www.ijmio.com

ScientificScholar®
Knowledge is power
Publisher of Scientific Journals

International Journal of Molecular and Immuno Oncology

Original Article

Real-world study on the effect of nab-paclitaxel treatment on clinical outcomes and laboratory parameters in patients across metastatic tumor sites

Vikas Talreja[1], Sangeeta Khetwani[2], Ethirajan Nanadagopal[3], Nilesh Eknath Borkar[3], Kunal Khobragade[3]

[1]Department of Medical and Hemato Oncology, Regency Hospital, [2]Department of Pediatric Oncology, Rama Hospital, Kanpur, Uttar Pradesh, [3]Department of Medical Affairs, Mankind Specialties, Mumbai, Maharashtra, India.

***Corresponding author:**
Vikas Talreja,
Department of Medical and Hemato Oncology,
Regency Hospital, Kanpur,
Uttar Pradesh, India.

oncohematkanpur@gmail.com

Received: 29 February 2024
Accepted: 12 March 2024
EPub Ahead of Print: 24 July 2024
Published: 21 November 2024

DOI
10.25259/IJMIO_5_2024

Quick Response Code:

ABSTRACT

Objectives: PacliALL™ is the first and only indigenously developed brand of nab-paclitaxel in India that has shown bioequivalence to the global reference (Abraxane®). However, real-world Evidence is scarce about the use of it in different tumor sites beyond approved indications. This study assessed the effects of nab-paclitaxel (PacliALL™) on clinical outcomes in patients diagnosed with different metastatic cancers in a tertiary care hospital in India.

Material and Methods: In this retrospective study, data on demographics, medical history, and laboratory investigations were collected from medical records of patients with metastatic cancer. Patients on nab-paclitaxel were included, and data on laboratory findings, including hematological, liver, and kidney function tests and prognostic outcomes, were evaluated.

Results: The study population consisted of 73 patients with metastatic cancer (mean age- 54.6 years). Primary sites of cancer in most patients were the oral cavity (40.8%), followed by breast and ovary (15.3%, each). The Eastern Cooperative Oncology Group score was 0 in 84.3% and 1 in 14.3% of patients. Weekly analyses showed no significant differences in hemoglobin, neutrophil, creatinine, random blood glucose (RBG), and serum glutamic-oxaloacetic transaminase levels. A significant proportion of patients reported anemia and RBG >125 mg/dL at baseline (97.1% and 63.4%, respectively) and week 17 (85.1% and 88.1%, respectively). Most patients had a partial response at week 17 (76.8%), respectively. No serious adverse reactions were reported, requiring a change in treatment.

Conclusion: Nab-paclitaxel showed manageable tolerability and favorable response rates in metastatic cancer patients. It is widely used beyond approved indications in a significant proportion of patients across various tumor sites.

Keywords: Nab-paclitaxel, Neutropenia, Metabolic, Metastatic cancer, Real-world

INTRODUCTION

Managing cancer is an ever-evolving journey marked by the ongoing development of innovative treatment options. Conventional treatment approaches for cancer consist of surgery, chemotherapy, and radiotherapy, whereas contemporary methods encompass hormone therapy, anti-angiogenic treatments, stem cell therapy, immunotherapy, and dendritic cell-based immunotherapy.[1] For years, chemotherapy has played a central role in treating metastatic

cancers, with a widely recognized consensus that taxanes are among the most potent individual agents.[2]

Paclitaxel is a commonly employed pharmaceutical preparation derived from natural anti-cancer compounds extracted from a plant source, *Taxus brevifolia*. It holds significant importance in the treatment of various cancer types, including breast cancer, lung cancer, pancreatic cancer, and more, making it a typical and essential component in chemotherapy.[3] The solvent-based paclitaxel may require premedication with prophylactic steroids, antihistamines, and H2 receptor blockers due to a risk of hypersensitivity. In addition, it has limitations in terms of slower tissue penetration and elimination, which results in lower intratumoral drug concentrations.[4,5] In January 2005, the United States Food and Drug Administration approved nanoparticle albumin-bound paclitaxel (nab-paclitaxel), Abraxane®, which uses albumin to deliver paclitaxel, as a safer alternative to toxic solvents. It is indicated for the treatment of various cancers, including metastatic breast cancer (MBC), after failed combination chemotherapy or relapse within six months of adjuvant chemotherapy, locally advanced or metastatic non-small-cell lung cancer (NSCLC) in combination with carboplatin for patients' ineligible for curative surgery or radiation therapy, and metastatic adenocarcinoma of the pancreas in combination with gemcitabine as a first-line treatment.[6] In 2011, DCGI India approved PacliALL™ as an anti-cancer treatment, which is a cost-effective generic alternative to Abraxane® based on a series of pre-clinical studies in which it established comparable tumor regression benefits and a multi-centric bioequivalence study in MBC comparing Abraxane®.

The nab-paclitaxel offers numerous practical benefits, such as a reduced infusion duration of only 30 min and the elimination of the need for pre-medications to prevent hypersensitivity reactions. Furthermore, nab-paclitaxel exhibited quicker and more extensive tissue penetration, a briefer period of elevated systemic exposure, and delayed elimination of paclitaxel in comparison to cremophor EL-paclitaxel.[7] In addition, it exhibits improved response rates and enhanced tolerability in patients with advanced MBC and NSCLC.[8,9] Evidence suggests that the nab formulations of paclitaxel achieve 49% higher dose delivery and 33% higher intratumoral concentration of paclitaxel as compared to solvent-based paclitaxel formulations.[4,10] A randomized, open-label, two-period, two-treatment, single-dose, crossover, and bioequivalence study comparing generic nab-paclitaxel (PacliALL) and originator nab-paclitaxel (Abraxane®) was conducted in MBC patients across 15 centers in India. The 90% confidence interval (CI) of the relative mean C_{max} (90.33%, 121.47%), AUC_t (84.74%, 113.80%), and AUC_i (82.68%, 112.02%) of the generic nab-paclitaxel to originator product formulation was within the bioequivalence criteria, thus indicating that generic nab-paclitaxel is bioequivalent to originator nab-paclitaxel along with comparable safety profile. The bioequivalence study in MBC holds the most promising alternative for originators in India at an affordable cost.

Although several clinical studies from the US and Europe have demonstrated the efficacy and safety of nab-paclitaxel in various cancer types, including head and neck, ovary, gallbladder, and biliary tract,[3,11-15] the real-world Evidence demonstrating effectiveness and tolerability is limited, especially from India. Therefore, to address these gaps in the real-world evidence of nab-paclitaxel use in Indian settings, this study aimed to assess the effects of nab-paclitaxel (PacliALL) on clinical outcomes in patients diagnosed with different metastatic cancers.

MATERIAL AND METHODS

This retrospective study was carried out in patients with metastatic cancers who underwent treatment with nab-paclitaxel injection in a tertiary care hospital from Kanpur, Uttar Pradesh, India, from January 2022 to June 2023. It was conducted in accordance with ethical principles that are consistent with the Declaration of Helsinki. The study protocol was approved by the Institutional Ethics Committee.

Patients with metastatic cancers who underwent treatment with PacliALL (nab-paclitaxel) injection, a bioequivalent to Abraxane®, were selected and retrospectively analyzed for this study. The detailed inclusion criteria were patients aged between 18 and 85 years diagnosed with metastatic cancer (any stage) that was histopathologically/cytologically confirmed, refractory/recurrent to the previous treatment, with Eastern Cooperative Oncology Group (ECOG) performance status between 0 and 2, with at least one measurable lesion as per the Response Evaluation Criteria in Solid Tumors, with a known case of type 2 diabetes, hypertension, or dyslipidemia and treated with nab-paclitaxel for six cycles. Patients with a known history of hypersensitivity to paclitaxel or any other taxane or compounds chemically/biologically related to paclitaxel or excipients, known central nervous system lesions (brain metastasis or carcinomatous meningitis), active infections, systemic corticosteroid use in a year or with hematologic malignancies, life expectancy more than six months, or with any other medical condition, in which the opinion of the investigator would prohibit the patient's inclusion in the study and pregnant or lactating women were excluded from the study.

Data collection

Details of demographic data, medical history, and laboratory investigations were collected from the medical records of the selected patients. Laboratory investigations, including hematological tests (hemoglobin and neutrophils), liver

function test (serum glutamic-oxaloacetic transaminase [SGOT]), kidney function test (serum creatinine), and random blood glucose (RBG) test at week 1, week 2, and week 3 for each of the six cycles were evaluated. Patients' prognoses and adverse reactions were also identified from the medical records.

Statistical analysis

Statistical analysis was done using the Statistical Package of the Social Sciences software version 23. Descriptive statistics was used to summarize the categorical variables using frequency and percentages, while continuous variables were presented as mean and standard deviation. In addition, the K-independent *t*-test was used to analyze variation in laboratory parameters over six cycles. $P < 0.05$ was considered as statistically significant.

RESULTS

The data of 73 patients diagnosed with metastatic cancer and who were initiated with nab-paclitaxel injection were analyzed in this study. The mean (standard deviation) age of the study population was 54.6 (12.0) years with a male predominance (52.7%) [Table 1]. The mean height, weight, and body surface area were 157.9 cm, 70.6 kg, and 1.7 m^2, respectively. The majority of the patients presented with an ECOG performance scale score of 0 (84.3%), followed by those with a score of 1 (14.3%) and a score of 2 (1.4%). The primary site of cancer in the majority of the patients was the oral cavity (40.8%), followed by the breast (15.3%) and ovary (15.3%). All patients did not receive prior treatment except one patient who had received prior treatment with chemotherapy.

The analyses of response to treatment were done at week eight and week 17, with the majority of the patients demonstrating a partial response (87.1% and 76.8%, respectively), followed by those with progressive disease (11.4% and 14.5%, respectively). Complete response was observed in 1.4% of patients at week 8, while stable disease was observed in 8.7% of patients at week 17.

Patients received nab-paclitaxel over a mean period of 18 weeks in six cycles. None of the patients required a pre-medication while administration of nab-paclitaxel. None of the patients required a treatment change during the study period. Weekly analysis over a period of six cycles revealed no significant differences in hemoglobin, neutrophil, serum creatinine, RBG, and SGOT levels [Table 2] ($P > 0.05$). The majority of patients reported anemia at week 0 (97.1%), week 8 (90.0%), and week 17 (85.1%). The majority of the patients documented high levels of neutrophils (>60%) at week 8 (53.5%) and week 17 (62.7%). Similarly, greater number of patients had creatinine levels within normal limits at week 8 (68.6%) and week 17 (73.2%). Compared to baseline, at week 8, the percentage of patients with RBG levels exceeding 125 mg/dL was higher (80.0%) and further increased (88.1%) at week 17 [Table 3]. No serious adverse reactions leading to drug discontinuation were documented during the study period.

Table 1: Baseline characteristics of the study population.

Parameters	Number of patients (*n*=73)
Age (years) [*n*=72]	54.6 (12.0)
Gender [*n*=72], *n* (%)	
Male	38 (52.7)
Female	34 (47.2)
Height (cm) [*n*=72]	157.9 (5.4)
Weight (kg) [*n*=72]	70.6 (3.9)
BSA (m^2) [*n*=72]	1.7 (0.1)
ECOG [*n*=70], *n* (%)	
0	59 (84.3)
1	10 (14.3)
2	1 (1.4)
Primary site of cancer [*n*=72], *n* (%)	
Oral cavity	29 (40.8)
Breast	11 (15.3)
Ovary	11 (15.3)
Head and neck	5 (6.9)
Lung	3 (4.2)
Esophagus	2 (2.8)
Cervix	2 (2.8)
Others	10 (12.5)
Prior treatment [*n*=72], *n* (%)	
Yes	1 (1.4)
No	71 (98.6)
Concomitant treatment	
Carboplatin	64 (87.7)
Carboplatin + Cisplatin + Nimotuzumab	1 (1.4)
Carboplatin + Cetuximab	2 (2.7)
Carboplatin + Trastuzumab	4 (5.5)
Carboplatin + Trastuzumab + Gemcitabine	1 (1.4)
Trastuzumab	1 (1.4)

Data presented as mean (SD), unless otherwise specified. Others: vulva (1), vallecula (1), gallbladder (1), adenocarcinoma (1), endometrium (1), invasive duct carcinoma (1), CA and canal (1), Squamous CBLC carcinoma larynx (1), Squamous cell carcinoma with PNI (1) and missing (1). BSA: Body surface area, ECOG: Eastern Cooperative Oncology Group

DISCUSSION

The nab-paclitaxel is a solvent-free version of paclitaxel crucial in treating breast, lung, pancreatic, and other cancers. Nab formulations of paclitaxel demonstrate enhanced tumor-targeting activity through the binding mechanisms of Gp60 (a 60-kDa sialoglycoprotein) and secreted protein acidic and rich in cysteine (SPARC). On the surfaces of endothelial and cancer cells, Gp60 and SPARC are

Table 2: Variation in laboratory parameters during different cycles of nab-paclitaxel treatment.

Cycles	Week 1	Week 2	Week 3	*P*-value
Hemoglobin (g/dL)				
Cycle 1	10.5 (1.9)	10.9 (0.9)	10.9 (1.0)	0.941
Cycle 2	10.9 (1.1)	11.0 (1.1)	11.0 (1.1)	0.889
Cycle 3	11.0 (1.5)	11.0 (1.6)	10.9 (1.2)	0.976
Cycle 4	10.9 (1.1)	11.0 (1.1)	10.9 (1.1)	0.650
Cycle 5	11.0 (1.2)	10.9 (1.1)	11.0 (1.2)	0.778
Cycle 6	10.9 (1.1)	10.8 (1.7)	10.9 (1.8)	0.835
Neutrophils (%)				
Cycle 1	59.1 (1.8)	60.2 (2.2)	60.3 (2.2)	<0.0001
Cycle 2	60.6 (2.1)	60.5 (2.2)	60.4 (2.3)	0.760
Cycle 3	60.0 (2.3)	60.1 (2.3)	60.5 (2.4)	0.280
Cycle 4	60.3 (2.4)	60.7 (2.4)	60.3 (2.6)	0.603
Cycle 5	60.3 (2.3)	60.3 (2.4)	60.4 (2.0)	0.999
Cycle 6	60.4 (2.0)	60.5 (2.4)	61.3 (2.1)	0.068
Serum creatinine (mg/dL)				
Cycle 1	0.7 (0.1)	0.7 (0.2)	0.7 (0.1)	0.735
Cycle 2	0.7 (0.2)	0.7 (0.1)	0.7 (0.1)	0.812
Cycle 3	0.7 (0.1)	0.7 (0.2)	0.7 (0.1)	0.995
Cycle 4	0.7 (0.1)	0.7 (0.1)	0.7 (0.1)	0.806
Cycle 5	0.7 (0.2)	0.7 (0.1)	0.7 (0.1)	0.817
Cycle 6	0.7 (0.1)	0.7 (0.1)	0.7 (0.1)	0.656
SGOT (IU)				
Cycle 1	34.0 (11.3)	34.0 (11.2)	34.4 (11.4)	0.828
Cycle 2	34.1 (11.2)	34.4 (11.2)	34.4 (11.2)	0.823
Cycle 3	34.8 (11.1)	34.3 (11.8)	35.1 (11.2)	0.954
Cycle 4	34.2 (11.0)	34.4 (11.0)	34.6 (10.9)	0.821
Cycle 5	35.9 (15.9)	34.7 (11.1)	34.5 (10.9)	0.998
Cycle 6	34.6 (10.8)	34.5 (10.8)	34.4 (11.4)	0.981
Random blood glucose (mg/dL)				
Cycle 1	129.2 (6.0)	129.3 (5.9)	129.2 (5.6)	0.399
Cycle 2	129.4 (5.9)	129.3 (5.9)	129.2 (5.6)	0.907
Cycle 3	129.4 (5.9)	129.7 (5.8)	130.0 (5.9)	0.895
Cycle 4	129.5 (5.9)	129.8 (5.6)	129.6 (5.5)	0.786
Cycle 5	129.7 (5.6)	130.9 (9.2)	129.6 (5.5)	0.973
Cycle 6	129.9 (5.6)	130.0 (5.6)	130.3 (5.5)	0.842

Data presented as mean (standard deviation). SGOT: Serum glutamic-oxaloacetic transaminase

present.[16] Intratumoral delivery of nab-paclitaxel is higher than polymer-based formulations, which indicates higher targeted drug delivery, resulting in higher efficacy and lesser side effects due to better targeting of cancer cells.[17] Further, PacliALL is inherently present in an albumin-bound form, rendering it readily available for action without subjecting the patient to the exposure of synthetic polymeric formulations.

This study gathered real-world Evidence of the utilization of nab-paclitaxel in metastatic cancers and the key findings were as follows: (i) primary cancer sites were the oral cavity, breast, and ovary in a greater number of patients; (ii) weekly analysis over six cycles showed no significant differences in hemoglobin, neutrophil, creatinine, RBG, and SGOT levels; (iii) response at week eight and week 17 showed most of the patients reporting a partial response and smaller percentage reported progressive disease, and (iv) no major adverse reactions leading to discontinuation were reported during the study treatment.

In this study, the common sites of cancers reported were the oral cavity (40.8%), breast cancer (15.3%), and ovary (15.3%). A previously conducted retrospective study demonstrated a higher number of patients with breast (16.8) and ovarian (14.1%) cancer who were treated with nab-paclitaxel in metastatic cancers.[3] Furthermore, a prior Japanese study assessed paclitaxel's efficacy as a third-line treatment in patients who failed gemcitabine-cisplatin and fluoropyrimidine, indicating a promising disease control rate (83%) and a median overall survival of 9 months.[13] In the present study, the mean laboratory findings, including hemoglobin, neutrophil count, creatinine, SGOT, and RBG, were comparable from cycle 1 to cycle 6 of nab-paclitaxel

Table 3: Range of laboratory parameters in the study population.

Laboratory parameters	At week 0	At week 8	At week 17
Hemoglobin Level (g/dL)	[*n*=70]	[*n*=70]	[*n*=67]
≥12.0 (F) and ≥13.0 (M)	2 (2.9)	7 (10.0)	10 (14.9)
<12.0 (F) and <13.0 (M)	68 (97.1)	63 (90.0)	57 (85.1)
Neutrophils (%)	[*n*=71]	[*n*=71]	[*n*=67]
>60%	10 (14.1)	38 (53.5)	42 (62.7)
40–60%	61 (85.9)	33 (46.5)	25 (36.8)
<40%	0	0	0
Serum creatinine (mg/dL)	[*n*=70]	[*n*=70]	[*n*=67]
0.7 to 1.3 (M)	11 (15.7)	14 (20.0)	17 (25.4)
0.5 to 1.1(F)	33 (47.1)	34 (48.6)	32 (47.8)
<0.7 and >1.3 (M)	25 (35.7)	22 (31.4)	18 (26.9)
<0.5 and >1.1 (F)	1 (1.4)	0	0
Random blood glucose (mg/dL)	[*n*=71]	[*n*=70]	[*n*=67]
≤125	26 (36.1)	14 (20.0)	8 (11.9)
>125	45 (63.4)	56 (80.0)	59 (88.1)

Data presented as *n* (%). F: Female and M: Male

treatment, indicating a relatively stable metabolic profile during the treatment. However, few studies have proposed a potential correlation between the utilization of nab-paclitaxel and an elevated likelihood of developing metabolic disorders. Nab-paclitaxel at a dose of 100 or 125 mg/m^2/w exhibits fewer or comparable grade 3/4 specific adverse events than traditional taxanes, with a lower incidence of allergy. Despite fractional dosage analyses suggesting an increased risk of neurotoxicity, the median recovery times for neurotoxic events were notably shorter at 25 days for nab-paclitaxel versus 64 days for solvent-based paclitaxel. This underscores the importance of considering dosage and recovery timelines in evaluating the overall safety profile of nab-paclitaxel.[18] Another retrospective real-world study of MBC patients treated with nab-paclitaxel monotherapy also reported the absence of grade 3/4 hypersensitivity reactions, with only 1.9% of patients reporting low-grade hypersensitivity reactions.[19] Similarly, various other studies have reported better efficacy and tolerability of nab-paclitaxel in metastatic cancers.[10,20-22] Furthermore, Zheng *et al*. found a significant increase in the neutrophil count from baseline to cycle two during nab-paclitaxel treatment. In addition, they demonstrated a decrease in SGOT and creatinine in contrast to this study.[3] This variation warrants larger studies to be conducted in patients with metastatic cancers.

Anemia was reported in 97.1% at the baseline, which reduced to 90.0% and 85.1% of patients at weeks 8 and 17, respectively. These observations indicate that nab-paclitaxel treatment had no negative impact on anemia incidences. The average hemoglobin levels were higher in patients undergoing nab-paclitaxel treatment compared to those receiving paclitaxel for breast and pancreatic cancer.[23] Contrastingly, a decrease in hemoglobin was reported over two cycles of nab-paclitaxel.[3] Another study also demonstrated contrasting observations wherein anemia was documented in a greater number of patients with NSCLC who were on nab-paclitaxel as compared to those on solvent-based paclitaxel.[24]

In this study, at baseline, 63.4% of patients already had high RBG (>125 mg/dL), and further, a modest proportion of increase in patients with high RBG was reported at week 8 (80.0%) and week 17 (88.1%) from baseline (63.4%) indicating a slight increase in blood sugar levels post nab-paclitaxel treatment. However, it is crucial to highlight that hyperglycemia was observed in fewer patients undergoing nab-paclitaxel treatment as opposed to those receiving cremophor-based paclitaxel for breast cancer.[25] Similarly, in patients with ovarian cancer on nab-paclitaxel, high blood glucose was reported in only 5.0% of patients.[11]

At week 17, 76.8% of patients showed a partial response to treatment, and 14.5% had progressive disease. The partial response rate observed in this study is relatively higher than in the literature. A previous study in patients with metastatic head-and-neck squamous cell carcinoma treated with nab-paclitaxel, cetuximab, and carboplatin for three weeks, followed by nab-paclitaxel and cetuximab for three weeks until progression found that the overall response rate was 60%.[26] A meta-analysis documented the cumulative overall response rate to be 40%, followed by the cumulative partial remission reaching 38% and stable disease of 28% in patients with MBC who were treated with nab-paclitaxel monotherapy.[27] Furthermore, patients with NSCLC demonstrated a partial response (41.2%) to nab-paclitaxel treatment and progressive disease in 25.6% of patients.[28] In patients with ovarian cancer, the use of nab-paclitaxel was associated with progression-free survival (Hazards ratio = 0.411, 95% CI (0.224–0.753), P = 0.004).[11]

Limitations

The retrospective nature of this study poses a limitation. In addition, the limited number of participants restricts the ability to draw robust conclusions and extrapolate the results to broader populations, emphasizing the need for cautious interpretation. Furthermore, readers should note potential variations in concomitant treatments during the six cycles of nab-paclitaxel, introducing inherent limitations to the study's findings.

CONCLUSION

The retrospective evaluation found that nab-paclitaxel had been employed in a range of solid tumor sites, with the most common ones being ovarian, breast, and oral malignancies. The majority of patients reported essentially a partial response to therapy, and there were no serious side effects that necessitated discontinuing the medication. Throughout the course of six cycles, nab-paclitaxel therapy did not significantly alter hemoglobin, neutrophil percentage, creatinine, or SGOT levels; nevertheless, a greater proportion of patients endured increased RBG. Overall, the data from patients with various types of metastatic cancers signify the safety and efficacy of generic nab-paclitaxel use in Indian patients.

Acknowledgment

The authors would like to thank the study investigators and study participants, as well as their families/caregivers who were involved in this study. The medical writing support was provided by Kajol Lalwani and Tejal Vedak of Sqarona Medical Communications LLP, Pune and paid by Mankind Pharma Ltd.

Ethical approval

The research/study approved by the Institutional Review Board at Institutional Ethics Committee Regency Hospital, number ECR/825/INST/UP/2016/RR-19, dated 31st January, 2024.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

The study was funded by Mankind Pharma Ltd, India.

Conflicts of interest

Ethirajan Nandagopal, Nilesh Borkar, and Kunal Khobragade are employees of Mankind Pharma Ltd, India. All other authors have nothing to disclose.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript, and no images were manipulated using AI.

REFERENCES

1. Ueno NT, Mamounas EP. Neoadjuvant nab-paclitaxel in the treatment of breast cancer. Breast Cancer Res Treat 2016;156:427-40.
2. Anand U, Dey A, Chandel AK, Sanyal R, Mishra A, Pandey DK, *et al.* Cancer chemotherapy and beyond Current status, drug candidates, associated risks, and progress in targeted therapeutics. Genes Dis 2022;10:1367-401.
3. Zheng Q, Wang H, Xue C, Yang S, Wang Y, Hou W, *et al.* A retrospect study based on real-world data to observe metabolic function in cancer patients using albumin-bound paclitaxel. Sci Rep 2023;13:9028.
4. Desai N, Trieu V, Yao Z, Louie L, Ci S, Yang A, *et al.* Increased antitumor activity, intratumor paclitaxel concentrations, and endothelial cell transport of cremophor-free, albumin-bound paclitaxel, ABI-007, compared with cremophor-based paclitaxel. Clin Cancer Res 2006;12:1317-24.
5. Chen N, Li Y, Ye Y, Palmisano M, Chopra R, Zhou S. Pharmacokinetics and pharmacodynamics of nab-paclitaxel in patients with solid tumors: Disposition kinetics and pharmacology distinct from solvent-based paclitaxel. J Clin Pharmacol 2014;54:1097-107.
6. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021660s047lbl.pdf23 [Last accessed on 22020 Oct 12].
7. Tian Z, Yao W. Albumin-bound paclitaxel: Worthy of further study in sarcomas. Front Oncol 2022;12:815900.
8. Stinchcombe TE. Nanoparticle albumin-bound paclitaxel: A novel Cremphor-EL-free formulation of paclitaxel. Nanomedicine (Lond) 2007;2:415-23.
9. Yardley DA. Nab-Paclitaxel mechanisms of action and delivery. J Control Release 2013;170:365-72.
10. Gradishar WJ, Tjulandin S, Davidson N, Shaw H, Desai N, Bhar P, *et al.* Phase III trial of nanoparticle albumin-bound paclitaxel compared with polyethylated castor oil-based paclitaxel in women with breast cancer. J Clin Oncol 2005;23:7794-803.
11. Wang H, Fan L, Wu X, Han Y. Efficacy evaluation of albumin-bound paclitaxel combined with carboplatin as neoadjuvant chemotherapy for primary epithelial ovarian cancer. BMC Womens Health 2022;22:224.
12. Adkins D, Ley J, Trinkaus K, Thorstad W, Lewis J Jr., Wildes T, *et al.* A phase 2 trial of induction nab-paclitaxel and cetuximab given with cisplatin and 5-fluorouracil followed by concurrent cisplatin and radiation for locally advanced squamous cell carcinoma of the head and neck. Cancer 2013;119:766-73.
13. Tajima H, Ohta T, Shinbashi H, Hirose A, Okazaki M, Yamaguchi T, *et al.* Phase I study of weekly palliative chemotherapy with low-dose third-line paclitaxel for biliary

tract cancer. Mol Clin Oncol 2017;6:753-7.
14. Patel A, Sirohi B. Nab-paclitaxel - Third-line chemotherapy in advanced gallbladder cancer. Indian J Med Res 2020;152:442-3.
15. Weiss J, Gilbert J, Deal AM, Weissler M, Hilliard C, Chera B, *et al.* Induction chemotherapy with carboplatin, nab-paclitaxel, and cetuximab for at least N2b nodal status or surgically unresectable squamous cell carcinoma of the head and neck. Oral Oncol 2018;84:46-51.
16. Ma Y, Yu S, Ni S, Zhang B, Kung AC, Gao J, *et al.* Targeting strategies for enhancing paclitaxel specificity in chemotherapy. Front Cell Dev Biol 2021;9:626910.
17. Madaan A, Singh P, Awasthi A, Verma R, Singh AT, Jaggi M, *et al.* Efficiency and mechanism of intracellular paclitaxel delivery by the novel nanopolymer-based tumor-targeted delivery system, Nanoxel(TM). Clin Transl Oncol 2013;15:26-32.
18. He F, Liu J, Shen X, Wang Z, Li Q, Li G. Adverse event profile for nanoparticle albumin-bound paclitaxel compared with solvent-based taxanes in solid-organ tumors: A systematic review and meta-analysis of randomized clinical trials. Ann Pharmacother 2022;56:898-909.
19. Kim JS, Suh KJ, Lee DW, Woo GU, Kim M, Kim SH, *et al.* A real-world efficacy of nab-paclitaxel monotherapy in metastatic breast cancer. Cancer Res Treat 2022;54:488-96.
20. Lei L, Chen R, Fan L, Zheng W, Wang X. Efficacy and safety of nanoparticle-albumin-bound paclitaxel compared with conventional taxanes in women with breast cancer: A systematic review and meta-analysis. Ann Palliat Med 2022;11:2382-94.
21. Wang L, Li S, Zhu D, Qin Y, Wang X, Hong Z, *et al.* Effectiveness and safety of nab-paclitaxel and platinum as first-line chemotherapy for ovarian cancer: A retrospective study. J Gynecol Oncol 2023;34:e44.
22. Vishnu P, Roy V. Safety and efficacy of nab-paclitaxel in the treatment of patients with breast cancer. Breast Cancer (Auckl) 2011;5:53-65.
23. Alhebshi SA, Alsanosi SM, AlQashqri HS, Alhindi YZ, Bamagous GA, Ayoub NA, *et al.* Toxicity of nab-paclitaxel compared to paclitaxel in a tertiary hospital in Jeddah, Saudi Arabia: A retrospective cohort study. Cureus 2023;15:e39872.
24. Hirsh V, Ko A, Pilot R, Renschler MF, Socinski MA. Weekly nab-paclitaxel in combination with carboplatin as first-line therapy in patients with advanced non-small-cell lung cancer: Analysis of safety and efficacy in patients with diabetes. Clin Lung Cancer 2016;17:367-74.
25. Henderson IC, Bhatia V. Nab-paclitaxel for breast cancer: A new formulation with an improved safety profile and greater efficacy. Expert Rev Anticancer Ther 2007;7:919-43.
26. Adkins D, Ley J, Atiq O, Powell S, Spanos WC, Gitau M, *et al.* Nanoparticle albumin-bound paclitaxel with cetuximab and carboplatin as first-line therapy for recurrent or metastatic head and neck cancer: A single-arm, multicenter, phase 2 trial. Oral Oncol 2021;115:105173.
27. Lu H, Zha S, Zhang W, Wang Q, Jiang D, Xu X, *et al.* A systematic review and meta-analysis of nab-paclitaxel mono-chemotherapy for metastatic breast cancer. BMC Cancer 2021;21:830.
28. Dechow T, Riera-Knorrenschild J, Hackanson B, Janssen J, Schulz H, Chiabudini M, *et al.* First-line Nab-paclitaxel plus carboplatin for patients with advanced non-small cell lung cancer: Results of the NEPTUN study. Cancer Med 2021;10:8127-37.

How to cite this article: Talreja V, Khetwani S, Nanadagopal E, Borkar NE, Khobragade K. Real-world study on the effect of nab-paclitaxel treatment on clinical outcomes and laboratory parameters in patients across metastatic tumor sites. Int J Mol Immuno Oncol 2024;9:46-52. doi: 10.25259/IJMIO_5_2024