Do different initial doses of L-T4 within the range of 10-15 mcg/kg/die influence neurodevelopment during the first two years of life in children with congenital hypothyroidism?

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Background and Objective

The initial L-T4 dose currently recommended in the treatment of congenital hypothyroidism (CH) is 10-15mcg/kg/day.
We designed a multicenter randomized trial in children with CH to evaluate whether we could identify an L-T4 dose, within the range of 10-15mcg/kg/day, which could be associated with a better neurocognitive development.

Methods

Seventy-two children with CH diagnosed by neonatal screening were enrolled in the study.
They were randomly assigned to receive an initial L-T4 dose of 10-12.5mcg/kg/day (group A) or 12.6-15 mcg/kg/day (group B).
All patients underwent clinical examination and FT4 and TSH measurement periodically during the first two years of life.
At the age of 12 and 24 months they underwent Griffiths Mental Development Scales to evaluate cognitive development.

Results

Clinical and hormonal details at study entry are reported in Table 1.

Growth during the first two years of life was comparable in the two groups of patients (Table 2).

Neurodevelopmental evaluation showed no significant differences in Global and Subscales Quotients between the two groups both at 12 and at 24 months of age (Figure 1).

Figure 1 – Global Developmental quotient and Subscales at 24 months.

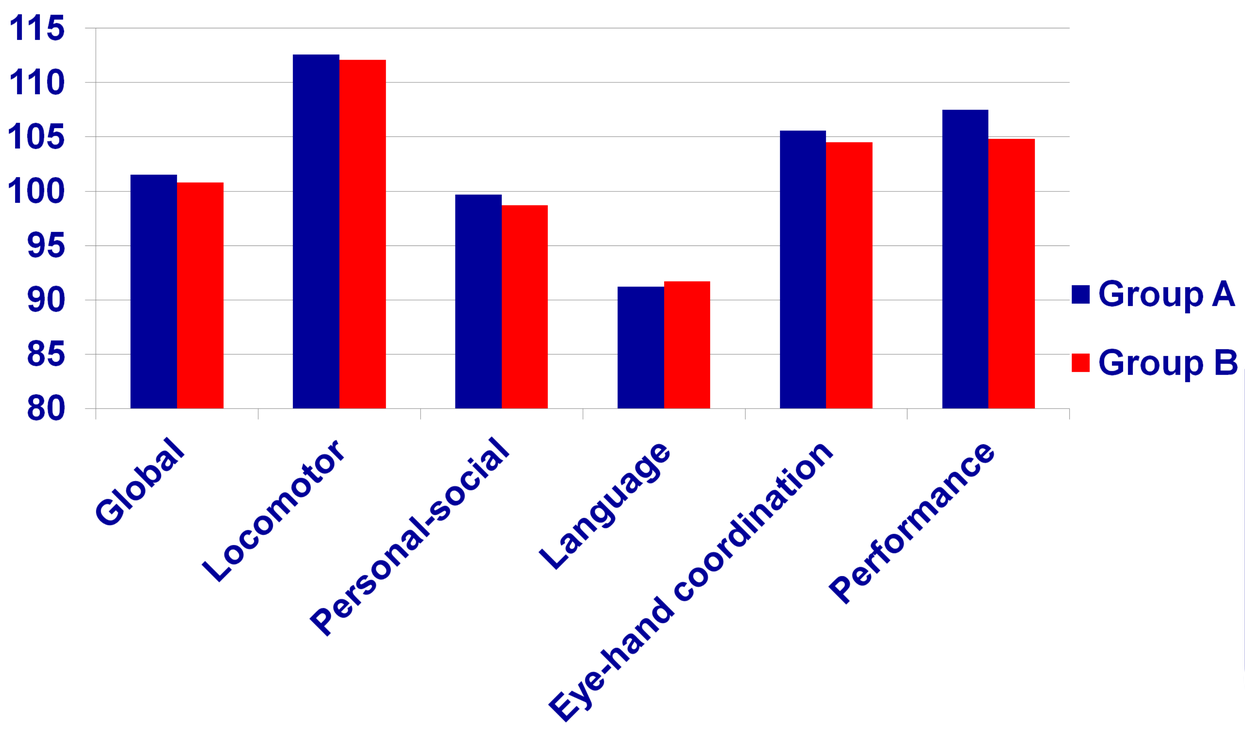

Table 1 – Features of patients at study entry.

	Group A	Group B
Gestational age (weeks)	40,0±2,1	39,4±1,4
Age (days)	13,2±5,6	13,7±6,9
TSH (mcU/ml)	332,7±280,0	296,0±235,0
FT4 (ng/dl)	0,53±0,51	0,48±0,51
Graffar	12,8±4,3	12,6±3,6
Severity (moderate/severe)	23/11	21/12
Etiology (eutopic/noneutopic thyroid)	13/21	16/18
L-T4 starting dose (mcg/kg/day)	13,5±0,9	11,6±0,6

Table 2 – Growth parameters at 12 and 24 months.

	Group A	Group B	p
12 months			
Length (SDS)	-0,05±1,03	0,20±1,20	ns
Weight (SDS)	0,06±1,41	0,34±1,08	ns
24 months			
Length (SDS)	0,18±0,94	0,54±0,98	ns
Weight SDS)	0,11±1,28	0,28±1,08	ns

Conclusions

Different initial doses of L-T4 within the range of 10-15 mcg/kg/day are not associated with differences in growth and neurodevelopment during the first two years of life in CH patients.

The authors have nothing to declare.

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