

ORIGINAL RESEARCH—SURGERY

Penile Prosthesis and the Litigious Patient: A Legal Database Review

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DOI: 10.1111/jsm.12649

ABSTRACT

Introduction. Erectile dysfunction (ED) is a common problem with significant impact on patient quality of life. Penile prosthesis implantation provides an effective treatment for ED but as an invasive procedure carries with it an increased risk of medicolegal liability.

Aim. To investigate factors associated with malpractice litigation surrounding penile prosthesis implantation.

Methods. The Westlaw legal database was used to perform an advanced search for case reports using the term “medical malpractice” in combination with “penile” or “penis” and “prosthesis” or “implant” with dates between the January 1990 and December 2013.

Main Outcome Measures. Each report was examined for trial information including patient demographics, device model and indications, alleged breach of duty, alleged damages, progression to trial, case outcome, and plaintiff award(s).

Results. The initial search yielded 76 cases that were narrowed to 40 after exclusions. There were 23 (57.5%) cases that were found in favor of the defendant, while 17 (42.5%) cases led to indemnity payment to the plaintiff including two cases (5.0%) that were settled out of court and 15 (37.5%) favoring the plaintiff in front of a jury. The mean settlement received was \$335,500 compared with the mean indemnity award of \$831,050 for verdicts decided in favor of the plaintiff ($P = 0.68$). The most common breach of duty was error in surgical decision making, present in 20 cases (48.8%). Informed consent was an issue in 13 filings (31.7%), and postoperative infection was seen in 13 cases (31.7%). In cases that identified the type of implant used, 58.3% were malleable implants, and 41.7% were inflatable devices.

Conclusions. The main issues involved in malpractice litigation for penile prosthesis implants included surgical performance, informed consent, and postoperative management. Urologists must be aware of these potential issues in order to minimize their malpractice liability. **Sunaryo PL, Colaco M, and Terlecki R. Penile prostheses and the litigious patient: A legal database review. J Sex Med 2014;11:2589–2594.**

Key Words. Medical Malpractice; Malpractice Litigation; Penile Prosthesis; Erectile Dysfunction; Liability

Introduction

In recent years, healthcare reform has become a major issue of concern for our nation. Any successful reform initiatives will need to consider the topic of medical malpractice and tort reform. The annual direct cost spent defending against malpractice claims is estimated to be \$6.5 billion dollars in legal fees, malpractice premiums, and

indemnity payments [1]. In an environment of defensive medicine with the frequent use of non-essential diagnostic testing, indirect expenses may raise the total cost much more [2]. Furthermore, the process of defending a lawsuit can have a significant psychological impact on a physician, potentially leading to decreased productivity.

The cost of medical malpractice is particularly noted within surgical fields as the inherent risks of

surgery and patients dissatisfied by adverse outcomes are linked to higher insurance premiums. A recent study demonstrated that specialties witnessing the highest volume of malpractice claims were either surgical or primarily procedure based [3]. Among the 25 specialties examined, urology saw the eighth most malpractice claims. Additionally, it has been estimated that the average urologist will be sued at least twice in his or her career [4]. As such, litigation is of particular importance to the urological community.

One of the most common disease processes managed by urologists is erectile dysfunction (ED). According to the Massachusetts Male Aging Study, more than 50% of men between the ages of 40 and 70 experience some degree of ED, with 35% of men reporting moderate to complete inability to achieve erection [5]. Furthermore, this disease state has a significant impact on patient quality of life: ED is the most often cited cause of dissatisfaction following radical prostatectomy [6] and is a major component of postprostatectomy treatment regret [7]. In order to combat this life-altering problem, urologists may offer a variety of treatments including surgical intervention after failure of more conservative management. Generally, these treatments are very effective: Patient and partner satisfaction rates following placement of an inflatable penile prosthesis range 92–100% and 91–95%, respectively [8]. As with any surgery, however, there is a risk of complications. Taking steps to minimize these complications is vital not only to good patient care but may also impact the chance of subsequent litigation.

The goal of this study is to investigate the factors associated with litigation in cases surrounding penile implants. In doing so, we aim to cultivate strategies that limit malpractice exposure for urologists who routinely perform penile prosthesis implantation and to encourage the best possible patient outcomes and expectation management.

Materials and Methods

The Westlaw database (Thomson Reuters, New York, NY, USA) was used to perform an advanced search for jury verdict reports using the term “medical malpractice” in combination with “penile” or “penis” and “prosthesis” or “implant.” The initial search included trials taking place between the January 1990 and December 2013. This database is composed of public records collected via numerous vendors from many jurisdictions and has been validated in the past by analysis

of other medicolegal issues in a variety of specialties including otolaryngology [9–11], emergency medicine [12], genetics [13], and urology [14]. As the database does not contain any protected patient information, it was exempt from institutional review board review. Data collection was performed in March 2014.

Each case was examined for information regarding year and location of trial, demographics of patient, specialty of defendant, breach of duty, underlying indication for device implantation, type of implant received, claims regarding informed consent, progression to trial, case outcome, and plaintiff award(s).

Statistical Analysis

A Student’s *t*-test was used for comparison of normally (symmetric) distributed continuous data, and a Mann–Whitney *U*-test was used for asymmetric (nonparametric) continuous data, with threshold for significance set at $P < 0.05$. SPSS version 20 (SPSS Inc., Chicago, IL, USA) was used for statistical calculation.

Results

The initial search yielded 76 cases that were narrowed to 40 after exclusion of 17 duplicates, 18 not involving prosthetic implantation, and one with incomplete information. One case featured two defendants for a total of 41 claims. Of the total case pool, 34 cases documented plaintiff age with a mean of 56.5 years (range 44–71). There were 23 (57.5%) cases that were found in favor of the defendant, while 17 (42.5%) cases led to indemnity payment to the plaintiff, including two cases (5.0%) that were settled out of court and 15 (37.5%) favoring the plaintiff in front of a jury (Figure 1). The mean settlement received was \$335,500 compared with the mean indemnity award of \$831,050 for verdicts decided in favor of the plaintiff (Figure 2). The difference between these values did not reach sta-

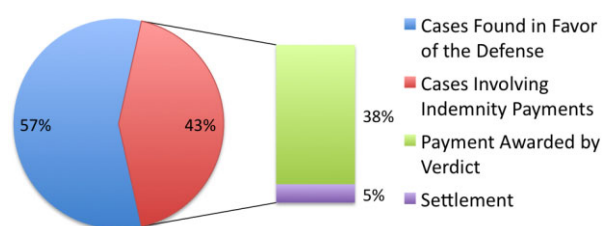


Figure 1 Distribution of results of penile implants malpractice litigation

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