

Endoscopist-administered propofol: A retrospective safety study

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BACKGROUND: Propofol is an anesthetic agent that is commonly used for conscious sedation. Propofol has advantages as a sedative agent for endoscopic procedures including rapid onset, short half-life and rapid recovery time. However, concerns exist regarding the potential for respiratory depression, hypotension, perforation due to deep sedation and the need for monitoring by an anesthetist. Propofol has been used under endoscopist supervision at the Stanton Territorial Hospital in Yellowknife, Northwest Territories since 1996 (approximately 7000 cases).

METHODS: A retrospective chart review of endoscopic procedures conducted at the Stanton Territorial Hospital between January 1996 and May 2007 was performed. A random sample of 680 procedures was reviewed from a total of 6396 procedures.

RESULTS: The mean (\pm SD) baseline systolic blood pressure (SBP) was 122.8 ± 17.0 mmHg. The mean lowest SBP was 101.7 ± 14.5 mmHg. The mean absolute drop in SBP was 21.1 ± 16.7 mmHg, with a mean per cent drop of $16.3\% \pm 11.7\%$. Eighty-eight patients (12.9%) developed transient hypotension (SBP lower than 90 mmHg). All patients regained normal blood pressure spontaneously on repeated measurement. No patients required intravenous fluid resuscitation. The mean O_2 saturation was $96.4\% \pm 2.1\%$. One patient (0.1%) transiently desaturated (O_2 saturation 89%), but recovered spontaneously on repeat measurement with no intervention. No procedures were aborted for patient safety. There were no major complications, including perforation or death. There was one mucosal tear during nontherapeutic colonoscopy (0.1%).

CONCLUSIONS: Propofol can be safely administered in a community hospital setting under endoscopist supervision, with no additional support or monitoring.

Key Words: Anesthesia; Colonoscopy; Endoscopy; Gastroscopy; Propofol; Sedation

Propofol is an anesthetic agent that is commonly used for conscious sedation. It has many characteristics that make it an attractive agent for use in endoscopy including rapid onset, short half-life and rapid recovery time after the procedure. However, a number of questions have been raised concerning potential side effects such as respiratory depression and hypotension, possible perforation due to deep sedation and the

Propofol administré par l'endoscopiste : Étude rétrospective d'innocuité

HISTORIQUE : Le propofol est un anesthésique couramment utilisé pour la sédation consciente. Il a des avantages à titre de sédatif lors d'interventions endoscopiques, notamment un début d'action rapide, une demi-vie brève et un temps de récupération rapide. Par contre, les risques associés à la dépression respiratoire et à l'hypotension, le risque de perforation associé à la sédation profonde et la nécessité d'une surveillance anesthésique peuvent poser problème. Le propofol est utilisé sous la supervision de l'endoscopiste au Stanton Territorial Hospital de Yellowknife, dans les Territoires du Nord-Ouest, depuis 1996 (environ 7 000 cas).

MÉTHODE : Les auteurs ont procédé à une analyse rétrospective des dossiers d'interventions endoscopiques réalisées au Stanton Territorial Hospital entre janvier 1996 et mai 2007. Ainsi, ils ont analysé un échantillon aléatoire de 680 interventions sur un total de 6 396.

RÉSULTATS : La tension artérielle systolique (TAS) de départ moyenne (\pm É.-T.) était de $122,8 \pm 17,0$ mm Hg. La TAS moyenne la plus basse était de $101,7 \pm 14,5$ mm Hg. La baisse moyenne absolue de la TAS a été de $21,1 \pm 16,7$ mm Hg avec une baisse moyenne en pourcentage de $16,3\% \pm 11,7\%$. Quarante-huit patients (12,9 %) ont présenté une hypotension transitoire (TAS inférieure à 90 mm Hg). Chez tous les patients, la tension artérielle est spontanément revenue à la normale lorsqu'elle a été revérifiée. Aucun patient n'a eu besoin de réanimation liquidienne. La saturation moyenne en oxygène était de $96,4\% \pm 2,1\%$. Un patient (0,1 %) a présenté une désaturation transitoire (saturation en O_2 89 %), qui s'était corrigée sans intervention lors du contrôle. Aucune intervention n'a dû être interrompue pour la sécurité du patient. On n'a noté aucune complication majeure, ni perforation ni décès. Une seule laceration muqueuse est survenue lors d'une colonoscopie non thérapeutique (0,1 %).

CONCLUSION : Le propofol peut être administré de manière sécuritaire dans les hôpitaux régionaux sous la supervision de l'endoscopiste, sans autre soutien ou surveillance.

need for concomitant monitoring by an anesthetist (1). The US Food and Drug Administration product label states that "[propofol] should be administered only by persons trained in the administration of general anesthesia." The American Gastroenterological Association Institute Review of Endoscopic Sedation (2) reports that worldwide, the experience with gastroenterologist-directed administration of propofol now

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TABLE 1
Patient demographics (n=680)

Characteristic	Results
Age, years, mean \pm SD	43.2 \pm 15.7
Sex, n (%)	
Male	321 (47)
Female	359 (53)
Comorbidity, n (%)	
Coronary artery disease	10 (1.5)
Cardiovascular risk factor	191 (28.1)
Congestive heart failure	3 (0.4)
Valvular heart lesion	7 (1.0)
Chronic obstructive pulmonary disease	16 (2.4)
Asthma	31 (4.6)
Smoker	107 (15.7)
Home medications, n (%)	
Benzodiazepines	7 (1.0)
Narcotics	20 (2.9)
Benzodiazepines + narcotics	2 (0.3)

exceeds 200,000 patient experiences with no mortalities. These studies generally follow two models for the administration of propofol – either administration by a gastroenterologist (3,4) or by a trained nurse whose sole responsibilities are patient monitoring and the administration of propofol (5-7). This experience, as well as our increased understanding of dosing by titrating to moderate sedation, has led many professional associations to support the use of propofol administration by health care professionals other than anesthesiologists. The American Gastroenterological Association, the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy all support gastroenterologist-directed propofol administration, stating that “with adequate training, physician-supervised nurse administration of propofol can be done safely and effectively” (8). The Canadian Association of Gastroenterology recently published a statement on the use of propofol for sedation that supports the recommendations of the joint American gastroenterology societies (9).

Propofol has been used at the Stanton Territorial Hospital (a community hospital in Yellowknife, Northwest Territories) in approximately 7000 cases between 1996 and 2007. In this setting, propofol was administered by the endoscopist or a trained endoscopy nurse under the supervision of the endoscopist. Propofol was given as an initial bolus of 1 mg/kg to 2 mg/kg. Repeated smaller boluses of 0.5 mg/kg to 1 mg/kg were given to maintain moderate sedation based on patient comfort. The usual interval between boluses was 4 min to 5 min. Two nurses were involved in the procedures – one to administer propofol and monitor the patient, and one to assist with the procedure. All patients received a baseline of 2 L of O₂ by nasal prongs. O₂ saturation (SpO₂) and heart rate were monitored continuously using the Nellcor Puritan Bennett NPB-290 pulse oximeter (Nellcor Puritan Bennett LLC, USA), with a sound alarm set at 85%. Blood pressures were obtained by manual measurement before the procedure, after the procedure and at any time that was clinically indicated (ie, heavy sedation, or change in SpO₂ or heart rate). If the

TABLE 2
Procedure demographics (n=680)

Characteristic	Results
Procedure, inpatient:outpatient, n (%)	
Gastroscopy	26:270 (44)
Colonoscopy	19:277 (44)
Gastroscopy + colonoscopy	4:84 (12)
Acuity, n (%)	
Urgent	34 (5.0)
Intervention, n (%)	
Biopsy or polypectomy	400 (58.8)
Dilation	27 (4.0)
Injection or cautery	4 (0.6)
Variceal banding	1 (0.1)
Duration of procedure, min, mean \pm SD	
Gastroscopy	5.2 \pm 3.0
Colonoscopy	12.3 \pm 6.1
Gastroscopy + colonoscopy	14.6 \pm 6.2

patient was hypotensive, or if the clinician thought there was a significant drop in blood pressure from baseline, blood pressure measurements were repeated immediately. No further boluses of propofol were given if patients were hypotensive.

METHODS

A retrospective chart review of endoscopic procedures conducted at the Stanton Territorial Hospital between January 1996 and May 2007 was performed. A random sample of 680 procedures was reviewed, from a total of 6396 procedures. Charts were selected by health records personnel who were blinded to the intention of the study. Every 10th procedure was chosen from a chronological list of procedures performed in both inpatient and outpatient settings. Patients were considered eligible for the present study if they underwent gastroscopy and/or colonoscopy between January 1996 and May 2007, were 18 years of age or older and received only propofol for sedation. Patients were excluded from the study if they required cardiorespiratory support in the intensive care unit, or if an alternate sedation regimen was used (ie, propofol with narcotic and benzodiazepine, or narcotic and benzodiazepine alone).

Data on patient demographics, procedure demographics, propofol dose administered, and sedation and procedural complications were collected from the endoscopy records of each patient.

RESULTS

Patient demographics

Patient demographics are summarized in Table 1. The mean (\pm SD) age was 43.2 \pm 15.7 years. Three hundred fifty-nine patients (53%) were female and 321 (47%) were male. The population was relatively healthy, with low rates of comorbidities and home use of narcotics and benzodiazepines.

Procedure demographics

Procedure demographics are summarized in Table 2. Procedures included 296 gastroscopies (44%), 296 colonoscopies (44%) and 88 combined procedures (12%). Thirty-four cases (5.0%) were

TABLE 3
Propofol dosing (n=680)

Procedure	Dose, mg, mean \pm SD	Dose, mg/kg, mean \pm SD
Gastroscopy	167.9 \pm 52.7	2.2 \pm 0.6
Colonoscopy	226.9 \pm 60.1	3.0 \pm 0.9
Gastroscopy + colonoscopy	291.6 \pm 86.5	3.9 \pm 1.1

of an urgent nature. Interventions were performed in 432 patients (63.5%), including biopsy or polyp removal in 400 patients (58.8%), dilation in 27 patients (4.0%), injection or cautery in four patients (0.6%) and variceal banding in one patient (0.1%). The mean duration of each procedure (scope in to scope out) was: gastroscopy 5.2 \pm 3.0 min; colonoscopy 12.3 \pm 6.1 min; and combined gastroscopy and colonoscopy 14.6 \pm 6.2 min. Mean discharge time after the procedure (scope out to discharge from unit) was 44.3 \pm 15.5 min.

Propofol dosing

Dosing information is summarized in Table 3. The mean dose for each procedure was: gastroscopy 2.2 \pm 0.6 mg/kg, colonoscopy 3.0 \pm 0.9 mg/kg, and combined gastroscopy and colonoscopy 3.9 \pm 1.1 mg/kg.

Safety data

Safety data are summarized in Table 4. The mean baseline systolic blood pressure (SBP) was 122.8 \pm 17.0 mmHg. The lowest SBP recorded during the procedure was used for statistical analysis. The mean lowest SBP was 101.7 \pm 14.5 mmHg. The absolute drop in SBP was 21.1 \pm 16.7 mmHg, with a mean per cent drop of 16.3% \pm 11.7%. Eighty-eight patients (12.9%) developed transient hypotension (SBP lower than 90 mmHg). All patients regained normal blood pressure spontaneously on repeat measurement. No patients required intravenous fluid resuscitation. The mean SpO₂ was 96.4% \pm 2.1%. One patient (0.1%) transiently desaturated (SpO₂ 89%), but recovered spontaneously on repeat measurement. No patients required more than the baseline supplemental O₂ at 2 L/min. No procedures were aborted for patient safety. There were no major complications, including perforation or death. There was one mucosal tear during non-therapeutic colonoscopy (0.1%).

DISCUSSION

To our knowledge, the present study is the largest to describe the use of endoscopist-directed administration of propofol for sedation during endoscopy in Canada. The results of the present retrospective safety study indicate that adequately trained endoscopists and nurses who are familiar with the use of propofol can administer propofol safely in an outpatient setting, with no additional support or monitoring.

Concerns exist regarding the potential for respiratory depression and hypotension with the use of propofol. This was not observed in our study. One patient (0.1%) transiently desaturated (SpO₂ 89%) and 88 patients (12.9%) developed transient hypotension (SBP lower than 90 mmHg). All patients recovered spontaneously on repeat measurement, with no interventions. The present study's rate of sedation events is comparable with that quoted in the literature for both sedation with propofol and combination benzodiazepine and narcotic (10).

TABLE 4
Safety data

Characteristic	Results
Systolic blood pressure	
Baseline, mmHg, mean \pm SD	122.8 \pm 17.0
Lowest, mmHg, mean \pm SD	101.7 \pm 14.5
Drop, mmHg, mean \pm SD	21.1 \pm 16.7
Drop, %, mean \pm SD	16.3 \pm 11.7
O ₂ saturation, %, mean \pm SD	96.4 \pm 2.1
Sedation event, n (%)	
Systolic blood pressure <90 mmHg	88 (12.9)
O ₂ saturation <90%	1 (0.1)
Total	89 (13.1)

Concerns also exist regarding the theoretical potential for increased rates of perforation due to the possibility of deep sedation using propofol. There were no perforations in our study. One mucosal tear was reported during nontherapeutic colonoscopy. This was treated successfully with conservative measures. The literature cites perforation rates for colonoscopy without therapeutics to be 1.4 in 1000 procedures at a tertiary care teaching hospital (11). As such, our study, which involved 680 patients, was large enough to detect a perforation rate higher than that quoted in the literature. It has also been suggested that if patients are heavily sedated, they might not be able to inform the endoscopy team if they are having increasing pain during the procedure. However, the short half-life of propofol should allow patients to communicate clearly with the endoscopy team in only a few minutes after the last dose of propofol is given. Also, many other cues such as abdominal rigidity and change in vitals would still be available and contribute to the clinical picture as a whole if perforation was suspected.

The final concern regarding the use of propofol during endoscopy is that of patient monitoring and the need for support by anesthesia. At the Stanton Territorial Hospital, where our study was conducted, propofol is given by the endoscopist or a trained endoscopy nurse under direct supervision. All patients receive baseline supplemental O₂ at 2 L/min. SpO₂ and heart rate are monitored continuously, and blood pressure is monitored at regular intervals. Some clinicians purport the need for electrocardiography and capnography. These monitoring devices are not used at our site. The basic level of monitoring used at our site, as described previously, allowed us to identify sedation events as discussed above, and no other clinically significant cardiovascular complications occurred.

With the growing body of literature to support the safety of endoscopist-directed administration of propofol, its use is becoming more widely accepted in Canada. Our retrospective study offers a glimpse into the experience at a Canadian community hospital where endoscopist-directed propofol administration has been routinely used for the past 10 years. However, many questions remain that our study was not able to address due to its retrospective nature and the limitations of the study population – a young, healthy population (median age in the Northwest Territories is 31.2 years; 4.8% are older than 65 years [12]) in a community hospital setting. An area for future study is to assess the use of endoscopist-directed administration of propofol in a large, tertiary care setting where a

larger proportion of procedures would be done in an inpatient setting, and potentially in more emergent situations. In our setting, a direct comparison between propofol and a more standard sedation regimen used in Canada, such as a benzodiazepine and/or narcotic combination, was not possible because propofol alone has been used in the majority of endoscopies since 1996. A comparison between these regimens would be interesting to help address any differences in safety, and patient and physician satisfaction. A formal cost-benefit analysis of the use of endoscopist-directed administration of propofol in Canada should also be performed to determine whether the benefits of shorter induction time, more rapid recovery time and potentially faster discharge time outweighs the additional costs of closer monitoring, likely involving an additional nurse whose sole responsibilities are administration of propofol and patient monitoring.

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CONCLUSIONS

Propofol can be safely administered in a community hospital setting under endoscopist supervision. Endoscopists and nurses using propofol should obtain additional education and training before using propofol. Additional work is needed to determine the nature and duration of training that is required to ensure that the widespread use of propofol proceeds safely. Based on our experience, we propose that the minimal standard for training should include advanced cardiac life support training and teaching by an endoscopist, anesthetist or intensivist familiar with the use of propofol.

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