Background

Patient groups were compared with respect to the distribution of:

- The performance of the marker panel developed using data from the
- Salivary soluble CD44 (solCD44), a tumor initiating marker
- Each year 50,000 individuals in the United States and 500,000 worldwide are
- Did not meet inclusion criteria (Excluded
- In untreated areas, CD44 and total protein were significantly associated with cancer status. The AUC was improved to 0.783 in a multivariable model including adjustments for important variables and their interactions (Table 2).
- Analysis using multivariate recursive partitioning resulted in a reference group and 4 risk groups for cancer (Table 3).
- Sensitivity was 60.7% for Stages I+IV and 85% for Stage I. Specifically, 48.7% for the hospital-based cohort. For the target screening group, specificity was 74% (n=150) after one baseline evaluation but reached 96% in subjects retested at one year.
- Based on multivariate analysis including tumor stage, age, gender, race and ethnicity, and SES hospital-based cases with CD44 levels ≥ 0.33 ng/ml, had reduced PFS and OS compared with cases in the reference group. Kaplan-Meier curves shown in Figure 2.

Methodology

- A case-control, hospital-based design with 150 oral cavity (OC) and oropharyngeal (OP) cases and 150 frequency-matched controls was used to determine whether salivary CD44 (CD44) and total protein levels in oral rinses were associated with oral cancer independent of age, gender, race, ethnicity, tobacco and alcohol use, and socioeconomic status (SES).
- The performance of the marker panel developed using data from the hospital-based case-control study, was evaluated in 150 participants from a large screening target community previously determined to be at elevated risk for oral cancer due to poverty and smoking.
- Levels of solCD44 (normal and variant forms) were measured using a sandwich ELISA assay (Abbreviata, Inc), with previously published modifications (1). We performed the DC protein assay (Bio-Rad Laboratories) according to the manufacturer’s protocol using saliva samples prepared as previously published. Each sample was tested in duplicate and the technician was blinded to disease status.
- Patient groups were compared with respect to the distribution of potentially important categorical covariates. Logistic regression analysis and multivariate recursive partitioning was used to assess the association between markers and the risk for oral cancer. Odds ratio (OR) estimates were reported with corresponding 95% confidence interval (95%CI) and area under the curve (AUC) of the receiver operating characteristic curve (ROC) for fitted models. Kaplan-Meier and Cox regression models were used to evaluate progression-free survival (PFS) and overall survival (OS). Hazard ratio (HR) estimates and corresponding 95% CI are reported (SAS v9.2 and R packages).