

PROPHYLACTIC DYSPHAGIA TREATMENT PLANS IN PATIENTS WITH HEAD AND NECK CANCER: APPLICATION OF EVIDENCE VS THEORY BASED PRACTICE

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Objectives

1. The participant will be able to cite and discuss 3 research resources describing the current evidence for prophylactic swallowing exercises in patients undergoing CRT
2. The participant will be able to define theory based practice as it applies to prophylactic swallowing treatment programs for patients with HNC
3. The participant will be able to name and describe at least 2 outcome measures appropriate for use with the HNC patient population

Radiation Associated Dysphagia (RAD)

- Broadly defined as
 - *Dysphagia arising secondary to radiation based therapy for head and neck cancer*
 - *Treatment can and often does involve chemotherapy*

McCulloch, Carroll, and Magnuson, 2010

Common Radiation Toxicities & Timing

Acute Phase: during treatment through 3-6 mos following completion

- Mucositis
- Xerostomia
- Edema
- Candida
- Odynophagia
- Reduced appetite
- Reduced taste and/or smell

Chronic Phase: >6mos and in first 2 years after completion of treatment

- Xerostomia
- Dysgeusia, hyposmia
- Edema, candida, odynophagia
- Fibrosis
- Trismus
- Dysphagia or dysphonia
- Dental caries

King, Dunlap, Tennant, & Pitts 2016

Common Radiation Toxicities & Timing

- Late phase toxicities can be defined as those that are present >2 years post completion of treatment and can include any of the chronic toxicities with the addition of osteoradionecrosis, thyroid dysfunction, and lower cranial neuropathy.
- Radiation fibrosis develops from what is believed to be an abnormal and progressively pathologic healing process.
- Late stages (>5 years) can result in local/compartimentalized injury resulting in nerve dysfunction, muscle atrophy, and/ or neuropathic pain.

King et al., 2016

Late Radiation Associated Dysphagia

- Late RAD was defined by Hutcheson in 2013 as "Dysphagia that develops or progresses in disease-free HNC survivors 5 years or more after radiotherapy."
- In 2011, Stubblefield coined the term "radiation fibrosis syndrome" *radiation induced damage can include "radiculo-plexo-neuro-myopathy" therefore can occur at many different neuromuscular levels*

nerve root- nerve/vessel networks-peripheral nerves-muscle fibers

Late Radiation Associated Dysphagia

- Often includes muscular fibrosis (weakness, stiffness) as well as radiation associated cranial neuropathies observed on physical exam (unilateral paralysis, muscle wasting)
- Typically characterized by severe oropharyngeal pathophysiology resulting in silent aspiration and profound pharyngeal residue
- Progressive functional deterioration is common in late RAD
 - can be described as "frozen laryngopharynx" or "dysfunctional larynx"
 - may be dependent upon a tracheostomy and/or gastrostomy tube for the remainder of their life

Hutcherson, 2013

Late Radiation Associated Dysphagia Swallowing Therapy

- Restoring function is extremely challenging in this population
- "Because the fibrotic process that underlies RFS cannot be directly affected, insidious progression of weakness and dysfunction is ultimately unavoidable. Adherence to life-long exercise programs is of paramount importance to maximize and maintain function and quality of life" (Stubblefield, 2011).

Radiation Associated Dysphagia (RAD)

- Dysphagia is not only recognized as one of the most serious and persistent complications of chemoradiation therapy, but also often regarded by patients as a devastation to quality of life
- "Difficulty swallowing" shown to be the strongest driver of decisional regret among long term oropharyngeal carcinoma survivors (Goepfert et al., 2017)
- In an effort to decrease the devastating effects of chemoradiation on the swallow, significant emphasis has been placed on the use of pre-treatment or prevention-based swallowing exercise programs and early intervention by the SLP

McCulloch, et al., 2010

Standard of Care and the SLP

Well established in literature since at least 2004, Gillespie.

- Pre-treatment swallowing assessment
 - including the use of patient reported outcome measures (ideally one that allows measurement of impact of dysphagia on QOL)
- Provide education and initiate prophylactic treatment program
- Provide continuous assessment and treatment during and immediately after CRT/RT treatment concludes
- Primary goals being: keep the swallow mechanism moving & avoid any prolonged period of NPO

The Literature: What does it tell us?

- When do these patients benefit? Why? How? From what?
- Who are "these patients"?
- What is the goal of early referral to SLP and initiation of prevention-based treatment programs?
- What evidence do we have to support our treatment plans?

Research: Preventative Swallowing Therapy in Head and Neck Cancer

- The evidence supporting improvement in swallow function from dysphagia treatment is highly variable and nonspecific
- Difficult population to study
 - There are 5 different types of HNC, each with various tumor locations
 - Many studies contain patients with different TMN staging, comorbidities, treatment modalities, SLP treatment pathways, etc
 - Adherence (huge issue)
 - Drop Out

Established Evidence

- When assessed 3 months after treatment, the position of tongue base during swallowing was closer to the PPW, and epiglottis inversion was more normal in patients completing exercises before and during CRT compared to patients completing exercises after CRT. PEG tube removal at 12 mos. post was the same (Carroll et al., 2008).
- Patients randomly assigned to a swallowing exercise program throughout CRT had better diet related outcomes (FOIS & PSS-HN "normalcy of diet") at 3 & 6 mos. post tx. No difference immediately, 9, or 12 mos. post CRT (Kotz et al., 2012).

Established Evidence

- Patients completing a swallowing exercise program during CRT demonstrated less structural change in muscle size and composition in the swallowing musculature (genioglossus, hyoglossus, mylohyoid) at 6 mos. post treatment. Functional swallowing outcomes were favorable in this group as well; oral diet, normalcy of diet, weight loss <10% (Carnaby-Mann, Crary, Schmalfuss & Amdur, 2012).
- Patients who maintained oral intake & a prophylactic swallowing exercise program during CRT or RT demonstrated shorter length of G-tube dependence and were more likely to eat a regular diet up to ~2 years post treatment (Hutcheson et al., 2013).

Established Evidence

- Patients randomly assigned to complete a prophylactic swallowing therapy program during CRT demonstrated significantly better oromotor function, incisal opening, and fewer pharyngeal phase impairments at 3-6 mos. post treatment. Oral intake was better at 3 mos.(not statistically significant). There were no differences between groups at 12 & 24 mos. (Messing et al., 2017).

Review of Evidence

- We mainly have RCTs and retrospective studies. Few blinded outcome assessments, bias could be an issue.
- Recent systematic review of 20 studies (14 "prophylactic") indicates that behavioral swallow interventions are beneficial for swallow physiology and function. There is not enough evidence regarding specific exercises or optimal timing/intensity.
- "Future high-quality trials are needed to clarify the most effective time, type, and intensity of behavioral dysphagia interventions for these HNC patients"

Greco et al., 2018

Evidence Based Practice

- There is an abundance of definitions of evidence-based practice (EBP). Fortunately, most of them say essentially the same thing. The most well-known definition is that put forth by David Sackett and colleagues:
- ❖ "Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values."

<https://www.asha.org/Research/EBP/Introduction-to-Evidence-Based-Practice/>

Evidence Based Practice

- In 2004, ASHA's executive board convened a coordinating committee on evidence-based practice.
- ❖ The goal of EBP is the integration of: (a) clinical expertise/expert opinion, (b) external scientific evidence, and (c) client/patient/caregiver values to provide high-quality services reflecting the interests, values, needs, and choices of the individuals we serve.

Theory

- An orderly set of statements that explains or predicts behavior and that is subject to scientific verification for continued existence
- Theory provides a framework that is essential for understanding the behaviors of interest and can serve as a reliable guide for intervention planning; however, given its inherent limitations, theories cannot encompass all aspects of behavior
 - *Theories are models that work in a limited range of settings, vs laws of science that hold and apply universally*
- "Commitment to theory is fundamental for building effective and efficient intervention programs"

Friel-Patti, 1994

Evidence Based Clinical Practice

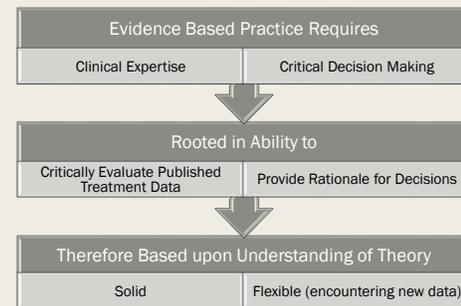
- Because EBP is client/patient/family centered, a clinician's task is to **interpret** best current **evidence** from systematic research **in relation to an individual** client/patient, including that individual's preferences, environment, culture, and values regarding health and well-being.
 - ✓ *Interpret current research evidence in relation to the individual patient*
- Because EBP is a continuing process, it is a **dynamic integration of ever-evolving clinical expertise** and **external evidence** in to **day-to-day practice**.
 - ✓ *Effectively combine progressive & adaptable clinical expertise with knowledge of current research evidence to daily clinical practice*

<https://www.asha.org/Research/EBP/Introduction-to-Evidence-Based-Practice/>

The Role of Theory in Evidence Based Practice

- **Clinical Expertise** & Appropriate **Clinical Decision Making**
 - *Rooted in the ability to critically evaluate published treatment data, and provide rationale for decisions*
 - *Therefore based upon a solid understanding of theory that is also flexible when presented with new data*

Kleinow, 2015



Clinical Practice Evidence & Theory Based

Clinical Expertise & Appropriate **Clinical Decision Making**

- ✓ The ability to interpret current research evidence in relation to the individual patient
- ✓ In order to effectively combine our progressive & adaptable clinical expertise with the knowledge of current research evidence to our daily clinical practice

"Commitment to theory is fundamental for building effective and efficient intervention programs"

Evidence Review: What Else Do We Know?

- Radiation fibrosis syndrome-neuromuscular fibrosis—a progressive and irreversible process causing extreme functional impairments to the upper airway and swallowing mechanism
- HPV: >25% of HNCAs, >50% of Oropharyngeal CAs, younger, different demographic, greater cure potential, greater expectations, more lifetime after radiotherapy
- There is a growing number of long-term HNC survivors who therefore have a lifetime risk of developing late RAD.
- Growing support for prevention based programs, but long term benefit?

Theory Based Practice Radiation Induced Dysphagia

- Therapy initiated before/during RT appears to be more beneficial than when initiated after
- Applying some concepts of the pathophysiology of radiation induced dysphagia with established evidence:
 - Atrophy: loss of muscle mass, cell death, disuse
 - Cranial nerve injury: radiation field, fibroatrophic phase
 - Movement is key—maybe even for mucositis and nociceptive pain
- Risk factors related to treatment include chemotherapy, total radiation dose, radiation dose to superior pharyngeal constrictors, and muscle disuse (period of NPO)

King et al., 2016

Theory Based Practice Radiation Induced Dysphagia

- Manual Therapy-Myofascial Release Principles
 - Passive and/or active movement of joints and soft tissue, in this case, low load, long duration stretches
 - MFR can include gentle sustained pressure to connective tissue and/or areas of perceived restriction
 - Goals to improve ROM, function, pain
- Adherence and Long Term Benefit
 - Study by Messing and colleagues illustrates not only the success of a pathway but of the multidisciplinary team: "Regular and ongoing services were provided and attended by most patients, with positive long-term swallowing outcomes achieved by most as measured by PROs"

Messing et al., 2019

Theory Based Practice Radiation Induced Dysphagia

- Clinical Expertise & Appropriate Clinical Decision Making
- ✓ The ability to interpret current research evidence in relation to the **individual patient**, including that **individual's** preferences, environment, culture, and values regarding health and well-being
 - "Larger, high quality studies, which include patient-reported outcome measures, are required to underpin the development of patient-centered rehabilitation programs. There is also a particular need to develop and evaluate interventions, which address the psychological and/or social aspects of eating" (Cousins, et al., 2013).
 - And the adherence problem..

Patient Reported Outcome Measures

- Pre-treatment swallowing assessment should include the use of patient reported outcome measures (PROs), ideally one that allows measurement of impact of dysphagia on quality of life (QOL).
- The M.D. Anderson Dysphagia Inventory (MDADI)
 - Self-administered questionnaire designed specifically for evaluating the impacting of dysphagia on the QOL of patients with HNC
 - Questions divided into global, emotional, functional, and physical subsets

Gillespie, 2004

Patient Reported Outcome Measures

- Functional Assessment of Cancer Therapy-Head and Neck Cancer (FACT-HN)
 - Self-reported instrument, specifically designed for HNC
 - 4 domains including physical, social/family, emotional, and functional well being which is further supplemented by 12 site-specific items to assess for H&N related symptoms
- Performance Status Scale for Head and Neck Cancer Patients (PSS-HN)
 - Administered by the health professional; "unstructured interview format"
 - HNC specific measure, designed to evaluate performance in areas of functioning most likely affected by HNC and its treatment: Normalcy of Diet, Eating in Public, Understandability of Speech

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