Minimally invasive video-assisted parathyroidectomy versus open minimally invasive parathyroidectomy for a solitary parathyroid adenoma: a prospective, randomized, blinded trial

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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 compared two minimally invasive parathyroidectomy (MIP) techniques in the surgical treatment of primary hyperparathyroidism (pHPT) caused by a solitary parathyroid adenoma. The techniques were video-assisted MIP and open MIP.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The population comprised patients with pHPT caused by a solitary parathyroid adenoma, who were referred for surgery and found to be eligible for MIP under general anaesthesia. The inclusion criteria were:

- diagnosis of pHPT confirmed by biochemical evaluation (increased serum calcium of $\geq 2.6$ mmol/L and serum intact parathyroid hormone level $>65$ pg/mL),
- a single parathyroid gland disease (concurrent localisation with high-resolution ultrasound of the neck and 99mTc-MIBI subtraction scintigraphy),
- a parathyroid adenoma not exceeding 30 mm in the largest diameter,
- no previous neck surgery, and
- the absence of nodular goiter requiring one-step thyroid surgery.

Exclusion criteria were:
- a familial history of pHPT (MEN 1, MEN 2, hereditary pHPT),
- negative or discordant localisation studies,
- suspicion of multiglandular disease,
- extracervical ectopy,
- parathyroid cancer,
- concomitant goiter with volume larger than 30 mL,
pregnancy or lactation,
age below 18 years,
high-risk patients American Society of Anesthesiology grade 4,
emergency surgery for hypercalcaemic crisis, and
inability to comply with scheduled follow-up.

Setting
The setting was secondary care. The economic study was carried out in Krakow, Poland.

Dates to which data relate
The effectiveness evidence was gathered from patients who were referred for first-time surgery between December 2002 and December 2004. The price year was not recorded.

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

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

Study sample
The sample size was estimated on the basis of detecting a 10% difference in the success rate, hypocalcaemia rate and pain intensity, with an 80% probability at p<0.05. Among 84 consecutive patients, 60 (95%) individuals were found eligible and were randomised to either video-assisted VIP (30 patients) or open MIP (30 patients). Reasons for exclusion included negative (n=2) or discordant (n=7) localisation studies, suspicion of multiglandular disease (n=4) and concomitant goiter larger than 30 ml in volume (n=8). Three eligible patients refused consent in favour of conventional bilateral cervical exploration. Age, gender and preoperative clinical and biochemical data were similar in the two groups.

Study design
A single-centre, prospective, randomised controlled trial (RCT) was performed. Randomisation was performed using sealed envelopes. Six months’ follow-up was recorded and no patients were lost to follow-up. Patients, nurses providing postoperative care, and the data entry analyst were blinded to the group assignment.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary end points were the success rate in achieving cure from the hyperparathyroid state and the hypocalcaemia rate. The secondary end points were:

the operating time,

the scar length,

pain intensity (assessed by visual analogue scale),
analgesia request rate,
analgesic consumption,
quality of life within 7 postoperative days (SF-36),
cosmetic satisfaction,
duration of postoperative hospitalisation, and
cost-effectiveness analysis.

**Effectiveness results**
All (100%) patients were cured.

Patients undergoing video-assisted MIP versus open MIP were characterised by:
similar operative time (44.2 +/- 18.9 versus 49.7 +/- 15.9 minutes; p=0.22);
transient hypocalcaemia rate (3 versus 3 individuals; p=1.0);
lower pain intensity at 4, 8, 12 and 24 hours after surgery (24.9 +/- 6.1 versus 32.2 +/- 4.6 at 4 hours; 26.4 +/- 4.5 versus 32.0 +/- 4.0 at 8 hours; 19.6 +/- 4.9 versus 25.4 +/- 3.8 at 12 hours; and 15.5 +/- 5.5 versus 20.4 +/- 4.7 points at 24 hours, p<0.001);
lower analgesia request rate (63.3% versus 90%; p=0.01);
lower analgesia consumption (51.6 +/- 46.4 versus 121.6 +/- 50.3 mg of ketoprofen; p<0.001);
better physical functioning aspect and bodily pain aspect of quality of life on early recovery (88.4 +/- 6.9 versus 84.6 +/- 4.7 and 90.3 +/- 4.7 versus 87.5 +/- 5.8; p=0.02 and p=0.003, respectively);
shorter scar length (17.2 +/- 2.2 versus 30.8 +/- 4.0 mm; p<0.001); and
higher cosmetic satisfaction rate at 1 month after surgery (85.4 +/- 12.4% versus 77.4 +/- 9.7%; p=0.006).

**Clinical conclusions**
The authors concluded that both video-assisted MIP and open MIP are safe and offer a valuable approach with similar excellent success rates and low morbidity. They found that the advantages of video-assisted MIP included easier recognition of recurrent laryngeal nerve, lower pain intensity within 24 hours of surgery, lower analgesia request rate, lower analgesia consumption, shorter scar length, better physical functioning and bodily pain aspects of the quality of life on early recovery, and higher early cosmetic satisfaction rate.

**Measure of benefits used in the economic analysis**
No summary outcome measure was used in the economic analysis. The analysis was, in effect, a cost-consequences analysis.

**Direct costs**
Discounting was not relevant. Cost analysis was performed using an official in-hospital price list for medical procedures. The costs included unit costs for ultrasonography, sestamibi scintigraphy, intraoperative intact parathyroid hormone assay, frozen section examination, minutes of anaesthesia, minutes of operating theatre time, minutes of use of videoscopic equipment, and days of hospital stay. Quantities of resources were measured over the study period (2002-2005). The price year was not reported.
Statistical analysis of costs
The statistical analysis was based on Student’s t-tests.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($). Conversion rates from the Polish zloty were not reported.

Sensitivity analysis
A sensitivity analysis was not carried out, although the cost results were presented for surgery alone and for total costs.

Estimated benefits used in the economic analysis
Not relevant.

Cost results
Video-assisted MIP was more expensive than open MIP ($1,150 +/- 63.4 versus $1,015 +/- 61.8; p<0.001).

The difference was driven by the charges for endoscopic tool involvement since other components, including localisation studies, were similar.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The advantages associated with video-assisted minimally invasive parathyroidectomy (MIP) were achieved at a higher cost because of the involvement of endoscopic tools. Whether or not they are sufficient to compensate will depend on the local health care system and the acceptance of the outcomes.

CRD COMMENTARY - Selection of comparators
The comparators were justified on the basis that they represented two types of MIP commonly used in the authors’ setting. It was unclear why these techniques and not other types were chosen. You should decide whether video-assisted MIP and open MIP are relevant comparators in your own setting.

Validity of estimate of measure of effectiveness
The study was based on an RCT design, which was appropriate for the study question. It used a relatively small sample size, which was based on a calculation in which a 20% difference in success rates across the treatments was assumed (no difference was found). Since the study sample was one of convenience at a single centre, it was unclear whether it was representative of the study population. The patient groups were shown to be comparable at analysis. The analysis of effectiveness was handled credibly using an intention to treat approach.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. The study was, in effect, a cost-consequences study.
Validity of estimate of costs
The perspective of the analysis was not reported. However, the costs appear to have been collected from the perspective of a third-party payer. Some relevant costs were omitted from the analysis (e.g. nurse time), although it is possible that these were included in the daily hospital charge. Omissions are unlikely to have affected the conclusions, given that the main cost-difference was that associated with the use of endoscopic equipment in the video-assisted MIP group. The unit costs and total costs were reported, but the quantities of resources used were not. No statistical analysis of the quantities was reported. Cost-differences were tested using Student's t-test. The sources of the unit cost data were reported. Currency conversions to US dollars and the price year were not described.

Other issues
The authors made some appropriate comparison of their findings with those from other studies. The issue of generalisability to other settings was not discussed. The authors did not present their results selectively and their conclusion reflected the scope of the analysis. They did not report any further limitations of their study.

Implications of the study
The authors stated that the routine use of the intraoperative intact parathyroid hormone assay is essential in both video-assisted MIP and open MIP to avoid surgical failures of overlooked multiglandular disease.

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Other publications of related interest
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Indexing Status
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MeSH
Adenoma /surgery; Aged; Analgesics /therapeutic use; Cost-Benefit Analysis; Female; Humans; Hypocalcemia /epidemiology /etiology; Incidence; Male; Middle Aged; Minimally Invasive Surgical Procedures; Pain, Postoperative /drug therapy /etiology; Parathyroid Neoplasms /surgery; Parathyroidectomy /adverse effects /economics; Patient Satisfaction; Prospective Studies; Quality of Life; Single-Blind Method; Video-Assisted Surgery

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