Design and evaluation of a bladder volume surveillance system

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ABSTRACT

This study was carried out at the Institute of Clinical Medicine, Aarhus University Hospital, Skejby Sygehus, and the Department of Electronics and Information Technology, University College of Aarhus. The aim was to design and evaluate an ultrasound-based bladder volume monitor.

Continuous monitoring of bladder volume over extended periods of time may be useful in the study of several conditions and during treatment or management of various urological disorders, such as children afflicted with nocturnal enuresis. However, the bladder scanners and monitors developed so far have been too bulky, too inaccurate, or unsuited for surveillance of urine production over time.

The design of the bladder volume monitor was based on two MRI studies performed in young volunteers. These studies showed that bladder position and shape were unaffected by recumbent body position, resulting in a simpler design of the monitor than anticipated. The system was divided into a patient-mounted device (PMD) and a laptop computer, communicating via a Bluetooth radio. The PMD was based on seven ultrasonic phased-array transducers ergonomically arranged in a circular pattern to optimize detection of the bladder walls perpendicular to the abdomen.

The monitor was evaluated both in vitro and in vivo. A calibration phantom and a homemade gelatin phantom were used to determine static and dynamic performance, respectively. The in vitro-evaluation showed that the monitor made no significant systematic errors and had no significant drift caused by time or temperature. Precision in terms of absolute mean error was 2.9%. After the in vitro-studies, the system was calibrated and tested by using measurements in one male volunteer with high resolution MRI as reference. The calibration confirmed that the system could be used in vivo without systematic error and with a mean absolute error of 4.8%.

The clinical evaluation was performed in 30 urological patients during urodynamic investigation. The bladders of the patients were infused with saline during two cystometries from empty to maximum capacity, while the bladder monitor measured volume every 30 s. In the male patients, correlation between infused volume and the measurements made by the monitor ranged from 0.876 to 0.997 with a median value of 0.970. In female patients, small bladders were generally located outside the field-of-view of the monitor because the monitor was designed for future use in children.

In conclusion, the designed bladder volume monitor was shown to work properly in adult male volunteers with properties that seem better or comparable to other more bulky instruments. A minor redesign of the present prototype evolving a slightly pivoted transducer unit should insure proper operation in adult females and some obese males.