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Global myeloma trial participation and drug access in the era of novel therapies
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Introduction: The globalization of clinical trials has accelerated recent advances in multiple myeloma (MM). However, it is unclear whether trial enrollment locations are reflective of the global burden of MM and whether access to novel therapies is timely and equitable for countries that participate in those trials.

Methods: To assess this, we characterized the countries where MM trials that led to United States Food and Drug Administration (FDA) approvals were conducted. Then, we determined how often and quickly these drug regimens received approval for use in their participating trial countries based on country income level and geographic region.

To identify pivotal trials, a systematic review was conducted to identify all MM clinical trials that led to FDA approval from 2005-2019. A total of 18 pivotal MM clinical trials were conducted. Then, we determined how often and quickly these drug regimens received approval for use in their participating trial countries based on country income level and geographic region.

Results: A total of 18 pivotal MM clinical trials were identified. High-income countries enrolled patients in 100% (18/18) of the trials identified while upper-middle and lower-middle-income countries were represented in 61% (11/18) and 28% (5/18) of trials respectively. No patients from low-income countries were enrolled in these trials. One trial enrolled patients in Sub-Saharan Africa and no trials enrolled patients in South Asia or the Caribbean. For drugs/regimens that were approved in their participating countries, the median time from FDA approval to approval was 10.9 months. There were no drugs approved in lower-middle-income trial countries.

Conclusions: MM trials leading to FDA approval are generally conducted in countries that are high-income and located in Europe or Central Asia. However, in the lower-income countries where trials are run, these agents remain unavailable for use. The underrepresentation of low-income, South Asian, Caribbean, and Sub-Saharan African countries in MM clinical trials continue to exacerbate disparities.

COVID – 19 vaccine uptake in patients with multiple myeloma and AL amyloidosis: a cross-sectional observational study from India
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Introduction: Patients with multiple myeloma (MM) and immunoglobulin light chain amyloidosis (AL amyloidosis) are prone to immune impairment and infections. COVID-19 related mortality is also increased, emphasising protection given by vaccination. Two vaccines widely used in India are Covishield [ChAdOx1 nCoV-19; Oxford–AstraZeneca] manufactured by Serum Institute of India, and Covaxin [BBV152] by Bharat Biotech. Vaccine acceptance rates in LMICs are comparable, if not higher, than in developed nations. We report the outcome of active counselling for COVID-19 vaccination in patients with MM and AL amyloidosis and the reasons for hesitancy in those who were unvaccinated.

Methods: Institutional Ethics committee clearance was obtained. This was a cross-sectional observational study carried out in a tertiary care cancer hospital in South India. At diagnosis or follow-up, patients with MM and AL amyloidosis who visited the hospital between January 1 to June 30, 2021, were enquired about their COVID-19 vaccination details. The vaccination details were confirmed and verified on the Indian government’s purpose-built platform (https://www.cowin.gov.in).

Results: Out of 195 patients, 178 (91%) were included in the study; 17 were lost to follow-up; MM – 176 (99%), AL amyloidosis– 2 (1%). Patients were actively counselled for COVID-19 vaccination during OPD visits or hospital admission. In subsequent hospital visits, the reasons behind vaccine hesitancy were identified. Baseline characteristics: Age: 30-85 years [median: 58]; males 101 (57%). The most widely used treatment regimen at the time of vaccination was thalidomide or lenalidomide maintenance in 81 (46%) cases. At the time of vaccination, 61 (34%) were on induction chemotherapy. Of the 178 patients, 15 (8%) developed COVID-19 infection during the study duration; out of the 15 patients, 7 did not receive a single dose of vaccine before infection. 2 out of 3 patients who died due to COVID-related causes were unvaccinated. At least a single dose of either vaccine was received in 154 (86%) patients, and both doses were administered in 119 (67%). Vaccine-related mild side-effects were reported in 4 (2%) patients; no vaccine-related thrombotic events or hospitalisations due to adverse events noted. Among the 24 (13%) patients who were not vaccinated, 9 reported a poor general health condition, 8 reported lack of advice from doctors as the reason for hesitancy, 2 did not take the vaccine owing to fear of side-effects, and 2 did not receive the vaccine due to unavailability of a vaccine delivery center nearby. 3 patients did not give any specific reason for not taking the vaccine. Our study reported a higher vaccine uptake rate compared to previous studies assessing acceptance of COVID-19 vaccine in patients with hematological malignancy. Around 70% took both the doses of COVID-19 vaccine.

Conclusions: Vaccine hesitancy among high-risk patients can be reduced with targeted counselling and reassurance by health personnel.