

Medical malpractice litigation related to gastrointestinal endoscopy in Japan: A two-decade review of civil court cases

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Abstract

AIM: To examine the allegations in malpractice litigations related to gastrointestinal endoscopy in Japan.

METHODS: A retrospective review of cases tried in the civil court system during the 21-year period from 1985 to 2005, identified in a computerized legal database, was undertaken.

RESULTS: Eighteen malpractice litigations and a total of 30 allegations were identified. Of the 18 (44%) malpractice litigations, 8 (44%) were related to esophagogastroduodenoscopy, 4 (22%) to colonoscopy, 4 (22%) to endoscopic sphincterotomy, and 2 (11%) to endoscopic retrograde cholangiopancreatography. Seventeen (94%) cases pertained to complications, and the remaining (6%) case pertained to misdiagnosis. In 10 cases, the patient died of the complications. Allegations were categorized as: (1) performance error during the endoscopic procedure ($n = 12$, 40%); (2) lack of informed consent ($n = 9$, 30%); (3) performance error during the treatment after the endoscopic procedure ($n = 4$, 13%); (4) premedication error ($n = 3$, 10%); (5) diagnostic error ($n = 1$, 3%); and (6) indication error for the endoscopic procedure ($n = 1$, 3%).

CONCLUSION: These data may aid in the design of risk prevention strategies to be used by gastrointestinal endoscopists.

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Key words: Gastrointestinal endoscopy; Malpractice; Litigation; Risk management

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INTRODUCTION

The number of negligence litigations against physicians has been continuously increasing, not only in Western countries but also in Japan^[1,2] where a 10-fold increase in malpractice litigations from 102 to 1019 cases per year, has been observed between 1960 and 2003. As the frequency of malpractice claims has risen, physicians have begun to focus on risk management activities. Gastrointestinal endoscopy plays an important role in medical practice. Not only is simple endoscopic examination performed, but also treatment procedures such as endoscopic polypectomy, endoscopic mucosal resection and endoscopic sphincterotomy (EST) are performed. However, various complications associated with these procedures have been reported^[3,4]. Thus, gastrointestinal endoscopy is a field in which malpractice actions frequently occur^[1,2,5-13].

Furthering the awareness of physicians may be one method of reducing the number of malpractice claims. However, little is known about the allegations underlying medical malpractice litigations in Japan or about those pertaining to gastrointestinal endoscopy in particular. To identify the allegations in malpractice litigations pertaining to gastrointestinal endoscopy, we undertook a review of all Japanese civil court trials from 1985 to 2005 that involved gastrointestinal endoscopy. Our goal was to extract medical information from published court reports to determine the types of gastrointestinal endoscopist errors in these cases.

MATERIALS AND METHODS

A listing of Japanese civil court trials pertaining to gastrointestinal endoscopy from 1985 to 2005 was retrieved from a computerized legal database (MASTER Library, Shinnippon-hoki Publishing, Tokyo, Japan). Published reports of court decisions in these cases were then obtained from volumes of judicial precedents, and medical information was abstracted from these precedents.

Table 1 Litigations related to gastrointestinal endoscopy in Japan, 1985-2005

Procedure	Complication/diagnostic error	Allegation 1	Decision	Allegation 2	Decision	Allegation 3	Decision
1 ERCP	Death due to peritonitis induced by duodenal perforation	Performance error during procedure	P				
2 EGD	Massive hemorrhage	Performance error during procedure	L				
3 EGD	Death due to premedication shock	Premedication error	P				
4 Colonoscopic polypectomy	Colonic perforation	Indication error	L	Lack of informed consent	P		
5 Colonoscopy	Colonic perforation	Performance error during procedure	P				
6 EST	Death due to pancreatitis	Performance error during procedure	L	Performance error after procedure	P		
7 EGD	Death due to premedication shock	Premedication error	L	Lack of informed consent	L		
8 EGD	Massive hemorrhage	Performance error during procedure	P				
9 EGD removal of foreign body	Unexpected emergent surgery due to fixation of foreign body	Lack of informed consent	P	Performance error during procedure	P		
10 EGD	Traffic accident due to the effect of sedative agent	Lack of informed consent	P				
11 EGD	Death due to premedication shock	Premedication error	L	Lack of informed consent	P		
12 Colonoscopy	Colonic perforation	Performance error during procedure	L	Lack of informed consent	P		
13 EGD	Misdiagnosis of gastric cancer	Diagnostic error	P				
14 EST	Death due to pancreatitis	Performance error during procedure	L	Performance error after procedure	L	Lack of informed consent	L
15 EST	Death due to pancreatitis	Performance error during procedure	L	Performance error after procedure	L	Lack of informed consent	L
16 ERCP	Death due to pancreatitis	Lack of informed consent	L	Performance error during procedure	P	Performance error after procedure	P
17 Colonoscopy	Colonic perforation	Performance error during procedure	P				
18 EST	Death due to peritonitis induced by duodenal perforation	Performance error during procedure	P				

ERCP: Endoscopic retrograde cholangiopancreatography; EGD: Esophagogastroduodenoscopy; EST: Endoscopic sphincterotomy. P: The claim prevailed; L: The claim was lost.

All allegations of negligence were assigned to 1 of the 6 categories: (1) performance error during the endoscopic procedure, (2) lack of informed consent, (3) performance error during treatment after the endoscopic procedure, (4) premedication error, (5) diagnostic error, and (6) indication error for the endoscopic procedure. Court decisions were also considered.

RESULTS

Eighteen cases and 30 allegations related to gastrointestinal endoscopy were identified (Table 1). Of the 18 cases, 8 (44%) were related to esophagogastroduodenoscopy (EGD), 4 (22%) to colonoscopy, 4 (22%) to EST, and 2 (11%) to endoscopic retrograde cholangiopancreatography (ERCP). Seventeen (94%) cases pertained to complications, and the remaining (6%) case pertained to misdiagnosis. In 10 cases, the patient died of complications. Perforation was identified in 4 cases, massive hemorrhage in 2 cases, a traffic accident due to the effect of a sedative agent in 1 case, and emergency surgery in 1 case (Table 2). Allegations were as follows: (1) performance error during the endoscopic procedure, $n = 12$ (40%); (2) lack of informed consent, $n = 9$ (30%), (3) performance error during treatment after the endoscopic procedure, $n = 4$ (13%); (4) premedication error, $n = 3$ (10%); (5)

diagnostic error, $n = 1$ (3%), and (6) indication error for the endoscopic procedure, $n = 1$ (3%).

In cases related to performance error during the endoscopic procedure, the most frequent procedure was EST (4 cases, 33%) followed by colonoscopy (3 cases, 25%). In all cases related to EST, the patients alleged performance error due to bad technique. Three of the 4 (75%) patients who underwent EST had severe acute pancreatitis after the procedure. The fourth patient died of panperitonitis due to duodenal perforation during the procedure. The 3 cases related to colonoscopy had colonic perforation during the procedure. In these 12 cases, allegations prevailed in 7 (58%) cases.

In cases related to lack of informed consent, 8 of the 9 (89%) allegations involved failure to warn the patient of risks of the procedure, such as possible pancreatitis after ERCP and EST, or the side effects of premedication. In the case related to the side effects of premedication, there were no documented instructions prohibiting driving after endoscopic sedation in the hospital. The remaining case had a foreign body in the patient's stomach, namely an artificial tooth that was 5 cm in length with sharp edges. Because both edges of the tooth were lodged in the esophageal wall during attempted endoscopic removal, the endoscopists abandoned the procedure and performed emergency surgery to remove the tooth. In this case, the

Table 2 Complications referred to in the litigations (*n* = 17)

Complication	<i>n</i> (%)
Death	9 (53)
Shock due to premedication of EGD	3 (18)
Severe acute pancreatitis due to ERCP	1 (6)
Panperitonitis due to duodenal perforation during ERCP	1 (6)
Severe acute pancreatitis due to EST	3 (18)
Panperitonitis due to duodenal perforation during EST	1 (6)
Perforation	4 (24)
Colonoscopy	3 (18)
Colonoscopic polypectomy	1 (6)
Massive hemorrhage after EGD	2 (12)
Traffic accident due to the effect of a sedative used for EGD	1 (6)
Unexpected emergency surgery due to lodging of a foreign body	1 (6)

EGD: Esophagogastroduodenoscopy; ERCP: Endoscopic retrograde cholangio-pancreatography; EST: Endoscopic sphincterotomy.

allegation was lack of information about the possible need for emergency surgery. The issue of informed consent never stands alone. In these 9 cases, allegations prevailed in 5 (44%) cases.

Three of the 4 (75%) cases of performance error during treatment after the endoscopic procedure were related to EST, and the remaining case was related to ERCP. All patients in these cases died of severe acute pancreatitis after the procedure. Diagnostic delay and inappropriate treatment to prevent pancreatitis were also alleged. The allegations prevailed in 2 of the 4 (50%) cases.

All of the premedication errors were related to EGD. All patients in these cases suffered shock just after administration of anesthesia or anti-cholinergic agent. Anaphylactic shock was diagnosed in the first 2 cases and acute poisoning due to overadministration of lidocaine was diagnosed in the third case. The allegations prevailed in 1 of the 3 (33%) cases.

The case of diagnostic error was related to misdiagnosis of scirrhous gastric cancer. The patient's stomach was not completely empty during EGD, thus complete gastric examination was not performed. However, the doctor diagnosed gastritis and did not re-examine the patient. She had scirrhous gastric cancer and died 6 mo after the examination. Her family alleged that the doctor overlooked the gastric cancer. The allegation prevailed.

The case of indication error was related to colonic polypectomy. In this case, colonic perforation occurred after colonoscopic polypectomy. The patient alleged that there was no indication for treatment, the allegation was lost.

DISCUSSION

Medical malpractice has become a predominant concern of physicians in Japan as well as in Western countries. Clinical risk management is the process of collecting, evaluating, and applying data to reduce the frequency of preventable patient injuries^[8]. Although general risk management information is abundant in the medical and lay literature, published material specific to gastrointestinal endoscopy is limited to editorials and case presentations^[8]. The

literature describes various adverse events associated with endoscopy. However, these reports focus on the frequency and nature of procedural complications, avoiding issues of negligence^[5,4]. Endoscopists need an understanding of malpractice allegations to develop appropriate risk-reduction strategies for gastrointestinal endoscopy.

In the present study, the most frequent procedure was EGD (39%), followed by EST (22%), colonoscopy (17%), and ERCP (11%). However, according to a Japanese report^[2], EGD has been performed 47 times as often as ERCP and 3.5 times as often as colonoscopy. The number of EST procedure is approximately one-tenth that of ERCP. Therefore, the relative frequency of litigation in Japan may be the highest in relation to EST, followed by ERCP and colonoscopy. Additionally, the mortality and complication rates of all endoscopies in Japan have been reported to be 0.00084% and 0.018%, respectively^[2]. The mortality rate has been reported to be 0.00045% for EGD and 0.048% and 0.0063% for EST and ERCP, respectively^[2]. Given these data showing the remarkable safety of endoscopy, serious complications naturally raise the issue of substandard care. However, an analysis in USA that was derived from an insurance industry database showed that the relative risks of malpractice claims arising from the performance of EGD, ERCP, and colonoscopy are similar^[14]. Thus, the relative frequency of litigation may be higher in relation to EST and ERCP in Japan but not in USA. One possible explanation for this discrepancy may be the bias of claims filed against the insurance industry in USA. Another possibility is that strict informed consent may be obtained for EST and ERCP in USA, because of a high frequency of related adverse events. Sufficient information about the adverse events associated with these procedures may decrease litigations.

Performance error during the endoscopic procedure was the most frequent allegation in the malpractice litigations against endoscopists. The potential complications of endoscopy are known to be numerous and well documented. The significant risk of adverse events should be emphasized during the informed consent process^[15-17]. Disclosure results in a sharing of risk between the endoscopist and patient may be protective for the endoscopist.

The second most frequent allegation was lack of informed consent. Studies have shown that increased communication reduces malpractice risk, thus the process of informed consent can be a useful tool for reducing this risk^[7]. The process of disclosing the inherent risks of a procedure or a medical treatment decision essentially asks the patient to accept those risks as part of the medical plan and procedure. The risk shift does not apply to substandard care, but it would apply to many of the complications that can occur even when procedures are performed properly and medications are administered prudently.

The one diagnostic error in the present study pertained to misdiagnosis of gastric cancer. This case illustrates how an opportunistic diagnosis without complete examination can lead to charges of malpractice^[18]. If a complete examination is not performed, doctor should recommend re-examination.

Knowledge of the factors leading to preventable patient injury is needed to develop optimal strategies for reducing malpractice risk related to gastrointestinal endoscopy. On the basis of our study results, we suggest the following risk prevention strategies to decrease the number of malpractice claims related to gastrointestinal endoscopy practice.

First, documenting possible complications during the informed consent process is essential. Complications during endoscopy frequently lead to litigation, especially if the possibility of such complications has not been discussed with the patient in advance.

Second, continued training in safe endoscopic techniques remains the principal method of preventing such complications. For example, participation in morbidity and mortality conferences may help physicians improve their diagnostic and therapeutic skills. Neale^[7] examined malpractice claims against gastroenterologists and reported that 44% arose from adverse events related to endoscopy and that there was evidence of serious fault in 50% of the cases, confirming the importance of continued medical education and training in safe endoscopic techniques.

Third, it is important to establish practice guidelines, especially in areas vulnerable to litigation. Such guidelines offer the best method of decreasing endoscopist errors leading to malpractice litigation.

Fourth, endoscopists should recognize that delayed diagnosis of a disease, particularly malignancy, is the most common cause of litigation. Improving the diagnostic ability of endoscopists is essential. In some cases, other modalities such as radiologic and ultrasonographic methods, may aid in prompt and correct diagnosis. Use of other modalities in cases for which a definite diagnosis is not obtained may ensure proper treatment.

In Japan as in USA, most malpractice cases are settled out of court. It has been reported that approximately 90% of malpractice cases in Japan are settled out of court, and the remaining cases lead to litigations^[19]. The court decisions are given in only approximately 30% of litigated cases. The compromised and withdrawn cases are not reported or available for review. Therefore, the denominator of the present study might have some bias. However, the aim of this study was to extract medical information from published court reports to determine the sources of endoscopy-related errors in cases requiring litigation. It is hoped that dissemination of the results of the present study among endoscopists can serve as a risk prevention strategy for reducing both complications and malpractice claims pertaining to gastrointestinal endoscopy.

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