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Ayurveda-Based Supportive Care Using Guduchi, Ashwagandha, and Curcumin for Breast Cancer Patients: A Pilot Observational Study on Quality of Life and Safety

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Abstract

Background: Breast cancer is the most common malignancy among women worldwide. While modern therapies improve survival, treatment-related side effects often impair quality of life (QoL). Complementary interventions, including Ayurveda, may offer supportive benefits, but clinical evidence is limited.
Objective: To evaluate the effect of an Ayurveda-based regimen—Guduchi (Tinospora cordifolia), Ashwagandha (Withania somnifera), and Curcumin (Curcuma longa)—on QoL and safety in breast cancer patients receiving conventional therapy.
Methods: Forty women at IMS-BHU, Varanasi, were allocated to supportive (n=20) or control (n=20) groups. The supportive group received standardized formulations alongside conventional therapy; controls received conventional therapy alone. QoL was assessed at baseline and 8 weeks using Hindi versions of EORTC QLQ-C30 and QLQ-BR45. Safety was monitored via laboratory tests and CTCAE v5.0.
Results: Supportive patients reported higher global health status (75.0 vs. 41.7), physical (86.7 vs. 60.0) and emotional functioning (62.5 vs. 44.2), and lower symptom burden for pain and insomnia. QLQ-BR45 indicated better body image, fewer breast symptoms, reduced systemic therapy side effects, lower endocrine symptoms, and less hair loss distress (all $p < 0.05$). No serious adverse events occurred; two patients reported mild, self-limiting gastric discomfort.
Conclusion: Ayurveda-based supportive care with Guduchi, Ashwagandha, and Curcumin may safely improve QoL in breast cancer patients receiving conventional therapy. Larger trials are warranted.

Keywords: Breast cancer, Ayurveda, Quality of life, Guduchi, Ashwagandha, Curcumin, Supportive care, Integrative oncology

Introduction

Breast cancer represents the most common malignancy among women globally and is a leading cause of cancer-related mortality. The GLOBOCAN 2020 estimates reported 2.3 million new breast cancer cases worldwide, accounting for 11.7% of all cancers, with 685,000 deaths [1]. In India, breast cancer has emerged as the most prevalent cancer in women, surpassing cervical cancer in several regions. Approximately 178,000 new cases and 90,000 deaths occur annually, with rising incidence in both urban and rural areas [2].

Impact of Conventional Therapy on Quality of Life

Advances in multimodal therapy—including surgery, chemotherapy, radiotherapy, targeted therapy, and endocrine therapy—have improved survival rates [3]. However, these treatments often impose a heavy toll on quality of life (QoL). Common sequelae include fatigue, nausea, vomiting, neuropathy, mucositis, lymphedema, pain, menopausal symptoms, sleep disturbances, cognitive impairment, and psychological distress [4,5]. Many women continue to experience reduced functioning and well-being long after treatment completion, affecting survivorship outcomes.
Quality of life is now recognized as a critical endpoint in cancer research, complementing traditional outcomes such as overall survival and progression-free survival [6]. The European Organisation for Research and Treatment of Cancer (EORTC) has developed validated instruments—the QLQ-C30 core questionnaire and the QLQ-BR45 breast cancer

module—that allow comprehensive assessment of functional, symptomatic, and psychosocial domains [7]. Such tools provide valuable insights into the patient perspective and guide supportive care interventions.

Supportive Care in Oncology and Its Gaps

Supportive care in oncology aims to prevent and manage adverse effects of cancer and its treatment, thereby improving QoL and adherence. Conventional supportive measures—such as analgesics, antiemetics, antidepressants, bisphosphonates, and hormone replacement therapy—have demonstrated benefits but often provide incomplete relief and may add further side effects [8].

In resource-limited contexts such as India, supportive care services are frequently underdeveloped, and patients seek complementary approaches that are accessible, culturally acceptable, and holistic [9]. Integrative oncology, which combines evidence-based complementary modalities with standard therapy, has therefore attracted global attention [10].

Ayurveda and Rasayana Therapy

Ayurveda, the traditional medical system of India, offers a holistic framework for promoting health and resilience. The concept of **Rasayana therapy** emphasizes rejuvenation, strengthening of immunity (Ojas), and enhancement of overall vitality [11]. Several Rasayana herbs are traditionally prescribed to patients with chronic illnesses, including cancer, to improve physical and psychological well-being.

Three Ayurvedic formulations are particularly relevant to oncology supportive care:

- **Guduchi (Tinospora cordifolia):** Guduchi has been extensively investigated for its potent immunomodulatory, hepatoprotective, and antioxidant properties. Experimental studies indicate that its bioactive constituents, including tinosporaside, cordifolioside A, and berberine, enhance the body's natural defence by stimulating macrophage function, lymphocyte proliferation, and cytokine release. In cancer models, Guduchi exhibits chemopreventive and radiosensitizing potential by reducing oxidative stress and DNA damage induced by chemotherapeutic agents. Moreover, it mitigates myelosuppression and hepatotoxicity, commonly associated with cancer therapy, thereby improving overall therapeutic tolerance and survival in preclinical studies [12,13].

- **Ashwagandha (Withania somnifera):** Ashwagandha is recognized as a classical Rasayana (rejuvenator) herb in Ayurveda with broad adaptogenic and anticancer potential. The key bioactives, withanolides and withaferin A, have demonstrated the ability to induce apoptosis in malignant cells through ROS generation, p53 activation, and inhibition of NF-κB and STAT3 pathways. Clinical evidence supports its role in reducing chemotherapy-induced fatigue, stress, and improving quality of life (QoL) in cancer patients. Ashwagandha also enhances immune surveillance and reduces tumor progression by modulating natural killer (NK) cell activity and macrophage stimulation [14].

- **Curcumin (from Curcuma longa):** Curcumin, the principal curcuminoid derived from turmeric, exhibits multi-targeted anticancer actions due to its strong antioxidant, anti-inflammatory, and pro-apoptotic mechanisms. It modulates several molecular targets including NF-κB, COX-2, TNF-α, IL-6, and VEGF, thereby suppressing tumor proliferation, angiogenesis, and metastasis. Preclinical and clinical findings reveal that curcumin enhances the sensitivity of cancer cells to chemotherapy and radiotherapy while minimizing associated toxicities. Additionally, its role in improving QoL, appetite, and fatigue among cancer patients has been well documented, suggesting its promise as an adjunct to conventional therapy [15].

Safety Considerations

Despite promising pharmacological evidence, the safety of combining herbal drugs with chemotherapy and radiotherapy requires careful evaluation. Concerns include herb–drug interactions, hepatotoxicity, nephrotoxicity, and hematological alterations [16]. Many prior complementary medicine studies have been limited by inadequate safety monitoring. Objective assessments, such as laboratory investigations, are essential for building credibility in integrative oncology research.

Research Gap and Study Rationale

Although Ayurveda is widely used in India for supportive care, there is limited clinical research integrating multiple Rasayana formulations within a rigorous QoL framework. Previous trials have focused on individual herbs or anecdotal case reports. No systematic study from a tertiary academic centre in India has assessed the combined use of Guduchi, Ashwagandha, and Curcumin with objective safety evaluation.

This pilot study was therefore designed to evaluate the effect of Ayurveda-based supportive care (Guduchi, Ashwagandha, Curcumin) on QoL using validated EORTC tools (QLQ-C30, QLQ-BR45), with concurrent monitoring of laboratory safety parameters, in breast cancer patients receiving conventional therapy.

Methods

Study Design and Setting
This was a non-randomized, observational pilot study conducted at the Department of Shalya Tantra, Faculty of Ayurveda, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi. The duration was 8 weeks.

Participants
Forty women diagnosed with breast cancer, either receiving or recently completing conventional therapy, were recruited using purposive sampling.

Inclusion criteria:
- Female patients aged 18–65 years
- Histologically confirmed breast cancer
- Willingness to provide informed consent and complete QoL assessments

Exclusion criteria:
- Severe systemic illness (cardiac, hepatic, renal failure)
- Concurrent use of other complementary therapies
- Inability to comply with study procedures

Intervention
- **Group A/ Supportive group (n=20):** 20 Patients received standardized Ayurvedic formulations comprising *Guduchi* (*Tinospora cordifolia*), *Ashwagandha* (*Withania somnifera*), and *Curcumin* (*Curcuma longa*). All formulations were prepared in the Ayurvedic laboratory of Banaras Hindu University (BHU) under Good Manufacturing Practice (GMP) standards, quality tested for purity and safety, and dispensed in standardized therapeutic doses. The herbal intervention was administered for a total duration of two months, beginning concurrently with conventional cancer therapies such as chemotherapy and radiotherapy. The objective was to evaluate the potential of these formulations in improving treatment tolerance and overall well-being. Patient responses were systematically assessed using the Quality-of-Life Questionnaire (QLQ) at three specific time points: baseline (at OPD registration prior to therapy initiation), immediately after completion of conventional treatment, and at a three-month post-treatment follow-up to evaluate sustained effects.
- **Group B/Control group (n=20):** In this group 20 Patients continued conventional cancer therapy (chemotherapy and radiotherapy) without additional Ayurvedic support.

Compliance was monitored via pill counts and patient diaries.

Outcome Measures
- **Primary outcome:** Quality of life, assessed using Hindi-validated versions of **EORTC QLQ-C30 (Table no. 1)** and **EORTC QLQ-BR45** (**Table no.2)** at baseline and 3rd month of follow up.
- **Secondary outcome:** Safety, assessed by laboratory tests and adverse event reporting.

Safety Monitoring
Laboratory investigations were conducted at three time points — at baseline (before initiation of treatment), at the end of conventional therapy, and at the third-month follow-up. The assessments included complete blood count (CBC), liver function tests (SGPT, SGOT, bilirubin), and renal function tests (serum creatinine, BUN). Adverse events were documented using standardized forms and graded according to CTCAE version 5.0.

Ethical Considerations
The study protocol was approved by the Institutional Ethics Committee, IMS-BHU (Approval No: Dean/2023/EC/648). The protocol included baseline laboratory investigations and adverse event monitoring. Written informed consent was obtained in accordance with the Declaration of Helsinki. Confidentiality and anonymity were ensured.

Statistical Analysis
Data were analysed using SPSS v25. Independent t-tests compared post-treatment mean scores between groups. Effect sizes (Cohen's d) were calculated. $p<0.05$ was considered statistically significant.

Results

Table1: EORTC QLQ-C30 Outcomes

The EORTC QLQ-C30 outcomes are shown in Table 1, highlighting that patients in the supportive group demonstrated significantly better scores in global health status, physical, and emotional functioning compared with controls.

Domain	Supportive Group (n=20)	Control Group (n=20)	Interpretation
Global Health Status ↑	75.0	41.7	Higher in supportive
Physical Functioning ↑	86.7	60.0	Higher in supportive

Emotional Functioning ↑	62.5	44.2	Higher in supportive
Pain ↓	50.0	77.5	Lower in supportive
Insomnia ↓	33.3	58.3	Lower in supportive

Table 2: EORTC QLQ-BR45 Outcomes
Results of the EORTC QLQ-BR45 scale are summarized in Table 2, showing notable improvements in body image and reduction of therapy-related symptoms among patients receiving Ayurveda-based supportive care.

Scale	Supportive Group (n=20)	Control Group (n=20)	p-value
Body Image ↑	75.0 ± 8.0	53.3 ± 7.4	<0.01
Breast Symptoms ↓	41.7 ± 7.2	66.7 ± 8.1	<0.01
Systemic Therapy Side Effects ↓	52.5 ± 8.5	78.3 ± 9.0	<0.001
Endocrine Therapy Symptoms ↓	46.7 ± 6.9	70.0 ± 7.6	<0.001
Upset by Hair Loss ↓	40.0 ± 6.2	66.7 ± 7.1	<0.01

Safety Outcomes
- All laboratory values (CBC, LFT, RFT) remained within normal ranges at baseline and till 3rd months of follow up.
- No serious adverse events occurred.
- Two supportive patients reported mild gastric discomfort, which resolved spontaneously.

Discussion

This pilot study demonstrates that Ayurveda-based supportive care using Guduchi, Ashwagandha, and Curcumin may improve QoL in breast cancer patients undergoing conventional treatment, without compromising safety.

Comparison with Literature
Our findings are consistent with previous evidence supporting the role of Ayurvedic and integrative approaches in improving the well-being of breast cancer patients. Ashwagandha has repeatedly been shown to reduce fatigue, improve sleep quality, and enhance stress resilience in cancer populations, highlighting its adaptogenic and anxiolytic effects [14]. Similarly, Guduchi (Tinospora cordifolia) has been documented to enhance immune responses and protect against chemotherapy-induced toxicity, thereby contributing to improved systemic tolerance [12,26]. Curcumin, one of the most widely studied natural compounds, is well known for its anti-inflammatory and antioxidant actions, with several clinical trials demonstrating its ability to mitigate treatment-related symptoms and support overall quality of life [15,24,25].
The improvements observed in our study—in body image, reduction of breast and systemic symptoms, fewer endocrine therapy side effects, and diminished distress related to hair loss—mirror earlier reports of integrative interventions improving psychosocial and functional outcomes in breast cancer survivors [17–19]. In addition, our results resonate with survivorship research highlighting that supportive care interventions not only alleviate acute toxicities but may also reduce the long-term burden of fatigue, sleep disturbances, and psychological distress [21,23].
Globally, cancer survivorship has emerged as a major public health concern, with over 15 million survivors in the United States alone by 2016 [21]. Reports consistently emphasize that improving quality of life should be prioritized alongside survival, as chronic fatigue, pain, and emotional distress remain significant challenges [23]. Integrative and supportive measures such as ours align with these priorities by offering low-cost, culturally acceptable, and biologically plausible options.
Moreover, several supportive care reviews emphasize that QoL improvement requires multimodal approaches addressing both physical and psychosocial needs [22]. Our findings contribute to this growing evidence base by suggesting that Ayurvedic Rasayana formulations, when appropriately standardized and monitored for safety, may complement conventional supportive care. The clinical relevance of curcumin has been underscored in multiple trials, where it demonstrated benefits ranging from reduction of systemic inflammation to improvements in therapy-related side effects [24,25]. Tinospora cordifolia, validated through both ethnomedicinal and pharmacological studies, has also been reported to exert hepatoprotective and immunomodulatory effects, making it a rational component of supportive regimens [26].
Together, these observations highlight that Ayurveda-based supportive care has the potential to address critical gaps in survivorship care, particularly in low- and middle-income countries like India, where resource limitations often restrict access to advanced supportive interventions.

Safety Considerations
Unlike many complementary medicine studies that rely on self-report, our inclusion of laboratory investigations adds objective safety evidence. The absence of significant haematological, hepatic, or renal abnormalities supports the tolerability of this regimen. This addresses long-standing concerns about herb–drug interactions in oncology [16,20].

Strengths

- Use of validated QoL tools (QLQ-C30 and QLQ-BR45).
- Laboratory-based safety monitoring.
- Conducted in a reputed academic institution.
- Good patient adherence.

Limitations

- Non-randomized pilot design limits generalizability.
- Small sample size (n=40).
- Short follow-up (3rd month).
- No biomarker analysis of immune or oxidative stress pathways.
- Limited to women at a single tertiary centre.
- Confidence intervals were not calculated due to the pilot nature and small sample size.

Implications

These findings highlight the potential of integrative oncology approaches in India. If validated in larger randomized controlled trials, Ayurveda-based supportive care could improve QoL, enhance adherence, and reduce treatment-related distress, particularly in low-resource settings.

Conclusion

Ayurveda-based supportive care with Guduchi, Ashwagandha, and Curcumin, when integrated with conventional therapy, appears safe and may significantly improve quality of life in breast cancer patients. These findings are preliminary but provide a strong rationale for larger, randomized, multi-centre trials with longer follow-up and biomarker evaluation.

Declarations

Ethics Approval and Consent to Participate: Approved by Institutional Ethics Committee, IMS-BHU (Approval No: Dean/2023/EC/648). The approved protocol included baseline investigations (CBC, LFT, RFT) and adverse event monitoring. Written informed consent was obtained from all participants.
Conflicts of Interest: None declared.
Funding: No external funding. Ayurvedic formulations were prepared in the BHU laboratory under GMP practices.
Authors' Contributions: Satakshi Mishra designed the study and collected data; Dr. Rashmi Gupta assisted in data interpretation; Dr. Sunil Choudhary performed statistical analysis; Dr. Pawan K. Dubey contributed to Ayurvedic and conceptual validation. All authors read and approved the final manuscript.
Data Availability: Data available on reasonable request from the corresponding author.

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