Local Anesthesia for Fine-Needle Aspiration Biopsy of Palpable Breast Masses:
The Effectiveness of a Jet Injection System

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To determine the effectiveness of the Biojector® 2000 needle-free lidocaine injection system in achieving satisfactory local anesthesia for fine-needle aspiration (FNA) of palpable breast lesions, we studied 29 female patients. Each patient served as her own control and had two FNA biopsies performed on the lesion. The first FNA biopsy was preceded by either no anesthesia, ethyl chloride cold spray, or traditional needle lidocaine injection. The second FNA was preceded by the Biojector 2000. Twenty-four patients (83%) reported that they preferred the Biojector 2000 over either no anesthesia, ethyl chloride spray, or needle and syringe lidocaine injection. The Biojector 2000 needle-free injection system is an effective and useful method of local anesthesia for FNA of palpable breast masses. Diagn. Cytopathol. 1997;17:472–476.

Key Words: FNA; local anesthesia; breast; jet injection

The utilization of local anesthesia prior to performing fine-needle aspiration (FNA) biopsy of palpable breast lesions varies among practitioners. Some physicians, believing that the use of an injectable anesthetic is as painful as the procedure, use no local anesthesia at all. Other practitioners, in an attempt to reduce the discomfort associated with FNA, use conventional lidocaine injection or topical ''freezing'' agents.

Fixed-nozzle needle-free jet injectors have been utilized in the U.S. since 1947.[1] They work by creating a high-pressure liquid stream that penetrates the skin and delivers the medication into the underlying tissue. The Biojector 2000 (Bioject Inc., Portland, OR), is a newly designed state-of-the-art pneumatically powered needle-free injection system that has recently become available on the market. This system utilizes a disposable nozzle and syringe medication unit that eliminates both the labor-intensive sterilization[2] and threat of cross-contamination[3,4] associated with the older fixed nozzle jet injector devices. We studied the effectiveness of the Biojector 2000 needle-free injection system to administer lidocaine in achieving satisfactory local anesthesia for FNA of palpable breast lesions.

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Materials and Methods

Patient Selection

Twenty-nine female patients participated in the study. Each patient agreed to have an FNA of her breast lesion at least twice: once using the FNA practitioner's normal routine for providing local anesthesia (if any) and another with lidocaine anesthesia using the Biojector 2000. The target lesion had to be located where the underlying breast tissue could support the maximum 1.2-cm depth of injection penetration.

Study Design

The purpose of the study was explained and a written consent for the FNA procedure obtained for each patient. Each patient served as her own control. At least two FNA biopsies were obtained from the lesion. Prior to the first FNA, the practitioner used his/her normal routine for preparing the patient for the biopsy.

The second FNA was preceded by a 0.75 cc 1% lidocaine injection with the Biojector 2000 needle-free injection system in a different area of the lesion than the first sample. After the FNA procedure, the majority of patients were given questionnaires to fill out (23 patients) or were verbally queried (6 patients) by the FNA practitioner requesting them to: (1) rate the amount of pain felt during the FNA biopsy

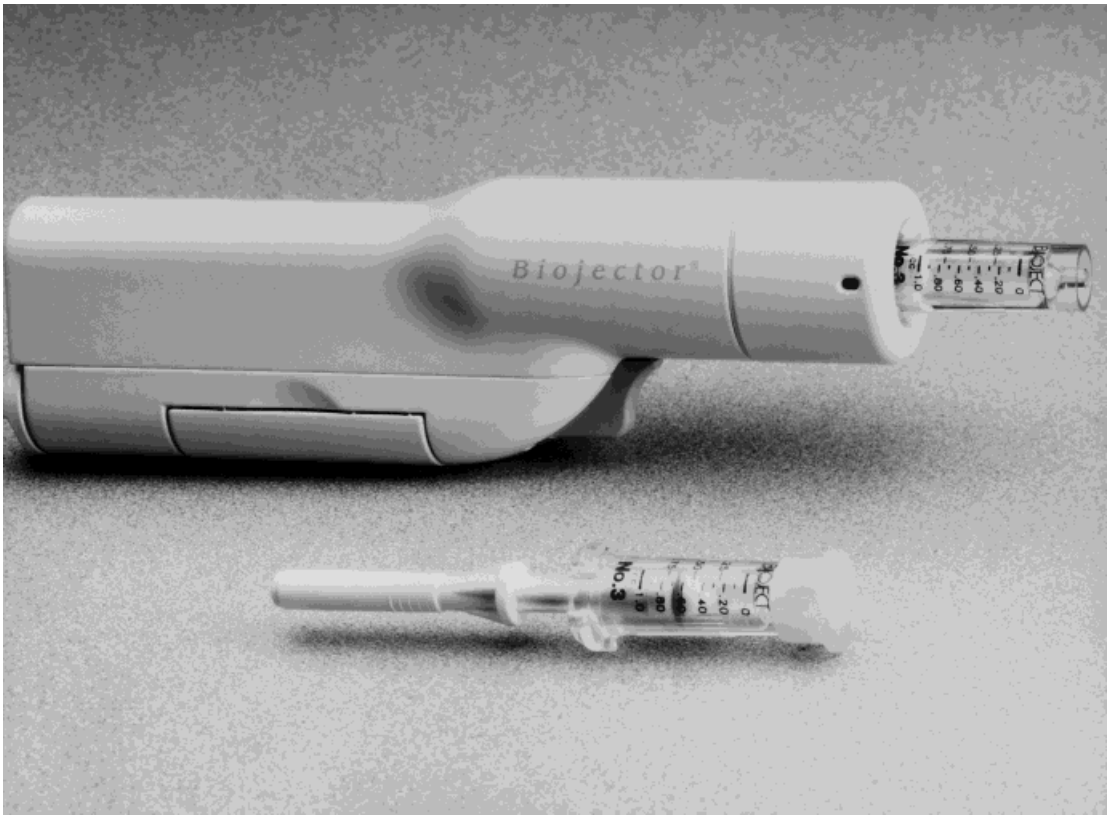

Fig. 1. Top: Biojector 2000 injector with syringe in place. The CO_2 cartridge is located inside the injector. **Bottom:** Syringe with plunger. A sterile plastic cap covers the orifice until use.

after local anesthesia with lidocaine using the Biojector 2000 as compared to either: (i) no anesthesia, (ii) ethyl chloride spray anesthesia, or (iii) needle and syringe method of lidocaine injection; (2) choose which method of anesthesia they would prefer in the future if a repeat FNA were to be necessary; and (3) add any general comments they might have. For the assessment of pain, a four-point rating scale was used (none, mild, moderate, and severe). In addition, each patient agreed to a follow-up phone call several days after the procedure to evaluate possible complications.

Technique of Ethyl Chloride Spray Topical Anesthesia

After cleansing the area with alcohol, the skin was sprayed for several seconds according to the manufacturer's instructions until it became frosted. The FNA biopsy procedure was then performed immediately.

Technique of Needle and Syringe Lidocaine Injections

Lidocaine (0.75 cc of 1%) was drawn into a 1-cc syringe. After cleansing the skin with alcohol, a small amount was first injected under the epidermis with a 25-gauge needle, and the remainder was injected into the underlying tissue in the usual manner. Several minutes were allowed to elapse before proceeding with the FNA biopsy to assure adequate time for the anesthetic to work.

Technique of Lidocaine Injection Utilizing the Biojector 2000 (Fig. 1)

The Biojector 2000 is a needle-free jet injection device designed to deliver medications either subcutaneously or intramuscularly. It consists of a syringe and an injector. Several differently sized orifices are available to control the depth of penetration. The syringe used in this study was the no. 2 syringe, which is designed for subcutaneous injection. The syringe holds the medication to be delivered and includes a small orifice that is 100 μm in diameter, approximately one third the diameter of a 29-gauge needle. The syringe holds up to 1 cc of medication, which is drawn up through a sterile attached needle. The needle is then removed and discarded, and a sterile plastic protective cap is placed over the filled syringe until use. The syringe fits into an injector powered by a disposable cartridge of compressed CO_2 gas that delivers approximately 10 injections. When the injector is actuated, it pushes on the syringe plunger, causing the medication to flow through the syringe orifice at approximately 230 m per second. This causes the liquid to penetrate to a depth of approximately 1.2 cm of adipose tissue. Literature suggests that the probability of inadvertent injections of material into veins is less than with a needle and syringe.[5] Published animal studies for this type of technology also indicate that the pressure is not enough to

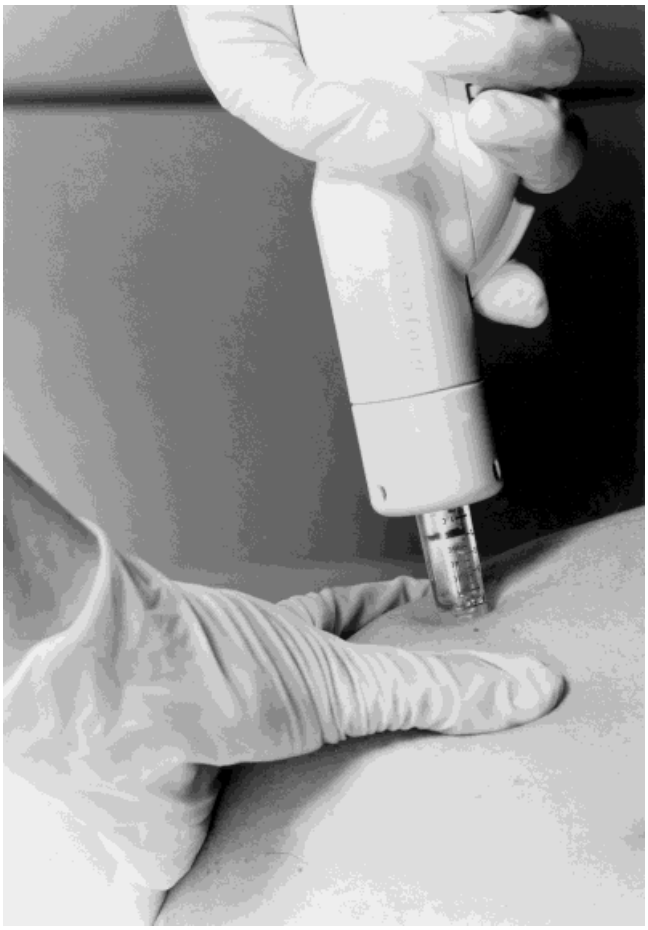

Fig. 2. The Biojector 2000 is positioned at a 90° angle to the skin and the actuator (switch) pressed to deliver the lidocaine.

puncture the media of large blood vessels; rather the jet-injected solution appears to take the path of least resistance and thus gets dispersed above these structures.[6]

Prior to the Biojector 2000 injection, each patient was informed that a ''pop'' and a ''hiss'' could be expected in addition perhaps to a slight stinging sensation. The skin was then cleaned with alcohol and kept taut by the operator's free hand. The Biojector 2000 was positioned at a 90° angle to the skin, and the actuator (switch) pressed and released to deliver the injection (Fig. 2). The Biojector 2000 was kept firmly applied throughout and for a few moments after the injection. If the injection was done correctly, a ''bull's-eye'' type of skin imprint was present after removal of the Biojector 2000. The outer ring of the bull's-eye was caused by the skin tension ring of the syringe and the inner dot (the size of a pinprick) was caused by a spot of blood marking the entrance of the lidocaine stream through the skin (Fig. 3). After the injection, pressure was applied over the area for several seconds with a gauze pad by the patient and several minutes were allowed to elapse before proceeding with the FNA biopsy procedure to assure optimal anesthesia.

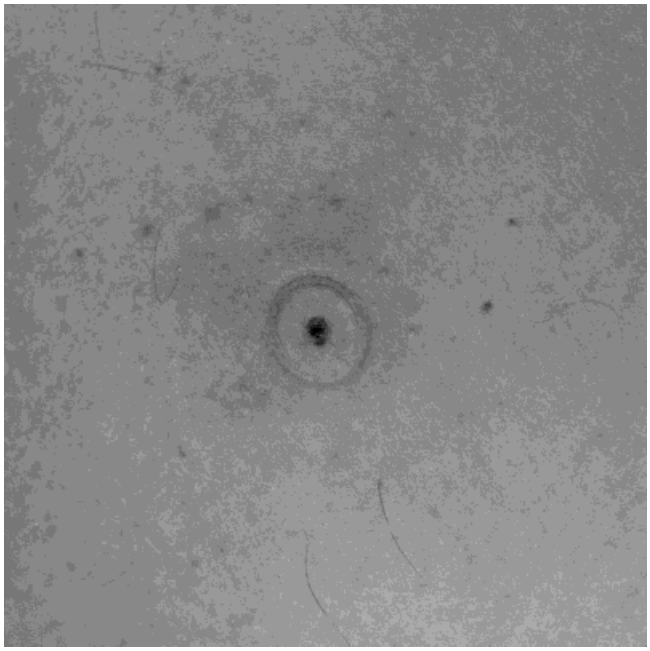

Fig. 3. The bull's-eye type of skin imprint caused by the Biojector 2000 injection. The FNA needle is inserted in the centrally located spot.

To achieve maximum effectiveness, the anesthetic was injected in the skin directly over where the subsequent FNA needle biopsy insertion was to be done. The small drop of blood located at the injection site marked the area of maximum anesthesia and was used as a guide for the FNA biopsy needle. For subareolar lesions, as with other injectable anesthetics, a lateral approach was taken.

Results

For the initial FNA, 12 patients had no anesthesia, 12 received ethyl chloride spray, and 5 received a lidocaine injection by needle and syringe. For the second FNA, all 29 patients had the Biojector 2000 injections of lidocaine. The patients ranged in age from 20 to 64 with a median age of 40.

Perception of Pain With the Biojector 2000 (Table I)

When the Biojector 2000 was used 17 patients (59%) reported no pain, 10 patients (34%) reported mild pain, and 2 patients (7%) reported moderate pain. None reported severe pain. With all the other methods combined, 5 patients (17%) reported no pain, 16 patients (55%) reported mild pain, 7 patients (24%) reported moderate pain, and one (3%) reported severe pain.

Anesthetic Preference

Twenty-four patients (83%) reported that they preferred the Biojector 2000 over either no anesthesia, ethyl chloride spray, or needle and syringe lidocaine injection (Fig. 4). Eleven of the 12 patients (92%) who underwent the first FNA pass without any anesthesia, 8 of the 12 patients (67%)

Table I. Amount of Pain Reported From FNA Procedure

	No pain	*Mild pain*	*Moderate pain*	*Severe pain*	*Total*
No anesthesia	1	8	3	0	12
vs.					
Lidocaine by Biojector 2000	7	5	0	0	12
Ethyl chloride cold spray	3	5	3	1	12
vs.					
Lidocaine by Biojector 2000	7	3	2	0	12
Lidocaine by needle and syringe injection	1	3	1	0	5
vs.					
Lidocaine by Biojector 2000	3	2	0	0	5
Total with other methods	5	16	7	1	29
vs.					
Biojector 2000	17	10	2	0	29

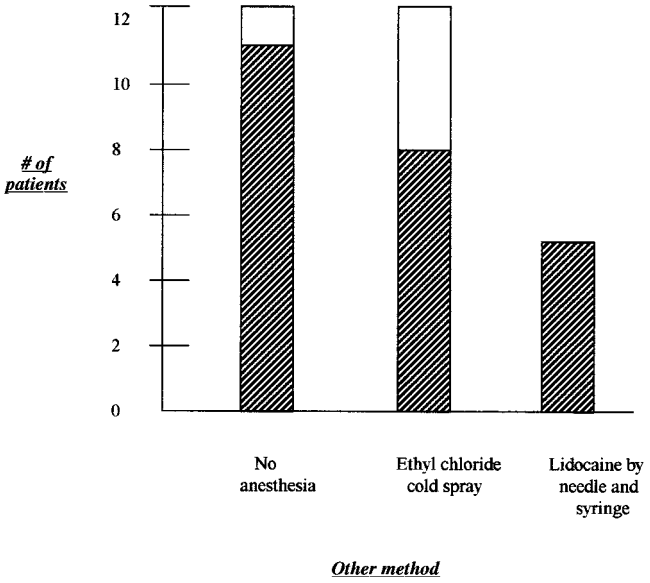

Fig. 4. Patient preference for Biojector as compared to other method. Hatched bars, preferred Biojector 2000; open bars, preferred other method.

who received ethyl chloride spray before their first pass, and all 5 (100%) who received a needle lidocaine injection prior to the first FNA preferred the Biojector 2000. Of the four patients who preferred the ethyl chloride spray, one stated that she found the ''noise'' of the Biojector 2000 to be frightening. A second patient complained of severe pain during the Biojector 2000 injection, although the FNA biopsy itself was painless. In this case, however, the FNA practitioner inadvertently anesthetized an area directly overlying a rib, most likely hitting the periosteum with the jet stream. The other two patients reported less pain with the spray than with the Biojector 2000.

Reactions/Complications at the FNA Biopsy Site

Follow-up was available in 19 patients. Of these, 9 (47%) reported no reaction/complications at the biopsy site. The remaining 10 (53%) patients reported mild reactions such as redness, swelling, and tenderness that in most cases lasted less than a few days. These reactions may have been related to the anesthetic method, biopsy, or both.

Discussion

Ethyl Chloride Cold Spray Compared to the Biojector 2000

With both the Biojector 2000 and the traditional needle and syringe technique, several minutes are needed in order for the lidocaine to fully numb the area. For this reason, in our busier clinics some FNA operators preferred either no anesthetic or ethyl chloride's rapid partial anesthetic effect over the Biojector 2000 for those patients with easily approachable breast masses requiring only one pass. The spray, however, was found to be inferior to the Biojector 2000 in that it provided for only short-acting partial anesthesia; therefore, the FNA operator had to be ready to insert the FNA biopsy needle immediately after application of the topical spray, otherwise the ''freezing'' effect might have already worn off.

Needle and Syringe Technique Compared to the Biojector 2000

Patients were less likely to be apprehensive when told they could receive the same ''numbing medication used by their dentist'' without a needle. The pioneers in needle-free jet injection in the 1950s were quite aware of this fact when they noted that ''the principle of jet injection is a sound one which offers a substitute for the needle in certain types of parenteral therapy whereby inventive and self-defensive man has found a more pleasing method of receiving his medicine.''[7]

Another advantage of the Biojector 2000 was the rapid injection time. It took only 1 second to inject the lidocaine through the Biojector 2000, while several seconds were needed with needle and syringe injections. Patients noted that even though the intensity of the ''sting'' caused by the lidocaine injection may have been the same by both methods, the fact that it lasted for less time by the Biojector 2000 made this method preferable.

All FNA practitioners reported preferring the Biojector 2000 over the needle and syringe technique. They noted that the instrument was easy to handle and operate and took less time to prepare for operation between patients than did conventional needle and syringe injections. The sterile, single-use Biojector syringes were found to be both easy to use and dispose of. The lidocaine could be drawn up into as many syringes as were necessary or ''batched'' for the expected daily patient load and held in a container for the entire day, cutting down on the preparation time between patients to no more than a few seconds. In addition, there was no concern for an inadvertent needle stick injury. Tissue swelling was observed to be minimal and did not interfere

with subsequent palpation and targeting of the underlying mass for the FNA procedure.

Limitations of the Biojector

Although the Biojector 2000 did provide for complete anesthesia of the skin overlying the lesion to be aspirated in all cases, 12 patients (41%) still complained of feeling mild to moderate pain during the FNA procedure. This pain appeared to be more common in patients who had deep masses, and in those requiring vigorous suction (such as fibrotic fibroadenomas). One way of anesthetizing deep lesions might be to inject additional lidocaine into the deep soft tissue overlying the mass (utilizing a needle and syringe) through the skin puncture mark made previously by the Biojector 2000. Pain, due to the aspiration of the mass itself, is almost impossible to control by any type of local anesthesia. An injection of lidocaine directly into a neoplasm is not recommended because of the theoretical risk of pushing neoplastic cells into the vascular system by the positive lidocaine stream and also because of the possibility of obtaining a ''lidocaine aspirate.''

Limitations of the Study

Because the study was not blinded, both the patients and practitioners knew beforehand whether or not the FNA procedure was preceded by an anesthetic, and if so what type. In addition, because the Biojector 2000 injection was done on the second pass this probably provided an additional positive bias towards the Biojector 2000. The first ''pass'' is usually more anxiety producing and therefore perceived as more painful by the patient than subsequent passes.

Conclusion

Although the pain associated with an FNA of palpable breast masses was well tolerated by the majority of patients even without any anesthesia, we found that a patient's perception of pain decreased when given an anesthetic agent. Our results indicate that ethyl chloride spray and traditional needle and syringe injections occupy an intermediate position in their ability to decrease the pain associated with an FNA procedure as compared to either no anesthesia (mild to moderate pain) or the Biojector 2000 (little or no pain).

As with any procedure/device combination, patient selection may be important. Until more experience is gained with larger patient samples, it would be prudent to avoid using the Biojector 2000 in patients with masses that lie very close to the chest wall. This way painful inadvertent infiltration of costal periosteum is avoided and also the theoretical risk of introduction of lidocaine into the pleural space.

The Biojector 2000 needle-free injection system is an effective and useful method of local anesthesia for FNA of palpable breast masses.

Author's Addendum

Recently we have tried using other methods of anesthesia for both palpable masses in the breast and lesions at other sites. In addition to the Biojector 2000 for breast lesions and ethyl chloride spray, here are two more that we have found to be quite effective and easy to use.

1. EMLA® cream (Astra USA, Inc. Westborough, MA). This is an emulsion cream which consists of a mixture of lidocaine and prilocaine and is applied to intact skin under an occlusive dressing. The advantages of this type of anesthesia is that it can be used at any site in the body as long as the overlying skin is intact and can provide for skin anesthesia over an area of several centimeters. The disadvantages are that it must be applied at least one hour before the procedure.
2. Cetacaine® Topical Anesthetic Spray (Cetylite Industries, Inc. Pennisauken, N.J.). This spray is effective only on mucous membranes and is excellent for providing anesthesia for intraoral and nasopharyngeal lesions. The spray consists of a combination of benzocaine, butyl aminobenzoate and tetracaine hydrochloride and has a pleasant banana flavor. Maximum anesthesia is produced within one minute. It can be used with a long nozzle to reach lesions located in the back of the throat.

Acknowledgments

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