

miocardiopatia congestiva, neuropatia periférica (incluindo a síndrome do túnel cárpico) ou autonômica, hepatomegalia ou os achados característicos de macroglossia e equimoses peri-orbitárias devem levar à suspeição de amiloidose AL. A coexistência de mieloma múltiplo e amiloidose AL é um fator de mau prognóstico. A abordagem terapêutica destas duas doenças exige quimioterapia e, em alguns casos, transplante medular autólogo. A utilização de novos agentes, e a rigorosa seleção de candidatos ao transplante medular melhoraram a sobrevida destes doentes atingidos por neoplasias hematológicas ainda incuráveis.

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**DARATUMUMAB (DARA),
CYCLOPHOSPHAMIDE, THALIDOMIDE AND
DEXAMETHASONE FOR TRANSPLANT
ELIGIBLE NEWLY DIAGNOSED MULTIPLE
MYELOMA (TE NDMM) PATIENTS: RESPONSE
RATE IMPACTS ON PFS**

EQ Crusoe^{a,b}, JSLRD Santos^b, JAD Santos^{a,b},
HHM Santos^a, AS Santos^c, LF Lucas^b,
AM Almeida^d, VT Hungria^e, MA Salvino^{a,b},
MGB Arruda^b

^a Universidade Federal da Bahia (UFBA), Salvador, BA, Brazil

^b Rede D'Or Oncologia, Salvador, BA, Brazil

^c Laboratório de Imunologia, Molecular e Citometria, Instituto de Ciências da Saúde (ICS), Universidade Federal da Bahia (UFBA), Salvador, BA, Brazil

^d Unidade de Transplante de Células-Tronco, Universidade Federal da Bahia (UFBA), Salvador, BA, Brazil

^e Departamento de Hematologia e Oncologia, Clínica São Germano, São Paulo, SP, Brazil

Background: The four-drug combo has becoming one of the main induction treatment for TE NDMM patients (pts). We conducted a phase 2 study to assess the safety and preliminary efficacy of Cyclophosphamide (C), thalidomide (T), dexamethasone (d)-(CTd) and Dara combination. MAXDARA study has shown in the primary analysis with 21 included patients (pts), 4 and 8 pts MRD negativity after four induction cycles and two consolidation cycles post transplant, respectively. (Crusoe E et al ASH 2020, 2416 poster presentation). In the present analysis we evaluate the effect of deep response rate on PFS. **Methods:** This is a phase II, open-label single-center clinical trial. The main inclusion criteria were: TE NDMM, creatinine clearance > 30 ml/min, normal cardiac, renal and liver function and the ECOG performance status = 0 - 2. The protocol was Dara-CTd for up to four 28-day induction cycles: C-500mg oral (PO) on days 1,8 and 15, T at 100-200mg PO on days 1 to 28, (d) at 40mg PO on days 1,8,15 and 22 and Dara at 16mg/Kg/dose intravenous (IV) on days 1,8,15 and 22 during cycles 1 - 2 and every other week in cycles 3 - 4, followed by ASCT. All pts received up to four 28-day consolidation cycles that was started at D+30 after ASCT: Dara at 16mg/Kg and (d) at 40mg every other week, associated with T at 100mg PO on

days 1 - 28. Dara at 16mg/Kg was used monthly as maintenance until progression or limiting toxicity. The MRD was evaluated by next-generation flow (NGF) 10–6 and PET-CT was performed when the patient obtained NGF negativity or finished consolidation. PFS outcome was estimated using Kaplan–Meier method and PFS analysis were performed based on the different response rates. (Data cut-off was April 2022) **Results:** A total of 24 pts were included. The median age being 58 (range 37–67 years), 15 (62.5%) pts were female, 22 (92%) were non-white, 6 (25%) had an R-ISS = 1, 12 (50%) had an R-ISS = 2 and 4 (16%), an R-ISS = 3. Sixteen (66.7%) pts were IgG isotype and Six (25%) had high-risk chromosomal abnormalities [1q+, del17p, t(4;14) or t(14;16)]. To date, 23 pts have completed induction, 21 performed transplant and 14 are still in treatment after one year of dara maintenance. By ITT analysis, 22 pts (91.6%) achieved ($\geq$ PR) after 4 induction cycles. One pts achieved SD, one MR and one sCR. Eleven (39%) pts achieved PR, and 10 (35.7%) VGPR. After two consolidation cycles, ORR was 68%, 8 (28.6%) and 11 (39.3%) pts obtained sCR and VGPR, respectively. The best response during any time of the treatment were PR in 3 (12.5%) pts, VGPR in 12 pts (50%) and sCR in 8 (33.3%) pts. In a ITT analysis, NGF MRD 10–6 negativity were observed in 4(16.6%) after four induction cycles, and in 17 (70.8%) pts after two consolidation cycles post-ASCT. In a ITT analysis, after a median follow up (FU) of 26 months, the PFS was 37months for the entire group. The median PFS comparing sCR vs $\leq$ VGPR were 37m vs 27m ($p=0.021$), respectively, and comparing MRD negative by NGF vs no, had impacted even more on PFS with a median of 37m vs 16m ($p=0.004$), respectively. The OS was not yet achieved and 83% of the patients still alive after a median FU of 27m. Four pts died from infection, two of them related with covid infection (one before transplant and one during maintenance). Another case post-transplant, considered not related to the investigational agent and one after consolidation, related to the investigational agent. **Summary/Conclusion:** The Daratumumab - CTd protocol is an active and safe regimen capable of producing deep and sustainable responses. The deeper response rate impacted on PFS, confirm that MRD negativity is critical to patient outcome.

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**HEMOSTASIA E PAREDE VASCULAR: DOENÇAS DE
PLAQUETAS**

**TROMBOCITOPENIA IMUNE: DIAGNÓSTICO E
EVOLUÇÃO DE PACIENTES ACOMPANHADOS
EM SERVIÇO DE REFERÊNCIA DO ESTADO DE
SÃO PAULO**

G Augusto, ACP Silva, P Vicari, VLP Figueiredo

Serviço de Hematologia, Hospital do Servidor Público do Estado de São Paulo (HSPE), Instituto de Assistência Médica ao Servidor Público Estadual (IAMSPE), São Paulo, SP, Brasil

Introdução: Trombocitopenia imune ou púrpura trombocitopenica idiopática (PTI), é uma doença mediada por autoanticorpo IgG causando destruição plaquetária. Acomete adultos