INTRODUCTION

Percutaneous coronary intervention (PCI) is among the most common major medical procedures provided by the U.S. healthcare system and constitutes a significant portion of the Medicare inpatient payments to hospitals. Femoral arterial access for coronary angiography and intervention (transfemoral approach, TFA) has traditionally been the preferred access site for many operators. Risks associated with TFA PCI include access site bleeding and other major vascular complications, with retroperitoneal hematoma being one of them, leading to higher risk of subsequent morbidity, mortality, and increase in length of stay and cost. Retroperitoneal hemorrhage is an uncommon but potentially fatal complication of TFA PCI occurring in approximately 0.5–0.74% of transfemoral procedures. Female gender, low body surface area, chronic renal failure, use of glycoprotein IIb/IIIa inhibitors, presentation with acute myocardial infarction (MI), and high placement of the sheath (above the
inferior epigastric artery) have been reported as the most significant risk factors for retroperitoneal hemorrhage in various studies.\cite{6,7,10} Mortality rates following retroperitoneal hemorrhage remain high, 8.6% in those experiencing a bleeding episode versus 2.4% in contemporary clinical practice, which has led to the modification of procedure strategies aiming to reduce its incidence.\cite{6,7,10} Transradial approach (TRA) for cardiac catheterization has consistently demonstrated significant reduction in bleeding and vascular complications as shown in multiple clinical trials\cite{8-10} and has led to increasing adoption of TRA worldwide. In the United States, the adoption of TRA has lagged overall and now is estimated at 30% of all diagnostic and PCI procedures performed.\cite{11}

Medical malpractice litigation cases constitute an important aspect of physician daily practice with their incidence correlating to the frequency of procedures. Characteristics of medical professional liability claims in the field of cardiac catheterization have been previously described, offering invaluable advice to practicing physicians and subsequently improved patient care.\cite{12} As TRA completely obviates the possibility of access-related retroperitoneal bleeding, we sought to analyze the available medicolegal evidence on retroperitoneal bleeding associated with TFA. This descriptive study focuses on the medical professional liability claims associated with retroperitoneal hemorrhage following PCI and its implications on access choice in contemporary practice.

MATERIALS AND METHODS

A systematic search on The LexisNexis Academic database (LexisNexis is division of Reed Elsevier, Dayton, Ohio)\cite{13}, a publically available and searchable archive, for published legal case opinions was performed. The combinations of keywords used were “retroperitoneal,” “retroperitoneal hemorrhage,” and “retroperitoneal bleeding.” All cases were decided according to the US legal system from 1976 to 2015.

After initial screening of title and summary, full text of the opinion statements considered relevant were assessed for eligibility. Criteria for including legal cases were as follows: (1) cases that involved patients who underwent diagnostic catheterization and/or PCI for any indication (primary PCI, rescue PCI, and elective PCI) and (2) cases that reported retroperitoneal hemorrhage after the respective procedure was performed. Each case was thoroughly reviewed and information about the date the case was decided, the plaintiff, the defendant, the claim, and trial outcome were extracted. Cases were further grouped and analyzed based on the patient outcome as well as on the inclusion of physician in the lawsuit.

RESULTS

From a total of 342 lawsuit claim records identified in LexisNexis database search, 17 cases of TFA and TFA-PCI-related retroperitoneal hemorrhage decided between 1995 and 2015 were included in the study. The litigation characteristics and outcomes of these cases are shown in Table 1.

According to the data collected, the most commonly filled claim was medical malpractice (52.9% of the cases), followed by wrongful death (17.6%) and review of the Commissioner's decision to deny application for Supplemental Security Income (11.8%). About 47.1% of the cases were won by the defense, 29.4% by the plaintiff, and 23.5% were remanded for a new trial (Table 2). PCI-related retroperitoneal hemorrhage litigation involved the physician in 82.3% of the cases. The plaintiff won all the cases not involving the physician. However, when the physician was involved as a defendant, only 14% of the cases were won by the plaintiff.

In our study of TFA-related retroperitoneal hemorrhage, death was the most common outcome with 58.8% of the reported claims being filled by a third person acting as an executor of the deceased estate (Figure 1). Physicians and the hospital were included in the lawsuit in all of the cases. Interestingly, only one case was decided in favor of the plaintiff and two cases were remanded for a new trial. The remaining 70% of the cases were decided in favor of the defending physician and hospital, suggesting that patient outcome did not seem to influence the verdict in the plaintiff’s favor (Figure 2).

Medical litigation involved judgments and rulings at numerous levels of the US legal system. In 23.5% of the cases, the decision was made at the District Court, 41.2% were decided at the Court of Appeals, 5.9% at the Common Pleas Court, and 11.8% at the Superior Court. Furthermore, 17.6% of the claims required a Supreme Court ruling.

DISCUSSION

In this analysis of the LexisNexis Academic database, we have demonstrated for the first time the medicolegal implications and outcomes of retroperitoneal hemorrhage following TFA and TFA PCI in the United States from 1995 to 2015.

Health-care-related litigation affects physicians in many countries around the world either as an existing or emerging issue. The fear of legal action is ubiquitous in daily medical practice, and its impact is acute among medical service
<table>
<thead>
<tr>
<th>Case</th>
<th>Year</th>
<th>Patient status</th>
<th>Sued</th>
<th>Reason</th>
<th>Outcome</th>
<th>Court site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horwitz vs. Yale New Haven Hosp.</td>
<td>1996</td>
<td>Died</td>
<td>Hospital and Physician</td>
<td>Medical Malpractice Claim</td>
<td>Defendants did not deviate from the applicable standard of care</td>
<td>Superior Court of Connecticut</td>
</tr>
<tr>
<td>Woodmancy vs. Colvin</td>
<td>2013</td>
<td>Alive</td>
<td>Commissioner of the Social Security Administration</td>
<td>Review of Commissioner’s decision to deny her applications for disability insurance benefits and for Supplemental Security Income (SSI) benefits</td>
<td>Commissioner of Social Security’s decision is reversed</td>
<td>Nebraska District Court</td>
</tr>
<tr>
<td>Young vs. Thota</td>
<td>2013</td>
<td>Died</td>
<td>Hospital and Physician</td>
<td>Medical Malpractice Claim</td>
<td>Defendants did not deviate from the applicable standard of care</td>
<td>Court of Appeals Texas</td>
</tr>
<tr>
<td>Nelson vs. Waxman</td>
<td>1999</td>
<td>Died</td>
<td>Hospital and Physician</td>
<td>Wrongful death claim</td>
<td>Judgment of the trial court is reversed, and the case is remanded for a new trial</td>
<td>Court of Appeals Missouri</td>
</tr>
<tr>
<td>Johnson vs. Genesis Med. Ctr.</td>
<td>2004</td>
<td>Died</td>
<td>Hospital, Physician and Nurse</td>
<td>Survival and wrongful death claim</td>
<td>Defendants did not deviate from the applicable standard of care</td>
<td>Court of Appeals Iowa</td>
</tr>
<tr>
<td>Comstock vs. Astrue</td>
<td>2013</td>
<td>Alive</td>
<td>Commissioner of Social Security Administration</td>
<td>Review of the Commissioner’s decision to deny her applications for Supplemental Security Income (SSI) benefits</td>
<td>Commissioner’s decision is reversed and this case is remanded for further proceedings</td>
<td>Northern Iowa District Court</td>
</tr>
</tbody>
</table>
| Kapacs vs. Martin             | 2005 | Died           | Hospital and Physician | Wrongful Death, Survival Action and Negligent Infliction of Emotional Distress | 1. Defendants’ Preliminary Objections in the form of a Motion to Strike or in the alternative is SUSTAINED  
2. Defendants’ Preliminary Objections to the Plaintiffs’ claim for punitive damages both individually and vicariously are OVERRULED  
3. Defendants’ Preliminary Objections to the Plaintiffs claim for Negligent Infliction of Emotional Distress are OVERRULED  
4. The Defendants’, Preliminary Objections to the Plaintiffs’ claim of corporate negligence are SUSTAINED. | Common Pleas Court of Lackawanna County |
| Baxter vs. Cardiology Assoc.   | 1995 | Died           | Hospital and Physician | Medical Malpractice Claim                                             | Patient died as a result of the professional negligence                  | Superior Court of Connecticut   |
| Sheila Orta Tellado vs. Saurin | 2009 | Died           | Hospital and Physician | Medical Malpractice Claim                                             | Defendants did not deviate from the applicable standard of care          | Court of Appeals Massachusetts   |
| Snyder vs. George Washington Univ. | 2006 | Alive          | Hospital, Physician and other medical employees | Medical Malpractice Claim                                             | Reverse the judgment of the trial court and remand this case for a new trial | District of Columbia Court of Appeals |
| Talmore vs. Baptist Hosps. of Southeast Tex. | 2006 | Died           | Hospital and Physician | Healthcare Liability Suit                                             | The written expert reports was not adequate and claim was dismissed       | Court of Appeals Texas          |
| Bradshaw vs. Lenox Hill Hosp.  | 2015 | Alive          | Hospital, Physician and Nurse | Medical Malpractice Claim                                             | Case is remanded for a new trial                                         | Supreme Court of New York , Appellate Division |
| Neal vs. Sparks 2012 Reg’l Med. Ctr., | 2012 | Died           | Hospital, Physician and Medical Malpractice Claim Nurse | Medical Malpractice Claim                                             | Summary judgment awarded to the hospital                                | Supreme Court of Arkansas       |

To be continued...
providers who pay increasingly high medical malpractice premiums. In 2001, physicians alone spent $6.3 billion obtaining medical malpractice coverage. According to the American Medical Association report, physicians and institutional health-care providers in 18 states face severe challenges in obtaining affordable professional liability insurance and similar conditions are developing in another 26 states. Despite the rising interest on medical malpractice, available research data show that only a small portion of the involved patients file a legal claim and claims lacking evidence of error are not uncommon. Interestingly, plaintiffs win only 42% of all malpractice cases and only one-third of the cardiac-catheterization-related claims. Our findings on TFA-related retroperitoneal hemorrhage are consistent with the aforementioned observations. In our study, physicians were part of the indictment in 82.3% of the available legal claims. However, only 29.4% of the available cases were won by the plaintiff, as the remaining 71.6% case were either won by the defense (47.1%) or were remanded for a new trial (23.5%).

Even when identified early, retroperitoneal hemorrhage can result in high rates of morbidity and mortality regardless of the therapeutic strategy. Observed mortality rate in patients with TFA-related retroperitoneal hemorrhage has been previously reported to be 8.6%. Medical litigation related to in hospital mortality after TFA was significantly higher in our study, constituting 58.8% of all claims. This finding can be partially attributed to a higher tendency for family member to pursue legal advice and file a legal claim against the physician and the hospital after a...
When the impact of practicing “defensive medicine” is considered, the economic costs are even higher both for the health system as well as for medical services consumers who face increased medical care costs. In this setting, TRA has emerged as a reliable alternative to the traditional femoral approach. TRA has been shown to reduce mortality both in ST-segment elevation myocardial infarction and non-ST-segment elevation acute coronary syndrome (NSTE ACS).

Equally important, in patients with acute coronary syndromes, TRA and TRA PCI have been associated with significantly lower-access-related complication both in male as well as in female in contrast to femoral artery access. Blood transfusion rates have also been proven to be significantly reduced in the TRA populations, with one study reporting a 50% reduction in the blood transfusion rates when compared to TFA.

These findings have led to a more widespread adoption of radial access in contemporary PCI procedures worldwide and in the United States.

The reduction in access-related complications seen with TRA notably correlates with the reduction in retroperitoneal hemorrhage incidence. While this highly morbid complication is infrequently encountered, the expenses associated with its diagnosis and treatment are substantial. The financial repercussions extend beyond medicolegal implications and pose a great challenge for health-care providers in the United States with the implementation of the Affordable Care Act and Medicare Alternative Payment Models.

Our study has several potential limitations. It includes cases available at LexisNexis database that were decided at court. Cases settled outside court are usually not reported in the database. Reported data collection was reliant on LexisNexis database accuracy and degree of available information. Opinions provided in the database are from nonmedically trained judges.

In conclusion, retroperitoneal hemorrhage is a significant complication of TFA. Although uncommon, it is associated with high mortality rates. Practicing physicians should be able to identify this complication early and address it in a timely manner based on the applicable standard of care. When so, our current analysis shows the ruling of medical litigation to be in favor of the defending physician, irrespective of patients’ mortality. TRA is a safe and effective alternative to TFA associated with reduced morality, lower access site complications rates, and reduced blood transfusion rates. In contemporary practice, TRA should be offered to patients during the consent process to avoid potential medicolegal liability.
Conflicts of Interest

None declared.

REFERENCES


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