



Extended Abstract

# Clinical Validation of 13-Gene DNA Methylation Analysis from Oral Brushing: A Non Invasive Sampling Procedure for Early Detection of Oral Squamous Cell Carcinoma. A Multicentric Study †

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## 1. Introduction

In a recent study our research group described a non-invasive sampling procedure based on DNA methylation analysis of a set of 13 genes with a high level of accuracy (sensitivity 96.6%, specificity 100%) in the detection of squamous cell carcinoma of the oral cavity (OSCC) [1].

The purpose of the present study was to test the diagnostic performance of this non invasive sampling procedure in an italian multicentric study.

## 2. Materials and Methods

Oral brushing specimens were collected in ten different Italian units of oral medicine. Each oral medicine unit collected blindly 10 brushing specimens from patients affected by OSCC and an equal number of age and sex-matched healthy controls. 13-gene DNA methylation analysis was performed and each sample was considered positive or negative in relation to a predefined cut-off value.

## 3. Results

181 out of 200 planned specimens were analyzed. DNA could not be amplified in 4 cases (2.2%). 86/93 (92.5%) specimens derived from OSCC patients were detected as positive and 70/84 (83.3%) specimens derived from healthy donors showed a negative score.

## 4. Conclusions

Data from multicentric study confirmed a high level of sensitivity of our procedure whereas level of specificity is slightly lower if compared to our previous study. These data suggest that our procedure may be proposed as a first level diagnostic test with the aim to avoid a diagnostic delay in Oral Squamous Cell Carcinoma.

**Conflicts of Interest:** As a possible conflict of interest, L. Morandi and D.B.G. submitted a patent (the applicant is the University of Bologna) in November 2016 to the National Institute of 398 Industrial Property; however, we believe that this is a natural step of translational research (bench-to-bedside) 399 and guarantee that the scientific results are true. The remaining authors declare that they have no competing 400 interest.

## References

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