RESEARCH

Establishing an anaesthetist-delivered propofol sedation service for advanced endoscopic procedures: implementing the RCA/BSG guidelines

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SUMMARY

Background Following recommendations from the Royal College of Anaesthetists and the British Society of Gastroenterology, we report our results of propofol sedation for complex endoscopic procedures delivered by a single consultant anaesthetist over a 5-year period.

Methods A weekly session was provided in the endoscopy department for procedures that were complex or could previously not be completed successfully. Deep sedation was provided by intermittent propofol bolus doses, supplemented with fentanyl where necessary, titrated to clinical effect. Patients were usually in semiprone or lateral positions and spontaneously breathed air supplemented with nasal oxygen. Service evaluation included patient recall, endoscopist satisfaction with conditions, procedural success and airway-related adverse outcomes.

Results We completed 1000 procedures, 42.5% of which were endoscopic retrograde cholangiopancreatography, with the remainder comprising a diverse range of endoscopic procedures of 3–156 min duration. Procedural conditions were excellent in 79% of cases, 261 procedures were completed which had been previously abandoned, 246 patients (24.6%) had a better experience than previously and none recalled any part of their procedure. Three patients required transient bag and mask ventilation, and nasal airways were used in 12 patients, but none required tracheal intubation or vasopressor support.

Conclusions These guidelines facilitated a propofol sedation service with considerable benefits for patients and endoscopists. Provision of deep propofol sedation by an anaesthetist, in patients with an unsecured airway, appears practical, effective and efficient. Small adjustments to the airway were fairly common,

but the incidence of adverse events and requirement for airway instrumentation was low.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) may be prolonged and highly complex, requiring great precision from the endoscopist, made more challenging by unpredictable movements in an uncomfortable, inadequately sedated and uncooperative patient.¹ Similar considerations apply to many other therapeutic endoscopic procedures.²

Sedation for endoscopy is typically provided by midazolam and opioids,^{3–5} but is often inadequate for longer, more complex, therapeutic procedures. More prolonged and satisfactory sedation can be provided by the anaesthetic propofol.^{6–9} The choice of this agent should be based on the specific sedation requirements of the patient and procedure, as well as a consideration of potential disadvantages, including aspiration risk.⁹ Propofol requires specific training and skills because of its potential to rapidly and profoundly change conscious level. While used by non-anaesthetists in the USA and parts of Europe, this is highly controversial, with many arguing that only anaesthetists should administer it.¹⁰ In the UK, a joint working party from the British Society of Gastroenterology (BSG) and the Royal College of Anaesthetists (RCA) recognised the advantages of propofol and recommended its administration and monitoring ‘should be the responsibility of a dedicated and appropriately trained anaesthetist’.¹¹ However, 5 years later, less than a third of English

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trusts had regular access to propofol sedation and two-thirds had no access.¹² Over a similar period there has been continuing expansion in endoscopic practice, resulting in an unmet need for streamlined sedation practices for those that need deep sedation for longer procedures.

The first experience of propofol sedation following the working party recommendations was published as a series of 40 cases in 2013.¹³ We report the largest UK series to date from a single consultant anaesthetist in a high-volume endoscopy centre (>15 000 procedures per annum). In this we attempted to determine patients' and endoscopists' assessment of sedation quality, airway-related and other early complications, and the apparent benefits of deep sedation with propofol.

METHODS

Propofol sedation was provided in the endoscopy department by one experienced consultant anaesthetist (IS) on an average of one morning per week, scheduled by mutual agreement to best meet demand.

Patients and procedures

Outpatients were selected based on procedural complexity, previous incomplete, unsuccessful or poorly tolerated interventions, or patient request for 'general anaesthesia'. Some relatively stable urgent inpatient cases were added to agreed sessions, where possible, according to similar criteria. Patients were positioned semiprone for ERCP and left lateral for other procedures except percutaneous endoscopic gastrostomy (PEG), for which patients were supine but semisitting to minimise airway obstruction. Patients received supplemental oxygen at 2–4 L/min by nasal cannula. Lidocaine spray to a maximum dose of 100 mg was used where indicated. Monitoring was the same as for conventional sedation, including a pulse oximeter placed on the most accessible hand. All patients were fasted according to current guidelines.^{14 15} Intravenous fluids were not routinely administered. After the procedure, patients were recovered according to our existing protocols.

Sedation regimen

While the room was being prepared between cases, all patients received a preprocedural visit by the anaesthetist to assess the effects of general health, medications and comorbidities on their likely sedation requirements.¹⁵ An initial propofol dose of 20–30 mg was administered to relax the patient and assess their responsiveness to sedation. Further propofol was administered slowly until the patient no longer responded to verbal contact, at which point the endoscope was passed. Sedation was maintained by administering further small (10–30 mg) bolus doses of propofol as needed, based on patient response, movement, change in breathing rate or pattern, changes

in heart rate, or if increased procedural stimulus was anticipated. Fentanyl, 25–50 µg, was given when post-procedural pain was anticipated, primarily during dilatations and balloon sphincteroplasties. Hyoscine butylbromide (Buscopan) was given as requested, with glucagon used where it was contraindicated or had been ineffective.

Service evaluation

Data recorded included the procedure undertaken, duration and cumulative doses of propofol and other adjuvant drugs. The endoscopist was asked to rate the quality of sedation on a 5-point verbal rating scale (very poor, poor, good, very good or excellent), taking into account response to intubation and subsequent conditions. After recovery, patients were asked if they had any memories of the procedure and, if applicable, to compare their experience with any previous endoscopy. The anaesthetist and endoscopist also recorded a subjective record of any perceived benefits based on outcome, patient experience and the reason for requesting propofol. Any serious complications were recorded and, from May 2014, the degree of airway support required to achieve unobstructed ventilation and haemoglobin oxygen saturations of 92% or greater.

RESULTS

From October 2012 until September 2017, we completed 1000 endoscopic procedures (table 1), of which 42.5% were for ERCP. Twenty one of the oesophageal dilatations were performed on two young patients who had experienced oesophageal trauma. Both had proved very difficult to manage with conventional sedation, one having been awake and fully responsive after 12.5 mg of midazolam. A total of 17 consultant endoscopists used the service to some extent; 453 cases were performed by upper gastrointestinal (GI) surgeons, 2 by colorectal surgeons and 545 by gastroenterologists.

The total dose of propofol was extremely variable (table 2), reflecting procedure length and intensity, patient age and frailty. Prophylactic fentanyl was administered to 159 patients. Only 37 patients required fentanyl for pain after awakening, 14 of these (38%) had already received prophylactic fentanyl.

The effectiveness of our propofol sedation regimen is reported in table 3. None of the patients directly questioned had recall of any aspect of their endoscopic procedure. Awareness was not specifically sought in the first six patients and could not be assessed due to severe learning difficulties or confusional states in a further 66. However, we have no reason to believe that any of these patients had recall either. In contrast, 246 patients (24.6%) specifically reported a significantly better experience than with conventional sedation, which had been associated with awareness of distress and/or discomfort. The endoscopist never rated

Table 1 Patient characteristics and procedures undertaken

	ERCP	Other endoscopy	Total
Number (n)	425 (42.5%)	575 (57.5%)	1,000
Age (yrs)	65.6 ± 17.0	53.7 ± 19.6	58.8 ± 19.4
Gender (male / female)	179 / 246	247 / 328	426 / 574
ASA (1/2/3/4)	43/258/117/7	41/361/150/23	84/619/267/30
Nature (elective / urgent)	340 / 85	517 / 58	857 / 143
Endoscopic procedure (n):			
ERCP*	425 (42.5%)	–	–
stone clearance	139		
stent insertion, removal or change	160		
balloon sphincteroplasty or stricture dilatation	65		
negative trawl	69		
other miscellaneous procedures	32		
procedure abandoned	28		
Upper GI endoscopy	–	437 (43.7%)	–
diagnostic oesophagoscopy and/or gastroscopy		125	
diagnostic endoscopic ultrasound		58	
stent insertion or change		56	
EMR polypectomy		33	
oesophageal dilatation		43	
PEG insertion or change		41	
ultrasound-assisted stenting or drainage		11	
other therapeutic procedure		67	
procedure abandoned		3	
Lower GI endoscopy	–	122 (12.2%)	–
diagnostic colonoscopy		64	
EMR polypectomy		31	
dilatation		8	
other therapeutic procedure		13	
procedure abandoned		6	
Diagnostic upper & lower GI endoscopy	–	16 (1.6%)	–
Procedure duration (min)	34.9 ± 19.5 (3–128)	23.5 ± 19.1 (3–156)	28.3 ± 20.1 (3–156)

Values are mean±SD (range) or number (%) of occurrences.

*Some patients had more than one procedure performed during ERCP.

ASA, American Society of Anesthesiologists; EMR, endoscopic mucosal resection; ERCP, endoscopic retrograde cholangiopancreatography; GI, gastrointestinal; PEG, percutaneous endoscopic gastrostomy.

procedural conditions as less than good and 79% were rated excellent. A clear benefit from propofol sedation was evident in over 60% of cases. Despite propofol

Table 2 Sedative and other medications administered

	ERCP	Other endoscopy
Propofol dose (mg)	361 ± 197	333 ± 203
	330 (50–1360)	280 (60–1560)
Received fentanyl (n)	94 (22%)	65 (11%)
dose administered (µg)	50 (25–100)	50 (25–100)
Received antiperistaltic agent (n):		
hyoscine butylbromide	190 (44.7%)	63 (11.0%)
glucagon	3 (0.7%)	2 (0.3%)
hyoscine butylbromide and glucagon	26 (6.1%)	5 (0.9%)

Values are mean±SD, median (range) or number (%) of occurrences.

ERCP, endoscopic retrograde cholangiopancreatography.

sedation, a small number of procedures could not be completed (table 3), mostly for technical reasons. Eight patients underwent a subsequent successful procedure, also with propofol, while the remainder were managed by alternative means.

Over a quarter (26.5%) of our patients underwent diagnostic procedures. These patients differed significantly ($p < 0.01$) compared with the therapeutic group in terms of younger age (50.8 ± 18.5 vs 61.7 ± 18.9 years), shorter procedure duration (17.7 ± 12.7 vs 32.2 ± 20.8 min) and reduced propofol consumption (293 ± 146 vs 364 ± 214 mg), respectively. Only seven patients having diagnostic procedures received fentanyl and only one required postprocedural analgesia. Diagnostic patients were also more likely to report an improved experience from previously (41.1% vs 18.6%), probably because they were also more likely to have had a previous procedure. Procedural conditions were not significantly different.

Table 3 Surgical and patient experience and outcomes after propofol for endoscopic procedures

	ERCP	Other endoscopy
Patient experience:		
complete amnesia	409 (96.2%)	519 (90.3%)
(better than previously)	(71)	(175)
unable to assess	14 (3.3%)	52 (9.0%)
not recorded	2 (0.5%)	4 (0.7%)
Operator's assessment of conditions:		
excellent	341 (82.2%)	449 (78.08%)
very good	67 (15.8%)	107 (18.6%)
good	17 (4.0%)	17 (3.3%)
Clear benefit from propofol:	214 (50.4%)	395 (68.7%)
previously unable to complete or tolerate procedure	88	173
patient with challenging co-morbidities	23	62
patient request for propofol sedation or general anaesthesia	19	91
improved patient experience	31	28
endoscopist request for complex procedure	53	41
Procedure unable to be completed:	28 (6.6%)	9 (1.6%)
unable to locate or cannulate ampulla	14	—
unable to cannulate desired duct	9	—
unable to pass stricture	1	4
full stomach*	1	—
lost iv access*	1	—
inadequate bowel preparation	—	3
suspected perforation	—	1
endoscope failure	1	—
unable to pass pharyngeal pouch*	1	—
further investigation (EUS) required	—	1

Values are number (%) of occurrences.

*Directly related to sedation or possibly avoidable with general anaesthesia.

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound.

All patients breathed spontaneously, except three with severe sleep apnoea who had prophylactic non-invasive ventilation applied before sedation. Three patients (0.3%) required transient bag and mask ventilation. Nasal airways were inserted in 12 patients with frequent airway obstruction, and approximately 5% required almost continuous chin support because of obstruction. All other patients required little or no airway intervention (table 4), with no significant difference between diagnostic and therapeutic groups. No patient required tracheal intubation and none showed early signs of aspiration. Vasopressors were not required in any patient.

DISCUSSION

Our initial experience supports the success of this consultant-delivered propofol sedation endoscopy

Table 4 Airway complications with propofol for endoscopic procedures

Required bag and mask ventilation (n)	3
Required tracheal intubation (n)	0
Other airway interventions required:*	
no airway intervention required	556 (70.7%)
occasional chin support	173 (22.1%)
almost continuous chin support	37 (4.7%)
nasal airway required	12 (1.5%)
tracheostomy in situ	5 (0.6%)
prophylactic NIV used (for PEGs)	3 (0.4%)

Values are number (%) of occurrences.

*Only recorded in the last 786 patients.

NIV, non-invasive (nasal) ventilation; PEG, percutaneous endoscopic gastrostomy.

service, with no recorded episodes of procedural recall, high-quality conditions for the endoscopist and a clearly evident benefit in more than half of cases. Propofol sedation was very flexible and effectively infinitely extendible, with procedures lasting from 3 to 156 min, but still with acceptably rapid recovery. In our series, early termination of procedures due to propofol sedation-related reasons occurred in at most 0.3% of cases. This compares favourably with reported failure rates for propofol sedation of 0.6%¹⁶ to 1.2%.¹⁷ In contrast, 294 procedures were successfully concluded which had not been tolerated or completed with conventional sedation or which would have previously required general anaesthesia. Our success is also illustrated by the wide range of procedures performed in a service initially set up primarily for ERCP.

As far as we can tell, no patients recalled any part of their procedure. This compares favourably with a previous report of propofol sedation by anaesthetists in which 15 of 238 patients (6.3%) had recall of some parts of their ERCP procedure despite midazolam also being used in 73% of cases.¹⁸ When patients were adequately sedated with propofol, most interventions were insufficiently stimulating to require a specific analgesic. The use of fentanyl has declined from 45% during the first 100 cases to less than 5% in the last 100, without an obvious increase in postprocedural pain.

Numerous regimens for propofol sedation have been described, including intermittent boluses,^{19 20} manual bolus plus infusion regimens^{21 22} and target-controlled infusions (TCI).²³ Both manual infusions and TCI were found to achieve similar quality of sedation, procedural conditions and recovery profile compared with intermittent bolus,²⁴ although the latter necessarily required more interventions by the anaesthetist. We deliberately chose an intermittent technique for precisely this reason as the brief duration of each bolus should improve safety when reduced lighting and impaired patient access make close monitoring difficult and where infusion regimens could readily result

in unintended and progressive deepening of sedation. Repeated boluses also required close observation of the intravenous cannula, facilitating early detection of its displacement, avoiding a common cause of unintended awareness from inadequate anaesthesia.²⁵ An intermittent technique is highly flexible where the level of stimulus is frequently changing. It is also inherently simple and inexpensive and associated with a low incidence of complications when used for upper GI endoscopy or colonoscopy.^{19 20}

Anaesthetists may be uncomfortable delivering deep sedation to patients with an unprotected airway and some have chosen general anaesthesia with tracheal intubation in approximately 11% of patients requiring ERCP.¹⁸ However, others argue tracheal intubation is not part of 'the state of the art approach' to sedation for advanced endoscopy.²⁶ In our experience, the prone or lateral position causes the tongue to fall away from the roof of the mouth, usually resulting in a clear airway, which can be directly observed and readily monitored. While aspiration of gastric contents is a theoretical risk,⁹ this position also provides some protection; additionally patients are routinely fasted and the endoscopist is able to remove residual gastric contents by suction. In practice, aspiration pneumonia is very rare in endoscopy²⁷ and can also occur with tracheal intubation.¹⁸ In addition, general anaesthesia considerably prolongs the procedure¹ and exposes the patient to the well-known hazards of direct laryngoscopy.^{28 29} Like other sedative techniques, propofol sedation is not appropriate in the emergency patient who is likely to have a full stomach, or in patients with significant gastric outlet obstruction. As a cardiovascular depressant, propofol may also be less appropriate than midazolam in the severely cardiac-compromised patient or a patient with hypovolaemia. However, these challenging patients are best managed within the operating theatre where greater support is available.

Relatively minor airway interventions, such as intermittent chin support, were fairly common, as described previously.¹⁶ However, such active airway management is best regarded as a normal preventative measure against prolonged hypoxaemia and apnoea,²⁶ rather than an adverse event. Most airway manoeuvres were triggered by audible or visual signs of partial obstruction, rather than oxygen desaturation, and such early interventions by anaesthetists represent a greater contribution to the safety of deep sedation than their ability to manage a seriously compromised airway.³⁰ Three patients (0.3%) required bag and mask ventilation. The first was a young obese smoker who subsequently admitted to a blocked nose. During ERCP they experienced several episodes of transient haemoglobin oxygen desaturation with a more severe episode at completion of the procedure, which was rapidly resolved by 30s of bag and mask ventilation. It is likely that a nasal airway, which was unavailable at the time, would have prevented this complication.

The remaining cases both occurred in a young patient with severe cystic fibrosis requiring a PEG insertion and, subsequently, revision prior to lung transplantation. Propofol sedation resulted in coughing, followed by apnoea, with bag and mask ventilation applied after the endoscopic part of the procedure was completed. Recovery was uneventful and the patient was very satisfied with both episodes of care.

Our results are comparable to other series, where the requirement for bag and mask ventilation ranges from 0.4% to 0.6%,^{17 18 31} although one retrospective review of over half a million cases placed the incidence closer to 0.1%.³² None of our patients required tracheal intubation. This contrasts with 18 unplanned tracheal intubations (3.8%) during or immediately after 470 ERCP procedures managed with propofol sedation administered by anaesthetists.¹⁸ However, many others have found unplanned tracheal intubation to be extremely rare.^{16 17 19 20 31–33} We also experienced no serious adverse cardiopulmonary events, defined as hypoxaemia, hypovolaemia and arrhythmias, notable in the context of a cohort of patients with multiple comorbidities including some unfit for surgery or with inoperable disease.¹ While our series is too small to accurately define their true incidence, we can estimate the 95% CI for these events to be 0% to 0.3%.³⁴ A recent meta-analysis of 27 studies with 2518 patients supports a similarly low incidence.³⁵

The most significant resource implication of this service is the consultant anaesthetist's salary. There is also a modest increase in drug costs with propofol, partly offset against reduced use of midazolam and fentanyl. As suggested in the RCA/BSG guidelines,²⁶ we did not find an operating department practitioner to be necessary, saving some additional resource, as anaesthetic assistance was adequately provided by the endoscopy nurses on the rare occasions it was required. We feel this assistance would also have been adequate were tracheal intubation required and retain a dedicated equipment box for such an eventuality. The presence of the anaesthetist meant that a nurse was no longer dedicated to airway management and monitoring, potentially freeing up additional resource, and allowed the endoscopist to concentrate solely on the procedure. There would also have been a cost benefit from completing procedures on one occasion, and the requirement to manage patients under general anaesthesia on operating lists has also declined dramatically. Propofol was no slower to deliver than conventional sedation and was associated with rapid recovery, managed according to existing protocols, so patient turnover was not compromised, in contrast to general anaesthesia.¹ We did not perform any additional preprocedural assessment, other than a visit from the anaesthetist while the room was being prepared for the next case.

The main strength of this study is that all sedation cases (including data collection) were managed by a

single anaesthetist. Study weakness would be the lack of data with regard to aspiration risk and procedural complications, for example ERCP-related pancreatitis in patients who received propofol sedation. As far as we are aware, surrogate markers for complications such as 8-day readmission, 30-day mortality and length of hospital stay (for inpatients) were not increased in this group of patients. Published data also confirm a low risk of aspiration (0.10%) with propofol sedation³⁶ and a low complication rate in ERCP patients.³⁷ In summary, the joint RCA/BSG guidelines facilitated the establishment of a propofol sedation service with considerable benefits to patients and endoscopists. Provision of deep propofol sedation by an anaesthetist in patients with an unsecured airway appears practical, effective and efficient with a very low incidence of adverse events or requirement for airway instrumentation. This is consistent with an excellent safety record in the extensive published literature from around the world.

Significant of this study

What is already known on this topic?

- ▶ Propofol sedation is known to provide favourable conditions for therapeutic endoscopy, and UK guidelines suggest how it can be implemented.
- ▶ However, many units still lack access to this service.

What this study adds?

- ▶ We describe our process for establishing propofol sedation.
- ▶ This is the largest patient series for propofol sedation in a day-case endoscopy setting in the UK.
- ▶ Our data support the safety and efficacy of incremental bolus propofol administration for endoscopy.

How might it impact on clinical practice in the foreseeable future?

- ▶ Endoscopists should liaise with their anaesthetic departments to establish a propofol sedation service in order to improve patient outcomes.
- ▶ Our results should help convince anaesthetists of the utility of propofol sedation over general anaesthesia.
- ▶ However, this may have implications for resources, specifically the availability of anaesthetists with specific training in deep sedation with propofol.

Contributors IS delivered propofol sedation to all patients, collected data and wrote the first draft of the manuscript and its revisions. DD, KWL and SH performed 284, 224 and 96 of the cases reported, respectively, and all contributed to service development and evaluation and manuscript preparation.

Competing interests None declared.

Ethics approval As this constituted a service development, we did not seek ethics committee approval or individual patient consent to collect anonymised data from routine clinical records and a personal anaesthetic logbook.

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