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 patient-controlled analgesia (PCA) for Chinese women in the first 24 hours following elective gynaecological surgery was compared with the use of intermittent intramuscular (IM) injection. A PCA machine delivered morphine intravenously by bolus, with a lockout time of 8 to 10 minutes. For IM treatment, the morphine doses were 0.1 - 0.2 mg/kg, with a maximum of 10 mg every 3 hours.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised Chinese women aged 18 to 72 years in the first 24 hours following elective gynaecological surgery. The exclusion criteria specified women who had a history of drug abuse, psychiatric disorder, or visual or motor disability.

Setting
The setting of the study was secondary care. The economic study was carried out at a teaching hospital in Hong Kong.

Dates to which data relate
The effectiveness data were collected from October 2000 to October 2001. Although the authors did report the date for the resources used, the data appear to have been collected during the same time as the study was conducted. 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 prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The authors stated that, from the results of another study (Cohen 1992, see 'Other Publications of Related Interest' below for bibliographic details), 64 patients per group were needed to determine a medium effect size of 0.5, at a power of 0.8 and a 0.05% significance level. Of the 150 patients approached, 17 (11%) did not complete the data.
The 125 patients had a mean age of 44.4 years (standard deviation, SD=9.20; age range: 14 - 72). Sixty-two were allocated to the PCA group and 63 to the IM group by computer-generated randomisation. There were no significant differences in the baseline characteristics of the patients.

**Study design**

The study was an unblinded, prospective, randomised controlled trial that was carried out at a single centre. The research assistant and ward staff were blinded to the research hypotheses, to reduce the influence of preconceived expectation. The patients were followed up for 24 hours. Assessments were performed 30 minutes after the patient arrived back in the ward, then every 2 hours for the first 4 hours, every 6 hours for the next 18 hours, and then at 24 hours. No loss to follow-up was reported. Prior to the study, a pilot study was conducted to modify some wording in the nursing activity chart and to amend the inclusion criteria.

**Analysis of effectiveness**

Although not explicitly stated, it appears that the basis for the clinical analysis was intention to treat. The health outcomes used were:

- the level of pain while at rest and during motion,
- the level of satisfaction with pain management,
- the amount of morphine used,
- side effects (i.e. the occurrence of nausea, vomiting, dizziness and itching), and
- the pain-related nursing time.

The level of pain was measured by using visual analogue scales (ranging from 0 to 100). The level of satisfaction with pain management was assessed using a patient satisfaction questionnaire.

**Effectiveness results**

The mean level of pain at rest was 15.84 points (SD=9.27) for the PCA group and 27.67 points (SD=16.44) for the IM group. The difference of 11.83 points (95% confidence interval, CI: 7.14 - 16.52) was significant, (p<0.001).

The mean level of pain during motion was 30.80 points (SD=14.96) for the PCA group and 42.53 points (SD=17.82) for the IM group. The difference of 11.73 points (95% CI: 5.96 - 17.50) was significant, (p<0.001).

The mean satisfaction level with pain management was 28.84 (SD=2.70) for the PCA group and 26.03 (SD=2.54) for the IM group. The difference of 2.81 (95% CI: 1.98 - 3.73) was significant, (p<0.001).

The total amount of morphine used was 45.65 (SD=27.96) for the PCA group and 22.35 (SD=11.56) for the IM group. The difference of 23.30 (95% CI: 15.82 - 30.78) was significant, (p<0.001).

Nausea occurred in 64.9% of the PCA group and 35.1% of the IM group. The difference of 29.8% (95% CI: 0.25 - 35.9) was significant, (p<0.003). In terms of the occurrence of vomiting, dizziness and itching, both groups were not significantly different.

**Clinical conclusions**

PCA was more effective than conventional IM injections after laparotomy for gynaecological surgery, although patients on PCA had more nausea.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. The study was, in effect, a cost-consequences analysis.

Direct costs
The total costs for pain management included those of pain-related nursing time, equipment and drugs used. The quantities and costs were estimated using actual data. Pain-related nursing time was recorded using a chart that was developed to identify the main type of pain-related nursing activities. The costs and the quantities were reported separately for all categories of costs. The quantity/cost boundary adopted was not reported. The costs were not discounted since the follow-up period was less than 2 years. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not reported.

Currency
Hong Kong dollars (HK$).

Sensitivity analysis
A sensitivity analysis was not performed.

Estimated benefits used in the economic analysis
Owing to the cost-consequences approach, please refer to the 'Effectiveness Results' section.

Cost results
The cost per patient was HK$81.10 higher for the PCA group than for the IM group (HK$939.44 versus HK$858.34).

Synthesis of costs and benefits
The costs and benefit were not combined as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Patient-controlled-analgesia (PCA) was more effective than conventional intramuscular (IM) injection after laparotomy for gynaecological surgery, although it was more costly.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. IM injection was routinely used in the authors’ setting. You should consider if this applies to your own setting.

Validity of estimate of measure of effectiveness
The study design involved a randomised approach, and the sample size was determined by a power calculation performed in another published paper. Hence, the effectiveness results derived in the clinical study are likely to be internally valid. The method of randomisation was reported and it appears to have been appropriate. The study groups
were comparable in terms of their demographics and baseline characteristics. The study sample was shown to be representative of the study population. Appropriate statistical analyses were performed to ensure the accuracy of the comparison.

**Validity of estimate of measure of benefit**
No summary measure of benefit was used in the study as a cost-consequences analysis was conducted. The reader is therefore referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The authors did not report the perspective adopted in the analysis. It appears, however, that most of the direct costs incurred by the health service have been included. The costs and the quantities were reported separately, which will enhance the generalisability to other settings. A statistical analysis of resources used and sensitivity analysis of the unit costs were not carried out. The price year was not stated, thus hampering any possible reflation exercises.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, and gave reasons for the differences among the findings. The issue of generalisability to other settings was discussed by comparing the findings with those from studies of patients undergoing other types of surgery. The authors did not present their results selectively and their conclusions reflected the scope of the study. The authors commented on the limitations of their analysis. For example, the absence of details on the type and duration of surgery may make it difficult to deal with potential confounding factors.

**Implications of the study**
The study implied that PCA was more effective than IM injection after laparotomy for gynaecological surgery, although it was more costly and patients had more nausea, because it resulted in a considerable gain in pain control and, hence, more patient satisfaction with pain management.

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**Other publications of related interest**


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