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Original Research Article

A study on adverse events following ChAdOx1 nCoV-19 Covishield™ vaccination among beneficiaries at tertiary care centre, Hyderabad, India

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ABSTRACT

Background: COVID-19 vaccine in present pandemic situation has been emerged as a blessing in disguise. Studies found to be associated with vaccine side-effects and it is an important factor that influences the confidence of vaccine uptake in general population. Present study was designed to provide an independent evidence on ChAdOx1 nCoV-19 vaccine side effects.
Methods: A cross sectional study was conducted between January 2021 and February 2021 at our tertiary care centre among health care workers vaccinated using a validated questionnaire. Study subjects were contacted through phone to know about any adverse events following immunization for 0-24 hours, 24-48 hours and 48-72 hours. Data collected was entered and analysed with MS excel software 2007 and Epi info 3.5.3.
Results: Healthcare workers participated were 1364. Majority of the symptoms following immunization were highest in age group of 18-28 years. Reported symptoms were pain at the site of injection- 619 (45.4%), fever- 423 (31%), Body pains- 318 (23.3%), headache- 189 (13.9%), tiredness- 142 (10.4%), swelling at the site of injection- 40 (2.9%), dizziness- 30 (2.2%), redness at the site of injection- 25 (1.8%), joint pains- 23 (1.7%), rash- 06 (0.4%), Breathlessness- 03 (0.2%) respectively.
Conclusions: Overall results found the occurrence of side-effects which are in terms of manufacturer's data and it has been noticed in young age. This study imparts the confidence for taking vaccination and further studies are required to minimize vaccine hesitancy (VH) and strengthen the public to boost their confidence in present vaccination drive.

Keywords: Adverse events following immunization, ChAdOx1 nCoV-19, COVID-19, Vaccination, Vaccine hesitancy

INTRODUCTION

The appearances of the pandemic COVID-19, its effect on the healthcare system, high mortality lead to the robust research for the development of vaccines. Different government and private agencies to protect the mankind, especially healthcare workers and front line workers developed vaccines in short time. The main hurdle in vaccinating the population has come in terms of vaccine hesitancy (VH)- it is the refusal to take vaccine, due to the fear of side effects. A study from Israel has found that the healthcare workers are inclined to take the vaccine, compared to the parents, nurses staff those not dealing with COVID-19 cases has expressed the VH.[1] A study from Lucia and coworker found that the medical students in United States were not willing to take vaccines due to the concern for serious side effects was independently predictive of lower odds of intent to participate in a COVID-19 vaccine trial (AOR=0.41, p=0.01).[2] A study from the China suggested to infuse the 5C (more

confidence, more collective responsibility and less complacency, constraints, and calculation) in the vaccination campaign to enhance the confidence among those vaccine hesitancy population to take up the vaccine during the drive.

Several studies reported the short term side effects post vaccination period. A cross sectional study has found post vaccination, 8% of the cases found the appearance of oral side effects.[3] It was postulated that the oral side effects is due to the high expression of angiotensin-converting enzyme 2 (ACE_2) receptors in oral region. Polack et al studied the safety and efficacy of BNT162b2 mRNA COVID vaccine and found characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was very low and among vaccine and placebo groups.[4] A study from Czech Republic has done an independent study on the side effects of the Pfizer-BioNTech COVID-19 vaccine reported injection site pain (89.8%), fatigue (62.2%), headache (45.6%), muscle pain (37.1%), and chills (33.9%) were the most commonly reported side effects and found in consistency with the manufacturers data.[5] In the present study we aim to evaluate the adverse events following ChAdOx1 nCoV-19 vaccination among the healthcare workers administered with the first dose of the vaccination.

METHODS

A cross-sectional study was conducted at the Kamineni hospitals to assess the various adverse events following vaccination among beneficiaries and to study the associated factors and pattern of adverse events following vaccination. The study with sample size of 1364, included health care professionals, paramedical staff, housekeeping staff, executive staff and administrative staff members who gave oral consent for the participation in the study were included in the study and who are not willing to participate in the study excluded. Study has been conducted during January 2021 to February 2021.

Details of the study subjects were recorded using structured predesigned and pretested questionnaire. It includes socio-demographic variables (age, sex, address). Study subjects were contacted through phone to know about any adverse events following immunization for 0-24 hours, 24-48 hours and 48-72 hours. The staff deployed for the survey/telephonic interview of the beneficiaries were as follows: one post graduate from the department of community medicine, two internees, two administrative staff members.

The beneficiaries were asked to inform the health facility regarding any adverse event occurring after ChAdOx1 nCoV-19 (manufactured by Serum Institute of India Pvt. Ltd.) immunization. The following were adverse events following immunization (AEFI): pain at the site of injection, erythema at the site of injection, swelling at the site of injection, fever, fatigue, head ache, myalgia, joint pains, skin rash, dizziness, breathlessness, nausea, vomiting, convulsions, toxic shock syndrome, any co incidental events, death.[6] All the data collected was entered and analysed with MS excel software 2007 and Epi info 3.5.3.

RESULTS

Of the total 1364 participants, 844 (62%) were females and 520 (38%) were males (Figure 1). In our study 894 (65.5%) belonged to 18-28 years age group, 243 (17.8%) in 28-38 years, 117 (8.6%) in 38-48 years, 85 (6.2%) in 48-58 years and >58 years age group were 25 (1.8%) (Figure 2). Vaccine beneficiaries were followed up for 3 consecutive days, all the other age groups has been mentioned (Table 1).

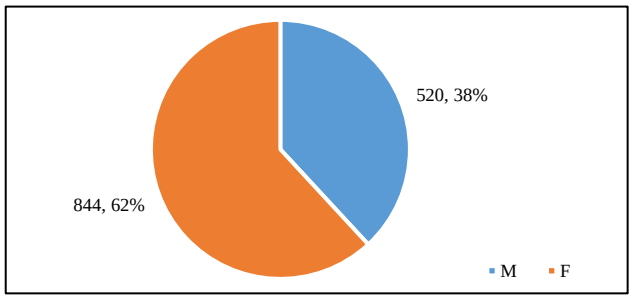

Figure 1: Pie chart showing sex-wise distribution of beneficiaries.

*M= Male; F=Female.

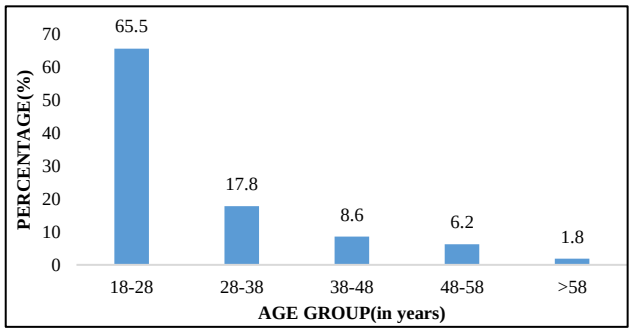

Figure 2: Bar chart showing age-wise distribution of beneficiaries.

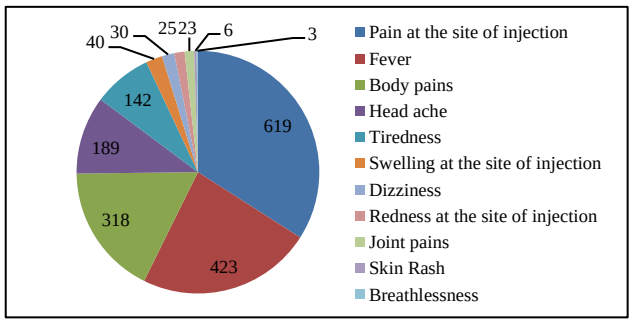

Figure 3: Pie chart showing symptom-wise distribution of adverse events following immunization among beneficiaries.

Table 1: Age-wise distribution of adverse events following immunization among beneficiaries.

Age (in years)	18-28	28-38	38-48	48-58	>58
Pain at the site of injection (619)	482 (77.8)	75 (12.1)	30 (4.8)	27 (4.3)	05 (0.8)
Fever (423)	321 (75)	63 (14)	21 (4.9)	15 (3.5)	03 (0.7)
Body pains (318)	222 (69.8)	44 (13.8)	24 (7.5)	22 (6.9)	06 (1.8)
Headache (189)	139 (73.5)	25 (13.2)	11 (5.8)	11 (5.8)	03 (1.5)
Tiredness (142)	101 (71)	18 (12.6)	11 (7.7)	10 (7.0)	02 (1.4)
Swelling at the site of injection (40)	32 (80)	02 (05)	03 (7.5)	03 (7.5)	0 (0)
Dizziness (30)	22 (73.4)	07 (23.3)	01 (3.3)	0 (0)	0 (0)
Redness (25)	16 (64)	04 (16)	02 (08)	03 (12)	0 (0)
Joint pains (23)	15 (65.2)	03 (13.0)	03 (13.0)	02 (8.6)	0 (0)
Skin Rash (6)	02 (33.4)	01 (16.6)	02 (33.4)	01 (16.6)	0 (0)
Breathlessness (03)	01 (33.3)	01 (33.3)	01 (33.3)	0 (0)	0 (0)

Table 2: Day-wise distribution of adverse events following immunization among beneficiaries.

Events	Day-1	Day-2	Day-3
	N (%)	N (%)	N (%)
Pain at the site of injection	347 (25.4)	8 (5.7)	58 (4.2)
Fever	243 (17.8)	39 (2.8)	29 (2.1)
Body pains	213 (15.6)	38 (2.8)	26 (1.9)
Head ache	157 (11.5)	32 (2.3)	16 (1.1)
Tiredness	119 (8.7)	25 (1.8)	19 (1.3)
Swelling at the site of injection	26 (1.9)	11 (0.8)	07 (0.5)
Dizziness	25 (1.8)	11 (0.8)	07 (0.5)
Redness at the site of injection	22 (1.6)	4 (0.3)	02 (0.1)
Joint pains	16 (1.2)	1 (0.1)	0 (0)
Skin rash	3 (0.2)	2 (0.1)	0 (0)
Breathlessness	3 (0.2)	1 (0.1)	0 (0)

We found in our study that beneficiaries after post ChAdOx1 nCoV-19 vaccination, had AEFI like pain at the site of injection- 619 (45.4%), fever- 423 (31%), body pains- 318 (23.3%), headache- 189 (13.9%), tiredness- 142 (10.4), swelling at the site of injection- 40 (2.9 %,), dizziness- 30 (2.2%), redness at the site of injection- 25 (1.8%,) joint pains- 23 (1.7%), rash- 06 (0.4%), breathlessness- 03 (0.2%) respectively (Figure 3). The median age of the healthcare workers was 38 years corresponds to the mean average age of the Indian healthcare workers had been used as a cut-off to COVID-19 vaccine side effects of the participants.

Within 1st 24 hours following vaccination, the most common symptom following immunization found among beneficiaries was pain at the site of injection (347) in 25.4% beneficiaries, followed by fever (243) in 17.8%, body pains (213) in 15.6%, head ache (157) in 11.5%, tiredness (119) in 8.7% beneficiaries and a limited number of people reported with swelling at the site of injection (26)-1.9% dizziness (25)-1.8%, redness at the site of injection (22)-1.6%, joint pains (16)-1.2%, rash (03)- 0.2%, breathlessness (03) -0.2%. In the next 24-48 hours there was a major decline in the symptoms reported compared to the symptoms reported in the 1st 24 hours which included pain at the site of injection (78)- 5.7%, fever (39)- 2.8%, body pains (38)- 2.8%, headache (32)- 2.3%, tiredness (25)- 1.8% respectively. In the last 48-72 hours following post vaccination almost all the symptoms reported showed decreasing trends like pain (58)- 4.2%, fever (29)- 2.1%, body pains (26)- 1.9%, headache (16)- 1.1%, and tiredness (19)- 1.3% in comparison with the previous two days. There were no cases reported with joint pains, rash, and breathlessness on the third day (Table 2).

Table 3: Prevalence of adverse events following immunization in younger and older age groups.

AEFI	Age <38 years	Age >38 years	P value (<0.05 =statistically significant)
Pain at the site of injection (619)	557	62	0.000*
Redness at the site of injection (25)	20	05	0.649
Swelling at the site of injection (40)	34	06	0.777
Fever (423)	384	39	0.000*
Tiredness (142)	119	23	0.880
Headache (189)	164	25	0.174
Body pain (318)	266	52	0.874
Joint pain (23)	18	05	0.508
Rash (6)	03	03	0.028*
Dizziness (30)	29	01	0.048*
Breathing difficulty (03)	02	01	0.437

*- statistically significant

The prevalence of the general side-effects has been found difference among the different ages of the patients,

symptoms including pain at the site of injection, fever, appearance of skin rash and dizziness has been noticed to be statistically significant among younger group less than 38 years of age irrespective of gender (Table 3). The gender wise distribution of symptoms has been noticed (Table 4).

Table 4: Gender-wise distribution of adverse events following immunization among beneficiaries.

AEFI	Males	Females	P value (<0.05 =statistically significant)
Pain at the site of injection (619)	198	421	0.000*
Redness at the site of injection (25)	12	13	0.305
Swelling at the site of injection (40)	12	28	0.283
Fever (423)	124	299	0.000*
Tiredness (142)	48	94	0.263
Headache (189)	56	133	0.010*
Body pain (318)	118	200	0.670
Joint pain (23)	09	14	0.920
Rash (6)	02	04	0.809
Dizziness (30)	08	22	0.191
Breathing difficulty (03)	01	02	0.864

*- statistically significant

DISCUSSION

Vaccination is seen as the agent to bring down the morbidity and the mortality and to make the world safe again. Several vaccines have been introduced into healthcare system to curtail the effect of COVID-19 as well as making general population immune to the disease. Studies have found that the vaccination has been associated with the side effects and it is one of the major factors for the genesis of VH in general population. The present independent study was aimed to evaluate the side effects of ChAdOx1 nCoV-19 among our healthcare workers and we found the appearance of adverse reactions for few days following the vaccine shot. We found statistically significant difference among age groups, especially in terms of pain at the site of the injection, fever, rash and dizziness has been noticed more in younger generation. The symptom, pain at the site of injection has been noticed in larger study group, which implies the nursing staff and medical staff should be highly recommended for receiving appropriate training on optimal injection techniques. The present study has been found in accordance with Kaur et al who has done a systemic study and found the appearance of symptoms for 3-4 days, without any occurrence of major adverse events.[7]

A study of randomized, cross-sectional study on healthcare workers with detailed self-reported symptoms with COVID-19 mRNA-1273 vaccine found occurrence of non-life threatening symptoms which were resolved within few days.[8] A prospective study from UK, reduction in systemic and local side-effects within 12 days of post vaccination echoing our study implies that vaccination is safe to take and can overcome the VH factor occurring in the general population.[9] According to the CDC, during vaccination we have to be cautioned with the occurrence of major adverse events such as anaphylaxis and rarely myocarditis.[10] Further studies are needed to confirm the results with long term follow up. The limitations of the study were disparity of the gender selection, not following more than 3 days of the post vaccination, any prehistory of suffering with the COVID-19.

The present study conclude that the vaccination imparts protection against the COVID-19 infection, the appearance of side effects should not hamper the vaccination drive as well as it will encourage to overcome the VH effect.

CONCLUSION

The overall results found the occurrence of side-effects are in the terms of the manufacturer's data and it has been noticed in young age. The presence of local side effects should not hamper the vaccination drive to protect against the pandemic. This study imparts the confidence for taking vaccination and further studies are required to strengthen the will of public to boost confidence to take vaccine in the present vaccination drive.

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