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Does Light Pressure Effleurage Reduce Pain and Anxiety Associated With Genetic Amniocentesis? A Randomized Clinical Trial

Richard L. Fischer,* Kathryn W. Bianculli, Harish Sehdev, and Mary L. Hediger

Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Cooper Hospital/University Medical Center, Camden, New Jersey

Objective: To determine if light pressure effleurage (leg rubbing) during genetic amniocentesis reduces procedure-related pain and anxiety.

Methods: Two hundred women with singleton gestations undergoing genetic amniocentesis between 15–22 weeks recorded their level of anticipated pain and anxiety on a 10-cm linear visual analog scale prior to the amniocentesis. Subjects were then randomized to receive effleurage or no effleurage by the assisting nurse during the procedure. Subjects were blinded to the effleurage nature of the study. Following the amniocentesis, subjects repeated the pain and anxiety scoring.

Results: The two groups were similar with respect to subject and procedure characteristics, as well as anticipated pain or anxiety prior to amniocentesis. Postamniocentesis pain and anxiety scoring were similar in the two groups. The mean effleurage acceptance score was 8.3 ± 1.8 (out of 10), and 90.2% of subjects reported that they would want effleurage with future amniocenteses.

Conclusions: Although well accepted by women, light pressure effleurage during genetic amniocentesis does not reduce procedure-related pain or anxiety. *J. Matern.-Fetal Med. 2000;9:294–297.*

Key words: genetic amniocentesis; effleurage; pain perception

INTRODUCTION

Effleurage, a form of therapeutic massage, has been used for centuries for the management of both chronic and acute pain, including labor pain [1–4]. While some find effleurage effective because it serves as a pleasant, relaxing distraction, there may be a physiological basis for its mode of action [5]. Known as the "gate control theory," cutaneous stimulation carried through large myelinated afferent neurons is theorized to inhibit at the spinal cord the transmission of pain impulses to the brain [6]. It has also been suggested that various forms of cutaneous stimulation, including transcutaneous electrical nerve stimulation (TENS) units [7] and therapeutic massage may release endogenous opiates (endorphins), which also act to reduce pain [2]. Despite the widespread support for cutaneous stimulation in textbooks and nursing literature, there is a relative paucity of adequately controlled trials in the medical literature. Patients often serve as their own controls, with measurements obtained before and after therapeutic massage [1]. Such studies are prone to bias, as pain perception is highly subjective and might easily be influenced by the patient's knowledge of a proposed intervention.

Genetic amniocentesis is often associated with a high degree of anxiety, related to potential risks as well as perceived pain of the procedure. When effleurage in the form of leg rubbing was initiated during genetic amniocentesis at our institution, we were impressed by the number of unsolicited positive responses by our patients. Review of the medical literature revealed no prior evaluation of effleurage in the mediation of pain during genetic amniocentesis. This led us to initiate this single-blind study of effleurage during amniocentesis. Our purpose was to determine the effect of light pressure effleurage on both the perception of pain and overall anxiety associated with genetic amniocentesis. We

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*Correspondence to: Richard L. Fischer, 1 Cooper Plaza, Room 623, Dorrance Building, Camden, NJ 08103.

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hypothesized that effleurage would be associated with a 25% reduction of pain related to amniocentesis.

MATERIALS AND METHODS

Two hundred women with singleton gestations undergoing genetic amniocentesis between 15–22 weeks from April, 1998, to July, 1999, were enrolled in this prospective randomized trial involving three testing sites in southern New Jersey: Cooper Hospital/University Medical Center in Camden, Memorial Hospital of Burlington County in Mount Holly, and Robert Wood Johnson University Hospital at Hamilton. Because of the subjective nature of pain and anxiety, it was felt that the subjects' prior knowledge of the two arms of the study would likely bias their perception of discomfort. Therefore, with approval from each site's Institutional Review Committee, all subjects were masked to the effleurage nature of this study. Eligible women were simply asked to participate in a questionnaire regarding pre- and postamniocentesis pain and anxiety. None of the women declined participation. The first question asked the subject to rate how nervous she was about the upcoming amniocentesis, and the second asked how much she anticipated the amniocentesis would hurt. Responses were made on a visual analog scale, a simple and widely used tool for self-reported pain assessment [8]. The scale consisted of a 10-cm horizontal line with two extreme responses on either end (no pain or anxiety on the lefthand side, worst pain or anxiety on the right-hand side). Subjects were asked to place a single vertical line along the horizontal scale that indicated their anticipated level of pain or anxiety.

Prior to amniocentesis, subjects were randomly assigned to an effleurage or control group. Group allocation was determined at each testing site by a random permuted block technique using blocks of six, with each assignment kept in sequentially numbered, sealed, opaque envelopes stored at each testing site. Those subjects assigned to the effleurage group were offered light leg rubbing during the amniocentesis by the assisting nurse and given the opportunity to refuse. Those assigned to the control group were not touched by the nurse unless specifically requested by the subject. Prior to the study, all nurses at the three sites were taught the technique of light pressure effleurage in a standardized manner by one of two authors (RLF, KWB). The technique consisted of light stroking with the fingertips and the palms of the hand applied over clothing along the lower leg and foot just prior to and during the amniocentesis. There was no attempt to control for other sensory stimuli, such as talking calmingly to the subjects during the procedure. The presence or absence of a support person, and whether the subject was touched by the support person during the procedure, were also recorded. Amniocentesis was performed without the use of local anesthesia by one of five Maternal-Fetal Medicine physicians employing either a 20 or 22 gauge needle (67.5% and 32.5% of procedures, respectively). A separate syringe was utilized to discard a small volume of amniotic fluid in 26.5% of procedures prior to aspiration of the usual 20 ml of fluid.

TABLE 1. Subject Characteristics

	Effleurage (n = 103)	Control (n = 97)	P*
Age (years)	33.3 ± 5.2	34.4 ± 5.3	0.12
Gravidity	2.4 ± 0.8	2.5 ± 0.7	0.41
Nulliparous	32 (31.1%)	25 (25.8%)	0.41
Ethnicity			0.49
Caucasian	75 (72.8%)	77 (79.4%)	
African-American	14 (13.6%)	14 (14.4%)	
Hispanic	11 (10.7%)	4 (4.1%)	
Other	3 (2.9%)	2 (2.0%)	
Private insurance	83 (80.6%)	80 (82.5%)	0.73
Gestational age at amniocentesis (weeks)	17.5 ± 1.5	17.0 ± 1.4	0.01
Maternal weight (kg)	71.2 ± 13.6	71.1 ± 17.0	0.95
Body mass index	26.9 ± 5.1	26.0 ± 5.8	0.26
Prior amniocentesis or chorionic villus sampling	12 (11.8%)	22 (22.7%)	0.04

Data presented as mean ± standard deviation or number (%).
*t-test/chi-square test, two-tailed, significance at $P < 0.05$.

Following amniocentesis, subjects rated their perception of procedure-related pain and how nervous they would be with future amniocentesis. Those subjects receiving effleurage also rated how well they were tolerated effleurage on a 10-cm visual analog scale and asked if they would want effleurage with a future amniocentesis.

For analytic purposes, the visual analog scoring was converted to a numerical value by measuring the distance in centimeters from the left-most portion of the 10 cm horizontal scale to the vertical marking. All values had a potential range of 0 (representing the least pain or anxiety) to 10 (representing the greatest pain or anxiety). Analysis was by intent-to-treat. Statistical methods included Student's t-test, chi-square test, and analysis of covariance where appropriate, with a P-value < 0.05 considered statistically significant.

RESULTS

Of the 200 subjects, 103 were randomized to the effleurage group and 97 to the control group. One subject assigned to the effleurage group failed to receive leg rubbing during her amniocentesis, but was analyzed in the effleurage group (intent-to-treat). Another subject randomized to the effleurage group requested that the nurse hold her hand during the procedure. The nurse complied while performing effleurage on her upper arm.

There were no significant differences between the two groups with respect to age, race, gravidity, parity, maternal weight, height, body mass index, or insurance status (Table 1). The effleurage group had a slightly higher

TABLE 2. Amniocentesis Characteristics

	Effleurage (n = 103)	Control (n = 97)	P*
Indication			0.92
AMA	61 (59.2%)	59 (60.8%)	
Positive triple test	29 (28.2%)	24 (24.7%)	
Elevated MSAFP	3 (2.9%)	3 (3.1%)	
Fetal anomaly	7 (6.8%)	6 (6.2%)	
Other	3 (2.9%)	5 (5.2%)	
Performing MD			0.33
RLF	64 (62.1%)	65 (67.0%)	
HS	23 (22.3%)	19 (19.6%)	
Other	15 (14.6%)	13 (13.4%)	
20 g needle	70 (68.0%)	65 (67.0%)	0.89
One amniocentesis attempt	99 (96.1%)	95 (97.9%)	0.39
Support person present	85 (83.3%)	74 (76.3%)	0.22
Support person touching subject	63 (62.4%)	51 (53.1%)	0.19

Data presented as number (%).
*Chi-square test, two-tailed, significance at $P < 0.05$.

TABLE 3. Pain and Anxiety Scoring

	Effleurage (n = 103)	Control (n = 97)	P*
Preamnio pain score	4.6 ± 2.4	4.3 ± 2.3	0.45
Preamnio anxiety score	5.3 ± 2.9	5.1 ± 3.1	0.68
Postamnio pain score	2.7 ± 2.4	2.4 ± 2.3	0.36
Postamnio anxiety score	2.7 ± 2.4	2.7 ± 2.9	0.90
Delta (pre–post) pain score	1.9 ± 2.9	2.0 ± 3.4	0.90
Delta (pre–post) anxiety score	2.6 ± 2.7	2.4 ± 3.3	0.60

Data presented as mean ± standard deviation.
*t-test, two-tailed, significance at $P < 0.05$.

gestational age at the time of amniocentesis (17.5 ± 1.5 vs. 17.0 ± 1.4, $P = 0.01$), while there was a significantly higher proportion of subjects with a history of prior amniocentesis or transabdominal chorionic villus sampling in the control group (22.7% vs. 11.8%, $P = 0.04$). There were no significant differences with regard to procedure indication, performing physician, gauge of needle employed, number of amniocentesis attempts, and the percentage of subjects with a support person either present or touching the subject (Table 2).

Analysis of the preamniocentesis anticipated pain and anxiety scores showed no statistically significant differences between the two groups, nor were there differences in the postamniocentesis scores (Table 3). Comparing the differences in pain scoring before and after the procedure, a similar proportion of subjects reported that the amniocentesis hurt less than expected (70.9% in the effleurage group vs. 71.1% in the control group, $P = 0.97$). The mean delta pain score (pre- minus postamniocentesis) was 1.9 ± 2.9 in the effleurage group vs. 2.0 ± 3.4 in the control group, a nonsignificant difference ($P = 0.90$). Similarly, there was no significant difference in the mean delta anxiety score (2.6 ± 2.7 vs. 2.4 ± 3.3, $P = 0.60$).

Those women with a history of a prior amniocentesis or transabdominal chorionic villus sampling had a significantly lower mean preamniocentesis pain score (3.4 ± 2.4 vs. 4.7 ± 2.4, $P = 0.007$) and anxiety score (3.8 ± 2.9 vs. 5.5 ± 3.0, $P = 0.002$), although there were no significant differences in the postamniocentesis pain or anxiety scores. When the effleurage and control groups were adjusted for prior procedures using analysis of covariance, there remained no differences in pain or anxiety reduction with effleurage.

Despite the absence of any measurable pain or anxiety reduction with effleurage, it appeared to be well accepted by subjects, with a mean score of 8.3 ± 1.8 (maximum score of 10). Of the 103 subjects receiving effleurage, 90.2% indicated that they would want effleurage performed during a future amniocentesis, while the remaining 9.8% responded that they "didn't care." No respondent indicated that she would not want repeat effleurage.

DISCUSSION

Effleurage comes from the French verb *effleurer*, meaning "to touch lightly." This modality has been utilized for many years by nurse midwives to reduce pain during labor, and has been applied to other clinical situations as well [1,3,4]. Effleurage may work by inducing a relaxed state in patients with labor pain, cancer pain, as well as in critically ill patients. Additionally, effleurage may mediate pain by inhibiting pain fibers in the spinal cord or by direct release of opiates from the central nervous system. Unfortunately, there is a dearth of published studies that evaluate therapeutic massage in a scientifically rigorous manner. Many studies are plagued by the absence of blinded treatment and control groups [1]. Due to the subjective nature of pain perception, it is often difficult to objectively separate pain mediation from a placebo effect in response to nonpharmacological therapies.

Amniocentesis can be an anxiety-provoking procedure, due to concern about underlying fetal abnormalities and, procedure-related loss, as well as pain from the needle. Local anesthesia may reduce pain at the cutaneous level, but not at the peritoneum. After the routine initiation of effleurage by the nurses at our institution, we were struck by the positive response by our patients, some of whom specifically requested effleurage for repeat procedures. This study sought to determine whether effleurage actually reduced the pain from the procedure, or simply made it more tolerable. If it simply relaxed the patients, it might reduce the anxiety associated with amniocentesis, with no appreciable affect on pain.

The visual analog scale was chosen as our tool for self-reporting of pain and anxiety. Unlike a numerical pain scale, in which subjects assign pain intensity to discrete

numbers ranging from zero to ten, the visual analog scale permits subjects to select along a continuum of values which can then be analyzed with parametric statistical tests [8]. This tool is widely utilized as a reproducible self-reporting assessment, having been used in other studies of pharmacologic and nonpharmacologic pain relief [1,9].

Our results indicated no significant benefit of light pressure effleurage on amniocentesis pain as measured by the difference between the pre- and postprocedure scores. Similarly, effleurage did not reduce the level of anxiety for future amniocentesis. Our findings may be explained in a number of ways. First, amniocentesis was not judged to be a very painful procedure, with an average postprocedure score of 2.6 out of 10. This is similar to a mean score of 2.9 out of 10 found in a prior study of 100 women undergoing amniocentesis [10]. In another survey of 52 women having genetic amniocentesis at 16 weeks, 96% experienced either discomfort or mild pain and 83% felt less pain than had been anticipated [11]. Therefore, the benefits of effleurage may not be appreciated as much as it might with a more painful procedure. Second, our lack of any significant difference might be due to a Type II error from an inadequate number of subjects. Our power to detect a 25% decrease in the postamniocentesis pain score was only 45%. In order to increase the power to 80%, 233 subjects would be needed in each arm. Finally, it may be that effleurage simply does not work as a pain mediator. It may be perceived as a pleasurable sensation, accounting for the 90% who would desire repeat effleurage with future procedures, but one that does not physiologically or psychologically reduce pain.

The strength of our study lies in the proper randomization and blinding of the subjects to the two arms of our study. This was allowable by the Institutional Review Committees because of the minimal risk of the study, our inability to objectively assess subject responses without blinding, our willingness to either withhold or provide effleurage at the patient's request, and our willingness to reveal the nature of the study following completion of the postamniocentesis scoring.

In conclusion, we found no significant improvement in the perception of pain or anxiety from genetic amniocentesis with the use of light pressure effleurage. Effleurage during genetic amniocentesis was perceived favorably by the majority of patients, most likely for benefits other than pain mediation.

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