

CAMRELIZUMAB COMBINED WITH PACLITAXEL AND NEDAPLATIN AS NEOADJUVANT THERAPY FOR LOCALLY ADVANCED ESOPHAGEAL SQUAMOUS CELL CARCINOMA (ESPRIT): A PHASE II, SINGLE-ARM, EXPLORATORY RESEARCH

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Background Camrelizumab has been approved as a standard therapy in the second-line treatment of esophageal squamous cell carcinoma (ESCC). This study aimed to explore the efficacy and safety of camrelizumab combined with commonly used chemotherapy (paclitaxel and platinum) in neoadjuvant treatment of ESCC.

Methods In this single-arm, phase II study, patients with advanced ESCC who were expected to receive neoadjuvant therapy followed by radical surgery were recruited. The patients received 2–4 cycles of camrelizumab (200mg, iv, q3w) in combination with paclitaxel (155mg/m², iv, q3w) and nedaplatin (80mg/m², iv, q3w) as neoadjuvant therapy, and the therapeutic effects were determined every 2 cycles. The radical surgery was performed on patients whose tumors were evaluated as resectable. The primary endpoint was pathological complete remission (pCR) rate, and the secondary endpoints were objective response rate (ORR), disease control rate (DCR), disease-free survival (DFS), overall survival (OS) and safety.

Results From June 2020 to July 2021, 42 patients with a median age of 63 years (range 48–73 years) were enrolled. The median treatment duration was 67 days. Among all patients, 23 patients were available for efficacy analysis, of which 1 patient achieved complete response, 12 patients achieved partial response, and 10 patients had stable disease. The ORR was 56.52% and DCR was 100%. The tumor in 1 patient shrank significantly after neoadjuvant therapy and the patient preferred radiotherapy instead of surgery as the radical therapeutic method. 2 patients abandoned surgery because of personal reasons. 23 patients were in the process of neoadjuvant therapy and had not undergone surgery yet. The remaining 16 patients underwent radical surgery and 6 patients (37.5%) achieved pCR (pT0N0M0). The adverse reactions in this study includes reduction of red blood cell (21.4%), anemia (21.4%), hypomagnesemia (19.1%), fatigue (16.7%), thrombocytopenia (16.7%), proteinuria (14.3%), hand-foot skin reaction (14.3%), hyponatremia (11.9%), neutropenia (7.1%) and reactive cutaneous capillary endothelial proliferation (7.1%). The main treatment-related grade 3/4 adverse event (AE) was neutropenia (2.3%). All the AEs were manageable. The average intraoperative blood loss was 206 ml and the average hospitalization time after operation was 11 days (range 7–19 days). No anastomotic leakage and treatment-related death occurred.

Conclusions The ESPRIT study suggested that camrelizumab in combination with paclitaxel and nedaplatin as a neoadjuvant therapy was well tolerated. 37.5% of the patients can achieved pCR, which was of great significance for improving the prognosis and prolonging the survival time. This encouraging result promoted us to continue this phase II study.

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