

estudos. Porém, em países desenvolvidos, ainda é 8 vezes maior se comparado a pacientes não infectados. A incidência de neoplasias definidoras de AIDS, como os LNH, diminuiu em 60% na era cART (após anos 2000). No Brasil, dados sobre incidência de NLM nessa população são escassos e pouco se sabe sobre o impacto do uso da cART na sobrevida de crianças e adolescentes infectados e o desenvolvimento dessas neoplasias. O objetivo do estudo foi avaliar a incidência de neoplasias linfoproliferativas malignas (NLM) em pacientes de 0 a 20 anos incompletos, com TV de HIV, que iniciaram acompanhamento em 6 hospitais de referência para HIV/AIDS no Rio de Janeiro de 01/01/1995 a 01/01/2018, e estudar sua sobrevida. Trata-se de um estudo observacional, de coorte retrospectiva de pacientes pediátricos portadores de HIV por TV. Foram estudados 1.307 pacientes com TV de HIV, com 27 linfomas encontrados no total. A coorte foi dividida em 3 eras – Early cART, Midle cART e Pós cART (pontos de corte: 1995-1999, 2000-2003 e 2004-2018). Quanto à densidade de incidência de linfomas, o valor foi de 1,83 a cada 1.000 pessoas-ano para o estudo global, bem como de 2,71 a cada 1.000 pessoas-ano no período Early, 2,63 na era Midle e 0,37 na era Pós. Foi encontrada uma probabilidade cumulativa de evento total de 3,1% em 23 anos de acompanhamento. Entre as eras, a mesma foi de 5,1% na era Early, de 4,0% na era Midle e de 0,7% na era Pós, com p (logrank) valor de 0,005. O tempo de acompanhamento mediano foi de 12,83 anos para a coorte Early, 13,50 anos para a Midle e de 11,63 anos para a coorte Pós, sendo o total de 12,63 anos. A Hazard Ratio (HR) entre as Eras Midle e Early foi de 0,956 (IC = 0,436 – 2,095; p = 0,910), entre as Eras Pos e Early foi de 0,131 (IC = 0,030 – 0,580; p = 0,007) e, entre as eras Pos e Midle foi de 0,135 (IC = 0,030 – 0,601; p = 0,009). Tais achados confirmam a eficácia da cART na redução da incidência de neoplasias relacionadas à imunossupressão pelo HIV. Além disso, a proporção de tipos de linfomas encontrados está de acordo com a literatura. Embora o Brasil tenha um programa para redução de TV de HIV, o número de crianças e adolescentes infectados ainda é elevado. Dessa forma, esse estudo trouxe resultados robustos e inéditos para o entendimento do espectro de NLM nessa população.

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INDUCTION R2 FOLLOWED BY MAINTENANCE IN PATIENTS WITH RELAPSED/REFRACTORY MANTLE CELL LYMPHOMA: INTERIM ANALYSIS FROM THE PHASE 3B MAGNIFY STUDY

JP Sharman^a, JM Melear^b, A Yacoub^c, SR Fanning^d, DJ Andorsky^e, GS Nowakowski^f, MJ Rummel^g, F Lansigan^h, J Liⁱ, JR Ahn^j, M Ghariboⁱ, M Coleman^j

^a Willamette Valley Cancer Institute and Research Center, US Oncology Research, Eugene, United States

^b Texas Oncology-Austin, US Oncology Research, Austin, United States

^c University of Kansas Cancer Center, Westwood, United States

^d Prisma Health, US Oncology Research, Greenville, United States

^e Rocky Mountain Cancer Centers, US Oncology Research, Boulder, United States

^f Mayo Clinic, Rochester, United States

^g Justus-Liebig Universität, Giessen, Germany

^h Dartmouth-Hitchcock Medical Center, Lebanon, United States

ⁱ Bristol Myers Squibb, Princeton, United States

^j Clinical Research Alliance Inc, Weill Cornell Medicine, New York, United States

Objectives: The combination of lenalidomide + rituximab (R²) has shown complementary clinical activity and is a tolerable regimen in both untreated and relapsed or refractory (R/R) indolent non-Hodgkin lymphoma (NHL), as well as mantle cell lymphoma (MCL), an uncommon but aggressive form of NHL. The MAGNIFY phase 3 trial previously reported an ORR of 54% in patients with R/R MCL (Sharman J, et al. *Hematol Oncol*. 2019). Presented here are updated analyses from this trial. **Materials and methods:** MAGNIFY is a multicenter, phase 3b trial (NCT01996865) in patients with R/R follicular lymphoma (FL) grades 1–3b, transformed FL, marginal zone lymphoma, and MCL. Lenalidomide 20 mg on d 1–21 of a 28-d cycle + rituximab 375 mg/m²/wk cycle 1 and then every 8 wk starting with cycle 3 (R²) is given for 12 cycles followed by 1:1 randomization in patients with stable disease, partial response, or complete response/complete response unconfirmed (CR/CRu) to R² vs rituximab maintenance for 18 mo. The primary end point is progression-free survival (PFS) by 1999 International Working Group (IWG) criteria. Secondary end points include safety, CR rate, duration of response (DOR), duration of CR (DOCR), time-to-response (TTR), time-to-next antilymphoma therapy, and overall survival. This analysis evaluates the interim primary endpoint of overall response rate (ORR) by 1999 IWG criteria and safety of R² induction in patients with MCL in the induction intention-to-treat population. **Results:** As of August 28, 2020, 73 patients with MCL were enrolled (median age, 70.0 y [range, 51–88]); 89% had stage III/IV disease, and 41% had bulky disease (> 7 cm or > 3 cm × 3 lymph nodes). All patients had received prior rituximab-containing therapy, with 25 (34%) rituximab refractory (progression ≤ 6 mo after last rituximab dose). Seven patients (10%) had received prior ibrutinib. Median follow-up was 31.7 mo for patients still alive. ORR was 51%, with 34% CR rate (CR + CRu). Response rates were similar in patients refractory to rituximab (ORR = 48%, CR/CRu = 32%) and patients not refractory to rituximab (ORR = 52%, CR/CRu = 35%). Median DOR was 31.6 mo; median DOCR was not reached; median TTR was 2.8 mo, and median PFS was 28.0 mo, with 1-year PFS rate of 57%. The most common treatment emergent adverse events (TEAEs) of any grade were neutropenia (51%), fatigue (44%), diarrhea (32%), constipation (28%), cough (28%), dyspnea (26%), and nausea (26%). Grade 3/4 neutropenia was 46%; all other grade 3/4 TEAEs were ≤ 11%. **Discussion:** R² is an active and tolerated regimen with durable responses among patients with R/R MCL and mostly naive to Bruton tyrosine kinase inhibitor therapy. **Conclusions:** These results suggest that R² should be considered as a therapeutic option for patients with R/R MCL.

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