Natural History of Complex Renal Cysts: Clinical Evidence Supporting Active Surveillance

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Purpose: We evaluated intervention rates, progression and cancer specific survival outcomes in patients with complex renal cysts in a single center experience.

Materials and Methods: We used the Montage™ radiology data mining system to retrospectively identify all reported cases of complex renal cyst at our institution from 2001 to 2013. The primary study end points were overall and cancer specific survival. The secondary end points included radiographic progression and upgrading, clinical progression and final histology on surgical pathology.

Results: We identified 336 patients with a complex renal cyst, of whom 185 (55.1%), 122 (36.3%) and 29 (8.6%) had Bosniak IIF, III and IV cysts, respectively. Median followup was 67.1 months (range 34.4 to 101.6). In the 332 patients with followup there was 1 cancer specific death (0.3%) and overall mortality was 6.2%. Ten (5.4%), 37 (30.3%) and 18 patients (62.1%) with Bosniak IIF, III and IV, respectively, underwent surgical or ablative intervention. The indication for intervention was predominantly age (intervention vs no intervention mean ± SD age 50.1 ± 15.9 vs 62.5 ± 13.9 years) and complexity. Surgery with radical and partial nephrectomy (23 patients or 35% and 37 or 57%, respectively) was most common and favorable final pathology was identified. Two treated patients experienced recurrence during followup. When excluding patients with von Hippel-Lindau syndrome, the cancer specific survival rate was 100%.

Conclusions: Cancer survival and overall survival in patients with Bosniak IIF to IV renal cysts was high with only 1 cancer specific death. No cancer deaths were recorded in patients who did not undergo intervention. Reconsidering management guidelines for complex renal cysts is warranted, particularly consideration for initial surveillance of Bosniak III cysts.

Key Words: kidney neoplasms; carcinoma, renal cell; cysts; von Hippel-Lindau disease; mortality

Abbreviations and Acronyms

CSS = cancer specific survival
FG = Fuhrman grade
RCC = renal cell carcinoma
SRM = small renal masses
VHL = von Hippel-Lindau syndrome

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THE incidence of RCC has been steadily increasing by 3% to 4% annually, likely due to greater use of cross-sectional imaging with stage migration toward SRMs.[1–3] In 2016 there were approximately 62,700 new cases of RCC but mortality has not increased by the same amount.[4] With the increasing identification of solid SRMs and RCC there has also been increased identification of cystic renal masses and 8% to 15% of them may have a complex appearance.[5–7]

Since the introduction of the Bosniak classification of renal cysts,[8] the management of renal cysts has been

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primarily guided by radiographic assessment. Based on radiographic features of possible malignancy (septa presence and thickness, calcifications, enhancement, solid components and size) identified on triphasic computerized tomography, cystic renal masses are classified as Bosniak I to IV. Modification of the classification in 1993 introduced the IIF category or Bosniak II cysts with features that warranted short term (3 to 6-month) imaging surveillance.[9–11]

Recent meta-analyses have described a RCC incidence of 6% to 18%, 51% to 55% and 89% to 91% for Bosniak IIF, III and IV cysts, respectively.[11] Based on this correlation guidelines for managing cystic renal masses have typically recommended surgical excision for Bosniak III and IV lesions while close surveillance is recommended for Bosniak IIF lesions.[12,13]

However, more recent population based studies have established that cystic RCC has better CSS than solid clear cell RCC of the same clinical stage, specifically clinical T1b and T2 lesions.[14,15] Smith et al surveyed a small cohort of patients with Bosniak IIF and III cysts, and found that locally advanced or metastatic disease developed in none of them.[14] With no large studies of the natural history of cystic renal masses it is unclear whether these incidentally found cystic renal masses warrant the aggressive surgical treatment that is currently recommended.

As active surveillance has continued to change the management of small solid renal masses, perhaps the time has come to consider surveillance of potentially indolent cystic renal masses. We describe what is to our knowledge the largest institutional series of surveillance for cystic renal masses.

PATIENTS AND METHODS

The research and ethics board approved a retrospective review of all radiology reports at our academic health center, including 2 large urban general hospitals and Princess Margaret Cancer Centre, between 2001 and 2013. The unique Montage™ radiology record crawler system was used to search for the term "complex cyst" in patients who underwent abdominal imaging (computerized tomography, ultrasound or magnetic resonance imaging) for any reason.

Montage is a leading software solution used for health care data mining which enables users to search entire databases using terms of interest. It subsequently generates anonymized reports with accession numbers, which were then used to retrieve patient identifiers in the radiology information system.[16]

Following this identification we reviewed the imaging report and the patient chart to confirm accuracy. After selecting all patients with accurately identified Bosniak IIF, III and IV renal cysts we performed a detailed chart review. Patient demographics (age, gender, proven VHL status, smoking status and comorbidities), cyst characteristics during followup (location, Bosniak classification features and category, and size), imaging modalities (modality, number of scans and radiologist upgrade) and intervention rate (percutaneous biopsy and/or definitive therapy, and pathology findings) were recorded.

Patients were stratified by the initial Bosniak classification. Descriptive statistics were then used to assess these cohorts. We recorded the median and range of continuous variables and used the frequency and proportion to describe categorical variables. Continuous variables were compared by the Mann-Whitney test and categorical variables were compared by the Fisher exact test.

Followup was defined as the time in months between the initial abdominal imaging test with sufficient detail to provide the Bosniak classification to the date of the last clinical assessment, the final scan or patient death.

The primary study end points were CSS and overall survival. The secondary end points were radiographic or clinical progression, the rate of surgical/ablative intervention, radiologist upgrading and final histology on surgical pathology. Radiologist upgrading was defined as formal Bosniak upgrading to a higher classification or subjective worsening of radiographic features in the same Bosniak classification.

All statistical tests were 2-sided with $p < 0.05$ considered significant. The 95% CIs are reported. All analyses were performed with R (https://www.r-project.org/).

RESULTS

Demographics

Of the 336 identified patients 185 (55.1%), 122 (36.3%) and 29 (8.6%) had Bosniak IIF, III and IV cysts, respectively (table 1). Besides having slightly larger cysts at diagnosis and a higher incidence of VHL, patients with Bosniak IV cysts were more likely to undergo biopsy and intervention than patients with Bosniak IIF or III cysts. The 3 cohorts were similar in age and gender. Median followup in the entire cohort was 67.1 months and it was similar among the 3 subsets. In the patients a median of 6 abdominal images (IQR 3–9) were obtained per year.

Active Surveillance Outcomes

Radiologist upgrading was noted during followup in 10 surveillance cases, including 5 upgraded from Bosniak IIF to III (table 2). There were no upgrades from Bosniak III to IV.

Metastatic spread developed in only 1 patient undergoing surveillance. This 89-year-old man was on surveillance for 12 years for an asymptomatic Bosniak IV cyst, which was 2.3 cm at diagnosis. He refused treatment and was followed for 2 years with stable imaging and no evidence of progression.

Table 1. *Patient demographics by Bosniak stratification*

	Bosniak IIF	Bosniak III	Bosniak IV	p Value
No. pts	185	122	29	—
Mean ± SD age at diagnosis	60.84 ± 13.73	59.66 ± 16.30	57.17 ± 18.42	0.443
No. gender (%):				0.782
M	119 (64.3)	75 (61.5)	17 (58.6)	
F	66 (35.7)	47 (38.5)	12 (41.4)	
No. smoking status (%):				0.328
Active or prior smoker	55 (29.9)	28 (23.1)	10 (35.7)	
Nonsmoker	63 (34.1)	38 (30.9)	7 (24.1)	
Unknown	66 (35.9)	56 (46.3)	11 (39.3)	
No. VHL diagnosis (%)	0	1 (0.8)	3 (10.7)	<0.001
Median max cm initial size (IQR)	3.70 (2.25–5.95)	3.50 (2.30–5.70)	3.80 (2.30–8.60)	0.03
Median No. abdominal scans/yr (IQR)	6 (4–9)	6 (3–9)	3 (2–8)	0.548
No. biopsy (%)	7 (3.8)	26 (21.3)	5 (17.2)	<0.001
No. treatment (%):	10 (5.4)	37 (30.3)	18 (62.1)	<0.001
Radical nephrectomy	6 (3.2)	12 (9.8)	5 (17.2)	
Partial nephrectomy	4 (2.2)	20 (16.4)	13 (44.8)	
Ablation	0	5 (4.1)	0	
Median mos followup (IQR)	68.90 (33.0–105.03)	64.58 (34.84–91.85)	64.63 (38.00–93.27)	0.379
No. last followup status (%):				0.001
Unknown	2 (1.1)	1 (0.8)	1 (3.4)	
Alive, nonmetastatic or no disease evidence after intervention	166 (89.7)	120 (98.4)	23 (79.3)	
Alive, metastatic disease	0	0	2 (6.7)	
Died	17 (9.2)	1 (0.8)	3 (10.3)	

However, he was subsequently lost to followup until 2012, by which time the mass had enlarged to 7.0 cm and included a 1.8 cm solid component, but he again refused treatment. He was last seen in 2014 at age 89 years and asymptomatic pulmonary metastases had developed. At that time the patient and family elected watchful waiting.

Percutaneous Biopsy and Intervention Data

Of the 38 patients (11.3%) who underwent percutaneous core needle biopsy of a solid nodule in the cysts, 13 (34.2%) were found to have RCC (fig. 1, *A*)

With regard to intervention 10 (5.4%), 37 (30.3%) and 18 patients (62.1%) with Bosniak IIF, III and IV cysts, respectively, underwent surgical or ablative intervention. Of note, median time to intervention from initial identification was 6.1 months (range 1.2 to 89.1) (fig. 2). Table 3 summarizes indications and time to intervention. The indication for intervention was predominantly age and Bosniak classification. The mean age of patients who underwent intervention was 50.1 years compared to 62.5 years in those who did not receive intervention.

Extirpative surgery with radical and partial nephrectomy in 23 (35%) and 37 patients (57%), respectively, was the predominant treatment, while 5 (8%) underwent ablation. Figure 1, *B* shows histology on final pathology in those who underwent surgery. Of the cases 88.8% were FG 1 or 2 while in 6 (11.1%) FG 3 was found on final pathology. All 53 cases for which pT stage was reported were pT1 or pT2, including pT1a in 28, pT1b in 11, pT2a in 11 and pT2b in 3, and all reported surgical margins were negative.

Table 2. *Reasons for radiologist upgrading in patients undergoing surveillance*

	No. Bosniak		
	IIF	III	IV
Surveillance:			
+ Stable imaging	165	71	10
+ Radiologist downgrade	4	11	0
+ Radiologist upgrade	6	3	1
Upgrade indications:*			
Radiographic metastases	0	0	1
Internal hemorrhage on recent scan	0	1	0
Increased size	2	1	0
Increased or new vascularity	4	1	0
Thickened or irregular septae	1	1	0
Increased solid component	2	1	0

* Multiple descriptors.

Survival Outcomes

There was 1 cancer specific death among the 332 patients (0.3%) for whom we had followup, resulting in 99.7% CSS and 93.8% overall survival. Because metastases developed in only 2 patients, the metastasis-free survival rate was 99.1%. When excluding patients with VHL, CSS was 100%.

In the subset of patients who underwent intervention only 2 had evidence of recurrence during followup. A young man with VHL underwent staged bilateral partial nephrectomies at age 27 years, followed by laparoscopic radical nephrectomy at age 33 years. All findings were FG 2-3 clear cell RCC. Recurrences subsequently developed in the solitary kidney, including a complex cyst. After another partial nephrectomy for clear cell RCC he eventually progressed to metastatic RCC. Ultimately he died of the disease, representing the only cancer specific mortality in the cohort.

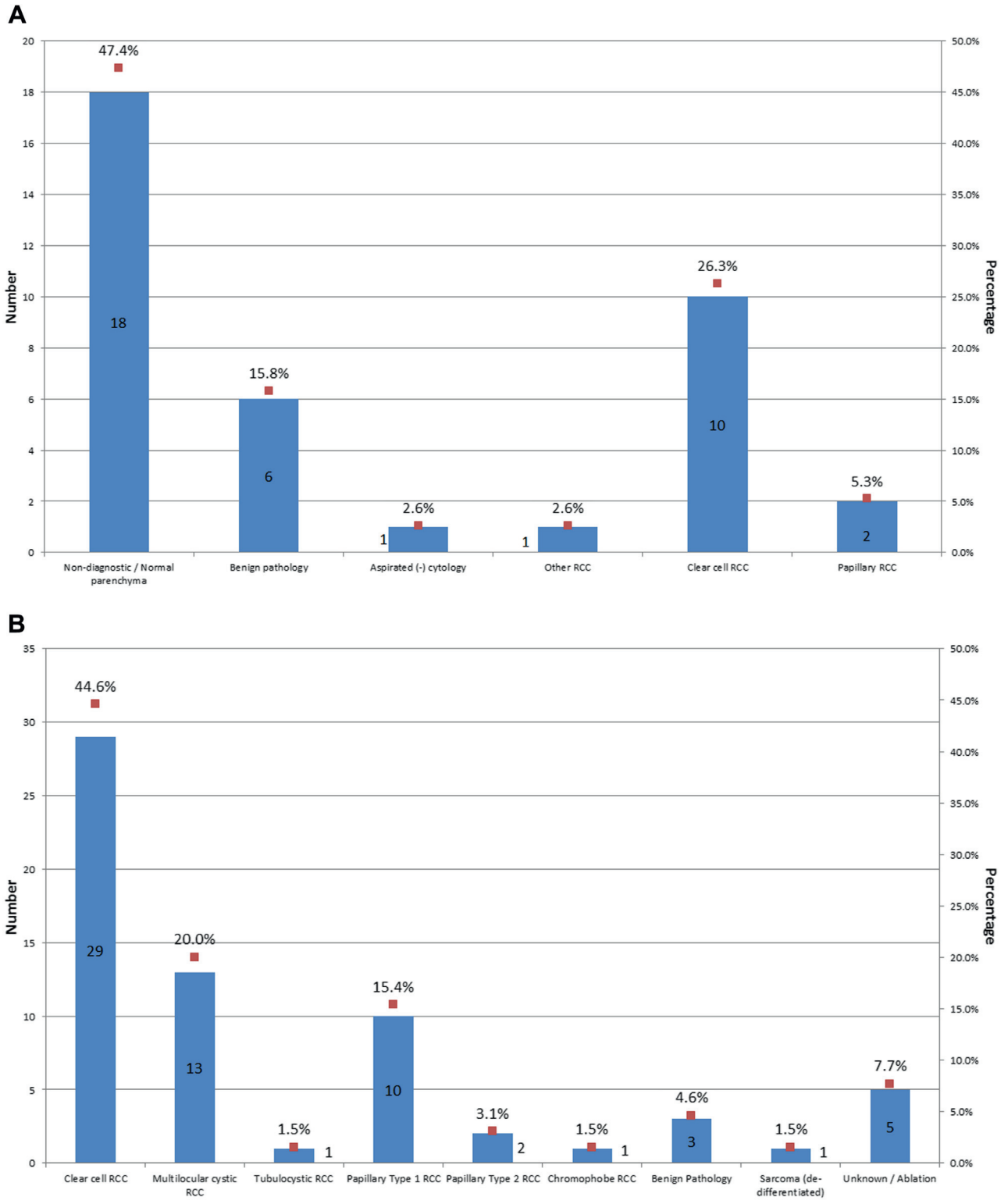

Figure 1. Histological pathology outcomes. *A*, percutaneous biopsy. *B*, surgical/ablative intervention.

A 33-year-old woman with a 6 cm Bosniak IV complex cyst underwent open partial nephrectomy, which revealed pT2a, papillary type II, FG 3 RCC. Unfortunately nodular recurrence developed in the resection bed, requiring completion nephrectomy and distal pancreatectomy. She was found to have node positive disease and was referred for discussion of adjuvant therapy. Genetic evaluation

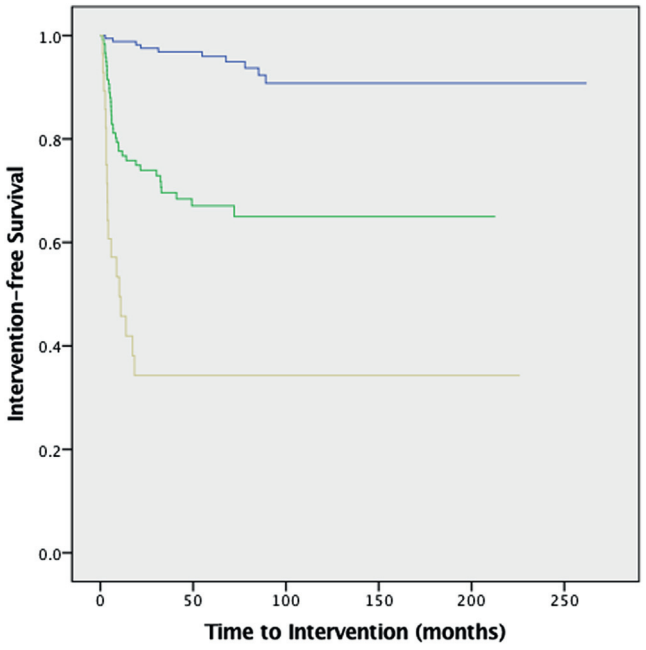

Figure 2. Intervention-free survival stratified by initial Bosniak classification, including Bosniak IIF (blue curve), III (green curve) and IV (yellow curve).

identified a fumarate hydratase gene mutation (hereditary leiomyomatosis and renal cell cancer). At last followup she had no evidence of further recurrence.

DISCUSSION

Active surveillance for solid SRMs has now become an established management option, given the natural history and the low metastatic potential.[17,18] However, for cystic renal masses the natural history has not been defined to our knowledge. Management of these masses has been guided by a radiographic classification system established 30 years ago[8] with no significant change since then. While the Bosniak classification system of complex renal cysts has correlated with the risk of RCC at surgery,[10,11] RCC in a complex cyst may not be as aggressive as its solid renal mass counterpart.[12,14,15] To better define the natural history and metastatic potential of complex renal cysts requires further investigation.

Table 3. *Indications for intervention in patients treated with surgery or ablation stratified by time to intervention*

Intervention Indication	No. Initial Evaluation/Imaging-Intervention Time (%)			
	Less Than 6 Mos	6–12 Mos	Greater Than 12 Mos	Total No. (%)
Overall	31 (47.9)	13 (20.0)	21 (32.3)	65 (100)
Young age	18 (27.7)	6 (9.2)	10 (15.4)	34 (52.3)
Concurrent ipsilat renal mass	5 (7.7)	4 (6.2)	1 (1.6)	10 (15.4)
Bilat renal masses or solitary kidney	1 (1.6)	4 (6.2)	2 (3.1)	7 (10.8)
Genetic predisposition*	3 (4.6)	1 (1.6)	1 (1.6)	4 (6.2)
Bosniak cyst complexity:				
IIF/III	11 (16.9)	3 (4.6)	10 (15.4)	24 (36.9)
IV	10 (15.4)	3 (4.6)	3 (4.6)	16 (24.6)
End stage renal disease + native kidney mass	3 (4.6)	0	4 (6.2)	7 (10.8)
Pt choice†	2 (3.1)	0	4 (6.2)	6 (9.2)
Other/unknown	5 (7.7)	0	3 (4.6)	8 (12.3)

* Family history, VHL or other.
† Surveillance was offered.

In this study we present what is to our knowledge the largest, single institution, retrospective series of cystic renal masses to date. While care was at the discretion of the primary urologist, 80.7% of patients were treated nonoperatively in this series. Although Bosniak IV cysts were slightly larger at diagnosis than Bosniak IIF and III cysts, patients in all 3 cohorts were similar in age and gender. With the mean followup of 74.5 months in the entire cohort this represents the longest followup of complex renal cysts to our knowledge.

Briefly, 11.3% of patients in our series underwent percutaneous biopsy. While biopsy of cystic renal masses is less accurate than biopsy of SRMs, it can be diagnostic for cystic masses with a solid enhancing nodule.[19] Of the group that was biopsied, which itself defines a slightly higher risk population, only 34.2% were found to have RCC, similar to other cohorts.[20] While it may help guide decision making, in general we do not routinely biopsy these lesions.

Table 3 summarizes indications for treatment. As the majority of those treated underwent intervention soon after diagnosis, patient age and cyst complexity were the predominant driving factors. Many of these patients also had a genetic predisposition potentially predisposing them to less indolent tumor behavior. Despite a selection bias toward surgical excision of more complex cysts, the histopathology findings of the final surgical specimens were favorable. Three patients had benign pathology and most specimens with RCC in the final specimen showed clear cell or multilocular cystic RCC. Only 3 of the remaining RCC specimens were papillary type II RCC, while the rest were benign variants such as tubulocystic RCC, chromophobe RCC and papillary type I RCC. Importantly, when FG was provided, 88% of cases were FG 1 or 2 and only 11% were FG 3. No sarcomatoid histology or other more aggressive variants were found.

Prior work by our group demonstrated that multilocular cystic RCC has an excellent prognosis despite clinical T stage and conservative management should be considered.[21] Winters et al also suggested that RCC identified in cystic renal masses has improved cancer specific outcomes compared to the solid RCC counterparts.[15] Ultimately it would

appear that the final pathology of even more aggressive-appearing cystic renal masses often shows more indolent findings than those of comparable solid renal masses.

Unlike prior studies in which surgically treated patients were followed, we assessed cancer specific and overall survival in a large cohort of patients with Bosniak IIF to IV cysts at diagnosis, including 80.7% treated with active surveillance. Regardless of management, there was 1 cancer specific death (0.3%), leading to 99.7% cancer specific survival and 93.8% overall survival. Excluding patients with VHL, there were no cancer specific deaths. Even when cases were observed with an average of 3 abdominal scans per year, these complex cysts did not appear to progress significantly.

Table 2 summarizes radiologist evaluations of these cysts. Regardless of Bosniak classification most cases were initially stable on followup imaging. However, it should be noted that an increase in size did not trigger an upgrade in complexity and, thus, an increasing volume of fluid alone was considered stable. According to the radiologist 10 cases were upgraded during followup. Primarily this was due to increased complexity (increased vascularity, new mural nodularity, an increased solid component or the changing nature of septae). While half of the cases were upgraded from Bosniak IIF to III, no Bosniak III cysts were formally upgraded to Bosniak IV. Consistent with prior studies demonstrating a low rate of upgrading from Bosniak IIF to III,[11,22] our results further support the relatively benign natural history of complex renal cysts.

Indeed, in the only patient with metastasis while on active surveillance, progression developed after 12 years despite the initial diagnosis of a Bosniak IV cyst. This further emphasizes the favorable natural history of complex renal cysts. In a systematic review Schoots et al noted that only 1 of 373 patients with a Bosniak III cyst went on to metastatic disease after 8 years of surveillance and this patient was salvaged with local treatment and lung oligometastatectomy.[11] It has already been established that surgical excision with the goal of identifying RCC on final pathology likely results in overtreatment in 50% of patients with Bosniak III cysts. However, Schoots et al also pointed out that the number needed to treat to prevent metastatic spread may be as high as 140 for Bosniak III cysts and 40 for Bosniak IV cysts.[11] As such, with the goal of preventing overtreatment and limiting metastatic spread active surveillance for Bosniak III cysts should be considered a safe alternative. However, better clinical selection criteria such as nodule size or number may help better identify the small subset that may metastasize.

As a retrospective, single institution series, our study has certain limitations. Selection bias, specifically for the decision to pursue intervention vs active surveillance, was the primary limitation. Also, several genitourinary radiologists read images without a single reference radiologist assessing all scans, which improved the generalizability of our results. The lack of detailed information on comorbidities and other risk factors precluded the ability to assess competing risks. Lastly, many of the patients were routinely followed only by abdominal ultrasound with contrast enhancement after initial axial imaging. As such, the lack of regular axial imaging limited our ability to comment on anatomical complexity and growth kinetics.

Ideal surveillance strategies have also not been well established in our series or in the literature, although our current institutional protocol is ultrasound every 6 months with axial imaging as needed.

CONCLUSIONS

Ultimately despite its limitations to our knowledge our series represents the largest single center experience of surveillance for complex renal cysts. Active surveillance of complex renal cysts is feasible and safe. In the absence of reliable long-term natural history studies we need to challenge the central dogma of surgical treatment of these lesions. In particular Bosniak III cysts can be monitored in most patients with treatment considered if and when the lesion becomes Bosniak IV. Further research, ideally in the form of randomized, controlled trials, will be important to define the optimal management of these complex cysts.

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EDITORIAL COMMENTS

Urologists commonly evaluate and treat patients for cystic renal masses. Historically surgery was recommended for more complex cysts (Bosniak III or IV) because of the increased risk of RCC. However, the results of a systematic review of treatments for complex cysts suggests that surgical treatment may often not be necessary (reference 11 in article). In addition, recent large series have demonstrated that progression to metastatic disease following surgery for cystic RCC is exceptionally rare,[1,2] further supporting an increased role for active surveillance.

Chandrasekar et al describe outcomes in a large series of patients with complex renal cysts treated with active surveillance with a median followup greater than 5 years. It is important to note that the authors identified this cohort from a radiology database, which is less likely to be biased by increased observation of tumors with more concerning features. Cancer specific survival was 100% for cystic renal masses in patients without hereditary RCC syndromes. This study provides valuable insight into the natural history of cystic renal masses and these findings strengthen the growing body of evidence supporting active surveillance as a preferred treatment strategy.

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Increased use of cross-sectional imaging has led to a rise in the detection of SRMs.[1] Given that 15% to 20% of SRMs are benign and most of the remainder harbor indolent pathology, active surveillance has become a core initial management strategy to better pair disease biology with treatment intensity.[2] Complex renal cysts represent a significant opportunity to minimize overtreatment of low risk lesions since the solid component in cystic tumors rarely exceeds 3 to 4 cm and cystic RCC is associated with favorable long-term prognoses (references 15 and 21 in article).

In this study Chandrasekar et al provide a significant contribution to the urological literature supporting active surveillance of cystic renal lesions. At a median followup of 67.1 months none of the 307 Bosniak IIF or III tumors progressed to metastasis or cancer specific death. However, these data underscore that surveillance must be done with some caution. In the Bosniak IV group 10.3% of patients experienced metastatic spread and 1 had a RCC specific death. Moreover, 11.1% of lesions that proceeded to resection harbored high grade histology, underscoring the current limitations of imaging to distinguish between true cystic lesions and biologically more aggressive mimics.[3]

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