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Title:
qMIDS: A Digital Diagnostic Test for Oral Cancer

Abstract:

Introduction: A critical surgical goal for oral cancer is achieving negative resection margins with no residual malignant cells, to prevent disease recurrence. The quantitative Malignancy Index Diagnostic System (qMIDS) is the first FOXM1 oncogene-based diagnostic test developed for quantifying oral squamous cell carcinoma. This highly sensitive technique converts gene expression into a digital index to quantify cancer risk.

Methods: qMIDS compares total expression of 16 genes with median normal gene expression levels. Real-time absolute quantitative PCR is used for mRNA transcript quantification. By conversion of gene levels via the qMIDS algorithm into a metric 'malignancy index' score, risk of a given biopsy sample becoming cancerous can be quantified. This project aimed to validate a faster version of the qMIDS protocol, taking less than 90 minutes to obtain diagnostic results.

Results: Testing OSCC patient biopsies from normal margin and tumour cores, results demonstrate a high detection rate (>90%) and low false positive rate (<3%), indicating good test performance at a qMIDS cut-off of 4.0. qMIDS is capable of segregating the malignancy status of OSCC clinical tissue biopsies with a high degree of confidence ($p < 0.001$). Molecular tissue topology can also be reconstructed using qMIDS on surgical samples for margin assessment and determination of tumour heterogeneity.

Conclusion: The qMIDS assay robustly measures a FOXM1-driven oncogenic program in OSCC to quantify malignancy. Benefits include its objectivity as a reproducible, diagnostic method to quantitatively measure the malignancy of a biopsy tissue sample based on digital molecular profile in HNSCC diagnosis and tumour margin analysis.