Sedation for endoscopy: the safe use of propofol by general practitioner sedationists

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ABSTRACT

Objective: To determine the incidence of adverse events related to an endoscopy sedation regimen that included propofol, delivered by general practitioner (GP) sedationists.

Design: Audit of reports of sedation-related adverse events in patients undergoing endoscopy. A sample of 1000 patients' medical records was also reviewed to determine the drugs and dosages used and the proportion of sedations delivered by GPs.

Setting and participants: All patients undergoing gastroscopy and/or colonoscopy from January 1996 to December 2000 in two private endoscopy centres in Canberra. Sedation was provided by GPs or a specialist anaesthetist, in most cases using a drug regimen that included propofol.

Main outcome measures: Incidences of respiratory arrest, airway obstruction, hypoxia requiring intervention, hypotension, and death; number of interventions to correct these events, including extra airway management, bag-mask ventilation, intravenous fluid infusion, endotracheal intubation and the use of reversal agents, and admission to hospital.

Results: 28 472 procedures were performed in the five years. There were 185 sedation-related adverse events (6.5/1000 procedures; 95% CI, 5.6–7.4): 107 for airway or ventilation problems (3.8/1000) and 77 hypotensive episodes (2.7/1000). Respiratory-related adverse events were more common in patients managed by GPs than anaesthetists, but this was not significant ($P = 0.1$). Interventions were recorded in 234 patients (8.2/1000; 95% CI, 7.2–9.3): 123 to maintain ventilation, and 111 intravenous infusions. GPs were more likely than anaesthetists to intervene to manage respiratory-related adverse events ($P = 0.03$). Four patients required transfer or admission to hospital. No patients required endotracheal intubation, and there were no deaths.

Conclusions: The GP sedationists encountered a low incidence of adverse events, which they managed effectively. It appears that appropriately selected and trained GPs can safely use propofol for sedation during endoscopy.

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OVER THE PAST 30 YEARS, gastrointestinal endoscopy has become one of the most commonly performed invasive procedures in clinical practice. Gastroscopy and colonoscopy have become established as the definitive diagnostic procedures for the upper gastrointestinal tract and colon, respectively, and therapeutic applications have advanced considerably. During the year ended June 2000, Medicare alone provided rebates for more than 430 000 examinations.[1] During most of these examinations, the subject is sedated to ensure patient comfort and enable the procedure to be completed without interference from patient restlessness.

Although the Australian and New Zealand College of Anaesthetists (ANZCA) and the Gastroenterological Society of Australia (GESA) have published joint guidelines[2] that have assisted in standardising sedation, there is still considerable variation in sedation delivery. In many endoscopy units, the endoscopist supervises the sedation, whereas in others a specialist anaesthetist is present. One of the arguments put forward for employing an anaesthetist is that this allows the use of more sophisticated sedating agents such as propofol.

Propofol is a short-acting anaesthetic agent widely used for induction of anaesthesia and as a sedative agent in intensive care settings. Its rapid onset (within 30 seconds) and short half-life (2–4 minutes) make it suitable for use in a day-procedure setting. However, the use of propofol by non-specialist anaesthetists is controversial, as evidenced by a recent editorial in *Endoscopy*,[3] which concluded "The smaller therapeutic ratio seen with propofol means that, in our opinion, there is an inadequate margin of safety when this drug is used by non-anaesthetists".

Over the past five years, propofol has been routinely included in the sedation regimen given by both general practitioners and specialist anaesthetists in our two endoscopy centres in Canberra. This article analyses the safety of the use of low doses of propofol in combination with midazolam and fentanyl by trained GP sedationists.

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METHODS

Data analysis

Using the centres' electronic database, the figures for all endoscopies per-

formed at the centres were analysed for the period January 1996 to December 2000 inclusive. All adverse events that related to the provision of sedation were extracted.

In addition, to determine the combinations and doses of drugs used for sedation and the proportion of sedations delivered by GPs, the medical records of 100 patients for each procedure for each year (total 1000) were randomly selected and the relevant data were extracted.

Statistical analysis

A descriptive analysis was undertaken showing population-based rates per 1000 of sedation-related events and interventions for sedation-related events. A 95% confidence interval was calculated for each rate, with a logarithmic adjustment when the number of events or interventions was less than 50. For drug use, the descriptive statistics included mean doses, associated 95% confidence intervals, median doses and dose ranges. Pearson χ^2 tests with Yates' continuity correction were used to test for differences between GPs and anaesthetists in relation to respiratory events and interventions.

Endoscopy centre procedures

Organisation

Both endoscopy centres are accredited by the Australian Council on Healthcare Standards. The policy for the delivery of sedation to patients follows the guidelines recommended by ANZCA and GESA.[2] In selecting applicants for the positions of sedationist, GPs with prior experience in anaesthesia or intensive care have been preferred, but this is not a prerequisite.

All GP sedationists are required to:

- Attend endoscopy lists with the Director of Anaesthesia to learn the sedation regimen and familiarise themselves with the endoscopy centre routines both before undertaking lists on their own and at least once every year;
- Attend two training sessions each year to discuss protocols, reinforce the knowledge of the pharmacology of all drugs used, and train in emergency procedures;
- Provide sedation for at least 200 patients per year; and
- Participate in the quality assurance program of the endoscopy centres.

Patient selection

Patients classified by the American Society of Anesthesiologists[4] as grade IV and V (ie, high risk), and patients with major acute emergencies better treated in a major hospital environment, are not treated in the endoscopy centres. Patients identified as being at higher than average risk are selected for the specialist anaesthetists' lists. Therapeutic procedures including polypectomy, stricture dilatation, oesophageal and haemorrhoid band ligation, oesophageal stent placement and percutaneous endoscopic gastrostomy tube placement are performed as indicated. The minimum age of patients treated is 12 years.

Sedation regimen

All patients receive supplemental oxygen. The sedative drug doses are titrated to the clinical and perceived anxiety status of the patient: most fit adult patients receive an initial dose of 25–75 μg fentanyl and 2–5 mg midazolam. At the commencement of the procedure, the first dose of propofol (20–40 mg) is injected. Further 10–30 mg doses of propofol are provided as required. Some patients receive further doses of midazolam or fentanyl. The aim is to titrate the dose so that patients are able to respond to stimuli, maintain their own airway without assistance and breathe spontaneously, while remaining comfortable.

Patient monitoring

All patients have automated pulse-oximetry and non-invasive blood pressure recorded by the sedationist at five-minute intervals. This monitoring is continued in the recovery area until the patient is alert. Any patient with a history of cardiac disease has electrocardiographic monitoring. The goal is to maintain oxygen saturation of greater than 90% at all times.

Incident reporting program

The centres have a mandatory incident-reporting scheme that requires any adverse event or non-standard treatment to be recorded on an "Incident Report Form".

Sedation-related events that must be reported include:

- any airway obstruction that is sustained for more than 30 seconds;
- a fall in oxygen saturation below 85%;
- systolic blood pressure less than 80 mmHg;
- pulse rate below 40 bpm;
- drug reactions; and
- possible aspiration.

Interventions that must be recorded include:

- bag-mask ventilation;
- the use of a Guedel or endotracheal airway;
- administration of any drug-reversal agent or intravenous fluids; and
- transfer of the patient to hospital.

Compliance with these requirements is fostered by having a non-punitive response to the results of these reports, and by demonstrating that they lead to organisational changes to assist the clinical staff. All staff understand that they have an obligation to ensure that incident reports are completed. The nurses are particularly helpful in achieving this outcome. Every patient receives a phone call from one of the centre's nursing staff the day after his or her procedure to check on their condition and ensure that the recommended management program is understood. This also provides an opportunity to detect any adverse events.

The incident reports are assessed by the Director of Anaesthesia and at the monthly quality assurance committee meeting. They are also entered into an electronic database to facilitate the development of clinical indicator reports to the Australian Council on Healthcare Standards.

RESULTS

A total of 28 472 procedures were performed from January 1996 to December 2000 (Box 1). Data from the random sample of 1000 patients indicate that GPs administered sedation in almost 80% of cases. The drug doses used are shown in Box 2.

Adverse events

During the five-year period, there were 185 sedation-related adverse events

1: Number of procedures performed in each year of the study

	1996	1997	1998	1999	2000	Total
Gastroscopy	2 590	2 599	2 487	2 738	2 790	13 204
Colonoscopy	2 859	3 023	2 680	3 144	3 562	15 268
Total	5 449	5 622	5 167	5 882	6 352	28 472

2: Drugs used in the procedures*

Procedure	Drug	% Patients receiving drug	Mean dose (95% CI)	Median dose	Dose range
Colonoscopy	Fentanyl	98.2%	74.5 μg (71.7–77.3)	75 μg	25–150 μg
	Midazolam	100%	4.1 mg (3.9–4.2)	4 mg	1–10 mg
	Propofol	97.2%	67.2 mg (63.4–71.1)	60 mg	10–220 mg
Gastroscopy	Fentanyl	78.2%	51.3 μg (50–52.6)	50 μg	25–150 μg
	Midazolam	99.6%	4 mg (3.8–4.1)	4 mg	1–7 mg
	Propofol	75.8%	33.8 mg (31.5–36)	25 mg	5–120 mg

* Numbers in this Table are based on a random sample of 500 patients for each procedure (100 for each year 1996–2000). Dose range varies with patient age, weight, perceived level of anxiety, and procedure duration.

(6.5/1000 procedures; 95% CI, 5.6–7.4): 107 respiratory-related and 77 hypotensive events (Box 3). The increased incidence of hypotension in 1998–2000 (Box 3) was attributed to prolonging the pre-colonoscopy fasting period to minimise the risk of aspiration, and was addressed by providing intravenous fluids to any patient considered dehydrated.

Four patients required admission to hospital: three for management of aspiration, and one patient with severe chronic airway limitation who became apnoeic during the procedure and was resuscitated but remained mildly hypoxic after recovery. The patient did not require intensive care management. There were no deaths.

GPs had a higher rate of respiratory adverse events than anaesthetists, but this did not reach significance (Box 4).

Interventions

The interventions used to maintain ventilation and blood pressure are shown in Box 5. There were more interventions than adverse events: 16 patients without respiratory difficulties received reversal agents to hasten recovery, and intravenous infusions were delivered to 34 normotensive patients assessed as dehydrated. GPs used these procedures significantly more frequently than anaesthetists (Box 4). GPs were particularly more likely to use drug-reversal agents — all but one of the 53 uses of these drugs was by GPs.

DISCUSSION

As gastrointestinal endoscopy is performed so frequently, it is vital that it is undertaken as safely as possible. There are surprisingly few published studies that analyse the safety of endoscopy. In 1991, the British Society of Gastroenterology[5] carried out a prospective audit of 13 036 gastroscopies performed in 36 hospitals over a four-month period. The survey revealed a mortality of 1 in 2000 for diagnostic procedures and 1 in 100 for therapeutic procedures. These results were attributed to many of the hospitals having poorly designed endoscopy units, inadequate and junior staffing and sub-optimal standards of patient monitoring. Their figures are quite at odds with our own experience: since opening our first endoscopy centre in 1982, we have performed more than 68 000 examinations without any deaths.

The British Society of Gastroenterology study is used to argue that the supervision provided to patients undergoing endoscopy is so substandard that if non-anaesthetists use propofol (which has the capacity to induce anaesthesia) they court disaster.[3] However, all drugs used to sedate endoscopy patients can result in airway obstruction, hypotension or respiratory depression. In particular, even small doses of benzodiazepines may occasionally induce prolonged apnoea. Therefore, it is essential that endoscopy is performed only in a setting where these events can be promptly recognised and corrected, whatever drugs are used.

Are the effects of propofol sufficiently advantageous to justify the expense and any extra care in delivery? All our endoscopists had extensive prior experience of using the combination of midazolam and fentanyl, and their subjective impression was that addition of propofol markedly improved the sedation, facilitating the examination. There are many published reports relating to the use of propofol for day-only procedures, but we were unable to find a study using this combination of drugs in the manner described. There is, however, strong evidence that there are powerful synergistic effects in combinations of the three drugs used.[6,7]

Propofol has been shown to allow more rapid patient recovery than would occur for the same level of sedation with benzodiazepines and opiates,[8,9] but it is

3: Number of sedation-related adverse events

	1996	1997	1998	1999	2000	Total	Rate/1000 (95% CI)
Airway obstruction	5	7	3	2	2	19	0.7 (0.4–1.1)
Hypopnoea	17	12	24	18	13	84	3.0 (2.3–3.6)
Aspiration	0	1	0	2	1	4	0.1 (0.1–0.4)
Total respiratory	22	20	27	22	16	107	3.8 (3.1–4.5)
Hypotension	3	6	18	25	25	77	2.7 (2.1–3.3)
Vasovagal	0	0	1	0	0	1	0 (0–0.3)
Deaths	0	0	0	0	0	0	0
Total events	25	26	46	47	41	185	6.5 (5.6–7.4)

4: Comparision of number of respiratory adverse events and interventions for GPs and anaesthetists

	1996	1997	1998	1999	2000	Total	Number of procedures*	Event rate/1000 procedures (95% CI)
Adverse events								
GP	15	19	26	18	13	91	22 379	4.1† (3.3–4.9)
Anaesthetist	7	1	1	4	3	16	6 093	2.6† (1.6–4.2)
Total	22	20	27	22	16	107	28 472	3.8 (3.1–4.5)
Interventions								
GP	16	21	28	21	21	107	22 379	4.8‡ (3.9–5.7)
Anaesthetist	7	1	1	4	3	16	6 093	2.6‡ (1.6–4.2)
Total	23	22	29	25	24	123	28 472	4.3 (3.5–5.1)

*Number of procedures for GPs and anaesthetists calculated from relative proportions in a sample of 1000 patients (100 for each procedure in each year). † $\chi^2 = 2.3$, df = 1, $P = 0.1$. ‡ $\chi^2 = 4.7$, df = 1, $P = 0.03$.

5: Numbers of interventions for sedation-related events

	1996	1997	1998	1999	2000	Total	Rate/1000 (95% CI)
Air viva	1	2	3	5	6	17	0.6 (0.4–1.0)
Airway	0	1	2	1	1	5	0.2 (0.1–0.4)
Reversal	18	6	13	7	9	53	1.9 (1.4–2.4)
Combination	4	13	11	12	8	48	1.7 (1.3–2.2)
ET intubation	0	0	0	0	0	0	0
Total Resp Int	23	22	29	25	24	123	4.3 (3.5–5.1)
Intravenous fluids	3	6	19	48	35	111	3.9 (3.2–4.6)
Total interventions	26	28	48	73	59	234	8.2 (7.2–9.3)

Air viva = The use of bag-mask ventilation. Airway = The placement of a Guedel airway. Reversal = The administration of a reversal agent (flumazenil or naloxone). Combination = Those patients for whom more than one of these interventions was used. ET intubation = Endotracheal intubation. Total Resp Int = Total interventions for respiratory problems.

our observation that, when used in the manner described, it has additional benefits, including:

- The ability to provide adequate, prolonged sedation for patients undergoing difficult procedures, removing a sense of urgency to complete the procedure;
- The capacity to be used in a wide dose range depending on need, so that anxious patients or those experiencing more severe pain can be adequately sedated; and
- The fact that patients who require deep sedation to manage an especially painful manoeuvre do not subsequently become apnoeic once the painful stimulus is removed (as may happen with high dose benzodiazepines).

In short, propofol, given in small doses, provides much greater flexibility in titrating the sedation to the patient's needs. This is indicated by the wide range of doses provided for both gastroscopy and colonoscopy (Box 2).

Our data demonstrate that sedation by GPs has been associated with a low incidence of adverse events. The GP sedationists do appear to have a slightly higher incidence of the minor respiratory-related adverse events, and they are significantly more likely to intervene by administering drug-reversal agents. Nevertheless, these events were managed without the need for muscle paralysis or endotracheal intubation, let alone significant morbidity or death.

The GP sedationists in our centres have demonstrated that they can manage airway obstruction and hypopnoea, as well as less common events, without any adverse patient outcome. It appears that appropriately selected and trained GPs can safely use propofol for endoscopy sedation.

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COMPETING INTERESTS

None declared.

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