6%	0.6%	100%
Total	929	100%	100%	

By applying T-test we find a statistically significant relationship with p-value 0.044 (<0.05) between propofol sedation and level of patient satisfaction as shown in Table 3. Chi-Square Test results showed a statistically significant association between satisfaction of patients undergoing different endoscopic procedures and type of endoscopic procedures, indication of procedure, level of sedation, procedure completed, mask ventilation required and use of propofol sedation again for next time, With p<0.05 except gender of patients, pre-procedure risk of anesthesia (ASA classes), intervention and adverse effects within 24 hours of procedure.

Table 3 Propofol sedation for endoscopy procedure satisfactory

Indication of procedure	Did you find propofol sedation for your endoscopy procedure satisfactory?		Total	p-value
	Yes	No		
UGIB	308	4	312	<0.05
Follow up EGD	184	0	184	
Epigastric Pain	178	0	178	
Dysphagia	42	0	42	
Obstructive jaundice	29	2	31	
S.EGD	4	0	4	
any other	178	0	178	
Total	923	6	929	

DISCUSSION

To perform an endoscopic procedure under sedation has shown increased patient compliance and comfort, and the majority of procedures are now carried after administering the recommended dose of sedatives to the patients undergoing routine gastrointestinal endoscopic procedures. Our study did not report any major risk associated with the use of propofol when administered to the patients, this was well supported by a meta-analysis in which endoscopist administered the required doses of propofol, that leads to reduced risk of associated procedural complications. Several studies in which propofol was administered by nurse for sedation showed minimal associated adverse events.

Since 2010 administration of propofol to patients undergoing any gastrointestinal endoscopic procedure can be led by a trained nurse, which in our studies further conferred that nurse administered propofol is indeed safe in ambulatory care gastroenterology practice. As described in the methods propofol was administered following the ASA classification, and sedation protocol strictly following the guidelines. To decrease the rate of any respiratory event all the patients were given supplemental oxygen. Also, respiratory rate, pulse rate, systolic and diastolic blood pressure, partial oxygen saturation and recovery time were found to be in satisfactory range without any major complications in most of the patients.

This study was performed in a highly controlled manner but however, if overdosage occurs, the patient can recover easily by simply dose reductions by interruption of dose infusion. Moreover, dose should be reduced in elderly patients. Thus, instantaneous onset of action and very rapid and predictable recovery period of propofol has very good impacts on satisfaction of patients, general follow of endoscopy unit and post-procedure education. All these features make propofol popular for use for short term procedures like GIT endoscopy [7]. Met analysis in 2005 and 2013 provides a shorter recovery time and better sedation compared traditional sedative agents without increasing the risks of cardiopulmonary complications which supports our study results [9,10]. Routine gastrointestinal endoscopic screening procedures are carried out across multiple tertiary care hospital settings in Pakistan, yet there is minimal published data with respect to this part of the world regarding outcomes and post-procedure patient satisfaction. This study explored the safety and effectiveness of Endoscopist-directed nurse-administered propofol sedation (EDNAPS) in low-risk patients undergoing routine gastrointestinal endoscopic procedures.

The aim of our study was to review the safety and effectiveness of propofol during GIT endoscopic procedures in Pakistani population which were concluded to be safe and cost and time effective in majority of patients. We also compared the level of patient satisfaction and a possible choice of propofol as sedative agent in their future endoscopic procedures which was considered and found to be the choice of patients. In this study, we also collated the occurrence of major and minor adverse events followed by propofol sedation. We also demonstrated the possible effects of propofol on respiratory rate, pulse rate, systolic and diastolic blood pressure, partial oxygen saturation and recovery time and our study did not report any major risk associated with the use of propofol when administered to the patients, this was well supported by a meta-analysis in which endoscopist administered the required doses of propofol, that leads to reduced risk of associated procedural complications. Several studies in which propofol was administered by nurse for sedation showed minimal associated adverse events [11,12].

CONCLUSION

Endoscopist-directed nurse-administered propofol sedation (EDNAPS) during GIT endoscopic procedures is safe and effective in selected patients.

DECLARATIONS

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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