PS4-10-01 – Neoadjuvant Immune Checkpoint Inhibitors Plus Chemotherapy in Early-Stage Triple-Negative Breast Cancer: A Systematic Review and Meta-Analysis.

Stamatia Alexiou[1] , Georgios Mavrovounis[2], Emmanouil Saloustros[3]

1. Department of Internal Medicine, General Hospital of Larissa, Larissa, Greece 2. Department of Emergency Medicine, 3. Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece

Introduction

Triple-negative breast cancer (TNBC) is an aggressive subtype with limited treatment options and poor prognosis. Immune checkpoint inhibitors (ICIs) have shown efficacy in the early-stage setting when combined with chemotherapy. We conducted a meta-analysis to evaluate their efficacy in terms of event-free survival (EFS), overall survival (OS), and pathological complete response (pCR).

Methods

We performed a systematic literature search of PubMed, Scopus, and ClinicalTrials.gov to identify randomized controlled trials comparing neoadjuvant or perioperative chemotherapy with or without ICIs in early-stage TNBC. Eligible trials reported on at least one of the following outcomes: EFS, OS, or pCR. Study selection, data extraction, and quality assessment were conducted independently by two reviewers, with discrepancies resolved by consensus. Hazard ratios (HRs) were pooled for EFS and OS using inverse-variance weighting. For pCR, both risk difference (RD) and risk ratio (RR) were calculated using Mantel-Haenszel methods. Heterogeneity was assessed using the I^2 statistic. Pre-specified subgroup and sensitivity analyses were conducted, and publication bias was evaluated via funnel plot asymmetry. The study protocol was registered in PROSPERO (ID: CRD420251082981).

Results

Six phase II–III trials (KEYNOTE-522, IMpassion031, NeoTRIP Michelangelo, GeparNuevo, GeparDouze, CamRelief) comprising 3.952 patients were included. ICIs significantly improved EFS (HR = 0.76; 95% CI: 0.65–0.89; p = 0.0005; I^2 = 3%) and OS (HR = 0.69; 95% CI: 0.57–0.84; p = 0.0002; I^2 = 49%). For pCR, the absolute increase was 8% (RD = 0.08; 95% CI: 0.05–0.11; p < 0.00001; I^2 = 0%), and the relative increase was 15% (RR = 1.15; 95% CI: 1.09–1.22; p < 0.00001; I^2 = 3%). Notably, OS was not available in NeoTRIP and CamRelief, and EFS was not available in GeparNuevo. Sensitivity analyses (e.g., model selection) confirmed robustness. No evidence of publication bias was detected.

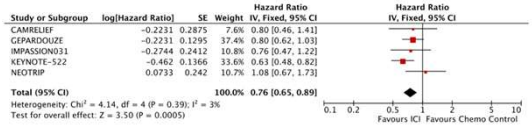


Figure 1. Forest plot showing the effect of ICIs on Event-free survival (EFS).

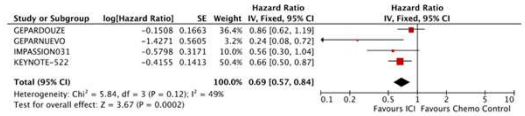


Figure 2. Forest plot showing the effect of ICIs on Overall survival (OS).

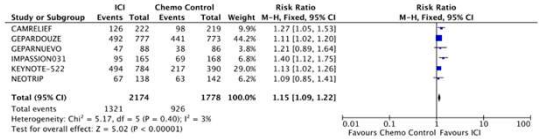


Figure 3. Forest plot showing the Relative Risk (RR) for pathologic complete response (pCR) with ICIs versus chemotherapy.

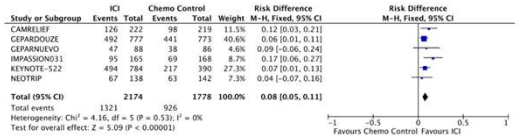


Figure 4. Forest plot of the Risk Difference (RD) for pathologic complete response (pCR) with immune checkpoint inhibitors versus chemotherapy.

Conclusions

ICIs combined with chemotherapy significantly improve EFS, OS, and pCR in early-stage TNBC. These data support their incorporation into standard neoadjuvant treatment. Further studies should refine predictive biomarkers and long-term safety monitoring.

References

1. Mittendorf EA, Assaf ZJ, Harbeck N, Zhang H, Saji S, Jung KH, et al. Peri-operative atezolizumab in early-stage triple-negative breast cancer: final results and ctDNA analyses from the randomized phase 3 IMpassion031 trial. Nat Med. 2025 Jul;31(7):2397–404.
2. Schmid P, Cortes J, Pusztai L, McArthur H, Kümmel S, Bergh J, et al. Pembrolizumab for Early Triple-Negative Breast Cancer. N Engl J Med. 2020 Feb 27;382(9):810–21.
3. Gianni L, Huang C, Egle D, Bermejo B, Zamagni C, Thill M, et al. LBA19 Event-free survival (EFS) analysis of neoadjuvant taxane/carboplatin with or without atezolizumab followed by an adjuvant anthracycline regimen in high-risk triple negative breast cancer (TNBC): NeoTRIP Michelangelo randomized study. Annals of Oncology. 2023 Oct;34:S1258–9.
4. Chen L, Li H, Zhang H, Yang H, Qian J, Li Z, et al. Camrelizumab vs Placebo in Combination With Chemotherapy as Neoadjuvant Treatment in Patients With Early or Locally Advanced Triple-Negative Breast Cancer: The CamRelief Randomized Clinical Trial. JAMA. 2025 Feb 25;333(8):673–81.
5. Geyer C, Tang G, Nekljudova V, Rastogi P, Reinisch M, Acosta J, et al. Abstract GS3-05: NSABP B-59/GBG-96-GeparDouze: A randomized double-blind phase III clinical trial of neoadjuvant chemotherapy with atezolizumab or placebo followed by adjuvant atezolizumab or placebo in patients with Stage II and III triple-negative breast cancer. Clinical Cancer Research. 2025 Jun 13;31:GS3-05.
6. Loibl S, Untch M, Burchardi N, Huober J, Sinn BV, Blohmer JU, et al. A randomised phase II study investigating durvalumab in addition to an anthracycline taxane-based neoadjuvant therapy in early triple-negative breast cancer: clinical results and biomarker analysis of GeparNuevo study. Annals of Oncology. 2019 Aug;30(8):1279–88.

Contact

Prof. Emmanouil Saloustros
Division of Oncology, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece
Email: esaloustros@med.uth.gr

This presentation is the intellectual property of the author/presenter. Contact them at <<your email address>> for permission to reprint and/or distribute.
© Poster Template by Genigraphics® 1.800.790.4001 www.genigraphics.com