Clinical Research Office of the Endourological Society : the highest quality in global data collection

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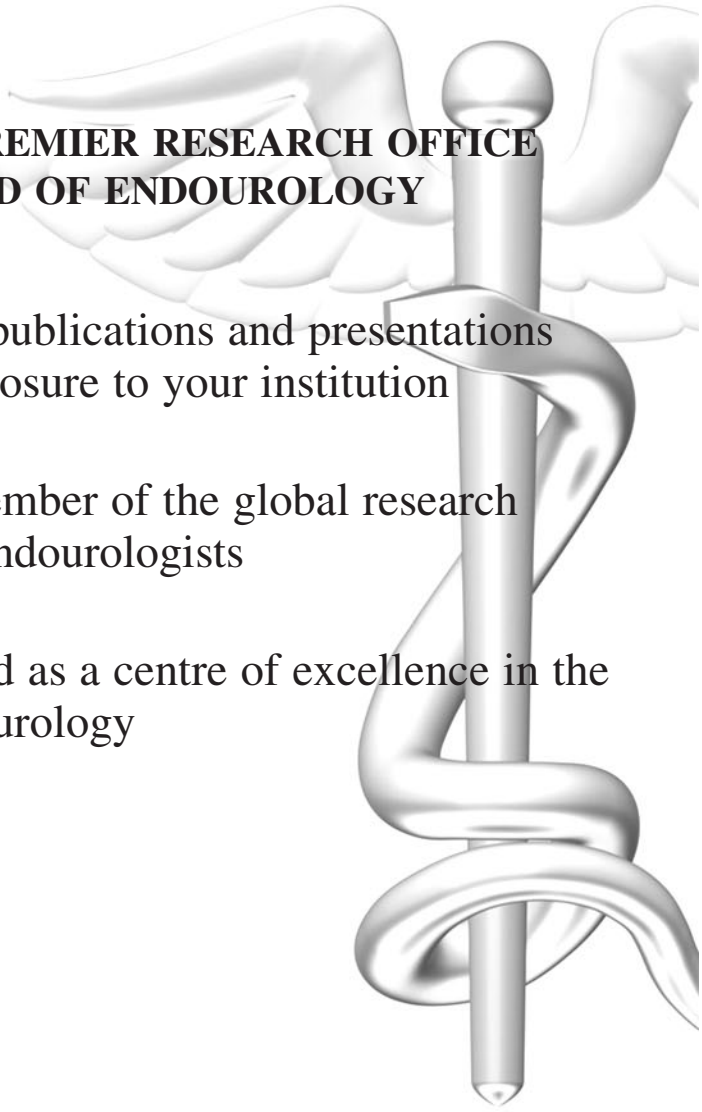

CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGICAL SOCIETY: THE HIGHEST QUALITY IN GLOBAL DATA COLLECTION

Hessel Wijkstra,[1] Miranda Wijdenes,[2] Peter Alken,[1] Tomonori Habuchi,[1] Andreas Skolarikos,[1] Chang-Jun Yin,[1] and Glenn Preminger[3]

Introduction

The Clinical Research Office of the Endourological Society (CROES) supports and promotes endourology by the initiation and performance of well-coordinated, high-quality, patient-centered research.[1] The collection of these data worldwide results in ''big data'' that can be analyzed to enable answers to questions that otherwise never could be answered. The success of the CROES is clearly demonstrated by the fact that, at this moment, more than 15,000,000 data items are present in the web-based data management system. More than 20 studies have been published, or are in preparation, to provide the urology community with the important information collected by the CROES.

Yet, quality of data is important to ensure reliable analyses and conclusions.[2–5] For this, the CROES Audit Committee makes sure that:

- Data collection is bound to the rules set by (inter)national authorities. Institutional Review Board approval or a letter from the principal investigator assuring quality and ethical standards is mandatory.
- All principal investigators must sign an (online) agreement by which they state that they will only submit high quality data.
- Data are collected centrally by a web-based, reliable, and user-friendly data management system.
- The CROES makes use of advanced automated quality-control systems to regularly monitor the quality of data.

The above practices are only the first steps toward the highest quality in data collection. The next process is the implementation of manual audits. These audits are initiated by the Audit Committee of the CROES. The data managers coordinate these audits with the Audit Committee and the results are analyzed. Conclusions can be made, and the final report is reviewed by the Audit Committee.

Since its founding, the CROES has committed itself to transparency in communication with all participants. In this newsletter, we present the manual audit process of the Narrow Band Imaging (NBI) study as an example of the CROES' efforts to guarantee high data quality standards.

[1]Audit Committee members.
[2]Data Manager, Narrow Band Imaging study.
[3]Chairman, Audit Committee.

Methods

The NBI study started August 10, 2010. During the audit the following procedures were performed:

1. After closure (end 2013), the input screens or electronic Case Report Forms (eCRFs) of pre- and intraoperative data were blinded to make sure that these data items were no longer visible. The eCRFs of follow-up data were kept visible to ensure ongoing collection of follow-up data.
2. A form (Fig. 1) was constructed and sent to all centers asking for 14 data points from randomly selected patients. Because of the blinded eCRFs, the data had to be extracted again from the source documents. The request for delivering these data was send December 3, 2013.
3. A first reminder was sent to all participating sites on December 17, 2013, in case the data manager had not received a reply.
4. After additional reminders, the audit was closed March 20, 2014, and the responses were analyzed (see below).
5. The data managers generated the CROES NBI Audit Report, and this was sent to the Audit Committee members for review.
6. The audit report was approved by the Audit Committee.

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NBI STUDY AUDIT

DATE	
CENTRE	
PRINCIPAL INVESTIGATOR	Prof./Dr.

Queries

1) Please confirm Weight (kg) value for the following patient:

PATIENT	VALUES

2) Please confirm Pre-operative symptoms for the following patient:

PATIENT	VALUES
	Symptoms: yes / no **Specify**:
	Symptoms: yes / no **Specify**:
	Symptoms: yes / no **Specify**:

3) Please confirm Tumor location, number and size for the following patient:

PATIENT	**Location**	**Tumor number**	**Tumor size (mm)**
	Left lateral		
	Right lateral		
	Trigone		
	Posterior wall		
	Dome		
	Prostatic urethra		
	Unknown (???)		
	Left lateral		
	Right lateral		
	Trigone		
	Posterior wall		
	Dome		
	Prostatic urethra		
	Unknown (???)		

4) Please confirm Operation time (min) for the following patient:

PATIENT	VALUE

5) Please confirm Pathological classification (pT) for the following patient:

PATIENT	VALUE
	pTx / pT0 / pTa / pTIS / pT1 / pT2 / Other / NA
	pTx / pT0 / pTa / pTIS / pT1 / pT2 / Other / NA
	pTx / pT0 / pTa / pTIS / pT1 / pT2 / Other / NA

6) Please send an anonymized copy of the Pre-operative cystoscopy picture or bladder map showing the size and location of the tumor for the following patient:

PATIENT	

7) Please send an anonymized scanned copy of the Operation report for the following patient:

PATIENT	

Please email this form back to: info@croesoffice.org

FIG. 1.

Results

1. Response rates. After the first invitation, 77% of the sites returned the forms with the requested data. After the first reminder, the response rate increased to 81%, and after the audit closure, a 100% response rate was achieved.
2. Data points. There were 46% of centers that had a perfect score: No mismatch between the stored data and the items on the audit form. For the total number of audit items, the mismatch rate was 18.4%. Most of the mismatches were found on the parameter tumor location, and reasons for this were no documentation regarding the exact sizes or an overlapping location. Of the 26 centers with a reporting problem, 25 were able to justify their mismatches. Three centers received an additional audit because of a high mismatch rate. One center could not justify all mismatches; however, the center completed all pre-, intra- and postoperative data and is very active in entering follow-up data. It was decided to not exclude this center.

Conclusions

- All centers participating in the CROES NBI study have been audited.
- The audit was performed by requiring 14 data points from randomly selected patients from each site.
- The eCRFs with requested data items were not visible during the audit.
- Final response rate was 100%.
- 18.4% mismatch in audit items.
- 25 of 26 centers could justify their mismatches.

The CROES Audit Committee believes that these kinds of manual audits, next to the automated checks on data quality and integrity as implemented in the web-based data management system, result in the highest quality in global data collection. Furthermore, the Committee continues to improve and extend the automated and manual audit procedures. With these procedures in place, the Audit Committee believes that all investigators involved in various CROES projects can rely on valid and accurate data, analyses, and conclusions that in the end will improve patient-centered research and the clinical practice in endourology all over the world.

The Audit Committee would therefore like to express its utmost gratitude to all involved experts in the CROES organization and especially to all investigators for collecting these most important data.

References

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- The Global Ureteroscopy study, Global GreenLight™ Laser Study, and the Global Renal Mass Study were closed in 2012. The first four articles on ureteroscopy and the first one on renal mass have been published. The first two articles of the GreenLight™ Laser Study are under review.
- The randomized study on Narrow Band Imaging *vs* White Light Imaging has closed in 2013. The first results are being analyzed.
- Ongoing project: The Irreversible Electroporation Study for focal therapy, including a pilot study, a randomized controlled trial, and a registry.
- New project: The randomized study on SPIES *vs* White Light Imaging.
- New project: The Global Upper Tract-Transitional-Cell Carcinoma study.
- For further information please visit: www.croesoffice.org or contact the Executive Director of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).