Prospective oral mucositis audit (POMA): occurrence and consequences of severe oral mucositis in high-dose melphalan and BEAM conditioning

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Origin of Study The Netherlands

Type of Study PROSPECTIVE, OBSERVATIONAL AUDIT

Objectives Assess the incidence and duration of severe oral mucositis (World Health Organization [WHO] grades 3/4) in patients with multiple myeloma or non-Hodgkin's lymphoma (NHL).

Assess the incidence and duration of oral mucositis by grade, patient burden and healthcare resource use, and evaluate current medial practice for oral mucositis prevention and treatment.

Explore determinants of oral mucositis incidence and duration.

Study Design Patients with multiple myeloma or NHL from 25 transplant centers across 13 European countries received high-dose melphalan or carmustine (BiCNU), etoposide, cytarabine, and melphalan (Alkeran; BEAM) followed by autologous stem cell transplant.

Prospective oral mucositis assessments (eg, severity of oral mucositis, temperature, hospitalization, use of additional treatments) were conducted daily from the start of conditioning until 30 days post transplant or hospital discharge.

To achieve high and consistent quality of oral mucositis assessment, physicians, nurses, and dentists underwent multimedia-assisted, face-to-face training before the study's start.

Patients In all, data on 197 patients (109 with multiple myeloma, 88 with NHL; mean age, 54 ± 11 years; 43% female) were assessed.

Observations The incidence of severe oral mucositis was 46% for multiple myeloma patients and 41% for NHL patients; severe episodes lasted for a mean of 5.4 ± 3.3 days in multiple myeloma patients and 5.3 ± 3.2 days in NHL patients.

Ulcerative oral mucositis occurred in 67% of multiple myeloma patients and 60% of NHL patients, lasting a mean of 6.6 ± 4.4 days and 6.5 ± 3.8 days, respectively.

WHO scale results and indicators of specific oral mucositis symptoms showed similar temporal patterns that reached a maximum at approximately day 12 following the start of conditioning in both groups.

No clinically relevant links with type of disease/conditioning or gender were detected; a nonstatistically significant trend associating oral mucositis duration with age was suggested. Fever ≥ 38°C occurred in 68% of patients with severe oral mucositis and in 47% of those without.

Mean hospital stay was 21.1 ± 4.0 days in patients with severe oral mucositis and 19.9 ± 4.8 days in patients without. Assessment was truncated at 30 days post transplant.

Conclusions Severe oral mucositis is a substantial clinical problem in patients receiving high-dose melphalan or BEAM conditioning chemotherapy.

Occurrence and consequences of severe oral mucositis in high-dose melphalan and BEAM conditioning

Discussion

Oral mucositis is a common and debilitating complication of high-dose chemotherapy. Trial-based reports of its occurrence vary widely, with evidence of underreporting, and there are limited data on the incidence and impact of oral mucositis in routine practice. Furthermore, there is no consensus on the best oral assessment instrument, which adds to the variability in reporting. The EBMT, therefore, aimed to clarify the problem by means of a prospective audit involving 25 transplant centers across 13 European countries. Final assessment included 197 patients—109 with multiple myeloma and 88 with non-Hodgkin's lymphoma.

"This audit, which is based on multidisciplinary collaboration of nurses, physicians, and dentists, is the first prospective and robust data on oral mucositis in high-dose melphalan and BEAM conditioning chemotherapy," noted Dr. Blijlevens.

Prospective assessments for oral mucositis were conducted daily, beginning at the start of conditioning until 30 days post transplant or hospital discharge. To achieve high and consistent quality of assessment, all healthcare providers underwent multimedia-assisted, face-to-face training before the study began. The WHO scale was used for assessment of grade.

In the overall population, severe oral mucositis occurred in 44% and ulcerative mucositis occurred in 64%. Severe episodes of oral mucositis, on average, lasted over 5 days and ulcerative mucositis lasted over 6 days. The mean WHO oral mucositis symptom score peaked (at around 1.5) on day 12 after the start of conditioning, corresponding with symptom-specific scores of measurement and dryness. There were no statistically significant associations between oral mucositis incidence or duration and age, gender, or type of disease, but a preliminary multivariate analysis adjusting for other potential predictors confirmed a significant association with both fever ≥ 38° C and longer hospital stay ($P < 0.005$).

"We found that the incidence of severe oral mucositis—44%—is higher than previously reported. Its association with fever and longer hospital stay indicate that this condition has potentially harmful clinical sequelae and relevant economic consequences," Dr. Blijlevens said.

Key Points

- The incidence of oral mucositis is higher than reported previously.
- Associations with fever and length of hospitalization indicate potentially harmful clinical sequelae and relevant economic consequences of these therapies.
- Links with confirmed infection and resource use for management of oral mucositis still must be assessed.

Reference

Blijlevens NNA, McCann S, Bacon P, et al. Prospective Oral Mucositis Audit (POMA): occurrence and consequences of severe oral mucositis in high dose melphalan and BEAM conditioning. Presented at the 48th Annual Meeting of the American Society of Hematology; December 9–12, 2006; Orlando, Florida. Abstract 46.