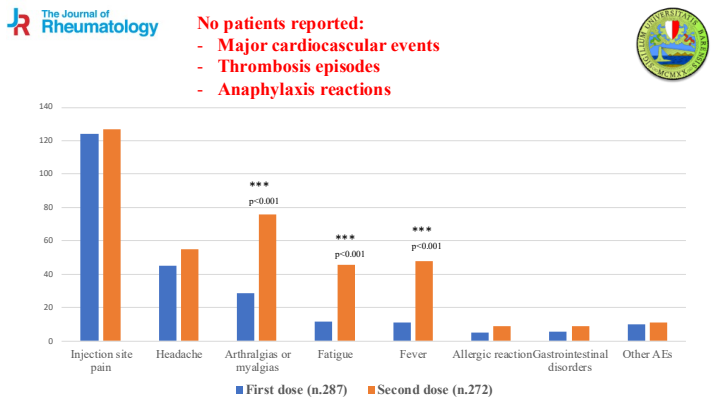
could contact our centre by phone or email, and patients reporting a worsening of the disease were promptly seen in the outpatient clinic of our department. Moreover, all patients were evaluated during a routine follow-up visit after the second vaccine dose.

**Slide 3:** 287 patients filled in the survey after the first vaccine dose, and 272 completed the second one, as 15 patients who had previously taken the SARS-CoV-2 infection received a single vaccine dose. The figure shows the side effects and adverse events recorded during follow-up. The main side effect recorded was pain at injection, both after the first and second dose. In our cohort, a condition of flu-like syndrome was significantly increased after the second vaccination dose. In fact, after the second dose of vaccine, a higher percentage of patients reported arthralgias, worsening of fatigue, and appearance of fever. No major AEs, such as major cardiovascular events, thrombosis, or anaphylaxis reactions were observed. All side effects were self-limiting, and no patients needed hospitalization.




**Slide 4:** As shown in the table, excluding injection site pain, multiple regression analysis showed that female gender, a high/moderate disease activity according to PhGA at baseline, and advanced age were statistically significant predictors for the appearance of side effects.

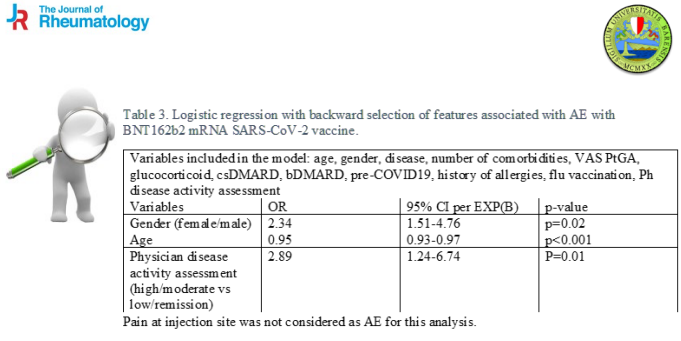


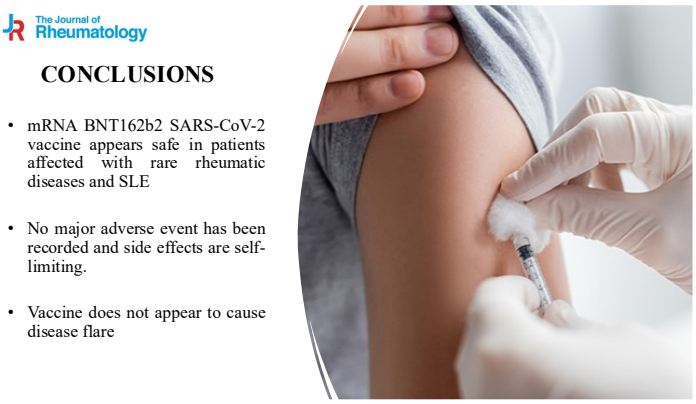

Table 3. Logistic regression with backward selection of features associated with AE with BNT162b2 mRNA SARS-CoV-2 vaccine.

| Variables included in the model: age, gender, disease, number of comorbidities, VAS PtGA, glucocorticoid, csDMARD, bDMARD, pre-COVID19, history of allergies, flu vaccination, Ph disease activity assessment | | | |
|---|---|---|---|
| Variables | OR | 95% CI per EXP(B) | p-value |
| Gender (female/male) | 2.34 | 1.51-4.76 | p=0.02 |
| Age | 0.95 | 0.93-0.97 | p<0.001 |
| Physician disease activity assessment (high/moderate vs low/remission) | 2.89 | 1.24-6.74 | P=0.01 |

Pain at injection site was not considered as AE for this analysis.

**Slide 4:** No differences in VAS-PGA of disease activity during the vaccination period was observed. While the SLEDAI in SLE patients, the BDCAF in behcet patients and the CPK levels and MMT-8 score in inflammatory myopathies remained stable in our cohort. No disease flare was observed at follow-up visit.


**Slide 5:** In view of our results, this study supports the use of BNT162b2 mRNA SARS-CoV-2 vaccine in patients with rare rheumatic diseases, in whom we highlighted a low probability of serious adverse reactions and disease relapse.




**Slide 6:** Thank you for your time and attention.

Finally, I would like to thank all the medical doctors, resident, medical students and nurses who have participated and continue to participate in the vaccination campaign and made possible to record the data shown in this work