Effects of restricting levothyroxine dosage strength availability

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Prescribing restricted versus nonrestricted dosage strength of levothyroxine to patients requiring thyroid hormone replacement or suppression of thyrotropin (TSH). The nonrestricted use of levothyroxine consisted of tablets containing 25, 50, 75, 100, 112, 125, 150, 175, 200, and 300 micrograms, while in the restricted-use, only five dosage strengths (25, 50, 100, 125, 150 micrograms) were available.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients requiring thyroid hormone replacement or suppression of thyrotropin (TSH).

Setting
Hospital. The economic study was carried out in Kentucky, USA.

Dates to which data relate
The dates for data collected for the effectiveness analysis, resources used, and prices were not specified.

Source of effectiveness data
The evidence for final outcomes was derived from a single prospective study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
The sample size was not determined by a power calculation. Thirty-three endocrinologists prescribing levothyroxine were randomly designated to one of the restricted or nonrestricted groups: 15 to the restricted group and 18 to the nonrestricted group. The clinical outcomes were evaluated for 434 patients, but 193 (44%) were excluded from the study. There were 89 patients in the restricted group and 152 in the nonrestricted group. Based on patients’ types (requiring primary replacement, secondary or tertiary replacement, suppression) the patients in each group were divided into three subgroups.
Study design
The study was a randomised controlled trial. The duration of follow-up was not stated. The stratification of
endocrinologists was based on a retrospective 6-month computerized survey of their previous levothyroxine prescription
volume.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. The clinical outcome measures were thyroid
function tests (free and total thyroxine, total triiodothyronine, thyrotropin), number of clinic visits, and compliance
(measured by a questionnaire). The prescribing endocrinologists were shown to be comparable in clinical experience
and gender distribution, but not in age. The endocrinologists in each group were shown to be comparable in their
success rates. The patients in the groups were shown to be comparable in gender distribution, study period, heights, and
weights but not in age. The primary and secondary replacement subgroups were comparable according to their clinical
diagnoses, but the suppression subgroup displayed a different pattern of clinical diagnoses.

Effectiveness results
Thomas’s stratified test showed no significant differences in the thyroid function tests, analysed by patient group
between the restricted and nonrestricted groups (P=0.510). When the results of the thyroid function tests, analysed by
physicians, were compared by likelihood ratio analysis, no significant differences between alternative groups were
discovered (P=0.810). The restricted group had 0.25 clinic visits per month on average. The corresponding figure for
the nonrestricted group was 0.26. The results of the response of 78% of patients to the self-report questionnaire
measuring the level of compliance revealed no differences between the alternative groups.

Clinical conclusions
There were no significant differences in the therapeutic outcomes of the two formulary systems.

Measure of benefits used in the economic analysis
Since the effectiveness analysis showed no difference in effectiveness between the intervention and the comparator, the
economic analysis was based on the difference in costs only.

Direct costs
Quantities and costs were not reported separately. The inventory records of the hospital were used to estimate the
inventory and patient costs. Costs of additional laboratory tests and visits were omitted from the economic study. The
dates to which the price data referred were not specified.

Statistical analysis of costs
Student t test was utilized to compare the average costs between the two alternative groups. P-values below 0.05 were
treated as significant.

Indirect Costs
Not reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.
Estimated benefits used in the economic analysis
Not applicable.

Cost results
The average yearly cost of levothyroxine for the restricted group was $114.02 (+/- 7.25) and for the nonrestricted group was $109.31 (+/- 4.81). A two-tailed test revealed no significant difference between the alternative groups.

Synthesis of costs and benefits
No synthesis was carried out since the alternative groups were not statistically different in regard to both the therapeutic outcomes and the costs.

Authors' conclusions
Restriction of levothyroxine's dosage strength did not significantly alter therapeutic outcomes. However, the restricted formulary was associated with more complex dosing regimens, and resulted in no significant cost saving. It is not known whether such restriction would adversely affect the care of patients of nonspecialists. Prospective studies are required to verify presumed cost-containment measures before such measures are adopted for widespread application.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear.

Validity of estimate of measure of benefit
As the authors noted, the lack of any blinding methods for the physicians and patients participating in the study may have had adverse effects on the power of the study to detect differences in the benefit measures between the alternative groups.

Validity of estimate of costs
Resource quantities were not reported separately from prices. Adequate details of the method of cost estimation were given. Some important cost items were omitted.

Other issues
The issue of generalisability to other settings was addressed. As pointed out by the authors, the results of the study may not apply to other physician and patient populations (for example, patients of nonspecialists). Lack of sensitivity analysis may cast some further doubts on the generalisability of the results to other settings/countries.

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