Breakthrough COVID-19 Vaccine Injury Study Links mRNA Vaccines to Triggering Autoimmune Diseases

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Physician-investigators at King Fahad University Hospital in Khobar, Eastern Province Saudi Arabia recently conducted a study, the largest of its kind, linking rare COVID-19 vaccine-related injuries and incidence of new onset of autoimmune disease, including systemic lupus erythematosus (SLE). The study team tapped into sources including the hospital's electronic medical record finding 31 patients with new onset post COVID-19 vaccine autoimmune diseases and a severe exacerbation of an existing disease including patients with connective tissue disorders, vasculitis, as well as neurologic diseases. With results uploaded to Dovepress, the study team led by internal medicine physician-scientist Reem Alsulaiman found out of the 31 cases involving immune-mediated disease, 18 females (58%) and 13 males (42%) with only 4 of the total patients (13%) showing evidence of an autoimmune condition prior to the COVID-19 jab. The average time between vaccination and new-onset disease symptoms equaled 7 days. The breakdown of cases included: 7 patients (22.5%) had new-onset vasculitis, 2

cases had IgA vasculitis, and 5 cases had ANCA vasculitis. Another 6 of the patients presented neurological diseases (19.3%), 4 cases (12.9%) presented new-onset systemic lupus erythematosus (SLE), 3 cases (9.6%) presented with new-onset inflammatory arthritis, and one had Sjogren's syndrome (3.2%). The study authors find multiple reported cases linking COVID-19 vaccination (mRNA and adenovirus vector vaccines) with the development of new onset autoimmune disease from reactive arthritis and autoimmune hepatitis to systemic lupus erythematosus (SLE), vasculitis, immune thrombotic thrombocytopenia, transverse myelitis, and multiple sclerosis.

This is an important study, given these Saudi investigators produced what they believe may be the largest cohort of patients reported in the literature (and a first for this part of the world). What follows is a *TrialSite* breakdown of the results. *TrialSite* emphasizes the study results here need peer review and ensuing publication in a reputable scientific medical journal. The current results should not be cited as medical evidence.

First and foremost, is there literature investigating the relationship between vaccines and autoimmune reactions?

Yes.

What's a common hypothesis for the association?

Molecular mimicry, and as the Saudi authors posit, this represents the same mechanism associated with the virus

triggering an autoimmune process which may contribute to the COVID-19 vaccine injury in rare cases.

So, is the development of COVID-19 vaccine-induced autoimmune disease possibly associated with cross-cell reactivity as a consequence from a lack of tolerogenic effect?

Yes. The authors from King Fahad University Hospital in Khobar point out that "clonal expansion of T cells and B cells upon exposure to the antigen is the key for immune tolerance." But they emphasize that both genetic and environmental factors can "affect the immune tolerance as well."

They ponder whether some of the observations in the present case series subjects/patients involving autoimmune disease could be comparable to the mechanism associated with other autoimmune diseases such as rheumatoid arthritis and systemic lupus erythematosus (SLE) develop.

Is the Pfizer-BioNTech mRNA vaccine (BNT162b2) associated with a case of vaccine-induced SLE?

Yes. In the study *Raviv et* al., the doctors report on a case involving a male patient with no underlying medical condition who presents SLE just two days after receiving BNT162b2—his skin rash and arthralgia improved with hydroxychloroquine and topical treatment. See the link. Another case reported by *Nune et al.* found that a young Caucasian male investigated for fever, arthralgia, and lymphadenopathy which developed 2 weeks after getting

the Pfizer-BioNTech SARS-CoV-2 vaccine was found to have SLE. See the link.

What did the Saudi study find in regard to SLE and the vaccines?

The study team reports on 4 cases (12.9%) who developed SLE—only one case had a previous history of autoimmune disease (immune thrombocytopenic purpura).

Moreover, the Saudi team writes:

"Other reports indicated that SLE can be exacerbated by SARS CoV vaccines. The largest study of mRNA vaccines and whether they exacerbate or cause new onset of inflammatory disorders included 27 patients from different centers in 3 countries. Of those, 2 were known to have underlying SLE who had exacerbation after receiving the mRNA SARS CoV vaccine." See the link.

Is there any way to predict the exacerbation and organs impacted?

No. See link.

Are these cases suggesting COVID-19 vaccines may trigger for Immunoglobulin A Nephropathy (IgAN)?

Yes. See Nakatani et al. for the first case of IgAN in a 47-year-old male with a background of hypertension and hyperuricemia who developed skin lesions in the lower extremity after receiving the first dose COVID-19 vaccine and his symptoms were exacerbated 15 days after the

second dose.

In another case, a 94-year-old male presented IgAN 10 days after the second jab of the COVID-19 vaccine. Additionally, the Saudi team reports additional cases of new onset IgA vasculitis less kidney involvement post administration of not only BNT162b2 (Pfizer-BioNTech), but also mRNA1273 (Moderna) and the AstraZeneca-Oxford vaccines.

In the present study the authors report:

"…We reported 2 cases of new onset IgA vasculitis in the form of nephritis and IgA nephropathy. One of these 2 cases needed dialysis. Several reports described reactivation of IgAN 24 hours after COVID-19 vaccination."

What about neurological diseases associated with the COVID-19 vaccines?

Yes. In the present Saudi study, the investigators report 6 neurological diseases (19.3%), ranging from peripheral neuropathy to more severe conditions such as central demyelination, encephalitis, myasthenia gravis, meningeal headache, and Guillain-Barre syndrome.

The Saudi team breakdown several other findings at the source uploaded at *Dovepress*.

What research is needed moving forward?

Reem Alsulaiman and colleagues point out that investigations into COVID-19 have included deep molecular characterization techniques yet "no studies have been conducted on vaccine related autoimmune response." In order to develop an efficient COVID-19 vaccination approach with a low risk of side effects, the new clinical studies should focus on understanding the impact of BNT162b2 immunization on groups of various autoimmune problem patients.

Concluding Thoughts

Health authorities have been leery to acknowledge COVID-19 vaccination injuries likely due to fear of contributing to vaccine hesitancy. Yet these injuries exist, as this critically important Saudi-led study and thousands of other case series chronicles. *TrialSite* has published hundreds of articles covering some of these scenarios.

Opportunities to study these injuries exist. While the National Institutes of Health and the Food and Drug Administration earlier in the pandemic engaged with a small sample of COVID-19 vaccine injured, they ceased all communications with this cohort.

TrialSite has partnered with React19, the largest COVID-19 vaccine injury advocacy to provide support for this vulnerable group. The group is currently developing an electronic referral exchange and registry which can be used for the exact types of studies *Alsulaiman et al.* suggest.

About King Fahd University Hospital

Based in the Eastern Province, King Fahd Hospital of the University (KFHU) in Khobar is affiliated with Imam Abdulrahman Bin Faisal University which was previously part of King Faisal University. Founded in 1981, under the 'Five Hospitals Project', the hospital serves as a training center for students during clinical years. With a 440-bed capacity the hospital provides three primary services including 1) Curative services 2) Teaching services, and 3) Research,

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Other authors are listed at the source.

Call to Action: Follow the link to review the full study report.

References

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