ACTIVE SURVEILLANCE FOR SMALL RENAL MASSES ≤2CM: RESULTS FROM AN ITALIAN, MULTI-INSTITUTIONAL PROSPECTIVE PROTOCOL (ID NCT03804320)

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Introduction & Objectives

Small renal masses (SRMs) have become increasingly common due to the extensive adoption of abdominal imaging scans.

Numerous treatment approaches such as surgical interventions, tissue ablation and active surveillance have all been proved to play a role in the management of SRMs.

In this study, we report the first descriptive results from this prospective, non-randomized, multi-institutional protocol for the active surveillance of SRMs ≤2

Methods

The protocol has been introduced in April 2014 in 5 Italian centres.

Patients with monolateral SRM (≤2cm of diameters), with more than 50 years of age and without symptoms related to the mass have been enrolled in the protocol.

Patients with previous history of renal cancer, single kidney, hereditary tumours, presence of metastasis, immunodepressant therapy or with a life expectancy lower than 1 year have been considered not eligible.

All the patients underwent a standardized follow up scheme and collection of urine and blood samples for the creation of a biobank of biological samples.

The protocol has been registered in ClinicalTrials.gov with the identifier: NCT03804320

Table 1; Demographic characteristics of the cohort

		Enrolled Patients (N=59)	
		n	%
Sex	Male	42	71.2
	Female	17	28.8
	Total Reported	59	100.0
Age (years)	<65 yrs	14	23.7
	65-84 yrs	44	74.6
	>= 85 yrs	1	1.7
	Total Reported	59	100.0
ECOG PS	0	53	89.8
	1	4	6.8
	2	1	1.7
	3	1	1.7
	Total Reported	59	100.0
Smoking History	Never smoked	29	49.2
	Current smoker	5	8.5
	Former smoker	25	42.4
	Total Reported	59	100.0
CCI Score	<9	58	98.3
	Missing	1	1.7
	Total Reported	59	100.0
P.A.D.U.A Score	>=4	59	100.0
	Total Reported	59	100.0

Results

To date, **59** patients have been enrolled in the protocol, **2/59 (3.4%) have dropped out from the study and 0/59 have died in the study period.**

The mean follow-up time was 24.7 months (SD 8.6).

No patients have developed symptoms or paraneoplastic syndromes during the follow up period.

At the enrolment, the mean linear diameter was 1.3 cm (SD 0.36) and the mean volume was 1.8 cm^3 (SD 1.22).

The mean annual increase in the linear growth has been 0.13cm/year and the mean annual increase in the volumetric growth has been 0.71cm^3/year.

3/59 (5%) have been submitted to percutaneous biopsy and the cause was the tumour growth (2 RCC treated with thermal ablation and 1 angiomyolipoma, not treated).

Furthermore, 2/59 (3.4%) patients are currently elected for partial nephrectomy.

Overall, 4/59 (6.8%) patients have been submitted to active treatment due to tumour growth.

Table 2; Renal masses characteristics at study entry

		Enrolled Patients (N=59)	
		n	%
Site of Lesion	Kidney	58	98.3
	Total Reported	58	98.3
Location of Lesion	Central	22	37.3
	Polar	36	61.0
	Total Reported	58	98.3
Exophyitic Rate	< 50%	15	25.4
	>= 50%	26	44.1
	Entirely Endop	17	28.8
	Total Reported	58	98.3
Consistency of Lesion	Cystic	3	5.1
	Solid	55	93.2
	Total Reported	58	98.3
Max diameter measurement (cm)	>/=1.5	25	42.4
	Missing	33	55.9
	Total Reported	58	98.3

Table 2; Observation Time by Time Window

	Enrolled Patients (N=59)		Evaluable Patients (N=34)	
	n	%	n	%
Time on Study can't be computed	1	1.7		
Less than one year	25	42.4	1	2.9
12 months or longer	33	55.9	33	97.1
24 months or longer	20	33.9	20	58.8
36 months or longer	3	5.1	3	8.8

Conclusions

Our data suggests the feasibility and the safety of the introduction of an active surveillance protocol for small renal masses.

Also in our experience, this approach may represent a valuable option to offer to patients older than 50 years old and diagnosed with a SRM ≤2cm. The biomolecular aspects of these masses will be evaluated in future studies.