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Shaping management of metastatic breast cancer patients treated within SOLTI network using Foundation One molecular platform

Xavier Gonzalez¹, Núria Chic², César A. Rodríguez³, Ángel Guerrero⁴, Pablo Tolosa⁵, Jordi Canes⁶, Laia Paré⁶, Maria Valls⁶, Helena Masanas⁶, Patricia Villagrasa⁶

1) Hospital Universitari General de Catalunya 2) Hospital Clínic de Barcelona 3) Hospital Universitario de Salamanca 4) Instituto Valenciano de Oncología 5) Hospital Universitario 12 de Octubre 6) SOLTI

Introduction

In recent years, the revolution in fields such as molecular biology, bioinformatics and the availability of high-throughput technologies, has promoted a huge qualitative leap in the knowledge of tumor biology. This has enabled the emergence of precision medicine and the implementation of molecular data in the management of cancer patients.

Nowadays, different platforms can be used for biomarker identification but unfortunately, routine approaches in clinical practice do not comprise the use of most of those technologies. At SOLTI, precision medicine is one of our corner stones. This is evidenced in one of our several research milestones, the Biomarker program. SOLTI's Biomarker program aims to use the power of our network to identify the distribution of "actionable" targets and promising predictive/prognostic biomarkers in selected cohorts of patients. This program comprises also prospective studies such as AGATA (NCT02445482), which offers three different platforms to molecularly screen selected patient populations and utilizes this information for tailoring treatment. Here, we report the results of another prospective approach using FoundationOne (FOne) solution.

Objectives

The proposed work aims to describe the molecular profiles of the patients included in the study and to explain the experience that SOLTI partners have had using the Foundation Medicine diagnostic platform (FoundationOne) in the management of Breast cancer (BC) patients.

Materials and Methods

A total of 12 hospitals within the SOLTI network participated in the FOne experience. DNA sequencing of the coding region of 315 cancer-related genes as well as introns from 28 genes often rearranged or altered in cancer was interrogated by The FOne test to a median depth of coverage greater than 500X. Microsatellite status and Tumor Mutation Burden were also assessed. In each FOne report a therapeutic option according to the molecular profile of the patient was provided. The primary objective was to determine the success rate of matching a DNA alteration to an experimental drug or drug class. Secondary objective included to determine the logistic feasibility of using this molecular platform at the national level, and identify potential barriers.

Results

Between December 2017 and March 2018, 65 metastatic BC patients participated in the study. Reports of Fifty patients (76.9%) were collected; of those, two were non-breast tumors (mesothelioma and glioblastoma multiforme), and one was not done due to the quality of the sample. Here we present the BC cases results (n=47, 72.3%). Patients characteristics were: mean age 56 years (32-89); 29 Hormone receptor-positive/HER2-negative (61.7%), 3 HER2-positive (6.4%) and 15 Triple negative BC (31.9%). The total number of genetic alterations

identified was 265; the median number of mutations per tumor was 5.4 and ranged from 1 (n=4) to 15 (n=1). In one case, no alterations were detected. TP53 mutation was the most common GAs (8%, n=20/265), followed by CCND1 amplification (4%, n=11/265), FFGF19 amplification (4%, n=11/265), PIK3CA mutation (4%, n=11/265) and FGF4 amplification (3%, n=9/265). Median Tumor Mutation Burden was 5.6 Muts/Mb and cannot be determined in 3 cases. In 22 (46%) cases the platform made recommendations of available targeted therapies, or suggestions to include the patients in a particular clinical trial. The physicians followed the recommendation in 7 (15%) cases. Furthermore, in 6 (12%) occasions the resulting analysis reinforced their position about the therapeutic strategy or provided information for futures lines of treatment. Finally, the oncologists' level of satisfaction with the experience was good or very good in 46 out of the 48 cases.

Conclusions

Nearly half of patients had tumors with alterations that could potentially be matched to a drug or drug class. All participant oncologists agreed that it would be helpful for their daily routine, not only because they received a suggestion in the clinical management, but it also shed some light on the evolution of the disease. Thanks to this experience, we can also reinforce the fact that SOLTI's hospital network offers an excellent opportunity to assess the feasibility to use diagnostic platforms nationwide. The information obtained by this type of analysis may became a potent tool to help physicians in BC management.

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