

Three Courses of Neoadjuvant Camrelizumab Combined with Chemotherapy in Locally Advanced Esophageal Squamous Cell Carcinoma (ESCC): A Prospective Phase II Clinical Trial

Xu Zhang¹, Guozhen Yang¹, Xiaodong Su¹, Yating Zheng², Mengli Huang²,

¹Sun yat-sen university cancer center, Guangzhou, China; ²The Medical Department, 3D Medicines, Inc., Shanghai, China



Poster: #1256P

Background

The efficacy and safety of two cycles of neoadjuvant immunochemotherapy in locally advanced ESCC have been investigated. However, it is unclear whether more cycles of neoadjuvant immunochemotherapy could improve the efficacy without increasing toxicity.

Methods

- Patients: newly diagnosed locally advanced ESCC (clinical stage T₂₋₃, N₀₋₃)
- Neoadjuvant therapy (3 cycles, every 3 weeks)
- Immunotherapy: Camrelizumab 200mg ivgtt day1
- Chemotherapy: nab-paclitaxel 260 mg/m² ivgtt day 1 plus capecitabine 1250 mg/m² days 1-14
- Surgery: 4-6 weeks after the last dose
- 47 patients were planed to enroll
- The primary endpoint: pCR rate
- The second endpoint: safety, 1-year OS, 1-year DFS

All events	No. of patients (%)		
	Total	Grade 1-2	Grade 3-4
Alopecia	32(68.1)	32(68.1)	0(0)
Reactive cutaneous capillary endothelial proliferation	28 (59.6)	28 (59.6)	0 (0)
Fatigue	26(55.3)	25(53.2)	1(2.1)
Anemia	25(53.2)	24 (51.1)	1 (2.1)
Muscle soreness	20 (42.6)	20 (42.6)	0 (0)
Limb numbness	20 (42.6)	19 (40.4)	1 (2.1)
Increased alanine transaminase	11 (23.4)	11 (23.4)	0 (0)
Constipation	8 (17.0)	8 (17.0)	0 (0)
Diarrhea	4 (8.5)	4 (8.5)	0 (0)
Immune-related hyperthyroidism	4 (8.5)	4 (8.5)	0 (0)
Leukopenia	3 (6.4)	3 (6.4)	0 (0)
Vomiting	2 (4.3)	2 (4.3)	0 (0)
Nausea	2 (4.3)	2 (4.3)	0 (0)
Immune-related hypothyroidism	2 (4.3)	2 (4.3)	0 (0)
Thrombocytopenia	2 (4.3)	2 (4.3)	0 (0)
Immune-related myocarditis	1 (2.1)	0 (0)	1 (2.1)
Cough	0 (0)	0 (0)	0 (0)
Immune-related pneumonia	0 (0)	0 (0)	0 (0)
Immune-related hepatitis	0 (0)	0 (0)	0 (0)
Immune-related nephritis	0 (0)	0 (0)	0 (0)

Figure1. Treatment related adverse events

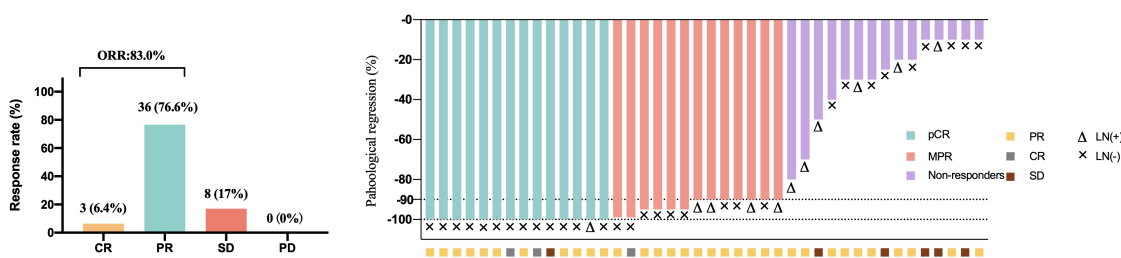


Figure2. Clinical and pathological response to neoadjuvant Camrelizumab plus chemotherapy

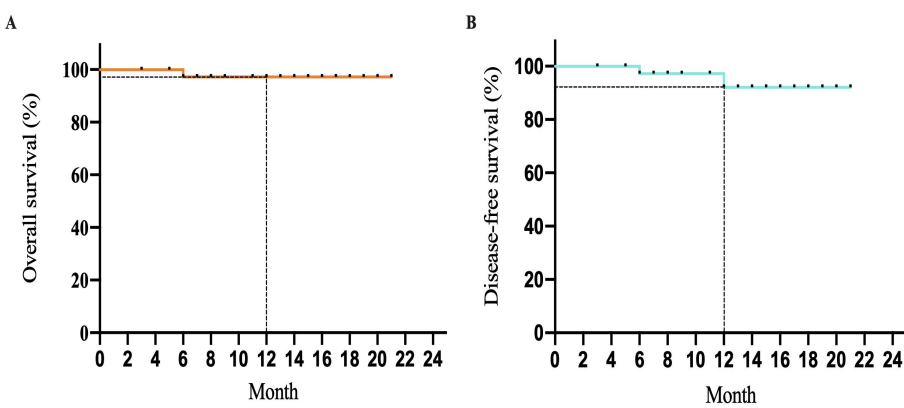


Figure3. Survival of paitents after treatment

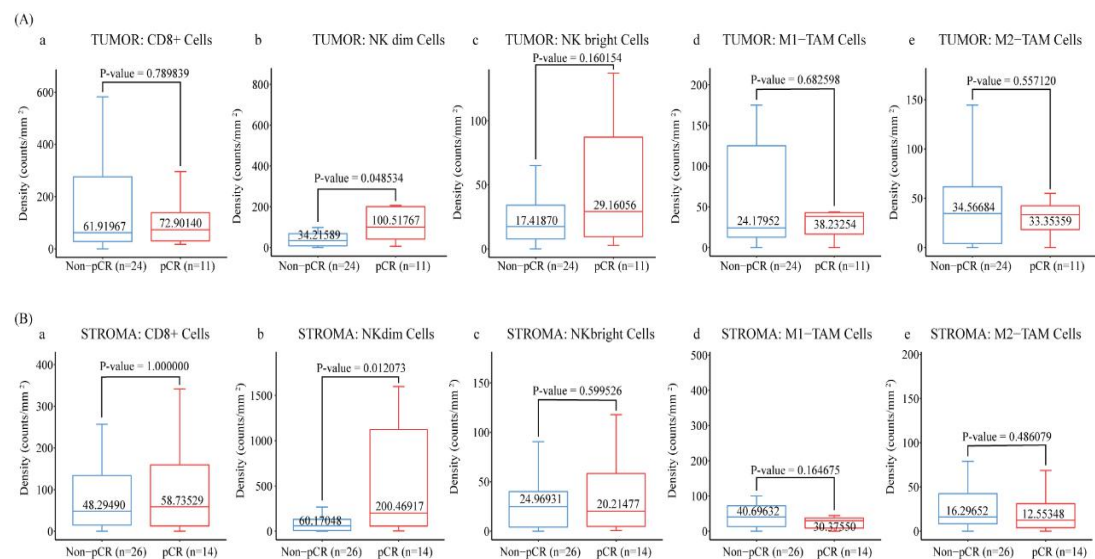


Figure4. Correlation between tumor immune microenvironment (TIME) and pathological response.

Results

- Three cycles of Camrelizumab plus chemotherapy was associated with tolerated side effects (figure1.).
- The ORR rate was 83.0% and the pCR rate was 33.3% (figure 2).
- 1-year OS and DFS was 97.3%, 92.1 % respectively (figure 3).
- Higher abundance of CD56^{dim} natural killer cells was associated with better pathological response in the primary tumor (figure 4).

Discussion

Three cycles of neoadjuvant camrelizumab plus nab-paclitaxel and capecitabine is safe, feasible and effective in locally advanced ESCC and is worth further investigation.