



BioNTech/Pfizer-Vaccine, Statin Therapy and Self Limiting Rhabdomyolysis

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Introduction

In mid July 2021 an 80-year-old woman received her second COVID-19 immunization with the BioNTech/Pfizer-vaccine (Comirnaty®). After 24 h she developed severe myalgia in her thighs (8/10 NRS) followed by a progressive muscle weakness. Ten days later, she presented herself to our emergency room with a proximal tetraparesis without sensory deficits. She had no fever and reported no relevant trauma or toxic exposures. She complained of general malaise and had painful thigh and deltoid muscles on palpation. She was neither able to walk nor to rise out of bed without assistance but could lift her head and showed symmetrical abdominal contractions and no scapula alata. Handgrip, speech, swallowing and ocular motor functions remained intact throughout. Her lab results revealed elevated serum Creatine Kinase (CK) (9.603 U/L, ref. <195 U/L) and myoglobin (11.162 µg/L, ref. 25 µg/L to 58 µg/L) levels while TSH, fT4 and CRP were unremarkable. She had no hyperkalemia (4.0 mmol/L) taking hydrochlorothiazide (25 mg) on a regular basis. To avoid further muscle damage we halted her long running statin therapy (80 mg simvastatin) and ensured adequate volume substitution. She developed no signs of acute kidney injury. Within the next seven days her deficits and lab results progressively improved and finally returned to normal (Figure 1). We discharged her seven days later after making a full recovery apart from minor residual muscle pain. In a follow-up over the telephone four weeks later, she indicated no lasting symptoms or deficits.

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Received Date: 30 Mar 2022

Accepted Date: 14 Apr 2022

Published Date: 03 May 2022

Citation:

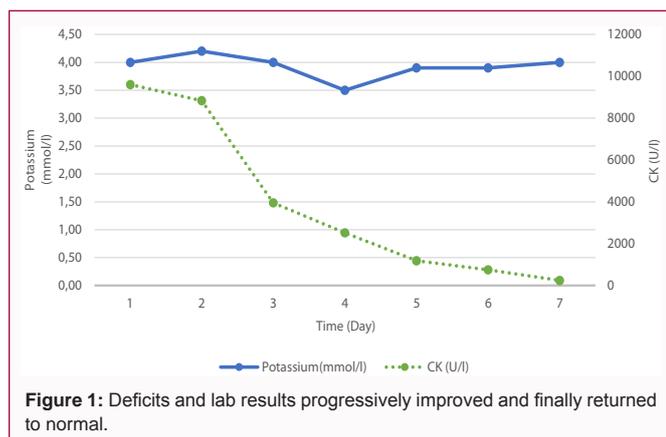
Hacker J, Vazifeh M, Schoser B, Hansen HC. BioNTech/Pfizer -Vaccine, Statin Therapy and Self Limiting Rhabdomyolysis. *Ann Clin Case Rep.* 2022; 7: 2178.

ISSN: 2474-1655

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Rhabdomyolysis is a clinical syndrome resulting from large scale necrosis of skeletal muscle cells. Among the most common causes are trauma, drugs (e.g. statins), seizures and infections. The classic constellation of symptoms consists of myalgia, weakness and darkening of urine. The necrosis of striated cells leads to the release of especially myoglobin and potassium. The former can lead to a temporary drop-in kidney function and even acute kidney injury; the latter can cause severe arrhythmias and even cardiac arrest. Regular controls of electrolytes and kidney function are therefore required. It is widely agreed upon that Creatine Kinase (CK) is the most pertinent parameter for monitoring, indicating muscle necrosis and also correlating with the degree of muscle damage. In clinical practice, one generally assumes rhabdomyolysis if the CK is repeatedly elevated by at least 5-times the normal value. Treatment consists of aggressive fluid resuscitation to ensure adequate urine output and if necessary dialysis. Some patients also benefit from urine alkalization. In general rhabdomyolysis has a favorable prognosis, especially when treatment starts early and aggressively.

Our patient developed severe rhabdomyolysis within 24 h after her BioNTech/Pfizer-vaccination. So far only two other cases of a BioNTech/Pfizer-vaccine associated rhabdomyolysis have been reported [1,2]. According to the German vaccination regimen at that time, our patient had been immunized with the AstraZeneca-vaccine five weeks earlier without any problems and this-like in the aforementioned case report-was the first exposure to the BioNTech/Pfizer-vaccine, which suggests a possible link to this particular compound. Although we did not exclude myositis as a differential diagnosis through a muscle biopsy, the negative serum-antibody levels and the benign clinical course argue against this differential diagnosis. Blaming the rhabdomyolysis solely on the use of statins seems questionable as our patient had been using them in the same dose for years. Nonetheless the statins could be a contributing factor. Interestingly there are reports of influenza-vaccine associated rhabdomyolysis in which the authors suggest that the use of statins with the vaccine as the trigger caused the pathology [3-5]. None of the other as yet published case reports of COVID-19-vaccine associated rhabdomyolysis reported any statin use [1,2,5-7] making this the first promulgated case of its kind. However when consulting the "Vaccine Adverse Event Reporting



System” (VAERS) (<https://wonder.cdc.gov/vaers.html>; last accessed on August 30th, 2021) one finds multiple cases of COVID-19-vaccine associated rhabdomyolysis with concomitant statin-use further bolstering the aforementioned hypothesis of a vaccine triggered rhabdomyolysis in patients ingesting statins. One possible caveat is that we cannot entirely exclude hypokalemia as a possible cause or contributing factor. Our patient regularly took hydrochlorothiazide (25 mg), which can decrease potassium levels. Fittingly-despite rhabdomyolysis, which routinely causes an increase in serum potassium - she had low-normal potassium levels upon admission.

Although we cannot irrefutably prove that the vaccination was the singular cause for the observed rhabdomyolysis, the temporal

correlation and the absence of other relevant causes are nonetheless suggestive. Thus, it might be advisable to closely follow-up on patients taking statins after they have been vaccinated against SARS-CoV-2.

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