Adjunctive ultrasonography for breast cancer screening in women aged 40-49 with dense breasts; Up-dated data from an RCT, J-START

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Background
In breast cancer screening, mammography is the only proven method that reduces mortality, although it is inaccurate in young women or women with dense breasts.
Methods
To assess the efficacy of adjunctive ultrasonography a randomized controlled trial (RCT) was conducted in the Japan Strategic Anti-cancer Randomized Trial (J-START). Between July 2007, and March 2011, we enrolled asymptomatic women aged 40-49 at 42 study sites in 23 prefectures. Eligible women had no history of any cancer in previous 5 years and were expected to live more than 5 years. Participants were randomly assigned in 1:1 ratio to undergo mammography and ultrasonography (intervention group) or mammography alone (control group) twice in 2 years (*Lancet*, 387: 341-348. 2016). The primary outcome was sensitivity, specificity, cancer detection rate, and stage distribution at the first round screening.
Results
A total of 76,196 participants were enrolled. After exclusion by original protocol criteria, 72,998 were assigned to each group, intervention (n=36,859) and control (n=36,139). Sensitivity was significantly higher in intervention group (91.1%, 95% CI [87.2-95.0] *vs* 77.0% [70.3-83.7]; p=0.0004), whereas specificity was lower (87.7% [87.3-88.0] *vs* 91.4% [91.1-91.7]; p<0.0001). More cancers were detected in the intervention group than in the control (184[0.50%] *vs* 117[0.32%], p=0.0003) and were more frequently stage 0 and I (144[71.3%] *vs* 79[52.0%], p=0.0194). The increment detection rate was 36.0% in the first-round screening by adjunctive ultrasonography among women at average risk. 18 interval cancers were diagnosed in intervention group compared with 35 in the control (p=0.034). The up-dated data in women with dense breasts demonstrated that adjunctive ultrasonography detected 97.4% as compared to 65.2% by mammography alone.
Conclusion
Adjunctive ultrasonography was associated with a significantly higher detection rate than mammography alone. Therefore, ultrasonography could offer a low-cost way to increase sensitivity and detection rate of early cancers in women with dense breasts.