Meta-analysis: the efficacy of rectal beclomethasone dipropionate vs. 5-aminosalicylic acid in mild to moderate distal ulcerative colitis

Manguso F, Balzano A

CRD summary
The authors concluded that treatment with rectal beclomethasone dipropionate is as effective as 5-aminosalicylic acid in symptom improvement for active left-sided UC, proctosigmoiditis and proctitis. Despite potential methodological limitations amongst the included studies, the authors’ conclusions are likely to be reliable.

Authors’ objectives
To compare the efficacy of rectal beclomethasone dipropionate (BDP) with 5-aminosalicylic acid (5-ASA) in treating mild to moderate distal ulcerative colitis (UC).

Searching
MEDLINE (1966 to March 2007), EMBASE (1980 to March 2007), SciSearch via Web of Science (1980 to March 2007) and BIOSIS Previews (1985 to March 2007) were searched for relevant studies. In addition, conference proceedings of the major worldwide gastroenterology meetings were handsearched. There were no language restrictions.

Study selection
Randomised controlled trials (RCTs) comparing BDP (3 mg) and 5-ASA (from 1 to 4 g), administered as enema or foam once daily for at least 4 weeks, were eligible for inclusion. The treatment time in the included studies ranged from 4 to 8 weeks. Studies involving patients with mild to moderate UC with proctitis, proctosigmoiditis and left-sided colitis were eligible for inclusion. The included studies were conducted in Italy and the Netherlands. Partial or complete clinical remission (response) of intestinal disease was the outcome of interest, measured by the Disease Activity Index (DAI) or by a four-part assessment of clinical activity (details were reported in the paper). Definitions of response differed across the included studies.

Two reviewers independently assessed the studies for eligibility. Any discrepancies were resolved by discussion.

Assessment of study quality
Two reviewers independently assessed the quality of the studies, based on allocation concealment, blinding, use of intention-to-treat (ITT) analysis and adequacy of follow-up.

Data extraction
Data were extracted on the proportion of patients reporting improvement or resolution of symptoms following either intervention, in order to calculate odds ratios (ORs) along with 95% confidence intervals (CIs). Per-protocol and ITT data were extracted.

Two reviewers independently extracted the data from the included studies.

Methods of synthesis
The ORs were weighted and pooled in a meta-analysis using the Mantel-Haenszel fixed-effect method. Heterogeneity was assessed using Cochran’s Q statistic. The results were presented by ITT and per-protocol analysis.

Results of the review
Four RCTs (n=428) were included in the review. The authors reported that allocation concealment was adequate in 3 studies and double-blinding was used in 3 studies.

The analysis included 209 patients treated with 5-ASA (1 to 4 g once daily) and 219 patients treated with BDP (3 mg...
once daily). Treatment with 5-ASA resulted in induced improvement or remission of UC in 146 patients (69.9%) compared with 143 patients (65.3%) receiving BDP. The pooled OR was 1.23 (95% CI: 0.82, 1.85) when using ITT analysis and 1.43 (95% CI: 0.86, 2.39) when using per-protocol analysis.

There was no statistically significant heterogeneity between the studies.

Cost information
Comparative costs for rectal BDP (range: 1.3 to 2.8 euros per day) and rectal 5-ASA (range: 3.8 to 5.7 euros per day) were reported.

Authors' conclusions
Treatment with rectal BDP is as effective as rectal 5-ASA in symptom improvement for patients with active left-sided UC, proctosigmoiditis and proctitis.

CRD commentary
The review question was clear and was supported by explicit inclusion criteria. The search strategy appears appropriate to the topic area and included appropriate attempts to avoid publication and language biases. A validity assessment was carried out and the results were used in the discussion of review findings. All parts of the review process were conducted with transparency, thus reducing the potential for error and bias. Adequate details of the primary studies were given and the method of synthesis was appropriate given the absence of statistical heterogeneity. The authors acknowledged the limitations imposed by the small sample size and lack of clarity with regard to the methodological quality of some studies. However, their conclusions reflect the evidence presented and are likely to be reliable.

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

Research: The authors stated that further randomised controlled double-blind trials are needed to evaluate the role of rectal BDP in patients with mild to moderate UC limited to below the splenic flexure.

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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.