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Title (type in CAPITAL LETTERS, leave one blank line before the text):

QUALITY ALGORITHM FOR AMBULATORY CYSTOMETRY

Introduction

The appraisal of Ambulatory CystoMetry (ACM) as a diagnostic instrument is increasing. Especially when conventional urodynamics fail to reproduce or explain LUTS and for the assessment of therapeutic modalities [1].

Several filling and voiding phases are registered during a period of 6 to 8 hours under circumstances bringing about the specific conditions causing the individual complaints. Major problems in the old situation were: only the analyst judged quality of the ACM-investigation retrospectively. Furthermore, the design of the diary could be improved and the discrimination between filling and voiding phases was not always evident

Aim of the study

The aim of this study is to investigate the advantages of introducing a new quality algorithm to improve and assure the quality of ACM.

Methods

Redesign and validation of the algorithm are based on a method called improvement management of design processes in a clinical environment [2]. The most important advantages of this method are elimination of sources of variation, the introduction of structural feedback during or after every six steps of ACM, using standardised failure codes by both the operator and the analyst.

Based on data of 1204 ACM investigations in women (mean age 47 0, std. 22.3) and 432 in men (mean age 30.8, std. 15.0) between 1989 and 1997, a new quality algorithm was designed, implemented and validated The result was tested in 264 ACM investigations in women (mean age 51.5, std. 9.2) and 2 in men (mean age 52 9) between 1998 and 2000. The effects of the new algorithm were assessed by comparing the distribution of quality indices before and after the introduction Quality indices 5= event-button used correctly, duration investigation longer than five hours, transducers in right position, valid for research purposes, no technical failures, 4= as 5, but urethral transducers not in right position, some problems with interpretation due to the catheters, 3= as 4, but event-button used partly incorrect but registration can still be used for research purposes; 2= as 3 but, unsuitable for research purposes, some clinical value, 1= no interpretable value, 0= no data Moreover, effect were assessed by comparing the inter-observer agreement (ICC_A) of the analysis outcome with respect to bladder overactivity (Detrusor Activity Index, [3]).

Results

Pressing the event-button twice to mark begin and end of the voiding phases and the introduction of 52 standardized failure codes are the most important improvements incorporated in the new algorithm. Failure codes refer to four phases of ACM i.e. preparation of the investigation, instruction of the patient, installation of the equipment and assurance of signal quality, ending the investigation with signal consistency check

Figure 1 shows the distribution of quality indices (0 = failed, 5= excellent quality) before and after introduction of the new quality algorithm. There is an evident quality improvement of 18% (p<0 001) in ACM's with research quality The theoretical

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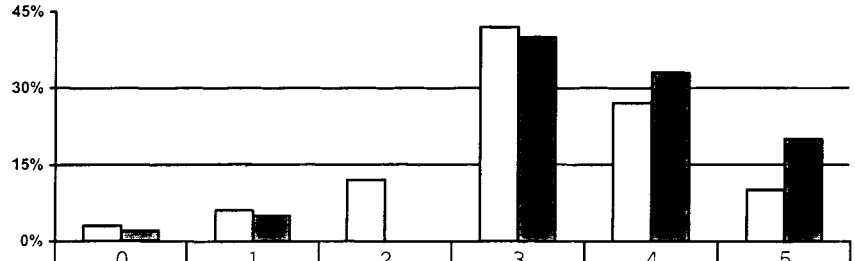

	0	1	2	3	4	5
Before introduction new algorithm n=1636	3%	6%	12%	42%	27%	10%
After introduction new algorithm n=266	2%	5%	0%	40%	33%	20%

Figure 1 Improvement of quality distribution ACM

Conclusions

In this study the design of a quality algorithm is presented. Presently, the quality algorithm is part of the quality system of the urodynamic laboratory. Due to this project, the quality of the entire ACM-investigation has improved noticeably and measurably. The designed quality algorithm has been nominated for a quality award in our hospital

Our methodology is applicable in many forms of clinical research.

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3 BJU International (1999) **83**, Suppl. 2,16-21

4 The design and analysis of clinical experiments, 1986 New York

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