

PRIOR TO ORIGINAL PUBLICATION (MARCH 2017), THIS GUIDELINE UNDERWENT REVIEW BY THE CUA GUIDELINES COMMITTEE, CUA MEMBERS AT LARGE, AND THE CUA EXECUTIVE BOARD. THE 2023 UPDATES WERE APPROVED BY THE CUA GUIDELINES COMMITTEE AND CUA EXECUTIVE BOARD.

2023 UPDATE – Canadian Urological Association guideline: Management of cystic renal lesions

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SUMMARY OF CHANGES

The current guideline summarizes the state-of-the-art knowledge on the management of cystic renal lesions by updating the 2017 Canadian Urological Association (CUA) guideline on the topic. To do so, we updated our search strategy on June 18, 2022, and have identified 38 relevant articles, which led to a revision of the content of the original publication.

The panel formulated several recommendations using the GRADE evidence to decision framework — a methodological improvement compared to the previous iteration.

Three key recommendation changes were made compared to the previous iteration:

1. Patients with a renal cyst should be classified as per the v2019 Bosniak classification.

2. For Bosniak III or IV cyst measuring ≤ 2 cm, active surveillance is now suggested as the preferred strategy.
3. For Bosniak III or IV cyst measuring 2–4 cm, active surveillance or surgery are suggested as equal options.

The panel made these changes in an attempt to decrease the burden of care for patients, but also acknowledges the low-quality evidence supporting these changes. Consequently, we emphasize the need for shared decision-making. Patients opting for non-surgical strategies should be made aware of the higher uncertainty surrounding the data supporting their treatment of choice.

INTRODUCTION

Cystic renal lesions are usually diagnosed incidentally on routine imaging. With the increasing use of abdominal imaging, there is a growing number of individuals being diagnosed with renal cystic disease.¹ It is estimated that up to one-third of individuals over 60 years of age will be diagnosed with at least one simple renal cyst following abdominal imaging.² Therefore, patients are often referred to urologists for guidance and management of these lesions. Physicians need to distinguish cystic lesions from solid renal masses with necrotic components, which behave more aggressively.³ Hence, the characterization of these cystic renal masses is crucial to determine the best clinical approach. We reviewed the literature and updated the previous iteration of the CUA guideline with the aim of offering guidance to physicians managing cystic renal lesions and to standardize their management across Canada.⁴

METHODS

A comprehensive search of the literature was carried out on June 30, 2016, in MEDLINE and PubMed, which identified 77 relevant studies to inform the development of the 2017 CUA guideline on the management

SUMMARY OF RECOMMENDATIONS

1. For patients first identified with a complex cyst on ultrasound, contrast-enhanced cross-sectional imaging is recommended to better characterize the cyst (*Strong recommendation, moderate certainty in evidence of effects*).
2. Patients identified with a renal cyst should be classified according to the v2019 Bosniak classification (*Expert opinion*).
3. For patients where disagreement or doubt exists regarding the classification of a complex renal cyst, it is the panel's opinion that such cases should be presented at a multidisciplinary meeting if it has the potential to alter management (*Expert opinion*).
4. For patients with a Bosniak I or II cyst, followup imaging is not recommended (*Strong recommendation, moderate certainty in evidence of effects*).
5. For patients with a Bosniak I or II cyst, intervention is only warranted if the cyst becomes symptomatic (*Clinical principle*).
6. For patients with a Bosniak IIF cyst, a followup every 6–12 months is suggested for the first year, and then yearly if the cyst is stable (*Expert opinion*).
7. For patients with a Bosniak IIF cyst that do not demonstrate progression on imaging, a followup of five years is suggested (*Conditional recommendation, very low certainty in evidence of effects*).
8. For patients with a Bosniak III or IV complex renal cyst measuring ≤ 2 cm in size, active surveillance is suggested as the preferred strategy (*Conditional recommendation, low certainty in evidence of effects*).
9. For patients with a Bosniak III or IV complex renal cyst measuring 2–4 cm in diameter, active surveillance or surgery are suggested as the preferred management options (*Conditional recommendation, very low certainty in evidence of effects*).
10. For patients with a Bosniak III or IV cyst measuring >4 cm, surgical excision is suggested as the preferred strategy (*Conditional recommendation, low certainty in evidence of effects*).
11. For patients with a Bosniak III or IV complex renal cyst and significant comorbidities and/or limited life expectancy, observation (or watchful waiting) is suggested as the preferred strategy (*Conditional recommendation, low certainty in evidence of effects*).
12. For patients with a Bosniak III or IV cyst undergoing surgery, partial nephrectomy is suggested over radical nephrectomy when technically and oncologically feasible, especially for small complex cysts (*Conditional recommendation, moderate certainty in evidence of effects*).
13. Patients with a Bosniak III or IV cyst under active surveillance should be offered definitive treatment when the oncological risk increases or when the patient wishes to undergo treatment for personal reasons. Patients should be transitioned to watchful waiting when the competing risks outweigh the benefits of treatment (*Clinical principle*).
14. Patients diagnosed with a ≤ 3 cm Bosniak III or IV cyst considering treatment with thermal ablation should be informed of the higher uncertainty surrounding the data on the efficacy and harms of percutaneous thermal ablation treatment compared to surgery (*Expert opinion*).
15. Patients diagnosed with a Bosniak IV cyst may be considered for biopsy if there is a significant solid component amenable to biopsy and if the result may alter management. Renal masses without a solid component should not be biopsied due to low diagnostic yield (*Adopted from Kidney Cancer Research Network of Canada [KCRNC] consensus statement on the role of renal mass biopsy in the management of kidney cancer; expert opinion*).

of cystic renal masses (Supplementary Figure 1; available at cuaj.ca). An updated search of the literature was completed on June 18, 2022, using the same search terms, and identified an additional 38 relevant articles, which led to a revision of the content of the original publication (Supplementary Figure 2; available at cuaj.ca).⁴ The search terms used were: Bosniak, Bosniak classification, renal cysts, renal cell carcinomas, renal and kidney cancers. Prospective or retrospective studies, as well as review studies providing data on the classification, management, and outcomes of complex cystic renal masses were included. Reports limited to children or animal and basic science studies were excluded. Similarly, reports limited to congenital or acquired renal cystic diseases and case reports of five or fewer cases were also excluded.

For each recommendation, the panel considered, when available, the 11 domains of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence-to-decision framework: 1) problem; 2) desirable effects; 3) undesirable effects; 4) certainty of evidence; 5) values; 6) balance of effects; 7) resource required; 8) certainty of evidence of required resources; 9) cost-effectiveness; 10) equity; and 11) acceptability. The strength of each recommendation was rated as strong or conditional (weak).

Strong recommendations were made when the desirable benefits of treatment outweighed the undesirable consequences (harms) and are worded as *recommends*. Conditional recommendations were made when the benefits of treatment probably outweighed the harms and are worded as *suggests*. When insufficient evidence was available for a recommendation, the panel reported additional information as clinical principle or as expert opinion. Importantly, all recommendations are based on expert review of the literature and represent the consensus of all co-authors of this guideline.

The objectives of this guideline were to perform a comprehensive review of the literature and to make recommendations on the characterization, management, and followup of incidentally discovered cystic lesions. The panel proceeded with full awareness of the limitations of the cystic renal lesions literature. The low-quality evidence made it difficult to make strong recommendations for the optimal treatment and followup of cystic renal lesions. Furthermore, as the majority of Bosniak category II and IIF cystic lesions are managed conservatively, the literature tends to overestimate the true malignancy risk of these lesions, as only the most complex ones undergo surgery. Nevertheless, while taking these limitations into account, the panel did its best to summarize the current literature and provide some guidance on the management of cystic lesions.

EVIDENCE SYNTHESIS

Bosniak classification – Introduction

■ RECOMMENDATION 1

For patients first identified with a complex cyst on ultrasound, contrast-enhanced, cross-sectional imaging is recommended to better characterize the cyst (Strong recommendation, moderate certainty in evidence of effects).

■ RECOMMENDATION 2

Patients identified with a renal cyst should be classified according to the v2019 Bosniak classification (Expert opinion).

■ RECOMMENDATION 3

For patients where disagreement or doubt exists regarding the classification of a complex renal cyst, it is the panel's opinion that such cases should be presented at a multidisciplinary meeting if it has the potential to alter management (Expert opinion).

Renal cysts can be easily identified using standard medical imaging and, in most cases, a histological diagnosis is not required; however, lesions that are more complex may require more detailed characterization to inform the differential diagnoses and guide subsequent management. It is especially important for physicians managing the more complex cystic lesions to differentiate them from solid renal masses with necrotic components, which behave more aggressively.³

The Bosniak renal cyst classification was initially described in 1986⁵ and was later updated to add a new category called category IIF.⁶ It was originally described using computed tomography (CT) imaging but other modalities, such as magnetic resonance imaging (MRI), ultrasound (US), or contrast-enhancement ultrasound (CEUS), are now being used to help better delineate these lesions.⁷⁻¹⁷ For patients first identified with a complex cyst (Bosniak classification >2) on US, contrast-enhanced, cross-sectional imaging is recommended to better characterize the cyst.

Although the Bosniak classification remains the most commonly used classification to characterize renal cysts, it has traditionally been subject to poor interobserver agreement.^{4,6,10,18-23} Most of the observed variation was seen among cysts categorized as Bosniak II, IIF, and III. In an attempt to diminish the shortcomings of the traditional Bosniak classification, namely the inter-reader variability, Silverman et al have proposed a revision of the classification (Bosniak v2019 classification).^{24,25} A detailed description and rationale for the proposed

revision may be found in the original publication.²⁵ Although its clinical impact and benefit of the inter-rater variability remain to be well-studied, the panel members believe that the v2019 classification is currently the preferred Bosniak classification.²⁶⁻³⁰ Importantly, if there is disagreement or doubt regarding the classification of a complex renal cyst, it is the panel's opinion that such cases should be presented at a multidisciplinary meeting if this has the potential to alter management.

Description of Bosniak classification

By means of the Bosniak classification, renal cystic lesions can be categorized in increasing order according to risk of malignancy. Table 1 details the traditional Bosniak classification and the proposed update (v2019).

BOSNIAK CATEGORY I

Lesions classified as category I are simple renal cysts and represent the majority of renal lesions detected by abdominal imaging.² These lesions are characterized by their regular contour and a clear interface with the renal parenchyma. They do not contain any septa or calcifications, nor do they demonstrate enhancement following intravenous contrast agent injection. They are homogeneous, with fluid attenuation varying from 0–20 HU on CT scan. These lesions are also easily identifiable by US and appear as thin-walled, anechoic lesions with posterior enhancement and sharply marginated smooth walls.^{6,9} The v2019 classification has slightly refined the criteria for this category by limiting the thickness of the cyst wall to ≤ 2 mm and enhancement of the cyst wall may be observed.²⁵

BOSNIAK CATEGORY II

These cysts are slightly more complex than category I cysts.⁶ The v2019 Bosniak classification has described six different types of Bosniak II cysts on CT scans, while three are described on MRIs.³¹ The v2019 classification describes category II cysts as thin wall cysts (≤ 2 mm) that may contain thin (≤ 2 mm) and few septa (≤ 3) that may or may not enhance and/or calcifications of any type. Other types of Bosniak II cysts are detailed in Table 1. Importantly, homogeneous, non-enhancing, hyperdense cysts (≥ 20 HU), regardless of size, are also categorized as Bosniak II cysts based on the v2019 classification. The traditional Bosniak classification categorized these cysts as Bosniak IIF if > 3 cm.

Regardless of the Bosniak classification version being used, the overwhelming majority of Bosniak category II cysts are considered benign. Although review of the literature has demonstrated that approximately 10% of the operated category II cysts are malignant, this is an overestimation of the true malignancy risk, as a

Table 1. Bosniak classification v.2019 and management recommendations

Bosniak v.2019 CT scan classification	Recommendations
Bosniak category I (simple renal cyst) <ul style="list-style-type: none"> – Well-defined, thin (≤ 2 mm), smooth wall – No septa or calcification – Homogenous simple fluid (-9 to 20 HU) – The wall may enhance 	– No followup required
Bosniak category II 6 types; all with well-defined, smooth wall: <ol style="list-style-type: none"> 1. Cystic mass with thin (≤ 2 mm) and few (1–3) septa; septa and wall may enhance; calcification of any type 2. Homogeneous hyperattenuating (> 70 HU) at non-contrast CT 3. Homogeneous non-enhancing masses > 20 HU at renal mass protocol CT, may have calcification(s) 4. Homogeneous mass -9–20 HU at non-contrast CT 5. Homogeneous mass 21–30 HU at portal venous-phase CT 6. Homogeneous low-attenuation masses that are too small to characterize 	– No followup required
Bosniak category IIF <ul style="list-style-type: none"> – Smooth, minimally thickened (3 mm), enhancing wall – Smooth, minimally thickening (3 mm) of one or more enhancing septa – Many (≥ 4) smooth, thin (≤ 2 mm), enhancing septa 	– Followup recommended – Imaging every 6–12 months for the first year and annually for 5 years if no progression
Bosniak category III <ul style="list-style-type: none"> – One or more enhancing thick (≥ 4 mm) wall or septa – One or more enhancing nodule(s) (displaying ≤ 3 mm convex protrusion with obtuse margins – perpendicular axis) 	– Active surveillance if ≤ 2 cm – Active surveillance or surgical excision if 2–4 cm – Surgical excision if > 4 cm – Thermal ablation in select cases
Bosniak category IV <ul style="list-style-type: none"> – One or more enhancing nodule(s) (displaying > 4 mm convex protrusion with obtuse margins – perpendicular axis) – One or more enhancing nodule(s) (convex protrusion of any size with acute margins) 	– Active surveillance if ≤ 2 cm – Active surveillance or surgical excision if 2–4 cm – Surgical excision if > 4 cm – Thermal ablation in select cases – Potential role for biopsy of solid component to confirm malignancy

For the v2019 MRI classification, please refer to the Silverman et al original publication.²⁵ CT: computerized tomography; HU: Hounsfield units.

significant proportion of these studies were published before the addition of the Bosniak IIF category and many of these cysts were managed conservatively without pathological confirmation (Table 2). If we exclude the earlier studies and believe that most of the conservatively managed cysts were benign, the risk of malignancy for these lesions would be $< 5\%$. This rate is still believed to be a gross overestimation of the true risk, as most of the malignant category II lesions had features that made them too complex to be considered a true category II cyst.

BOSNIAK CATEGORY IIF

This category represents moderately complex cystic lesions. Any lesions not fulfilling the criteria for category II but not as complex as category III should be classified

Table 2. Studies and risk of malignancy for complex cystic lesions (pathologically confirmed)

Authors (year of publication)	Cohort size n (pathology confirmed)	Bosniak category I* n (%)	Bosniak category II n (%)	Bosniak category IIF n (%)	Bosniak category III n (%)	Bosniak category IV n (%)
Brown (1989) ⁴¹	24 (24)	0/2 (0)	0/4 (0)	–	3/12 (25)	4/6 (67)
Aronson (1991) ³⁹	16 (16)	–	0/4 (0)	–	5/9 (56)	7/7 (100)
Wilson (1995) ²¹	24 (24)	0/7 (0)	4/5 (80)	–	4/4 (100)	6/6 (100)
Cloix (1996) ¹⁸	32 (32)	1/2 (50)	1/7 (14)	–	4/13 (31)	5/10 (50)
Siegel (1997) ⁵⁶	70 (70)	0/22 (0)	1/8 (13)	–	5/11 (46)	26/29 (90)
Bielsa (1999) ⁴⁰	20 (20)	–	1/8 (13)	–	7/9 (78)	3/3 (100)
Curry (2000) ¹⁹	116 (82)	0/4 (0)	0/11 (0)	–	29/49 (59)	18/18 (100)
Koga (2000) ⁴⁹	35 (35)	0/11 (0)	1/2 (50)	–	10/10 (100)	12/12 (100)
Limb (2002) ⁵⁰	57 (57)	–	3/28 (11)	–	8/29 (28)	–
Harisinghani (2003) ⁴⁴	28 (28)	–	–	17/28 (61)	–	–
Israel (2003) ⁴⁵	81 (40)	–	–	0/3 (0)	9/21 (43)	16/16 (100)
Israel (2003) ⁴⁶	42 (3)	–	–	2/3 (67)	–	–
Israel (2004) ⁴⁹	69 (25)	0/1 (0)	–	0/1 (0)	12/15 (80)	8/8 (100)
Spaliviero (2005) ⁵⁹	47 (47)	1/1 (100)	2/9 (22)	1/4 (25)	6/12 (50)	19/21 (91)
Loock (2006) ⁵¹	53 (17)	–	–	2/2 (100)	4/8 (50)	6/7 (86)
Quaia (2007) ⁵⁴	40 (30)	–	–	–	3/12 (25)	18/18 (100)
Clevert (2008) ⁷	37 (14)	–	–	1/1 (100)	3/6 (50)	7/7 (100)
Song (2008) ⁵⁸	104 (104)	–	3/26 (12)	0/3 (0)	21/38 (55)	32/37 (86)
Gabr (2009) ⁴²	50 (7)	–	1/3 (33)	4/4 (100)	–	–
O'Malley (2009) ⁵²	112 (34)	–	–	0/1 (0)	27/33 (82)	–
Kim (2010) ⁶²	125 (125)	0/34 (0)	3/23 (13)	1/10 (10)	21/25 (84)	28/33 (85)
Pinheiro (2011) ⁵³	37 (37)	–	–	–	5/15 (33)	19/22 (86)
Weibl (2011) ⁷⁹	113 (69)	–	0/2 (0)	1/1 (100)	15/27 (56)	30/39 (77)
You (2011) ⁶¹	75 (75)	–	–	–	22/39 (56)	31/36 (86)
Smith (2012) ⁵⁷	213 (123)	–	–	4/16 (25)	58/107 (54)	–
Han (2012) ⁴³	98 (98)	–	0/9 (0)	3/18 (17)	21/39 (54)	29/32 (91)
Graumann (2013) ³²	32 (3)	–	–	2/3 (67)	–	–
El-Mokadem (2014) ²⁰	154 (39)	–	–	8/9 (89)	10/16 (63)	12/14 (86)
Kim (2014) ⁴⁸	164 (85)	–	–	6/21 (29)	26/38 (68)	26/26 (100)
Hindman (2014) ³³	156 (19)	–	–	17/19 (90)	–	–
Reese (2014) ⁵⁵	113 (113)	–	2/16 (13)	2/6 (33)	21/32 (66)	50/59 (85)
Xu (2014) ⁶⁰	87 (87)	–	–	0/10 (0)	14/26 (54)	47/51 (92)

*Studies limited to the ones where complex lesions were also evaluated. †Overall, 142 Bosniak category II, 1018 Bosniak category IIF, 182 Bosniak category III, and 51 Bosniak category IV were managed by surveillance. ‡Represent an overestimation of the true malignancy risk given the fact that the majority of lesions were managed with surveillance.

in this category. These cysts were traditionally described as cysts containing an increased number of thin septa or slightly thickened but smooth septa. They may also

contain thick or nodular calcification but without contrast-enhancing features. Large, hyperdense cysts (≥ 3 cm and >20 HU) were also traditionally classified as

Table 2. Studies and risk of malignancy for complex cystic lesions (pathologically confirmed)

Authors (year of publication)	Cohort size n (pathology confirmed)	Bosniak category I* n (%)	Bosniak category II n (%)	Bosniak category IIF n (%)	Bosniak category III n (%)	Bosniak category IV n (%)
Smith (2015) ⁶³	286 (100)	–	–	3/8 (38)	29/72 (40)	18/20 (90)
Oh (2016) ¹²²	324 (324)	1/103 (1)	2/53 (4)	7/41 (17)	27/71 (38)	46/56 (82)
Moussessian (2017) ¹¹	86 (60)				28/39 (72)	18/21 (86)
Zhong (2017) ¹¹²	35 (28)			0/4 (0)	5/9 (56)	15/15 (100)
Bileskiene (2018) ¹¹³	73 (43)				24/43 (56)	
Nouhaud (2018) ¹¹⁴	216 (216)			5/9 (56)	60/86 (70)	110/121 (91)
Lam (2018) ¹¹⁵	25 (25)				15/25 (60)	
Kashan (2018) ⁹⁷	176 (129)				49/70 (70)	49/59 (83)
Pruthi (2018) ⁹⁵	140 (29)			2/4 (50)	8/15 (53)	9/11 (82)
Pitra (2018) ¹¹⁶	35 (31)	0/1 (0)		0/1 (0)	5/16 (69)	13/15 (86)
Keseroglu (2019) ¹¹⁷			3/38 (8)	7/22 (32)	21/38 (55)	40/58 (69)
Sefik (2021) ¹¹⁸					49/79 (62)	
Lucocq (2021) ¹¹⁹	317 (75)				23/29 (79)	39/46 (85)
Yan (2021) ¹²⁰	73 (73)					
Audenet (2022) ¹²¹	52 (52)				19/52 (37)	
Couture (2022) ³⁶	181 (3)		0/3			
Total	3032 (2106)[‡]	3/188 (2)	26/259 (10)[†]	95/340 (28)[†]	708/1228 (58)	770/862 (89)

*Studies limited to the ones where complex lesions were also evaluated. †Overall, 142 Bosniak category II, 1018 Bosniak category IIF, 182 Bosniak category III, and 51 Bosniak category IV were managed by surveillance. ‡Represent an overestimation of the true malignancy risk given the fact that the majority of lesions were managed with surveillance.

Bosniak IIF cysts, but this is no longer the case with the v2019 classification.³²⁻³⁴

In an attempt to diminish inter-reader variability, the v2019 classification has further defined what was meant by an increased number of septa or a slightly thickened septum. Thus, v.2019 Bosniak IIF cysts are described as: 1) cysts with smooth minimally thickened (3 mm) enhancing wall; 2) cysts with ≥ 1 thickened enhancing septa (3 mm); or 3) cysts with many (≥ 4) smooth, thin (≤ 2 mm), enhancing septa.

The review of the literature revealed that approximately 28% of surgically treated Bosniak IIF lesions were malignant; however, as previously reported, this is likely an overestimation of the true malignancy risk.⁴ If all conservatively managed Bosniak IIF cysts were benign, the risk of malignancy would approach 7% (Table 2). Similar findings were reported by two separately conducted systematic reviews.^{22,35}

Consequently, although helpful, the addition of the Bosniak IIF category did result in a substantial number of patients being followed for a benign cyst. Interestingly, Couture et al have examined the impact of the v2019

classification on cysts classified as IIF based on the traditional classification.³⁶ The authors found that 76% (138/181) of Bosniak IIF cysts would have initially been diagnosed as Bosniak II according to the revised classification. The v2019 classification misidentified one cyst that eventually progressed to Bosniak IV, but the authors reported that the patient was managed by active surveillance with no signs of metastases >6 years after progressing to Bosniak IV. Thus, the authors concluded that the v2019 revision may help minimize the overdiagnosis and followup of such cysts, avoiding important costs and harm to patients.^{37,38}

BOSNIAK CATEGORY III

This category encompasses a variety of cystic lesions whose differentiation between malignant and benign cannot be reliably made by imaging.⁶ According to the traditional Bosniak classification, these cysts present with wall irregularity and thickening, as well as wall nodularity. They may also demonstrate contrast-enhanced septa (usually multiple) that are usually irregular, thickened, and/or calcified. A significant proportion of these cysts

are thought to be malignant (mean of 58%) (Table 2)^{4,7,18-21,32-34,39-63} with larger lesions or cysts containing septal nodule being more likely to be malignant than smaller ones^{4,22,64} or than septated cysts without nodularity.⁶⁴

In an attempt to decrease the number of benign cysts classified as a Bosniak III, the v2019 has attempted to better define the characteristics of this category and has removed the requirement that all cystic masses with 'measurable enhancement' be included as either a Bosniak III or IV.²⁵ Consequently, the v2019 classification now defines Bosniak III cysts as: 1) cysts with one or more enhancing thickened septa/wall (≥ 4 mm width); and/or 2) cysts with one or more irregular wall or septa (displaying ≤ 3 mm obtusely margined convex protrusion – perpendicular axis).^{25,65,66} The clinical impact of these modifications remains to be properly evaluated. According to a report for Tse et al, the prevalence of malignancy for v2019 Bosniak III cysts was 60%.⁶⁷ The prevalence varied according to subclasses. For examples, thick wall/septa Bosniak III cysts had a malignancy rate of 49%, while the rate was 76% for Bosniak III cysts displaying nodule(s) with obtuse margin of protrusion.

BOSNIAK CATEGORY IV

According to the original classification, category IV cysts may have similar characteristics to those classified as category III. They usually demonstrate wall thickening and/or gross and nodular thickened septa, but a solid contrast-enhancing component is also observed adjacent to the cyst wall or septa.^{6,20,34,68-70} The v2019 classification has only made small modifications to this category, as it defines Bosniak IV cysts as cysts with a nodular component of any size if the margins of protrusion are acute, or a nodular component ≥ 4 mm if the margins of protrusion are obtuse (perpendicular axis).

Lesions in this category should be considered malignant until proven otherwise, with a mean malignancy rate of 89% (Table 2).^{6,34,71} Here again, the clinical impact of the v2019 classification remains to be properly studied, but Tse et al have reported a slightly higher rate of malignancy among cysts categorized as a IV due to a nodule with acute margins of protrusion compared to Bosniak IV cysts displaying nodule with obtuse ones (87 vs. 76%).⁶⁷

Intervention and followup

■ RECOMMENDATION 4

For patients with a Bosniak I or II cyst, followup imaging is not recommended (*Strong recommendation, moderate certainty in evidence of effects*).

■ RECOMMENDATION 5

For patients with a Bosniak I or II cyst, intervention is only warranted if the cyst becomes symptomatic (*Clinical principle*).

BOSNIAK CATEGORY I

This category is composed of simple cysts that are considered benign. One should remember that the natural history of these cysts is that the majority will grow over time and thus, growth should not necessarily be considered a sign of malignancy.^{72,73} Transformation into a more complex cyst is rare and has been reported in only a handful of cases.⁷²⁻⁷⁷ Therefore, as this is a rare occurrence, followup imaging is not recommended and intervention is only warranted if the cyst becomes symptomatic (i.e., bleeding, recurrent infection, or pain). Treatment options include percutaneous management (aspiration \pm sclerotherapy) or surgery.⁷⁸ Percutaneous cyst decompression may also be considered prior to offering definitive treatment as a means to confirm that the source of symptoms are cyst-related.

BOSNIAK CATEGORY II

These minimally complex cysts are also generally considered benign, but there are reports in the literature of category II lesions being malignant (Table 2),^{4,18,19,21,39-43,47,49,50,55,56,58,59,71,79} however, the literature is thought to overestimate the true risk of malignancy among category II cysts, as the majority were managed conservatively or had features that made them too complex to be categorized as a Bosniak II cyst.^{7,19,42,45,47,48,51,54,79} Importantly, even if malignant, most behave in a relatively benign fashion. Thus, for patients diagnosed with a properly classified Bosniak II cyst, followup is not suggested. Similar to Bosniak I cysts, intervention is only warranted if the cyst becomes symptomatic. When there is doubt as to their categorization based on imaging characteristics, these lesions should be considered as being Bosniak category IIF lesions and followed accordingly.

BOSNIAK CATEGORY IIF

■ RECOMMENDATION 6

For patients with a Bosniak IIF cyst, a followup every 6–12 months is suggested for the first year, and then yearly if the cyst is stable (*Expert opinion*).

■ RECOMMENDATION 7

For patients with a Bosniak IIF cyst that do not demonstrate progression on imaging, a followup of five years is suggested (*Conditional recommendation, very low certainty in evidence of effects*).

The risk of malignancy among these cysts is low (Table 2) but not trivial, and as the “F” in category IIF stipulates, a followup of these cysts is suggested. Although the traditional belief was that approximately 15% of category IIF cysts will progress in complexity over time (to Bosniak category III or IV), more recent reports have suggested that the rate was closer to 5%.^{8,20,32,33,52} Progression is more likely to occur within the first two years and rarely occurs after three years.^{36,52,80} Unfortunately, a clear progression pattern is yet to be identified and as a result, there is no evidence-based time limit for followup imaging.

Bosniak IIF cysts have a low malignancy rate and if malignant, a low metastatic potential. Thus, it seems reasonable to follow these lesions with imaging every 6–12 months for the first year, and then yearly thereafter if the cyst is stable. Closer monitoring may be performed but may potentially reduce the detection of a progression if the changes in the cysts from imaging to imaging are very small. CEUS may also be used to better delineate the septa number, septa and/or wall thickness, solid component, and the enhancement.⁷⁻¹⁷ Ultrasound in combination with contrast-enhanced CT or MRI may be used if the lesion is stable on followup. A followup of five years is suggested for cysts that do not demonstrate progression on imaging.

BOSNIAK CATEGORIES III AND IV

■ RECOMMENDATION 8

For patients with a Bosniak III or IV complex renal cyst measuring ≤ 2 cm in size, active surveillance is suggested as the preferred strategy (*Conditional recommendation, low certainty in evidence of effects*).

■ RECOMMENDATION 9

For patients with a Bosniak III or IV complex renal cyst measuring 2–4 cm in diameter, active surveillance or surgery are suggested as the preferred management options (*Conditional recommendation, very low certainty in evidence of effects*).

■ RECOMMENDATION 10

For patients with a Bosniak III or IV cyst measuring >4 cm, surgical excision is suggested as the preferred strategy (*Conditional recommendation, low certainty in evidence of effects*).

■ RECOMMENDATION 11

For patients with a Bosniak III or IV complex renal cyst and significant comorbidities and/or limited life expectancy, observation (or watchful waiting) is suggested as the preferred strategy (*Conditional recommendation, low certainty in evidence of effects*).

■ RECOMMENDATION 12

For patients with a Bosniak III or IV cyst undergoing surgery, partial nephrectomy is suggested over radical nephrectomy when technically and oncologically feasible, especially for small complex cysts (*Conditional recommendation, moderate certainty in evidence of effects*).

■ RECOMMENDATION 13

Patients with a Bosniak III or IV cyst under active surveillance should be offered definitive treatment when the oncological risk increases or when the patient wishes to undergo treatment for personal reasons. Patients should be transitioned to watchful waiting when the competing risks outweigh the benefits of treatment (*Clinical principle*).

Studies of resected Bosniak III and IV lesions have found that 50–60% and 80–90% of these cysts, respectively, are malignant (Table 2). The vast majority of malignant cystic renal masses are multilocular cystic renal cell carcinomas (mRCC)⁸¹ but all RCC subtypes may present in a predominantly cystic form.⁸³ There is increasing evidence that cystic RCCs have relatively low metastatic potential and carry an excellent prognosis.⁸²⁻⁸⁷ To reflect this indolent behavior, the International Society of Urological Pathology (ISUP) has modified its terminology and now recommends calling these lesions multilocular cystic renal neoplasm with low malignant potential.⁸¹

Although the traditional treatment dogma was to surgically excise all Bosniak III and IV cysts, recent direct and indirect evidence suggest that this may lead to significant overtreatment. Firstly, they have a relatively high rate of benign histology. Secondly, several studies have compared the prognosis of mRCCs to that of solid RCCs. mRCCs have consistently fared better than their counterparts on both cancer-specific and overall survival.^{40,85,86,88-93} One potential explanation for this better prognosis is that the majority of mRCCs tumor volume is fluid and thus, the actual tumor burden is much lower when compared to similar-sized solid tumors.⁸⁶ As the outcomes of these tumors do not seem to be influenced by the overall lesion size, some experts have even suggested abandoning the current pathological T staging for mRCC and to reassign them a new stage called pT1c (c for cystic).⁸⁶

Given the relatively high rate of benign histology and relatively indolent nature even if malignant, there is emerging evidence suggesting that these Bosniak III and IV cysts, like small renal masses, can be safely managed by active surveillance.^{7,19,20,45,47,48,51,54,57,65,79,86} A small number of retrospective studies has supported this claim and one prospective Canadian study on the topic is currently ongoing (NCT04558593).^{67,94-98}

Given their low risk of kidney cancer-related mortality, observation (or watchful waiting) is suggested as the preferred strategy for patients with significant comorbidities and/or limited life expectancy, regardless of the cyst size. Extrapolating mainly from the small renal mass literature and similar to the recommendations from CUA guideline on the management of small renal mass,⁹⁹ active surveillance is suggested as the preferred management strategy for patients with a Bosniak III or IV cyst measuring ≤ 2 cm. Immediate definitive treatment (i.e., surgery or thermal ablation — its role is further discussed below) remains an option and should be discussed with patients to ensure they are fully informed.

Given the absence of clear evidence, the panel was unable to achieve a consensus as to the preferred strategy for patients with a Bosniak III or IV cyst measuring 2–4 cm. Consequently, active surveillance or surgery are suggested as the preferred management options. Ideal candidates for active surveillance were felt to be: well-informed patients, patients at lower risk for malignancy (e.g., Bosniak III cyst with no wall/septa irregularity, Bosniak III or IV cysts with small nodular component), or patients at high surgical risk due to comorbidities or limited life expectancy. Thermal ablation therapies also remain an option in well-informed patients (further discussed below).

For patients with a Bosniak III or IV cyst measuring >4 cm, surgical excision is suggested as the preferred strategy. Partial nephrectomy is suggested as the surgery of choice when technically and oncologically feasible, although radical nephrectomy should still be discussed as an option.⁹⁹ Given the low metastatic potential of RCC, the panel members believe that close surgical margins can be safely performed with low risk of tumor recurrence. Although, surgical excision is the preferred strategy for these patients, active surveillance may still be considered in select cases, notably for Bosniak III patients with no wall/septa irregularity or for patients at high surgical risk due to comorbidities.

Patients managed with active surveillance should be made aware of the higher uncertainty surrounding the data and of the lack of clear intervention criteria specific to this population. In the absence of specific criteria, it is the panel members' opinion that the same criteria as the ones used to define progression in the small renal mass population should be applied (i.e., growth of tumor to >4 cm, consecutive growth rate >0.5 cm/year, progression to metastases, and patient's choice).⁹⁹ Patients under active surveillance should be transitioned to watchful waiting when the competing risks outweigh the benefits of treatment. Likewise, there is currently no evidence to dictate any specific followup scheme. As

such, it is the panel members' opinion that the same followup scheme as the one proposed for the small renal mass population should be observed (i.e., abdominal imaging every 3–6 months for the first year, and then once every 6–12 months, if the cyst remains stable).⁹⁹

Thermal ablation therapies

■ RECOMMENDATION 14

Patients diagnosed with a ≤ 3 cm Bosniak III or IV cyst considering treatment with thermal ablation should be informed of the higher uncertainty surrounding the data on the efficacy and harms of percutaneous thermal ablation treatment compared to surgery (*Expert opinion*).

Extrapolating mainly from the small renal mass literature, thermal ablation therapies may be considered an alternative in select cases.⁹⁹ There is also some evidence from small case series supporting radiofrequency ablation (RFA) as a treatment alternative for this population.^{23,100-103} Overall, given the limited data, RFA should be reserved to patients with small (generally ≤ 3 cm) Bosniak category III and IV cysts who are poor operative candidates and in whom active surveillance is not being considered. To the best of our knowledge, the role of cryotherapy in the management of Bosniak III or IV cysts is not well-defined, with only a handful of cases reported to have been treated by the approach in the literature.⁵² Patients opting for the treatment alternative should be made aware of the sparse literature on the management of cystic renal lesions using these approaches.

Role of renal tumor biopsy in the management of cystic lesions

■ RECOMMENDATION 15

Patients diagnosed with a Bosniak IV cyst may be considered for biopsy if there is a significant solid component amenable to biopsy and if the result may alter management. Renal masses without a solid component should not be biopsied due to low diagnostic yield (*Adopted from Kidney Cancer Research Network of Canada [KCRNC] consensus statement on the role of renal mass biopsy in the management of kidney cancer; expert opinion*).

There is now substantial evidence supporting the role of renal tumor biopsy (RTB) for the pretreatment identification of the histology of solid renal masses.^{104,105} RTB is safe, accurate, and reliable. Additionally, needle core biopsy has been shown to decrease overtreat-

ment rates when used in the management of solid small renal masses,^{105,106} however, its role in the management of cystic renal masses is not clearly defined.

There is evidence that RTBs are significantly less informative for the diagnosis of cystic lesions than for solid ones.^{104,106-109} Therefore, the utility of RTB in cystic lesions is less than that observed with solid renal masses. Nevertheless, there is literature supporting the role of RTB for histological identification of complex cysts.^{44,100,101,107} It is generally felt that RTB is not diagnostic for most Bosniak III cysts, as there is minimal targetable solid component and therefore should be avoided. For Bosniak IV cysts, a biopsy of the solid component may be considered to confirm the presence of a malignant tumor and to help with decision-making if the result has the potential to alter management or if a treatment by thermal ablation is planned.^{6,44,100,101,107,108} Of interest, some reports have suggested that the combination of fine needle aspiration (FNA) and core biopsy may lead to a slightly higher diagnostic yield than core biopsy alone.¹¹⁰ Nevertheless, in most centers of experience, RTB are performed using core biopsy alone, as the combination is thought to add minimal value. Experts have also reported a higher diagnostic rate in Bosniak IV cyst when the solid component was > 1 cm.¹⁰⁸

CONCLUSIONS

The evidence for optimal management of cystic RCC, including followup, is of low quality and based on case series and indirectly from the management of solid small renal masses. Nevertheless, this guideline provides some guidance to urologists on how to best manage and follow these cystic lesions.

In summary, Bosniak category I and II cysts do not routinely require followup, whereas Bosniak category IIF cysts should be followed with routine imaging. Extrapolating from the small renal mass literature, active surveillance is now suggested as the management of choice for patients with a Bosniak category III or IV cyst measuring ≤ 2 cm. For patients with a Bosniak III or IV complex renal cyst measuring 2–4 cm in diameter, active surveillance or surgery are both suggested as the preferred management options. For patients with a Bosniak category III or IV cyst measuring > 4 cm, surgical excision remains the mainstay treatment. Patients opting for non-surgical strategies should be aware of higher uncertainty surrounding the data supporting their treatment of choice.

The panel members recognize that there is a dire need for further studies that will offer guidance to physicians as to the optimal selection criteria for active surveillance and to define what criteria should be used as indications for intervention for patients who selected active surveillance as their initial management strategy.

COMPETING INTERESTS: Dr. Richard has been an advisory board member for Bayer, Janssen, and Sanofi; and a speakers' bureau member for Abbvie, Amgen, Astellas, Ferring, and Janssen. Dr. Bhindi has been an advisory board member for Bayer and Janssen; and has received speaker honoraria from Merck. Dr. Breaux has been an advisory board member for Ferring (bladder cancer). Dr. Jewett has been an advisory board member for and received payment from Sesen Bio and Theralase Technologies Ltd. Dr. Kapoor held consultant or advisory roles with Amgen, Bristol-Myers Squibb, Eisai, Ipsen, Janssen Oncology, Merck, Novartis, and Pfizer; and received institutional research funding from Bristol-Myers Squibb. Dr. Pouliot has been an advisory board member for and received payment or grants from Amgen, Astellas, Astra Zeneca, Bayer, Janssen, Merck, Novartis, TerSera, and Tolmar; holds investments in Allogene Therapeutics; and has participated in clinical trials supported by CUOG and Kidney Cancer Canada. Dr. Leveridge has participated in advisory board meetings for Bayer and Pfizer; and has received honoraria from Bayer, Janssen, and Pfizer. Dr. So has been an advisory board member for Abbvie, Amgen, Bayer, Ferring, Janssen, Merck, and TerSera. Dr. Rendon has been an advisory board and speakers' bureau member for and has received honoraria from Abbvie, Amgen, Astellas, Astra Zeneca, Bayer, Ferring, Janssen, Pfizer, Roche, Sanofi, and Tolmar; has received honoraria/grants from Abbvie, Astellas, Bayer, Ferring, Janssen, Sanofi, TerSera, and Tolmar; holds investments in Myovant; and has participated in clinical trials supported by Abbvie, Astellas, Bavarian Nordic, Bayer, Ferring, Janssen, Myovant, and Sanofi. Dr. Tanguay has received honoraria from Pfizer, Roche Canada, and Sanofi; and has held consulting or advisory roles with BMS, Merck, Pfizer, Roche Canada, and Sanofi. The remaining authors do not report any competing personal or financial interests related to this work.

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