



# Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina: observational study from RelevarEM.

**Verónica Tkachuk**<sup>1</sup>, Marina Alonso Serena<sup>2</sup>, María E. Balbuena<sup>1</sup>, Pablo A. Lopez<sup>3</sup>, Juan Pablo Pettinicchi<sup>3</sup>, Agustín Pappolla<sup>4</sup>, Jimena Miguez<sup>4</sup>, Liliana Patrucco<sup>4</sup>, Edgardo Cristiano<sup>5</sup>, Carlos Vrech<sup>6</sup>, Susana Liwacki<sup>7-8</sup>, Jorge Correale<sup>9</sup>, Mariano Marrodan<sup>9</sup>, María I. Gaitán<sup>9</sup>, Marcela Fiol<sup>9</sup>, Laura Negrotto<sup>9</sup>, María C. Ysraelit<sup>9</sup>, Marcos Burgos<sup>10</sup>, Felisa Leguizamón<sup>11</sup>, Dario Tavolini<sup>12</sup>, Norma Deri<sup>13</sup>, Carolina Mainella<sup>14</sup>, Geraldine Luetic<sup>15</sup>, Patricio Blaya<sup>16</sup>, Javier Hryb<sup>17</sup>, María L. Menichini<sup>18</sup>, Amelia Alvez Pinheiro<sup>19</sup>, Pedro Nofal<sup>20</sup>, Gisela Zanga<sup>21</sup>, Andrés Barboza<sup>22</sup>, Ivan Martos<sup>23</sup>, Luciana Lazaro<sup>24</sup>, Emanuel Silva<sup>25</sup>, Santiago Bestoso<sup>26</sup>, María E. Fracaro<sup>27</sup>, Adriana Carrá<sup>28,29</sup>, Orlando Garcea<sup>30</sup>, Nora Fernandez Liguori<sup>24,31</sup>, Alejandro Caride<sup>3</sup>, Juan I. Rojas<sup>5,32</sup>, Edgar Camero Contentti<sup>3</sup>.

1-Sección Esclerosis Múltiple y Enfermedades Desmielinizantes, Servicio de Neurología - Hospital de Clínicas José de San Martín, CABA, 2- Servicio de clínica médica, Hospital Italiano de Buenos Aires, CABA, 3-Neuroimmunology Unit Department of Neuroscience, Hospital Aleman, Buenos Aires (CABA), 4-Servicio de Neurología, Hospital Italiano de Buenos Aires, Buenos Aires, 5- Centro de esclerosis múltiple de Buenos Aires, CABA, 6- Departamento de Enfermedades desmielinizantes - Sanatorio Allende, Córdoba, 7-Clinica Universitaria Reina Fabiola, Córdoba, 8-Servicio de Neurología - Hospital Córdoba, Córdoba, 9-Departamento de Neurología - FLENI, CABA, 10-Servicio de Neurología - Hospital San Bernardo, Salta, 11- Hospital de Agudos, Dr. Teodoro Álvarez, CABA. 12- INECO Neurociencias Oroño - Fundación INECO, Rosario, Santa Fe. 13-Centro de Investigaciones Diabaid, CABA. 14-Hospital Español de Rosario, Santa Fe. 15-Instituto de Neurociencias de Rosario, Santa Fe. 16- Neurocomp, Trelew, Chubut. 17-Servicio de Neurología - Hospital Carlos G. Durand, CABA. 17-Sanatorio Británico, Rosario, Santa Fe. 19-Hospital San Martín, Paraná, Entre Ríos, 20- Hospital de Clínicas Nuestra Señora del Carmen, San Miguel de Tucumán, Tucumán, 21-Unidad asistencial César Milstein, CABA. 22-Hospital Central de Mendoza, Mendoza. 23- Clinica San Jorge. Ushuaia. Tierra del fuego. 24-Sanatorio Güemes, CABA. 25-Predigma - Centro de Medicina Preventiva, Posadas, Misiones. 26-Servicio Neurología - Hospital Escuela José F. de San Martín Corrientes, Corrientes. 27-Clinica el Castaño, San Juan, 28- Sección de Enfermedades Desmielinizantes - Hospital Británico, CABA. 29-Instituto de Neurociencias - Fundación Favabro/INECO, CABA. 30- Centro Universitario de Esclerosis Múltiple - Hospital Dr. J. M. Ramos Mejía. Facultad de Medicina - UBA, CABA. 31- Hospital Enrique Tornú, CABA. 32- Servicio de Neurología, Hospital Universitario de CEMIC, CABA.

**Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina: observational study from RelevareM**



## **Conflicts of interest**

The authors do not have any potential financial conflict of interest relating to this poster.

Irrestrictive research grants from Biogen Argentina, Genzyme Argentina, Merck Argentina, Novartis Argentina and Roche Argentina allowed the development and implementation of the Registry (RelevareM). Those grants did not interfere in the development plan, variables, PI selection, patient information nor other aspects of the Registry.

## Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina: observational study from RelevareM



### Introduction and objective

Several retrospective studies have demonstrated the clinical benefits of immunosuppressive therapies (IST) such as azathioprine (AZA), mycophenolate mofetil (MMF) and rituximab (RTX) in reducing relapse rates in neuromyelitis optica spectrum disorders (NMOSD) patients. However, there is considerable uncertainty regarding the relative benefits and harms associated with each of these IST in real world clinical practice and current data describing the strategies are limited.

The objective of this study was to describe the incidence of relapses in patients with NMOSD under IST included in the Argentinean MS and NMOSD registry (RelevareM, NCT 03375177).

Mealy M. et al. Comparison of relapse and treatment failure rates among patients with neuromyelitis optica: Multicenter study of treatment efficacy. *JAMA Neurol* 2014; 71(3): 324–330

Jeong et al. Comparative analysis of treatment outcomes in patients with neuromyelitis optica spectrum disorder using multifaceted endpoints. *Multi Scler* 2016 Mar;22(3):329-39.

Huang H. et al Pregnancy in neuromyelitis optica spectrum disorder: A multicenter study from South China. *J Neurol Sci.* 2017 Jan 15;372:152-156

Yang et al. Comparison of efficacy and tolerability of azathioprine, mycophenolate mofetil, and lower dosages of rituximab among patients with neuromyelitis optica spectrum disorder. *J Neurol Sci.* 2018 Feb 15;385:192-197.

## Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina: observational study from RelevarEM



### Methods

- \*RelevarEM is a longitudinal, strictly observational multiple sclerosis (MS) and NMOSD registry in Argentina.
- \*Epidemiological, serological test and neuroimaging (MRI) data from NMOSD were described.
- \*Only patients under IST were included in the analysis. Patients contributed person-years of follow-up for the study period. Incidence rates and 95% CI were calculated. Global and associated with each IST density incidence of relapses was estimated.

## Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina: observational study from RelevareEM



### Results

\*We included a total of 132 patients (77% women) NMOSD patients with a median age at diagnosis of 36 years (27-47) and a disease duration of 6 years (4-10). Aquaporin-4 antibody was positive in 54.8%.

\*At the time of entering the registry, 39.4% were treated with RTX, 33.3% with AZA, 3.6% MMF. The global density incidence of relapse was 0.032/person-year (CI95% 0,021-0,048), for RTX 0.051 (CI95% 0,024-0,1) and for AZA 0.031 (CI95% 0,016-0,06). There were no relapses in the group of MMF during this period of time.

## Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina: observational study from RelevareEM



|  | Results (n=165) |
|--|-----------------|
| Age at diagnosis*                              | 36 (27-47)      |
| Age at last visit*                             | 44 (34-54)      |
| Female (%)                                     | 77% (127)       |
| AQP4   | 88,5% (146)     |
| –Positive                                      | 54,8% (80/146)  |
| AQP4 assay                                     |                 |
| –IFI   | 39,7% (58)      |
| –ELISA   | 2,7% (4)        |
| –CBA   | 38,4% (56)      |
| –Unknown                                       | 19,2% (28)      |
| Time of disease duration to last visit, years* | 6 (4-10)        |
| Treatment at the time of entering the registry |                 |
| –Rituximab                                     | 33,3% (55)      |
| –Azathioprine                                  | 39,4% (65)      |
| –Mycophenolate mofetil                         | 3,6% (6)        |
| –Without treatment                             | 20% (33)        |
| –Others  | 3,6% (6)        |
| – Tocilizumab                                  | 2               |
| – Eculizumab                                   | 1               |
| – Plasma exchange                              | 1               |
| – Meprednisone                                 | 1               |
| – Methotrexate 7,5 mg/week                     | 1               |

\*Mean (IIQ)

## Results

| Treatment           | Relapses | Person-year | Density incidence | IC95%       |
|---------------------|----------|-------------|-------------------|-------------|
| <b>Global</b>       | 23       | 716,74      | 0,032             | 0,021-0,048 |
| <b>Rituximab</b>    | 7        | 136         | 0,051             | 0,024-0,1   |
| <b>Azathioprine</b> | 9        | 287         | 0,031             | 0,016-0,06  |

*There were no relapses in the group of MMF during this period of time.*

**Incidence of relapses in NMOSD patients under immunosuppressive therapies in Argentina:  
observational study from RelevareEM**



## Conclusions

This study showed a low incidence of relapses in NMOSD patients under IST during this analyzed period. Further studies will help expand our initial findings, hopefully leading to improve treatment options for NMOSD patients.

Email: [veronica.tkachuk@gmail.com](mailto:veronica.tkachuk@gmail.com)