

INPLASY PROTOCOL

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Corresponding author:
Tobias Vogelmann

tv@link-care.de

Author Affiliation:
LinkCare GmbH

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Protocol of a systematic review and meta-analysis comparing digital breast tomosynthesis (DBT) plus synthesized two-dimensional mammography (s2D) to digital mammography (DM) alone in breast cancer screening

Heywang-Köbrunner, SH¹; Jänsch, A²; Hacker, A³; Weinand, S⁴; Vogelmann, T⁵.

Review question / Objective: This systematic review and meta-analysis aims to investigate the cancer detection rates (CDR), recall rates, interval cancer rates (ICR), biopsy rates, and positive predictive values for recalls (PPV-1), - biopsies recommended (PPV-2), and - biopsies performed (PPV-3) of women screened with digital breast tomosynthesis (DBT) plus synthesized two-dimensional mammography (s2D) compared to digital mammography (DM) alone.

Condition being studied: The condition of interest is DBT plus s2D in comparison to DM in population-based breast cancer screening programmes.

Information sources: Studies are searched on PubMed between January 1, 2010 and September 2, 2020.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 April 2021 and was last updated on 12 April 2021 (registration number INPLASY202140073).

INTRODUCTION

Review question / Objective: This systematic review and meta-analysis aims to investigate the cancer detection rates (CDR), recall rates, interval cancer rates (ICR), biopsy rates, and positive predictive values for recalls (PPV-1), - biopsies recommended (PPV-2), and - biopsies

performed (PPV-3) of women screened with digital breast tomosynthesis (DBT) plus synthesized two-dimensional mammography (s2D) compared to digital mammography (DM) alone.

Condition being studied: The condition of interest is DBT plus s2D in comparison to

DM in population-based breast cancer screening programmes.

METHODS

Search strategy: A systematic literature search is performed using predefined search terms to identify relevant studies published on PubMed between January 1, 2010 and September 2, 2020. Studies published in English language and with available abstracts are searched for.

Participant or population: Asymptomatic patients of all ages with an average risk of breast cancer presenting for screening are considered. Women with symptoms at regular screening could be part of the population.

Intervention: Digital breast tomosynthesis (DBT) plus synthesized two-dimensional mammography (s2D) is considered.

Comparator: Digital mammography (DM) alone is defined as comparator of interest.

Study designs to be included: Prospective and retrospective studies with a comparative design (paired or unpaired) are included.

Eligibility criteria: Studies without human subjects or studies including only women with symptoms are excluded. No restriction regarding countries is set.

Information sources: Studies are searched on PubMed between January 1, 2010 and September 2, 2020.

Main outcome(s): Cancer detection rates (CDR), recall rates, interval cancer rates (ICR), biopsy rates, and positive predictive values for recalls (PPV-1), - biopsies recommended (PPV-2), and - biopsies performed (PPV-3).

Additional outcome(s): None.

Data management: Microsoft Excel and Review Manager 5.4.

Quality assessment / Risk of bias analysis: Quality Assessment of Diagnostic Accuracy Studies (QUADAS)-2 tool is used to evaluate the risk of bias and applicability of included studies by two reviewers independently.

Strategy of data synthesis: Binary variables are analysed using risk ratios (RR) and their 95% confidence intervals (CI). Heterogeneity is ascertained visually by forest plots and statistically using the Higgins I². Depending on heterogeneity, random effects model (REM) or fixed effects models (FEM) are used for the calculation of pooled estimates.

Subgroup analysis: None.

Sensitivity analysis: Sensitivity analyses are performed using the leave-one-out approach if at least three studies are included in the meta-analysis.

Language: English.

Country(ies) involved: All authors are from Germany.

Keywords: Systematic Review; Meta-Analysis; Mammography; Breast Neoplasms; Early Detection of Cancer.

Contributions of each author:

Author 1 - Sylvia H. Heywang-Köbrunner.

Author 2 - Alexander Jänsch.

Author 3 - Astrid Hacker.

Author 4 - Sina Weinand.

Author 5 - Tobias Vogelmann.

Conflicts of interest: Tobias Vogelmann is owner and employee and Sina Weinand is employee of LinkCare GmbH which has received consulting fees from Hologic. The authors of this manuscript declare no other relationships with any companies, whose products or services may be related to the subject matter.