

Apatinib monotherapy in patients with advanced ovarian cancer after platinum resistance : a prospective, exploratory study



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Background:

Apatinib is a novel tyrosine kinase inhibitor targeting vascular endothelial growth factor receptor 2. This prospective, exploratory, single-arm, multicenter clinical study to observe and evaluate the efficacy and safety of apatinib in patients with advanced ovarian cancer(OC) who failed standard treatment.

Methods:

Forty-five female patients (age ≥ 18 yrs, ≤ 70 yrs) with pathologically diagnosed OC after standard treatment failure (which advanced OC with platinum resistance) met the inclusion criteria and were treated with apatinib (250/500 mg/day). Clinical information on the patients was collected. Clinical efficacy (complete response, CR; partial response, PR; stable disease, SD; progressive disease, PD; objective response rate, ORR; duration of response, DRR) based on mRECIST criteria, progression-free survival(PFS) and adverse events(AEs) were evaluated.

Results:

From June 1, 2018 to April 26, 2019. 45 patients were included in the analysis. The age of the patients was 53 yrs. Patients with Eastern Cooperative Oncology Group (ECOG) score 1 accounted for 86.7%, 24(55.8%) patients received less than third-line treatment, and 19 (44.2%) patients received more than third-line treatment. Total 71.1% patients received apatinib at the dose of 500mg. There were 28 patients eligible for efficacy evaluation. Among them, 6 achieved PR, 21 achieved SD, and 1 achieved PD, resulting in an ORR of 21.4% and a DCR of 96.4%. The mPFS and OS data was still in follow-up.

This study showed the incidence of AEs was 85.7% and the grade 3/4 treatment-related AEs was 11.4%. The most common treatment-related AEs were hypertension (37.5%), hand-foot syndrome (28.6%), debilitation (17.2%), proteinuria (5.7%), anorexia (2.9%), and diarrhea (5.7%).

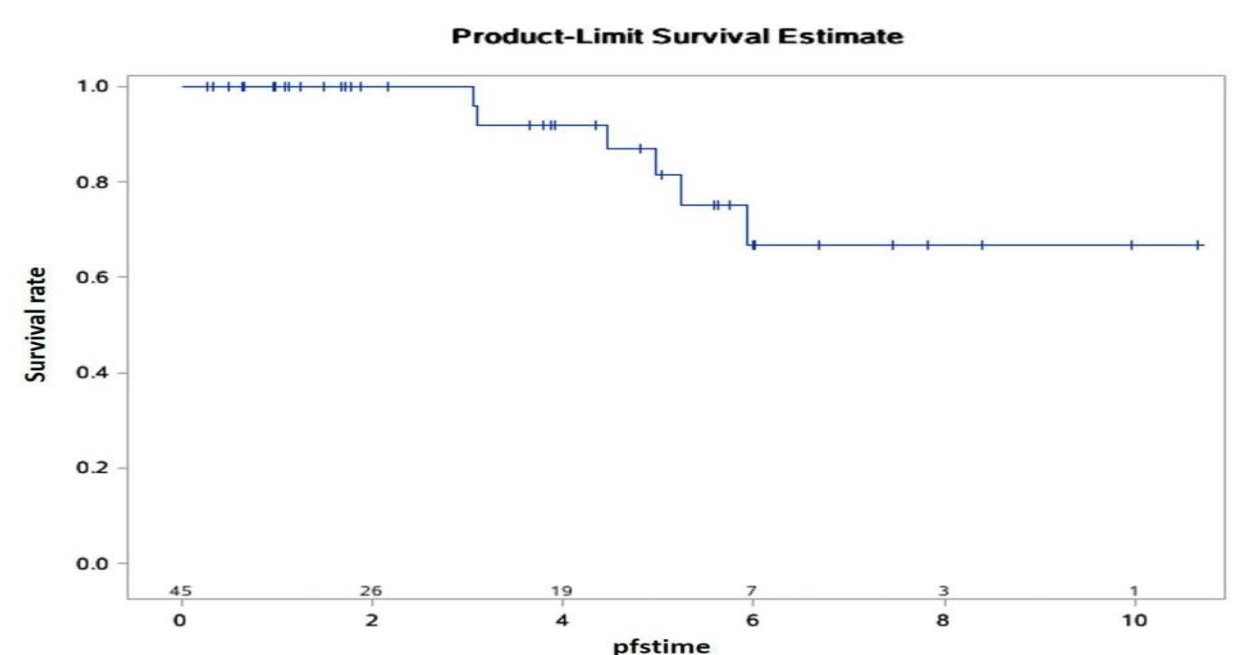
Table 1 Patient characteristic

Characteristics	N(%)
Age, years	
Median(Mean \pm SD)	54.16 \pm 9.26
Treatment line	
≤ 3	24(55.8%)
> 3	19(44.2%)
ECOG	
0	6(13.3%)
1	39(86.7%)

Table 2 Efficacy evaluation

Complete clinical efficacy	
CR	0
PR	6
SD	21
PD	1
ORR	21.4%
DCR	96.4%

Figure1 Progression-free survival



Conclusions:

In this exploratory study, apatinib monotherapy exhibited potential efficacy and manageable toxicity for OC patients who failed standard treatment. Although PFS and OS have not been achieved, it could be predicted that PFS will exceed 6 months and OS will exceed 10 months.