

Letter to the editor (674 words)

Dear Editor

**Re: Hilton P, Bryant A, Howel D, McColl E, Buckley BS, Lucas MG, et al. Assessing professional equipoise and views about a future clinical trial of invasive urodynamics prior to surgery for stress urinary incontinence in women: A survey within a mixed methods feasibility study. Neurourol Urodyn. 2012;31(8):1223-30.**

As part of the mixed methods feasibility study INVESTIGATE-I,[1] in August 2011 we undertook a survey of members of the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons - Section of Female, Neurological and Urodynamic Urology (BAUS-SFNUU). This sought to establish their views on the place of invasive urodynamic testing (IUT) in female lower urinary tract symptoms and their level of support for a future randomised controlled trial of IUT prior to surgery for stress urinary incontinence (SUI).[2] Since our initial survey, two further trials have been published.[3, 4] Both were of a non-inferiority design and, whilst using slightly different patient groups and methodologies, both concluded that outcomes from treatment based on clinical/office evaluation were not inferior to those based on IUT. Before publishing the final report on our feasibility studies we therefore wished to establish whether clinicians in the UK had changed their opinions in the intervening two-year period, based on the findings from these two trials.

We therefore re-surveyed consultant members of the same specialist societies in June 2013, indicating in the covering email that we were investigating changes in opinion in view of recently published studies. There were 145/498 (29%) responses, compared to 34% in the initial survey, although the demographic profile of respondents was very similar.

Respondents were asked to consider the following research question:

*'Does invasive urodynamic testing prior to surgical treatment of stress or stress predominant mixed urinary incontinence improve the clinical and cost-effectiveness of treatment compared to clinical assessment with non-invasive testing?'*

Of all respondents, 74% rated this research question ‘very important’ or ‘extremely important’, compared to 69% in 2011 (see Figure 1). On a scale of ‘willingness to randomise’ (where 0 indicated ‘not at all willing’ and 10 indicated ‘totally willing’) 68% recorded a score  $\geq 7/10$ , compared to 65% in 2011 (see Figure 2); in addition, 102/145 (70%) provided email addresses, indicating their interest in contributing to a possible future definitive trial in the UK. Responses to the initial survey were anonymous, so we are not able to determine to what extent individuals who responded to both surveys may have changed their opinion over the two-year period.

Of consultant respondents to our initial (2011) survey, 88% reported undertaking IUT on most of their patients with SUI or stress predominant mixed incontinence, and the majority, when faced with a range of clinical scenarios of varying symptom complexity, indicated that IUT was necessary in all women with SUI with or without other symptoms, prior to surgical treatment.[2] Hence there was clear evidence of lack of personal equipoise in the majority of respondents. Nevertheless, even after the publication of two major trials, a majority still see the place of IUT prior to surgical treatment as an important area of uncertainty (2013), and one in which many would be prepared to randomize their patients. It is possible therefore that, in recognition of a degree of professional community equipoise, clinicians might be able to ‘suspend’ their lack of personal equipoise to facilitate further enquiry.

Two recent systematic reviews with meta-analysis of urodynamics in the management of urinary incontinence, both of which include the new trials that we have cited here, reach apparently conflicting conclusions. Rachaneni & Latthe included data from 3 trials ( $n=775$ ) and concluded that in women undergoing primary surgery for SUI or stress-predominant MUI without voiding difficulties, there was no evidence that urodynamics improved outcomes compared to careful office evaluation (OR for treatment success 0.96, 95%CI 0.41-2.25,  $p=0.92$ ).[5] The most recent iteration of the Cochrane review included data from 7 trials ( $n=1036$ ) and found that while IUT did change clinical decision making, this did not result in better outcomes. The authors reported the included studies to be often small, with one or more factors increasing the risk of bias, and with variable GRADE quality (low to high).[6] Hence they indicated that larger definitive trials are still needed in which people are randomly allocated to management according to urodynamic

findings or to management based on history and clinical examination to determine if the performance of urodynamics results in higher continence rates after treatment.[7] It is gratifying therefore that we found evidence that sufficient numbers of clinicians remain prepared to take part, to make a definitive trial in the UK not only highly relevant to clarifying practice in this area, but also feasible.[1]

Paul Hilton, Andrew Bryant, Denise Howel, Elaine McColl, Jing Shen, Tara Homer, Luke Vale, Brian S Buckley, Malcolm G Lucas, Douglas G Tincello, and Natalie Armstrong, on behalf of the INVESTIGATE studies group<sup>†</sup>.

<sup>†</sup>Other members of the studies group are listed in the final report.[1]

## REFERENCES

1. Hilton P, Armstrong N, Brennand C, Howel D, Shen J, Bryant A, *et al.* INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): a mixed methods study to assess the feasibility of a future randomised controlled trial of invasive urodynamic testing prior to surgery for stress urinary incontinence in women. *Health Technology Assessment Journal*. 2015;19(15).
2. Hilton P, Bryant A, Howel D, McColl E, Buckley BS, Lucas MG, *et al.* Assessing professional equipoise and views about a future clinical trial of invasive urodynamics prior to surgery for stress urinary incontinence in women: A survey within a mixed methods feasibility study. *Neurourol Urodyn*. 2012;31(8):1223-30.
3. Nager CW, Brubaker L, Litman HJ, Zyczynski HM, Varner RE, Amundsen C, *et al.* A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med*. 2012;366(21):1987-97.
4. van Leijsen SA, Kluivers KB, Mol BW, Hout J, Milani AL, Roovers JP, *et al.* Value of urodynamics before stress urinary incontinence surgery: a randomized controlled trial. *Obstet Gynecol*. 2013;121(5):999-1008.

5. Rachaneni S, Latthe P. Does preoperative urodynamics improve outcomes for women undergoing surgery for stress urinary incontinence? A systematic review and meta-analysis. *BJOG*. 2015;122(1):8-16.
6. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, *et al*. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *Brit Med J*. 2008;336(7650):924-6.
7. Clement KD, Lapitan MCM, Omar MI, Glazener CMA. Urodynamic studies for management of urinary incontinence in children and adults. *Cochrane Database of Systematic Reviews*. 2013(10):Art. No.: CD003195.