Head and neck cancer patients treated with concomitant chemoradiotherapy involving the oral cavity and oropharynx: is another choice possible than prophylactic gastrostomy?

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Purpose of review
Recent recommendations on cachexia highlight, in head and neck cancers, the heterogeneity of studies, focusing on weight loss and sequelae including swallowing disorders. The current national guidelines emphasize that, in cases of concurrent chemoradiotherapy (cCRT) involving the oral cavity and oropharynx, prophylactic gastrostomy placement should be carried out systematically. We review why this technique is particularly relevant in this specific location for the feasibility of cCRT.

Recent findings
A randomized trial is underway on swallowing disorders and the quality of life of patients after prophylactic vs. reactive gastrostomy in advanced oropharyngeal cancer patients treated with CRT. Concurrently, recent literature reviews emphasize the importance of the cumulative dose of chemotherapy for local control and survival. In cases of cCRT involving the oral cavity or the oropharynx, nutritional support could have a beneficial or detrimental impact on chemotherapy.

Summary
Specifically for patients treated with cCRT involving the oral cavity and oropharynx, prophylactic gastrostomy would be able to fulfill the three objectives of local control, survival, and quality of life, minimizing complications related to nutritional support. Studies need to be more homogeneous. In clinical practice, nutrition should primarily assist in carrying out cancer treatment when survival is the main goal.

Keywords
chemoradiotherapy, head and neck cancer, nutrition, prophylactic gastrostomy, supportive care, tube feeding

INTRODUCTION

In 2017, France witnessed the diagnosis of 15 000 new cases of head and neck cancer, with a staggering 75% of them affecting men [1]. The incidence of these cancers has surged, especially among women, owing to an uptick in tobacco and alcohol consumption. Additionally, a higher prevalence of human papillomavirus (HPV) infections has been linked to the increased occurrence of these cancers [2].

The primary mode of treatment for patients involves chemoradiotherapy, sometimes coupled with surgery. The widespread adoption of concurrent chemoradiotherapy (cCRT) and intensified radiotherapy in the late 1990s and early 2000s has proven to yield significantly improved locoregional control and overall survival compared to radiotherapy alone. However, this approach comes with a notable surge in side effects [3,4]. Consequently, the potential for severe acute adverse effects to increase treatment interruptions exists, thereby compromising disease-free survival and overall survival [5].

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Curr Opin Oncol 2024, 36:128–135

DOI:10.1097/CCO.0000000000001031

KEY POINTS

- Patients treated with cCRT involving the oral cavity and oropharynx experience specific and severe acute toxicities that cannot be ignored.
- A systematic and coordinated nutritional management is necessary and should be done prior to cancer treatments.
- Prophylactic gastrostomy could participate to achieve all three objectives of local control, survival, and quality of life, while also minimizing complications associated with nutritional support during treatments.

Among the acute severe effects, impaired eating or swallowing is a common issue, often necessitating the initiation of enteral nutrition during cCRT. Despite this, the paramount objective remains cancer treatment, and artificial nutrition should never jeopardize the oncologic treatment. The national guidelines of the Société Francophone de Nutrition Clinique et Métabolisme (SFNCM), published in 2012 and incorporating personalized care plans [6], emphasize that in cases of cCRT involving the oral cavity and oropharynx, prophylactic gastrostomy placement should be systematic [7]. This practice aims to enhance the quality of life and optimize the delivery of oncologic treatment by reducing treatment interruptions. Recently, the European Society for Medical Oncology (ESMO) clinical practice guidelines on cancer cachexia in adult patients, focusing on body weight and weight loss, have been published [8].

Since 2012, the clinical nutrition team at the Montpellier Cancer Institute (ICM) has followed the national guidelines for patients treated for head and neck cancer. This includes the systematic insertion of a prophylactic gastrostomy before beginning cCRT involving the oral cavity and oropharynx. As part of a physiotherapy study on the prevalence of trismus [9], our objective was to assess our enteral nutrition management in patients undergoing cCRT and the significance of prophylactic gastrostomy.

MATERIALS AND METHODS

This evaluation was carried out at the Montpellier Cancer Institute based on the prospective trial entitled: "Trismus occurrence and preventive physiotherapy associated with patient education for patients treated with concomitant chemoradiotherapy for a head and neck cancer" (PHRIP -15–0526, NCT 03979924). The study protocol was approved by the ethics committee (Comité de Protection des Personnes Sud Méditerranéen III, 1 June 2016) and by an institutional review board. It complied with the Declaration of Helsinki and the requirements of good clinical practice.

Patients

Inclusion criteria encompassed patients with head and neck cancers who met the following conditions: age at least 18 years, patients understanding French, histologically proven squamous cell carcinoma of the oral cavity, oropharynx or cavum and planned treatment with radiotherapy at least 54 Gy, including the oropharynx with concomitant chemotherapy, with or without prior surgery. Patients were not included if they had no medial or lateral incisors, or had previous condition or trauma affecting jaw mobility with permanent trismus, or metastases. Moreover, if they had a legal incapacity to participate and medical or psychological conditions interfering with their consent, they were not included. All patients were informed and gave written consent before the start of the study.

Treatments

Oncologic treatments in this study were not study-specific but adhered to the standard of care at ICM, Montpellier, as determined by the multidisciplinary tumor committee. Radiotherapy, administered through Intensity-Modulated Radiation Therapy (IMRT), utilized Volumetric-Modulated Arc Therapy (VMAT) with a RapidArc planning and delivery system. All patients received concomitant chemotherapy in accordance with established protocols, and decided by a multidisciplinary tumor committee.

Since 2016, a specialized nurse coordinated all patients diagnosed with head and neck cancer. The coordination includes internal connections with all support care teams and the link with the patient while at home, professionals and caregivers.

Nutrition

Patients at ICM, Montpellier, underwent treatment in accordance with the established standard of care. Regarding the gastrostomy process, as per national guidelines [7], the radiotherapy team systematically proposed and endorsed prophylactic gastrostomy before cCRT involving the oral cavity and oropharynx. Prophylactic gastrostomy was defined as the placement of a gastrostomy tube before treatment regardless of the nutritional status. A dedicated consultation with a gastroenterologist followed, during which the patient signed a routine, procedure-specific consent. Gastrostomy insertion, performed under local or general anesthesia based on

individual circumstances, employed an introducer technique. Patients were admitted to the hospital overnight for postprocedural monitoring, ensuring the absence of serious adverse effects and optimizing pain control, a common concern postprocedure. Enteral nutrition was initiated on the evening of insertion, serving both to ensure the safety of the process and to reassure patients about its tolerance. In cases of malnutrition, enteral nutrition continued at home after gastrostomy placement. If the patient was not malnourished, enteral nutrition was then interrupted.

Regarding the enteral nutrition process, the overarching goal for all patients was to maintain nutritional status, aiming for an average intake of 25–30 kcal/kg body weight/day. This was adjusted based on the patient's current oral intake, following established guidelines [7,8]. The team outlined a protocol for enteral nutrition in alignment with guidelines [10]. Nutritional monitoring was a collaborative effort involving the dedicated nurse coordinator, the home service provider, and private practitioners. National guidelines defined malnutrition for patients with weight loss exceeding 5% or a BMI below 18.5 for patients under 70 years old or below 21 for patients aged 70 years or above [7]. Without malnutrition, patients initiated enteral nutrition under the guidance of the dietitian when indicated. Indications for initiation included weight loss or a decrease in food intake based on a verbal scale less than 8/10 [7,11].

Table 1. Clinical features and habits of included patients at baseline

Feature	*n* = 45
Age (years), median [range]	61 [41–77]
Sex	n (%)
Male	35 (77.8)
Female	10 (22.2)
Location	
Oropharynx	33 (73.3)
Oral cavity	9 (20.0)
Cavum	3 (6.7)
Previous surgery	15 (33.3)
WHO performance status	
0	24 (54.6)
1	14 (31.8)
2–3	6 (13.6)
Missing	1
Smoking status	
Nonsmoker	7 (15.6)
Former smoker	30 (66.7)
Smoker	8 (17.8)
Alcohol consumption	
None	15 (33.3)
Former drinker	11 (24.4)
Current drinker	19 (42.2)

Evaluation criteria and statistical method

The primary objective was to assess our management of artificial nutrition in patients with head and neck cancer undergoing cCRT involving the oral cavity and oropharynx. This evaluation aligned with the Nutritional Care Personalized Plan ("Plan Personnalisé de Soins", PPS4) outlined in the SFNCM guidelines [6]. Our inquiry aimed to determine the proportion of patients who underwent gastrostomy, required artificial nutrition, the duration of such nutrition, and whether nutrition-related treatment disruptions occurred.

Quantitative variables were presented as means with 95% confidence intervals or medians with extreme values.

RESULTS

Patients and oncological treatments

Between October 20th, 2016, and December 31st, 2017, our study enrolled 45 patients (Table 1) [9]. The median age was 61 years (range: 41–77), with a predominant male representation at 77.8%. The primary tumor locations were predominantly in the oropharynx (73.3%) or oral cavity (20.0%). Most patients exhibited a WHO performance status of 0 (54.6%) or 1 (31.8%), while 13.6% had a WHO status of 2 or 3. Notably, 33% of patients underwent surgery before the initiation of cCRT. Two postsurgery patients from the University Hospital had a gastrostomy in place when attending radiotherapist consultations. The median radiotherapy dose was 70 Gy (range 60–70) delivered in a median number of 35 fractions (range 30–35) during a 6 to 7-week period. All patients except one expected a chemotherapy based on cisplatin ($n = 36$) or cetuximab ($n = 8$) (Table 2).

Nutrition

In the realm of nutrition, all 45 patients were systematically offered prophylactic gastrostomy before the beginning of cCRT, and 43 patients (96%) accepted. The mean time for gastrostomy placement before cCRT was 13 days (range: 3–41). Two

Table 2. Dose reduction of chemotherapy

Chemotherapy	Expected[a]	Finally done
PG[b] ($n=31$)	CDDP[d], $n=21$ Cetuximab[e], $n=5$ TPF[f] + CDDP, n = 4 CDDP + Elabenzumab/placebo, $n=1$	Complete: $n=17$ Dose reduction: $n=13$ CDDP, 2 courses or cetuximab $\geq$ 6 courses, $n=12$ CDDP, 1 course or cetuximab < 6 courses, $n=1$ No chemotherapy : $n=1$
EnPG[c] ($n=12$)	CDDP, $n=7$ Cetuximab, $n=2$ CDDP + Elabenzumab/placebo, $n=2$ TPF + carboplatin/5FU, $n=1$	Complete: $n=5$ Dose reduction: $n=7$ CDDP, 2 courses or cetuximab 6 or 7 courses, $n=6$ CDDP, 1 course or cetuximab < 6 courses, $n=1$
No PG	CDDP = 1 Cetuximab = 1	Dose reduction : $n=2$ CDDP, 2 courses and cetuximab, 7 courses,

[a]Chemotherapy initially decided by multidisciplinary tumor committee.
[b]PG: prophylactic gastrostomy, inserted before cCRT.
[c]EnPG: malnourished patients with enteral nutrition before cCRT.
[d]CDDP: Cisplatin 100 mg/m^2 on days 1, 22, 43.
[e]Cetuximab 400 mg/m^2 loading dose 1 week before followed by seven weekly infusions of 250 mg/m^2.
[f]TPF: docetaxel + cisplatin + 5-fluorouracil.

operated patients already had the gastrostomy in place at their initial consultation with the radiotherapist.

Before cCRT, 12 malnourished patients (26.7%) received enteral nutrition through prophylactic gastrostomy (EnPG group), while 31 nonmalnourished patients (68.9%) did not receive enteral nutrition (PG group). Two nonmalnourished patients (4.4%) did not have a prophylactic gastrostomy, because of one refusal and one contraindication.

At the end of the follow-up, 40 out of 45 patients (89%) had received enteral nutrition. The mean total duration of enteral nutrition was 198.5 days (range: 35–1548), with a median of 124.5 days.

(1) EnPG group ($n=12/45$, 26.7%): The mean total duration of enteral nutrition was 202.6 days (range: 84–557), with a median of 295.5 days. The gastrostomy was removed at a mean of 288 days after the end of cCRT (range: 84–666). For three patients, the tube remained in place until death due to progressive disease.
(2) PG group ($n=31/45$, 68.9%): Enteral nutrition commenced at a mean of 25.8 days (range: 1–51) after day 1 of cCRT. The mean total duration of enteral nutrition was 168.4 days (range: 35–1548), with a median of 93.5 days. The gastrostomy was removed at a mean of 113.8 days after the end of cCRT (range: 2–555). Among these 31 patients, five did not receive enteral nutrition (16.1%).
(3) Two nonmalnourished patients (4.4%) did not receive a prophylactic gastrostomy: For the patient who refused, a gastrostomy was inserted during cCRT, 32 days after day 1, for a duration of 213 days. For the contraindicated patient with parenteral nutrition first, a nasogastric tube was inserted 32 days after the beginning of cCRT for a duration of 66 days.

Gastrostomy-related complications, hospitalization and chemotherapy dose reduction

Major complications occurred for two patients with prophylactic gastrostomy before cCRT:

(1) An infectious complication observed 4 days after placement (induration and discharge), treated with amoxicillin/clavulanic acid for 7 days. The patient started treatment as planned 1 week after gastrostomy insertion.
(2) One patient required surgical repositioning the day after insertion because it was located outside the stomach in contact with the greater curvature. Surgical repositioning by mini-laparotomy took place without infectious or hemorrhagic complications. The patient started treatment 10 days later than originally planned.

No major complications related to the gastrostomy occurred during cCRT.

Fourteen emergency hospital admissions ($n=12$ patients) were observed for various reasons, including dehydration ($n=4$), febrile neutropenia ($n=3$), infection of central venous device ($n=2$), general deterioration ($n=1$), hematemesis ($n=1$), pneumopathy ($n=1$), diabetes ($n=1$) and falls ($n=1$). Hospitalization rates were 25% in the EnPG group (3/12 patients), 22.5% in the PG group (7/31 patients) and

100% in the group without prophylactic gastrostomy (two patients). For the two patients without prophylactic gastrostomy, 1-week emergency hospitalization was necessary for the patient who initially refused due to nutritional and dehydration problems, leading to the insertion of a gastrostomy. The second patient with parenteral nutrition required 1-week hospitalization for the decompensation of diabetes related to parenteral nutrition. One week later, a central venous device infection was identified.

Regarding chemotherapy (Table 2), 22 patients (48.9%) received all expected chemotherapy, with 17/31 (54.8%) in the PG group, 5/12 (41.6%) in the EnPG group, and none in the group without gastrostomy ($n = 2$). The others received two courses of cisplatin (CDDP) (200 mg/m^2) and six or seven courses of cetuximab, except for two patients in the PG group and one patient in the EnPG group. One patient did not receive any chemotherapy (PG group) due to the identification of a central venous device infection, subsequently developing pneumopathy. Ultimately, this patient underwent radiotherapy alone.

DISCUSSION

In our cohort of head and neck cancer patients undergoing cCRT involving the oral cavity and oropharynx, a substantial 96% accepted prophylactic gastrostomy. The average duration of enteral nutrition was approximately 6.5 months. For patients without preexisting malnutrition ($n = 33$), the initiation of enteral nutrition generally occurred between the third and fourth weeks of cCRT, with 85% of patients who used enteral nutrition ($n = 28$ patients). The average duration of enteral nutrition spanned approximately 5.5 months. No gastrostomy-related complications were identified after starting cCRT for patients with prophylactic gastrostomy.

Prophylactic gastrostomy was introduced in our center in 2001 to reduce treatment interruptions caused by either malnutrition or the occurrence of nutritional complications [12]. Cumulative duration of treatment interruption for toxicity was 100 days with prophylactic gastrostomy vs. 236 days without prophylactic gastrostomy [12]. As we reflect on our two-decade experience and align our practices with the current literature and international guidelines, the fundamental question persists: how can we maximize chemotherapy administration during radiotherapy, especially when patients may face challenges in eating or drinking in the coming weeks?

This ongoing debate underscores the differing perspectives between oncologists and nutritionists. The key considerations include the main treatment goals of oncologists, focusing on locoregional control and survival, contrasted with the concerns of nutritionists who emphasize weight loss and swallowing difficulties [8]. A recently published ongoing trial seeks to compare prophylactic gastrostomy vs. reactive gastrostomy in terms of their impact on swallowing function [13▪]. The potential risk is that a technique deemed essential in specific situations might be at risk of fading away due to these contrasting viewpoints.

The essential goal of this discussion is to bridge the gap between these perspectives, fostering collaboration to optimize patient care. The prophylactic gastrostomy, despite being a valuable tool in preventing treatment interruptions, must be considered within the broader context of individual patient needs, treatment goals and potential complications.

In 2004, two pivotal similar phase III randomized studies, led by Bernier and Cooper, highlighted the superiority of cCRT with cisplatin (100 mg/m^2 on Days 1, 22 and 43) over radiotherapy alone for locally advanced head and neck cancer patients initially treated with surgery [3,4]. The introduction of cisplatin, however, resulted in a notable increase in the incidence and severity of acute toxicity. The challenging nature of these side effects, including difficulties in eating, altered taste and smell, food aversion, loss of appetite, oral mycosis, severe pain requiring morphine therapy and the need for specific appliances to manage dental problems, emphasized the impact of the location of cCRT. Bernier included on average 56% of oral, oropharyngeal tumor and Cooper on average 70%. Severe acute adverse side effects in the cCRT group were 41 and 77%, respectively. Another example, severe acute side effects for locally advanced oropharyngeal cancer treated by cCRT were 80% of grade 3 mucositis and 70% grade 3 dysphagia [14]. For oropharyngeal cancer, the use of cisplatin or cetuximab in cCRT demonstrated similar effects on acute severe grade 3 or more toxicity with 80% incidence for cisplatin and 78% for cetuximab [15]. In this study, 66% of patients had planned percutaneous gastrostomy insertion before treatment [15]. On the contrary, larynx tumors treated with cCRT exhibited fewer grade 3 or 4 acute toxic effects. For example, a phase 2 study utilizing induction chemotherapy and cCRT with cetuximab reported 26% mucositis and 5% dysphagia [16]. However, many studies encompassed tumors from various locations, making it challenging to isolate the specific effects on oral cavity or oropharyngeal cancers.

Furthermore, the cumulative dose of cisplatin emerged as a crucial factor for both survival and

locoregional tumor control. The delivery of a cumulative cisplatin dose of 200 mg/m^2 is a major goal, the optimal standard exposure being 300 mg/m^2 [17▪]. A statistically significant association between cumulative cisplatin dose and improved overall survival was observed for higher doses from prospective randomized trials [18]. Therefore, complications arising during cCRT, such as infections, surgery, dehydration, might necessitate an interruption of chemotherapy, impacting the ability to achieve the desired cumulative dose and compromising the potential for recovery.

It is therefore crucial to consider nutrition as a factor that should enable the patient to benefit from the best possible oncological treatment. Under no circumstances should the approach or nutrition worsen the patient's condition to the extent that premature cessation of cCRT becomes necessary. In fact, the question does not concern malnourished patients. Currently we know that weight loss, low muscle mass index, a decrease in oral intake are poor prognostic factors [19,20]. Therefore, in case of malnutrition, the use of enteral nutrition in accordance with guidelines, and the preference for prophylactic gastrostomy comparatively to nasogastric tube, in the case of cCRT involving the oral cavity and oropharynx, reflects a balance between improving nutritional status and preserving quality of life [21]. In our study, all malnourished patients received enteral nutrition during 6–7 months on average. The acknowledgment that prophylactic gastrostomy might extend the duration of enteral nutrition compared to nasogastric tube placement is an important practical consideration. Similarly, it is the same for the prevention of swallowing disorders and trismus [9].

The critical question arises concerning nonmalnourished patients at the outset. Should prophylactic gastrostomy be proposed for them, considering potential future side effects of cCRT involving the oral cavity and oropharynx? This question opens up a discussion about various options, such as reactive gastrostomy, reactive nasogastric tube placement, reactive parenteral nutrition, or no nutrition support until the end of cCRT. The detailed exploration of different nutritional support strategies in head and neck cancer patients undergoing cCRT is insightful and raises critical considerations.

Reactive gastrostomy

In our study, 96% of patients accepted prophylactic gastrostomy. Are there risks associated with gastrostomy insertion? We encountered two major complications (4.5%) before the commencement of treatment, despite the team's experience. Complications following gastrostomy tube insertion in patients with head and neck cancer are common, ranging from 6 to 9% for major complications [22]. What if these complications had arisen during the treatment? In our study, we performed one gastrostomy insertion during the treatment, without specific complication, leading to the cessation of chemotherapy. Consequently, there could be a compromised disease-free survival for this patient. We think that reactive gastrostomy should not be recommended during treatment because, in case of complications, chemotherapy may be interrupted, and the primary objective of completing the cCRT to prevent recurrence might not be achieved. It might be advisable to inform patients before starting cCRT involving the oral cavity and oropharynx that approximately 85% of patients will require artificial nutrition (26 out of 31 patients in our series for an average duration of 5.6 months). Decisions could be made collaboratively with patients regarding the best strategy before and during cCRT. This approach also allows patients to be informed that, in some cases (approximately 15%), a gastrostomy may be placed even though artificial nutrition will not be necessary.

Parenteral nutrition

This is the same concern regarding reactive gastrostomy: in cases involving chemotherapy and parenteral nutrition, 87% of patients experienced chills or body temperature variations [23]. In this observational study, the median interval between the end of hospitalization and the first episode of chills was 11 days, leading to the removal of the implantable site in 22% of cases. If chemotherapy is interrupted, the primary objective of completing the treatment to prevent recurrence may not be achieved. In our study, two patients experienced infections of the central venous device: for one, chemotherapy was not administered, and for the other, it was reduced.

Reactive nasogastric tube

This is probably the preferable option for completing oncologic treatment in cases where prophylactic gastrostomy was not inserted. This approach is also endorsed by numerous teams globally [24]. While many teams worldwide use nasogastric tubes, a recent meta-analysis, limited by only including five studies (three randomized studies) with highly diverse definitions of prophylactic gastrostomies and reactive enteral nutrition (gastrostomies or nasogastric tubes), was conducted ($n = 298$) [21]. Among them, one study randomized patients to prophylactic gastrostomy vs. clinical practice [25]. Although the difference was not statistically significant, one patient vs. seven patients, respectively, interrupted cCRT.

In real-life scenarios, the essential question is: even if patients give their consent before starting cCRT to use a nasogastric tube, how many, in the face of severe acute toxicities, will accept the tube or be able to tolerate it until the completion of oncological treatment? In digestive cancers, the overall acceptability averaged 80%, less in cases of malnutrition [26]. Concerning patients without malnutrition before cCRT, in our study, the mean total duration of enteral nutrition was 5.6 months on average, with a minimum of one month. The patient, who initially refused prophylactic gastrostomy and agreed to a nasogastric tube, ultimately, did not tolerate it. A gastrostomy was inserted.

No nutrition until the end of concurrent chemoradiotherapy

The initiation of enteral nutrition occurs, on average, between the third and fourth week of treatment, placing the patient approximately midway through the treatment course, just after the second course of chemotherapy (D21), with an average of 3 more weeks of treatment to come. Limited data are available for these patients. A retrospective study involving 109 patients compared prophylactic feeding tube placement vs. reactive feeding tube placement vs. no feeding tube [27]. All patients (64% with oral cavity and oropharyngeal tumors) underwent cCRT. Patients with prophylactic tube feeding completed a significantly higher proportion of chemotherapy cycles (96.0%) compared to the no-feeding tube group (81.7%) and the reactive feeding group (72.5%). In real life, is it ethical, even though the expected side effects are known in this well defined population of head and neck tumors undergoing cCRT involving the oral cavity and oropharynx to treat patients without clear information initially? Furthermore, is it ethical not to anticipate these difficulties in advance, which will affect 85% of nonmalnourished patients?

CONCLUSION

Ultimately, this work and discussion underscore the complexity and the crucial collaboration required between radiotherapists, oncologists and nutritionists to optimize the treatment of head and neck tumors. It seems important not to use prophylactic gastrostomy in all situations. Radiotherapy alone and cCRT have different consequences, as does the location of the tumor. Despite the absence of a uniform and robust study, it appears desirable to incorporate this technique for all patients undergoing cCRT involving the oral cavity and oropharynx as part of their treatment in order to enhance outcomes. We recommend initiating enteral nutrition as soon as the tube is in place for malnourished patients and as soon as intake is reduced during cCRT for other patients. In the absence of prophylactic gastrostomy, nasogastric tube feeding may be used, or no artificial nutrition may be administered until the end of the cCRT, depending on the maintenance of oral intake and the timing of the onset of side effects.

The ongoing efforts to conduct randomized trials and gather more evidence in this area are crucial for bridging the gap between the perspectives of nutritionists and radiotherapists and establishing more informed guidelines for nutritional care in cancer patients undergoing treatments like cCRT.

Acknowledgements

The authors thank all the patients who were enrolled in the study for their trust and collaboration in developing educational tools, and all healthcare members of the Head and Neck cancer - pathway at Montpellier Cancer Institute for their valuable participation. The authors extend our thanks to Caroline Constant for her significant contribution as clinical research assistant. They also thank Doctors Flori and Stoebner for their contribution.

Financial support and sponsorship

None.

Conflicts of interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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