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[Intervention Review]

Methotrexate for induction of remission in ulcerative colitis

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ABSTRACT

Background

Ulcerative colitis is a chronic inflammatory bowel disease. Corticosteroids and 5-aminosalicylates are the most commonly used therapies. However, many patients require immunosuppressive therapy when their disease becomes steroid-refractory or dependent. Methotrexate is a medication that is effective for treating a variety of inflammatory diseases, including Crohn's disease. This review was performed to determine the effectiveness of methotrexate at inducing remission in patients with ulcerative colitis.

Objectives

To review randomized trials examining the efficacy of methotrexate for remission induction in patients with ulcerative colitis.

Search methods

MEDLINE (PUBMED), EMBASE, The Cochrane Central Register of Controlled Trials, the Cochrane IBD/FBD group specialized trials register, review papers on ulcerative colitis, and references from identified papers were searched in an effort to identify all randomized trials studying methotrexate use in patients with ulcerative colitis. Abstracts from major gastroenterological meetings were searched to identify research published in abstract form only.

Selection criteria

Randomized controlled trials comparing methotrexate with placebo or an active comparator in patients with active ulcerative colitis were considered for inclusion.

Data collection and analysis

Data were extracted independently by each author, analyzed on an intention-to-treat basis, and treated dichotomously. Methotrexate was compared to placebo in one trial. The odds ratio and 95% confidence interval were calculated and P-values were derived using the chi-square test.

Main results

Only 1 trial fulfilled the inclusion criteria. This study randomized 30 patients to methotrexate 12.5 mg orally weekly and 37 patients to placebo for 9 months. During the study period, 14/30 patients (47%) assigned to methotrexate, and 18/37 patients (49%) assigned to placebo achieved remission and complete withdrawal from steroids (OR 0.92, 95% CI 0.35-2.42; P = 0.87). The mean time to remission was 4.1 months in the methotrexate group and 3.4 months in the placebo group.

Authors' conclusions

A single trial of methotrexate 12.5 mg orally weekly showed no benefit over placebo in remission induction in patients with active ulcerative colitis. There is no evidence on which to base recommendations for treating ulcerative colitis patients with methotrexate. However, the possibility of a type 2 error exists, and a higher dose of methotrexate may be effective. A new trial in which adequate numbers of patients are randomized to placebo or a higher dose of methotrexate should be considered.

PLAIN LANGUAGE SUMMARY**Methotrexate for treatment of chronic active ulcerative colitis**

Low dose oral methotrexate (12.5 mg/week) was not shown to be effective for inducing remission in chronic active ulcerative colitis. A trial in which larger numbers of patients receive a higher dose of methotrexate should be considered. A new study could also determine if methotrexate is effective for maintaining remission in non-active ulcerative colitis.