Image quality control in mammography using control charts

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Aims and objectives

Mammography is still the gold standard in the study of breast pathology. Therefore, the image control is a requirement in order to achieve efficient diagnosis. As a consequence of better image control, there is not the need to repeat the examination and to have the repeated exposure of the patient to ionizing radiation. A study in order to evaluate the equipment performance and quality of the “Centro Hospitalar do Algarve (CHA)” was developed in the greater public hospital in this region, namely in the Portimão unit. The main goal of this present study was focused on the Quality Control of Mammography Image through the preparation of Control Charts. Regarding the specific objectives, these are:

- Assessment of the quality of mammography images;
- Identification and quantification of the compliance and the non-compliance of each image;
- Understanding of the cause(s) of the non-compliance’s existence;
- Reduction the incidence of non-compliance;
- Suggestion of the corrective actions for improvement.
Methods and materials

The study is a retrospective study because it collects data from previously registered information or participants' testimonies. On the other hand, this study is also quantitative as it seeks to quantify existing non-compliance in each mammography. The study was conducted in the Hospital do Algarve EPE, specifically in Portimão unit. Finally, the target population of this study is the users of the Hospital do Algarve EPE, including mammograms performed in Portimão unit during the data collection period.

Sample:

The analyzed sample is a non-probability sample of convenience.

The individuals were chosen based on their localization, namely the place of collection of data, and at a specific time, in which the researcher was collecting the data.

The laboratory tests will be mammograms in two basic incidences, craniocaudal (CC) and mediolateral oblique (MLO).

The tests used in the study were performed in the department mentioned above, during the period of one year, between March 2013 and March 2014.

The sample size, the total incidence taken during the collection of data, comprises the number of mammograms performed during the period of one year, from March 2013 to March 2014 (n=485).

Instrument, Variables and Procedures

The instruments needed to complete the study were: Check lists; Data tables and CHA Database.

The checklists are used to ensure that pre-established procedures are complied and they are presented in the form of tables, in order to facilitate the collection, analysis and discussion of the data.

The data tables are provided for characteristics' identification as the year, the month, the day, the number of evaluation and the sample size and can be composed by different elements such as the test number to be evaluated, the time it was performed, the type of examination, non-conformities identified according to the evaluation criteria, among others. The purpose of these data tables is to organize the information, so that it becomes clear and concise.
Finally, the service database in question allows the visualization of the existing mammograms and consequently, the calculation of compliance and non-compliance in each exam.

The existing variable in this study is the variable attribute:

- It is correspondent to features present in individuals, objects or situations, that can change within time.
- It can comprise different values that can be measured, manipulated or controlled and corresponds to the characteristics observed in mammograms and whether it agrees or not with pre-established criteria.
- Among the attribute variables are: the quality of the equipment, the radiology technician experience during the mammography performance, the collaboration of the patient, the equipment available to the service and the incidence of the study.
- Among the dependent variables are: the existence of compliance and non-compliance in the mammograms.

Regarding the data collection procedure, after an affirmative answer to the request for authorization submitted to the CHA Administration Council in January 2014, it was accomplished the Portimão centre included in the Hospital do Algarve.

The collection of mammograms was performed in a retrospective manner and randomly, between March 2013 and March 2014.

After data collection, its evaluation was performed taking into account several important aspects in the study as the quality criteria in Mammography and the counting of the present conformities or non-conformities. With the analysed data, the control charts that will monitor the processes were constructed. These control charts allow the checking of the state of statistical control of the same in order to identify: which ones are controlled and those who are out of control, identification of the cause or causes of non-conformities found and the creation of corrective actions in order to proceed to a continuous improvement.

After the data collection and organization, they are converted to the computer system and analysed for subsequent publication using the *Excel 2013 Microsoft Office* program.
Results

The data comprises a total of 495 examinations performed within one year from March 2013 to March 2014.

The collected data followed the two fundamental criteria in the study:

• Do not belong to mastectomy patients;
• Do not belong to male patients;

In order to decrease the complexity the data analysis, these data were introduced, organized and analysed using the Excel 2013 Microsoft Office program.

Control Charts

The control charts constructed in this research work were the charts by attribute as the characteristic quality is not measurable.

From this type of chart, there is three different categories:

• Type p that quantifies the proportion of non-conforming examinations CC incidence and OML incidence.
• Type np that quantifies the non-conforming items in each incidence mammography (CC and OML).
• Type c that quantifies the number of non-conformities in the mammograms that are non-conforming.

P Chart

Firstly, the p charts were constructed for the two incidences, and as observed in the chart there are values in the p chart for MLO incidence that are outside to the control limits. Therefore, it was necessary to make adjustments so that they would meet within statistical control.

The p chart for the CC incidence shows the values within limits. Nevertheless, the limits were decreased: the Central Limit (CL) from 92% to 90%, the Upper Control Limit (UCL) from 95% to 94% and the Lower Control Limit (LCL) from 89% to 86%.
After the adjustments, the p chart for the MLO presents the values within limits. The limits were also decreased: the Central Limit from 92% to 91%, the Upper Control Limit from 95% to 94% and the Lower Control Limit of 89% to 88%.
Fig. 2: P Chart - MLO incidence

References: Radiology Department, School of Health - University of Algarve - Faro/PT

NP Chart

The control np chart type allows the study of the number of non-conformities for each incidence. This is based on the total number of failed tests per sample. Two control charts were constructed, one for the cc incidence and one for the MLO incidence because the number of failed tests varies.

The results of the np chart for the CC incidence presents the following values: the Central Limit (22.55), the Superior Control Limit (25.15) and the Lower Control Limit (18.05). The following graph shows the proportion of non-conforming tests in total in cc incidence.
Fig. 3: NP Chart - CC incidence

References: Radiology Department, School of Health - University of Algarve - Faro/PT

The np chart for the MLO presents the values within limits. Nevertheless, the limits were decreased: the Central Limit from 22.65 to 21.08, the Superior Control limit from 26.93 to 26.00 and the Lower Limit of Control from 18.37 to 17.60.
NP Chart - MLO Incidence

Fig. 4: NP Chart - MLO incidence

References: Radiology Department, School of Health - University of Algarve - Faro/PT

C Chart

The c charts were constructed and as a first instance, the values for CC and MLO incidences were outside of the control limits. Thus, values adjustment was realized to include them in statistical control. The following graphs show values within the limits.

The c chart for the CC incidence shows the values within limits. The limits were changed: the Central Limit decreased from 70.55 to 59.93, the Superior Control limit decreased from 95.75 to 83.15 and the Lower Control Limit of 45.35 to 36.71.
The c chart for the MLO incidence shows the values within limits. As a consequence, the Central Limit changed from 86.45 to 86.50, the Upper Control limit from 114.35 to 114.4 and the Lower Control limit from 58.55 for 58.60.
During the period of data collection, 495 mammograms were analyzed, it is important to point out that all are females and not mastectomies.

As for the examination, it was composed of two views, CC and MLO whereby each woman made every two incidences for each breast, one CC incidence and one MLO incidence on the right breast and a one CC incidence and one MLO incidence for the left breast.

The following tables are intended to illustrate the amount of conformity tests, not in accordance exams and also the number of nonconformities per incidence performed.

The table below shows the values for the CC incidence.
Table 1: CC incidence

References: Radiology Department, School of Health -University of Algarve - Faro/PT

This table shows the results for the CC incidence, with the total of 495 members. Within these results, 451 presented as non-conforming, with a total of 1411 non-conformities, wherein 725 were registered for the right breast and 686 registered for the left breast.

The table below shows the values for the OML incidence.
This table shows the results for the MLO incidence, with the total of 495 members. Within these results, 458 presented as non-conforming, with a total of 1729 non-conformities, wherein 835 were registered for the right breast and 894 registered for the left breast.

**Non-conformities**

The non-conformities found in mammograms were previously defined. The "type of non-compliance" was defined according to consulting various works related to breast mammography study and study. Consequently, an examination was considered "non-compliant" if it had one or more nonconformities in each exam.

Therefore, the non-conformities were organized in a table, rapid response, which were marked with an "x" depending on the answer was affirmative or not, the examination was moving to non-compliant.
The criteria for non-compliance were the following for Incidence cc:

- No patient name
- No date of birth of the patient
- Shoulder overlay on the image
- View artifacts and skin folds in the image
- No retro-breast muscle
- Profile nipple absence
- No quadrant symmetry with respect to axis nipple
- Absence of a high tissue contrast and great contrast in the image
- Inadequate penetration in dense areas
- Apparent movement

It can be argued that the criteria of not more frequent conformities were four, and they are: the artifacts display and skin folds in the image (11%), the absence of retro-breast muscle (58%), lack of access to nipple (14%) and the absence of symmetry relative to the quadrants nipple shaft (17%). The largest percentage refers to the difficulty to manage to insert the muscle in the picture, with many causes, including the fact that it is very difficult to enter the muscle in the image once the examination is uncomfortable and not always the patient works of best with the radiographer.

As for, the criteria for non-compliance were the following for Incidence MLO:

- Patient’s name Absence
- No date of birth of the patient
- Profile nipple Absence
- Lack of insertion of the pectoral muscle to the nipple area
- Lack of infra-mammary groove
- Inadequate penetration in dense areas
- Evident Movement
- Lack of a high tissue contrast and great contrast in the image
- View artifacts and skin folds in the image

Analyzing and tabling the results it is clear that the criteria of not more frequent compliance were four, and they are: the display of artefacts and skin folds in the image (9%), the lack of visualization of the insertion of the pectoral muscle to the nipple area (34%), the absence of the profile nipple (15%) and the absence of the infra-mammary fold (42%). The largest percentage refers to the difficulty to manage to insert the pectoral muscle in the examination, as with the retro-mammary muscle cc incidence.

**Analysis and interpretation of the Control Charts type p:**

The values of limits obtained for the Control Chart type p regarding the CC incidence were: 92% for the Central Limit, 94% for the Superior Control Limit and 89% for the Lower Control Limit. For MLO incidence the values were 92% for the Central Limit, 95% for the Superior Control Limit and 89% for the Lower Control Limit.
Subsequently, since some values were outside of the control limits, designated as outliers, adjustments were performed in order to include these values within the limits and the process within the statistical control.

After the calculations to eliminate the outliers, the new limit values were achieved. The limits in the CC incidence were 90% for the Central Limit, 94% for the Superior Control Limit and 86% for the Lower Control Limit. Regarding the MLO incidence the limit values were 91%, 94% and 88% for the Central Limit, the Superior Control Limit, the Lower Limit control, respectively. With these modifications, the whole process is in statistical control and the new estimated limits are considered as the standard reference to the type p Chart.

**Analysis and interpretation of the Control Charts type np:**

The values of limits obtained for the Control Chart type np regarding the CC incidence were: 22.55 for the Central Limit, 25.15 for the Superior Control Limit and 18.05 for the Lower Control Limit. For MLO incidence the values were 22.65 for the Central Limit, 26.93 for the Superior Control Limit and 18.37 for the Lower Control Limit.

Subsequently, since some values were outside of the control limits, designated as outliers, adjustments were performed in order to include these values within the limits and the process within the statistical control. After the calculations to eliminate the outliers, the new limit values were achieved. The limits in the MLO incidence were 21.08 for the Central Limit, 26 for the Superior Control Limit and 17.60 for the Lower Control Limit.

With these modifications, the whole process is in statistical control and the new estimated limits are considered as the standard reference to the type np Chart.

**Analysis and interpretation of the Control Charts type c:**

Finally, the values of limits obtained for the Control Chart type c regarding the CC incidence were: 70.55 for the Central Limit, 95.75 for the Superior Control Limit and 45.35 for the Lower Control Limit. For MLO incidence the values were 86.45 for the Central Limit, 114.35 for the Superior Control Limit and 58.55 for the Lower Control Limit.

Subsequently, since some values were outside of the control limits, designated as outliers, adjustments were performed in order to include these values within the limits and the process within the statistical control.

After the calculations to eliminate the outliers, the new limit values were achieved. The limits in the CC incidence were 59.93 for the Central Limit, 83.15 for the Superior Control Limit and 36.71 for the Lower Control Limit. Regarding the MLO incidence the limit values were 86.50, 114.4 and 58.60 for the Central Limit, the Superior Control Limit, the Lower Limit control, respectively. With these modifications, the whole process is in statistical control.
control and the new estimated limits are considered as the standard reference to the type c Chart.

**Discussion of data obtained from non-conformities:**

To conduct the study about the non-conformities in mammograms was no need to percentages of each non-compliance because compliance are various and exist in different percentages in each issue.

**Discussion of data is non-conformities in CC incidence:**

There are a total of 10 types of non-conformities, and of these, only four types of non-compliances have words with the remaining a null expression.

Noncompliance with expression in the study were the following: the display of skin folds and artifacts in the image responsible for 11% of total non-compliance, non-visualization of the retro-mammary muscle responsible for 58% of total non-compliances obtained, the no profile nipple display accounted for 14% of total non-compliances obtained and the lack of symmetry in the quadrants, internal and external to the nipple axis accounts for 17% of total non-compliance obtained for the CC incidence. Finally, it is concluded that the non-conformities with the highest expression is not the view of the retro-mammary muscle so there are many causes for this case in particular the non-cooperation of the patient in the position that causes the muscle does not appear in final image.

**Discussion of data is non-conformities in MLO incidence:**

There are a total of 10 types non-conformities, and of these, only four types of non-compliances have words with the remaining a null expression.

Non-conformities with expression in the study were the following: the display of skin folds and artifacts in the image responsible for 11% of total non-conformities, non-visualization of the retro-mammary muscle responsible for 58% of total non-conformities obtained, the no profile nipple display accounted for 14% of total non-conformities obtained and the lack of symmetry in the quadrants, internal and external to the nipple axis accounts for 17% of total non-conformities obtained for the MLO incidence. Finally, it is concluded that non-conformities with the highest expression is not the view of the retro-mammary muscle so there are many causes for this occurrence, such as the non-cooperation of the patient positioning.
Conclusion

After the completion of this research work, it was found that the control of the quality of an image is still under development. In the literature, the term "image quality control" is regularly used to define the quality control associated to the equipment and not to the produced image itself. Thus, the control of the final image is essential - the image that will represent the diagnosis of a possible pathology. Moreover, the control of the entire acquisition process of the mammographic images, using a list of quality criteria appropriate for breast and use of control charts, should performed to check whether or not the process is under the statistical control.

The radiology department of Portimão unit of Centro Hospitalar do Algarve is covered by ISO 9001: 2008. This legislation defines the work instructions for the completion of all tests performed in the service. Although there is no quality control program devoted exclusively to the analysis of all radiological examinations carried out and consequent construction of charts and pareto’s tables in order to find the causes of problems and suggest corrective measures for future application.

As results of this study, in the majority of mammograms presented non-conformities, wherein at least one quality criteria was not met. The number of examinations with non-conformities was much higher than the conforming number. The most common quality criteria were previously presented in tables, according to the literature. The causes for the high number of failed tests are several, including the existence of little cooperating patients, the bad positioning condition due to age’s patient, the high volume of work in the service, among others.

To sum up, this present study demonstrates that the implementation of a quality control program in radiology departments brings a final homogeneous product and stimulates the Radiology service technicians to be insightful, confident, active and demanding during their professional work.
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Fig. 7: School of Health - University of Algarve, Portugal

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References


