Painless intravenous catheterization by intradermal jet injection of lidocaine: a randomized trial

Zsigmond E K, Darby P, Koenig H M, Goll E F

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
Different devices for local anaesthetic infiltration, both to manage or reduce pain when establishing anaesthesia, and also when subsequently inserting an intravenous catheter. Specifically traditional needle and syringe delivery, and two jet injection systems, the MedEJet (MedEJet Corporation, Cleveland, Ohio, USA) and the Biojector (Bioject Corporation, Portland, Oregon, USA), were examined.

Type of intervention
Other (pain management).

Economic study type
Cost-effectiveness analysis.

Study population
Adult hospital surgical outpatients requiring IV catheterisation, classified as ASA I or II.

Setting
The setting was a hospital. The economic analysis was conducted in Chicago, IL, USA.

Dates to which data relate
Dates for the collection of the effectiveness and resource data were not provided. No base price year appears to have been stated.

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

Link between effectiveness and cost data
Costing was not undertaken using the same patient sample as in the effectiveness analysis. It is unclear when the cost data were collected.

Study sample
Power calculations were not used to determine sample size. The method of sample selection was not stated. Age, weight and gender were reported. In total there were 75 patients, 25 in each of the three groups: MedEJet, Biojector and needle/syringe.
Study design
This was a single-centre, randomised, controlled trial. Patients were randomised between the three groups using the
Novanet Random Numbers Scrambler. There was no loss to follow-up. Patients were followed-up for 24 hours after
surgery.

Analysis of effectiveness
The analysis of effectiveness was based on the intention to treat approach. The primary health outcomes used in the
analysis were cutaneous sensitivity during anaesthesia and during catheterisation, determined by patients using a visual
analogue scale (VAS) pain scoring system (0 = no pain, 10 = worst possible pain) and a verbal pain intensity scoring
system (0 = no pain, 4 = intolerable pain). At baseline the demographic and clinical characteristics of patients in all
three groups were shown to be comparable.

Effectiveness results
During anaesthesia delivery mean VAS scores for patients in the three groups were 0.00 (+/- 0.00) for MedEJet, 0.04
(+/- 0.20) for Biojector and 2.4 (+/- 2.2) for needle/syringe.

The needle/syringe group had significantly greater levels of pain than the other two groups, (p<0.001).

25 and 22 patient in the first two groups reported no pain at all using the VAS scale. Only 3 patients in the
needle/syringe group reported no pain.

Mean PIS scores for patients in the three groups were: MedEJet, 0.00 (+/- 0.00); Biojector, 0.16 (+/- 0.5); and
needle/syringe 1.24 (+/- 1.0). Again the needle/syringe group had significantly greater levels of pain than the other two
groups, (p<0.001).

During IV catheterisation mean VAS scores for patients in the three groups were: MedEJet, 0.12 (+/- 0.33); Biojector,
0.44 (+/- 0.20) and needle/syringe, 1.64 (+/- 1.50). The needle/syringe group had significantly greater levels of pain
than the other two groups, (p<0.001).

25 and 22 patient in the first two groups reported no pain at all using the VAS scale. Only 6 patients in the
needle/syringe group reported no pain.

Similarly mean PIS scores for patients in the three groups were: MedEJet, 0.00 (+/- 0.00); Biojector, 0.00 (+/- 0.00);
and needle/syringe, 0.76 (+/- 0.88). The reduction in pain when inserting the catheter for patients in the needle/syringe
group did not reduce significantly, suggesting that this method of anaesthesia did not provide sufficient pain relief.

No complications related to IV insertion were reported in any of the three groups in the 24 hours following insertion.

Clinical conclusions
Jet injection systems provide almost painless anaesthesia for IV catheterisation, in contrast to conventional
needle/syringe delivery where considerable pain may be experienced by patients. Furthermore jet injection methods,
where the device does not come into contact with the skin, removes the risk of needle stick injury and infections,
associated with conventional delivery.

Measure of benefits used in the economic analysis
Subcutaneous sensitivity to anaesthesia delivery and intravenous catheter insertion was estimated. This, however, was
done not with one composite measure but was reported using two different outcome measurements. Therefore the
economic analysis took the form of a cost-consequences analysis.

Direct costs
Medication and materials costs were estimated. Drug costs were estimated using the average wholesale price at the
study institution, and material costs were taken from the manufacturers’ list price. Labour costs were excluded from the analysis. It was assumed, based on manufacturers’ data, that the costs of each of the two jet injectors could be amortised over 10,000 deliveries. The price years used were not stated. Costs were not discounted, which was appropriate given the short duration of the study. The economic analysis appears to have been conducted from the perspective of the study hospital. Only average costs were reported.

Statistical analysis of costs
No statistical analysis of costs was conducted.

Indirect Costs
Indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported earlier.

Cost results
The total price per dose was $0.13 when using the MedEJet, $0.50 with needle/syringe and $0.94 with the Biojector.

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
The authors concluded that the jet injectors had exceeded the expectations of their a priori hypothesis, being associated not with a simple reduction in pain, but with the virtual elimination of pain in anaesthesia delivery and intravenous catheter insertion. They also eliminated the risk of needle stick injuries and risk of infections. Furthermore jet injection systems have several cost advantages over conventional needle/syringe, as they do not require sterilisation, require less safety equipment, and require less preparation time (virtually none at all in the case of the MedEJet). The authors also concluded that using a jet injector also reduced the costs of catheter insertion.

CRD COMMENTARY - Selection of comparators
A justification was provided for the comparators chosen, namely that the Biojector was an alternative jet injector, and that needle/syringe represented the conventional method for anaesthesia delivery. You, as a user of this database, should consider whether these comparators are appropriate in your own setting.

Validity of estimate of measure of effectiveness
Effectiveness data were collected using a randomised controlled trial thus helping to limit bias in the study. The method by which the study sample was selected was not, however, reported, although in the case of such a common intervention, the study sample selected is likely to be representative of the appropriate study population. However, it would have been interesting to have identified any individuals in the study sample who may have suffered from needle
stick phobia, which is a relatively common condition, and may have influenced study findings. Furthermore, patient
groups were shown to be comparable at baseline analysis. No dates were provided for the collection of the effectiveness
data.

Validity of estimate of measure of benefit
The authors derived no single measure of health benefit, and therefore the study took the form of a cost-consequences
analysis.

Validity of estimate of costs
The cost data in this study were rather limited, and no base price year, or dates for the collection of data were provided.
The authors stated no study perspective, which was unsurprising given that their primary focus was on clinical outcomes
rather than costs. The economic analysis appears to have been undertaken from the perspective of the study institution.
Only medication and material costs were included in the analysis. Given the authors’ conclusions, these limitation may
serve to provide a conservative estimate of the cost advantage of jet injectors over syringe/needle delivery, particularly
as preparation and administration labour costs were not included in the analysis. It would, however, be helpful to
provide a more comprehensive analysis of costs in any future evaluation. Generalisability was enhanced by the fact that
costs and quantities of drug required for each of the three interventions were reported separately. No analysis of
quantities of drug administered was undertaken. However, this was appropriate given that each dosage was pre-
calibrated according to the study protocol. Costs were not discounted, which was also appropriate.

Other issues
This study was not designed as an economic evaluation, but as an effectiveness study which included a very limited cost
component. Therefore some of the standard features of an economic evaluation were missing from this analysis.
Nevertheless the study does serve to illustrate the economic advantages of jet injection systems. The authors stated that
this study was the first to examine the use of jet injectors for subcutaneous anaesthesia delivery, and therefore cannot
be compared with the findings of other studies. The authors did acknowledge that their cost data were not easily
generalisable to other institutions or settings.

Implications of the study
Jet injectors are an appropriate alternative to needle/syringe delivery mechanisms, reducing pain and lowering costs.
They also have favourable implications for public health and because of ease of delivery may also be the only
appropriate delivery mechanism for drugs in major public emergencies.

Source of funding
None given

Bibliographic details
Zsigmond E K, Darby P, Koenig H M, Goll E F. Painless intravenous catheterization by intradermal jet injection of

PubMedID
10386277

Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Cutaneous; Adult; Aged; Anesthetics, Local /administration & dosage; Catheterization /methods;
Female; Humans; Injections, Jet; Lidocaine /administration & dosage; Male; Middle Aged; Pain /prevention & control;
Prospective Studies

AccessionNumber
21999001214

Date bibliographic record published
31/01/2002

Date abstract record published
31/01/2002