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Review Article

Navigating Neurological Risks After COVID-19 Vaccination Campaign: Insights And Strategies For Covishield And Beyond

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ABSTRACT

The COVID-19 pandemic prompted an urgent global response to develop vaccines, leading to the rapid deployment of several candidates, including Oxford-AstraZeneca and Johnson & Johnson's vaccines. However, reports of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) raised concerns, resulting in temporary halts in vaccine administration. India, with its vast population, initiated an extensive vaccination campaign, predominantly using the Covishield vaccine. This article synthesizes existing guidelines and discusses the challenges associated with VITT/CVST, emphasizing the importance of heightened pharmacovigilance and physician awareness. It also highlights the emerging neurological symptoms post-Covishield vaccination for TTS mitigation. As India expands its vaccination drive, monitoring, and addressing adverse effects are crucial.

INTRODUCTION

The COVID-19 crisis unfolded rapidly, straining healthcare systems worldwide and exacting a heavy toll on lives and economies [1, 2]. In response, extensive efforts were made to develop effective vaccines swiftly. Collaborative initiatives yielded cutting-edge vaccines with notable efficacy and safety records within remarkably short timeframes [3, 4, 5]. However, the rollout of vaccines such as Oxford-

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AstraZeneca and Johnson & Johnson faced setbacks when reports of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) surfaced, leading to temporary halts [6, 7, 8].Though thorough risk-benefit analyses justified their resumption, medical communities globally continue grappling with understanding the pathophysiology and mechanisms behind these neurological adverse effects to enhance identification, diagnosis, and treatment [9, 10, 11]. One implicated mechanism revolves around the adenovirus-based vector utilized in these vaccines, a vector shared by Covishield, India's predominant vaccine [12, 13]. As India progresses to vaccinate younger adults, there's a possibility of similar adverse effects emerging [14, 15, 16].This review delves into the temporary suspension of vaccine administration due to VITT/CVST, synthesizes existing guidelines regarding diagnosis and treatment of these neurological disorders, and emphasizes the imperative of heightened pharmacovigilance and physician awareness [17, 18, 19, 20,]. Implementing screening for potential risk factors, advocating hydration, and offering vaccination choices for high-risk populations could mitigate these rare yet potentially grave outcomes [21, 22, 23].Since the emergence of the first cluster of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wuhan, China, in December 2019, the COVID-19 pandemic has rapidly spread, placing immense strain on global healthcare systems [24, 25, 26, 27]. As of August 13, 2021, the global tally surpassed 205,338,175 confirmed cases and recorded 4,333,103 deaths. To put this into perspective, the death toll from COVID-19 has already surpassed that of influenza over the past century, marking an unprecedented public health challenge [28]. The devastating toll on lives and economies prompted an urgent push for vaccine development and distribution [29, 30]. Initially, more than 200 vaccine candidates were explored, with 18 advancing to human clinical trials to assess their efficacy and safety [31, 32]. Recognizing the need for scaled-up production, several multinational pharmaceutical companies partnered with Indian firms [33, 34]. AstraZeneca collaborated with the Serum Institute of India, while Johnson & Johnson joined forces with Biological E India [35, 36, 37].

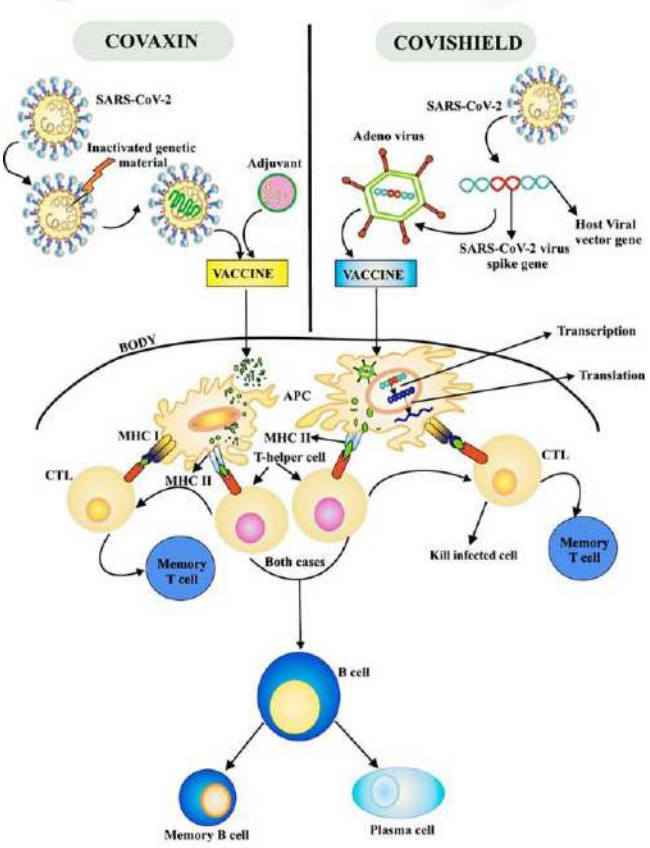

Fig.1. General Mechanism of Covaxin and Covishield

In India, three vaccines have received approval for public use: COVISHIELD, COVAXIN, and SPUTNIK V. COVISHIELD, developed by Oxford-AstraZeneca, utilizes a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein, with local manufacturing facilitated by the Serum Institute of India[38, 39, 40, 41]. COVAXIN, an inactivated whole-virion vaccine, is India's homegrown product developed by Bharat Biotech, in collaboration with the Indian Council of Medical Research (ICMR) and the

National Institute of Virology (NIV) [42, 43]. SPUTNIK V, another adenoviral-vector-based vaccine, was introduced in major Indian cities in May 2021 through collaboration between the Russian Direct Investment Fund (RDIF) and Dr. Reddy's Laboratories [44, 45]. Numerous other candidate vaccines are undergoing trials at various stages across India, reflecting ongoing efforts to combat the pandemic through vaccine research and deployment.While mass vaccination campaigns are expected to mitigate COVID-19 outbreaks by reducing infection rates, hospitalizations, and fatalities, it's crucial to monitor for adverse events post-vaccination to assess the risk-benefit balance of each authorized vaccine [46, 47]. Of particular concern are rare but serious adverse events such as vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) [48]. This review underscores the importance of these adverse events in the context of vaccination strategies in India and offers recommendations to address them effectively.

Overview of Vaccine-Induced Thrombosis-Thrombocytopenia Syndrome (VITT) in COVID-19 Vaccination:

Thrombosis-thrombocytopenia syndrome (TTS), characterized by the concurrent presentation of cerebral venous sinus thrombosis (CVST) and thrombocytopenia, has been termed vaccine-induced immune thrombotic thrombocytopenia (VITT) in the context of COVID-19 vaccination [49, 50]. The Brighton Collaboration draft defines TTS case identification by a platelet count <150 × 109/L [51]. Two vaccines, Oxford-AstraZeneca's Vaxzevria (ChAdOx nCoV-19) and Johnson & Johnson's (JJ) vaccine (AD26.COV2·S), have been associated with TTS [52, 53]. The Center for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) investigated 15 reported TTS cases in the United States (US) following the JJ COVID-19 vaccine, while the European Medicines Agency (EMA) reported 169 cases of CVST among adults who received the AstraZeneca vaccine in the European Union, leading to temporary suspension of these vaccines' use in several countries [54, 55, 56]. COVISHIELD, the Indian equivalent of the AstraZeneca vaccine, has been extensively administered in India without reported CVST incidents [57]. However, estimated incidents by EMA suggest there should have been approximately 320 cases for every 80 million doses administered in India. In initial case series, VITT after the AstraZeneca vaccine manifested symptoms between 5-24 days post-vaccination, predominantly in women under 55 years old [58, 59]. Mortality rates for TTS were approximately 40%. Similarly, all initial TTS cases were in white women aged 18-59 years, with symptoms emerging within a median of 8 days [60, 61]. Platelet counts ranged from 19 × 103/μL to 127 × 103/μL, and abnormal D-dimer or fibrinogen values were universa l62, 63]. CDC updated its interim clinical considerations, alerting women aged 18 to 49 years of the heightened TTS risk following the JJ vaccine [64]. Published estimates suggest VITT incidence ranges from 1 case per 26,000 to 1 case per 127,000 doses of AstraZeneca vaccine administration [65, 66]. TTS mortality following AstraZeneca vaccination was 50% in Europe and 25% in US patients, significantly higher than the baseline CVST mortality rate of 4.4% [67, 68].

Assessment of Thrombosis-Thrombocytopenia Syndrome (TTS) Risk in COVID-19 Vaccines

As of April 2021, there were 169 reported cases of CVST associated with TTS among approximately 34 million recipients of the AstraZeneca (AZ) vaccine in the European Union [69]. In contrast, US regulatory agencies documented 15 cases of TTS among about 7 million recipients of the Johnson & Johnson (JJ) vaccine [70, 71]. While the causal link between these vaccines and TTS

was considered plausible, both the CDC and EMA emphasized that the overall benefits of these vaccines outweigh the risks [72, 73]. Consequently, on April 23, 2021, the Advisory Committee on Immunization Practices recommended the continued use of both vaccines for individuals aged 18 and older [74]. Reports of cerebral venous thrombosis associated with VITT are detailed in below. Currently, Norway and Denmark have suspended the use of the AZ vaccine, while Iceland and Germany have restricted its use to individuals older than 60 years [75, 76, 77]. The UK advises that adults under 30 years old without underlying health conditions should be offered an alternative non-adenoviral vector-based COVID-19 vaccine, if available [78]. Canada offers the AZ vaccine to all adults with additional warnings on the vaccine label [79, 80]. Similarly, the US allows the use of the JJ vaccine in all adults, accompanied by information on the risk of TTS in educational materials [81].

Comparative Analysis of CVST Cases Associated with AstraZeneca, Janssen, and COVISHIELD COVID-19 Vaccines

Recent reports have reveal on cases of cerebral venous sinus thrombosis (CVST) occurring after the administration of various COVID-19 vaccines [82, 83]. This article presents a comparative analysis of reported CVST cases associated with AstraZeneca, Janssen, and COVISHIELD vaccines. Regarding reported and confirmed CVST cases, AstraZeneca had 413 reported cases and 227 confirmed cases, Janssen had 13 reported cases and 13 confirmed cases, and COVISHIELD had 1 reported case with confirmation information unavailable [84, 85]. In terms of age distribution, recipients of AstraZeneca vaccines ranged from 21 to 77 years old, Janssen recipients were aged between 18 and 60 years, while COVISHIELD recipients had a median age of 36 years [86, 87]. Symptoms associated with CVST varied, with AstraZeneca recipients experiencing headache, visual disturbance, and leg/arm weakness, Janssen recipients presenting symptoms such as headache, lethargy, fever, pain, and limb weakness, while information on COVISHIELD symptoms was not available [88, 89, 90]. The onset of symptoms occurred within 5-24 days post-vaccination for AstraZeneca and 6-15 days (median 8 days) for Janssen recipients, but information for COVISHIELD was not available [91, 92]. The results of the Platelet Factor 4-Heparin Assay were positive for both AstraZeneca and Janssen, but information for COVISHIELD was not available [93]. These findings provide insights into the incidence and characteristics of CVST cases associated with different COVID-19 vaccines, emphasizing the importance of ongoing monitoring and research to ensure vaccine safety [94].

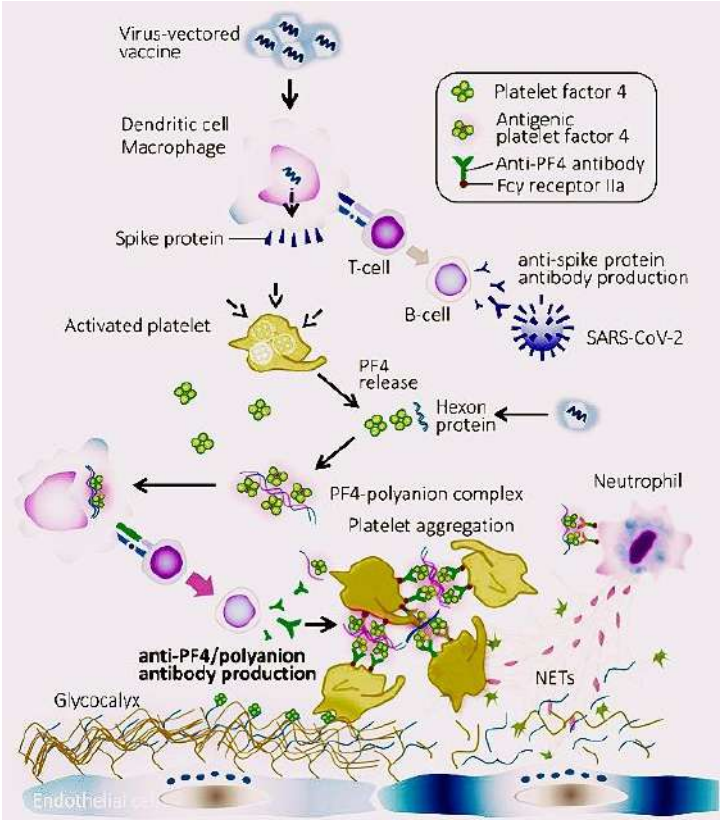

Fig. 2: Mechanism of Vaccine-Induced Thrombosis-Thrombocytopenia Syndrome (VITT)

Thrombosis-Thrombocytopenia Syndrome (TTS): Insights into CVST, Diagnosis, and Treatment

Cerebral venous sinus thrombosis (CVST) typically affects young adults, particularly women of childbearing age, with over 80% of patients having identifiable thrombosis risk factors such as coagulopathies or hormonal contraception. Prior to the COVID-19 pandemic, CVST associated with thrombocytopenia was rare [95, 96]. However, with COVID-19 vaccination, thrombosis-thrombocytopenia syndrome (TTS) encompasses more common thrombotic events like deep vein thrombosis and ischemic stroke, besides CVST. Studies indicate that the risk of CVST post-COVID-19 infection is significantly higher than after vaccination [97, 98, 99] . Symptoms of thrombosis-thrombocytopenia syndrome (TTS) following Covishield vaccination, manufactured by AstraZeneca in India, can present diversely, including severe or worsening headaches not responsive to typical pain relief measures, visual disturbances like blurred vision, breathing difficulties, persistent abdominal pain, leg swelling or pain, emergence of small red or purple skin spots (petechiae or bruises), neurological symptoms such as confusion or seizures, and gastrointestinal issues like nausea, vomiting, or ongoing abdominal discomfort [100, 101, 102, 103] . Immediate medical attention is crucial for any unusual or severe symptoms appearing within days to weeks post-Covishield vaccination

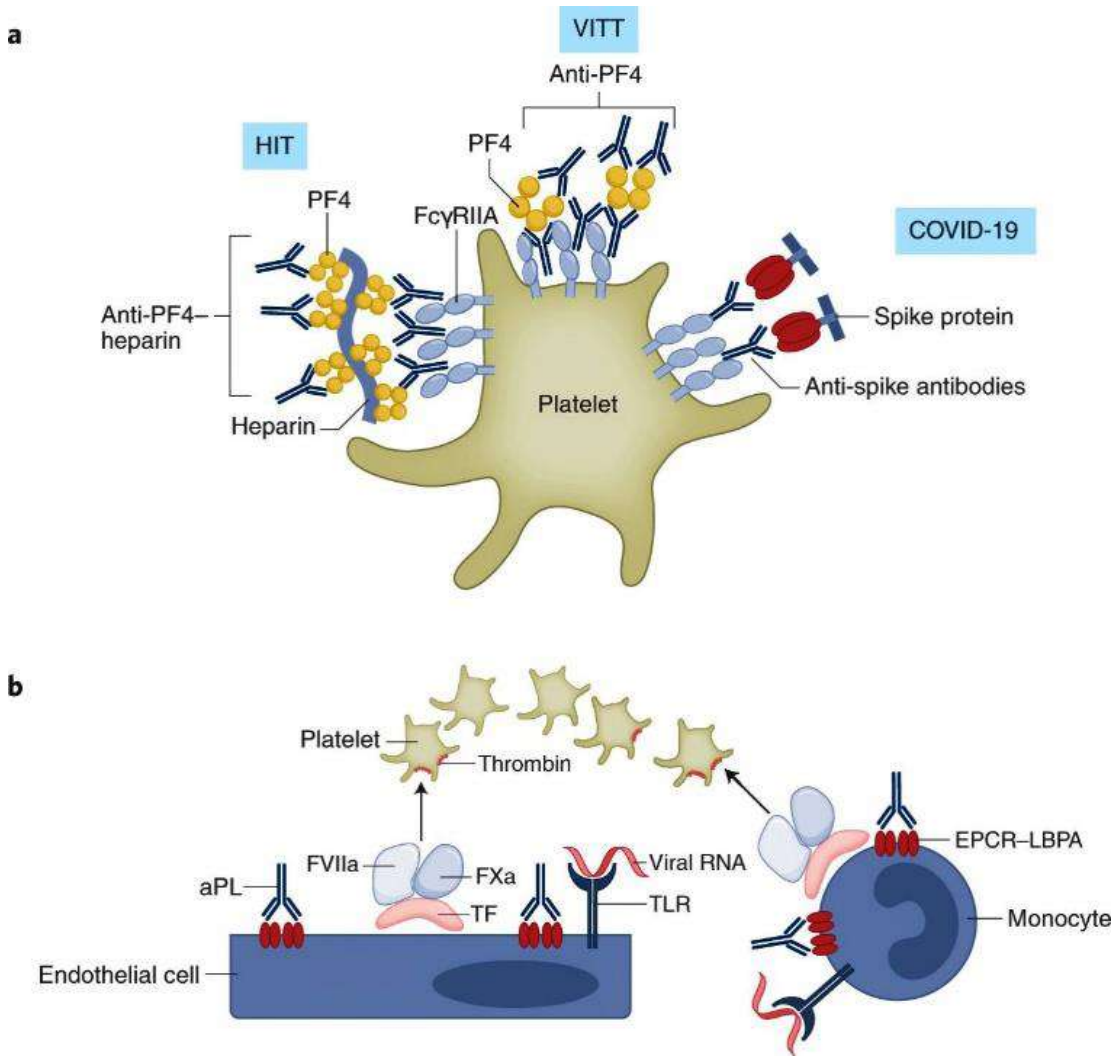

Fig. 3: Autoimmune Antibody Repertoires Responsible For the Excessive Activation of Coagulation and Platelets

especially for individuals with a history of blood clotting disorders or previous thrombotic events104, 105]. Diagnosis of CVST should be considered in young patients with unusual headaches or stroke-like symptoms, and imaging techniques like MRI or CT with venogram are crucial for accurate detection [106]. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is more likely if symptoms arise within 4-28 days post-vaccination [107, 108]. Diagnostic tests include complete blood count, coagulation profiles, D-dimer, and platelet factor 4 (PF4) antibody assay [109, 110]. The pathogenesis of VITT involves high levels of antibodies to PF4-polyanion complexes, akin to autoimmune heparin-induced thrombocytopenia [111]. Treatment typically involves non-heparin anticoagulants and intravenous immunoglobulins (IVIG) to mitigate the prothrombotic response and improve platelet count [112, 113]. In severe cases, direct endovascular treatment or neurosurgical intervention may be necessary [114].

India's COVID-19 Vaccination Campaign: Global Impact, Challenges, and Neurological Symptoms Post-Covishield Vaccination

Bruce Y Lee from the CUNY Graduate School of Public Health and Health Policy in New York, USA, emphasized the significance of India's COVID-19 vaccination campaign in controlling the global spread of SARS-CoV-2 due to India's

vast population size, constituting over one-seventh of the world's population [115, 116]. According to Brian Wahl from the Johns Hopkins Bloomberg School of Public Health in Baltimore, MA, USA, India's robust domestic vaccine industry facilitated one of the largest and fastest COVID-19 vaccination drives globally [117] . India initiated its vaccination program on January 16, 2021, and as of August 13, 2021, has administered over 539 million doses, with COVISHIELD being the predominant vaccine, accounting for 87% of the total doses [118, 119]. Despite the government's aim to inoculate all eligible citizens by the year-end, the campaign has faced challenges such as slow progress, vaccine shortages, and hesitancy, resulting in only 8.65% of the population being fully vaccinated, with 30.2% having received the first dose [120, 121, 122] . Although there has been only one suspected case of vaccine-induced immune thrombotic thrombocytopenia (VITT) reported in India out of 304.5 million COVISHIELD doses administered, data from the Adverse Events Following Immunization (AEFI) report dated March 17, 2021, lists three deaths possibly linked to vaccine administration [123, 124]. However, the accuracy of these numbers in comparison to estimates by the European Medicines Agency (EMA) is debatable, raising questions about misdiagnosis, reporting failures, or documentation errors [125]. India's AEFI surveillance program relies on passive reporting by healthcare professionals and the public, with serious unexplained AEFIs within 30 days post-vaccination requiring immediate investigation [126, 127]. Despite concerns about underreporting, the current AEFI reporting rate for COVID vaccines remains low at 0.008% [128] . Immediate recognition and management of serious AEFI cases, particularly those involving cerebral venous sinus thrombosis (CVST) or TTS, are vital [129]. With India expanding its vaccination drive to include younger populations, there may be an increase in reported cases of CVST and TTS, necessitating careful screening and surveillance efforts [130, 131]. Enhancing vaccine production, supply, and accessibility, along with public awareness campaigns, are essential steps to mitigate the impact of the pandemic and restore confidence in vaccination efforts, crucial for preventing future medical crises like those witnessed during India's second wave of COVID-19 [132, 133].Newly emerging neurological symptoms post-Covishield vaccination, aimed at mitigating thrombosis-thrombocytopenia syndrome (TTS), include severe or persistent headaches unresponsive to standard pain relief, visual disturbances such as blurred vision, impairment in speech comprehension or articulation, weakness or sensory deficits in facial, upper limb, or lower limb regions, particularly unilateral, occurrence of seizures or convulsions, altered mental status characterized by confusion or cognitive difficulties, impaired coordination and balance, abrupt and intense onset of nausea or vomiting with no discernible trigger, and appearance of petechiae or ecchymoses on the skin. Individuals experiencing these symptoms within days to weeks following Covishield vaccination should promptly seek medical attention for thorough evaluation and management, particularly if TTS or other serious adverse events are suspected.

CONCLUSION

In conclusion, the COVID-19 pandemic has necessitated the rapid development and deployment of vaccines globally. While vaccines like Oxford-AstraZeneca and Johnson & Johnson's have shown remarkable efficacy, reports of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) have raised concerns. Despite temporary halts and thorough risk-benefit analyses, medical communities worldwide continue to grapple with understanding the

mechanisms behind these neurological adverse effects. As India progresses with its vaccination campaign, there's a need for heightened pharmacovigilance and physician awareness, particularly regarding the COVISHIELD vaccine. Screening for risk factors, advocating hydration, and offering vaccination choices for high-risk populations are crucial mitigation strategies. The global impact of India's vaccination campaign underscores the importance of monitoring and addressing adverse events effectively. Enhancing vaccine production, supply, accessibility, and public awareness are essential for controlling the pandemic and preventing future medical crises. Recognition and management of serious adverse events, such as CVST and TTS, remain vital, especially with the emergence of new neurological symptoms post-Covishield vaccination. Immediate medical attention for individuals experiencing such symptoms is paramount to ensure timely evaluation and management. Through collaborative efforts and ongoing research, we can navigate these challenges and strengthen vaccination strategies to combat COVID-19 effectively.

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