Safety Profile and Patient Satisfaction of the Routine use of Propofol in Gastrointestinal Endoscopy.

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Citation

Gurung RB, Purbe B, Malla B, Dhungel A,Yogol S, Poudel A, et al. Safety Profile and Patient Satisfaction of the Routine use of Propofol in Gastrointestinal Endoscopy. *Kathmandu Univ Med J* 2014;46(2):101-5.

ABSTRACT

Backgroud

Routine use of sedation in upper gastrointestinal endoscopy is uncommon in Nepal. There is no study on use of propofol sedation in routine endoscopy examination in Nepal. This study was conducted in order to assess the patient satisfaction and safety profile in patient undergoing routine upper GI endoscopic examination on outpatients.

Objective

To study safety profile and patient satisfaction of use of propofol in patients undergoing upper GI endoscopy.

Method

A prospective, observational study was conducted in the endoscopy unit of Dhulikhel hospital, Kathmandu University Hospital from July 2011 to 2012 July. Patients who were referred to upper GI endoscopy were offered to sedation under propofol. Informed consent was taken after explaining side effects, advantages and risk-benefit to the clients. The propofol was administered by the endoscopy nurse under guidance and supervision of the endoscopy performing physician.

Data were collected and analyzed using SPSS version 16.0 with 0.05 level of significance.

Result

Total of 203 patients included in the study. Among 203 patients, 21. 2% were males and 78.8% were females; 83.7% were of less than of 60 years age and 16.3% above 60 years of age. The mean total dose of propofol required was 136.08 ± 48.82 mg. Total of 29.1 % of cases required O_2 administration during the procedure time due to transient drop in O_2 saturation. Total of 4.4% of cases required fluid administration due to transient fall in blood pressure. Total of 68.0% of cases were completely sedated; 28.6% had minor restless and 3.4% showed agitation during induction period of propofol sedation. Total of 99.5% of patients reported pleasant experience while 0.5% reported unpleasant. Among 203 respondents, 98.5% responded they would prefer to do the procedure under propofol sedation in the future; 1.5% responded they did not want sedations in the future.

Conclusion

Upper GI endoscopy can safely be performed under propofol sedation administered by registered trained nurse under the supervision of endoscopist.

KEY WORD

Endoscopy, patient safety, patient satisfaction, propofol sedation

INTRODUCTION

The use of intravenous sedation in routine gastrointestinal endoscopy in Nepal is uncommon. The upper GI endoscopy is commonly performed under pharyngeal Xylocain spray or gargle. As a sedative, the midazolam and the opiods are probably the agents employed by many endoscopists in Nepal. Although, the diagnostic upper GI endoscopy can be performed in most of the patients without intravenous sedation, the patient discomfort and un-cooperation is frequently encountered during the procedure resulting in compromisation with the quality of assessment and risk of incomplete examination. On the other hand, the use of benzodiazepam and opiods though effective and safe, has potential to cause longer post-procedure sedation and psychomotor in-coordination rendering the patients especially coming from far-off places or patients on automobile difficult or unsafe to return their home.

Propofol, (or 2-6 diisopropylphenol) is an ultrashort acting sedative hypnotic agent that has received increased attention for use during endoscopy.[1-7] Propofol has a shorter time to recovery and, hence, earlier discharge from the endoscopy unit. Patients who receive propofol (half-life 2 min to 4 min) as a single agent recover normal neurological and social functioning significantly quicker than benzodiazepines (half-life 30 min) and/or narcotics (half-life 3 h to 4 h). Therefore, a quicker onset of action and less patient discomfort; both of which benefit the endoscopist and the patient .[8-10]

Several studies have addressed the safe and effective use of propofol during gastrointestinal endoscopy, by either physicians or trained nurses. In 2005 the cumulative reported experience with non-anesthesiologists-administered propofol during gastrointestinal endoscopic procedures was more than 80 000 patients. [11-14] However, there are no studies on use of propofol in routine upper GI endoscopy practice in Nepal.

This study was conducted in order to assess the patient satisfaction and safety profile in patient undergoing routine endoscopic examination on outpatients

METHODS

A prospective, observational study was conducted in the endoscopy unit of Dhulikhel hospital, Kathmandu University hospital from July 2011 to 2012 July. Patients who were referred to upper GI endoscopy were offered to sedation under propofol. Informed consent was taken after explaining side effects, advantages and risk-benefit to the clients. The propofol was administered by the endoscopy nurse under the guidance and supervision of the endoscopy performing physician.

All the patients who gave written consent for use of propofol were enrolled. The exclusion criteria were: 1) patient with underlying cardio-respiratory diseases; 2) Unstable vital signs; 3) emergency conditions; 4) patient without a companion; and 4) patient who was unwilling or reluctant to have sedation after explanation.

After a thorough examination by the physician, the propofol was administered by the registered nurse who was trained in IV propofol sedation, monitoring and securing the basic airway maneuvers. Two nurses were employed: one for propofol administration and monitoring, and another for assisting the endoscopist. The continuous O_2 saturation and pulse rate was monitored and recorded in the chart every two minute. Blood pressure was measured before administration of propofol and every five minute and at the end of procedure. Any change in O_2 sat, pulse rate and blood pressure was informed to the physician and prompt appropriate actions were taken. The O_2 supply, ambu bag and intubation set were ready at the patients side.

Propofol administration:

The propofol was administered as follow: an initial dose of 30–50 mg was followed by doses of 10–20 mg after 1 to 2 min later. Additional bolus doses was determined by the level of sedation and continuous clinical monitoring of vitals . The initial bolus dose was not exceeded more than 60 mg. The total dose of propofol, level of sedation, total duration of sedation and procedure time and recovery time were all recorded. Intra-procedural adverse events, interventions in the form of O_2 administration, IV fluid administration, ambu-bagging/intubation were all documented. Interview with the patient on post-procedural effects and experience was obtained after full recovery. After the full recovery, all the patients were asked if they would prefer sedation should they have to repeat endoscopy in the future.

Data were collected and analyzed using SPSS version 16.0 with 0.05 level of significance.

RESULTS

Total of 203 patients who underwent upper GI endoscopy under propofol sedation administered by registered nurses were included in this study. Out of 203 patients, 83.7% were of less than of 60 years age. Among 203 patients, 21. 2% were males and 78.8% were females (Table 1).

Table 1. Demographic variables N=203

Variables	Number	Percentage
Age		
</=16 years	10	4.9
17-24	43	21.3
25-40	55	27.1
41-60	62	30.5
60 and above	33	16.3
Sex		
Male	43	21.2
Female	160	78.8

Out of 203 cases, 172(84.7 %) had onset of sedation within 2 minutes; 8 (3.9%) within 3 min and 23 (11.4) had onset upto 4 minute. The mean total dose of propofol required was 136.08 ± 48.82 mg. The full recovery from propofol sedation was 15.13± 6.80 min. Total of 138 (68.0%) of cases were completely sedated; 58(28.6%) had minor restless, and 7(3.4%) had agitation during induction period of propofol sedation (Table 2).

Table 2. Dosage and effects of Propofol administration.

Variables	Number	Percent
Onset of sedation		
1min	92	45.3
2min	80	39.4
3min	8	3.9
4 and more	23	11.4
Level of sedation		
Complete	138	68.0
Minor restless	58	28.6
Violent	7	3.4
Mean total dose of propofol	136.08±48.823 mg	
Mean duration of procedure	6.91±5.66 min	
Recovered fully from sedation	15.13±6.80 min	

The mean systolic blood pressure fall was 4.81 mm Hg; the mean pulse rate during the propofol administration was 87 .71 ±13.8 and the mean O_2 saturation during the procedure was 94.89±2.81(Table 3).

Table 3. Change in vital signs during Propofol administration.

Variables	Before procedure (mean±SD)	During Procedure (mean±SD)
Systolic blood pressure	114.29±17.201	109.48 ±14.771
Pulse rate -	83.81±13.95	87.71±13.822
Spo_2	96.75 ±2.315	94.89 ±2.810

In one (0.5%) patient the O_2 saturation dropped below 85%; the O_2 saturation fall was between 86 to 89 % in 8 (3.9%); 90 to 93 % in 32 (15.8%). In 162 (79.8%), there was no significant fall in O_2 saturation during propofol administration (Table 4).

Table 4. SPO_2 changes during procedure N=203

Variables	Number	Percent
Category of SPO_2 changes		
<85%	1	0.5
85-90%	8	3.9
90- 93%	32	15.8
>93%	162	79.8

Total of 59(29.1 %) cases required O_2 administration during the procedure due to transient drop in O_2 saturation; 9 (4.4%) cases required intravenous fluid for the transient fall in systolic blood pressure (Table 5).

Table 5. Respiratory/Circulatory support required during procedure N=203

Variables	Number	Percent
Respiratory support		
Required	59	29.1
Not required	144	70.9
Oxygen therapy (n=59)		
Yes	59	29.1
Circulatory support		
Required	9	4.4
Not required	194	95.6

Post-procedure patient evaluation revealed: 202 (99.5%) reported pleasant experience whereas only one (0.5%) reported unpleasant; 200 (98.5%) of patients responded that they would prefer propofol sedation again if had to undergo endoscopy in the future; only 3 (1.5%) did not want propofol if needed repeat endoscopy examination in the future (Table 6).

Table 6. Patient satisfaction N=203

Variables	Number	Percent
Prefer propofol sedation if repeat in the future		
Yes	200	98.5
No	3	1.5
Experience of propofol sedation		
Pleasant	202	99.5
Unpleasant	1	0.5

DISCUSSION

Although there are several studies on propofol administration in the west our study on nurse administered propofol sedation for routine upper GI endoscopy was first in Nepal. [15-17]

This study which included 203 patients comprised majority of female sex (78.8%); and 83.8% of patients were of age less than 60 years (Table 1). This higher number of younger age and female sex could be due to increased incidence of anxiety related to endoscopy examination resulting in increased willingness to undergo procedure under sedation.

The majority of patients 172 (84.7 %) achieved complete sedation within 1 to 2 minutes (Table 2) with 68 % having complete sedation, while 28.6 % had minor restlessness during intubation, and 3.4 % showed agitation during induction. However, all the patients successfully completed examination and recalled no unpleasant experience which shows the amnestic property of this sedative agent .

In our study, the significant fall in O_2 sat (< 90%) was seen in 9 (4.4 %); however, the effect was transient (less than one minute) and managed with simple airway securing maneuver : chin lift /jaw thrust , and O_2 administration. This finding was comparable and even lower than some of the studies.[18-21] None of the patients required endotracheal intubation, bag-mask ventilation or help by anesthesiologist. In a similar study done in Denmark showed up to 4.4% of patients events of hypoxemia (<92%) and 1.1% needed assisted ventilation and anesthesiologic assistance was requested 10 times. Two patients required endotracheal intubation in this study; however, no mortality was seen in this study .[22]

There was no significant fall in systolic blood pressure in our study. Out of 203 patients, 9 (4.4%) required IV fluid bolus administration for transient fall in systolic blood pressure. No patient required more than 500 ml of normal saline and all patients were discharged after full recovery on the same day. In the study by Jensen JT et al, among the 1764 patients, 554 (31 %) demonstrated a change in systolic blood pressure by more than 20 mmHg. All the episodes were transient (less than 2 min) and managed with saline and trendelenburg maneuver. The mean total dose of propofol required in our study was 136.08 ± 48.82 mg (Table 2); where as in the study by Jensen JT et al it was 347 mg (median 300 mg, range 50 – 1940 mg).[22] This dose difference could also be the reason for more adverse events in this study.

Based on the interview taken at the time of discharge, 98.5 % said they would prefer propofol sedation again if they had to repeat endoscopy in the future. This high rate of satisfaction is attributable to amnestic effect of propofol. In one randomized study comparing propofol with midazolam and fentanyl during upper GI endoscopy , the satisfaction rate was significantly higher in propofol group [22]

Our study has some limitations. The sample size is small compared to most published studies abroad. We enrolled patients mostly younger age group without any cardio-respiratory comorbidities which may explain the lower rate of adverse cardio-respiratory adverse events. Our assessment of patient satisfaction was based on the interview taken on the same day after full recovery.

CONCLUSION

Upper GI endoscopy can safely be administered by registered trained nurse under the supervision of trained physician endoscopist. However, continuous and careful monitoring of O_2, BP and pulse rate along with provision to administer oxygen and secured IV line is mandatory. Nevertheless, extra cost of medicines, and human resources, and potential need for skilled intervention in case of serious cardio-respiratory compromise should be given serious thought before indicating propofol sedation in Nepal.

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