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Nanoparticle-Based Doxorubicin Delivery for Triple-Negative Breast Cancer: A Systematic Review and Meta-Analysis.

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ABSTRACT

Background and aim: Triple-negative breast cancer (TNBC) is challenging due to its aggressive nature and limited targeted therapies. Doxorubicin-loaded nanoparticles have been proposed as a novel strategy to increase treatment efficacy and reduce side effects. This study aimed to conduct the first meta-analysis to evaluate the efficacy of these systems in in vitro and in-vivo TNBC models.

Material and methods: This study was conducted as a systematic review and meta-analysis. A systematic search of reputable scientific databases was conducted to identify studies published over the last 10 years, from January 2015 to September 2025. Eligible studies included those reporting quantitative data related to cell viability, IC50, and tumor volume reduction. Meta-analyses were performed using a random-effects model (DerSimonian–Laird), and subgroup analyses were conducted by nanoparticle type and TNBC cell model.

Results: A total of 8 eligible studies, including 15 datasets, were included in the meta-analysis. Doxorubicin-loaded nanoparticles resulted in a significant reduction in cell viability (effect size = 0.44), with more pronounced effects observed in FZD7-targeted nanoparticles and the MDA-MB-231 cell line. IC50 analysis indicated that exosome-based nanoparticles and polymeric nanoparticles exhibited the lowest IC50 values, reflecting enhanced drug cytotoxicity. Additionally, in vivo data demonstrated a significant reduction in tumor volume (effect size = 0.44), particularly for FZD7-targeted nanoparticles and sol–gel doxorubicin nanoparticles.

Conclusions: Doxorubicin-loaded nanoparticles significantly enhance TNBC treatment efficacy in vitro and in animal models, providing strong quantitative evidence for the development and clinical translation of these systems.

1. Introduction

One of the main causes of cancer-related deaths, especially in women, is breast cancer, which is highly prevalent worldwide;[1] according to global statistics from the World Health Organization, about 2.3 million new cases of breast cancer and more than 670,000 deaths from it occurred in 2022. By 2050, new cases and deaths will have increased by 38% and 68%, respectively.[2] Triple-Negative Breast Cancer (TNBC) is one of the most challenging types of breast cancer, due to its lack of estrogen, progesterone, and HER2 receptors.[3] TNBC accounts for approximately 10% to 20% of all breast cancer cases and is associated with aggressive behavior, high recurrence rates, rapid metastasis, and poor response to targeted therapies.[4, 5] The mainstay of treatment for patients with TNBC is chemotherapy based on anthracyclines and taxanes.[6] Doxorubicin is a key drug with a high therapeutic index, as it inhibits DNA synthesis in cancer cells.[7] However, non-targeted drug distribution in the body, dose-dependent cardiotoxicity, drug resistance, and reduced selectivity in tumor cells over healthy cells are limitations to the use of doxorubicin.[8] These limitations reduce the drug's clinical efficacy, necessitating consideration of new drug-delivery technologies. Nanotechnology is an innovative approach to drug delivery. Drug-carrying nanoparticles can enhance drug penetration and accumulation in tumor tissue, controlled release, reduced systemic toxicity, and tumor-specific targeting, thereby significantly enhancing drug efficacy.[9] In triple-negative breast cancer (TNBC), where effective targeted treatment options are limited, nanoparticle-based delivery of doxorubicin has the potential to enhance therapeutic outcomes while reducing treatment-related toxicities. Although a growing number of preclinical and clinical studies have explored various doxorubicin nanoparticle formulations for TNBC, the available evidence remains inconsistent and widely dispersed. Consequently, a comprehensive systematic review and meta-analysis are needed to integrate existing findings quantitatively and to clarify the overall efficacy and safety of nanoparticle-based doxorubicin delivery systems in the management of

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TNBC. Therefore, the present systematic review and meta-analysis aimed to evaluate the therapeutic efficacy and safety of nanoparticle-based doxorubicin delivery systems in patients with TNBC.

2. Material and methods

Search strategy

According to the PRISMA 2020 checklist,[10] the current study was conducted by searching PubMed, EMBASE, and Web of Science from January 2015 to September 2025 using relevant keywords; reviewing more recent studies (within the last ten years) ensures that the research results align with the latest evidence and up-to-date clinical approaches, thereby increasing their generalizability to current healthcare system conditions. Additional articles were identified by reviewing the references and relevant articles. Only English-language articles were included. Titles, abstracts, and full texts of studies were assessed through separate literature searches by two independent, blinded authors.

The following Mesh terms were used to retrieve literature:

(((((("Breast Neoplasms"[Mesh] OR "Triple Negative Breast Neoplasms"[Mesh]) OR ("Triple Negative Breast Neoplasms/classification"[Mesh] OR "Triple Negative Breast Neoplasms/complications"[Mesh] OR "Triple Negative Breast Neoplasms/diagnosis"[Mesh] OR "Triple Negative Breast Neoplasms/drug therapy"[Mesh] OR "Triple Negative Breast Neoplasms/mortality"[Mesh] OR "Triple Negative Breast Neoplasms/prevention and control"[Mesh] OR "Triple Negative Breast Neoplasms/surgery"[Mesh] OR "Triple Negative Breast Neoplasms/therapy"[Mesh])) AND ("Nanoparticles"[Mesh] OR "Nanoparticle Drug Delivery System"[Mesh])) OR ("Nanoparticles/administration and dosage"[Mesh] OR "Nanoparticles/adverse effects"[Mesh])) OR ("Nanoparticle Drug Delivery System/administration and dosage"[Mesh] OR "Nanoparticle Drug Delivery System/adverse effects"[Mesh] OR "Nanoparticle Drug Delivery System/toxicity"[Mesh])) AND "Doxorubicin"[Mesh].

Selection criteria

Inclusion criteria

Studies that met the requirements of the PICOS strategy were included:

Population (P): patients with TNBC.

Intervention (I): Nanoparticle-Based Doxorubicin Delivery

Comparison (C): Undefined control group

Outcome (O): clinical outcome

Studies (S): in-vitro/in-vivo studies.

Exclusion criteria

1. Reviews, literature, Letters to the Editor, Congress Abstracts.
2. Studies with incomplete or scattered data, failure to report complete data in the text of the article, lack of access to data.
3. Published language of the article other than English.
4. Studies that did not focus specifically on TNBC.
5. Studies that used non-nanoparticle formulations of doxorubicin.
6. Patients with metastases.
7. Patients with coagulation disorders, cardiac, hepatic, or renal dysfunction.

Data extraction

Two researchers independently and blindly extracted data from each included study using a researcher-made "Demographic and Primary Data Extraction" form; a third researcher resolved any disagreements between researchers. The data extraction form included the name of the first author, year of publication, Nanoparticle type, TNBC model, Study type, outcomes in vitro, and outcomes in vivo.

Quality assessment

In articles related to nanomedicine, an adapted version of OHAT is used to assess study quality, including design, reporting, and data analysis.

Statistical analysis

Statistical heterogeneity among studies was evaluated with the use of the I^2 statistic and Q test p-value < 0.05: No heterogeneity: 0.0% < I^2 < 24.9%; low heterogeneity: 25.0% < I^2 < 49.9%; Moderate heterogeneity: 50.0% < I^2 < 74.9%; High heterogeneity: 75.0% < I^2 < 100%. STATA/MP.v17 (College Station, Texas, USA) was used to perform the analyses. The random-effect model with the DerSimonian–Laird method was used to determine effect size (ES). Subgroup analyses were performed based on nanoparticle type and TNBC cell model.

3. Results

Literature search

According to the PRISMA 2020 Flow Diagram, after a comprehensive search based on keywords in international databases, 342 articles were found. After reviewing the titles of the articles, articles that did not meet the inclusion and exclusion criteria were excluded; the abstracts of 215 articles were reviewed and studies that did not meet the study selection criteria were excluded at this stage (n=184); Two blinded and independent authors carefully reviewed the full text of 31 articles, and a third researcher resolved disagreements; finally, after removing irrelevant articles, eight articles were included in the study for meta-analysis (Fig. 1).

Study characteristics

Table 1 summarizes the articles selected for the present study. Data extraction for each included study is reported in Supplementary Tables 1 Categorizing data for meta-analysis reported in Supplementary Table 2.

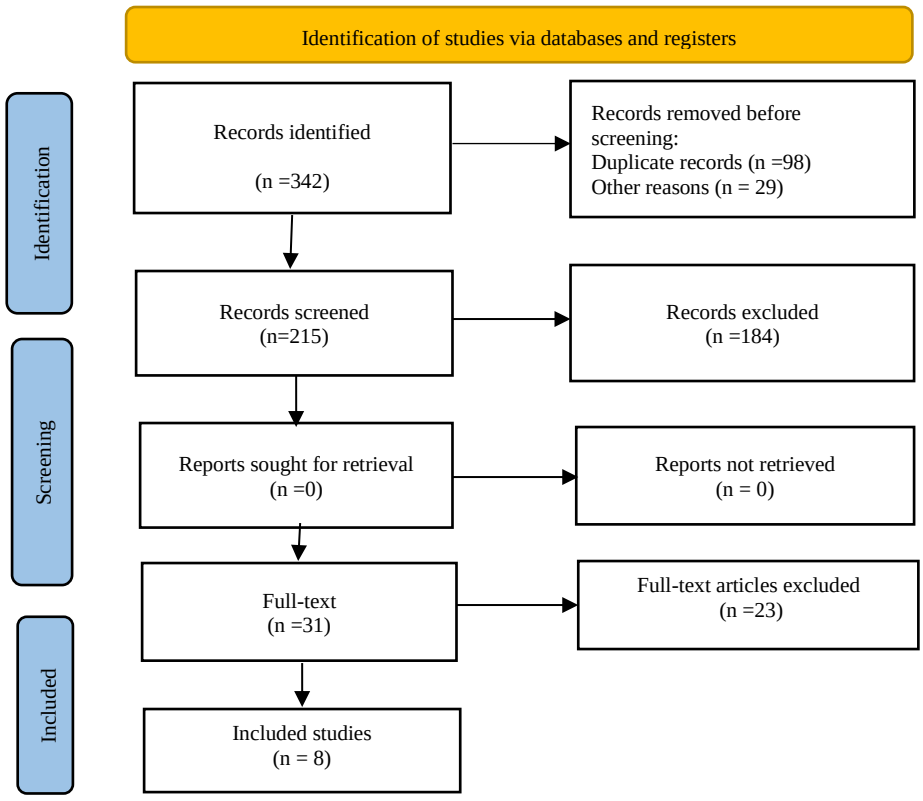

Fig. 1. PRISMA 2020 Flow Diagram.

Table 1. Characteristics of in vitro studies are included.

No.	Study. Years	Nanoparticle Type	TNBC Model	Study Type	Outcomes In-vitro	Outcomes In-vivo
1	Hoover et al., 2024[11]	FZD7-targeted NP	TNBC cell lines	in-vitro + mouse xenograft	viability, apoptosis, uptake	tumor volume reduction, apoptosis markers
2	Sarkar et al., 2024[12]	Exosome-silica NP	TNBC stem-like cells	in-vitro + xenograft	proliferation, EMT inhibition	tumor growth, metastasis
3	Zhang et al., 2024[13]	Exosome-mimetic NP	TNBC cell lines	in-vitro + mouse	migration, uptake, apoptosis	tumor size, survival
4	Wei et al., 2024[14]	Au-Fe_3O_4 Janus NP	TNBC cell lines	in-vitro + mouse	ROS, ferroptosis	tumor regression, ROS in tissue
5	Cavanagh et al., 2024[15]	polymer nanoparticles	TNBC cell lines	in-vitro	IC50 ،nuclear localization ، synergy, cell survival,	-----
6	Zhang M, 2023[16]	Magnetic-targeted NP	TNBC cell lines	in-vitro + mouse	uptake, viability	tumor accumulation, volume
7	Zhou et al., 2023[17]	ROS-responsive galactosylated NP	TNBC cell lines	in-vitro + xenograft	IC50, cytotoxicity	tumor growth inhibition
8	Krausz et al., 2018[18]	sol–gel based DOX nanoparticles ا	TNBC cell lines	in-vitro	MTT/SRB viability, dose–response metrics	-----

Bias assessment

Using the adapted OHAT risk of bias tool, most included in vitro studies were judged to have a low risk of bias across key domains. Selection bias and exposure characterization were consistently well addressed, reflecting appropriate cell line sourcing and detailed nanoparticle characterization. Confounding bias was rated as probably low in most studies, given standardized culture conditions and the inclusion of appropriate controls. Blinding was rarely reported and therefore classified as unclear across studies. Older studies demonstrated a moderate risk associated with incomplete outcome reporting and limited nanoparticle characterization (Table 2). A random-effects meta-analysis including nine in vitro comparisons demonstrated that nanoparticle-based doxorubicin delivery significantly reduced TNBC cell viability (45%) (pooled effect size = 0.45; 95% CI: 0.37–0.53; $P < 0.001$). Moderate heterogeneity was observed across studies (I^2 = 41.69%). Subgroup analysis based on nanoparticle type showed a significant reduction in viability for FZD7-targeted nanoparticles (effect size = 0.45; $P < 0.001$), whereas ROS-responsive nanoparticles did not reach statistical significance. However, no significant differences were detected between nanoparticle types ($P = 0.74$). When stratified by the TNBC model, studies using MDA-MB-231 cells demonstrated a statistically significant effect (effect size = 0.45; $P < 0.001$), while results in 4T1 models were inconclusive due to limited data. No significant differences were detected between the TNBC model ($P = 0.70$). (Fig. 2)

Table 2. OHAT risk of bias assessment.

Study	Selection	Confounding	Exposure Characterization	Outcome Assessment	Incomplete Data	Selective Reporting	Other Bias	Overall
Hoover et al., 2024[11]	Low	Probably low	Low	Low	Low	Low	Unclear	Low
Sarkar et al., 2024[12]	Low	Probably low	Low	Low	Low	Low	Unclear	Low
Zhang et al., 2024[13]	Low	Low	Low	Low	Low	Low	Unclear	Low
Wei et al., 2024[14]	Low	Probably low	Low	Low	Low	Low	Unclear	Low
Cavanagh et al., 2024[15]	Low	Moderate	Low	Low	Moderate	Low	Unclear	Moderate
Zhang M, 2023[16]	Low	Probably low	Low	Low	Low	Low	Unclear	Low
Zhou et al., 2023[17]	Low	Moderate	Moderate	Low	Moderate	Low	Unclear	Moderate
Krausz et al., 2018[18]	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Unclear	Moderate–High

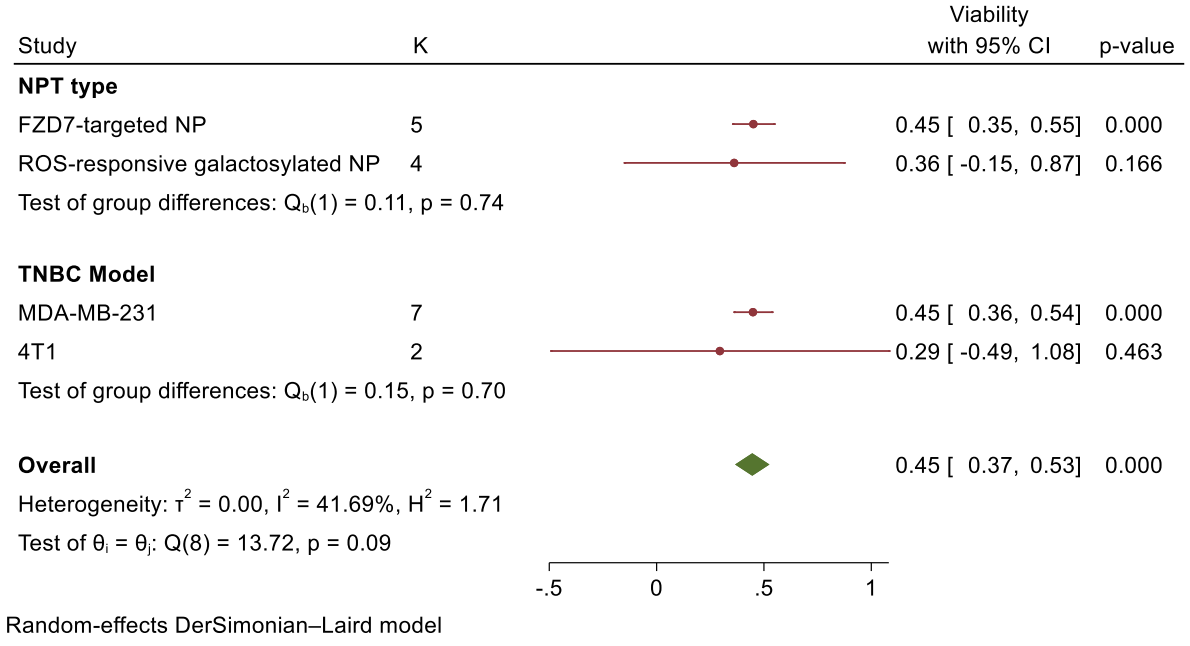

Fig. 2. The forest plot shows subgroup meta-analyses of TNBC cell viability.

The subgroup analysis revealed a statistically significant difference between nanoparticle types (Q_b= 36.71, P < 0.001), indicating that NP formulation significantly influenced IC50 values. Polymeric nanoparticles demonstrated the lowest pooled IC50 (3.93 µM), followed by sol–gel DOX-loaded nanoparticles (5.61 µM), both of which showed statistically significant cytotoxic enhancement. ROS-responsive nanoparticles exhibited the highest pooled IC50 (14.72 µM) with wide confidence intervals. Exosome–silica nanoparticles showed a very low pooled IC50 (0.33 µM); however, this estimate did not reach statistical significance due to the limited number of included studies (n = 2) and wide uncertainty. Despite stratification, high within-subgroup heterogeneity persisted across all NP categories (I^2 > 85%) (Fig. 3). Subgroup analysis based on TNBC cell lines demonstrated a significant between-group difference (Q_b = 8.05, P = 0.045), suggesting that the cellular model modulated cytotoxicity to nano-DOX formulations. The murine 4T1 cell line showed the highest pooled IC50 (24.04 µM), whereas human TNBC cell lines MDA-MB-231 and MDA-MB-468 exhibited substantially lower IC50 values (3.46 µM and 3.71 µM, respectively). The SUM149PT cell line demonstrated an intermediate response (5.61 µM). Heterogeneity within each cell-line subgroup remained high (I^2 > 90%) (Fig. 3).

Subgrouping by TNBC model revealed that studies conducted in MDA-MB-231 xenograft models showed a statistically significant reduction in tumor volume (ES: 44%; 95% CI: 0.39–0.49; P<0.001) (Fig. 3).

According to tests of subgroup differences, no statistically significant differences were found between nanoparticle types (Q(b) = 0.58, P = 0.989) or TNBC models ($Q_{(b)}$ = 0.46, P = 0.793), suggesting a broadly consistent tumor volume–reducing effect across formulations and biological models (Fig. 3).

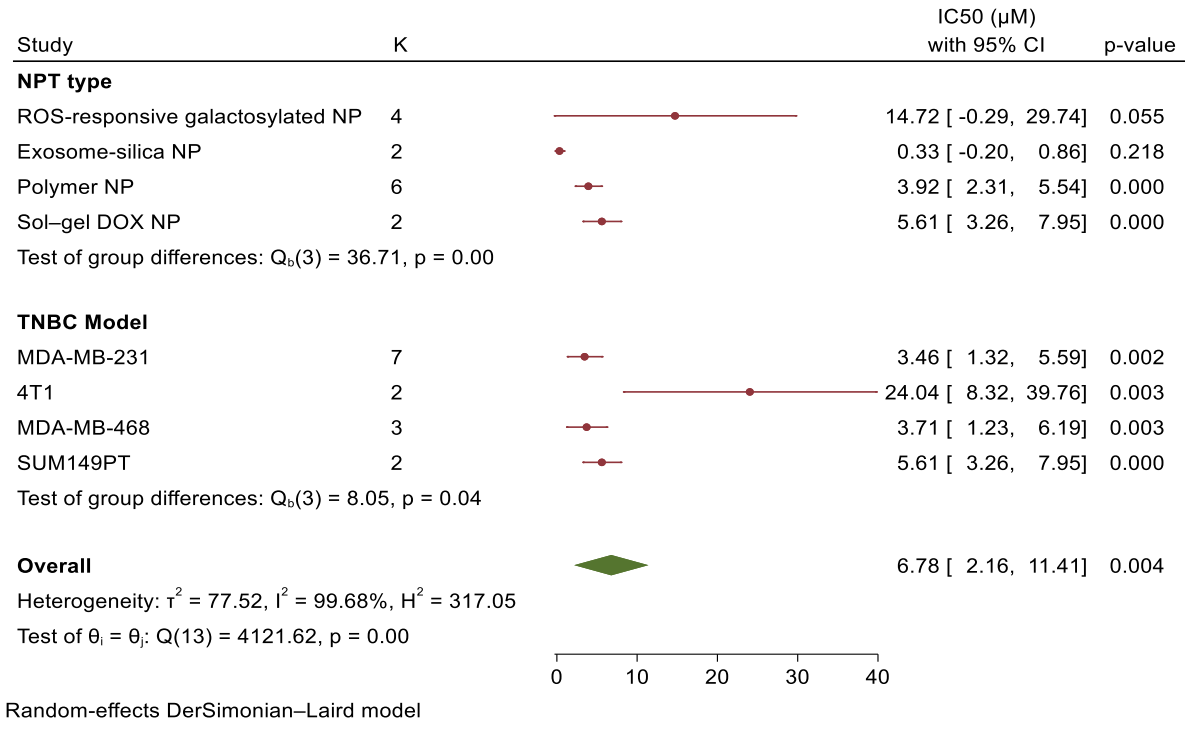

Fig. 3. The forest plot shows subgroup meta-analyses of IC50 (μM).

The meta-analysis demonstrated a statistically significant reduction in tumor volume, with an overall effect size of 44% (95% CI: 0.39 to 0.49, P<0.001). This finding indicates that nanoparticle-mediated DOX delivery is associated with consistent tumor volume suppression across in vivo TNBC studies. no statistical heterogeneity was detected in the overall analysis (I^2 = 0.0%, P = 1.000) (Fig. 4).

FZD7-targeted nanoparticles demonstrated a statistically significant tumor volume reduction (ES: 44%; 95% CI: 0.39–0.49; P<0.001). Sol–gel DOX nanoparticles exhibited a significant reduction in tumor volume (ES: 60%; 95% CI: 0.12–1.09; P = 0.015). In contrast, Au–Fe_3O_4 Janus nanoparticles, exosome–silica nanoparticles, magnetic-targeted nanoparticles, and ROS-responsive nanoparticles showed non-significant pooled effects (Fig. 4).

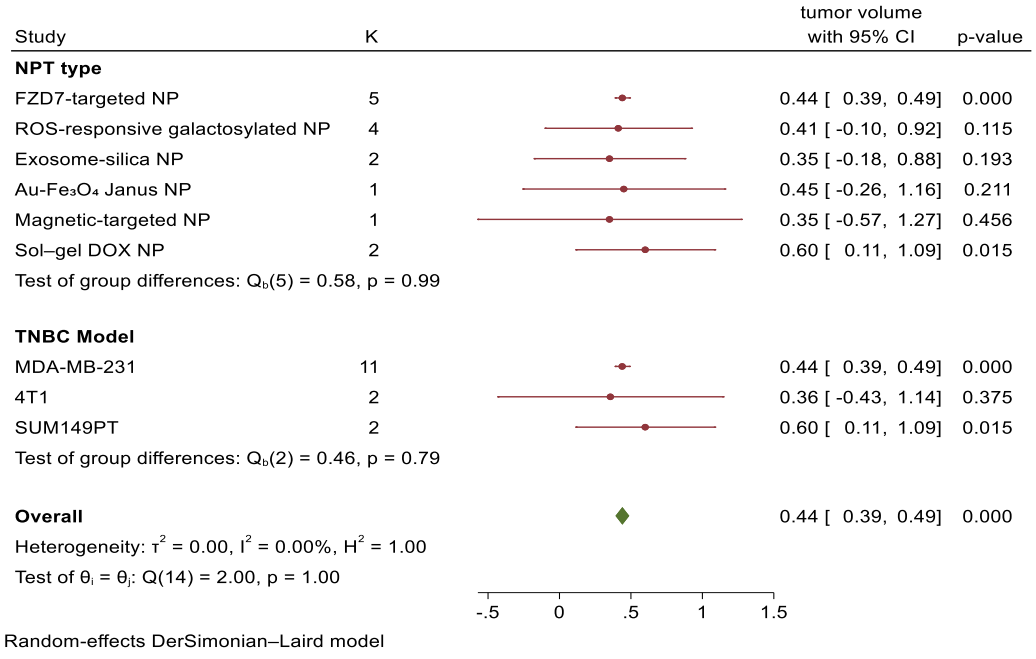

Fig. 4. The forest plot shows subgroup meta-analyses of tumor volume.

4. Discussion

For the first time, the present study has conducted a comprehensive quantitative meta-analysis on doxorubicin-loaded nanoparticles for the treatment of triple-negative breast cancer (TNBC), encompassing both in vitro and in vivo models. While previous systematic reviews have mainly focused on qualitative assessments or specific models, this research combines quantitative data. It performs subgroup analyses to reveal the effects of different nanoparticle types and cellular models on key outcomes, including viability, IC50, and tumor volume reduction. This approach allows for direct comparisons between nanoparticle types and cell models, filling an important gap in the existing literature. The results of this meta-analysis showed that the use of nanoparticles significantly increased the efficacy of doxorubicin in in vitro and in-vivo models. Based on the results of the present meta-analysis, the pooled mean cell viability following doxorubicin-loaded nanoparticle treatment was 0.44, indicating a significant reduction in TNBC cell survival. This effect was particularly pronounced for FZD7-targeted nanoparticles and in the MDA-MB-231 cell model. These findings are consistent with previous systematic reviews; for instance, Ramayanam et al.,[19] reported that targeted nanoparticles enhance intracellular uptake and induce apoptosis in TNBC cells. However, due to the high heterogeneity of formulations, quantitative meta-analysis was not feasible in those studies.

The present research, by aggregating quantitative data, largely fills this gap and provides a clearer estimate of the efficacy of different nanoparticle types in reducing TNBC cell viability.[19] The IC50-related findings indicated that nanoparticle type plays a decisive role in determining TNBC cell sensitivity to doxorubicin. Exosome-based and polymeric nanoparticles exhibited the lowest IC50 values, indicating a marked enhancement in the drug's cytotoxic potency when delivered via these systems. In contrast, ROS-responsive nanoparticles, although mechanistically innovative, demonstrated substantial heterogeneity across studies. These results are consistent with the Sen et al. (2023) study, which reported that biomimetic delivery systems such as exosomes offer superior drug delivery efficiency compared with synthetic nanoparticles, while also emphasizing that their standardization and reproducibility remain significant challenges.[20] The meta-analysis of tumor volume outcomes demonstrated that doxorubicin-loaded nanoparticles significantly reduced tumor volume in in vivo models (effect size = 0.44). FZD7-targeted nanoparticles and sol–gel DOX nanoparticles exhibited the greatest tumor growth inhibition, indicating superior antitumor efficacy among the evaluated delivery systems. The very low heterogeneity observed in this analysis suggests high consistency across studies, strengthening the robustness of the findings. These results are in line with the Choi et al. (2023) study, which reported that targeted nanoparticle formulations achieve enhanced tumor accumulation and reduced systemic toxicity compared with free doxorubicin.[21] Subgroup analyses indicated that both nanoparticle type and cellular model influence therapeutic efficacy; however, between-subgroup differences were not statistically significant for some outcomes. This lack of significance is likely attributable to the limited number of studies within certain subgroups and to substantial methodological variability, including differences in drug dosage, treatment duration, and outcome assessment methods. Previous reviews have similarly highlighted these limitations and emphasized the need for more standardized experimental designs to enable more robust quantitative comparisons.

The strengths of the present study include the first quantitative meta-analysis focused on nanosized doxorubicin in TNBC, simultaneous analysis of in vitro and in-vivo data, and careful assessment of bias using the OHAT tool. However, limitations such as high heterogeneity in IC50 data, limited clinical studies, and differences in trial design should be considered when interpreting the results.

5. Conclusion

This meta-analysis provides clear evidence that nanoparticle-based delivery systems substantially enhance the therapeutic performance of doxorubicin in triple-negative breast cancer. By overcoming key limitations of free doxorubicin, namely poor selectivity and systemic toxicity, nanoparticle formulations enable more effective drug–tumor interactions, translating into improved cellular cytotoxicity and meaningful tumor growth suppression in vivo. The present study established a comparative framework to evaluate the impact of different types of nanoparticles in TNBC and observed that targeted and biomimetic systems consistently outperformed non-targeted approaches. Overall, the present results support the integration of rationally designed nanocarriers into future TNBC therapeutic paradigms and provide a quantitative benchmark for the development, optimization, and clinical application of next-generation doxorubicin-based nanotherapeutics. The results of the present study suggest that nanoparticle systems, especially targeted and biomimetic nanoparticles, could be a promising strategy for improving TNBC treatment. However, translating these findings into the clinic requires well-designed clinical trials, standardized reporting, and direct comparison with free doxorubicin.

Conflict of Interest

The authors declared that there is no conflict of interest.

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