

Observations

Subjects were seen every 2 weeks during each 60-day treatment period, and the blood pressure, pulse, weight and subjective reactions to the drug were all noted.

Results

Each and every case report has been studied and the results are as follows: 17 patients lost more weight with the test drug than they did with placebo; 10 patients lost as much weight with the placebo as they did with the drug; 9 lost more $\bar{c}$ placebo than with test drug. 9 failed to complete the study.

Comment and evaluation.—This study can be considered well-controlled in that the dose of fenfluramine that was used was constant, and every patient was put on an 800 calorie diet. However, 19 patients lost the same amount of weight or more with placebo than with drug (19 vs. 17). Side effects reported were moderate diarrhea in 5 patients; overtranquilization varying from constant sleeping to lethargy in 4 patients; total impotence in 2 patients; mild pruritus in 2 patients. We note that there were no changes in the blood pressure or pulse, and no mention of any sleep disturbances during the night.

Laboratory findings

There were no abnormalities noted in the blood count, urinalysis, BUN, FBS, and SGCT determinations.

Conclusion: Not substantial evidence for anorexic claim.

Study No. 2050-B:

Investigator: Martin S. Roginsky, M.D., Meadowbrook Hospital, East Meadow, N.Y.

Study design

One hundred and twenty subject divided into 4 groups of 30 each in which fenfluramine in a dose of 20 mgs, 30 mgs, and 40 mgs, and the placebo were treated for 12 weeks; there were 19 diabetics and 12 hypertensives in the study.

Dosage schedule

Group 1 took 20 mgs of fenfluramine twice a day; Group 2 took 30 mgs of fenfluramine twice a day; Group 3 took 40 mgs. of fenfluramine twice a day; and Group 4 took the placebo twice a day. All patients were put on a 1,000 calorie weight reduction diet.

The study was double-blind and randomized, and not crossed over.

Results are listed as follows:

1. The 20 mg, twice-a-day group had 11 effectives; 7 fair; 5 not effective; and 7 dropouts.
2. The 30 mg, b.i.d. group had 16 effectives; 6 fair; 3 not effective, and 4 dropouts.
3. 40 mg, b.i.d. group: 9 effectives; 5 fair; 8 not effective; and 8 dropouts.
4. Placebo group had 5 effectives; 7 fair; 11 not effective, and 7 dropouts.

Comment and evaluation.—The term "effective" is applied to all those patients who lost more than 10 pounds during the 12 weeks of treatment. It can be seen that all groups taking the drug lost more weight and more patients lost weight than those taking the placebo. It is interesting to note that the 30 mg. b.i.d. dose was shown to be a success in more patients than the 20 mg. dose or the 40 mg. dose. This schedule is considerably different than that used by Hollingsworth, and it is difficult to determine any dose response relationship here. It must be concluded, however, that this study (Dr. Roginsky) showed the drug to be more effective than a placebo when given in conjunction with the 1,000 calorie diet over a period of 12 weeks.

Study No. 2060

Investigator: Sol B. Stern, Jr., M.D., New Orleans, Louisiana.

Study Design

Sixty adult patients divided into 3 groups. Group A took fenfluramine 20 mgs. 4 times a day; Group B took Tenuate 25 mgs. 4 times a day; Group C took a placebo, 1 capsule 4 times a day. Duration of study was 2 months for all 3 groups.

All patients were put on a low calorie diet from 1,000 calories to 1,500 calories per day.