Reviewer’s report

Title: Diagnostic performance and inter-observer concordance in lesion detection with the Automated Breast Volume Scanner (ABVS)

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Reviewer: Osman Erogul

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Diagnostic performance and inter-observer concordance in lesion detection with the Automated Breast Volume Scanner (ABVS)

The manuscript by S.Wojcinski et al investigates “diagnostic performance and inter-observer concordance in lesion detection with the Automated Breast Volume Scanner (ABVS)”. The subject is relevant and statistical methods used are familiar and well known. Diagnostic performance of ABVS is rarely reported in the literature and this work is a good effort. However, the most important problem of this manuscript is that it is not well-written.

In addition, I have the following specific comments for the authors:

- Major Compulsory Revisions

1) The authors claim in the “Materials and Methods” section that the responsible ethical committee did not require additional approval for this non-interventional study-design. But, it is unclear informed consent or waiver of informed consent for at the beginning of study. The authors must indicate that if there is any informed consent at the beginning of the study.

2) The authors were expressed this study is a cohort study in the “Materials and Methods, and Results” sections. But, the definition of cohort study is “In statistics and demography, a group of subjects who have shared a particular event together during a particular time span [1]. Cohorts may be tracked over extended periods in a cohort study. A cohort study is a form of longitudinal study (a type of observational study) used in medicine, social science, actuarial science, and ecology. A longitudinal study is a correlation research study that involves repeated observations of the same variables over long periods of time—often many decades. But this study was carried out between March 2010 and July 2011. So, this study can’t be considered as the cohort study.

3) In the “Statistical analysis” section, details of the used statistical methods are missing, and/or poorly justified/interpreted. In this section, the authors were specified three different statistical analyses. Firstly, the diagnostic sensitivity and specificity, as well as the accuracy of the ABVS, were calculated based on the Bayesian theorem using Fisher’s exact test. Secondly, the statistical analysis of the extent of agreement between the two raters was based on Cohen’s Kappa test. At the end, pair wise comparisons of proportions were performed using the Z-test. But it wasn’t explained that why these methods used for these statistical analyses. How the authors decided to use this tests? Why the authors didn’t
used a receiver operating characteristic (ROC), or simply ROC curve instead of Fisher’s exact test? I suggest that, this section must be reevaluated by the authors.

4) In the “Statistical analysis” section, the authors were stated that, “Microsoft® Office Excel® 2007 (Microsoft Corporation) was used for data collection” and “statistical analysis was performed by the author SW and validated by the other authors”. But they didn't mentioned, how they calculated the Fisher’s exact test vales and, Cohen’s Kappa test values that presented in the results section. If any statistical program used the calculation of the statistical parameters in the study, this issue should be clarified.


- Minor Essential Revisions

1. In the introduction section, the authors expressed that “Furthermore, not all of the images data from ultrasound examinations can be stored, and only subjectively chosen screenshots are archived.” At the present time, the new ultrasonography devices can be stored all the images data from ultrasound examinations. But the physician may archived only subjectively chosen screenshots. The authors could correct this matter.

2) The sample size of the study population was not clearly expressed (how many women? or how many breast examination?) from the "Patient Database" subsection in "Materials & Methods" that the patients enrolled in this study have given informed consent. This issue should be clarified.

3) The authors stated that the discussion section many prior studies about the ABVS accuracy, specificity and the sensitivity. A table listing these studies and key characteristics would be helpful.

- Discretionary Revisions

1) In the introduction section, there is a “Mammography has demonstrated excellent sensitivity, specificity and inter-observer concordance.” sentence. At the end of this sentence a reference may be added

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.