Letter in Reply

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Letter in Reply: indirect comparison of quality-of-life scores between patients with advanced breast cancer receiving palbociclib and abemaciclib in combination with fulvestrant

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We thank the correspondents for their complimentary and thoughtful response to our indirect comparison of quality-of-life scores between patients with advanced breast cancer receiving palbociclib (in PALOMA-3) and abemaciclib (in MONARCH-2) in combination with fulvestrant [1]. We agree that the clinical relevance of findings from indirect comparisons to patients and clinicians is contingent on a careful evaluation of the methodological rigor of the study design and analysis, made possible through transparent reporting. We welcome the opportunity to reply to the points raised by the correspondents that primarily concern the interpretation of our results.

First, the correspondents used 'visual evaluation' to qualitatively compare the efficacy of palbociclib and abemaciclib in an underpowered subgroup of patients without sensitivity to previous endocrine therapy. However, Rugo and colleagues conducted a quantitative analysis using similar methods to the present study to compare the relative efficacy of palbociclib against ribociclib and abemaciclib, concluding that the three agents demonstrated similar overall survival after adjusting for known cross-trial differences [2]. To state otherwise is speculation and not empirically supported by systematic analysis.

Second, the authors suggest that the efficacy of abemaciclib demonstrated in the adjuvant setting is supportive of its clinical effectiveness. However, the disease processes and prognosis of early versus advanced breast cancer are as different as they are complex. Again, empiric evidence within a specific disease indication should be used to support treatment decision-making as opposed to extrapolation from another setting.

Finally, we agree that patient-reported outcome end points are 'exceedingly important'. However, we disagree with the general statement that patients prefer 'clinical activity' over an excess risk of diarrhea and lower patient reported GI symptoms and global quality of life scores. As stated earlier, there is no evidence that abemaciclib is superior to palbociclib after careful adjustment of population differences. Moreover, the risk of diarrhea was rated as the most important attribute for treatment choice in a real-world sample of patients with advanced breast cancer [3]. While this result is based on a mean preference, at minimum it suggests that patients will make different trade-offs based on the anticipated safety risk.

Shared decision making is defined as 'an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences' [4]. We maintain it is up to patients, with guidance from their clinicians, to decide on what agents are best for them and their quality of life.

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