



Available active surveillance follow-up protocols for small renal mass: a systematic review

Giacomo Rebez¹ · Nicola Pavan¹ · M. Carmen Mir² 

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Abstract

Purpose To evaluate follow-up strategies for active surveillance of renal masses and to assess contemporary data.

Methods We performed a comprehensive search of electronic databases (Embase, Medline, and Cochrane). A systematic review of the follow-up protocols was carried out. A total of 20 studies were included.

Result Our analysis highlights that most of the series used different protocols of follow-up without consistent differences in the outcomes. Most common protocol consisted in imaging and clinical evaluation at 3, 6, and 12 months and yearly thereafter. Median length of follow-up was 42 months (range 1–137). Mean age was 74 years (range 67–83). Of 2243 patients 223 (10%) died during the follow-up and 19 patients died of kidney cancer (0.8%). The growth rate was the most used parameter to evaluate disease progression eventually triggering delayed intervention. Maximal axial diameter was the most common method to evaluate growth rate. CT scan is the most used, probably because it is usually more precise than kidney ultrasound and more accessible than MRI. Performing chest X-ray at every check does not seem to alter the clinical outcome during AS.

Conclusion The minimal cancer-specific mortality does not seem to correlate with the follow-up scheme. Outside of growth rate and initial size, imaging features to predict outcome of RCC during AS are limited. Active surveillance of SRM is a well-established treatment option. However, standardized follow-up protocols are lacking. Prospective, randomized, trials to evaluate the best follow-up strategies are pending.

Keywords Small renal masses · Active surveillance · Follow-up · Kidney mass elderly · Senior · Geriatric · Aging · Octogenarian

Introduction

Small renal masses (SRM) are usually defined as incidentally discovered enhancing renal masses < 4 cm in maximal diameter with imaging consistent with cT1aN0M0 disease [1]. Incidental detection of SRM has become more common due to widespread use of ultrasound and cross-sectional imaging [2, 3]. SRM have a clinically diverse spectrum of disease due to the different natural history of renal tumors based on histology and size [4, 5]. All treatment options, including extirpative surgery (i.e., partial or radical nephrectomy), tissue ablation (i.e., cryotherapy and radiofrequency

ablation), and active surveillance (AS), have been proved to be effective in the management of SRM [1, 6–8]. AS is defined as the initial monitoring of tumor size by serial abdominal imaging (US, CT, or MRI) with delayed intervention reserved for tumors showing clinical progression during follow-up [9]. Elderly and comorbid patients with incidental SRM have a low RCC-specific mortality and significant competing-cause mortality. In properly selected patients, AS can be an attractive treatment strategy. To date, optimal protocols and imaging modalities are still lacking on follow-up strategies for SRM [1]. Several groups have suggested different follow-up strategies for AS and Delayed Intervention (DI). The current review aimed to evaluate follow-up strategies for AS SRM.

✉ M. Carmen Mir
mirmare@yahoo.es

¹ Urology Clinic, Department of Medical, Surgical and Health Science, University of Trieste, Trieste, Italy

² Department of Urology, Fundacion Instituto Valenciano Oncologia, Valencia, Spain

Evidence acquisition

Search strategy

A comprehensive search of the Embase, Medline, and Cochrane databases was performed.

The search strategy included English language articles reporting on renal masses and surveillance from January 2000 to July 2020. The search terms are “surveillance”, “renal mass”, “renal cell carcinoma”, “kidney cancer”, and “elderly”.

Study selection

The results of the literature search were screened preliminarily by one reviewer (GR) using titles and abstracts’ duplicates have been eliminated. A secondary screening was performed (NP, CMM). The full texts and references of potentially appropriate literature were searched for further screening as recommended in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Studies were considered relevant to the current systematic review when they included adult patients (age > 18 years) diagnosed with an SRM and enrolled on AS to compare growth rates and oncologic outcomes.

Inclusion criteria

Both prospective and retrospective studies evaluating adult patients (> 18 years old) who underwent AS and or delayed intervention (DI) for small renal masses were included. The following data were required: baseline demographics of patients; English language; schedule of follow-up and follow-up methods, and study enrolled at least 10 patients.

Exclusion criteria

The exclusion criteria were as follows: reviews or editor letters and single case report; non-English language publications; studies without consistent information on follow-up protocol and studies with insufficient or unconfirmed information.

Data extraction

Complete data, including the first author, publication year, number of patients, median age of patients, median FU,

FU range, FU scheme, rate of delayed intervention, and metastatic progression, were extracted from the selected papers.

Assessment of the risk of bias

The risk of bias was minimized by the different revision of papers made by three authors (GR, NP, and CMM).

Final study selection

Using these search criteria, an initial selection of 1534 articles was considered. After exclusion of case series, review articles, and articles without follow-up protocol, we narrowed down to 110 studies which were selected for abstract screening. Finally, after the removal of duplicates, conference proceedings, abstracts, and non-English texts, 68 abstracts were reviewed. After a comprehensive review process, 20 full-text articles were included in this review, in accordance with the aforementioned inclusion criteria. A PRISMA flowchart is represented in Fig. 1. Primary outcome of interest was to evaluate method and frequency on follow-up protocols for SRM AS. Secondary outcomes included rate of delayed intervention and cancer-related mortality.

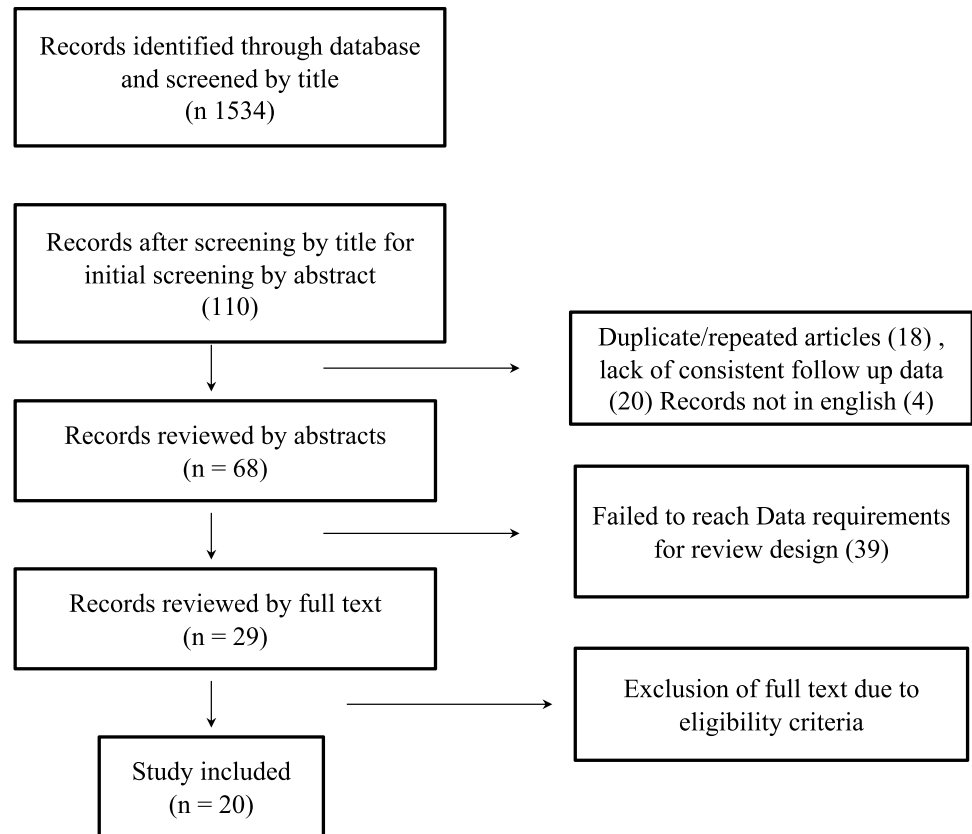
Evidence synthesis

Overall characteristics

Twenty studies were selected during the systematic search and their characteristics are detailed in Tables 1 and 2. Seven studies reported prospective collection with clear inclusion criteria and well-described follow-up. The remaining studies were based on retrospective reports.

Follow-up protocols

Follow-up protocols varied widely among the series, as shown in Table 2. Most common protocol was to perform imaging and clinical evaluation at 3, 6, and 12 months and yearly thereafter. Six studies performed a complete evaluation (CT/MRI + clinical evaluation and blood tests) every 6 month during the total length of follow-up (range 6–248 months). Overall, Abdominopelvic CT scan with iv iodine contrast was the most commonly used both for baseline and follow-up evaluation in accordance with the literature. Kidney ultrasound was used in 11 series, varying from a rate of 2% to 100% of patients; Fernando [12] and Pierorazio [20] reported 100% of FU through kidney ultrasound after an initial cross-sectional imaging at baseline. Moreover, all the seven prospective series performed

Fig. 1 Summary of literature search

kidney ultrasound. Four of the retrospective manuscripts reported the use of ultrasound (Table 2). Contrast enhanced ultrasound were not reported in any of the selected articles. MRI was performed in 12 studies (6–34%) (Table 2); Two series used magnetic resonance, because the first renal mass diagnosis was on MRI. Four prospective studies reported MRI evaluations at baseline and follow-up. Other series did not report the percentage of patients and/or the number of follow-up performed by MRI.

Characteristics of selected studies

The characteristics of the studies included are presented in Table 1. The follow-up was described in all the studies with a median length of 42 (range 1–137) months. Mean age was 74 years (range 67–83). Of 2243 patients, 223 (10%) died during the follow-up and 19 (0.8%) patients died of kidney cancer. After enrollment of AS, 50 patients (2.2%) were diagnosed with metastasis during follow-up. Rate of delayed intervention, metastatic patients, and related deaths were reported in all the studies except one (Parker) and are listed in Table 1. Overall 421 patients (19%) underwent delayed intervention, as shown in Table 2. It should be noted that two series described a retrospective collection of patients who could not undergo surgery immediately; therefore, the two studies reported a 100% rate of delayed intervention

between 9 and 97 months. The delayed intervention rate was consistent among the series (range 0–30%). No differences were reported about different timing of follow-up and different rate of DI.

No study reported the rationale of their frequency of follow-up schedules.

No series reported difference in efficacy of detecting growth rate between follow-up methods.

Chest investigation

Chest X-ray (CXR) was performed as routine in 9 studies. Only Lamb 2004 [10] performed CXR at every follow-up. Four series performed CXR during baseline evaluation and two others performed CXR at baseline and at 1 year follow-up. Chest CT was not performed as a routine exam in any series. Haramis [11] and Fernando [12] performed Chest CT if metastatic disease was suspected or detected.

Growth rate

All the selected studies used the growth rate (GR) of the solid mass to evaluate disease progression. Maximal axial diameter was used to evaluate growth rate (GR) in 90% of the studies. As previously stated, CT scan was the most used also to determine the growth rate of the index lesion.

Table 1 Summary of active surveillance for small renal mass series available including follow-up schedules

References	Study design	# Patients	# Lesions	Median age at diagnosis (year)	Median FU (month)	FU range (month)	Metastatic patients % (n)	Median tumor size (cm)	Median growth rate (cm/year)	SRM biopsy % (n)	Delayed intervention % (n)	Delayed intervention median time (month)	Cancer-related death % (n)	Overall death events % (n)
Lamb 2004 [10]	Retrospective	36	36	76	24	3–136	2.7 (1)	6.0 ^a	0.39	66.7 (24)	0	ns	0	36 (13)
Kouba 2007 [26]	Retrospective	43	46	67	36	ns	0	2.92	0.7	0 (0)	30 (13)	ns	0	9.3 (4)
Fernando 2007 [12]	Retrospective	13	13	82	38	19–105	7.6 (1)	5.0 ^a	0.17	0 (0)	0	ns	7.6 (1)	53 (7)
Crispen 2008 [15]	Retrospective	82	87	71	21	9–97	0	5.10 ^a	ns	0 (0)	100 (87) ^b	14	0	ns
Beisland 2009 [40]	Retrospective	67	67	76	37	1–134	17.2 (12)	3.40	< 1	11 (7)	13 (9)	ns	4.4 (3)	ns
O'Connor 2009 [41]	Retrospective	26	26	78	28	12–72	15.3 (4)	4.25 ^a	0.44	9 (2)	0	ns	3.8 (1)	42 (11)
Rosales 2010 [25]	Retrospective	212	223	71	35	6–137	1.8 (4)	2.80	0.34	19 (40)	5.1 (11)	ns	0.4 (1)	12 (15)
Lane 2010 [42]	Retrospective	105	105	81	45	28–77	5.7 (6)	2.30	ns	2.3 (13)	0	ns	5.7 (6)	ns
Haramis 2011 [11]	Retrospective	44	51	77	77	60–137	0	2.67	0.15	38.6 (17)	5.2 (2)	ns	2.2 (1)	15 (8)
Mason 2011 [19]	Retrospective	82	84	74	36	9–96	1.2 (1)	1.90	0.25	8.5 (7)	10.9 (9)	27	0	1.2 (1)
Li 2012 [14]	Retrospective	32	32	ns	47	6–248	0	2.14	0.80	0 (0)	100 (32) ^b	12	0	0
Parker 2013 [43]	Retrospective	100	100	72	24	24	ns	2.30	0.17	17 (17)	ns	ns	ns	ns
Tang 2017 [44]	Retrospective	31	31	83	51	23–81	6.45 (2)	2.70	ns	0 (0)	16 (5)	ns	6.4 (2)	35 (11)
Siu 2007 [45]	Prospective	41	47	68	29	12–80	2.43 (1)	1.80	0.27	24 (10)	34 (14)	ns	2.4 (1)	2.4 (1)
Jewett 2011 [46]	Prospective	178	209	73	28	ns	1.12 (2)	2.10	0.13	55 (99)	11.5 (9)	12	0	12 (10)
Schiavina 2014 [33]	Prospective	70	72	77	93	ns	2.8 (2)	2.10	0.60	40 (28)	25 (18)	ns	0	24 (17)
Pierorazio 2015 [20]	Prospective	223	223	70	24	ns	0	1.90	0.11	6.4 (32)	9.4 (21)	ns	0	3, 24 ^c
Uzosike 2018 [13]	Prospective	271	271	70	40	ns	0	2.50	0.09	12 (33)	14 (38)	ns	0	10 (28)

Table 1 (continued)

References	Study design	# Patients	# Lesions	Median age at diagnosis (year)	Median FU (month)	FU range (month)	Metastatic patients % (n)	Median tumor size (cm)	Median growth rate (cm/year)	SRM biopsy % (n)	Delayed intervention % (n)	Delayed intervention median time (month)	Cancer-related death % (n)	Overall death events % (n)
McIntosh 2018 [47]	Prospective	457	544	72	67	41–94	8	2.10	0.19	24 (109)	33.4 (153)	21	1 (5)	15.9 (73)
Finelli 2020 [21]	Prospective	134	136	70	69	40–90	6	2.0	0.19	100 (136)	1.4 (2)	ns	2.23 (3)	21 (29)

^aReferred to the total study population and not only the specific AS subgroup

^bThe study was designed to evaluate delayed intervention; no progression was detected to anticipate scheduled intervention

^c4% at 2 years of FU and 25% at 5 years of FU

Fernando [12] and Pierorazio [13] scheduled the follow-up performing kidney ultrasound in 100% of the patients and using CT or MRI as per physician’s choice in case of uncertainty or changes in ultrasound findings.

Delayed intervention

Delayed intervention is defined as surgery (radical or partial nephrectomy) and/or radiofrequency postponed at least 6 months following the diagnosis. Two series reported 100% of DI (Li 2012 [14] and Crispen 2009 [15] see Table 1), because the design of the study was a retrospective evaluation of patients who did not receive immediate surgical treatment and started an active surveillance. Overall 421 (19%) patients underwent delayed intervention (13% without the two series with 100% rate of delayed intervention). The delayed intervention rate was consistent among the series, with 0–30% rate of DI (Table 1). The most common trigger for delayed intervention was a growth rate > 0.5 cm/yr.

Renal biopsy was performed in a small representation of patients (< 30% see Table 1). No renal biopsy was scheduled in the follow-up protocol in any article of the series.

Discussion on different regimens of follow-up and current evidence

Within the literature guidelines [1] (AUA, EAU), AS remains an important therapeutic option for selected patients. It may be ideal to spare the surgical intervention with its complications in those patients who carry significant comorbidity profiles. Our analysis highlights that most of the series used different protocols of follow-up without consistent differences in the outcomes, as shown in Table 1. This reinforces that many patients can remain on active surveillance for a prolonged period of time regardless of the FU protocol. Furthermore, there was a considerable difference between prospective and retrospective studies as the follow-up was not standardized. Of 2243 patients, only 19 (0.8%) died because of renal cancer and only 50 had cancer-related metastasis (2.2%). These results might be explained by several reasons (elder patients, high rate of delayed intervention); however, it does not seem to correlate with the FU scheme.

In addition to initial tumor size, the natural history of SRM can be characterized by their growth kinetics [16]. The change in maximum tumor diameter over time, known as linear tumor growth [17, 18], is used as a parameter to evaluate disease progression and decide on delayed intervention during AS [19–21]. It is expressed by variations of cm/year, and usually, two evaluations per year should be enough to determine significant variations of tumor growth [20]. Disease progression is considered when mass grows

Table 2 Follow-up scheme protocols. (A) retrospective studies providing detail on follow-up schedules; (B) prospective studies providing detail on follow-up schedules

References	Follow-up timing (month)	Abdominal pelvis CT scan			MRI	US	Chest X-ray
		Baseline	During follow-up	Disease progression			
(A)							
Lamb 2004	Every 6 months	36/36	36/36	0/26	No	No	36/36
Kouba 2007	3–6–12–yearly	43/43	43/43	0/43	No	No	NS
Fernando 2007	3–6–12–yearly	13/13	0/13	1/13	No	13/13	43/43 Baseline
Crispen 2009	Every 6 months	82/82	82/82	0/82	No	No	82/82
Beisland 2009	3–6 months	60/67	60/67	NS	7/67	No	NS
O'Connor 2009	3–6 months	26/26	21/26	1/26	No	5/26	NS
Rosales 2010	3–6–12–yearly	185/212	212/212	15/212	26/212	70/212	212/212 Baseline
Lane 2010	Every 6 months	105/105	105/105	5/105	No	No	NS
Haramis 2011	3–6–12–yearly	ns/44 ^a	ns/44 ^a	1/44	ns/44 ^a	No	44/44
Mason 2011	Every 6 months	ns/82 ^a	ns/82 ^a	1/82	ns/82 ^a	ns/82 ^a	NS
Li 2012	Every 6 months	ns/32 ^a	ns/32 ^a	0/32	ns/32 ^a	No	NS
Parker 2013	3–12–24–yearly	100/100	100/100	NS	No	No	NS
Tang 2017	Every 6 months	31/31	31/31	5/31	No	No	NS
(B)							
Siu	6	36/41	36/41	15/41	7/41	1/41	NS
Schiavina	3–6–12–yearly	70/70	70/70 Baseline and 6 months	NS	ns/70 ^a	70/70 12 months thereafter	70/70 Baseline and 12 month
Pierorazio	4–6 first 2 year 6–12 thereafter	223/223	0/223	NS	ns/223	223/223	223/223
Uzosike	4–6	170/271	170/271	38/271	71/271	30/271	NS
McIntosh	6	251/457	251/457	153/457	159/457	50/457	NS
Finelli/Jewett ^b	3–6–12–yearly	67/134	67/134	87/134	8/134	58/134	Baseline

^aNumber of patients not known; 100% FU: Exam performed at every follow-up visit; baseline is different if stated; *NS* not stated, *DP* disease progression suspected

^bSame series and same protocols

more than 0.5 cm/year or over 4 cm, due to the higher rate of metastasis if one or both of these conditions are present [6]. Outside of growth rate and initial size, imaging features to predict outcome of RCC during AS are limited [22]. For those placed on AS, the American Urological Association (AUA), the National Comprehensive Cancer Network (NCCN), and the European Association of Urology (EAU) guidelines recommend abdominal imaging with CT or MRI within 6 months from initiation of AS and subsequent imaging (CT, MRI, or ultrasound) performed annually thereafter for as long as the patient is on active surveillance [23]. During this time, the size of the lesion should be closely monitored, as growth kinetics is a commonly cited surrogate for metastatic potential and decision for further intervention. No differences are reported regarding the method of follow-up in any guideline. Although the growth rates for SRM may be highly variable, several studies in our series have reported a mean growth rate varying between 0.3 and 0.4 cm/year [24–26]. A systematic review showed lesions

on AS that progressed to metastatic disease demonstrated a significantly higher growth rate (0.8 cm/year) compared to those with favorable outcomes (0.3 cm/year) [27]. Anyway, despite general consensus in the literature about certain criteria to trigger delayed intervention, there are no formal guidelines on the topic.

Performing CXR at every check does not seem to alter the clinical outcome during AS. In fact, CXR is known to be a low yield diagnostic tool for detecting pulmonary metastasis in patients treated for RCC [28, 29] and does not seem to affect the outcomes of active surveillance if performed at every FU step [30]. Ideally, follow-up imaging should be performed with a consistent modality to limit inter-modality variability in mass characterization and size measurements [16]. CT scan is the most used exam mainly because it is usually more precise than kidney ultrasound and more accessible than MRI [31]. Abdominal CT provides information on function and morphology of the contralateral kidney during enrollment [32],

primary tumor extension; enlargement of locoregional LNs; condition of the adrenal glands and other solid organs.

Eleven studies (55%) performed US during follow-up; Fernando [20], Schiavina [12], and Pierorazio [33] followed every patient by kidney ultrasound, while CT or MRI were used at the discretion of the physician in case of uncertainty or changes in ultrasound findings. US can be time -saving, accessible, and precise enough on growth rate, unfortunately burdened by being operator-dependent, difficult to reproduce and unreliable to detect disease progressions. US is considered the preferred imaging modality for the screening of RCC (sensitivity and specificity of 82–83% and 98–99%, respectively [22]).

Twelve studies (60%) performed MRI during the AS; MRI is able to perform precise axial imaging on patients who are allergic to iv iodine contrast [22, 34] and it is an option for CKD patients with GFR 30–60 mL/(min 1.73 m²) who cannot undergo CT with iodine contrast (recommended GFR > 60 mL/(min 1.73 m²) [35]. MRI appears to have a good sensitivity and specificity on RCC diagnosis, but it can be expensive and time-consuming [36]. MRI should not be considered a perfect replacement for CT during staging and follow-up as CT's sensitivity for pulmonary nodules is clearly superior [37]. Less common use of MRI, in comparison to CT (see Table 2), stems from its higher associated costs, its decreased accessibility, and poorer patient tolerance [38]. Future developments in imaging technology, including the identification of predictive imaging biomarkers, can be promising advances that may help predict patient outcomes [39].

The type and timing of follow-up was poorly described in most of the series. Indeed, a comparison between different outcomes regarding different methods of follow-up was not reported.

On the basis of these studies and current guidelines, most common enrollment into AS is with initial abdominal axial imaging (CT or MRI) and chest imaging. The most used initial follow-up imaging is every 6 months in the early AS period (2 years), while a longer time interval (every 12 months) for the late AS period assuming radiographic stability of the SRM. Regarding SRM progression the vast majority of patients underwent DI when tumor GR > 0.5 cm/year or absolute tumor size > 4 cm.

Randomized, longer term, prospective studies are required to find the best intervals that reduce the harms, costs, and invasiveness of serial imaging while minimizing the risk of under-treating masses that harbor metastatic potential.

Conclusions

Active surveillance of SRM is a well-established treatment option. However, standardized follow-up protocols are lacking. Prospective, randomized, trials to evaluate the best follow-up strategies are pending.

Author contributions All authors have contributed to the information and material submitted for publication and all authors have read and approved the manuscript. GR: data collection, data analysis, and manuscript writing. NP: data collection, data analysis, and manuscript writing. MCM: data collection, data analysis, and manuscript writing.

Data availability We declare that all materials and all data are available and do not involve plagiarism.

Compliance with ethical standards

Conflict of interest Authors have no direct or indirect commercial financial incentives associated with publishing the manuscript.

Human participants and/or animals No research involving human participants and/or animals.

Informed consent No informed consent required.

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