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
Nalbuphine and diphenhydramine in the treatment of intrathecal morphine-induced pruritus following Caesarean section.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients scheduled to undergo elective Caesarean section.

Setting
Hospital. The economic study was performed in Canada.

Dates to which data relate
It is not clear when the effectiveness and resource use data were collected. 1996 prices were used.

Source of effectiveness data
The evidence for final outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
Eighty ASA class I or II, patients scheduled to undergo elective Caesarean section. There were 40 patients in each of the two treatment arms: group NAL (nalbuphine) and group DIP (diphenhydramine). No power calculations were used to determine the sample size. Exclusion criteria included: contraindications to regional anaesthesia, non-elective surgery, current use of mood altering drugs and known allergy to any of the study medications.

Study design
The study was a randomized, double-blind, controlled clinical trial in a single centre. Patients were allocated to the two groups according to a computer-generated randomisation. All patients completed the study protocol. Assessment and treatment of pruritus and/or nausea and vomiting was carried out by nurses blinded to the patient group allocation and
treatment protocol.

**Analysis of effectiveness**
The analysis of the clinical study was based on intention to treat. The primary outcomes used were: the level of sensory block, and occurrence of intraoperative adverse events, including hypotension, nausea and vomiting, pruritus and pain. All patients completed the study protocol and demographic data were similar in the two treatment groups.

**Effectiveness results**
Ninety percent of patients in both treatment groups had postoperative pruritus; 66.7% of subjects in group NAL and 58.3% in group DIP requested treatment for this adverse event. There was no difference in the intensity of pruritus, as measured by visual analogue scale (VAS), in the patients requesting treatment in the two groups (NAL 5 +/- 2, DIP 5 +/- 2). Patients received an average of two doses for the treatment of pruritus in both study groups. The proportion of patients who achieved a VAS score of zero after treatment for pruritus was higher in group NAL than in group DIP (83% versus 43%, p<0.01). In addition, the change in VAS following treatment was greater when nalbuphine was administered (p<0.003). One patient in the NAL group and six patients in the DIP group failed to respond to the treatment protocol (4% versus 29%, p<0.04). There was no difference in the proportion of patients in each group who were sedated with anti-pruritic therapy; eight patients reported being sedated, three in the NAL group and five in the DIP group. None of these patients had respiratory depression nor were they difficult to arouse. Postoperative nausea and/or vomiting was observed in 62.5% of NAL-treated patients and 42.9% of DIP-treated patients (NS, p=0.31).

The overall incidence of nausea and/or vomiting among all study patients, including those not treated for pruritus, was 62.5%. No patient required supplemental postoperative narcotics for breakthrough pain, and no adverse events were seen in this study. A greater proportion of patients in the NAL group rated their pruritus treatment as being good to excellent (63% versus 33%, p<0.004).

**Clinical conclusions**
The authors found that nalbuphine was superior to diphenhydramine in the treatment of pruritus caused by intrathecal morphine given as analgesia after Caesarean section. A higher proportion of nalbuphine-treated patients had either greater or total symptom relief and fewer patients experienced treatment failure.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis and only separate outcomes were reported. Patient satisfaction was assessed by conducting a structured, questionnaire-based interview, 24-48 hours postoperatively. Patients were asked to rate their satisfaction with pruritus treatment and pain management on a four-point scale (excellent, good, fair, poor). They were also asked to rate their overall satisfaction with the quality of care provided, and were asked if they would elect to have the same anaesthetic again.

**Direct costs**
Only drug costs were considered and were based on the pharmacy provision cost of each medication as at April 1996. Resource quantities were reported separately.

**Currency**
Canadian dollars (Can$).

**Sensitivity analysis**
Not carried out.
Estimated benefits used in the economic analysis
A greater proportion of patients in the NAL group rated their pruritus treatment as being good to excellent (63% versus 33%, p<0.004). Pain relief was described as being good to excellent by all but one patient in both study groups. Nearly all patients were satisfied with the quality of care they received, and they unanimously said they would have the same anaesthetic again with the exception of one patient in the DIP group.

Cost results
Treatment of intrathecal morphine-induced pruritus with nalbuphine was associated with higher direct drug costs than with diphenhydramine, with a mean cost per patient of Can$6.4 (+/- 3.1) and Can$1.7 (+/-0.7), respectively, (p<0.0001).

Synthesis of costs and benefits
Although methodologically necessary, no synthesis of costs and benefits was performed.

Authors' conclusions
Nalbuphine was superior to diphenhydramine for the treatment of pruritus caused by subarachnoid morphine given during Caesarean section and its use was associated with a higher degree of patient satisfaction. There was a minor cost increment with the use of nalbuphine relative to the use of diphenhydramine for this indication, but this increment was easily justified given the patient response to treatment.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
No estimate of the measure of benefit was used in the economic analysis and only separate effectiveness results were presented. No synthesis of costs and benefits was presented although the authors concluded that the slightly higher costs associated with nalbuphine were justified by the patients' responses to treatment. No power calculations were used to determine the study sample size.

Validity of estimate of costs
Resource quantities were reported separately from prices but the cost perspective taken was very narrow; only drug costs were considered and other important cost items, such as labour costs, may therefore have been omitted (although the authors suggested these would have strengthened the relative cost-effectiveness of nalbuphine).

Other issues
Given the uncertainties in the data the authors' conclusions were justified. Appropriate comparisons were made with other studies.

Implications of the study
Further studies are needed in order to assess the cost-effectiveness of nalbuphine and diphenhydramine for the treatment of intrathecal morphine-induced pruritus.

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