

A dietitian led clinic for patients receiving (chemo)radiotherapy for head and neck cancer.

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Abstract

Purpose

Malnutrition is prevalent in head and neck cancer patients and is associated with poorer outcomes and increased healthcare costs. This study aimed to evaluate the acceptability, organisational efficiency and clinical outcomes of a dietitian led head and neck cancer clinic.

Methods

Two consecutive, independent, patient cohorts were studied with a pre-post test design of 98 patients prior to introduction of a dietitian led clinic (DLC) and the subsequent one hundred patients who attended the newly formulated DLC. The two groups were compared for frequency of dietitian intervention, weight loss, enteral feeding, hospital admissions and post treatment medical follow up requirements.

Results

Nutritional management in a DLC was associated with reduced nutrition related admissions from 12% to 4.5% ($p=0.0029$), unplanned nasogastric tube insertions from 75% to 39% ($p=0.02$), improved transition to oral diet post radiotherapy from 68.3% to 76.7% ($p=0.10$) and reduced radiation oncologist review at two weeks post radiotherapy from 32% to 15% patients ($p=0.009$) compared to the cohort prior to the DLC.

Conclusions

A dietitian led head and neck cancer clinic is associated with improved efficiency and nutritional management of head and neck cancer patients and offers a feasible model of care.

Key words: head and neck cancer, radiotherapy, dietitian led clinic, nutrition, care pathway

Introduction

The global incidence of head and neck tumours is approximately 500 000 new cases per year and continues to rise [1]. Treatment regimens for these patients depend on tumour site and stage, but include both surgery and adjuvant radiotherapy or chemotherapy or primary concurrent chemoradiotherapy. Malnutrition is a significant issue in head and neck cancer patients, both before, during and following treatment. It is frequently present prior to treatment (25 – 50% of patients) and has been shown to have a significant impact on the severity and time to recovery of treatment-related toxicities [2-4]. Enteral feeding tube insertion, nasogastric tube (NGT) or percutaneous endoscopic gastrostomy (PEG), are required in up to 57% of patients [5]. Malnutrition has also been shown to be associated with shorter survival time, decreased quality of life, treatment interruptions, reduced response to treatment and increased healthcare costs through unplanned admissions to correct dehydration and malnutrition [2,3,5]. Late recognition of malnutrition can have serious implications for patient outcomes and organisational efficiency.

Background and Rationale for Study

Nutritional care of head and neck cancer patients undergoing chemoradiation at our centre has traditionally been managed in a general dietitian outpatient clinic in a separate location to the radiation oncology clinic limiting opportunity for multidisciplinary collaboration. Patient access to the clinic was limited and had a high non-attendance rate (27%). This contributed to less frequent patient review than evidence indicates and thus potentially, suboptimal nutritional care. Co-locating dietetic reviews with radiation oncologist and nursing clinics has been demonstrated to improve team communication, leading to efficient identification and resolution of symptoms associated with nutritional complications, and reduction in unplanned admissions [2,7]. The concept of non-medically led services, in particular nurse led services, is an increasingly common feature of healthcare services internationally and evidence indicates their clinical service efficiency and their safety and acceptability to patients [8].

In the setting of increased demand on health care services, innovative and cost effective new service delivery models are being sought. Evidence indicates that some models of traditional follow up may be better suited to nursing or allied health led models [8,9].

This study set out to test a new model of care delivery within the head and neck service at a major metropolitan cancer centre to assess the feasibility and acceptability of dietitian led review for patients undergoing radiotherapy treatment for a range of head and neck cancer diagnoses and evaluate the potential for enhanced patient outcomes and organisational cost savings. The primary aims of the study were to determine the impact of a dietitian led clinic (DLC), guided by evidence based nutrition care pathways, on the frequency of dietitian review, patient weight loss, enteral feeding (timing of nasogastric tube insertion, planned versus unplanned insertions and post treatment transition to oral diet), the number of nutrition related inpatient admissions, requirement for a medical review at two weeks following radiotherapy (RT). Secondary aims were dietitian adherence to care pathways and patient satisfaction with the DLC.

Materials and Methods

Study Design

A two, consecutive, independent cohort study, with a pre-post test design.

Cohort 1 were patients identified ahead of the introduction of the DLC (usual care) to retrospectively establish baseline data.

Cohort 2 were patients recruited in the DLC.

Approval from our institutions ethics committee was obtained to undertake the study.

Participants

Patients were identified from weekly new patient start lists. Consent was sought from cohort 2 participants ahead of data collection.

Eligibility

Patients in both cohorts were required to meet the following inclusion criteria: primary diagnosis of head and neck cancer, ≥18yrs of age, chemo-radiotherapy naïve and receiving treatment with at least 15 fractions of RT or chemo-radiotherapy.

Patients were excluded from participating in the study if they were receiving palliative treatment or induction chemotherapy.

Patients recruited to the study were classified as high or low nutritional risk according to the following criteria: *High nutritional risk*; Oral cavity T3 or T4, oropharynx/ hypopharynx/ larynx T3 or T4 and/or N2 or N3, adjuvant chemoradiation, accelerated hyper fractionated radiotherapy (infield boost); *Low nutritional risk*; Adjuvant RT, all other diagnosis that don't fit into high risk categories.

In both cohorts dietitian consultations involved measuring patient weight and weight history, completing a checklist of current nutrition impact symptoms, taking a diet history, estimating energy and protein requirements, educating patients on the expected side effects of treatment and individualised dietary counselling. Enteral feeding, in both cohorts, was commenced via NGT in patients expected to require less than 8 weeks enteral nutrition or via PEG in patients expected to require greater than 8 weeks enteral nutrition. PEG insertion occurred either prior to RT or within the first one to two weeks of RT. NGT insertion occurred during RT, usually in an ambulatory setting.

The Dietitian Led Clinic Process

The DLC was set up to operate alongside the twice weekly radiation oncologist (RO) on-treatment review clinics to enable multidisciplinary collaboration. In the DLC, nutritional intervention was managed according to two evidence based care pathways for patients during RT (figure 1) and post RT (figure 2).

Fig.1 Nutritional Management During Radiotherapy

Fig.2 Nutritional Management Post Radiotherapy

The DLC pathways were based on critical appraisal of relevant articles identified from a literature review as well as recommendations from Australian evidence based guidelines for the nutritional management of patients receiving radiotherapy [10]. The care pathways were developed in collaboration with the multidisciplinary team.

Patients attending for review during RT in usual care (cohort 1) were scheduled for an initial assessment in week one of RT and then reviewed as frequently as deemed necessary by the attending dietitian and radiation oncologist.

Patients recruited in the DLC (cohort 2) attended weekly consults with a dietitian during RT, with the exception of week two of radiotherapy for low risk patients. Cohort 2 patients attended two to four dietitian-led consults in the eight weeks post RT either in person or were reviewed by a dietitian by phone call.

Commencement of enteral feeding in cohort 1 was at the instigation of the RO or the dietitian and usually related to weight loss of more than 5kg or significantly reduced oral intake (less than 50% of estimated nutrition requirements). An integral part of the DLC was the shift from usual care to enable dietitians to prescribe and initiate enteral feeding tube (NGT, PEG) insertions. Criteria for commencement of enteral feeding and feeding tube removal are described in Figures 1 and 2 respectively.

RO reviews at two weeks post RT were replaced by dietitian reviews, as the high risk of compromised nutrition was usually the greatest clinical issue in this immediate post treatment period. Suitability of patients for no RO review during this period was established at the completion of RT through discussion of each individual patients needs at a multidisciplinary team meeting.

The Dietitian Led Clinic team

Nutritional care was led by three dietitians who held Masters of Nutrition and Dietetics and who had specialist experience in head and neck cancer (range from two to five years). Dietitians were trained in the use of the Ottery's Patient Generated Subjective Global Assessment (PG-SGA) [11] and the requirements of the nutrition care pathways to ensure standardised implementation of the DLC interventions.

Resource Requirement

An initial DLC assessment was allocated between 20 to 30 minutes and each review appointment was allocated 10 to 20 minutes of direct patient contact. Two dietitians were present in each clinic.

Data Collection and Study Measures

Participant's demographic data (age, gender, diagnosis, treatment plan) was collected through the hospital's patient record system.

Data was collected on the following variables:

The Frequency of Dietitian Review.

The timing of patient's first contact with a dietitian and frequency of review during and post RT were recorded for cohort 1 and 2 through recording clinic attendance.

Patient Weight Loss.

Patient weight was recorded (to one decimal place on digital scales -Seca robusta 813, Hamburg Germany) in week one of RT, at time of NGT insertion (where applicable), in final week of RT and week four post RT. Body Mass Index (BMI) (kg/m^2) was collected at week one only.

Percentage weight loss was recorded for the time between week one and the final week of RT, week one and NGT insertion (where applicable), week one RT and week four following RT, the final week RT and week four following RT.

Enteral Feeding.

The average timing during RT to NGT insertion, the number of unplanned NGT insertions, the number of patients expected to require a NGT (those classified as high nutrition risk) and the number of planned NGT insertions in these patients, were recorded for both cohorts for a six month period prior to the implementation of the DLC (cohort 1) and for six months after the implementation of the DLC (cohort 2). An unplanned NGT insertion was defined as less than 24 hours notice of a tube insertion.

The number of patients who required enteral feeding (NGT or PEG) and the presence of a feeding tube (NGT or PEG) was recorded at week eight following treatment completion, when management of patients in the DLC ceased, for the 16 month duration of the study.

The Number of Nutrition Related Inpatient Admissions. The number of hospital admissions for nutrition-related complications was recorded for both cohorts. A nutrition related admission included for NGT insertion (if unable to be inserted in the ambulatory setting), loss of weight, poor nutritional intake, dehydration or intolerance of enteral feeds.

Data were collected for six months prior to the implementation of the DLC (cohort 1) and for six months after the implementation of the DLC (cohort 2).

Requirement for a Medical Review at Two Weeks Following Radiotherapy.

To assess the feasibility and safety of replacing RO reviews with dietitian reviews at two weeks post RT, the number of patients requiring review by a RO during the two week post-treatment period was recorded for both cohorts.

The following data were collected for cohort 2 only:

Dietitian Adherence to Care Pathways.

Adherence to the DLC care pathways was recorded by dietitians in the DLC through completion of a checklist of care pathway requirements immediately following patient review.

Patient Satisfaction with the Dietitian Led Clinic

The intent was not to compare satisfaction between cohort 1 and 2, but to identify aspects of the DLC potentially in need of revision. Patient satisfaction with the DLC was measured with a self-administered questionnaire adapted with permission from a validated tool developed by the Rheumatism Research unit, University of Leeds [12]. Patients were given the questionnaire following their week four post treatment review at the clinic. Satisfaction was measured for the following aspects of care: general satisfaction, giving of information, empathy with the patient, technical quality and competence, attitude towards the patient and access and continuity. Overall satisfaction was measured by combining the scores of each of the satisfaction domains to give a total score out of 5. A score greater than 3 indicates satisfaction.

Sample Size Calculation

A minimum sample size of 200 patients was calculated to be required in order to detect a difference of 2% body weight loss with a significance level of 0.05 between cohort 1 (usual care) and cohort 2 (DLC) groups, with a power of 80%.

Statistical Analysis

Descriptive statistics (mean, standard deviation) were performed to compare cohort 1 and cohort 2 with respect to demographics, weight loss and dietitians adherence to care pathways data. Student t-test was used to compare the means, with the associated p-value. To compare difference in proportions, we used a Z test, which is based on the normal approximation to the binomial distribution.

Results

One hundred eligible patients were identified by the research assistant for cohort 1, however, two patients were later found not to meet the inclusion criteria and were subsequently excluded from the analysis. Of the 183 patients attending the DLC during the recruitment period 132 were eligible, 24 were not approached by the research assistant due to the timing of appointments and 100 consented to the study. This gave a total of 198 study patients.

Participant characteristics are described in Table 1. There were more males in cohort 2 than cohort 1 but no other significant differences between the groups. Table 1 details the general intensity of treatment in each patient cohort, radiotherapy alone, concurrent chemoradiation using platinum based chemotherapy, or altered fractionation (in-field boost regimen). Conformal radiotherapy techniques were used in all patients. There were no significant differences in the median radiotherapy dose (60 Gy versus 66 Gy) nor treatment intensity of either cohort ($p= 0.084$). The percentage of patients who required enteral feeding was similar in each cohort, with 42% ($n= 41$) in cohort 1 and 43% ($n=43$) in cohort 2 ($p=0.89$). Twenty three (56%) patients in cohort 1 had an NG tube compared with 33 (77%) in cohort 2. Eighteen patients (44%) in cohort 1 had a PEG tube, compared with 10 (23%) in cohort 2.

The Frequency of Dietitian Review.

The DLC operated twice per week with an average of 21 (range: 7 – 36) patients seen in each DLC. The frequency of patients first contact with the dietitian improved significantly in cohort 2 with 81% ($n=81$) of patients seen by a dietitian in the first five days of RT compared to 39.8% ($n= 39$) in cohort 1 ($p= <0.0001$). High nutritional risk patients were analysed separately with 82% ($n= 56$) of patients seen by a dietitian within the first 5 days of RT in cohort 2 compared to 50% ($n= 29$) in cohort 1 ($p= <0.0001$). The proportion of patients who were reviewed as frequently as recommended in care pathways are shown in figure 3.

Fig.3 Frequency of Dietitian Contact

Patient Weight Loss.

There was no significant difference in weight loss between the two cohorts between any of the specified time points (Table 2).

Enteral Feeding.

Changes in the timing of and planning of NGT insertions are shown in Table 2. There was no significant difference in the number of high nutritional risk patients expected to require a NGT between the cohorts ($p=0.68$).

Post Treatment Transition to Oral Diet. In the post treatment period 76.7% ($n= 33$) of the patients in cohort 2 requiring enteral feeding during RT had transitioned to oral diet by week eight post treatment completion, compared to 68.3% ($n= 28$) in cohort 1 ($p=0.10$). Of the patients who had not yet transitioned to oral diet by this time, 7.3% ($n=3$) had a NGT and 24.4% ($n=10$) had a PEG in situ in cohort 1. In cohort 2, 13.9% ($n=6$) had a NGT and 9.3% ($n=4$) had a PEG.

The Number of Nutrition Related Hospital Admissions. Nutritional management in the DLC was associated with a significant reduction in the percentage of patients admitted for nutrition related reasons from 12% ($n= 26$) in cohort 1 to 4.5% ($n= 10$) in cohort 2 ($p= 0.003$). The total number of nutrition related admission days reduced from 199 in cohort 1 to 62 in cohort 2. This a difference of 137 nutrition related admission days which based on a cost per day (excluding radiotherapy costs) of \$693 (AU) equates to a saving of \$95,000 (AU) per annum.

Requirement for a Medical Review at Two Weeks Following Radiotherapy. The percentage of patients reviewed by a radiation oncologist in the first two weeks post RT reduced by 53% from 32% (n= 32) of patients in cohort 1 to 15% (n=15) of patients in cohort 2 (p=0.009).

Dietitian Adherence to Care Pathways. Dietitian adherence to the care pathways ranged from 92.3 to 99.7% across all time points. Reasons for non adherence were weight not measured or PG-SGA not completed due to patient illness or the review being conducted via a phone call.

Patient Satisfaction. Of the 100 patients recruited into cohort 2, 96 (96%) completed the patient satisfaction questionnaire (Table 3). Overall satisfaction was 4.0, indicating a high level of patient satisfaction with the DLC, and no requirement to refine any aspect of the new DLC model.

Discussion

With the high incidence of malnutrition and requirement for enteral nutrition support in the head and neck population, a role was identified for dietitians to lead nutritional aspects of patient care during and post radiotherapy treatment. This is an innovative and previously untested model of supportive care delivery. Its strength lies in encompassing collaboration across the multidisciplinary team with a clearly defined intent to improve patient management through the delivery of evidence based nutritional care by specialist head and neck cancer dietitians.

Previous studies have established the benefits of dietary counselling and nutrition support in head and neck cancer patients undergoing RT [13-15]. The current study was designed to test a new model for providing intensive nutrition intervention to head and neck cancer patients undergoing RT. Frequency of nutrition intervention during and post RT substantially improved in cohort 2 and is consistent with recommendations in the literature [10,13]. A high

level of clinician compliance with the evidence based care pathways demonstrates the feasibility of a DLC and the ability to successfully translate best-practice guidelines into patient care.

Despite the improved frequency of interventions, we found no significant difference in patient weight loss between the two groups. This is at odds with the results of previous studies [13] and may be explained by the multidisciplinary team's high baseline awareness and referral for enteral nutrition support prior to significant weight loss in cohort 1.

The DLC enabled dietitians to prescribe and initiate referrals for enteral feeding tube insertions. Medical staff were informed when these referrals had been made. The percentage of patients who required enteral feeding was similar in each cohort (n=41/41% cohort 1, n=43/43% cohort 2) and is consistent with the range of 32 – 57% cited in the literature [5,16]. However, we found improved efficiencies in the process of NGT insertions with an earlier, although not statistically significant improvement in the timing of NGT insertion during RT (week 5.35 cohort 1, week 4.75 cohort 2). The number of unplanned NGT insertions in all patients and the number of planned NGT insertions in high nutritional risk patients both improved significantly ($p=0.02$, $p=0.037$ respectively). Both cohorts had a low level of feeding tube dependency by week 8 post RT, however, more patients in cohort 2 had transitioned back to oral diet by week 8 post treatment. This is most likely due to the intensity of nutrition intervention during the post RT period.

The DLC model was associated with a significant decrease in nutrition related hospital admissions. This is the first study to demonstrate an association between evidence based, intensive nutrition interventions and decreased hospital admissions in the head and neck cancer population. The total number of nutrition related admission days reduced from 199 in cohort 1 to 62 in cohort 2, a cost saving of \$95,000 (AU) per annum based on a cost per day

of \$693 (AU) excluding radiotherapy costs. This impact of a DLC is an important outcome to health services.

In the immediate post RT phase, up to 4 weeks post treatment, patients continue to experience acute toxicities from treatment [17,18]. During this period patients are at risk of further nutritional decline but may not require the frequent medical treatment reviews required during RT. In the DLC, radiation oncologist reviews at two weeks post RT were replaced with dietitian review for ongoing intensive nutrition intervention. Referral to the radiation oncologist was initiated if non nutritional issues were identified by the dietitian. Only 15% of patients in cohort 2 required a radiation oncologist review at this time point, demonstrating the feasibility and safety of replacing radiation oncologist reviews at this time with a well defined cohort of patients. To our knowledge, this is the first study to demonstrate this. This is another area of potential cost saving enabled by a DLC.

Patient satisfaction with care is an important aspect of any health care service and an important outcome to consider when developing a new model of care. In this study patients indicated satisfaction with all domains of the DLC.

One of the limitations of our study was that the DLC commenced after patients had started their RT treatment and not all patients were consistently seen by a dietitian prior to commencing RT. The opportunity for dietitians to identify patients requiring prophylactic PEG placement was therefore missed. Debate still surrounds the decision to use a PEG or NGT to provide nutrition to head and neck cancer patients with acute toxicities from RT treatment [19-21]. There remains no high level evidence to guide decisions regarding which specific patients would benefit from prophylactic PEG placement, particularly focusing on valid nutritional outcomes and swallowing rehabilitation, and this remains an area requiring further high level research [22,23]. In addition, co-location of nutritional management with the RO on

treatment review clinics was not tested separately to the DLC model. Therefore the impact of co-location alone remains unknown.

Conclusion

This pre-post test study of a dietitian led clinic demonstrated efficient nutritional management and potential for cost savings in the treatment of head and neck cancer patients during and post RT. The DLC was associated with a reduction in nutrition related hospital admissions, a reduction in unplanned NGT insertions and reduced requirements for medical follow up in the immediate post treatment phase as well as improved transition to oral diet in the post treatment period. This study has shown a DLC to be a feasible model of care and an effective way of integrating best-practice guidelines into clinical care.

Acknowledgements:

Ms Anna Boltong, Ms Sally Muir, Ms Wendy Poon, Dr Andrew Coleman, Dr Ieta D'Costa, Dr Chen Liu, Dr Tsien Fua, Dr Mark Lee, PMCC Nutrition Department and Head and Neck Service for their support of the project.

This study was undertaken with a supportive care infrastructure grant from the Victorian Cancer Agency.

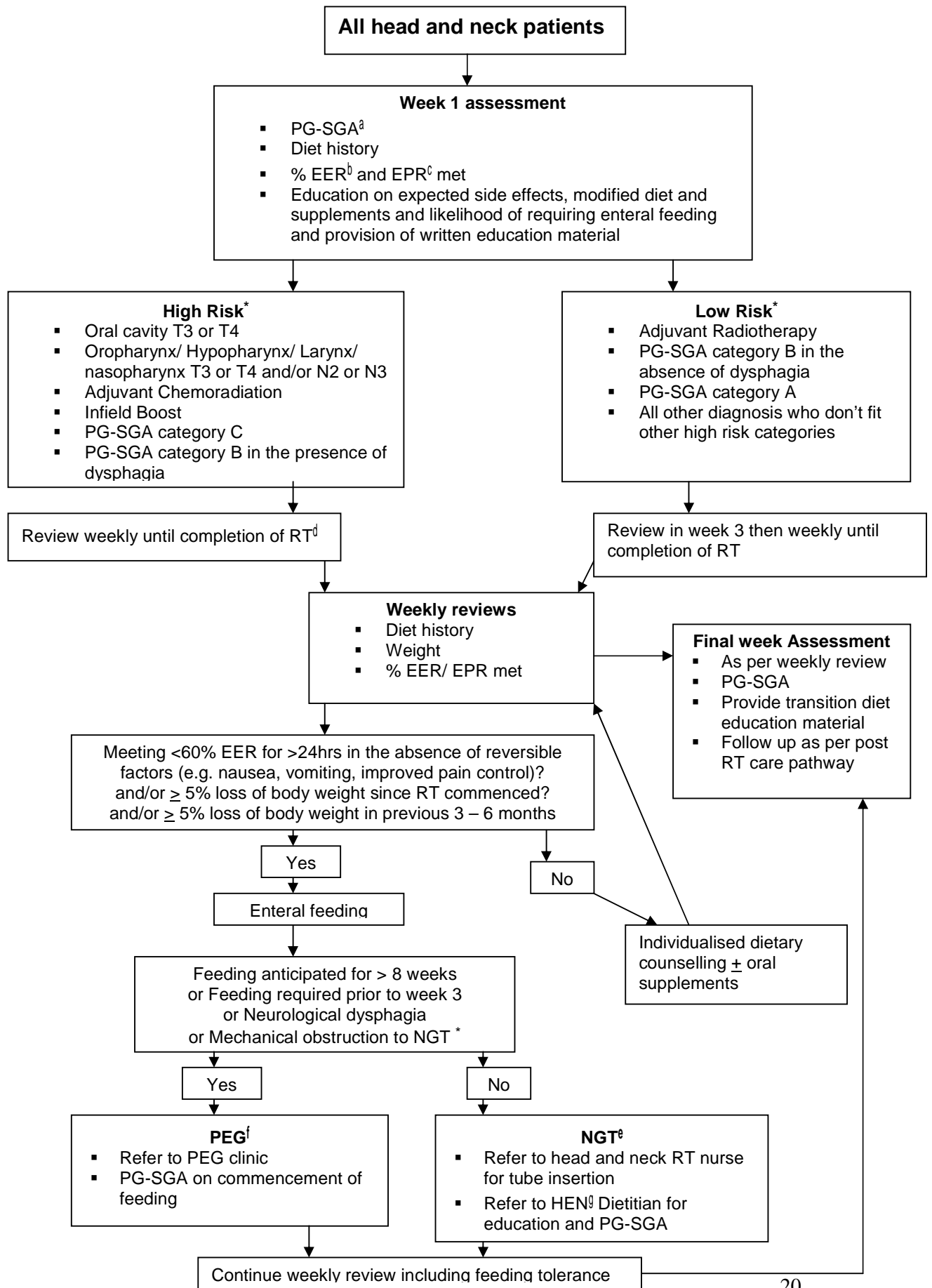
The authors have no conflict of interest to declare, have full control of all primary data and agree to allow the journal to review the data if requested.

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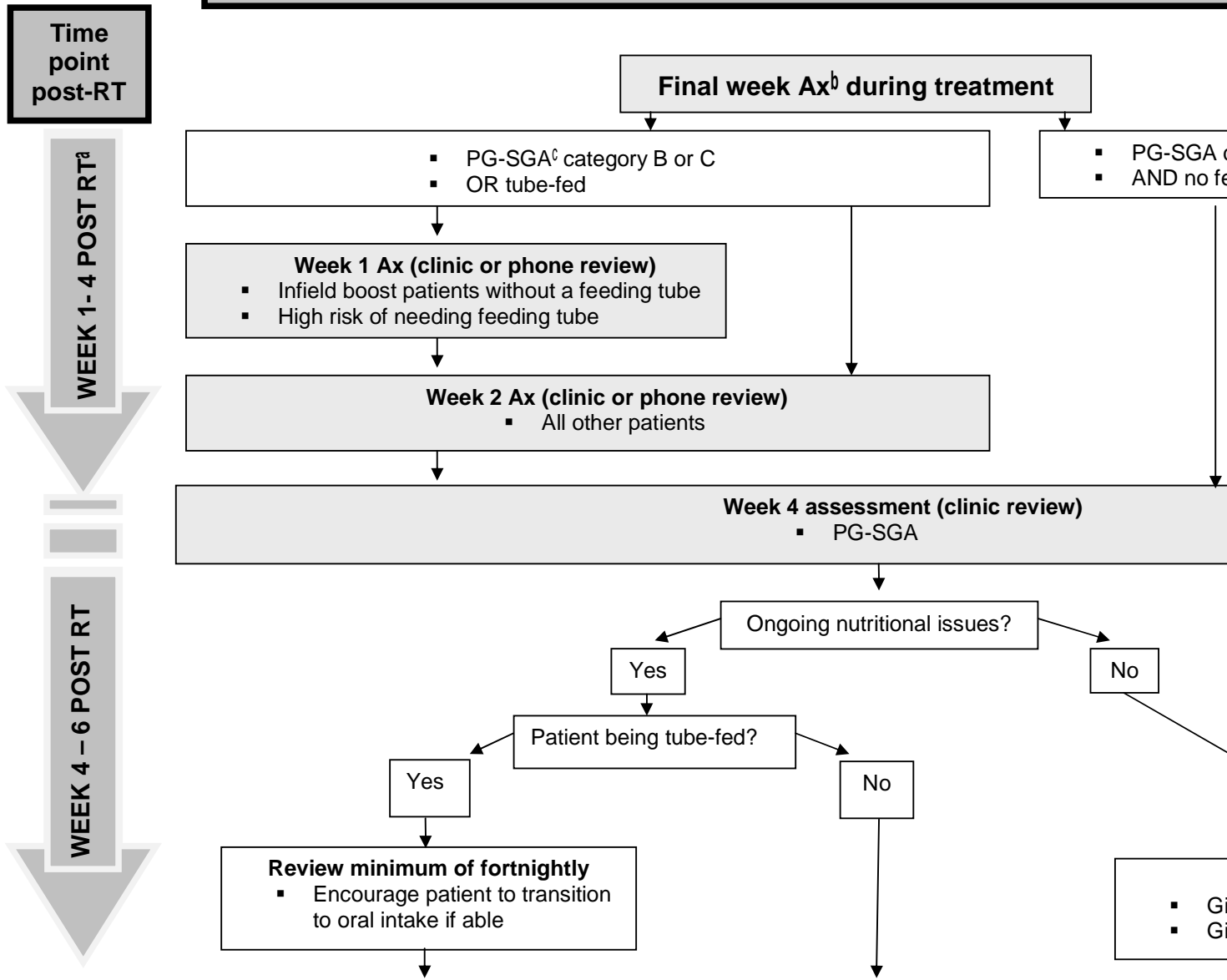
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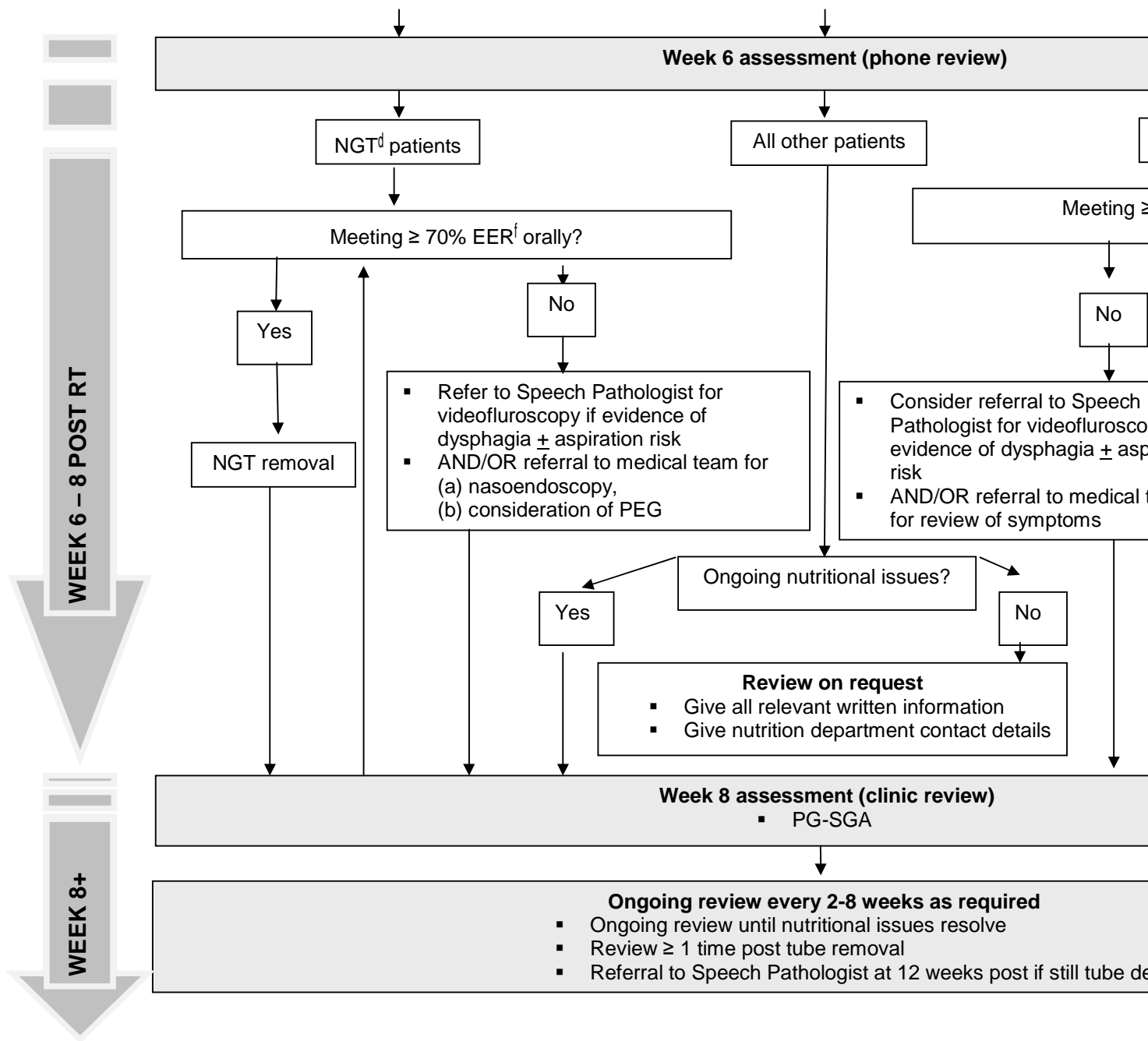
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^aPatient generated subjective global assessment; ^bEstimated energy requirement; ^cEstimated protein requirement;
^dRadiotherapy; ^eNasogastric tube; ^fPercutaneous endoscopic gastrostomy; ^gHome enteral nutrition.
*These criteria are guidelines. Some variation for individual patients may be necessary

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^aRadiotherapy; ^bAssessment; ^cPatient generated subjective global assessment; ^dNasogastric tube;

^ePercutaneous endoscopic gastrostomy; ^fEstimated energy requirements

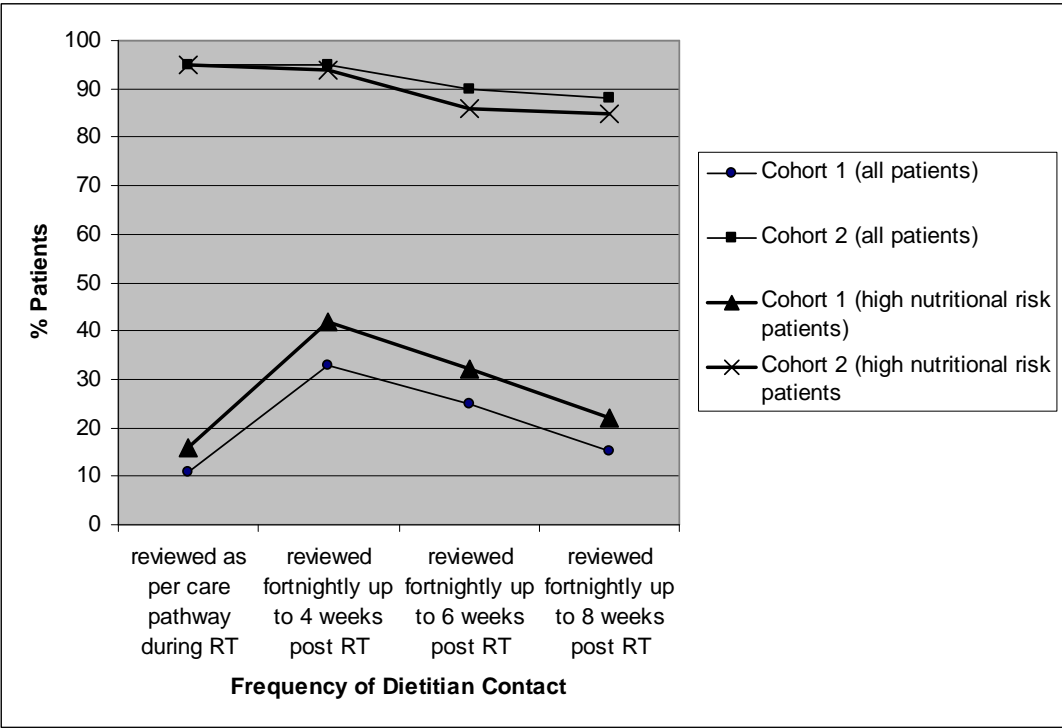


Table 1: Patient Characteristics

| Parameter | Mean (range) or no. (%) | | P value |
|---------------------------------------|----------------------------|-------------------|---------|
| | Cohort 1 n=98 | Cohort 2 n=100 | |
| Age (years) | 60.2 (18 – 91) | 63.12 (21 – 90) | 0.14 |
| Weight (kg) | 75.5 (40 – 106) n= 72 | 80.9 (47 – 180) | 0.05 |
| BMI (kg/m ²) ^a | 25.8 (16 – 38) n= 68 | 27.2 (16 – 49) | 0.072 |
| Gender | | | |
| Male | 66 (67.3) | 84 (84) | 0.006 |
| Female | 32 (32.7) | 16 (16) | |
| Primary site | | | |
| Oropharynx | 20 (20.4) | 33 (33.0) | 0.26 |
| Oral cavity | 18 (18.4) | 11 (11.0) | |
| Larynx/ hypopharynx | 23 (23.5) | 22 (22.0) | |
| Nasopharynx/ paranasal sinuses | 8 (8.2) | 9 (9.0) | |
| Other | 29 (29.6) | 25 (25.0) | |
| TNM Stage | | | |
| I | 15 (15.3) | 18 (18.0) | 0.43 |
| II | 19 (19.3) | 18 (18.0) | |
| III | 20 (20.4) | 25 (25.0) | |
| IV | 38 (38.8) | 38 (38.0) | |
| N/A | 3 (3.1) | 1 (1.0) | |
| X | 3 (3.1) | 0 | |
| Treatment | | | |
| ChemoRT ^b | 46 (46.9) | 55 (55.0) | 0.084 |
| Infield boost/ b.d ^c . RT | 6 (6.1) | 9 (9.0) | |
| RT alone | 45 (45.9) | 36 (36.0) | |
| Median RT dose (Gy) | 60 (50 – 70) | 66 (50 – 70) | |
| Nutritional risk | | | |
| High ^d | 57 | 68 | 0.151 |
| Low ^e | 41 | 42 | |

^aBody Mass Index; ^bRadiotherapy; ^cBi-daily; ^dHigh nutritional risk defined as oral cavity T3 or T4, oropharynx, hypopharynx, larynxT3 or T4 and/or N2 or N3, adjuvant chemoradiation, accelerated hyper fractionated radiotherapy (infield boost); ^eLow nutritional risk defined as adjuvant radiotherapy, all other diagnosis that don't fit into high risk category.

Table 2: Weight loss and enteral feeding in each cohort

| Variable | Cohort 1 Mean (SD) ^a | Cohort 2 Mean (SD) | p value |
|--|------------------------------------|-----------------------|-----------------|
| % weight loss between | | | |
| Week 1 and final week RT ^{b*} | -4.4 (4.0) | -4.0 (4.4) | NS ^c |
| Week 1 and week 4 post RT | -6.2 (5.9) | -5.4 (5.3) | NS |
| Week 1 and NGT ^d insertion | -6.2 (5.4) | -5.7 (4.6) | NS |
| Final week and week 4 post RT | 1.1 (3.8) | 1.6 (3.6) | NS |
| NGT insertions | | | |
| Unplanned | 15 (75) | 11 (39) | 0.02 |
| Planned (high nutrition risk Patients) | 4 (23) | 14 (56) | 0.04 |
| Timing during RT (week of RT) | 5.35 | 4.75 | 0.18 |

^aStandard deviation; ^bRadiotherapy; ^cNot significant; ^dNasogastric tube.

* The percentage weight loss is calculated by the following formula [(final week – week 1)/ week 1]*100

Table 3: Patient satisfaction with the DLC model of care

| No. Patients | Individual aspect of care satisfaction (score out of 5) | | | | | | Overall score (out of 5) |
|--------------|---|-----------------------|--------------------------|----------------------------------|-----------------------------|-----------------------|--------------------------|
| | General satisfaction | Giving of information | Empathy with the patient | Technical quality and competence | Attitude toward the patient | Access and continuity | |
| 96 | 4.1 | 3.9 | 3.9 | 4.3 | 4.0 | 3.8 | 4.0 |