Health Technology Assessment 1997; Vol. 1: No. 13 (Executive summary)

Review

Executive summary

Systematic review of the effectiveness of laxatives in the elderly

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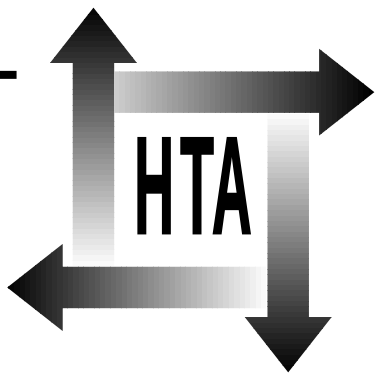

Executive summary

Objectives

To determine the effectiveness and cost of laxatives in the prevention and treatment of constipation in the elderly.

How the research was conducted

Study design

Randomised controlled trials (RCTs) of treatment or prevention of constipation were included in the review.

Interventions

The four classes of laxatives, bulk, osmotic, stimulant laxatives and faecal softeners, were covered by the review. The main laxatives included in the trials were bran, psyllium, prucara, cascara, dioctyl sodium, lactulose, and lactitol.

Participants

Elderly people suffering from chronic functional constipation. A trial was eligible for inclusion if all participants were aged 55 years or older and being treated for chronic constipation. The trials reviewed did not provide further subcategorisation by aetiology.

Main outcomes

Number of bowel movements per week; symptom improvement; stool consistency; abdominal pain.

Data sources

The recent systematic review by Tramonte and colleagues was used as a source of trials (*J Gen Intern Med* 1997;**12**:15–24). In addition, the following databases were searched: Embase, Psychlit, Medline, the Cochrane library, the nursing database CINAHL, International Pharmaceutical Abstracts, and the alternative therapies database, AMED. Authors and manufacturers were also asked for information. Studies in any language were eligible for inclusion. Decisions on the relevance of primary studies were made independently by two reviewers.

Economic information was searched for in Current Contents/Clinical Medicine, Medline, and the NHS Economic Evaluation Database (NEED).

Validity assessment

The quality of primary studies was summarised on a 6-item scale. This covered reporting of inclusion and exclusion criteria, randomisation method, standardised assessment of adverse effects, double-blind design, description of withdrawals, and statistical analysis. The assessment of validity of included studies was carried out independently by two reviewers. Data were extracted from studies independently by two reviewers. Authors were contacted for more information where necessary to obtain unpublished information.

Clinical trials included

Ten trials comparing single agents with placebo were identified, with a total of 367 patients who had a mean age of about 74 years. Two of these presented no information on the numbers of men and women. Just over half of the included patients were women (54%) in the remaining eight trials. The majority of patients were in an institutional setting, such as a nursing home or hospital.

Ten trials compared one laxative agent with another. The mean age of participants in these trials was estimated at 77 years. Only one trial examined patients in an outpatient setting; the other trials were carried out in nursing homes or hospitals.

Data synthesis

The studies were combined by narrative review, with quantitative summary of the results of similar trials where appropriate. This involved meta-analysis of outcome data using Cochrane Revman software. Differences between subgroups were investigated narratively.

Research findings

Four previous systematic reviews were identified, although none of these had specifically examined the effectiveness of laxatives in the elderly.

Clinical effectiveness

Most of the studies of the prevention of constipation had been observational studies. Two RCTs were identified but these were not double-blinded.

Most of the participants in the ten treatment trials were living in hospitals or nursing homes.

In most placebo-controlled trials, non-significant trends in favour of treatment were shown for the number of bowel movements per week; however, most trials were small and may have lacked statistical power. Many trials also reported non-significant improvements in stool consistency and pain.

It was not possible to determine the relative effectiveness of different types of laxative as few good quality comparative studies have been carried out. However, a combination of a bulk plus stimulant laxative (Agiolax®) was found in two good quality trials to be more effective in improving stool consistency and frequency than an osmotic laxative alone (lactulose).

Three trials of the prevention of constipation in the elderly were found, none of which found any significant benefit of laxatives in preventing constipation.

No RCTs were found that specifically examined the role of laxatives in preventing faecal impaction in the elderly.

Cost

There have been very few economic evaluations of either laxative treatment or the prevention of constipation.

The cost to the NHS of prescription laxative items is approximately £43 million per year in England. The cost of 1 week of treatment ranges widely. Stimulant laxatives are the second most commonly prescribed class of laxatives, and the total cost of this class appears to be increasing. However, there is no evidence that they are more effective than other laxatives. There is also no evidence that the widely used stimulant laxatives, co-danthramer and co-danthrusate, are more effective than cheaper alternatives.

Conclusions

There have been so few comparative studies, and the trials have been so small, that it is difficult to determine what constitutes effective treatment of constipation in the elderly.

The majority of trials have been carried out in hospitals and nursing homes so there has been no adequate assessment of the effectiveness of laxatives in elderly people living in the community who are likely to be younger and more mobile.

There have been few direct comparisons between different classes of laxatives and between different types of laxative within classes.

The cost of treatment with laxatives varies widely. Some of the most expensive laxatives, in particular, are also becoming the most widely used, without the danthron laxatives, evidence that they are more effective.

Much additional research is therefore needed to determine the most cost-effective method of treating constipation in the elderly.

Recommendations

- Laxatives may not be appropriate for all constipated elderly people. When possible, therefore, constipation should be managed by a 'stepped-care' approach, with the first step (after exclusion of co-morbidity) being advice about dietary improvement. If this fails, patients could then be prescribed the cheapest laxative treatment and, if this also fails, other laxative preparations could be given.
- There is no evidence that the expensive danthron laxatives are more effective than other laxative preparations, and they should not be used routinely in the treatment of constipation.
- Further research is required to determine the most effective ways of preventing and treating constipation in the elderly. In particular, research is needed into the non-pharmacological prevention and treatment of constipation (that is, through dietary change).
- Trials comparing the different classes of laxative are also needed (for example, comparisons of bulk laxatives with stimulant and osmotic laxatives). These studies should include assessments of the effects of treatment on symptoms and, if possible, on stool consistency. They should also involve standardised assessments of the side-effects of treatment. If appropriate, future studies should also provide stratified analyses to reflect different clinical subgroups of patients or different subcategories of constipation.

Publication

Petticrew M, Watt I, Sheldon T. Systematic review of the effectiveness of laxatives in the elderly. *Health Technol Assessment* 1997; **1**(13).

NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health.

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http://www.soton.ac.uk/~hta ISSN 1366-5278