

## Safety of a mRNA COVID-19 Vaccine in Patients with Indolent Systemic Mastocytosis

### Segurança de uma Vacina COVID-19 mRNA em Doentes com Mastocitose Sistémica Indolente

**Keywords:** COVID-19/immunology; COVID-19 Vaccines; Mastocytosis; Systemic/immunology; RNA, Messenger

**Palavras-chave:** COVID-19/imunologia; Mastocitose Sistémica/imunologia; RNA Mensageiro; Vacinas contra a COVID-19

Mastocytosis is an abnormal clonal mast cell hyperplasia that can involve many organs. Symptoms, when present, can range from flushing to anaphylaxis (as high as 49% in some cohorts) and the most common triggers include venom stings, drugs and food.<sup>1</sup> The report of allergic reactions with coronavirus disease 2019 (COVID-19) vaccines has led to growing concern about their safety, especially in high-risk populations, such as patients with systemic mastocytosis.<sup>2,3</sup> Until now, data concerning the tolerance of COVID-19 vaccination in patients with mastocytosis remains limited.<sup>3-5</sup>

We conducted a retrospective descriptive analysis of patients with indolent systemic mastocytosis referred to our Allergy and Clinical Immunology Department, between June 2021 and February 2022, for COVID-19 vaccination. Patients were divided into two groups according to their risk of allergic reaction: low/moderate-risk (no history of severe allergic reaction, with or without a history of allergic disease) and high-risk (history of any severe allergic reaction). All patients were premedicated with 60 mg of oral prednisolone 24 hours and one hour prior to inoculation, and with an oral antihistamine one hour before vaccine administration. Low/moderate-risk patients were monitored for 30 minutes after vaccine inoculation. A peripheral venous access was placed in high-risk patients, who remained under medical surveillance for 60 minutes.

A total of 45 patients were included in the analysis (Table 1): 64.4% were female, with a mean age of 48.8 years (range: 22 - 85).

Since this was a retrospective observational analysis of clinical records in which patients were not identified, no application was made to the ethics committee. Informed consent was waived since no experimental study was carried

out, and we used a prophylaxis protocol similar to others instituted for other high-risk situations, in which patients are not expected to sign informed consent to take prophylaxis.

The median tryptase level was 15.6 ng/mL (range: 4.3 - 185 ng/mL); 11 (24.4%) were in the high-risk group (eight with history of anaphylaxis to hymenoptera venom and three with prior drug anaphylaxis). Low/moderate-risk and high-risk groups had similar median levels of serum tryptase (15.5 vs 16.6 ng/mL,  $p = 0.932$ ). All patients received the BNT162b2 mRNA COVID-19 vaccine and a total of 118 doses were administered (24.6% in the high-risk group). No adverse events, including allergic reactions, after vaccine inoculation were recorded during the surveillance period.

Our data showed that with pre-medication, patients with indolent systemic mastocytosis can be safely vaccinated against COVID-19, even when there is an increased risk of allergic reactions (24.4% of our patients). This is consistent with other series reported in the literature.<sup>3-5</sup> In our population, there were no reactions to the vaccine for a follow-up period of 30 - 60 minutes, which is different from other series but might be explained by the use of high-dose prednisone.<sup>3,5</sup> The limitations of our study include its retrospective nature and small sample size, as well as the fact that there was only one type of vaccine included.

#### AWARDS AND PREVIOUS PRESENTATIONS

This study was presented as a poster at the EAACI Hybrid Congress 2022, from July 1<sup>st</sup> - 3<sup>rd</sup> of July, Prague, Czech Republic.

#### AUTHOR CONTRIBUTIONS

All authors contributed equally to this manuscript.

#### PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

#### DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

Table 1 – Patient characteristics

	Patient characteristics	
	Low/moderate-risk group	High-risk group
Number of patients, n (%)	34 (75.6%)	11 (24.4%) -8 hymenoptera venom anaphylaxis -3 drug anaphylaxis
Female patients, n (%)	22 (64.7%)	7 (63.6%)
Age, mean years	47	54.5
Serum tryptase, mean, ng/mL	15.5	16.6
Doses of BNT162b2 mRNA COVID-19 vaccine, n (%)	89 (75.4%)	29 (24.6%)
Adverse reactions	0	0

**COMPETING INTERESTS**

The authors have declared that no competing interests exist.

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