



TITLE: Digital Tomosynthesis for the Screening and Diagnosis of Breast Cancer: Diagnostic Accuracy and Guidelines

DATE: 23 December 2014

RESEARCH QUESTIONS

1. What is the clinical effectiveness of digital tomosynthesis compared with mammography for breast cancer screening?
2. What is the clinical effectiveness of digital tomosynthesis as an adjunct to mammography compared with mammography alone for breast cancer screening?
3. What is the clinical effectiveness of digital tomosynthesis compared with mammography for breast cancer diagnosis?
4. What is the clinical effectiveness of digital tomosynthesis as an adjunct to mammography compared with mammography alone for breast cancer diagnosis?
5. What are the evidence-based guidelines regarding the use of digital tomosynthesis for breast cancer screening and diagnosis?

KEY FINDINGS

Two systematic reviews, 17 non-randomized studies, and one evidence-based guideline were identified regarding digital tomosynthesis for screening and diagnosis of breast cancer.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 12), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. For research questions 1-4 methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and non-randomized studies. For research question 5 methodological filters were applied

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to limit retrieval to guidelines. Where possible, retrieval was limited to the human population. For research questions 1-4 the search was also limited to English language documents published between August 1, 2013 and December 17, 2014. For research question 5 the search was also limited to English language documents published between January 1, 2010 and December 17, 2014. Internet links were provided, where available.

SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria	
Population	Adult women, subgroups: <ul style="list-style-type: none"> • Adult women ages 40 to 49 • Adult women ages 50 to 74 • Adult women with low breast density • Adult women with high breast density
Intervention	Digital tomosynthesis with or without mammography
Comparator	Mammography alone
Outcomes	Q1-Q4: Accuracy, sensitivity, specificity, detection rates Q5: Guidelines and recommendations
Study Designs	Q1-Q4: Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies Q5: Evidence-based guidelines

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Two systematic reviews, 17 non-randomized studies, and one evidence-based guideline were identified regarding digital tomosynthesis for screening and diagnosis of breast cancer. No relevant health technology assessments or randomized controlled trials were identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

1. Garcia-Leon FJ, Llanos-Mendez A, Isabel-Gomez R. Digital tomosynthesis in breast cancer: A systematic review. Radiologia. 2014 Oct 9. [PubMed: PM25306860](#)
2. Lei J, Yang P, Zhang L, Wang Y, Yang K. Diagnostic accuracy of digital breast tomosynthesis versus digital mammography for benign and malignant lesions in breasts: a meta-analysis. Eur Radiol. 2014 Mar;24(3):595-602.

[PubMed: PM24121712](#)

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

Screening

3. Bernardi D, Caumo F, Macaskill P, Ciatto S, Pellegrini M, Brunelli S, et al. Effect of integrating 3D-mammography (digital breast tomosynthesis) with 2D-mammography on radiologists' true-positive and false-positive detection in a population breast screening trial. *Eur J Cancer*. 2014 May;50(7):1232-8.
[PubMed: PM24582915](#)
4. Caumo F, Bernardi D, Ciatto S, Macaskill P, Pellegrini M, Brunelli S, et al. Incremental effect from integrating 3D-mammography (tomosynthesis) with 2D-mammography: Increased breast cancer detection evident for screening centres in a population-based trial. *Breast*. 2014 Feb;23(1):76-80.
[PubMed: PM24316152](#)
5. Durand MA, Haas BM, Yao X, Geisel JL, Raghu M, Hooley RJ, et al. Early Clinical Experience with Digital Breast Tomosynthesis for Screening Mammography. *Radiology*. 2014 Sep 1;131319.
[PubMed: PM25188431](#)
6. Friedewald SM, Rafferty EA, Rose SL, Durand MA, Plecha DM, Greenberg JS, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. *JAMA*. 2014 Jun 25;311(24):2499-507.
[PubMed: PM25058084](#)
7. Greenberg JS, Javitt MC, Katzen J, Michael S, Holland AE. Clinical performance metrics of 3D digital breast tomosynthesis compared with 2D digital mammography for breast cancer screening in community practice. *AJR Am J Roentgenol*. 2014 Sep;203(3):687-93.
[PubMed: PM24918774](#)
8. Houssami N, Macaskill P, Bernardi D, Caumo F, Pellegrini M, Brunelli S, et al. Breast screening using 2D-mammography or integrating digital breast tomosynthesis (3D-mammography) for single-reading or double-reading--evidence to guide future screening strategies. *Eur J Cancer*. 2014 Jul;50(10):1799-807.
[PubMed: PM24746887](#)
9. Lourenco AP, Barry-Brooks M, Baird G, Tuttle A, Mainiero MB. Changes in Recall Type and Patient Treatment Following Implementation of Screening Digital Breast Tomosynthesis. *Radiology*. 2014 Sep 22;140317.
[PubMed: PM25247407](#)
10. McCarthy AM, Kontos D, Synnestvedt M, Tan KS, Heitjan DF, Schnall M, et al. Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program. *J Natl Cancer Inst*. 2014 Nov;106(11).

[PubMed: PM25313245](#)

11. Rose SL, Tidwell AL, Ice MF, Nordmann AS, Sexton R, Jr., Song R. A reader study comparing prospective tomosynthesis interpretations with retrospective readings of the corresponding FFDM examinations. *Acad Radiol.* 2014 Sep;21(9):1204-10.
[PubMed: PM25107868](#)
12. Haas BM, Kalra V, Geisel J, Raghu M, Durand M, Philpotts LE. Comparison of tomosynthesis plus digital mammography and digital mammography alone for breast cancer screening. *Radiology.* 2013 Dec;269(3):694-700.
[PubMed: PM23901124](#)

Diagnosis

13. Morel JC, Iqbal A, Wasan RK, Peacock C, Evans DR, Rahim R, et al. The accuracy of digital breast tomosynthesis compared with coned compression magnification mammography in the assessment of abnormalities found on mammography. *Clin Radiol.* 2014 Nov;69(11):1112-6.
[PubMed: PM25100302](#)
14. Rafferty EA, Park JM, Philpotts LE, Poplack SP, Sumkin JH, Halpern EF, et al. Diagnostic accuracy and recall rates for digital mammography and digital mammography combined with one-view and two-view tomosynthesis: results of an enriched reader study. *AJR Am J Roentgenol.* 2014 Feb;202(2):273-81.
[PubMed: PM24450665](#)
15. Thomassin-Naggara I, Perrot N, Dechoux S, Ribeiro C, Chopier J, de Bazelaire C. Added value of one-view breast tomosynthesis combined with digital mammography according to reader experience. *Eur J Radiol.* 2014 Nov 15.
[PubMed: PM25467641](#)
16. Wu Y, Alagoz O, Vanness DJ, Trentham-Dietz A, Burnside ES. Pursuing optimal thresholds to recommend breast biopsy by quantifying the value of tomosynthesis. *Proc Soc Photo Opt Instrum Eng [Internet].* 2014 Mar 11 [cited 2014 22 Dec];9037:90370U. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4112817>
[PubMed: PM25076829](#)
17. Zuley ML, Guo B, Catullo VJ, Chough DM, Kelly AE, Lu AH, et al. Comparison of two-dimensional synthesized mammograms versus original digital mammograms alone and in combination with tomosynthesis images. *Radiology.* 2014 Jun;271(3):664-71.
[PubMed: PM24475859](#)
18. Thibault F, Dromain C, Breucq C, Balleyguier CS, Malhaire C, Steyaert L, et al. Digital breast tomosynthesis versus mammography and breast ultrasound: a multireader performance study. *Eur Radiol.* 2013 Sep;23(9):2441-9.
[PubMed: PM23673573](#)

Screening and Diagnosis

19. Gennaro G, Hendrick RE, Toledano A, Paquelet JR, Bezzon E, Chersevani R, et al. Combination of one-view digital breast tomosynthesis with one-view digital mammography versus standard two-view digital mammography: per lesion analysis. *Eur Radiol*. 2013 Aug;23(8):2087-94.
[PubMed: PM23620367](#)

Guidelines and Recommendations

20. National Guidelines Clearinghouse [Internet] Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); [1997] - . Guidelines summary: American College of Obstetricians and Gynecologists (ACOG). Breast cancer screening; 2011 Aug [cited 2014 Dec 22]. Available from:
<http://www.guideline.gov/content.aspx?id=34275&search=tomosynthesis>
See: Note following 'Interventions and Practices Considered'

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APPENDIX – FURTHER INFORMATION:

Systematic Reviews and Meta-analyses – Non-English Publications with English Summary

21. Institut national d'excellence en santé et en services sociaux (INESSS). La tomosynthèse mammaire numérique [Internet]. Montréal: INESSS; 2014 [cited 2014 Dec 22]. Available from: <http://www.inesss.qc.ca/en/publications/publications/publication/la-tomosynthese-mammaire-numerique.html>
22. Pichon Riviere A, Augustovski F, Garcia Marti S, Alcaraz A, Glujovsky D, Lopez A, et al. Tomosíntesis digital para el diagnóstico de patología mamaria [Digital tomosynthesis for the diagnosis of breast cancer] [Internet]. Buenos Aires: Institute for Clinical Effectiveness and Health Policy (IECS), 2013 [cited 2014 Dec 22]. (Informe Técnico Breve N° 46. 2013). Available from: http://www.iecs.org.ar/iecs-frame-visor-publicaciones.php?cod_publicacion=1552&origen_publicacion=publicaciones

Clinical Practice Guidelines – Methodology Not Specified

23. Toward Optimized Practice (TOP) Working Group for Breast Cancer Screening. Breast cancer screening: clinical practice guideline [Internet]. Edmonton (AB): Toward Optimized Practice, 2013 Sep. [cited 2014 Dec 22]. Available from: http://www.topalbertadoctors.org/download/243/breast_cancer_guideline.pdf

Review Articles

24. Blue Cross and Blue Shield Association. Special Report: Screening Asymptomatic Women with Dense Breasts and Normal Mammograms for Breast Cancer [Internet]. Chicago: The Association; April 2014. (Technology Evaluation Center) [cited 2014 Dec 22]. Available from: http://www.bcbs.com/blueresources/tec/vols/28/28_15.pdf
25. Zervoudis S, Iatrakis G, Tomara E, Bothou A, Papadopoulos G, Tsakiris G. Main controversies in breast cancer. World J Clin Oncol [Internet]. 2014 Aug 10 [cited 2014 Dec 22];5(3):359-73. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4127607>
[PubMed: PM25114851](#)
26. Technology assessment No. 9: Digital breast tomosynthesis. Obstet Gynecol. 2013 Jun;121(6):1415-7.
[PubMed: PM23812488](#)
27. Canadian Agency for Drugs and Technologies in Health. Digital Tomosynthesis for the Screening and Diagnosis of Breast Cancer: A Review of the Diagnostic Accuracy [Internet]. Ottawa: The Agency; September 2013. (Rapid response report). [cited 2014 Dec 22]. Available from: <http://www.cadth.ca/media/pdf/htis/oct-2013/RC0482-Tomosynthesis-Final.pdf>