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ORIGINAL RESEARCH

Successful Implementation of COVID Vaccination Programme of India and AEFI reported COVID Vaccination in a tertiary care Teaching Hospital of North India

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Abstract

Background: With Introduction of COVID VaccinationProgramme in India it was important to generate the safety and efficacy data so that public confidence can be generated for the successful COVID vaccination programme implementation.

Objective: The current study aimed to make an assessment of AEFI, Beak though infections and acceptance and Implementation of COVID vaccination among the first target group enrolled in COVID vaccination programme in India at vaccination Centre at a tertiary care teaching hospital in India.

Methods: It was a structured interview based qualitative study, where subjects were interviewed immediately after vaccination within 48 hrs and after one month gap for various aspects of effective implementation of Programme, AEFI and Beak though Infections after COVID vaccination.

Results: One thousand subjects were enrolled.(99%) study population was satisfied with arrangements & SOPs at the vaccination center. Majority (98.7%) of the study population was convinced that vaccine is safe as well as effective (97.3%). A total of 79% AEFI were reported, with 99% being mild,0.6% moderate and 0.3% severe/ serious respectively. 65.7% of the population requiring brief medication for the management of AEFI with only 0.3% hospitalization rate. The most common AEFI was Fever, Myalgia and Pain at Local Site. There was no death reported & only 5.7% of the population reported breakthrough infection and majority of the subject acquired mild to moderate COVID disease and did not required hospitalization or prolonged treatment and recovered completely.

Conclusion:majority of AEFI were mild requiring either no medication or hospitalization and very less breakthrough infections after COVID vaccination were reported establishing safety and efficacy of current COVID Vaccination and also reported effective implementation of COVID Vaccination programme of India following all SOPs strictly.

Key Word: COVID Vaccination Programme, AEFI, Breakthrough Infections

Introduction

In our country vaccines from serum institute of India (COVISHIELD) and Bharat Biotec (Covaxin) were the first 2 vaccines approved for the emergency use. Although. three potential COVID vaccine sought emergency use authorization against coronavirus disease (COVID-19) from the Government of India in the first week of December 2020, [1]following

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which full-fledged preparation for vaccine rollout began in December 2020.The COVID 19 vaccination in UT of J&K was rolled out on 14th Jan 2020[2] for emergency use among health care workers and first line workers and elderly. There were many challenges in the initial stages due to uncertainty, unawareness, very less information of safety and efficacy data of these introduced COVID vaccines. Further implementation of the vaccination role out programme in the highly populated and diverse country like India was huge challenge for health care providers. Training of HCW, creation of emergency teams for monitoring, creation of infrastructure facilities at vaccination Centre, data collection facilities, as well AEFI facilities at vaccination centre across the country and seating up the supply chain and targeted vaccination to prioritygroups were also some of the important challenges.

As it wasimportant to generate the safety and efficacy data regarding COVID vaccination was utmost important in the initial stage in the country, so that public confidence can be generated for the successful COVID vaccination programme implementation of the same successfully. The current study aimed to identify the strengths, weaknesses, opportunities, and threats (SWOT) in the rollout of the COVID-19 vaccination campaign in India as well as to make an assessment of AEFI, Breakthrough Infections and acceptance of COVID vaccination among the first target group enrolledinitially in COVID vaccination programme in India at vaccination Centre at a tertiary care teaching hospital in India.

Material and Methods

This was a structured interview based qualitative studywhich was conducted after getting due permission from Institutional Ethical Committee vide no: IEC/GMC/Cat/2021/496 dated 15-04-21 and after informing the concerned local authorities for a period of six months.

Health Care Workers, Frontline Workers engaged in delivery of essential services such as police staff, defense, municipal workers population with age ≥50 years prioritized for vaccination and population age < 50 years population with associated comorbidities in etc prioritized for COVID-19 vaccination in first phase, were included in the current study.

The subjects were picked up after verbal consent from their contact numbers and asked to fill the questioners created on google form for the educated subjects and for the less educated lot were approached with same questioners immediately with 48 hours and were also followed telephonically for any breakthough infection or any delayed complication or AEFI after one month of receipt of vaccination. The questionnaire was pretested and validated by the preliminary analysis. The questionnarie had three domains first including demographic information, second domain included the questions regarding effective implementation of immunization programme and third domain included AEFI related information.Total 1000 subjects were included in the current analysis the *demographic domain* contained information regarding age, sex, education level, urban Vs Rural, type of target priority group, comorbid condition suffering. The information sought under *effective implementation of programme* at vaccination site were, satisfaction with arrangement, counseling facilities before COVID vaccination, following of SOPs of COVID Prevention at vaccination site, belief about efficacy and safety of the vaccine, availability of AEFI reporting unit in place, availability of data entry and COWIN facility and availability of emergency monitoring unit at vaccination site etc.The information sought under any *AEFI immediately* or within one month were like type of AEFI, Severity of AEFI, seriousness of AEFI, Medication required, hospitalization required, willingness to take second dose and any breakthrough infection within one month of vaccination etc.

Results

The Demographic Profile of Study Population is depicted in **table 1**.

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Table1: Showing Demographic Profile of Study Population

S. No	Parameters	N (%)	P-Value
1.	Number of Subjects	1000	
	Mean Age ±SD	43.8±12.5	
2.	Male vs Female	620 (62%) Vs 380 (38%)	The Fisher exact test statistic value is 0.0011. p< .05.
3.	First Line Workers Vs Health Care Workers Vs Elderly	483 (48.3%) Vs 497 (49.7%) Vs 20(2%)	The chi-square statistic with yates' correction is 10.58. p-value is .001143 p < .05.
4.	Urban Vs Rural	820 (82%) Vs 180 (18%)	The chi-square statistic with Yates's correction is 79.38. The p-value is <0.00001.
6.	Co-morbidities: Nil vs hypertension vs DM-II vs Asthma/COPD	867 (86.7%) vs 100 (10%) vs 30 (3%) vs 90 (9%)	The chi-square statistic is 241.5587. The p-value is < 0. 00001.

Male population dominated the study group. Majority of the population was from urban sector. 48.3% population was Front line workers while 49.7% were health care workers and 2% were the elderly population with mean age of 43.8 years. Hypertensive and diabetic population accounted 10% and 3% of the population respectively.The parameters asked regarding effective implementation of COVID-19 Programme of India at the respective COVID vaccination centre showed very promising response as depicted in **table.2.**

Table2: showing effective implementation of COVID-19 Programme of India

S. No	Parameters	N (%)	P-Value
1.	Satisfied with arrangements Vs Not Satisfied	990 (99%) vs 10 (1%)	The chi-square statistic with yates' correction is 188.18. The p-value is < 0.00001.
2.	Received Counseling Vs Didn't Received Counseling at vaccination site	997 (99.7%) vs 3 (0.3%)	The Fisher exact test statistic p-value is 0.00001.
3.	Underwent Monitoring Vs No monitoring	997 (99.7%) Vs 3 (0.3%)	The Fisher exact test statistic p value is 0.00001.
4.	Satisfied vs Not Satisfied	990 (99%) vs 10 (1%)	The Fisher exact test statistic p value is 0.00001.
5.	SOPs as per GOI guidelines Followed at Vaccination Site Vs Not Followed	997 (99.7%) vs 3 (0.3%)	The Fisher exact test statistic p value is 0.00001.
6.	Vaccine considered Safe Vs Not Safe	987 (98.7%) Vs 13 (1.3%)	The Fisher exact test statistic p value is 0.00001.
7.	Vaccine considered effective Vs not effective	973 (97.3%) Vs 27 (2.7%)	The Fisher exact test statistic p value is 0.00001.
8.	Physical Distance maintained Vs Not maintained at vaccination site	833 (83.3%) vs 167 (16.7%)	The Fisher exact test statistic p value is 0.00001.

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9.	Use of Mask and Practice of hand Hygiene Followed Vs Not Followed	997 (99.7%) vs 3 (0.3%)	The Fisher exact test statistic p value is 0.00001.
10.	AEFI Reporting provision Available Vs not available at vaccination site	967 (96.7%0 vs 33 (3.3%)	The Fisher exact test statistic p value is 0.00001.
11.	Emergency management unit Present Vs Not Present	997 (99.7%) vs 33 (0.3%)	The Fisher exact test statistic p value is 0.00001.
12.	Control room services Present Vs Not Present	833 (83.3%) vs 167 (16.7)	The Fisher exact test statistic p value is 0.00001.
13.	Data Entry unit present Vs Present	967 (96.7%) vs 33 (3.3)	The Fisher exact test statistic value is 0.00001.
14.	Cold chain facility available Vs Not available	997 (99.7%) vs 3 (0.3%)	The Fisher exact test statistic p value is 0.00001.
15.	COWIN software entry provision at Vaccination site Available Vs Not Available	1000 (100%) vs 0	The Fisher exact test statistic p value is 0.00001.
16.	Non Eligible Candidate allowed vaccination Vs Not allowed	1000 (100%) vs 0	The Fisher exact test statistic p value is 0.00001.

(99%) study population was satisfied with arrangements at the vaccination center with (99.7%) study population received counseling & monitoring for half an hour at the vaccination site. Majority (98.7%) of the study population was convinced that vaccine is safe as well as effective (97.3%), with 97.7% of the study population convinced that all the Sops of appropriate COVID behavior were adopted at the vaccination site, along with use of mask and practice of hand hygiene, with 83.3% study population agreed that physical distancing was maintained at the vaccination site. The provision of emergency management unit (99.7%), control room services (83.3%) and data entry in COWIN software (100%) were reported to be established at the vaccination site as per the recommendations of Govt of India. 97% of the study population received injection Covishield. A total of 79% AEFI were reported, with 99% being mild,0.6% moderate and 0.3% severe/ serious respectively. Only 11% of the study population had previous exposure to COVI-19 infection with 65.7% of the population requiring medicine for the management of AEFI with only 0.3% hospitalization rate. The most common AEFI was Fever, Myalgia and Pain at Local Site. 34.4% of population required medication for the AEFI for brief period or single dose. AEFI persisted for very Brief period in majority of the cases. Three cases reported severe/Serious AEFI(Hypotension, anaphylaxis's and Neurological Deficit) also recovered completely after medication and brief hospitalization. There was no death reported Interestingly only 5.7% of the population reported breakthrough infection and majority of the subject acquired mild to moderate COVID disease and did not required hospitalization or prolonged treatment and recovered completely **(Table 3 & 4).**

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Table3: Showing Profile of AEFI Among Health Care Workers And Frontline Workers Vaccinated With COVID Vaccine

S. No	Parameters	N (%)	p-value
1.	Suffered from Covid-19 after vaccination within one month of vaccination Vs Not suffered Vs Not sure	57 (5.7%) Vs 833 (83.3%) Vs 110 (11%)	The chi-square statistic is 167.07. the p-value is <0.00001.
2.	Covishieldvs Others	977 (975) Vs 33 (3%)	The Fisher exact test statistic value is 0.00001.
3.	AEFI present vs not present	790 (79%) Vs 210 (21%)	The Fisher exact test statistic value is 0.00001.
4.	Mild Vs Moderate Vs Severe	190(19%) Vs 17 (1.7%) Vs 3(0.3%)	The Fisher exact test statistic value is 0.00001.
5.	Serious Vs Non-serious	3 (o.3%) Vs 997 (99.7%)	The Fisher exact test statistic value is 0.00001.
6.	Medication not Required Vs Required	657 (65.7%) Vs 343 (34.3%)	The Fisher exact test statistic value is 0.00001.
7.	Willing to take 2nd Dose Vs not willing to take 2nd Dose	950 (95%) Vs 50 (5%)	The Fisher exact test statistic value is 0.00001.
8.	Hospitalization required Vs Not required	3 (0.3%) Vs 997 (99.7%)	The Fisher exact test statistic value is 0.00001.

Table4: Most common AEFI following Immunization

S. No	Parameters	N (%) First Dose
1.	High grade Fever	130 (13%)
2.	Low Grade fever	30(3%)
3	Pain at local site	37(3.7%)
4	Myalgia	48(4.8%)
5	malaise	13(1.3%)
6	Generalized weakness	11(1.1%)
7	Anxiety spell	2(0.2%)
8	Anaphylaxis	1(0.1%)
9	Hypotension	1(0.1%)
10	Neurological deficit	1(0.1%)

Discussion

The result of the current study revealed that implementation of COVID-19 Programme of India at the designated vaccination center was very effective and the designated centre was following all prescribed norms and sops strictly. This possibly has become possible due to High-level coordination at national, state, and district levels for effective cooperation and collaboration among the key departments and stakeholders involved in COVID-19 vaccination. The results are in agreement with the anticipated approach regarding implementation and surveillance system for Indian COVID Vaccination Programmee as documented by few studies. [3,4]

The study of Al-Mohaithef M*et al*[5] suggested in their study conducted on 992 respondents, that 642 showed interest to accept the COVID-19 vaccine if it is available. Willingness to accept the future COVID-19 vaccine has been reported relatively high among older age groups, being married participants with education level postgraduate degree or higher (68.8%), non-Saudi (69.1%), employed in government sector (68.9%). In a multivariate

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model in the said study, respondents who were above 45 years (aOR: 2.15; 95% CI: 1.08-3.21) and married (aOR: 1.79; 95% CI: 1.28-2.50) were significantly shown to be associated with vaccine acceptance ($p < 0.05$). The results are in accordance to the current study which also showed very high acceptance and readiness for subsequent doses of COVID vaccine amid pandemic.

The study of Supangat*et al*[6] reported the most common AEFI of SARS-CoV-2 vaccinations to be localized pain in the injection site during the first dose with 25 (45 %) reports and the booster dose with 34 (67 %) reports. This was followed by malaise, the first dose with 20 (36 %) reports and the booster dose with 21 (41 %) reports. Other symptoms like headache, fever, shivering, sleepiness, nausea, dysphagia, and cold were also reported. Thereby, suggesting that CoronaVac SARS-COV-2 vaccine has several mild symptoms of AEFI. The current study was in agreement to the said study as we recorded only three serious AEFI warranting hospitalisation and majority has the mild AEFI with fever as main presentation.

In the study ofBasavaraja CK *et al*[7], a total of 11,656 doses of COVID-19 vaccine were administered at the study site during the study period, of which 9292 doses were COVISHIELD™ and 2364 doses were COVAXIN™. In all, 445 AEFIs were reported from 269 subjects with an incidence rate of 3.48%. The majority of the subjects with AEFIs belonged to the age group of 18-45 years. Out of the total 445 AEFIs, 418 AEFIs were expected as per the fact sheets, 409 with COVISHIELD™ and 9 with COVAXIN™. After the causality assessment, out of 433 AEFIs to COVISHIELD^{TM} vaccine, 94.22% (n = 408) of events were categorized to have 'consistent causal association with immunization'. Out of 12 adverse events following COVAXIN™, 8 (66.66%) events were categorized as 'consistent causal association with immunization'. All AEFI were Mild in nature and all of them recovered from their adverse events without any squeal. The results were in accordance to the current study, thereby establishing the safety of both COVID vaccines.

In the study ofJeon M, Kim J *et al*[8] a total of 1,503 HCWs were vaccinated, and the data of 994 HCWs were reported for AEFI. The most commonly reported AEFIs were tenderness at the injection site (94.5%), fatigue (92.9%), pain at the injection site (88.0%), and malaise (83.8%). The severity of most AEFIs was mild-to-moderate, and the severity and number of AEFIs were less in the older age group. There were no serious events requiring hospitalization, and most AEFIs improved within a few days. The results were in agreement to our study, however, the fever was the most common AEFI in our study reported.

The result of the current study were in agreement with the study of Kamal D *et al*[9] as they reported 1020 non-serious and two serious AEFI (altered sensorium) within 48 hours of first dose. Two hundred and twenty non-serious AEFI were reported within 48 hours of second dose. No AEFI was reported after 15 days for both the doses. We found no association of AEFI with sex and profession ($p >0.5$). Significant association of AEFI was found with age ($p <0.01$). Symptoms were mild in severity and short-lived. No serious AEFI attributable to vaccines were reported.

Similarly, in the study of Kaur U *et al*[10], AEFIs following first dose were reported in 321 (40%). Among 730 participants who completed a 7-day follow-up post second dose, AEFIs occurred in 115 (15.7%). Majority of AEFIs were mild-moderate and resolved spontaneously. Serious AEFIs, leading to hospitalization was noticed in 1 (0.1%) participant with suspicion of immunization stress related response (ISRR). AEFIs of grade 3 severity (FDA) were recorded in 4 participants (0.5%). No deaths were recorded. Thereby, suggesting like our study that COVISHIELD carries an overall favourable safety profile with AEFI rates much less than reported for other vaccines.

Conclusion

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The study suggested that COVID Vaccination Programme of India is Successfully Implemented strictly as per the prescribed SOPs as reported by the study population and majority of AEFI were mild requiring either no medication or hospitalization and very less breakthrough infections after COVID vaccination were reported establishing safety and efficacy of COVID Vaccination and also established effective immplementation of COVID Vaccination programme of India.

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