

LONG TERM COMPARISON BETWEEN LIQUID AND TABLET FORMULATIONS OF L-THYROXINE (L-T4) IN THE TREATMENT OF CONGENITAL HYPOTHYROIDISM (CH)

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The authors declare that they have no potential conflict of interest

Introduction and objectives

Few studies have been published comparing the liquid and tablet formulations of L-T4 in pediatric patients, with a short follow-up period. Both formulations seemed to produce a rapid normalization of thyroid function with a tendency of a greater TSH inhibition in children taking the L-T4 liquid drops. The aim of our study is to compare the long-term effectiveness and safety of both liquid and tablet L-T4 therapy in CH patients up to 3 years old via a multicenter study.

Methods

254 children affected with CH identified by neonatal screening were included in this study: 117 treated with liquid formulation (Group D = drops) and 137 treated with tablets (Group T = tablets). Birth data, growth parameters, TSH and FT4 values and L-T4 dose were collected at 15 days, 1-3-6-12-24-36 months. The liquid formulation contains ethanol as an excipient: to further evaluate its influence on childrens' cognitive development, we evaluated the patients' Developmental Quotient (DQ) at 1 and 3 years of age.

Results

There was no significant difference in birth weight and length, TSH and FT4 at diagnosis, and etiology of CH between groups D and T. Group D began therapy with a median dose of 11.24 mcg/kg/die (range 3.5 – 15.67) and group T with 11.16 mcg/kg/die (range 4.6 – 14.8) ($p=0.676$; $\alpha=0.006$). L-T4 dose, TSH at 1, 3, 6, 12, 24, 36 months and FT4 serum levels at every determination were no significantly different between the two groups. TSH serum levels at 15 days were statistically different ($p=0.002$; $\alpha=0.006$): however, median values were in range in both groups (group D 1.19 mcU/ml; group T 3.35 mcU/ml). (Figure 1)

The median DQ at 1 and 3 years of age was 102 (range 50 - 135) and 105 (range 90 - 133) in group D, and 109 (range 74 - 127) and 110 (range 72 - 125) in group T, without a significant difference between the two groups ($p=0.074$ at 1 year; $p=0.22$ at 3 years; $\alpha=0.05$). (Figure 2)

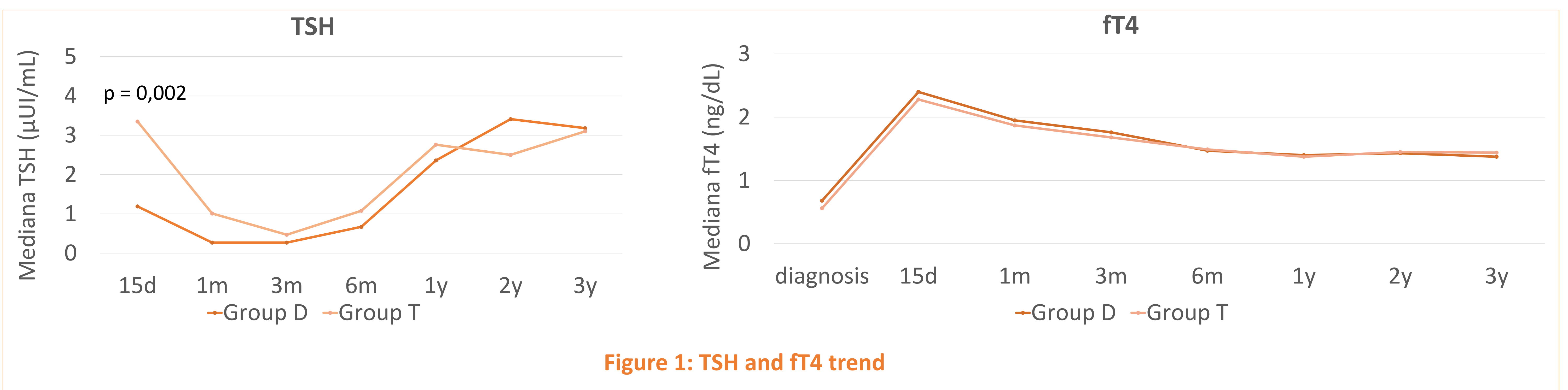


Figure 1: TSH and ft4 trend

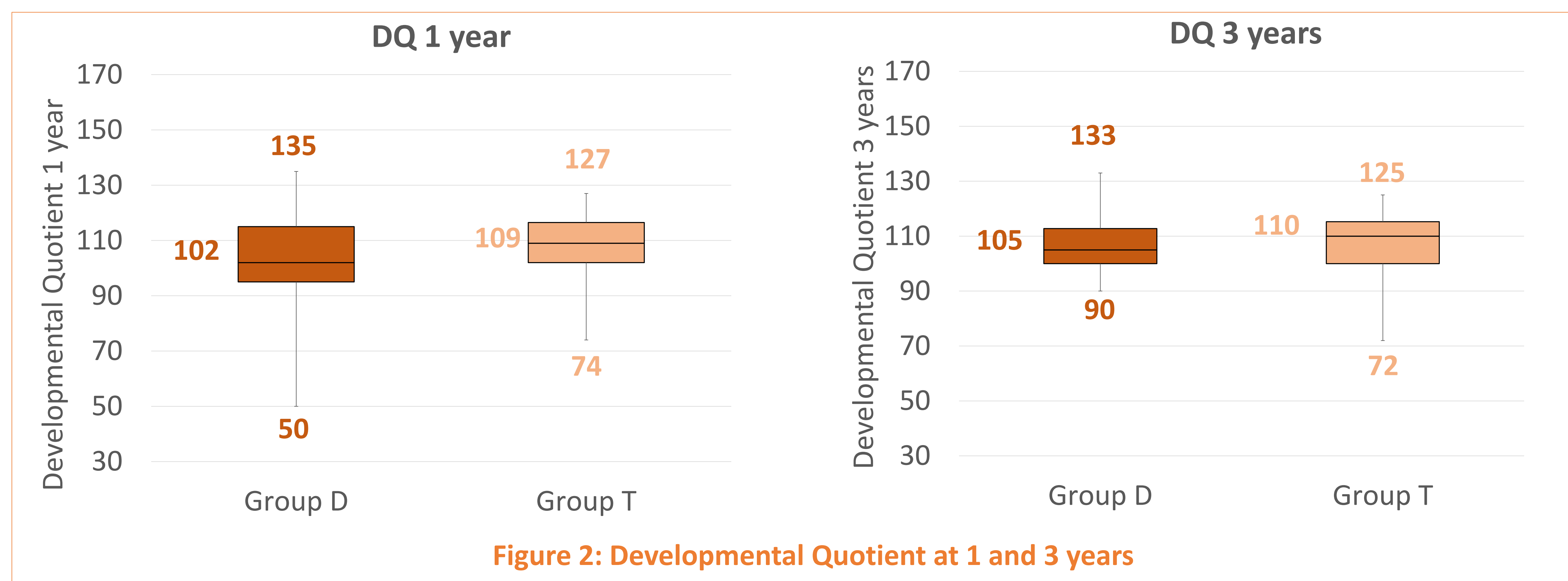


Figure 2: Developmental Quotient at 1 and 3 years

Conclusions

This data confirms that both liquid and tablet formulations are efficient at treating CH, not showing at any time TSH inhibition when using the liquid formulation.

No negative effects in cognitive development were observed in the patients treated with liquid drops.