Efficacy and safety of nanosomal docetaxel lipid suspension based chemotherapy in metastatic ovarian carcinoma: A retrospective study

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Abstract. The aim of the current study was to assess the efficacy and safety of nanosomal docetaxel lipid suspension (NDLS) based chemotherapy in patients with metastatic epithelial ovarian carcinoma. In the present multicenter study, the medical records of patients who received NDLS (60-75 mg/m^2; 3-weekly cycles) based chemotherapy for metastatic epithelial ovarian cancer in routine clinical care were retrospectively evaluated. Patients were followed-up from September 2014 until September 2018. The efficacy endpoints were the overall response rate (ORR) and disease control rate measured in accordance with the Response Evaluation Criteria in Solid Tumours 1.1. Overall survival (OS) and safety were also evaluated. Of the 13 patients evaluated, 46.2% (6/13) received NDLS-based first-line chemotherapy and 53.8% (7/13) patients received second-line chemotherapy [platinum-sensitive, 57.1% (4/7); platinum-resistant, 42.9% (3/7)]. The ORRs were 60.0% (3/5) and 57.1% (4/7) for patients receiving first- and second-line chemotherapy, respectively. The estimated median OS for patients receiving NDLS-based first-line chemotherapy was 17.4 months (follow-up duration, 4.3-49.4 months). The estimated median OS was 26.1 months (follow-up duration, 5.1-37.5 months) in patients with platinum-sensitive disease, whereas the OS was 14.8 months (follow-up duration, 3.5-14.8 months) in patients with platinum-resistant disease. No grade III/IV adverse events (AEs) were observed; ≥1 AE in grade I-II was reported in 84.6% (11/13) of patients. Overall, NDLS-based chemotherapy was efficacious and well-tolerated in the management of metastatic epithelial ovarian carcinoma.

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Introduction

Among malignancies, ovarian cancer accounts for the seventh most common cancer in females globally (1). As per GLOBOCAN 2018 data, there were 295,414 new ovarian cancer cases with 184,799 cancer deaths (1.9% of all cancers) (2). In Indian females, it is the third most common cancer (new cases: 36,170, 6.2%) (2). A 5-year survival rate of ~45% (3), indicates a low prognosis rate compared with other gynecological cancers. The high mortality rate of ovarian cancer can be attributed to the delayed disease diagnosis leading to increased cancer stage or metastasis of the disease in most (~75%) of the patients (4).

More than 95% ovarian cancers are of epithelial type arising from ovarian surface, fallopian tube or peritoneum (5,6). The mainstay of ovarian cancer management include cytoreduction or surgical debulking followed by chemotherapy. The cornerstone of chemotherapy for advanced disease include the use of platinum-agents containing regimens. The landmark GOG-111 and EORTC studies in advanced ovarian cancer have reported significantly improved OS with combination of paclitaxel and a platinum agent (7,8). Docetaxel, owing to its favorable neurotoxicity profile than paclitaxel, was evaluated as a first-line therapy with platinum agents in ovarian cancer (9,10). In platinum-sensitive/resistant cases, docetaxel has also been assessed as a single agent for second-line therapy (11), or as a combination therapy with cisplatin (12), carboplatin (13), or cyclophosphamide (14).

The conventional docetaxel formulation has several toxicity concerns which are greatly related to the formulation vehicles polysorbate 80 and ethanol (15-19). To overcome the toxicity issues, nanosomal docetaxel lipid suspension (NDLS, DoceAqualip) formulation was developed, which does not contain formulation vehicles polysorbate 80 and ethanol. Using the patented 'NanoAqualip' technology (20), NDLS was developed with lipids generally regarded as safe (GRAS) by

the US FDA. Nanosomal lipid-based particles (<100 nm) of NDLS may increase delivery of docetaxel to tumor tissues due to damaged tumor vasculature, and may result in enhanced permeability and retention (EPR) effect, leading to increased docetaxel systemic availability, (20,21) hence, enhanced therapeutic outcomes are anticipated (22). In addition, polysorbate 80 and ethanol related toxicity issues can be circumvented, thus improving overall outcomes. NDLS is approved in India for advanced gastric adenocarcinoma, androgen independent (hormone refractory) metastatic prostate cancer (HRPC), locally advanced or metastatic breast cancer (MBC) after failure of prior chemotherapy, non-small cell lung cancer (NSCLC) after failure of prior chemotherapy, and for the induction treatment of locally advanced squamous cell carcinoma of head and neck (LA SCCHN).

NDLS has demonstrated efficacy and safety in several cancers including breast, gastric, cervical, penile, HRPC, NSCLC and sarcoma (23-27). Although NDLS is not approved for ovarian cancer treatment, its effectiveness and safety is reported for ovarian cancer management in the published literature (26,28). We report here a real-life clinical experience on NDLS use for managing metastatic epithelial ovarian carcinoma.

Methods

Study design. Medical charts of adult women with metastatic epithelial ovarian carcinoma were reviewed in this retrospective study. The women should have received NDLS based chemotherapy for clinical care between from September 2014 to September 2018. The efficacy parameters were the overall response rate (ORR), disease control rate (DCR) and overall survival (OS). The ORR was defined as the proportion of patients achieving complete response (CR, disappearance of all target lesions or reduction to <10 mm in short axis of any lymph nodes) and partial response (PR, ≥30% decrease in tumor diameter). The DCR was defined as the proportion of patients achieving CR, PR, and stable disease (SD, no ≥30% decrease or ≥20 increase in tumor diameter). The OS was calculated as time from initiating the treatment to death due to any cause. Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 was used for tumor response assessment (29). The medical charts of the patients were screened for documented adverse events (AEs), and the incidence of AEs were recorded and graded per Common Terminology Criteria for Adverse Events (as per CTCAE) 5.0 criteria (30).

Ethics statement. The study was conducted after due approval from OM ethics committee (ECR/1168/Inst/GJ/2018), in accordance with the ethical principles of Declaration of Helsinki, International Council for Harmonistion (ICH) Good Clinical Practice (GCP) guidelines, and protocol requirements. Patient consent to review their medical records was not required by the ethics committee as this was a retrospective study where patients received NDLS as part of natural course of their treatment. In addition, the data presented in the current study was analyzed data without identifying any patient. Throughout the data analysis and manuscript preparation, patient confidentiality was completely maintained and data were anonymized.

Table I. Patient disposition and baseline characteristics.

Parameter	Ovarian carcinoma (n=13)
Age, years (range)	52.9±9.9[a] (42-70)
BSA, m^2	1.4±0.2[a]
Female, n (%)	
Premenopausal	5 (38.5)
Post-menopausal	8 (61.5)
Metastasis site, n (%)[b]	
Lymph node	7 (53.8)
Liver	2 (15.4)
Peritoneum	5 (38.5)
ECOG score, n (%)	
0	2 (15.4)
1	8 (61.5)
2	2 (15.4)
3	1 (7.7)
Line of therapy, n (%)	
First-line	6 (46.2)
Second-line	7 (53.8)
Platinum-sensitive patients	4 (57.1)
Platinum-resistant patients	3 (42.9)
Comorbid disease, n (%)	
Hypertension	4 (30.8)
Diabetes	3 (23.1)
Hypothyroidism	2 (15.4)
Other	3 (23.1)

[a]Data are presented as the mean ± SD. [b]Metastasis sites can overlap. Other comorbid diseases include asthma, coronary artery disease and ischemic heart disease. BSA, body surface area; ECOG, Eastern Cooperative Oncology group.

Statistical analyses. Descriptive statistics were used for demographic and baseline characteristics whereas frequency and percentage were provided for categorical variables. Count, mean, standard deviation (SD), median, minimum and maximum were provided for continuous variables. The frequency and % of patients were reported for response rate. Kaplan-Meier estimates were used for calculating OS. The AEs were summarized as frequencies and percentages by type of reactions. All statistical analyses were done using SAS® version 9.4 (SAS Institute, Inc.).

Results

Patient disposition and demographics. Data of thirteen women with metastatic epithelial ovarian carcinoma, who received NDLS based chemotherapy, was retrospectively reviewed. Table I summarizes the baseline patient and disease characteristics.

In all patients, NDLS was given as 1-hour infusion in 3-weekly cycles. The NDLS doses of 60 mg/m^2 or 75 mg/m^2 were administered in 23.1% (3/13) and 76.9% (10/13) patients, respectively. Overall, 46.2% (n=6/13) patients received NDLS based first-line combination chemotherapy (NDLS/gemcitabine,

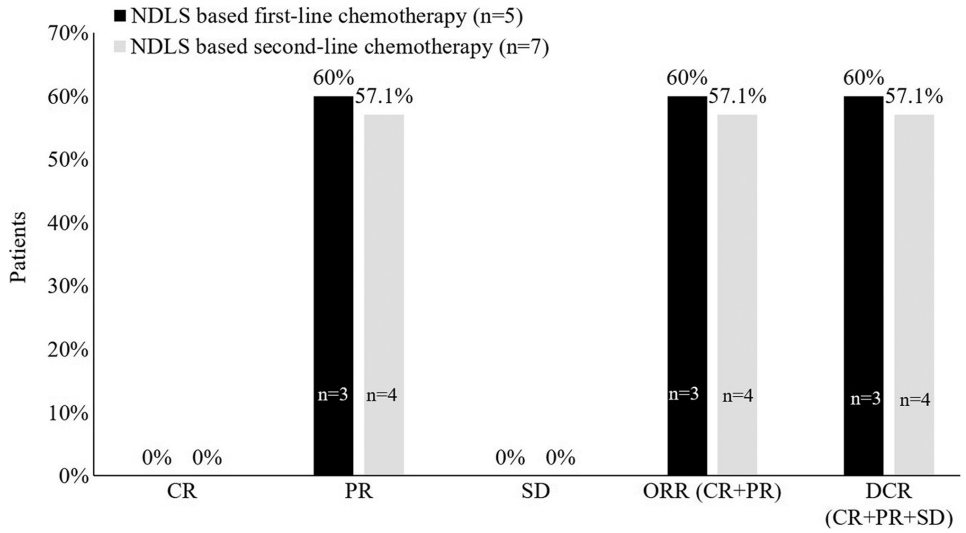

Figure 1. Response rate of NDLS based chemotherapy in metastatic epithelial ovarian carcinoma (n=12). CR, complete response; DCR, disease control rate; NDLS, nanosomal docetaxel lipid suspension; ORR, overall response rate; PR, partial response; SD, stable disease.

n=2; NDLS/cisplatin, NDLS/oxaliplatin, NDLS/liposomal doxorubicin, NDLS/oxaliplatin/bevacizumab, n=1 each); of the remaining 53.8% (n=7/13) patients who received NDLS based second-line combination chemotherapy, 4 patients were platinum-sensitive (NDLS/cisplatin, n=2; NDLS/carboplatin, n=1; NDLS/oxaliplatin/bevacizumab, n=1), and 3 patients were platinum-resistant (NDLS monotherapy, n=2 and NDLS/cyclophosphamide, n=1). The median number of NDLS based chemotherapy cycles were: 5.5 (range: 3-6) for first-line therapy, 6 for platinum-sensitive cases (all 4 patients received 6 cycles) and 6 (range: 2-6) for platinum-resistant cases. All the patients were administered granulocyte-colony stimulating factor (GCSF) support as primary prophylaxis.

Efficacy. Of 13 patients, efficacy data was available for 12 patients. For patients receiving NDLS based first-line and second-line chemotherapy, the ORRs were 60% (PR, n=3/5) and 57.1% (PR, n=4/7), respectively (Fig. 1). For patients receiving NDLS based second-line chemotherapy, the ORR was 25% (PR, n=1/4) for platinum-sensitive and 100% (PR, n=3/3) for platinum-resistant patients.

Overall survival. The patient survival data was collected from the initiation of NDLS treatment till the date the patient was followed-up and the date of death for patients who succumbed. OS was censored at the last follow-up date for alive patients at the time of data analysis or who were lost to follow-up, At a median follow-up duration of 15.1 months (range: 4.3-49.4 months), there were 7 (53.8%) deaths. For patients receiving NDLS based first-line chemotherapy, the estimated median OS was 17.4 months (follow-up duration: 4.3-49.4 months). Similarly, for platinum-sensitive cases, the estimated median OS was 26.1 months (follow-up duration: 5.1-37.5 months). For platinum-resistant cases, the estimated median OS was 14.8 months (follow-up duration: 3.5-14.8 months) (Fig. 2). As the sample size in the subgroups of platinum-sensitive (n=4) and platinum-resistant (n=3) cases were very low, comparing OS would not yield clinically meaningful data, and hence, they were not compared. Fig. 3 enlists the key details of the study and its findings.

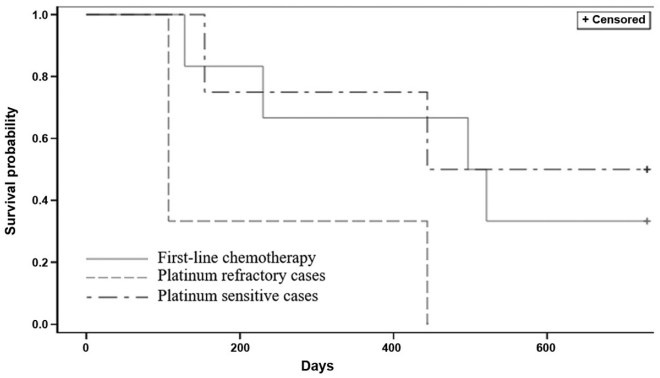

Figure 2. Kaplan Meier estimates of OS with NDLS based chemotherapy in metastatic epithelial ovarian carcinoma (n=13). For patients who were alive at the time of data analysis or who were lost to follow-up, OS was censored at the last recorded date that the patient was known to be alive. OS, overall survival.

Safety. There were no grade III/IV AEs reported. Eleven (84.6%) patients had ≥1 AEs. Grade I AEs were reported in 84.6% (11/13) and grade II in 30.8% (4/13) patients. Hematological AEs included anemia, lymphopenia thrombocytopenia, and neutropenia while the non-hematological AEs were hyperglycemia, nausea, vomiting and edema (Table II).

Discussion

The combination of taxane with platinum compounds has been the cornerstone of ovarian cancer management. The landmark GOG-111 study first demonstrated significantly higher response rates and patient survival with cisplatin plus paclitaxel versus cisplatin plus cyclophosphamide (7), which was further confirmed by the EORTC trial (8). Docetaxel has been effective and well-tolerated in combination with a platinum agent for managing ovarian carcinoma (6,31). Docetaxel monotherapy or docetaxel plus carboplatin are recommended palliative treatment options for managing ovarian carcinoma for platinum-sensitive or platinum-resistant ovarian cancers (30).

Table II. Safety profile of NDLS based chemotherapy in metastatic ovarian cancer (n=13).

A, Hematological AEs

AE	All grades, n (%)	Grade I, n (%)	Grade II, n (%)
Anemia	7 (53.8)	6 (46.2)	4 (30.8)
Lymphopenia	4 (30.8)	3 (23.1)	1 (7.7)
Thrombocytopenia	4 (30.8)	4 (30.8)	-
Neutropenia	2 (15.4)	2 (15.4)	-

B, Non-hematological AEs

AE	All grades, n (%)	Grade I, n (%)	Grade II, n (%)
Hyperglycemia	3 (23.1)	3 (23.1)	-
Nausea	1 (7.7)	-	-
Vomiting	1 (7.7)	-	-
Edema	1 (7.7)	1 (7.7)	-

AEs in different grades and individual AEs may occur in ≥1 patient; hence, the cumulative number of patients in different grades may exceed the total number of patients with individual AEs. AE, adverse event; NDLS, nanosomal docetaxel lipid suspension.

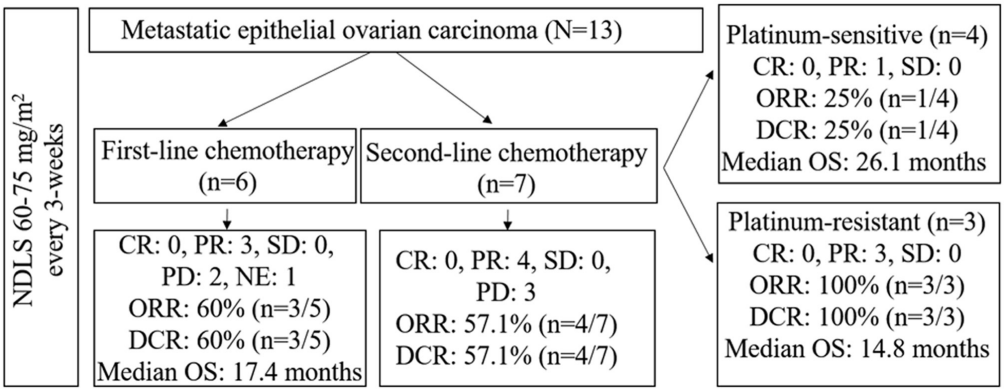

Figure 3. Key study findings. NDLS 60-75 mg/m^2 administered every 3-weeks demonstrated efficacy as first- and second-line chemotherapy for patients with metastatic epithelial ovarian carcinoma (n=13). CR, complete response; DCR, disease control rate; NDLS, nanosomal docetaxel lipid suspension; NE, not evaluated; ORR, overall response rate; OS, overall survival; PD, progressive disease; PR, partial response; SD, stable disease.

NDLS evaluated for metastatic ovarian carcinoma treatment in this study resulted in ORR/DCR rates of 60% and 57.1% when used as first- and second-line therapies, respectively. In patients receiving NDLS based first-line chemotherapy, the estimated median OS was 17.4 months. First-line therapy with docetaxel and cisplatin was evaluated by the Scottish Gynaecological Cancer Trials Group (n=100), which showed an ORR of 69% (6). In Asian patients (n=44), Mokhlesuddin *et al*, demonstrated a response rate of 80% with the 2-year OS at 62% with docetaxel-cisplatin regimen (32). In our study, NDLS and cisplatin based first-line therapy evaluated in 1 patient resulted in a PR. First-line therapy with docetaxel and gemcitabine followed by carboplatin (n=44) evaluated in SCOTROC 2A study reported an ORR of 77.3% (33). NDLS-gemcitabine based chemotherapy was used in 2 patients in our study and reported a PR in one patient while the other patient had disease progression. NDLS/liposomal doxorubicin, NDLS/bevacizumab/oxaliplatin and NDLS/oxaliplatin were the other regimens used as first-line treatment.

Second-line chemotherapy with docetaxel based regimens has shown an OS between 8-10.4 months in ovarian cancer (34). In our study, patients receiving NDLS based chemotherapy as a second-line treatment showed an ORR/DCR of 57.1% (platinum-sensitive cases: 25% and platinum-resistant cases: 100%). The estimated median OS was 26.1 months for platinum-sensitive cases (follow-up duration: 5.1-37.5 months). Ota *et al*, treated 39 patients with irinotecan plus cisplatin/nedaplatin and 21 patients with docetaxel/cisplatin and divided in two groups: Group A-29 patients refractory to initial platinum-based chemotherapy; group B-31 platinum-sensitive patients. The study reported a response rate of 41.9% with the median OS at 9.23 months, in group B (12). In our study, two patients with platinum-sensitive disease, were administered NDLS/cisplatin therapy and resulted in a PR in one patient.

The estimated median OS was 14.8 months for platinum-resistant cases (follow-up duration: 3.5-14.8 months). Docetaxel/cyclophosphamide use reported the remission

of ovarian cancer in a patient with platinum-resistant disease (14). In our study, NDLS/cyclophosphamide used in one patient of platinum-resistant disease and reported a PR. Kavanagh *et al*, reported a response rate of 40% in patients with failed platinum chemotherapy (n=55) (11). In our study, NDLS monotherapy showed partial responses in all 2 patients with platinum-resistant disease.

In the current safety analysis no severe AEs (grade III/IV) were reported. The hematological AEs included anemia, lymphopenia, thrombocytopenia, and neutropenia while the non-hematological AEs were hyperglycemia, nausea, vomiting and edema. Previous studies have highlighted the potential role of formulation vehicles polysorbate 80 and ethanol with AEs generally occurring with docetaxel such as acute hypersensitivity reactions, cumulative fluid retention, peripheral neuropathy (15), severe nonimmunologic anaphylactoid reactions (16), injection-site reactions (17), and alcohol intoxication (18,19). Furthermore, these AEs can still be observed despite corticosteroid and antihistamine premedication, generally used to limit these toxicities (35). In our study, AEs like neurotoxicity, fluid retention and acute hypersensitivity reactions were not reported with NDLS based chemotherapy. In previous studies with docetaxel and cisplatin combination, neutropenia was the major toxicity. First-line therapy with docetaxel-cisplatin (n=100) reported grade 3/4 neutropenia in >75% of patients with advanced ovarian cancer. The AEs leading to treatment discontinuations were neurotoxicity (n=6), nephrotoxicity (n=3), neutropenia (n=2), hypersensitivity, diarrhea and vomiting, skin rash, and clinical deterioration (n=1, each) (6). Another study evaluating docetaxel-cisplatin as a first-line chemotherapy showed grade III neutropenia (25%) among other AEs (32). For docetaxel based triple-drug combination as a first-line therapy, neutropenia (42.4%) followed by leukopenia (13.6%), hypertension (8.3%), fatigue and nausea (6.1% each) were most common grade III/IV AEs (36). Docetaxel-based chemotherapy in platinum-sensitive ovarian cancer showed that neutropenia was the most common grade III/IV hematologic AE (60%) and diarrhea the non-hematologic AE (12%). Hypersensitivity reaction led to dose reduction in one patient (13). In platinum-refractory disease, neutropenia (98%) was the main toxicity whereas the AE of cumulative fluid retention required dose modification. The common AEs reported with docetaxel monotherapy were alopecia (100%), anemia (87%), dermatitis (67%), gastrointestinal disorders (53%), stomatitis (49%), neurotoxicity (45%), excessive lacrimation (33%), and hypersensitivity reactions (11%) (11).

Corticosteroids premedication is routinely administered in patients receiving conventional docetaxel to mitigate the toxicity issues such as hypersensitivity and fluid retention (35). In a recent study, Obradović and colleagues used transcriptional profiling of tumors and matched metastases in mice with patient-derived xenograft models and suggested a possible role of glucocorticoid receptor (GR) activation resulting in breast cancer progression and metastasis (37). Corticosteroid premedication is not warranted with NDLS formulation as it does not contain the solvent polysorbate 80, hence, it may potentially help in circumventing the risk of disease progression.

As this is a retrospective data collection study, lack of completeness of data for safety as well as survival data is a major limitation. The data on disease progression and the serial scans for most of the patients were not available for most of the timepoints for analysis of progression free-survival (PFS) as this was a real-world study, which is a major limitation.

In conclusion, NDLS regimens were effective and well-tolerated in the management of metastatic ovarian cancer. This data provides valuable insights into the effectiveness and safety of NDLS in the management of ovarian cancer in clinical practice. Prospective studies with a larger patient pool are required to confirm these results.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

SS and AS researched patient data, were involved in data acquisition and critically revised the manuscript for intellectual content. NJ, JS, MAK and IA designed the current study, interpreted the data and critically revised the manuscript for intellectual content. IA and MAK confirm the authenticity of all the raw data. All authors had full access to all the data in the study and take responsibility for integrity of the data and the accuracy of the data analysis. All authors meet ICMJE criteria and all those who fulfilled those criteria are listed as authors. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The current study was conducted after due approval from the OM Ethics Committee, in accordance with the ethical principles of Declaration of Helsinki, ICH GCP guidelines and protocol requirements. Patient consent to review their medical records was not required by the ethics committee as this was a retrospective study where patients received NDLS as part of natural course of their treatment. In addition, the data presented in the current study was analyzed data without identifying any patient. Throughout the data analysis and manuscript preparation, patient confidentiality was completely maintained and data were anonymized.

Patient consent for publication

Not applicable

Competing interests

MAK, NJ and JS and are employees of Intas Pharmaceutical Ltd., India. IA is an employee of Jina Pharmaceutical Inc. (USA). The remaining authors had no competing interests.

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