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Hodnotenie vedľajších príhod po očkovaní

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Centrum pre očkovanie detí s komplikáciami po očkovaní a kontraindikáciami očkovania
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Košice



Vedľajšia príhoda po očkovaní

symptóm

ochorenie

patologický
laboratórny
nález

ktoré sa vyskytli po očkovaní

Vedľajšia príhoda \neq príhoda v príčinnej súvislosti

Očakávané príhody po očkovaní

populácia



Frekvencia výskytu

jednotlivec



Intenzita reakcie

Frekvencia výskytu príhody

Kategórie:

Veľmi časté (> 10%) - lokálne - bolestivosť v mieste vpichu, erytém
- celkové - zvýšená teplota/zimnica, bolesti svalov, hlavy, kĺbov
únava

Časté (1 - 10%) - lokálne - opuch, indurácia
- celkové - strata chuti do jedla, podráždenosť, poruchy spánku

Menej časté (0,1 - 1%) - respiračné symptómy

Zriedkavé (0,01- 0,1%) - dyspeptické ťažkosti

Veľmi zriedkavé (< 0,01%) - anafylaxia, kŕče

Intenzita príhod po očkovaní

Stupne:

1. nezávažná príhoda

- plná tolerancia očkovanou osobou
- bez zdravotného diskomfortu
- bez obmedzenia denných činností

2. stredne závažná príhoda

- mierny zdravotný diskomfort osoby
- bez obmedzenia v obvyklých denných činnostiach

3. závažná príhoda

- výrazný zdravotný diskomfort osoby
- výrazné obmedzenia v základných denných činnostiach
- vyžaduje návštevu lekára, medikáciu ev. hospitalizáciu

Závažná príhoda po očkovaní

Neočakávaný výskyt stavu:

- je život ohrozujúci
- vyžaduje hospitalizáciu
- vedie k vzniku postihnutia/následkov
- vedie k smrti
- spôsobí u dieťaťa očkovanej matky vrodené anomálie

Imunitne mediované príhody po očkovaní

	Klinický prejav
IgE sprostredkované	urtikária, angioedém, rinokonjunktivitída, bronchospazmus, anafylaxia , gastrointestinálne ťažkosti (hnačka, vracanie, bolesti brucha)
Imumokomplexové (IgG)	vaskulitída, myokarditída
T- bunkami sprostredkované	makulopapulárny exantém, ekzém, akútna generalizovaná pustulóza (AGEP), erythema multiforme
Non-IgE-spostredkované (pseudoalergické)	urtikária, angioedém, anafylaktoidná reakcia, gastrointestinálne ťažkosti
Autoimúnne/zápalové	trombocytopenia, vaskulitída, MMF, reumatoidná artritída, Reiterov syndróm, sarkoidosis (juvenile), bulózný pemphigoid, lichen planus, Guillain-Barrého syndróm

Definícia vedľajšej príhody

„Brighton Case Definitions“

Štandardizácia

- hlásenia vedľajších príhod po očkovaní
- zberu údajov
- definície prípadu
- vyhodnotenia vedľajšej príhody z pohľadu príčinnej súvislosti

Definícia vedľajšej príhody



Available online at www.sciencedirect.com



Vaccine 25 (2007) 5675–5684



www.elsevier.com/locate/vaccine

Anaphylaxis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data[☆]

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Babatunde Imoukhuedeⁱ, Ali Khamesipour^j, Michel Erlewyn-Lajeunesse^k,
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The Brighton Collaboration Anaphylaxis Working Group³

Vedľajšie príhody

Vakcíny proti COVID-19

Závažné vedľajšie príhody po očkovaní

THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination

Andreas Greinacher, M.D., Thomas Thiele, M.D., Theodore E. Warkentin, M.D., Karin Weisser, Ph.D., Paul A. Kyrle, M.D., and Sabine Eichinger, M.D.

ABSTRACT

BACKGROUND
Several cases of unusual thrombotic events and thrombocytopenia have developed after vaccination with the recombinant adenoviral vector encoding the spike protein antigen of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (ChAdOx1 nCov-19, AstraZeneca). More data were needed on the pathogenesis of this unusual clotting disorder.

METHODS
We assessed the clinical and laboratory features of 11 patients in Germany and Austria in whom thrombosis or thrombocytopenia had developed after vaccination with ChAdOx1 nCov-19. We used a standard enzyme-linked immunosorbent assay

From Institut für Immunologie und Transfusionsmedizin, Universitätsmedizin Greifswald, Greifswald (A.G., T.T.), and the Division of Safety of Medicinal Products and Medical Devices, Paul-Ehrlich-Institut (Federal Institute for Vaccines and Biomedicines), Langen (K.W.) — both in Germany; the Departments of Pathology and Molecular Medicine and of Medicine, McMaster University, Hamilton, ON, Canada (T.E.W.); and the Department of Medicine I, Division of Hematology and Hemostaseology, Medical University of

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Topic Outline

SUMMARY AND RECOMMENDATIONS

INTRODUCTION

PATHOPHYSIOLOGY

EPIDEMIOLOGY

Inactivated vaccines

Incidence and risk factors

CLINICAL FEATURES

Overview of clinical presentation

Thrombotic events

Thrombosis

Coagulation abnormalities

Bleeding

EVALUATION

When to suspect

Laboratory testing

PTT assays

Imaging to diagnose thrombotic arterial disease

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COVID-19: Vaccine-induced immune thrombotic thrombocytopenia (VITT)

Authors: Theodore E. Warkentin, M.D., Sabine Eichinger, M.D., Karin Weisser, Ph.D., Paul A. Kyrle, M.D., Thomas Thiele, M.D., Andreas Greinacher, M.D., Sabine Eichinger, M.D.
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Contributor Disclosures

All topics are updated as new evidence becomes available and our [quality control process](#) is complete.
Literature review current through: Aug 2021. | This topic last updated: Aug 20, 2021.

INTRODUCTION

Vaccination is considered the most promising approach for ending or containing the coronavirus disease 2019 (COVID-19) pandemic. Available vaccines have proven highly safe and effective. (See "COVID-19: Vaccines to prevent SARS-CoV-2 infection".)

In late February of 2021, a prothrombotic syndrome was observed in a small number of individuals who received the ChAdOx1 nCov-19 vaccine (AstraZeneca, University of Oxford, and Serum Institute of India), an adenoviral vector-based vaccine. Subsequently, similar findings were observed in a small number of individuals who received the AZD1225 S vaccine (Janssen, Johnson & Johnson), also based on an adenoviral vector. This syndrome has been designated vaccine-induced immune thrombotic thrombocytopenia (VITT). It has also been called thrombosis with thrombocytopenia syndrome (TTS) and vaccine-induced prothrombotic immune thrombocytopenia (VIPIT).

The exact incidence of VITT is unknown, but it appears to be rare. Despite the very low incidence, mass vaccination of many millions of individuals has resulted in several hundred patients developing this condition, as discussed below (see "Incidence and risk factors" below). Thus, clinicians need to be aware of prevention features and appropriate evaluation and management, which are rapidly evolving and

Vedľajšie príhody

Vakcíny proti COVID-19

Závažné vedľajšie príhody po očkovaní

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CASE REPORT

General Medicine



Myocarditis and pericarditis after vaccination for COVID-19

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Abstract

Two previously healthy males presented to the emergency symptoms with signs of pericarditis/myocarditis after being vaccinated with an mRNA vaccine for COVID-19.

KEYWORDS

COVID-19, cardiology, ECG, myocarditis, pericarditis, vaccine

1 | INTRODUCTION

With the rapid development and rollout of vaccinations for COVID-19 patients are reporting a variety of possible vaccine-related adverse

2 | NARRATIVE

2.1 | Case #1

Heart, Lung and Circulation (2021) 30, 1425–1429

1443-9506/21/\$36.00

<https://doi.org/10.1016/j.hlc.2021.07.011>

EDITORIAL

Myocarditis, Pericarditis and Cardiomyopathy After COVID-19 Vaccination[☆]



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Keywords

mRNA vaccine • COVID-19 • Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
• Myocarditis • Pericarditis • Cardiomyopathy • Cardiovascular disease • Australia • CSANZ • ANZSCTS

Definícia vedľajšej príhody

Myocarditis Brighton Collaboration Case Definition

Pericarditis Will Be Integrated Once WG Approves Draft Release in Coming Days

Early Draft Release Under Brighton's Pandemic Emergency Response Process

(Click link below to register for frequent updates and to provide comments to help improve the draft case definition)

<https://brightoncollaboration.us/myocarditis-case-definition-update/>

Brighton Collaboration

Myocarditis Case Definition (Pandemic Emergency Response Process_Draft Release)

Level of Certainty (LOC) Classification

Version_1.4.2_30.May.2021

Stupne istoty na základe dôkazov

Myocarditis_Level of Certainty - 1 (Definitive Case) (Pandemic Emergency Response Process_Draft Release)

Histopathologic examination of myocardial tissue (autopsy or endomyocardial biopsy) showed myocardial inflammation

OR

Elevated myocardial biomarkers (at least 1 of the findings below)

Troponin T

Troponin I

AND

Abnormal Imaging study

Abnormal Cardiac Magnetic Resonance Study (at least 1 of the findings below)

Edema on T2 weighted study, typically patchy in nature

Late gadolinium enhancement on T1 weighted study with an increased enhancement ratio between myocardial and skeletal muscle typically involving at least one non-ischemic regional distribution with recovery (myocyte injury).

OR

Abnormal Echocardiogram (at least 1 of the findings below)

New focal or diffuse left or right ventricular function abnormalities (eg. decreased ejection fraction)

Segmental wall motion abnormalities

Global systolic or diastolic function depression/abnormality

Ventricular dilation

Wall thickness change

Intracavitary thrombi

v_1.4.2_30.May.2021

Stupne istoty na základe dôkazov

Myocarditis_Level of Certainty - 2 (Probable Case)

(Pandemic Emergency Response Process_Draft Release)

Clinical Symptoms

Cardiac Symptoms (at least 1 finding below)

- Acute chest pain or pressure
- Palpitations
- Dyspnea after exercise or lying down
- Diaphoresis
- Sudden death

OR

Non-Specific Symptoms (at least 2 findings below)

- Fatigue
- Gastrointestinal symptoms (nausea, vomiting, abdominal pain)
- Dizziness/Syncope
- Edema
- Cough

OR

Infants and young children (at least 2 findings below)

- Irritability
- Vomiting
- Poor feeding
- Tachypnea
- Lethargy

AND

Testing supporting diagnosis (Biomarkers, ECHO, and EKG)

Elevated myocardial biomarkers (at least 1 of the findings below)

- Troponin T
- Troponin I
- CK Myocardial band

OR

Stupne istoty na základe dôkazov

Myocarditis_Level of Certainty - 3 (Possible Case) (Pandemic Emergency Response Process_Draft Release)

Clinical Symptoms

Cardiac symptoms (at least 1 finding below)

- Acute chest pain or pressure
- Palpitations
- Dyspnea after exercise or lying down
- Diaphoresis
- Sudden death

OR

Non-Specific Symptoms (at least 2 findings below)

- Fatigue
- Abdominal pain
- Dizziness/syncope
- Edema
- Cough

OR

Infants/Young children (at least 2 findings below)

- Irritability
- Vomiting
- Poor feeding
- Tachypnea
- Lethargy

AND

NO Alternative etiology for symptoms

v_1.4.2_30.May.2021

Vedľajšia príhoda po očkovaní

1. úroveň: **definitívny** (potvrdený) prípad

2. úroveň: **pravdepodobný** prípad

3. úroveň: **možný** prípad

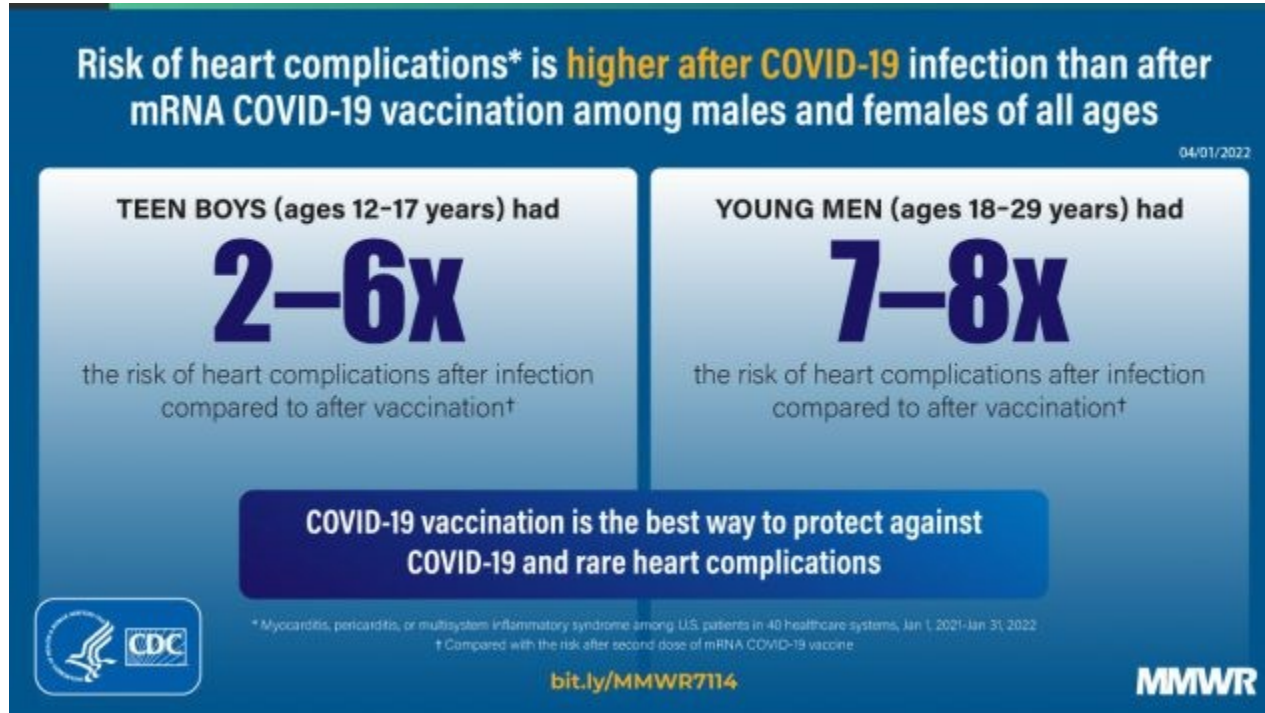
Vedľajšie príhody po očkovaní

skutočné príhody

sprievodné príhody

Nežiaduca príhoda súvisiaca s očkovaním
diagnóza per exclusionem

Očkovanie verzus prirodzená infekcia



Zdroj: Block JP, Boehmer TK, Forrest CB, et al. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:517-523. DOI: <http://dx.doi.org/10.15585/mmwr.mm7114e1>

Ďakujem za pozornosť

