Innovative workflow for a new technology: A multicenter study examining agreement between radiologists and non-physicians in the assessment of BI-RADS breast density to determine eligibility for SoftVue™ automated whole breast ultrasound tomography screening at the same visit as annual mammogram

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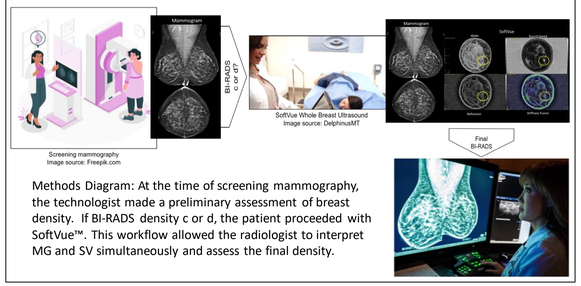
INTRODUCTION

- In the United States, over 40% of women ages 40-74 have dense breasts. Dense breasts are associated with a 1.6-to-2-fold increased risk of breast cancer. Women with dense breasts may benefit from adjunct ultrasound (US) screening since dense breasts can mask a cancer making it harder to identify on the mammogram.
- In many states, women identified with dense breast tissue on their mammogram are informed of their breast density and the impact of dense breasts on the accuracy of their mammography (MG) results. They are recommended for a supplemental screening study, usually whole breast US.
- SoftVue (SV), a novel 3D automated whole breast US tomography technique, is an efficient, accurate, radiation-free, and operator-independent adjunct screening for women with dense breasts that can be incorporated into same-day MG workflow.
- SoftVue™ received the U.S. Food and Drug Administration premarket approval in October 2021 for use as an adjunct to digital MG in screening asymptomatic women with dense breast tissue.
- Patient triaging based on dense breast tissue enables a single-visit workflow for screening MG followed by SoftVue™. This study determined how frequently the assessment of BI-RADS density performed by a trained non- physician staff agreed with that of the radiologist.

MATERIALS & METHODS

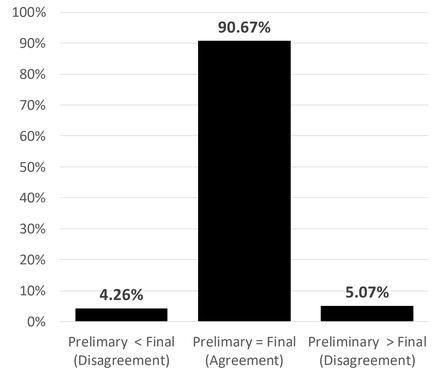
- Potential participants were identified on the daily screening MG schedule at 10 imaging centers in the United States during July 2017- Oct 2019.
- At each imaging center, non-physician staff such as technologists and research coordinators received the same 15-minute training video on how to assess breast density BI-RADS based on MG.
- A preliminary BI-RADS breast density was recorded by the technologist at the time of the mammographic imaging.
- Those patients with preliminary BI-RADS composition density c or d were recruited to enroll in the study and undergo SV.
- The radiologists then interpreted MG and SV simultaneously and included a final BI-RADS composition density.
- The preliminary and final BI-RADS composition densities were analyzed for agreement to determine if non-physician staff can be trained to effectively triage patients for adjunct screening with SoftVue™.
- Additional analysis was completed for the disagreement cohorts to investigate the rates at which technologists' preliminary assessments over and under rated composition density when compared with radiologists' final assessment.



Methods Diagram: At the time of screening mammography, the technologist made a preliminary assessment of breast density. If BI-RADS density c or d, the patient proceeded with SoftVue™. This workflow allowed the radiologist to interpret MG and SV simultaneously and assess the final density.

RESULTS

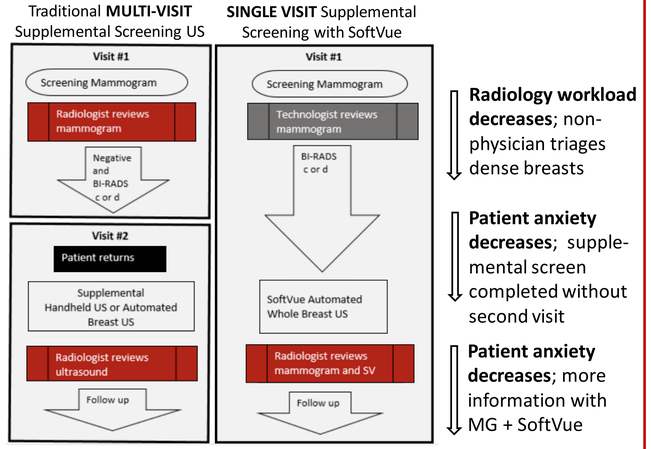
AGREEMENT: High agreement between technologist and radiologist BI-RADS assessment in 7252 asymptomatic women with dense breasts.



Overall, the technologist's preliminary density assessment agreed with the radiologist's final density assessment 90.67% (95% CI: 89.97%, 91.32%).

The technologists' preliminary BI-RADS was at a lower density level than the radiologist's final BI-RADS in 4.3% (95% CI: 3.8%, 4.7%) and at a higher density level in 5.07% (95% CI: 4.58%, 5.60%).

FEASIBLE WORKFLOW: Women with dense breast tissue can get their screening mammogram and supplemental screening US with SoftVue in 1 visit.



Radiology workload decreases; non-physician triages dense breasts

Patient anxiety decreases; supplemental screen completed without second visit

Patient anxiety decreases; more information with MG + SoftVue

MG + SV identifies up to 20% more cancers with greater accuracy and increases specificity by 8% at the BIRADS 3 threshold, potentially decreasing unnecessary biopsies for women with dense breasts.

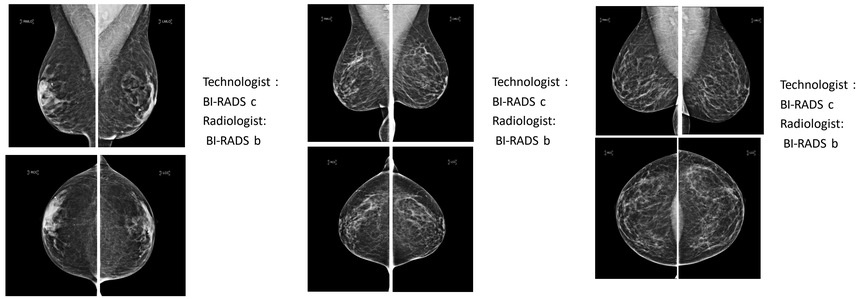
DEMOGRAPHICS

As part of a prospective, 10-site case collection registry study in the United States, 7252 asymptomatic women were screened and assessed with FFDM by a research coordinator or radiology technologist as BI-RADS breast density categories c or d. All the women received screening MG and SoftVue™ automated whole breast US tomography.

Patient Demographics (N=7252)	
Mean Age (years)	53.9 ± 9.68
Race (White)	87.2%
Final BI-RADS by radiologist	**BI-RADS b** 0.14% **BI-RADS c** 81.45% **BI-RADS d** 18.41%
Provider Characteristics (N= 10 centers)	
Academic	30%
Community-based	50%
Private practice	20%

CASE EXAMPLES FROM DISAGREEMENT GROUP

Among those in the disagreement cohort where preliminary BI-RADS was at a higher density level than the final, an assessment of scattered density BI-RADS b by the radiologist occurred at a rate of 0.14% (10/7252).



TAKEAWAYS

- **Non-physician staff, including schedulers, can be trained to effectively triage patients for SoftVue™ based on their density assessments from prior mammogram reports and/or at the time of screening MG.**
- Technologist triaging of women with dense breasts at the time of screening MG offers the benefits of same day sequential screening, including accurate and radiation free whole breast US without the added radiologist workload and patient compliance issues inherent in a multi-visit breast screening workflow.
- Technologists' preliminary breast density assessment provides the opportunity to educate women at the time of screening about the increased risk of breast cancer in dense breasts, the masking effect on MG, and the need for supplemental screening exams.
- Triaging by non-physician staff based on BI-RADS at the time of screening MG can result in a small potential missed opportunity for same day adjunct screening US (4.3% of cases). In these cases, the patient would get incorporated into the appropriate dense breast screening recommendations after the radiologist provides the final exam result.
- There was inherent bias in this study to over-assess density by the non-physicians to get higher enrollment because the centers were incentivized to recruit patients with dense breasts. This expected bias was not observed in the final results. Only 0.14% of the total cases where technologists triaged patients based on their BI-RADS at the time of screening MG resulted in cases where an extra screening may not have been medically recommended (preliminary BI-RADS c was greater than final BI-RADS assessment of BI-RADS b by the radiologist).

CONCLUSION

- A single-visit workflow for screening mammography and SoftVue™ is feasible.
- SV is the only FDA-approved adjunct study to screening MG that does not require MG results before performing automated whole breast screening US.
- Non-physician staff can accurately decide which patients can undergo SV at the time of screening MG, eliminating the need for a second visit or disrupting the radiologists' workflow.

CLINICAL RELEVANCE STATEMENT

SoftVue™ is a novel automated screening US tomographic technology that is FDA PMA approved and will likely result in improved implementation of screening breast US in women with dense breasts.

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