Submitted: 15 March, 2023 Accepted: 16 June, 2023 Published: 15 August, 2023 DOI:10.22514/ejgo.2023.061

ORIGINAL RESEARCH

European Journal of Gynaecological Oncology

# Study on the intake and efficacy of nab-paclitaxel in patients with advanced cervical cancer

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## Abstract

Cervical cancer is the second most common malignant tumor in women. This study aimed to investigate the intake and effect of nab-paclitaxel in chemotherapy for patients with advanced cervical cancer, to collect more evidence for clinical medication. A total of 96 patients with advanced cervical cancer who received chemotherapy treatment in Wuhan Third Hospital from July 2021 to July 2022 were randomly divided into observation group (treated with nab-paclitaxel + cisplatin) and control group (treated with paclitaxel + cisplatin) by envelope method. The short-term efficacy, tumor markers, immune function indicators, adverse reactions and quality of life of both groups were observed and compared with each other. After treatment, serum tumor markers were notably decreased, while cluster of differentiation 4 (CD4)+ and CD4+/cluster of differentiation 8 (CD8)+ were clearly increased in both groups. The observation group showed the improvement effect of each index in a statistically significant manner ($p < 0.05$) than the control group. The effective disease control rate of observation group was higher than that of the control group while the incidence of treatment-related adverse reactions in the observation group was higher than that of the control group. The observation group indicated improved effective rate of Karnofsky Performance Scale (KPS) than the control group ($p < 0.05$). In conclusion, nab-paclitaxel has significant advantages in chemotherapy for patients suffering from advanced cervical cancer, which can strengthen immune function, improve the effectiveness of disease control, and promote the improvement of functional status.

## Keywords

Nab-paclitaxel; Advanced stage; Cervical cancer; Application efficacy

## 1. Introduction

Cervical cancer is the second most common female malignant tumor globally. In China, cervical cancer leads to nearly 50,000 deaths and 132,000 new cases yearly. Currently, its clinical incidence has increased remarkably, especially in younger women [1, 2]. It was one of the "two cancers" observed during screening of women of appropriate age in China, which improved the early detection rate to some extent [3]. If not detected at early stages, it usually progresses to advanced stages at the time of diagnosis. It is mainly due to the deep anatomical location of the cervix as female patients cannot discover the lesion timely. Besides, there are no obvious clinical symptoms and manifestations during early stages of cancer, which leads to the spread of cancerous tissues during the progression of disease [4]. Previously, radiotherapy was the commonly used method to treat advanced cervical cancer. However, due to the higher infiltration range of tumor cells in advanced cervical cancer patients and the critical situation of patients, radiotherapy cannot control this cancer. Chemotherapy, however, can control advanced cervical cancer. At present, nab-paclitaxel is one of the most used chemotherapeutic drugs. Being a new type of paclitaxel, it has better absorption, transport, utilization rate and overall therapeutic effect in humans. Nab-paclitaxel is safer as compared to the common paclitaxel. In recent years, many clinical experiences have confirmed better clinical efficacy of nab-paclitaxel during the treatment of gynecological tumors [5–10]. Therefore, to further investigate the intake effect of nab-paclitaxel in patients with advanced cervical cancer, a comparative study was conducted in advanced cervical cancer patients admitted in Wuhan Third Hospital from July 2021 to July 2022.

## 2. Materials and methods

### 2.1 Materials

A total of 96 advanced cervical cancer patients treated with chemotherapy in Wuhan Third Hospital were screened as observation subjects. The treatment lasted from July 2021–July 2022. These 96 subjects were divided into A and B groups by random envelope method with 48 subjects in each

group. Group A was given paclitaxel + cisplatin chemotherapy, while group B was treated with nab-paclitaxel + cisplatin chemotherapy. The inclusion criteria were as below: (1) aged 45–65 years; (2) confirmation of the advanced stage cervical cancer by clinical comprehensive diagnosis and pathological results; (3) the expected survival time was not less than 6 months; (4) the first treatment was received in Wuhan Third Hospital, without any previous chemotherapy treatment from any other hospital; (5) the liver and kidney functions were normal and kept in line with the treatment criteria for chemotherapy; (6) and the patient showed good compliance, cooperating to complete the study, voluntarily participating after specifically understanding the study, and signing the relevant documents. The exclusion criteria were as follows: (1) combined with other malignant tumors; (2) combined with infectious diseases; (3) pregnant women; (4) chemotherapeutic contraindications; (5) and unable to cooperate with the follow-up. The general data of patients in the above different groups were homogeneous ($p < 0.05$).

## 2.2 Method

Before treatment, dexamethasone, H2 receptor antagonists and antihistamines were administered to prevent and control adverse reactions.

### 2.2.1 Control group

This group was administered paclitaxel + cisplatin as the chemotherapy regimen. Paclitaxel intake was at a standard total dose of 175 mg/m$^2$ by intravenous drip over a period of 3 hours. Cisplatin was administered intravenously at a total dose of 60 mg/m$^2$ over 1 hour. A 21-days treatment course was repeated after 21-days intervals.

### 2.2.2 Observation group

This group was given nab-paclitaxel + cisplatin as the chemotherapy regimen. The total dose of nab-paclitaxel was 175 mg/m$^2$, administered by intravenous drip. Nab-paclitaxel (100 mg) was diluted with 20 mL normal saline (NS, 0.9%), for slow intravenous drip administration. The drip time was not less than 30 minutes and nab-paclitaxel reaction was closely observed. If there was no obvious discomfort, the remaining nab-paclitaxel diluted with NS (@ 5:1) was administered intravenously. The infusion time was 30 minutes. Cisplatin was utilized in the same way as the control group. A 21-days course of treatment was repeated after 21-days intervals.

Both groups required 3 consecutive courses of treatment.

The observation period for this study was 3 months.

## 2.3 Outcome measures

### 2.3.1 Clinical data of patient

Patient age, body mass index (BMI), tumor diameter, KPS score, pathological type/differentiation and International Federation of Obstetrics and Gynecology (FIGO) stage were summarized.

### 2.3.2 Short-term efficacy

After 3 courses of treatment, the treatment effect was evaluated, including complete response (after chemotherapy, the tumor shrank to half of its size, and the disease control was good), partial response (after chemotherapy, the tumor shrinkage was not up to 1/2, and the disease could be controlled), stability (after chemotherapy, the tumor increased in size, but below 1/5 or the tumor shrank slightly in size), and progression (after chemotherapy, the tumor volume was increased by no less than 1/5). The effective control rate was = complete response rate + partial response rate + stable disease rate.

### 2.3.3 Tumor markers

Before and after treatment, peripheral venous blood was drawn under fasting conditions to evaluate the level of serum tumor markers, including squamous cell carcinoma antigen (SCC-Ag), carcinoembryonic antigen (CEA), and carbohydrate antigen 125 (CA125).

### 2.3.4 Immune function indicators

T lymphocyte subsets were measured to evaluate the immune function, and the indicators observed were CD4+, CD8+ and CD4+/CD8+.

### 2.3.5 Treatment-related adverse reactions

Associated gastrointestinal reactions, bone marrow suppression, hepatic impairment, and renal impairment were summarized for the on-treatment period.

### 2.3.6 Quality of life improvement

According to Karnofsky Performance Scale (KPS), the evaluation was divided into the following aspects: increased quality of life (score was increased no less than 10 points after treatment as compared to untreated); stable quality of life (score was increased/decreased within 10 points after treatment as compared to untreated); and decreased quality of life (score was decreased by more than 10 points after treatment as compared to untreated).

## 2.4 Statistical analysis

SPSS 22.0 (IBM Corporation, Armonk, NY, USA) was utilized to process the data, ($\bar{x} \pm s$) indicated measurement data, while (%) indicated enumeration data, which was subjected to $t$ test and $\chi^2$ test, respectively. $p < 0.05$ demonstrated statistical significance.

# 3. Results

## 3.1 Comparison of clinical data between groups

Both groups did not show any substantial difference ($p > 0.05$) with each other regarding the baseline data of patients in the two groups. The results were detailed in Table 1.

## 3.2 Analysis of short-term efficacy

Regarding the effective disease control rate, there was a significant difference between both groups, which was relatively higher in the observation group ($p < 0.05$), as shown in Table 2.

**TABLE 1. Comparison of clinical data between groups (n (%), $\bar{x} \pm s$).**

| Indicators | Item | Observation group (n = 48) | Control group (n = 48) | $\chi^2/t$ | $p$ |
|---|---|---|---|---|---|
| Pathological type | | | | | |
| | Squamous cell carcinoma | 41 | 40 | | |
| | Adenocarcinoma | 4 | 4 | 0.1552 | 0.9253 |
| | Other | 3 | 4 | | |
| FIGO stage | | | | | |
| | Stage IIb | 15 | 13 | | |
| | Stage III | 29 | 30 | 0.2709 | 0.8733 |
| | Stage IV | 4 | 5 | | |
| Pathologic differentiation | | | | | |
| | Poorly differentiated | 13 | 15 | | |
| | Moderately differentiated | 25 | 24 | 0.2159 | 0.8977 |
| | Well-differentiated | 10 | 9 | | |
| Age (yr) | | 55.86 ± 2.37 | 56.10 ± 2.52 | 0.4807 | 0.6319 |
| Tumor diameter (cm) | | 4.26 ± 0.38 | 4.30 ± 0.41 | 0.4957 | 0.6212 |
| BMI (kg/m$^2$) | | 22.38 ± 1.15 | 22.47 ± 1.20 | 0.3752 | 0.7084 |
| KPS score | | 84.25 ± 2.11 | 84.36 ± 2.21 | 0.2494 | 0.8036 |

*BMI: body mass index; KPS: Karnofsky Performance Scale; FIGO: International Federation of Obstetrics and Gynecology.*

**TABLE 2. Analysis of short-term efficacy (n (%)).**

| Group | Case | Complete response | Partial response | Stability | Progression | Effective control rate |
|---|---|---|---|---|---|---|
| Observation group | 48 | 9 (18.75) | 20 (41.67) | 13 (27.08) | 6 (12.50) | 42 (87.50) |
| Control group | 48 | 7 (14.58) | 16 (33.33) | 10 (20.83) | 15 (31.25) | 33 (68.75) |
| $\chi^2$ value | | | | | | 4.9371 |
| $p$ value | | | | | | 0.0263 |

### 3.3 Comparison of serum tumor marker indicators

At enrollment, little difference was observed in the level of the three serum tumor markers between the two groups ($p > 0.05$). After treatment, indicators of both groups decreased remarkably ($p > 0.05$). After treatment, indicators in the observation group were relatively lower ($p < 0.05$). The results are displayed in Table 3.

### 3.4 Comparison of immune function indicators

At enrollment, there was little difference in the profile of immune function indicators between the two groups ($p > 0.05$). After treatment, CD4+ and CD4+/CD8+ levels were prominently increased. After treatment, the observation group had comparatively higher level ($p < 0.05$) of CD4+ and CD4+/CD8+. The results were presented in Table 4.

### 3.5 Analysis of treatment-related adverse reactions

The incidence of treatment-related adverse reactions was significantly different in both groups, which was relatively lower in the observation group ($p < 0.05$). The results were manifested in Table 5.

### 3.6 Evaluation for KPS improvement

The effective rate of KPS improvement showed prominent significance between both groups being relatively higher in the observation group ($p < 0.05$). The results were presented in Table 6.

## 4. Conclusions

Cervical cancer and ovarian cancer being malignant tumors of the reproductive organs show a relatively high incidence in women, and are characterized by both morbidity and mortality. Till now, the mechanism of induction of cervical cancer is unclear. It is believed to have close association with factors like delivery, viral infection, sexual behavior, and environment [11, 12]. Patients with advanced cervical cancer usually undergo chemotherapy when surgical treatment cannot be performed or the patients cannot tolerate surgery [13, 14]. Radiotherapy is mostly used when cancer is at clinically advanced stages. However, due to the serious situation in advanced cervical cancer patients and the wide spread of cancer cells, radiotherapy does not give presumed results. Several studies have confirmed that chemotherapy of cervical cancer patients

**TABLE 3. Comparison in indicators of serum tumor marker ($\bar{x} \pm s$, $\mu$g/L).**

| Indicators | Time | Observation group (n = 48) | Control group (n = 48) | *t* | *p* |
|---|---|---|---|---|---|
| SCC-Ag | | | | | |
| | Pre-treatment | 40.17 ± 6.36 | 39.82 ± 6.80 | 0.2604 | 0.7951 |
| | Post-treatment | 19.75 ± 3.28 | 24.67 ± 3.42 | 7.1933 | <0.001 |
| | *t* | 19.7700 | 13.7898 | | |
| | *p* | <0.001 | <0.001 | | |
| CEA | | | | | |
| | Pre-treatment | 16.35 ± 2.36 | 16.21 ± 2.14 | 0.3045 | 0.7614 |
| | Post-treatment | 7.01 ± 1.28 | 9.25 ± 1.52 | 7.8097 | <0.001 |
| | *t* | 24.1024 | 18.3705 | | |
| | *p* | <0.001 | <0.001 | | |
| CA125 | | | | | |
| | Pre-treatment | 40.20 ± 7.36 | 39.65 ± 6.80 | 0.3802 | 0.7046 |
| | Post-treatment | 19.65 ± 3.28 | 23.77 ± 4.23 | 5.3327 | <0.001 |
| | *t* | 17.6692 | 3.7382 | | |
| | *p* | <0.001 | <0.001 | | |

*SCC-Ag: squamous cell carcinoma antigen; CEA: carcinoembryonic antigen; CA125: carbohydrate antigen 125.*

**TABLE 4. Comparison of immune function indicators ($\bar{x} \pm s$, %).**

| Indicators | Time | Observation group (n = 48) | Control group (n = 48) | *t* | *p* |
|---|---|---|---|---|---|
| CD4+ | | | | | |
| | Pre-treatment | 29.37 ± 3.45 | 29.41 ± 3.58 | 0.0557 | 0.9557 |
| | Post-treatment | 41.55 ± 4.01 | 35.36 ± 3.62 | 7.9384 | <0.001 |
| | *t* | 15.9523 | 8.0968 | | |
| | *p* | <0.001 | <0.001 | | |
| CD8+ | | | | | |
| | Pre-treatment | 26.45 ± 2.52 | 26.60 ± 2.57 | 0.2887 | 0.7734 |
| | Post-treatment | 27.20 ± 2.36 | 26.36 ± 2.26 | 1.7810 | 0.0781 |
| | *t* | 1.5050 | 0.4859 | | |
| | *p* | 0.1357 | 0.6282 | | |
| CD4+/CD8+ | | | | | |
| | Pre-treatment | 1.06 ± 0.17 | 1.08 ± 0.18 | 0.5597 | 0.5770 |
| | Post-treatment | 1.60 ± 0.28 | 1.35 ± 0.12 | 5.6857 | <0.001 |
| | *t* | 11.4213 | 8.6469 | | |
| | *p* | <0.001 | <0.001 | | |

*CD4+: cluster of differentiation 4; CD8+: cluster of differentiation 8.*

**TABLE 5. Analysis of treatment-related adverse reactions (n/%).**

| Group | Case | Gastrointestinal reactions | Myelosuppression | Hepatic impairment | Renal impairment | Incidence |
|---|---|---|---|---|---|---|
| Observation group | 48 | 3 (6.25) | 2 (4.17) | 1 (2.08) | 1 (2.08) | 7 (14.58) |
| Control group | 48 | 7 (14.58) | 5 (10.42) | 4 (8.33) | 2 (4.17) | 16 (33.33) |
| $\chi^2$ | | | | | | 4.6313 |
| *p* | | | | | | 0.0314 |

**TABLE 6. Evaluation for KPS improvement (n/%).**

| Group | Case | Increased | Stable | Decreased | Effective rate |
|---|---|---|---|---|---|
| Observation group | 48 | 23 (47.92) | 20 (41.67) | 5 (10.42) | 43 (89.58) |
| Control group | 48 | 20 (41.67) | 15 (31.25) | 13 (27.08) | 35 (72.92) |
| $\chi^2$ | | | | | 4.3761 |
| $p$ | | | | | 0.0364 |

showed satisfactory therapeutic results, prolonging survival time and reducing the impact of the disease on quality of life of patients [15, 16]. Hence, chemotherapeutic drugs and treatment regimens continue to be optimized, substantially improving the clinical treatment effect of the cancer [17, 18].

Paclitaxel combined with platinum chemotherapy yields good results in gynecological tumors, and the clinical application of paclitaxel considerably improves the effectiveness of chemotherapy. Drugs can then inhibit tubulin depolymerization stabilizing the tubulin characteristics, with better therapeutic effects. However, it produces serious adverse reactions [19, 20]. Being practically insoluble in water, absolute ethanol (1:1) or polyethylene castor oil is needed to dissolve paclitaxel in clinical practice. Although polyethylene castor oil assists paclitaxel molecule to enter the blood by surrounding it, it affects the drug absorption and utilization rate, reducing the therapeutic effect, and producing histamine in the body, thus leading to severe allergy. Hence, despite pre-treatment before medication, the incidence of clinical adverse reactions is high [21–24].

Corresponding studies have validated the critical role of nab-paclitaxel in the clinical treatment of distinct malignant tumors and has been well-received by physicians and patients [25, 26]. In this study, advanced cervical cancer patients in the observation group were treated with nab-paclitaxel combined with cisplatin during chemotherapy. As confirmed by the results, the therapeutic effect and safety were notably improved as compared to patients receiving simple paclitaxel. It confirmed that nab-paclitaxel is excellent from a medication and safety perspective. Nab-paclitaxel is a new generation of targeted agents, which use nanotechnology to produce gelatinous particles, increasing their water solubility. No pretreatment is required when nab-paclitaxel is used for treatment, effectively avoiding the increased risk of adverse reactions caused by bulk pretreatment of paclitaxel [27, 28]. Albumin acts as nab-paclitaxel carrier transporting it into the tumor cells *via* endocytosis, thereby ensuring drug concentration in the interstitial space enhancing anti-tumor efficacy [29, 30].

The level of serum tumor marker was lower in the treated group, and the immune function index was higher in the observation group. Typical tumor markers, serum squamous cell carcinoma antigen (SCC Ag), carcinoembryonic antigen (CEA) and cancer antigen 125 (CA125) are used for the diagnosis of malignant tumors and the judgment of therapeutic effect. The index level was lower in this observation group, suggesting that the therapeutic effect was more suitable. SCC-Ag, a tumor marker previously used for the diagnosis of squamous cell carcinoma with good specificity, can differentiate cervical cancer from benign gynecological diseases. SCC-Ag elevation was mainly observed in cervical squamous cell carcinoma, but not adenocarcinoma. The detection of SCC-Ag can be used for the differential diagnosis of cervical squamous cell carcinoma. The concentration of SCC-Ag increases with increasing stage of cervical squamous cell carcinoma. Hence, the detection of SCC-Ag plays a guiding role in the clinical management of disease stage, classification, and the selection of treatment options. CEA is a broad-spectrum tumor marker observed in gynecological, lung, and colorectal cancers and a variety of other malignant tumors. CEA is commonly used for the differential diagnosis, disease monitoring and prognosis of cervical cancer. CA125 is detected in epithelial ovarian cancer antigens and binds to monoclonal antibodies. Meanwhile, CA125 serves as a specific marker of ovarian cancer, and increases the level of CA125 in patients with endometrial cancer, cervical cancer, and breast cancer.

Treatment, increased levels of CD4+ and CD4+/CD8+ in the observation group, implying that nab-paclitaxel was conducive for strengthening the ability of T lymphocyte subsets, enhancing the ability of virus invasion, and the anti-tumor effect. The KPS scores of both groups were analyzed after treatment. The results showed that the higher effective rate of KPS improvement in the observation group. It is mainly since nab-paclitaxel strengthens the immune function of the body controlling adverse reactions, thereby promoting functional status of the patients, improving their life quality, and enhancing the overall benefits for patients.

In summary, nab-paclitaxel is quite beneficial for advanced cervical cancer patients in combination with chemotherapy, as it strengthens the immune function, improves the effectiveness of disease control, and promotes functional status. However, the single source of patients, relatively insufficient sample size and the shorter subsequent follow-up time are main limitations of this study. In depth clinical studies are required on nab-paclitaxel in advanced cervical cancer patients to verify its long-term efficacy.

## AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

## AUTHOR CONTRIBUTIONS

AHW, FZZ and XHZ—designed the study and carried them out; supervised the data collection, analyzed the data, interpreted the data, prepare the manuscript for publication and reviewed the draft of the manuscript. All authors have read and approved the manuscript.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Wuhan Third Hospital (Approval no. 2021012). Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.


## ACKNOWLEDGMENT

Not applicable.

## FUNDING

This research received no external funding.


## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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**How to cite this article:** Aihua Wang, Feizhong Zhang, Xiaohua Zhang. Study on the intake and efficacy of nab-paclitaxel in patients with advanced cervical cancer. European Journal of Gynaecological Oncology. 2023; 44(4): 95-101. doi: 10.22514/ejgo.2023.061.