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# Validation of a simple patient questionnaire to assist self-detection of overactive bladder

## *A study in general practice*

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**Objective** – To develop and validate a simple patient questionnaire for the detection of overactive bladder (OAB).

**Design** – An open, non-randomized multicentre study.

**Setting** – A pilot study (n=133) was conducted to bring forward five questions from initially 14 questions, for detection of OAB. These five questions were subject to further validation in the main study (n=520).

**Subjects** – 531 adults responding to a newspaper advertisement regarding symptoms of OAB and patients seeing a physician for other reasons were attending 28 general practitioners.

**Main outcome measures** – Agreement rate, sensitivity, and specificity.

**Results** – The agreement rate between the patients' own diagnosis based on the patient questionnaire, and the physicians' diagnosis based

on medical history, urine analysis, and micturition chart, was 0.78 ( $\kappa=0.89$ ). Sensitivity and specificity were 0.98 and 0.90, respectively.

**Conclusion** – The validated questionnaire may become a useful tool to decide whether a patient has overactive bladder. The questionnaire corresponds well with the physicians' diagnosis.

**Key words:** diagnostics, general practice, incontinence, overactive bladder.

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Overactive bladder (OAB) is characterized by increased frequency of micturition and a sudden desire to void (urgency), and it may be associated with urinary urge incontinence. In the condition of OAB uncontrolled contractions of the bladder muscle (detrusor) occur during the bladder's filling period. The cause of OAB could be loss of neural control of the detrusor, for example neurological diseases (stroke, Parkinson's disease, multiple sclerosis, senile dementia) or local dysfunction of detrusor, but in most cases the cause of OAB is unknown. There is little definite and reliable epidemiological information available on the prevalence of OAB (1). In a population-based study where almost 17 000 interviews were conducted in 6 European countries, the prevalence of OAB in individuals aged  $\geq 40$  years was 16.6%. The prevalence of OAB increased with age and OAB was equally apparent in men and women (2,3).

OAB is a chronic condition that restricts the patient's social life and physical activities significantly (1,4–7). In spite of this, very few patients with OAB seek medical help (8–11). Many believe that their bladder problems are a normal part of ageing and that there is no treatment available (2,9). Patient questionnaires for correct self-detection of OAB may aid patients' awareness of their health problem and help them to seek relevant medical assistance.

The primary objective of this study was to develop and validate a simple patient five-question questionnaire (5Qquestionnaire) for self-detection of OAB. This was done by assessing the agreement rate between the patients' own diagnosis of OAB based on the simple questionnaire and the physicians' diagnosis of OAB based on medical history, urine analysis, and a micturition chart and then to evaluate whether this simple patient questionnaire is a useful tool to detect OAB.

Overactive bladder is an overlooked condition, which can often be treated by simple means.

- A simple patient questionnaire for correct self-detection of overactive bladder may be used as a tool in primary health care.
- The agreement rate between the questionnaire evaluation and the physician's evaluation was high.
- Many of the patients, both incontinent and continent, wanted treatment for their overactive bladder.

## MATERIAL AND METHODS

This study took place in general practice in Norway, and was carried out from December 2001 to June 2002. In the study OAB was defined as eight or more micturitions per 24 hours and with urgency. This is the most common definition of OAB in clinical trials. The study was conducted in two steps: a pilot study to find the relevant patient questions, and a main study for further validation of the selected questions. The patient questionnaire should be simple, short, and easy to read without the need for any guidance. The study was approved by the Regional Ethics Committee and The Norwegian Board of Research in General Practice.

### *Pilot study*

Five GP centres participated in the pilot study. Patients with OAB were recruited by an advertisement in the local newspaper. The subject was asked to contact the GP by phone, and suitable subjects were given an appointment to see the GP. At the first visit the subject answered 14 OAB specific questions in writing. Medical history was recorded and urine analysis was carried out, and a 24-hour micturition chart was given to the subject to be completed. Based on the medical history, the urine analysis, and micturition chart, the physician decided at the next visit whether the subject had OAB or not. Data from 133 subjects who had contacted the GP because they thought they had OAB ( $n = 101$ ) or who had seen the physician for other reasons ( $n = 32$ ) were analysed. The physicians classified 79 subjects as OAB+ (did have OAB) and 49 as OAB- (did not have OAB) whereas five subjects were defined as OAB? (not decided if the subject had OAB or not). From the "14-questionnaire" a score system was developed to separate OAB+ from OAB-. Based on the agreement rate, the sensitivity, and the specificity for all relevant question/answer combinations in the pilot study, five questions (out of 14) with a simple binominal weighting (given the score zero or one) were chosen to be used and to be validated in the main study (Fig. 1). If the subjects in the main study had a total score of four or more in the 5Qquestionnaire, they were characterized as OAB+.

### *Main study*

A total of 28 GP centres participated in the main study. The subjects were recruited by advertisements in the local newspapers, showing the 5Qquestionnaire (see Fig. 1). The subject was asked to contact the GP by phone if she/he gave positive answers to four or five questions in the 5Qquestionnaire. As in the pilot study, both possible OAB patients and patients seeing the physician for other reasons were recruited. In-

dividuals were classified as OAB+ by the 5Qquestionnaire ( $n = 360$ ), whereas the OAB-group were subjects who came to see the physician for other reasons than OAB and/or who after completing the 5Qquestionnaire still were not classified as OAB patients ( $n = 160$ ).

Subjects  $\geq 18$  years old and having signed a written informed consent were included in the study. The following subjects were excluded from the study: subjects with known OAB, subjects under assessment/investigation of lower urinary tract function, subjects with indwelling catheter or practising intermittent self-catheterization, subjects treated within the last 14 days with any anticholinergic drug, pregnant subjects, and subjects with any condition that in the opinion of the physician made the subject unsuitable for inclusion. Subjects with urinary tract infection could be included in the study after finishing antibiotic therapy. Eighteen specific and standardized questions regarding medical history were completed as a tool for the physician's judgement of OAB. The questions were mapping urinary tract infections, haematuria, urgency, urge incontinence, nocturia, concomitant medications, diabetes mellitus, symptoms of prostate hyperplasia, and neurological diseases. The subject was asked to give a urine sample for analysis at Visit 1 and to complete a 24-hour micturition chart prior to Visit 2 (2-7 days after Visit 1).

### *GP assessment*

At Visit 2 the physician gave the final evaluation of whether the subject had OAB or not. This assessment was based on medical history, the urine analysis, and the completed micturition chart. The physician could classify the subject in three different categories: OAB+, OAB- and OAB?. Subjects with symptoms of OAB but with only 5-7 micturitions on average per 24 hours or with a mean voided volume  $> 2500$  ml per 24 hours were classified as OAB?. An expert group (consisting of one urologist and one experienced GP) assessed those OAB? subjects by looking closely at all the subject data including the micturition chart.

### *Statistics*

The main efficacy variable was the agreement rate between the physician and the 5Qquestionnaire in classifying the presence of OAB. To describe this, the kappa coefficient ( $\kappa$ ), sensitivity and specificity were calculated:  $\kappa$  is a measure for agreement with values ranging from 0 to 1 (0 gives no agreement, 0.4 gives moderate agreement, and 0.8 is a very high agreement). Sensitivity is how many subjects the questionnaire classifies as positive among those whom the physician classifies as positive. Specificity is how many subjects the questionnaire classifies as negative among

**1. Føler du at du later vannet for ofte?**  
(Do you feel you have to void too often?)

nei (no)  ja (yes)

**2. Hvor ofte later du vannet hver dag ?**  
(How many times do you void each day?)

1-4 ganger (1-4 times)  5-7 ganger (5-7 times)  8-11 ganger (8-11 times)  Over 11 ganger (More than 11 times)

**3. Opplever du at hyppige vannlatinger eller lekkasje er et problem for deg?**  
(Do you experience frequent voiding or urine leakage as a problem?)

nei (no)  ja, enkelte ganger (yes, sometimes)  ja, en god del (yes, a great deal)  ja, helt klart (yes, definitely)

**4. Hvor ofte må du late vannet på nytt mindre enn 2 timer etter forrige vannlating?**  
(How often do you need to void less than 2 hours after the previous voiding?)

aldri (never)  flere ganger i uken (several times a week)  daglig (daily)  flere ganger om dagen (several times a day)

**5. Hvor ofte kjenner du en plutselig og/eller sterk vannlatingstrang som gjør at du må skynde deg til toalettet?**  
(How often do you feel a sudden and/or strong urge to void, resulting in a rush to the toilet?)

aldri (never)  flere ganger i måneden (several times a month)  flere ganger i uken (several times a week)  hver dag/natt (each day/night)

Fig. 1. The original Norwegian patient 5Qquestionnaire validated in the present study (an English translation is given in italics). If the subjects gave positive answers, four or five marks within the shadowed area, they were asked to contact the GP.

those whom the physician classifies as negative. The main variable is presented with a rate and the one-sided 95% confidence interval to the rate.

## RESULTS

In the present study data from 531 subjects were collected. Some 11 subjects were dismissed from the data analysis because they did not show up at Visit 2 ( $n=8$ ), were included by mistake ( $n=2$ ), or still had urinary tract infection verified after treatment with antibiotics ( $n=1$ ). Of 520 subjects, 214 were males (41%) and 306 were females (59%). Mean age was 54 years ( $SD \pm 15$ ). Twelve patients (2.3%) needed assistance to fill out the questionnaire. Eight patients had verified urinary tract infections. Two subjects did not deliver a urine sample.

At Visit 2, the physician classified 258 subjects as OAB+, 167 subjects as OAB- and 95 subjects as OAB?

The results from the simple questionnaire compared with the physician's final evaluation at Visit 2 are given in Table I. The agreement rate between the 5Qques-

tionnaire evaluation and the physician's evaluation was 0.78 (lower 95% confidence level was 0.76 and  $\kappa=0.89$ ). There was no difference between the genders. The sensitivity of the questionnaire was 0.98 and the specificity was 0.90.

From the physicians' final evaluations 95 subjects received the diagnosis OAB?. Revised results evaluated by the expert group were implemented and are given in Table II. The agreement rate between the 5Qquestionnaire and the physician assessment when data from the expert group were included was 0.86 ( $\kappa=0.78$ ). The sensitivity was 0.98 and the specificity was 0.77. A total of 225 subjects, out of those 258 subjects who were assessed to have OAB at visit 2, wanted to be followed up and treated for their condition. There was no difference between incontinent and continent patients as to whether they wanted to be treated or not. Some 8% of the subjects were referred for further examination by specialists.

As much as 75% of the subjects with OAB recorded that they occasionally had involuntary leakage. In the OAB population 32% used pads because of urinary incontinence.

Table I. Comparison of the patient's own diagnosis of OAB based on the 5Qquestionnaire and the physician's evaluation at visit 2. The agreement rate was 0.78 ( $\kappa=0.89$ ), the sensitivity was 0.98, and the specificity was 0.90.

Physician's evaluation	The "5-question-questionnaire" evaluation		
	OAB+	OAB –	Total
OAB+	253	5	258
OAB –	16	151	167
OAB?	91	4	95
Total	360	160	520

## DISCUSSION

The present study shows that the validated patient questionnaire with five simple questions is a useful tool to detect OAB. The conclusion from the questionnaire corresponds well with the physicians' diagnosis. The sensitivity and specificity for the questionnaire are high. The questionnaire may also be a good tool for physicians to identify patients with OAB in clinical practice.

In our study, 95 of 520 subjects were uncharacterized after the clinical evaluation. The GPs' classifications were dictated by the study protocol defining that subjects with symptoms of OAB, but with <8 micturitions per 24 hours or voided volume >2500 ml per 24 hours, should be classified as OAB?. An expert group therefore evaluated the patient data closer and gave a second opinion on whether this was an OAB patient or not, also taking fluid intake during the micturition chart period into account. In clinical practice most GPs would be able to give a diagnosis for those OAB? subjects. In our opinion the key to definite detection of OAB is the physician's ability to interpret micturition charts.

Previously, an American questionnaire, where the questions are related to bladder problems, was developed and validated (12). In that questionnaire it was asked whether the subject had observed blood in the urine or if the subject had felt pain related to voiding. If this was the case the subject was excluded and asked to see a physician. Our patient questionnaire did not include questions to identify patients with other potential serious illnesses. Even if not included in

our questionnaire, such questions are relevant and important in obtaining the medical history in patients with abnormal lower urinary tract symptoms.

This was an open study; however, every subject, independent of how he/she entered the study, was thoroughly evaluated and classified based on the medical history, micturition chart, and urine analysis.

The questionnaire was validated against the physician's diagnosis based on "best practice", which in our opinion is the most interesting and relevant standard against which to validate the questionnaire. When doing this, some questions from the patient's questionnaire will necessarily overlap with the physician's assessment. This may give a higher agreement rate than if the questionnaire had been validated against other "gold standards" (e.g. urodynamic assessments).

Since the objective of the present study was to find a simple way to diagnose OAB in practice, the diagnosis was based on symptoms, including evaluation of patient afflictions. In the new definition made by the International Continence Society the condition of OAB is mainly based on symptoms, and the level of afflictions is not included (13). However, we do not think the difference mentioned has any significance for the outcome of the study.

Many of the subjects (87%) with OAB wanted to be treated for their condition, which is in accordance with the impression that OAB patients are under-treated (2,8,14,15). Voiding disorders are still difficult to talk about for many patients. It may be that GPs also give such problems low priority. Answering the patient questionnaire prior to the consultation may save time

Table II. Comparison of the patient's own diagnosis of OAB based on the 5Qquestionnaire and physician's evaluation at visit 2 after implementation of the evaluated patient data (OAB?, n=95) by the expert group. The agreement rate was 0.86 ( $\kappa=0.78$ ), the sensitivity was 0.98, and the specificity was 0.77.

Physician's evaluation (included the expert group evaluation)	The "5-question-questionnaire" evaluation		
	OAB+	OAB –	Total
OAB+	296	6	302
OAB –	45	152	197
OAB?	19	2	21
Total	360	160	520

for the GP. In addition, if the patient is asked to complete a 24-hour micturition chart this will contribute to a far better evaluation of the lower urinary tract problem. An important challenge is to increase the awareness of OAB and to stress the importance to primary care physicians of identifying OAB. Though a risk of medicalization of a widespread condition is present, the intention of identifying people with a bothersome OAB and offering them treatment considerably reduces the risk of medicalization.

Only 8% of the subjects in the present study were referred for further examinations by specialists. This indicates that OAB can usually be handled in general practice. In most cases there is no need for invasive specialized examinations to diagnose OAB. This correlates with the international attitude and approach to the problem (1,16).

Placed in the waiting room at the general practice, the 5Qquestionnaire for detection of OAB can be a suitable tool to increase patients' awareness and understanding of their own health problems. It may contribute to better medical assistance, necessary investigation, and treatment. Therefore the 5Qquestionnaire can be useful for both the patient and the physician when lower urinary tract problems are in question.

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