

From the Vascular and Endovascular Surgery Society

## Malpractice litigation in the endovascular era

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### ABSTRACT

**Objective:** The standard of care in the treatment of vascular disease continues to evolve as endovascular therapies develop. Currently, it is unclear how medical malpractice litigation has adapted to the “endovascular era.” This retrospective case review is the most comprehensive analysis to date of malpractice actions involving endovascular procedures performed by vascular surgeons (VSs), interventional radiologists (IRs), interventional cardiologists (ICs), and cardiothoracic surgeons (CTSs).

**Methods:** The legal databases LexisNexis and Westlaw were searched for all published legal cases in the United States involving endovascular procedures. The search was limited to state and federal cases up to and including the year 2016. Keywords included “malpractice,” “vascular,” “endovascular,” “catheter,” “catheterization,” “stent,” “angiogram,” “angiography,” and “surgery.” Cases involving tax revenue, insurance disputes, Social Security Disability, and hospital employment contract disputes were excluded. Data were analyzed using  $\chi^2$  test.

**Results:** There were 2115 initial search results identified, and 369 cases were included in final analysis. The rate of endovascular procedure-related lawsuits (per 1000 active physicians in the specialty) was highest for ICs (105.56), whereas rates for VSs and IRs were comparable (18.47 and 16.85, respectively); 93% of the IC cases were related to coronary interventions. Overall, 55% (148/271 classifiable cases) of actions were related to elective procedures. For VSs specifically, 46% (25/54) of cases arose from diagnostic angiography and inferior vena cava filter placement, two relatively minor procedure types. Overall, 83% (176/211 finalized cases) of verdicts favored defendants, with no significant differences across the specialties; 43% (157/368) of total cases involved death of the patient. Among the four specialties, there was a significant ( $P = .0004$ ) difference in the primary allegation (informed consent, preprocedure negligence, intraprocedure complications, or postprocedure complications) underlying the litigation. For CTSs and VSs, there was a predominance of informed consent and preprocedure negligence allegations (70% [7/10] and 52% [28/54], respectively). Intraprocedure negligence was the most common allegation for IRs (59% [23/39]), whereas allegations were more evenly distributed among ICs.

**Conclusions:** Key issues were identified regarding malpractice litigation involving the specialties that commonly perform endovascular procedures. Despite the increasing number of ICs doing peripheral interventions, a large majority of IC cases were related to coronary treatments. A surprisingly large percentage of VS cases were related to seemingly minor cases. There were significant interspecialty differences in the primary underlying allegations. As the scope of endovascular procedures broadens and deepens, it is important for clinicians to be aware of legal considerations relevant to their practice. (J Vasc Surg 2018;■:1-6.)

The standard of care in the treatment of central and peripheral vascular diseases continues to evolve as endovascular therapies develop. The scope of procedures performed, the types of pathologic processes treated, and the specialties using endovascular techniques have

grown considerably since the clinical feasibility of such catheter-based procedures was first demonstrated.<sup>1</sup> In light of these rapid technologic changes, it is presently unclear how medical malpractice litigation has adapted to this “endovascular era.”<sup>2</sup> This retrospective litigation review represents the most comprehensive analysis to date of malpractice actions involving endovascular procedures performed by vascular surgeons (VSs), interventional radiologists (IRs), interventional cardiologists (ICs), and cardiothoracic surgeons (CTSs).

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### METHODS

The legal databases LexisNexis and Westlaw were searched for all published legal cases in the United States involving endovascular procedures. These databases routinely archive malpractice cases litigated in the state and federal courts and are the two largest legal databases in the United States.<sup>3</sup> In addition, LexisNexis and Westlaw maintain law reviews from >800 journals and U.S. Supreme Court decisions.

The search was limited to all state and federal cases up to and including the year 2016. The selected time frame encompasses all endovascular procedures performed since reports of Werner Forssmann's seminal self-catheterization experiment.<sup>4</sup> Keywords included "malpractice," "vascular," "endovascular," "catheter," "catheterization," "stent," "angiogram," "angiography," and "surgery." Because VSs perform both diagnostic and therapeutic procedures, we included analogous procedures performed by other specialties. Cases involving tax revenue, insurance disputes, Social Security Disability, and hospital employment contract disputes were excluded (Fig 1). Data were analyzed using  $\chi^2$  test.

## RESULTS

There were 2115 initial search results identified using the search criteria. After application of exclusion criteria and adjustment for duplicate search results, 369 cases were included in final analysis.

Across all specialties, the majority of malpractice actions were brought within the past 10 years (Fig 2). The rate of endovascular procedure-related lawsuits (per 1000 active physicians in the specialty; Fig 3) was highest for ICs (105.56), whereas the rates were comparable for VSs and IRs (18.47 and 16.85, respectively) and lowest for CTSs (2.36); 93% of the IC cases were related to coronary procedures, both diagnostic and interventional. Coronary interventions may reasonably be viewed as being in a different category from the other procedures in this analysis because of their potential for dramatic adverse outcomes. When these procedures were excluded, the rate of endovascular procedure-related lawsuits fell to 78.17 per 1000 active ICs. Overall, 55% (148/271 classifiable cases) of actions were related to elective procedures.

For VSs specifically, diagnostic angiography and inferior vena cava (IVC) filter placement, two relatively minor procedure types, were the underlying procedure and primary reason for litigation in 46% (25/54) of cases. The other specified procedures were aortic stents (3/54), thrombectomy (7/54), and peripheral angioplasty/stents (10/54). In comparison, IVC filter placements in particular composed the basis for only two of the cases against IRs, the specialty that more commonly performs this procedure in the community.

For VSs, private practitioners were most commonly named as defendants (33.9% [19/56]), followed by community hospitals (30.4% [17/56]) and academic institutions (16.1% [9/56]; Fig 4). For ICs, community hospitals were the most common defendants (32.9% [100/304]), followed by academic institutions (29.3% [89/304]) and private practice (27.6% [84/304]). For IRs, the most common defendants were academic centers (31.3% [15/48]) and community hospitals (29.2% [14/48]). For CTSs, the most common defendants were private practitioners (45.5% [5/11]) and academic centers (36.4% [4/11]).

Overall, 83% (176/211 finalized cases) of verdicts favored defendants, with no significant differences across the

specialties (Fig 5); 43% (157/368) of total cases involved death of the patient. Among the four specialties, there was a significant ( $P = .0004$ ) difference in the primary allegation (informed consent, preprocedure negligence, intraprocedure complications, or postprocedure complications) underlying the litigation (Fig 6). For CTSs and VSs, there was a predominance of informed consent and preprocedure negligence allegations (70% [7/10] and 52% [28/54], respectively). Intraprocedure negligence was the most common allegation for IRs (59% [23/39]), whereas allegations were more evenly distributed among ICs.

## DISCUSSION

This study represents the most comprehensive analysis to date of malpractice litigation involving endovascular procedures. We found in this analysis that the rate of lawsuits related to endovascular interventions was highest for ICs, intermediate and similar for VSs and IRs, and lowest for CTSs. The rate for ICs remained elevated even when we excluded coronary interventional cases. These differences may reflect not only the underlying comorbidities and pathologic processes of the patients but also practice patterns and historical context. The higher rate for ICs is entirely related to coronary procedures. This could be because these procedures are more prone than noncoronary procedures to result in lawsuits, but another possibility is that coronary procedures are much more common for ICs. We adjusted in this study for the number of physicians in each specialty, but we could not adjust for each specialist's case mix. An alternative explanation is that ICs have been performing catheter-based coronary procedures for a longer time than VSs, IRs, and CTSs have. As a result, malpractice attorneys may have had a longer opportunity to develop a more robust jurisprudential infrastructure for identifying and addressing deviations from the standard of care. The low malpractice rate against CTSs is likely due to the low volume of endovascular procedures done by CTSs. Despite the disparate malpractice rates in the four specialties, there were no significant differences in malpractice outcomes across the specialties. Overall, available verdicts favored defendants in 83% of cases.

Another striking finding was that there was a significant difference in the primary underlying allegation against the four specialties. For both CTSs and VSs, a majority of the cases arose from issues regarding preprocedure negligence, specifically informed consent. Although the specific definition of informed consent varies by jurisdiction, the doctrine in general requires that a medical provider disclose to a patient all of the potential material risks, benefits, and alternatives for an intervention in order for the patient to make a reasonable decision about treatment. Material risks include those risks that may cause a reasonable patient to refuse a procedure as well as the unique considerations for a specific patient.

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