Effective management of a diabetic patient with hormone-receptor-positive, HER2-negative metastatic breast cancer using nanosomal docetaxel lipid suspension for 12 cycles: A case report

PRASANNA RAMMOHAN[1], LAV PATEL[2], DEEPAK BUNGER[2], ALOK CHATURVEDI[2] and IMRAN AHMAD[3]

[1]Department of Medical Oncology, Cancure Cancer Centre, Trichy, Tamil Nadu 620018, India; [2]Department of Medical Affairs, Intas Pharmaceuticals Limited (Corporate Office), Ahmedabad, Gujarat 380054, India; [3]Jina Pharmaceuticals Inc., Libertyville, IL 60048, USA

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Abstract. The present study reports a case of a 40-year-old diabetic female patient diagnosed with hormone receptor-positive, HER2-negative metastatic breast cancer (MBC) in July 2017 and admitted to Cancure Cancer Centre (Tiruchirappalli, India). Following initial surgery and adjuvant treatment with four cycles each of fluorouracil, doxorubicin, and Cyclophosphamide chemotherapy and paclitaxel, radiotherapy and tamoxifen, the patient developed multiple metastases to the liver, lung and bones 3 years later. Palliative treatment with nanosomal docetaxel lipid suspension (NDLS) was started, resulting in a partial response (PR) after six cycles. NDLS was continued for 12 cycles in total, with good tolerance and no serious adverse effects. The patient maintained a PR and was managed with maintenance leuprolide, letrozole and palbociclib. The patient developed disease progression and died in July 2024, leading to a progression-free survival of ~ two years and an overall survival of two years and six months. To the best of our knowledge, the present case is among the first to report the safety and efficacy of 12 cycles of NDLS in MBC.

Introduction

Breast cancer (BC) is the most common malignancy among female patients worldwide (1-3). In India, the incidence and mortality of breast cancer have increased over the past two decades (2). In 2020, GLOBOCAN reported 178,361 cases of BC in India, representing 13.5% of all cancer cases and 10.6% of all cancer-associated deaths (3). Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative BC, characterized by estrogen or progesterone receptors and the absence of HER2, constitutes 60-70% of all BC cases (4,5). While this subtype is more common in postmenopausal patients, it can also affect premenopausal patients, with risk increasing with age (6).

In metastatic BC (MBC), the primary goals are disease control and maintaining quality of life. Endocrine therapy is the first choice for HR-positive, HER2-negative MBC. When hormonal agents fail or metastases progress, chemotherapy (either single-agent or combination) is recommended based on disease aggressiveness, metastatic sites and patient factors such as age, comorbidities and performance status. In palliative settings, chemotherapy remains central (7). Anthracyclines and taxanes are recommended for HR-positive and HER2-negative MBC. Traditional taxanes such as docetaxel and paclitaxel have notable toxicity profiles, leading to treatment interruption and discontinuations. Although premedication with corticosteroids, antihistamines and other agents can reduce some toxicities, they do not eliminate the long-term challenges (8).

The conventional formulation of docetaxel uses polysorbate 80 and ethanol, which are associated with hypersensitivity reaction, fluid retention, peripheral neuropathy and other adverse effects (9,10). To address these issues, the nanosomal docetaxel lipid suspension (NDLS; Intas Pharmaceuticals Ltd., Ahmedabad, India) formulation was developed using lipids generally recognized as safe by the United States Food and Drug Administration (FDA) and is free of polysorbate 80 and ethanol and the related toxicities. NDLS has been approved by the Drugs Controller General of India for several types of cancer, including hormone-resistant prostate, advanced breast and non-small cell lung cancer (10). NDLS has been developed, using the 'NanoAqualip' technology, in which the drug is encapsulated in a lipid core and avoids the use of organic solvents or detergents at any stage of the manufacturing process. NDLS enhances systemic availability of docetaxel through enhanced permeability and retention effect, thereby potentially improving therapeutic outcomes (11). To evaluate the efficacy and safety of NDLS in treating BC, an open-label, randomized, multiple-dose, parallel-group study was conducted; this study compared NDLS with

Correspondence to: Dr Prasanna Rammohan, Department of Medical Oncology, Cancure Cancer Centre, C-88 Sasthri Road, Thillai Nagar, Trichy, Tamil Nadu 620018, India
E-mail: prasumoh81@gmail.com

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polysorbate-based docetaxel in patients with locally advanced or MBC who had previously failed chemotherapy. Overall therapeutic response (complete + partial) rate in patients with metastatic BC treated with NDLS and Taxotere were 35.5 and 26.3%, respectively, indicating a better response in patients treated with NDLS. Patients in the NDLS group were not premedicated with steroid premedication but the safety results of NDLS were found to be comparable with Taxotere (10). The safety and efficacy of NDLS has also been demonstrated in real-world settings (11-13). The present study reports the case of a premenopausal patient with HR-positive MBC with metastases to the liver, lung and bones and managed with NDLS.

Case report

In July 2017, a 40-year-old female patient presented to Cancure Cancer Centre at Tiruchirappalli, India and was diagnosed with HR-positive, HER2-negative left breast carcinoma. The patient underwent a modified radical mastectomy and received adjuvant chemotherapy with 5-fluorouracil 500 mg/m^2 i.v., doxorubicin 50 mg/m^2 i.v. and cyclophosphamide 500 mg/m^2 i.v., every 3 weeks for 4 cycles, followed by four cycles of paclitaxel (175 mg/m^2 i.v every three weeks) and 50 Gy/25 fractions of post-mastectomy radiation therapy. Tamoxifen (20 mg orally once daily) was administered starting January 2018.

In March 2021, a routine follow-up showed a solitary liver nodule. By October 2021, the patient had developed bilateral lung nodules (Fig. 1A) and multiple liver metastases (Fig. 1B), as well as metastases to the spine, sacral region and other bones. In December 2021, ultrasonography (USG) guided histopathological examination was performed. The tissue was collected from liver secondary lesion with the largest sample measuring 0.6x0.1x0.1 cm^3. Samples underwent fixation with buffered formalin for 5 h at room temperature (10 mm thickness) and rinsing with phosphate buffered saline. The dehydration was done with increasing concentrations of ethanol. Xylene was used as clearing agent to displace ethanol and remove fat from tissue and it was embedded in molten paraffin wax. Further, the formalin-fixed paraffin-embedded (FFPE) tissue block was stored at room temperature, was oriented in the center of block, and sectioning (5-10 um slice) was done with microtome. The tissue section was stained using hematoxylin and eosin (H&E), it was deparaffinized and rehydrated and stained in Mayers hematoxylin for 1 min followed by washing with tap water. The tissue section was counterstained with alcoholic eosin for 1 min and dehydrated with ethanol and cleared with xylene for 1 min. The tissue section was stained at 120˚C for 3 min and was further mounted in slide with cover slip for microscopic study using light microscope (Olympus CX23-10x, 40x) for morphological evaluation. TissueQuant Software (Version 4.0, Manipal School of Information Sciences, Manipal, India) was used for image analysis.

The histopathological examination (HPE) confirmed metastatic adenocarcinoma with high Ki-67 of 30% (normal range ≤5%: low; ≥30%: high), and an elevated CA15-3 of 74.2 U/ml (normal range: ≤30 U/ml). Due to secondary endocrine resistance and visceral crisis, palliative chemotherapy with NDLS (75 mg/m^2 i.v., every three weeks) was planned. The patient was diagnosed with type 2 diabetes in September 2021; HbA1c level at diagnosis was 7.2% (data not shown). Treatment was initiated with oral teneligliptin (20 mg) and metformin (500 mg) twice daily along with proper diabetic diet and physical exercise. The HbA1c level was 6.9% before the initiation of NDLS therapy (Fig. 1). To avoid hypersensitivity/infusion-associated reactions with conventional docetaxel, and corticosteroid premedication-associated hyperglycemia, NDLS 120 mg (75 mg/m^2 every three weeks) was administered. The patient received six cycles of NDLS and monthly zoledronic acid from January to June 2022 with no serious adverse events. Following 6 and 12 cycles of NDLS, the HbA1c level was 5.8 and 6.2% respectively (Fig. 2).

In June 2022, positron emission tomography-computed tomography (PET-CT) scan (Siemens 64 slice Hybrid) showed a partial response with decreased size of lung (Fig. 1C) and liver lesions (Fig. 1D), though residual osseous metastases remained. By December 2022, PET-CT revealed inactive lung (Fig. 1E) and hepatic (Fig. 1F) metastases with persistent but less active skeletal metastases, indicating a continued partial response. Maintenance hormonal therapy with leuprolide (11.25 mg intramuscular once every three months), oral letrozole and denosumab (120 mg subcutaneously every four weeks) was started and oral palbociclib (at a daily dose of 125 mg, with a regimen of 21 days on medication followed by 7 days off, every 28 days) was added in January 2023. Follow-up PET-CT scans in April 2023 showed stable lytic and sclerotic lesions with decreased metabolic activity in femoral lesions (data not shown). However, a PET-CT scan in November 2023 indicated disease progression, evidenced by an increased in the size of lesions in both lobes of the liver, predominantly in the left lobe. Subsequently, the patient was initiated on palliative hormonal therapy with fulvestrant (500 mg i.m) administered once a month for five months, until March 2024. A follow-up PET-CT in March 2024 revealed further disease progression, with enlargement of liver lesions, peritoneal nodules, and pelvic nodes (Fig. 3). An USG-guided liver biopsy and IHC analysis confirmed the presence of ER+/PR-/HER2-positive disease with a Ki67 index of 60%. Subsequently, the patient was commenced on palliative anti-HER2 therapy with trastuzumab emtansine (3.6 mg/kg, i.v, every 3 weeks). However, the patient succumbed to the disease in July 2024 leading to a progression-free survival (PFS) of approximately two years and an overall survival of two years and six months with NDLS and palliative maintenance therapy.

Discussion

BC is the most common malignancy in the world (14). The HR-positive/HER2-negative subtype, accounting for ~70% of new BC cases (14,15), is typically treated with endocrine therapy (ET), including selective estrogen receptor (ER) modulators and down regulators and aromatase inhibitors. ET remains the preferred treatment unless a visceral crisis is present. Visceral crisis, marked by severe organ dysfunction due to rapid disease progression, affects 10-15% of patients with advanced BC and necessitates more aggressive treatment. In cases of visceral crisis, cyclin-dependent kinase 4/6 inhibitors (CDK4/6is) combined with ET have shown better survival outcomes compared with ET alone (16). Palbociclib, the first FDA-approved CDK4/6i, has shown positive real-world

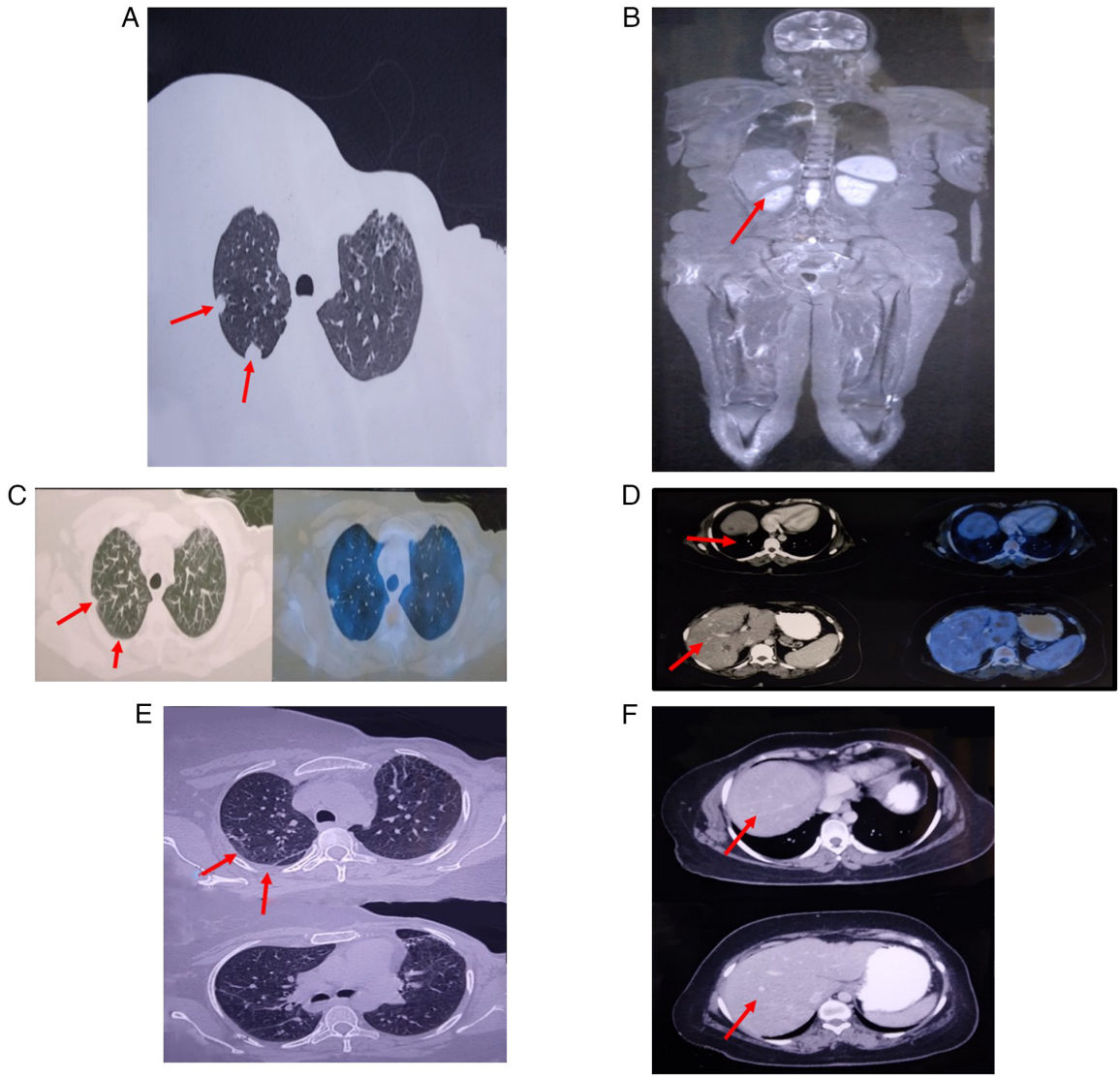

Figure 1. Positron emission tomography-computed tomography-based radiological response to NDLS treatment in a female diabetic patient with hormone receptor-positive metastatic breast cancer. (A) Bilateral lung nodules and (B) multiple liver metastases (arrow) were observed prior to NDLS treatment. Partial response was achieved following six cycles of NDLS, resulting in decreased size of (C) lung nodules and (D) liver lesions. Partial response was sustained following 12 cycles of NDLS, indicated by inactive (E) lung nodules and (F) liver lesions. NDLS, nanosomal Docetaxel Lipid Suspension.

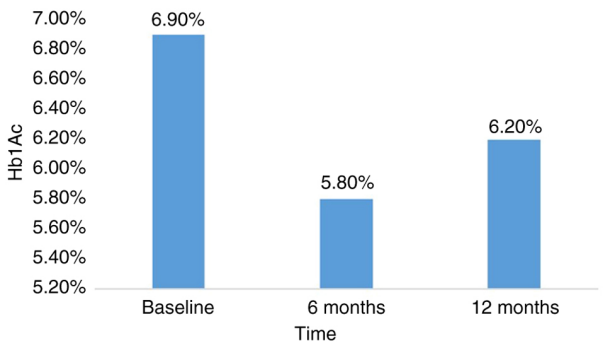

Figure 2. Changes in Glycated hemoglobin levels following treatment with Nanosomal docetaxel lipid suspension.

outcomes in combination with ET (16,17). The present patient, who was treated with palbociclib following NDLS chemotherapy, experienced improvement in condition.

Despite generally good prognoses for early ER-positive, HER2-negative BC, some patients face recurrences years after initial treatment (15). Docetaxel is commonly used for MBC, especially following anthracycline-based therapy failure. Docetaxel is a potent antineoplastic agent commonly used in the treatment of various types of cancer, including BC. Its mechanism of action involves the disruption of the microtubular network, which serves a crucial role in both mitotic and interphase cellular functions. It binds to free tubulin and promotes its assembly into stable microtubules while simultaneously inhibiting their disassembly (18) This leads to the formation of abnormally stable microtubule bundles that no longer perform their key functions in cell division. Consequently, the drug induces cell cycle arrest, primarily in the G2/M phase, thereby preventing proper mitotic progression and leading to cell death. Unlike many spindle poisons currently used in clinical practice, docetaxel binding to microtubules does not alter the number of protofilaments in the microtubules. This suggests that docetaxel may function through a unique mechanism compared with

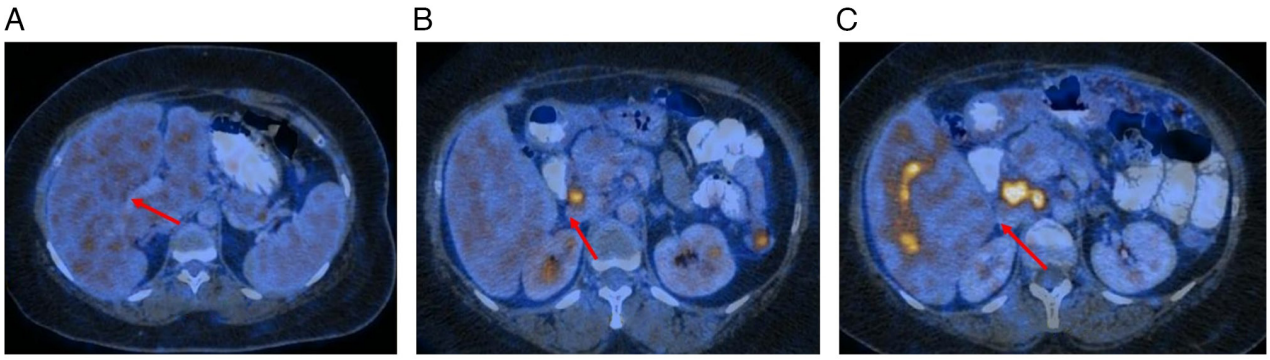

Figure 3. Positron emission tomography-computed tomography-based follow-up responses. (A) In April 2023, the stable multiple ill-defined FDG non-avid hypodense lesions were seen in segments III, V, VI and VIII of liver, the largest one measuring ~17x15 mm^2 in segment VIII. (B) In November 2023, there was an increase in the size of hypodense lesions seen in both lobes of liver, predominantly in the left lobe largest measuring ~48x43 mm^2 in segment III (previously measured ~17x15 mm^2 in segment VIII) with appearance of metabolic activity (SUV max=7.4): Active hepatic metastases (C) I n March 2024, there was a further increase in size, number and metabolic activity of hypodense lesions seen in both lobes of the liver, predominantly in the left lobe measuring ~56x51 mm^2 (previously measured ~48x43 mm^2) in segment III (SUV max=10) NDLS, nanosomal Docetaxel Lipid Suspension. Red arrows indicate the site of metastatic lesions.

other drugs that affect microtubule dynamics by altering protofilament numbers (19). Docetaxel is primarily metabolized by the cytochrome P450 enzyme CYP3A4, making it a substrate for this enzyme. *In vitro* studies have demonstrated that the metabolism of docetaxel is influenced by the concomitant administration of drugs that either induce or inhibit CYP3A4 or are metabolized by this enzyme (20-24). *In vivo* studies have shown a 2.2-fold increase in docetaxel exposure when co-administered with ketoconazole, a potent CYP3A4 inhibitor. Protease inhibitors, especially ritonavir, increase docetaxel exposure due to their inhibitory effects on CYP3A4 (25-28). Therefore, concomitant use of docetaxel with drugs that inhibit CYP3A4 should be approached with caution, as this may increase the risk of docetaxel-associated toxicity. In clinical practice, if the use of a potent CYP3A4 inhibitor is unavoidable, close monitoring for signs of toxicity is recommended (29). A dose reduction of docetaxel may be considered in such cases to minimize the risk of adverse effects (19).

NDLS, a lipid-based docetaxel formulation free from polysorbate 80 and ethanol, has demonstrated higher response rates and better tolerability compared with conventional docetaxel (11). Intravenous NDLS, at 75 mg/m^2 every 3 weeks for six cycles, offers improved outcomes compared with docetaxel with no severe hypersensitivity reactions (10). In real-world settings, NDLS has shown an objective response rate of 64.7% and a disease control rate of 70.6%, with a median OS of 30.4 months (13).

In India, diabetes is a comorbid condition prevalent among patients with BC. Up to 10 to 20% of patients with breast cancer have type 2 diabetes mellitus. The key risk factors for type 2 diabetes are old age and obesity, which are also risk factors for breast cancer (30,31). The present diabetic patient with HR-positive MBC received 12 cycles of NDLS, achieving a partial response with no notable safety issues. The HbA1c level of the patient was 7.2% at the time of diagnosis. After 12 cycles of NDLS treatment, HbA1c level was 6.2%. With conventional docetaxel, corticosteroids are administered as premedication to minimize the infusion-associated toxicity responsible for hyperglycemia (32). With NDLS, the corticosteroid premedication is avoided, which helps avoid hyperglycemia and contributes to the overall glycemic control of the patient. A retrospective study by Subramanian *et al* (13) in patients with BC (n=91) who were treated with NDLS formulation and had a median follow-up duration of 21 months, suggested that NDLS-based treatment was well tolerated without notable safety concerns; 33% of the patients with MBC were diabetic at baseline (14). This implies NDLS formulation avoids the need for steroid premedication, which could facilitate better glycemic control. The present case report highlighted the successful use of 12 cycles of NDLS in a diabetic patient with HR-positive MBC, demonstrating its efficacy and tolerability. However, the present case report did not include biopsies or molecular analyses, particularly for markers of resistance to establish the molecular or cellular pathways of NDLS.

The present study reports the successful management of a diabetic patient with HR-positive, HER2-negative MBC using an extended 12-cycle regimen of NDLS combined with maintenance hormonal therapy. The patient achieved a PFS of ~2 years and an OS of two years and six months. Further studies with larger sample sizes and a longer follow-up are needed to confirm efficacy and safety.

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Availability of data and materials

The data generated in the present study are not publicly available due to institutional restrictions but may be requested from the corresponding author.

Authors' contributions

AC, IA and PR analyzed data and wrote the manuscript. IA, PR, LP and DB conceived and designed the study and wrote and revised the manuscript. AC, DP, LP performed the literature review and constructed figures. LP and DB analyzed and interpreted data. DB, AC and IA edited the manuscript. All authors have read and approved the final manuscript. AC and IA confirm the authenticity of all the raw data.

Ethics approval and consent to participate

The study was conducted in accordance with the ethical principles of International Conference on Harmonization E6 (R2) guideline on Good Clinical Practice and Declaration of Helsinki (Fortaleza, Brazil, October 2013). Informed consent was obtained from the patient.

Patient cconsent for publication

The patient provided written consent for publication of the case report and accompanying images.

Competing interests

LP, DB and AC are affiliated with Intas Pharmaceuticals Limited, who supplied NDLS, which was developed based on patented technology. The remaining authors declare that they have no competing interests.

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