Painful procedures in children with cancer: comparison of moderate sedation and general anesthesia for lumbar puncture and bone marrow aspiration

Iannalfi A, Bernini G, Caprilli S, Lippi A, Tucci F, Messeri A

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 either moderate sedation or general anaesthesia for children undergoing lumbar puncture or bone marrow aspiration.

Moderate sedation consisted of either premixed nitrous oxide (50%) and oxygen (50%) or intravenous midazolam (0.1 mg/kg for children weighing less than 15 kg and 0.05 mg/kg for those weighing more than 15 kg), or a combination of both these methods. In some cases, moderate sedation was accompanied by non-pharmacological techniques.

General anaesthesia consisted of one or more of the following: nitrous oxide (50% in oxygen), intravenous midazolam (0.2 to 0.5 mg/kg), fentanyl (1 to 2 microg/kg), intravenous S(+)-ketamine (0.25 to 1 mg/kg), and 2% to 4% sevoflurane in oxygen.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children (aged 16 years or younger) undergoing lumbar puncture or bone marrow aspiration.

Setting
The setting was tertiary care. The economic study was carried out in Florence, Italy.

Dates to which data relate
The effectiveness and resource use data related to the period between September and December 2003. No price year was reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data were collected from the same patient sample that provided the effectiveness evidence. The paper did not report whether the data collection was prospective or retrospective.
Study sample
Thirty-one children undergoing 65 procedures were included in the study. Fourteen children underwent 30 procedures with moderate sedation, while 17 children underwent 35 procedures under general anaesthesia. No sample size or power calculations were described in the paper. There were also no details of how the patient sample was selected, although the authors stated that random enrolment was undertaken.

Study design
The study appears to have been a single-centre, randomised controlled trial, although no details of randomisation methods were reported. The patients were followed up until they recovered from the procedure, so no loss to follow-up was reported. The oncologist undertaking the procedure was blinded to the sedation method.

Analysis of effectiveness
The primary health outcomes were:

- the observed side effects,
- the use of antagonists,
- the recovery time, and
- the oncologist's assessment of difficulty due to sedation on a scale of 1 (minimum difficulty) to 1.2 (maximum difficulty).

The child's (if aged 6 years or older) and parent's perceptions of the procedure were assessed through a questionnaire using 4-point scales. A Procedure Behaviour Check List (PBCL) was completed by an independent observer. This recorded muscle tension, screaming, crying, restraint needed, verbalised pain and anxiety, and physical resistance. No differences in the baseline characteristics of the two patient groups were reported. The authors provided demographic data (by procedure) for the total study sample.

Effectiveness results
The mean recovery time was 43 minutes (range: 36 to 51) for patients who received moderate sedation and 115 minutes (range: 97 to 137) for those who received general anaesthesia, (p<0.05).

There were no statistically significant differences in side effects (7.1% in the moderate sedation group versus 8.6% in the general anaesthesia group) or the use of antagonists (0% in the moderate sedation group versus 2.9% in the general anaesthesia group).

There was no statistically significant difference in the assessment of the procedure by the oncologist (1 for the general anaesthesia group compared with 1.2 in the moderate sedation group).

There were no statistically significant differences between the two patient groups in the results of the parent's perception questionnaire, the child's perception questionnaire, or the PBCL.

Clinical conclusions
The authors concluded that moderate sedation compared favourably with general anaesthesia during lumbar puncture and bone marrow aspiration.

Measure of benefits used in the economic analysis
No measure of health benefit was combined with the cost data. In effect, a cost-consequences study was undertaken.
Direct costs
The costs of the hospital were identified in this study. These included drug costs and professional resources. Additional inclusions were the cost of anaesthesiologist and nurse of the Pain Unit for the general anaesthesia strategy, and the cost of the training programme to have sedation performed by a non-anaesthesiologist for the moderate sedation strategy. The resource use data were obtained from the trial that provided the clinical effectiveness evidence. The source of the unit costs was not provided in the paper, nor was a breakdown of resource use and unit costs. No price year was reported.

Statistical analysis of costs
The cost data were treated deterministically.

Indirect Costs
No indirect costs were included in the study.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were undertaken.

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

Cost results
The total costs were $75.82 per procedure (assuming 100 procedures) when using moderate sedation and $101.00 per procedure (assuming 100 procedures) when using general anaesthesia.

Synthesis of costs and benefits
Not relevant.

Authors’ conclusions
Moderate sedation compared favourably with general anaesthesia in terms of safety, patient and clinician experience, and costs for children undergoing lumbar puncture or bone marrow aspiration.

CRD COMMENTARY - Selection of comparators
This study compared moderate sedation with general anaesthesia for lumbar puncture and bone marrow aspiration in children. The authors did not provide any rationale for their choice of treatments, but these may not be the only sedation options for these procedures. You should consider how these options compare with usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The measure of clinical effectiveness was taken from a single study. The study appears to have been a randomised controlled trial, although limited reporting of study design methodology makes it difficult to ascertain whether a true randomisation process was undertaken. The trial comprised three groups of patients (moderate sedation alone, moderate sedation with non-pharmacological therapy, and general anaesthesia). However, for analysis purposes, the patients who
received moderate sedation were treated as one group. This means that not all patients in the moderate sedation group received the same treatment. This may limit the validity of the study results.

No power or sample size calculations were reported in the paper. Therefore, given the relatively small sample size (31 children), it is unclear whether the study had sufficient power to identify differences between the two sedation methods. The authors did not compare their study sample with the wider population of children undergoing lumbar puncture or bone marrow aspiration, and it was unclear whether their study sample was representative of this wider group.

**Validity of estimate of measure of benefit**
No measure of health benefit was used in the economic analysis. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The paper did not state the perspective adopted in the study, but a hospital perspective appears to have been used. All appropriate costs appear to have been included for this perspective. No breakdown of resource use and unit costs was reported, nor was the source of the unit costs. No sensitivity or statistical analysis of the cost or resource use data was undertaken. This means that the extent of uncertainty around the figures reported in the paper was not considered. These factors limit the generalisability of the study findings. In addition, no price year was reported, which will prevent any future reflation exercises. Overall, the reporting of the costing was limited and greater detail would have enhanced the quality of the paper.

**Other issues**
The authors do not appear to have presented their results selectively. Their conclusions reflected their analysis, although they did not acknowledge the level of uncertainty around the study results. The authors did not consider how their findings could be generalised to other settings.

**Implications of the study**
The authors did not make any direct recommendations for changes to practice or for further research.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
16106428

**DOI**
10.1002/pbc.20567

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Analgesics, Non-Narcotic; Anesthesia, General /methods; Bone Marrow Examination /methods; Child; Child,