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Head Neck. 2003 Nov;25(11):911-21.

The utility of tlonium chloride rinse in the diagnosis of recurrent or second primary cancers in patients with prior upper aerodigestive tract cancer.

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Abstract

BACKGROUND: The clinical utility of tlonium chloride rinse was compared with unaided visual examination alone in the diagnosis of oral carcinoma in patients previously treated for carcinoma of the upper aerodigestive tract.

METHODS: A total of 668 patients were enrolled in this multicenter study. At each site, an oral clinical visual examination was completed by one investigator followed by tlonium chloride rinse and examination by a second investigator blinded to the examination findings of the first investigator. If a lesion was considered suspicious (urgent biopsy required at the first visit), the lesion was biopsied after tlonium chloride rinsing. Patients with lesions characterized at the first visit as not suspicious (biopsy not urgent) or that stained with tlonium chloride were asked to return for a second visit. At the second visit, any residual lesion or lesions that retained tlonium chloride were biopsied.

RESULTS: A total of 96 biopsies was performed in 81 of the 668 patients (12.1%), of which 30 (31.3%) were diagnosed histologically as carcinoma/carcinoma in situ (CIS) and the remainder as inflammation (31.3%), keratosis (26.6%), dysplasia (21.9%), ulcer (2.1%), other (3.1%), or no abnormality (1.0%). Of the 30 lesions with the diagnosis of carcinoma/CIS, 12 (sensitivity 40.0%) were considered to be clinically suspicious (CS+), whereas 29 (sensitivity 96.7%) retained tlonium chloride ($p = .0002$). The predictive values of a positive test for clinical examination and tlonium chloride staining were similar (36.4% vs 32.6%; $p = .5871$), indicating that the greater sensitivity of tlonium chloride was not associated with an excessive number of unnecessary biopsies (false positives).

CONCLUSIONS: Tlonium chloride rinse is more sensitive than clinical examination alone in detecting lesions that might be found on biopsy to be

carcinoma or CIS. The increased sensitivity is largely attributed to lesions that stain but were not detected clinically on visual examination.

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PMID:14603451[PubMed - indexed for MEDLINE]

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