

## Original Article

# Considerations on nutritional treatment in head and neck cancer patients undergoing concomitant chemo- and radiotherapy

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**ABSTRACT:** Nutritional problems due to oral mucositis in patients with head and neck cancer undergoing concomitant radio-chemotherapy (RT/CT) significantly correlate with outcome. The aim of our prospective study was to investigate the impact of an early and intensive nutritional program, intensive dietary counseling, and enteral nutrition through a nasogastric tube on performance status and quality of life in head and neck cancer patients undergoing RT/CT. Thirty-five consecutive patients with locally advanced, unresectable head and neck cancer who were referred for RT/CT were enrolled. All patients were evaluated for nutritional status (PG-SGA score), serum prealbumin, ECOG performance status and quality of life (measured with EORTC QLQ-C30 version 3.0) before, at the end of, and 1 month after completion of RT/CT. Sixteen patients (46%) were compliant with the nutritional program. Placement of the nasogastric tube was simple, safe and well tolerated by patients. The median duration of enteral nutrition was 31 days (range, 10-93 days). At the end of and 1 month after RT/CT, 94% of compliant patients had maintained or improved their nutritional status, while in all noncompliant patients the nutritional status had worsened at the end of RT/CT, and 1 month later nutritional status had improved in only 1 of them ( $p < 0.001$ ). Nutritional status correlated significantly with ECOG performance status and quality of life. (*Nutritional Therapy & Metabolism* 2006; 24: 176-82)

**KEY WORDS:** Quality of life, Head and neck cancer, Radiotherapy, Enteral nutrition

## INTRODUCTION

Concomitant radio-chemotherapy (RT/CT) in patients with squamous cell head and neck carcinoma (HNC) often produces significant mucositis and dysphagia. RT/CT-induced morbidity (dysphagia, odynophagia, xerostomia, dysgeusia, nausea, vomiting and anorexia) may compromise both nutritional status and functional ability (1-4). Ravasco et al recently demonstrated the association between nutritional status and overall morbidity and quality of life in cancer patients and the positive influence of intensive dietary counseling on outcome for HNC patients undergoing RT (5, 6). Our study investigated the impact of an intensive nutritional program on performance status and quality of life in a group of HNC patients undergoing RT/CT.

## PATIENTS AND METHODS

We enrolled 35 consecutive outpatients (24 men, 11 women), median age 58 years (range, 18-78 years) with locally advanced (stage III and IV) unresectable HNC who were referred for RT/CT. Exclusion criteria were comorbidity (diabetes, liver and kidney failure), history of alcoholism, tracheotomy, mouth sores, severe anorexia, xerostomia, dysgeusia and dysphagia before treatment. The patients' characteristics are described in Table I and the tumor locations in Table II. Treatment consisted of CDDP (5 mg/m<sup>2</sup>/day by intravenous infusion over 24 hours for 5 days) ± 5-FU (200 mg/m<sup>2</sup>/day by intravenous infusion over 24 hours for 5 days) plus external-beam RT (56-70 Gy; 66% >68Gy) for 6-7 weeks. Patients were asked to follow an intensive nutritional pro-

**TABLE I - BASELINE CHARACTERISTICS OF 35 HNC PATIENTS**

Male	24 (69%)
Female	11 (31%)
Mean age (years)	57 ± 14
Median BMI (kg/m <sup>2</sup> )	25.3 (18-31.2)
Median weight loss (%)	2.5 (0-12)
Median PG-SGA score	3 (1-5)
Median ECOG score	0 (1-2)

**TABLE II - TUMOR LOCATION**

Nasopharynx	12 (34%)
Oropharynx	8 (23%)
Base of the tongue	7 (20%)
Submandibular gland	2 (6%)
Palate	2 (6%)
Larynx	1 (3%)
Hypopharynx	1 (3%)
Retromolar region	1 (3%)
Alveolar ridge	1 (3%)

gram during treatment. All patients were evaluated for nutritional status (PG-SGA score) (7), serum prealbumin (normal range 20-40 mg/dL), ECOG performance status, and quality of life (measured with QLQ-C30 version 3.0) (8) before, at the end of, and 1 month after completion of treatment.

### Statistical analysis

For statistical analysis we used SPSS for Windows, release 10.1.0. The analysis compared HNC patients who were compliant with those who were noncompliant with the nutritional program associated with RT/CT. Age and serum prealbumin were expressed as mean ± standard deviation. Serum prealbumin variations were analyzed with the paired Student *t* test. PG-SGA score variations were expressed as the number of patients with a maintained/improved or worsened nutritional status at the end of RT/CT and 1 month later; data were analyzed with the chi-square test. Performance status and quality of life scores were expressed as median values and were analyzed with the Wilcoxon rank sum test. Correlations were analyzed with the nonparametric Spearman test. Significance was reported at the conventional  $p < 0.05$  level.

### Nutritional program

Nutritional requirements were estimated on the basis of nutritional status and degree of catabolism (moderate-severe). In non-malnourished patients (weight loss <10% in the last 6 months or <5% in the last month) the estimated energy requirement was 30 kcal (%EN C:L=60:40) and the protein requirement was between 0.8 and 1.0 g/kg per day. In obese patients we considered theoretical weight. In malnourished patients (weight loss ≥10% in the last 6 months or ≥5% in the last month) we estimated energy requirements between 30 and 35 kcal (%EN C:L=60:40) and daily protein requirements between 1.0 and 1.5 g/kg. The aim of the nutritional program was to enable each patient to achieve his or her calculated energy and protein requirements. Due to oral mucositis (G3-G4), more than 90% of HNC patients undergoing RT/CT drastically reduce their food intake after 2 weeks of treatment (11, 12). For this reason all patients were referred for an intensive nutritional program consisting of:

1. intensive dietary counseling from the start of oncological treatment to the second week of RT/CT;
2. enteral nutrition (EN) by nasogastric tube from the third week of RT/CT;
3. intensive dietary counseling (from nasogastric tube removal to the resumption of normal food intake).

### Intensive dietary counseling

Dietary counseling involved the prescription of a therapeutic diet that used regular foods, which was further modified to provide for individual requirements. The diet was based on the need for an adequate intake and was adjusted both to the individual's preferences and side effects of cancer treatment. Normally we prescribe a hypercaloric and hyperproteic semiliquid or liquid regime (EN% P=20/22, L=35/30, C=45/48). After removal of the nasogastric tube, in case of insufficient oral intake (<30-40% of nutritional requirements) we prescribe a commercial oral nutrition supplement to fulfil the nutritional needs of the patient. We generally use a high-protein, energy-dense liquid polymeric formulation, omega-3 enriched because of the high CRP (C-reactive protein) value. The commercial brand and the flavor of the sip feed depend on patient compliance (9).

### Enteral nutrition

We used a polyurethane nasogastric tube (10 Ch) and a hypercaloric and hyperproteic solution (6.3 g of protein and 125 kcal/100 mL: EN% P=20, L=35, C=45).

When the patient was not compliant with EN we prescribed parenteral nutrition (PN).

### Parenteral nutrition

We used an industrial 3-chamber bag for peripheral parenteral nutrition (2.375 g of protein and 62.5 kcal/100 mL – maximum infusion rate 3-3.7 mL/kg/h). We considered about 20-22 hours of EN and PN infusion a day effective, because artificial nutrition is interrupted during radiotherapy (2 sessions a day). The maximum infusion rate was 110 mL/h (2200 mL/day) for EN and 125 mL/h (2500 mL/day) for PN.

**TABLE III - BASELINE CHARACTERISTICS OF COMPLIANT AND NONCOMPLIANT HNC PATIENTS**

Variable	Compliant patients (n = 16)	Noncompliant patients (n = 19)
Men	11	11
Women	5	8
Age (years)	50 ± 16	63 ± 10
BMI (kg/m <sup>2</sup> )	23.1 (15.2 – 31.2)	26.4 (18 – 34.1)
Weight loss (%)	3 (0 – 12)	0 (0 – 10)
PG-SGA score	3 (1 – 5)	3 (1 – 5)
Serum prealbumin (normal range 20-40 mg/dL)	25 ± 6	25 ± 4
ECOG Performance status	0 (0 – 1)	0 (0 – 2)

Age and serum prealbumin expressed as mean ± SD  
 BMI, % weight loss, PG-SGA score, and ECOG performance status expressed as median (range)

### RESULTS

All patients experienced severe mucositis and dysphagia (G3-G4) and drastically reduced their oral food intake after 2 weeks of RT/CT; only 16 (46%) of the patients were compliant with the proposed nutritional program. In Table III we describe the baseline characteristics of the 16 compliant patients (CPs) and 19 noncompliant patients (NCPs). In CPs the median duration of EN was 31 days (range, 10-93 days) and oral nutrition was resumed within an average of 15 days after the end of RT/CT. None of the CPs had any oropharyngeal complications in addition to those related to treatment. The only complication was the accidental removal of the nasogastric tube in 4 patients (25%); in all cases we immediately inserted a new nasogastric tube without interruption of EN (Tab. IV). The NCPs refused both insertion of a nasogastric tube and percutaneous endoscopic gastrostomy and reduced their food and water intake dramatically after 4 weeks of RT/CT. Eighteen (95%) of them were admitted to hospital because of severe dehydration and malnutrition. All admitted NCPs needed PN, because they still refused percutaneous endoscopic gastrostomy or nasogastric tube insertion during their stay in hospital. In case of PN during chemotherapy infusion through a totally implanted device (TID), we did not use the TID to infuse PN because of the high incidence of bacterial and fungal leukopenia-related infections in these patients. One of the NCPs continued on a liquid diet plus sip feeds, but he had to stop anticancer treatment definitively. All CPs reached their nutritional requirements, whereas only one NCP did (p<0.001; Tab. V).

**TABLE IV - ENTERAL NUTRITION DURATION AND ACCIDENTAL NASOGASTRIC TUBE REMOVAL**

Gender	Cancer location	EN duration (days)	Accidental removal
Male	Nasopharynx	37	No
Male	Tongue	53	No
Male	Alveolar ridge	39	No
Male	Larynx	60	No
Male	Tongue	50	No
Female	Nasopharynx	14	Yes
Male	Retromolar region	30	No
Female	Oropharynx	22	No
Male	Nasopharynx	42	No
Female	Oropharynx	10	No
Male	Oropharynx	10	No
Female	Oropharynx	23	Yes
Male	Hypopharynx	15	No
Male	Nasopharynx	93	Yes
Male	Oropharynx	15	No
Male	Nasopharynx	35	Yes

### Nutritional status

Involuntary weight loss (median 2.5%, range, 0-12%) was observed in 53% of patients before treatment. The median PG-SGA score before treatment was 3 (range, 1-5). At the end of RT/CT, 90% of CPs had maintained or improved their nutritional status, with a body weight recovery of  $1.1 \pm 2.9$  kg, whereas all surviving NCPs had a worsened nutritional status with a weight loss of  $11 \pm 5.5$  kg ( $p < 0.001$ ). Thirty days after completion of RT/CT 90% of CPs maintained their nutritional status and weight ( $-0.4 \pm 1.3$  kg), whereas 83% of NCPs had a worsened nutritional status and continued to lose weight ( $-1.7 \pm 3.8$  kg) ( $p = 0.033$ ) (Tab. VI).

### Serum prealbumin

At baseline, the mean value  $\pm$  SD of serum prealbumin in the enrolled patients was  $25.3 \pm 5.0$  mg/dL. In CPs, serum prealbumin had not changed significantly at the end of RT/CT (mean  $\pm$  SD  $26.8 \pm 6.4$  mg/dL,  $p = 0.876$ ) and 1 month later (mean  $\pm$  SD  $29.1 \pm 5.5$  mg/dL,  $p = 0.236$ ). In surviving NCPs, serum prealbumin had decreased significantly at the end of RT/CT (mean  $\pm$  SD  $17.6 \pm 1.2$ ,  $p < 0.001$ ) and 1 month later (mean  $\pm$  SD  $19.3 \pm 2.5$ ,  $p = 0.029$ ).

### ECOG performance status

At baseline the median score in all patients was 0 (range, 0-2). At the end of RT/CT and 1 month later, in

CPs ECOG performance status had not changed significantly (median 0, range 0-1;  $p > 0.062$ ). Conversely, in surviving NCPs the ECOG score had worsened significantly at the end of RT/CT (median 2, range 1-2) ( $p < 0.022$ ) and one month after (median 2, range 1-2;  $p < 0.018$ ) and this was correlated with the serum prealbumin reduction ( $r = -0.682$ ,  $p = 0.002$ ).

### Quality of life

The median quality of life scores for compliant and noncompliant patients are listed in Table VII. At baseline the differences between CPs and NCPs were not significant. At the end of RT/CT, in CPs, despite RT/CT-induced symptoms, the global health status score had improved significantly ( $p < 0.020$ ), whereas in NCPs it had worsened ( $p < 0.022$ ), and this was proportional to the serum prealbumin reduction ( $r = 0.759$ ,  $p = 0.001$ ). Physical function did not change significantly in CPs ( $p > 0.054$ ), whereas in NCPs it worsened significantly ( $p < 0.020$ ). Role function worsened significantly only in NCPs ( $p < 0.022$ ). Emotional function improved significantly in CPs ( $p < 0.020$ ), whereas it worsened in NCPs ( $p < 0.022$ ). As regards symptom scales and single items, at the end of RT/CT all HNC patients experienced fatigue, pain, nausea and anorexia. One month after the end of RT/CT, in CPs all quality of life function scores improved significantly ( $p < 0.020$ ), whereas in NCPs they worsened ( $p < 0.020$ ). All symptom scores and single items improved in CPs: fatigue ( $p < 0.018$ ), pain ( $p < 0.020$ ), nausea ( $p < 0.018$ ) and anorexia ( $p > 0.046$ ). In

TABLE V - ENERGY INTAKE DURING ARTIFICIAL NUTRITION (AN)

Patients	AN	Energy estimate (kcal)	mL - day infused (mean $\pm$ SD)	Energy infused (kcal)	Difference (%)
CP	EN	1860 (1410 - 2380)	1885 $\pm$ 299	1860 (1410 - 2380)	0
NCP	PN	1890 (1380 - 2160)	2471 $\pm$ 92	1563 (1380 - 1563)	-17 (0/- 28)

TABLE VI - CHANGES OF PG-SGA SCORE AT THE END OF CT/RT AND AFTER 1 MONTH

	Compliant patients*				Noncompliant patients**			
	Worsened		Maintained / Improved		Worsened		Maintained / Improved	
	End CT/RT	1 month	End CT/RT	1 month	End CT/RT	1 month	End CT/RT	1 month
PG-SGA	1	1	15	15	17	12	0	2

\*Surviving CPs at the end of CT/RT: 16; 1 month later: 16

\*\*Surviving NCPs at the end of CT/RT: 17; 1 month later: 14

NCPs, symptom scores, with the exception of pain, remained as poor as reported at the end of RT/CT and were significantly worse than at baseline ( $p < 0.022$ ); this deterioration was proportional to serum prealbumin reduction ( $r = -0.697$ ,  $p = 0.003$ ).

### Mortality

Five of the NCPs died (2 due to septic complications, 1 due to cachexia, 1 due to ARDS and 1 due to aspiration pneumonia, while none of the CPs died ( $p = 0.049$ ). In the patients who died, median serum prealbumin was 9 mg/dL (range, 9-20 mg/dL). Forty-two percent of patients with serum prealbumin less than 20 mg/dL died, but the correlation between serum prealbumin and mortality was not significant ( $p = 0.089$ ) (Fig. 1).

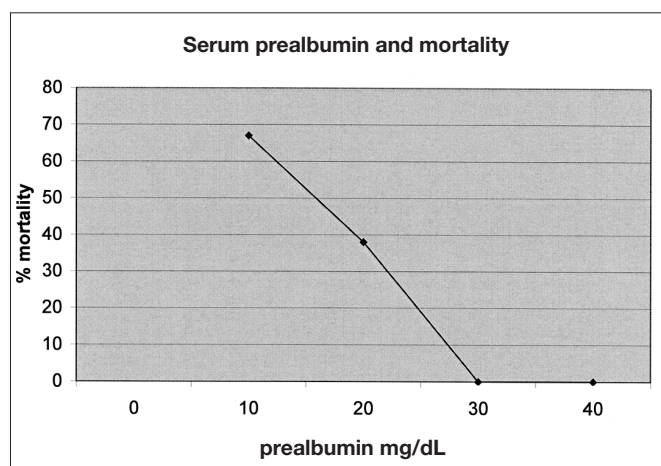


Fig. 1 - Correlation between serum prealbumin and mortality.

### DISCUSSION

Our data may be useful to generate some considerations about nutritional treatment in HNC patients undergoing concomitant RT/CT treatment. Unfortunately, nutritional intervention is not the routine in these patients. Ravasco recently demonstrated the impact of nutritional status on outcome in HNC patients undergoing radiotherapy, but in this study patients received sequential instead of concomitant RT/CT; in fact, all patients had been previously treated with chemotherapy (5-fluorouracil + cisplatin + folinic acid-based regimen) (6).

Radiation-induced toxicity consists more frequently of mild to moderate mucositis (G1-G2), in which case oral nutrition (semiliquid or liquid diet) is still possible. In our study all patients received concomitant RT/CT. With such treatment, according to the WHO and NCI-CTC systems (11, 12), more than 90% of patients are expected to develop severe oral mucositis (G3-G4), resulting in the impossibility to eat or drink for a long time. This raises the following questions: When should nutritional support be started? How should it be given? At present,

TABLE VII - MEDIAN QLQ-C30 SCORES

Items	Compliant patients			Noncompliant patients		
	Baseline	CT/RT end	1 month	Baseline	CT/RT end	1 month
Function scale						
Physical function	87	80	90	87	27	33
Role function	67	67	83	67	33	17
Emotional function	58	83	92	58	25	25
Social function	67	67	83	50	33	33
Cognitive function	92	83	90	75	33	33
Symptom scales						
Fatigue	11	33	17	17	67	67
Pain	9	67	17	17	83	67
Nausea and vomiting	0	33	17	9	67	67
Symptoms single items						
Dyspnea	0	17	0	0	67	17
Insomnia	33	67	17	33	67	67
Appetite loss	33	50	17	33	67	67
Constipation	0	10	0	0	0	0
Diarrhea	0	0	0	0	0	0
Financial difficulties	0	0	0	0	0	0
Global health status	50	67	83	58	33	33

the preferred route of nutritional support for patients with HNC undergoing RT/CT is EN (13-16). In our experience, in patients who refused nasogastric tube insertion and percutaneous endoscopic gastrostomy, peripheral PN was insufficient. The more frequent risks associated with PN are leukopenia-related infections and the difficulty to reach the nutritional requirements because of the fluid overload risk; in fact, during artificial nutrition all HNC patients also receive antibacterial and antifungal solutions by infusion (not less than 500 mL a day). In addition, the nutritional requirements and duration of artificial nutrition in HNC patients do not allow the use of a peripheral vein; furthermore, the central vein must only be used for chemotherapy administration because of the high risk of catheter infection or obstruction. For these reasons we think that in HNC patients undergoing RT/CT the nutritional requirements are hard to meet with PN. For EN, 2 commonly used methods are nasogastric tube feeding and percutaneous endoscopic gastrostomy. Which is better? Mekhail and many others concluded that, although patients treated for HNC find percutaneous endoscopic gastrostomy a more acceptable route for EN than a nasogastric tube, percutaneous endoscopic gastrostomy was required for longer times and was associated with more persistent late dysphagia and increased need for pharyngoesophageal dilatation (16-19). On the other hand, many authors think that percutaneous endoscopic gastrostomy, frequently created before treatment, is the primary route of nutrition in these patients (20). The cosmetic effect, social issues for the patient, and oropharyngeal lesions related to nasogastric tube and long-term EN (more than 2 to 3 weeks) are the main reasons to prefer percutaneous endoscopic gastrostomy (21). The central question is whether nasogastric tube feeding is likely to maintain or improve the quality of life of HNC patients during RT/CT. Relative to cosmetic problems, we think the visual effect of severe RT-induced dermatitis is more depressing than a properly positioned nasogastric tube. In our experience, nasogastric tube insertion was simple, safe and well tolerated; we did not observe any other local or general side effects like irritation, ulceration, bleeding, or vomiting than in the noncompliant group. All CPs reached their nutritional requirements. The only complication was the accidental removal of the nasogastric tube in 4 patients, which is certainly less dangerous than some complications of percutaneous endoscopic gastrostomy. The median duration of EN was 31 days and oral nutrition was resumed within a few days (mean 15 days). We observed only persistent dysphagia in a patient submitted to PN; in this patient percutaneous endoscopic gastrostomy was done for long-term EN (more than 24 months until now). Only patients who followed

the nutritional program significantly improved their performance status and all quality of life function scores, with a reduction of all symptom and single-item scores, whereas the noncompliant patients had a significantly worsened function and maintained poor fatigue, nausea and anorexia scores in association with their nutritional status deterioration.

## CONCLUSIONS

Our data suggest that an early and intensive nutritional approach in HNC patients undergoing RT/CT may improve performance and quality of life. The association of intensive dietary counseling with EN makes the nasogastric tube an efficacious choice. A randomized prospective trial is needed to test these observations.

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Received: August 9, 2006

Accepted: October 17, 2006