

plasmócitos. Entre 2008 e 2017, a incidência no Brasil foi estimada em 1,24 casos por 100 mil habitantes. Clinicamente, o MM se manifesta por hipercalcemia, insuficiência renal, anemia ou lesões ósseas líticas; associadas à $\geq 10\%$ de plasmócitos clonais na medula. No Sistema Único de Saúde (SUS), antes de 2022, o tratamento era baseado em agentes alquilantes, corticoides e imunomoduladores, com destaque para o esquema talidomida, ciclofosfamida e dexametasona (CTD). Para pacientes elegíveis, o TACTH é uma terapêutica consolidada. Em 2022, o bortezomibe foi implementado no SUS. **Objetivos:** Avaliar dados clínicos-laboratoriais e resposta ao tratamento com CTD seguidos de TACTH em pacientes com MM. **Material e métodos:** Estudo retrospectivo com análise de prontuários de pacientes tratados com CTD seguido de TACTH em um serviço do SUS, antes da implementação do bortezomibe. **Resultados:** Foram avaliados 23 pacientes no diagnóstico. A idade variou entre 42 e 74 anos (média de 61,17; mediana 62), com predomínio feminino (60,87%). O pico monoclonal foi detectado em 43,47% e em 65,22% casos, pela eletroforese de proteínas (EP) e imunofixação sérica (IFS), respectivamente. Quanto ao estadiamento ISS (International Scoring System): 47,83% estavam em estágio III, 17,39% em II e 34,78% em I. Em relação às manifestações: 30,43% apresentaram hipercalcemia (média cálcio iônico: 2,70; mediana 1,27); 9% insuficiência renal (média creatinina: 1,79 mg/dL; mediana: 0,9 mg/dL); anemia (hemoglobina média: 10,67 g/dL; mediana 9,9 g/dL); e 34,78% tinham ≥ 1 lesão osteolítica. A média de plaquetas foi de 243.957/mm³ (mediana: 235.000/mm³). Todos foram submetidos ao TACTH: 9% menos de 12 meses, 78,26% em 1 ano, e 13% após mais de 1 ano. Quanto à resposta: 26,09% alcançaram resposta completa (RC), 4,34% resposta parcial muito boa (RPMB), 30,43% resposta parcial (RP) e 39,13% resposta ausente (RA). O tempo de seguimento teve média de 5,17 anos (mediana: 4 anos). **Discussão:** A média etária (61,17 anos) está de acordo com a epidemiologia do MM, predominando após 60 anos. Apesar do leve predomínio masculino na literatura, observou-se maior proporção de mulheres (60,87%). A alta frequência de pacientes em ISS III (47,83%) sugere diagnóstico tardio, refletindo barreiras no acesso precoce. A anemia foi a manifestação mais comum (73,91%). A alta taxa de pico monoclonal na IFS (65,22%) reflete a elevada prevalência desse achado em pacientes com MM e reforça a maior sensibilidade da técnica em relação à EP. O tempo prolongado até o TACTH, maioria após 12 meses, pode comprometer os desfechos, sendo o ideal entre 4 e 6 meses após a indução. A taxa de RC (26,1%) é semelhante à de estudos com CTD em populações sem acesso ao bortezomibe. Apesar de inferior aos esquemas modernos, o CTD segue como opção viável e custo-efetiva no SUS diante das limitações de acesso a novas terapias. **Conclusão:** O regime CTD seguido de TACTH demonstrou eficácia em parte dos pacientes, mesmo com limitações. O diagnóstico tardio e longo intervalo até o TACTH revelam fragilidades no SUS. Estratégias para diagnóstico e tratamento precoce são fundamentais para melhorar os desfechos no MM.

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HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH TRANSPLANT-INELIGIBLE OR TRANSPLANT-DEFERRED NEWLY DIAGNOSED MULTIPLE MYELOMA (MM) IN THE PHASE 3 CEPHEUS TRIAL

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Introduction: Previous daratumumab clinical trials showed no detriment to health-related quality of life (HRQoL) with addition of daratumumab as part of a triplet or quadruplet treatment regimen. In the phase 3 CEPHEUS trial (NCT03652064), minimal residual disease negativity and progression-free survival improved with subcutaneous daratumumab plus bortezomib and Rd (DVRd) vs VRd in pts with newly diagnosed multiple myeloma (NDMM). **Objetives:** Evaluate HRQoL of DVRd vs VRd in CEPHEUS. **Material and methods:** Pts had transplant-ineligible (TIE) or transplant-deferred (TD) NDMM, ECOG performance status ≤ 2 , and International Myeloma Working Group frailty score ≤ 1 . Pts were randomized 1:1 to DVRd or VRd. Patient-reported outcomes (PROs) were evaluated at baseline (BL), once each cycle to C8D1, and every 3rd C from C9D1 until disease progression. PROs included the European Organization for Research and Treatment of Cancer quality of life questionnaire core 30 (EORTC QLQ-C30), EORTC QLQ multiple myeloma 20 (EORTC QLQ-MY20), and the Euro-Qol 5-Dimension 5-Level (EQ-5D-5L). **Results:** The intent-to-treat population had 395 pts (DVRd, n = 197; VRd, n = 198). Median follow-up was 58.7 months; 135 pts in the DVRd arm and 106 in the VRd arm were on study treatment at C36. Compliance was $>85\%$ at BL and $>81\%$ through C36 in both arms. For all questionnaires, BL means were comparable, and similar improvements in least square (LS) mean change from BL were seen across arms. At C36, the LS mean change from BL (95% CI) in EORTC QLQ-C30 global health status was 8.2 for DVRd and 8.5 for VRd with no apparent difference between arms. For EORTC QLQ-C30, the LS mean change from BL at C36 was 3.6 for DVRd and 5.1 for VRd (difference -1.5 [-6.4 ,

3.4], $P = 0.54$). For fatigue, these changes were -4.7 ($-8.6, -0.7$) for DVRd and -5.4 ($-9.6, -1.2$) for VRd (difference 0.7 [$-4.9, 6.3$], $P = 0.80$). For pain, reduction from BL was numerically higher with DVRd (-14.8) vs VRd (-8.7 ; difference -6.1 [$-12.7, 0.5$], $P = 0.06$). LS mean change from BL in EORTC QLQ-MY20 disease symptoms score at C36 was -8.4 for DVRd and -9 for VRd (difference 0.6 [$-3.5, 4.7$], $P = 0.78$). For EQ-5D-5L visual analogue scale (VAS) score, these changes were 7.3 () in DVRd and 5.6 () in VRd (difference 1.7 [$-2.4, 5.7$], $P = 0.41$). For all scales, a similar median time to worsening and time to improvement were observed across arms. PROs of the TIE subgroup had similar results. **Discussion and conclusion:** DVRd-treated pts in CEPHEUS had improved HRQoL and physical functioning as well as symptom (pain, fatigue, overall disease symptoms) reduction from BL. Improvements were similar vs VRd with no apparent differences between arms, indicating no detriment to HRQoL with addition of daratumumab. **Funding:** This study was funded by Johnson & Johnson. Medical writing support was provided by Shuang Li, PhD, of Eloquent Scientific Solutions, and funded by Johnson & Johnson.

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IMPACT OF BORTEZOMIB MAINTENANCE ON MULTIPLE MYELOMA PATIENT'S SURVIVAL

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Introduction: Lenalidomide improves survival in multiple myeloma (MM) but is unavailable in the Brazilian public health system (SUS). Bortezomib (BTZ) was incorporated into SUS only in September 2020. Before that, transplant-eligible patients were mainly treated with CTd, and ineligible patients with MPT. Currently, VCD/VTd and VMP are the most used first-line regimens in our public hospital, with biweekly BTZ maintenance. We present 10-year updated data focusing on the impact of BTZ. **Objectives:** To evaluate the impact of BTZ on progression-free survival (PFS) and overall survival (OS) in the overall population, in both induction and maintenance settings, and in subgroups by treatment regimen and autologous stem cell transplantation (ASCT) status. **Material and methods:** In this single-center, retrospective study, patients with newly diagnosed MM were consecutively enrolled from November 2014 to August 2025. Of 133 patients, 17 were excluded (4 due to incomplete data, 10 with asymptomatic MM, 1 with primary amyloidosis, 1 with MM-like post-transplant lymphoproliferative disorder, and 1 who had already received first-line therapy elsewhere). At the data cut-off (August 6, 2025), 100 of 116 patients (86.2%) had ≥ 1 year of follow-up and were analyzed. PFS was defined as the time from

first-line therapy to progression, death, or last follow-up, and OS as the time from diagnosis to death or last follow-up. **Results:** Median age was 63.3 years (range, 28.5–85.8), 60% were male, and 57% had the IgG subtype. The most common induction regimens were CTd (42.4%), VCD (22.2%), MPT (15.2%), VMP (6.1%), VTd (5.1%), and MP (4%). ISS stage II/III was observed in 32.8%/51.7%, and 67% were ASCT-eligible. ASCT was performed in 42.4% (42/99), 73.8% in first line. BTZ was used in induction in 36.8% (32/87), and 43.8% (14/32) of these also received BTZ maintenance; overall, BTZ maintenance was given to 40.3% (35/87). Four-year PFS was: CTd 15.2%, MPT 11.1%, VCD/VTd 48.7%, VMP not mature; median PFS for all patients was 1.6 years (95% CI 1.1–2.0). Five-year OS was: CTd 45.5%, MPT 42.1%, VCD/VTd 63.5%, VMP not mature; median OS for all patients was 3.5 years (95% CI 2.5–6.0). First-line VCD/VTd + ASCT ($N = 10$) achieved a 10-year OS of 100% versus a median OS of 3 years and a 2-year OS of 66.7% without ASCT ($N = 3$; $p = 0.09$). For CTd, 5-year OS was similar with or without ASCT (56.4% vs 71.4%; $p = 0.296$). In both regimens, first-line ASCT significantly improved PFS (VCD/VTd: $p = 0.0008$; CTd: $p = 0.003$). BTZ induction did not significantly improve 10-year OS (58.9% vs 22.7%, $p = 0.74$) but trended toward better 5-year PFS (42.5% vs 14.3%, $p = 0.06$; HR 0.94). In patients without BTZ induction, BTZ maintenance trended toward improved 4-year PFS (30.6% vs 4.24%, $p = 0.07$) and 4-year OS (62.9% vs 33.65%, $p = 0.0546$). After BTZ induction, BTZ maintenance significantly improved 2-year PFS (56.25% vs 23.9%; $p = 0.0339$; HR 0.371, 95% CI 0.139–0.988) and 2-year OS (82.5% vs 36.1%; $p = 0.0012$; HR 0.467, 95% CI 0.02–0.55). **Discussion and conclusion:** In HOVON-65/GMMG-HD4, BTZ induction plus maintenance significantly improved PFS and OS compared with non-BTZ regimens, with greater benefit in high-risk subsets, despite BTZ maintenance not being routine practice. In our resource-limited setting, BTZ induction improved 5-year OS by 21.4% versus CTd, and BTZ maintenance after BTZ induction significantly improved both PFS and OS. Where lenalidomide is unavailable, BTZ may be a viable maintenance option.

Reference:

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IMPACTO DO ESTADIAMENTO ISS E DAS MANIFESTAÇÕES CLÍNICAS NA SOBREVIVÊNCIA DO MIELOMA MÚLTIPLO: EVIDÊNCIAS REAIS DE UM CENTRO PÚBLICO

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