Optimal pressure for Digital Breast Tomosynthesis

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26374

Source
Nationaal Trial Register

Brief title
OP4DBT

Health condition

Mammography / Mammografie
Tomosynthesis / Tomosynthese
Compression / Aandrukking
Breast / Borst
Diagnosis / Diagnose

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Sigmascreening B.V., Enschede

Intervention

Outcome measures

Primary outcome

In order to identify which level of contact-pressure (6, 8, 10 or 12 kPa) is optimal, the

investigators team defines a weighed sum of the three output measures:

Compression Score = 2 * Lesion Conspicuity Score (3 rater average: ¨C8 to +6 scale)

¨C 1 * Relative Dose Score (relative AGD difference: ¨C5 to +5 scale)

¨C 1 * Clinical Pain Score (recoded NRS scores: 0 to +10 scale)

The formula reflects the clinically relevant weights of the three interests as chosen by the investigators team: improving lesion conspicuity is rated twice as important as reducing (note the minus-sign) absorbed glandular x-ray dose and reducing the clinical pain score.

Secondary outcome

The two-in-one DBT-recording design is unique in providing two image sets of the same breast with slightly different compression level, which enables compression blinking and x-ray elastography. In order to assess the diagnostic value of these techniques, a panel of five to ten radiologist will be asked for their opinion in two ways: clinical and subjective.

Study description

Background summary

Rationale: In conventional mammography, one of the reasons for breast compression is lateral spreading of the tissue to reduce overprojection. Because Digital Breast Tomosynthesis (DBT) combines multiple projection images from various angles into a pseudo 3-dimensional image, overprojection is less of a concern. It has therefore been hypothesised that less compression may be sufficient, however, all results in literature are based on reducing the target force. A 2015 PhD dissertation from the University of Amsterdam shows that pressure-standardized compression is preferred because it adjusts the compression force to the size and firmness of the individual breast. This is shown to reduce pain experience without compromising the image quality or increasing the absorbed glandular x-ray dose (AGD). Therefore, the AMC standard-of-care compression protocol since 2014 is to use a contact area average pressure of 10 kPa (¡Ö 75 mmHg) for all women. For DBT, it is however not yet known which level of contact-pressure (compression force divided by the breast-paddle contact area) is optimal.

Objective: The objective of this study is to statistically identify the optimal level of contact-

pressure for DBT. ¡°Optimal¡± is defined as a weighed sum of three clinical interests: as high as possible lesion conspicuity, as low as possible absorbed glandular x-ray dose and as low as possible pain experience.

Study design: The objective is most directly achieved by using a within-women comparison study. Each breast will get a customized two-in-one DBT-recording whereby two DBT image sets are acquired at two different levels of contact-pressure without repositioning the breast. The levels are randomly assigned to be 4, 5, 6, 8, 10, 12, 15 or 19 and the mildest level is always performed first. Three radiologists will compare lesion conspicuity. The absorbed glandular dose is retrieved from the DBT image information header (DICOM) and the participants are asked to rate their pain experience directly after each of the two DBT image-acquisitions.

Study population: The study population consists of women older than 30 years of age with an appointment for DBT mammography in the AMC. Women who have or previously had endo-prosthesis will be excluded. Two relevant and prevalent groups of participants are included separately: women who have not had any breast treatment on either breast and women who have had Breast Conserving Therapy (BCT) on at least one breast. Statistical power analysis showed a required sample size of 600 breasts. The study therefore includes 300 women who each have two untreated breasts, and 600 women who have at least one BCT-treated breast.

Intervention: One of the DBT-recordings per breast is replaced by a custom ¡°two-in-one¡± DBT-recording. Instead of releasing the breast immediately after the x-ray exposure, the mammography technologist will apply slightly more pressure and make a second DBT-recording.

Main study parameters: We study the influence of the level of contact-pressure on three parameters: lesion conspicuity, absorbed glandular dose and pain experience. The primary analysis consist of two balanced one-way ANOVA tests, one for untreated and one for BCT-treated breasts. From this we determine whether one of the five levels of contact-pressure is significantly optimal for DBT.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants will receive one extra DBT-recording per breast on top of two routine recordings. The extra DBT-recording will increase the total absorbed glandular dose per breast but has the advantage of providing a second image set in which the breast is exactly in the same position but slightly more compressed. Differences between these two

image sets will be visualized by blinking, which highlights the deformability of internal structures. Combined with the pressure-levels, we will calculate the strain map, which quantifies the elasticity of internal structures. Both can increase the conspicuity of malignant lesions.

For obtaining the two-in-one DBT-recording, the breast will be flattened and immobilized approximately twice as long (60 to 90 seconds instead of 30 to 45 seconds). This could be more painful, however, all compression levels are based on the contact-pressure: the forces are therefore already adjusted to the size and firmness of the individual breast. The study will add two to five minutes to a total of 10 to 15 minutes.

Study objective

The primary objective of this study is to statistically determine the optimal contact-pressure (compression force divided by breast-paddle contact area) for breast compression in Digital Breast Tomosynthesis. In this study, ¡°optimal¡± is defined as the level of contact-pressure for which the following three interests are maximized:

- As high as possible conspicuity of radiologically suspect lesions

- As low as possible absorbed glandular x-ray dose

- As low as possible pain

Study design

One - the appointment for mammographic examination

Intervention

The investigational product is a variation in the level of contact-pressure during breast compression for Digital Breast Tomosynthesis. Instead of the normal DBT-recording, participants in this study will receive a custom two-in-one DBT-recording consisting of two x-ray exposures at two levels of contact-pressure. Following a specific randomization scheme, the technologist initially applies 4, 5, 6, 8, 10 or 12 kPa of contact-pressure and makes the first DBT-recording. Instead of automatically releasing the breast as normal, the technologist increases the compression to 6, 8, 10, 12, 15 or 19 kPa of contact-pressure and makes the second DBT-recording. Thus, two DBT-image sets are obtained from the breast in the same position with a slight difference in compression level. The two-in-one DBT-recording will take approximately twice as long (60 ¨C 90 seconds) as a normal DBT-recording (30 ¨C 45 seconds). The technologist who performs the procedure will ask the participant to verbally rate her pain experience on a 0 ¨C 10 Numerical Rating Scale both immediately after the first

DBT-recording (i.e. before applying more pressure), and immediately after the second DBT-recording (i.e. when the breast is released).

Contacts

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Eligibility criteria

Inclusion criteria

1, female

2, older than 30 years of age

3. receives DBT as standard procedure or as indicated by the responsible radiologist on site

Exclusion criteria

1. unable to understand the patient information folder

2. has or previously had breast endo-prostheses (implants)

3. underwent any form of breast surgery or therapy, with the exception of Breast Conserving Therapy with radiotherapy

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2018
Enrollment:	1122
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6636
NTR-old	NTR6822

Register	ID
Other	: ABR NL-63445

Study results

Summary results

General:
- de Groot JE, Broeders MJ, Branderhorst W, den Heeten GJ, Grimbergen CA. A novel approach to mammographic breast compression: Improved standardization and reduced discomfort by controlling pressure instead of force. Med Phys 2013;40:081901.
- de Groot JE, Branderhorst W, Grimbergen CA, den Heeten GJ, Broeders MJ. Towards personalized compression in mammography: A comparison study between pressure- and force-standardization. Eur J Radiol 2015;84:384-91.