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REVIEW

Updates in medical professional liability: a primer for electrophysiologists

Christopher Austin[1] · Fred Kusumoto[2]

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Abstract
Medical professional liability (MPL), traditionally known as medical malpractice, affects most electrophysiologists some point during their career, either directly through personal experience or indirectly by the experiences of colleagues. Despite this, most physicians struggle to accurately describe MPL in the context of clinical practice. Providers know little about the outcomes of malpractice claims as reporting of settled or litigated MPL cases is sparse in the medical literature. In the USA, individual patients can file a malpractice claim in a tort-based system, whereas in other parts of the world, no-fault malpractice systems are increasingly prevalent. Tort reform remains a topic of much debate as the economic costs of malpractice contribute to the ever-expanding costs of health care in the USA. This review provides a framework to define MPL, describes the tort and no-fault systems of malpractice, and details the economic impacts of MPL on health care and the practice of cardiology in the USA. Current policy trends towards MPL including tort reform are reviewed, and MPL as it relates to the practice of cardiac electrophysiology is detailed.

Keywords Medical malpractice · Malpractice · Medical professional liability · MPL · Cardiology · Electrophysiology · Tort

1 Introduction

Medical professional liability (MPL), traditionally known as medical malpractice, has far reaching impacts in the practice of medicine. All practicing physicians are affected by MPL at some point during their career, either directly through personal experience or indirectly by the experiences of colleagues. Fear of MPL has resulted in defensive medical practices such as overuse of advanced imaging in the emergency room, particularly cardiac stress testing with nuclear perfusion. The economic costs of MPL are believed to be exorbitant; however, actual data regarding these costs remains relatively scarce, likely due in no small part to the secretive nature of MPL litigation as physicians are often instructed by attorneys to not discuss ongoing litigation or settled claims. This practice creates an environment of mystery and fear surrounding MPL. MPL litigation is often long and arduous, creating potential financial and emotional hardships for patients and physicians alike. Patients who have sustained substantial injuries and are deserving of quick resolution often go years without payment of claims, which can ultimately result in greatly diminished payments to the plaintiff due to ballooning attorney's fees. Furthermore, prolonged litigation can create emotional duress for the patient and physician alike.

This review aims provide a framework to define MPL, describe the economic impacts of MPL on health care and the practice of cardiology in the USA, current policy trends towards MPL, and MPL as it relates to the practice of cardiac electrophysiology.

2 Medical malpractice: clarifying a confusing terminology

Despite the awareness of MPL in today's practice climate, few physicians can clearly describe what constitutes medical malpractice. One such definition would be "a tort or civil wrong

✉ Christopher Austin
christopher.austin@medicine.ufl.edu

Fred Kusumoto
kusumoto.fred@mayo.edu

[1] Department of Cardiology, University of Florida, Gainesville, FL 32607, USA

[2] Division of Cardiovascular Disease, Mayo Clinic Florida, Jacksonville, FL, USA

committed by a professional acting in his or her professional capacity" [1]. Perhaps, a more descriptive definition of medical malpractice is "a breach of the physician's duty that causes foreseeable injury to the patient" [2]. Because of the inherent difficulties in delineating what constitutes MPL, Fisher and Schneider described a four-part test to more clearly identify MPL [2]. Four terms that must be clearly stated are essential in the adjudication of medical malpractice: *duty*, *breach*, *injury*, *and causation* (Table 1).

Duty, otherwise known as the *duty of care*, in which "a physician's behavior is expected to be reasonable, prudent and consistent with the standard of care" [3]. The definition of standard of care is frequently a topic of debate and has varied conceptually and regionally over the years; however, recent cases have repeatedly upheld that the standard of care is "what a minimally competent physician in the same field would do in the same situation, with the same resources" [4]. Importantly, for a physician to have a duty of care, a physician-patient relationship must exist. Without this relationship, there is no legal duty and therefore no potential liability for breach of duty [5]. The physician-patient relationship is generally considered a contract between doctor and patient and may be established through various means. In certain circumstances, the relationship is implicit based on the circumstances of those providing medical care and those seeking care; for example, the relationship between an on-call interventional cardiologist and a patient seeking emergency care for an acute myocardial infarction even if they are unable to consent for a procedure due to clinical decompensation.

Table 1 Fisher and Schneider's four key terms for defining medical malpractice [2]

Key Terms	Description	Example
Duty	A physician-patient relationship exists in which the physician has a duty to care for the patient.	A patient with atrial fibrillation is referred to a cardiologist for evaluation and management of atrial fibrillation.
Breach	The physician breaches their duty to provide the patient with care.	The patient has CHADS2VASC = 3, and no obvious contraindications to anticoagulation, however, is not counseled on the risk of stroke nor offered anticoagulation for prevention of stroke.
Injury	An injury occurs, most often persistent and substantial.	The patient experiences an acute embolic stroke with permanent neurologic deficits.
Causation	The injury is directly linked to the breach of duty and is foreseeable to a reasonable physician.	The incidence of stroke was foreseeable in this patient, and the risk would have been reduced by anticoagulation.

The term *breach* refers to a physician's act or omission and is the first consideration to the determination of whether medical malpractice has occurred [3]. Breach may be active (an act) or passive (an omission). If the act or omission results in a failure of duty then, in general legal terms, the act or omission is negligent. From a legal perspective, the breach can be of any duty, for example failure of the duty to warn a patient about bleeding risk prior to starting anticoagulation.

The patient must incur some magnitude of *injury* for medical malpractice to be present. This is the injury that occurs during the course of treatment and is the result of the breach of duty. Generally, an injury must be persistent and substantial to form the basis of medical malpractice litigation; however, indemnity payments have been made to patients suffering emotional or temporary injuries only [2, 6].

Causation is the most complex component of the four part test that Fisher and Schneider describe for the identification of medical malpractice [2]. A causal link must exist between the breach of duty and the injury sustained for malpractice to be present. Importantly, causation has two key elements: *causation-in-fact* and *foreseeability*. Causation-in-fact identifies the specific links between the injury in question and the physician's breach of duty. Foreseeability refers to the predictable nature of the injury in question by a reasonably prudent physician [3]. Clearly, what may or may not be foreseeable is subject to debate. Furthermore, most states require that the act or omission be the cause of the injury to a reasonable degree of medical certainty, specifically greater than 50% likelihood. As determination of medical certainty and standard of care are often the crux of malpractice litigation, expert testimony is typically required to determine standard of care in any specific circumstance. Ultimately, the decision upon what constitutes MPL is decided on a case-by-case basis by a jury often lacking in medical sophistication and subject to the laws of the state in which the claim is filed.

3 Medical malpractice in the USA and abroad: tort and no-fault liability systems

In developed countries worldwide, most malpractice systems can be classified as a tort litigation system or a no-fault system [7]. A tort, an act or omission that gives rise to injury or harm to another and amounts to a civil wrong, is the basis of the malpractice litigation system in the USA. In a tort system, an injured patient may be compensated when negligent care is proved to be the cause of injury to the aggrieved party. Negligence is the issue that is adjudicated and is measured against the standard of care as decided by a jury. In the tort system, adverse medical outcomes in the absence of negligence do not confer liability [8]. The system acts to both

compensate victims of negligent care and deters negligent behavior by providers through monetary penalties. The patient may receive compensation for direct economic losses and non-economic losses, as well as punitive damages assessed against the provider.

A no-fault malpractice system compensates patients for physical injury during medical or health care activities without proof of providers' fault [7]. The no-fault system provides insurance to its members and is funded via public funds in the form of taxes or fees. This system has set prerequisites for filing of a claim, and compensation is granted or denied based on patient eligibility rather than physician's fault [9]. Compensation, however, will not be paid if the injury is the consequence of assumed risk in the process of treating a life-threatening injury or illness. The main goal of the no-fault system is to increase access and timely compensation for members that have experienced physical injury during medical treatment. No-fault claims usually do not require legal representation leading to lower litigation costs, and outcomes of claims are more consistent and predictable; however, appealing a decision is often difficult, and payments are considerably lower when compared to jury awards from a tort system. The system does not act as a deterrent to negligent physician behavior due to the separation of fault from an award; instead, it aims to foster an improved relationship between the medical system and the physician with the goal of improved patient safety in the health care system. No-fault malpractice systems have been successfully implemented in multiple countries worldwide, with Sweden having more than 30 years of experience [10].

4 The impacts of medical professional liability in the USA

Annual medical liability system costs, including defensive medicine, have previously been estimated to account for 2.4% of health care spending in the USA, or roughly $55.6 billion in 2008 [11] (Fig. 1). Litigation can be slow and expensive, with an average of 4 to 5 years between a claim and a MPL award payment leading to defense costs which, on average, exceed $83,000 per paid claim for cardiologists, the highest amount for any specialty [12, 13]. In a review of nearly 1500 malpractice claims, 97% of claims involved an adverse outcome [14]. In most cases in which injuries occurred because of error, the plaintiff received compensation (73%). However, nearly 80% of trial verdicts were won by the defense. When compared to the average practicing physician, cardiologists were at higher risk of facing a MPL claim with 8.6% of cardiologists facing litigation annually [15, 16]. Despite concerns about MPL and its economic impacts, little objective data is available regarding specific MPL claims. Physicians are often dissuaded by insurance carriers to avoid discussing their cases for fear that these discussions, including the traditional morbidity and mortality conference, could become discoverable. Although the disconnect between the economic and patient safety impacts of MPL is recognized at the highest levels of government, it remains unresolved. In 2006, then US senators Barak Obama and Hillary Clinton proposed the establishment of a federal office to oversee a national patient safety database as well as a program to improve transparency and reporting of medical errors known as the National MEDiC Act [17]; however, the bill died in senate committee and no further efforts have been put forth to transparently collect MPL litigation or patient safety data [18].

The most complete source of MPL litigation is maintained by The Physician Insurers Association of America, which collects registry data voluntarily submitted by its member organizations. In 2010, the group published details of 230,624 closed MPL claims between 1985 and 2007 [6]. There were 4248 closed claims involving cardiologists with 18% of these claims resulting in payment to the claimant which, interestingly, is lower than the 30% payment rate for claims against all physicians. Some would argue that this indicates a high rate of frivolous claims against physicians in general and cardiologist in particular [19]. Overall, the total indemnity paid amongst all physicians over 22 years was $13.9 billion. The average payment of a successful claim against a cardiovascular physician was $248,291, which was higher than the overall average payment of $204,268 for all physicians included in this database. The most common breach of duty was diagnostic error, and the most common diagnosis was coronary artery disease. Most claims against cardiovascular physicians involved death of the patient (53%) resulting in a high rate of claim payment (21%). Claims involving aortic aneurysm or dissection resulted in a high rate of paid claims (30%) with a very high average claim payment ($417,298). Cardiac dysrhythmia claims accounted for 3% of claims with 12% resulting in payment with an average of $276,774. Atrial fibrillation and flutter accounted for 2% of claims with 15% resulting in payment of an average of $362,833. Notably, 54% of claims against cardiovascular physicians were uncategorized with payment in 19% of these cases on average $186,786. Overall, the claims most likely to result in indemnity payment (30%) were grave injury, which also resulted in the highest average payment ($522,614). Interestingly, medical record errors resulted in the highest rate of paid claims (54%). Despite the large volume of closed claims included in this database, significant limitations exist as it lacks physician demographic data and contains few claims against physicians in large groups and academic centers.

A more recent study of paid malpractice claims from the National Practitioner Data Bank included claims from January 1, 1992 to December 31, 2014 [13]. During that period, cardiologists experienced one paid MPL claim per 63 years of medical practice. The rate of paid MPL claims against

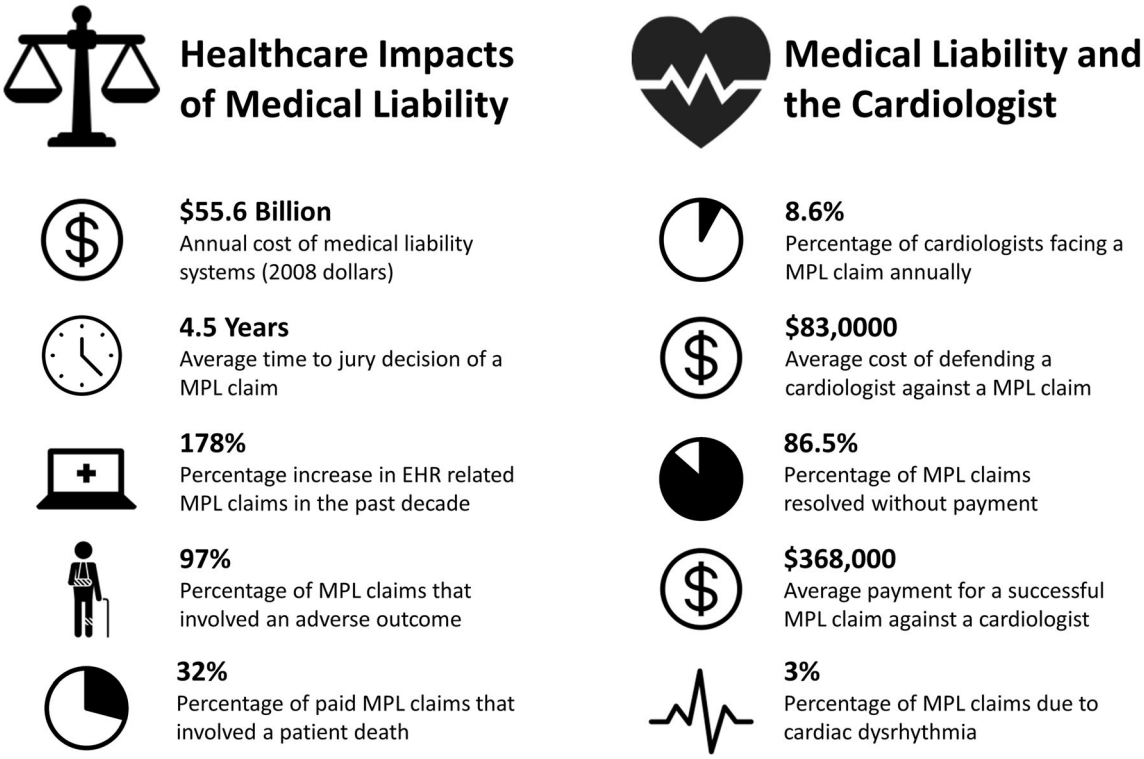

Fig. 1 The impacts of medical liability on health care and the specialty of cardiology in the USA

cardiologists have declined over the past decade and a half, with annual rates dropping from a peak at 18.0% during the 1997–2002 period to 13.5% during the 2009–2014 period. Interestingly, although there was a decrease in paid claims, cardiologists experienced the smallest percentage change of paid claims (− 13.5%) amongst all specialties over the span from 1992 to 2014, while the percentage of paid malpractice claims amongst all specialties decreased by 55.7%. Mean payments for MPL claims against cardiologists have increased by 9.1%, from $337,605 to $368,350 and were more likely to be successful if the injury resulted in significant physical harm (25.5%) or death (58.1%). Cardiologists were most commonly alleged to have committed malpractice with regard to medication or treatment of a condition (40.0%). Although this study provided insight into trends of paid MPL claims in the USA, the lack of data regarding unpaid claims, claims settled prior to litigation, or payments by an institution result in significant limitations.

5 Current policy trends and medical malpractice in the USA

For many years, tort reform has been proposed as a critical mechanism to reduce the burden of MPL litigation in the USA. Despite a push for reform from medical societies and many bipartisan legislators, little has changed in the past decade. Litigation of MPL is subject to state laws which vary broadly in both scope and limitations (Fig. 2). In the past several decades, efforts to create practical and meaningful tort reform at the federal level have been without yield, perhaps in part due to the dearth of physicians and abundance of attorneys in the elected legislative bodies [19]. More recently, however, there has been renewed hope of meaningful tort reform, in large part due to the influx of relative political outsiders and effective grassroots campaigns that have turned Washington, D.C. upside down in the most recent election cycles. Seizing this opportunity, the American College of Cardiology (ACC) has made strong calls for legislation that (1) creates a cap on non-economic damages associated with malpractice claims and (2) places a limit on plaintiff's attorney fees [20]. Currently, plaintiff awards are dependent on the opinion of the presiding jury and are without limit in many states. The potential for unlimited awards can create a co-plaintiff environment with the plaintiff's attorney standing gain monetarily as they often receive a percentage of the award, incentivizing the attorney to push for the highest amount possible. As the laws affecting MPL litigation vary from state to state, a clear understanding of local regulations is essential. Many states have implemented some flavor of tort reform with a wide variety of including caps on non-economic damages, loser pays winner's trial costs, and mandatory scheduling timeframes.

More recently, communication between the physician and patient has become a point of emphasis in MPL litigation. Despite the best efforts of health care providers, unexpected medical complications inevitably occur. These negative

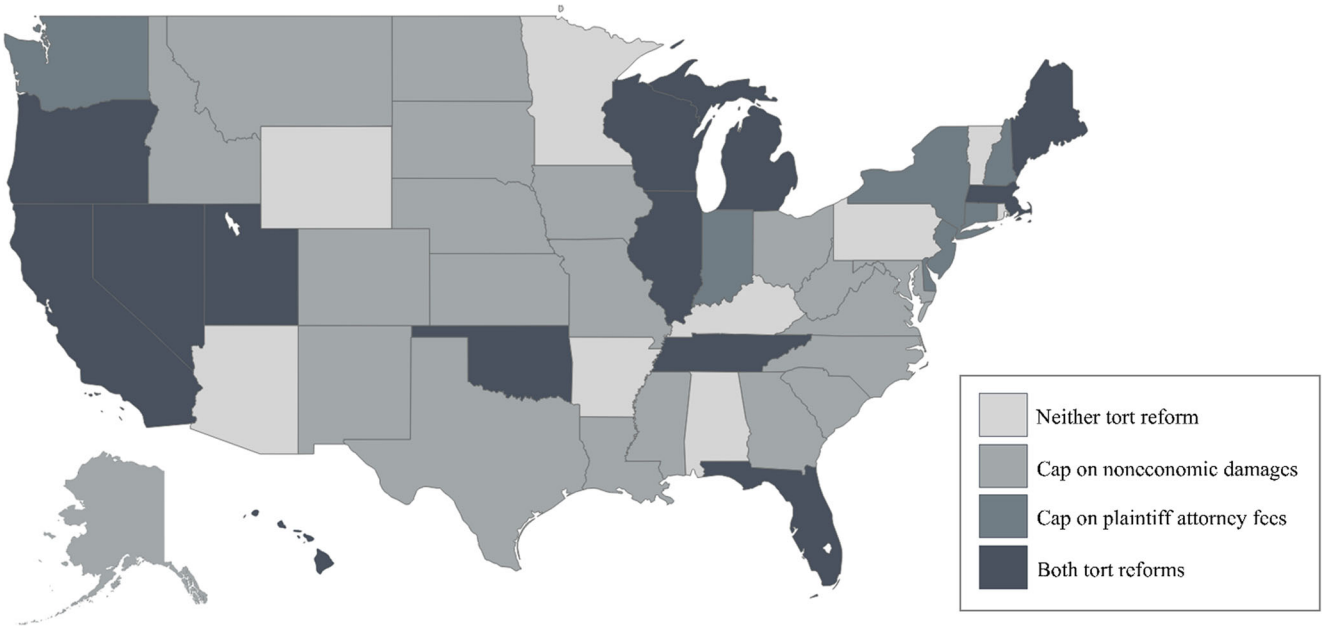

Fig. 2 US states with tort reform laws applying a cap on non-economic damages or a cap on plaintiff attorney fees

outcomes take a toll on physicians and patients alike, often leaving physicians feeling guilty and responsible regardless of the causation of the bad outcome. The instinct of many physicians is to provide not only condolences but also to apologize to those affected by such an unexpected outcome, driven by codes of professional ethics and personal integrity. Traditionally, lawyers have often advised physicians to remain silent out of fear of the potential of these communications being the basis for malpractice [21]. In an effort to remedy this apparent disconnect between patients and physicians, many states have enacted apology laws, allowing expressions of sympathy without the statement of condolence being misconstrued as an admission of liability [22]. Currently, 36 states and the DC have laws that prevent such an apology as being admissible in a legal proceeding. Apology laws vary broadly from state to state, and such variations are beyond the scope of this review; however, a few important differences should be noted. Many states define a clear distinction between *statements of sympathy* which are generally protected by apology laws and *admission of fault* which is not protected from admission in legal proceedings in many states. Additionally, timeframes for inadmissibility for expressions of sympathy may vary broadly from state to state, with periods as short as 72 h to months after the incident in question [23].

In general, although tort reform is necessary to reduce the economic burden of MPL litigation, previously enacted reforms are not without their detractors. For example, following comprehensive tort reform in TX, an increase in complaints to the medical board and subsequent increase in disciplinary action including revocation of licensure (up to 96%), and financial penalties imposed (up to 367%) were noted [24]. Even apology laws are subject to criticism, with a recent analysis suggesting a possible uptick in MPL litigation risk following an apology [25]. Situations of asymmetric information, described as situations in which the physician has greater knowledge of the risk than the patient, may create a scenario in where the patient learns of the risk through the process of the apology, leading to increased risk of MPL litigation regardless of the inability of the plaintiff to introduce the apology as evidence. Similar pratfalls likely exist for differing versions of tort reform; however, it is reasonable to believe that tort reform is necessary, and well-planned legislature will result in far more benefit for both the patient and physician than the status quo.

6 Medical professional liability and cardiac electrophysiology: the great unknown

Cardiac electrophysiologists (EP) diagnose and manage conditions that are often life-threatening as well as perform invasive procedures on some of the very sickest patients. However, little published data is available regarding the MPL risk and claims results specific to this specialty. Although complications associated with EP treatments are well known to practicing electrophysiologists and painstaking efforts are often employed to avoid such complications, unfortunately, most will have some experience with one or more during their career. As discussed previously, the reasons for this lack of data are multifactorial and unlikely to change soon give the current structure of MPL claims reporting. The ACC, through data made available by an MPL provider, The Doctors Company, has reported that three complications represented the majority of MPL claims against electrophysiologists: (1) arterial laceration during a pacemaker implantation or electrophysiology study, (2) atrioventricular

node damage during ablation that required pacemaker placement, and (3) pulmonary vein stenosis after ablation [26]. Another important, albeit non-procedural, target for MPL claims is the prescribing and monitoring of high-risk medications including amiodarone, dofetilide, and warfarin. The value of a meticulous informed consent cannot be understated when facing MPL claims. Similarly, management of a complication should include highly-detailed documentation, appropriate workup, and timely follow-up. Failure to act to appropriately manage a complication can quickly turn a routine complication into a lawsuit. Additionally, attention should be paid to non-cardiac findings that may arise during cardiovascular treatments such as possible cancer diagnosis that may be reveled through routine CT scans. Non-cardiac misdiagnosis is a well-described scenario leading to MPL claims.

It is important for the EP to adhere to the most recent societal guidelines or consensus statements, most commonly published by the ACC, American Heart Association (AHA), or Heart Rhythm Society (HRS), whenever possible. When management deviates from guideline statements or other expert consensus statements, clear documentation regarding the rational of the treatment plan should be provided in the medical record. Despite the best efforts of these societies to provide recommendations based on the latest available research, some of the most feared EP complications are limited to anecdotal description or case series.

6.1 Atrioesophogeal fistula as a complication of atrial fibrillation ablation

Perhaps the most feared complication of catheter ablation, the reported incidence of atrioesophogeal (AE) fistula following atrial fibrillation ablation is low, between 0.02 and 0.11%. However, the incidence of AE fistula in clinical practice is likely higher than reported. The low reported incidence precludes well-powered studies into the prevention of this often-catastrophic complication. Although available data suggests no clear benefit of proton pump inhibitors following atrial fibrillation ablation, 65% of the HRS writing group note personal use of these medications after ablation and state that proton pump inhibitors are "justified as a singular preventative therapy" following ablation, despite not providing a formal recommendation of this therapy [27]. A keen awareness of the presenting symptoms of AE fistula, which often include focal neurologic symptoms and febrile illness, is important not only for the electrophysiologist but also for others that may be caring for the patient during the following hospital discharge. Outcomes of MPL litigation regarding AE fistula have not been publicly reported.

6.2 Complications from lead extraction

As clinical indications for cardiac implantable electronic devices continue to broaden, so does the need for device extraction. Lead extraction is generally considered a safe procedure when performed by an experienced extractor in a high-volume center. Major complications, defined as those that pose an immediate threat to life or result in death, occur in 0.19 to 1.8% of lead extractions [28]. Minor complications, defined as those that require minor procedural interventions but not affecting the patient's function, are reported in 0.6 to 6.2% of patients. Despite the lower rate of major complications, the perception of lead extraction as an unacceptably high-risk procedure remains for many in the cardiology community. A well-developed plan for pre-, intra-, and post-procedural care greatly mitigates risk and potential for MPL and is detailed in the Heart Rhythm Society expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Outcomes of MPL litigation regarding lead extraction have not been publicly reported.

6.3 Complications from vascular access

Despite the relative frequency of MPL claims due to vascular access complications, there are no formal recommendations for vascular access technique in EP guidelines. Guidelines do, however, note the usefulness of ultrasound guidance [27]. Some authors go as far as recommending that ultrasound-guided vascular access should be the standard of care given a 60% reduction in major vascular complications when used appropriately [29, 30]. It is important to be aware of practices such as these as MPL claims are most often reviewed by an expert witness and are contingent on what a "reasonable physician" may opt do when faced with a similar scenario.

6.4 Cardiac tamponade after ablation

The most common major acute complication in atrial fibrillation ablation, cardiac tamponade, occurs in 1.3% of patients undergoing the procedure [28, 31]. The risk of bleeding in the pericardium is unavoidably increased by catheter manipulation and ablation as well as intense intra- and post-procedural anticoagulation which are required to reduce the risk of thrombotic embolism. Intracardiac ultrasound or transesophageal echocardiography is often used during the procedure to monitor for accumulation of pericardial fluid, particularly during times of hemodynamic instability during the procedure. This practice is likely to improve clinical outcomes and mitigate risk from MPL. Although rare, delayed cardiac tamponade (> 1 h after procedure) has also been reported in 0.2% of ablations with the median presentation 12 days after the procedure [28]. Although presenting symptoms were nonspecific, echocardiography was diagnostic in all cases, and the electrophysiologist should be aware of such an entity.

6.5 Remote cardiac monitoring

Remote cardiac monitoring has recently emerged recently as a viable way for physicians and care teams to reduce adverse clinical events and improve satisfaction in patients with cardiac implantable electronic devices. Accordingly, HRS has recommended a strategy of scheduled and ad hoc remote monitoring for surveillance of device function, detected arrhythmia, and device therapies [32]. Liability concerns regarding the timely interpretation and clinical response to remote transmissions have slowed the adoption of this technology [33]. A remote transmission may pass through the hands of a non-medical staff, technical specialist nurses, midlevel providers, general cardiologists, and electrophysiologists during its lifecycle, thus creating questions about how MPL would be adjudicated in the setting of an adverse event related to a delayed response. Regardless, as remote monitoring has become the standard of care, it should be offered to all patients with cardiac implantable electronic devices with this functionality. Third-party vendors may offer remote monitoring services, assuming the liability for the contractually agreed upon services. Patients must assume some responsibility for their care and are expected to appropriately maintain the home monitoring unit as well as to return to the office for scheduled in-person follow-up. Setting appropriate patient expectations for clinical communication regarding remote transmissions would seem a reasonable strategy to improve patient satisfaction and potentially mitigate risk of MPL. Outcomes of MPL litigation regarding remote monitoring have not been publicly reported.

7 Conclusion

Medical professional liability is a pervasive in the practice of cardiology and cardiac electrophysiology. MPL is complex, costly, and anxiety provoking for physicians of all specialties. Having a fundamental understanding of what constitutes MPL as well as recognizing common scenarios for MPL claims may help the physician reduce or mitigate the risk of MPL litigation.

Compliance with ethical standards

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

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