氟唑帕利单药对比联合阿帕替尼治疗胚系 *BRCA1/2* 突变的HER2－转移性乳腺癌的成本-效用分析Δ

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摘 要 目的 从我国卫生体系视角，评价氟唑帕利单药对比联合阿帕替尼用于伴有胚系 *BRCA1/2* 突变的人表皮生长因子受体2阴性（HER2－）转移性乳腺癌二线及后线治疗的经济性。**方法** 基于FABULOUS研究，建立分区生存模型模拟疾病进展过程，模拟周期为21 d，研究时限为10年，贴现率为4.5%。模型以质量调整生命年（QALYs）及总成本作为产出评价指标，采用成本-效用分析法进行分析，通过比较两种方案的增量成本-效果比（ICER）和意愿支付（WTP）阈值来评价方案经济性。WTP阈值设为2025年我国2倍人均GDP（199 330元/QALY）。通过单因素敏感性分析、概率敏感性分析和情境分析以检验模型稳健性。**结果** 对于伴有胚系 *BRCA1/2* 突变的HER2－转移性乳腺癌患者，使用氟唑帕利联合阿帕替尼方案较氟唑帕利单药方案可获得更多健康获益（1.91 QALYs vs. 1.69 QALYs），同时总成本更低（1 634 119.3元 vs. 1 855 264.2元），为绝对优势方案。单因素及概率敏感性分析结果表明基础分析结果稳健。情境分析结果中，变动研究时限为5年或将贴现率调整为3%，基础分析结论均保持稳健；但当变动外推分布模型时，结果发生翻转。**结论** 在现有WTP阈值下，与氟唑帕利单药方案相比，氟唑帕利联合阿帕替尼方案用于我国伴有胚系 *BRCA1/2* 突变的HER2－转移性乳腺癌患者的二线及后线治疗更具经济性。

关键词 氟唑帕利；阿帕替尼；胚系 *BRCA1/2* 突变；人表皮生长因子受体2阴性；转移性乳腺癌；成本-效用分析；分区生存模型

Cost-effectiveness analysis of fluzoparib monotherapy versus combination with apatinib in the treatment of germline *BRCA1/2*-mutated HER2-negative metastatic breast cancer

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ABSTRACT OBJECTIVE To evaluate the cost-effectiveness of fluzoparib monotherapy versus combination with apatinib as second-line or later-line treatment for patients with germline *BRCA1/2*-mutated human epidermal growth factor receptor 2-negative (HER2－) metastatic breast cancer, from the perspective of the Chinese healthcare system. **METHODS** Based on the FABULOUS trial, a partitioned survival model was developed to simulate disease progression, with a cycle length of 21 days and a time horizon of 10 years. A discount rate of 4.5% per annum was applied. Model outputs included total costs and quality-adjusted life years (QALYs). Cost-utility analysis was conducted by comparing the incremental cost-effectiveness ratio (ICER) between the two regimens against a willingness-to-pay (WTP) threshold set at twice China's per capita gross domestic product in 2025 (199 330 yuan/QALY). Robustness of the base-case results was tested through one-way sensitivity analysis, probabilistic sensitivity analysis, and scenario analyses. **RESULTS** For patients with germline *BRCA1/2*-mutated HER2－ metastatic breast cancer, fluzoparib combination with apatinib provided greater health benefits (1.91 QALYs vs. 1.69 QALYs) and incurred lower total costs (1 634 119.3 yuan vs. 1 855 264.2 yuan) compared with fluzoparib monotherapy, thus representing a dominant strategy. One-way sensitivity and probabilistic sensitivity analyses confirmed the robustness of the base-case findings. Scenario analyses showed that the conclusion remained robust when the time horizon was shortened to 5 years or when the discount rate was changed to 3%; however, the results reversed when the extrapolation distribution model was altered. **CONCLUSIONS** Under the current WTP threshold, compared with fluzoparib monotherapy, the combination of fluzoparib and apatinib is more cost-effective as a second-line or later-line treatment for Chinese patients with germline *BRCA1/2*-mutated HER2－ metastatic breast cancer.

KEYWORDS fluzoparib; apatinib; germline *BRCA1/2* mutation; human epidermal growth factor receptor 2-negative; metastatic breast cancer; cost-effectiveness analysis; partitioned survival model

乳腺癌是全球女性最常见的恶性肿瘤之一。根据国际癌症研究机构2022年全球癌症统计数据，女性乳腺癌占总患癌病例的11.6%，是女性癌症患者死亡的主要

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