Patient satisfaction with medication for gastroesophageal reflux disease: a systematic review

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CRD summary
The review concluded that patient satisfaction was high with medication for gastroesophageal reflux disease and particularly for proton pump inhibitors (more than 70%). There was also a positive association between patient satisfaction and symptom resolution and health-related quality of life. Potential limitations to study quality and the review process imply the authors' conclusions should be treated with caution.

Authors' objectives
To evaluate patient satisfaction with medication for gastroesophageal reflux disease.

Searching
PubMed and EMBASE were searched from January 1966 to 14 August 2009 for publications in English; search terms were reported. Reference lists of selected review articles were handsearched.

Study selection
Clinical trials that evaluated proton pump inhibitors, histamine type 2 receptor antagonists (H2RAs), antacids and prokinetics for gastroesophageal reflux disease (GERD) were eligible for inclusion. Eligible studies had to evaluate GERD patient-reported satisfaction with their treatment (the primary outcome). Relevant interventions could include on-demand treatment. Secondary outcomes were symptom improvement and health-related quality of life (HRQoL). Studies were excluded if therapy was used in conjunction with surgery, data presented in the congress abstract was not reported in the full article or the study focused on patient satisfaction after switching medication. Levels of satisfaction were defined as very satisfied or satisfied (details reported in the review).

All the trials were of proton pump inhibitor therapy (omeprazole 10mg, 20mg or 40mg, esomeprazole 20mg or 40mg, lansoprazole 15mg or 30 mg, pantoprazole 40mg or rabeprazole 20mg, generally once daily or on-demand). Some studies were also of H2RAs (ranitidine 150mg twice daily and cimetidine 400mg four times per day). Length of treatment ranged from two weeks to 12 months. Only one trial included a placebo; the others compared interventions. The most common baseline symptom was frequency of heartburn. Reflux oesophagitis status was specified in most trials. Most trials (75%) measured satisfaction using multi-item scales. Details of included surveys were reported.

The authors did not report how many reviewers performed the study selection.

Assessment of study quality
There was no formal assessment of study quality.

Data extraction
Percentages of patients (in each treatment group or the overall) who were satisfied or very satisfied with their treatment were extracted. Percentages of patients with reflux symptom relief (improvement), resolution (complete absence of symptoms) and mean HRQoL scores were also extracted.

The authors did not report how many reviewers performed the data extraction.

Methods of synthesis
Results were pooled for the trials of PPIs after four weeks treatment to give weighted average percentages with 95% confidence intervals (CI). Subgroup analyses were performed to compare continuous and on-demand proton pump inhibitor therapy, different PPIs and for participants with reflux oesophagitis. Results were pooled for the trials of H2RAs. The relationship between patient satisfaction and reflux symptom relief and resolution and changes in HRQoL scores were examined. Separate meta-analyses or narrative summaries were performed for the trials and the surveys.

Results of the review
Twenty studies were identified (52,269 participants, range 65 to 11,064): 12 clinical trials (14,673 participants, range 65 to 1,902) and eight surveys (37,596 participants, range 400 to 11,064). Of the seven trials initially open-label and then randomised, two were randomised single-blind, one was randomised double-blind, three randomised and one randomised open-label. The four RCTs were all double-blind, one of which progressed to open-label. Results of surveys and clinical trials were reported in the paper; results for clinical trials are presented here.

**Patient satisfaction**: In 12 trials of proton pump inhibitor therapy 57% to 97% patients were satisfied and 56% to 100% patients were very satisfied with their therapy.

A pooled analysis after four weeks proton pump inhibitor treatment found weighted averages of 93% patients (95% CI 87% to 99%) were satisfied and 73% of patients (95% CI 62% to 83%) were very satisfied (eight trials).

Pooled analyses of satisfaction of patients for individual PPIs were 77% (95% CI 61% to 93%; three trails) for omeprazole, 84% (95% CI 72% to 95%; two studies) for lansoprazole, 95% (95% CI 92% to 98%; four studies) for esomeprazole and 79% for one study of pantoprazole; whether differences were important was unclear.

Three trials compared different PPIs. One trial found significantly more patients (5% more) were satisfied with on-demand esomeprazole versus continuous daily lansoprazole. The other trials compared continuous omeprazole, lansoprazole and pantoprazole, and daily rabeprazole versus daily esomeprazole and found no significant differences.

Three of four trials found significantly higher satisfaction for long-term (three to six months) continuous treatment than for on-demand treatment, mainly using esomeprazole. In two trials satisfaction was higher for PPIs than for other GERD medications (significance not reported). Two trials that reported satisfaction with H2RAs found that 79% of patients were satisfied and 33% to 34% were very satisfied.

**Patient satisfaction, symptom resolution and HRQoL**: Seven trials found a positive correlation between patient satisfaction and symptom improvement. The weighted average of patients satisfied with their treatment was 11% higher (95% CI 2.5% to 18.9%; five trials) than that for symptom relief and 10.6% higher (95% CI 2.2% to 19.0%; seven trials) than that for complete symptom resolution.

**Authors’ conclusions**

More than a half of the patients were satisfied with their proton pump inhibitor medication in trials. More patients were satisfied with PPIs than other medication types. An association between patient satisfaction and symptom resolution was found, which suggested that patient satisfaction was a useful end point for evaluating GERD treatment success.

**CRD commentary**

The review addressed a well-defined question in terms of study design, participants, interventions and relevant outcomes. The search was adequate but did not include unpublished studies and only included studies published in English so some relevant studies could have been missed. There was no assessment of publication bias. There was no formal assessment of study quality and very little relevant information was provided to enable the reader to assess study quality. There was a possibility of error and bias in the review processes as the authors did not report how many reviewers conducted study selection and data extraction.

Some relevant study information was provided but no details of the gender or age of patients were reported. The synthesis combined a narrative review with some meta-analyses. It was unclear whether the meta-analyses were appropriate as reporting was unclear. The authors appropriately considered the results of trials and surveys separately. Most of the trials were of PPIs so conclusions for other medication types were uncertain. The authors noted that most studies did not use validated treatment satisfaction or symptom relief questionnaires.

Two reviewers were employed by Oxford PharmaGenesis Ltd.

Potential limitations in study quality, review processes and reporting of results imply that the authors’ conclusions should be treated with caution.

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

**Practice**: The authors proposed that the patient evaluation of treatment could be particularly important in the
management of chronic disease. The authors noted that physicians tended to overestimate the benefit of proton pump inhibitor treatment in GERD.

**Research:** The authors proposed that future research should use validated questionnaires to measure patient satisfaction with GERD treatment using multi-item scales with balanced positive and negative items. Research should focus on other clinical end points (including healing of reflux oesophagitis, prevention of relapse and adverse effects in addition to changes in individual symptoms such as heartburn frequency and severity) which could contribute to improved patient care and long-term treatment success. They suggested that there was an unmet need for effective treatment in some patients that required further study.

**Funding**
Funded in full by AstraZeneca, Sweden.

**Bibliographic details**

**PubMedID**
22506259

**Original Paper URL**
http://www.pulsus.com/journals/abstract.jsp?sCurrPg=abstract& jnlKy=2& atlKy=10551& isuKy=1020& isArt=t& fromfold=

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Antacids /administration & dosage /adverse effects; Gastroesophageal Reflux /complications /drug therapy /physiopathology; Heartburn /drug therapy /etiology /physiopathology; Humans; Laryngopharyngeal Reflux /drug therapy /etiology /physiopathology; Patient Participation /statistics & numerical data; Patient Satisfaction /statistics & numerical data; Proton Pump Inhibitors /administration & dosage /adverse effects; Quality of Life; Research Design; Severity of Illness Index; Sickness Impact Profile; Time Factors; Treatment Outcome

**AccessionNumber**
12012024801

**Date bibliographic record published**
07/07/2012

**Date abstract record published**
15/11/2012

**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.