Evaluation de l'utilisation du dissecteur ultrasonique Ultracision en chirurgie thyroidienne: étude prospective randomisée [Evaluation of the Ultracision ultrasonic dissector in thyroid surgery: a prospective randomized study]

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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 an ultrasonic hook (HS 002, Ultracision, Ethicon Endosurgery) in thyroid surgery was compared to conventional haemostasis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised euthyroid patients with multinodular goiter undergoing total thyroidectomy.

Setting
The setting was secondary care. The economic evaluation was carried out in Belgium.

Dates to which data relate
The dates of the data were not reported. The price year was not reported.

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

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used for the effectiveness study. Insufficient information was provided in the paper to determine whether the costing had been undertaken retrospectively or prospectively.

Study sample
No power calculations were reported. Consecutive euthyroid patients undergoing total thyroidectomy formed the sample. The initial study sample appears to have been appropriate for the clinical study question. Overall there were 34 patients in the study, with 17 in the Ultracision group and 17 in the conventional group. The mean age in the Ultracision group was 48.1 years and 52.1 years in the conventional group. There were 14 females and 3 males in each group. The study did not report whether there were any refusals to participate or whether any subjects were excluded from the initial sample.
**Study design**
The study was a randomised controlled trial. Patients were randomised using the software Graph Prism. The study was carried out in a single centre. The duration of follow-up was, on average, 3 days, depending on the length of stay of the patient in hospital. No losses to follow-up were reported. Blinding was not reported for the assessment of outcomes.

**Analysis of effectiveness**
The basis for the analysis of the clinical study (intention to treat or treatment completers only) was not reported. The primary health outcomes used in the analysis were blood loss during surgery (measured by the weight of bandages used), weight of the removed organ, number and type of complications during surgery, number and type of postoperative complications, and postoperative analgesic consumption. Groups were shown to be comparable at analysis with respect to age, sex, and other biochemical parameters.

**Effectiveness results**
The average blood loss in the Ultracision group was 74.5 grams compared to 134.6 grams in the conventional group, (p<0.05).

The weight of the removed organ was 79 grams in the Ultracision group and 85.6 grams in the conventional group, (not statistically significant).

There were no complications during surgery in either group.

There was one postoperative complication (transient hypoparathyroidism) in the Ultracision group and four complications (transient hypoparathyroidism) in the conventional group, (p=0.09).

The average consumption of analgesics was 700 mg in the Ultracision group and 1,888 mg in the conventional group, (p<0.005).

**Clinical conclusions**
Use of the ultrasonic hook, Ultracision, results in significantly less intraoperative blood loss and postoperative analgesic consumption and may also reduce the incidence of transient hypoparathyroidism.

**Measure of benefits used in the economic analysis**
No summary measure was used for health benefits. As clinical outcomes were left disaggregated, a cost-consequences analysis was performed.

**Direct costs**
Discounting was not performed as the study lasted less than a year. Quantities and costs were measured separately. The quantities measured were the duration of surgery, the duration of hospitalisation and the quantity of materials used during the operation such as the hook and clips. The estimation of the quantities and costs was based on actual data. The source of the resource use data was the patient sample. The source of the costs was not specified. The price year was not recorded.

**Statistical analysis of costs**
Costs were compared using Student t tests.

**Indirect Costs**
Indirect costs were not included in the analysis.
Currency
Euros.

Sensitivity analysis
No sensitivity analyses were conducted.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported earlier.

Cost results
Total costs for both groups were not reported. Costs results were presented in a disaggregated manner. There was no significant difference in length of hospital stay. There was a significant difference in the length of surgery, with the Ultracision group requiring less time, (p<0.005). There was no significant difference in the cost of materials used during surgery, except for an increased use of clips in the conventional group, (p<0.005) and the cost of the hook for the Ultracision group. However, if more than 15 patients used the same hook, then the cost of the hook was less than the clips required for the conventional group. The duration of follow-up for the costs corresponded to the patients’ hospital stay. The costs of adverse effects, such as transient hypoparathyroidism, were not included in the analysis.

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
Although the use of the ultrasonic dissector does not allow a major cost saving in total thyroidectomy, the essential advantages were a significant reduction in intraoperative blood loss, length of operating time and postoperative analgesic consumption.

CRD COMMENTARY - Selection of comparators
A justification for the comparator used was given, namely haemostasis, the conventional health technology used during surgery for total thyroidectomy. You, as a user of this database, should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The study design, a randomised controlled trial, was appropriate for the study question. The study sample, patients undergoing total thyroidectomy, was representative of the study population. Patient groups were shown to be comparable at analysis. However, it was not clear whether blinding was used in the assessment and analysis of the results and this would have strengthened the analysis of effectiveness. Power calculations were not provided and this would have been useful given the small sample size of the study.

Validity of estimate of measure of benefit
Outcome measures were left disaggregated and a cost-consequences analysis was performed. The use of a single measure of benefit would have strengthened the economic analysis.

Validity of estimate of costs
Positive aspects of the costing include the statistical analysis of costs and quantities. However, there were some problems with the costing. From the perspective of the hospital, the cost of personnel (surgeons, nurses) and the cost of
complications were not included in the analysis. These omissions may affect the conclusions of the study. Some costs and quantities were reported separately, although not all resource use (e.g. duration of surgery, bandages for blood loss) was subsequently costed. The authors did not present the total costs incurred by each group. The source of the costs and the price year were not reported.

Other issues
The authors made some comparisons with other studies, although it was not clear whether these were economic evaluations. The issue of generalisability to other settings was not addressed. The authors did not appear to present their results selectively. The study enrolled patients undergoing total thyroidectomy and this was reflected in the authors' conclusions. The authors did not report any further limitations to their study.

Implications of the study
Although the use of the ultrasonic dissector does not allow a major cost-saving in total thyroidectomy, the authors felt that there was a significant reduction in intraoperative blood loss, length of operating time and postoperative analgesic consumption.

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