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A DOUBLE BLIND RANDOMISED PLACEBO CONTROLLED TRIAL OF THE EFFECTIVENESS OF BLADDER TRAINING WITH OXYBUTYNIN OR IMIPRAMINE IN THE MANAGEMENT OF DETRUSOR OVERACTIVITY (DO).

Hypothesis / aims of study

To assess the efficacy and cost effectiveness of drug therapies as a second line therapy in men and women aged 40 years and over with DO or mixed incontinence.

Study design, materials and methods

Design: 3-arm double blind randomised controlled trial.

Participants: 282 community dwelling men and women aged 40 years and over with DO who had failed primary behavioural intervention (bladder training). Randomised to receive either oxybutynin (n=97), imipramine (N=91) or placebo (n=94) for 12 weeks. All groups continued with bladder training.

Main Outcome Measures: Primary, incontinence episode frequency (recorded in a voiding diary). Secondary: patient perception of problem, voiding and other symptoms of over active bladder (voiding frequency, nocturia and urinary urgency recorded in a diary) and 24 hour pad tests. Validated scales for urinary dysfunction and impact on quality of life, together with economic data and satisfaction were collected at an independent home interview.

Results

There was no significant improvement in incontinence episode frequency, voiding frequency or nocturia in the active groups compared to placebo. There was a significant improvement in urgency in the oxybutynin group compared to placebo. There were side effects to medication despite closely monitored titration, resulting in many patients either not taking medication or using low (possibly sub-therapeutic) doses.

Interpretation of results

In patients who have already undergone 8 weeks of high quality bladder training for urinary dysfunction the addition of oxybutynin or imipramine shows no advantage on clinical measurement. However, the continuation of bladder training alone may also lead to further improvement in some patients.

Concluding message

Our evidence does not support the prescription of oxybutynin or imipramine within such a care pathway contrary to many guidelines. The role of other medications within a similar pathway requires further investigation.

Specify source of funding or grant	**Medical Research Council** **NHS Research and development**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Leicestershire REC**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**