Statement regarding the potential risk of thrombotic/bleeding events after COVID-19 vaccination

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Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ)

Haematology Society of Australia and New Zealand (HSANZ)

Introduction

The THANZ and HSANZ societies recommend that all eligible adults continue to receive their COVID-19 vaccinations and vaccination programs should proceed as per government instruction.

Based on all available data to date, the benefits of COVID-19 vaccination strongly outweigh any potential complications even for patients with a history of blood clots or for those taking blood thinning medications. This is also consistent with advice given by other international professional societies (ISTH) and regulatory authorities (EMA) provided in the links below

https://www.isth.org/news/556057/ISTH-Statement-on-AstraZeneca-COVID-19-Vaccine-and-Thrombosis.htm

https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-prac-investigating-cases-thromboembolic-events-vaccines-benefits

Reports of a rare syndrome of blood clots in conjunction with low platelets, or of clots in blood vessels in the brain (Cerebral Venous Sinus thrombosis, CVST) from Europe have been reviewed by the Australian regulatory authorities - TGA and ATAGI. These clots are rare conditions which can also occur naturally in the absence of vaccination. There is no evidence that clots at typical locations (leg vein thrombosis, pulmonary embolism) are more common after vaccination with the AstraZeneca COVID-19 vaccine than in the age-appropriate normal population.

Given the rarity of cases, vaccination with any COVID-19 vaccine should only be deferred for people who have a history of the following condition, as a precautionary measure, until further information is available:

1. Those with a confirmed medical history of CVST; and/or
2. Those with a confirmed medical history of heparin induced thrombocytopenia (HIT). HIT is usually an immune-mediated complication of treatment with heparin that affects platelet function. A HIT-like mechanism is being investigated as a potential, but unconfirmed, pathway to occurrence of CVST post COVID-19 vaccination.

See TGA and ATAGI advice links below

https://www.tga.gov.au/alert/astrazeneca-chadox1-s-covid-19-vaccine

https://www.health.gov.au/news/atagi-statement-and-clinical-guidance-on-astrazeneca-covid-19-vaccine-following-european-medicines-agency-ema-safety-review

https://www.health.gov.au/news/atagi-statement-for-health-care-providers-on-suitability-of-covid-19-vaccination-in-people-with-history-of-clotting-conditions

Clinical advice for Health Professionals

- Flu-like symptoms such as joint, muscle and headache that persist for 1–2 days after vaccination are a common side effect and are not a cause for concern.
- Patients who develop a persistent or recurrent headache after vaccination (particularly in the first 14 days and persisting for more than 24 hours and unresponsive to simple analgesics) should be evaluated in detail with a low threshold for detailed brain imaging. D-dimer of <0.5 mg/L has strong negative predictive value for cerebral venous sinus thrombosis.
- Vaccination should only be avoided in patients with a confirmed history of CVST or HITS until further information is available.
- Vaccination is recommended for people with deep venous thrombosis and/or pulmonary embolism; people with risk factors for thrombosis (such as use of oral contraceptives or smoking); people with thrombocytopenia (low platelets); people with known thrombophilic disorders; people on anticoagulants (e.g. warfarin) and people with a history of cardiovascular disease (such as myocardial infarction or stroke).
- Thromboses should be investigated and treated on their merits as per the treating team with comprehensive testing for other causes such as anti-phospholipid antibody syndrome. In the event of thrombocytopenia and / or evidence of thrombosis after vaccination, testing for heparin-induced thrombocytopenia (HIT) should also be carried out regardless of previous exposure to heparin. Consult a haematologist or a physician with expertise in thrombosis for decisions on alternative anticoagulation.
- Until (autoimmune) HIT has been ruled out, if the clinical situation, availability and experience permit, anticoagulation with heparins should be avoided and alternative, HIT-compatible preparations should be used. An (autoimmune) HIT is formally excluded only if the functional confirmation test (e.g. serotonin release assay or similar) turns out negative.
- Patients with pre-existing thrombotic problems (other than CVST or HITS) who are vaccinated should be monitored very closely after vaccination, as should those who are have pre-existing thrombocytopenia for any reason. Treatments for worsening thrombocytopenia should be discussed with haematologist or a physician with expertise in treating these disorders as there is potential for use of agents such as intravenous immunoglobulin.
- Patients with the rare complement-driven disorders (on treatment or not) require detailed discussions with experts in these rare diseases on timing of vaccination and monitoring after vaccination.
- The COVID-19 vaccine is given as an injection into the upper arm (intramuscular). Individuals taking direct oral anticoagulation (apixaban, dabigatran and rivaroxaban), warfarin in therapeutic INR range, full dose heparin or fondaparinux injections can all receive the COVID-19 vaccination. Vaccinating prior to the next dose of direct oral anticoagulant may be considered rather than immediately after taking the agent. It is generally safe to administer the vaccine as an intramuscular injection and local pressure for 5mins can reduce risk of bruising at the site.

Please report any adverse events following immunisation using the following link

https://www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine

Please visit the TGA and ATAGI websites for updates on vaccine information.