CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGICAL SOCIETY

URS – A PROSPECTIVE INTERNATIONAL OBSERVATIONAL STUDY ON INDICATIONS AND PERIOPERATIVE OUTCOMES

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Introduction

During the past years there has been an increased interest in flexible and semi rigid Ureteroscopy (URS) as primary treatment for ureter stones and smaller sized (lower pole) renal stones. URS is truly on the rise, most probably due to technical refinements of the (flexible) endoscopic equipment and because of more realism about the efficacy of the SWL therapy.

There are some fundamental (institutional) differences, however, concerning indication for surgery, equipment used and maybe outcomes. Moreover specific factors may influence treatment related morbidity. In this prospective work, the Endourological Society, through CROES, will study on a global basis the indications and outcomes of both flexible and semi rigid URS. Each centre or site participating in this project will enter data on all patients undergoing ureteroscopy during the study period of one year at their site.

Data collection and analysis

1. Inclusion of data on all patients treated for a one-year period of patients.
2. Study initiated from each site once the first patient is enrolled.
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, Boston Scientific may propose study sites, 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 8-10 international members and a chairman. A representative of the CROES council will be a member of the Steering Committee. A liaison from Boston Scientific can attend all the Steering Committee meetings.

Primary study objective:

1. To assess the current indications for URS and the treatment outcomes in terms of the stone free rate.

Secondary study objectives:

1. To assess the peri-operative morbidity (30 days), including SAE, and translate them in the Clavien score.
2. To define risk factors for the development of peri-operative morbidity after URS.

The following variables will be included to correlate in a logistic regression and uni/multivariate analysis.

1. The use of antibiotics and incidence of infections.
2. The type of ureteral access used (balloon dilatation, access sheet) and the possible differences in morbidity.
3. Specific medical conditions (age, BMI, DM, anticoagulants, cardiovascular disease) versus outcome and morbidity.
4. The success of URS treatment following prior failed SWL.
5. Outcomes in complicated cases (mono-kidney, renal congenital anomalies, neurogenic problems).
6. To study preferences in intra-operative technique (device for fragmentation, use of ureteral stents, device to avoid intra-operative stone migration).
7. To study differences between lower and higher volume sites.

Data analysis

As mentioned, data analysis is responsibility of the Steering Committee on the study on URS. 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, the study participant members can present data 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 URS 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.