



DOI: 10.1089/end.2011.1537

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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

CONTACT

For more information please contact Sonja van Rees Vellinga (info@croesoffice.org).



UPDATE FROM THE CROES STEERING COMMITTEES MEETING

Jean de la Rosette, Sonja van Rees Vellinga, and Stavros Gravas

The Clinical Research Office of the Endourological Society (CROES) has encouraged and sponsored the meeting of the members of the different projects Steering Committees and the CROES Council on a regular basis to discuss the progress of the studies, but most importantly to identify problems and solve them in a timely manner with the ultimate goal to achieve the high quality standards set by the Research Office and the Endourological Society. In accordance with its commitment for transparency and communication with all the participants in the global studies, CROES presents the key points from the last Steering Committees meeting that took place in Noordwijk, the Netherlands, on May 25, 2011, before the Focal Therapy meeting and in Paris on June 8, 2011, before the Challenges in Endourology meeting.

General Key Points

Publication

According to the CROES publication guidelines, the first article prepared from each project should be a descriptive one authored by all the members of the Steering Committee. The initial articles will be submitted to the Journal of Endourology; later articles can be submitted to other journals, although the Journal of Endourology remains top priority. The members of the Steering Committee can put forward their ideas by sending a proposal to the executive director, Mrs. Sonja van Rees Vellinga (info@croesoffice.org). The ideal aim is to include each participant in at least one of the articles based on criteria that have been described previously.¹

An important reminder is that 6 months after closing a study, all contributors may propose to the Steering Committee topics for analysis. Each proposal will be carefully considered by the CROES office and the Steering Committee. If the proposal is feasible, the author can include up to four coauthors from his/her institution in the manuscript. The analysis will be prepared by the CROES office. The contributor will be responsible for preparing the manuscript in due time, but editing and submission of the manuscript will be coordinated by the CROES publication office.

Although the participants have signed a data transfer agreement, this does not keep them from publishing their own data at their own discretion.

Audit

It is commonplace that all participating centers contribute their data in good faith and on a voluntary basis; however, monitoring, validation, and quality control of the data coming from the different studies is of outmost importance for CROES to safeguard that the conclusions coming from the studies are impeccable and accurate. Once again, during the Steering Committees meeting, the importance of the Audit Committee that has been recently installed was clearly underlined.² It was announced that the Audit Guidelines are prepared. The sites may be selected randomly and/or in case the centers belong to the outliers. Key parameters will be defined, and data will be collected electronically. Dr. Preminger (chairman of the Audit Committee) introduced the idea to give a quality

score to all centers. In the future, the aim is to prepare a quality report for each principal investigator on the progress of the study in their institution.

New projects and funding

The aim is to conduct more randomized studies, but these are also more expensive because of the costs of Institutional Review Board (IRB) approval. All new centers that will sign up should be members of the Endourological Society. CROES welcomes the suggestion of new projects and specifically encourages American investigators to take the lead for that. At present, to start a new project, funding has to be secured by the investigator who then will become the chairman of the Steering Committee.

Specific Minutes from the Meetings

CROES Renal Mass Steering Committee Meeting

Present: Pilar Laguna (chairman), Ferran Algaba, Benjamin Lee, Adrian Joyce, Giovanni Pagliuca, and Sonja van Rees Vellinga.

At the moment, there are 120 centers actively participating with more than 3000 patients included. Big contributors are Turkey, France, Czech Republic, and the United States. About half of the centers have finished the 1-year recruitment. The study will stay open until January 2012, so all centers will be able to finish their recruitment. The study will continue also for the follow-up.

Mr. Giovanni Pagliuca is the contact person for questions regarding the study (renalmass@croesoffice.org). He will also check the data and approach the centers about the progress and incorrect/missing data.

At the 2011 World Congress of Endourology (WCE) meeting in Kyoto, Japan, there will be an update on CROES. By that time, the dataset will be almost complete, and a total overview could be given.

CROES Percutaneous Nephrolithotomy (PCNL) Steering Committee Meeting

Present: Jean de la Rosette (chairman), Stavros Gravas, Tadashi Matsuda, Ravindra Sabnis, Margaret Pearle, Ahmet Tefekli, Jorge Gutierrez, Christine McKillop, Dedan Opondo, Giovanni Pagliuca, and Sonja van Rees Vellinga.

The study has been closed since the end of 2009, and the data have been analyzed centrally at the CROES office. Currently, three articles have been published in the Journal of Endourology, and five more manuscripts have been accepted for publication. Approximately 10 more articles will follow on the PCNL study. The list of possible authors and the publications was approved by the members of the Steering Committee. Proposals for additional publications were sent by Dr. Glenn Preminger, Dr. Hassan Razvi, Dr. Selcuk Guven, Dr. Tim Averch, Dr. Arthur Smith, and Dr. Luigi Cormio. The proposed topics included urosepsis and type of lithotripters, stone-free check methods, the impact of body mass index, and outcomes in super-obese patients.

In addition, two posters were presented at the American Urological Association (AUA) meeting on the efficacy and safety of PCNL in patients with renal malformations and solitary kidneys. For the WCE in Japan, six more abstracts will be submitted. It was repeated that participants can present on behalf of the CROES in national meetings, but the CROES office will provide the presentation.

It was suggested that one of the advantages of the CROES studies and specifically of the Global PCNL is to identify areas with conflicting results and conduct prospective studies to investigate potential gaps in our knowledge.

CROES Narrow Band Imaging (NBI) Steering Committee Meeting

Present: Seiji Naito (chairman), Jean de la Rosette, Stavros Gravas, Tadashi Matsuda, Rik Bryan, Marek Babjuk, Rolf Muschter, Koji Shimomura, Masayoshi Hasegawa, Christine McKillop, Dedan Opondo, Giovanni Pagliuca, and Sonja van Rees Vellinga.

The study was initiated at the beginning of August 2010. There is active involvement, mainly from centers in Asia and Europe. At the moment, 14 centers are actively including patients. The rest

of the centers are still working on IRB approval. By now, close to 200 patients have been included. It is important to randomize one patient at a time and close to the operation date to guarantee the ratio at 1:1. The data manager, Mr. Giovanni Pagliuca, is the contact person for questions regarding the study (nbi@croesoffice.org).

At the 2011WCE meeting in Japan, there will be an update on CROES studies at which the NBI study will be a main topic. It is expected that 300 to 400 patients will be included by that time.

CROES Ureteroscopy (URS) Steering Committee Meeting

Present: Jean de la Rosette (chairman), Stavros Gravas, Francis Keeley, Tadashi Matsuda, Margaret Pearle, John Denstedt, Glenn Preminger, Christine McKillop, Dedan Opondo, Giovanni Pagliuca, and Sonja van Rees Vellinga.

At the moment, there are 150 centers actively participating with more than 12,000 patients included. The sites are located in 38 different countries, of which India, Romania, Turkey, Italy, and the United States are contributing with large numbers. The study will stay open until January 2012; therefore, all centers will be able to finish their recruitment. As an extra service, the CROES offers the centers the opportunity to keep on collecting data after the 1-year recruitment has passed.

Mr. Giovanni Pagliuca is the contact person for questions regarding the study (urs@croesoffice.org). He will also check the data and approach the centers about the progress and incorrect/missing data.

At the 2011WCE meeting in Japan, there will be an update on CROES. By that time, the dataset will be almost complete and a total overview could be given.

CROES GreenLight Laser Steering Committee Meeting

Present: Jean de la Rosette (chairman), Stavros Gravas, Seiji Naito, Alexis Te, Carl-Jørgen Arum, Christine McKillop, Dedan Opondo, Giovanni Pagliuca, and Sonja van Rees Vellinga.

At the moment, there are 30 centers actively participating with almost 900 patients included. The study will stay open until April 2012. The countries that have included most patients are Japan, the Netherlands, Norway, and Greece. Most of the cases in the database are GreenLight laser; a smaller proportion consists of monopolar and bipolar cases of transurethral resection of the prostate. Prof. Te indicated that the XPS laser is coming up, but HPS is still popular in the United States. The data manager, Mr. Hiren Sodha, is the contact person for questions regarding the study (hps@croesoffice.org). He will also check the data and approach the centers about the progress and incorrect/missing data.

At the 2011 WCE meeting in Japan, there will be an update on this study, and at the 2010 AUA meeting, it is expected the dataset will be almost complete and an overview could be given.

Last But Not Least

CROES is delighted to announce that the Global Network of all the studies currently consists of 350 centers and 720 investigators. CROES is you; therefore, send us your feedback or suggestions to further improve our common effort. The time is now—with CROES, the ability is yours.³

References

1. de la Rosette J, Gravas S. Quality and transparency in CROES research projects. *J Endourol* 2010;24:317–319.
2. de la Rosette J, Gravas S. Guidelines for the implementation of the Audit Committee. *J Endourol* 2011;25:361–363.
3. de la Rosette J. A platform for global endourological research. *J Endourol* 2009;23(10):1551–1553.

- The global PCNL observational study was closed in December 2009.
- The Global Ureteroscopy study and the Global Renal Mass Study were closed for initiating new sites in January 2011. The Global Greenlight Laser study was closed for initiating new sites in April 2011.
- Ongoing project: the randomized study on Narrow Band Imaging versus White Light Imaging.
- For further information please visit: www.croesoffice.org or contact the Office Manager of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).