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Comparing Two Prophylactic Dysphagia Treatments for Patients with Head and Neck Cancer

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Introduction

Dysphagia (swallowing impairment) is the most common side effect of radiation therapy (RT) in patients with head and neck cancer (HNC) (Greven et al., 2003; McColloch, Carroll, Magnuson, 2010). Dysphagia in this population is primarily a result of RT toxicity that includes mucositis (painful inflammation of the mucosal lining of the mouth, pharynx, and larynx), reduced taste, nausea, and dry mouth (Agarwala & Sbeitan, 2006; Gaziano, 2002; Groher & Crary, 2010; Sonis, 2004). Severe dysphagia necessitates the use of a feeding tube in many patients. Over 50% of patients remain dependent on a feeding tube at five months post RT and 10% to 30% continue to be dependent at one year (Greven et al., 2003; Ishiki et al., 2012; Paleri & Patterson; 2010, Rieger et al., 2006).

Persistent dysphagia in this population is primarily due to disuse atrophy of the swallowing muscles, reduced sensation, and chronic dry mouth (Gurney et al., 2008; Harrison, et al., 1997; Hutcheson et al., 2008; List et al., 1997; Maurer et al., 2011; Nguyen et al., 2006). Symptoms include difficulty eating dry foods, food sticking in the mouth or throat, and coughing on food or liquid secondary to food/liquid entering the airway. (Hutcheson et al., 2008; Langmore & Krisciunas, 2010; Logeman et al., 2008). These deficits contribute to reduced quality of life (QOL).

Several studies have shown that prophylactic swallowing exercises (PSE) for these patients minimizes dysphagia (Carnaby-Mann et al., 2011; Carroll et al., 2008; Kotz et al., 2012; van der Molen et al., 2011); however, compliance to PSE programs is often poor due to

swallowing pain (Roe and Ashforth, 2011; van der Molen et al., 2011).

Specific Aims and Objectives

The specific aims of this study are: 1) determine the efficacy of a PSE protocol that consists solely of indirect swallowing exercises (swallowing exercises that do not require actual swallowing), and 2) determine if such a protocol minimizes patient discomfort, maximizes QOL, and improves exercise compliance. The study compares a PSE protocol consisting solely of indirect swallowing exercises to a PSE program similar to prior prophylactic studies that consists of both direct (exercises that require swallowing) and indirect swallowing exercises (Carnaby-Mann et al., 2011; Carroll et al., 2008; Kotz et al., 2012; Kulbersh, 2006; van der Molen et al., 2011).

Methods

Participants

Adult participants diagnosed with cancer of the tongue, palate, pharynx, or larynx, whose primary treatment is RT, qualify for the study. Participants are excluded if they have an existing diagnosis of dysphagia unrelated to their current HNC diagnosis, or if they are diagnosed with a progressive neurological disorder that could contribute to dysphagia.

Procedures

Participants are instructed in either the indirect or the combination PSE protocol prior to beginning RT. The exercises are prescribed three times per day, seven days per week throughout RT. Outcome measures are taken at baseline, three times during RT, and one month, three months, and six months post-RT.

Outcome Measures

An instrumental swallow study is administered to determine baseline swallowing

function. The Eating Assessment Tool-20 (EAT-20), Functional Oral Intake Scale (FOIS), MD Anderson Dysphagia Inventory (MDADI), the European Organization for Research and Treatment of Cancer global QOL questionnaire (EORTC QLQ-C30), the EORTC Head and Neck module (EORTC H&N35), and a study-specific nutrition and pain questionnaire are used as outcome measures.

The EORTC QLQ-C30 is a validated measure of global QOL following treatment for cancer. The EAT-20, MDADI, and EORTC H&N35 are validated, self-administered, survey questionnaires designed to assess swallowing-related QOL. The FOIS is a validated 7-point scale of oral diet tolerance. It ranges from complete feeding tube dependence (level 1) to a full oral diet without restriction or compensation (level 7). The study-specific nutrition and pain questionnaire gathers information related to percent oral intake versus enteral nutrition, body mass index, and swallowing pain. The FOIS, MDADI, and EORTC questionnaires have been used in previous studies with similar populations and will allow for cross-study comparisons.

Anticipated Results

It is hypothesized that the indirect PSE protocol will be as effective as a combination PSE protocol for minimizing dysphagia, but the indirect PSE protocol will be more comfortable for patients, which will contribute to better compliance to the PSE exercises and better QOL.