Title: Presence of Frank's Sign: A Comparative Evaluation in Smokers and Non-Smokers

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Study Design and Ethical Approval

This study was conducted as a cross-sectional study with a control group in the outpatient clinics of the Department of Family Medicine at Samsun University Faculty of Medicine (Smoking Cessation, Family Medicine, Traditional and Complementary Medicine, Home Health Services, and Obesity Clinics). Ethical approval for the study was obtained from the Samsun University Non-Interventional Clinical Research Ethics Committee (Approval No: 2024/11/1, Date: 05/06/2024).

Study Population and Sample

The study population consisted of all individuals aged 40–59 years presenting to the clinics. Considering data from previous periods, approximately 2,000 presentations were anticipated over a 6-month period. The minimum sample size was calculated as 323 participants, with a 95% confidence level and a 5% margin of error.

Data Collection

The participants' sociodemographic data, histories of chronic diseases, medication use, family histories, and smoking habits were recorded by the researchers via face-to-face interviews (average duration: 5 min). Digital photographs obtained from both ears in a well-lit environment (Figure 1b) were evaluated by the study researchers (SM, EA, OÖ). The presence of FS and its staging according to the Modified Patel–Lopez classification were confirmed by a positive assessment from at least two researchers (Figure 1a).

Inclusion and Exclusion Criteria

Individuals aged 40–59 years who presented to the relevant outpatient clinics were included in the study. The exclusion criteria included being outside the specified age range, the presence of an earring or piercing on the earlobe, a history of trauma affecting the integrity of the ear, the presence of soft tissue diseases, or ear malformations.

Statistical Analysis

The analyses were conducted using SPSS 26.0. Descriptive data were presented as mean ± standard deviation and percentages. The normality of distribution was assessed with the Kolmogorov–Smirnov test. Student's *t*-test was used for comparisons between two groups, ANOVA for comparisons between multiple groups, and the Chi-square test was used for comparison of categorical variables. A p-value <0.05 was considered statistically significant.