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ORIGINAL ARTICLE

Robotic sacrocolpopexy: adverse events reported to the FDA over the last decade

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Abstract

Introduction and hypothesis As surgeons increase the volume of robotic abdominal sacrocolpopexies (rASCs) and become more experienced, a subsequent decrease in the number of adverse events is expected over time. Further, as the leading manufacturer of the operative robot (Intuitive Surgical) improves the technology, adverse events should also decrease. We hypothesized that there has been a decrease in adverse event reporting for rASCs and that serious adverse events are rare.

Methods We performed a search of the FDA Manufacturer and User Facility Device Experience (MAUDE) database. All entries with the manufacturer "Intuitive Surgical" were exported from 2007 to 2017. All entries with "sacrocolpopexy" were then isolated and analyzed.

Results The number of adverse events reported for rASC peaked in 2013 and 2014, at 107 and 124 respectively. In 2015 and 2016, the number dropped to 11 and 7 respectively. There were 334 reported adverse events from 2007 to 2017. Five (1.50%) were categorized as death, 33 (9.88%) as injury, and 296 (88.62%) as malfunction. Analysis of the malfunction reports found that 15 out of 296 (5.07%) were converted to open surgery, 4 out of 296 (1.3%) were converted to laparoscopic surgery, 4 out of 296 (1.3%) cases were aborted, and 6 out of 296 (2.03%) malfunctions resulted in patient injury.

Conclusions Although the MAUDE database has its limitations, it does indicate that the number of adverse events reported for rASC peaked in 2013 and 2014 and has decreased annually since then. This may be due to improved proficiency of the surgeon and surgical team, in addition to improvements in the robot. When malfunctions do occur, they infrequently cause serious injury or have an impact on surgical approach.

Keywords Abdominal sacrocolpopexy · Adverse events · Pelvic organ prolapse · Robotic surgery

Abbreviations

rASC	Robotic abdominal sacrocolpopexy
MAUDE	Manufacturer and user facility device experience
POP	Pelvic organ prolapse
RAEs	Reported adverse events

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Introduction

Pelvic organ prolapse (POP) is a common condition and the number of women affected is expected to increase from 3.3 million in 2010 to anywhere between 4.9 and 9.2 million by 2050 [1]. The lifetime risk for a woman to require at least one surgical procedure for prolapse is 12.8% [2]. The importance of the anatomical support of vaginal apex has emerged as a critical component of the surgical treatment of POP [3]. For decades, the use of abdominal sacrocolpopexy (ASC) to address the vaginal apex has been considered the gold standard for treating apical prolapse [3]. In response to the increased recognition of the need to address the vaginal apex, the use of transvaginal mesh emerged; however, the complications and legal ramifications associated with the use of transvaginal mesh resulted in surgeons returning to sacrocolpopexy as a durable POP treatment.

Abdominal sacrocolpopexy can be performed open or laparoscopically with or without the assistance of the operative robot. Generally, the learning curve for laparoscopic surgery is somewhat steeper than robotic surgery, which is largely attributed to the wrist articulation provided by the robot, in addition to improved visualization (three dimensions and magnification) and decreased reliance on the surgical skills of the bedside assistant. These factors, in addition to increasing patient demand, led to the rapid adoption of the robotic-assisted ASC (rASC), despite a lack of comparative outcomes. A recent systematic review found that, at 6 months or longer, rASC is a safe and effective treatment for vaginal vault prolapse with good anatomical outcomes [4]. We also found previously that robotic outcomes were excellent at 1 year after surgery and outcomes were comparable with laparoscopic approaches, with no mesh complications [5].

We sought to analyze adverse events of rASC over time using the publicly available FDA Manufacturer and User Facility Device Experience (MAUDE) database. We anticipated that the rising adoption [6] of rASC would result in increased surgeon experience, in addition to improvement in robotic software and equipment. We therefore hypothesized that there would be a decrease in adverse events reported to the FDA over time. Further, we hypothesized that a majority of claims would be related to device malfunctions, rather than death or injuries.

Materials and methods

We performed a search of the FDA MAUDE database. The FDA MAUDE database catalogs medical device adverse event reports and serves as a record of device-associated deaths, serious injuries, and device malfunctions. It serves as a tool to monitor the safety and efficacy of surgical technology. Adverse event reports are submitted to the FDA by mandatory reporters, which include manufacturers, importers, and device user facilities, in addition to voluntary reporters such as healthcare professionals, patients, and consumers [7].

All entries with the manufacturer "Intuitive Surgical" were exported from the years 2007 to 2017. All entries with "sacrocolpopexy" were then isolated and analyzed. The following data points were collected: event date, event type (malfunction, injury, death), date received, and brand name. The event type was reclassified based on event description text, if appropriate. The event description text sometimes provided more details on the event, but specific details were not present for all events. According to the FDA website, the event description should include what happened to patient before, during, and after the event. Further, it should include whether a medical or surgical intervention was required. We classified injury as any malfunction resulting in injury to the patient, whether it was a technical error or robotic malfunction. Duplicate entries were removed. IRB approval requirement was waived for this study, given that the FDA MAUDE database is publicly available.

Results

Baseline trends in reported adverse events in robotic sacrocolpopexy

A total of 21,129 reported adverse events (RAEs) were found between 2007 and 2017 under Intuitive Surgical. Three hundred and thirty-nine sacrocolpopexy procedures were identified using keyword search and 5 were removed from the analysis. There was a total of 334 RAEs for rASCs. Of those, 296 malfunction events (88.62%) were caused by robotic or instrument malfunction, 33 patient injury events (9.88%), and 5 death events (1.50%). The reporting requirements for mandatory reporters indicate that an event must be reported within 1 month, unless the event requires "remedial action to prevent an unreasonable risk of substantial harm to the public health," in which case the mandatory reporting requirement is within 5 days [8].

Trends in RAEs by year

Less than 4% of the total number of RAEs occurred per year between 2007 and 2011 (Fig. 1). There was an increase in RAEs in 2012, with over 12% (43 RAEs) occurring that year. There was a peak in RAEs in 2013 and 2014, with 31.75% (107 RAEs) and 36.80% (124 RAEs) occurring each year, respectively. This number decreased substantially in 2015, with only 3.26% (11 RAEs), and has continued to decrease since then. The number of RAEs reached a decade-long low in 2017, with only 0.59% (2 RAEs) for the entire year (the lowest number of RAEs over the last decade). No adverse events were reported in 2007.

Malfunctions, injuries, and death in robotic sacrocolpopexy

We next sought to better understand the types of malfunction events that caused each RAE. We found that of the 296 events, the majority were malfunctions of the Mega Needle Driver (100 events; 33.78%), followed by 76 (25.68%) reported malfunctions of the large needle driver (Table 1). Malfunctions of the Da Vinci Surgical System, ProGrasp® forceps, and Fenestrated Bipolar occurred at similar frequencies, each consisting of 25–28 (8–9%) total malfunctions. Six out of 296 (2.03%) malfunctions resulted in patient injury.

Next, we looked to examine the types of injuries reported. The majority of injuries (17 events; 51.52%) were bowel injuries, 7 of which were successfully repaired intra-operatively,

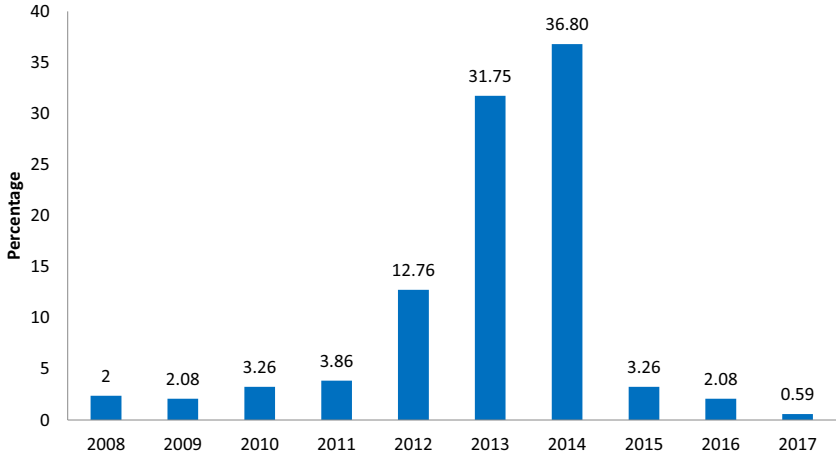

Fig. 1 Trends in reported adverse events (RAEs) by year, number (%). The overall number of RAEs remained stable from 2008 to 2011, peaked in 2013 and 2014, and then declined substantially

whereas an additional 7 were repaired through an exploratory laparotomy in the post-operative period and likely not recognized at the time of the rASC (Table 2). The next most common type of injury was vascular injury (5 events; 15.15%) and skin burns (4 events; 12.12%). All injuries occurred at a low frequency, with each occurring between one to three times, comprising between 3 and 10% of all injuries, over the last decade.

There was no evidence for system or mechanical malfunction in the five reported deaths. The deaths were surgical complications that were due to technical error.

Adverse events outcomes

An analysis of the malfunction reports found that 15 out of 296 (5.07%) were converted to open surgery, 4 out of 296 (1.3%) were converted to laparoscopic surgery, 4 out of 296 (1.3%) cases were aborted, and finally, 6 out of 296 (2.03%) malfunctions resulted in patient injury.

Table 1 Further classification of the 296 total instrument and robotic malfunctions

Malfunction	Number	Percentage
Mega Needle Driver	100	33.78
Large Needle Driver	76	25.68
Surgical System	28	9.46
ProGrasp Forceps	26	8.78
Fenestrated Bipolar	25	8.45
PK Dissecting Forceps	18	6.08
Maryland Bipolar	11	3.72
Monopolar Curved Scissors	6	2.03
Other	6	2.03
Total	296	100

Discussion

As the volume of robotic surgeries increases, we sought to understand the number and types of complications associated with rASC. Although RAEs reported to the FDA that involved injury or death were rare, it must also be considered that deaths caused 1.5% of the total events submitted, which seems to be high for this surgery. A recent literature review of rASC outcomes had a pooled analysis of 577 cases and no deaths were reported [4]. The actual morbidity rate is much lower when taking into account all sacrocolpopexies as the denominator; however, these exact numbers are not available.

Further, the number of RAEs has decreased annually, despite an increase in the number of robotic surgeries performed each year. Although we do not have specific data regarding the number of rASC procedures performed per year, we do known that the number of gynecological cases (which includes rASCs) has increased every year based on the 2017 annual report from Intuitive Surgical [6]. There are currently a limited number of gynecologic surgeries that are FDA approved to be performed using the da Vinci Surgical System, including myomectomy, hysterectomy, and sacrocolpopexy [6]. According to the Intuitive Surgical 2017 annual report,

Table 2 Total number and percentage of injury types

Injury	Number	Percentage
Bowel injury (7 repaired intra-operatively, 7 ex-lap post-operatively, 3 unknown details)	17	51.52
Vascular injury	5	15.15
Skin burn	4	12.12
GU injury	3	9.09
Foreign body	2	6.06
DVT	1	3.03
Liver injury	1	3.03
Total	33	100

"gynecology was [the] largest U.S. surgical specialty and the procedure volume was approximately 252,000 in 2017, compared with 246,000 in 2016 and 238,000 in 2015. [Intuitive Surgical] believes that the modest growth in gynecologic procedures over the past several years was primarily driven by consolidation of surgical volumes into surgeons that focus on cancer and complex surgeries, as well as higher sacrocolpopexy procedure volume" [6]. The report also states that "[Intuitive Surgical] has experienced procedure growth for a number of benign conditions, including hysterectomies for benign conditions, sacrocolpopexies, hernia repairs, cholecystectomies, and certain other surgeries" [6]. As a point of comparison, 136,000 surgeries were performed across the globe among all specialties using the Da Vinci Surgical System in 2008 [6]. Thus, there has been a substantial growth in the use of robotic surgery and rASCs.

The decrease in MAUDE reports is likely due to both improvements in technology and increased surgical skill. Instrument malfunctions encompass both surgical malfunctions that did not result in patient injury in addition to technological malfunctions. We do not believe that surgeons blamed the problems on the device, but rather that it was a combination of both surgical technical challenges and instrument malfunctions. It is also possible that surgeons who were performing this surgery and had a number of complications, stopped performing RASCs. In addition, it is possible that more attention may have been focused on reporting events to the FDA MAUDE database in 2013 and 2014.

Given that the average interval between event date and reporting date was approximately 1 month for this data set, the data for 2016 and 2017 can be presumed to include all events from those years. Thus, the decrease noted in recent years cannot be attributed to a reporting delay. Both of these findings are consistent with our hypothesis that the rates of RAE would decrease with increasing experience and robot improvements, and that the majority of the adverse events associated with rASC did not lead to patient harm. We did, however, see a rise in complications in 2013 and 2014. It is possible that this was directly due to the increased adoption of the rASC and the associated learning curve.

Other researchers have previously evaluated the MAUDE database to analyze the RAEs associated with robotic surgery; however, the most recent of these works evaluated results from the MAUDE database only through 2012 [9, 10]. In contrast to our work, previous researchers found that, as the number of robotic surgeries increased, so did the complications. Further, most of the previous works focused on robotic surgery in general, and not on specific urogynecological procedures. One study did evaluate gynecological procedure complications with the Da Vinci robot between 2006 and 2012. This study also found an increasing trend of adverse events reported to the FDA for all gynecological procedures, although a sub-analysis with respect rASCs was not performed, which differentiates our work.

The MAUDE database, and therefore our study conclusions, is limited by the quality of the data submitted by the reporters to the FDA. On the MAUDE homepage, the FDA notes that "… this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data" [7]. In addition, any party may submit claims to this database, regardless of their accuracy, including patients and lawyers. Unlike other data analyses of the MAUDE database that we have carried out, namely transvaginal mesh, the majority of these submissions appear to have event descriptions that were made by individuals familiar with the event. They were more specific and did not appear to be the same complaints copied and pasted across different submissions. It is important to note that details available for each RAE were variable and ultimately have an impact on the ability of researchers to fully analyze and understand the events. Researchers have evaluated the quality of the FDA MAUDE database with respect to the accuracy of reporting for transvaginal mesh and found that "the MAUDE database was limited in its ability to collect, quantify, and standardize real-life adverse events related to transvaginal mesh" [11]. It is a significant limitation of our study that we do not have data on the number of rASCs performed annually; therefore, we cannot calculate annual complication rates. A limitation regarding nomenclature also exists if MAUDE reporters elected to report a complication for a sacrocervicopexy rather than a sacrocolpopexy.

Our study found that the number of adverse events for rASC peaked in 2013 and 2014 and has decreased annually since then. This may be due to the improved proficiency of the surgeon and surgical team, in addition to improvements in the robot. When malfunctions do occur, they infrequently cause injury or have an impact on the surgical approach. Our study highlights a new finding compared with the previous studies—we may have reached a point where, with more experience of performing robotic surgeries and technology improvements, the complication rate of rASC has now decreased to an all-time low, despite the increase in the number of robotic surgeries. This information may be useful when counseling patients regarding complications and the safety of rASC with the caveat that the database has a limited scope and may contain biased or inaccurate reports.

Compliance with ethical standards

Conflicts of interest None.

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