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Original Article

Frequency of Inactivated COVID-19 Vaccine Side Effects in a Tertiary Care Hospital of Karachi

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ABSTRACT

Objective: to determine the frequency of the possible side effects of the COVID -19 inactivated vaccine.
Study Design: Cross-sectional survey.
Place and Duration of Study: Pakistan Naval Ship Shifa Hospital, Karachi Pakistan from Jan to Apr 2021.
Methodology: A total of 305 recipients of inactivated COVID-19 vaccine were asked to fill out a questionnaire themselves or by the health care worker via telephonic conversation. The questionnaire comprised queries regarding general and local side effects that the participants experienced after getting vaccinated for COVID-19.
Results: Out of 305 recipients, 270(88.5%) were men, and 35(11.5%) were women. Participants' age ranged from 18-60 years. After the first dose, 83(27.2%) cases [male 63(23.3%) vs. female 20(57.1%)], were reported with side effects, while 75(24.5%) recipients, [male: 54(19.9%) vs. female: 21(58.8%)], had side effects after the second dose. Generalized symptoms were fever, headache, dizziness, and body aches, while local side effects were pain, itching, swelling and rash at the injection site. 259(84.9%) recipients reported spontaneous recovery after the first dose. After the second dose, 286(93.8%) recipients recovered spontaneously. The remaining 44(13%) of the recipients' required symptomatic treatment. After the second dose, only 19(6%) recipients needed symptomatic treatment.
Conclusion: It is important to document the possible side effects of COVID vaccine so that public awareness and education can be made to minimize public fear of vaccine side effects. Inactivated vaccine for COVID-19 has minimal reported side effects and hence has a good safety profile.

Keywords: COVID-19, COVID-19 pandemic, Inactivated vaccine, SARS-CoV-2, Side effects.

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INTRODUCTION

The world has been facing multiple outbreaks of COVID-19 for the last two years. Since then, various strains/variants have emerged with increasing lethality.[1] Vaccination against the COVID-19 virus has a pivotal role, along with other precautions, in ending this pandemic.[2] Any drug or vaccine side effects are very important for public safety and gaining their trust to maximize the potential benefits of a vaccine or drug.[3] The vaccine safety evidence was exclusively obtained from manufacturer-sponsored studies at the beginning of the year.[4]

The risk of COVID-19 disease spread is high in Pakistan because of a weak healthcare system, high population density, and poor compliance with hygiene practices.[5] In addition, the general public has emerging concerns regarding the vaccine's potential side effects, safety and efficacy. Inactivated viral vaccine was the first vaccine administered to the Pakistani population and was acceptable as WHO's target has more than 50% efficacy.[6] Now, mRNA vaccines have also been rolled out in Pakistan.[7] So far, 65 M population is fully vaccinated, around 28% of the total population.[8,9] Despite the large numbers of COVID-19 cases and the early start of the vaccination campaign in Pakistan, there is little data on clinical outcomes of infection or even the SE of vaccines.[10] Therefore, collecting data on these SE of distributed vaccines is important to inform and educate the public on this issue and minimize the general population's fear regarding vaccine safety.

This study was one such effort to highlight the main side effects of the inactivated vaccine, which the Pakistan government rolled out initially.

METHODOLOGY

This study was cross-sectional survey conducted at Pakistan Naval Ship (PNS) Shifa Hospital, Karachi Pakistan between January to April 2021. The ethical approval was granted (Letter number ERC/2021/MEDICINE/74) by the Hospital Ethical Review Committee. The consecutive sampling was employed and all the study participants gave consent for participation.

Inclusion Criteria: All the vaccine recipients of either gender, aged 18 years and above, vaccinated at the COVID vaccination centre were included in the study.

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Exclusion Criteria: People with comorbid, fever, pregnancy, autoimmune diseases and chemotherapy were excluded from the study.

They were asked to fill out a questionnaire by themselves or were filled out by the health care workers either in person or through telephonic conversation. The anonymous questionnaire was composed of questions regarding gender, age, general and local side effects, spontaneous recovery or hospital visits due to side effects after the first and second doses.

Statistical Package for Social Sciences (SPSS) version 22.0 was used for the data analysis. Quantitative variables were summarized as mean±SD and qualitative variables were summarized as frequency and percentages.

RESULTS

A total of 305 recipients participated in the study. Of these, 271(88.9%) were males, and 34(11.1%) were females. The age of recipients was from 18-60 years. 83(27.2%) cases reported side effects after the first dose. Of these, 63(23.3%) were males, and 20(57.1%) were females. After the second dose, 75(24.5%) cases reported side effects. Of these, 54(19.9%) were males, and 21(58.8%) were females.

The first vaccination dose resulted in generalized side effects, including fever, headache, dizziness and body aches, localized pain, itching, swelling and rash at the injection site. The frequency of side effects after the first dose were mentioned in Table-I.

Table-I: Side Effects of Inactivated COVID-19 Vaccine after First Dose (n=305)

Symptoms	Male n(%) (n=271)	Female n(%) (n=34)
Fever	20(7.4)	7(20)
Headache	33(12.2)	11(31.4)
Dizziness	12(4.4)	6(17.1)
Body aches	18(6.7)	7(20)
Pain at site	24(8.9)	10(28.6)
Itching at site	3(1.1)	3(8.6)
Swelling at site	2(0.7)	3(8.6)
Rash	2(0.7)	3(8.6)

The same generalized and localized side effects at the injection site were reported after the second vaccination dose. The frequency of these side effects after the second dose were mentioned in Table-II.

Spontaneous recovery without any medication was reported by 259(84.9%) recipients, [male: 232 (85.9%) vs. females: 27(77.1%)], after the first dose. After the second dose, 286(93.8%) recipients, [male: 260 (95.9%) vs. female: 26(76.5%)], recovered spontaneously. The remaining 44(13%) recipients required Paracetamol and antiallergics, and only 2(0.6%) required detention and steroids after the first dose. After the second dose, only 19(6 %) recipients needed symptomatic treatment with Paracetamol mainly.

Table-II: Side Effects of Inactivated COVID-19 Vaccine after Second Dose (n=305)

Symptoms	Male n(%) (n=271)	Female n(%) (n=34)
Fever	17(6.3)	8(23.5)
Headache	37(13.7)	11(32.4)
Dizziness	10(3.7)	3(8.8)
Body aches	21(7.7)	13(38.2)
Pain at site	16(5.9)	8(23.5)
Itching at site	4(1.5)	2(5.9)
Swelling at site	0	2(5.9)
Rash	0	2(5.9)

DISCUSSION

In order to control the COVID-19 outbreak, clinical trials were being conducted throughout the world. Public awareness and education regarding COVID-19 vaccination and its safety profile play a key role in achieving mass vaccination.[11]

Our study focused on inactivated vaccine side effects, as it was the most widely rolled out vaccine in Pakistan since the very beginning. Approximately 1/4th of the recipients showed side effects after the vaccine. After the first dose, 83(27.2%) had side effects, while 74(24.3%) recipients experienced side effects after the second dose. This is in comparison with other studies that reported minimal side effects with inactivated vaccines, considered to have a "quiet" profile regarding side effects.[12,13]

Our study revealed the greater frequency of side effects in the younger age group. We observed that 68% of the recipients who showed reactogenicity were in their second and third decade (19-26 years). This fact is also evident in other studies which reported a significant difference in side effects between different age groups, more in those <49 years of age.[14-16] A combined study done in Jordan, the UK, and Iraq showed no relationship between age and gender.[17]

There was a significant relationship between side effects and gender, more in females. After the first dose, 57.1% of females had post-vaccine side effects, while only 23.3% of males experienced it. Most vaccine side effects after the second dose were evident in 58.8% of females, and only 19.9% of males had these side effects. This could be because females are more apprehensive and have more psychosomatic symptoms. This was also observed in other studies in India, Iraq and UAE.[16-19]

The most frequently observed side effects in our study were: fever (8.9% after the first dose and 8.2% after the second dose), body aches (8.2% after the first dose, 11.1% after the second dose) and pain at the site of injection (11.1% after the first dose, 7.9% after the second dose). Clinical trials in China, UAE, the Czech Republic and Iraq also reported fever, headache, body aches and pain at the site as the most commonly encountered side effects.[12,17-20]

A local study reported inactivated vaccine side effects in healthcare workers. It showed minimal side effects, which were more common in females. The most common side effects in this study were body aches, pain at the site of injection, fever and headache.[21] We also observed certain side effects more common after the second dose. Headache was observed more after the second dose in our study.

LIMITATIONS OF STUDY

In this study, the number of female recipients was quite less; therefore could not correlate the gender with possible side effects.

CONCLUSION

Mass vaccination is needed to end the COVID-19 pandemic or minimize the severity of the disease. The major hurdle is the general population fear of the possible side effects of this new vaccine. An inactivated vaccine has a lower prevalence of reported adverse effects. Therefore, observing and documenting the possible side effects of the COVID vaccine is crucial so that public awareness and education can be achieved. That will help minimize public fear of possible vaccine side effects and to reach the mass target vaccination.

Conflict of Interest: None.

Author's Contribution

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

GAKN: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

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

NAA & MLS: Conception, critical review, 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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