A Descriptive Study on Individually Titrated Levothyroxine in the Management of South African Hypothyroid Patients (DeuTSH)

Helena Oosthuizen MBChB, MMed(Int Med), Registered Endocrinologist, MSc (Clin Ep), Philip F Smuts BSc (Hons); Elsabé JE de Kock Dip Pharm; Jaco CJ Jürgens M.B.Ch.B (UOFS) MBL (UNISA), Hermanus S Schoeman DSc (Pret) PrScNatl, Rudy Onia MBChB (UCT)

BACKGROUND

Currently few data regarding hypothyroidism in South Africa exists, but from the international literature it is evident that a significant number of patients fail to reach target TSH levels. i,ii

OBJECTIVES

This observational study measured the efficacy of individually titrated doses of levothyroxine to achieve a euthyroid state. Target TSH was set at 0.5 - 2.0 mIU/L, initially 50 µg/day in younger patients, but adapted after the publication of new hypothyroidism guidelines. iii Secondary objectives were the evaluation of mean doses per kg bodyweight to reach euthyroidism, predictive value of initial TSH in determining therapeutic dosage, and assessment of the value of a 25 microgram formulation.

METHODS

Patients with hypothyroidism, treatment naïve or insufficiently controlled as any levothyroxine formulation, with a confirmed laboratory TSH value outside the target range, were included in the study. Investigators made an independent decision to prescribe levothyroxine (Euthyrox®) to patients, prior to inclusion for consideration in the study. Physicians were provided with a published treatment guideline and algorithm as well as education on hypothyroidism. Patient follow-up occurred every seven weeks until an outcome was reached, an outcome was defined as reaching target TSH value. A follow-up visit was scheduled every 7 weeks with ± 5 day flexibility. Patients were followed up for a maximum of 28 weeks. TSH levels, levothyroxine dose changes, compliance, concurrent medication use, weight and changes in disease symptoms were assessed at each visit.

RESULTS

290 evaluable patients were enrolled. The age distribution of participating patients can be seen in the following graph:

![Age Distribution Graph]

The majority of patients were in the age-group 40-60 years. Overall 221 (76.2%) patients reached TSH target levels of which 103 (46.4%) reached target levels by follow-up visit 1.

Table 2 shows different starting dosages for treatment naïve and pretreated patients. Unsurprisingly, higher dosages were prescribed more frequently in pre-treated patients compared to naïve patients. Mean starting dose in the naïve group was 75.8 µg/day (median of 100 µg/day). Mean starting dose in the pre-treated group was 114.8 µg/day (median of 100 µg/day).

Table 3 illustrates the numbers of patients that left the study at each visit, after an outcome was reached.

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DISCUSSION

The total control rate in the study was 76.2% (95% CI: 71.0% - 80.7%). 34.11% of patients were over-treated at the end of the study. On the other end of the spectrum, 35 (12.1%) of patients still needed to be up-titrated further to achieve control of the TSH value.

CONCLUSIONS

The value of treatment algorithms used to assist HCPs with titration of thyroid hormone dosages for treating hypothyroidism.

For all 290 patients at enrollment 16 patients withdrew from the study after the baseline visit for different reasons: lost to follow-up, missing data, withdrawal consent. 148 patients reached an outcome at follow-up visit 1. Other outcomes, target TSH or withdrawal from the study, was reached from the first follow-up visit onward, except for the final visit at week 28, at which point the study was ended, regardless of TSH value.

The mean TSH at the start of the study was 15.9 mIU/L and the median 6.6 mIU/L.

Health Care Physicians (HCPs) used the starting dose as per their usual practice, regardless of TSH value.

The mean thyroxin dosage of 1.12 µg/kg bodyweight in controlled patients was 8.2% of patients.

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The variability in dosages used in the study suggests that there is value in having several strengths of levothyroxine dosages for treating hypothyroidism.

The 25 µg thyroxin dosage was used in 44.4% of patients and the 12.5 µg dosage in 8.2% of patients.

The mean thyroxin dosage of 1.12 µg/kg body weight in controlled patients is lower than the recommended 1.6 µg/kg.

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