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Association of buccal MN cytome assay biomarkers with disease and their relevance for clinical studies

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Micronucleus (MN) test in exfoliated buccal cells is widely applied with different purposes, mostly to assess the genotoxic impact of environmental and occupational exposure to genotoxic agents. In the last years the investigations on a potential clinical application of the assay, mainly in patients with oral cancer and oral premalignant lesions, substantially increased. Given the limited extent of clinical data concerning MN frequency in buccal cells, results on buccal cells were compared with MN frequency in lymphocytes in cancer and non-cancer diseases, and will be discussed extensively. In all diseases examined, MN in lymphocytes and exfoliated cells were higher than in controls, with the exception of prostate cancer. The ratio of MN frequency in subjects with disease vs controls in lymphocytes (2.3 and 2.0 for non-cancer diseases and cancer, respectively) was significantly lower than the corresponding estimates observed in exfoliated cells (3.6 and 6.1). The best association was found for those cases in which MN were measured in cells from the same tissue in which cancer was diagnosed (i.e., oral cancer). How to validate and translate the application of MN assays into clinical practice will be discussed, and a possible roadmap driving this process will be illustrated. Critical steps are the following: a) differentiate disease patients from unaffected individuals and identify important variables that can modify the MN biomarker in healthy and disease subjects; b) drive the transition from the use of MN assays at group level to the individual level; and 3) run prospective cohort studies and randomised controlled trials to verify that MN assays are predictive of disease and that MN frequency modification alters disease outcomes. Pragmatic trials will also be required before inclusion in routine clinical practice, to provide the decisive evidence to support their adoption by the medical and public health community.