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V. A new route, jet injection of lidocaine for skin wheal for painless intravenous catheterization

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Key words
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Abstract. Objective: The objective of this study was to compare the efficacy of intradermal lidocaine anesthesia by two jet injectors to the routine needle infiltration and to the topical EMLA cream. Subjects and methods: In a randomized, prospective, controlled trial, 100 consenting surgicenter patients in a university hospital setting were divided into four groups (n = 25, each); intradermal lidocaine anesthesia was given either by the conventional 25 g needle/syringe or the Med-E-Jet or Biojector injector or EMLA cream was applied on the skin. Visual analogue pain scores (VAS) or verbal pain intensity scores (PIS) were reported by the patients at lidocaine application and i.v. catheterization. Cost was also assessed. Results: At lidocaine application, no pain was reported, since proportions of VAS = 0 were 25/25 (CI: 0.868, 0.999) with Med-E-Jet; 24/25 (0.804, 0.991) with Biojector; 25/25 (0.868, 0.999) with EMLA; in contrast to pain, 3/25 (0.044, 0.302) with the needle (PP > 0.999). The VAS scores (mean ± SD) were 0.00 ± 0.00, 0.04 ± 0.20, 0.00 ± 0.00, and 2.4 ± 2.2 respectively (p < 0.001). No pain was reported by proportions of PIS = 0 with Med-E-Jet: 25/25 (CI: 0.868, 0.999); with Biojector: 23/25 (0.749, 0.976); EMLA 25/25 (0,868, 0.999); but pain with the needle: 5/25 (0.090, 0.394) (PP > 0.999). The mean ± SD PIS scores were 0.00 ± 0.00, 0.16 ± 0.55, 0.00 ± 0.00, and 1.24 ± 1.00, respectively (p < 0.001). At i.v. catheterization, the proportions of VAS = 0 scores were 22/25 with Med-E-Jet (0.698, 0.956); 21/25 (0.651, 0.934) with Biojector; but some pain with needle: 6/25 (0.116, 0.436) (PP > 0.999). The mean ± SD VAS scores were: 0.12 ± 0.33, 0.44 ± 0.20, and 1.64 ± 1.50, respectively (p < 0.001). No pain was reported by PIS = 0 scores in 24/25 (0.804, 0.991) with Med-E-Jet; 24/25 (0.804, 0.991) with the Biojector; but pain by zero PIS scores 13/25 (0.334, 0.703) in half of the patients in the needle group (PP > 0.999). The mean ± SD scores were 0.00 ± 0.00, 0.00 ± 0.00, and 0.76 ± 0.88, respectively (p < 0.001). The EMLA cream was not evaluated because of inadequate duration of application prior to anesthetic induction. Cost/application were: Med-E-Jet = $ 0.13; needle = $ 0.50; Biojector = $ 0.94 and EMLA = $ 3.76. Conclusion: Almost completely painless i.v. catheterization by jet injection of lidocaine was accomplished, while needle infiltration produced pain/discomfort and did not significantly reduce it at the i.v. needle insertion.

Introduction

Insertion of an intravenous (i.v.) catheter is a painful procedure performed daily in millions of patients worldwide. As yet, it is often being performed without analgesia. The two currently used techniques to reduce the pain associated with i.v. catheterization are local anesthetic infiltration with a small needle (# 25 gauge) and topical application of a eutectic mixture of lidocaine and prilocaine (EMLA cream). Nonetheless, patients often experience some pain, either at the time of intradermal lidocaine injection or at the actual time of i.v. catheterization or both. Surveys of hospitalized patients show that pain caused by needle, manipulations, and surgical procedures ranks first among their complaints.

Jet injection, conceived by Robert Hingson, is a nearly painless route of drug administration [Hingson and Hughes 1947]. The Med-E-Jet inoculator, called "peace gun" has been utilized for the vaccination against contagious diseases of over a billion patients worldwide. It has also been used to a limited extent for adminstration of insulin [Cohn et al. 1972, 1974]. Recent studies have demonstrated that jet injector route of sedation with midazolam and anesthetic induction with ketamine in pediatric patients is effective, safe, rapid, and almost painless [Zsigmond et al. 1995, 1996] and peak blood levels are reached faster than with the intramuscular route [Domino et al. 1997, 1998].

The traditional Med-E-Jet inoculator was designed for vaccination. For intradermal injection of BCG vaccine for tuberculosis testing an intradermal spacer had to be developed [Dull et al. 1968]. On preliminary testing we could reliably raise a skin wheal with 0.2 ml of lidocaine with either of the jet injectors studied with our modified intradermal spacer.

Our a priori hypothesis was that an intradermal wheal with a jet injector is less painful than with a needle. Therefore, we compared lidocaine cutaneous analgesia for i.v. insertion by two jet injectors with the conventional needle infiltration and with the EMLA cream.

Subjects and methods

Following Institutional Review Board approval informed consent was obtained from 100 patients at a university hospital outpatient surgical unit. They were prospectively randomized to four groups:

- needle/syringe (n = 25),
- Med-E-Jet (n = 25),
- Biojector (n = 25), and
- EMLA cream (n = 25).

Drug preparation

All drugs were supplied by the operating room pharmacy. Carbonated lidocaine for the Med-E-Jet group was prepared as follows: 5 ml of 8.4% (1 meq/ml) sodium bicarbonate (American Reagent Laboratories Inc., Shirley, NY 11967) were added to a 50 ml 1% lidocaine HCl multidose vial containing sodium chloride, 7 mg, methylparaben, 1 mg, and HCl (Abbott Laboratories, North Chicago, IL 60064) to make a final concentration of approximately 1% (0.9% actual final concentration) lidocaine with 0.1 meq sodium bicarbonate per ml. This vial was then attached to the medicinal spout of the Med-E-Jet.

Carbonated lidocaine for the needle/syringe and Biojector groups was prepared by the standard procedure of the Pharmacy Department for the Operating Room Pharmacy as follows: 100 ml 4% lidocaine from a single use vial (preservative-free, with sodium hydroxide and/or hydrochloric acid) (Astra Pharmaceutical Products, Inc., Westborough, MA 01 581), and 40 ml of 8.4% (40 meq) sodium bicarbonate (American Reagents Laboratories) were added to 260 ml 0.9% sodium chloride (Abbott) to make a final concentration of 1% lidocaine with 0.1 meq sodium bicarbonate per ml. Under a sterile hood in the pharmacy, 3 ml aliquots of this solution were prepared. The batch that was distributed to the Surgicenter was then dispensed into the special disposable Biojector # 2 syringes (Biojector group) or into 1 ml syringes (needle/syringe group) (0.2 ml/dose).

For the EMLA group, EMLA cream (25 mg lidocaine and 25 mg prilocaine per gram) (Astra) unmodified from company supplies was utilized.

Local anesthetic application

The local anesthetic application, the subsequent insertion of the intravenous Jelco # 18 gauge catheter and its fixation were all carried out by a specially trained nurse (P.D.) The site of i.v. catheterization was on the dorsum of the hand in all cases. Following skin preparation with an alcohol sponge, the site was anesthetized with the method determined by the randomization.

For the needle/syringe group, local cutaneous anesthesia was established by raising a skin wheal with 0.2 ml 1% carbonated lidocaine from a 25 gauge needle and a 1 ml syringe.

The Med-E-Jet medicinal head and the vial spout were sterilized and the multidose vial was spiked by the vial spout under sterile conditions. Once assembled, the Med-E-Jet inoculator was set to deliver 0.2 ml of 1% carbonated lidocaine. Then, the intradermal spacer was attached. At the injection of lidocaine, the intradermal spacer was tightly held to the skin and the jet injector fired. This Med-E-Jet was used repeatedly (~ 120 times) without the necessity of reloading it with lidocaine, since there was adequate volume in the lidocaine multidose vial. Once spiked, the lidocaine can be used for up to three days at which time it expires.

For the Biojector group, the Biojector syringe had to be filled through a needle to a volume of 0.2 ml from a 3 ml syringe prefilled with 0.2 ml of 1% carbonated lidocaine, then it was was mounted into the instrument by a bayonet lock. Then the custom-made 20 mm intradermal spacer was attached to the injection port of the syringe. This was tightly held to the skin and the jet injector fired. Then, the needle and disposable syringe were safely disposed. For each subsequent Biojector patient, the same procedure had to be carried out, since it utilizes single use, disposable syringes.

For the EMLA cream group, 2.5 grams of EMLA cream were topically applied to the skin site, covered with dressing. At the time, the i.v. catheterization had to be performed, less than 60 minutes after EMLA application, pain sensation was assessed by a needle (25 g) prick and temperature sensation by ice. Space and time constraints in our Surgicenter did not allow adequate time for EMLA application, therefore, many had inadequate analgesia. For these patients, rescue therapy with one of the other three methods used was applied prior to insertion of the i.v. catheter. These patients were included in the evaluation of pain scores during the initial local anesthetic application, but not at the time of i.v. catheterization, although they were rated.

Cutaneous sensitivity assessment

The patient rated his skin sensitivity by two currently accepted methods: visual analogue scores (VAS) and subjective pain intensity scores (PIS) [Ohnhaus and Adler 1975, Olsen et al. 1992]. The VAS is a scoring system where the patient indicates on a 10 cm scale the degree of discomfort experienced with a certain procedure, where 0 is no pain and 10 is the worst possible or intolerable pain. The PIS is a verbal rating scale where the patient indicates the degree of discomfort/pain on a scale of 0 – 4 where 0 is not painful at all, 1 is discomfort, 2 is tolerable pain, 3 is very painful, and 4 is intolerable pain. These assessments were performed at the time of local anesthetic application and at the time of i.v. catheterization, The i.v. team nurse, P.D. instructed the patients in the use of the rating scales before the study and recorded all the replies to the questions on the case report forms. Pain evaluation at the time of catheterization utilized only the response to insertion of the needle into the vein rather than to the advancement of the Jelco 18 gauge catheter into the vein. In 14 patients repeated attempts at catheterization were required, since the catheter would not advance without trauma to the vein wall. Therefore, the catheter was removed and another insertion was made. The response of the patients to repeated attempts were not scored again and not included in the evaluations for two reasons: in many instances a smaller caliber needle or a different type of i.v. catheter had to be used; in face of failure on the first attempt, the cooperation of the patient could have been adversely influenced so that an objective evaluation could not have been made.

Site assessment

The site of local anesthetic application was assessed and categorized as poorly visible, average, and prominent by the intravenous team nurse (P.D.).

I.v. catheterization

In all groups, an 18G Jelco catheter was inserted in less than 2 minutes after local anesthetic application with the exception of the EMLA group. The ease of cannulation was rated as easy, average, or difficult by P.D. The number of attempts at catheter placement was also recorded.

Statistical analysis

A computer program was utilized for the descriptive statistics, one-way analysis of variance, paired t-test and pair-wise multiple comparisons (Tukey test) for the analysis of demographic and other descriptive data, particularly for mean scores. The Bayesian method for comparing binominal probabilities were applied to the proportion of zero scores. The posterior probability (PP) corresponding to each hypothesis reflects its likelihood given the observed proportions. The range of PP is from 0 to 1; if PP is close to 1 or 0 there is strong evidence in favor of or against the hypothesis, respectively. If PP is close to 0.5, there is no evidence to support or reject the hypothesis. For convenience of expression, if PP is at least 0.9 or at most 0.1, the corresponding hypothesis is said to be significantly accepted or rejected respectively [Szlyk et al. 1993, Viana 1991].

Table 1. Patient demographics.

	Needle/syringe	Med-E-Jet	Biojector	EMLA
age*	52.2 ± 16.3	46.7 ± 17.2	49.1 ± 15.4	50.4 ± 17.6 (p = 0.502)
weight*	69.4 ± 17.4	72.0 ± 15.7	74.5 ± 19.9	74.1 ± 18.7 (p = 0.596)
sex (M : F)	9 : 16	10 : 15	5 : 20	10 : 15

* = mean ± SD

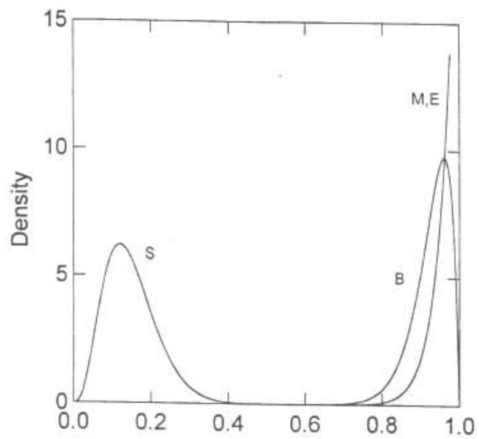

Figure 1. Posterior probability densities for VAS = 0 scores at local anesthetic application. Note that the confidence interval (CI) into which 95% of patients with VAS = 0 fall is 80 – 100% for the B, E, M groups in contrast to 0 – 30% for the S group. S = Syringe/needle; B = Bioject; M = Med-E-Jet; E = EMLA cream 0 = 0.0; 1.0 = 100%

Table 2. Proportion of zero pain scores.

	At local anesthetic application			
	Needle/syringe	Med-E-Jet	Biojector	Posterior probability
VAS	3/25	25/25	24/25	> 0.999
PIS	5/25	25/25	23/25	> 0.999
	At i.v. catheterization			
	Needle/syringe	Med-E-Jet	Biojector	Posterior probability
VAS	6/25	22/25	21/25	> 0.999
PIS	13/25	24/25	24/25	> 0.999

Cost comparison

A cost comparison was done for all four groups. Total cost was based on medication and material cost in our institution. Labor was not considered. Drug costs were based on average wholesale price and material costs were based on manufacturers list price. For the jet injection groups, device acquisition was the major cost: Med-E-Jet = $ 1,040.00 and Biojector = $ 860.00. The acquisition cost was amortized on estimated 10,000 applications, the minimum use claimed by the manufacturers.

Results

The four groups were not different with regard to age (p = 0.596), weight (p = 0.502), and gender (Table 1). There were no complications related to any method of local anesthetic application.

Evaluation of cutaneous sensitivity

At the time of local anesthetic application, there was no pain experienced as the proportions of VAS = 0 scores indicated in the Med-E-Jet: 25/25 (CI: 0.868, 0.999); Biojector: 24/25 (0.804, 0.991) and EMLA: 25/25 (0.868, 0.999) groups; in contrast to the needle/syringe group: 3/25 (0.044, 0.302) (PP > 0.999) representing a definite discomfort/pain. The Bayesian analysis showed that two distinct groups of patients could be separated: One group of patients composed of the Med-E-Jet, Biojector and EMLA cream groups had zero scores; the other group, the needle/syringe group scores from 1 – 10, or

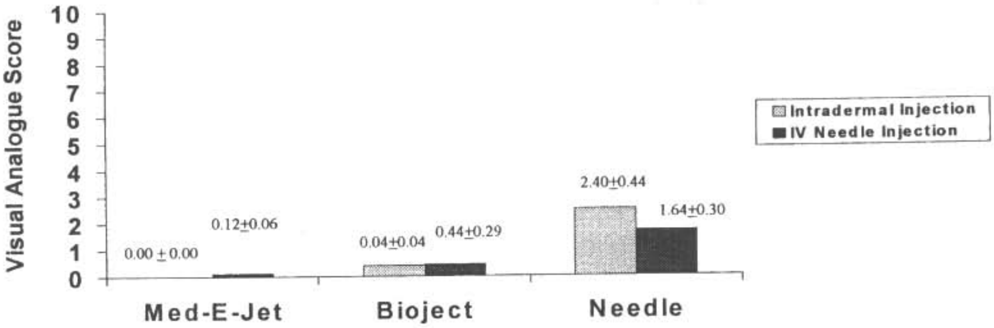

Figure 2. Pain scores on intradermal injection for skin anaesthesia and intravenous needle insertion. Visual analogue scores (VAS) for pain: 0 = no pain and 10 = worst possible pain. n = 25 per group. Values are expressed as mean ± SEM.

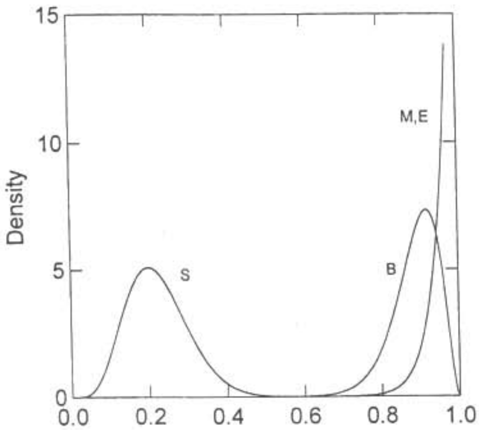

Figure 3. Posterior probability densities of PIS = 0 at local anesthetic application. Note that the confidence interval (CI) into which 95% of patients with PIS = 0 fall is 75 – 100% for the B, E, M groups in contrast to 0 – 39% for the S group. S = syringe; M = Med-E-Jet; B = Bioject; E = EMLA 0.0 = 0%; 1.0 = 100%.

other than zero (Figure 1). The posterior probability observed, PP > 0.999 signifies that there were statistically significant differences in the observed pain scores between the needle syringe and the other groups as assumed in our a priori hypothesis (Table 2). The mean scores were analyzed by the ANOVA and the means (± SD) were for the Med-E-Jet: 0.00 ± 0.00; for the Biojector: 0.04 ± 0.20; for the EMLA group: 0.00 ± 0.00 and for the needle/syringe group: 2.4 ± 2.23. The latter was differed significantly from the other groups (p < 0.001) (Figure 2). The proportions of PIS = 0 scores were 25/25 (CI: 0.868, 0.999) in the Med-E-Jet; 23/25 (0.749, 0,976) in the Biojector; 25/25 (0.868, 0.999) in the EMLA group (PP > 0.999), further corroborating the absence of pain observed by VAS = 0 scores in the jet injector groups (Figure 3). In contrast, in the needle/syringe group, a proportion of 5/25 (CI: 0.090, 0.394) with PIS = 0 again confirmed discomfort/pain (Table 2). The corresponding mean PIS scores were: Med-E-Jet: 0.00 ± 0.00; Biojector: 0.16 ± 0.55, EMLA group: 0.00 ± 0.00 and needle/syringe: 1.24 ± 1.0 (p < 0.001) (Figure 4).

At the time of i.v. catheterization, there was no pain as proportions of VAS = 0 scores indicated with the Med-E-Jet: 22/25 (0.698, 0.956) or Biojector: 21/25 (0.651, 0.934), but discomfort/pain with the needle: 6/25 (0.116, 0.436). The calculation of the Bayesian estimates of the proportions of VAS = 0 with the Med-E-Jet, Biojector and with the needle resulted in a PP > 0.999 indicating almost complete lack of pain with the jet injectors vs moderate pain with the needle confirming our a priori hypothesis (Figure 5, Table 2). The corresponding VAS scores (mean ± SD) were 0.12 ± 0.33, 0.44 ± 0.20, and 1.64 ± 1.50, respectively (p < 0.001) (Figure 2). No pain by proportions of PIS = 0 scores with Med-E-Jet: 24/25 (0.804, 0.991); Biojector: 24/25 (0.804, 0.991), but pain with needle: 13/25 (0.334, 0.701) (Figure 6). The corresponding PIS scores were 0.00 ± 0.00, 0.00 ± 0.00, and 0.76 ± 0.88, respectively. In the needle/syringe group neither the reduction of the mean VAS score from 2.4 ± 2.23 to 1.64 ± 1.50 nor the PIS score from 1.24 ± 1.00 to 0.76 ± 0.88 reached significance (p = 0.179, 0.161) indicating a lack of adequate protection by the intradermal wheel by the 25 gauge needle from the pain caused by the subsequent i.v. catheter insertion.

Complete lack of cutaneous sensitivity at i.v. insertion was not observed in the EMLA group as the application time was less than 60

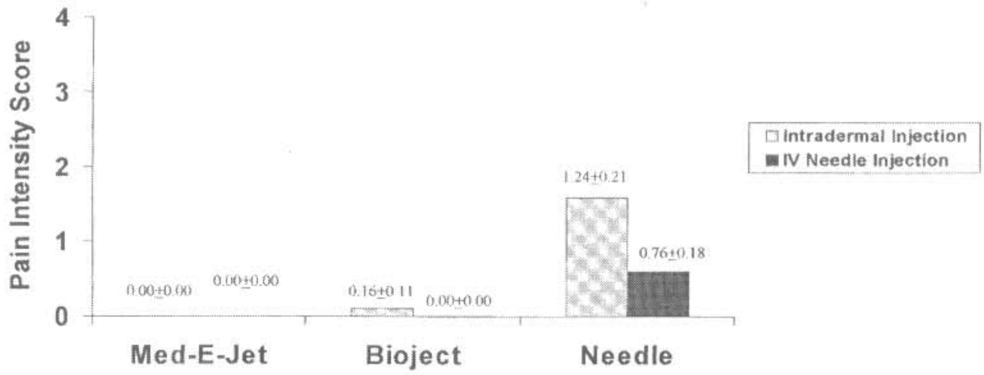

Figure 4. Pain scores on intradermal injection for skin anaesthesia and intravenous needle insertion. Pain intensity scores (PIS) 0 = not painful, 1 = discomfort, 2 = tolerable pain, 3 = very painful, 4 = intolerable pain. n = 25 per group. Values are expressed as mean ± SEM.

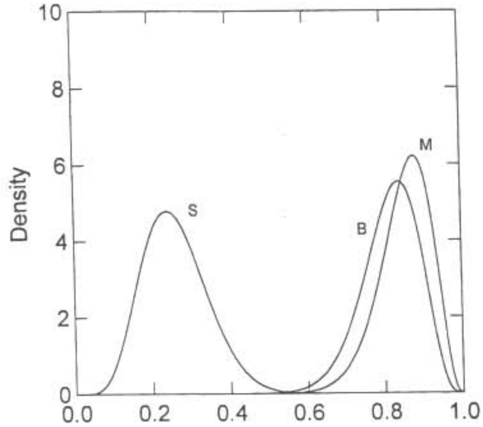

Figure 5. Posterior probability densities for VAS = 0 at intravenous catheterization. Note that the confidence interval (CI) into which 95% of patients with VAS = 0 score fall is 75 – 100% for the B, E, M groups in contrast to 11 – 43% for the S group. S = needle/syringe; M = Med-E-Jet; B = Biojector: E = EMLA 0.0 = 0%; 1.0 = 100%

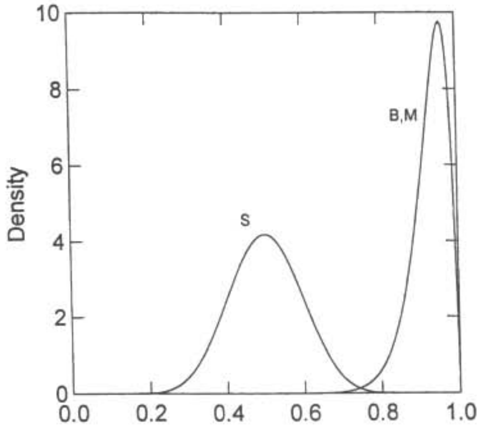

Figure 6. Posterior probability densities for PIS = 0 at the intravenous catheterization. Note that the confidence interval (CI) into which 95% of the patients with PIS = 0 score fall is 80 – 100% for the B, E, M groups in contrast to 12 – 44% for the S group. 0.0 = 0%; 0.5 = 50%; 1.0 = 100%.

minutes. This was inadequate time for complete analgesia in all 25 patients when the i.v. catheterization had to be performed. Since only 11 patients had even partial analgesia and 14 had complete absence of pain relief, they required rescue local anesthesia by one of the three other methods. Therefore, the data for the EMLA group at the time of i.v. catheterization were not included in the statistical analysis.

Ease of cannulation

No differences were detected among the groups (Table 3). A second attempt to insert the i.v. cannula was necessary in five patients in the Med-E-Jet group, and two patients, each, in the Biojector and needle/syringe groups. One patient each in the Med-E-Jet, needle/syringe and EMLA groups required a third attempt to insert the i.v. catheter.

Appearance of the injection site

After local anesthetic application it was similar between the four groups so either method of intradermal injection resulted in an adequate similarly appearing skin wheal (Table 4). After the insertion of the intravenous catheter, the appearances of the insertion site again were almost identical. There were no lacerations, bruising or bleeding related to

Table 3. Ease of cannulation.

	Score evaluation	EMLA	Needle/syringe	Med-E-Jet	Biojector
1)	Easy	11	15	19	7
2)	Average	12	5	2	10
3)	Difficult	2	5	4	8
	Mean scores	1.6	1.6	1.4	1.4

Table 4. Appearance of injection site.

	Score evaluation	Needle/ syringe	Med-E-Jet	Biojector	EMLA
3)	Prominent	0	3	5	3
2)	Average	17	12	1 1	13
1)	Poorly seen	8	10	9	9
	Mean Scores	1.60	1.64	1.84	1.68

Table 5. Cost comparison.

	Device	Drug	Needle/syringe (single use)	Total price (per dose)
Med-E-Jet*	$ 0.11	$ 0.02	$ 0.00	$ 0.13
Needle/syringe	$ 0.00	$ 0 30	$ 0.20	$ 0.50
Biojector#	$ 0.09	$ 0.30	$ 0.55	$ 0 94
EMLA	$ 0.00	$ 3.76	$ 0.00	$ 3.76

* = Acquisition cost = $ 1040 prorated for 10,000 applications, # = acquisition cost = $ 860 prorated for 10,000 applications

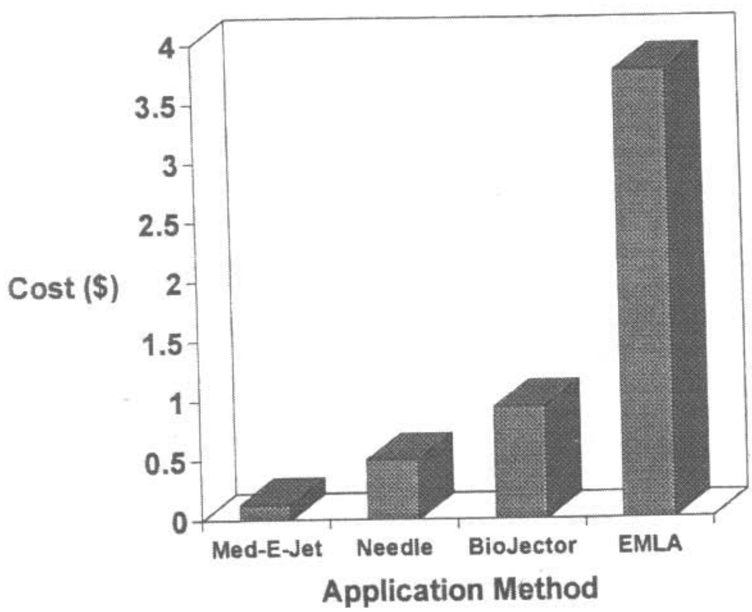

Figure 7. Cost comparison of various methods of intradermal anesthesia.

local anesthetic application in any patient. During the 24-hour postoperative telephone interview by recovery room nurses there were no reports of any complications by patients when specifically questioned about their i.v. sites.

Cost comparison

The cost of drug and materials per patient in this study was as follows: Med-E-Jet ($ 0.13), needle/syringe ($ 0.50) Biojector ($0.94), and EMLA ($ 3.76). (Table 5, Figure 7).

Discussion

This is the first scientific study which reports the use of jet injectors for intradermal local skin analgesia. No discomfort or pain was reported on injection in any patient with the Med-E-Jet injector and only in one patient with the Biojector in contrast to the patients injected with the needle. These findings confirmed our a priori hypothesis that the jet injection of lidocaine for intradermal wheal causes almost no pain. Though our a priori hypothesis was that jet injection would hurt less than a needle, an almost complete lack of discomfort and/or pain with the jet injectors was unexpected. Moreover, we were surprised that many patients reported discomfort and/or pain with a 25 gauge needle infiltration of carbonated lidocaine, contrary to the commonly held notion that a skin wheal by a 25 gauge needle makes the subsequent insertion of an intravenous catheter pain-free. Though great care was taken to instruct the patients to rate only their cutaneous sensitivity, it cannot be entirely ruled out that there was an emotional or situational anxiety component, a fear of needles, in the scores observed in the needle/syringe group. This should be further studied.

Another objective of our study was to prove that the use of a jet injector is more efficacious, faster and less costly than that of the EMLA cream. The application of the EMLA cream is painless when pasted on the skin, but it must be applied for at least 60 minutes prior to needle insertion to provide effective analgesia. The long waiting period for its effect limits its usefulness for two reasons: the cream may be inadvertently wiped off and must be reapplied repeatedly; the duration of skin contact may be insufficient for the development of effective analgesia, when surgical schedules dictate that the procedure must begin without delay. Indeed, in this study, there was inadequate time to wait for the full effect of the EMLA cream (less than 40 minutes) after the admission of the patient to the surgicenter. When we repeatedly observed high pain scores on testing with a 25 gauge needle in eleven patients who had been applied the EMLA cream for 30 – 45 minutes, we decided to rescue the remaining patients preferably with one of the jet injectors. Therefore, rescue intradermal lidocaine anesthesia with either needle/syringe or jet injector was given to 14 patients prior to i.v. catheterization.

Most anesthesiologists prefer the i.v. catheter to be placed in the dorsum of the hand, so it can be easily accessed during most surgical procedures. This site is more sensitive than the forearm or antecubital fossa. Since all our patients had their i.v.s placed in the dorsum of the hand and the appearance of the injection sites did not differ among the groups, the groups were comparable as to the ease of intravenous catheterization.

The Federal Food and Drug Administration (FDA) approved the Med-E-Jet injector use for nerve block anesthesia with local anesthetics many years ago. However, the technique of intradermal injections was not perfected until it was proposed for tuberculosis testing in the sixties [Dull et al. 1968]. We had to redesign this spacer introduced for tuberculine testing to ensure there was no unintentional subcutaneous drug delivery or unwanted injury to the underlying vein. This was critically important in the dorsum of the hand, where a thin subcutaneous layer covers the vein. We preformed preliminary injections on volunteers and modified the intradermal spacer for the two jet injectors, including custom making an intradermal spacer for the Biojector prior to the start of this study.

Drug toxicity is not a problem with either technique, since the amount of lidocaine injected is small, 0.2 ml 1% solution or 2 mg total dose per injection. Therefore, even if the initial injection or i.v. insertion is not successful, it is safe to use the jet injector repeatedly. Moreover, reinjection with a jet injector is almost pain-free in most patients, as we also observed in our study, when the EMLA group patients were rescued prior to intravenous catheterization (mean VAS score = 0 in 9 patients).

Med-E-Jet can be used rapidly and repeatedly for many patients with essentially no setup time between patients, since it was designed for rapid mass inoculation of thousands of individuals. Literally, a quick wipe of the skin and the tip of the injector with an alcohol sponge prior to intradermal injection of lidocaine is all that is necessary prior to lidocaine injection with the Med-E-Jet. For the Biojector, a # 2 disposable syringe filled with lidocaine from another lidocaine-containing dispenser syringe must be mounted on the injector for each patient or each application and the intradermal spacer must be reattached. Either jet injector requires less setup time than the needle/syringe, hence their use is more cost-effective. The use of needleless injection also decreases the risk of infection and cross contamination and requires less safety equipment, e.g. gloves, sharps containers, and sharps disposal, thereby reducing costs. Consequently, this method holds promise in clinical practice, since it provides almost painless local analgesia for i.v. access and reduces the overall cost of intravenous catheterization.

Besides the major personal advantage of jet injection of intradermal lidocaine to the patient providing almost complete pain relief during i.v. catheterization, there is a marked public health benefit, the prevention of transmission of communicable diseases and infections. Over a million needle-stick injuries are reported in the USA annually. It is suspected that an additional 40 – 60% are not reported at all [Cardo et al. 1997, Harahan and Reutter 1997]. Studies indicate that the rate of needlestick injuries and sharps injuries are approximately 1.8 per year for physicians and 0.98 for nurses. The risk of transmission of hepatitis-B virus is estimated to be 6 – 30%, that of the hepatitis-C virus to be 3 – 6% and of HIV to be 0.2 – 0.4% of known needle injuries [Cardo et al 1997, Harahan and Reutter 1997, McCray 1986]. The jet injectors function without needle and the injection port of the medicinal head does not come into contact with the patients skin during use. This eliminates the potential for needle-stick injuries and the attendant risk of infectious complications from the cutaneous anesthesia needed for i.v. catheterization. Therefore, the Med-E-Jet and Biojector can be reused for multiple patients without costly sterilization procedures. In addition, the cost of hazardous waste disposal can be reduced.

The ease of cannulation was not influenced by either of the three methods of intradermal injection. When repeated attempts were required, it was not related to the method of local anesthetic application or introduction of the needle into the vein, but rather to the difficulty advancing the catheter within the vein. However, by a jet injector, repeated almost painless lidocaine injections may be given immediately for repeated attempts at i.v. catheterization.

The site selected for local anesthetic application was visualized in the majority of the patients and there were no significant differences among the groups at the time of i.v. catheterization. Although 5 in the Med-E-Jet and 4 in Biojector group had to have repeated catheterization as compared to 2 in the needle/syringe group, the difference did not reach statistical significance. No patient experienced a reaction to the local anesthetic application, to the i.v. catheter insertion or had an abnormal appearance of the i.v. site at the time of discharge to home.

The calculation for the total cost of each application was based on the average wholesale price of the drug and the manufacturers list price for the required materials (Table 5, Figure 7). These prices are not our institutions actual acquisition costs. The actual acquisition costs may be less expensive and will vary from institution to institution. In addition, labor was not considered in the total cost of each application. The Med-E-Jet resulted in the lowest cost due to its design to deliver multiple doses from a multidose lidocaine vial without the necessity of refilling each syringe such as the case with the Biojector. The Biojector utilized an individual disposable syringe adding \$ 0.55 to the cost, resulting in an increase cost over the needle/syringe application. Furthermore, the Biojector disposable syringe had to be filled with the use of another needle and syringe containing the dispensed lidocaine. Since the study was completed, a new needle-less disposable syringe and a disposable spike for the use with a multidose vial for the Biojector were made commercially available from the Bioject Corporation. This could potentially reduce the total cost of the intradermal anesthesia by the Biojector to \$0.66 by reducing the lidocaine cost from \$ 0.30 to \$ 0.02. The cost of the lidocaine is reduced because the cost of batching lidocaine into individual syringes is eliminated. The EMLA cost was the highest among the different applications as expected. The largest portion of the cost for the Med-E-Jet and Biojector application was the initial aquisition cost of these devices: Med-E-Jet = \$ 1,040.00 and Biojector = \$ 860.00. In our calculations, the device cost was prorated based on 10,000 applications, the suggested minimum use expectancy claimed by the manufacturers.

The pain and infectious risk associated with needle and syringe injection techniques may be eliminated with intradermal jet injection of lidocaine not only prior to i.v. catheterization but also prior to the use of many other painful invasive procedures, e.g. arterial catheterization, sternal, epidural, and spinal punctures. These potential new applications of jet injectors are currently being investigated. Moreover, in catastrophic situations (e.g. mass casualties, tornado, war) where sterile supplies are in high demand and short supply, the jet route for drug delivery may be the only practical route. In summary, lidocaine intradermal injection given by a jet injector is definitely less painful, easier to administer, safer for health care providers, and is less costly then the conventional needle/syringe technique.

Conclusions

Jet injection route of intradermal lidocaine almost painlessly, quickly, and consistently anesthetizes the skin site for i.v. catheterization. In contrast, the conventional 25G needle infiltration with lidocaine causes considerable discomfort/pain and does not eliminate the pain of i.v. catheterization completely, although it somewhat alleviates it. Jet injection and EMLA cream application eliminate the risk of contaminated needle-stick for the health care provider applying the local anesthetic, but the onset of the EMLA cream is protracted, which limits its routine use in a Surgicenter.

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