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BREAKFAST WITH LIQUID LEVOTHYROXINE (LEVOTIRSOL®) A SINGLE-CENTER EXPERIENCE.

Settimio D'Andrea*¹, Antonella Berardicurti², Livia Santarelli¹, Walter Vena³

¹ Ospedale SS Annunziata, Diabetology Unit and Endocrinology Service, Sulmona, Italy

² Università degli Studi "Gabriele d'Annunzio", Department of Medicine and Ageing Sciences, Chieti, Italy

³ Humanitas Research Hospital, Endocrinology, Diabetology and Andrology Unit, Cascina Perseghetto, Italy

*dandrea.settimio@outlook.com

INTRODUCTION. Levothyroxine (LT4) tablets are the most used treatment for hypothyroidism worldwide. LT4 tablets should be taken in the morning and have a fasting state because food ingestion interferes with intestinal LT4 absorption. Some patients could be unable to adhere to this recommendation resulting in poor therapy compliance and thyrotropin (TSH) serum concentration above the upper normal limits. A previous double-blind placebo-controlled trial showed that LT4 liquid could be ingested during breakfast without a significant difference in TSH values. Recently, a new LT4 liquid (Levotirsol®, IBSA Farmaceutici S.r.l., Lodi, Italy) was released in Italy improving therapeutic options. Our study aimed to explore the possibility to recommend LT4 liquid directly at breakfast.

METHODS. We performed an observational, retrospective, and non-controlled study at the Unit of Diabetology and Endocrinology Service of Hospital "Sant'Annunziata" of Sulmona (Italy). We enrolled hypothyroid patients treated with LT4 tablets that refer poor or unsatisfied compliance to the treatment. All included participants received LT4 liquid at the same dose of LT4 tablets to ingest during breakfast. After at least 40 days, they were contacted by telephone to obtain data on TSH and fT4. All statistical analyses were performed with R statistical software (version 4.1.2, 2021, The R Foundation for Statistical Computing, Vienna, Austria).

RESULTS. We enrolled 26 hypothyroid patients in therapy with LT4 tablets that express poor compliance and/or unsatisfaction with tablets. Three patients were lost at follow-up and one patient back spontaneously to tablets treatment. Finally, we had data about 22 patients aged 54.3 (IQR= 48.6-59.3) years. All selected participants were female and were affected by primary hypothyroidism. Eighteen patients were affected by chronic autoimmune thyroiditis that leads to hypothyroidism, 4 of them underwent thyroidectomy for thyroid carcinoma and one for goiter. The duration of LT4 liquid treatment was 68.5 (IQR= 57.3-73.5) days. Ten enrolled subjects showed TSH serum levels before LT4 liquid above 5 mU/mL for poor therapy compliance, the remaining 13 subjects presents a TSH value in the normal range but referred that the tablets adherence was difficult and impaired quality of life. We reported that TSH serum levels after LT4 liquid treatment during breakfast (3.9, IQR=2.1-4.4) were significantly lower compared to TSH at the beginning (4.8, IQR= 3.9-6.9; $p=0.03$). Furthermore, freeT4 serum levels after liquid therapy were higher respect to freeT4 levels before liquid therapy (1.0, IQR= 0.8-1.2 VS 0.9, IQR=0.7-1.1; $p=0.0002$). When only patients with TSH above the range were considered for analysis, TSH serum levels decreased significantly after LT4 liquid therapy ($p=0.02$).

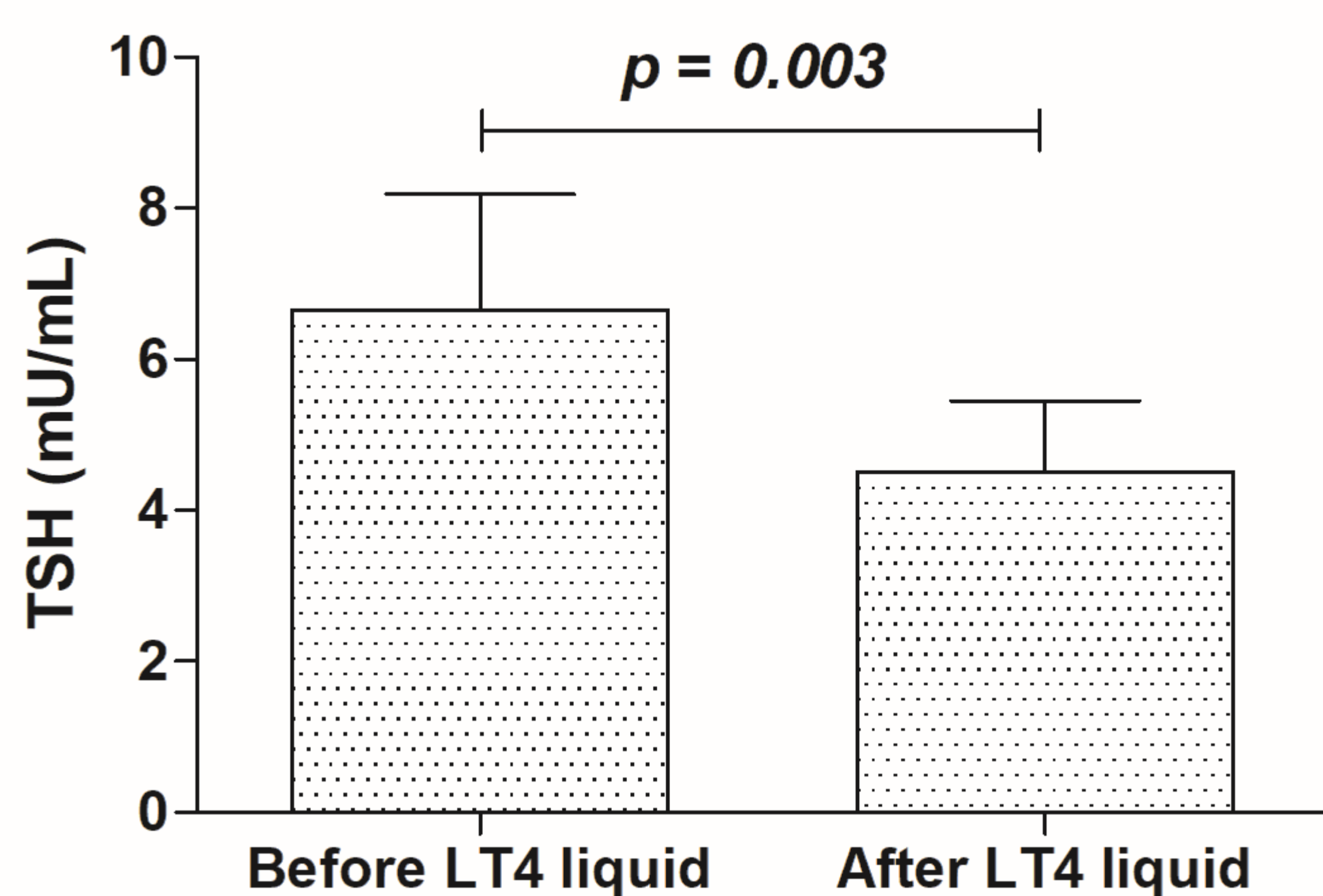


Figure 1. TSH serum levels before and after LT4 liquid

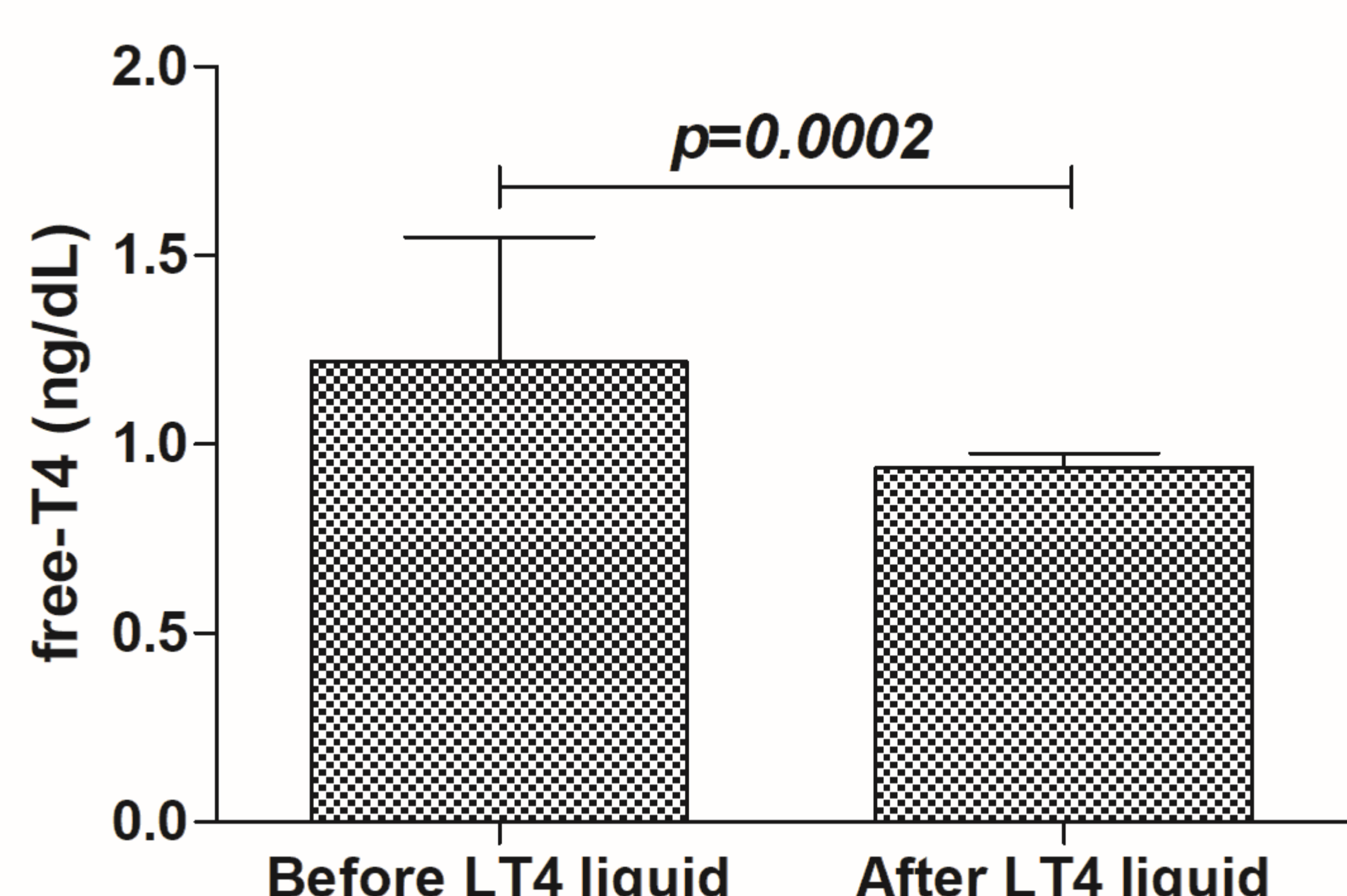


Figure 2. fT4 serum levels before and after LT4 liquid

DISCUSSION & CONCLUSIONS. We showed that LT4 liquid in hypothyroid patients with poor therapy compliance improves TSH serum levels, probably due to better treatment adherence. LT4 liquid ingested during breakfast could represent an improving therapeutic choice, especially in patients with poor therapy compliance. However, further longitudinal trials are needed to confirm these data and to explore the possibility to recommend LT4 liquid without a fasting state.