Period (P = .95). The mean duration of new RAS episodes was also similar between the 2 arms (9.01 days in the multivitamin arm vs 9.49 days in the placebo arm) (P = .82). Furthermore, there were no differences in mouth pain, normalcy of diet, and study medication compliance between the 2 arms. There were no adverse events associated with multivitamin use.

Conclusions. Daily multivitamin supplementation, with the RDI of the essential vitamins, showed no benefit for reducing the number or duration of RAS episodes.

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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 at baseline by 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 Weirsoe 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.