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Device-related complications during renal cryoablation: insights from the Manufacturer and User Facility Device Experience (MAUDE) database

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Abstract

Introduction and objectives: Cryoablation offers a treatment option for small renal masses ideally suited ≤3 cm. In well-selected candidates, it is associated with less perioperative morbidity compared to more invasive options, such as partial or radical nephrectomy. However, little is known regarding device-related complications associated with the procedure. We provide an analysis of reports on renal cryoablation from the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database.

Methods: Reports on renal cryoablation submitted to the MAUDE database from 2015 through 6/2021 were analyzed. Cases not pertaining to renal cryoablation were excluded ($n = 33$). Reports were examined to identify patient morbidity related to a potential device malfunction, as well as manufacturer assessment. Complications were graded based on an established MAUDE complication-reporting stratification. Fisher's Exact test was utilized to analyze for associations between device-related adverse events and severity of post-treatment sequelae.

Results: Two hundred and thirty-nine unique cases were identified. Adverse events were related to issues with the needles or system (212 cases), technical error (12 cases), or complication related to patient or tumor complexity (14 cases). There were 187 (78.6%) minor complications (MAUDE 1−2) and 52 (21.4%) major complications (MAUDE 3−4). The manufacturer performed formal device review in 164 (68.6%) cases, accepting responsibility for malfunction in 41. Notable MAUDE 3 complications included 29 (12.1%) cases aborted due to instrument/system malfunction and 14 (5.9%) cases of hemorrhage requiring a subsequent procedure. All 3 reported patient deaths (MAUDE 4) appeared to be a consequence of poor baseline health. On statistical analysis, major complications were seen in a significantly higher proportion of non-device related adverse events compared to device related events (85.2% vs. 13.7%, $P < .001$).

Conclusion: While renal cryoablation is associated with low overall perioperative morbidity, there is a diverse set of device-related and procedural complications reported in recent years. Device-related adverse events were often associated with minor complications, and major complications were often seen in higher risk patients with comorbidities, more complex tumors, and after technical error. These findings highlight the need for standardized reporting of complications, optimized patient selection and counseling to ensure the best outcomes.

Keywords: Complications, Cryoablation, MAUDE, Medical devices, Renal mass
Abbreviations: MAUDE, Manufacturer and User Facility Device Experience; FDA, Food and Drug Administration

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1. Introduction

Due to advances and increased utilization of abdominal cross-sectional imaging, the discovery of small renal masses is increasing [1,2]. Nephron-sparing surgical techniques have been recommended for renal masses <4 cm with equivalent oncologic outcomes, favorable mortality, and improved functional outcomes compared to radical nephrectomy [3−5]. Minimally-invasive ablative techniques (radiofrequency ablation, cryoablation, etc.), have been increasingly employed for suboptimal surgical candidates—older patients with comorbidities, surgical contraindications, multiple tumors, or poor renal function—or for those refusing surgery [6,7]. Since its inception in 1995, utilization of cryoablation has been consistently expanding, specifically for the treatment of low-stage renal cell carcinoma, with decreased morbidity and mortality compared to surgery [8−10]. As an ablative technique, cryoablation remains a popular method with comparable oncologic outcomes to other modalities like radiofrequency ablation [11,12]. Compared to partial nephrectomy, percutaneous cryoablation offers several advantages, including avoidance of general anesthesia, potential avoidance of instrumentation of the peritoneal cavity as well as preservation of anatomic structures, such as Gerota's fascia to contain postprocedural bleeding [13].

However, there remains a dearth of information regarding adverse events related to cryoablation. While complications have been initially described, the impact of the surgeon's experience, patient, and technique-related factors are less well understood. In particular, very little has been published about device-related adverse events. The Manufacturer and User Facility Device Experience (MAUDE) database is a Food and Drug Administration (FDA) maintained public database that collects anonymous reports of device-related incidents for a plethora of different types of cases and may be freely queried with unrestricted access. The anonymous nature of the reports allows for unbiased improvement to team awareness and overall patient safety [14,15]. We examined renal cryoablation-associated events reported to the MAUDE database for device malfunctions or patient injuries. Implementing a previously described MAUDE complication classification system, we sought to define the range of adverse events, and their impact on patient outcomes [14].

2. Materials and methods

2.1. Data source and report inclusion criteria

An Institutional Review Board exemption was obtained for this study as the FDA MAUDE database is publicly accessible and inherently deidentified. The database was queried for any renal cryoablation device-related malfunction/deviation and adverse sequelae that may have occurred in relation to the device using the combination of the terms "renal," "kidney," and "cryoablation" (search performed online at www.fda.gov on 7/10/21 at 10:00). Reports were reviewed for the period of January 2015 to June 2021. The reports yielded from the preliminary search were examined regarding device malfunction, manufacturer assessment, and potential complications or changes to patient care or outcome. In some cases, the location of the cryoablation site was not reported, and thus were excluded. Only reports specifically identifying renal cryoablation were included. In addition, laparoscopic vs. percutaneous approaches were not always reported. Information regarding the type of cryoablation needle and whether the needle used was reusable was also obtained. Excluding incomplete reports and non-renal sites yielded 239 evaluable renal cryoablation cases that formed the basis of this study.

2.2. Report tabulation and stratification process

Review of reports yielded a proposed source of the error, a specific adverse event, and potential patient sequelae. When possible, the cryoablation needle was returned to the manufacturer for review to determine whether the instrument was defective. To stratify complications, a previously established and externally validated classification system developed by Gupta et al. was utilized [14]. This classification system, modeled from the Clavien-Dindo complication classification, assigns a level of severity to each device-related event: 1 (mild) − no harm to the patient with minimal change in outcome, 2 (moderate) − enough harm to the patient necessitating minor intervention, 3 (severe) − enough harm to the patient necessitating aborting the case or major intervention, and 4 (life threatening or death) − enough harm to the patient requiring Intensive Care Unit (ICU) management or patient mortality.

2.3. Statistical analysis

To assess potential impact of device-related adverse events, Fisher's Exact test analysis was performed to compare rates of high grade complications (MAUDE stratification level 3-4) between device-related and non-device related complications. A *P*-value of less than 0.05 was considered statistically significant. All statistics were performed using SPSS version 27 (IBM, Armonk, New York).

3. Results

From 2015 through 6/2021, 239 cryoablation cases were identified to be localized to the kidney. In 95.4% of cases the cryoablation equipment was manufactured by Galil (Arden Hills, MN), with the remaining 4.6% made by Healthtronics Endocare (Austin, TX). 211 of 239 (88.3%) cryoablation cases were able to be successfully completed by the operating physician. There were 165 (69.0%) MAUDE 1, 22 (9.2%) MAUDE 2, 49 (20.5%) MAUDE 3, and 3 (1.3%) MAUDE 4 adverse events (Table 1). In the

Table 1
Complications and sequelae reported from the Manufacturer and User Facility Device Experience (MAUDE) database

Total MAUDE complications total − 239 cases	What malfunctioned	Complications	Sequelae
1 − 165 (69.0%) No harm	Instrument issue - 165	Needle shaft frosting - 78	Procedure completed successfully without harm to the patient
		Needle causing muscle spasm - 73	
		Needle causing shaft frosting and muscle spasm - 5	
		Needle with gas leak - 2	
		Delayed thaw - 1	
		Needle difficult to remove - 1	
		Faulty needle was replaced - 1	
		Needle cooling malfunction - 4	
2 − 22 (9.2%) Minor harm requiring medical therapy	Instrument issue - 18	Needle shaft frosting causing numbness - 1	Managed medically
		Needle shaft frosting causing thermal burn - 15	
		Needle causing muscle spasm with patient movement leading to hemorrhage - 2	
	Patient/tumor complexity - 2	Intraoperative arrhythmia - 1	
		Postoperative hemorrhage - 1	
	Technical error - 2	Needle cable placement caused thermal burn - 1	
		Bowel injury and obstruction- 1	
3 − 49 (20.5%) Major harm requiring operative/procedural intervention	Instrument issue - 21	Issue with needle freezing ability - 19	Procedure aborted, required another procedure
		Clogged probe - 2	
	System malfunction - 8	Gas leak - 4	
		Unit failure - 4	
	Technical error - 1	Traumatic removal of needle by physician causing hematoma - 1	
	Patient/tumor complexity - 8	Hemorrhage - 7	Required further procedural intervention
		Renal failure and dialysis - 1	
	Technical error - 10	Higher than expected number of needles inserted causing hematoma - 7	
		Inadvertent needle placement causing damage to surrounding structures - 3	
	Unclear - 1	Needle track seeding - 1	
4 − 3 (1.3%) Life threatening harm	Patient baseline complexity - 3	Unresponsive and deteriorated post procedure, died - 2	ICU and Death
		Arrhythmia, subsequent deterioration, death n − 1	

ICU = intensive care unit; MAUDE = Manufacturer and User Facility Device Experience.

164 (68.6%) reports where the device was later evaluated by the manufacturer, the company's review found a specific device defect in 41 (25%) cases. The device was listed as a single-use needle in 203 (84.9%) reports.

Table 1 presents organized tabulation of the reports, as well as stratification based on complication level. Most complications were minor in nature, with MAUDE 1 events comprising 69% of cases. Such complications were seen to be a minor issue with the cryoablation needle, such as needle shaft frosting without thermal burn (47.3%) or needle-related muscle spasm (44.2%) that did not impede procedural success. Medical management was required for 22 events (MAUDE 2). While most cases in this category were related to instrument issue (e.g., thermal burn from needle shaft frosting), there were four cases not related to possible instrument malfunction, including single cases of intraoperative arrhythmia, hemorrhage requiring transfusion, bowel injury managed conservatively, and thermal burn from accidental placement of needle cables on patient skin by the operator.

In terms of higher grade complications that required at least surgical intervention (MAUDE 3−4), there were 52 reports (21.8%). In 49 cases (MAUDE 3), further surgical intervention including repeat cryoablation due to inability to perform the initial procedure, subsequent partial nephrectomy, emergent embolization, and bowel resection were required. Aborting the case, where the procedure was stopped with subsequent later intervention performed, was identified in thirty cases with 29 reports featuring device malfunctions and one case of technical error; in all instances, the patient was maintained under anesthesia until the decision to stop the case was made. MAUDE 3 complications also included 11 of the total 13 adverse events due to operator technical error. With all 11 cases, subsequent surgical intervention was required due to bleeding from placement of higher-than-expected number of needles for a given tumor size or errant needle placement with several traumatic instrument passes required and associated surrounding tissue harm. The three patient deaths that occurred in the perioperative period were found to be unrelated to any device malfunction based on manufacturer review, and per the report, each case featured patients with extensive comorbidity. Interestingly, while 88.7% of all

Table 2
Statistical analysis to assess impact of device-related adverse events with renal cryoablation

Chi square tables

	Minor complications (MAUDE 1−2)	Major complications (MAUDE 3−4)	Total cases
Non-device related adverse event	4	23	27
Device related adverse event	183	29	212
Total cases	187	52	239

Fisher's exact test

	Non-device related	Device-related	
MAUDE 3−4 complications	13.7%	85.2%	$P < 0.001$*

MAUDE = Manufacturer and User Facility Device Experience.
* Denotes significant *P*-value.

complications (MAUDE 1−4) were device-related, only 13.7% of device-related events were associated with major complications. Furthermore, compared to non-device related events, device-related events were less likely to be associated with major complications (at least MAUDE 3) (13.7% vs. 85.2%, respectively; $P < 0.001$) (Table 2).

4. Discussion

This is the first study to examine device-related complications during renal cryoablation and is also one of the few to evaluate perioperative adverse events. Review of cases utilizing a validated MAUDE-complication reporting system identified a spectrum of problems, including some related to the cryoablation system itself, operator error, inherent patient comorbidity or tumor complexity [14]. While 212 cases were attributed to the instrument/system in the reports, the instrument was only returned to the manufacturer in 68.6% of cases and specific device defect only found in 25% of submitted instruments. Interestingly, device malfunction was statistically less likely to cause major complications. On the other hand, 85.2% of non-device related complications related to either operator error or patient/tumor complexity were high grade, including the three reported patient deaths attributed to baseline patient comorbidity. Implementation of the established MAUDE classification system provides a standardized method of analyzing the periprocedural adverse events, addresses complications specifically associated with devices, and assists with overall complication reporting [14,16,17].

Prior studies have attempted to demonstrate the breadth of possible clinical complications associated with renal cryoablation including perioperative hemorrhage, vascular thrombosis, ureteral stricture, and urinary fistula, among others [7,18,19]. Collecting system injuries are rare, with few reported cases [20]. Likely this finding is associated with the fact that cryoablation is less likely to be utilized to treat a central tumor rather than a peripheral tumor, although certain studies have demonstrated safety of central mass renal cryoablation [20,21]. Comparing percutaneous vs. laparoscopic modalities, Tsivian et al. found in their 2010 single center experience of 195 cryoablation procedures (72 laparoscopic s. 123 percutaneous) that laparoscopic cryoablation was associated with more medical and anesthesia-related complications due to the use of general anesthesia; however, on multivariate analysis, the chosen approach was not associated with risk of complications [22]. In that study, they identified 36 total complications with 19.4% requiring a procedural intervention, including renal abscess needing drainage, stent for urine leak, nephrectomy for intractable bleeding, postoperative myocardial infarction, and embolization for pseudoaneurysm [22]. Similarly, in a single surgeon series of 80 laparoscopic renal cryoablation cases from 1997 to 2008 with 8-year mean follow-up, Aron et al. similarly identified 2 high grade complications (pneumothorax requiring chest tube and intercostal arterial injury with operating room return) out of 8 total events (25%) [23].

In another larger study, Atwell et al. examined complications in a series of 311 percutaneous renal cryoablation cases, finding increased age, tumor size, central location, and number of probes as significant predictors on univariate analysis for bleeding complications [24]. Of these, tumor size and age were found to be significant predictors on multivariate analysis. In that study, hemorrhagic complications were the most prevalent (15 of 41 total complications), with 16 (39.0%) classified as at least Clavien-Dindo 3 [24]. Conversely, Okhunov et al. in their analysis of 190 patients undergoing percutaneous renal cryoablation for T1a tumors identified only 16 complications with none considered high grade, although their mean tumor diameter was noted to be 2.2 cm compared to 3.2 cm in the Atwell et al. study [24,25]. Nonetheless, their multivariable analysis similarly demonstrated larger tumor dimension to be a significant predictor of major complications, along with usage of additional probes [25]. Similarly, our study identified non-device related factors, such as tumor and patient factors to be significantly associated with higher grade complications, highlighting the need for careful patient selection for these cases that have traditionally been reserved for older patients or those with greater comorbidity. Interestingly, none of these studies reported on device-related complications, nor was there any information on manufacturer device review. Seen in 12.6% of MAUDE reports, premature case termination was generally also not discussed in these studies, although Tsivian et al. did comment on 2 procedures resulting in incomplete ablation requiring repeat cryoablation [22]. Thus, our findings complement the reported literature and augment these important studies by providing the perspective of an administrative database review incorporating standardized complication reporting and device manufacturer assessment.

With 212 of 239 (88.7%) cases identified to be device-related adverse events, it would seem prudent to next obtain the total number of cryoablation procedures done during the study period to assess their incidence. Of note, the MAUDE database innately does not provide a total number of cryoablation procedures, nor are there any reports of exact totals in the United States during this time. Importantly, submitting reports is not mandatory and is inherently subject to under-reporting; combined with the fact that a true "denominator" of total cases is unavailable, any comment on incidence is speculative in nature. Nonetheless, using prior literature, an estimate may be obtained. Weinberg, et al. utilized the Nationwide Inpatient Sample to identify 4,421 laparoscopic cryoablation cases between 2008 and 2010 [26]. Using the average of 1,474 cases per year in that study, we can extrapolate an approximate incidence of device-related cryoablation complications to be low, possibly around 2.6%. Notably, the true denominator is probably higher as more annual cases likely have been done since the Weinberg, et al. study, and the total case number does not include percutaneous cryoablation. Also, the voluntary nature of submitted reports may have inadvertently enriched available MAUDE data with more significant device-related adverse events. However, when they did occur, instrument-related complications were overwhelmingly associated with low grade complications (86.3%), with the majority avoiding any harm to the patient (MAUDE 1). Thus, device-associated renal cryoablation adverse events appear to largely have minimal impact to the patient; though speculative in nature, we postulate that the incidence is low.

We note further limitations of our study. The FDA MAUDE database does not capture certain data, including patient demographics and comorbidities, tumor size and location, laparoscopic vs. percutaneous approach, or surgeon experience and training. The reports are anonymous and not every device is sent back to the manufacturer for examination. It is unclear why most of the reports involved Galil instruments compared to Healthtronics; while both are the primary manufacturers of cryoablation products, any possible explanation for the difference is purely speculative at this time. The MAUDE database has previously been utilized to evaluate other urologic surgeries including robotic surgery, percutaneous nephrolithotomy, ureteroscopy, mid-urethral slings, and more [14,15,17,27–30]. The anonymous nature of the reporting allows the MAUDE database to potentially include reports that would otherwise not be submitted. These reports enhance periprocedural safety, partly in the form of timely product recalls, where the manufacturer or the FDA implements measures to correct/remove a faulty device. An example is the 2012 FDA recall for the Galil Visual-ICE Cryoablation system due to a gas-regulating issue rendering certain devices inoperable. Furthermore, the manufacturer's review of the affected device in some cases allows for differentiation between confirmed device malfunctions and other etiologies. MAUDE reports should be utilized to inform proceduralists of potential device-related issues that may be encountered, allowing for better training and improved implementation of troubleshooting protocols. While the exact rate of device-related adverse events is unknown, physicians should use this data to enhance patient counseling and experience, explaining that instrument malfunction adds to the breadth of perioperative complications but appears to have minimal impact on outcomes. Future quality improvement endeavors should include incorporating an objective third party for instrument malfunction review. In addition, promoting mandatory device-related adverse event reporting would help elucidate their true incidence. Such an undertaking could be implemented as part of post-operative time-out protocol and would require honest reporting, as well as buy-in from proceduralists, operating room staff, and manufacturer representatives. Continuing efforts to understand the impact of device malfunctions is crucial as technology is further incorporated into surgical practice.

5. Conclusions

Utilizing the FDA MAUDE database, we studied recent reported adverse events associated with renal mass cryoablation. Device-related adverse events add to the breadth of possible renal cryoablation complications but appear to generally be mild in nature, with minimal patient impact. On the other hand, complications associated with patient and operator factors were more likely to be high grade. As such, the findings highlight the continued importance of patient selection and counseling, as well as comprehensive training in the proper utilization of cryoablation instruments.

Authors' contributions

All authors have made significant contributions to the development of this manuscript.

Conflict of interest

The authors do not have any conflict of interest to disclose.

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