Ischemic Stroke and Vaccine-Induced Immune Thrombotic Thrombocytopenia following COVID-19 Vaccine: A Case Report with Systematic Review of the Literature

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Keywords
Stroke · Vaccine-induced immune thrombotic thrombocytopenia · COVID-19 vaccine · Large vessel occlusion · Thrombotic thrombocytopenia

Abstract
Introduction: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a prothrombotic syndrome observed after adenoviral vector-based vaccines for severe acute respiratory syndrome coronavirus 2. It is characterized by thrombocytopenia, systemic activation of coagulation, extensive venous thrombosis, and anti-platelet factor 4 antibodies. Arterial thrombosis is less common and mainly affects the aorta, peripheral arteries, heart, and brain. Several cases of ischemic stroke have been reported in VITT, often associated with large vessel occlusion (LVO). Here, we describe a case of ischemic stroke with LVO after Ad26.COV2.S vaccine, then we systematically reviewed the published cases of ischemic stroke and VITT following COVID-19 vaccination. Methods: We describe a 58-year-old woman who developed a thrombotic thrombocytopenia syndrome with extensive splanchnic vein thrombosis and ischemic stroke due to right middle cerebral artery (MCA) occlusion, 13 days after receiving Ad26.COV2.S vaccination. Then, we performed a systematic review of the literature until December 3, 2021 using PubMed and EMBASE databases. The following keywords were used: (“COVID-19 vaccine”) AND (“stroke”), (“COVID-19 vaccine”) AND (“thrombotic thrombocytopenia”). We have selected all cases of ischemic stroke in VITT. Results: Our study included 24 patients. The majority of the patients were females (79.2%) and younger than 60 years of age (median age 45.5 years). Almost all patients (96%) received the first dose of an adenoviral vector-based vaccine. Ischemic stroke was the presenting symptom in 18 patients (75%). Splanchnic venous thrombosis was found in 10 patients, and cerebral venous thrombosis in 5 patients (21%). Most patients (87.5%) had an anterior circulation stroke, mainly involving MCA. Seventeen patients (71%) had an intracranial LVO. We found a high prevalence of large intraluminal thrombi (7 patients) and free-floating thrombus (3 patients) in extracranial vessels, such as the carotid artery, in the absence of underlying atherosclerotic disease. Acute reperfusion therapy was performed in 7 of the 17 patients with LVO (41%). One patient with a normal platelet count underwent intravenous thrombolysis with alteplase, while 6 patients underwent mechanical thrombectomy. A malignant infarct occurred in 9 patients and decompressive hemicraniectomy was performed in 1 patient. Conclusions: VITT after COVID-19 vaccination is a rare but potentially life-threatening complication. Early recognition and prompt treatment are crucial to prevent significant morbidity and mortality.
was performed in 7 patients. Five patients died (21%). **Conclusion:** Our study points out that, in addition to cerebral venous thrombosis, adenoviral vector-based vaccines also appear to have a cerebral arterial thrombotic risk, and clinicians should be aware that ischemic stroke with LVO, although rare, could represent a clinical presentation of VITT.

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**Introduction**

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been associated with an increased risk of arterial and venous thromboembolic complications, probably mediated by an abnormal hypercoagulative and inflammatory state. Several vaccines against SARS-CoV-2 have been developed and administered worldwide within a year of the COVID-19 outbreak. These vaccines are divided into two main categories: the messenger RNA (mRNA) – based vaccines (including BNT162b2 [BioNTech/Pfizer] and mRNA-1273 [Moderna]) and the adenoviral vector – based vaccines (including Ad26.COV2.S [Janssen/Johnson & Johnson] and ChAdOx1 nCoV-19 [AstraZeneca – Oxford]). Since the start of vaccination, a prothrombotic syndrome characterized by severe thrombocytopenia, systemic activation of coagulation, and extensive venous thrombosis has been observed especially after ChAdOx1 nCoV-19 vaccine [1–3] and in a few individuals after the Ad26.COV2.S vaccine [4, 5]. This prothrombotic syndrome is similar to the heparin-induced thrombocytopenia (HIT), with high levels of antibodies to anti-platelet factor 4 (PF4) and has been designated vaccine-induced immune thrombotic thrombocytopenia (VITT) or thrombosis with thrombocytopenia syndrome. Thrombosis occurs at unusual sites including cerebral venous thrombosis (CVT) and splanchnic vein thrombosis (SVT), in addition to deep venous thrombosis (DVT) and pulmonary embolism [6]. Arterial thrombosis appears to be less frequent and mainly affects the aorta, peripheral arteries, heart, and brain. The first cases of ischemic stroke described during VITT were often associated with large vessel occlusions (LVOs) and negative outcomes [7, 8]; since then, several other reports have been published. Here we describe a case of ischemic stroke associated with severe thrombocytopenia and extensive SVT after the Ad26.COV2.S vaccine, and then we performed a systematic review of the literature searching for cases of ischemic stroke and thrombotic thrombocytopenia after COVID-19 vaccination. In this study, we aim to describe the demographic, clinical characteristics, and the outcome of patients with stroke in the context of VITT.

**Case Presentation**

A 58-year-old white Caucasian obese woman, suffering from hypertension, presented to our hospital having been found unconscious and hypotensive at home. She had received the Ad26.COV2.S vaccine 13 days earlier and started complaining of abdominal pain a few days before admission. A thoraco-abdominal computed tomography (CT) scan showed extensive SVT (involving portal, hepatic, splenic, superior and inferior mesenteric veins), DVT (involving left iliac and femoral veins), spleen infarction, and hemopereitoneum. The patient underwent urgent explorative laparotomy with blood drainage and splenectomy. Blood and platelet transfusion and fresh frozen plasma were administered shortly before the emergency surgery. Several hours later, the patient woke up with left hemiparesis, neglect, and right gaze preference. Non-contrast CT and CT angiography (CTA) revealed occlusion of the M1 segment of the right middle cerebral artery (MCA) with extensive ischemic changes and 7 mm of midline shift due to a datable infarct for at least several hours. An urgent decompressive hemi-craniectomy was performed. Blood test revealed severe thrombocytopenia (platelet count 18 × 10^9/L, range 140–440), high D-dimer 35,000 μg/L fibrinogen equivalent units (FEU) (range 0–550) and low fibrinogen; antithrombin activity was normal. Anti-PF4 IgG antibodies enzyme-linked immunosorbent assay (ELISA) and heparin-induced platelet aggregation assay were negative. Coagulation tests (INR, PT, aPTT), anti-phospholipid antibodies, ADAMTS-13, von Willebrand Factor, and blood smear were normal. The SARS-CoV-2 real-time reverse-transcriptase polymerase-chain-reaction test on a nasopharyngeal swab was negative. Considering the clinical scenario, temporal association, thrombosis location and laboratory findings, VITT was suspected. Therefore, intravenous immunoglobulin (1 g/kg/day for 2 days) and high-dose dexamethasone (40 mg for 4 days) were administered and anticoagulation with argatroban was started 2 days after hemicraniectomy. Transthoracic echocardiography and transcranial doppler with bubble test excluded cardiac embolic sources and paradoxical embolization. Then the patient clinically improved, platelet count increased and returned to normal (range 140–440 × 10^9/L). After serial imaging re-evaluations (through cranial CT) of the cerebral ischemic lesion excluding its hemorrhagic transformation, fondaparinux treatment (7.5 mg daily) was initiated and, after imbrication, anticoagulation with warfarin continued (Fig. 1).

**Methods**

**Study Selection Criteria**

A systematic review was performed, applying the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [9] (shown in Fig. 2, PRISMA checklist available as online suppl. material; for all online suppl. material, see www.karger.com/doi/10.1159/000524290). Full-text articles were selected from a comprehensive search of PubMed and EMBASE databases. The following keywords were combined in each database as follows: (“COVID-19 vaccine”) AND (“stroke”), (“COVID-19 vaccine”) AND (“thrombotic thrombocytopenia”). No filters were applied on the publication date of the articles, and all results from each database were included until December 3, 2021. Data from each article were extracted into the Microsoft Excel soft-
ware. We identified 751 studies. After the duplicates were removed, 484 studies were screened. All articles were evaluated through a reading of titles and abstracts. Articles in any other language other than English, reviews, guidelines, paper statements, research studies, or records with nonrelevant topics were excluded. Overall, 155 records were subjected to an accurate reading to assess eligibility. Two researchers (A.C.R. and G.G.) independently searched and identified eligible studies. Controversies were resolved by the senior author (E.C.A.). Articles were included if they met the following inclusion criteria: (I) described patients who had an ischemic stroke after COVID-19 vaccination and a thrombotic blood disorder (II) included at least some information related to clinical features, imaging, and laboratory results. After an accurate revision of full manuscripts, data extraction was performed on 20 articles satisfying the inclusion criteria.

**Statistical Analysis**

Descriptive statistics were calculated for all included patients. Continuous data are presented as means and standard deviations or medians and ranges (as appropriate), categorical data as counts and proportions (as \( n/N \) [%], where \( n \) is the number of patients in which that variable is present and \( N \) the total number of patients for which that particular variable was reported).

**Results**

We identified 20 records describing patients with ischemic stroke and thrombotic blood disorder after COVID-19 vaccination. Two records were excluded because the stroke was due to secondary vaccine-induced immune thrombocytopenia (ITP) and thrombotic thrombocytopenic purpura (TTP), respectively [10, 11]. Eighteen articles (\( n = 23 \) patients) [3, 7, 8, 12–26] were included in our review. Baseline demographics, relevant clinical data, stroke characteristics, and outcome of patients described in these studies, including our case, are shown in Tables 1 and 2. Quantitative synthesis of the data is shown in Tables 3 and 4.

**Demographics**

Among all 24 patients, the median age was 45.5 years (range 21–73) and eighteen patients (75%) were younger than 60 years. Nineteen patients (79.2%) were women.
All patients were healthy or clinically stable at the time of the event. Cardiovascular risk factors were present in 37.5% (hypertension and dyslipidemia in 5 patients, smoking in 2 patients, diabetes in 1 patient, atrial fibrillation in 1 patient, obstructive sleep apnea in 1 patient). Two patients suffered from migraine. Most patients (83.3%) had no known prothrombotic factors. Among the remaining cases two young women were known to take the oral contraceptive pill [20, 26], a 69-year-old man suffered from prostate cancer [15], and a 70-year-old man who had been diagnosed a metastatic pancreatic cancer during hospitalization [25]. Almost all patients had received the first dose of an adenoviral vector-based vaccine (ChAdOx1 nCoV-19 in 20 patients, Ad26.COV.2.S in 3 patients), only one patient had received a m-RNA-based vaccine (mRNA-1273). The first dose was administered from 8 to 21 days before medical admission (median 9.5 days). None of the patients have had recent symptoms of SARS-CoV-2 infection. SARS-CoV-2 real-time reverse-transcriptase polymerase-chain-reaction test on nasopharyngeal swab was negative in all individuals tested (13 patients). None had been exposed to heparin recently.

**Laboratory Results**

The majority of patients (23 out of 24, 95.8%) had platelet count <150 × 10⁹/L (median 40, range 5–152) and 58% had severe thrombocytopenia (<50 × 10⁹/L). D-dimer levels (converted to ng/mL FEU for case comparison) were very high (>4,000 ng/mL FEU; range 1,100–106,200) in 90.9% of available cases (22 patients), in one patient D-dimer was normal. Five patients had low fibrinogen levels (median 2.30 g/L, range 1.5–4.0). Anti-PF4 antibodies (ELISA assay) were present in 22 of the 23 tested patients (92%), in our case negative results were obtained. A platelet functional test was performed in 16 patients; the result was negative in 3 patients (19%), including our case. These patients with negative anti-PF4 or platelet functional assay met all other clinical and laboratory criteria for the diagnosis of VITT [27, 28] and received specific treatment.
| Author                      | Case No. | Patient (sex, yr) | SARS-CoV-2 RT-PCR test | Vaccine                  | Medical history                        | Time from vaccine to admission, days | Platelet count (nadir) Cells x10^9/L | D-dimer (peak), FEU ng/mL | Fibrinogen (nadir), g/L | anti-PF4 (ELISA assay) | Platelet functional assay | Other thromboses diagnosed and/or hemorrhages | Case definition                          |
|-----------------------------|----------|-------------------|------------------------|--------------------------|----------------------------------------|--------------------------------------|---------------------------------------|----------------------------|-------------------------|-------------------------|------------------------------------------|---------------------------------------------|-------------------------------------------|
| Scully et al. [3]           | 1        | F, 39             | Neg                    | ChAdOx1 nCoV-19          | Hypertension, dyslipidemia             | 10                                   | 57                                    | >5,000                      | 4.4                     | Pos                     | ND                        | —                             | Definite VITT                            |
|                             | 2        | M, 21             | Neg                    | ChAdOx1 nCoV-19          | Low                                    | 10                                   | 113                                   | 22,903                      | 1.0                     | Pos                     | ND                        | —                             | Definite VITT                            |
| D’Agostino et al. [12]      | 3        | F, 54             | Neg                    | ChAdOx1 nCoV-19          | Meniere disease                        | 12                                   | Low                                   | High                        | Normal                  | ND                      | ND                        | CVT, PE, PVT, HVT, coronary artery thrombosis, hemoperitoneum, adrenal, and cerebral hemorrhages | Probable VITT                            |
| Blauenfeldt et al. [7]      | 4        | F, 60             | NA                     | ChAdOx1 nCoV-19          | —                                      | 7                                    | 5                                     | 106,200                     | 2.3                     | Pos                     | Pos                      | Adrenal and renal hemorrhages            | Definite VITT                            |
| Al-Mahyani et al. [8]       | 5        | F, 35             | NA                     | ChAdOx1 nCoV-19          | —                                      | 11                                   | 64                                    | 11,220                      | NA                      | Pos                     | ND                        | PVT                          | Definite VITT                            |
|                             | 6        | F, 37             | NA                     | ChAdOx1 nCoV-19          | —                                      | 12                                   | 9                                     | 34,000                      | NA                      | Pos                     | ND                        | Definite VITT                            |
|                             | 7        | F, 43             | NA                     | ChAdOx1 nCoV-19          | —                                      | 21                                   | 48                                    | 24,000                      | NA                      | Pos                     | ND                        | —                             | Definite VITT                            |
| Garnier et al. [13]         | 8        | F, 26             | NA                     | ChAdOx1 nCoV-19          | Low                                    | 8                                    | NA                                    | Low                         | Pos                     | Pos                     | PE, PSM, DVT               | Probable VITT                            |
| Jacob et al. [14]           | 9        | F, 39             | Neg                    | ChAdOx1 nCoV-19          | Migraine                               | 9                                    | <50                                   | >10,000                     | —                       | Pos                     | Neg                       | —                             | Definite VITT                            |
| Bourgoignon et al. [15]     | 10       | M, 69             | NA                     | ChAdOx1 nCoV-19          | Diabetes, hypertension, obstructive sleep apnea, prostate cancer | 12                                   | 29                                   | >20,000                     | 2.0                     | Pos                     | Pos                      | CVT, UVT, PE, DVT, HVT            | Definite VITT                            |
| Walter et al. [16]          | 11       | M, 31             | Neg                    | ChAdOx1 nCoV-19          | Smoking                                | 8                                    | 152                                   | 1,100                       | 2.3                     | Pos                     | Pos                      | —                             | Possible VITT                            |
| Tiede et al. [17]           | 12       | F, 67             | Neg                    | ChAdOx1 nCoV-19          | Hypcholesterolemia                      | 8                                    | 40                                    | >35,200                     | 2.7                     | Pos                     | Pos                      | —                             | Definite VITT                            |
|                             | 13       | F, 61             | Neg                    | ChAdOx1 nCoV-19          | —                                      | 9                                    | 25                                    | >35,200                     | 0.9                     | Pos                     | Pos                      | Popliteal artery thrombosis, upper extremity DVT, UVT | Definite VITT                            |
| De Michele et al. [18]      | 14       | F, 57             | Neg                    | ChAdOx1 nCoV-19          | —                                      | 9                                    | 23                                    | >4,318                      | 3.22                    | Pos                     | Pos                      | PE, PVT, PE, PVT              | Definite VITT                            |
|                             | 15       | F, 55             | Neg                    | ChAdOx1 nCoV-19          | —                                      | 10                                   | 59                                    | 31,646                      | 3.22                    | Pos                     | Pos                      | —                             | Definite VITT                            |
| Patsouqu et al. [19]        | 16       | F, 45             | NA                     | ChAdOx1 nCoV-19          | —                                      | 8                                    | <50                                   | >35,200                     | 3.22                    | Pos                     | Pos                      | DVT, PE, CVT, renal infarct, bilateral adrenal, and venous cerebral hemorrhage | Definite VITT                            |
| Costentin et al. [20]       | 17       | F, 26             | NA                     | ChAdOx1 nCoV-19          | OCT                                    | 7                                    | 17                                    | 0.89                        | Pos                     | ND                      | PE, PVT                   | Probable VITT                            |
| Goereci et al. [21]         | 18       | F, 42             | NA                     | ChAdOx1 nCoV-19          | —                                      | 9                                    | 40                                    | 35,000                      | NA                      | Pos                     | Pos                      | —                             | Definite VITT                            |
| Ceschia et al. [22]         | 19       | F, 73             | NA                     | ChAdOx1 nCoV-19          | Hypercholesterolemia, hypertension     | 20                                   | 32,559                               | 3.99                        | Pos                     | Pos                      | DVT, PE, CVT, renal vein thrombosis, popliteal artery thrombosis | Definite VITT                            |
| Rodriguez-Pardo et al. [23] | 20       | M, 46             | NA                     | Ad26.COV2.S              | Smoking, hypertriglyceridemia          | 125                                  | Normal                                | Normal                      | Pos                     | Neg                      | —                        | Probable VITT                            |
| Kenda et al. [24]           | 21       | F, 51             | Neg                    | ChAdOx1 nCoV-19          | Dyslipidemia                           | 7                                    | 54                                    | 35,783                      | mildly elevated          | Pos                      | Pos                      | —                             | Definite VITT                            |
Table 1 (continued)

| Author                | Case No. | Patient (sex, yr) | SARS-CoV-2 RT-PCR test | Vaccine       | Medical history                                               | Time from vaccine to admission, days | Platelet count (nadir) | Platelet functional assay | D-dimer (peak), FEU ng/mL | Fibrinogen (nadir), g/L | anti-PF4 (ELISA assay) | Other thromboses diagnosed and/or hemorrhages | Case definition   |
|-----------------------|----------|------------------|------------------------|---------------|--------------------------------------------------------------|-------------------------------------|------------------------|----------------------------|--------------------------|------------------------|------------------------|---------------------------------------------------------------------------------|-------------------|
| Su et al. [25]        | 22       | M, 70            | Neg                    | mRNA-1273     | Atrial fibrillation, pancreatic cancer, hypertension, COPD | 7                                   | 17                     | 28,550                    | 0.63                     | Pos                    | Pos                    | –                                                                                  | Definite VITT     |
| Chandimou et al. [26] | 23       | F, 37            | Neg                    | Ad26.COV2.S   | Migraine, OCT                                               | 10                                  | 30                     | 80,000                    | Normal                   | Pos                    | NA                     | Upper extremity and femoral DVT                                                  | Definite VITT     |
| Present case          | 24       | F, 58            | Neg                    | Ad26.COV2.S   | Hypertension, obesity                                       | 13                                  | 18                     | 35,000                    | 1.21                     | Neg                    | Neg                    | PSM, DVT, hemopto-neum, spleen infarction                                       | Probable VITT     |

COPD, chronic obstructive pulmonary disease; CVT, cerebral venous thrombosis; DVT, deep venous thrombosis; FEU, fibrinogen equivalent units; HVT, hepatic vein thrombosis; IJVT, internal jugular vein thrombosis; NA, not available; ND, not done; Neg, negative; OCT, oral contraceptive therapy; PE, pulmonary embolism; Pos, positive, PSM, porto-spleno-mesenteric venous thrombosis; PVT, portal vein thrombosis; Ref, reference range; VITT, vaccine-induced thrombotic thrombocytopenia; RT-PCR, reverse-transcriptase polymerase-chain-reaction.

Table 2. Stroke features and outcome of published reports (including our case)

| Author                      | Case No. | Symptoms on admission | Neurological stroke deficit | Vascular territory | LVO | Extracranial vessel findings | Acute reperfusion therapy | Diagnostic workup | Anticoagulation | Complications | Outcome                           |
|-----------------------------|----------|-----------------------|----------------------------|-------------------|-----|-----------------------------|--------------------------|-------------------|-----------------|----------------|-----------------------------------|
| Scully et al. [3]           | 1        | Stroke                | NA                         | MCA               | NA  | NA                          | NA                       | NA                | NA              | NA              | Alive                             |
|                            | 2        |                       | NA                         | MCA               | NA  | NA                          | NA                       | NA                | NA              | NA              | NA                                |
| D’Agostino et al. [12]      | 3        | Left side signs, GCS 6 | Worsening coma, PCA, Cerebellar, Pons | Basilar          | Aortic arch floating thrombus | –                       | NA                | –               | –               | Malignant infarct, brain herniation | Death               |
| Blauenfeldt et al. [7]      | 4        | Abdominal pain        | Hemiparesis                | MCA               | ICA | –                           | –                       | NA                | Dalteparin      | Malignant infarct, hemi-resection | Death               |
| Al-Mahyani et al. [8]       | 5        | Stroke                | Hemiparesis, gaze preference, drowsiness | MCA-M1           | –   | –                           | –                       | NA                | Fondaparinux   | Hemorrhagic transformation, malignant infarct, hemi-resection | Death               |
|                            | 6        | Stroke, headache      | Arm weakness, hemianopsia, confusion | MCA (borderzone infarcts) | Bilateral ICA occlusion (postbulbous and at origin) | –                       | NA                | Fondaparinux   | –               | Alive                             |
|                            | 7        | Stroke                | Dysphasia                  | MCA               | –   | –                           | –                       | NA                | Fondaparinux   | Hemorrhagic transformation      | Alive               |
| Garnier et al. [13]         | 8        | Stroke                | Hemiplegia, aphasia (NIHSS 8) | MCA               | MCA-M1 | –                         | MT                      | NA                | NA              | Hemorrhagic transformation       | Alive               |
| Jacob et al. [14]           | 9        | Stroke, headache      | Left-sided weakness, confusion (NIHSS 15) | MCA | MCA-M1 | Moderate to severe ICA stenosis due to large intraluminal thrombus at origin | – | TTE | Argatroban, fondaparinux plus aspirin | Hemorrhagic transformation, malignant infarct, hemi-resection | Alive               |
| Bourguignon et al. [15]     | 10       | Stroke, headache      | Left-sided weakness, confusion | MCA               | MCA | ICA thrombosis               | –                       | NA                | Fondaparinux   | Rivaroxaban | Hemorrhagic transformation       | Alive               |

COPD, chronic obstructive pulmonary disease; CVT, cerebral venous thrombosis; DVT, deep venous thrombosis; FEU, fibrinogen equivalent units; HVT, hepatic vein thrombosis; IJVT, internal jugular vein thrombosis; NA, not available; ND, not done; Neg, negative; OCT, oral contraceptive therapy; PE, pulmonary embolism; Pos, positive, PSM, porto-spleno-mesenteric venous thrombosis; PVT, portal vein thrombosis; Ref, reference range; VITT, vaccine-induced thrombotic thrombocytopenia; RT-PCR, reverse-transcriptase polymerase-chain-reaction.
| Author                  | Case No. | Symptoms on admission | Neurological stroke deficit | Vascular territory | LVO | Extracranial vessel findings | Acute reperfusion therapy | Diagnostic workup | Anticoagulation | Complications | Outcome |
|------------------------|----------|-----------------------|----------------------------|-------------------|------|-----------------------------|--------------------------|-----------------|----------------|---------------|---------|
| Walter et al. [16]     | 11       | Stroke, headache      | Hemiplegia, aphasia        | MCA               | MCA-M1 | Carotid bulb floating thrombus | IVT                      | TEE, TCD-B       | Aspirin, danaparoid, phenprocoumon | –               | Alive   |
| Tiede et al. [17]      | 12       | Headache, stroke      | –                          | r-MCA, I-PCA (small – cortical infarcts) | MCA, ACA | Multiple thrombi in the aortic arch and CCA origin | –                       | NA              | Argatroban, apixaban             | –               | Alive   |
|                        | 13       | Stroke, headache      | Dysarthria, hemiplegia, conjugated gaze palsy (NIHSS 17) | ICA + MCA-M1 | MT + CAS | –                            | –                       | TEE, TCD-B       | Argatroban               | Hemorrhagic transformation, malignant infarct, hemicecrtomy | Alive   |
| De Michele et al. [18] | 14       | Stroke                | Hemiplegia, dysarthria, MCA neglect | MCA-M1           | –      | MT                           | TEE, TCD-B             | Fondaparinux     | Malignant infarct, hemicecrtomy, MCA reocclusion | Malignant infarct, hemicecrtomy | Alive   |
|                        | 15       | Abdominal pain        | Transient aphasia and hemiparesis, seizure, coma | Right ICA, left MCA-M1 | –      | –                            | TEE                     | –               | Argatroban, fondaparinux | –               | Alive   |
| Patrizi et al. [19]    | 16       | Stroke                | Confusion, decreased level of consciousness | Cerebellar        | VA      | Bilateral VA occlusion, left ICA and CCA thrombus | –                       | –               | Argatroban, fondaparinux | –               | Alive   |
| Costentin et al. [20]  | 17       | Headache              | Hemiplegia, aphasia, NIHSS 15 | MCA               | MCA-M1 | –                            | MT                      | TE, CM           | NA                        | Hemorrhagic transformation | Alive   |
| Goereci et al. [21]    | 18       | Stroke, headache      | Visual impairment, transient hemiparesis and aphasia | MCA               | ICA    | ICA occlusion at bifurcation | –                       | OM, TEE, CUS     | Argatroban, apixaban             | –               | Alive   |
| Ceschia et al. [22]    | 19       | Lower limb pain       | –                          | PCA               | –      | –                            | –                       | NA              | Fondaparinux, warfarin | Adrenal hematoma, anemia | Alive   |
| Rodriguez-Pardo et al. [23] | 20       | Stroke                | Amaurosis fugax, blurry speech, arm weakness | AChA              | –      | Carotid bulb floating thrombus | –                       | CM, TTE, TTE-B, CUS | Fondaparinux, rivaroxaban       | –               | Alive   |
| Kenda et al. [24]      | 21       | Stroke                | Aphasia, hemiplegia, hemianopsia NIHSS 20 | MCA               | MCA-M1 | Chronic ICA dissection with 10 mm pseudoaneurysm | MT                      | TTE, 24 h-Holter | Fondaparinux, aspirin | Hemorrhagic transformation, MCA restenosis | Alive   |
| Su et al. [25]         | 22       | Stroke                | Left-side weakness         | Bilateral MCA (multiple scattered infarcts), PCA | –      | –                            | –                       | –               | Rivaroxaban (Afib prevention) | Respiratory failure, ascites, upper GI bleeding, cardiac arrest | Death   |
| Charidimou et al. [26] | 23       | Stroke, headache      | Hemiparesis, neglect, gaze deviation NIHSS 15 | MCA, ACA          | –      | MT                           | TEE                     | Argatroban       | Malignant infarct, hemicecrtomy | –               | Alive   |
| Present case           | 24       | Abdominal pain        | Hemiparesis, gaze deviation | MCA               | MCA-M1 | –                            | TTE, TCD-B, OM         | Fondaparinux, warfarin | Argatroban, fon | Hemorrhagic transformation, malignant infarct, hemicecrtomy | Alive   |

ACA, anterior cerebral artery; AChA, anterior choroidal artery; CAS, carotid artery stenting; CCA, common carotid artery; CM, cardiac monitoring; CUS, carotid ultrasound; GCS, Glasgow coma scale; ICA, internal carotid artery; IVT, intravenous thrombolysis; MCA, middle cerebral artery; MT, mechanical thrombectomy; NA, not available; ND, not done; NIHSS, National Institute of Health Stroke Scale; PCA, posterior cerebral artery; PLTs, platelets transfusion; TCD-B, transcranial doppler bubble test; TEE, transesophageal echocardiography; TTE, transthoracic echocardiography; VA, vertebral artery.
Additional thrombosis other than stroke was found in 13 of 24 patients (54.2%) and 11 out of 13 patients had multiple sites of thrombosis (see Table 3). Most of the cases had venous thrombosis at unusual sites; in particular, 77% (10 patients) had SVT (more often affecting the portal circulation). CVT was present in 5 of 24 patients (20.8%), an isolated thrombosis of the internal jugular vein was detected in another patient. In 2 cases, CVT was complicated by secondary intracranial venous hemorrhage. Deep extremity veins and pulmonary arteries were the second most common site of additional venous thrombosis and were affected in 12 of the 24 patients (50%) (8 cases of DVT and 9 cases of pulmonary embolism; 5 patients had both). In addition to ischemic stroke, an arterial thrombosis was found in 5 cases (2 popliteal artery thrombosis, 1 myocardial infarction, 1 renal infarct, and 1 spleen infarction). SVT was complicated by intra-abdominal hemorrhage in 4 patients (3 adrenal hemorrhages, 2 hemoperitoneum, and 1 renal hemorrhage).

Classification

Patients were defined to have VITT according to five criteria (time to onset from vaccination, presence of thrombosis, thrombocytopenia <150,000 × 10⁹/L, elevated D-dimer >4,000 FEU and positive anti-PF4 antibodies on ELISA) as established by several guidelines and studies [28–30]. People who met all five criteria were judged to have definite VITT, while those who did not meet one, two, or more criteria were defined to have probable, possible, unlikely VITT [30]. Of the 24 patients included in our review, 18 were classified as having definite VITT, 5 as having probable VITT because one of the criteria was not met. One patient was classified as having possible VITT due to D-dimer levels <4,000 FEU and platelet count 150,000 × 10⁹/L [16].

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Table 3. General characteristics in patients with ischemic stroke and VITT

|                     | Entire cohort (N = 24) |
|---------------------|-----------------------|
| Demographics        | n/N (%)               |
| Age, median (range) | 45.50 (21–73)         |
| Female, sex         | 19/24 (79.2)          |
| Vascular risk factors |                       |
| Hypertension        | 5/24 (20.8)           |
| Dyslipidemia        | 5/24 (20.8)           |
| Smoking             | 2/24 (8.3)            |
| Diabetes            | 1/24 (4.2)            |
| Atrial fibrillation | 1/24 (4.2)            |
| Prothrombotic risk factors |           |
| Oral contraceptive therapy | 2/24 (8.3)  |
| Cancer              | 2/24 (8.3)            |
| Vaccine             |                       |
| ChAdOx1 nCoV-19     | 20/24 (83.3)          |
| Ad26.COV2.S         | 3/24 (12.5)           |
| mRNA-1273           | 1/24 (4.2)            |
| Days from vaccination to admission, median (range) | 9.50 (7–21) |
| Platelet count nadir, ×10⁹/L, median (range) | 40 (5–152) [22] |
| D-dimer level peak, ng/mL FEU, median (range) | 32,102 (1,100–106,200) [20] |
| Fibrinogen level, g/L, median (range) | 2.30 (0.63–4.40) [14] |
| Anti-PF4 positive   | 22/23 (95.7)          |
| Platelet functional assay positive | 13/16 (81.3) |
| Additional venous thrombosis | 13/24 (54.2)   |
| SVT                 | 10/13 (77)            |
| Deep vein thrombosis | 8/13 (61.5)          |
| Pulmonary embolism  | 9/13 (69)             |
| Cerebral venous sinus thrombosis | 5/24 (20.8) |
| Arterial thrombosis (other than stroke) | 5/24 (20.8) |

[N] available data. Categorical variables are given as n/N (%).
Stroke Features

Ischemic stroke was the reason of medical presentation in 18 patients (75%). Among the remaining cases (6 patients), 3 patients presented to the emergency department complaining of abdominal pain, 1 patient with lower limb pain due to DVT, 1 patient arrived with left-sided signs and a mild comatose state from intracerebral venous hemorrhage, and 1 patient complaining headache due to CVT. In these cases, ischemic stroke occurred after hospital admission, on the same day (3 patients) or the day after (2 patients). In another patient, a cerebral infarct was an accidental finding after brain MRI. Analyzing stroke characteristics (Table 4), the majority of patients had focal deficits. Motor deficit was the most common symptom (75%), followed by language (aphasia and/or dysarthria), visual deficit, and neglect. In 2 patients with posterior stroke circulation and 1 patient with bilateral carotid infarction, the onset was characterized by confusion and a decreased level of consciousness up to severe coma. In 1 case, neurological examination was irrelevant except for headache. Prodromes (such as flu-like symptoms, fatigue, headache) have been frequently reported a few days after vaccination. Most patients (87.5%) had an anterior circulation stroke, mainly involving MCA. Multi-territorial vascular infarction with bilateral anterior or both anterior and posterior circulation was reported in 4 patients (16.7%). Of all the available data, 77% of patients (17/22) had an intracranial LVO involving the MCA-M1 segment (64.7%, 11/17), intracranial ICA (35.3%, 6/17), and posterior circulation (basilar artery and vertebral artery, respectively) (11.8%, 2/17). In 45.4% of available cases (10 out of 22) examination of the cervical vessels (by ultrasonography, CTA, MR-angiography, and/or invasive angiography) revealed a carotid occlusion at the neck due to large or multiple intraluminal thrombi (7 patients) or the presence of carotid or aortic arch free-floating thrombus (3 patients) (Tables 2, 4). In one patient, CTA revealed extreme tortuosity and chronic dissection of the proximal left ICA with a 10 mm pseudoaneurysm; in this case, the stroke was probably due to distal embolization of a thrombus formed within the pseudoaneurysm [24]. Regarding the diagnostic workup, cardiacological data were available in only 10 patients (42%) and tests excluded cardiac embolic sources and/or paradoxical embolization.

| Baseline characteristics | Entire cohort (N = 24) |
|--------------------------|-----------------------|
| Stroke as presenting symptom | 18/24 (75) |
| Neurological deficit | |
| Motor | 18/24 (75) |
| Language | 10/24 (41.2) |
| Visual deficit | 4/24 (16.7) |
| Neglect | 3/24 (12.5) |
| Altered state of mind | 3/24 (12.5) |
| Vascular territory | |
| Anterior circulation | 21/24 (87.5) |
| Posterior circulation | 5/24 (20.8) |
| Multi-territory (bilateral or both anterior and posterior) | 4/24 (16.7) |
| LVO | 17/22 (77) |
| MCA – M1 | 11/17 (64.7) |
| ICA | 6/17 (35.3) |
| VA, BA | 2/17 (11.8) |
| Extracranial vessel intraluminal thrombus | 10/22 (45.4) |
| Acute reperfusion therapy | 7/22 (31.8) |
| Thrombolysis | 1/22 (4.5) |
| Mechanical thrombectomy | 6/22 (27.3) |
| Malignant infarct | 9/22 (41) |
| Decompressive hemicraniectomy | 7/22 (31.8) |
| Death | 5/24 (20.8) |

Categorical variables are given as n/N (%).
Stroke Treatment and Outcome

Acute reperfusion therapy was performed in 7 of the 17 patients with LVO (41%). One patient with a normal platelet count underwent intravenous thrombolysis with alteplase, while 6 patients underwent mechanical thrombectomy. In one patient with tandem occlusion, urgent carotid artery stenting, other than MT, was performed. The remaining cases had no indication for acute revascularization due to severe thrombocytopenia, hemorrhage in other sites, large ischemic changes on CT scan, or absence of treatable penumbra on perfusion CT. Re-occlusion and restenosis of the same vessel after mechanical thrombectomy were reported in two patients. Anticoagulation was administered in 90% of patients with available data (n = 20). Non-heparin anticoagulants including argatroban, fondaparinux, danaparoid, and direct oral anticoagulants were used in most patients. Direct oral anticoagulants, including rivaroxaban and apixaban, were used in 25% (5 patients), mainly in the subacute and chronic phases (4 patients). Heparin was administered in only 1 case at the start of the vaccination campaign. Malignant infarct occurred in 9 patients and decompressive hemicraniectomy was performed in 7 patients (31.8%). At the time of publication, 19 patients were alive, but 1 patient was in critical condition, and 5 patients had died (20.8%). Data about final neurological functional status are lacking.

Isolated Ischemic Stroke versus Ischemic Stroke plus Venous Thrombosis

We compared baseline (demographics, vascular and prothrombotic risk factors, laboratory results) and stroke characteristics between patients with isolated arterial ischemic stroke and patients with additional venous thrombosis other than stroke, to examine if these 2 groups of patients are intrinsically the same (online suppl. Table e1). Patients with stroke plus venous thrombosis were older, more often women, had lower platelet count and higher D-dimer levels. Furthermore, strokes were more frequently due to LVO (92.3% vs. 55.5%), often evolving into a malignant infarct.

Discussion

VITT is an autoimmune disorder, characterized by antibodies that directly activate platelets, triggering thrombosis in the arterial and venous circulation. It is characterized by severe thrombocytopenia, systemic activation of coagulation (suggested by disproportionately elevated D-dimer levels and reduced fibrinogen), extensive venous thrombosis present at multiple and unusual sites such as CVT and SVT (including mesenterial, portal, hepatic, splenic, or adrenal veins), and positive anti-PF4 [6]. This syndrome was initially reported after ChAdOx1 nCov-19 vaccine, several cases have been also described following Ad26.COV2.S vaccine [4, 5] with similar clinical and laboratory features. Unlike the Pfizer-BioNTech and Moderna vaccines, which are mRNA-based, the ChAdOx1 nCov-19 and Ad26.COV2.S vaccines are nonreplicating adenovirus vector-based DNA vaccines, both use an adenoviral vector, human and chimpanzee, respectively. The pathophysiology of VITT is still incompletely understood and a major area of uncertainty is how adenoviral vector vaccines trigger this syndrome. This disorder is strongly similar to autoimmune HIT, but anti-PF4 and thrombotic complications develop in the absence of previous exposure to heparin. Several hypotheses have been proposed and it has been supposed that a component of the vaccine might interact directly with PF4 and could take the place of heparin, causing a novel autoimmune humoral response that induces platelet activation and a hypercoagulative state [6, 31]. Some clinical data seem to suggest a different pathophysiology between these two adenoviral vaccines, regarding the hypothesized HIT-like mechanism. In fact, patients receiving Ad26.COV.2.S tend to present CVT less frequently and later, have lower D-dimer and aPTT levels than ChAdOx1 nCov-19 and while anti-PF4 antibodies were present in most patients with either vaccine, platelet function tests were rarely positive in the Ad26.COV.2.S group [32]. Although anti-PF4 positivity (ELISA assay) is considered a standard criterion for VITT, negative or equivocal results have been obtained in several cases [3, 33]. These results could be likely related to several biases such as different ELISA assays, lack of standardization in the functional platelet tests, sample timing (platelet transfusion or immunotherapy before the blood draw could give false negatives), or cases that may require testing by more than one ELISA assay before anti-PF4 can be proven. In addition, the potential for cases of VITT unrelated to anti-PF4 mediated pathophysiological mechanism should be considered. Arterial thrombosis appears to be a rare event compared to venous thrombosis. In a recent UK report of 220 cases, only 47 patients (21%) had one or more arterial thrombotic events and only 17 cases had a cerebrovascular accident [30]. In a German report, only 9 cases of primary ischemic stroke were retrospectively identified after COVID-19 vaccination, and 5 patients had a high VITT risk grade [34]. At present, far fewer cases of ischemic stroke
have been published following COVID-19 vaccination, compared to cases with CVT. In our systematic review of the literature, we found 23 cases of ischemic stroke and VITT. Other published reports of strokes due to different thrombotic disorders, such as ITP, immune thrombocytopenic purpura (ITP), or catastrophic antiphospholipid syndrome, were identified but excluded from this study. Furthermore, we described a case of ischemic stroke with extensive SVT, severe thrombocytopenia and elevated D-dimer within 13 days of Ad26.COV2.S vaccination. Our patient had negative anti-PF4 ELISA and platelet functional assay, but tests were obtained after several platelet transfusions and were not repeated (if we had suspected VITT earlier, we would have treated the patient differently by not giving platelets). Nevertheless, severely reduced platelet count, high D-dimer levels (>4,000 FEU), and low fibrinogen levels were strongly indicative of systemic activation of coagulation. ITP was excluded and a complete differential diagnosis was made for other coagulation disorders. TTP was ruled out by the absence of schistocytes and normal ADAMTS13, the biochemical panel was not compatible with disseminated intravascular coagulation (unremarkable changes in PT, aPTT, antithrombin), catastrophic anti-phospholipid syndrome was considered, but tests for anti-phospholipid antibodies were all negative. A causal relationship between thrombosis with thrombocytopenia syndrome and vaccine was highly suspected and according to the last guidelines [27–29] all mandatory criteria (uncommon thrombosis location, thrombocytopenia, and laboratory results) were satisfied to confirm at least a probable VITT diagnosis [29]. Furthermore, although the stroke was found a few hours after surgery, the presence of ischemic changes with midline shift on the first CT scan would allow it to be dated several hours earlier, probably misdiagnosed as the patient was unconscious. In our review, all reports of ischemic stroke followed the first dose of an adenoviral vector vaccine, except for 1 patient who received a mRNA-based vaccine (Moderna). However this patient, despite meeting all the criteria for definite VITT diagnosis, had several cardiovascular and thrombotic risk factors such as atrial fibrillation and metastatic pancreatic cancer that could have triggered a thrombotic phenomenon. A probable case of VITT was yet reported in the USA after Moderna vaccination [35]. In a study from the USA [36] among over 350 vaccine recipients, only three cases of VITT after mRNA-1273 (Moderna) were identified, with a reporting rate of 0.00855. These reports may complicate hypotheses that implicate adenoviral vectors as the sole cause of VITT. However considering the very low reporting rate for VITT following mRNA-based COVID-19 vaccines, it is difficult to establish a clear causal correlation and these reports may represent a background rate of cases of spontaneous HIT with a different pathophysiological mechanism. Ischemic stroke during VITT mostly affects healthy young adults, especially women without known prothrombotic risk factors. Stroke, when it occurs, is often the initial presenting symptom, may be isolated or associated with thrombosis in other venous or arterial sites. Among the included cases we found a very high prevalence of LVOs (71%) that was higher (92.3%) in patients with additional venous thrombosis. Moreover, in these patients platelet count was lower compared to those with isolated ischemic stroke, thus confirming a more severe thrombotic disorder in this subgroup. Ischemic stroke with LVO usually represents 10–30% of all AISs [37] with this percentage varying according to which vessels are considered. A higher prevalence of LVOs (up to 47%) was also found in stroke patients with SARS-CoV-2 infection, across all age groups, even in the absence of risk factors or comorbidities. Moreover, in young patients prevalence reached up to 68.8% [38, 39]. Another unusual feature of ischemic stroke in VITT is the high prevalence of both large intraluminal thrombi and free-floating thrombi in extracranial vessels, such as carotid artery, in the absence of underlying atherosclerotic disease. Floating carotid thrombus is an unusual finding in clinical practice, present in only 1.5% of all stroke patients [40]. Cases of asymptomatic carotid thrombi or causing a TIA have also been reported after COVID-19 vaccine [41, 42]. These findings emphasize even more the severe immune-mediated hypercoagulative state induced by the vaccine. In fact, the high prevalence of large intraluminal arterial thrombi could be explained by several hypotheses some of which support that some vaccine proteins could damage endothelial cells, triggering inflammation and platelet activation, causing PF4 release and thrombosis [6]. Furthermore, re-occlusion and restenosis of the same vessel were reported in two patients after mechanical thrombectomy; authors hypothesized it was probably due to the PF4/VWF complexes aggregation recognized by anti-PF4 antibodies on the post-thrombectomy injured arterial endothelium [18, 24]. Anticoagulation is mandatory in VITT and was administered in 90% of patients. However, the initiation of anticoagulation shortly after a major ischemic stroke is burdened with an increased risk of hemorrhagic infarction which occurred in 10 patients, with possible consequences in terms of death, prognosis, and functional neurological outcome. Patients with VITT of-
Ischemic Stroke and VITT following COVID-19 Vaccination

In VITT, the etiology of ischemic stroke is likely due to an abnormal immune-mediated intravascular coagulation that induces the formation of large arterial thrombi occluding intracranial and extracranial vessels. Considering the massive brain thrombosis and clinical severity, prompt treatment is essential. While intravenous thrombolysis is usually avoided due to severe thrombocytopenia and high bleeding risk, the endovascular treatment seems feasible and safe, even if restenosis or re-occlusion of the revascularized artery may occur because of the hypercoagulative state. Our study points out that, in addition to venous thrombosis, adenoviral-vector vaccines also appear to have a cerebral arterial thrombotic risk and clinicians should be aware that ischemic stroke with LVO, although rare, could represent a clinical presentation of VITT. However, caution is needed in questioning the safety of adenoviral vector vaccines, considering the rarity of VITT and the low prevalence of ischemic stroke, and keeping in mind that COVID-19 itself carries a much greater risk of arterial thrombotic complications. In conclusion, our case adds and confirms what has already been reported in literature, but the strength of our study, through the systematic review, is to consolidate the phenotype of ischemic stroke in the context of VITT, of which physicians and in particular vascular neurologists should be aware.

**Statement of Ethics**

Written informed consent was obtained from our patient for publication of the medical details and any accompanying images. An ethics statement is not applicable for the remaining cases because this study is based on published literature.

**Conflict of Interest Statement**

The authors have no conflicts of interest to declare.

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**Author Contributions**

Angelo Cascio Rizzoconcepted and drafted the manuscript, the tables, and figures, and acquired data and worked up the clinical case as physician of care. Giuditta Giussani acquired data and provided revision of the manuscript. Elio Clemente Agostoni conceived, supervised and planned the manuscript, and provided revision of the manuscript.

**Data Availability Statement**

All data generated and analyzed in this study are included in this article and its online supplementary material. Further inquiries can be directed to the corresponding author.

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