

SOURCES OF BIAS IN THE MEASUREMENT OF BLADDER AND BOWEL SYMPTOMS

Hypothesis / aims of study

In the era of evidence based medicine clinicians strive to provide good clinical care that derives from high levels of scientific proof that an intervention or group of therapies works. Patient report is one way of evaluating the outcome of clinical practice, however it can be flawed by factors such as lack of assumed knowledge and misunderstanding of concepts. The aim of this study is to identify confounding factors of several patient reported LUTS and common sources of bias that may influence interpretation of such measures.

Study design, materials and methods

705 completed data sets from a cross-sectional study examining the relationship between report of childhood symptoms by adults with and without LUTS [1] were examined. The variables "currently experiencing a bladder problem", "currently bothered by a bowel problem", general health status, low versus high childhood scores and a range of adult LUTS were modelled using logistic regression. Variables were then stratified by gender and age below or above 40 years. Crude risk measures and stratified OR were calculated and compared for evidence of interaction and confounding.

Results

As seen in Table 1 individual symptom report did not agree with patient response to the binary question whether or not they were experiencing bladder problems. Independent predictors for perceiving oneself to have bladder problems differed between genders. Logistic regression for male self report of a bladder problems retained leaked urine (urge incontinence $p < 0.001$, insensible leak $p < 0.001$), voiding every two hours or more often ($p = 0.014$) and a recent UTI ($p = 0.002$). In addition to these same predictors, women's perception was also significantly influenced by not voiding to completion ($p = 0.015$), post void leak ($p = 0.045$) and nocturia ($p = 0.004$). Predictors of the perception of having a bowel problem also showed a gender difference. Logistic regression showed men to equate this definition with faecal incontinence only ($p < 0.001$) whereas women self-classified based on the need to intervene for constipation and having a predictable bowel routine (p both < 0.001). Male response to a general health question was independently affected by only 1 LUTS, namely urge leak ($p = 0.009$). Female general health response was independently predicted by 3 symptoms: insensible leakage ($p = 0.012$), recent UTI ($p < 0.001$), constipation ($p = 0.001$) with nocturia having a marginal influence ($p = 0.056$). The crude OR for good or very good general health was 3.28 (2.02-5.31) and when stratified by presence of LUTS dropped to 0.59 (0.5-0.7) indicating poor health or worse. In the absence of LUTS there was a 1.9 times likelihood of having good or very good health (CI 1.40-2.68). Thus both an interaction and a confounding effect were observed. The crude OR for having a paediatric symptom score of 4 or less was 2.99 (1.89-4.75) rising to 5.33 (2.49-11.37) in respondents older than 40 years and falling to 2.5 (1.26-4.96) in younger subjects; thus demonstrating an interactive effect of age on recall-based symptom scoring.

Interpretation of results

Outcome measures that rely on patients classifying themselves as having a bladder or bowel problem are open to bias. This study has demonstrated a clear gender difference with women including a wider range of symptoms than men in a definition of dysfunction. These results also caution about variables and sample characteristics that may cause over or under estimation of effect. We noted symptomatology and age to have a confounding effect on a general health question when included in a symptom-specific measurement tool, making this a poor choice for pre and post treatment comparison. The well-known effect of age bias was demonstrated clearly in relation to recall of childhood symptoms.

Concluding message

Questionnaire measures are particularly attractive to capture cross sectional and treatment response data, but are open to errors in both patient self-reporting and clinician interpretation. Efforts to minimise and expose patient misunderstanding, such as clearly defining key terms, are needed. Data derived from questionnaires should be scrutinised to identify and control for possible confounding variables and population characteristics before conclusions are drawn.

Table 1: Proportion of respondents reporting individual symptoms when classified according to self- report of experiencing bladder problems or not

	% of "bladder problem" group reporting symptom	% of "no bladder problem" group reporting symptom
Urgency	79	70
Urge leak	59	22
Stress Incontinence	25	15
Insensible leak	37	5
Adult NE	15	8
Hesitancy	56	50
PV leak	66	36
Incomplete emptying	65	39
Increased frequency	87	56
Nocturia > once / night	45	52
UTI last 1 yr	38	5
Treatment for constipation	22	10
FI	22	27

References

1. *J Urol* 2005 Oct;174(4 Pt 2):1623-7

<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Survey and Ethics Commitee Chinese University of Hong Kong
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes