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A Case-Control Study

! **A case-control study of metabolic therapy for fibromyalgia: long-term follow-up comparison of treated and untreated patients.** John C. Lowe, MA, DC, Alan J. Reichman, MD, Jackie Yellin, BA: *Clinical Bulletin of Myofascial Therapy*, 3(1):65-79, 1998.

Abstract. The long-term effectiveness of metabolic therapy for fibromyalgia syndrome (FMS) involving the use of exogenous thyroid hormone was evaluated. Twenty treated FMS patients were compared with 20 matched evaluated but non-treated FMS patients. Treated patients successfully underwent metabolic therapy and were released as significantly improved or recovered between 1991 and 1995. Untreated patients were evaluated during this same time frame, but were not able to undergo treatment because of insufficient or absent insurance coverage. Patients were contacted by mail; they each filled out and returned a questionnaire with forms used to evaluate FMS status. Treated patients were matched with untreated patients based on time since initial evaluation, sex, and thyroid status. In each group, 10 (50%) patients had been classified as euthyroid, 6 (30%) as primary hypothyroid, and 4 (20%) as central hypothyroid. Of treated patients, all but 1 euthyroid patient used T3, and all but 1 hypothyroid patient used T4.

Both groups were compared at baseline and follow-up using *chi* square analysis for discontinuous variables. These included age, employment, thyroid status, duration of illness, and use of medications and other forms of treatment. Groups were also compared using analysis of variance for continuous variables at baseline and follow-up. These included pain distribution by the percentage and the ACR methods, mean symptom intensity, and scores on the Fibromyalgia Impact Questionnaire (FIQ) and Zung's Self-Rating Depression Scale (Zung's). Because some patients were not available for physical examination at follow-up, mean algometer scores of tender points for the two groups were compared only for the initial evaluation. There were no significant differences at baseline between treated and non-treated groups.

At follow-up, Wilcoxon Matched Pairs Signed Rant Test showed that treated patients had decreased their use of antidepressants and NSAIDs; untreated patients had increased their use of antidepressants and anxiolytics. Comparison of baseline measures with follow-up measures for each group by *t*-tests showed that treated patients improved on all FMS measures, while untreated patients improved on none. Multivariate analysis of variance showed significant differences between the two groups on FMS measures (F=<0.0005). Univariate analysis of variance revealed that at follow-up, compared to the untreated group, the treated group significantly improved specifically in pain distribution via the ACR method (F=0.0002) and in pain distribution via the percentage method, mean symptom intensity, FIQ, and Zung's (F=<0.00005).

We conclude that at 1-to-5 year follow-up, the FMS status of euthyroid and hypothyroid patients who underwent metabolic therapy, including the use of exogenous thyroid hormone, significantly improved compared to matched untreated FMS patients. The continuation of improved FMS status for 1-to-5 years effectively rules out a placebo effect as the mechanism of improvement.