CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGICAL SOCIETY

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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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GREENLIGHT LASER FOR BENIGN PROSTATIC HYPERPLASIA STUDY: A PROSPECTIVE INTERNATIONAL OBSERVATIONAL STUDY ON INDICATIONS AND PERIOPERATIVE OUTCOMES

Jean de la Rosette and Stavros Gravas

The last two decades have witnessed a significant change in the management of benign prostatic hyperplasia (BPH). Various minimally invasive treatments have been developed and the range of therapeutic options for the management of BPH continues to widen. Among them, laser treatment is truly on the rise and has renewed enthusiasm for laser prostatic surgery, most probably due to technical refinements of the technology and endoscopic equipment.

There are some fundamental (institutional) differences, however, concerning indication for surgery, experience, technique used and maybe outcomes. Moreover, specific factors may influence treatment-related morbidity. In this prospective study we will study on a global base the indications and outcomes of HPS greenlight laser treatment or transurethral resection of the prostate (TURP) for BPH. During a one-year period, each center participating in this project will treat the patients with greenlight laser or TURP at their site.

Data collection and analysis

1. Study initiated from each site once the first patient is enrolled.
2. 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, American Medical Systems (AMS) may propose study sites, the members from the Steering Committee or on recommendation from a third party.
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. A data transfer agreement that defines the obligations and rights of each involved party regarding the use of data, is available.[1] Guidelines on CROES publications have been previously presented in detail.[2]
5. Epidemiological and statistical support will be provided by CROES to fulfill the primary and secondary objectives as well as any *ad hoc* analysis derived from the prospective data collection.
6. 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 HPS greenlight laser treatment and the treatment outcomes in terms of objective and subjective improvement.

Secondary study objectives:

1. To assess the perioperative morbidity (30 days) by using the Clavien system.
2. To define risk factors for the development of perioperative morbidity after HPS greenlight laser treatment.

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. Possible differences in morbidity.
3. Specific medical conditions (age, body mass index, diabetes mellitus, anticoagulants, cardiovascular disease) versus outcome and morbidity.
4. Outcomes in complicated cases (coumarine use, large prostates, etc.)
5. To define the learning curve.
6. To study differences between lower and higher volume sites.

Recent evidence has shown that the Greenlight laser vaporization has overall low perioperative morbidity, efficacy comparable to TURP in the short term, and a higher reoperation rate indicating that Greenlight laser represents a promising alternative to TURP.[3] The Global Greenlight Laser study will provide useful insight into areas of remaining uncertainty and, interestingly, will reveal if this laser is currently being limited in selective cases or if it is challenging TURP in daily practice.

References

1. de la Rosette J, Gravas S. Data transfer agreement form for CROES research projects. J Endourol 2010;24:501–504.
2. de la Rosette J, Gravas S. Guidelines for CROES publications. J Endourol 2010;24:167–169.
3. Naspro R, Bachmann A, Gilling P, et al. A review of the recent evidence (2006–2008) for 532-nm photoselective laser vaporisation and holmium laser enucleation of the prostate. Eur Urol 2009;55:1345–1357.

- Ongoing CROES projects include: the Global Greenlight Laser observational study, the Global Ureteroscopy study, and the Global Renal Mass study.
- The Narrow Band Imaging versus White Light Imaging study is being launched.
- For further information please visit: www.croesoffice.org or contact the Office Manager of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).

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