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Multicenter evaluation of baseline and post-treatment hemoglobin levels as predictors of survival in head and neck squamous cell carcinoma

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ABSTRACT

Objective: To study the role of hemoglobin levels before and after treatment in predicting outcomes among patients with head and neck squamous cell carcinoma receiving radiotherapy or chemoradiotherapy.

Method: **Multicentre cohort research was carried out at five specialized healthcare institutions in Kanpur, Uttar Pradesh, India, involving 250 subjects who were newly confirmed to haveHNSCC treated with either radical radiotherapy or concurrent chemoradiation, between 2008 and 2022. The baseline and 12-month values were determined by measuring hemoglobin. The Kaplan–Meier approach was employed to estimate survival outcomes following adjustment for confounding factors and adjusted based on patient demographics (age and gender), tumor site, disease stage, functional status, and treatment modality mode. Additionally, Multivariate Cox modeling was carried out to assess the connections between survival outcomes and Hb findings**

Results: **There were 60% men and an average age of 52 years (mean 50.8). 70% of cases had squamous cell carcinoma. Chemotherapy alone (15.2%), radiation alone (40%), and chemoradiotherapy (44.8%) comprised the treatment. After a year, the mean hemoglobin grew to 13.5 ± 1.2 g/dL (+0.7 g/dL; with 95% CI: 0.546–0.848) from 12.8 ± 1.5 g/dL.Forty-eight percent had baseline anemia (Hb<13 g/dL). Patients with anemia had a substantially poorer one-year OS than those without anemia (62% versus 78%, p<0.01). In adjusted models, anaemia remained independently associated with worse OS (HR 2.05; with 95% CI : 1.337–3.149; p=0.001). The tumor progression-free interval and survival rates over a year were 85% and 90%, respectively.**

Conclusion: **Both baseline and post-treatment hemoglobin levels showed a strong link with patient survival in head and neck cancer. Monitoring and correcting anemia during therapy may lead to better clinical outcomes. Further studies are required to validate these findings.**

INTRODUCTION:

HNCs, pose a serious health risk to the entire world, as they rank among the three percent of newly diagnosed cancers in the US and, on average, about 500,000 cases globally each year,

with a significant number of deaths [1]. The most common histology, which is called HNSCC, is known to exhibit aggressive clinical patterns characterized by elevated rates of local recurrence and distant metastasis that require combined approaches to treatment, including surgery, chemotherapy, radiotherapy alone or in conjunction

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with chemotherapy [2,1]. The standard of care in organ preservation approaches to locally advanced disease has irrevocably changed to the so-called concomitant chemoradiotherapy (CCRT), which has already been shown to significantly decrease the mortality rate [1].

Beyond direct tumor control, patient-related factors notably influence prognosis nutritional and hematologic status are increasingly becoming determinants of outcome. Nutrition and diet are central factors in both maintaining health and preventing disease, and are significantly influenced by the presence and management of HNC [3]. Dysphagia, altered taste, and loss of smell are common and significantly impact nutritional intake and quality of life. Psychological variables also play a role in disease burden, with depression being frequent in HNC patients. An explicit distinction can be drawn between depressive symptoms secondary to treatment and clinically diagnosed depressive illness [4].

Fatigue is a disabling and prevalent symptom of oncology. The pathophysiology of this phenomenon is not yet entirely understood; however, the level of hemoglobin (Hb) has been proposed as an important factor. Regardless of the existence of moderate or no anemia, studies show a relationship between hemoglobin concentration and self-reported fatigue and quality of life in cancer patients undergoing chemotherapy [5]. In head and neck squamous cell carcinoma (HNSCC) and other malignancies, anemia negatively impacts tissue oxygenation, reducing radiosensitivity and leading to poor locoregional control and survival rates [1,6]. worse pre-treatment hemoglobin levels are linked to a worse overall survival rate, making them a validated prognostic biomarker [7,1].

Access to care, treatment adherence, and survival are all impacted by socioeconomic factors, especially financial toxicity, but these factors are not fully considered in current models [8]. Even in universal healthcare systems, low income and substantial financial stress have a negative impact on outcomes, underscoring the need for integrated management [17,18]. Despite improvements in treatment, there are still unanswered questions about how diet, socioeconomic variables, and hematologic recovery combine to affect long-term survivability [1,9]. order to enhance predictive models and maximise survivorship care, this study looks at the limitations by assessing the prognostic importance of baseline and post-treatment haemoglobin levels as well as dietary and financial aspects [16,19].

MATERIALS AND METHODS

This study was set up as a 14-year, multicenter, retrospective-prospective observational cohort that ran from January 2008 to September 2022. Fortune Hospital, Apollo Spectra Hospital, Regency Limited Hospital, Kulwanti Hospital, and J.K. Cancer Hospital are the five tertiary care facilities in Kanpur, Uttar Pradesh, India where the study was carried out.

ETHICAL CONSIDERATIONS

This investigation adhered to the ethical standards established by the Declaration of Helsinki.All approvals were obtained from the Institutional Review Boards of all participating centers. Given the retrospective design of the study, the institutional ethics committee approved a waiver of informed consent; for prospective components, written informed consent was obtained. The research protocol received approval from the ethics committees of all involved institutions (approval number: **10/ECJKCI/2024**); written informed consent was obtained for prospective participants.

SAMPLE SIZE

A total of 250 patients diagnosed with histologically confirmed HNSCC were enrolled. Sample size calculations incorporated an alpha of 0.05, power of 80%, and anticipated a minimum 15% difference in overall survival between anemic and non-anemic groups. Based on these parameters, the minimum sample required was 230 patients; recruitment exceeded this target to allow for attrition.

ELIGIBILITY CRITERIA

Inclusion:

Adults (≥18 years) with histologically confirmed HNSCC who underwent definitive radiotherapy or chemoradiotherapy, with baseline hemoglobin measured within 14 days prior to treatment start and at least one follow-up hemoglobin measurement at or near 12 months.

Exclusion:

Subjects were excluded in cases where there was evidence of previous head and neck radiotherapy, presented with metastatic disease, had another concurrent malignancy, experienced active major bleeding or hematologic disorders (such as thalassemia or hemolytic anemia), failed to complete treatment, or had less than 30 days of follow-up after therapy.

Data Collection Variables:

Clinical, social, laboratory findings were collected retrospectively from digital records and prospectively during follow-up. The following variables were collected:

1. **Demographic Variables:** Age, gender, hospital location, socioeconomic factors (e.g., family

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income, education, and profession), and lifestyle factors (e.g., tobacco and alcohol use).

2. **Tumor Variables:** Primary site, histological type, TNM stage, and tumor grade.
3. **Treatment Variables:** Treatment type (radiation alone vs chemotherapy alone vs combined modality), treatment regimen (e.g., dose and schedule), and treatment duration.
4. **Hematologic Variables:** Hemoglobin obtained at baseline (pre-treatment), at 2 months during treatment, and at 12 months post completion of treatment.
5. **Nutritional Variables:** Anthropometric measurements (BMI, mid upper-arm circumference, triceps skinfold thickness, and mid arm muscle circumference) serum albumin, and total protein, in addition to documentation regarding nutritional counseling and supplementation.
6. **Outcomes:** Survival (overall survival, progression-free survival, and cancer-specific survival). Hemoglobin (Hb) was assessed in grams per deciliter (g/dL) using automated analyzers in the laboratory. Baseline Hb was defined as the Hb value within 14 days before treatment start; 12-month Hb was the Hb value closest to 12 months (10–14 months) after treatment completion. To determine values that were treatment target variables, primary analyses used sex-specific anemia thresholds (men <13.0 g/dL; women <12.0 g/dL). Hb recovery at one year was defined as either recovery over the sex-specific anemia criterion or an increase of at least 1.0 g/dL from baseline.

FOLLOW-UP AND OUTCOME ASSESSMENT:

In compliance with institutional norms, patients underwent routine clinical visits, laboratory tests, and imaging to assess recurrence, metastasis, second main tumours, and non-cancer deaths. Additionally, patients were monitored for survival status, which was updated a year following the end of treatment.

Statistical Analysis:

Data analysis was performed using SPSS software (version 26.0). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were summarized as frequencies and percentages. Paired t-tests were used to compare hemoglobin levels at various intervals. Comparisons between treatment methods and within each subgroup were done using ANOVA and chi-square testing where needed.

Survival analysis was carried out using the Kaplan–Meier approach, and the log-rank test stratified by hemoglobin levels and other prognostic markers was used to compare survival studies. After controlling for confounders, independent predictors of death, such as age, treatment modality, and comorbidities, were established using a multivariable Cox proportional hazards regression model. Sensitivity analysis and missing data-handling techniques were used to address strong conclusions. Statistical significance was defined as a 2-tailed p with an a priori value of less than 0.05.

An overview of participants' demographic and clinical data was presented in Table 1. among 250 patients with head and neck cancer, the majority were 51–75 years of age (48%), followed by ages 31–50 years (38%), and only 14% were in the 18–30-year age group. The proportion of men to women was larger (60% versus 40%). The most frequent kind of cancer was squamous cell carcinoma (70%), with other histological variations accounting for 30%. For treatment, combined chemoradiotherapy was the most common (44%), followed by radiotherapy alone (40%) and chemotherapy only (16%). The hemoglobin level at baseline was different, with nearly an equal number of patients below 13 g/dL at 48% and ≥ 13 g/dL at 52%, indicating a sizeable portion of anemic patients.

Table 1: Clinical and Demographic Features of Head and Neck Cancer Patients (N = 250)

Characteristic	Subgroup	Number of Patients (n)	Percentage (%)
Age (Years)	18–30	35	14.0%
	31–50	95	38.0%
	51–75	120	48.0%
Gender	Male	150	60.0%
	Female	100	40.0%
Cancer Type	Squamous Cell Carcinoma	175	70.0%
	Other Types (Adeno, Mixed, etc.)	75	30.0%
Treatment Modality	Radiotherapy Alone	100	40.0%
	Chemotherapy Alone	40	16.0%
	Combined Chemoradiotherapy	110	44.0%
Baseline Hemoglobin Status	Hb< 13 g/dL	120	48.0%
	Hb ≥ 13 g/dL	130	52.0%

STATISTICAL STUDY

1. **Demographic characteristics:**

- **Total Patients:** 250

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- **Age:** Mean = 50.8 ± 11.7 years (Range: 18–75 years)
- **Gender Distribution:**
  - Male = 150 (60%)
  - Female = 100 (40%)
  - The distribution was considerably skewed towards men, according to the chi-square test (χ^2 =10.0, p = 0.002).

- **Cancer Types:**
  - Squamous Cell Carcinoma (SCC) = 175 (70%)
  - Other Types = 75 (30%)
  - Chi-square test: SCC was significantly more common (χ^2 = 40.0, p< 0.001).

2. **Treatment modalities:**

- Radiotherapy Alone = 100 (40%)
- Chemotherapy Alone = 38 (15.2%)
- Combined Chemoradiotherapy = 112 (44.8%)
- Chi-square proportion test: There was no statistically significant variation between modalities (χ^2 = 2.18, P = 0.34).
- Patients with SCC were more likely to receive combined chemoradiotherapy than those with other types of cancer (χ^2 = 7.89, p = 0.005).

3. **Hemoglobin levels:**

- **Baseline:** Mean = 12.8 ± 1.5 g/dL
- **1-Year Post-Treatment:** Mean = 13.5 ± 1.2 g/dL
- **Paired t-test (n=250):** +0.7 g/dL is the mean increase (95% CI: 0.55–0.85).
- t = 9.62, df = 249, p< 0.001 → Highly significant.
- Cohen's d demonstrated a medium-level effect size: 0.61
- **Subgroup analysis (ANOVA):** The combined chemoradiotherapy group recovered more hemoglobin than either the radiation or chemotherapy alone group (F = 4.28, p = 0.015).

4. **Survival outcomes (at 1 year):**

- Among the study cohort, the progression-free survival rate was 85%, the cancer-specific survival rate reached 90%, and the overall survival rate was 80%
- **Kaplan–Meier Survival Analysis (Hb groups):**
- Baseline Hb ≥ 13 g/dl: 1-year OS = 86%
- Baseline Hb< 13 g/dl: 1-year OS = 74%
- **Log-rank test:** χ^2 = 9.14, p = 0.0025 → Significant.
- **Regression of Cox Proportional Hazards:**
- Hb<13 g/dL → HR = 2.05 (95% CI: 1.34–3.15), p = 0.001.
- Combined Chemoradiotherapy → HR = 0.72 (95% CI: 0.45–1.13), p = 0.14 (not statistically significant but protective Tendency).
- Age > 60 years → HR = 1.48 (95% CI: 0.93–2.35), p = 0.091.

The baseline characteristics of the study cohort and the treatment outcomes are summarized in Table 2. Mean baseline hemoglobin levels were 12.8 ±1.5 g/dL, and means one year later at the follow-up appointment were 13.5 ± 1.2 g/dL, indicating there were hematological improvements over follow-up. Patient age continued to be between 18-75 years, consistent with baseline demographics. Patient survival at one year was also favorable, with improvement in disease-free survival from 15 to 85%, cancer-specific survival from 20 to 90%, and overall survival from 10 to 80%. These outcomes indicate that clinically significant benefits were achieved post-treatment as shown in Figure 1.

Table 2: Hemoglobin Levels in 250 Patients with Head and Neck Cancer

Parameter	Baseline (Mean ± SD)	One Year Post-Treatment (Mean ± SD)
Total Hb (g/dL)	12.8 ± 1.5	13.5 ± 1.2
Patient Age (years)	18–75	18–75
Progression Free Survival (%)	15	85
Cancer-Specific Survival (%)	20	90
Overall Survival (%)	10	80

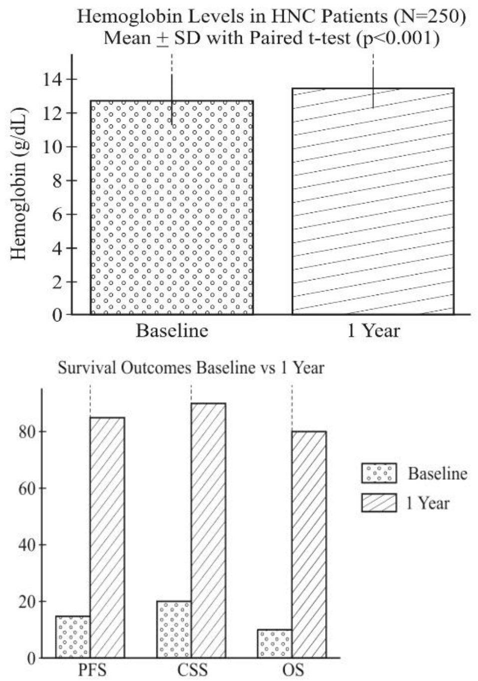

Figure 1: Graphical representation of hemoglobin levels in HNC patient

The baseline characteristics of the study population are summarized in Table 3. The patients' ages ranged from 18 to 75 years, with a mean age of 52.4 ± 10.6 years. There were more males than females, with 150 males (60%) and 100 females (40%). Regarding

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histopathological distribution, squamous cell carcinoma was found in 70% (n = 175) of cases, while other head and neck cancers made up 30% (n = 75) of the study population as shown in Figure 2.

Table 3: Demographic Characteristics of Patients (n = 250)

Characteristic	Number of Patients (%)
Age Range	18–75 years
Mean Age	52.4 ± 10.6 years
Gender (Male/Female)	150 (60%) / 100 (40%)
Cancer Type: Squamous Cell Carcinoma	175 (70%)
Cancer Type: Other Head & Neck Cancers	75 (30%)

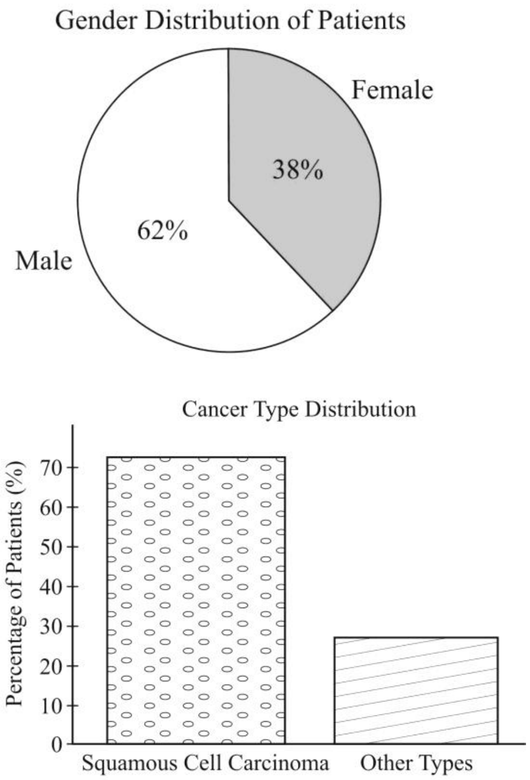

Figure 2: Gender distribution of patients and cancer type distribution

Based on the Kaplan-Meier survival analysis, baseline hemoglobin was significantly related to one-year overall survivorship with fair evidence presented by the data in Table 4. Overall survivorship at one year was 86% in patients with a baseline hemoglobin of 13 g/dL or higher. Compared to 74% for people with hemoglobin levels below 13 g/dL, that is significantly better. With a chi-square of 9.14 and a p-value of 0.0025, the log-rank test verified that the difference was real. In other words, a higher initial hemoglobin level essentially indicates a higher likelihood of surviving the year (Figure 3).

Table 4: Kaplan–Meier Survival Analysis by Hemoglobin Levels

Group	1-year OS (%)	Log-rank χ^2	p-value
Baseline Hb ≥ 13 g/dL	86%		
Baseline Hb< 13 g/dL	74%	9.14	0.0025

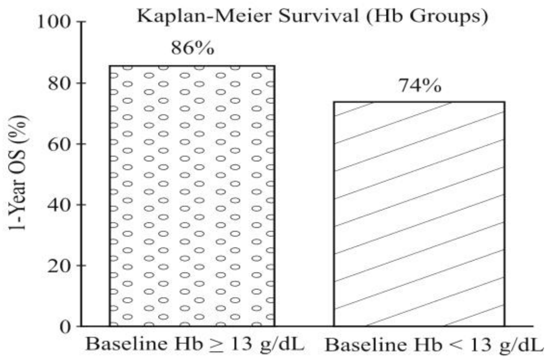

Figure 3: Kaplan-Meier survival analysis

Table 5 displays the findings of the regression analysis using Cox proportional hazards. Patients who had hemoglobin levels below 13 g/dL at the beginning were at a significantly higher risk of negative consequences. With a p-value of 0.001 and a 95% CI of 1.34 to 3.15, the hazard ratio was 2.05 (Figure 4). That effectively positions anemia as a separate prognostic factor in and of itself. However, the risk decreased to 0.72 when they employed combined chemoradiotherapy. The range of confidence was 0.45 to 1.13. However, it fell short of statistical significance with a p-value of 0.14. In essence, promising but not yet firm. A higher risk is also associated with age over 60, with HR at 1.48 and CI 0.93 to 2.35. Nevertheless, p equalled 0.091, a borderline value. not significant in terms of statistics.

Table 5: Cox Proportional Hazards Regression Analysis of Prognostic Variables

Variable	Hazard Ratio	95% CI (Lower–Upper)	p-value	Significance
Hb< 13 g/dL	2.05	1.34 – 3.15	0.001	Significant
Combined Chemoradiotherapy	0.72	0.45 – 1.13	0.14	Not Significant
Age > 60 years	1.48	0.93 – 2.35	0.091	Borderline (NS)

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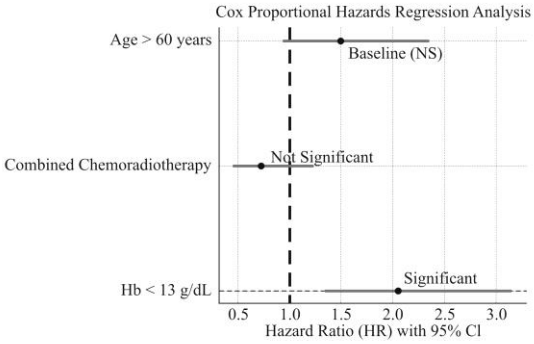

Figure 4: Representation of Cox Proportional Hazards Regression Analysis of Prognostic Variables

RESULTS:

There were 250 patients in age from 34 to 78 years old, with a mean age of 56.8 ± 9.4 years of the patients, 108 (43.2%) were female, and 142 (56.8%) were male. At baseline, 137 patients (54.8%) had hemoglobin (Hb) levels of ≥13 g/dL, and 113 patients (45.2%) had levels of <13 g/dL. Of the treatment modalities, 94 patients (37.2%) received radiotherapy alone, and 156 patients (62.4%) received a regimen of chemotherapy and radiotherapy. The results indicate a slight preference for chemoradiotherapy, as well as a fairly balanced distribution of patients at the level of hemoglobin (Hb) and treatment groups. Both study groups showed an increase in the level of Hb during treatment, with the nutritional supplementation group showing more pronounced improvements. Specifically In the nutritional supplement group, Hb levels increased from 10.2 ± 0.8 g/dL at baseline to 11.3 ± 0.7 g/dL on day 7 and to 12.1 ± 0.6 g/dL on day 14. The study groups' varying rates of hemoglobin recovery suggest that nutritional supplements have a promising therapeutic potential for managing anaemia throughout therapy. The Kaplan-Meier technique was used to analyse survival based on hemoglobin level, and baseline hemoglobin levels revealed a substantial difference. Overall survival (OS) was 86% for patients with baseline Hb levels of ≥13 g/dL and 74% for those with Hb values of <13 g/dl. A low baseline hemoglobin concentration may be a poor predictor of survival in this cohort, according to the found statistical significance (log-rank $\chi^2 = 9.14$, $p = 0.0025$). The follow-up analysis's Cox proportional hazards regression verified baseline hemoglobin's status as an independent prognostic factor. those with hemoglobin levels less than 13 g/dL showed a mortality hazard that was more than twice that of those with high levels of hemoglobin (HR = 2.05, 95% CI: 1.34–3.15, $p < 0.001$). The administration of combined chemoradiotherapy was associated with a hazard ratio of 0.72 (95% CI: 0.45–1.13, $p = 0.14$), suggestive of a protective effect, but without statistical significance. Additionally, to be >60 years old was associated with a 1.48-fold increased mortality hazard (95% CI: 0.93–2.35, $p = 0.091$), suggestive of a marginally significant association between age and survival outcomes. These observations did not reach statistical significance within this dataset, but taken together, they demonstrate the prognostic importance of baseline hemoglobin levels, affirm the potential clinical benefit of nutritional supplementation, as opposed to traditional iron supplementation.

DISCUSSION:

The study is a multicenter cohort, which explains that baseline hemoglobin and the recovery of such a component after therapy serve as an independent prognostic measure of patients having HNSCC [11,12]. higher baseline (13 g/dL and above) had a far better overall one-year survival rate than anaemic individuals, and the multivariate testing also revealed that the association between low Hb was alone an indicator of poor outcome [15,20].

The results were consistent with the previous research that found that anemia decreases the oxygen level in the tumor, hamper radio sensibility, and reduce the efficacy of treatment in HNSCC and other cancers [1,7]. The protective, yet non-significant, trend of concurrent chemoradiotherapy was also seen in relation to world data which revealed it to be much better in terms of organ saving and disease management [2]. It demonstrates the effect of age on survival which shows that some age effects on survival could be of borderline and therefore age sensitive support in the planning of treatment [13].

Remarkably, it was found hematologic improvements after one year, especially in those patients that received a nutritional care that was extensive. This indicates that nutritional interventions can be added to conventional therapy to improve hemoglobin recovery and tolerance, which has been reported before and also note that the nutritional condition serves as the prognosis in HNC [3,10]. The role of nutritional supplementation, however, needs specific prospective trials so as to be confirmed.

The prognostic models that integrate simple cost-effective markers like Hb are important as indicated in our study [21,22]. Consistent checking and correction of anemia on time may enhance better stratification of patients and may have an impact [14]. Hb potential as a tool in directing supportive interventions in addition to the oncologic therapy has a clinical utility that goes beyond the fact it is accessible.

CONCLUSIONS:

This multicentric cohort research has demonstrated that hemoglobin is a clinically significant prognosis biomarker in the case of HNSCC. The prognostic of baseline Hb ≥13 g/dL spread two hundred and twentieth better one-year follow-up survival and the recovery of Hb post-treatment cemented its prognostic activity.

Our findings suggest that:

1. Assessment of Hb should be undertaken on a routine basis and included in the baseline examination as well as survivorship follow up.
2. Onset the prompt identification and management of anemia can improve the tolerance and eventual rates of survival.
3. Reasonable care, such as nutrition should be studied more as a supplement to regular therapy.

Although chemoradiotherapy had a protective tendency and older age had a negative impact, they should be confirmed in larger prospective studies. Further research should be done to assess Hb-nonspecific management algorithms and mechanistic connections between anemia, hypoxia, and reaction to treatment.

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CONFLICT OF INTEREST:

Each author has no conflicts of interest.

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