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 increasing daily use 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.

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BOTULINUM TOXIN-A (BONT-A) IN TRIGEMINAL NEURALGIA (TN): OUTCOME OF PLACEBO-CONTROLLED RCT. David Siros, Monika Epler, Maryam Toufani, and Andrew Blitzer, New York University, New York. 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.

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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%)...