



Prophylactic feeding tubes for patients with locally advanced head-and-neck cancer undergoing combined chemotherapy and radiotherapy—systematic review and recommendations for clinical practice

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ABSTRACT

Goals

This work aimed to determine the benefits and risks of prophylactic feeding tubes for adult patients with squamous cell carcinoma of the head and neck who receive combined chemotherapy and radiotherapy with curative intent and to make recommendations on the use of prophylactic feeding tubes and the provision of adequate nutrition to this patient population.

Methods

A national multidisciplinary panel conducted a systematic review of the evidence and formulated recommendations to guide clinical decision-making. The draft evidence summary and recommendations were distributed to clinicians across Canada for their input.

Main Results

No randomized controlled trials have directly addressed this question. Evidence from studies in the target population was limited to seven descriptive studies: two with control groups (one prospective, one retrospective) and five without control groups. Results from ten controlled studies in patients treated with radiotherapy alone were also reviewed.

Conclusions

The available evidence was insufficient to draw definitive conclusions about the effectiveness of prophylactic feeding tubes in the target patient population or to support an evidence-based practice guideline. After review of the evidence, of guidelines from other groups, and of current clinical practice in Canada, the multidisciplinary panel made consensus-based

recommendations regarding comprehensive interdisciplinary clinical care before, during, and after cancer treatment. The recommendations are based on the expert opinion of the panel members and on their understanding of best clinical practice.

KEY WORDS

Practice guideline, systematic review, tube feeding, chemoradiation, head-and-neck cancer

1. INTRODUCTION

Malnutrition is common in patients with head-and-neck cancer because of pre-existing nutritional deficiencies, tumour location, and treatment-related side effects. Treatment of head-and-neck cancer may include surgery, radiation, or chemotherapy, and often a combination of those modalities. When administration of intensive multimodality treatments is concurrent, severe and often debilitating effects can compromise the patient's ability to maintain adequate nutrition and hydration. Thus, nutritional support is an integral component of care in these patients. Aggressive enteral feeding regimens are required to address malnutrition and nutritional decline, but there is disagreement regarding the best route (oral or tube feeding), when to initiate aggressive feeding (proactive or reactive), and the type of tube placement [nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG)].

Evidence-based clinical practice guidelines in oncology nutrition are limited in number, a situation that is in part related to the scarcity of randomized trials in this setting. Nonetheless, there are many circumstances in which clinicians need to provide nutrition care in the absence of high-quality evidence.

Without strong evidence and high-quality guidelines, practice tends to be highly variable. For

example, patients at some Canadian cancer centres routinely receive a PEG feeding tube before they start combined chemotherapy and radiotherapy. At other centres, a NG or PEG feeding tube is inserted during the course of treatment and only in patients who require nutritional support to complete treatment without experiencing further severe weight loss or other nutrition-related adverse effects.

To address those concerns, the Canadian Oncology Nutrition Clinical Practice Guideline (CON-CPG) Initiative conducted a systematic and comprehensive review of the literature on the use of prophylactic feeding tubes for patients undergoing combined chemotherapy and radiotherapy with curative intent for locally advanced head-and-neck cancer. The purpose of the review was to identify the benefits and risks to patients associated with this practice and to form the basis for a set of recommendations to guide clinical practice in Canada.

2. METHODS

2.1 Systematic Review

2.1.1 Questions

- Do adult patients with stage III or IV squamous cell carcinoma of the head and neck (including nasopharyngeal cancer) who receive combined chemotherapy and radiotherapy with curative intent, either as primary therapy or after surgery, have better outcomes and fewer adverse effects from treatment when a PEG tube is inserted prophylactically than when a feeding tube is not prophylactically inserted (that is, the patients are managed with oral feeding or they receive a feeding tube reactively after treatment starts)?
- In this patient population, are adverse effects associated with insertion of a prophylactic feeding tube, compared with oral feeding (and aggressive follow-up by a dietitian) or compared with reactive insertion of a feeding tube during active treatment?

2.1.2 Literature Search

Before primary studies were sought, searches were conducted of the U.S. National Guideline Clearinghouse (www.guideline.gov/), the Canadian Medical Association Infobase (mdm.ca/cpgsnew/cpgs/index.asp), and the MEDLINE (Ovid), CINAHL (Ovid), EMBASE (Ovid), and HealthSTAR (Ovid) databases for guidelines published in English between 2001 and 2006. Using Ovid, a search was then conducted at MEDLINE, EMBASE, CINAHL, HealthSTAR and the Cochrane Library for primary studies published between 1984 and August 2006. The search was updated in November 2007. Additional literature searches were conducted in April and October 2009, after completion of the guideline. The purpose of the update searches was to alert the guideline developers to any new controlled

studies in the target population. No such studies were found. The literature search strategy is available from the authors. Searches were not restricted by language.

The proceedings of the annual meetings of the American Society of Clinical Oncology for 2004–2006 and of the American Society for Therapeutic Radiology and Oncology for 2003–2005 were also examined to find abstracts of studies that had not yet been reported in full publications. Members of the expert panel also supplied bibliographies and papers from their personal files. Lists of references in published papers and reviews were scanned to identify additional studies and guidelines. Because three key journals (*Nutrition*, *Journal of Parenteral and Enteral Nutrition*, and *Nutrition in Clinical Practice*) are all indexed in the databases covered by the search, those journals were not searched by hand.

2.1.3 Eligibility Criteria

Three raters (CO, KB, MEJ) independently reviewed the titles and abstracts listed in the search output and selected studies that might be eligible for inclusion. Full reports of potentially eligible studies were then reviewed independently by the same three raters, using a checklist of eligibility criteria. Disagreements were resolved by consensus.

Studies were eligible for inclusion in the systematic review if they were published as full reports or publicly available abstracts in 1985 or later (that is, after the adoption of combined-modality treatment). Participants in the eligible studies were adult patients with squamous cell carcinoma of the head and neck (including nasopharyngeal cancer) who received combined chemotherapy and radiotherapy with curative intent, either as primary therapy or after surgery, and who had a PEG feeding tube inserted before receiving treatment. Although the primary interest was in studies of prophylactic feeding tubes in patients with stage III or IV disease who were treated with combined chemotherapy and radiotherapy, disease stages and curative treatment modalities covering a broader range were included. Given that few studies had been conducted in the target population, studies in patients with stage I–IV head-and-neck cancer and studies in patients who were treated with radiotherapy alone were also reviewed. Studies of nasopharyngeal cancer that included some patients with undifferentiated disease were also included. Ideally, evidence from well-conducted randomized trials was expected to be used to inform the recommendations. Because of the few randomized trials conducted in oncology nutrition, other study designs were also examined. Although comparative studies (those with a control group whose members did not receive a prophylactic feeding tube) provide the best evidence, single-arm studies that included the target population were also reviewed. Studies in patients with esophageal cancer were excluded.

2.1.4 Data Extraction

The expert panel identified the following outcomes of interest: completion of chemotherapy and radiotherapy, weight loss, treatment interruption, unplanned hospitalization, other adverse effects of therapy (for example, stomatitis, mucositis, dysphagia, and aspiration pneumonia), complications attributable to feeding tubes, length of feeding tube dependency, incidence of stenosis and stricture, and quality of life. Those data, together with details of the study design, patient population, and treatment, were extracted by a single reviewer (MEJ) and checked by two additional reviewers (CO, KB) against the papers reporting the studies.

2.1.5 Data Synthesis

All of the evidence came from descriptive studies and thus did not lend itself to quantitative pooling (that is, with a meta-analysis). The expert panel reviewed the available data and came to overall conclusions that addressed three key questions:

- Was the available evidence of sufficient quantity and quality to answer the systematic review questions?
- Was evidence from the studies in which patients had received radiotherapy alone generalizable to the target population for the guideline (that is, those treated with combined chemotherapy and radiotherapy)?
- Did patients who received prophylactic feeding tubes have better outcomes than those who did not?

2.2 Formulating Recommendations

The expert panel, which included oncology dietitians, a surgical dietitian, a speech language pathologist, two radiation oncologists, a medical oncologist, and an oncology nurse, reviewed the available evidence and guidelines from other groups. Attempts to secure a surgical oncologist for the panel were unsuccessful. Panel members came from British Columbia, Alberta, Manitoba, Ontario, and Newfoundland and Labrador. Although no formal consensus-building strategies were used, the panel's objective was to reach consensus on the specific wording of the recommendations. That goal was achieved primarily during meetings of the guideline panel, at which the co-chairs (CO, KB) facilitated discussion of the evidence and clinical issues, actively sought input from panel members and asked those in attendance if they agreed with each recommendation. Input was also obtained through e-mail correspondence with the panel members before and after meetings. The intent was to develop an evidence-based clinical practice guideline if possible. In the absence of high-quality evidence, expert opinion was to be used as the basis for the recommendations.

A draft of the systematic review and recommendations was circulated to practitioners across Canada for review and feedback. Practitioners were identified by oncology dietitians and members of the expert panel as having expertise in the care and management of head-and-neck cancer patients. In this way, a survey sample was assembled that represented, as far as possible, the clinical specialties involved in the care of the target population, the geographic regions of Canada, and the types of institutions at which cancer care is provided. Feedback was obtained through a survey mailed to 63 individuals (12 medical oncologists, 22 radiation oncologists, 3 surgeons, 14 nurses, 10 dietitians, and 2 speech language pathologists). The survey consisted of 9 items evaluating the methods used to assemble the evidence and asking whether the respondent agreed with the draft recommendations. Written comments were invited. The survey was mailed January 2008. Follow-up reminders were sent 2 weeks later by post and, after another 2 weeks, by e-mail. The expert panel reviewed the results of the survey and made changes to the report in response to feedback.

3. RESULTS

3.1 Guidelines from Other Groups

Three recent practice guidelines published in English that included recommendations related to prophylactic tube feeding in head-and-neck cancer patients were found¹⁻³.

The guidelines on enteral nutrition in non-surgical oncology from the European Society for Parenteral and Enteral Nutrition suggested tube feeding "if severe local mucositis is expected, which might interfere with swallowing, e.g., in intensive radiotherapy or in combined modality radio-chemotherapy regimens including radiation of throat or esophagus. Tube feeding can either be delivered via the transnasal or percutaneous routes. Because of radiation induced oral and esophageal mucositis a PEG may be preferred"¹. The associated guideline report cited evidence from four retrospective studies⁴⁻⁷ that weight loss was reduced when feeding tubes were used in patients with head-and-neck cancer. The guideline developers assigned a grade C to this recommendation, indicating that it was based on expert opinion.

In their cancer management guidelines, the BC Cancer Agency stated that "a feeding gastrostomy may be required and patients who are to be treated with regimens that usually produce severe mucositis will be offered prophylactic insertion of a feeding gastrostomy"². The authors did not provide a review of the evidence.

Guidelines developed locally for an English hospital in 2001 included an objective to "ensure prophylactic gastrostomy placement is an integral part of the management" of head-and-neck cancer

patients receiving radiotherapy and stated that prophylactic gastrostomy insertion must be considered for radical radiotherapy or chemoradiation to the oral cavity, nasopharynx, oropharynx, or hypopharynx. This guideline appeared in the appendix of a paper reporting on an audit of guideline implementation; no details about its development were included³.

3.2 Primary Studies

Twenty-one eligible studies were found (Table I), one of which is unpublished^a. None were randomized or quasi-randomized trials. One study was reported in two papers^{4,20}. Three key studies (that is, with attributes of higher quality relative to the others) are described later in this article. Results of the full systematic review, including evidence on adverse effects, can be found on the CON-CPG Web site at www.cpgnutrition.com.

3.2.1 Study Quality

Available studies were descriptive in nature and were not designed to generate comparable treatment and control groups. As a result, they cannot be expected to produce valid estimates of effect size. In most cases, the studies described the experiences of patients who received prophylactic feeding tubes because they were thought to be at increased risk for adverse outcomes related to cancer treatment. Of the twenty published studies, only four appear to be prospective^{3,4,12,13}, and only eleven reported enrolling consecutive patients^{3,4,8,10,11,14,15,17,18,21,22}. Eleven studies included a “control” group, which consisted of patients who did not receive prophylactic feeding^{4,5,7-9,14-19}. Assignments to intervention or to control were made for clinical reasons rather than randomly or by some other method of allocation intended to produce groups that were comparable in every respect except for the use of prophylactic feeding tubes.

3.2.2 Combined Chemotherapy and Radiotherapy

The search found seven studies for the present review in the target population: stage III or IV head-and-neck cancer patients treated with combined chemotherapy and radiotherapy^{6,8-13}. Table II summarizes the key results. Unfortunately, no data on rates of unexpected hospitalization or time to return to initial weight were reported. Evidence related to adverse events was spotty. Two studies with control groups^{8,9} are described next.

In a retrospective study by Bahl *et al.*⁸ at the Princess Margaret Hospital (Toronto, Ontario, Canada),

data were obtained from the charts of 78 consecutive patients with locally advanced nasopharyngeal cancer. They were treated between 1998 and 2002 with combined chemotherapy and radiotherapy followed by adjuvant chemotherapy, using the regimen evaluated in the Intergroup 0099 trial. During the study period, there was no institutional policy on the use of feeding tubes in this patient group. The investigators were not able to determine the reasons for the decision to use or not to use a prophylactic feeding tube in individual patients. Compared with patients not having a prophylactic feeding tube (called “controls” Table II), patients with a tube tended to be older and to have a lower weight before the start of treatment. Data were available for 75 patients who were followed for an average of 16 months after completion of treatment. Two patients died during the course of radiotherapy, but the remaining 73 received at least 95% of the intended dose. There was, however, a high rate of deviation from the concurrent chemotherapy regimen. Only 43% of patients received all 3 cycles, and 67% had a cumulative delay of more than 7 days. On average, patients received only 65% of the planned dose. There were similar problems with adjuvant chemotherapy, with only 61% of patients receiving all 3 cycles. Among 23 patients with a prophylactic feeding tube, 10 (43%) completed all treatment as planned; in the control group, 15 of 52 patients (29%) completed all planned treatment. Among the control patients, 17 (33%) received a feeding tube after the start of treatment because of toxicity. Over the first 100 days (during and after treatment), patients with a feeding tube lost more weight than did patients without a feeding tube (mean percentage of body weight: 18% vs. 14%), but the difference between patients with a prophylactic feeding tube and with a therapeutic feeding tube was somewhat smaller (18% vs. 16%). Grade 3 pharyngeal dysfunction or dysphagia was observed in 44% of patients with a prophylactic feeding tube, in 71% of those with a therapeutic feeding tube, and in 14% of control patients (that is, the patients who did not require a therapeutic feeding tube). Although some data on long-term outcomes were reported, interpretation is difficult because losses to follow-up beyond 6 months were substantial, especially among patients having a therapeutic feeding tube. Prophylactic feeding tubes were in place for an average of 145 days, compared with 116 days for feeding tubes inserted because of toxicity during treatment.

A second comparative study was reported by Allen *et al.*⁹ in 2007. That study was focused on an evaluation of the feasibility of a hyperfractionated concurrent chemoradiotherapy regimen. At the start of treatment, 42 patients with unresectable head-and-neck cancer were referred for PEG placement because the pharynx was in the high-dose radiotherapy volume. Of those patients, 22 received a prophylactic PEG feeding tube; the other 20 did not, either because

^a Tsang G, Bowman A. *The Efficacy of Prophylactic Gastrostomy Tubes in Nasopharyngeal Cancer Patients Undergoing Radiotherapy*. Dietetic intern research project. Halifax, NS: Victoria General Hospital; 1999. [Available from Angela Bowman at abowman@bccancer.bc.ca]

TABLE 1 Eligible studies

Reference	Inclusion criteria	Treatment	Patients (n)		Treatment details
			With tube	Control group	
<i>Combined chemotherapy and radiotherapy, with control group</i>					
Bahl <i>et al.</i> , 2004 ⁸	Stage III or IV nasopharyngeal cancer	Chemoradiotherapy	23	52	66–70 Gy over 33–35 daily treatments with cisplatin (100 mg/m ²) on days 1, 22, 43; followed by 3 cycles of adjuvant cisplatin + 5FU
Allen <i>et al.</i> , 2007 ⁹	Stage III or IV head-and-neck cancer	Chemoradiotherapy	22	20	1.25 Gy twice daily for 6 weeks (70 Gy total) with daily 5FU (600 mg/m ²) and cisplatin (12 mg/m ²) during weeks 1 and 5
<i>Combined chemotherapy and radiotherapy, no control group</i>					
Wiggenraad <i>et al.</i> , 2007 ¹⁰	Stage III–IV head-and-neck cancer	Chemoradiotherapy	50	—	68–70 Gy with cisplatin (100–150 mg/m ²) in most cases; regimens varied among patients
Nguyen <i>et al.</i> , 2006 ¹¹	Stage III–IV head-and-neck cancer	Chemoradiotherapy	104	—	66–72 Gy with cisplatin (100 mg/m ²) on days 1 and 21 and 5FU (1000 mg/m ²) as continuous infusion on days 1–4 and 21–24
Goguen <i>et al.</i> , 2006 ¹²	Stage III–IV head-and-neck cancer	Chemoradiotherapy	59	—	3 cycles of platinum-based induction chemotherapy followed by 70–74 Gy (2 Gy daily) with weekly carboplatin (AUC 1.5)
Nguyen <i>et al.</i> , 2004 ¹³	Stage III–IV head-and-neck cancer	Chemoradiotherapy	55	—	66–72 Gy with cisplatin (100 mg/m ²) on days 1 and 21 and 5FU as continuous infusion on days 1–4 and 21–24
Marcy <i>et al.</i> , 2000 ⁶	Stage IV carcinoma of oropharynx or hypopharynx	Chemoradiotherapy	50	—	1.2 Gy twice daily (75.6–80.4 Gy total) plus 3 cycles of cisplatin (100 mg/m ²) on day 1 + 5FU as continuous infusion on days 2–6
<i>Radiotherapy only or mixed, with control group</i>					
Mangar <i>et al.</i> , 2006 ¹⁴	Stage I–III head-and-neck cancer	Radiotherapy	30	130	Not reported
Beer <i>et al.</i> , 2005 ¹⁵	Aerodigestive tract cancer	Radiotherapy alone or chemoradiotherapy	78	73	Not reported
Zogbaum <i>et al.</i> , 2004 ¹⁶	Stage I–IV head-and-neck cancer	Radiotherapy alone or chemoradiotherapy	17	17	3960 rd–18,380 rd
Ehrsson <i>et al.</i> , 2004 ¹⁷	Stage I–IV head-and-neck cancer	Radiotherapy ± surgery	29	115	64 Gy in 32 fractions; 2 Gy daily 5 days per week
Beaver <i>et al.</i> , 2001 ¹⁸	Head-and-neck cancer	Radiotherapy alone or chemoradiotherapy	33	192	Not reported
Scolapio <i>et al.</i> , 2001 ¹⁹	Stage II–IV head-and-neck cancer	Radiotherapy ± surgery, chemotherapy	41	13	Median dose: 70 Gy given once (n=38) or twice (n=16) daily

TABLE I Continued

Reference	Inclusion criteria	Treatment	Patients (n)		Treatment details
			With tube	Control group	
<i>Radiotherapy only or mixed, with control group</i>					
Lee <i>et al.</i> , 1998 ⁵	Stage II–IV head-and-neck cancer	Radiotherapy or chemoradiotherapy	36	52	Accelerated twice-daily radiotherapy; median dose: 72.4 Gy (70 Gy with chemotherapy)
Tyldesley <i>et al.</i> , 1996 ⁷	Stage II–IV head-and-neck cancer	Radiotherapy	12	52	Ranged from 55 Gy in 20 daily fractions to 66 Gy in 33 daily fractions
Fietkau <i>et al.</i> , 1991 ⁴ and Senft <i>et al.</i> , 1993 ²⁰	Stage II–IV head-and-neck cancer	Radiotherapy ± surgery or chemotherapy	47	165	Not reported
Hujala <i>et al.</i> , 2004 ²¹	Upper aerodigestive tract malignancy	Radiotherapy, surgery, chemotherapy, or chemoradiotherapy	79	—	Not reported
<i>Radiotherapy only or mixed, no appropriate control group</i>					
Wood, 2005 ³	Stage II–IV head-and-neck cancer	Radiotherapy or chemoradiotherapy	8	—	Not reported
Lin <i>et al.</i> , 2001 ²²	Head-and-neck cancer	Radiotherapy ± chemotherapy	61	—	Not reported
Saunders <i>et al.</i> , 1991 ²³	Head-and-neck cancer (85% stage III–IV)	Radiotherapy	126	—	Not reported

5FU = 5-fluorouracil; AUC = area under the curve.

TABLE II Outcome data from studies in patients receiving combined chemoradiotherapy

Reference	Weight loss during chemoradiotherapy		Deviation from treatment regimen		Length of feeding tube dependency		Stenosis or stricture	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
<i>Studies with a control group</i>								
Bahl <i>et al.</i> , 2004 ⁸	Mean: 18%	~14%	57%	71%	Mean: 145 days	Mean: 116 days ^a	NR	NR
Allen <i>et al.</i> , 2007 ⁹	Median: 3.8%	7.9%	NR	NR	14 patients required feeding tube for >3 months	7 patients (32%)	NR	NR
<i>Studies without a control group</i>								
Wiggenraad <i>et al.</i> , 2007 ¹⁰	Mean: 2.8% (2.3 kg)	—	28%	—	Median: 178 days	—	NR	—
Nguyen <i>et al.</i> , 2006 ¹¹	Mean: 8.5 kg Median: 8 kg	—	NR	—	Mean: 8 months Median: 5 months	—	NR	—
Goguen <i>et al.</i> , 2006 ¹²	Median: 9.6 kg (13% of body weight)	—	NR	—	Median: 21 weeks	—	8 patients (14%)	—
Nguyen <i>et al.</i> , 2004 ¹³	Median: 8 kg	—	20%	—	22 (40%) required feeding tube for >3 months	—	3 patients (5.4%)	—
Marcy <i>et al.</i> , 2000 ⁶	Mean gain: 2.5 kg	—	NR	—	Up to 605 days	—	NR	—

^a Among those who had a feeding tube inserted because of toxicity during treatment. Intervention = prophylactic feeding tube; Control = feeding tube inserted during treatment, or no feeding tube needed; NR = not reported.

they refused or because treatment began before the PEG could be inserted. Among those 20 “control” patients, 14 (70%) required PEG placement during or within 3 weeks after completion of treatment because of progressive dysphagia and weight loss. On average, patients with a prophylactic feeding tube lost less of their body weight than did patients without a prophylactic feeding tube (3.8% vs. 7.9% of body weight, $p = 0.08$). During a median follow-up of 3 months, grade 2 dysphagia was observed in 7 patients and grade 3 dysphagia in another 7. Although 14 patients required a feeding tube for more than 3 months, it was not clear whether those tubes had been placed prophylactically or therapeutically.

3.2.3 Radiotherapy Only

Thirteen published studies examined the use of prophylactic feeding tubes in patients with head-and-neck cancer who were treated with radiotherapy alone^{3–5,7,14–19,21–23}. Among nine studies with a control group, only the study by Fietkau *et al.*⁴ (also reported by Senft *et al.*²⁰) was a prospective study of prophylactic feeding tubes in patients treated with radiotherapy. This German study was originally planned as a randomized trial, but was converted to a comparative cohort study because some clinicians were inserting prophylactic feeding tubes rather than randomizing patients. Of 212 consecutive patients treated between 1987 and 1990, 47 received a planned PEG before or within 2 weeks after starting radiotherapy, 31 patients received a PEG later (15%), and 134 received oral nutrition. Of the participants, 82% had stage III or IV disease. Data were reported only for the planned PEG group and the group that was maintained with oral nutrition alone. At the start of radiotherapy, the PEG patients weighed less than the control patients (average weight: 62 kg vs. 73 kg). During radiotherapy, the PEG group gained an average of 2 kg, and the control group lost an average of 3 kg. A subgroup of 25 patients treated with sequential chemotherapy and radiotherapy gained an average of 0.5 kg with PEG, and controls lost an average of 3.5 kg. In addition to body weight, 5 other measures of nutrition status were reported, most of which were better in the control group at baseline. Upper arm muscle circumference, a measure of lean body mass, remained relatively stable during radiotherapy with or without the use of a PEG. By contrast, triceps skinfold thickness, an indicator of fat reserves, dropped during radiotherapy among control patients but improved in patients with a PEG. Patients with prophylactic feeding tubes also experienced improvements in their levels of 3 visceral proteins (prealbumin, cholinesterase, and retinol-binding protein); the control group experienced declines in those measures. Before radiotherapy start, the PEG group had lower scores on a subjective measure of quality of life than did the oral nutrition group. Average quality-of-life scores among the PEG patients appeared to remain relatively stable during

and after radiotherapy. In the oral nutrition group, a decline in quality of life was observed during radiotherapy, with recovery over the subsequent 18 weeks. Data on feeding tube dependence and dysphagia were not reported.

3.3 External Review

From among the 63 surveys sent to external reviewers, 29 responses were received (46% response rate).

Among respondents, 86% agreed that there is a need for recommendations on the use of prophylactic feeding tubes in patients undergoing combined chemotherapy and radiotherapy for locally advanced head-and-neck cancer. Although 79% stated that they would feel comfortable having the draft recommendations applied in their hospital, and 83% stated that they were likely to make use of the recommendations in their own practice, only 66% agreed with the draft recommendations as stated.

Written comments were provided by 18 respondents (2 surgeons, 4 radiation oncologists, 4 medical oncologists, 4 nurses, and 4 dietitians). Some noted that prophylactic feeding tubes were in use at their institutions; others emphasized the need for an individualized approach to the use of prophylactic feeding tubes, based on risk factors. Several respondents expressed concerns about feeding tube dependence and the need to preserve swallowing function.

4. DISCUSSION

The strength of the available evidence—in terms of a measurable and valid effect size and temporality of the association between prophylactic feeding tubes and patient outcomes—is weak. The highest level of evidence available at the time of this systematic review came from nonrandomized comparative studies with contemporaneous controls, referred to as level 3 evidence²⁴. In the absence of data from randomized trials, the review panel gave most weight to studies that enrolled consecutive patients with stage III or IV disease treated with combined chemotherapy and radiotherapy, that collected data prospectively, and that included a control group. Supplementary evidence from noncomparative studies was also considered (level 5). Given the insufficient quantity and quality of evidence, conclusions could not be drawn about the effectiveness of prophylactic feeding tubes in patients with squamous cell carcinoma of the head and neck who receive combined chemotherapy and radiotherapy with curative intent. Overall, the body of evidence is not strong enough to form the basis for an evidence-based clinical practice guideline.

Randomized controlled trials of prophylactic versus reactive PEG are needed. Until such trials can be mounted, well-designed prospective studies should be conducted. In the meantime, decisions about the use of prophylactic feeding tubes should be made in

consultation with a dietitian in the context of ongoing care by that dietitian during and after therapy. The decision about placement of a prophylactic feeding tube requires in-depth assessment of the potential benefits to the individual patient and should take into consideration the patient's current nutrition status and symptoms and the ongoing nutrition care required during and after therapy.

In addition to considering the use of prophylactic feeding tubes, clinicians are concerned with preserving swallowing function over the long term. There is no evidence that the insertion or use of a feeding tube is the major cause of the swallowing difficulties that some patients experience. Swallowing difficulties are, in fact, the result of the cancer treatment, the tumour location, and the tumour extent. There is evidence, however, that oral food intake decreases drastically in week 2 of treatment. Tube feeding allows patients to maintain weight or to lose less weight, leading to improved outcomes such as fewer treatment interruptions, fewer infections, fewer hospital admissions, and better survival rates²⁵. It is important to maintain swallowing function during and after completion of combined chemotherapy and radiotherapy. Swallowing exercises and relevant interventions designed to improve swallowing function and to possibly prevent or decrease the severity of swallowing disorders, should be applied before, during, and after treatment. A clinician with expertise in swallowing preservation, ideally a speech language pathologist, should be involved in the patient's care in cancer centres or host hospitals.

5. RECOMMENDATIONS

The advice that follows is based on the expert opinion of a multidisciplinary panel. The panel reached consensus on the recommendations after review of the available evidence, guidelines from other groups, current clinical practice in Canada, and feedback on the draft recommendations from clinicians. The recommended approach is consistent with the Canadian Oncology Nutrition Standards of Practice, which direct oncology dietitians to “develop client-centred nutrition care goals based on assessment findings and formulate individualized nutrition care plans” and to “consult with interdisciplinary team members regarding nutritional care”²⁶.

5.1 Interdisciplinary Approach to Care

- All patients with stage III or IV squamous cell carcinoma of the head and neck (including nasopharyngeal cancer) undergoing combined chemotherapy and radiotherapy with curative intent either as primary therapy or after surgery should be provided with comprehensive interdisciplinary clinical care, before, during, and after cancer treatment.
- The interdisciplinary care team should have representation from radiation, medical, and surgical oncology; oncology nutrition; oncology nursing; speech language pathology; psychosocial oncology; radiation therapy; dentistry; and occupational therapy.

5.2 Screening and Referral

- A nutrition screening and referral program should be in place to assist in identifying new head-and-neck patients who are at risk of developing or who are currently experiencing malnutrition.
- A validated screening tool should be used to assist the dietitian in determining nutrition risk and prioritizing patient care.

5.3 Monitoring During and After Combined Chemotherapy and Radiotherapy

- Nutrition intervention should be proactive and frequent and should include intensive symptom management.
- At some point during treatment, most patients undergoing combined chemotherapy and radiotherapy experience difficulty with optimal nutrition and fluid intake. This necessitates, at a minimum, a recognized process for the delivery of adequate nutrition when patients are unable to orally consume the required amounts.
- Tube feeding should be considered in patients with a functional gut who are unable to meet their nutrition requirements orally.
- The delivery of adequate nutrition should consider optimal patient care, patient preference, facility philosophy, and operational capacities in terms of feeding regimens. These parameters may dictate the type of tube placement (NG or PEG) and the timing of tube insertion (reactive or prophylactic).
- Prophylactic feeding tube insertion should be seriously considered for individuals initially presenting with 1 or more of the following symptoms: significant weight loss (more than 5% in 1 month or more than 10% in 6 months), body mass index below 18.5, dysphagia, anorexia, dehydration, pain, or any other symptom that interferes with the ability to eat.
- The interdisciplinary team should follow these patients weekly during active treatment to ensure adequate provision of nutritional requirements, effective symptom management, and preservation of the swallowing mechanism.
- Once treatment is complete, the interdisciplinary care team should provide patient follow-up and monitoring at frequent regular intervals.
- Post-treatment follow-up should recognize the importance of proper rehabilitation with regard to resumption of oral intake in an effort to prevent feeding tube dependence.

5.4 Updates to the Recommendations

The recommendations are based on work completed in May 2008. Recommendations from the CON-CPG Initiative are reviewed and updated annually. Future updates, a detailed description of the methods used to develop this guideline, and information about the Initiative can be found on the CON-CPG Web site www.cpgnutrition.com.

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7. CONFLICT OF INTEREST DISCLOSURES

The authors have no financial conflicts of interest to declare.

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