

Oncology: Adrenal/Renal/Upper Tract/Bladder

Guideline for Management of the Clinical T1 Renal Mass

Steven C. Campbell,*† Andrew C. Novick,‡ Arie Belldegrun,§ Michael L. Blute, George K. Chow, Ithaar H. Derweesh, Martha M. Faraday, Jihad H. Kaouk,¶ Raymond J. Leveillee,|| Surena F. Matin,** Paul Russo†† and Robert G. Uzzo‡‡

From the American Urological Association Education and Research, Inc., Linthicum, Maryland

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* Correspondence: Section of Urologic Oncology, Glickman Urological and Kidney Institute, Glickman Tower, 9500 Euclid Ave., Cleveland Clinic, Cleveland, Ohio 44195 (telephone: 216-444-5595; FAX: 216-636-0770; e-mail: Campbes3@ccf.org).

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‡ The Panel dedicates this work to Dr. Andrew Novick, who served as Chair of the Panel until his untimely death in 2008. Dr. Novick was well recognized for his contributions to renal surgery, and kidney cancer in particular.

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For other articles on a related topic see pages 1582, 1588 and 1594.

DETECTION of clinical stage 1 (<7.0 cm) renal masses has increased in frequency and is now a common clinical scenario for the practicing urologist.¹⁻⁴ These tumors are very heterogeneous, with 20% benign and only about 20-25% exhibiting potentially aggressive kidney cancer at the time of diagnosis.⁵⁻⁸ Treatment options have expanded greatly, engendering much controversy in the field.⁹ Traditionally, these tumors have been treated aggressively, most often with radical nephrectomy.¹⁰⁻¹³ However, this predisposes patients to chronic kidney disease with attendant cardiovascular risks and increased mortality.^{14,15} Nephron-sparing approaches such as partial nephrectomy,¹⁶⁻²⁰ thermal ablation²¹⁻²⁴ and

active surveillance²⁵⁻²⁹ have also emerged as viable options for the management of these patients. Recognizing that current practice is potentially discordant with what the literature supports, the Practice Guidelines Committee of the American Urological Association commissioned a Panel to review the literature and provide Guidelines for the management of this challenging patient population.

Literature searches on English-language publications were performed using the MEDLINE® database from January 1, 1996 to September 30, 2007 using the terms “renal carcinoma” and “renal mass” in conjunction with the interventions evaluated. A total of 114 articles met the

Abbreviations and Acronyms

AS	= active surveillance
AUA	= American Urological Association
CKD	= chronic kidney disease
Cryo	= cryotherapy
CT	= computed tomography
LPN	= laparoscopic partial nephrectomy
LRN	= laparoscopic radical nephrectomy
MRI	= magnetic resonance imaging
NSS	= nephron-sparing surgery
OPN	= open partial nephrectomy
ORN	= open radical nephrectomy
PGC	= Practice Guidelines Committee
PN	= partial nephrectomy
RCC	= renal cell carcinoma
RFA	= radio frequency ablation
RN	= radical nephrectomy
TA	= thermal ablation

Table 1. Patient Demographics and Study Information

	AS	Cryo	RFA	LPN	OPN	LRN	ORN
Patient Age (yrs) Mean/Median (# studies; # pts)	67.1/68.2 (12 studies; 390 pts)	66.9/66.3 (15 studies; 644 pts)	68.5/70.0 (19 studies; 745 pts)	60.5/60.1 (26 studies; 2245 pts)	60.1/60.0 (28 studies; 6418 pts)	60.9/61.0 (17 studies; 1581 pts)	62.5/63.0 (16 studies; 6235 pts)
Tumor Size (cm) Mean/Median (# studies; # pts)	2.7/2.2 (12 studies; 390 pts)	2.6/2.6 (15 studies; 644 pts)	2.7/2.7 (19 studies; 745 pts)	2.6/2.6 (26 studies; 2245 pts)	3.2/3.0 (25 studies; 5596 pts)	4.8/5.1 (15 studies; 1391 pts)	5.0/5.4 (14 studies; 5849 pts)
Follow-Up (mos) Mean/Median (# studies; # pts*)	29.6/29.0 (12 studies; 390 pts)	19.5/16.7 (10 studies; 463 pts)	22.9/19.4 (10 studies; 528 pts)	20.8/15.0 (17 studies; 1639 pts)	55.5/46.9 (22 studies; 5057 pts)	30.2/17.7 (8 studies; 795 pts)	60.8/58.3 (13 studies; 5294 pts)

* pts = patients; Note: numbers of studies and patients differ across variables because some studies did not report all information

inclusion criteria and were included in the systematic review and meta-analysis (for detailed methodology and meta-analytic findings, see the full guideline at <http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/renalmass09.pdf>). The panel evaluated data from studies of open and laparoscopic partial and radical nephrectomy, thermal ablation (radio frequency and cryoablation), and active surveillance; outcomes included procedural complications, recurrence, and survival.

As expected, the peer-reviewed literature was most substantial (ie the largest number of studies and patients) and mature (ie the longest followup) for open surgical approaches. The literature also revealed important differences in the demographics of patient populations exposed to the treatments evaluated, reflecting strong selection biases, as illustrated in table 1. For example, patients managed with radical nephrectomy tended to have larger tumors, and those managed with AS or TA tended to be older. Although these differences limited meaningful statistical comparisons across treatments, they provided important contextual information regarding the generalizability of treatments that assisted the Panel in structuring the treatment algorithm. The Panel also relied on a small number of statistically significant comparisons for which confounding factors were unlikely to account for differences. Other relevant limitations of the available literature are detailed on the website. Most importantly, the available studies were observational, there were almost no comparative studies, and length of followup was inadequate for many of the newer modalities.

Recognizing the strong data correlating RN to CKD,^{14,30} nephron-sparing approaches are emphasized in the management of patients with clinical T1 renal masses, presuming that adequate oncologic control can be obtained. The importance of preserving long-term kidney function was considered with full understanding that surgical PN approaches may carry higher urologic comorbidity.³¹ The meta-analysis revealed that PN procedures (open and laparoscopic) were associated with the highest risk of urologic complications, such as urine leak or postoperative hemorrhage, with laparoscopic PN rates the highest (table 2). The Panel interpreted this finding as valid because PN procedures tended to be applied to younger patients and for smaller tumors—patients who would be less likely to have such complications unless the complications were associated with procedural characteristics. The panel also relied on an important study from three centers of excellence that examined urologic morbidity after laparoscopic PN vs open PN and found that LPN had shorter operative times and less blood loss than OPN, but higher rates of urologic complica-

Table 2. Major Urological Complications

Study Type	# of Studies	Complication Rate (%) ¹	95% Confidence Interval ²		Mean/Median Patient Age (yrs) ³	Mean/Median Tumor Size (cm) ³
			Lower Limit (%)	Upper Limit (%)		
Cryo	15	4.9	3.3	7.4	67.0/66.7	2.6/2.6
RFA	20	6.0	4.4	8.2	68.5/70.0	2.7/2.7
LPN	22	9.0	7.7	10.6	60.4/59.9	2.6/2.6
OPN	15	6.3	4.5	8.7	59.5/59.0	3.2/3.0
LRN	13	3.4	2.0	5.5	60.7/61.0	4.8/5.1
ORN	6	1.3	0.6	2.8	62.7/62.3	4.9/5.2

¹ Statistically significant differences ($p < 0.05$): ORN rates are significantly lower than all other interventions; LPN rates are significantly higher than Cryo, RFA, LRN, and ORN rates; OPN rates are significantly higher than LRN and ORN rates; Cryo, RFA, and LRN rates are significantly higher than ORN rates; LPN and OPN rates are statistically indistinguishable; OPN, Cryo, and RFA rates are statistically indistinguishable; Cryo, RFA, and LRN rates are statistically indistinguishable

² Calculated using a random effects model

³ Values may differ from Table 1 based on subgroup of studies included in analysis

tions,²⁰ paralleling the meta-analytic findings. The Panel evaluated these findings in the context of the serious consequences of impaired kidney function and concluded that PN approaches are still preferred to maximize patient survival and quality of life.^{14,15,30}

Local recurrence was defined as any persistent or recurrent disease present in the treated kidney or associated renal fossa after initial treatment. This definition was adopted from the working group of Image-Guided Tumor Ablation.³² TA, either cryoablation or radio frequency ablation, had significantly lower rates of local recurrence free survival than all other treatments (table 3). Considering that these modalities were used to treat relatively small tumors and had short followup durations, the Panel interpreted this finding as valid. In fact, it has been estimated that when confounding factors such as length of followup are taken into consideration, the local recurrence rates for TA will be substantially higher than for surgical excision.³³ Many such recurrences can be salvaged with repeat ablation, but when this is not possible, surgical salvage can be very challenging.^{34,35} Long-term outcomes data are limited, but in one of the few studies to provide this, disease-free survival after cryoablation was only 87.5% at 5 years.²³ In addition, radiographic parameters for success have been questioned, particularly

for radio frequency ablation.³⁶ Given these considerations, the Panel emphasized the use of TA as most appropriate in situations of high surgical risk after thorough patient counseling (see figure). The Panel also advocated a direct role of the urologist in the informed consent process.

Analyses of metastasis-free, cancer specific and overall survival indicated that survival rates were relatively high across treatments, possibly reflecting the limited biological aggressiveness of many renal tumors. Given the clinically relevant patient age, tumor size and followup differences across treatments, the Panel judged that comparisons would not be informative (for descriptive data see the AUA website).

The Panel framed its findings in terms of each treatment modality's utility in the context of four index patients defined by tumor size (T1a vs T1b) and general health. The final draft was sent to 69 peer reviewers of whom 35 provided comments; the Panel revised the document based on the comments received. The guideline was approved by the PGC and the Board of Directors of the AUA.

A final recommendation of the panel was for research priority for renal mass biopsy with molecular profiling to improve our estimation of tumor aggressiveness, and to promote more rational treatment selection in this challenging field.

Table 3. Local Recurrence-Free Survival

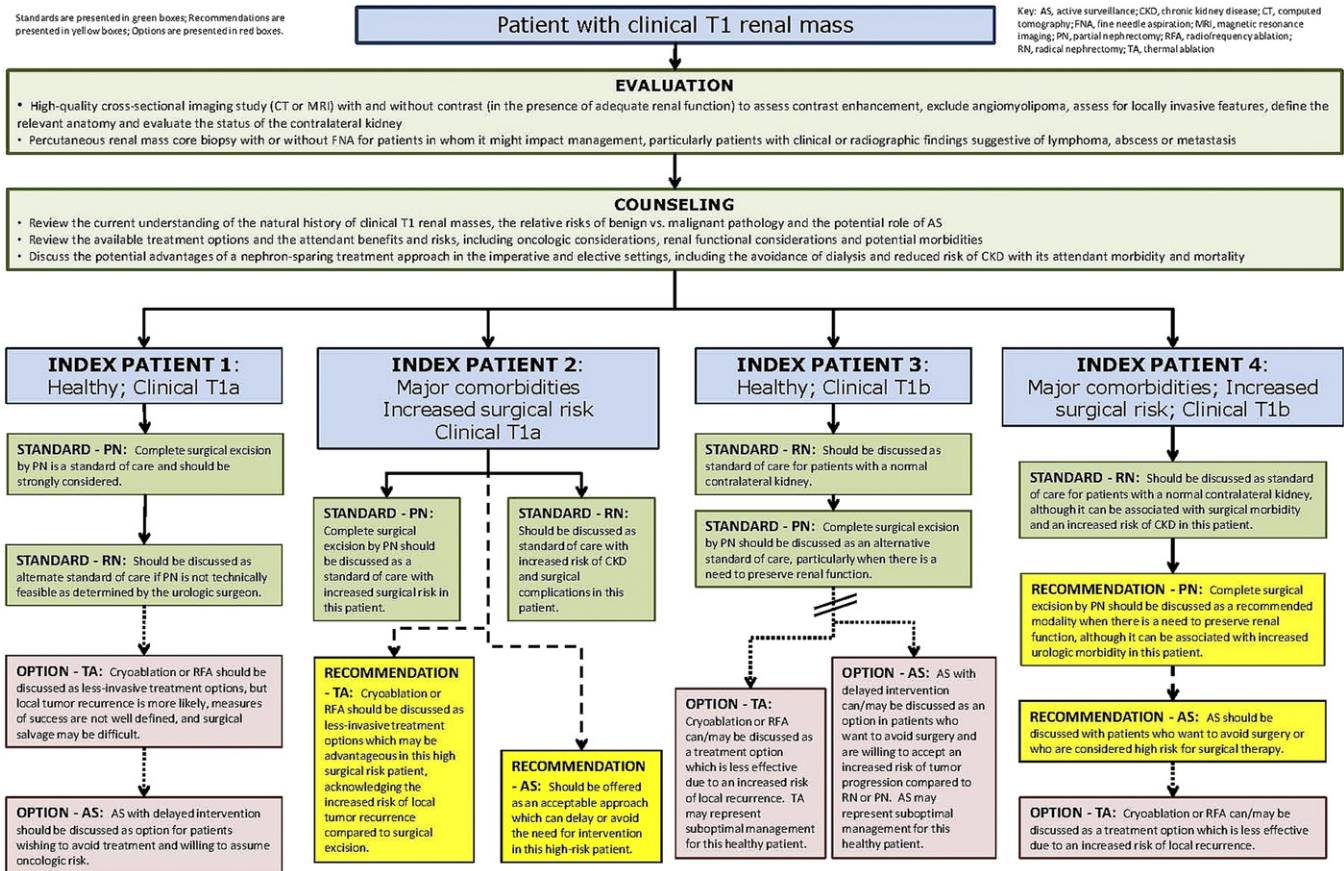
Study Type	# of Studies	Survival Rate (%) ¹	95% Confidence Interval ²		Mean/Median Patient Age (yrs) ³	Mean/Median Tumor Size (cm) ³	Mean/Median Follow-Up (mos) ³
			Lower Limit (%)	Upper Limit (%)			
Cryo	10	90.6	83.8	94.7	67.0/67.0	2.5/2.6	19.5/18.2
RFA	10	87.0	83.2	90.0	67.6/70.0	2.8/2.7	22.9/19.4
LPN	17	98.4	97.1	99.1	61.2/61.0	2.6/2.6	20.8/15.0
OPN	21	98.0	97.4	98.5	60.5/60.0	3.3/3.1	55.5/46.9
LRN	8	99.2	98.2	99.7	60.7/61.0	4.6/4.6	30.2/17.7
ORN	10	98.1	97.3	98.6	62.6/63.0	4.6/4.8	59.3/58.3

¹ Statistically significant differences ($p < 0.05$): LPN, OPN, LRN, and ORN rates are statistically indistinguishable and are all significantly higher than Cryo and RFA rates; Cryo and RFA rates are statistically indistinguishable

² Calculated using a random effects model

Standards are presented in green boxes; Recommendations are presented in yellow boxes; Options are presented in red boxes.

Key: AS, active surveillance; CKD, chronic kidney disease; CT, computed tomography; FNA, fine needle aspiration; MRI, magnetic resonance imaging; PN, partial nephrectomy; RFA, radiofrequency ablation; RN, radical nephrectomy; TA, thermal ablation



PANEL CONSENSUS REGARDING TREATMENT MODALITIES

• RN, particularly laparoscopic RN, is very appealing to patients and physicians but it is greatly overutilized.⁹ Nephron-sparing approaches should be considered in all patients with a clinical T1 renal mass as an overriding principle, presuming adequate oncologic control can be achieved, based on compelling data demonstrating an increased risk of CKD associated with RN and a direct correlation between CKD and morbid cardiovascular events and mortality on a longitudinal basis.^{14,15,30,37} RN is still a viable option when necessary based on tumor size, location or radiographic appearance if the surgeon judges that nephron-sparing surgery is not feasible or advisable. A laparoscopic approach to RN is now an established standard and should be considered if this procedure is required as it is associated with a more rapid recovery.^{12,13}

• Active surveillance is a reasonable option for the management of localized renal masses that should be discussed with all patients and should be a primary consideration for patients with decreased life expectancy or extensive comorbidities that would make them high risk for intervention.^{26,29} For patients who are candidates for intervention, counseling about AS

should include a balanced discussion of the small but real risk of cancer progression, lack of curative salvage therapies if metastases develop, possible loss of window of opportunity for NSS and substantial limitations of the current AS literature.^{26,38} Larger tumors (>3 to 4 cm) and those with aggressive appearance, such as infiltrative growth pattern, may be associated with increased risk and should be managed in a proactive manner.^{39,40}

• Thermal ablation (cryoablation or RFA), either percutaneous or laparoscopic, is an available treatment option for the patient at high surgical risk who wants active treatment and accepts the need for long-term radiographic surveillance after treatment.²⁴ Tumor biopsy (core biopsy is recommended for better diagnostic accuracy) should always be performed prior to treatment to define histology and should also be considered after treatment, particularly if there is any suspicion of recurrence. Counseling about thermal ablation should include a balanced discussion of the increased risk of local recurrence when compared to surgical excision, potential need for reintervention, lack of well-proven radiographic parameters for success,³⁶ potential for difficult surgical salvage if tumor progression is found^{34,35} and the substantial limitations of the current thermal ablation literature. Larger tu-

mors (>3.5 cm) and those with irregular shape or infiltrative appearance may be associated with increased risk of recurrence when managed with thermal ablation.²⁴

- **Surgical excision by PN** is a reference standard for the management of clinical T1 renal masses, whether for imperative or elective indications, given the importance of preservation of renal parenchyma and avoidance of CKD.^{30,37} This treatment modality is greatly underutilized.⁹ PN has well established longitudinal oncologic outcomes data comparable to RN.^{16–19} Adequate expertise and careful patient selection are important. A laparoscopic approach can provide more rapid convalescence, but has been associated with an increased risk of major urologic complications and longer warm ischemia times when compared to traditional OPN.²⁰ In general, OPN is preferred for complex cases such as tumor in the renal hilum, tumor in a solitary kidney or multiple tumors.

GRADING THE RECOMMENDATIONS

All statements are graded with respect to the degree of flexibility in application. A “standard” is the most rigid treatment policy. A “recommendation” has significantly less rigidity, and an “option” has the largest amount of flexibility. These terms are defined as follows:

1. **Standard:** A guideline statement is a standard if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. **Recommendation:** A guideline statement is a recommendation if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable, but not unanimous majority agrees on which intervention is preferred.
3. **Option:** A guideline statement is an option if: (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

TREATMENT GUIDELINE STATEMENTS

The Panel developed the following guideline statements (see [figure](#)) from a careful assessment of the meta-analysis, the use of expert opinion when data were lacking or incomplete, and panel consensus. These statements apply to the treatment of patients with clinical T1 renal masses. Inherent in these guideline statements is the importance of individu-

alizing patient diagnostic evaluation and therapy. In an attempt to recognize commonly encountered clinical variations, each guideline statement addresses a specific patient.

For All Index Patients

Standard: Physicians should obtain a high-quality cross-sectional imaging study, computed tomography (CT) or magnetic resonance imaging (MRI), with and without contrast (in the presence of adequate renal function) to assess contrast enhancement, exclude angiomyolipoma, assess for locally invasive features, define the relevant anatomy and evaluate the status of the contralateral kidney and its vasculature.

[Based on Panel consensus.]

Standard: Physicians should discuss with the patient the current understanding of the natural history of clinical stage 1 renal masses, the relative risks of benign vs malignant pathology and the potential role of active surveillance.

[Based on Panel consensus.]

Overall, about 20% of clinical stage T1 enhancing renal masses are benign. In addition, a potentially aggressive variant is only observed in 20% to 25% of all renal cell carcinomas (RCC) in this size range. Tumor size and gender are important determinants of the risk of benign vs malignant pathology.

Standard: Percutaneous renal mass core biopsy with or without fine needle aspiration should be performed in all patients undergoing thermal ablation and in patients for whom it might impact management, particularly patients with clinical or radiographic findings suggestive of lymphoma, abscess or metastasis.

[Based on Panel consensus.]

Standard: Physicians should review with the patient the available treatment options and the attendant benefits and risks, including oncologic considerations, renal functional considerations and potential morbidities.

[Based on Panel consensus.]

Standard: Physicians should counsel the patient about the potential advantages of a nephron-sparing treatment approach in the imperative and elective settings. These advantages include avoidance of the need for dialysis and a reduced risk of develop-

ing chronic kidney disease with the attendant morbidity and mortality.

[Based on Panel consensus.]

Radical nephrectomy can lead to an increased risk of CKD, which is associated with increased risk of morbid cardiac events and death according to population-based studies. Management should focus on optimizing renal function rather than merely precluding the need for dialysis.

For Index Patient No. 1: *A healthy patient with a clinical T1a (≤ 4.0 cm) enhancing renal mass*

Standard: Complete surgical excision by partial nephrectomy is a standard of care and should be strongly considered.

[Based on review of the data and Panel consensus.]

Both open and laparoscopic approaches to PN can be considered, dependent on tumor size, location and the surgeon's expertise. LPN can provide more rapid recovery, although this approach has been associated with increased warm ischemic times and an increased risk of urological complications including postoperative hemorrhage and urinary fistula. Most patients with a solitary kidney, preexisting renal dysfunction, hilar tumor, multiple tumors or predominantly cystic tumor are best managed with an open surgical technique. With improved laparoscopic instrumentation and greater dissemination of expertise, improved outcomes and more widespread application of LPN is anticipated in the future.

Standard: Radical nephrectomy should be discussed as an alternate standard of care which can be performed if a partial nephrectomy is not technically feasible as determined by the urologic surgeon.

[Based on review of the data and Panel consensus.]

Radical nephrectomy can lead to an increased risk of CKD, which is associated with increased risks of morbid cardiac events and death according to population-based studies. Management should focus on optimizing renal function rather than merely precluding the need for dialysis. PN is a greatly underutilized procedure that is often feasible even for central or hilar tumors, given adequate surgeon expertise. Nevertheless, occasional localized renal tumors in this size range are not amenable to PN, and RN should be considered an alternative standard of care. A laparoscopic approach can provide reduced blood loss and more rapid recovery and should be considered, presuming adequate surgeon expertise.

Option: Thermal ablation, such as cryoablation or radio frequency ablation, should be discussed as a less-invasive treatment

option, but local tumor recurrence is more likely than with surgical excision, measures of success are not well defined, and surgical salvage may be difficult.

[Based on review of the data and Panel consensus.]

Thermal ablation is associated with a substantially increased risk of local recurrence, the majority of which can be managed with a second attempt at thermal ablation. However, some local recurrences are not amenable to this approach and require surgical salvage. In this setting laparoscopic surgery and PN are often not possible due to extensive reactive fibrosis within the perinephric space. In addition, measures of success for thermal ablation have come into question with some studies demonstrating apparently viable cancer cells despite loss of contrast enhancement. It is possible that outcomes associated with ablative modalities will improve with further advances in technology and application; however, judicious patient selection and counseling remain of paramount importance for these less-invasive technologies.

Option: Active surveillance with delayed intervention should be discussed as an option for patients wishing to avoid treatment and willing to assume oncologic risk.

[Based on review of the data and Panel consensus.]

Approximately 80% of all clinical T1a renal masses are malignant, and of these, about 20% to 30% demonstrate potentially aggressive histologic features. The risk of tumor progression that could preclude NSS or lead to unsalvageable systemic metastases is not well defined in the current literature. Enhanced renal mass biopsy (incorporating molecular analyses) holds promise for assessing aggressive potential; however, further research will be required to define the utility and limitations of this approach. Healthy patients considering AS must be willing to assume a calculated risk of tumor progression.

For Index Patient No. 2: *A patient with major comorbidities/increased surgical risk and a clinical T1a (≤ 4.0 cm) enhancing renal mass*

Standard: Complete surgical excision by partial nephrectomy should be discussed as a standard of care with increased surgical risk in this patient.

[Based on review of the data and Panel consensus.]

Partial nephrectomy is associated with an increased risk of perioperative morbidity when compared to RN, a relevant consideration for this patient with increased risk for surgical intervention. Nevertheless, PN or other nephron-sparing approaches should be considered whenever preservation of renal function is a primary issue. Both open and laparoscopic approaches to PN can be considered, dependent on tumor size, location and the surgeon's expertise.

Standard: Radical nephrectomy should be discussed as a standard of care with an increased risk of surgical complications and chronic kidney disease in this patient.

[Based on review of the data and Panel consensus.]

Radical nephrectomy is another standard of care in this high-risk patient population with substantial comorbidities. However, RN can lead to an increased incidence of CKD with its attendant risks, and some patients may have relative or imperative indications to avoid RN. A laparoscopic approach to RN can provide reduced blood loss and more rapid recovery and should be considered, presuming adequate surgeon expertise.

Recommendation: Thermal ablation should be discussed as a less-invasive treatment option which may be advantageous in this high surgical risk patient, acknowledging the increased risk of local tumor recurrence compared to surgical excision.

[Based on review of the data and Panel consensus.]

Thermal ablation is a reasonable option for this high surgical risk patient that allows for proactive treatment without the risks associated with major surgical intervention. However, an increased risk of local recurrence should be discussed during counseling.

Recommendation: Active surveillance should be offered as an acceptable approach which can delay or avoid the need for intervention in this high-risk patient.

[Based on review of the data and Panel consensus.]

Active surveillance has been associated with relatively low rates of tumor growth and metastatic progression during short-term (2 to 3 year) followup. Overall, about 20% of clinical T1a renal masses are benign, and a potentially aggressive variant is only observed in 20%–30% of all RCCs in this size range. AS should be a primary consideration in patients

with decreased life expectancy or those who are particularly high risk for proactive intervention.

For Index Patient No. 3: A healthy patient with a clinical T1b (>4.0 cm to <7.0 cm), enhancing renal mass

Standard: Radical nephrectomy should be discussed as a standard of care for patients with a normal contralateral kidney.

[Based on review of data and Panel consensus.]

Radical nephrectomy is associated with less perioperative morbidity than PN and remains a standard of care for clinical T1b tumors, presuming a normal contralateral kidney. A laparoscopic approach can provide reduced blood loss and more rapid recovery and should be considered, presuming adequate surgeon expertise.

Standard: Complete surgical excision by partial nephrectomy should be discussed as an alternative standard of care, particularly when there is a need to preserve renal function.

[Based on review of data and panel consensus.]

Even in patients with a normal contralateral kidney, RN can lead to an increased risk of CKD, which is associated with increased risks of morbid cardiac events and death based on population-based studies. PN is an alternative standard of care for this patient, presuming favorable tumor location and adequate surgeon expertise.

Option: Thermal ablation can/may be discussed as a treatment option which is less effective due to an increased risk of local recurrence.

[Based on Panel consensus.]

Tumors that are 4 cm to 7 cm in diameter are difficult to adequately treat with thermal ablation, and the risks of local recurrence and complications are high in this patient population. Thermal ablation may represent suboptimal management for this healthy patient, and this should be emphasized during patient counseling.

Option: Active surveillance with delayed intervention can/may be discussed as an option in patients who want to avoid surgery and are willing to accept an increased risk of tumor progression compared to partial nephrectomy or radical nephrectomy.

[Based on review of the data and Panel consensus.]

The risk of malignancy and potentially aggressive histologic features is substantially increased for clini-

cal T1b tumors. Hence, the risk of tumor progression that could preclude nephron-sparing approaches or lead to unsalvageable systemic metastases is also increased. AS may represent suboptimal management in this scenario and should only be considered in patients that are willing to assume a high risk of adverse oncologic outcomes related to delayed intervention.

For Index Patient No. 4: *A patient with major comorbidities/increased surgical risk and a clinical T1b (>4.0 cm to <7.0 cm), enhancing renal mass*

Standard: Radical nephrectomy should be discussed as a standard of care for patients with a normal contralateral kidney, although it can be associated with surgical morbidity and an increased risk of chronic kidney disease.

[Based on review of the data and Panel consensus.]

Radical nephrectomy is associated with less perioperative morbidity than PN, a relevant consideration for this patient with increased risk for surgical intervention. RN thus remains a standard of care, presuming a normal contralateral kidney. However, RN can lead to an increased risk of CKD with its attendant risks, and some patients may have relative or imperative indications to avoid RN. A laparoscopic approach to RN can provide a more rapid recovery and should be considered, presuming adequate surgeon expertise.

Recommendation: Complete surgical excision by partial nephrectomy should be discussed as a recommended modality when there is a need to preserve renal function, although it can be associated with increased urologic morbidity.

[Based on review of the data and Panel consensus.]

Partial nephrectomy can be associated with an increased risk of urologic morbidity, an important consideration in this high-risk patient. Nevertheless, PN or other nephron-sparing approaches should be considered whenever preservation of renal function is a primary issue.

Recommendation: Active surveillance should be discussed with patients who want to avoid surgery or who are considered high risk for surgical therapy.

[Based on review of the data and Panel consensus.]

The risk of tumor progression that could preclude nephron-sparing approaches or lead to unsalvageable systemic metastases may be increased in this patient. Nevertheless, AS should be a pri-

mary consideration in patients with limited life expectancy or those who are particularly high risk for proactive intervention.

Option: Thermal ablation can/may be discussed as treatment option which is less effective due to an increased risk of local recurrence.

[Based on Panel consensus.]

Clinical T1b tumors are difficult to adequately treat with thermal ablation, and the risks of local recurrence and complications are high in this patient population.

ACKNOWLEDGMENTS AND DISCLAIMERS

The supporting systematic literature review and data analysis and the drafting of this document were conducted by the Renal Mass Guideline Panel created in 2006 by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel chair who in turn appointed the Panel facilitator and members, urologists with specific expertise in this disease. The mission of the Panel was to develop either analysis or consensus-based recommendations, depending on the type of evidence available, to support optimal clinical practices in the management of the clinical stage 1 renal mass. Funding of the Panel and of the PGC was provided by the AUA, although Panel members received no remuneration for their work. Each member of the PGC and of the Panel furnished a current conflict of interest disclosure to the AUA.

The final report is intended to provide medical practitioners with a current understanding of the principles and strategies for the management of the clinical stage 1 renal mass. The report is based on an extensive review of the available peer-reviewed literature, as well as on clinical experience and expert opinion.

This document provides guidance only, and does not establish a fixed set of rules or define the legal standard of care. As medical knowledge expands and technology advances, the guideline will change. Today the guideline statements represent not absolute mandates but provisional proposals or recommendations for treatment under the specific conditions described. For all these reasons, the guideline does not preempt physician judgment in individual cases. Also, treating physicians must take into account variations in resources, and in patient tolerances, needs and preferences. Conformance with the guideline reflected in this document cannot guarantee a successful outcome.

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