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Comparison of Results from Three Different Density Assessment Methods on Mammographic Density (MD) in Screening Patients Receiving Vitamin D (Vit D): Results of CALGB 70806 (Alliance)

Thursday, Nov. 29 12:45PM - 1:15PM Room: BR Community, Learning Center Station #2

Participants
H. Carisa Le-Petross, MD, FRCPC, Houston, TX (*Presenter*) Nothing to Disclose
Drew K. Seisler, Rochester, MN (*Abstract Co-Author*) Nothing to Disclose
Despina Kontos, PhD, Philadelphia, PA (*Abstract Co-Author*) Nothing to Disclose
Heshan Liu, Rochester, MN (*Abstract Co-Author*) Nothing to Disclose
Jayne R. Charlamb, MD, Syracuse, NY (*Abstract Co-Author*) Nothing to Disclose
Sin-Ho Jung, PhD, Durham, NC (*Abstract Co-Author*) Nothing to Disclose
James R. Marshall, PhD, Buffalo, NY (*Abstract Co-Author*) Nothing to Disclose
Marie Wood, MD, Burlington, NY (*Abstract Co-Author*) Nothing to Disclose

For information about this presentation, contact:

hlepetross@mdanderson.org

PURPOSE

To compare the different methods used for assessing MD in this screening population receiving Vit D for its breast cancer prevention properties, in CALGB 70806, a randomized phase II trial.

METHOD AND MATERIALS

Premenopausal women randomized to receive either 2000IU of Vit D or placebo for 12 months had mammogram at baseline and at 12 months. MD was determined by Clinical Breast Imaging Reporting and Data System (BI-RADS), the semiautomatic software Cumulus 6.0 (University of Toronto, Toronto, Canada), and fully automated method by the Laboratory for Individualized Breast Radiodensity Assessment (LIBRA, by Computational Breast Imaging Group at University of Pennsylvania). Blinded central review of all submitted mammograms was performed. Eligible women were premenopausal, age <55, with at least 25% dense breast tissue. Kappa statics were used to measure agreement between local and central MD readings using BI-RADS. MD measurements were compared using Wilcoxon rank-sum test.

RESULTS

300 women from 41 US centers were accrued from 2011 to 2013. 150 women received Vit D and 150 placebo. Mean age was 42.6 years with 14% Hispanic, 12% African American, and 74% Caucasian. 72% of participants completed treatment; the rest withdrew. As previously reported, 1 year Vitamin D therapy did not significantly change MD (p=0.7048). Sub-analysis demonstrated moderate agreement between local and central MD readings using BI-RADs classification at baseline and at 12 months, with Kappa coefficients of 0.48 and 0.41 respectively. Increased MD from Cumulus and LIBRA were noted in heterogeneously dense and dense BI-RADs cases (p <0.0001). When the readings for CC view was compared to MLO view, CC views showed slightly higher readings at baseline and at 12 months (p=0.05 and 0.02 respectively). Cumulus readings were consistently higher than LIBRA readings (table 1, P <0.0001).

CONCLUSION

The subjective method of BI-RADS, semi-automated method CUMULUS, and automated method LIBRA were in agreement for the majority of cases, with least variability noted from LIBRA than the other two methods.

CLINICAL RELEVANCE/APPLICATION

The automated method is more reliable and reproducible than the semi-automated or BI-RADs method for assessing breast density.
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