Original Article

A systematic review and meta-analysis: value of ultrasound-guided vacuum-assisted biopsy in the diagnosis and treatment of breast lesions

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Background: In recent years, according to global statistics, breast cancer is the main disease affecting women. Ultrasound-guided vacuum-assisted biopsy (VAB) has become a frequently used method for breast cancer detection because of its accuracy, simplicity, and fewer complications.

Methods: In PubMed, Medline, EMbase and Cochrane central register of controlled trials, the retrieval time was from the establishment of the database to March 2021, and the keywords included breast tumor, breast cancer-related diseases, breast lesions, vacuum-assisted breast biopsy, sensitivity and specificity. Meta-analysis was performed using RevMan5.3 software provided by the Cochrane Collaboration.

Results: A total of 10 articles were included using a random-effects model that pooled the sensitivity, specificity, and other accuracy measures of VAB. The summary receiver operating characteristic (SROC) characteristic curve was used to summarize the overall accuracy. The sensitivity range was 0.94 to 1.00 (mean, 0.981; 95% CI, 0.972–0.987) with a specificity range of 0.87–1.00 (mean, 0.999; 95% CI, 0.997–0.999). The preoperative platelet-lymphocyte ratio (PLR) was 93.84 (95% CI, 41.55–211.95), the neutrophil to lymphocyte ratio (NLR) was 0.05 (95% CI, 0.03–0.09), the sensitivity and specificity of χ^2 were 37.10 (P=0.011) and 32.00 (P=0.043), respectively, while those of PLR, NLR, and duration of response (DOR) were 46.98 (P=0.001), 54.92 (P=0.001), and 43.49 (P=0.002), respectively. Differences were considerable.

Discussion: In this meta-analysis, a total of 10 articles were included. VAB is an accurate type of biopsy to detect female breast cancer. The results of the meta-analysis were stable, and VAB had high sensitivity (98%) and specificity (nearly 100%).

Keywords: Breast cancer; vacuum-assisted biopsy (VAB); ultrasonic; meta-analysis

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Introduction

According to the global statistics, breast cancer is the main disease affecting women, with more than two million women diagnosed with breast cancer, and more than 700,000 deaths from breast cancer, which comprises a large proportion of cancer deaths (1). Deaths from breast cancer account for about 20% of global deaths (2). Early detection, early diagnosis, and early treatment can effectively improve the cure rate and survival rate of breast cancer patients, and accurate diagnosis is crucial for the follow-up treatment of breast cancer patients. The vacuum-assisted biopsy system was introduced in 1995. Because it can completely remove small breast lesions, it provides continuous and sufficient tissue specimens for pathological diagnosis through a single operation, while minimizing the damage to the breast tissue and maintaining the breast. The shape of the tissue is therefore widely used in the early diagnosis of breast cancer. Prognostic factors for recurrence of ipsilateral breast tumors after breast-sparing breast cancer include patient factors (young and BRCA gene mutations), tumor factors (large tumor burden, high histological grade, triple negative, and HER2 positive, etc.), and treatment factors (did not receive adjuvant radiotherapy and systemic treatment), and the resection of benign breast lesions. Due to the fluctuating accuracy of fine-needle aspiration (FNA) biopsy and the inability to distinguish between carcinoma *in situ* and invasion, it is no longer routinely used in most hospitals. Currently, the most commonly used biopsy methods in breast surgery are hollow needle aspiration biopsy (CNB) and vacuum-assisted biopsy (VAB) (3). VAB is accurate, simple and has fewer complications. According to the existing literature, the sensitivity of VAB is 85–97% and the false negative rate is 0–9% (4,5). With the rapid development of medical standards, doctors recommend that women have mammograms. Mammography can reduce the death rate from breast cancer (6). However, varying degrees of lesions in thymus tissue have been detected during screening, which could not be distinguished from malignancy, such that a histological evaluation was required (7). Approximately 20% of suspicious lesions have been found to be malignant upon histological evaluation (8,9). In addition, future imaging may be compromised by scarring after a surgical biopsy. Minimally invasive surgery is an ideal option. Recent data on the accuracy of fine needle aspiration biopsy (FNAB) vary widely. Ductal carcinoma *in situ* (DCIS) or invasive carcinoma (IC) cannot be distinguished with FNAB (10). Core needle biopsy (CNB) achieved 85–97% sensitivity and 100% specificity (11,12). However, the high correlation between imaging and histological findings is compelling. Inconsistencies between mammography and histological assessment require repeat CNB or open surgery (13,14). One limitation of microcalcification assessment using CNB is that insufficient samples may be obtained. Therefore, CNB failed to improve calcification surgery in patients compared to high-quality surgery (15,16). Proposed in 1995 to address these problems (17,18), vacuum-assisted breast biopsy (VAB) has the following characteristics: single insertion, the ability to obtain consecutive and larger tissue samples, and the ability to orient samples. The biopsy instrument is 11 inches in diameter and allows more samples to be obtained. The tissue volume of VAB is 10 times larger than that of CNB (19,20). Therefore, VAB is more accurate than CNB in assessing microcalcifications. Much research (19,20) has been conducted on the usefulness of VAB in the early diagnosis of breast tumors. It can lead to more accurate conclusions to provide clinical guidance.

The purpose of this systematic review was to summarize the evidence on case detection rates and assess the results of the diagnosis and treatment value of ultrasound-guided VAB for breast lesions. A total of 10 articles were included, the results of domestic and foreign comparative studies were reviewed, and a meta-analysis was performed. This meta-analysis provides the scientific and theoretical basis to enhance the accuracy of breast cancer biopsy detection, improve the detection rate of breast cancer and reduce detection sequelae.

We present the following article in accordance with the PRISMA reporting checklist (available at https://dx.doi.org/10.21037/gs-21-611).

Methods

Literature search strategy

PubMed, Medline, Embase, and Cochrane Central Register of Controlled Trials database were searched, related research published from January 1, 2001 to March 2021 was analyzed. The search keywords included breast tumors, breast cancer related diseases, breast lesions, vacuum-assisted breast biopsy, sensitivity and specificity, safety, accuracy, missed diagnosis rate, underestimation rate and other descriptive terms. According to the pre-established inclusion and exclusion criteria, the full text of the target document was obtained, manual search was conducted, and

the required documents were screened.

Inclusion and exclusion criteria

Inclusion criteria: (I) documents containing keywords; (II) patients experienced preterm labor and premature rupture of membranes; (III) clinical trials; (IV) the patient had breast cancer; (V) patients aged 18 years and over; (VI) articles had to be published, and non-published articles were not considered.

Exclusion criteria: (I) duplicate publications; (II) articles that did not report the outcomes being assessed; (III) non-clinical trials; (IV) other methods of biopsy; (V) patients with other breast diseases; (VI) articles in Chinese language; (VII) other meta-analyses were used as references but not included in the analyses; and/or (VIII) unclear results and incomplete patient data records.

Literature screening

Articles were screened independently and results were compared. If there was a difference, it needed to consult a breast lesion specialist in the hospital for an assessment of the difference.

Data extraction

Data extraction in this study was carried out independently by two researchers. During data extraction, data were extracted independently by two researchers, and Excel tables were used to capture basic details of the articles, characteristics of the research objects, intervention measures, outcome indicators, and risk of bias evaluations. After extraction, crosschecks were conducted. During the process of data extraction, if there were differences of opinions, they were discussed and resolved through consultation with a third researcher. The following data were extracted: basic article information (title, author, year of publication, author), basic characteristics of subjects (gender, age, study sample size, baseline comparability), the method of literature research, research design, experimental and control group interventions, and research result.

Quality assessment

Risk of bias of the included articles was assessed using criteria specified in the *Cochrane Handbook for Systematic Reviews of Intervention 5.0.2*. Specifically, it included: (I) generation of random sequence (whether a random number table or other random method was utilized for grouping of research objects); (II) allocation concealment (whether there was randomization and whether the randomization remained concealed); (III) subject blinding (whether study subjects knew whether they were in the experimental group and which group they were in); (IV) outcome assessor blinding (whether the researcher or outcome assessor knew the group status of subjects); (V) data integrity (whether data were complete and whether there were missing data); (VI) selective reporting (whether there was selective reporting); and (VII) other biases. If data extracted by the two researchers were inconsistent, the inconsistency was discussed and resolved. If no consensus was achieved, a third researcher was consulted.

Result display

Forest plots clearly show the results of individual studies and combine studies with corresponding confidence intervals. If there is no overlap between the confidence intervals of the individual studies, the plot indicates statistical inhomogeneity between the studies. Further subgroup analysis is required to combine stochastic and fixed models with acceptable inhomogeneity. Subgroups are divided according to different study designs, and then the impact of each subgroup can be ignored if the inhomogeneity between studies is substantial and the sources of the inhomogeneity cannot be addressed. An appropriate statistical model was selected. Sensitivity analysis: Sensitivity analysis of the research results was performed by investigating whether individual studies affected the overall results of the included studies substantially. Each study included in the meta-analysis was removed one at a time. Combined with the results of the remaining studies, the combined results of each study were compared with the individual results to confirm whether the results were the same. Generally, individual studies will influence the overall results substantially under the following two circumstances. First, if a study is deleted, the presumption of the size of the combined effect is 95% of the size of the combined effect. When a study is deleted, the results yield significantly different results. If one study affects the overall results with little difference, it indicates the sensitivity of the combined results and the results obtained are not stable. On the contrary, in this case, the results show that the sensitivity is stable and the conclusions are correct.

Statistical analysis

RevMan5.3 software provided by the Cochrane Collaboration was used for meta-analysis. Odds ratios (OR) were used describe the effect size, together with 95% confidence interval (CI). Heterogeneity was first tested for the included studies, with α=0.1 as the test level. If there was no heterogeneity among the studies (P>0.1, I^2<50%), a fixed-effect model was selected for meta-analysis; otherwise, subgroup analysis was performed for the included data. P<0.05 was considered as indicating statistical significance. When the number of references included in the analysis of a single risk factor was more than 10, funnel plots were used to analyze the publication bias of each risk factor. RevMan5.3 software was used to analyze publication bias using Begg's and Egger's tests. If the result yielded P>0.05, it was considered that there was no publication bias, otherwise, it was considered that there was publication bias.

Results

Literature search results

A total of 2,519 literatures were included in the database from its construction to March 2021, and 1298 literatures were excluded from the retrieved articles. Based on the titles and abstracts read, 832 articles were excluded. Reading the full text, 89 cases of non-breast lesions were excluded, 211 cases of non-vacuum-assisted biopsy were excluded, and 82 cases were excluded that could not be combined with other RTC. Finally, 10 articles meeting the inclusion criteria were included in the analysis (21-30) (*Figure 1*, *Tables 1-3*).

Bias-risk assessment of included articles

The risk of bias of the 10 articles included in this study was judged using the *Cochrane Handbook* (version 5.0.2) of the systematic review writing manual. Review Manager 5.3 was utilized to generate a chart illustrating the details of risk of bias (*Figures 2*,*3*).

Meta-analysis of vacuum-assisted detection of breast cancer

Figure 4 shows a forest plot illustrating sensitivity and specificity of diagnosis of breast cancer using VAB. As presented in *Figure 4*, the sensitivity ranged from 0.94 to 1.00 (mean, 0.981; 95% CI: 0.972–0.987). In addition, specificity was 0.87–1.00 (mean, 0.999; 95% CI: 0.997–0.999). Sensitivity and specificity of χ^2 were 37.10 (P=0.011) and 32.00 (P=0.043), respectively, and those of PLR, NLR, and DOR were 46.98 (P=0.001), 54.92 (P=0.001), and 43.49 (P=0.002), respectively, indicating notable heterogeneity between studies (*Figure 4*). In addition, PLR was 93.84 (95% CI: 41.55–211.95), NLR was 0.05 (95% CI: 0.03–0.09), and DOR was 1,891.7 (95% CI: 683.8–5,233.4).

High vacuum-assisted detection of breast cancer SROC curve

The SROC curve provides a global summary of test performance and shows the trade-off between sensitivity and specificity. SROC plots of VAB biopsy results show true and false positive rates for individual studies. In this study, the SROC curve was near the ideal upper left corner of the SROC curve. The area under the curve (AUC) was 0.98, suggesting high accuracy (*Figure 5*). The maximum joint sensitivity and specificity (q) was 0.93.

Discussion

In this meta-analysis, a total of 10 articles (21-30) were included. Regarding the quality evaluations of the 10 articles, there was only one article with quality grade A and 9 articles with quality grade B. A total of 9 of the 10 studies reported basic data such as age, disease type, and disease stage. Limitations of the interventions in this study mean that measurement biases may be present. To improve the reliability and applicability of similar future research, the research methods and design need to be amended. Due to the large fluctuations in the accuracy of fine needle aspiration biopsy (FNAC) and the inability to distinguish between carcinoma *in situ* and invasiveness, most hospitals are no longer routinely used. At present, the most commonly used biopsy method in breast surgery is core needle aspiration biopsy (CNB) and vacuum assisted biopsy (VAB) (31,32). Compared with other methods, the biggest advantage of ultrasound-guided vacuum-assisted biopsy is its accuracy, simplicity, and fewer complications. The advantages of vacuum-assisted biopsy are precise positioning and accurate puncture of the lesion, especially for deeper and smaller tumors that are not clinically accessible. It also has sufficient materials in disease examination and immunohistochemical detection, it may provide more pathological information before treatment, which can greatly increase the detection rate of breast cancer and provide a basis for the formulation of clinical treatment plans (33). In addition, the puncture port is

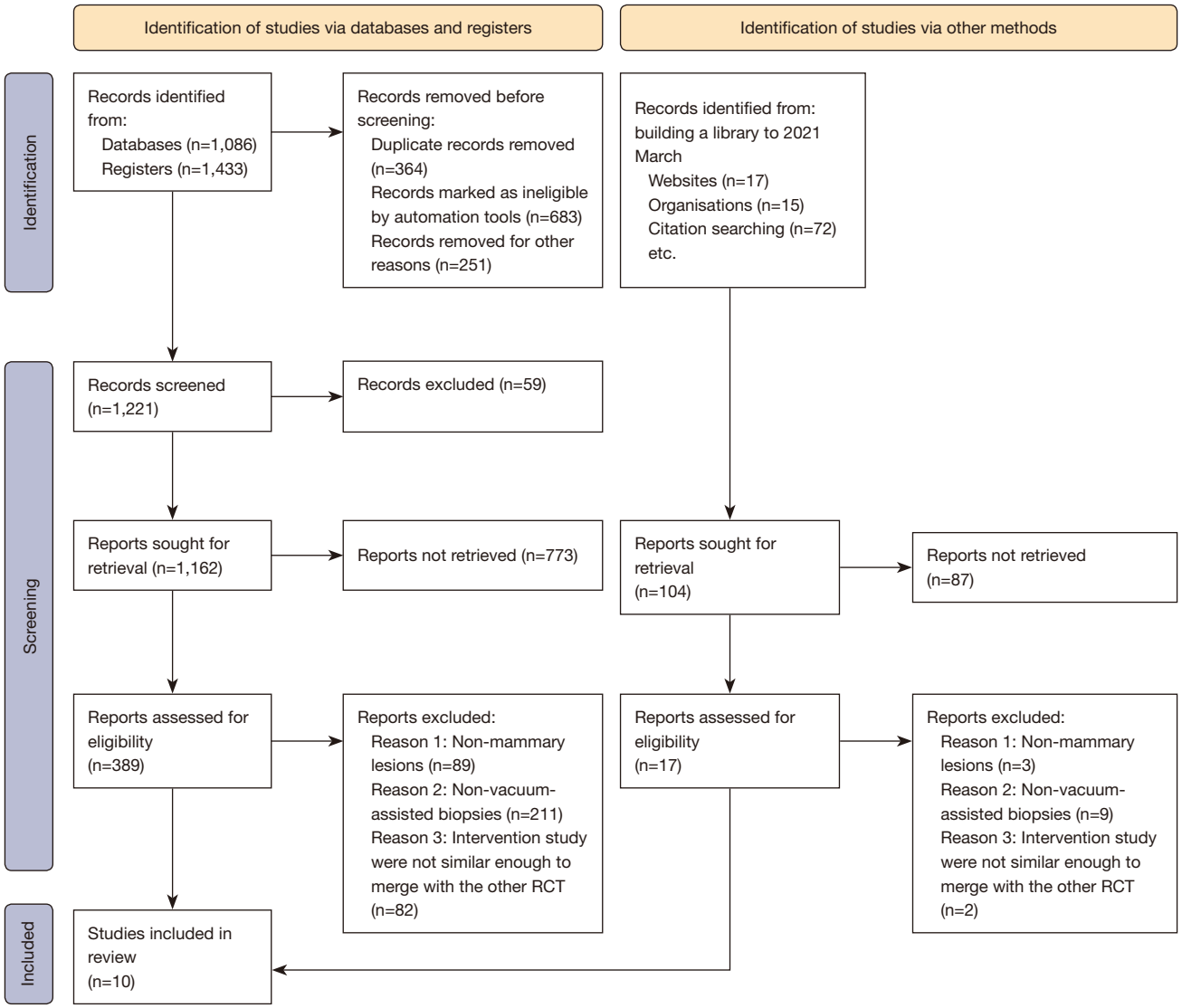

Figure 1 Literature retrieval process.

Table 1 Quality of 10 included studies

	Quality Assessment of Diagnostic Accuracy Studies (QUADAS item)													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Yes (n)	11	13	13	2	13	2	13	13	13	13	3	13	4	4
No (n)	3	0	0	11	13	11	0	0	0	0	0	0	0	0
Unknown (n)	0	0	0	0	0	0	0	0	0	0	10	0	12	10
Yes (%)	86	100	100	10	0	86	100	100	100	100	5	100	10	10

Table 2 Basic characteristics of included articles

First author	Year	No. of cases	Biopsy needle size	Ultrasonic guidance or not	Range of age (years)
Cassano (21)	2007	266	11	Yes	>18
Choo (22)	2008	58	8	Yes	53
Hung (23)	2001	49	11	Yes	22–58
Kim (24)	2008	59	11	Yes	20–70
Lacambra (25)	2012	85	11	Yes	24–88
Meloni (26)	2001	73	11	Yes	30–77
Perretta (27)	2008	47	9	Yes	30–73
Shin (28)	2008	123	8	Yes	21–75
Simon (29)	2000	67	11	Yes	23–82
Vag (30)	2007	65	10	Yes	24–88

Table 3 General information included in articles

The first author	Year	No. of cases	TP	FP	FN	TN	Score
Cassano (21)	2007	266	76	0	2	188	8
Choo (22)	2008	58	8	0	0	50	7
Hung (23)	2001	49	4	0	0	45	7
Kim (24)	2008	59	29	0	1	29	9
Lacambra (25)	2012	85	10	0	0	75	7
Meloni (26)	2001	73	36	0	2	35	5
Perretta (27)	2008	47	15	0	1	31	8
Shin (28)	2008	123	2	0	0	121	9
Simon (29)	2000	67	17	2	1	47	8
Vag (30)	2007	65	28	0	1	36	7

TP, true positive; FP, false positive; FN, false negative; TN, true negative.

small and the cosmetic effect is good, only 3–5 mm, no suture, no scar; and multiple lesions on the same breast can be punctured through one puncture port (less than 3, the distance is not more than 10 cm). It avoids incision of the skin, subcutaneous tissue and normal glands. The tissue damage is small and the recovery is quick. For patients with deep breast masses and obesity, the advantages are particularly obvious (34). It can obtain larger specimens and completely solve the problem of insufficient specimen size, and as such diagnostic accuracy is higher. Due to the larger diameter of the excised specimen, it is a convenient and accurate approach for pathologists to use to detect prognostic indicators. This is particularly important for patients with locally advanced breast cancers, as these patients often show changes or loss of molecular information after neoadjuvant chemotherapy (35). At the same time, VAB can complete the diagnosis and treatment of benign tumors simultaneously and has characteristics similar to those of minimally invasive and aesthetic procedures. The disadvantage of VAB is that it is expensive and therefore may not be affordable for patients with limited financial means. Underestimation is present if a carcinomatous lesion is reported as high risk using CNB or VAB, or if it is reported as ductal carcinoma in situ (DCIS) of the breast and confirmed as invasive cancer after surgery. Such high-risk lesions include atypical hyperplasia, lobular

carcinoma *in situ*, radial scar, etc. Therefore, patients diagnosed as having high-risk lesions using the above two methods must undergo surgical biopsy to avoid missed diagnoses. Since the SROC curve is not easy to interpret and use in clinical practice, the value of likelihood ratio is more meaningful in clinical treatment and diagnosis, and PLR and NLR are used as indicators of diagnostic accuracy. Likelihood ratio is a method that combines the sensitivity and specificity of the test and assesses the probability of whether a positive or negative result alters an existing condition, such as disease status. The PLR was 93.8, indicating that patients with breast cancer were about 94 times more likely to have a positive VAB result than those without breast cancer. This high probability suggests that a positive VAB result can initiate surgery or other treatment. NLR was found to be 0.05. Overall, the quality of the included studies was higher than the median level of Quality Assessment of Diagnostic Accuracy Studies (QUADAS). Some studies failed to meet item 4 (disease progression bias), 5 (partial validation), 11 (reference standard review bias), 13 (unexplained test results), or 14 (withdrawal). Based on detailed analysis of the QUADAS assessment tool and the included studies, there may be erroneous classification biases. With the exception of two articles (28,31), most studies conducted follow up for less than 2 years. These biases can affect the accuracy of the VAB analysis. Various aspects were included in the analysis of the basic data: QUADAS score, needle size, imaging guidance system, patient testing location, and methodology and design (prospective and retrospective studies).

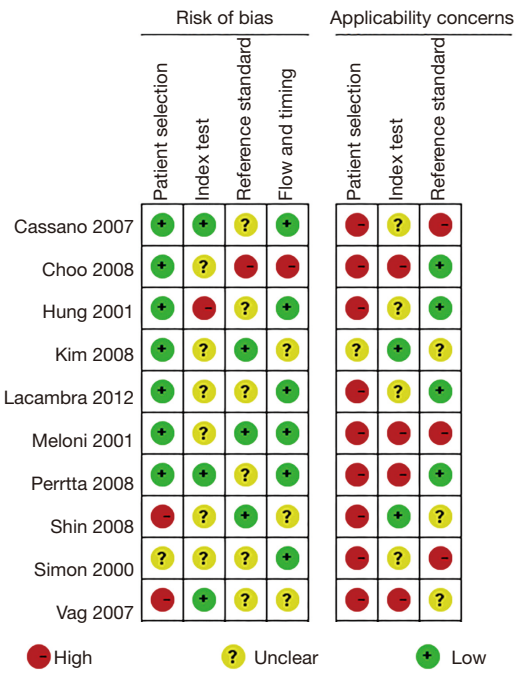

Figure 2 Risk of bias assessment diagram of included articles.

In this meta-analysis, a lot of foreign studies were included, which addressed various risk factors. In addition, since there were no comparisons between the control and treatment groups, the relevant Chinese literature was not included. In addition, the treatment time of 10 included studies in this study was contradictory, which may have influenced the results of this meta-analysis. Randomization methods were not reported. Therefore, it is recommended to further improve experimental plans; standardize the specific duration of follow up, methodology and drug of the intervention; and implement high-quality, large-scale sample, multi-center randomized controlled trials to obtain more reliable evidence.

Conclusions

To summarize the evidence of the case detection rate and study the results of the diagnosis and treatment value of ultrasound-guided VAB for breast lesions, 10 articles were included, and the results of domestic and foreign studies were reviewed, and various screening and meta-analysis

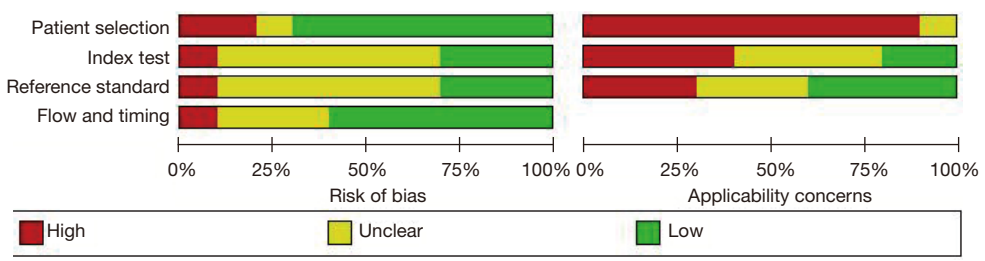

Figure 3 Risk of bias evaluation bar graph of included articles.

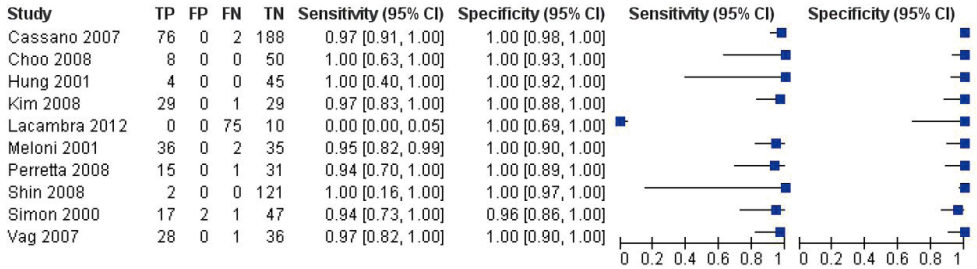

Figure 4 Forest plot of sensitivity and specificity to vacuum-assisted biopsy in breast cancer diagnosis.

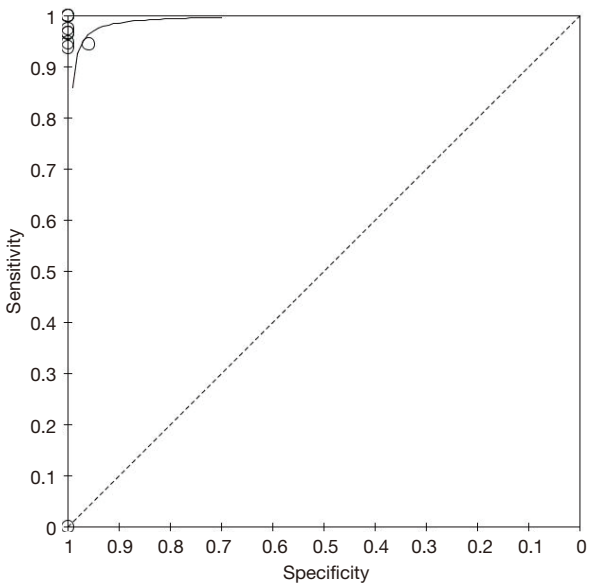

Figure 5 Summary receiver operating characteristic (SROC) curve of vacuum-assisted biopsy.

were conducted. VAB has proven to be an accurate biopsy method to detect breast cancer in women. The results of the meta-analysis were stable, and VAB showed high sensitivity (98%) and specificity (100%), indicating that it is a promising alternative to open breast biopsy and can improve breast cancer therapy. However, this meta-analysis has some limitations: the retrieval of articles may not have been sufficiently comprehensive; and there were differences in risk factor assessment and measurement in different studies, which may have affected the results. All the studies included in the meta-analysis were published articles, and the failure to include unpublished sources may have led to potential publication bias. It is suggested to carry out more high-quality and multicenter original studies with large sample sizes for verification of results in the future to provide clinical guidance and a scientific basis for the treatment of breast cancer and more rapid and efficient detection of breast cancer.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/gs-21-611). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable fsor all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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