

Impact of Oral Mucositis and Its Sequelae on Quality of Life

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Origin of Study	USA
Type of Study	DEVELOPMENT AND VALIDATION OF QOL MEASUREMENT TOOL
Objectives	Estimate the impact of oral mucositis and its sequelae on health-related quality of life (HRQOL) Develop a daily diary measure of mucositis-related HRQOL in patients receiving mucotoxic cancer therapy
Study Design	Two focus groups were conducted with patients who were suffering or had suffered from mucositis as a result of mucotoxic cancer therapy. Patients were invited to refine a daily diary questionnaire of mucositis severity and interference with activities. The resulting questionnaire has two components: severity of mouth and throat soreness and interference with daily activities.
Patients	Forty-seven patients receiving hematopoietic stem cell transplantation or treatment for stage III or IV colorectal cancer or head and neck cancer completed the daily diary questionnaire, along with other ratings of functional activity. Patients were evaluated for a mean of 15 ± 1.5 (SD) days after the start of chemotherapy. Thirty patients (63%) were hospitalized. Average age was 51 years (range, 24–74 years); 58% of patients were women.
Observations	On a 5-point mouth and throat soreness question, 28% had “quite a lot” or “extreme” soreness, 19% reported “some” soreness, 30% reported “a little” soreness, and 23% reported “no” soreness. Ratings for worst pain and soreness correlated ($r = 0.82$), providing support for the construct validity of the soreness question within the daily diary. Patients taking opioids or receiving intravenous pain medication reported greater soreness ($t = 4.5$, $P < 0.001$ and $t = 4.9$, $P < 0.001$, respectively). Patient global ratings of HRQOL correlated negatively with mouth and throat soreness ($r = -0.46$, $P = 0.001$) and nurse-rated ECOG performance status ($r = 0.54$, $P < 0.001$). Severity of soreness related most strongly to the activities of swallowing, eating, and drinking. Other activities negatively affected by mucositis included sleeping, talking, and doing things for fun.
Conclusions	Results of this study provide support for the validity of the brief daily diary questionnaire developed to monitor the impact of mucositis on HRQOL. Mucositis was found to negatively impact a variety of activities. Mouth and throat soreness correlated well with mouth and throat pain and with HRQOL, performance status, and medication use.
Discussion	Oral mucositis afflicts 40%–70% of patients who receive conventional chemotherapy or radiation treatment. Hematopoietic stem cell transplant recipients have a mucositis rate of over 90%. Despite the frequency of severe oral mucositis in these patients, little attention has been given to its effects on their functioning and well-being or HRQOL.

Impact of Oral Mucositis and Its Sequelae on Quality of Life

This study sought to estimate the impact of oral mucositis and its sequelae on HRQOL and to develop a daily diary measure of mucositis-related HRQOL in patients receiving mucotoxic anticancer therapy.

Researchers and clinicians conducted two focus groups with patients who were suffering or had suffered from mucositis as a consequence of mucotoxic anticancer therapy to refine a daily diary questionnaire of mucositis severity and its interference with patient activities. Patients indicated that “soreness,” rather than “pain,” better described their full range of mouth and throat sensations, and they provided a list of activities important to them that were impacted by mucositis.

The resulting questionnaire addresses two issues: the severity of mouth and throat soreness and its interference with their activities. Forty-seven patients receiving hematopoietic stem cell transplantation or treatment for stage III or IV colorectal cancer or head and neck cancer completed the Mucositis Daily Questionnaire at two time points after the start of their treatment cycle: between days 14 and 17 and between days 21 and 24. The diary took only 1 or 2 minutes to complete.

On a five-point mouth and throat soreness question, 28% of the patients had “quite a lot” or “extreme” soreness, 19% reported “some” soreness, 30% reported “a little” soreness, and 23% reported “no” soreness. The ratings for the worst pain and soreness correlated, providing support for the construct validity of the soreness question within the daily diary.

Additionally, patients taking opioids or receiving intravenous pain medication reported greater soreness. The severity of the soreness related most strongly to swallowing, eating, and drinking, but other activities negatively affected by mucositis included sleeping, talking, and doing things for fun.

The results support the validity of the brief, daily diary questionnaire developed to monitor the impact of mucositis on HRQOL.

Key Points

- Patient responses to the Mucositis Daily Questionnaire developed in this study correlated with traditional measures of mucositis toxicity requiring medical staff evaluation and patient self-reporting of pain using the EORTC QLQ-30 Pain Scale.
- Mucositis negatively impacted a variety of daily living activities.

References

Stiff P, Bensinger W, Emmanouilides C, et al. Treatment of mucositis with palifermin improves patient function and results in a clinically meaningful reduction in mouth and throat soreness (MTS): phase 3 results. Paper presented at the 45th Annual Meeting of the American Society of Hematology; December 6–9, 2003; San Diego, Calif. Abstract 676. **See page 75.**

Syrjala KL, Hays RD, Kallich JD, Farivar SS, Abrams JR, Erder MH. Impact of oral mucositis and its sequelae on quality of life. Paper presented at the 45th Annual Meeting of the American Society of Hematology; December 6–9, 2003; San Diego, Calif. Abstract 2771.