

# The Effect of Deep Oscillation Therapy in Fibrocystic Breast Disease. A Randomized Controlled Clinical Trial

ORIGINAL

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## Abstract

**Introduction:** Fibrocystic breast disease is the most widespread disorder in women during their phase of sexual maturity. Deep oscillation (DO) therapy has been used on patients who have undergone an operation for breast cancer as a special form of manual lymphatic drainage.

**Method:** Experimental, prospective case-control studies were conducted in 401 women diagnosed with fibrocystic breast disease. The sample was selected at random and was divided into three groups, a study group and two control groups.

**Results:** Pain was reduced in the three therapies applied. This was statistically significant in the study group. The sonography study presented a predominance of its fibrous form. Upon completion of the treatment a resolution of the fibrosis was observed in the study group. The women were using their bra in an incorrect manner.

**Conclusions:** Pain was reduced in the three therapies applied. In the study group this reduction was statistically significant. It is possible to verify the magnitude of the resonant vibration in the connective tissue from surface to deep layers by viewing the effect of the deep oscillations through the use of diagnostic ultrasound. The most frequent sonographic finding was fibrosis. Deep oscillation therapy produces a tissue-relaxing, moderate vasoconstriction effect, favours local oedema reabsorption and fibrosis reduction. A factor that may affect breast pain is incorrect bra use. The majority of women studied were using their bra incorrectly.

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## Keywords

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## Introduction

Fibrocystic breast disease (CIE 10 N 64.0) is the most widespread disorder in women during their phase of sexual maturity, with or without clinical manifestations. The breast is one of the target organs of ovarian hormones; disruptions in the ovarian cycle lead to fibrocystic disease, which causes considerable discomfort in a high number of women between the ages of 35 and 50 [1]. Its clinical-histopathological alterations are produced by a possible oestrogen-progesterone hormonal imbalance, which induces persistent changes in the ductal-lobular unit, both in the epithelial and in the conjunctival component. It is characterised by inflammatory events and proliferative histological changes that may be cysts, apocrine metaplasia, conjunctival hyperplasia, ductal ectasia, epithelial hyperplasia [2-4].

Generally a painful breast complaint indicates a functional disorder or a benign illness; however, breast cancer can present itself with pain, and so in the presence of any kind of breast pain it is recommended to pay special attention [5-7].

Fibrocystic breast disease accounts for 54% of breast diseases and 70% of benign lesions; it affects one of every two women of childbearing age although it may appear in any stage of life. In Cuba it represents 49.8% of all breast disease and thus constitutes an important problem in women's health. Many do not consider it a disease but rather an unpleasant condition for women, one with which they have to learn to live, given that it is a process that occurs clinically and histologically in between 50% and 90% of women [8].

The term *benign breast condition* includes:

- Fibrocystic disease (also called mammary dysplasia, fibrocystic condition, fibrocystic changes, among others).
- Benign tumours.
- Inflammations.

Fibrocystic changes can be grouped into 3 histopathological forms:

- Fibrous hyperplasia, with a predominance of conjunctival tissue.
- Cystic hyperplasia, with a predominance of variable-size cysts.
- Sclerosing adenosis, when the following associate: increase of small lobes, intracanalicular lobular fibrosis and variable degrees of epithelial hyperplasia [9].

In fibrocystic disease micro-cysts predominate. They are more frequent in the 40 to 50 age range (42%). Pain and nodules are almost constant symptoms; nipple discharge is infrequent. Pain drives the woman to consult a doctor, although in some cases it is nodularity that does this, which can be unilateral or bilateral; its intensity increases as the menstrual cycle progresses and is relieved or disappears with the onset of menstruation. A differential diagnosis should be made with other types of breast pain in order to rule out selective dysplasias or cancer. It becomes important to make the differential diagnosis with malignant neoplasms that may be overestimated in the premenstrual phase and lead to errors in interpretation; sometimes they are identical to carcinoma. Between 5% and 10% of cases are due to extramammary causes: ribcage osteochondritis, intercostal neuralgia, stress-related muscle pain (pectoralis major muscle, latissimus dorsi), mammary pain due to spinal root syndrome, cervical radiculopathy, intramammary adenitis and premenstrual syndrome, among others.

In all cases it is important to physically examine the breasts and the underarm region, complemented with sonography, mammogram and pap smear [10-12]. A sonogram is the most useful study, as it defines whether the lesions are cystic or solid; it is also required as a complement to a mammogram in lesions of an undefined nature.

A biopsy or fine-needle aspirate cytology is an innocuous method and in doubtful cases provides a cytological diagnosis, particularly in complex nodules or masses that are non-painful or discretely

painful as well as in lesions that undergo little or no modification in the fluctuations of the menstrual cycle. It also permits the evacuation of septated cysts, which are frequent in the involutive phase of the process.

Pharmacological treatment for fibrocystic breast disease is heterogeneous. It includes therapies with: danazol, tamoxifen, ormeloxifene, oral analgesic and anti-inflammatory treatments, local nonsteroidal anti-inflammatory treatment, progesterone, ginseng, linseed, phytoestrogens (isoflavones), evening primrose oil, vitamin B6, vitamin E [13-17].

Anti-inflammatory treatment relieve pain and swelling in general without modifying the course of the illness. Their effect depends on the inhibition intensity of prostaglandin synthesis. The majority of adverse effects also depend on this action.

Treatment should be aimed at combating the causes that give rise to it, with three basic objectives:

- Dietary and hygienic measures,
- Invasive treatment (puncturing cysts, surgical excision of nodes, complex cystic lesions or their residual capsule, etc.)
- Provide all possible information, modify lifestyles and promote the systematic practice of breast self-examination.

Stress is a contributing or resulting factor in pain and controlling it is an integral part of treatment through evaluation and the use of psychological support techniques, complemented with educating the patient and providing her with information.

Another critical factor to take into account is the right postural treatment of the cervico-dorsal spinal column and the correct use of the bra. The use of a well-fitting breast brace that provides full support should be considered in achieving a reduction of cyclical and non-cyclical breast pain. Vitamins E and B6 are often prescribed in patients with fibrocystic breast disease. Revised studies conclude that the consumption of vitamin E has not demonstrated any evidence for consideration in the treatment of breast pain, and for the consumption of vitamin

B6 there is insufficient evidence to demonstrate its effectiveness.

There is little research into breast pain in regard to the administration of pain relief such as acetaminophen or nonsteroidal anti-inflammatory treatments.

In contrast to the above-mentioned conventional therapies, which act on the neuromuscular system, treatment with electrotherapy in deep oscillation therapy acts on the conjunctival tissue through weak electrostatic charges [18-19].

This therapy has been used in the treatment of patients who have undergone an operation for breast cancer, as a special form of manual lymphatic drainage that has made it possible to start using a prophylactic procedure right from the first day of the postoperative period thanks to the early rechanneling of the lymphatic drainage tracts in order to prevent both the formation of lymphedemas and painful shoulder syndrome. This therapy has been shown to be efficacious in diminishing the secondary effects of radiotherapy [20, 21].

For these reasons it was decided to conduct a study of patients diagnosed with fibrocystic breast disease treated with deep oscillation therapy, comparing their evolution with those treated in a conventional manner.

## Method

Experimental, prospective case-control research was conducted in 401 women diagnosed with fibrocystic breast disease in the period from December 2009 to December 2014. The universe comprised female patients between 20 and 50 years of age who attended the specialised breast disease clinic. The sample was selected randomly and was divided into three groups. Approved by the Ethics Committee of the University Polyclinic Luis de la Puente Uceda. Register number 01245

- Group I or study group: 106 patients who were given deep oscillation therapy (with a Hivamat 200<sup>®</sup> device by *PHYSIOMED*<sup>®</sup>) based on the

following parameters: frequency, intensity, vibration and mode. The treatment plan covered 3 weeks (15 sessions), a daily session from Monday to Friday.

- Group II: 146 patients who were treated with ibuprofen (nonsteroidal anti-inflammatory treatment), 1 400-mg tablet every 12 hours for three weeks.
- Group III: 149 patients who were treated with medroxy-progesterone, 1 25-mg ampoule administered intramuscularly from the second half of the menstrual cycle onwards and on alternate days, for a total dosage of 150 mg.

## Objective

### General

To evaluate the efficacy of deep oscillation therapy in fibrocystic breast disease.

### Specific

- To assess the effect of the treatment on the evolution of pain.
- To describe the effect of the treatment according to sonogram evolution.
- To determine incorrect bra use.

## Criteria for the selection of the sample

### For inclusion

- Patients with fibrocystic breast disease aged between 20 and 50 years.
- Patients who were given prior information on the characteristics of the study and accepted the conditions.

### For exclusion

- Patients with decompensated cardiovascular conditions, pacemakers in the treatment area.
- Patients with infectious skin conditions in the region being treated.
- Patients with nipple discharge.
- Malignant diseases.
- Pregnancy.
- Sensitivity to electric fields.

### Exit criteria

- Patients who stopped treatment after they were included in the study.

### Study phases

- Diagnostic phase
- Treatment phase
- Evaluation phase

### Diagnostic phase

After the sample had been selected and formed after having confirmed the diagnosis of fibrocystic breast disease, the clinical history was drawn up, which included initial assessment, questioning, physical examination and diagnosis as well as a sonogram study and BAFF puncture where appropriate.

### Treatment phase

The patients from the study group were given deep oscillation therapy (Hivamat 200<sup>®</sup> device) under the following parameters: frequency, intensity, vibration (mode), time and sessions.

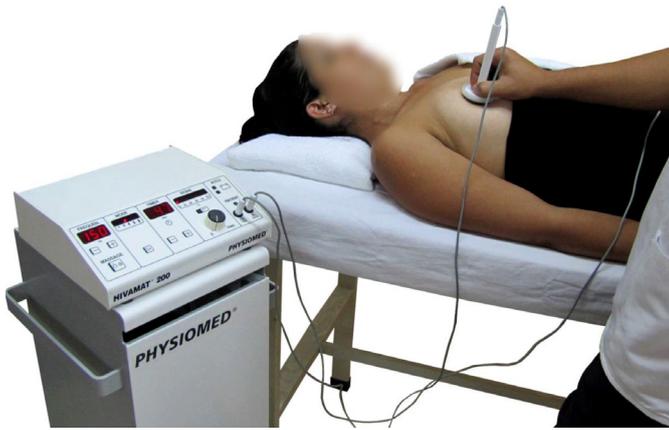
- First time: 5 min, frequency of 160 Hz, 50% intensity, vibration (mode) 2. This plan succeeded in dissolving the fibrosis and relieved pain.
- Second time: 3 min, frequency of 60 Hz, 50% intensity, vibration (mode) 2. This plan succeeded in stimulating lymphatic drainage and reducing breast congestion.
- Third time: 4 min, frequency of 15 Hz, 50% intensity, vibration (mode) 2. This plan succeeded in increasing interstitial liquid flow and improving the release of adjacent muscular fascia.

Total programme time: 12 minutes (for each breast).

### Procedure

Patient in a supine position with the hand corresponding to the treated breast placed underneath the nape, devoid of clothing; with the use of the 5-centimetre manual applicator, at the level of the affected breast (s), in a clockwise direction, during 12 min. **(Figure 1)**

**Figure 1:** Treatment method with deep oscillation therapy in fibrocystic breast disease.



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## Evaluation phase

When the rehabilitation treatment sessions were completed, and by means of questioning, physical examination and evolutionary sonogram study, we checked for persistence of symptoms and sonogram patterns. We proceeded likewise with those who received conventional treatment.

Visual analogue scale (VAS) for pain severity:

On the continuous line, the patient marks the degree of painful sensation between both ends, with the rating from 0 to 10 indicated on the back. The scale was subdivided to group it into:

- 0 No pain
- 1-3 slight pain
- 4-7 moderate pain
- 8-10 severe pain

The principal advantage is that it does not require verbal or reading abilities and is sufficiently versatile for using it in different situations. Thanks to its validity, reliability and capacity to reflect changes in pain intensity, it is one of the most widely used scales.

A database and clinical histories were created with the initial assessment, questioning, physical examination, diagnosis, BAFF puncture and sonogram study.

## Experimental procedure

### Conditions of the device

German-made HIVAMAT 200<sup>®</sup> devices by *PHYSIOMED*<sup>®</sup> were utilised, with the use of the 5-centimetre manual applicator and suitable contact between patient and manual applicator. Talcum powder was used as a vehicle between the membrane of the manual applicator and the patient's skin.

### Search for information

The search strategy for conducting the research was developed over the period between December 2009 and January 2013. Searches were made in online databases: EBSCO, LILACS, Medline and Cochrane Library, supported by the EndNote 7 personal database manager. The MeSH (*Medical Subject Headings*) terms: *mammary dysplasia*, *fibrocystic breast disease*. We reviewed reference books by relevant authors on oncology, surgery and gynaecology and obstetrics, pharmacology, physical therapeutic agents and specialised magazines. The levels of evidence and degrees of recommendation were hierarchically based on the classification system of the *Agency for Healthcare Research and Quality*.

### Statistical analysis

We used descriptive statistics of the data with summary indicators of absolute frequency (No) and relative frequency (%) in individuals, depending on the category described.

As a statistical test, to conduct corroborating treatment evolution according to the above-mentioned pain scales and sonogram results, we used the sign test. For hypothesis corroboration we set  $p < 0,05$ . The statistical packages used for analysis were *Stagraphic plus* and *NCSS-PASS-GESS* for Windows. The results were recorded on tables.

All ethical aspects of biomedical research were met and guarantees were provided that there would be no conflict of interest with *PHYSIOMED*<sup>®</sup>, the company that produces the deep oscillation devices.

## Results

**Table 1** shows a predominance of ages between 31 and 40 years in the distribution by age: in Group I with 64 patients for 60.4%, Group II with 86 patients for 58.9% and Group III with 95 patients for 63.8% of the members of these groups. In regard to the presence of toxic habits in the patients studied, the most frequent one to be evinced was coffee ingestion in 30.2% of patients and 23.7% with a smoking habit, which was significant in both identified factors. There were no statistically significant differences between the groups.

**Table 2** shows the use of contraceptives in the studied groups, where 34.7% of patients used oral contraceptives and 11.5% injectable contraceptives, while 53.9% used no contraceptive hormones at all. There were no significant differences between the groups ( $p=0.67$ ).

Pain assessment is presented in **Table 3**, where the data gathered at the end of the treatment show that 63.2% of patients in Group I had no pain, nor did 24.6% of patients in Group II nor 21.5% of patients in Group III, with significant statistical differences in pain relief between the 3 therapies ( $p=0.01$ ). In the study group, at the end of the treatment no patient had any pain of moderate or severe intensity.

A sign test was conducted to check the differences in scores before and after treatment. The study group revealed significant differences between scores for pain before and after treatment for  $p \leq 0.04$  ( $Z=-6.161$ ;  $p=0.00$ ).

When comparing the group treated with deep oscillations with the control groups with pharmacological treatment, statistically significant differences were found between the results of the scores reported for the pain scale before and after treatment, for  $p \leq 0.05$  ( $Z=-1.136$ ;  $p=0.01$ ). Based on these data, it is possible to state that there are statistically significant differences in the evolution of pain in patients treated with deep oscillations when compared to those who received pharmacological treatment.

**Table 1.** Distribution by age and toxic habits.

Groups	Total	Ages						Coffee		Tobacco	
		20-30		31-40		41-50		Total	%	Total	%
		Total	%	Total	%	Total	%				
I	106	25	23.6	64	60.4	17	16.0	32	30.2	22	20.8
II	146	33	22.6	86	58.9	27	18.5	46	31.5	29	19.9
III	149	30	20.1	95	63.8	24	16.1	43	28.8	44	29.5
Total	401	88	22.0	245	61.0	68	17.0	121	30.2	95	23.7

Source: Survey  $\chi^2=0.98$   $p=0.81$   $\chi^2=1.72$   $p=0.97$ .

**Table 2.** Use of contraceptives.

Groups	Total	Oral contraceptives		Injectable contraceptives		No contraceptives	
		No	%	No	%	No	%
		I	106	36	34.0	12	11.3
II	146	47	32.2	17	11.6	82	56.2
III	149	56	37.6	17	11.4	76	51.0
Total	401	139	34.7	46	11.5	216	53.9

Source: Survey  $\chi^2=2.86$   $p=0.67$ .

**Table 3.** Presence of pain according to verbal numerical scale, by therapeutic plan at the start and end of the treatment.

Groups	Start				End			
	No Pain	Slight	Moderate	Severe	No Pain	Light	Moderate	Severe
	I	0	30.2	56.7	14.2	63.2	36.8	0
II	0	34.2	53.4	12.3	24.6	46.6	26.0	2.7
III	0	32.9	52.3	14.8	21.5	43.0	25.5	10.1
Total	0	32.7	53.6	13.7	33.7	42.6	18.9	4.7

Source: Survey  $\chi^2=0.98$   $p=0.80$   $\chi^2=1.72$   $p=0.01$ .

**Table 4.** Sonogram findings by therapeutic plan at the start and end of the treatment.

Sonogram findings	Before			After		
	GI	GII	GIII	GI	GII	GIII
Fibrosis	75.5	72.0	73.8	17.5	67.1	67.1
Adenosis	15.1	21.2	13.0	11.3	17.8	10.7
Cyst	9.4	6.8	13.4	5.7	10.3	12.7
Total	0	32.7	53.6	13.7	33.7	42.6

Source: Survey  $\chi^2=1.52$   $p=0.05$ .

**Table 4** shows the results of the sonogram study conducted with patients before and after treatment. The initial assessment showed a predominance of its fibrous form (78.5%), followed by adenosis (16.4%) and cystic form (10.0%). The fibrosis represented 75.5% in group I, 72.0% in group II and 73.8% in group III, similar figures to a study conducted on 1,551 patients in which fibrocystic disease in its fibrous form prevailed. Upon completion of the treatment, statistically significant changes were observed in the resolution of the fibrosis in group I. In groups II and III, while the number of patients with fibrosis diminished, this reduction was not statistically significant.

During the physical examination appropriate bra use was explored in regard to breast size in the 401 patients studied. Of these, 320 women, 70.1%, were using the bra incorrectly, and of these 52.4% the cup size was smaller than the breast size.

## Discussion

Behaviour relating to age, toxic habits and use of contraceptives in this study allows us to determine the resemblance of the groups and the diminution in bias in their comparison. These variables are presented separately, but we can announce that there are no statistically significant differences in these variables in the different groups, which speaks in favour of comparing them.

In regard to age, we observed that fibrocystic disease is more frequent after the age of 30. Some papers record that it is more frequent between the ages of 25 and 40 and others between 40 and 50, a phase which coincides with sexual maturity and consequently frequent hormonal disorders [1, 8, 22]. **Table 1** shows that of a total of 401 patients, 61.0% were aged between 31 and 40 years and only 17.0% between 41 and 50.

In regard to the presence of toxic habits in the patients studied, there were no statistically significant differences between the groups. Coffee drink-

ing was a habit among 30.2% of patients and smoking among 23.7%. Data similar to those found in the literature we consulted, based on non-endocrine theories, are supported by a biochemical basis from observing excessive quantities of AMPc in breast tissue owing to excessive consumption of methylxanthines, which are abundant in drinks such as tea, coffee, chocolate, colas, alcoholic beverages, as well as the harmful effect of nicotine, which would be the most likely direct cause [23, 24]. The consumption of tea, chocolate, cola or alcoholic beverages was not significant.

In relation to the use of contraceptives, no statistically significant differences were found between the groups. 34.7% used oral and 11.5% injectable contraceptives. Revised studies consider that the use of contraceptives can trigger crises, while others hold that it bears no relation at all. In this study, in a total of 34.7% of women the disease was associated with the use of oral contraceptives [25, 26].

The presence of breast pain or mastodynia is the most persistent syndrome cited by the patients and the most frequent reason for seeking a consultation. In a study conducted on 1,171 healthy premenopausal US women, 11 per cent presented moderate to severe breast pain that interfered with regular sexual activity, everyday physical activities, social and school activities [27, 28]. In this study 53.6% of patients presented moderate pain and 13.7% severe pain at the start of the treatment. Pain was reduced in the three therapies applied. Pain reduction in the group treated with deep oscillations was statistically significant when compared to the groups treated with ibuprofen and medroxi-progesterone. Studies conducted on the use of deep oscillation therapy in conservative breast carcinoma surgery, from the immediate postoperative period onwards, preventive treatment and complementary lymphedema therapy, showed encouraging results [29-30].

The DEEP OSCILLATION<sup>®</sup> device uses the forces of friction and pulsed electrostatic attraction to cau-

se oscillations that act on the epidermis, dermis and subcutaneous layers of tissue.

At the start of this research we checked the magnitude of resonant vibration of the connective tissue from the surface to the deep layers. This was done by applying diagnostic ultrasound at the same time as the treatment on patients, making it possible to view the effect of the deep oscillations. This mechanical effect on a localised level activates moderate vasoconstriction and reabsorption of localised oedemas. Furthermore, the uninterrupted vibrating effect leads to a relaxation in the connective tissue, inhibiting localised fibrosis. For the first time, this study permitted viewing *in situ* the vibrating effect of the deep oscillation therapy.

A sign test was conducted with the purpose of checking for any significant differences in the scores before and after the treatment. This test allows us to compare the hypothesis that the responses to two or more treatments belong to identical populations. For the use of this test the only thing required is for the underlying populations to be continuous and that the responses of each associated pair be measured on at least an ordinal scale. The results of this study allow us to state that there are differences between the results of the reported score for the pain scale before and after treatment, for  $p \leq 0.05$  ( $Z = -1.136$ ;  $p = 0.256$ ) when comparing the group treated with deep oscillations with the groups that received pharmacological treatment.

In the analysis of the sonogram findings at the start of this study, the most frequent alteration found was the presence of fibrosis, something that corresponds with what is described in the literature where, while it is reported as one of the principal clinical characteristics of breast dysplasia, which is present in approximately 44% to 55.5% of women, particularly between 25 and 40 years of age [8], other authors consider that in fibrocystic breast disease there is inflammation as a characteristic of the advanced phase, a consequence of cyst rupture, which liberates the contents to the underlying

stroma, leading to chronic inflammation and fibrosis scar tissue, which are responsible for the palpable breast hardness. No studies were found that assessed the ultrasound scan as a parameter of fibrocystic disease evolution after treatment with deep oscillation therapy.

Through the resonant vibration produced on tissue, deep oscillation therapy facilitates moderate vasoconstriction, reduces edema and thus favours blood flow and the right amount of oxygen supply to tissues propitiates a positive therapeutic effect in fibrocystic breast disease, which is attributable to three fundamental reasons: relaxing effect on tissues, moderate vasoconstriction effect and increased interstitial drainage, which favours reabsorption of localised oedema and reduces localised fibrosis.

Several studies document the anti-inflammatory, analgesic, muscle-relaxant and tissue-regenerating effect of deep oscillation therapy.

Incorrect bra use is a factor that may have a bearing on breast pain. In the study of 401 women who attended the clinical evaluation consultation to participate in the research, they were asked which bra size they were currently wearing and then we analysed whether the bra size was correct. 398 women were wearing the wrong bra size. The multiple regression analysis to evaluate the correlation of the various factors, such as wrong bra size, showed a strong link (Pearson's correlation = 0.53,  $p < 0.001$ ) between incorrect band measurement and excess weight of the women wearing the wrong bra size. In 254 women the band measurement was incorrect; in 100 the cup size was wrong and 44 of them had the wrong band size-cup size correlation. During the interview we investigated the aspects they took into account in order of priority when selecting a bra. 86% alleged that priority was given to the model, followed by colour. We can state that the majority of the women studied were using a bra incorrectly, propitiating the persistence of pain.

## Conclusions

Pain was reduced in the three therapies applied. In the study group this reduction was statistically significant.

It is possible to check the magnitude of the resonant vibration in the connective tissue, from the surface layers to the deep layers, by viewing the effect of deep oscillations through the use of a diagnostic ultrasound scan.

The most frequent sonogram finding was fibrosis. Deep oscillation therapy produces a tissue-relaxing and moderate vasoconstriction effect, favours reabsorption of localised oedema and reduces fibrosis.

A factor that may have a bearing on breast pain is the incorrect use of the bra. Most of the women studied were using the bra incorrectly.

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