Title
Abstract OT3-03-02: Personalized breast cancer screening in a population-based study: Women informed to screen depending on measures of risk (WISDOM)

Journal
Cancer Research, 80(4_Supplement)

ISSN
0008-5472

Authors
Che, Mandy
Fiscallini, Allison Stover
Acerbi, Irene
et al.

Publication Date
2020-02-15

DOI
10.1158/1538-7445.sabcs19-ot3-03-02

Abstract OT3-03-02: Personalized breast cancer screening in a population-based study: Women informed to screen depending on measures of risk (WISDOM)

Mandy Che, Allison Stover Fiscallini, Irene Acerbi, Yiweh Shieh, Lisa Madlensky, Jeffrey Tice, Elad Ziv, Martin Eklund, Amie Blanco, Barry Tong, Deborah Goodman, Lamees Nassereddine, Nancy Anderson, Heather Harvey, Steele Fors, Hannah L Park, Antonia Petruse, Skye Stewart, Janet Wernisch, Larissa Risty, Ian Hurley, Barbara Koenig, Celia Kaplan, Robert Hiatt, Neil Wenger, Vivian Lee, Diane Heditsian, Susie Brain, Leah Sabacan, Barbara Parker, Alexander Borowsky, Hoda Anton-Culver, Hoda Anton-Culver, Arash Naeim, Andrea Kaster, Melinda Talley, Laura van't Veer, Andrea LaCroix, Olufunmilayo I Olopade, Deepa Sheth and WISDOM Study and Athena Breast Health Network Investigators and Advocate Partners and Laura Esserman

DOI: 10.1158/1538-7445.SABCS19-OT3-03-02 Published February 2020

Abstracts: 2019 San Antonio Breast Cancer Symposium; December 10-14, 2019; San Antonio, Texas

Abstract

Background: WISDOM is a 100,000 healthy women preference-tolerant, pragmatic study comparing traditional annual screening to personalized risk-based breast screening. The novelty of WISDOM personalized screening is the integration of previously validated genetic and clinical risk factors (age, family history, breast biopsy results, ethnicity, mammographic density) into a single risk assessment model that directs the starting age, timing, and frequency of screening. The goal of WISDOM is to determine if personalized screening, compared to annual screening, is as safe, less morbid, enables prevention, and is more accepted by women. The study is registered on ClinicalTrials.gov, NCT02620852.

Methods: Women aged 40-74 years with no history of breast cancer or DCIS, and no previous double mastectomy can join the study online at wisdomstudy.org. Participants can either elect randomization or self-select a study arm. Then, they can provide electronic consent and sign the Release for Medical Information via DocuSign. For all participants, 5-year risk of developing breast cancer is calculated according to the Breast Cancer Screening Consortium (BCSC) model. Participants in the personalized arm undergo panel-based mutation testing (BRCA1, BRCA2, TP53, PTEN, STK11, CDH1, ATM, PALB2, and CHEK2), and their 5-year risk is calculated using the BCSC score combined with a Polygenic Risk Score (BCSC-PRS) that includes 75 single nucleotide polymorphisms (SNPs) known to increase breast cancer risk (will increase to 229). The SNPs and mutations are assessed by saliva-based testing through Color Genomics. 5-year risk level thresholds are used to stratify for low-, moderate- and high risk. Risk stratification determines age to start, stop, and frequency of screening.

Accrual: As of July 2019, the WISDOM study is open to all eligible women in California, North Dakota, South Dakota, Minnesota, Iowa, Illinois, and New Jersey. To date, 30,392 eligible

women have registered, and 21,392 women have consented to participate in the trial. The median age was 56 years. 85% of participants were Caucasian, 2% African-American, and 5% Asian. 6% self-reported Hispanic ethnicity. WISDOM is actively partnering with Blue Cross Blue Shield Association for national coverage, self-insured companies (Salesforce, Genentech, Qualcomm, CalPERS) and Medi-Cal (Inland Empire Health Plan) using a coverage with evidence progression approach.

Accrual expansion and diversity: To strengthen generalizability, the WISDOM Study is enhancing the diversity of our potential participant population by expanding to other states (Alabama, Louisiana), and partnering with other health insurers and self-insured companies. Future expansion regions include Texas, Florida, South Carolina, Oklahoma, Montana, and New Mexico. Additionally, we have translated the whole study experience to Spanish to further reach Spanish-speaking communities. With the engagement of patient advocates and community partnerships, expanding diversity recruitment will strengthen our scientific knowledge of breast cancer risk and increase access to personalized breast cancer screening recommendations for all women. WISDOM enrollment will continue through 2020.

Conclusions: Results at 5 years will enable us to demonstrate that personalized screening improves healthcare value by reducing screen volumes and costs without jeopardizing outcomes.

Citation Format: Mandy Che, Allison Stover Fiscallini, Irene Acerbi, Yiweh Shieh, Lisa Madlensky, Jeffrey Tice, Elad Ziv, Martin Eklund, Amie Blanco, Barry Tong, Deborah Goodman, Lamees Nassereddine, Nancy Anderson, Heather Harvey, Steele Fors, Hannah L Park, Antonia Petruse, Skye Stewart, Janet Wernisch, Larissa Risty, Ian Hurley, Barbara Koenig, Celia Kaplan, Robert Hiatt, Neil Wenger, Vivian Lee, Diane Heditsian, Susie Brain, Leah Sabacan, Barbara Parker, Alexander Borowsky, Hoda Anton-Culver, Hoda Anton-Culver, Arash Naeim, Andrea Kaster, Melinda Talley, Laura van't Veer, Andrea LaCroix, Olufunmilayo I Olopade, Deepa Sheth, WISDOM Study and Athena Breast Health Network Investigators and Advocate Partners and Laura Esserman. Personalized breast cancer screening in a population-based study: Women informed to screen depending on measures of risk (WISDOM) [abstract]. In: Proceedings of the 2019 San Antonio Breast Cancer Symposium; 2019 Dec 10-14; San Antonio, TX. Philadelphia (PA): AACR; Cancer Res 2020;80(4 Suppl):Abstract nr OT3-03-02.