Efficacy, safety, and cost of intravenous sedation versus general anesthesia in children undergoing endoscopic procedures

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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
Intravenous sedation of general anesthesia in children undergoing endoscopic procedures.

Type of intervention
Anaesthesia.

Economic study type
Cost-effectiveness analysis.

Study population
Patients under 18 years undergoing an endoscopic procedure.

Setting
Hospital. The economic study was performed in Dallas, Texas, USA

Dates to which data relate
Effectiveness and cost data were assessed for patients admitted for endoscopy between January and December 1990.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
Costing was not undertaken for the same sample of patients and was completed retrospectively.

Study sample
All patients aged between 1 month and 18 years who underwent endoscopic procedures in either the gastroenterology laboratory (GIL) or the operating room (OR) at the Children’s Medical Centre of Dallas between January and December 1990.

There was no randomisation procedure between general anaesthesia and intravenous sedation. 226 patients were analysed in total: 103 (46%) received IV-S in the gastroenterology laboratory and 123 (54%) received GA. The sample size was not determined by power calculation.

Study design
This was a single centre non-randomised trial with concurrent controls. The duration of follow-up was not stated. The patients were allocated to either general anaesthesia or intravenous sedation by the attending gastroenterologist.

**Analysis of effectiveness**
Primary outcomes used in the study were:

(a) the dose of intravenous sedation required,
(b) the heart rate before, during and after the procedure,
(c) the sedation level determined by the Relative Adequacy Scale,
(d) the procedure room time.

The patient age groups were not analysed for comparability in sex distribution of children or for relative sizes of groups.

**Effectiveness results**
Midazolam and meperidine were used for intravenous sedation. The mean dosage of midazolam given to patients between 6 and 9 undergoing oesophagogastroduodenoscopy was significantly higher than that given to children under 2 or over 10 (0.1mg/kg <2 years, 0.15mg/kg 6 to 9 years, 0.11mg/kg >10 years; p<0.05). The mean dosage of meperidine given to patients from 3 to 5 and 6 to 9 years undergoing oesophagogastroduodenoscopy was significantly higher than that given to children under 2 and over 10 years (1.5mg/kg <2 years, 2.3mg/kg 3 to 5 years, 2.4mg/kg 6 to 9 years, 1.8mg/kg >10 years; p<0.5). Doses of meperidine and midazolam given to the children undergoing colonoscopy were not significantly different in any age group.

No significant differences in heart rate were reported within similar age groups during procedures. Heart rates before and after procedures were significantly higher in the under 2 years group given intravenous sedation than in those given general anaesthesia (156 beats/minute before and 153 beats after in the intravenous sedation group, versus 138 beats/minute before and 135 after in the general anaesthesia group; p<0.01).

The Relative Adequacy Scale (RAS) was constructed to assess the patients’ arousal and cooperation during intravenous sedation only on a scale of 1 (asleep throughout the procedure) to 6 (unable to complete the procedure despite extra medication and nursing assistance). From 103 procedures, 90 (87%) were performed without the need for additional nursing support (RAS<=4).

The mean procedure room time was longer for patients under 2 and from 6 to 9 years who had oesophagogastroduodenoscopy under IV-S than those under GA (75 versus 44 minutes <2 years; p<0.01 and 84 versus 58 minutes 6 to 9 years; p<0.01). No statistically significant differences were noted between procedure room times for patients undergoing colonoscopy.

**Clinical conclusions**
Satisfactory sedation can be achieved in all age groups in a majority of patients using IV-S. Higher doses of medication may be required in children from 3 and 9 years.

**Measure of benefits used in the economic analysis**
No specific outcome measure was used for the economic analysis. The quality of anaesthesia or sedation was judged by direct measurement of the Relative Adequacy Scale for IV-S only, heart rate of the patient before, during and after the procedure, and the procedure room time.

**Direct costs**
A random sample of hospital charges to patients undergoing comparable procedures in the gastroenterology laboratory or the operating room was reviewed. These charges did not include gastroenterologists’ or pathologists’ fees.

**Currency**

US dollars ($)

**Sensitivity analysis**

Not included.

**Estimated benefits used in the economic analysis**

The safety of GA and IV-S were considered to be the same under the conditions and protocols used in the study.

**Cost results**

Average charges were estimated to be $768.52 in the IV-S group and $1,965.42 in the GA group.

**Synthesis of costs and benefits**

The IV-S strategy seemed to be dominant.

**Authors’ conclusions**

Charges to the patient were substantially lower when procedures were performed with well-monitored IV-S than when they were performed under GA. Further studies were called for, in order to assess whether other drug combinations used for IV-S are more effective and to carry out more complete endoscopic cost procedure analysis.

**CRD Commentary**

The analysis was based on an observational study of consecutive paediatric patients who were admitted for endoscopic procedures in 1990. Since patients were not randomised to receive either general anaesthetic or intravenous sedation, there is no control of confounding factors and the extent to which professional bias may have influenced the judgement of the gastroenterologist who assigned treatments is not clear.

At the authors’ own admission, no details were provided on the breakdown of costs (including discounting, prices, etc.) and it was not clear to what extent the random sample of hospital charges to patients undergoing comparable procedures related to the patients studied. Also, there was no clear connection made between cost and effect since the overall quality of anaesthesia was not assessed in the same way for both groups.

**Implications of the study**

A well designed RCT with adequate cost information, directly comparing intravenous sedation with general anaesthesia in paediatric patients undergoing endoscopic procedures, is needed in order to substantiate such claims.

**Source of funding**

None stated

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