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TENDÊNCIA TEMPORAL DA MORTALIDADE POR MIELOMA MÚLTIPLO E NEOPLASIAS MALIGNAS DE PLASMÓCITOS NO BRASIL DE 2000 A 2023

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Introdução: Mieloma Múltiplo (MM) e outras neoplasias malignas de plasmócitos são neoplasias hematológicas caracterizados pela proliferação clonal de plasmócitos na medula óssea. Apesar de serem mais comuns em indivíduos idosos, a faixa etária de 35 a 75 anos concentra grande parte dos óbitos. Analisar a tendência temporal da mortalidade por essas neoplasias é essencial para compreender sobretudo a dinâmica de incidência e óbitos tanto no âmbito nacional quanto mundial. **Objetivos:** Analisar a tendência temporal da mortalidade por mieloma múltiplo e neoplasias malignas de plasmócitos no Brasil de 2000 a 2023, segundo sexo e raça. **Material e métodos:** Trata-se de um estudo ecológico de série temporal dos óbitos por mieloma múltiplo e neoplasias malignas de plasmócitos no Brasil entre 2000 e 2023. Os dados de mortalidade foram obtidos do Sistema de Informações sobre Mortalidade do Departamento de Informática do Sistema Único de Saúde (SIM/DATASUS), estratificados por grupos etários (30-39, 40-49, 50-59, 60-69 e ≥ 70 anos), sexo (masculino e feminino) e raça/cor da pele (branco, preto e pardo). As populações dos anos censitários (2000 e 2010) foram obtidas do Instituto Brasileiro de Geografia e Estatística (IBGE), e as estimativas para os anos intercensitários foram calculadas pelo método geométrico. Foram calculadas as taxas de mortalidade, as quais foram padronizadas pelo método direto, utilizando a população padrão do Brasil estimada para 2010 como referência. A análise de tendência temporal foi realizada utilizando modelos de regressão Joinpoint, com um nível de significância de 5%. **Resultados:** Entre 2000 e 2023, foram registrados 57.053 óbitos por mieloma múltiplo e neoplasias malignas de plasmócitos em adultos no Brasil, sendo 51,2% entre indivíduos do sexo masculino e 48,8% entre o sexo feminino. Em ambos os sexos, a maior proporção de óbitos ocorreu entre pessoas brancas (62,4% entre homens e 64,5% entre mulheres), seguidas por pardas (29,1% e 26,8%, respectivamente) e pretas (8,4% e 8,7%). Entre os homens, observou-se tendência crescente de 1,3% ao ano entre brancos (IC95%: 0,9 a 5,9; $p = 0,008$) e de 4,7% ao ano entre pardos (IC95%: 3,8 a 21,3; $p = 0,005$) até 2018, seguida de estabilização. Homens pretos apresentaram tendência crescente durante todo o período analisado (APC=2,8%; IC95%: 2,2 a 3,5; $p < 0,001$). Entre as mulheres, a mortalidade também aumentou significativamente entre brancas (APC=0,7%; IC95%: 0,1 a 8,4; $p = 0,043$) e pardas (APC=3,8%; IC95%: 3,2 a 5,4; $p < 0,001$) até 2018, com posterior estabilização. Mulheres pretas, apresentaram tendência crescente ao longo de todo o período analisado

(APC=2,1%; IC95%: 1,4 a 3,0; $p < 0,001$). **Discussão e conclusão:** A estabilização recente das taxas de mortalidade por mieloma múltiplo entre brancos e pardos no Brasil pode indicar avanços no acesso ao diagnóstico e tratamento. No entanto, o crescimento contínuo entre pessoas pretas evidencia que essa melhora não é homogênea, reforçando desigualdades no sistema de saúde. O contraste entre o aumento mais acentuado da mortalidade na China (AAPC=4,07%) e a elevação mais moderada no Brasil (AAPC=1,37%) pode refletir diferentes estágios de envelhecimento populacional, transição epidemiológica e desigualdades no acesso a terapias. Projeções indicam aumento contínuo da carga da doença até 2046 em todos os países do BRICS, exceto a África do Sul. Isso sinaliza a necessidade urgente de o Brasil investir em estratégias de rastreamento precoce, ampliação da cobertura terapêutica e políticas públicas focadas na equidade em saúde.

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TREATMENT PATTERNS AND OUTCOMES IN THE SECOND AND THIRD LINES AND AFTER TRIPLE-CLASS EXPOSURE: SUBANALYSIS OF THE LATIN AMERICAN MULTIPLE MYELOMA REGISTRY STUDY (MYLACRE)

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Introduction: Patterns of care for multiple myeloma (MM) vary across countries. MYLACRE was a non-interventional registry of patients (pts) diagnosed with MM between in Latin America. We analyzed MYLACRE pts treated in the 2nd and 3rd lines of therapy (LOT2 and LOT3), with the objective of characterizing treatment (tx) patterns. We also investigated tx strategies and outcomes in the subset of triple-class exposed (TCE) pts. **Objectives:** Characterizing treatment (tx) patterns. We also investigated tx strategies and outcomes in the subset of triple-class exposed (TCE) pts. **Material and methods:** Data were retrospectively collected, and tx was left to investigators' discretion. The LOT2 Population comprised all pts who

had an entry for the start date of LOT2. The LOT3 Population comprised all pts from the LOT2 Population who had an entry of the start date of LOT3. We defined TCE pts as those who had received ≥ 1 proteasome inhibitor (PI), ≥ 1 immunomodulatory drug (IMiD), and ≥ 1 anti-CD38 antibody, regardless of tx duration. We analyzed TCE pts with at least one subsequent LOT after becoming TCE. We analyzed time to next treatment (TTNT) and overall survival (OS), with TTNT measured between Day 1 of the LOT of interest and Day 1 of the subsequent LOT. **Resultados:** Of the 1029 pts originally analyzed, 405 and 167 entered the LOT2 and LOT3 Populations, respectively. In LOT2, the most frequently used PI, IMiD, and anti-CD38 were bortezomib (41.0%), lenalidomide (41.0%) and daratumumab (26.2%). Other agents used in $>10\%$ were carfilzomib (17.0%) and thalidomide (19.3%). The median TTNT was 21.2 months (mo), and median OS was 26.1 mo. In LOT3, Carfilzomib (26.9%), Lenalidomide (34.7%), and Daratumumab (18.6%) were, respectively, the most common PI, IMiD, and anti-CD38. Bortezomib (25.7%) and thalidomide (10.8%) were the next most frequent. The median TTNT was 12.2 mo, median OS was 14.5 mo. A total of 166 (16.1%) pts had a record of tx with ≥ 1 PI, ≥ 1 IMiD, and ≥ 1 anti-CD38 at some point. Of these pts, 48 (48/166=28.9%) initiated a subsequent LOT after TCE and entered the TCE Population. These pts became TCE after LOT1 (n = 5), LOT2 (n = 27), LOT3 (n = 8), or later (n = 8). Considering agents belonging to the PI, IMiD, and anti-CD38 classes, Carfilzomib was the agent most frequently used in the first LOT after TCE (52.1%), followed by Lenalidomide (22.9%), pomalidomide (20.8%), Daratumumab (18.8%), and Thalidomide (10.4%). Forty-five TCE pts could be analyzed for TTNT and OS. The median TTNT was 9.5 mo (95% CI, 5.9 to 19.4 mo). The median OS was 13.4 mo (95% CI, 10.6 to 17.7 mo). **Discussion and conclusion:** This snapshot of pts with MM treated in Latin America shows heterogeneity in txs used in LOT2, LOT3, and after TCE status, suggesting a lack of standard of care in the real world. The difference between real-life drug use and international guidelines could also be determined by access barriers. The short OS, especially after TCE, highlights the importance of more effective tx options to improve outcomes. **Funding:** This study was funded by Johnson & Johnson and Legend Biotech USA Inc.

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UPDATED RESULTS OF SONROTOCLAX + DEXAMETHASONE, AN ALL-ORAL TREATMENT, IN PATIENTS WITH T(11;14)-POSITIVE RELAPSED/REFRACTORY MULTIPLE MYELOMA

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Introduction: Despite the clinical efficacy of BCL2 inhibition in t(11;14)-positive multiple myeloma (MM), no BCL2-targeted treatments are approved. Sonrotoclax (BGB- 11417), a next-generation BCL2 inhibitor, is a more selective and pharmacologically potent inhibitor of BCL2 than venetoclax, with a shorter half-life and no drug accumulation. BGB-11417-105 (NCT04973605) is an ongoing phase 1b/2 study of sonrotoclax mono- or combination therapy in patients (pts) with t(11;14)-positive relapsed/refractory (R/R) MM. **Objectives:** To assess safety and efficacy of sonrotoclax + dexamethasone (dex) in pts from BGB-11417-105. **Material and methods:** Eligible pts had R/R MM with centrally confirmed t(11;14) and received oral daily sonrotoclax (320 or 640 mg) and weekly dex (40 mg) until end of treatment. Adverse events (AEs) were graded by CTCAE v5.0, and efficacy was assessed by the investigator per IMWG criteria. **Results:** As of January 20, 2025, 14 and 36 evaluable pts were enrolled in sonrotoclax 320- and 640-mg cohorts, respectively; median (range) follow-up was 6.2 months (2.6- 34.5) and 12.1 months (0.1-28.9), respectively. In the 320- vs 640-mg cohorts, respectively, median age (range) was 69.5 y (44-86) vs 69.0 y (48-80); 42.9% vs 52.8% were male; and 57.1% vs 75.0% were White. Pts had a median of 3 prior treatment lines in both the 320-mg (range, 1-7) and 640-mg (range, 1-12) cohorts; 78.6% and 66.7% of pts were refractory to 3 treatment classes, respectively. At data cutoff, 7 pts (50.0%) in the 320-mg cohort and 14 (38.9%) in the 640-mg cohort remained on treatment; progression was the most common reason for discontinuation (35.7% and 41.7%, respectively). The ORR (95% CI) was 64.3% (35.1%-87.2%) for 320 mg and 80.6% (64.0%-91.8%) for 640-mg, with VGPR or better rates (95% CI) of 35.7% (12.8%-64.9%) and 55.6% (38.1%-72.1%), respectively. The median time to response was 0.7 months in both cohorts. Median (95% CI) duration of response was 5.9 months (1.8-not estimable [NE]) in the 320-mg cohort and 12.2 months (8.3-18.9) in the 640-mg cohort. Median (95% CI) progression-free survival was 6.6 months (2.9-NE) in the 320-mg cohort and 13.3 months (9.0-19.6) in the 640-mg cohort. The safety profile was tolerable and manageable for both cohorts. The most common TEAEs were fatigue (35.7%) in the 320-mg cohort, and insomnia (38.9%) and diarrhea (38.9%, all grade 1 or 2) in the 640-mg cohort. Grade ≥ 3 TEAEs occurred in 5 pts (35.7%) in the 320-mg cohort and 17 pts (47.2%) in the 640-mg cohort; serious TEAEs occurred in 3 (21.4%) and 10 (27.8%), respectively. Grade ≥ 3 hematologic TEAEs occurred in 1 (7.1%) and 9 (25.0%) and grade ≥ 3 infections in 3 (21.4%) and 4 (11.1%) pts, respectively. Two pts (14.3%) in the 320-mg cohort and 2 (5.6%) in the 640-mg cohort died during the treatment-emergent portion of the study for reasons unrelated to sonrotoclax or dex (320-mg: pneumonia RSV and COVID-19; 640-mg: hypoventilation due to lung-involved progressive disease and metastatic pancreatic cancer). Four additional deaths