Feasibility of 3D Breast Ultrasound in comparison with 3D breast MRI Amendement: Analysis of false positive rate with 3D ultrasound

Published: 07-10-2010
Last updated: 04-05-2024

Primary Objective: Examining the value of ABVS in relation to current breast imaging techniques by: - comparison of ABVS findings with MRI findings. - comparison of ABVS findings with mammography and hand-held US. Secondary Objectives: - assessment…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON36527

Source
ToetsingOnline

Brief title
3D Breast Ultrasound in comparison with 3D breast MRI

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
Breast neoplasmata

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: 3D ultrasound, Breast, MRI

Outcome measures

Primary outcome

Study parameters -Study parameters are the difference in detection performance,

reproducibility and inter-observer agreement of ABVS compared to MRI and

hand-held US. -Detection performance is measured by detection rate,

sensitivity, specificity, positive and negative predictive values, and area

under the ROC based on BIRADS scores.

Amnedement: analysis of the false positive rate.

Secondary outcome

n.a. (see primairy study parameters)

Study description

Background summary

Over the last decades there has been a steady increase in incidence of breast cancer in women. With an incidence of breast cancer in 2005 of 12 to 13% in general population in The Netherlands, breast cancer is the single most diagnosed cancer in women(1). Modalities currently used in breast imaging are mammography, hand-held ultrasound and magnetic resonance imaging (MRI). MRI is nowadays regarded as gold standard in breast imaging with high sensitivity (91-100%)(2,3,4). However a limited specificity of 72% is reported in a meta-analysis due to enhancement of benign lesions(5). Other drawbacks of MRI are the limited availability, relatively long examination time, higher costs and in 10% of patients MRI cannot be performed due to claustrophobia(6) or contraindications (e.g. implantable cardioverter defibrillator)(7,8).

Ultrasound (US) is cost-effective, lacks radiation, readily available and well tolerated by patients. Currently a radiologist or technologist using a hand-held transducer carries out a 2D US examination. Only impressions are caught and stored in a PACS. This manual scanning is time-consuming and operator dependent. Modern volumetric viewing and batch reading of 2D US images are not possible. Operator dependency and interobserver variability are disadvantages of 2D US. In several studies with women at risk of developing breast cancer 2D US seemed better to equal in comparison to mammography(9-13). A promising new technique is 3D US or ABVS (automated breast volume scanning) (14,15). The ACUSON S2000* Automated Breast Volume Scanner (Siemens, Erlangen) has been cleared for commercialization by the US Food and Drug Administration (FDA) and will be used in accordance with its cleared labeling. In contrast to hand-held 2D US, is ABVS operator independent and standardized acquisition is possible by a radiologist or an instructed technician. The 3D US data sets can be stored in PACS and are available for interpretation on a workstation. Also correlation with other available examinations such as mammography and 3D MRI becomes possible. As 3D images can be archived and viewed later, reliable comparison with previous examinations becomes feasible. These are regarded as major steps forward in making ultrasound less operator dependent and thus suitable for follow-up and screening. First experience with 3D whole breast ultrasound shows another promising advantage: image reconstructions in planes perpendicular to the transducer can reveal spiculated patterns surrounding malignant lesions that are well known as specific signs of cancer in mammography. Such patterns could not be observed well or were completely absent in 2D US(16). The purpose of this study is to assess the feasibility of 3D US in comparison with 3D MR imaging as gold standard and mammography and 2D US

Study objective

Primary Objective: Examining the value of ABVS in relation to current breast imaging techniques by: - comparison of ABVS findings with MRI findings. - comparison of ABVS findings with mammography and hand-held US. Secondary Objectives: - assessment of operator dependency of ABVS data acquisition. - assessment of tolerability of ABVS image acquisition - assessment of interobserver variability of ABVS data interpretation. -
Amendement: Analysis of the false positive rate in patients with low a priori change of having breast cancer.

Study design

General A prospective study design will be used to assess reproducibility of image acquisition and the feasibility and accuracy of breast tumor detection with ABVS in patients scheduled for breast MRI. All participants receive written information and need to sign an IRB-approved informed consent prior to inclusion. An ABVS examination will be carried out and will be interpreted within 1 week prior or following MRI. The interpreters are blinded for the MRI

findings. Imaging findings will be compared with MRI findings and if available also with surgical and histopathological findings. Imaging study MRI The examination will be carried out with a 1.5T MRI scanner (General Electric: Signa) using a routine screening protocol. The patients is positioned in the prone position. A a dedicated bilateral multi-element breast surface coil is used. The MRI examinations are performed 5 - 15 days after the first day of the last menstrual period. Indication for MRI are high risk patients, pa(General Electric Signa 1,5T) tients with dense breast tissue with inconclusive prior examination, evaluation of suspected or histological proven malignancy, preoperative evaluation of lesion size, multifocality and multicentricity, follow-up of patients with a treatment regiment with neo-adjuvant therapy and patients with breast implants. ABVS All subjects will be examined with 3D ABVS (ACUSON S2000*: Automated Breast Volume Scanner, Siemens). ABVS imaging acquisition is restricted to 3 examiners (an experienced mammoradiologist (MJCM Rutten, MD, PhD) and two radiology residents (I. Dubelaar,MD and M. de Jong,MD).
Amendement: MAMMOGRAPHY: The examination will be performed by dedicated technicians in breast imaging with a mammography unit (Mammomat inspiration, Siemens).

Study burden and risks

The use of ultrasound in breast imaging is not associated with any know hazards. the extra burden for the patients will be the exam itself, total acquisition time takes 10 minutes. The Greatest benefit of the exam is expected if a new lesion is found only on 3D ABVS imaging, and cancer is detection only with 3D ABVS. As a negative side effect, is an expected increase in needle biopsies. If there are abnormalities visualised only on the ABVS image data, that are not visible with or not reported with the other imaging studies the following will be undertaken; - If a lesion has a typical benign appearance (BIRADS 2), no further steps are taken. - If a lesion is probably benign (BIRADS 3) or possibly / probably malignant (BIRADS 4 or 5) the patient will be contacted; targeted hand-held US will be advised and when considered necessary a biopsy specimen will be taken. Prior to inclusion all participants are informed about this possibility, the procedure and the risks of this procedure (attached to this file as a separate document).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients who are scheduled for MRI of the breast in accordance of current practice in the Jeroen Bosch Hospital will be invited to participate. Inclusion period will be approximatly 3 months.
Amendement: Additionally patients will be included who are scheduled for a routine mammography

Exclusion criteria

1.Patients who are unable to provide informed consent; 2.Patients who cannot undergo adequate examination with breast ultrasound and MRI or who are unable to cooperate; 3.Patients who, for logistic reasons, cannot be examined by ABVS within a period of one week prior or after MRI.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	01-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33455.060.10