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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 ON CROES AT THE AMERICAN UROLOGICAL ASSOCIATION ANNUAL MEETING

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

The Clinical Research Office of the Endourological Society (CROES) aims at promoting and supporting high quality international patient-centered research in a transparent way.

The CROES recognizes the importance of the active involvement and recognition of the participating centers. At the American Urological Association (AUA) Annual Meeting in Atlanta, all investigators who are participating in CROES studies were invited to join the investigators meeting at the Omni Hotel. We discussed the current projects and exchanged ideas on new studies in a friendly and relaxed setting. Almost 100 persons joined the reception regarding the update on all five CROES projects. We would like to thank all participants for joining the meeting, and we would like to present a short summary for those who were not able to attend.

The global percutaneous nephrolithotomy (PCNL) study was the first study launched, and at present, data from 5803 patients who were treated in 96 centers are analyzed. The value of the PCNL study is that it is a real-life study; it demonstrates contemporary global practices in stone management. The dataset provides significant insight on academic and community practice and covers all spectrums from centers with high to more restricted volume. These data allow us to assess the current indications, perioperative morbidity, and stone-free outcomes for PCNL worldwide.

Currently, 17 articles have been published or are in press in the *Journal of Endourology*, *Journal of Urology*, *BJU International*, *European Urology*, and *World Journal of Urology*. Approximately 13 more articles are currently under review or in preparation. The conclusions of these papers and



CROES investigators meeting.



CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGY SOCIETY

Percutaneous nephrolithotomy and Chronic Kidney Disease

Krish Sairam¹, Cesare M. Scoffone², Peter Alken³, Burak Turna⁴, Hiren S. Sodha⁵, Jorge Rioja⁶, J. Stuart Wolf, Jr.⁷, Jean de la Rosette⁸,
on behalf of CROES PCNL study group

¹Global Hospitals & Health City, Chennai, Tamilnadu, India ²Cottolengo Hospital, Torino, Italy ³University Hospital Mannheim, Mannheim, Germany ⁴Ege University School of Medicine, Izmir, Turkey ⁵Rg Stone Urology & Laparoscopy hospital, Mumbai, India ⁶Hospital Miguel Servet, Zaragoza, Spain ⁷University of Michigan, Michigan, USA ⁸AMC University Hospital, Amsterdam, the Netherlands

OBJECTIVES

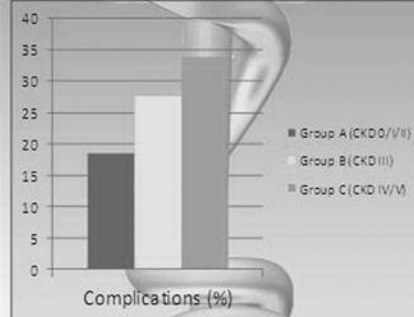
Kidney stones are a risk factor for chronic kidney disease. This study compared characteristics and post operative outcomes based on differences in preoperative renal function in patients who underwent percutaneous nephrolithotomy (PCNL).

MATERIALS & METHODS

The Clinical Research Office of the Endourological Society (CROES) collected data centrally on patients treated with PCNL. Each participating center collected data prospectively on consecutive patients for a full year period. Patients with pre-operative creatinine measurement were included in this study.

Estimated glomerular filtration rate (eGFR) was calculated using the Modification of Diet in Renal Disease (MDRD) formula. Patients were divided into three groups using Chronic Kidney Disease (CKD) classification. Group A (CKD 0, I and II), Group B (CKD III), Group C (CKD IV/V).

Patient characteristics and outcomes were compared between the three groups using percentages and means for categorical and continuous variables respectively. Repeated chi-square tests were done to compare outcomes between each of the three categories. Tukey's HSD were done to compare continuous variables. The level of statistical significance was 0.05.



RESULTS

Between November 2007 and December 2009, 5803 patients were treated at 95 centers worldwide. Mean ages were 47.0(15.2), 57.8(13.8) and 56.2(13.8) for Group A, B and C respectively. Group C patients had higher staghorn stone rates 42.6% versus 32.0% (p=0.004) and 25.3% (p=0.001) in Group B and A respectively. Positive urine cultures were higher in Group C (36.3%) versus 21.9% (p=0.001) and 13.4% (p=0.001) in Groups B and A.

Mean operating time increased with higher CKD groups - Group A, 83.3(46.9) vs Group B, 88.8(50.1), (p=0.003); and Group C vs A, 94.9(59.1), (p=0.001); . Stone free rates were 76.9%, 73.2% and 71.2% in Group A, B and C respectively. Fever (A: 9.7%, B: 11.7%, C: 18.3%) and blood transfusion rates (A: 4.9%, B: 6.1%, C: 18.4%) increased with CKD groups. Overall complication rates were also higher among the higher CKD groups, Group C 33.8% vs A 18.5%, p<0.001, while Groups B 27.6% vs A 18.5%, p<0.001

CONCLUSION

PCNL is possible in patients with chronic kidney disease but with higher risks for post operative complications, need for blood transfusion and longer post operative stay.

CROES poster: PCNL and chronic kidney disease.

the new developments in PCNL were discussed at the investigators meeting. We will highlight some of the recent publications that were also presented at the AUA Annual Meeting.

In the first podium presentation, Dr. de la Rosette presented the Clavien score for use in PCNL and standardization of complications. In the manuscript recently accepted in *European Urology*,¹ data for 528 patients with complications after PCNL were used to create a set of 70 unique complication-management combinations. Clinical case summaries for each complication-management combination were compiled in a survey to 98 urologists who rated each combination using the Clavien classification. The conclusion of this article is that the Clavien score is valid for grading complications in PCNL. The Clavien score has low reliability, however, for minor (more common) PCNL complications. To improve the outcomes of research in PCNL, it would be good if explicit categories for scoring complications were created.

The second podium presentation, by Dr. Fuller, was on PCNL in superobese patients. This article is currently under review and describes the outcomes in the superobese. As the worldwide prevalence of obesity continues to rise, urologic surgeons will increasingly face the challenges associated with providing safe, high-quality care to obese patients. After exclusion criteria were applied, 3709 eligible patients were reviewed, of whom 97 were identified as superobese, with a body mass index in excess of 40 kg/m². These patients were matched according to stone characteristics with 97 patients of normal weight. A multidimensional match of 97 superobese patients with 97 patients of normal weight was created using propensity score matching (PSM). Two equal groups were created after the matching process. PCNL in superobese patients is associated with longer operative duration, higher rates of reintervention, and an increased risk of minor perioperative complications. With this knowledge, urologists should seek to develop strategies to optimize the perioperative management of such patients.



CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGY SOCIETY

Does imaging modality used for percutaneous renal access make a difference?

An analysis of the Clinical Research Office of the Endourological Society (CROES) PCNL Global Study database

Sero Andonian¹, Cesare M. Scoffone², Michael K. Louie³, Andreas J. Gross⁴, Magnus Grabe⁵, Francisco P.J. Daels⁶, Hemendra N. Shah⁷, Jean de la Rosette⁸
on behalf of CROES PCNL study group

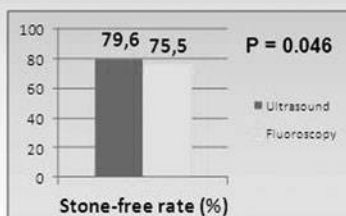
¹McGill University Health Center, Montreal, Canada ²Cottolengo Hospital, Torino, Italy ³University of California, Irvine, USA ⁴Asklepios Hospital Barmbek, Hamburg, Germany ⁵Skåne University Hospital, Malmö, Sweden ⁶Centro de Litiasis (CELIT) Hospital Italiano, Buenos Aires, Argentina ⁷R. G. Stone Urology & Laparoscopy Hospital, Mumbai, India ⁸AMC University Hospital, Amsterdam, the Netherlands

OBJECTIVES

To assess peri-operative outcomes of percutaneous nephrolithotomy (PCNL) using ultrasound or fluoroscopy guidance for percutaneous access.

MATERIALS & METHODS

A prospectively collected international CROES database containing 5803 patients treated with PCNL was used for the study. Patients were divided into two groups based on the methods of percutaneous access: Ultrasound only vs Fluoroscopy only. Patient characteristics, operative data and post-operative outcomes were compared.



RESULTS

Percutaneous access was obtained using ultrasound guidance only in 509 patients (14.3%) and fluoroscopic guidance only in 3042 patients (85.7%).

In 93% of all procedures, renal access was obtained by the urologist. There was a lower proportion of PCNLs being performed in the supine position in the ultrasound group (5.7 vs 21.5%, $p < 0.001$).

There were no significant differences between the two groups in terms of frequency and pattern of Clavien complications ($p = 0.7$). However, post-operative bleeding and transfusions were significantly higher in the fluoroscopy group, (6.1 vs 8.9%; $p = 0.033$) and 3.6 vs 6.2%; $p = 0.020$, respectively.

Mean access sheath size was significantly greater in the fluoroscopy group (29.1F vs 22.7F; $p < 0.001$). Stone-free rates were slightly higher in the ultrasound group (79.6 vs. 75.5%, $P = 0.046$). Mean hospitalisation was significantly longer in the ultrasound group (5.3 vs 3.8 days; $p < 0.001$).

Multivariate analysis of postoperative bleeding and access method adjusting for size of sheath

Variable	Odds ratio	95% CI	P value
Guidance Method			
Ultrasound (Reference)	1.00	-	-
Fluoroscopy	1.17	0.62-2.20	0.628
Sheath size range			
Small ($\leq 18F$) (Reference)	1.00	-	-
Medium (24F, 26F)	4.17	0.94-18.60	0.061
Large (27F, 28F, 30F)	5.50	1.22-24.71	0.026
Largest (32F-34F)	9.84	2.07-46.73	0.004

CONCLUSION

Although fluoroscopic guided percutaneous access was found to be associated with higher incidence of postoperative bleeding, on multivariate analysis this was found to be related to greater access sheath size ($\geq 27F$). Prospective randomized trials are needed to clarify this issue.

CROES poster: PCNL and imaging modality.

In addition, two posters were presented. Dr. Sodha presented a poster on chronic kidney disease (CKD) and PCNL. In this study it was shown that poor renal function impacts negatively on post-PCNL outcome. Although other factors almost certainly contribute to CKD, by more aggressively removing these stones, particularly staghorn stones, at first presentation and more vigilantly attempting to prevent recurrence through infection control, pharmacologic or other interventions, the progression of CKD from nephrolithiasis may be halted.

Dr. Andonian presented a poster on perioperative outcomes of PCNL using ultrasonographic or fluoroscopy guidance for percutaneous access. The conclusion of these investigators: "Although fluoroscopy-guided percutaneous access was found to be associated with higher incidence of hemorrhage, on multivariate analysis, this was found to be related to greater access sheath size ($\geq 27F$). Prospective randomized trials are needed to clarify this issue."

Three other CROES projects have been closed this year. The Global Ureterscopy (URS) study² is the largest prospective database of patients treated with URS to be reported to date. Approximately 130 sites have included more than 15,000 cases; the results reflect the routine clinical treatment of patients with a variety of indications for URS, and thus represent the use of this technique in a "real-life" scenario. The study is currently being audited, and the data will be ready for analysis October 1, 2012. The data were entered by institutions from 36 countries worldwide. The patients who are included have a mean age of approximately 50 years. Most stones are ureteral stones, and about one quarter of the patients treated have renal stones. The distribution by site is equal. The type of URS most frequently performed is semirigid (around 75%). In about 85% of the cases, it was indicated that the treated area was stone free after URS. A complication was reported in approximately 3% of the cases. The first results are expected in November 2012.

The Renal Mass study³ was launched in January 2010, and 113 centers have included more than 5000 cases. In this prospective study, we aim to assess on a global basis the indications, treatment modality,

and outcomes of instrumental treatment for renal masses including radical or partial nephrectomy and ablative treatments. The study is currently being audited, and the data will be ready for analysis September 1, 2012.

The biggest contributions in number of cases come from countries such as Turkey, France, and the United States. The mean age of the patients included in the database is approximately 60 years, but also a significant portion of younger patients is included. The technique most frequently performed is still radical nephrectomy, but also partial nephrectomy is often performed. In approximately 15% of the cases, an ablative therapy was used. The first results are expected in October 2012.

In the Global Greenlight Laser study,⁴ we will study on a global base the indications and outcomes of High Performance System GreenLight laser treatment for benign prostatic hyperplasia. This study has closed in April 2012, and at the moment, 27 centers have included more than 1000 patients. The data were successfully audited with a return rate of 90%. This summer, the first publication on this study will be prepared.

The first randomized study, comparing the use of Narrow Band Imaging in addition to White Light cystoscopy in the treatment of nonmuscle invasive bladder cancer, is still open for new centers.⁵ Close to 30 centers worldwide have accepted the challenge and will randomize their cases according to a strict inclusion protocol during a 1-year period. This milestone project will open new avenues in endourologic research.

The CROES studies are open to centers from all over the world, therefore enabling institutions from developing countries to also take part in studies and publications. All participants will be recognized in publications, will receive a certificate, and will have the opportunity to present themselves at national and international meetings. The CROES publication office aims to include all principal investigators in at least one of the publications. In addition, all centers will be acknowledged in each publication resulting from the study in which they participated. This will offer the institutions great exposure and the chance to be recognized as a center of excellence in the field of endourology. All feedback is welcome, and we invite you to contact the CROES office with new ideas and suggestions regarding ongoing studies and future projects. At the upcoming World Congress of Endourology meeting in Istanbul, CROES is looking forward to present you with a new update on the CROES projects.

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- The global PCNL observational study was closed in December 2009.
- The Global Ureteroscopy study, the Global Renal Mass study, and the Global Greenlight Laser study are closed January 2012.
- Ongoing project: the randomized study on Narrow Band Imaging *vs* White Light Imaging.
- For further information please visit: www.croesoffice.org or contact the Executive Director of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).