

## DO WE NEED TO PERFORM URODYNAMICS STUDIES BEFORE SURGERY FOR URINARY INCONTINENCE IN WOMEN? COCHRANE SYSTEMATIC REVIEW AND META-ANALYSIS

### Hypothesis / aims of study

The aim of this systematic review is to determine if treatment for urinary incontinence following urodynamics is better than treatment following any other diagnostic method, in terms of changes in clinical care and better clinical outcomes in women with urinary incontinence. Two new large RCTs (VUSIS and ValUE) have recently been published, hence the need to update the evidence.

Urodynamic testing aims to diagnose and differentiate between different types of incontinence and other objective urinary symptoms, so that the best advice on treatment can be given. However, urodynamics is expensive, time-consuming and generally considered to be an unpleasant experience by patients. The overall benefit of testing, particularly before surgery for urinary incontinence, is currently unclear.

### Study design, materials and methods

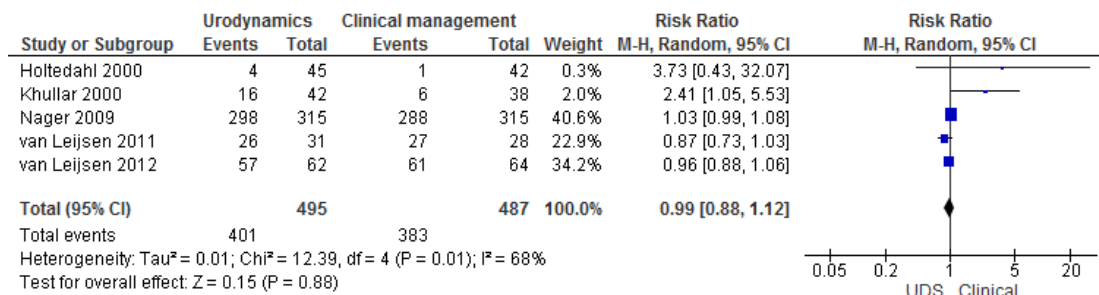
We searched the Cochrane Incontinence Group Specialised Register of Controlled Trials (21<sup>st</sup> November 2012), the reference lists of relevant articles along with hand searching of conference proceedings. We included trials which compared assessment of incontinence in women with and without urodynamics. The main outcomes included changes in clinical management following assessment and the subsequent clinical outcomes in these women. Trials studying other lower urinary tract symptoms such as those secondary to bladder outlet obstruction were excluded.

Two reviewers independently performed abstract and full-text screening. Randomised and quasi-randomised trials were included in this systematic review. Any disagreement was resolved by discussion or arbitration with a third party. Data extraction was carried out by at least two reviewers according to the pre-defined outcomes and meta-analysis was conducted where appropriate. For categorical outcomes, we used risk ratio (RR) whereas with continuous outcomes, means and standard deviations were used to determine a mean difference. A fixed effect model was used to pool results and obtain 95% confidence intervals (CI) except if there was statistically significant heterogeneity in which case a random-effects model was considered. Risk of bias assessment was carried out on all trials as described in the Cochrane Handbook. Quality of evidence of the critical outcomes was assessed by adopting the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

### Results

We identified 8 RCTs, of which one provided no useable data leaving 7 trials studying 1,036 women in total, with 526 undergoing urodynamic testing. The search produced 209 trials, of which 118 were excluded for not meeting the inclusion criteria. 83 further trials were excluded as they failed to randomise women to at least one type of urodynamic investigation, or one method of performing a urodynamic investigation. All trials included women only and so the use of urodynamics in men and children with urinary incontinence could not be assessed. Risk of bias assessment demonstrated various limitations in the trials. The 4 deaths and 12 dropouts in the control arm versus none in the urodynamic arm were of concern in one trial. Data were available for five out of the seven outcomes which were selected for GRADE.

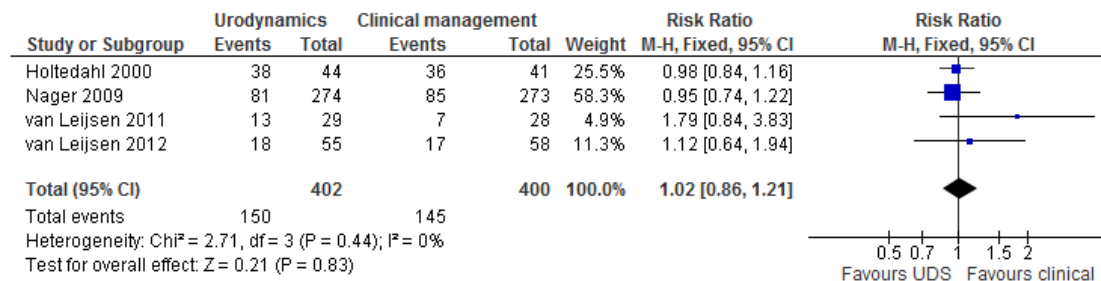
Women who underwent urodynamic testing in three trials (n = 272) were more likely to have a change in management (proportion with change in management 17% versus 3% in the non-urodynamic group, RR 5.07, 95% CI 1.87 to 13.74), although there was statistical heterogeneity whose importance was unclear. With regard to clinical decision-making following assessment, two trials (n = 673) showed the women receiving clinical assessment with urodynamics were more likely to receive pharmacotherapy (45% versus 21% receiving drugs in non-urodynamic group, RR 2.09, 95% CI 1.32 to 3.31). However, there was no difference in the numbers of women undergoing surgery in five trials (n = 982, 81% versus 79% in the non-urodynamic group, RR 0.99, 95% CI 0.88 to 1.12) although this analysis demonstrated significant heterogeneity ( $I^2 = 68\%$ ,  $P = 0.01$ ) and was therefore carried out using a random-effects model (Figure 1).



**Figure 1: Number treated with surgery**

There was no statistically significant difference in the number of people with incontinence after one year (subjective) in four trials (37.3% versus 36% in the control arm, RR 1.02, 95% CI 0.86 to 1.21) (Figure 2). Lastly, the number of women not

satisfied with treatment was given in two trials (n=644) and showed no statistically significant difference between groups (RR 0.90, 95% CI 0.55 to 1.49).



**Figure 2: Number with incontinence after first year (subjective)**

Interpretation of results

Based on the available analyses, urodynamic studies did affect the decision-making process in clinicians: women receiving urodynamics were more likely to receive drugs following assessment although they were not more likely to undergo surgery. Unfortunately, there was no consequent improvement in the incontinence rates between the groups undergoing urodynamics or not. However, the confidence interval could not rule out a clinically important difference in either direction, and so the clinical implications of these findings remain unclear.

Concluding message

We conclude that the clinical benefit from this invasive investigation remains unproven: despite changes in management, there was no clear improvement in clinical outcomes for women undergoing the investigations, and most received surgery regardless of the urodynamic findings.

Further, well-designed randomised controlled trials following the CONSORT guidelines are needed to determine if urodynamic testing and the subsequent alterations in management plan improve patient clinical outcomes and satisfaction.

Disclosures

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