

Legal Review of Vasectomy Litigation and the Variables Impacting Trial Outcomes



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OBJECTIVE	To demonstrate the substantial litigious risks associated with vasectomy, a common urologic procedure. We examined the risk factors and types of negligence involved in vasectomy cases that go to trial and their associated outcomes.
METHODS	Using the Westlaw legal database, we searched all jury verdicts and settlements for the term “vasectomy” from January 1, 1990 to December 31, 2017. Each case was evaluated for defendant specialty, alleged malpractice breach, resulting complications, outcome including verdict and monetary payment, and whether or not a pregnancy was involved.
RESULTS	The Westlaw database query returned 67 unique cases which were settled (13.3%) or went to trial in court (86.7%). Of these, the majority (64.2%) were decided in favor of the defending physician. The most commonly alleged breach of duty was negligence in postoperative care (38.8%). This was followed by negligent surgical performance (37.3%) and negligence in performing informed consent (29.9%). The cases filed for negligence in postoperative care, surgical performance, and informed consent were all generally decided in favor of the defendant (61.5%, 56%, and 90%, respectively). Of the 57 cases that specified, 82.5% of the physicians listed in the litigation were urologists. The average settlement won by each plaintiff was \$401,913, although most cases were settled for the medical and litigation costs themselves.
CONCLUSION	Medical malpractice cases related to the perioperative aspects of vasectomy involve many areas of negligence. This data may guide vasectomists in where to focus time and communication to best serve patients and minimize litigation. UROLOGY 131: 120–124, 2019. © 2019 Elsevier Inc.

The costs of medical malpractice litigation are of considerable concern to physicians, litigators, insurers, and patients internationally. A 2010 study found that in 2008 \$55.6 billion was spent on medical malpractice litigation in the United States alone, comprising 2.4% of total health care spending that year.¹ Elements in this total include indemnity payments, lost clinician work time, administrative expenses, and defensive medical costs. These considerable costs are concerning to all parties involved, including physicians in high-risk surgical subspecialties, like urology.

It has been previously reported that 50%-77% urologists will be sued at least once in their career, the likelihood of which increases with every year in practice.² A similar study revealed that the average urologist is sued 2.1 times throughout their career.³ American urologists, on average, are involved in 22 medical malpractice cases per year that result in an indemnity payment to the plaintiff.⁴ When compared to other subspecialties, urologists, in particular, are at high risk to have medical malpractice

claims filed against them, and were ranked eighth out of 25 specialties in 2011 in claims filed against.⁸ And, as the rate of litigation has increased, so too has the average indemnity payment – from nearly \$200,000 in 1988 to over \$420,000 in 2012.⁵ This rise has been consistent without any sign of plateau, as indemnity payments continue to significantly increase every year.⁴

Vasectomy is a common urologic clinic procedure with an estimated 500,000 cases performed annually in the United States.^{6,7} It is generally considered low risk with the most common complications of hematoma, infection, and chronic pain occurring at rates of 2% or less. More significant complications, including failure and pregnancy after negative postvasectomy semen analysis, occur at rates of <1% and <0.05%, respectively.⁷ While uncommon, complications or failure can have negative medical, financial, and emotional consequences for men and their families, which can lead to medical malpractice claims against the vasectomy provider. Many providers offer vasectomy services, including family practitioners, general surgeons, and urologists. The goal of this study is to quantify the number of claims, their costs, and factors associated with the claim. This information may help those performing this procedure to understand the reasons why patients

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bring suit, while also providing recommendations to improve practice to benefit patients and limit such claims.

MATERIALS AND METHODS

The Westlaw database (Thomson Reuters, New York, NY) was used to perform an advanced search of cases and verdict reports from January 1990 to December 2017 using the term: “vasectomy.” The Westlaw database is composed of cases that advance far enough through the legal process to be included within public records from numerous unique vendors across multiple jurisdictions. It is publicly searchable and has been validated for many medicolegal specialties including emergency medicine, otolaryngology, neurosurgery, and urology.^{5,6}

Data extraction occurred on August 3, 2018. Cases were reviewed jointly by 2 authors (AJB and CMD). Institutional review board approval was not required as data were either de-identified or publicly available. Each case was reviewed for medical information including year of the verdict, defendant specialty, alleged malpractice breach, resulting complications, and outcome including verdict and monetary payment, if available. Specifically, we compared outcomes and monetary payments between cases involving pregnancy and those that did not.

RESULTS

The Westlaw database query returned 127 cases, which, after exclusions for duplicates or unrelated cases, decreased to 67 unique cases that were settled (9; 13.3%) or went to trial in court (58; 86.7%). Of these, 43 (64.2%) were decided in favor of the defending physician and 23 (34.3%) resulted in indemnity payments to the plaintiff. One case was remanded to retrial with no further available results. The most commonly alleged breach of duty was negligence in postoperative care (26; 38.8%). This was closely followed by negligent surgical performance (25; 37.3%) and negligence in performing informed consent (20; 29.9%) (Fig. 1). Several cases were filed in multiple categories and were analyzed as a part of each category. The cases filed for negligence in postoperative care and surgical performance were generally decided in favor of the defending physician (61.5% and 56%,

respectively). Interestingly, the cases filed for negligence in informed consent decided heavily in favor of the defending physician (90%). Of the 57 cases that described physician specialty, 47 (82.5%) of the physicians listed in the litigation were urologists. The others included family practice physicians (12.3%) and general surgeons (5.2%). The filed damages included pregnancy/wrongful birth, sexual dysfunction, chronic scrotal pain, scrotal injury, infection and/or abscess, hematoma, chemical burn, and need to progress to orchiectomy and/or epididymectomy (Fig. 2). Of the 67 total cases, 33 (49.3%) resulted in payment to the plaintiff or defendant. Of these, 21 (65.6%) resulted in a specific payment to the plaintiff or defendant, while the remaining 12 (36.4%) were settled for undisclosed medical/legal costs. These medical/legal costs were not available via our Westlaw analysis. In total, the average overall disclosed monetary payment was \$158,701 (Table 1). When removing cases where the reported payment was \$0 or undisclosed, the average payment was \$375,112. The average payment made to a plaintiff was \$401,913, while it was only \$107,097 to the defendant physician (Fig. 3). When pregnancy/wrongful birth was alleged, 66.7% of cases were decided for the defendant provider. Average payment value for cases of wrongful pregnancy was \$115,462, while those not involving pregnancy was \$451,179.

DISCUSSION

Today’s medicolegal environment in the United States provides major concerns for physicians in high-risk surgical subspecialties like urology. Although the legal filing rates for medical malpractice cases and payments have been declining over the past 5 years, there are still more than 8000 payments to plaintiffs every year.⁹ With specific reference to Urology, there are 22 medical malpractice cases per year that involve a urologist and result in a payment to the plaintiff. After correcting for inflation there is a 191% increase in urologic payments each year. Current medical malpractice data also reveal that of urology cases that go to trial, 22% are ruled in favor of the plaintiff with a mean payment of \$247,887.⁴ Our results showed that

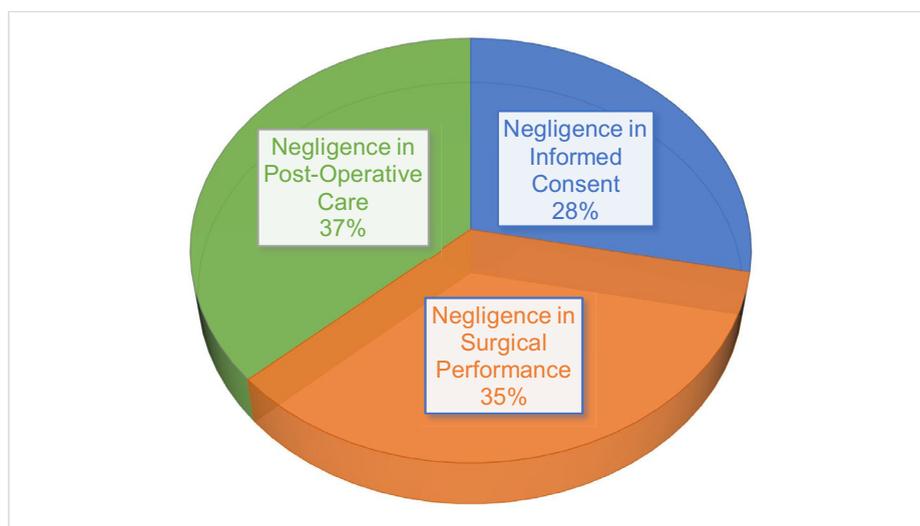


Figure 1. Distribution of claimed breaches of duty. (Color version available online.)

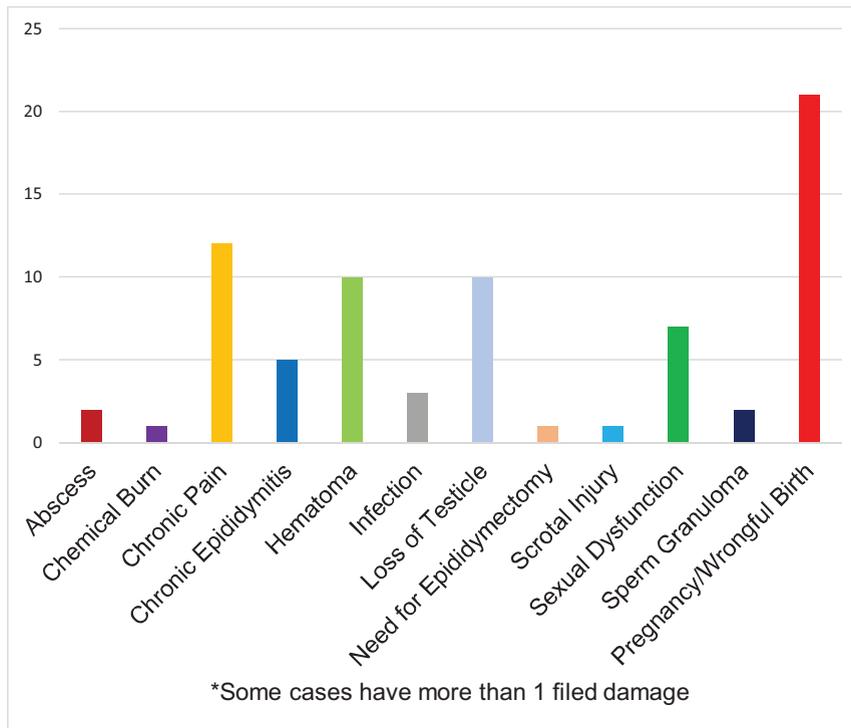


Figure 2. Most commonly claimed damages. (Color version available online.)

34.3% of vasectomy cases were decided for the plaintiff at an average payment of \$375,112. This is consistent with Westlaw data from Colaco et al that revealed that 35% of medicolegal cases surrounding nephrolithiasis treatment were won by the plaintiff.¹⁰ Similarly, 20.8% of medicolegal cases following radical prostatectomy were decided in favor of the plaintiff.¹¹ An empirical analysis of patient complaint data for urologic malpractice claims showed that urologists specializing in stone disease and oncology have the highest risk of malpractice claim compared to other urologic subspecialties.¹² Our data suggest that urologists who perform vasectomies have similar risk for medicolegal malpractice suits. Given the increasing volume and medicolegal risks of performing vasectomies, it is essential that practicing urologists remain well informed of the associated risks of malpractice claims and their financial ramifications.

Legally, 4 unique elements of negligence must be proven in order for a plaintiff to win a medical malpractice case. These elements include: (1) existence of duty by the physician to the patient, (2) a breach of duty by deviation from

standard of care, (3) a result of harm or injury to the plaintiff, and (4) a causal connection between the physician's deviation from standard of care and the plaintiff's injury.¹³ For a malpractice case to be won by the plaintiff, all of these elements must be proven. If even one of these is shown to not exist, then the defending physician will win the case. In this study, we examined the alleged breaches of duty, cited damages, and indemnity payments in vasectomy cases.

The 4 most common types of medical negligence include: medical misdiagnosis, negligence in informed consent, negligence in surgical technique, and negligence in postoperative care. With vasectomies, there can be no medical misdiagnosis, as no diagnosis is made; it is an elective procedure with the goal of sterility. Of the other forms of medical negligence, our results showed that negligence in postoperative care was the most commonly alleged breach. This is also the most commonly filed breach of duty in other types of urologic malpractice cases.¹⁴ In our study, negligence in postoperative care included issues of lack of communication about the need for postvasectomy semen analysis or not reporting these results to patients. Some of these even resulted in wrongful pregnancy. This also involved postoperative complications including abscess formation, infection, epididymitis, hematoma, and loss of testicle. In our sample, plaintiffs who filed under this breach won the case 38.5% of the time with total payments averaging \$444,736. Thus, we recommend following the AUA guidelines throughout the vasectomy process and stress the importance of the patient following up with their provider until a negative post-vasectomy semen analysis is achieved to ensure the patient and their partner of sterility. Providing detailed instructions in

Table 1. Average indemnity payment per breach of duty/damage

Breach of Duty/Damage	Average Payment
Negligence of postoperative care	\$444,736
Negligence of surgical performance	\$401,034
Negligence of informed consent	\$69,000
Cases with pregnancy as filed damage	\$115,462
Cases not involving pregnancy	\$451,179

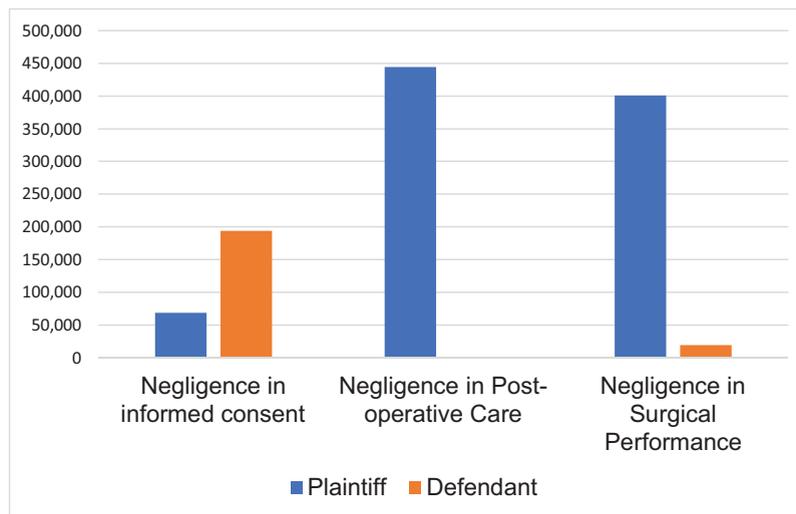


Figure 3. Average indemnity payment per type of breach. (Color version available online.)

writing to patients regarding postprocedure care and postvasectomy semen analysis may aid in achieving this goal while also improving compliance and mitigating risk to providers.

Even though medicolegal risk is highest postoperatively, our results indicate that there is also substantial risk in the procedure room. In our study, negligence of surgical performance was the second most claimed breach of duty. These cases were decided in favor of the plaintiff 44% of the time, the highest percentage among all the breaches. This can be attributed to the straightforward nature of the procedure: identify the vas on each side, then ligate each vas. Surgical complications or failures often result from the inability to complete these 2 steps. One of the cases examined involved a patient who lost his testicle as a result of the physician ligating the testicular artery instead of the vas deferens, returning \$1.25 million to the plaintiff. Cases involving negligence in surgical performance have an average payment of \$401,034.

For consent to be legally valid 3 criteria must be met: (1) A patient must have capacity and capability to give consent (2) must be adequately informed to make a measured decision (3) and must give consent voluntarily.¹⁵ When these criteria are met, little can be done to show medical negligence without considerable evidence demonstrating significant deviation from standard of care or duty. Our data are consistent with this statement. Negligence in informed consent was the least common filed breach at 29.9%, and was only won by the plaintiff 10% of the time with an average payment of \$69,000. Among the cases examined, the most commonly filed damage for cases involving negligence in informed consent was wrongful pregnancy. However, the AUA Guidelines defines wrongful pregnancy and/or vasectomy failure as known complications of this procedure. Thus, a thorough informed consent process based on the known risks and benefits detailed by AUA guidelines should always be performed to mitigate the risk of these claims.

The physician-patient relationship is an important structure founded directly on communication. As

mentioned previously, 2 of the 3 breaches of duty are centered on communication. The literature clearly shows that patients who suffer from a medical error want honesty, transparency, and empathy from their provider. One study indicates that patients, who reported feeling rushed, ignored, received inadequate explanations or advice, or perceived spending less time with their physician, were 2 times more likely to sue.¹⁶ Another study revealed that in over 70% of depositions in medical malpractice cases patients reported communication issues in their patient-provider relationship.¹⁷ Again, this highlights the importance of communication in both the informed consent process and in the postoperative period for vasectomies. This collection of information leads us to highly recommend providers take sufficient time and energy to detail all of the risks, benefits, and recommendations made by the AUA guidelines in all the preoperative informed consent process, immediate postoperative period, and with the postoperative post-vasectomy semen analysis (PVSA).

LIMITATIONS

Although this database has been used in multiple settings, it nonetheless has limitations. Cases are voluntarily reported within public records from unique vendors in every state, with additional cases submitted anonymously in some instances. Not all jurisdictions require reporting or have variable-reporting requirements, leading to likely incomplete data capture. Additionally, out of court settlements, dropped cases, or cases that do not progress to trial are not included in this database and cannot be searched. The above contribute to the small sample size. As with many large databases, the amount of information conveyed in each case is highly variable. For some, case details are unknown or incomplete, limiting the conclusions that can be drawn. Neither operative/procedure notes nor any medical records are available to review how technique or aftercare contributed to the legal

proceedings. Costs reported do not include pretrial or out of court settlements. Nonetheless, Westlaw remains the largest publicly available database and has been used to review other urologic malpractice cases.^{10,18,19} Two other potential resources for a better understanding of vasectomy litigation include the National Practitioner Data-Bank which is unavailable to the public since 2011, and the Physician Insurers Association of America but the authors do not have access to this currently.⁵

CONCLUSION

Over their career, most US urologists will be involved in litigation at least once, with the average urologists being sued at least twice. Vasectomy is a commonly performed procedure and carries a risk of litigation if there is a complication. Malpractice claims involving vasectomy most commonly allege negligence in postoperative care and informed consent, followed by negligence in surgical technique. In this analysis, most defendants were urologists, who perform the majority of vasectomies in the United States. Pregnancy was the most commonly claimed damage. Negligence in surgical technique, specifically failure to identify proper anatomy, was significantly linked to larger indemnity payments. For cases not involving negligence in surgical technique, urologists were much more likely to have a successful defense. Care and communication in informed consent and documentation, completion of the procedure, and adequate follow-up remain key for vasectomy, to provide expert level clinical care and a positive patient experience, as well as avoid possible litigation.

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