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RESEARCH PAPER

Impact of second wave of COVID-19 pandemic on the hesitancy and refusal of COVID-19 vaccination in Puducherry, India: a longitudinal study

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ABSTRACT

The second wave of COVID-19 pandemic has spread rampantly throughout India between April and May 2021, leading to high mortality rates. Identifying any change in the rate of vaccine hesitancy or refusal due to such mass casualty events will provide further insights on developing appropriate risk communication strategy. Hence, this study was undertaken to identify the vaccine hesitancy and refusal before and during the second wave of COVID-19 pandemic. We conducted a longitudinal study among 900 adults to know about their vaccine hesitancy and refusal pattern before (March 2021 – round-1) and during the second wave of COVID-19 pandemic (May 2021 – round-2). Telephonic interview was conducted using the pre-tested semi-structured questionnaire. There was an increase in the vaccine hesitancy (27.8% in round-1 to 32.7% in round-2) and refusal (25.6% in round-1 to 35.6% in round-2) during the second wave of pandemic in Puducherry. In adjusted analysis, vaccine hesitancy was found to increase by 1.19 times during the round-2 survey compared to round-1 survey (aIRR = 1.19; 95%CI: 1.03–1.37). We also found that the vaccine refusal increased by 1.40 times during the round-2 survey compared to round-1 survey (aIRR = 1.40; 95%CI: 1.22–1.62) after adjusting for age, place of residence, and occupation. We found that the confidence in COVID-19 vaccine efficacy and safety has declined over time leading to increase in the vaccine hesitancy and refusal in our study cohort, with more than one-third refusing to get themselves vaccinated during the second wave of pandemic.

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Introduction

The COVID-19 pandemic continues to wreak havoc across countries with around 170 million confirmed cases and claiming the lives of over 4 million people globally.[1] In India, the death toll reached more than 3 lakhs by mid-June 2021, with 1.3% of reported cases culminating in death.[2] But global efforts to generate effective treatment options and preventive solutions were promptly undertaken, which aided in considerable reduction of mortality rate. The major turning point in these efforts to control the infections was the development of vaccines against COVID-19, with countries striving to accelerate the production and vaccinate their populations for achieving the herd immunity.

In January 2021, Drugs Controller General of India (DGCI) has issued emergency approval for "Covaxin" and "Covishield" and allowed mass administration in the country.[3] On a priority basis, the vaccination campaign was initially launched among health care workers in the country on high-risk based rollout, which was consequently scaled up to cover general public. So far, around 30 million doses of vaccine have been administered in the country.[2] In order to fully functionalize this vaccination strategy, a prudent approach is essential in devising communication strategies, which ensure transparency and spreads right information about the COVID-19 vaccines. However, in any mass vaccination campaign, hesitancy poses a major threat leading to decline in the coverage of vaccine. The "*Strategic Advisory Group of Experts on Immunization (SAGE)*" defines vaccine hesitancy as "*a delay in acceptance or refusal of vaccines despite availability of vaccine services.*"[4] Many studies conducted around the world have proved that the COVID-19 vaccine availability does not directly translate to vaccine acceptance.[5,6] This points to an intricate interplay of various correlates such as age, gender, risk perception, knowledge, cultural beliefs, etc.[5] It is a complex process, deciphering which would require an in-depth understanding of these factors, which also tend to vary across different geographical regions. Thus, a region-specific understanding of determinants is required to address vaccine hesitancy.

Previous evidences and research have reported that the vaccine hesitancy and refusal differ significantly from country to country.[7] Globally, there was a wide variation in the vaccine hesitancy and refusal ranging from 20% to 90%.[8–10] There was also huge variation over the period of time with alternate increasing and declining trend.[10] Various factors such as risk perception toward COVID-19 infection, trust in the authorities, perception toward vaccine efficacy and safety have influenced such wide variation over time and between the countries.[10] Hence, WHO has proposed that the individual countries should take dynamic responses for identifying the vaccine hesitancy and refusal "hot spots" by utilizing various behavioral and social mediums.[5,11] The national updates and statistical information on COVID-19 form the cornerstone of the COVID-19 vaccination program and its coverage.

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In India, the second wave of COVID-19 pandemic has spread rampantly throughout the country between April and May 2021, leading to high mortality rates and instilled fear among the citizens. Identifying any change in the rate of vaccine hesitancy or refusal due to such mass casualty events will provide further insights on developing appropriate risk communication strategy. Hence, this longitudinal study was conducted to identify the vaccine hesitancy and refusal before and during the second wave of COVID-19 pandemic among the adult population in Puducherry, India.

Methods

Study setting

The Union Territory (UT) of Puducherry is located in southern India with a population of nearly one million. Majority (69.2%) of the residents are urban dwellers with a literacy rate of nearly 85%.[12] This study was conducted in district Puducherry, one of the four districts in the UT. Puducherry had more than 100,000 cases and nearly 1000 deaths due to this COVID-19 pandemic.-[13] The chief COVID-19 control efforts taken in Puducherry to halt this pandemic were stringent lockdown measures, promotion of COVID-19 appropriate behaviors through mass media campaign, and conducted mass vaccination drive in the form of *"Tika Utsav"* (vaccination festival), which has managed to deliver around 372,000 vaccine doses to the general public.[13] Apart from the intensive vaccination drive by means of vaccination festival, Puducherry government has also launched door-to-door vaccination facility, special COVID-19 vaccination camps, etc., to achieve universal coverage of COVID-19 vaccination among adult population. Till July 2021, roughly one-third of the adult population has received at least one dose of COVID-19 vaccination.[13]

Study participants and sampling

All adults aged 18 year and above and residing in Puducherry were eligible to participate in this study. Two rounds of the survey were conducted: first round during March 2021 (before the second wave of COVID-19 pandemic in India) and second round during May 2021 (during the second wave). During the round-1 survey, 900 adults were selected by means of multistage random sampling technique. The district was first stratified into rural and urban region. In urban area, there was a total of 92 wards and in the rural area, a total of 62 villages were present in the district. Twenty-one wards in the urban area and 9 villages in the rural area were chosen randomly, totaling to 30 clusters. Subsequently, 30 households from each cluster were selected using systematic random sampling. One person from each household was selected using KISH technique and they were included in the survey and interviewed (Supplementary Figure 1). The second round of survey was conducted among these same set of participants to identify any change in vaccine hesitancy or refusal. However, 861 adults completed the interview during the second round (response rate = 95.6%).

Data collection procedure and tools

Data collection for this community-based survey was carried out by door-to-door visits during the first round and through telephonic interviews (with the same set of participants) during the second round. Data collection was started after obtaining informed consent from the selected participants. A pre-tested semi-structured questionnaire was used and it consisted of three sections. First section had questions related to socio-demographic details of the participants. Second section had questions assessing the indicators of COVID-19 vaccination eagerness. It was developed from the COVID-19 vaccine communication strategy monitoring indicator proposed by Ministry of Health and Family Welfare, India. (9) Third section had questionnaire from SAGE working group on vaccine hesitancy containing eight questions in Likert scale form to assess vaccine hesitancy.[4] This section also contained the questions related to the assessment of vaccine hesitancy and refusal over time.

Operational definitions

Vaccine hesitancy were assessed using the question:

Do you think that you should take Covid vaccine?

Participants responding "No" were considered to have vaccine hesitancy.

Vaccine refusal was assessed using the question:

Will you take Covid vaccine when it is available?

Those who responded with "No" were considered to be prone for vaccine refusal.

Statistical analysis

Data were entered into EpiCollect5 and analysis was performed using STATA version 14.2 software (StataCorp, CollegeStation, TX, USA). Descriptive statistics used for continuous variables were mean and standard deviation (SD) or median and interquartile range (IQR) depending on the distribution of data, while the categorical variables were summarized as proportions. Vaccine hesitancy and vaccine refusal were interpreted as proportion with 95% confidence interval (CI). Two separate generalized linear models with binomial family and log-link were run for identifying the factors associated vaccine hesitancy and refusal before and during the second wave of COVID-19 pandemic. Adjusted prevalence ratio (aPR) with 95% CI was reported.

We have used generalized estimating equation (GEE) (to account for the within-subject correlation of responses on the outcome variables in longitudinal dataset) applying Poisson regression model with robust error variance to analyze the group-by-time differences of the outcome variables such as vaccine hesitancy and refusal. Sociodemographic factors such as residence, gender, age group, education, occupation, and comorbidities were considered as explanatory variables. Factors significant at a p value less than 0.2 in unadjusted analysis were considered for multivariable model. The backward stepwise method was employed and the model with only

significant variables was considered as the final model. Adjusted incident rate ratio (aIRR) with 95% confidence interval (CI) was reported and p-value less than 0.05 was considered statistically significant.

Results

In total, 900 participants participated and completed the survey during the first round. During the subsequent round, 861 participants completed the survey with loss-to-follow-up rate of 4.3%. Sociodemographic characteristics of the study participants (round-1 and 2) are provided in Table 1. There was no significant difference in the characteristics due to the loss-to-follow up participants during the round-2 of survey.

Table 1. Sociodemographic characteristics of the study participants.

Characteristics	Round-1 (N = 900) n (%)	Round-2 (N = 861) n (%)
Age categories (in year)		
<45	464 (51.6)	447 (51.9)
45–59	251 (27.9)	239 (27.8)
≥60	185 (20.5)	175 (20.3)
Gender		
Male	337 (37.4)	319 (37.1)
Female	563 (62.6)	542 (62.9)
Educational qualification		
No formal education	135 (15.0)	124 (14.4)
Primary	169 (18.8)	164 (19.1)
Secondary	394 (43.8)	379 (44.0)
Higher	202 (22.4)	194 (22.5)
Place of residence		
Urban	632 (70.3)	613 (71.3)
Rural	267 (29.7)	247 (28.7)
Nature of work		
Non-health care worker	872 (96.9)	833 (96.7)
Health care worker	28 (3.1)	28 (3.3)
Co-morbidities		
Present	292 (32.4)	280 (32.5)
Absent	608 (67.6)	581 (67.5)

Table 2. Factors associated with vaccine hesitancy before and during the second wave of COVID-19 pandemic (round 1 and 2 of the survey) in Puducherry.

	Round 1 (N = 900)			Round 2 (N = 861)		
Characteristics	aPR	95%CI	p-value	aPR	95%CI	p-value
Age category (y)						
<45	Ref	-	-	Ref	-	-
45–59	0.60	0.44–0.81	0.001*	1.55	1.23–1.96	<0.001*
≥60	0.83	0.61–1.12	0.23	1.85	1.44–2.37	<0.001*
Place of residence						
Urban	Ref	-	-	Ref	-	-
Rural	1.24	1.01–1.53	0.04*	1.25	1.03–1.52	0.02*
Healthcare worker vs non-healthcare worker						
HCW	Ref	-	-	Ref	-	-
Non-HCW	2.89	0.99–8.44	0.06	2.68	0.92–7.79	0.07
Comorbidity condition						
Absent	1.24	0.94–1.63	0.12	0.98	0.80–1.21	0.86
Present	Ref	-	-	Ref	-	-

Unadjusted model had variables such as age group, gender, education, residence, occupation and comorbidities; out of these, gender and education had p-value more than 0.20 in both round-1 and round-2 survey models and they were excluded from the final multivariable analysis.
aPR, adjusted prevalence ratio.
CI, confidence interval.
*p-value statistically significant.

Table 2 shows the factors associated with vaccine hesitancy before and during the second wave of COVID-19 pandemic (round-1 and round-2 survey) in Puducherry. Unadjusted model was run with the explanatory variables such as age group, gender, education, residence, occupation, and comorbidities. Out of these, gender and education had p-value more than 0.20 in both round-1 and round-2 survey models and they were excluded from the final multivariable analysis. In both round-1 and round-2 survey, people belonging to rural area of residence had significantly higher prevalence of vaccine hesitancy compared to people belonging to urban area of residence ($p < 0.05$). However, there was a change in the magnitude and direction of association between round-1 and round-2 survey with respect to age group. The people belonging to 45–59 y and 60 y and above age groups had lower prevalence of vaccine hesitancy during the round-1 survey. However, there was a significantly higher prevalence of vaccine hesitancy in these age groups compared to younger age groups during the round-2 survey ($p < .05$). The same set of explanatory variables were used to assess the factors associated with vaccine refusal before and during the second wave of COVID-19 pandemic in Puducherry (Table 3).

The factors identified for vaccine refusal and its trend before and during the second wave were similar to the results obtained for vaccine hesitancy. In both the rounds of survey, people belonging to rural area of residence had significantly higher prevalence of vaccine hesitancy compared to people belonging to urban area of residence ($p < 0.05$). There was a change in the magnitude and direction of association between both the rounds of survey with respect to age group. Similar to vaccine hesitancy, the people belonging to 45–59 y and 60 y and above age groups had lower prevalence of vaccine refusal during the round-1 survey. However, during the round-2 survey, there was a

Table 3. Factors associated with vaccine refusal before and during the second wave of COVID-19 pandemic (round 1 and 2 of the survey) in Puducherry.

	Round 1 (N = 900)			Round 2 (N = 861)		
Characteristics	aPR	95%CI	p-value	aPR	95%CI	p-value
Age category (y)						
<45	Ref	-	-	Ref	-	-
45–59	0.59	0.43–0.80	0.001*	1.63	1.28–2.08	<0.001*
60 and above	0.78	0.56–1.08	0.13	1.85	1.41–2.43	<0.001*
Educational qualification						
No formal education				Ref	-	-
Primary				1.45	1.09–1.94	0.01*
Secondary	[Not included in the model]			1.32	0.99–1.76	0.06
Higher				1.51	1.04–2.18	0.03*
Residence						
Urban	Ref	-	-	Ref	-	-
Rural	1.32	1.05–1.64	0.02*	1.23	1.02–1.49	0.03*
HCW vs non-HCW						
HCW	Ref	-	-	Ref	-	-
Non-HCW	2.67	0.92–7.80	0.07	1.88	0.84–4.15	0.12
Comorbidity						
Absent	1.23	0.92–1.64	0.17	1.02	0.84–1.24	0.84
Present	Ref	-	-	Ref	-	-

Unadjusted model had variables such as age group, gender, education, residence, occupation and comorbidities; out of these, gender and education had p-value more than 0.20 in round-1 survey model and were excluded from the final multivariable analysis, while only gender had p-value more than 0.20 in round-2 survey model and it was excluded from the adjusted analysis.
aPR, adjusted prevalence ratio.
CI, confidence Interval.
*p-value statistically significant.

Table 4. GEE models for change in vaccine hesitancy and refusal over time.

	Vaccine hesitant			Vaccine refusal		
Characteristics	aIRR	95%CI	p-value	aIRR	95%CI	p-value
Timepoint 1[#] vs Timepoint 2[$]						
Timepoint 1	Ref	-	-	Ref	-	-
Timepoint 2	1.19	1.03–1.37	0.02*	1.40	1.22–1.62	<0.001*
Age group (in y)						
<45	Ref	-	-	Ref	-	-
45–59	0.97	0.82–1.16	0.76	0.99	0.84–1.17	0.94
60 and above	1.20	1.01–1.43	0.04*	1.14	0.95–1.36	0.15
Residence						
Urban	Ref	-	-	Ref	-	-
Rural	1.28	1.10–1.48	0.001*	1.26	1.09–1.46	0.002*
HCW vs non-HCW						
HCW	Ref	-	-	Ref	-	-
Non-HCW	2.68	1.15–6.28	0.02*	2.04	1.03–4.05	0.04*

Unadjusted model had variables such as age group, gender, education, residence, occupation, timepoint, and comorbidities; out of these, gender, education and comorbidities had *p*-value more than 0.20 and were excluded from the final multivariable model.

aIRR, adjusted incidence rate ratio; CI, confidence Interval; HCW, healthcare workers.

*p-value statistically significant.

[#]Before the second wave of COVID-19 pandemic.

[$]During the second wave of COVID-19 pandemic.

significantly higher prevalence of vaccine hesitancy in these age groups compared to younger age groups ($p < 0.05$). In addition to these factors, educational qualification was also identified to be a significant risk factor for vaccine refusal during the round-2 survey. We found that higher the educational qualification of the participants, more the prevalence of vaccine refusal compared to participants with no formal education during the round-2 survey and it was statistically significant ($p < 0.05$).

Table 4 shows the GEE models for change in vaccine hesitancy and refusal over time after adjusting for the potential confounders. We found that the vaccine hesitancy increased by 1.19 times during the round-2 survey compared to round-1 survey (aIRR = 1.19; 95%CI: 1.03–1.37). We also found that the vaccine refusal increased by 1.40 times during the round-2 survey compared to round-1 survey (aIRR = 1.40; 95%CI: 1.22–1.62) after adjusting for age, place of residence, and occupation.

Supplementary Table 1 shows the trend in the indicators of vaccine eagerness before and during the second wave of COVID-19 pandemic. There was a decline in the participants' perception toward COVID-19 vaccine efficacy (77.3% in round-1 to 72.6% in round-2) and safety (76.3% in round-1 to 67.3% in round-2), which in turn lead to increase in the vaccine hesitancy (27.8% in round-1 to 32.7% in round-2) and refusal (25.6% in round-1 to 35.6% in round-2) during the second wave of pandemic in Puducherry. Supplementary Table 2 shows the in-depth assessment of vaccine hesitancy using SAGE questionnaire during both the rounds of survey. It showed there was a slight decline the participants' perception toward the vaccine efficacy, safety, and trust in information provided by doctors and government.

Discussion

We found that over one-fourth (27.4%) and one-third (35.6%) of the population had hesitancy and reluctance to COVID-19 vaccines. In comparison to the current study finding, countries such as Ecuador (97%),[14] Indonesia (93%),[15] and neighboring countries such as China (88.6%)[16] and Malaysia (94.3%)[17] have reported higher levels of vaccine acceptance. The refusal to COVID-19 vaccine observed in our study was substantially higher compared to the western countries like United States of America (20%).[18] However, studies from Middle East, Russia, Africa, and European region have shown higher level of hesitancy to COVID-19 vaccines.[19] Studies from Bangladesh have reported vaccine hesitancy ranging between 31% and 41.1%, considerably higher than the current study finding.[20–22] This difference in the COVID-19 uptake behavior between the countries could be attributed to factors such as methodological variations (variations in the definitions used to determine vaccine hesitancy, and mode of survey) and sociodemographic variation between the countries (economy, literacy, and cultural differences across the study populations).

In India, there was no previous longitudinal research on COVID-19 vaccine hesitancy. But there are studies assessing the burden of COVID-19 vaccine hesitancy across different states of India. One such study was an online based survey, which showed a wide variation in the burden of COVID-19 vaccine hesitancy across the different states of the country. However, Southern states like Tamil Nadu (cultural and sociodemographic characteristics similar to Puducherry) had the highest vaccine hesitancy (40%) compared to other regions in the country with the lowest being in Uttarakhand (14%).[23]

The results obtained in our study was surprising, given that India was one of the worst affected countries due to COVID-19 pandemic, especially during this second wave. Given the catastrophic health and socioeconomic impact of second wave since April 2021, it was expected to have higher risk perception with consequent decline in the vaccine hesitancy and refusal. However, the findings obtained in our study were contradictory. We found a significant increase in vaccine hesitancy (from 27.8% before the second wave to 32.7% during the second wave) and refusal (25.6% to 35.6%) during the second wave of pandemic compared to the time point before the start of second wave. This increase was also found to be statistically significant even after adjusting for potential confounders.

Reasons for the decline in the vaccine uptake behaviors should be explored as it could be a complex interaction of multiple factors.[24,25] However, one possible reason for such finding, which was explored and identified in our study, was the decline in the participants' perception toward COVID-19 vaccine efficacy (77.3% to 72.6%) and safety (76.3% to 67.3%) before and during the second wave of COVID-19 pandemic. We also identified a decline in other factors related to vaccine hesitancy and refusal such as importance of taking COVID-19 vaccine for self and others, and reliance on the information about vaccine given by healthcare providers.

Several external factors are responsible for such decline in the belief about the vaccines. Given the wider availability and reach of smartphones, a greater number of people have access to the internet connection and social media. Though, this has the capacity to contribute immensely for the self-education of public, a key factor for the decision-making toward vaccination, it can also pose several challenges like misinformation (including the circulation of 'anti-vaxx' messages), incomplete information, complicated and inconsistent scientific information that are

difficult to understand for general public. Now the situation is further complicated, given the emergence of new COVID-19 variants,[26,27] leading to emergence of newer vaccines in the market. Hence, it is important to be considerate and maintain a balance in the communication of known facts and acknowledgment of uncertainties to the public. Clinicians, public health professionals, researchers and pharmaceutical companies should be forthcoming with the research data on the COVID-19 vaccines, making it readily available.[25] Reporting of the adverse events following immunization (AEFI) is an important part of monitoring implementation of the vaccination program. Though, it is important for the documentation and reporting of these events, intense media coverage focusing on these events might discourage the people from vaccinating themselves. Hence, the media should act more responsibly and report such incidents in a transparent manner and weigh the risk-benefits of vaccination, thereby providing unbiased and clear information to the general public. Finally, internet and social media users including the researchers and clinicians should also act responsibly in avoiding the spread of false information or use language that might be misinterpreted and potentially lead to vaccine hesitancy and refusal.

We also found that the vaccine hesitancy and refusal was significantly higher among people aged ≥45 years (including the elderly) and those residing in the rural areas. This was more worrisome as the hesitancy and refusal rates was higher during the second wave of pandemic in these groups, than the rate before the start of second wave. It is a well-known fact that the elderly people and those aged ≥45 years with comorbidities are at higher risk of developing severe form of COVID-19 infection, leading to deaths. In addition, the seroprevalence of COVID-19 infection is higher in urban area compared to rural areas, leaving higher amount of susceptible population in these regions. Hence, higher rate of hesitancy and refusal in rural area again puts lots of people at risk of developing severe form of infection, which in turn increases mortality rates in the country. Hence, the growing trend of hesitancy and refusal in the elderly age groups and rural areas is distressing and it should be handled immediately by the governments with appropriate risk communication strategy. The Government of Puducherry had initiated many initiatives to dispel myths and encouraging citizens to come forward for Covid-19 vaccination.

Strengths and limitations of the study

The major strength of our study was the longitudinal evaluation of the trend in vaccine hesitancy and refusal before and during the second wave of COVID-19 pandemic, in addition to the assessment of associated sociodemographic factors. Due to prospective nature of our study, we were also able to assess the changes in individual level factors responsible for vaccine hesitancy and refusal over time. The loss-to-follow up rate was less than 5%, with no significant difference in the characteristics over time due to the dropouts. We will also correlate the actual vaccine uptake with the hesitancy and refusal using the same cohort in the coming months. However, our study also has certain limitations. Though, we have longitudinally assessed the trend in vaccine hesitancy and refusal and the possible factors responsible for it, we did not qualitatively assess the reasons responsible for such change in behavior during the devastating second wave of the pandemic. The study reported the findings during the initial phase of vaccination drive in the UT and it takes time for any programme to show effect. In addition, during the adjusted analysis for all the models, there was a possibility of having unmeasured or uncontrolled confounding.

Implications for public health practice

In the study, we found that the confidence in COVID-19 vaccine efficacy and safety has declined over time leading to increase in the vaccine hesitancy and refusal in our study cohort, with more than one-third refusing to get themselves vaccinated during the second wave of pandemic. The finding was more worrisome as the people belonging to vulnerable sections like elderly population and those living in rural areas are at higher risk of such hesitancy and refusal. To address these target groups, Government should undertake intense information education and communication strategies and address the vaccine-related concerns, educate the general public about the nuances and importance of herd immunity and the indirect effects and benefits of the vaccination. It is important to leave out no groups unvaccinated, to mitigate the public health threat and the long-lasting impact of COVID-19 pandemic.

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Data sharing statement

No additional data are available. All data from the study are available to all qualified researchers/research groups on request.

Author contributions

Jeyanthi Anandraj - data curation, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing - original draft, and writing - review and editing.
Yuvaraj Krishnamoorthy - Data curation, formal analysis, investigation, methodology, software, validation, visualization, writing - original draft, and writing - review and editing.
Parthibane Sivanantham - data curation, formal analysis, investigation, methodology, project administration, software, validation, visualization, and writing - review and editing.
Jilisha G - data curation, formal analysis, methodology, resources, software, visualization, and writing - review and editing.

Sitanshu Sekhar Kar - conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing - original draft, and writing - review and editing.

Ethical statement

The study was approved by the Institutional Human Ethics Committee of JIPMER.

Informed consent

Informed verbal consent was obtained.

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