

Role of *Basti*, *Nasya* and allied therapies for improving quality of life in oral cavity cancer patients post conventional treatment

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Oral cavity cancer (OCC) and its conventional treatments, especially radiotherapy, often lead to side effects that impair oral intake, nutrition, and immune function, resulting in significant patient debility. These complications necessitate supportive interventions to mitigate adverse effects and improve quality of life (QoL). Previous studies suggest that *Shamana Chikitsa* (palliative-oral Ayurvedic medicines) and *Panchakarma Chikitsa* (PNK—detoxifying therapies), described in the *Shashti Upakrama* (sixty therapeutic measures for wound care), can help reduce radiotherapy-induced side effects. Based on these findings the present study was designed to assess the efficacy of *Basti*, *Nasya*, and allied procedures on symptoms of oral cavity cancers, side effects of radiotherapy and improve the quality of life of post radiotherapy OCC patients.

This double-armed, open-label, single-centre, prospective randomized clinical study evaluated 70 OCC patients post-radiotherapy. The intervention group (n=35) received PNK treatments—*Basti* (therapeutic enema), *Nasya* (medication through nasal route), and allied procedures such as *Gandusha* (holding of medicated liquid in mouth), *Mukhopratisarana* (application of medicated paste or powders in oral cavity), *Shirodhara* (therapeutic streaming over the head), and *Karnapurana* (filling of ear with medicated liquid)—for 7 days along with *Shamana Chikitsa*. The control group (n=35) received only *Shamana Chikitsa* for 1 year. Outcomes were assessed on Day 7 and Day 30 using OCC symptom scores, radiotherapy side effects, QoL questionnaires (QLQ-C30 and QLQ-H&N35), and the Karnofsky Performance Scale. The intervention group demonstrated markedly greater percentage improvement compared with the control group in stomatitis (58.7% vs 8.7% at D7; 71.74% vs 30.43% at D30), xerostomia (34.38% vs 5.41% at D7; 68.75% vs 29.73% at D30), dysphagia (46.15% vs 4.76% at D7; 50.0% vs 11.90% at D30), and pain (41.82% vs 5.17% at D7; 63.64% vs 17.24% at D30), indicating superior clinical improvement in the intervention group. Along with notable QoL improvements. This study concludes that *Basti*, *Nasya* and allied therapies significantly alleviate symptoms and side effects of conventional treatment in OCC patients and enhance overall well-being and quality of life.

Keywords: *Basti*, Conventional treatment, *Mukharoga*, *Nasya*, Oral cavity cancer, Quality of life

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Oral cavity cancers (OCCs) affect various sites within the oral cavity and oropharynx and rank among the top 10 most common cancers globally¹. Despite advancements in research and therapy, survival rates have not significantly improved, posing a persistent challenge². According to GLOBOCAN 2020, OCCs are the second most common cancer in India³, with higher prevalence among men and low-income groups due to habits like tobacco chewing⁴. Squamous cell carcinoma (SCC) is the most common histological type of OCC⁵. Limited awareness of screening leads to delayed diagnosis, contributing to high mortality

rates. The global 5-year survival rate for OCC patients is approximately 50-60%⁶.

Surgery is the primary treatment for OCCs, often followed by radiotherapy or chemoradiotherapy⁷. Both the disease and its conventional treatments can cause side effects that impact aesthetics and function, leading to difficulties in eating, malnutrition, and immune suppression, resulting in patient debility⁸. Common symptoms of OCC include tumors, ulcerative lesions, stomatitis, trismus, sticky saliva, foul breath, loss of taste, anorexia, dysphagia, and weight loss. Radiotherapy and chemotherapy can cause similar side effects, such as stomatitis, xerostomia, trismus, loss of taste, sticky salivation,

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nausea, fever, and debility⁹. Despite advances in diagnosis and treatment, survival rates and recovery outcomes remain limited, significantly affecting patients' quality of life¹⁰.

Acharya Sushrut described 65 *Mukharogas* (oral cavity diseases) affecting seven sites: *Oshtha* (lips), *Dantamula* (gums), *Danta* (teeth), *Jivha* (tongue), *Talu* (palate), *Gala* (throat), and *Galadi* (entire oral cavity)¹¹. Of these, 13 *Mukharoga* share similarities with the symptoms of oral cavity cancers and the side effects of radiotherapy. Acharya Sushrut also detailed *Shashti Upakarma* (sixty therapeutic procedures) for managing *Vranashotha* (wound inflammation)¹². Many *Mukharoga* involve *Shotha* (inflammation) or *Vrana* (wounds) in their pathogenesis. Treatments include therapies like *Nasya* (medication through nasal route), *Dhoopana* (fumigation), *Pratisarana* (application of medicated paste or powders in oral cavity), *Kavala-Gandusha* (gargling), *Lepa* (anointment), and *Sweda* (sudation), along with *Shodhana* (detoxification) and *Shastra Karma* (surgical procedures).

At our center, a pilot study¹³ was conducted involving 40 patients with oral cavity cancer who had completed standard conventional treatment. These patients received a 7-day intervention consisting of *Panchakarma*, including *Basti* (therapeutic enema)¹⁴, *Nasya*¹⁵ as well as adjunct therapies such as *Gandusha*, *Mukha Pratisarana*¹², *Shirodhara* (therapeutic streaming over the head), and *Karnapurana* (filling of ear with medicated liquid)¹⁶. Clinical assessments were performed before and after the intervention, focusing on radiotherapy-induced adverse effects, KPS, and quality of life using the EORTC QLQ-C30 and QLQ-H&N35 questionnaires. The results demonstrated statistically significant improvements in pain and stomatitis ($p < 0.0001$), as well as in dysphagia and trismus ($p < 0.05$). Additionally, there was a significant enhancement in functional scores ($p < 0.05$) and a reduction in symptom scores ($p < 0.05$). These findings suggest the potential efficacy of *Basti* and associated procedures in alleviating long-term radiotherapy-related side effects associated with vitiated *Vata* and *Pittadosha* (pain and inflammatory conditions). This demonstrated that Ayurvedic treatments significantly alleviate symptoms and reduce side effects of conventional therapies, thereby improving patients' quality of life. Based on these observations, a present randomized clinical trial was conducted to assess the efficacy of *Basti*, *Nasya*, *Gandusha*,

Mukhopratisarana, *Shirodhara*, and *Karnapurana* in OCC patients.

Materials and Methods

Study design

This was an open-label, double-arm, randomized clinical trial designed to assess the efficacy of oral Ayurvedic medicine (OAM) and PNK in OCC patients. Patients attended the Oncology Out-patient department at our center from 2015 to 2019 were screened based on predefined inclusion and exclusion criteria. Informed consent of patients was taken before enrollment in the study. Patient selection in both groups was done on the basis of stage, grade, conventional treatment, and willingness to participate. The duration of the study was one year. The study was commenced after approval by Institutional Ethics Committee (IEC) meeting held at Aug 2006. All eligible and consenting patients were questioned regarding demographic data, medical history, present illness history, conventional treatment details etc. in specially designed case record form.

Inclusion and exclusion criteria

OCC patients aged between 20 to 85 years, irrespective of gender, grade I to III, stage I to IV with SCC type who had undergone conventional treatment like surgery and/ or radiotherapy and/ or radiotherapy along with concurrent chemotherapy, having long-terms side effects of radiotherapy like xerostomia, dysphagia, stomatitis, foul smelling, trismus, excessive salivation, debility and pain were included in the study while the patients above 85 years, other than SCC type, and having acute illness like fever, diarrhea were excluded from the study. Patients with comorbidities were evaluated with baseline (hematological and biochemical) investigations at enrolment and found to be on regular medications, with all parameters within normal limits.

Sample size

The sample size was calculated using a standard formula based on established statistical principles. A total of 200 patients were screened for eligibility. Among them, 90 patients met the inclusion criteria. However, 20 eligible patients were excluded prior to the commencement of the trial due to unavoidable reasons (Fig. 1). Subsequently, randomization was performed using the lottery method. Each eligible patient was assigned a unique number on a separate slip of paper, placed in sequentially numbered, sealed,

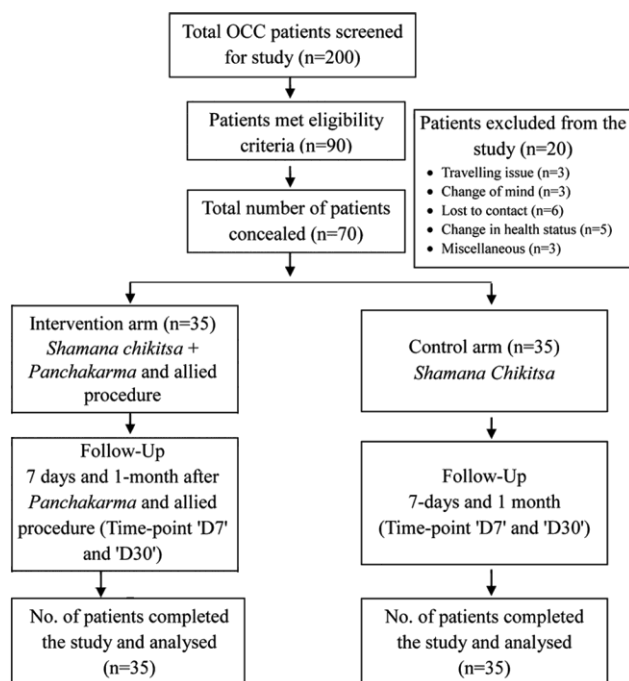


Fig. 1 — Timeline of health events

opaque envelopes. These envelopes were placed in a container and thoroughly mixed. At the time of enrolment, each patient drew a sealed envelope from the container arranged sequentially, which was opened only after the patient had been enrolled, thereby ensuring concealment of allocation until assignment. This process continued until the required sample size was reached. In this manner, 70 patients were randomly allocated into two arms—intervention and control—and completed the study (Fig. 1).

Treatment groups

The OCC patients who had completed conventional treatment were grouped into two groups viz., Intervention arm ($n=35$ patients) were treated with 7 days of *Basti*, *Nasya*, *Gandusha*, *Mukhapratisarana*, *Shirodhara*, and *Karnapurana* along with *Shamana Chikitsa* and Control arm ($n=35$ patients) were treated with only *Shamana Chikitsa* i.e., without PNK and allied therapies.

Intervention

The finished products needed for the intervention were obtained from Atharva Nature Healthcare Pvt. Ltd, Wagholi, Pune; an FDA-approved and GMP-certified Ayurvedic manufacturing company.

Matra Basti and allied procedure

The patients in the intervention arm, who received *Basti*, *Nasya* and allied treatments, were admitted to

the in-patient department of our center for a 7-day period. Before treatment began, routine blood investigations were conducted to rule out any underlying acute illnesses.

Following this, the patients underwent pre-procedural treatments, including *Snehana* (therapeutic oleation) and *Swedana* (Sudation), which were followed by allied procedures such as *Karnapurana*, *Shirodhara*, *Nasya*, *Gandusha*, *Mukha pratisarana* and *Matra Basti*. A detail of medicines used for PNK and allied procedures are given in (Table 1).

Before starting the pre-procedural treatments, patients were advised to consume their usual food in a slightly reduced quantity (about one-fourth less than normal) and to drink a glass of water (~100 mL). After eating, patients were encouraged to walk for a 10 min, followed by the elimination of feces and urine (if necessary).

Snehana and Swedana: As part of the pre-procedural treatment, the patient underwent *Snehana* (oleation therapy). This was performed on the entire body using lukewarm *Balataila* (50 mL), applied with synchronized strokes in the same direction for 30 min. After that, whole body *Swedana* was performed with steam of *Dashamoola* coarse powder decoction for 10 min.

Karnapurana: During *Snehana* procedure, simultaneously 2 mL of lukewarm *Atharva Dashamoola Taila* was instilled into the ear while the patient lay in a lateral position. The oil was retained for 5 min. If it was performed in the right ear, the patient was positioned in the left lateral position, and vice versa.

Shirodhara: The patient lay in a supine position on the *Shirodhara* table with a small towel or pillow supporting the neck. The *Shirodhara* pot was positioned approximately 10 cm above the forehead to allow a steady stream of lukewarm *Atharva Jatamansi Taila* (500 mL per session) to flow directly onto the center of the forehead for 10 min. The oil was poured in a continuous stream, with the pot gently moved side to side to ensure coverage of the entire forehead. The patient was instructed to relax and enjoy the soothing effect during the procedure. Patients were also instructed to avoid exposure to wind, sunlight, chilled or heavy foods, and daily head baths during the treatment period.

Nasya: The patient was then positioned in the supine position with a thin pillow under the neck. Four drops (0.05 mL) of lukewarm *Atharva Yashtimadhu Taila* were instilled into each nostril.

Table 1 — Details of the Panchakarma and allied procedure protocol sequentially used in OCC patients

Sr. No.	Procedure	Drug administered	Ingredients	Dose	Duration of procedure	Probable mode of action
1.	<i>Sarvang</i> <i>Snehana</i> (full body massage)	<i>BalaTaila</i>	<i>Bala</i> (<i>Sida cordifolia</i>), <i>Chandan</i> (<i>Santalum alba</i>), <i>Shaileyaka</i> (<i>Parmelia perlata</i>), <i>Shatavari</i> (<i>Asparagus racemosus</i>), <i>Punarnava</i> (<i>Boerhavia diffusa</i>) <i>Tilataila</i> (Sesame oil)	50 mL	30 min	<i>Snehana</i> helps to loosens <i>doshas</i> so that to eliminate easily from body, prevents dryness, gives soothing effect ³⁸ .
2.	<i>Karnapurana</i> (administering warm oil in ear)	<i>Atharva Dashmoola Taila</i>	<i>Bruhat Panchamoola*</i> <i>Laghu Panchamoola**</i> <i>Tilataila</i> (sesame oil)	2 mL/ ear	5 min	Pacifies <i>Vatadosha</i> , Relieves neck stiffness ⁴⁷ .
3.	<i>Sarvang</i> <i>Swedana</i> (sudation)	<i>Dashmoola</i> coarse powder	<i>Bruhat Panchamoola*</i> <i>Laghu Panchamoola**</i>	--	10 min	Penetrates microcirculatory channels, increasing the permeability of capillary and bringing the morbidities into an extracellular fluid by dilating and clearing the channels of the body ⁴⁰ .
4.	<i>Shirodhara</i> (special head anointing treatment with oil)	<i>Atharva Jatamansi Taila</i>	<i>Jatamansi</i> (<i>Nardostachys jatamansi</i>) <i>Tilataila</i> (sesame oil)	500 mL/ session	10 min	Possess <i>Medhya</i> , <i>Balya</i> , <i>tridoshahara</i> qualities and showed mind relaxation effect in breast cancer patients ⁴⁸ .
5.	<i>Nasya</i> (instillation of medicines in nostrils)	<i>Atharva Yashtimadhu Taila</i>	<i>Yashtimadhu</i> (<i>Glycyrrhiza glabra</i>) <i>Tilataila</i> (sesame oil)	4 drops/ nostril (~0.2 mL)	5 min	Sense organs become clean. Mouth emits good smell, bestows strength to the Supraclavicular organs ⁴⁵ .
6.	<i>Gandusha</i> (gargling with medicated decoction)	<i>Atharva Gandush Churna</i>	<i>Haritaki</i> (<i>Terminalia chebula</i>), <i>Bibhitaki</i> (<i>Terminalia bellirica</i>), <i>Amalaki</i> (<i>Phyllanthus emblica</i>), <i>Haridra</i> (<i>Curcuma longa</i>)	200 mL (40 mL/ aliquot)	5 min	Anti-microbial activity, keeps oral hygiene ⁴⁸ .
7.	<i>MukhaPratisarana</i> (oral application)	<i>Atharva Yashtimadhu Ghruta</i>	<i>Yashtimadhu</i> (<i>Glycyrrhiza glabra</i>) <i>Goghrita</i> (cow's ghee)	10 mL	5 min	Reduces inflammatory conditions (like stomatitis) ³⁴ .
8.	<i>Matra Basti</i> (medicated oil enema)	<i>Atharva Dashmoola Taila</i>	<i>Bruhat Panchamoola*</i> <i>Laghu Panchamoola**</i> <i>Tilataila</i> (sesame oil)	50 mL	10 min	Regulates the <i>Vatadosha</i> of the body Strengthens colon and easily eliminates toxins through fecal matter ⁴¹ .

**Bruhat Panchamoola*- *Bilva* (*Aegle marmelos*), *Agnimantha* (*Premna integrifolia*), *Shyonaka* (*Oroxylum indicum*), *Patala* (*Stereospermum suaveolens*), *Gambhari* (*Gmelina arborea*),

***Laghu Panchamoola*- *Prishniparni* (*Uraria picta*), *Shalaparni* (*Desmodium gangeticum*), *Brihati* (*Solanum indicum*), *Kantakari* (*Solanum xanthocarpum*), and *Gokshura* (*Tribulus terrestris*)

After instillation, the patient remained lying down for 2 min. If sputum or the medicine was expelled, the patient was instructed to spit it out.

Gandusha: A 200 mL medicated decoction of *Atharva Gandush Churna* was asked to hold in the mouth for 30 sec in 40 mL aliquots and then spit out.

Mukha Pratisarana—After *Gandusha*, the patient was made to sit comfortably in an upright position

and 10 mL of lukewarm *Atharva Yashtimadhu Ghruta* was gently applied in the oral cavity with a gloved finger. The patient was instructed to retain the *Ghruta* in the oral cavity as long as patient could retain it.

Matra Basti: After that, patient was instructed to lie on their left lateral position on a comfortable bed, after which 50 mL of *Atharva Dashmoola Taila* was administered. Following the administration of the

enema, a gentle massage was given to the buttock region, and the patient was allowed to rest in a supine position with the head lowered for 15 min. The oil enema may either be eliminated after approximately 9 h or absorbed completely by the body. Once the patient feels hungry, she was allowed to consume light, easily digestible food like Khichdi, or Vegetable soup.

In both the groups, the *Shamana Chikitsa* comprised of *Atharva Vasadi Vati* 750 mg (after lunch and dinner with water), *Mouktikyukta Kamdudha*¹⁷ 250 mg (after morning and evening breakfast with cow's milk), *Atharva Yashtimadhu Ghruta* 5 mg (after lunch and dinner with warm water), *Atharva Sukshma Triphala Vati* 500 mg (after lunch and dinner with warm water) and *Triphala Guggulu*¹⁸ 500 mg (after lunch and dinner with warm water). The duration of *Shamana Chikitsa* is for one year.

Time points for assessment

In both the arms, the assessment was done at three time-points, i.e., time point 'D0' corresponded before starting, time point 'D7' after the completion i.e., 7th day, and time point 'D30' to one month after the completion of the treatment in the form of PNK and allied procedures w.r.t intervention group.

Assessment criteria

Symptoms of oral cavity cancers and side-effects of radiotherapy

The scoring of the symptoms of oral cavity cancers and side-effects of radiotherapy like stomatitis, trismus, xerostomia, excessive salivation, dysphagia, foul smell of the mouth, debility, and pain was done on the basis of Common Terminology Criteria for Adverse Events (CTCAE) version 4.03¹⁹.

Quality of life (QoL) assessed by QLQ-C30 and QLQ H & N 35

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) was used to collect patient-reported outcomes by patient's perspective. This 30-item questionnaire measures the Quality of Life (QoL) of cancer patients through functional, symptom, and global scores. Functional scores (daily activities) are calculated from questions 1–7 and 20–27, symptom scores (symptomatology) from questions 8–19 and 28, and global health/QoL scores (overall health and quality of life) from questions 29 and 30. Additionally, the QLQ-H & N35 module, designed for head and neck cancer patients across

various stages and treatments, assesses symptoms, treatment side effects, social function, and body image/sexuality through 35 questions.

Well-being assessment by Karnofsky performance status scale

The Karnofsky Performance Status Scale (KPS) is an assessment tool between 0 to 100 score for functional impairment where in a '0' score means a fatal condition and '100' indicate healthy status. In most serious illnesses, the lower the KPS, the worse the likelihood of survival²⁰.

Statistical analysis

The data collected during the study were tabulated in MS Excel 2019 and presented as Mean $\pm$ SE. For intergroup analysis, the means of both groups at time points 'D7' and 'D30' were compared using the unpaired t test. Intra-group analysis was conducted by comparing the mean values at time points 'D7' and 'D30' with those at time point 'D0' using the paired t-test. A p-value of <0.05 was considered statistically significant.

Results

Distribution of patients

The distribution of cancer sites was almost equal in both the intervention and control arms. In the present study, the maximum number of patients belong to 51–60 years of age (intervention -49%, control-29%), of stage III (intervention - 34%, control-43%) and grade II (intervention -69%, control-57%). Majority of patients had buccal mucosa cancer (Both had 31%) followed by tongue cancer (intervention - 23%, control- 9%). Majority of patients had undergone surgery followed by radiotherapy or radiotherapy alone. The details are mentioned in (Table 2). There were no dropouts/ deaths during the period of study.

Effect of PNK and OAM on the symptoms of OCC and side-effects of radiotherapy

The efficacy of PNK and OAM on the symptoms of OCC and side effects of radiotherapy was measured by comparing both the arms at D7 and D30 time points. The results showed the statistically significant improvement in stomatitis (58.7% vs 8.7%, p=0.002 at D7; 71.74% vs 30.43%, p=0.003 at D30), xerostomia (34.38% vs 5.41%, p=0.02 at D7; 68.75% vs 29.73%, p<0.001 at D30), dysphagia (46.15% vs 4.76%, p<0.001 at D7; 50.0% vs 11.90%, p=0.001 at D30), and pain (41.82% vs 5.17%, p=0.002 at D7; 63.64% vs 17.24%, p=0.001 at D30),

Table 2 — Interpreting the demographic and clinico-pathological data of both the arms

Parameters		Number of patients (%)	
		Intervention	Control
Age (in years)	21-30	0	01 (2.86)
	31-40	04 (11.43)	05 (14.29)
	41-50	11 (31.43)	06 (17.14)
	51-60	13 (37.14)	10 (28.57)
	61-70	04 (11.42)	07 (20)
	71-80	03 (8.57)	03 (8.57)
	81-90	0	03 (8.57)
Stage	I	06 (17.14)	03 (8.57)
	II	06 (17.14)	06 (17.14)
	III	12 (34.29)	15 (42.86)
	IV	11 (31.43)	11 (31.43)
Grade	I	08 (22.86)	07 (20)
	II	24 (68.57)	20 (57.14)
	III	03 (8.57)	08 (22.86)
Treatment received	SU	02 (5.71)	05 (14.29)
	CT	0	01 (2.86)
	RT	15 (42.86)	10 (28.57)
	SU+ RT	17 (48.57)	15 (42.86)
Site of cancer	CT+ RT	0	02 (5.71)
	SU+ CT+ RT	01 (2.86)	02 (5.71)
	Alveolus	02 (5.71)	01 (2.86)
	Buccal Mucosa	11 (31.43)	11 (31.43)
	Cheek	0	01 (2.86)
	Epiglottis	0	02 (5.71)
	Hypopharynx	01 (2.86)	0
	Larynx	03 (8.57)	03 (8.57)
	Lip	01 (2.86)	01 (2.86)
	Mandible	01 (2.86)	0
	Maxilla	0	01 (2.86)
	Oropharynx	01 (2.86)	01 (2.86)
	Post Cricoid	02 (5.71)	01 (2.86)
	Pyriform Fossa	02 (5.71)	0
	Retro molar	01 (2.86)	01 (2.86)
	Trigone		
	Supra glottis	0	01 (2.86)
	Tongue	08 (22.86)	03 (8.57)
	Vocal Cord	02 (5.71)	03 (8.57)

SU: Surgery; CT: Chemotherapy; RT: Radiotherapy

at both the time points. While, trismus and excessive salivation showed improvement but were not statistically significant (Fig. 2 a, b).

Efficacy of PNK and OAM on the improvement of quality of life of OCC patients by health scores

The effect of PNK and OAM on patients' quality of life was evaluated by using EORTC QLQ C-30 and QLQ H&N35 questionnaire at D7 and D30 time points, the intervention arm showed a statistically significant improvement in the functional score (7.05% vs 6.48%, $p=0.03$ at D7, 10.53% vs 8.85%, $p=0.01$ at D30) and a significant improvement in the global score (10.15% vs 8.07%, $p=0.004$ at D7, 17.29% vs 14.35%, $p=0.002$ at D30). The symptom scores significantly decreased at

both time points (23.05% vs 13.82%, $p=0.008$ at D7, 46.91% vs 18.16%, $p=0.001$ at D30). Additionally, the Head and Neck symptom score decreased at both time points, with a significant reduction observed at time point 'c' (Fig. 3).

Treatment response was assessed on the basis of increase, decrease or stable KPS of oral cavity cancer patients at time point 'D7' and 'D30' as compared to time point 'D0' (Fig. 3).

The KPS score showed an improvement in 69% and 83% of intervention arm patients at the respective time points, while it remained stable in 31% and 17% of patients. In contrast, the KPS score in the control arm increased in 23% and 49% of patients at the same time points, while remaining stable in 71% and 34% of patients. Additionally, the KPS score decreased in 6% and 17% of control patients at both time points.

Immediate and long-term effect of the PNK and OAM on the OCC patients

The immediate and the long-term effect of the PNK along with OAM on the OCC patients was measured by comparing D0 with the D7 and D30 time points in the both the arms.

In the intervention arm, a significant improvement was observed in all 14 parameters namely KPS, quality of life scores, reflecting enhanced functional ability of patients both immediately after treatment and at the 1-month follow-up. Additionally, a significant reduction in symptom scores and significant improvement in the aforementioned symptoms were noted at both time points (D7 and D30). In contrast, in the control arm, significant decrease was observed in only 4 out of the 14 parameters at D7, namely body weight, symptom scores of QLQ C-30 and QLQ H&N 35, and debility. By D30, significant improvements in 8 out of the 14 parameters were noted in the control arm, including symptom scores of QLQ C-30 and QLQ H&N 35, stomatitis, trismus, xerostomia, foul smell of the mouth, debility, and pain (Table 3).

Discussion

An integrative approach to managing chronic illnesses such as cancer involves the combination of conventional treatments with evidence-based complementary therapies aimed at disease prevention and health optimization. The prevalence of complementary medicine use among cancer patients has been reported to range from approximately 40% to 84% across various studies²¹.

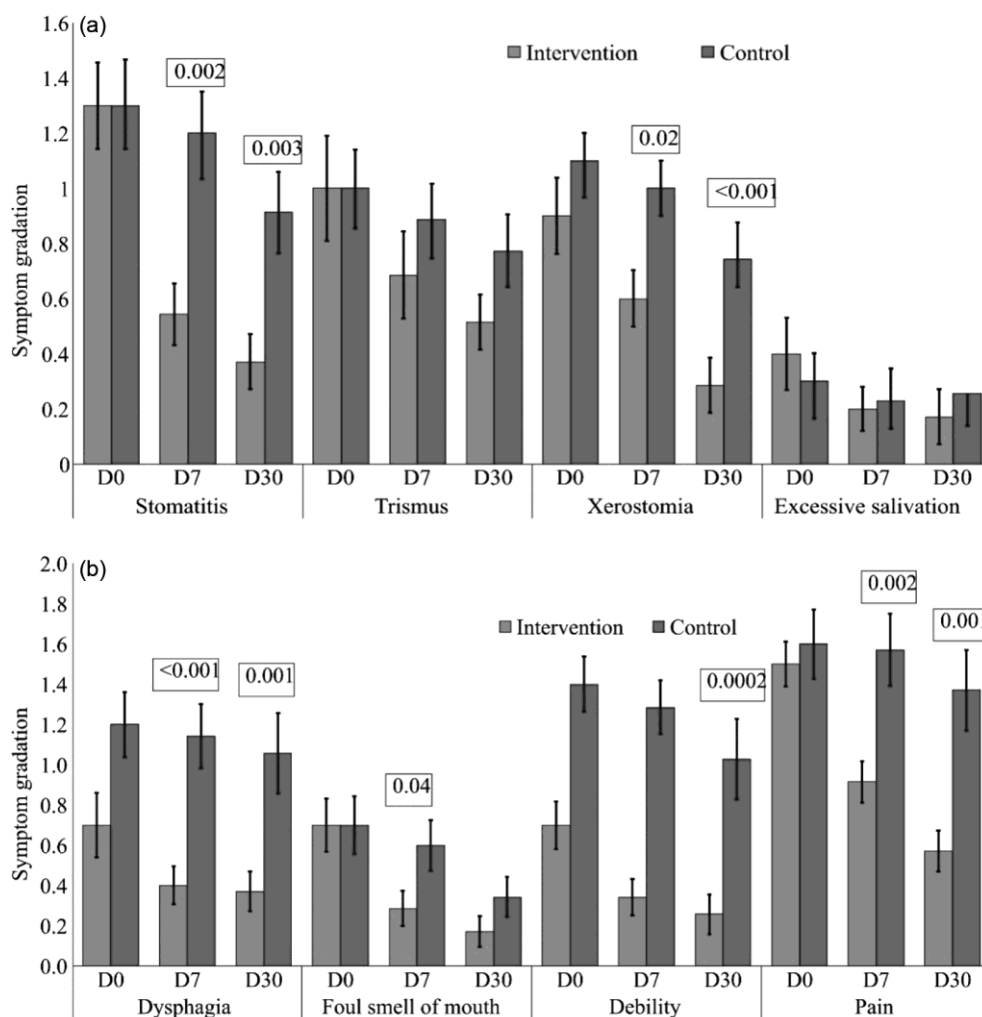


Fig. 2 — Comparative analysis of both the arms at time point 'D7' and time point 'D30' for symptoms, (a) Stomatitis, Trismus, Xerostomia, Excessive Salivation, (b) Dysphagia, Foul Smell of Mouth, Debility and Pain. The difference of mean was compared by Unpaired t test

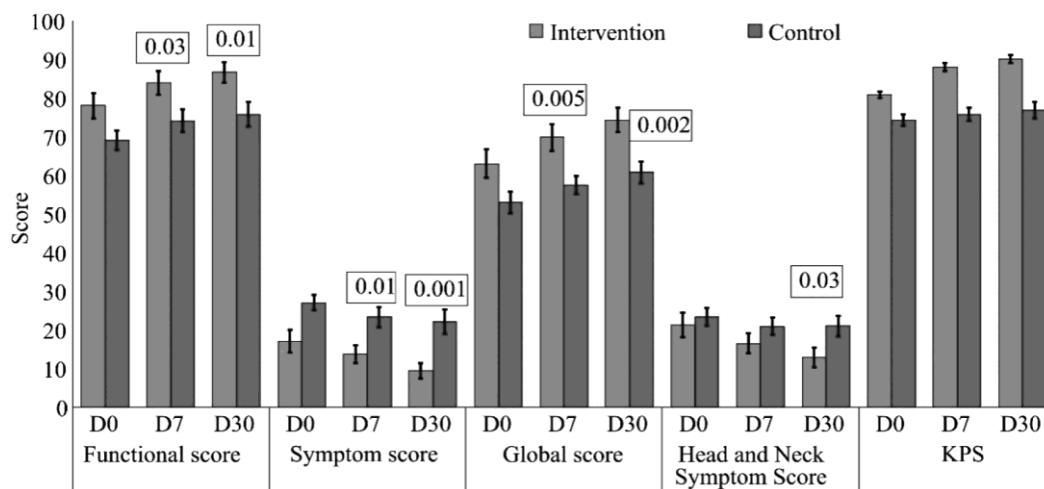


Fig. 3 — Analysis of quality of life scores of both the arms at time points 'D7' and 'D30'. Functional, Symptoms, and Global scores of QLQ-C 30, Head & Neck symptom score of QLQ-H&N 35 and Karnofsky Performance Score (KPS). The difference of mean was calculated by unpaired t test

Table 3 — Efficacy of Panchakarma along with OAM in OCC patients in both the groups after completion of treatment and 1-month after completion of treatment with respect to 'D0'

Parameters	Intervention (Mean±SE)					Control (Mean±SE)				
	D0	D7	MD (p value)	D30	MD (p value)	D0	D7	MD (p value)	D30	MD (p value)
1. Karnofsky Performance score	80.9±0.9	88.0±1.1	7.1 (0.00)	90.0±1.0	9.1 (0.00)	74.3±1.4	75.7±1.7	1.43 (0.1)	76.9±2.1	2.57 (0.07)
2. Body weight	61.6±1.8	61±1.7	0.6 (0.001)	61.1±1.7	0.5 (0.01)	58.2±2.3	58±2.4	0.17 (0.05)	57.8±2.4	0.4 (0.1)
3. Functional score of QLQ C-30	78.3±3.3	83.9±3.1	5.5 (0.00)	86.6±2.6	8.3 (0.00)	72.7±2.5	74.1±3.0	1.40 (0.5)	75.7±3.2	3.05 (0.19)
4. Symptom score of QLQ C-30	17.8±2.9	13.7±2.3	4.1 (0.002)	9.5±2.0	8.4 (0.00)	27.3±2.0	23.3±2.7	4.03 (0.04)	22.1±3.2	5.20 (0.05)
5. Global score of QLQ C-30	63.3±3.6	69.8±3.5	6.4 (0.00)	74.3±3.2	11 (0.00)	57.2±2.8	57.4±2.4	0.14 (0.95)	60.7±2.8	3.48 (0.17)
6. QLQ H&N35	21±3.2	16±2.6	4.8 (0.00)	13±2.6	8.5 (0.00)	23±2.3	21±2.2	2.45 (0.00)	21±2.6	2.59 (0.003)
7. Stomatitis	1.3±0.2	0.5±0.1	0.8 (0.00)	0.4±0.1	0.9 (0.00)	1.3±0.2	1.2±0.2	0.11 (0.1)	0.9±0.1	0.4 (0.00)
8. Trismus	1.0±0.2	0.7±0.2	0.3 (0.0002)	0.5±0.1	0.5 (0.00)	1.0±0.1	0.9±0.1	0.09 (0.08)	0.8±0.1	0.20 (0.01)
9. Xerostomia	0.9±0.1	0.6±0.1	0.3 (0.00)	0.3±0.1	0.6 (0.00)	1.1±0.1	1.0±0.1	0.06 (0.16)	0.7±0.1	0.31 (0.00)
10. Excessive salivation	0.4±0.1	0.2±0.1	0.2 (0.01)	0.2±0.1	0.2 (0.003)	0.3±0.1	0.2±0.1	0.09 (0.08)	0.3±0.1	0.49 (0.06)
11. Dysphagia	0.7±0.2	0.4±0.1	0.3 (0.0002)	0.37±0.1	0.4 (0.00)	1.2±0.2	1.1±0.2	0.06 (0.32)	1.1±0.2	0.14 (0.06)
12. Foul smell of mouth	0.7±0.1	0.3±0.1	0.5 (0.00)	0.2±0.1	0.6 (0.00)	0.7±0.1	0.6±0.1	0.06 (0.16)	0.3±0.1	0.31 (0.00)
13. Debility	0.7±0.1	0.3±0.1	0.4 (0.00)	0.3±0.1	0.5 (0.00)	1.4±0.1	1.3±0.1	0.11 (0.04)	1.0±0.2	0.37 (0.003)
14. Pain	1.6±0.1	0.9±0.1	0.7 (0.00)	0.6±0.1	1 (0.00)	1.7±0.2	1.6±0.2	0.09 (0.18)	1.4±0.2	0.29 (0.01)

MD: Mean Difference, Data presented in Mean±SE, the difference in mean at time point D7 and D30 is compared to D0 by Paired t test.

Oral cavity cancer, itself as a disease as well as its conventional treatments has known side effects which mainly interfere with oral intake of food, nutrition, and immune system leading to the debility of the patient⁸. A lot of resemblances are found between the symptoms of OCC and side effects due to conventional treatment in OCC patients and the symptoms of *Mukharoga* (oral cavity disease) as mentioned in Ayurvedic classics. Symptoms like *Mukhadaha*²² (burning sensation in mouth), *Krichhen Vivrinoti Mukham*²² (difficulty in opening the mouth), *Tikshna Asaha*²² (intolerance to spicy food), *Mukhashosha*²³ (dryness of mouth), *Arasadnyayata*²³ (improper gustatory sensation), *Mukhantargata Vrana*²² (mouth ulcer), etc. can be found.

Ayurvedic pathogenesis attributes stomatitis to increased *Pittadosha* and vitiation of *Raktadhatu* (blood tissue). Conditions like *Sarvasara*¹¹ and *Talupaka*¹⁰ resemble radiotherapy-induced stomatitis. Trismus, caused by tumors near temporo-mandibular joint or radiotherapy adverse effects, is a *Vata*-dominant condition correlating with *Hanugraha*²⁴, treated with *Snigdha Chikitsa* (unctuous therapies)¹². Xerostomia, can be described as *Talushosha*¹¹, which is a *Vata-Pitta* dominant condition, often occurs post-radiotherapy. Excessive salivation (*Mukhasrava*) in OCC, seen as *Kapha*-dominant *Mukharoga*²³, is

managed with *Kapha*-reducing therapies like *Gandusha*²².

In Ayurveda, dysphagia is described as *Annajalavirodhi* (obstructing food and water entry into gastrointestinal tract) in the disease *Gallough*, caused by *Kapha* and *Raktadhatu* vitiation¹¹. Foul breath in OCC patients, often due to secondary infections, poor hygiene during radiotherapy, or ulcerative lesions²⁵, corresponds to *Putimukha*, a type of *Mukharoga* with *Raktadhatu* and *Tridosha* vitiation, which includes treatment of *Nasya*²². Debility in OCC patients arises from hampered oral intake due to radiation-induced stomatitis, xerostomia, trismus, and dysphagia, leading to malnutrition and reduced quality of life. Psychological stress further exacerbates this condition. Pain, a common symptom in advanced OCC, varies with *dosha* dominance: pricking (*Vata*), burning (*Pitta*), or dull aching (*Kapha*)¹⁵. However, pain always involves *Vata* vitiation, making *Vata*-pacifying treatments essential for management²⁶.

Thus, the symptoms of OCC and the side effects of conventional treatments for OCC are predominantly *Vata-Pitta* dominant *Tridosha* in nature. Since the disease process involves both localized pathological changes at the lesion site (*Sthanadushṭi*) and systemic *Doṣha-Dhatu* imbalance, therapeutic interventions were planned to address both local and systemic

Table 4 — Details of the Shamana protocol used in both the arms of OCC patient

Sr. No.	Drug administered	Drug administration Timing	Ingredients	Probable mode of action
1.	<i>Mouktikyukta Kamdudha</i> 250 mg	After morning and evening breakfast with cow's milk	<i>Swarna gairik</i> (Cow's ghee roasted red ochre) <i>Abhraka bhasma</i> (Incinerated mica) <i>Shankha bhasma</i> (Incinerated conch) <i>Shukti bhasma</i> (Incinerated mother pearl) <i>Kapardik bhasma</i> (Incinerated cowry) <i>Mukta bhasma</i> (Incinerated pearl) <i>Praval bhasma</i> (Incinerated coral) <i>Guduchi sattva</i> (Starch of Giloy)	Anti-inflammatory Relieves burning sensation and inflammation of gastrointestinal system, Anti-cancer, immunomodulatory ³¹⁻³³
2.	<i>Atharva Vasadi Vati</i> 750 mg	After lunch and dinner with water	<i>Vasa</i> (<i>Adhatoda vasica</i>) <i>Yashtimadhu</i> (<i>Glycyrrhiza glabra</i>) <i>Kankola</i> (<i>Piper cubeba</i>)	<i>Tikshna</i> (penetrating), Good for throat, relieves pain and inflammation, foul smell, taste enhances, improves body strength ³⁹ .
3.	<i>Atharva Yashtimadhu Ghruta</i> 5 g	After lunch and dinner with water	<i>Yashtimadhu</i> (<i>Glycyrrhiza glabra</i>) <i>Goghru</i> (Cows' ghee)	Improves complexion, good for throat, alleviates <i>Pitta-Vatadosha</i> , reduces inflammation, removes toxins ³⁹ . Anti-inflammatory Anti-oxidant ³⁴ .
4.	<i>Atharva Sukshma Triphala Vati</i> 500 mg	After lunch and dinner with water	<i>Kajjali</i> (Black sulphide of mercury) <i>Triphala</i> *	Alleviates <i>Kapha-pittadosha</i> , useful infective conditions and helps in wound healing ³⁵
5.	<i>Triphala Guggulu</i> 500 mg	After lunch and dinner with water	<i>Triphala</i> * <i>Pippali</i> (<i>Piper longum</i>) <i>Shuddha Guggulu</i> (<i>Commiphora wightii</i>)	Anti-inflammatory, anti-oxidant and wound healing activity ³⁶ .

**Triphala-Haritaki* (*Terminalia chebula*), *Bibhitaki* (*Terminalia bellirica*), *Amalaki* (*Phyllanthus emblica*)

levels for comprehensive management. Ayurvedic treatments in the form of *Shamana Chikitsa* and *Shodhana Chikitsa* can be beneficial in such conditions. Radiation therapy increases intercellular reactive oxygen species levels resulting in increased oxidative stress²⁷ which can affect the overall physiology of the entire body. This oxidative stress contributes a range of side effects, salivary gland damage, increased susceptibility to dental caries, inflammation that may lead to fibrosis or scarring, weakening of neck muscles, and narrowing of the pharynx and esophagus²⁸. The drugs used in the *Panchakarma* protocol exhibit antioxidant, anti-inflammatory properties, making them effective in addressing these symptoms²⁹.

The combination of formulations administered to both arms provides palliative benefits by strengthening the organs of the head and neck, pacifying *Pittadosha*, reducing *Shotha* (inflammatory conditions), aids in wound healing and acting as a *Rasayana* (immunomodulator)³⁰⁻³⁵. A detailed mode of action along with the list of ingredients is presented in (Table 4).

Shodhana (PNK) helps to eliminate accumulated morbid *doshas*, *malas*, and undigested or unwanted free radicals from the body. Studies have reported that it enhances metabolic functions, including liver detoxification and regulation of the gut microbiota. Proper cleansing of the body through this process serves as a preventive strategy to reduce disease recurrence, improve quality of life, and support prolonged patient survival³⁶.

Bala Taila, used for oleation, has a *Pitta*-pacifying action due to its ingredients, which possess anti-inflammatory, muscle relaxant, and strength-enhancing properties¹². The base oil, *Tila Taila*, facilitates deep penetration of these herbal components into microchannels, owing to its *Vyavayi* (substances with quick spread even without digestion) and *Sukshma* (microchannel-penetrating) properties¹⁶. As a highly effective *Vata*-pacifying agent, it is particularly useful in treating conditions such as trismus, debility, and pain.

Sudation with coarse powder of *Dashmoola* due to its *Vata*, *Pitta*, and *Kapha* pacifying action is helpful for mobilization of immobilized joints, reduces muscle stiffness, and alleviates swelling and pain³⁷.

Owing to its *Ushna* and *Ruksha* properties, the intervention enhances local circulation and facilitates better absorption of medications³⁸, while reducing *Kapha* responsible for excessive secretion, thereby helping alleviate adverse effects such as trismus, excessive salivation, and pain.

Matra Basti, a type of oil enema administered in small quantities, acts both locally and systemically by being absorbed through the colon. Initially, the medicated oil reaches the *Pakvashaya* (colon), the primary site of *Vatadosha*, and helps regulate *Vata* throughout the body. According to physiology, the drug is absorbed through the colonic epithelium primarily via transcellular diffusion, a process that occurs through the cells and is positively correlated with the lipophilicity of the drug. From an osmotic perspective, the oil used in retention enemas is typically hypotonic or isotonic, promoting the movement of fluid into the colon. This influx of water helps soften the stool and enhances the therapeutic effect³⁹. Hence, *Dashmoola Taila* used for *Matra Basti* strengthened the colon and easily eliminated accumulated toxins, and soften fecal matter from the intestines and rectum to pacify *Vata Dosha* and addresses related symptoms like pain, stiffness, dryness, restricted movements, fatigue. This treatment is particularly useful in reducing symptoms such as stomatitis, xerostomia, dysphagia, debility, and pain.

Nasya therapy aids in removing *Srotorodha* (obstructions in *Urdhwajatra*- head and neck region channels), thus facilitating the proper functioning of the oral cavity and head region¹⁵. Nasal drugs can exert both local and systemic effects through three primary pathways- neurological (via olfactory and trigeminal nerves, enabling direct access to the brain), diffusion (involving passive diffusion across nasal epithelial cells) and vascular pathways (through absorption into the rich vascular network of the nasal mucosa for systemic circulation)^{40,41}. *Yashtimadhu* oil nasal drops^{33,42}, which pacifies *Pitta* and *Vata dosha*, strengthen the muscles and joints of the oral cavity⁴³. As a result, it is beneficial in managing conditions such as stomatitis, trismus, xerostomia, foul mouth odor, and pain.

Allied local therapies, such as *Mukha Pratisarana* and *Gandusha*, play a significant role in cleansing and promoting wound healing¹². *Mukha Pratisarana* with *Yashtimadhu Ghruta* possesses *Ropana* (healing) properties and pacifies *Pittadosha*. Its anti-inflammatory, antimicrobial, antifungal activities³³

make it beneficial in reducing symptoms of stomatitis, trismus, xerostomia, and dysphagia. *Gandusha* with *Gandusha Churna* decoction exhibits *Raktaprasadana* (blood purifying), *Ropana*, and *Kaphadosha*-reducing actions. Its anti-inflammatory, antimicrobial, and antifungal properties are effective in treating secondary fungal and bacterial infections in the oral cavity, thereby alleviating side effects like stomatitis, foul mouth odor, dysphagia, and local pain⁴⁴. *Karnapurana* aids in pacifying vitiated *Vatadosha*¹⁶. It is important to prevent early aging and weakening of the sense organ due to radiation exposure. Administering *Dashamoola Taila* in *Karnapurana* alleviates neck stiffness, dryness through its *Vatadosha*-pacifying action, making it useful in relieving symptoms such as trismus, xerostomia, and pain. *Shirodhara* with *Jatamansi* oil reduces psychological stress, promotes proper functioning of sense organs, strengthens the joints of the head and neck region and is also beneficial in debility^{37,45}. During the course of the 7-days of PNK treatment, patients did not have any adverse events. The treatment regimen in the intervention arm led to notable improvements in patients' daily activities and functional abilities, along with significant relief from symptoms and side effects associated with conventional treatment. Consequently, there was an enhancement in KPS, functional and global scores of the EORTC QLQ, and a reduction in symptom scores—indicating an overall improvement in quality of life.

In this study, the observed clinical benefits may be attributed to a multi-dimensional mechanism of action. Radiotherapy-induced toxicity is largely mediated by oxidative stress, inflammatory cytokines, and mucosal damage. The Ayurvedic interventions/*Shamana* protocol used for both the groups received, which helped to achieve relief in the patients due to their anti-inflammatory, immunomodulatory activities properties that likely mitigate these pathological processes. *Basti*, by acting on the primary site of *Vata*, may exert systemic regulatory effects through neuro-immunological and gut-mediated pathways, while *Nasya* enables targeted drug delivery to the head and neck region via olfactory and vascular routes. Additionally, the preparatory procedures, *Snehana* and *Swedana*, improves microcirculation and facilitate the deeper penetration of drugs. Concurrently, local therapies such as *Gandusha* and *Mukhapratisarana* provide

direct mucosal protection, reduce microbial load, and enhance epithelial healing. This combined systemic and local action explains the significantly greater improvement in symptoms such as stomatitis, xerostomia, dysphagia, and pain observed in the intervention group compared to control.

Limitations of the study

This study was conducted with a small sample size, limiting the statistical power and generalizability of the findings. Future research with larger populations and multicentric trials is recommended to validate the outcomes.

In this study, the intervention and follow-up period were short (1-month) which may have limited the ability to observe the long-term effects and sustainability of the treatment benefits. Longer study period can fully assess the impact on disease progression, recurrence, and survival outcomes. Secondly, this study relied on subjective assessment criteria, which may introduce response and observer bias. Future studies will incorporate objective evaluation parameters to strengthen the validity, reliability, and generalizability of the findings.

A wide time frame for patient enrollment may have introduced variability in the severity and grading of radiotherapy-related symptoms, potentially affecting baseline comparability and study outcomes.

Additionally, only a single set of therapies was administered due to time constraints. Periodic administration (e.g., once or twice a year for 14 days) might have demonstrated more significant therapeutic benefits.

Conclusion

The integration of selected *Panchakarma* therapy—including *Basti*, *Nasya*, and specific allied procedures mentioned in sixty procedures of *Vrana* such as *Gandusha*, *Mukha Pratisarana*, *Shirodhara*, and *Karnapurana*—alongside *Shamana Chikitsa*, has demonstrated significant efficacy in alleviating symptoms like dysphagia, debility, stomatitis, and local pain in oral cavity cancer patient's post-conventional treatment, while control arm showed delayed improvement in certain symptoms. This suggest that combined therapeutic approach not only provide immediate relief but also exhibit sustained benefits up to one month after completion, indicating their long-lasting effects. Additionally, they have been effective in reducing the severity of xerostomia,

excessive salivation, trismus, and foul mouth odor, thereby substantially enhancing patients' quality of life. This underscores the importance of a combined *Panchakarma* and oral therapeutic approach in managing long lasting post-conventional complications in oral cavity cancer patients.

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Author Contributions

The present study was conceptualized and designed by SPS, AK, VD, SS. The resources were provided by VD, SPS, SG and executed by SS, NS, SK, VG, DD, VA, AD, SKS, AS. The study was supervised by VD, SPS. Acquisition of the work, analysis, interpretation, and drafting of work revising it critically for important intellectual content was done by VD, SG, NS, SS, SSS. Original draft was written by SS, NS and reviewed and edited by SC, SSS, VD, and all the rest of the authors had read and approved the manuscript. All authors have agreed to be accountable for all aspects of the work.

Conflict of Interest

The authors declared no conflicts of interest in preparing this report.

Ethics Statement

The approval was documented "Role of Basti, Nasya and allied therapies for improving quality of life in oral cavity cancer patients post conventional treatment" through the Ethics Committee meeting proceedings/minutes dated [04/08/2006]. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and applicable institutional guidelines.

Informed Consent

A written informed consent was taken from every patient before commencement of the study.

Use of Artificial Intelligence (AI)

Author did not use any AI tool for data interpretation and development of original manuscript.

Data Availability

The dataset generated during this study is available from the corresponding author upon reasonable request. It is not publicly accessible due to privacy and ethical considerations involving human participants.

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