

EFFECTIVENESS AND SAFETY OF COVID-19 VACCINATION IN PATIENTS WITH IMMUNE-MEDIATED DISEASES ON BIOLOGICAL THERAPY

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BACKGROUND AND IMPORTANCE

The effectiveness and safety of COVID-19 vaccines has been demonstrated in the pivotal trials that have led to their approval. However, there is no specific information available regarding COVID-19 vaccination in patients with immune-mediated diseases (IMD).

AIM AND OBJECTIVES

Evaluate the effectiveness and safety of COVID-19 vaccines in patients with IMD who are being treated with biological drugs (BD).

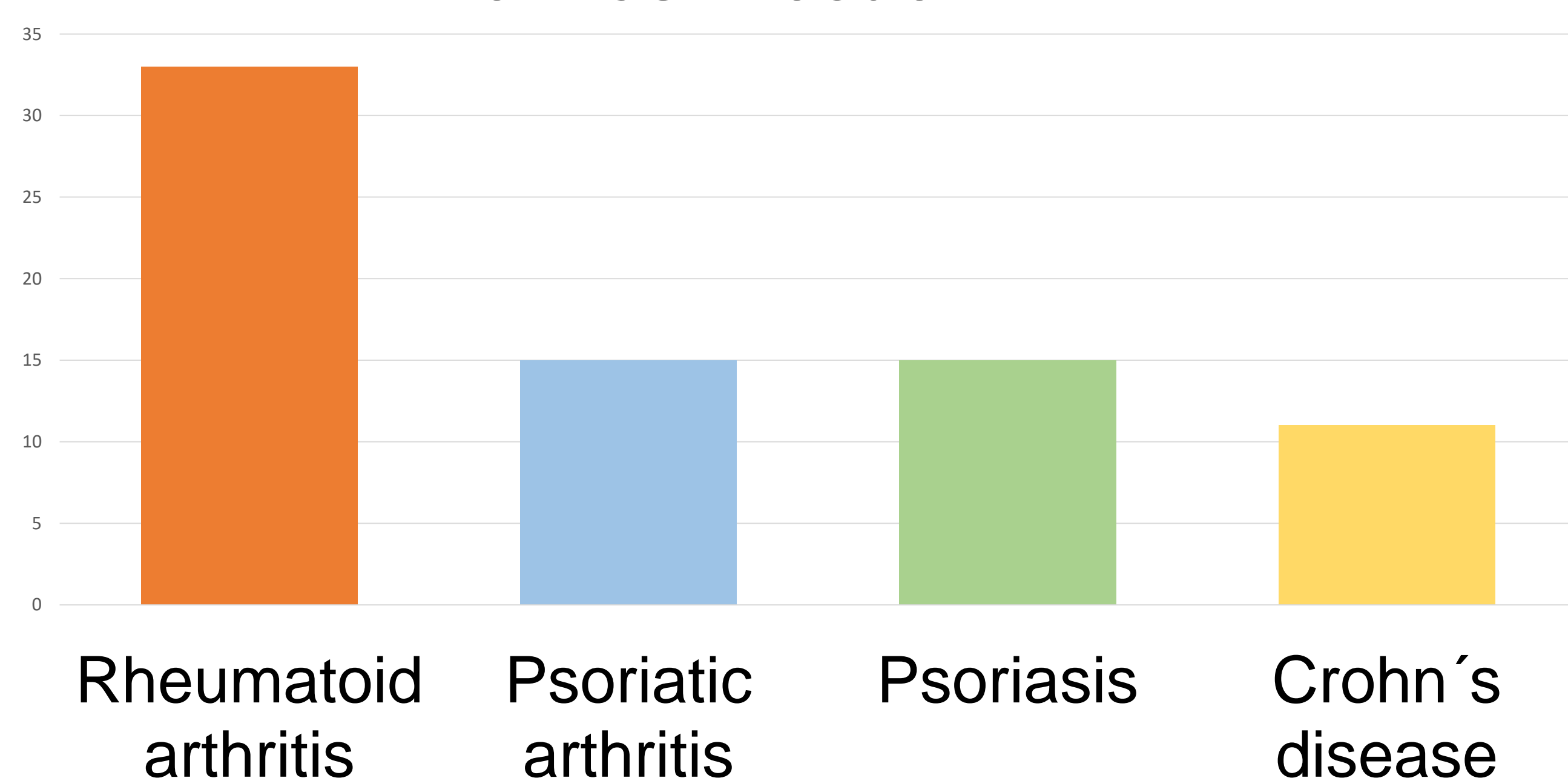
MATERIALS AND METHODS:

- Prospective descriptive observational study of patients with IMD treated with BD.
- Assessing effectiveness: number of patients who became infected with SARS-CoV-2 after vaccination and whether the infection was asymptomatic, with mild symptoms or required hospital admission.
- Assessing safety: standardised interview of adverse reactions observed in the first seven days after COVID-19 vaccination
- Approved by the Ethics Committee of Research with Medicines under code: 2021/435.

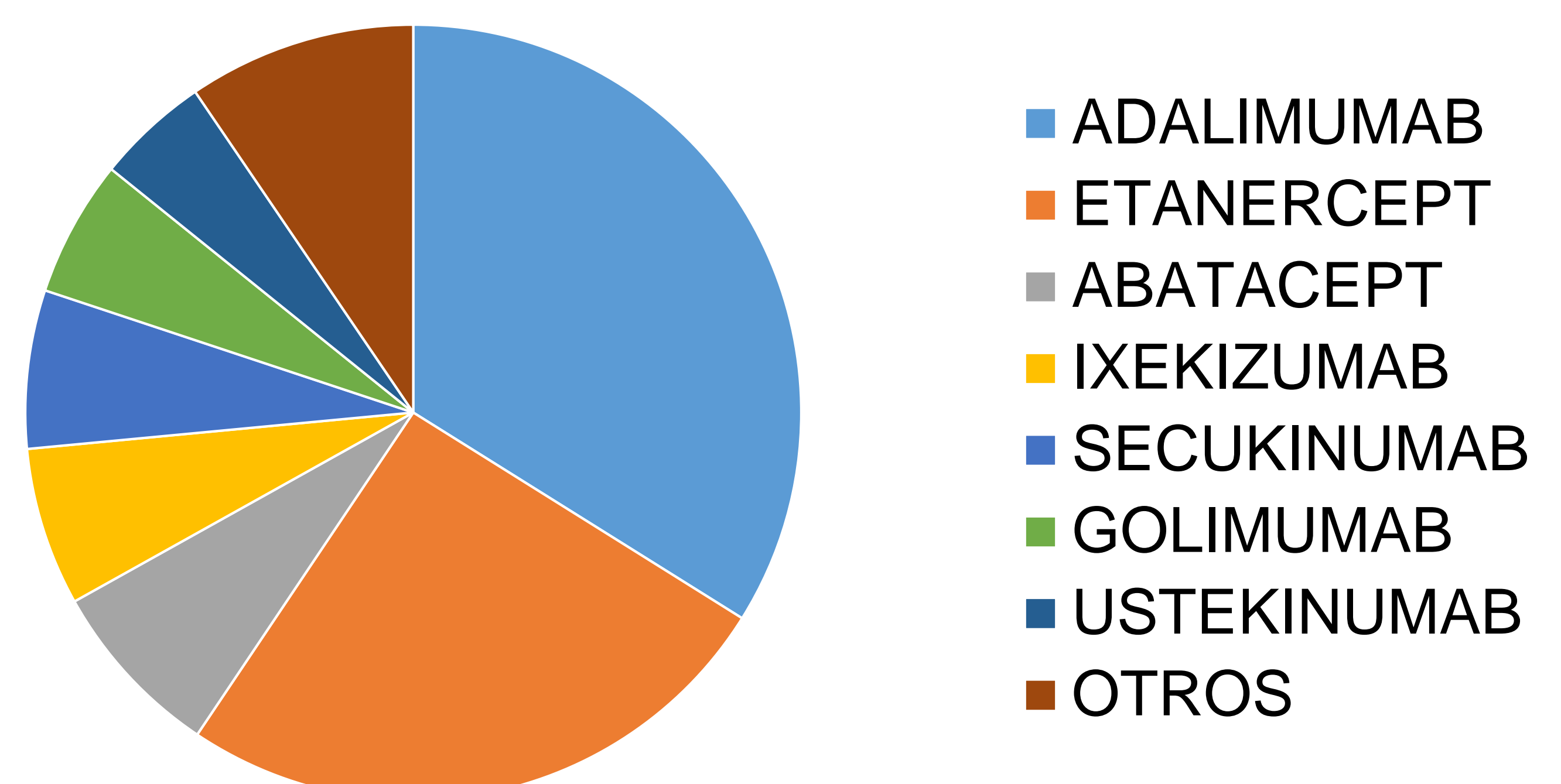
RESULTS:

106 patients (52.8% female) were included, with a median age of 53 years(21-76)

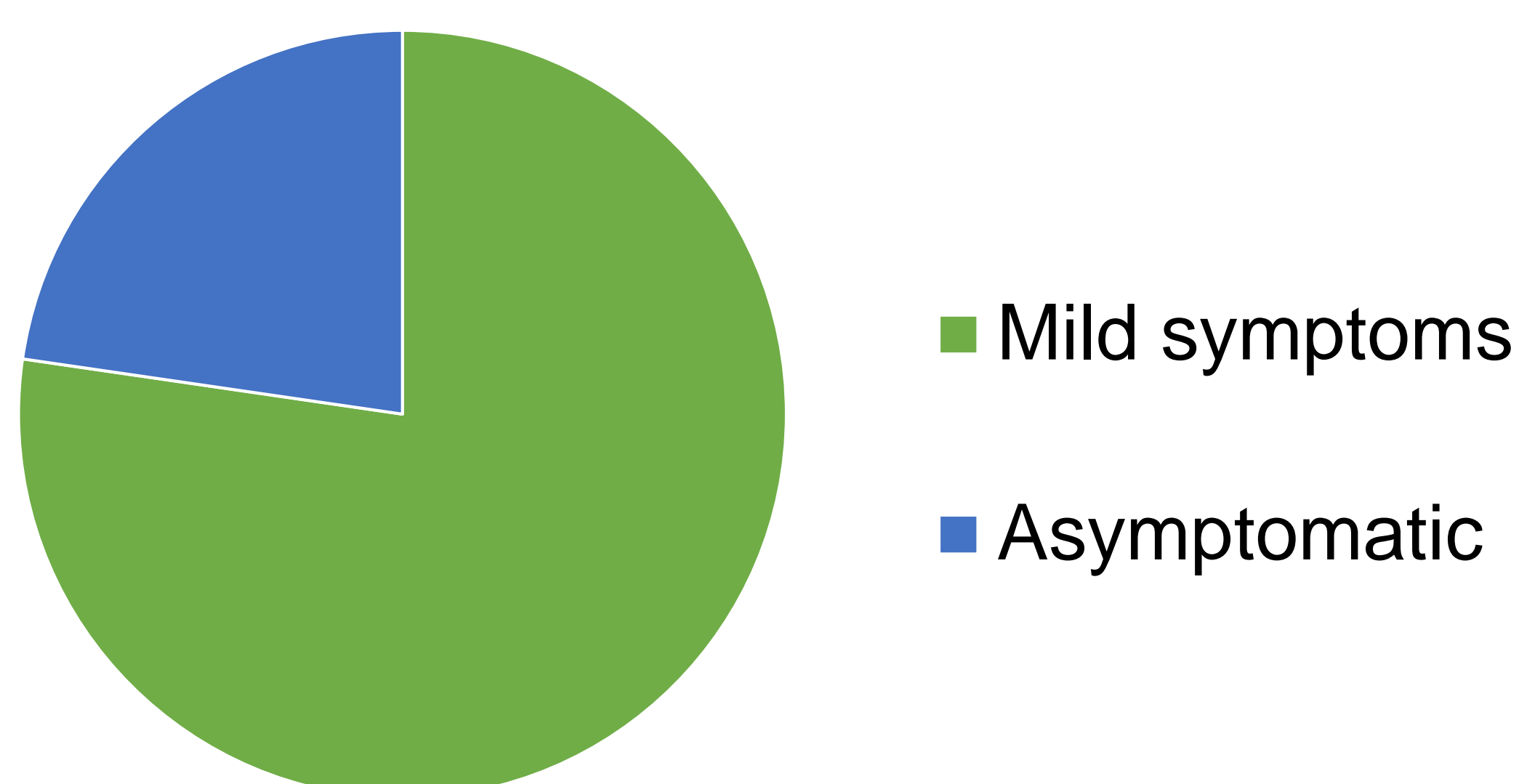
The most frequent IMD:



The most used BD



Twenty-two patients(20.75%) were infected after receiving doses of COVID-19 vaccines: 2 after the first dose, 6 after the second dose and 14 after the third dose. No patient required hospital admission.



The most common adverse reactions:

Pain at the injection site (79,2%)	Arthralgia (25,5%)
Fatigue (48%)	Fever (21,7%)
Malaise (42,4%)	Pruritus (11,3%)
Myalgia (35,8%)	Nausea/vomiting (9,4%)
Headache (33%)	Lymphadenopathy (9,4%)

CONCLUSION AND RELEVANCE

- 79.25% of the patients studied were not infected with SARS-CoV-2 after vaccination.
- Most of the infected patients had mild symptoms and none of them required hospital admission.
- Adverse reactions were similar to those described in the general population, the most frequent being pain at the injection site, fatigue and malaise.
- COVID-19 vaccines were effective and safe in patients with IMD treated with BD included in the study.