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Sonja van Rees Vellinga
Amsterdam (The Netherlands)
info@croesoffice.org

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).



PROGRESS REPORT ON THE CROES STUDIES

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

The Clinical Research Office of the Endourological Society (CROES) was set up in 2008 and is responsible for organizing, structuring and facilitating a global network for endourological research under the umbrella of the Endourological Society. Since then CROES has embarked on 5 global studies. The purpose of the present newsletter is to update all the members of the Endourological Society on the progress of those studies.

The Percutaneous Nephrolithotomy (PCNL) Global Study

The first study undertaken by CROES focused on percutaneous nephrolithotomy (PCNL) for renal stone removal, and was conducted from November 2007 until December 2009. Nearly 100 sites from Asia, Europe and the Americas participated in the PCNL Global study, and in the course of one year, nearly 6000 patients were treated and data were prospectively collected. At this moment eight manuscripts have been finalized and several more are in progress. In addition, posters have been presented on the PCNL study at several occasions, such as meetings of the American Urological Association (AUA), European Association of Urology (EAU) and World Congress of Endourology (WCE).

The PCNL study manuscripts that have been finalized are:

- a. The Clinical Research Office of the Endourological Society (CROES) Percutaneous Nephrolithotomy (PCNL) Global Study: Indications, Complications and Outcomes in 5803 Patients, by Jean de la Rosette, Dean Assimos, Mahesh Desai, Jorge Gutierrez, James Lingeman, Roberto Scarpa and Ahmet Tefekli, on behalf of the CROES PCNL Study Group. Published in *Journal of Endourology*.¹

The objectives of this work are to assess the current indications for PCNL, perioperative morbidity and the treatment outcomes in terms of stone-free status. It was concluded that with a high success rate and a low major complication rate, PCNL is an effective and safe technique overall for minimally invasive removal of kidney stones.

- b. The Clinical Research Office of the Endourological Society (CROES) Percutaneous Nephrolithotomy (PCNL) Global Study: Tract Dilation Comparisons in 5537 Patients, authored by Tome Lopes, Kandasami Sangam, Peter Alken, Benjamin Silva Barroilhet, Christian Saussine, Lei Shi and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Accepted for publication in *Journal of Endourology*.

The objectives of this study are to describe the choice of tract dilatation method for PCNL patients and to compare the clinical characteristics and outcomes of patients treated using telescopic/serial dilation or balloon dilation. It was concluded that dilatation of the PCNL tract is globally equally performed using telescopic or balloon dilators. There is more of a preference for telescopic dilators in Asian countries and high volume centers. Balloon dilatation results in more bleeding and longer operating times.

- c. Operating Times and Bleeding Complications in Percutaneous Nephrolithotomy (PCNL): A Comparison of Tract Dilation Methods in 5537 Patients in the Clinical Research Office of the Endourological Society (CROES) PCNL Global Study, by Akito Yamaguchi, Andreas Skolarikos, Niels-Peter Noor Buchholz, Gonzalo Bueno Chomon, Michael Grasso, Pietro Saba, Stephen Nakada and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Accepted for publication in *Journal of Endourology*.

One objective of this analysis is to describe the bleeding and operating time in patients who underwent percutaneous nephrolithotomy using either telescopic/serial or balloon dilation. Another objective is to identify factors that may predict bleeding during percutaneous nephrolithotomy. It was found that prognosticators for the presence of bleeding are size of access sheath, dilatation method, caseload, stone load and operating time. Method of dilatation is related to operating time

- d. The Percutaneous Nephrolithotomy (PCNL) Global Study: Classification of Complications, by Gaston Labate, Pranjal Modi, Anthony Timoney, Luigi Cormio, Xiaochun Zhang, Michael Louie, Magnus Grabe and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Accepted for publication in *Journal of Endourology*.

The objectives of this study are to identify common complications in PCNL and to compare the Clavien score classification in the Global PCNL study and the original Clavien Cohort of the year 2004. Moreover, we want to assess the risk factors for the development of perioperative morbidity after PCNL. It was concluded that PCNL results in complication in one out of five patients treated. The Clavien score has a positive association with the American Society of Anesthesiologists (ASA) Score, age, diabetes mellitus, cardiovascular disease, anticoagulant use and urinary tract infection.

- e. The Clinical Research Office of the Endourological Society Percutaneous Nephrolithotomy Global Study: Staghorn Versus Non-Staghorn Stones by Mahesh Desai, Antonello De Lisa, Burak Turna, Jorge Rioja, Helena Walfridsson, Allesandro D'Addessi, Carson Wong and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Accepted for publication in *Journal of Endourology*.

The objectives of this study are to describe the characteristics and clinical outcomes of patients who had staghorn stones and to compare the characteristics and clinical outcomes between staghorn and nonstaghorn-bearing patients. It was concluded that PCNL in staghorn is safe but results in a lower stone-free rate, longer hospital stay, longer operating time, higher level of postoperative fever, bleeding and blood transfusion than in nonstaghorn patients.

- f. Supine Versus Prone Position During Percutaneous Nephrolithotomy (PCNL): A Report from the Clinical Research Office of the Endourological Society (CROES) PCNL Global Study, by José Valdivia Uria, Roberto Scarpa, Mordechai Duvdevani, Andreas Gross, Robert Nadler, Kikuo Nutahara and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Under review by *Journal of Endourology*.

The aim of this study is to characterize the patients who were operated in supine and prone positions and to compare the outcomes between both positions. In this study, the patient characteristics and the technique used for both positions is more or less the same. Since operating time and stone-free rates favor prone PCNL, but patient safety favors supine PCNL, the choice of patient position should be tailored to individual patient characteristics and the surgeon's preference.

- g. Percutaneous Nephrolithotomy Among Patients with Renal Anomalies: Patient Characteristics and Outcomes: a Subgroup Analysis of the CROES Global PCNL Study, by Palle Osther, Hassan Razvi, Evangelos Liatsikos, Timothy Averch, Alfonso Crisci, Juan López Garcia, Arup Mandal and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Under review by *Journal of Endourology*.

In this study the characteristics and outcomes of PCNL between renal malformations and normally developed upper urinary tracts were compared. It was concluded that in patients undergoing PCNL the presence of renal malformation is likely to extend operating time. Stone-free rates as well as incidence of complications following PCNL are similar irrespective of the presence of renal anomalies.

- h. The Clinical Research Office of the Endourological Society (CROES) Percutaneous Nephrolithotomy (PCNL) Global Study: Nephrolithotomy in 189 Patients with Solitary Kidneys, by Viorel Bucuras, Ganesh Gopalakrisnan, Stuart Wolf, Jr., Ying Hao Sun, Giampaolo Bianchi, Tibet Erdogru and Jean de la Rosette, on behalf of the CROES PCNL Study Group. Under review by *Journal of Endourology*.

The objectives of this study are to compare characteristics and outcomes in patients with solitary and bilateral kidneys treated with percutaneous nephrolithotomy. It was concluded that patients with a solitary kidney had a higher cardiovascular risk and ASA score. Outcomes related to morbidity and stone-free rate were less favorable for solitary kidneys.

In addition to the PCNL study, four more studies have been initiated, namely the Global URS study, the Renal Mass study, the Greenlight Laser study and the NBI study for bladder cancer.

The Ureteroscopy Study

Ureteroscopy (URS) has benefited from technical refinements of the (flexible) endoscopic equipment that has resulted in an increased use of URS as the primary treatment for ureter stones and smaller-sized (lower pole) renal stones. The URS study² was initiated in January 2010, and 150 centers have included more than 10,000 patients since then. The aim of this prospective study is to assess on a global basis the indications and outcomes of both flexible and semi-rigid URS. This study has been closed with regard to the recruitment of new centers; however, the data collection for participating centers is still ongoing.

The Renal Mass Study

The Renal Mass study³ is a prospective, global study that aims to assess the indications, treatment modality and outcomes of surgical treatment for renal masses including (open/laparoscopic/robotic) radical or partial nephrectomy and (percutaneous/laparoscopic-assisted) tumor ablation using cryo or radiofrequency. Each center participating in this project will include during a one-year period all the patients with a diagnosis of a renal mass treated at their site. This study was launched in January 2010, and 120 centers have included nearly 3000 cases. It should be underlined that this study has also been closed with regard to the recruitment of new centers, but the data collection for participating centers is still ongoing.

The Greenlight Laser Study

Laser treatment of symptomatic benign prostatic hyperplasia (BPH) is truly on the rise, most probably due to technical advancement of technology and refinement of endoscopic equipment. The aim of this prospective study was to evaluate on a global base the indications and outcomes of HPS greenlight laser treatment for BPH.⁴ Each center participating in this project will include during a one-year period the patients treated with greenlight laser or transurethral resection of the prostate (TURP) at their site.

In April 2011 this study will close the recruitment of new centers; at the moment 33 centers have included almost 600 patients.

The Narrow Band Imaging Study

This is the first randomized study coordinated by CROES. The aim of this multi-center trial is to compare the safety (morbidity) and efficacy (recurrence rate) between NBI-assisted transurethral resection of bladder cancer (TURB) and White Light (WL)-assisted TURB.⁵ Patients will be followed during their hospital stay, after 3 months and after 12 months. At present, 11 centers are actively participating and have included 120 patients. CROES expects more centers will follow shortly, as many of them are currently in the process of obtaining Institutional Review Board (IRB) approval. The recruitment for new centers is still open until August 1, 2011.

Future projects and actions

CROES aims to be the premier research office in endourology and share the outcomes in evidence-based communications. We encourage all institutions to join the CROES global network. CROES can offer you interesting research projects with a sophisticated data management system. The CROES publication office aims to include all principal investigators in one of the publications. Secondly, all centers will be acknowledged in each publication resulting from the study in which they participated. This will offer your institution great exposure and the chance to be recognized as a center of excellence in the field of endourology.

In addition, several other projects are in preparation, including a study on cryosurgery and a study on minimally invasive treatment for prostate cancer.

At the AUA annual meeting there was a reception with all CROES investigators. The CROES team considered this a unique opportunity to meet with all investigators to discuss the state of our current projects and to exchange ideas on new studies in a relaxed setting. The echo of this meeting will be presented in one of the upcoming newsletters. Investigators who were not able to join us will be invited for another update at the occasion of the WCE meeting.

Last but not least, the next meeting of the Steering Committees will take place in Paris on June 8, 2011, during the Challenges in Endourology meeting.

References

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2. de la Rosette J, Gravas S. Global URS study: A prospective international observational study on indications and perioperative outcomes. *J Endourol* 2010;24:1–3.
3. Laguna P, Gravas S. Global renal mass study – a prospective international study on indications, treatment modalities and outcomes. *J Endourol* 2009;23:1930–1931.
4. de la Rosette J, Gravas S. Greenlight laser for benign prostatic hyperplasia study: A prospective international observational study on indications and perioperative outcomes. *J Endourol* 2010;24:882–883.
5. de la Rosette J, Stavros G. A multi-center, randomized international study to compare the impact of narrow band imaging versus white light cystoscopy in the recurrence of bladder cancer. *J Endourol* 2010;24:660–661.

- The Global Uteroscopy study and the Global Renal Mass study were closed in January 2011 and the Global Greenlight Laser Observational study was closed in April 2011 for the participation of new centers.
- Ongoing projects are: the randomized study on Narrow Band Imaging versus White Light Imaging.
- The next meeting of the Steering Committees will take place in Paris on June 8, 2011.
- For further information please visit: www.croesoffice.org or contact the Executive Office Manager of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).

