# Acquired Thrombotic Thrombocytopenic Purpura following inactivated COVID 19 vaccines: Two case-reports and a short literature review

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**Abstract**

The Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak from December 2019 causing millions of deaths all over the world and the lack of specific treatment for severe forms of coronavirus disease 2019 (COVID-19) has led to vaccines development in record time with emergency use authorization in several countries increasing the risk of vaccine safety issues. Recently, several cases of Thrombotic Thrombocytopenic Purpura (TTP) have been reported following COVID-19 vaccination. TTP represents a life-threatening consumptive coagulopathy requiring urgent diagnosis and prompt treatment. It is a rare disease characterized by thrombocytopenia, microangiopathic hemolytic anemia and ischemic end-organ lesions. It can be either congenital or acquired. Various events such viral infections, medication, pregnancy, malignancies, and vaccinations may cause TTP. Clinicians should consider this diagnosis when evaluating thrombocytopenia in the post-vaccine period. Here, we report two cases of acquired TTP following Sinopharm COVID-19 vaccine (BBIBP-CorV) and Sinovac COVID-19 vaccine (CoronaVac). Diagnosis was based on clinical presentation and confirmed with severe reduction in the activity of von Willebrand factor-cleaving protease ADAMTS-13 and the presence of inhibitory autoantibodies. The two patients were successfully treated with corticosteroids, plasma exchange therapy and rituximab in the acute phase. In the literature, the reported cases of TTP induced by COVID-19 vaccination occurred after Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based COVID-19 Vaccines. To the best of our knowledge, this is the first report of acquired TTP after inactivated virus COVID-19 vaccines. A short literature review regarding acquired TTP patients following COVID-19 vaccines is also included.

## Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel virus first detected in Wuhan in December 2019. Few months later, the World Health Organization (WHO) declared a worldwide pandemic. This virus may cause severe viral pneumonia with acute respiratory distress syndrome causing millions of deaths.[1,2] Currently, there is no effective treatment for coronavirus disease 2019 (COVID-19).[3] However, several vaccines have been developed worldwide to reduce COVID-19 mortality and morbidity.[4] Those vaccines have obtained emergency use approval by the WHO in several countries increasing the risk of vaccine safety issues and some adverse events have been reported.[5–7] Most frequent were injection site reactions or systemic effects (eg, fatigue, headache, body pain, fever), with rare serious adverse events (eg, anaphylaxis, Guillain-Barré, thrombosis with thrombocytopenia Syndrome).[8–10] Several cases of Thrombotic Thrombocytopenic Purpura (TTP) induced by COVID-19 vaccination have been reported in the literature.[11–14] TTP is a rare hematologic disorder classically characterized by the pentad of fever, hemolytic anemia, thrombocytopenia, renal failure, and neurologic dysfunction. However, most patients do not have the entire pentad.[15] This disease is caused by a severe decrease in the activity of the von Willebrand factor-cleaving protease ADAMTS-13

which can be either congenital or acquired due to anti-ADAMTS-13 autoantibodies.[11] Various events may initiate the production of those antibodies such viral infections, medication, pregnancy, malignancies and occasionally vaccinations.[16] Here, we report two cases of acquired TTP after two inactivated COVID-19 vaccines: BBIBP-CorV vaccine known as the Sinopharm COVID-19 vaccine and CoronaVac known as the Sinovac vaccine. To the best of our knowledge, the present cases are the first reported cases of acquired TTP after inactivated virus COVID-19 vaccines.

**Case presentations**

The Ethics Committee of Farhat Hached hospital approved the publication of the two-cases retrospectively obtained and anonymized data.

**Case 1**

A 38-year-old Tunisian woman with no medical history presenting with dizziness and ecchymosis in her upper limbs was referred to the hematology department. The patient reported that she had received a first dose of an inactivated virus COVID-19 vaccine Sinopharm (BBIBP-CorV) twenty days before symptom onset. Laboratory findings revealed hemoglobin 6 g/dl, platelet count $6\times10^9$/L, lactate dehydrogenase (LDH) 1074 UI/L, haptoglobin 0.54 g/l, creatinine 66 µmol/L, urea 20.7 mg/dl, total bilirubin 3.75 mg/dl and indirect bilirubin 2.88 mg/dl. Peripheral blood smear showed schistocytes (1 to 2%). During her hospital stay, the patient presented left hemi-body heaviness and dysarthria. A brain MRI revealed an ischemic stroke in the territory of the infero-posterior cerebellar artery. A curative anticoagulation was started. A few hours after ICU admission, the patient presented a sudden generalized tonico-clonic seizure with status epilepticus requiring her intubation. Glycemia and electrolytes were within the normal ranges. The patient was promptly given clonazepam and intravenous sodium valproate. Analgo-sedation was prolonged with remifentanyl and midazolam to achieve a Richmond Agitation Sedation Scale (RASS)[17] at -5 to control the status epilepticus and obtain patient-ventilator synchronization. The presence of thrombocytopenia, hemolytic anemia and neurologic symptoms were indicative of a presumptive diagnosis of TTP. The PLASMIC score, used to identify patients with ADAMTS-13 deficiency in suspected TTP patients, was at 6 (range, 0-7) indicating a high risk of severe ADAMTS-13 deficiency ¡10%. The patient was promptly treated by methylprednisolone 1000 mg daily for three consecutive days, then 1 mg/kg/day in combination with daily plasma exchange therapy (PEX).

Infectious screening tests (e.g., Human immunodeficiency virus (HIV), hepatitis, SARS-CoV-2, Epstein-Barr Virus, and Cytomegalovirus) were negative. Autoimmunity investigations revealed severe ADAMTS-13 deficiency (6%) with positive anti ADAMTS-13 autoantibodies more than 15 U/ml (normal<12 U/ml) confirming the diagnosis of an acquired TTP.

The patient remained seizure free and was extubated on day 5 of ICU stay. She had a fully recovery after a 17-day course of glucocorticoids, 12 sessions of PEX and Rituximab. Laboratory parameters improvement trends (platelet and hemoglobin level) are displayed in **figure 1** . The patient was discharged with hemoglobin at 10 g/dl and platelet count at 370 $\times10^9$/L with a follow up at the hematology department. Prednisone was tapered off over 5 weeks. The patient made a complete recovery and is currently living a normal life. The latest ADAMTS-13 activity at the 6-month follow up visit showed 94%.

**Case 2**

A previously healthy 30-year-old male presented to the emergency department with headache, fever, dysarthria and right hemiparesis. He had received a second dose of an inactivated COVID-19 vaccine CoronaVac one month prior to consultation. Laboratory findings showed hemoglobin 7.2 g/dL, platelet count, $9\times10^9$/L, LDH 1268 UI/L, D-dimer 1890µg/L, haptoglobin 0.26 g/L and creatinine 105 µmol/L. Peripheral blood smear showed schistocytes (2%). PLASMIC score was at 5 (range, 0-7). A presumptive diagnosis of TTP was made. The patient was admitted to the ICU. On the initial examination, the patient had a fluctuating consciousness, dysarthria and right hemiparesis without any petechiae or purpura. The brain CT scan revealed no abnormalities. No triggering factors such as viral infections or medication, alcohol or illicit drugs

use were identified. Infectious screening tests were negative. Investigations revealed severe ADAMTS-13 deficiency (< 0.2 %) with positive anti ADAMTS-13 autoantibodies (12 U/ml). All other autoimmune tests returned negative.

The patient received methylprednisolone 1000 mg daily for three consecutive days followed by prednisone 1 mg/kg/day in combination with daily PEX. Weekly infusion of Rituximab for 4 weeks was started two weeks after admission due to issues concerning the patient's health insurance.

The patient had a fully recovery after 31-day course including 26 sessions of PEX (**figure 2** ). The patient was discharged with hemoglobin at 10 g/dl and platelets at 180 $\times 10^9$/L with a follow up at the hematology department. The steroids dose was tapered off over 4 weeks. One month later, the control of activity of ADAMTS-13 was 74%.

**Discussion**

Thrombotic Thrombocytopenic Purpura (TTP) is a rare blood disorder with an incidence of 3 to 10 cases per million adults per year.[16] It was first described by Eli Moschcowitz in 1924.[18,19] The pathogenesis of this disorder includes the formation of small-vessel platelet rich thrombi leading to ischemic end organ injury.[20] The historical pentad (fever, hemolytic anemia, thrombocytopenia, neurological or renal dysfunction) is only seen in < 10% of the patients.[21,22]Microangiopathic hemolytic anemia (reduced Hb and haptoglobin, increased LDH and presence of schistocytes) and thrombocytopenia are sufficient for presumptive diagnosis of TTP. The PLASMIC Score derived by Bendapudi et al [23] stratify patients according to their risk of having severe ADAMTS-13 deficiency. When dichotomized at high (score 6-7) vs low-intermediate risk (score 0-5), the PLASMIC Score predicted severe ADAMTS-13 deficiency with positive predictive value at 72%, negative predictive value at 98%, sensitivity, 90% and specificity, 92%.[24] A severe reduction in the activity of von Willebrand factor (VWF) cleaving metalloprotease (ADAMTS-13) (less than 10%) and the presence of inhibitory antibodies confirm the diagnosis.[20]

TTP can be classified into two types: congenital or acquired (autoimmune TTP). Autoimmune TTP can be triggered by infections, malignancy, pregnancy, medications and vaccines.[11,19] Rarely some vaccines (e.g., Influenza, pneumococcus, rabies and H1N1) have been reported to induce acquired TTP.[11,21,25–27] Vaccines have been hypothesized to activate the immune system leading to autoantibody formation and hence the development of an autoimmune disorders like TTP.[21,28]

Worldwide, in response to the COVID-19 pandemic, several vaccines have been developed using various techniques: messenger RNA (mRNA) (Pfizer-BioNTech [BNT162b2], Moderna and CureVac), human or primate adenovirus vectors (Janssen-Johnson & Johnson [Ad26.COV2-S], Astra-Zeneca [chAdOx1 nCoV-19], Sputnik-V, and CanSino) and an inactivated whole-virus SARS-CoV-2 (Bharat Biotech, Sinopharm and Sinovac)[22]. The emergency use authorization of these vaccines in several countries increased the risk of safety issues.[5,7] In the literature, there have been some reported cases of TTP following Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based Covid-19 Vaccines.[11,29] Indeed, vaccines against viral pathogens have been reported to be associated with onset and/or relapse of TTP.[30] This rare autoimmune disease may occur after the first or the second dose of COVID-19 vaccines typically one to two weeks after vaccination.[13]

For TTP, vaccine-induced immune thrombotic thrombocytopenia (VITT) is a differential diagnosis. VITT is another adverse event that has been recently reported after COVID-19 vaccination. It is a novel clinical syndrome demonstrating striking similarities to TTP. VITT is diagnosed clinically by the presence of mild to severe thrombocytopenia, documented evidence or suspicion of thrombosis and positive antibodies against platelet factor 4 (PF4).[31,32] In the present two cases, severely reduced ADAMTS-13 activity and the presence of schistocytes or microangiopathic hemolytic anemia on the blood smear supports the diagnosis of TTP. Temporal association and absence of other triggering factors for secondary TTP led to the diagnosis that this disorder was induced by COVID-19 vaccination. The two cases were recorded within a two-year-long COVID-19 pandemic including just one year of active vaccination in Tunisia in which more than five hundred COVID-19 patients were admitted to a 12-bed medical ICU along with another 600 non-COVID-19 patients in the same two-year period. This highlights the scarcity of such complication in our hospital.

On April 5, 2022, a personal literature review based on a 2020–2022 PubMed search [key items: "Thrombotic thrombocytopenic purpura" AND "COVID-19 vaccines" AND "case report"] found 19 papers including 32 cases published in English language. Among these studies, TTP was reported as an adverse event of respectively Pfizer-BioNTech (n=24), Moderna (n=3), Astra-Zeneca (n=4) and Janssen-Johnson & Johnson (n=1) (**Table 1** ; Results of the 32 Cases, Published During the 2020–2022 Period, Including Thrombotic thrombocytopenic purpura following COVID-19 Vaccination).[11–14,20–22,26–30,33–39]

To our knowledge, this is the first report of acquired TTP after inactivated virus COVID-19 vaccines. In the current cases, TTP occurred after 20 days after first dose of Sinopharm and 30 days after second dose of CoronaVac.

A careful clinical surveillance must be done in the post-vaccine period. Clinicians should consider the possibility of TTP when evaluating thrombocytopenia following vaccination. Without prompt initiation of adequate treatment, TTP is a life-threatening thrombotic microangiopathy. It is a medical emergency requiring rapid diagnosis and treatment usually in intensive care units. According to the International Society of Thrombosis and Haemostasis, PEX represents the cornerstone of TTP treatment with strong recommendation for adding corticosteroids.[28,40]Rituximab (a monoclonal anti-CD20 antibody) and Caplacizumab (an anti-VWF antibody fragment) can improve TTP outcomes and decrease the duration of PEX. Caplacizumab is not yet available worldwide and it has a significant cost.[41]

## Conclusion

This report highlights potential safety issues that can be encountered after COVID-19 vaccination. The benefits of vaccination in fighting the ongoing pandemic outweigh the risk of side effects. Additional surveillance is required in the post vaccine period to detect adverse events in a timely fashion. TTP is a very rare life-threatening complication of COVID-19 vaccination. It is a medical emergency that is almost always fatal if adequate treatment is not initiated early. Further research should be conducted to correctly identify the mechanism linking thrombotic microangiopathic disorders with COVID-19 vaccines.

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