

# A Systematic Review of the Quality of Evidence of Ablative Therapy for Small Renal Masses

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## Abbreviations and Acronyms

GRADE = Grading of Recommendations Assessment, Development and Evaluation

LPN = laparoscopic partial nephrectomy

RFA = radio frequency ablation

STROBE = Strengthening the Reporting of Observational Studies in Epidemiology

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**Purpose:** We critically assessed the methodological and reporting quality of published studies of ablative techniques for small renal masses.

**Materials and Methods:** We performed a systematic PubMed® and EMBASE® literature search from January 1966 to March 2010 to identify all full text, original research publications on ablative therapy for renal masses. Six reviewers working independently in 3 teams performed duplicate data abstraction using Strengthening the Reporting of Observational Studies in Epidemiology criteria, which were pilot tested in a separate sample.

**Results:** A total of 117 original research publications published in a 15-year period (1995 to 2009) met eligibility criteria. No randomized, controlled trials were identified. All studies were observational and 88.9% had 1 arm with no comparison group. Median sample size was 18 patients (IQR 5.5, 40.0) and 53.8% of studies included 20 or fewer patients. Median followup was 14.0 months (IQR 8.0, 23.8) and only 19.7% of studies had an average followup of greater than 24 months. Of the studies 20.5% mentioned the number of operators involved and only 6.0% provided information on their experience level. Of the studies 66.7% addressed the recurrence rate. Disease specific and overall survival was reported in only 15.4% and 16.2% of studies, respectively.

**Conclusions:** The published literature on the therapeutic efficacy of ablative therapy for renal masses is largely limited to uncontrolled, 1-arm observational studies. In the absence of higher quality evidence ablative therapy outside research studies should be limited to select patients who are not candidates for surgical intervention.

**Key Words:** kidney, kidney neoplasms, ablation techniques, cryosurgery, review

NEPHRON sparing surgery, consisting of laparoscopic or open partial nephrectomy, is the current gold standard treatment of small renal masses and the treatment modality most recommended by recent clinical practice guidelines. Studies show excellent intermediate and long-term cancer control rates, similar to those of radical

nephrectomy.<sup>1-3</sup> To decrease the morbidity associated with the surgical treatment of small renal masses there is strong interest in minimally invasive ablative techniques.<sup>4</sup> These techniques hold the promise of an outpatient procedure with the potential avoidance of general anesthesia, decreased pain and shorter convales-

cence time.<sup>5</sup> These advantages have led to the increased use of ablative therapies for small masses, of which the most popular are RFA and cryoablation, by open, laparoscopic or percutaneous techniques.

We systematically reviewed the evidence supporting the increased use of minimally invasive ablative techniques for small renal masses.

## MATERIALS AND METHODS

A systematic literature search was done in September 2009 and updated in March 2010 using PubMed and EMBASE to identify all published, original research studies relating to RFA or cryoablation for small renal masses in humans from 1966 to March 2010. The search terms used were cryosurgery, cryoablation, cryotherapy, radiofrequency ablation, radio frequency ablation, focal therapy, kidney cancer, renal cell carcinoma and renal mass. Search limitations included human based studies and studies published in English. A hand search of article references was done to ensure that all publications on this topic were found. We included only studies of primary, localized renal masses. Further study exclusion criteria included editorials, abstracts, letters to the editor and narrative review articles. Systematic reviews were used only if the review included original research data from the publishing institution. Two independent reviewers screened the studies for eligibility. Final consensus on study selection was achieved by discussion between the 2 reviewers and arbitration by the lead investigator.

A standardized abstraction form was designed using the criteria of the STROBE statement,<sup>6</sup> a well established standard for high quality reporting of observational studies. Before review the data abstraction form was pilot tested in a separate sample of 10 articles on prostatic cryotherapy to ensure the greatest possible interobserver agreement.

Three teams of 2 independent reviewers each performed data abstraction of an equal number of studies assigned at random. A detailed analysis of key clinical outcomes, such as cancer specific survival and ablation failure rates, was performed for comparative studies of RFA vs cryoablation, cryoablation vs LPN and RFA vs LPN. Data abstraction for analysis was done in duplicate. Evidence quality was rated according to GRADE as high, moderate, low or very low.<sup>7</sup>

Statistical testing was performed to address a predefined null hypothesis, that is that the methodological and reporting quality of studies published during the first half of the publication period of included studies vs those published during the second half were unchanged to reflect a shift from exploratory case series aimed at feasibility and safety to therapeutic effectiveness. All statistical testing was 2 sided at predefined  $\alpha = 0.05$ . Statistical analysis of the methodological and reporting quality of the studies was performed using SPSS®, version 17.0. Interobserver agreement beyond chance was assessed using the  $\kappa$  statistic. Review Manager, version 5.1 (The Cochrane Collaboration®) was used for the meta-analysis of key clinical outcomes data. We performed no formal adjustment for multiple testing.

## RESULTS

The systematic literature search identified 1,012 published articles, which were then screened for eligibility. A total of 117 articles met study inclusion criteria and were included in analysis. The first article on ablative therapy for small renal masses was published in 1995. Thus, the first half of the publication period of included studies was identified as 1995 to 2002 while the second half was 2003 to 2010. Case reports and noncomparative case series comprised 104 of the 117 studies identified (89%). This increased as a proportion of the studies with time. The overall quality of evidence for all outcomes was rated as very low according to GRADE.<sup>7</sup>

A total of 20 articles (17.1%) were published between 1995 and 2002 while 97 (82.9%) were published between 2003 and March 2010. No randomized, controlled trials were found. Of the 117 studies 104 (88.9%) were case reports or noncomparative case series and only 3 (2.6%) were cohort studies. A total of 68 articles (58.1%) were published in the urological literature with *Urology*® as the single largest contributor with 24 (20.5%). A total of 46 articles originated from the radiology literature.

Of the 117 studies 72 (61.5%) described RFA as a treatment modality and the most common approach was percutaneous (87 or 74.4%). A total of 108 included articles (92.3%) were from a single center. Only 14 series (12.0%) mentioned the clinical TNM stage of ablated tumors, although size was often addressed. Pathological validation or biopsy was not done in 25 evaluated series (21.4%). Of the studies 73 (62.4%) discussed the efficacy of ablation at surgery.

Median sample size was 18 patients (IQR 5.5, 40). Of the articles 24 (20.5%) mentioned the number of operators involved and 7 (6.0%) provided information on their experience level. Median followup was 14.0 months (IQR 8.0, 23.8). Followup was not reported in 17 (14.5%) of the studies that were abstracted. Disease specific and overall survival data were reported rarely (18 studies or 15.4% and 19 or 16.2%, respectively).

We separately analyzed the outcomes for a subset of comparative studies comparing cryoablation, RFA and LPN. On cryoablation vs RFA analysis only 2 of 5 series discussed all cause mortality or cancer specific survival. Outcomes appeared similar between the 2 groups.

The quality of reporting of all studies was assessed based on STROBE criteria.<sup>6</sup> The mean  $\pm$  SD  $\kappa$  to assess STROBE criteria was  $0.73 \pm 0.15$  (range 0.54 to 1.00). Select criteria were met by a large proportion of studies, for example an explanation of the study background in 108 (92.3%), complications in 101 (86.3%) and cautious result interpretation in the context of existing studies in 115 (98.3%). Other

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