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Research Progress on the Effects of Immunonutrition on Oral Mucositis and Nutritional Status in Patients with Head and Neck Cancer Undergoing Radiotherapy

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Abstract

Patients with head and neck cancer (HNC) undergoing radiation therapy (RT) frequently face oral mucositis (OM), a challenging and highly prevalent acute toxic reaction. OM not only causes severe pain, dysphagia, and impaired nutritional intake but also intertwines with malnutrition to form a vicious cycle that is difficult to break, thereby significantly compromising treatment efficacy and patients' quality of life. While traditional nutritional support can barely maintain basic energy supply, it proves inadequate in modulating the cytokine storm and immune response. In contrast, immunonutrition, as an emerging therapeutic paradigm, attempts to exert "pharmacological-level" regulatory effects by precisely incorporating specific components such as arginine, ω-3 polyunsaturated fatty acids (EPA, DHA), and nucleotides into standard formulas, aiming to suppress inflammation and oxidative stress while providing nutrients. In recent years, the academic community has focused on immunonutritional formulations represented by IMPACT®, deeply exploring their clinical value in the HNC radiotherapy population. This review aims to systematically organize and analyze relevant evidence to discuss how immunonutrition intervenes in the prevention and management of oral mucositis and improves patients' nutritional status. Existing data suggest that immunonutritional intervention can not only effectively reduce the incidence of severe (grade ≥3) oral mucositis and alleviate its severity and progression but also demonstrate unique advantages in stabilizing patient body weight, lean body mass (muscle mass), and plasma protein levels (albumin, prealbumin), holding promise for breaking the causal chain between malnutrition and mucositis. Its underlying mechanisms may stem from recalibrating the balance of pro-inflammatory/anti-inflammatory cytokines (e.g., downregulating IL-6 and TNF-α while upregulating IL-10), reinforcing the body's antioxidant defenses, and maintaining lymphocyte count and function. Certainly, existing research results still exhibit heterogeneity, often involving multiple variables such as timing of intervention, dosage range, duration of treatment, subject characteristics, and control settings. Looking ahead, there is an urgent need for more rigorously designed, large-sample multicenter randomized controlled trials, supplemented by in-depth mechanistic exploration and long-term follow-up, to clarify the optimal strategies, cost-effectiveness, and true impact on long-term prognosis of immunonutrition in supportive care for HNC radiotherapy.

Keywords: head and neck cancer, immunonutrition, radiotherapy, oral mucositis, nutritional status

1. Introduction

Head and neck cancer (HNC) is one of the common malignant tumors worldwide, and radiotherapy (RT) serves as a core modality for both curative treatment and postoperative adjuvant therapy (Yang, T. T., Chen, Y., Hu, J.

J., et al., 2025). While radiation precisely targets tumor cells, it inevitably damages the rapidly proliferating normal mucosal epithelium in the oral cavity and pharynx, leading to oral mucositis (OM) (Liang, L. F., Song, Z. X., & Wang, R. S., 2024). OM is among the most common and distressing dose-limiting toxicities encountered during RT for HNC, clinically manifesting as mucosal erythema, edema, erosion, and ulceration, accompanied by severe pain, dysphagia, taste alterations, and reduced salivary secretion (Liang, L. F., Song, Z. X., & Wang, R. S., 2024; De Sanctis V, Bossi P, Sanguineti G, et al., 2016). Statistics indicate that over 80% of HNC patients undergoing curative radiotherapy develop oral mucositis (OM) of varying severity, with approximately 30–50% progressing to severe (grade 3–4) OM. This condition often renders patients unable to eat orally, causes rapid weight loss, and drastically reduces quality of life, frequently resulting in interruptions to radiotherapy or reductions in treatment dosage, thereby compromising local tumor control rates and long-term patient survival (Trotti A, Bellm L A, Epstein J B, et al., 2003; Qin, X. J., & Qin, W. Y., 2023).

Malnutrition is a prominent clinical issue throughout the diagnosis and treatment of patients with head and neck cancer (HNC). The tumor itself causes mechanical obstruction, altered taste, and anorexia, while treatment-induced side effects such as oral mucositis (OM), xerostomia, nausea, and vomiting collectively lead to severe deficiencies in energy and protein intake (Bossola M., 2015). Studies indicate that approximately 20–40% of HNC patients present with malnutrition at diagnosis, with both the prevalence and severity worsening during radiotherapy (De Pasquale G, Mancin S, Matteucci S, et al., 2023). A vicious cycle of mutual exacerbation exists between malnutrition and OM: severe OM directly impedes oral intake, thereby aggravating malnutrition; conversely, the state of malnutrition impairs mucosal epithelial repair capacity and reduces immune function, rendering the mucosa more susceptible to radiation injury, intensifying inflammatory responses, and thus worsening the severity and persistence of OM (Wu, J. Y., Wang, A. H., & Zou, J., 2022).

Conventional nutritional support therapy, including oral dietary guidance, enteral nutrition (oral nutritional supplementation and tube feeding), and parenteral nutrition, primarily aims to correct energy-protein deficiency. Although foundational, it constitutes a “passive supplementation” approach with limited efficacy in modulating the core pathological processes of excessive inflammation and immune dysregulation induced by radiotherapy (Krzywon A, Kotylak A & Rutkowski T., 2025; Gu Y, Lu W, Mao Y, et al., 2025). Therefore, there is a clinical need for a novel nutritional strategy capable of actively intervening in this vicious cycle.

Against this backdrop, immunonutrition has emerged as a research hotspot in the field of supportive cancer care. Immunonutrition is not merely an accumulation of nutrients; rather, it involves adding specific pharmacologically active nutrients—such as arginine, ω-3 polyunsaturated fatty acids, nucleotides, and glutamine—to standard nutritional formulas (Wu, J. F., Gao, T., & Sun, X. J., 2023; Liu, X. R., & Liu, Y. H., 2024). These components aim to modulate the body’s pathophysiological responses at their root by regulating immune cell activity, influencing the production of inflammatory mediators, and enhancing antioxidant defenses. Thus, while providing nutritional substrates, they also exert therapeutic effects as “nutritional drugs” (Liu, X. R., & Liu, Y. H., 2024; He, J., Li, J., & Ma, J., et al., 2020). In recent years, numerous clinical studies have focused on the application of immunonutrition in patients with head and neck cancer (HNC) undergoing chemoradiotherapy. This review aims to systematically summarize and analyze current clinical evidence regarding immunonutrition interventions for preventing and treating oral mucositis and improving nutritional status in HNC patients receiving radiotherapy, and to explore their potential mechanisms of action, thereby providing references for clinical practice and future research directions.

2. Core Components of Immunonutrition and Their Potential Mechanisms of Action

The efficacy of immunonutritional formulations stems from the synergistic effects of their core components; understanding the biological characteristics of these components is fundamental to elucidating their clinical outcomes.

2.1 L-Arginine

L-Arginine is a conditionally essential amino acid with significantly increased demand under stress conditions, serving as the direct precursor for nitric oxide (NO) synthesis. NO plays a dual role in immune regulation: appropriate levels of NO promote vasodilation, improve microcirculation in mucosa and tissues, facilitate injury repair, enhance macrophage phagocytic function, promote T-lymphocyte proliferation and activity, and strengthen cellular immune responses. In the context of mucositis, arginine promotes mucosal healing by supporting immune cell function and improving local blood flow (Liu, X. R., & Liu, Y. H., 2024; Molendijk E B D & Blijlevens N M A., 2021; Gogoi M, Datey A, Wilson K T, et al., 2016).

2.2 ω-3 Polyunsaturated Fatty Acids (ω-3 PUFAs)

The primary ω-3 polyunsaturated fatty acids are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Their core mechanism involves competitively inhibiting the synthesis of potent pro-inflammatory mediators—specifically prostaglandin E2 [PGE2] and leukotriene B4 [LTB4]—derived from the metabolism of

ω-6 PUFAs (arachidonic acid). Simultaneously, EPA and DHA serve as substrates for generating lipid mediators such as Resolvins and Protectins, which possess active anti-inflammatory and pro-repair properties. ω-3 PUFAs can be incorporated into the phospholipids of immune cell membranes, influencing membrane fluidity and signal transduction, regulating immune function, and exhibiting certain antioxidant properties (Calder P C., 2015). In radiotherapy scenarios, ω-3 PUFAs are believed to mitigate excessive inflammatory responses and oxidative stress induced by radiation (Zhang Y, Zhang B, Dong L, et al., 2019).

2.3 Nucleotides

As the basic units of DNA and RNA, nucleotides are essential substances for cell proliferation and protein synthesis. Within the immune system, rapidly proliferating immune cells (lymphocytes, intestinal mucosal epithelial cells) have a high demand for nucleotides (Raczyńska A, Leszczyńska T, Skotnicki P, et al., 2025). Exogenous supplementation of nucleotides is considered to support lymphocyte proliferation and differentiation, particularly when endogenous synthesis is insufficient due to high metabolic stress states, thereby helping to maintain the integrity of immune system function (Raczyńska A, Leszczyńska T, Skotnicki P, et al., 2025; Gil A., 2002).

2.4 Synergistic Effects and Comprehensive Mechanisms

The aforementioned components do not act in isolation but produce synergistic effects. Immunonutritional intervention influences OM and nutritional status through the following comprehensive pathways: (1) Anti-inflammatory and immunomodulatory effects: Downregulating pro-inflammatory cytokines (TNF-α, IL-1β, IL-6), upregulating anti-inflammatory cytokines (IL-10), balancing Th1/Th2 responses, and maintaining immune homeostasis. (2) Antioxidant protection: Enhancing the body's ability to scavenge free radicals, reducing oxidative damage caused directly or indirectly by radiation, and protecting normal cells. (3) Improvement of anabolism and nutrient utilization: Based on the provision of high-quality protein and energy, reducing muscle protein breakdown and promoting the preservation of lean body mass through an anti-inflammatory and pro-anabolic environment. (4) Maintenance of gut barrier function and microecology: Some evidence suggests that immunonutrition benefits intestinal mucosal health, and gut-axis communication may indirectly influence systemic inflammatory status (Raczyńska A, Leszczyńska T, Skotnicki P, et al., 2025; Howes N, Atkinson C, Thomas S, et al., 2018).

3. Analysis of Clinical Evidence for Immunonutrition in the Prevention and Treatment of Oral Mucositis

3.1 Early Exploration and Positive Signals

Early prospective studies and Phase II clinical trials have provided preliminary evidence for the application of immunonutrition. Some studies observed that among patients with head and neck cancer (HNC) receiving concurrent chemoradiotherapy, those who regularly took oral immunonutritional formulas (IMPACT®) showed a trend of lower-than-expected or lower-than-historical-control incidence rates of grade 3-4 severe oral mucositis (OM) (Assenat E, Latournerie M, Thézenas S, et al., 2011). Another Phase II study indicated that immunonutritional support helps improve the inflammatory status of patients with head and neck squamous cell carcinoma during chemoradiotherapy, thereby preventing severe acute oral mucositis (Machon C, Thezenas S, Dupuy A M, et al., 2012). Although these studies had limited sample sizes, they stimulated the conduct of larger-scale research.

3.2 Evidence from Randomized Controlled Trials

Subsequent multiple randomized controlled trials (RCTs) have provided high-level evidence. A double-blind RCT focusing on patients with locally advanced HNC receiving chemoradiotherapy found that, compared to patients receiving isonitrogenous and isocaloric standard enteral nutrition, those receiving immunonutrition had a reduced risk of developing ≥ grade 3 OM. Furthermore, in the immunonutrition group, the time to first onset of mucositis was delayed until the 5th week (compared to the 3rd week in the control group), and both the analgesic usage rate (18.5% vs. 93.8%) and the requirement for nasogastric tube insertion (0% vs. 8.5%) were significantly reduced. This indicates that immunonutritional intervention can effectively delay the progression of mucosal injury and mitigate its severity (Pattanayak L, Panda N, Dash M K, et al., 2016). Other studies have reported similar results, showing that patients in the immunonutrition group had a lower incidence of severe OM, with the peak severity occurring later and lasting for a shorter duration, suggesting an effect in delaying and alleviating the process of mucosal injury (Tan S E, Abdul Satar N F & Majid H A., 2022).

3.3 Pivotal Phase III Trials and Controversies

The results of the largest Phase III double-blind trial (the IMPATOX study) have sparked extensive discussion. In this study involving HNC patients receiving postoperative adjuvant chemoradiotherapy, the intention-to-treat analysis showed no statistically significant difference between the immunonutrition group and the standard nutrition group regarding the primary endpoint of severe OM incidence. This negative result suggests that the

efficacy of immunonutrition may be influenced by the study population (postoperative status), timing of intervention (adjuvant therapy phase), and other confounding factors. Meanwhile, subgroup analysis of this study revealed that among patients with good compliance (taking ≥ 75% of the planned dose), the immunonutrition group showed a trend toward prolonged progression-free survival and overall survival, implying potential long-term benefits (Boisselier P, Kaminsky M C, Thézenas S, et al., 2020).

3.4 Comprehensive Conclusions from Meta-Analyses

To integrate findings from different studies, several systematic reviews and meta-analyses have been published. One meta-analysis, including 27 studies and nearly 1,500 patients, provided relatively clear conclusions: although immunonutrition did not reduce the overall incidence of OM of all grades, it could lower the risk of developing ≥ grade 3 severe OM, with a pooled relative risk (RR) of approximately 0.45–0.65. This indicates that the core value of immunonutrition lies in preventing or mitigating "severe" mucositis, which most significantly affects treatment progress and quality of life. Comprehensive analysis suggests that immunonutrition has definite clinical value in preventing and treating severe OM associated with radiotherapy in HNC, with its effects achieved through modulating local and systemic inflammatory responses. The heterogeneity in efficacy is closely related to factors such as the timing of intervention initiation (prophylactic use is superior to therapeutic use), duration of intervention, specific formulations of the preparations, and the baseline nutritional and immune status of patients (Zheng X, Yu K, Wang G, et al., 2020).

4. Clinical Observation of the Impact of Immunonutrition on the Nutritional Status of Radiotherapy Patients

4.1 Maintenance of Body Weight and Body Composition

Multiple studies consistently report that patients receiving immunonutrition intervention experience less weight loss during and after radiotherapy compared to those receiving standard nutritional support. Body composition analysis reveals that immunonutrition is particularly effective in reducing the loss of lean body mass (muscle mass). For instance, studies utilizing bioelectrical impedance analysis (BIA) or CT imaging have found that patients in the immunonutrition group exhibit a smaller decline in the skeletal muscle index (SMI). Maintaining lean body mass is crucial for preserving patient physical strength, immune function, treatment tolerance, and long-term prognosis (Cuesta-Sancho S, Gomez J J L, García-Luna P P, et al., 2025; Vasson M P, Talvas J, Perche O, et al., 2014).

4.2 Improvement of Hematological Nutritional Indicators

Plasma protein levels are sensitive indicators reflecting nutritional status and anabolic state. Clinical observations indicate that the decline in serum albumin and prealbumin (which has a shorter half-life and is more sensitive) levels during radiotherapy is less pronounced in the immunonutrition group compared to the control group (Yang, Q., Chai, H. Y., & Guo, L., et al., 2021). This suggests that immunonutrition provides raw materials (amino acids) for protein synthesis and, through its anti-inflammatory effects, reduces inflammation-induced protein catabolism and vascular leakage, thereby better maintaining visceral protein reserves. Comprehensive scores such as the Nutritional Risk Index (NRI) are typically better maintained in the immunonutrition group (Chao P C & Lin F C F., 2020).

4.3 Reduction in the Need for Escalated Nutritional Support

Due to better maintenance of oral intake capacity and nutritional status, patients receiving immunonutrition require escalation from oral nutritional supplements to full-volume tube feeding enteral nutrition or parenteral nutrition at a later time point and in lower proportions compared to the standard nutrition group (Kiss N, Findlay M, Frowen J, et al., 2026). This indicates that immunonutrition delays or reduces the need for higher-level nutritional support, indirectly reflecting its effectiveness in maintaining patients' inherent eating ability.

5. Considerations on Clinical Application, Existing Issues, and Future Prospects

5.1 Current Considerations on Clinical Application

Based on existing evidence, immunonutrition should be regarded as an integral component of comprehensive supportive care for patients with head and neck cancer (HNC) undergoing radiotherapy, rather than a substitute. The recommended application strategies are as follows: (1) Early intervention: Initiate before or at the onset of radiotherapy to exert a preventive effect. (2) Adequate dosage and duration: Ensure sufficient dosing and coverage throughout the period of acute toxicity risk (typically extending several weeks post-radiotherapy). (3) Individualized selection: Patients with high nutritional risk or those planned for high-intensity chemoradiotherapy (concurrent chemotherapy) stand to benefit more. (4) Multidisciplinary collaboration: Implement under the joint management of medical oncology, radiation oncology, and nutrition departments, integrating it into standard protocols for pain management, oral care, and nutritional support.

5.2 Existing Issues and Challenges

Currently, there is no globally unified standard regarding the optimal regimen for immunonutrition. Specifically, variations exist among different studies concerning formula composition, recommended daily dosage, timing of initiation, and duration of treatment, which may contribute to inconsistent results across clinical trials. In terms of cost-effectiveness, immunonutrition formulations are generally more expensive than conventional nutritional support products. Although they may reduce overall healthcare expenditures by lowering the incidence of severe complications, shortening hospital stays, and minimizing treatment interruptions, further economic evaluation data based on different healthcare systems are required for validation. Existing evidence predominantly focuses on Western populations, while large-scale, high-quality clinical studies targeting Chinese patients with head and neck cancer remain relatively insufficient. Given that differences in genetic background, dietary habits, and spectra of underlying diseases among ethnic groups may influence intervention outcomes, there is an urgent need to conduct clinical studies tailored to local population characteristics to provide more direct evidence. Although immunonutrition has demonstrated certain efficacy in clinical practice, its specific mechanisms of action at the molecular, cellular, and systemic levels, particularly the biological pathways involved in the specific context of head and neck cancer radiotherapy, still require further elucidation through deeper translational medical research.

5.3 Future Research Directions

Conducting large-scale, multicenter randomized controlled trials is crucial for clarifying the specific role of immunonutrition in tumor therapy. Such studies should focus on specific patient subgroups—for instance, those with different tumor sites or receiving different treatment regimens—and explore the practical value of combining immunonutrition with emerging radiotherapy technologies (such as proton therapy). While accumulating evidence on efficacy, future research must strive to identify biomarkers capable of predicting responses to immunonutrition, including baseline inflammatory markers and gene polymorphisms, thereby promoting the development of “precision nutrition” interventions and ensuring that medical resources serve patients likely to benefit more precisely. Beyond focusing on short-term toxicities, attention should also be paid to the impact of immunonutrition on long-term patient outcomes. This includes quality of life, functional recovery, late complications (such as trismus and swallowing dysfunction), and overall survival rates; these endpoint indicators can more comprehensively reflect the integrated value of the intervention. On this basis, innovative formulations and combination strategies hold promise for further enhancing efficacy. For example, developing novel immunonutrition formulas or exploring their combined application with other approaches such as mucosal protectants (e.g., epithelial growth factor, stem cell therapy) and probiotics/prebiotics may generate synergistic effects, bringing greater clinical benefits to patients.

6. Conclusion

In summary, current clinical evidence strongly supports the value of immunonutrition interventions in the management of patients with head and neck cancer undergoing radiotherapy. As a strategy combining nutritional support and pharmacological modulation, immunonutrition effectively reduces the risk and severity of severe oral mucositis and demonstrates significant advantages in maintaining body weight, preserving lean body mass, and improving plasma protein levels. Its benefits are primarily attributed to the synergistic anti-inflammatory, immunomodulatory, antioxidant, and anabolic effects of its core components (arginine, ω-3 fatty acids, and nucleotides). While further exploration is needed regarding optimal application protocols and cost-effectiveness, integrating immunonutrition into standard supportive care regimens for HNC radiotherapy patients is undoubtedly a rational and effective clinical choice that can improve treatment tolerance, enhance quality of life, and potentially influence prognosis. Future in-depth basic and clinical research holds promise for further optimizing application strategies to benefit more patients.

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