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# Efficacy and Safety of DoceAqualip in a Patient With Metastatic Triple-Negative Breast Cancer Beyond 40 Cycles: A Case Report

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## Abstract

Triple-negative breast cancer (TNBC) is an aggressive breast cancer subtype characterized by the absence of estrogen receptor, progesterone receptor, and human epidermal growth factor receptor 2 (HER2) expression and is associated with a high risk of recurrence, early metastasis, and limited therapeutic options in the metastatic setting. A 54-year-old woman with a history of diabetes mellitus was diagnosed with metastatic TNBC and treated at Ivy Hospital, Mohali, Punjab, India, in January 2019. She was initially diagnosed with early-stage TNBC in July 2018 and received six cycles of neoadjuvant chemotherapy followed by modified radical mastectomy. During follow-up, she developed radiologically confirmed multiple pulmonary metastases. Disease progression was observed despite treatment with several systemic chemotherapy regimens, including gemcitabine plus cisplatin, capecitabine, and eribulin. Given the paucity of effective treatment options in this heavily pretreated setting, palliative therapy with nanosomal docetaxel lipid suspension (NDLS) was initiated. Following six cycles of NDLS, radiological assessment demonstrated a partial response (PR). Owing to the favorable clinical response and excellent tolerability, treatment was continued, and the patient ultimately received a total of 48 cycles of NDLS. Subsequent imaging confirmed a complete response (CR), which has been sustained during long-term follow-up. Notably, prolonged NDLS administration was not associated with any significant toxicity or grade ⩾3 treatment-related adverse events. At 3.5 years following initiation of NDLS therapy, the patient remains alive, clinically stable, and free of disease progression. This case represents one of the earliest reported experiences demonstrating durable complete remission, prolonged progression-free survival, and an excellent safety profile with extended NDLS treatment in metastatic TNBC. The findings suggest that NDLS may offer meaningful long-term clinical benefit in select patients with heavily pretreated metastatic TNBC and warrant further investigation in larger clinical studies.

**Categories:** Oncology
**Keywords:** breast cancer, docetaxel, metastatic, ndls, tnbc

## Introduction

Triple-negative breast cancer (TNBC) is recognized as a highly aggressive subtype of breast carcinoma, characterized by the absence of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor-2 (HER-2) expression. The American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines define TNBC as tumors demonstrating ER and PR expression in ⩽1% of tumor cells, along with HER-2 negativity, indicated by immunohistochemistry scores of 0 or 1+ [1]. This subtype is associated with poor clinical outcomes and distinct metastatic dissemination patterns [2]. TNBC constitutes approximately 24% of newly diagnosed breast cancer cases, and its incidence has been reported to be increasing over time [3]. Data from GLOBOCAN 2022 indicate that breast cancer accounts for 13.6% of all newly diagnosed malignancies in India and contributes to 10.7% of cancer-related deaths. The reported prevalence of TNBC in the Indian population ranges from 10% to 43%, which is considerably higher than the 12%-17% reported in Western countries [4]. Prognosis remains unfavorable, with an average survival duration of approximately 15-18 months. Five-year survival rates are estimated at 65% for regionally localized disease, declining sharply to 11% in patients with metastatic involvement [5]. Conventional docetaxel formulations contain polysorbate 80 and ethanol, excipients associated with adverse events such as hypersensitivity reactions, fluid retention, and peripheral neuropathy [6,7]. To overcome these limitations, nanosomal docetaxel lipid suspension (NDLS; also known as docetaxel lipid suspension, DoceAqualip®; Intas Pharmaceuticals Ltd., Ahmedabad, Gujarat, India) was developed using lipid components classified as Generally Recognized As Safe (GRAS) by the United States Food and Drug Administration, thereby eliminating the need for polysorbate 80 and ethanol and reducing their associated toxicities. NDLS utilizes NanoAqualip technology, in which docetaxel is encapsulated within a lipid core without the use of organic solvents or detergents at any stage of production. This formulation improves systemic drug exposure through the enhanced permeability and retention (EPR) effect, which may lead to improved therapeutic outcomes. NDLS has received approval from the Drugs Controller General of India for the treatment of various malignancies, including hormone-refractory prostate cancer, advanced breast cancer, head and neck cancer, gastric cancer, and non-small cell lung cancer [7]. However, real-world

clinical evidence supporting the use of NDLS specifically in TNBC remains limited. In this report, we describe the case of a 54-year-old BRCA-negative female patient with relapsed, metastatic TNBC who was successfully treated with a regimen incorporating NDLS.

## Case Presentation

In January 2019, a 54-year-old female patient presented with relapsed metastatic TNBC (mTNBC) at Ivy Hospital, Mohali, Punjab, India. The patient was initially diagnosed with early-stage TNBC in July 2018. Following neoadjuvant chemotherapy (NACT) with four cycles of 5-fluorouracil 500 mg/m2 intravenously (i.v.), doxorubicin 50 mg/m2 i.v., and cyclophosphamide 500 mg/m2 i.v., every three weeks for four cycles, followed by two cycles of paclitaxel (175 mg/m2 i.v. every three weeks), the patient underwent modified radical mastectomy (MRM) followed by local radiotherapy (X-RT). In January 2019, she presented to us with fever; a contrast-enhanced computed tomography (CECT) scan of the abdomen showed minimal left-sided pleural effusion with at least two nodular lesions in the left lung lower lobe (LUL; approx. 5.3 x 3.1 x 3.2 cm and 2.0 x 1.9 cm in size) and a few prominent lymph nodes in aortocaval and left para-aortic locations, suggestive of progression of disease (PD) (images not available). The patient received chemotherapy with gemcitabine 1000 mg/m2 i.v. on day 1 and day 8 and cisplatin 75 mg/m2 i.v. on day 1 every three weeks (Q3W), she completed six cycles of chemotherapy in May 2019. A whole-body positron emission tomography-computed tomography (PET-CT) scan conducted in September 2019 demonstrated no definitive evidence of metabolic activity and local residual/recurrent disease in relation to right chest wall region or distant metastatic disease (Figure *1*).

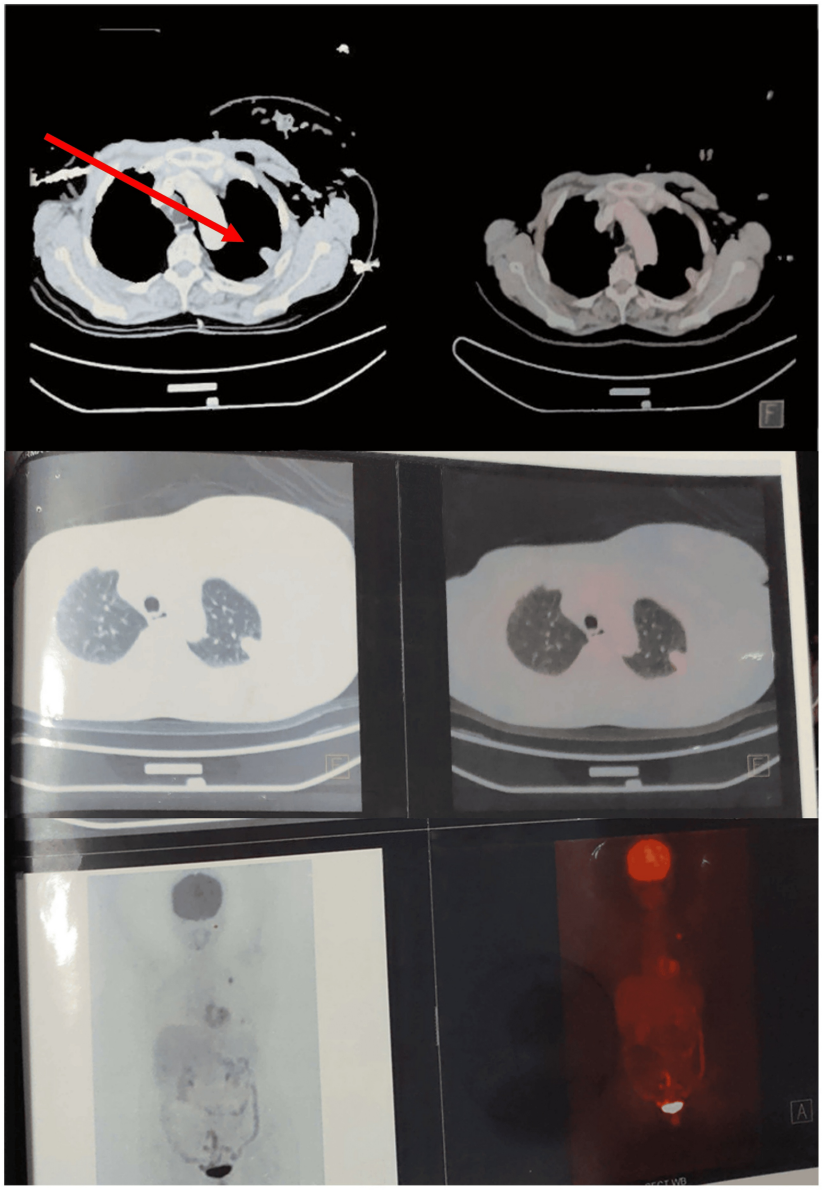


**FIGURE 1: A PET-CT scan conducted post six cycles of gemcitabine and cisplatin (September 2019)**

FDG: 18-fluoro-deoxyglucose; LUL: left lung upper lobe; LLL: left lung lower lobe; PET-CT: positron emission tomography-computed tomography

FDG-avid (SUVmax 5.1 vs previous 2.5) pleural based/subpleural soft tissue density lesions/nodular opacities are observed in the LUL and LLL, the largest measuring 18 x 17 mm (AP x TR) in the LUL apico-posterior segment (interval increase in size and FDG avidity)

Further, the patient was initiated on palliative capecitabine 1000 mg/m2 orally twice daily on day 1-14 Q3W and completed six cycles in January 2020. A PET-CT scan conducted in February 2020 demonstrated a significant increase in size and fluoro-deoxyglucose (FDG) avidity in pulmonary lesions and an FDG-avid pleural-based heterogeneous soft tissue mass in the left lung upper lobe (LUL) (approx. 5.2 x 3.7 x 4.5 cm and approx. 3.4 x 3 x 4.4 cm in size) (Figure *2*).

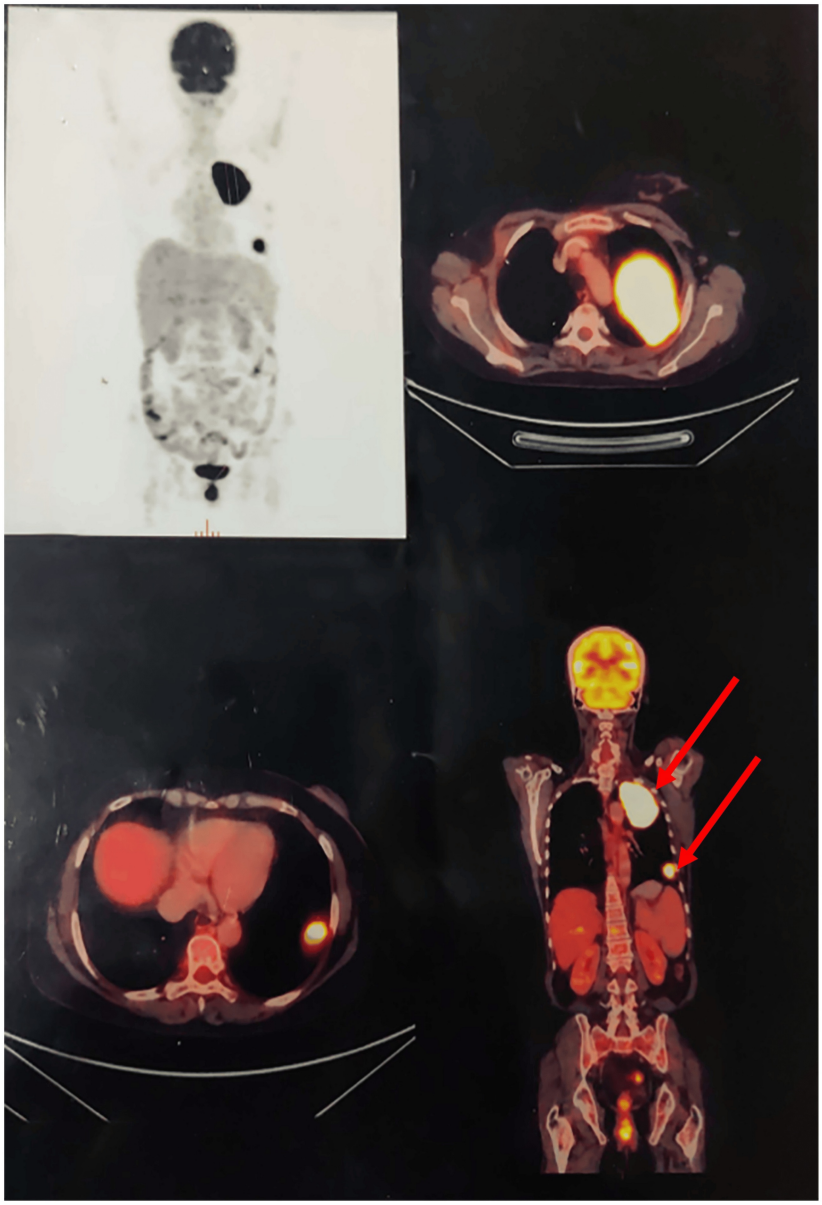


**FIGURE 2: A PET-CT scan conducted post completion of six cycles of capecitabine (February 2020)**

FDG: 18-fluoro-deoxyglucose; LUL: left lung upper lobe; LLL: left lung lower lobe; PET-CT: positron emission tomography-computed tomography

A significant increase in size and FDG avidity in pulmonary lesions and an FDG-avid pleural-based heterogeneous soft tissue mass in the LUL (SUVmax 15.3 vs 11.05, approx. 5.2 x 3.7 x 4.5 cm) and LLL (SUVmax 15.3 vs 11.05, approx. 3.4 x 3 x 4.4 cm) were observed

The patient was initiated on palliative eribulin 1.4 mg/m2 i.v. on days 1 and 8 Q3W. A PET-CT scan conducted in April 2020 post-completion of three cycles of eribulin demonstrated a significant decrease in size and FDG avidity of pulmonary lesions (Figures *3*-*4*).

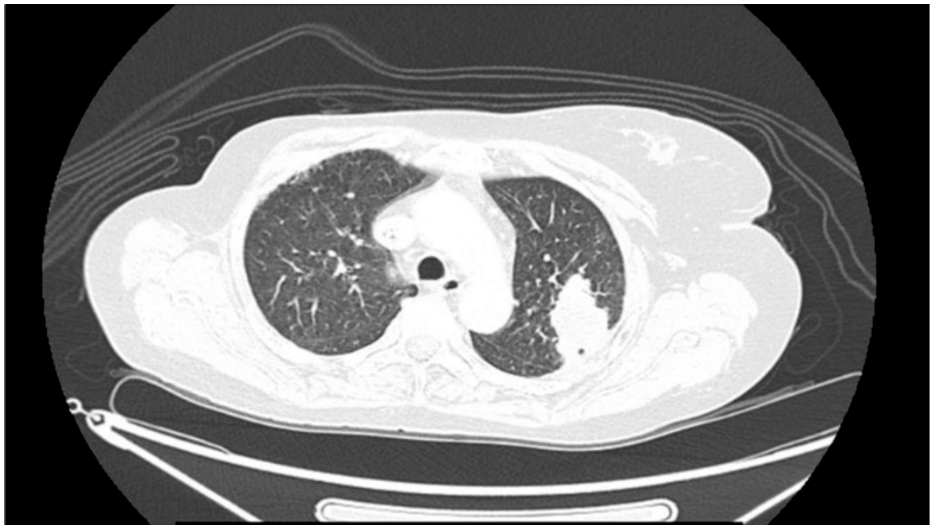


**FIGURE 3: A PET-CT scan conducted post completion of three cycles of eribulin (April 2020)**

FDG: 18-fluoro-deoxyglucose; LUL: left lung upper lobe; LLL: left lung lower lobe; PET-CT: positron emission tomography-computed tomography

A significant increase in size and FDG avidity of pulmonary lesions was observed; LUL (SUVmax 11.05, ~ 5.3 x 3.1 x 3.2 cm) and LLL (SUV max 11.1, ~ 2 x 1.9 cm)

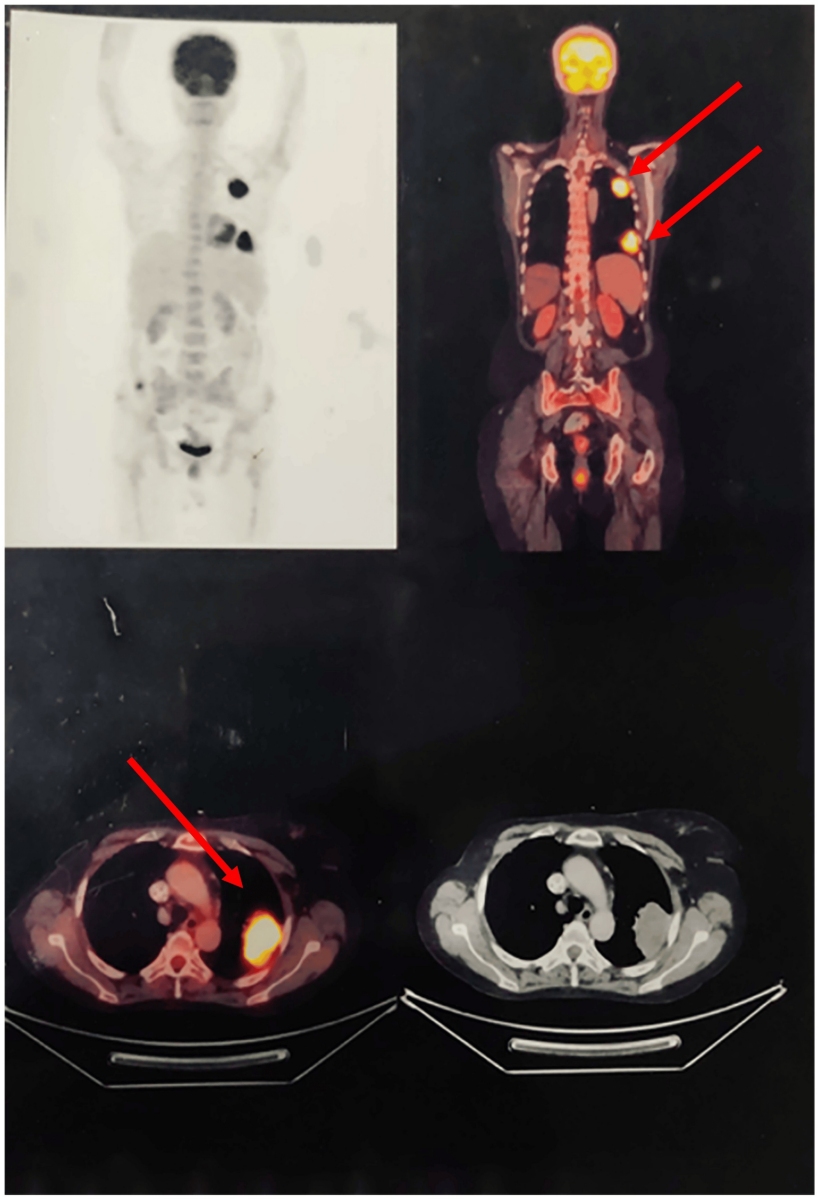


**FIGURE 4: A PET-CT scan conducted post-completion of three cycles of eribulin (April 2020)**

FDG: 18-fluoro-deoxyglucose; LUL: left lung upper lobe; LLL: left lung lower lobe; PET-CT: positron emission tomography-computed tomography

A significant increase in size and FDG avidity of pulmonary lesions was observed: LUL (SUVmax 11.05, ~ 5.3 x 3.1 x 3.2 cm) and LLL (SUV max 11.1, ~ 2 x 1.9 cm)

Eribulin was continued, and after completion of eight cycles, a PET-CT scan conducted in August 2020 showed hypermetabolic left-sided pleural-based lesions and an increase in size and metabolic activity of the lung lesions, suggestive of PD (Figure *5*).

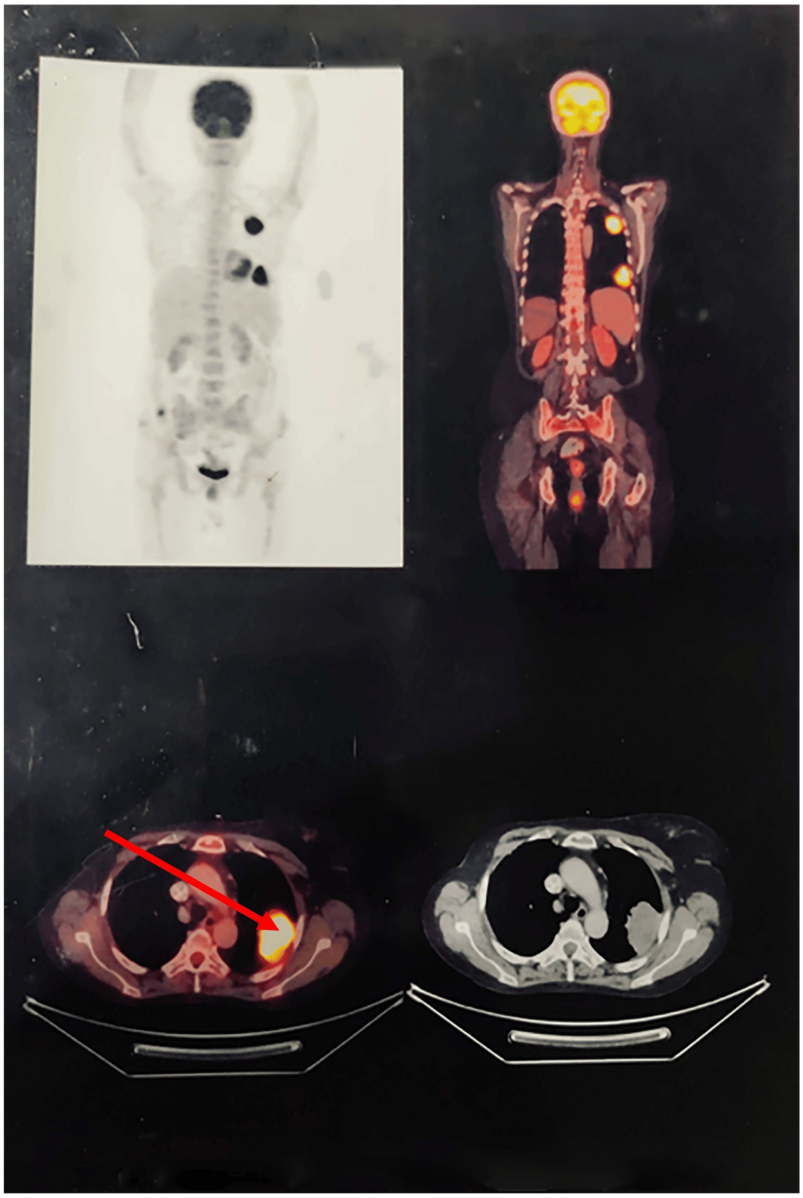


**FIGURE 5: A PET-CT scan conducted after completion of 8 cycles of eribulin (August 2020)**

FDG: 18-fluoro-deoxyglucose; LUL: left lung upper lobe; LLL: left lung lower lobe; PET-CT: positron emission tomography-computed tomography

High-grade FDG avidity was noted in the pleural-based, heterogeneous soft tissue-based mass in the LUL (SUVmax 15.3, ~5.2 x 3.7 x 4.5 cm) and SUVmax 10.5, ~3.4 x 4 x 4.4 cm in the LLL)

The patient was then initiated on palliative NDLS 75 mg/m2 i.v. Q3W and carboplatin area under the curve (AUC) of 6 i.v. on day 1 Q3W. A PET-CT scan conducted in October 2020, post-completion of three cycles of NDLS and carboplatin, showed no abnormal hypermetabolism or soft tissue lesion in the post-MRM right chest wall (images not available); a significant decrease in size and metabolic activity of the LUL lesion and complete resolution of metabolic activity with a significant decrease in size of the LLL lesion, suggestive of PR. The patient was continued on NDLS and carboplatin and completed six cycles in December 2020. In a PET-CT conducted in January 2021, a mild decrease in metabolic activity and size of lesions was noted, and no abnormal hypermetabolism/new lesions were observed (Figure *6*).

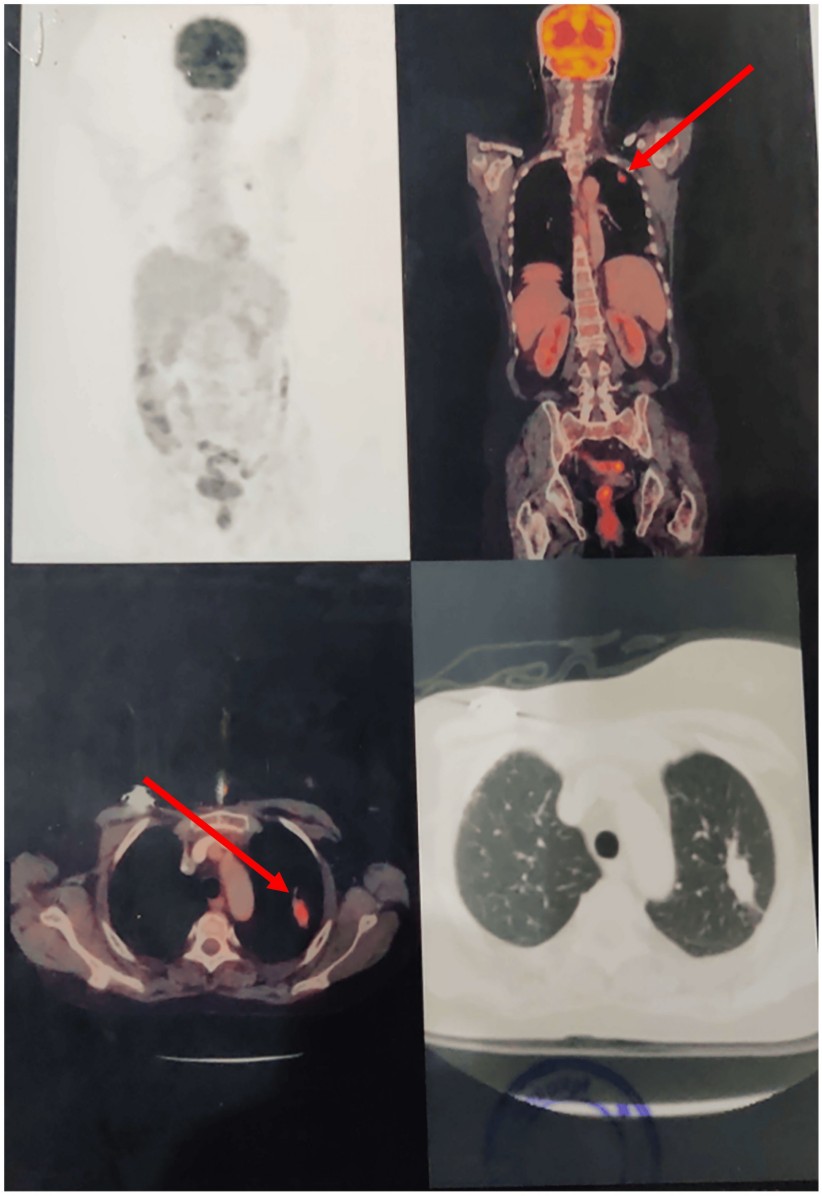


**FIGURE 6: A PET-CT scan conducted post completion of 6 cycles of NDLS and carboplatin (January 2021)**

PET-CT: positron emission tomography-computed tomography; NDLS: nanosomal docetaxel lipid suspension

A mild decrease in metabolic activity and size of lesions was noted, and no abnormal hypermetabolism/new lesions were observed

BRCA 1 and 2 tests were negative; the patient was initiated on maintenance therapy with NDLS and bevacizumab 7.5 mg/kg body weight i.v. Q3W, and she completed eight cycles. A PET-CT scan conducted in July 2021 showed no recurrent/residual metastatic disease or new lesions (images not available). There was a slight increase in metabolic activity of the previously seen lung lesion (LUL), and no new lesions were observed; she received palliative radiotherapy to the solitary lung lesion. NDLS and bevacizumab were continued Q3W. A PET-CT scan conducted in December 2021 demonstrated complete resolution of metabolic activity of the previously seen lung lesion, and no abnormal hyper metabolism/soft tissue lesion in the right anterior chest wall was observed, suggestive of a complete response (CR) (images not available). The patient was continued on NDLS without bevacizumab and completed 20 cycles of NDLS in May 2022. A PET-CT scan conducted in August 2022 showed no new lesion and mild inflammatory changes noted over the right anterior chest wall (images not available). The patient completed 25 cycles of NDLS in August

2022. In a PET-CT scan conducted in December 2022, no abnormal hypermetabolism/new lesion anywhere was observed, and there was a further decline in the size of the previously seen lung lesion (LUL, images not available). The patient underwent right thyroid lobectomy and parathyroidectomy in March 2023; the histopathology report was suggestive of parathyroid adenoma. The patient completed 34 chemotherapy cycles of NDLS in July 2023 and tolerated the therapy well, with no major adverse event reported during the entire treatment regimen. A PET-CT scan conducted in September 2023 revealed no recurrent/metastatic lesions (Figure *7*); the patient completed 38 cycles of NDLS. A follow-up PET-CT scan conducted in March 2024 showed no local/distant hypermetabolic lesions; the patient completed 41 cycles of NDLS (Figure *8*). The patient has completed 48 cycles of NDLS; the therapy is still ongoing, and after 3.5 years of initiation of NDLS, the patient is alive and doing well. NDLS was generally tolerated well. During the NDLS therapy, the patient suffered from grade 1/2 neutropenia and thrombocytopenia; the neutropenia was managed with administration of pegfilgrastim and filgrastim. Thrombocytopenia was generally managed by extending the cycle duration from every three weeks to every four weeks whenever required.

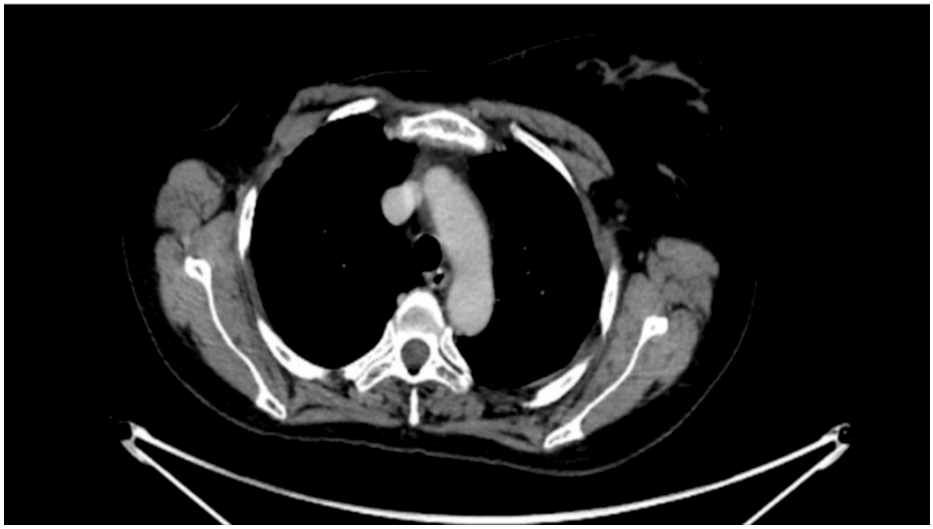


**FIGURE 7: A PET-CT scan conducted in post 38 cycles of NDLS (September 2023)**

PET-CT: positron emission tomography-computed tomography; NDLS: nanosomal docetaxel lipid suspension; LUL: left lung upper lobe

Non-FDG avid pleural based consolidatory lesion is noted in the apicoposterior segment of the LUL (~2.7 x 1 cm). No recurrent local/metastatic lesions were observed

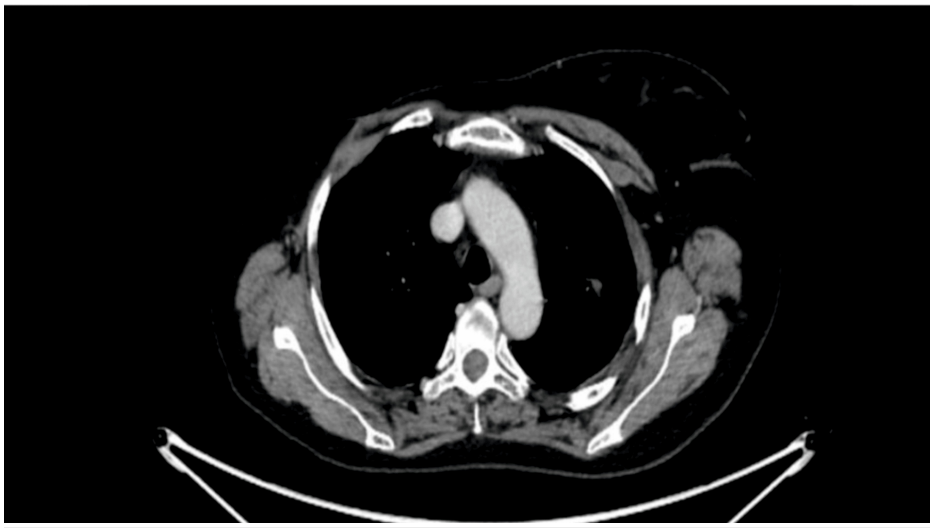


**FIGURE 8: A PET-CT scan conducted post 41 cycles of NDLS (March 2024)**

PET-CT: positron emission tomography-computed tomography; NDLS: nanosomal docetaxel lipid suspension; LUL: left lung upper lobe

A non-FDG-avid pleural-based consolidative lesion is noted in the apicoposterior segment of the LUL (~2.7 x 1 cm); no local/distant hypermetabolic lesions/metastases were observed

## Discussion

NDLS is a lipid-based formulation that does not contain polysorbate 80 or ethanol and has been shown to provide superior tolerability and improved response rates when compared with conventional docetaxel. Administration of NDLS at a dose of 75 mg/m² intravenously every three weeks for six cycles has demonstrated better clinical outcomes, with the added advantage of minimal severe hypersensitivity reactions. Samar et al. conducted studies to compare the safety and efficacy of NDLS with conventional docetaxel; both were administered at a dose of 75 mg/m² in patients with metastatic breast cancer (MBC) [8-10].

In patients with locally advanced or metastatic breast cancer, NDLS monotherapy achieved a higher overall response rate (ORR) of 35.5%, compared with 26.3% observed with conventional docetaxel at the same dosage [10]. Furthermore, real-world data in MBC patients indicate that NDLS is associated with an objective response rate of 64.7% and a disease control rate of 70.6%, along with a median overall survival of 30.4 months. The safety and efficacy of NDLS have also been demonstrated across multiple malignancies, including breast, gastric, ovarian, cervical, penile, hormone-refractory prostate, and non-small cell lung cancers [8,9].

In addition, an expert consensus developed by Indian oncologists has recommended the use of NDLS in patients with metastatic disease, individuals at increased risk of hypersensitivity reactions, patients with diabetes, and those who are unable to receive steroid premedication. To the best of our knowledge, the present report represents the first documented case in which NDLS has been administered to a patient with TNBC for an extended duration of 47 cycles and is still ongoing. Previously, NDLS had been administered for up to 40 cycles in patients with metastatic castration-resistant prostate cancer (mCRPC) without any major safety concerns [11].

In the current case, the patient completed 48 cycles of therapy. The treatment was well-tolerated, and no significant adverse events were observed during therapy. This case report highlights the long-term safety and sustained efficacy of NDLS as maintenance therapy in a patient with metastatic, BRCA-negative TNBC. However, larger studies and trials are required to establish the long-term efficacy. Notably, a phase III clinical trial is presently underway to compare the safety and effectiveness of NDLS with conventional docetaxel in patients with TNBC (NCT03671044) [12].

### Limitations

A key limitation of this case report is the absence of a repeat biopsy and molecular characterization at the time of metastatic progression. Although re-biopsy could have provided updated histopathological and molecular information, the patient presented with visceral crisis requiring prompt initiation of systemic therapy and was unwilling to undergo an additional invasive diagnostic procedure. Consequently, treatment

decisions were based on the available clinical, radiological, and prior pathological findings. In addition, given the prolonged treatment duration and extended follow-up period spanning several years, some historical imaging records were unavailable for retrospective review and inclusion in this report. While the major radiological assessments documenting treatment response were available, the loss of certain older imaging studies limited the completeness of the longitudinal radiographic documentation. These factors should be considered when interpreting the clinical course and outcomes described in this case.

## Conclusions

Based on the findings described above, this case uniquely demonstrates the long-term safety and sustained clinical benefit of prolonged NDLS therapy in a patient with metastatic TNBC. To the best of our knowledge, this is the first reported instance in which NDLS has been administered for an extended duration of 47 cycles and is still being continued. This outcome highlights the potential role of NDLS as a well-tolerated long-term maintenance strategy in selected patients with TNBC, particularly those with comorbidities such as diabetes or at risk of hypersensitivity reactions.

## Additional Information

### Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

**Concept and design:** Jatin Sarin, Rimpi Sarin, Meenakshi Mittal

**Acquisition, analysis, or interpretation of data:** Jatin Sarin, Vijay Bansal, Meenakshi Mittal

**Drafting of the manuscript:** Jatin Sarin, Rimpi Sarin, Vijay Bansal

**Critical review of the manuscript for important intellectual content:** Jatin Sarin, Rimpi Sarin, Vijay Bansal, Meenakshi Mittal

**Supervision:** Jatin Sarin, Rimpi Sarin

### Disclosures

**Human subjects:** Informed consent for treatment and open access publication was obtained or waived by all participants in this study. ACEAS IEC issued approval ECR/281/Indt/GJ/2017/RR-25. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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## References

1. Almansour NM: Triple-negative breast cancer: a brief review about epidemiology, risk factors, signaling pathways, treatment and role of artificial intelligence. Front Mol Biosci. 2022, 9:836417. 10.3389/fmolb.2022.836417
2. Ensenyat-Mendez M, Llinàs-Arias P, Orozco JI, et al.: Current triple-negative breast cancer subtypes: dissecting the most aggressive form of breast cancer. Front Oncol. 2021, 11:681476. 10.3389/fonc.2021.681476
3. Schneeweiss A, Denkert C, Fasching PA, et al.: Diagnosis and therapy of triple-negative breast cancer (TNBC)-recommendations for daily routine practice. Geburtshilfe Frauenheilkd. 2019, 79:605-17. 10.1055/a-0887-0285
4. Sarkar S, Akhtar M: Triple negative breast cancer prevalence in Indian patients over a decade: a systematic review. Int J Clin Biostat Biom. 2022, 8:045.
5. Baranova A, Krasnoselskyi M, Starikov V, et al.: Triple-negative breast cancer: current treatment strategies and factors of negative prognosis. J Med Life. 2022, 15:153-61.
6. McKeage K: Nanosomal docetaxel lipid suspension: a guide to its use in cancer . Clin Drug Investig. 2017, 37:405-10. 10.1007/s40261-017-0510-7
7. Narayanan P, Dattatreya PS, Prasanna R, et al.: Efficacy and safety of nanosomal docetaxel lipid suspension-based chemotherapy in sarcoma: a multicenter, retrospective study. Sarcoma. 2019, 2019:3158590. 10.1155/2019/3158590
8. Naik R, Khan MA: Doceaqualip in a patient with prostate cancer who had an allergic reaction to

conventional docetaxel: a case report. Mol Clin Oncol. 2017, 6:341-3. 10.3892/mco.2017.1147

9. Subramanian S, Prasanna R, Biswas G, et al.: Nanosomal docetaxel lipid suspension-based chemotherapy in breast cancer: results from a multicenter retrospective study. Breast Cancer (Dove Med Press). 2020, 12:77-85. 10.2147/BCTT.S236108
10. Samar A, Tiwari S, Subramanian S, Joshi N, Sejpal J, Khan MA, Ahmad I: A multicentric, retrospective efficacy and safety study of Nanosomal docetaxel lipid suspension in metastatic castration-resistant prostate cancer. Prostate Cancer. 2020, 2020:4242989. 10.1155/2020/4242989
11. Tiwari S, Bisaria A, Kaur H, Joshi N, Sejpal J, Khan MA: Biweekly DoceAqualip in mCRPC patients beyond 20 cycles: a case series. J Oncol Pharm Pract. 2021, 27:2030-4. 10.1177/10781552211008223
12. A study to evaluate the efficacy and safety of nanosomal docetaxel lipid suspension in triple negative breast cancer patients. (2025). Accessed: August 22, 2025: https://clinicaltrials.gov/study/NCT03671044?intr=docetaxel%20lipid%20suspension&rank=1&t ab=table#symbol-legend.