

INPLASY202560074

doi: 10.37766/inplasy2025.6.0074

Received: 18 June 2025

Published: 18 June 2025

**Corresponding author:**

Tobias Vogelmann

tv@link-care.de

**Author Affiliation:**

LinkCare GmbH.

**Vacuum-assisted breast biopsy compared to core needle biopsy: Results of a Systematic Review and Meta-Analysis**

Sharma, N; Theis, S; Vogelmann, T; Pijnappel, R.

**ADMINISTRATIVE INFORMATION****Support** - This study has received funding by Hologic.**Review Stage at time of this submission** - Data analysis.

**Conflicts of interest** - The authors of this manuscript declare relationships with the following companies: Nisha Sharma receives honorariums from Hologic for educational events. Ruud Pijnappel receives honorariums for consultancy from Bayer and Hologic and from Hologic for educational events. Tobias Vogelmann is owner and employee and Sina Theis is an employee of LinkCare GmbH; both received consulting honorariums from Hologic. The authors of this manuscript declare having no other relationships with any companies whose products or services may be related to the subject matter of this article.

**INPLASY registration number:** INPLASY202560074

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 June 2025 and was last updated on 18 June 2025.

**INTRODUCTION**

**Review question / Objective** The aim of this systematic review and meta-analysis is to compare the vacuum-assisted breast biopsy (VABB) to the core needle biopsy (CNB) in terms of ductal carcinoma in-situ (DCIS) and atypical ductal hyperplasia (ADH) underestimation rate, the repeat biopsy rate, the concordance rate, the (micro)calcification retrieval rate as well as sensitivity, specificity, and the false-negative rate.

**Rationale** Single studies exist comparing outcomes of VABB and CNB, but only one comparative meta-analysis was identified summarizing multiple study results. Huang et al. [1] included studies published until June 2016 reporting diagnostic performance of VABB and

CNB in women with breast microcalcifications. As the latest published studies are not included in this meta-analysis, and the focus is set on breast microcalcifications only, we planned to run a systematic review, considering more different outcomes and the latest published results.

**Condition being studied** Patients with suspected breast cancer who receive breast biopsy for further diagnosis.

**METHODS**

**Search strategy** We searched for relevant studies in English language on PubMed and Cochrane Library, published between January 1, 1995 and July 19, 2024.

**Participant or population** Patients with suspected breast cancer who received breast biopsy for further diagnosis were eligible for this review with no exclusions based on ethnicity or age.

**Intervention** Vacuum-assisted breast biopsy (VABB); no restriction regarding imaging-guidance or needle gauges.

**Comparator** Core needle biopsy (CNB); no restriction regarding imaging-guidance or needle gauges.

**Study designs to be included** Studies with comparative study designs were included. Studies without human subjects and studies only describing technical features were excluded.

**Eligibility criteria** As previous mentioned. Additional, the search was limited to studies published in English language and with available abstracts.

**Information sources** We searched for relevant studies in English language on PubMed and Cochrane Library, published between January 1, 1995 and July 19, 2024.

**Main outcome(s)** Ductal carcinoma in-situ (DCIS) underestimation rate, atypical ductal hyperplasia (ADH) underestimation rate, repeat biopsy rate, concordance rate, (micro)calcification retrieval rate.

**Additional outcome(s)** Sensitivity, specificity, and false-negative rate.

**Data management** All records were screened for eligibility first using the information given in the title and abstract and second, using the full texts. Screening were done by two reviewers independently – a third reviewer was asked in case of any disagreement among reviewers. Data were extracted into a pretested spreadsheet according to the checklist of the data extraction for complex meta-analysis (DECiMAL) guide [2].

**Quality assessment / Risk of bias analysis** The risk of bias and applicability are evaluated by two reviewers independently using QUADAS-2 [3]. In case of any disagreement a third reviewer is asked for assessment and consensus is reached by discussion.

**Strategy of data synthesis** Pooled differences of ADH underestimation rate, DCIS underestimation rate, repeat biopsy rate, concordance rate, (micro)calcification retrieval rate, and false-negative rate between VABB and CNB are

analysed using risk ratios with 95% confidence intervals. Pooled point sensitivities and specificities are calculated for VABB and CNB with 95% CI. Random-effects models are used for all analyses. Review Manager and Excel will be used for data analysis.

**Subgroup analysis** Subgroup analyses are planned, only considering X-ray guidance.

**Sensitivity analysis** Sensitivity analyses are planned using the leave-one-out approach.

**Language restriction** English only.

**Country(ies) involved** Germany, UK, The Netherlands.

**References** [1] Huang XC, Hu XH, Wang XR, et al (2018) A comparison of diagnostic performance of vacuum-assisted biopsy and core needle biopsy for breast microcalcification: a systematic review and meta-analysis. *Irish Journal of Medical Science* (1971 -) 187:999–1008.

[2] Pedder H, Sarri G, Keeney E, et al (2016) Data extraction for complex meta-analysis (DECiMAL) guide. *Syst Rev*.

[3] Whiting PF, Rutjes AWS, Westwood ME, et al (2011) QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. *Ann Intern Med* 155:529–536

**Other relevant information** Research of the systematic review take also place at: Department of Health Services Research, LinkCare GmbH, Ludwigsburg, Baden-Württemberg, Germany

**Keywords** Vacuum-assisted breast biopsy; core needle biopsy; breast cancer; diagnosis; meta-analysis.

**Dissemination plans** Publication in a peer-reviewed journal.

#### Contributions of each author

Author 1 - Nisha Sharma.

Email: nisha.sharma2@nhs.net

Author 2 - Sina Theis.

Email: st@link-care.de

Author 3 - Tobias Vogelmann.

Email: tv@link-care.de

Author 4 - Ruud Pijnappel.

Email: prof.pijnappel@gmail.com