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Evaluation of the Clinical Outcome of Nab-paclitaxel on Multiple Primary Malignancies: A Systematic Review and Meta-analysis

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ABSTRACT

Background and aim: In the present study, an attempt has been made to analyze the side effects of nab-paclitaxel compared to sb-paclitaxel and docetaxel. The present study aimed to evaluate the clinical outcome of Nab-paclitaxel on Multiple primary malignancies.

Material and methods: All articles published in international databases such as PubMed, Scopus, Science Direct, ISI Web of knowledge, and Embase between 2012 to July 2022 are included. 95% confidence interval on odds ratio were done with the fixed effect model and Mantel-Haenszel method. Meta-analysis data collected from selected studies were performed using Stata/MP.V17 software.

Results: In the initial review, duplicate studies were eliminated, abstracts of 311 studies were reviewed, two authors reviewed the full text of 43 studies, and finally, nine studies were selected. The odds ratio of treatment termination and treatment delay due to adverse events between Nab-paclitaxel and the control group was 0.72 (OR, 95% CI 0.53, 0.92; p=0.00) and -0.52 (OR, 95% CI -0.69, -0.35; p=0.00). The odds ratio of deaths due to treatment-related adverse events between Nab-paclitaxel and the control group was 0.37 (OR, 95% CI 0.11, 0.63; p=0.01).

Conclusions: According to the present meta-analysis, hematological and non-hematological side effects were higher in the group receiving nab-paclitaxel compared to the group receiving sb-paclitaxel and docetaxel.

1. Introduction

Taxanes are the most widely used cytotoxic agents in the treatment of cancers. The available evidence has confirmed the effectiveness of traditional taxanes in treating several tumors; solvent-based paclitaxel (sb-paclitaxel) and docetaxel are traditional taxanes. Studies have shown that traditional taxanes have complications such as long-term sensory neuropathy and allergic reactions, and their administration should be done carefully and in limited patients. Nanoparticle albumin-bound paclitaxel (nab-paclitaxel) can prevent hypersensitivity.[1-3] Studies have shown that using Nab-paclitaxel effectively treats patients with metastatic breast cancer and other solid tumors. The evidence indicates a stronger anti-tumor effect of Nab-paclitaxel compared to traditional taxanes.[4-8] A study showed that patients with metastatic breast cancer treated with nab-paclitaxel had a long survival without recurrence.[9]

Nevertheless, the comparison of nab-paclitaxel and traditional taxanes is of high importance and highly controversial. Also, a study has shown that in the comparison of nab-paclitaxel and traditional taxanes, sensory neuropathy is observed in nab-paclitaxel groups.[10] A study also reported that in the group treated with nab-paclitaxel, increased toxicity was resolved after reducing the dose and stopping the treatment.[9] During the past years, immunotherapy has received much attention, and the combination of immunotherapy with chemotherapy has shown promising results in treating various types of tumors. It has been reported that using Nab-paclitaxel with immunotherapy does not have an immunosuppressive effect and can have better results due to the lack of steroid drugs. Studies have confirmed using Nab-paclitaxel with immunotherapy to treat metastatic squamous small-cell lung and breast cancer.[11-14]As mentioned before, in the past years, immunotherapy has been of great interest and is expanding, and the use of nab-paclitaxel has also been more effective than traditional taxanes. Therefore, it is important to examine

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side effects in patients who have received traditional taxanes with those who have received nab-paclitaxel; Considering the importance of the topic, the present study was conducted to evaluate the clinical outcome of Nab-paclitaxel on multiple primary malignancies.

2. Material and methods

Search strategy

Based on PRISMA guidelines,[15] the present study conducts a systematic review and meta-analysis of all articles published between January 2012 and July 2022 in international databases, including PubMed, Scopus, Science Direct, Embase, and ISI Web of Knowledge. The Google Scholar search engine employed the PICO strategy to answer the research questions (Table 1).

Table1. PICO strategy.

PECO Strategy	Description
P	Population: Cancer patients
I	Intervention: nab-paclitaxel
C	Comparison: traditional taxanes
O	Outcome: adverse events, severe neurotoxicity, symptom and disease-specific

The following keywords were used to search: (((((("Neoplasms"[Mesh]) OR ("Neoplasms/classification"[Mesh] OR "Neoplasms/complications"[Mesh] OR "Neoplasms/drug therapy"[Mesh] OR "Neoplasms/statistics and numerical data"[Mesh] OR "Neoplasms/therapy"[Mesh])) AND ("Nanoparticles"[Mesh] OR "Nanoparticle Drug Delivery System"[Mesh])) OR ("Nanoparticles/pharmacology"[Mesh] OR "Nanoparticles/standards"[Mesh] OR "Nanoparticles/statistics and numerical data"[Mesh] OR "Nanoparticles/toxicity"[Mesh])) AND "Paclitaxel"[Mesh]) OR "docosahexaenoyl-paclitaxel" [Supplementary Concept].

Eligibility criteria

Inclusion criteria

1. Randomized controlled trials and cohort studies.
2. The article's full text was accessible.
3. Only English-language articles with published studies were selected.
4. Comparison of nab-paclitaxel with sb-paclitaxel and docetaxel.
6. Human samples.

Exclusion criteria

1. Cross-sectional and retrospective studies, in-vitro and in-vivo studies, Review studies, case reports, and letters to the editor.
2. No comparison with the control group.

Selection process and data collection process

Two reviewers blindly and independently extracted data from the included papers' full texts and abstracts for Data extraction. Kappa statistics were used to check the amount of agreement between the reviewers before the screening. The values of kappa were higher than 0.80. Studies data were reported by the first author's name, years, study design, several patients, and outcome.

Risk of bias assessment

The randomized control trial studies' quality was assessed using the Cochrane Collaboration's tool.[16] Low risk received a scale score of 1, while high and unclear risk received a score of 0. The scale scores have a range of 0 to 6. High quality means a higher score.

Data analysis

Effect measures and synthesis methods

Stata/MP.V17 software was used to analyze the data. The odds ratio (95% confidence interval) was done with the fixed effect model and the Mantel-Haenszel method. The level of heterogeneity was assessed using the I^2 index test (I^2 50% = low levels, 50-I^2 75% = moderate, and I^2>75% = high levels).

3. Results

After the initial search for them in databases, 311 articles were identified. Duplicate articles were deleted (n=49) after importing all articles into the EndNote.X9 software. 262 articles were entered and examined in the second stage. At this stage, 219 unrelated articles were excluded from the study while reviewing the titles and abstract articles. The full texts of 43 articles were reviewed in the third step. Nine articles that met the inclusion criteria were included (Fig. 1).

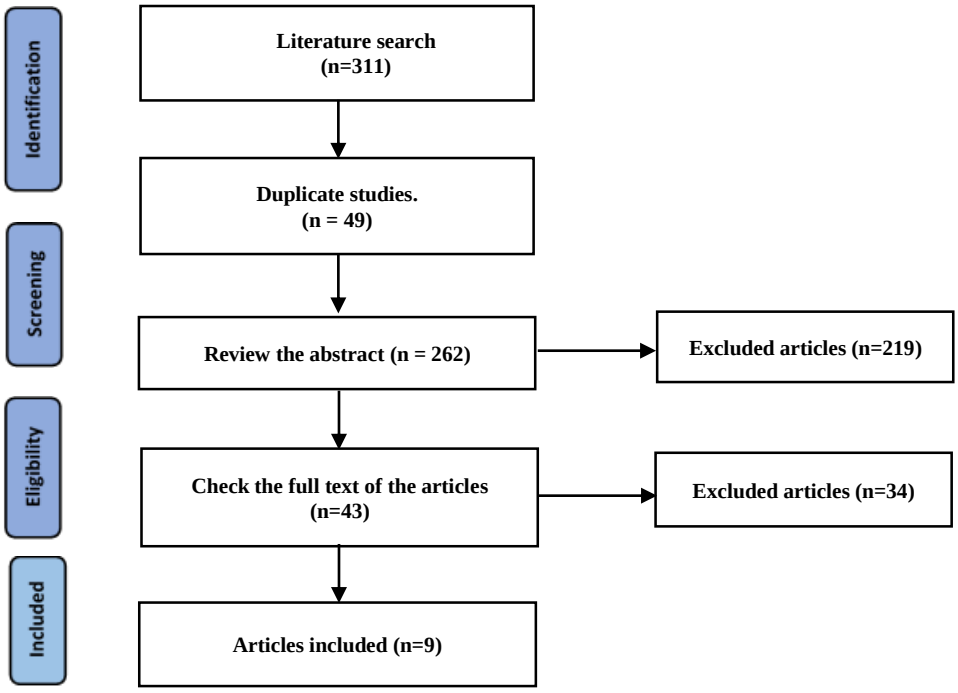

Fig. 1. PRISMA flowcharts.

Characteristics

Two thousand five hundred twenty-nine patients were evaluated in the Nab-paclitaxel group and 2268 patients in the control group; A total of 4797 patients were included in the study. The drug dose and duration of the intervention in the Nab-paclitaxel and control groups are summarized in Table 2.

Table 2. Summary of the findings reported in selected studies.

Study. Years	Type of Cancer	Number of Patients		Dose		Time on Intervention (Weeks)	
		Nab-paclitaxel	Control	Nab-paclitaxel	Control	Nab-paclitaxel	Control
Ciruelos et al., 2019[17]	Breast cancer	46	14	100 mg/m^2, Q week 150 mg/m^2, Q week 150 mg/m^2, Q2 weeks	80 mg/m^2, Q week	NR	NR
Sridhar et al., 2020[18]	Urothelial	100	100	260 mg/m^2, Q3 weeks	175 mg/m^2, Q3 week	NR	NR
Kuwayama et al., 2018[19]	Breast cancer	74	77	100 mg/m^2, Q weeks	75 mg/m^2, Q3 week	16	16
Gianni et al., 2018[20]	Breast cancer	337	335	125 mg/m^2, Q weeks	90 mg/m^2, Q week	16	16
Tamura et al., 2017[21]	Breast cancer	100	100	150 mg/m^2, Q weeks	75 mg/m^2, Q3 week	NR	NR
Shitara et al., 2017[22]	Gastric cancer	485	243	260 mg/m^2, Q3 weeks 100 mg/m^2, Q weeks	80 mg/m^2, Q week	8	12
Furlanetto et al., 2017[23]	Breast cancer	606	600	150 mg/m^2, Q weeks 125 mg/m^2, Q weeks	80 mg/m^2, Q week	12	12
Rugo et al., 2015[24]	Breast cancer	267	275	150 mg/m^2, Q weeks	90 mg/m^2, Q week	20	20
Socinski et al., 2012[25]	Non-small-cell lung cancer	514	524	100 mg/m^2, Q weeks	200 mg/m^2, Q3 week	18	18

Adverse event

The odds ratio of treatment termination due to adverse events between Nab-paclitaxel and the control group was 0.72 (OR, 95% CI 0.53, 0.92; p=0.00) (I^2=69.36%; P=0.01; moderate heterogeneity). Based on Fig. 2, a statistically significant difference was observed between the two groups (p=0.00); In the group receiving nab-paclitaxel, the termination of treatment due to adverse events was more than in patients in the control group.

The odds ratio of treatment delay due to adverse events between Nab-paclitaxel and the control group was -0.52 (OR, 95% CI -0.69, -0.35; p=0.00) (I^2=98.98%; P=0.00; high heterogeneity). Based on Fig. 3, a statistically significant difference was observed between the two groups (p=0.00); In the group receiving nab-paclitaxel, treatment delay due to adverse events was lower than in the control group.

The odds ratio of deaths due to treatment-related adverse events between Nab-paclitaxel and the control group was 0.37 (OR, 95% CI 0.11, 0.63; p=0.01) (I^2=77.60%; P=0.00; high heterogeneity). Based on Fig. 4, a statistically significant difference was observed between the two groups (p=0.01); In the group receiving nab-paclitaxel, deaths due to treatment-related adverse events were lower than in the control group.

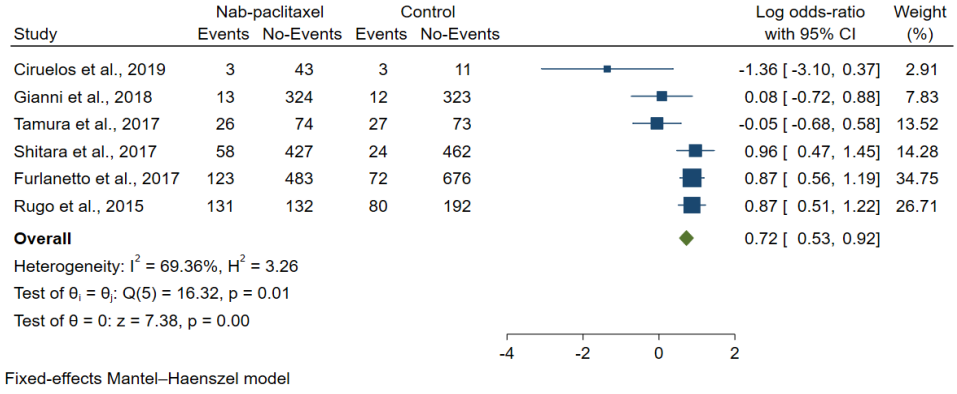

Fig. 2. The forest plot showed the odds ratio of treatment termination due to adverse events.

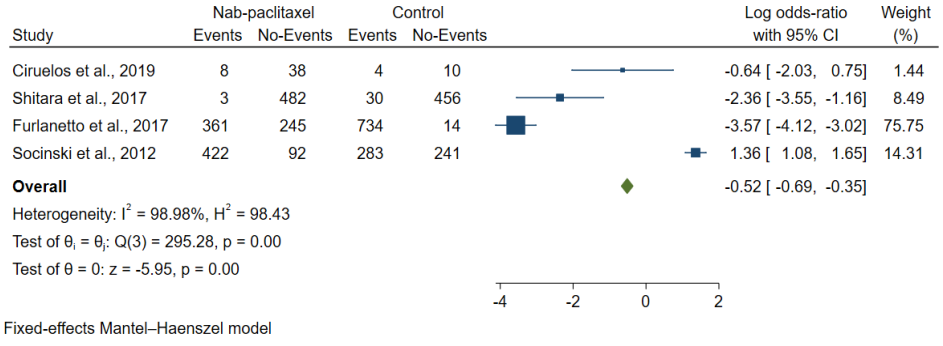

Fig. 3. The forest plot showed the odds ratio of treatment delay due to adverse events.

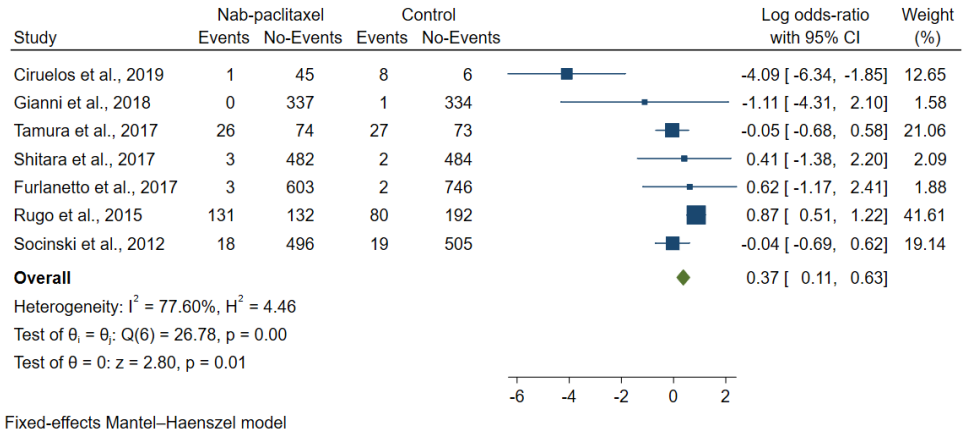

Fig. 4. The forest plot showed the odds ratio of deaths due to treatment-related adverse events.

Neurotoxicity-specific

The odds ratio of Neurotoxicity-specific between Nab-paclitaxel and the control group was 0.53 (OR, 95% CI 0.33, 0.73; p=0.00) (I^2=14.90%; P=0.32; low heterogeneity). Based on Fig. 5, a statistically significant difference was observed between the two groups (p=0.00); Neurotoxicity was more common in patients who received nab-paclitaxel compared to the control group.

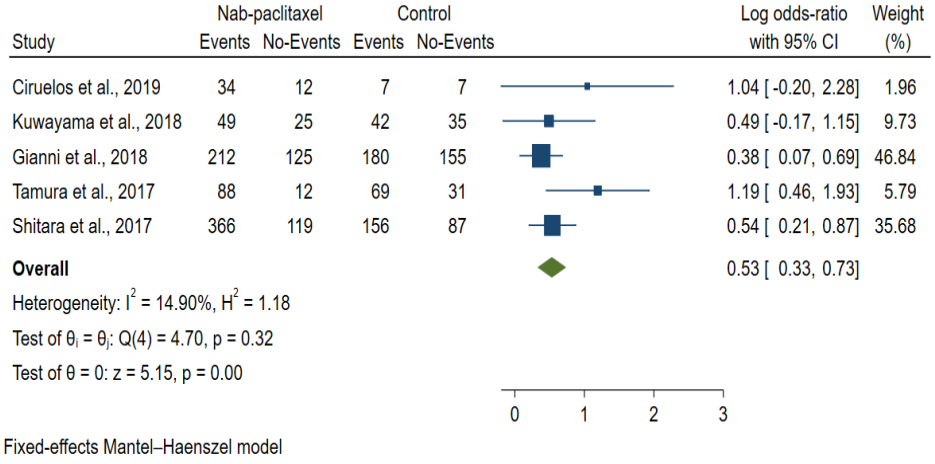

Fig. 5. The forest plot showed the odds ratio of Neurotoxicity-specific.

Severe neurotoxicity (Grade 3/4)-specific

The odds ratio of Severe neurotoxicity (Grade 3/4)-specific between Nab-paclitaxel and the control group was 1.40 (OR, 95% CI 0.88, 1.93; p=0.00) (I^2=0%; P=0.55; low heterogeneity). Based on Fig. 6, a statistically significant difference was observed between the two groups (p=0.00); Severe neurotoxicity (Grade 3/4)-specific was more common in patients who received nab-paclitaxel compared to the control group.

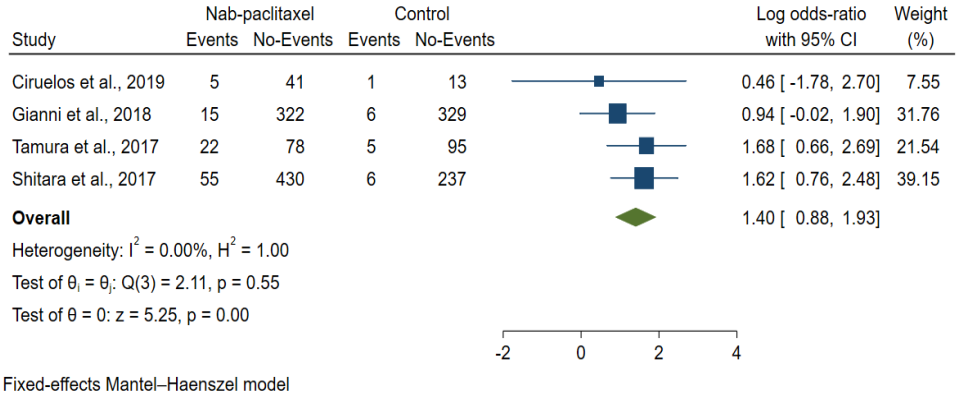

Fig. 6. The forest plot showed the odds ratio of Severe neurotoxicity (Grade 3/4)-specific.

Symptom and disease-specific

Subgroup meta-analysis showed Odds ratio of neutropenia between Nab-paclitaxel and control group was 0.87 (OR, 95% CI 0.68, 1.05; p=0.03) (I^2=81.71%; P=0.55; high heterogeneity); Odds ratio of leukopenia between Nab-paclitaxel and control group was 0.40 (OR, 95% CI 0.19, 0.60; p=0.09) (I^2=62.53%; P=0.02; moderate heterogeneity); Odds ratio of anemia between Nab-paclitaxel and control group was 0.48 (OR, 95% CI 0.15, 0.81; p=0.00) (I^2=47.67%; P=0.15; low heterogeneity); Odds ratio of emesis and diarrhea between Nab-paclitaxel and control group was 0.22 (OR, 95% CI 0, 0.44; p=0.00) (I^2=48.26%; P=0.09; low heterogeneity); Odds ratio of rash between Nab-paclitaxel and control group was 0.22 (OR, 95% CI -0.05, 0.49; p=0.02) (I^2=40.72%; P=0.17; low heterogeneity); Odds ratio of allergy between Nab-paclitaxel and control group was -1.51 (OR, 95% CI -2.23, 0.79; p=0.00) (I^2=0%; P=0.37; low heterogeneity); Odds ratio of pruritus between Nab-paclitaxel and control group was 0.87 (OR, 95% CI 0.21, 1.54; p=0.00) (I^2=0%; P=0.48; low heterogeneity). Overall Odds ratio of Symptom and disease-specific was 0.44 (OR, 95% CI 0.35, 0.54) (I^2=76.26%; P=0.00; high heterogeneity). The test of group differences showed a statistically significant difference between groups (Fig. 7).

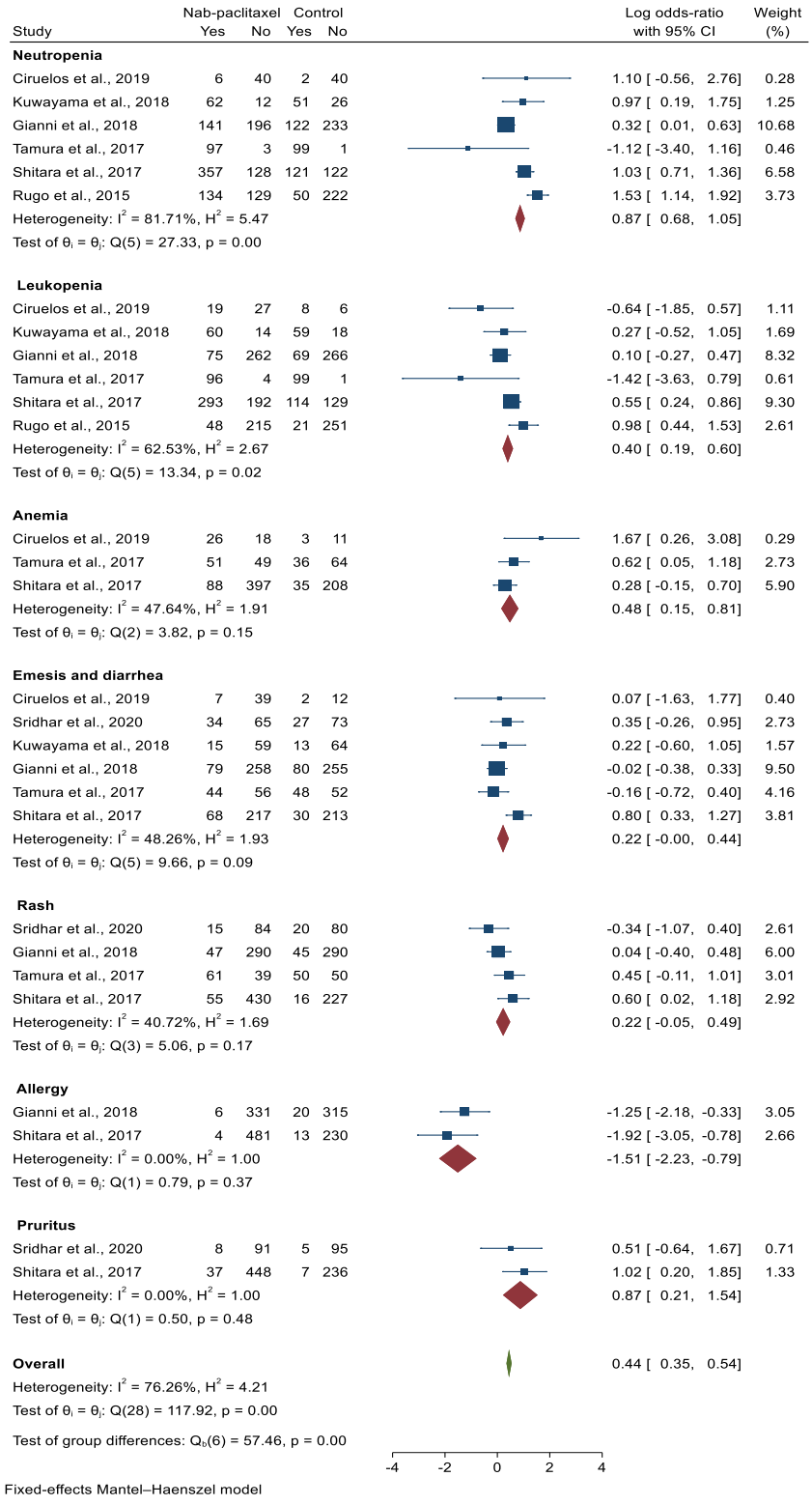

Fig. 7. The forest plots showed symptom and disease-specific.

4. Discussion

In the present study, an attempt has been made to analyze the side effects of nab-paclitaxel compared to sb-paclitaxel and docetaxel. In previous clinical studies and meta-analyses, the toxicity of traditional taxanes compared to nab-paclitaxel has been investigated, and there are disagreements between the results of the studies. The present study investigated the side effects of using nab-paclitaxel compared to traditional taxanes. According to the present meta-analysis, the probability of side effects and severe complications (grade 3) in the group receiving traditional taxanes, compared to nab-paclitaxel. Patients who received nab-paclitaxel experienced discontinuation due to high

treatment-related adverse events. Disease-related adverse events were generally higher in the nab-paclitaxel group. Studies have reported side effects related to the immune system in patients receiving traditional taxanes.[26, 27] According to the results of studies, among the most common side effects are skin complications that can be observed in patients in a mild to moderate form.[28] Based on the available evidence and literature, using taxanes and immunotherapy can have a better effect on tumor recovery.[29] It should be mentioned that the use of nab-paclitaxel is preferred due to the lack of need for steroid pre-medication along with immunotherapy. Based on the findings of the present meta-analysis, the incidence of allergic events in the group receiving nab-paclitaxel was lower than in the group receiving traditional taxanes. More studies are needed to confirm the evidence and provide stronger results and a better understanding of side effects in patients receiving nab-paclitaxel and immunotherapy. Based on the present study's findings, neurotoxicity was more common in the group receiving nab-paclitaxel; However, the recovery time in this group was shorter than in the group receiving traditional taxanes.

Therefore, nab-paclitaxel use in patients at risk of neurotoxicity is significant because it can facilitate recovery from this adverse toxicity. Based on the findings of studies, the anti-tumor activity in the group receiving nab-paclitaxel was higher than that of traditional taxanes. In these studies, the prescribed dose was high.[30] Also, regarding the incidence of alopecia and fatigue, the nab-paclitaxel group was less than the docetaxel group, and less allergy was observed in the nab-paclitaxel comparison than the sb-paclitaxel group. Considering that the use of nab-paclitaxel in higher doses is more effective, however, the best-prescribed dose is 125 and 100 mg, which patients tolerate better. A study reported that a dose of 125 mg/m^2/w for nab-paclitaxel could have better compliance without compromising efficacy than a dose of 150 mg/m^2/w. Based on the present meta-analysis comparing traditional taxanes and nab-paclitaxel with doses of 125 and 150 mg/m^2/w, the incidence of neurotoxicity and side effects related to hematology in the nab-paclitaxel group was acceptable. Based on the present meta-analysis comparing traditional taxanes and nab-paclitaxel with doses of 125 and 150 mg/m^2/w, the incidence of neurotoxicity and side effects related to hematology in the nab-paclitaxel group was acceptable. The current study had some limitations, such as the data on side effects varied in granularity, and the method of determining side effects in the studies was different. In some studies, all the side effects that occurred in each patient were reported, while in other studies, only Complications were reported in 10% of patients. The number of RCT studies was small, making the present study's statistical significance less. More studies with a larger sample size are needed to provide stronger evidence.

5. Conclusion

According to the present meta-analysis, hematological and non-hematological side effects were higher in the group receiving nab-paclitaxel compared to the group receiving sb-paclitaxel and docetaxel. However, the recovery time of neurotoxicity was observed in the group receiving nab-paclitaxel. Using nab-paclitaxel at a lower dose than traditional taxanes and administration for three weeks leads to better patient tolerance.

Conflict of Interest

The authors declared that there is no conflict of interest.

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