Quality of life aspects and costs in treatment of Graves' hyperthyroidism with antithyroid drugs, surgery, or radioiodine: results from a prospective, randomized study

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
The use of alternative treatments for Graves' hyperthyroidism. The three treatment alternatives were an antithyroid drug plus thyroxine combination, subtotal thyroidectomy, and iodine-131. Those patients aged 20 to 34 years received either the antithyroid drug plus thyroxine combination (young medical group), or subtotal thyroidectomy (young surgical group). Those patients aged 35 to 55 years received either the antithyroid drug plus thyroxine combination (old medical group), subtotal thyroidectomy (old surgical group), or iodine-131 (iodine-131 group).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all patients with Graves’ hyperthyroidism that were referred to the authors’ institution over the 7-year study period. The patients were aged between 20 and 55 years. The other selection criteria were published elsewhere (see Other Publications of Related Interest nos.1-2).

Setting
The setting was a hospital. The economic analysis was carried out in the USA.

Dates to which data relate
The effectiveness, resource use, and cost data were collected over a 7-year period, the dates of which were not specified. The price year was 1995.

Source of effectiveness data
The effectiveness data were derived from a single study using patient questionnaires.

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

Study sample
One hundred and seventy-nine patients with Graves' hyperthyroidism, who were referred to the institution over the 7-year study period, were enrolled in the study. Of the patients aged 20 to 34 years, there were 28 in the young medical group and 29 in the young surgical group. Of the patients aged 35 to 55 years, there were 40 in the old medical group,
37 in the old surgical group, and 40 in the iodine-131 group. Thus, the total number of patients studied was 174; there was no explanation provided for this discrepancy in patient numbers. No power calculations were performed to determine sample size. The median time from start of symptoms to diagnosis was 5 months (interquartile range: 2 - 10). No other baseline characteristics were given.

**Study design**

This study took the form of a prospective randomised trial carried out at a single centre. Randomisation was performed by telephone to a centre that kept balanced lists for the two age groups; these were unavailable to the clinicians. The mean follow-up period was 7 years (range: 48 - 121 months). The questionnaires were completed by 89% of the patients in the young medical group, 93% of those in the young surgical group, 88% of those in the old medical group, 97% of those in the old surgical group, and 95% of those in the iodine-131 group.

**Analysis of effectiveness**

The clinical study was analysed on the basis of treatment completers only. The primary health outcomes were various measures of quality of life and the relapse rate. These reflected the health status prior to and during therapy, and its influence on the physical and psychological status and well-being, and on the social and economic interactions. These were scored (%) according to category. It was stated that the questions were "reviewed by a professional interviewer at the Swedish National Centre of Health Statistics". No other evidence of validity was given, and the domains were not comprehensively listed. "Relapse" was not defined. The authors did not report any results on the comparability of groups.

**Effectiveness results**

It was reported that there were no significant differences between the groups in terms of the following:

- fear of adverse reactions,
- satisfaction with treatment,
- problems with treatment,
- the effect of treatment on working ability and social life,
- patients' opinions on possible difficulties in managing the treatment,
- recommendation of treatment to a friend with a similar disease.

The level of significance was not given.

The relapse rate was 42% in the young medical group, 6% in the surgical groups, 34% in the old medical group, and 38% in the iodine-131 group.

The questionnaire results were only presented as bar charts for the different treatment groups. It was therefore not possible to report the percentages in each category, by treatment group.

The rates of endocrine ophthalmopathy were presented according to the ophthalmologist (O) and patient (P). These were:

- for the young medical group, 25% (O) and 44% (P);
- for the young surgical group, 8% (O) and 26% (P);
- for the old medical group, 18% (O) and 29% (P);
for the old surgical group, 24% (O) and 39% (P); and
for the iodine-131 group, 45% (O) and 61% (P).

No significant difference was found in terms of the effect of eye problems on social activities or work.

**Clinical conclusions**
The authors reported that the results showed there were no significant differences in opinion between the five treatment groups, with regard to any of the quality of life questions. Eye problems occurred significantly more frequently in the iodine-131 group.

**Measure of benefits used in the economic analysis**
The authors did not report a summary health benefit and left clinical outcomes disaggregated. Hence, a cost-consequences analysis was conducted.

**Direct costs**
It was unclear whether the authors discounted direct costs, even though the timeframe of the cost analysis was 2 years. The quantities and unit costs were reported separately for clinic visits and treatment. The direct costs were those for visits to the outpatient clinic, and additional costs for services such as operation and iodine-131 therapy. The quantity/cost boundary adopted was that of the hospital. The quantities and costs were estimated from actual data. The source of cost data was the authors' institution. The cost estimates were based on the official hospital reimbursement system. The price year was 1995.

**Statistical analysis of costs**
The costs were treated stochastically with frequency distributions and mean values given. However, any differences were not tested statistically.

**Indirect Costs**
No indirect costs were included.

**Currency**
US dollars ($). The exchange rate was $1 = 7.50 Swedish kroner.

**Sensitivity analysis**
Variations in the costs were investigated by the inclusion or exclusion of relapse costs.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs were given only as bar charts. The total costs (excluding relapses) were approximately $1,100 in the young medical group, $2,800 in the young surgical group, $1,100 in the old medical group, $2,900 in the old surgical group, and $1,900 in the iodine-131 group.

The total costs (including relapses) were approximately $2,300 in the young medical group, $2,900 in the young surgical group, $2,000 in the old medical group, $3,200 in the old surgical group, and $2,600 in the iodine-131 group.
The cost proportion in the young groups between the medical and surgical treatments was 1:2.5 before and 1:1.3 after inclusion of the relapse costs.

The cost proportion in the old groups between the medical, surgical, and iodine-131 treatment was 1:2.5:1.6 before and 1:1.6:1.4 after inclusion of the relapse costs.

**Synthesis of costs and benefits**
Not applicable.

**Authors’ conclusions**
The patients' views on the different quality of life aspects of the three treatment modalities were similar, and appear to have been independent of their age. The costs were similar for antithyroid drug and iodine-131 treatments, but somewhat higher for surgery.

**CRD COMMENTARY - Selection of comparators**
The comparators were justified on the grounds that they represented commonly employed strategies. You should decide if these health technologies are relevant to your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective randomised controlled trial, which was appropriate for the study question. The authors did not show whether the study sample was representative of the study population, and did not report baseline characteristics. The authors also did not show whether the treatment groups were comparable at analysis. The effectiveness estimates were based on patients' views. No information was provided on how the patient questionnaire was developed or on the validity of the questions. Finally, since no power calculation was performed, the lack of statistical significance observed could have been due to the small sample size.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit.

**Validity of estimate of costs**
A good feature of the cost analysis was that all direct cost categories relevant to the health service perspective were included. However, no sensitivity or statistical analyses were conducted on the cost data. In addition, the costs were estimated from the official hospital reimbursement system. This means that the estimates were not based on actual resource use and unit costs for the clinics, but on the arbitrary units of service required for investigating and treating a patient and their prices. Thus, it would be difficult to generalise to other settings.

**Other issues**
The authors did not compare their findings with those from other studies, and did not address the issue of generalisability to other settings. The authors did not present the actual values of results, thus making criticism difficult. The authors seem to have assumed that the lack of statistical significance means a lack of difference. The study considered patients with Graves' hyperthyroidism, but provided no baseline data to define this population.

**Implications of the study**
The authors did not state any further conclusions or implications. Despite a good design, it is difficult to see how this study would inform a decision on the adoption of a technology. In particular, given the lack of evidence of validity of the effectiveness instrument, the lack of effectiveness results, and the lack of power calculations.
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Other publications of related interest


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