

Urethral catheters and medical malpractice: a legal database review from 1965 to 2015

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Background: Urethral catheters (UCs) are commonly used in medicine and are associated with complications such as urinary tract infections (UTIs) and trauma. Given UC complications and their ubiquitous usage in healthcare, there is a potential for liability risk. We aim to explore litigation involving UC-related complications.

Methods: The LexisNexis legal database was queried for all state and federal cases from January 1965 through October 2015 using the terms “urethral catheter” or “Foley catheter” in combination with “medical malpractice”, “negligence”, “medical error”, and “trauma”. Each case was reviewed for reported medical characteristics and legal aspects, including the outcome of the case.

Results: Our search yielded 29 cases. Urologists were the most common providers cited as defendants (21%), all of whom were successful in their defense. The most common malpractice claim was for traumatic insertion (48%). Pain was the most common type of damage claimed by plaintiffs (28%), followed by UTI (24%). Nineteen (66%) cases favored defendants, while 10 (34%) cases favored the plaintiffs, of which 2 (7%) were settled out of the court. In settled cases, the mean settlement received by plaintiffs was \$55,750 (range, \$25,000–\$86,500). The mean award to plaintiffs for cases determined by the court was \$112,991 (range, \$4,000–\$325,000).

Conclusions: Despite widespread usage of UC over a 50-year period, lawsuits centered on UC misuse are rare at the state and federal court levels. Of litigated cases, urologists are commonly involved yet have successful defenses.

Keywords: Malpractice; negligence; trauma; urethral catheters (UCs)

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Introduction

Medical malpractice lawsuits have increased in United States (US) over the last 150 years (1). Prior to 1840, medical malpractice suits were mainly limited to cases that result in severe injury and death (1,2). The increase in medical malpractice claims has prompted physicians

to practice “defensive medicine” which is defined as the deviation from standard medical practices induced by fear from liability (3). This may affect the quality of patient care and promote overuse of health services (4).

Urethral catheters (UCs) are one of the most commonly used medical devices since their invention in the 1930s (5).

It is estimated that 25% of hospital inpatients have UCs inserted during their hospital stay (6). Despite widespread usage of UCs, providers are unaware of UC placement in 28% of their patients (7). Furthermore, UCs may be inserted for inappropriate reasons such as monitoring urine output in non-critical patients (7-10). UC complications, including catheter associated urinary tract infections (CAUTIs), non-infectious catheter related complications, and device malfunction are common (11-13). Given the prevalence of UC usage and related complications, healthcare providers are vulnerable to medical liability. Our objective is to characterize UC-related litigation over the past 50 years using a robust legal database.

Methods

Medical legal cases processed at the state and federal courts are routinely archived in LexisNexis—one of the largest legal databases in the US. The database maintains law reviews from more than 800 journals, US Supreme Court decisions, US Circuit Courts of Appeals decisions, and US District Courts decisions for all 50 US states and territories (14).

LexisNexis was queried for medical malpractice claims surrounding the placement, management, or removal of UCs. The search was limited to all state and federal cases from January 1965 through October 2015. The following search terms were utilized to build our query: “urethral catheter” or “Foley catheter” in combination with “medical malpractice”, “negligence”, “medical error”, and “trauma”. We included legal cases whereby the UC was primarily implicated as the main cause of harm reported by the plaintiff. We excluded cases in which a UC was merely mentioned in the claim however it was not central to the plaintiff’s claim.

Using our selected search terms, we reviewed legal cases for: date of trial, state location, plaintiff(s)’ gender, plaintiff(s)’ and defendant(s)’ identity, the identity of medical personnel inserting the UC, alleged causes of medical malpractice, damages claimed by plaintiffs, trial outcomes including the indemnity amount awarded by the jury and out of court settlement amounts. Case details were extracted through a review of court proceedings by two independent urologists (MAA and ECO). Statistical analysis was performed with STATA v14 (College Station, TX, USA). Descriptive statistics were primarily utilized.

Results

Of state and federal cases in LexisNexis database, 324 medical

legal cases were found using the defined search terms. Of these, 29 cases met the inclusion criteria whereby UC usage was central to the plaintiff’s claim. Court proceedings took place in 18 different states within the US. Demographics of plaintiffs, defendants and healthcare providers involved with UC insertion or removal are summarized in *Table 1*. Overall, when individuals were named, the plaintiffs were most commonly males (52%). Hospitals alone or in combination with healthcare providers were most often named in UC-related litigation (18/29, 62%). Of the healthcare providers implicated, urologists (6/16, 38%) were the most common provider involved. Urologists were successful in defending all of their cases, and hospitals were involved with them as defendants in half of the time. When hospitals or nursing homes were involved either alone or with different healthcare providers, nurses were most often the providers involved with placing or removing the catheter (16/21, 76%). No nurses were cited as defendants solely.

The characteristics of each case are presented in *Table 2*. In these cases, the UC was primarily inserted for monitoring of urine output, or treatment of urinary retention, followed by routine post-operative care. The most common claim for a breach in medical practice was a traumatic insertion, followed by UC removal related errors. Pain was the most common complaint claimed by plaintiffs, followed by urinary tract infection (UTI) and fistula. Plaintiffs claimed death from urosepsis in cases. Six cases involved a second plaintiff. Each second plaintiff was a spouse and all claimed loss of consortium (deprivation of the benefits of a family relationship due to injuries caused by a tortfeasor). A verdict favoring the defendant was achieved in (19/29, 66%) cases, while (8/29, 28%) cases delivered an indemnity award for the plaintiffs, all of which involved institutions solely as defendants without any health care providers. Two (2/29, 7%) cases were settled out of court. The mean indemnity award paid to plaintiffs was \$112,991 (median \$35,100, range \$4,000–\$325,000). The mean settlement received by plaintiffs was \$55,750 (median \$55,750, range \$25,000–\$86,500). A detailed summary of cases included are presented in *Table 3*.

Discussion

In this study we reviewed medical malpractice cases that have been filed from 1965 through 2015 at the state and federal level in the US. Defendants named in these cases ranged from institutions, such as hospitals and nursing

Table 1 Basic demographics of plaintiffs, types and numbers of defendants and health providers involved with urethral catheter insertion or removal[†]

	N [%]
Plaintiff(s) gender [‡]	
Male	15 [52]
Female	2 [7]
Multiple plaintiffs	11 [38]
Plaintiff(s) identity [‡]	
Self	17 [59]
Family	10 [34]
Advocate	1 [3]
Institution	1 [3]
Defendants	
Hospital	10 [34]
Nursing homes	3 [10]
Nurse + hospital	3 [10]
Urologist	3 [10]
Urologist + hospital	2 [7]
Gynecologist	2 [7]
Urologist + nurse + hospital	1 [3]
Surgeon	1 [3]
Surgeon + hospital	1 [3]
Gynecologist + hospital	1 [3]
United States of America	1 [3]
United States of America + nurse	1 [3]
Health provider involved with insertion or removal when hospitals and nursing homes were defendants	
Nurses	16 [76]
Urologists	2 [9]
Other health providers	3 [14]

[†], all missing data in cases were excluded from analysis; [‡], in one case, an institution was the plaintiff.

homes, as well as individuals, particularly urologists and nurses. Among individuals, urologists were most commonly implicated, however urologists were always successful in defending their cases in UC-related lawsuits. Overall, hospitals were most likely to be named in UC-related lawsuits.

Among inpatients, UCs are among the most commonly used medical devices with 25% of inpatients requiring a catheter during their hospitalization (6). With 36.5 million hospital stays in the US per year, there are over 9 million UCs placed annually (15). Given the yearly volume of UC placement, the potential for UC-related

Table 2 Characteristics of cases[†]

Characteristics	N [%]
Main reason for catheter insertion	
Monitoring	10 [35]
Retention	10 [35]
Post-op	5 [17]
Trauma	1 [3]
C-section	1 [3]
Comatose patient	1 [3]
Not mentioned	1 [3]
Alleged breach of standard of care	
Trauma/improper insertion	14 [48]
Removal related	8 [28]
Mechanical failure	3 [10]
Lack of consent	3 [10]
Non-sterile insertion	1 [3]
Damages claimed by plaintiffs [‡]	
Pain	8 [28]
Urinary tract infection	7 [24]
Fistula	6 [21]
Extra surgery	4 [14]
Incontinence	4 [14]
Death due to sepsis	4 [14]
Impotence	3 [10]
Stricture	2 [7]
Hematuria	2 [7]
Other	3 [10]
Trial outcome	
Defendant verdict	19 [66]
Plaintiff verdict	8 [28]
Settlement	2 [7]
Mean indemnity award for plaintiffs [range]	112,991 [4,000-325,000]
Mean settlement amount [range]	55,750 [25,000-86,500]

[†], all missing data in cases were excluded from analysis;

[‡], plaintiffs had more than one claim in some cases.

complications arise (16). As such, there is a concern that malpractice cases pertaining to UC-related complications may contribute to the burden of lawsuits faced by many healthcare providers.

Medical malpractice lawsuits are a concern and burden for all health care providers. A recent comprehensive review on urology malpractice studies as well as analysis of claims data

Table 3 Detailed summary of UC litigation cases from 1965 to 2015

Case No.	Year	Defendant(s)	Reason for UC insertion	Alleged breaches of duty by physician	Damages claimed by plaintiff	Summary of the cause of lawsuit	Trial outcome	Plaintiff award or settlement
1	2009	Hospital	Urine output monitoring	Failure to timely remove the UC and development of UTI	UTI, sepsis and death	Following surgery to repair a hip fracture, hospital staff failed to timely remove the UC as ordered by the physician and failed to recognize a urinary tract infection	Plaintiff	\$325,000
2	1969	Hospital	Urinary retention	UC insertion despite patient's wishes	Severe pain, UTI, and hematuria	Plaintiff claimed that the catheter was not necessary and the nurse instructed the patient that it was essential	Plaintiff	\$4,000
3	2000	Hospital	Urine output monitoring	Failure to connect a UC to its drainage tube	Acute lumbosacral strain, acute hip strain and several body contusions	Plaintiff slipped and fell while visiting a patient who had a UC that was not properly connected to the drainage tube	Plaintiff	\$7,710
4	1977	Hospital	Routine post-operative care	UC trauma without deflating balloon	Urinary incontinence	Defendant failed to fully deflate the UC balloon and plaintiff claimed damage to his urinary sphincter after developing stress urinary incontinence	Plaintiff	\$35,100
5	2011	Hospital	Routine post-operative care	UC trauma with inflated balloon	Pain and impotence	After completion of the plaintiff's surgery, the UC was accidentally pulled out inflated while the plaintiff was being transported	Plaintiff	\$84,128.95
6	1975	Hospital	Not mentioned	Removed a UC with the balloon inflated	Bladder fistula	removed a UC with the balloon inflated	Plaintiff	Not mentioned
7	2015	Nursing home	Urinary retention	Failure to reinsert UC	Pain, UTI, sepsis and death	Plaintiff suffered a stroke and had a neurogenic bladder. The nursing home failed to reinsert a UC after 4 days of overflow incontinence and urinary retention	Plaintiff	\$310,000

Table 3 (continued)

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Case No.	Year	Defendant(s)	Reason for UC insertion	Alleged breaches of duty by physician	Damages claimed by plaintiff	Summary of the cause of lawsuit	Trial outcome	Plaintiff award or settlement
8	1990	Nursing home	Urinary retention	Inserting an indwelling UC against plaintiffs desire	UTI, pain and hematuria	Plaintiff claims that a UC was inserted against his will by nursing staff. Prior, the patient was managed with external condom catheters	Plaintiff	\$25,000
9	1983	Hospital	Urinary retention	Improper UC insertion	Not mentioned	Plaintiff had the UC balloon inflated in his prostatic urethra	Settlement	\$25,000
10	1980	Hospital	Urinary retention	A defective UC was inserted	Additional surgical procedures	Patient had a UC inserted for a urethroplasty, but urine leaking from what was later discovered to be a leaking catheter caused the urethroplasty to fail, leading to more extensive surgery and complications	Settlement	\$86,500
11	2005	Urologist	Urine output monitoring	Failure to insert a UC and obtain an informed consent for additional procedure	Additional procedure and post-operative complications	Intraoperative UC insertion was complicated and a Urology consultation was obtained. Subsequent cystoscopy revealed a stricture and an open cystostomy and suprapubic tube was inserted	Defendant	
12	2013	Urologist	Urine output monitoring	Lack of informed consent for UC insertion	Assault, battery, and punitive damages	Plaintiff underwent an inguinal hernia repair and was unaware of intraoperative UC insertion despite lack of catheter-associated complications	Defendant	

Table 3 (continued)

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Case No.	Year	Defendant(s)	Reason for UC insertion	Alleged breaches of duty by physician	Damages claimed by plaintiff	Summary of the cause of lawsuit	Trial outcome	Plaintiff award or settlement
13	1998	Urologist	Routine post-operative care	A piece of a UC was left inside plaintiff's body	Additional surgical procedures	Following a radical prostatectomy, the patient's UC was removed non-intact and a residual piece of the UC had broken off into his bladder. This required a cystoscopy to remove the plastic foreign body	Defendant	
14	2010	Urologist + hospital	Urinary retention	Failure to use the appropriate technique to insert and/or remove a UC	Additional surgical procedures	Plaintiff developed urinary retention after discharge following trauma and returned to Emergency Room whereby multiple attempts by nurses to insert a UC failed. A Urologist was consulted and found a bulbar stricture requiring cystoscopy and internal urethrotomy	Defendant	
15	1973	Urologist + hospital	Routine post-operative care	UC insertion caused urethritis and an injury to the dorsal tip of the penis	Urethral erosion	Plaintiff claims that multiple UC insertions were attempted and prolonged UC drainage caused urethral erosion	Defendant	
16	2013	Urologist + nurse + hospital	Routine post-operative care	Inadvertent early removal of UC	Pain + several surgical procedures	Plaintiff had a transurethral resection of a bladder tumor and the catheter was removed prematurely on postoperative day 1 instead of postoperative day 5. As a result, the plaintiff claimed unnecessary UC replacement	Defendant	
17	1978	Hospital	Urine output monitoring	UC balloon malfunction and negligence of hospital employees	Not mentioned	Plaintiff claimed a UC device malfunction and lack of timely evaluation	Defendant	

Table 3 (continued)

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Case No.	Year	Defendant(s)	Reason for UC insertion	Alleged breaches of duty by physician	Damages claimed by plaintiff	Summary of the cause of lawsuit	Trial outcome	Plaintiff award or settlement
18	2012	Hospital	Urinary retention	Unintentional traumatic removal of UC	Urinary incontinence	An unknown hospital employee became entangled in the UC drainage tube and the fully-inflated UC was forcibly removed. Pt reported blood and tissue came out of his penis and he experienced "great pain and fear." A nurse tried to reinsert another UC but failed and called a urologist who was consulted who reinserted a UC	Defendant	
19	2007	Nurse + hospital	Urine output monitoring	Failure to empty the UC bag in a timely manner	Urine incontinence and permanent pain and discomfort	Nurse failed to empty the UC bag "from the time it was inserted until the following morning"	Defendant	
20	1996	Nurse + hospital	Urine output monitoring	Nurse failed to remove all of a UC from a prior surgery	Stress incontinence and UTI	Plaintiff claimed that failure to remove a piece of an inserted UC in 1971 caused her subsequent urinary tract infections and stress urinary incontinence	Defendant	
21	1998	Nurse + hospital	Urinary retention	Negligence placing a UC and associated UTI	Pain and UTI	Plaintiff claimed that the nurse had 2 inch long-fingernails that pierced a sterile glove while UC was being placed	Defendant	
22	2004	Gynecologist + hospital	C-section	Failure to supervise a resident's insertion of a UC	Vesico-vaginal fistula	Plaintiff had an emergency hysterectomy following a complicated C-section. A senior resident placed a UC and the following day urine was leaking on a surgical pad under the patient. The patient ultimately underwent a vesicovaginal fistula repair	Defendant	

Table 3 (continued)

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Case No.	Year	Defendant(s)	Reason for UC insertion	Alleged breaches of duty by physician	Damages claimed by plaintiff	Summary of the cause of lawsuit	Trial outcome	Plaintiff award or settlement
23	2010	Surgeon	Urine output monitoring	Injury during UC insertion	Fistula	Plaintiff claimed a nurse failed to place a 16 French UC and attempted a 12 French UC. A Urologist was consulted who placed a suprapubic tube	Defendant	
24	2003	Surgeon + hospital	Urine output monitoring	Traumatic insertion of UC and perforation of urethra	Urethral stricture and impotence	Patient was having diagnostic laparoscopy for lower abdominal pain and a nurse and the surgeon tried to insert a UC before the surgery for monitoring, but failed due to resistance. A urologist was consulted intra-operatively and found a severe urethral stricture requiring dilation and UC placement	Defendant	
25	1974	Gynecologist	Trauma	Negligence in postoperative care of plaintiff UC following a hysterectomy	Vesico-vaginal fistula	The defendant lacerated the bladder during hysterectomy and it was repaired primarily and a suprapubic tube and UC were placed. The plaintiff claimed negligence in monitoring, emptying, and management of her UC and suprapubic tubes	Defendant	
26	2003	Gynecologist	Urine output monitoring	Bladder injury following urethral sling surgery	Pain, impotence and additional surgical procedure	Defendant performed a urethral sling and injured the bladder. Plaintiff claimed prolonged catheterization and required an additional procedure for mesh removal from the bladder	Defendant	

Table 3 (continued)

Table 3 (continued)

Case No.	Year	Defendant(s)	Reason for UC insertion	Alleged breaches of duty by physician	Damages claimed by plaintiff	Summary of the cause of lawsuit	Trial outcome	Plaintiff award or settlement
27	2008	Nursing home	Comatose patient	Failing to perform proper UC care and maintenance	UTI, sepsis and death	A Department of Human Services investigation determined that the nursing home abused a resident by failing to perform proper catheter care and maintenance based on the resident's condition which caused him sepsis and death	Defendant	
28	1999	United States of America (USA)	Urinary retention	Premature removal of UC	Recto-urethral and urethro-cutaneous fistulas	Patient had radical prostatectomy and UC was removed 10 days postoperatively. The patient developed urinary retention and multiple failed attempts at UC replacement failed and a UC was inserted cystoscopically. The plaintiff argued that the premature removal of UC caused multiple fistulae	Defendant	
29	1990	USA + nurse + corporation	Urinary retention	UC trauma	Bladder injury and wrongful death	Plaintiff claimed that his bladder was punctured with a UC upon insertion	Defendant	

UC, urethral catheter; UTI, urinary tract infection.

from companies of the Physicians Insurers Association of America (PIAA) have shown that it is common for urologists to face malpractice litigation at some point in their career. However, as in our study, only a minority lose their cases (17). When faced with malpractice, urologists reported spending an average of 21.8 days away from work defending their first lawsuit. This results in reduced access to care for patients seeking urologic care (18). Previous studies suggest that urologists average around two lawsuits during their careers, irrespective of their professional reputation (19). Information regarding a history of malpractice litigation, even when favorably resolved, must be reported on various applications

indefinitely. This information is now publicly available to facilitate total transparency within the medical profession. On a psychological level, the impact can be personally devastating. The physician may feel personally attacked and betrayed. Another aspect commonly ignored in malpractice litigation is the time it takes to resolve cases. In a recent study of testicular torsion malpractice cases, the average time from patient presentation to final verdict was 5 years (20). Understanding the characteristics of cases that have been both successfully and unsuccessfully litigated by institutions and practitioners alike may help urologists reduce their practice of "defensive medicine".

Types of defendants

As individuals, urologists are the most common defendant in UC-related lawsuits. Over the 50-year period of our study, urologists were always successful in defending UC-related litigation at the state and federal levels. Other studies examining medical malpractice cases found that urologists are successful among 60% of defenses for cases dealing with endourology, 57.5% of defenses for penile prosthesis litigation, and 66% of defenses for litigation on testicular torsion (21-23). We demonstrate that UC litigation favors the defendant who is a urologist. This is reassuring for urologists, but it is important to examine how such lawsuits might be prevented.

When urologists were named as the sole defendant, common allegations were: a lack of informed consent, inadvertent UC removal, premature UC removal, UC-related trauma, and a retained UC fragment. Although most hospitals do not require a written consent form for placement of UCs (24), an informed discussion of the procedure, the reason for insertion, and its possible complications in conjunction with documentation may prevent misunderstandings between patients and urologists.

Institutions, usually hospitals but also nursing homes, were named in the majority of cases involving UC. Hospitals were named as defendants in (18/29, 62%) of lawsuits. Nurses were most commonly involved with the insertion and removal of catheters when hospitals or nursing homes were sued. Nurses were named in (5/29, 17%) lawsuits related to UCs. Notably, if they were named, nurses were never the sole defendant and the outcomes favored the defendant in all cases. The lawsuits involving nurses as defendants focused on specific behaviors by individual nurses involving UC placement, UC care, and UC removal.

Outcomes in favor of plaintiff

For UC-related lawsuits that resulted in indemnity payments to plaintiffs, the reasons for the lawsuits involved four UC removal-related cases (*Table 3*: Cases #1, 4, 5 and 6), three UC trauma or improper insertion cases (Cases #3, 7 and 9), two lack of patient consent cases (Cases #2 and 8), and one UC mechanical failure case (Case #10).

Cases of urethral trauma from UC placement and/or removal are often decided in favor of the plaintiff. Incomplete balloon deflation or premature balloon inflation causing prostatic or urethral trauma was also a common reason that plaintiffs won indemnity payments or

settlements—4/5 cases were decided in favor of plaintiffs (Case #4, 5, 6, 9). The standard practice of using catheter securing devices and training staff on safe UC placement and removal techniques has been shown to reduce catheter-related trauma by 78.6% (25,26). We also identified a lawsuit whereby a portion of the UC being left in the bladder. Training for hospital personnel who remove UCs should include inspecting it grossly and documenting whether the catheter was removed intact.

In our study, (7/29, 24%) cases were complicated by a CAUTI; four were closed with an indemnity payment to the plaintiffs. UCs may contribute up to 80% of healthcare-associated UTIs leading to extended hospital stays, increased health care costs, and patient morbidity and mortality (27). Monitoring urine output was the leading cause for UC insertion in our malpractice population. The risk of a CAUTI can be prevented by minimizing unnecessary and prolonged use of UCs (10,28,29). Hospitals should take advantage of on-line tools designed to increase awareness of and to prevent CAUTI (30-32). Furthermore, adhering to UC hospital policies may help hospital defendants defend instances of appropriate catheter use. A study done by Gokula *et al.* showed that staff education and an indication checklist for each UC placement reduced the total number of unnecessary UCs used (33).

It has been found that catheterization in older patients without specific indications is associated with greater risk of death and a longer hospital stay (34). In (4/29, 14%) cases in our study, serious complications and even death from urosepsis were claimed with two cases favoring the plaintiff and an average of \$317,500 was awarded in indemnity payments. While minimizing risk of UTI is usually focused on removing unnecessary catheters, in Case #7 the UTI and subsequent death of the patient was attributed to a delay in UC placement for a patient in urinary retention.

Indemnity payments

In this study, plaintiffs were more likely to win if the defendant was a hospital or nursing home. No indemnity payments were awarded to plaintiffs when defendants were individual physicians. With a small sample size, it is unclear if being a urologist is protective against UC-related litigation. The mean indemnity award paid to plaintiffs was \$112,991 in catheter-related litigation, which is lower than estimated average medical malpractice indemnity payments in endourology (\$364,722) and penile prosthesis malpractice suits (\$831,050), although these studies used

other legal databases than LexisNexis (21,23). Moreover, institutions, such as hospitals and nursing homes, rather than urologists, have been historically responsible for all indemnity payments.

Our study has limitations. Given how UC usage are exceedingly common, our sample size is relatively small and derived over a long time period. Although the LexisNexis database includes most state and federal cases, it does not give the total number of claims filed and the percentage of claims closed with or without indemnity payments. It does not give the total number of patients undergoing UC placement. Furthermore, it captures incomplete data about trial verdict outcomes and lacks data on settlements before trial. Presumably, many smaller cases are likely settled or resolved outside of court. These parameters are essential to accurately assess the true unbiased risk of UC liability. Some variables that could affect malpractice litigation were not included in the study due to varying availability in each case in the database such as physical exam findings, plaintiffs' demographic characteristics or provider counseling role.

Despite these limitations, we believe that this study best characterizes the litigation surrounding UC use in medicine. Based on cases that ended in favor of plaintiffs in this study, our recommendations to all healthcare providers are as follows: (I) all healthcare providers should be well trained in UC insertion and proper technique prior to initiating placement; (II) providers should assess the integrity of UC and balloon prior to insertion; (III) providers should ensure that the UC is properly secured to prevent trauma; (IV) providers should periodically review the necessity of UCs and always remove them when no longer indicated; (V) providers should ensure that the UC balloon is fully deflated prior to removal. Perhaps if these six suggestions had been followed by providers, the prevalence of UC-related litigation would be even lower.

Finally, we believe that by understanding the defendant and claim characteristics of UC-related litigation, our results are reassuring to practicing urologists whom historically are not faulted in UC-related litigation. Future areas of research should focus on examining litigation correlating legal verdicts with patient's perception of care to understand drivers of patient satisfaction.

Conclusions

Despite widespread usage of UCs over a 50-year period, state and federal lawsuits involving UC misuse are rare. Of litigated cases, urologists are commonly involved yet

have successful defenses in both state and federal courts. **Counseling healthcare providers on pitfalls of UCs use may be beneficial to prevent injury and malpractice litigation.**

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

References

1. Mohr JC. American medical malpractice litigation in historical perspective. *JAMA* 2000;283:1731-7.
2. De Ville K. Medical malpractice in nineteenth-century America: origins and legacy. New York: NYU Press, 1992.
3. Hershey N. The defensive practice of medicine. Myth or reality. *Milbank Mem Fund Q* 1972;50:69-98.
4. Studdert DM, Mello MM, Sage WM, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. *JAMA* 2005;293:2609-17.
5. Feneley RC, Hopley IB, Wells PN. Urinary catheters: history, current status, adverse events and research agenda. *J Med Eng Technol* 2015;39:459-70.
6. Haley RW, Hooton TM, Culver DH, et al. Nosocomial infections in U.S. hospitals, 1975-1976: estimated frequency by selected characteristics of patients. *Am J Med* 1981;70:947-59.
7. Saint S, Wiese J, Amory JK, et al. Are physicians aware of which of their patients have indwelling urinary catheters? *Am J Med* 2000;109:476-80.
8. Fernández-Ruiz M, Calvo B, Vara R, et al. Inappropriate use of urinary catheters in patients admitted to medical wards in a university hospital. *Enferm Infecc Microbiol Clin* 2013;31:523-5.
9. Munasinghe RL, Yazdani H, Siddique M, et al. Appropriateness of use of indwelling urinary catheters in patients admitted to the medical service. *Infect Control Hosp Epidemiol* 2001;22:647-9.
10. Stamm WE, Martin SM, Bennett JV. Epidemiology of nosocomial infection due to Gram-negative bacilli: aspects relevant to development and use of vaccines. *J Infect Dis* 1977;136 Suppl:S151-60.
11. Tambyah PA, Oon J. Catheter-associated urinary tract

- infection. *Curr Opin Infect Dis* 2012;25:365-70.
12. Hollingsworth JM, Rogers MA, Krein SL, et al. Determining the noninfectious complications of indwelling urethral catheters: a systematic review and meta-analysis. *Ann Intern Med* 2013;159:401-10.
 13. Gonzalgo ML, Walsh PC. Balloon cuffing and management of the entrapped Foley catheter. *Urology* 2003;61:825-7.
 14. LexisNexis Academic Brochure. 2015; Available online: http://www.lexisnexis.com/pdf/academic/LexisNexis_Academic_Brochure_2015.pdf
 15. Weiss AJ, Elixhauser A. Overview of Hospital Stays in the United States, 2012. Statistical Brief #180, 2016.
 16. Meddings J, Rogers MA, Krein SL, et al. Reducing unnecessary urinary catheter use and other strategies to prevent catheter-associated urinary tract infection: an integrative review. *BMJ Qual Saf* 2014;23:277-89.
 17. Sherer BA, Coogan CL. The Current State of Medical Malpractice in Urology. *Urology* 2015;86:2-9.
 18. Sobel DL, Loughlin KR, Coogan CL. Medical malpractice liability in clinical urology: a survey of practicing urologists. *J Urol* 2006;175:1847-51.
 19. Kaplan GW. Malpractice risks for urologists. *Urology* 1998;51:183-5.
 20. Gaither TW, Copp HL. State appellant cases for testicular torsion: Case review from 1985 to 2015. *J Pediatr Urol* 2016. [Epub ahead of print].
 21. Sunaryo PL, Colaco M, Terlecki R. Penile prostheses and the litigious patient: a legal database review. *J Sex Med* 2014;11:2589-94.
 22. Colaco M, Heavner M, Sunaryo P, et al. Malpractice Litigation and Testicular Torsion: A Legal Database Review. *J Emerg Med* 2015;49:849-54.
 23. Duty B, Okhunov Z, Okeke Z, et al. Medical malpractice in endourology: analysis of closed cases from the State of New York. *J Urol* 2012;187:528-32.
 24. Manthous CA, DeGirolamo A, Haddad C, et al. Informed consent for medical procedures: local and national practices. *Chest* 2003;124:1978-84.
 25. Kashefi C, Messer K, Barden R, et al. Incidence and prevention of iatrogenic urethral injuries. *J Urol* 2008;179:2254-7; discussion 2257-8.
 26. Manalo M Jr, Lapitan MC, Buckley BS. Medical interns' knowledge and training regarding urethral catheter insertion and insertion-related urethral injury in male patients. *BMC Med Educ* 2011;11:73.
 27. Kleinpell RM, Munro CL, Giuliano KK. Targeting Health Care-Associated Infections: Evidence-Based Strategies. In: Hughes RG. editor. *SourcePatient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville (MD): Agency for Healthcare Research and Quality (US), 2008. Chapter 42.
 28. Daifuku R, Stamm WE. Association of rectal and urethral colonization with urinary tract infection in patients with indwelling catheters. *JAMA* 1984;252:2028-30.
 29. Umscheid CA, Mitchell MD, Doshi JA, et al. Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. *Infect Control Hosp Epidemiol* 2011;32:101-14.
 30. CDC CAUTI Prevention Guidelines. Available online: http://www.cdc.gov/HAI/ca_uti/uti.html (April 26, 2016).
 31. American Nurses Association CAUTI Prevention Tool. Available online: <http://nursingworld.org/ANA-CAUTI-Prevention-Tool> (April 27, 2016).
 32. Catheter-associated Urinary Tract Infection (CAUTI) Toolkit. Available online: http://www.cdc.gov/HAI/pdfs/toolkits/CAUTItoolkit_3_10.pdf (April 27, 2016).
 33. Gokula RM, Smith MA, Hickner J. Emergency room staff education and use of a urinary catheter indication sheet improves appropriate use of foley catheters. *Am J Infect Control* 2007;35:589-93.
 34. Holroyd-Leduc JM, Sen S, Bertenthal D, et al. The relationship of indwelling urinary catheters to death, length of hospital stay, functional decline, and nursing home admission in hospitalized older medical patients. *J Am Geriatr Soc* 2007;55:227-33.

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