

[From Canadian Medical Association Journal, vol. 6, June 3, 1967, pp. 1454-1459]

EVALUATION OF INDOMETHACIN BY A CONTROLLED, CROSS-OVER TECHNIQUE IN 30 PATIENTS WITH ANKYLOSING SPONDYLITIS*

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A clinical evaluation of indomethacin employing a controlled, cross-over technique with an inert placebo was undertaken in 30 patients with ankylosing spondylitis. Patients were studied for the frequency and dose relationship of side effects and for the subjective response of morning stiffness, chronic spinal pain, acute exacerbations of pain and peripheral arthralgia. Objective evaluation assessed measured change in movements of the cervical and lumbar spines, in chest expansion and in the range of movement of involved peripheral joints.

Evaluation of the results indicated that a significant number of patients experienced side effects in the form of headache and dizziness while receiving indomethacin in doses above 150 mg. per day. Many other side effects reported by the patients were not found to occur at a statistically significant level. The significance of pulmonary infections encountered in three patients was reviewed. Relief of chronic spinal pain and peripheral arthralgia occurred in 14 and 16 patients, respectively ($p < 0.05$). Relief of morning stiffness and acute exacerbation of pain, and increase in the range of movement of any of the segments of the spine or the involved peripheral joints were not significant ($p > 0.05$). Based on the results of this study, it is suggested that the role of indomethacin in the management of ankylosing spondylitis be re-evaluated and that the daily therapeutic dose of this drug which has been heretofore recommended be decreased.

Indomethacin is a non-steroid anti-inflammatory drug which has been reported to be of therapeutic value in a variety of rheumatic diseases.¹⁻⁴ Among the latter, ankylosing spondylitis has been reported to respond particularly well.⁵⁻⁷ Because a large group of patients with ankylosing spondylitis previously studied⁸ was available at Queen Mary Veterans' Hospital, a detailed controlled, crossover trial with indomethacin and a placebo was conducted on some of these patients to assess further the therapeutic efficacy of this agent.

MATERIALS AND METHODS

All patients in this study conformed to the criteria proposed by Kellgren⁹ for the diagnosis of ankylosing spondylitis. Forty-eight patients were chosen at random as possible candidates; all of the latter were specifically advised of the side effects which were known to occur with indomethacin. Table I illustrates the eventual composition of the series. Only those patients who had clearly defined and persistent symptomatology were started on therapy. All patients were continued on their previous forms of medication, and these are indicated in Table II.

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Presented at Second Laurentian Rheumatology Conference, International Symposium on Non-steroid Anti-inflammatory Compounds, Saint Marguerite, P.Q., Canada, October 20-22, 1966.

NOTE.—Numbered footnotes at end of article, p. 3412.