SWALLOWING OUTCOMES AFTER RADIOTHERAPY FOR HEAD AND NECK CANCER: A SYSTEMATIC REVIEW

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Abstract: Background. A systematic review of the current data on swallowing function after radiotherapy or chemoradiotherapy is presented.

Methods. Electronic databases were searched for 1966–2005. Papers were categorized according to level of evidence, methodological quality, and the specific domain of swallowing being measured.

Results. Of 109 papers retrieved, 33 were identified and reviewed. Evidence was primarily classified as either level III.2 (cohort studies) or level IV (case series). Methodological quality was found to be compromised in most studies. Although many researchers had investigated swallowing impairment, a wide variety of measurement tools were employed.

Conclusions. There are limited data on swallowing outcomes after radiotherapy or chemoradiotherapy for head and neck cancer. Further work is needed to ascertain which aspects of swallowing should be measured, and then to use such measures in well-designed clinical trials and prospective cohort studies of this underresearched population.

Keywords: swallowing; dysphagia; head and neck neoplasms; radiotherapy; systematic review

Descriptions of, and outcomes from, organ preservation treatment(s) for head and neck cancer have proliferated in the literature over the past 2 decades. Large clinical trials, using differing radiotherapy fractionation schedules, delivery techniques, and adjuvant chemotherapeutic agents, have been published.1–4

The choice of radiotherapy or chemoradiotherapy, with implicit organ preservation, may seem attractive to patients diagnosed with head and neck cancer, who perceive that this will not only maintain appearance, but also maintain the function of the organ(s) involved. However, many clinicians working in the area of head and neck radiation oncology acknowledge the limitations of organ preservation protocols; appreciating that the preservation of structure does not necessarily translate to the preservation of function.5

Dysphagia (difficulty in swallowing) after treatment for head and neck cancer has always been an outcome of concern to patients and clinicians. After major surgical resection and reconstruction for large head and neck cancers, the (often devastating) effects on swallowing ability are well documented.6,7 When obtaining informed consent to surgery, there is evidence available for clinicians to advise patients accurately on their likely swallowing (dis)ability, and research continues into rehabilitation techniques to minimize such adverse outcomes from surgery.8

Radiotherapy or chemoradiotherapy are relatively new as curative options for large head and
neck cancers, so a focus on the functional outcomes after these types of treatments is timely. Clinicians currently lack good evidence of swallowing outcomes after organ preservation treatment(s) for head and neck cancer, so it is difficult to make an objective assessment of the relative benefits of 1 treatment over another and to accurately advise patients, before starting treatment, of likely swallowing outcomes.

In the present study, we systematically review the current data available on swallowing function after radiotherapy or chemoradiotherapy treatments for head and neck cancer to answer the question: What is the current evidence for changes in swallowing outcomes after radiotherapy for head and neck cancer? We summarize the methodological quality and levels of evidence found. To enable more thorough examination of the currently available evidence, the retrieved data were categorized, using the World Health Organization (WHO) International Classification of Functioning, Disability, and Health (ICF) domains of impairment, activity limitation, and participation restriction, according to which of these aspects of swallowing were being measured.

**International Classification of Functioning, Disability, and Health Categories.** The ICF enables a common framework and language to be used when describing function and disability associated with different health conditions. The ICF encompasses domains such as an individual’s body functions and structures activities that they engage in, and areas of life in which they participate.

Impairment(s) of Body Functions and Structures. “Body functions” refers to physiological functions of body systems, whereas “body structures” are anatomical parts of the body, such as organs and limbs. The ICF classifies impairments as “problems in body function or structure, such as significant deviation or loss” (Ref. 9, p. 12).

Impairment of swallowing may include delayed initiation of the swallowing reflex, pooling of a bolus within the pharynx, and aspiration of a bolus.

Activity Limitations. “Activity,” according to the ICF is “the execution of a task or action by an individual” (Ref. 9, p. 12). Activities may include holding a conversation or washing oneself. Activity limitations, therefore, are defined as “difficulties an individual may have in executing activities” (Ref. 9, p. 12).

Activity limitations pertaining to swallowing include an individual’s inability to safely manage certain foods and fluids, requiring modification of consistencies and/or use of specific strategies. At a more severe level, activity limitations may mean that an individual is unable to manage any oral intake safely, such that alternative nutrition (ie, enteral tube feeding) is required.

**Participation Restrictions.** The term “participation” refers to involvement in life situations. Life situations may include relationships with family or employment. Using the ICF, participation restriction is defined as “problems an individual may experience in involvement in life situations” (Ref. 9, p. 12).

Participation restriction(s) resulting from dysphagia may reduce an individual’s involvement in work, family, community, or social situations. For example, the ability to go out with friends to a restaurant or to enjoy a meal with the family will be significantly restricted, if an individual is unable to safely swallow and/or relies on enteral tube feeding for nutrition.

**Quality of Life.** It is important to note that quality of life (QOL) is not part of the ICF classification. Rather, this is a complex, and somewhat abstract, concept that essentially represents an individual’s sense of well-being, fulfillment, or satisfaction with their own life. “Measurement” of QOL is often attempted through surrogate ratings of items such as pain, swallowing measures, throat irritation, appearance, energy, changes in employment, and involvement in recreation/entertainment. The evaluation of the “meaningfulness” of a person’s life differs from an evaluation of health function, as defined by the ICF, and is examined qualitatively, usually being described by the individual. Given the significant differences between measures of QOL and the 3 ICF domains of impairment, activity limitation and participation restriction, QOL was not an evaluation or outcome of relevance for this review and will not be addressed further.

**Measurement of Swallowing.** Swallowing ability is measured using various tools. These measurement tools may provide information about the impairment, activity limitation, and/or participation restriction(s) of the individual in the context of their swallowing ability.

To measure impairment of swallowing function, the most commonly used instrumental method is a videofluoroscopy swallowing study (VFSS). AVFSS
(also referred to as the modified barium swallow [MBS]) involves the use of dynamic fluoroscopic images, recorded on videotape. During the procedure, an individual swallows various bolus consistencies, mixed with radiopaque barium, to ensure a clear view of the path of the bolus under x-ray, during the swallow. One of the primary benefits of a VFSS is the ability to observe movements of anatomic structures simultaneously with the movement of a bolus. Clinicians may obtain data from a VFSS by using the videotaped record to make temporal, distance, or biomechanical measures of structural and/or bolus movements, or by observing the presence of abnormalities.

Measurement of activity limitation and/or participation restriction may be obtained through use of clinician rating scales or from patient self-report. A number of published, standardized rating scales are available. These include the Performance Status Scale questionnaire, the Hillel 10-point scale (standardized for ALS), and the swallowing scale of the Australian Therapy Outcome Measures (AusTOMs). Researchers have often developed their own measurement tools. These are rarely validated but usually consist of 4 or 5 point rating scales, with written descriptors for rating activity limitations and/or participation restrictions. Examples of such descriptors range from “impaired swallowing requiring dietary alterations” to “entirely dependent on tube feeding.” Using such distinct, nonvalidated tools means that comparisons cannot be confidently made across studies, limiting their application and usefulness.

In addition to the use of rating scales, activity limitation and participation restriction have also been measured through patient self-reports of estimated percentages of oral intake (versus enteral nutrition) taken, description of food consistencies that are avoided, and personal perception of whether swallowing problems are experienced. These subjective reports again limit the potential for results between studies to be compared, and the reliability and validity of such measures may be questioned.

The method of swallowing measurement used must be appropriate to the aims of the study in hypothesis-driven research. It is important to recognize that the type information provided will be significantly different, depending on which ICF domain the measurement represents. As there is no direct correlation between the domains, each should be treated independently. For example, an impairment of body function does not always equate to a limitation in activity. Similarly, an individual may have a marked limitation in activity (such as swallowing), without an associated restriction in societal participation.

**METHODS**

**Search Strategy.** This systematic review was designed to investigate the question: What is the current evidence for swallowing outcomes after radiotherapy for head and neck cancer? A search was undertaken from January to July 2005, using the following electronic databases: MEDLINE (1966 to July Week 2, 2005), CINAHL (1982 to July Week 3 2005), AMED (1985 to July 2005), Embase (1988 to 2005 Week 29), the Cochrane Database of Systematic Reviews, and the Cochrane Controlled Trials Register. The following MeSH terms were exploded and used for each database search: radiotherapy, adjuvant radiotherapy, adjuvant chemotherapy, combined modality therapy, head and neck neoplasms, deglutition, deglutition disorders, speech therapy, and speech-language pathology. The following free-text terms were exploded and used on each database search: head and neck cancer, swallowing, swallowing disorders, and dysphagia. Reference lists of relevant papers were then hand-searched for additional publications. Any unpublished studies through the Dissertation Abstracts International database were also searched, using the same terms as stated above.

Initially, 109 papers were identified using this search strategy. Abstracts of all 109 papers were read, and papers that did not meet the inclusion criteria (stated below) were excluded. The full texts of the remaining 33 papers were then read and independently categorized by 2 reviewers (JF and AP) according to the Joanna Briggs Institute for Evidence Based Nursing and Midwifery levels of evidence. Papers were then further categorized based on the ICF component of swallowing being measured, and the measurement tool(s) used were noted.

**Selection Criteria.** The purpose of this systematic review was to identify and retrieve studies in which swallowing outcomes were either the primary focus, or the focus in addition to, for example, speech or voice outcomes. A large number of clinical trials (ie, research studies conducted with patients to evaluate a new treatment or drug) investigating different radiotherapy treatment regimens and techniques were identified. Many were
randomized controlled trials. These clinical trials were reviewed, but the searching and evaluation of these studies was not extensive, as swallowing outcomes were not their primary focus.

Studies using any type of methodological design, except for single case studies,
were included in this review. For inclusion, studies had to consist of adult patients who had been treated with radiotherapy for head and neck cancer, with a curative intent to treatment. Studies were also included in which patients had received adjuvant treatment, such as surgery or chemotherapy. Studies had to include at least 1 form of swallowing measurement. All published articles included in this systematic review were published in a peer-reviewed journal and written in English.

Studies were excluded where they consisted of patients who had received surgery only, unless these surgical patients were used to compare against patients who had received radiotherapy. Papers were also excluded in which only QOL was assessed (even if swallowing-related), for reasons explained earlier.

**Evaluation of the Literature.** The papers included in this systematic review were categorized and evaluated according to the strength of the evidence, the methodological quality of the study, and the swallowing-related ICF component being measured and analyzed.

**Strength of the Evidence.** Papers were initially categorized according to the Joanna Briggs Institute for Evidence Based Nursing and Midwifery (JBI) levels of evidence. Although several “evidence hierarchies” are available, all of which provide a framework for ranking the strength of evidence, from strong to weak, the JBI levels of evidence were considered the most appropriate framework to use in this review for a number of reasons.

As stated by Reilly,
not only are the levels of evidence used in the JBI framework relatively straightforward and easy to apply but level IV is included, when this level is often omitted from other published evidence hierarchies. In addition, “mid-range” levels (ie, level III in the JBI framework) are further subdivided, allowing more specific rankings of scientific value to be given to the papers reviewed.

The JBI framework follows the traditional model of evidence hierarchies, where level I evidence is considered the strongest, and level IV is considered the lowest level of evidence (see Figure 1). It should be noted that this systematic review utilizes the JBI’s most recent definition of level IV, as originally defined by the National Health and Medical Research Council (NHMRC).

**Methodological Quality.** Methodological quality was assessed for all study designs included in this review. Because of the broad variation of study designs reviewed, separate guidelines were used for each, drawn from lists of suggested criteria published by Khan and colleagues and Greenhalgh. Methodological quality was evaluated independently by 2 raters (JF and AP).

**International Classification of Health Function Domains Measured.** Each paper was further categorized according to the ICF domain(s) being measured and analyzed. Studies in which researchers use instrumental assessment, such as VFSSs, provided data on impairment in swallowing, whereas in studies that included clinician-rating scales or subjective patient reports, researchers were usually assessing activity limitation and/or participation restriction.

**Data Synthesis.** It was not possible to perform a meta-analysis on the data. No level I or II studies were identified, and the level III and IV studies included in this review were heterogeneous, so they could not be appropriately combined. Sources
of heterogeneity included the populations described, the interventions (if any) used and, in particular, the studies’ varying designs and methodological quality. Therefore, evaluation of, and results from, the studies are presented descriptively and summarized in Table 1.14,20–22,29–59

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year*</th>
<th>Study design</th>
<th>Level of Evidence</th>
<th>ICF classification§</th>
</tr>
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<tbody>
<tr>
<td>Akst(29)</td>
<td>2004</td>
<td>Retrospective cohort study</td>
<td>Level III.2</td>
<td>Activity limitation</td>
</tr>
<tr>
<td>Alexander(30)</td>
<td>1989</td>
<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Impairment</td>
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<td>Carrara-de Angelis(31)</td>
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<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Impairment</td>
</tr>
<tr>
<td>Chang(32)</td>
<td>2003</td>
<td>Comparative case series (cross-sectional)</td>
<td>Level IV</td>
<td>Impairment</td>
</tr>
<tr>
<td>Eibbruch(33)</td>
<td>2002</td>
<td>Descriptive case series: pre-test/post-test</td>
<td>Level IV</td>
<td>Impairment</td>
</tr>
<tr>
<td>Ekberg(34)</td>
<td>1983</td>
<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Impairment</td>
</tr>
<tr>
<td>Gillespie(35)</td>
<td>2005</td>
<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Impairment and activity limitation</td>
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<td>2003</td>
<td>Prospective cohort study</td>
<td>Level III.2</td>
<td>Impairment, activity limitation, participation restriction</td>
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<td>1994</td>
<td>Comparative case series</td>
<td>Level IV</td>
<td>Activity limitation and participation restriction</td>
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<td>Hughes(38)</td>
<td>1998</td>
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<td>Level IV</td>
<td>Impairment</td>
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<tr>
<td>Kendall(39)</td>
<td>2000</td>
<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Impairment</td>
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<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Impairment</td>
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<td>Prospective cohort study</td>
<td>Level III.2</td>
<td>Impairment</td>
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<td>Level IV</td>
<td>Impairment</td>
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<td>Case-controlled study</td>
<td>Level III.2</td>
<td>Impairment</td>
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<td>Case-controlled cohort study</td>
<td>Level III.2</td>
<td>Impairment</td>
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<td>Impairment and participation restriction</td>
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<td>Impairment and activity limitation</td>
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<td>Murry(48)</td>
<td>1998</td>
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<td>Activity limitation</td>
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<td>Prospective cohort study</td>
<td>Level III.2</td>
<td>Activity limitation</td>
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<td>Newman(49)</td>
<td>2002</td>
<td>Controlled trial without randomisation</td>
<td>Level III.1</td>
<td>Impairment</td>
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<td>2004</td>
<td>Descriptive case series: post-test</td>
<td>Level IV</td>
<td>Activity limitation</td>
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<td>Pauloski(51)</td>
<td>1998</td>
<td>Cohort study with case controls</td>
<td>Level III.2</td>
<td>Impairment</td>
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<td>Pauloski(52)</td>
<td>2000</td>
<td>Descriptive case series: pre-test/post-test</td>
<td>Level IV</td>
<td>Impairment</td>
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<td>Pauloski(53)</td>
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<td>Prospective cohort study</td>
<td>Level III.2</td>
<td>Impairment and activity limitation</td>
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<td>2002</td>
<td>Comparative case series</td>
<td>Level IV</td>
<td>Activity limitation and participation restriction</td>
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<td>Rademaker(55)</td>
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<td>Prospective cohort study</td>
<td>Level III.2</td>
<td>Activity limitation</td>
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<tr>
<td>Smith(56)</td>
<td>2000</td>
<td>Prospective case series</td>
<td>Level IV</td>
<td>Impairment</td>
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<tr>
<td>Smith(57)</td>
<td>2004</td>
<td>Prospective cohort study</td>
<td>Level III.2</td>
<td>Impairment and activity limitation</td>
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<tr>
<td>Wu(58)</td>
<td>2000</td>
<td>Descriptive case series: post-test</td>
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<td>Impairment</td>
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<tr>
<td>Zelefsky(59)</td>
<td>1996</td>
<td>Comparative case series</td>
<td>Level IV</td>
<td>Activity limitation and participation restriction</td>
</tr>
</tbody>
</table>

* Year of publication.
† Based on the NHMRC guidelines(58, 59).
§ Based on the JBI Levels of Evidence(23).
‖ Based on the WHO International Classification of Health Function(9).
Levels of Evidence. The search failed to identify any level I or II (systematic reviews or randomized controlled trials) studies in which swallowing outcomes after radiotherapy for head and neck cancer were investigated. Most papers identified (18 from a total of 33 papers) were categorized as descriptive (level IV) studies, with 1 being a cross-sectional survey, and the remaining 17 studies being case series (see Table 1).

The methodology used in these studies involved a group of participants (sample sizes ranging from 6 to 184) who completed 1 VFSS or other type of swallowing measurement at a given point in time after radiotherapy treatment. The outcomes of these measurements were then used to describe the nature of swallowing impairments (or activity limitations/participation restrictions) after radiotherapy for head and neck cancer. Although 3 of these studies had admirable sample sizes of 50 or more, the use of a single episode of evaluation, with an absence of any pre-treatment data or longitudinal follow-up, meant that only a low level of evidence could be allocated.

Fifteen papers were categorized as level III, with 1 of these being level III.1 (controlled trial without randomization), 13 being level III.2 (cohort or case-controlled studies), and the remainder being level III.3 (multiple time-series). The levels of evidence and the design of each study identified are summarized in Table 1.

The level III.2 cohort studies differed from the level IV descriptive case series in that their design usually involved a group of participants who completed a VFSS or other type of swallowing measurement at a number of allocated points over time. Sample sizes ranged from 11 to 255 participants, although the latter sample dropped to 90 by the final evaluation.

Eleven of the 13 level III.2 studies included evaluations before radiotherapy treatment, which allowed more valid generalizations to be made about the effects of radiotherapy on swallowing than could be made from those level IV studies in which the pretreatment swallowing function of participants was not known.

The highest level of evidence found in this review was from 1 study, identified as level III.1 (i.e., controlled trial without randomization), which was published by Newman et al in 2002. In this study, swallowing outcomes after 2 different chemoradiotherapy protocols were compared by conducting VFSSs on a total of 30 participants before, and again 1 month after, treatment. Although the results of this study may only be of direct relevance to clinicians and patients interested in the 2 treatment protocols used in the study (radiation plus cisplatin vs conventional chemoradiation), the authors highlighted the importance of outcomes, such as dysphagia, as factors to consider when selecting between different organ preservation protocols.

Significant Cohort Studies. A number of cohort studies that have contributed significantly to our current understanding of swallowing after radiotherapy were identified.

Lazarus et al compared swallowing between 2 groups: 13 head and neck cancer patients before, and 2 months after, treatment, and 13 age- and sex-matched controls. They found that patients with head and neck cancer had significantly reduced tongue strength, both before and after treatment, when compared with control subjects. Both before and after treatment, patients with head and neck cancer had a higher incidence of oral residue and of aspiration than did the controls.

Pauloski et al compared swallowing impairments between 9 head and neck cancer patients treated with surgery and radiotherapy and 9 patients individually matched for tumor resection site and volume but treated with surgery alone. VFSSs were completed before treatment and again at 1, 3, 6, and 12 months posttreatment. When compared with the surgery alone cohort, the patients treated with surgery and radiotherapy were found to have worse swallowing on a number of different measures such as amount of pharyngeal residue, OPSE (oropharyngeal swallow efficiency), and duration of cricopharyngeal sphincter opening.

In a large prospective cohort study of 132 patients with head and neck cancers at various sites, Pauloski et al completed VFSSs before radiotherapy or chemoradiotherapy and again at 1, 3, 6, and 12 months posttreatment. Measures made from VFSSs were compared between patients who did and those who did not complain of dysphagia. Analysis revealed that patients who complained of dysphagia had worse swallowing on a number of different measures, including aspiration, indicating that patients were able to accurately recognize that their swallowing function was impaired. It was found that these patients often limited their oral intake as a result of their perceived problems.

In a further prospective study, List et al completed the Performance Status Scale on 64 patients with head and neck cancers of various primary
sites, before chemoradiation and again at a number of stages posttreatment. Scores for the normalcy of diet and the ability to eat in public declined during treatment, with only limited recovery in these scores over time. Statistical analysis indicated that pretreatment scores were not correlated with scores at 12 months posttreatment, and no baseline characteristic was significantly related to the normalcy of diet at 12 months. The authors recommended that further studies be conducted using a larger cohort to allow for comparisons of tumor site and radiation field.

**Methodological Quality.** The methodological quality of many of the papers reviewed was disappointing. Although nearly one half of the studies identified were categorized at level III evidence, suggesting strong validity of the research, design weaknesses meant that only limited conclusions could be made. For simplicity, the most common and significant methodological limitations identified throughout the literature are discussed.

**Sample Size.** Of the 33 studies identified in this review, more than one half of them involved 20 participants or less, with sample sizes as few as 6, 7, 9, 7, and 9. The largest reviewed study involved 255 participants, although this had dropped to 90 by the final 12-month evaluation, and only crude, subjective swallowing measures were used, thus providing limited information on functional outcomes.

**Heterogeneity of Populations.** The use of heterogeneous populations, with respect to the site of the primary tumor, was apparent throughout the literature. Most studies investigating swallowing after radiotherapy (n = 24) included participants with varying primary sites of head and neck cancer within the 1 cohort. Researchers have also combined tumor sizes, ie, included patients with T classifications ranging from T1 to T4, although most published studies report on patients with advanced (T3–T4) stage disease only.

In a small number of studies, the researchers investigated swallowing after radiotherapy with post hoc stratification of data, analyzing outcomes by primary tumor site. Murry et al attempted to find site-specific differences in their study of 58 participants with oropharyngeal, hypopharyngeal, and laryngeal cancer. By comparing participants’ subjective reports of swallowing, before and after chemoradiotherapy, a number of site-specific differences between participants were found, and the authors concluded that disease site is an important variable to consider when assessing swallowing status and quality of life.

Kotz et al reported significantly longer duration of laryngeal motion during swallowing in 7 patients with hypopharyngeal tumors when compared with 7 patients with oropharyngeal tumors. Pauloski et al reported that patients with oral cavity tumors demonstrated very little aspiration, whereas patients with pharyngeal and laryngeal tumors who complained of dysphagia had a significantly larger incidence of aspiration than those who had no swallowing complaints. The base of tongue appears to be a specific site of concern for risk of dysphagia. Patients with base of tongue tumors have been found to have a much larger pharyngeal area at maximum constriction, when compared with pharyngeal and laryngeal cancer groups, suggesting poorer tongue mobility and/or worse poor pharyngeal wall contraction during swallowing. In a further study, patients with base of tongue tumors reported significantly worse normalcy of diet when compared with other sites in the head and neck region; this result was irrespective of tumor size.

**Absence of Baseline Data and Longitudinal Design.** Much of the early research on swallowing after radiotherapy for head and neck cancer is based on retrospective reviews, conducted months, or years, after treatment. The first published studies to investigate swallowing function, both before and after radiation treatment, did not occur until the late 1990s, but obtaining pretreatment data has recently become more common. In a study by Pauloski et al, the authors used pretreatment function as a covariate in analysis, to ensure that any posttreatment differences observed were attributable only to the treatment effects. In that study, radiotherapy was found to affect both the oral and pharyngeal phases of swallowing, when pretreatment and posttreatment data were compared.

**Measurement of International Classification of Health Function Domains.** Most researchers investigating swallowing outcomes after radiotherapy for head and neck cancer assess swallowing impairment, using VFSS (see Table 1). In the following section, the retrieved data have been classified according to the ICF domains: impairment, activity limitation, and participation restriction.

**Impairment.** Impairment was the most common domain to be measured in dysphagia studies and it was reported on in 24 of the 33 studies. This domain
Swallowing was assessed by means of VFSS or, less commonly, by using fiberoptic endoscopic evaluation of swallowing (FEES). Analysis involved observation of the presence or absence of swallowing abnormalities and/or the use of computer software to allow temporal, distance, and biomechanical measures to be made.

Although this review has highlighted that the current literature on swallowing after radiotherapy is limited, commonly described impairments of swallowing function after radiotherapy were identified. These included: poor pharyngeal motility, with subsequent pharyngeal residue, reduced laryngeal excursion, poor closure of the laryngeal vestibule, aspiration, and reduced laryngeal excision. These changes in swallowing function and/or the use of computer software to allow temporal, distance, and biomechanical measures to be made.

Activity Limitation and Participation Restriction.

In less than one half of the studies identified (n = 14), activity limitation and/or participation restriction were measured as outcomes of interest. The tools used in these studies were numerous: subjective, independently developed questionnaires, asking patients about perceived swallowing problems; an independently developed 4-point rating scale of eating ability; patient self-assessment, such as their estimated percentage of nutrition taken orally, food consistencies eaten and their own perception of whether dysphagia is present; the presence/absence of tube feeding; the M. D. Anderson Dysphagia Inventory (MDADI) and the Performance Status Scale (PSS) questionnaire, which is a scale specifically developed for use with head and neck cancer patients. Of the 14 studies that included activity limitation and/or participation restriction measures, only the studies that used the PSS or the MDADI involved standardized assessment tools.

Results of activity limitations and/or participation restrictions after radiotherapy were variable. Graner et al found that 7 of 11 patients still relied on enteral nutrition at 5 months postchemoradiation. List et al reported 82% of patients with advanced-stage head and neck cancer still had a restricted diet at 12 months postchemoradiation, whereas Rademaker et al found that although the percentage of oral intake versus enteral nutrition reduced sharply immediately postchemoradiation, this improved to near baseline (pretreatment) levels by 12 months posttreatment.

Swallowing Outcomes from Clinical Trials. Radiotherapy-related literature that reveals strong levels of evidence (ie, level I, systematic reviews; level II, randomized controlled trials) are usually medically instigated clinical trials, where the aim(s) are to investigate specific radiotherapy or chemoradiotherapy regimens. During the literature search, a large number of clinical trials were identified. As the purpose of this review was to identify and analyze papers where dysphagia was the outcome of interest, these clinical trials were not thoroughly reviewed. However, given the large number of papers retrieved, with the populations involved being identical, acknowledgment and a short discussion of these studies follows.

Since 1965, more than 70 medically instigated randomized controlled trials with more than 12,000 patients have been conducted to investigate the influence of different radiotherapy and chemotherapy regimens on survival, complication rates, and/or functional outcomes. Trials are usually multi-center and may include many hundreds of subjects. Unfortunately, despite the widely accepted importance of functional outcomes and acknowledgment that preservation of structure does not necessarily translate to preservation of function, the reporting of swallowing outcomes from clinical trials, particularly randomized controlled trials, was found to be lacking.

Acute and late radiotherapy reactions are often reported in clinical trials. These are generally rated using scales such as the Radiation Therapy Oncology Group (RTOG) acute toxicity scale, the RTOG/European Organization for Research and Treatment of Cancer (EORTC) late toxicity scale, the National Cancer Institute (NCI-CTC) scale, the WHO acute grading or, less commonly, the Late Effects on Normal Tissues/Subjective, Objective, Management, and Analytic (LENT/SOMA) scales, and Dische scales. These scales do not allow for accurate ratings of swallowing to be made.

Clinical trials in which swallowing was measured, with either VFSSs or other standardized methods, were, with a few exceptions, lacking. In a nonrandomized trial by Mittal et al, swallowing
evaluation was completed pretreatment and again 3 months posttreatment in 39 head and neck cancer patients. Eighteen of these patients were treated with, and 21 treated without, tissue/dose compensation (TDC, ie, modulation of the radiation beam). Using VFSSs and the Performance Status Scale, it was found that patients who received TDC had better swallowing at 3 months posttreatment than did the patients who did not receive TDC. In a small case series after concurrent chemoradiotherapy for resectable head and neck cancers, Koch et al reported that most of the 22 patients studied had some degree of swallowing deficit at 3 months posttreatment, but improvement was noted by 12 months posttreatment.

Clinical trials have been conducted where swallowing has been measured using somewhat crude, nonstandardized scales. In most clinical trials, however, swallowing has not been an outcome of interest to the researcher(s).

DISCUSSION

Levels of Evidence and Methodological Quality. The current evidence regarding swallowing function after radiotherapy for head and neck cancer remains limited. Many studies are flawed, either in the strength of their evidence and/or their methodological design. Studies with relatively high levels of evidence (ie, level III.2 cohort studies) are often compromised by methodological weaknesses, such that any conclusions should be made with caution.

Nevertheless, there is sufficient convincing evidence of swallowing function after radiotherapy for head and neck cancer being severely impaired in many people, and the available evidence provides preliminary data to suggest where further investigation is most necessary.

It is apparent that the way forward in investigating the nature of swallowing problems after radiotherapy is to first, include accurate and detailed swallowing measures in medically instigated clinical trials and second, for clinicians (ie, speech pathologists) to conduct well-designed cohort studies that address the methodological weaknesses identified in prior research. The most notable weaknesses are small sample size, use of heterogeneous populations, and an absence of well-designed longitudinal studies that included data collected at baseline (before treatment).

Small Sample Size. Accruing large numbers of participants is often a problem in the area of head and neck cancer, as patients are often elderly with multiple comorbidities and may undergo multiple different treatments. In many countries, head and neck cancer services are not centralized, further increasing the "geographical spread" of treated patients. This makes patient accrual and the overall logistics of conducting research difficult, and the reality of patients being prepared to travel wide distances for involvement in research has to be considered. These issues may only be realistically addressed by conducting multi-centered research.

Heterogeneous Tumor Site. Analyzing heterogeneous samples within a study, by aggregating data from people with different primary tumor sites, will result in poor validity of research results. This risk was identified and addressed by Taylor et al in a clinical trial examining variables that influence subcutaneous tissue damage. The authors analyzed patients by separating them into 8 subgroups, determined by their primary head and neck cancer site and the stage of their disease. The rationale for separating participants in their analysis was stated as: "(a) the normal tissues contained in the high dose [radiation] field differ by primary site, (b) the [radiation] field size varies according to primary site and T classification, and (c) a large primary tumor may itself cause destruction of normal tissue and hence contribute to a higher incidence of late complications" (Ref. 67, p 4). Researchers who have not stratified participants with different tumor sites in their analyses have justified such aggregation by stating that radiation fields were relatively homogenous, with only a 1–2-mm difference between any given field. However, points (a) and (b) in the above quote suggest that the assumption of homogeneity of radiation fields should be questioned. It remains unclear whether tumors in different locations of the head and neck, and of different sizes, result in different swallowing outcomes after radiotherapy. This can only be resolved by authors separately analyzing individuals based on their tumor site and size.

Baseline Data. It is widely accepted that, before treatment, most cancers within the head and neck region will impact on speech and/or swallowing function. A study’s results may be rendered invalid if pretreatment data have not been collected in order to control for tumor effects in the analysis of posttreatment data. The pretreatment swallowing dysfunctions identified in recent studies
have led authors to state that: “it is critical that posttreatment function is compared with the baseline pretreatment, dysfunction” (Ref. 69, p374). The completion of swallowing evaluations during clinical trials and well-designed longitudinal cohort studies would address this limitation.

**International Classification of Health Function Domains and Measurement of Swallowing.** Significant variations in the type and quality of the measurements used to assess swallowing after radiotherapy were identified. Even when the same ICF domain was being measured, there was an inconsistency in the reliability, validity, and suitability of chosen tools. Such variability in data further limits our ability to make generalizations about swallowing after radiotherapy and does not allow comparisons across studies to be made. The following section highlights the inconsistencies identified in the measurement and analysis of swallowing, and discusses them in relation to their ICF classification.

**Impairment.** Most researchers measuring swallowing impairment used VFSS as the measurement tool, while 1 used FEES. Although VFSS has long been considered the “gold standard” in the assessment of swallowing disorders, such tools are only as good as the quality of the subsequent measurement and analysis. Many researchers have used computer software for detailed temporal, distance, and biomechanical measures from individual swallows using VFSSs. This results in the availability of a new dataset for analysis and interpretation. These data could be considered more “objective,” and therefore more reliable, than data obtained from observation and clinical interpretation. However, interrater and intrarater reliability still need to be ensured whenever these new measurements are used.

From the 24 studies identified in which swallowing impairment was assessed, clinical observation of abnormalities, and/or temporal, distance, and biomechanical measures were described. Further, many measurements were only slight variations of each other, e.g., presence of base of tongue weakness, maximum posterior movement of the base of tongue, and tongue base to posterior pharyngeal wall contact. Although researchers seem to be heading in the direction of accurate and detailed swallowing measures, because of these variations we remain unable to compare much of the data across studies, thereby limiting their application.

**Activity Limitation and Participation Restriction.** There is significant variation in the tools used to measure activity limitation and participation restriction. As highlighted in Results, of the 14 papers that reported on activity limitation and participation restriction, only 6 of those papers used a standardized rating scale.

Again, results between studies cannot be compared when subjective, nonstandardized measures are used. They provide a more limited contribution to the current knowledge about swallowing after radiotherapy than would be provided by any of the quick and easy to use standardized tools that are available to clinicians. Such scales include the Performance Status Scale questionnaire, the MDADI, the Therapy Outcome Measures (TOMs), and the Australian Therapy Outcome Measures (AusTOMs).

**Swallowing Measurements from Clinical Trials.** The absence of specific swallowing outcome data from large, often influential, clinical trials is disappointing. Many researchers purport to analyze swallowing outcomes; however, other than the NCI-CTC and the Dische scales, the commonly used scales (i.e., RTOG acute toxicity scale, RTOG/EORTC late toxicity scale, WHO acute grading, and LENT/SOMA) do not measure true oropharyngeal dysphagia. The RTOG acute toxicity scale includes the term “dysphagia,” but it is not clear exactly what is being rated, as the same subscale includes odynophagia and complications such as complete obstruction, ulceration, or fistula. Equally confusing, the RTOG/EORTC late toxicity scale includes the term “swallowing,” yet the corresponding rating actually refers to swallowing difficulties as a result of esophageal stricture.

The NCI/CTC toxicity scale and the Dische Morbidity Recording Scheme both include ratings of “true” oropharyngeal dysphagia. These are crude, 5-point ratings, ranging from “no dysphagia” to “complete obstruction (cannot swallow saliva)” (NCI/CTC scale) and “severe difficulty swallowing fluids” (Dische scheme). Ratings are usually based on results from clinician questioning and patient self-report.
It can be seen that, although researchers often claim to have evaluated and reported on radiation toxicity (acute and/or late), “toxicity” rarely includes an accurate rating of swallowing. Of note, the few specific swallowing scales that have been adopted during clinical trials were all measurements of activity limitation and did not include measurements of swallowing impairment. This information represents how people are carrying out activities and participating in life situations (in relation to swallowing), but does not record physiological changes in swallowing (ie, impairment). As 1 domain does not directly correlate with another, both need measuring.

Although the limitations in the current reporting of swallowing outcomes during clinical trials has been acknowledged, it has been stated that instrumental measures such as a VFSS are generally “not feasible” within large clinical trials. This perception should be challenged. As the current best available swallowing evaluation, VFSS should be part of a routine assessment of all patients involved in clinical trials of head and neck cancer in whom swallowing is likely to change. This is particularly important because of the reportedly high prevalence of silent aspiration, which cannot be accurately detected without the use of VFSS or FEES.

The rating scales that are currently used in the oncologic clinical trials are not sufficient for assessing swallowing. In addition, clinicians and researchers need to establish more specific standards with respect to what are the most pertinent measurements and analyses to be completed. In order to make VFSS a realistic and efficient evaluation within large clinical trials, it may be necessary to use alternative methods of analysis, rather than labor-intensive computer software used to make complex biomechanical measures. A quickly completed assessment is needed, to provide accurate information about swallowing and change over time. A version of the ALS severity scale, adapted for head and neck patients, could be such a tool. A minimum agreed dataset for capturing swallowing, universally adopted by researchers working with patients with head and neck cancer, would greatly enhance the quality of research in this area.

CONCLUSION

Despite organ preservation protocols becoming more widely used for the treatment of head and neck cancer, this review highlights an absence of data regarding swallowing function after such treatments. Although a number of studies have been published over the past 2 decades with the aim of reporting postradiotherapy swallowing function, many of these papers are classified as having low levels of evidence and are limited by methodological flaws. This means that clinicians are left with a number of significant questions, including: Which patients develop dysphagia after radiotherapy and chemoradiotherapy? When does this develop? To what extent does it occur?

Swallowing evaluations should be included in clinical trials, and there is a need for speech pathologists to undertake well-designed prospective longitudinal cohort studies that will contribute to the current knowledge on swallowing function after radiotherapy and chemoradiotherapy. As part of this process, agreement is needed on what aspects of swallowing are important to measure, and how these could be measured efficiently. Only when we have a better understanding of post-treatment swallowing dysfunction can we reliably inform patients of potential outcomes, accurately compare the results of different treatment protocols, and investigate rehabilitation and treatment strategies to more effectively reduce the major swallowing morbidity that often results from head and neck cancer treatment.

REFERENCES


