MOLECULAR PRESCREENING VS. UNSELECTED CLINICAL TRIALS FOR CANCER PATIENTS IN A TERTIARY ONCOLOGY DEPARTMENT

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Aim: Introduction: In the recent years the use of molecular biomarker–based in patient tumour samples has become more frequent for novel agents entering clinical development. However this strategy does not seem to translate into greater clinical benefit. Our study analyses the current clinical trial development scenario and if there are differences in terms of clinical results for patients participating in clinical trials (CTs) that require molecular prescreening comparing to patients who participate in unselected CTs.

Methods: All clinical studies for patients with cancer refractory to standard therapy from Jan to Dec 2013 participating in our Clinical Trials Unit were analysed. Electronic medical records of patients enrolled in clinical trials according to molecular prescreening results, tumor type, previous lines of chemotherapy and number of cycles and best clinical response to the novel agent were recorded retrospectively. We analysed if molecular screening were performed in formalin-fixed, paraffin-embedded (FFPE) or in fresh biopsy samples.

Results: A total of 126 patients with metastatic disease were treated in 34 CTs. Of those, 26,5% were phase I, 38,2% were phase II and 26,5% were phase III. 48,8% CTs were performed in melanoma cancer patients, 17,5% in colon cancer pts, 13,5% in stomach-esophagus pts, 7,9% in breast and ovarian cancer pts each one, and in less percentage CTs were done in head and neck, pancreas and GBM cancer pts. 73% CTs required a mandatory biopsy for molecular screening, 50% were from archival tumour sample and 50% were from fresh biopsy. The median number of cycles were 4. Best complete response was CR 2,38%, PR 22,2%, SD 18,2%, PD 23,8% and 33,3% non evaluable. We did not observe any significant difference with regards median of treatment cycles nor response between CTs with molecular prescreening and those unselected CTs. Furthermore, there were no difference with regards clinical response between CTs using archival tumour samples vs. CTs using fresh biopsy.

Conclusions: Molecular prescreening does not seem to add clinical benefit comparing to unselected CTs. More robust preclinical validation is required to better identify reliable molecular markers to predict clinical response.

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