VolparaDensity Used to Guide Patient Selection in First Breast MRI Screening Trial for Women with Extremely Dense Breasts

Design of Randomized-Controlled DENSE Trial Featured in RADIOLOGY

WELLINGTON, New Zealand (PRWEB) July 07, 2015 -- The DENSE Trial, the first randomized trial investigating the additional value of MRI for screening women with dense breasts, is featured in the current issue of Radiology. The article, “MR Imaging as an Additional Screening Modality for the Detection of Breast Cancer in Women Aged 50–75 Years with Extremely Dense Breasts: The DENSE Trial Study Design,” presents the rationale and design of the DENSE Trial. Run by Dr. Carla van Gils and Dr. Wouter Veldhuis from University Medical Center Utrecht (UMCU) in the Netherlands, the trial seeks to determine the effectiveness of screening with mammography and MRI compared to mammography alone in women who have extremely dense breasts.

Approximately one million women are screened every year in the Netherlands as part of the Dutch Breast Screening Program. To study the additional value of MRI, the DENSE Trial uses a randomized controlled design with one group receiving mammography and the other group receiving mammography and MRI. VolparaDensity software from Volpara Solutions is being used in the trial to provide objective, volumetric breast density values. Participants with extremely dense breasts and a negative mammography result are randomized into two arms: one to have an additional MRI (n=7,237) and the other to follow the usual mammography screening program (n=28,948). The primary outcome is the difference in proportion of interval cancers between the arms. In order to be an effective screening strategy, the extra MRI screen-detected cancers have to be accompanied by a subsequent reduction in interval cancers.

Research has shown that mammography alone has significantly lower sensitivity in women with extremely dense breasts than in women with fatty breasts. With high sensitivity, even in the dense breast, MRI has the potential to improve cancer detection at an early stage; however, MRI is more costly and can increase the number of false-positives. The DENSE Trial aims to validate personalization of the national breast cancer screening program by incorporating information on mammographic density.

“Automated, objective density assessment was critical for this project, which is why we selected Volpara. The software’s robust nature and clinical track-record was once again validated by the results of the ASSURE project we recently presented at ECR which demonstrated the direct correlation of mammographic screening performance to each patient’s breast density categorization as determined by VolparaDensity,” stated Dr. van Gils.

“The major strength of the DENSE Trial is its parallel-group randomized controlled design. As far as we are aware, DENSE is the first randomized trial investigating the additional value of MRI in women with extremely dense breasts” added Dr. van Gils.

“We are very pleased to support the ground-breaking DENSE Trial, the first randomized controlled study to examine the effectiveness of screening women with extremely dense breast with MRI and mammography, compared to mammography alone. We are proud that VolparaDensity is an integral part of the patient selection process by providing consistent, clinically proven breast density scores,” said Ralph Highnam, PhD., Volpara Solutions CEO and Chief Scientist.
VolparaDensity is in use at breast imaging centers worldwide to help radiologists objectively assess density from both digital mammography and tomosynthesis images and to determine which women would benefit from additional screening. Highly correlated to breast MR assessments, VolparaDensity is a reliable tool that automatically generates an objective measurement of volumetric breast density correlated to the ACR (American College of Radiology) breast density categories. To date, more than 5-million women have had their breast density analyzed using VolparaDensity.

About the Dutch Breast Cancer Screening Program
The Dutch National Breast Cancer Screening Programme screens more than 1 million women each year. Once every two years, women in the Netherlands between the ages of 50 and 75 years are invited for a two-view mammogram. Screening takes place at 67 predominantly mobile mammography units and all mammograms are independently read by two radiologists, who must reach consensus to refer a woman for further clinical assessment. Since the introduction of the Breast Cancer Screening Programme in the Netherlands in 1990, mortality associated with the disease has decreased by more than 30%. The decline in mortality is attributable partly to screening-based early detection and treatment, and partly to improved treatment methods.

About Volpara Solutions
Founded with the goal of helping radiologists give women the most accurate information possible regarding their breast health, Volpara Solutions is the wholly owned sales and marketing arm of Matakina Technology Limited of New Zealand. Cleared by the FDA, HealthCanada, the TGA, and CE-marked, VolparaDensity provides an objective volumetric measure of breast density from both digital mammography and tomosynthesis images. VolparaDensity is part of a suite of quantitative breast imaging tools built on the Volpara Solutions algorithm that allows for personalized measurements of density, patient-specific x-ray dose, breast compression and other factors designed to provide critical insight for breast imaging workflow. For more information, visit www.volparasolutions.com.

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