

TABLE I.—PATIENTS' CHARACTERISTICS AT BEGINNING OF TRIAL
[41 males; 80 females]

	Median	90 percent Range
Age (years).....	53	31 to 72.
Duration of disease (years).....	6	1½ to 21.
Duration of morning stiffness (hours).....	2	¼ to 7.
Number of clin. active joints ¹	23	5 to 54.
Grip strength (mm. Hg): ²		
Males.....	95	53 to 260.
Females.....	96	44 to 237.
50-ft. walk (second).....	14	9 to 34.
FSR (mm. in 1 hour).....	40	10 to 86.

¹ Total possible joints (excluding hips): 66.² 2 males and 2 females had maximum registrable strength, 260 mm. Hg.

RESULTS

The data from 8 of the 121 patients presented problems in the analysis; e.g., one patient had received phenylbutazone from a private physician during the trial, one had fractured her hip and one had disappeared entirely. After the analysis of the data from the remaining 113 patients, the 8 problem cases were incorporated in such a way as to avoid bias in favor of the drug. The effect on the main results was negligible. In some instances, however, specific figures were not available for the problem cases; therefore the results given below are from the 113 cases, 60 on placebo and 53 on the drug. In certain analyses some cases had to be excluded; e.g., 11 in the walking test because of inability to walk or absence of lower limb lesions, and 11 in the E.S.R. records because of unreliable laboratory work at one clinic. None of the omissions are due to defective reporting by observers. All comparisons cover the whole six months of the trial.

Note: To avoid the statistical term "significant," with its suggestion of "importance," drug-placebo differences are stated to be "adequately accounted for by individual variation" if they would occur in more than 5 per cent of random assignments (such as were used in this trial) when there was no difference at all between treatments. On the other hand, a difference is interpreted as being "associated with the drug" if the frequency of occurrence in purely random assignments would be less than 5 per cent—2 or 3 per cent at most.

Total group comparisons by individual indexes

In Table II all the differences appear to favor the drug, but all could be readily accounted for by individual variation. Moreover, the two groups differ very little in the average (median) amount of change, and the individual variation is high in both groups.

TABLE II.—TOTAL GROUP COMPARISONS BY 5 INDEXES

Index	Placebo (60 patients)				Drug (53 patients)			
	Num- ber	Improved (percent)	Median change	90 percent range	Num- ber	Improved (percent)	Median change	90 percent range
Duration of morning stiffness.....	56	54	-¼ hour..	-3 to +4½..	53	66	-¾ hour..	-4½ to +1½
Number of clin. active joints.....	60	62	-3 joints..	-19 to +16..	53	70	-7 joints..	-32 to +6.
Grip strength.....	56	70	+12 mm....	-47 to +55..	51	86	+29 mm....	-17 to +123.
50-foot walk.....	54	46	0 seconds..	-6 to +14..	48	50	0 seconds..	-10 to +8.
ESR.....	49	45	+1 mm....	-34 to +34..	42	64	-7 mm....	-37 to +55.

Subdivision by initial severity

In four indexes (morning stiffness, number of clinically active joints, walking time and E.S.R.) a much more clear-cut drug-placebo difference was found when the data from patients who were more severely affected at the beginning of the trial (a quarter to a third of the total patients) were examined separately (Table III). In the first two of these indexes the differences were clearly associated with the drug. In grip strength, the patients who were *stronger* initially showed the greater drug-placebo difference.