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Evaluation of the Diagnostic Accuracy of Carbon Nanoparticle Suspensions in Sentinel Lymph Node Biopsy of Breast Cancer: A Systematic Review and Meta-analysis

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ABSTRACT

Background and aim: The present study investigated the diagnostic accuracy of carbon nanoparticle suspensions in sentinel lymph node biopsy of breast cancer.

Material and methods: The present study used the PRISMA 2020-27-item checklist. To find the studies conducted in line with the purpose of the study, PubMed, Web of Science, Scopus, Science Direct, Web of Knowledge, EBSCO, Wiley, ISI, Elsevier, Embase databases, and Google Scholar search engines were reviewed from 2013 to July 2023. Meta-analysis used effect size (sensitivity and specificity) with a 95% confidence interval. The Egger test and funnel plot checked the publication bias, and data analysis was done using STATA/MP-V.17 software.

Results: Ten articles with 799 patients were reviewed. The sensitivity of carbon nanoparticle suspensions in sentinel lymph node biopsy was 91% (ES, 95%CI; 78%,100%. I2=0.00%; p=1.00). The specificity of carbon nanoparticle suspensions in sentinel lymph node biopsy was 99% (ES, 95% CI; 86%,100%. I2=0.00%; p=1.00).

Conclusions: Carbon nanoparticle suspensions have the highest sensitivity and specificity in sentinel lymph node breast cancer biopsy.

1. Introduction

Breast cancer is the most common specific cancer in women and the first cause of death from cancer in reproductive-age women (20-50 years).[1] The prevalence of breast cancer increases over 50 years and is also detected at a higher rate in screening mammograms at older ages.[2] Biopsy and surgery of the sentinel lymph node, known as the first draining gland of breast cancer, is used to evaluate regional lymph nodes.[3] Usually, patients evaluated with this method are negative regarding lymph node involvement in clinical examination and imaging methods.[4] In various studies, the usefulness of Sentinel Lymph Node Biopsy (SLNB) in the diagnosis of axillary lymph node Biopsy (ALNB) has been shown. This surgery positively affects the patients' way of life, and complications such as limb swelling, movement restriction, pain, and sensory disturbance in patients who underwent SLNB are less than in the group that underwent ALNB.[5, 6] During the last decade, minimally invasive methods have been of great interest. Studies have shown that SLNB is as effective as ALNB in diagnosis but has fewer complications.[7, 8] In the SLNB, the radioisotope material alone or together with isosulfan blue is injected into certain areas of the breast. The movement path of these materials is identified to reach the lymph nodes, and from these two factors, in order to discover the gland, Sentinel lymph is used.[9] Various studies have shown that the simultaneous use of radioisotope material and isosulfan blue increases the accuracy of diagnosis compared to using these two methods alone.[10, 11] Specialized equipment and a protected place (against radiation) are needed to use the radioisotope material, so its use is limited. Also, isosulfan blue has a low detection rate.[12] After identifying the sentinel lymph node, this node is sent for pathological evaluation, and in case of its metastatic involvement, the search and identification of cancerous lymph nodes in the armpit at levels 1 and 2 are performed.[13] In the modern age, nanomaterials and nanotechnology can be seen in various fields. In 2004, Chinese-made carbon nanoparticle suspensions (CNSs) were introduced, promoting the development of lymph node trackers. This product is a stable suspension of carbon nanoparticles with a diameter of 150 nm, which is smaller than the gap of lymphatic capillary endothelial cells (120 to 500 nm) and larger than the gap of capillary endothelial cells (30 to 50 nm).[14] In addition, CNSs with features of black and strong colored ability make lymph nodes easier to identify, making the process easier. Furthermore, CNSI is characterized by slow metabolism and is visible in vivo after approximately 3-4 months.[15, 16] Considering that CNSI has received much attention in the last few years and by examining the results of various studies and their possible advantages in lymphatic mapping, which are most likely the best trackers of lymph nodes at the moment, hope to provide strong evidence in this field, the present study conducted to

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investigate the diagnostic accuracy of CNSI in SLNB of breast cancer.

2. Material and methods

Search strategy and Information sources

The present study was based on the PRISMA 2020-27-item checklist.[17] The reviewed documents were the results of the search in the international databases PubMed, Web of Science, Scopus, Science Direct, Web of Knowledge, EBSCO, Wiley, ISI, Elsevier, Embase databases, and Google Scholar search engine, and the search was limited to 10 years. Recent and updated up to August 2023 were among the articles published in English.

Searching in the mentioned databases, Keywords “Breast Cancer”, “Lymph Node”, “Sentinel Lymph Node Biopsy”, “Diagnosis”, “sensitivity”, “specificity”, “positive likelihood ratio”, “negative likelihood ratio”, “diagnostic accuracy”, “Carbon Nanoparticle Suspensions” were used to search the mentioned databases. The keywords were standardized in MeSH and finally, the strategy with ((((((((("Breast Neoplasms"[Mesh]) OR "Breast Neoplasms/diagnosis"[Mesh]) AND "Lymph Nodes"[Mesh]) AND "Sentinel Lymph Node Biopsy"[Mesh]) OR ("Sentinel Lymph Node Biopsy/methods"[Mesh] OR "Sentinel Lymph Node Biopsy/statistics and numerical data"[Mesh])) AND "Diagnosis"[Mesh]) OR "Sensitivity and Specificity"[Mesh]) AND "Nanoparticles"[Mesh]) AND "Carbon"[Mesh]) AND "Predictive Value of Tests"[Mesh] keywords was used for searching. In addition to this list of sources, the selected articles were screened to find relevant references. Two researchers searched independently to avoid bias.

Study selection criteria

Inclusion criteria

Breast cancer patients, negative lymph nodes, diagnostic accuracy of SLNB, studies reported sensitivity and specificity, and availability of the full text of the article. Studies with incomplete results, case studies, case reports studies, in vitro, in vivo studies, and review articles were excluded.

Selection and data collection process

Two researchers independently extracted data from the articles using a standard data collection form prepared in advance to reduce reporting bias and errors in data collection. This form was first designed by the study team, which included the following items: author's name, year of publication, average age of patients, and number of patients.

Study risk of bias assessment

The present study assessed reporting quality using the STARD 2015 (standards for reporting diagnostic accuracy studies) checklist. STARD statement was used for the complete improvement and transparency of diagnostic accuracy study reports.[18]

The quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool is used to assess the risk of bias for selected studies.[19] For each item, the risk of bias is reported as low, high, or unclear.

Data analysis

Meta-analysis was performed using effect size with a 95% confidence interval. To estimate the heterogeneity of the studies, the index I^2 (<25%: weak heterogeneity, 25-75%: moderate heterogeneity, and more than 75%: high heterogeneity) was used. The results were combined using the fixed effect model (Inverse–variance method) in meta-analysis. The Egger test checked the publication bias and Beggs funnel plot, and data analysis was done using STATA/MP—V17 software. A p-value of less than 0.05 was considered significant.

3. Results

Study selection

First, a search was conducted with relevant keywords, and then a list of titles and abstracts of all articles searched in international databases was prepared. This work was done independently by two researchers. Then, the articles were entered into EndNote.X8 software, and articles with duplicate titles were removed (14 articles). In the following, the abstract of 800 articles was reviewed to find suitable studies, and the articles that met the exclusion criteria and did not meet the inclusion criteria were excluded at this stage. The full text of 14 articles was carefully reviewed by two researchers independently and blindly, and the third researcher reviewed the selected articles until a consensus was reached. At this stage, articles with duplicate data, incomplete data, and failure to meet the inclusion criteria were removed, and at the end, 14 articles were selected for analysis (meta-analysis) (Fig. 1).

Study characteristics

Seven hundred ninety-nine patients were examined. A summary of the demographic data of the studies is summarized in Table 1.

Risk of bias in studies

According to QUADAS-2, studies were rated at low risk of bias; However, on examining the examined items, some studies had a high and unclear bias (Fig. 2 and Table 2). The mean STARD compliance among all studies was 24/30 criteria.

Sensitivity and specificity of carbon nanoparticle suspensions in SLNB

The sensitivity of carbon nanoparticle suspensions in SLNB was 91% (ES, 95%CI; 78%,100%. I^2=0.00%; p=1.00 (Fig. 3). The specificity of carbon nanoparticle suspensions in SLNB was 99% (ES, 95%CI; 86%,100%. I^2=0.00%; p=1.00 (Fig. 4).

Subgroup meta-analysis

Dose of carbon nanoparticle suspensions (ml)

Sensitivity of carbon nanoparticle suspensions (⩽1 ml) in SLNB was 94% (ES, 95%CI; 70%,100%. I^2=0.00%; p=1.00), and sensitivity of carbon nanoparticle suspensions (2ml) in SLNB was 92% (ES, 95%CI; 57%,100%. I^2=0.00%; p=0.96 (Fig. 5).

Specificity of carbon nanoparticle suspensions (⩽1 ml) in SLNB was 99% (ES, 95%CI; 76%,100%. I^2=0.00%; p=1.00, and specificity of carbon nanoparticle suspensions (2ml) in SLNB was 100% (ES, 95%CI; 65%,100%. I^2=0.00%; p=0.96 (Fig. 6).

Based on the test of group differences, no statistically significant difference was found between doses of carbon nanoparticle suspensions, and both presented similar results (p>0.05).

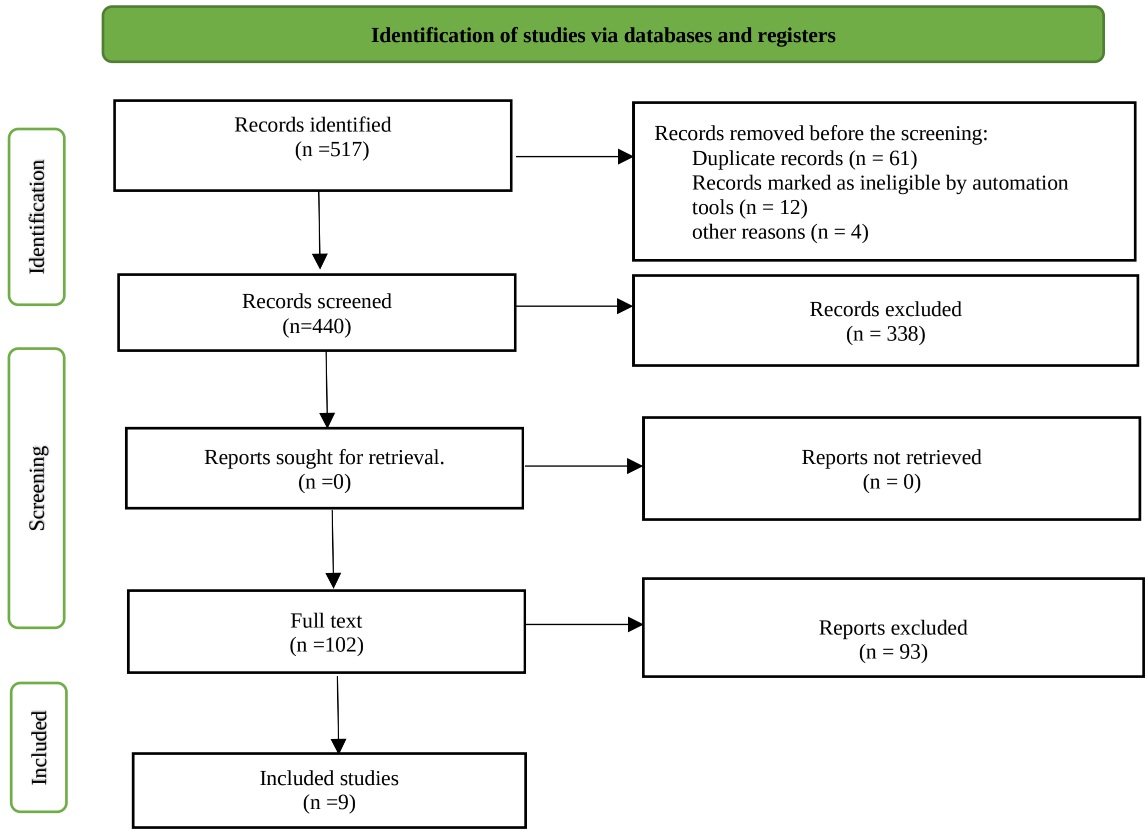

Fig. 1. PRISMA 2020 Checklist.

Table 1. Summary characteristics of studies.

No.	Study. Years	Number of Patients	Mean of Age	Dose of CNSs (ml)	True Positive	False Positive	False Negative	True Negative
1	Lin et al., 2023[20]	32	45.7±10.3	NR	11	0	1	14
2	Wei et al., 2021[21]	152	49	0.5	45	8	28	62
3	Gao et al., 2018[22]	58	47.2±15.1	2	24	0	2	32
4	Li et al., 2018[23]	47	43.25±10	2	15	0	1	31
5	Yang et al., 2018[24]	136	50±10.8	1	55	0	4	77
6	Zhang et al., 2018[25]	91	NR	1	47	0	2	42
7	Zou et al., 2017[26]	86	NR	0.5	23	0	2	60
8	Tu et al., 2015[27]	58	52.5±13.1	0.5	15	0	1	42
9	Wu et al., 2015[28]	83	NR	NR	24	0	3	56
10	Lei et al., 2014[29]	56	NR	1	20	0	1	35

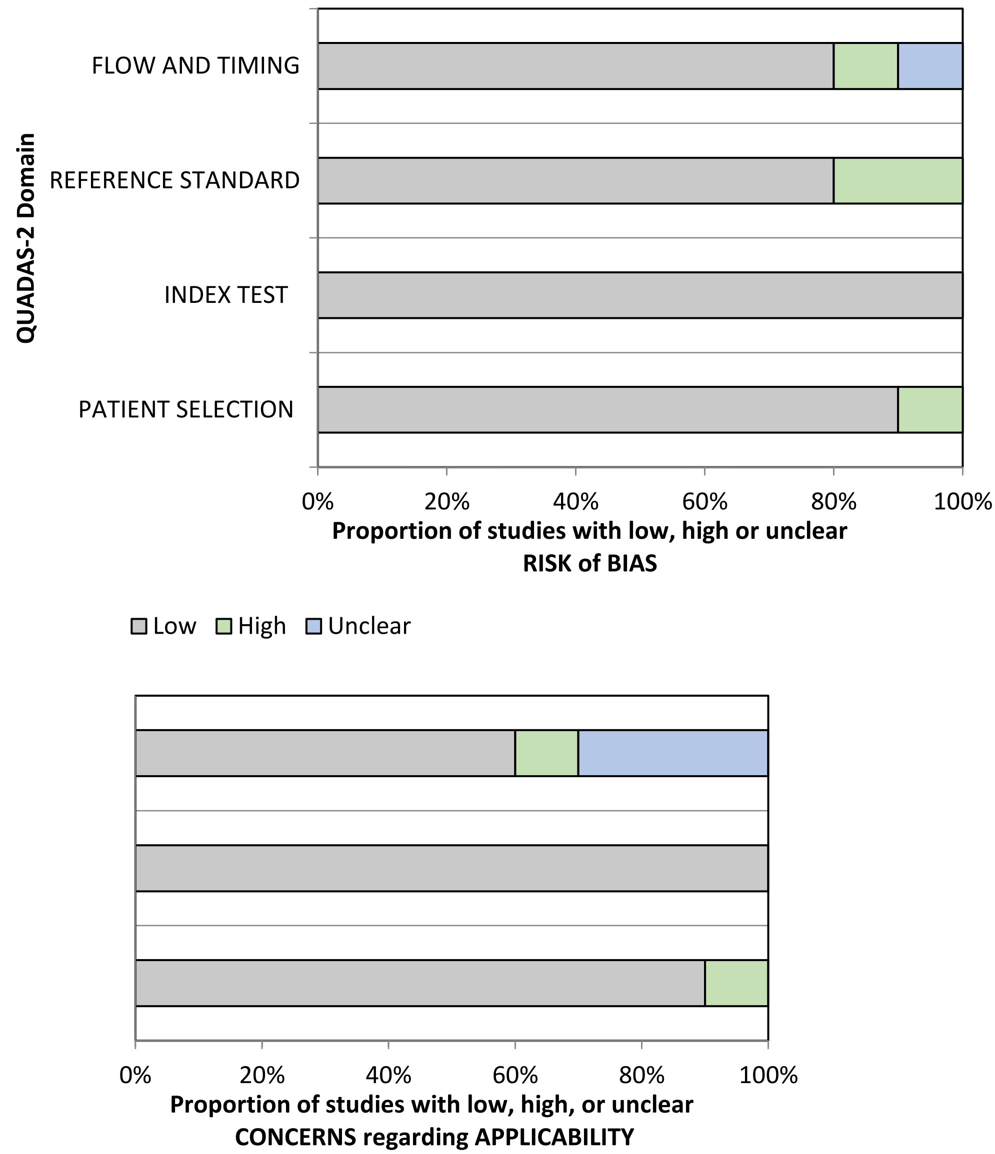

Fig. 2. QUADAS criteria among all studies.

Table 2. Quality assessment of included articles based on QUADAS-2 guideline

Study	Risk of Bias				Applicability Concerns		
	Patient Selection	Index Test	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Lin et al., 2023[20]	+	+	+	+	+	+	?
Wei et al., 2021[21]	+	+	+	+	+	+	+
Gao et al., 2018[22]	-	+	+	+	-	+	+
Li et al., 2018[23]	+	+	+	-	+	+	+
Yang et al., 2018[24]	+	+	+	+	+	+	+
Zhang et al., 2018[25]	+	+	+	+	+	+	+

Zou et al., 2017[26]	+	+	-	+	+	+	?
Tu et al., 2015[27]	+	+	+	+	+	+	+
Wu et al., 2015[28]	+	+	+	?	+	+	-
Lei et al., 2014[29]	+	+	-	+	+	+	?

(+)Low Risk (-) High Risk (?) Unclear Risk

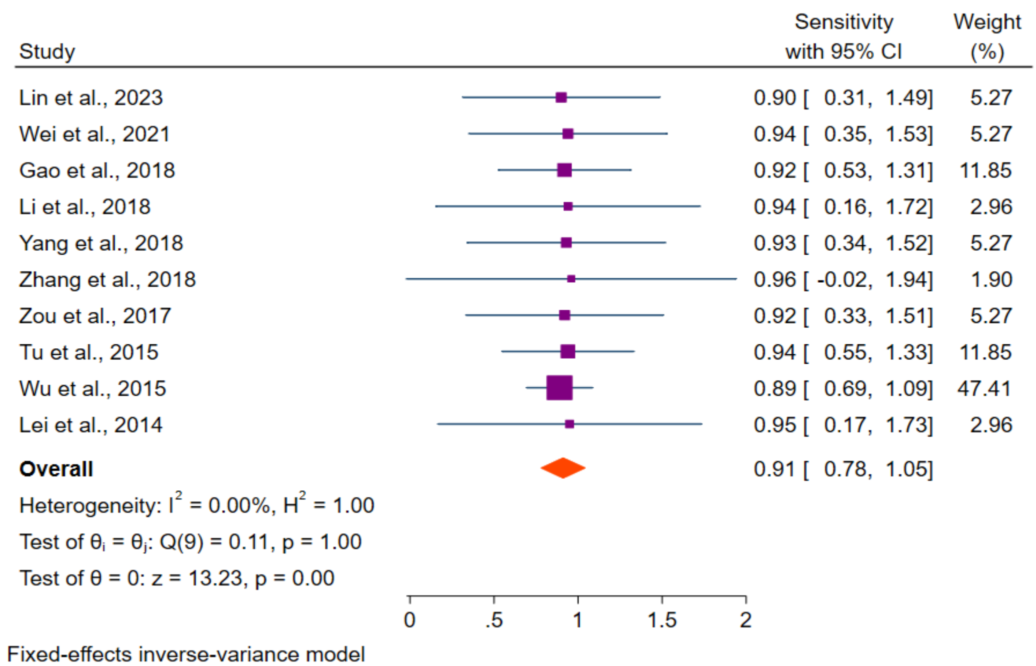

Fig. 3. The forest plot showed the sensitivity of carbon nanoparticle suspensions in SLNB.

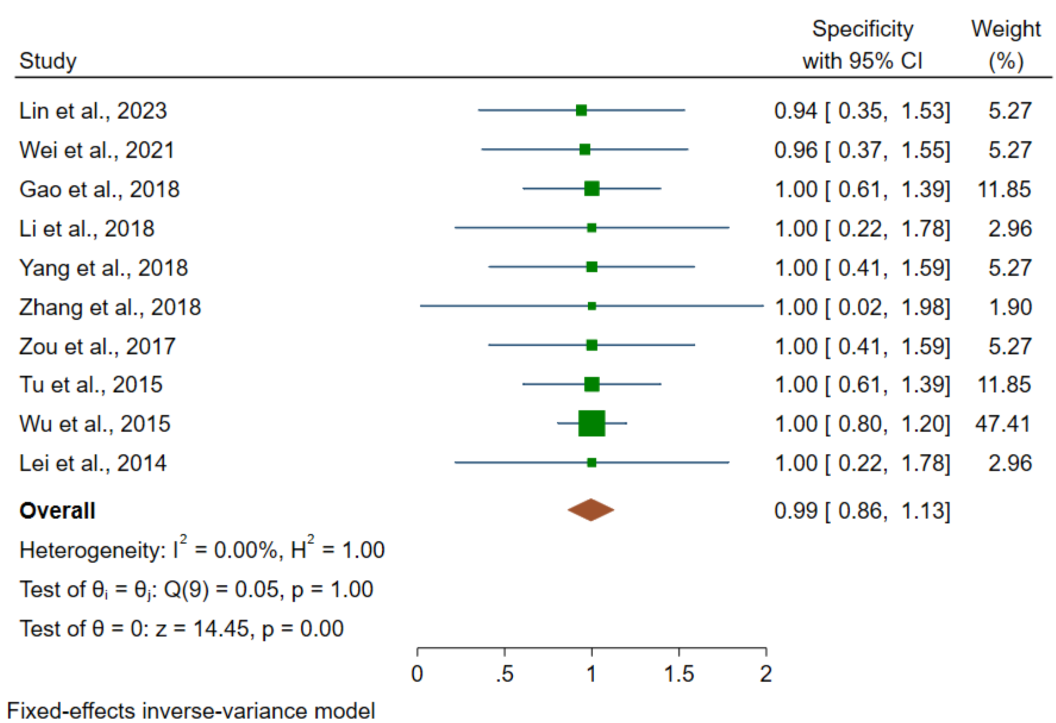

Fig. 4. The forest plot showed the specificity of carbon nanoparticle suspensions in SLNB.

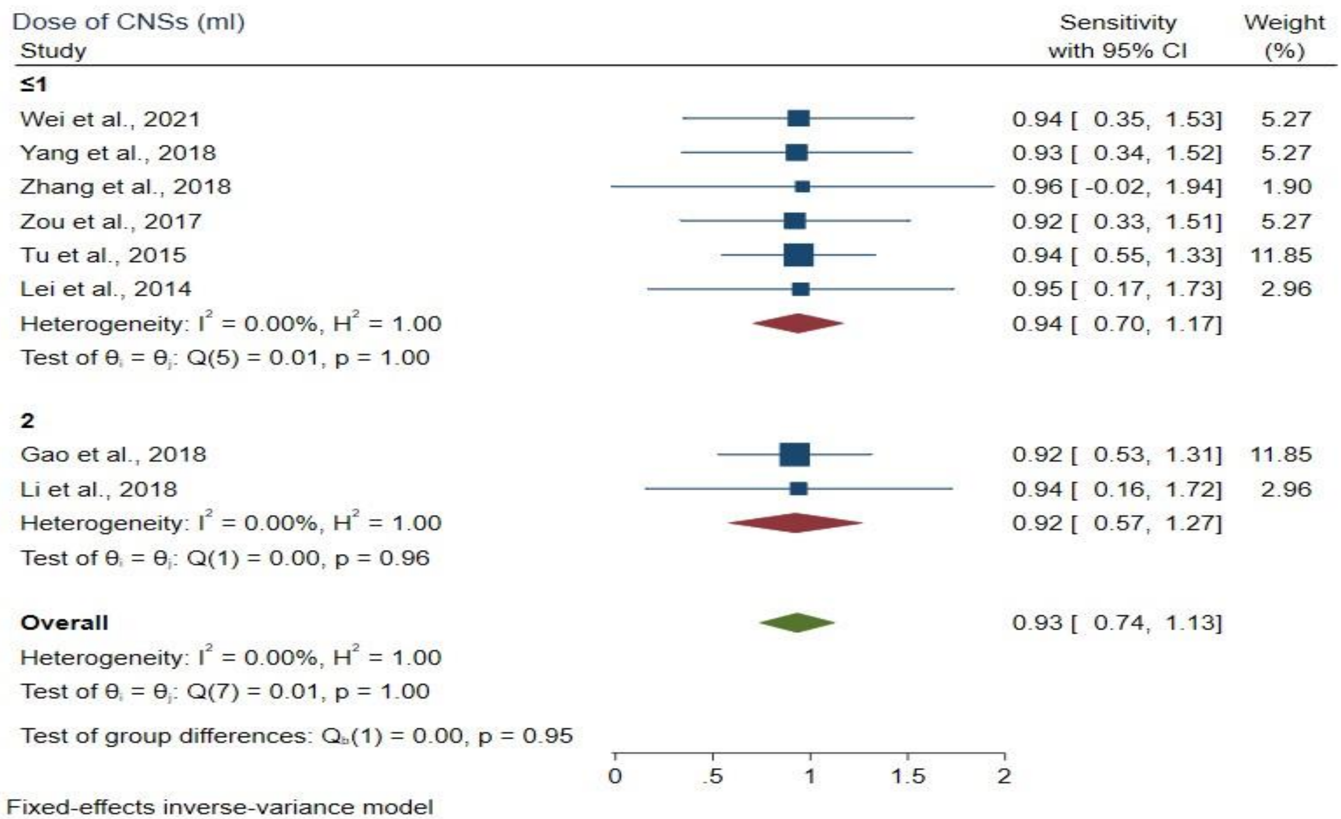

Fig. 5. The forest plot showed the sensitivity based on Carbon Nanoparticle injection doses.

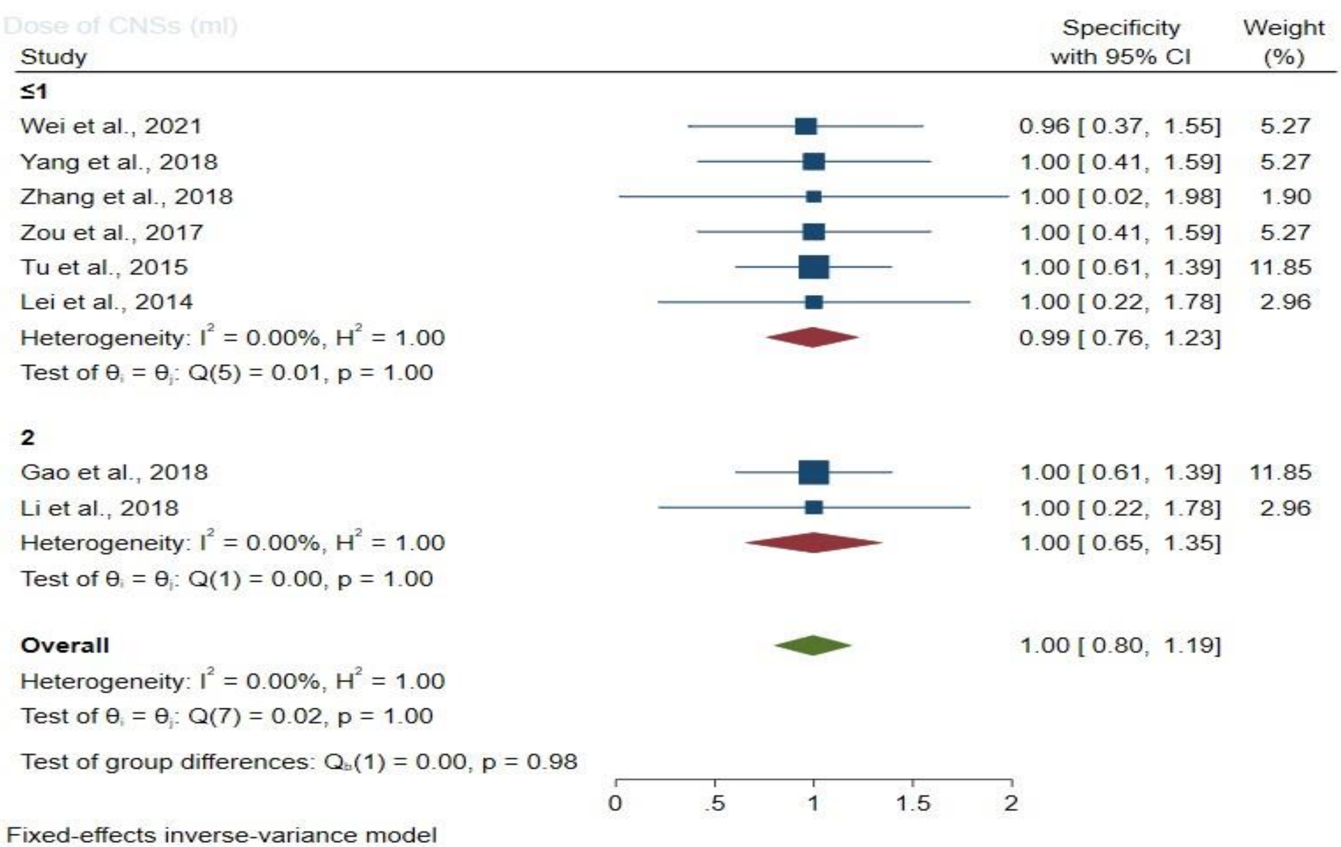

Fig. 6. The forest plot showed the specificity based on the Carbon Nanoparticle injection doses.

Injection site

Sensitivity of the carbon nanoparticle suspensions injected into the subareolar and peritumoral (Mixed) in SLNB was 92% (ES, 95%CI; 64%,100%. I^2=0.00%; p=1.00), and sensitivity of the carbon nanoparticle suspensions was injected into the subareolar was 91% (ES, 95%CI; 75%,100%. I^2=0.00%; p=1.00) (Fig. 7).

Specificity of the carbon nanoparticle suspensions injected into the subareolar and peritumoral (Mixed) in SLNB was 100% (ES, 95%CI; 71%,100%. I^2=0.00%; p=1.00), and specificity of the carbon nanoparticle suspensions was injected into the subareolar was 100% (ES, 95%CI; 84%,100%. I^2=0.00%; p=1.00) (Fig. 8).

Based on the test of group differences, no statistically significant difference was found between doses of carbon nanoparticle suspensions, and both presented similar results (p>0.05).

According to the funnel plot (Fig. 9), no publication bias was observed in the selected studies. As can be seen, the funnel plot shows an approximate symmetrical result, which indicates the absence of diffusion bias; Egger's test also confirms the results of the funnel plot (p>0.05).

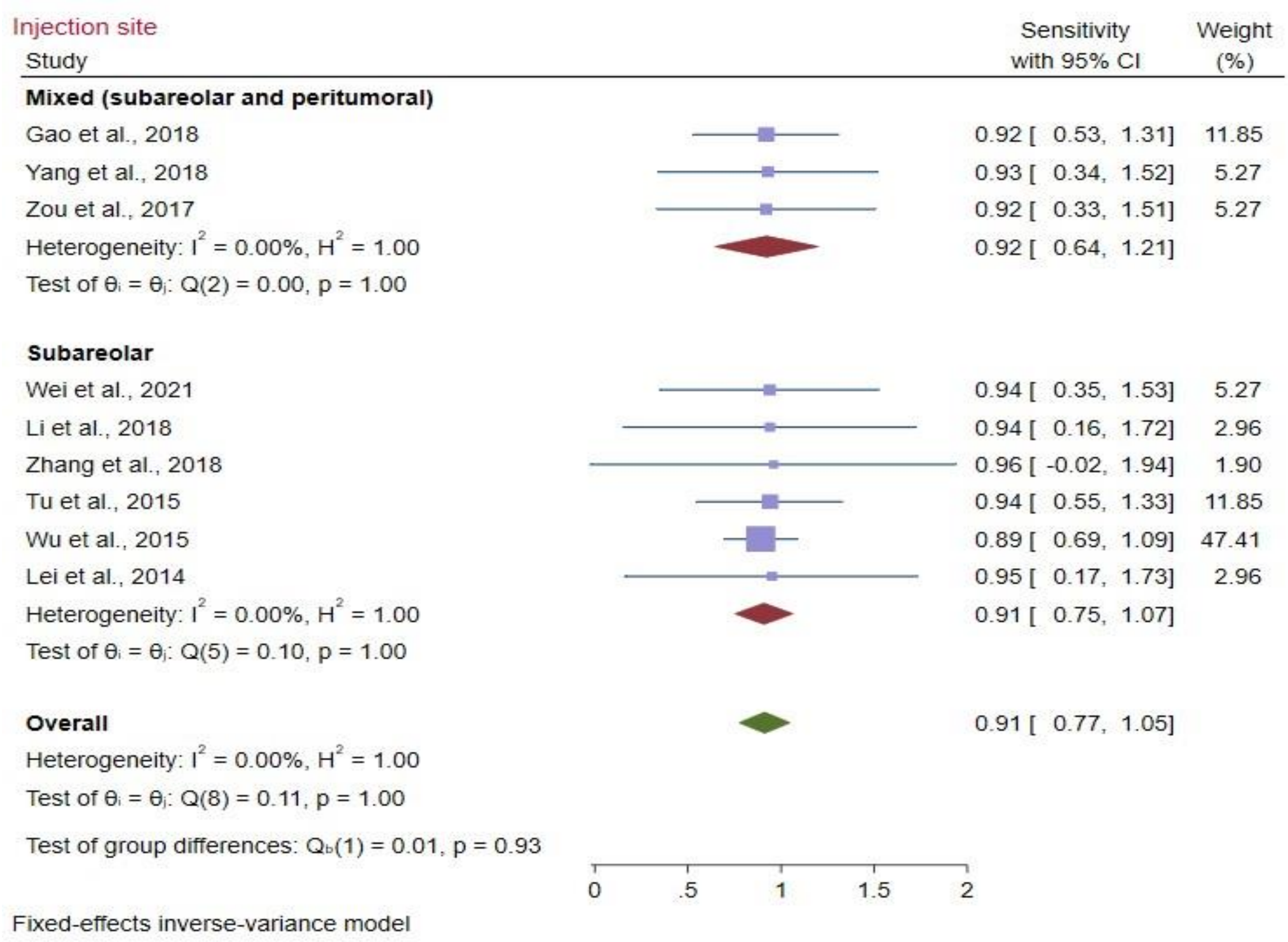

Fig. 7. The forest plot showed the sensitivity based on the Carbon Nanoparticle injection site.

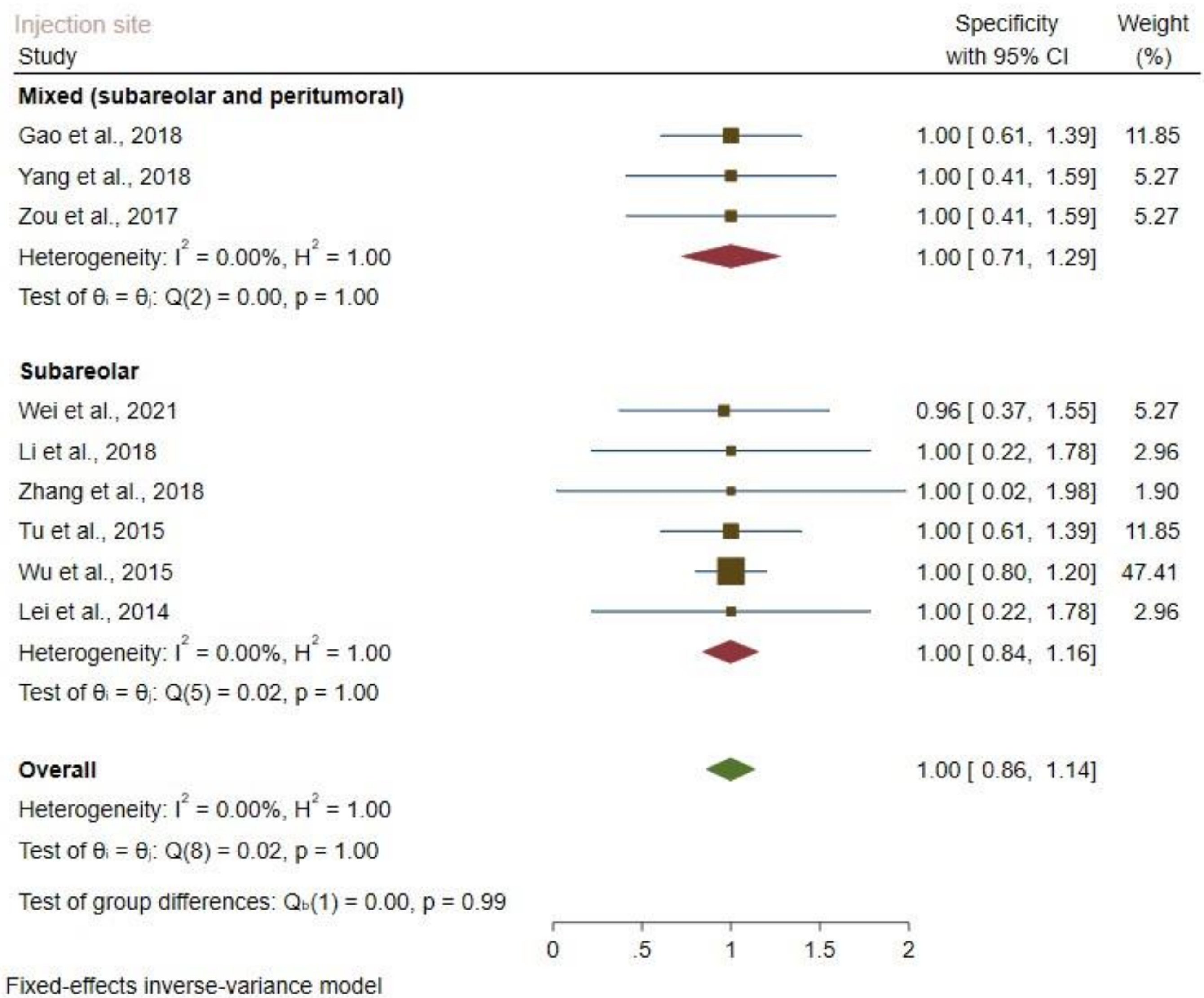

Fig. 8. The forest plot showed the specificity based on the Carbon Nanoparticle injection site.

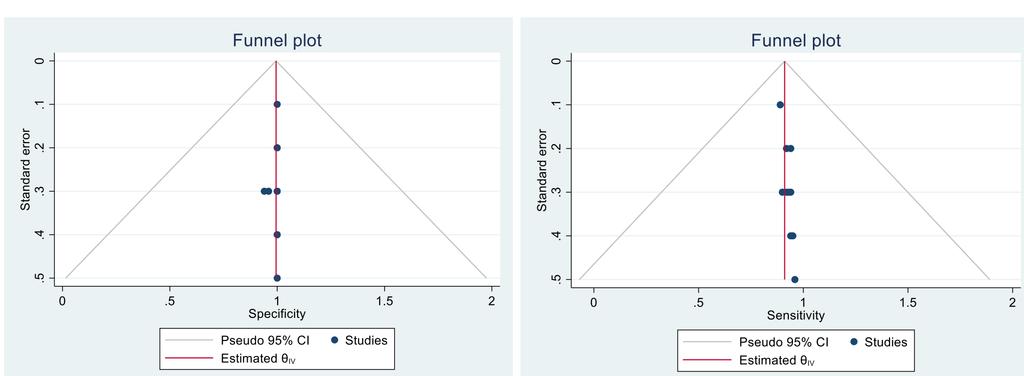

Fig. 9. The funnel plot showed publication bias of studies.

4. Discussion

SLNB has recently been widely used in breast cancer patients due to its significant benefits and low side effects(30). Carbon Nanoparticle is one of the new methods for SLNB without requiring specialized medical facilities. In the present study, the diagnostic accuracy of Carbon nanoparticles was investigated. Based on the present meta-analysis, very high sensitivity and specificity of Carbon nanoparticles for SLNB in breast cancer was observed. Therefore, Carbon nanoparticles can be used to identify actual positive patients. One of the topics that is discussed a lot is what dose of Carbon nanoparticles is more appropriate. According to the present sub-group meta-analysis, there was no statistically significant difference between the 1 and 2ml doses, and the dose range of less than 1 to 2 ml showed high sensitivity and specificity. Also, in terms of injection, no statistically significant difference was observed between Carbon Nanoparticle subareolar injection and Carbon Nanoparticle mixed injection, and both injections were suitable. Studies have shown that skin discoloration is one of the side effects of Carbon nanoparticles (25). The injection depth can cause this limitation; It is better to use subcutaneous injection instead of intradermal injection. Based on the results of a study, Carbon Nanoparticles are not only used as lymph node trackers but may also be helpful as a carrier for anti-tumor therapy(31, 32).

5. Conclusion

The present meta-analysis indicates that Carbon Nanoparticles are an ideal SLNB tracer for breast cancer. In breast cancer diagnosis, high sensitivity and specificity were reported for carbon nanoparticle suspensions in SLNB.

Conflict of Interest

The authors declared that there is no conflict of interest.

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