Benefits resulting from 1- and 6-hour parathyroid hormone and calcium levels after thyroidectomy

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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 study aimed to evaluate the use of a post-thyroidectomy hypocalcaemia monitoring protocol. The protocol involved the measurement of serum parathyroid hormone (PTH) at 1, 6, 12 and 20 hours after operation and twice daily after that period, and corrected calcium levels at 1 and 6 hours. PTH measurements were conducted using the Roche Elecsys System 2010 electrochemiluminescence immunoassay (Roche Diagnostics, Mannheim, Germany). The normal values for PTH were 10 to 70 ng/L. The comparator was no use of PTH measurements.

Type of intervention
Other: Postoperative (thyroidectomy) patient management.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had undergone total thyroidectomy. Patients who had completion thyroidectomy, neck dissections and those with coexisting parathyroidectomy were excluded from the study. No further inclusion or exclusion criteria were reported.

Setting
The setting was tertiary care (a university teaching hospital). Although not explicitly stated, the economic study appears to have been carried out in Canada.

Dates to which data relate
The dates to which the effectiveness and cost data referred 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
Although not explicitly stated, it would appear that the costing was carried out retrospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The study sample was not determined in the planning phase. In addition, power calculations were not conducted retrospectively to assure a certain power. An initial sample of 95 consecutive patients who had had total thyroidectomy
at the authors’ setting was recruited into the study. It was reported that 3 patients were excluded from the study due to the fact that the 6-hour PTH was not measured. All patients were asked for written informed consent and no patients were reported to have refused to participate. Overall, 46 patients were recruited before the implementation of the protocol and these served as the control, while 46 patients were recruited after protocol implementation.

**Study design**
The analysis was based on a single-centre prospective comparative study with historical control. The timeframes during which the data for the current and historical study groups were collected were not reported. The duration of follow-up was also not reported. No patients were reported to have been lost to follow-up.

**Analysis of effectiveness**
It was not reported whether all of the patients included in the study were considered at analysis. The authors did not report whether the two groups were comparable in terms of their demographic characteristics. The mean (±/- standard error) age was 50 (±/- 1.8) in the control group and 50 (±/- 1.6) in the intervention group. The control group comprised 10 males and 36 females, while the intervention group comprised 6 males and 40 females. The primary outcomes assessed were the rate of transient hypocalcaemia and duration of hospitalisation. Hypocalcaemia was documented if one of the subsequent criteria were met:

- a serum corrected calcium level \(\leq 1.90 \text{ mmol/L (7.6 mg/dL)}\),
- signs and symptoms of hypocalcaemia (i.e. perioral numbness, paresthesias of the upper-extremity digits, or a positive Trousseau's sign).

**Effectiveness results**
Thirteen (28%) patients in the control group developed hypocalcaemia, compared with 4 (9%) patients in the PTH protocol group. The odds ratio (control/case) was 0.13 (95% confidence interval: 1.46 - 9.82; chi-squared test, \(p=0.016\)).

It was also reported that of the 42 patients who did not develop hypocalcaemia, 16 (38%) reached the 6-hour critical level and 23 (54%) met these criteria 12 hours after operation. Four patients in the intervention group had a 1-hour PTH of \(\leq 8 \text{ ng/L}\), and of these 2 developed hypocalcaemia.

**Clinical conclusions**
The authors concluded that the application of a protocol using PTH and corrected calcium levels at 1 and 6 hours resulted in a decreased number of blood tests, a lower incidence of transient hypocalcaemia and shorter hospitalisation.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit. In effect, the study is classified as a cost-consequences analysis.

**Direct costs**
The health care costs included in the analysis were for hours spent in hospital, blood tests, calcium, albumin, phosphate, magnesium and PTH. The costs and the quantities were reported separately, expect for the unit cost of hospitalisation. The quantities of resources used were derived from the effectiveness analysis, but the source of the cost data was not reported. The time horizon of the study was not reported but, since it appears that the costs were incurred during a short time, discounting was not relevant. The dates to which the costs referred and the price year were not reported.

**Statistical analysis of costs**
The costs were treated deterministically. The authors carried out chi-squared tests to evaluate cost-differences between the control and the intervention group.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
Although not explicitly stated, Canadian dollars (CAD) appear to have been used.

Sensitivity analysis
No sensitivity analysis was conducted.

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

Cost results
The total costs per patient were reported. The total costs were CAD 4,124 in the control group and CAD 3,358 in the intervention (PTH) group.

The use of PTH and corrected calcium levels at 1 and 6 hours resulted in cost-savings equal to CAD 766 per patient (CAD 35,236 for the 46 patients treated in the PTH group).

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The implementation of the parathyroid hormone (PTH) protocol resulted in significant cost-savings.

CRD COMMENTARY - Selection of comparators
The authors chose the control group of the trial as the comparator. They did not discuss the existence of alternative tests. If there are any, which is likely, then a more comprehensive analysis might have provided relevant information.

Validity of estimate of measure of effectiveness
The analysis was based on a cohort study with a historical control, which seems to have been appropriate given the study question. The study sample was representative of the study population, but no statistical analysis was undertaken to ascertain whether the patient groups were comparable at analysis. In addition, no power calculations were reported. Therefore, it was not possible to ascertain whether the results obtained were due to intervention or to chance. Given the observational nature of the study design and the lack of adjustment or control for confounding, the internal validity of the effectiveness results is likely to be low.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).
Validity of estimate of costs
The perspective adopted in the economic analysis was not reported, but it was clearly not societal since the indirect costs were not included. However, from the costs included it was unclear which perspective the authors were trying to capture. Apart from hospitalisation costs, the costs and the quantities were reported separately. The source of the cost data and the price year were not reported, and no sensitivity analysis on resources or costs was carried out. These issues may introduce uncertainty into the results and limit the reproducibility of the study to other settings. Overall, the costing was very poorly reported and appears to have been extremely limited.

Other issues
The authors compared their findings with those from other studies, and reported consistency in their results. The issue of the generalisability of the results to other settings was not directly addressed. The authors do not appear to have presented their results selectively and they reported the results from the statistical tests they performed. The study enrolled patients who underwent thyroidectomy and this was reflected in the authors' conclusions. The authors did not report any limitations to their study.

Implications of the study
The authors did not make any explicit recommendations for changes in policy or practice, or the need for future research.

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