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COVID-19 Breakthrough Cases: A Descriptive Study from Pakistan Naval Hospitals

Chaudhry Muhammad Qamar Ul Haq Noor, Wasim Alamgir*, Gulnaz Ahmad, Muhammad Aslam Channa, Muhammad Usman Rafique, Afaq Ahmed*****

Department of Health Care Administration, Medical Directorate, Naval Headquarters, Islamabad Pakistan, *Department of Medicine, General Headquarters, Rawalpindi Pakistan, **Department of Accounting & Finance, Medical Directorate, Naval Headquarters, Islamabad Pakistan, ***Department of Information Security, Medical Directorate, Naval Headquarters, Islamabad Pakistan

ABSTRACT

Objective: To measure the frequency of COVID-19 breakthrough infection in entitled vaccinated clientele of Pakistan Navy.
Study Design: Prospective longitudinal study
Place and Duration of Study: Naval Hospitals at Islamabad and Karachi Pakistan, from Mar to Aug 2021.
Methodology: Who received 04 types of vaccine including Sinopharm (n=18,246), Sinovac (n=10,716), Cansino (n=20,250) and Sputnik vaccine (n=20,000). These individuals were monitored over time for development of COVID-19 infection. Vaccine breakthrough case is defined as an individual who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after completing the authorized SARS-CoV-2 vaccine. The data was collected by the record maintained in hospital statistics office. The data was entered, stored and managed in the central data base as maintained at public health department.
Results: Out of the total 69592 individuals who were inoculated 0.15% (i.e., n=111) cases developed COVID-19 breakthrough infection. Cinopharm showed highest number of breakthrough cases 79(0.43%), Sinovac 19(0.17%), Cansino 07(0.034%) and Sputnik 6(0.0003%). Age wise the highest recorded cases were belonging to less than 39 years followed by 37 cases among individual aging 40 to 65 years, 08 cases in individuals age between 66 to 75 years and 10 cases were diagnosed in people having more than 75 years of age.
Conclusion: Sinopharm vaccination was associated with highest frequency of breakthrough COVID-19 infection. While Sputnik showed the least number of breakthrough COVID-19 infection cases.

Keywords: COVID-19, COVID-19 Breakthrough Infection, Cansino, Sinopharm, Sinovac, Sputnik.

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INTRODUCTION

The emergence of SARS-CoV2 infection has just not caused an ever increasing disease related morbidity and mortality but led developed and emerging economies to suffer due to lockdowns and efforts to reduce the spread of infection.[1] Apart from the real threat our global community is facing the information presented has half-truths with knowledge beyond the understanding of a common man's understanding has led to extremes of behaviors from denial to obsessive compulsiveness.[2] Ever since the advent of COVID-19 in Wuhan, China and its subsequent emergence as a pandemic, scientists had been arduously pursuing all efforts to formulate a vaccine to prevent or modify the outcomes of this disease. The purpose of developing these vaccines was to protect against developing severe disease, hospitalization and death. Success was heralded by the introduction of the first vaccine by Pfizer/ BioNtech and was listed for WHO Emergency Use Listing (EUL) on 31 Dec 2020, followed by the first mass vaccination program in early December 2020.[3]

Keeping astride the global preventive measure of en masse COVID19 inoculation, the Government of Pakistan's COVID-19 vaccination drive began in February 2021, one year after the first case reported in the country. More than 4.5 million people have been fully vaccinated, and more than 18 million people partially vaccinated against COVID-19 so far. Pakistan Armed Forces including Pakistan Navy, commenced their COVID19 vaccination campaign with full vigor and pace, aiming to effectively and efficiently implement the National vaccination policies including vaccine procurement, distribution, storage, administration protocols and especially community mobilization. In Pakistan Navy, 98% of uniform and civilian personnel have been vaccinated by 1st August 2021. The impact of COVID-19 vaccines on controlling the pandemic is dependent on several factors including the effectiveness/efficacy; time invested in vaccine approval, manufacturing and cold-chain

Correspondence: Dr Gulnaz Ahmad, Department of Health Care Administration, Medical Dte, Naval Headquarters, Islamabad Pakistan
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maintenance till delivery and number of people being vaccinated within a time frame.[4-6] Previous data on COVID-19 vaccination efforts have demonstrated high levels of efficacy.[7,5] According to literature reviewed by WHO for two-dose vaccines a good immune response kicks in within two weeks of the first dose.[8] However, it is the second dose that boosts the immune response within a shorter duration of time. An Indian study primarily addressing B.1.617.2 has shown marked reduction in people who have been vaccinated or at least less severe symptomology among subjects who received Coishield and Covaxin vaccination.[9] Similarly another study from US identified 133 individuals who were positive from molecular testing for SARS-CoV2 after mRNA vaccination either demonstrated negative sequencing results (n=24) or minimally symptomatic after vaccination implying a positive effect of vaccination.[10] A detailed search on pakmedinet.com did not yield any local study on COVID-19 breakthrough infections.

It is important to monitor breakthrough cases to identify unexpected trends or clustering in the patients (i.e., demographics, geography, underlying medical conditions, time since vaccine receipt, and clinical severity), the administered vaccine (i.e., type, dosing, lot, storage, and handling), vaccine degradation due to inadequate cold chain management or evolving viral variants.[9,10] While some studies have found that neutralizing antibodies persist for months following natural infection with SARSCoV-2, others have detected some waning immunity over time.

In the backdrop of various evolving viral variants from year-2000, differences in vaccines and generating our own local data a study was planned to measure the COVID- 19 breakthrough infections among our community.

METHODOLOGY

This Prospective longitudinal studywas conducted at Naval Hospitals at Islamabad and Karachi from Mar-2021 to Aug-2021. After approval from the ethical committee. A nonprobability convenience sampling technique was used to collect the samples.

Inclusion Criteria: The target population included subjects who visited any Naval hospitals for vaccination against COVID-19 infection.

Exclusion Criteria: The patients who did not give consent were excluded.

The individuals were evaluated for previous allergies, co-morbid conditions and willingness for recruitment into the vaccination program. All data pertaining to subjects was documented. These individuals were followed overtime and till to date for development of any COVID-19 breakthrough infection diagnosed based upon a molecular test or a Rapid Antigen test. All cases detected as "Reactive" were confirmed by a molecular test i.e., RT-PCR.

"Vaccine COVID-19 breakthrough case" is defined as an individual who has SARS- CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after completing the authorized SARS-CoV-2 vaccine. An acceptable respiratory specimen includes a nasal swab, nasopharyngeal/ oropharyngeal swab. A case will be excluded if they received a COVID-19 vaccine that is not authorized or approved or the respiratory specimen that was positive for SARS-CoV-2 RNA or antigen was collected <14 days after completing vaccination. Vaccines included Sinopharm, Sinovac, Cansino and Sputnik vaccine.

Further data related to patent demographics including age, gender, laboratory confirmation, COVID-19 vaccination history, underlying medical conditions, clinical signs and symptoms, hospitalization, clinical course & outcomes were recorded. Total sample size was 69592.

The data was collected by the record maintained in hospital statistics office. The data was entered, stored and managed in the central data base as maintained at public health department. Data was aggregated across all reported cases and analyzed using excel data sheets.

The statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 28.0. Qualitative variables were summarized as Mean±SD, while qualitative variables were summarized as frequency and percentages.

RESULTS

69,592 individuals have been inoculated in different vaccination centres across Pakistan have used following types of vaccination as (a) SinoVac: 10,716 (15.3%), (b) SinoPharm: 18,246 (26%), (c)Can Sino: 20,250 (29%) and (d)Sputnik: 20,000 (29%). During the study tenure there were 2,152 positive COVID-19 cases (Table). Out of these cases, 480 positive cases (22%) were advised home isolation and 1672 positive cases (78%) were admitted in different Naval hospitals. Age wise segregation of vaccinated showed

<39 years of age: 619(29%), 40- 65 years of age: 792(37%), 65-75 years of age: 687(32%) and >76 years of age: 54(02%). The subjects were also segregated based upon disease severity as: (a) Very mild/ asymptomatic: 469(22%), (b) Mild disease: 853(40%), (c) Moderate: 434(20%) and (d) Severe: 285(13%). There were 285(13%) cases who had known co-morbid conditions. During the course of study, a total of 115(5%) subjects faced fatal outcomes. Out of the 2,152 positive cases, 111 positive cases (5%) are classified as COVID 19 vaccine breakthrough cases. 11(9%) of the breakthrough cases were asymptomatic and were advised home isolation whereas 100 cases (91%) were admitted in designated Naval hospitals. Figure-1 shows "Breakthrough cases" as per age and type of vaccines. Figure-2 demonstrates "Breakthrough cases" as per severity comparison between vaccinated and non- vaccinated case.

Table: Breakthrough Cases Along with Vaccine Wise Distribution among our Data (n=69592)

Vaccine	Total	Breakthrough cases n(%)
Sinopharm	18,246	79(0.43)
Sinovac	10,716	19(0.17)
Cansino	20,250	07(0.034)
Sputnik	20000	06(0.0003)

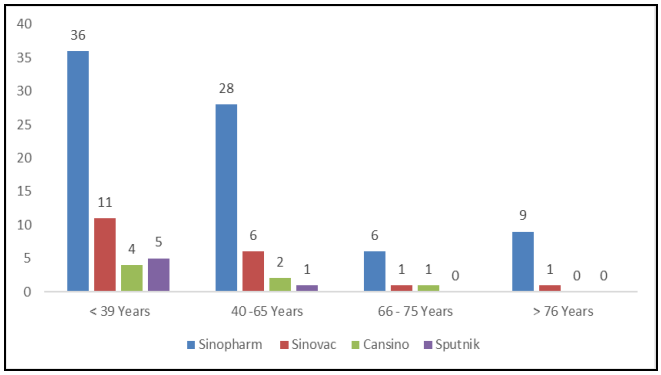

Figure-1: Breakthrough Cases – Age Wise Distribution and Vaccine

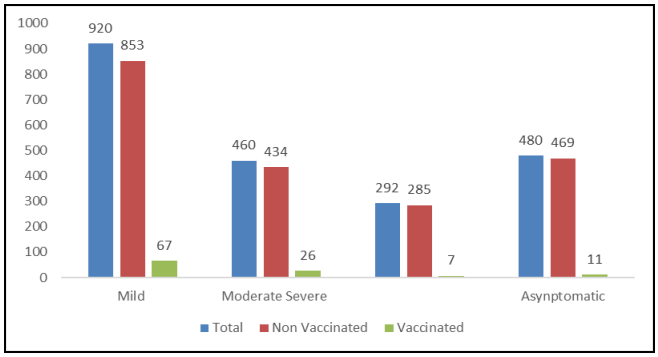

Figure-2: Breakthrough Cases: Severity Comparison with Non-Vaccinated Cases

DISCUSSION

Our study demonstrated that most people who had any category of vaccination were least likely to acquire "COVID-19 Breakthrough Infection". Among the vaccines types utilized for protection against SARS-CoV2 infection, Sinopharm followed by Sinovac demonstrated the highest number of breakthrough infections. Cansino administration in study subjects were least likely to be affected by "COVID-19 breakthrough infection". Sputnik also demonstrated low rate of such infections. While reasons could be multifold but it seems that the inactivated viral vaccines in comparison to viral vector ones which enter the clinical arena later in our part of the world were more effective against the disease as depicted through our results.[11,12] However, the message conveyed through our data without a doubt leads to grasp the reality of vaccine utility in terms of very low infection rates including those having very severe disease. This aspects highlights the facts that no vaccine vs any vaccine drastically supersedes the chances of breakthrough infections, acquiring early herd immunity and possibly the severity. Our findings are in accordance with the earlier work from other authors.[13-15]

In a CDC cumulative vaccine break through data analysis USA, out of 163 million vaccinated people in USA 6,587(0.004%) cases with COVID 19 vaccine breakthrough infection were hospitalized. 62% of these cases reported with mild symptoms, while asymptomatic cases comprised of 19% of total cases and 19% cases had a severe form of disease with 19% fatalities. These fatalities had coexisting chronic ailments/ co-morbids.[9] While our study did not include mRNA vaccines but as the data suggests these next generation vaccine naturally allowing the resistance against the virion may possibly perform better than inactivated vaccines and viral vectors.[16] However, there cost alongwith stringent cold chain management will be a bigger challenge for third world countries which lack wide-scale storage and distribution facilities for such vaccines.[17]

Few limitations in our data must be acknowledged: Firstly, the data is preliminary in nature and very early in the time course of pandemic. There are very few studies on breakthrough infections in COVID-19 infections especially in our region and whenever, they are available they are not comparing the vaccines which we have compared in our study. Furthermore, our study has not addressed other side

effects of vaccination including "Antibody Dependent Enhancement (ADE)" though a very unlikely possibility in SARS-CoV2 infection like dengue RNA virus, still more data is needed to evaluate such like aspects Antibody based vaccines.[18] However, in our clinical experience we had not encountered such side effects.

Our study has significant clinical implications for our population: We feel that this this is the pioneer study evaluating the frequency of COVID-19 breakthrough infections in our region and can guide future authors and policy makers to assess our data and fine tune happenings in alignment to our findings. The vaccine fear mongers may be relieved by the exuberant evidence of vaccination utility in COVID-19. While the quality in our society is measured by the price tag and that may have its own set of pros and cons. However, in comparison to expensive mRNA vaccines, the viral antibody vaccines can provide reasonable protection, though slightly less than Cansino and Sputnik and mRNA vaccines. Still the authors believe all these vaccines provide a reasonably better and affordable degree of immunity against COVID-19 infection.

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CONCLUSION

Casino and Sputnik has resulted lower COVID-19 breakthrough infections than Sinopharm and Sinovac. However, all vaccines were able to reduce the number and degree of infections. Safe and effective COVID19 vaccines are a game-changing tools to allow human kind to launch a real-time defense against ongoing pandemic especially by breaking the chain of transmission. With millions of unvaccinated people around the world new variants will emerge, resulting in vaccinated people contracting new COVID- 19 variants. We in Pakistan should also allow and get involved in "Vaccination for all approach".

DECLARATION

Ethical approval: Our study "COVID-19 Breakthrough Cases: A Descriptive Study From Pakistan Nval Hospital" had a formal ethical approval by hospital authorities.

Participant's approval: Study participants were formally consented and explained the study protocols, design and study outcome including use of data for research purpose and confidentiality issues.

Availability of data and materials: The data outputs can be made available once requested formally to corresponding author.

Conflict of Interest: None.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

CMQUHN & WA: Data acquisition, data analysis, critical review, approval of the final version to be published.

GA & MAC: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MUR & AA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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