Analgesic Effect of Auricular Acupuncture for Cancer Pain: A Randomized, Blinded, Controlled Trial

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Purpose: **During the last 30 years, auricular acupuncture has been used as complementary treatment of cancer pain when analgesic drugs do not suffice. The purpose of this study is to examine the efficacy of auricular acupuncture in decreasing pain intensity in cancer patients.**

Patients and Methods: **Ninety patients were randomly divided in three groups; one group received two courses of auricular acupuncture at points where an electrodermal signal had been detected, and two placebo groups received auricular acupuncture at points with no electrodermal signal (placebo points) and one with auricular seeds fixed at placebo points. Patients had to be in pain, attaining a visual analog score (VAS) of 30 mm or more after having received analgesic treatment adapted to both intensity and type of pain, for at least 1 month of therapy. Treatment efficacy was based on the absolute decrease in pain intensity measured 2 months after randomization using the VAS.**

Results: **The main outcome was pain assessed at 2 months, with the assessment at 1 month carried over to 2 months for the eight patients who interrupted treatment after 1 month. For three patients, no data were available because they withdrew from the study during the first month. Pain intensity decreased by 36% at 2 months from baseline in the group receiving acupuncture; there was little change for patients receiving placebo (2%). The difference between groups was statistically significant ($P < .0001$).**

Conclusion: **The observed reduction in pain intensity measured on the VAS represents a clear benefit from auricular acupuncture for these cancer patients who are in pain, despite stable analgesic treatment.**

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CANCER PAIN is a difficult problem for clinicians because analgesic drugs do not always procure complete relief.[1] After curative cancer treatment, pain often remains the dominant symptom affecting the patient's physical and psychological state. Chronic pain in cancer patients is dominated by the neuropathic component even when associated with nociceptive pain.[2] Neuropathic pain is the most difficult type of pain to treat in cancer patients, and in general, does not respond well to drug treatment.[3] Acupuncture activates central brain pathways, thus inhibiting the maladaptive reflex that contributes to neuropathic pain.[4]

Acupuncture, for treatment of chronic pain, has been evaluated in many trials. A systematic review of these trials showed that three out of four of them were poor in quality, and the conclusion was that there was inconclusive evidence that acupuncture was more effective than a placebo.[5] Two Cochrane reviews and a systematic review focusing on acupuncture for idiopathic headache,[6] low back pain,[7] and neck pain[8] respectively, reached the same conclusions.

There are no randomized trials published in the English literature testing the efficacy of auricular acupuncture in reducing cancer pain. For the last 30 years, auricular acupuncture[9,10] has been used as complementary treatment of cancer pain when analgesic drugs do not suffice; it is routinely used in our institution and we have decided, pragmatically, to evaluate its efficacy.

In a recent observational study of 20 cancer patients, we showed a reduction of chronic pain following auricular acupuncture.[11] This result, together with those of experimental studies,[12,13] encouraged us to design a randomized, controlled trial with two placebo groups and blind evaluation of the results in cancer patients experiencing chronic pain. The objective was to find out if auricular acupuncture would reduce pain in cancer patients as compared to placebo. In our current study, we report the results of this clinical trial conducted among 90 patients with cancer pain treated between February 1999 and June 2001 in the Pain Management Unit at the Institut Gustave Roussy, a large comprehensive cancer center in Villejuif, France.

PATIENTS AND METHODS

Patients

Eligible patients were adults being consulted at the Pain Management Unit at the Institut Gustave Roussy for the treatment of chronic peripheral or central neuropathic pain arising after treatment of a cancer. Patients had to have attained a pain level evaluated at 30 mm or more on a visual analog score (VAS) graduated from 0 to 100 mm,[14] despite analgesic treatment adapted to the intensity and to the type of pain, and prolonged for at least 1 month before randomization. Patients were excluded from the study if they had had previous auricular acupuncture or were part of another clinical trial at the time of recruitment. All patients gave their written informed consent before randomization. The trial protocol had been approved by the institu-

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tional ethics committee and by the local review board. Five months after starting the study, recruitment was extended to patients who had not received analgesic drugs or who had decided to discontinue all analgesics at least 1 month before their participation in the trial. This was decided because of slow patient accrual.

At time of randomization, patients were examined by a clinician to evaluate the location, type, and intensity of pain, and to verify inclusion and exclusion criteria.

Treatments Compared

To evaluate the effect of acupuncture in a randomized study, the best design is to compare true acupuncture—needles inserted at acupuncture points—to a noneffective acupuncture. Acupuncture relies on two hypotheses: that there are specific points that should be treated for a given patient with given symptoms; and that insertion of needles at these points alleviates the symptoms. When noneffective acupuncture is performed, needles are inserted at points that are not acupuncture points; this tests the first hypothesis but not the second one. To test the two hypotheses, we used two control groups, one with insertion of needles and another without insertion of needles. The comparison of the two control groups tests for the effect of needle insertion (at nonacupuncture points).

It is often stated that only standardized procedures of acupuncture can be evaluated, and some randomized trials of acupuncture[5-8] have used the same treatment points for all patients. However, one of the basis of acupuncture is that the points have to be selected individually for each patient, and auricular acupuncture is based on the belief that clinical symptoms are projected onto the ear according to a precise somatic topography.[15] We have therefore decided to evaluate an auricular acupuncture corresponding to the current practice of most acupuncturists, where the number of points and the location of points are selected individually for each patient.

Acupuncturists identify the points by the detection of an electrical signal. Given that symptoms are associated with electrical signals at given ear points,[16] the signal is proportional to both the intensity and the duration of the symptom,[17] and the disappearance of the signal is associated with disappearance of the corresponding symptom.

Selection of Auricular Points

An electrical chart of the ear was established for each patient by measuring the electrodermal response at the points on the ear where projected pain was suspected, based on clinical symptoms. The information was recorded using the codes for ear points proposed by Oleson et al,[12] who divides the ear into 150 areas. The recording was made with an electronic microvoltmeter, measuring the potential difference with two isolated coaxial electrodes that were loaded on springs, respectively calibrated at a pressure of 15g and 80g after sending a 9 volt detection current on a sensitivity scale of 10 levels (Pointo Select DT+, Schwa Medico, Rouffach, France; Fig 1). This method has been validated in an experimental setting where the effects of tactile stimulation of the thumb and acupuncture stimulation of the site on the ear corresponding to the thumb were compared using functional magnetic resonance imaging.[18]

Placebo points were defined as ear points outside the areas of projected pain on the ear (ie, points eliciting no electrical response). The number of placebo points treated for a given patient in a placebo group was equal to the number of points eliciting an electrical response. Patients in the first placebo group had steel implants inserted in placebo points; in the second placebo group, auricular seeds (Marco Polo Matériel Acupuncture, Albi, France) were used and fixed to placebo points with an adhesive patch sold with the seed. Auricular seeds are commonly used in acupuncture practice as a method of stimulating acupuncture points without skin insertion. Figure 1 shows two ears treated, one with steel implants and one with auricular seeds.

Randomization

Randomization was performed by the clinician who accessed a centralized computerized randomization system. After entering the trial identifier and his individual password, the clinician was asked to enter the patient's identifiers and the characteristics required to verify eligibility. In return, the computer determined the assigned treatment, which was registered in the computer with the patient's identification and could not be modified. This system precludes foreknowledge of the assignment of the next patient and prevents allocation being changed after assignment. The random allocation sequence was in blocks of six, stratified on VAS for pain intensity in mm (30 to 49 *v* 50 to 69 *v* 70+). Patients were randomly assigned to one of the following three treatments: auricular acupuncture at points where an electrical response had been detected, auricular acupuncture at placebo points, and auricular seeds fixed at placebo points.

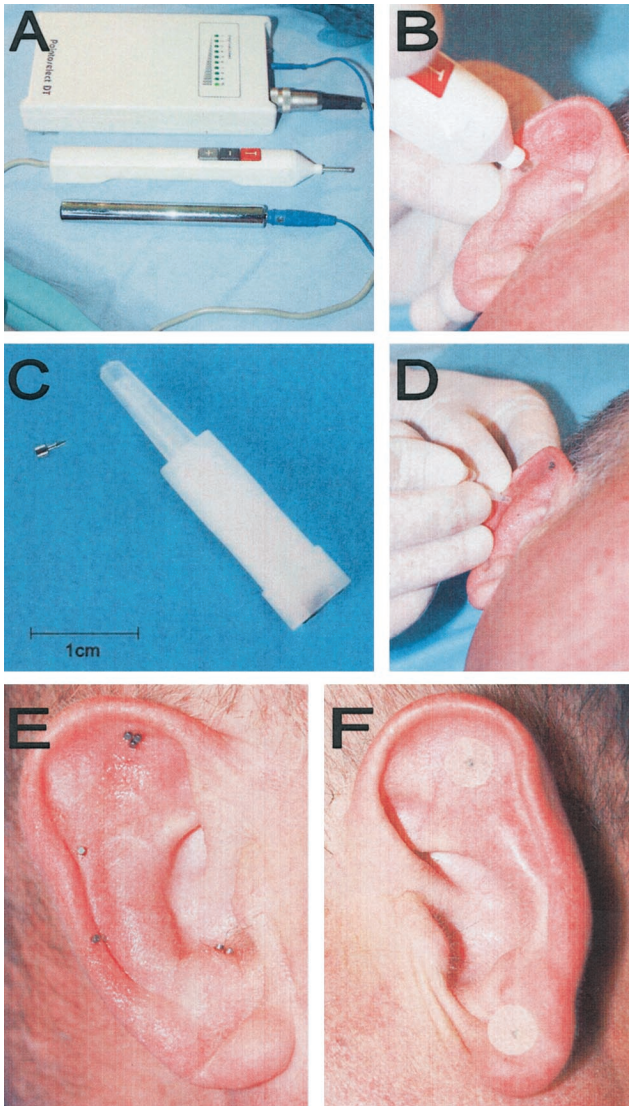

Fig 1. Auricular acupuncture technique. Microvoltmeter (A) and measurement of the electrical potential difference at the ear where projected pain is suspected (B); sterile steel implant with its container (C), and technique of auricular acupuncture (D); ear treated by auricular acupuncture (E), and by placebo seeds (F).

Implant Placement

The ears were disinfected with alcohol before treatment. Identical single-use sterile steel implants (Sedatelec, Irigny, France) were used for the first two groups. These spear-headed implants are 3.4 mm long, and have a cylindrical head with 1.2 mm diameter and height. The maximum diameter of the part of the needle that enters the skin is 0.7 mm. Each implant is at the end of a small sterile plastic container that contains compressed air. Locating

the end of the container at the acupuncture point and putting pressure on the container releases the implant (Fig 1).

Follow-Up

Patients were requested by the treating physician to maintain the same analgesic drug treatment after randomization. Just after the first treatment course, patients were given a leaflet with an image of the ear with points where each needle had been inserted or where each seed had been fixed, and were asked to report the dates when the needles or seed fell out/off. This leaflet was also used to record their consumption of analgesics. All patients were invited to return to the unit 1 month later.

During this second visit, pain intensity was evaluated by a clinician who was blinded to the treatment received. A second electrical chart of the ear points where an electrical response had initially been detected was established and a second treatment course, using the same points as during the first treatment, was administered. After the second course of treatment, the patients were given a second leaflet to record the dates needles or seeds fell out/off, and their consumption of analgesic drugs. The second course of treatment, identical to the first one, was not delivered to patients who decided to withdraw from the study, nor to patients whose analgesic treatment had been modified. A final evaluation, including VAS pain measurement and an electrical chart of the ear, was conducted again about 1 month later.

Consumption of Treatments

Analgesic use was monitored by patient self-report diary. These treatments include analgesic drugs (WHO level 1 to 3), coanalgesic drugs (tricyclic antidepressants and antiepileptics), and other drugs such as benzodiazepines or muscle relaxants. The treatments used in the trial are described using the WHO classification,[19] with additional levels 0 for drugs other than WHO analgesics or coanalgesics, and 2a for coanalgesics associated (or not) with WHO level 1 analgesics or with other drugs.

Data Collection

There were three evaluations of pain intensity and an equivalent number of electrical charts of the ear: before the administration of the first course of treatment (D0); about 1 month later before the second course of treatment (D30); and again about 1 month later, at completion of the study (D60).

All the electrical measurements and auricular treatments were performed by the same person, a medical doctor/associate professor teaching auricular acupuncture at Paris XIII medical school (Bobigny, France).

The main outcome was pain intensity at D60 measured on the VAS. Secondary outcomes were pain intensity at D30, average electrical potential differences at D60, and average electrical potential differences at D30. The last two are computed by averaging the results at the different points for each patient.

We chose the VAS as the main end point because it evaluates pain directly. Many trials of analgesic procedures use the consumption of analgesic medication as the primary end point, but in our study, the patients were supposed to have a stable analgesic treatment and were expected to remain on this treatment.

Throughout the trial, patients and nurses remained blinded to the treatment received and the analysis was performed independently of the clinicians.

Statistical Analysis

Based on our previous experience,[11] we estimated that 27 patients per arm would be necessary to demonstrate a difference of 20 mm on the VAS between two treatment groups after 2 months of treatment (type I error, 0.05; power, 0.90; two-sided test: SE, 22 mm), and thus decided to include 90 patients in the trial, 30 per arm.

The comparison of pain intensity at D60 was adjusted for pain intensity at baseline, using an analysis of the covariance technique. This is the recommended method to adjust for a baseline covariate which is correlated to the outcome.[20,21] Similarly the analyses of pain intensity at D30, and the electrical potential differences at D30 and D60 were compared between treatment groups, using an analysis of the covariance model, taking baseline measurements into account. The three treatment groups were coded using two binary variables, coding respectively for skin penetration and for true acupuncture sites. True acupuncture was therefore coded {1, 1}, as was placebo acupuncture {1, 0}, and placebo seeds {0, 0}. This allows separate tests of the effect of skin penetration and of needle insertion at true acupuncture points. If there is no effect of skin penetration, this variable can be removed from the model, which is reduced to a comparison of the true acupuncture group and the pooled placebo groups.

When a patient decided to withdraw from the study or when his/her analgesic treatment was modified, the patient was invited to return 1 month after treatment for evaluation. There were two options for the analysis: to remove this patient from the analysis or carry forward the last measurement for the outcome. We have chosen the second option; the last evaluation, even if performed on D30, was used as final evaluation data.

Data were collected on standard sheets, entered in a database managed with PIGAS (Gustave Roussy Institute, Villejuif, France),[22] and analyzed with SAS software (SAS/STAT User's Guide, Version 6; SAS Institute, Cary, NC).

RESULTS

Among the 432 patients who came to the Analgesia Unit between February 1999 and May 2001 and had never been treated by auricular acupuncture, 102 met the inclusion criteria, 12% refused to participate, and 90 were included in the trial; 29 in the auricular acupuncture group, 30 in the placebo auricular acupuncture group, and 31 in the placebo auricular seed group. Figure 2 shows the flow of participants through the trial schema.

Pain evaluation was not available for three patients because they withdrew from the study before D30. These patients are not assessable and are excluded from the analysis.

Pain evaluation was performed at D60, as planned, for 79 patients. Contrary to the protocol, three patients had their analgesic treatment modified by their general practitioner or medical oncologist within the first 30 days, and they have been included in the analysis. Eight patients provided follow-up data only at D30; seven of these were in the placebo groups. Five of these patients, including the patient with true acupuncture, refused the second treatment and decided to withdraw from the study at D30 because their pain had increased.

Table 1 describes the assessable patients. Baseline characteristics were similar in the three randomized groups. More than two-thirds of the patients were women and most of them had been treated for a breast cancer. The mean age was 57 (range

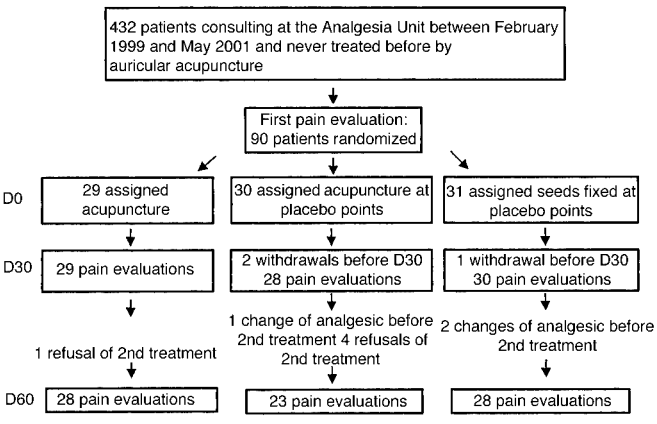

Fig 2. Trial profile.

Table 1. Initial Characteristics by Treatment Group

Initial Characteristics	Treatment Group: Acupuncture (n = 29) No. of Patients	%	Acupuncture at Placebo Points (n = 28) No. of Patients	%	Seeds Fixed at Placebo Points (n = 30) No. of Patients	%
Sex						
Females	20	69	27	90	23	77
Age, years						
Mean	57		56		57	
Range	38-84		42-72		37-80	
Cancer site						
Head and neck	3	10	4	14	5	17
Breast	16	55	14	50	15	50
Lung	0	0	2	7	0	0
Other	10	35	8	29	10	33
Cancer stage						
Local	9	31	13	46	14	47
Locoregional	19	65	14	50	16	53
Metastatic	1	3	1	4	0	0
WHO performance status						
0	22	76	27	96	27	90
1	6	21	1	4	3	10
2	1	3	0	0	0	0
Type of pain						
Neuropathic	25	86	27	96	28	93
Neuropathic and nociceptive	4	14	1	4	2	7
Frequency of pain						
Constant	24	83	24	86	26	87
Intermittent	5	17	4	14	4	13
Baseline pain intensity on VAS	58		58		57	
Range	32-100		32-94		32-98	
Number of painful zones	6		6		7	
Range	2-12		3-12		2-12	
Maximum level of analgesic drug*						
No drug	4	14	1	4	0	0
0	0	0	1	4	0	0
1	1	4	3	11	0	0
2a	7	24	13	46	13	43
2	14	48	8	28	13	43
3	3	10	2	7	4	14
Number of analgesic drugs*	2		2		2	
Range	0-4		0-4		1-4	
Baseline average electrical potential difference at auricular points	5.7		5.6		5.4	
Range	3.6-7.8		3.6-7.2		3.7-7.2	

Abbreviation: VAS, visual analog score.

*Drugs prescribed for analgesic purpose, including analgesic drugs (WHO level 1 to 3), coanalgesic drugs (tricyclic antidepressants and anti-epileptics), and other drugs such as benzodiazepines or muscle relaxants, described using the WHO classification, with additional levels 0 for drugs other than WHO analgesics or coanalgesics, and 2a for coanalgesics associated or not with WHO level 1 analgesics or with other drugs.

37–84). All the patients experienced neuropathic pain that was constant in 85% of the cases. Initial pain, as measured on the VAS, was 58 mm on average (standard deviation [SD], 17). Five patients had no analgesic drug treatment at randomization, having stopped pain-adjusted analgesics because they were either inefficient or provoked side effects; these patients were included after the inclusion criteria had been extended to this category of patients. For the other patients, the analgesic treatment at inclusion consisted of two drugs on average with more than 90% of the patients receiving coanalgesics or WHO level 2 or 3 analgesics. Baseline average electrical potential differences were similar in the three treatment groups. Figure 3 shows that baseline pain intensity and baseline average electrical potential difference are significantly correlated ($R^2 = 0.56$; $P < .0001$).

Analgesic use was extremely stable. Between D0 and D30, two patients in the auricular acupuncture group reduced their consumption of analgesic drugs and one patient in the placebo auricular acupuncture group increased the dose of amitriptyline.

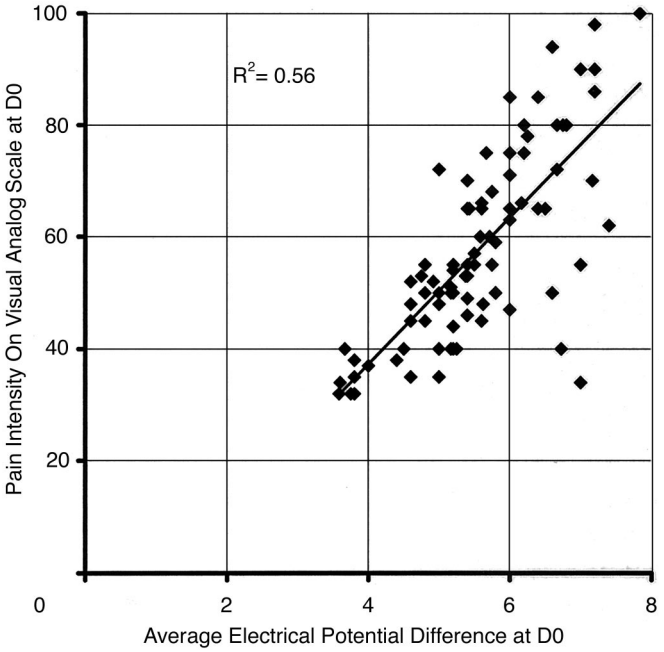

Fig 3. Correlation between pain intensity on Visual Analog Scale at D0 and average electrical potential difference at D0.

Three patients had their analgesic treatment modified between D30 and D60, one in each group of treatment, and they are included in the analysis.

Table 2 shows that the main treatment characteristics were similar across treatment groups. An average of six auricular points with an electrodermal response were found at the ear points where projected pain was suspected. The duration of each treatment was, on average, 44 minutes and was not significantly different for the first visit that included randomization, pain evaluation, and the first treatment course, and for the second visit which included pain evaluation and the second treatment course. Needles or seeds used for the study fell out/off between 1 and 34 days (average 12 days) after the treatment.

D60 pain scores were lower in the true acupuncture group (mean ± SD, 37 ± 19) than in either the placebo acupuncture (mean ± SD, 55 ± 24) or the placebo seeds (mean ± SD, 58 ± 20) groups (Table 3). The analysis of covariance for pain intensity at D60 showed no effect of skin penetration (3.1 decrease in pain intensity) but a significant effect of true acupuncture (18.4 decrease in pain intensity; $P < .001$; Fig 4). Removing skin penetration from the model strengthens these results (difference between acupuncture and placebo groups, 20.0; 95% CI, 11.2 to 28.8).

D30 pain scores were also lower in the true acupuncture group (mean ± SD, 44 ± 19) than in either the placebo acupuncture (mean ± SD, 54 ± 25) or the placebo seeds groups (mean ± SD, 56 ± 19). The analysis of covariance for pain intensity at D30 showed no effect of skin penetration and a significant effect of true acupuncture (10.9 decrease in pain intensity; $P = .02$).

D60 average electrical potential differences were lower in the true acupuncture group (mean ± SD, 3.9 ± 1.0) than in either the placebo acupuncture (mean ± SD, 5.5 ± 1.2) or the placebo seeds groups (mean ± SD, 5.4 ± 0.9; Table 3). The analysis of covariance showed no effect of skin penetration but a significant effect of true acupuncture (decrease of 1.6 for the average electrical potential difference; $P < .01$).

The same analysis at D30 gave similar results with no effect of skin penetration and smaller decreases in electrical potential difference with true acupuncture than at D60 (decrease equal to 0.8; SD, 0.2; $P < .01$).

The decrease in pain intensity between D0 and D60 was correlated with the decrease in the average electrical potential difference at auricular points and the correlation was higher in the auricular acupuncture group than in the other groups ($R^2 = 0.76$; $P < .01$ *v* $R^2 = 0.36$ and 0.32; Fig 5).

During the trial, no infection at treated ear points was reported by the patients nor recorded by the clinicians. No other adverse events were reported.

DISCUSSION

Our study shows that auricular acupuncture at points where an electrodermal signal is detected is associated with a significant reduction in pain intensity in patients with neuropathic pain. It also shows that the reduction in pain is associated with a decline in the average electrical signal detected at ear points. The observed reduction of 20 mm on the VAS is of clear benefit for these cancer patients who, despite stable analgesics, continue to be in pain, especially considering the low cost, low inconvenience, and low risk of auricular acupuncture.

The acupuncture treatment was adapted to each patient. Our trial is therefore more relevant to acupuncturists, who generally use an individualized treatment with points adapted to each patient, than if we had used a standardized treatment with the same points for each patient.

Table 2. Treatment Characteristics

	Treatment Group					
	Acupuncture (n = 29)		Acupuncture at Placebo Points (n = 28)		Seeds Fixed at Placebo Points (n = 30)	
Treatment Characteristics	Mean	Range	Mean	Range	Mean	Range
No. of auricular points with detectable signal	7	5-18	6	4-12	6	4-12
No. of days before needles or seeds fell out/off after each treatment	13	2-25	10*	3-33	12	1-34
Duration of each treatment session, minutes	43	25-54	43	30-57	44	30-54
Follow-up duration, days	62	35-70	58	28-77	65	56-84

*Unknown for the second course of treatment for one patient.

Table 3. Mean Pain Intensity on VAS and Average Electrical Potential Difference at Auricular Points at Baseline, at D30, and at D60 According to the Treatment Group

	Treatment Group					
	Acupuncture (n = 29)		Acupuncture at Placebo Points (n = 28)		Seeds Fixed at Placebo Points (n = 30)	
Outcome	Mean	Range	Mean	Range	Mean	Range
Pain intensity on VAS						
Baseline	58	32-100	58	32-94	57	32-98
D30	44	0-75	54	9-100	56	5-89
D60	37	0-92	55	9-98	58	14-100
Average electrical potential difference at auricular points						
Baseline	5.7	3.6-7.8	5.6	3.6-7.2	5.4	3.7-7.2
D30	4.7	1.5-6.1	5.2	0-8.1	5.4	3.0-6.8
D60	3.9	1.7-7.0	5.5*	2.8-7.4	5.4	2.8-7.2

Abbreviation: VAS, visual analog score.
*Unknown for one patient.

The acupuncturist was not blinded to the treatment. This introduced a difference between the groups in the treatment procedure. However, we verified that the duration of the visit was similar in the three treatment groups and pain was evaluated by a clinician who was unaware of the treatment received, at a time when all needles or seeds had fallen out. The patients were blinded to the two acupuncture treatments since they could not distinguish true from placebo acupuncture sites. On the other hand, the auricular seeds fixed on brown adhesive were identifiable as different from the two acupuncture treatments.

The exclusion of the five patients without analgesic drug treatment at entry does not change the conclusion. The question of the efficacy of auricular acupuncture is as relevant for the patients in chronic pain who refuse analgesic medications because of their side effects, as it is for the patients who are on medication.

The main analysis included all patients, and considered the last pain evaluation as the main end point, which was at D60 for 79 patients and D30 for eight patients. Restricting the analysis to the patients evaluated at D60 and/or excluding the three patients who had their analgesic treatment modified before D60 leads to similar results.

Contrary to our expectation, we observed no effect of the placebo treatments whether they implied skin penetration or not. Chronic pain, stable after a 1 month treatment, may be less susceptible to placebo effects than an acute pain.

The lack of effect in the two placebo groups with and without skin penetration provides evidence that it is the insertion of needles at specific points that provides pain relief. The localization of these points is validated both by the correlation between pain intensity and average electrical potential difference at baseline, by the larger correlation between change in electrical potential difference at the auricular points after treatment, and pain decrease in the true acupuncture group than in the placebo groups.

This study relies on a single experienced acupuncturist; this is a strength of the study because it ensures the homogeneity of the procedures, but it is also a limit to the general applicability of the conclusions. It would be interesting to repeat the study with several acupuncturists. It would also be of interest to evaluate the reliability and repeatability of potential difference measurement. The division of the ear into 150 areas, which is taught and used by all auricular acupuncturists, allows treatments 1 month apart in the same small area.

Very few trials have investigated whether auricular acupuncture, auricular acupressure, or electrical stimulation of ear points are able to treat pain efficiently. We have identified four randomized trials,[23-26] including one in a French journal that is

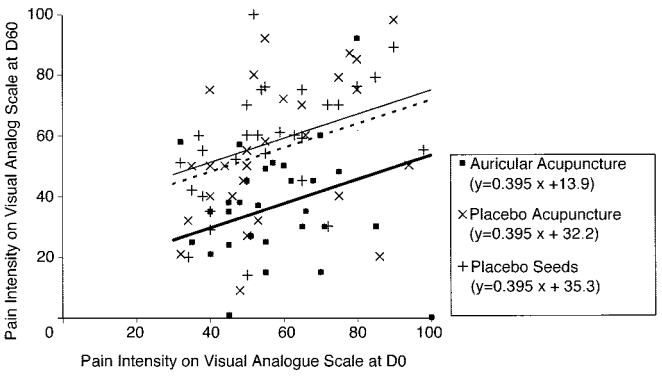

Fig 4. Visual analog score (VAS) at D60 as a function of VAS at D0 in each treatment group. The lines correspond to fitted values based on the analysis of covariance (equations in the legend).

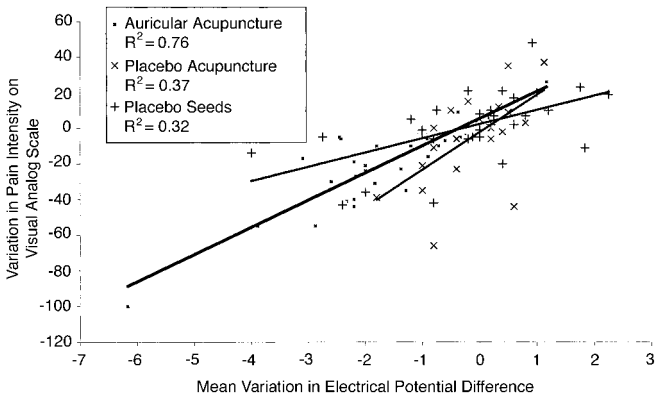

Fig 5. Relation between the D0 to D60 variation in pain intensity on visual analog scale and the mean D0 to D60 variation in electrical potential difference.

not indexed in MEDLINE. This study, the only study of patients with chronic pain included 36 patients, and failed to demonstrate the efficacy of transcutaneous electrical stimulation at ear points.[23] Two other trials studied patients with acute back pain and acute postoperative pain, included 29 and 102 patients, and evaluated the injection of lidocaine at ear points and acupressure respectively.[24,25] The results were reported to be positive, but the quality of the reports and the trials are not fully convincing. A single trial evaluated auricular acupuncture for postoperative pain and included 60 patients. The quality of the report is substandard and we are not certain whether the trial was properly randomized.[26]

Our trial of auricular acupuncture is the first properly randomized evaluation demonstrating the efficacy of this treatment for neuropathic chronic pain, a pain which has been so far resistant to effective intervention. The low cost of such therapy argues in favor of its use for the management of pain in cancer patients.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The authors indicated no potential conflicts of interest.

REFERENCES

1. Portenoy RK, Lesage P: Management of cancer pain. Lancet 353:1695-1700, 1999

2. Caraceni A, Portenoy RK: A working group of the IASP Task Force on Cancer Pain. An international survey of cancer pain characteristics and syndromes. Pain 82:263-274, 1999

3. Filshie J: The non-drug treatment of neuralgic and neuropathic pain of malignancy. Cancer Surv 7:161-193, 1988

4. Oleson T: Auriculotherapy stimulation for neuro-rehabilitation. NeuroRehabilitation 17:49-62, 2002

5. Ezzo J, Berman B, Hadhazy VA, et al: Is acupuncture effective for the treatment of chronic pain? A systematic review. Pain 86:217-225, 2000

6. Melchart D, Linde K, Fischer P, et al: Acupuncture for idiopathic headache. Cochrane Database Syst Rev 1: CD001218, 2001

7. Tulder Mv, Cherkin DC, Berman B, et al: Acupuncture for low back pain. Cochrane Database Syst Rev 2:CD001351, 2000

8. White AR, Ernst E: A systematic review of randomized controlled trials of acupuncture for neck pain. Rheumatology 38:143-147, 1999

9. Bossy J: Bases neurobiologiques des réflexothérapies. Paris, France, Masson, 1975

10. Nogier P: Traité d'auriculothérapie. Moulin-lès-Metz, France, Maisonneuve, 1969

11. Alimi D, Rubino C, Leandri EP, et al: Analgesic effects of auricular acupuncture for cancer pain. J Pain Symptom Manage 19:81-82, 2000

12. Oleson TD, Kroening RJ, Bresler DE: An experimental evaluation of auricular diagnosis: the somatotopic mapping or musculoskeletal pain at ear acupuncture points. Pain 8:217-229, 1980

13. Simmons MS, Oleson TD: Auricular electrical stimulation and dental pain threshold. Anesth Prog 40:14-19, 1993

14. McDowell I, Newell C: Measuring Health: a guide to rating scales and questionnaires. Oxford, UK, Oxford University Press, pp 235-239, 1987

15. Yi L, Minko MM: Management of cancer pain. The external ear/embryo relationship explains the basis of ear acupuncture. Pacific Journal of Oriental Medicine 7:20-23, 1996

16. Pontigny J, et al: Instrumentation and Acupuncture. Moulin-lès-Metz, France, Maisonneuve, 1989

17. Senelar-Auziech: Histologie des points d'Acupuncture et d'Auriculothérapie : mise en évidence du complexe neurovasculaire. Soran, CNRS1990

18. Alimi D, Geissmann A, Gardeur D: Auricular acupuncture stimulation measured on functional magnetic resonance imaging. Medical Acupuncture 13:18-21, 2002

19. Traitement de la douleur cancéreuse. 2ème édition. Genève, Suisse, Organisation Mondiale de la Santé, 1997

20. Vickers AJ, Altman DG: Statistics notes: Analysing controlled trials with baseline and follow up measurements. BMJ 323:1123-1124, 2001

21. Pocock SJ, Assmann SE, Enos LE, et al: Subgroup analysis, covariate adjustment and baseline comparison in clinical trial reporting: current practice and problems. Stat Med 21:2917-2930, 2002

22. Wartelle M, Kramar A, Jan P, et al: PIGAS. An interactive statistical database management system, in: Proceedings of the Second national Workshop on Statistical Database Management. Hammond R, Mac Carty JL: Los Altos California, Laurence Berkeley Laboratory - Statistics Canada, pp: 124-132, Sept 27-29, 1983

23. Melzack R, Katz J: Auriculotherapy fails to relieve chronic pain. A controlled crossover study. JAMA 251:1041-1043, 1984

24. Grobglas A: Traitement des lombalgies aiguës par auriculotherapie : essai randomisé en double aveugle contre placebo. Semaine des Hôpitaux-Paris 69:639-646, 1993

25. Wu H, Bi L, Xu C, et al: : Analgesic effect of pressure on auriculoacupoints for postoperative pain in 102 cases. J Tradit Chin Med 11:22-25, 1991

26. Lequang T, Badaoui R, Riboulot M, et al: Postoperative analgesia by auriculotherapy during laparoscopic cholecystectomy. Cah Anesthesiol 44: 289-292, 1996