The Use of Propofol by Gastroenterologists: Medico-Legal Issues

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Key Words

Malpractice · Non-anesthesiologist-administered propofol · Legal consequences

Abstract

The increasing use of non-anesthesiologist-administered propofol for sedation during gastrointestinal endoscopy has both clinical and legal consequences. As medical practices develop, the law of clinical negligence will be applied in the context of such developments. While the law will recognize the desirability of advanced techniques and methods, in circumstances where an injury or adverse outcome occurs, the facts of a particular case will be scrutinized to determine whether or not the duty of care between patient and clinician has been breached. This paper considers a number of specific matters likely to arise in the context of a clinical negligence/malpractice claim resulting from the use of non-anesthesiologist-administered propofol, in particular the role and standard of care expected of gastroenterologist and/or anesthetic provider, the relevance of FDA labeling, the implementation and use of protocols, the importance of patient selection and informed consent.

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Introduction

The use of sedatives in gastrointestinal endoscopy gives rise to a number of potential legal consequences. These include allegations of negligence/malpractice, ethical considerations, regulatory/disciplinary consequences and (in extreme circumstances) criminal offences.

This article focuses upon the principals of clinical negligence law (otherwise known as medical malpractice) as they may apply to the use of propofol as a sedative by gastroenterologists. Non-anesthesiologist-administered propofol is an increasingly recognized and important part of gastrointestinal endoscopy in certain countries around the world (particularly Germany and the US). The potential legal consequences of its use when administered without the supervision of an anesthesiologist are considered below. The content of this article is not intended to represent legal advice, as such would require specific instruction and would be subject to the applicable laws of the relevant jurisdiction.

Adverse Outcome

Firstly, it is important to recognize that clinical negligence lawyers apply the law through the prism of an adverse outcome or injury. Although the use of sedation in

appropriate circumstances is relatively safe, Murphy's Law states that 'anything that can go wrong, will go wrong'. When it does, lawyers will consider two crucial elements in order to determine liability, namely: Was the clinical care substandard (breach of duty) and did the substandard care cause the injury complained of (causation)?

Adverse outcomes which occur as a consequence of the administration of anesthesia may range from immediate complications such as cardiopulmonary problems to less proximate difficulties such as premature vehicle use resulting in road traffic accidents [1]. The nature of the injury and the circumstances in which it occurred will dictate the investigation of care (e.g. patient selection, monitoring, availability of emergency care or pre-/post-procedural advice).

The Use of Propofol

Depending upon the facts of the particular case, if an adverse outcome is associated with the use of propofol, it can be anticipated that a court will wish to examine some or all of the following areas:

- Should the gastroenterologist have administered propofol?
- Was patient selection and risk management adequate?
- What is the standard of care required of the clinician and his/her expected level of expertise?
- Was emergency medical support available?
- What information did the patient receive regarding the risks (informed consent)?
- Was the training of those involved sufficient?
- Were the protocols and/or available guidelines adhered to?

Why Did the Gastroenterologist Use Propofol to Sedate Me and Why Wasn't I Informed of the Risks or the Alternatives?

Assuming the adverse outcome arose from a complication due to sedation, it is inevitable that the issue of treatment choice will arise. The benefits of propofol for endoscopic procedures is well documented and its use is widespread. However, there are alternatives. If the adverse outcome arose due to a complication peculiar to propofol, which would otherwise not have occurred, the issue of informed consent will be at the forefront of the lawyer's mind. The question of what information a patient is entitled to receive varies between jurisdictions. In the United Kingdom, the extent and detail of information

required of a clinician has been assessed based on a reasonable body of medical opinion [2]. However, more recently there has been a trend within the United Kingdom towards a less paternal and more patient led approach as adopted in jurisdictions such as Canada and the USA [3]. The information provided may include a brief explanation of the rationale underpinning the choice of sedation and the alternatives (if any).

Why Wasn't an Anesthesiologist Present to Supervise My Sedation?

In the United Kingdom, the gastroenterologist will not be guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical opinion [4]. This test is reflected in the United States as the 'responsible minority rule'. The decision to proceed without an anesthesiologist will fall under particular scrutiny due, in part, to the FDA product labeling, which includes:

... should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of surgical/diagnostic procedure. Patients should be continuously monitored, and facilities for maintenance of patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available ... [5].

FDA product labeling is, however, by no means conclusive and the use of drugs in a manner different from that approved by the FDA is legal and common [6]. Nevertheless, it will be a factor in determining whether or not the risks associated with sedation using propofol have been adequately addressed. With the benefit of expert evidence, the court will scrutinize current practice and published studies, the risks of complication and the importance of patient selection, staffing and training, and the adequacy of procedures and protocols.

What Standard of Care Can I Expect from the Gastroenterologist If I Suffer a Sedative-Related Complication?

Is the gastroenterologist expected to exercise the care and skill of anesthesiologist? Having adopted responsibility for the administration of propofol, it is questionable whether there is any basis for accepting a lower level of expertise with regard to recognition and management of sedative-related complications. However, this specific issue needs to be considered in context, namely: patient selection (ASA 1–3), availability of emergency medical support, the level of sedation targeted, training and monitoring, and research-based

guidelines and protocols. It is questionable whether a higher standard of expertise will be imposed upon a gastroenterologist working within these parameters and supported by published data/guidelines demonstrating safe practice.

However, if a clinician elects to undertake a procedure without attempting to limit the associated risks of complication to those which he or she is reasonably competent to address, there can be little complaint when he or she is judged by the standard of a different clinician competent in the management of such complications, which should have been foreseen and avoided.

Why Was the Sedation Protocol Not Followed?

From a legal perspective, it is important to recognize that the creation of a protocol acts as both a shield and a sword. With the increasing use of protocols and reliance on published guidance, the clinician has a point of reference indicative of good practice. The existence of a protocol improves consistency of treatment, patient safety and may be relied upon to support the rationale underpinning treatment choice (e.g. according to the protocol, this patient was correctly selected for this treatment). However, it is the first document to which a claimant will turn should there be any departure from the guidance. This will include patient selection, method of drug administration, monitoring, etc.

Concluding Remarks

In the absence of case law relating directly to the use of propofol, a definitive view upon the risk of litigation arising from its use under the direction of gastroenterologists and/or registered nurses is not possible. Should statistical data establish that, with appropriate safeguards (e.g. proper training and patient selection), gastroenterologist-directed use of propofol can be carried out without additional risk to the patient, the decision of an individual clinician to adopt such a practice will be difficult to criticize.

As stated at the outset of this summary, clinical negligence claims occur following an adverse outcome or injury consequent upon medical treatment. The absence of an anesthesiologist will only be relevant if it materially affected the outcome. In order for this to be the case, some element of the management of patient's care would have to fall below the standard expected of a competent anesthesiologist. The formulation of the protocols, patient selection and training are intended to limit the nature and frequency of complications to those which can be safely managed by the gastroenterologist. In reality, the most likely cause of litigation is not the decision to proceed without an anesthesiologist, but departure from protocols and/or substandard of care below that legitimately expected of the gastroenterologist.

References

- 1 Chung F, Assmann N: Car accidents after ambulatory surgery in patients without an escort. *Anesth Analg* 2008;106:817–820.
- 2 Bolam v Friern Hospital Management Committee (1957) 1 WLR 582 QBD.
- 3 Chester v Afshar (2005) 1 AC 134 and Pearce v United Bristol Hospitals NHS Trust (1999) ECC 167 CA.
- 4 Bolitho (Deceased) v City and Hackney HA (1998) AC 232 HL, applying Bolam Friern Hospital Management Committee (1957) 1 WLR 582 QBD.
- 5 Diprivan (propofol) Injectable Emulsion 30193-00, rev 08/05. AstraZeneca.
- 6 Stafford RS: Regulating off-label drug use – rethinking the role of the FDA. *N Engl J Med* 2008;358:1427–1429.