

## Oral mucositis-related morbidity and resource utilization in a prospective study of head and neck cancer patients

<b>Authors</b>	J. Isitt, B. A. Murphy, J. L. Beaumont, A. S. Garden, C. K. Gwede, A. Trotti, R. F. Meredith, J. B. Epstein, Q. Le, D. M. Brizel, L. A. Bellm, N. Wells, and D. Cella
<b>Origin of Study</b>	USA
<b>Type of Study</b>	PROSPECTIVE, MULTICENTER, SINGLE-ARM OBSERVATIONAL STUDY
<b>Objectives</b>	Examine the burden of oropharyngeal mucositis and its downstream resource consumption and risk of complications in head and neck cancer patients receiving radiation with or without chemotherapy.
<b>Study Design</b>	<p>At baseline and at weeks 2, 4, and 6, the severity and impact of oral mucositis were assessed using the oral mucositis weekly questionnaire for head and neck cancer (OMWQ-HN), a 12-item instrument measuring mouth and throat soreness and pain and limitations in oral function (eg, eating, drinking, swallowing, talking).</p> <p>During week 4, patients were asked to complete the OMWQ-HN twice, 24–48 hours apart. In addition, clinicians recorded their perception of patients' mouth and throat soreness.</p> <p>Patient use of resources was collected every other week at the ends of weeks 2, 4, and 6 or at the end of radiotherapy, whichever came first.</p> <p>Hospitalization costs were reported from the Healthcare Utilization Project Nationwide Inpatient Sample.</p>
<b>Patients</b>	<p>In all, 75 patients were enrolled from 6 US centers.</p> <p>Patients were <math>\geq 18</math> years of age (mean age, 58.8 years; 61% male) and had histologically documented carcinoma involving the oral cavity, oropharynx, larynx, nasopharynx, hypopharynx, or neck disease (nodal or soft tissue) of unknown origin.</p> <p>Patients were scheduled to receive radiotherapy with or without chemotherapy and were not receiving an investigational agent for mucositis.</p>
<b>Observations</b>	<p>In all, 67% of patients received concurrent chemoradiation. Severe mouth and throat soreness occurred in 76% of patients.</p> <p>Opioid analgesics were prescribed for 85% of patients; pain of the mouth and throat accounted for 78% of opioid uses.</p> <p>During weeks 1 and 2, 38% of patients experienced severe difficulty in swallowing (59% by week 6), with 67% of them taking opioids (84% by week 5). In addition, 51% of the patients had a feeding tube placed, 37% were hospitalized (mean length of stay, 4.9 days), with 30% of the hospitalizations related to mucositis.</p> <p>The national average cost for a 5-day hospitalization over this study period was approximately \$23,000.</p>
<b>Conclusions</b>	<p>Mucositis is a frequent, severe, and costly complication that results from treatment of head and neck cancer.</p> <p>Over the study period, patients experienced increased mouth and throat soreness, which corresponded with a steady decline in oral function.</p> <p>Most patients received opioid analgesics to treat mouth and throat soreness; however, functional im-</p>

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pairment related to mucositis persisted. Further, patients on opioids appeared to experience incremental impairment in their ability to eat.

Mucositis was associated with increased medical resource use and related costs.

**Discussion**

Oral mucositis is a serious adverse effect of radiation therapy and chemotherapy for head and neck cancer, impairing patients' ability to eat, talk, swallow, and sleep. However, data on the burden of oral mucositis for patients and for the healthcare system are limited.

This study was conducted among patients undergoing radiation therapy, with or without chemotherapy, for head and neck cancer. The investigators used a questionnaire (*Epstein et al. J Clin Oncol* 2006;24(18S):5548) to assess oral mucositis-related morbidity and recorded use of healthcare resources during 6 weeks of treatment.

More than three fourths of patients reported "quite a lot of" or "severe" mouth and throat soreness during treatment, and two thirds of all patients were prescribed opioids solely because of this pain. By week 6, over 50% of patients reported "a lot" of difficulty or inability when it came to swallowing, eating, drinking, and talking; moreover, this impairment was similar between patients who were and were not taking opioids. Finally, more than half of patients required a feeding tube, and about 30% had mucositis-related hospitalizations.

"Pain was just a horrifically difficult problem for these patients undergoing head and neck radiation... and it was present despite the use of significant amounts of opioids," Dr. Murphy commented; more importantly, this pain led to profound functional impairment. An additional conclusion, she said, was that "oral mucositis is an expensive, resource-intense complication of therapy."

"More attention needs to be paid to the manifestations of mucositis," said Dr. Murphy. "People are accustomed to thinking of mucositis as an ulcer...but that's really not what mucositis is all about. It is about the myriad manifestations—it's about the pain and it's about the function loss."

The findings have implications for both clinical practice and research, Dr. Murphy noted. "What physicians have to do is ask about all of the functional implications of the mucositis, and not only do they have to ask about that during therapy, but they have to follow it up after therapy is completed." Researchers testing new treatments should also adopt a more comprehensive view of oral mucositis, she recommended. "We have to look beyond just the ulcerative lesion and we have to measure all of these outcome parameters ... because if [a new drug] affects all of these other things, we've got a winner of a drug," she said.

**Key Points**

- Effective interventions for mucositis may relieve patient suffering and reduce healthcare consumption and downstream costs.

**Reference**

Isitt J, Murphy BA, Beaumont JL, et al. Oral mucositis-related morbidity and resource utilization in a prospective study of head and neck cancer patients. Oral Mucositis Study Group. Presented at the 42nd Annual Meeting of the American Society of Clinical Oncology; June 2–6, 2006; Atlanta, Georgia. Abstract 5539.