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MISSION

Through worldwide collaboration, CROES seeks to assess, using evidence based scientific methodology, the various aspects of clinical endourology.

VISION

By applying rigorous scientific evaluation to the field of clinical endourology, CROES will enable all urologic surgeons to bring to their patients the most effective and efficient care possible.

PROJECTS

- Global PCNL study
- Global URS study
- Global Greenlight Laser study
- Global Renal Mass study
- Global NBI study

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GLOBAL URS STUDY: A PROSPECTIVE INTERNATIONAL OBSERVATIONAL STUDY ON INDICATIONS AND PERIOPERATIVE OUTCOMES

Jean de la Rosette and Stavros Gravas

During the past years there has been an increased interest in flexible and semirigid ureteroscopy (URS) as the primary treatment for ureteral stones and smaller sized (lower pole) renal stones. The driving forces behind this explosion of ureteroscopic procedures include technical refinements of the endoscopic equipment, resulting in an increased success rate and reduced complication rates and more realism about the efficacy of the extracorporeal shockwave lithotripsy (SWL) therapy.

Technologic advances have been made in semirigid ureteroscopy and flexible ureterorenoscopy, including improvements in ureteroscope design, video/imaging equipment, intracorporeal lithotripsy devices, accessory instruments, ureteral access, and ureteral stents.¹ High level evidence indicates that ureteroscopic removal of ureteral stones achieves a higher stone-free state but with a higher complication rate and a longer hospital stay compared to SWL.²

There are some fundamental (institutional) differences, however, concerning indication for surgery, equipment used, and possible outcomes. Moreover, specific patient and technical factors may influence treatment-related morbidity. For these reasons, the Endourological Society, through CROES, will conduct the Global Ureteroscopy study. The aim of this prospective study is to assess on a global basis the indications and outcomes of both flexible and semirigid URS. Each center or site participating in this project will enter data on all patients with stones who undergo ureteroscopy during the study period of one year at their site.

Data collection and analysis

1. Study initiated from each site once the first patient is enrolled.
2. 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.
3. Electronic database will be maintained at the central data collection site and shall be updated on a regular basis. A manager selected by the CROES council at the central data collection site will maintain and coordinate the data collection.
4. Prior to approval of the site by the CROES council, for quality assurance, either an Internal Review Board (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.
5. The members of the study group will receive feedback on the data collected on a regular basis, as determined by the CROES council.

Primary study objectives:

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 Serious Adverse Events (SAE) and translate them in the Clavien score.
2. To define risk factors for the development of peri-operative morbidity after URS.

In addition 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 sheath) and the possible differences in morbidity.
3. Specific medical conditions (age, body mass index, diabetes mellitus, anticoagulants, and 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, and neurogenic problems).
6. To study preferences in intra-operative technique (device for fragmentation, use of ureteral stents, and device to avoid intra-operative stone migration).
7. To study differences between lower and higher volume sites.

In the Global PCNL study participating centers prospectively enrolled almost 5,000 patients in one year. A much higher volume of patients is anticipated to be enrolled in the URS study based on the fact that the number of URSs performed worldwide is significantly higher than the number of PCNLs, and that the participation rate in the URS study, so far, is beyond any expectation. CROES embraces every center willing to participate in this project because as it was stated in a recent editorial in *Journal of Endourology*: 'with your contribution, CROES will be able to help each of us reach the ultimate goal of our professional career: to provide the absolute best, least invasive, quality of care for all patients. The time is now – with CROES, the ability is yours'.³

References

1. Beiko DT, Denstedt JD. Advances in Ureterorenoscopy. *Urol Clin N Am* 2007;34:397–408.
2. Nabi G, Downey P, Keeley F, Watson G, McClinton S. Extra-corporeal shock wave lithotripsy (ESWL) versus ureteroscopic management for ureteric calculi. *Cochrane Database Syst Rev* 2007; Jan 24;(1):CD006029.
3. de la Rosette J. A platform for global endourological research. *J Endourol* 2009;23(10):1551–1553.

- Ongoing projects are: the Global PCNL observational study, the Global Greenlight Laser observational study, the Global Ureteroscopy study, and the Global Renal Mass study.
- For further information please visit: www.croesoffice.org or contact the Office Manager of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).

