Cost-effectiveness of long-term intrathecal morphine therapy for pain associated with failed back surgery syndrome


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
Use of intrathecal morphine therapy (IMT) administered via an implantable pump in patients suffering from intractable pain attributed to failed back surgery syndrome.

Type of intervention
Treatment and supportive care.

Economic study type
Cost-effectiveness analysis.

Study population
Hypothetical cohort of patients suffering from intractable pain attributed to failed back surgery syndrome.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness data were obtained from studies published between 1985 and 1994. No dates were specified for the resource use data (a detailed list or representative pattern was reported to have been developed). The price year was 1994.

Source of effectiveness data
Effectiveness data were derived from a literature review and estimates based on clinical opinion.

Modelling
A decision analytic model in SmilTree was constructed to project outcomes for a simulated cohort of 1000 patients, to estimate the costs, and to perform a sensitivity analysis in a time frame of 60 months. A panel of experts devised scenarios representing the treatment pathways in a Monte Carlo simulation.

Outcomes assessed in the review
The review assessed rates of minor and major post-surgical complications, minor and major long-term complications, decision to discontinue IMT therapy, and the median pump life of an IMT device.

Study designs and other criteria for inclusion in the review
Studies on IMT in cancer patients were pooled with those for failed back surgery syndrome and an analysis of returned product data for pump failure rates by the manufacturer. No further information was given regarding the designs of the studies included in the review.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
No judgement criteria were reported. The original raw data from three studies were reported.

Number of primary studies included
A total of five studies were included in the review.

Methods of combining primary studies
The mean of observed event rates was used in the base case with lowest and highest reported rates for best-case and worst-case scenarios.

Investigation of differences between primary studies
Differences between the IMT studies in terms of the description of complication events, patient characteristics, and duration of follow-up were reported to have existed.

Results of the review
The mean annual event rates (best case, worst case) were as follows:

- 37% (5.4%, 44%) for minor post-surgical complications;
- 2.7% (1.4%, 5.4%) for major post-surgical complications;
- 8.7% (4.4%, 17.4%) for minor long-term complications;
- 7.2% (4.5%, 11.8%) for major long-term complications;
- 3.1% (1.6%, 6.2%) for decision to discontinue IMT therapy; and
- median pump life was 48 months.

These were the principal effectiveness input parameters used in the model.

Methods used to derive estimates of effectiveness
Assumptions were also made by the authors based on clinical opinion.

Estimates of effectiveness and key assumptions
Adverse event rates were assumed to remain constant over the 60-month period of the model. Furthermore, in the model, a patient whose pump fails before month 60 receives a replacement pump (posing a risk of post-surgical
comparisons).

**Measure of benefits used in the economic analysis**
The efficacy of IMT as measured by the proportion of patients achieving "good to excellent" pain relief was the benefit measure used in the analysis. Expected months of pain relief over a 60-month period were calculated.

**Direct costs**
Costs were discounted. Some quantities were reported separately from the costs, and all cost components were reported separately. Cost analysis for IMT therapy covered the costs of professional fees and hospital charges for cost items of screening evaluation, initial implant, minor complications, major complications, ongoing therapy (including pump refill and supplement medication), pump replacement, and explant pump. The corresponding cost analysis for alternative (medical) therapy for a hypothetical patient eligible for IMT covered the costs of medication, hospital admission (unscheduled) for uncontrolled pain, emergency room visits for breakthrough pain, physician office visits, passive physical therapy, chiropractic, nerve blocking agent, psychiatrist/psychologist, and biofeedback. The perspective adopted in the cost analysis was that of the third party payer.

The source of resource use data was a detailed list for the IMT therapy and representative pattern of care for the alternative (medical therapy). The main sources of cost data were an analysis of billing data plus different state-wide and nation-wide reports and studies. Fee-for-service billed charges were used for base-case calculations, while low (65% of the base case) and high (135% of the base case) charges employed in sensitivity analyses represented Medicare or managed care payment rates and relatively costly components, respectively. 1994 price data were used. The cost analysis did not cover the costs of repeated surgery.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-way sensitivity analyses were conducted on all parameters of the model by varying their values across low to high ranges to assess the effects on projected total cost (elasticity values were calculated). Analyses of extremes were performed based on best case, worst case scenarios.

**Estimated benefits used in the economic analysis**
Based on a mean (best case, worst case) IMT efficacy rate of 0.73 (0.81, 0.65), the expected duration of pain relief was 43.8 (48.6, 39) months. The corresponding value for the conventional medical therapy was assumed to be 0.

**Cost results**
The discount rate was 5%. The mean (best case, worst case) total cost over 5 years was $82,186 ($53,468, $125,102) for IMT therapy versus $85,186 ($85,186, $85,186) for the alternative medical therapy.

**Synthesis of costs and benefits**
The incremental cost per year of pain relief was calculated as the measure of cost-effectiveness analysis, leading to a value of -$624 (-$7,832 best case and $12,276 for worst case). The sensitivity analyses established the general robustness of the results to alterations in parameter values, with identification of the cost of the pump/catheter implant, ongoing monthly expenses for therapy, and pump replacement as the most sensitive factors of the model with an
elasticity value of about 20%.

**Authors’ conclusions**
Results from a computer simulation designed to collect the costs not included in previous empirical research indicated that IMT appeared to be cost-effective when compared with alternative (medical) management for selected patients when the duration of therapy exceeds 12 to 22 months.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator. It was regarded as the conventional therapy in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

**Validity of estimate of measure of benefit**
The internal validity of the estimate of benefit can not be reasonably guaranteed, as acknowledged by the authors, due to the paucity of data on the complications of IMT as well as inconsistent reporting in the published literature. It was further noted that there was a general lack of information on the course of intractable pain and the effectiveness of modalities other than IMT. These issues, coupled with high levels of heterogeneity in the patient characteristics in different studies and the varying degree of follow-up, require that some caution be exercised in the interpretation of the study results. Furthermore, it is not exactly clear why the authors considered a benefit of zero (0 month of pain relief) for the comparator; this is probably methodologically unsound.

**Validity of estimate of costs**
Some quantities were reported separately from the costs. Adequate details of methods of cost estimation were given. Regarding the internal validity of the cost results, the authors noted that the estimates of costs for alternative (non-IMT) therapy were based on anecdotal evidence, and actual patterns of care varied widely. Charge data were used rather than of true costs. The cost analysis did not cover the indirect costs incurred by the patients or society at large.

**Other issues**
The authors’ conclusions appear to be justified given the extensive sensitivity analyses performed. The issue of generalisability to other settings or countries was addressed by performing sensitivity analysis. Appropriate comparisons were made with other studies.

**Implications of the study**
The authors stated that, as no standard protocol exists for screening candidates for IMT, research is needed to establish optimal patient selection criteria. Cost of illness studies should review expenditures over time in relation to the level of distress or impairment, while also documenting the impact of indirect cost-related factors (such as employment status and economic effects on other members of the household).

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