

Tomosynthesis and Breast Cancer:
Diagnostic Evaluation and Other Uses

English summary

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

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SUMMARY

Tomosynthesis and Breast Cancer: Diagnostic Evaluation and Other Uses

The purpose of the diagnostic evaluation of breast cancer is to confirm or rule out suspected cancer following an abnormal screening test or in the presence of clinical signs or symptoms. Several imaging modalities can be used, such as two-dimensional (2D) mammography, ultrasound and magnetic resonance imaging. However, these modalities have certain inherent limitations when used in this context.

Tomosynthesis could be of added value in the diagnostic evaluation of breast cancer if it could clarify the diagnosis of uncertain cases and reduce unnecessary additional investigations compared to the imaging modalities currently used. This would improve the quality of the diagnosis and the subsequent management of the disease.

The ministère de la Santé et des Services sociaux (MSSS) asked the Institut national d'excellence en santé et en services sociaux (INESSS) to examine the evidence on the use of tomosynthesis in breast cancer screening and diagnosis. The use of tomosynthesis in breast cancer screening has already been the subject of a first evaluation ([Tomosynthèse mammaire et dépistage du cancer du sein](#)). The purpose of this report is to assess the suitability of tomosynthesis (alone or in combination with two-dimensional mammography) for clinical uses other than screening, such as diagnosing breast cancer, preoperative evaluations, localization during breast biopsies, evaluating margins and surgical specimens, surveillance after breast cancer treatment, and surveillance of patients with a current or past history of breast cancer.

The performance of tomosynthesis combined with mammography appears to be superior, or at least equivalent, to that of mammography alone for breast cancer diagnosis in terms of sensitivity, specificity and the ROC-AUC value, an indicator whose measure reflects the relationship between a test's specificity and sensitivity. The available data on positive and negative predictive values are insufficient and cannot be used to rule on this indicator for the purpose of establishing the performance of tomosynthesis combined with mammography. The data do, however, suggest a favourable trend for its use.

Several types of abnormalities (e.g., asymmetric densities, masses, architectural distortions and microcalcifications) can be detected during a breast imaging examination. In most cases, further investigation will yield a negative or benign result. Although the available data are limited and cannot be used to rule on the use of tomosynthesis combined with mammography according to the type of abnormality, the experts on the advisory committee felt that tomosynthesis has added value in the detection of architectural distortions and asymmetric densities but not microcalcifications.

Tomosynthesis combined with mammography appears to reduce the number of uncertain diagnoses following an abnormal mammography result by reclassifying them mostly as benign cases. For some women, this would mean a cessation of investigations and follow-up, in addition to reducing some of their stress and anxiety. On the other hand, the radiation dose incurred in tomosynthesis combined with mammography is about twice as high. The clinical impact of this increased radiation in patients is not known.

Tomosynthesis combined with 2D synthetic image reconstructed from 3D, an alternative to combined tomosynthesis and mammography, appears to reduce radiation exposure. However, the available data on the performance of combined tomosynthesis and 2D synthetic image in diagnosing breast cancer are insufficient. If this technology proves to be effective, it could alleviate the increase in radiation incurred with tomosynthesis combined with mammography.

Tomosynthesis has also been evaluated for other uses related to the diagnostic investigation of breast cancer. The tomosynthesis-guided breast biopsy success rate appears to be at least equivalent, if not superior, to the success rate of stereotactic biopsies, with the procedure taking approximately half the amount of time. The available data are not sufficient for ruling on the use of tomosynthesis for preoperative evaluations, margin and specimen evaluations, surveillance after breast cancer treatment or surveillance of patients with a current or past history of breast cancer.

From an organizational standpoint, the digital file size is larger with tomosynthesis, and storage and modernization of the reading stations need to be taken into consideration. Because of the higher number of images to be interpreted by radiologists, this could have a significant impact at clinics designated for breast cancer diagnosis.

Although tomosynthesis is used in Québec to diagnose breast cancer, a picture of its actual use cannot be provided, given that there is no billing code. It is also difficult to comment on the costs associated with the addition of new indications for the use of tomosynthesis in the absence of an economic study. Most of the mammography equipment consists of mammography units that can be upgraded for tomosynthesis. The costs associated with equipment upgrades and user training and the waiting times for the upgraded equipment to become available need be taken into account.

Having examined this matter, INESSS makes the following recommendations:

- Tomosynthesis combined with mammography is indicated for completing a breast investigation and specify an abnormality detected on mammography in women recalled after an abnormal mammogram or who have clinical signs or symptoms.

Tomosynthesis combined with mammography is recommended for characterizing architectural distortions and asymmetric densities (expert opinion).

Tomosynthesis combined with mammography is not recommended for characterizing microcalcifications (expert opinion).

- Tomosynthesis-guided breast biopsies are indicated, when this imaging modality is available, for evaluating suspicious lesions that may have been occult on mammography and ultrasound.

The available data are not sufficient for taking a position regarding the use of tomosynthesis for the following:

- Preoperative evaluations;
- Evaluating margins and specimens;
- Surveillance after cancer treatment;
- Surveillance of patients with a current or past history of breast cancer.

Comments accompanying the recommendations:

- If the technology is implemented, adequate training should be provided to radiologists, mammography technologists and medical physicists.
- Adequate technological support will need to be put in place, e.g., modernizing the picture archiving and communication systems (PACS) to ensure that they can handle the computer files generated by tomosynthesis.
- The organization of the workflow at the clinics designated for cancer diagnosis, such as CRIDs (designated investigation referral centres), may have to be optimized to reduce the time to reading resulting from the increased number of tomosynthesis examinations.

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