Impact of Geographic Region on Benefit of Approved Anticancer Drugs Evaluated in International Phase III Clinical Trials

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AIMS
International collaboration allows for enhanced accrual and more generalisable results of phase III randomised controlled trials (RCTs). The impact of geographic region on the outcomes of new anticancer agents is unclear.

MATERIALS AND METHODS
International RCTs evaluating approved systemic therapy for advanced solid tumours that reported efficacy of new anticancer drugs based on geographic regions were eligible. Data for overall (OS) or progression-free survival (PFS) were pooled in a meta-analysis. The primary analysis was the comparison of developed versus developing countries. A meta-regression analysis explored the impact of differences in gross national income (GNI) per capita on the hazard ratio comparing developed and developing countries. Secondary analyses compared geographic regions irrespective of GNI.

RESULTS
Of the 63 identified studies, 12 independent RCTs were eligible; five reported data for OS and nine for PFS. Improvements in overall survival were greater in developed as compared with developing countries (hazard ratio 0.82, 95% confidence interval 0.68-0.99, P = 0.04). This effect was seen only among studies of cytotoxic chemotherapy and not among those of targeted agents. No difference was seen for PFS (hazard ratio 0.93, 95% confidence interval 0.79-1.09, P = 0.36). Meta-regression showed a significant negative association between GNI per capita and overall survival, but a non-significant negative association with PFS (β = -0.774, P = 0.05 and β = -0.211, P = 0.29, respectively). No differences were observed in PFS between Asian and non-Asian countries or North America and Western Europe.

CONCLUSION
Compared with patients from developing countries, those from developed countries derive greater improvement in overall survival from cytotoxic chemotherapy, but similar benefit from targeted drugs.
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