Abstract 1838
Primary results of the first nationwide molecular screening program in Spain for patients with advanced breast cancer (AGATA SOLTI-1301 study)

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Background
SOLTI, as a collaborative Spanish network, designed AGATA, the first multi-institutional molecular screening program ever implemented in this country. Here we report the primary results of the pilot study.

Methods
A total of 10 sites within the SOLTI network in Spain participated. DNA sequencing of 56 cancer related genes was performed using FFPE tumor samples (primary or metastatic). Each clinical case was reviewed by a multidisciplinary advisory board (MAB), which recommended, in a prospective manner, potential experimental treatments, mainly in the context of clinical trials. The primary objective was to determine the success rate of matching a DNA alteration to an experimental drug or drug class. Secondary objectives included a comprehensive molecular characterization of tumor samples by PAM50 subtyping.

Results
From September 2014 to July 2017, 305 patients were screened and 260 (85.3%) were included. Patients’ characteristics were: mean age 54 (29-80), ER+/HER2- (n=192; 74%), HER2+ (n=30; 11.5%) and TNBC (n=38; 14.5%). 163 primary tumors and 97 metastatic samples were profiled. Regarding the primary objective, 116 patients (44.6%) presented at least one gene mutation (range 1-6) and were matched to a drug or drug class. No mutation was detected in 97 (37.3%) patients, and 47 patients (18.1%) presented a mutation but no match was possible. The most common alterations were mutations in PIK3CA (34%), TP53 (22%), AKT1 (5%), ESR1 (3%), and ERBB2 (3%). Intrinsic subtype distribution in 177 samples was: 34% Luminal A (n=60); 21% Luminal B (n=36); 13% HER2E (n=22); 19% Basal-like (n=34) and 13% Normal-like (n=23). Compared to primary tumors (n=110), the proportion of HER2-enriched disease in metastatic tumors (n=63) was significantly higher (6% vs 20%; p=0.005).

Conclusions
Nationwide molecular screening in Spain is feasible. Nearly half of patients had tumors with mutation(s) (mostly in PIK3CA) that could potentially be matched to a drug or drug class. Further studies are needed to evaluate if a more comprehensive molecular characterization including proteomics may increase therapeutic options for patients with or without somatic mutations.
Clinical trial identification
NCT02445482

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