

# HIGH RISK OF PNEUMONIA IN MS PATIENTS TREATED WITH ANTICD20 MABS: DATA FROM A REAL-WORLD COHORT AND CORRELATION WITH LYMPHOCYTE SUBPOPULATIONS AND IMMUNOGLOBULIN LEVELS



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## INTRODUCTION

Pneumonia has been rarely reported as an adverse event in the phase III clinical trials of ocrelizumab (OPERA study) and ofatumumab (ASCLEPIOS study). However, in our experience in a real-world setting, the **frequency of pneumonia in MS patients treated with ocrelizumab/ofatumumab appears to be higher**. In this study, we calculated the frequency of pneumonia in a cohort of MS patients treated with antiCD20 mAbs ocrelizumab, ofatumumab and rituximab; moreover we assessed the risk factors for pneumonia in this population.

## AIMS

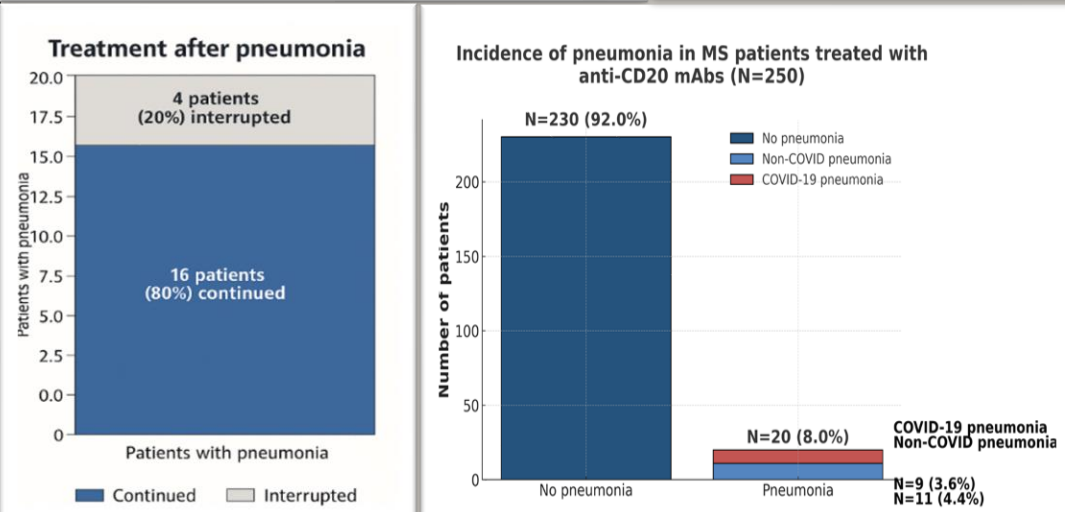
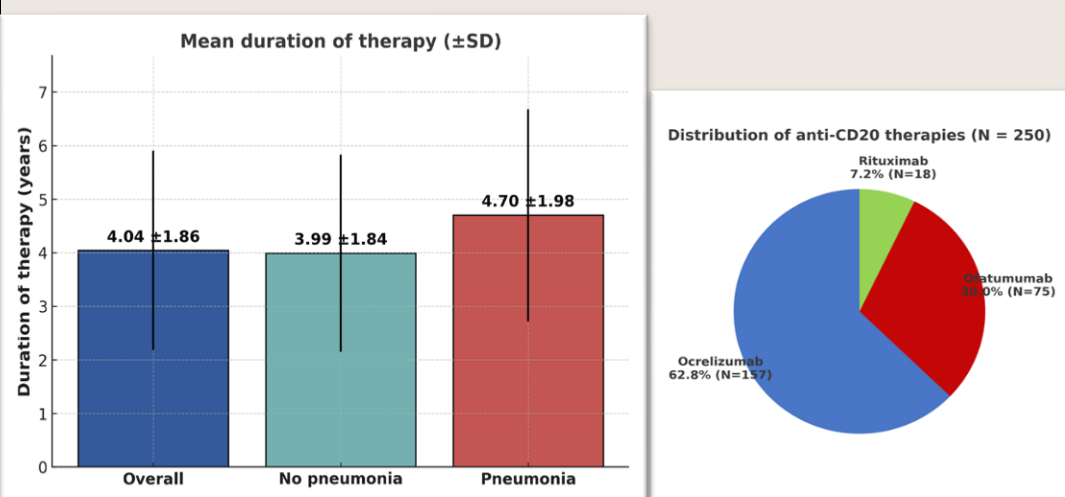
In this study, we calculated the frequency of pneumonia in a cohort of MS patients treated with ocrelizumab or ofatumumab, and we assessed the risk factors for pneumonia in this population.

## METHODS

The study included all MS patients in our center treated with anti CD20 mAbs and in which lymphocyte subpopulations and immunoglobulin (IgG, IgA, IgM) levels (tested every 6 months) were available. All pneumonia events in the last 2 years were recorded.

Category	Variables included
Demographics	Age, Sex
Disease characteristics	EDSS, Duration of treatment
Lifestyle factors	Smoking status
Comorbidities	Cardiovascular comorbidities, Diabetes, Overweight
Immunological markers	CD4+, CD8+, CD19+ lymphocyte counts, Immunoglobulin levels
Dependent variable (outcome)	Pneumonia (Yes / No)

Table 1: Independent variables in logistic regression model

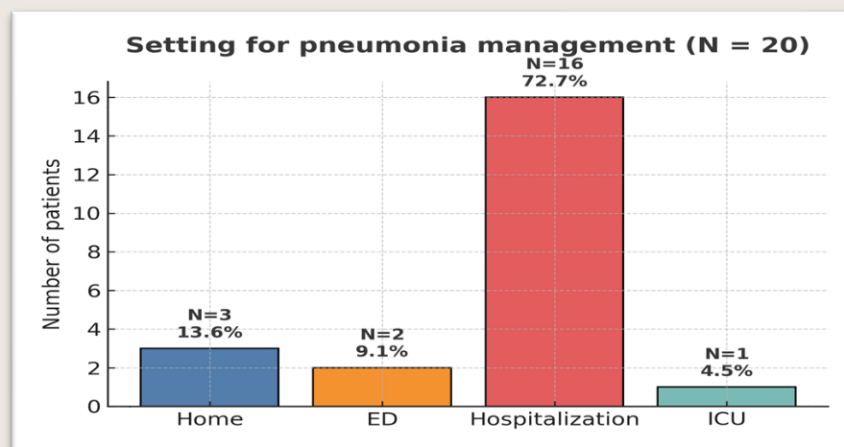


## RESULTS

Over the course of **2 years, 20 pneumonia events in a cohort of 250 patients were observed** (9 SarsCov2-positive, 11 SarsCov2-negative).

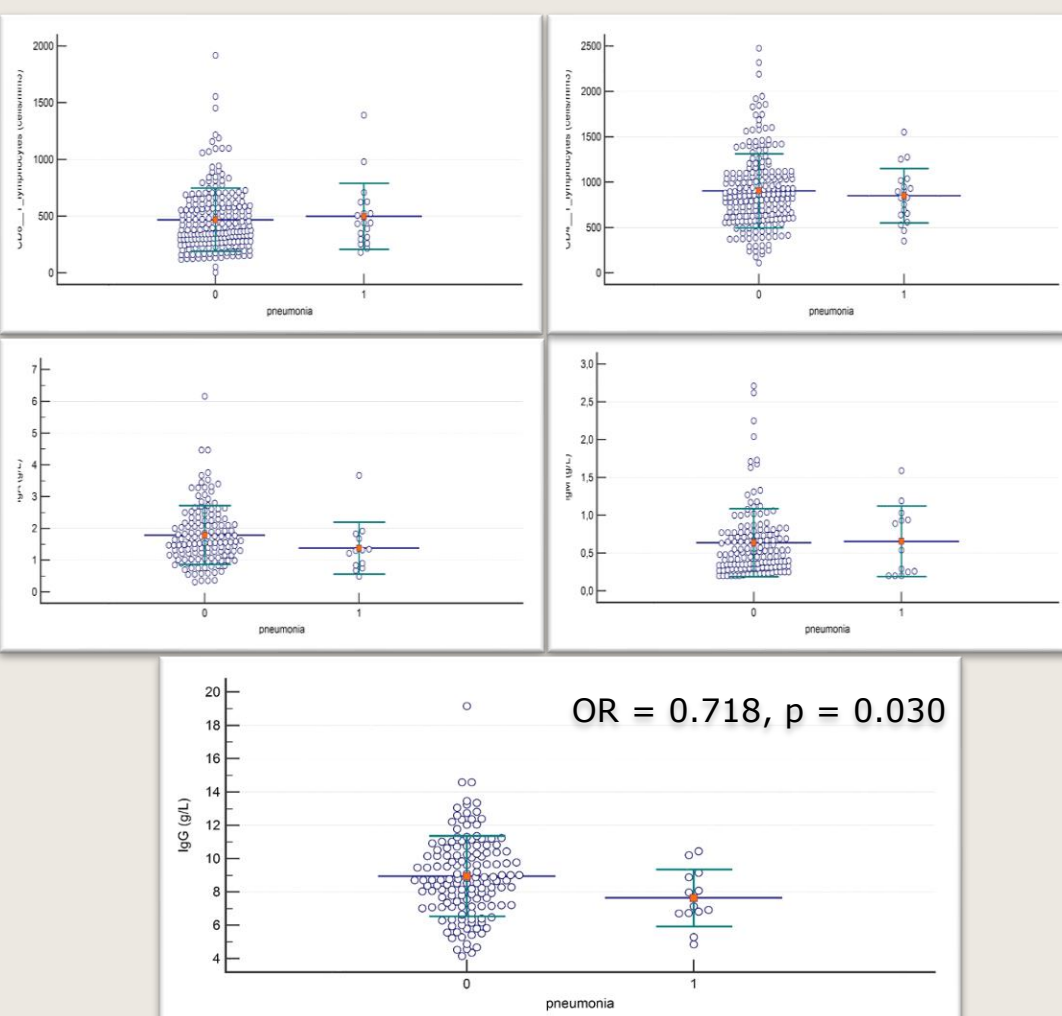
Variable	Value
Total number of patients	250
Mean age (years) ± SD	41.6 ± 11.4
Median EDSS (range)	4.0 (0 - 7.5)
Sex (F/M)	156 / 94
Treatment-naïve patients	50/250 (20%)
Smoking status	137 (54.8%) never, 59 (23.6%) ex, 52 (20.8%) current
Vascular comorbidities	54 (21.6%)
Diabetes comorbidities	8 (3.2%)
Obesity comorbidities	22 (8.8%)
COPD comorbidities	8 (3.2%)

Table 2: Population characteristics (N = 250)



## CONCLUSION

We observed a relatively high frequency of pneumonia (**20/250 over 2 years**) in a real-world cohort of MS patients treated with anti CD20 mAbs, higher than the frequency reported in phase III trials (1/894 in OPERA and 3/946 in ASCLEPIOS). **Immunoglobulin G levels were the only predictive variable for the risk of pneumonia in this real-world cohort.**



## DISCLOSURE

ML Vassallo, A Rolando, P Garelli, C Bosa, S Marasciulo, V Gallina: nothing to disclose. P Cavalla and M Vercellino received honoraria as speaker or travel grants to attend national and international conferences or consultation for advisory boards from Alexion, Almirall, Biogen, BMS, Merck-Serono, Roche, Novartis, Sanofi Genzyme, Janssen, Sandoz; P Cavalla is the principal investigator in clinical trials for Roche, Sanofi-Genzyme, Novartis and Merck Serono.

## REFERENCES

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