

“最毒乳腺癌”靶向精准治疗新突破

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“最毒，”靶向精准治疗新突破。1月9日，复旦大学附属肿瘤医院教授邵志敏、王中华、江一舟、范蕾临床科研团队领衔，完成了一项名为FUTURE-SUPER针对转移性三阴性乳腺癌一线治疗的随机对照伞形II期临床研究。该研究于1月9日在线发表于《柳叶刀—肿瘤学》。

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Optimising first-line subtyping-based therapy in triple-negative breast cancer (FUTURE-SUPER): a multi-cohort, randomised, phase 2 trial

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Summary

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Summary

Background

Triple-negative breast cancers display heterogeneity in molecular drivers and immune traits. We previously classified triple-negative breast cancers into four subtypes: luminal androgen receptor (LAR), immunomodulatory, basal-like immune-suppressed (BLIS), and mesenchymal-like (MES). Here, we aimed to evaluate the efficacy and safety of subtyping-based therapy in the first-line treatment of triple-negative breast cancer.

Methods

FUTURE-SUPER is an ongoing, open-label, randomised, controlled phase 2 trial being conducted at Fudan University Shanghai Cancer Center (FUSCC), Shanghai, China. Eligible participants were females aged 18–70 years, with an Eastern Cooperative Oncology Group performance status of 0–1, and histologically confirmed, untreated metastatic or recurrent triple-negative breast cancer. After categorising participants into five cohorts according to molecular subtype and genomic biomarkers, participants were randomly assigned (1:1) with a block size of 4, stratified by subtype, to receive, in 28-day cycles, nab-paclitaxel (100 mg/m², intravenously on days 1, 8, and 15) alone (control group) or with a subtyping-based regimen (subtyping-based group): pyrotinib (400 mg orally daily) for the LAR-*HER2*^{neg} subtype, everolimus (10 mg orally daily) for the LAR-*PI3K/AKT*^{mut} and MES-*PI3K/AKT*^{mut} subtypes, camrelizumab (200 mg intravenously on days 1 and 15) and famitinib (20 mg orally daily) for the immunomodulatory subtype, and bevacizumab (10 mg/kg intravenously on days 1 and 15) for the BLIS/MES-*PI3K/AKT*^{WT} subtype. The primary endpoint was investigator-assessed progression-free survival for the pooled subtyping-based group versus the control group in the intention-to-treat population (all randomly assigned participants). Safety was analysed in all patients with safety records who received at least one dose of study drug. This study is registered with [ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/show/study?term=NCT04395989) (NCT04395989).

Findings

Between July 28, 2020, and Oct 16, 2022, 139 female participants were enrolled and randomly assigned to the subtyping-based group (n=69) or control group (n=70). At the data cutoff (May 31, 2023), the median follow-up was 22.5 months (IQR 15.2–29.0). Median progression-free survival was significantly longer in the pooled subtyping-based group (11.3 months [95% CI 8.6–15.2]) than in the control group (5.8 months [4.0–6.7]; hazard ratio 0.44 [95% CI 0.30–0.65]; p<0.0001). The most common grade 3–4 treatment-related adverse events were neutropenia (21 [30%] of 69 in the pooled subtyping-based group vs 16 [23%] of 70 in the control group), anaemia (five [7%] vs none), and increased alanine aminotransferase (four [6%] vs one [1%]). Treatment-related serious adverse events were reported for seven (10%) of 69 patients in the subtyping-based group and none in the control group. No treatment-related deaths were reported in either group.

图片来源于《柳叶刀—肿瘤学》

团队共完成临床试验的139位转移性三阴性乳腺癌或无法接受手术三阴性乳腺癌的患者入组。依据入组患者的亚型和基因组生物标志物检测结果，研究团队将她们分为5个治疗臂，并随机分成白蛋白结合型紫杉醇标准化疗组，和接受传统联合靶向或免疫药物的精准治疗组。

研究显示，在为期22.5个月的中位随访期内，精准治疗组患者的中位无疾病进展生存期为11.3个月，相比传统化疗组的5.8个月，延长了5.5个月。需要指出的是，其中免疫调节型的患者是精准治疗方案中无疾病进展期生存期增幅最大的一批患者，她们中位无疾病进展生存期达到15.1个月，比传统化疗延长了8.6个月，这是目前全球最佳的生存获益。此外，基底样免疫抑制型和间质型的患者在接受精准治疗后，比传统化疗生存期延长5.2个月。

这项临床研究揭示了基于患者分子亚型和基因组标志物，采用化疗联合靶向或免疫的精准治疗新疗法，显著延长了转移性三阴性乳腺癌患者的疾病无进展生存期，且毒性可控，改变了既往治疗方式单一且疗效不佳的临床问题。（来源：中国科学报 江庆龄）

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