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Clinical Study

Observation on lower-reinforcing and upper-reducing acupuncture method for hyperplasia of mammary gland and its influence on estradiol and progesterone

观察下补上泻针刺法治疗乳腺增生病的疗效及对血清雌二醇和孕酮的影响

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Abstract

Objective: To observe the clinical effect of lower-reinforcing and upper-reducing acupuncture method for hyperplasia of mammary gland (HMG) and its influence on estradiol (E_2) and progesterone (P).

Methods: A randomized, single-blinded and controlled trial was conducted. A total of 124 cases conforming to the inclusion criteria were randomized by random number table into a treatment group and a control group, with 62 cases in each group. Patients in both groups received acupuncture therapy at the same acupoints, while patients in the treatment group received lower-reinforcing and upper-reducing method, and patients in the control group received even reinforcing-reducing manipulation. The treatment started around 10 d before menstruation and was conducted every other day. Patients received 5 treatments in each menstruation cycle for consecutive 3 cycles. The levels of E_2, P and E_2/P and clinical efficacy were measured before and after treatment.

Results: After treatment, the breast lump size, pain intensity and concomitant symptoms score in both groups were substantially lower than those before treatment, showing statistical significances (all P<0.01), and the improvement in the treatment group was higher than that in the control group, and the between-group comparisons showed statistical significances (all P<0.01). After treatment, the overall effective rate was 91.9% in the treatment group, higher than 72.6% in the control group, and the between-group comparison showed a statistical significance (P<0.01). After treatment, levels of E_2, P and E_2/P value showed no statistical significance when compared with those before treatment in the two groups (all P>0.05).

Conclusion: Lower-reinforcing and upper-reducing acupuncture method can effectively alleviate clinical symptoms and signs in HMG patients, and produce a better effect than even reinforcing-reducing manipulation. The majority of HMG patients' E_2, P level and E_2/P value were not beyond the normal ranges; therefore, acupuncture showed no substantial influence on E_2 and P levels and E_2/P value.

Keywords: Acupuncture Therapy; Method of Reinforcing-reducing; Acupuncture Reinforcing Method; Acupuncture Reducing Method; Fibrocystic Breast Disease; Estradiol; Progesterone; Randomized Controlled Trial

【摘要】目的：观察下补上泻针刺法治疗乳腺增生病的临床疗效，以及对雌二醇(E_2)和孕酮(P)水平的影响。**方法：**采用随机、单盲、对照设计，将124例符合纳入标准的患者按随机数字法随机分为观察组和对照组，每组62例。两组取穴相同，观察组采用下补上泻针刺法，对照组予平补平泻针刺法。两组均于月经前10 d针刺，隔日治疗1次。每个月经周期治疗5次，连续治疗3个月经周期。观察治疗前后两组E2、P、E2/P值的变化及治疗后的临床疗效。**结果：**治疗后，两组患者的乳房肿块大小、疼痛程度及伴随症状评分均较同组治疗前明显降低(均P＜0.01)，且观察组的改善程度优于对照组，组间评分差异均有统计学意义(均P＜0.01)。治疗后，观察组的总有效率为91.9%，高于对照组的72.6%，组间差异具有统计学意义(P＜0.01)。治疗后，两组患者E_2、P及E_2/P值与治疗前均无统计学差异(均P＞0.05)。**结论：**下补上泻针法能有效缓解乳腺增生病患者的临床症状和体征，疗效优于平补平泻针刺法。因多数乳腺增生病患者的E_2、P及E_2/P值并未超出正常范围，故针刺治疗对患者E_2、P及E_2/P值的影响不明显。

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【关键词】针刺疗法; 针刺补泻; 针刺补法; 针刺泻法; 纤维囊性乳房疾病; 雌二醇; 孕酮; 随机对照试验
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Hyperplasia of mammary gland (HMG) pertains to Ru Pi (nodules of breast) in traditional Chinese medicine. It is the most common breast diseases and often affects both sides. Normally, HMG has a long duration and a high relapse rate. It is clinically manifested as breast lump and pain, accompanied by agitation and irritability, soreness and aching pain in waist and knees, dizziness, tinnitus, and dysmenorrhea. The lumps are scattered, the distending pain is periodic and associated with menstruation and emotions. HMG causes severe impact on women's health, thus it is crucial to seek a safe and effective treatment for HMG. Our study observed the clinical effect of lower reinforcing and upper reducing acupuncture method for HMG and its influence on estradiol (E_2) and progesterone (P). The report is now given as follows.

1 Clinical Materials

1.1 Diagnosis criteria

Conforming to the modified *Diagnosis and Clinical Efficacy Evaluation Criteria for Hyperplasia of Mammary Gland* stipulated at the Eighth Meeting of the Mammary Gland Diseases Committee, China Traditional Chinese Medicine Surgery Association (2002)[1].

Symptoms and signs: Distending, stabbing or dull pain that radiates to the axilla or shoulder-back region; related to menstruation or emotion change; with a duration of consecutive 3 months or intermittent 3-6 months without alleviation; single or multiple lumps with varied sizes or shapes on one or bilateral sides, and the lump can disperse to the whole breast and show no obvious border, but without adhesion to deep tissues; lump is movable and may hurt after palpation; lump can change with menstruation and emotion; may be accompanied by nipple discharge or itching.

Exclusion items: Breast development in children before the first menstruation, gynecomastia and malignant tumor of breast.

Assistant examination: Molybdenum target X-ray, B-ultrasonography, fiber optic ductoscopy of mammary gland, fine needle aspiration cytology or histological examination or infrared thermal imaging scan.

Diagnosis can be made with one of the items in symptoms and signs and without exclusion items, and also with the help of the assistant examination.

1.2 Inclusion criteria

Conforming to the diagnostic criteria above; aged between 20-55 years; informed consent and good compliance.

1.3 Exclusion criteria

Being diagnosed with mastitis, benign or malignant tumor of mammary gland or benign mammary gland tumor alone; complicated condition which cannot determine the pattern; during gestation or lactation or having severe irregular menstrual periods or functional uterine bleeding; with severe organic diseases of heart, liver, kidney or hemopoietic system; with mental disorders; used hormone agents within the past half a year; gynecomastia or breast development in children before the first menstruation.

1.4 Statistical methods

All data were analyzed with SPSS version 18.0 software. Measurement data conforming to normal distribution were described as mean ± standard deviation ($\bar{x} \pm s$), paired sample *t*-test was used for intra-group comparison, and independent sample *t*-test was used for between-group comparison; data not conforming to normal distribution were described as median (interquartile range) [M(IQR)], and non-parametric test was used for comparison. Rank-sum test was used for between-group comparison. Chi-square test was used for non-ratio comparison. A *P* level less than 0.05 indicated a statistical significance.

1.5 General data

A total of 124 HMG patients who applied to join the trial between January 2014 and December 2016 were included, and all cases were bilateral onset. The patients all conformed to the inclusion criteria and were diagnosed by B-ultrasonography. The patients were aged between 22 and 50 years with a disease duration of 3 months to 10 years. They were randomized by random number table into a treatment group and a control group, with 62 cases in each group. The differences in general data between the two groups showed no statistical significances (all $P>0.05$), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of general data

Group	*n*	Average age ($\bar{x} \pm s$, year)	Average course ($\bar{x} \pm s$, month)
Treatment	62	35.9±7.0	51.0±4.5
Control	62	34.9±6.6	47.2±4.5
t-value		0.606	0.361
P-value		0.438	0.549

2 Treatment Methods

2.1 Treatment group

Acupoints: Jianjing (GB 21), Danzhong (CV 17), Zhongwan (CV 12), Qihai (CV 6), Guanyuan (CV 4), Sanyinjiao (SP 6), Taixi (KI 3) and Taichong (LR 3).

Method: Patients took a supine position and exposed the manipulation area. After routine sterilization, filiform needles of 0.25 mm in diameter and 40 mm in length were used. The practitioner used the right hand for manipulation. Applied transverse insertion method to Danzhong (CV 17) to insert 0.5 cun and perpendicular insertion to Zhongwan (CV 12) to insert 0.8 cun. Upon qi arrival, applied open-closed and twirling reducing method, in which thumb rotated backward and index finger rotated forward, and the method was done for several times. During manipulation, took a large rotating angle, a heavy force and a high frequency, and waggled handle to expel qi at needle withdrawal. Then perpendicularly punctured Qihai (CV 6) and Guanyuan (CV 4) for 0.8 cun. Upon qi arrival, took even reinforcing-reducing manipulation, namely performing mild lifting-thrusting and twirling methods for several times with the same range of rotation. Then perpendicularly punctured Sanyinjiao (SP 6) and Taixi (KI 3) for 0.5 cun, and obliquely punctured Taichong (LR 3) for 0.5 cun. At qi arrival, took open-closed and twirling reinforcing manipulations, namely rotating thumb forward and index finger backward for several times during twirling with the right hand. Took a small range, light force and low frequency manipulation. Then pressed the hole with a dry cotton ball immediately after withdrawing the needle. The reinforcing and reducing methods were done following qi arrival and the needles were retained for 20 min, and the manipulation was done at the moment when qi arrived, 10 min during retaining and before needle withdrawal respectively for a total of 3 times.

2.2 Control group

Acupoints: Same acupoints as in the treatment group.

Methods: Used the same needles as in the treatment group. Took even reinforcing-reducing manipulation upon qi arrival, and retained the needles for 20 min. The manipulation was done at the moment when qi arrived, 10 min during retaining and before needle withdrawal respectively for a total of 3 times.

Patients in both groups started treatment about 10 d before menstruation (for those who had irregular period, started the treatment 10 d after the last menstruation), and the treatment was done 20 min each time, every other day. Took 5 times of treatment in each menstruation for consecutive three menstruation cycles, for a total of 15 times.

3 Therapeutic Efficacy Evaluation

3.1 Observation items

3.1.1 E_2 and P levels

The levels of E_2 and P were tested in both groups.

Schedule for the first test: After inclusion and before treatment, during 1-3 d after the last menstruation cycle.

Schedule for the second test: After the whole treatment was finished, during 1-3 d after the last menstruation cycle.

All tests were done at about 9 a.m. at empty stomach after a 30-minute rest. The venous blood of patients was collected by personals in the Laboratory Department in our hospital and was used for examination.

3.1.2 Degree and score of breast pain

The breast pain severity was graded and scored according to the following criteria.

Level 0 (6 points): no pressing or spontaneous pain; level 1 (12 points): pressing pain without spontaneous pain; level 2 (18 points): spontaneous pain, mainly premenstrual and paroxysmal onset; level 3 (24 points): persistent spontaneous pain, without affecting normal life; level 4 (30 points): persistent spontaneous pain, radiating to axilla or shoulder-back region, affecting normal life.

3.1.3 Degree and score of lump

The hardness of lump was graded and scored according to the following criteria.

Level 1 (3 points): soft like normal gland; level 2 (6 points): tough like the tip of the nose; level 3 (9 points): hard like forehead.

The lump scale was graded and scored according to the following criteria.

1 quadrant of breast was scored 1.5. Level 1 (3 points): limited to quadrant 1 and 2; level 2 (6 points): reached quadrant 3 and 4; level 3 (9 points): reached quadrant 5 and 6; level 4 (12 points): reached quadrant 7 and 8.

The lump size (the maximum diameter of the lump) was graded and scored according to the following criteria.

Level 1 (3 points): <2 cm; level 2 (6 points): 2.1-5 cm.

3.1.4 Grading for the systemic concomitant score

Grading for the emotion change. Invalid: 3 points; improved: 2 points; back to normal: 1 point.

Grading for menstruation disorder. Invalid: 3 points; improved: 2 points; back to normal: 1 point.

Grading for soreness of waist and knees. Invalid: 3 points; improved: 2 points; back to normal: 1 point.

Grading for hypochondrium distention. Invalid: 3 points; improved: 2 points; back to normal: 1 point.

Grading for blood stasis symptom. Invalid: 3 points; improved: 2 points; back to normal: 1 point.

The total symptoms score was the aggregation of the breast pain score, lump grading and systemic concomitant scores. The total score ranged from 20 to 72 points, and a higher score indicated a more serious condition.

3.2 Therapeutic efficacy evaluation

The therapeutic efficacy evaluation criteria in this study were based on the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*[2] and the *Diagnosis and Clinical Efficacy Evaluation Criteria for Hyperplasia of Mammary Gland* stipulated at the Eighth Meeting of the Mammary Gland Diseases Committee, China Traditional Chinese Medicine Surgery Association (2002)[1]. The total score was used to calculate the improvement rate and for therapeutic efficacy evaluation.

Improvement rate = (Total score before treatment − Total score after treatment) ÷ Total score before treatment × 100%.

Cure: The improvement rate ≥90%.

Marked effect: The improvement rate ≥70%, but <90%.

Effective: The improvement rate ≥30%, but <70%.

Invalid: The improvement rate <30%.

3.3 Results

3.3.1 The total score of breast pain, lump and systemic concomitant symptoms

After treatment, the scores of breast pain, lump and systemic concomitant symptoms in both groups dropped obviously when compared with those before treatment, and intra-group comparisons showed statistical significances (all $P<0.01$); after treatment, the D-value of total score in the two groups showed a statistical significance, indicating a better improvement in the treatment group (Table 2).

Table 2. Comparison of the total score of breast pain, lump and systemic concomitant symptoms ($\bar{x}\pm s$, point)

Group	*n*	Before treatment	After treatment	D-value
Treatment	62	49.45±6.21	27.16±3.36[1)]	22.29±5.58[2)]
Control	62	44.13±6.11	29.69±3.65[1)]	14.44±4.11

Note: Intra-group comparison, 1) $P<0.01$; between-group comparison, 2) $P<0.01$

3.3.2 Clinical efficacy

After treatment, the total effective rate was 91.9% in the treatment group, obviously higher than 72.6% in the control group, and the between-group comparison showed a statistical significance ($P<0.01$), (Table 3).

3.3.3 Levels of E_2, P and E_2/P value

Before treatment, most HMG patients' E_2 and P levels did not exceed the normal range or were even lower than normal. After treatment, the levels of E_2, P and E_2/P value of HMG patients in both groups showed no statistical significance when compared with those before treatment ($P>0.05$), (Table 4).

Table 3. Comparison of the clinical efficacy (case)

Group	*n*	Cure	Marked effect	Effective	Invalid	Total effective rate (%)
Treatment	62	0	0	57	5	91.9
Control	62	0	0	45	17	72.6
x^2 value						7.957
P-value						0.005

Table 4. Comparison of the levels of E_2, P and E_2/P value [M (IQR)]

Group	*n*	E_2 (pmol/L)			P (nmol/L)			E_2/P		
		Before treatment	After treatment	D-value	Before treatment	After treatment	D-value	Before treatment	After treatment	D-value
Treatment	62	171.0 (119.0)	184.5 (123.0)	31.5 (154.0)	0.7 (0.4)	0.9 (0.6)	0.2 (0.3)	270.7 (217.6)	209.5 (174.7)	−10.4 (215.9)
Control	62	149.5 (143.5)	213.5 (129.3)	39.0 (140.3)	0.7 (0.4)	0.8 (0.5)	0.2 (0.2)	245.7 (231.7)	248.5 (213.7)	10.5 (180.9)

4 Discussion

HMG pertains to Ru Pi (nodules of breast) in traditional Chinese medicine. The basic pathogenesis is over- thought harming the spleen, over-anger harming the liver and qi stagnation. The onset of HMG is closely related to emotion change, affecting the liver and spleen. Some scholars hold that the axis of kidney qi-Tian Gui-Conception and Thoroughfare Vessel-uterus-breast is a female physical regulation system, and kidney qi works as the center, influencing the development of HMG[3-4]. Modern researches and

clinical experiences have shown that HMG patients are deficiency in root and excess in manifestations, and the deficiencies of kidney, Conception Vessel and Thoroughfare Vessel act as the root; liver depression, qi stagnation, blood stasis and congealing phlegm are the manifestations, which usually coexist and interact as both cause and effect. Based on visceral and channel theory, the main organs linking with HMG are liver and kidney, and the main meridians are the Conception and Thoroughfare Vessels[5-9].

Modern medicine holds that HMG is connected with imbalance of sex hormones, and regulated by hypothalamic-pituitary-ovarian axis.

Our previous study has investigated the infrared thermal specialty of HMG-related acupoints[10-16], revealing that the acupoints in HMG patients of different patterns were in different deficiency-excess states. The infrared thermal temperature of HMG patients showed a decreasing tendency from proximal to distal part. The temperature of acupoints on trunk including Danzhong (CV 17), Qimen (LR 14), Zhongwan (CV 12), Qihai (CV 6), and Guanyuan (CV 4) was higher than that in normal people, and the temperature of acupoints on lower limbs including Taixi (KI 3) and Taichong (LR 3) was lower than that in normal people. Such results indicated that HMG patients were in an upper-excess and lower-deficiency state. Therefore, we chose acupoints including Danzhong (CV 17), Zhongwan (CV 12), Qihai (CV 6), Guanyuan (CV 4), Taichong (LR 3), Taixi (KI 3) and Sanyinjiao (SP 6) in this study. Based on the treatment principle of treating the deficiency by reinforcing and treating the excess by reducing, we used open-closed and twirling reducing manipulations at Danzhong (CV 17) and Zhongwan (CV 12), and even reinforcing-reducing manipulation at Qihai (CV 6) and Guanyuan (CV 4), and open-closed and twirling reinforcing manipulations at Sanyinjiao (SP 6), Taixi (KI 3) and Taichong (LR 3). We also took the ordinary treatment as the control to compare the clinical efficacy. The result showed that lower-reinforcing and upper-reducing method can improve clinical symptoms and signs in HMG patients, and the clinical efficacy of such method was superior than that of even reinforcing-reducing manipulation.

Hormone changes in animal experiment may not be consistent with that in HMG patients, because animal experiment usually uses man-made model stimulated by hormones or other exterior methods, and the elevated E_2 level may be caused by exterior factors[17-20]. To observe the relationship between HMG and levels of E_2 and P and E_2/P value, we tested such indicators before and after treatment. The result showed that the hormone levels of HMG patients were in normal range before treatment. After treatment, hormone levels showed no obvious change. Therefore, hormone imbalance is the mechanism of HMG animal model, and the regulation of hormone levels is one of the treatment approaches. While in real life, a large number of HMG patients have a normal menstruation and their hormone levels are also in a normal range. Therefore, HMG symptoms may not be caused by hormone imbalance alone. Abnormal sensitivity to hormone or other factors in HMG patients' mammary gland might be the mechanism. Therefore, acupuncture treatment can reduce lump and pain in HMG patients, while it showed no obvious regulating effect on hormone levels. So, the condition of HMG may not be directly related to the levels of E_2 and P and E_2/P value. The occurrence, development and outcome of HMG may be related to the sensitivity of mammary gland to E_2 and P. The mechanism of acupuncture treatment may not be connected with the regulation of the levels of E_2 and P and E_2/P value, but with the adjustment of qi and blood, and decrease the sensitivity of mammary gland to E_2 and P. Thus, a further investigation is required to reveal the mechanism of acupuncture for the treatment of HMG.

Moreover, there were no cured or marked effect cases after treatment in the two groups, and the possible reason may be the short treatment course. The whole treatment course was 3 menstruation cycles (15 times). The primary clinical effects were mainly manifested as alleviation of breast pain and systematic concomitant symptoms. Lumps tended to soften while not decreased in size. Therefore, the insignificant changes in lump size further accounted for the low improvement rate and the failure to reach the criteria of cured or marked effect. Thus, a longer course of treatment is needed in further research to better evaluate the clinical efficacy of acupuncture treatment for HMG.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants in this study.

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