PAIN CAN PREDICT POOR PROGNOSIS IN PATIENTS WITH ORAL SCC. Jun Sato, Yutaka Yamazaki, Akira Satoh, Ken-ichi Notani, Yoshimasa Kitagawa, Hokkaido University, Sapporo, Japan.

Objectives. We have reported that histologic mode of invasion of OSCC is a significant risk factor for spontaneous pain (Odontology 2010). This study was undertaken to elucidate whether cancer pain could be a risk factor to predict a poor prognosis of patients with OSCC.

Methods. A total of 117 patients (85 men, 32 women; mean age 64 years) with untreated OSCC were examined. The primary site of the cancer was the tongue (54 cases), lower gingiva (22 cases), buccal mucosa (14 cases), floor of the mouth (12 cases), upper gingiva (12 cases), and palate (3 cases). The clinical stage of the cancer was stage I in 22 cases, II in 35 cases, III in 20 cases, and IV in 40 cases. Presence or absence of pain in the region of the cancer was confirmed by medical interview at the first visit. We evaluated the relationships between the OS rates and the clinicopathological variables, including gender, age, T-stage, N-stage, the degree of histologic differentiation, the histologic mode of invasion, and pain. OS curves were plotted using the Kaplan-Meier methods. The prognostic significance of factors for OS was analyzed using log-rank test and Cox multivariable proportional hazards regression analysis.

Results. At the first examination, 43 (37%) of the 117 patients reported spontaneous pain. The mean duration of the follow-up period was 39 months. In univariate analysis, the OS rate of patients with pain was significantly lower than that of patients without pain (P = .006). Moreover, univariate analysis revealed that T-stage (P = .0007) and N-stage (P < .0001) were both significantly associated with the OS rate. Multivariate analysis revealed that the spontaneous pain (P = .04, risk ratio: 0.4) and N-stage (P < .0001, risk ratio: 0.1) were independent significant factors for OS.

Conclusions. This study suggests spontaneous pain before treatment may be associated with poor prognosis of the patients with oral squamous cell carcinoma (OSCC).

IMPAIRED SALIVARY FLOW DOES NOT IMPAIR MICONAZOLE BUCCAL TABLET EFFICACY. Rene-Jean Bensadoun, Naomi Musaji, and Pierre Attali, CHU de Poitiers, Poitiers, France.

Objectives. Miconazole buccal tablet (MBT) provides an immediate and sustained release of miconazole into the mouth for local treatment of oropharyngeal candidiasis (OPC). A post hoc analysis evaluated whether reduced salivary flow, resulting from radiotherapy treatment for head and neck cancer (HNC), affects the efficacy of MBT or miconazole oral gel (MOG).

Methods. Radiotherapy-treated HNC patients with OPC were evaluated in an open-label, noninferiority trial comparing 50 mg MBT once daily (n = 107) to 125 mg MOG 4 times daily (n = 106) for 14 days. This post hoc analysis evaluated improvement in OPC lesion and symptom scores (rated on 4-point Murray scale) in patients stratified by baseline salivary flow (absent, partial, normal). The primary efficacy variable was clinical success (CS: disappearance or improvement of lesions by 2 points) at day 14 (D14) in the per-protocol (PP) population (previously reported).

Results. At baseline, 95% of all PP patients had absent or partial salivary secretion and CS for MBT (58%) was not statistically inferior to MOG (55%) (P < .0001). More MBT patients at baseline (n = 22, 21%) had no salivary secretion versus MOG (n = 15, 14%). In these patients, 64% treated with MBT experienced ≥1 point improvement in lesion score versus 53% with MOG (P = .42), and the proportion of patients who were lesion free at D14 was 36% MBT versus 27% MOG. The number of patients with no burning/soreness at D14 increased 23% from baseline with MBT and by 27% with MOG; patients with no odynophagia at D14 increased by 5% with MBT and by 13% with MOG. Patients with partial salivary flow at baseline also demonstrated improvement in lesion and symptom scores. Similar results were obtained in the modified-ITT population.

Conclusions. In the presence of normal or reduced salivary flow, MBT is an effective topical treatment for OPC with the convenience of once-daily dosing.

Data were presented at the Multinational Association of Supportive Care in Cancer Meeting, Vancouver, British Columbia, June 2010.

MODERATE-DOSE ADJUVANT CHEMOTHERAPY TEMPORARILY IMPAIRS ORAL HEALTH-RELATED QUALITY OF LIFE. Siri Beier Jensen, Camilla Kragelund, Anja Weirsøe Dynesen, Henning T. Mouridsen, Jesper Reibel, and Birgitte Nauntofte, University of Copenhagen, Denmark.

Objectives. The aim was to assess if oral adverse effects of adjuvant chemotherapy (CT) in early-stage breast cancer patients have an impact on oral health–related quality of life during and 1 year after treatment.

Methods. Forty-five consecutive breast cancer patients, eligible for adjuvant CT with cyclophosphamide, epirubicin or methotrexate, and 5-fluorouracil were followed before, during, and 6 months and 1 year after CT. Subjective assessment of xerostomia, taste disturbances, oral mucosal, gingival, and dental soreness or pain, as well as objective findings, including unstimulated (UWS) and stimulated (SWS) whole saliva flow rates, oral mucosal erythema and ulceration, gingivitis, and oral candidiasis were examined and related to oral health–related quality of life as assessed by the Oral Health Impact Profile (OHIP). Statistical hypotheses testing was performed by fixed-effects model of analysis of variance for OHIP changes over time and Pearson correlation coefficients for testing of correlations of clinical oral adverse effects and OHIP variables.

Results. The subscale scores of functional limitations (P = .002), physical pain (P = .02), physical disability (P = .0001), and psychological disability (P = .04) increased significantly over time indicating a worsening during CT. During CT, xerostomia was correlated with worsening of functional limitation.
(P = .009), physical pain (P = .03), and handicap (P = .03); xerostomia and taste disturbances correlated with physical disability (P = .0005 and P = .02, respectively); and lower UWS was correlated with worsening of psychological discomfort (P = .048). All OHIP domains except from psychological disability had returned to baseline levels at 6 months and 1 year after CT. OHIP domain subscale scores of psychological discomfort, social disability, and handicap did not change significantly over time.

Conclusions. The results suggest that xerostomia, lower UWS, and taste disturbances induced by moderate-dose adjuvant CT in breast cancer patients may impair domains of oral health-related quality of life; however, the effects were temporary and generally had returned to baseline levels 6 months after CT.

Funding sources: Danish Cancer Society.

MOUTHWASH USE AND ORAL CANCER RISK: QUANTITATIVE META-ANALYSIS OF EPIDEMIOLOGIC STUDIES. Peter Boyle, Sara Gandini, Paolo Boffetta, Eva Negri, and Carlo La Vecchia, International Prevention Research Institute, Lyon, France.

Objectives. The potential association between use of mouthwash and an increased risk of oral cancer has been a source of controversy for several decades. In recent times, attention has focused on a role for those mouthwashes containing alcohol. A quantitative analysis of published epidemiologic studies of mouthwash and oral cancer and, specifically, mouthwash containing more than 25% alcohol, was undertaken.

Methods. A comprehensive search for published studies was undertaken in several databases, including the reference lists of the retrieved articles and preceding reviews on the topic. Studies were required to have sufficient information to allow adequate estimation of the RR and 95% confidence intervals (95% CI). Summary estimates were obtained with maximum likelihood estimates from random effects models. Sensitivity analyses were conducted to evaluate the influence of various inclusion/exclusion criteria and specific studies.

Results. Through the literature search strategy outlined previously, 18 full-text articles were found for consideration for inclusion in the meta-analysis. There was no statistically significant association found between regular use of mouthwash and risk of oral cancer (1.13 [0.95-1.35]). There was no significant trend in risk of oral cancer associated with increased daily usage of mouthwash (P = .11). In sensitivity analyses, there was no association found when analysis was restricted to a number of factors, including oral cancer only, smokers, nonsmokers, and when all possible studies were included. There was no association between reported use of mouthwash specifically containing alcohol and risk of oral cancer (RR = 1.0; 95% CI 0.39, 2.60).

Conclusions. This quantitative analysis of all published epidemiologic studies of mouthwash use and oral malignancy revealed (1) no statistically significant association between mouthwash use and risk of oral cancer, including no significant trend in risk with increasing daily use; and (2) no association between use of mouthwash containing alcohol and oral cancer risk.

Funding sources: Johnson and Johnson provided funding for a multidisciplinary meeting to discuss mouthwash use and oral malignancy. None of the authors received any honorarium from any manufacturer.


Objectives. Determine efficacy of BoNT-A in reducing pain associated with primary TN.

Methods. Seventeen subjects meeting criteria were enrolled and randomized to receive placebo (saline) or BoNT-A; investigators and subjects were blind to treatment group. Pain history and distribution, and medication use were recorded. We injected 2.5 U/cm2 BoNT-A or the equivalent volume of saline (placebo) into the region of TN pain. Pain frequency (number of attacks per day), intensity (1-10 scale), and % global pain relief (GPR) were assessed at 4 weeks: responders (>50% GPR) were reevaluated at 8-, 12-, 16-, and 24-week intervals. For all nonresponders at week 4, randomization code was broken: placebo subjects crossed over to active BoNT-A and nonresponders previously receiving BoNT-A were given a booster dose of 2.5 U/cm2 and assessed at 4, 8, 12, 16, and 24 weeks after injection. This study was approved by the New York University institutional review board for human research.

Results. Twelve female and 5 male subjects (mean age 57.7 ± 12.1 years) completed the study. Distribution of pain by dermatome: 16 unilateral, 1 bilateral; 10 with single and 7 with multiple dermatomes; affecting V1 (4), V2 (13), V3 (8). Because placebo nonresponders cross over, there are more BoNT-A interventions than placebo: 8 placebo and 15 BoNT-A interventions were completed. Responders (primary definition >50% GPR) were 11/15 BoNT-A (active) (mean GPR 71%) and 2/8 placebo (mean GPR 95%) (P < .05 Fisher’s exact test, 2 tailed); mean GPR for nonresponders was 11.7%. Mean change in pain frequency was 55.7% and 89.6% decrease for BoNT-A and placebo responders, respectively, and 16% decrease for nonresponders. Mean change in pain intensity was 52.2% and 80.0% decrease for BoNT-A and placebo responders, respectively, and 3.4% increase for nonresponders.

Conclusions. This study suggests that BoNT-A may provide significant pain relief (>50% GPR) for classical TN compared with placebo.

Funding sources: Allergan, Inc and NYUCD Student Research Program.

Data were presented in part at the International Association for Dental Research Meeting, San Diego, CA, March 2011.

CHARACTERIZATION OF ORAL INVOLVEMENT IN ACUTE GRAFT-VERSUS-HOST DISEASE. DI Ion, K Stevenson, SB Woo, R Soiffer, JH Antin, and NS Treister, Brigham and Women’s Hospital, Boston, MA.

Objectives. Acute graft-versus-host disease (aGVHD) is a major complication of allogeneic hematopoietic cell transplantation (HCT). The purpose of this study was to characterize the oral features associated with aGVHD.

Methods. Patients who underwent allogeneic HCT at Dana-Farber/Brigham and Women’s Cancer Center (Boston, MA) between 1995 and 2010 and developed prominent oral aGVHD were identified. Data were collected from patient medical records and analyzed descriptively.

Results. Eighteen cases were identified, of which 5 (28%) demonstrated only oral features; the remaining 13 had variable involvement of skin (13/18, 72%), liver (6/18, 33%), and gut (5/18, 28%). Oral mucositis preceded aGVHD in 10 (56%)

Funding sources: Johnson and Johnson provided funding for a multidisciplinary meeting to discuss mouthwash use and oral malignancy. None of the authors received any honorarium from any manufacturer.