



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

Version January 1st 2010

Steering committee

Pilar Laguna (Netherlands)
Adrian Joyce (UK)
Ferran Algaba (Spain)
Hein van Poppel (Belgium)
Jaime Landman (USA)
Inderbir Gill (USA)
Michael Blute (USA)
Jeffrey Cadeddu (USA)
Ralph Clayman (USA)
Benjamin Lee (USA)
Yoshinari Ono (Japan)
Hyeon Hoe Kim (Korea)

Office manager

Galina Filkova

Representatives Sponsor (STORZ)

Helmut Wehrstein
Gilles Pratabuy

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 for treatment and 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 or candidates for active surveillance (AS).

Data collection and analysis

1. Inclusion of data on all consecutive patients treated or in AS 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. All the sites commit themselves to provide follow-up data up to five years minimum or at request of the data manager.
4. There is no minimum or maximum number of sites participating in this study; however, all sites must receive prior approval of the CROES council.
5. 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.
6. 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.
7. 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.
8. The members of the study group will receive feedback on the data collected on a regular basis, as determined by the CROES council.
9. The data analysis shall be the responsibility of the Steering committee for the study group.
10. The Steering committee shall be comprised of a maximum of 10-12 international members and the chairperson. A good balance among the different specialists is desirable. Representatives of the CROES council may be joining during the Steering committee meetings.
11. 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.

Secondary study objectives:

1. To assess perioperative morbidity (30 days) by using the Clavien score
2. To assess operative complications.
3. To define risk factors for the development of operative and peri-operative morbidity after instrumental treatment.
4. To assess the long term risk of renal insufficiency
5. To assess pathological characteristics of the renal masses

Eventually collection on long-term follow up (10 years) 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.