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Review of Literature Omicron- 'Variant Of Concern'

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ABSTRACT-
On 26 Nov 2021, WHO named B.1.1.529 as Omicron and classified it as a 'Variant of Concern'. On 30 Nov 2021, The United States designed Omicron as a Variant of Concern. WHO classified Omicron as a variant of concern based on epidemiological data indicating increase in infections in South Africa with detection of Omicron. European centre for Disease Prevention and Control classified Omicron as variant of concern due to concerns "regarding immune escape and potentially increased transmissibility compared to Delta variant." It is of concern due to detection of cases in multiple countries, rapid transmission as replacement of Delta as predominant variant in South Africa, number and location of substitutions in spike proteins, reduction in neutralization by vaccines and convalescent sera and certain monoclonal antibody treatments.

Keywords: Omicron, immune escape, increased transmissibility, increased mutations, antibody sensitivity, increased ACE binding, neutralization of vaccines, variant of concern.

ORIGIN[2]-

The Novel coronavirus was identified from an outbreak in Wuhan, Hubei Province in December 2019 and declared as a pandemic on 11 March 2020. International Committee on Taxonomy of Viruses (ICTV) announced SARS-COV-2 as name of new virus on 11 Feb 2020. World Health Organization (WHO) announced Covid-19 as the name of new disease on 11 Feb 2020. As of 8 May 2022, over 514 million confirmed cases and over 6 million deaths have been reported globally due to Covid-19.

On 24 Nov 2021, a new variant was reported to WHO which was first detected in specimen collected on 11 Nov2021 in Botswana and on 14 Nov2021 in South Africa. On 26 Nov2021, WHO named B.1.1.529 as Omicron and classified it as a variant of concern. On 30 Nov2021, The United States designed Omicron as a Variant of Concern. On 1 Dec2021, first confirmed U.S case of Omicron identified and on 21 Dec2021, BA.2 was first identified in United States from sample collected on 14 Dec2021 in New Jersey.[2]

VARIANT OF CONCERN[1]-

Variants may be classified as variants being monitored, variants of interest, variants of concern and variants of high consequence. A variant of concern is Omicron. Delta is another variant of concern.Variants of Interest can be defined as -A SARS-COV-2 variant: with genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; AND identified to cause significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of casesover time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.

A variants of concern can be defined as -A SARS-COV-2 variant that meets the definition of a VOI and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance: Increase in transmissibility or detrimental change in COVID-19 epidemiology; OR Increase in virulence or change in clinical disease presentation; OR Decrease in effectiveness of public health and social measures of available diagnostics, vaccines, therapeutics.[1]

VARIANT OF CONCERN[1]			
WHO Label	Pango lineage	Earliest documented samples	Date of designation
Delta	B.1.617.2	India, Oct-2020	VOI: 4-Apr-2021 VOC: 11-May-2021
Omicron(Including	B.1.1.529	Multiple countries, Nov-2021	VUM: 24-Nov-2021

BA.1, BA.2, BA.3, BA.4, BA.5)			VOC: 26-Nov-2021
PREVIOUSLY CIRCULATING VOCs			
WHO Label	Pango lineage	Earliest documented samples	Date of designation
Alpha	B.1.1.7	United Kingdom, Sep-2020	VOC: 18-Dec-2020 Previous VOC: 9-Mar-2022
Beta	B.1.351	South Africa, May-2020	VOC: 18-Dec-2020 Previous VOC: 9-Mar-2022
Gamma	P.1	Brazil, Nov-2020	VOC: 11-Jan-2021 Previous VOC: 9-Mar-2022
PREVIOUSLY CIRCULATING VOIs			
WHO Label	Pango lineage	Earliest documented samples	Date of designation
Epsilon	B.1.427 B.1.429	United States of America, Mar-2020	VOI: 5-Mar-2021 Previous VOI: 6-Jul-2021
Zeta	P.2	Brazil, Apr-2020	VOI: 17-Mar-2021 Previous VOI: 6-Jul-2021
Eta	B.1.525	Multiple countries, Dec-2020	VOI: 17-Mar-2021 Previous VOI: 20-Sept-2021
Theta	P.3	Philippines, Jan-2021	VOI: 24-Mar-2021 Previous VOI: 6-Jul-2021
Iota	B.1.526	United States of America, Nov-2020	VOI: 24-Mar-2021 Previous VOI: 20-Sept-2021
Kappa	B.1.617.1	India, Oct-2020	VOI: 4-Apr-2021 Previous VOI: 20-Sept-2021
Lambda	C.37	Peru, Dec-2020	VOI: 14-Jun-2021 Previous VOI: 9-Mar-2022
Mu	B.1.621	Colombia, Jan-2021	VOI: 30-Aug-2021 Previous VOI: 9-Mar-2022

OMICRON[3]-

WHO classified Omicron as a variant of concern based on epidemiological data indicating increase in infections in South Africa with detection of Omicron. European centre for Disease Prevention and Control classified Omicron as variant of concern due to concerns "regarding immune escape and potentially increased transmissibility compared to Delta variant." It is of concern due to detection of cases in multiple countries, rapid transmission as replacement of Delta as predominant variant in South Africa, Number and location of substitutions in spike proteins, reduction in neutralization by vaccines and convalescent sera and certain monoclonal antibody treatments. The threat posed by Omicron can be summarized in four basic key questions 1) How transmissible is the Omicron variant 2) How well vaccines and prior infection protect against infection, transmission, clinical features and death 3) Virulency of variant compared to other variants 4) How population understand these dynamics, perceive risk and follow control measures, including public health and social measures (PHSM).[3]

OMICRON- STRUCTURAL CHARACTERISTICS[2,5]-

Omicron has higher number of mutations including 26-32 mutations in the spike protein

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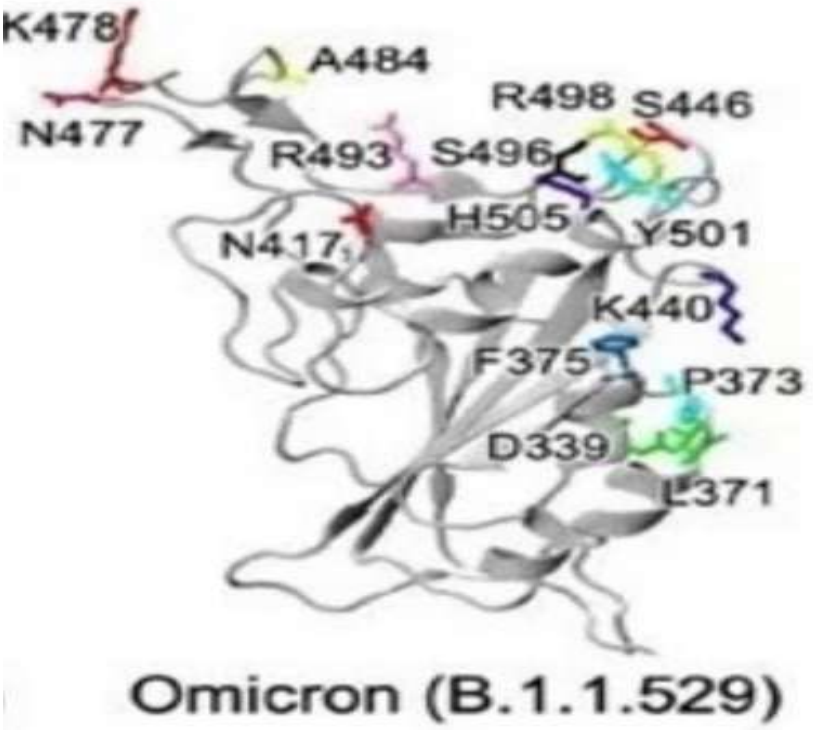
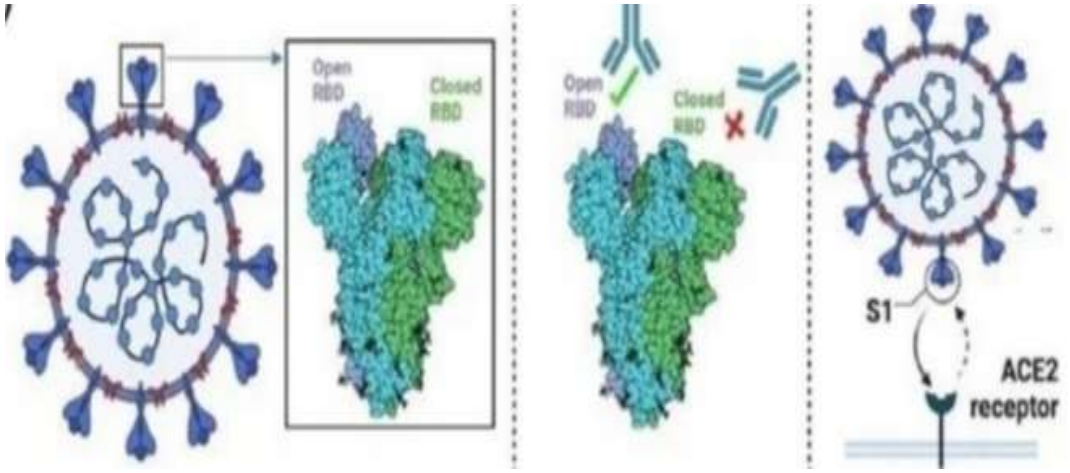
some of which are associated with higher transmissibility and have humoral escape potential. Every spike on a coronavirus, has three identical proteins twisted together looking like a head of broccoli with three stalks. Each stalk has receptor binding domain (RBD), the N-terminal domain (NTD), and the furin cleavage site (FCS). Spike protein of Omicron has 30 amino acid substitutions, 3 small deletions and one small insertion. The key amino acids in Receptor Binding Domain are nearly 15. They are G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H.[2]



COURTESY- Dr. Sanchari Sinha Dutta, Omicron RBD mutations increase ACE2 binding and reduce antibody sensitivity



COURTESY-Dr. Sanchari Sinha Dutta, Omicron RBD mutations increase ACE2 binding and reduce antibody sensitivity

Analysis of spike protein indicates its increased transmission compared to Delta. N501Y increases binding to ACE2 receptor, Q498 increases binding affinity more, H655Y is proximal to furin cleavage site and increases cleavage and hence helps in transmission. P681H which enhances spike cleavage is also found in Alpha variant.[2]

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Interaction between ACE2 and spike RBD requires RBD to open from closed form spike trimer. During RBD opening, the interdomain hydrogen bonds that holds 3RBDS in closed form trimmer are needed to break. In Omicron, one primary hydrogen bond 4505(A)-F374(B) is lost due to 4505 H mutation and minor hydrogen bonding with multiple residues is lost due to polar to hydrophobic mutation in S371L. It is also observed in S373P and S375F which causes separation in residues by mutation. S371and S375 are potent antibody binding sites and separation causes reduce efficiency of antibody binding thus facilitating Omicron to escape antibody mediated neutralization and high immune escape ability as RBD mutations are located at important epitomes. Unique hydrogen bonds and hydrogen bond pairs indicate more efficient and stable Omicron RBD-ACE2 interaction due to interfacial interactions.[5]

HOST TROPISM[3]-

Cleavage efficiency of Omicron is lower than Wild Type and Delta which leads to impaired fusogenicity and reduced syncytia formation, reducing pathogenicity.

Omicron enters cells via endosomal (TMRPSS-2 Independent) pathway. Efficient cleavage of spike protein is necessary for the virus TMRPRSS-2 dependent entry into human cells; cells that express TMPRSS-2 are abundant in lower respiratory tract compared to upper respiratory tract. Omicron replicates less efficiently compared to Delta in freshly harvested human lung tissue.[3]

CLINICAL FEATURES[6]-

According to a study done on 40 patients infected with SARS-COV-2 Omicron variant in Korea, the clinical characteristics include- Sore Throat, Fever, Headache, Cough, Runny Nose/Corzya, Myalgia, Fatigue/Weakness, Loss of taste or Smell, Nausea, Arthralgia.[6]

SURVEILLIANCE AND TESTING[3]-

Suspected cases of Omicron should be confirmed by sequencing. Targeted sequencing of spike gene (using Sanger sequencing or Next Generation Sequencing) or whole genome sequencing can be used to confirm presence of Omicron.[3]

PCR based screening assays (SNP-Single Nucleotide Polymorphisms) may be useful and should be validated in given setting when used as proxy marker for Omicron. Antigen detection rapid diagnostic tests (Ag-RDT) does not appear to be significantly impacted by Omicron.[3]

Most Omicron variants sequences include deletion in S gene which causes S gene target failure (SGTF) in PCR assays.BA.2 lineages lacks the 69-70 deletion; they will be missed by a screening method called as SGTF. Using SGTF as proxy marker to screen for Omicron will miss lineage lacking the deletion. (BA.2).[3]

SUMMARY OF CURRENT EVIDENCE ON OMICRON[4]-

Domain	Indicator	Main results
Epidemiology	Impact on transmission	Previous analyses of GISAID data[7] consistently showed Omicron having a steadily increasing growth rate advantage over Delta in all countries with sufficient sequence data (last update included data available up to 4 April 2022). Applying this approach yielded results in favour of a growth rate advantage of the Omicron sublineage BA.2 over the sublineage BA.1. However, the recent identification of several sublineages of the Omicron variant does not yet allow for updated estimates to be obtained. A recent modelling study in India[8] that included samples submitted to GISAID found a higher basic reproductive number for BA.2 (2.45, 95% highest posterior density [HPD] intervals: 1.53-3.76) compared to BA.1 (1.70, 95% HPD: 1.43-2.46).

	Impact on disease severity	Omicron had been associated with lower severity when compared to Delta across several settings.[9-13] A recent study conducted in England, United Kingdom[14] reported a lower risk of emergency unit attendance following infection with Omicron compared to infection with Delta (HR: 0.39 (95% CI: 0.30 – 0.51; P<.0001). On the contrary, a study in Indonesia[15] and the United States[16] found no difference in hospitalisation and mortality following infection with Omicron compared to infection with Delta. This suggests that the severity of Omicron infection could vary in different settings, although vaccination coverage, population immunity, age distribution and other factors could influence disease severity.
Immune Response	Impact on reinfection	Higher rates of reinfection were initially reported for Omicron as compared to other SARS-CoV-2 VOCs. However, a protective effect of previous infection was reported in a recent study conducted in the United States of America[17], which found increased antibody titres and neutralisation activity (79.5%) against Omicron among vaccinated solid organ transplant recipients who were previously infected with SARS-CoV-2, compared to those who had no previous infection (34%). Similarly, another study conducted in Canada[18] reported that infection with a different SARS-CoV-2 variant resulted in a reduction in the risk of infection (44%; 95% CI: 38-48) and hospitalisation (81%; 95%CI: 66-89) with Omicron. Previous infection with one of the Omicron sublineages has been suggested as potentially conferring protection against infection with other Omicron sublineages: 94.9% (95% CI: 88.4-97.8%) protection against BA.2 following infection with BA.1, and 85.6% (95% CI: 77.4-90.9%) protection against BA.1 following infection with BA.2.[19]
	Impact on vaccination	Results of vaccine effectiveness (VE) studies should be interpreted with caution because estimates vary with the type of vaccine administered and the number of doses and scheduling (sequential administration of different vaccines).
	Impact on antibody responses	There have been no new studies on antibody responses to BA.2. Previous studies have reported lower neutralising antibody titers to BA.1 and BA.2 compared to the index virus, and similar responses for BA.1 and BA.2.[20,21] Similar non-neutralising antibody responses to BA.1 and BA.2 were also reported in vaccinated individuals.[22] However, another study reported reduced vaccine-induced and infectioninduced neutralization of BA.1 and BA.2, with higher neutralisation activity against BA.2 compared to BA.1.[23] Therefore, these results indicate lower humoral responses to BA.1 and BA.2, but inconsistent findings regarding BA.1 versus BA.2.

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Diagnostic Tools	Impact on PCR assays	BA.1, BA.4 and BA.5 contain the 69-70 deletion, responsible for S-gene target failure. Most BA.2 sequences lack the 69-70 deletion and will be positive for the S-gene target. PCR assays that include multiple gene targets maintain their accuracy to detect Omicron. Specifically, early assessments of several PCR tests predicted limited impact of the Omicron variant (BA.1) on the accuracy of these assays.[24,25]
	Impact on Rapid Diagnostic tests	Though many studies have reported comparable sensitivity of Ag-RDTs to detect Omicron compared to other VOCs or the index virus[26-28], others have shown reduced sensitivity.[29-30]These contradictory findings will require further investigation.
Impact on Treatment	Impact on antivirals	Consistent with preliminary data showing no difference in the effectiveness of antiviral agents (Remdesivir, Molnupiravir, and PF07304814) against the Omicron variant, a recent review reported similar efficacy of antiviral agents against Omicron and previous SARSCoV-2 variants.[31]
	Impact on biologicals	Initially, studies on the effectiveness of monoclonal antibodies for treating patients with Omicron reported conserved neutralizing activity for three broadly neutralizing monoclonal antibodies (sotrovimab, S2X259 and S2H97) and a reduced effectiveness of other monoclonal antibodies.[32-35] However, additional preclinical evidence shows reduced neutralizing activity of sotrovimab against the BA.2 sublineage and lack of efficacy of casirivimab-imdevimab against the BA.1 Omicron sublineage (see WHO Therapeutics living guideline). A recent phase 2 clinical trial[36] found a shorter time to hospital discharge among patients on high titre convalescent plasma compared to patients on standard titre (HR = 1.94 [95% CI 1.05, 3.58], p=0.02).
	Other treatment options	There is no evidence available on the effectiveness of interleukin-6 receptor blockers and corticosteroids for the management of severe patients with Omicron.

THERAPEUTIC INTERVENTIONS[37]-

Therapeutic interventions for management of patients with Omicron associated COVID-19 that target host responses are expected to remain effective.[3]

Tab.Molnupiravir (oral pill) can be effective against Omicron and any SARS-COV-2 variant.

Paxlovid revealed better interim results by reducing hospitalization among high-risk patients treated within three days of symptoms onset by almost 90% with no death reported so far.

Corticosteroids and IL6 Receptors Blockers appear to be effective.

VACCINES[4]-

23 studies from 10 countries assessed the duration of protection of 5 vaccines against the Omicron variant. Finding from these studies expressed reduced Vaccine Effectiveness (VE) of COVID-19 primary series vaccines against the Omicron variant (six studies assessed VE of primary series vaccination only, six assessed VE of a booster dose vaccination only, and 11 assessed both) for all outcomes (Severe disease, symptomatic disease, and infection) that has been observed forother VOCs. In majority of studies VE

estimates against Omicron variant remain higher for severe disease.

Booster vaccination improves VE for all outcomes and all combinations of schedules available, both primary series and booster vaccination.[4]

PREVENTIVE MEASURES[37]-

COVID Appropriate Behaviour (CAB).

Increased Surveillance, Screening/Testing, Genome sequencing,

Rapid and effective screening at international airports (2 RT-PCR within 96 hours of arrival), isolation and monitoring of patients with travel history.

Hospital Wards on standby and Facility of Mass Screening.

Adequate Vaccine Supply and Precautionary jabs for Health workers, Front line workers and people with comorbidities.

Public Awareness for Covid and Omicron and safety measures.

CONFLICTS OF INTEREST-

The Author has no conflict of Interest.

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