Experience of pain during mammographic screening by three different compression paddles

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Introduction

Experience of pain during screening mammography is shown to affect further attendance negatively. We aimed to explore the experience of pain during mammography using three different breast compression paddles.

Methods

Using a self-report questionnaire, we collected information on pain experienced during mammography from 938 women screened in Bodø in 2018, as a part of BreastScreen Norway. Pain was assessed by a numeric rating scale (NRS, 0-10). A fixed paddle, a flexible paddle or a fixed paddle standardizing pressure (study paddle) were used during screening. Compression force (kg) was recorded by the radiographers for each screening examination. Log-binomial regression was used to determine the relative risk (RR) of severe (≥7 on NRS) versus mild/moderate (<7 on NRS) experience of pain associated with type of compression paddle, adjusting for breast tenderness, shoulder(s) and/or neck pain prior to screening, compression force, age, body mass index and screening history.

Results

Mean score of self-reported experienced pain was 2.8 for the fixed, 2.3 for the flexible and 2.8 for the study paddle ($p<0.01$ for fixed versus flexible and for flexible versus study paddle). Adjusted RR of severe pain was higher for the fixed (RR^{Adj} 2.01, 95%CI 1.13-3.59) and the study paddle (RR^{Adj} 2.52, 95%CI 1.44-4.42) compared to the flexible paddle. Breast tenderness was associated with a higher risk (RR^{Adj} 1.93, 95%CI 1.04-3.58) of severe pain compared to no breast tenderness.

Conclusion

Women screened with the flexible paddle reported lower experience of pain than those screened with the fixed or study paddle.

Implication for practice

The flexible compression paddle might be the best choice regarding experience of pain in mammographic screening. Breast tenderness should be considered by the radiographers in a practical screening setting.

Key words: Mammography; Breast Compression; Pain; Breast Cancer; Surveys and Questionnaires

Introduction

Breast compression in mammography ensures high image quality and reduces blurring and radiation dose to the examined women [1]. Some women experience pain during and/or after compression [2-4]. The consequences can reduce attendance in mammographic screening and increase anxiety about seeking mammography for breast symptoms [2-5].

The impact of breast compression on experience of pain during mammography has been studied using screen-film mammography [2,3,6]. The transition to digital mammography (DM) systems has influenced the women's experiences of mammography, as it is claimed that these systems require less compression force to achieve the required immobilization of the breast due to the automated exposure control and flexible compression paddles [7,8]. Flexible compression paddles provide various tilting angles and were introduced with an aim of decreasing pain for women [9,10]. To our knowledge, no evidence exists to support or deny this suggestion. However, the question of reduced image quality associated with flexible paddles has been raised [10,11].

A limited number of studies on the experience of pain during mammography have investigated compression force (kg or newton, N) or pressure (kilopascal, kPa) [2-4,6,12]. Information about compression force is shown to radiographers during image acquisition and stored in the Digital Information and Communications in Medicine (DICOM) header. The applied compression force varies substantially between breast centers and among radiographers [13,14]. Compression pressure indicated during image acquisition is suggested as a measure more closely related to experienced pain compared to compression force [15-17]. Following recent developments in fixed paddle technology, the compression paddle standardizing pressure to 10 kPa in real time is assumed to cause less pain as it helps radiographers apply the physiologically appropriate compression pressure (15). However, there are substantial knowledge gaps related to experience of pain associated with the use of different types of compression paddles applying either force or pressure-based compression [16-19].

In this study, we aimed to compare the experience of pain during mammography for a fixed paddle, a flexible paddle, and a fixed paddle standardizing compression pressure (study paddle) among women participating in BreastScreen Norway. Further, we aimed to compare image quality for positioning parameters for the three paddles.

Methods

The study was approved by the Data Protection Official at Oslo University Hospital (2017/6481). The data was disclosed with legal bases in the Cancer Registry Regulations section 3-1 and the Health

Register Act section 19 a to 19 h [20,21]. The Cancer Registry of Norway administers the population-based breast cancer screening program, BreastScreen Norway, that serves about 670,000 female residents aged 50-69 years. The women are offered biennial mammographic screening that typically includes four DM images with craniocaudal (CC) and mediolateral oblique (MLO) views of each breast. The annual participation rate is about 75%. The time and date of screening appointments are scheduled by the Cancer Registry of Norway and given in the invitation letter to screening, and women are invited according to the birth cohorts. The program has been described in detail elsewhere [22].

Study sample

A total of 2027 women, who attended the screening unit in Bodø at Nordland Hospital as a part of BreastScreen Norway during the study period, March-May and September-November 2018, were invited to participate in the study at the standard pre-screening interview conducted by the radiographers. A total of 1,342 agreed to participate (Figure 1). The participating women received a questionnaire, which included a study identifier and questions about experienced pain related to their mammography examination. The women completed the questionnaire immediately after the examination and submitted it in a closed letter case at the screening unit. Responding to the questionnaire was considered an informed consent for using the data in this study.

We excluded women without a study identifier (n=37) or information on type of compression paddle (n=45), or force used (n=12). Women who did not report experienced pain (n=104), pain in breasts, shoulder(s) and/or neck prior to screening (n=41) or had no information about weight and height (n=157) were excluded. The final study population included 938 women; 287 were screened with the fixed, 313 with the flexible, and 338 with the study paddle.

Image quality assessment was conducted for a subgroup of randomly selected examinations (including right and left CC and MLO images), 58 for the fixed, 73 for the flexible, and 69 for the study paddle. Three of the co-authors performed the assessment according to the following parameters: nipple in profile, retroareolar area, pectoral muscle length and width (for MLO only), inframammary angle (for MLO only), fibroglandular tissue towards chest wall (for CC only) and fibroglandular tissue towards pectoral muscle (for MLO only), and blurring. Each of the four images in an examination were classified as perfect, adequate, or inadequate (Table A1).

Compression paddles

Mammography was performed with the fixed, flexible, or study paddle. Each compression paddle was used for six weeks over the 18 weeks study period, according to the standard screening

procedure [23]. The paddles were changed every two weeks starting with the fixed paddle. All three paddles were available in sizes: 24 x 31 cm and 19 x 23 cm. While using the flexible and fixed paddles, the radiographers were recommended to apply compression force based on the breast size and the recommendations from the Quality Assurance Manual in BreastScreen Norway (8.0-18 kg or 80-180 N) [23]. The study paddle, a rigid Sensitive Sigma™ Paddle (Sigmascreening, Amsterdam, the Netherlands), included integrated force sensors, x-ray transparent foil with a conducting layer and controller with light-emitting diode pressure indicators to ensure that the pressure applied to each breast was measured individually [17,24]. The radiographers were trained to use the light pressure indicator of the paddle to perform compression according to the level of compression pressure.

The variables of interest

The radiographers noted on each questionnaire what compression paddle and force were used per image view (right/left CC and right/left MLO) before the women received the questionnaire, filled it out and submitted. The radiographers sent the questionnaire to the Cancer Registry of Norway once a week, where the information was manually coded. Information about the women's age (continuous, years, and categorical, <55; 55-59; 60-64; and ≥65 years) and screening history (first screening attendance versus subsequent or more than one screening attendance) was obtained from the Cancer Registry.

A numeric rating scale (NRS) from 0, no pain, to 10, strong pain, was used for measuring experience of pain [25]. In the study, pain on NRS was presented as a continuous (0-10), categorical (no pain [0]; mild [1-3]; moderate [4-6]; and severe pain [7-10]), and dichotomous variable (<7 versus ≥7). A score of <7 corresponded to moderate or mild pain, while a score of ≥7 included severe pain [25]. The cut-off was chosen to identify women who reported severe pain, as the values ≥7 were considered a strong negative experience of mammography, perceived as a procedure causing significant and/or unbearable pain. Variables of interest obtained from the questionnaire included body mass index (BMI, continuous, kg/m^2, and categorical, <25.0kg/m^2; 25.0-29.9kg/m^2; and ≥30.0kg/m^2), pain location (breast, chest wall, shoulder, neck, skin, axillary area, and under breast), breast tenderness prior to screening (yes/no), shoulder(s) and/or neck pain prior to screening (yes/no), compression force (continuous for CC, MLO and both, kg; and categorical, <12.3kg; 12.3-13.7kg; 13.8-14.9kg; and ≥15.0kg).

Statistical analyses

Means with standard deviations (SD) and 95% confidence intervals (CI) were used to describe

continuous variables (pain, age, BMI, and compression force for CC, MLO, and average for both views) by compression paddles. A t-test was used to compare the means. A two-sample test of proportions was used to compare the percentages between compression paddles for categorical variables (pain, pain location, age, BMI, screening history, breast tenderness prior to screening, shoulder(s) and/or neck prior to screening, and compression force). Boxplots of the experienced pain (on NRS) for age (categorical), body mass index (categorical) and compression force categorical) were shown by the three paddles. A log-binomial regression model was used to determine the relative risk (RR) of severe pain (≥7 NRS) versus moderate, mild, or no pain (<7 NRS) associated with the paddles. Other covariates in the model were breast tenderness (present versus absent), shoulder(s) and/or neck pain prior to screening (present versus absent), compression force (categorical), age (categorical), BMI (categorical) and screening history. The average number (numbers for right and left CC and MLO divided by four, or numbers for right and left CC or MLO divided by two) and percentage of perfect images for the included image quality parameters were calculated. The image quality criteria and the numbers and percentages of perfect images for each image (right and left CC and MLO separately) were presented in the Appendix. All analyses were conducted using STATA® 15.0 (StataCorp, Texas, USA).

Results

Mean age of the women included in the study was 58.8 years, and mean BMI was 26.8 kg/m^2 (Table 1). The mean values for age and BMI did not differ by compression paddles.

Experience of pain was reported to be lower for women compressed with the flexible paddle (2.3 on NRS), compared to the fixed (2.8 on NRS), and study paddle (2.8 on NRS) (p=0.03 for both) (Table 1). A higher proportion of women did not experience any pain during mammography with the flexible compared to the fixed and study paddle (p=0.03 for both). No women screened with the flexible paddle experienced severe pain compared to 2% of women screened with the fixed and study paddle (p=0.02 for both). Most of the women experienced pain located in the breast itself during mammography (57%) followed by the chest wall (16%) and the axillary area (8%). The proportion of women who experienced pain in the axillary area during mammographic screening was higher for the fixed (12%) compared to the flexible (8%) and study paddle (6%) (p<0.01 for the fixed versus flexible paddle and p=0.04 for the fixed versus study paddle). Mean compression force for CC and MLO was lower for the flexible paddle (10.9kg and 14.4kg) compared to the fixed (12.3kg and 15.2kg) and study paddle (12.8kg and 15.5kg) (p<0.01 for both). A compression force of <12.3 kg was used for 37% of women screened with the flexible compared to 12% and 18% of those screened with the fixed

and study paddle, respectively. A compression force of ≥15.0 kg was used for only 8% of the women screened with the flexible paddle compared to 22% and 46% of those screened with the fixed and study paddle, respectively ($p<0.01$ for all).

Median values of experienced pain did not differ substantially by age or BMI groups (Figure 2 and Figure 3).

Median values of pain on NRS were 2.0 in all four compression force groups for the flexible compression paddle (Figure 4). For the applied force of <12.3kg, the value was 3.0 for the fixed and the study paddle. For the force of 12.3-13.7kg, the value was 3.5 for the fixed paddle.

In adjusted analyses, RR of severe (≥7 on NRS) pain was higher for the fixed paddle (RR 2.01, 95% CI 1.13-3.59) and study paddle (RR 2.52, 95%CI 1.44-4.42) compared to the flexible paddle (Table 2). Breast tenderness was associated with a higher risk (RR 1.93, 95%CI 1.04-3.58) of severe pain compared to no breast tenderness. Compression force of ≥15.0kg was associated with a lower risk (RR 0.53 95%CI 0.23-0.97) of severe pain compared to an applied force of <12.3kg.

The average percentage of images with perfect quality for the parameter fibroglandular tissue towards chest wall for CC images was 71% (52/73) for the flexible paddle and 87% (50/58) for the fixed paddle ($p=0.04$) (Table 3).

Discussion

The mean score of experienced pain during mammographic screening on an 11-point numeric rating scale varied from 2.3 to 2.8 by three different compression paddles. Mean experienced pain was lower for the flexible compared to the fixed paddle and the paddle standardizing compression pressure (study paddle). Using the flexible paddle as reference, relative risk of severe pain was higher for the fixed and study paddle.

The superior result of the flexible paddle might be associated with a more even distribution of compression force over the breast area due to tilting [11]. The flexible paddle might provide better immobilization of the breast at lower applied force and the examination was therefore associated with less pain for the women. A similar study comparing compression paddles showed that the flexible paddle was associated with the same experience of pain as the study paddle, but the compression force was higher for the flexible versus study paddle [19]. A study from the Netherlands comparing fixed and flexible paddles did not identify any difference in experienced pain for the screened women [10], but radiation dose was lower for the flexible compared to the fixed paddle and a paddle standardizing compression pressure [10,19]. Compression performed with flexible paddles might result in a longer settling time, compared to fixed paddles, which can lead to motion blur [26].

However, our study showed no differences in blurring by paddles. Further, using the flexible paddle was shown to increase the likelihood of omitted breast tissue close to the chest wall in the image compared to the fixed paddle, which might negatively affect the reader's ability to find abnormalities [10]. Our results of a lower percentage of CC images with perfect quality regarding fibroglandular tissue towards the chest wall for the flexible versus fixed paddle corroborate these findings. However, no images with completely inadequate quality were obtained (data not shown) and the results regarding fibroglandular tissue towards the pectoral muscle were similar for all paddles.

Severe pain was more frequent and represented a higher risk for the fixed and study versus flexible paddle. These results contradict the conclusions of the studies by de Groot et al. (2015) and Branderhorst et al. (2014), indicating that standardization of compression pressure could lead to less pain [15,16]. However, the aforementioned studies investigated protocols of compression force and pressure standardization and not different paddles. Women who experience or anticipate severe pain usually ask the radiographer to stop compressing and receive generally lower force and pressure than those who tolerate higher forces. This might explain that the force of ≥15.0kg was associated with a lower risk of severe pain in our study. Higher pain values for the study paddle might be associated with the highest mean average compression force compared to the force for the fixed and flexible paddle. Further, the uneven force application might play an important role in the women's pain experience. A study from Sweden reported that force was mainly applied to the juxtathoracic structures in 42% of the imaged breasts [27], which might be one of the reasons for experienced pain among women screened with the fixed or study paddle. Pain location most commonly reported in the breast itself and chest wall might corroborate the issue of applying the main force to the juxtathoracic structures in our study.

The percentage of women reporting breast tenderness was low in our study compared to other studies [28-33]. Breast tenderness occurs mainly among menstruating women, associated with the hormonal changes during the menstrual cycle, and strongly affects the experienced pain during breast compression [34]. This is a factor the radiographers should be aware of in a busy screening setting.

The differences in force by paddles might be related to the force distribution during compression. Higher forces for the fixed and study paddles might have been necessary as the breast volumes were high [35-37]. We did not have information about the breast volume in our study, but as about 60% of women had a BMI of 25.0kg/m^2 or higher, high breast volumes might be assumed among these women.

A study from BreastScreen Norway showed that a compression force of 130N (13kg) or higher was associated with more favorable performance indicators [38]. The values could be considered an indirect measure of optimal image quality. Therefore, our findings on compression force might suggest that the resultant image quality when using the flexible paddle could be better than when using the other paddles. Another study from BreastScreen Norway using a fixed paddle indicated a compression force of 100-140N to be acceptable regarding reported pain during mammography [39], and a second study supported the range of 100-130N in association with subsequent attendance among women screened for the first time [40]. A study from the UK concluded that 90-130N might represent an appropriate compression termination point [41]. The results of our study suggest that an applied force of ≥15kg is not associated with an increased risk of severe pain. However, it is not possible to make one recommendation for all three compression paddles as the differences might be related to women's requests to terminate compression or high breast volumes, which were not accounted for. Recommendations of ranges should serve the compression force individualization and thus make the screening examination a better experience for the women.

Study strengths and limitations

Three types of compression paddles were used in the same mammography unit with examinations performed by the same radiographers. The study included multiple factors to investigate women's experience of pain during mammography. However, presence or absence of benign or malignant lesions and anxiety level [34] were not considered. Further, we were not able to obtain data on compression pressure, contact breast area, compressed breast thickness and breast characteristics (volume and mammographic density). The lack of precise guidelines and data on breast volume might have been the reason to increase or decrease the pressure from the point of 10kPa for the study paddle, resulting in higher forces. This study did not provide information on the radiation dose. However, the dose has been shown to be lower for the flexible compared to the fixed [10] and study paddle [19]. We were unable to investigate if one mammographic view was more painful for the women as the questionnaire considered the examination as one event. Lastly, the study was performed before the new GDPR were released, and the lack of an active informed consent is a limitation.

Conclusions

The flexible compression paddle performed superior regarding experience of pain during mammography compared to a fixed paddle and a paddle optimizing breast compression at a 10kPa pressure among 938 women screened in BreastScreen Norway. Attention to image quality and presentation of breast tissue on the mammogram should be taken when using the flexible paddle.

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Table 1. Descriptive information on experienced pain on the numeric rating scale (NRS), pain location, age, body mass index, screening history, breast tenderness, pain in shoulders and/or neck, and compression force (kg, continuous and categorical) by compression paddles among 938 women screened in Bodø at Nordland Hospital, 2018

	Total		Fixed paddle		Flexible paddle		Study paddle		P-value*		
	n=938		n=287		n=313		*n=338*		Fixed vs Flexible	Fixed vs Study	Flexible vs Study
	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI			
Experienced pain (NRS)	2.6	(2.5-2.8)	2.8	(2.5-3.1)	2.3	(2.1-2.6)	2.8	(2.5-3.0)	0.03	0.98	0.03
Experienced pain (NRS)											
0 (no)	56%		55%		62%		53%		0.03	0.66	0.03
1-3 (mild)	29%		30%		26%		30%		0.31	0.88	0.22
4-6 (moderate)	13%		13%		12%		14%		0.69	0.72	0.44
7-10 (severe)	2%		2%		0%		2%		0.02	0.86	0.02
Pain location**											
Breast	56%		53%		61%		55%		0.66	0.70	0.40
Chest wall	16%		18%		14%		15%		0.08	0.20	0.62
Shoulder	5%		4%		5%		6%		0.82	0.27	0.36
Neck	5%		4%		6%		4%		0.54	0.96	0.55
Skin	4%		3%		4%		6%		0.77	0.21	0.32
Axillary area	8%		12%		6%		7%		0.00	0.04	0.33
Under breast	6%		6%		5%		6%		0.41	0.91	0.46
Age (years)	58.8	(58.4-59.1)	59.4	(58.7-60.0)	58.5	(57.8-59.1)	58.6	(58.0-59.2)	0.05	0.08	0.84
Age (groups)											
<55 years	30%		28%		31%		30%		0.41	0.54	0.82
55-59 years	24%		22%		26%		24%		0.26	0.48	0.64
60-64 years	26%		25%		23%		29%		0.69	0.27	0.12
≥65 years	21%		25%		20%		17%		0.10	0.01	0.33
Body mass index (kg/m^2)	26.8	(26.5-27.1)	26.6	(26.1-27.2)	27.2	(26.6-27.8)	26.6	(26.1-27.1)	0.17	0.90	0.10
Body mass index (categorical)											
<25.0kg/m^2	40%		40%		38%		40%		0.72	0.97	0.68
25.0-29.9kg/m^2	40%		42%		40%		38%		0.59	0.32	0.65
≥30.0kg/m^2	20%		18%		22%		22%		0.27	0.24	0.96
Screening history											
First #	13%		11%		14%		13%		0.24	0.55	0.54
Subsequent ##	87%		89%		86%		87%				
Breast tenderness											
Yes	6%		6%		6%		7%		0.80	0.53	0.70
Pain in shoulders and/or neck											
Yes	28%		28%		28%		29%		0.84	0.77	0.61
Compression force											
CC, kg	12.0	(11.9-12.2)	12.3	(12.1-12.5)	10.9	(10.7-11.8)	12.8	(12.5-13.1)	<0.01	0.01	<0.01
MLO, kg	15.0	(14.9-15.1)	15.2	(15.0-15.4)	14.4	(14.2-14.6)	15.5	(15.3-15.6)	<0.01	0.07	<0.01
Average, kg	13.5	(13.4-13.6)	13.7	(13.6-13.9)	12.7	(12.5-12.8)	14.1	(13.9-14.3)	<0.01	0.01	<0.01
Compression force (categorical)											
<12.3 kg	22%		12%		37%		18%		<0.01	0.07	<0.01
12.3-13.7 kg	27%		32%		34%		15%		0.59	0.25	<0.01
13.8-14.9 kg	25%		34%		21%		21%		<0.01	<0.01	0.98
≥15.0 kg	26%		22%		8%		46%		<0.01	<0.01	<0.01

SD – Standard deviation
CI – Confidence interval
CC - craniocaudal view
MLO – mediolateral oblique view
*P-value for comparison of means was calculated using t-test; p-value for comparison of proportions was calculated for the test for proportions
** Women could choose more than one category of pain location
# Attended screening for the first time
Attended screening more than once

Table 2. Relative risk (RR) with 95% confidence interval (95% CI) of severe (≥7 on NRS) pain associated with type of compression paddle and related factors among 938 women screened in BreastScreen Norway, 2018

	Crude			Adjusted*		
	RR	95% CI	p-value	RR	95% CI	p-value
Paddle						
Fixed	1.76	1.00-3.09	0.05	2.01	1.13-3.59	0.02
Flexible	Ref			Ref		
Study	2.11	1.24-3.59	<0.01	2.52	1.44-4.42	<0.01
Breast tenderness	1.95	1.07-3.55	0.03	1.93	1.04-3.58	0.04
Shoulder/neck pain prior to screening	1.24	0.82-1.89	0.31	1.20	0.79-1.83	0.39
Compression force						
<12.3kg	Ref			Ref		
12.3-13.7kg	0.93	0.55-1.59	0.80	0.84	0.49-1.43	0.52
13.8-14.9kg	0.70	0.39-1.26	0.23	0.66	0.31-1.03	0.06
≥15.0kg	0.79	0.45-1.38	0.41	0.53	0.29-0.97	0.04
Age (group)						
<55 years	Ref			Ref		
55-59 years	1.45	0.82-2.58	0.20	1.51	0.78-2.95	0.22
60-64 years	1.58	0.91-2.57	0.11	1.67	0.87-3.22	0.13
≥65 years	1.32	0.72-2.43	0.37	1.49	0.73-3.02	0.27
Body mass index						
Normal (<25.0kg/m^2)	Ref			Ref		
Overweight (25.0-29.9kg/m^2)	1.09	0.70-1.68	0.71	1.27	0.82-1.99	0.29
Obese (≥30.0kg/m^2)	0.82	0.46-1.47	0.51	1.01	0.55-1.86	0.96
Screening history						
First attendance**	Ref			Ref		
Subsequent attendance***	1.29	0.66-2.50	0.45	1.04	0.46-2.38	0.93

Ref - Reference

*Adjusted for shoulder/neck pain prior to screening (yes/no), breast tenderness (yes/no), compression force (categorical), age (categorical), body mass index (categorical) and screening history

**Attended screening for the first time

***Attended screening more than once

Table 3. Number and percentage of perfect images based on averaged values for right and left craniocaudal (CC) and mediolateral oblique (MLO) views for 7 image quality criteria among 200 women screened using fixed (n=58), flexible (n=73), and study (n=69) compression paddles

	Number and percentage of images classified as perfect*			
	Fixed (n=58)	Flexible (n=73)	Study (n=69)	Total (n=200)
Nipple in profile, n (%)	34 (59%)	48 (66%)	46 (66%)	130 (65%)
Retroareolar area, n (%)	55 (95%)	68 (94%)	63 (91%)	186 (93%)
Pectoral muscle length for MLO, n (%)	40 (69%)	58 (80%)	55 (79%)	152 (76%)
Pectoral muscle width for MLO, n (%)	54 (93%)	60 (82%)	61 (88%)	174 (87%)
Inframammary angle for MLO, n (%)	36 (62%)	53 (72%)	46 (67%)	135 (67%)
Fibroglandular tissue towards chest wall for CC, n (%)	50 (87%)	52 (71%)**	54 (78%)	156 (78%)
Fibroglandular tissue towards pectoral muscle for MLO, n (%)	55 (95%)	60 (82%)	60 (88%)	175 (88%)
Blurring, n (%)	48 (83%)	59 (81%)	52 (77%)	160 (80%)
Total average, n (%)	46 (79%)	57 (79%)	54 (79%)	157 (79%)

*Based on averaged values for right and left CC and MLO views

**P=0.04 for comparing the fixed and the flexible compression paddle

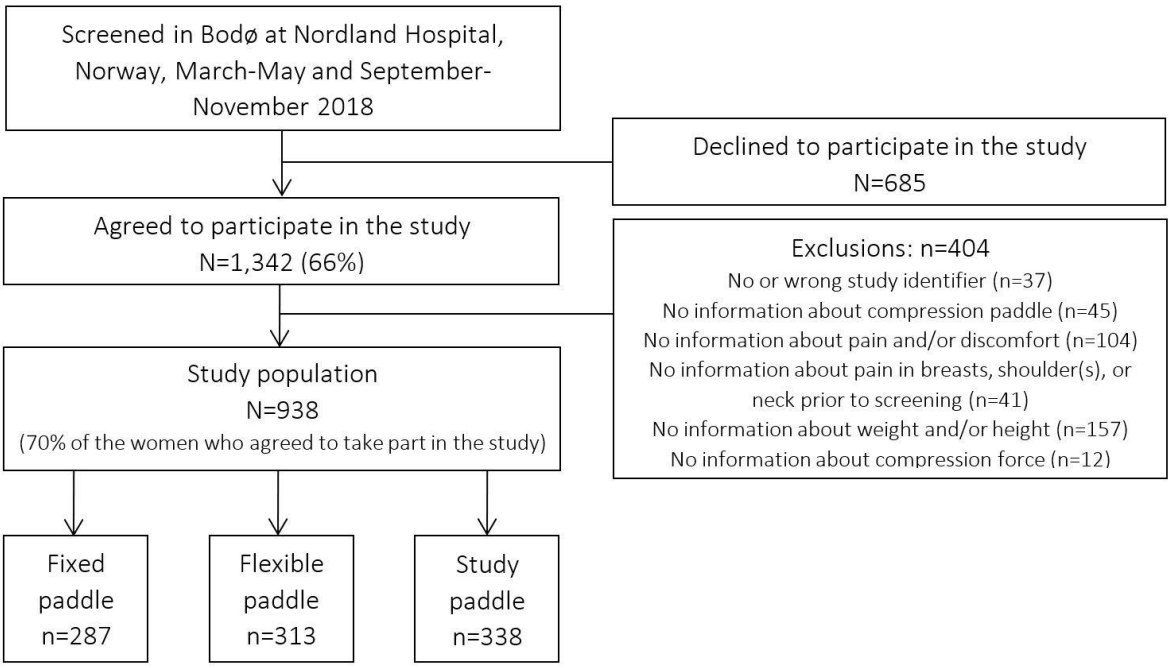

Figure 1. Flow chart of the study population and exclusions

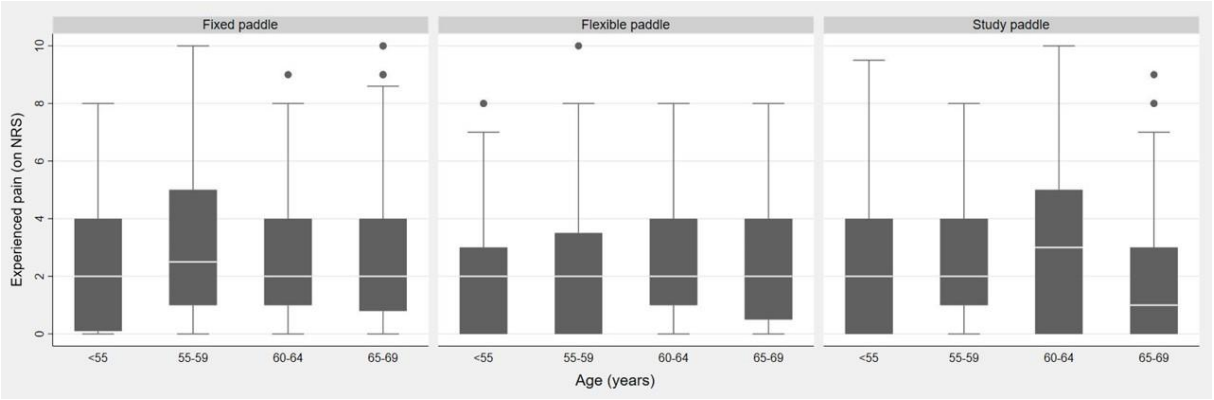

Figure 2. Experienced pain on the numeric rating scale (NRS) reported by the 938 women screened in BreastScreen Norway, 2018, by age groups (<55, 55-59, 60-64 and ≥65 years) for the fixed, flexible and study paddle. Each box contains 50% of the data (from the 25th to 75th percentile), and the horizontal white line represents the median value. The whiskers of the boxes represent the range of values of the remaining 25% in each direction. Extreme values are indicated with a grey circle

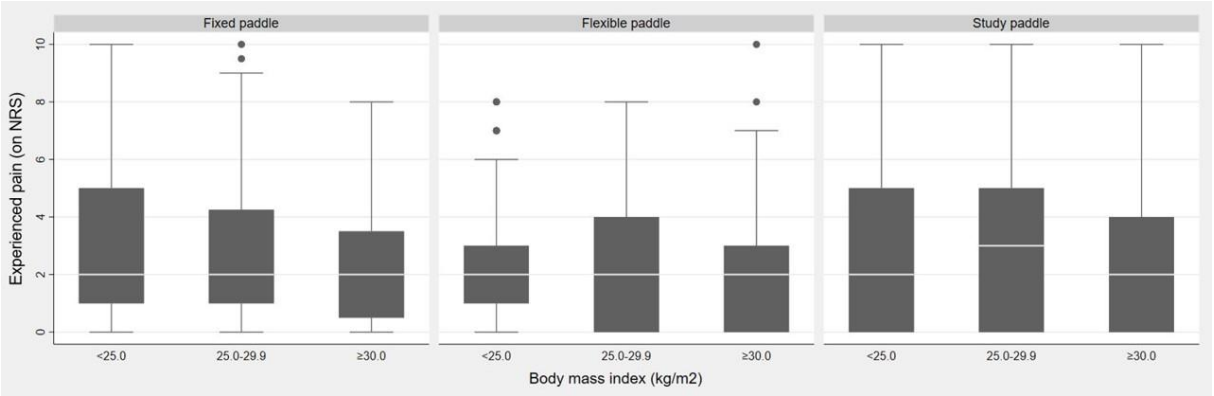

Figure 3. Experienced pain on the numeric rating scale (NRS) by body mass index (<25.0 kg/m^2; 25.0-29.9 kg/m^2; and ≥30.0 kg/m^2) for the fixed, flexible and study paddle among 938 women screened in BreastScreen Norway, 2018. Each box contains 50% of the data (from the 25th to 75th percentile), and the horizontal white line represents the median value. The whiskers of the boxes represent the range of values of the remaining 25% in each direction. Extreme values are indicated with a grey circle

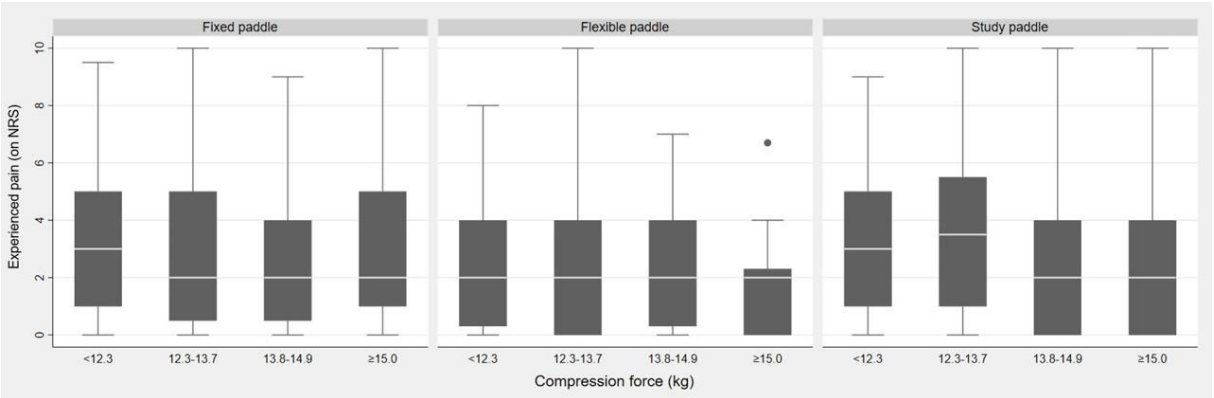

Figure 4. Experienced pain on the numeric rating scale (NRS) by compression force (<12.3 kg; 12.3-13.7 kg; 13.8-14.9 kg; and ≥14.5 kg) for the fixed, flexible and study paddle among 938 women screened in BreastScreen Norway, 2018. Each box contains 50% of the data (from the 25th to 75th percentile), and the horizontal white line represents the median value. The whiskers of the boxes represent the range of values of the remaining 25% in each direction. Extreme values are indicated with a grey circle

Appendix

Table A1. Definition of the image quality criteria for assessment

Perfect	**Adequate**	**Inadequate**
Craniocaudal view		
The nipple is in profile and freely projected	The nipple is partly in profile and/or freely projected	The nipple is not in profile or not freely projected
Retromammary area is clearly visualized	Retromammary area is partly missing/not visualized	Significant parts of the retromammary area are missing/not visualized
Fibroglandular tissue towards chest wall is clearly visualized	Fibroglandular tissue towards chest wall is partly missing/not visualized	Significant parts of the fibroglandular tissue towards chest wall are missing/not visualized
No blur	Blur that has no significance for diagnostics	Blurring is significant
Mediolateral oblique view		
The nipple is in profile and freely projected	The nipple is partly in profile and/or freely projected	The nipple is not in profile or not freely projected
Retromammary area is clearly visualized	Retromammary area is partly missing/not visualized	Significant parts of the retromammary area are missing/not visualized
Pectoral muscle length is visualized to the nipple level	Pectoral muscle length is partly visualized until the nipple level	Pectoral muscle length is not visualized until the nipple level
Pectoral muscle width is 30 mm or more	Pectoral muscle width is < 30 mm	Pectoral muscle width is not accountable
Fibroglandular tissue towards pectoral muscle is clearly visualized	Fibroglandular tissue towards pectoral muscle is partly visualized	Fibroglandular tissue towards pectoral muscle is not visualized
No blur	Blur that has no significance for diagnostics	Blurring is significant

Table A2ABCD. Number and percentage of perfect images for A. right craniocaudal (RCC); B. left craniocaudal (LCC); C. right mediolateral oblique (RMLO); and D. left mediolateral oblique (LMLO) views for 7 image quality criteria among 200 women screened using fixed (n=58), flexible (n=73) and study (n=69) compression paddles

	Number and percentage of images classified as perfect			
	Fixed (n=58)	Flexible (n=73)	Study (n=69)	Total (n=200)
A. RCC				
Nipple in profile, n (%)	37 (64%)	52 (71%)	44 (64%)	133 (67%)
Retroareolar area, n (%)	57 (98%)	70 (96%)	64 (93%)	191 (96%)
Fibroglandular tissue towards chest wall for CC, n (%)	49 (85%)	52 (71%)**	53 (77%)	154 (77%)
Blurring, n (%)	51 (88%)	59 (81%)	53 (77%)	163 (82%)
Total average, n (%)	47 (84%)	58 (80%)	54 (79%)	160 (80%)
B. LCC				
Nipple in profile, n (%)	26 (45%)	48 (66%)**	48 (70%)§	132 (66%)
Retroareolar area, n (%)	56 (97%)	68 (93%)	61 (88%)	185 (93%)
Fibroglandular tissue towards chest wall for CC, n (%)	51 (88%)	52 (71%)**	54 (78%)	157 (79%)
Blurring, n (%)	51 (88%)	59 (81%)	54 (78%)	164 (82%)
Total average, n (%)	46 (79%)	58 (80%)	54 (79%)	160 (80%)
C. RMLO				
Nipple in profile, n (%)	39 (67%)	46 (63%)	48 (70%)	133 (67%)
Retroareolar area, n (%)	55 (95%)	69 (95%)	65 (94%)	189 (95%)
Pectoral muscle length for MLO, n (%)	40 (69%)	57 (78%)	55 (79%)	152 (76%)
Pectoral muscle width for MLO, n (%)	56 (96%)	60 (82%)**	62 (90%)	178 (89%)
Inframammary angle for MLO, n (%)	36 (62%)	51 (70%)	46 (67%)	133 (67%)
Fibroglandular tissue towards pectoral muscle for MLO, n (%)	55 (95%)	63 (86%)	62 (90%)	180 (90%)
Blurring, n (%)	44 (76%)	55 (75%)	49 (71%)	148 (74%)
Total average, n (%)	46 (80%)	57 (78%)	55 (79%)	159 (80%)
D. LMLO				
Nipple in profile, n (%)	35 (60%)	46 (63%)	42 (61%)	123 (62%)
Retroareolar area, n (%)	53 (91%)	66 (90%)	60 (87%)	179 (90%)
Pectoral muscle length for MLO, n (%)	40 (69%)	58 (80%)	54 (78%)	152 (76%)
Pectoral muscle width for MLO, n (%)	52 (90%)	59 (81%)	59 (85%)	170 (85%)
Inframammary angle for MLO, n (%)	36 (62%)	54 (74%)	46 (67%)	136 (68%)
Fibroglandular tissue towards pectoral muscle for MLO, n (%)	55 (95%)	56 (77%)**	59 (86%)	170 (85%)
Blurring, n (%)	47 (81%)	63 (86%)	56 (81%)	166 (83%)
Total average, n (%)	45 (78)	57 (79%)	58 (78%)	157 (78%)

**P<0.05 for comparing the fixed and flexible paddle

§ P<0.05 for comparing fixed and study paddle