Assessing the clinical efficacy of sildenafil for the treatment of female sexual dysfunction

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CRD summary
The authors concluded that the data suggested a possible role for sildenafil in the treatment of female sexual dysfunction, but this should be interpreted cautiously as many of the trials had small samples and used inappropriate statistical tests and non-validated assessment tools. There were possible sources of bias in the review process so the reliability of these conclusions is unclear.

Authors' objectives
To assess the efficacy and safety of sildenafil for the treatment of female sexual dysfunction.

Searching
MEDLINE was searched from 1950 to February 2009 for studies published in English. A bibliographic search was also conducted.

Study selection
Clinical trials of sildenafil treatment for premenopausal or postmenopausal women with sexual dysfunction or women with sexual dysfunction due to concomitant medications, disease states, or both, were eligible for inclusion. The patients in the included trials were diagnosed with female sexual arousal disorder or female sexual dysfunction, with or without a secondary sexual dysfunction, spinal cord injury, multiple sclerosis, or type 1 diabetes, or orgasm or arousal related disorders, and one study was of antidepressant-induced female sexual dysfunction. The sildenafil dose ranged from 10 to 100mg (inconsistent between table and text) and duration of treatment was from a single dose to 36 weeks. Outcome measures varied between trials; most of the trials involved questionnaires and some included physiological measurements.

The authors did not state how the papers were selected for the review.

Assessment of study quality
The authors did not state that they assessed trial validity.

Data extraction
The authors did not state how the data were extracted for the review.

Methods of synthesis
The trials were pooled in a narrative synthesis and grouped by premenopausal women with female sexual dysfunction, postmenopausal women with female sexual dysfunction, and female sexual dysfunction with concomitant disease states.

Results of the review
Twelve trials were included, with 13 treatment arms (n=1,369 women; range 12 to 781). Six arms were randomised, double blind, and placebo controlled (three were also crossover) (n=1,007); one was randomised, double blind, and crossover (n=12); one was double blind and placebo controlled (n=202); two arms were double blind, placebo controlled, and crossover (n=55); and three arms were open label (n=93).

Eight trials reported benefit from treatment with sildenafil for female sexual dysfunction; four trials showed no significant difference with treatment.

One trial reported that the most frequently reported adverse event was headache (43% for sildenafil compared with 27% for placebo, p=0.09); other adverse events with sildenafil were flushing (the number-needed-to-harm, NNH, was four), dyspepsia (NNH eight), nasal congestion (NNH three), and transient visual disturbances (NNH eight).
Authors' conclusions
The data suggested a possible role for sildenafil in the treatment of female sexual dysfunction, but it should be interpreted cautiously as many of the trials had small samples, used inappropriate statistical tests, and used non-validated assessment tools.

CRD commentary
The research question was supported by inclusion criteria for participants, intervention, and study design. Only one database was searched for trials in English, and it was therefore possible that relevant trials could have been missed. The review process was not reported, so it is not known whether steps were taken to reduce the risk of reviewer error and bias. Trial quality was not formally assessed (although some aspects were described in the text), so it was difficult to assess the reliability of the trials. A narrative synthesis appeared to be appropriate as a range of intervention durations and doses, and outcomes were reported.

The authors' conclusions were cautious, but there were several possible sources of bias in the review process and so their reliability is unclear.

One author received an honorarium from Pfizer regarding linezolid, but not sildenafil.

Implications of the review for practice and research
Practice: The authors stated that sildenafil might be beneficial in women with female sexual dysfunction secondary to neurodegenerative diseases and in women with antidepressant-induced sexual dysfunction, but it should only be used after traditional measures have failed.

Research: The authors stated that newer terms and categories to describe female sexual dysfunction might be beneficial to better assess sildenafil's role in the treatment of female sexual dysfunction and validated instruments need to be used to determine clinical significance.

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