Efficacy and costs of 3 anesthetic regimens in the prevention of postoperative nausea and vomiting

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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 examined the use of an 8-mg ondansetron tablet, thiopentone induction and isoflurane-nitrous oxide (N2O) maintenance (Group I+O) or placebo tablet, propofol induction and propofol-air/O2 maintenance (Group P), versus a control group, for the prevention of postoperative nausea and vomiting (PONV).

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women undergoing laparoscopic gynaecological surgery. Women were excluded from the study if they had contraindications to the anaesthetics, had experienced nausea or vomiting in the 24 hours prior to anaesthesia, or had taken drugs known to have anti-emetic properties.

Setting
The setting was secondary care. The economic study was carried out in Finland.

Dates to which data relate
The dates to which the effectiveness and resource use data referred were not reported in the paper. The price year was not stated.

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

Link between effectiveness and cost data
The resource use data were collected from the same patient sample that provided the clinical effectiveness data.

Study sample
A total of 150 consecutive eligible patients scheduled to undergo gynaecologic laparoscopy were recruited into the study. Of these, 50 were in Group P, 51 were in Group I+O and 49 were in Group I. Sample size calculations were reported. These showed that the sample had an 80% power of detection at the 0.05 level. The study included both inpatients and outpatients.
Study design
The study was a randomised controlled trial that was conducted in a single centre. Randomisation was undertaken using sealed opaque envelopes. The patients were followed up for 24 hours following surgery. No loss to follow-up was reported. Both patients and health professionals were blind to whether the patient had received ondansetron (double-blinding), while patients were also blind to the anaesthetic regimen (single-blinding).

Analysis of effectiveness
The health outcomes used in the analysis were the incidence of PONV, emetic episodes per patient, the use of rescue anti-emetics and recovery times. The analysis was undertaken on an intention to treat basis. The three patient groups were shown to be comparable in terms of their age, height, weight, history of PONV, history of motion sickness, smoking status and risk factors for PONV.

Effectiveness results
The incidence of PONV was 38% in Group P, 33% in Group I+O and 59% in Group I. The difference between Group I+O and Group I was significant, (p<0.05).

The incidence of nausea was 22% in Group P, 27% in Group I+O and 37% in Group I (differences not significant).

The incidence of vomiting was 26% in Group P, 22% in Group I+O and 49% in Group I. The difference between Group I+O and Group I was significant, (p<0.05).

There were 0.9 emetic episodes per patient in Group P, 0.6 in Group I+O and 1.5 in Group I. The difference between Group I+O and Group I was significant, (p<0.05).

The only statistically significant difference in recovery times was the time before patients were ready for ward transfer from recovery. This was 90 minutes in Group I+O compared with 64 minutes in Group I, (p <0.05).

Clinical conclusions
The authors concluded that anaesthesia with propofol-air/O2 alone and isoflurane-N2O combined with ondansetron had similar efficacy, but isoflurane-N2O alone is less effective in terms of PONV.

Measure of benefits used in the economic analysis
The measure of health benefit used was the number (of patients)-needed-to-treat to prevent one case of PONV.

Direct costs
The perspective of the study was not reported. The study identified the cost of anaesthetic drugs (i.e. ondansetron, hypnotics, opioids, muscle relaxants and antagonists) and any disposables associated with their administration. Resource use was taken from actual drugs used during the trial period. The unit costs of some drugs were identified and reported, although a complete breakdown of resource use was not presented. The source of the unit costs was not specified, but the unit costs were based on acquisition costs. The currency of the costs was not stated clearly in the paper and the price year was not reported.

Statistical analysis of costs
The cost data were treated deterministically.

Indirect Costs
No indirect costs were included in this study.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis
Compared with Group I, 4.76 patients in Group P and 3.85 patients in Group I+O needed to be treated to prevent one case of PONV.

Cost results
The median cost of drugs was $31 in Group P, $35 in Group I+O and $18 in Group I.

Synthesis of costs and benefits
Compared with Group I, an additional 4 patients would need to be given ondansetron (Group I+O) at an additional cost of $68 to prevent one case of PONV (absolute risk reduction of 26%) and an additional 5 patients would need to be given propofol-air/O2 (Group P) at an additional cost of $65 to prevent one case of PONV (absolute risk reduction of 21%).

Authors' conclusions
Anaesthesia with propofol-air/O2 alone and isoflurane-nitrous oxide (N2O) combined with ondansetron had similar efficacy and costs. Isoflurane-N2O alone was cheaper, but less effective, in terms of postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic gynaecological surgery.

CRD COMMENTARY - Selection of comparators
This study compared three anaesthetic regimens for laparoscopic gynaecological surgery. It was unclear why Group I was chosen as the comparator in this study. You should consider how these three regimens compare with usual practice in your setting prior to applying the results of this study.

Validity of estimate of measure of effectiveness
The effectiveness data were taken from a randomised control trial, which was appropriate to the study question. Power calculations were conducted, which will have helped to limit the possibility of the results being obtained by chance. In addition, the authors reported the methods of randomisation, blinding and allocation concealment, all of which enhance the internal validity of the study results. The consecutive selection of patients should mean that the sample is representative of the study population. However, the authors did not compare their study sample with the wider patient population. Hence, the generalisability of the findings to other population groups has not been established.

Validity of estimate of measure of benefit
The measure of health benefit (number-needed-to-treat) was taken directly from the clinical trial that provided the effectiveness evidence. The use of a quality of life measure would have been better to facilitate comparisons with other technologies.

Validity of estimate of costs
The perspective of the analysis was not reported, and this makes it difficult to determine whether all the relevant cost were included. The paper did not clearly state the currency for the cost data, and a comprehensive breakdown of the unit costs and resource use was not provided. These factors make it difficult to apply the findings of this study to other
countries. The resource use and cost data were treated deterministically and no sensitivity analysis was undertaken. This means that the extent of uncertainty around the data was not considered. No price year was stated, which will prevent any future reflation exercises. Overall, the level of reporting for the cost analysis was limited.

Other issues
The authors did not present their results selectively and their conclusions reflected the scope of their analysis. They compared their findings with one other similar study and discussed the possible differences in drug costs between Finland and the UK.

Implications of the study
The authors did not make any recommendations for further research or changes to practice.

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