Female sexual dysfunction in postmenopausal women: systematic review of placebo-controlled trials

Modelski K, Cummings S

CRD summary
This review assessed treatments for postmenopausal women with female sexual dysfunction. The authors concluded that due to insufficient evidence it was not possible to state which (if any) treatment was appropriate for which groups of women. The authors’ conclusions reflect the paucity of evidence found by the review.

Authors' objectives
To identify studies which investigate treatments for postmenopausal women with female sexual dysfunction (FSD).

Searching
Sources including MEDLINE, HealthSTAR and EMBASE were searched from January 1990 to February 2002 using the search terms listed in the paper. Reference lists were screened for other research of interest, and conference proceedings and bibliographies of published articles were handsearched.

Study selection
Study designs of evaluations included in the review
Randomised placebo-controlled trials (RCTs) were eligible for inclusion. Open-labelled, non-randomised trials with retrospective analyses were excluded, as were trials that did not specifically state the use of placebo.

Specific interventions included in the review
Treatments for women with sexual dysfunction were eligible for inclusion. Studies were found on the effect of sildenafil citrate (Viagra), hormone replacement therapy (HRT) and tibolone. Studies that included the use of non-pharmacologic therapy, moisturisers, lubricants and clitoral stimulating devices were excluded.

Participants included in the review
Postmenopausal women were eligible for inclusion. The women were aged from 18 to over 65 years.

Outcomes assessed in the review
The outcomes do not appear to have been pre-specified. The outcomes included were increase in sexual desire and arousal, frequency of sexual intercourse and orgasm, vaginal lubrication and sexual fantasies.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors do not appear to have formally assessed validity, but issues such as sample size, drop-outs and outcome measures were discussed in the report.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were combined narratively according to the type of treatment they investigated: sildenafil citrate, HRT and tibolone.

How were differences between studies investigated?
The differences between the studies, in terms of trial design, participants, interventions and outcomes, were discussed within the text.

Results of the review
Six RCTs were included in the review (n=799, range: 20 to 583).

One trial (n=583) looked at the effect of sildenafil citrate on postmenopausal women with female sexual arousal disorder and found this treatment to be ineffective in improving sexual response (no data provided). Three trials investigated the effect of HRT. One trial that looked at the effect of oestrogen-progesterone therapy (n=48) found a statistically significant improvement in arousal and sexual desire in comparison with no treatment. Two trials investigated the effect of oestrogen-androgen therapy. One trial (n=20) was found to statistically, significantly improve the women's desire, sensation and frequency of intercourse when compared with an oestrogen placebo. The other trial (n=75) reported that women who received transdermal testosterone had statistically, significantly improved sexual function than those receiving placebo. There was a 24% drop-out rate reported in this trial related to adverse events.

One of the two trials that investigated the effect of tibolone on FSD found no significant effect on sexual drive when compared with placebo (n=35). A drop-out rate was not reported. The second trial (n=38) found tibolone to significantly improve sexual desire, arousability, vaginal blood flow and lubrication. However, tibolone did not change the frequency, initiation and rejection of sexual activity in comparison with placebo, neither did it affect the rate of orgasm.

Authors’ conclusions
The authors concluded that due to limitations in the evidence-base it was not possible to state which treatment is appropriate for which groups of women.

CRD commentary
The authors provided clear inclusion and exclusion criteria for the intervention and study design. They searched a variety of sources for published trials. However, it was unclear whether unpublished and foreign language material was included. The review did not provide any information on how the studies were selected for inclusion, whether this assessment was made independently and by more than one reviewer, and how the data were extracted. Hence, it is not possible to determine whether the study selection procedure was unbiased. No formal quality assessment was performed, but the review did restrict the included studies to RCTs, some details of which were tabulated.

The authors justified their decision not to statistically pool the findings due to clinical heterogeneity between the treatments, populations and outcome measures. The authors noted that some studies used oestrogen as a placebo instead of no treatment and that this prevents any assessment of the effectiveness of oestrogen in the treatment of FSD. Also noted was the inconsistency in the outcome measures and scales, further restricting the comparability of the studies.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors noted that the effectiveness and side-effects of treatments for postmenopausal women with FSD need to be established in large placebo-controlled RCTs of longer duration than those to date.

Bibliographic details

PubMedID
12548231

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Androgens /therapeutic use; Controlled Clinical Trials as Topic; Drug Therapy, Combination; Estrogen Replacement Therapy; Estrogens /therapeutic use; Female; Humans; MEDLINE; Middle Aged; Norpregnenes /therapeutic use; Piperazines /therapeutic use; Placebos; Postmenopause; Purines; Randomized Controlled Trials as Topic; Sexual Dysfunction, Physiological /therapy; Sildenafil Citrate; Sulfones

AccessionNumber
12003000437

Date bibliographic record published
31/08/2004

Date abstract record published
31/08/2004

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.