THERAPY

The prescribed dosage of drug or corresponding placebo was one 200 mg. tablet four times daily. Assignment of drug or placebo by random numbers was performed at the Coordinating Center at New York University. Approximately equal numbers of drug- and placebo-treated patients were studied at each clinical center. During the trial, systemic steroids, gold and phenylbutazone or related drugs were not permitted, nor were antimalarials. Aspirin was permitted or prescribed at the discretion of the individual observers.

METHODS OF EVALUATION

Two initial examinations were made, one week apart, and on the second visit therapy was started. Thereafter the patients were examined six times at 28 day intervals (maximum permissible deviation, ±7 days). All observations on any one patient were made by the same observer. The following methods of assessment were used.

1. *American Rheumatism Association functional classifical,*[5] *with reference* to the patient's *usual* occupation (recorded on each visit).

   Class I—able to carry on all usual activities without handicap.

   Class II—able to carry on all usual activities despite handicap of discomfort or limited mobility of one or more joints.

   Class III—able to perform few or none of the usual activities or self-care.

   Class IV—largely or wholly incapacitated; bedridden or confined to wheelchair, with little or no ability for self-care.

2. *Duration of morning stiffness*—estimated for an "average" or "typical" day (recorded on each visit).

3. *Number of clinically active joints*—determined by tenderness on pressure and/or pain on passive movement and/or swelling other than bony proliferation (recorded at beginning of trial again after 3 months and after 6 months).

4. *Grip strength*—determined by folded blood pressure cuff attached to mercury sphygmomanometer, with patient's arm unsupported. Read height of column maintained (not initial spurt) by squeezing. Record mean of three readings on each hand (recorded on each visit).

5. *Walking time*—the time, recorded by stop watch, required to walk 50 feet as fast as possible (without running) from a standing start (recorded at beginning of trial, again after 3 months and after 6 months).

6. *Erythrocyte sedimentation rate*—Westergren method, one hour reading (obtained at beginning of trial, again after 3 months and after 6 months).

7. *X-ray films*—postero-anterior, both hands (obtained at beginning and end of trial).

8. *Observer's overall assessment*—the observer's opinion at end of trial regarding the change in the patient's arthritis since the beginning of the trial, recorded as "better," "about the same" or "worse."

9. *Patient's impression*—recorded at end of trial in the same terms as the observer's assessment.

Undesirable signs and symptoms during the preceding four weeks were reported at each visit.

The trial extended from December 1960 through September 1961. It involved 121 eligible patients from 10 clinics (7 to 20 per clinic), including 63 on placebo and 58 on the drug.

PATIENTS' CHARACTERISTICS AT BEGINNING OF TRIAL

Table I shows the principal characteristics recorded. The distribution by A.R.A. functional classes was: Class I–11; II–68; III–38; IV–4. Rheumatoid factor tests were reported as follows: positive—76; negative—18; doubtful—1; not investigated recently—26. In Table I the range of individual variation represents approximately the middle 90 per cent of the frequency distribution. In none of the characteristics was there any important difference between the placebo and drug-treated patients.

[5] Steinbrocker, O., Traeger, C. H., and Batterman, R. C., *J.A.M.A.*, 140:659, 1949.