Authors' objectives
The authors aimed to critically review evidence that chitosan leads to weight reduction in overweight or obese patients.

Searching
MEDLINE, EMBASE, BIOSIS Previews, CISCOM and the Cochrane Library were searched from their inception to January 1998 for randomised controlled trials (RCTs) on the use of chitosan for obesity, using the terms 'chitosan', 'chitin' and 'Fat Magnets'. In addition, manufacturers of chitosan products were contacted for published and unpublished material, the authors' own library was searched, and references of studies were scanned to identify further studies. There was no restriction on language of publication.

Study selection
Study designs of evaluations included in the review
Randomised, placebo-controlled, double-blind trials were included.

Specific interventions included in the review
Administration of chitosan or identical placebo (4 tablets/day) either in conjunction with dietary intervention (hypocaloric diet of 1000 to 1200 calories/day) or without. Controls received placebo and dietary intervention, whilst cases received chitosan alone or with dietary intervention. Evaluations where chitosan was not the main active constituent were excluded.

Participants included in the review
Patients who were overweight or obese (between 10 to 25% excess weight), or who were overweight or obese and had hyperlipidaemia (hyperlipidaemia was not defined).

Outcomes assessed in the review
The outcome assessed in this review was mean body weight reduction in kg. The outcomes included in the individual studies were body weight, blood-pressure, blood lipids, body fat and skinfold thickness.

How were decisions on the relevance of primary studies made?
Two reviewers assessed methodological quality, trial outcomes and details of the investigation in a pre-defined fashion.

The predefined criteria are not detailed in the review, with the exception of the methodological quality assessment and the stated focus on RCTs in overweight or obese patients with chitosan treatment as the main intervention. Studies had to be published in peer-reviewed journals to be included in the review.

Assessment of study quality
The methodological quality of the identified studies was assessed using a scoring system developed by Jadad et al. (See Other Publications of Related Interest). A point was given for each of the following criteria if they were met:

1. The study was described as randomised and included the use of words such as 'random', 'randomly' and 'randomisation'.
2. The study was described as double-blind.
3. Withdrawals and drop-outs were described.
4. The method of randomisation was described and appropriate (e.g. random number tables or computer-generated).
5. The method of double-blinding was described as appropriate (e.g. identical placebo, active placebo, dummy).

In addition one point was deducted if:

6. The method of randomisation was described and inappropriate (e.g. alternate allocation or allocation by date of birth, hospital number).

7. If the method of double-blinding was described and inappropriate (comparison of tablet versus injection with no double dummy).

A maximum of 5 points could be achieved. In terms of methodological quality, papers were given a score of a maximum of 5 points. The assessment was carried out by two independent reviewers and any disagreements were resolved by discussion.

Data extraction
The authors present data on study design, sample size and drop-outs, active therapy, control treatment, treatment period, end points, results and adverse effects.

Methods of synthesis
How were the studies combined?
The trial results were pooled and analysed by meta-analysis using RevMan 3.01 software. A random-effects model was used to calculate the weighted mean difference and 95% confidence intervals (CIs).

How were differences between studies investigated?
Heterogeneity between the studies was not assessed in this review.

Results of the review
In total, 386 patients across 5 studies were examined.

Four studies satisfied all five criteria of the methodology score. They contributed 100, 90, 86 and 80 patients respectively to the analysis. One paper scored 4 points and contributed 30 patients. The weighted mean difference between intervention and placebo groups was 3.28 kg (95% CI: 1.5, 5.1) after 28 days. The authors suggest that a statistically-significant and clinically-relevant difference between the groups is achieved when chitosan is given orally as an adjunct to a hypocaloric diet.

Authors’ conclusions
The meta-analysis implies that the mean difference in terms of weight reduction between chitosan and placebo is 3.28 kg after 28 days of treatment. This result has to be viewed with caution as concerns have been raised about the original studies. Rigorous independent trials are required to assess the clinical effectiveness of chitosan as a means of weight reduction.

CRD commentary
The review addresses an important clinical and public health question, and a rigorous and comprehensive literature search without language restrictions was conducted. Some study selection criteria were presented, e.g. RCTs of obese patients with chitosan as the main intervention. The authors used an established checklist for assessing methodological quality and individual study details were tabulated. Two independent reviewers assessed the studies but it is unclear how many researchers were involved in data extraction. The methods used to pool and analyse the data were appropriate, although heterogeneity was not assessed. The authors point out that all trials included in this study were published in the same journal, and they have reservations about the fact that these studies were not found on any of the searched databases but retrieved from one manufacturer of chitosan preparations. Potential problems with the original studies include the combination of chitosan intervention with a hypocaloric diet. The authors argue that the diet may have
confounded the results although they fail to mention in what way. The authors therefore have reservations about the strength of evidence based on these trials.

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

Practice: Chitosan seems to be an effective treatment to achieve weight reduction in overweight and obese patients. This is important in the light of a growing obesity epidemic and the known link between obesity and serious health risks.

Research: Whether chitosan is truly effective cannot be conclusively answered by this review. There is a need for independent high-quality clinical trials.

**Bibliographic details**


**Other publications of related interest**


**Indexing Status**

Subject indexing assigned by CRD

**MeSH**

Chitin; Obesity /drug therapy; Weight Loss

**AccessionNumber**

11999000080

**Date bibliographic record published**

31/12/2001

**Date abstract record published**

31/12/2001

**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.