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ORIGINAL ARTICLE

Cholecystectomy-related malpractice litigation: predictive factors of case outcome

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Abstract

Complications following cholecystectomy may lead to malpractice litigation. Little research exists regarding cholecystectomy-related malpractice, the complications that lead to litigation, and the outcomes of such cases. This study is a retrospective analysis utilizing the legal database Verdictsearch (ALM Media Properties, LLC, New York, NY). Medical malpractice cases between July 2004 and November 2017 were identified using the search term "gallbladder." Case information was recorded, including patient information, medical details, trial outcome, and resulting payments. Of 46 cases examined, 39 went to trial with a favorable plaintiff (patient) verdict in 43% (20/46) and a favorable physician verdict in 41% (19/46) of the cases. Only 7% (3/46) of the cases resulted in a settlement, with 4% (2/26) concluding in mixed verdicts or arbitration. The mean plaintiff victory payment was $723,844 ± $1,119,457, while the mean settlement payment was $1,350,000 ± $563,471. Intraoperative care was the most frequently litigated phase of care (67%, 31/46 cases). Problematic visualization of the surgical field was the most frequent intraoperative allegation (67.7%, 21/46 cases). Cases of problematic visualization often resulted in favorable plaintiff trial victory (66.7% vs. 19% in defendant victory). Only 9.5% of the problematic visualization cases settled. Bile duct injuries accounted for 43.5% of the injuries (plaintiff victory rate 60.0%; mean payment $736,434 ± $1,365,424). In cholecystectomy litigation, allegations of problematic intraoperative visualization are both the most common allegation and the most likely to end in physician loss. Bile duct injuries remain the most frequent patient injury leading to cholecystectomy litigation

Keywords Gallbladder · Cholecystectomy · Malpractice · Bile duct

Introduction

General surgeons have one of the highest probabilities of facing malpractice lawsuits of all medical specialties [1], and cholecystectomy complications are frequent causes for litigation [2]. A routine procedure performed over 600,000 times a year in the United States [3], cholecystectomies are generally performed laparoscopically, as has been the standard of care for over 2 decades. Despite these advances, cholecystectomies still present with a wide range of inadvertent and potentially dangerous complications [4, 5]. Injury to the bile duct has been frequently observed to be the most common risk associated with laparoscopic cholecystectomies [2, 5-10], with such injuries frequent enough to elicit debate over its nature as an inherent complication of gallbladder procedures [11].

Within the past decade, a comprehensive investigation of cholecystectomy litigation trends has not been performed, and there is limited research examining the variety of plaintiff allegations leading to malpractice trials. The objective of this investigation is to evaluate recent trends in cholecystectomy-related malpractice, the complications that generate litigation, and the outcomes of such cases.

Methods

This study is a retrospective analysis utilizing the Verdictsearch database (ALM Media Properties, LLC, New York, NY), which provides comprehensive case information for over 200,000 lawsuits from across the United States. This database has been validated in previous publications examining medical malpractice [12-15]. Relevant cases

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were identified using the database search features, searching within medical malpractice cases for reports classified as "gallbladder" by the set Verdictsearch criteria. Case information was recorded, including patient information, medical details, trial outcome, and resulting payments. Plaintiff verdicts indicate cases in which the physician was found guilty of malpractice, while cases concluding in defense verdicts found the physician not guilty of medical malpractice and resulted in no payment. Settlements suggest agreement between the physician and plaintiff party resulting in physician payment without a trial verdict. Mixed verdicts, categorized separately in the Verdictsearch database, suggest a verdict against the physician differing from the full accusations originally brought forward. Arbitration cases indicate a binding verdict made outside the court by an external third party which often result in payment. All information was obtained on trials occurring between July 2004 and November 2017.

Cases were further categorized by allegation phase of care and subtype. Allegations of improper post-surgical treatment claim that the addressing of complications following surgery was negligent, while incorrect pre-surgical assessment allegations claim that negligent assessment of the patient prior to surgery caused adverse outcomes during/following procedure. Failure to treat alleges that the procedure was insufficient or incorrect to treat the patient, unnecessary surgery alleges that the patient did not require the cholecystectomy, and intraoperative error claims negligent errors were made during surgery, either in surgeon judgement or execution. Within intraoperative error, complications were further defined by subcategory. Problematic visualization allegations allege incorrect identification of anatomy and/or incorrect procedure or technique used to visualize structures/regions, as directly noted in the lawsuit. Improper response to damage claimed insufficient or negligent response to complications, both anticipated or unanticipated, during surgery. Failure to convert to open surgery cases directly claimed that a physician failure to change from a laparoscopic to open cholecystectomy was the reason for adverse medical outcomes, and surgical injury cases accused the defendant of inadvertent damage unrelated to the specific structures being addressed during the procedure, such as colon damage or equipment burns. Quantitative evaluation of case components including percentages, mean payments, and standard deviations were performed using Microsoft Excel.

Results

Case characteristics

The Verdictsearch database yielded 49 cases, 3 of which were not primarily gallbladder related and were discarded, and 46 cases were identified which accused malpractice related to cholecystectomy procedures (Table 1). Plaintiffs were predominantly female (67%, 31/46 cases) versus male (33%, 15/46 cases), with the average plaintiff age of 47.1 ± 15.5 years. Of the 12 states with filed cases represented, California was the most frequent state for litigation (26%, 12/46 cases), consistent with what has been observed in similar Verdictsearch studies [13-15] and likely most attributable to state population. Further patient demographic info was not consistently available to analyze. All the cases collected litigated general surgeons as the primary defendant, while 3/46 cases listed a secondary practitioner as well (a nurse, a vascular surgeon, and a radiologist). A vast majority of cases involved planned cholecystectomies (95.7%, 44/46 cases) compared to gallbladder removal performed during exploratory laparotomies (4.3%, 2/46 cases).

Intraoperative error was the phase of care most frequent featuring allegations (67%, 31/46 cases), with other phases of care combined accounting for 33% of the cases. The plaintiff (patient) was victorious in 43% (20/46) of the cases, while the trial concluded in favor of the physician in 41% (19/46) of cases. Cases were least likely to conclude with settlements, accounting for only 7% (3/46) of all the cases. Four percentage (2/46) of the cases concluded each through arbitration and mixed verdicts, both of which awarded financial payouts to the plaintiff.

Table 1 Case characteristics of cholecystectomy malpractice lawsuits

Variable	*n* (%)
Total lawsuits	46
Sex of plaintiff	
Female	31 (67)
Male	15 (33)
Mean age of plaintiff	47.1 ± 15.5
States represented	12
Reason for surgery	
Planned	44 (95.7)
Emergency	2 (4.3)
Allegation phase of care	
Intraoperative error	31 (67)
Improper post-surgical treatment	5 (11)
Incorrect pre-surgical assessment	4 (9)
Failure to treat condition	3 (7)
Unnecessary surgery	3 (7)
Trial outcome	
Plaintiff verdict	20 (43)
Defendant verdict	19 (41)
Settlement	3 (7)
Arbitration	2 (4)
Mixed	2 (4)

By nature of the Verdictsearch reporting process, many cases were not directly identified as either laparoscopic or open. The procedure was specifically identified to have been performed laparoscopically in 63.0% (29/46) of the cases. Of these cases, 55.2% (16/29) concluded in plaintiff victory for a mean plaintiff payment of $554,539 ± $529,642 and 37.9% (10/29) concluded in a physician victory. The procedure was not specifically defined by the Verdictsearch database as laparoscopic in 32.6% (15/46) of cases, in which 26.7% (4/15) of cases concluded in patient victory with a mean payment of $1,401,067 ± $2,402,051, and 46.7% (7/15) ended in a physician victory. 4.3% (2/46) were identified as emergency gallbladder removals, and both concluded in defendant victories.

Allegations

Defendant surgeons were most frequently litigated for allegations of intraoperative error, with 67.4% (31/46, Table 2) of the total cases claiming physician negligence during surgery. Improper post-surgical treatment was the second most frequent allegation (10.9%, 5/46 cases). Intraoperative error claims were most likely to conclude in a plaintiff victory (51.6%, 16/31 cases), and least likely of all allegations to conclude in a defense verdict (32.3%, 10/31 cases). Only 6.5% (2/31) of intraoperative error cases concluded in settlements, while improper pre-surgical assessment, failure to treat condition, and unnecessary surgery allegations saw no settlements. Allegations of failure to treat condition, in which patients alleged otherwise successful surgeries were not sufficient, concluded entirely in defensive verdicts. Though rare, settlements across allegations had a larger mean payment ($1,350,000 ± $563,471) compared to plaintiff verdicts ($723,844 ± $1,119,457).

Intraoperative error

Intraoperative error allegations were further categorized based on the alleged type of negligence leading to litigation (Fig. 1). The most frequent allegation of negligence was problematic visualization (67.7%, 21/31 cases, Fig. 1a). Surgical injury, which alleged inadvertent damage unrelated to the specific structures being addressed during the procedure (colon damage or equipment burns), was the least frequent reasons for surgical negligence litigation (6.5%, 2/31 cases). The plaintiff was primarily victorious in cases alleging problematic visualization as the source of intraoperative error (66.7%, 14/21 cases) with a particularly low rates of defensive verdicts (19.0%, 4/21 cases) and only 2/21 settlement cases (9.5%). All the cases alleging either failure to convert to open surgery or surgical injury separate from the gallbladder concluded in favor of the physician. All the cases concluding in mixed verdicts were due to improper response to damage. Problematic visualization

Table 2 Outcomes between phases of care in which malpractice occurred

Phase of care	Number of cases (% of total)	Plaintiff verdicts (% of phase), mean payment ± SD	Defense verdicts (% of phase)	Settlements (% of phase), mean payment ± SD	Arbitration (% of phase), mean payment ± SD	Mixed verdicts (% of phase), mean payment ± SD
Intraoperative error	31 (67.4%)	16 (51.6%) $542,476 ± $539,152	10 (32.3%)	2 (6.5%) $1,525,000 ± $671,751	1 (3.2%) $348,720	2 (6.5%) $1,580,481 ± $381,158
Improper post-surgical treatment	5 (10.1%)	2 (40%) $2,625,000 ± $3,358,757	2 (40%)	1 (20%) $1,000,000		
Incorrect pre-surgical assessment	4 (8.7%)	1 (25%) $338,826	2 (50%)		1 (25%) $100,444	
Failure to treat condition	3 (6.5%)		3 (100%)			
Unnecessary surgery	3 (6.5%)	1 (33.3%) $208,440	2 (66.7%)			
Total	46 (100%)	20 (43.5%) $723,844 ± $1,119,457	19 (41.3%)	3 (6.5%) $1,350,000 ± $563,471	2 (4.3%) $224,582 ± $175,558	2 (4.3%) $1,580,481 ± $381,158

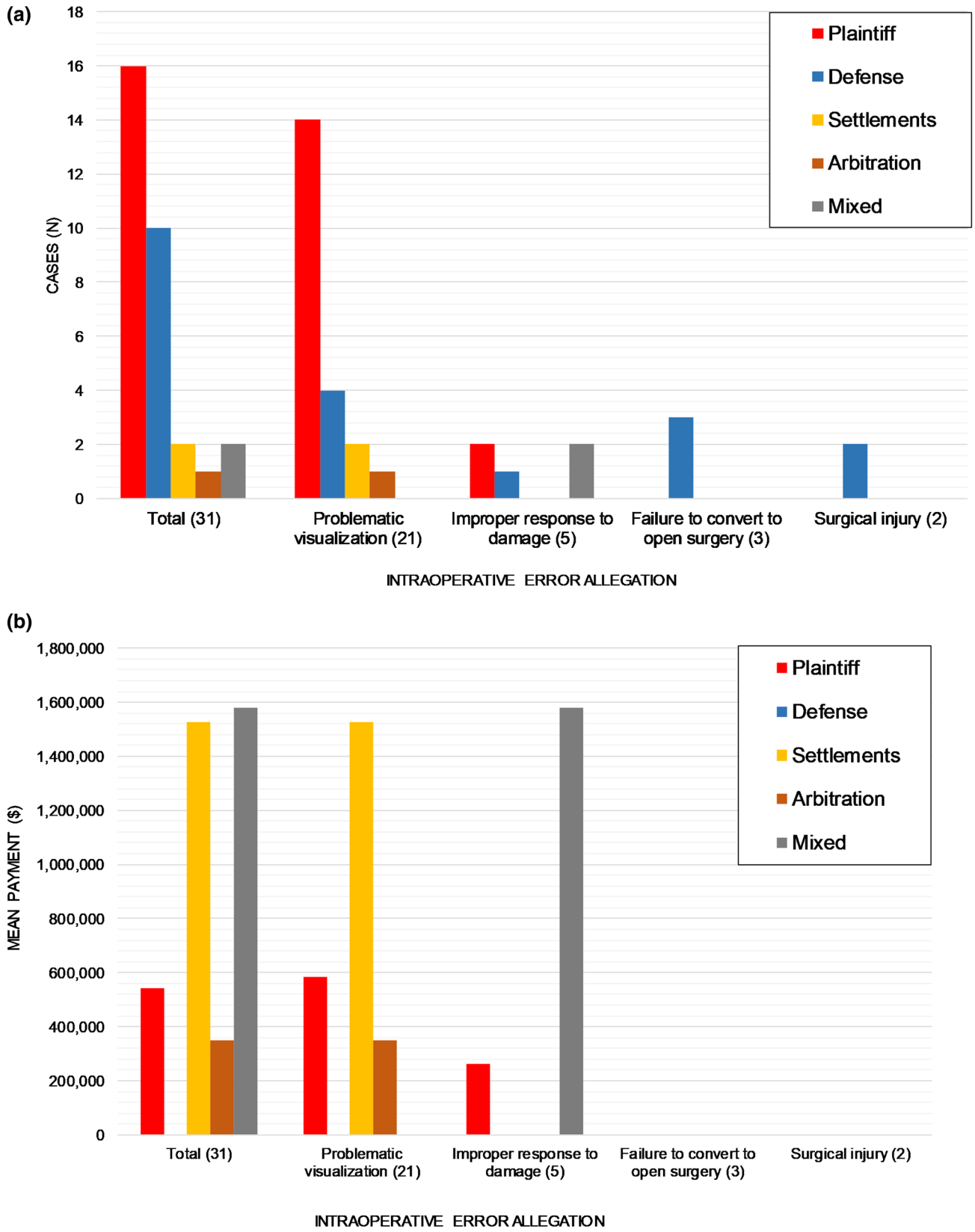

Fig. 1 Outcomes of intraoperative error allegations: **a** Trial outcomes (*n*); **b** Payments ($)

lawsuits resulted in the highest mean plaintiff payment ($948,167 ± $669,008, Fig. 1b). Both cases concluding in settlements, as well as both mixed verdicts, saw higher payments than the mean plaintiff verdict payout (mean settlement payment $1,525,000 ± $671,751, mean mixed verdict payment $1,580,481 ± $381,158).

Medical outcomes

Lacerated ducts accounted for a majority of malpractice cases (60.9%, 28/46 cases, Table 3), with damage to the bile duct being overall the most frequent complication to occur (43.5%, 20/46 cases). Lacerated hepatic ducts were the second most frequent reason for litigation (15.2%, 7/46 cases), followed by lacerated iliac artery and allegations of general surgical complications including burns from equipment or improperly sealed wounds (each 10.9%, 5/46 cases). The plaintiff was most frequently victorious in cases alleging lacerated bile ducts (plaintiff victory rate 52.9%, mean payment $929,245 ± $1,547,354), followed by myocardial infarctions (plaintiff victory rate 50%, mean payment $338,826) and perforated intestines (plaintiff victory rate 50%, mean payment $280,426 ± $101,803). General surgical complication trials ended in favor of the physician in 80% (4/5) of the cases.

Death was the ultimate medical outcome in 10.9% (5/46 cases) of litigations. Cases resulting in death saw the highest plaintiff verdict payments (plaintiff victory rate 40%, mean payment $2,669,413 ± $3,295,948) and both the highest rate of settlement and highest settlement payments (settlement rate 40%, mean payment $1,525,000 ± $671,751) of all medical complications.

Table 3 Complications of cholecystectomies leading to litigation

Medical outcome: (n, %, mean payment ± SD)
Myocardial infarction: 2 (4.3%)
Plaintiff: 1 (50%) $338,826
Arbitration: 1 (50%) $100,444
Perforated intestine: 4 (8.7%)
Plaintiff: 2 (50%) $280,426 ± $101,803
Defense: 2 (50%)
Gallstones disrupted into abdominal cavity: 1 (2.2%)
Defense: 1 (100%)
Lacerated bile duct: 20 (43.5%)
Plaintiff: 12 (60.0%) $736,434 ± $1,365,424
Defense: 5 (25.0%)
Settlement: 2 (10.0%) $1,500,000 ± $707,107
Arbitration: 1 (5.0%) $348,720
Lacerated cystic duct: 1 (2.2%)
Defense: 1 (100%)
Lacerated hepatic duct: 7 (15.2%)
Plaintiff: 2 (28.6%) $1,132,500 ± $1,226,830
Defense: 3 (42.9%)
Mixed: 2 (28.6%) $1,580,481 ± $381,158
Lacerated iliac artery: 5 (10.9%)
Plaintiff: 2 (40%) $1,150,000 ± $494,975
Defense: 3 (60%)
Lacerated portal vein: 1 (2.2%)
Settlement: 1 (100%) $1,050,000
Surgical complication [a]: 5 (10.9%)
Plaintiff: 1 (20%) $175,000
Defense: 4 (80%)

[a]Indirect from procedure, including wound infection, equipment burn, and missed cancer

Discussion

Despite the frequency with which cholecystectomies are performed and complications occur, there has been minimal investigation of relevant malpractice trends in the past decade. This investigation examined available malpractice data to observe general trends in gallbladder-related litigation through a retrospective investigation of the Verdictsearch database. Though other legal databases including Westlaw and LexisNexis have also been used for similar research [16, 17], Verdictsearch allows for effective qualitative analysis of a limited number of cases. We studied 46 cases of cholecystectomy-related litigation between 2004 and 2017 to examine if the ubiquitous adoption of laparoscopic cholecystectomy saw different surgical complications and factors contributing to litigation than procedures of previous decades.

As expected, intraoperative care was the phase of care most frequently involved in lawsuits, with surgical errors accounting for a majority of malpractice lawsuits (67.4%) and the highest rate of plaintiff victories (51.6%). Within these allegations, problematic visualization was the most frequently cited reason for litigation (67.7%), consistent with the notion seen throughout the literature that proper visualization and anatomic identification may be the most effective means to minimize surgical error [2, 8, 9, 18]. A majority of the cases alleging problematic visualization as the factor causing intraoperative error concluded in favor of the plaintiff (66.7%) and saw the highest payments to victorious plaintiffs ($582,301 ± $566,115) compared to all other surgical negligence accusations, also higher than cases alleging negligence in different phases of care including improper post-surgical treatment (plaintiff payment $338,826) or unnecessary surgery (plaintiff payment $208,440). Few cases concluded in settlement overall (3/46, 7%), notably less than has been observed in other surgical practices including anterior cruciate ligament reconstruction

[14], pancreaticoduodenectomy [19], and bariatric surgery [20].

The most recent investigation by McLean and colleagues [6] examining laparoscopic cholecystectomy malpractice litigation from 1999 to 2004 found bile duct injury in 78% of cases, with 60% of all cases concluding in plaintiff verdicts with a mean payment of $508,341. In our investigation, the plaintiff was victorious in 43% of lawsuits, less than the 60% plaintiff victory rate observed by McLean and colleagues [6], and the 57% rate observed between 1993 and 1996 [7]. Conversely, we saw a larger mean plaintiff payout than was seen between 1999 and 2004, with a mean payment of $723,844 ± $1,119,457 compared to $508,341.

Consistent what has been well documented in the literature regarding cholecystectomies [2, 5-10], we found injury to the bile duct to be the most frequently reported complication leading to litigation (43.5%). This is a lower frequency than seen in previous malpractice studies, which reported 78% [6] and 61% [7] of the injuries involving the bile duct. Injuries to the hepatic duct were the second most frequent complication observed (15.2%). Perforated intestines occurred in 8.7% of the cases, a frequency between the earliest reported 16% [7] and the 2% [5] as previously observed. Unsurprisingly, in the 10.9% of cases involving patient death, the highest mean values for both plaintiff payments ($2,669,413 ± $3,295,948) and settlement payments ($1,525,000 ± $671,751) compared to all injury types were observed. Only 4.3% (2/46) of all cases involved unplanned cholecystectomies performed during exploratory surgery, a markedly lower rate than that of planned procedures, and both cases concluded in a defendant physician victory.

Substantial efforts have been made to reduce the risk of bile duct injuries and other complications during cholecystectomies, with recognition that visualization of the surgical region is the principle component behind risk reduction [8]. Techniques such as intraoperative cholangiography (IOC) during surgery may be beneficial [18], but there is no consensus on the benefit of IOC in reducing bile duct injuries [21].

With continued innovation in minimally invasive procedures [22], laparoscopic cholecystectomy continues to be the "gold standard" procedure as it has been since 1992 [23], though it has been suspected of higher rates of bile duct injury compared to the open procedure [9]. However, recent investigations suggest the rate of surgical injury during laparoscopic versus open procedures is not significantly different, as previously thought [21, 24]. The increasingly commonplace performance of laparoscopic cholecystectomies over the past 30 years has generated an overall reduction in bile duct injuries, but no significant reduction in mortality or morbidity [25]. Likewise, the shift to laparoscopic procedures allows for different possible intraoperative complications such as iliac artery injury [11], a laparoscopy-specific injury which we observed in 10.9% (5) of cases. Though the laparoscopic learning curve varies amongst physicians, our examination from a medicolegal perspective further shows the significance of bile duct injuries over a span of time in which laparoscopic cholecystectomy had become the standard, in contrast with previous medicolegal studies examining periods of more significant transition.

While the Verdictsearch database is a useful tool for investigating malpractice cases, utilizing such databases presents with several inherent limitations. The data were obtained from a 13-year window which encompasses broad changes in cholecystectomy practices that may not fully observed in the legal data. The cases available represent only a fraction of all available cholecystectomy malpractice lawsuits from a small sample size of states, with only a relatively small amount of cases being recorded in the database. Legal abstracts are not submitted to Verdictsearch by medical professionals, and the medical depth of information provided varies greatly between cases, making some comparisons (such as laparoscopic vs. open, or timing of complication recognition) difficult to perform. In particular, case reports often did not directly describe whether a procedure was laparoscopic or open, making a comparison between the two procedure types difficult to analyze. While Verdictsearch includes payment values for plaintiff victories and settlements, there is limited information regarding other dealings and interactions outside of the court.

Though the data obtained are largely consistent with what has been previously reported in the literature, it provides an update on malpractice trends in the age of laparoscopic cholecystectomy, meaningful for patients giving informed consent and for physicians aiming to improve their standard of care. Visualization of the operative field during cholecystectomies remains an utmost priority in minimizing damage to the biliary tree, and legal data reflect this. Intraoperative identification techniques such as fluorescent imaging with indocyanine green are currently being implemented to successfully reduce biliary tree injuries [27], and the role of such visualization in conjunction with advancing robotic techniques [18, 28] suggests a promising future. As was seen in the shift from open to laparoscopic operations [2, 4-6], upcoming shifts towards more advanced and minimally invasive cholecystectomy procedures including single-incision laparoscopy [22] and robotic surgery [30] may see further changes in both intraoperative complications and litigation trends. Investigations into these trends, potentially reflective of a physician learning curve or inherent risks of the new procedures, will be able compare to present research to better understand the changing nature of cholecystectomies.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Research involving human participants and/or animals This study is conducted in compliance with the ethical standards. This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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