Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: a cost-effectiveness analysis

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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 use of intrathecal drug therapy (IDT) through a continuous analgesic delivery pump was compared with conventional pain therapies (CPT) in patients suffering from lower back pain caused by failed back syndrome. The drug administered through IDT was morphine. CPT comprised interventions such as oral medication, physiotherapy, chiropractic therapy, acupuncture, muscle relaxation techniques and behaviour modification.

Type of intervention
Palliative care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had suffered from chronic pain due to failed back syndrome and who had visited a multidisciplinary pain clinic where treatment with CPTs had failed to provide adequate pain relief.

Setting
The setting was secondary care. The economic study was conducted at Regina General Hospital (SK), Canada.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not specified. The price year was 2000.

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 sample of patients as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size were reported and no specific sample size was planned. A database of over 400 patients who were referred for a trial of spinal cord stimulation therapy was assessed. Of the database population, 88 patients failed to achieve satisfactory pain relief and were randomly divided into two groups. The two groups were then matched in terms of age, gender and number of operations undergone. The 44 patients assigned to group A received a trial bolus of intrathecal morphine in a double-blind fashion. Those who responded favourably received a further trial bolus of morphine to confirm long-term pain relief. The 44 patients assigned to group B
continued to receive CPT. In Group A, 21 patients were excluded from the study due to poor response, undesirable side effects (e.g. intolerable pruritus, persistent urinary retention, hallucinations, cold sweats, confusion or nightmares), or a patient’s unwillingness to accept the procedure. Thus, 23 patients were finally selected from group A to have a permanent pump implemented. The age and gender of the patients was not reported in the paper.

Study design
The study was a randomised controlled trial that was carried out in one centre (Regina General Hospital). The duration of follow-up was 5 years. The loss to follow-up was unclear for group A and not stated for group B. The method of randomisation was not reported in the study.

Analysis of effectiveness
The analysis of the clinical study was conducted on the basis of treatment completers only. The primary health outcomes were patient satisfaction and quality of life (QoL). The impact of IDT on the QoL of the patient, before implant and each year thereafter, was measured using the Oswestry Pain Questionnaire and visual analogue scale (VAS) evaluations. The patients were also offered another questionnaire in which they were asked about their satisfaction with the treatment, whether they would undergo a repeat procedure even if the initial procedure failed for some reason, and whether they would recommend this procedure to friends or relatives suffering from similar pain. The patients receiving CPT were also given the Oswestry Pain Questionnaire and VAS evaluations throughout the 5-year period. The results were then averaged and compared with the scores obtained from patients in group A. The groups were shown to be comparable in terms of the cause of pain, age and gender distribution.

Effectiveness results
Patients in group A experienced an improvement in disability of 27% averaged over a 5-year period, as measured using the Oswestry Disability Index, whereas those in group B achieved a mean improvement of 12%.

In group A, the mean 5-year VAS pain relief score was 61% (+/- 5.2). For those who were able to return to work, the mean VAS score was 72.3% (+/- 3.2).

The VAS pain relief scores for group B were not reported.

Of the patients in group A, 14 (60%) reported that they were very satisfied with the therapy, 6 (28%) reported that they were satisfied and only 3 (12%) reported they were unsure about the therapy.

The patients’ satisfaction was not collected for group B.

Clinical conclusions
The authors concluded that QoL considerations support the use of IDT.

Measure of benefits used in the economic analysis
No summary measure of benefit was derived. The study has therefore been classified as a cost-consequences analysis.

Direct costs
The resource quantities and the costs were reported separately. The cost calculations were undertaken from the point of view of the health service. The direct costs were divided into five categories. The equipment costs were obtained from the manufacturer’s price list for 2000 (Medtronics, Canada). The personnel costs were based on the 200 payment schedule of the Saskatchewan Medical Association and on the nursing union contract. The diagnostic costs were determined by the finance department of the Regina Health District. The hospitalisation costs were determined at the rate at which the Saskatchewan Government reimbursed Regina General Hospital in the year 2000 (i.e. $627 per day). The pharmacotherapy costs were calculated according to the Saskatchewan Health Formulary, allowing for a
predetermined mark-up schedule and a flat rate for dispensing. These costs were then tabulated and averaged for a 5-year period for each group. The costs were not discounted even though discounting was relevant (the costs were incurred during a 5-year period). The price year was 2000.

**Statistical analysis of costs**
The costs were treated deterministically. However, a pooled two-sample Student's t-test was undertaken to test the null hypothesis that the mean annual cost of CPT is higher than that of the mean annual cost of IDT. The analysis was conducted using statistical software (Minitab Inc.).

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

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

**Sensitivity analysis**
To investigate the generalisability of the results, a sensitivity analysis was carried out on variables considered to be sensitive. These included the cost of the pump, changes in the pump battery's life, and complications associated with surgery for IDT caused by infection or catheter displacement, occlusion, or fracturing. The authors also looked at the best- and worst-case complication scenarios and their impact on the treatment decision.

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

**Cost results**
The total annual costs per patient during the 5-year period were Can$29,410 for patients in group A (IDT) and Can$38,000 for patients in group B (CPT). The mean annual cost was Can$5,882 for group A and Can$7,600 for group B. The costs were compared statistically and a significant difference between the mean treatment costs of IDT and CPT was found, (p=0.028). The costs of adverse effects were included in these results.

**Synthesis of costs and benefits**
Not relevant as a cost-consequences analysis was carried out. The sensitivity analyses showed that a 50% increase in the pump cost would lead to a 24% increase in the total costs, and thus the recovery period would be lengthened to 33 months. In addition, if technology extended the life expectancy of the pump, a second pump may not be required within the 5-year period. Finally, if the costs of complications were decreased by 50%, the total costs would decrease by 7.9% and the recovery period would be shortened to 26 months. It is difficult to interpret how these findings would affect the treatment decision. The findings of the best- and worse-case scenarios showed that, even in the worst case with high complications, IDT was still the most cost-effective treatment choice.

**Authors' conclusions**
Intrathecal drug therapy (IDT) is a cost-effective method of treating non-malignant pain caused by failed back syndrome in patients who respond positively to an initial trial of IDT. This holds even when multiple complications may be involved. Additional benefits include an increased ability to work and an improved quality of life (QoL) with better pain control.

**CRD COMMENTARY - Selection of comparators**
Although no explicit justification was given for the comparator used, it would appear to represent current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population and the patient groups were shown to have been comparable at analysis. Although a randomised controlled trial was conducted and the groups were matched for patient age, gender and the number of operations undergone, to minimise confounding the outcomes were analysed for treatment completers only. Due to the nature of the analysis undertaken, attrition bias cannot be ruled out. In addition, the lack of information on the randomisation and matching procedure suggests that the internal validity of the study may be limited. The authors appear to have been selective in their reporting as they have failed to provide the effectiveness results for group B.

Validity of estimate of measure of benefit
No summary measure of benefit was derived since a cost-consequences analysis was conducted.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted appear to have been included in the analysis. The costs and the quantities were reported separately, thus enhancing the generalisability of the results to other settings. The unit costs were taken from a variety of sources, all of which were clearly reported. The price year was given as 2000, thus aiding any future reflation exercises. The rate at which Regina General Hospital is reimbursed by the Government of Saskatchewan was used as a proxy for the hospitalisation costs. The authors did not discount either the costs or health benefits, even though this would have been appropriate since the costs were incurred during a 5-year period.

Other issues
The authors made appropriate comparisons of their findings with those from other studies and addressed the issue of generalisability to other settings. In addition, they pointed out that the costs in Canada are lower than elsewhere due to pricing differences from the manufacturer and the fee schedules of provincial and federal governments. However, as this applies to both study groups, the authors' conclusions remain valid. The authors also pointed out that the length of hospitalisation in the province of Saskatchewan is longer because of its socialised pattern of medicine, its sparse population which means the patient is obliged to travel long distances to receive treatment, and the lack of a supportive infrastructure. This factor biases the results in favour of CPTs. However, as the age and gender of the study sample were not stated, this may hamper generalisability to other settings.

It was unclear if the authors presented their results selectively since the study focused on treatment completers only, the loss to follow up was at best unclear, and the authors did not describe the study sample appropriately. A further limitation of this study was that the authors did not assign a monetary value to the degree of pain relief, the ability to return to work, or an improved QoL. If these had been taken into consideration, the payoff from IDT may have been even greater. The authors acknowledged that, ideally, patients in group B would have undergone surgery to implant the pump and would have received an infusion of saline as placebo. However, this would have been an unethical and morally unacceptable solution, as the patients would have undergone a surgical procedure specifically designed not to benefit the patient.

Implications of the study
The authors recommended a better understanding of the long-term cost implications of IDT, compared with CPT, which would lead to a more effective allocation of scarce health care resources.

Source of funding
None stated.
Bibliographic details

PubMedID
12405366

DOI
10.3171/jns.2002.97.4.0803

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Analgesics, Opioid /administration & dosage; Back Pain /drug therapy /economics; Canada; Chronic Disease; Cost-Benefit Analysis; Drug Utilization; Female; Follow-Up Studies; Humans; Infusion Pumps /economics; Injections, Spinal /economics; Male; Morphine /administration & dosage; Practice Patterns, Physicians'; Quality of Life

AccessionNumber
22002001831

Date bibliographic record published
31/03/2004

Date abstract record published
31/03/2004