

The results of the patient global assessment after 12 weeks are presented in Figure 8.

Efficacy comparison in rheumatoid arthritis: patient global assessment (All patients stabilized with diclofenac 30 days prior to the start of study.)

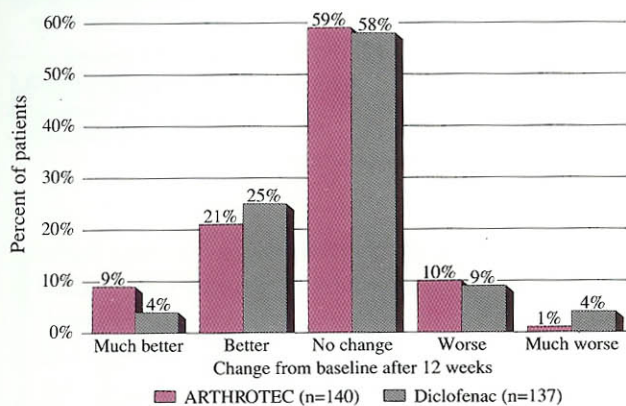


Figure 8. Patient global assessment. Rheumatoid arthritic patients.^{106,111}

The entry criteria of the second study differed somewhat from that of the first.^{4,107} For this study, the arthritis history could have been less than 6 months and patients with inactive disease were eligible. Chronic analgesic and NSAID use during the 30 days prior to enrollment was allowed. Stabilization of arthritis with diclofenac prior to study entry was not required and the functional capacity classification was not limited. A pretreatment endoscopy was performed and patients with significant upper GI mucosal damage (ie, >10 erosions in the stomach; >10 erosions in duodenum; esophageal, gastric, pyloric channel or duodenal ulcer) were excluded from participation.

The primary arthritis assessments included only physician and patient global assessments of the arthritic condition.^{108,109} Secondary assessments were of duration of morning stiffness,¹⁰⁸ ESR, and functional capacity classification.¹¹⁰ The other procedures and observations performed for this trial were the same as those described for the first study; however, this study also included pre- and posttreatment endoscopies.

Fifty-nine investigators in 13 different countries participated in the trial. Of these, 43 enrolled at least one patient. Three hundred thirty-nine (339) patients were enrolled and randomized, with 164 patients receiving diclofenac/misoprostol and 175 receiving diclofenac. These patients constituted the intent-to-treat cohort. The proportion of patients on b.i.d. and t.i.d. regimens was similar. Dosing regimens were changed during the study from b.i.d. to t.i.d. and vice versa at the physician's discretion. The treatment groups were similar for age, gender, and primary assessments of arthritis.

Disease status remained essentially unchanged throughout the study regardless of the treatment. When changes did occur, the proportions of patients who improved and worsened in each group were similar. There were no statistically significant differences between the treatments for any of the parameters compared.

Two hundred eighty-nine (289) patients completed the study with all arthritis assessments. The patient global assessment from this study is presented in Figure 9.

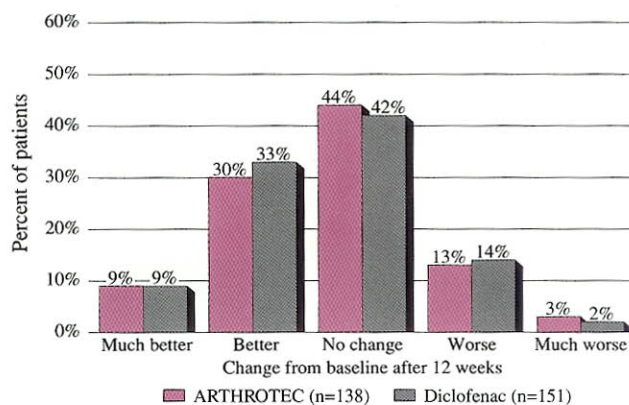


Figure 9. Patient global assessment. Rheumatoid arthritic patients.^{107,111}

In addition to primary and secondary arthritis assessments, endoscopies were performed to assess the GI mucosa. Only patients who had a normal mucosa, petechiae, or ≤ 10 erosions, were admitted to the trial. All patients completing the trial underwent a final endoscopy at the end of the study.