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WISDOM and MyPeBS: Personalized breast cancer screening trials operating in distinct international contexts

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BACKGROUND ON THE WISDOM & MyPeBS TRIALS

- **WHAT:** WISDOM (Women Informed to Screen Depending on Measures of risk) (NCT02620852) & MyPeBS (My Personal Breast Screening) (NCT03672331) are two prominent risk-based breast cancer screening (RBS) trials based in the US and Europe & Israel, respectively.

- **SIMILAR TRIAL AIMS:** Both trials aim to:
  - Assess whether RBS is as safe as current screening (no increased incidence of stage> II/IIB breast cancers)
  - Enhance resources to those who are high risk, while minimizing harm to those at lowest risk

- **TRIAL ENROLLMENT:** WISDOM (2016-2023; 46,289 women); MyPeBS (2019-2023; 53,143 women)

- **TRIAL DESIGN - RECRUITMENT:**
  - Eligibility between the two trials were similar, (40-74 vs 40-70) & no prior breast cancer history
  - Both are randomized 1:1 to RBS vs. country-based standard of care screening (WISDOM had a pragmatic option).

RISK ASSESSMENT & SCREENING ASSIGNMENTS

	WISDOM	MyPeBS
RISK ASSESSMENT	Yes	Yes
BCSC (version 2)	Yes	Yes (Mammorisk®, identical to BCSCv2)
PRS (up to 313 SNPs)	Yes	Yes
9 gene panel of breast cancer susceptibility genes	Yes	No
SCREENING ASSIGNMENT		
Highest Risk	Yearly MRI and Mg	Yearly MRI and Mg
Elevated Risk	Yearly Mg	Yearly Mg
Average Risk	Every two year Mg	Every two year Mg
Lowest risk	No screen until risk = avg. 50-year-old	Mg in 4 years
Control	Yearly Mg	Every two year Mg
Control group screening starting age	40	40
SCREENING GUIDELINES		
	Annual (ACR, NCCN) to biennial screening @ 40 (USPSTF)	2 yrs in (France, Belgium, Italy, Spain, Israel) to 3 yrs in the UK @ 45-50

Table 1: Comparison of MyPeBS & WISDOM Risk Assessment & Screening Assignments

RESULTS: RISK DISTRIBUTION IN WISDOM & MyPeBS

Figure 1: WISDOM Risk Assessment & Stratification[1] in the Risk-Based WISDOM Cohort

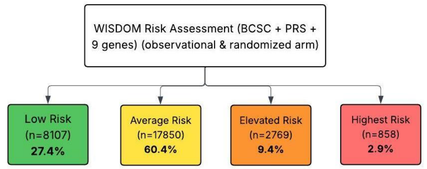


Figure 2: MyPeBS Risk Assessment & Stratification in the Risk-Based MyPeBS Cohort

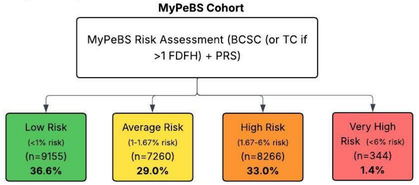
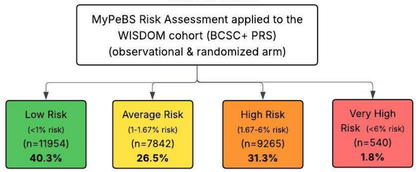


Figure 3: MyPeBS Risk Assessment & Stratification in the Risk-Based WISDOM Cohort



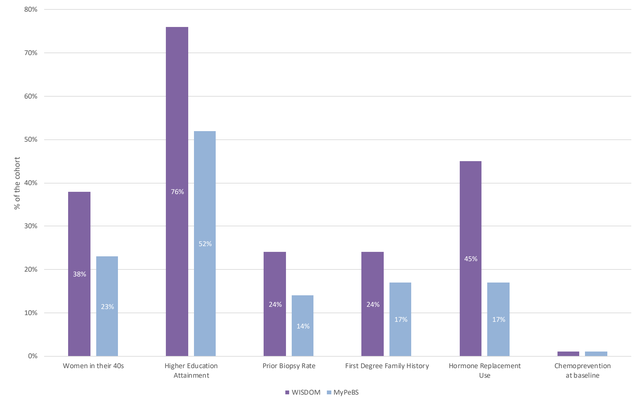
Legend:
BCSC: Breast Cancer Surveillience Consortium version 2 5-year risk; **PRS**: Polygenic Risk Score (up to 313 SNPs); **TC**: Tyrer Cuzick 5-year risk assessment; **FDFH**: First Degree Family History
[1]WISDOM risk stratification is as follows (utilizing BCSC + PRS 5-year risk): Highest: >6% 5-year risk; Elevated: top 2.5% risk by age; Average: women with a ≥1.3% risk by age (or age 50-74); low: women 40-49 with 5-year risk <1.3%. To note, women with genetic mutations, history of chest wall radiation or extremely dense breasts (40-49) were assigned to corresponding categories that did not necessary correspond to their 5-year risk.

VARIATION IS AN OPPORTUNITY TO LEARN

	WISDOM	MyPeBS
Number of recommended yearly Mgs per 100,000 using a RBS strategy	49510	59450

Table 2: Estimated number of recommended yearly mammograms (Mg) by study

RESULTS: BASELINE CHARACTERISTCS



- Baseline risk demographics were different between the two trials
- Median age was similar (54 vs. 55).
- Baseline BMI was higher in WISDOM (27.6 vs 25.3).

DISCUSSION/CONCLUSION

- Baseline characteristics were different, especially in prior biopsy rates and hormone replacement use.
- Screening schemes are also similar, except for low-risk women (every 2 yrs (WISDOM) vs. every 4 yrs (MyPeBS))
- While the risk *distribution* using standard cutoffs were similar across trials, the two studies classified risk (i.e. elevated/low) differently. This provides an exciting opportunity to learn.
- Data emerging from both trials should be generalizable and have the potential to be practice-changing.
- The results of WISDOM 1.0 will be presented at SABCS.

Join the WISDOM 2.0 Study



Join the WISDOM 2.0 Study & invite your friends and family!
- WISDOM 2.0 is actively enrolling and is exploring how to better predict who is at risk for different types of cancer
- Enroll in WISDOM at our website – www.thewisdomstudy.org

The WISDOM Study is sponsored by the Patient Centered Outcomes Research Institute (PCORI), the National Cancer Institute (NCI), and the Department of Defense. The MyPeBS study is funded by the European Commission and the French National Cancer Institute.

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