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 25% alcohol, was under-

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/exclu-

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 and oral cancer and, specifically, mouthwash containing more than 25% alcohol, was under-

Funding sources: Danish Cancer Society.


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 nonre-

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%)
patients. The median time to onset of oral aGVHD was 34 days (range 11-159). Sites affected by nonspecific ulcerations included the tongue (16/18, 89%; dorsum in 7/18), buccal mucosa (16/18, 89%), labial mucosa (13/18, 72%), palate (12/18, 67%; hard palate in 7/18), and floor of mouth (6/18; 33%); 7 (39%) cases presented with prominent lip ulceration and crusting. Salivary gland disease features included severe hypofunction (1/18; 6%) and palatal mucoceles (1/18; 6%). In addition to systemic therapies, topical preparations of dexamethasone (10/18; 56%), tacrolimus (7/18; 39%), and morphine (3/18; 17%) were used for ancillary support. Of the 13 (72%) patients who survived beyond day 100, 2 developed oral cGVHD.

Conclusions. Oral features of aGVHD include extensive nonspecific ulcerations of keratinized and nonkeratinized mucosa and are often observed in the context of concurrent skin, liver, and gut involvement. Intensive topical therapies may be helpful in reducing symptoms and promoting healing. Concurrent salivary gland involvement appears to be infrequent. Oral medicine specialists should be aware of this potential complication of allogeneic HCT, and can play an important role in both its diagnosis and management.

Data were presented at the European Association of Oral Medicine Meeting, London, September 2010.

**Efficacy of Miconazole Buccal Tablet in Severe Oropharyngeal Candidiasis.** L.L. Patton, J. B. Epstein, N. Musaji, and P. Attali, University of North Carolina, Chapel Hill, NC

**Objectives.** This post hoc analysis of the Study of Miconazole Lauriad Efficacy and Safety (SMiLES) evaluated efficacy of MBT and CT according to the extent and severity of oropharyngeal candidiasis (OPC) lesions and symptoms of erythema and palatal mucoceles (1/18; 6%). In addition to systemic therapies, topical preparations of dexamethasone (10/18; 56%), tacrolimus (7/18; 39%), and morphine (3/18; 17%) were used for ancillary support. Of the 13 (72%) patients who survived beyond day 100, 2 developed oral cGVHD.

Conclusions. Oral features of aGVHD include extensive nonspecific ulcerations of keratinized and nonkeratinized mucosa and are often observed in the context of concurrent skin, liver, and gut involvement. Intensive topical therapies may be helpful in reducing symptoms and promoting healing. Concurrent salivary gland involvement appears to be infrequent. Oral medicine specialists should be aware of this potential complication of allogeneic HCT, and can play an important role in both its diagnosis and management.

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**Objectives.** This post hoc analysis of the Study of Miconazole Lauriad Efficacy and Safety (SMiLES) evaluated efficacy of MBT and CT according to the extent and severity of oropharyngeal candidiasis (OPC) lesions and symptoms of erythema and burning/soreness at baseline to determine if efficacy differed in patients with severe OPC (defined as extensive lesions or moderate/severe symptoms).

**Methods.** SMiLES was a noninferiority, double-blind, multicenter study of HIV-positive patients with OPC randomized to 50 mg MBT once daily or 10 mg CT 5 times/day. The primary efficacy end point was clinical cure, defined as complete resolution of OPC signs/symptoms, after 14-days of treatment (at Test of Cure visit). This post hoc analysis investigates clinical cure and relapse rates at day 35 based on patients’ severity of symptoms at baseline.

**Results.** The primary efficacy analysis for clinical cure among 577 subjects demonstrated MBT (176/290; 61%) was not inferior to CT (187/287; 65%), with treatment difference -0.045 (95% CI: -0.12-0.03). At baseline, lesion extent by treatment group was as follows: MBT: 13% single, 54% multiple, and 33% extensive lesions, versus CT: 13% single, 59% multiple, and 28% extensive lesions. At baseline, symptom profile by group was as follows: for MBT: 13% none, 58% mild, and 29% moderate/severe symptoms, versus CT: 14% none, 55% mild, and 31% moderate/severe symptoms. For the patients with extensive OPC lesions at baseline, 54% MBT and 48% CT achieved clinical cure, and 35% MBT and 41% CT relapsed. When baseline symptoms were either moderate or severe, 60% MBT and 45% CT achieved clinical cure.

Conclusions. MBT once daily can effectively treat patients with severe OPC. This study showed topical azoles have utility even in severe OPC in HIV-positive subjects.

**ORAL CONDITIONS IN CANCER PATIENTS RECEIVING HOSPICE CARE.** Dena J. Fischer, Joel B. Epstein, and Diana J. Wilkie, University of Illinois at Chicago, Chicago, IL.

**Objectives.** Cancer patients at the end of life are suffering with advanced disease, at which time the focus of care is on quality of life. Oral health plays an essential role by contributing to symptom management, social interaction, and nutritional intake. The purpose of this study was to characterize the presence, severity, and functional impact of oral health conditions in advanced cancer patients in hospice care.

**Methods.** Seventy-five subjects with various cancers (mean age 64.3 ± 16.4 years, 44% male) participated in this prospective, observational study. Subjective measures included xerostomia and oral pain intensity and impact (0-10 scale), xerostomia correlates, orofacial pain, taste, and functional (FUNC) and social (SOCIAL) impact (1-5 scale). Objective indicators included salivary hypofunction, fungal infection, stomatitis and ulcerations. SPSS was used for descriptive and comparative statistics (ANOVA, χ²).

**Results.** Subjective xerostomia scores were the greatest (3.0 ± 0.9), followed by taste change (2.8 ± 1.4), FUNC (2.4 ± 0.8), orofacial pain (1.9 ± 0.8), and SOCIAL (1.7 ± 0.9). Measures of xerostomia, taste, and FUNC were significantly greater than orofacial pain and SOCIAL (P < .02). Xerostomia had a significantly greater impact on daily functions (2.8 ± 2.6) than oral pain (2.0 ± 2.5; P < .03). Thirty-seven percent of subjects rated their oral health worse than physical health. Objective findings revealed that 77% of subjects had candidiasis, 65% stomatitis, 29% ulcerations, 35% caries, and 28% moderate/severe gingival inflammation. Salivary hypofunction was mild in 14% of subjects, moderate in 47%, and severe in 39%. Compared with subjects without mucosal ulcerations, those with ulcerations reported high orofacial pain (F = 7.99, P < .01) and SOCIAL (F = 4.24, P < .05) scores. Poor oral hygiene predicted greater severity of fungal infection (χ² = 6.83, P < .05).

Conclusions. Salivary hypofunction was a universal finding, and oral conditions were prevalent in this population. Positive objective findings predicted increased oral symptoms. Recognition and management of oral conditions may decrease symptom burden and improve social interaction for vital life closure activities.

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Data were presented at the International Association for Dental Research Meeting, Barcelona, Spain, July 2010.