

1. **Ten-year survival of neoadjuvant dual HER2 blockade in patients with HER2-positive breast cancer**
Supervivencia a diez años del bloqueo neoadyuvante dual de HER2 en pacientes con cáncer de mama HER2 positivo

INVESTIGADORES: Paolo Nuciforo, John Townend, Martine J Piccart, Shona Fielding, Panagiota Gkolfi, Sarra El-Abed, Evandro de Azambuja, Gustavo Werutsky, Judith Bliss, Volker Moebus, Marco Colleoni, Alvaro Moreno Aspitia, Henry Gomez, Andrea Gombos, Maria A Coccia-Portugal, Ling-Ming Tseng, Georg Kunz, Guillermo Lerzo, Joohyuk Sohn, Vladimir Semiglazov, Cristina Saura, Judith Kroep, Antonella Ferro, David Cameron, Richard Gelber, Jens Huober, Serena Di Cosimo

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Background: Dual anti-HER2-targeted therapy in breast cancer (BC) significantly increased the rate of pathological complete response (pCR) compared to single blockade when added to chemotherapy. However, limited data exist on the long-term impact on survival of the additional increase in pCR. Methods: Neoadjuvant lapatinib and/or trastuzumab treatment optimisation (NCT00553358) is an international, randomised, open-label, phase III study investigating the addition of lapatinib to chemotherapy plus trastuzumab in HER2-positive early BC. Ten-year event-free survival (EFS), overall survival (OS) and safety were assessed on intention-to-treat population. The association between pCR and EFS or OS was investigated in landmark population. Results: A total of 455 patients were randomised to receive lapatinib (154), trastuzumab (149) or the combination (152). Ten-year EFS estimates were 63% (95% confidence interval [CI], 54%-71%) in the lapatinib group, 64% (95% CI, 55%-72%) in the trastuzumab group and 67% (95% CI, 58%-74%) in the combination group. Ten-year OS rates were 76% (95% CI, 67%-83%), 75% (95% CI, 66%-82%) and 80% (95% CI, 73%-86%) in the lapatinib, trastuzumab and combination groups, respectively. Women who achieved a pCR had improved EFS (hazard ratio 0.48, 95% CI, 0.31-0.73) and OS (hazard ratio 0.37, 95% CI, 0.20-0.63) compared with those who did not. The numerical difference in survival according to pCR status was greater in women treated with the combination and those with hormone-receptor-negative tumours. There were no new or long-term safety concerns. Conclusions: Patients with HER2-positive BC showed a durable survival benefit of neoadjuvant anti-HER2, irrespective of treatment arm. Patients who achieve pCR have significantly better outcomes than patients without pCR.

2. **First Isolates of OXA-48-Like Carbapenemase-Producing Enterobacteriaceae in A Specialized Cancer Center**

Primeros aislamientos de enterobacterias productoras de carbapenemasas similares a OXA-48 en un centro oncológico especializado

INVESTIGADORES: Freddy Villanueva-Cotrina, Dick Mamani Condori, Tamin Ortiz Gomez, Katia Mallma Yactayo, Heli Barron-Pastor.

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Background: OXA-48-like carbapenemases have been found in a growing and varied number of carbapenemase-producing Enterobacteriaceae (CPE) isolates, and they are spreading to several countries. Although this oxacillinase leads to weak resistance to carbapenems without affecting broad-spectrum cephalosporin activity, when they are associated with other resistance mechanisms, the level of resistance to these antibiotics may be significantly higher. This weak resistance against carbapenems and cephalosporins, along with the absence of other resistance mechanisms, could render OXA-48-like harboring isolates undetected in the laboratory routine. In addition, the lack of a specific screening test for this enzyme complicates the detection of these isolates. This report characterizes the first isolates of OXA-48-like CPE detected in our laboratory.

Materials and methods: The study was carried out at the Instituto Nacional de Enfermedades Neoplásicas, Lima- Peru, between March and December 2021. OXA- 48-like CPE isolates were detected as part of the routine microbiological study, and clinical data were obtained by reviewing medical records. The automated microbiological system provides the bacterial identification and antimicrobial susceptibility profile by the dilution method. Additionally, the column chromatography test is used to detect carbapenemase enzymes, including OXA-48-like. Finally, the molecular identification of the OXA-48-like enzyme was carried out by Polymerase Chain Reaction PCR amplification for the blaOXA-48-like. **Results:** Seven OXA-48-like CPE strains were isolated. Notably, in all cases, the automated system issued a minimum inhibitory concentration (MIC) of ≥ 1 ug/mL for ertapenem and a MIC of $>64/4$ ug/mL for piperacillin/tazobactam. In addition, resistance category to imipenem and meropenem was found (2/7), at least one indeterminate category for any of these carbapenems (5/7), and other serine β -lactamases such as Extended-spectrum beta-lactamases (3/7) and AmpC (3/7). The immunochromatographic study confirmed the presence of the OXA-48-like enzyme in all isolates, while class A and class B were ruled out for them. Finally, the multiplex PCR, for the five isolates that could be recovered, showed amplification for carbapenemase OXA-48-like, while none of the other carbapenemases was amplified for class A or class B carbapenemase genes. **Conclusion:** We confirm the emergence of OXA-48-like CPE isolates in our cancer center and highlight the need to implement surveillance and detection measures of these strains, for controlling their dissemination. We found practical and inexpensive methodologies for the detection of OXA-48-like CPE: (1) the finding of resistance to ertapenem and piperacillin/tazobactam in the antibiogram in the absence of class A and B carbapenemases, for screening and (2) immunochromatographic study, for confirmation.

3. Knowledge, attitudes, and behaviors toward fertility preservation in patients with breast cancer: A cross-sectional survey of physicians

Conocimientos, actitudes y comportamientos hacia la preservación de la fertilidad en pacientes con cáncer de mama: una encuesta transversal de médicos

INVESTIGADORES: Soo Yeon Baek, Kyung-Hun Lee, Sung-Bae Kim, Henry Gomez, Tatiana Vidaurre, Yeon Hee Park, Hee Kyung Ahn, Yoo Seok Kim, In Hae Park, Sung Gwe Ahn, Jeeyeon Lee, Jae Ho Jeong, Seonok Kim, Hee Jeong Kim.

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Background: Fertility is an important issue for young women with breast cancer, but studies about physicians' knowledge, attitudes, and practices toward fertility preservation (FP) are largely based on Western populations and do not reflect recent international guidelines for FP. In this international study, we aimed to assess the knowledge, attitudes, and practices of physicians from South Korea, other Asian countries, and Latin America toward FP in young women with breast cancer, and identify the related barriers. Methods: The survey was conducted anonymously among physicians from South Korea, other Asian countries, and Latin America involved in breast cancer care between November 2020 and July 2021. Topics included knowledge, attitudes, and perceptions toward FP; practice behaviors; barriers; and participant demographics. We grouped related questions around two main themes-discussion with patients about FP, and consultation and referral to a reproductive endocrinologist. We analyzed the relationships between main questions and other survey items. Results: A total of 151 physicians completed the survey. Most participants' overall knowledge about FP was good. More than half of the participants answered that they discussed FP with their patients in most cases, but that personnel to facilitate discussions about FP and the provision of educational materials were limited. A major barrier was time constraints in the clinic (52.6%). Discussion, consultations, and referrals were more likely to be performed by surgeons who primarily treated patients with operable breast cancer (FP discussion odds ratio [OR]: 2.90; 95% confidence interval [CI]: 1.24-6.79; FP consultation and referral OR: 2.98; 95% CI: 1.14-7.74). Participants' knowledge and attitudes about FP were significantly

associated with discussion, consultations, and referrals. Conclusion: Physicians from South Korea, other Asian countries, and Latin America are knowledgeable about FP and most perform practice behaviors toward FP well. Physicians' knowledge and favorable attitudes are significantly related to discussion with patients, as well as consultation with and referral to reproductive endocrinologists. However, there are also barriers, such as limitations to human resources and materials, suggesting a need for a systematic approach to improve FP for young women with breast cancer.

4. End-of-neoadjuvant treatment circulating microRNAs and HER2-positive breast cancer patient prognosis: An exploratory analysis from NeoALTTO

Pronóstico de pacientes con cáncer de mama HER2 positivo y microARN circulantes al final del tratamiento neoadyuvante: un análisis exploratorio de NeoALTTO

INVESTIGADORES: Serena Di Cosimo, Chiara M Ciniselli, Sara Pizzamiglio, Vera Cappelletti, Marco Silvestri, Sarra El-Abed, Miguel Izquierdo, Mohammed Bajji, Paolo Nuciforo, Jens Huober, David Cameron, Stephen Chia, Henry L Gomez, Marilena V Iorio, Andrea Vingiani, Giancarlo Pruneri, Paolo Verderio.

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Background: The absence of breast cancer cells in surgical specimens, i.e., pathological complete response (pCR), is widely recognized as a favorable prognostic factor after neoadjuvant therapy. In contrast, the presence of disease at surgery characterizes a prognostically heterogeneous group of patients. Here, we challenged circulating microRNAs (miRNAs) at the end of neoadjuvant therapy as potential prognostic biomarkers in the NeoALTTO study. Methods: Patients treated within the trastuzumab arm (i.e., pre-operative weekly trastuzumab for 6 weeks followed by the addition of weekly paclitaxel for 12 weeks; post-operative FEC for 3 cycles followed by trastuzumab up to complete 1 year of treatment) were randomized into a training (n= 54) and testing (n= 72) set. RT-PCR-based high-throughput miRNA profile was performed on plasma samples collected at the end of neoadjuvant treatment of both sets. After normalization, circulating miRNAs associated with event free survival (EFS) were identified by univariate and multivariate Cox regression model. Results: Starting from 23 circulating miRNAs associated with EFS in the training set, we generated a 3- circulating miRNA prognostic signature consisting of miR-185-5p, miR-146a-5p, miR-22-3p, which was confirmed in the testing set. The 3-circulating miRNA signature showed a C-statistic of 0.62 (95% confidence interval [95%CI] 0.53-0.71) in the entire study cohort. By resorting to a multivariate Cox regression model we found a statistical significant interaction between the expression values of miR- 194-5p and pCR status (p.interaction =0.005) with an estimate Hazard Ratio (HR) of 1.83 (95%CI 1.14- 2.95) in patients with pCR, and 0.87 (95%CI 0.69-1.10) in those without pCR. Notably, the model including this interaction along with the abovementioned 3-circulating miRNA signature provided the highest discriminatory capability with a C-statistic of 0.67 (95%CI 0.58-0.76). Conclusions: Circulating miRNAs are informative to identify patients with different prognosis among those with heterogeneous response after trastuzumab-based neoadjuvant treatment, and may be an exploitable tool to select candidates for salvage adjuvant therapy.

5. Clinical Features and Outcomes of Triple-Negative Breast Cancer Among Latin American Adolescents and Young Adults Compared to Middle-Aged and Elder Females: A Cohort Analysis Over 15 Years

Características clínicas y resultados del cáncer de mama triple negativo entre adolescentes y adultas jóvenes latinoamericanas en comparación con mujeres de mediana edad y mayores: un análisis de cohorte durante 15 años

INVESTIGADORES: Bryan Valcarcel, J Smith Torres-Roman, Daniel Enriquez-Vera, Gabriel De-la-Cruz- Ku.

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Purpose: Outcomes of females with triple-negative breast cancer (TNBC) are rarely explored in adolescents and young adults (AYAs). We compared clinical and survival outcomes of Latin American AYAs (≤ 39 years) with middle-aged (40-59 years) and older (≥ 60 years) females with TNBC by cancer stage. Methods: We performed a single-center retrospective cohort study among treated females with cancer stages I-III diagnosed from 2000 to 2014 in Peru. We evaluated overall survival (OS) and event-free survival (EFS). Time-to-event methods were used for analyses. Results: Of 1582 females with TNBC, 350 (22%) were AYAs, 887 (56%) were middle-aged, and 345 (22%) were older women. Tumor size >5 cm, histological grade III, and brain metastasis were more common features in AYAs. AYAs were treated more frequently with neoadjuvant chemotherapy. With a median follow-up of 102 months, the 5-year OS/EFS for AYAs was 55%/53%, similar to middle-aged (54%/49%) and older females (56%/51%). AYAs were not at higher risk for decreased OS or EFS in the multivariable Cox analysis. Our findings remained consistent by cancer stage. Conclusion: Although Latin American AYAs with TNBC have more aggressive clinical features at diagnosis, survival outcomes were comparable with middle-aged and older women with TNBC, suggesting that age is not a risk factor for worse survival outcomes if treatment is given according to cancer stage. Our findings should be interpreted with caution given the lack of information on certain covariates such as comorbidities. Strategies for early detection in primary care and prompt referral for treatment initiation should be developed.

6. Breast cancer subtype and clinical characteristics in women from Peru

Subtipo de cáncer de mama y características clínicas en mujeres de Perú

INVESTIGADORES: Valentina A Zavala, Sandro Casavilca-Zambrano, Jeannie Navarro- Vásquez, Lizeth I Tamayo, Carlos A Castañeda, Guillermo Valencia, Zaida Morante, Mónica Calderón, Julio E Abugattas, Henry L Gómez, Hugo A Fuentes, Ruddy Liendo- Picoaga, Jose M Cotrina, Silvia P Neciosup, Katia Roque, Jule Vásquez, Luis Mas, Marco Gálvez-Nino, Laura Fejerman, Tatiana Vidaurre.

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TIPO D CANCER: Mamas y tejidos blandos

ABSTRACTO: Introduction: Breast cancer is a heterogeneous disease, and the distribution of the different subtypes varies by race/ethnic category in the United States and by country. Established breast cancer-associated factors impact subtype-specific risk; however, these included limited or no representation of Latin American diversity. To address this gap in knowledge, we report a description of demographic, reproductive, and lifestyle breast cancer-associated factors by age at diagnosis and disease subtype for The Peruvian Genetics and Genomics of Breast Cancer (PEGEN-BC) study. Methods: The PEGEN-BC study is a hospital-based breast cancer cohort that includes 1943 patients diagnosed at the Instituto Nacional de Enfermedades Neoplásicas in Lima, Peru. Demographic and reproductive information, as well as lifestyle exposures, were collected with a questionnaire. Clinical data, including tumor Hormone Receptor (HR) status and Human Epidermal Growth Factor Receptor 2 (HER2) status, were abstracted from electronic medical records. Differences in proportions and mean values were tested using Chi-squared and one-way ANOVA tests, respectively. Multinomial logistic regression models were used for multivariate association analyses. Results: The distribution of subtypes was 52% HR+HER2-, 19% HR+HER2+, 16% HR-HER2-, and 13% HR-HER2+. Indigenous American (IA) genetic ancestry was higher, and height was lower among individuals with the HR-HER2+ subtype (80% IA vs. 76% overall, $p=0.007$; 152 cm vs. 153 cm overall, $p=0.032$, respectively). In multivariate models, IA ancestry was associated with HR-HER2+ subtype (OR=1.38, 95%CI=1.06-1.79, $p=0.017$) and parous women showed increased risk

for HR-HER2+ (OR=2.7,95%CI=1.5-4.8, p<0.001) and HR- HER2- tumors (OR=2.4,95%CI=1.5-4.0, p<0.001) compared to nulliparous women. Multiple patient and tumor characteristics differed by age at diagnosis (<50 vs. ≥50), including ancestry, region of residence, family history, height, BMI, breastfeeding, parity, and stage at diagnosis (p<0.02 for all variables). Discussion: The characteristics of the PEGEN-BC study participants do not suggest heterogeneity by tumor subtype except for IA genetic ancestry proportion, which has been previously reported. Differences by age at diagnosis were apparent and concordant with what is known about pre- and post- menopausal-specific disease risk factors. Additional studies in Peru should be developed to further understand the main contributors to the specific age of onset and molecular disease subtypes in this population and develop population-appropriate predictive models for prevention.

7. Triple-Negative PAM50 Non-Basal Breast Cancer Subtype Predicts Benefit from Extended Adjuvant Capecitabine

El subtipo de cáncer de mama no basal PAM50 triple negativo predice el beneficio de la capecitabina adyuvante extendida

INVESTIGADORES: Karama Asleh, Ana Lluch, Angela Goytain, Carlos Barrios, Xue Q Wang, Laura Torrecillas, Dongxia Gao, Manuel Ruiz-Borrego, Samuel Leung, José Bines, Ángel Guerrero-Zotano, Jose Ángel García-Sáenz, Juan Miguel Cejalvo, Jesus Herranz, Roberto Torres, Juan de la Haba-Rodriguez, Francisco Ayala, Henry Gómez, Federico Rojo, Torsten O Nielsen, Miguel Martin.

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TIPO DE CANCER: Mamas y tejidos blandos

ABSTRACTO: Purpose: Predictive biomarkers for capecitabine benefit in triple-negative breast cancer (TNBC) have been recently proposed using samples from phase III clinical trials, including non-basal phenotype and biomarkers related to angiogenesis, stroma, and capecitabine activation genes. We aimed to validate these findings on the larger phase III GEICAM/CIBOMA clinical trial. Experimental design: Tumor tissues from patients with TNBC randomized to standard (neo)adjuvant chemotherapy followed by capecitabine versus observation were analyzed using a 164-gene NanoString custom nCounter codeset measuring mRNA expression. A prespecified statistical plan sought to verify the predictive capacity of PAM50 non-basal molecular subtype and tested the hypotheses that breast tumors with increased expression of (meta)genes for cytotoxic cells, mast cells, endothelial cells, PDL2, and 38 individual genes benefit from adjuvant capecitabine for distant recurrence-free survival (DRFS; primary endpoint) and overall survival. Results: Of the 876 women enrolled in the GEICAM/CIBOMA trial, 658 (75%) were evaluable for analysis (337 with capecitabine and 321 without). Of these cases, 553 (84%) were profiled as PAM50 basal-like whereas 105 (16%) were PAM50 non-basal. Non-basal subtype was the most significant predictor for capecitabine benefit [HRcapecitabine, 0.19; 95% confidence interval (CI), 0.07-0.54; P < 0.001] when compared with PAM50 basal-like (HRcapecitabine, 0.9; 95% CI, 0.63-1.28; P = 0.55; Pinteraction<0.001, adjusted P value = 0.01). Analysis of biological processes related to PAM50 non-basal subtype revealed its enrichment for mast cells, extracellular matrix, angiogenesis, and features of mesenchymal stem-like TNBC subtype. Conclusions: In this prespecified correlative analysis of the GEICAM/CIBOMA trial, PAM50 non-basal status identified patients with early-stage TNBC most likely to benefit from capecitabine.

8. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer

Capivasertib en el cáncer de mama avanzado con receptor hormonal positivo

INVESTIGADORES: Nicholas C Turner, Mafalda Oliveira, Sacha J Howell, Florence Dalenc, Javier Cortes, Henry L Gomez Moreno, Xichun Hu, Komal Jhaveri, Petr Krivorotko, Sibylle Loibl, Serafin Morales Murillo, Meena Okera, Yeon Hee Park, Joohyuk Sohn, Masakazu Toi, Eriko Tokunaga, Samih Yousef, Lyudmila Zhukova, Elza C de Bruin, Lynda Grinsted, Gaia Schiavon, Andrew Foxley, Hope S Rugo; CAPItello-291 Study Group

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Background: AKT pathway activation is implicated in endocrine-therapy resistance. Data on the efficacy and safety of the AKT inhibitor capivasertib, as an addition to fulvestrant therapy, in patients with hormone receptor-positive advanced breast cancer are limited. Methods: In a phase 3, randomized, double-blind trial, we enrolled eligible pre-, peri-, and postmenopausal women and men with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer who had had a relapse or disease progression during or after treatment with an aromatase inhibitor, with or without previous cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor therapy. Patients were randomly assigned in a 1:1 ratio to receive capivasertib plus fulvestrant or placebo plus fulvestrant. The dual primary end point was investigator-assessed progression-free survival assessed both in the overall population and among patients with AKT pathway-altered (PIK3CA, AKT1, or PTEN) tumors. Safety was assessed. Results: Overall, 708 patients underwent randomization; 289 patients (40.8%) had AKT pathway alterations, and 489 (69.1%) had received a CDK4/6 inhibitor previously for advanced breast cancer. In the overall population, the median progression-free survival was 7.2 months in the capivasertib-fulvestrant group, as compared with 3.6 months in the placebo-fulvestrant group (hazard ratio for progression or death, 0.60; 95% confidence interval [CI], 0.51 to 0.71; $P < 0.001$). In the AKT pathway-altered population, the median progression-free survival was 7.3 months in the capivasertib-fulvestrant group, as compared with 3.1 months in the placebo-fulvestrant group (hazard ratio, 0.50; 95% CI, 0.38 to 0.65; $P < 0.001$). The most frequent adverse events of grade 3 or higher in patients receiving capivasertib-fulvestrant were rash (in 12.1% of patients, vs. in 0.3% of those receiving placebo-fulvestrant) and diarrhea (in 9.3% vs. 0.3%). Adverse events leading to discontinuation were reported in 13.0% of the patients receiving capivasertib and in 2.3% of those receiving placebo. Conclusions: Capivasertib-fulvestrant therapy resulted in significantly longer progression-free survival than treatment with fulvestrant alone among patients with hormone receptor-positive advanced breast cancer whose disease had progressed during or after previous aromatase inhibitor therapy with or without a CDK4/6 inhibitor. (Funded by AstraZeneca and the National Cancer Institute; CAPitello-291 ClinicalTrials.gov number, NCT04305496.).

9. **Effect of receiving a customizable brochure on breast cancer patients' knowledge about their diagnosis and treatment: A randomized clinical trial**

Efecto de recibir un folleto personalizable sobre el conocimiento de los pacientes con cáncer de mama sobre su diagnóstico y tratamiento: un ensayo clínico aleatorizado

INVESTIGADORES: Cynthia Villarreal-Garza, Ana S Ferrigno, Cynthia De la Garza-Ramos, Daniela Vazquez-Juarez, Brizio Moreno-Jaime, Yuly Remolina-Bonilla, Manuel Segura-Gonzalez, Ignacio Mariscal-Ramirez, Florencia Perazzo, Georgina Garnica-Jaliffe, Silvia Neciosup-Delgado, Emilio Conde-Flores, Shirly Mysler, Arlette Hernandez-Ayala, Alondra Barajas-Sanchez, Maria Del Socorro Rios Mercado, Nelia Maria Noh-Vazquez, Ricardo Garcia-Rodriguez, Ana Platas, Jaime Tamez-Salazar, Teresa Mireles-Aguilar, Alejandra Platas.

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TIPO DE CÁNCER: Mamas y tejidos blandos

ABSTRACTO: Background: Patients' lack of knowledge about their own disease may function as a barrier to shared decision-making and well-being. This study aimed to evaluate the impact of written educational materials on breast cancer patients. Methods: This multicenter, parallel, unblinded, randomized trial included Latin American women aged ≥ 18 years with a recent breast cancer diagnosis yet to start systemic therapy. Participants underwent randomization in a 1:1 ratio to receive a customizable or standard educational brochure. The primary objective was accurate identification of molecular subtype. Secondary objectives included identification of clinical stage,

treatment options, participation in decision-making, perceived quality of information received, and illness uncertainty. Follow-up occurred at 7-21 and 30-51 days post-randomization. Clinicaltrials: gov identifier: NCT05798312. Results: One hundred sixty-five breast cancer patients with a median age of 53 years and 61 days from diagnosis were included (customizable: 82; standard: 83). At first available assessment, 52%, 48%, and 30% identified their molecular subtype, disease stage, and guideline-endorsed systemic treatment strategy, respectively. Accurate molecular subtype and stage identification were similar between groups. Per multivariate analysis, customizable brochure recipients were more likely to identify their guideline-recommended treatment modalities (OR: 4.20, $p = 0.001$). There were no differences between groups in the perceived quality of information received or illness uncertainty. Customizable brochure recipients reported increased participation in decision-making ($p = 0.042$). Conclusions: Over one third of recently diagnosed breast cancer patients are incognizant of their disease characteristics and treatment options. This study demonstrates a need to improve patient education and shows that customizable educational materials increase patients' understanding of recommended systemic therapies according to individual breast cancer characteristics.