INPLASY PROTOCOL

Corresponding author:
Dehui Ma

mdh610869137@126.com

Author Affiliation:
Changchun University Of Chinese Medicine

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
None.

Massage treatment of hyperplasia of mammary glands A protocol for a systematic review and meta-analysis: study protocol

Ma, D[1]; Liu, G[2]; Gao, T[3]; Zhang, Q[4]; Liu, M[5].

Review question / Objective: The purpose of this study is to explore the curative effect of massage on hyperplasia of mammary glands and to find the best treatment of breast hyperplasia. The type of studies included in this study is randomized controlled trials.

Condition being studied: Mammary gland hyperplasia is a degenerative disease and progressive connective tissue growth caused by hyperplasia of mammary fiber and epithelial tissue. Studies show that breast hyperplasia is the highest incidence rate of female breast diseases, and has a certain correlation with the menarche time, the number of fetal birth, social economic status and education level. About 75% of women have a certain degree of breast hyperplasia, and about 20% of women will be troubled by their clinical symptoms, among which 25-45 years old women have the highest incidence rate. the clinical manifestations of postmenopausal women were obvious atrophy of glands and aggravation of cystic lesions. Atypical hyperplasia is a precancerous lesion. The incidence rate of breast hyperplasia is also increasing with the increase of the disease course. According to the literature statistics, the canceration rate is between 1.25% and 50%.

INTRODUCTION

Review question / Objective: The purpose of this study is to explore the curative effect of massage on hyperplasia of mammary glands and to find the best treatment of breast hyperplasia. The type of studies included in this study is randomized controlled trials.

Rationale: Massage therapy is one of the important external therapies of traditional

Chinese medicine, which has the function of regulating viscera and dredging meridians. It cannot only effectively treat breast hyperplasia, but also avoid adverse drug reactions and cross drug reactions. However, there are few meta-analysis literatures about massage treatment of hyperplasia of mammary glands.

Condition being studied: Mammary gland hyperplasia is a degenerative disease and progressive connective tissue growth caused by hyperplasia of mammary fiber and epithelial tissue. Studies show that breast hyperplasia is the highest incidence rate of female breast diseases, and has a certain correlation with the menarche time, the number of fetal birth, social economic status and education level. About 75% of women have a certain degree of breast hyperplasia, and about 20% of women will be troubled by their clinical symptoms, among which 25-45 years old women have the highest incidence rate. the clinical manifestations of postmenopausal women were obvious atrophy of glands and aggravation of cystic lesions. Atypical hyperplasia is a precancerous lesion. The incidence rate of breast hyperplasia is also increasing with the increase of the disease course. According to the literature statistics, the canceration rate is between 1.25% and 50%.

METHODS

Search strategy: Database retrieval includes: PubMed, Cochrane Central Register of control trials (central), ScienceNet, EMBASE, CBM, CNKI, VIP and Wanfang database. The retrieval date is October 20, 2020. According to the needs of different databases, the corresponding retrieval format is adopted. In order to avoid omission, the search scope includes subject words, keywords or full text. The key words in Chinese are "hyperplasia of mammary glands", "hyperplasia of mammary glands" and "massage", while those in English are "hyperplasia of mammary glands", "hyperplasia", "massage" and "massage".

Participant or population: Participants met the clinical diagnostic criteria for breast hyperplasia and were not lactating women; patients and their families informed the study and signed the consent form. At the same time, there are no restrictions on age, gender, region, nationality and nationality. Cases associated with serious illness, pregnancy and drug-induced obesity were not included.

Intervention: Massage therapy (such as massage, finger pressing, etc.) or massage combined with other therapies to intervene in the treatment of breast hyperplasia.

Comparator: Observation group: the intervention time of massage therapy was at least 4 weeks. Massage therapy was stopped during menstruation, and the treatment time was postponed. Control group: mainly used oral medicine or placebo or other traditional Chinese medicine. However, it be combined with other treatments during the treatment.

Study designs to be included: Only RCTs are included in our studies. Other designs, such as in vivo, in vitro, case reports, retrospective studies and non-RCTs will be excluded. There are no restrictions on languages.

Eligibility criteria: Adults with breast hyperplasia treated by both massage therapy (such as massage, finger pressing, etc.) and massage combined with other therapies.

Information sources: Search PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, EMBASE, CBM ,CNKI, VIP and Wanfang databases were searched by computer. The retrieval date was up to October 20, 2020. According to the requirements of different databases, the corresponding retrieval format is adopted.

Main outcome(s): The main criteria were: complete disappearance of pain symptoms; diameter and area of breast mass; hormone levels of LH, E2 and PRL. The secondary outcome measures were abnormal menstruation and mood

changes. At the same time, observe whether there are adverse reactions or adverse events in the treatment process to comprehensively evaluate the clinical efficacy and safety of massage in the treatment of breast hyperplasia.

Quality assessment / Risk of bias analysis: The literature quality of this study was assessed using the bias risk table recommended by the Cochrane Collaboration. The risk table includes six items: random sequence generation method, allocation concealment, blinding of subjects and intervention providers, blinding of outcome evaluators, completeness of result data, selective result reporting and other sources of bias. The criteria for assessing the risk of bias were "low risk", "high risk" and "unclear". In this process, two reviewers independently evaluate the quality of methodology. In case of disagreement, a third party will be invited to make a decision.

Strategy of data synthesis: We will use Review Manager 5.3 software for Mean difference (MD) was used as measurement data, odds ratio (or) was used as measurement index for categorical variables, and 95% CI was used as effect quantity. Firstly, the statistical heterogeneity of the included clinical RCTs was analyzed by Cochrane I2 test. When I2 < 50% or P > 0.05 indicated that there was no statistical heterogeneity among the studies, the fixed effect model was selected to combine the effect amount; otherwise, the random effect model was adopted. The therapeutic effect of massage in the experimental group was compared with that in the control group by forest map, and the sensitivity analysis was carried out according to the main aspects that may lead to clinical heterogeneity to identify the source of heterogeneity.

Subgroup analysis: None.

Sensibility analysis: sensitivity analysis will also be employed to explore possible factors that may lead to heterogeneity. If quantitative synthesis is not appropriate, we will conduct a narrative synthesis.

Language: None.

Country(ies) involved: China.

Keywords: Massage, Hyperplasia of mammary glands, meta-analysis, systematic review.

Contributions of each author:
Author 1 - Dehui Ma.
Author 2 - Guochao Liu.
Author 3 - Tianjiao Gao.
Author 4 - Qi Zhang.
Author 5 - Mingjun Liu.