

# **GLOBAL RENAL MASS STUDY – A PROSPECTIVE INTERNATIONAL STUDY ON INDICATIONS, TREATMENT MODALITIES AND OUTCOMES**

## **Steering committee**

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## **Introduction**

Over the last 10 years, we have witnessed an increasing interest in the management of Renal masses. Three main reasons are responsible for this: the increasing diagnostic incidence which leads to the incidental discovery of small renal masses, the development and consolidation of partial nephrectomy and minimal invasive surgical treatments, the latter including both a laparoscopic approach and ablation techniques, and the increasing trend to nephron sparing surgery.

However, there are some fundamental differences concerning the indications for surgery and the technique used, mainly based on experience and institutional characteristics. Those factors may modulate outcomes. Similarly, specific patient and technical factors may influence treatment related morbidity.

In this prospective study we aim to assess on a global basis the indications, treatment modality and outcomes of surgical treatment for renal masses including (laparoscopic/robotic) radical or partial nephrectomy and (percutaneous/laparoscopic assisted) ablative treatments. Each centre participating in this project will include during a one-year period all the patients treated at their site, with a diagnosis of a renal tumour.

## **Data collection and analysis**

1. Inclusion of data on all consecutive patients treated during a one-year period.
2. Study initiated from each site once the first patient is enrolled. Each centre will close its participation exactly one year after inclusion of the first patient.
3. There is no minimum or maximum of number of sites participating in this study, however, all sites must receive prior approval of the CROES council.
4. Subject to the approval of the CROES council, the lead investigator at study sites must be a member of the Endourological Society and in good standing. Subject to the approval of the CROES council, study sites may be proposed by the members from the Steering committee or on recommendation from a third party.
5. Electronic database will be maintained at the central data collection site selected by the CROES council and shall be updated on a regular basis as determined by the CROES council. A manager, selected by the CROES council, at the central data collection site will maintain and coordinate the data collection.
6. Prior to approval of the site by the CROES council, for quality assurance, either an IRB approval or a letter from the principal investigator of the study site assuring the quality and ethical standards of data collection will be provided.
7. The members of the study group will receive feedback on the data collected on a regular basis, as determined by the CROES council.
8. The data analysis shall be the responsibility of the Steering committee for the study group.
9. The Steering committee shall be comprised of 6-8 international members and a chairman. A good balance among the different treatment specialists is desirable. Representatives of the CROES council may be joining during the Steering committee meetings.
10. Representatives from the supporter of the study will join the Steering Committee.

## **Primary study objectives:**

1. To assess the current patterns of surgical or instrumental treatment and indications for RCC treatment and treatment outcomes in terms of objective and subjective improvement.

## **Secondary study objectives:**

1. To assess the peri-operative morbidity (30 days) by using the Clavien score.
2. To define risk factors for the development of peri-operative morbidity after instrumental treatment.
3. To assess quality of life related to the different treatment modalities.
4. To assess pathological characteristics of the renal masses

Eventually collection on long-term follow (5-10 years) up would be recommended to all participant centres. Long-term data can be used to correlate initial pathology and

treatment modality with oncological outcome as well as to test the predictive ability of different staging systems (TNM / Risk systems)

## **Methodology**

Data will be collected prospectively. Variables will include preoperative assessment, operative data, histological results and postoperative period until 30 days. A CRF will be available on line.

Basically data will be grouped as follows:

1. Demographic (patient's and Centre)
2. Co-Morbidity - (Charlson – age index; other specific conditions e.g. BMI, anticoagulants, susceptible to drive treatment modality)
3. Surgical or instrumental modality
4. Histological data and Classification
5. Peri-operative complications (Clavien Grade)
6. Perioperative Outcome (at the end of the preoperative period: 30 days)
7. Short – Medium - Long term follow-up (data annually collected up to 10 years).

Upon decision on treatment the Centre will start to collect preoperative data in a prospective manner.

## **Data analysis**

As mentioned, data analysis is responsibility of the Steering Committee on the study on renal masses. Epidemiological and statistical support will be provided by CROES to fulfil the primary and secondary objectives as well as any “ *ad hoc* ” analysis derived from the prospective data collection.

## **Data property and publication**

Primarily data belongs to the CROES in its function as organ of the Society of Endourology. Eventually, data can be presented by the study participant members after a request to the Steering Committee and authorization from the CROES Council.

The Steering Committee will revise and give final approval to any paper derived from the data collected in the course of the study. A list of all participant members and centres will be included in any publication derived from this data collection. However the name and order of the main authors of any of the papers derived from this data collection will be decided by the Steering Committee of the Study on Renal Mass according to their level of input and contribution and subsequent approval by CROES council.

Patient Confidentiality: Data sent to the site is fully encrypted and therefore patient confidentiality is maintained.