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The safety and efficacy of cadonilimab in the treatment of advanced and metastatic cervical cancer: A retrospective, real-world study.

Shi Fan, Tao Wang, Qiying Zhang, Juan Wang, Jin Su, Jing Zhang, Fei Wang, Zi Liu; Department of Radiation Oncology, The First Affiliated Hospital of Xi'an Jiao Tong University, Xi'an, China

Background: Recurrent/metastatic cervical cancer (r/m CC) patients have limited treatment options. Cadonilimab, a PD-1/CTLA-4 bi-specific antibody, was approved in China on 29 June 2022 for the treatment of patients with r/m CC who have progressed on or after platinum-based chemotherapy. As monotherapy provides encouraging safety and efficacy, it may be better combined with another therapy including chemotherapy, radiotherapy, targeted therapy, or immunotherapy. The objective of this retrospective study was to evaluate the safety and efficacy of Cadonilimab monotherapy/combination therapy in patients with advanced r/m CC. **Methods:** Patients with FIGO stage IIIc2r-IVb CC treated with Cadonilimab containing therapy were enrolled. All patients received at least one dose of Cadonilimab (10mg/kg, Q3W), among them, 5 patients received Cadonilimab monotherapy, 11 patients received concurrent radiotherapy, 19 patients received concurrent chemotherapy, 12 patients received targeted therapy, and 4 patients received local injection s of oncolytic virus. Treatment-related toxicity (TRAEs), objective response rate (ORR) and disease control rate (DCR) were evaluated. **Results:** 26 patients with a median age of 54 years (40-73 years) were evaluated up to 20 January 2023. As shown in the table, 21 patients were still on treatment, 5 patients were discontinued due to death. In the efficacy-evaluable population(n=24), the ORR was 70.8% (17/24,95% CI:51.2%-90.4%) with 3 (12.5%) CR,14 PR, 2 SD, and the DCR was 79.2%(19/24,95% CI:61.6%-96.7%). Immune-related AEs (irAEs) were all G1-2, and occurred in 4 (16.7%) patients. Main irAEs included hypothyroidism (n=3, 12.5%), fatigue (n=1, 4.2%), loss of appetite (n=1, 4.2%), hematologic toxicity (thrombocytopenia) (n=1, 4.2%), mucositis (n=1, 4.2%), and rash (n=1, 4.2%). Rashes and loss of appetite typically developed after the first cycle of Cadonilimab treatment, while hypothyroidism usually developed after the second or third cycle. 2 (8.3%) patients experienced G3-5 TRAEs, which were thought to be primarily related to chemotherapy. All the 5 deaths were heavily pretreated (≥3 lines) patients who received Cadonilimab monotherapy. Among the 24 patients, only 1 patient delayed treatment after the 1st cycle due to economic reasons. There were no toxic deaths reported. **Conclusions:** In the real world, Cadonilimab showed a manageable safety profile. Patients with advanced r/m CC tend to benefit from first-line/ second-line Cadonilimab containing combination therapies due to the excellent response rates. Research Sponsor: None.

Baseline characteristic, safety and efficacy results.

		Combined treatment				TRAEs	irAEs		
Lines	Enrolled (n)	Radiation (n)	Chemo (n)	Target (n)	Oncolytic virus (n)	G3-5 n(%)	G1-2 n(%)	ORR (%)	DCR (%)
Niave	6	6	6	4	0	0(0%)	1(4.2%)	100%	100%
1L	8	3	8	5	1	2(8.3%)	3(12.5%)	100%	100%
2L	1	1	1	1	0	0(0%)	0(0%)	100%	100%
≥3L	9	1	4	2	3	0(0%)	0(0%)	22%	44%