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Neoadjuvant toripalimab combined with chemotherapy for locally advanced penile squamous cell carcinoma: A multicenter prospective, single-arm, phase II clinical trial

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Background

The neoadjuvant regimen of paclitaxel, ifosfamide, and platinum (TIP) regimen is recommended for local advanced penile squamous cell carcinoma (La-PSCC); however, its objective response rate (ORR) is only 50%, with limited long-term survival outcomes. This phase II study was designed to evaluate the efficacy and safety of toripalimab combined with TIP chemotherapy as neoadjuvant therapy in chemotherapy-naïve patients with La-PSCC.

Methods

This was a prospective, multicenter, single-arm phase II study. Eligible patients were those with T4/N2-3 M0 PSCC. All patients received up to four cycles of neoadjuvant toripalimab combined with TIP chemotherapy, followed by consolidative surgery. Postoperatively, toripalimab maintenance therapy was administered every three weeks for up to 17 cycles. The primary endpoint was the ORR assessed according to RECIST v1.1. Secondary endpoints include pathological complete response (pCR), event-free survival (EFS), overall survival (OS), and the incidence of treatment-related adverse events (TRAEs).

Results

A total of 25 patients received ≥2 cycles of toripalimab combined with TIP chemotherapy were enrolled. The ORR was 84.0%, with 2 patients achieving CR and 19 achieving PR. 21 patients received following consolidative surgery, with a pCR rate of 48.0%. All patients experienced TRAEs of any grade, and grade 3-4 TRAEs occurred in 84.0% of patients. The most common grade 3-4 TRAEs were neutropenia. Immune-related Hypothyroidism occurred in 2 patients. No treatment-related deaths were observed. At a median follow-up of 16.1 months (95%CI, 12.3-20.0), the 12-month EFS and OS rates were 72.0% (95% CI: 56.4-91.9) and 88.0% (95% CI: 76.1-100), respectively. Median EFS and OS were not reached. Compared with HPV-negative patients, positive patients showed favorable trends in both EFS (HR: 0.32, p=0.15) and OS (HR: 0.01, p=0.07). Mature survival data are awaited with longer follow-up.

Conclusions

Neoadjuvant toripalimab combined with TIP chemotherapy exhibits significant efficacy in chemotherapy-naïve patients with La-PSCC, with acceptable toxicity. This combination holds great promise as a new standard treatment for La-PSCC.

Clinical trial identification

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Legal entity responsible for the study

Hui Han.

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Disclosure

All authors have declared no conflicts of interest.

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