



The Effect of Vitamin B6 on Reducing the Number and the Size of Breast Cysts and the Amount of Recurrence after Aspiration in Women

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2019/v31i630348

Editor(s):

(1) Rafik Karaman, Professor, Bioorganic Chemistry, College of Pharmacy, Al-Quds University, Jerusalem, Palestine.

Reviewers:

(1) Mohd Javaid, Jamia Millia Islamia, India.

(2) Eman Maher Elbaz, Cairo University, Egypt.

Complete Peer review History: <http://www.sdiarticle4.com/review-history/53394>

Original Research Article

Received 05 October 2019
Accepted 10 December 2019
Published 12 December 2019

ABSTRACT

Introduction: Palpable breast lumps are one of the most prevalent breast problems in women who visit a doctor. Most of these lumps are benign, and many of these benign lumps, have cystic nature. One of the suggested treatments for breast cyst is vitamin B6 intake. So, this study aimed to determine the effect of vitamin B6 on reducing the number and the size of breast cysts and reducing the amount of recurrence after aspiration.

Materials and Methods: This study is a double-blind randomized clinical trial. Patients simply divided into two groups randomly, intervention group (receiving 150 mg vitamin B6 twice a day for two months) and control group (placebo). After data collection, the database produced, and information came in by SPSS-22 software. Descriptive results extracted in the form of tables and graphs. In all cases was used $\alpha=0.05$.

Results: At the end of the study, 65 patients (34 people in the intervention group, and 31 people in the control group) studied. At the end of the survey in the non-palpable cysts, was observed a

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significant decrease in the number and the size of breast cysts in each group receiving vitamin B6 or placebo. Still, the difference was not significant in comparing the two groups. 19 patients (2.29%) had palpable cysts that aspiration performed in all cases. After the study period, no recurrence of cysts observed in any of the intervention and control groups.

Conclusion: The study showed that vitamin B6 had no effect on reducing the size and the number of non-palpable breast cysts and prevent recurrence of palpable cysts after aspiration.

Keywords: Breast cyst; vitamin B6; fibrocystic changes.

1. INTRODUCTION

Breast cysts in women are the most prevalent cause of palpable lumps in pre-menopausal ages, especially between the ages of 30 and 50. Nevertheless, it can occur at any age, although it is not common at menopause age. The most prevalent breast problems in women who visit the doctor have pain, discharge from the nipple, and palpable lumps in the breast [1]. One study found that 84% of women who visit for breast problems had palpable lumps, 73% of whom were benign, and many of these benign lumps were cystic [2]. The cysts have elliptical or rounded structures that originate from the end gland ducts and filled with fluid. They are soft and movable and can be painful when touched and can be seen in a variety of sizes. Besides, they may be singular or multiple and can be seen in every quart of the breast [3].

The causes of breast cysts have not yet fully specified, but some of the interferer factors have suggested:

1. **Hormonal imbalance:** Changes in hormone levels that occur 1 to 2 weeks before the menstrual cycle begins, affects the breast glands and causes fluid to form in the ducts of the glands and then result is a cyst.
2. **GLA (Gamalinoleic acid):** One of the essential fatty acids in the formation of the hormone precursor (prostaglandin). The reduction of this precursor has been found to contribute to the onset of breast disease. Daily consumption of omega3 (fish oil), which is a rich source of GLA, has beneficial and auxiliary effects in the therapy of breast diseases.
3. Methyl Xanthine in compounds such as coffee, tea, and chocolate plays a role in the spread of breast cysts.
4. Wearing a bra limits the flow of lymph to the lymphatic vessels, which may slow or block the harvesting waste materials

through the lymphatic system and provide the context for breast cyst formation.

5. Lack of necessary elements in the body like vitamins E, B6, C, and beta-carotene [4].

Vitamin B6 is one of the water-soluble vitamins and a part of the Vitamin B complex. Its active form is Pyridoxal phosphate-5 (PLP), which is a cofactor in many metabolic reactions in the body [5]. The effects of vitamin B6 are still not specified, and some studies have found that vitamin B6 reduces signs in fibrocystic breast disease [6,7]. Most studies have examined the effect of vitamin B6 on premenstrual syndrome (PMS) and mastalgia as part of this syndrome [8]. It had also been investigated as a treatment for cyclic and noncyclic mastalgia [9]. Therapeutic uses of Vitamin B6 include wound healing, quit alcohol, anxiety, vitiligo, osteoporosis, heartburn, and the therapeutic dose is different in each case and have found that the active form of Vitamin B6 (Pyridoxal phosphate-5) acts as a coenzyme in the dopaminergic system by stimulating dopamine release in so doing, it stimulates dopamine release and subsequently inhibits prolactin discharge, which reduces pain and swelling of the breast in patients with PMS [10]. Vitamin B6, on the other hand, acts as a cofactor in metabolizing and conjugating estrogen. Increased estrogen levels than progesterone are one of the major causes of breast texture change [11]. The purpose of the study is to evaluate the effect of vitamin B6 on reduction of the number and the size of breast cysts and the amount of recurrence after aspiration in women.

2. MATERIALS AND METHODS

This study was a double-blinded randomized clinical trial. The statistical society includes all women who referred to Amir-al-Momenin Hospital in Semnan, Iran, because of breast problems. Sampling was done easily. Data collection tools were a questionnaire, clinical

checkup, and sonography. Patients with inclusion criteria enrolled in the study and the selected samples were randomly divided into case and control groups by a systematic random method.

2.1 Inclusion Criteria

1. The existence of palpable or non-palpable cysts
2. Be at fertility age

2.2 Exclusion Criteria

1. Their cysts diagnosed with Complex Cyst (Compound ultrasound)
2. Aspirated fluid from their cysts is bloody
3. After aspiration, the cyst does not completely heal
4. There may be malignant changes in their mammography (calcification in cyst or irregular margin)
5. OCP Consumer Patients

2.3 Procedure

After obtaining informed written consent and calculating the number of samples based on a preliminary pilot study, according to the study time, 93 patients examined and randomly divided into two groups of case and control groups. Only 65 patients completed the study, and the other 28 patients excluded because of the lack of referral, unwillingness to take medication, and lack of access to a researcher. Of the 65 patients studied, 34 patients randomly assigned to the case group and 31 patients to the control group. Then, the sonography obtained from patients and evaluated whose cyst reported on ultrasound. At first, a complete history was taken of each patient, and the patient examined. The group had palpable cysts, were aspirated. For the case group, 150 mg vitamin B6 (powdered vitamin B6 tablets that poured into the capsule) was prescribed twice a day for two months, and the control group placebo (containing sugar in capsules similar to the case group drug) was prescribed twice a day in the same way. The case and control group capsules were made by the pharmacy and had the same color and shape. The researcher who was assessing the patient did not know the type of drug and the drug was given to patients by the pharmacy titled A and B. In each patient, the number of cysts, the largest cyst size, and the average of cysts size were recorded based

on the information in their sonography report, patient information, and type of drug received in the questionnaire. The patient was told to visit again two months after starting the medication. At the second visit, another sonography and clinical examination obtained from the patient. Clinical examination of those who had palpable cysts, repeated touching of the cyst indicated recurrence of the cyst, and no response to treatment. At the end of the study, after collecting the necessary samples, according to the information in the questionnaire, the rate of changes in the size and the number of cysts and recurrence of cysts after aspiration were compared in the case and control groups.

2.4 Data Analysis Method

After gathering data, it was entered into SPSS 22 software (© IBM SPSS Inc., 2013). Descriptive results were extracted in the form of tables and diagrams. In order to compare the effect of the intervention on the number and the size of cysts, the mean reduction of these two variables was done by ordinary or paired t-test. In all cases was used $\alpha = 0.05$.

3. RESULTS

This study was ultimately done on 65 female patients who visited doctor because breast cysts. Of the 65 patients, 34 patients were in the case group (vitamin B6 receiver) and 31 patients were in the control group (placebo receiver). Therefore, 52.3% of the people were in the case group and 47.7% were in the control group. The average age of the participants was 36.72 ± 7.67 years. 19 patients (29.2%) had palpable cysts, 10 in the case group and 9 in the control group. All of these patients at the beginning of the study had aspirated cysts. None of these patients had bloody cyst fluid and all of their cysts completely disappeared after aspiration.

The number and the size of cysts in the case and control groups before and after the intervention evaluated in Table 1. Using the table showed that the number of palpable and non-palpable breast cysts after vitamin B6 intake significantly decreased in both case and control groups ($P < 0.001$). However, no significant relation found between the two vitamin B6 receiver and control groups in terms of reduction in the number of breast cysts after the intervention.

Table 1. Comparison of the number and the size of cysts in the two participating groups before and after the intervention

Comparison of the two groups in terms of decreasing variable values	Control group		Case group			All patients	Variable	
	P ^b	P ^a	After the intervention	Before the intervention	P ^a			After the intervention
>0.05	<0.001	1.45±1.56	2.32±1.51	<0.001	1.94±2.08	2.65±1.73	2.49±1.63	The average number of cysts in sonography
		0	0.48		0	0.52	1.11±0.31	The average number of palpable cysts
>0.05	<0.001	3.91±3.50	10.97±9.84	<0.001	3.80±3.20	11.42±9.09	11.21±9.38	The average largest cyst diameter in sonography
							25.18±8.42	The average the largest diameter of palpable cyst

^b T-test ; ^a Paired T-test

The average largest diameter breast cysts at ultrasound and palpation decreased in the vitamin B6 receiver group ($P < 0.001$). In the control group, the average largest diameter breast cysts at ultrasound and palpation was decreased ($P < 0.001$). However, no significant relation found between the two groups in terms of reduction in the diameter of the breast cyst after the intervention. About recurrence of palpable cysts, no recurrence was observed in both groups after the aspiration. There was no significant relation found between vitamin B6 receiver and control groups in terms of recurrence of cyst after the intervention.

4. DISCUSSION

Breast cyst is the most prevalent breast lump that observed in women. Cysts are usually seen at the age of 35-50 years and disappear after menopause age except in women who take ovarian hormones after menopause age. The size of the cysts is very different and varies from a few millimeters to a few centimeters. To reduce the risk of recurrence of the cyst, drinking tea, coffee and salt should be avoided [12]. Therefore, in the present study, the effect of vitamin B6 on the number and the size of palpable and non-palpable breast cysts was investigated.

About non-palpable cysts that identified in sonography, the study showed that vitamin B6 intake did not have a significant effect related to placebo in decreasing the size and the number of breast cysts. As shown in both vitamin B6 receiver and control groups, both the number and the size of breast cysts decreased after two months of medication use, and in both groups this decrease was significant but compared to the two groups, this decrease has not significantly different. Apparently, with or without treatment, non-palpable cysts decreased in size or disappeared, that is consistent with Brener et al.'s study, in which mentioned most breast cysts disappeared or resized during the first year, or eventually, during the second year. In their study of 68 patients, in two-thirds of patients by the end of the second year, the cysts completely and spontaneously recurred without treatment [13].

In another study which was about how to treat breast cysts, performed by Morrov in 2000, mentioned that unlike macrocysts that require aspiration, non-palpable cysts identified in sonography or mammography require no

cure [1]. The findings of our study of non-palpable cysts appear to emphasize this issue.

In various studies, the effect of vitamin B6 on signs of PMS has been raised a lot and has shown to be effective in reducing pain and tenderness of the breast. But regarding its effect on breast fibrocystic disease and multiple and non-palpable cysts as part of it, the findings are inconsistent [14] and have been reported to be ineffective in another study [7]. In the study done by Brush, et al. Consumption of vitamin B6 reduced the signs of fibrocystic disease [15] or in the study, consumption of vitamin B6 caused clinical and mammographic changes in fibrocystic breast disease. Apparently, vitamin B6 is more effective in the clinical signs of fibrocystic disease [16], whereas the present study did not examine the clinical signs but rather the size and the number of breast cysts and indeed the sonographic signs of the cysts investigated. Vitamin B6 may be ineffective in the size and the number of breast cysts but can reduce its clinical signs.

About palpable cysts In the present study, 19 patients (2.29%) had palpable cysts and aspiration was performed in all cases. No recurrence of cysts was observed in any of the both case and control groups after the study period (two months). In other words, vitamin B6 has no effect on recurrence of breast cysts after aspiration. There seems to be some recurrence in the natural course of these cysts, but why there was no recurrence in the present study could be for two reasons: firstly, our patient were fewer, and secondly, we followed up the patients for only two months. Whereas, the study done by Wendie et al. mentioned that cysts were followed up to 6, 12 and 24 months later [17]. In fact, the short duration of patient's follow up is one of the limitations of the present study.

Another limitation of the present study was the lack of similar studies. About the dose of the medication, because the investigation had not the same one, the dose used to treat premenstrual syndrome and fibrocystic disease was used that used in various studies from 100 mg/day [18] to 200 mg/day [18]. Wyatt, et al. [19] or 300 mg daily [20], and we also used 300 mg daily. Whether the effect of vitamin B6 on the size and the number of breast cysts was due to low doses of this medication should be investigated in further studies. Another limitation

of this study is not using a single radiologist for the ultrasound. Because ultrasound depends on the skill and accuracy of the radiologist, the findings of the study may be partly influenced by this issue.

5. CONCLUSION

Generally, the present study concluded that vitamin B6 never had an effect on reducing the size and the number of non-palpable breast cysts and nor prevent recurrence of palpable cysts after aspiration. Further studies with other doses of the medication and with a single radiologist are suggested to make the findings more accurate.

CONSENT AND ETHICAL APPROVAL

This study was approved by Research Ethics Committee of the Semnan University of the Medical Science, protocol. Procedures were conducted in accordance with the Declaration of Helsinki for human studies of the World Medical Association. All people entered the study with satisfaction and correct information. All patient's information was kept confidential. Patient's written consent has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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The peer review history for this paper can be accessed here:
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