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Patterns of dysphagia and acute toxicities in patients with head and neck cancer undergoing helical IMRT ± concurrent chemotherapy

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ABSTRACT

Background: There is limited prospective data reporting the extent of treatment related toxicities associated with helical Intensity Modulated Radiotherapy (H-IMRT) for head and neck cancer (HNC). The study aim was to investigate severity, peak incidence and recovery patterns of dysphagia and related toxicities in patients undergoing H-IMRT ± chemotherapy to examine when patients are experiencing symptoms requiring supportive clinical care.

Methods: Prospective study of 212 patients undergoing H-IMRT. Dysphagia and associated acute toxicities were monitored weekly during treatment and at weeks 2, 4 and 12 post treatment using the CTCAE v4, Functional Oral Intake Score and National Dysphagia Diet Descriptors.

Results: 75% experienced Grade 2–3 dysphagia. Over 70% had grade 2–3 dysguesia, xerostomia, and thick saliva, and >50% experienced grade 2–3 pharyngeal mucositis, oral mucositis, and nausea. 13% patients declined to NBM requiring complete enteral nutrition, 25% required enteral nutrition but maintained some form of oral intake. Symptoms peaked in final week of treatment, consistently improving thereafter, with the majority better than baseline by 12 weeks post-treatment. Concurrent chemotherapy at least doubles the odds of experiencing most symptoms excepting xerostomia, taste and fluid level.

Conclusion: Despite advancements in radiation techniques, results confirm a high proportion of HNC patients experience dysphagia and related toxicities requiring supportive care during H-IMRT. Patients receiving H-IMRT alone experience a lower incidence of symptoms compared with those receiving concurrent chemotherapy. The data confirms the ongoing need for active on treatment monitoring with implications for the timing and intensity of patient support services.

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Introduction

Radiotherapy with or without chemotherapy as definitive treatment for head and neck cancer (HNC) aims to cure the malignancy but to also maintain organ preservation and ensure structural integrity is retained. However, it is well documented that multiple negative functional consequences are associated with the effects of treatment [1–4]. Dysphagia following radiotherapy ± chemotherapy is common, up to two-thirds of HNC patients experience some degree of swallowing difficulty following chemoradiotherapy (CRT) [5,6] with reports of penetration ranging from 7 to 95.9% and aspiration from 0 to 100% [7]. Largely due to the proximity of key swallowing structures to the radiation treatment field [1,3,8,9]. The nature and severity of dysphagia is also influenced by both tumour presence and multiple toxicities associated with treatment including mucositis, pain, xerostomia, thick saliva, dysguesia, nausea, fatigue, altered sensation and fibrotic tissue changes within the head and neck region [3,5,10,11]. These symptoms are further intensified with the addition of chemotherapy [6].

Emerging studies support that the nature and severity of dysphagia experienced during non-surgical treatment is influenced by the dose, field and mode of radiation delivery [8,12,13]. In the past decade, the introduction of new conformal methods of radiotherapy delivery have highlighted the potential for increased protection of key anatomy involved in swallowing, often referred to

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as the dysphagia/aspiration related structures (DARS) [9]. Studies have demonstrated the use of intensity modulated radiotherapy (IMRT) to reduce the volume of the DARS receiving >50 Gy without compromising target dose [9]. It has also been demonstrated that the use of IMRT aimed at sparing specific swallowing structures may achieve positive gains in dysphagia outcomes [14–16]. Recent evolution of static beam IMRT has led to the introduction of rotational IMRT techniques such as volumetric rotational IMRT and helical IMRT [17]. Helical IMRT is delivered by a dedicated helical IMRT linear accelerator, combining helical IMRT and image guided radiation therapy. Proponents of this approach describe the potential to achieve greater homogeneity of dose and control of dose distributions using steep dose gradients to minimise volumes received by healthy tissue without compromising target coverage [18–21]. Studies have now demonstrated superior parotid sparing with reduced xerostomia incidence with the use of helical IMRT compared to linac based IMRT [22,23].

Whilst the potential benefits of helical IMRT have been discussed in both retrospective and theoretical planning studies, there are currently a limited number of prospective studies that quantify a change in patient outcomes and toxicity rates, particularly dysphagia. The studies that have been conducted, have focused on only one or two key outcomes (e.g. mucositis), and have not provided a comprehensive report of the extent and severity of dysphagia and critical dysphagia-related treatment toxicities. Furthermore, toxicity data is typically reported using only "maximum incidence" figures (e.g. 30% reached grade 3 toxicity). Whilst this informs our understanding of the overall treatment impact, it fails to elucidate the first presentation, symptom peak and recovery patterns. Such detailed information on the pattern of presentation during treatment is necessary to inform when and to what extent patients require supportive services, such as speech pathology, for management of the dysphagia and related toxicities [24–26].

Evidence is needed regarding outcomes for patients following helical IMRT to ultimately support whether such new treatment approaches are resulting in improved functional benefit for patients. This information is needed to help inform clinical services and enhance patient education regarding anticipated treatment effects. Hence, the aim of this study was to describe severity, peak incidence and the pattern of early recovery of a range of acute toxicities, including dysphagia, in a prospective cohort of HNC patients undergoing either helical IMRT (H-IMRT) only or helical IMRT with concurrent chemotherapy (CH-IMRT).

Materials and methods

Participants

Patients who commenced either H-IMRT or CH-IMRT between September 2013 and November 2014 were prospectively recruited through the Combined Head and Neck Clinic (CHNC) at a large tertiary referral hospital. Patients were excluded if they were: managed by surgical methods only; receiving a radiation technique other than helical IMRT; or were scheduled for less than 60 Gy of radiation (including palliative management). Consensus decisions regarding which patients undertook helical IMRT as opposed to 3D conformal radiation treatment methods were made at the institution's Tomotherapy Triage Meeting. Only complex patients were accepted for helical IMRT, usually requiring bilateral cervical lymph node and complex primary cancer radiotherapy. All patients who attend CHNC and proceed to radiation treatment are seen by the joint speech pathology/dietetic service. The decision to place a prophylactic PEG is made as per published guidelines of the institution [27,28] though management may be altered on the decision of the treating medical officer. Ethical clearance was obtained through the local Human Research Ethics Committee (approval number: HREC/13/QRBW/444).

Treatment planning and delivery

Helical IMRT (often referred to as helical tomotherapy) was delivered by TomoTherapy (TomoTherapy Inc., Madison, WI, USA). All patients were immobilised with thermoplastic shell and custom neck and head rest, and treated by simultaneous integrated boost technique. IMRT inverse planning was generated using the Hi-Art Planning Station (TomoTherapy Inc.). Patients received helical IMRT in standard 2 Gy per fraction to the high dose volume dosing 5 days per week. Patients receiving definitive radiotherapy received a total dose of 70 Gy over 7 weeks to gross disease whereas patients receiving post-operative adjuvant radiotherapy received 60–66 Gy over 6–6½ weeks. Dose constraints guidelines for the following organs at risk (OARs) were routinely contoured where possible: median dose (1) parotids <26 Gy, (2) constrictors <50 Gy, (3) oral cavity, larynx, oesophagus, trachea <25 Gy and (4) spinal cord maximum point dose 40 Gy.

The concurrent chemotherapy regime delivered with helical IMRT, comprised of either high dose cisplatin 100 mg/m^2 intravenous (IV) q3 weekly (weeks 1, 4 and 7), weekly cisplatin 40 mg/m^2 IV, or cetuximab 400 mg/m^2 IV loading dose 1 week prior to radiotherapy followed by weekly 250 mg/m^2 for the duration of radiotherapy.

Procedure

Toxicity data relating to dysphagia and treatment induced side effects was prospectively collected for both the H-IMRT and CH-IMRT cohorts through routine speech pathology and dietetic joint clinics, at set time intervals including: (a) baseline assessment (week 1 or 2 of treatment); (b) weekly over weeks 3–6/7 during treatment; (c) then at 2, 4, and 12 weeks post treatment. All data was collected on standard forms during routine clinical examinations and entered into a secure database by the chief researchers.

Severity of acute toxicities resulting from treatment were rated using the Common Toxicity Criteria for Adverse Events (CTCAE version 4.0) including: symptoms of dysphagia, oral mucositis, pharyngeal mucositis, dysgeusia, xerostomia, salivary duct inflammation (thick saliva) and nausea. CTCAE v4 was chosen as it uses functional descriptors for grading symptoms and all treating clinicians had 5+ years of experience in HNC. The national dysphagia diet descriptors [29] for fluids (unmodified/regular, mildly thick, moderately thick, extremely thick) and foods (unmodified/regular, soft, minced and moist, puree) were used to record the nature of patients' oral intake with the addition of two categories of liquids only and nil by mouth (NBM). In addition, an overall functional diet rating was collected using the Functional Oral Intake Scale (FOIS) a 1–7 scale where 1 represents complete enteral nutrition and 7 normal intake [30]. For any patients who received a prophylactic PEG, their FOIS reflected enteral nutrition once enteral feeding had commenced based on nutritional need.

Statistical methods

Differences in baseline characteristics between the H-IMRT and the CH-IMRT groups were assessed via Pearson's Chi-squared or Fisher's Exact test for categorical variables and *t*-test for continuous variables. Dysphagia at baseline was defined as a FOIS score less than or equal to 5 at week 1 of treatment or if unavailable, on initial assessment at CHNC. Initial descriptive analysis involved calculating the maximal incidence data (i.e. proportion of patients achieving a maximum of a Grade 1, 2 or 3 toxicity across all time-

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