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Title **Recombinant Human Thyroid Stimulating Hormone (rhTSH) – Diagnostic Agent for Use in Well-differentiated Thyroid Cancer**

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Aim

To assess the safety, effectiveness, and cost effectiveness of recombinant human thyroid stimulating hormone (rhTSH) in detecting thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression and at risk of recurrence of thyroid cancer, relative to the comparator method of thyroid hormone therapy (THT) withdrawal.

Conclusions and results

Safety: About 800 patients have received rhTSH in clinical trials. Adverse events associated with rhTSH appear to be mild, the most frequent being headache and nausea. However, some individual case studies report serious adverse events associated with the swelling of metastases after rhTSH administration. To reduce the incidence of serious adverse events, pretreatment with corticosteroids may be considered prior to administering rhTSH in patients with metastatic disease in confined spaces. Adverse events associated with rhTSH should be considered in the context of the hypothyroidism in patients undergoing THT withdrawal. *Effectiveness:*

Diagnostic accuracy: The primary efficacy measure was the diagnostic accuracy using rhTSH relative to using the comparator, THT withdrawal. When used with concurrent serum Tg testing and whole body scanning, the unadjusted sensitivity of rhTSH was 87%, specificity 95% and accuracy 89%. Using rhTSH instead of THT withdrawal would reduce diagnostic accuracy, so that 11% of patients' disease status would be misclassified.

Quality of life: This assessment suggests that patients experience a poorer general quality of life during THT withdrawal compared with rhTSH. Although the magnitude of the differences is considerable, the effect is transient and infrequent.

Cost-effectiveness: A decision-analytic cost-utility model was used to determine the cost effectiveness of rhTSH relative to THT withdrawal in the cohort of patients who have already had one negative followup using THT withdrawal. With significantly increased cost and a marginal improvement in average utility, the incremental cost effectiveness in this patient group is AUD 51 344 per quality-adjusted life-year.

Recommendation

MSAC recommended that on the strength of evidence pertaining to the diagnostic use of rhTSH in well-differentiated thyroid cancer, public funding should be supported for this procedure only in patients in whom THT withdrawal is medically contraindicated. Also, based on current evidence, both rhTSH-stimulated whole body scanning and serum Tg testing should be undertaken concurrently. MSAC recommended that public funding for rhTSH should not be supported in patients who are able to tolerate THT withdrawal, on the basis of lower diagnostic accuracy and a high cost-effectiveness ratio. The Minister for Health and Ageing accepted this recommendation on 16 October 2002.

Methods

The medical literature on rhTSH was systematically reviewed. A thorough search of the literature was carried out via electronic databases and HTA websites. Citations that met predefined inclusion criteria were included. The value-for-money of rhTSH relative to the standard THT withdrawal method in detecting well-differentiated thyroid cancer or thyroid remnants in post-thyroidectomy patients maintained on hormone suppression and at risk of recurrence of thyroid cancer, was evaluated using a decision-analytic cost-utility model.

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