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Application of mass spectrometry imaging in the diagnosis of difficult melanocytic lesions

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In a previous study, we identified differences on a proteomic level between Spitz nevus (SN), a type of benign mole, and Spitzoid melanoma (SM), melanoma that histologically mimics SN. Five peptides, comprising a specific proteomic signature, were differentially expressed by the melanocytic component of SN and SM in formalin-fixed, paraffin-embedded tissue samples. We sought to determine whether mass spectrometry imaging (MSI) could assist in the diagnosis and risk stratification of Atypical Spitzoid Neoplasms (ASN), lesions that show histologic features of both, benign SN and SM, and for which a definitive diagnosis of benign or malignant cannot be made with absolute certainty. We performed MSI in a large series of cases of ASNs with known clinical follow-up. In each case, we compared the diagnosis rendered by MSI with the histopathologic diagnosis and also correlated the diagnoses with clinical outcome. Patients were divided into four clinical groups representing best to worst clinical behavior. The association among MSI findings, histopathologic diagnoses, and clinical groups was assessed. When analyzing ASNs, for which neither melanoma nor nevus was favored histopathologically, MSI appeared to be more accurate in predicting the benign character of ASNs than histopathology and correlated better with their clinical behavior. Histopathology often over diagnosed either atypical features or malignancy. We found a strong association between the diagnosis of SM by MSI and an adverse clinical outcome when clinical group 1 (no recurrence or metastasis beyond a sentinel node) was compared with groups 2, 3, and 4 (recurrence of disease, metastases or death). In addition, the diagnosis of SM by MSI was statistically strongly associated with adverse clinical behavior. MSI analysis using a proteomic signature may be able to provide more reliable diagnosis and clinically useful and statistically significant risk assessment of ASNs, beyond the information provided by histology and other ancillary techniques.

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Role of GC-MS and LC-MS/MS in pharmaceutical industry with special reference to Quantification of genotoxic impurities

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Pharmaceutical genotoxic impurities (PGIs) may induce genetic mutations, chromosomal breaks (rearrangements) and they have potential to cause cancer in human was observed by Bolt et al.1 Jacobson and McGovern2 investigated that exposure to even low levels of such impurities present in final active pharmaceutical ingredient (API) may be of significant toxicological importance. Hence it is important for process chemists to avoid such genotoxic impurities in the manufacturing process3. However, it would be difficult or impossible to eliminate PGIs completely from the synthetic scheme. Therefore, it is a great challenge to analytical chemists to develop an appropriate analytical method to quantify the impurity accurately and control their levels in APIs. According to the European Medicines Agency (EMEA) and feedback from US Food and Drug Administration (USFDA) the proposed use of a threshold of toxicological concern (TTC), it is accepted that genotoxic impurities will be limited to a daily dose of 1.0– 1.5 µg/day4,

The present study was undertaken to develop a sensitive and rapid LC-MS/MS method for the determination of genotoxic impurity in Esmolol Hydrochloride API and the quantification of genotoxic impurity in Ketobomodine hydrochloride using GC-MS technique. The newly developed methods were validated according to ICH guidelines.

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