BERLIN 2025 ESMO congress

LBA15

Low dose pembrolizumab in addition to neoadjuvant anthracycline and taxane in triple-negative breast cancer: A randomized controlled trial

A. Batra[1], S. Bakhshi[1], A. Kumar[1], A. Arora[1], H. Baskarane[1], A. Gogia[2], K. Kalra[3], A. Mishra[4], S. Suhani[5], J. Sharma[6], R. Parshad[5], V. Seenu[5], K. Asuri[7], V.K. Bansal[5], P. Ranjan[5], B. Bansal[8], B. Kumar[5]

[1] Department of Medical Oncology, AIIMS - All India Institute of Medical Sciences, New Delhi, India, [2] Medical Oncology Department, Institute Rotary Cancer Hospital, New Delhi, India, [3] Medical Oncology, VMMC-SJH - Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi, India, [4] Surgical Oncology Department, IRCH, AIIMS - All India Institute of Medical Sciences, New Delhi, India, [5] Surgery, AIIMS - All India Institute of Medical Sciences, New Delhi, India, [6] Surgery & Oncology Dept., AIIMS - All India Institute of Medical Sciences, New Delhi, India, [7] Surgical Dept., AIIMS - All India Institute of Medical Sciences, New Delhi, India[8] Department of Surgical Oncology, AIIMS - All India Institute of Medical Sciences, New Delhi, India

Background

Low-dose immune checkpoint inhibitor trials have demonstrated encouraging results in certain tumors. However, it remains unclear whether adding low-dose pembrolizumab (LDPm) to neoadjuvant chemotherapy (NACT) improves pathological complete response (pCR) rates in triple-negative breast cancer (TNBC).

Methods

This phase II open-label randomised controlled trial was conducted at a tertiary care cancer centre in New Delhi, India. Patients with untreated stage II-III TNBC without access to standard dose pembrolizumab (SDPm) were randomized (1:1) to receive neoadjuvant dose-dense chemotherapy (4 cycles of doxorubicin and cyclophosphamide followed by 4 cycles of paclitaxel) with or without 50 mg LDPm administered every 6 weeks for 3 cycles. The primary endpoint was pCR.

Results

Between February 2024 and February 2025, 157 patients were randomized to receive NACT with or without LDPm. Baseline characteristics were well-balanced in the two arms (Table). Of these, 152 patients underwent surgery after completing NACT. In the intention-to-treat population, pCR was achieved in 53.8% (95% confidence interval [CI], 42.8%-64.9%) of patients in the experimental arm compared to 40.5% (95% CI, 29.7%-51.3%) in the control arm, representing an absolute difference of 13.3% (95% CI, -2.1%-28.8%; one-sided P=0.047). Among patients who underwent surgery, pCR was observed in 56.7% versus 41.0% (absolute difference, 15.7%; one-sided P=0.031). The incidence of grade 3 or higher adverse events was observed in 50% and 59.5% patients in the experimental and control arm, respectively, with one treatment-related death due to toxic epidermal necrolysis attributed to LDPm.Table: LBA15

	NACT with low-dose pembrolizumab (n=78)	NACT (n=79)
Baseline characteristics		
Age, yMedian (Interquartile range)	45 (38-53)	45 (38-52)
Primary tumor stageT1-2T3-4	35 (44.9%)43 (55.1%)	39 (49.4%)40 (50.6%)
Nodal statusNegativePositive	15 (19.2%)63 (80.8%)	18 (22.8%)61 (77.2%)
Menopausal statusPremenopausalPostmenopausal	42 (53.8%)36 (46.2%)	44 (55.7%)35 (44.3%)
Pathological complete response		
Modified intention-to-treat(P=0.047)	42/78 (53.8%)	32/79 (40.5%)
Surgery performed(P=0.031)	42/74 (56.7%)	32/78 (41.0%)

NACT (neoadjuvant chemotherapy): 4 cycles doxorubicin/cyclophosphamide and 4 cycles paclitaxel (q2weekly). Pembrolizumab given at 50 mg 6 weekly for 3 doses.

Conclusions

The absolute benefit with LDPm appears numerically comparable to that observed with SDPm in the KN522 trial. Therefore, in resource-constrained settings where SDPm is inaccessible, a low-dose alternative strategy may provide a viable treatment option in patients with TNBC.

Clinical trial identification

CTRI/2024/01/062088.

Legal entity responsible for the study

The authors.

Funding

Indian Council of Medical Research.

Disclosure

All authors have declared no conflicts of interest.