The search for cost-effective prevention of postoperative nausea and vomiting in the child undergoing reconstructive burn surgery: ondansetron versus dimenhydrinate


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 ondansetron versus dimenhydrinate in the prevention of postoperative nausea and vomiting (PONV) among children with burns who were undergoing reconstructive burn surgery (RBS). The unit-dose of ondansetron was 0.1 mg/kg and the unit-dose of dimenhydrinate was 0.5 mg/kg. The first dose was administered intravenously, no more than 30 minutes before the end of the operation, while a second dose was administered 4 hours after the first.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children with burns who were undergoing RBS.

Setting
The setting was a hospital. The economic study was carried out in Shriners Hospitals for Children, Cincinnati (OH), USA.

Dates to which data relate
The dates relating to the effectiveness and resource data were not reported. 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 authors did not report whether the costing was carried out retrospectively or prospectively, or whether it was carried out on the same sample or a different sample of patients.

Study sample
No power calculations were used to determine the sample size, but power calculations were performed retrospectively using the existing sample size. Informed consent was required. Patients aged 2 to 25 years, who were undergoing RBS, were assigned by the pharmacy to either the placebo, ondansetron, or dimenhydrinate treatment group according to a randomised, double-blind protocol. From 104 patients enrolled in the study, 100 were studied. The placebo group consisted of 36 patients with an age of 11.3 (+/- 0.8) years. The ondansetron group contained 34 patients with an age of
11.0 (± 0.9) years. The dimenhydrinate group comprised 30 patients with an age of 13.1 (± 0.9) years. The authors did not provide any evidence that the initial study sample was appropriate for the clinical study question. Four patients were dropped from the study because of violations of study protocol or cancellation of their surgical procedures.

Study design
A prospective, randomised, double-blind placebo-controlled comparison trial was carried out at a single institution. The patients, evaluators, and investigators assessing the outcomes were blinded, and only the pharmacy was aware of the patients' allocation. The duration of follow-up was 8 hours after the surgical intervention. There was no loss to follow-up.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcomes assessed included preoperative anxiety, emergence delirium, the number of episodes of nausea, retching and vomiting, and the number of patients receiving rescue medication. A 4-point anxiety scale and a 4-point emergency scale were administered. The patients were also assigned a PONV score, according to the number of episodes of PONV experienced. The three groups were shown to be comparable in terms of the patients' age, weight, gender, history of previous PONV, perioperative narcotic dosing, use of intraoperative gastric suctioning, type and length of anaesthesia and surgery, preoperative anxiety, and emergence delirium, (p>0.05 for all comparisons among groups).

Effectiveness results
Patients who received ondansetron or dimenhydrinate had significantly less PONV and less postoperative vomiting than patients who received placebo, (p<0.05 for inter-group comparisons).

The incidence of PONV was reduced from 69% in the placebo group to 47% in the ondansetron group and 40% in the dimenhydrinate group.

Postoperative vomiting was reduced similarly, from 61% in the placebo group to 29% in the ondansetron group and to 40% in the dimenhydrinate group.

When ondansetron and dimenhydrinate were compared, there were no significant differences in the efficacy of preventing PONV, or in the effectiveness of preventing postoperative vomiting, (p>0.05).

There was no difference in the use of rescue medication among the groups, (p>0.05).

No adverse effects were noted in patients from any group.

Clinical conclusions
The results of the study showed that, for the study sample analysed, ondansetron and dimenhydrinate had the same efficacy in preventing PONV and postoperative vomiting in comparison with placebo.

Measure of benefits used in the economic analysis
No summary health benefit measure was used in the economic analysis. Therefore, a cost-consequences analysis was performed.

Direct costs
The costing was performed only on the costs associated with the drugs (costs to the pharmacy). Moreover, only the average drug acquisition cost per patient was considered. This figure did not include other costs of drug administration such as syringes, intravenous tubing, and preparation. The justification given for this was that these costs should be identical for the two drugs.
Discounting was not carried out, but it was irrelevant given the short time period considered. The quantities and the costs were not reported separately. The pharmacist at the hospital estimated the costs, therefore the cost estimation was derived from actual data. The price year was not given.

**Statistical analysis of costs**
No statistical analysis of the costs was reported.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The average drug acquisition cost per patient was estimated to be $0.90 for dimenhydrinate, and $19.34 for ondansetron.

**Synthesis of costs and benefits**
Not applicable due to the cost-consequences approach adopted.

**Authors’ conclusions**
Paediatric patients with burns who were undergoing reconstructive burn surgery (RBS), and who received dimenhydrinate or ondansetron, experienced significantly less PONV than patients who received placebo. Dimenhydrinate was as effective as ondansetron for the prevention of postoperative nausea and vomiting (PONV) and postoperative vomiting. Therefore, the two drugs were found to be of equal efficacy for the prevention of PONV, but dimenhydrinate was much less expensive.

**CRD COMMENTARY - Selection of comparators**
The comparators, ondansetron and dimenhydrinate, were justified on the grounds that studies have found them to be effective, but there were no differences between them in terms of the costs or the duration of time they have been used.

**Validity of estimate of measure of effectiveness**
The analysis used a single, randomised study, which was appropriate for the study question. The study sample appears to have been representative of the study population. The patient groups were shown to be comparable at analysis, (p>0.05 for all comparisons among groups). The date to which the effectiveness data related was not reported. The authors indicated that the fact that there were no differences among the groups in terms of the use of rescue medication, may have been due to the absence of fixed criteria for its use. This resulted in a higher percentage of patients receiving rescue drugs than the percentage of patients who actually experienced PONV in the ondansetron and dimenhydrinate groups. The study population was stated to be children undergoing RBS. Although the mean age within
each treatment group was around 11 to 13 years, patients up to 25 years of age were considered. There is some uncertainty as to whether patients as old as 25 years should have been considered as children for the purposes of the study.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
Only the costs of the drugs were considered in the analysis. Some other relevant direct costs were excluded because they were considered to be common to both alternatives. Therefore, these omissions are unlikely to have affected the authors’ conclusions. The costs and the quantities were not reported separately, but the resource quantities can be easily estimated (each patient received two doses of the allocated drug). However, the date to which the costs related and the price year were not reported, thus hindering reflation exercises to other settings.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. Some of the findings of other studies did not accord with their own findings, due to differences in the patient population studied. The authors did not address the issue of generalisability of their findings to other settings.

Implications of the study
The authors suggested that preoperative anxiety-reducing measures may be beneficial when used in conjunction with medications such as ondansetron or dimenhydrinate. Moreover, as dimenhydrinate (the cost-effective alternative) was found to reduce but not completely eliminate PONV, the authors suggested further investigation of different drugs, different doses, and different strategies for the alleviation of preoperative anxiety, in order to prevent PONV. They also recommended enumerating strict criteria for the administration of rescue drugs in future studies, so that they are used only with patients for whom the treatment is definitely not effective.

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Other publications of related interest


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