How effective is current medical therapy for severe ulcerative and Crohn's colitis: an analytic review of selected trials

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Authors' objectives
To determine the efficacy of current medical therapies in the treatment of severe ulcerative colitis and Crohn's colitis.

Searching
MEDLINE was searched from 1967 to 1990 using the terms 'severe ulcerative colitis', 'severe Crohn's colitis', 'severe granulomatous colitis', 'drugs' and 'therapy'. The reference lists of relevant studies, textbooks and review articles were also examined.

Study selection
Study designs of evaluations included in the review
For severe ulcerative colitis: prospective studies with a fixed protocol of drug management, pre-determined entry criteria and well defined outcome criteria. For severe Crohn's colitis: retrospective and prospective studies with a fixed protocol of drug management, pre-determined entry criteria and well defined outcome criteria.

Specific interventions included in the review
Five treatment regimens were evaluated for severe ulcerative colitis. All included large intravenous doses of steroids (prednisolone, beclomethasone, hydrocortisone, adrenocorticotrophin), 3 included steroid enemas, 2 included antibiotics and 1 included cyclosporine A. The duration of therapy ranged from 5 to 21 days. Five treatment regimens were evaluated for severe Crohn's colitis. Four included total parenteral nutrition: this was the only treatment used in 1 regimen, whereas in the other 3 it was supplemented with other steroids. A fifth regimen included cyclosporines and steroids. The duration of therapy ranged from 18 to an average of 110 days.

Participants included in the review
People with severe ulcerative colitis (6 or more bowel movements per day, macroscopic blood in the stool, fever, tachycardia, anaemia, elevated sedimentation rate and abdominal tenderness, guarding, spasm or rebound). People with severe Crohn's colitis (severely ill patients fulfilling either the criteria described above or classified as severe on a Crohn's disease activity index).

Outcomes assessed in the review
Remission, improvement, colectomy and death were assessed.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The studies were compared using the following criteria: use of standard criteria for assessing disease severity, uniform entrance criteria and study design (prospective and retrospective). The authors do not state how the papers were assessed for validity, or how many of the authors performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.
Methods of synthesis
How were the studies combined?
The studies were combined by tabular summaries and a narrative review.

How were differences between studies investigated?
Different treatment regimens were fully described.

Results of the review
Severe ulcerative colitis: 1 controlled trial and 4 uncontrolled before-and-after studies involving 319 treatment episodes in 306 patients. Severe Crohn's colitis: 1 controlled trial and 4 uncontrolled before-and-after studies involving 68 patients.

Severe ulcerative colitis: remission was achieved by 150 of the 306 patients included in the review (49%). In individual studies, remission rates ranged from 43 to 80%. A further 41 patients (13%) were judged to have improved. 115 patients (38%) failed with medical therapy and were given colectomies.

Severe Crohn's colitis: remission was achieved by 44 of the 68 patients included in the review (65%), or by 44 of the 59 patients included in trials which reported remission as an outcome. In one study of 9 patients, remission was not reported but 7 were judged to have improved. In the other 4 individual studies, remission rates ranged from 55 to 94%. 15 patients (22%) went on to receive colectomy and 2 died.

Authors' conclusions
Even in the hands of skilful clinicians with long experience in treating severe ulcerative colitis, only approximately half [see CRD commentary] of the patients treated by an intensive programme which included large doses of steroids, went into remission. Intensive medical therapy appears to spare slightly less than two-thirds of patients early colectomy.

CRD commentary
The large reliance placed on MEDLINE in the search strategy may have meant that relevant studies were missed. We would be more confident about the elimination of bias or error from this review, if it was clear that more than one person had made or checked decisions about inclusion criteria and data extraction. Little information was provided about the individual studies. The quality of evidence available from the primary studies was limited. There is a discrepancy between the text and table 1 regarding the proportion of patients with severe ulcerative colitis in whom remission was achieved. It seems that slightly less than half of these patients achieved remission, rather than a little more than half as the authors' conclude.

Bibliographic details

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Other publications of related interest

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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.