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Early Use of Next Generation Sequencing Provided Alternative Treatment Options to 32.24% of Advanced Stage Cancer Patients (Avoiding or Delaying Chemotherapy)-Retrospective Study in Solid Tumors at <u>Beverly Hills Cancer Center</u>

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Abstract

Our providers' continuous efforts to obtain Next-Generation Sequencing for their cancer patients as early as possible followed by appropriately matched therapy has provided new therapeutic options to our patients. This retrospective study included 95 solid tumor patients who were genotyped with the FDA-approved Guardant360 CDx liquid biopsy that provides comprehensive genomic results from a blood draw in seven days X (https://guardanthealth.com/media/). Our oncologists use it on regular basis for tumor mutation profiling, also known as comprehensive genomic profiling (CGP), across all solid cancers.

Keywords: Metastatic solid tumors • lung cancer • colorectal cancer • breast cancer • metastatic; next-generation sequencing • NGS • molecular profiling • targeted therapy • precision medicine • Beverly Hills Cancer Center

Summary

Historically, when a patient is diagnosed with cancer that has metastasized to distant organs, the standard of care treatment options were limited to chemotherapy.

Recently, as additional therapies are studied and proven to provide better results and less adverse events than chemotherapy, the goal has shifted to identify more effective and targeted alternative treatment options as early as possible. These efforts were boosted with commercialization of high-throughput testing that can identify gene alterations associated with cancer.

In many cases, some of the identified genetic changes in each patient can be matched to a targeted therapy or immunotherapy. The respective therapeutic agent(s) is (are) approved in this indication or in other indications and in many cases an available clinical trial can be identified for the patient. In this retrospective study, we studied how the use of NGS in the community setting affected the determination of treatment options for cancer patients.

All 152 patients with metastatic solid tumors had cancer-related genetic alterations, and, in 49 of them (32.24%), these could be, in theory, matched to a genomically directed therapy. 37 patients (24.34%) were initially matched to an ongoing clinical trial whether at Beverly Hills Cancer Center or at another institution within a 50 miles radius.

Sample Size and Diagnosis

This retrospective review included patients seen at the Beverly Hills Cancer Center during the last year, starting September 2020 - October 2021. Total number of cases included in this reviewed was 152.

Diagnosis	Number of patients	Percentage
Colorectal adenocarcinoma	97	63.82%
Lung adenocarcinoma	16	10.53%
Breast Carcinoma	15	15.13%
Pancreatic ductal adenocarcinoma	3	1.97%
Melanoma	3	1.97%
Gastric adenocarcinoma	3	1.97%
Small cell lung carcinoma	2	1.32%
Prostate adenocarcinoma	2	1.32%
Uterine leiomyosarcoma	1	0.66%
Squamous cell carcinoma of oropharynx	1	0.66%
Squamous cell carcinoma	1	0.66%
Soft tissue sarcoma	1	0.66%
Rectal Cancer	1	0.66%
Hepatocellular carcinoma	1	0.66%
GIST (Gastrointestinal stromal tumor)	1	0.66%
Gallbladder carcinoma	1	0.66%
Extrahepatic Cholangiocarcinoma	1	0.66%
Cholangiocarcinoma	1	0.66%
Ampullary carcinoma	1	0.66%
Total	152	100%

 Table 1: Distribution of cancer diagnoses in our sample

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Genetic Alterations and treatment options:

Genetic alterations were identified in all specimens.

49 patients (32.24%) had potentially actionable mutation and were matched to an FDA-Approved genetically guided therapy accordingly.

 Table 2: Frequency of Actionable mutation with associated FDA-approved therapies

Actionable mutation with associated FDA- approved therapies	Number of Patients	Percentage
No	112	73.68%
Yes	49	32.24%
Grand Total	152	100.00%

37 patients (24.34%) were initially matched and recommended to participate in an ongoing clinical trial within 50 miles radius based on inclusion/exclusion criteria posted on clinicaltrials.gov (some of these trials were open at Beverly Hills Cancer Center and this resulted in successful enrollment).

Table 3a: Availability of Clinical Trials

Clinical Trials	Number of patients	
N/A	115	75.66%
Yes	37	24.34%
Grand Total	152	100.00%

Table 3b: Frequency of Gene or Biomarker detected

Gene or Biomarker	Number of patients	Percentage
MSI-High	55	18.64%
TP53	51	17.29%
PIK3CA	20	6.78%
EGFR	15	5.08%
RB1	11	3.73%
ERBB2	11	3.73%
ARID1A	10	3.39%
APC	10	3.39%
FGFR2	8	2.71%
ATM	8	2.71%
BRAF	7	2.37%
KRAS	6	2.03%
CDK12	6	2.03%
MET	5	1.69%
BRCA2	5	1.69%
MYC	4	1.36%
ESR1	4	1.36%
CCNE1	4	1.36%
CCND1	4	1.36%
TERT	3	1.02%
SMAD4	3	1.02%

KIT	3	1.02%
DDR2	3	1.02%
AR	3	1.02%
PTEN	2	0.68%
PDGFRA	2	0.68%
NRAS	2	0.68%
NF1	2	0.68%
HNF1A	2	0.68%
GNAS	2	0.68%
FGFR3	2	0.68%
FBXW7	2	0.68%
CDKN2A	2	0.68%
BRCA1	2	0.68%
VHL	1	0.34%
STK11	1	0.34%
ROS1	1	0.34%
RET	1	0.34%
RAF1	1	0.34%
NTRK3	1	0.34%
NTRK1	1	0.34%
MLH1	1	0.34%
JAK2	1	0.34%
IDH1	1	0.34%
HRAS	1	0.34%
FGFR2-TACC2	1	0.34%
FGFR1	1	0.34%
CTNNB1	1	0.34%
CDK6	1	0.34%
AKT1	1	0.34%
Grand Total	295	100.00%
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Lack of response:

NGS sequencing showed evidence of lack of response to a specific treatment option in 3.95% of these patients and helped avoid treatment failure or resistance.

Lack of Response	Number of patients	Percentage
Evidence of Lack of response to a specific treatment option	6	3.95%
No evidence	146	96.05%
Grand Total	152	100.00%

Table 4: Frequency of Lack of response to therapeutic option.

Research Location

As a private, academic community-based cancer center, Beverly Hills Cancer Center not only provides state-of-the-art cancer treatment modalities all under one roof, but also leading clinical trials and research for cancer, which are offered at very few centers in the world, attracting patients globally, and saving lives. By providing access to groundbreaking clinical trials, the Beverly Hills Cancer Center offers patients the opportunity to participate in the most advanced cancer treatments currently in development in the world. (www.bhcancercenter.com)

Supplementary Materials

X Guardant Health Showcases Data at ESMO 2021 Demonstrating Utility of Guardant360® Liquid Biopsy to Obtain Comprehensive Molecular

Information to Guide Targeted Therapy Options for Late-Stage Cancers, 09/15/2021

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