Comparaison du Rocgel et d'un anti-h2 sur la symptomatologie du reflux gastro-oesophagien sans oesophagite [Comparison of Rocgel with an H2-antihistamine on the symptomatology of gastroesophageal reflux without esophagitis]

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Symptom control of gastro-oesophageal reflux without oesophagitis using boehmite (Rocgel) versus ranitidine. The dosage for boehmite was four sachets per day (1 sachet one hour after each meal and one at bedtime) and for ranitidine the dosage was 300mg per day (150mg in the morning and 150mg in the evening).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of males and females with an age range of 18 to 75 who had had gastro-oesophageal reflux symptoms for a period of seven months with at least one episode per day. Patients were excluded if they had oesophagitis, a stomach ulcer, if they had undergone extensive digestive system surgery, if they were classified as alcoholics (100gy), or if they smoked more than 40 cigarettes a day.

Setting
The study was conducted in gastroenterology centres in France.

Dates to which data relate
The effectiveness, resource and cost data related to the duration of the study which was conducted between January 1993 and May 1994. The price year was not stated.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
The cost and effectiveness data related to the same study population. The study was conducted prospectively.

Study sample
The study sample consisted of 66 patients who were divided into two groups; 34 received boehmite and 32 received ranitidine. No power calculations were used in determining the sample size.
Study design
The study was a randomised controlled trial conducted across 11 centres in France. The trial was double blinded, employed a double placebo, and the duration of follow-up was four weeks. A loss to follow-up of 2 patients (one from each group) occurred since they did not complete clinical evaluation.

Analysis of effectiveness
The study was based on intention to treat. The effectiveness was measured in terms of the ability of each treatment to alleviate six related symptoms (for example: heartburn, regurgitation, night cough etc) by comparing them before and after treatment. A global clinical score and patient self-assessments were conducted in determining the effectiveness results. The two groups were comparable.

Effectiveness results
Significant symptomatic improvement occurred in both groups (both global clinical score and self-assessment by patients, p<0.001). Between the two groups, the disappearance of heartburn was 52% with boehmite and 53% with ranitidine, disappearance of regurgitation was 48% for each group. 33% of the patients became symptom-free (10 in the boehmite group and 11 in the ranitidine group) (p=NS).

Clinical conclusions
There was no statistically significant difference between the effectiveness of boehmite and ranitidine in treating the symptoms of gastro-oesophageal reflux.

Measure of benefits used in the economic analysis
Since there was no statistically significant difference between the two groups, the economic analysis was based on the difference of costs only.

Direct costs
The costs of each treatment were included in the direct costs. The price year was not stated.

Currency
Not stated.

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
Not explicitly stated, but boehmite was cheaper than ranitidine. The costs of side effects were not included in the costs.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The study showed that boehmite was as effective as the alternative treatment but cost considerably less, making it the dominant treatment. The authors concluded that ‘as a safe, locally active mucosal protecting agent and antacid, boehmite is an effective drug for the treatment of reflux oesophagitis without macroscopic lesions. Due to its lower cost when compared with ranitidine, it was the more cost-effective treatment.

CRD Commentary
The study was a straightforward and well organised trial which compared two alternative treatments. However, it had a number of limitations in terms of its reporting of key data. These included:

1. Cost data for each treatment regime. The study just stated that one treatment was lower in cost than the other and no detailed costings were given.

2. The study mentioned a double placebo, but does not describe exactly how it was used in the trial, as it is stated that all patients received either boehmite or ranitidine. The authors did note, however, that despite the use of placebos, a high compliance rate was achieved in both groups.

3. The methods of randomization were not specified.

Bibliographic details

PubMedID
7486823

Indexing Status
Subject indexing assigned by NLM

MeSH
Adolescent; Adult; Aged; Aluminum Hydroxide /administration & dosage /therapeutic use; Aluminum Oxide /administration & dosage /therapeutic use; Double-Blind Method; Female; Gastroesophageal Reflux /diagnosis /drug therapy; Histamine H2 Antagonists /therapeutic use; Humans; Male; Middle Aged; Ranitidine /administration & dosage /therapeutic use; Time Factors

AccessionNumber
21995001295

Date bibliographic record published
26/06/1997

Date abstract record published
26/06/1997