TABLE I.—*Composition of study*

	Patients
Originally chosen for study	48
Started on medication	[1] 38
Lost to study:	
Failed to cooperate	5
Developed side effects	3
Completed study	30

[1] 10 omitted—inability to cooperate or lack of consistent, well-defined symptoms.

TABLE II.—DISTRIBUTION OF TYPES OF MEDICATION EMPLOYED (OTHER THAN INDOMETHACIN) IN 30 PATIENTS WITH ANKYLOSING SPONDYLITIS

Type of medication	Daily dosage range (mg.)	Number of patients [1]
A.S.A.[2]	≤1,200	12
	>1,200	9
Phenylbutazone	≤400	10
	>400	0
Steroids [3]	≤5	3
	>5	0
None		5

[1] Total exceeds 30, since some patients employed more than 1 type of medication.
[2] A.S.A.=acetylsalicylic acid.
[3] Steroids expressed in equivalents of prednisone.

The range of the duration of illness in these patients was from 13 to 26 years, with a mean of 20.1 years. Capsules of indomethacin (25 mg.) and the placebo for oral use, and rectal suppositories of indomethacin (100 mg.) and the placebo were provided in identical forms. One suppository of the appropriate form was used at bedtime during the first six days of the first period of assessment. This procedure was not repeated during the second period of assessment, since it was felt that the patients would have become aware that substitution or "cross-over" had taken place. The dosage schedule for capsule therapy was 25 mg. twice a day for two days, then 25 mg. four times a day for two days, then 50 mg. three times a day for two days and then 50 mg. four times a day. Although indomethacin and placebo were assigned in a random manner, patients were advised to modify the daily dose, depending upon the occurrence and severity of the side effects experienced.

Reassessment was carried out by the same physician at three, six, nine and 12 weeks after the start of therapy. Cross-over to either indomethacin or placebo was carried out at the end of six weeks, but the assessing physician was not aware of which substance the patient had received. All medication was dispensed in the clinic by one physician who also assessed the frequency and severity of side effects, modification of the dosage schedule was recommended to the patients by this physician when it seemed appropriate. All medication which had not been consumed during each three-week period of assessment was returned by the patients to this physician, who then provided a further supply of a known amount of the appropriate medication.

Assessment of the therapeutic response was based upon both subjective and objective evaluation of the patients. The subjective evaluation was based on patients' opinions, which were graded as to whether the following showed "no change", were "worse" or "improved"; (a) duration and severity of morning stiffness, (b) severity of chronic pain in some or all segments of the vertebral column, (c) frequency and severity of acute exacerbations of pain, and (d) frequency and severity of peripheral arthralgia. Objective response was assessed by the following measurements: (1) movement in the cervical and lumber spines as shown by the range of forward flexion and lateral flexion, extension and rotation, (2) maximal chest expansion, (3) degree of tenderness on "punch" palpation of the sacroiliac joints and (4) range of movement of the involved peripheral joints. The following criteria were employed to designate objective improvement: increase of at least 15° in each of two of the four basic movements in the cervical and lumbar spines, respectively; a sustained increase of at least one-half inch in chest expansion, improvement in the range of movement of two or more peripheral joints, or of at least 25% in a single peripheral joint.

Laboratory tests were done on each patient at each clinic visit in order to assess