CLINICAL STUDY

A Comparison of Bleeding Complications in Patients Undergoing Percutaneous Renal Cryoablation Using Cryoprobes with and without Heat-Based Track Ablation

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ABSTRACT

Purpose: To determine if the use of heat-based track ablation with new-generation cryoprobes is associated with decreased renal cryoablation bleeding complications.

Materials and Methods: Eighty-nine patients who underwent percutaneous cryoablation for treatment of a solitary renal mass with the use of cryoprobes with track ablation (CwTA) from October 29, 2015, to May 18, 2017, were compared with a propensity score–matched control group of 178 patients who underwent treatment with the use of cryoprobes without track ablation (Cw/oTA) from January 5, 2012, to October 28, 2015. Bleeding complications were assessed with the use of the Clavien-Dindo classification system and compared between the matched patient groups by means of conditional logistic regression, both univariately and in a multivariate model to adjust for imbalanced covariates. Change in patient hemoglobin was evaluated as a secondary measure of periprocedural bleeding.

Results: Seven of the 89 patients (7.9%) who underwent percutaneous renal cryoablation with the use of CwTA developed major (grade $\geq$3) bleeding complications, versus 13 of the 178 patients (7.3%) treated with the use of Cw/oTA. Conditional logistic regression analysis adjusted for potential confounders showed that major, minor, and overall bleeding complications were not associated with the type of cryoprobes used for treatment (P values .727, .370, and .733, respectively). There was also no significant difference in post-procedural change in hemoglobin for patients treated with the use of CwTA compared with Cw/oTA ($P = .909$). Furthermore, total duration of track ablation in patients with bleeding complications (mean 169 seconds, SD 68, range 60–240) was not significantly different than in patients without bleeding complications (mean 171 seconds, SD 86, range 30–360; $P = .940$).

Conclusions: The use of cryoprobes with heat-based track ablation did not decrease the incidence of bleeding complications after renal cryoablation compared with procedures performed without track ablation.

ABBREVIATIONS

CwTA = cryoprobes with track ablation, Cw/oTA = cryoprobes without track ablation, RF = radiofrequency

Percutaneous cryoablation and radiofrequency (RF) ablation have both proven to be effective and safe minimally invasive treatments for select patients with small renal tumors (1–8). Oncologic outcomes with the use of renal cryoablation have generally been better than those with RF ablation, particularly for treatment of tumors >3–4 cm in size and tumors located centrally in the kidney (1,9,10). The ability to use more than 3 ablation probes, intraprocedural

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computerized tomographic (CT) visualization of the ablation ice ball to confirm adequate ablation margins, and the ability of cryoablation to overcome the thermal sink effect centrally within the kidney are significant advantages over RF ablation (10). Complications, however, specifically bleeding complications, are lower with RF ablation than cryoablation, likely related to the well-recognized role of RF energy in inducing coagulation (11). In a study by Atwell et al, the overall bleeding complication rate from perinephric bleeding and hematuria for 311 percutaneous renal cryoablations was 7.4%, compared with only 1.2% for 254 percutaneous renal RF ablations (12).

An ideal renal ablation system would combine the oncologic efficacy of cryoablation with the low bleeding complications of RF ablation. Recently, a new generation of cryoprobes (Galil Medical, Arden Hills, Minnesota) was introduced for percutaneous ablation. These cryoprobes incorporate a heating element inside the distal probe shaft for thawing the ablation ice ball and subsequent track ablation. The goal of the present study was to test the hypothesis that renal mass cryoablation with the use of new-generation cryoprobes capable of heat-based track ablation would decrease the incidence of bleeding complications.

MATERIALS AND METHODS

Approval for this study was obtained from our Institutional Review Board, and the study was compliant with the Health Insurance Portability and Accountability Act.

Patient and Tumor Characteristics

Retrospective review of a single-institution renal ablation registry demonstrated that 96 consecutive patients underwent renal cryoablation with the use of cryoprobes with track ablation (CwTA) from October 29, 2015, to May 18, 2017. Patients treated for more than 1 renal mass (n = 5) and patients who did not give consent for research (n = 2) were excluded. The resulting 89 patients in the study group were matched with a control group of 178 patients treated for a solitary renal mass with the use of cryoprobes without track ablation (Cw/oTA). Matching was performed by means of propensity scoring based on renal tumor and patient characteristics that have been shown to affect renal cryoablation bleeding complications. These factors include size of the renal mass, central location of the renal mass, and age of the patient (12). The control group was chosen from a group of 265 patients with solitary renal masses treated with the use of Cw/oTA from January 5, 2012, to October 28, 2015. A cutoff date of January 1, 2012, for the potential control group patients was selected because it included a large enough group of patients for effective propensity score matching (study group × ~3). It was also thought that cases since January 1, 2012, were recent enough that there would not be a significant difference in cryoablation techniques, procedural experience, or threshold for sending patients to subsequent intervention for postprocedural bleeding between the 2 groups.

The mean age of patients in the study group was 66.5 years (SD 10.7, range 35-87), and 57 patients (64%) were male. Renal tumor characteristics were determined from preprocedural cross-sectional imaging by 1 of 3 interventional radiologists (A.N.K., T.D.A., G.D.S.), with 7–12 years of renal ablation experience each. The mean maximal diameter of renal tumors in the study group patients was 3.0 cm (SD 1.1, range 1.0–6.5), and 45 tumors (50.6%) were centrally located (abutting the renal sinus fat). Axial tumor location (anterior, posterior, medial, lateral) was determined with the use of an orthogonal grid perpendicular to the plane of the body without rotation, as previously described (13). Additional patient demographics and tumor characteristics for the study group, and a comparison of these characteristics with patients in the control group, are included in **Table 1**. Only patient sex, tumor RENAL nephrometry score, and patient international normalized ratio (INR) were significantly different between the 2 groups (*P* values .042, .043, and .001, respectively).

All patients were required to have a serum platelet count of $\geq 50 \times 10^9$/L and an INR of ≤ 1.5 before cryoablation. Patients were also requested to abstain from anticoagulants, including aspirin and clopidogrel, for ≥5 days before cryoablation. Exceptions included 6 patients (6.7%) in the study group and 4 (2.2%) in the matched control group who were continued on aspirin therapy through the cryoablation because of a high risk for periprocedural cardiovascular and/or cerebrovascular events. Nine of these patients were taking an 81-mg aspirin and 1 was taking a 325-mg aspirin daily.

Cryoablation Technique

Percutaneous renal cryoablation was performed as previously described (2,9). In brief, all patients were treated under general anesthesia in a single treatment session. Ultrasound and/or CT guidance was used to place the cryoprobes into the renal mass. Probes were placed with 1–2 cm spacing within the tumor in a configuration to achieve a confluent ice ball with a margin of ≥0.5 cm around the entire tumor. A freeze–passive thaw–refreeze cryoablation cycle was performed. An active thaw was completed before removal of the cryoprobes. Arterial tumor embolization was performed on the day before renal cryoablation in 2 patients (2.2%) in the study group and ten (5.6%) in the matched control group, with the use of techniques previously described by Woodrum et al (14). Tumor embolization was performed in an attempt to decrease subsequent cryoablation bleeding complications in 8 patients with tumors >5 cm in diameter and 2 patients with centrally located tumors >4 cm in diameter. In 63 study patients (70.8%) and 143 matched control patients (80.3%), 1 to 3 renal tumor core biopsy specimens were obtained at the time of the cryoablation procedure after cryoprobe placement with the use of an 18-gauge × 2-cm biopsy device (Bard Monopty; CR Bard). The remainder of patients underwent biopsy at a date prior to the cryoablation.