Sedation versus no sedation in the performance of diagnostic upper gastrointestinal endoscopy: a Canadian randomized controlled cost-outcome study

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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 diagnostic upper gastrointestinal oesophagogastroduodenal endoscopy (EGDE) with sedation was considered. It is the most commonly performed endoscopy, with an incidence of about 8.6 per one thousand population. In Canada it represents 51 to 65% of all gastrointestinal endoscopic procedures performed in teaching hospitals.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a racially and ethnically diverse outpatient population from a large metropolitan Canadian city. The population was identified from the outpatient endoscopy list at Montreal General and Royal Victoria Hospitals, from 1999 to 2002. The following inclusion criteria were fulfilled by all potential participants:

- the patient was of legal age;
- they had no other significant cardiorespiratory or medical co-morbidities precluding their participation (i.e. they were deemed able to tolerate routine sedation);
- they had no known documented allergy to lidocaine anaesthetic spray; and
- they had no anticipated need for antibiotic coverage or therapeutic endoscopic intervention.

The exclusion criteria included a low baseline oxygen saturation (below 85% on room air), significant pre-existing respiratory co-morbidity, emergency procedures, and an American Society of Anesthesiologist physical status classification (ASA score) greater than 4 (suggesting severe systemic disease). Also excluded were patients with documented drug dependence or a documented oropharyngeal swallowing disorder.

Setting
The setting was secondary care. The economic study was carried out in McGill University Health Center, Canada.

Dates to which data relate
The effectiveness data were gathered prospectively between 1999 and 2002. The resource use and cost data were obtained from an activity-based approach study that ran concurrently with this randomised controlled trial (Crott et al. 2002, see ‘Other Publications of Related Interest’ below for bibliographic details). The price year was not reported.
Source of effectiveness data
The evidence was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used for the effectiveness analysis.

Study sample
The sample size necessary to detect the smallest possible difference in the main outcome was calculated. The results suggested that a sample of 419 patients was needed to detect a difference as small as 10% in patient satisfaction with a Type I error of 0.05 and a power of 85%. A total of 210 patients were allocated to the active group and 209 to the placebo group.

Study design
This study was a multi-centre, double-blind, placebo-controlled randomised trial. The patients were randomised in blocks of 20 by a computer-generated randomisation list that had been produced by an independent bio-statistician. Concealment of allocation was respected by a non participating nurse. The follow-up period was 24 hours after the procedure.

Analysis of effectiveness
The basis of the analysis was intention to treat. The primary health outcome was "successful endoscopy". The secondary outcomes included:

- patient satisfaction alone,
- recovery room time,
- technical adequacy of the procedure,
- the time spent by a patient in a monitored recovery room, and
- the patients' willingness to repeat the procedure under the same conditions.

Clinical factors were assessed to ensure equal distribution between the study groups. More specifically, demographic characteristics (gender, age, level of education, and cultural background), life style (smoking, alcohol use), prior experience with endoscopy, expectations of endoscopy, and pharyngeal sensitivity of the patient. The latter was observed by the endoscopist during the application of topical anaesthetic spray and the administration of open-labelled active medication.

To eliminate the use of pharyngeal anaesthesia as a potential confounder of successful endoscopy, all patients received pharyngeal anaesthesia with titrated doses of xylocaine spray in a standardised fashion, to emulate a "real life clinical setting". The endoscopists' impression of sedation status was recorded at the end of the procedure prior to unblinding, so that it could also be measured as a potential confounder.

There was an equal gender distribution (52% female) between the two groups, and the majority of the participants were Caucasian (86%). Forty-nine per cent had a prior history of ECDGE experience, and 74% had positive expectations of their upcoming endoscopic examination. Overall, the baseline characteristics were similar between the two treatment arms.

Effectiveness results
Overall, 61% of EGDE procedures were successful (76% active versus 46% placebo). The unadjusted odds ratio (OR) was 3.77 (95% confidence interval, CI: 2.5 - 5.7).
For the sub-group of patients above 75 years of age, the proportion of patients with successful endoscopy was greater in the unsedated arm (n=30) than in the sedated arm (n=23) (63% placebo versus 57% active; OR 0.75, 95% CI: 0.25 - 2.29). However, this result was not statistically significant.

There was no statistically significant difference between the two groups in terms of the endoscopist’s objective assessment of technical adequacy.

Patient satisfaction was 79% in the sedated arm versus 47% in the placebo arm. Among patients aged over 65 years (n=124), satisfaction was rated 73% in the sedated arm versus 54% in the unsedated arm (OR 2.20, 95% CI: 1.07 - 4.9). Among patients aged over 75 years (n=53), satisfaction was rated 67% in the sedated arm versus 63% in the unsedated arm (OR 1.16, 95% CI: 0.36 - 3.7).

Patients randomised to sedation were more likely to agree to repeat their procedure under similar test conditions (81% active versus 65% placebo; OR 2.4, 95% CI: 1.5 - 3.8).

Those patients who had received active medication spent significantly more time in the recovery room (28.9 minutes, standard deviation, SD=16.0) than those who had undergone an unsedated procedure (14.5 minutes, SD=13.7), (p<0.001).

Clinical conclusions
The results of the study indicated that sedated endoscopy remains the most efficacious strategy, as it increases clinical efficacy.

Measure of benefits used in the economic analysis
The main benefit considered in the economic analysis was the number of successful endoscopies. This was defined as a composite score of patient satisfaction (with the procedure) and quality of the examination (technical adequacy) as assessed by the operator. These were determined by the administration of standardised Likert scales.

Direct costs
The cost/quantity boundary adopted was that of the health service. Broad expenditure items included capital expenses for equipment (annualised over their economic lifespan), repair and maintenance costs. Also included were hospital overhead costs, which were grouped by administrative activities, clinical medical support activities, and technical repair and maintenance activities. Physician reimbursement fees for biopsy analysis and the professional fee for the endoscopist were not included, as they would have been identical in both groups. Discounting was not relevant because of the short follow-up period. No price year was reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
No indirect costs were included in the study.

Currency
Canadian dollars (Can$).

Sensitivity analysis
The authors investigated variability in the data. A one-way sensitivity analysis was performed to explore variability in the clinical probabilities of successful endoscopy. The total change in percentage of successful endoscopy was varied
over a range of 10% from the base-case estimate.

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

**Cost results**
The total cost for unsedated endoscopy was Can$103.09, compared with Can$130.11 for the sedated procedure.

**Synthesis of costs and benefits**
For every additional successful endoscopy with sedation, one must spend Can$90.06 (95% CI: 69.03 - 126.38).

The unsedated strategy became dominant in patients older than 75 years. Thus, for each additional unsedated procedure performed, there were cost-savings of Can$450.00 (95% CI: -80.85 - 136.53).

For each additional satisfied patient scoped under sedated conditions, you must spend Can$84.44 (95% CI: 66.37 - 116.42).

When stratified by age, the cost of an additional sedated procedure increased with advancing age to Can$142.21/additional sedated procedure in patients older than 65 years (95% CI: -76.37 - 1,211.66) and Can$675/additional sedated procedure in patients older than 75 years (95% CI: -116.47 - 90.49).

The cost to ensure an additional patient is willing to repeat their procedure under sedated test conditions was Can$168.88 in all comers (95% CI: 106.64 - 335.65), Can$168.88 in patients above 65 years (95% CI: -6,928.21 - 84.73), and Can$300.22 in patients above 75 years (95% CI: -143.95 - 72.83).

When the proportion of successful endoscopies (active-placebo) was varied to be 30% and 20% in the sensitivity analysis, the incremental costs per additional successful endoscopy with sedation were Can$67.11 (95% CI: 55.40 - 85.10) and Can$133.37 (95% CI: 91.94 - 241.25), respectively.

**Authors' conclusions**
For the primary outcome of successful endoscopy, although sedated diagnostic oesophagastroduodenal endoscopy (EGDE) is more costly, it remains the most efficacious strategy by increasing clinical efficacy. This conclusion may differ for elderly patients in whom an unsedated strategy may dominate.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The authors chose placebo as a comparator for the sedation group so as to evaluate standard clinical practice when performing EDGE.

**Validity of estimate of measure of effectiveness**
This clinical study was a double-blind, randomised controlled trial that assigned patients to sedation versus placebo. It appears to have been reasonably well conducted, so bias should be at a minimum. Appropriate statistical analyses were conducted and the results were clearly presented. The measures of effectiveness adopted by the authors were successful endoscopy, patient satisfaction alone, recovery room time, technical adequacy of the procedure, the time spent by a patient in a monitored recovery room, and the patients' willingness to repeat the procedure under the same conditions. These appear to have been valid measures of effectiveness.

**Validity of estimate of measure of benefit**
The main benefit considered in the study was the number of successful endoscopies. This appears to have been a valid
measure of benefit. However, this variable was constructed on the basis of a 5-point Likert scale, and ceiling and floor effects could hamper its discriminatory ability.

Validity of estimate of costs
Given the study perspective, it appears that the relevant cost categories have been included. There was little detail on the costing methods, as the authors referred to another paper (Crott et al. 2002) for a more detailed description of the costing exercise.

Other issues
The authors made extensive and detailed comparisons of their findings with those from earlier research. Their conclusions conformed to a prior trend of comfortable and technically adequate, unsedated diagnostic EDGE. The authors acknowledged that they were unable to guarantee blinding of the endoscopist to the randomisation group in all cases. In addition, that the study was conducted in an academic tertiary centre, which might affect the generalisability of the findings to other settings, and that the lack of an accepted biometric tool could hamper the ability to assess patient satisfaction. Also, the summary measure of benefits was specific to gastrointestinal endoscopy. This means that it is difficult to make comparisons with other studies and technologies necessary to help decision-makers in the allocation of resources.

Implications of the study
The results of the study supported the recommendation of sedated diagnostic EDGE, except for elderly patients in whom an unsedated strategy may dominate. This area merits future research with a larger number of elderly patients required to confirm this exploratory result.

Source of funding
None stated.

Bibliographic details

PubMedID
15330904

DOI
10.1111/j.1572-0241.2004.40157.x

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Confidence Intervals; Conscious Sedation /methods; Double-Blind Method; Endoscopy, Gastrointestinal /methods; Female; Gastrointestinal Neoplasms /diagnosis /epidemiology; Humans; Male; Middle Aged; Odds Ratio; Pain Measurement; Patient Satisfaction; Probability; Quebec /epidemiology; Reference Values; Risk Assessment

AccessionNumber
22004001204

Date bibliographic record published
31/12/2005

Date abstract record published
31/12/2005