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Malpractice Litigation in the Setting of Prostate Cancer Diagnosis

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Abstract

Introduction: Medical malpractice and prostate cancer screening are important issues in the current landscape of health care. We identified factors contributing to litigation in the diagnosis of prostate cancer.

Methods: We used the Westlaw® database to search for jury verdict reports using the term medical malpractice combined with prostate cancer with dates ranging from January 2000 to December 2013. Each case was examined for trial year, patient age, prostate specific antigen at alleged breach of duty and at diagnosis, defendant specialty, alleged cause of malpractice, whether there was metastasis, the outcome of cases that went to trial or were otherwise settled, and the plaintiff award.

Results: The initial search produced 256 results, which was narrowed to 106 cases. Of these cases 64.1% went to trial, including 66.2% that were decided for the defendant. The mean out of court settlement was $945,000, significantly lower than the mean plaintiff verdict award of $2.1 million ($p = 0.0009$). Primary care physicians (74.1%) were the most commonly named defendants, followed by urologists (19.6%). The most common cause was failure to perform an initial prostate specific antigen test (26.8%), followed by failure to follow elevated prostate specific antigen (22.3%).

Conclusions: Causes of malpractice revolved mostly around prostate specific antigen testing. Primary care physicians and urologists must continue to educate patients to minimize malpractice claims made in this setting. It will be important to follow data to see trends following recent guidelines.

Key Words: prostate; prostate-specific antigen; malpractice; liability, legal; guidelines as topic

Abbreviations and Acronyms

AAFP = American Academy of Family Physicians

AUA = American Urological Association

PCP = primary care physician

PSA = prostate specific antigen

USPSTF = United States Preventive Services Task Force

Medical malpractice is an important component in the current debate over United States health care and it impacts the continuing increasing costs of the current system. It was estimated that the annual cost to defend malpractice claims is $6.5 billion.[1] Such costs are of particular importance to surgeons such as urologists because the inherent risks of surgery place their risk exposure and subsequent insurance premiums higher than those of other physicians. Urology ranked eighth of 25 specialties in the number of claims reported and it was estimated that the average urologist would be sued at least twice in a career.[2,3] Although urology sees many claims due to surgical performance and outcomes, missed diagnosis represents 15% of urological malpractice claims overall.[4]

Prostate cancer is the most common cancer in American men and the second leading cause of cancer death in men in the United States. However, despite the prevalence there is ongoing debate regarding whether and how men should be screened for prostate cancer. In May 2012 the USPSTF as well as the AAFP established a grade D recommendation, stating their stance against PSA based screening for prostate cancer regardless of patient age (see Appendix).[5] This was an update to the 2008 recommendation against screening men older than 75 years that was based on several large-scale, randomized clinical trials that failed to show a mortality benefit in patients who underwent prostate cancer screening.[6,7] However, the single largest randomized, controlled trial, ERSPC (European Randomized Study of Screening for Prostate Cancer), demonstrated a 20% reduced rate due to prostate cancer in a screened population.[8] Based on these findings as well as subgroup analysis of the

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other available data in 2013 the AUA organically developed a set of guidelines.[9] These guidelines broke down into 4 recommendations, chiefly a grade B recommendation that men 55 to 69 years old should undergo PSA testing.

While the clinical implications of this debate are obvious, they also have an underlying medicolegal implication. We identified the causes and contributing factors to litigation in the diagnosis of prostate cancer with a specific focus on screening issues.

Materials and Methods

We used the Westlaw database to search for jury verdict reports using the term medical malpractice combined with prostate cancer with dates ranging from January 2000 to December 2013. Jury verdict and settlement reports found on Westlaw represent legal proceedings that advance far enough for inclusion in publicly available federal and state court records. Different commercial vendors from various jurisdictions supply these records to Westlaw. While some jurisdictions provide voluntarily (attorney) submitted records with the express purpose of educating legal professionals, most jurisdictions also include records with the legal parties labeled with terms that preserve anonymity, such as Jane vs John Doe, confidential and anonymous.

Because requirements for cases that progress far enough for inclusion in publicly available federal and state court records differ by jurisdiction and commercial vendor collection patterns, a resource such as Westlaw is ideal to examine detailed considerations raised in included proceedings rather than to estimate the overall incidence of litigation related to a specific topic. It was previously used to analyze several other medicolegal issues in various other specialties, including neurosurgery,[10] otolaryngology,[11,12] emergency medicine[13] and genetics.[14] Since the database does not contain any protected patient information, this study was exempt from institutional review board review. Data were collected in February 2014.

After an initial review all unique cases related to the initial diagnosis of prostate cancer were included in our analysis. Each qualifying case was examined for various parameters, including trial year, patient age, defendant specialty, alleged cause of malpractice, PSA at the alleged time of breach of duty and at diagnosis of prostate cancer, whether there was metastasis, the outcome of cases that went to trial or were otherwise settled, and the plaintiff award.

Statistical Analysis

The Student t-test was used to compare normally (symmetrical) distributed continuous data and the Mann-Whitney U-test was used for nonparametric (asymmetrical) continuous data with significance considered at $p < 0.05$. SPSS®, version 20 was used for statistical calculation.

Results

The initial search produced 263 results, which were narrowed to 106 cases after various exclusions, including 61 of prostate cancer, 54 duplicates and 35 cases that did not involve the initial diagnosis.

Of the 106 cases 75 reported patient age. Mean age was 58.4 years (range 41 to 80). Patients in the sixth and seventh decades of life represented 42.7% and 30.7% of cases, respectively, and were the most common demographics (fig. 1). There was an increasing trend in the mean award for the plaintiff as age decreased with patients in the fifth decade of life receiving a mean award of $2.4 million (fig. 2). The most prevalent years for malpractice claims were between 2005 and 2007, consisting of 34.9% of the cases (fig. 3).

Of the examined cases 68 went to trial, of which 66.2% were decided for the defendant. The remaining 38 cases were settled out of court. Six cases had a codefendant along with the primary defendants. Five of these cases were settled out of court while 1 went to court in favor of the defendant. The mean settlement made out of court was $945,000, significantly lower than the mean $2.1 million plaintiff verdict that went to court ($p = 0.0009$, fig. 4).

PCPs were the most commonly named defendants (74.1%), followed by urologists (19.6%), internal medicine physicians (5.4%) and pathologists (0.9%) (fig. 5). When looking at PCP cases, 38.6% were settled out of court for a mean of $1.0 million (fig. 4). Of those that went to court 36.5% were resolved in favor of the plaintiff with significantly higher awards than settlements (average $2.3 million, $p = 0.0025$). Of claims against urologists 45.5% were settled out of court for a mean of $803,000 (fig. 4). Of cases that went to trial 83.3% were resolved in favor of the defendant. Those that resolved for the plaintiff had a mean award of $621,000, which was not significantly lower than the mean settlement ($p = 0.48$). Settlement and verdict awards involving urologists were not significantly lower than PCP awards ($p = 0.173$ and 0.58, respectively).

The alleged cause of malpractice in the initial diagnosis of prostate cancer in most cases revolved around PSA testing. The most common reason overall was failure to determine an initial PSA value (26.8% of cases) (see table). Of the most common alleged causes of malpractice failure to report an increase in PSA to the patient was the only one that resulted in a verdict in favor of the plaintiff more often than for the

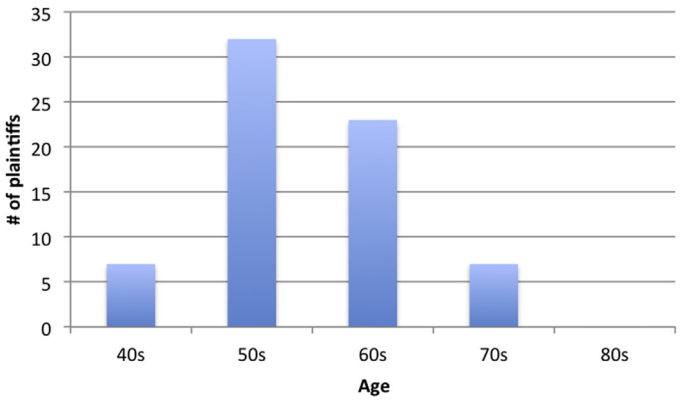

Figure 1. Plaintiff age distribution

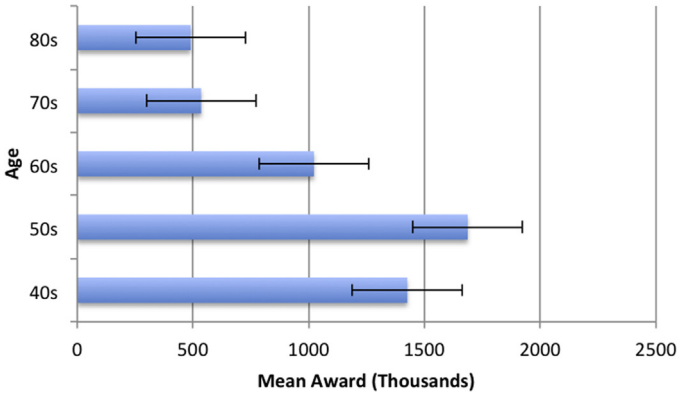

Figure 2. Damages awarded by plaintiff age. Error bars represent SEM.

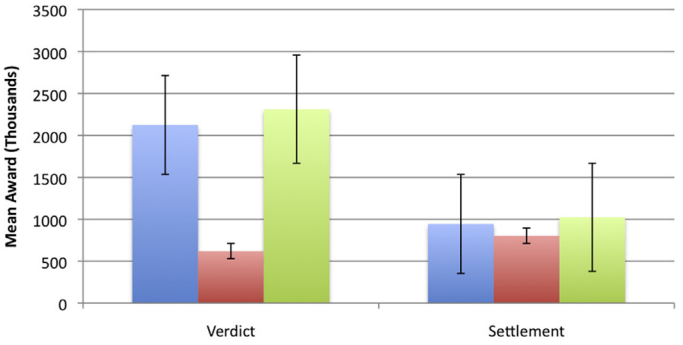

Figure 4. Damages awarded by juries with settlements. Blue bars represent overall. Red bars represent urologists. Green bars represent PCPs. Error bars represent SEM.

defendant (fig. 6). Furthermore, failing to follow elevated PSA and reporting a PSA increase to the patient led to more out of court settlements than trials. Urologists were sued in 60% of cases for issues regarding prostate biopsy, such as failure to perform an initial biopsy, report a positive biopsy, repeat a biopsy or improperly performing a biopsy.

A total of 14 filings reported metastasis in the plaintiffs due to the delay in diagnosis. Of those cases 50% were settled out of court while 57.1% of those that went to trial resolved in favor of the defendant. Most defendants (78.6%) were PCPs or internal medicine physicians. In 12 cases the patient was reported to have died due to a misdiagnosis of prostate cancer. Of these cases 83.3% went to trial, resulting in 80% in favor of the defendant and 20% for the plaintiff.

Discussion

Medical malpractice includes 4 components, including 1) the duty of care of the physician, 2) the breach of duty, 3) a direct and proximate injury resulting from the breach and 4) damage to the patient.[15] All of these elements must be met for a jury to find a defendant physician guilty of malpractice. Since all of these plaintiffs were patients in the care of a physician, the duty of care is obvious. The breach of that duty was common to all examined cases in the form of a delayed diagnosis of prostate cancer. In this scenario the direct and proximate injury is argued to be any prognosis that is worse than it otherwise would have been if cancer had been diagnosed in a timely manner. Given that more than 230,000 cases of prostate cancer are diagnosed annually, it is important that those who diagnose this condition are aware of the potential legal risks.[16]

Our results show that the most common cause of malpractice revolved around using PSA to screen for prostate cancer. Specifically the most commonly alleged breach of duty was failure to perform an initial PSA test (see table). These findings underscore the importance of uniform guidelines for PSA screening. Under the 2 schools of thought doctrine if there are 2 conflicting sets of guidelines, each offered by equally authoritative bodies, juries are instructed that the defendant physician acted acceptably if he or she followed either guideline.[17] However, application of this doctrine is unreliable and does not always protect against litigation risk. This is especially true for PCPs since they were the most common defendants with the highest plaintiff awards and settlements (figs. 4 and 5).

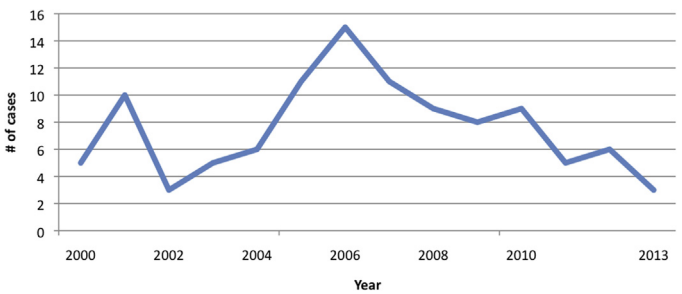

Figure 3. Prostate cancer screening malpractice litigation from 2000 to 2013

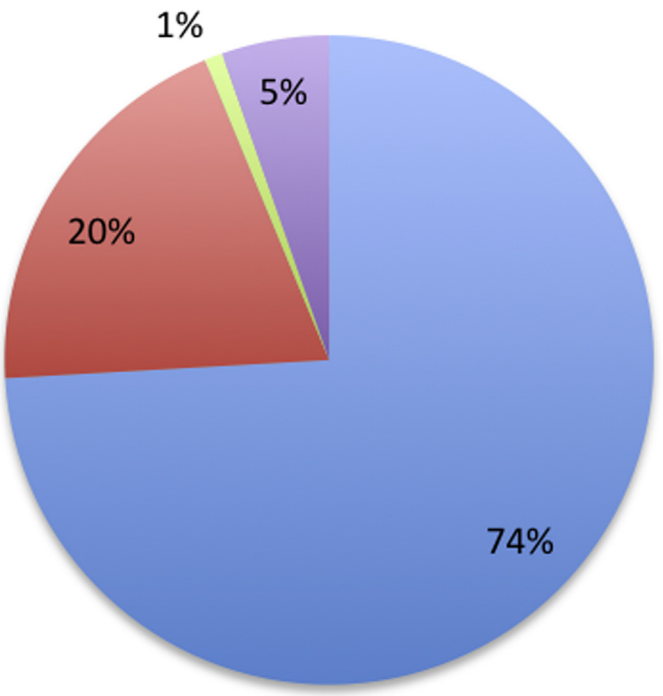

Figure 5. Distribution of specialties among defendants. Blue area indicates PCPs. Red area indicates urologists. Green area indicates pathologists. Purple area indicates internal medicine.

Table.
Alleged causes of malpractice

Alleged Cause	No. Pts (%)
Failure to perform PSA test	30 (26.8)
Failure to follow elevated PSA	25 (22.3)
Failure to report PSA increase	16 (14.3)
Unspecified	11 (9.8)
Failure to perform PSA test and digital rectal examination	7 (6.3)
Failure to refer to urologist	7 (6.3)
Failure to perform biopsy	6 (5.4)
Failure to report pos biopsy to patient	3 (2.7)
Improper biopsy technique	1 (0.9)
Inaccurate biopsy reading	1 (0.9)
Failure to repeat biopsy	1 (0.9)
Failure to follow abnormal digital rectal examination	1 (0.9)
Failure to perform magnetic resonance imaging	1 (0.9)
Failure to perform repeat PSA test after neg biopsy	1 (0.9)
Failure to follow pos bone scan	1 (0.9)

However, despite the legal and clinical risks a recent study showed that there has been a significant decrease in screening frequency from 8.6% in 2011 before the USPSTF and AAFP guidelines to 7.6% in 2012 after the publication of these guidelines.[18]

The incidence of malpractice cases in this study peaked between 2005 and 2007, and decreased in 2008 (fig. 3). While these cases did not occur under the current guidelines, they still reflect the current thinking of many physicians regarding the need for prostate cancer screening. This is especially true for patients in the sixth and seventh decades of life because screening in this group has a grade B recommendation from the AUA. Plaintiffs in failure to screen cases were most often from this age range (fig. 1).

For physicians who find themselves in a malpractice suit an individualized approach is always warranted since the outcome can depend on any number of unique local characteristics, such as quality of counsel, jury composition and the comfort of the physicians going to trial. With that said our overall review of the awards indicates that settlement may be a prudent strategy in many cases. Cases that go to trial are almost a coin flip.

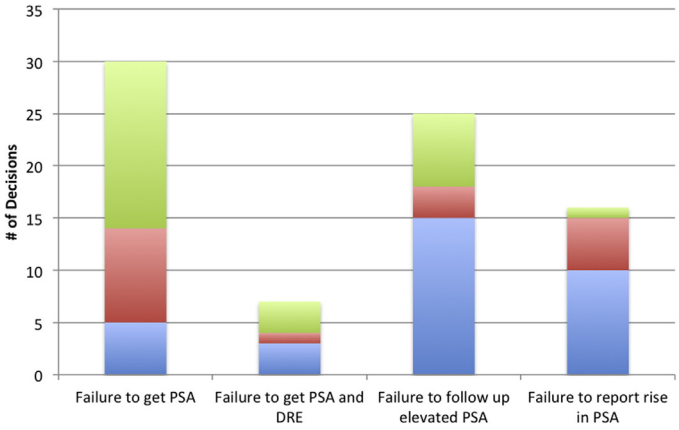

Figure 6. Decisions by most common alleged causes of malpractice. *DRE*, digital rectal examination. Green bars represent verdict for defense. Red bars represent verdict for plaintiff. Blue bars represent settlement before verdict.

While the mean out of court settlement was $945,000, the mean plaintiff verdict was $2.1 million (fig. 4). However, these findings may be more related to PCPs because verdicts were made in favor of the defense more often for urology defendants (83%) than for PCP defendants (63%).

Finally, health care providers must also consider the patient perspective on PSA testing. Since no uniform set of guidelines is currently used by physicians, it is difficult for patients to understand the implications of not screening for prostate cancer. In a survey performed after the most recent USPSTF statement 62% of men stated that they agreed with the recommendation.[19] However, only 13% of respondents intended to follow the recommendation while 54% declared that they would still undergo a PSA test in the future.[19]

This study has several limitations, including the lag time between the application of recent guidelines and the generation of malpractice claims. Only 9 cases took place between 2012 and 2013, the time in which conflicting guidelines were set forth. Therefore, in the future relevant details may be revealed on how physicians, patients and juries will interpret the new guidelines and their effects on missed diagnoses of prostate cancer.

In addition, there are limitations to the database. Although the Westlaw database was used in the past for studies of malpractice cases[10–14,20] and it is widely accepted in the legal community as one of the foremost electronic case libraries, there are limitations in its application. Case reporting requirements vary by jurisdiction and as such the Westlaw database comprises voluntary and involuntary filings. Thus, it is not a complete record of malpractice litigation. Specifically, out of court settlements or dropped cases may be underrepresented in this database because they may not have progressed far enough to be reported. Currently the only major data source that includes all malpractice litigation is the NPDB (National Practitioner Data Bank) but this database has unfortunately been closed to the public since 2011. Should public access to the NPDB ever be restored, it would be a boon to public health research and the understanding of malpractice litigation.

Conclusions

Prostate cancer is the most common malignancy in men in the United States and screening for the disease is an important issue. Most cases were settled out of court and those that went to court were decided for the defendant more often than for the plaintiff. Most defendants were PCPs who also had higher verdict and settlement awards than the average physician in this study. Causes of malpractice mostly revolved around PSA testing. As the debate over PSA testing continues, it will be important to monitor the effects of the recent conflicting guidelines set forth by the USPSTF, AAFP and AUA in the setting of medical malpractice. Since there is no current uniform set of guidelines on prostate cancer screening, physicians must continue to educate patients to minimize the number of malpractice claims in this setting. The choice to undergo PSA testing must be a joint decision between physician and patient, and care providers must have robust mechanisms to ensure the

timely delivery of results and their interpretations for future decision making. Finally, as urologists it is our duty to inform our general practice colleagues of the rationale and data support for the AUA recommendations, and the possible medical and medicolegal repercussions of not following these recommendations.

Appendix.
Comparison of recent guidelines on PSA testing for prostate screening

USPSTF (2012)	AAFP (2012)	AUA (2013)
USPSTF recommends against PSA based screening for prostate cancer. (Grade D)	AAFP recommends against PSA based screening for prostate cancer. (Grade D)	Panel recommends against PSA screening in men younger than 40 years. (Grade C) Panel does not recommend routine screening in men 40 to 54 years old at average risk. In men younger than 55 years at higher risk (eg positive family history or black race) decisions regarding prostate cancer screening should be individualized. (Grade C) Panel strongly recommends shared decision making in men 55 to 69 years old who are considering PSA screening and proceeding based on the values and preferences of the man. (Grade B) Intervals for re-screening can be individualized by baseline PSA level. (Grade C) Some men 70+ years old who are in excellent health may benefit from prostate cancer screening. (Grade C)

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