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Extended Research Article

Invasive urodynamic investigations in the management of women with refractory overactive bladder symptoms: FUTURE, a superiority RCT and economic evaluation

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Disclaimer

This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

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Scientific summary

Background

Overactive bladder (OAB) affects 12–14% of the UK adult female population. Symptoms include urinary urgency, with or without urgency incontinence, increased daytime urinary frequency and nocturia. OAB has a negative impact on women's social, physical and psychological well-being. Initial treatment includes lifestyle modifications, bladder retraining, pelvic floor exercises and pharmacological therapy. However, these measures are unsuccessful in 25–40% of women (refractory OAB). Before considering invasive treatments, such as botulinum toxin injection A (BoNT-A) or sacral neuromodulation (SNM), most guidelines recommend urodynamics to confirm diagnosis of detrusor overactivity (DO). However, urodynamics may fail to show evidence of DO in up to 45% of cases, hence the timely need to evaluate its clinical and cost effectiveness.

Objectives

To compare the clinical and cost-effectiveness of urodynamics plus comprehensive clinical assessment (CCA) versus CCA only in the management of refractory OAB symptoms in women.

Design

Female Urgency, Trial of Urodynamics as Routine Evaluations (FUTURE) was a parallel-group, multicentre, superiority, randomised controlled trial. The cost-effectiveness analysis took the NHS perspective with a model-based lifetime time horizon, as informed by a within-trial analysis.

Setting

FUTURE involved 63 secondary and tertiary hospitals across the UK.

Participants

Women aged 18 years and over with refractory OAB or urgency-predominant mixed urinary incontinence (MUI), who had failed conservative management and pharmacological treatment and were being considered for invasive treatment, were invited to participate.

Women were excluded if any of the following criteria were met: predominant stress urinary incontinence (SUI); previous urodynamics in last 12 months; current pelvic malignancy or clinically significant pelvic mass; bladder pain syndrome; neurogenic bladder; urogenital fistulae; previous treatment with BoNT-A or SNM for urinary incontinence; previous pelvic radiotherapy; prolapse beyond introitus; pregnant or planning pregnancy; recurrent urinary tract infection where a significant pathology had not been excluded; and inability to give an informed consent.

Interventions

Eligible and consenting participants were randomised to one of the following two treatment arms in a 1 : 1 allocation ratio using a remote web-based randomisation service:

- urodynamics plus CCA (urodynamics arm)
- CCA only (CCA only arm).

The randomisation process used stratified random permuted blocks with (1) site and (2) diagnosis of OAB versus urgency-predominant MUI used as strata.

Main outcome measures

The primary clinical outcome measure was participant-reported success at their last follow-up time point (either 15 or 24 months post randomisation) as measured by the Patient Global Impression of Improvement (PGI-I). Success was defined as participant response of 'very much improved' or 'much improved'. The primary economic outcome was incremental cost per quality-adjusted life-year (QALY) gained.

Secondary outcome measures included: a less strict definition of success at the last follow-up time point where success was defined as 'very much improved', 'much improved' or 'improved'; proportion of women receiving invasive treatment during follow-up; participant-reported success in the first 2 months following BoNT-A (for women who received BoNT-A only); OAB symptoms measured by the International Consultation on Incontinence Questionnaire (ICIQ) overactive bladder (ICIQ-OAB) and the Urgency Perception Scale (UPS); urgency and urgency urinary incontinence episodes measured using the 3-day bladder diary; other urinary symptoms measured using the three domains of ICIQ female lower urinary tract symptoms (ICIQ-FLUTS; filling, voiding and incontinence) and the bladder diary; general health-related quality of life (HRQoL) status measured using generic [EuroQol-5 Dimensions, five-level version (EQ-5D-5L)] and condition-specific [ICIQ-LUTSQoL (ICIQ lower urinary tract symptoms quality of life)] assessment tools; adverse events; cost; and cost-effectiveness.

Data collection during follow-up

Participant-reported outcomes were assessed by self-completed questionnaire at baseline and 3, 6 and 15 months post randomisation. An additional 24-month post-randomisation questionnaire was completed by participants whose treatment had been delayed by the COVID-19 pandemic. A self-completed 3-day bladder diary was also collected at baseline and 6 and 15 months post-randomisation.

Sample size

Outcome data were required on 986 participants per group for 90% power to detect a minimum of 10% superiority of urodynamics over CCA only. Based on an expected 10% drop-out rate, the recruitment target was 1096 participants in total (548 participants per group).

Statistical analysis

Analyses were conducted in adherence with the intention-to-treat principle. Analyses used a two-sided 5% significance level with corresponding 95% confidence intervals (CIs). The primary outcome was analysed using repeated-measures mixed-effects logistic regression. Secondary outcomes were analysed using the appropriate generalised linear model.

Economic evaluation

The economic analysis consisted of a within-trial analysis up to 24 months and a decision-analytic modelling framework to inform cost-effectiveness over a lifetime horizon. Costs and outcomes were collected on participant questionnaires and case report forms. EQ-5D-5L scores were used to estimate QALYs. Costs took the NHS perspective and were calculated at 2020–1 price levels. Increments were estimated using regression models with multiple imputation. Deterministic sensitivity analyses examined a complete-case analysis, a societal perspective and alternative utility and cost estimates. Probabilistic sensitivity analyses were undertaken. A subgroup analysis based on initial diagnosis was undertaken. To estimate longer-term economic differences, a hybrid model with a decision tree describing short-term events and Markov processes describing long-term events was developed using external evidence that captures clinical and patient events beyond the end of the trial.

Qualitative interviews

The principal aim of the qualitative interviews was to establish the perspectives of clinicians and patients in the decision-making processes regarding investigation for refractory OAB, and participant perspectives following treatment.

The qualitative data management software NVivo 10 (QSR International, Warrington, UK) was used to conduct the analyses. Purposive sampling was used to identify potential participants already recruited into FUTURE. Recruitment continued until data saturation was reached and there were no new emerging themes. Telephone interviews were audio-recorded and transcribed verbatim, and data transcripts were coded and analysed using a thematic analysis.

Management of the study

The study was supervised by the project management group, which consisted of representatives from the study office and grant holders. The study was further overseen by an independent Trial Steering Committee, and an independent Data Monitoring Committee.

Results

Recruitment

Between November 2017 and January 2021, 3066 potentially eligible participants were screened, 1511 (49.3%) confirmed eligible and 1103 (73.0%) gave their consent and were randomised. There was a pause in recruitment between March 2020 and August 2020 due to the COVID-19 pandemic. Following randomisation, four participants were considered ineligible and recorded as post-randomisation exclusions. Therefore, 1099 participants (550 in the urodynamics arm and 549 in the CCA only arm) were included in the trial.

Baseline characteristics

At baseline, both groups were similar, with a mean age of 60 and a mean body mass index of 31. Two-thirds of the population were clinically classified as OAB, with the remaining third as urgency-predominant MUI. Urgency was classed as severe by 64% and 63% of the respective groups. All participants had received previous conservative treatment, with bladder training and pelvic floor muscle training being the most common conservative treatment received (69% and 84% respectively).

At baseline the EQ-5D-5L scores were 0.653 and 0.674 respectively, a lower quality-of-life score than the population mean for this age group.

Clinical effectiveness

At the final follow-up time point, there was no significant difference between the success rates on the PGI-I: urodynamics arm 23.6% (117/496) versus CCA only arm 22.7% (114/503), odds ratio (OR) 1.12 (95% CI 0.73 to 1.74); $p = 0.60$. This is consistent with the effect sizes obtained for the less strict definition of success and when multiple imputation was used as a sensitivity analysis. The per protocol analysis was also consistent and showed no significant difference between the groups: urodynamics [113/454 (24.9%)] vs. CCA only [111/483 (23.0%)], OR 1.22 (95% CI 0.78 to 1.91); $p = 0.39$. The subgroup analysis comparing OAB to urgency-predominant MUI also did not show any significant difference in the effect of urodynamics [1.14 (99% CI 0.33 to 3.90); $p = 0.79$] nor did restricting the PGI-I assessment to those who received BoNT-A and rated their success '2 months following treatment' (63.8% vs. 60.0% [OR 1.17 (99% CI 0.73 to 1.89); $p = 0.52$]). Women in the CCA only arm were significantly more likely to show earlier improvement in their symptoms, that is, at 3-month follow-up [OR 0.35 (95% CI 0.19 to 0.66); $p = 0.001$].

Secondary outcomes

On the UPS, there was improvement in urgency perception between baseline and final follow-up in both groups, with the effect sizes for level of urgency [OR 0.87 (95% CI 0.63 to 1.21); $p = 0.42$], cure [OR 2.04 (95% CI 0.86 to 4.80); $p = 0.10$] and improvement [OR 1.12 (95% CI 0.78 to 1.62); $p = 0.53$] showing no significant difference between groups.

In both groups there was improvement on the ICIQ-OAB score from baseline to the final follow-up. At final follow-up, the difference tended to favour urodynamics but was not significant [adjusted mean difference −0.4 (95% CI −0.9 to 0.0); $p = 0.06$].

On both the ICIQ-FLUTS filling and incontinence domain scores there was improvement from baseline to final follow-up in both groups, with no significant differences between groups, except for the filling domain score favouring

urodynamics [adjusted mean difference −0.4 (95% CI −0.9 to −0.0) p = 0.04]. No improvement from baseline was observed on the voiding domain nor was there a significant difference between the groups.

There was no difference between the groups in HRQoL on the specific ICIQ-LUTSQoL score nor the more generic EQ-5D-5L, although there was an indication of improvement from baseline on the former. Interference in everyday life from urinary symptoms was similar between the groups at all time points.

Treatments received

The percentage of CCA only participants receiving any treatment following assessment was slightly higher than for the urodynamics group [87.2% (479/549) vs. 84.9% (467/550)]. The treatments with the highest frequencies were BoNT-A, medical treatment and physiotherapy. Of those receiving treatment, the percentage of participants receiving BoNT-A was higher in the CCA only group [71.6% (343/479)] compared to the urodynamics group [59.3% (277/467)]. The other invasive treatments of surgery for SUI, SNM and percutaneous tibial nerve stimulation were only received by 21, 19 and 48 participants respectively.

Role of urodynamics in the decision-making process

In women with refractory OAB/MUI who underwent urodynamics, urodynamics did not show evidence of DO in 34% of cases, while 58% were diagnosed with DO or DOI and 8.0% with urodynamic MUI. Despite a baseline diagnosis of OAB or urgency-predominant MUI, 13% of participants had a diagnosis of urodynamic stress incontinence (USI) following urodynamics. However, only 20% of those with USI had a treatment decision for SUI surgery. No evidence of DO or USI was noted in 20% of cases.

Safety

In FUTURE, 21.4% of participants reported at least one adverse event, with slightly higher reporting in the CCA only arm; 122 (22.2%) versus 113 (20.5%), with urinary tract infections, need for prophylactic antibiotics and clean intermittent self-catheterisation having the highest rates.

As BoNT-A was the most comment treatment received, adverse events associated with BoNT-A (such as limb weakness and pain) were most often seen due to the higher number of participants receiving this treatment.

Health economic results

For the primary analysis, the mean costs in the urodynamics group were £463 higher (95% CI £48 to £877) compared with those in the CCA only group. This was principally due to the intervention itself and more clinic visits in this group. There was evidence of greater numbers of interventions for SUI in participants undergoing urodynamics, but all other effects are highly uncertain, and not statistically significant.

There is no clear evidence of differences in HRQoL (as measured by the EQ-5D-5L) at any time point. When modelled with imputation, a small but not statistically significant difference in QALYs of 0.011 (95% CI −0.044 to 0.065) was estimated in favour of the urodynamics group.

Based on the estimated incremental costs and QALYs of urodynamics (£463 and 0.011, respectively), the incremental cost-effectiveness ratio was £42,643 per QALY gained. The higher mean costs and QALYs therefore led to urodynamics not being cost-effective at a funding threshold of £20,000 per QALY gained, with only a 34% chance of it being cost-effective. However, this was sensitive to imputation, with the complete-case analysis showing a 67% chance of urodynamics being cost-effective. The subgroup analysis suggests larger health benefits for participants with an initial diagnosis of urgency-predominant MUI, which is associated with a 72% chance of cost-effectiveness.

Modelling the results over a lifetime horizon reduces the cost-effectiveness of urodynamics further. The primary, model-based economic analysis shows that urodynamics has a low probability of being cost effective at £20,000 per QALY gained (23.4%), producing modestly higher costs (£1380) and slightly lower QALYs (−0.002) per patient.

However, this analysis, together with a value of information analysis, should be updated once more information is available about the longer-term follow-up of participants recruited to FUTURE.

Qualitative

The qualitative interviews among clinicians highlighted that the main driver for the inclusion of urodynamics in their existing practice was its recommendation in guidelines and clinical judgement. For some, urodynamics was perceived to provide additional information to aid the treatment decision-making process, while others consider it of little additional value. Key components of the CCA include the bladder diary and history-taking, which clinicians acknowledged should be of high quality to offer maximum value to patient assessment. A clear message emerged that clinicians would like the option to include urodynamics only where it was deemed necessary but would be happy to consider not using it as a routine investigation dependent on the evidence. A desire for evidence-based guidance on the added value of urodynamics was expressed, which it was hoped would be provided through FUTURE.

Interviews among FUTURE participants highlighted a broad spectrum of opinion, reflecting individual personalities as well as the investigation itself. Participant views ranged from those who were prepared to undergo urodynamics as a means to provide direction for treatment for their enduring symptoms, through to those who were extremely worried about the discomfort and embarrassment associated with the procedure, to the point of refusing it. Given the refractory nature of the symptoms among the FUTURE participants, many were at a stage where they were 'willing to try anything'. The decision-making process is multifactorial though and not only based on views of the investigation itself. Guidance provided by the clinical team is a primary driver. Other factors include anecdotal experience, practicalities of urodynamics such as timescales, impact on work life and location of potential subsequent treatments. An element of 'validation' was described whereby a test suggests additional findings to guide treatment and makes women feel that their symptoms are taken seriously. Given the spectrum of perspectives, however, there was also articulated a sense of relief when avoidance of urodynamics was the outcome.

Conclusion

In participants with refractory OAB or urgency-predominant MUI, the participant-reported success rates following treatments in participants who undergo urodynamics and CCA are not superior to those who undergo CCA only up to 15-months follow-up. Significantly more women who undergo CCA only report earlier improvement in their symptoms. Urodynamics plus CCA is not cost-effective at a threshold of £20,000 per QALY gained.

Trial registration

This trial is registered as ISRCTN63268739.

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