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Feasibility of assessing patient health benefits and incurred costs resulting from early dysphagia intervention during and immediately after chemoradiotherapy for head-and-neck cancer

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ABSTRACT

Background Resource limitations affect the intensity of speech–language pathology (SLP) dysphagia interventions for patients with head-and-neck cancer (HNC). The objective of the present study was to assess the feasibility of a prospective clinical trial that would evaluate the effects on health and patient costs of early SLP dysphagia intervention for HNC patients planned for curative concurrent chemoradiotherapy (CCRT).

Methods Patients with HNC planned for curative CCRT were consecutively recruited and received dysphagia-specific intervention before, during, and for 3 months after treatment. Swallowing function, body mass index, health-related quality of life (QOL), and out-of-pocket costs were measured before CCRT, at weeks 2 and 5 during CCRT, and at 1 and 3 months after CCRT. Actuarial percutaneous endoscopic gastrostomy (PEG) removal rates and body mass index in the study patients and in a time-, age-, and disease-matched cohort were compared.

Results The study enrolled 21 patients (mean age: 54 years; 19 men). The study was feasible, having a 95% accrual rate, 10% attrition, and near completion of all outcomes. Compared with the control cohort, patients receiving dysphagia intervention trended toward a higher rate of PEG removal at 3 months after CCRT [61% (32%–78%) vs. 53% (23%–71%), $p = 0.23$]. During CCRT, monthly pharmaceutical costs ranged between $239 and $348, with work loss in the range of 18–30 days for patients and 8–12 days for caregivers.

Conclusions We demonstrated the feasibility of comparing health and economic outcomes in patients receiving and not receiving early SLP dysphagia intervention. These preliminary findings suggest that early SLP dysphagia intervention for HNC patients might reduce PEG dependency despite worsening health. Findings also highlight effects on financial security for these patients and their caregivers.

Key Words Head-and-neck cancer, dysphagia interventions, patient costs, lost income, quality of life

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BACKGROUND

Patients with squamous cell carcinoma of the head and neck frequently undergo radiotherapy (with or without chemotherapy) as a primary curative modality for organ preservation. However, because of anatomic and functional changes, preservation of swallowing function is not always successful[1]. As a result, about 44% of patients require enteral tube feeding at 3 months after treatment[2], and approximately 7% remain tube-dependent at 1 year[3].

Emerging evidence suggests that assessment and intervention by a speech–language pathologist (SLP) before, during, and shortly after treatment might improve

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swallowing function and reduce the need for enteral feeding[4–6]. Earlier dysphagia intervention is also shown to have an overall positive effect on quality of life (QOL) for these patients[7]. Yet because of resource limitations, preventive SLP dysphagia intervention for patients with head-and-neck cancer (HNC) is not common and varies from one institution to another[8].

Standard practice at our facility is to prophylactically place enteral feeding tubes for all patients before they receive intensified, curative, organ-sparing treatment such as concurrent chemoradiotherapy (CCRT), and to refer to SLP for dysphagia assessment only if and when the oncology physician team identifies swallowing problems.

In a climate of limited absolute health dollars, using an economic lens to examine the potential benefit of an intervention from a societal perspective is informative. To date, only two studies have addressed economic aspects of HNC. Their findings suggest that health care costs for these patients are high[9] and that, compared with late dysphagia intervention, early intervention might be more cost-effective[10]. Unfortunately, small samples and a single-country perspective (United States) limited the applicability of those data.

The primary aim of our study was to examine the feasibility of conducting a prospective clinical trial that would assess the effects on health and patient costs of early SLP dysphagia intervention for HNC patients planned for curative CCRT. Little has been published addressing the combined perspective of health and economics with respect to this topic. In the present study, we also assessed longitudinal changes in health, QOL, overall utility, and out-of-pocket costs before, during, and up to 3 months after treatment. Costs incurred by study patients and their families were compared with costs previously obtained for patients with cancers other than HNC treated in Ontario[11].

METHODS

Patients

After research ethics approval was obtained, consecutive newly diagnosed English-speaking patients with squamous cell carcinoma of the pharynx, larynx, or oral cavity, or an unknown HNC primary were recruited prospectively from radiation oncology clinics at a large tertiary care facility, the Princess Margaret Cancer Centre. To be eligible, patients had to be proficient in spoken and written English, had to be planned for organ-preserving curative CCRT without preceding surgery, and had to have no pre-existing dysphagia from causes other than their current HNC.

Outcomes

Study feasibility was measured by patient consent rate, acceptability of each outcome, and adherence to the intended schedule for outcome capture. Our primary outcome of clinical interest was delay to removal of an enteral feeding tube after completion of treatment. At various time points, we included 7 health outcomes, among which 5 with established reliability and validity were patient-reported (Figure 1).

The M.D. Anderson Dysphagia Inventory is a 20-item questionnaire that assesses dysphagia-related QOL in patients with HNC[12]. The Functional Assessment of Cancer Therapy–Head and Neck Cancer (version 4: FACIT.org, Elmhurst, IL, U.S.A.) is a QOL questionnaire standardized for all HNC patients. It consists of 28 general and 11 head-and-neck–specific items, each rated on a 5-point ordinal scale[13]. The Functional Assessment of Cancer Therapy–Enteral Feeding (FACIT.org) is a 20-item enteral feeding–specific QOL questionnaire applicable to patients currently using a feeding tube[14]. The 15-item Swallow Quality of Care questionnaire assesses patient-perceived quality of care and patient satisfaction related to swallowing[15]. The health state classifier EQ-5D-5L (EuroQol Research Foundation, Rotterdam, Netherlands) is a health utility instrument whose 5 items have been used in HNC populations to target mobility, self-care, usual activities, pain or discomfort (or both), and depression or anxiety (or both)[16]. The Functional Oral Intake Scale is a 7-point ordinal clinician-derived score (from chart review or patient report) of food intake,

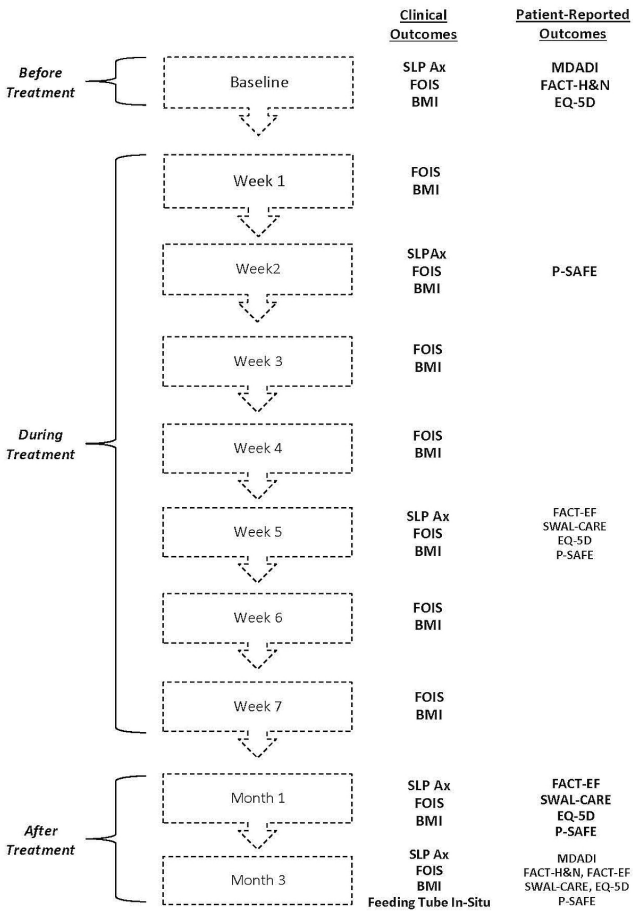

FIGURE 1 Study flow diagram. SLP Ax = speech–language pathology assessment; FOIS = Functional Oral Intake Scale; BMI = body mass index; MDADI = M.D. Anderson Dysphagia Inventory; FACT-H&N = Functional Assessment of Cancer Therapy–Head and Neck (FACIT.org, Elmhurst, IL, U.S.A.); EQ-5D = EQ-5D-5L (EuroQol Research Foundation, Rotterdam, Netherlands); P-SAFE = Patient Self-Administered Financial Expenditure; FACT-EF = Functional Assessment of Cancer Therapy–Enteral Feeding (FACIT.org); SWAL-CARE = Swallow Quality of Care.

ranging from nothing by mouth to a totally unrestricted oral diet[17]. An additional health outcome was body mass index, derived from height and weight.

Economic outcomes were collected over time using the Patient Self-Administered Financial Expenditure (P-SAFE) questionnaire. The P-SAFE items were first used in a Canadian study targeting adult patients with cancers other than HNC[11]; the questionnaire has since been refined based on both user and analysis feedback during the past 15 years. A formal validation of the tool is currently underway, and the items used in our pilot are those that were incorporated in the validation phase. The P-SAFE captures information about insurance coverage, patient out-of-pocket costs, lost time from work, travel costs, and perceived financial burden associated with treatment and follow-up care.

Procedures

A part-time research assistant approached eligible patients before the start of their curative cancer treatment (baseline). Consenting patients underwent clinical swallow assessment by a SLP. The assessments were repeated at four time points: in weeks 2 and 5 during curative CCRT, and at months 1 and 3 after CCRT (Figure 1). Depending on the swallowing difficulties identified during each swallow assessment, the SLP subsequently provided the study patient with customized strategies to address the specific dysphagia. The goal was to maintain a safe and efficient swallow. The recommendations provided were similar to those provided during usual SLP care, which included any combination of oral exercises, laryngeal exercises, compensatory postural techniques, and suggested changes to food textures. Study patients also received any additional follow-up that the SLP considered necessary. The SLP follow-up occurred either in person during the patient's regularly scheduled hospital visits or during a brief telephone conversation. The follow-ups were intended to informally monitor any change in the patient's swallow status and to clarify any issues related to swallowing for the patient.

Patients completed the health and economic questionnaires at multiple time points between baseline and 3 months after CCRT. At the same time points, information about feeding-tube status and weight was collected (Figure 1).

To explore the health benefits to study patients, we compared the number of days without a feeding tube from the end of CCRT therapy to 3 months after treatment had ended for the study patients and for a time-matched patient cohort similar in age, disease site, disease stage, and human papillomavirus status, who received the usual SLP swallowing care. The control cohort was derived by random sampling while matching on the foregoing variables among all eligible patients in our existing Anthology of Outcomes database. The Anthology is a prospective quality assurance tool consisting of data from all HNC patients treated with radiotherapy at the Princess Margaret Cancer Centre from 2003 onward[18].

To explore out-of-pocket costs incurred by HNC patients, we noted and compared the responses to P-SAFE items by study patients with published data from other adult patients treated in Ontario for cancers other than HNC[11,19].

Analysis

Demographic, feasibility, clinical, and economic data are summarized using descriptive statistics. The health outcome of "gain in feeding tube–free days" at 3 months after curative treatment in study patients was compared using Kaplan–Meier survival analysis in our patients and the matched control cohort. Using the nonparametric Wilcoxon signed-rank test, change over time in health outcomes was assessed from baseline to each time point up to 3 months after curative treatment; change in economic outcomes was assessed from week 2 to 3 months after curative treatment.

A pragmatic sample size of 20 patients was chosen *a priori* and considered sufficient to inform the feasibility of the study design for a future large clinical trial. Furthermore, the sample was sufficient to explore differences in feeding tube dependency in the study patients and in a time-, age-, and disease-matched cohort, and differences in out-of-pocket costs incurred by the study patients and by patients with non-HNC tumours who incurred similar costs (determined from published reports). Our sample was also considered sufficient to explore the direction and magnitude of change over time in patient health, utility, and out-of-pocket costs.

RESULTS

Over a 6-month period, 22 patients were approached, and 21 (95%) agreed to be enrolled (mean age: 54 years; 19 men; Tables I and II). Tumour sites were the nasopharynx ($n = 4$),

TABLE I Patient characteristics

Characteristic	Patient group		
	Overall	Intervention	Control
Patients (*n*)	42	21	21
Mean age (years)	54±9.5	54.5±8.3	53.4±10.7
Sex [*n* (%) men]	36 (85.7)	19 (90.5)	17 (81)
Smoking history [*n* (%)]			
Nonsmoker	15 (35.7)	10 (47.6)	5 (23.8)
Current smoker	11 (26.2)	4 (19)	7 (33.3)
Mean pack–years	32.6±11.3	34±16.1	31.7±9
Ex-smoker	15 (35.7)	7 (33.3)	8 (38.1)
Mean pack–years	19.5±15.7	27.6±17.5	12.5±10.5
Alcohol history [*n* (%)]			
Non-drinker	9 (21.4)	5 (23.8)	4 (19)
Light drinking	14 (33.3)	5 (23.8)	9 (42.9)
Moderate drinking	8 (19)	7 (33.3)	1 (4.8)
Heavy drinking	8 (19)	3 (14.3)	5 (23.8)
Ex-drinker	1 (2.4)	0 (0)	1 (4.8)
Unknown	2 (4.8)	1 (4.8)	1 (4.8)
HPV status [*n* (%)]			
Negative	4 (9.5)	1 (4.8)	3 (14.3)
Positive	26 (61.9)	14 (66.7)	12 (57.1)
Not available	12 (28.6)	6 (28.6)	6 (28.6)

HPV = human papillomavirus.

TABLE II Additional characteristics of the intervention patient group

Characteristic	Value [*n* (%)]
Marital status	
Married	13 (61.9)
Common law	2 (9.5)
Single, never married	2 (9.5)
Widowed	1 (4.8)
Separated	2 (9.5)
Not available	1 (4.8)
Living situation	
Lives alone	3 (14.3)
Lives with ...	
1 Other person	10 (47.6)
2 Other people	3 (14.3)
3 Other people	2 (9.5)
More than 3 other people	2 (9.5)
Not available	1 (4.8)
Highest level of education	
Some high school	4 (19)
Completed high school	5 (23.8)
Some college or university	5 (23.8)
Completed university or college	5 (23.8)
Not available	2 (9.5)
Pre-tax family income last year	
<$5,000	1 (4.8)
$10,000–$14,999	1 (4.8)
$15,000–$19,999	1 (4.8)
$30,000–$39,999	1 (4.8)
$40,000–$49,999	3 (14.3)
$60,000–$79,999	5 (23.8)
>$80,000	6 (28.6)
Not available	3 (14.3)

TABLE III Disease and treatment characteristics

Characteristic	Patient group		
	Overall (*n*=42)	Intervention (*n*=21)	Control (*n*=21)
Site [*n* (%)]			
Nasopharynx	10 (23.8)	4 (19)	6 (28.6)
Oropharynx	26 (61.9)	13 (61.9)	13 (61.9)
Larynx	3 (7.1)	2 (9.5)	1 (4.8)
Unknown primary	3 (7.1)	2 (9.5)	1 (4.8)
Tumour stage [*n* (%)]			
T0	3 (7.1)	2 (9.5)	1 (4.8)
T1	10 (23.8)	5 (23.8)	5 (23.8)
T2	14 (33.3)	7 (33.3)	7 (33.3)
T3	11 (26.2)	5 (23.8)	6 (28.6)
T4	2 (4.8)	0 (0)	2 (9.5)
T4a	2 (4.8)	2 (9.5)	0 (0)
Lymph node status [*n* (%)]			
N0	3 (7.1)	1 (4.8)	2 (9.5)
N1	3 (7.1)	2 (9.5)	1 (4.8)
N2	4 (9.5)	0 (0)	4 (19)
N2a	3 (7.1)	1 (4.8)	2 (9.5)
N2b	15 (35.7)	8 (38.1)	7 (33.3)
N2c	10 (23.8)	6 (28.6)	4 (19)
N3	4 (9.5)	3 (14.3)	1 (4.8)
Stage [*n* (%)]			
II	2 (4.8)	1 (4.8)	1 (4.8)
III	8 (19)	4 (19)	4 (19)
IVA	28 (66.7)	12 (57.1)	16 (76.2)
IVB	4 (9.5)	4 (19)	0 (0)
Squamous cell histology [*n* (%)]	42 (100)	21 (100)	21 (100)
Radiation treatment			
Mean treatments (*n* fractions)	34.9±0.3	35±0.2	34.9±0.4
Total dose (Gy)	69.7 (1.7)	69.9 (0.4)	69.5 (2.3)
Chemotherapy			
Mean total cisplatin dose (mg)	409.3 ±114.5	380.3 ±118.1	438.3 ±105.6

oropharynx (*n* = 13), and larynx (*n* = 2), with 2 unknown primaries (Table III). Two patients left the study early, one at week 3 during CCRT, and the other at 1 month after CCRT, because of cancer progression. All available data for those patients were retained and analyzed accordingly.

Success in capturing the clinician-administered and patient-reported health outcomes is shown in Tables IV and V respectively. With respect to the surveillance schedules of 1 and 3 months after CCRT for all study patients, successful administration of clinical tests deviated from the targets by medians of 5 days (range: 0–19 days) and 12 days (range: 0–22 days) respectively. Clinician tests were occasionally missed when a patient's oncology appointment was rescheduled and the part-time research assistant was unaware or unavailable (Table IV). Whenever possible, missing clinical data were then extracted from the patient record. That approach proved helpful for data points related to food intake and weight. Relative to the clinician-administered data, fewer patient-reported data were missed at the various time points (Table V). Although administration of the questionnaires was also aligned with the regularly scheduled clinic appointments for the patients, the outcomes did not depend on in-person patient visits because we invited missed patients to submit completed questionnaires by mail. Of the 7 missed patients, 3 agreed to mail their questionnaires, thereby reducing by almost half the overall missed data points at month 3.

Health outcomes for study patients, including swallow and weight, worsened at subsequent time points (Table VI). Likewise, head-and-neck and swallow-related QOL outcomes both significantly worsened from baseline to 3 months after CCRT (Tables VII and VIII). Health utility also worsened over time, but significantly so only at week 5 during CCRT. Patient satisfaction with dysphagia care increased, with the highest satisfaction at month 3.

TABLE IV Successful capture of clinician-administered health outcomes, by study time point

Assessment	Patients whose assessment data were captured at ...																	
	Baseline (*n*=21)		Week 1 (*n*=21)		Week 2 (*n*=21)		Week 3 (*n*=20)		Week 4 (*n*=20)		Week 5 (*n*=20)		Week 6 (*n*=20)		Week 7 (*n*=20)		Month 1 (*n*=19)		Month 3 (*n*=19)	
	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)
Functional Oral Intake Scale	21	100	20	95.2	20	95.2	20	100	20	100	19	95	20	100	20	100	17	89.5	16	84.2
Speech–language pathology assessment	21	100	NA		20	95.2	NA		NA		14	70	NA		NA		14	73.7	12	63.2
Speech–language pathology impression	21	100	NA		20	95.2	NA		NA		14	70	NA		NA		14	73.7	12	63.2
Body mass index	20	95.2	21	100	21	100	20	95.2	20	100	20	100	20	100	20	100	14	73.7	12	63.2

NA = not available.

Although not statistically significant, the feeding tube removal rate was observed to be higher in the study group than in the matched control cohort at 3 months after CCRT [61% (32%–78%) vs. 53% (23%–71%), $p = 0.23$; Figure 2]. In contrast, a trend toward greater weight loss was observed in the study patients compared with patients from the matched cohort (11.7 kg vs. 9.4 kg, $p = 0.58$).

The out-of-pocket patient costs varied over time (Table IX). Notably, monthly patient costs for pharmaceuticals ranged between $348 (week 2) and $239 (week 5) during active treatment and declined by approximately 50% in follow-up (months 1 and 3). Supplement costs were low during CCRT, but peaked at $780 during month 1 after CCRT. Device costs also peaked at $250 by month 1. Patient work loss was lowest at week 2 (mean: 18 days), remaining high (mean: 22–28 days) at all subsequent time points. For caregivers, work loss peaked at 5 weeks (mean: 12 days), but by month 3 after CCRT was low (mean: 3 days). Lost time from work was observed for both HNC patients and their caregivers, with lost work time peaking at week 5 (27 days) and remaining fairly constant for patients at 1 and 3 months after CCRT (22 and 28 days respectively). Lost caregiver work time peaked at week 5 (12 days) and dropped afterward to 7 and 3 days at 1 and 3 months respectively after CCRT (Table X). Travel costs such as parking peaked during CCRT (mean: $699–$868), but dropped after CCRT (mean: $92–$248; Table XI). Patient-reported financial burden (costs and lost income) was "significant" or "unmanageable" for 33% and 20% of patients respectively during CCRT, dropping to 21% and 16% after CCRT (Table XII).

In comparison with costs reported for patients having other common solid cancers[a] in Ontario, costs related to pharmaceuticals, supplements, devices, and hospitalization were higher for patients with HNC. Furthermore, a relatively higher proportion of HNC patients were employed during CCRT treatment. However, of all patients with any cancer who remained employed, HNC patients took more days off work.

DISCUSSION

Dysphagia is a common sequela for patients with HNC treated with radiotherapy, with or without chemotherapy. Despite provincial[20–24] and international[25,26] guidelines that advocate for SLP dysphagia intervention for those patients, limited resources reduce SLP intervention.

In the present study, we assessed the feasibility of conducting a longitudinal clinical study to determine the effect on patient health and enteral feeding duration of early SLP dysphagia intervention in adult HNC patients planned for organ-sparing curative CCRT. We did not measure the effect of our intervention on expenses because we had no comparative data for HNC patients.

Our findings identified a motivated patient group, resulting in an almost perfect accrual rate and minimal attrition at 3 months after CCRT. Furthermore, completed tests and questionnaires were successfully captured within an acceptable allowance of the targeted time. Missed

[a] Specifically, breast, colorectal, lung, and prostate.

TABLE V Successful capture of patient-reported outcomes, by study time point

Assessment	Patients whose assessment data were captured at ...									
	Baseline (*n*=21)		Week 2 (*n*=21)		Week 5 (*n*=20)		Month 1 (*n*=19)		Month 3 (*n*=19)	
	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)
EQ-5D-5L[a]	21	100	NA		15	75	14	73.7	15	78.9
Functional Assessment of Cancer Therapy[b] module										
Enteral Feeding[c]	NA		NA		13	92.9	14	87.5	3	75
Head and Neck Cancer	21	100	NA		NA		NA		15	78.9
M.D. Anderson Dysphagia Inventory	21	100	NA		NA		NA		15	78.9
Swallow Quality of Care	NA		NA		17	85	14	73.7	15	78.9
Patient Self-Administered Financial Expenditure	NA		20	95.2	17	85	15	78.9	15	78.9

[a] EuroQol Research Foundation, Rotterdam, Netherlands.
[b] FACIT.org, Elmhurst, IL. U.S.A.
[c] Applicable only to patients with a feeding tube *in situ* (14 in week 5, 16 in month 1, 4 in month 3).
NA = not available.

TABLE VI Health outcomes, by time point

Assessment	Outcome at ...				
	Baseline (*n*=21)	Week 2 (*n*=21)	Week 5 (*n*=20)	Month 1 (*n*=19)	Month 3 (*n*=19)
Functional Oral Intake Scale (score)					
Median	7	7[a]	3[b]	3[c]	6[a]
Range	5–7	3–7	1–6	1–7	3–7
Speech–language pathology impression [*n* (%)]		[a]	[c]	[c]	[c]
Unimpaired	20 (95.2)	12 (57.1)	0 (0)	3 (15.8)	2 (10.5)
Mild dysphagia	1 (4.8)	4 (19)	3 (15)	5 (26.3)	5 (26.3)
Moderate dysphagia	0 (0)	3 (14.3)	6 (30)	4 (21.1)	5 (26.3)
Severe dysphagia	0 (0)	1 (4.8)	5 (25)	2 (10.5)	0 (0)
Not available	0 (0)	1 (4.8)	6 (30)	5 (26.3)	7 (36.8)
Weight (kg)					
Median	83.5	80.0[c]	78.9[b]	77.4[c]	65.4[c]
Range	57.9–122	55.6–119	55.3–111.8	53–95.1	54–92.5
Body mass index (kg/m^2),					
Median	27.1	26.9[c]	25.76[c]	24.7[c]	23.1[c]
Range	18.5–36.8	18.1–35.9	18.1–33.8	18.6–32.6	18.4–32

[a] Significant at $p < 0.05$ compared with baseline.
[b] Significant at $p < 0.001$ compared with baseline.
[c] Significant at $p < 0.01$ compared with baseline.

clinician-administered tests after CCRT were a challenge. Clearly, a future clinical trial will have to ensure more research staff resources and improved communication with clinic booking clerks. Fewer patient-reported health outcomes were missed because of the option for mailing questionnaires as needed. To summarize, with adjustments to follow-up clinic visits by patients, our findings demonstrated that a longitudinal study design is feasible and should be well-received by patients with HNC.

Our findings also explored changes in health over time. Study patients experienced declining swallowing function that was worse at 1 month after therapy, but recovered to near-normal at 3 months. Compared with a matched control group who did not receive early SLP dysphagia intervention, study patients were less likely to be dependent on tube feeding by 3 months. The benefit of early intervention has been shown before, with SLP swallowing therapy interventions that were more intense (daily rather than as indicated from clinical testing)[4–6]. However, our study is the first to show a reciprocal and gradual decline in patient body mass index despite the positive transition to an oral diet. Identification of a decline in weight is critical, given the potential effect of nutrition on overall patient recovery[27]. That finding suggests that, alongside

TABLE VII Patient reported outcomes, by time point

Assessment	Outcome at ...									
	Baseline (*n*=21)		Week 2 (*n*=21)		Week 5 (*n*=20)		Month 1 (*n*=19)		Month 3 (*n*=19)	
	Median	Range	Median	Range	Median	Range	Median	Range	Median	Range
Functional Assessment of Cancer Therapy[a]										
Head and Neck Cancer module										
Personal well-being	25	14–28	NA		NA		NA		23	6–27[b]
Social and family well-being	24	1.2–29							24	17–29
Emotional well-being	18	7.2–22							20	14–24[b]
Functional well-being	20	7–28							19	4–21
General module	83.3	61–104							84	48–94
Additional concerns	34	14–39							20	8–33[c]
TOTAL	117	76.6–140							105	59–125[b]
M.D. Anderson Dysphagia Inventory										
Global	5	1–5	NA		NA		NA		4	2–5[c]
Total score	86.3	52.6–100							71.1	35.8–88.4[c]
Swallow Quality of Care										
Clinical advice	NA		NA		47	10–77	51.5	24–76	63	20–87
General advice					44	0–72	40	4–68	52	20–88
Patient satisfaction					55	25–60	45	10–60	57.5	0–60
EQ-5D-5L[d] index score	0.9	0.7–1	NA		0.8	0.3–0.9[b]	0.8	0.6–0.9	0.8	0.6–1

[a] FACIT.org, Elmhurst, IL. U.S.A.
[b] Significant at $p < 0.05$ compared with baseline.
[c] Significant at $p < 0.01$ compared with baseline.
[d] EuroQol Research Foundation, Rotterdam, Netherlands.
NA = not applicable.

TABLE VIII Functional Assessment of Cancer Therapy–Enteral Feeding[a], assessment[b] by time point

Variable	Week 5 (*n*=14)		Month 1 (*n*=16)		Month 3 (*n*=4)	
	Median	Range	Median	Range	Median	Range
Total score	50	39–69	50.5	31–67	44	39–64

[a] EuroQol Research Foundation, Rotterdam, Netherlands.
[c] Applicable only to patients with a feeding tube *in situ*.

intervention from a SLP to address swallowing status, there is need for a dietitian to continue active monitoring of the patient's nutrition status after treatment. Study patients also reported a decline in cancer-specific and dysphagia-related QOL, although satisfaction with dysphagia care improved over time. Satisfaction for QOL and overall care have the potential to influence how adherent patients will be, especially with behavioural dysphagia therapy[28]. Those outcomes are therefore important confounding variables and have to be included in future therapeutic clinical trials.

Our study sought preliminary information about out-of-pocket patient costs, an outcome that has not previously been reported in HNC. Out-of-pocket expenses reported by our patients were higher than those reported for adult patients with other solid tumours[11,19]. However, lost time from work among our study patients was similar to time lost by breast cancer patients[29,30].

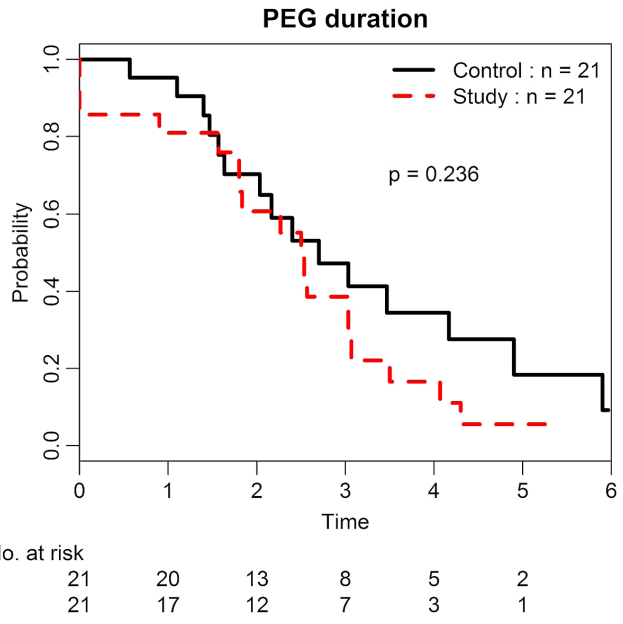

FIGURE 2 Duration of percutaneous endoscopic gastrostomy (PEG) in the study and control groups.

Generally, the greater costs in HNC patients might be explained by either greater cancer severity or greater

TABLE IX Patient out-of-pocket costs, assessed by Patient Self-Administered Financial Expenditure, by time point

Cancer-related expenditure	Week 2 (*n*=21)		Week 5 (*n*=20)		Month 1 (*n*=19)		Month 3 (*n*=19)	
	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)
Prescription drugs								
No	2	9.5	1	5	3	15.8	7	36.8
Yes								
Paid by self	6	28.6	7	35	4	21.1	3	15.8
Paid by private insurance	5	23.8	3	15	3	15.8	2	10.5
Paid by gov't	2	9.5	2	10	2	10.5	1	5.3
Paid by self and private insurance OR gov't	4	19.1	3	15	1	5.3	1	5.3
Paid by private insurance and gov't	0	0	1	5	2	10.5	1	5.3
Paid by self, private insurance, and gov't	1	4.8	0	0	0	0	0	0
Not available	1	4.8	3	15	4	21.1	4	21.1
Mean amount if paid by self ($)	347.54±512.62		238.5±192.40		167.00±104.99		106.93±85.42	
Vitamins and supplements, including special diets								
No	14	66.7	8	40	9	47.4	9	47.4
Yes								
Paid by self	4	19	4	20	3	15.8	2	10.5
Paid by private insurance	0	0	1	5	0	0	1	5.3
Paid by gov't	1	4.8	2	10	2	10.5	3	5.3
Paid d by other	0	0	2	10	0	0	0	0
Not available	2	9.5	3	15	5	26.3	4	21.1
Mean amount if paid by self ($)	73.75±84.79		110.67±84.51		780.00±593.97		20.00	
Accommodation and meals								
No	14	66.7	13	65	14	73.7	15	78.9
Yes								
Paid by self	5	23.8	2	10	0	0	0	0
Paid by gov't	0	0	1	5	1	5.3	0	0
Paid by other	0	0	1	5	0	0	0	0
Not available	2	9.5	3	15	4	21.1	4	21.1
Mean amount if paid by self ($)	107.00±129.75		250.00±212.13		—		—	
Devices or equipment								
No	15	71.4	14	70	9	47.4	12	63.2
Yes								
Paid by self	4	19	1	5	3	15.8	0	0
Paid by gov't	0	0	2	10	3	15.8	3	15.8
Not available	2	9.5	3	15	4	21.1	4	21.1
Amount if paid by self ($)	186.30±132.52		100.00		250.00±304.14		—	

treatment intensity. However, we cannot rule out the possibility that some of the differences might relate to recent changes in the levels of public coverage for health care in Ontario. Our earlier work was based on public and private coverage in 2001–2003[11,19,31]. Although we did not see a substantial change in insurance coverage rates from then to the time of our study[11], it is possible that patients in the present study had partial or reduced coverage or increased co-payments. Private sector behaviour suggests that, in Canada, insurers and corporations are managing increasing pharmaceutical- and devices-related health care costs for their employees by increasing co-payments and lowering service limits. In particular, the relatively higher out-of-pocket costs for supplements in HNC are likely a result of the high cost of the dietary supplements needed for enteral feeding, much of which would be borne by patients once they are discharged home. Given that supplement costs are relatively specific to HNC, it is not surprising that costs in that category are much higher than are seen in other common solid cancers (breast, colorectal, lung, and prostate)[11,19].

We note that our study patients reported more lost time from work than is seen in patients with other cancers[29,30]. Perhaps our capture of multiple time points allowed us to more accurately assess lost-time peaks, which our earlier

TABLE X Lost patient and caregiver income, assessed by Patient Self-Administered Financial Expenditure, by time point

Variable	Week 2 (*n*=21)		Week 5 (*n*=20)		Month 1 (*n*=19)		Month 3 (*n*=19)	
	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)
Patient employment status								
Employed full-time	13	61.9	9	45	8	42.1	9	47.4
Employed part-time	1	4.8	0	0	0	0	0	0
Retired	3	14.3	2	10	3	15.8	2	10.5
Homemaker	0	0	0	0	0	0	1	5.3
On disability	2	9.5	4	20	3	15.8	2	10.5
Unemployed	1	4.8	2	10	1	5.3	1	5.3
Not available	1	4.8	3	15	4	21.1	4	21.1
Took time off work in last 30 days to receive treatment related to cancer								
Yes	10	47.6	6	30	6	31.6	6	31.6
Not available	1	4.8	3	15	3	15.8	10	52.6
Mean days off work[a]	18±9.7		27±4.5		22±12.2		28±4.5	
Quit work in last 30 days because of illness								
Yes	4	19	3	15	2	10.5	1	5.3
Not available	1	4.8	3	15	3	15.8	10	52.6
If took time off work ...								
With full pay	4	19	2	33.3	2	33.3	0	0
With partial pay	2	9.5	2	33.3	2	33.3	1	5.3
Without pay	3	14.3	2	33.3	2	33.3	3	15.8
With partial pay and using personal days, including sick days	1	4.8	0	0	0	0	0	0
Not available	1	4.8	0	0	0	0	15	78.9
Friends or family took time off work in last 30 days related to patient's treatment								
Yes	10	47.6	8	40	6	31.6	5	26.3
Not available	1	4.8	3	15	5	26.3	5	26.3
Mean days off work	9.2±8.5		12±9.8		7.4±8.5		3±1.4	

[a] This estimate could be a slightly high, because a typical work schedule consists of about 22 work days per month, but some patients clearly assumed that a full month off work represented 30 lost work days.

TABLE XI Patient travel cost and parking, assessed by Patient Self-Administered Financial Expenditure, by time point

Variable	Week 2 (*n*=21)	Week 5 (*n*=20)	Month 1 (*n*=19)	Month 3 (*n*=19)
Mean trips to PMH or UHN in last 30 days (*n*)	19.3±9	24.2±12.7	5.5±7.7	2±1.5
Mean one-way distance (km)	60.1±54.1	59.6±54.8	71.8±57.2	62.4±57.3
Mean fare or parking cost ($)	32.13±43.51	38.65±65.32	21.46±16.20	20.31±9.35
TOTAL (mean $)				
Parking	32	39	21	20
Travel	667	829	227	72
Parking and travel	699	868	248	92

[a] $0.575/km per Canada Revenue Agency, 2014.
PMH = Princess Margaret Hospital; UHN = University Health Network.

studies missed with the inclusion of only one time point per person.

Patient travel costs were determined by the required number of clinic visits and the duration of cancer treatment. The costs reported by our study group were similar to those reported for other oncology patients[11]. Patient-perceived financial burden was similar to that reported in Ontario in the early 2000s in non-HNC patients[11,19], with up to 33% of the study subjects reporting "significant" or "unmanageable" financial burden.

TABLE XII Patient financial burden, assessed by Patient Self-Administered Financial Expenditure, by time point

Financial burden caused by out-of-pocket expenditures	Week 2 (*n*=21)		Week 5 (*n*=20)		Month 1 (*n*=19)		Month 3 (*n*=19)	
	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)
Not a burden at all	3	14.3	2	10	4	21.1	5	26.3
Only a slight burden	5	23.8	7	35	3	15.8	3	15.8
Somewhat of a burden	4	19	4	20	4	21.1	4	21.1
Significant burden, but manageable	7	33.3	2	10	3	15.8	3	15.8
Unmanageable burden	0	0	2	10	1	5.3	0	0
Not available	2	9.5	3	15	4	21.1	4	21.1

Limitations

Although the demographic details for our patients are representative of the general HNC population referred for organ-sparing treatment[1,3–6], our study is, in keeping with the primary aim of feasibility, limited by sample size. Differences between the groups or changes over time in health and out-of-pocket patient costs are therefore exploratory and hypothesis-generating. Furthermore, because of the small sample, we are unable to assess the effects of individual patient characteristics or cancer treatments on either patient health or incurred costs.

CONCLUSIONS

The present study demonstrated that conducting a longitudinal study to assess the benefit of early SLP dysphagia intervention for patients with HNC is feasible and likely to be well accepted by patients. We identified design strategies to minimize missed tests and to ensure comprehensive capture of both potential benefits and harms from dysphagia therapy. Although underpowered, our findings suggest that early SLP dysphagia intervention benefits patient health with reduced use of an enteral feeding tube at 3 months after CCRT. Our findings also suggest that CCRT is perhaps more detrimental to HNC patients and their caregivers than to patients with other solid tumours with respect to out-of-pocket costs and lost income.

Having established the feasibility of our study design, a larger randomized trial to more fully assess the effects of early SLP dysphagia intervention and CCRT on patient health and costs is now warranted.

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on disclosing conflicts of interest, and we declare that we have none.

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