

Publication

An oral care self-management support protocol (OrCaSS) to reduce oral mucositis in hospitalized patients with acute myeloid leukemia and allogeneic hematopoietic stem cell transplantation: a randomized controlled pilot study.

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INTRODUCTION: Oral mucositis (OM) is a common and debilitating side effect of chemoradiotherapy in patients awaiting allogeneic hematopoietic stem cell transplantation (aHSCT). **PURPOSE:** The aim of this pilot RCT was to compare an oral care self-management support protocol (OrCaSS) to usual pre-aHSCT care. Feasibility was tested, effect sizes calculated for OM (primary outcome), and patient adherence was measured (secondary outcome). **METHODS:** Eighteen AML patients awaiting aHSCT and hospitalized between August 2012 and April 2013 were randomized 1:1 to usual care (UCG) and intervention (IG) groups. The OrCaSS protocol consisted of two sessions of educational and behavioral interventions, the first delivered 1 week pre-admission (T1), the second on admission day (T2). Via field notes, practicability and acceptability were evaluated to explore the feasibility of intervention and study procedures. OM data were collected at T1, T2, and daily for 28 days using the WHO scale. The effect size r was calculated (r less than -0.1 and greater than or equal to -0.3). Patients' adherence to the protocol was assessed at T1, T2, and 8-10 days post-HSCT (T3). **RESULTS:** Research and intervention procedures were feasible. OM incidence was 100 %. The IG's median highest OM grade was 2.0 (IQR=2); the UCG's was 3.0 (IQR=2; $r = -0.1$). Median OM durations were 12 days in the IG and 14 days in the UCG ($r = -0.1$). OM onset was 2 days later in the IG than in the UCG ($r = -0.1$). Over the course of the study, patient adherence decreased in both groups. **CONCLUSIONS:** OrCaSS is a promising intervention to delay and reduce OM. These results can serve to plan a larger RCT.

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