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### BRAZILIAN REAL-WORLD MULTIPLE MYELOMA (MM) ELECTRONIC PLATFORM REGISTER PROJECT

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**Introduction:** An epidemiological database is an important tool to characterize the population disease distribution, long-term effects of the diseases, impact of evolving treatments, to identify adverse events (AE) and their possible mitigation and to improve the healthcare system. Another reason to create a database is to rapidly identify, recruit and enroll individuals for research activities. Based on these, the Brazilian Multiple Myeloma Study Group (GBRAM) developed an electronic database platform with the intention of registering the MM cases diagnosed at Brazilian healthcare services. **Methods:** This is a prospective, multicenter, open, epidemiological study, based on an electronic register. Patients diagnosed with MM after January 1, 2018 have been included. The eligibility criteria were: intent-to-treat (ITT) MM, aged over 18 years and under care in any healthcare system (private, public and academic). All clinical and lab data, prognostic profiling, treatment patterns and responses, AE and survival were compiled. The data were analyzed with the NCSS®2020 software. This project is registered in the Brazilian study platform control (Plataforma Brasil) linked to federal health authorities by the number CAAE-05340918.3.1001.8098. **Results:** To date, 1,113 patients at 44 reference centers were included. The median age was 64 (25 -96) years and 578 (52%) were male. According to the ECOG PS: 0 = 185 (16.5%), 1 = 257 (23.2%), 2 = 144 (13%), 3 = 105 (9.5%), 4 = 62 (5.5%) and the not available data (NA) = 359 (32.3%). The ISS 1, 2, and 3 were 219 (19.7%), 286 (25.7%)

and 406 (36.5%), respectively, the NA being 202 (18.1%). MM isotypes were 524 (47.1%) IgG, 202 (18.2%) IgA, 192 (17.2%) free-light chain, 4 (0.5%) IgM, 7 (0.8%) biclonal, 9 (0.7%) non-secretor and 175 (15.5%) NA. Regarding the treatment backbone, 427 (38.4%) patients received immunomodulators (IMiD- thalidomide), 277 (20.4%), proteasome inhibitors (PI-bortezomib), 84 (7.6%), the combination of PI + IMiD, 72 (6.6%), combinations with anti-CD38 monoclonal antibody (Daratumumab) and 253 (27%), other treatments. The ITT analysis of 1003 cases, 636 (63.4%) patients were planned for bone marrow transplantation (BMT) and 367 (36.6%) not. After a median follow-up of 14.0 months, 150 (23.6%) of the planned patients had undergone the procedure, 284 (44.7%) had not yet been submitted and 202 (31.7%) had NA data. The OS was 80.9% for the total group at 20 months, 73.5% for ineligible and 95.5% for eligible. There was a significant improvement in eligible patients who had performed BMT, as compared to those who had not, HR 0.15 (0.09 - 0.26),  $p < 0.0001$ . A total of 142 deaths (12.8%) occurred, 51 (36%) of them being during the first 180 days. **Discussion:** This epidemiological study prospectively enrolled patients diagnosed since January 2018 and is of a nationwide scope. To date, 1,113 new cases were included. Despite the short follow-up, this analysis has identified differences in survival, comparing ISS stratifications and whether a BMT was performed or not. **Conclusion:** This project demonstrates the feasibility and importance of electronic platforms in the compilation of MM populational data for a better understanding of the clinical characteristics, treatment patterns and outcomes in the real world, permitting a clearer perception of local issues and thus, addressing possible improvement in public healthcare policy, such as the improvement of BMT access. Estudo desenvolvido pelo GBRAM.

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### CARFILZOMIB, DEXAMETHASONE, AND DARATUMUMAB VERSUS CARFILZOMIB AND DEXAMETHASONE IN RELAPSED OR REFRACTORY MULTIPLE MYELOMA: SUBGROUP ANALYSIS OF THE PHASE 3 CANDOR STUDY BY NUMBER OF PRIOR LINES OF THERAPY AND PRIOR THERAPIES

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**Objectives:** The CANDOR trial showed that KdD (carfilzomib, dexamethasone, and daratumumab) improved progression-free survival (PFS) vs Kd (carfilzomib and dexamethasone; hazard ratio, 0.63; 95% confidence interval, 0.46–0.85) in patients with relapsed or refractory multiple myeloma (RRMM). We present the results of subgroup analyses in CANDOR by number of prior lines of therapy (pLOTs) and prior therapies (Tx). **Material and methods:** Patients with RRMM (1–3 pLOTs) were randomized 2:1 to receive KdD or Kd. The primary endpoint was PFS; secondary endpoints included overall response rate (ORR), minimal residual disease (MRD)-negative complete response (CR) at 12 months (threshold,  $10^{-5}$ ), and safety. Patients were evaluated by number of pLOTs and prior lenalidomide (LEN) or bortezomib (BOR) Tx. **Results:** Of the 466 patients randomized, 43% had one pLOT; 57% had  $\geq 2$  pLOTs; 42% were LEN exposed; 33% were LEN refractory; 91% were BOR exposed; and 33% were BOR refractory. Treatment effects were generally consistent and improved with KdD vs Kd treatment across subgroups for PFS, ORR, and MRD-negative CR rates. Median PFS could not be estimated in most subgroups, especially in the KdD treatment arm, except for BOR refractory (14.2 months for KdD vs 14.9 months for Kd). The ORR for the one-pLOT subgroup was 90% for KdD vs 76% for Kd; these rates were 80% vs 74% for  $\geq 2$  pLOTs, 79% vs 74% for LEN exposed, 88% vs 75% for LEN naïve, 80% vs 73% for LEN refractory, 86% vs 76% for LEN nonrefractory, 79% vs 69% for BOR refractory, and 87% vs 78% for BOR nonrefractory. The interaction test for all presented subgroups (treatment by subgroup) was not statistically significant (with multivariate model adjusting for other baseline factors as appropriate). MRD-negative CR rates were consistently higher in KdD-treated patients vs Kd-treated patients across all subgroups (eg, 17% vs 2% for one pLOT, 10% vs 1% for  $\geq 2$  pLOTs, 11% vs 0% for LEN exposed, 13% vs 3% for LEN naïve, 13% vs 0% for LEN refractory, 12% vs 2% for LEN nonrefractory, 7% vs 2% for BOR refractory, and 15% vs 1% for BOR nonrefractory). The rate of grade  $\geq 3$  treatment-emergent adverse events in the pLOT subgroups (83% KdD vs 74% Kd for one pLOT and 82% KdD vs 74% Kd for  $\geq 2$  pLOTs) was similar to that in the broader CANDOR population. A comprehensive analysis of these subgroups, including patient characteristics and safety profiles, will be presented at the meeting. **Discussion:** Median PFS was not reached in the KdD treatment arm in most subgroups. While there were no differences in overall survival, KdD-treated patients across multiple subgroups had better ORR and

MRD-negative CR rates compared with Kd-treated patients. **Conclusion:** Safety and efficacy results were generally consistent across subgroups, irrespective of LEN- or BOR-refractory status or number of pLOTs. ClinicalTrials.gov: NCT03158688. This encore abstract was accepted and originally published at EHA 25 Virtual (European Hematology Association) in June 2020.

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#### CHARACTERIZATION OF MULTIPLE MYELOMA PATIENTS THROUGH FLOW CYTOMETRY AND CYTOGENETIC STUDIES 2013 – 2018

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**Objective:** To characterize by flow cytometry and cytogenetic studies the patients with multiple myeloma. **Methods:** descriptive and observational study, carried out in a highly complex institution in the city of Medellín – Colombia. The patients over 18 years of age with a diagnosis of multiple myeloma were included. The collection of information was performed by review of clinical histories and the data obtained was analyzed in the IBM SPSS version 24 program. **Results:** 89 patients were included: 52.8% were male, 33.7% had between 61 and 70 years, the median hospitalization time was 17 days. The most frequent clinical manifestations were anemia, predominantly lumbar bone pain and kidney failure in 78%, 61.8% and 58.4% of the patients respectively. The CD38 + and CD56 markers+ were the most common immunophenotype, present in 39.3% of patients. Regarding clinical outcomes, 70.8% of the patients were discharged and 28.1% died, with the progression of the multiple myeloma being the main cause of death in 36% of cases. **Conclusion:** Multiple myeloma is a pathology that affects adults, it leads to an increase in hospital stay, non-specific symptoms such as weight loss, edema, bone pain and pathological fractures, which affect quality of life and increase the mortality of people. Thanks to flow cytometry, this study found that the so-called aberrant immunophenotype was the most common in the included population.

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#### DERRAME PLEURAL MIELOMATOSO: RELATO DE CASO E REVISÃO LITERÁRIA

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