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Homeopathy in Breast Cancer Supportive Care: A Critical Review of Clinical Evidence, Safety and Methodological Challenges

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Abstract

Breast cancer care is complicated by its severe effects on the patients' physical, psychological and social functioning. Hence, supportive care has emerged as an essential adjuvant component of holistic cancer therapy. Homoeopathy for menopausal symptoms, hot flashes, exhaustion, joint pain, skin responses related to radiation and postoperative problems has been studied as supplementary medicine in the care of breast cancer–related symptoms. This study objectively assesses the existing clinical data for the many uses of homoeopathy, safety and methodological constraints in supportive treatment of breast cancer. A narrative, descriptive evaluation of relevant clinical trials, observational studies, systematic reviews and integrative oncology guidelines were examined in this study. certain studies indicated positive findings on postoperative measures and certain patient-reported symptoms. By contrast, randomised placebo-controlled trials have shown little or limited advantage of homoeopathy above placebo, especially in relation to the menopausal symptoms of endocrine treatment. Evidence for aromatase inhibitor-associated arthralgia, radiation-induced skin toxicity and postoperative recovery is preliminary and restricted by small sample size and methodological heterogeneity. Furthermore, systematic cancer reviews find considerable variation in trial design, treatment schedules and outcome measures and little adverse-event reporting. To summarise, current research does not suggest that homoeopathy is beneficial when added to therapeutic treatment of breast cancer. Larger and better-designed clinical studies with validated treatments and outcomes and with long-term safety evaluation are needed to explain the real role which homoeopathy may play in supportive care, as an adjuvant but not an alternative to cancer therapy, standard or otherwise.

Keywords: Breast Cancer, Homeopathy, Integrative Oncology, Supportive Care.

Introduction

Breast cancer is a worldwide public health problem and is one of the most prevalent cancers of females. Disease detection, molecular diagnosis and therapy have greatly improved management and survival. Nevertheless, breast cancers remain associated with substantial physical, psychologic and social sequelae as a consequence of diagnosis, treatment and surviving. Treatment modalities are based on cancer stage, molecular subtype, hormo ne receptor status and other clinicopathological fe atures. Chemotherapy, surgery, radiation, targeted biological agents and endocrine therapy are all routinely part of treatment. Although these modalities have improved disease management and survival, they are often accompanied with toxicities in both short and long term, with frequent compromise of their quality of life (1, 2). Therefore, breast cancer care has started to use supportive care to relieve treatment- related symptoms, promote functional well-being and to assist patients in their treatment.

Integrative oncology has developed as a framewor k that includes certain supplementary practices with established cancer therapies. It includes evidence based complementary methods such as acupuncture, yoga, meditation, psychiatric interve ntions, dietary counselling and other complementary techniques (3). Such therapies are increasingly being investigated for symptom management and improvement of overall wellness of patients. Homeopathy, an alternative medical system, based on the principles of individualised treatment, the law of similars and serial dilution with succussion. Homoeopathic medicines are chosen based on the unique symptoms and features of the patient. When considering cancer therapy, homoeopathy has been predominantly studied as add-on therapy for the relief of treatment -related symptoms and not of the disease itself (4).

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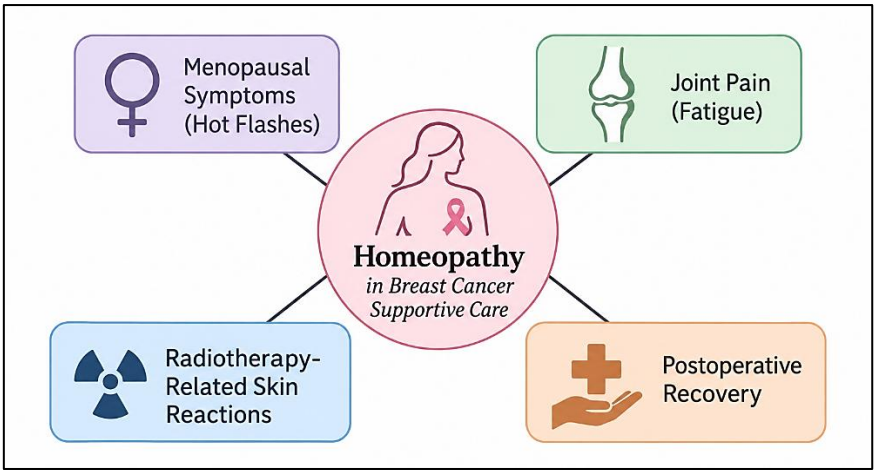


Figure 1: Homeopathy in Breast Cancer Supportive Care

In breast cancer, putative supporting roles of homoeopathy have been studied clinically (4). Homoeopathy has been studied in endocrine therapy-related menopausal symptoms, hot flushes, fatigue, psychological distress, radiotherapy-related skin responses and surgical complications, as shown in Figure 1 (4). One research has published the individualised homoeopathic therapy of oestrogen withdrawal symptoms in women with breast cancer and noted a number of patient-reported benefits (5). Meanwhile, the latest randomised double-blind placebo-controlled study reported no difference between personalised homoeopathy and placebo for primary clinical outcomes (6). The next trial review was a preliminary randomised controlled trial of homoeopathic preparations for menopausal symptoms in breast-cancer survivors (7). Some quality-of-life variables were improved; however, the intensity of hot flashes (primary outcome) did not change proportionately in treatment vs. placebo groups.

BRN-01, a homoeopathic preparation, was investigated for hot flashes in women receiving adjuvant endocrine treatment (8). In a multicentre, double-blind, placebo-controlled phase III study, the homoeopathic preparation failed to outperform placebo. Homoeopathy has also been used in radiotherapy-induced skin responses. Belladonna 7cH and X-ray 15cH were studied in individuals with breast cancer receiving radiation (9). Some variations were seen in recovery measures and individual skin metrics but generally the results were inconclusive for a therapeutic effect. Another prospective study also observed radiation-induced itching after breast cancer therapy and studied the effect of personalised homoeopathy (10). The results were promising for alleviation of itching symptoms but were hampered by the lack of a control group.

Homoeopathic preparations have also been evaluated in the postsurgical setting of seroma formation, bleeding and postoperative recovery after breast surgery (11-13). In another study of homoeopathy in aromatase inhibitor AEs for joint pain, Ruta graveolens 5CH and Rhus toxicodendron 9CH were compared in aromatase inhibitor users (14). Although there have been some preliminary clinical findings, due to methodological constraints, these studies failed to demonstrate the therapeutic effectiveness of homoeopathy. Despite the increased awareness and increased interest in homoeopathy in supportive cancer, the scientific data is few and disputed. One analysis analysed 18 clinical trials of 2,016 cancer patients, the most often studied malignancy being breast cancer (4). However, the authors reported tremendous variability in design methods, treatments and outcome assessments. This and other evaluations have led to a dearth of evidence of therapeutic benefit of homoeopathic remedies for most side effects of cancer therapy (14, 15). One study provided preliminary evidence for several uses but also stated that there was a lack of persuasive evidence for most remaining therapies (13).

Another aspect of supplementary therapies is safety in the course of treatment for breast cancer. Patients taking chemotherapy, radio therapy, or endocrine therapy from this cohort may be at risk for complementary treatment toxicities (or incorrect withdrawal from treatment). Homoeopathic preparations might not be associated with the same risk as pharmacologically active drugs

due to the large dilutions involved; yet, safety and manufacturing quality cannot be assured. Adverse consequences of homoeopathy have been reported, such as replacement of conventional therapy (16). Therefore, we intended to review the clinical data, safety concerns and methodological flaws of homoeopathy before adopting it as a supportive care for breast cancer.

The goals of the current review are to objectively evaluate homoeopathy in supportive breast cancer therapy by:

a) To review described homoeopathic uses in breast cancer-related side effects/symptoms (fatigue, pain, menopausal complaints, emotional distress).
b) To examine the clinical evidence for the use of homoeopathy for radiotherapy-induced skin responses and surgical complications.
c) To evaluate the impact of homoeopathy on the health and quality of life of breast patients.
d) To evaluate the safety and any negative effects of homoeopathic medicines when used in conjunction with standard cancer treatment.
e) To address shortcomings of previous clinical trials and lack of research.

The review is innovative in the first to aggregate clinical observations on menopausal symptoms, joint pain syndromes, skin responses to radiation and surgery recoveries in various applications of homoeopathy for using breast cancer supportive treatment. Moreover, by addressing concerns about methodology and safety, we separate initial supportive-care findings from solid evidence of positive treatment outcome.

Methodology

The present study was designed as a descriptive narrative review to explore the reported role of homeopathy in breast cancer supportive care. A narrative approach was selected to provide a broad overview of the available clinical literature and critically examine findings from different types of investigations without undertaking a formal systematic review or quantitative meta-analysis (17, 18).

Relevant scientific publications were identified through searches of electronic databases, including PubMed, Google Scholar, Scopus and Web of Science. The literature search focused on studies investigating homeopathic preparations in breast cancer patients, particularly in relation to treatment-associated symptoms, supportive care and patient-reported outcomes.

The search strategy involved combinations of the following keywords: Homeopathy, Homeopathic Medicine, Breast Cancer, Breast Neoplasms, Supportive Care, Integrative Oncology, Chemotherapy, Radiotherapy, Hot Flashes, Fatigue, Quality of Life, Postoperative Care, Joint Pain and Safety. Relevant combinations of these terms were used to identify original research articles, randomised controlled trials, observational studies, systematic reviews and relevant clinical guidelines.

Publications were considered relevant when they addressed homeopathic interventions in breast cancer patients, either independently or alongside conventional oncological treatment. Of particular interest were studies on quality of life, postsurgical problems, joint complaints with aromatase inhibitors, skin complaints under irradiation and menopausal complaints under endocrine treatment. Other cancer studies were also included where they offered relevant patient-reported outcomes, safety or supportive care data. However, data on mixed cancer populations were differentiated from data on breast cancer patients. Studies demonstrating anticancer effects of homoeopathic medicines unrelated to supportive treatment were not highlighted. Finally, included papers were reviewed descriptively for aims, research design, patient demographic, homoeopathic intervention, clinical results provided and methodological weakness. Particular care was paid to sample size, adequate controls, comparison with placebo, outcome measures and reporting of adverse events.

The results were grouped according to clinical use. The literature was interpreted and presented based on guidelines for increasing the quality of narrative reviews, for example by stating explicit goals, adequate reference and critical reflection on the strength of the evidence supplied (17-19). This is a descriptive narrative review and does not attempt a full systematic search, formal risk of bias assessment or quantitative metanalysis. Results were critically analysed highlighting the gaps and scope for further clinical research.

Results and Discussion

Homoeopathy and Supportive Care in Breast Cancer

A number of approaches have been published for the use of homoeopathy in supportive care and treatment-related complaints in breast cancer, including endocrine therapy, radiation and surgery. Clinical research has mainly examined menopausal symptoms, hot flushes, exhaustion, arthralgia, skin responses to radiotherapy and post-surgical recuperation. Both observational research and clinical trials have investigated single homoeopathic treatments as well as the tailored homoeopathic approach (4, 14).

However, the studies differ widely in design, treatment procedures, therapies and defined end points and only a few specialised trials in breast cancer. Positive improvements in patient-reported symptom amounts were recorded in some but not all investigations, which revealed no meaningful differences from placebo. As a whole, the data represents a cross section of the indications examined rather than demonstrating clinical benefit of homoeopathy in supportive treatment of breast cancer.

Homeopathy and Treatment Associated Menopausal Symptoms

Menopausal symptoms, particularly hot flashes, are common among breast cancer patients receiving endocrine therapy. Treatments such as tamoxifen and aromatase inhibitors can produce or aggravate vasomotor symptoms, affecting sleep, daily functioning and overall quality of life.

A study conducted a prospective observational study involving 45 women with breast cancer experiencing oestrogen-withdrawal symptoms (5). Individualised homeopathic treatment was associated with improvements in reported hot flashes, fatigue, mood disturbances, anxiety, depression and quality of life. However, the absence of a placebo-controlled comparison limited the ability to determine whether these improvements resulted specifically from the homeopathic intervention.

Subsequently, a randomised, double-blind, placebo-controlled pilot study involving 53 breast cancer survivors experiencing symptoms of oestrogen withdrawal (6). Both groups demonstrated improvements in symptom and mood scores during the study period, but no statistically significant difference was observed between the homeopathy and placebo groups. These findings indicated that the reported improvements could not be attributed specifically to the homeopathic preparations.

Individualised and combination homeopathic preparations in a preliminary randomised, double-blind, placebo-controlled trial, involving breast cancer survivors with menopausal symptoms was reported (7). Although improvements in general health-related quality-of-life scores were reported in the homeopathy groups, the primary outcome of hot-flash severity did not demonstrate a significant difference between treatment and placebo. The authors also acknowledged that the small sample size limited definitive interpretation.

A larger multicentre, randomised, placebo-controlled phase III trial was conducted to investigate BRN-01 (Actheane®) for managing endocrine therapy-associated hot flashes (8). The study included a population of 299 patients, of whom 138 were randomised to receive either the homeopathic preparation or placebo. The results did not demonstrate a significant advantage of BRN-01 over placebo in reducing hot-flash severity.

Collectively, these investigations indicate that homeopathy has been explored for managing endocrine therapy-associated menopausal symptoms. Nevertheless, the placebo-controlled findings do not establish a specific therapeutic benefit and further adequately powered clinical trials would be required to determine its potential role.

Homeopathy and Radiotherapy Associated Skin Reactions

Radiotherapy-associated skin reactions represent another area in which homeopathic interventions have been investigated. Acute radiation dermatitis can present with erythema, dryness, itching, pigmentation changes and, in some cases, more severe skin reactions. These complications may cause considerable discomfort and affect patients' quality of life during breast cancer treatment.

A randomised, double-blind, placebo-controlled study involving 66 women undergoing radiotherapy following breast cancer surgery was investigated (9). The investigators evaluated a combination of Belladonna 7cH and X-ray 15cH for managing acute radiodermatitis. The assessment

included skin colour, temperature, swelling and pigmentation. Although the overall severity scores during radiotherapy did not demonstrate statistically significant differences between the treatment and placebo groups, some differences were reported in individual skin parameters and during the recovery period. The authors acknowledged that the limited sample size and treatment regimen could have influenced the findings.

Additionally individualised homeopathic treatment for radiation induced itching in a prospective observational study involving 25 breast cancer patients was studied. The study reported reductions in patient-recorded itching scores following treatment. However, the lack of a control group and the short follow-up period limit the interpretation of these findings (10).

The Cochrane review also examined homeopathic interventions for adverse effects associated with cancer treatment (14). It identified preliminary evidence for selected interventions, including topical calendula for radiotherapy-associated dermatitis. However, calendula preparations should not be considered equivalent to highly diluted homeopathic oral preparations and the findings cannot be generalised to all homeopathic interventions.

Overall, homeopathic interventions have been investigated for radiation-associated skin complications, but the available evidence remains insufficient to establish a consistent therapeutic benefit.

Homeopathy and Aromatase Inhibitor Associated Joint Symptoms

Joint pain and stiffness are frequently reported among breast cancer patients receiving aromatase inhibitors. These symptoms may negatively affect physical activity, treatment adherence and quality of life.

A prospective observational pilot study was conducted involving 40 women with hormone receptor-positive breast cancer (11). The investigation evaluated the use of Ruta graveolens 5CH and Rhus toxicodendron 9CH alongside aromatase inhibitor treatment. After three months, the group receiving additional homeopathic preparations demonstrated a more favourable change in joint-pain scores compared with the control group. Differences were also reported in analgesic consumption and the impact of joint pain on sleep.

However, the non-randomised design, limited sample size and potential influence of other clinical factors restrict the interpretation of these findings. The authors recommended larger randomised controlled studies to establish whether the reported improvements could be attributed specifically to the homeopathic preparations.

Therefore, the available evidence concerning homeopathy for aromatase inhibitor-associated joint symptoms remains preliminary.

Homeopathy in Postoperative Supportive Care

Postoperative recovery following mastectomy and breast reconstruction has also been investigated in relation to homeopathic interventions. Surgical complications such as seroma formation, bleeding, pain and prolonged drainage may influence recovery and increase the need for additional clinical management.

A randomised, placebo-controlled study was conducted involving 53 women undergoing unilateral total mastectomy (12). The study examined the effects of Arnica montana 1000K on postoperative bleeding and seroma formation. Although the primary per-protocol comparison did not demonstrate a statistically significant difference in drainage volume, an adjusted regression analysis indicated a reduction in blood and seroma collection in the treatment group. The authors suggested that further investigations involving larger patient populations were necessary.

Subsequently Arnica montana and Bellis perennis was examined following mastectomy and immediate breast reconstruction (13). The study reported a shorter duration before drain removal in the homeopathy group, although several secondary outcomes, including postoperative pain and quality-of-life measures, did not demonstrate significant differences.

These studies provide preliminary observations concerning the possible application of homeopathy in postoperative breast cancer care. Nevertheless, the limited sample sizes, variations in treatment preparations and differences in outcome assessment require cautious interpretation.

Safety and Patient Reported Outcomes

Safety and patient-reported outcomes are important considerations when evaluating

complementary interventions in oncology. Some investigations have reported improvements in subjective well-being and selected quality-of-life parameters, whereas others have not demonstrated significant differences compared with placebo.

A pragmatic randomised controlled trial conducted involving 410 patients with different malignancies to evaluate adjunctive classical homeopathy alongside conventional cancer treatment (20). The study reported improvements in global health status and subjective well-being in the homeopathy group compared with the control group. However, the study involved a mixed cancer population and evaluated a broader homeopathic treatment approach. Therefore, its findings cannot be directly interpreted as evidence of effectiveness in breast cancer patients.

The systematic review identified heterogeneous findings across 18 studies involving 2,016 cancer patients (4). The review highlighted variations in clinical outcomes, treatment protocols and methodological quality. In addition, the reporting of adverse events and tolerability was inconsistent across the included studies.

No serious adverse effects attributable to the homeopathic preparations in the trials was found in a review (14). However, a systematic review of published case reports and case series, identified both direct and indirect adverse effects associated with homeopathy (16). These included adverse outcomes arising from the use of certain preparations and the replacement of conventional medical treatment.

The National Cancer Institute and the National Center for Complementary and Integrative Health also emphasise the importance of evaluating complementary approaches carefully and avoiding the substitution of established cancer treatments with unproven interventions (21, 22).

Thus, although some studies have reported favourable patient-reported outcomes, the available literature does not provide sufficient evidence to establish the clinical effectiveness or comprehensive long-term safety of homeopathic interventions in breast cancer supportive care.

Further study highlighted the importance of methodological quality and potential bias when evaluating the specific effects of homeopathic preparations in placebo-controlled clinical trials (23). Furthermore, established integrative oncology guidelines emphasise the use of selected evidence-based interventions for managing anxiety, fatigue, pain and quality-of-life concerns in breast cancer patients, rather than establishing homeopathy as a standard supportive-care intervention (24, 25). Overall, the existing literature demonstrates that homeopathy has been explored in several areas of breast cancer supportive care, but the available clinical evidence remains insufficient to establish consistent therapeutic efficacy.

Conclusion

This has been studied seriously by researchers in homoeopathy who believe in evidence-based medicine such as sick-incident discomfort, radiodermatitis and wound-healing problems after surgery. However, the data is inconsistent and involves results from placebo-controlled trials using homoeopathy for clinical benefit. This research underscores the need to differentiate between claimed improvements in symptom management and subjective well-being and demonstrated therapeutic effectiveness. The research to date has been limited by small sample numbers, varied treatments, differences in study design and poor safety reporting. There is a need for better planned appropriately powered RCTs in the future with a defined treatment procedure and verified clinical outcome and long-term safety reporting. It is important to state that homoeopathy should not be used as a replacement or delay of evidence-based breast cancer treatments, and, if used, should be further explored with the treating oncology team.

Existing work on homoeopathy in breast cancer supportive treatment involves a range of methodological shortcomings. Many studies are small, with limited statistical power and generalisability of conclusions. In addition, variability in the homoeopathic preparations and dilutions, length of therapy and personalised prescription of homoeopathy further challenge the ability to compare across research. Furthermore, the observational designs of certain studies raise the risk of selection/recruitment bias, placebo effects and confounding. Lack of clear definitions of adverse events reporting and non-standardised outcome measures limits the interpretation of clinical data.

Future studies should be well-designed, multicentre, randomised, double-blind, placebo-controlled trials with clearly specified inclusion criteria and standardised outcome measures. They should also differentiate between particular homoeopathic formulations and personalised homoeopathic therapy and include the measurement of clinically relevant outcomes using validated instruments. Long-term follow-up is also required to examine the durability of claimed benefits and to detect harmful consequences. Importantly, future research should safeguard against complementary therapies compromising standard oncologic therapy or access to evidence-based medical care. Improved transparency in terms of trial registration, methodology, statistics and adverse events reporting will make research in this area more reliable and reproducible.

Abbreviations
None.

Acknowledgement
None.

Author Contributions
Both the authors contributed equally.

Conflict of Interest
All authors declare no conflict of interest regarding this research.

Data Availability
The dataset generated and/or analysed during the current study is available from the corresponding author upon reasonable request.

Declaration of Artificial Intelligence (AI) Assistance
AI tools were used for language editing, grammar correction, formatting assistance and editing figures. The authors are responsible for verifying all scientific content, analyses, interpretations and references.

Ethics Approval
Not Applicable.

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