GREENLIGHT LASER FOR BPH – A PROSPECTIVE INTERNATIONAL STUDY ON INDICATIONS AND OUTCOMES

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Introduction

During the past two decades we are witnessing the incorporation of an increasing number minimal invasive treatments for BPH. Laser treatment is truly on the rise, most probably due to technical refinements of the technology and refinement of 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 for BPH. Each centre participating in this project will include during a one-year period the patients treated with greenlight laser or TURP at their site.

Data collection and analysis

- Inclusion for a one year period of patients treated by greenlight laser or TURP
- Study start per site once the first patient is included
- 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, AMS may propose study sites, the members from the Steering Committee or on recommendation from a third party
- Electronic database will be made available. Once a month an update of the database is provided to the central data collection centre. At the centre a contact person will coordinate the data handling
- Prior to approval of the site by the CROES council, for quality assurance, either an 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.
- The members of the study group will receive on a regular base an update of the data collected.
- The data analysis is supported by a Steering committee that are members of the study group
- The Steering committee is composed of 6-8 international members, a chairman and a representative from the sponsor.

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

The following variables will be included to correlate in a logistic regression and uni/multivariate analysis.

- The use of antibiotics and incidence of infections.
- Possible differences in morbidity.
- Specific medical conditions (age, BMI, DM, anticoagulants, cardiovascular disease) versus outcome and morbidity
- Outcomes in complicated cases (coumarine use, large prostates, etc)
- To define the learning curve
- To study differences between lower and higher volume sites

Data analysis

As mentioned, data analysis is responsibility of the Steering Committee on the study on greenlight laser. Epidemiological and statistical support will be provided by CROES to fulfil the primary and secondary objectives as well as any " *ad hoc* ' analysis derived from the prospective data collection.

Data property and publication

Primarily data belongs to the CROES in its function as organ of the Society of Endourology. Eventually, the study participant members can present data after a request to the Steering Committee and authorization from the CROES Council.

The Steering Committee will revise and give final approval to any paper derived from the data collected in the course of the study. A list of all participant members and centres will be included in any publication derived from this data collection. However the name and order of the main authors of any of the papers derived from this data collection will be decided by the Steering Committee of the Study on greenlight laser according to their level of input and contribution and subsequent approval by CROES council.

Patient Confidentiality: Data sent to the site is fully encrypted and therefore patient confidentiality is maintained.