Gender-based mortality follow-up from the program on the surgical control of the hyperlipidemias (POSCH) and meta-analysis of lipid intervention trials: women in POSCH and other lipid trials

Authors' objectives
To assess the clinical results of lipid-lowering therapy in women.

Searching
The authors do not specify which sources were searched, or give the search strategy used.

Study selection
Study designs of evaluations included in the review
The design of the included studies is not stated, although all included trials had both control and intervention groups.

To be included, the trial must have included women and published data that could be encoded to allow separate analysis of women with respect to clinical end points.

Specific interventions included in the review
Primary and secondary lipid and atherosclerosis interventions: fibric acid drugs (clofibrate), bile acid-binding resin (colestipol), hydroxymethylglutaryl-coenzyme A reductase inhibitor (simvastatin, pravastatin), diet, diet plus surgery (partial ileal bypass).

Participants included in the review
Primary intervention trials in women; secondary intervention trials in women with pre-existing atherosclerotic coronary heart disease (ACHD); hypercholesterolaemia with and without a prior myocardial infarction (MI); mild-to-moderate elevations in cholesterol levels. Data were also reported for men.

Outcomes assessed in the review
Overall mortality, ACHD mortality, cardiovascular end points (first nonfatal, silent, definite and probable MI), and stroke.

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

Assessment of study quality
The authors do not report the criteria used to assess validity, or how the validity assessment was performed.

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

Methods of synthesis
How were the studies combined?
A narrative synthesis for all of the outcomes of interest. Both fixed-effect and random-effects meta-analyses were performed using overall mortality as the outcome measure.
How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.

Results of the review
Seven trials with 7,066 female and 11,173 male patients...

Three of the 7 trials demonstrate a possible benefit in ACHD prognosis from effective lipid interventions in women, the other 4 did not.

Both meta-analyses (random-effects and fixed-effect) of overall mortality produced a statistically-significant reduction in mortality for men, but not for women. The random-effects model yielded an overall mortality risk ratio for patients in the intervention, compared to control group, of 0.81 (95% confidence interval, CI: 0.67, 0.98, p=0.027) for men and 0.89 (95% CI: 0.60, 1.32, p=0.56) for women. The results for the fixed-effect model were qualitatively similar.

Authors’ conclusions
The available clinical trials data fail to demonstrate any overall mortality or other convincing clinical benefits from effective lipid intervention in women. This is either because the mechanism of coronary obstruction is different in men and women, or that female mortality rates in the included studies are too low for a statistically-significant result.

CRD commentary
There are a number of methodological weaknesses to this review. There are no details of the search strategy, and there are insufficient details about the design of the primary studies. There are no stated inclusion criteria or validity criteria for the studies. The statistical analyses reported are not explained clearly. No statistical tests of significance are reported for the results from the individual studies. The random-effects meta-analysis method used could account for differences between studies, but no test for heterogeneity was reported. It is not adequately explained why the authors undertook both fixed-effect and random-effects meta-analyses, or a number of different pooled risk calculations, which will increase the likelihood of observing a statistically significant result by chance.

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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.