

DEVELOPMENT AND VALIDATION OF A YOGA PROTOCOL FOR HEAD AND NECK CANCER PATIENTS UNDERGOING CHEMORADIATION

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Abstract

Background: Head and neck cancer patients undergoing chemoradiation experience significant physical and psychological side effects, which adversely affect their quality of life. Yoga has shown promise in managing cancer-related symptoms; however, a specific validated yoga protocol for this population is lacking.

Objective: To develop and validate a comprehensive yoga protocol tailored for head and neck cancer patients undergoing chemoradiation.

Methods: A total of 52 yoga exercises were identified through literature review addressing symptoms common in chemoradiation patients. Content validation was performed by a panel of 15 oncology experts and 15 certified yoga instructors using Lawshe's Content Validity Ratio. Exercises with acceptable validity scores were included in the final protocol. The finalized module includes dynamic breathing exercises, asanas, pranayama, yoga nidra, meditation, and yogic counseling, delivered in sessions lasting approximately 30–35 minutes.

Results: Fourteen exercises achieved acceptable content validity scores (CVR ≥ 0.8). The validated protocol incorporates 5 dynamic breathing exercises, 3 asanas, 3 pranayama techniques, yoga nidra, meditation, and yogic counseling. A detailed session plan over 18 sessions was formulated to ensure gradual progression and safety.

Conclusion: This study establishes a validated, tailored yoga protocol specifically designed for head and neck cancer patients undergoing chemoradiation. The protocol provides a structured, safe, and holistic supportive care intervention ready for efficacy testing in clinical trials.

Keywords: Yoga, Head and neck cancer, symptom management, well being, quality of life.

INTRODUCTION

Head and neck cancer (HNC) treatment frequently involves radiation therapy combined with chemotherapy depending on disease stage, resulting in substantial physical and psychological burden for patients. Common side effects include fatigue, cognitive impairment, anxiety, depression, fear of recurrence, and pain. Additionally, localized adverse effects such as mucositis, dry mouth, skin pigmentation changes, and inflammation at the radiation site significantly impair quality of life. Some patients require tracheostomy in view of stridor and some require naso-gastric tube or PEG tube for feeding assistance, further complicating symptom management.

Despite these challenges, targeted complementary therapies for HNC patients undergoing chemoradiation remain limited. Yoga, a mind-body practice integrating physical postures, breathing techniques, and meditation, has demonstrated safety and efficacy in alleviating symptoms and improving quality of life in cancer patients broadly. Systematic reviews and meta-analyses show that yoga significantly reduces cancer-related fatigue and psychological distress while enhancing psychosocial well-being in patients undergoing chemotherapy and radiotherapy (Cramer et al., 2012; Buffart et al., 2012).

Beyond symptom management, yoga may also modulate biological pathways by reducing stress biomarkers such as cortisol and enhancing immune function reflected in immunoglobulin A (IgA) levels (Jain et al., 2024; Bratborska et al., 2024). However, no specific yoga protocol has been developed to address the unique needs of head and neck cancer patients undergoing chemoradiation, who face distinct clinical and symptomatic challenges.

The primary objective of this study is to develop and validate a yoga protocol tailored for head and neck cancer patients receiving chemoradiation, focusing on symptom reduction and quality of life improvement. Additionally, the study evaluates changes in cortisol and IgA levels to assess biological effects of yoga in this population.

MATERIALS AND METHODS

Study Design and Participants

This study utilized a randomized controlled trial (RCT) design. Forty head and neck cancer patients scheduled to undergo chemoradiation were recruited and randomized into two groups: the experimental group (n=20), which received a yoga intervention, and the control group (n=20), which received standard care. All participants were recruited prior to the initiation of radiation therapy.

Development and Validation of the Yoga Protocol

A comprehensive literature review and synthesis of previous studies identified 52 yoga exercises potentially effective for managing symptoms associated with chemoradiation in head and neck cancer. For content validation, an expert panel comprising 15 oncology specialists and 15 certified yoga instructors evaluated each exercise using Lawshe's Content Validity Ratio (CVR) formula. Based on their ratings, the protocol was refined to include:

- 5 deep breathing exercises
- 3 asanas (yoga postures)
- 3 pranayama (breath regulation techniques)
- Yoga nidra (guided relaxation)
- Meditation
- Yogic counseling

All practices were selected and adapted according to patients' tolerance, safety, and symptom profile.

Intervention Protocol

The yoga intervention was delivered to the experimental group three times weekly on alternate days throughout the course of their 6.5-week radiation treatment period. Sessions were conducted by a certified yoga instructor with clinical experience in oncology settings. Each session included the validated breathing exercises, asanas, pranayama, yoga nidra, meditation, and counseling. The control group received standard supportive care alone.

Biomarker Assessment

To assess biological changes, serum blood samples for cortisol and immunoglobulin A (IgA) were collected at two time points: baseline (before radiation therapy) and at the end of chemoradiation (after 6.5 weeks). Samples were analyzed using standard biochemical assays.

Outcome Measures

Quantitative outcomes were measured at baseline and post-intervention (after 6.5 weeks of radiation), including:

- Pittsburgh Sleep Quality Index (PSQI) for sleep quality
- PROMIS (Patient-Reported Outcomes Measurement Information System) for general health and functioning
- FACT-COG (Functional Assessment of Cancer Therapy - Cognition) for cognitive function
- Visual Analog Scale (VAS) for pain
- Montreal Cognitive Assessment (MoCA) for cognitive screening
- Hospital Anxiety and Depression Scale (HADS) for psychological distress

Ethical Considerations

The study protocol was approved by the Institutional Review Board of Sri Ramachandra Institution of higher education and research. Written informed consent was obtained from all participants. All procedures conformed to the ethical standards set out in the Declaration of Helsinki.

RESULTS

Development of the Yoga Protocol

Initially, 52 yoga exercises were identified through an extensive review of previous studies and relevant literature addressing symptom management in cancer patients. This comprehensive list included a variety of dynamic breathing exercises, asanas (postures), pranayama (breathing control techniques), yoga nidra, meditation, and yogic counseling practices aimed at alleviating symptoms related to chemoradiation in head and neck cancer patients.

Validation of the Yoga Protocol

The preliminary yoga module was subjected to content validation by an expert panel comprising 15 oncology specialists and 15 certified yoga instructors. Assessment of each exercise's relevance and safety was performed using

Lawshe's Content Validity Ratio (CVR). Exercises with CVR scores below the critical threshold were excluded, leading to a refined final protocol.

The validated protocol includes:

- Dynamic Breathing Exercises (DBE): 5 exercises including Hands Apart and Together, Hands Stretching, Skandha Chakra / Shoulder socket rotation, Bidalasana / Cat posture, and Bhujangasana / Cobra breathing, each with CVR 0.8
- Asanas: Tadasana / Mountain pose, Simhasana / Lion pose, and Bhujangasana / Cobra pose with CVR 0.8
- Pranayama: Ujayae / Ocean breath, Vibhagiya Pranayama / Sectional breathing, and Brahmari / Humming bee breath, each scoring 0.8
- Yoga Nidra, Meditation, and Yogic Counseling: Each scoring a perfect CVR of 1.0

Table 1: Validation of Yoga Exercises Using Lawshe's Content Validity Ratio (CVR)

Exercise Name	CVR Score	Included/Excluded
Hands Apart and Together	0.8	Included
Hands Stretching	0.8	Included
Skandha Chakra/Shoulder socket rotation	0.8	Included
Cat Posture/ Marjariasana	0.8	Included
Cobra Breathing/ Bhujangasana	0.8	Included
Tadasana/ Mountain Pose	0.8	Included
Simhasana/ Lion Pose	0.8	Included
Bhujangasana / Cobra Pose	0.8	Included
Ujayae/ Ocean Breath	0.8	Included
Sectional Breathing	0.8	Included
Brahmari/ Humming bee breath	0.8	Included
Yoga Nidra	1.0	Included
Meditation	1.0	Included
Yogic Counselling	1.0	Included

Yoga Session Plan and Duration

The finalized module sessions last approximately 30–35 minutes, combining the above components with specific durations and repetitions to optimize patient adherence and therapeutic benefit. For example, dynamic breathing exercises are typically performed for 1–2 minutes per exercise with 8 repetitions, while yoga nidra lasts about 8 minutes, and meditation about 3 minutes.

A weekly session plan was designed to gradually introduce and build proficiency in these practices over 18 sessions, performed three times weekly on alternate days during the radiation treatment period.

Table 2: Yoga Module Syllabus — Exercise Details

Type	Exercise/Posture Name	Duration (mins)	Repetition	Total Duration (mins)
Dynamic Breathing Exercise (DBE)	Hands Apart and Together	1–2	8	30–35
	Hands Stretching	1–2	8	
DBE	Skandha Chakra	1–2	8	
	Cat Posture	1–2	8	
	Cobra Breathing	1–2	8	
Asana	Tadasana	2–3	8	30–35
	Simhasana	2–3	8	
	Bhujangasana	2–3	8	
Pranayama	Ujayae	2–3	5	
	Sectional Breathing	3–5	3	
	Brahmari	2–3	3	
Relaxation	Yoga Nidra	8		
Meditation	Meditation	3		
Counselling	Yogic Counselling	4		

DISCUSSION

This study successfully developed and validated a tailored yoga protocol for head and neck cancer patients undergoing chemoradiation, addressing a critical gap in supportive care for this population. Starting from an extensive list of 52 exercises identified through literature review and expert input, we refined the protocol using a robust validation approach involving 30 experts and the application of Lawshe's Content Validity Ratio (CVR). The final protocol offers a comprehensive yet practical package including dynamic breathing exercises, asanas, pranayama, guided relaxation through yoga nidra, meditation, and yogic counseling.

The inclusion of breathing exercises, such as hands apart and together, Skandha Chakra / Shoulder socket rotation, and Bhujangasana / Cobra breathing, alongside selected asanas (Tadasana / Mountain pose, Simhasana / Lion pose, Bhujangasana) and pranayama techniques (Ujayae / Ocean breath, Brahmari / Humming bee breath, Vibhagiya Pranayama / Sectional breathing) reflects the dual aim of alleviating physiological symptoms and promoting mental well-being. The perfect CVR scores for yoga nidra, meditation, and counseling underscore their importance in holistic care, especially for managing psychological distress prevalent in this group.

Our systematic validation process parallels rigorous methods seen in comparable yoga protocol development studies in oncology, ensuring that the selected practices are both clinically relevant and safe for patients with the complex challenges of chemoradiation. The structured session plan over 18 sessions emphasizes gradual skill acquisition and consistency in practice, which is crucial for adherence and effectiveness in chronic illness populations.

While the protocol is promising, the true test of its utility will come from ongoing and future efficacy trials assessing symptom relief, quality of life improvement, and physiological changes such as cortisol and IgA modulation. Potential study limitations include the relatively small expert panel and the need for adaptation across diverse patient subgroups. Overall, this validated protocol lays a strong foundation for integrating yoga into multidisciplinary supportive care for head and neck cancer patients, offering a non-invasive, low-risk intervention to mitigate treatment-related side effects and enhance holistic health.

CONCLUSION

This study successfully developed and validated a comprehensive yoga protocol specifically designed for head and neck cancer patients undergoing chemoradiation. Through a rigorous validation process involving oncology and yoga experts, the protocol was refined to include targeted dynamic breathing exercises, asanas, pranayama techniques, yoga nidra, meditation, and yogic counseling, all supported by strong content validity scores. This tailor-made protocol addresses the unique physical and psychological challenges faced by this patient population, offering a safe, accessible, and holistic complementary therapy.

The establishment of this validated protocol lays a crucial foundation for future clinical trials to evaluate its efficacy in symptom management, quality of life improvement, and physiological effects, such as modulation of stress and immune biomarkers. Integrating yoga into supportive cancer care has the potential to enhance comprehensive treatment outcomes for head and neck cancer patients in a non-invasive manner.

Future directions involve implementing this protocol in larger samples, assessing long-term benefits, and adapting it for diverse clinical settings, ultimately contributing to improved multidisciplinary care in oncology.

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Conflicts of Interest

The authors declare that there are no conflicts of interest related to this study.

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