Treatment of overactive bladder in women

CRD summary
The authors concluded that the evidence did not allow definitive conclusions on the relative benefit and harm of different treatments to achieve similar results. High-quality research was imperative to provide women and their care providers with better information to guide their choices. This was generally a well-conducted piece of research and the authors’ cautious conclusions seem appropriate.

Authors’ objectives
To assess the evidence on treatment of overactive bladder, urge urinary incontinence and related symptoms in women.

Searching
PubMed, EMBASE and CINAHL were searched between 1966 and October 2008 for English-language publications. Search terms were reported. Reference lists of relevant articles were handsearched.

Study selection
Studies that assessed short- and long-term outcomes of treatments prescribed or provided by a healthcare practitioner for women with overactive bladder (defined as idiopathic urinary urgency and frequency with or without associated urge urinary incontinence, not related to neurogenic conditions or as a result of (stress incontinence) surgery) were eligible for inclusion. Eligible studies were required to include at least 50 participants at enrolment, 75% of whom needed to be women. Studies with fewer than 75% women had to present results for women separately or be controlled for gender. Studies that provided data only for stress or mixed urinary incontinence were excluded. Outcomes of interest were urinary urge incontinence episodes, urgency, incontinence, voids, nocturia, quality of life, urodynamic measures and adverse events.

Included studies were conducted worldwide. Inclusion and exclusion criteria varied among studies. Mean age of patients who received pharmacological interventions ranged from 47.0 to 64.5 years. Some studies reported that patients had received some form of previous overactive bladder treatment (such as pharmacological, surgical and non-surgical). Where reported, duration of overactive bladder ranged from three months to 15 years.

Pharmacologic treatments included oxybutynin, tolterodine, fesoterodine, solifenacin, darifenacin, trospium and oral oestrogen therapy. Treatments were compared to each other, behavioural therapy or placebo. Procedural and surgical treatments included sacral or peripheral neuromodulation, electromagnetic therapy, bladder instillation or injection of drugs, bladder distension and bladder transection. Comparisons included other procedural or surgical treatments, sterile water, control (with or without medical therapy), sham and placebo. Behavioural studies included assessment of bladder training, multi-component behavioural training (with or without biofeedback), pelvic muscle exercises or training, vaginal electrical stimulation and caffeine reduction. Comparisons included other behavioural treatments, pharmacological treatment, placebo and control. Complementary and alternative therapies included acupuncture, foot reflexology and hypnotherapy.

Two reviewers independently screened studies for inclusion. Discrepancies were resolved through referral to a third reviewer.

Assessment of study quality
Two reviewers independently assessed the internal and external validity of the included studies. Criteria included those on randomisation, allocation treatment, blinding, adequate description of patients and control selection criteria, loss to follow-up and dropouts, power calculation, description of statistical issues and intention-to-treat analysis. Studies received an overall quality rating of good, fair or poor. Disagreements were resolved through discussion.

Data extraction
One reviewer extracted the number of urge incontinence episodes and number of voids per day, or converted
appropriate data to the number per day. Standard deviations were extracted or calculated. A second reviewer checked the data extraction for accuracy. Discrepancies were resolved through consensus.

**Methods of synthesis**
Where appropriate, a fixed-effect model was used to combine mean daily reductions in urge incontinence and voids and 95% confidence intervals (CIs), weighted by the inverse variance. Adjustments were made for mean age and proportion of women in each treatment arm. Findings were reported by treatment type.

Where meta-analysis was not appropriate, data were presented as a narrative synthesis and in tables.

**Results of the review**
Pharmacological treatment (110 studies, 68 of which were RCTs); four good-quality studies, 75 fair and 31 poor. Follow-up ranged from two to 52 weeks. All pharmacological treatments significantly reduced one or more overactive bladder symptoms compared to placebo. Extended release formulations reported greater effects compared to immediate release forms (it was unclear how many RCTs were involved in the meta-analysis and forest plots were not presented). Extended release forms reduced urinary urge incontinence by 1.78 episodes per day (95% CI 1.61 to 1.94) and voids by 2.24 per day (95% CI 2.03 to 2.46). Immediate release forms reduced urinary urge incontinence episodes by 1.46 (95% CI 1.28 to 1.64) and voids by 2.17 per day (95% CI 1.81 to 2.54). Direct comparisons between different pharmacological treatments showed that no one treatment was superior to another.

Procedures and surgical treatment (five RCTs and 13 case series); 11 fair-quality studies and seven poor. One RCT showed a statistically significant reduction in episodes of incontinence per day with sacral neuromodulation (average reduction of 7.1) compared to usual care/medical therapy (2.1 increase in episodes). One RCT showed significantly greater reductions in the number of voids per day using instillation of oxybutynin compared to sterile water (6.8 versus 2.4). One RCT showed greater benefits with botulinum toxin treatment.

Behavioural interventions (five RCTs, one prospective cohort and three retrospective case series). Follow-up ranged from four to 12 weeks. Significant heterogeneity among studies prevented pooling of the results. All behavioural interventions reduced incontinence episodes (by up to 1.9 episodes per day) and reduced voids (up to approximately four per day). No one behavioural approach was superior to another over any time period up to 12 weeks. For comparisons of treatments, seven studies directly compared behavioural versus pharmacologic treatments; one study reported significantly greater reductions in incontinence episodes with multicomponent behavioural modification compared to oxybutynin, but no studies reported differences in reductions in voids. Six studies compared behavioural and pharmacologic treatment versus pharmacologic treatment alone and reported no significant differences in incontinence episodes. The findings were conflicting for combined behavioural and pharmacologic treatments on the number of voids per day.

Complementary and alternative therapies (two RCTs and one prospective case series); two fair-quality studies and one poor. Follow-up ranged from three to 12 weeks. Acupuncture significantly reduced the number of voids per day by 1.4 episodes, but there was no significant difference in urinary urge incontinence compared to sham treatment (one RCT). Reflexology and hypnotherapy (one study each) did not provide any supportive evidence for these treatments.

Results for other outcomes and modifiers of effect were reported in the review.

**Authors’ conclusions**
The available evidence did not allow definitive conclusions on relative benefit and harm of different treatments to achieve similar results. High-quality research was imperative to provide women and their care providers with better information to guide their choices.

**CRD commentary**
The review question and supporting inclusion criteria were clearly defined. Appropriate sources were searched for relevant studies. The search was limited by language and it was unclear whether attempts were made to locate unpublished data, so language and publication biases could not be ruled out. Each stage of the review process was
performed in duplicate, which minimised risks of reviewer error and bias. Study quality was assessed using appropriate criteria, but (as the authors acknowledged) the quality of the included studies was limited. Appropriate methods were used to combine the results, although it was difficult to confirm some of the findings, particularly for the meta-analyses. It appeared that statistical heterogeneity was not formally assessed, but the authors acknowledged clinical and methodological heterogeneity among studies. Some treatment comparisons included only a limited number of studies. Follow-up durations were generally short.

This was generally a well-conducted piece of research and a large body of evidence was found. The authors acknowledged some of the limitations of the included studies and their cautious conclusions seem appropriate.

**Implications of the review for practice and research**

**Practice:** The authors stated that generalisability to clinical practice of pharmacologic treatment was limited due to the generally short-term period over which the studies were conducted.

**Research:** The authors stated that larger high-quality research that reflected the severity of conditions in both primary care and speciality practice settings was needed.

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