

Article details: 2020-0211	
Title	Evaluation of the quality of mammographic breast positioning: a Quebec-wide representative study
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Reviewer 1	Dr. Marie-Hélène Guertin
Institution	Institut national de santé publique du Québec, Québec, Que.
General comments (author response in bold)	<p>This study presents the results of a professional inspection of bilateral mammograms realised in Quebec. Problems with positioning of the breast on screening mammograms were noted previously in the province. The results of this more recent analysis confirms that obtaining adequate positioning on mammograms is still a challenge in the province. Some comments/suggestions are presented below.</p> <p>We were very pleased to see that we received feedback from Dr. Guertin. We would like to thank this reviewer for taking the time to review our manuscript.</p> <p>Introduction/Methods</p> <p>The study presents a new evaluation tool developed for this study. Some questions could be addressed in more detail. Will it be used in future evaluations? In what context should this tool be used? Will it yield similar results than the tool used by the CAR or the ACR or is it specific for the needs of the inspections carried out by the OTIMROEPMQ?</p> <p>We thank Reviewer 1 for the questions. Currently, the tool is being used by OTIMROEPMQ as part of their rolling inspection in the quality assessment of breast positioning among its members. This tool was also developed with the aim of being used in other settings outside of OTMROEPMQ for quality assessment of breast positioning among technologists.</p> <p>Modification to text: N/A</p> <p>Analysis/Results</p> <p>Results are coherent with the analysis but more results could be added. The data collection was detailed for technologists, baseline characteristics of patients and the positioning specific criteria. More information could be included in the tables that would be interesting to the reader.</p> <p>- Only the most common reasons for critical failures were presented for CC and MLO views. A more detailed table (maybe as a supplement) describing the frequency at which each criterion is not met would be useful.</p> <p>We thank Reviewer 1 for the suggestion. We have calculated the frequencies of images evaluated as critical failures in CC view and MLO view, which are now presented in Supplementary Table 4.</p> <p>Modification to text: Please see Supplementary Table 4 (frequencies and percentage of failure by criterion)</p> <p>- Some patients' characteristics were collected in the study. Results were not adjusted to take into account those characteristics and the effect of these characteristics on positioning quality was not discussed. Previous studies have shown that BMI and or breast density are associated with mammography quality. One of the conclusion focuses on training for technologists. Results presented with both technologists and patients' characteristics could inform on more specific challenges that would need to be addressed in additional positioning training for</p>

technologists.

We thank Reviewer 1 for the recommendation. We have now calculated the percentage of within-group failure and between-group differences in failure (with 95% CI) for those patient characteristics, which are presented in Supplementary Table 6, which also expands on Comment #15 from the Editorial team that suggested providing failure rates by technologist/centre characteristics.

Modification to text: Please Supplementary Table 6

- It would also have been interesting to show results by mammography modality (computed radiography compared to digital mammography). This could also be useful for future training planning.

We agree with Reviewer 1 and have incorporated this in Supplementary Table 6.

Modification to text: Please see Supplementary Table 6

Interpretation:

p. 13 line 29. "Future studies with large sample sizes should assess the impact of improper breast positioning on breast cancer incidence". I am not sure if breast cancer incidence is really the outcome of interest. Cancer detection rates or mammography sensitivity are more likely to be affected by poor mammography quality.

We fully agree with Reviewer 1 and this was most likely removed from the text.

Modification to text: N/A

Limits:

It is mentioned that the study is not large enough to assess the impact of positioning on missed breast cancers. If we focus on screening mammograms, a simple random sample of mammograms would need to be very very large to allow such analyses. That is why studies analysing this association are selecting mammograms among women who developed breast cancers (detected or interval). So the sample size is not as much of a concern. Another limitation pertains the new tool to assess positioning. It is new and it is therefore difficult to compare the results with other studies on the subject.

We agree with Reviewer 1. The limitations have been changed to reflect these concerns and to also address Comment #10b from the Editorial team.

Modification to text: Page 13. Furthermore, the quality assessment tool had a good inter-rater agreement between the expert evaluators. However, as with all quality assessment tools, some subjectivity is inherently present.

Because the tool was specifically developed for this professional audit, it was thus impossible to directly compare the results with other assessment methods. Future studies will be needed to compare this tool with other assessment methods in different settings.

Supplementary material

p. 47, Line 47 (Supplementary Methods 2): With the final percent agreement, the final Cohen's Kappa would also be useful.

We agree with Reviewer 1. Cohen's Kappa has been added, which also addresses Comment #10c from the Editorial team.

Modification to text: Page 5. "The tool was tested for inter-rater agreement

	<p>by the expert panel using two samples, for a final raw agreement of 97% and a Cohen's kappa coefficient of 0.63, indicating good inter-rater agreement." Supplementary Methods 2. "The final raw agreement was 97%, corresponding to a near-perfect agreement between the evaluators, and a Cohen's kappa coefficient of 0.63, indicating good inter-rater agreement."</p>
Reviewer 2	Dr. Waseem Sharieff
Institution	BC Cancer Agency Abbotsford Centre, Abbotsford, BC
General comments (author response in bold)	<p>The authors address an important question which has policy and practice implications. There are many strengths including large imaging data and vigorous quality assessment.</p> <p>We would like to thank Dr. Sharieff for taking the time to provide comments and for the helpful review of our manuscript.</p> <p>1. How cut off was chosen a priori, to categorize low volume versus high volume centre? Median can only be computed after analyzing the results. We thank Reviewer 2 for the question. The data was collected by OTIMROEPMQ and volume was decided prior to conducting the analysis. Modification to text: N/A</p> <p>2. How cut off was chosen a priori, to categorize low versus high case volume per technologist? Median can only be computed after analyzing the results. Similar to our response above for Comment #1, the data was collected prior to the analysis and was known by OTIMROEPMQ. Modification to text: N/A</p> <p>3. How information on breast size and density was collected from medical records? I am not aware that any health professional measures breast size and record that in the chart. Breast density is usually determined from mammograms. Please clarify if these variables were measured from the mammograms rather than collected from chart review. We thank Reviewer 2 for this question. The text has been clarified to indicate that technologists used a case report form to abstract age, weight, and height from the medical record, and breast size and type of mammography from the mammographic exam. Modification to text: Page 6. "For each mammogram submitted, the technologist completed a case report form, abstracting selected patient characteristics from medical records (age, weight, and height) and mammogram files (breast size and type of mammography)."</p> <p>4. Sample size calculation for the stratified sample is missing. We did not perform a sample size calculation due to the design chosen for our study. Indeed, we requested that 15% of our total population be sampled to obtain an achievable number of images to be evaluated. We added these details in the manuscript. Modification to text: Page 4. "With 520 technologists active technologists certified in mammography in Quebec in 2017, it was deemed that a 15% sample (n=78) would maximize feasibility while generating an acceptable variance in estimates."</p> <p>5. The statement regarding ethics approval does not accurately reflect what</p>

authors state on page 42. It seems REB exempted them from obtaining patients' consent because it is a quality improvement study.

We see that page 42 refers to the title of the study in the Supplement, so perhaps Reviewer 2 meant another page. Regarding the question of ethics however, an updated statement has been added to the main manuscript, which also addresses Comment #13 from the Editorial team regarding ethics. We hope that this response will help answer the question from Reviewer 2.

Modification to text: Page 7. "Ethics approval was not required as this was professional audit requested by the OTIMROEPMQ and deemed a quality improvement study by the Research Ethics Board of the Jewish General Hospital"

6. 21/48 strata did not have active certified technologist?? How were they conducting mammograms without technologists?

To generate the 48 strata, we used different permutations of four criteria:

- 1. centre location (urban vs rural)**
- 2. annual volume of mammograms in the centre (low vs high)**
- 3. annual volume of mammograms by technologist (low vs high)**
- 4. years of experience (<3, 3-14, >15)**

A total of 21 of the 48 strata did not have technologists, which means that for those strata no technologist met some specific permutations. For example, one possible permutation was a technologist with less than 3 years of experience AND performing a high volume of mammograms AND working in a rural centre with a high annual volume of mammograms. No such technologist was registered in the OTIMROEPMQ database.

Modification to text: N/A

7. Consider including diagrams or images to show how critical failures were determined and how body-nipple distance was measured.

We thank Reviewer 2 for their suggestion. Unfortunately, we are unable to provide diagrams or images of the patients.

Modification to text: N/A

8. Regarding the exploratory analysis, can authors graphically show failures against some clinically meaningful cut off for case volume and training. Based on the results, they may come up with a recommendation that mammograms should be done in a centre with at least x number of case volume and y number of technologist experience.

We thank Reviewer 2 for the comment. We have added a table presenting the results by centre characteristics and technologist characteristics. We are mindful of the small number of centres and technologists in our study, and therefore we are cautious not to make inferences regarding these results.

Modification to text: Please see Supplementary Table 5

9. I will also suggest that authors exclude diagnostic mammograms, patients with implants and patients with previous surgery or radiotherapy. That is limit the inclusion criteria to screening studies only.

We thank Reviewer 2 for the helpful suggestion. We are proposing to stratify the results by screening vs diagnostic exams and have included these

	<p>results in Supplementary Table 6. For the exclusion of patients with previous surgery or radiotherapy, we have not collected this information from patients.</p> <p>Modification to text: Please see Supplementary Table 6</p>
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