Techniques in Gastrointestinal Endoscopy 000 (2019) 150622

Contents lists available at ScienceDirect

Techniques in Gastrointestinal Endoscopy

journal homepage: www.techgiendoscopy.com/locate/tgie

Medicolegal aspects of ERCP in the era of duodenoscope-related infections

Peter J. Hoffman[a], Albert Bixler[a], Brooke M. Alston[a], Andrew J. Bond[a], Andrew D. Feld[a,b,*]

[a] Eckert Seamans Cherin & Mellott, LLC, Philadelphia, Pennsylvania
[b] Division of Gastroenterology, Washington Permanente Medical Group, and University of Washington, 125 16th Ave East, CSB-2, Seattle, Washington 98112

ARTICLE INFO

Article history:
Received 28 February 2019
Revised 2 July 2019
Accepted 10 July 2019

Keywords:
Infections
Duodenoscope
ERCP
Legal

ABSTRACT

Endoscopic Retrograde Cholangiopancreatography (ERCP) provides an important medical procedure for patients in a generally safe and effective manner. It can be technically complex, often performed during serious illness, and has the highest potential complication rate of procedures commonly performed by gastroenterologists. The issue of duodenoscope-related infections has been more recently added the list of potential ERCP adverse events. This chapter will take a risk management approach to help the endoscopists understand and manage the risks associated with ERCP, with particular concentration on duodenoscope-related infections. This chapter is written for educational purposes only and cannot be considered legal advice. For specific legal advice, one should consult a health care attorney.

© 2019 Published by Elsevier Inc.

1. Introduction

An unfortunate fact for many physicians practicing in the United States is that they may be forced to deal with medical malpractice suits at some point in their careers. While data specific to gastroenterology malpractice lawsuits are difficult to find, the Physician Insurers Association of America has reported that out of the 28 specialty fields of medicine analyzed from 1985 to 2004, gastroenterology ranked 21st in the number of claims reported [1], representing about 2% of the total overall number of claims. A 2007-2008 survey of 5825 physicians, not limited by subspecialty, showed that 42.2% of all physicians had a malpractice claim filed against them at some point in their career [2]. Of all physicians aged 55 and older, 60.5% of the respondents had been sued at some point during their career. Incidents of medical liability claims were much higher among men (47.5%) than among women (23.9%) [2].

In 2017, *JAMA Internal Medicine* published additional statistical findings related to medical malpractice claims [3]. *JAMA* reported that the rate of claims paid on behalf of all physicians had declined by 55.7% between 1992 and 2014; from 20.1 per 1000 physicians to 8.9 per 1000 physicians [3]. The mean payment for the 280,368 claims reported in the National Practitioner Data Bank during this time frame was $329,565 (adjusted to 2014 dollars) [3]. *JAMA* also reported that, between 2004 and 2014, diagnostic error served as the most prevalent basis for allegations of medical negligence against all physicians [3]. These allegations comprised 31.8% of claims during this period. With respect to gastroenterologists, prior data for 1985-2004 similarly suggest that diagnostic interview, evaluation, or consultation results in the most claims against this group of physicians [3].

An emerging legal issue for gastroenterologists and endoscopists is lawsuits related to endoscope-associated infections. In addition to naming physicians and hospitals, these suits often include the manufacturer of the endoscope on a variety of "product liability" theories. The allegations against physicians in these types of suits revolve around alleged failure to follow the manufacturer's policies and procedures to disinfect, clean, and maintain the endoscope. The claims against the manufacturer often allege defective design or manufacture or a failure to provide adequate warnings or instructions. Endoscope-associated infection lawsuits present unique issues for physicians and hospitals. Below is an overview of the litigation process and recommendations regarding the best practices to avoid and deal with endoscope-associated infections.

2. Risk management overview in general

Malpractice claims brought against a hospital or doctor can be alleged on a number of theories. Below are just some of the possible theories of liability that can be brought against a physician or hospital:

Negligence: One of the most common theories a physician may be sued under is negligence. To state a negligence claim against a physician, a plaintiff must show that the doctor owed the patient a duty recognized by law, that the physician breached that duty, that the alleged breach resulted in injury to the patient, and that the patient sustained legally recognized damages as a result. In a lawsuit brought

Declaration of competing interest: No conflicts of interest to declare.

* Corresponding author.
E-mail addresses: afeld@uw.edu, feld.a@ghc.org (A.D. Feld).

https://doi.org/10.1016/j.tgie.2019.07.009
1096-2883/© 2019 Published by Elsevier Inc.

on the basis of claimed medical negligence, a patient claims that a physician, in the course of rendering treatment, failed to meet the applicable standard of care.

Informed consent: Another theory is informed consent. A physician must obtain full, knowing, and voluntary informed consent from her patient for any nonemergency surgical procedure. A patient's lack of consent claim is premised on the allegation that the physician failed to reveal a significant risk, which caused harm to the plaintiff, and that, had the potential risk been disclosed, a reasonable person would not have consented to the treatment or procedure. Informed consent requires more from a physician than simply having the patient sign a form. The physician performing the procedure for which consent is required must ensure that the patient is aware of the benefits of the proposed treatment, the material risks of the treatment, alternative options to the proposed treatment, and possible consequences of declining the treatment. This information must be communicated to a patient so that she clearly understands it.

Contractual liability of doctor to patient: Physicians and patients can enter into express written contracts regarding the care provided. These contracts can include various treatment plans, the likelihood of success, and even the physician's promise to cure. Traditionally, courts have respected a physician's freedom to contract as he or she chooses. However, once a contract is formed, a plaintiff may have a cause of action for breach of contract if the outcome of the treatment is not what was promised.

Vicarious liability: A hospital or other employer may be held vicariously liable for the acts of another health care provider such as a physician through principles of ostensible agency. Typically, the evidence must show that a reasonably prudent person in the patient's position would be justified in the belief that the care in question was being rendered by the hospital or its agents or the care in question was advertised or otherwise represented to the patient as care being rendered by the hospital or its agents. If proven, this will typically establish a cause of action against the hospital itself.

Corporate negligence: Another basis for establishing a malpractice liability claim against a hospital or system regarding is under a theory of corporate negligence. These claims usually involve breaches of nondelegable duties owed by hospitals to patients. Typically, a corporate negligence claim involves alleged failure to maintain safe and adequate facilities or equipment; employ competent physicians and staff; oversee providers to practice medicine within the system; and/or adopt adequate rule and policies to ensure quality care for patients. A claim of corporate negligence is solely against the system and never the individual physician.

Overall, malpractice claims against a physician or hospital can be alleged or established by patients on a number of theories. Many depend upon the law of the particular state in which the claim is brought. All require different approaches on how best to defend the physician or hospital.

3. Specific legal issues related to ERCP

Although ERCP is mostly successful in providing life-enhancing benefits, if complications occur [4], those complications can produce enough harm to make plaintiff's lawsuits feasible. The prudent ERCP practitioner is advised to be aware of issues such as appropriate indications for ERCP, specialty society literature and clinical practice guidelines, adequate informed consent, manufacturer's policies and procedures, understanding the level of experience necessary for both local credentialing and meeting national standards, and the best practices for managing endoscopic complications.

Perhaps the most common cause for an ERCP lawsuit is inadequate indication for a procedure that leads to a serious complication. Procedures performed for pain alone are potentially exposing the practitioner to increased medicolegal risk [5]. Further, advances in research now in the medical literature generally no longer support ERCP with sphincterotomy for Sphincter of Oddi Dysfunction type III (SOD type III) [6]. Remaining current in the literature regarding prevention of postprocedure pancreatitis is advised [7,8].

The process of informed consent is particularly important for procedures with risk, especially if the patient has not really had an informed discussion about the procedure. First meeting the ERCP patient on the endoscopy table immediately prior to the procedure is not optimal and raises the legal issue of "coerced consent" [9].

As ERCP has become more complex, going from initially diagnostic to now mostly therapeutic, and with increasing complex therapeutic possibilities, the experience of the provider with advanced techniques has emerged as a potential issue. Hospital credentialing committees have increased the number of ERCPs required to receive and maintain credentials. Within the gastroenterology literature and gastroenterology societies can be found admonitions regarding inexperienced providers [10].

An emerging discussion of the best practices in approach and management of postprocedure complications is relevant all endoscopic procedures, including ERCP [11].

4. What if infection happens?

4.1. How to disclose

Upon discovery of potential infection incident regarding the use of an endoscope, the physician should immediately disclose the incident to risk management, compliance, or their hospital's legal counsel to gain guidance on how the hospital plans approach the issue.

The hospital will determine the source of the patient's infection and whether or not it is related to a failure to appropriately sanitize or disinfect an endoscope prior to initiating the patient's procedure. Steps should be taken in compliance with hospital policies to minimize and prevent further patient exposures.

The hospital will likely determine the strategy for approaching patient and family members regarding disclosure of potential infection. It has been proven that good quality communication between providers and patients is important and can potentially reduce the risk of the patient initiating a lawsuit.

The hospital will consider any applicable state or federal regulations regarding disclosure of the infection. It will guide the nature and method of the hospital's disclosure regarding the potential infection or risk of infection.

Overall, it is critical that the first step upon discovery of potential scope-related infection incident is to notify to the appropriate hospital personnel so that the policies and procedures that have been put into to place can be implemented. Prompt and proper disclosure to the appropriate personnel will best assist in the defense of the physician or hospital in any future litigation that occurs.

4.2. How to handle lawsuit

If a lawsuit occurs because of an endoscope-related infection issue, the first step for a physician who has been sued is to notify the insurer immediately, as this may be required under their policy for coverage. It is also the best practice to notify the carrier and/or the hospital (if it occurred at the hospital) of any incident or serious event, bad outcome, or letters from lawyers representing the patients. This allows for early investigation and, in some cases, intervention.

It is imperative that the physician not under any circumstances, add or alter the plaintiff's medical records or destroy or alter physical evidence such as the endoscope in question. Although they have continued access to electronic medical records, accessing or altering these documents leaves an electronic trail. Attorneys are now frequently requesting an "audit trail" during discovery, which shows who and when someone accessed or altered relevant medical records. Additionally, it is likely that the plaintiff's counsel has already obtained and reviewed records for their client. As such, counsel will notice any

alterations and will require an explanation as to the same. If it is discovered that the physician did alter any medical records, it is important that they notify their attorney about the specifics of such. The physician should not discuss anything about the case with anyone other than their spouse and attorney. This will prevent plaintiff's counsel from deposing additional witnesses and limit the amount of people potentially forced to testify.

After an attorney has been secured, it is critical that the physician arrange a meeting to develop a positive relationship early in the litigation process. A medical malpractice case can be a long and arduous process, which requires parties be involved with their attorney during the course of the litigation. For the attorney-client relationship to be successful, it is imperative that the physician knows and feels comfortable with their attorney and develop confidence and trust in them. Without this trust, it will be difficult to accept various decisions or suggestions that the attorney believes are in the physician's best interest.

A good relationship with the physician will also aid the attorney in educating themselves on medical concepts relating to the case. It worth remembering the physician's attorney most likely has not attended medical school and many of the medical concepts will initially be new. By the time trial arrives, however, the attorney will be very familiar with the medical issues in the case. In these suits, the attorney is the physician's ally. It is the attorney's job to help the physician and/or hospital. Thus, it is essential that the physician respond fully and honestly to all questions posed by their attorney and disclose all possibly relevant information.

At some point during the lawsuit, the plaintiff's attorney will take depositions. The plaintiff's attorney will strive to obtain concessions that establish the standard of care, breach of the standard, causation, and damages. Depositions are not the time to provide explanations. It is the time to concisely answer specific questions posed by counsel without volunteering any additional information. Ultimately, trials build on what occurs during depositions. Preparation is key. Physicians should be open to advice or criticisms from lawyers.

If a case goes to trial, it can last anywhere from 1 to 3 weeks. The physician's daily presence (including at the jury selection before the trial begins) is mandatory and in their own best interest. Likely, the lawyer will have little control over the date on which the trial will occur. That date will be set by a judge, who will not be sympathetic to scheduling problems. The jury's perception of the physician and hospital can be influenced their presence and demonstrated dedication to their defense.

5. Recommendations related to scope infections

If an infection related to the use of an endoscope occurs, the circumstances of the care or incident at issue should be reviewed so that the physician, hospital, or group can gain insights about potential litigation and possibly take steps to minimize future risks and exposure.

Before any claim is made, a physician should work with their practice group, interdisciplinary team members, and hospital personnel to ensure their scope sanitization and disinfection procedures are following the recommendations of the product manufacturer, the CDC, and FDA. During a lawsuit, plaintiff's attorneys or experts involved in the lawsuit will rely upon these sources to support their contentions regarding proper procedures to follow and in supporting their version of the standard of care.

Hospitals should consider organizing an interdisciplinary committee to specifically monitor scope sanitation and disinfection procedures to ensure the most up-to-date guidelines for sanitation and disinfection are being followed. It may be beneficial to contact consultants or the endoscope manufacturer's representatives that can educate the group or hospital staff regularly on the proper sanitation and decontamination procedures to follow. The endoscope manufacturers are constantly working to improve their products, and may at any time produce new scopes that allow for greater preprocedure. Hospitals and physicians should make a point to be informed and circulate information to relevant providers about updates in the available scopes and purchasing the safest scopes on the market.

Policies of the group or facility should be carefully drafted keeping in mind the manufacturer, FDA, and CDC guidelines and be reviewed by risk management, compliance, or legal counsel. Informed consent documentation should be reviewed to ensure that all potential risks are disclosed to the patient regarding the use of the scope and the risk of infections. In addition, these risks should be discussed in person with the patient by the physician.

Of course, even the best and most thoughtful policies fail if they are not implemented. Policies should include a process to document that disinfection and sterilization procedures have been completed.

Hospitals should consider taking extra disinfection steps and allowing additional time after a procedure on a patient with a known highly contagious or difficult to treat infection. Infection prevention committees often consider the decontamination process to be more important than the procedure itself. While often physicians will have multiple cases in 1 day, it is important that pressure is not placed on the disinfection team to rush or skip steps in the process.

Remember that medical malpractice lawsuit arise from omitted acts and not just committed acts, meaning that liability can come from the omission of a step in infection prevention, such as missing a step in the scope sterilization process. While it can be easy to pass off sterilization and decontamination as "someone else's job," it is advised that physicians take individual ownership and be proactive in their oversight role before starting any procedure.

Overall, expenses in the short-term to ensure patient safety and compliance with manufacture regulations regarding cleaning of scopes are an investment in deterring future litigation costs.

6. Conclusion

ERCP is a valuable procedure in the endoscopy toolbox, often providing the best therapeutic option for patients. However, serious adverse events may occur. This review notes general legal issues important for the physician performing ERCP, such as appropriate indications, keeping up to date with the literature and clinical practice guidelines, adequate informed consent, experience and credentialing, and managing endoscopic complications. Endoscopists should be aware of the emerging issue of lawsuits related to endoscope-associated infections and should maintain an active role in understanding and executing current guidelines pertaining to endoscope reprocessing.

References

[1] Physician Insurers Association of America. PIAA claim trend analysis: gastroenterology, iv. Lawrenceville, NJ: PIAA; 2004. http://www.piaa.us.
[2] Kane C. Policy research perspective: medical liability claim frequency: 2007-2008 snapshot of physicians. American Medical Association; 2010. p. 4.
[3] Schaffer AC, et al. JAMA Intern Med 2017;177:710–8.
[4] Chandrasekhara V, Khashab MA, Muthusamy VR, et al. ASGE guideline: adverse events associated with ERCP. Gastrointest Endosc 2017;85:32–47.
[5] Cotton PB. Analysis of 59 ERCP lawsuits; mainly about indications. Gastrointest Endosc 2006;63:378–82.
[6] Cotton PB, Pauls Q, Keith J, et al. The EPISOD study: long term outcomes. Gastrointest Endosc 2018;87:205–10. https://doi.org/10.1016/j.gie.2017.04.015. Epub 2017 Apr 25.
[7] ASGE Standards of Practice Committee, Maple JT, Ikenberry SO, et al. The role of endoscopy in the management of choledocholithiasis. Gastrointest Endosc 2011;74:731–44.
[8] Chathadi KV, Chandrasekhara V, Acosta RD. ASGE guideline: the role of ERCP in benign diseases of the biliary tract. Gastrointest Endosc 2015;81:795–803.
[9] Feld AD. Informed consent: not just for procedures anymore. Am J Gastroenterol 2004;10:977–80.
[10] Faulx A, Lightdale J, Accosta RD, et al. Guidelines for privileging, credentialing, and proctoring to perform GI endoscopy. Gastrointest Endosc 2017;85:273–81.
[11] Richter JM, Kelsey PB, Cambell EJ. Adverse event and complication management in gastrointestinal endoscopy (PMID:26753887) Am J Gastroenterol 2016; 111:348–52.