ais. Resultados: Do total dos pacientes, 59,26% apresentaram diminuição de TAS e TAH no período analisado pós avaliação de perfil de farmacocinética, sendo encontrado redução significativa (p = 0,029 e p = 0,03). Foi optado por implementação do tratamento conforme os regimes sugeridos no programa myPKFiT® para 29,62% dos pacientes, os outros 70,37% foram mantidos com o tratamento habitual ou receberam um tratamento diferente daquele sugerido pelo software. Daqueles que receberam o tratamento conforme a sugestão do programa, 62,5% apresentaram melhora pela diminuição de episódios de sangramento, porém sem significância estatística. Foi demonstrado também um aumento significativo na quantidade mensal de fator nos regimes de tratamento profilático sugeridos pelo programa de avalição de PK em comparação às quantias habituais (p<0,001), o que se traduziu também em aumento de custo mensal. Discussão: Pode-se afirmar que houve melhora no perfil de sangramento, observado pela diminuição significativa no número de eventos nas TAH e TAS. E também que, caso implementados, os regimes de infusão sugeridos pelo myPKFiT® acarretariam num aumento significativo tanto da quantidade de fator quanto do custo mensal do tratamento. Conclusão: Pode-se concluir que esta ferramenta teve impacto positivo no manejo dos pacientes avaliados neste estudo no que se traduziu a redução do número de episódios de sangramento.

https://doi.org/10.1016/j.htct.2020.10.103

103

BRAZILIAN REGISTRY OF PERSONS WITH HEMOPHILIA A RECEIVING EMICIZUMAB (EMICIZUMAB CASES, EMCASE PROJECT)

R.M. Camelo^a, N. Dantas-Silva^b, J. Álvares-Teodoro^c

^a Faculdade de Medicina, Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, MG, Brazil ^b Fundação Centro de Hematologia e Hemoterapia do Estado de Minas Gerais (Hemominas), Belo Horizonte, MG, Brazil ^c Faculdade de Farmácia, Universidade Federal de

^c Faculdade de Farmácia, Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, MG, Brazil

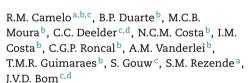
Emicizumab (MC-Ab) is a humanized bispecific antibody which binds to factors IX-activated and X, speeding up the activation of factor X. It solved some unmet needs in hemophilia A (HA) treatment, such as regimen (once weekly up to once monthly infusion) and route of administration (subcutaneous). Although it is an effective non-replacement alternative in the prophylaxis of people with HA (PwHA) with (PwHAi) or without inhibitor, its safety has not been clarified yet, and a few cases of thrombosis and development of anti-MC-Ab antibody have been described. The aim of this project is to create a national registry to follow up PwHA receiving MC-Ab. EMCase Project is an observational study and any PwHA receiving MC-Ab can be included (e.g., sex, age, inhibitor status etc. are not inclusion nor exclusion criteria). It has been approved centrally by the Committee on Ethics in Research of the Universidade Federal de Minas Gerais (CAAE 10664919.6.0000.5149) and registered in the Brazilian Registry

of Clinical Trials (RBR-57rnpz). The treatment will be decided among the patient, the physician, and the interdisciplinary team of the hemophilia treatment center (HTC). The research group developed a brochure with suggestions on classical outcome assessment tools (e.g., bleeding rate, joint health, absenteeism, adherence, quality of life and mortality) which can be evaluated as the judgement of the HTC team. Outcome data, laboratory results and therapeutic progression will be compiled yearly over a maximum of 10 years. Pharmacovigilance and economic analyses will also be included. Finally, a national guidance will be developed. In 2016, there were 10,123 PwHA in Brazil, of whom 4,003 (39.54%) were severe and 451 (4.46%) were PwHAi. There were 268 PwHAi on immune tolerance induction (ITI), of which we can expect a 30% rate of failure. Since MC-Ab has been approved only for PwHAi who failed ITI in Brazil, we expect to include at least 50 PwHAi. Currently, 10 HTCs are registered in the EMCase Project, while 7 other HTCs are in process of formal ethical approval. The first patient was included in July/2020. We expect to establish some outcome assessment tools to aid the interdisciplinary team to manage hemophilia treatment with MC-Ab as well as to help clarifying the safety of this bispecific antibody.

https://doi.org/10.1016/j.htct.2020.10.104

104

CARDIOVASCULAR RISK FACTOR PROFILE AMONG NORTH-EASTERN BRAZILIAN ADULTS WITH HAEMOPHILIA



^a Ciências Aplicadas à Saude do Adulto,
Universidade Federal de Minas Gerais (UFMG),
Belo Horizonte, MG, Brazil
^b Fundação de Hematologia e Hemoterapia de
Pernambuco (Hemope), Recife, PE, Brazil
^c Department of Clinical Epidemiology, Leiden
University Medical Center, Leiden, Netherlands
^d Centre for Clinical Transfusion Research,
Sanquin/Leiden University Medical Center, Leiden,
Netherlands

Since the introduction of episodic and prophylaxis treatment with safer products, the life expectancy of people with haemophilia (PwH) enhanced considerably. This comes with an increasing number of older PwH and with associated diseases, such as cardiovascular disease (CVD). HemoCardio was a cross-sectional study aimed to describe CVD risk factors among North-eastern Brazilian PwH. Male PwH 30 years or older were interviewed, had physical examinations, and provided blood samples. CVD risk scores were estimated according the Framingham Risk Score (FRS) tool. This tool predicts the 10-year risk of major CVD events (coronary disease—chronic arterial disease, stroke, peripheral obstructive arterial disease, or heart failure). The variables collected are described in Table 1. The estimated FRS was catego-

