



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 [†]

Davide B. Gissi ^{1,*}, Umberto Romeo ², Gianluca Tenore ², Monica Pentenero ³,
Giuseppina Campisi ⁴, Rodolfo Mauceri ⁴, Giuseppe Colella ⁵, Roberto De Luca ⁵, Rosario Serpico ⁶,
Dario Di Stasio ⁶, Giacomo Oteri ⁷, Paolo Vescovi ⁸, Michele D. Mignogna ⁹, Noemi Coppola ⁹,
Andrea Santarelli ¹⁰, Luca Morandi ¹¹ and Lucio Montebugnoli ¹

- ¹ Department of Biomedical and Neuromotor Sciences, Section of Oral Sciences, University of Bologna, 40159 Bologna, Italy; lucio.montebugnoli@unibo.it
 - ² Department of Oral and Maxillofacial Sciences, "Sapienza" University of Rome, 00100 Rome, Italy; umberto.romeo@uniroma1.it (U.R.); gianluca.tenore@uniroma1.it (G.T.)
 - ³ Oral Medicine and Oral Oncology Unit, Department of Oncology, University of Turin, 10043 Orbassano, Italy; monica.pentenero@unito.it
 - ⁴ Department of Surgical, Oncological and Stomatological Disciplines, Sector of Oral Medicine, University of Palermo, 90127 Palermo, Italy; giuseppina.campisi@unipa.it (G.C.); rodolfo.mauceri@unipa.it (R.M.)
 - ⁵ Multidisciplinary department of Medical, Surgical and Dental Specialty, Maxillofacial Surgery Unit, University of Campania "Luigi Vanvitelli", 80100 Naples, Italy; giuseppe.colella@unicampania.it (G.C.); robertodeluca89@yahoo.it (R.D.L.)
 - ⁶ Multidisciplinary Department of Medical-Surgical and Dental Specialties, University of Campania "Luigi Vanvitelli", 80100 Naples, Italy; rosario.serpico@unicampania.it (R.S.); dario.distasio@unicampania.it (D.D.S.)
 - ⁷ Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina, University Hospital "Gaetano Martino", 98124 Messina, Italy; oterig@unime.it
 - ⁸ Department of Medicine and Surgery, Oral Medicine and Laser Surgery Unit, University of Parma, 43100 Parma, Italy; paolo.vescovi@unipr.it
 - ⁹ Head & Neck Clinical Section, Department of Neuroscience, Reproductive and Odontostomatological Sciences, Federico II University of Naples, 80138 Naples, Italy; mignogna@unina.it (M.D.M.); noemi.coppola91@gmail.com (N.C.)
 - ¹⁰ Department of Clinical Sciences and Stomatology, Marche Polytechnic University, 60121 Ancona, Italy; andrea.santarelli@staff.unipvm.it
 - ¹¹ Department of Biomedical and Neuromotor Sciences, Functional MR Unit, IRCCS Istituto delle Scienze Neurologiche di Bologna, University of Bologna, 40139 Bologna, Italy; luca.morandi2@unibo.it
- * Correspondence: davide.gissi@unibo.it; Tel.: +39-0512088123
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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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