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SELENIUM SUPPLEMENTATION DOES NOT IMPROVE HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH HYPOTHYROIDISM DUE TO AUTOIMMUNE THYROIDITIS: THE CHRONIC AUTOIMMUNE THYROIDITIS QUALITY OF LIFE SELENIUM TRIAL (CATALYST)

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Background: A substantial number of patients with autoimmune thyroiditis (AIT) have impaired quality-of-life (QoL) despite biochemical euthyroidism on levothyroxine (LT4) substitution. Previous studies indicate that selenium supplementation decreases thyroid autoantibody levels. As autoimmunity *per se* may have a negative impact on QoL we hypothesized that selenium supplementation improves QoL in patients with autoimmune thyroiditis and devised the "CATALYST" trial (ID: NCT02013479).
Methods: 412 patients ≥18 years with serum thyroid peroxidase antibody (TPOAb) level ≥100 IU/mL and treated with LT4 were included in a multicentre double-blinded randomized clinical trial. The patients were randomized 1:1 to daily supplementation with either 200 µg selenium-enriched yeast or matching placebo tablets for 12 months, as add-on to the LT4 treatment. QoL, assessed by the Thyroid-related Patient-Reported Outcome questionnaire (ThyPRO-39), was measured at baseline, after 6 weeks, 3, 6 and 12 months supplementation with selenium or placebo and after 18 months (6 months off intervention). Blood samples were obtained at baseline and after 3, 12, and 18 months, and serum (s) was analysed for thyrotropin (TSH), free thyroxin (FT4), free triiodothyronine index (FT3I), TPOAb and selenium.
Results: In total, 332 patients (81%, 85% women) completed the intervention. At 12 months, s-selenium was 139.9 µg/L [95%CI: 133.2-146.4] in the selenium group vs. 84.3 µg/L [79.9-88.62] in the placebo group ($P < 0.001$). No difference in any of the 11 ThyPRO-39 scales was found between the selenium group and the placebo group at baseline or after 12 months intervention. Employing linear mixed model regression, no difference between the two groups was observed in the ThyPRO-39 composite score after 12 months intervention (28.8 [24.5-33.6] and 28.0 [24.5-33.1], respectively; $P=0.602$). Stratifying the patients according to duration of the disease (longer or shorter than three months), baseline QoL (ThyPRO-39 composite score <30 or ≥30), TPOAb level or selenium status at baseline did not change the results. TPOAb levels after 12 months of intervention were lower in the selenium group than in the placebo group (1995 IU/mL[95%CI:1512-2512] vs. 2344 IU/mL[1862-2951];$P=0.016$), but did not influence levothyroxine dosage or FT3I/FT4 ratio.
Conclusion: In hypothyroid patients on levothyroxine therapy due to autoimmune thyroiditis, supplementation with 200 ug selenium daily for 12 months did not improve QoL, levothyroxine dosage, or FT3I/FT4 ratio, compared to placebo supplementation, despite a significantly greater decrease in TPOAb level. These findings do not justify the routine use of selenium supplementation in patients with AIT-induced hypothyroidism.