Comparison of intra-articular lidocaine and intravenous sedation for reduction of shoulder dislocations: randomized, prospective 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 intra-articular lidocaine (Xylocaine) for the sedation of patients with acute anterior glenohumeral dislocations. The affected shoulder was prepared with three swabs of povidone-iodine, and 20 mL of 1% lidocaine was injected into the glenohumeral joint.

Type of intervention
Other: anaesthesia.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged between 18 and 70 years with an acute anterior shoulder dislocation. The exclusion criteria were multiple trauma, an associated fracture (except a Hill-Sachs compression defect) of the glenoid or tuberosities, open growth plates, a history of allergic reactions to the medications used in the study, and the inability to be placed in the prone position.

Setting
The setting was an emergency department. The economic study was carried out at the Mount Sinai Hospital (private hospital) and the Elmhurst Hospital Center (an urban level-I trauma hospital) in New York (NY), USA.

Dates to which data relate
The effectiveness and resource use data were gathered from November 2000 to May 2001. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were performed in the preliminary phase of the study. These showed that 14 patients per group were required to give a 90% power (alpha = 0.05) to identify a 30-minute difference in emergency room stay. A sample of 42 consecutive patients with acute anterior glenohumeral dislocation was identified in the study period. However, 8
patients were excluded because they had a fracture of the greater tuberosity. In addition, 2 cases could not be placed in the prone position, and 2 refused to participate (both had prior multiple dislocations and stated that they preferred sedation and the manual manipulation technique). Thus, the final study sample included 30 patients, 16 in the lidocaine group and 14 in the i.v. sedation group. In the lidocaine group, the mean age was 33 years (age range: 17 - 54) and 4 prior dislocations were reported. In the i.v. sedation group, the mean age was 35 years (age range: 17 - 69) and 5 prior dislocations were reported.

Study design
This was a randomised controlled trial that was carried out in two centres. Patients with an odd medical record number were allocated to the lidocaine group, while those with an even medical record number received i.v. sedation. The patients were not followed-up after discharge from the emergency department.

Analysis of effectiveness
All patients included in the initial study sample were taken into account in the effectiveness study. The health outcomes used in the analysis were:

- the occurrence of side effects after anaesthesia,
- the number of successful dislocation reductions,
- the need for additional medication,
- the average time for the reduction,
- the average time in the emergency room, and
- the average pain score.

The average pain score was obtained using a questionnaire where pain was rated from 1 (very mild pain) to 10 (the worst pain one could ever have) when the patient was in the prone position. A subgroup analysis was conducted in which the success of the reduction and the time for the reduction to occur were evaluated after the exclusion of patients who had a history of dislocation. The authors did not comment on the baseline comparability of the study groups. However, it appears that the groups were quite similar with respect to age and the number of prior dislocations.

Effectiveness results
There were no side effects in any of the study groups.

There were 14 successful dislocation reductions in the lidocaine group and 11 in the i.v. sedation group, (p=1.00).

There was no need for additional medication.

The average time for the reduction was 11.4 minutes (range: 3 - 22) in the lidocaine group and 8.5 minutes (range: 1 - 20) in the i.v. sedation group, (p=0.42).

The average time in the emergency room after shoulder reduction was 75 (+/- 48) minutes in the lidocaine group and 185 (+/- 26) minutes in the i.v. sedation group, (p<0.01).

The average pain score was 7.0 (+/- 2.6) in the lidocaine group and 7.4 (+/- 2.5) in the i.v. sedation group, (p=0.37).

The success of the reduction and time for the reduction to occur were comparable in the subgroup analysis.

Clinical conclusions
The effectiveness study showed that the lidocaine injection was as safe and effective as standard i.v. sedation. However, the average time in the emergency room after shoulder reduction was significantly lower after lidocaine injection.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. A cost-consequences analysis was therefore conducted.

Direct costs
Discounting was not relevant since the costs were incurred in a short period of time. The unit costs were not reported separately from the quantities of resources used for all cost items, but a detailed breakdown of the costs was provided. The health services included in the economic evaluation were for the syringe, needle, lidocaine, fentanyl, midazolam, i.v. set-up, saline solution and nursing time. The cost/resource boundary of the study was not explicitly reported. The costs were estimated from the information provided by the hospital pharmacy and distribution centre. Resource use was estimated alongside the effectiveness study. No price year was reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The estimated costs per patient were $0.52 in the lidocaine group and $97.64 in the i.v. sedation group.

Synthesis of costs and benefits
The costs and benefits were not combined due to the cost-consequences design employed.

Authors' conclusions
There was no difference between the two groups in terms of the success rate of the Stimson technique or the time required to reduce the shoulder. However, patients in the lidocaine group left the emergency room significantly sooner than those in the standard intravenous (i.v.) sedation group, and the costs were lower.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Intravenous sedation was selected as the basic comparator because it represented the standard sedation approach for patients with acute anterior glenohumeral dislocations. You
should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a two-centre, randomised clinical trial, which was appropriate for the study question. The study sample was unselected and appears to have been representative of the study population. The sample size was small, but preliminary power calculations were performed. These ensured that the study was powered to detect statistically significant differences in the main outcome measure. Subgroup analyses were also performed. The baseline comparability of the two groups was not discussed, but the patients appear to have been fairly comparable. The methods of sample selection and randomisation were described. These aspects of the study enhance the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The perspective adopted in the study was not explicitly reported. Only those costs strictly related to the interventions were included in the analysis. The indirect or other medical and non-medical costs were not included, although it appears that their inclusion would favour the study intervention. The costs were treated deterministically and the estimates were specific to the study setting. Sensitivity analyses were not performed. The source of the cost data was reported. The price year was not given, thus making reflation exercises in other settings difficult. However, the dates during which the economic data were collected were mentioned.

**Other issues**
The authors made extensive comparisons of their findings with those from other studies, and commented on the consistency with the results observed in the literature. However, the issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted. Thus, the external validity of the analysis is likely to be low. The study referred to patients with an acute anterior shoulder dislocation and this was reflected in the conclusions of the analysis.

**Implications of the study**
The study results suggest that the use of lidocaine in conjunction with the Stimson technique to reduce anterior dislocation of the shoulder is an effective approach that substantially reduces the nursing time, costs and time spent in an emergency room, compared with standard i.v. sedation.

**Source of funding**
None stated.

**Bibliographic details**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adolescent; Adult; Aged; Anesthetics, Local /administration & dosage; Comparative Study; Conscious Sedation
AccessionNumber
22003000061

Date bibliographic record published
31/01/2004

Date abstract record published
31/01/2004