JSES International 8 (2024) 237-238

Contents lists available at ScienceDirect

JSES International

journal homepage: www.jsesinternational.org

Authors' response—how are vaccines related to frozen shoulder development?

The authors thank Birsel et al for raising the appropriate questions regarding the results of our study titled "Frozen Shoulder After COVID-19 Vaccination."¹⁰ We are thankful that we have been given the opportunity to clear some of the fundamental doubts that may exist in the minds of many orthopedic surgeons. Notably, the senior author had earlier published another viewpoint article that delved into the doubt plaguing the physician's mind on the occurrence of frozen shoulder after COVID-19 vaccination.⁹ Therefore, we will take this opportunity to clarify these doubts sequentially.

First, can we determine if the vaccine directly causes the presumed frozen shoulder problem?

At this time, I do not think it is possible to determine that a vaccine can directly cause the frozen shoulder problem. As the authors rightfully point out, the bursa can be injured and inflamed due to the vaccine needle.⁸ However, an inflammation of the bursa leads to subacromial and subdeltoid bursitis. Subacromial-subdeltoid bursitis after COVID-19 vaccination and their rapid improvement have been noted in ours⁸ and several other publications.^{3,6} On the other hand, frozen shoulder is an inflammation and fibrosis of the shoulder joint capsule. However, the vaccine needle reaching and injuring the capsule at the typical vaccination site (lateral and a few finger breadths below the acromion) is extremely unlikely. It may, thus, be presumed that the vaccine causing the frozen shoulder directly is extremely unlikely.

Should it be labeled primary or secondary if it is presumed frozen shoulder?

If it is frozen shoulder, then labeling it as a secondary frozen shoulder is unlikely because Itoi et al's cited paper on the ISAKOS (International Society of Arthroscopy, Knee Surgery, and Orthpaedic Sports Medicine) consensus on frozen shoulder also says that stiffness should be labeled as secondary when there is a "known" secondary cause.⁷ Vaccine-related frozen shoulder has only been published in two small series and some case reports in the entire medical literature.^{2,5,10} There is no definitive evidence or pathogenesis explanation of how a vaccine can directly cause frozen shoulder. Thus, it is not a "known cause" and cannot be a direct

DOIs of original article: https://doi.org/10.1016/j.jseint.2023.06.026, https://doi.org/10.1016/j.jseint.2022.02.013.

causative agent for frozen shoulder. Hence, I think it cannot be labeled secondary. Now, can it be labeled primary? The ISAKOS consensus paper defined the primary frozen shoulder as a stiff shoulder of idiopathic origin with predisposing factors such as cardiac diseases, pulmonary diseases, and even certain medicines such as protease inhibitors prescribed for HIV.⁷ It is unclear how vaccines have caused frozen shoulder or led to its development. Hence at this time, the vaccines may be best understood as associated with frozen shoulder development, and therefore, frozen shoulder may be labeled as primary.

Is this frozen shoulder?

We commend the authors for questioning whether these patients had true frozen shoulder diagnoses. Painful stiffness may be confused with a frozen shoulder, but painful stiffness resolves in a few weeks or months, as reported in a recent study.⁵ However, we followed up with all our patients for more than a year. This follow-up study is still under review; hence, we cannot state the results in detail, but it suffices to say that most patients took a year or more than a year to recover, as is typically seen in frozen shoulder. None of the patients recovered in the first few months; hence, we cannot label them as having painful stiffness.

Regarding the comment that there was no explosive increase in the number of frozen shoulders due to vaccination

An explosive increase in the number of frozen shoulder due to vaccination is not expected because, as we stated already, it is a rare diagnosis with an ill-understood etiopathogenesis mechanism. However, the senior author $(D.S.)^8$ is one of the very few surgeons in the country who has an exclusive practice of shoulder orthopedics, and because the country has seen one of the biggest vaccination drive in a short duration, the author has been able to report on the short series of cases. It is possible that other physicians may have seen this problem, but due to the lack of awareness, adequate attention and follow-up may not have been done.⁹

Demyttenaere et al reported on the increased incidence of frozen shoulder from March 2020 to January 2021, the period preceding our study period.⁴ However, applying their findings to our study will be an unjustified extrapolation without any direct relation because Demyttenaere et al accepted that the increased incidence of frozen shoulders during the said period of COVID lockdowns could have been due to various reasons, such as mismanaged diabetes due to difficult medical care, a lower incidence of other sports injuries because of stay-at-home regulations, reduced





Institutional review board approval was not required for this response letter.

https://doi.org/10.1016/j.jseint.2023.08.009

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total number of appointments available during the period, or temporary closure of public health services.⁴

Finally, we should accept that frozen shoulder is still poorly understood.¹ The natural history and etiopathogenesis of idiopathic frozen shoulder have not been sufficiently elucidated.¹ Its three-phase clinical cycle is still hypothetical¹¹; hence, whatever we know today could be proven wrong tomorrow.

Disclaimers:

Funding: There was no funding for the study or the response letter. Conflicts of interest: The author, his immediate family, and any research foundation with which he is affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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