

with larger prospective trials. **Keywords:** CML, chronic myeloid leukemia, tyrosine kinase inhibitor, elective switch, efficacy, safety

CML-252

Current Patient Management and Outcomes of Chronic Myeloid Leukemia (CML) in Colombia: On Behalf of ACHO's RENEHOC Investigators

Virginia Abello Polo^{1,2,3,4*}, Claudia Sossa Melo^{4,5,6,7}, Angela María Peña^{4,5,6,7}, Rigoberto Gómez Gutiérrez^{4,8}, Isabel Munevar^{4,9}, Claudia Casas^{1,2,4}, Guillermo Quintero-Vega^{4,10,11}, Henry Idrobo^{4,12,13}, Jheremy Reyes^{4,14}, Juan Manuel Herrera^{4,15}, William Armando Mantilla Duran^{4,16}, José Domingo Saavedra^{4,17}, Kenny Galvez^{4,18}, Carmen Rosales^{4,20}, Yasmín Borjas Chirinos^{4,21}

¹ Fundación Universitaria de Ciencias de la Salud, Bogotá, Colombia, ² Hospital de San José, Bogotá, Colombia, ³ Clínica del Country, Bogotá, Colombia, ⁴ Asociación Colombiana de Hematología y Oncología, Colombia, ⁵ Universidad Autónoma de Bucaramanga, Bucaramanga, Colombia, ⁶ Clínica Foscal, Bucaramanga, Colombia, ⁷ Centro de hematología PROTEHOS, Bucaramanga, Colombia, ⁸ HematoOncólogos SA, Cali, Colombia, ⁹ Hematooncólogos Asociados, Bogotá, Colombia, ¹⁰ Universidad de los Andes, Bogotá, Colombia, ¹¹ Fundación Santa Fe de Bogotá, Bogotá, Colombia, ¹² Universidad del Valle, Cali, Colombia, ¹³ Centro Médico Julián Coronel, Cali, Colombia, ¹⁴ Clínica Los Nogales, Bogotá, Colombia, ¹⁵ Clínica imbanaco Quiron Salud, Cali, Colombia, ¹⁶ Fundación Cardioinfantil Instituto de Cardiología, Bogotá, Colombia, ¹⁷ Clínica Vida, Medellín, Colombia, ¹⁸ Hospital Pablo Tobón Uribe, Medellín, Colombia, ¹⁹ Hospital Universitario San Vicente Fundación, Medellín, Colombia, ²⁰ Sociedad de Oncología y Hematología del Cesar, Valledupar, Colombia, ²¹ Clínica Astorga, Medellín, Colombia

Context: Tyrosine kinase inhibitors (TKIs) dramatically changed outcomes in CML; achieving and maintaining treatment milestones is highly dependent on adherence. Colombia subscribes a principle of universal health coverage; however, there is significant difference in access to high-cost drugs between different insurance types (Subsidized [SS] *vs* Contributory [SC]). **Objective:** To describe the current patient management and outcomes of CML in Colombia and possible factors associated with outcomes. **Design:** ACHO's hematological disease registry (RENEHOC) is a multicenter study that has collected information on CML patients since 2019. **Setting:** RENEHOC is a real-world registry that captures information from 16 academic and general community centers in 5 cities in Colombia. **Patients or Other Participants:** Adult CML patients. **Interventions:** Due to its observational nature, all treatment decisions depend on treating investigator preferences. **Main Outcomes Measures:** RENEHOC is an online database. This report summarizes data on CML patients as of May 2020, focused on general descriptive statistics. The Kaplan-Meier method was used to assess progression free survival (PFS) rates, defined as progression to AP/BP or death.

Hazard ratios (HR) using Cox proportional hazards regression modeling were estimated. **Results:** A total of 442 patients have been registered with a median follow-up of 60 months (IQR 26.5–106.5). At diagnosis, mean age was 54 years (SD 15.23), 58.6% (259) were males, most patients were in chronic phase (92.3%) and most had intermediate or high risk Sokal (35.6% and 36%, respectively). Median time from symptoms to diagnosis was 4 weeks (IQR 1–11), with no difference between SS and CS ($p=0.54$) and from diagnosis to treatment 4 in SS *vs* 0 in CS ($p=0.041$). Imatinib was the first-line treatment in 62.9%, dasatinib in 20%, and nilotinib 15%. Median OS and EFS were 60 (IQR 26.5–106.5) and 51 months (IQR 21–91), respectively. Only 7 (2.5%) patients died; all deaths were CML-related. Type of insurance (median EFS 51 CS *vs* 38.5 months SS; $p=0.04$), phase at diagnosis ($p=0.039$), and achieving MMR with first-line were the only factors related with EFS. **Conclusions:** OS for CML is excellent (97.5%) in Colombian patients. Unequal treatment between insurance types appears to have an impact on outcomes, which has to be addressed. **Keywords:** CML, chronic myeloid leukemia, tyrosine kinase inhibitors, Colombia, registry

CML-268

Study to Evaluate the Effect of Fatty Meals on Nilotinib Drug Levels in Patients with CML-CP

Ankur Nandan Varshney^{1*}, Laxmi Moksha², Mohini Mehndiratta¹, Ranjit Kumar Sahoo¹, Prabhat Singh Malik¹, Lalit Kumar¹, Man Singh², Thirumurthy Velpandian²

¹ Department of Medical Oncology All India Institute of Medical Sciences, New Delhi, India, ² Department of Ocular Pharmacology All India Institute of Medical Sciences, New Delhi, India

Context: Nilotinib is an oral tyrosine kinase inhibitor used in chronic myeloid leukemia (CML) and is known to have food interactions. It is recommended for administration in a fasting state (meals taken either 2 hours after dose or 1 hour before a dose). Food, especially fat-rich food, has been shown to increase the bioavailability of drugs. If the drug is allowed to be taken with food, it will be convenient for patients and also lower the dose needed to produce clinical benefit. This will decrease the cost of therapy and will improve the quality of life of patients. **Objective:** To assess the effect of fatty meals on nilotinib drug levels in patients with CML. **Design/Setting/Patients/Intervention:** It is a single-center, open-label, pharmacokinetic study. There were 5 cohorts with 6 patients enrolled in each. A total of 30 patients were included in the study. The patient population included patients of newly diagnosed CML (chronic phase). The dose of nilotinib in each cohort was 150 mg OD, 200 mg OD, 150 mg BD, 200 mg BD, and 300 mg BD, respectively. The drug was given an empty stomach for an initial 8 days, followed by fatty meals for the next 8 days. Fatty meals were defined as 2 slices of bread with 10 grams of butter. Two ml blood was withdrawn at specified time points at 0 hours, 1 hour, 2 hours, 3 hours, 4 hours, 6 hours, 8 hours, 10 hours, 12 hours, 16 hours, 20 hours, and 24 hours and on day 8 (0 hour and 3 hours). Nilotinib drug levels were estimated by liquid chromatography mass