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Robotic Urologic Surgery: Trends in Litigation Over the Last Decade

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Abstract

Background: There is a lack of information regarding malpractice claims and indemnity payments associated with robotic cases in surgery. Malpractice claims and indemnity payouts will elucidate and mitigate harms of future adoption of new technology into surgery. We analyzed claims filed against Intuitive Surgical, Inc. from 2000–2017.

Methods: A law librarian identified product liability claims from 2000–2017 with the defendant “Intuitive Surgical, Inc.” using the Bloomberg Law database. We reviewed all available legal documents pertaining to identified claims, and extracted data points including filing date, surgery date, surgery type, robot type, instrument type, complications, and case outcomes.

Results: Since 2000, 123 claims were filed; 108 met criteria for inclusion. Gynecologic surgeries comprised the majority of claims (62%, 67 claims), followed by urologic surgeries (20%, 22 claims). Claims filed peaked in 2013 (30%, 32 claims) and then decreased each year, with 6% (7 claims) filed in 2016, and only 1% (1 claim) filed in 2017. Of the 22 claims regarding robotic urologic surgeries, 19 claims (86%) pertained to prostatectomy. Commonly alleged injuries in urologic cases were bowel injury (8 claims), erectile dysfunction (5 claims), bowel fistulas (4 claims), and incontinence (4 claims). Device failure was cited in only 2 claims.

Conclusions: Early adopters of robotic surgery were at highest risk of litigation. This risk subsequently decreased despite the wide spread adoption of this technology. Almost all claims were secondary to surgical complications and not device failure, thus demonstrating a need for more systematic training for novel devices and early adopters.

Keywords

robotic surgery; da Vinci; litigation; claim; lawsuit

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Conflict of Interest: Authors Farnoosh Nik-Ahd, Colby P. Souders, Hanson Zhao, Justin Houman, Lynn McClelland, Bilal Chughtai, and Jennifer T. Anger declare that they have no conflict of interest.

Introduction

Robotic surgeries have become increasingly common since the U.S. Food and Drug Administration's (FDA's) approval of Intuitive Surgical, Inc.'s da Vinci Surgical Systems in the year 2000. There were less than 100,000 surgeries performed robotically in 2007, compared to 877,000 surgeries in 2017 [1]. This growth has led to a tremendous amount of research on proposed advantages of robotic techniques. However, there has been less research on adverse events and complications pertaining to robotic surgeries. A study by Cooper et al. found that complications associated with the surgical robot were underreported to the FDA [2]. Launched in 2010, the Bloomberg Law database is a legal research database which provides legal documents to legal professionals for research purposes. This database enables access to litigation and court dockets, enabling access to comprehensive files pertaining to legal cases.

Litigation trends are significant as they may be a surrogate marker of surgical complications and patient safety. This data is particularly important in fields such as urology, where there is a high utilization of robotic surgical techniques. Here we sought to characterize complications associated with robotic surgery by evaluating legal cases involving robotic procedures, with a particular emphasis on robotic urologic surgeries. Using the Bloomberg Law database, we analyzed claims filed against Intuitive Surgical, Inc. from 2000 to 2017 to gain a better understanding of the nature of patient injuries and claims.

Materials and Methods

Claims Identification and Data Analyses

After obtaining Institutional Review Board approval, data on product liability claims from the year 2000, the year robotic-assisted surgery was FDA approved, to 2017 with the defendant "Intuitive Surgical, Inc." were identified by a law librarian using the Bloomberg Law database. Intuitive Surgical, Inc. is currently the only manufacturer of the robotic platform. Claims were read to ensure they were patient claims against the company for issues with the surgical robot. We reviewed all available legal documents related to each claim. Data points extracted include the date the claim was filed, date of surgery, surgery type, robot type (S, Si, Xi), instrument type, complications, and case outcomes. Fourteen class action claims were excluded, as the above data points could not be abstracted. One additional claim was excluded from analysis as it was unrelated to robotic surgery.

Results

Baseline Trends in Robotic Surgery Litigation

A total of 123 claims were filed from 2000 to 2017 (Figure 1). Fifteen claims were excluded from analysis for aforementioned reasons, resulting in a sample size of 108 claims. The majority of claims (62%, 67 claims), were related to gynecologic surgeries, followed by 20% (22 claims) pertaining to urologic surgeries, and a total of 11% (11 claims) were pertaining to other surgical fields, including cardiothoracic surgery, colorectal surgery, general surgery, and endocrine surgery. A total of 7% (8 claims) pertained to unknown surgeries.

Litigation as a Function of Time

The number of claims filed against Intuitive Surgical, Inc. remained fairly stable from 2006 to 2011, with a total of 0 to 3 claims filed each year (Figure 2). The peak filing year was 2013, reaching 30% (32 claims) of all claims, and the number of claims remained elevated in 2014 (20%, 22 claims) and 2015 (21%, 23 claims). Since 2016, there has been a substantial decrease in claims each year, with 6% (7 claims) filed in 2016, and only 1% (1 claim) filed in 2017. The year was unknown for 3% (3 claims).

On average, 24 months lapsed between surgery date and claim filing date across all surgical subspecialties. Specifically, 26 months lapsed from surgery date to claim filing date for urologic claims, 23 months for gynecological claims, 25 months for cardiovascular claims, 25 months for colorectal claims, and 24 months for general surgery claims.

Claims Filed Pertaining to Robotic Urologic Surgeries

Of the 22 claims filed regarding robotic urologic surgeries, 19 claims (86%) pertained to prostatectomy, while partial nephrectomy and pyeloplasty each represented one claim (5%) (Figure 4). In one claim the type of urologic surgery was not available.

Injury was the most common alleged complication reported in claims (Figure 4). The most commonly cited injury in urologic cases was bowel injury (mentioned in 8 claims), followed by erectile dysfunction (5 claims), bowel fistula formation (4 claims), and incontinence (4 claims). Only three claims filed alleged that additional surgery was required. The alleged complications seen in the fewest number of claims were bladder injury, deep vein thrombosis (DVT), injury to the testicle or scrotum, small bowel obstruction, and urinary fistula, each of which was mentioned in one claim only. Interestingly, device failure was cited in only two claims, suggesting that most alleged complications resulted from reasons other than robot malfunction.

Litigation Outcomes

Of the 123 claims filed since 2000, approximately 35% (43 claims) were ultimately dismissed. Of the 22 claims filed pertaining specifically to urologic surgery, 45.5% (10 claims) were dismissed. No other information regarding settlements or trial outcomes was available through the Bloomberg Law database or any of the available documents pertaining to each claim.

Discussion

We found that the majority of claims resulted from gynecological surgeries, followed by urologic surgeries. Interestingly, our data suggest that the most common alleged complication in claims pertaining to urologic surgery is bowel injury, and, in the case of prostatectomy, erectile function, bowel fistula formation, and incontinence. Robot failure/malfunction was alleged in a very small number of claims. In fact, the majority of claims, such as erectile dysfunction or urinary incontinence after prostatectomy, are not unique to robotic surgery. In fact, risk of erectile dysfunction and urinary incontinence has been shown to be lower after robotic (vs open) techniques [3, 4].

While early adopters and surgical innovation prepares the road to better care, it also introduces risk and a learning curve for patients, providers and hospital systems. Specifically, with the exponential growth in robotic surgery, it is important to understand the patient safety factors as well as medico-legal risks associated with the use of this technology. In a study by Schiavone et al. of 192 hospital web sites analyzed, the majority of web sites reported claims of less pain (88.0%), shorter recovery time (91.2%), and less blood loss (76.0%) for robotic surgery. In addition, a substantial number of sites described robotic surgery as overall better (41.2%) or the most effective option (26.0%) [5]. Our data suggest that the plaintiffs in these claims may not have fully understood these risks, suggesting that one area of focus may be improving the surgical consent process so patients are increasingly aware of and educated regarding these known potential complications.

Although the number of claims filed remained stable from 2006 to 2011, this number peaked in 2014, and decreased substantially in 2016 and 2017. One of the most significant findings in our results is the decrease in claims filed in 2016 and 2017, particularly given the substantial annual increase in robotically performed surgeries since its approval in 2000. In fact, the number of claims filed in 2017 matched the number of claims filed in 2006, the first year a claim was filed against Intuitive Surgical, Inc., a notable finding given there was a record-breaking 877,000 surgical procedures performed with da Vinci Surgical Systems in 2017 alone [1].

The fact that the rate of lawsuits filed is not increasing at a dramatic rate despite as the volume of robotic surgeries performed annually continues to increase may be a surrogate for an increase of the quality of surgical skills with the robot, as well robot software and instruments. However, it may also be due to a lag time between surgery date and claim filing, given an average of 24 months lapsed between the surgery date and claim filing date across surgical subspecialties.

Our current findings suggest that among urologic surgeries, bowel injury is the most common alleged complication in claims filed, in addition to being the most commonly reported adverse event. Interestingly, although fistula formation is a far rarer reported adverse event than bowel injuries, it is the third-most common alleged complication in claims filed. Although we do not know whether bowel injuries and fistula formation occurs more or less commonly in robotic (vs. open or laparoscopic) cases, it is possible that the magnified visual field on the console might predispose to missed bowel injuries. Therefore, ensuring that surgical instruments are never out of view and improving training approaches for bedside surgical assistants may also help prevent some of these injuries.

Interestingly, our data show that erectile dysfunction and incontinence are some of the most common alleged complications in claims filed against urologists. We also found that prostatectomy was the most commonly cited procedure in these claims.

Our study has inherent limitations due to the limited information available in the Bloomberg Law database. Although we reviewed all documentation pertaining to each claim, it is possible that the records available were not complete. Additionally, sometimes we did not have access to outcomes other than the fact that cases were dismissed, making it unclear how

many cases resulted in settlements or went to trial. Additionally, the Bloomberg Law Database does not have access to all state court documents, as some court documents may only be obtained in person at the court. Therefore, it is possible that some case filings in state courts were missed. Despite these limitations, the Bloomberg law database enabled us to have the most thorough access to legal documentation pertaining to each claim. Robotic surgery with the da Vinci Surgical System has become one of the most common technologies used in urologic surgery. As common urologic surgeries are increasingly performed robotically, it is imperative for urologists to understand trends in litigation pertaining to robotic surgeries so that areas of quality improvement can be identified and incorporated into surgical training.

Conclusions

Early adopters of robotic surgery were at highest risk of litigation. This risk subsequently decreased despite the widespread adoption of this technology. Almost all claims were secondary to surgical complications and not device failure, thus demonstrating a need for more systematic training for novel devices and early adopters.

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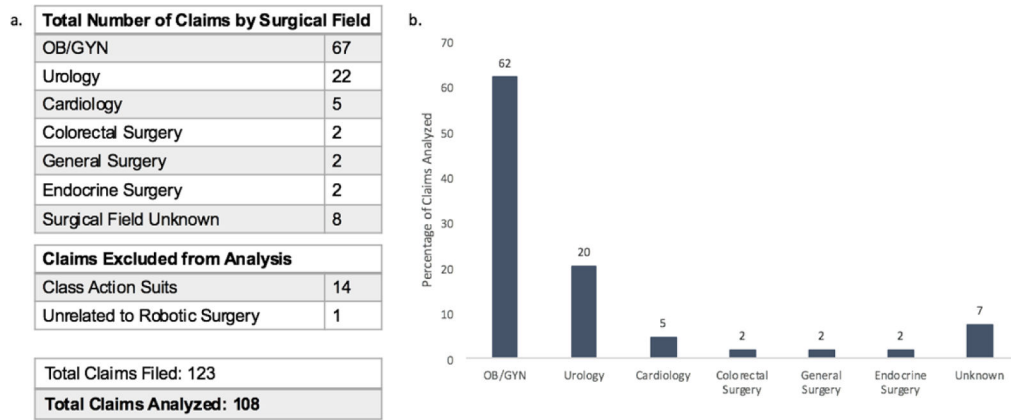


Figure 1: a. Total number of claims filed against Intuitive Surgical, Inc. since 2000 listed by surgical field.

123 total claims were filed, of which 14 class action suits and 1 unrelated claim were excluded from analysis. 108 claims met criteria for analysis. **b. Percentage of claims analyzed by surgical subspecialty.** Of the 108 claims analyzed, the majority of claims (62%) came from gynecologic surgeries, while 20% came from urologic surgeries.

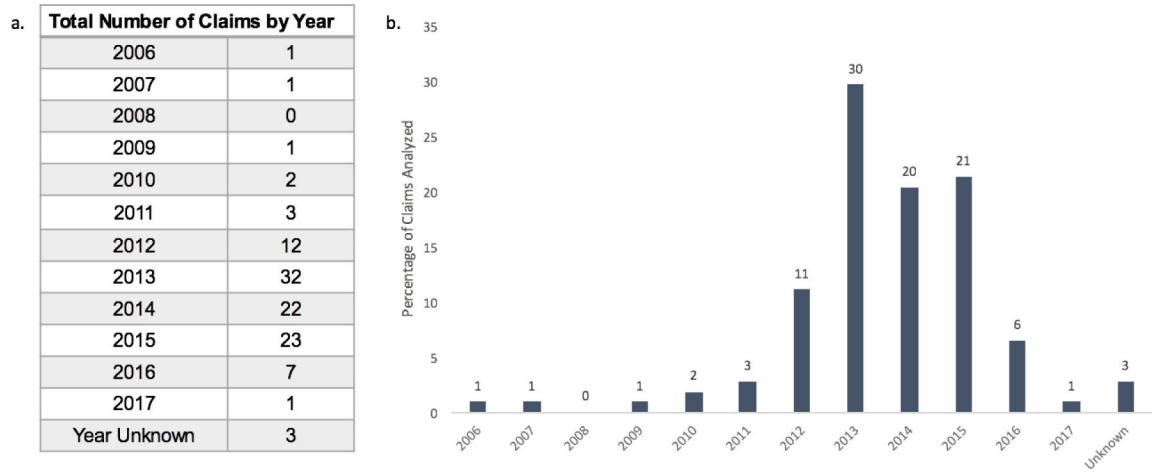


Figure 2: Claims filed against Intuitive Surgical, Inc. by year (a) and as a percentage of claims analyzed (b).

There were 0–3 claims filed each year from 2006–2011. A peak in claims was seen in 2013–2015, with 32 claims (30%) filed in 2013, 22 claims (20%) filed in 2014, and 23 claims (21%) filed in 2015. The number of claims decreased substantially in 2016 and further in 2017, despite an increase in the total number of robotic cases performed annually using Intuitive Surgical, Inc. devices.

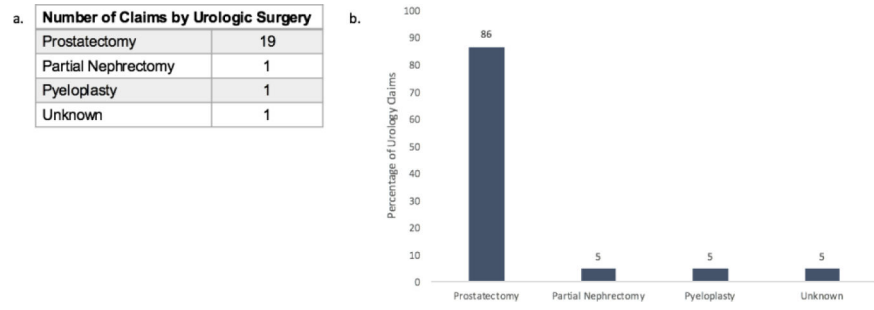


Figure 3. Urologic surgeries resulting in claims filed against Intuitive Surgical, Inc., shown as total number (a) and percentage (b) of claims.
 86% of claims were from robotic prostatectomy, while partial nephrectomy and pyeloplasty each comprised 5% of claims.

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Alleged Complication	Total Number of Occurrences
Bowel Injury	8
Erectile Dysfunction	5
Bowel Fistula	4
Incontinence	4
Bleeding	3
Infection	3
Injury to Ureter or Kidney	3
Ostomy	3
Incomplete Prostatectomy	2
Nerve Damage from Positioning	2
Bladder Injury	1
DVT	1
Injury to Testicle/Scrotum	1
Small Bowel Obstruction	1
Urinary Fistula	1
Required Additional Surgery	3
Robot Failure	2
Not Specified	4

Figure 4. Alleged complications in urologic surgeries.

Bowel injuries were the most common complication reported in plaintiff claims, followed by erectile dysfunction, bowel fistula, and incontinence. Robot failure was reported in only two claims, suggesting that most alleged complications resulted from surgical error and issues with informed consent, rather than robot malfunction.

Outcomes of All Claims	
Total Number of Claims	123
Number of Dismissed Claims	43
Percentage of Dismissed Claims	34.96%

Outcomes of Urologic Surgery Claims	
Total Number of Claims	22
Number of Dismissed Claims	10
Percentage of Dismissed Claims	45.45%

Figure 5. Outcomes of all claims (a) and claims from urologic surgery (b).
Nearly 35% of all claims were ultimately dismissed, while 45% of urologic claims were dismissed.