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Feasibility and safety of image-guided vacuum-assisted breast biopsy: A PRISMA-compliant systematic review and meta-analysis of 20 000 population from 36 longitudinal studies

Ming Fang | Guilin Liu | Guoliang Luo | Tianyu Wu

Department of Ultrasound, The Second Affiliated Hospital (Jiande Branch), Medical School of Zhejiang University, The First People's Hospital of Jiande, Hangzhou, China

Correspondence
Ming Fang, The Second Affiliated Hospital (Jiande Branch), Medical School of Zhejiang University, The First People's Hospital of Jiande, Hangzhou, China.
Email: fangminghi@163.com

Abstract

Breast cancer is a serious disease in women. We estimated the global technical success rate and complication rates of percutaneous vacuum-assisted breast biopsy (VABB). PubMed, Embase, Web of Science, and Scopus databases were retrieved up to July 2018 to find studies in which technical success rate and complication rates of VABB were available. Pooled rates were calculated according to location mode (ultrasonography [US] or mammography) and needle type (8- or 11-gauge Mammotome probes). Of the 36 articles with 20 868 cases, we found the pooled technical success rate 0.9999(0.9997, 1.0000) ($I^2 = 17.1\%$, $P = .187$) and low complication risks including haematoma 0.1092(0.0748, 0.1437) ($I^2 = 98.3\%$, $P < .001$), pain 0.0738(0.0334, 0.1141) ($I^2 = 95.9\%$, $P < .001$), vasovagal reflex 0.0281(0.0035, 0.0527) ($I^2 = 92.5\%$, $P < .001$), and infection 0.0027(−0.0019, 0.0073) ($I^2 = 49.8\%$, $P = .113$). In this systematic review and meta-analysis, the pooled data suggested that VABB with US or mammography could be promising for diagnosis and treatment of breast disease. Further studies were necessary to identify strategies for these findings.

KEYWORDS

breast, mammography, meta, ultrasound, vacuum-assisted breast biopsy

1 | INTRODUCTION

Breast cancer is the most common malignancy worldwide. A total of about 1.7 million people were diagnosed with this disease in 2012 worldwide, and 521 900 patients died from it.[1-3] Breast cancer incidences were high in Western (0.960 ‰) and Northern (0.916 ‰) Europe, Northern America (0.894 ‰), and Australia/New Zealand (0.858 ‰); mortality rates were high in Western (0.201 ‰) and Northern (0.174 ‰) Africa, melanesia (0.197 ‰), and Central and Eastern Europe (0.165 ‰).[3] Before the treatment for breast masses, traditional staging examinations included chest radiograph, abdominal ultrasound, and computed tomography (CT) scans. And its diagnosis was usually identified using core biopsy. Early finding is important to decrease the number of cancer deaths and to improve prognosis.

In the recent decades, percutaneous vacuum-assisted breast biopsy (VABB) has been the minimally invasive technique for preoperative histopathologic diagnosis of breast masses. VABB is usually performed under ultrasonography (US) or mammography guidance. Regarding complication rates for haematoma, bleeding, skin ecchymosis, pain,

Abbreviations: CI, confidence interval; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis; VABB, vacuum-assisted breast biopsy.

vasovagal reflex, and infection using VABB, data available through the literature were insufficient. Therefore, we conduct this meta-analysis to quantify the complication rates in order to confirm the safety and efficacy of these procedures.

Key Messages

- the pooled data suggested that vacuum-assisted breast biopsy with ultrasonography or X-ray mammography could be promising for diagnosis and treatment of breast disease
- the results from the 36 articles with 20 868 cases showed high technical success and low complication risks including haematoma, bleeding, skin ecchymosis, pain, vasovagal reflex, and infection
- the combination of VABB with US or mammography could be a promising candidate of the standard biopsy methods for detecting nonpalpable lesions

2 | METHODS

2.1 | Search strategy

PubMed, Embase, Web of Science, and Scopus databases were searched by two individuals from database inception to July 2018. We used both MeSH terms and keywords for breast, mammotome, puncture, biopsy, complication, and related and exploded terms. No limitations were ruled for language or publication year.

2.2 | Study selection

We included cohort and cross-sectional studies for this meta-analysis, in which technical success rate was checked or at least one defined complications of VABB were reported, such as hematoma, bleeding, skin ecchymosis, pain, vasovagal reflex, and infection. Articles failing to fulfil the inclusion criteria (did not report a definable outcome measure of interest) were excluded from next screening. We used Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) to guide this meta-analysis.[4] In addition, because this is the meta-analysis, patient informed consent were not available by the Institutional Review Board.

2.3 | Data extraction and statistical analysis

Following the initial screening for studies, more detailed information for each study was extracted by other two investigators based on the established form, which mainly included basic characteristics such as author, patient recruitment years, needle type, location mode, design, number of patients, age, and quality of the evidence. In this study, the technical success rate was calculated and its 95% credible confidence (CI). In order to estimate the risk of VABB complications, we included articles that presented incidence in haematoma, pain, vasovagal reflex, and infection, and then estimated their pooled values. When zero events encountered in one or two groups in the included studies, we add 0.5 into each group. Between-study heterogeneity was explored by the I^2 statistic[5] and appraised as low (25%-50%), moderate (50%-75%), and high (75%-100%).[6] Subsequently, we conducted a subgroup analysis for each complication according to location mode (US or mammography) and needle type (8- or 11-gauge Mammotome probes).

We assessed the risk of bias for each study according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria. A total of four quality dimensions (high quality, moderate quality, low quality, and very low quality) were useful for each study.[7] All included studies were all individually cross-checked and assessed to minimise subjectivity and bias. Sensitivity analysis was performed by excluding each study. Publication bias was estimated using Egger's test.[8] All statistical analyses were performed using the Stata 12.0 software.

3 | RESULTS

3.1 | Study selection and description of studies

The detailed flow chart of study selection is displayed in Figure 1, in which 20 528 articles were potentially relevant after initial searching. Table 1 shows the characteristics of all included studies. Among the final 36 eligible studies, 31 were cohort studies (20 142 cases),[9-39] 1 was randomised

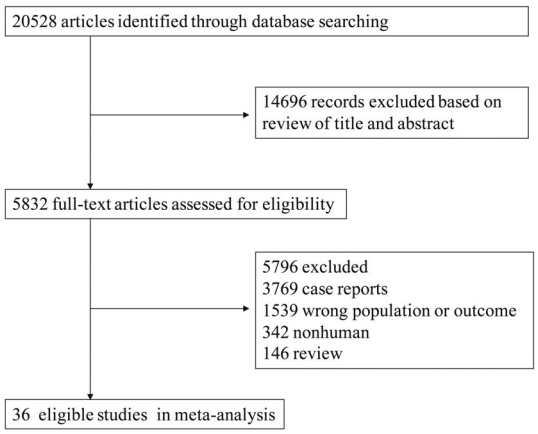

FIGURE 1 Study identification and selection

TABLE 1 Characteristics of the 36 studies of image-guided vacuum-assisted breast biopsy in this meta-analysis

Author	Patient recruitment years	Needle type	Location mode	Design	Number of patients	Age (years)
Park et al[9]	2003.1-2015.12	8	US	Retrospective cohort	8748	37.8
Liu et al[10]	2009.1-2014.1	8	US	Retrospective cohort	1267	39.1 ± 12.36
Berná-Serna et al[11]	NA(18 months)	10	US	Retrospective cohort	118	34.5 ± 12.7
Pinkney et al[40]	2014.5-2015.2	9	X-ray mammography	RCT	74	57.9 ± 12.4
Choi et al[12]	2013.3-2014.12	13	US	Retrospective cohort	114	50
Pagni et al[13]	2009.12-2013.12	8/11/14	US	Retrospective cohort	712	55
Ohsumi et al[14]	1999.5-2007.2	11/14	X-ray mammography	Retrospective cohort	488	51
Yi et al[15]	2005.12-2011.12	8	US	Retrospective cohort	136	48.4
Kibil et al[16]	2000-2011	11	US	Retrospective cohort	76	51.5
Jiang et al[17]	2008.1-2012.12	8	US	Retrospective cohort	3681	37.8
Wang et al[18]	2005.3-2009.5	8	US	Retrospective cohort	143	40.1 ± 21.2
Schaefer et al[41]	2008.1-2009.12	8/11	US	NRCT	115	52
Luo et al[19]	2007.6-2009.5	8	US	Retrospective cohort	1119	36.6
He et al[20]	2006.1-2010.1	8	US	Retrospective cohort	20	24.7
Abbate et al[21]	2010	11	US	Retrospective cohort	141	48
Nakamura et al[22]	2005.6-2007.3	11	X-ray mammography	Retrospective cohort	124	52.5
Salem et al[23]	2001.6-2005.5	8/11	X-ray mammography	Retrospective cohort	967	53.6 ± 10.3
Hertl et al[24]	2005.10-2006.2	11	US	Prospective cohort	45	50
He et al[25]	2006.6-2007.7	8	US	Retrospective cohort	86	36
Faour et al[26]	2003.1-2006.8	11	X-ray mammography	Retrospective cohort	101	50
Govindarajulu et al[27]	NA	11	US	Prospective cohort	77	NA
Weber et al[42]	1997.4-2003.8	11	X-ray mammography	NRCT	228	56
Kettritz et al[28]	2000.1-2003.8	11	X-ray mammography	Retrospective cohort	485	56
Diebold et al[29]	2002	8	X-ray mammography	Prospective cohort	58	NA
Costantini et al[30]	1998.3-2002.7	11/14	US	Retrospective cohort	305	54
Sperber et al[31]	1999.5-2001.5	11	US	Prospective cohort	52	19–68
Mariotti et al[32]	1999.6-2001.12	11/14	X-ray mammography	Retrospective cohort	282	51
Greenberg et al[33]	NA	11	X-ray mammography	Retrospective cohort	39	NA
Fine et al[34]	NA	8/11	US	Retrospective cohort	216	36 ± 11
Baez et al[35]	NA	11	US	Retrospective cohort	20	39.2
Johnson et al[36]	2000.4-2002.1	8/11	US	Retrospective cohort	81	46.8 ± 15.4
Parker et al[37]	2000.5-2000.7	11	US	Retrospective cohort	113	NA
Meloni et al[43]	1999.6-2000.4	11	US	NRCT	73	51.4 ± 8.6
Dennis et al[38]	1996.1-1999.6	11	US	Retrospective cohort	49	52
Klem et al[39]	1996.11-1997.12	11	X-ray mammography	Retrospective cohort	279	52.1 ± 11.4
Heywang-Köbrunner et al[44]	NA	11/14	X-ray mammography	NRCT	236	NA

Abbreviations: NA, not available; NRCT: non-randomised controlled trial; RCT, randomised controlled trial; US, ultrasonography.

controlled trial (RCT) (74 cases),[40] and 4 non-randomised controlled trials (NRCTs) (574 cases),[41-44] describing a total of 20 868 patients (mean age, 36–56 years), derived from China (7), United States (6), Italy (5), Germany (5), Korea (2), Japan (2), Spain (1), Poland (1), France (1), United Arab Emirates (1), Britain (1), Switzerland (1), Israel (1), New Zealand (1), and Canada (1). VABB was performed using US (24) and mammography (12) location modes. In this study, it mainly used five techniques: VABB of 8-(14), 9-(1), 10-(1), 11-(24), or 14-(5) gauge Mammotome probes.

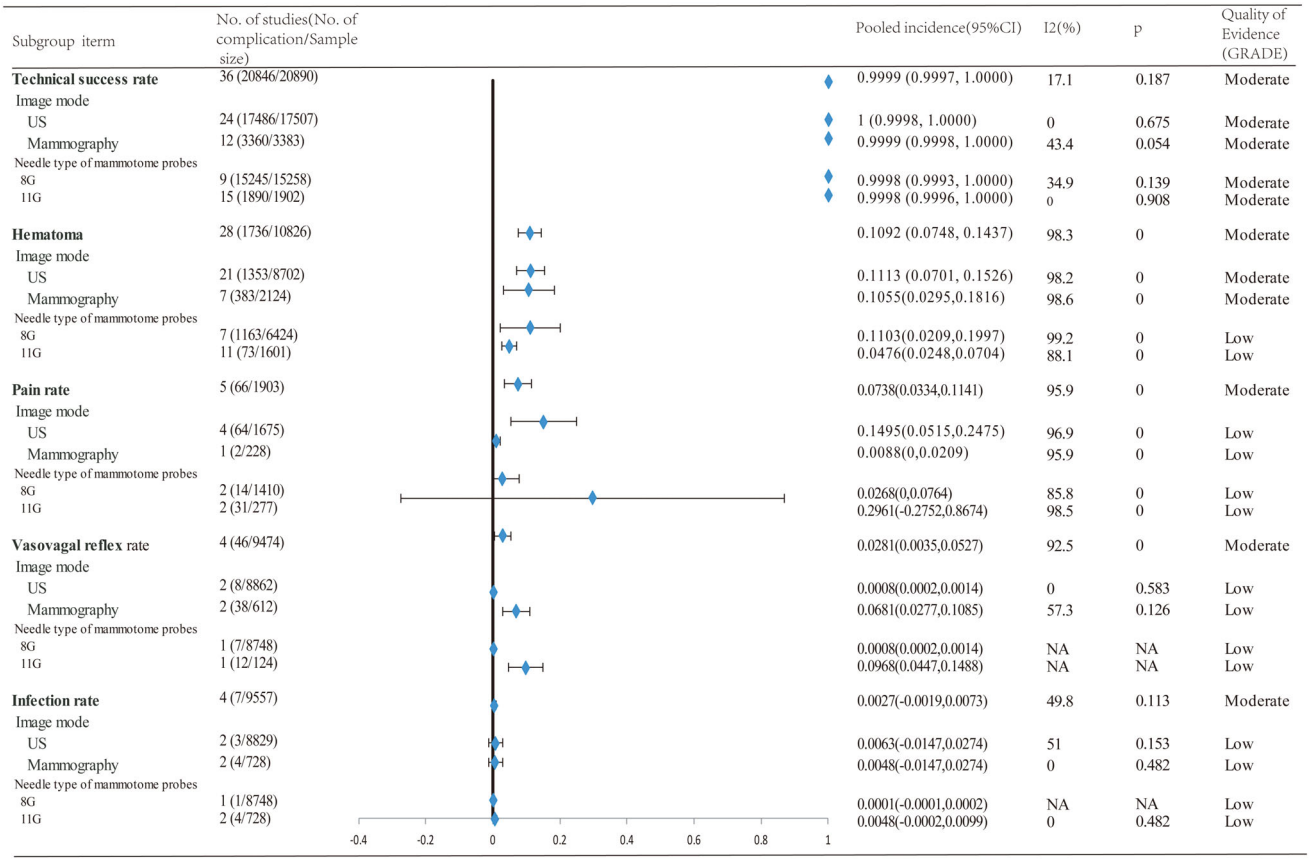

FIGURE 2 Results of subgroup analysis for the pooled complication incidences of VABB for breast masses. VABB, vacuum-assisted breast biopsy

Through GRADE guidelines, we assessed the quality of evidence for each study as high (4), moderate (19), low (13), and very low (1) (Table 1).

3.2 | Subgroup analysis

To assess the complication risk in VABB for diagnosis of breast masses, we pooled results from all included studies and found pooled high technical success rate 0.9999 (0.9997, 1.0000) ($I^2 = 17.1\%$, $P = .187$), and low complication risks including haematoma 0.1092 (0.0748, 0.1437) ($I^2 = 98.3\%$, $P < .001$), pain 0.0738 (0.0334, 0.1141) ($I^2 = 95.9\%$, $P < .001$), vasovagal reflex 0.03 (0–0.05) ($I^2 = 92.5\%$, $P < .001$), and infection 0.0027 (−0.0019, 0.0073) ($I^2 = 49.8\%$, $P = .113$) (Figure 2).

Subgroup analysis indicated that the technical success rate in US and mammography was 1 (0.9998, 1.0000) and 0.9999 (0.9998, 1.0000), and complication rates in US and mammography were as the following: haematoma 0.1113 (0.0701, 0.1526) and 0.1055 (0.0295, 0.1816); pain 0.1495 (0.0515, 0.2475) and 0.0088 (0,0.0209); vasovagal reflex 0.0008 (0.0002, 0.0014) and 0.0681 (0.0277, 0.1085); infection 0.0063 (−0.0147, 0.0274) and 0.0048 (−0.0147, 0.0274). Subgroup analysis suggested that the technical success rate in 8- and 11-gauge Mammotome probes were 0.9998 (0.9993, 1.0000) and 0.9998 (0.9996, 1.0000), and complication rates in US and mammography were as the following: haematoma 0.1103 (0.0209, 0.1997) and 0.0476 (0.0248, 0.0704); pain 0.0268 (0, 0.0764) and 0.2961 (−0.2752, 0.8674); vasovagal reflex 0.0008 (0.0002, 0.0014) and 0.0968(0.0447, 0.1488); infection 0.0001 (−0.0001, 0.0002) and 0.0048 (−0.0002, 0.0099) (Figure 2).

3.3 | Sensitivity analysis and publication bias

Sensitivity analysis indicated that no individual study has an impact on the overall pooled results. There were evidences of publication bias using the Egger test in technical success rate, bleeding, skin ecchymosis, infection ($t = -8.05$, $P < .01$; $t = 2.28$, $P = .035$; $t = 2.29$, $P = .037$; $t = 605.02$, $P < .01$).

4 | DISCUSSION

In recent decades, more breast lesions have been diagnosed by US and many other tests. In 1982, it was reported that

mammotome began to be clinically used.[45] In our meta-analysis, we assessed the pooled technical success rate and complication rate of VABB in terms of haematoma, bleeding, skin ecchymosis, pain, vasovagal reflex, and infection. Haematoma is the most common postoperative complications after VABB. Most breast masses are centrally distributed with an affluent blood supply. Kettritz et al indicated that 6 patients developed haematomas at least 4 cm in diameter after VABB in 500 women with microcalcifications.[28] Similarly, haematoma occurred in 12 (8.82%) patients using the 8-gauge probe, of which size ranged from 3 to 6 cm.[15] Pagni et al reported the haematoma rate 9% (62/712) with 8-, 11-, or 14-gauge Mammotome probes.[13] Furthermore, considering the different needle sizes of VABB, a previous study indicated that bleedings and haematomas for 8-gauge Mammotome system were significantly more than that following 11-gauge Mammotome system (41.9% vs 8.4%, $P < .001$; 35.5% vs 16.7%, $P = .029$).[41] Most haematomas recorded were minimal, and they could be gradually resolved without special management. During ultrasound-guided VABB for 8748 patients, only one case experienced massive bleeding requiring a blood transfusion of about 1000 mL.[9] It was reported that bloody nipple discharge was observed in 5.40% (9/136) patients using the 8-gauge probe.[15] Lidocaine and puncture needle were used in the targeting region in the procedure. Most haematomas and bleeding may result from inadequate compression or fixation, and they gradually resolved in short time.

In addition, in this study, the scar formation rate was 0.0738(0.0334, 0.1141). Wang et al retrospectively showed that pains appeared in 5.6% (8/143) cases with 8-gauge Mammotome system,[18] consistent with 9.7% reported by Fine et al.[34] Previous studies revealed that in a total of 8748 patients, vasovagal reactions existed in seven cases following 1% lidocaine injection during VABB, such as bradycardia, dyspnea, nausea, and hypotension.[9]

Mammotome has a single insertion of the puncture needle with the repeated incision, avoiding repeated puncture and reducing the incidence of needle-tract implantation metastases. Sufficient biopsy acquisitions led to a reduction in false-negative rates and underestimation of histology. For small benign breast tumours, therapeutic resection could be performed without the permanent scar for minimising the cosmetic injury. Particularly within US guidance, US could display where the puncture needle was in real time and enable the accurate location according to the different angles and depths. Comparing US, the mammography guidance of breast is relatively fixed. When the three-dimensional positioning is performed at the puncture point, the position and depth of the puncture needle are fixed. All these advantages guarantee the safety of VABB.

There were several limitations in the present meta-analysis. First, most included studies were retrospective in study design, which could result in the patient selection bias. Second, the number of included studies was small in different complications, particularly in vasovagal reflex and infection, which may contribute to heterogeneity in the results. Third, we used random-effect models to pool studies and could cause overly narrow credible intervals, particularly when there were a few studies.[46] Fourth, different sizes of needles may cause different levels of complications. Because some literature studies reported several types of needles, we performed subgroup analysis according to 8- and 11-gauge needles here.

Due to the high prevalence of benign and malignant breast masses in women, finding a quick and safe way to facilitate diagnosing breast disease became an urgent problem. In this meta-analysis, we appraised the risk of bias for each study using GRADE guidelines. To minimise potential heterogeneity, we estimated the reliability and safety of VABB using the random-effects model through technical success rate and possible complications.

5 | CONCLUSIONS

In a word, the combination of VABB with US or mammography is minimally invasive, safe, and accurate in view of the low complication rate and effectiveness, which could be regarded as a promising candidate of the standard biopsy methods for detecting nonpalpable lesions. Further research studies will be continually needed to identify these findings.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

AUTHOR CONTRIBUTIONS

M.F. contributed to the study concept and design, the drafting of the manuscript, and study supervision. M.F., G. Li., G.Lu., and T.W. contributed to the acquisition of data. M.F. and G.Li. contributed to the analysis and interpretation of data. G.Li. and G.Lu. did the critical revision of the manuscript for important intellectual content and did the statistical analysis. G.Lu. and T.W. contributed to technical or material support.

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