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1 Higher risk of short term COVID-19 vaccine adverse events in myositis patients with
2 autoimmune comorbidities: results from the COVAD study

3

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381 **Disclaimer:** Part of the results from the ongoing COVAD Study were published as conference
382 proceedings of the American College of Rheumatology (ACR) Convergence 2021.

383 **Data Availability Statement:** The datasets generated and/or analysed during the current study are
384 not publicly available but are available from the corresponding author upon reasonable request.

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386 **Key message:** Inflammatory myopathies with comorbid autoimmune disease are associated with
387 increased frequency of AEs following COVID-19 vaccination

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397 **Higher Risk of Short Term COVID-19 Vaccine Adverse Events in Myositis Patients with**
398 **Autoimmune Comorbidities: Results from the COVAD study**

399

400 **Abstract**

401 **Background:** Patients with idiopathic inflammatory myopathies (IIMs) often have multiple
402 autoimmune comorbidities (IIM-AIDs) with a potentially increased risk of COVID-19 vaccine-related
403 adverse events (AEs). The COVID-19 Vaccination in Autoimmune Diseases (COVAD) study aimed to
404 assess 7-day post COVID-19 vaccination-related AEs in IIM-AIDs compared with IIMs and healthy
405 controls (HCs).

406 **Methods:** The COVAD survey, a global patient self-reported e-survey was circulated by the COVAD
407 Study Group (152 collaborators, 106 countries) from March 2021 to February 2022. 7-day COVID-19
408 vaccine AEs were compared among patients with IIM-AID, IIM alone, and HCs in multivariable analysis
409 with baseline adjustment.

410 **Results:** 6099 participants (22.7% IIMs, 77.2% HCs, 66.3% women) were included. 41.0% had IIM-AIDs,
411 59.0% with IIMs alone, and rest HCs. People with IIMs were older [median age 54 (45-66) IIM-AIDs, 64
412 (50-73) IIMs, 34 (26-47) HCs years].

413 IIM-AID patients reported higher overall AEs (OR 1.50 [1.10-2.10]), minor AEs (OR 1.50 [1.10-2.10]),
414 major AEs (OR 3.00 [1.50-5.80]), and higher body ache, nausea, headache, and fatigue (OR 1.30-2.30)
415 compared to IIM alone. After adjusting for the number of AIDs, major AEs equalized, but overall and
416 minor AEs, including fatigue, remained higher in IIM-AIDs. Among patients with active IIMs, those with
417 additional AIDs were more vulnerable for major and minor AEs. Dermatomyositis patients with AIDs
418 were at a higher risk of major AEs than DM alone (OR 4.3 [1.5-12.0])

419 **Conclusion:** COVID-19 vaccination is safe in patients with IIMs without concomitant AIDs. However,
420 autoimmune multimorbidity conferred higher risk of short-term vaccine AEs particularly in patients
421 with active IIMs

422 **Letter to Editor**

423 Dear Sir,

424 Vaccination against coronavirus disease 2 (COVID-19) is known to reduce adverse infection
425 outcomes in the general population. However, most COVID-19 vaccination studies have excluded
426 immunosuppressed individuals and those with systemic autoimmune diseases (SAIDs), including
427 idiopathic inflammatory myopathies (IIMs), leading to a lack of safety data for this patient group.
428 Studies of self-reported adverse events (AEs) following vaccination against COVID-19 have yielded
429 conflicting results, with either higher or comparable adverse events in IIMs versus healthy controls
430 (HCs) [1, 2]. This could potentially be explained by the effect of coexistent comorbidities on AEs in
431 these patients, especially comorbid autoimmune conditions, an area that remains under-studied.

432 The COVID-19 Vaccination in Autoimmune Diseases (COVAD) study is an ongoing international
433 collaborative study involving 106 countries and 152 investigators [3, 4]. It captures data including
434 vaccination uptake, AEs, COVID infection and comorbidities in people with SAIDs, by means of an
435 online survey [5, 6]. We previously reported a modest increase in the incidence of severe adverse
436 events 7-day post-vaccination in 1227 patients with IIMs compared to 5033 HCs, as well as other SAIDs
437 [2]. Notably, adverse events were higher in the dermatomyositis (DM) group and active disease [2].
438 The COVAD study is currently in its second phase which captures data on the long-term efficacy of
439 vaccines, vaccine-induced disease flares, de novo emergence of autoimmune diseases, effects of
440 booster vaccine doses, and specific risks of antenatal vaccination [7].

441 Patients with IIM often have multiple comorbidities, and the effects and burden of these
442 comorbidities on patient-reported outcomes are seldom accounted for. We hypothesized that
443 harboring multiple autoimmune comorbidities may influence post-vaccination AEs and outcomes.
444 Therefore, we explored the influence of autoimmune multimorbidity (i.e. defined as 1 or more
445 coexistent autoimmune diseases in patients with IIMs) on their self-reported AEs, and the effect of
446 adjustment for these factors in the IIM-SAID group with IIMs alone and HCs.

447 We previously published the COVAD study protocol and details of the global electronic survey
448 with accompanying methods [3]. The e-survey collected respondent demographics, SAID details,
449 COVID-19 vaccination details, and 7-day vaccine AEs. We compared COVID-19 vaccination-related AE
450 in patients with IIMs with other SAIDs (Table 1) in patients with IIMs only and HCs. We performed
451 multivariable regression analysis with adjustment for age, sex, ethnicity, vaccine type and
452 immunosuppressants received, by number of AID comorbidities, and stratified by country of residence
453 (Baseline Logistic Regression, BLR). We further performed propensity score matching between
454 patients with IIMs with SAIDs and HCs with a tolerance of 0.1. We compared vaccine-related AEs
455 among patients with IIMs with different numbers of SAID comorbidities using the chi-square test, with
456 Bonferroni corrected p values as statistically significant. Statistical analyses were performed using
457 SPSS version 26.

458 A total of 6099 participants were included, comprising 573 people with IIMs and other SAIDs,
459 814 with IIMs without other SAIDs, and 4712 HC (Supplementary Table S1). Individuals with IIMs were
460 older than those with HCs (mean age in individual with IIMs and other SAIDs, 54 years; in individuals
461 with IIMs alone, 64 years; HCs, 34 years). The majority of the participants were women (66.3%). The
462 most commonly administered vaccine across all participants was Pfizer-BioNTech (BNT162b2) (37.5%),
463 followed by Oxford/AstraZeneca (ChAdOx1 nCoV-19) (11.1%) and Moderna (mRNA-1273) (8.5%).

464 Notably, individuals with IIMs with autoimmune multimorbidity (at least one other SAIDs)
465 were more likely to experience any AEs following COVID-19 vaccination than those with IIMs alone

466 (OR 1.50 [1.10-2.10], p=0.003 (Table 1). After adjusting for the number of SAIDs, an increased risk
467 remained for injection site pain (OR 1.40 [1.01-2.00], p=0.044), body ache (OR 1.50 [1.02-2.00],
468 p=0.037), headache (OR 1.7 [1.20-2.40], p=0.004), and nausea and vomiting (OR 2.20 [1.20-4.00],
469 p=0.012). Fortunately, there was no increase in the risk of major AEs in the autoimmune
470 multimorbidity IIM group.

471 When compared to healthy controls in the multivariable analysis, patients with IIMs and other
472 SAIDs were significantly more likely to experience headache (OR 1.20 [1.01-1.60], p=0.035), nausea
473 and vomiting (OR 1.40 [1.01-2.00], p=0.045), fatigue (OR 1.30 [1.03-1.60], p=0.023), and overall, any
474 major AEs (OR 2.00 [1.20-3.30], p 0.005) (Supplementary Table S2). Conversely, when compared with
475 HCs, patients with IIMs alone were less likely to experience any AEs overall (OR 0.70 [0.56-0.87],
476 p=0.002), suggesting that the AEs were largely limited to the autoimmune multimorbidity group
477 (Supplementary Table S3). When considering patients with inclusion-body myositis or active IIMs with
478 SAIDs, compared to those without SAIDs, patients with multimorbidity were more likely to experience
479 any AEs (minor and major) following vaccination (p<0.05).

480 It is noteworthy that increasing numbers of coexisting SAIDs in people with IIMs were
481 associated with an overall increased likelihood of any minor or major AEs especially: myalgia, nausea
482 and vomiting, hypertension, and dizziness (all p<0.003) (Supplementary Table S4).

483 This pattern was also seen in specific subgroups of IIM, particularly we noted patients with
484 Dermatomyositis (DM) and other co-existent SAIDs at a higher risk of major AEs [OR 3.1 (1.3-7.6),
485 p=0.006] compared to those with DM alone (Supplementary Table S5)

486 Thus, to conclude, patients with IIMs and coexisting SAIDs experience more frequent AEs
487 following vaccination against COVID-19 compared to those with IIMs alone and HCs. Our study adds
488 to the growing body of evidence on the safety of COVID-19 vaccination in people with SAIDs,
489 specifically contributing more granular detail on patients with IIMs including the vulnerable and
490 relatively understudied proportion of these patients with autoimmune multimorbidity, compared to
491 other global studies on COVID-19 vaccination related adverse events [1].

492 Fortunately, the associated risks are minor and the frequency of major AEs is not significant
493 in the majority of cases. People with a greater number of SAIDs in addition to IIMs are more likely to
494 experience certain AEs and have an overall increased risk of AEs. It is important to ascertain the long-
495 term outcomes after vaccination in this group [8].

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