
USEFULNESS OF A PRAGMATIC INTEGRATIVE MEDICINE APPROACH IN THE MANAGEMENT OF BREAST CANCER: A CASE SERIES WITH LITERATURE REVIEW

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ABSTRACT

Complementary and alternative medicine approaches are widely used by breast cancer patients. We present a case series of four patients with breast cancer who underwent a pragmatic integrative medicine protocol in an inpatient integrative oncology setting. The participants were three metastatic and one non-metastatic breast cancer patient who did not undergo any standard cancer therapies. The holistic integrative medicine protocol includes counselling, oncothermia, high-dose vitamin C therapy, ozone therapy, diet therapy, liposomal curcumin therapy, vitamin D supplementation, artesunate injections, probiotic supplementation, Co-Q enzyme therapy, hyperbaric ozone therapy, medical cannabis, coffee enema, colour therapy, sun exposure, and yoga therapy. The treatment duration varied from person to person. All the patients have shown significant improvement in their complete blood cell counts, reduction in their cancer markers. The thermal scan has shown a complete arrest of disease activity in the breast compared to baseline. Further, all the patients have shown improvement in their body weight and expressed a complete revival of subjective wellbeing. The holistic integrative medicine protocol looks promising in the management of breast cancer. However, large-scale randomized control trials are warranted to validate the present findings.

Keywords: Breast cancer, Integrative medicine, Vitamin C therapy, Oncothermia, Case Report

1. INTRODUCTION

Breast cancer is one of the most common types of cancers across the globe, accounting for nearly 6.85 lakh deaths and representing 1 in 8 cancer diagnoses [1]. This poses a significant physical, psychological, and economic burden on both the patients and their caregivers. The gold standard of therapeutic recommendations for breast cancer includes surgery, hormonal therapy, chemotherapy, radiation, and immunotherapy. Despite the beneficial effects of these therapies, they are associated with severe side effects [2]. On the other side integrative oncology is emerging as a promising avenue that promotes collaborative clinical practice and research in cancer [3]. Furthermore, integrating complementary and alternative medicine (CAM) therapies in the management of breast cancer is becoming popular among patients and caregivers [4]. Homeopathy, traditional Chinese medicine, biological-based practices, energy medicine (Pranic healing, Reiki), mind-body medicine techniques (yoga, meditation, progressive muscle relaxation) and manipulative and body-based practices are the common CAM therapies used in breast cancer [5]. We report the cases of four patients diagnosed with breast cancer who underwent integrative medicine therapies at an exclusive integrative oncology setting in India.

2. CASE PRESENTATION

All the patients underwent an integrative medicine protocol (Mirakle™ protocol) curated by a group of physicians that included experts from yoga, naturopathy, modern medicine, and homoeopathy. The Mirakle™ protocol included counselling, oncothermia, high-dose vitamin C therapy, ozone therapy, diet therapy, liposomal curcumin therapy, vitamin D supplementation, artesunate injections, probiotic supplementation, Co-Q enzyme therapy, hyperbaric ozone therapy (HBOT), medical cannabis, coffee enema, colour therapy, sun exposure, and yoga therapy.

These therapies were used in varying permutations and combinations as per the individual needs of the patient. While the majority of the treatments were administered to all patients with the same frequency, as shown in Table 1, other therapies, such as hyperbaric ozone, yoga, medicinal cannabis, and vitamin D supplements, were combined depending on the patient's condition. Only patients with healthy, large veins were able to receive hyperbaric ozone therapy; patients' physical conditions determined whether yoga therapy was recommended; only patients experiencing excruciating pain were eligible for medical cannabis; and the patient's vitamin D levels determined whether vitamin D supplementation was necessary. All the patients signed an informed consent for sharing their de-identified information.

Patients were selected based on the following criteria: PET CT- confirmed, biopsy-proven carcinoma of the breast, with or without metastasis, any type of breast cancer, and a willingness to undergo integrative medicine therapies. None of the patients in this case series underwent standard conventional therapies due to varying reasons like fear of side effects, lack of confidence, belief in CAM therapies, and economic constraints. The treatment duration varied from patient to patient. Even though all the patients had a confirmatory diagnosis of cancer through a positron emission tomography (PET) scan, we have used a thermography technique[6], which is a non-invasive and sensitive test to screen breast cancer (a thermography camera captures these temperature differences in the breast area, which are then analyzed for abnormalities) along with the other cancer markers, to evaluate the prognosis in these patients from the baseline. We further assessed the subjective well-being of our patients by qualitatively exploring their personal experiences, emotions, and perceptions related to their diagnosis, treatment, and overall quality of life.

2.1. Case 1

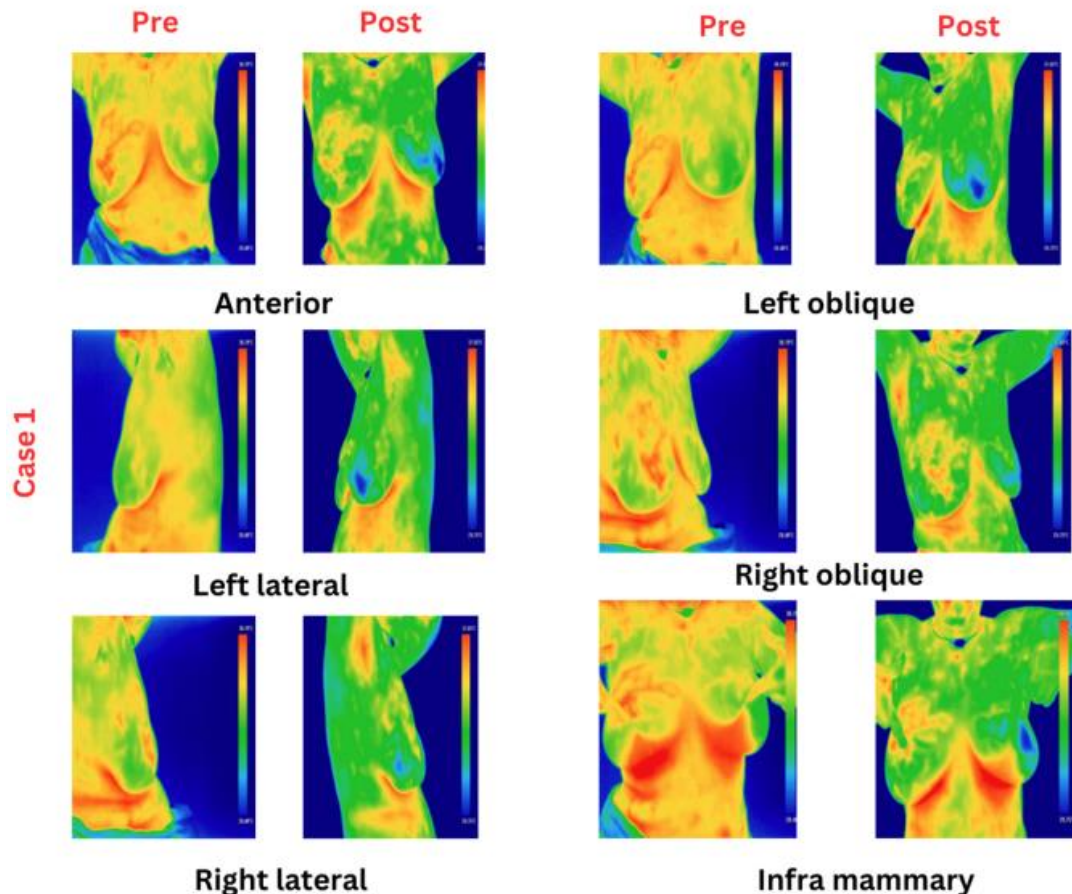
The patient was a 49-year-old female of Indian ethnicity, diagnosed with carcinoma of the right breast with metastasis to the right axillary nodes and skeleton. She was diagnosed with carcinoma of the right breast in November 2021 through a biopsy and PET scan. She initially underwent flower therapy and Siddha (a traditional Indian medicine practice) at her hometown, but did not find any relief in her symptoms. She presented to our setting with severe pain in the left hip region associated with difficulty walking in September 2023. Her baseline thermography reports suggested the presence of hyperthermic lesions in her right breast with cellular activity.

She underwent the Mirakle™ protocol for 3 months, where she reported improvement in subjective quality of life, reduction in fatigue, pain, and stability in body weight. Her thermography report from November 2023 has shown regression of the right breast lesion with no cellular activity (Fig. 1). Even though the patient has shown significant subjective improvement in her cancer-related symptoms and well-being, there was a rise in the cancer markers at the end of the third month. The detailed changes in the clinical parameters are tabulated in Table 2. At present, the patient follows the diet regimens and supplements (liposomal vitamin C drink, liposomal curcumin, CoQ-10 enzyme, probiotics, vitamin D) advised at home and visits the hospital every 15 days for maintenance therapy.

Table 1
The Mirakle™ Protocol: An integrative oncology protocol.

Intervention	Frequency of intervention	Role in cancer therapeutics
Counselling	Daily	Yoga and naturopathy based counselling techniques was utilized in our patients to remove the fear of disease, fear of death, build hope and resilience among patients and caregivers.
Oncothermia	Alternate days (A total of 12–24 sessions was provided to the patients depending upon patient's condition and affordability)	Oncothermia uses a modulated radiofrequency which helps in selectively stimulating the programmed cell death of cancer cells and arresting the metastasis.
High dose vitamin C therapy	2–3 times per week, the total dose not exceeding 90 g per week.	It acts as a scavenger of reactive oxygen species (ROS), inhibits the growth of cancer cells, reduces the side effects of conventional therapies, and reduces the symptoms associated with cancers.
Ozone therapy	Daily (Ozone is administered in the form of rectal insufflation/vaginal insufflation/ saline ozone, Minor autohaemotherapy and major autohaemotherapy)*.	Ozone exhibit anti-tumor effect by its anti-oxidant property which promotes tumor cell apoptosis. Furthermore, it improves the oxygen carrying capacity of the cells, acts as an anti-microbial agent, and modulate the immune system.
Diet therapy	Daily (A complete Millet-based, sugar free, maida free, refined grains free diet was advised to our patients. This also includes carrot, beetroot, apple juice, fresh vegetable salads, and soups.)	A low glycemic index diet rich in phytonutrients, vitamins and minerals can help in addressing the macro and micronutrient deficiencies that are common in cancer.
Liposomal curcumin therapy	Daily (5–10 ml liposomal curcumin drink is consumed by all the patients)	Liposomal curcumin induces cytotoxicity, inhibit the cancer cell growth and induce apoptosis.
Vitamin D supplementation	Daily (The doses are decided based on the vitamin D deficiency ranging from 10000 to 60000 IU after monitoring the levels of parathyroid hormones and ionized calcium levels.)	Adequate levels of vitamin D has shown to check the progression, tumorigenesis and alter the cancer cell-microenvironment interaction.
Artesunate injections	Weekly once (The doses starts from 60 g and gradually elevated up to 180 g after monitoring the haemoglobin levels of the patients)	Artesunate induces tumor cell apoptosis and arrests the tumor cell growth.
Probiotic supplementation	Daily (Two doses of Liv-Bio alpha Pre and probiotic supplements are provided to all the patients.)	Upregulating the gut flora improves the diversity of gut microbiota which upregulate the metabolic and immune functions in cancer.
Co-Q enzyme therapy	Daily (5–15 ml liposomal Co-Q 10 enzyme were consumed by all the patients)	Co-Q enzyme upregulate the mitochondrial dysfunction and increase the energy levels of patients.
Hyperbaric oxygen therapy	Once in a month	Hyperbaric oxygen therapy influence the antioxidant activities and inhibits cancer growth.
Medical cannabis	As per need 4–8 drops (Cannaronil- cannabidiol: tetrahydrocannabinol 1:4)	Helps in relieving cancer symptoms pain, anxiety, insomnia as well as inhibit cancer growth and promote apoptosis.
Coffee enema	Thrice in a week	Functions as a detoxifier of liver, promotes antioxidant capacity
Colour therapy	Once in a week (Hydrosun light therapy)	It combines the oriental medicine concept of chakra, chromotherapy and properties of light. It is useful in relieving pain, induce calmness and activate the immune system.
Sun exposure	Daily 10–20 minutes (between 10 am to 3 pm)	Sun exposure helps in upregulating the vitamin D levels, improves mood and cognition.
Yoga therapy	Daily 30–45 minutes (Includes pranayama, meditation and asanas)	Yoga helps in improving the mental health, builds resilience and also helps in regaining homeostasis.

* The choice of treatments varies from patient to patient



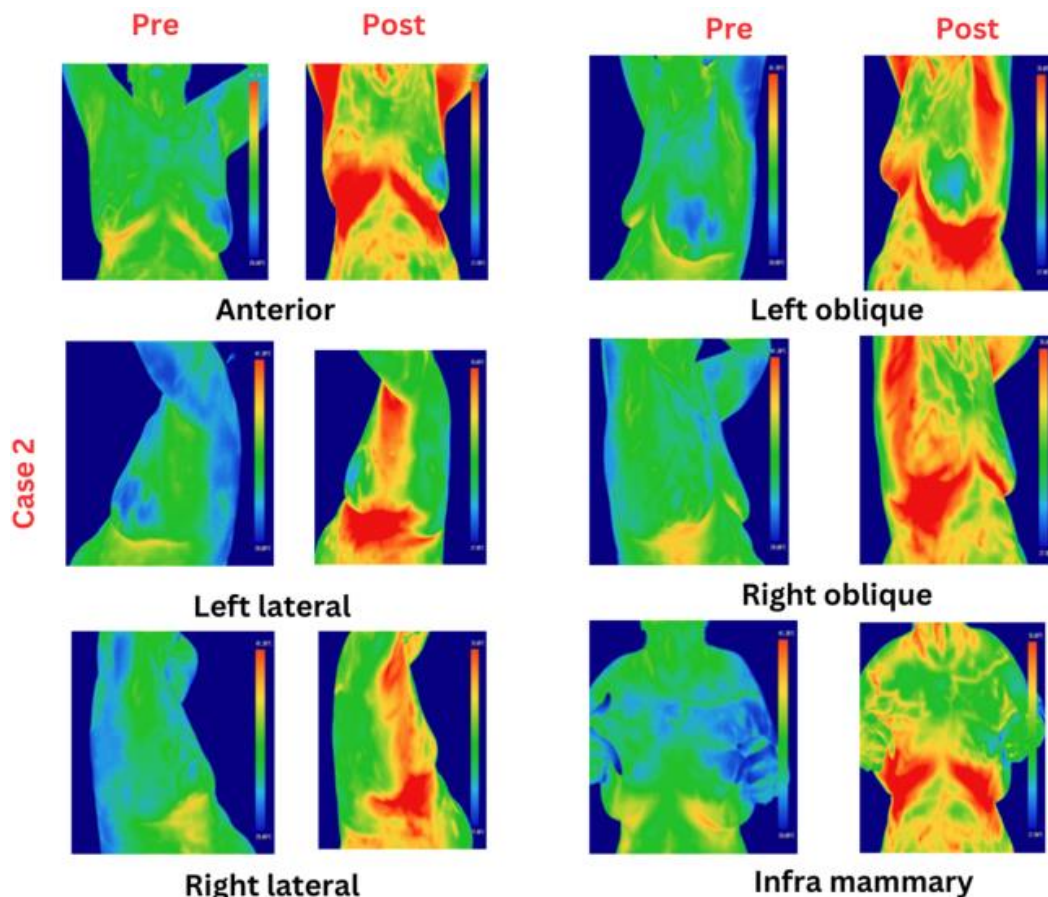


Fig. 1. Changes in the thermal scan before and after the treatment.

2.2. Case 2

The patient was a 76-year-old female of Indian ethnicity, diagnosed with carcinoma of the right breast with axillary node metastasis in December 2021. She visited our hospital in January 2022 with severe pain in the right breast, both shoulders, and a freely mobile hard mass in the right breast. She was a known case of rheumatoid arthritis and type 2 diabetes mellitus, for which she was taking metformin 500 mg twice daily. Her baseline thermography report suggested small hyperthermic lesions in the right breast and large hyperthermic lesions in the left breast with irregular borders. She underwent the Mirakle™ protocol as an inpatient for 4 months at different intervals since January 2022.

Besides this, during the intervals of her inpatient stay, she visited the hospital for maintenance therapies once every 15 days with regular supplements, as mentioned in Case 1. Her thermograph report in June 2023 was similar to that of the baseline report with respect to the breast. The lymph nodes appeared normal in the follow-up thermograph (Fig. 1). Nevertheless, the patient expressed complete relief from her pain, fatigue, and improvement in quality of life. We have observed a significant reduction in the cancer markers across the past year, suggesting reduced disease progression (Table 2). Currently, she is visiting the hospital once a month and continuing the maintenance therapy.

Table 2
Changes in the biochemical markers across time points.

Time points		RBC	Hb	PCV	TC	N	L	E	RDW-CV	Platelets	ESR	FE	CEA	Ca 15.3	LDH	D-DIMER	hs-CRP	Weight
P1	Baseline	3.7	9.1	27	6410	56.5	33.2	1.5	13.1	401	35	7.5	2.18	33.26	172	1600	1.7	66.7
	3 rd month	3.61	8.9	26.7	7890	63.1	31.6	1.5	15	394	50	20.7	2.1	61.65	170	2471	0.6	64.7
P2	Baseline	4.06	10	26.9	9910	58	34	3	13.6	413	25	16.8	3.3	43.9	273	1590	10.63	62.9
	1 st month	3.97	10.4	28.1	7	46	45	4	14.3	276	28	NE	4.1	37.1	251.7	1120	6.35	59.3
	3 rd month	3.88	11.1	29.1	5.6	56	34	4	12.3	287	26	72.9	3.8	32.7	480.63	1910	4.85	60.2
	6 th month	3.6	10.9	28.6	6.7	60	32	3	13.7	255	28	NE	NE	29.3	332.4	850.6	2.7	63.9
	12 th month	4.16	10.8	31.9	8.43	60	34	2	12.9	392	22	NE	NE	19.33	207	NE	12.85	67.5
	18 th month	4.36	11.3	33.4	12400	58.5	32.8	1.2	12.1	444	50	NE	NE	20.53	208	1019	13.5	67
P3	Baseline	4.43	12.6	33.8	9400	76	19	2	12.5	251	23	39.3	3.8	59.9	350.6	260	1.54	71.8
	1 st month	4.65	13.5	36.1	7700	66	25	4	12.8	257	36	49.1	4.3	56.6	520.97	285	1.15	69
	3 rd month	4.26	12.1	32.3	8900	67	27	2	12.3	244	20	40	2.87	42.6	324.49	310	5.2	67.3
	6 th month	4.45	12.9	37.9	7630	64.3	26.1	3	14.8	336	25	69.4	4.1	24.17	274.1	310	1.62	65.8
P4	Baseline	4.53	11.8	36.4	9600	64	30	2	15.2	243	40	125.2	2.81	12.99	158	504	3.1	64.1
	3 rd month	4.36	11.4	33.6	8120	55.8	34.7	2.6	11.1	293	12		1.78	10.48	155	206	2.8	64.4

P-Patient; RBC- Red Blood Cells (million/cu mm); Hb- haemoglobin (g/dL); PCV- Packed Cell volume (%); TC- Total Count (cells/cu mm); N- Neutrophils (%); L-Lymphocytes(%); E-Eosinophils(%); RDW-CV- Red Cell distribution width (%); ESR- Erythrocyte sedimentation rate (mm); FE- Ferritin(ng/ml); CEA- Carcinoembryonic antigen (ng/ml); Ca 15.3- Cancer antigen 15.3 (U/ml); LDH- Lactate Dehydrogenase (U/L); D-DIMER (ng/ml); hs-CRP- High sensitive C-reactive protein (mg/L); Weight (Kg); NE- Not evaluated

2.3. Case 3

The patient was a 69-year-old female of Indian ethnicity, diagnosed with carcinoma of the left breast with nodal metastasis in December 2021. She presented to the hospital on January 2022 with pain in the left breast, inverted nipples, and an enlarged left breast. She was a known case of hypertension and was taking calcium channel blockers and beta blockers for it. The initial thermography report has shown hyperthermic lesions in her left breast with cellular activity. She took the Mirakle™ protocol for 3 months as an inpatient at different intervals, followed by visiting as an outpatient once a month since June 2022. During the course of treatment, she had persistent pricking pain in her left breast and upper limbs, as well as disturbances in sleep. Her thermograph report from June 2023 has shown complete remission of the lesion from her left breast (Fig. 2). We noted a subsequent reduction in her cancer markers (Table 2), an improvement in her subjective quality of life, and a complete reduction of symptoms. She is currently taking maintenance therapy once a month.

2.4. Case 4

A 58-year-old female of Indian ethnicity, diagnosed with carcinoma of the left breast in May 2023 visited our setting in June 2023. She did not have any specific complaints related to her disease except for severe fatigue. She was a known case of type 2 diabetes mellitus and is taking metformin for the same. Her baseline thermography report has shown a hyperthermic patch over the upper quadrant of the left breast with an irregular border and cellular activity. She underwent the Mirakle™ protocol for 3 months as an outpatient, where the therapies were scheduled every alternate day. Within two weeks of the initiation of the protocol, the patient expressed remarkable improvement in her energy levels; however, the lump was still palpable in her left breast. By the end of the third month, we noticed that there were no palpable lumps, and the thermography report also showed that there were no hyperthermic patches or cellular activity in her breasts (Fig. 2), indicating remission. Further, her cancer markers have also shown a significant reduction (Table 2). Her therapy frequency was reduced to once a week for one month, and at present she is taking maintenance therapy once a month. The detailed timeline of events is presented in Fig. 3.

3. DISCUSSION

This case series discusses the usefulness of a comprehensive integrative medicine protocol in the management of breast cancer. All the patients responded well to the therapies provided and have shown improvement in their symptoms and cancer markers. No adverse events were reported by any of the patients. These therapies were intended to promote cancer cell death, upregulate

mitochondrial function, reduce tissue hypoxia, improve mental health and quality of life, and reduce symptoms. The integrative medicine therapies used in this protocol have Table been shown to have potential anti-tumor effects. Oncothermia, which uses a modulated radiofrequency current, has been shown to target and destroy cancer cells by disrupting the extracellular membrane of cancer cells. It induces programmed cell death; however, it does not affect normal cells [7]. Earlier studies have also shown oncothermia to be beneficial in treating different types of cancer [8,9].

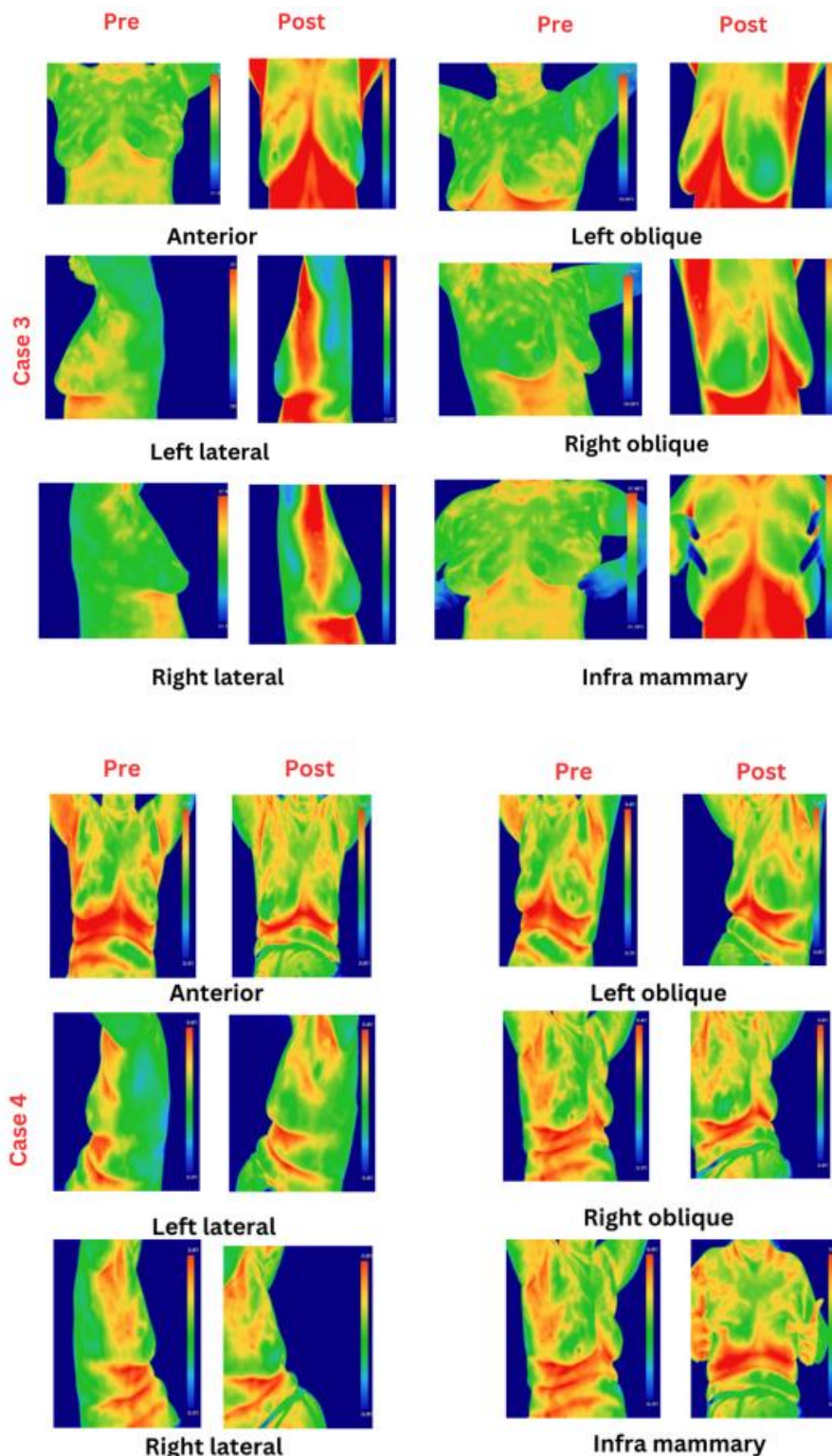


Fig. 2. Changes in the thermal scan before and after the treatment.

This is the first study to report the use of oncothermia in breast cancer patients. This study also reports the use of high-dose vitamin C as a potential anti-cancer therapy. The doses were tolerated well by all the patients without any adverse events. The role of vitamin C as an anti-cancer agent has been reported in earlier studies as well [10]. Vitamin C in higher doses suppresses the invasion and metastases of breast cancer cells by inhibiting epithelial-mesenchymal transition [11]. The role of ozone therapy in cancer is presently being studied through in vitro and clinical studies. Ozone applications have been shown to improve tissue oxygenation, reduce oxidative stress, stimulate mitochondria, and promote and modulate immune function[12,13].

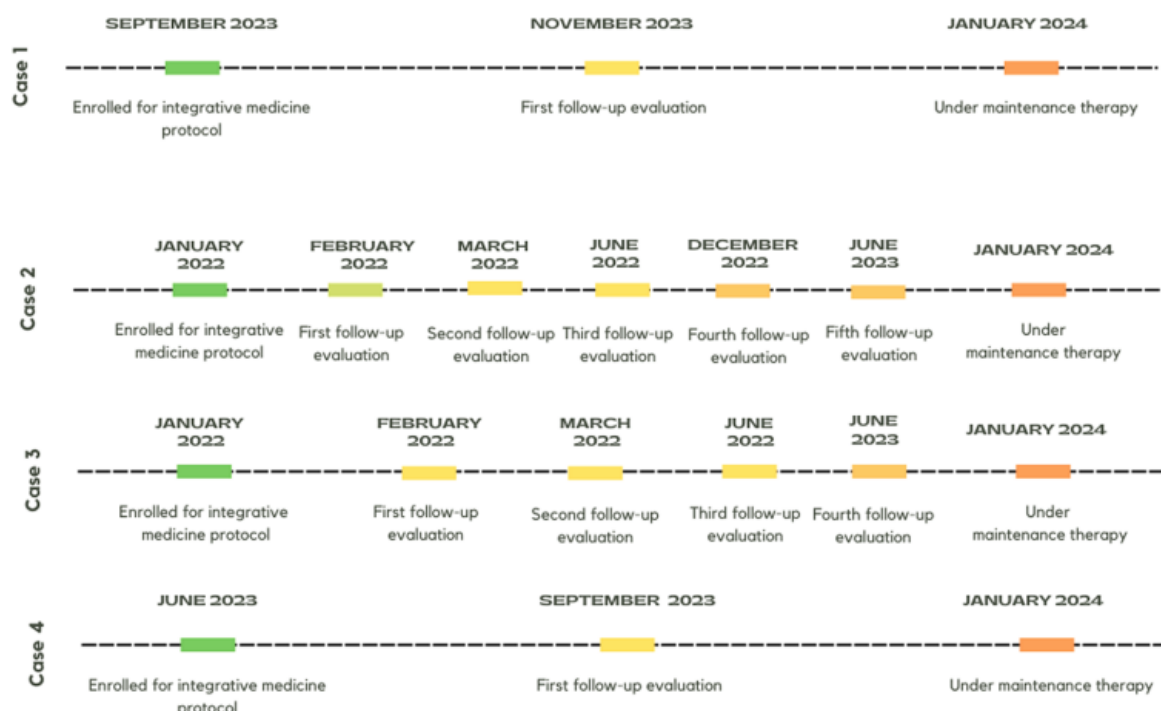


Fig. 3. Timeline of events.

While whole grain consumption has been suggested in the management of cancer, millets may be the most appropriate choice owing to their high nutrient content, lack of acid-forming properties, and glutenfree status in comparison to other grains[14,15]. It is paramount that adequate nutrition is provided to cancer patients from the right source. We observed significant improvements in body weight and physical wellbeing among study participants, which may be attributed to adequate nourishment through millets in addition to the other therapies. In vitro and in vivo studies suggest curcumin exhibits an anti-cancer effect in breast cancer by accelerating programmed cell death, modulating the inflammatory process, inhibiting angiogenesis, and inhibiting cancer metastases[16]. A liposomal based curcumin was used in this study, as liposomal curcumin increases the bioavailability of curcumin and possesses significant pro-apoptotic and inhibitory effects on cancer cells[17].

Vitamin D deficiency is considered a risk factor for breast cancer and is also associated with its poor prognosis. Combining vitamin D supplementation with other breast cancer therapies has been thought to have potential anticancer activity by influencing intracellular mechanisms like cell differentiation, proliferation, programmed cell death, and epithelial-mesenchymal transition [18]. All

the patients in the current case series presented with vitamin D deficiency, and the supplementation of the same might have contributed to the better prognosis. In addition to this, we also recommended 10–15 minutes of sun exposure to all the participants, as sun exposure is found to be protective against breast cancer, which is further associated with vitamin D synthesis in response to sun exposure [19].

Artesunate injections have been an integral part of this protocol. Artesunate is a derivative of *Artemisia annua*, which has been shown to possess potential anticancer effects such as promoting apoptosis, autophagy, improving redox balance, inhibiting angiogenesis, and inducing ferroptosis [20]. Prebiotics and probiotics were used as part of this protocol since gut dysbiosis is thought to play a significant role in the development and metastasis of breast cancer [21]. Probiotic use is recommended as an effective approach to enhance immunomodulation and quality of life in patients with breast cancer [22]. Further, coenzyme Q10 was consumed by the participants of this study. Coenzyme Q10 is an important component in the mitochondrial electron transport chain, whose deficiency will result in mutations of mitochondrial DNA and subsequent mitochondrial dysfunction. Studies have shown a depletion in the coenzyme Q10 among breast cancer patients and recommend its supplementation as a prognostic strategy [23].

Cancer cells thrive in a hypoxic environment, as it helps in angiogenesis and further metastasis. Furthermore, this induces structural and functional damage to the adjacent healthy cells [24]. As discussed earlier, ozone therapy helps in addressing tissue hypoxia. Besides this, we have also used HBOT, a more powerful tissue oxygenation method, with our patients. There are reports suggesting the usefulness of HBOT as an adjuvant in the management of breast cancer [25,26]. HBOT augments tissue functions by improving the oxygen supply, reducing inflammation, reinstating the redox balance, and promoting apoptosis [27].

Managing the psychological burden and pain associated with cancer remains one of the primary challenges in cancer therapeutics. In our protocol, we primarily use yoga therapy and medical cannabis preparations to manage pain, insomnia, anxiety, depression, and stress among our patients. A mixture of cannabidiol and tetrahydrocannabinol was used in our patients primarily to control pain and upregulate their mental health status. Earlier studies recommend the use of cannabis in breast cancer as it improves mental health symptoms, forbids cancer cell progression, promotes apoptosis, and arrests tumor angiogenesis [28–30]. Yoga is known to reduce pain, fatigue, improve the quality of life, and increase physical activity among patients with breast cancer [31,32].

A coffee enema was given to all the patients in this study as a detoxification measure. Coffee enemas are reported to detoxify the liver by enhancing the activity of antioxidants such as glutathione and S-transferase activity [33,34]. There are reports on the adverse effects associated with coffee enema as well [35]. However, we did not find any adversities associated with coffee enema among our participants. Nevertheless, this needs to be validated through large-scale studies. Colour healing is one of the most common methods used in complementary and alternative medicine settings. Colour therapy has been reported to alleviate cancer-related symptoms like insomnia, pain, fatigue, poor appetite, nausea, and mood disturbances [36]. Our participants also reported improvements in their symptoms and mental health status, which may be attributed to the use of colour therapy as well.

This is the first case series reporting the pragmatic use of an array of CAM therapies in the management of breast cancer. There are substantial limitations in the present report that warrant future large-scale studies. The use of multiple treatments, all of which have potential anticancer effects, limits our ability to understand the specific role of each therapy. Nevertheless, the primary intention was to holistically support the patients with all the possible CAM approaches. Besides the cancer-related markers, this study did not use any conventional imaging techniques like PET scans or CT (computed tomography) scans. Even though a thermal scan is considered a reliable technique for detecting breast cancer, evidence suggests it could be used only as a supplementary diagnostic technique alongside a mammogram[6,37,38]. Furthermore, our patients were not ready to take a PET/CT scan or mammogram. This might be considered a limitation, as it can affect the reliability of the outcomes presented. Another limitation of this study is that we did not assess the changes in quality of life using any established quality of life instruments. This study did not collect any data beyond the cancer-related markers, which may be considered a limitation.

All patients in this case series did not receive any standard medical care. Even though there are favourable outcomes, there are probabilities that the patient may or may not have minimal residual disease. A PET scan would have ideally revealed if there was any minimal residual disease. Since our patients refused to undergo a PET scan or mammogram, the authors do not have enough evidence to comment on this aspect. This needs to be investigated in future randomized controlled studies.

The study design, being a case series, limits the generalizability of the present findings, which is a limitation. One of the primary limitations of this case series is the small sample size, which inherently restricts the power of any statistical analysis. While case series are valuable for generating hypotheses and exploring potential benefits of treatments, they lack the robustness required to establish definitive cause-and-effect relationships. The absence of a control group further limits the ability to draw firm conclusions about the efficacy of the interventions studied. Consequently, the findings should be interpreted with caution, and further research with larger, controlled studies is necessary to validate these observations. Nevertheless, this report offers promising directions for research and clinical practice in integrative oncology.

4. PATIENT PERSPECTIVE

All the patients were happy that they could improve their quality of life and achieve considerable control over their condition with an integrated approach. They opined that involving them in the decisionmaking process of treatment planning gave them confidence to continue the therapies.

Ethics approval and consent to participate

The ethical approval was waived by the institutional ethics committee of Mirakle Integrated Health centre. All the participants signed an informed consent to share their de-identified information.

Consent for publication

All the participants consented to publish their reports.

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None

CRedit authorship contribution statement

Manickam Mahalingam: Writing – review & editing, Resources, Project administration, Methodology, Funding acquisition, Conceptualization. Thangavelu R: Resources, Project administration, Investigation, Conceptualization. Sekar Sivaranjini: Project administration, Methodology, Formal analysis, Data curation, Conceptualization. Maruthanayagam Saranya: Project administration, Investigation, Data curation, Conceptualization. Muniappan Devibala: Project administration, Methodology, Investigation, Data curation, Conceptualization. Renganathan Ramalakshmi: Project administration, Investigation, Data curation, Conceptualization. Pradeep MK Nair: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability

Data will be made available on request.

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None

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