



DOI: 10.1089/end.2010.1510

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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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A MULTI-CENTER, RANDOMIZED INTERNATIONAL STUDY TO COMPARE THE IMPACT OF NARROW BAND IMAGING VERSUS WHITE LIGHT CYSTOSCOPY IN THE RECURRENCE OF BLADDER CANCER

Jean de la Rosette and Stavros Gravas

The standard in diagnostics of transitional cell carcinoma (TCC) of the bladder is the visual approach, including the need for biopsies or transurethral resection (TURB). Although most of the bladder tumors can be identified with white light cystoscopy, it has been shown that especially in high-grade tumors areas of carcinoma *in situ* are missed.¹ A new development in imaging is the narrow band cystoscopy. Narrow band imaging (NBI) is a high-resolution endoscopic technique that enhances the fine structure of the mucosal surface without the use of dyes. NBI is based upon the phenomenon that the depth of light penetration depends on its wavelength: the longer the wavelength, the deeper the penetration. The first prototype NBI system (Olympus Corp, Tokyo, Japan) is based upon a light source with sequential red, green, and blue illumination. In urology there is limited experience for the role of NBI in detecting bladder cancer, but results are most promising.²⁻⁵ However, NBI may contribute to a more thorough primary tumor resection, resulting in a reduction of the number of missed tumors. This could impact the subsequent recurrence rate, reduce the number of required cystoscopic procedures during disease course, and ultimately lead to a better quality of life for patients and a reduction in the cost of their care.

For these reasons, the Endourological Society, through CROES, will conduct the NBI Study. This study is a randomized multi-center blinded study to compare the safety (morbidity) and efficacy between NBI-assisted TURB and white light (WL)-assisted TURB. This clinical trial will be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki, in compliance with the approved protocol, Good Clinical Practice (GCP) and applicable regulatory requirements. Eligible patients will be randomized, in a ratio of 1:1, to either arm A (NBI-assisted TURB) or arm B (WL-assisted TURB). Patients will be followed during their hospital stay, and after 3 and 12 months. At follow-up visits, patients will undergo WL cystoscopy; possible recurrence will be searched for and will need histological confirmation. It is preferable that the surgeon performing the follow-up be different from the one who performed the TURB.

Data collection and analysis

1. Inclusion of data on all primary patients undergoing TURB.
2. There is no minimum or maximum number of sites participating in this study; however, all sites must receive prior approval of the CROES council.
3. Electronic database will be maintained at the central data collection site selected by the CROES council and shall be updated on a regular basis as determined by the CROES council. 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, an Internal Review Board (IRB) approval will be provided to the central data collection center.
5. The members of the study group will receive feedback on the data collected on a regular basis, as determined by the CROES council.
6. The data analysis shall be the responsibility of the Steering Committee for the study group.

Primary study objective:

To compare recurrence rate at 1 year after narrow band imaging with white light transurethral resection of bladder cancer (TURB) in patients with bladder cancer (NMIBC). The study is designed to be powered at 80% to detect an estimated reduced recurrence rate of 10% at 1 year between the two groups of treated patients.

Secondary study objectives:

1. To assess the persistence/recurrence of tumor at first follow-up (<3 months) after narrow band imaging or white light TURB in patients with NMIBC.
2. To assess the perioperative morbidity (30 days) of TURB between NBI and WL resection by using the Clavien score.
3. To define risk factors for the development of perioperative morbidity after instrumental treatment.
4. To assess the recurrence rate related to the surgeon performing the procedure.
5. To assess the recurrence rate related to additional treatment following TURB.

Until now, CROES has been conducting observational studies. The NBI trial represents the next step of CROES to promote high quality research on endourology/laparoscopy since it is the first randomized study introduced by CROES. Randomized controlled trials are considered the reference standard for evaluating therapy alternatives and establishing standards of care in diagnostics and treatments. It seems that the creation of a global network facilitates and makes feasible the implementation of multi-center, relatively low-cost studies that have the ability to generate large samples rapidly. Therefore, the results of the NBI project (both clinical and organizational) are awaited with great interest.

References

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- The Global PCNL observational study was closed on December 31, 2009.
- Ongoing projects are: 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).

