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Data Article

Data of safety in a single-center alemtuzumab treated population

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ABSTRACT

Alemtuzumab is approved for highly active MS and, in Europe, can be employed after other disease-modifying treatments (DMTs) as an escalation approach or first therapeutic option. The occurrence of secondary autoimmune adverse events and infections differs depending on the employed approach.

In the manuscript entitled "Alemtuzumab treatment of multiple sclerosis in real-world clinical practice: report from a single Italian center" by di Ioia M. and collaborators, efficacy and safety data of alemtuzumab were evaluated in a real-world MS population. The aim of the article is to describe in detail the unexpected serious adverse events which occurred in this cohort during and after the administration of the alemtuzumab treatment.

Adverse events were observed in 45,7% of the patients. These events were ranked as severe in 23% of the patients. We reported, in particular, cases of autoimmune hemolytic anemia (AIHA), pancytopenia, viral hepatitis E and noninfectious meningo-encephalomyelitis.

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Specifications Table

Subject	Neurology
Specific subject area	Adverse events of alemtuzumab in MS treatment
Type of data	Description of clinical cases
How data were acquired	Observational study. Data were acquired using The iMed software and patients records.
Data Format	Analysed
Parameters for data collection	Collected data derived from real-world clinical practice
Description of data collection	Data were collected through the i-Med electronic database and patients records
Data source location	Chieti/Abruzzo Italy
Data accessibility	Data is with this article
Related research article	di Ioia M., Di Stefano V., Farina D., Di Tommaso V., Travaglini D., Pietrolongo E., Sensi S.L., Onofrj M., De Luca G. Alemtuzumab treatment of multiple sclerosis in real-world clinical practice: a report from a single Italian center. Multiple Sclerosis and Related Disorders https://doi.org/10.1016/j.msard.2019.101504

Value of the Data

- Safety profile of alemtuzumab may differ in real-world MS population when compared to clinical trials because of different comorbidities and previous drug history of the patients
- Clinicians expert in treatment of MS before switching to alemtuzumab must take into account previous therapies and patients comorbidities
- Real-world studies like this may clarify safety profile of alemtuzumab in different MS patients and help to understand the better sequencing of MS drugs
- This data lead to reflect on the better-in-place of alemtuzumab in MS therapy

1. Data description

Thirty-five patients treated with alemtuzumab in a single MS Center were followed for at least thirty-six months. Adverse events were observed in 45,7% of the patients and ranked as severe in 23% of them [1]. In addition to the expected adverse events such as thyroid dysfunctions, immune thrombocytopenia (ITP) and infections, rare and unexpected adverse events, described below, were also observed.

A 34-year-old man developed, eleven months after the first alemtuzumab course, albuminuria and AIHA (May 2017) [2]. ITP occurred three months later (August 2017). The patient was treated for ITP with Rituximab; ten months later (June 2018), he was also diagnosed with glomerulonephritis and treated with cyclophosphamide until September 2018. One year after cessation of cyclophosphamide (October 2019), laboratory tests were stable with persistent albuminuria, brain and spinal cord MRI was stable but he had worsening ataxia, so he was scheduled to start ocrelizumab. A case of AIHA, associated with warm reactive autoantibodies (IgG), was observed in a female 36-year-old patient, four months after the second alemtuzumab course. She was treated with erythrocytes transfusion, steroids, and intravenous immunoglobulins, a regimen that produced remission. The patient, six months later, relapsed with AIHA and was then treated with mycophenolate. We also observed a case of pancytopenia that occurred in a 45-year-old male patient eighteen months after the second alemtuzumab course. The patient was treated with prednisone. All the patients had a history of previous treatments with three to six other DMTs before alemtuzumab.

A female 36-year-old patient developed, after the second alemtuzumab course, viral hepatitis E (Hev). She exhibited high levels (1600 U/L) of alanine aminotransferase (ALT). Besides this case and another patient who developed recurrent cystitis, no other infections were observed.

Finally, a 45-year-old male patient was diagnosed with meningo-encephalomyelitis. He developed a spinal cord syndrome with a T10 sensitive level associated with tinnitus; he showed multiple Gd + lesions in the brain and spinal cord as well as signs of diffuse of leptomeningeal enhancing signals that occurred five months after the first alemtuzumab course (August 2018). Infectious and neoplastic

causes were excluded by laboratory tests and targeted instrumental exams. The patient was treated with methylprednisolone (5000 mg), acyclovir (750 mg; three times a day), and ampicillin. Treatment resulted in partial clinical and radiological improvements. In November 2018, the patient was admitted to our inpatient clinic and exhibited ataxia and signs of worsening of the gait (EDSS 6.5). An MRI scan revealed two new Gd + lesions in the cerebral white matter. He was treated with methylprednisolone (6000 mg iv) followed by oral steroid tapering that produced no recovery. The patient underwent plasmapheresis (five cycles; from November 23rd to December 5^{th,} 2018), a regimen that produced a mild clinical improvement. A second MRI scan showed a new lesion in the medulla oblongata, the CSF was normal, viral and bacterial infections were excluded, and the patient was scheduled to start ocrelizumab. Detection of anti-myelin oligodendrocyte glycoprotein (MOG) antibody was positive (1:80), while detection of *anti*-aquaporin-4 (AQP-4) antibody was negative. Six months after the first ocrelizumab infusion (June 2019) brain MRI showed new enhancing and non enhancing lesions and the patient was clinically stable whereas follow-up MRI six months later was stable.

2. Experimental design, materials, and methods

We described unexpected serious adverse events observed in 16 of 35 patients treated with alemtuzumab from October 2014 to January 2019 at the MS Center in Chieti. All the adverse events (expected and unexpected) and their percentages were reported in Supplementary data. All the data were collected through the i-Med electronic database and patients records and then analysed by a clinician specialist in MS. i-Med database is the Italian Multiple Sclerosis Registry containing both personal data and disease related data (onset, diagnosis, relapses, disease modyfing drugs, etc.). All patients gave their consent to data entry and use of their data for research purposes. More details about study design can be found in the related article [1]. For the unexpected events we provided a detailed description in this article and a final interpretation and discussion in the related article published in Multiple Sclerosis and Related Disorders [1].

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dib.2020.105341.

References

[1] M. di Ioia, V. Di Stefano, D. Farina, V. Di Tommaso, D. Travaglini, E. Pietrolongo, S.L. Sensi, M. Onofrj, G. De Luca, Alemtuzumab treatment of multiple sclerosis in real-world clinical practice: a report from a single Italian center, Mult Scler Relat Disord 38 (2019 Nov 6) 101504, https://doi.org/10.1016/j.msard.2019.101504 [Epub ahead of print].

[2] M. di Ioia, D. Farina, V. di Tommaso, D. Travaglini, E. Pietrolongo, M. Onofrj, G. De Luca, Simultaneous early-onset severe autoimmune hemolytic anemia and albuminuria during alemtuzumab treatment for multiple sclerosis, Mult. Scler. 24 (6) (2018) 813–815, https://doi.org/10.1177/1352458517743093.