Point of Care Device/Lab based assay for Screening and Diagnosis of Oral Cancer
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BACKGROUND

Oral cancer is the 6th most common cancer in the world today, with 350,000 annual deaths worldwide (11,000 in US). In India, it is number 1 cancer in males and number 3 cancer in females, partly as a result of the widespread use of gutka, a carcinogenic stimulant similar to nicotine. Unfortunately, most oral cancers are not diagnosed until they have reached an advanced stage. At present, oral cancer is diagnosed by scalpel biopsy, followed by a pathology review. This diagnosis is costly, invasive and subjective, which creates an unmet need for a rapid, low-cost, non-invasive, objective screening of oral cancer.

Researchers at Case Western Reserve University discovered that the ratio between the proteins, human beta defensin 3 (hBD-3) and human beta defensin 2 (hBD-2) can detect early signs of oral cancer in suspicious lesions of the oral cavity. Based on this discovery, they are developing a Lab based assay along with a point-of-care test that are cost-effective, reliable and non-invasive.

TECHNOLOGY

The proposed point of care device consists of a microfluidic chip to analyze cell samples collected with a cytobrush from 1) a suspected lesion and 2) healthy tissue on the opposite side. The ratio of two analytes (hBD-3:hBD2) is measured in the samples to provide a score that can indicate whether the lesion is cancerous or not. Results can be analyzed with a handheld device coupled to a smart phone.

ADVANTAGES

Non-invasive Biomarker Test
• Robust and specific assay
• Can allow oral cancers to be identified at a much earlier stage to improve survivability
• Can determine whether a biopsy is needed
• Can be used for continued monitoring of lesions

Lab based Assay/Point of Care Device
• Can be performed in any dental or ENT clinic as part of oral health check-up
• Provides rapid, objective results in one day (Lab based)/30 minutes (POC)
• 1/10th cost of biopsy.

INTELECTUAL PROPERTIES
• U.S. Patent 8,076,088
• PCT/US2016/066972

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