Diclophenac Sodium in Rheumatoid Arthritis and Osteo-arthritis

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SUMMARY

In a double-blind study the efficacy and tolerability of diclophenac sodium (GP 45'840, Voltaren), a non-pyrazole compound, were compared with indomethacin and ibuprofen in patients with rheumatoid arthritis and osteo-arthritis.

No statistically significant differences could be detected during the first week between the 3 preparations tested, apart from the patients' feeling of well-being while on indomethacin. All 3 trial preparations were effective during the first week, apart from the changes in joint circumference which appeared to be of no value, possibly because of the short duration of the trial.

Minor side-effects were reported in 5 of the 32 patients who received diclophenac sodium. In no patient was it necessary to discontinue treatment. Gastro-intestinal side-effects, due to this preparation, occurred in 2 patients—1 complained of nausea and 1 had abdominal distension.

Two patients discontinued the test, 1 while on ibuprofen, but probably not for drug-related reasons, and 1 while receiving indomethacin.

S. Afr. Med. J., **48**, 213 (1974).

The efficacy and tolerability of diclophenac sodium (GP 45'840, Voltaren), a non-pyrazole compound with known anti-inflammatory and analgesic properties, were compared with indomethacin and ibuprofen in patients suffering from rheumatoid arthritis and osteo-arthritis. The comparison was made among patients in a short-term double-blind trial. Two consecutive treatment periods of 7 days were included in the trial in an attempt to minimise spontaneous changes in the patients' disease activity.

SELECTION OF PATIENTS

Group 1

This group comprised patients with 'definite' rheumatoid arthritis, including those with synovitis of the interphalangeal finger joints and of the hands, who could safely be taken off all current therapy for one week before the trial period.

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Date received: 21 August 1973.

Group 2

This group comprised patients with osteo-arthrosis of the knee (minimal radiological criteria of Kellgren and Lawrence[1]). Both anterior and medial compartment osteo-arthrosis were included without distinction. Only the worst knee was assessed in bilateral cases.

Exclusions

Patients excluded from the trial were those who were under 16 years of age, those who were pregnant, those with a previous or past history of peptic ulceration, a history of drug allergy, or patients treated with corticosteroids during the past 6 months.

CONDUCT OF TRIAL

Objective and subjective factors were measured to assess the analgesic and antirheumatic activity of 3 trial medications. Assessments were made before treatment (after a 1-week wash-out period) and subsequently on days 7 and 14. Measurements were, whenever possible, carried out at the same time of the day in an attempt to minimise diurnal variation. Tolerability and side-effects were evaluated by unsolicited subjective statement.

Each patient received active medication for 14 days. The sequence of administration, viz. GP 45'840 for the first 7 days, comparative medication for the second 7 days or vice versa, followed a predetermined randomisation list balanced in the forward and reverse direction. All medication was given in identical form and administered 4 times a day with meals. The dosage regimen is shown in Table I.

Group 1—Rheumatoid Arthritis

Objective measurements: Articular index or joint tenderness was recorded according to the method of Ritchie *et al.*[2] and graded accordingly. Tenderness was elicited by firm pressure over the joint margins except for the cervical spine, hips, talocalcaneal and midtarsal joints which were tested by response to passive movements.

Grip strength was measured for each hand with a sphygmomanometer cuff inflated to 30 mmHg. A single sustained squeeze was performed and the sum of both hands recorded. The proximal interphalangeal joint circumference of all 10 digits was measured in millimetres by means of the Geigy apparatus and the sum recorded.[3]

Subjective measurements: Visual analogue scales[4] were used to assess early-morning stiffness, pain, ability to walk and general feeling of well-being. Preference statements were made by both investigator and patients as to which trial medication they preferred.

Group 2—Osteo-arthrosis

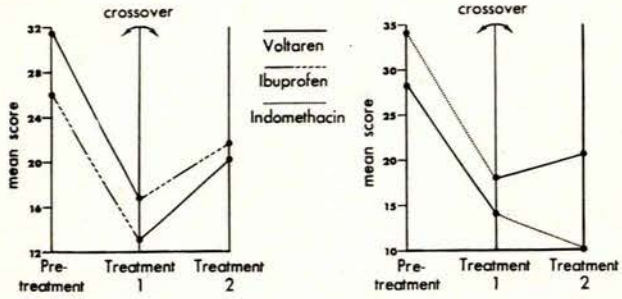
The worst knee was selected for the measurements.

Objective measurements: Knee circumference was measured across the midpoint of the patella. Quadriceps

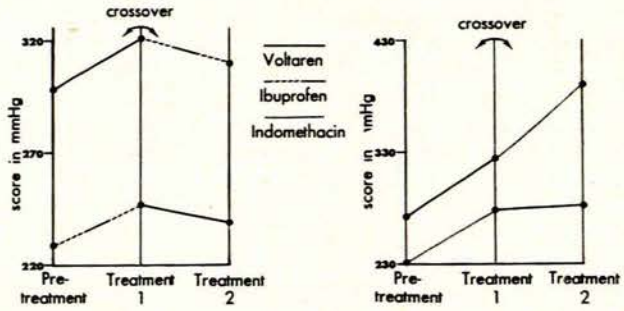
TABLE I. DAILY DOSAGE SCHEDULE

	Breakfast	Lunch	Dinner	Evening snack	Total
GP 45'840 (mg)	50	25	25	50	150
Ibuprofen (mg)	150	150	150	150	600
Indomethacin (mg)	25	25	0	25	75

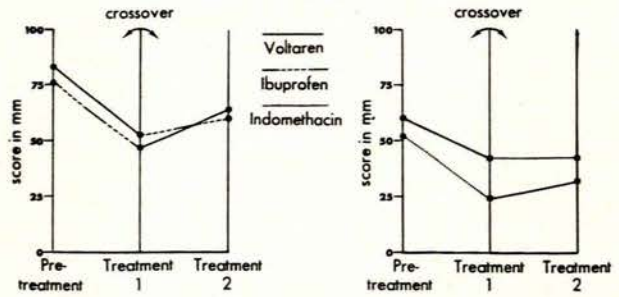
EFFECT OF G.P.45'840 (VOLTAREN), INDOMETHACIN AND IBUPROFEN ON THE ARTICULAR INDEX IN RHEUMATOID ARTHRITIS



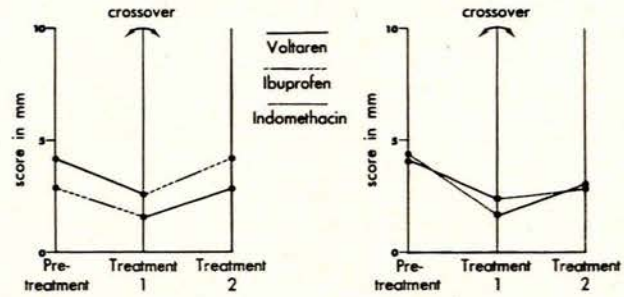
EFFECT OF G.P.45'840 (VOLTAREN), INDOMETHACIN AND IBUPROFEN ON THE GRIP STRENGTH IN RHEUMATOID ARTHRITIS



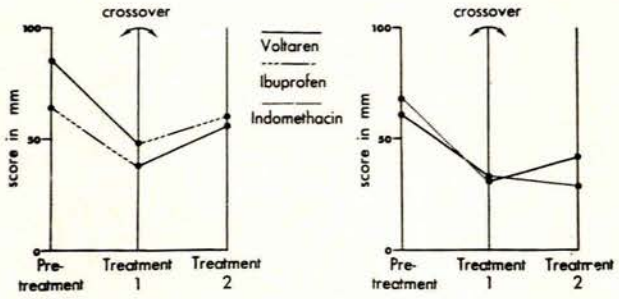
EFFECT OF G.P.45'840 (VOLTAREN), INDOMETHACIN AND IBUPROFEN ON EARLY MORNING STIFFNESS ASSESSED BY A VISUAL ANALOGUE SCALE



EFFECT OF G.P.45'840 (VOLTAREN), INDOMETHACIN AND IBUPROFEN ON PATIENTS ABILITY TO WALK AS ASSESSED BY A VISUAL ANALOGUE SCALE



EFFECT OF G.P.45'840 (VOLTAREN), INDOMETHACIN AND IBUPROFEN ON THE PATIENTS FEELING OF WELLBEING AS ASSESSED BY A VISUAL ANALOGUE SCALE



EFFECT OF G.P.45'840 (VOLTAREN), INDOMETHACIN AND IBUPROFEN ON PAIN AS ASSESSED BY A VISUAL ANALOGUE SCALE

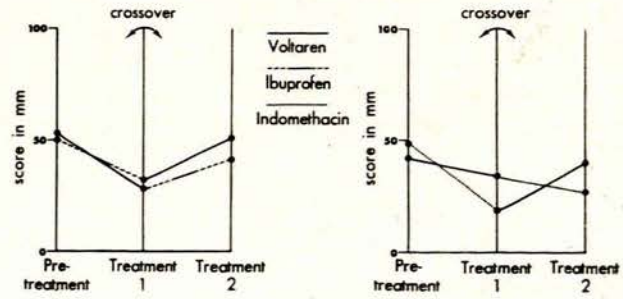


Fig. 1. See text.