Background Several immune checkpoint inhibitors (ICIs), represented by programmed cell death protein 1 (PD-1)/programmed cell death ligand 1 (PD-L1) antibodies, have been approved for treatment of various malignant tumors (including advanced esophageal cancer) worldwide, and previous studies confirmed that they can significantly improve overall survival. However, there has been limited research on the use of ICIs as neoadjuvant therapy for patients with esophageal cancer. Toripalimab is a humanized IgG4 monoclonal antibody that targets PD-1. The objective of this study is to evaluate the efficacy and safety of toripalimab plus chemotherapy as a neoadjuvant therapy regimen for treatment of patients with locally advanced esophageal squamous cell carcinoma (ESCC).

Methods This single-arm, single-center study enrolled patients with ESCC at clinical stage T2-T4/N0-N2/M0, who were eligible for radical resection and regional lymph node dissection. The patients received 2–3 cycles of toripalimab (240 mg d1, Q3W) in combination with nab-paclitaxel (260 mg/m² d1, Q3W) and carboplatin (AUC=5 d1, Q3W) before surgery. Preoperative evaluation was performed within 4 weeks after the last administration of chemotherapy. The primary endpoints were pathologic complete response (PCR) and major pathologic response (MPR), and the secondary endpoints were safety and feasibility of the neoadjuvant immunotherapy.

Results Seventeen patients diagnosed with ESCC at a pre-treatment clinical stage of T2-T4/N0-N2/M0 were included. After neoadjuvant therapy, 15 of 17 patients (88.2%) experienced downstaging and met the surgical criteria. Twelve patients (80.0%) underwent surgery without delay and 3 patients (20.0%) refused surgery. The tumors were completely removed in all 12 patients (R0 resection rate: 100%). Seven patients (58.3%) achieved MPR and 2 (16.7%) achieved PCR. The median post-surgical follow-up time was 4.5 months, and there were no recurrences. Treatment-related adverse events (TRAEs) of the neoadjuvant therapy were tolerable. Grade 3 or higher TRAEs occurred in 2 patients (11.8%), but these did not delay surgery.

Conclusions Toripalimab in combination with chemotherapy as neoadjuvant therapy showed promising anti-tumor activity with acceptable tolerability for locally advanced ESCC, as demonstrated by reducing the tumor burden, improving the R0 resection rate, reducing the postoperative recurrence rate, and no delays in surgery.

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Ethics Approval This study was approved by the Ethics Board of the Army Medical center of the PLA, approval number 142(2018).

Consent Written informed consent was obtained from the patient for publication of this abstract and any accompanying images. A copy of the written consent is available for review by the Editor of this journal.

REFERENCE

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