Intraoperative quick parathyroid hormone versus same-day parathyroid hormone testing for minimally invasive parathyroidectomy: a cost-effectiveness 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 intraoperative quick parathyroid hormone (QPTH) measurement versus same-day parathyroid hormone (PTH) testing for minimally invasive parathyroidectomy (MIP). This measurement is carried out to eliminate failures during MIP. The QPTH results are considered predictive of cure if the 10-minute post-tumour excision PTH levels decrease within normal limits and to less than 50% of the preoperative PTH levels.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The patients were men and women undergoing parathyroidectomy for primary hyperparathyroidism (HPT), who fulfilled the criteria for undergoing MIP. The patients had asymptomatic indications for parathyroidectomy.

Setting
The study setting was an institution. The economic study was carried out in Sydney, Australia.

Dates to which data relate
The dates, during which the effectiveness evidence, resource use data and prices were collected, were not reported.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study and the authors' assumptions.

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

Study sample
There was no mention of whether the sample size had been determined by power calculations. The study sample comprised 92 consecutive patients who fulfilled the inclusion criteria to undergo an MIP. The mean age was 63 years (range: 30 - 90). There were 23 men and 69 women. All patients underwent MIP with a uniform scan-directed, focused lateral approach and were hospitalised overnight, with discharge planned within 24 hours. The patients underwent serum calcium estimations on postoperative days 1 and 7, and at 3 weeks' and 3 months' follow-up. The mean preoperative serum calcium level was 11.2 mg/dL (normal: 8.8 - 10.4) and the mean preoperative PTH level was 150.01
pg/mL (normal: 12 - 72). Four patients were excluded from the study, as the samples collected for QPTH testing were incomplete, inadequate or haemolysed. Eighty-eight patients were left in the study.

**Study design**
The study was a non-randomised trial carried out in a single centre. The patients were followed up for 3 months.

**Analysis of effectiveness**
The basis for the analysis of the clinical study (intention to treat or treatment completers only) was not explicitly stated. The implication was that it was intention to treat. The primary outcomes used in the analysis were the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the tests carried out. It was not explicitly stated that the patients were comparable.

**Effectiveness results**
Of the 88 patients who underwent an MIP, 3 continued to have persistent hyperparathyroidism after the first procedure, as shown by the high calcium levels in the follow-up period.

In terms of QPTH, 78 patients had true-positive results (correctly predicted cure), 7 patients had false-negative results (wrongly predicting persistent HPT), and 2 had true-negative results (correctly predicting HPT).

These results were used to derive the sensitivity and specificity results of the interventions. For QPTH, the sensitivity was 91.8%, the specificity 66.7%, the PPV 98.7%, and the NPV 22.2%. For same-day PTH, the sensitivity was 100%, the specificity 66.7%, the PPV 98.9%, and the NPV 100%.

The overall accuracy was 90.9% for QPTH and 98.9% for same-day PTH.

The number of patients who underwent unnecessary conversions or reoperation was 7 for the QPTH group and 1 for the same-day PTH group.

One patient was discharged from each group with persistent HTP.

**Clinical conclusions**
The authors concluded that QPTH estimation is an accurate test, but the false-positive and false-negative rates significantly reduce its effectiveness.

**Modelling**
A decision analysis tree was used to estimate the costs. Three management strategies were created.

1. QPTH measurement not performed and the patient is discharged from hospital for routine check-up. The decision to reoperate at subsequent admission is made on the basis of postoperative serum calcium results.

2. QPTH measured intraoperatively and the results are made available to the surgeon intraoperatively. The decision to convert to an immediate open bilateral exploration is based on the failure of the QPTH results to decrease to within the normal limits or to less than 50% of the preoperative level at 10 minutes.

3. The measurement of PTH levels in blood samples collected intraoperatively by a routine laboratory run on the day of the operation. The results are made available the same evening in conjunction with a serum result. The decision to reoperate during the same hospital admission is based on the failure of the PTH levels to decrease to the aforementioned criteria, and the failure of the serum calcium level to normalise.

**Measure of benefits used in the economic analysis**
The outcome measurement used in the economic analysis was the correct estimation of PTH levels to avoid failed operations.

**Direct costs**
No discounting was carried out since the costs were occurred over less than two years. The quantities and the costs were estimated from actual data and were also derived using modelling. The surgical and hospital data were derived from estimates of standard charges in an Australian setting. These costs included hospital admission (one day), operating theatre charges for parathyroidectomy, personnel charges (surgeon, anaesthesiologist and pathologist) for the parathyroid operation, a single PTH assay on a routine laboratory run, a single PTH assay with a dedicated machine (including the amortised capital cost of a dedicated machine, reagents and technician time), and a single estimation of the serum calcium. There was no mention of when the quantities of resources were measured. The price year was not reported.

**Statistical analysis of costs**
The deterministic costs were presented. A sensitivity analysis identified the areas of uncertainty associated with the estimates.

**Indirect Costs**
The indirect costs were not considered since the study was conducted from a provider perspective.

**Currency**
Australian dollars (Aus$).

**Sensitivity analysis**
Sensitivity analyses were carried out to test the robustness of the cost-effectiveness results, by varying cost assumptions.

**Estimated benefits used in the economic analysis**
For the first scenario of the model, if no QPTH had been made available and operative decisions had been based solely on the preoperative localisation studies and clinical acumen, 85 of the 88 patients would have been cured at the initial operation. No patient would have undergone an unnecessary conversion to an open procedure.

In the second scenario, two patients would have undergone conversion to an open procedure and would have benefited with presumed care. However, 7 patients would have undergone an unnecessary conversion to an open procedure.

In the third scenario, 3 patients would have had persistent HPT and the procedures in 2 patients would have been failed. However, no patients would have undergone an unnecessary conversion.

**Cost results**
The total cost was Aus$19,801.19 for intraoperative QPTH and Aus$624.73 for intraoperative PTH plus calcium.

**Synthesis of costs and benefits**
The benefits and the costs were combined in terms of the cost per one failed operation.

From the sensitivity analysis, if the bed-day costs were doubled to Aus$582.40, the cost-effectiveness of QPTH versus routine PTH plus calcium was Aus$20,406.45 versus Aus$322.47.

If the bed-day costs were quadrupled to Aus$1,164.86 per day, the respective costs would be Aus$21,747 (QPTH) and
Aus$153.61 (PTH plus calcium).

If the cost of QPTH were reduced by a quarter to Aus$382.29, the respective costs would be Aus$14,641.49 (QPTH) versus Aus$624.73 (PTH plus calcium). If they were halved to Aus$254.80, the respective costs would be Aus$9,481.79 (QPTH) versus $624.73 (PTH plus calcium).

The main difference in cost-effectiveness arises from the difference in the cost of performing a single PTH assay as part of the routine laboratory run ($17.36) versus the cost of having a dedicated machine and technician employed in the operating room.

Authors' conclusions
The results of the first scenario may lead to a higher rate of persistent recurrent hyperparathyroidism (HPT). The second scenario of using intraoperative quick parathyroid hormone (QPTH) results appears to be a sensitive tool for confirmation of cure, but seems unnecessary in most patients. In addition, it is subject to high false negatives and operating costs. The third scenario appears to be a good compromise that would allow early identification of patients with persistent HPT. By supplementing these results with early post parathyroidectomy serum calcium results, the false-negative results of intraoperative PTH estimations could be overcome. This would make this treatment strategy reliable, yet cost-effective. The authors concluded that intraoperative QPTH estimation is an accurate test, although the false-positive and false-negative rates significantly reduce its cost-effectiveness when it is used as part of an intraoperative decision.

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the choice of the comparator used. It would appear to represent current practice in the authors' setting. You should consider whether this is a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the study cannot be guaranteed due to the non-randomised nature of the study design, and thus the possibility of bias and confounding. In addition, power calculations were not performed and the comparability of the patients was not investigated.

Validity of estimate of measure of benefit
The estimation of the benefits was modelled. The instrumental estimation of the benefits was obtained directly from the effectiveness analysis. This choice of benefit was justified.

Validity of estimate of costs
The source of the direct costs was stated. However, it should be noted that charges were used to proxy prices and, as such, do not reflect the true opportunity costs. The dates to which the prices related were not stated. The authors undertook a range of sensitivity analyses on important cost elements, such as the bed-day costs and reduced costs due to improving technology. The authors made a number of assumptions that may limit the generalisability of their results since they are specific to the authors' setting, although the sensitivity analysis assists with generalisability issues.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was partially addressed, and sensitivity analyses were used to test the robustness of the cost results. The authors acknowledged some weaknesses in their study. In particular, the exclusion of the long-term follow-up results and the fact that the outcomes in a small proportion of patients may possibly change in the long term.

Implications of the study
The authors state that, although the QPTH test is well established, the surgeon's clinical judgment based on available information is also highly accurate. This means that, in most cases, intraoperative QPTH is simply unnecessary with 97% of the patients being cured without any need to assess the PTH level.

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