Systematic review: endoscopic dilatation in Crohn's disease

CRD summary
This review assessed endoscopic dilatation for strictures in Crohn's disease. The authors concluded that the treatment was safe and effective for short strictures and substantially impacted the disease process in such patients. The conclusions were based on a poorly reported review of retrospective uncontrolled evidence with a limited search. The reliability of the conclusions could not be determined.

Authors' objectives
To evaluate the association between main clinical and endoscopic variables and to assess the efficacy and safety of endoscopic dilatation in Crohn's disease.

Searching
MEDLINE was searched from January 1990 to January 2007.References of identified articles were checked. Only studies reported in English were eligible for inclusion.

Study selection
Studies of endoscopic dilatation in Crohn's disease were eligible for inclusion in the review. It appeared that studies using bougies rather than through-the-scope (TTS) balloons for dilatation were excluded from the review. No inclusion criteria were stated for study design. The primary review outcome appeared to be successful endoscopic dilatation defined as the patient being surgery free at the end of follow-up. Technical success of the dilatation was also included in the review. The assessment of safety was limited to the occurrence of major complications such as bleeding, perforation, infection or other event resulting in hospitalisation.

All included studies were retrospective case series that originated in medical or endoscopic departments rather than surgical departments. The mean length of enrolment in the studies was nine years. Mean follow up was 33 months. Patients had a mean age of 54 years and 54% were female. The mean time from diagnosis to dilatation was 13 years and the mean time from previous surgery was six years. Most strictures (66%) dilated were at the level of ileocolonic anastomosis. Strictures had a mean length of 2.7cm (range 0.5 to 20cm). Most studies included patients with active disease; three studies excluded such patients. All studies used the appearance of obstructive symptoms as an indication to perform endoscopic dilatation; most also required unresponsiveness to steroids or other medical therapy. Concomitant immunosuppressive therapy was employed in some studies. Some studies employed maximal dilatation from the outset and others employed gradually increasing balloon diameters. The number and duration of dilatations per session varied between studies. Local injections of steroids were employed in some studies.

The authors stated neither how the papers were selected for the review nor how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The percentages of patients surgery-free and those with technically successful procedures and complications were extracted. The authors stated neither how the data were extracted for the review nor how many reviewers performed the data extraction. It appeared that means were calculated for review outcomes and that individual patient data were extracted.

Methods of synthesis
Statistical synthesis that consisted of calculation of means weighted by sample size was carried out for all variables. Subgroups were compared using a $X^2$ test with Yates' correction for small numbers and t-tests. A sensitivity analysis
excluded studies with fewer than 10 patients. Meta-regression analyses were conducted to determine the impact of a large number of independent variables, which included previous surgery and length of strictures. Odds ratios with 95% confidence intervals (CIs) were calculated for each variable.

**Results of the review**

Thirteen studies (n = 347) were included in the review.

**Successful dilatation:** 203 (58%) of patients were surgery free at the end of follow up. When technical failures for procedural reasons were excluded the figure was 68%. Where failure occurred, the mean interval between dilatation and surgery was 15 months (range one month to 70 months). When studies with fewer than 10 patients were excluded the success rate was 64%.

**Complications:** Major complications occurred in 14 cases (2%); 13 of these cases were bowel perforation. In 11 of the 13 studies the complication rate was less than 5%. In the other studies it was 11% and 18%.

Meta-regression showed an association between steroid injection and efficacy, as it was performed in 40% of patients above the efficacy cut off (median of 64%) and in only 3% of those below it (p<0.0001).

Results were reported for individual patient data analysis for the nine studies (n = 167) for which this was possible. The success rate in this analysis was 67% (112 patients). The meta-regression showed that a stricture length of 4cm or less was associated with a surgery-free outcome (odds ration was 4.01, 95% CI: 1.16 to 13.8, p<0.028). No other independent variable was found to be significantly associated with successful outcome.

**Authors’ conclusions**

Endoscopic dilatation was an effective and safe treatment for short strictures caused by Crohn's disease and had a substantial impact on the natural history of the disease in these patients.

**CRD commentary**

The review question was clear, but the inclusion criteria were not clearly stated. Only one database was searched, the review was limited to English-language articles and the authors did not report searching for unpublished articles; these may have meant that some relevant studies were not included in the review. The authors did not report using methods designed to minimise bias and error in the selection of studies for the review or in the data extraction; neither did they report conducting an assessment of study validity. The authors did not fully report the methods used to perform the statistical synthesis. It was not clear that the decision to employ such a synthesis was appropriate. The authors’ conclusions appeared overstated because: all the evidence stemmed from retrospective case series; there was a limited search; and all aspects of the review methodology were reported poorly. The reliability of the conclusions is unclear.

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

**Practice:** The authors stated that it was unacceptable not to offer endoscopic dilatation to patients with Crohn's disease. Patients should be informed that nearly one-third of them will experience a long-term surgery-free period with only one dilatation.

**Research:** The authors stated that the real perforation rate associated with endoscopic dilatation should be subject to further monitoring. They also suggested that controlled studies that evaluated the efficacy and safety of more aggressive dilatations were required.

**Funding**

No external funding was received.

**Bibliographic details**

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.