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Phase II Clinical Trial of Celecoxib in Addition to Standard Therapies for Primary Oral Cancer

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Solid tumor overexpression of cyclooxygenase-2 (COX-2) has been associated with worse outcome in head and neck squamous-cell carcinoma (HNSCC). In the pre-clinical trials, we have investigated that the selective COX-2 inhibitor celecoxib showed preventive effects against cancer progression and occurrence of oral squamous cell carcinoma. Additionally, we found that increasing the daily dose and medication time of celecoxib decreased risk in development of oral cancer in a retrospective cohort study.Patients with oral cancer (concurrent radiotherapy and/or cisplatin with or without celecoxib in patients with primary oral squamous cell carcinoma) were preregistered as a phase II clinical trial in the ClinicalTrials.gov, and the patients were assigned to group with (200 mg per day) or without celecoxib treatment for 6 months. The primary objective was to elucidate the improvement of celecoxib use in relapse-free survival after a 6-month treatment. To date, the study was enrolled 83 treated and 300 untreated patients. There were no significant differences between treated and untreated patients at surgery age, gender, substance use of alcohol drinking, betel chewing and cigarette smoking, radiotherapy, chemotherapy, cancer site and stage, and clinical risk features. The finding showed the risk of mortality in patients with oral cancer was significantly decreased after a complete treatment of celecoxib, comparing with untreated patients (p=0.0061).However, the log-rank test in survival analysishas not yet to reach a significantly preventive effect on the risk of mortality in treated patients after a 36-month follow-up starting from the first participant in the study(p=0.0620).A sustained effort to get larger sample sizeand longer follow-up period is ongoing for elucidating whether patients with oral cancer could actually benefit from celecoxib use.