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CLINICAL TRIAL TO EVALUATE THE EFFECT OF VARANADI KWATHA BHAVITHA SHILAJATU IN COLORECTAL CARCINOMA

[1]Dr. Athira U, [2]Dr. Abdul Shukkoor M M, [3]Dr. Deepa Jose

[1]MS Scholar (Ayurveda), [2]Professor, [3]Associate Professor

[1,2,3]Department of Salyatantra, Government Ayurveda College, Tripunithura, Kerala, India

Abstract : Colorectal carcinoma is a highly prevalent gastrointestinal malignancy associated with severe morbidity, high mortality rates, and significant treatment-related toxicities. Despite advancements in modern oncology, high recurrence rates and adverse effects continually diminish patient quality of life. In Ayurveda, this pathological condition correlates closely with Arbuda, characterized by abnormal tissue growth resulting from Tridosha vitiation primarily affecting the Mamsa Dhatu, Rakta Dhatu, and Meda Dhatu, making integrative approaches utilizing classical formulations essential for comprehensive supportive oncological care. To evaluate the therapeutic effect of Varanadi Kwatha Bhavitha Shilajatu on specific tumour marker levels, namely Carcinoembryonic Antigen, and the overall quality of life in patients diagnosed with colorectal carcinoma, a single-group, pre-post interventional clinical trial was conducted at the inpatient department of Government Ayurveda College Hospital, Tripunithura. Twenty-one diagnosed patients, aged forty to eighty years, were administered fifteen grams of Varanadi Kwatha Bhavitha Shilajatu orally, accompanied by ninety millilitres of Varanadi Kwatha as Anupana, twice daily for thirty days. The clinical parameters assessed included Carcinoembryonic Antigen, Total White Blood Cell count, Erythrocyte Sedimentation Rate, Haemoglobin, Faecal Occult Blood, and the EORTC QLQ-CR29 questionnaire, with data analysed using the paired t-test, repeated measures ANOVA, Friedman test, and Cochran's Q test. Results showed a statistically significant reduction in mean Carcinoembryonic Antigen levels from 6.28 to 5.92 ng/ml ($p=0.008$). Systemic inflammatory markers significantly decreased, while Haemoglobin and quality of life scores demonstrated highly significant improvements ($p<0.001$), though faecal bleeding positivity increased during the intervention. Ultimately, the intervention significantly reduced tumour markers, decreased systemic inflammation, and improved patient quality of life, demonstrating substantial potential as a supportive adjuvant therapy in oncology.

IndexTerms - Arbuda, Carcinoembryonic antigen, Colorectal carcinoma, Shilajatu, Varanadi kwatha.

Introduction

Colorectal cancer (CRC) ranks as the third most frequently diagnosed cancer globally and the second leading cause of cancer-related mortality. In recent years, an estimated 1.9 million new cases have been reported worldwide annually, accounting for over 900,000 deaths. The state of Kerala exhibits a particularly elevated prevalence of CRC, an epidemiological trend closely associated with rapid lifestyle transitions, a high consumption rate of red and processed meats, increased dietary fat, decreased dietary fibre intake, and pervasive sedentary behaviour. The contemporary management of CRC relies heavily on a multidisciplinary approach, including endoscopic mucosal resection, partial colectomy, proctectomy, colostomy, chemotherapy, radiation therapy, and targeted immunotherapy. However, despite significant multidisciplinary advancements and aggressive treatment protocols, patients frequently experience low survival rates, high incidences of postoperative recurrence, distant metastasis, and severe systemic toxicity that compromise daily functioning. Consequently, an impactful, holistic integrative approach is essential to decrease surgical intervention frequency, enhance the patient's quality of life, and prevent aggressive disease recurrence.

In modern clinical practice, Carcinoembryonic Antigen (CEA) is widely established as a critical, reliable tumour marker in colorectal carcinoma. It is routinely utilized by oncologists for predicting prognosis, monitoring therapeutic response, assessing total disease burden, and detecting early recurrence. Reductions in serum CEA levels serve as a primary indicator of a favourable clinical response to treatment.

From an Ayurvedic perspective, neoplastic swellings, malignant tumours, and severe systemic malignancies correlate deeply with the classical concept of Arbuda. Acharya Sushruta comprehensively describes Arbuda as a massive, deep-rooted, fixed, slow-growing, and non-suppurating swelling. This pathology results from the profound vitiation of Mamsa Dhatu (muscle tissue), leading to Mamsopachaya Shopha (fleshy swelling), which is driven by the aggregated and severely imbalanced Tridosha (Vata, Pitta, and Kapha). The fundamental pathogenesis of this condition originates from Agnidushti (impaired digestive fire) and the pathological accumulation of Ama (metabolic toxins) within the Koshta (gastrointestinal tract). This localized disruption impairs the physiological functions of Samana Vayu, Pachaka Pitta, Kledaka Kapha, and Apana Vayu. Consequently, this leads to profound Srotodushti (channel affliction) within the Annavaha Srotas and Pureeshavaha Srotas, which eventually breaches deeper tissues, localizing morbidly in the Mamsa Dhatu, Rakta Dhatu, and Meda Dhatu.

Given this highly complex, multi-systemic pathogenesis, therapeutic measures in Ayurveda must focus simultaneously on multiple pathways: Deepana (enhancing digestion), Pachana (metabolizing toxins), Anulomana (restoring normal downward physiological flow), Srotovishodhana (clearing microchannels), and Rasayana (cellular rejuvenation and immunomodulation). Shilajatu, an exudate revered in Ayurvedic classics, is celebrated for its Tridoshashamana (balancing all three doshas), Sarvarogahara (curing all diseases), and Chedana (scraping and excising) properties. It is specifically indicated as Guda-Raktahrit (alleviating rectal bleeding), Prabala-Shoolanashana (mitigating severe pain), and Panduroganashana (treating anaemia and pallor). Modern pharmacological studies affirm its high content of fulvic acid and dibenzo-α-pyrones, which confer potent anti-inflammatory, antioxidant, immunomodulatory, and selective cytotoxic properties against malignant cell lines.

To optimize and target these effects specifically for gastrointestinal malignancies, Shilajatu was processed (Bhavana) with Varanadi Kwatha. This classical decoction is indicated for Antarvidradi (internal swellings and abscesses) and is known for its potent Kapha-Medohara (reducing kapha and fat) and Lekhana (scraping) actions. Its individual herbal ingredients, such as Shigru, Bilwa, and Bhallataka, possess heavily documented anticancer properties that induce apoptosis and inhibit tumour angiogenesis. Thus, the present clinical trial was conceptualized and conducted to systematically evaluate the clinical effect of Varanadi Kwatha Bhavitha Shilajatu on serum CEA levels, systemic haematological inflammatory parameters, and overall quality of life in patients diagnosed with colorectal carcinoma.

Aims and Objectives

Primary Objective: To evaluate the effect of the internal administration of Varanadi Kwatha Bhavitha Shilajatu on specific tumour marker levels, specifically Carcinoembryonic Antigen (CEA), in patients with colorectal carcinoma.

Secondary Objectives: To evaluate the formulation's effect on improving the patient's quality of life, as assessed by the EORTC QLQ-CR29 questionnaire. Furthermore, to rigorously assess therapeutic changes in Total White Blood Cell (TWBC) count, Erythrocyte Sedimentation Rate (ESR), Haemoglobin (Hb%) concentration, and Faecal Occult Blood (FOB) across the intervention period.

Materials and Methods

Study Design and Setting: A single-group, pre-post interventional clinical trial was established and conducted at the inpatient department (IPD) of the Salyatantra Department, Government Ayurveda College Hospital, Tripunithura, Kerala. The clinical trial protocol was subjected to rigorous ethical review, prospectively registered with the Clinical Trial Registry of India (CTRI/2025/04/085407), and received formal ethical clearance from the Institutional Ethical Committee (Approval No: 02/SL/IEC).

Subject Selection and Sample Size: Patients definitively diagnosed with colorectal carcinoma who were attending the IPD, and who were either deemed medically unfit for surgical intervention or were actively seeking supportive oncological care, were consecutively enrolled into the study. The required sample size was calculated utilizing standard statistical formulas for continuous variables, specifically $N=2C\sigma2/d2$ (where C=7.84 for a 95% Confidence Interval and 80% Power, with a standard deviation σ of 21.45, and an effect size d of 19). This calculation yielded a requirement of 19.8 subjects. Incorporating a standard 10% dropout consideration, the final sample size was established at 21 participants.

Inclusion Criteria: Diagnosed cases of colorectal carcinoma aged between 40 to 80 years, irrespective of gender, who provided fully informed written consent to participate in the 30-day intervention.

Exclusion Criteria: Patients exhibiting severe haematological compromise, defined as Haemoglobin (Hb) levels below 8 g/dl, or exceptionally advanced disease burdens indicated by Carcinoembryonic Antigen (CEA) levels exceeding 600 ng/ml.

Preparation of the Trial Drug (Shodhana of Shilajatu): Raw Shilajatu rock exudate was mechanically mixed with two parts of purified water and half a part of Triphala Kashaya. The mixture was continuously and vigorously stirred to fully dissolve the Shilajatu matrix, then exposed to intense direct sunlight for one Yama (approximately 3 hours) to facilitate solar thermal processing. The resulting solution was then meticulously filtered through a fine cotton cloth to extract physical impurities, environmental toxins, and heavy metal residues. The clean filtrate was subsequently dried to yield therapeutically purified Shilajatu.

Preparation of Varanadi Kwatha for Bhavana: A coarse botanical powder was prepared containing strictly equal parts of sixteen herbs: Varuna (Crataeva nurvala), Saireyaka (Barleria prionitis), Satavari (Asparagus racemosus), Dahana (Plumbago zeylanica), Morata (Marsdenia tenacissima), Bilwa (Aegle marmelos), Vishanika (Gymnema sylvestre), Brihathi (Solanum indicum), Kantakari (Solanum xanthocarpum), Karanja (Pongamia pinnata), Puthikaranja (Holoptelea integrifolia), Tarkari (Clerodendrum phlomidis), Haritaki (Terminalia chebula), Shigru (Moringa oleifera), Darbha (Desmostachya bipinnata), and Rujakara (Semecarpus anacardium). One part of this complex mixture was boiled in 8 parts of water and reduced via continuous heat to 1/8th of its original volume to form a highly concentrated Kashaya.

Bhavana Process: The purified Shilajatu resin was subjected to Bhavana (a specialized process of trituration and levigation) utilizing the concentrated Varanadi Kashaya. This levigation was repeated for seven consecutive iterations, significantly enhancing its cellular bioavailability and targeted therapeutic potency.

Administration: All 21 participants were administered 15 g of the finalized Varanadi Kwatha Bhavitha Shilajatu orally. The dosage was divided and given twice daily at precisely 6:00 AM and 6:00 PM, exactly one hour prior to meals, to ensure optimal absorption on an empty stomach. This solid dose was immediately accompanied by 90 ml of freshly prepared Varanadi Kwatha, which acted as the Anupana (liquid vehicle) to drive the medicine into the Srotas. The intervention protocol was maintained strictly for a continuous duration of 30 days.

Data Collection and Assessment Criteria: Primary and secondary clinical data were systematically collected via structured case proformas, routine clinical examinations, and specialized laboratory investigations. Primary Objective Parameter: Serum CEA values were quantitatively analyzed via blood draw on Day 0 (baseline) and Day 31 (post-intervention). Secondary Objective Parameters: Total White Blood Cell (TWBC) count, Erythrocyte Sedimentation Rate (ESR), Haemoglobin (Hb%) levels, and Faecal Occult Blood (FOB) presence were systematically analyzed on Day 1, Day 15, and Day 30 to track chronological progress. Subjective Parameter: The internationally validated EORTC QLQ-CR29 (Quality of Life Questionnaire for Colorectal Cancer) was administered via patient interview on Day 1, Day 15, and Day 30. This specific tool assesses symptom burden and functional well-being, where higher scores mathematically denote a higher and more severe symptom level.

Ethical Considerations: Fully informed, written consent was obtained from all study participants prior to enrolment, ensuring they understood the nature of the Ayurvedic intervention. Absolute confidentiality of the participants' medical data and personal identifiers was strictly maintained throughout the research process.

Statistical Analysis: Data extracted from the clinical trial were systematically recorded in a master chart and subjected to rigorous statistical evaluation. Continuous variables were summarized mathematically as mean ± standard deviation (SD) for normally distributed data, and as median with interquartile range (IQR) for non-parametric data distributions. Pre- and post-intervention numerical changes in CEA levels were analyzed utilizing the paired t-test. Outcomes measured across multiple chronological time points (Day 1, Day 15, Day 30) were evaluated using repeated measures ANOVA (specifically for ESR and Hb%) or the Friedman test (for non-parametric data like TWBC and QLQ-CR29 scores). Categorical status changes (such as positive/negative FOB) were assessed utilizing the Cochran's Q test, an extension of McNemar's chi-square. Statistical significance across all parameters was established strictly at a p-value < 0.05.

Results

Demographic and Clinical Profile: The demographic assessment of the 21 participants indicated a marked and distinct male predominance, comprising 71.43% of the study population compared to 28.57% females. The majority of the patients were aged between 51-60 years (33.33%), followed closely by the 61-70 years demographic bracket (28.57%), while 14.28% were 41-50 years old, and 23.80% were 71-80 years old. Socioeconomically, the cohort was predominantly middle class (52.38%) and low middle class (33.33%), with 14.28% from the upper middle class. Educational backgrounds were moderate across the group, with 33.33% holding undergraduate degrees, 9.52% holding postgraduate degrees, 14.28% holding a plus-two level, 28.57% having a 10th standard education, and 14.28% possessing below 10th standard education. Occupationally, a highly significant 47.62% of the subjects were engaged in entirely sedentary work, 38.10% were engaged in hard physical work, and 14.28% were involved in moderate work, highlighting sedentary behaviour as a major lifestyle risk factor associated with decreased colonic motility.

Dietary and lifestyle assessments revealed profound systemic disruptions. Exactly 100% of the participants suffered from clinically disturbed sleep patterns. A heavy, non-vegetarian diet was preferred by 52.38% of subjects, while 47.62% consumed a mixed diet. Furthermore, 61.90% reported a significantly reduced appetite (Agnimandya), and 80.95% complained of chronic improper digestion. Prakruthi analysis indicated a strong, underlying prevalence of Vatapitham (28.57%) and Vatakapham (19.05%) constitutions, followed by Kaphavatam (14.29%), Kaphapitham (9.52%), Pithakapham (9.52%), Pitha vatam (4.76%), Vata (4.76%), and Pitha kapham (4.76%), predisposing these individuals to tissue-level inflammatory and obstructive pathologies. Psychologically, the burden of the malignancy was heavy; a significant 57.14% exhibited clinical signs of depression, 19.05% experienced high anxiety, 9.52% experienced anger, and only 14.29% were categorized as normal or stable.

Gastrointestinal evaluations demonstrated severe and chronic bowel irregularities. Irregular bowel habits were reported by a massive 95.24% of the participants, with only 4.76% reporting regularity. Regarding daily frequency, 57.14% passed stools more than twice daily in a state of hypermotility, 28.57% were chronically constipated, 9.52% went once daily, and 4.76% went twice daily. Painful defecation was experienced by 52.38% of the cohort, while 47.62% had painless defecation. The visual presence of mucus (38.10%), blood (28.57%), or a pathogenic mixture of both blood and mucus (19.05%) was frequently observed upon clinical questioning, with only 14.29% reporting completely clear stools.

Effect on Carcinoembryonic Antigen (CEA): At the commencement of the clinical trial (Day 1), 66.67% of the participants exhibited pathologically elevated CEA levels (>5 ng/ml), signifying active and heavy disease burden. Following the strict 30-day intervention, 61.90% still maintained levels above 5 ng/ml, but the proportion of patients moving into the completely normal range (<5 ng/ml) increased from 33.33% to 38.10%. Rigorous statistical evaluation utilizing the paired t-test confirmed a significant overall reduction in the mean CEA levels from a baseline of 6.28 ± 2.11 ng/ml down to 5.92 ± 1.77 ng/ml. The resulting computational t-value of 2.994, with 20 degrees of freedom, yielded a p-value of 0.008, conclusively demonstrating that the intervention exerted a statistically significant positive effect on systemic tumour marker reduction.

Table 1: Statistical analysis of CEA levels

Assessment Point	N	Mean (ng/ml)	Std. Deviation	t-statistic	df	p-value
Day 1	21	6.28	2.11	2.994	20	0.008
Day 30	21	5.92	1.77			

Pre- and post-intervention statistical comparison of serum Carcinoembryonic Antigen (CEA) levels using a paired t-test, demonstrating a statistically significant reduction over 30 days.

Effect on Erythrocyte Sedimentation Rate (ESR)

Systemic inflammation, robustly measured via ESR, showed a highly favourable and rapid response to the Shilajatu formulation. On Day 1, a massive 80.95% of patients exhibited moderate elevation (41–100 mm/hr), 9.5% showed severe elevation (>100 mm/hr), and 9.5% showed mild elevation (20–40 mm/hr). By Day 15, the cohort shifted dramatically, with 47.61% dropping into the mild elevation category and 52.39% into moderate elevation. By the conclusion on Day 30, 80.95% of participants presented with only mild elevation, 14.28% had moderate elevation, and 4.76% achieved a completely normal ESR (<20 mm/hr). The mean

ESR plummeted heavily from 69.48 ± 25.48 mm/hr at baseline to 46.14 ± 19.59 mm/hr on Day 15, and 31.05 ± 12.97 mm/hr on Day 30, verified as highly statistically significant by Repeated Measures ANOVA ($F = 38.97$, $p < 0.001$).

Effect on Total White Blood Cell (TWBC) Count

At baseline, 52.39% of the study population exhibited mild leucocytosis (11,000–20,000 cells/µL), indicative of chronic systemic inflammatory or immune activation triggered by the malignancy, while 47.61% were in the normal range (4,000–11,000 cells/µL). By Day 15, normal counts were successfully achieved by 71.42% of participants, leaving only 28.57% with mild leucocytosis. Remarkably, by Day 30, 100% of the entire cohort demonstrated fully normalized TWBC levels. The non-parametric Friedman test confirmed this continuous cellular decline (from a high mean of 11,650 ± 2887.96 cells/µL on Day 1, to 9791.43 ± 1568.35 on Day 15, down to 8,560.95 ± 1035.42 cells/µL on Day 30) was statistically significant ($\chi^2 = 34.38$, $p < 0.001$).

Effect on Haemoglobin (Hb%)

Profound nutritional and haematological deficits are classic hallmarks of advanced colorectal carcinoma. At baseline, 52.39% of participants suffered from mild anaemia (10–12 g/dL), 4.76% experienced moderate anaemia (7–10 g/dL), and 42.85% possessed normal levels (>12 g/dL). The intervention facilitated a steady, progressive rise in mean Hb% from 11.89 ± 1.51 g/dL on Day 1, to 12.22 ± 1.23 g/dL on Day 15, reaching 12.65 ± 1.00 g/dL by Day 30. Repeated Measures ANOVA confirmed a highly significant improvement in blood parameters ($F = 19.12$, $p < 0.001$), resulting in a remarkable 66.66% of patients achieving normal, healthy haemoglobin levels by the study's conclusion, with only 33.33% remaining in the mild anaemia category.

Effect on Quality of Life (EORTC QLQ-CR29) & Faecal Occult Blood

The QLQ-CR29 questionnaire accurately measures total symptom burden and functional status, where a higher score reflects a poorer quality of life. The mean score systematically and rapidly reduced from 38.38 ± 7.41 (median 36) at baseline to 28.38 ± 4.74 (median 27) on Day 15, and settled at 25.33 ± 4.34 (median 25) on Day 30. The Friedman test demonstrated that this massive reduction in symptom severity was highly significant ($\chi^2 = 39.975$, $p < 0.001$), indicating robust and undeniable improvements in patient-reported functional outcomes.

Conversely, the clinical analysis of faecal occult blood (FOB) demonstrated an unexpected and contrary trajectory during the trial. On Day 1, 47.62% of participants tested positive for FOB while 52.38% were negative. This positivity rate progressively increased to 66.67% by Day 15 (33.33% negative) and culminated at a high of 85.71% by Day 30 (14.29% negative). Cochran's Q test ($Q = 10.67$, $p = 0.005$) indicated a statistically significant difference across the time points, confirming a progressive increase in gastrointestinal bleeding during the study period rather than resolution.

Discussion

The foundational rationale for formulating and clinically selecting Varanadi Kwatha Bhavitha Shilajatu lies in the critical, unmet need for an integrative approach to successfully manage the extensive disease burden, high recurrence rates, and severe treatment-associated morbidities of colorectal carcinoma. The demographic findings of this clinical trial strongly validate global epidemiological data, demonstrating that CRC predominantly afflicts individuals in their sixth and seventh decades of life, presenting heavily with a male predominance (71.43%). Notably, a massive 47.62% of the participants led entirely sedentary lifestyles. This is a known, critical risk factor contributing to severely reduced gastrointestinal motility, increased focal adiposity, and prolonged mucosal exposure to dietary carcinogens.

From an Ayurvedic paradigm, sedentary habits, irregular and disturbed sleep, and inappropriate diets (Apathya Ahara, primarily heavy meats) massively exacerbate Kapha dominance and instigate severe Agnimandya. This digestive failure subsequently generates toxic Ama, disturbing both Vata and Pitta, and manifesting structurally as the malignant mass known as Arbuda. The Prakruthi assessment revealed a high underlying incidence of Vatapitham (28.57%) and Vatakapham (19.05%) constitutions among the patients. Vata instability directly accounts for the observed chaotic bowel rhythms, severe pelvic pain, and tissue degeneration, while the Pitta association contributes heavily to mucosal inflammation and bleeding, and Kapha facilitates tumour induration and structural blockages. Furthermore, profound psychological distress was evident, with 57.14% of patients exhibiting clinical depression, heavily compromising their Manodoshas and overall physiological treatment resilience.

The primary objective parameter—Carcinoembryonic Antigen (CEA)—showed a statistically significant reduction ($p = 0.008$) following the 30-day intervention. While the absolute mean reduction (from 6.28 to 5.92 ng/ml) was numerically modest, the strict statistical significance highlights the formulation's inherent capability to modulate tumour marker expression and systemic disease activity. This effect is theoretically grounded in the aggressive Chedana (scraping and excision of pathological tissue) and Tridoshashamana actions of Shilajatu. The complex phytochemistry of Shilajatu, extraordinarily rich in humic substances, fulvic acids, and dibenzo-α-pyrones, is renowned in modern science for inducing oxidative stress-mediated apoptosis, suppressing epithelial-mesenchymal transition (EMT), and arresting cell cycles specifically in malignant cells.

The efficacy of raw Shilajatu was substantially amplified through the Bhavana process with Varanadi Kwatha. This specific decoction is a potent Kapha-Medohara agent, inherently designed by classical texts to resolve Srotodushti and dismantle solid pathological masses (Vidradhihara). Active constituents within the Kwatha, such as Varuna (Crataeva nurvala) and Shigru (Moringa oleifera), possess robust, heavily documented anticancer and anti-inflammatory properties. For instance, the compound plumbagin found in Dahana (Plumbago zeylanica) aggressively induces G1 phase cell cycle arrest and promotes apoptosis, while specific compounds in Shigru inhibit Epstein-Barr virus activation, showcasing distinct and targeted chemopreventive traits.

The intervention proved exceptionally successful in mitigating total systemic inflammation, evidenced by the highly significant reductions in both ESR ($p < 0.001$) and TWBC counts ($p < 0.001$). This reflects the formulation's profound, targeted ability to suppress pro-inflammatory cytokines, stabilize lysosomal membranes (attributable to the steroidal alkaloids present in Brihathi and Kantakari), and scavenge destructive free radicals, effectively breaking the deadly cycle of chronic inflammation that sustains and accelerates carcinogenesis. Moreover, the highly significant, steady increase in Haemoglobin levels ($p < 0.001$) confirms the

powerful Rasayana and Balya (strength-promoting) actions of Shilajatu and included herbs like Satavari (Asparagus racemosus), which successfully mitigated the cancer-induced cachexia and severe anaemia seen at baseline.

These combined, powerful physiological improvements translated directly into enhanced clinical well-being, as measured by the rigorous EORTC QLQ-CR29 questionnaire. The significant drop in patient symptom scores ($p < 0.001$) reflects the total restoration of Jatharagni, the normalization of the downward Apana Vayu, and the profound alleviation of debilitating constitutional symptoms such as severe fatigue and pain, proving the formulation's immense value as a palliative and supportive oncological therapy.

Despite these comprehensive systemic benefits, the formulation did not alleviate Faecal Occult Blood; rather, FOB positivity increased significantly ($p = 0.005$) over the 30 days. This contradictory finding indicates that while Varanadi Kwatha Bhavitha Shilajatu modulates widespread systemic inflammation and circulating tumour markers, its short-term efficacy is completely insufficient to arrest localized mucosal ulceration, tumour friability, or active gastrointestinal haemorrhaging driven by the physical presence of advanced colorectal tumours. The physical friability and necrosis of the malignancy likely require highly extended therapeutic durations, specialized localized treatments such as Piccha Basti, or rapid integration with modern surgical and endoscopic haemostatic interventions to prevent dangerous blood loss.

Conclusion

The clinical trial establishes conclusively that the internal administration of fifteen grams of Varanadi Kwatha Bhavitha Shilajatu, accompanied by ninety millilitres of Varanadi Kwatha acting as an Anupana, delivers substantial and measurable therapeutic benefits to patients suffering from colorectal carcinoma. Over the concise thirty-day intervention period, the formulation facilitated a statistically significant reduction in serum Carcinoembryonic Antigen (CEA) levels, Erythrocyte Sedimentation Rate, and Total White Blood Cell counts. Simultaneously, it achieved highly significant, progressive improvements in systemic Haemoglobin levels and patient-reported quality of life, effectively alleviating profound symptom burdens that severely impact daily functioning. While the therapy did not demonstrate any efficacy in arresting localized faecal occult blood within this short timeframe, the profound systemic, anti-inflammatory, and Rasayana outcomes affirm its role as a safe, highly relevant, and incredibly valuable adjuvant in supportive oncological care. This intervention effectively addresses the Agnimandya and Srotodushti underlying the core pathogenesis of Arbuda, restoring physiological balance and mitigating the toxicities commonly associated with advanced malignancies. By heavily leveraging the Chedana properties of Shilajatu alongside the Kapha-Medohara actions of Varanadi Kwatha, this integrative protocol significantly enhances total patient resilience. To definitively establish its long-term survival impacts, optimal dosage scaling, and safe integration into standard oncology protocols, further multicentre, randomized controlled trials with highly extended follow-up durations are strongly recommended. This study provides a vital, foundational evidence base supporting the use of traditional Ayurvedic formulations in contemporary cancer management.

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Conflict of Interest

None declared.

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