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NAREERAT THAMMASITCHAI : EVALUATION OF EFFICACY AND SAFETY OF DEXFENFLURAMINE IN OBESE WOMEN. THESIS ADVISORS : VICHAI TANPHAICHITR, M.D.,Ph.D., PREEYA LEELAHAGUL, D.Sc., RATANA PAKPEANKITVATANA, D.Sc. 146 P. ISBN 974-662-284-6

The purpose of the study is to evaluate the efficacy and safety of low dosage of dexfenfluramine treatment (15 mg/d) for 12 wks compared to regular dosage of dexfenfluramine treatment (30 mg/d) for another 12 wks in 15 obese women aged 22-63 yrs. Each woman participated in a 28-wk study. Throughout the study, subjects were advised to reduce their energy intake with dietary energy distribution of 15-20% protein, 20-30% fat, and 50-65% carbohydrate calories. During wks -4 to wk 0 dietary advice only was given and during wks 0-12 and wks 12-24 each woman was treated daily with 15 and 30 mg of dexfenfluramine, respectively. Only during the 24-wk dexfenfluramine treatment, were there significant decreases in subjects' mean body weight, body mass index, body fat mass (BFM), fat-free mass (FFM), waist circumference, and hip circumference. The rates of changes in these parameters during wks 0-12 were significantly higher than those during wks 12-24. During wks 0-12, subjects' mean net body weight loss was 3.72 kg which consisted of 2.42 kg (65.05%) loss of BFM and 1.30 kg (34.95%) loss of FFM, whereas for wks 12-24, subjects mean net body weight loss was 2.16 kg which consisted of 1.03 kg (47.68%) loss of BFM and 1.13 kg (52.31%) loss of FFM. Over the 24-wk dexfenfluramine treatment there were mean net decreases of 0.26 mmol/L of serum total cholesterol (5.07%), 0.32 mmol/L of serum LDL-C (9.58%), 0.05 mmol/L of serum triglyceride (4.03%), 0.26 mmol/L of fasting blood glucose (4.55%) and 1.13 mmol/L of 2-hr postprandial blood glucose (14.95%) but there was a mean net increase in 0.07 mmol/L of serum HDL-C (5.93%). These 15 obese women faced the problem of biochemical linoleate deficiency evidenced by their significantly lower serum 18:2 n-6 levels, serum and RBC 20:3 n-6 levels, and serum and RBC 20:4 n-6 levels together with significantly higher serum and RBC 20:3 n-9/20:4 n-6 ratios than those in healthy adults. Their higher serum and RBC 14:0 and 16:0 at wks 0, 4, 12, 16 and 24 than those in healthy adults were most likely due to impaired fatty acid oxidation. There were no clinical and laboratory adverse effects related to dexfenfluramine observed during the study.