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Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline

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Editor's note: This ASCO Clinical Practice Guideline provides recommendations, with comprehensive review and analyses of the relevant literature for each recommendation. Additional information, including a Data Supplement with additional evidence tables, a Methodology Supplement, slide sets, clinical tools and resources, and links to patient information at www.cancer.net, is available at www.asco.org/small-renal-masses-guideline and www.asco.org/guidelineswiki.

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ABSTRACT

Purpose
To provide recommendations for the management options for patients with small renal masses (SRMs).

Methods
By using a literature search and prospectively defined study selection, we sought systematic reviews, meta-analyses, randomized clinical trials, prospective comparative observational studies, and retrospective studies published from 2000 through 2015. Outcomes included recurrence-free survival, disease-specific survival, and overall survival.

Results
Eighty-three studies, including 20 systematic reviews and 63 primary studies, met the eligibility criteria and form the evidentiary basis for the guideline recommendations.

Recommendations
On the basis of tumor-specific findings and competing risks of mortality, all patients with an SRM should be considered for a biopsy when the results may alter management. Active surveillance should be an initial management option for patients who have significant comorbidities and limited life expectancy. Partial nephrectomy (PN) for SRMs is the standard treatment that should be offered to all patients for whom an intervention is indicated and who possess a tumor that is amenable to this approach. Percutaneous thermal ablation should be considered an option if complete ablation can reliably be achieved. Radical nephrectomy for SRMs should only be reserved for patients who possess a tumor of significant complexity that is not amenable to PN or for whom PN may result in unacceptable morbidity even when performed at centers with expertise. Referral to a nephrologist should be considered if chronic kidney disease (estimated glomerular filtration rate < 45 mL/min/1.73 m^2) or progressive chronic kidney disease occurs after treatment, especially if associated with proteinuria.

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INTRODUCTION

The purpose of this guideline is to provide evidence-based recommendations for practicing physicians and other health care providers concerning the management of clinically localized small renal mass (SRM). We define SRMs as incidentally image-detected, contrast-enhancing renal tumors ≤ 4 cm in diameter that are usually consistent with stage T1a renal cell carcinoma (RCC).[1] On rare occasions, SRMs may be unusual malignant tumor types, such as lymphoma, sarcoma, or a metastasis to the kidney. More than one imaging modality may be required to confirm that the lesion is solid and/or enhancing. In certain cases, noncontrast computed tomography or magnetic resonance imaging can detect macroscopic fat within the mass, which is consistent with an angiomyolipoma—a benign tumor—that, when small, can often be managed conservatively. With more widespread use of axial imaging[2,3]—usually ordered for nonspecific GI or musculoskeletal symptoms—there has been a continued increase in the rate of incidentally detected SRMs. As many as 25% of SRMs are benign renal cortical tumors, for example, oncocytoma, metanephric adenoma, and angiomyolipoma. Another 25% are indolent in nature with limited metastatic potential, for example, chromophobe, type 1 papillary renal cancer.[4] Although certain renal tumor histologies have distinct imaging characteristics, current radiologic imaging cannot reliably discriminate

ASSOCIATED CONTENT

Appendix
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Data Supplement
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THE BOTTOM LINE

Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline

Guideline Questions

For patients diagnosed with a small renal mass (SRM):

- When is renal tumor biopsy (RTB) indicated?
- What is the contemporary accuracy and complication profile of RTB?
- Is there an age limit at which active surveillance is a better option than surgical resection or thermal ablation?
- Is there an anticipated life expectancy for which active surveillance is a better option than surgical intervention or thermal ablation?
- Are patients with significant medical comorbidities (eg, chronic kidney disease [CKD], congestive heart failure, coronary artery disease, or chronic obstructive pulmonary disease) better treated with active surveillance than surgical intervention or ablation?
- What are the optimal indications for partial nephrectomy, radical nephrectomy, or thermal ablation?
- What is the impact of these procedures on renal function?

Target Population

Patients with an SRM.

Target Audience

Medical, surgical, and radiation oncologists; interventional radiologists; urologists and urologic oncologists; nephrologists; oncology nurses; physician assistants; pathologists; general practitioners; and patients.

Methods

An Expert Panel (Appendix Table A1, online only) was convened to develop clinical practice guideline recommendations on the basis of a systematic review of the medical literature.

Key Recommendations

Recommendation 1.0: On the basis of tumor-specific findings and competing risks of mortality, all patients with an SRM should be considered for RTB when the results may alter management (type: evidence based; evidence quality: intermediate; strength of recommendation: strong).

Recommendation 2.0: Active surveillance should be an initial management option for patients who have significant comorbidities and limited life expectancy (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate). Qualifying statement: absolute indication: high risk for anesthesia and intervention or life expectancy $<$ 5 years; relative indication: significant risk of end-stage renal disease if treated, SRM ($<$ 1 cm), or life expectancy $<$ 10 years.

Recommendation 3.1: Partial nephrectomy (PN) for SRMs is the standard treatment that should be offered to all patients for whom an intervention is indicated and who possess a tumor that is amenable to this approach (type: evidence based; evidence quality: intermediate; strength of recommendation: strong).

Recommendation 3.2: Percutaneous thermal ablation should be considered an option for patients who possess tumors such that complete ablation will be achieved. A biopsy should be obtained before or at the time of ablation (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

Recommendation 3.3: Radical nephrectomy for SRMs should be reserved only for patients who possess a tumor of significant complexity that is not amenable to PN or where PN may result in unacceptable morbidity even when performed at centers with expertise. Referral to a surgeon and a center with experience in PN should be considered (type: evidence based; evidence quality: intermediate; strength of recommendation: strong).

Recommendation 3.4: Referral to a nephrologist should be considered if CKD (estimated glomerular filtration rate $<$ 45 mL/min/1.73m^2) or progressive CKD develops after treatment, especially if associated with proteinuria (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

(continued on following page)

THE BOTTOM LINE (CONTINUED)

Additional Resources

More information, including a Data Supplement with additional evidence tables and a Methodology Supplement with information about evidence quality and strength of recommendations, slide sets, and clinical tools and resources, is available at www.asco.org/small-renal-masses-guideline and www.asco.org/guidelineswiki. Patient information is available at www.cancer.net

ASCO believes that cancer clinical trials are vital to inform medical decisions and improve cancer care, and that all patients should have the opportunity to participate.

benign from indolent or potentially malignant tumors. In addition to the diagnostic dilemma, the natural history of these lesions is variable, and many tumors demonstrate an indolent course. In the past 20 years, surgical treatment of SRMs has transitioned from radical nephrectomy for all renal tumors, regardless of size, to elective partial nephrectomy whenever technically feasible. In the past 5 years, newer approaches, including renal tumor biopsy (RTB), active surveillance for select patients, and percutaneous thermal ablation, have been increasingly used. This guideline provides a framework of information for clinicians and other health care providers to help provide optimal care to their patients with SRMs.

GUIDELINE QUESTIONS

This clinical practice guideline addresses the following clinical questions:

For patients who are diagnosed with an SRM, when is RTB indicated and what are the contemporary accuracy and complications of biopsy?

In patients with an SRM, is there an age limit for which active surveillance is a better option than surgical resection or thermal ablation? Is there an anticipated life expectancy for which active surveillance is a better option than surgical intervention or thermal ablation? Are patients with significant medical comorbidities—for example, CKD, congestive heart failure, coronary artery disease, or chronic obstructive pulmonary disease—better treated with active surveillance than surgical intervention or ablation?

In patients with an SRM, what are the optimal indications for PN, radical nephrectomy, or thermal ablation? What is the impact of these procedures on renal function?

METHODS

Guideline Development Process

An Expert Panel with multidisciplinary representation met via teleconference and/or webinar and corresponded through e-mail. On the basis of the consideration of the evidence, the authors were asked to contribute to the development of the guideline, provide critical review, and finalize guideline recommendations. Members of the Expert Panel were responsible for reviewing and approving the penultimate version of the guideline, which was then circulated for external review and submitted to *Journal of Clinical Oncology* for editorial review and consideration for publication. All ASCO guidelines are ultimately reviewed and approved by the Expert Panel and the ASCO Clinical Practice Guideline Committee before publication.

The Expert Panel developed the recommendations by using evidence that was identified through online searches of Medline from January 2000 through September 2015. This search was complemented by panel members' additional suggestions of articles that were missing from the original searches. Data Supplement 2 includes full details on the search string. Articles were selected for inclusion in the systematic review of the evidence on the basis of the following criteria:

- Population: Patients with clinically localized SRM.
- Publications that reported rigorously conducted systematic reviews (with or without meta-analyses), randomized clinical trials (RCTs), and prospective or retrospective observational studies.

Articles were excluded from the systematic review if they were meeting abstracts that were not subsequently published in peer-reviewed journals; editorials, commentaries, letters, news articles, case reports, or narrative reviews; or published in a non-English language. Further details on the systematic review can be found in the Methodology Supplement.

Guideline recommendations were crafted, in part, by using the Guidelines Into Decision Support methodology and accompanying BRIDGE-Wiz software.[5] In addition, a guideline implementability review was conducted. On the basis of the implementability review, revisions were made to the draft to clarify recommended actions for clinical practice. Ratings for the type and strength of recommendation, evidence, and potential bias are provided with each recommendation. Detailed information about the methods that were used to develop this guideline is available in the Methodology Supplement at www.asco.org/small-renal-masses-guideline, including an overview (eg, panel composition, development process, and revision dates), literature search and data extraction, the recommendation development process (Guidelines Into Decision Support and BRIDGE-Wiz), and quality assessment.

The ASCO Expert Panel and guidelines staff will work with cochairs to keep abreast of substantive updates to the guideline. On the basis of formal review of the emerging literature, ASCO will determine the need to update. This is the most recent information as of the publication date. Visit the ASCO Guidelines Wiki at www.asco.org/guidelineswiki to submit new evidence. In some selected cases in which evidence is lacking but there was a high level of agreement among Expert Panel members, informal consensus is used (as noted with the Recommendations).

Guideline Disclaimer

The Clinical Practice Guidelines and other guidance published herein are provided by ASCO to assist providers in clinical decision making. Information herein should not be relied upon as being complete or accurate, nor should it be considered to be inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time that information is developed and when it is published or read. Information is not continually updated and may not reflect the most recent evidence. Information addresses only the topics that are specifically identified herein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Furthermore, information is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients.

Recommendations reflect high, moderate, or low confidence that the recommendation reflects the net effect of a given course of action. Use of words like "must," "must not," "should," and "should not" indicates that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an as-is basis and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information, or for any errors or omissions.

Guideline and Conflicts of Interest

The Expert Panel was assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines (Policy, found at www.asco.org/rwc). All members of the Expert Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment; leadership; stock or other ownership; honoraria; consulting or advisory role; speaker's bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the Expert Panel did not disclose any relationships that constituted a conflict under the Policy.

RESULTS

Characteristics of Studies Identified in the Literature Search

A total of 83 studies[6-88] met eligibility criteria and form the evidentiary basis for the guideline recommendations. Identified trials included 20 systematic reviews[6-25]—17 on different SRM treatment modalities[6-22] and three on RTB[23-25]—and 63 primary studies.[26-88] Seven of the primary studies were retrospective studies on the treatment of elderly patients with SRMs.[26-32] There were six retrospective[33-38] studies on surveillance; nine retrospective studies on renal tumor biopsy[39-47]; and three RCTS,[56,63,78] two prospective comparative trials,[54,67] and 27 retrospective studies on different surgical interventions for SRMs.[48-53,55,57-62,64-66,68-77,79] In addition, nine retrospective studies evaluated the impact of these interventions on renal function.[80-88]

Primary outcomes reported in studies on therapeutic interventions included overall survival (OS), cancer-specific survival, disease-free survival, and peri- and postoperative complications. Studies on active surveillance and the elderly reported tumor growth rate, OS, and cancer-specific survival, and studies on biopsy reported diagnostic accuracy and complications. Table 1 gives a summary of the included studies; details on the study characteristics are found in Data Supplement 1. The systematic review flow diagram is included in Data Supplement 2.

Study Quality Assessment

Study design aspects related to individual study quality, strength of evidence, strength of recommendations, and risk of bias were assessed. Refer to the Methodology Supplement for more information and for definitions of ratings for overall potential risk of bias.

Table 1. Summary of Included Studies

Interventions	Study Design	No. of Studies
Systematic reviews		
Radical nephrectomy		7
Partial nephrectomy		
Ablative therapies		
Active surveillance		
Biopsy		2
Meta-analysis		
Radical nephrectomy		10
Partial nephrectomy		
Ablative therapies		
Active surveillance		
Biopsy		1
Primary Studies (N = 63)		
Elderly patients with SRM	Retrospective	7
Active surveillance	Retrospective	6
Biopsy	Retrospective	9
Radical nephrectomy	RCT	3
Partial nephrectomy	Prospective comparative	2
Ablative therapies	Retrospective	27
Studies on impact on renal function	Retrospective	9

Abbreviations: RCT, randomized clinical trial; SRM, small renal mass.

RECOMMENDATIONS

CLINICAL QUESTION 1

For patients who were diagnosed with an SRM, when is RTB indicated? What is the contemporary accuracy and complication profile of RTB?

Recommendation 1.0

On the basis of tumor-specific findings and competing risks of mortality, all patients with an SRM should be considered for RTB when the results may alter management (type: evidence based; evidence quality: intermediate; strength of recommendation: strong).

Literature review and analysis: Contemporary RTB accuracy. SRMs are commonly discovered incidentally during diagnostic evaluation for other medical conditions. SRMs represent a heterogeneous group of tumors that spans the full spectrum of metastatic and growth potential[89] and include benign, indolent, and more aggressive tumors. A large series of surgically resected SRMs concluded that a substantial proportion of these lesions are benign.[90] In larger (> 4 cm) masses, the likelihood of malignancy increases, and radiologic features (heterogenous mass or irregular tumor contour), branched renal vein tumor extension, and peritumoral infiltration or neovascularity may also indicate a potentially malignant tumor. However, at the current time, magnetic resonance imaging, computed tomography, and ultrasound imaging cannot make an absolute diagnosis of cancer, whether indolent or aggressive. As there is no imaging modality to accurately distinguish malignant SRMs from benign SRMs, a number of studies have examined the accuracy and efficacy of percutaneous biopsies.[4,23-25] For the purpose of this guideline, RTB specifically refers to core biopsy given the superior diagnostic rates compared with fine-needle aspirate.[4]

A recent systematic review summarized the current outcomes of RTB.[4] Median overall diagnostic rate was 92%. Sensitivity and specificity of RTB were 99.7% and 93.2%, respectively. In cases where surgical pathology and RTB material were both available, good (k = 0.683) and fair (k = 0.34) agreement were observed between histologic subtype and tumor grade, respectively. A low rate of Clavien ≥ 2 complications was reported after RTB. The review by Marconi et al[4] is consistent with the largest single-institution RTB series that was recently published.[40] In addition to similar results with the aforementioned systematic review, Richard et al[40] showed that, conservatively, 10% of patients could have avoided treatment of tumors with confirmed benign histology.

Clinical interpretation. A definitive diagnosis of a malignant SRM on the basis of imaging alone is not possible, and, therefore, RTB can play an important role in the management of SRMs. This is especially true if the patient is a borderline surgical candidate because of medical comorbidities or if the clinician is concerned that an unusual diagnosis, such as renal lymphoma or a rare metastasis to the kidney, may be possible, and that systemic treatments may be indicated. Predominantly cystic masses, those originating in the collecting system, or a clinical suspicion for urothelial cancer should not undergo biopsy. In addition to histopathologic characterization, biopsy tissue may provide prognostic information, such as grade, and with further research, biomarker expression may one day guide patient management. Occasionally, a patient who is uncertain whether to undergo definitive treatment of an SRM may elect an RTB, and histopathologic characterization can significantly impact management. If a fat-poor angiomyolipoma is diagnosed, surgery is not indicated, whereas a clear-cell RCC in a young fit patient would more likely lead to intervention.

Although helpful, there are challenges with RTB. Nondiagnostic biopsies occur in 10% to 20% of cases, and consideration for repeat biopsy or upfront treatment should be discussed with the patient. A designation of oncocytic neoplasm can be challenging, as it is not always clear whether the lesion is a benign oncocytoma or a malignant variant. Tumor heterogeneity—in terms of morphology, grade, and molecular characteristics—is well recognized in renal tumors, including SRMs. Clinicians should have an understanding of how this issue could impact RTB results and a treatment plan for a given patient. Review of RTB findings, including correlation with final histology in selected surgical specimens, at multidisciplinary patient conferences and/or tumor boards provides an excellent opportunity for pathologist interaction in this regard.

Although there has been much recent research that has attempted to define renal tumors in molecular and genetic terms, at the present time, RTB is used principally to provide histopathologic information. In the future, genomic information from RTB may provide prognostic information that could further change current treatment approaches.

Furthermore, RTB should be performed when results might alter surgical management. Patients who are considered for an active surveillance protocol may also benefit from a biopsy to assess risk for metastasis while undergoing surveillance and to inform patient counseling; however, RTB is not necessary for all patients who undergo surveillance. For patients with SRMs that are considered for thermal ablation, preablation RTB should be performed to establish a diagnosis and appropriate follow-up schedule, preferably as a separate procedure to provide sufficient time for complete pathologic assessment before intervention.

CLINICAL QUESTION 2

In patients with an SRM, is there an age limit at which active surveillance is a better option than surgical resection or thermal ablation? Is there an anticipated life expectancy for which active surveillance is a better option than surgical intervention or thermal ablation? Are patients with significant and active medical comorbidities—that is, CKD, congestive heart failure, coronary artery disease, and chronic obstructive pulmonary disease—better treated with active surveillance than surgical intervention or ablation?

Recommendation 2.0

Active surveillance should be an initial management option for patients who have significant comorbidities and limited life expectancy (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

Qualifying statement: absolute indication: high risk for anesthesia and intervention or life expectancy < 5 years; relative indication: significant risk of end-stage renal disease (ESRD) if treated, SRM (< 1 cm), or life expectancy < 10 years.

Literature review and analysis. Presentation of SRMs has changed during the past decades, and the majority of cases now present as small, asymptomatic masses, many of which were diagnosed incidentally.[91] Moreover, many of these asymptomatic masses that are present in older patients (age > 70 years) can be relatively indolent and of marginal clinical significance compared with other comorbidities that are frequently present in these patients.[3,92,93] Thus, in many of these patients, competing comorbidities, taken alone or together, far outweigh the oncologic impact of an SRM. Hence, active surveillance with serial imaging may be a more rational approach that can spare the patient the serious potential risks and toxicities of more aggressive treatments. SRMs ≤ 1 cm are benign in 50% of cases, and the risk of malignancy increases to 75% in lesions 1 to 2.9 cm in size,[90] yet the risk of metastatic disease that ensues within the first 3 years of surveillance is low (< 5%), which provides a window of ≥ 5 years during which the patient faces minimal risk from the lesion. Most SRMs will grow slowly (average, 2 to 3 mm per year), and for ≤ 40%, no significant growth is documented at > 3 years, even in biopsy-proven RCC.[94,95] Growth alone is not an indication of histology, as both benign and malignant lesions can grow at similar rates or not at all.[95] The reported rate of metastasis is 1% to 2% in the first 3 years of surveillance; metastasis is usually preceded by rapid local growth that can be detected early on appropriately compared serial imaging.[17]

The most important aspect of this recommendation is to perform a detailed, multidisciplinary assessment of a patient's overall medical condition and functional status. The Charleston Comorbidity Index (CCI) has often been evaluated as a tool for this assessment.[96] CCI includes such factors as patient age, along with 19 key medical conditions, such as diabetes mellitus, heart failure, vascular disease, and others.[96] CCI has been validated to predict 1-year mortality.[97] For patients with RCC, two studies have examined the CCI as an aid to decision making regarding a pathway

of active surveillance versus intervention.[98,99] In both of these studies, the conclusion was that the CCI score should be used in the decision-making process and that those who are at the highest risk for mortality as a result of competing comorbidities should be candidates for active surveillance. Other retrospective studies have showed similar results with either the CCI or other comorbidity assessment tools.[100-103]

The American Urological Association renal mass guideline treatment algorithm states that active surveillance is an option for those patients with surgical risks or competing comorbidities[104]; however, there is little specificity in defining these high-risk patients. Other groups have developed nomograms to assess the risks of active surveillance with calculations of RCC-specific mortality, other cancer mortality, and noncancer mortality.[105,106] These nomograms also include CCI-determined patient morbidity and are available online.[106,107] As a result of competing mortality risks in most patients age > 75 years, delay in initial treatment seems to be associated with an exceedingly low rate of cancer mortality. Until data regarding long-term SRM progression risks mature, there is no actuarial life expectancy for which active surveillance is a better option than intervention, which suggests that clinical decisions must be individualized.

In particular, death rates from cardiovascular disease exceed death rates from cancer in the age group of patients who are most frequently diagnosed with SRMs. Thus, special attention should be paid to estimate cardiovascular risk before surgical treatment. In addition, the functional risk of advanced CKD and perioperative dialysis complications likely outweigh the oncologic risks of SRM progression. Even in expert hands, a PN may rarely need to be converted to a radical nephrectomy, and, thus, careful assessment of renal function using such formulas as the Modification of Diet in Renal Disease (MDRD) or Chronic Kidney Disease Epidemiology (CKD-EPI) equations is critical in preoperative planning.

Patients with SRMs with significant cardiovascular disease or CKD should therefore proceed with appropriate risk stratification of their nononcologic conditions. In fact, a study that used the SEER database revealed that in older patients (age > 70 years), one third died as a result of causes that were unrelated to RCC within 5 years after therapy.[108] Furthermore, in selected patients with renal masses, such as those with extensive comorbidities or age > 80 years, active surveillance has demonstrated that the majority of patients do not experience disease progression or die as a result of RCC.[17,27,94,109-111] If surveillance is chosen, follow-up strategies continue to be refined but include a staging chest x-ray and axial abdominal imaging (or ultrasonography) every 3 months in the first year, twice in the second and third years, and yearly thereafter.[95] This should be modified by growth kinetics: if the tumor grows > 0.5 cm per year or reaches > 4 cm in size, consideration should be given to treatment, depending on the patient's comorbidities and life expectancy.[17,95,105]

Clinical interpretation. In those patients who are older (age > 70 years) and/or have significant comorbidities, it is critical to assess the risk of active surveillance versus ablative or surgical intervention. Nomograms to estimate competing outcomes allow better assessment of potential results and can refine selection for active surveillance in elderly patients.[107] Arbitrary age cutoffs or simple assessments of lists of comorbidities should be avoided, and, instead, a more detailed, patient-specific quantitative assessment should be performed.

Currently, evidence for an absolute upper age limit when the risk of cancer mortality is less than the competing risks is not available. The anticipated functional and survival impact of existing comorbidities at 1, 3, and 5 years should be estimated before recommending treatment of an SRM in appropriate patient populations.

CLINICAL QUESTION 3

In patients with an SRM, what are the optimal indications for undergoing PN, radical nephrectomy, or thermal ablation? What is the impact of these procedures on renal function?

Recommendation 3.1

PN for SRMs is the standard treatment that should be offered to all patients in whom an intervention is indicated and who possess a tumor that is amenable to this approach (type: evidence based; evidence quality: intermediate; strength of recommendation: strong).

Literature review and analysis. A number of studies that used observational data have compared outcomes of PN with radical nephrectomy for tumors < 4 cm.[7,10,11,21,32] Observational studies, albeit prone to bias, have consistently demonstrated benefits for long-term renal function and OS while maintaining equivalent oncologic outcomes. PN is associated with a higher complication rate than radical nephrectomy.[56,78] This is particularly true of early laparoscopic PN experience. It has not yet been established whether adoption of robotic-assisted PN can shorten the surgical learning curve and lessen the rates of intraoperative and perioperative complications.[8,18] A European Organization for Research and Treatment of Cancer randomized control trial of PN versus radical nephrectomy found no significant difference in OS for patients with renal cancer who were treated with PN or radical nephrectomy, but its recent renal functional follow-up study did demonstrate superior renal functional outcomes with PN.[56,78] Given an OS advantage for radical nephrectomy in the intent-to-treat analysis, this study has been the subject of much debate[56]; however, on the basis of the only significant randomized trial in this field, it seems that PN does not have a deleterious impact on OS compared with radical nephrectomy, and the medical benefits of preserving renal function are potentially important. On the basis of this and other large single- and multicenter nonrandomized studies, major urologic association guidelines (American Urological Association, European Association of Urology) continue to state that PN is the standard of care for SRMs that are candidates for this surgical treatment.[104,112,113]

Both methods provide excellent oncologic results. In the intent-to-treat population, nephron-sparing surgery may be less effective than radical nephrectomy regarding OS; however, in the targeted population of patients with RCC, the trend in favor of radical nephrectomy is no longer significant. The small number of progressions and deaths as a result of renal cancer cannot explain any possible OS differences between treatment types.

Clinical interpretation. Although partial nephrectomy for SRMs was originally reserved for patients with essential indications, such as solitary kidney, multifocal and bilateral renal

masses, and patients with severe preexisting renal dysfunction, it has become the standard for treating T1a RCC in the elective setting for patients with a normal contralateral kidney.[104] PN is associated with an excellent cancer-specific survival rate, but carries a certain potential for treatment-related complications, which is greatest among the surgical treatment options for SRMs.[79] Despite well-documented benefits of elective PN in reducing the risk of CKD, morbidity and mortality associated with CKD after treatment remain unclear.[80] PN, regardless of the approach, is the treatment of choice for SRMs that are amenable to nephron-sparing surgery. Despite a decade of progress in this area of clinical research, PN remains underused for the treatment of SRMs in both the United States and Canada.[114] The reason for this is likely multifactorial and relates to training, lack of surgical expertise in PN by any technique, and/or a desire to use minimally invasive radical nephrectomy instead of the more challenging open or minimally invasive partial nephrectomy.

Recommendation 3.2

Percutaneous thermal ablation should be considered an option for patients that possess tumors such that complete ablation will be achieved. A biopsy should be obtained before or at the time of ablation (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

Literature review and analysis. The majority of thermal ablation studies are observational and retrospective in nature.[12-14,19] RCTs that compare thermal ablation with nephron-sparing surgery or active surveillance have not been performed. Restricted indications for thermal ablation, inconsistent reporting of renal mass histopathology, and evolving ablation techniques—for example, increase in image-guided percutaneous ablation relative to laparoscopic approach—have reduced the volume of high-quality data that are available for analysis. In addition, as published ablation studies typically assess outcomes and complications in an older population with many comorbid conditions, there is limited generalizable knowledge regarding optimal patient selection. Inconsistent reporting of definitive biopsy-proven RCC pathologic diagnosis in many series also prevents meaningful comparative analysis. Several renal mass ablation studies have been compromised by an admixture of percutaneous, laparoscopic, or open surgical ablative approaches, and various definitions of technical success have resulted in misleading or uninterpretable findings.[13,115]

There are a number of meta-analyses that compare thermal ablation with radical nephrectomy and PN[9,15,16,19]; however, the literature that compares longer-term oncologic control with patient experience after nephron-sparing SRM interventions is sparse. Only recently have studies that report $\geq$ 5 years of clinical follow-up emerged for thermal ablation procedures, although most commonly in the form of retrospective reviews of single-institution experience.[48]

In addition to medical comorbidities, renal mass location and size seem to be associated with complication rates after ablation. The benefits and risks of ablation should be carefully weighed for centrally located masses or those in close proximity to structures such as ureters, ureteropelvic junction, small or large bowel, or nerves.[116] Ideally, a working relationship between an interventional radiologist and urologic kidney surgeon would provide an optimal and safe approach for patients who are considering renal tumor ablation.

Perioperative outcomes, such as length of hospital stay, estimated blood loss, and open surgical conversion, favor thermal ablation relative to surgical options.[15,22] Meta-analysis of percutaneous and surgical (open or laparoscopic) ablation strategies reveals a lower major complication rate for percutaneous ablation.[22] Percutaneous renal ablation does not typically adversely impact renal function, even in patients with CKD,[81] and, thus, may be particularly suited for patients who require maximum conservation of renal parenchyma.

Furthermore, contemporary studies that describe procedural complications after renal mass surgery or thermal ablation benefit from increasingly standardized data collection. For example, patient characteristics, composite renal tumor complexity scores, and ablation margin analyses begin to address concerns regarding patient selection bias,[58,116-119] and nephrometry scores predict local tumor progression and potential complications.[120] Thermal ablation failure may be amenable to repeat ablation or require surgical intervention. PN after ablation is difficult and may result in total nephrectomy.[121] This consideration should be discussed and reviewed before ablation. Data on long-term outcomes after ablation are still limited.[122]

Clinical interpretation. Indications for thermal ablation should be considered in relation to each patient's renal mass characteristics; comorbidity and competing risk profiles; and alternate management strategies, including active surveillance or surgical resection. For patients with reasonable life expectancy, the rationale for ablation or surgical resection is to achieve local tumor control, as cancer-specific mortality increases with higher-stage disease as a result of the modest efficacy of systemic treatments. Even in this context, definitive patient selection strategies remain elusive as a result of uncertainties regarding competing risks and the range of SRM biologic propensities.

Current American Urological Association and European Association of Urology guidelines recommend PN as the standard of care for T1aN0M0 renal masses.[104,113] In reaching these recommendations, these organizations considered the higher reported rates of recurrence after thermal ablation as well as the lack of evidence regarding long-term oncologic efficacy; however, more recent studies have not demonstrated a superior cancer-specific survival benefit for either approach. Given the favorable natural history of these lesions, any advantage in cancer-specific survival would require a significant number of patients and many years of follow-up to demonstrate.

Percutaneous thermal ablation should be considered an option for patients who possess tumors that are located such that complete ablation can be achieved. Ablation should be reserved for carefully selected and counseled patients. Ideally, a good working relationship between an interventional radiologist and urologic oncologist would provide an optimal and safe approach. The historical notion that ablation should be limited to unfit and vulnerable patients with SRMs who are rejected for surgical intervention should be discouraged because, as described above, those patients may be better served with active surveillance.

Recommendation 3.3

Radical nephrectomy for SRMs should only be reserved for patients who possess a tumor of significant complexity that is not

amenable to PN or for whom PN may result in unacceptable morbidity even when performed at centers with expertise. Referral to a surgeon and a center with experience in PN should be considered (type: evidence based; evidence quality: intermediate; strength of recommendation: strong).

Literature review and analysis. As discussed in the section supporting PN for SRMs, there seems to be a limited role for radical nephrectomy in this setting[123]; however, in the setting of a normal contralateral kidney, no associated conditions that predispose to CKD, and complex tumor location on the basis of nephrometry scoring, one could consider radical nephrectomy.[80,124,125] In the rare instance that radical nephrectomy is performed for an SRM, a minimally invasive approach is the preferred option given the evidence that supports lower morbidity and equivalent cancer-specific survival.[104]

Although controversial, there is a limited but acknowledged role for this intervention.

Clinical interpretation. Radical nephrectomy was the primary treatment option for SRMs up until the current decade, when its use decreased to < 50%.[126] The original description of radical nephrectomy applied for large and/or locally advanced renal tumors and described removal of the kidney, investing tissue, adrenal gland, and regional lymph nodes. Given the low likelihood of involvement of the adrenal gland and regional metastasis with an SRM, the contemporary description of radical nephrectomy is primarily the removal of the entire kidney. Radical nephrectomy can be performed through a variety of surgical approaches, including open and minimally invasive techniques. Because the entire kidney is removed, it is associated with the lowest risk of recurrence and avoids treatment-related complications from nephron-sparing surgery, such as urinary fistula and pseudoaneurysm. The most significant drawback, however, is the detrimental impact on kidney function and the risk of CKD after treatment.

Recommendation 3.4

Referral to a nephrologist should be considered for patients with CKD (estimated glomerular filtration rate [eGFR] < 45 mL/min/1.73 m^2) or progressive CKD after treatment, especially if associated with proteinuria (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

Literature review and analysis. A normal GFR is approximately 130 mL/min/1.73 m^2 for men and 120 mL/min/1.73 m^2 for women, with a mean rate of decline of 0.75 mL/min/year.[127] All exogenous filtration markers—inulin, iothalamate, iohexol, DTPA, and EDTA—have drawbacks, and 24-hour urine collections overestimate GFR by approximately 10% to 20%.[128] Consequently, KDIGO (Kidney Disease Improving Global Outcomes) recommends using a creatinine-based GFR estimating equation.[129] CKD-EPI and MDRD are the most commonly used serum creatinine–based GFR estimating equations. CKD-EPI is more accurate with GFR > 60 mL/min/1.73 m^2 and is a better predictor of adverse outcomes (ESRD and mortality) compared with MDRD.[130] MDRD underestimates GFR in patients with normal renal function and performs better with GFR < 60 mL/min/1.73 m^2. When precision is required, GFR can be measured by using an exogenous filtration marker. GFR estimates can be inaccurate in non–steady-state conditions, such as diabetes (hyperfiltration), extremes of muscle mass or weight (eg, obesity, amputees), or after surgery.[131]

Radioisotope renal scans can provide differential renal function to estimate GFR after radical nephrectomy; however, actual GFR after radical nephrectomy is approximately 12% (interquartile range, 2% to 25%) higher than that predicted by renal scan.[132]

Comparative renal function outcomes. PN leads to more favorable short- and long-term GFR compared with radical nephrectomy.[82-85,133] An RCT showed that PN reduced the incidence of moderate renal dysfunction (eGFR < 60 mL/min) compared with radical nephrectomy (64.7% *v* 85.7%) but showed no difference in incidence of ESRD or improvement in OS.[56] Factors that are associated with renal function recovery after radical nephrectomy have been previously described.[134] Data that are available on renal function after cryoablation or radiofrequency ablation are limited but suggest no change[81] or a small decrease.[86] In patients with a solitary kidney, percutaneous ablation has been associated with a lower risk of new-onset CKD compared with PN[87]; however, another larger study observed no difference.[88]

Predictors of long-term GFR after surgery, modifiable. Optimizing renal function after PN depends on the amount of vascularized remaining renal parenchyma (kidney quantity) and the preoperative function of the kidney (kidney quality).[135,136] Longer periods of warm ischemia are associated with diminished postoperative eGFR, whereas the impact of short durations (< 25 minutes) is controversial.[136,137] Cold ischemia with ice slush safely facilitates longer durations of ischemia and is associated with improved renal functional outcomes.[135,138]

Predictors of long-term GFR after surgery, not modifiable. Several factors predict worse long-term GFR after surgery: lower baseline GFR, higher body mass index, increasing age, higher CCI score, male sex, hypertension, diabetes mellitus, and increasing tumor size.[134,139-147]

Etiology of CKD: Surgical versus medical. Average annual eGFR decline after kidney surgery depends on whether CKD is surgery induced (−0.7%) or is the result of a combination of surgery and medical conditions that adversely affect renal function (−4.7%).[148] After adjusting for known covariates, the likelihood of a 50% decrease in eGFR, need for dialysis, and overall mortality is lower for patients with surgery-induced CKD compared with those with CKD induced by surgery and medical conditions.[80,149]

Clinical interpretation. Nephron-sparing interventions—PN and ablation—are associated with the greatest protection against CKD. Other variables contribute to the risk of CKD after treatment. Patients with relevant medical comorbidities, preexisting CKD, prolonged ischemia time during PN, and/or significant parenchymal loss with resection or ablation are the most vulnerable.[80,136]

DISCUSSION

Management of localized RCC has undergone significant change over the past two decades. It has transitioned from an era of radical nephrectomy for all uncharacterized lesions to one of more personalized care. Selecting a management strategy currently requires integration of numerous patient- and tumor-related factors. The

natural history of SRMs is variable but often indolent, and many patients with incidentally detected lesions are age > 70 years and have significant competing health risks. RTB series have informed us of the frequency of benign histology, and active surveillance cohorts—with short- to midterm follow-up—have confirmed that many people succumb to other diseases in the near term and not RCC. However, there is a critical need to understand the metastatic potential of SRMs given that metastatic RCC is rarely curable. Likewise, a better understanding and appreciation of CKD and its impact on well-being and survival has led to greater use of kidney-sparing interventions, such as PN and thermal ablation. This guideline serves to provide direction in a rapidly evolving field of urologic oncology. Within the limitations of the available literature, we propose the aforementioned recommendations to inform and improve the current care of patients with SRMs.

Patient and Clinician Communication

The dizzying pace of scientific advance has provided new reasons for hope to patients and families; however, at the same time, these advances—combined with new team-based, patient-oriented care models—have created an environment of greater complexity. In this environment, strong and clear communication between physicians, patients, and families has become more important than ever. Establishing quality and optimal communications between all members of the care team is essential to a favorable outcome, and good communication is a shared responsibility. The following are some basic guidelines for clinicians:

To begin, remember that today's empowered patient will expect a greater role in his or her care. This means taking steps to ensure the patient is well educated and informed. Clinicians should take the time to orient the patient to his or her care but also make available recommended sources for information, including both print materials and online information. Encourage patients, family, and caregivers to keep good records and especially to note changes in symptoms or health conditions after active treatment begins. Establish an atmosphere in which patients feel empowered to share what is on their minds.

The clinician should share details of test results, including pathology reports, promptly and take the time to ensure that the patient understands the information being provided. To ensure comprehension, ask patients to repeat key information, speak slowly, and avoid overly technical terminology. The cancer staging system should be thoroughly explained, if appropriate, including tumor categories, as well as the four-stage RCC grouping system.

If the patient is a candidate for clinical trials, clinicians should take the time to explain the dual benefit of participation: obtaining access to innovative treatments, but also helping advance researchers' understanding of kidney disease.

Because patients who deal with SRMs may be emotionally affected during diagnosis, it is important to display compassion and support. Steps should be taken to establish rapport with the patient, including use of the patient's first name, sitting at eye level, and making an effort to keep from seeming rushed or inattentive. In addition, be mindful of interrupting: studies show a link between good communication between patient and physician and eventual care outcomes.[148] The extra few minutes of listening are worth the effort.

Finally, clinicians should remember that good communication with families and caregivers of patients is important: the love and support of family members and friends impacts every phase of diagnosis and treatment. Experienced clinicians know that helping the family is another way to help the patient.

Excellent informational resources for patients with SRMs include the Web sites of the Kidney Cancer Association (www.kidneycancer.org), National Cancer Institute (www.cancer.gov), American Cancer Society (www.cancer.org), and the National Coalition for Cancer Survivorship (www.canceradvocacy.org).

Health Disparities

Although ASCO clinical practice guidelines represent expert recommendations on the best practices in disease management to provide the highest level of cancer care, it is important to note that many patients have limited access to medical care. Racial and ethnic disparities in health care contribute significantly to this problem in the United States. Patients with cancer who are members of racial or ethnic minorities suffer disproportionately from comorbidities, experience more substantial obstacles to receiving care, are more likely to be uninsured, and are at greater risk of receiving care of poor quality than are other Americans.[150-153] Many other patients lack access to care because of their geographic location and distance from appropriate treatment facilities. Awareness of these disparities in access to care should be considered in the context of this clinical practice guideline, and health care providers should strive to deliver the highest level of cancer care to these vulnerable populations.

Multiple Chronic Conditions

Creating evidence-based recommendations to inform treatment of patients with additional chronic conditions—a situation in which the patient may have two or more such conditions, which is referred to as multiple chronic conditions (MCCs)—is challenging. Patients with MCCs are a complex and heterogeneous population, which makes it difficult to account for all of the possible permutations to develop specific recommendations for care.[154] In addition, the best available evidence for treating index conditions, such as cancer, is often from clinical trials whose study selection criteria may exclude these patients to avoid potential interaction effects or confounding of results associated with MCCs. As a result, the reliability of outcome data from these studies may be limited, thereby creating constraints for expert groups to make recommendations for care in this heterogeneous patient population.

Because many patients for whom guideline recommendations apply present with MCCs, any treatment plan needs to take into account the complexity and uncertainty that are created by the presence of MCCs; this highlights the importance of shared decision-making regarding guideline use and implementation. Therefore, in consideration of recommended care for the target index condition, clinicians should review all other chronic conditions that are present in the patient and take those conditions into account when formulating the treatment and follow-up plan.

In light of the above considerations, practice guidelines should provide information on how to apply the recommendations for patients with MCCs, perhaps as a qualifying statement for recommended care. This may mean that some or all of the

recommended care options are modified or not applied, as determined by best practice in consideration of any MCC.

Limitations of the Literature and Future Directions

The literature on SRMs is limited to case series, observational studies, and nonrandomized comparative studies using statistical means to compensate, as best as possible, for inherent biases. Unfortunately, this is common in surgical literature and, in particular, with conservative management strategies that are often applied initially to vulnerable patients and those who are unfit for intervention. The growing body of literature on renal tumor RTB, active surveillance, and treatment of SRMs continues to suggest a risk of overtreatment. Given our current understanding of the natural history of SRMs, studies are required to more accurately characterize these lesions beyond histopathology such that the true metastatic potential can be appreciated and guide management decisions.

ASCO believes that cancer clinical trials are vital to inform medical decisions and improve cancer care, and that all patients should have the opportunity to participate

GUIDELINE IMPLEMENTATION

ASCO guidelines are developed for implementation across health settings. Barriers to implementation include the need to increase awareness of guideline recommendations among front-line practitioners and survivors of cancer and caregivers, as well as to provide adequate services in the face of limited resources. The guideline Bottom Line Box was designed to facilitate implementation of recommendations. This guideline will be distributed widely through the ASCO Practice Guideline Implementation Network. ASCO guidelines are posted on the ASCO Web site and most often published in *Journal of Clinical Oncology* and *Journal of Oncology Practice*.

EXTERNAL REVIEW AND OPEN COMMENT

Draft recommendations were released to the public for open comment from April 6 to April 20, 2016. A total of 71% to 100% of the respondents either agreed or agreed with slight modifications to the recommendations, whereas 14% to 29% of respondents disagreed. Comments received were reviewed by the Expert Panel and integrated into the final manuscript before approval by the Clinical Practice Guideline Committee.

ADDITIONAL RESOURCES

More information, including a Data Supplement with additional evidence tables, a Methodology Supplement with information about evidence quality and strength of recommendations, slide sets, and clinical tools and resources, is available at www.asco.org/small-renal-masses-guideline and www.asco.org/guidelineswiki. Patient information is available at www.cancer.net. Visit www.asco.org/guidelineswiki to provide comments on the guideline or to submit new evidence.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at ascopubs.org/journal/jco.

AUTHOR CONTRIBUTIONS

Data analysis and interpretation: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors
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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Appendix

Table A1. Guideline Expert Panel Membership

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Abbreviation: PGIN, Practice Guidelines Implementation Network.