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

Sedation with ketamine or midazolam in children with small, simple, facial lacerations. Ketamine was given intramuscularly, whereas midazolam was administered either per rectum or intranasally.

Type of intervention

Treatment.

Economic study type

Cost-effectiveness analysis.

Study population

Children with small, simple, facial lacerations. A simple facial laceration was defined as a laceration of 2.5cm or less that required sutures but which did not cross the vermilion border of the lip or the lid margin of the eye and that did not prompt a facial surgery consult. In addition, patients with bite wounds, intraoral wounds, those with multiple lacerations, and those evaluated for other injuries were excluded. This definition was used because the need for sedation in this group of patients would probably be optional and would be performed at the discretion of the treating physicians.

Setting

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

Dates to which data relate

Effectiveness and resource use data corresponded to patients seen in the ED between May 1994 and December 1995. The price year was not explicitly specified.

Source of effectiveness data

The evidence for final outcomes was based on a single study.

Link between effectiveness and cost data

Costing was retrospectively conducted on the same patient sample as that used in the effectiveness analysis.

Study sample

Power calculations were not used to determine the sample size. The sample consisted of 152 charts for patients who met the inclusion criteria, of whom 38 patients (mean (SD) age of 25 (10) months) received midazolam, 14 (mean (SD) age of 29 (11) months) were given ketamine, and 100 (mean (SD) age of 28 (12) months) were given no sedation for the
repair of a simple facial laceration.

**Study design**
Retrospective cohort study, carried out in a single centre. The duration of the follow-up appears to have been until discharge. Loss to follow-up was not reported. Midazolam and ketamine were the sedative agents commonly used by physicians in the authors' ED when sedation was required. Eligible patients were identified by a computerised search of billing records.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness (intention to treat or treatment completers only) was not explicitly specified. The health outcome measure was patient time in the ED (time from placement into an examination room until discharge). The three groups were comparable in terms of age, sex, and the length of the wound. Patients receiving ketamine were more likely to have a layered repair. An analysis of the ketamine patients with and without layered repair was performed.

**Effectiveness results**
The mean (SD) patient time in the ED was significantly longer for those given ketamine, 149 (37) minutes (p<0.0001) or midazolam, 98 (31) minutes (p=0.02), compared with those given no sedation (82 (28) minutes) for the laceration repair. The length of ED stay was also significantly longer for the ketamine group compared with the midazolam group, (p<0.0001). The analysis of the ketamine patients with and without layered repair revealed no difference in ED time.

**Clinical conclusions**
This study found that the use of either midazolam or ketamine for sedation statistically increased the length of ED stay. However, the patients receiving midazolam had an average ED stay of only 16 minutes longer than those receiving no sedation, which is not a clinically significant increase in length of stay. On the other hand, patients receiving ketamine remained in the ED for about one hour more than those patients receiving midazolam or no sedation. This difference is somewhat more clinically significant, but it is still a relatively modest increase in time, particularly considering the efficacy of ketamine (when compared with midazolam, ketamine produces a deeper level of sedation and requires a longer recovery period).

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis.

**Direct costs**
Costs were not discounted due to the short time frame of the cost analysis. Quantities were not reported separately from the costs, except for the patient time in the ED. Cost items were not reported separately. Cost analysis covered the costs of the ED visit, including physician, the ED facility and pharmacy, and equipment. The perspective adopted in the cost analysis appears to have been that of the parents. Charge data were used instead of true costs, but the marginal cost to the hospital due to increased use of monitoring equipment arising from the use of ketamine was discussed. The source of the charge data was the study hospital billing records. The price year was not given.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The patient charges were significantly higher in those given ketamine, $695 (SD, 172; p<0.0001) or midazolam, $498 (153; p<0.0001) compared with those given no sedation, $390 (86). The charges were also significantly higher for the ketamine group compared with the midazolam group, (p<0.0001).

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors’ conclusions
The results of this study demonstrate that sedation with ketamine or midazolam increases the length of ED stay compared with using no sedation. However, the increased lengths of stay were modest, particularly for midazolam. Fear of prolonged recovery time should not dissuade clinicians from using either sedative for minor procedures. The patient charges are considerably higher with both midazolam and ketamine, but they may not reflect the actual cost of patient care.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (no sedation). It was felt that some clinicians may be reluctant to use sedation, in part because of concerns about increased patient charges and for fear that the emergency department (ED) stay would be prolonged. You, as a database user, should consider whether this is applies in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results cannot be guaranteed due to the retrospective nature of the study design (as acknowledged by the authors). However, the patients were selected to be homogeneous, and were comparable in terms of age, sex, and the length of the wound. It was claimed that the exclusion of patients who needed a facial surgery consultation eliminated excess time for consultation as a confounder. Patients receiving ketamine were more likely to have a layered repair. An analysis of the ketamine patients with and without layered repair was performed. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

Validity of estimate of costs
Quantities were not reported separately from the costs, except for patient time in the ED. Insufficient details of the methods of cost estimation were given (for example, cost breakdown). The price year was not given. The perspective adopted in the cost analysis appears to have been that of the patients. Using charge data instead of true costs may have adversely affected the internal and external validity of the cost results. The marginal cost to the hospital due to increased use of monitoring equipment arising from the use of ketamine was discussed and was deemed to be low. The effects of different procedures on indirect costs were not addressed. Statistical analysis was performed on charge data. Charge results may not be generalisable to other settings or countries, as acknowledged by the authors.
Other issues
Given the retrospective nature of the study design, lack of sensitivity analysis, and absence of a detailed profile of resource use, some degree of caution needs to be exercised in the interpretation of the study results. Regarding the issue of generalisability to other settings, it was noted that the study results cannot be generalised to other institutions with different monitoring practices and criteria for discharge after sedation, and institutions using other sedative agents, particularly if they are administered intravenously or if two agents (e.g. midazolam and fentanyl) are selected. The study sample consisted of children requiring the repair of a simple facial laceration, and this limitation in the breadth of the study sample was appreciated in the study comments. One extra limitation of the study was deemed to be the accuracy of the times recorded. The time frame ran from being placed in the examination room to the time of patient discharge. A more accurate method would have been to use the time from the physician first seeing the patient to the time of discharge. However, it was speculated that the waiting time would be likely to be similar in all three study groups.

Implications of the study
Physicians and parents might want to consider factors such as charges and length of stay in the ED when deciding whether or not to sedate a child for simple facial laceration.

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None stated.

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