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Radiation Therapy-Related Mucositis, Mucositis Pain, and Self-Care Behaviors of the Head and Neck Cancer Patient

by

Gayle Harumi Shiba

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF NURSING SCIENCE

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA

San Francisco

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Acknowledgment

This dissertation represents the attainment of a once only dreamed of goal in my life. I feel a tremendous sense of pride and satisfaction, both personal and professional, as I complete this dissertation and the doctoral program. At times I felt that I would never get to this point. While the dissertation is viewed as a personal endeavor, I owe much of my success in completing the Doctorate in Nursing Science degree and dissertation to a number of people whom I wish to acknowledge now.

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Abstract

Radiation Therapy-Related Mucositis, Mucositis Pain, and Self-Care Behaviors of the Head and Neck Cancer Patient

Gayle Harumi Shiba
University of California, San Francisco

Radiation therapy (RT)-related mucositis, mucositis pain, xerostomia, taste changes, and weight loss are significant and distressing problems for patients with head and neck (H&N) cancer. Currently, the patient and family bear the primary responsibility for the care and treatment of RT-related side effects. No previous studies have examined or characterized the impact of this combination of RT-related side effects on the patient with H&N cancer. The primary purpose of this study was to describe the onset, severity, and time course of RT-induced mucositis and mucositis related pain. Secondly, the severity of xerostomia, taste changes, and weight loss was examined. The use of self-care activities for these side effects was determined. Finally the relationship(s) among the mucositis, mucositis-pain, xerostomia, taste changes, and weight loss were examined. Patients were seen three times a week during RT, and at the one month follow-up visit. RT-related mucositis, mucositis severity, xerostomia, and taste changes were determined using the MacDibbs Mouth Assessment Tool and a weekly Self-Care Diary. Pain was measured using the Pain Profile and Weekly Pain Assessment Questionnaire and the MacDibbs Mouth Assessment Tool. Self-care activities were determined from the weekly Self-Care Diary. Fifty patients consented to the study with 49 patients evaluable for the study. Results showed that all H&N RT side effects studied were severe and distressing. Side effects, once they occurred, remained constantly present throughout the treatment

and lasted longer than expected, often past the follow-up appointment. All patients developed mucositis, mucositis ulcers, and oropharyngeal pain during RT. Patients reported pain with increasing severity throughout RT. However, patients experienced significant differences in pain when swallowing or not swallowing at all time points evaluated starting week 2, with more severe pain present with swallowing impacting on the patients ability to eat and drink. The severity of side effects and duration of each was worse than most patients were prepared for or expected. Over 72% of patients were experiencing all the anticipated side effects by mid-therapy, with greater than 80% still reporting these side effects at the end of treatment. Patients employed self-care activities over the course of treatment with moderate success, with pain, mouthsores, and xerostomia indicated as the side effects for which patients utilized the most self-care activities. A troubling finding of this study was the high percentage (20%, n=10) of patients requiring unscheduled hospitalization for what appeared to be treatment-related problems. An additional nine patients (18%) were seen in emergency rooms for similar problems.

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CHAPTER I

Introduction

The Study Problem

Cancers of the head and neck (H&N) region comprise approximately 5% of all cancer incidence and include cancers of the oral cavity and pharynx, nasal cavity and paranasal sinuses, salivary glands, and the larynx. It is estimated that more than 41,500 new cases of H&N cancer will be diagnosed in 1997 - more than 4,700 in California alone (American Cancer Society, 1997).

While H&N cancer treatment is determined by the clinical stage, as well as the pathologic characteristics, for early disease, surgery and/or radiation therapy (RT) is frequently the primary treatment of choice. Radiation therapy is a local treatment producing therapeutic and deleterious effects in the normal, as well as cancerous, tissues and cells of the irradiated region. These effects frequently manifest as symptoms or side effects of treatment. Patients receiving H&N irradiation, especially for cancer of the oral cavity, oropharynx, hypopharynx, and nasopharynx, experience radiation-induced changes at these sites that frequently result in reported symptoms or problems of mucositis, pain, xerostomia, taste changes, and weight loss (Greenberg, Sawicka, Eisenthal, & Ross, 1992; Madeya, 1996a; Madeya,1996b; Scully & Epstein, 1996; Strohl, 1989; Youngblood, Williams, Eyles, Waring, & Runyon, 1994).

Statement of the Problem

Acute reactions from radiation treatments can occur during or immediately following

treatment (i.e., up to 90 days after the initiation of therapy). These problems are a direct result of the effects of ionizing radiation on normal cells.

The goal of radiation treatment in the patient with H&N cancer is to destroy or damage cancer cells while minimizing the adverse effects of radiation to normal cells and tissues. The higher the cumulative dose of radiation, the greater the possibility for tumor eradication or control. However, the higher the radiation dose, the greater the damage to normal tissue. Pain, mucositis, xerostomia, taste changes, and decreases in body weight are common acute adverse reactions from H&N irradiation (Delaney, Fisher, Smee, Hook, & Barton, 1995; King, Nail, Kreamer, Strohl, & Johnson, 1985; Rubin, McDonald & Qazi, 1993; Strohl, 1989). However, research-based information on the occurrence, pattern, severity, and time course of these reactions remains limited. Literature related to the associated self-care needs demonstrated by patients and the self-care behaviors they use to deal with RT effects is also lacking.

A pilot study of 10 patients with H&N cancer receiving RT treatments to the oral cavity and oropharynx was conducted to characterize a profile of this population and to identify symptoms that they found most distressing. The following symptoms were either self-reported by patients or observed in them during treatment: mucositis (100%), taste changes (100%), "severe" oral pain (80%), weight loss of greater than 10% of body weight (70%), and "severe" xerostomia (40%). Mucositis, oral cavity pain, and weight loss were significant problems for the 10 participants in the pilot study. Additionally, all patients reported changes or problems in their ability to eat during treatment. These

findings not only support the presence of these problems, but also, the extent to which they occur - even in this small sample. These are obviously significant problems for the patient with H&N cancer who is receiving RT. The ability to further identify, describe, and characterize radiation-related mucositis, pain, decreases in body weight, taste changes, and xerostomia, as well as the self-care needs and behaviors of this patient population will assist nurses and other health-care providers in assessing for potential problems in a timely manner and in providing appropriate interventions.

Significance of the Problem

Patients with H&N cancer undergoing RT treatment in all or part of the oropharynx region experience significant treatment-related morbidity. Clinical records support the occurrence of mucositis, pain, xerostomia, decreases in saliva, taste changes, and weight loss resulting from the administration of RT treatments with these patients. The actual occurrence, pattern, severity, and time course of these radiation-related reactions have not been evaluated within the same prospective study. The effects of radiation on the oral mucosa include physical and physiological changes and can be either transient or permanent. The reaction of normal tissues within the treatment field(s) depends on the type of radiation administered, each treatment dose (i.e., fraction), duration between fractions, the total cumulative dose, and the area/volume of irradiation.

Severe mucositis is painful. Mucosal ulcerations may increase susceptibility to oral infections, which may in turn make eating difficult. In addition to pain, taste changes and xerostomia can have negative affects on the patient's ability to eat, resulting in weight loss.

These treatment morbidities are potentially life threatening. Ultimately, if these side effects necessitate delays or *breaks* in the RT plan, the overall curative or control goal could be adversely affected (Martin, 1993). All of these treatment-related problems "take a toll" on the general well-being of this patient population.

A study to elucidate the incidence, severity, pattern, location, and etiology of pain in the patient with H&N cancer receiving RT will provide a better understanding of the pain these patients are experiencing. The benefits of this type of investigation might include the ability to predict and prophylactically treat pain in this patient population, thus reducing pain-related morbidity.

Studies focused on the time course and severity of pain associated with RT-induced mucositis are extremely important. There is no previous research that has addressed the pain experience of patients with H&N cancer receiving RT looking specifically at mucositis pain, its intensity, its impact on activities such as eating and drinking, and treatment-related factors. The incidence and severity of radiation-related oral mucositis and the resultant pain can be profound. The effects of radiation treatments on the taste buds and salivary glands, the taste changes and xerostomia in combination with mucositis and pain, has not been documented in the literature.

No research of patients with H&N cancer receiving RT has been published that sought to determine the pattern of weight changes - specifically weight loss - over the course of therapy, as well as its association with other treatment-related morbidity parameters such as mucositis, pain, xerostomia and taste changes. In addition, weight loss prior to the

initiation of therapy and determination of actual body weight compared to ideal body weight at the start of therapy has not been reported. It appears that the greater the weight loss during the course of therapy, the greater the occurrence of treatment-related morbidity causing delays or interruptions in treatment (Donaldson, 1977; Donaldson & Lenon, 1979; Johnston, Keane, & Prudo, 1982).

Patients with H&N cancer receive RT primarily on an outpatient basis. Since morbidity from RT can potentially be severe, the patient and his or her family will bear the primary responsibility for care in the event of problems arising from the treatments. The patient and family can initiate self-care behaviors to meet needs and/or demands resulting from the treatments and treatment-related side effects. The *self-care needs* of these patients are directly related to the RT side effects. No studies have examined the self-care needs produced by these side effects or the use of self care behaviors specifically related to the effects of mucositis, pain, xerostomia, taste changes, and weight loss. Being able to characterize and describe these self-care needs of the patient with H&N cancer receiving RT would provide valuable assistance to the nurse in anticipating their potential occurrence, assessing severity, and intervening in an appropriate and timely manner.

Purpose of the Study

The primary purpose of this study is to describe the onset, severity, and time course of radiation-induced mucositis and mucositis-related pain, as well as the use of self-care behavior(s) by patients with H&N cancer receiving RT. Secondly, the severity of xerostomia, taste changes, and weight loss, and the use of self-care behaviors by patients

with H&N cancer will be described. Finally, the relationship among xerostomia, taste changes, mucositis severity, and mucositis-related pain, as they relate to weight loss, will be presented.

CHAPTER II

Physiological Mechanisms and Literature Review

Patients undergoing radiation therapy (RT) for head and neck (H&N) cancers can potentially experience many problems as a resultant of the treatment. This study will focus on the problems of radiation-induced mucositis and mucositis-related pain, as well as the use of self-care behaviors associated with these side effects (i.e., self-care needs). In addition, xerostomia, taste changes, mucositis severity, and mucositis-related pain, as they relate to weight loss, will also be examined. These problems and behaviors do not occur in isolation but are often interrelated, as observed in clinical practice and reported in the literature.

Despite the fact that the occurrence of mucositis and mucositis pain are reported in H&N cancer patients receiving RT, the onset, severity, and time course of these problems are not well documented. The relationship of xerostomia, taste changes, mucositis severity, and mucositis pain to weight loss in this patient population also presents a gap in the literature. Previously documented research clearly indicates inadequacies in the measurement and management of these problems by health-care professionals. In addition, no studies exist reporting the self-care behaviors used by this patient population with these identified problems. In fact, only a few studies of self-care behaviors even include H&N cancer patients (Dodd, 1984b, 1987; Hagopian, 1990; Hanucharurnkul, 1989).

As stated previously, the RT-related problems and associated self-care behaviors do not occur in isolation. In fact, many of these problems can affect the presence and

perception of other problems resulting from RT. Patient response or reaction to these problems may be the initiation of self-care behaviors.

Mucositis

Radiation-induced mucositis is an acute inflammation of the oral mucosa that occurs during or after a series of RT treatments. Mucositis is the result of the direct effects of radiation on the epithelium. Of patients undergoing radiation treatments to the oral cavity and/or pharynx, 30-60% will develop mucositis, and this estimate exceeds 90% in patients receiving combination therapies such as concurrent chemotherapy or chemotherapy preradiation therapy (Dreizen, 1990; Englemeier & King, 1983; Epstein, Stevenson-Moore, Jackson, Mohamed, & Spinelli, 1989). Radiation-induced mucositis is usually a short-term complication. However, it may be extremely painful, can have significant adverse effects on food intake, and is a site conducive to the development of oral infections.

Effects of Radiation Treatment

The oral mucosa lines the oral cavity from the mucocutaneous junction of the lips to the oropharynx. It separates the interior of the oral cavity from the complex underlying organs and has two separate components, namely epithelial and connective tissues. Under normal circumstances, the epithelial lining of the oral mucosa is a constantly renewing cell population maintaining a homeostatic balance between new and dying cells. The effects of radiation on the oral mucosa include physical and physiological changes and can be either transient or permanent. The reaction of normal tissues within the treatment field depends

on the type of radiation used, each treatment dose (i.e., fraction), duration between fractions, the total dose, and the area/volume of irradiation (i.e., field) (Parsons, 1994).

In addition, the incidence and severity of radiation-induced mucositis are also dependent upon the cumulative radiation dose, the quality of oral hygiene, and the patient's adherence to an oral care regimen (Dreizen, 1990; Rothwell & Spektor, 1990; Spijkervet, van Saene, Panders, Vermey, & Mehta, 1989). Patients receiving hyperfractionated (i.e., twice-a-day) RT schedules usually develop mucositis earlier than those receiving one daily treatment. With hyperfractionation, acute reactions occur earlier and are often more severe but are also shorter in duration than conventional treatment schedules (Thames, Peters, Withers, & Fletcher, 1982; Wang, Blitzer, & Suit, 1985).

Radiation-induced complications are the result of direct and indirect physiochemical changes caused by radiation to the cells (National Institute of Health, 1989). The direct effects of radiation involve damage to DNA. This damage is manifested by single or double-stranded breaks, faulty cross linkages, or damage to the nitrogenous bases of the DNA complex. Indirect effects occur due to physiochemical reactions, primarily the ionization of water in the cell, caused by radiation. These reactions create toxic changes in the cell that adversely affect cell function and survival. Single-strand DNA breaks occur more frequently than double-strand breaks and are more easily repaired and less lethal to the cell. Double-strand breaks can also be repaired but are more likely to misrepair, which can ultimately lead to cell death, the most common of which results from the loss of cell reproductive integrity (Parker & Withers, 1995).

Another widely recognized mode of radiation cytotoxicity resulting in cell death is *apoptosis* (Harms-Ringdahl, Nicotera, & Radford, 1996; Parker & Withers, 1995; Szumiel, 1994). Radiation-induced apoptosis involves changes within the nucleus of the cell that are caused by ionizing radiation, resulting in impairment of cellular metabolism and autodigestion (Thompson, 1995). Apoptotic cells generally die in the interphase portion of the cell cycle prior to entering mitosis (Szumiel, 1994).

It is believed, based upon animal studies, that RT produces a depletion in the progenitive layers of the mucosa. In patients receiving RT to the oral cavity, the homeostatic balance between new cells and dying cells is upset and the oral tissue is destroyed or damaged more rapidly than new replacement cells are produced. The result can be the development of mucositis or a mucositis ulcer. Mucositis is defined as an inflammatory reaction of the mucosa of the oral cavity and oropharynx, resulting directly from the toxic effects of treatments such as RT. A mucositis ulcer occurs when the mucosa surface breaks down or is eroded (Rothenberger, 1988; Toth, Martin, & Fleming, 1992).

The changes that occur in the oral cavity are a result of the radiation's effect on the oral immune system. There is often a decrease in salivary flow and a biochemical change in the saliva. One of the immunological changes noted is a decrease in salivary immunoglobulin A, which is important in the regulation and control of the oral microbial flora (Martin, 1993). Radiation-induced mucositis appears to be caused by a combination of changes in the oral flora, as well as, changes in the tissue itself (Blozis & Robinson,

1968). Besides the change in the balance of dying and new cells in the oral cavity, RT also affects the microvasculature within the treatment field resulting in inflammation, edema, and cellular misrepair.

When the radiation dose to the oral cavity reaches approximately 1000 centigray (cGy), the oral mucosa will often appear whitish in color. This change is caused by a decrease in the mitotic activity of the mucosal cells that results in longer retention of superficial cells, allowing them to proceed to a greater degree of keratinization (Blozis & Robinson, 1968). As these superficial cells are lost, epithelial cells are not produced in sufficient quantities to replace the lost cells; therefore, thinning of the oral mucosa occurs. The reddish appearance of the mucosa, occurring at approximately 2500 cGy, is due to inflammatory changes in the submucosa. Mucositis can manifest as white patches that progress to confluent ulcerative lesions.

Eventually the mucosal layer becomes completely denuded and a bleeding or nonbleeding ulcer can develop. A fibrous exudate may cover the ulcer giving it a tan-colored appearance. A radiation-induced mucositis ulcer contains an area where the normal oral mucosal layer is eroded and the underlying tissue is exposed. Mucositis ulcer development often progresses with the appearance of small, white or slightly yellow patches. In many patients, the small mucositis ulcers become confluent. Ulcer development generally occurs approximately 2 to 3 weeks into treatment (i.e., 2000-3000 cGy) (Parsons, 1994; Thames, Bentzen, Turesson, Overgaard, & van der Bogaert, 1990). Pain,

burning, and discomfort are frequently experienced and these symptoms are exacerbated with eating.

With conventional therapy (i.e., daily treatments, 5 days/week), soreness, dysphagia, and dryness of the oral mucosa usually begin during the second week (i.e., 2000-2500 cGy) of treatment. The soft palate, tonsillar pillars, buccal mucosa, lateral borders of the tongue, and the pharyngeal walls are locations where mucositis and ulcerations tend to occur (Blozis & Robinson, 1968; Carnel, Blakeslee, Oswald, & Barnes, 1990). During the fifth week (i.e, 5000-6000 cGy), the greatest reactions are noted - significant pain and discomfort is often present. These symptoms improve within 2 to 4 weeks after the last treatment, and the entire healing phase is usually completed in 1 to 2 month (Cooper, 1994).

Related Research

Thames et al. (1990) reported that the timing of the onset of mucositis depends on the rate of dose accumulation rather than on the size of the fraction. This finding emerged from their study of the effect of various dose fractions on mucositis development. At 245-275 cGy/day, the mucous membrane of the soft palate begins to develop mucositis at the end of the second week. Mucositis peaks during the middle of the third week, and begins to regress during the fifth week. With a dose of 200-220 cGy/day, the onset of mucositis occurs at 2.5 to 3 weeks, while fractions between 180-200 cGy/day result in an even later onset. The 2 to 3-week onset of mucositis can be physiologically explained by the fact that

basal cells mature in approximately 2 weeks. With daily radiation treatments, the rate of destruction of basal cells will exceed the rate of new cell production.

Van de Schueren, van den Bogaert, and Kian (1990) studied the effects of multiple fractions per day on oral mucosa of patients with H&N cancer. The threshold dose for the development of confluent mucositis (i.e., patches of 0.5 cm) appeared to be approximately 20 Gy or 2000 cGy. These findings concurred with those of Thames et al. (1982) who found that the development of mucositis was dependent on the rate of dose accumulation rather than on the fraction size. For patients receiving conventional, once-daily treatment, mucositis occurred later than in those patients receiving multiple fractions per day. Patients receiving multiple daily fractions generally received more radiation on a daily basis than those treated once per day. Van der Schueren et al. (1990) also compared various multiple fraction sizes and found that patients receiving higher daily doses over a shorter period of time developed mucositis sooner than patients receiving the same total dose but in smaller multiple fractions over a longer duration.

While the occurrence of mucositis in the H&N cancer patient receiving RT has been studied, most of the research involved various treatment modalities and their outcomes. Study weaknesses include the measurement of mucositis which is addressed in this current research..

The effect of two oral care protocols on the physical condition of the mouth and patient perception of oral comfort in those receiving RT treatment (i.e., a minimum of 5000 cGy) to the oral cavity was studied by Dudjak (1987). Fifteen patients were

randomly assigned to follow one of two oral-care protocols - the use of half-strength hydrogen peroxide or sodium bicarbonate mixed with water. Both hydrogen peroxide and sodium bicarbonate are considered cleansing agents. Oral care was performed every 4 hours while awake until mucositis developed, then every 2 hours thereafter. Dudjak used modified versions of Beck's (1979) Oral Assessment Guide and Oral Perception Guide to assess the physical condition of patients' mouths and their perceptions of oral comfort.

Dudjak (1987) found no differences between patient groups in the physical condition of the oral tissue; however, patients who used the hydrogen peroxide reported significantly greater comfort than the bicarbonate group. Dudjak stated that these results indicated that performance of oral care may be more effective in minimizing the destructive effects of RT on the oral mucosa than the oral agent used. While Dudjak assessed for the presence of oral infections weekly, and had patients complete a daily oral-care record, actual assessments of the physical condition of the mouth and subjective patient perceptions were collected only at the beginning of RT (less than 400 cGy cumulative dose), upon the completion of treatments, and at the 1-month follow up. If the presence or absence of mucositis was observed during treatment, it was not documented.

Several studies have used chlorhexidine gluconate mouthrinses to determine its effects on treatment-related oral mucositis (Ferretti et al., 1990; Foote et al., 1994; Spijkervet et al., 1989). Chlorhexidine, a bis-biguanide compound, is an antiplaque agent with antimicrobial activity. Minimal adverse side effects have been reported with its use (Ferretti et al., 1990; Spijkervet et al., 1989). The mechanism of action within the

chlorhexidine molecule is that it binds with negatively charged salivary mucins or glycoproteins and not directly to epithelial tissues (Goldschmidt, 1976).

Ferretti et al. (1990) investigated the effect of chlorhexidine mouthrinses on oral mucositis severity and the incidence of oral and systemic infectious complications. The investigators implemented a protocol using 0.12% chlorhexidine as the experimental solution and a placebo, a rinse identical in composition to the experimental solution but without the chlorhexidine, for the control solution. All participants were instructed to rinse three times daily.

The Ferretti (1990) sample population was comprised of patients receiving either chemotherapy or radiation therapy. Thirty patients received "high dose" radiation therapy - the actual dosage was not reported. Mucositis severity was measured using a scoring system developed by the researchers. Severity was assessed at baseline and on Days 7, 14, 21, and at follow-up on approximately Day 28. While the chlorhexidine mouthrinse significantly reduced oral mucositis incidence and resolved the condition more quickly in the chemotherapy group, the findings differed for the RT group. No differences in mucositis development (i.e., incidence) were noted between the control group and chlorhexidine group. Most H&N cancer patients receiving RT generally receive 6 to 7 weeks of treatment. If this had been the case in the Ferretti study, the patients would have several weeks of treatment remaining at this time and it is possible that no differences in the resolution of their mucositis would have been realized since use of chlorhexidine was

discontinued at Day 21. The sample size of each group may have been insufficient in detecting all differences between them.

Spijkervet et al. (1989) studied the effect of chlorhexidine rinses on the oral flora since oral flora is thought to contribute to radiation mucositis in H&N cancer patients. The study sample consisted of 30 patients receiving a minimum of 5000 cGy to the H&N region. A double-blind trial utilized a 0.1% chlorhexidine rinse, four times a day, compared to administration of a placebo solution. No differences were noted in age, sex, tumor staging, or radiation dose between the two groups. Monitoring of mucositis was conducted three times per week with an instrument developed by the researchers. Oropharyngeal flora sampling was conducted three times per week along with a baseline measure. No significant differences were observed between the two groups in mucositis development or severity. In addition, the investigators found no group differences in the suppression of oral flora, thus concluding that disinfecting mouthrinses were not successful in decreasing severity of mucositis. Again, a small population sample presents a limitation with this study.

Recent research was conducted by Foote et al. (1994) to determine the effects of a chlorhexidine mouthwash on radiation-induced oral mucositis. Using a double-blind, placebo-controlled trial, 52 patients were randomized to either a chlorhexidine or placebo group. Oral assessments were conducted weekly using World Health Organization (1979) criteria for mucositis. The investigators reported that the chlorhexidine mouthwash failed to lower mucositis incidence in H&N cancer patients receiving RT. In fact, strong

evidence was presented indicating that chlorhexidine was actually detrimental to the treatment goals. The chlorhexidine group demonstrated a trend toward more frequent and severe mucositis and experienced significantly more side effects (i.e., mouthwash induced discomfort, taste alterations, and teeth staining) than patients in the placebo group. Because of their findings, the investigators closed the chlorhexidine arm of the study.

Other investigators (Barker, Loftus, Cuddy, & Barker, 1991; Dodd, 1997) have used sucralfate for the treatment of RT-related mucositis - a drug indicated for the treatment of duodenal ulcers and cytoprotective on the mucosa. When used orally, it appears to form an adhesive, paste-like substance that ionically attaches to proteins in the damaged mucosa. This protective coat provides a barrier to further mucosal irritants and damage (Richardson, 1982; Solomon, 1986). Sucralfate most likely interferes with the ability of the microbes to adhere to the mucous membranes. Its cytoprotective effect is believed to mediate through enhanced prostaglandin release from the mucosa, and the result is an increase in mucosal blood-flow, mucus production, mitotic activity, and surface migration of cells (Tarnawski, 1984).

Barker et al. (1991) - in a prospective, double-blind study - compared the effectiveness of sucralfate suspension to a mixture of diphenhydramine syrup plus kaolin-pectin in alleviating radiation mucositis and related pain. These investigators randomized 14 patients receiving at least 4600 cGy to the oral cavity. Participants began mouth rinses at a RT cumulative dosage level of 1600 cGy. The investigators conducted weekly evaluations for mucositis grade, weight loss, interruption of therapy, perceived pain via daily patient

diaries, and effectiveness of the rinses toward symptom relief. An instrument developed by the researchers specifically for this study facilitated the evaluations. Results indicated no statistical difference between the two groups on any parameter, although the sucralfate group reported less pain and greater duration of pain relief. Limitations of the Barker et al. study included patients being allowed to use systemic analgesics, which could bias the findings related to pain relief. In addition, the sample size (n = 14) would have presented insufficient power to detect differences between groups.

Several investigators have studied the use of benzydamine hydrochloride (BZD) - a nonsteroidal analgesic and anti-inflammatory compound - in H&N cancer patients experiencing radiation-induced mucositis and related pain (Epstein et al., 1989; Kim, Chu, Lakshmi, & Houde, 1986; Samaranayake et al., 1988). BZD acts on the chemical mediators of inflammation, including prostaglandin, serotonin, histamine, and acetylcholine. It can be administered topically or systemically, and no major toxicities or allergic reactions have been reported. BZD has been used in various clinical trials to prevent and promote healing of RT-induced mucositis.

Epstein et al. (1989) and Kim et al. (1986) conducted studies of BZD versus placebo comparisons to determine the analgesic and anti-inflammatory effectiveness of BZD as a rinse in patients with radiation-induced mouth and/or throat pain. Additionally, the Epstein group of researchers evaluated the effectiveness of BZD in the prevention and management of oral mucositis. Both studies implemented an experimental, double-blind,

randomized control-study design. There were 67 participants in the Kim et al. sample and 43 in the Epstein et al. study.

Patients in the Epstein et al. study (1989) received either 4500 cGy in 3 weeks or 6000 cGy in 5 weeks. They were instructed to rinse four times a day and were provided additional topical anesthetics or analgesics for oral discomfort as needed. Signs and symptoms of mucositis and pain were recorded weekly on a standardized form developed by the researchers specifically for the study. The subjective evaluation of pain and other symptoms resulting fro the treatment were obtained by having patients complete visual analogue scales on a weekly basis.

Findings reported by the investigators (Epstein et al., 1989) indicate statistically significant results in the prevention of mucositis in the BZD group compared to the placebo group. A trend toward less pain -including less pain with eating - and reduction of existing pain with BZD use was also reported; however, these findings were not statistically significant due to the small sample size ($n = 43$).

The 67 H&N cancer patients receiving RT that were randomized in the Kim et al. (1986) study, complained of mouth and/or throat pain during treatment. The patients were seen daily, up to 4 days, for evaluation of mucositis and pain with a measurement tool developed by the researchers specifically for this study. Participants were also required to complete a diary three times a day, recording any experience of pain, with or without swallowing. The investigators reported significant and clinically meaningful alleviation of oropharyngeal mucositis symptoms. They found significant improvement in the reduction

of mucositis in the BZD group compared to the placebo group. The BZD group reported better symptom relief (i.e., less pain and the ability to eat) than the placebo group and BZD was also found to be significantly more effective in preventing mucositis development.

Prada, Lozza, Moglia, Sala, and Chiesa (1985) conducted a study of 20 H&N cancer patients receiving RT and randomized the sample to either a group using BZD or a group using sodium bicarbonate mouthwashes. BZD was found to be statistically more effective in controlling the signs and symptoms of mucositis - namely burning and oral pain - than the bicarbonate rinses. Prada et al. also reported that BZD was shown to delay mucositis onset and to significantly reduce the swelling and lysis of the oral epithelium. The researchers indicated that the findings supported the histoprotective effect of BZD as a prophylactic rinse in these patients. Measurement intervals and instruments were not discussed.

A common limitation of these studies (Epstein, et al., 1989; Kim et al., 1986; Prada et al., 1985) was the small size of the population samples, especially in the Epstein et al., and Prada et al. research. Additionally, the allowance of systemic analgesics was not accounted for in the pain relief results. All of the studies, with the exception of the Epstein et al. research utilized measurement tools developed specifically for the respective study, usually with criteria defining mucositis that was broad, general, and subject to interpretation.

The studies cited (Epstein, et al., 1989; Kim et al., 1986; Prada et al., 1985) have focused primarily on mucositis, as measured by objective criteria, and the presence or absence of discomfort. Minimal research exists on the onset and presentation of mucositis, other than from an objective standpoint (e.g., appearance of mucosa or changes in mucosa).

The occurrence of mucositis in H&N cancer patients receiving RT can result in an increase in treatment-related morbidity. While studies indicate that a large number of these patients will experience this side effect, the ability to accurately assess and diagnose problems related to the oral cavity varies widely (Martin, 1993; Spijkervet et al., 1989). Not only is the timely identification of mucositis crucial, but identification of other critical factors is of equal importance, including patient perception of changes occurring in the oropharynx that may indicate the initial onset of mucositis.

Measurement

Since mucositis is an expected side effect of treatment, and one of the major side effects experienced by H&N cancer patients receiving RT to the oral cavity and oropharynx, the assessment and treatment of this condition has been the focus of many studies (Barker et al., 1991; Carl & Emrich, 1991; Denham & Abbott, 1991; Englemeier & King, 1983; Epstein et al., 1989; Spijkervet et al., 1989; Toth et al., 1990). Many of these investigators, as indicated previously, developed instruments measuring mucositis that were specifically designed for their respective studies (Barker et al., 1991; Carl & Emrich, 1991; Epstein et al., 1989; Spijkervet et al., 1989; van der Schueren et al., 1990).

Others used the World Health Organization (1979) Mucositis Index or the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer criteria (John, 1993). The limitations of these latter instruments are that they are broad and general, with little or no guidelines for use, thus the interpretation of the scale is left to the researcher. In addition, while most of the instruments included objective characteristics of mucositis (e.g., erythema and ulceration), there was little, if any, subjective or qualitative information obtained from the patient (e.g., interference with eating and/or pain). Reliability and validity data were not reported for the majority of the instruments utilized.

Instruments for quantifying the severity of mucositis typically measure a variety of factors. Many instruments include primarily objective measures of oral mucositis, that is, the observable changes in the oral cavity indicating the development and presence of mucositis (Eilers, Berger, & Petersen, 1988; John, 1993; Spijkervet et al., 1989; World Health Organization, 1979). Some researchers (Beck, 1979; Dibble, Shiba, MacPhail, & Dodd, 1996; Dudjak, 1987) have included in their own instruments not only the objective manifestations of oral mucositis, but also the subjective and perceptual aspects such as changes in the oral saliva, dryness, thickening of saliva, pain, and changes in taste.

The ability to assess for and identify the cause(s) of oral mucositis is complicated by the fact that many of the factors contributing to the development of mucositis can occur simultaneously. In addition, the signs and symptoms of RT-induced mucositis, as opposed to other etiologies, are often similar in appearance and presentation. Accurate assessment for and identification of causes is essential because treatment can vary depending upon the

etiology of the mucositis. For example, oral mucositis resulting from RT is treated differently than mucositis related to an infection.

Radiation therapy to the oral cavity can significantly alter the oral flora, salivary quantity and composition, and epithelial maturation (Poland, 1991). The physiologic state of the oral cavity from such changes makes the possibility of oral infections more likely. The ability to distinguish radiation-related mucositis from infection-induced mucositis may not be visually obvious. A further complication is that pain will usually be present in both cases.

Mucositis related to RT generally does not occur before 1000-1500 cGy has been delivered, with ulcerations not presenting until a cumulative dose of approximately 4000 cGy of radiation (Lockhart, 1986). Fungal, bacterial, or viral infections can appear at the start of RT, or prior to or during treatment. Candida infections occur frequently in H&N cancer patients receiving RT and are fairly characteristic in appearance. Fungal infections can be diagnosed with fungal cultures, potassium hydroxide, and gram-stained smears. Bacterial and viral cultures should be obtained to clearly identify the cause of mucositis, if these organisms are suspected to facilitate the initiation of appropriate treatment. Infections are responsive to the appropriate antifungal, antimicrobial, or antiviral treatment, while radiation-related mucositis is dependent upon time for healing, and supportive measures to manage the symptoms (Lockhart, 1986; Poland, 1991; Sandow & Baughman, 1994). Lockhart, Poland, and Sandow and Baughman, while advocating the use of oral cultures to determine the cause of mucositis, also state that clinicians

frequently treat patients empirically, if a cause is suspected, until the culture results are obtained. The longer an infection is left undiagnosed and untreated, the greater the chance of local and systemic spread (Poland, 1991). No reports could be found in the literature of the actual percentage of patients who present with oral symptoms and are cultured.

The MacDibbs Mouth Assessment (Dibble et al., 1996) was selected for use in this current study as it evaluates both the objective and subjective dimensions of mucositis. The instrument is easy to administer and appears to be sensitive to changes in mucositis over time, which is essential when studying the course and characteristics of RT-related mucositis during treatment. In addition, the MacDibbs Assessment tool was developed to evaluate the oral cavity in order to distinguish between RT-related mucositis and incidence from other causes (i.e., candida infections or herpes), based upon objective, subjective, and treatment-related factors.

Pain

Pain is present in about half of all newly diagnosed cancer cases, and of that number, 30-40% of patients on active therapy suffer with pain (Foley & Arbit, 1993). H&N cancer patients can experience pain resulting from various causes including their RT treatments (e.g., pain associated with RT-related mucositis).

Although other symptoms related to the treatment of cancer, such as fatigue and poor appetite, are reported by patients as often as pain, unless the pain is addressed and controlled, the other symptoms or problems are almost impossible to manage (Ashby, 1993). When pain is not adequately managed, many patients experience levels that can

interfere with routine activities and their overall quality of life (Portenoy, 1988; Ward et al., 1993). RT is often effective in providing palliation of pain from cancer (Ashby, 1993; Mauch & Drew, 1993).

Physiological Processes of Pain

There are four physiological processes that must occur almost simultaneously for pain to occur: transduction, transmission, modulation, and perception (Fields, 1987). Individual perception of the pain, as well as responses, are derived from these processes.

Transduction is the first process in the neural pathway and signals the onset of pain. Activation of nociceptive primary afferents occurs when noxious stimuli - chemical, mechanical, or thermal - are converted and coded into electrochemical impulses in peripheral sensory nerve endings. The exact mechanism for this activation is unknown, though Fields (1987) suggests several possibilities: 1) activation of nociceptors by chemical substances released in response to cellular damage; 2) sensitization of nociceptors through the release of chemical substances (e.g., Substance P) from primary afferents resulting in vasodilation, edema, histamine release from mast cells, and serotonin release from platelets; and/or 3) sensitization of nociceptors by other chemical mediators.

In the RT patient, primary afferent nociceptor activation can occur through the direct effects of the tumor on tissues and organs, or by the cellular damage caused by the treatment which results in chemical changes and the release or production of by-products in the tissues and cells (e.g., prostaglandins). Nociceptors may be sensitized either directly or indirectly by analgesic substances such as potassium, adenosine triphosphate,

bradykinin, Substance P, and prostaglandins released from the cells or derived from blood vessels resulting from tissue damage (see Table 1 & Figure 1) (Fields, 1987; Payne, 1990). Mechanical stimulation of nociceptors in cancer patients most often occurs through an increase in the volume of organs, displacement of tissues, or by occlusion of hollow organs with the resultant production of inflammatory mediators.

Pain transmission - the next step in the nociceptive processing system - involves a series of neural events that result in the electrical impulses activated during transduction being carried from the periphery or point of activation to the central nervous system. Nociceptive impulses from subcutaneous tissues and somatic and visceral structures are conducted by either small myelinated fibers (i.e., A-delta) or unmyelinated fibers (i.e., C) through the dorsal horn of the spinal cord, ascending the spinothalamic and spinoreticular fibers to regions in the thalamus and cerebral cortex. The A-delta fibers serve mainly discriminative functions in nociception. Acute pain is associated with activity in myelinated fibers while chronic pain is associated with activity in unmyelinated fibers. The myelinated fibers are thought to conduct impulses rapidly along the nerve tracts, as opposed to the unmyelinated fibers that conduct at a slower rate (Andersson, 1987).

Pain modulation involves the neural processes that can affect pain transmission neurons. Pain modulation can occur in the spinal cord and be influenced by higher cortical centers as well. Modulation of noxious stimuli may partially account for the variability of pain reports in humans.

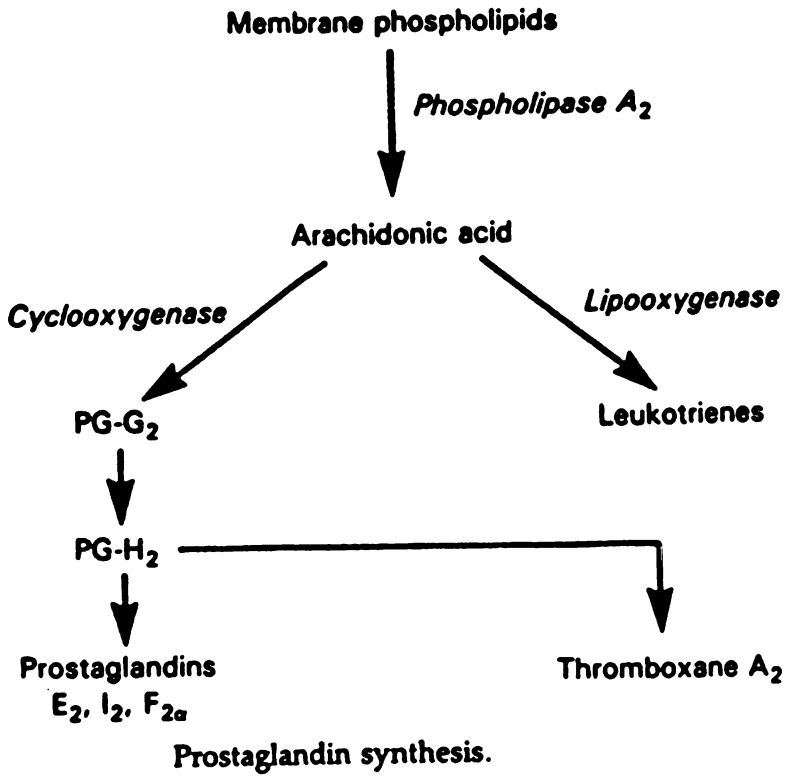
Table 1

Chemical Intermediaries in Nociceptive Transduction

Substance	Source	Enzyme	Produces pain in man	Effect on primary afferent
Potassium	Damaged cells		++	Activate
Serotonin	Platelets		++	Activate
Bradykinin	Plasma kininogen	Kallikrein	+++	Activate
Histamine	Mast cells		+	Activate
Prostaglandins	Arachidonic acid — damaged cells	Cyclooxygenase	+/-	Sensitize
Leukotrienes	Arachidonic acid — damaged cells	Lipoxygenase	+/-	Sensitize
Substance P	Primary afferent		+/-	Sensitize

Note. From *Pain* (p.92), by H. L. Fields, 1987, New York: McGraw-Hill Book Company. Copyright 1987 by McGraw-Hill Book Company.

Figure 1. Schematic diagram of prostaglandin synthesis



Prostaglandin synthesis.

Finally, *pain perception*, is a more subjective than physiological process. It involves a wide range of complex behavioral, emotional, and psychological factors contributing to the individual perception and response to pain. The exact area in the cerebral cortex where the nociceptive impulses are transmitted and translated into a conscious sensation of pain is unknown. However, cortical processes are believed to be partially responsible for integrating specific aspects of pain (e.g., location, quality, severity, and intensity) to the overall perception of the pain experience. Perception is influenced by previous pain experience and expectations regarding the pain, as well as numerous other factors (Foley & Arbit, 1993; Tonnessen, 1990).

Currently, three types of cancer pain have been described in the literature, based presumably on different mechanisms: somatic, visceral, and deafferentation (Ashby, 1993; Payne, 1989; Payne, 1990; Ventafridda & Caraceni, 1991). Somatic pain (e.g., pain from bone metastasis) is the most common in cancer patients (Elliott, 1993). Visceral pain is most often the result of obstruction, infiltration, or compression of the viscera. Neuropathic pain is related to compression or infiltration of nerves, nerve roots, or nerve structures by the cancer.

The pathophysiology of cancer pain is complex and not fully understood (Payne, 1990). It is understood that patients may experience more than one pain at any given time, and that a combination of pain mechanisms can exist in any one patient. For example, in our analysis of data from a large descriptive study, we found that 4% of the RT patients

had a combination of somatic and deafferentation types of cancer pain (Shiba, Miaskowski, & Dibble, 1996).

Pain in the Head and Neck Cancer Patient

Raj and Phero (1987) described the mechanisms of pain in H&N cancer as (a) stimulation of mucosal and submucosal nerve endings by either tumor involvement or the resultant effects of RT on the tissues (e.g., leading to ulceration and/or infection), (b) involvement of nerve branches, (c) bone invasion, and (d) post-radiation damage. Somatic pain due to tissue damage and inflammation from RT is seen most frequently in the H&N cancer patient.

Stimulation of mucosal and submucosal nerve endings may be caused by exophytic or erosive lesions. The pain presents primarily as a local burning sensation, superficial pain, or neuralgic pain. Many cancers that arise from the mucous membranes of the oropharynx are ulcerated due to necrosis of the tumor and microtrauma. In addition, radiation treatments can injure the normal mucosa and cause ulcerations, which can, in turn, effect free nerve endings and cause pain. Ulcerations and mucosal infections can cause further complications of edema, inflammation, and pressure, also resulting in pain.

H&N cancers can infiltrate into deep tissues and frequently involve nerves branches and nerve trunks. If such an infiltration occurs, constant and severe pain is likely. One of the most frequently involved nerves is the lingual nerve, which innervates the mobile area of the tongue and floor of the mouth.

Pain also occurs when a tumor invades bone and involves nerve branches. Additionally, pain can occur when the path of cancer infiltration is followed by a bacterial infection producing osteomyelitis.

Radiation injury to the H&N region produces acute pain associated with mucositis or chronic pain associated with conditions such as osteoradionecrosis. RT can also cause reactive fibrosis in the tissues and muscles, which can cause painful contractions.

It is important to attempt to distinguish the type of pain a patient is experiencing prior to the initiation of RT so that appropriate interventions can be promptly implemented. Assessment for the presence or absence, as well as the character and quality, of the pain at this time is also important to distinguish pain associated with the RT from that of another etiology. If a patient presents with pain within the treatment field, radiation treatments can frequently cause an exacerbation (Ashby, 1993).

If the patient is undergoing RT for the treatment of pain related to the tumor, most patients will obtain moderate to good pain relief if the tumor is radiosensitive. As the tumor is destroyed, the cause of the pain should be removed, unless permanent damage to surrounding tissues or nerves has occurred. Patients should experience pain relief toward the end of treatment and maximal relief approximately one month after treatment completion (Cooper, 1994).

Related Research

Vecht, Hoff, Kansen, de Boer, and Bosch (1992) studied 25 H&N cancer patients with severe pain and determined the types and causes of their pain. Seventy-six percent of the

patients were found to have nociceptive pain that could be categorized as somatic or visceral. The cause of nociceptive nerve pain was secondary to tumor recurrence in the majority of the patients. The remaining 23% had non-nociceptive pain or neuropathic pain secondary to neck dissection. Most patients (76%) reported continual pain regardless of type. Those with neuropathic pain stated that the pain was uninterrupted and occurred in paroxysms or had a predominantly "shooting" quality.

The researchers (Vecht et al., 1992) stated that patients with severe pain were individually evaluated; however, they did not report the time course of the pain, nor was there any determination documented as to acuteness or chronicity. The sample size was small ($n = 25$). All patients evaluated had H&N cancer, but there were seven different diagnoses for the 25 patients. No information was provided regarding previous or present treatment (e.g., surgery, chemotherapy, or radiation therapy) other than RT, nor was current disease status reported.

Weissman, Janjan, and Byhardt (1989) studied 21 newly diagnosed H&N cancer patients receiving RT to characterize the temporal development and quality of pain associated with radiation-induced mucositis. The patients received a cumulative dose of RT between 5040 cGy and 7020 cGy and completed daily pain assessment questionnaire diaries. These diaries included verbal descriptor scales for the presence of pain. The four possible responses were *not present, present only occasionally, present throughout most of the day*, or *always present*. For severity of pain, the four possible responses were *no pain, mild pain, moderate pain*, or *severe pain*. The questionnaire also included questions

related to the pain affecting various activities (i.e., sleep, energy, eating, or mood) and the use of pain medication. Of the 21 study participants, seven left 75% of their daily diaries uncompleted and were therefore eliminated from the study. Ten patients reported no pain at the start of RT, and the remaining four patients reporting mild to moderate pain involving the mouth, tongue, throat, or neck.

All patients in the Weissman et al. (1989) study developed mucositis and pain, usually beginning during the second or third week of RT. Severe pain was noted by patients starting the fifth week of treatment. Despite the use of analgesics, pain was rated moderate or severe on 37% of the treatment days. Mild pain was reported on 39% of the treatment days, moderate pain on 33%, and severe pain on 3%. No pain was reported on 25% of the treatment days and patients reported pain as "always present" on 29% of treatment days. With regard to the effectiveness of analgesic treatment for their pain, only 3% of the treatment days was pain reported to be relieved completely. Patients reported eating and sleeping disturbances related to pain on 55% and 34% of the treatment days respectively, and eight patients experienced over 2 kilograms in weight loss during treatment.

This small study (Weissman, et al., 1989) was one of the first to focus solely on H&N cancer patients receiving RT. Patients who presented with pain at the start of RT ($n = 4$) were not evaluated for the cause of their initial 23 pain. In addition, data from these patients were not analyzed separately to determine if there were differences in their pain experience during RT.

Pain secondary to mucositis is common by the midpoint of RT. Janjan, Weissman, and Pahule (1992) studied two groups of patients undergoing RT for a variety of H&N carcinomas to determine the effect on pain of a daily nursing intervention involving a defined mouth care regimen and analgesic treatment protocol for oral mucositis. One group of patients (n = 19) received the described daily nursing intervention while a second group receiving routine care were used as the controls. This control group consisted of the 14 patients from the Weissman et al. (1989) study. All patients were required to complete a daily pain questionnaire, which was not described in detail. An evaluation sheet, developed by the researchers, was completed weekly by the physician who scored the observed mucosal reactions and levels of pain as reported by the patients. A 5-point mucosal reaction rating system was implemented: 0 = none, 1 = mild, 2 = moderate, 3 = severe, and 4 = most severe. The same descriptors were used to rate level of pain.

The intervention group (n = 19) (Janjan et al., 1992) received the daily nursing intervention for pain management. This entailed daily assessment of the presence or absence of pain, interventions for its treatment, evaluation of the effectiveness of the intervention, and implementation of a new intervention such as increasing the dose of pain medication, if pain had not been managed adequately by the initial intervention. The intervention group was then compared to the previously studied group (n = 14) who had received routine care (Weissman et al., 1989).

In the group receiving the daily intervention (Janjan et al., 1992), patients reported mucosal pain on 57% of the treatment days, and neck and mouth pain on 28% and 11%

respectively. Pain with swallowing occurred on 40% of the treatment days. In this same group, mild pain was present on 43% of the treatment days, moderate pain on 23%, and severe pain on 6%. Pain peaked during the fourth and fifth weeks of treatment for both groups. However, a significantly smaller percentage of patients in the daily intervention group experienced pain compared to the routine care group (76% vs. 95% at week 4, 86% vs. 90% at week 5). Of all the study participants, 29% experienced moderate to severe pain at some time during the course of RT.

One of the limitations of this study (Janjan et al, 1992) is the small sample size for each group. The same control group had been studied previously and there was no mention of the time span that had elapsed between the two studies. This study only addressed pain related to mucositis and data were not provided on the presence or absence of pain from other causes prior to therapy initiation. Additionally, it appears that the instruments used for data collection from these two groups were not the same. The daily diary that patients completed had different numbers of items -15 in this study and 10 in the Weissman et al. (1989) study; hence comparisons are difficult to interpret.

Based on the way the data were reported it appears that the researchers (Janjan et al., 1992) analyzed their data on the assumption that all pain was related to radiation treatments, and this pain can indeed occur upon onset of treatment. While this hypothesis is reasonable, the results as reported may not reflect the actual source or severity of the pain experienced by the patients in this study. Pain that was present prior to the first treatment was not discussed or evaluated separately, and appears to have been analyzed as

pain related to RT. Radiation-induced mucositis pain usually appears during the second or third week of treatment. The pain data would have been more meaningful if the information were displayed in percentage of days in pain and related to the specific days within the course of treatment with the cumulative dose of radiation provided.

Epstein and Stewart (1993) measured pain intensity in 34 H&N cancer patients receiving RT. The purpose of this study was to develop a pain questionnaire applicable to H&N and oral pain in cancer patients. The questionnaire included visual analogue scales to measure pain intensity, a medication log, a space for recording the efficacy of pain medications, anatomical diagrams to allow graphical representation of pain location, descriptors of pain, and a portion of the McGill pain questionnaire. Data were collected from at their pre-radiation therapy evaluation, at midpoint of RT, upon completion of RT, at the 1-month follow-up, and between 6 to 12 months following completion of RT. Patients received between 5000-6000 cGy total RT dose to the H&N region, which included the oral cavity. Patients who had surgery prior to RT, experienced acute surgical pain resolution before initialization of RT.

Eighty-two percent of the patients in the Epstein and Stewart (1993) study reported pain at the time of diagnosis, with the majority describing their pain as mild. By mid-therapy all patients (n = 34) experienced pain ranging from "mild" (n = 10) to "distressing" (n = 17) and "horrible" (n = 7), with a mean visual analogue scale score of 38 mm (0 = no pain, 100 = worst possible pain). At the completion of treatment, all patients except one reported pain, with a mean visual analogue scale score of 45 mm. At the 1 month and 6 to

12- month follow ups, 59% and 46% of the patients still complained of pain, though the majority reported the pain as "mild", with five patients reporting it as "distressing" at the 1-month follow-up, and two reporting the same at the 6 to 12-month follow-up.

Epstein and Stewart (1993) reported treatment-related pain as the predominant type of pain in these patients, with severity increasing throughout the course of therapy. These results appear to contradict the findings of Janjan et al. (1992) who reported that the percentage of treatment days with moderate to severe pain peaked at midtreatment, and declined as treatment continued. In addition, Epstein and Stewart reported that pain was related to tumor size, and when this is the scenario, therapy-related pain is reported as the predominant type.

The researchers stated that the purpose of their study (Epstein & Stewart, 1993) was to characterize pain over the course of therapy, but only two data points - namely at treatment midpoint and upon completion - were collected. According to the reported findings pain appears to increase in severity during treatment; however more frequent evaluations during the course of therapy would have provided a clearer pattern of the pain experience in the H&N cancer patient receiving RT. The report of 82% of patients reporting pain at the time of diagnosis - and possibly prior to the start of RT - contradicts results from previous studies where few patients reported pain at the start of RT (Janjan et al., 1992; Vecht et al., 1992; Weissman et al., 1989).

Only these four studies (Epstein & Stewart, 1993; Janjan et al., 1992; Vecht et al., 1992; Weissman et al., 1989) were found that examined the problem of pain in H&N

cancer patients undergoing RT. Their findings are limited due to small sample sizes and the fact that the time course and intensity of the pain were not evaluated. The authors failed to differentiate the causes of the pain and this lack is a major limitation of the study because 82% of the patients presented with pain at the beginning of the study. It is difficult to compare the severity of pain experienced by this population across studies because the measurement tools were different and the timing of the measurements were not consistent.

Further studies are needed to elucidate incidence, severity, location, and etiology of pain in the H&N cancer patient undergoing RT to better understand the pain experience of these patients. The benefits of this type of investigation might include the ability to predict and prophylactically treat pain in these patients.

Studies on the time course and severity of pain associated with RT-induced mucositis are extremely important. No research thus far has addressed the pain experience of the H&N cancer patient receiving RT, looking specifically at mucositis pain, as well as the intensity of the pain, its impact on routine activities such as eating and drinking, and treatment-related factors that may be associated.

The ability to distinguish between mucositis and other types of pain should be achievable if questions are directed at attempting to characterize the qualities of pain. Somatic and neuropathic types of pain can be distinguished based on description and, perhaps in this population, based on location. However, patients may not be able to distinguish different pain intensities if they are experiencing more than one type.

Measurement

Pain was initially studied as a unidimensional experience. However, it is generally agreed upon that pain is a multidimensional experience, consisting of physiologic, sensory, affective, cognitive, behavioral, and sociocultural components (Ahles & Martin, 1992; International Association for the Study of Pain, 1986; McGuire, 1988). Even with general agreement on the multidimensional experience of pain, a variety of problems are associated with its measurement, including the extremely subjective nature and meaning of the pain experience to the patient. Pain experiences are not necessarily comparable. In addition, specific patient characteristics (e.g., ethnic background, age, education, and gender) may influence the perception of the pain.

When considering the instruments available for measuring pain in the H&N cancer patient receiving RT, several factors are important to consider in addition to the general characteristics previously discussed. For example, is the instrument valid and reliable within a H&N cancer patient population receiving RT? What are the dimensions of pain that need to be measured to answer the question of study, and does the instrument of choice include an assessment of these dimensions? Depending on the focus of study, the instrument selected will vary. The type of pain relevant in the H&N cancer group receiving RT and experiencing mucositis is acute somatic pain; therefore, an instrument that measures or distinguishes this type of pain is essential in a study with this focus. Finally the feasibility and versatility of the instrument for use in practice is important (McGuire, 1988).

The Head and Neck Pain Profile (Epstein & Stewart, 1993) is a questionnaire that was developed specifically to study pain in the H&N cancer patient and was tested in 34 such patients who received a cumulative dose of radiation between 5000 and 6000 cGy to the oral cavity. It is a multidimensional measure of pain that is easy to administer and easily understood. The marked visual analogue scales address the intensity of the pain experienced, the patient's usual level of pain, and the lowest severity experienced. In addition, the verbal descriptor list addresses patient perception/quality of the pain. Questions addressing patient response to the pain and the effectiveness of those actions are also incorporated into the questionnaire.

The Pain Assessment Questionnaire (Weissman et al., 1989) was specifically developed for use in a repeated measures fashion for H&N cancer patients receiving RT. Modified versions of both the Head and Neck Pain Profile and the Pain Assessment Questionnaire were utilized in this current study.

Weight Loss

This section will address RT-related side effects of xerostomia and taste changes. These two side effects, along with mucositis severity and mucositis-related pain, are presented as possible factors associated with and resulting in weight loss in the H&N cancer patient undergoing RT.

Xerostomia

Xerostomia is the subjective experience of mouth dryness. In RT of H&N cancer patients, xerostomia is associated with a decreased production of saliva as a result of

treatment (Goodman, Ladd, & Purl, 1993; Madeya, 1996a; Madeya, 1996b). Under normal conditions, the salivary glands produce approximately 1 to 1.5 liters of saliva per day (Guyton, 1991). The major salivary glands - the parotid glands, submandibular glands, and sublingual glands - produce approximately 90% of the saliva, with the remainder produced by minor salivary glands located throughout the mouth (Guyton, 1991; Parsons, 1994; Wang, 1997).

Two important protein secretions are produced by the salivary glands - a serous secretion and a mucous secretion. The serous secretion contains the enzyme *ptyalin,* or *amylase*, which is needed to digest starches, while the mucous secretion contains *mucin,* which is necessary for lubrication. The parotid glands produce only the serous type while the submandibular and sublingual glands produce both types of secretions. The buccal glands produce only mucous secretions.

Effects of Radiation Therapy. Xerostomia is a common side effect of RT to the salivary glands located in the H&N region. Xerostomia results from damage to the salivary glands which alters salivary function (Goodman et al., 1994). The severity of xerostomia varies with the radiation dose and the size and location of the RT fields (Englemeier & King, 1983; Iwamoto, 1992). The effects of radiation on the salivary glands are a result of inflammatory and degenerative changes in the acinar and ductal cells, as well as changes in the vasculature of the gland, thus affecting salivary gland function (Blozis & Robinson, 1968; Dudjak, 1987; Parsons, 1994). The structural and functional changes that occur can result in concurrent changes in the volume of saliva produced, as well as its pH, viscosity,

and chemical composition (Carl, Schaaf, & Chen, 1972; Parsons, 1994; Silverman & Chierici, 1965).

According to Parsons (1994), if only the submandibular and sublingual glands are included in the treatment field, patients report little subjective difference in saliva though, objectively saliva flow is altered. However, if one or both of the parotid glands is irradiated, with or without the submandibular or sublingual glands, patients report a greater sensation of dryness.

Depending upon the site and glands irradiated, a loss up to 50% of normal salivary flow can occur during the first week of RT, followed by a continual but slower loss of flow as treatment progresses (Mossman, 1984). Salivary glands are radiosensitive and changes and decreases in saliva flow have been noted as early as 1000 cGy of cumulative radiation. At radiation doses of 4000 cGy or greater, the damage to the salivary glands can result in permanent dysfunction of the gland - namely minimal to no saliva production.

Related Research. Three studies of salivary flow and salivary gland function in H&N cancer patients receiving RT were found (Leslie & Dische, 1994; Marunick, Seyedsadr, Ahmad, & Klein, 1991; Valdez, Atkinson, Ship, & Fox, 1993). Of the three, only the Leslie and Dische (1994) study followed the salivary flow of H&N cancer patients during the course of RT. Forty-seven patients agreed to participate in the Leslie and Dische study. None of them had undergone surgery to the major salivary glands or were receiving medication that could affect salivary gland function. Patients received either conventional (i.e., once daily), fractionated therapy to a total dose of 6600 cGy (n = 10)

or hyperfractionated (i.e., three times daily) therapy to a dose of 5400 cGy (n = 37).

Salivary flow was measured prior to the initiation of treatment, then weekly for the conventional fractionated group (Leslie & Dische, 1994). The hyperfractionated group was evaluated prior to the initiation of treatment, then on the third, sixth, and tenth day of treatment. Resting, whole saliva was collected by the spitting method where patients spit into a container at will for a period of 10 minutes. Stimulated parotid flow was achieved by collecting parotid saliva simultaneously from both glands using a cup method. Stimulation of saliva was achieved with three drops of 2% citric acid to the dorsum of the tongue at 2-minute intervals and collection carried out over a period of 10 minutes. The saliva was then measured and flow reported in milliliters per minute. In addition, subjective patient ratings were collected using a 2 or 3-point scale to indicate mouth dryness (0 = asymptomatic, 1 = mild dryness, 2 = moderate dryness requiring the patient to carry water or artificial saliva, or 3 = severe dryness resulting in serious incapacitation), loss of taste (0 = no loss, 1 = partial loss, and 2 = complete loss), and saliva consistency (0 = normal/watery, 1 = slightly thickened, and 2 = thick/sticky). Patient ratings were collected weekly for the daily treatment patients and on treatment Days 3, 6, and 10 for the patients undergoing hyperfractionated treatment. Upon treatment completion patients were tested at 8 and 12 weeks post RT initiation.

Significant decreases in salivary flow were noted during the first 2 weeks of RT (Leslie & Dische, 1994). These decreases were more pronounced in the hyperfractionated group during the initial 2-week period. However, by Week 8, the reduction in salivary flow from

pre-treatment values was similar in both groups. The decrease in flow rate was directly associated with the salivary glands irradiated. The extent of irradiation to the parotid gland was highly correlated with the saliva flow rate. The more radiation the parotid gland received, or if both glands were irradiated, the more marked the decrease in flow rate. Radiation to the sublingual and submaxillary glands appeared to affect overall flow less than radiation to the parotids.

None of the patients in the Leslie and Dische (1994) study complained of taste changes or mouth dryness prior to initiating RT. Of the 16 patients who received conventional RT to all salivary tissues, all reported changes in taste, saliva consistency, and increased mouth dryness by the second week of treatment. A third of the patients who received hyperfractionated RT to all salivary tissues (3 of 9) reported symptoms by the fourth day of treatment. The researchers concluded that the sensitivity of salivary tissue is seen to reflect the rate of accumulation of the RT dose. The hyperfractionated group in this study exhibited related changes earlier and to a greater degree or extent than the conventionally fractionated group. This study not only directly measured the objective salivary flow rates, but also correlated these rates with subjective symptom reports.

Marunick et al. (1991) studied 18 H&N cancer patients receiving RT and matched them with 24 subjects with no history of H&N cancer. Salivary flow of the cancer patients was measured prior to the initiation of treatment and then at Months 1, 4, 7, 9, and every 6 months thereafter for up to 26 months post-RT. Whole salivary flow, both stimulated and resting, was collected using the spitting method.

The average salivary flow rates for the 18 H&N cancer patients in the Marunick et al. (1991) study during their most recent follow-up evaluations were reduced by 83% from pretreatment rates for resting measures and by 86% for stimulated flow rates. The investigators also documented that the stage of disease, location of the primary tumor, total RT dose administered, and volume of salivary glands treated are important factors when predicting for xerostomia. No subjective data appears to have been obtained from the study participants.

In a study by Valdez et al. (1993), effects of radiation on the major salivary glands were evaluated. Average total RT dose was 6034 cGy for a sample of 50 patients. These patients were compared with 50 nonradiated controls. Salivary flow - unstimulated and stimulated - was obtained using the cupping method to collect saliva from specific salivary glands. Samples were collected from RT patients once upon treatment completion. An average of 1.9 years had elapsed, with a range of 1 month to 12 years, since the completion of RT treatments and obtaining new saliva samples.

These investigators (Valdez et al., 1993) concurred with the previous researchers (Leslie & Dische, 1994; Marunick et al., 1991) that the extent of radiation-induced salivary gland dysfunction depends upon the total radiation dose delivered and the volume or field size treated. They also found that the extent of xerostomia was related to the radiation field and the total radiation dose administered. No subjective or symptomatic data from the patients were reported.

Additionally, the findings of these studies (Leslie & Dische, 1994; Marunick et al., 1991; Valdez et al., 1993) indicate the extent to which the salivary glands are encompassed in the RT field, and the fractionation schedule all have an impact on salivary flow. The symptomatic or subjective characteristics for various levels of salivary flow dysfunction are less clear. Because of this lack of clearly defined relationships, this current study measured salivary flow as whole flow using the spitting method, as well as the stimulated and nonstimulated salivary flow from specific salivary glands (i.e., parotid glands) using the cupping and gentle suctioning method. Also, symptomatic and subjective data regarding saliva consistency, taste changes, and mouth dryness were collected in order to examine the relationship between these subjective findings and the objective changes in salivary flow rates.

Measurement. Evaluation of salivary gland functioning via saliva collection should be conducted using standardized methods because salivary flow can be influenced by various factors including time of day, postprandial time, and the method of salivary gland stimulation (Fox, vander Ven, Sonis, Weiffenbach, & Baum, 1985). Therefore, it is recommended that the salivary gland testing be conducted at the same time for each interval, and that patients follow the same preparation procedures.

Saliva collection can be accomplished in several ways: whole flow, parotid flow, submandibular and sublingual flow, and each of these either unstimulated or stimulated. Most of the studies reviewed used a combination of the whole flow and specific glandular flow methods (Fox, Busch & Baum, 1987; Fox et al., 1985; Franzen, Funegard, Ericson,

& Henriksson, 1992; LeVeque et al., 1993; Liu, Fleming, Toth, & Keane, 1990; McDonald, Meyerowitz, Smudzin, & Rubin, 1994; Valdez et al., 1993). Since the parotid glands produce the majority of the saliva, most of the previous studies sampled only these glands for glandular saliva production (Fox et al., 1985).

Whole saliva flow is not a true measure of total flow because the collection may be tainted with nonsalivary components such as food, desquammated cells, and other products from the oral cavity (Mandel, 1980). While whole saliva may be an indicator of salivary flow, it is highly recommended that actual output or flow be obtained if salivary glandular function is a focus of study (Fox et al., 1985, Mandel, 1980). In addition to the objective measures of salivary gland flow, subjective data such as mouth dryness and changes in saliva consistency should be collected from the patient to ascertain the relationship between the objective and subjective measures of xerostomia.

Changes in Taste

Taste changes can occur as a result of radiation treatment to the oral cavity. The receptors for taste and the taste buds are located on the anterior two thirds of the tongue, base of the tongue, tonsillar pillars, soft palate, glossopalatine arch, and the posterior wall of the pharynx (Parsons, 1994). The taste buds that allow an individual to distinguish the four primary taste sensations (i.e., sweet, sour, salty, and bitter) tend to be localized in specific areas of the tongue: sour on the lateral sides, sweet on the anterior surface and tip, salty over the entire area, and bitter on the circumvallate papillae (Guyton, 1991).

Effects of radiation therapy. Loss of taste can occur as early as 1 week into the course of RT. At doses of only 240-400 cGy, a 50% reduction in bitter and sour acuity has been reported (Semba, Mealey, & Hallman, 1994). Taste changes and diminished taste acuity progress quickly between 2000-4000 cGy (Parsons, 1994; Semba et al., 1994). Salivary changes tend to occur prior to taste loss.

Generally speaking, patients report that their taste is changed or diminished early in the RT treatment process, with some patients reporting a bitter or unpleasant taste (Parsons, 1994). Taste acuity appears to peak before meals for these patients and declines during the meal. A greater threshold for sweet-tasting foods and decreased threshold for bitter-tasting foods has been noted (Iwamoto, 1992). Taste acuity is often significantly diminished or absent by 3000 cGy of treatment (Semba et al., 1994).

Radiation disrupts and damages the taste buds at doses as low as 1000 cGy (Beumer, Curtis, & Harrison, 1979). The amount and location of radiation will influence the effect on taste sensation. Mossman and Henkin (1978) found that peak taste impairment appeared after only 3 weeks of conventional treatment. They also reported that alterations in salty and bitter tastes occurred first and lasted longest. Bitter and sour sensations were also reported to be the most sensitive to radiation (Donaldson, 1977). Sweet taste seems to be the least affected, with changes noted later in the treatment process, and return of normal state reported sooner (Mossman, Shatzman, & Chencharick, 1982). The return of taste to normal is quite variable and also related to the cumulative dose of radiation delivered. If taste buds are not permanently damaged, taste sensation may return within a

few months, but may take as long as a year to return to pretreatment condition (Iwamoto, 1992; Parsons, 1994; Silverman, 1993). When the total radiation dose exceeds 6000 cGy, permanent taste impairment can result (Semba et al., 1994).

Related Research. As reported previously in the pilot study of 10 patients for this current research, 100% of the participants reported changes in taste at some point in the course of the treatment. All patients experienced some form of change or problem in their ability to eat during RT.

Mossman and Henkin (1978) followed 18 H&N cancer patients receiving RT. Taste acuity - subjective and objective - were measured before, during, and approximately 1 month post-RT. Taste acuity was measured for the four primary taste sensations (i.e., salt, sweet, sour, and bitter). The investigators found that impaired taste acuity was observed in all of the study participants approximately 3 weeks following initiation of treatment. Bitter and salty taste sensations showed the earliest and greatest impairment, while sweet sensation exhibited the least change. They also found that objective measures in taste acuity were reported before changes in either detection or recognition thresholds, which were measured both subjectively and objectively. Of the 12 patients who reported loss of taste, 10 also reported the presence of xerostomia. Only two of the patients who experienced xerostomia did not complain of taste loss. All patients who reported loss of taste following RT also began to complain of dysgeusia (i.e., unpleasant taste).

While changes in taste were reported by all 18 patients in the Mossman and Henkin (1978) study, only seven of the patients were measured at all three time points. Precisely

when measurements were taken was not clear from the data reported. Was taste first measured at the 3-week point of RT or earlier in the treatment course? If patients were first measured for changes in taste at the 3-week time point that could explain the initial taste changes noted at three weeks, rather than at an earlier point in treatment as would be expected from a review of related literature.

Several other studies (Bolze, Fosmire, & Stryker, 1982; Conger, 1973; DeWys & Walters, 1975) reported similar findings; namely, that patients receiving radiation to the H&N region experience significant taste changes or taste loss. Again, the sensations of salty and bitter appear to be more sensitive to radiation treatments, and sweet less sensitive. DeWys and Walters reported that meats in particular were found to taste "abnormal" by patients. These studies also concluded that, as a consequence of changes in taste and taste loss, patients may lose the desire to eat resulting in reduced food intake and subsequent weight loss.

Other studies (Chencharick & Mossman, 1983; Hagopian, 1990; King, et al., 1985; Wilson, Herman, & Chubon, 1990; Woodtli & Van Ort, 1991) have reported that patients identify taste changes with RT treatment. However this information has usually been obtained via a single item on a questionnaire or interview format.

Measurement. Since changes in taste occur almost universally during RT treatment for the H&N cancer patient, assessment of such changes has been included in several studies (Bolze, 1982; DeWys & Walters, 1975; Huldij et al., 1986; Mossman & Henkin, 1978). The method of assessment has consistently been a subjective measure of taste change as

reported by the patient. No standard instrument was found across studies to measure these subjective changes. Objective measures to determine changes in taste acuity and taste thresholds for specific sensations were also conducted in several of the studies.

Mossman and Henkin (1978) requested information from the patients in their study related to their awareness of taste loss and the presence of an unpleasant taste sensation, xerostomia, and/or anorexia. Huldij et al. (1986) requested completion of a food appreciation questionnaire at seven different time points to determine changes in patient preferences toward 31 food items and primary tastes (i.e., salty, sour, sweet, and bitter) over a 5-month period. Another study (DeWys & Walters, 1975) queried patients as to any taste changes during the course of RT, and if the patient responded positively, further inquiry was made to determine specific changes.

Assessment for taste changes generally involves subjective patient inquiry. While it is well documented that H&N cancer patients receiving RT experience changes in taste - specifically taste acuity and taste threshold (Mossman, 1984), as measured objectively - the subjective manifestations, as reported by the patient, appear to correlate with the objective changes in taste function. The subjective measures do not appear to be as sensitive in determining early or minor changes (Mossman, 1984). However, Mossman and Henkin (1978) did report that, when patients presented with complaints of taste impairment during therapy and were objectively measured for taste acuity, they found that the subjective complaints of taste loss and measured decreases in taste acuity occurred at

approximately the same time. These results indicate that rapid changes in taste acuity can be perceived by the patient.

Taste changes as perceived by the patient, rather than objectively measured, was the variable of interest for this current study. The patient may experience taste changes when measured objectively, but may not have been previously aware of the change (Mossman, 1984). Patient perception of changes in taste, and the subsequent impact that can potentially have on their nutrition and physical weight, is of interest in this study.

Related Research

H&N cancer patients often present with nutritional problems and weight loss at the time of diagnosis due to a history of excessive alcohol intake and dietary/nutritional deficits (Copeland & Ellis, 1994).

The tissues of the H&N region - particularly the oropharynx - are very responsive to radiation treatments; hence, they are vulnerable to radiation injury or damage when treated with cumulative doses of radiation in excess of 65 Gy. Such side effects of treatment may affect the ability of the patient to maintain an adequate nutritional intake, resulting in weight loss.

When patients receive RT treatments to the H&N region that includes all or part of the oropharynx, mucositis runs a fairly predictable course. The severity of the reaction is related to the radiation dose delivered - both fractionated and cumulative dose - as well as the size of the area treated. Mucosal reactions range from erythema and edema to confluent mucositis ulcers. Patients may complain of oral pain, pain upon swallowing, dry

mouth, decreased appetite, and taste changes, all of which affect their ability to maintain an adequate dietary intake and healthy physical weight (Madeya, 1996b). The MacDibbs Mouth Assessment is an instrument that includes an assessment for the presence or absence of these side effects/symptoms as reported by the patient.

Of all the effects associated with RT treatments, with the exception of pain, taste alterations have the most significant impact on the nutritional status of the patient (Chencharick & Mossman, 1983; Donaldson, 1977; Woodtli & Van Ort, 1991). Weight loss in RT patients has been correlated with taste dysfunction (Bolze et al., 1982; Chemcharick & Mossman, 1983).

RT-induced morbidity has been evaluated in H&N cancer patients by measuring weight loss. In several studies (Chemcharick & Mossman, 1983; DeWys et al., 1980; Donaldson, 1981; Wilson et al., 1990) patients lost an average of 3.2 to 8 kilograms of body weight during the course of RT. Weight loss has been thought to be associated with other treatment morbidity parameters such as mucositis and pain, but clear relationships have not been established.

Johnston et al. (1982) studied 31 patients receiving RT for localized cancer of the H&N region. The purpose of the study was to examine weight loss as a function of the pretreatment characteristics of the population sample and its relationship to the size/volume and site treated, and treatment-related symptoms. During the study, 68% of the sample (21 of 31 patients) lost over 5% of their presenting weight within 1 month of treatment completion. The mean weight loss was 10% and the range was 5.4 - 18.9% of

presenting weight. Pretreatment dietary habits, serum albumin, absolute lymphocyte count, serum creatinine, and anthropometric measurements did not predict weight loss. However, the amount of weight loss was predicted by the treatment site and field size. A larger field size and inclusion of the oropharynx resulted in greater mean weight loss. In addition, oral or oropharyngeal symptoms such as pain, dysphagia, xerostomia, and dysgeusia were more severe and of longer duration in patients with greater than a 5% weight loss. The findings of this study indicate that anthropometric measures, while indicative of malnutrition, do not predict total weight loss. Weight loss was predicted by site treated and field size, supporting the use of presenting weight and subsequent weight loss during RT as an indicator of treatment-related morbidity.

H&N cancer patients who are nutritionally compromised and lose body weight during RT are at significant risk for treatment-related morbidity. With RT to the oral cavity and oropharynx, the majority of patients will develop mucositis and other side effects (e.g., taste changes), which can potentially interfere with their ability to eat and drink, further compromising their nutritional status. While studies have indicated that nutritional changes related to disease and treatment are a problem, most have implemented costly laboratory tests and anthropometric measures requiring specialized training to assess nutritional status. Brookes (1985) conducted a study of 114 H&N cancer patients and reported that only those patients (15%) who were evaluated as being "severely malnourished" prior to treatment were at significant risk of suffering from treatment-related morbidity. Those

identified as "mildly" or "moderately undernourished" did not experience increased treatment-related morbidity.

Macia et al. (1991) conducted a prospective study to evaluate nutritional status and dietetic care in 93 cancer patients about to undergo RT. Thirty-one of these patients presented with H&N cancer and were randomized to either a control or experimental group. The nutritional status of the sample was evaluated by body weight, body mass index, arm circumference, tricep skin fold thickness, and arm-muscle circumference. Changes in these parameters following RT were significant in all categories for the H&N cancer patients in the control group with no intervention versus the experimental group with a nutritional intervention. These findings did not hold true for the patients with breast or abdominopelvic cancers. The results suggest that treatment morbidity specifically related to weight and weight loss is worse for the H&N cancer patient than other patient groups, even when a nutritional intervention is administered. This study lends support to the reliance on measures such as body weight and body mass index as adequate indicators of nutritional status in the H&N cancer patient.

Studies conducted with H&N cancer patients on nutritional status have focused primarily on interventions aimed at changing/improving the nutritional state (Daly et al., 1984; Goodwin & Byers, 1993; Harvey, Bothe, & Blackburn, 1979; Lopez, Robinson, Madden, & Highbarger, 1994). Little research has been conducted with H&N cancer patients receiving RT to determine the pattern of weight changes prior to the start of treatment and subsequent weight loss over the course of therapy. The association of this

weight loss with other treatment-related morbidity parameters such as severity of mucositis, mucositis-related pain, xerostomia, and taste changes is also critical information lacking in previous studies. As mentioned earlier, costly laboratory tests that have not correlated with treat-related morbidity have been commonly documented. All of the nutritional studies reviewed support the occurrence of weight loss in the H&N cancer population receiving RT.

Weight loss in H&N cancer patients prior to and during RT has been reported in greater than 94% of this population (Donaldson & Lenon, 1979; Chencharick & Mossman, 1983), with an average weight loss of 3.7 kilograms documented (Donaldson & Lenon, 1979). The severity and frequency of weight loss during RT treatment has been correlated with the site and field size treated (Pezner & Archambeau, 1985). Johnston et al., (1982) reported that 68% (n = 20) of H&N cancer patients receiving RT in their study lost greater than 5% of their presenting body weight 1 month post-RT. The major factor that correlated with weight loss was a treatment field size greater than or equal to 8 cm by 8 cm and the inclusion of the oropharynx in the treatment field. DeWys and associates (1980) found that pretreatment weight loss, representing an alteration in nutritional status, is an independent and important prognostic factor in patients with cancer.

No studies could be found that have examined the relationship between weight loss and other morbidity parameters associated with RT (i.e., mucositis, pain, or fatigue). Mucositis and pain can affect eating ability and lead to weight loss and undernutrition. Since malnutrition and undernutrition, as well as weight loss, occur in a large percentage

of H&N cancer patients receiving RT, the question of interest is not to determine undernutrition, or to nutritionally intervene, but to characterize and describe weight loss in this patient population as it relates to specific treatment-associated morbidity parameters (i.e., mucositis severity, mucositis-related pain, xerostomia, or taste changes). Based upon these findings, appropriate weight measures would include usual weight, current weight, ideal weight, weight at start of RT, weight at pre-determined intervals during treatment, weight at the treatment completion, and weight at subsequent follow-up visits. From these data, a weight change percentage over the course of therapy can be computed.

Self-Care

Cancer treatment is being increasingly administered on an outpatient basis. This is especially true for H&N cancer patients undergoing RT. Treatment-related morbidity can be severe, and primary responsibility for managing treatment-related problems often falls to the patient and his or her family.

Orem's Self-Care Deficit Theory of Nursing

The use of Orem's (1995) Self-Care Deficit Theory of Nursing (S-CDTN) is appropriate in studying the H&N cancer patient undergoing RT treatments. Figure 2 depicts the conceptual structure of the S-CDTN in its entirety as proposed by Orem. Only the dimensions of the model applicable to the current study will be discussed: self-care behaviors, therapeutic self-care demand, self-care deficit, and self-care agency as it applies to self-care behaviors.

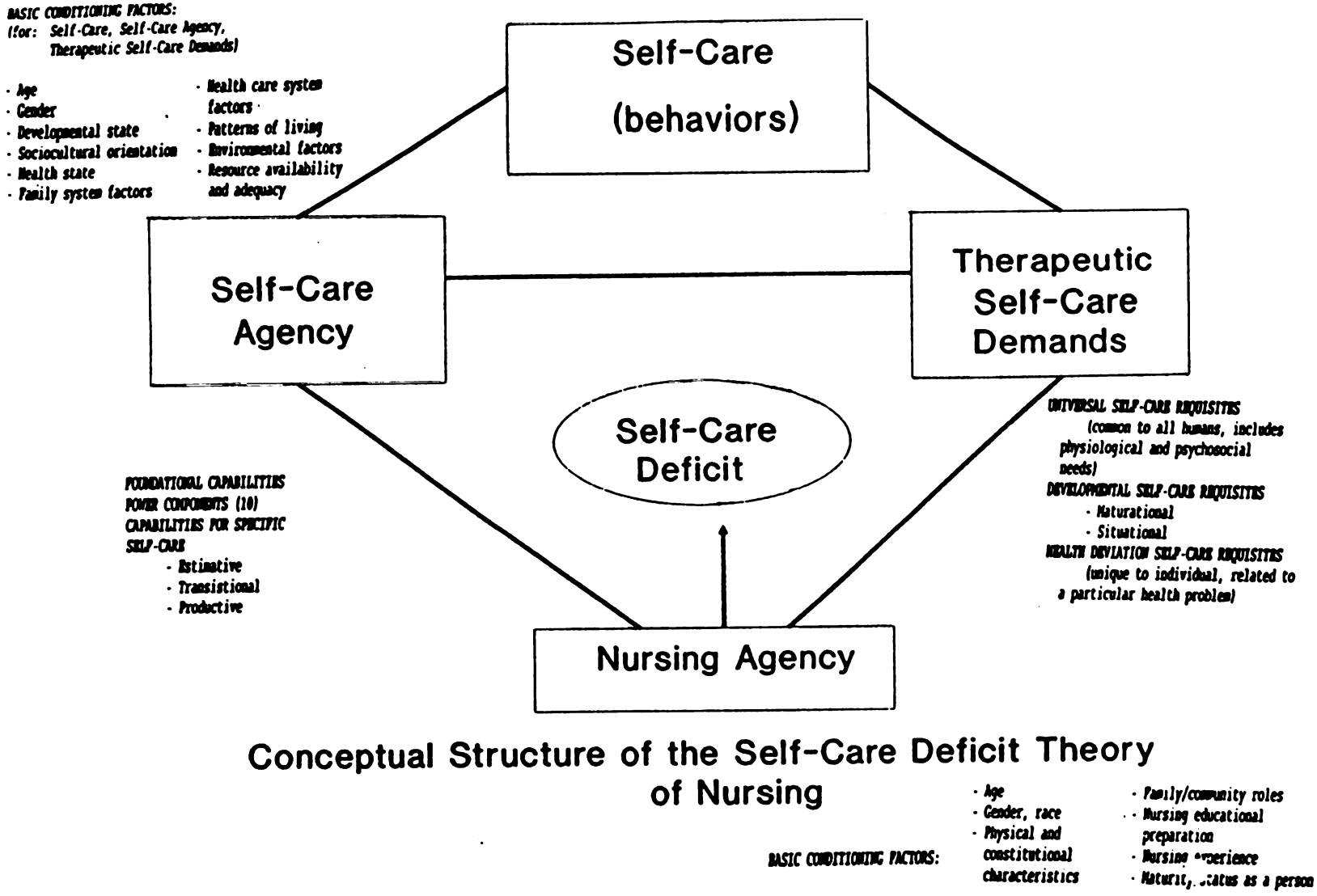


Figure2. Conceptual structure of the Self-Care Deficit Theory of Nursing

Note. Adapted from *Nursing: Concepts of Practice, 5th Edition* (p.213), by D. Orem, St. Louis: Mosby Year Book. Copyright 1995.

Self-care "is the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health, and well-being" (Orem, 1995, p. 104). Self-care is purposeful and conducted to meet self-care requisites (needs). The relationships among self-care, self-care agency, and therapeutic self-care demand are also depicted in Figure 2.

Therapeutic self-care demands (TS-CD) are the self-care actions necessary to meet known self-care requisites or needs. Orem (1995 specifically states that a TS-CD are the "a prescription for continuous self-care action through which identified self-care requisites can be met with stipulated degrees of effectiveness" (Orem, 1995, p111). Again, these actions are performed in order to fulfill an individual's self-care requisites or needs, or are the reasons for initiation of self-care behaviors.

Orem (1995) identified three categories of self-care requisites: universal, developmental, and health deviation. *Universal self-care requisites* are those needs that are common to all humans and include both physiological and psychosocial needs. *Developmental self-care requisites* are based upon age and/or stage of life. They are sometimes considered specialized expressions of universal self-care requisites that are specific to developmental processes or new requisites resulting from a situation or condition (e.g., pregnancy or death). These requisites are further defined as maturational or situational. *Health deviation self-care requisites* are unique to each individual because they are a result of a particular health problem or condition such as being diagnosed with cancer or suffering the effects of RT treatments for cancer. "The characteristics of health deviations as conditions extending over time determine the kinds of care demands that

individuals experience as they live with the effects of pathologic conditions and live through their duration" (Orem, 1995, p 200). Health deviation self-care requisites differ from situational self-care requisites because the problem or conditions resulting in health deviation self-care needs are pathologic and would not be expected to occur as a result of developmental processes. As they relate to the proposed study, TS-CDs are the result of the side effects from radiation therapy (e.g., mucositis, mucositis pain, taste changes, xerostomia, and weight loss).

A number of factors exist that can affect an individual's ability to maintain self-care and control the amount and kind of self-care needed. These factors are defined as basic conditioning factors and include, but are not limited to, age, gender, developmental state, health state, sociocultural orientation, family systems factors, pattern of living, environmental factors, and resource availability and adequacy (Orem, 1995). Basic conditioning factors can impact any area of Orem's model: self-care, self-care agency, therapeutic self-care demand, nursing agency, and/or nursing system.

Self-care agency is the acquired ability and/or power of the individual to engage in self- care. It is a composite of the capabilities and limitations of an individual in terms of meeting their therapeutic self-care demands. Central to self-care agency is experience, understanding, critical reflection, and critical judgment. There are three identified components of self-care agency: (a) foundational capabilities, (b) power components, and (c) capabilities for specific self-care (Orem, 1995). In this study, self-care agency will be

evidenced by the self-care behaviors patients initiate to manage the side effects of RT treatment to the H&N region.

In summary, self-care, according to Orem (1995) encompasses the actions that a person initiates on their own in order to maintain life, health, and well-being. The actions are implemented to meet self-care needs, or TS-CDs, identified by Orem as being either universal, developmental, or health deviation requisites. In addition, the individual must engage in self-care in order to develop the ability and capacity to perform the needed self-care actions (i.e., self-care agency).

Related Research

Many studies were found that focused primarily on self-care behaviors in the cancer patient (Dodd, 1982b, 1984b, 1984c, 1987, 1988a; Dodd & Dibble, 1993; Hagopian, 1990; Hanucharurnkul, 1989; Musci & Dodd, 1990; Rhodes, Watson, & Hanson, 1988; Robinson & Posner, 1992). However, only four studies (Dodd, 1984b, 1987; Hagopian, 1990; Hanucharurnkul, 1989) involved self-care behaviors in patients receiving RT.

Dodd (1984b) conducted a descriptive longitudinal study to determine self-care behaviors associated with RT side effects. A nonrandomized sample of 30 patients beginning their first course of RT for various types of cancer was obtained. The instruments utilized in the study included the State-Trait Anxiety Inventory, Multidimensional Health Locus of Control, the Self-Care Behavior Log, and demographic data including age, time since diagnosis, duration of treatment, cumulative radiation dose, Karnofsky Performance Status, social position, sex, and cancer site.

The Self-Care Behavior Log (SCBL) (Dodd, 1984b), an adaptation of an earlier log used by Dodd required that the patient record the date of onset for each side effect experienced, as well as its severity and the level of distress it caused. Severity and distress levels were recorded using separate 5-point rating scales (severity between a range of 1 = *barely noticeable* to 5 = *most severe*, and a range for level of distress between 1 = *minor annoyance* to 5 = *extremely distressing*. The patient also recorded the self-care activities implemented to alleviate the side effects, the date they were initiated, their effectiveness, and the source of the self-care information. The effectiveness of the self-care techniques implemented was rated on a 5-point scale (1 = *not relieved at all* to 5 = *completely relieved*).

Orem's (1995) S-CDTN was the theoretical basis for this study. The results of this study paralleled the results of Dodd's previous studies with chemotherapy patients (Dodd 1982b, 1983). Dodd found few self-care activities being used by patients for experienced side effects. The side effects for which patients did report initiating self-care behaviors were those publicized in the media with generally known remedies.

Patients receiving RT did not delay the initiation of self-care behaviors as did patients receiving chemotherapy (Dodd, 1982b, 1983). This difference was attributed to the fact that in the RT study (Dodd, 1984b), patients were requested to record the side effects they experienced and rate their severity and the distress levels they caused. By having the patients provide this data, Dodd hypothesized that it was difficult for them to take no action if a side effect was experienced. A significant positive association was found

between the patient's knowledge of potential side effects of RT and the number of self-care behaviors initiated. The more knowledge of side effects, the greater the number of self-care behaviors reported. In addition, a positive correlation was found between the distress level caused by a side effect and self-care activities, with an increased degree of distress associated with greater self-care activity.

This study (Dodd, 1984b)was an important contribution to the self-care literature because it served as a basis for subsequent studies focused on specific self-care behaviors and S-CDTN. As a result, theory-based interventions were developed to promote self-care. Additionally, refinements in the study design and instrumentation were made in a subsequent study (Dodd, 1987) based on these findings.

Dodd's 1987 study tested the effectiveness of providing patients with information related to the management of RT side effects before they occurred. Using an experimental design, 60 patients were randomized to either an experimental or control group. Measurements of self-care behaviors were taken using a SCBL developed by Dodd.

The SCBL was comprised of two sections - a preventive side effect self-care section, and an experienced side effect self-care section. For the preventive section, patients were requested to list the potential side effects of RT, record any preventive self-care behaviors initiated, and list the sources of information for the preventive self-care behaviors. For the experienced side effect section, once a side effect was experienced, patients were to record the side effect along with the behaviors initiated to alleviate the side effect, and the severity and degree of distress caused by the side effect. The effectiveness of the self-care

behaviors in alleviating the side effects were also recorded by the patient using the 5-point scale previously described.

Dodd (1987) found that patients in the experimental group receiving the self-care management techniques, performed a significantly greater number of self-care behaviors, but performed less preventive self-care behaviors than the control group who did not receive side effect management training. She reported that a nonsignificant relationship was found between the effectiveness of the self-care behaviors and overall self-care activities. The focus of this study was on preventive self-care activities, and an explanation for the nonsignificant findings could be attributed to the notion that patients are simply less likely to engage in preventive behaviors as opposed to behaviors directed at a side effect already experienced. In addition, the side effect management training/information focused primarily on the management of existing side effects, not on measures to prevent side effects. Analysis of demographic, disease, and treatment variables indicated no significant associations with self-care behavior scores or preventive self-care activity.

Hanucharurnkul (1989) examined whether self-care can be predicted jointly by social support and age, marital and socioeconomic status, living arrangements, and stage and site of cancer. This correlational, cross-sectional study was the first to test Orem's (1995) postulates as they relate to basic conditioning factors and dependent care, which was measured as social support in this study. Utilizing a convenience sample of 112 adult patients with cervical (62.5%) and H&N (37.5%) cancer patients receiving RT treatments in Bangkok, Thailand, data were collected upon completion of at least 15 RT treatments.

Instruments used in the study included: Self-Care Behavior Questionnaire (SCBQ), Social Support Questionnaire (which was a combination of a social support scale measuring informational and emotional support by Schaefer, Coyne, and Lazarus (1981) and Norbeck's Social Support Questionnaire (Norbeck, Lindsey, & Carrieri, 1981) measuring tangible support), and a sociodemographic questionnaire that included years of formal education, current income, and occupational prestige. The SCBQ is a 41-item, 5-point Likert Scale developed by the author to measure the amount of self-care performed by each patient. The questionnaire was based on Orem's (1995) conceptualization of self-care. Coefficient alpha for the SCBQ was reported as .87 for the H&N cancer patients, and .86 for the cervical cancer patients. Stability of the SCBQ was determined by test-retest procedure.

A total social support score was computed by totaling the scores for each type of social support: informational, emotional, and tangible. The stability of the Social Support Questionnaire, using test-retest, was conducted and correlations between Time 1 and Time 2 were .90 for the Total, Emotional, and Tangible Support Scale, and .89 for the Informational Support Scale. Coefficient alpha for the total Social Support Questionnaire was .97.

Orem's (1995) S-CDTN provided the theoretical framework for this study. The occurrence of cancer and subsequent treatment results in changes in patients' TS-CDs that affect self-care. Health deviation self-care requisites resulting from the disease and treatment can cause changes in universal and developmental self-care requisites.

Dependent care, according to Orem, is care provided by individuals on behalf of a socially-dependent individual and is equated with social support as it is defined for purposes of Hanuhcharurnkul's (1989) study.

Hanucharurnkul found that social support (dependent care) and socioeconomic status were significant predictors of self-care. Patients with higher social support scores and greater socioeconomic status performed more self-care behaviors. This finding was in opposition to a later study by Dodd and Dibble (1993) who found that, while social support was a significant predictor of self-care in cancer chemotherapy patients, those patients with lower social support scores, indicating less social support, performed significantly more self-care. The differences in findings of these two studies may be attributed to cultural differences and/or other differences within the patient populations (e.g., RT patients versus chemotherapy patients).

Hanucharurnkul (1989) reported that stage and site of cancer seemed to predict self-care, though indirectly through social support. The results of this study provide a better understanding and awareness of the relationships among factors (i.e., occupational prestige, stage of cancer, and site of cancer) and their effects on social support and self-care in patients undergoing RT. The author also points out that the data does clarify and support relationships proposed by Orem's (1995) S-CDTN, namely, that socioeconomic factors and social support, as available resources, affect the initiation and continuation of self-care.

Several limitations in the Hanucharurnkul (1989) study are worth noting. A cross-sectional design was utilized in which data were collected from patients upon completion of at least 15 RT treatments. The data collection point was not the same for all patients, thus differences in results are difficult to interpret. In addition, the Bangkok, Thailand sample population and the appropriateness of using Orem's (1995) theoretical model in populations outside the United States or in a Western culture has not been reported. Generalizability of these findings are therefore limited. Additional testing of the questionnaire should be conducted to determine its validity in samples of non-Western cultures.

Dodd and Dibble (1993) studied 127 adult cancer patients starting chemotherapy to determine predictors of self-care. They followed patients for four courses of chemotherapy treatments. They studied specific basic conditioning factors (age, gender, years of education, health state, health-care system factors, family system factors, and patterns of living) and specific power components (e.g., ability to maintain attention and exercise requisite vigilance with respect to self and internal conditions, controlled use of available physical energy for self-care operations, ability to reason within a self-care frame of reference; motivation toward self-care, and ability to acquire technical knowledge surrounding self-care) as possible predictors of self-care.

Instruments used in this study included the Karnofsky Performance Status Scale, the Chemotherapy Knowledge Questionnaire, the Norbeck Social Support Questionnaire, the Exercise of Self-Care Agency, the Perceived Self-Efficacy Scale, the Health Promoting

Lifestyle Profile, and the Profile of Mood States. Self-care behaviors for five experienced side effects - nausea and vomiting, mucositis, fatigue, pain, and hair loss - were recorded by the patients with the Self-Care Behavior Checklist - a 40-item instrument developed by Stetz and Dodd (1987). Dodd and Dibble (1993) reported that health state, which was measured with the Karnofsky Performance Scale; family systems factors (i.e., social support); and years of education accounted for 38% of the variance of in self-care activity. Patients with lower performance scores performed significantly more self-care activities, and the side effects of treatments acted as a stimulus to self-care.

Hagopian (1990) conducted a study to develop and test for reliability and validity of the Radiation Side-Effects Profile (RSEP) - an instrument designed to measure the self-care strategies used by patients to reduce the severity of RT-related side effects. A repeated-measures design was employed, and data was collected at Weeks l, 2, 4, and 5. A total of 56 patients with cancer were studied from a RT department within a university hospital. The RSEP is a self-report instrument that includes data related to side effects experienced and self-care behaviors performed.

Orem's (1995) theory of self-care is stated as the theoretical framework for Hagopian's (1990) study. Patients rated the severity of their side effects, reported self-care behaviors they implemented, and rated the effectiveness of their actions. These responses are derived from and address Orem's health deviation self-care requisites, and self-care theory, though this is not explicitly stated by Hagopian in the documentation of the study. Eight self-care strategies/categories were identified by Hagopian, though these are not

derived from Orem's theory. As mentioned earlier, the RSEP was developed to identify side effects resulting from RT and the self-care strategies utilized by patients to relieve the side effects. The purpose of the Hagopian study was to refine and test the RSEP in patients with various cancer diagnoses undergoing RT treatment. Further studies using this instrument are necessary to determine its validity and reliability in larger samples.

Kubricht (1984) used a descriptive-survey research design to interview 30 patients midway through their RT treatments to determine their TS-CDs. An open-ended interview technique queried patients on changes in their lives since beginning treatment to accomplish data collection. Orem (1995) was one of several perspectives cited as constituting the conceptual framework for this study. Data related to the variables of age, sex, race, education, duration of treatment, cancer location, area irradiated, and total radiation dose - all considered basic conditioning factors by Orem - were also collected.

Patients participating in the Kubricht (1984) study were able to identify their TS-CDs and they all reported changes in universal self-care requisites. The majority (20%) of responses related to the universal self-care requisite of protection from hazards. The mean number of TS-CDs reported was 18.4 (range 11-41). All patients experienced and expressed multiple physical, psychological, social, spiritual, and cognitive changes attributed to therapy.

Questions needing further consideration as a result of the Kubricht (1984) study are related to Orem's (1995) S-CDTN. Health deviation self-care requisites are those needs resulting from treatment (e.g., medical problem(s)). If changes experienced by patients

are due to RT, using universal self-care requisites as the focus of study may not be appropriate.

Limitations of Kubricht's study include sample size (n = 30), the convenience sampling technique used, absence of established validity and reliability of the data collection tool, and an interviewer unfamiliar to the participants, which may have affected responses. This study does have implications for nursing. The number of TS-CDs indicates that nursing can play a vital role in assessing the ability of patients to meet the demands placed upon them as a result of their treatment and subsequent interventions.

Measurement

In Orem's S-CDTN, the concept of self-care is central and is defined as "the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health, and well-being" (Orem, 1995, p.104). The reason that patients initiate self-care behaviors are multifaceted and can vary widely between individuals, as previously discussed. According to Orem's theory, self-care behaviors initiated by the H&N cancer patient to alleviate the side effects of RT treatment would be classified under TS-CDs fulfilling health deviation self-care requisites.

The measurement of self-care activity has not been easy to accomplish. The characteristics of self-care and supporting self-care behaviors are not specifically explicated. Based on Orem's theory and simply stated, the need for self-care results from the patients TS-CDs derived from their illness or treatment, requiring the patient to initiate self-care behaviors. Self-care behaviors initiated by an individual patient will vary

according to many factors such as the level of distress or discomfort experienced. This variability contributes to the difficulty in developing a uniform instrument to measure self-care. However, several instruments have been developed to attempt this: SCBL (Dodd, 1987), the Self-Care Diary (Nail, Jones, Greene, Schipper, & Jensen, 1991); and the RSEP (Hagopian, 1990).

The SCBL has been utilized with both chemotherapy and RT patients, while the RSEP was developed for use soley with RT patients, and the Self-Care Diary solely for chemotherapy patients. As discussed previously, the SCBL was implemented by Dodd to measure the self-care actions of cancer patients experiencing the side effects of chemotherapy (1982a) and RT (1984b, 1987). It has two parts - a preventive side-effect, self-care section and an experienced side-effect, self-care section - and serves as a self-report record. In the preventive section used with RT patients (1984b, 1987), the patient is requested to record the potential side effects that can occur with treatment, list the self-care activity planned to prevent the side effect from occurring, note the date the self-care activity is initiated, and note the source of the self-care activity information. The score for the preventive section is determined by the total number of items listed for each category. In the experienced side-effect, self-care section, patients are requested to record any side effects experienced from treatment and the date they occur; rate side effect severity on a 5-point Likert scale (i.e., 1 = *barely noticeable* to 5 = *most severe*); rate level of distress caused by the side effect on a 5-point Likert scale (i.e., 1 = *no distress* to 5 = *most distressing*); list the self-care activities initiated for relief of the side effect; rate the

effectiveness of each self-care behavior on a 5-point Likert scale (i.e., 1 = *did not help at all* to 5 = *completely alleviated*); and record the source of information for the self-care activity implemented. The patients then record the actions they took to deal with the side effect. The SCBL is maintained for the duration of treatment and patients are requested to bring their logs in for review by the nurse every other week.

In addition to descriptive statistics, four ratios are computed to examine the quantitative variable self-care behavior (Dodd, 1988a): (a) selected self-care activity (average # of less effective behaviors per side effect), (b) total self-care activity (average number of self-care behaviors per side effect), (c) SCB efficacy (average effectiveness rating for self-care behaviors), and (c) overall management of side effects (average maximal effectiveness of behaviors per side effect). Reliability and validity data have been reported for this instrument (Dodd, 1983, 1987, 1988a).

The patient is required to provide the requested side-effect information by writing it in the SCBL. While the log is easily understood and not difficult to complete, it does require patient completion on an ongoing basis, especially as side effects occur. Dodd (1988a, 1988b) found that as patients are more active participants in the study, the completion of the SCBL, for some, became more problematic. An instrument that is simpler to complete, such as one that allows patients to check off side effects or behaviors, would minimize the amount of missing data; however, this approach may also negatively affect the results due to prompted recall with a fixed list of side effects. One potential concern with using the SCBL is that, by requiring the patient to list potential side effects and their appropriate

self-care activities, patients may be unintentionally "cued" to "look for" treatment side effects. Additionally, patients may be implementing self-care activities simply because they feel it is expected since the SCBL asks for a report of such activities.

The SCBL, while addressing the dimensions of self-care that were of interest in this current study, may not be practical in other studies with H&N cancer patients receiving RT if the patients are required to provide other information as well. Anecdotally, H&N cancer patients have been reported to be "concrete" thinkers (Yuska, 1989). If this is indeed the case, instruments that provide more specific instructions and require little initiative would have a higher response rate with this patient population.

The RSEP is a 1-page instrument developed by Hagopian (1990) to measure self-care strategies implemented by patients toward the relief of RT side effects. It is a norm-referenced instrument with two separate interval scales and five parts. The first portion is comprised of a list of 11 side effects most commonly experienced by RT patients and allows respondents to list other experienced side effects not indicated on the list. The patients are then asked to rate the severity of the side effects on a 4-point scale (0 = *none* to 3 = *very bad*). They are then requested to supply information as to what they did to "relieve the side effect(s)". In the next section, they rate how "helpful" their actions were toward relief of the side effects on a 4-point scale (0 = *not at all* to 3 = *very*). The instrument concludes with a section requesting information related to where they obtained symptom-relief knowledge in dealing with their side effects.

The RSEP is a self-administered instrument. Two scores are obtained via a Severity Index and a Helpfulness Index. The Severity Index score is a summation of the scores in the *severity* column. The higher the Severity Index scores, the greater the severity of the side effects. The Helpfulness Index is a summation of the scores in the *helpful* column, with higher scores on this index indicating more helpful self-care activities. Reliability and validity of the instrument has been reported by Hagopian (1990).

The literature indicated that the RSEP was only used in one other Hagopian study of cancer patients undergoing RT treatments (Hagopian & Rubenstein, 1990). One of the purposes of their research was to examine the effects of a weekly telephone intervention on self-care. Hagopian and Rubenstein reported that the helpfulness of self-care measures increased as RT progressed, regardless of the implementation of the weekly telephone intervention. While helpfulness scores significantly increased as treatment progressed, the scores reported were still low, indicating that self-care measures were not very helpful in alleviating the side effects of treatment. These findings are similar to Hagopian's (1990) previous study in which she reported that, overall, patients did not find self-care measures helpful.

The RSEP is easier for patients to complete than the SCBL since it provides a "ready-made" list of side effects that can occur with RT. The patient is still required to provide the self-care activities used for each experienced side effect, and the criticisms expressed about the SCBL and the completion requirements are the same heard on this section of the RSEP.

Nail et al. (1991) developed the Self-Care Diary to measure the incidence and severity of 16 selected side effects of cancer chemotherapy treatment, as well as the use and efficacy of self-care activities to manage those side effects. Severity of a side effect is evaluated with a 5-point descriptor scale (i.e., *not at all, a little, moderately, quite a lot,* or *extremely*). Specific self-care activities are also listed for each side effect - 3 to 17 depending on the side effect. Effectiveness of the self-care activities are evaluated by the patient using a 6-point descriptor scale (0 = *not used*; 1 = *used, but no relief*; 2 = *used, a little relief*, 3 = *used, some relief*; 4 = *used, quite a bit of relief*, and 5 = *used, completely relieved*). Additional side effects and self-care activities may be supplied by the patient in a space provided.

The patient is instructed as to when to complete the diary and what time frame to consider during its completion (e.g., in the past three days, or since treatment) (Nail et al., 1991). The patient is to respond as to the absence or presence of each of the 16 listed side effects. If the patient indicates experience of a listed side effect, severity of that side effect is then evaluated via patient rating. Respondents are then requested to indicate from a list of self-care activities those which they did or did not use on a 5-item verbal descriptor scale. For those used, the patient is then requested to indicate the effectiveness of that activity in alleviating the side-effect, using a 5-point rating scale. Space is provided on the diary for the patient to add additional side effects and activities not listed.

Incidence and severity scoring of each side effect is obtained by summing and averaging the scores. The self-care activities are also summed and averaged. Reliability

and validity data were provided (Nail et al., 1991).

Since the Self-Care Diary was developed for use in chemotherapy patient populations, the reliability and validity may not be the same for RT patients receiving daily treatment since the effects of RT on the occurrence of side effects is related to cumulative dose. No other studies were found that reported use of the Self-Care Diary.

The Self-Care Diary is the most specific of the three instruments reviewed in this self-care activity section. While it is not specifically designed for the H&N cancer patients receiving RT (e.g., the inclusion of unrelated side effects such as constipation, diarrhea, and hair loss), a modification of the instrument could be easily made to facilitate its use with this population. By listing all the side effects, and their related self-care activities, the investigators may have influenced the amount of self-care activity employed by patients, as well as indirectly encouraging the patient to try self-care activities they would not have normally attempted. A positive aspect of this instrument was a high rate of response due to the format which required simple checking or circling of answers. "Filling in the blanks" was only required when patients desired to provide additional information not already listed.

In summary, all three of the self-care behavior measures have positive and negative aspects when considering their use with H&N cancer patient populations. A simple, easy to complete instrument is most desirable. However, in an attempt to make it easy to complete, one must be aware of the possible "pitfalls" of indirectly prompting the initiation of self-care activities that patients would not necessarily initiate on their own.

Additionally, with the provision of listed side effects, there is the potential for patients to focus on the personal development of such side effects that they may not normally have noticed. A modification of the Self-Care Diary instrument was used with the H&N cancer patients receiving RT and participating in the current study. This instrument was selected because of its ease of use and high response rate. While unintentional cueing may be an issue to consider, the previous two instruments also presented this same drawback, plus additional disadvantages.

Assumptions

The findings of the reviewed studies led to a number of assumptions forming the basis for the research questions. These assumptions are as follows:

1. H&N RT associated problems are interrelated.
2. H&N RT-related problems can be measured and quantified.
3. Self-care behaviors will be initiated in response to RT-related symptoms.
4. Self-report is the "gold standard" for evaluating symptoms.
5. Self-report is the "gold standard" for reporting self-care behaviors.

Research Aims

The primary research aims and goals of this study are as follows:

1. To determine the onset, severity, and time course of RT-induced mucositis in the cancer patient.

2. To determine the pattern, characteristics, severity, and time course of RT-related mucositis pain in the H&N cancer patient.

3. To determine the use of self-care behaviors for RT-related mucositis by the H&N cancer patient.

4. To determine the use of self-care behaviors for RT-related mucositis pain by the H&N cancer patient.

Secondary aim and goals to be addressed are as follows:

1. To determine the onset and severity of xerostomia experienced by the H&N cancer patient receiving RT.

2. To determine the severity of taste changes experienced by the H&N cancer patient receiving RT.

3. To determine the severity of weight loss in the H&N cancer patient receiving RT.

4. To determine if a relationship exists among xerostomia, taste changes, mucositis severity, mucositis-related pain, and weight loss in the H&N cancer patient receiving RT.

5. To determine the use of self-care behaviors for xerostomia by the H&N cancer patient receiving RT.

6. To determine the use of self-care behaviors for taste changes by the H&N cancer patient receiving RT.

7. To determine the use of self-care behaviors for weight loss by the H&N cancer patient receiving RT.

Definitions of Terms

For the purposes of this study, the following operational definitions will be used:

1. The *head and neck cancer patient* is a patient with a cancer suspected of occurring or present in the oral cavity and pharynx, tongue, nasal cavity and paranasal sinuses, salivary glands, or larynx.

2. *Radiation-induced mucositis* is an acute inflammation of the oral mucosa that occurs during or within 1 week after completion of RT .

3. *Radiation-induced mucositis ulcer* is an erosion of the oral mucosa that occurs during or within 1 week after the completion of RT as measured by the MacDibbs Mouth Assessment.

4. *Pain severity* is the quantification of the patient's perception of the amount of pain she or he is experiencing measured by a numeric scale included in the Pain Profile and Weekly Pain Assessment Questionnaire.

5. *Radiation-induced mucositis pain* is the patient's perception of pain resulting from RT-induced mucositis as measured by the Weekly Pain Assessment Questionnaire - an instrument adapted from the Head and Neck Pain Profile (Epstein & Stewart, 1993) and the Pain Assessment Questionnaire (Weissman et al., 1989). The Weekly Pain Assessment Questionnaire includes a numeric descriptor scale for the measurement of pain and a series of questions related to the pain the patients are experiencing at that point in treatment.

6. *Self-care behavior* is any activity initiated and performed by an individual on their

own behalf in response to RT-related side effects (i.e., xerostomia, taste changes, weight loss, pain, and mouthsores) to maintain their health and well-being as measured by the Weekly Self-Care Diary.

7. *Taste changes* are the subjective changes in taste reported by the patient after the initiation of RT as measured by the numeric descriptor scales of the MacDibbs Mouth Assessment and the weekly Self-Care Diary.

8. *Xerostomia* is the experience of mouth dryness commonly experienced by H&N cancer patients receiving RT. Xerostomia is subjectively measured, by the patient, using a numeric descriptor scale in the MacDibbs Mouth Assessment Tool and the weekly Self-Care Diary. Objective changes in saliva production will be determined using salivary flow studies.

9. *Weight loss* is any loss of body weight occurring after the initiation of RT. Weight loss is determined by subtracting the weight measured at the designated time points from the baseline weight obtained at the start of RT.

CHAPTER III

Methodology

Study Design

This study used a prospective, descriptive, repeated measures design to examine radiation therapy (RT)-related mucositis, mucositis pain, xerostomia, changes in taste, weight loss, and the use of self-care activities by patient with head and neck (H&N) cancer. Data collection occurred throughout the course of RT (i.e., 4 to 8.5 weeks) and through the 1-month follow-up visit.

Setting

The setting for patient accrual was the Radiation Oncology Department at the University of California, San Francisco, a large university medical center based RT department. The radiation oncology staff includes 11 radiation oncologists and two registered nurses. The RT department treats approximately 100 to 125 patients per day utilizing four linear accelerators. The department was chosen due to the large number of patients with H&N cancer seen and treated there annually, as well as the willingness of the staff to refer patients for participation in the study. Data collection occurred in the RT department.

Sample

Fifty patients with H&N cancer receiving RT consented to participated in this study. Subjects were eligible to participate in this study if they met the following criteria: (a) an adult, over 18 years of age, with a cancer located in the H&N region;

b) scheduled for RT treatments that included all or part of the oral cavity, or oropharynx; c) be able to read and understand English; (c) were capable of understanding and completing the informed consent; (d) were a willing participant; and (e) had not received previous RT treatments to the H&N region.

Every patient in the study completed the consent form (Appendix A). The names of the patients remained confidential, and the forms completed by the patients were coded by assigning an alphanumeric designation to each participant. Consent forms with participants' names were kept in secured files. This study was approved by the Committee on Human Research (CHR) at the University of California, San Francisco (H452-11857-01). The CHR approval form is found in Appendix B.

Data Collection Methods

Data collection occurred from September 1995 through March 1997. Data collection was accomplished using several techniques: oral examinations, sialometry studies, administration of questionnaires, and medical record reviews. A description of the instruments and techniques used for data collection are found in the following section.

Patient Demographic Questionnaire

The Patient Demographic Questionnaire (Appendix C) is a 20-item questionnaire that was developed for use in this study. It provided baseline information about the patient that included: age, gender, living situation, marital status, educational level, ethnicity, and employment status. Additionally, information on the use of tobacco products and the consumption of alcoholic beverages was obtained through this questionnaire. This document was completed by the patient.

Disease and Treatment Questionnaire

The Disease and Treatment Questionnaire (Appendix D) was used to obtain data about each patient and their treatment during RT. Each patient's height and pretreatment weight were recorded. Additional data collected on a weekly basis by the researcher included number of treatments received, cumulative RT dose, and weight.

Medical Record Review Form

The Medical Record Review Form (Appendix E) included 12-items that provided information about each patient's cancer diagnosis, tumor characteristics (i.e., histology, stage, grade, and extent of disease), RT treatment protocol, treatment goals, and response to RT. In addition it provided the total radiation dose the patient received, the fractionation schedule, the total number of fractions delivered over a total number of elapsed days, the location and size of the treatment fields, and interruptions in treatment. Information to complete this form was collected, by the researcher, from the patient's treatment record and medical record.

MacDibbs Mouth Assessment Tool

The MacDibbs Mouth Assessment Tool (Appendix F) is a 15-item instrument that includes eight subjective items and five objective items to assess RT-induced mucositis (Dibble, Shiba, MacPhail & Dodd, 1996). The MacDibbs Mouth Assessment Tool was developed to measure oral mucositis severity in the RT patient. The items are grouped into four sections: patient information, examination, potassium hydroxide (KOH) smear, and herpes simplex virus culture.

The patient information section includes 9 items that subjectively measure the patient's oral symptoms including problems with appetite, pain in the oral cavity or oropharynx (i.e., with swallowing and without swallowing), dryness, eating, talking, swallowing, taste and saliva consistency. These nine items are scored on a 4-point (i.e., 0 to 3) rating scale by the patient with 0 indicating *no problems* and 3 indicating *severe problems*. The total MacDibbs symptom score is determined by summing the scores of each individual item, with the final total score ranging from 0 to 27.

The five objective items on the examination section of the MacDibbs provided information about the number of ulcers, the size of the largest ulcer in millimeters, as well as the presence or absence of vesicles, reddened areas, or white patches. Ulcers were measured using a Marquis periodontal probe. This probe is color-coded by alternating silver and black bands that mark 3, 6, 9, and 12 millimeters.

Two additional sections, *KOH smear* and *HSV* culture, represents data that would be obtained if oral fungus or herpes simplex was suspected based on the oral examination. A section for comments is also included on the instrument, however these additional sections do not directly influence scoring of the instrument.

Data collection using the MacDibbs instrument occurred weekly for the first two weeks of treatment, and starting at the beginning of Week 3 of treatment, patients were assessed three times a week (e.g., Monday, Wednesday, Friday) with the three time points designated A, B, or C for that week of treatment. These assessments continued until the completion of RT and the 1-month follow-up. If patients reported symptoms during the first two week of treatment, they were started on the three times a week evaluation at that

point in treatment. Thus data points designated, for example 4B, would indicate the second evaluation period during Week 4, while 4C would indicate the third evaluation point during Week 4.

Reliability and Validity. In a pilot study of 10 adult outpatients with H&N cancer receiving RT, the ability of the MacDibbs Mouth Assessment Tool to determine the development and presence of RT-induced mucositis, as well as the sensitivity of the MacDibbs Mouth Assessment Tool to detect changes in mucositis over time was determined (Dibble, Shiba, MacPhail, & Dodd, 1996). Content validity of this tool was established through review by a panel of experts in dentistry, nursing, and radiation oncology.

Interrater reliability was excellent for all items on the tool (i.e., 100%) except for the size of the largest ulcer (85%) which varied by a much as two millimeters between raters when disagreements occurred. These size differences were with ulcers larger than 12 millimeters. The instrument was found to be sensitive to changes (e.g., improvement or worsening) in the course of mucositis over time. Interrater reliability was not a concern for this study since the researcher performed all of the evaluations using the MacDibbs Mouth Assessment Tool.

Pain Profile

The Pain Profile (Appendix G) is a self-administered and self-reported instrument consisting of 17 questions. The questionnaire is a comprehensive multidimensional survey instrument that was modified from the Head and Neck Pain Profile (Epstein & Stewart, 1993) and the Pain Assessment Questionnaire (Weismann, Janjan, & Byhardt, 1989). The

Pain Profile provides baseline pain information about the H&N cancer patient beginning RT treatments, including the presence of pain due to the present disease, and pain as a symptom at diagnosis. Patients were asked if they were currently having pain in the mouth, head, or neck. If they answered *yes*, they were asked to complete the remainder of the Pain Profile.

For those patients experiencing pain at the start of RT, the Pain Profile provided information related to incidence, severity, location, duration of pain, the effects of activities, and topical and systemic treatments on pain. It incorporates a numeric rating scale for pain, the recording of medications use, the efficacy of medications and treatments, anatomical diagrams to allow graphical representation of pain locations, and the impact of pain on various activities of daily living .

Pain severity is measured using a numeric rating scale with word descriptors of 0 = *none*, 2 = *mild*, 5 = *moderate*, 8 = *severe*, and 10 = *excruciating*. The pain descriptor list is from the McGill Pain Questionnaire and is scored as follows. The four indices of pain are: a pain rating index total (PRI-T) based on the mean scale values; pain rating index rank (PRI-R) based on the rank values of the words; number of words chosen (NWC); and the Present Pain Intensity (PPI) are obtained.

The PRI-T is a sum of the rank values of the words selected from the 20 words listed on the questionnaire. The word in each list indicating the least pain receives a value of 1, followed by the next word indicating more pain 2, and so on up to 4. The 20 lists can also be divided into four subgroups with lists 1-10 sensory, 11-15 affective, 16 evaluative, and 17-20 miscellaneous. These subclasses can be scored by adding the rank values of words

selected in each of the four subclasses. This scoring gives four minor pain ratings: PRI-sensory, PRI-affective, PRI-evaluative; and PRI-miscellaneous. When using this scoring system, higher pain rating scores indicate more pain.

Reliability and Validity. The original instruments were developed and pretested (Epstein & Stewart, 1993; Weisman et al., 1989). However, the results of the pretesting were not reported. Content validity and construct validity of the list of pain descriptors in cancer patients has been reported previously by other researchers (Byrne et al., 1982; Kremer & Atkinson, 1981; Melzack, 1975). The validity and reliability of the numeric descriptive rating scales have not generally been reported by researchers but it is believed that an individual's subjective rating of the pain intensity using this type of scales is a valid measurement (Cleeland, 1985; McGuire, 1988)

Weekly Pain Assessment Questionnaire

The Weekly Pain Assessment Questionnaire (Appendix H) is an instrument that is an abbreviated version of the Pain Profile described above that was developed by the researcher for this study to examine patients' pain over the course of H&N RT treatments. This self-report instrument, completed weekly by the patient, ascertains the presence of pain and location of the pain. If patients are experiencing pain located in the mouth, tongue, throat , or neck they complete the remainder of the questionnaire which characterizes the pain in the H&N region (i.e., severity, intensity, effects of medication on pain) and the effects the pain has on activities of daily living during that particular week. In addition, there are two questions asking patients about smoking or consuming alcoholic beverages during the week.

Reliability and Validity. Neither reliability or validity of the original instruments (Epstein & Stewart, 1993; Weissman et al., 1989) has been reported. As stated previously, the numeric descriptive rating scale for assessing pain in cancer patients is generally regarded a valid and reliable measure (Cleeland, 1985; McGuire, 1988).

Self-Care Diary

The Self-Care Diary (Appendix I) used in this study is a modification of the one developed by Nail et al. (1991). Nail's Self-Care Diary is an instrument to measure the incidence and severity of sixteen selected side-effects of cancer chemotherapy treatment (e.g., difficulty sleeping, constipation, sensitivity to light, funny taste in mouth), and the use and efficacy of self-care activities to manage the identified side effects. For purposes of this study, the instrument was modified to include the most common side effects/symptoms experienced by patients with H&N cancer who were receiving RT, namely, mucositis, mucositis pain, xerostomia, taste changes, weight loss, fatigue, and loss of appetite.

The patient completes the Self-Care Diary weekly. Patients are asked if they are presently experiencing a side effect (i.e., pain, mouth sores, mouth dryness, taste changes, weight loss, changes in appetite). If the response is *yes*, they are asked to rate the severity of the side effect using a 5-point numeric rating scale (i.e., 0 to 4) with descriptive anchors. Patients indicate any self-care activities they used, and the effectiveness of their self-care activities for that specific side-effect.

The number of self-care activities used for each side effect are summed and reported. The effectiveness score of self-care activities for each symptom/side effect is determined

by summing the relief scores of self-care activities attempted divided by the total number of self-care activities performed.

Reliability and Validity. Content validity of Nail et al.'s (1991) Self-Care Diary was established through review by two patients who were undergoing treatment and three oncology nurse specialists (Nail, et al., 1991). According to Nail, et al. (1991), the reliability of the side effect severity portion of the diary was addressed in their study, although no explanation was provided as to how this was achieved.

For the modified version of this instrument for H&N RT patients, the list of side effects and self-care activities was obtained from the literature of patients' experiences with RT (Hagopian, 1990; Strohl, 1989; Woodtli & Van Ort, 1991). Content validity of the current Self-Care Diary was established through a review by four patients with H&N cancer receiving RT and three radiation oncology nurses.

Whole Saliva Flow -- Unstimulated and Stimulated

Unstimulated whole saliva flow measurement is the total amount of saliva produced by a patient over a given period of time (Fox et al., 1987). There is no stimulation to the salivary glands to produce saliva in the unstimulated whole flow. In the stimulated whole flow, the salivary glands are stimulated, by having the patient chew gum, paraffin, or a similar substance during the saliva collection (Appendix I).

Unstimulated whole flow saliva collection begins by having the patient expectorate and discard any saliva in their mouth. All the saliva produced during the next 5 minutes is collected in a container. The patient collects the saliva by expectorating or spitting any saliva forming in the mouth into a container for the five minute period.

The stimulated whole flow sample is collected while the patient is chewing gum or paraffin. Patients are asked to chew the gum/paraffin for 5 minutes prior to the start of the collection. The procedure for collecting the stimulated whole flow sample is the same as described for the unstimulated whole flow sample, except the patient continues to chew during the 5-minute collection period. Saliva production is measured in milliliters and the number of milliliters over the collection time is reported.

Reliability and Validity. While no validity and reliability data were provided for these methods of saliva collection, the validity and reliability of these methods of saliva collection as an accurate indication of total flow production has been questioned because the collection may be tainted with nonsalivary components such as food or desquammated oral cavity cells (Mandel, 1980).

Parotid Flow -- Unstimulated and Stimulated

Unstimulated and stimulated parotid flow is the amount of saliva produced by the parotid glands when unstimulated and stimulated (Fox, et al., 1987). Only saliva produced by the parotid glands is collected.

Saliva is collected using tiny suction cups, Carlson-Crittenden cups, which are placed bilaterally over the parotid ducts. Once the suction cups are secured, saliva is collected for a 5-minute time period, with no stimulation of the parotid glands during the collection.

For the stimulated parotid collection, once the Carlson-Crittenden cups are secured over the parotid ducts, the lateral borders of the tongue are stimulated for five seconds with a lemon juice soaked cotton swab, and repeated every 30 seconds for the 5-minute collection time.

The amount of saliva collected for both the unstimulated and stimulated samples are measured in milliliters and reported in millimeter per collection time. Because of the potentially small amount of saliva production, the Carlson-Crittenden cups are weighed, in grams, prior to and after the collection. The difference in weight in grams is equivalent to milliliters of saliva produced. One gram is equivalent to one milliliter, therefore one gram difference in weight would be equivalent to one milliliter of saliva produced (Fox, et al., 1987).

Reliability and Validity - Data provided about the reliability and validity of this testing method indicate that the collection method is only as good as the technique used and accuracy of applying the Carlson-Crittenden cups over the parotid ducts (Fox et al., 1987). This method provides the most accurate way of measuring saliva production from the unstimulated and stimulated parotid glands (Fox, et al., 1987).

Procedures

Eligible patients were identified through collaboration of the investigator with the radiation oncologists and nurse. Patients were contacted by the researcher to participate in this study during the consultation visit, simulation visit, verification visit, or on the first day of treatment. If the patients were willing to participate, they were given the consent form. Once informed consent was obtained, the patient was instructed to complete the Demographic Questionnaire, Pain Profile, and the Self-Care Diary. The researcher conducted the MacDibbs Mouth Assessment and the saliva studies (i.e., whole flow, unstimulated and stimulated, and parotid flow, unstimulated and stimulated).

The patients were seen in the radiation oncology department, and the MacDibbs Mouth Assessment Tool and salivary flow studies were obtained by the researcher either before or after their daily RT treatments. The Self-Care Diary and Pain Assessment Questionnaire were completed weekly by the patients either at home or in the RT department and returned to the researcher.

Patients were seen weekly by the researcher for the first two weeks of treatment, then three times a week starting the third week of treatment. If patients reported symptoms during the initial two weeks of treatment when evaluated with the MacDibbs Mouth Assessment Tool, they were seen three times a week starting at that point in time and the MacDibbs Mouth Assessment Tool data was collected three times a week. Whole flow saliva studies and weight were obtained weekly.

The Disease and Treatment form was completed weekly and at the follow-up visit by the researcher.The Medical Record Review was compiled and reviewed at the baseline, end of treatment, and follow-up visits. The sequence of data collection for the study is outlined in Table 2.

Data Analysis

An initial analysis was done to identify patient characteristics in this sample. Means, standard deviations, and ranges were performed on continuous variables such as age, education, cumulative dose of RT, and number of treatments. Frequencies and percentages were calculated on nominal variables such as marital status, living arrangement, employment, smoking history, alcohol history, cancer site, stage of disease, treatment schedule, fraction dose, and hospitalizations.

Table 2

Sequence of Data Collection

Instruments	Baseline	W1	W2	W3	W4	W5	W6	W7	W8	End of RT	Follow-up
Patient Demographic Questionnaire	X										
MacDibbs Mouth Assessment Tool	X*	X*	X*	3X	3X	3X	3X	3X	3X	3X	3X
Weight	X	X	X	X	X	X	X	X	X	X	X
Pain Profile	X									X	X
Pain Assessment Questionnaire		X	X	X	X	X	X	X	X		
Salivary Flow											
Whole	X	X	X	X	X	X	X	X	X	X	X
Parotid	X										X
Self-Care Diary	X	X	X	X	X	X	X	X	X	X	X
Disease and Treatment Questionnaire	X	X	X	X	X	X	X	X	X	X	X
Medical Review	X									X	X

* Data collected weekly unless patient reporting the presence of symptoms, then data collected 3 times per week for remainder of treatment

3X - Data collected three times per week

For primary Research Aim 1, the onset, severity, and time course of RT-induced mucositis were determined from data collected using the MacDibbs Mouth Assessment Tool, Pain Assessment Questionnaire, and the Self-Care Diary. Mean number of days to onset and mean cGys to onset of RT-mucositis were determined. Means and frequencies were calculated for each time point for mucositis severity, and mean severity scores were plotted over the course of treatment.

For primary Research Aim 2, similar procedures as described for Aim 1 were used to address this aim. Pattern and time course were determined using data from the MacDibbs Mouth Assessment Tool and the Weekly Pain Assessment Questionnaire. Means and frequencies were calculated for pain severity, and appropriate data were plotted over time to ascertain patterns and time course of RT-related mucositis pain.

For primary Research Aims 3 and 4, frequencies and means of self-care activities performed by H&N cancer patients for RT-related mucositis and RT-related mucositis pain. Mean effectiveness scores of self-care activities was also determined.

To determine the severity of xerostomia and taste changes, and the use of self-care activities for each of these side effects, secondary aims of this study, mean severity and mean self-care activity scores were determined at each data collection time point using the Self-Care Diary, the MacDibbs Mouth Assessment Tool, and/or the Pain Assessment Questionnaire.

Mean weekly weight loss, cumulative weight loss, and total overall weight loss over the course of the study period was determined to address the severity of weight loss in this

patient population. Use of self-care activities by patients for experienced weight loss at each time point was also determined and plotted over the course of the study.

Finally, Pearson Product Moment Correlations was done to determine if relationships existed among the variables of mucositis-related pain, xerostomia, taste change, and weight loss. Spearman Rho correlations were used to determine if relationships existed among the variables presence of a mucositis ulcer, mucositis relate pain, xerostomia, taste change, and weight loss. Pearson Product Moment Correlations and Spearman Rho correlations were calculated at baseline, Week 3 (i.e., week when majority of patients begin experiencing symptoms), midtreatment, end of RT, and 1-month follow-up. The level of significance criteria is .05 for each test.

CHAPTER IV

Results

Sample Demographics

Fifty-nine patients were approached for participation in this study. Six patients refused to participate because they were either too overwhelmed by their current circumstances or they felt that they could not spare the time needed to participate in this study. Two patients were interested in participating in the study, however, they wanted to wait until they were into treatment before deciding if they wanted to participate. One patient refused because he was already participating in another study. The total refusal rate for this study was 15%.

Fifty patients consented to participate in the study. However, data from only 49 patients were used for the analyses. One patient was eliminated from the analyses having completed only four treatments when radiation therapy (RT) was discontinued for a re-evaluation of the patient's diagnosis. More than three quarters of the sample were men (n = 38; 78%), and middle-aged (M = 56.1 years). The educational level of this sample averaged almost two years of college, most were not married or partnered (n = 29; 60%), and the majority did not live alone (n = 31; 63%). The majority of the sample was Caucasian (n = 29; 60%), with Asians/Pacific Islanders (n = 8; 16%), and African Americans (n = 6; 12%) comprising the next largest ethnic groups of participants. At the initiation of RT treatment, patients were primarily retired (n = 18; 37%), working either full or part-time (n = 13; 27%), or claiming disability (n = 11; 22%). The majority of patients had a positive smoking (n = 36; 74%) and alcohol (n =39; 80%) history.

A summary of the sample's demographic characteristics are found in Table 3.

As summarized in Table 4, cancer of the tongue (24%) was the most common head and neck cancer in patients participating in this study, followed by cancers of the nasopharynx (18%), tonsil (14%), and pharynx (10%). Almost three quarters of the patients were staged either III (20%) or IV (52%) at diagnosis, with a histology of squamous cell carcinoma (66%) or undifferentiated carcinoma (20%) predominating.

Treatment Characteristics

The majority of the patients received the standard once a day RT treatment (82%) with a dose fraction of either 180 cGy (42%) or 200 cGy (38%). Only seven patients (14%) received a hyperfractionated RT treatment regimen. These seven patients were participants in a Radiation Therapy Oncology Group study and were randomized to the hyperfractionated or accelerated fractionation arm of the study.

The total cumulative dose of RT for patients receiving once a day treatment averaged 6638.59 cGy (range 4000-7800 cGy) over approximately 34 treatments. Patients receiving hyperfractionated or twice a day treatment averaged a cumulative dose of 7606.66 cGy over 58 treatment fractions. Treatment characteristics are presented in Table 5.

Forty-six of the 49 patients completed their RT course of treatment. Of the three (6%) patients not completing their course of treatment, two patients discontinued treatment for personal reasons, and one patient was hospitalized with serious medical problems making it impossible for him to complete RT. The treatment experience is summarized in Table 6.

During the course of treatment, 13 (27%) patients experienced breaks in their treatment longer than three treatment days. Most (85%) of treatment breaks were due to the

Table 3

Sample Demographics (n = 49)

Variable	n	M	SD
Age (years)	49	56.1	14.0
Education (years)	47	13.8	3.7
Karnofsky (baseline)	49	88.7	10.4

	n	%
Gender		
Women	11	22
Men	38	78
Married/Partnered		
Yes	19	40
No	29	60
Lives Alone		
Yes	18	37
No	31	63
Ethnicity		
Caucasian	29	60
Asian	8	16
African American	6	12
Other	6	12

Table 3 (continued)

Sample Demographics

Variable	n	%
Employment Status		
Retired	18	37
Full or Part-time	13	27
Disability	11	22
Other	7	14
Smoking History		
Yes	36	73
No	13	27
Alcohol History		
Yes	39	80
No	10	20

Table 4

Disease Characteristics

Variable	n	%
Diagnosis		
Tongue	12	25
Nasopharynx	9	18
Tonsil	7	14
Pharynx	5	10
Other	16	33
Stage of Disease		
I	4	8
II	3	6
III	13	20
IV	26	52

Table 5

Treatment Characteristics

Variable	n	%
Treatment Schedule		
Once a day treatment	42	86
Twice a day treatment	7	14
Fraction Dose (in centigrays)		
180	20	41
200	19	39
120 (twice a day treatment - hyperfractionated)	4	8
160 (twice a day treatment - accelerated)	3	6
other	3	6
Concurrent Chemotherapy Treatments	10	20

Variable	M	SD	Range
Once a day treatment			
Cumulative Dose (cGy)	6638.59	782.96	4000-7860
Number of Treatments	34.20	6.27	20-42
Twice a day treatment			
Cumulative Dose (cGy)	7606.66	383.18	7040-8040
Number of Treatments	58.33	10.19	44-67
Length of field (in cm) - primary site	11.80	2.65	5.5-20
Width of field (in cm) - primary site	11.38	2.32	5.5-16

Table 6

Treatment Experience (n = 49)

Treatment Course	n	%
Patients completing prescribed RT course	46	94
Patients with unscheduled breaks in treatment (breaks longer than three treatment days)	13	27
Patients requiring unscheduled hospitalization during the course of RT	14	28
Patients seen in ER, not hospitalized	10	20

medical condition of the patient requiring the delay in treatment. Only two of the treatment breaks were related to patients not coming in for treatment.

Fourteen patients (28%) required an unscheduled hospitalization during their course of treatment. Ten (71%) of the fourteen patients were admitted for problems of weakness, dehydration, and electrolyte imbalance, related to inadequate nutritional and fluid intake, and two (14%) of the fourteen patients were admitted for pain management (Table 7).

Table 7

Unscheduled Hospitalizations during RT (n = 14)

Reason for Hospitalization	n	%
Dehydration/electrolyte imbalance	10	72
Pain management	2	14
Other	2	14

Ten patients (20%) presented in an emergency room during the course of RT for treatment related problems. Half received intravenous fluids for dehydration and weakness. Three patients were seen for pain management, and two other patients were seen for weakness, inability to eat or drink adequate amounts of food and fluid which required the placement of a nasogastric tube (Table 8).

Table 8

Reasons for Emergency Room Visits (n = 10)

	n	%
Dehydration/weakness/intravenous fluids	5	50
Pain management	3	30
Weak/ Unable to eat/ NG tube placed	2	20

Ten patients (20%) of the 49 participating in this study received concurrent chemotherapy during RT. Of the twenty-three patients that were either hospitalized or seen in the ER, seven were receiving concurrent chemotherapy.

Mucositis - Baseline

The MacDibbs Mouth Assessment tool, an examination of the oral cavity, and the Self-Care Diary provided the information regarding oral symptoms, as well as the development and presence of mucositis. At the initiation of RT, only one patient had mucositis ulcers present on oral examination which were most likely related to a candida infection for which the patient

was being treated. On examination two days later, the ulcers had resolved. Nine patients had an ulcerative tumor that was visible in the oral cavity or oropharynx at the time of initial oral examination. Four patients (8%) were noted to have the presence of reddened areas in the oral cavity or oropharynx at the start of RT.

The severity of mucositis symptoms was determined using the MacDibbs Symptom Score (MSS) calculated from the patient information section of the instrument. This section contains 9 items that measure the patient's oral symptoms (i.e. appetite, pain with swallowing, pain in the oral cavity not associated with swallowing, dryness, eating, talking, swallowing, tasting, and saliva consistency) and is rated by the patient using a scale of 0 to 3 scale (0= *no problem*, 3 = *severe problem or change*). The MSS is determined by summing the scores from each of the individual items with a total potential score ranging from 0 to 27. The mean MacDibbs Symptom Score at the start of RT was 0.73.

Onset, Severity, and Time Course of RT-related Mucositis

Mean centigrays to onset, severity scores, and time course of RT-related mucositis were calculated from data collected with the MacDibbs Mouth Assessment instrument. Additional data were obtained from patient reports in the Self-Care Diary.

Redness was observed in all patients at an average of 1257.20 cGy (SD = 572.48; range 0-2400). Corresponding MSS were between 5.38 and 7.45. White patches were observed in 56% (n = 28) of the patients at an average cGy dose of 2530.00 (SD = 1148.24; range 900-5600). The corresponding mean MSS were between 14.82 and 15.90.

All patients developed mucositis ulcer(s) during the course of their treatment. Mean dosage in centigrays for mucositis ulcer development for the sample was 2129.5 and occurred

approximately 14.5 (SD = 5.79) days after the start of RT. Patients receiving once a day treatment (n = 42) developed mucositis ulcer(s) at approximately the same cumulative dose (2081.07 cGy) and elapsed days (14.9) while patients receiving twice a day treatment (n = 7) developed mucositis at a slightly higher cumulative dose (2320.00 cGy) and almost three days sooner than the once a day treatment patients. Table 9 presents a summary of this data. There were no statistical differences noted in MSS between the groups. MSS scores ranged from 11.71(SD = 3.94) for the once-a-day treatment group to 12.31 (SD = 4.90) for the twice-a-day treatment group.

When ulcers first appeared, ulcers ranged in size from 1 millimeter (mm) by 1 mm to a maximum 13 mm by 13 mm, with the modal size being 2 mm x 2 mm (n = 21; 42.8%). The average number of ulcers at onset was 3.39 (SD = 1.57; range 1-7). At their worst, the mucositis ulcers became confluent in all patients. Of the forty-nine patients who developed mucositis, 46 (94%) still had mucositis present when they stopped treatment or at the completion of their treatment.

At the follow-up visit (M = 5.6 weeks from RT completion) 59% of patients (n = 27) still had mucositis present compared to 41% (n = 19) whose mucositis has resolved. Mean MSS scores for the patients with mucositis (MSS = 13.78; SD = 3.92) were significantly different ($p < .0001$) when compared to patients without mucositis (mean MSS = 8.79; SD = 3.43).

Mucositis Ulcer Severity and Self-Care

From the Self-Care Diary completed by the patient at the start of RT, three (6%) patients reported having mouthsores during the previous week with a mean severity score of 2.5 on the five point scale (0 = sores not very severe to 4 = sores extremely severe). Table 10

Table 9

Onset of RT-induced Mucositis for Entire Sample and by Treatment Schedules

	Entire Sample (n=49)	Once-A-Day (n=42)	Twice-A-Day (n=7)
	M (SD) [Range]	M(SD) [Range]	M(SD) [Range]
Dose at onset (cGy)	2129.49 (614.43) [990-3780]	2081.07 (568.49) [990-3780]	2320.00 (834.82) [1560-3380]
Days to onset	14.53 (5.79) [7-36]	14.95 (5.92) [7-36]	12.00 (4.47) [7-19]
Dose per fraction	182.14 (22.64) [120-225]	189.42 (11.35) [160-225]	137.14 (21.38) [120-160]
MSS	11.81 (4.06) [6-23]	11.71 (3.94) [6-21]	12.31 (4.98) [8-23]

MSS = MacDibbs Symptom Score
M = mean
SD = standard deviation

Table 10

Symptom Severity, Self-Care Behavior, and Self-Care Effectiveness Scores for Mucositis

Baseline (n=49)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	3	2.50	1.32	1	6	-	4	-
Pain	13	1.69	0.44	9	1.89	1..36	2.73	0.85
Dryness	19	2.00	0.87	18	2.89	1.81	2.27	0.83
Taste Change	13	2.31	0.44	6	2.36	1.75	3.08	0.49
Weight Loss (pounds)	12	1.73	0.79	4	3.50	1.91	3.00	1.00

Week 2 (n=47)

Cumulative Dose of RT (M=1362.07; SD=255.61)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	11	1.96	1.06	8	3.75	1.39	3.47	1.39
Pain	22	1.89	1.13	18	2.39	1.50	2.14	0.78
Dryness	35	1.86	1.24	30	2.93	1.62	2.67	1.38
Taste Change	28	1.68	1.15	11	1.55	0.93	2.10	0.87
Weight Loss (pounds)	12	1.70	0.79	6	3.67	1.86	2.30	0.97

Table 10 (continued)

Symptom Severity, Self-Care Behavior, and Self-Care Effectiveness Scores for Mucositis

Week 3 (n=40)

Cumulative Dose of RT = (M=2414.00; SD=355.46

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	20	2.35	0.81	19	3.63	1.64	2.03	0.51
Pain	30	2.55	0.96	25	2.44	1.36	2.09	0.64
Dryness	37	2.58	0.98	36	3.16	1.78	2.22	0.73
Taste Change	32	2.64	1.09	18	2.00	1.28	2.00	1.56
Weight Loss (pounds)	19	1.63	0.89	13	3.62	1.17	1.84	0.93

Week 4 (n=41)

Cumulative Dose of RT (M=3340.37; SD=450.64)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	23	2.39	0.89	21	4.19	1.57	1.99	0.66
Pain	31	2.52	0.76	29	3.03	1.38	2.05	0.80
Dryness	39	2.87	1.09	34	2.97	1.53	2.39	1.09
Taste Change	30	2.87	1.08	12	3.98	2.81	1.33	0.84
Weight Loss (pounds)	29	2.05	1.21	19	3.32	1.73	1.34	0.81

Table 10 (continued)

Symptom Severity, Self-Care Behavior, and Self-Care Effectiveness Scores for Mucositis

Week 5 (n=44)

Cumulative Dose of RT = (M=4314.32; SD=355.46)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	23	2.61	0.80	22	3.50	1.71	2.00	0.61
Pain	33	2.70	0.87	32	2.84	1.32	2.31	0.57
Dryness	42	2.94	1.03	39	2.80	1.47	2.41	0.98
Taste Change	27	3.33	0.83	9	1.89	1.36	1.86	0.91
Weight Loss (pounds)	34	1.82	1.24	25	3.20	2.36	1.82	0.91

Week 6 (n=32)

Cumulative Dose of RT (M=5058.13; SD=607.36)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	15	2.87	0.92	15	3.47	1.77	1.73	0.65
Pain	25	2.84	0.85	25	3.00	1.41	2.13	0.73
Dryness	29	3.05	0.92	27	2.93	1.57	1.96	0.87
Taste Change	15	3.33	0.84	4	2.50	1.73	1.36	1.37
Weight Loss (pounds)	24	1.75	0.79	15	3.33	1.72	1.34	0.98

Table 10 (continued)

Symptom Severity, Self-Care Behavior, and Self-Care Effectiveness Scores for Mucositis

Week 7 (n=36)

Cumulative Dose of RT = (M=5891.69; SD=668.65)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	19	2.79	0.61	17	3.27	1.60	1.86	0.65
Pain	27	2.93	0.82	24	3.08	1.06	2.44	0.70
Dryness	33	2.96	0.98	29	2.79	1.35	2.20	0.78
Taste Change	16	2.75	1.13	6	3.00	2.68	2.04	0.55
Weight Loss (pounds)	26	1.67	0.81	14	3.29	1.59	1.79	0.62

Week 8 (n=28)

Cumulative Dose of RT (M=6685.61; SD=536.00)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	16	2.93	0.95	13	3.31	1.97	1.38	0.72
Pain	20	3.27	0.70	19	2.90	1.45	2.27	1.05
Dryness	26	2.90	0.90	21	2.62	1.50	2.35	0.96
Taste Change	10	3.20	0.72	3	5.00	3.61	2.08	0.88
Weight Loss (pounds)	15	2.53	0.83	11	2.73	2.90	1.13	0.92

Table 10 (continued)

Symptom Severity, Self-Care Behavior, and Self-Care Effectiveness Scores for Mucositis

Week 9 (n=12)

Cumulative Dose of RT = (M=5891.69; SD=668.65)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	6	2.92	0.80	5	3.60	1.34	1.33	0.65
Pain	9	3.00	0.71	9	3.22	1.72	2.09	0.70
Dryness	9	3.28	0.76	8	2.63	1.51	2.36	0.78
Taste Change	5	3.10	1.03	1	1.00	-	1.00	-
Weight Loss (pounds)	4	3.00	1.41	3	1.67	0.58	1.67	1.15

Follow-up (n=36)

Weeks since completing RT (M=5.63;SD=1.45)

	Severity			Self-Care Behaviors			Self- Care Effectiveness	
Variable	n	M	SD	n	M	SD	M	SD
Sores	14	2.46	0.75	12	2.58	1.08	2.22	0.88
Pain	24	2.38	1.09	21	2.00	0.89	2.50	0.84
Dryness	35	2.87	1.00	32	2.44	1.16	2.36	0.82
Taste Change	21	1.93	0.71	5	3.20	2.05	2.42	0.43
Weight Loss (pounds)	11	1.27	0.79	5	2.80	0.84	2.13	1.12

weeks of treatment progressed, more patients experienced mouthsores with 25 (50%) patients reporting sores during the fifth week of treatment. Reported severity of mouthsores steadily rose throughout the course of RT, from a mean score of 1.96 (SD = 1.06) during week 2 to a high mean score during week 9 of 2.92 (SD = 0.80). Mean severity score at the follow-up visit was 2.46 (SD = 0.75) indicating mouthsores were still moderate to severe.

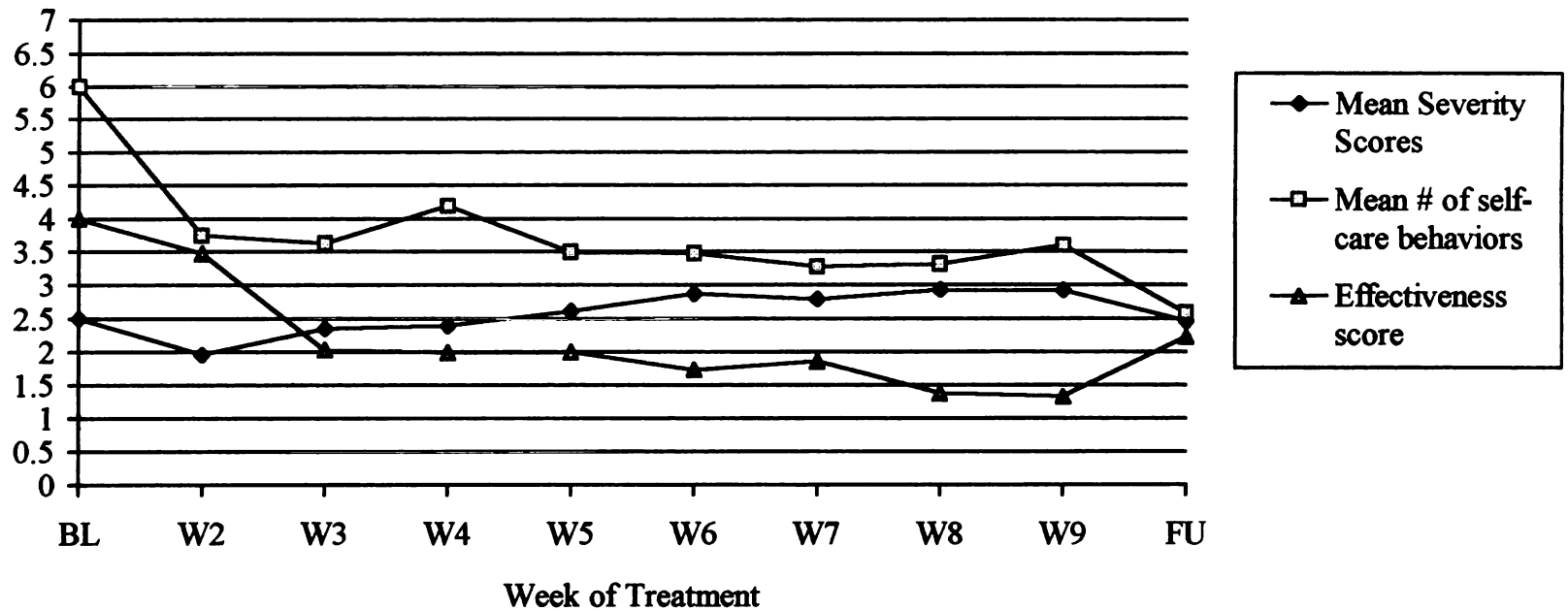
As the severity of mouthsores increased, the percentage of patients experiencing mouthsores and engaging in self-care activity remained fairly constant with more than 80% of patients engaging in self-care activities for all weeks except week two (n = 8 of 11; 72%). The number of self-care behaviors used for mouthsores throughout RT ranged from a mean number of 3.47 to 4.19.

The effectiveness of self-care activities was determined by summing the relief scores of self-care activities tried divided by the total number of self-care activities performed with an effectiveness score ranging from 0 = not effective to 4 = completely effective. Mean effectiveness self-care behavior scores for mouthsores during RT ranged from 2.15 (SD = 0.64; week 2) to 2.38 (SD = 0.59; week 5). Patients self-care activity effectiveness scores were lowest at the end of treatment, weeks 8 (M = 1.85; SD = 0.72) and 9 (M = 1.33; SD = 49) (Table 10).

At the follow-up visit, 12 of 14 patients who were still reporting mouthsores engaged in an average of 2.8 self-care activities directed at their mouthsores with an increased mean effectiveness score of 2.22 (SD = 88) indicating moderate effectiveness of their actions. Figure 3 illustrates the severity of mouthsores, the number of self-care behaviors used, and

Figure 3

Mouth Sores Severity Score, Use of Self-Care Behaviors, and Self-Care Effectiveness (data from Self-Care Diary)



effectiveness of self-care over the course of the study.

Pain - Baseline

Data on pain prior to the start of RT and throughout the study were obtained from the self-report Pain Profile, Weekly Pain Assessment Questionnaire, and the Self-Care Diary. Pain data specific to the oral cavity and oropharynx, associated with and without the act of swallowing, were obtained from patient information section of the MacDibbs Mouth Assessment.

Thirty-two (64%) of the 49 patients reported that they had experienced pain due to their present disease. About half (49%) of these patients indicated that pain was one of the presenting symptoms of their current disease. Of the 49 patients in the study, twenty (41%) reported having had surgery within the previous month (Table 11).

Twenty-five of the 49 patients reported having some pain in the H&N region at the time they filled out the Pain Profile prior to the start of H&N RT. The majority of these patients complained of having the most pain in the neck (n = 12; 48%), followed by mouth (n = 4; 16%), throat (n = 4; 16%), and head (n = 2; 8%).

On the eleven point (0 to 10) numeric pain scale with verbal descriptors (0 = *none*, 2 = *mild*, 6 = *moderate*, 8 = *severe*, 10 = *excruciating*) patients reported having an average *pain right now* score of 3.30 (SD = 2.31) and an average *daily pain* score of 3.94 (SD = 1.87). Patients *pain at its least* was 2.49 (SD = 2.31), and *pain at its worst* was 6.13 (SD = 2.51). Patients reporting pain, experienced pain that interfered with their mood or activity more than four (M = 4.34; SD = 3.01) days per week averaging more than 11 (M = 11.65; SD = 9.06) hours per day. Table 12 summarizes these pain scores and pain scores for the other times points for the study.

Table 11

Pain and Pain Factors Present Prior to the Start of H&N RT (n=49)

Factor	n	%
Pain with present disease	32	65
Pain as a presenting symptom	24	49
Surgery within the past month	20	41
Pain "now"	25	51
Most Pain Location (n=25):		
Neck	12	48
Mouth	4	16
Throat	4	16
Head	2	8
Other	3	12

Table 12

Pain Severity - Weekly Pain Assessment Questionnaire

	Baseline (n=25)			Week 2 (n=27)			Week 3 (n=37)		
Variable	M	SD	Range	M	SD	Range	M	SD	Range
Current Pain at Worst	6.13	2.51	(2-10)	5.76	2.19	(2-9)	6.42	2.19	(2-10)
Current Pain at Least	2.48	2.31	(0-7)	1.91	1.90	(0-7)	2.59	2.14	(0-8)
Average Daily Pain	3.94	1.87	(1-8)	3.94	1.76	(0.5-7)	4.22	1.94	(1-8)
Pain Right Now	3.30	2.31	(0-7)	3.78	1.87	(0-7)	3.73	2.20	(0-8)
	Week 4 (n=37)			Week 5 (n=42)			Week 6 (n=28)		
Variable	M	SD	Range	M	SD	Range	M	SD	Range
Current Pain at Worst	6.36	2.07	(2-10)	6.76	2.02	(2-10)	7.59	2.22	(1-10)
Current Pain at Least	2.64	1.82	(0-6)	2.50	1.98	(0-6)	3.54	1.92	(0-9)
Average Daily Pain	4.43	2.02	(1-8.5)	4.52	1.89	(0.5-8)	5.59	1.93	(2-10)
Pain Right Now	3.43	2.41	(0-10)	4.05	2.35	(0-8)	5.11	2.25	(0-10)

Table 12 (continued)

Pain Severity - Weekly Pain Assessment Questionnaire

	Week 7 (n=32)			Week 8 (n=24)			Week 9 (n=9)		
Variable	M	SD	Range	M	SD	Range	M	SD	Range
Current Pain at Worst	7.53	1.49	(3-10)	7.77	1.63	(2-10)	8.25	1.28	(7-10)
Current Pain at Least	3.27	1.70	(0-7)	4.15	1.80	(0-8)	5.19	2.67	(0-8)
Average Daily Pain	5.13	1.80	(1.5-9)	5.75	1.65	(2-8)	6.38	1.77	(4-9)
Pain Right Now	5.35	1.66	(1-8)	5.83	2.14	(0-8)	5.88	2.10	(3-9)

	Follow-up (n=20)		
Variable	M	SD	Range
Current Pain at Worst	5.33	3.0	(0-9)
Current Pain at Least	3.13	2.21	(0-8)
Average Daily Pain	4.25	2.43	(0-8)
Pain Right Now	4.30	2.52	(0-8)

When asked specifically in the Self-Care Diary about pain or soreness in the mouth in the week prior to the start of treatment, 13 patients reported experiencing this symptom with a mean severity score of 1.69 on a five point scale (0 = not very painful/sore to 5 = extremely painful/sore).

At the baseline MacDibbs Mouth Assessment, three patients (6%) reported having pain/soreness with swallowing and three patients (6%) stated that they had pain in areas of the mouth, throat, tongue, head, or neck, not associated with swallowing.

Changes in Pain Over Time

Patients experienced pain in various sites of the oral cavity, oropharynx and neck throughout RT. The sites of pain cited most frequently by patients during treatment were throat pain, followed by mouth, and tongue pain. Neck pain was reported less frequently. The percentages of patients reporting pain at these sites generally increased as treatment progressed and pain severity increased. As pain severity decreased at the follow-up visit the percentages of patients reporting pain at these sites also decreased. These data are presented in Table 13.

Pain in the oral cavity and oropharynx with swallowing and without swallowing was evaluated using the MacDibbs Mouth Assessment instrument. All patients reported pain with swallowing during the course of the treatment. The average cumulative dose of RT received at the onset of pain with swallowing was 1586.22 (SD = 606.06) cGy.

Pain in the oral cavity and oropharynx experienced while "resting" or when not swallowing was reported by 47 of the 49 patients. The onset of this pain occurred later (M = 1890.85 cGy; SD = 775.95) than pain reported with swallowing. These findings are found in

Table 13

Percentage of Patients Reporting Pain in Selected Areas on the Pain Assessment Questionnaire

	Week 2 (n=27)		Week 3 (n=37)		Week 4 (n=37)		Week 5 (n=42)		Week 6 (n=28)	
Site	n	%	n	%	n	%	n	%	n	%
Mouth	16	59	21	57	23	62	29	69	15	54
Tongue	12	44	21	57	18	49	18	43	15	54
Throat	18	66	28	76	28	76	36	86	25	89
Neck	10	37	11	30	11	30	19	45	12	43

	Week 7 (n=32)		Week 8 (n=24)		Week 9 (n=9)		Follow-up (n=20)	
Site	n	%	n	%	n	%	n	%
Mouth	20	63	17	71	6	67	9	45
Tongue	19	59	13	54	5	56	11	55
Throat	28	88	20	83	6	67	15	75
Neck	15	47	7	29	2	22	5	25

Table 14.

Pain severity scores as measured by the MacDibbs Mouth Assessment showed that patients oral cavity and oropharynx pain increased over the course of RT for both pain with swallowing and pain when not swallowing. Mean severity scores for pain with swallowing were higher than the severity scores when not swallowing and the difference between these scores were statistically significant ($p<.003$) at all time points measured starting week 2, at the third weekly time point measure (i.e., 2C). The pain scores for both pain measures peaked at week 7 - time 3 (i.e., 7C), with a mean severity score of 2.44 (SD = 0.80) swallowing indicating moderate to severe pain, and a mean severity score of 1.65 (SD = 0.80) when not swallowing or when mouth was "at rest" indicating mild to moderate pain. Pain scores

Table 14

Onset and Severity Scores of H & N RT-related Symptoms

Variable		Onset (cGy)			Severity Score		
	n	M	SD	Range	M	SD	Range
Pain with swallowing	49	1586.22	606.06	600-3780	1.30	0.65	0.5-3.0
Pain without swallowing	47	1890.85	775.95	720-3960	1.13	0.49	0.5-2.5
Dryness	49	1230.30	439.14	260-2400	1.35	0.70	0.5-3.0
Taste change	49	1361.53	477.43	720-2900	1.20	0.52	0.5-3.0

remained the same or slightly improved during the remainder of treatment with mean pain scores at the follow-up visit being lower for both measures (Table 15).

Figure 4 graphically shows the pain severity scores for pain in the oral cavity and oropharynx with swallowing and without swallowing over the study period.

The results from the Self-Care Diary indicate similar findings as the MacDibbs Mouth Assessment with pain increasing throughout treatment reaching its maximum severity at week 8 with a mean pain score of 3.27 also indicative of moderate to severe pain. At the follow-up visit, the pain severity ($M = 2.38$; $SD = 1.09$) score was significantly improved compared to pain severity ($M = 3.32$; $SD = 0.58$)($t = 11.76$; $p = 0.003$) at the end of treatment on the Self-Care Diary.

Table 12 summarizes the findings of Weekly Pain Assessment Questionnaire, that measured pain severity at its worst, least, daily average, and "right now". As with the MacDibbs Mouth Assessment and the Self-Care Diary, pain increased for all measures as treatment progressed with scores averaging between 7.53 and 8.25 for pain at its worst during weeks 6 through 9. Average daily pain scores for this same time period while lower ranged between 5.59 (week 6) to 6.38 (week 9) still indicating a moderate level of pain. At the follow up visit pain scores for all measures were lower, with an average "pain at worst" score of 5.33 ($SD = 3.0$) and "average daily pain" score of 4.25 ($SD = 2.43$) meaning that patients were still experiencing moderate levels of pain. Figure 5 shows the scores obtained from the Weekly Pain Assessment Questionnaire charted over time.

Pain and Self-Care

Table 10 includes the symptom severity scores and self-care behavior scores for pain

Table 15

Pain Scores - MacDibbs Mouth Assessment

Weekly Time Points[#]	Pain With Swallowing n	M	SD	Pain Without Swallowing M	SD	t	p
1A	49	0.11	0.47	0.13	0.50	0.65	0.80
1B	6	0.25	0.41	-	-		
1C	2	025	0.35	-	-		
2A	48	0.52	0.74	0.48	0.76	0.09	0.76
2B	31	0.73	0.81	0.58	0.70	0.62	0.44
2C	26	1.44	0.85	0.90	0.69	10.20	0.003
3A	45	1.54	1.05	0.91	0.73	17.99	0.0001
3B	44	1.72	0.92	1.03	0.74	29.76	*
3C	40	2.01	0.97	1.11	0.86	34.59	*
4A	45	1.89	0.78	0.90	0.74	93.34	*
4B	41	1.72	0.92	1.07	0.84	74.47	*
4C	43	2.02	0.78	0.95	0.67	97.08	*
5A	41	2.06	0.82	1.05	0.78	52.93	*
5B	41	2.05	0.92	1.00	0.86	50.66	*
5C	43	2.12	0.81	1.26	0.63	59.00	*
6A	41	2.31	0.77	1.22	0.61	101.94	*
6B	42	2.38	0.68	1.23	0.63	113.43	*
6C	39	2.24	0.72	1.40	0.75	42.31	*
7A	39	2.40	0.71	1.36	0.75	57.71	*
7B	36	2.42	0.79	1.33	0.68	83.31	*
7C	31	2.44	0.80	1.65	0.80	48.87	*
8A	28	2.41	0.77	1.41	0.90	35.16	*
8B	23	2.37	0.77	1.24	0.94	32.99	*
8C	18	2.39	0.90	1.17	0.92	29.28	*
9A	12	2.17	0.94	0.96	0.87	24.93	*
Follow-up	46	1.25	0.95	0.51	0.71	31.53	*

[#] 1A = week 1, time point1; 1B = week 1, time point 2, etc.

* $p<.0001$

Figure 4

Pain in Oral Cavity -MacDibbs Mouth Assessment

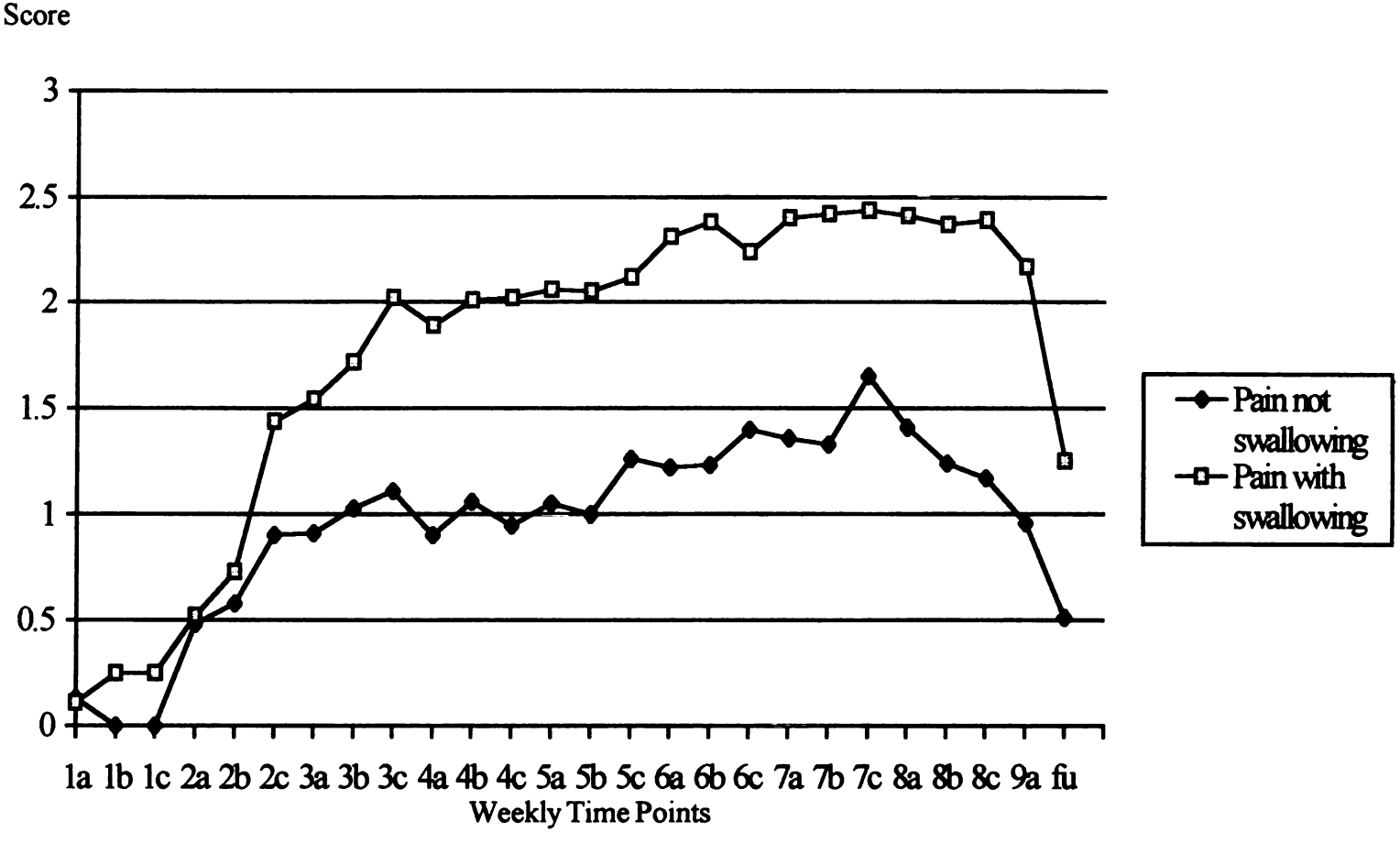
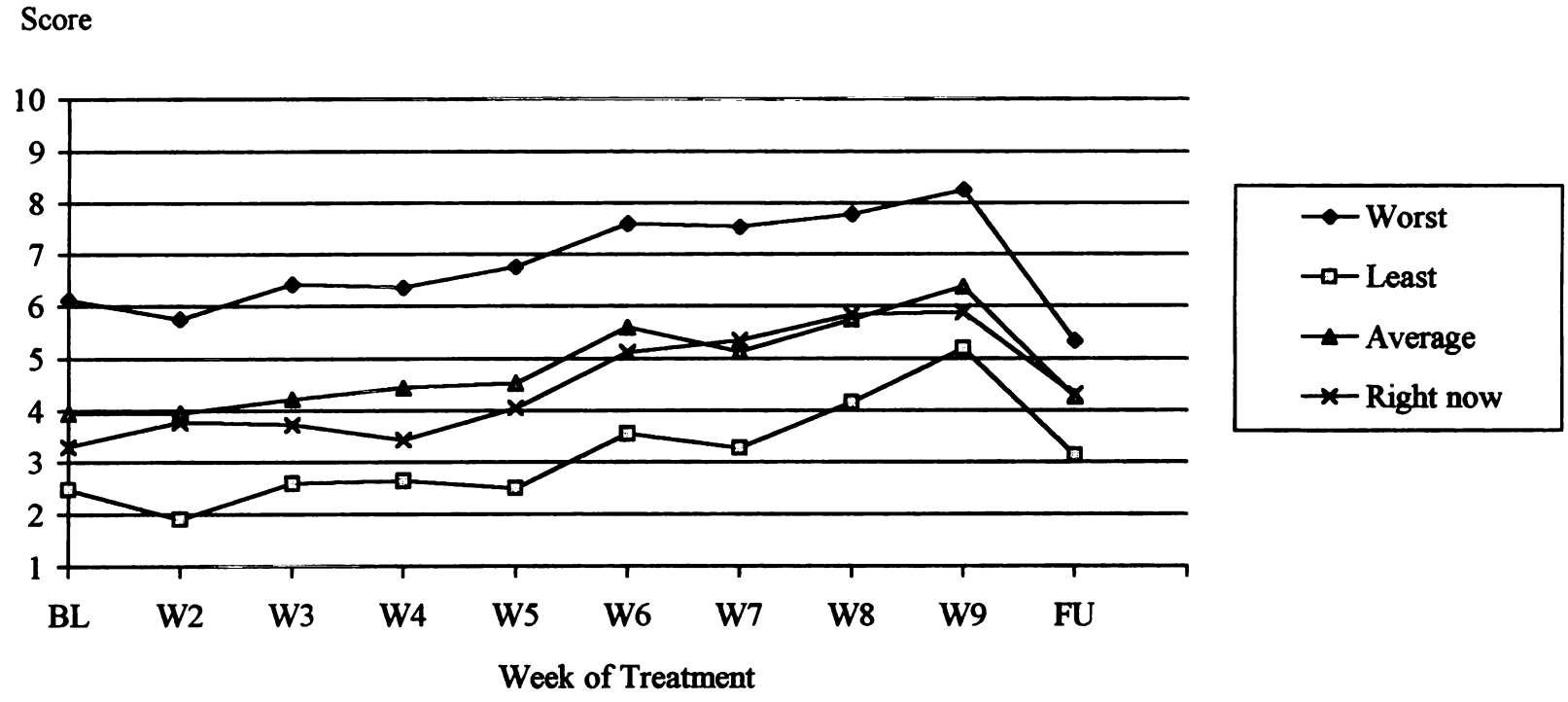


Figure 5

Mean Pain Severity Ratings for Pain in the Oral Cavity or Oropharynx at its Worst, Least, Average, and "Right Now"



compiled from the Weekly Self-Care Diary. As pain increased over the first four weeks of treatment, the average number of self-care behaviors increased from 1.89 (SD = 1.36) to 3.03 (SD = 1.38). As pain continued to increase over the remainder of the treatment course, the number of self-care behaviors used remained essentially the same. In addition, as pain increased the number of patients engaging in self-care activities increased ranging from a low of 88% (24 of 27) of patients in pain performing self-care activities during week 7 to 100% (25 of 25) of patients using self-care measures during week 5.

The effectiveness scores of self-care activities for pain during H & N RT remained fairly constant throughout RT ranging from a low of 2.05 (SD = 0.80) at week 4 to a high of 2.44 (SD = 0.70) during week seven. Table 10 summarizes the effectiveness scores of self-care behaviors for pain throughout the study period.

At the follow-up visit, 24 patients still reported having pain. Of these patients 21 of 24 (88%) were using self-care activities to manage their pain. Pain severity was significantly improved compared to the end of treatment as presented previously, and the number of self-care behaviors engaged in by patients at follow-up was also less (M = 2.18; SD = .88) than at the end of treatment (M = 3.0; SD = 1.0) and statistically significant (t = 7.54; p = .014). The highest self-care behavior effectiveness score during the study period was 2.50 (SD = 0.84) reported at the follow-up appointment.

Xerostomia - Baseline

Prior to the start of treatment, 19 patients (39%) reported in their Self-Care Diary that they had experienced some degree of mouth dryness during the week prior to the start of RT. However, when patients were assessed using the MacDibbs Mouth Assessment Tool for

mouth dryness at the time prior to the start of treatments, only four (8%) patients reported experiencing mouth dryness at that time.

Parotid saliva samples and whole saliva samples were collected from patients prior to the start of treatment. Parotid samples were obtained from forty-three patients. Seven patients were not able to provide the initial parotid samples because of pain or mouth tenderness (n = 3), mouth dryness (n = 1), and swelling (n = 3). Whole saliva samples were collected from 45 patients.

Baseline unstimulated parotid samples were collected on the first fifteen patients, however no parotid saliva was measurable for 12 of the fifteen patients. At the follow-up visit for these fifteen patients, there was no measurable saliva from either the right or left parotid glands during the unstimulated collection. Due to the lack of yield of saliva and the discomfort for patients in attempting to obtain these samples, the unstimulated parotid sampling was discontinued at both baseline and follow-up, and only the stimulated parotid collection was done at these time points for the remainder of the sample. A summary of the whole flow saliva studies is presented in Table 16 and the parotid saliva flow study results are in Table 17.

Onset and Severity of Xerostomia

All patients reported mouth dryness, xerostomia, during the course of treatment. Dose to onset of xerostomia calculated from MacDibbs Mouth Assessment Tool averaged 1230.30 cGy (SD = 439.14; range = 260-2400). Initial mean severity score at onset was 1.35 (SD = 0.70; range = 0.5-3.0).

The greatest decrease in saliva production occurred after the first week of treatment. Patients severity scores (M = 1.60) on the MacDibbs Mouth Assessment at the beginning of

Table 16

Whole Flow Saliva Studies

		Unstimulated (cc's per 5 minutes)			Stimulated (cc's per 5 minutes)		
Time Period	n	M	SD	Range	M	SD	Range
Baseline	45	1.98	1.67	0.10-7.00	6.04	3.63	0.70-14.20
Week 2	43	0.90	0.90	0.10-3.50	3.44	2.27	0.20-7.20
Week 3	43	0.71	0.58	0 - 2.30	2.85	2.22	0 -7.70
Week 4	42	1.17	1.90	0 - 9.00	2.51	1.93	0.30-6.80
Week 5	38	0.83	0.80	0.10-3.60	2.84	2.31	0.10-9.50
Week 6	37	0.71	0.54	0.10-2.10	2.28	1.85	0.20-5.70
Week 7	35	0.61	0.45	0-2.00	2.04	2.15	0.10-7.10
Week 8	25	0.65	0.26	0.20-1.00	2.17	1.68	0.70-5.70
Week 9	10	0.68	0.54	0.10-1.60	2.20	2.09	0-5.70
End of RT	40	0.66	0.72	0 - 2.20	2.22	1.71	0 - 6.20
Follow-up	43	1.19	0.93	0-3.10	2.80	1.79	0.40-7.10

Table 17

Parotid Saliva Flow Studies (cc's per 5 minutes)

		Stimulated Flow					
		Right			Left		
Time Period	n	M	SD	Range	M	SD	Range
Baseline	45	2.03	1.57	0.00-5.20	2.39	1.88	0.40-6.80
Follow-up	43	0.63	0.87	0.0-3.50	0.59	0.59	0.00-2.40

week 3 indicated a mild-moderate severity of mouth dryness experienced by patients. Severity scores increased over the course of treatment reaching moderate to severe levels and peaking during weeks 7 and 9 (M = 2.51 to 2.69) (Table 18). While the actual decrease in saliva production was not significantly different after week 4, the subjective reporting of xerostomia severity increased.

Saliva production at the follow-up appointment increased but was not statistically significant from the end of treatment measurement. The severity of dryness as reported by the patients was statistically significant ($t = 4.4$; $p = .04$) at the follow-up appointment with patients reporting a mean severity of 2.07 compared to 2.31 at the end of treatment. However many patients anecdotally stated that the severity in xerostomia, in general, was not significantly improved at the follow-up appointment when compared to the end of treatment.

Xerostomia and Self-Care

Symptom severity scores, use of self-care behaviors, and the effectiveness of self-care for xerostomia collected from the Self-Care Diary are presented in Table 10. Thirty-nine percent of patients ($n = 19$) reported experiencing mouth dryness prior to the start of RT and all patients except one reported using some form of self-care practice for the mouth dryness. Patients consistently initiated self-care activities during the course of RT for xerostomia, with more than 87% of patients experiencing this symptom initiating self-care each week except for week 8 (81%).

As severity of xerostomia increased, the number of self-care activities used remained basically constant over the course of RT. As severity scores increased, self-care effectiveness remained essentially unchanged, with neither measurable improvement or worsening of

Table 18

Mouth Dryness - MacDibbs Mouth Assessment

Weekly Time Point[#]	n	M	SD
1A	49	0.10	0.36
1B	6	1.50	0.84
1C	2	1.50	0.71
2A	48	0.96	0.81
2B	31	1.31	0.87
2C	26	1.42	0.64
3A	45	1.60	0.76
3B	44	1.61	0.70
3C	40	2.02	0.62
4A	45	2.08	0.68
4B	41	2.22	0.65
4C	43	2.26	0.68
5A	41	2.33	0.61
5B	41	2.28	0.68
5C	43	2.32	0.62
6A	41	2.37	0.70
6B	42	2.38	0.69
6C	39	2.39	0.71
7A	39	2.51	0.63
7B	36	2.47	0.70
7C	31	2.50	0.67
8A	28	2.36	0.84
8B	23	2.59	0.60
8C	18	2.69	0.57
9A	12	2.45	0.89
Follow-up	46	2.06	0.70

[#] 1A = week 1, time point 1; 1B = week 1, time point 2; 1C = week 1, time point 3; etc.

xerostomia over time. The relationships among xerostomia severity, mean number of self-care behaviors used, and the effectiveness of self-care is illustrated in Figure 6.

Taste Changes - Baseline

Changes in taste and its severity experienced by patients prior to, during the course of, and following RT were evaluated using the MacDibbs Mouth Assessment instrument and the Weekly Self-Care Diary. Eleven patients (22%) reported experiencing taste changes in the week prior to the start of RT in the Self-Care Diary. However, only two patients were experiencing taste changes when assessed with the McDibbs Mouth Assessment Tool at the start of RT. The two patients experiencing taste changes described the change as foods "not tasting right" or "not tasting the same".

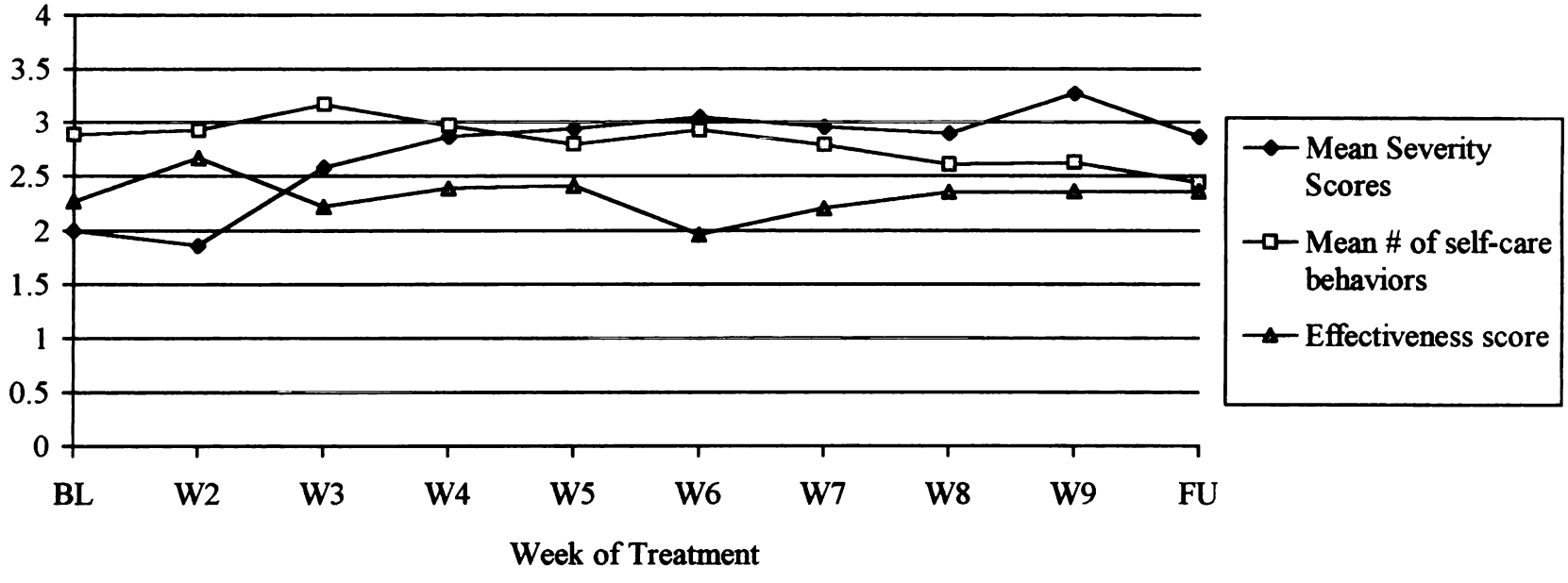
Changes in Taste Over Time

The Self-Care Diary was used to collect information from patients about their changes in taste from the previous week/time that they completed the questionnaire. By week two, twenty-eight of 49 (57%) patients reported changes in their taste on the Self-Care Diary. Sixteen of twenty-eight described their taste changes with the majority (n = 11; 68%) reporting a diminished or lessened ability to taste foods. The percentage of patients experiencing taste changes from the previous week as reported in the Self-Care Diary peaked at week 3 (n = 32; 80%) and gradually declined over the remainder of RT with 41% (n = 5) of patients still on treatment during week 9 reporting differences in taste changes from the previous week.

. The MacDibbs Mouth Assessment Tool obtained information from patients about the severity of changes in taste compared to their taste at the start of RT. Of the 49 patients in the

Figure 6

Mouth Dryness Severity Scores, Use of Self-Care Behaviors, and Self-Care Effectiveness (data from Self-Care Diary)



study, 100% of the patients reported experiencing changes in taste during the course of RT. Mean onset to the initial report of a taste change was 1361.53 cGy (SD = 477.43; range 720-2900 cGy). Mean severity score at onset was 1.20 indicating mild severity in taste change. All patients reported moderate to severe changes in their taste starting week 5 and continuing throughout the remainder of treatment, with the mean severity scores reaching a high of 2.90 (SD = 0.28) during week 7 indicating severe taste changes present (Table 19 and Figure 7).

At the follow-up visit all 46 of the patients evaluated still reported changes in taste with a mean severity score of 2.04 (SD = .60; range .5-3) indicating a moderate severity in taste change still present.

Taste Changes and Self-Care

Taste change severity scores, self-care behavior scores, and self-care effectiveness scores are presented along with other symptoms in Table 10. The greatest percentage of patients reporting taste changes occurred during weeks two (n = 11; 59%), three (n = 18; 80%) and four (n = 12; 73%). The mean number of self-care activities tried increased during those weeks reaching an average high of 3.98 (SD = 2.81) during week 4, then gradually decreased over the remainder of RT to an average low of 1.0 (SD = 3.10) self-care activity for taste changes. During week 8, the average number of self-care activities reported by patients was 5.0. However, this figure was based on only three patients, two of whom engaged in an unusually high number of self-care activities, one patient trying 8 activities, one patient using 6 activities, and the remaining patient trying only one activity.

The percentage of patients experiencing taste changes and engaging in self-care activities during the course of treatment ranged from 20% (week 9) to a high of 56% (week 3). The

Table 19

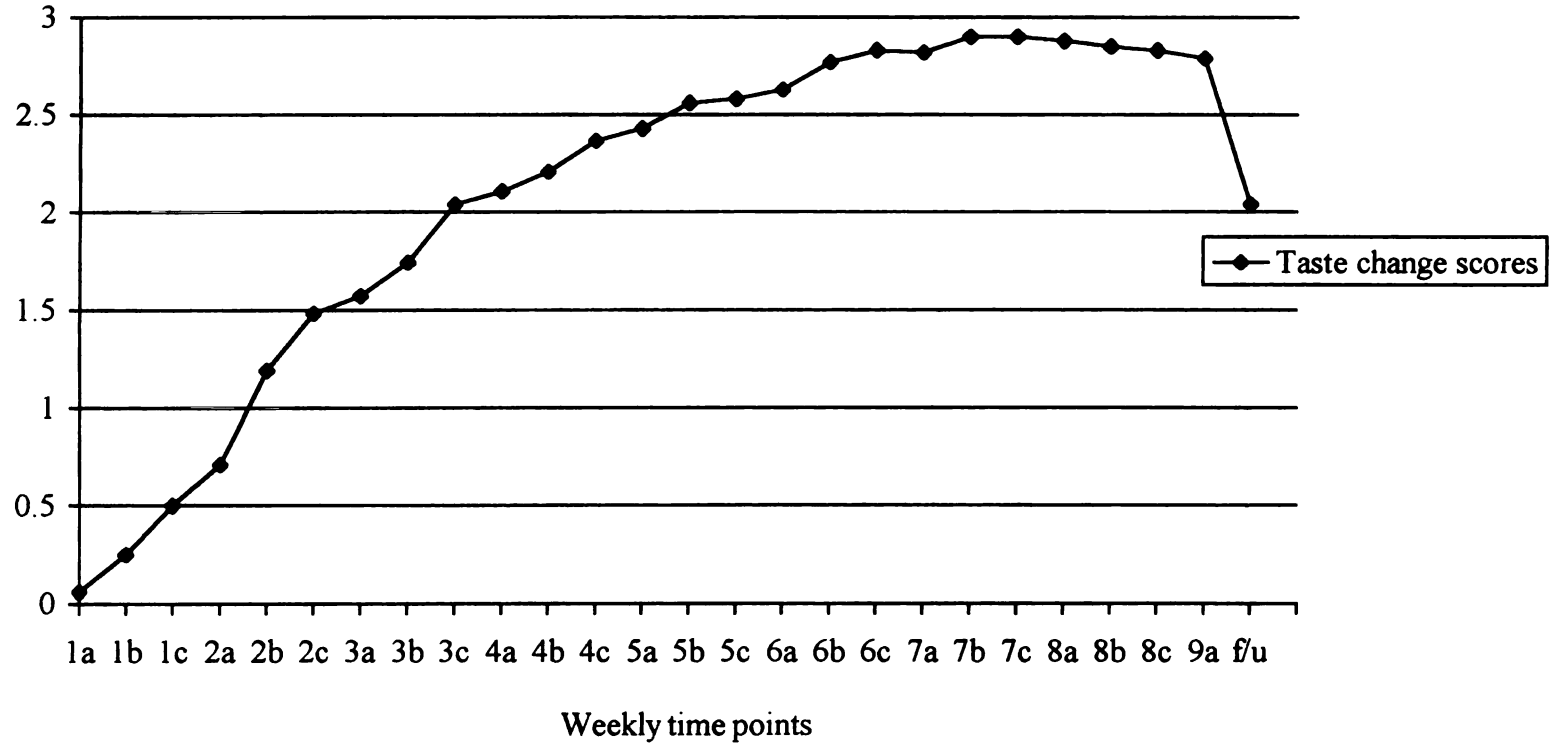
Taste Scores - MacDibbs Mouth Assessment

Weekly Time Point[#]	n	M	SD
1A	49	0.06	0.31
1B	6	0.25	0.41
1C	2	0.50	0.71
2A	49	0.71	0.65
2B	31	1.19	0.79
2C	26	1.48	0.73
3A	45	1.57	0.81
3B	44	1.74	0.77
3C	40	2.04	0.61
4A	45	2.11	0.60
4B	41	2.21	0.63
4C	43	2.37	0.66
5A	41	2.43	0.70
5B	41	2.56	0.49
5C	43	2.58	0.49
6A	41	2.63	0.48
6B	42	2.77	0.42
6C	39	2.83	0.37
7A	39	2.82	0.39
7B	36	2.90	0.28
7C	31	2.90	0.30
8A	28	2.88	0.29
8B	23	2.85	0.35
8C	18	2.83	0.34
9A	12	2.79	0.40
Follow-up	46	2.04	0.60

[#] 1A = week 1, time point 1; 1B = week 2, time point 2,; 1C = week 1, time point 3; etc.

Figure 7

Taste Scores - Mac Dibbs Mouth Assessment



mean number of self-care behaviors tried by patients increased during the first four weeks of RT, ranging from an average of 1.55 (SD = 0.93) during week two to an average of 3.98 (SD = 2.81) during week four. Severity of taste changes increased during this time period from a mean severity score of 1.68 (week 2) to 3.3 (week5) on a five point (0-4) severity scale. Correspondingly, as severity increased over the first four weeks of RT and the number of self-care activities attempted increased, the overall effectiveness of self-care activities decreased from an average of 2.10 (SD = 0.87), week 2, to an average of 1.33 (SD = 0.84), week 4 (Figure 8). Subsequently, fewer patients experiencing taste changes appeared to engaged in self-care activities during the remainder of RT. These findings indicate that self-care activities undertaken for taste changes were ineffective in providing relief from taste changes experienced and that alleviating taste changes may not be as great a priority for patients as compared to relieving pain, xerostomia, or mouthsores.

At the follow-up appointment, only 23% (n = 5) of patients experiencing taste changes engaged in self-care for their taste change, with a mean effectiveness score of 2.42 of a possible score of 4.0. This score was the highest effectiveness score reported for use of self-care for taste changes other than the self-care effectiveness score at baseline before the start of RT.

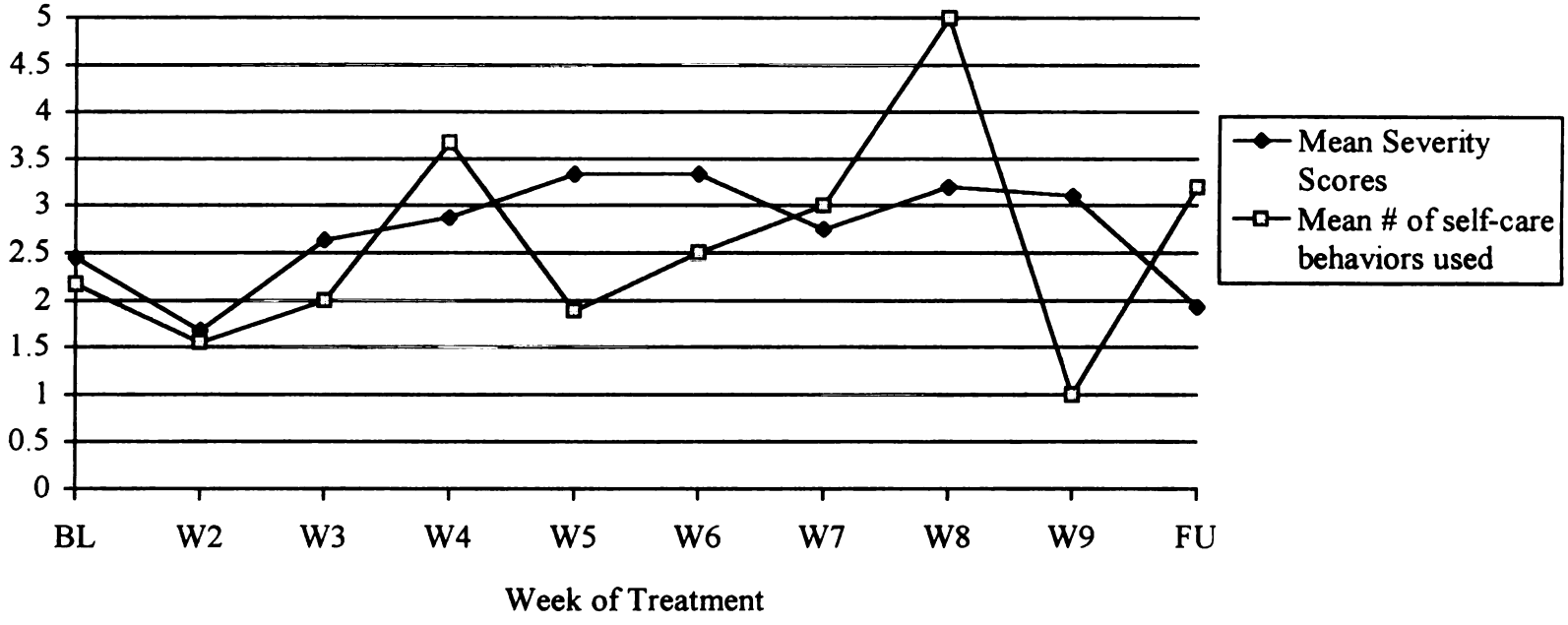
Weight - Baseline

Patients were weighed at the start of treatment, weekly, and at the end of treatment. Additional weight data were obtained from the Disease and Treatment form and from the Self-Care Diary.

At the start of RT, 25 patients (50%) reported experiencing a weight loss within the

Figure 8

Taste Change Severity Scores and the Use of Self-Care Behaviors (data from Self-Care Diary)



previous six months that averaged 12.14 pounds (SD = 7.59; range: 5-30). Of the 49 patients in the study, 82% of patients starting weight fell either within (n = 22) or above (n = 19) their ideal weight range, while nine patients weight fell below the ideal weight range. Ideal weight range was determined for each patient using the Metropolitan Life Insurance Company's (1983) height and weight tables for men and women. In Table 20, the decrease in the percentage of both "usual body weight" and "actual body weight" at the end of treatment and the follow-up visit compared to the start of treatment are presented.

Changes in Weight Over Time

Weight was evaluated in relation to the amount of weight loss in pounds across the study period. The mean weight loss was calculated during each week of RT, the end of RT, and at

Table 20

Percentage of Usual Weight and Actual Weight at Beginning, End of Therapy, and Follow-Up

		Percentage of Usual Weight		Percentage of Actual Weight	
Time	n	M	SD	M	SD
Beginning of RT	49	97.0	4.3		
End of RT	44	88.6	5.6	91.3	4.7
Follow-up	46	87.7	5.6	90.3	5.3

the follow-up appointment. Patients experienced weight loss throughout the course of RT with an average weight loss per week of 2 to 3 pounds during weeks 2 through 7 (Table 21).

The cumulative average weight loss for the entire course of RT was 13.72 (SD = 9.47) pounds. Weight loss continued following the completion of treatment to the follow-up visit with patients exhibiting a cumulative mean weight loss from start of RT to the follow-up appointment of 17.53 (SD = 10.87) pounds. All patients except one seen in follow-up (n = 46) lost weight during the course of treatment. Weight loss ranged from one pound to 54 pounds.

Weight was also evaluated by examining the percentage of usual weight to actual weight at the beginning of treatment, the end of treatment, and the follow-up appointment. Percentages of usual body weight were lower at the end of treatment and follow-up visit, accounting for more than a 10% mean loss in body weight.

The subjective data of weight loss were collected from the Self-Care Diary. The data are presented in the Table 10, where symptoms including weight loss are reported. The weight loss severity scores are graphed over time and presented in Figure 9 along with the number of self-care behaviors associated with weight loss. While actual weight loss remained fairly constant during weeks 2 through 7 and appeared to decline during weeks 8 and 9, the severity of weight loss as subjectively reported by the patient in the weekly Self-Care Diary remained fairly stable through week seven (mean scores ranging from 1.63 to 2.05 indicating moderate severity scores) then increased during the last two weeks of treatment reaching high mean severity scores of 2.53 (week 8) and 3.0 (week 9). While patients continued to lose weight through the follow-up visit, patient's reported mean severity score for weight loss at the follow up visit was lower (M = 1.27; SD = 0.79) than at any other time point during the course of the study.

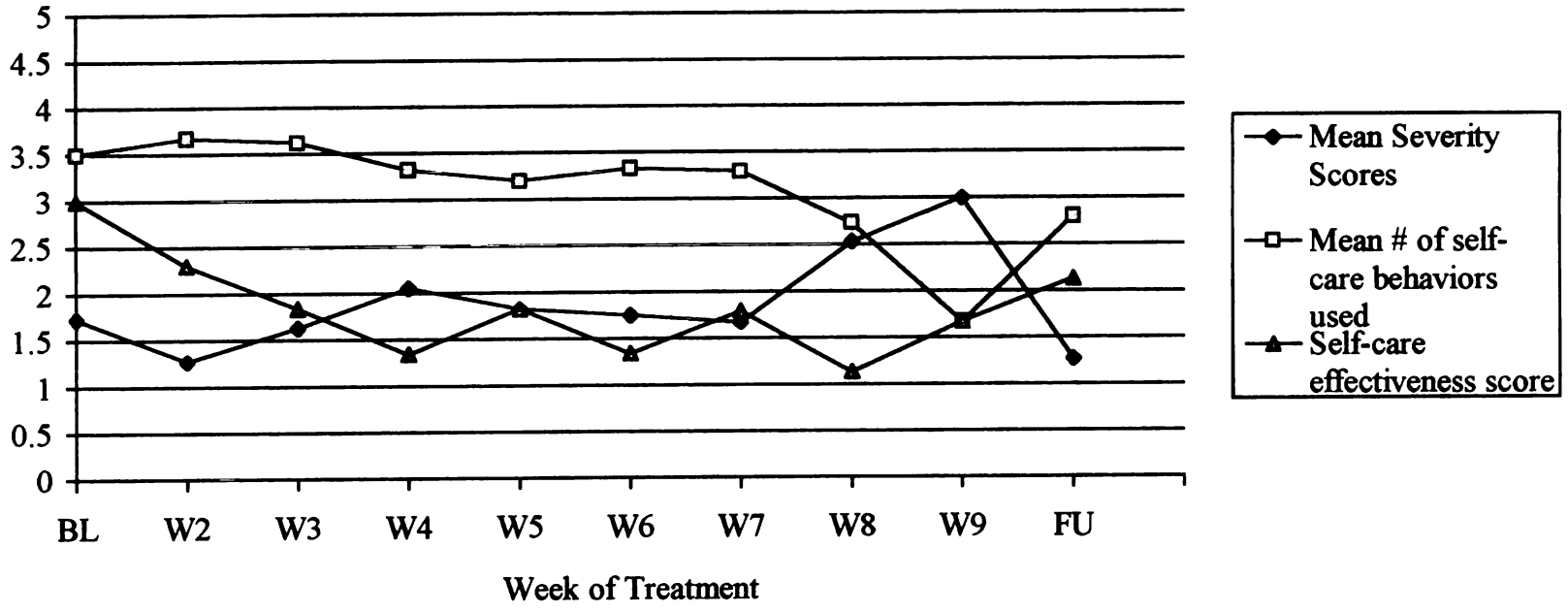
Table 21

Mean Weight Loss In Pounds

		Weekly Weight Loss		Cumulative Weight Loss	
Week	n	M	SD	M	SD
1	49	0.56	2.55	0.57	2.55
2	49	2.37	2.33	2.94	3.49
3	48	2.92	3.99	5.91	6.59
4	46	2.40	2.68	8.28	7.58
5	42	2.87	2.90	10.65	8.00
6	35	2.71	2.26	13.87	8.55
7	21	1.90	1.89	13.67	8.28
8	9	0.78	1.98	13.72	9.47
End of RT	44			15.53	9.30
Follow-up	46			17.53	10.87

Figure 9

Weight Change Severity Score, Use of Self-Care Behaviors, and Self-Care Effectiveness



Self-Care and Weight Loss

The scores for severity of weight loss, the use of self-care behaviors and the effectiveness of self-care behaviors for weight loss during the course of the study are summarized in Table 10). At baseline evaluation, 12 patients (24%) reported experiencing weight loss within the week prior to the start of RT. Of these 12 patients, 4 reported using self-care activities (M = 3.50; SD = 1.91) for their weight loss. As patients severity scores increased, the number of patients engaging in self-care activities for weight loss appeared to increase. However, the number of patients using self-care activities for reported weight loss ranged only from 50% (week 2) to highs of 73% during week 8, and 75% during week 9. This finding indicates that a number of patients while experiencing weight loss and reporting weight loss, still do not do anything for their weight loss. In addition, as treatment progressed, the number of self-care activities initiated decreased.

Effectiveness scores of self-care behaviors for weight loss indicate that self-care behaviors were not very effective in dealing with the weight loss. Effectiveness scores during treatment ranged from mean scores of between 1.13 to 2.30, the difference not being statistically significant.

Relationships among the Selected Variables of Presence of Mucositis, Pain without Swallowing, Pain with Swallowing, Xerostomia, Taste Change, and Weight Loss

Data collected from patients at selected time points were evaluated to answer the question of whether there are significant relationships among the five variables, presence of mucositis ulcer, mucositis-related pain (i.e., pain without swallowing, pain with swallowing), xerostomia, taste change, and weight loss during RT. The time points selected to examine the

relationships among the variables were baseline, week 3 (when most symptoms are expected to occur), midpoint of RT, end of RT, and the follow-up visit.

Pearson Product Moment Correlations were done to determine the relationships among the variables of mucositis related pain (i.e., pain without swallowing, pain with swallowing), xerostomia, taste change, and weight loss (Tables 22 to 26). The Spearman Rho correlations were used to determine the relationships among the variables presence of a mucositis ulcer, pain without swallowing, pain with swallowing, xerostomia, taste change, and weight loss (Table 27). Since the presence of mucositis is a dichotomous variable where 0 = no mucositis present and 1= mucositis present, this particular correlational technique was indicated.

At baseline, prior to the start of RT, the presence of a mucositis ulcer was associated with severity of xerostomia ($r = .47$; $p<.001$) and taste change ($r = .69$; $p<.001$). Pain with swallowing was significantly correlated to pain without swallowing ($r = .35$; $p = .01$). In addition, both xerostomia ($r = .41$; $p<.001$) and taste change ($r = .51$; $p<.001$) were moderately correlated with pain with swallowing. There was a high correlation between xerostomia and taste change ($r = .84$; $p<.001$) indicating that greater severity of xerostomia was associated with more severe taste change.

By week 3 of RT, a majority of patients were reporting symptoms related to their RT treatments, and similar relationships were found among the variables when compared to the baseline measures. The presence of mucositis ulcer was moderately correlated to both pain without swallowing ($r = .49$; $p<.001$) and pain with swallowing ($r = .34$; $p<.03$) indicating greater pain severity when mucositis ulcers are present (Table 27). The pain with swallowing and pain without swallowing was modestly correlated ($r = .41$; $p<.001$). A significant

Table 22

Significant Pearson Product Moment Correlations Between the Variables of Pain without Swallowing, Pain with Swallowing, Xerostomia, Taste Change, and Total Weight Loss - Baseline (n=49)

	Pain without swallowing	Pain with swallowing	Xerostomia	Taste change	Total Weight loss
Pain without swallowing	1.0	.35 (.01)	NS	NS	NS
Pain with swallowing		1.0	.41 (.00)	.51 (.00)	NS
Xerostomia			1.0	.84 (.00)	NS
Taste Change				1.0	NS
Total Weight Loss					1.0

NS - not significant

Table 23

Significant Pearson Product Moment Correlations Between the Variables of Pain without Swallowing, Pain with Swallowing, Xerostomia, Taste Change, and Total Weight Loss - Week 3 (n=45)

	Pain without swallowing	Pain with swallowing	Xerostomia	Taste change	Total Weight loss
Pain without swallowing	1.0	.41 (.00)	NS	NS	NS
Pain with swallowing		1.0	.51 (.00)	.33 (.02)	NS
Xerostomia			1.0	.39 (.01)	.56 (.00)
Taste Change				1.0	.35 (.02)
Total Weight Loss					1.0

NS - not significant

Table 24

Significant Pearson Moment Correlations Between the Variables of Pain without Swallowing, Pain with Swallowing, Xerostomia, Taste Change, and Weight Loss - Middle of RT (n=48)

	Pain without swallowing	Pain with swallowing	Xerostomia	Taste change	Total weight loss
Pain without swallowing	1.00	.64 (.00)	.28 (.05)	NS	NS
Pain with swallowing		1.00	.34 (.02)	.40 (.00)	NS
Xerostomia			1.00	.56 (.00)	.39 (.00)
Taste Change				1.00	.35 (.02)
Total Weight Loss					1.00

NS - not significant

Table 25

Significant Pearson Product Moment Correlations Between the Variables of Pain without Swallowing, Pain with Swallowing, Xerostomia, Taste Change, and Total Weight Loss - End of Treatment (n=46)

	Pain without swallowing	Pain with swallowing	Xerostomia	Taste change	Total Weight loss
Pain without swallowing	1.0	.47 (.00)	NS	NS	NS
Pain with swallowing		1.0	NS	NS	NS
Xerostomia			1.0	NS	NS
Taste Change				1.0	NS
Total Weight Loss					1.0

NS - not significant

Table 26

Significant Pearson Product Moment Correlations Between the Variables of Pain without Swallowing, Pain with Swallowing, Xerostomia, Taste Change, and Total Weight Loss - Follow-up Visit (n=46)

	Pain without swallowing	Pain with swallowing	Xerostomia	Taste change	Total Weight loss
Pain without swallowing	1.0	.46 (.00)	NS	.35 (.02)	NS
Pain with swallowing		1.0	.44 (.00)	NS	.41 (.00)
Xerostomia			1.0	.34 (.02)	NS
Taste Change				1.0	NS
Total Weight Loss					1.0

NS - not significant

Table

Significant Spearman Correlations Between the Presence of Mucositis Ulcer(s) and Other Symptoms of H&N RT

	Time (Weeks) (n)										
	Presence of Mucositis Ulcer										
Symptom	BL (50)	2 (49)	3 (49)	4 (44)	5 (41)	6 (41)	7 (38)	8 (19)	9 (12)	END (46)	FU (46)
Pain without swallowing	NS	NS	.54 (.00)	NS	NS	.38 (.01)	NS	NS	NS	.28 (.05)	.48 (.00)
Pain with swallowing	NS	NS	.37 (.01)	NS	NS	.37 (.02)	.39 (.01)	NS	NS	.31 (.03)	.48 (.00)
Xerostomia	.47 (.00)	.38 (.01)	NS	NS	NS	NS	NS	NS	NS	NS	---
Taste Change	.69 (.00)	.39 (.01)	NS	NS	NS	NS	NS	NS	NS	NS	---
Weekly Weight Loss	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	---
Total Weight Loss	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	---
MSS	NS	.32 (.03)	.49 (.00)	NS	NS	.33 (.03)	.37 (.02)	NS	NS	.34 (.02)	.56 (.00)

relationship between pain with swallowing and xerostomia ($r = .51$; $p<.001$) was again exhibited while a more modest correlation was found between pain with swallowing and taste changes ($r = .33$, $p = .02$). Both xerostomia and taste change were found to be significantly correlated with total weight loss, with higher xerostomia scores ($r = .56$; $p<.001$) and greater taste change scores ($r = .35$; $p = .02$) related to higher total weight loss. These findings are summarized in Table 23.

At the midpoint of prescribed RT, there were no significant relationships found between the presence of a mucositis ulcer and the other variables (Table 27). However, similar relationships were found among the other variables as in Week 3. At mid-therapy, pain with swallowing and pain without swallowing continued to be moderately and significantly correlated. At this time point, xerostomia was correlated with pain without swallowing, but only modestly ($r = .28$, $p = .05$). Xerostomia and taste changes continued to be significantly correlated to pain with swallowing, as well as to each other (Table 24) meaning that greater mouth dryness experienced was associated with more severe taste change, and higher mouth dryness scores and taste change scores were related to higher pain with swallowing scores.

Total weight loss was also significantly related to xerostomia and taste changes indicating that patients with greater taste changes or greater mouth dryness experienced greater total weight loss.

At the end of RT, the only significant relationships found were between the pain variables and the presence of a mucositis ulcer (Table 27) indicating greater pain with the presence of a mucositis ulcer. Consistent with other time periods, higher pain without swallowing scores were moderately associated with higher pain with swallowing scores ($r = .47$; $p<.001$).

A number of relationships were found at the follow-up appointment (Table 26). Once again the presence of a mucositis ulcer was moderately correlated with both pain without swallowing ($r = .48$; $p<.001$) and pain with swallowing ($r = .48$, $p<.001$). In addition, pain without swallowing was moderately related to pain with swallowing ($r-.46$; $p<.001$) and to taste changes ($r = .35$; $p = .02$). These findings suggest that higher pain without swallowing scores are associated with higher pain with swallowing scores and greater taste changes experienced. Higher pain with swallowing scores were also related to greater total weight loss experienced.

Xerostomia was also shown to be associated to pain with swallowing and taste changes. A higher xerostomia score indicated a modestly significant relationship to more severe pain with swallowing ($r = .44$; $p<.001$) and greater taste changes experienced ($r = .34$; $p = .02$).

Summary

The results of this study indicate that patients undergoing H&N RT experience significant treatment related problems of mucositis, mucositis pain, xerostomia, taste changes, and weight loss that are long lasting and severe. Most symptoms first appear within the first two to three weeks of treatment and the severity of symptoms tend to increase over the course of RT to the end of treatment. At the follow-up appointment, symptoms in general have improved somewhat or stayed about the same.

In this study, by mid-therapy, the majority of patients experienced the identified symptoms, ranging from 73% of patients experiencing pain without swallowing to 100% of patients reporting pain with swallowing, xerostomia, and taste changes. At the end of treatment over 90% of patients reported experiencing each of the identified symptoms except

for pain without swallowing (80%) which is not surprising. However, an interesting finding at the follow-up visit was that large proportion of patients were still reporting symptoms with significant severity or change still present. Table 28 is a summary of the percentage of H&N RT patients who were experiencing the symptoms of mouthsores, pain with swallowing, pain without swallowing, xerostomia, taste changes, and weight loss at the following time points, baseline, week 3, mid-therapy, end of RT, and follow-up visit, and Figure 10 show graphically and dramatically the percentage of patients experiencing these symptoms over time. The severity of symptoms at these designated time points is presented in Table 29.

In general, the use of self-care behaviors to deal with these problems varied from symptom to symptom, with self-care being used most consistently by patients for the symptoms of pain, mouthsores, and mouth dryness. This finding may indicate that these symptoms are indeed the three that are the most problematic or distressing for patients in dealing with treatment. The findings on the effectiveness of self-care activities suggest that such activities are at best only fair in dealing with the experienced symptoms.

In examining the relationship among the variables, the presence of a mucositis ulcer being related to both pain with swallowing and without swallowing is not unexpected, nor is the significant relationship between the two pain variables themselves surprising. However, pain was not significantly related to weight loss at any of the time points evaluated except at the follow-up visit.

Xerostomia and/or taste change were found to be significantly related to total weight loss and to pain with swallowing at all time points examined except the end of treatment. Mouth dryness and taste changes can have a serious impact on a patient's ability to eat and drink

Table 28

Percentage of H&N RT Patients with Selected Problems Over Time

	Baseline (n=49)		Week 3 (n=45)		Mid-therapy (n=48)		End of RT (n=46)		F/U (n=46)	
Cumulative RT Dose in cGy (SD)			2009.56 (299.35)		3245.20 (445.45)		6721.63 (744.60)			
Symptom	n	%	n	%	n	%	n	%	n	%
Mouthsores	1	2	28	64	47	98	43	93	27	59
Pain with swallowing	3	6	37	82	48	100	43	93	36	78
Pain without swallowing	4	8	32	71	35	73	37	80	18	39
Xerostomia	4	8	45	100	48	100	44	96	45	98
Taste changes	2	4	42	93	48	100	45	98	45	98
Weight loss	-	-	40	88	42	88	45	98	45	98

Figure 10

Percentage of H&N RT Patients Experiencing Selected Symptoms Over Time

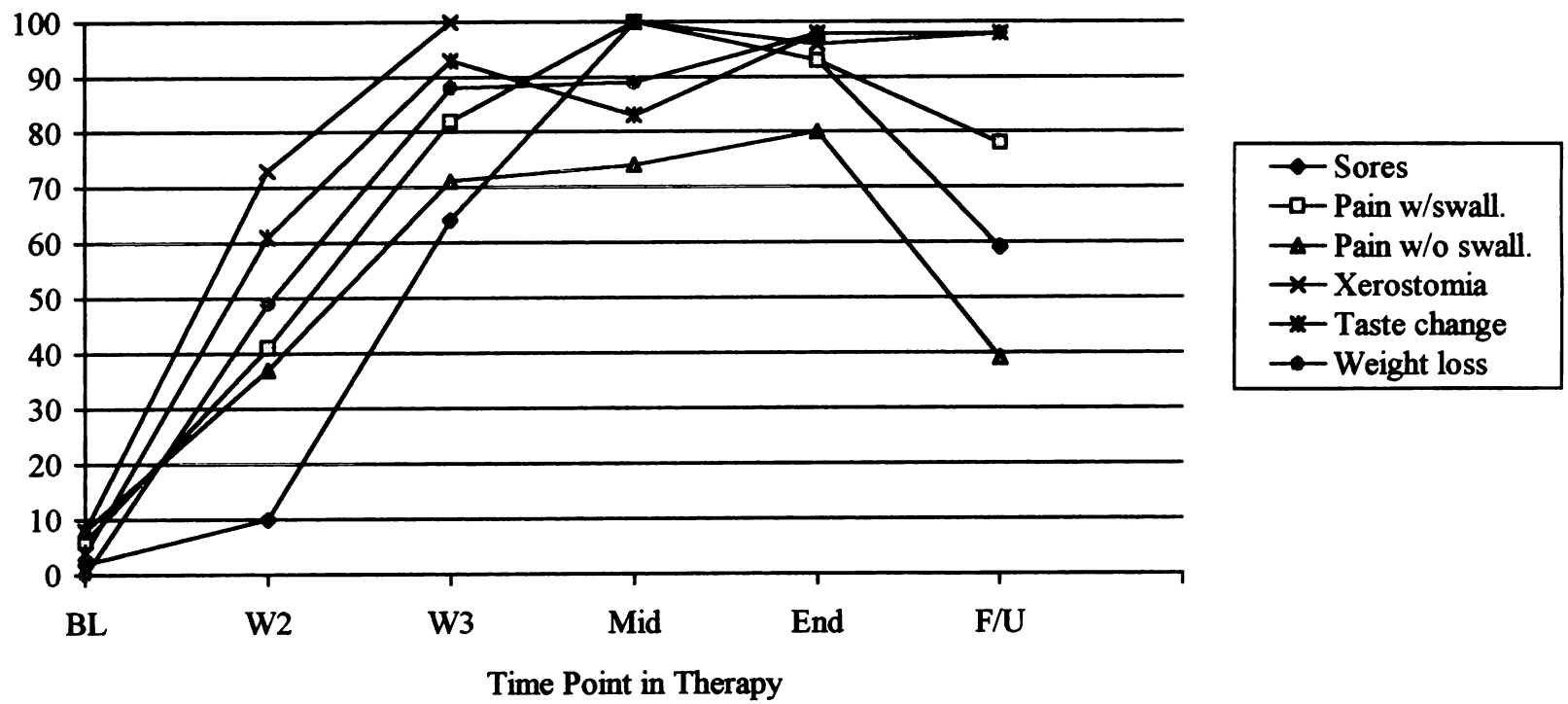


Table 29

Severity Scores of Selected Problems of H&N RT Patients Over Time

	Baseline (n=49)		Week 3 (n=45)		Mid-therapy (n=48)		End of RT (n=46)		F/U (n=46)	
Cumulative RT Dose in cGy (SD)			2009.56 (299.35)		3245.20 (445.45)		6721.63 (744.60)			
Symptom	M	SD	M	SD	M	SD	M	SD	M	SD
Pain with swallowing	.11	.47	1.54	1.05	2.03	.77	2.21	.91	1.25	.95
Pain without swallowing	.13	.51	.91	.73	.91	.73	1.32	.88	.51	.71
Xerostomia	.10	.37	1.60	.75	2.22	.61	2.32	.87	2.07	.70
Taste changes	.06	.32	1.57	.81	2.36	.57	2.88	.32	2.04	.60
Weight loss (cumulative in pounds)	-	-	2.94	3.46	5.60	6.40	16.20	9.19	17.53	10.88
MacDibbs Symptom Score (MSS)	.76	1.87	11.40	4.96	16.15	4.32	19.78	4.44	11.72	4.45

food and fluids. If mouth dryness and taste changes also are associated with pain with swallowing, this too may indirectly impact on a patient's ability to take in adequate amounts of nourishment.

The inter-relatedness of the variables suggest that the symptoms of H&N RT should not be viewed in isolation. That together, they comprise the reason for the high morbidity associated with H&N treatment (e.g., non-scheduled hospitalizations, emergency room visits).

Overall, the symptoms associated with H&N RT experienced by the patients were more severe than generally believed, and were far more long lasting than what was expected. The inability of patients to effectively alleviate symptoms was a source of concern and frustration for patients and healthcare professionals.

CHAPTER V

Discussion

Overview of Findings

The findings from this study confirm many of the head and neck (H&N) radiation therapy (RT) cancer patients worst fears - that some side effects from their cancer treatment were extremely severe and distressing. Patients frequently talked about almost unbearable suffering they experienced and the feelings of helplessness in trying to deal with the side effects. Many patients questioned whether the treatments were worth continuing because at times they felt so poorly and miserable they could not believe that the treatments were "working" and that they would ever feel "normal" again. Frequently experienced side effects from their treatment included mucositis, mucositis-related pain, xerostomia, taste changes, and weight loss. Once these side effects occurred, especially mucositis and mucositis-related pain, patients spoke about the severity and the never ending presence of these side effects and how they adversely affected their daily lives. A surprising finding was that the side effects once they occurred, not only remained constantly present throughout the treatment, but lasted longer than expected - beyond the end of treatment and often past the follow-up appointment (i.e., 4-7 weeks after to completion of RT).

Onset of Symptoms of H&N RT

Another notable study finding was the earlier onset of pain and xerostomia than is reported in the literature (Blozis & Robinson, 1968; Carnel et al., 1990). The onset of pain without the patient swallowing occurred at about 1900 cGy, and pain with swallowing at about 1600 cGy. Xerostomia occurred even earlier at approximately 1200 cGy, or at the

beginning of the second week of treatment.

Taste changes also appeared earlier than previously reported. While taste changes have been reported to occur as early as one week into the course of RT at cumulative doses as small as 240-400 cGy (Semba, et al., 1994), taste changes usually are noted and progress quickly between 2000-4000 cGy (Parsons, 1994, Semba, et al., 1994). In this study, the average cumulative RT dose to onset of taste changes was about 1360 cGy (range 720-2900 cGy) and occurred at about one and a half weeks into treatment. Unless a problem occurred during the first week of treatment, patients were assessed weekly for the first two weeks of treatment. Anecdotally, patients frequently reported experiencing changes in their taste prior to the assessment at the beginning of week 2 indicating that the onset in taste changes as subjectively noted by the patient may occur even earlier than what is reported in this study or that has been reported previously.

The taste change findings from Chencharick's (1983) study differed from the current study where a significant improvement in taste was reported during the sixth week of RT (the last evaluation time point). In the current study, taste changes remained severe (>2.5 on 4-point scale) starting during week 5 of treatment and lasted until the completion of treatment. These findings are consistent with other studies of H&N RT patients (Beumer, et al., 1979; Semba, et al., 1994) where taste change severity, once experienced, did not improve significantly throughout the remainder of treatment.

The mucositis ulcer development findings are consistent with other studies (Kaander & Ang, 1994; Thames et al., 1990), where patients developed mucositis ulcers on average 15 days after the start of treatment. However, in this study, several patients developed mucositis

ulcers as early as seven days after the initiation of treatment without any other causative etiology than RT. This study confirms that mucositis ulcer development in the once a day treatment patient occurs at an average RT dose of approximately 2000 cGy. For patients receiving twice-a-day treatment, the development of mucositis is expected sooner, and this was true in this study with ulcer development occurring 12 days from the start of treatment (M = 2320cGy).

Severity and Duration of Symptoms

This study is one of the first to examine this grouping of side effects (i.e., mucositis, mucositis-related pain, xerostomia, taste change, and weight loss) and examine the impact of this cluster of symptoms on H&N RT patients. This is an important contribution to our understanding of the RT experience for H&N patients.

The severity of the side effects along with how long each lasted was far worse than most patients were prepared for or expected. For example, patients would frequently rate their pain or xerostomia at its maximum severity of "worst imaginable" at one time point, and at subsequent time points would report that the severity of one or both of these side effects was even worse than before.

Another finding of interest was the proportion of patients who experienced these side effects. Over eighty-eight percent of patients were experiencing all the anticipated or potential side effects except for pain without swallowing at mid-therapy. All patients reported experiencing xerostomia, pain with swallowing, and taste changes at the mid-therapy time point. This finding again differs from other studies (Chencharick et al., 1983) where the proportion of patients studied experiencing problems was less, ranging from

approximately 70% reporting dysphagia, 83% xerostomia, and 90% taste change. The reason for these differences may be attributed to the treatments themselves.

While the results obtained regarding the presence of and severity of xerostomia and taste changes at the follow-up appointment were expected, the severity and the proportion of patients still experiencing mucositis, mucositis-related pain, and weight loss at this visit was not. At the follow-up visits, which occurred approximately five and a half weeks after the completion of treatment, 59% of the sample still had mucositis ulcers - down from 94% of the sample who had mucositis ulcers present at the end of RT, 78% of patients still had mild to moderate pain with swallowing, 38% had minimal pain without swallowing, and 98% had experienced weight loss since the end of treatment. Patients reported that their pain with swallowing often interfered with their ability to eat and drink making it difficult to maintain an adequate nutritional intake. A number of patients also became dehydrated and weak due to this decreased intake.

Mucositis has been reported to resolve within two to three weeks after the completion of treatment (Goodman, et al., 1997; Madeya, 1996; Sonis, 1993). And yet in the current study, 59% of the sample was still reporting mucositis of mild to moderate severity. This percentage was a significant improvement from the 93% of patients who had mouthsores at the completion of treatment but was still a serious problem for more than half of the patients. While severity scores were significantly improved at the follow-up appointment, anecdotally patients often commented that the improvement in their mouthsores were only slightly better from the end of treatment. The difference between moderate severity versus mild to moderate severity is apparently not that clinically different for patients. These findings

confirm reports that mucositis can persist for 2 to 4 weeks after the completion of RT and that the healing phase may take one to two months after treatment to complete (Blozis & Robinson, 1977; Cooper, 1994).

Patients continued to experience weight loss after the completion of RT, and at the one month post RT follow-up, patients had on average lost 10% of their presenting body weight. The results of this study confirm that weight loss is not limited to the period of treatment only. This continued weight loss was notable and unexpected. Only one study (Johnston, et al., 1982) reported weight loss in H&N RT patients beyond the end of treatment. The majority of patients still experiencing side effects from RT at the follow-up visit explained that they were not surprised that they continued to lose weight because the pain with swallowing, persistent xerostomia and taste changes interfered with their ability to eat and drink.

Pain

The evaluation of RT-related mucositis pain in the H&N RT patient revealed several important findings. First, patients reported pain with increasing severity throughout RT which was expected. However patients experienced significant differences in pain when swallowing or not swallowing. Surprisingly patients frequently reported experiencing little to no pain when not swallowing even if mucositis ulcers were present. However, the pain with swallowing was extreme. One patient described the pain with swallowing feeling like "razor blades cutting up your insides", while others said they tried to avoid swallowing at any cost because the pain was like no other pain ever experienced.

The duration of their RT-related mucositis pain lasted longer than expected as discussed previously, but what appeared to distress patients most was that they did not notice any marked improvement during the several weeks following the completion of treatment. They expected that once RT was completed, they would start feeling better even though they were instructed that the symptoms might persist or worsen over the several weeks following treatment. Patients voiced that the worsening of their symptoms or the lack of improvement in them, particularly pain, between the end of treatment and their follow-up appointment worried them that the pain was an indication that treatment "did not work" and that the cancer was still there, or that RT had permanently "burned" their mouth and throat and they would forever suffer in pain.

Finally, the treatment for pain was frequently reported to be effective for the pain experienced when not swallowing or when the mouth was "at rest", while the pain experienced as a result of swallowing was not managed well by any of the treatments, including systemic or topical analgesics, prescribed or recommended by the physician or nurse. The evidence of increasing pain over the course of treatment and persistence after treatment, in spite of the use of topical and systemic analgesics by the patient, indicates the need for improved pain control strategies.

Inadequate caloric and protein intake resulting from pain with swallowing may have prolonged the patients recovery from their experienced side effects. Pain also interfered with patients taking their pain medications (i.e., did not take in a timely fashion or waited longer because of pain with swallowing) thus resulting in even less pain control.

It is important to distinguish the pain associated with swallowing from pain not associated with swallowing because it is the pain with swallowing that usually interferes with the patient's ability to maintain an adequate nutritional intake (Dreizen, Daly, & Drane, 1977; Johnston, 1982; Madeya, 1996). Due to the significant differences in scores between the two pain experiences and the differences in apparent response to treatment and analgesics, these two pain experiences should be assessed separately, otherwise the pain evaluation will be seriously underestimated or overestimated.

Hospitalizations and Emergency Room Visits

A troubling finding of this study was the high percentage (20%; n=10) of patients requiring unscheduled hospitalizations for what appeared to be treatment related problems (i.e., weakness, dehydration, electrolyte imbalance, inability to eat or drink, pain management, or combinations of these). An additional nine (18%) patients were evaluated, treated, and released from emergency rooms for similar problems.

In studies of patients receiving concurrent chemotherapy and radiation therapy for H&N cancer, where treatment related toxicities are expected to be higher, the unscheduled hospitalization rates ranged from 10% (5/48) to 52% (10/19) (Adelstein, et al., 1994; Fountzilas, et al., 1994; Denham & Abbott, 1991). The reasons for hospitalization in these studies included fever, neutropenia, mucositis, inability to eat, and dehydration. Similar data for emergency room visits for H&N cancer patients undergoing treatment could not be found.

Adherence with Treatment Regimen

Patients with H&N cancer are often singled out as a group having problems with

compliance to treatment regimens and care (Richardson & Cullen, 1989; Lockhart & Clark, 1994). Completion of a full course of RT with its associated side effects often requires a great deal of patient diligence and commitment. In this study, only 3 (6%) patients of the 49 entered failed to complete the prescribed course of treatment. Four patients (8%) missed scheduled treatments which extended their overall length of time on treatment but these patients did complete the prescribed treatment planned. This finding shows that H&N RT patients are very compliant to treatment regimens and confirm the results of recent Radiation Therapy Oncology Group studies where upwards of 80-90% of patients complete the prescribed treatment plan.

These adherence to RT is especially noteworthy due to the remarkable diversity of this clinical population. Patients came from all walks of life ranging from the CEO of a major corporation who had unlimited resources and social support to obtain around the clock live-in assistance during treatment, to housewives with work and family responsibilities, to patients living in transient hotels or shelters who had little or no financial resources or social support. There were patients who continued to smoke and/or drink heavily during the course of RT and still managed to complete treatment. There was no discernible pattern as to which patients discontinued treatment prematurely.

Head and Neck Radiation Therapy Patients and Self-Care

All of the identified side effects studied received at their peak, mean severity scores indicating a moderate to severe rating. The self-care activities engaged for each side effect were reported as providing moderate relief throughout the study. However, none of the

reported self-care activities received mean effectiveness scores indicating complete relief of a side effect at any time point.

The use of self-care activities by patients for the experienced side effects of mouthsores, mucositis-related pain, and mouth dryness was greater than for other side effects of treatment (i.e., taste changes, weight loss) even though the severity scores for weight loss and taste changes were similar to the severity ratings reported for the other side effects. These results are of note and differ somewhat from previous studies of RT patients (Dodd, 1984b; Hanucharurnkul, 1989) and other cancer patients (Dodd 1984c, 1988a; Dodd & Dibble, 1993; Dodd, Thomas, & Dibble, 1991; Musci & Dodd, 1990) where severity scores were positively correlated to self-care activity.

The Self-Care Diary was effective in obtaining patients report of the presence of a side effect, as well as the use and effectiveness of self-care behaviors for the present study. Patients in this study reported greater use of self-care activities than patients in other studies (Dodd 1984b). While the Self-Care Diary has been criticized for "cueing" patients to engage in more self-care activities, patients did not try new self-care activities listed in the diary even if they reported that the self-care behaviors they used were not completely effective.

Patients in this study may have engaged in self-care more consistently and continuously because of their daily interaction with RT staff. Since patients were seen daily, the effectiveness or ineffectiveness self-care activities for side effects were reported within a few days of initiating such activities, and appropriate changes in self-care activities for side effects could be tried or suggested. These patients also saw the research nurse three times a

week (starting week 2 or 3) and the radiation oncologist weekly who would assess for and discuss anticipated problems as well as manage symptoms as they occurred.

These findings are consistent with Orem's Self-Care Deficit Theory of Nursing. H&N RT resulted in side effects that started early in treatment, increased in severity over time, and lasted longer than expected. In response to these side effects, patients had the ability (self-care agency) and capacity to initiate self-care actions necessary to deal with their self-care needs. In this study, patients continued to employ self-care behaviors for experienced side effects over the course of the treatment with moderate success. Those side effects that create the greatest need for patients to deal with, such as pain, mouthsores, and xerostomia, are the side effects for which patients will employ self-care. This theory was demonstrated in this study. As the perceived importance of self-care needs for experienced side effects appeared to diminish, the use of self-care actions by the patient addressing those needs (i.e., changes in taste, weight loss) also decreased.

Limitations of the Study

The group of patients who did not complete the treatment course and thus dropped out of the study (n=3) were not evaluated for their symptom occurrence and symptom severity. These patients dropped out of the study due to their inability to deal with side effects of their treatment or due to a worsening physical condition, not associated with a progression of their cancer.

During week 6 of the study, there were 42 patients still on active treatment, however six patients (14% for that time point) were hospitalized for treatment related problems and were unable to complete the Weekly Pain Assessment Questionnaire and the weekly Self-Care

Diary which could have impacted on the results.

The findings of this study may not be generalizable to H&N RT patients treated in smaller community settings. A number of patients were referred and treated in this large university setting due to the complexity of their care, or the sophisticated treatment techniques and equipment delivering the treatment available in this setting.

Implications for Nursing

Radiation oncology nursing is practiced in a multidisciplinary setting, and the role of the nurse includes assessing for and evaluating patients for problems or potential problems, and intervening when appropriate. The role also includes educating and assisting patients and families to manage the symptoms and side effects related to their treatment. The results of this study support the importance of these activities. Due to changes in health care and the limited amount of resources available, the burden of care is primarily the responsibility of the patient and family and especially since the side effects persist beyond treatment and follow-up visits. Patients are really on their own. By educating the patient and family to the anticipated effects of H&N RT, and by identifying and managing problems or potential problems early, more appropriate and cost effective use of resources may occur. Twenty percent of patients required hospitalization and 18% were seen in emergency room for treatment related problems indicating the high morbidity of H&N RT. If the onset of these problems could be identified earlier and effective nursing interventions started in the RT department or outpatient setting, the number of hospitalizations or emergency room visits may be decreased resulting in a better utilization of personnel and resources.

The findings of this study indicate the need to select measurement tools with scales that

are sensitive to or provide greater options for patients to report the severity of their side effects. For example, patients often reported experiencing the "worst pain possible" one day, and at the next visit would state that the pain was "even worse than before". However, on a numeric rating scale, the patients would not be able to report higher scores even if their pain was worse.

The results of this study also support the need for alleviating or controlling the identified side effects of H&N RT that are most problematic for patients. Mucositis related pain, mouthsores, and xerostomia are the three side effects that patients were most actively using self-care behaviors to deal with more effectively. However, these side effects do not occur in isolation but in clusters of symptoms. Therefore, strategies for alleviating or minimizing treatment related side effects require managing all of side effects as effectively as possible. It has been reported that with improvement in pain control in H&N RT patients, an improvement in oral intake and a reduction in weight loss can occur (Janjan, et al., 1992).

This study provides clinical information (percentage of patients experiencing identified side effects, and the severity of side effects) to nurses about what the H&N RT patient experiences during specific time points in treatment (i.e., prior to start of RT, at the beginning of the 3rd week of RT; mid-therapy; end of treatment; and follow-up appointment). This information is provided to assist nurses to anticipate potential patient needs and positively impact patient care in a more timely manner.

Implications for Future Studies

Mucositis related pain is a significant problem for H&N RT patients. The results of this study shows that this pain is not adequately managed and contributes to other problems such

as inability to eat and drink, and subsequent weight loss. These side effects if they become severe can ultimately result in hospitalization of the patient. Therefore, studies focused at finding effective pain management strategies for mucositis-related pain should be a priority for H&N RT patients.

While patients continue to experience severe mucositis pain, alternative and effective methods of maintaining protein, caloric, and fluid intake should be investigated. Would the insertion of a percutaneous endogastric tube prior to or early in treatment be beneficial and cost effective in reducing the morbidity from treatment compared to current practice? All patients in this study experienced weight loss and difficulty in maintaining an adequate oral intake. However, the severity of weight loss and decreased nutritional intake and the effect on patients varied. One patient, a woman in her seventies, weighing 86 pounds at the start of treatment lost only 3 pounds during the study and required no assistance with oral intake, while several other patients required feeding tubes (i.e., nasogastric, percutaneous endogastric tubes) to supplement or provide all their nutritional and caloric intake. Studies should be aimed toward identifying patient factors most likely to indicate patients at risk for severe nutritional problems requiring mechanical assistance during treatment. If this could be determined, only those patients needing nutritional intervention, a nasogastric or percutaneous endogastric tube, would receive one at the appropriate time. This intervention may improve the overall quality of life patients experience during RT and immediately following the completion of treatment.

The number of patients who required hospitalization or emergency room visits for treatment related problems is an area of future study. The development and testing of a

patient profile of high risk factors for hospital admissions and emergency room visits would be a valuable contribution. Once these patients are identified, measures could be employed during their RT treatments that would identify problems or potential problems early and could result in the initiation of timely interventions.

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Appendix A

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT

Radiation Therapy-Related Stomatitis, Stomatitis Pain, and Self-Care Behaviors of the Head and Neck Cancer Patient

A. PURPOSE AND BACKGROUND

Gayle H. Shiba, R.N., M.S.N., and Marylin J. Dodd, R.N., Ph.D., from the Department of Physiological Nursing are conducting a study to learn about stomatitis (sores in the mouth), mouth pain, and other side effects related to radiation therapy treatments and the activities used by patients to take care of these problems. Because I have a head and neck cancer and am receiving radiation therapy treatments to an area including my mouth and/or oral cavity, I am being asked to participate in this study.

B. PROCEDURES

If I agree to be in this study, the following will happen:

1. One of the investigators will ask me to respond to questionnaires about my health, and any pain or mouth sores I may experience, and my ability to manage these problems. In addition, I will be asked about my use of medications for pain, and my drinking of alcoholic beverages during my treatments. Most of these questionnaires will be completed in the radiation therapy department during my regular visits, or in my home at my convenience.

2. I will complete weekly questionnaires about of any pain, mouth sores, or other side effects I experience that may be related to my radiation treatments, and indicate what I do to take care of those side effects.

3. I will complete a weekly Self-Care Diary about specific side effects that may be related to my treatment, and indicate what I do, if anything, to take care of those side effects. I will also indicate how effective I feel that my actions were in taking care of the side effect listed. In addition, I may list other side effect(s) that I feel is related to my radiation therapy treatments that are not included in my Self-Care Diary.

4. The investigator will conduct exams of my mouth while I am on radiation therapy treatments. These exams will be done during my regular treatment visits.

5. Once a week, one of the investigators will measure the amount of saliva ("spit") I am able to make and spit into a container. For part of this collection, I will be asked to chew on some parrafin (wax) or other similar substance that will stimulate my
mouth to produce saliva. This collection should take about 15 minutes to complete and will be done while I am in the radiation therapy department for my regularly scheduled visit.

6. In addition to the saliva collection just described, four times during the study, the investigators will measure the amount of saliva produced by the parotid glands (the parotid glands are the main group of glands that produce saliva). To do this, the investigators will place small collecting tubes over the openings in my mouth where saliva from the parotid glands comes out. This collection will take 10 to 15 minutes. During part of this collection, to stimulate the parotid gland to make saliva, the investigator will occasionally stroke my tongue with a cotton applicator (Q-tip) soaked with a mild citric solution. This solution may taste sour.

7. The investigators will check my medical records to gather information about my radiation therapy treatments and any health problems I may experience while I am participating in the study.

8. Participation in the study will include the course of radiation therapy treatments and conclude with the one month follow-up visit, and will average 40 minutes of my time per week.

C. RISKS/DISCOMFORTS

1. Participation in research may result in a loss of privacy, however, study records will be kept as confidential as is possible. No individual identities will be used in any reports or publications resulting from this study. Study information will be coded and kept in locked files at all times. Only the investigators will have access to the files.

2. Participation in this study will not interfere with my appointments, but it may add time to some of my visits. To minimize this time, I may take the questionnaires home to complete and return them at my next appointment.

3. Some of the questions on the questionnaires may make me uncomfortable or upset, but I am free to decline to answer any question I don't wish to. I will be asked to provide information about my medication use for pain. I will also be asked about my use of alcoholic beverages during therapy.

minutes. This will not hurt, but it may feel uncomfortable having these tubes in my mouth. The citrus solution used to stimulate saliva production may taste sour and may also cause mild discomfort if I have sores on my tongue.

D. BENEFITS

There will be no direct benefit to me from participating in this study. It is hoped that the information gained from the study will help with the identification and treatment of mouth sores and pain related to radiation treatments in future cancer patients.

E. ALTERNATIVES

If I choose not to participate in this study, I will receive all my regular care, but I would not need to answer the questionnaires, complete the daily log, or have my saliva collected and measured.

F. COSTS

There will be no costs to me as a result of taking part in this study.

G. REIMBURSEMENT

I will not be reimbursed for participating in this study.

H. QUESTIONS

This study has been explained to me by Ms. Shiba or _____ and my questions were answered. If I have other questions about the study, I may call Ms. Shiba at (415) 476-0712 or Dr. Marylin Dodd at (415) 476-4320.

I. CONSENT

I have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to participated or to withdraw at any point in this study without jeopardy to my nursing or medical care.

If I wish to participate, I should sign below:

_____ _____

Date Patient's Signature

_____ _____

Date Witness' Signature

Appendix B

COMMITTEE ON HUMAN RESEARCH
OFFICE OF RESEARCH AFFAIRS, Box 0962
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CHR APPROVAL LETTER

TO: Marylin J. Dodd, R.N., Ph.D. Box 0610
Gayle Shiba, R.N. Box 0610

RE: Radiation Therapy-Related Stomatitis, Stomatitis Pain, and Self-Care Behaviors of the Head and Neck Cancer Patient

The Committee on Human Research, the UCSF Institutional Review Board holding Department of Health and Human Services Multiple Assurance #M-1169, has reviewed and approved this application to involve humans as research subjects.

APPROVAL NUMBER: H452-11857-01. This number is a UCSF CHR number and should be used on all consent forms, correspondence and patient charts.

APPROVAL DATE: August 22, 1995. **Expedited Review**

EXPIRATION DATE: September 1, 1996. If the project is to continue, it must be renewed *by the expiration date*. See reverse side for details.

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within ten working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

QUESTIONS: Please contact the office of the Committee on Human Research at (415) 476-1814 or campus mail stop, Box 0962.

Sincerely,

Reese T. Jones, M.D.
Chairman
Committee on Human Research

Project # 95011857

Appendix C

PATIENT DEMOGRAPHIC QUESTIONNAIRE

1. Your age: _____
2. Female _____ Male _____
3. Do you live alone? Yes _____ No _____
4. What is your current marital status?

   _____ Married/Partnered

   _____ Never married

   _____ Not married but living together

   _____ Widowed

   _____ Separated

   _____ Divorced

5. Circle the highest grade or year you completed in regular school, vocational school, college, or graduate professional training.

Grade School								High School			
1	2	3	4	5	6	7	8	9	10	11	12

College				Graduate School						
13	14	15	16	17	18	19	20	21	22	>22

6. Circle the number that best describes your ethnic group:

   1 American Indian

   2 Black/African American

   3 Caucasian/White

   4 Asian/Pacific Islander (please specify, i.e., Chinese, Filipino, etc.)

   _____

   5 Hispanic/Latino

   6 Mixed Ethnic Background

   7 Other (specify) _____

. What is your current employment status? (choose one)

_____ Full-time

_____ Part-time

_____ Homemaker

_____ Retired

_____ Unemployed

_____ Disability

_____ Other (please specify) _____

8. What is the purpose of your present cancer treatment?

_____ Cure my disease

_____ Control my disease

_____ I don't know the purpose

_____ Other (specify) _____

9. Do you smoke now? Yes _____ No _____

If YES:

a. How many cigarettes do you currently smoke each day?

_____ less than 10 per day

_____ less than 20 per day

_____ more than 20 per day

b. How many cigars do you currrently smoke each day?

_____

c. How many pipe fulls of tobacco do you currently smoke each day?

_____

10. Have you ever smoked? Yes _____ No _____

If YES: How many years did you smoke? _____

11. If you have quit smoking, how long ago (in years) did you quit?

_____

12. Do you use currently use chewing tobacco?

Yes _____ No _____

13. Have you ever used chewing tobacco? Yes _____ No _____

If YES: How many years did you chew tobacco? _____

How long ago did you quit? _____

14. Do you currently drink alcoholic beverages? Yes _____ No _____

If YES, which kind:

Beer	Yes _____	No _____
Wine	Yes _____	No _____
Liquor	Yes _____	No _____

15. Do you have your own teeth? Yes _____ No _____

16. Do you have:

Dentures	Yes _____	No _____
Partials	Yes _____	No _____
Bridges	Yes _____	No _____
Other	(please specify) _____	

17. How many times do you brush your teeth or clean your dentures each day?

_____ times

18. Do you use toothpaste?

Yes _____ No _____ Brand:

19. Do you use mouthwash?

Yes _____ No _____ Brand:

20.. Are you currently on a fluoride treatment program for your teeth?

Yes _____ No _____

Appendix D

*ID#:*_____

DISEASE AND TREATMENT QUESTIONNAIRE

DATE							
Treatment #							
Elapsed days							
cGy/fraction							
cGy(cumulative)							
Field/size							
Field/size							
Field/size							
Field/size							
Weight							
Tube Feedings (Type/amount)							
Karnofsky							
Lab Results: *WBC* *HGB* *HCT* *PLT* *Others:*							

Complete the following at the start of RT:

1. *Height:* _____
2. *Weight at start of RT:* _____ *Usual weight:* _____

   Ideal weight (for body frame and height): _____
3. *Any weight loss within the last 6 months?* *Yes* _____ *No* _____

   If YES, how much?: _____
4. *Tube feedings?* *Yes* _____ *No* _____ *If YES, how long?* _____

Appendix E

MEDICAL RECORD REVIEW
DEMOGRAPHIC AND TREATMENT VARIABLES

Study ID #: _____ **Medical Record #:** _____

1. Age/Birthdate:
2. Gender: Female _____ Male _____
3. Cancer Diagnosis / Site:
4. Histology:
5. Tumor Stage:
6. Initial diagnosis date:
7. Site(s) and extent of metastatic disease (if any):
8. Radiation Therapy:

   Prescribed cGy: _____

   Total cGy received: _____

   Fractionation schedule: QD _____

   BID _____

   Other (specify) _____

   Start date of treatment : _____

   Completion date of treatment : _____

   Cone down? Yes _____ No _____

   If yes, list cumulative dose and field and field size change

8. Radiation Therapy (con't)

Date	Field	Field size	Cumulative cGy

Breaks in treatment? Yes _____ No _____

# of breaks: _____

Dates of break(s):

If YES, specify reason for break:

9. Intent of therapy

_____ Cure

_____ Adjuvant

_____ Control

_____ Palliative

_____ Other (specify) _____

10. Has the patient had any previous cancer treatment?

Yes _____ No _____

If YES: _____ Surgery (specify:)

_____ Chemotherapy (list drugs:

_____ Radiation Therapy

_____ Biotherapy

_____ Other (specify) _____

11. Tumor response at the end of the study:

_____ Not applicable

_____ No change

_____ Decreased in size

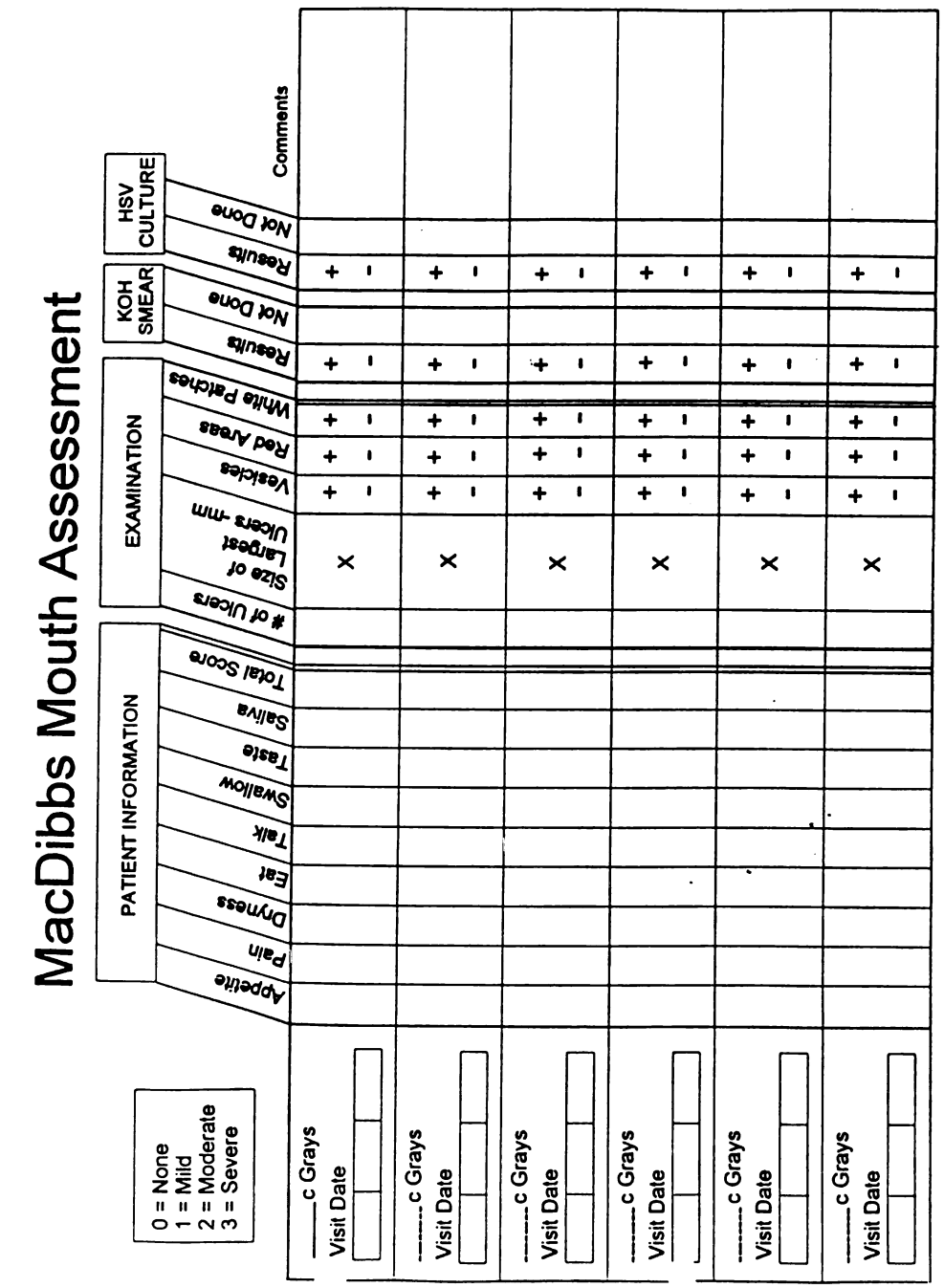
_____ Increased in size

_____ Information not available

_____ Other (specifiy) _____

12. Comments:

Appendix F


MacDibbs Mouth Assessment
0 = None
1 = Mild
2 = Moderate
3 = Severe
PATIENT INFORMATION
Appetite
Pain
Dryness
Eat
Talk
Swallow
Taste
Saliva
Total Score
EXAMINATION
# of Ulcers
Size of Largest Ulcers -mm
Vesicles
Red Areas
White Patches
KOH SMEAR
Results
Not Done
HSV CULTURE
Results
Not Done
Comments
_____c Grays
Visit Date
_____c Grays
Visit Date
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Visit Date
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Visit Date
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Visit Date
_____c Grays
Visit Date

Appendix G

PAIN PROFILE

1. Have you ever had pain due to your present disease?

   Yes _____ No _____ Uncertain _____

2. When you first received you diagnosis, was pain one of your symptoms?

   Yes _____ No _____ Uncertain _____

3. Have you had surgery to your head, neck, throat, or mouth in the past month?

   Yes _____ No _____

4. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain **other** than these everyday kinds of pain during the last week?

   Yes _____ No _____

   If **yes**, please describe: _____
   _____

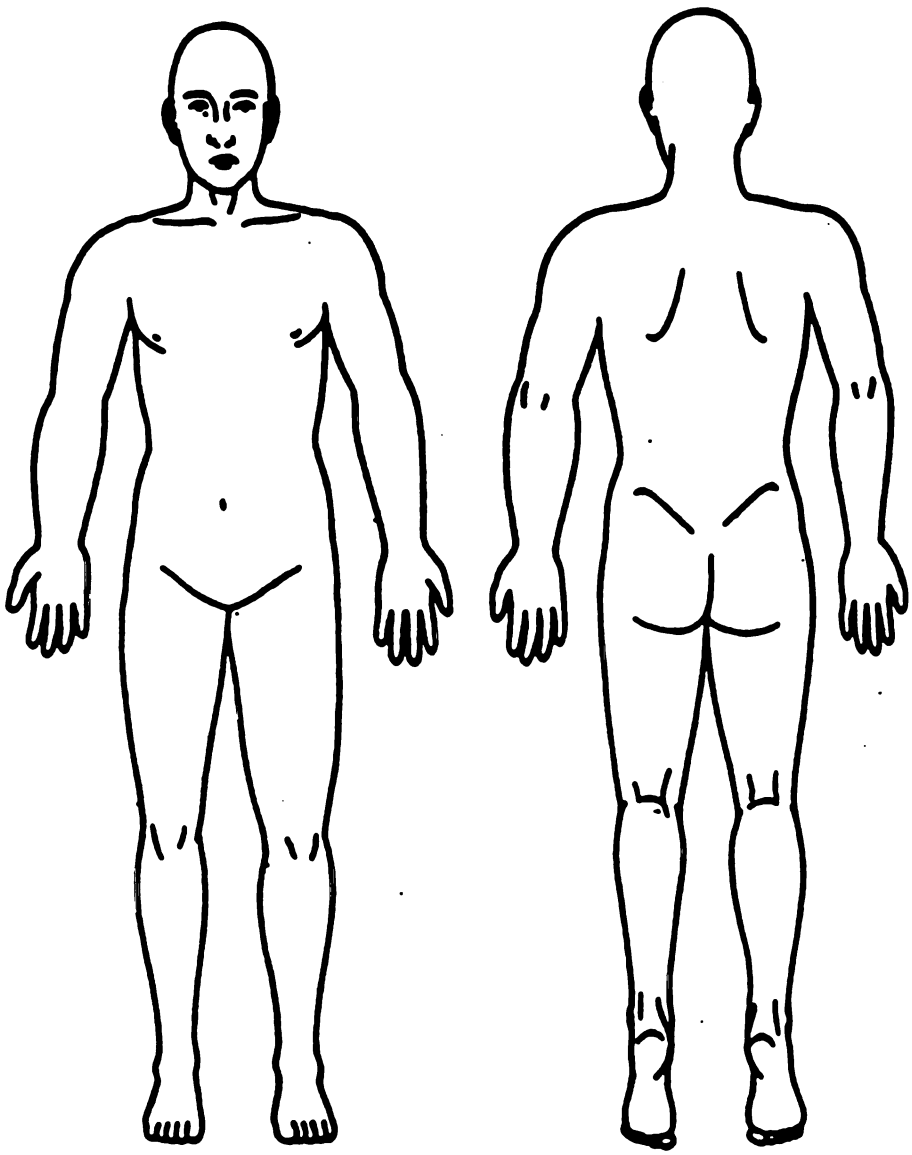
5. Do you currently have pain in your mouth, head, or neck?

   Yes _____ No _____

IF YOU ANSWERED YES TO QUESTION 5, PLEASE CONTINUE ON TO THE FOLLOWING QUESTIONS. IF YOU ANSWERED NO, YOU ARE FINISHED WITH THE PAIN PROFILE, PLEASE CONTINUE ON TO PAGE 12 ("PAIN MEDICATION").

6. Using this picture, show which parts of your body are affected by pain by shading them with a pen or pencil.

   If you have **more than one type** of pain, you may **use a different color for each**.



7. Where do you have the most pain? (check **only one**)

_____ head

_____ neck

_____ mouth

_____ other (specify) _____

8. Your current pain intensity:

Pain Scale

0	1	2	3	4	5	6	7	8	9	10
none		mild			moderate			severe		excruciating

a. Choose the number from the scale above which best describes your degree of pain for each of the following, and place it in the space provided:

_____ your pain right now

_____ your current average daily pain

_____ your current pain at its worst

_____ your current pain at its least

b. Consider the worse pain you have ever felt as 100%. What percent is your current pain level?
_____ %

c. How many days out of a typical week do you currently experience pain that interferes with your mood and/or activities?

_____ (enter how many days – 0 to 7)

d. On those days where you have pain, how many hours of the day does it currently last?

_____ (enter how many hours – 0 to 24).

9. Is your pain typically worse at any particular time of day?

Yes _____ No _____

If **yes,** at what time of day is your pain worse? (choose **only one)**

_____ morning

_____ afternoon

_____ evening

_____ night

10. What makes your pain worse? (choose **all** that apply)

_____ chewing

_____ drinking

_____ speaking

_____ swallowing

_____ other (specify) _____

10. How can you lessen your pain? (choose **all** that apply)

_____ use pain medicines

_____ use mouth rinses

_____ eat soft foods

_____ distract myself with TV, a book, or something else I enjoy doing

_____ other (specify) _____

11. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that most closely shows how much relief you have received.

0% No Relief	10%	20%	30%	40%	50%	60%	70%	80%	90%	100% Complete Relief

12. If you take pain medication, how many hours does it take before the pain typically returns?

_____ Pain medication doesn't help at all
_____ One hour
_____ Two hours
_____ Three hours
_____ Four hours
_____ Five to twelve hours
_____ More than twelve hours
_____ I do not take pain medication

13. Indicate the appropriate answer for each item.
I believe my pain is due to:

Yes _____ No _____ a. **the effects of the treatment** (e.g., medication, surgery, radiation)

Yes _____ No _____ b. **my primary disease** (meaning the disease currently being treated)

Yes _____ No _____ c. **a medical condition unrelated to my primary disease** (e.g., arthritis)

(continue to next page)

14. Some of the words below may describe your present pain. Circle as many words in each of the 20 groups if the group contains a word that describes your pain. Leave out any group that does not apply.

1	2	3	4	5
Flickering	Jumping	Pricking	Sharp	Pinching
Quivering	Flashing	Boring	Cutting	Pressing
Pulsing	Shooting	Drilling	Lacerating	Gnawing
Throbbing	Shocking	Stabbing		Cramping
Beating		Lacinating		Crushing

6	7	8	9	10
Tugging	Hot	Tingling	Dull	Tender
Pulling	Burning	Itchy	Sore	Taut
Wrenching	Scalding	Smarting	Hurting	Rasping
	Searing	Stinging	Aching	Splitting
			Heavy	

11	12	13	14	15
Tiring	Sickening	Fearful	Punishing	Wretched
Exhausting	Suffocating	Frightful	Grueling	Blinding
		Terrifying	Cruel	
			Vicious	
			Killing	

16	17	18	19	20
Annoying	Spreading	Tight	Cool	Nagging
Troublesome	Radiating	Numb	Cold	Nauseating
Miserable	Penetrating	Drawing	Freezing	Agonizing
Intense	Piercing	Squeezing	Icy	Torturing
Unbearable		Tearing		

15. **Circle** the one number that best describes how, during the past week **pain** has interfered with your:

a. **General Activity**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

b. **Mood**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

c. **Walking ability**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

d. **Normal work (includes both work outside the home and housework)**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

e. **Relations with other people**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

f. **Sleep**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

g. **Enjoyment of life**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

16. How likely do you feel that your pain will be relieved?

_____ impossible to relieve

_____ unlikely to be relieved

_____ uncertain

_____ likely to be relieved

_____ certain to be relieved

17. Please feel free to make any additional comments about your pain:

Appendix H

WEEKLY PAIN ASSESSMENT QUESTIONNAIRE

1. Today's date is: _____

2. Are you currently having pain : Yes _____ No _____

   If yes, where is your pain:

Mouth	Yes _____	No _____
Tongue	Yes _____	No _____
Throat	Yes _____	No _____
Neck	Yes _____	No _____
Other (specify) _____	Yes _____	No _____

3. Since the last time you completed this form, has your pain intensity:

   _____ increased
   _____ decreased
   _____ stayed the same
   _____ variable (increased + decreased)

Complete the following questions <u>only</u> if you are having pain in the mouth, tongue, throat, or neck.

0	1	2	3	4	5	6	7	8	9	10
none		mild			moderate			severe		excruciating

4. Choose the number from the scale above which best describes your degree of pain for each of the following, and place it in the space provided:

   a. _____ Your pain at its **<u>worst</u>** in the last week

   b. _____ Your pain at its **<u>least</u>** in the last week

   c. _____ Your pain on the **<u>average</u>** over the last week

   d. _____ Your pain **<u>right now</u>**

5. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief	10%	20%	30%	40%	50%	60%	70%	80%	90%	100% Complete Relief

6. If you take pain medication, how many hours does it take before the pain returns?

_____ Pain medication doesn't help at all
_____ One hour
_____ Two hours
_____ Three hours
_____ Four hours
_____ Five to twelve hours
_____ More than twelve hours
_____ I do not take pain medication

7. **Circle** the one number that best describes how, during the past week **pain** has interfered with your:

a. **General Activity**

0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes

b. **Mood**

0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes

c. **Walking ability**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

d. **Normal work (includes both work outside the home and housework)**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

e. **Relations with other people**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

f. **Sleep**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

g. **Enjoyment of life**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										**Completely interferes**

8. If you are taking pain medication, do you feel the medicine that you take for your pain:

_____ relieves all of your pain

_____ relieves most of your pain

_____ relieves little of your pain

_____ relieves none of your pain

9. Have you smoked since last completing this form?

Yes _____ No _____

10. Have you had any alcoholic beverages to drink since last completing this form?

Yes _____ No _____

Appendix I

SELF-CARE DIARY

Direction: I am interested in knowing about any side effects from your treatments that you may have experienced over the past week and what, if anything, you did to deal with them. For each of the side effects listed, please indicate if you experienced the side effect. If you check **NO, go to the next page.** If you check **YES, please indicate how severe the side effect was, what you did to deal with the side effect, and how helpful each of your actions were in relieving the side effect.**

1a. During the past week, have you had any **dryness of your mouth?**

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how **dry your mouth is or was.**

Not very dry				**Extremely dry**
0	**1**	**2**	**3**	**4**

1b. Please indicate your use of the actions listed below and circle the number that best describes the helpfulness of those actions.

I did not do anything for my mouth dryness _____ (Go to question 2a)

For my mouth dryness I did the following:

	Used	**No Relief**				**Complete Relief**
a. Drank more fluids		**0**	**1**	**2**	**3**	**4**
b. Used saliva substitutes		**0**	**1**	**2**	**3**	**4**
c. Ate soft foods		**0**	**1**	**2**	**3**	**4**
d. Used water to moisturize my mouth (sprayer)		**0**	**1**	**2**	**3**	**4**
e. Used medication that helps to moisten my mouth		**0**	**1**	**2**	**3**	**4**
f. Sucked on candies		**0**	**1**	**2**	**3**	**4**
g. Rinsed/cleaned my mouth more often		**0**	**1**	**2**	**3**	**4**
h. Other (please write in:)		**0**	**1**	**2**	**3**	**4**

2a. During the past week, have you had any **change(s) in your taste**?

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how severe your **change in taste is** or **was**.

Not much change in taste	**Extremely severe change in taste**
0——1——2——3——4	

2b. Describe your **change in taste**:_____

2c. Please indicate your use of the actions listed below and circle the number that best describes the helpfulness of those actions.

I did not do anything for my change(s) in taste _____ (Go to question 3a)

For my change(s) in taste I did the following:

	Used	**No Relief**	**Complete Relief**
a. Didn't eat or drink things that tasted different		**0——1——2——3——4**	
b. Ate more sour tasting foods		**0——1——2——3——4**	
c. Ate more sweet tasting foods		**0——1——2——3——4**	
d. Ate more salty tasting foods		**0——1——2——3——4**	
e. Ate spicier tasting foods		**0——1——2——3——4**	
f. Cleaned my mouth and teeth more often		**0——1——2——3——4**	
g. Stopped eating certain foods (List foods:)		**0——1——2——3——4**	
h. Ate cold food rather than hot food		**0——1——2——3——4**	
i. Other (please write in:)		**0——1——2——3——4**	

3a. During the past week, have you had any **soreness or pain in your mouth**?

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how **sore or painful** your mouth **is** or **was.**

Not very sore/painful				**Extremely sore/painful**
0	**1**	**2**	**3**	**4**

3b. Please indicate your use of the actions listed below and circle the number that best describes the helpfulness of those actions.

I did not do anything for my mouth soreness/pain _____ (Go to question 4a)

For my mouth soreness/pain I did the following:

	Used	**No Relief**				**Complete Relief**
a. Rinsed/cleaned my mouth more often		**0**	**1**	**2**	**3**	**4**
b. Used medicated mouthwash		**0**	**1**	**2**	**3**	**4**
c. Put pain medicine on the sores in my mouth		**0**	**1**	**2**	**3**	**4**
d. Took pain medicines		**0**	**1**	**2**	**3**	**4**
e. Wore my dentures/partials less		**0**	**1**	**2**	**3**	**4**
f. Kept busy to keep my mind off of my mouth soreness/pain		**0**	**1**	**2**	**3**	**4**
g. Changed my diet		**0**	**1**	**2**	**3**	**4**
h. Other (please write in:)		**0**	**1**	**2**	**3**	**4**

4a. During the past week, have you noticed any **sores in your mouth?**

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how severe the **mouth sores are or were.**

Sores not very severe				**Sores extremely severe**
0	**1**	**2**	**3**	**4**

4b. Please indicate your use of the actions listed below and circle the number that best describes the helpfulness of those actions.

I did not do anything for my mouth sores _____ (Go to question 5a)

For my mouth sores I did the following:

	Used	**No Relief**				**Complete Relief**
a. Did my mouth care more often		0	1	2	3	4
b. Used mouth rinses (List type:)		0	1	2	3	4
c. Put medicines on the sores in my mouth (e.g., Orabase, Ulcerease, Hurricane, etc.)		0	1	2	3	4
d. Ate soft foods		0	1	2	3	4
e. Drank cool liquids		0	1	2	3	4
f. Drank warm liquids		0	1	2	3	4
g. Took pain medicines		0	1	2	3	4
h. Other (please write in:)		0	1	2	3	4

5a. During the past week, have you had any **loss of appetite?**

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how **severe** your **loss of appetite is** or **was.**

Not much loss of appetite				**Extreme loss of appetite**
0	**1**	**2**	**3**	**4**

5b. Please indicate your use of the actions listed below and cirlce the number that best describes the helpfulness of those actions.

I did not do anything for my appetite loss _____ (Go to question 6a)

For my appetite loss I did the following:

	Used	**No Relief**				**Complete Relief**
a. Ate less		**0**	**1**	**2**	**3**	**4**
b. Ate more frequently		**0**	**1**	**2**	**3**	**4**
c. Ate high-protein foods		**0**	**1**	**2**	**3**	**4**
d. Ate high calorie foods		**0**	**1**	**2**	**3**	**4**
e. Ate/drank dietary supplements (e.g., Ensure, milk shakes, egg nog, etc.)		**0**	**1**	**2**	**3**	**4**
f. Tried to eat more food than usual		**0**	**1**	**2**	**3**	**4**
f. Made an extra effort to eat (How?)		**0**	**1**	**2**	**3**	**4**
g. Other (please write in:)		**0**	**1**	**2**	**3**	**4**

6a. During the past week, have you been more **fatigued or tired** than usual?

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how **fatigued or tired** you **are** or **were.**

Not very fatigued				**Extremely fatigued**
0	**1**	**2**	**3**	**4**

6b. Please indicate your use of the actions listed below and circle the number that best describes the helpfulness of those actions.

I did not do anything for my fatigue/tiredness _____ (Go to question 7a)

For my fatigue/tiredness I did the following:

	Used	**No Relief**				**Complete Relief**
a. Took naps		**0**	**1**	**2**	**3**	**4**
b. Slept more hours than usual		**0**	**1**	**2**	**3**	**4**
c. Went to bed earlier than usual		**0**	**1**	**2**	**3**	**4**
d. Slept later than usual		**0**	**1**	**2**	**3**	**4**
e. Kept busy to keep my mind off my fatigue		**0**	**1**	**2**	**3**	**4**
f. Limited my usual activities		**0**	**1**	**2**	**3**	**4**
g. Increased my usual activities		**0**	**1**	**2**	**3**	**4**
h. Exercised		**0**	**1**	**2**	**3**	**4**
g. Other (please write in:)		**0**	**1**	**2**	**3**	**4**

7a. During the **past week,** have you **lost weight?**

Yes _____ No _____ **(If NO, continue to next page)**

If YES, circle the number indicating how **severe** your **weight loss** was.

Not much weight loss				**Extreme weight loss**
0	**1**	**2**	**3**	**4**

7b. Please indicate your use of the actions listed below and circle the number that best describes the helpfulness of those actions.

I did not do anything for my weight loss _____ (Go to question 8a)

For my weight loss I did the following:

	Used	**No Relief**				**Complete Relief**
a. Ate the same amount of food		**0**	**1**	**2**	**3**	**4**
b. Ate more frequently		**0**	**1**	**2**	**3**	**4**
c. Ate high calorie foods		**0**	**1**	**2**	**3**	**4**
d. Ate high protein food		**0**	**1**	**2**	**3**	**4**
e. Tried to eat more food than usual		**0**	**1**	**2**	**3**	**4**
f. Ate/drank dietary supplements (e.g., Ensure, milk shakes, etc.)		**0**	**1**	**2**	**3**	**4**
g. Made an extra effort to eat (How?)		**0**	**1**	**2**	**3**	**4**
g. Weighed myself more often to keep track of my weight		**0**	**1**	**2**	**3**	**4**
h. Limited my usual activities		**0**	**1**	**2**	**3**	**4**
i. Other (please write in:)		**0**	**1**	**2**	**3**	**4**

8a. Have you experienced **any other side effects** from your treatment that have not already been listed?

YES _____ **NO** _____ **(You have completed this questionnaire)**

If YES, please indicate the **side effect** in the space provided:

_____

If YES, how severe was the side effect?

Not very severe				**Extremely severe**
0	**1**	**2**	**3**	**4**

8b. Please write in each action you took to deal with the side effect and circle the number which best describes the helpfulness of your action(s).

I did not do anything for the side effect _____

I did the following to deal with the side effect:

	Not Used	**No Relief**				**Complete Relief**
a.		**0**	**1**	**2**	**3**	**4**
b.		**0**	**1**	**2**	**3**	**4**
c.		**0**	**1**	**2**	**3**	**4**
d.		**0**	**1**	**2**	**3**	**4**

If you have experienced yet another side effect that was not listed, please complete the next page. Otherwise you have completed your weekly Self-Care Diary.

Thank you !!!

9a. Please indicate the **side effect** you experienced, not listed previously, in the space provided:

_____

How severe was the side effect?

Not very severe				**Extremely severe**
0	**1**	**2**	**3**	**4**

9b. Please write in each action you took to deal with the side effect and circle the number which best describes the helpfulness of your action(s).

I did not do anything for the side effect _____

I did the following to deal with the side effect:

	Not Used	**No Relief**				**Complete Relief**
a.		**0**	**1**	**2**	**3**	**4**
b.		**0**	**1**	**2**	**3**	**4**
c.		**0**	**1**	**2**	**3**	**4**
d.		**0**	**1**	**2**	**3**	**4**

Appendix J

ID#: _____ ***SALIVARY FLOW STUDIES***

	Date	cGy to date	Fx #	Meds	Whole Flow (5 min/1 min)		Parotid (5 min/1 min) Unstimulated		Parotid (5min/1min) Stimulated	
					U	S	R	L	R	L
B/L **										
1 **										
2										
3										
4										
5										
6										
7										
End **										
F/U **										

** Parotid studies to be conducted

U - unstimulated
S - stimulated

R - right
L - left

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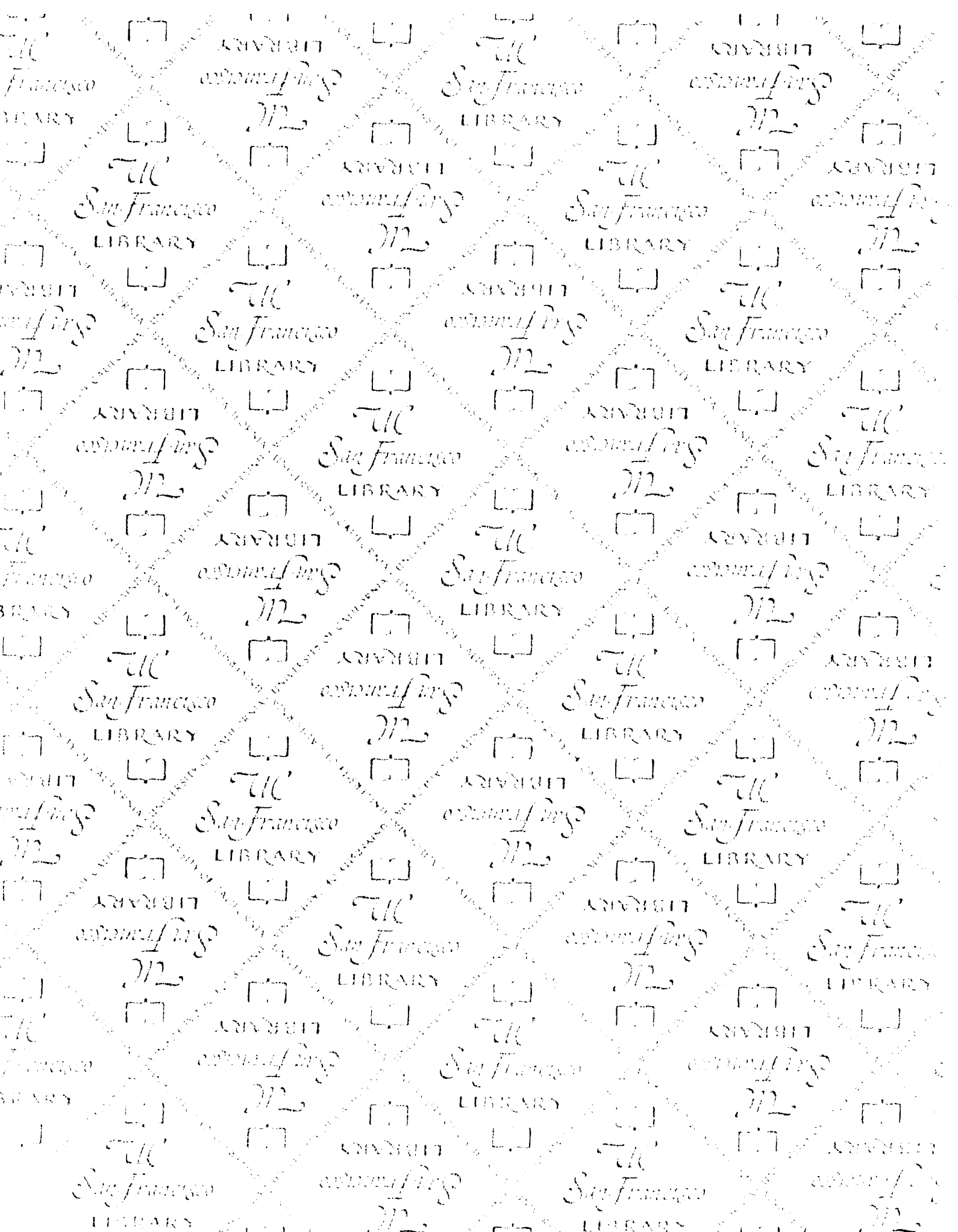
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