Effectiveness, safety, and cost-effectiveness of photodynamic therapy in Barrett's esophagus: a systematic review
Sanchez A, Reza M, Blasco JA, Callejo D

CRD summary
This review concluded that photodynamic therapy was effective in the ablation of dysplasia in Barrett's oesophagus, but evidence for its effectiveness compared with other endoscopic techniques or oesophagectomy was insufficient and inconclusive. In view of the poor quality and conflicting results of the included studies this conclusion appears appropriate, although other relevant studies may have been missed.

Authors' objectives
To assess the effectiveness, safety and cost-effectiveness of photodynamic therapy in the treatment of Barrett's oesophagus. This abstract includes details of the review of effectiveness and safety outcomes.

Searching
MEDLINE, EMBASE, CINAHL and Cochrane Central Register of Controlled Trials (CENTRAL) were searched in May 2008. Search terms were reported. No restrictions were applied.

Study selection
Randomised controlled trials (RCTs) that assessed photodynamic therapy for treatment of Barrett's oesophagus were eligible for inclusion. Studies had to report one of the outcomes: ablation of dysplasia, reduction of the histological grade of the lesion, recurrence, progression toward cancer, survival, adverse effects and treatment-related mortality. Studies in which photodynamic therapy was used in combination with other treatments and results were not reported separately for photodynamic therapy were not eligible for inclusion. Studies that involved an additional technique in the context of photodynamic therapy (such as the new balloon photodynamic therapy applicator) were not eligible for inclusion. Studies reported in German were not eligible for inclusion owing to the lack of translators.

The included studies used the 5-aminolevulinic acid photosensitizer or porfimer sodium, where specified. The control treatment was argon plasma coagulation in most studies. Most studies included patients with Barrett's oesophagus and high-grade dysplasia. Some studies included patients with Barrett's oesophagus and low-grade dysplasia or Barrett's oesophagus with no dysplasia. Most studies assessed ablation of dysplasia or ablation of Barrett's oesophagus as the effectiveness outcome.

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

Assessment of study quality
Study quality was assessed using Medical Literature User's Guides by the Evidence-Based Medicine Working Group.

The authors did not report how many reviewers performed the assessment.

Data extraction
It appeared that the authors extracted data on effectiveness and safety outcomes as reported in the original studies.

The authors did not state how many reviewers performed data extraction.

Methods of synthesis
Studies were grouped according to the control treatment. A narrative synthesis was presented.

Results of the review
Seven RCTs were included in the review (n=432 participants, range 21 to 208). Only one trial was double blind. Three trials did not report the randomisation procedure. Follow-up ranged from one month to five years. Most trials had small sample sizes. In the largest trial a very high proportion of patients (41% and 62% at two years in the two treatment groups) were lost to follow-up; the study authors suggested that the main reasons for losses were progression of dysplasia and need for other treatment.

Five trials compared photodynamic therapy with argon plasma coagulation. Two of four trials that assessed ablation or eradication of Barrett's oesophagus favoured argon plasma coagulation; two trials reported no difference in eradication rates and one of these trials showed no effect in either treatment group. One trial reported significantly higher rates of eradication of dysplasia in the photodynamic therapy group.

Two trials compared photodynamic therapy in combination with omeprazole versus omeprazole alone in patients with Barrett's oesophagus and high-grade dysplasia. In both trials the results favoured photodynamic therapy; in one trial fewer patients went on to develop cancer in the photodynamic therapy group.

Five trials reported adverse events. The authors stated that adverse event rates were generally high. Adverse events were generally more frequent in the photodynamic therapy group than the control group.

Cost information
Five good-quality economic assessments were included in a review of cost-effectiveness. In most studies photodynamic therapy was found to be more cost-effective or have greater cost utility than the comparator. The incremental cost-effectiveness ratio of photodynamic therapy fluctuated between US dollars $879 and $37,807 per quality adjusted life year for endoscopic monitoring and between dominance and $47,410 per quality adjusted life year for oesophagectomy.

Authors' conclusions
Photodynamic therapy was effective in the ablation of dysplasia in Barrett's oesophagus, although rates of adverse events are high. Evidence for its effectiveness compared with other endoscopic techniques or oesophagectomy was insufficient and inconclusive. Only incipient evidence existed for its effect on progression toward cancer when compared with treatment with omeprazole alone. More trials were needed before any definitive conclusions can be drawn.

CRD commentary
The review addressed a clear question. The authors searched several electronic databases to identify relevant studies. There were no language and publication restrictions, but no specific attempts were made to identify unpublished data and studies in German were excluded from the review, which increased potential for publication and language biases. The quality of the included studies was assessed and methodological limitations were tabulated and discussed. The included studies were generally of low methodological quality. The processes of study selection, data extraction and quality assessment were not described, so potential for reviewer bias and error could not be assessed. In view of the differences between studies, a narrative synthesis was appropriate.

The authors' conclusion that the effectiveness of photodynamic therapy in comparison with other techniques was inconclusive appears appropriate in view of the poor quality and conflicting results of the included studies. The lack of searching for unpublished studies and exclusion studies in German mean that other relevant studies may have been missed.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that more rigorous controlled blinded studies with larger numbers of patients and longer follow-up were needed before definitive conclusions could be drawn about the effectiveness of photodynamic therapy in the treatment of Barrett's oesophagus.
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