Editorial

Warm Greetings on the eve of World Sickle Cell Awareness Day (19th June 2021)!

A recent study predicted that a third wave of Covid-19 may be there but much less people will be affected than the second waive as because by then more people will be vaccinated. Another study conducted jointly by WHO and AIIMS reveals that there is no reason that more children below 18 will be affected in comparison to the adults. This finding has been based on a seroprevalence study done in five states on a sample size of 10,000. Covid -19 seroprevalence in the age group below 18 is 55.7 per cent and above 18 is 63.5 per cent. Children will not be disproportionately affected in the third wave, as it was projected, because they also have the same level of antibody. Overall, a large number of people have developed resistance against Covid-19.

Earlier a section of media was predicting that a third wave of Covid-19 may be there in India in the month of October and may affect more children below 18 years. This prediction had no scientific basis but relied on perception of some so called experts. Recently a section of public media is spreading some misguiding information which may develop wrong perception about Covid vaccination resulting apathy to Covid vaccination. These incidents demand more responsible behavior from the public media for the wellbeing of the society.

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New Drug: Aducanumab-avwa injection (Aduhelm), for intravenous use

INDICATIONS AND USAGE: ADUHELM is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

DOSAGE AND ADMINISTRATION: • Titration is required for treatment initiation. • The recommended maintenance dosage is 10 mg/kg administered as an intravenous infusion over approximately one hour every four weeks. (2.1) • Obtain a recent (within one year) brain MRI prior to initiating treatment. (2.2, 5.1) • Obtain MRIs prior to the 7th and 12th infusions. If radiographic severe ARIA-H is observed, treatment may be continued with caution only after a clinical evaluation and a follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H). (2.2, 5.1) • Dilution in 100 mL of 0.9% Sodium Chloride Injection, USP, is required prior to administration. (2.4) • Administer as an intravenous infusion over approximately one hour via a 0.2 or 0.22 micron in-line filter.

DOSAGE FORMS AND STRENGTHS: Injection: • 170 mg/1.7 mL (100 mg/mL) solution in a single-dose vial (3) • 300 mg/3 mL (100 mg/mL) solution in a single-dose vial

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: • Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated. (2.2, 5.1) • Hypersensitivity Reactions: Angioedema and urticaria have occurred. If a hypersensitivity reaction occurs, promptly discontinue the infusion of ADUHELM and initiate appropriate therapy.

ADVERSE REACTIONS: Most common adverse reactions (at least 10% and higher incidence compared to placebo): ARIA-Edema, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, and fall. (6.1) Ref. USFDA

Gabapentin, Pregabalin Risk of dizziness, somnolence, abuse and dependence

The Medsafe has announced that Gabapentin and Pregabalin should not be used with central nerve system (CNS) depressant (e.g. opioids) due to the risk of dizziness, somnolence, abuse and dependence. Gabapentin and Pregabalin are indicated for the treatment of neuropathic pain. Gabapentinoids are not licensed to treat other types of pain. Patients should not drive or operate complex machinery until it is known whether the medicine affects the ability to perform the activities. Dizziness and somnolence were the most commonly reported reasons for treatment discontinuation. Cases of abuse and dependence have also been reported with the use of Gabapentin and Pregabalin in New Zealand and in other countries. Concurrent treatment with opioids and Gabapentinoids increases the risk of abuse and dependence. Up to June 2020, the Centre for Adverse Reactions Monitoring (CARM) received 50 adverse reaction reports for Pregabalin (7 cases for withdrawal syndrome) and 248 reports for Gabapentin (7 cases for withdrawal syndrome).

Reference: Prescriber Update, Medsafe, March 2021 (www.medsafe.govt.nz/)

Interaction between Vildagliptin and ACE inhibitors increased risk of angioedema

The Medsafe has announced that combined use of vildagliptin and an angiotensin-converting enzyme (ACE) inhibitor increases the risk of angioedema, compared to use of either medicine alone. Vildagliptin is indicated for the improvement of glycemic control in type 2 diabetes. ACE inhibitors are indicated for treatment of diabetic nephropathy. Since 2018, the CARM has received four reports of angioedema that started vildagliptin use. In two cases, the patients were already taking an ACE inhibitor when vildagliptin was initiated.
COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19)

1. Risk of anaphylaxis and hypersensitivity Europe.

The Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that the product information for COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) should be updated to include anaphylaxis and hypersensitivity as adverse events with an unknown frequency. Additionally, existing warnings should be updated to reflect that cases of anaphylaxis have been reported. COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) is indicated to prevent COVID-19. Anaphylaxis is a known adverse reaction and is already included in the risk management plan for the product as a potential risk. The update is based on a review of 41 reports of possible anaphylaxis among approximately five million vaccinated individuals in the UK. The PRAC considered that a link to the vaccine was likely in at least some of these cases.


2. Possible link to very rare cases of unusual blood clots with low blood platelet counts Europe.

The PRAC has concluded that unusual blood clots with low blood platelets should be listed as very rare adverse effects of COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19). Most cases have occurred in women under 60 years of age within two weeks of vaccination. Specific risk factors have not been confirmed. The PRAC noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) together with low levels of blood platelets. The PRAC reviewed 62 cases of CVST and 24 cases of splanchnic vein thrombosis reported in EudraVigilance. The cases came mainly from the European Economic Area and UK, where around 25 million people had received the vaccine. The combination of blood clots and low blood platelets is an immune response, leading to a condition similar to one sometimes seen in patients treated with heparin. Health-care professionals should tell people receiving the vaccine that they must seek medical attention if they develop symptoms of blood clots, neurological symptoms or petechiae.


Pregabalin Risk of severe respiratory depression

The MHRA has announced that the product information for pregabalin (Lyrica®) will be amended to include new warnings for respiratory depression. Pregabalin is indicated for the treatment of peripheral and central neuropathic pain with partial seizures and for generalized anxiety disorder in adults. Use of pregabalin with opioid medicines or other central nervous system (CNS) depressant medicines has been previously associated with reports of respiratory failure, coma and deaths. A recent European review considered reports of severe respiratory depression thought to be related to the action of pregabalin alone on the CNS. Similar warnings are already in place for gabapentin (Neurotonin®) and other gabapentinoids medicines. Health-care professionals should consider whether adjustments are necessary for patients at higher risk of respiratory depression including those with compromised respiratory function and aged older than 65 years.

Reference: Drug Safety Update, MHRA, 18 February 2021 (www.gov.uk/mhra) (See also WHO Pharmaceuticals Newsletter No.1, 2020: Risk of serious breathing problems in US; No.6, 2017: Risk of severe respiratory depression in UK;
US Govt. to invest $3.2bn to develop Pills to treat Covid

The US is taking another medical moon shot to beat the pandemic, plowing in $3.2 billion to develop antiviral pills to treat Covid-19 infections. If all goes well, some of those pills might become available by the end of this year.

The new programme, coming on top of the $18 billion success story that resulted in effective vaccines in record time, will create platforms that will initially target corona viruses, and then could be expanded to other viruses with pandemic potential – helping to better prepare the nation for future viral threats, the US department of health and human services announced on Thursday.

The administration had already kicked off the programme by announcing that it would procure more than 1.5 million regimens of a Merck investigational antiviral treatment, should it receive emergency use authorization. The DHHS revealed that 19 therapeutic agents have already been prioritized for testing in rigorous trials for outpatients and inpatients with Covid-19. Having additional FDA-authorized antiviral medicines available within a year would be a major breakthrough in ongoing efforts to combat Covid-19.

The new funding appears in part to be a course correction after the Trump administration’s Operation Warp Speed invested heavily in vaccines with less emphasis on other treatments. Oral therapies will be easier to produce, transport, store, and administer. “New antivirals that prevent serious Covid-19 illness and death, especially oral drugs that could be taken at home early in the course of disease, would be powerful tools for battling the pandemic and saving lives,” said Anthony Fauci, chief medical adviser to US President, whose experience in helping develop anti-HIV pills underscores the current initiative.

Source: Economic Times