CAMRELIZUMAB COMBINED WITH PACLITAXEL AND NEDAPLATIN IN THE FIRST-LINE TREATMENT OF LOCALLY ADVANCED/ADVANCED ESOPHAGEAL SQUAMOUS CELL CARCINOMA: A PHASE II, SINGLE-ARM, EXPLORATORY RESEARCH

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Background Treatment options for patients with locally advanced/advanced esophageal squamous cell carcinoma (ESCC) are limited. Current guidelines for first-line treatment of advanced ESCC recommend chemotherapy containing a platinum and a paclitaxel agent. Camrelizumab demonstrated antitumor activity in the first-line treatment of advanced ESCC. This study aimed to explore the efficacy and safety of camrelizumab combined with paclitaxel and platinum in the first-line treatment of ESCC.

Methods In this single-arm, phase II study, patients were eligible for enrollment if they had a histologically or cytologically confirmed diagnosis of locally advanced/advanced unresectable ESCC. The patients received camrelizumab (200mg, iv, q3w) in combination with chemotherapy. The chemotherapy regimen consists of paclitaxel (155mg/m², iv, q3w) and nedaplatin (80mg/m², iv, q3w) for 6 cycles, and the therapeutic effects were determined every 2 cycles (6 weeks). The primary endpoint was the rate of 12-month overall survival, and the secondary endpoints were objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS).

Results From May 2020 to July 2021, 83 patients with a median age of 58 years (range 44–75 years) were enrolled. The median treatment duration was 87 days. Among them, 50 patients were available for efficacy analysis, of which 31 patients achieved partial response (PR), and 18 had stable disease (SD). The ORR was 62% and DCR was 98%. 33 patients were in the process of therapy and had not completed 2 cycles, and the efficacy evaluation cannot be performed yet. The adverse reactions in this study include reduction of red blood cell (20.1%), anemia (17.7%), hypomagnesemia (15.10%), fatigue (14%), thrombocytopenia (10.1%), hand-foot skin reaction (8.9%), proteinuria (7.6%), hyponatremia (6.3%), neutropenia (2.5%), reactive cutaneous capillary endothelial proliferation (10.1%) and immune pneumonia (1.2%). During the course of therapy, all adverse events (AEs) were grade 1/2, and no patient experienced grade 3/4 AEs. No patient was hospitalized because of treatment-related complications. The treatment was well tolerated and no toxic death occurred. All the AEs can be controlled and alleviated after symptomatic treatment.

Conclusions Camrelizumab in combination with paclitaxel and platinum displayed controllable security and similar therapeutic effect to other immune checkpoint inhibitors. This encouraging result promoted us to continue this phase II study.

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Trial Registration ChiCTR2100046355

Ethics Approval The study has obtained ethics approval. The name of the ethics committee: Chinese Ethics Committee of Registering Clinical Trials. Registration number: ChiCTR2100046355. The authors stated that the participants gave informed consent before taking part.