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Evaluation of the Diagnostic Accuracy of Superparamagnetic Iron Oxide Nanoparticles on Breast Cancer: A Systematic Review and Meta-analysis

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ABSTRACT

Background and aim: The present study was conducted to evaluate the diagnostic accuracy of Superparamagnetic iron oxide nanoparticles in breast cancer.

Material and methods: We examined all international databases, including PubMed, Scopus, Science Direct, ISI, Web of Knowledge, and Embase, searching until January 2023 based on keywords related to the objectives of the study. Based on the PRISMA 2020 checklist, the current study was conducted, and the Google Scholar search engine was also used to find related articles. A fixed-effect model and inverse-variance method were used to calculate the 95% confidence interval risk ratio. The meta-analysis was conducted using Stata/MP v. 17 software.

Results: The abstracts of 477 articles were reviewed, and 51 articles were selected for full-text review, of which 15 articles were included in the meta-analysis. The risk ratio of patient detection rate between superparamagnetic iron oxide nanoparticles and the standard method was 1.02 (RR, 1.02 95% CI 0.52, 1.53; $p>0.05$). Compared to the control group, the superparamagnetic iron oxide nanoparticles group showed a higher superiority in extracting more SLN (RR, 1.07 95% CI 0.52, 1.61; $p<0.05$).

Conclusions: Based on the findings of the present meta-analysis, superparamagnetic iron oxide nanoparticles can be a suitable alternative to standard methods in sentinel lymph node detection in breast cancer patients. It is suggested to study larger populations to confirm the present evidence.

1. Introduction

In the early stages of breast cancer, sentinel lymph node biopsy (SLNB) is used to confirm the metastatic status of axillary patients (node-negative disease). This is a standard procedure to find and remove a sentinel lymph node to check for cancer cells. Studies have reported the accuracy and feasibility of this method.[1] Some studies have mentioned the benefits of using this method in patients.[2, 3] However, using this method is also challenging because of the existing radioisotope; the management, disposal, and training of employees are among the things that need to be considered.[4] Generally, the injection is done by nuclear medicine staff, which is a limitation because the half-life of isotopes is short, around six hours, and it would be better if the surgeon himself did the injection. Also, being exposed to radiation is one of the concerns of many patients, especially pregnant people; on the other hand, the complications of anaphylaxis limit the use of this method.[5] Therefore, alternative methods need to be discussed. A recently introduced technique is superparamagnetic iron oxide (SPIO), a type of magnetic nanoparticle; which can be injected into the patient before or after induction of anesthesia, generally together with saline. After injection, these nanoparticles move to the lymph nodes and are absorbed; a manual magnetometer can be used for detection.[6] The diagnosis is that the color change in the nodes to brown or black helps to identify SLN.[7] Studies have reported advantages for SPIO, including their non-radioactive properties, long-term shelf life, and easy availability. One of the most important problems for SPIO is how to dispose of waste, which has also been solved.[8] Although there have been studies on the use of SPIO, a definite result has not been reported, and the issue remains very challenging; Therefore, in the present study, an attempt has been made to provide more comprehensive results by examining the results of the studies and summarizing the findings. Therefore, the present study was conducted to evaluate the diagnostic accuracy of Superparamagnetic iron oxide nanoparticles in breast cancer.

2. Material and methods

Search strategy

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The current study examined all international databases, including PubMed, Scopus, Science Direct, ISI, Web of Knowledge, and Embase, searching until January 2023 based on keywords related to the objectives of the study. The current study was conducted based on the PRISMA 2020 checklist,[9] and the Google Scholar search engine was used to search for articles and the PICO strategy to answer the research questions (Table 1). Keywords and the MeSH terms:

((((((("Neoplasms"[Mesh]) OR ("Neoplasms/diagnosis"[Mesh] OR "Neoplasms/surgery"[Mesh] OR "Neoplasms/therapy"[Mesh])) OR ("Breast Neoplasms/surgery"[Mesh] OR "Breast Neoplasms/therapy"[Mesh])) OR "Breast Cancer Lymphedema"[Mesh]) AND ("Sentinel Lymph Node"[Mesh] OR "Sentinel Lymph Node Biopsy"[Mesh])) AND "Nanoparticles"[Mesh]) OR "Nanoparticles/therapeutic use"[Mesh]) OR ("Magnetic Iron Oxide Nanoparticles"[Mesh] OR "Magnetite Nanoparticles"[Mesh])) OR "Magnetics"[Mesh].

Data items, data collection, and selection process

The specifications of samples of the selected studies were extracted based on a checklist that included five items: author's name, publication year, sample size, sentinel lymph nodes, positive patients, detailed information of the SPIO, and time intervals from SPIO injection to axillary surgery. Also, the data required for the meta-analysis, which includes the patient identification rates, were extracted from the findings of the studies. Two reviewers screened each record independently, and each report was retrieved. Inclusion and exclusion criteria were used to select all studies.

Eligibility criteria

Inclusion criteria: No language restrictions, randomized clinical trials, prospective and retrospective studies, and complete data.

Exclusion criteria: Case studies, case reports, and review papers. Full-text access is not available for studies and a sample size of less than 10.

Risk assessment

Research quality was assessed using the Risk of Bias in Non-Random Studies of Interventions (ROBINS-I). The categories for risk of bias judgments are "Low risk," "Moderate risk," "Serious risk" and "Critical risk" of bias. Notably, "Low risk" corresponds to the risk of bias in a high-quality randomized trial. The response options are: "Yes"; "Probably yes"; "Probably no"; "No"; and "No information". Responses of "Yes" are intended to have similar implications to responses of "Probably yes" (and similarly for "No" and "Probably no").

Table 1. PICO strategy.

PECO Strategy	Description
P	Population: breast cancer
I	Intervention: Superparamagnetic iron oxide
C	Comparison: standard technique
O	Outcome: patient Identification rate, Detection Rates

Data analysis

Potential heterogeneity between studies was reported according to the I^2 coefficient. Values less than 50% indicate low heterogeneity, values between 50% and 75% indicate moderate heterogeneity, and values above 75% indicate high heterogeneity. Inverse-variance method and fixed effect model were used to calculate 95% confidence intervals for the risk ratio. The meta-analysis was conducted using STATA/MP. V17.

3. Results

Study selection

In the initial keywords search, 498 articles were found, and all references were entered into EndNote X8 software. Among these articles, 10 articles were duplicated, 5 articles were due to Records marked as ineligible by automation tools, Six articles were removed for other reasons. Finally, the abstracts of 477 articles were reviewed, and 426 articles that did not meet the inclusion criteria were removed at this stage. Two blinded observers fully reviewed the full text of 51 articles. Incomplete articles, without data, and inconsistency with the objectives of the study were excluded (36 articles), and finally, fifteen articles were selected (Fig. 1).

Study characteristics

In the present study, 1379 breast cancer patients with 2329 nodes. Other extracted data are reported in Table 2.

Bias assessment

In Table 3, twelve studies were at low risk of bias, and three studies were at middle risk.

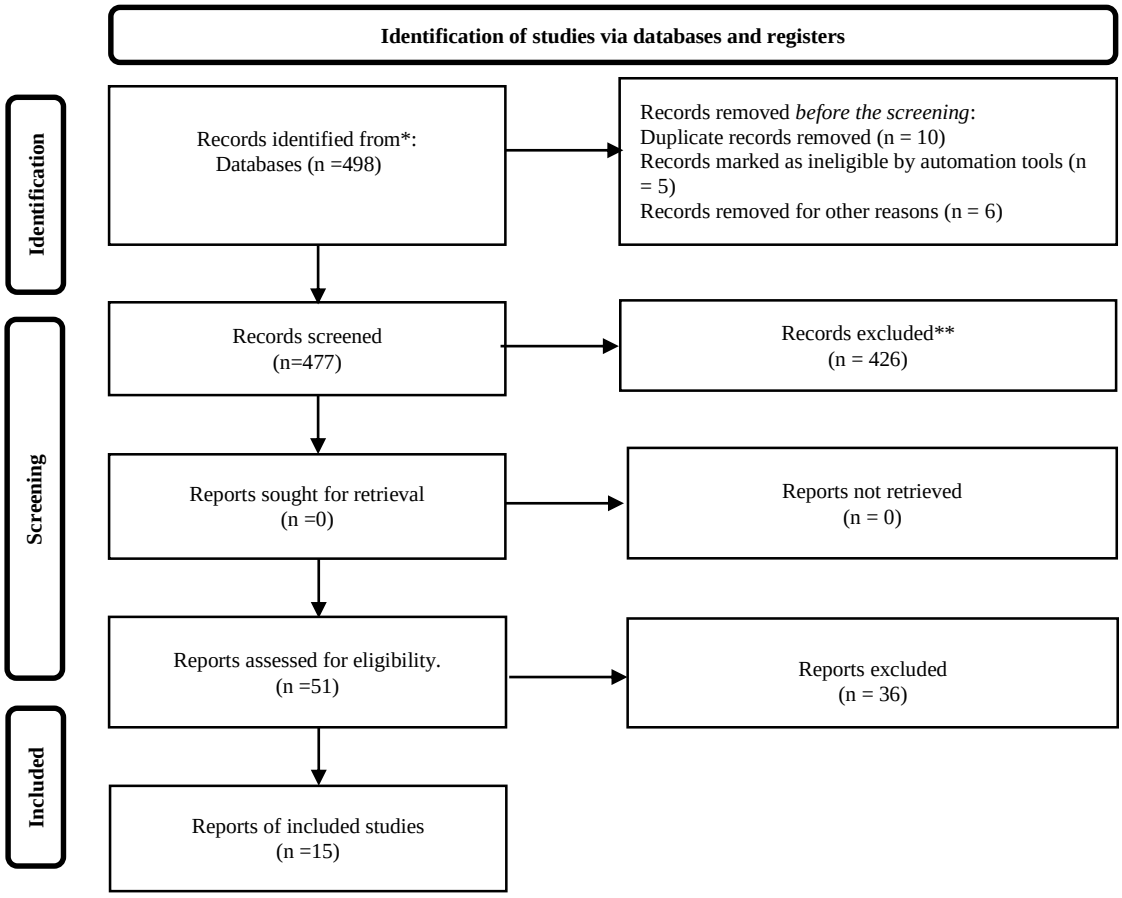

Fig. 1. PRISMA 2020 Checklist.

Table 2. Demographic information extracted from the full text of the selected studies.

Study. Years	Number of Patients	Sentinel Lymph Nodes	Positive %				SPIO			Time (min)	Injection Volume (ml)
			Patients		Sentinel Lymph Nodes		Dose (ml)	Specification (ml)	Concentration (mg iron per ml)		
			SPIO	Control	SPIO	Control					
Spiekerman van Weezelenburg et al., 2023[10]	39	40	98	100	99	100	2	2	27	15	2
Cengiz et al., 2023[11]	20	82	100	80.4	39	25.6	2	2	27	20	2
Vidya et al., 2022[12]	107	202	100	100	100	100	2	2	27	20	2
Climent et al., 2021[13]	89	129	100	85	95.4	86.4	2	2	27	20	2
Hersi et al., 2021[14]	165	371	97	100	NR	NR	2	2	27	20	1
Hamzah et al., 2020[15]	20	56	NR	NR	NR	NR	2	2	28	20	2
Rubio et al., 2020[16]	135	235	100	100	NR	NR	1	1	27	37	1, 1.5, 2
Makita et al., 2020[17]	62	183	NR	NR	100	68.4	1	1	27	20	0.5
Taruno et al., 2019[18]	210	NR	NR	NR	NR	NR	1	2	27	24	1

Alvarado et al., 2019[19]	146	369	95.6	95.5	96.6	91.1	2	2	27	20	2
Karakatsanis et al., 2019[20]	40	NR	NR	NR	NR	NR	2	2	27	20	2
Karakatsanis et al., 2018[21]	12	16	100	66	NR	NR	2	2	27	20	2
Ghilli et al., 2017[22]	193	308	98	96	94	93	2	2	27	20	2
Houpeau et al., 2016[23]	108	220	95	97	92	91	2	2	27	20	2
Ahmed et al., 2015[24]	33	118	91.7	94	NR	NR	2	2	27	20-25	0.5

NR: not reported.

Table 3. Bias assessment (ROBINS-I).

Study. Years	Bias due to confounding	Bias in the selection of participants into the study	Bias in the classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in the measurement of outcomes	Bias in the selection of the reported result	Overall
Spiekerman van Weezelenburg et al., 2023[10]	Low	Low	Low	Low	Low	Low	Low	Low
Cengiz et al., 2023[11]	Low	Low	Low	Low	Low	Low	Low	Low
Vidya et al., 2022[12]	Low	Low	Low	Low	Low	Low	Low	Low
Climent et al., 2021[13]	Low	Low	Low	Low	Low	Low	Low	Low
Hersi et al., 2021[14]	Low	Low	Low	Low	Low	Low	Low	Low
Hamzah et al., 2020[15]	Low	Low	Low	Low	Low	Middle	Low	Middle
Rubio et al., 2020[16]	Low	Low	Low	Low	Low	Low	Middle	Middle
Makita et al., 2020[17]	Low	Low	Low	Low	Low	Low	Low	Low
Taruno et al., 2019[18]	Low	Low	Low	Low	Low	Middle	Low	Middle
Alvarado et al., 2019[19]	Low	Low	Low	Low	Low	Low	Low	Low
Karakatsanis et al., 2019[20]	Low	Low	Low	Low	Low	Low	Low	Low
Karakatsanis et al., 2018[21]	Middle	Low	Low	Low	Low	Low	Low	Low
Ghilli et al., 2017[22]	Low	Low	Low	Low	Low	Low	Low	Low
Houpeau et al., 2016[23]	Low	Low	Low	Low	Low	Low	Low	Low
Ahmed et al., 2015[24]	Low	Low	Low	Low	Low	Low	Low	Low

Detection Rate

Patient

The risk ratio of patient detection rate between superparamagnetic iron oxide nanoparticles and the standard method was 1.02 (RR, 1.02 95% CI 0.52, 1.53; p>0.05) with low heterogeneity (I^2=0%; p =1.00). (Fig. 2). There was no statistically significant difference between the two groups (p>0.05).

Sentinel lymph node

The risk ratio of sentinel lymph node detection rate between superparamagnetic iron oxide nanoparticles and the standard method was 1.07 (RR, 1.07 95% CI 0.52, 1.61; p<0.05) with low heterogeneity (I^2=0%; p =1.00). (Fig. 3). Statistically, a significant difference was observed between the two groups (p<0.05). Compared to the control group, the superparamagnetic iron oxide nanoparticles group showed a higher superiority in the extraction of more SLN.

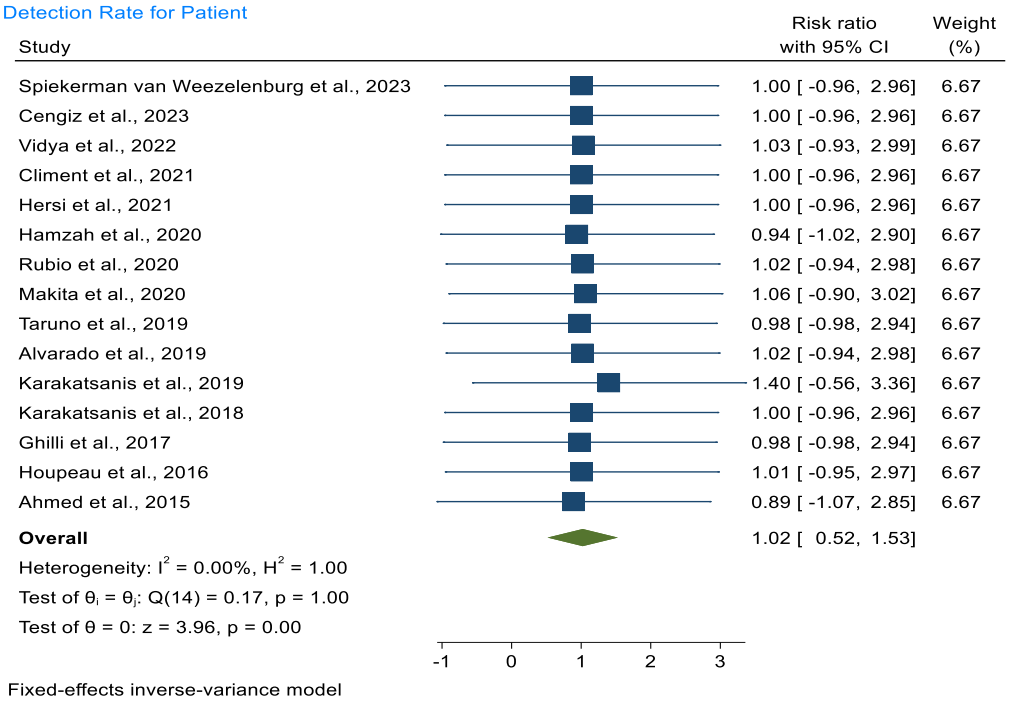

Fig. 2. The forest plot shows the Risk ratio of the patient detection rate.

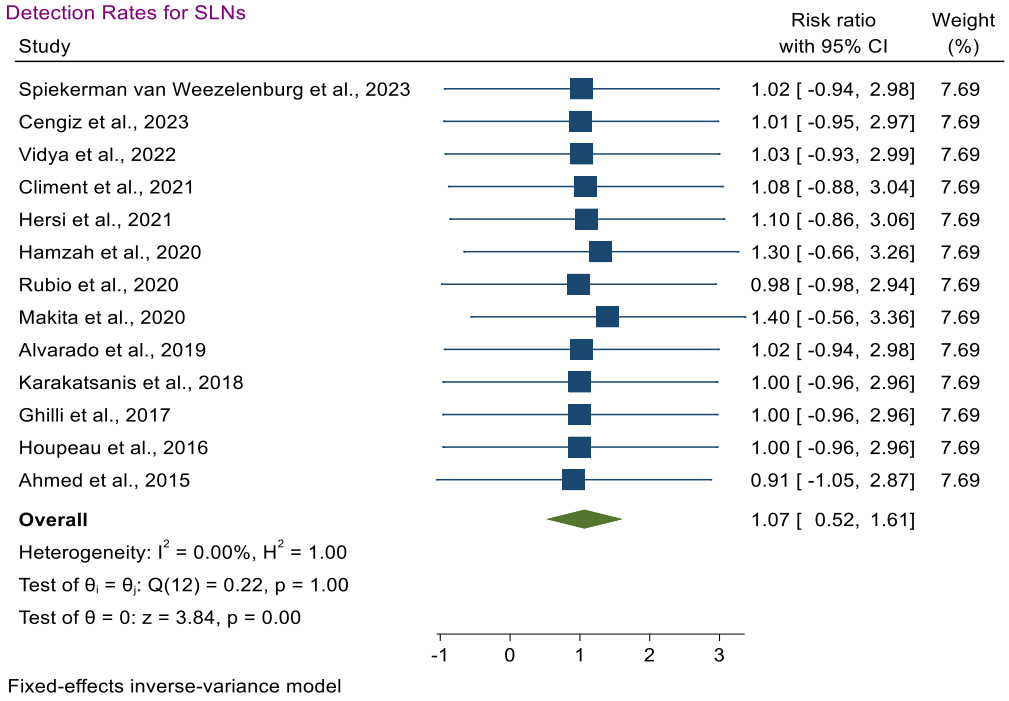

Fig. 3. The forest plot showed a sentinel lymph node detection rate.

Patients with Positive sentinel lymph node

The risk ratio of patients with positive sentinel lymph node detection rate between superparamagnetic iron oxide nanoparticles and standard method was 1.06 (RR, 1.01 95% CI 0.49, 1.62; p>0.05) with low heterogeneity (I^2=0%; p =1.00). (Fig. 4). There was no statistically significant difference between the two groups (p>0.05).

Positive sentinel lymph node

The risk ratio of positive sentinel lymph node detection rate between superparamagnetic iron oxide nanoparticles and the standard method was 1.01 (RR, 1.01 95% CI 0.36, 1.85; p>0.05) with low heterogeneity (I^2=0%; p =1.00). (Fig. 5). There was no statistically significant difference between the two groups (p>0.05).

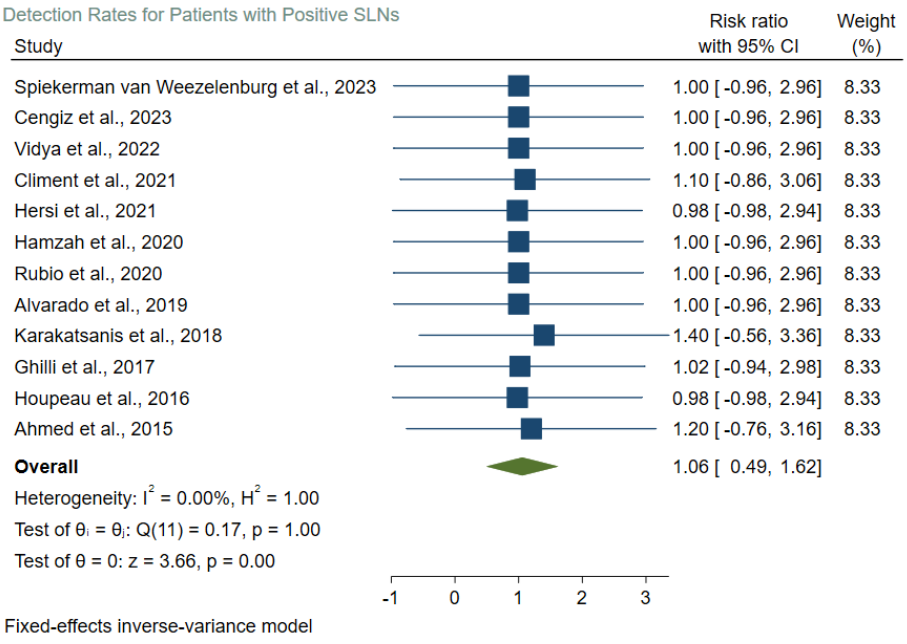

Fig. 4. The forest plot showed patients with positive sentinel lymph node detection rates.

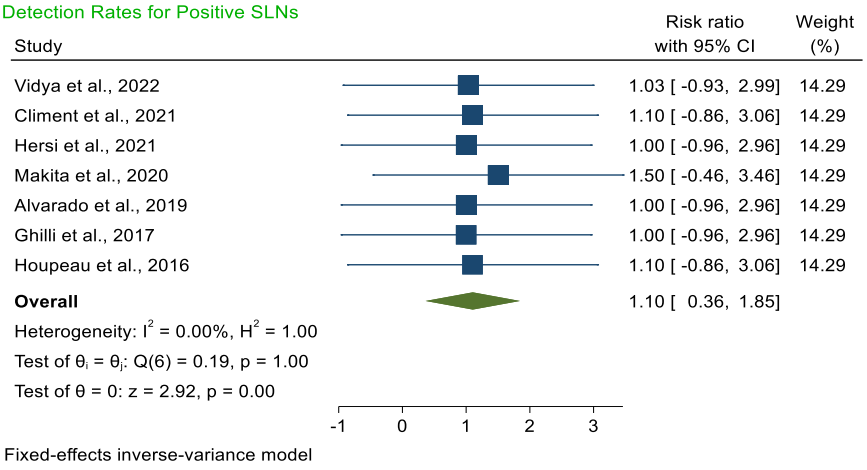

Fig. 5. The forest plot showed a positive sentinel lymph node detection rate.

4. Discussion

This study aimed to determine the performance of SPIO compared to the standard method so that it can be used as a suitable alternative. The present meta-analysis showed that the two groups did not have significant differences in patient detection rates, and both groups performed the same. Regarding the sentinel lymph node detection rate, SPIO had higher accuracy than the control group. Successful detection depends on many factors, including the site and dose of injection, pre- or perioperatively. In the studies selected in the present study, doses of 0.5, 1, 1.5, and 2 ml were used. Based on the findings of studies, a dose of 0.5 ml is sufficient to identify SLN.[25] Other studies have shown that the SLN detection rate per patient is not affected by the SPIO dose. Higher doses of SPIO have a better performance in diagnosing SLN.[16, 19] Studies have shown that if SPIO is injected before surgery, it has a higher detection rate than the day of surgery and a higher detection rate than the standard method.[21, 26] A study showed that SPIO injection seven days before surgery has a higher SLN detection rate compared to the standard method.[14] Based on the available evidence and the review of the findings of the selected studies, it can be stated that the injection interval before the operation can increase the rate of diagnosis of SLN. One of the useful advantages of SPIO is that they do not require special storage, and no risk of radiation exposure has been reported. The present meta-analysis showed no statistically significant difference in terms of Detection Rates for Patients with Positive SLNs and Detection Rates for Positive SLNs between SPIO and the standard method. As a result, using SPIO can be useful and bring lower costs to the patient. One of the important issues when using SPIO is that safety should be considered so that severe allergic reaction is not followed. It should be noted that no study was found that reported a severe allergic reaction. However, metal implants should be examined more carefully for patients sensitive to iron and dextran compounds. Skin staining is a concern after SPIO injection; However, the evidence indicates that most patients do not consider skin staining an uncomfortable issue.[16, 20] A study reported that the discoloration would be less if the injection were deeper.[22] In a study after SLNB via SPIO,

no toxicity was observed with radiotherapy or chemotherapy.[27] Since there was low heterogeneity between the studies and almost the results of the studies were close. In order to confirm the present findings and provide stronger evidence regarding the feasibility of the magnetic technique, studies with a larger sample size and more precise methods design are needed. Methods and conducting studies are needed and should be done prospectively. The present study had limitations, such as different cut points in applying the SPIO signal in the studies and variable blue colors in the standard method. However, it was not reported in clinical pathology studies, and these parameters were omitted.

5. Conclusion

Based on the present meta-analysis, SPIO can be a suitable alternative to standard methods in Sentinel Lymph Node Detection in Breast Cancer Patients. It is suggested to study larger populations to confirm the present evidence.

Conflict of Interest

The authors declared that there is no conflict of interest.

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