INESSS
LE SAVOIR PREND FORME

JANUARY 2019

Breast tomosynthesis and breast cancer screening

English summary

Une production de l'Institut national d'excellence en santé et en services sociaux (INESSS)

Direction des services de santé et de l'évaluation des technologies

Québec

This is the English summary of the guidance entitled Tomosynthèse mammaire et dépistage du cancer du sein published in January 2019.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

Membres de l'équipe projet

Auteures
Julie Lessard, Ph. D.
Marie-Christine Paquin, Ph. D.
Ingeborg Blancquaert, Ph. D.

Coordonnateurs scientifiques
Mélanie Martin, Ph. D.
Jim Boulanger, Ph. D.

Directrice
Michèle de Guise, M.D., FRCPC, M.M.

Repérage d'information scientifique
Caroline Dion, M.B.S.I., *bibl. prof.*
Mathieu Plamondon, M.S.I.
Lysane St-Amour, M.B.S.I.
Julien Chevrier, M.S.I.
Flavie Jouandon, *tech. doc.*

Soutien administratif
Jacinthe Clusiau

SUMMARY

The Ministère de la Santé et des Services sociaux (MSSS) asked the Institut national d'excellence en santé et en services sociaux (INESSS) to determine if combined tomosynthesis and mammography should replace mammography for breast cancer screening in women aged 50 to 69 years in the Québec Breast Cancer Screening Program (PQDCS), as well as in women under the age of 50 years and those 70 years of age and older.

Replacing one screening test with another in an existing screening program would be justified if it maximized the benefits for the participants and minimized the risks associated with the screening. In the context of breast cancer screening, no study identified has evaluated the mortality and morbidity associated with breast cancer or the overdiagnosis and adverse effects associated with the procedures performed because of a false-positive result on a screening test using tomosynthesis. Given the absence of such clinical data, this report is aimed at determining if combining tomosynthesis with mammography improves the performance of mammography, mainly by increasing the cancer detection rate, while at the same time reducing the drawbacks associated with false-positive recall rates. The performance indicators for tomosynthesis in combination with synthetic 2-dimensional (2D) image reconstruction and for tomosynthesis alone are presented as well.

Two randomized clinical trials (RCTs) in which women were randomly assigned to screening with one of the strategies were selected. One of these RCTs, for which an interim analysis of the results has been published, recruited women aged 50 to 69 years who were participating in a screening program, while the other included women aged 40 to 49 years at moderate or high risk for breast cancer. A few prospective studies in which each woman underwent combined tomosynthesis and mammography in a screening program were selected as well, as were several retrospective studies. The retrospective studies included a cohort of women who had undergone combined tomosynthesis and mammography and another cohort who had undergone mammography alone. Given that retrospective studies are more subject to selection bias, we based most of our conclusions on the results of the RCTs and the prospective studies.

Sensitivity and specificity are the performance parameters conventionally used to determine if a diagnostic test has a good ability to distinguish between individuals with or without the disease of interest, but obtaining such data requires a sufficiently long follow-up to document interval cancers, among other things, which was seldom done in the selected studies. The available data are therefore insufficient for ruling on the sensitivity and specificity of combined tomosynthesis and mammography in relation to mammography alone in the context of breast cancer screening.

According to the selected studies, the total cancer detection rate is higher with combined tomosynthesis and mammography than with mammography alone in breast cancer screening, regardless of the women's age or breast density. However, the proportion of

these additional cancers that would have caused symptoms or death in the affected women cannot be determined from the available data.

The recall rate reflects the proportion of screening participants who are proposed a follow-up or additional test, even a biopsy. For some of them in whom the lesions will turn out to be benign, certain tests would be considered unnecessary and could cause anxiety. Although the RCTs showed equivalent recall rates, the prospective studies yielded divergent results that are difficult to explain.

Women in whom a screening test reveals a suspicious lesion will want to know the likelihood of being diagnosed with cancer after the recall and the additional tests, that is, the test's recall positive predictive value. This value is the same or greater for combined tomosynthesis and mammography than for mammography alone.

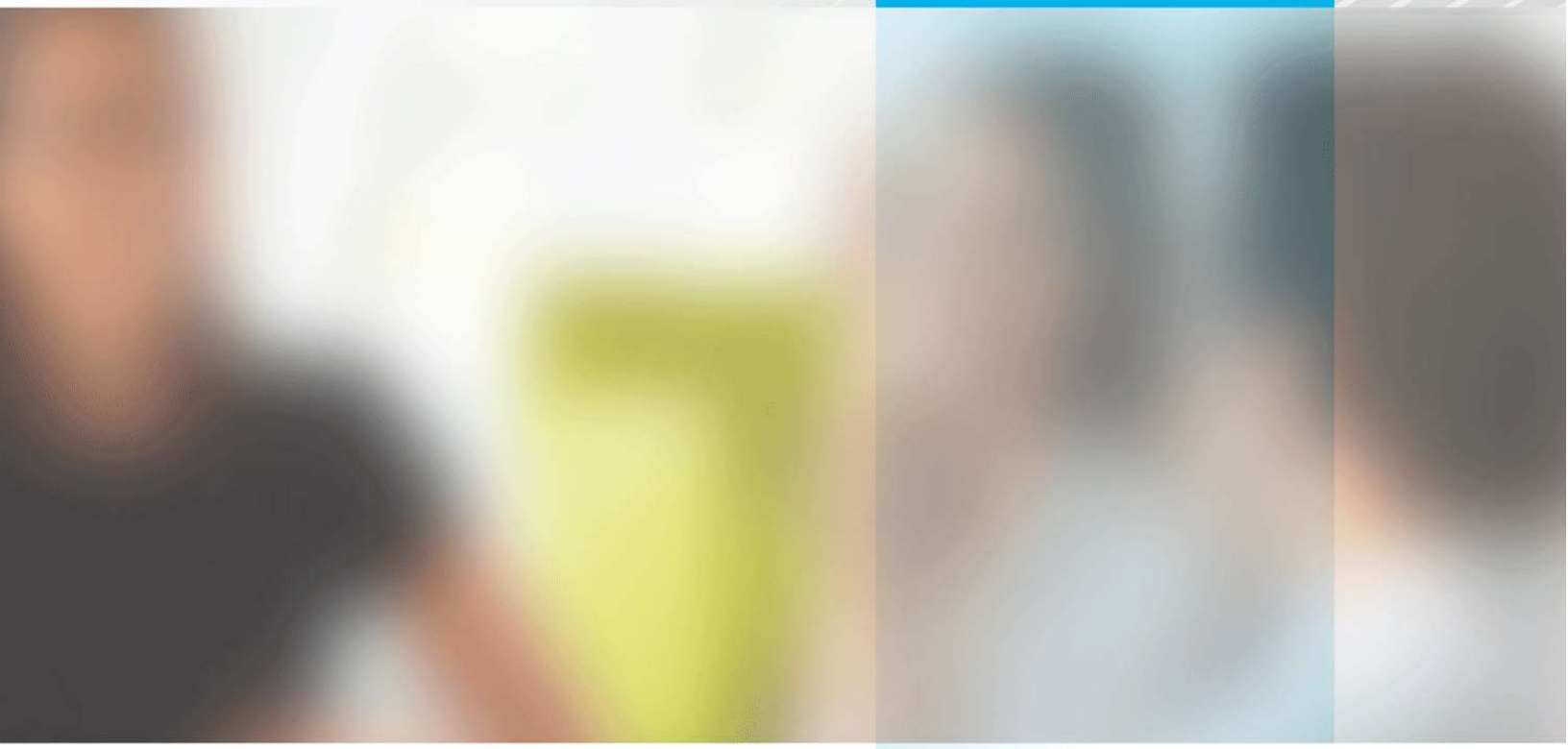
Tomosynthesis involves a radiation exposure similar to that in mammography. Therefore, combined tomosynthesis and mammography involves radiation exposure that is two to three times higher than in mammography alone. However, the clinical impact of this dose is not known.

Tomosynthesis in combination with synthetic 2D image reconstruction is an alternative to combined tomosynthesis and mammography, since it involves less radiation exposure. Additional data, such as data on interval cancers, are necessary for ruling on the performance of tomosynthesis in combination with synthetic 2D image reconstruction compared to that of mammography.

Because of the different organizational contexts in which the RCTs, prospective studies and retrospective studies were conducted, it is difficult to assess the impact that a technology replacement would have on recall rates, false-positive recall rates and positive predictive values in Québec. Furthermore, certain values for the PQDCS's performance indicators are relatively far from the values obtained for mammography in the selected studies in terms of, for example, recall rates, which are especially high in Québec. These differences could be explained, in part, by the European test reading standards, specifically, double reading, and the higher annual number of readings, as well as the medicolegal context in North America.

To date, few government agencies or expert panels have evaluated tomosynthesis in the context of breast cancer screening. The National Comprehensive Cancer Network (NCCN) and the American College of Radiology (ACR) recommend considering tomosynthesis when breast cancer screening is indicated. The US Preventive Services Task Force (USPSTF) and the Norwegian Institute of Public Health concluded, in 2016 and 2017, respectively, that the evidence was insufficient for assessing the benefits and drawbacks of tomosynthesis as the primary breast cancer screening test. There remain a number of uncertainties regarding the added value associated with a technology replacement with combined tomosynthesis and mammography for breast cancer screening, the possible adverse effects and the transferability of the performance results from the selected studies to the Québec screening context. Consequently, INESSS does not recommend replacing mammography with combined tomosynthesis and mammography for breast cancer screening in Québec.

Combined tomosynthesis and mammography and tomosynthesis in combination with synthetic 2D image reconstruction should be reevaluated when new data are published, in particular, data on interval cancers. Tomosynthesis in combination with synthetic 2D image reconstruction may involve less radiation exposure and provide a performance similar to that of combined tomosynthesis and mammography. Additional data, ideally from a screening context similar to that in Québec, are needed in order to take a position regarding this new technology.



Siège social

2535, boulevard Laurier, 5e étage
Québec (Québec) G1V 4M3
418 643-1339

Bureau de Montréal

2021, avenue Union, 12e étage, bureau 1200
Montréal (Québec) H3A 2S9
514 873-2563
inesss.qc.ca

Institut national d'excellence en santé et en services sociaux
Québec