Original Article

Nutritional outcomes with radiotherapy for head and neck cancer: a before and after comparison of 'best practice guidelines' implementation

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Background and Objectives: Malnutrition is prevalent amongst people with head and neck cancer treated with radiotherapy and can result in reduced tolerance to treatment and increased hospital admissions. Current best-practice guidelines recommend weekly dietetic review during radiotherapy and fortnightly review for six weeks following radiotherapy to minimize weight loss. The primary aim of this study was to compare percent weight loss during radiotherapy before and after the implementation of weekly dietetic review. In the post-guideline implementation group we aimed to investigate factors associated with greater weight loss and describe weight changes 4-8 weeks post radiotherapy. **Methods and Study Design:** Adults with head and neck cancer who received dietetic input and curative intent radiotherapy were included. Data were collected via retrospective chart audit of records from the Nutrition and Dietetics department. **Results:** The analysis involved 142 people, 66% (n=94) of whom received dietetic input in the post-guideline implementation period. Mean weight loss was not different between the pre- and post-guideline implementation groups (-5.9±6.34% vs -6.6±5.29%; p=0.477). In the post-guideline implementation group, advanced tumor stage and concurrent chemoradiation were associated with greater percent weight loss (p=0.006 and p<0.001, respectively). Mean weight loss increased by 1.9±4.96%, 4-8 weeks after radiotherapy (p=0.004). **Conclusions:** Percent weight loss during radiotherapy was not reduced following the implementation of weekly dietetic review. In the 4-8 weeks following radiotherapy, weight loss increased significantly over that between baseline and end of radiotherapy. Future research should explore and address the reasons why critical weight loss occurs despite improved access to dietetic care.

Key Words: head and neck cancer, dietetic counselling, malnutrition, nutrition support, radiotherapy

INTRODUCTION

Involuntary weight loss is frequently experienced by those diagnosed with cancer resulting in compromised nutritional status.[1,2] Head and neck cancer (HNC) patients have the highest risk of malnutrition with evidence suggesting critical weight loss (>5% body weight in 1 month or >10% in 6 months) affects 30-55% of patients.[2] The cause of weight loss in HNC patients is multifactorial and standard cancer treatments in the form of chemo- and radiotherapy are known to augment challenges to oral intake.[3] Dysphagia, dysgeusia and oral mucositis are the predominant treatment-related symptoms that correlate with weight loss in HNC patients receiving radiotherapy treatment.[4] In addition, high-risk tumor sites (oral cavity, larynx, hypopharynx, nasopharynx and oropharynx) and advanced stage tumors of the head and neck region are associated with increased risk of malnutrition during radiotherapy.[5]

Nutritional therapies aimed at the prevention and treatment of involuntary weight loss are dietetic counseling, oral nutrition support (ONS) and enteral nutrition support (ENS). While it is expected that patients will inevitably experience some weight loss due to both location and type of tumors as well as treatment modalities, determining effective dietetic interventions is essential to avoid adverse patient outcomes.[6] In the absence of nutrition support, patients undergoing radiotherapy experience more severe weight loss, which could result in reduced treatment efficacy and tumor control.[7] However, optimal nutritional support for management of HNC is unclear.[8-10] Whilst providing dietetic counseling correlates with weight maintenance in cancer patients, dietetic advice alone is typically only suitable for patients presenting with fewer nutrition impact symptoms.[5] However, ONS appears to have little effect on weight stabilization unless given in conjunction with ongoing dietetic counseling.[7] The effectiveness of ENS in supporting HNC patients' nutritional status is conflicting, however is often necessary for overcoming severe difficulties with oral intake.[6] In Australia, national evidence based guidelines were released in 2011 to standardize nutrition management of

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HNC patients and provide guidelines for clinicians working with this cohort.[11] The guidelines provide clinicians with a framework for the frequency, timing and type of nutritional therapy required to optimize patient nutritional status. Following the release of these guidelines, a large tertiary center in Western Australia with specialist cancer services formalized changes to its HNC dietetic service; with the implementation of nutrition assessments for all HNC patients in week one of radiotherapy, followed by weekly dietetic review during radiotherapy and fortnightly review for 6 weeks following radiotherapy.

The primary aim of this study was to compare percent weight loss over the course of radiotherapy before and after the implementation of weekly dietetic review for HNC patients. A secondary aim was to compare nutrition support methods used in the pre- and post-guideline implementation groups. In addition, for the post-guideline implementation group we aimed to determine the factors associated with weight loss and to describe weight changes in the 4-8 weeks following completion of radiation therapy.

METHODS

Data for the pre-guideline implementation period were collected in 2010 and these methods have been published elsewhere.[5] Briefly, this involved a retrospective chart audit review of records from the Nutrition and Dietetics Department. Data for the post-guideline implementation were collected via the same method. Patients who presented with HNC and received radiotherapy treatment at our hospital in the past three years (mid 2012 to mid 2015) were screened for inclusion. Standard dietetic practice at the center in the post-guideline implementation period involves a dietetic assessment for HNC patients in week one of treatment or before treatment commences. Weekly dietetic consultations are then recommended for the duration of radiotherapy treatment and fortnightly for six weeks post treatment.[11] Prior to the implementation of the guidelines HNC patients received fortnightly dietetic review during radiotherapy. There was no protocol in place for follow up after treatment.

Retrospective data collection was undertaken for five weeks commencing in August 2015. A total of 209 patient files were reviewed with 94 patients meeting the study criteria. Patients who were diagnosed with HNC, aged over 18 years and who had received radiotherapy alone or in conjunction with other treatments, were included in this study. Those excluded were patients who were receiving palliative radiotherapy, had a reoccurrence of disease, were missing demographic data, had thyroid/parathyroid cancer or lymphomas or were deceased at the time of auditing.

The study was approved by Curtin University Human Research Ethics Committee (HR142/2015) and the Quality Improvement Office at Sir Charles Gairdner Hospital (No: 9346). Patient consent was not required.

Nutrition and Dietetics department records were reviewed using a modified version of the tool utilized in the 2010 audit.[5] Modifications were made to correspond with recent changes to practice guidelines. Weight at baseline, end of radiotherapy and four to eight weeks post-treatment were collected. Patients with weight recorded within one week prior to or after completion of radiotherapy were included. Sex, age, tumor site, tumor stage and treatment type are documented by trained health professionals at initial assessment and included in files. Dietitians record weight, height and Patient-Generated Subjective Global Assessment (PG-SGA) rating on initial assessment. During radiotherapy, dietitians record weight, nutrition impact symptoms and type of nutrition support. Data extraction was performed predominately by a single investigator (PY) under supervision of the principal investigator (EJ) who conducted the 2010 audit.

The PG-SGA is comprised of questions related to dietary intake, nutrition impact symptoms and recent weight loss.[12] The answers to these questions are scored, and the clinician makes a global rating of nutritional status, (A) well nourished; B) moderate malnutrition; and C) severe malnutrition.

Weight was measured by a health professional and recorded in patient files. Height was measured by a health professional or self-reported by the patient and recorded in patient files. BMI was categorized using World Health Organization criteria.[13] Tumor stage, tumor site and treatment modality were obtained from medical notes included in Nutrition and Diet Therapy department records. Tumor stage was grouped as I&II or III&IV using a standard classification system[14] with advanced stage tumors labeled as III&IV. High-risk tumor sites reflect tumor size and/or spread and refer to tumors of the larynx, hypopharynx, nasopharynx, oropharynx and oral cavity, while low risk sites included salivary glands and cutaneous primary cancers. These were classified to correspond with the 2010 audit.[5] If tumor stage or tumor site was not documented in departmental records, then it was recorded as unknown.

Nutrition support provided was classified as counseling alone, ONS or ENS. Patients in the counseling category received instruction by a dietitian for high protein, high-energy diets plus information for management of nutrition impact symptoms. Those who consumed oral nutrition supplements were classified into ONS group, whereas those receiving supplements via feeding tubes were categorized into ENS group.

Weight change of HNC patients was examined by comparing weight at end of treatment and 4-8 weeks post-treatment to weight at initial consultation. Percentage weight change was calculated as weight (end radiotherapy and 4-8 weeks post-treatment) - weight (baseline)/weight (baseline) x 100.

Statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS) (version 23, IBM Corporation, Somers, NY, USA). Descriptive statistics were used for baseline patient characteristics. Chi-square and two-tailed independent samples t-tests were used to test for differences in baseline patient characteristics, weight loss and nutrition support methods between the pre- and post-guideline implementation groups. Chi-square, two-tailed independent samples t-tests and one-way ANOVA were used to assess the factors associated with weight loss and nutrition support method in the post-guideline implementation group. The level of statistical significance was set at p=0.05. Figures were created using GraphPad Prism (version 7, GraphPad Software, La Jolla,

Table 1. Comparison of participant characteristics between the pre- and post-guideline implementation groups

	Pre-guidelines		Post-guidelines		Mean difference (95% CI)	Test statistic	*p* value
	Mean (or n)	SD (or %)	Mean (or n)	SD (or %)			
Gender, male	40	83.3%	74	78.7%		χ^2=0.43	0.514
Age	63.0	13.3	63.4	14.0	-0.44 (-5.26-4.39)	t=-0.18	0.858
BMI	26.8	5.24	26.6	5.28	0.23 (-1.86-2.32)	t=0.22	0.830
BMI category							
<18.5	0	0.0%	3	3.2%		χ^2=1.22	0.749
18.5-24.9	13	38.2%	35	37.6%			
25.0-29.9	13	38.2%	32	34.4%			
≥30.0	8	23.5%	23	24.7%			
SGA global rating							
A: well nourished	28	77.8%	63	73.3%		χ^2=1.34	0.512
B: moderate malnutrition	8	22.2%	20	23.3%			
C: severe malnutrition	0	0.0%	3	3.5%			
Tumour stage	28		63				
I & II	6	21.4%	10	15.9%		χ^2=0.41	0.521
III & IV	22	78.6%	53	84.1%			
Tumour site	43		82				
High risk	30	69.8%	69	84.1%		χ^2=3.54	0.060
Low risk	13	30.2%	13	15.9%			
Treatment modality							
Radiation	15	31.3%	37	39.4%		χ^2=22.32	<0.001
Chemoradiation	12	25.0%	38	40.4%			
Induction chemotherapy + chemoradiation	7	14.6%	1	1.1%			
Surgery + chemoradiation	12	25.0%	7	7.4%			
Surgery + radiation	2	4.2%	11	11.7%			
Received concurrent chemoradiation	48		94				
Yes	31	64.6%	46	48.9%		χ^2=3.13	0.077
No	17	35.4%	48	51.1%			

California, USA).

RESULTS

Comparison of baseline patient characteristics between the pre- and post-guideline implementation groups

A total of 142 patients were included in the analysis, with 94 (66%) of these patients receiving dietetic input during the post-guideline implementation period. Patient characteristics from the pre and post-guideline implementation groups are summarized in Table 1. There were no significant differences between the two groups in gender (p=0.514), age (p=0.858), tumor stage (p=0.521) or tumor site (p=0.060). There were significant differences in treatment modality between the two groups (p<0.001) however, when treatment modality was reduced to a binary variable (concurrent chemoradiation; yes or no) the difference between the groups was no longer significant (p=0.077).

The nutritional status of patients was similar between the pre- and post-guideline implementation groups. Of the patients who had an SGA completed at baseline, three-quarters were well nourished (n=91) and there were no significant differences in nutritional status between the pre- and post-guideline implementation groups (p=0.512). The proportion of patients who had an SGA completed at baseline was significantly higher in the post-guideline implementation group compared to the pre-guideline implementation group, 91.5% vs 75.0%, χ^2 (1, n=142) =7.14, p=0.008.

Comparison of weight loss between the pre- and post-guideline implementation groups

Mean weight loss was not different between the pre- and post-guideline implementation groups (-5.9%±6.34 vs -6.6%±5.29; p=0.477) (Figure 1). In the post-guideline implementation group, approximately two-thirds of patients lost >5% of their body weight during radiotherapy and this value did not differ significantly between the pre- and post-guideline implementation groups, χ^2 (1, n=132) =0.002, p=0.964. Thirty percent of patients in the post-guideline implementation group experienced weight loss of ≥10% during radiotherapy, which was not different to the pre-guideline implementation group, χ^2 (1, n=132) =0.25, p=0.616.

Comparison of nutrition support practices between the pre- and post-guideline implementation groups

In the post-guideline implementation group, 22.3% of patients received counseling alone, 60.6% of patients received ONS and 17.0% of patients received ENS. There was no difference in nutrition support method between the pre- and post-guideline implementation groups, χ^2 (2, n=142) =0.83, p=0.660.

Factors associated with weight loss in the post-guideline implementation group

Stage III&IV tumors and concurrent chemoradiation were associated with significantly higher percent weight loss over the course of radiotherapy (p=0.006 and p<0.001, respectively) (Table 2). Weight loss experienced by those with high-risk tumour sites was approximately double

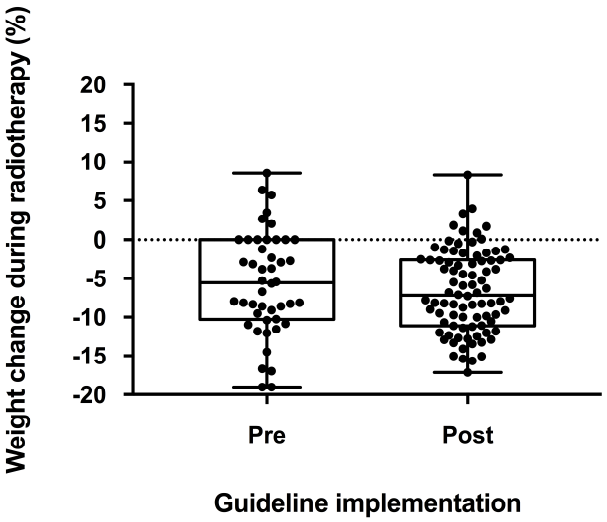

Figure 1. Percent weight change in the pre- and post-guideline implementation groups.

that of the low risk sites however, this difference was not statistically significant (-7.1%±5.41 vs -3.8%±5.36; p=0.067).

There was no relationship between baseline nutritional status and BMI category and >5% weight loss during radiotherapy χ^2 (2, n=79) =0.21, p=0.902 and χ^2 (2, n=85) =6.65, p=0.084, respectively. However, all patients (n=3) with a BMI <18.5 kg/m^2 lost <5% body weight.

Three quarters of patients experienced three or more nutrition impact symptoms and this was associated with an increased likelihood of experiencing >5% weight loss during radiation treatment. Sixty-eight percent of patients with ≥3 nutrition impact symptoms lost >5% body weight compared with 37.5% and 42.9% of those with 2 or ≤1 nutrition impact symptoms, respectively, χ^2 (2, n=86) =6.04, p=0.049.

There was a significant difference in percent weight loss between nutrition support methods as determined by one-way ANOVA, F(2, 83) =6.64, p=0.002. Mean weight loss was 8.2%±4.52 for patients receiving ONS, compared with 4.1%±5.46 and 4.1%±5.92 for those receiving counseling and ENS, respectively.

Factors associated with the nutrition support method in the post-guideline implementation group

There were significant differences in the nutrition support method used according to treatment modality. Of the patients who underwent surgery prior to radiation or chemoradiation, 38.9% received ENS compared to 11.8% of those who didn't have previous surgery, χ^2 (2, n=94) =7.54, p=0.023. There were no significant differences in the nutrition support method amongst those who received concurrent chemoradiation compared with those who did not, with 13.0% vs. 20.8% of patients respectively, receiving ENS, χ^2 (2, n=94) =4.71, p=0.095. There were no significant differences in nutrition support method according to tumor site or stage, χ^2 (2, n=82) =1.19, p=0.552 and χ^2 (2, n=63) =2.81, p=0.245, respectively.

Nutritional status and BMI category at baseline were also associated with significant differences in the nutrition support method used (Figure 2). Of the patients who were moderately or severely malnourished at baseline, 40.0% and 33.3% respectively, received enteral nutrition support, compared to 7.9% of well-nourished patients, χ^2 (2, n=86) =13.5, p=0.009. One hundred percent of patients (n=3) with a BMI of <18.5 kg/m^2 received enteral nutrition support, compared to 9.4-17.4% of patients in the remaining BMI categories, χ^2 (2, n=93) =15.8, p=0.015. There were no significant differences between the number of nutrition impact symptoms and nutrition support method, χ^2 (6, n=93) =1.94, p=0.925.

Post-radiotherapy weight loss in the post-guideline implementation group

Weight was recorded 4-8 weeks following radiation treatment for 59 (62.8%) patients in the post-guideline implementation group. In the 4-8 weeks after finishing radiation, 38 (64.4%) patients lost weight. Percent weight change at the end of radiation and at 4-8 weeks after radiation is presented in Figure 3. Mean weight loss increased from 7.2%±4.84 at the end of radiation to 9.1%±7.05, 4-8 weeks after the end of radiation. The mean difference in weight loss of 1.9%±4.96 was statistically significant (p=0.004).

DISCUSSION

In our study we reported that percent weight loss for HNC patients undergoing radiotherapy did not differ following the implementation of weekly dietetic review. Further, there was no difference in the proportion of patients receiving dietetic counseling, ONS or ENS in the pre- and post-guideline implementation groups. In the post-guideline implementation group, two-thirds of patients lost >5% body weight during radiotherapy. Tumor stage and concurrent chemoradiation were associated

Table 2. Percent weight change according to tumor site, tumor stage and treatment modality in the post-guideline implementation group

	Mean	SD	Mean difference (95% CI)	Test statistic	p value
Tumor stage					
I & II	-4.26	4.27	4.42 (1.35-7.49)	t=2.88	0.006
III & IV	-8.68	4.46			
Tumor site					
Low risk	-3.84	5.36	3.29 (-0.23-6.81)	t=1.86	0.067
High risk	-7.13	5.41			
Received concurrent chemoradiation					
No	-4.54	5.22	4.05 (1.94-6.16)	t=3.82	<0.001
Yes	-8.59	4.61			

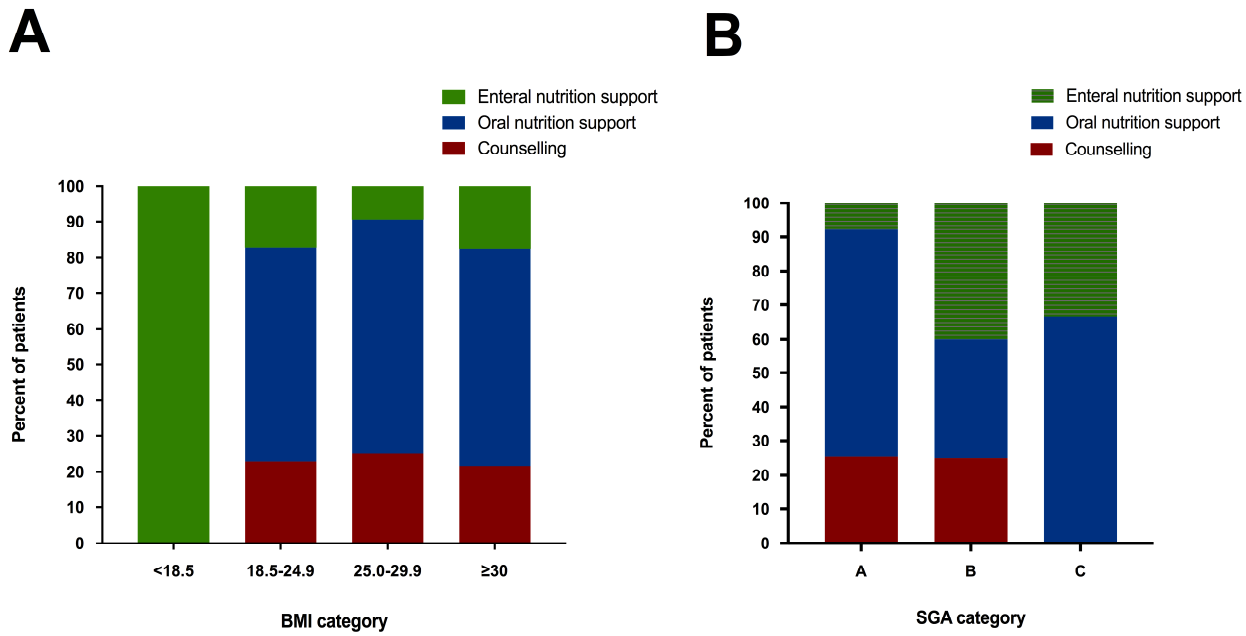

Figure 2. Nutrition support method used across BMI and SGA categories in the post-guideline implementation group.

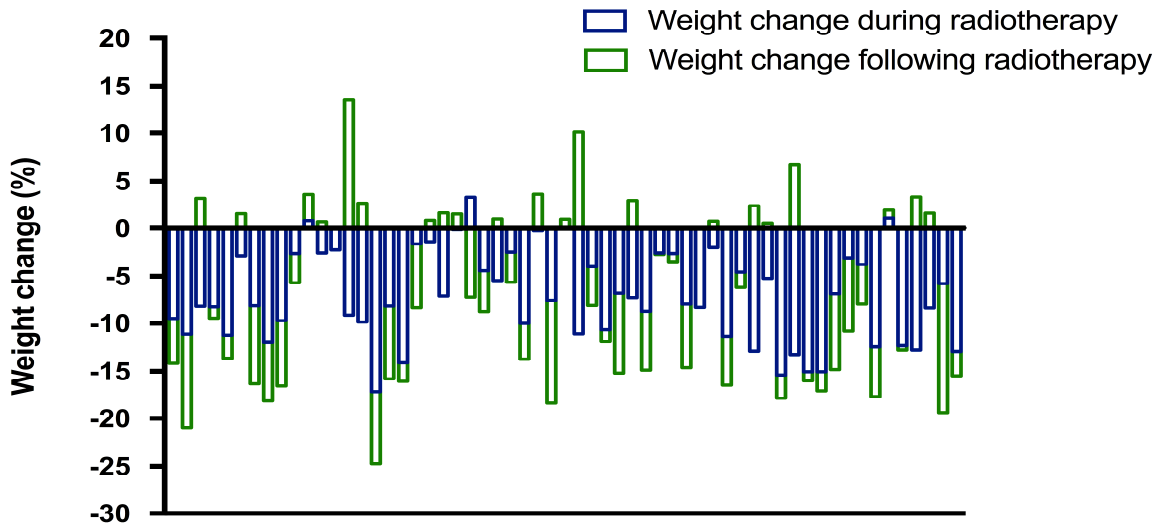

Figure 3. Percent weight change during and following radiotherapy in the post guideline implementation group.

with higher percent weight loss. In this study we also described weight loss in the 4-8 weeks following radiation treatment. The results demonstrate that patients continue to lose a significant amount of body weight in the period immediately following treatment.

On average, patients in both our pre- and post-guideline implementation groups had significant weight loss during radiotherapy, with percent weight loss 5.9% and 6.6%, respectively. There have been no published studies which have compared weekly with fortnightly dietetic review for patients with HNC receiving radiotherapy. The studies that have shown a beneficial effect for dietetic input on nutritional status have compared individualized dietary counseling with standard care which did not involve dietetic input.[9] However, in a prospective cohort study of 198 HNC patients who received radiotherapy, nutrition outcomes were compared pre- and post-the implementation of a dietitian led clinic designed to support adherence to weekly dietetic review.[15] The dietitian led clinic resulted in increased adherence to the protocol from approximately 10% to over 90% however, there was no significant difference in percent weight loss over the course of radiotherapy which averaged 4.4% and 4.0% pre- and post-implementation, respectively.[15] Thus, at present there is a paucity of evidence available to indicate that weekly dietetic review is superior to fortnightly review for HNC patients receiving radiotherapy. Prospective studies are needed to further investigate the differences in weight loss following weekly compared with fortnightly dietetic review during radiotherapy.

Implementation of weekly dietetic review for HNC patients receiving radiotherapy is resource intensive. Two studies have reported on the number of patients reviewed as part of a weekly dietetic review protocol, which ranged from 21[15] to 28[16] patients per week. One of these studies evaluated their weekly service provision for HNC patients by assessing the perceived need to attend the dietetic appointment (combined with Speech Pathology review) in

70 HNC patients.[16] Forty one percent of the patients assessed reported that they did not need to attend the appointment and 58.5% of the time this was in agreement with the clinician's perception. The authors concluded that there is the potential to over-service this group of patients. It is plausible that some patients could benefit from weekly dietetic review during radiotherapy, whilst others do not need such intensive review. In the context of finite dietetic resources, those patients at the greatest risk of significant weight loss should be prioritized for weekly dietetic review.

In this study we reported that tumor stage and concurrent chemoradiation were associated with higher percent weight loss during radiotherapy. A recent systematic review of 22 studies, including 6159 patients, found there was strong evidence that tumor stage, high BMI and concurrent chemoradiation were predictors of increased percent weight loss during radiotherapy.[17] Whilst in our study we didn't observe any differences in the proportion of patients who lost >5% body weight and BMI category, all patients who were classified as underweight lost <5% body weight and received ENS. It is the lack of ENS that the authors suggest may contribute to the higher weight loss experienced by overweight and obese HNC patients.[17] Tumor stage and chemoradiation are the predictors that have previously been used to identify high risk patients who would benefit from ENS and frequent dietetic review.[15, 18] The body of research in this area supports intensive dietetic review for patients with greater tumor stage, high BMI and those undergoing chemoradiation. However, our data indicate that increasing the frequency of dietetic review alone does not prevent significant weight loss.

A possible explanation for continued significant weight loss despite frequent dietetic intervention is patient non-adherence to dietetic recommendations. Compliance with dietetic recommendations was not assessed as part of this study. However, poor symptom control as well as psychological, social and financial issues are factors which could contribute to non-adherence. In a recent study of head and neck cancer patients with gastrostomy tubes, nausea, vomiting, feeling full and fatigue were patient-reported barriers to adherence to gastrostomy feeding.[19] In relation to psychological wellbeing, one study reported 13% of patients with HNC had moderate to severe depression at the start of radiotherapy and that this predicted malnutrition at the end of radiotherapy.[20] In another study of HNC patients, 21% of participants reported they had two or fewer friends and 30% reported financial stress at diagnosis.[21] The impact of the lack of social support and limited finances on nutrition outcomes in HNC has not been studied, however the presence of these factors is likely to have a negative effect on adherence to dietetic recommendations. Thus, the development of strategies to address barriers to adherence could be critical to achieving improved nutrition outcomes in this patient group.

Almost two-thirds of the patients in our study who had a weight recorded 4-8 weeks post radiotherapy had continued to lose weight. Mean weight loss in this time period was 1.9% which is consistent with another study published where mean weight loss was 1.6% at 4 weeks post radiotherapy.[15] In a prospective, randomized study of 712 HNC patients where weight loss was compared during conventional and accelerated radiotherapy, weight reached its lowest point 5 months following radiotherapy in both groups.[22] These outcomes highlight that the period immediately following treatment and up to 6 months after treatment are important phases for nutrition support. In our study there was limited adherence to dietetic review after radiotherapy, with only 62.8% of patients attending 4-8 weeks post treatment. Whilst we have not assessed the reasons for non-attendance at dietetic review following radiotherapy, it is possible that these appointments are inconvenient or burdensome for patients. Home visits or linking patients in with local community services if available, could improve patient engagement in dietetic review following treatment.

A strength of this study is that there was no difference in patient characteristics between the pre- and post-guideline implementation groups and thus a valid comparison of the nutrition outcomes between the two groups could be completed. Further, the proportion of patients receiving ENS compared with dietetic counseling and ONS did not change following the implementation of the guidelines. Therefore, our assessment of nutrition outcomes following the implementation of weekly dietetic review is not biased by differences in nutrition support practices.

A number of limitations should be considered when interpreting the study results. As the study was retrospective in nature, missing data resulted from the dietitian not documenting a variable. In particular, there was a large proportion of patients with no data on tumor stage. Regarding the anthropometric values, as some patients reported their own height and were not measured by a health professional, potential for error exists in the documented BMI. We did not assess patient compliance with weekly dietetic reviews during radiotherapy and it is probable that not all patients adhered to this protocol. Therefore, it is plausible that the nutrition outcomes could differ between those patients who adhered to the weekly dietetic review protocol and those who did not.

People with HNC experience significant weight loss despite the implementation of strategies such as weekly dietetic review during radiotherapy, fortnightly dietetic review following radiotherapy and prophylactic gastrostomy insertion and early ENS23 that are designed to lessen weight loss. It is important that future studies assess patient compliance with attendance at dietetic appointments and adherence to nutrition support recommendations. Researchers should also aim to understand the reasons for non-adherence so that the appropriate strategies can be implemented to improve compliance and ultimately improve nutrition outcomes. These strategies could include improved monitoring and management of symptoms and access to psychological, practical and financial support services. Secondly, weekly dietetic review for all people with HNC undergoing radiotherapy is resource intensive and in some clinical environments may not be feasible. Our study highlights the well-known characteristics associated with higher percent weight loss, such as tumor stage and concurrent chemoradiation and it may be these people who could benefit the most from weekly dietetic review. Thus, future studies could investigate

nutritional outcomes of a model of care where dietetic review during radiotherapy is adapted to risk of greater weight loss.

In summary, we found that for people with HNC receiving radiotherapy, percent weight loss following the implementation of weekly dietetic reviews did not differ from the weight loss experienced prior to the implementation of this practice. High rates of significant weight loss were observed during radiotherapy and for a large proportion of people, weight loss continued in the 4-8 weeks following radiotherapy. Prospective studies are needed to determine the optimal nutrition care pathway for weight maintenance. Future research should also explore and address the reasons that critical weight loss occurs despite improved access to dietetic care.

AUTHOR DISCLOSURES

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