Systematic review and evaluation of methods of assessing urinary incontinence

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Executive summary

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Executive summary

Background

Although urinary incontinence is not life threatening, it can have enormous costs to individuals and the health service in terms of expenditure and impact on quality of life. Epidemiological studies have demonstrated that urinary incontinence is a very common symptom, with a reported prevalence of any urinary incontinence (in those aged 40 and over) of 34% for women and 14% for men.

Pathways to diagnostic assessment are inconsistent, with some individuals being assessed and treated in primary care settings by GPs and nurses, and others being referred directly to a variety of specialists in secondary care (e.g. physiotherapists, gynaecologists and urologists) without any assessment or treatment. Assessment can be undertaken at a number of levels using different combinations of tests.

It is particularly important when implementing certain treatment interventions (e.g. medication that may have side-effects) that a diagnosis is made to determine the most effective treatment intervention, and it is imperative before surgical intervention. If a diagnosis is not made, then inappropriate and unnecessary interventions may be implemented. Two types of diagnosis can be made: symptomatic diagnosis and condition-specific diagnosis. In general, symptomatic diagnoses are made in primary care using clinical history-taking, urinary diaries, pad tests and validated symptom scales. Condition-specific diagnoses are made in secondary care using urodynamic techniques. The use of diagnostic assessment methods is influenced by the clinical setting and the expertise of the individual undertaking the assessment. The evidence available on the accuracy and acceptability of these diagnostic processes is inconsistent and variable.

Objectives

This systematic review aimed to:

- identify, appraise and summarise the published evidence relating to different methods of diagnostic assessment of male and female urinary incontinence: specifically urodynamic stress incontinence (USI) and detrusor overactivity (DO)
- quantitatively synthesise the extracted evidence using meta-analysis methods (where possible) or pooling of individual sensitivity and specificity data
- construct an economic model to examine the cost-effectiveness of simple, commonly used primary care tests
- identify gaps in the literature
- prioritise future clinical and research questions.

Methods

Data sources

The online bibliographic databases MEDLINE (1966–2002), CINAHL (1982–2002) and EMBASE (1980–2002) were used to obtain the literature. The search strategy was based on the Cochrane and NHS Centre for Reviews and Dissemination strategies for identifying studies of diagnostic performance.

Study selection

Study selection comprised a three-stage process using defined inclusion and exclusion criteria. All records were assessed for relevance by the first investigator on the basis of the abstract, or if the abstract was not available then title only. Papers were considered relevant to the systematic review if they considered the evaluation, appropriateness and/or cost of diagnostic assessment in the following categories:

- clinical history-taking
- simple investigations including validated scales, diaries and pad tests
- advanced (invasive) investigations (e.g. urodynamics).

To be included, a paper had to provide a quantitative comparison between two or more different methods of diagnosing urinary incontinence.

Data extraction

A panel consisting of at least three members of the review team, including at least one ▶

statistician, discussed all papers identified as of potential relevance. The panel determined whether study data were presented in a suitable format to calculate sensitivity and specificity.

Quality assessment

All relevant papers were assessed for quality using Quality Assessment of Diagnostic Studies (QUADAS), a tool designed specifically for studies on diagnostic accuracy. An initial pilot study on four papers resulted in a number of clarifications being added to the instructions of the QUADAS tool to ensure consistency between assessors. Seven of the authors performed the full quality assessment process, with 10% of the papers being assessed by two authors to test for inter-reader agreement.

Data synthesis

Studies that reported the results of applying the same diagnostic procedure using the same threshold value (cut-off) were pooled using a random effects meta-analysis model to produce pooled estimates of sensitivity, specificity and diagnostic odds ratio together with 95% confidence intervals.

Results

In total, 6009 papers were identified from the literature search, of which 129 were deemed relevant for inclusion in the review, and these papers compared two or more diagnostic techniques. The gold-standard diagnostic test for urinary incontinence with which each reference test was compared was multichannel urodynamics.

In general, reporting in the primary studies was poor; there was a lack of literature in the key clinical areas and minimal literature dealing with diagnosis in men. Only a limited number of studies could be combined or synthesised, providing the following results when compared with multichannel urodynamics. A clinical history for diagnosing USI in women was found to have a sensitivity of 0.92 and specificity of 0.56 and for DO a sensitivity of 0.61 and specificity of 0.87. For validated scales, question 3 of the Urogenital Distress Inventory was found to have a sensitivity of 0.88 and specificity of 0.60. Seven studies compared a pad test with multichannel urodynamics; however, four different pad tests were studied and therefore it was difficult to draw any conclusions about diagnostic accuracy. Of the four studies comparing urinary diary with multichannel urodynamics, only one presented data in a format that allowed sensitivity and specificity to be calculated. Their reported values of 0.88 and 0.83 suggest that a urinary diary may be effective in the diagnosis of DO in women. Examination of the incremental cost-effectiveness of three primary care tests used in addition to history found that the diary had the lowest cost-effectiveness ratio of between £35 and £77 per extra unit of effectiveness (or case diagnosed). Imaging by ultrasound to determine leakage was found to be effective in the diagnosis of USI in women, with a sensitivity of 0.94 and specificity of 0.83.

Conclusions

This is the first systematic review of methods for diagnosing urinary incontinence. As reporting of the primary studies was poor, clinical interpretation was often difficult because few studies could be synthesised and conclusions made. The following information could be deduced from the available data.

- A large proportion of women with USI can be correctly diagnosed in primary care from clinical history alone.
- On the basis of diagnosis the diary appears to be the most cost-effective of the three primary care tests (diary, pad test and validated scales) used in addition to clinical history.
- Ultrasound imaging may offer a valuable alternative to urodynamic investigation.
- The clinical stress test is effective in the diagnosis of USI. Adaptation of such a test so that it could be performed in primary care with a naturally filled bladder may prove clinically useful.
- If a patient is to undergo an invasive urodynamic procedure, multichannel urodynamics is likely to give the most accurate result in a secondary care setting.
- There is a dearth of literature on the diagnosis of urinary incontinence in men, with no studies meeting the study criteria for data extraction in the diagnosis of bladder outlet obstruction.

Implications for healthcare

- There is currently a lack of high-quality research in clinically relevant areas to inform clinical practice.
- Most diagnostic methods can be undertaken in primary or secondary care.
- Simple investigations (e.g. pad test and diary) may offer useful information on severity which, when combined with history, may provide sufficient information to commence primary care interventions (which are low cost and low risk).

►

Recommendations for research

Given the demographics of the UK population and the reported high prevalence of any urinary incontinence in the community-dwelling population, there will be an increasing burden placed on primary (and secondary) care services in terms of the diagnostic assessment and appropriate treatment of incontinence. Therefore, identifying which are the most clinically accurate and cost-effective diagnostic methods is of crucial importance.

There is a need for large-scale, high-quality primary studies evaluating the use of a number of diagnostic methods in a primary care setting to be undertaken so that the results of this systematic review can be verified or not. Such studies should include not only an assessment of clinical effectiveness, in this case diagnostic accuracy, but also an assessment of costs and quality of life/satisfaction to inform future health policy decisions.

Studies carried out should be reported to a better standard. The recommendations of the Standards for Reporting of Diagnostic Accuracy (STARD) initiative should be followed to ensure the accuracy and completeness of reporting design and results.

Publication

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NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 99/29/02. The contractual start date was in April 2002. The draft report began editorial review in December 2003 and was accepted for publication in April 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

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