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Retrospective Review of 374 Samples, Circulating DNA; As a Biomarker Assay to Support Clinical Management in Solid Tumors Treated with Multi Targeted Epigenetic Therapy (MTET)

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INTRODUCTION

Our current understanding of cancer biology and epigenetic science has transformed our ability to provide therapies more precisely to genetic and epigenetic targets causing tumor growth and disrupting its behavior. In concert with our efforts to regulate the transcription of altered genes involved in tumor biology, we have focused on a range of epigenetically regulated motor genes that control key molecular targets of the tumor, involved in its growth and metastases. Statistical analysis of the targets determined by epigenesis showed an improvement in the results compared to the historical control.

Unfortunately, epigenetic targets are expressed dynamically and no drug can be used clinically to target the epigenome because drugs have a static mechanism of action. This limiting factor has led researchers in the field to admit their failure in the development of an epigenetic formula or product having a significant clinical impact in the majority of types of cancer, mainly solid tumors. As a result, the effort to develop epigenetic drugs has shifted in recent years to hematological cancers, such as lymphomas and leukemias, where these drugs can make a difference in the clinic.

We had previously shown that a combination of histones and selective DNA demethylators used in a specific protocol was capable of significantly producing significant results in our experimental therapeutic models. Although cytotoxic therapies and targeted drugs have been studied in recent years to correlate with such relevance, the use of liquid biopsy in different types of cancer, including lung, lymphoma, kidney cancer, cancer breast cancer, colon cancer, ovarian cancer, this is to our knowledge the first time that this correlation with epigenetic drugs has been explored.

Materials and Methods

173 cases treated by MTET were collectively selected without selection bias. These cases were treated all in associated clinics of Medical centers of Hope.

The biomarker assays were performed through liquid biopsy through 374 samples. Amongst them 300 samples were positive for circulating DNA. 74 were negative. 66 patients had one sample and 63 patients had at least two samples Detection rate was 86 percent. The most and least common tumor types: 134 cases had breast cancer. 4 had glioblastoma. 20 cases carried BRCA alterations.

In average 64 percent of such cases were stage four and had no other viable options left.

Results

Serial monitoring of mutated allele fraction in circulating DNA analysis is feasible and clinically meaningful, when epigenetic drugs are applied in clinic and show positive clinical outcome based on such biomarker driven approach to epigenetic targets.Further analysis as of April of 2019, for 491 cases is currently on going and preliminary findings are consistent with this article with common genetic mutations reflected in breast cancer responding to the epigenetic therapies.

Conclusion

We conclude that such biomarker based epigenetic approach in cancer therapy could replace the current standard of care which is mainly blind shot and type specific.

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