Conference Abstracts

Disparity of race reporting and representation among US FDA approved tyrosine kinase inhibitors

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Keywords: research, clinical trials, disparities, Tyrosine kinase inhibitors, TKIs

https://doi.org/10.53876/001c.36115

International Journal of Cancer Care and Delivery  
Vol. 2, Issue Supplement 1, 2022

BACKGROUND

Tyrosine kinase inhibitors (TKIs) have altered the therapeutic landscape of multiple hematological and solid malignancies. FDA approved starting doses of TKIs are based on the recommended phase 2 dose (RP2D) in clinical trials, however, in patients are started on lower doses in practice. We assessed the dosing, drug reduction rates, and drug discontinuation rates among FDA approved TKIs and observed the disparity among study populations to understand if there was adequate representation of diversity in race.

METHODS

We established a database of all FDA approved TKIs from the FDA online label repository. We extracted descriptive data for indications and usage, type of approval, approval dosage, dose reduction recommendation, median age, race, dose reduction rates, drug discontinuation rates, dose modification, warnings, adverse reactions, clinical trial experience, and geriatric use above 65 yrs and 75 yrs.

RESULTS

Among all TKIs, median dose was 200 mg and average dose was 307.7 mg; 36(24%) were approved bid vs 107(72%) qd. Among approved indications, median rates of dose reduction rate (DRR), drug interruption rate (DIR), drug discontinuations rate (DDR) were 31%, 52%, and 10% respectively. Reasons for DRR, DIR, and DDR were diarrhea, fatigue, nausea, vomiting, hepatotoxicity, rash, and hypertension. Black and Hispanic races are consistently underrepresented among the TKI studies.

CONCLUSION

TKIs have a variable dose reduction and drug discontinuation rate but these studies were done mostly in White individuals. Clinical trials should evaluate multiple dosing regimens and schedules to lessen the toxicity burden and improve QOL in patients while broadening the study population so that the studies will be generalizable to patients in clinical practice. Future studies are warranted to increase representation in the studies to address the disparities.