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Changes in pain perception in women undergoing Breast Screening Mammograms: a Study based on Breast structure.

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## Changes in pain perception in women undergoing Breast Screening Mammograms: a Study based on Breast structure.

Deborah Esposito<sup>1</sup>, Carmen Ludeno<sup>1</sup>, Simona Marinelli<sup>1</sup>, Anna Bertoldi<sup>1</sup>, Valeria Selvestrel<sup>1</sup>, Marianna Giannattasio<sup>1</sup>, Lauretta Rizzari<sup>1</sup>, Vincenzo Marra<sup>1</sup>, Luisella Milanesio<sup>1</sup>, Alfonso Frigerio<sup>1</sup>, Andrea Luparia<sup>1</sup>, Adriana Aiello<sup>1</sup>, Livia Giordano<sup>2</sup>, Emanuela Bovo<sup>2</sup>, Elisa Camussi<sup>2</sup>, Franca Artuso<sup>1</sup>.

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#### **ABSTRACT**

#### INTRODUCTION

The study involved 100 women taking part to a Breast Screening session carried out by one Mammographer. Participants answered a questionnaire related to pain perception experienced during the mammogram. Breast density has been detected by Quantra Software. The study aims to explore the potential association between breast density, breast thickness and pain perception experienced during the Mammogram. Quality technical standards have been evaluated by two technical experts of Referring Regional Mammography Centers of Turin.

#### MATERIALS AND METHODS

Pain, in order to be detected, has been measured through the Visual Analogical Scale. Breast examinations have been performed using a digital Mammo-Machine, while density was evaluated using Quantra software. A Systematic Literature Review about the subject has been carried out.

#### **RESULTS**

Results demonstrated that the average pain perception was light-moderate, and mainly due to the compression applied during the Mammogram. It was observed that women with higher breast density experienced more pain than women with less density; however, no correlation was found between pain and breast thickness.

#### CONCLUSIONS

The study observes that pain perception during mammography is not solely dependent on subjective factors, such as psychological influences, but is also affected by breast density. Indeed, higher densities are associated to higher pain. However, no direct correlation between pain and breast thickness was identified. The finding suggests that a subjective component plays a significant role in pain perception.

Keyword: mammogram, breast density, breast thickness, mammographer.

#### INTRODUCTION

Breast Cancer (BC) Screening programs gained significant momentum and became more widely spread during the 1990s, contributing to a reduction in mortality from breast cancer for a targeted groups of women invited to regular check-up, supporting the decrease of mastectomy rates (a highly extensive surgery intervention) [1-6]. Breast Screening (BC) is a Public Health intervention addressed to women within a specific age range at higher risk of Breast Cancer.

The aim of BC screening programs is to identify cancer lesions in an early stage, allowing more effective and less invasive treatments.

An Institutional Program called "Prevenzione Serena" which offers a solid oncology prevention response, is active in Piedmont since 1992. It has been possible thank to an organized network including different Preventive Departments of Secondary Cancer Prevention and Oncology Prevention Center within the Region (called CPO Piedmont) [3]. Every year, "Prevenzione Serena" detects around 800 Breast Cancers at the very early stages, potentially preventing around 100 deaths/annually for BC.

In order to optimize mammography screening examinations, it is necessary to compress the breasts using specific devices called "compressors", in fact by flattering the breasts there is less tissue and consequently a lower dose of radiation is needed to produce a diagnostic quality image.

The current study aims to evaluate women's pain perception during BC mammograms, assessing the potential causes of pain and investigating the potential association between pain and breast thickness. Moreover, it has been questioned if pain perception during compression increases due to the breast thickness, evaluating all the possible causes and the technical skills of the mammography tests through the blind assessment of two expert Senior Mammographers.

A relevant aspect within BC Screening is represented by the communication approach of Mammographers to women during mammography [7-8]. Indeed, besides the correct positioning of patients following all the technical criteria, mammographers are responsible for ensuring the woman's comfort and reducing anxiety, positively influencing pain perception. Therefore, the role of some objective parameters is considered within the study e.g. breast density, or thickness, in order to evaluate if and how these indexes can affect not only BC diagnosis, but also pain perception and diagnostic-quality images.

#### MATERIALS AND METHODS

Women within a specific age group, specifically age range of 45-69 years participating at BC Screening Centre of San Giovanni at the old site of "A.O.U. City of Health and Science Hospital of Turin" (Italy), were requested to take part to a study focused on the possible causes of pain perception during the mammogram. All the Mammograms were performed by Professionals strictly following the European Guidelines on BC Screening [4].

Women with breast implants, metal devices, disabilities or mental illnesses have not been involved in the study. Women accepting to participate the study completed a brief questionnaire after the Mammogram, in order to evaluate pain perception. Pain was recorded using the VAS (Visual Analogue Scale - within a range: 0-10 points) [2]. Pain levels were classified as follows: 0 no pain, 1-3 light pain, 4-6 moderate pain, 7-9 severe pain, 10 unbearable pain. All mammography examinations were performed using innovative digital equipment by very skilled Mammographers.

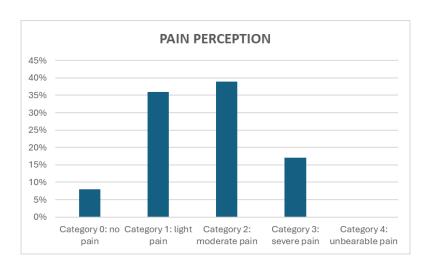
At the time of the exam, breast density was measured using Quantra software adopting a BI-RADS classification (from A to D) - also referred to as categories 1-4. After that, breast density was dichotomized as medium-low (A+B) or medium-high (C+D). Additionally, during the exam, the mean breast thickness and the mean compression strength were measured. Finally, the technical quality of mammographic exams was evaluated by two Senior Mammographers (experts in BC screening). For the image assessment, they adopted a system already implemented in Piedmont Region, centered on the "Evaluation of mammographic positioning image quality criteria for Mammography", allocating the following categories: "perfect-very good"; "good", "poor-unacceptable" [1].

#### Statistical analysis

Descriptive statistics have been calculated, considering the mean and standard deviation for continuous variables, and percentage of distribution for categorical ones. The association between pain and breast density has been taken in account, as well as the potential association of perceived pain with breast thickness or compression strength. Additional analyses were run for assessing the relationship between breast density and compression during the examination. The technical quality of tests was considered, investigating potential differences represented by breast density. The association between above-mentioned variables was at first evaluated graphically, using box-plots (for categorical variables) or scatter plots (for continuous variables). Statistical significance was assessed applying Chi-square test for dichotomous variables or ANOVA in case of multiple groups. For continuous variable, the correlation test (r) was selected. Statistical significance was set at p<0.05. Variation in technical quality of exams was studied according to breast density (A+B vs. C+D), applying the Chi-squared test. Furthermore ad-hoc analyses were run for severe mistakes-only. In conclusion, the concordance between evaluators upon technical quality was studied through the computation of the Kappa of Cohen concordance index, stratifying for breast density.

#### **RESULTS**

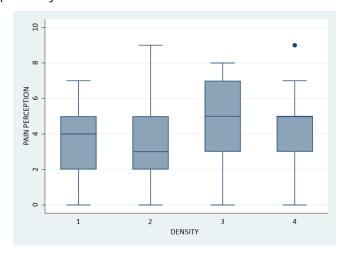
Overall, 100 women participated in the study. Among them, pain perception was mainly light (36% - category 1, pain intensity 1-3) or moderate (39% - category 2, pain intensity 4-6). Only 17% of interviewed women reported a severe pain (category 3, pain intensity 7-9), while none complained about an unbearable pain (10 points), requiring to stop the examination. Finally, 8% of participants stated no pain at all (Graph 1). Overall, the mean pain level was 4±2.2 points.



Graph 1. Perceived pain intensity: this graph reports the percentage distribution of perceived pain categories in the study sample. Pain is measured using the VAS scale with a range from 0 to 10 points, categorized as: Category 0 (no pain), Category 1 (score 1-3: light pain), Category 2 (score 4-6: moderate pain), Category 3 (score: 7-9: severe pain), and Category 4 (score: 10: unbearable pain).

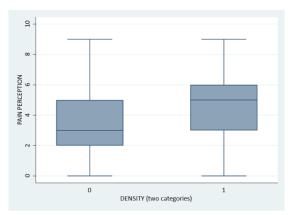
#### Classification of perceived pain based on objective examination parameters

First, the potential difference in pain perception by breast density was explored. Breast density was defined in four categories with increasing value (from A to D). Initially, this relationship was assessed by a graphic representation with a Box plot. Graphically, perceived pain seemed to increase with density (Graph 2). The mean perceived pain was  $3.6 \pm 2.0$  among women with density A,  $3.5 \pm 2.5$  in case of density B,  $4.4 \pm 2.2$  for women with density C, and  $4.6 \pm 2.2$  in case of density D, respectively.



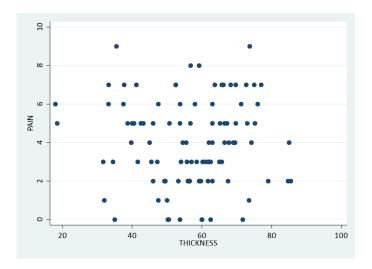
**Graph 2.** Graphical evaluation of the association between breast density (BIRADS 1-4, corresponding to densities A-D) and perceived pain, using box-plot. Perceived pain (according to VAS score) was reported by breast density categories measured at screening mammography (BIRADS classification from 1 to 4). From the graph, an increase in perceived pain with density appears, but the limited sample size could mask this association (see text for further specifications).

Considering the limited sample size, statistical analyses were conducted by grouping density as "medium-low" (A+B) and "medium-high" (C+D) (Graph 3). This analysis shows a significant difference (p=0.044), with greater perceived pain in case of higher breast density (4.5±2.2 vs. 3.6±2.2).



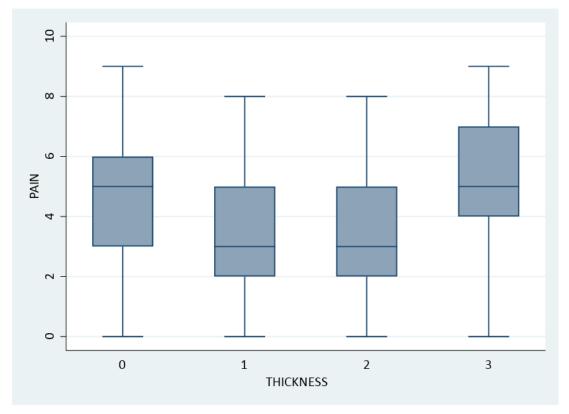
Graph 3. Graphical evaluation of the association between breast density, reported as a dichotomous variable (BIRADS 1+2 vs. 3+4/A+B vs C+D), and perceived pain (VAS scale), using a box-plot graph. By adopting this density classification (medium-low vs. medium-high), it is graphically highlighted how the perceived pain during the mammographic examination increased with breast density. Category 0 represents 1+2/A+B, whereas Category 1 represents 3+4/C+D (for further specifications, see text).

The potential correlation between perceived pain and breast thickness was then evaluated (Graph 4). Overall, considering the sample (N=100) mean measured breast thickness was  $56.4\pm13.9$ . The association with pain perception was initially explored with a graphic evaluation (scatter plot). This graph did not show any linear correlation. Similarly, the correlation test did not highlight a significant correlation between the two variables under study (p=0.896).



Graph 4. Graphical evaluation (scatter plot) of the correlation between perceived pain (VAS) and breast thickness measured at mammography. Each point of the scatter plot represents a participating woman (with the relative value of glandular thickness and perceived pain). The graph highlights the lack of a clear linear relationship between these two variables (see text for further details).

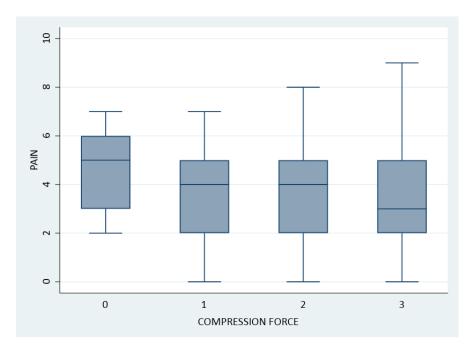
The analysis was repeated by categorizing breast thickness into distribution quartiles (0:  $\leq$ 47.35; 1: 47.35-58.25; 2: 58.25-65.935; 3: >65.935), see Graph 5. Even in this case no significant associations emerged (p=0.935).



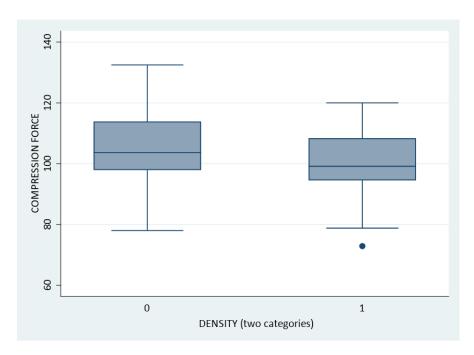
Graph 5. Graphical representation (box-plot) of the mean perceived pain (VAS score) by quartile of thickness measured at screening mammography (0: ≤ 47.35; 1: 47.35-58.25; 2: 58.25-65.93; 3: >65.93). In this case, glandular thickness is not represented as a continuous variable, but according to categories, indicating for each category the mean value of perceived pain. No clear relationships (increasing or decreasing) between glandular thickness and pain is evident. Indeed, perceived pain appears greater among women with less glandular thickness (category 0) as well as among those with greater thickness (category 3) (see the text for further specifications).

Then, the potential association between pain and compression applied during the mammographic examination was explored. The mean compression strength recorded in the study sample was  $102.8N\pm11.2N$ . The subsequent analysis was conducted by categorizing compression according to the distribution quartiles (0:  $\leq 95.95$ ; 1: 95.95-101.15; 2: 101.15-112.2; 3: >112.2). Graph 6 shows the graphic representation of the mean pain by compression classes (box plot), respectively equal to 4.8, 3.9, 3.8, and 3.5 for increasing categories of applied compression, with no significant differences between groups (p=0.212).

Additionally, the potential difference in compression applied during the examination was evaluated based on breast density (Graph 7), considering the two density categories of medium-low (A+B) and medium-high (C+D). The applied compression was significantly higher among women with lower breast density (105.1 vs. 100.5; p=0.0399).

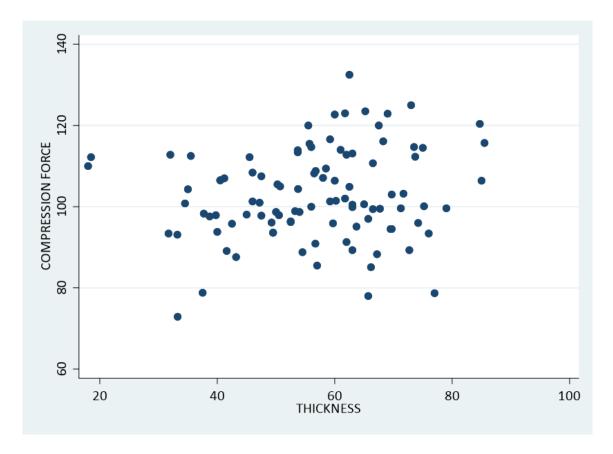


**Graph 6.** Graphic representation (box plot) of the mean pain (VAS score) by compression (N), measured at screening mammography and categorized according to the sample distribution quartiles (0:  $\leq$  95.95; 1: 95.95-101.15; 2: 101.15-112.20; 3: >112.20). No relationship is graphically highlighted. Further information on the statistical tests applied is provided in the text.



**Graph 7.** Graphical evaluation of the relationship between compression (N) and breast density (box plot), adopting the dichotomous classification of density (BIRADS classification: A+B vs. C+D). This figure is intended to evaluate whether there is a difference between the force applied during the examination by breast density (such as medium-low density vs. medium-high). The results of the statistical tests are reported in the text.

Finally, the association between breast thickness and compression applied during the examination was evaluated, as shown in the graph (Graph 8). No significant associations emerged (p=0.136).



**Graph 8.** Graphical evaluation of the possible association between compression force (N) and breast thickness through a scatter plot. Each point represents a participant in the study (characterized by thickness – abscissa axis and force – ordinate axis). No linear relationship is evident. This absence of association is confirmed by the correlation test (p = 0.136).

Finally, the possible association by thickness and strength categories was evaluated according to the 4 distribution categories of variables under study. Also in this case, no association was highlighted (p = 0.276).

#### Technical quality

The technical quality of the mammograms performed was evaluated by two experts Mammographers, considering Three Categories of Classification (Criteria): "perfect-very good", "good" and "poor-unacceptable".

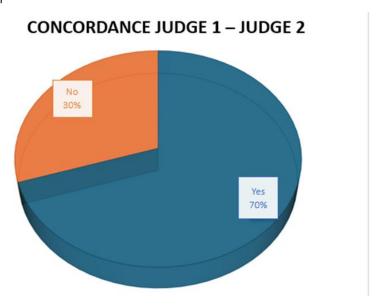
Overall, the first Professional evaluated the exams as good (perfect-very good: 85.0%, good: 10% and poor-unacceptable: 5.0%). The second Professional also found a good quality of mammograms (perfect-very good: 67.5%, good: 24.2% and poor-unacceptable: 8.3%), see Graph 9. The potential difference of quality by breast density (A+B vs. C+D) was considered for both

evaluators. In the case of the first evaluator, it seems to be a higher quality in the case of women with higher breast density (p<0.001), however the small sample size does not allow for further evaluations. In the case of the second evaluator, no differences in technical quality were highlighted based on breast density (p=0.139). Serious errors are generally very rare, and do not vary with breast density neither in the first (p=0.315) nor in the second evaluator (p=0.154). Then, the agreement between the two expert evaluators was evaluated.



**Graph 9.** Evaluation of the technical quality of mammography examinations by the two expert radiographers.

Regardless of breast density, a good agreement of 70% between the two evaluators was observed (p<0.001), Graph 10.



**Graph 10.** Differences in agreement by breast density: regardless of breast density, there is a 70% agreement between the judgments of rater 1 and rater 2.

This agreement is maintained even when considering the different breast density, even if it is higher for women with lower densities (p<0.001). In any case, the limited sample size does not allow further assumptions.

#### DISCUSSION

A total of 100 women participated in the study. These women were recruited during their screening mammogram examination. In this sample, no women perceived an unbearable pain, requiring to suspend the examination. Indeed, on average, light and moderate pain was reported. Considering the variation of perceived pain by breast density (A+B vs. C+D), an increased in stated pain increasing density was found (both graphically and at statistical tests). Subsequently, the association between pain and breast thickness was evaluated, highlighting the absence of a clear correlation between these two variables. Moreover, the relationship between pain and compression force applied during the mammographic examinations was investigating, highlighting, also in this case, no statistical significant associations.

From the additional analyses regarding compression during mammography test, it was outlined that the compression force applied was higher in women with lower breast density, while no differences emerged in compression by breast thickness.

Finally, the technical quality of the screening mammograms was evaluated. This assessment was performed in blind by two Senior Mammographers, expert in the breast field, rating the 100 mammograms of participating women as "perfect-very good", "good" or "poor-unacceptable". In this case, quality was overall very good, in accordance to both evaluators, confirming the quality of the mammographic examinations carried out during the study.

#### CONCLUSIONS

The assessment of service quality, performance, and the overall patient experience is also influenced by the level of pain experienced during mammography, which represents an important factor in the success of prevention campaigns. Considering pain perception, this variable, besides the role of well-known personal subjective characteristics such as psychological factors, resulted associated to breast density. Indeed, women with higher breast density perceived greater pain during the screening examination. Nevertheless, pain was not associated the thickness of the breast nor to the compression applied during the examination. In any case, it is important to apply compression homogeneously, including as much surface area of the breast as possible in order to improve the quality of the image. During the study, we additionally verified the absence of difference in compression by breast thickness. Furthermore, the study was useful to provide some common recommendations for the optimization of the technical quality of mammography.

Indeed, in our study, technical quality was greater among women with high dense breast for an evaluator. This finding could be due to the fact that, in adipose breasts, skin's folds form more easily since the glandular and fibrous component is particularly small, making homogeneous

compression difficult. According to the European guidelines, the more common errors emerging in the study were those considered as not serious, while for dense breasts being usually more compact a lower percentage of this issue occurs.

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