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Metastatic potential of a renal mass according to original tumour size at presentation

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OBJECTIVE

- To determine the metastatic potential of renal masses based on original tumour size.

MATERIALS AND METHODS

- We identified 2651 patients who had undergone surgical resection for a unilateral, sporadic renal tumour between 1990 and 2006.
- Associations of tumour size with synchronous metastasis at presentation [M1 renal cell carcinoma (RCC)] and development of metastases, death from RCC, and death from any cause after surgery were evaluated using logistic and Cox proportional hazards regression.

RESULTS

- Of the 2651 patients studied, 182 (6.9%) presented with M1 RCC. Tumour size was significantly greater in patients with M1 RCC than in patients with M0 RCC (a median size of 10 vs 4.5 cm; $P < 0.001$). Only 1 of the 629 patients (0.2%) with a tumour <3 cm had M1 RCC and that tumour was 2.5 cm. The risk of M1 RCC increased from 1.1% for patients with tumours 3–3.9 cm to 16.5% for patients with tumours ≥7 cm.
- Of the 2124 patients with M0 RCC, 430 developed distant metastases at a median (range) of 1.4 (0.1–16.2) years after surgery. Only 9 of the 498 patients (1.8%) with a tumour <3 cm developed distant metastases after surgery.
- Each 1-cm increase in tumour size increased the risk of death from RCC by 20% [hazard ratio (HR) 1.20; 95% confidence interval (CI) 1.18–1.22; $P < 0.001$] and death from any cause by 10% (HR 1.10; 95% CI 1.09–1.12; $P < 0.001$).
- For the 1346 patients who were still alive at last follow-up, the median (range) duration of follow-up was 6.9 (0.1–19.7) years.

CONCLUSIONS

- Tumour size is significantly associated with metastases in patients with renal masses.
- Patients with tumours <3 cm have a low risk of synchronous metastatic disease.

KEYWORDS

kidney neoplasms, renal cell carcinoma, nephrectomy, recurrence, neoplasm staging, neoplasm metastasis

INTRODUCTION

The incidence of RCC has progressively increased over the past three decades, coinciding with widespread use of routine abdominal imaging [1]. Historically, the risk of metastatic RCC at presentation and during surveillance has been directly related to original tumour size [2–5]. These findings were recently challenged by a multi-institutional study, which reported that tumour size was not a significant predictor of synchronous metastasis for small renal masses (SRMs) [6]. The authors discovered the incidence of metastatic disease was not different for tumours in the range 0.1–4.0 cm, and was 5–8%. Additionally, a study using the Surveillance, Epidemiology and End Results (SEER) database reported that 4–5% of patients with tumours <3 cm presented with concurrent metastases [7]. These studies create concern in an era of increasing nonoperative surveillance for SRMs, as the essential risk of metastatic disease and lack of pathological assessment during surveillance create uncertainty.

With these implications in mind, we readdressed the metastatic potential of RCC according to original tumour size. We reviewed our experience with surgically treated renal masses of all sizes and evaluated the incidence of synchronous metastatic disease and the potential development of asynchronous metastasis during surveillance.

MATERIALS AND METHODS

After institutional review board approval, we identified 2651 patients in our nephrectomy registry who were treated with radical or partial nephrectomy at our institution between 1990 and 2006. Patients with sporadic, unilateral solid renal masses with benign histology or any RCC histological subtype were eligible for inclusion. Patients who had undergone previous nephrectomy for a solid renal mass elsewhere and patients with <30 days of follow-up were excluded.

The clinical, surgical, and pathological features studied included age at surgery, gender, type of surgery, histological subtype classified according to the Union Internationale Contre le Cancer, American

FIG. 1. Predicted probability of metastasis at presentation based on primary tumour size. Dashed lines represent 95% CI.

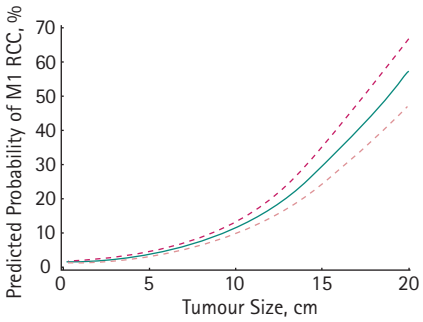

TABLE 1 Clinical, surgical and pathological characteristics by distant metastases at surgery for 2651 patients with solid renal masses

Characteristic	M0* RCC*N* = 2469	M1* RCC*N* = 182	*P*
Median (range) age at surgery, years	64 (19–90)	61 (25–88)	0.011
Median (range) tumour size, cm	4.5 (0.2–29.0)	10.0 (2.5–25.0)	<0.001
Gender, *n* (%)			
Male	1625 (65.8)	116 (63.7)	0.569
Female	844 (34.2)	66 (36.3)	
Type of surgery, *n* (%)			
Radical	1554 (62.9)	180 (98.9)	<0.001
Partial	915 (37.1)	2 (1.1)	
Histological subtype, *n* (%)			
Clear-cell RCC	1614 (65.4)	162 (89.0)	<0.001
Papillary RCC	362 (14.7)	8 (4.4)	
Chromophobe RCC	121 (4.9)	6 (3.3)	
Collecting duct RCC	6 (0.2)	2 (1.1)	
RCC, unclassified	21 (0.9)	4 (2.2)	
Oncocytoma	242 (9.8)	0	
Angiomyolipoma	71 (2.9)	0	
Papillary adenoma	4 (0.2)	0	
Metanephric adenoma	7 (0.3)	0	
Benign, unclassified	21 (0.9)		
Histological subtype, *n* (%)			
RCC	2124 (86.0)	182 (100)	<0.001
Benign	345 (14.0)	0	

**M0 and M1 were compared using chi-squared and Wilcoxon rank-sum tests.*

Joint Committee on Cancer (AJCC), and Heidelberg guidelines, tumour size and TNM classification. Metastatic evaluation included physical examination, blood pressure evaluation, CT/MRI abdomen/pelvis, chest x-ray, blood urea nitrogen (BUN), creatinine, alkaline phosphatase, liver function tests, serum calcium, complete blood count and urine analysis. In cases where there were pulmonary symptoms or an abnormal chest x-ray, chest CT was performed. In the event of suspected vena cava involvement, abdominal MRI and chest CT or MRI were ordered. A bone scan was necessary if there was bone pain, bone fracture, hypercalcaemia or elevated alkaline phosphatase. If there were any new neurological symptoms or abnormal neurological examination findings, brain CT or MRI was performed. A single pathologist (JCC) reviewed the microscopic slides from all specimens without knowledge of patient outcome to determine histological subtype. The pathological tumour size was used for the final analysis because previous publications have shown accurate tumour sizing from modern imaging or pathological evaluation [8]. A patient was considered to have metastatic disease if it was biopsy proven or if there was obvious radiographical evidence of metastatic disease. All potential metastatic lesions in patients with renal tumours ≤7 cm were reviewed by the authors before the statistical analysis. Of the 2651 patients, 41 patients with a tumour size ≤7 cm had potential metastasis at presentation. After review of lesion biopsy results and/or radiographical findings, it was verified that all 41 patients had M1 disease.

Disease status for patients in our nephrectomy registry is updated annually. If a patient has not been seen at our institution in the previous year, the patient is sent a disease status questionnaire. If there is evidence of disease progression in this questionnaire, the date, location and treatment are verified in writing with the patient's local physician. Patients' vital status is similarly updated on an annual basis. If a patient has died in the previous year, a death certificate is ordered to determine the cause of death. A visit to our institution within 6 months of the date of death for metastatic RCC is good documentation that RCC was the cause of death. If the death certificate does not support this, the medical history is reviewed by a urologist to determine the cause of death. If a death certificate cannot be obtained, the cause of death must be verified with the patient's family or local physician.

Clinical, surgical and pathological features for patients with and without distant metastases at surgery were compared using chi-squared and Wilcoxon rank-sum tests. The association of tumour size with distant metastases at surgery was further evaluated using a logistic regression model. Distant metastases-free survival, overall survival, and cancer-specific survival after surgery were estimated using the Kaplan–Meier method. The associations of tumour size with the development of distant metastases, death from any cause and death from RCC after surgery were evaluated using Cox proportional hazards regression models. Statistical analyses were performed using the SAS software package (SAS Institute; Cary, NC, USA). All tests were two-sided and a *P* value <0.05 was considered to indicate statistical significance.

RESULTS

Of the 2651 patients studied, 2306 (87%) had RCC and 345 (13%) had benign tumours. At surgery 7.9% (182/2306) of RCC patients had documented distant metastases and were considered to have M1 RCC. Figure 1 shows the probability of metastases at presentation based on tumour size. Distant metastatic disease at presentation was confirmed by biopsy and/or resection in 56% (102/182) of M1 RCC patients. A comparison of clinical, surgical and pathological features between patients with and without M1 RCC is shown in Table 1. Tumour size was significantly greater in patients with M1 RCC compared

TABLE 2 Incidence of synchronous distant metastases at surgery by tumour size for 2651 patients with solid renal masses

Tumour size, cm	Patients, *n*	M1, *n* (%)
<1	18	0
1 to <2	194	0
2 to <3	417	1 (0.2)
3 to <4	360	4 (1.1)
4 to <5	309	9 (2.9
5 to <6	266	11 (4.1
6 to <7	200	11 (5.5
≥7	887	146 (16.5

TABLE 3 Proportion of benign vs RCC tumours according to tumour size for 2469 patients with M0 RCC

Tumour size, cm	Patients, *n*	Benign tumours, *n* (%)	M0 RCC, *n* (%)
<1	18	9 (50.0)	9 (50.0)
1 to <2	194	43 (22.2)	151 (77.8)
2 to <3	416	78 (18.8)	338 (81.2)
3 to <4	356	66 (18.5)	290 (81.5)
4 to <5	300	37 (12.3)	263 (87.7)
5 to <6	255	34 (13.3)	221 (86.7)
6 to <7	189	15 (7.9)	174 (92.1)
≥7	741	63 (8.5)	678 (91.5)

TABLE 4 Patient outcome after surgery by tumour size for 2124 patients with M0 RCC

Tumour size, cm	Patients, *n*	Metastases, *n*	% 3-Year metastases-free survival (95% CI)	No. of deaths	% 3-Year overall survival (95% CI)	No. of deaths from RCC	% 3-Year cancer-specific survival (95% CI)	Median years follow-up of survivors (interquartile range)
<1	9	0	100	3	77.8 (54.9–100)	0	100	4.7 (3.5–11.2)
1 to <2	151	0	100	26	92.4 (88.1–96.8)	0	100	5.9 (4.1–9.5)
2 to <3	338	9	98.8 (97.6–100)	61	94.0 (91.5–96.6)	6	99.7 (99.1–100)	6.5 (4.4–10.2)
3 to <4	290	9	98.2 (96.6–99.8)	77	92.0 (88.9–95.2)	7	99.3 (98.2–100)	6.7 (4.3–10.4)
4 to <5	263	35	93.4 (90.4–96.5)	95	91.1 (87.8–94.7)	28	94.1 (91.2–97.0)	7.1 (4.3–10.4)
5 to <6	221	39	87.1 (82.7–91.8)	86	85.0 (80.4–89.8)	28	93.7 (90.5–97.1)	7.4 (4.9–11.2)
6 to <7	174	42	83.5 (78.0–89.4)	77	80.8 (75.2–86.9)	37	88.8 (84.1–93.8)	7.6 (4.3–11.8)
≥7	678	296	67.3 (63.8–71.1)	353	73.1 (69.8–76.5)	244	77.1 (74.0–80.4)	7.3 (4.6–11.0)

with M0 patients (median 10 vs 4.5 cm; $P < 0.001$). Among the subset of RCC patients, tumour size was still significantly associated with M1 after adjusting for age, gender and type of surgery [odds ratio (OR) 1.20; 95% CI 1.15–1.24; $P < 0.001$]. When evaluating the number of cytoreductive nephrectomies completed before and after the year 2000, 97 (6.7%) of 1466 patients treated between 1990 and 2000 had M1 RCC vs 85 (7.1%) of 1205 of patients treated between 2001 and 2006 ($P = 0.73$).

The incidence of M1 RCC by tumour size in 1-cm increments is shown in Table 2. Only 1 of the 629 patients (0.2%) with a tumour <3 cm had metastatic RCC at surgery, and that tumour was 2.5 cm. The risk of M1 RCC increased from 1.1% for patients with tumours 3–3.9 cm to 16.5% for patients with tumours ≥7 cm. Each 1-cm increase in tumour size was associated with a 26% increase in the incidence of M1 RCC (OR 1.26; 95% CI 1.22–1.31; $P < 0.001$).

Of the 2469 patients with M0 solid renal masses, benign tumours were significantly more likely to be diagnosed in women than in men (46 vs 32%, $P < 0.001$). No difference was detected in age between patients with benign and RCC tumours (median 66 vs 64 years old, $P = 0.120$). Tumour size was significantly smaller in benign tumours than in RCC (median 3.4 vs 5 cm, $P < 0.001$). The frequency of RCC by tumour size is shown in Table 3.

During follow-up, 430 (20.2%) of 2124 patients with M0 RCC developed distant metastases at a median (range) of 1.4 (0.1–16.2) years after surgery. Distant metastatic disease was confirmed by biopsy and/or resection in 57% (246/430) of the patients. At last follow-up, 778 patients had died, including 350 who died from RCC at a median (range) of 2.5 (0.2–16.5) years after surgery. For the 1346 patients who were still alive at last follow-up, the median (range) duration of follow-up was 6.9 (0.1–9.7) years. Distant metastases-free survival, overall survival and cancer-specific survival by tumour size are shown in Table 4. No patient with an original tumour size <2 cm developed a distant metachronous metastasis, while 2.9% (18 of 628) with tumours 2–3.9 cm developed metachronous metastases. Each 1-cm increase in tumour size increased the risk of developing distant metastases after surgery by 20% [hazard ratio (HR) 1.20; 95% CI 1.18–1.23; $P < 0.001$]. Similarly, each 1-cm increase in tumour size increased the risk of death from any cause and death from RCC by 10% (HR 1.10; 95% CI 1.09–1.12; $P < 0.001$) and 20% (HR 1.20; 95% CI 1.18–1.22; $P < 0.001$), respectively.

DISCUSSION

The standard of care for clinically localized RCC now includes tumour ablation and active surveillance of SRMs in selected older patients or those with extensive medical comorbidities [9]. Previous studies have shown growth rates of approximately 3 mm per year with only 1%

progression to metastatic disease for patients undergoing active surveillance [10]. However, many publications evaluating renal masses under surveillance excluded metastatic lesions and did not analyse the relationship between radiographical tumour size and metastatic disease [11,12]. While the prognosis of RCC is dependent on anatomical, clinical and histological data [13], in the situation where there is surveillance of SRMs without biopsy, the clinician is frequently limited to radiographical tumour size as an objective measure for counselling.

For years, tumour size has been an important prognostic feature and the AJCC TNM staging relies heavily on these observations [2,4,14,15]. The majority of these tumours, regardless of size, will be malignant and significant differences in prognosis have been observed when assessing survival rates based on tumour size [5,16,17]. The use of routine cross-sectional imaging has lead to an increase in the detection of SRMs and CT provides an accurate assessment of pathological tumour size [8]. Surveillance of these SRMs does not appear to limit delayed treatment with minimally invasive approaches to partial nephrectomy or significantly alter oncological outcomes [18]. Despite this, the percentage of patients presenting with synchronous metastatic disease has remained stable at 25–35% [19].

This recognition has led to a number of conflicting studies, including the present study, relating tumour size to synchronous metastatic disease [4,6,7,15,20]. The present study supports previous observations of a low risk of metastatic potential for SRMs and refutes the recent suggestion of a higher rate of synchronous metastasis. Klatte *et al.* [6] presented a multi-institutional study from Europe and the University of California, LA on 1208 patients with a renal mass. Tumour size was not significantly different between patients with metastatic and localized disease. They report presenting M1 incidences of 7, 6, 5 and 8% for tumour sizes of 0.1–1, 1.1–2, 2.1–3 and 3.1–4 cm, respectively. In an effort to verify true metastatic lesions, 56% of the cases were confirmed pathologically with biopsy of the metastatic lesion. Although, it is unknown if these biopsies were completed for tumour sizes of <4 cm or were skewed toward larger primary tumours, this high rate of pathologically confirmed M1 status suggests that SRMs may have greater malignant potential than currently thought. These concerns have been further propagated by the recent study by Lughezzani *et al.* [7]. The authors evaluated SEER data reporting that 4.8, 4.2 and 4.9% of patients were M1 at presentation with masses 0.1–1, 1.1–2 and 2.1–3 cm, respectively [7]. This percentage increased to 7.1% for masses 3.1–4 cm. When evaluating the patients who had undergone surgical resection, these percentages decreased to 1.6–2.2% for masses 0.1–3 cm and 3% for masses 3.1–4 cm.

Unfortunately, multi-institutional studies and SEER data are difficult to control and radiographical and pathological review is challenging. Differences in radiographical evaluation and thresholds for M1 inclusion in central databases are major contributors to substantially higher reported rates of M1 disease at presentation. Clearly there are significant implications raised by the discordance in reported rates of M1 at the time of diagnosis of SRM. As the urologist continues to expand the role of expectant management for SRMs, these reports necessitate further investigation.

In contrast to these studies, in the present study there was not a single synchronous metastasis at presentation in 212 tumours <2 cm, which was also the case for the institutional observation from Memorial Sloan-Kettering and Fox Chase Cancer Centers [15,20]. We observed only 1 synchronous metastasis at presentation in 417 tumours of 2–2.9 cm. Table 4 shows an important trend regarding asynchronous metastases. Patients with tumours <2 cm had virtually no risk of metastatic disease or RCC-specific death. For patients with 2–2.9 cm and 3–3.9 cm only nine patients in each group developed metastatic disease of 338 and 290, respectively. This corresponded to a RCC-specific 3-year survival of 99.7 and 99.3% for tumours 2–2.9 and 3–3.9 cm, respectively. For tumours ≥4 cm, the risk of metastatic progression and RCC-specific death increased significantly.

We found a 26 and 20% increase in the incidence of M1 at presentation and asynchronous metastases for each 1-cm increase in tumour size (OR 1.26 and HR 1.20), respectively. Observations from Memorial Sloan-Kettering had remarkably similar results to those presented in the present study, with only one patient having M1 disease with a primary tumour <3 cm. [20] As single, tertiary institution studies, both the present study and the Memorial Sloan-Kettering study were able to ensure follow-up and review all metastatic cases radiographically and/or pathologically for confirmation. Considerable biases are alleviated in this way and probably account for the higher percentage of M1 at presentation of SRMs in other studies. Using a strict definition of metastatic disease with histological confirmation in nearly 60% of the cases in the present study, our data support the concept that tumour size is directly related to the risk of metastatic disease.

The present study has some important limitations and biases. First, our data come from a single tertiary institution evaluating surgical patients. Consequently, there are inherent and selection biases which cannot be ignored. Our database is limited to patients who underwent surgical extirpation. Thus, patients presenting with metastatic disease outside our department may not have been included in the database. We did have expert pathology review of all cases but the retrospective nature of this study precluded standardized metastatic assessment. Additionally, not all patients underwent biopsy for pathological confirmation of metastatic disease, thus the diagnosis of metastatic disease was set by generally accepted radiographical criteria.

In conclusion, tumour size is significantly associated with synchronous and metachronous metastases and regardless of its limitations, the findings of the present study argue in favour of expectant management of SRMs in properly selected comorbid patients, suggesting a small risk of metastatic disease for tumours <3 cm.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **SEER**, Surveillance, Epidemiology and End Results; **HR**, hazard ratio; **SRM**, small renal mass; **AJCC**, American Joint Cancer Committee; **OR**, odds ratio.

EDITORIAL COMMENT

METASTATIC POTENTIAL OF A RENAL MASS ACCORDING TO ORIGINAL TUMOUR SIZE AT PRESENTATION

With increasing detection of incidental renal masses and both low incidence of metastasis at time of presentation and low progression to metastatic disease in primary renal tumours <3 cm, the inherent biology of newly diagnosed small renal tumors is unclear. Given that the size of renal masses is commonly used to make clinical decisions on their management, Umbreit *et al.* highlight a strong correlation between increasing renal size and synchronous or metachronous metastasis. A major caveat for this large single institutional study is the dataset, which consists of only those patients undergoing surgery and not all patients presenting with RCC metastasis at the institution during the study period. It is therefore possible that metastasis of several small tumours, or of unknown primary tumours, could have been missed in their analysis. Nevertheless, in this era of care surveillance for small renal masses the data could support the recommendation to counsel patients with renal masses <3 cm on the basis of a low probability of metastatic progression.

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