Physician connect

Vol 2 | Issue 26 | 2021

Dear Doctor,

Greetings from Micro Labs Limited. We are happy to bring you 'Physician connect' which contains latest and interesting news in the field of Medicine

This issue contains

- Safety and Efficacy of NVX-CoV2373 (Novavax), COVID-19 Vaccine
- Homocysteine predicts vascular target organ damage in hypertension and may serve as guidance for first-line antihypertensive therapy
- A Case Report of Tongue Discolouration

Should you require any specific article or medical information, please feel free to contact us at medicalservices@microlabs.in

Looking forward to your valuable feedback

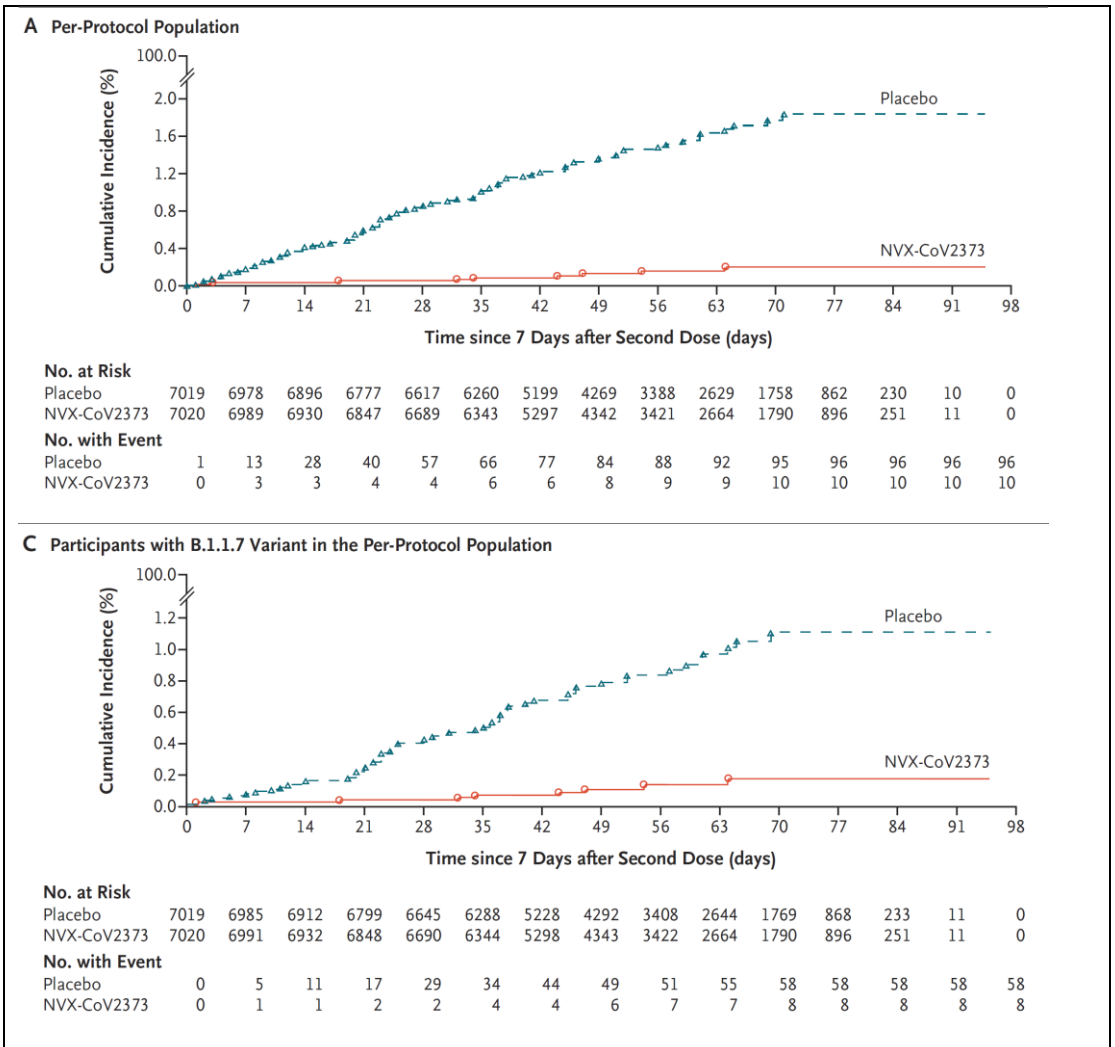
Best Regards,

Medical Team, Micro Labs Limited

Safety and Efficacy of NVX-CoV2373 (Novavax), COVID-19 Vaccine

More than a year after its emergence as a global pandemic, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has been associated with significant health burden. Early clinical data from studies of the NVX-CoV2373 vaccine (Novavax), a recombinant nanoparticle vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that contains the full-length spike glycoprotein of the prototype strain plus Matrix-M adjuvant, showed that the vaccine was safe and associated with a robust immune response in healthy adult participants. Additional data were needed regarding the efficacy, immunogenicity, and safety of this vaccine in a larger population. In this phase 3, randomized, observer-blinded, placebo-controlled trial conducted at 33 sites in the United Kingdom, we assigned adults between

the ages of 18 and 84 years in a 1:1 ratio to receive two intramuscular 5-µg doses of NVX-CoV2373 or placebo administered 21 days apart. The primary efficacy end point was virologically confirmed mild, moderate, or severe SARS-CoV-2 infection with an onset at least 7 days after the second injection in participants who were serologically negative at baseline.



Kaplan–Meier Plots of Efficacy of NVX-CoV2373 Vaccine against Symptomatic Covid-19.
Shown is the cumulative incidence of symptomatic Covid-19 in the per-protocol population (Panel A), and the perprotocol population with the B.1.1.7 variant (Panel C).
The timing of surveillance for symptomatic Covid-19 began after the first dose in the intention-to-treat population and at least 7 days after the administration of the second dose in the per-protocol population (i.e., on day 28) through approximately the first 3 months of follow-up.

A total of 15,187 participants underwent randomization, and 14,039 were included in the per-protocol efficacy population. Of the participants, 27.9% were 65 years of age or older, and 44.6% had coexisting illnesses. Infections were reported in 10 participants in the vaccine group and in 96 in the placebo group, with a symptom onset of at least 7 days after the second injection, for a vaccine efficacy of 89.7% (95% confidence interval [CI], 80.2 to 94.6). No hospitalizations or deaths were reported among the 10 cases in the vaccine group. Five cases of severe infection were reported, all of which were in the placebo group. A post hoc analysis showed an efficacy of 86.3% (95% CI, 71.3 to 93.5) against the B.1.1.7 (or alpha) variant and 96.4% (95% CI, 73.8 to 99.5) against non-B.1.1.7 variants. Reactogenicity was generally mild and transient. The incidence of serious adverse events was low and similar in the two groups. A two-dose regimen of the NVX-CoV2373 vaccine administered to adult participants conferred 89.7% protection against SARS-CoV-2 infection and showed high efficacy against the B.1.1.7 variant.

Source: Heath PT et al. N Engl J Med. 2021 Jun 30. doi: 10.1056/NEJMoa2107659.

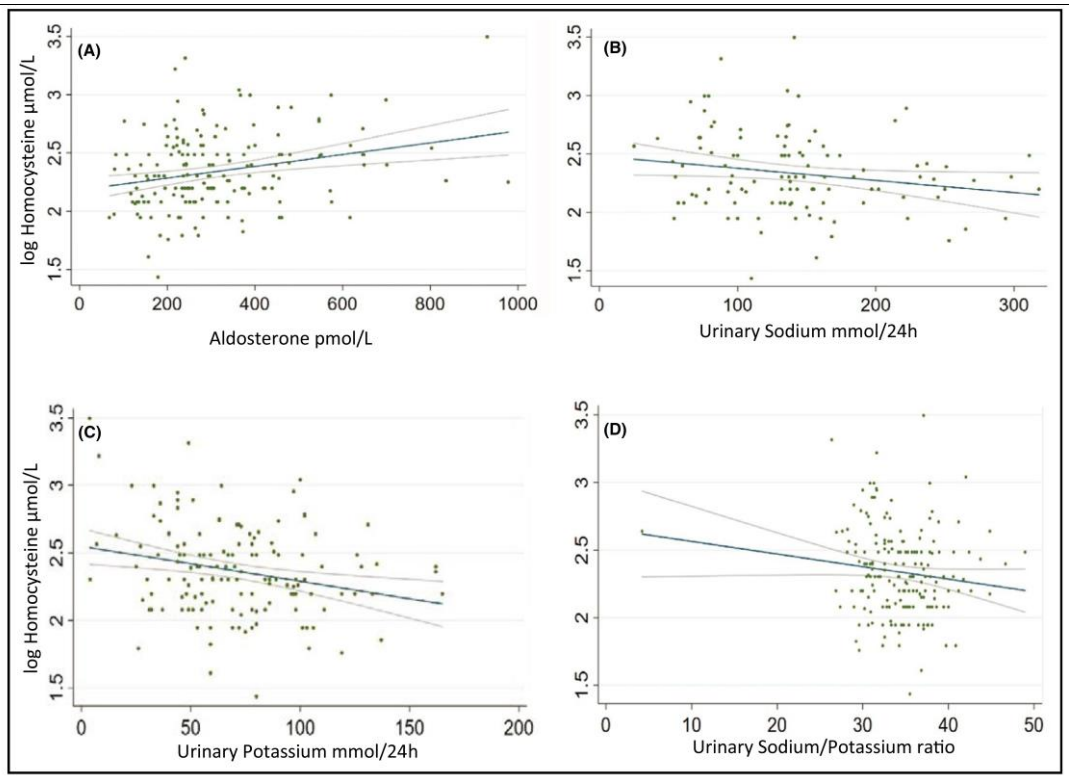
Homocysteine predicts vascular target organ damage in hypertension and may serve as guidance for first-line antihypertensive therapy

Homocysteine is an independent risk factor for cardiovascular and cerebrovascular disease and has been proposed to contribute to vascular dysfunction. We sought to determine in a real-world clinical setting whether homocysteine levels were associated with hypertension mediated organ damage (HMOD) and could guide treatment choices in hypertension.

This was a cross-sectional analysis of prospectively collected data in 145 hypertensive patients referred to our tertiary hypertension clinic at Royal Perth Hospital and analyzed the association of homocysteine with HMOD, renin-angiotensin-aldosterone system (RAAS), and RAAS blockade. The

average age of participants was 56 ± 17 years, and there was a greater proportion of males than females (89 vs. 56).

Regression analysis showed that homocysteine was significantly associated with PWV (β = 1.99; 95% CI 0.99-3.0; p < .001), albumin-creatinine ratio (lnACR: β = 1.14; 95% CI 0.47, 1.8; p < .001), 24 h urinary protein excretion (β = 0.7; 95% CI 0.48, 0.92; p < .001), and estimated glomerular filtration rate (β = -29.4; 95% CI -36.35, -22.4; p < .001), which persisted after adjusting for potential confounders such as age, sex, 24 h BP, inflammation, smoking, diabetes mellitus (DM), and dyslipidemia.

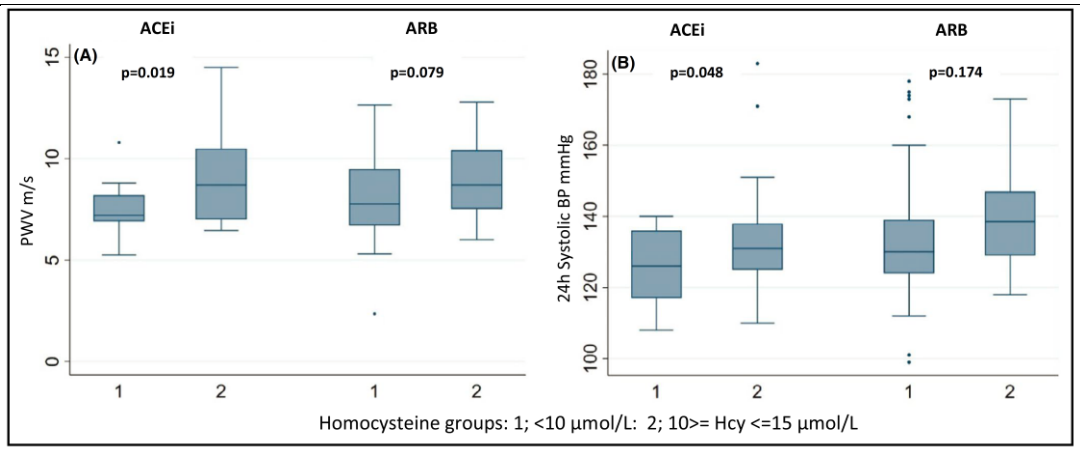


Homocysteine is associated with increased RAAS signaling, as assessed by serum aldosterone concentration and systemic salt retention.
Scatterplots of log homocysteine against the measures of RAAS including the unadjusted linear regression model fits (blue line) with the mean (gray line).
(A) Aldosterone; (B) 24 urinary sodium excretion; (C) 24 urinary potassium excretion; (D) 24 urinary sodium/ potassium ratio

Physician connect

Vol 2 | Issue 26 | 2021

A positive predictive relationship was observed between plasma homocysteine levels and PWV, with every 1.0 µmol/L increase in homocysteine associated with a 0.1 m/s increase in PWV. Homocysteine was significantly associated with elevated aldosterone concentration (β = 0.26; p < .001), and with attenuation of ACEi mediated systolic BP lowering and regression of HMOD compared to angiotensin receptor blockers in higher physiological ranges of homocysteine. Our results indicate that homocysteine is associated with hypertension mediated vascular damage and could potentially serve to guide first-line antihypertensive therapy.



Homocysteine is associated with attenuation of ACEi mediated systolic BP lowering and regression of HMOD. Boxplot comparing the influence of antihypertensive therapy. (A) Pulse wave velocity (PWV); (B) Systolic blood pressure (SBP) in homocysteine groups

Source: Carnagarin R et al. J Clin Hypertens (Greenwich). 2021 Jun. doi: 10.1111/jch.14265. Epub ahead of print. PMID: 34137162.

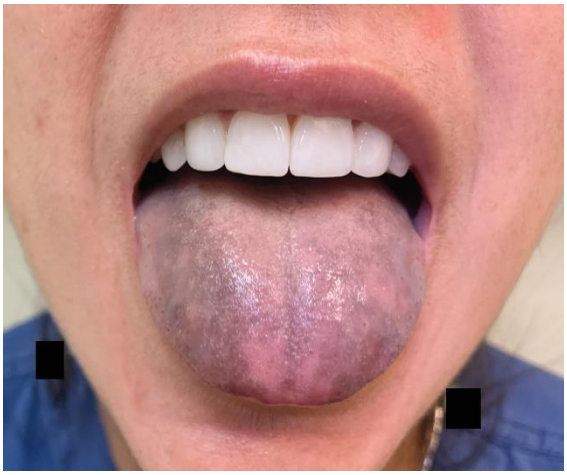
A Case Report of Tongue Discolouration

A 33-year-old woman with celiac disease presented to the dermatology clinic with a 3-week history of painless discoloration of the tongue. She reported that she had not used tobacco or bismuth compounds or consumed colored foods or candies, and she had no amalgam fillings. A progesterone-releasing intrauterine device had been placed in the patient 3 years earlier for

Physician connect

Vol 2 | Issue 26 | 2021

contraception, and she had been taking no other medications. She reported mild fatigue but otherwise felt well. Physical examination revealed hyperpigmented reticular patches on the dorsolateral aspects of her tongue, with sparing of the buccal mucosa, palate, gingiva, and other mucosa. Laboratory studies were notable for a normal complete blood count, a normal comprehensive metabolic panel, and normal vitamin B12 and thyrotropin levels. A cosyntropin stimulation test showed an insufficient adrenal response, with a baseline cortisol level of 7.9 µg per deciliter (218 nmol per liter), a 30-minute cortisol level of 9.5 µg per deciliter (262 nmol per liter), and a 60-minute cortisol level of 7.5 µg per deciliter (207 nmol per liter); the corticotropin level, measured in the afternoon, was elevated at 1102 pg per milliliter (243 pmol per liter) (reference value, <20 pg per milliliter [<4 pmol per liter]).



A 21-hydroxylase antibody test was positive, a finding consistent with a diagnosis of autoimmune adrenal insufficiency. In primary adrenal insufficiency, skin hyperpigmentation is often generalized and involves sun-exposed areas, the palmar creases, nail beds, and mucous membranes; isolated tongue discoloration is less common. Daily treatment with oral hydrocortisone was initiated, and she was counseled regarding the symptoms of adrenal crisis and the need for lifelong therapy. Within 4 to 8 weeks after the initiation of treatment, the tongue hyperpigmentation had resolved.

Source: Seeker P et al. N Engl J Med 2021; 384:e102. DOI: 10.1056/NEJMicm2100706