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O0246 Evaluation of PreTect HPV-Proofer (PreTect AS) and QuantiVirus® HPV E6/E7 RNA (DiaCarta) for the detection of human papillomavirus mRNA in oropharyngeal carcinomas

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Background Human papillomavirus (HPV) has emerged as an important factor leading to oropharyngeal cancer with distinct clinical characteristics and outcomes. The accurate establishment of the HPV involvement becomes fundamental for the diagnosis of these types of carcinomas in order to provide an adequate management of the disease. In this study, we evaluated the clinical performance of two assays in the detection of HPV-mRNA in formalin fixed paraffin embedded (FFPE) oropharyngeal cancer tissue samples.

Materials/methods: We analyzed 65 FFPE samples from oropharyngeal squamous cell carcinomas obtained at our hospital from 2005-2016. Two assays were evaluated: PreTect HPV-Proofer (PreTect AS), that performs direct genotyping of E6/E7 mRNA from HPV types 16, 18, 31, 33, and 45; and QuantiVirus® HPV E6/E7 RNA (DiaCarta), that detects 14 high-risk HPV types with HPV16 and HPV18 genotyping. Deparaffinization of the samples for PreTect HPV-Proofer testing was performed using MagCore® Genomic DNA FFPE One-Step Kit 405 (RBCBioscience) on one 10 µm-section of FFPE tissue. Pretreatment and deparaffinization of the samples for QuantiVirus® HPV E6/E7 RNA is not disclosed.

Results: Overall, the number of E6/E7 mRNA-positive samples was 14 (21,5%): QuantiVirus and PreTect HPV-Proofer detected detected viral mRNA in 12 (18,5%) and 11 (16,9%) samples respectively. All of the cases corresponded to single-type detection. The positivity rate with QuantiVirus, that did not yield invalid results, was 18,5%. PreTect HPV-Proofer's positivity rate was 16,9%, as the results for two samples were invalid. The concordance between assays, determined by the Cohen's κ value, was substantial (κ=0.730, IC 95%= 0.51-0.95), with general, positive and negative percent agreements of 92.1%, 75.0% and 96.1% respectively.

Concerning the genotyping identification, QuantiVirus and PreTect HPV-Proofer detected HPV-16 in 10 (83.3%) samples each. Additionally, one high-risk HPV-type was detected by QuantiVirus, and one HPV31 was identified by Pretect HPV-Proofer.

Conclusions: Although nucleic acid degradation in FFPE samples presents a challenge for mRNA testing, QuantiVirus and PreTect HPV-Proofer showed a comparable performance in the detection of HPV-mRNA, with substantial agreements. Both of them, targeting the most frequent HPV types associated to oropharyngeal carcinomas, appear as reliable tools useful in the diagnosis of HPV-related oropharyngeal cancer.