## Original Article

# An Observational Study Comparing the Adverse Effect Profiles of Sputnik V and Covaxin COVID-19 Vaccines in Adult General Population of Eastern India

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**Aim :** Currently no data is available on the safety profile of COVID-19 Vaccines like Covaxin and Sputnik V from Eastern India. Our aim was to evaluate the safety profiles of Covaxin and Sputnik V Vaccine in Eastern India.

**Methods :** 0.5 ml of Covaxin and Sputnik V given to 701 adults in a two-dose regimen at a private tertiary care Hospital, Kolkata, with the doses separated by 4-7 weeks in Covaxin and 3 weeks in Sputnik V. Data regarding local and systemic Adverse Event Following Immunizations (AEFIs) was collected 30 minutes after vaccination and also on the first- and seventh-day following vaccination after each dosage.

**Results :** Incidence of AEFI was 65% and 59% following the first dose of vaccination in Covaxin and Sputnik V groups, respectively. Incidence of AEFI was 83% and 70% after the second dose in Covaxin and Sputnik V groups. Pain in the injection site was the most common adverse effect. Body-ache, fever and tiredness were other systemic side effects. Adverse effects were noticeably more after the second dose. Over half of the reactions were mild in nature. Covaxin had a higher number of moderate adverse reactions after both doses. Adults with age >40 years, Co-morbidities, Hypertension and Diabetes had a smaller number of side effects following the first dose of vaccination. People with previous COVID-19 infections had noticeably fewer adverse effects after the second dose. Allergic adults were associated with more systemic side effects, whereas Hypertensive adults had less total AEFI.

**Conclusion :** Both Covaxin and Sputnik V had favorable safety profiles. Sputnik V vaccine had significantly fewer AEFIs compared to Covaxin. Age, co-morbidities, specifically hypertension, Diabetes, Allergy and previous history of COVID-19 infection, were important variables observed in the prevalence of side effects.

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***Key words*** **: COVID-19 vaccine, AEFI, Safety, Covaxin,Sputnik V, Adverse effects, Side effects, India.**

Coronavirus 2019 (COVID-19) is a viral pneumonia like illness which is the cause of worldwide destruction of public health and economic instability. According to WHO, over 450 million people were affected Worldwide till date, with a death rate of 6 million[1].40 million people had been affected in India till date with a death rate of 0.5 million[2].

***Editor's Comment :***

- COVID-19 is a viral pneumonia like illness causing worldwide destruction of public health and economic instability.
- Vaccination is an effective way to curtail the spread of the disease and decrease mortality. This study investigates the adverse effect profiles of COVID-19 vaccines Covaxin and Sputnik in adult general population of Eastern India.

Currently, supportive measures, ie, oxygen, anticoagulant and intravenous steroids, are the cornerstone of COVID-19 treatment. For this reason, vaccination can be an effective way to curtail the spread of COVID-19 disease and decrease mortality. The urgent need for vaccination to prevent COVID-19 spread has spurred the development of different vaccines.

Though several vaccines are currently given permission for emergency use in India, only Covishield, Covaxin and, Sputnik V are being used for mass vaccination purpose[3]. Covishield was used for almost 85% of mass vaccination, whereas Covaxin and

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Sputnik V are applied for 12% and 3-4% of vaccination in India[4]. Covaxin and Sputnik V having the efficacy of 78% and 91.65%, respectively, are the most common vaccines used in India for mass-vaccination purpose[5,6]. Despite the enormous usage of both vaccines, sufficient data is not available regarding the comparative safety of these vaccines worldwide. Only one study is available which compares the adverse effects of both vaccines in health workers of Iran[7]. However, no study is available comparing the side effects of both vaccines in the adult general population. This is the first study that measures the side effects of both vaccines in the Indian population.

## Materials and Methods

Our Prospective observational study was carried out at Peerless Hospital, Kolkata, from July 2021 to September 2021 after the approval of the Ethics Committee. Individuals over 18 years who consented to participate in the study were included. Positive COVID-19 patients were excluded from the study. Patients' demographic characteristics and incidence, type, pattern and severity of AEFI were collected. A 0.5ml dosage of Covaxin or Sputnik was injected intramuscularly at the deltoid in a two-dose regimen, with the doses separated by 4-7 weeks in Covaxin and 3 weeks in Sputnik. Data regarding AEFI after thirty minutes of vaccination were collected. Participants were contacted by phone after 24 hours following vaccination, as well as after each dosage on day 7. Individuals were especially questioned about local site symptoms such as pain, erythema, edema, soreness, and degree of physical activity limitation for safety analysis. They were also asked about systemic symptoms, including Fever, Headache, Nausea, Vomiting, Diarrhea, Rash, Chest tightness, Dyspnea, etc. Biochemical testing was not performed routinely on all vaccination recipients but was planned in the event of severe AEFI or AEFI persistence. Results were analysed using SPSS version 22. Descriptive statistics (Frequency and Percentage), Pearson's Chi-square test, Fisher's exact test, Mann-Whitney U test and logistic regression analysis were used. $p<0.05$ was considered statistically significant.

## Results

716 adult individuals were screened for their first dose of vaccination. Among them, the first doses of Covaxin and Sputnik V were given to 519 and 182 individuals, respectively. 200 and 182 individuals were given the second dose of vaccine in Covaxin and Sputnik group, respectively. The mean age of individuals in Covaxin and Sputnik V group was 41 and 39 years, respectively. History of previous COVID-19 infection in Covaxin and Sputnik V group was 47% and 41%, respectively.36% and 27% individuals had co-morbidities in Covaxin and Sputnik groups, respectively (Table 1). Total incidence of adverse effect and systemic side effect were significantly more in both groups after the second dose of vaccination (Table 2). Local adverse effect, ie, pain in the injection site was the most common side effect observed in both groups after both doses of vaccination. Among systemic side effects, body ache was the most prevalent one after first and second dose of vaccination in both groups. Other common adverse effects were Tiredness and Fever. Nausea-vomiting was noticeably more after the second dose of vaccination in both groups. Additionally, Fever, Tiredness, Malaise, Cough, and Sneezing were more frequently observed after the second dose of vaccination in the Covaxin group. Loss of sleep was observed more frequently after the first dose of vaccination in Covaxin group. Sneezing, difficulty in urination, change in appetite and increased sleep were not observed in the Sputnik V group. Incidence and pattern of side effects were not significant after the first dose of vaccination in both groups. The total incidence of adverse effect and systemic side effect were significantly lower in Sputnik group compared to Covaxin group ($p<0.05$) after the second dose of vaccination (Table 3). Additionally, Cough, Diarrhea, Sneezing and tiredness were observed more frequently in Covaxin group after the second dose.

In MEDRA SOC classification, Gastrointestinal disorders and Respiratory-thoracic-mediastinal disorders were observed more frequently in Covaxin group after the first and second dose of vaccination,

Table 1 — *Demographic details of population receiving first and second dose of vaccination*

| Demographic details | Covaxin group (n=519) | Sputnik V group (n=182) |
|---|---|---|
| Sex (Male) | 243 (46.82%) | 94 (51.65%) |
| Age | 41.11± 14.93 | 38.47± 12.56 |
| History of previous COVID infection | 242 (46.63%) | 74 (40.66%) |
| Co-morbidities | 187 (36.03%) | 49 (26.92%) |
| Arthritis | 5 (0.96%) | 0 (0%) |
| Thyroid disease | 27 (5.20%) | 3 (1.65%) |
| Hyper-lipoproteinemia | 1 (0.19%) | 4 (2.2%) |
| Asthma and COPD | 4 (0.77%) | 2 (1.1%) |
| Hypertension | 84 (16.18%) | 25 (13.74%) |
| Diabetes mellitus | 57 (10.98%) | 21 (11.54%) |
| Allergy | 26 (12.15%) | 6 (3.3%) |
| Liver disease | 3 (0.58%) | 1 (0.55%) |
| Chronic kidney disease | 4 ( 0.77%) | 0 (0%) |
| Others (cancer etc) | 4 ( 0.77%) | 1 (0.55%) |
| Concomitant medication | 149 (28.71%) | 40 (21.98%) |

Table 2 — *Comparison of adverse effects in covaxin group after first and second dose of vaccination*

| Adverse effects | First dose of vaccination (n=519) | Second dose of vaccination (n=200) | P value |
|---|---|---|---|
| Incidence of adverse effect | 339 (65.32%) | 166 (83%) | <0.001* |
| Incidence of systemic adverse effect | 258 (49.71%) | 145 (72.5%) | <0.001* |
| Fever | 92(17.73%) | 59 (29.5%) | 0.001* |
| Body ache | 163(31.41%) | 72 (36%) | 0.246 |
| Pain in injection site | 209(40.27%) | 90 (45%) | 0.251 |
| Nausea and vomiting | 6(1.16%) | 18 (9%) | <0.001* |
| Malaise | 29(5.59%) | 25 (12.5%) | 0.007* |
| Cough | 5(0.96%) | 10 (5%) | 0.012* |
| Diarrhoea | 25(4.82%) | 13 (6.5%) | 0.395 |
| Sneezing | 2(0.39%) | 9 (4.5%) | 0.006* |
| Urinary problem | 1(0.19%) | 1 (0.5%) | 0.565 |
| Skin-rash | 10(1.93%) | 10 (5%) | 0.063 |
| Loss of appetite | 8(1.54%) | 1 (0.5%) | 0.157 |
| Increase in appetite | 2(0.39%) | 4 (2%) | 0.116 |
| Loss of sleep | 4(0.77%) | 0 (0%) | 0.045* |
| Increase in sleep | 2(0.39%) | 2 (1%) | 0.415 |
| Tiredness | 59(11.37%) | 52 (26%) | <0.001* |

**Comparison of adverse effects in sputnik V group after first and second dose of vaccination**

| Adverse effects | First dose of vaccination (n=182) | Second dose of vaccination (n=182) | P value |
|---|---|---|---|
| Incidence of adverse effect | 108 (59.34%) | 127 (69.78%) | 0.036* |
| Incidence of systemic adverse effect | 77 (42.31%) | 107 (58.79%) | 0.001* |
| Fever | 36 (19.78%) | 49 (26.92%) | 0.106 |
| Body ache | 53 (29.12%) | 67 (36.81%) | 0.117 |
| Pain in injection site | 78 (42.86%) | 79 (43.41%) | 0.916 |
| Nausea and vomiting | 2 (1.1%) | 17 (9.34%) | <0.001* |
| Malaise | 12 (6.59%) | 14 (7.69%) | 0.684 |
| Cough | 1 (0.55%) | 2 (1.1%) | 0.562 |
| Diarrhoea | 4 (2.2%) | 4 (2.2%) | 1.000 |
| Sneezing | 0 (0%) | 0 (0%) | NA |
| Urinary problem | 0 (0%) | 0 (0%) | NA |
| Skin-rash | 1 (0.55%) | 4 (2.2%) | 0.176 |
| Loss of Appetite | 0 (0%) | 0 (0%) | NA |
| Increase in appetite | 0 (0%) | 0 (0%) | NA |
| Loss of sleep | 1 (0.55%) | 1 (0.55%) | 1.000 |
| Increase in sleep | 0 (0%) | 0 (0%) | NA |
| Tiredness | 18 (9.89%) | 27 (14.84%) | 0.151 |

*-p value<0.05,significant

respectively. In severity assessment, mild reactions were observed more frequently in Sputnik group after both first and second doses of vaccination. Adults with a history of comorbidity, hypertensive and diabetic adults had less adverse effects and systemic side effects after the first dose of vaccination. Additionally, adults >40 years had less adverse effects following the first dose. Furthermore, people with a history of allergy had more systemic side effects after the first dose. Also, more total systemic AEFIs were observed in allergic adults. People with the previous history of

Table 3 — *Comparison of adverse effects in both groups after first dose of vaccination*

| Adverse effects | Covaxin group (n=519) | Sputnik V group(n=182) | P value |
|---|---|---|---|
| Incidence of adverse effect | 339 (65.32%) | 108 (59.34%) | 0.149 |
| Incidence of systemic adverse effect | 258 (49.71%) | 77 (42.31%) | 0.085 |
| Fever | 92(17.73%) | 36(19.78%) | 0.537 |
| Body ache | 163(31.41%) | 53(29.12%) | 0.566 |
| Pain in injection site | 209(40.27%) | 78(42.86%) | 0.541 |
| Nausea and vomiting | 6(1.16%) | 2(1.10%) | 0.950 |
| Malaise | 29(5.59%) | 12(6.59%) | 0.619 |
| Cough | 5(0.96%) | 1(0.55%) | 0.602 |
| Diarrhoea | 25(4.82%) | 4(2.20%) | 0.127 |
| Sneezing | 2(0.39%) | 0(0%) | 0.402 |
| Urinary problem | 1(0.19%) | 0(0%) | 0.553 |
| Skin-rash | 10(1.93%) | 1(0.55%) | 0.198 |
| Loss of Appetite | 8(1.54%) | 0(0%) | 0.092 |
| Increase in appetite | 2(0.39%) | 0(0%) | 0.402 |
| Loss of sleep | 4(0.77%) | 1 (0.55%) | 0.760 |
| Increase in sleep | 2(0.39%) | 0(0%) | 0.402 |
| Tiredness | 59(11.37%) | 18(9.89%) | 0.583 |
| MEDRA SOC classification | Total number of AEFI in first dose of vaccination (n=617) | Total number of AEFI in first dose of vaccination (n=206) | P value |
| General disorder and administration site conditions | 389(63.05%) | 144(69.9%) | 0.067 |
| Musculoskeletal and connective tissue disorder | 163(26.42%) | 53(25.73%) | 0.845 |
| Gastrointestinal disorders | 41(6.65%) | 6(2.91%) | 0.016* |
| Skin and subcutaneous tissue disorders | 10(1.62%) | 1(0.49%) | 0.106 |
| Respiratory, thorasic, and mediastinal disorders | 7(1.13%) | 1(0.49%) | 0.314 |
| Psychiatric disorders | 6(0.97%) | 1(0.49%) | 0.536 |
| Renal and urinary disorders | 1(0.16%) | 0(0%) | 0.317 |
| Severity assessment (FDA) | Total number of AEFI in first dose of vaccination (n=617) | Total number of AEFI in first dose of vaccination (n=206) | P value |
| Grade 1(mild) | 399 (64.67%) | 156 (75.73%) | 0.002* |
| Grade 2(moderate) | 218 (35.33%) | 50 (24.27%) | 0.002* |

**Comparison of adverse effects in both groups after second dose of vaccination**

| Adverse effects | Covaxin group (n=200) | Sputnik V group (n=182) | P value |
|---|---|---|---|
| Incidence of adverse effect | 166 (83%) | 127 (69.78%) | 0.002* |
| Incidence of systemic adverse effect | 145 (72.5%) | 107 (58.79%) | 0.005* |
| Fever | 59 (29.5%) | 49 (26.92%) | 0.576 |
| Body ache | 72 (36%) | 67 (36.81%) | 0.869 |
| Pain in injection site | 90 (45%) | 79 (43.41%) | 0.754 |
| Nausea and vomiting | 18 (9%) | 17 (9.34%) | 0.908 |
| Malaise | 25 (12.5%) | 14 (7.69%) | 0.121 |
| Cough | 10 (5%) | 2 (1.1%) | 0.029* |

| | | | |
|---|---|---|---|
| Diarrhoea | 13 (6.5%) | 4 (2.2%) | 0.042* |
| Sneezing | 9 (4.5%) | 0 (0%) | 0.004* |
| Urinary problem | 1 (0.5%) | 0 (0%) | 0.339 |
| Skin-rash | 10 (5%) | 4 (2.2%) | 0.145 |
| Loss Of Appetite | 1 (0.5%) | 0 (0%) | 0.339 |
| Increase in appetite | 4 (2%) | 0 ( 0%) | 0.055 |
| Loss of sleep | 0 (0%) | 1 (0.55%) | 0.294 |
| Increase in sleep | 2 (1%) | 0 ( 0%) | 0.176 |
| Tiredness | 52 (26%) | 27 (14.84%) | 0.007* |
| MEDRA SOC classification | Total number of AEFI in second dose of vaccination (n=366) | Total number of AEFI in second dose of vaccination (n=264) | P value |
| General disorder and administration site conditions | 226(61.75%) | 169(64.02%) | 0.561 |
| Musculoskeletal and connective tissue disorder | 72(19.67%) | 67(25.38%) | 0.092 |
| Gastrointestinal disorders | 36(9.84%) | 21(7.95%) | 0.409 |
| Skin and subcutaneous tissue disorders | 10(2.73%) | 4(1.52%) | 0.284 |
| Respiratory, thorasic, and mediastinal disorders | 19(5.19%) | 2(0.76%) | 0.001* |
| Psychiatric disorders | 2(0.55%) | 1(0.38%) | 0.756 |
| Renal and urinary disorders | 1(0.27%) | 0(0%) | 0.317 |
| Severity assessment (FDA) | Total number of AEFI in second dose of vaccination (n=366) | Total number of AEFI in second dose of vaccination (n=264) | P value |
| Grade 1(mild) | 194 (53.01%) | 183 (69.32%) | <0.001* |
| Grade 2(moderate) | 172 (46.99%) | 81 (30.68%) | <0.001* |

*-p value<0.05,significant

COVID-19 infection had fewer number of adverse effects after the second dose of vaccination. Also, Hypertensive adults had less total AEFI in our study (Table 4).

## Discussion

The COVID-19 is a Viral Respiratory disease and characterized by pneumonia-like illness. It is the cause of worldwide destruction of public health and economic instability. Supportive measures, ie, Oxygen, Steroid, and Anti-coagulants, are the cornerstone of treatment of this deadly disease. The vaccine is the most effective way to prevent the spread of COVID-19 disease. Though Covishield is the main Vaccine for Mass Vaccination purpose, Covaxin and Sputnik V are some of the commonly used vaccines in India[4].

We have observed that both Covaxin and Sputnik V vaccine have a favorable safety profile and are suitable for the Mass-Vaccination purpose. Incidence of AEFI was 65% and 59% following the first dose of vaccination in Covaxin and Sputnik V groups, respectively. Incidence of AEFI was 83% and 70% after the second dose in Covaxin and Sputnik V groups. According to the Zare's study in Iran[7], Covaxin and Sputnik V are associated with 92.9% and 81.9% side effects, respectively. Our study has also revealed that Sputnik V Vaccine had less number of side effects which is consistent with the Iranian study. Pain in the injection site was the most common adverse effect. Body-ache, fever and tiredness were other systemic side effects. According to Bharat Biotech's data on Covaxin, side effects reported are pain in the injection site, Fever, Malaise, Nausea-vomiting and rashes, consistent with our study[8]. In contrast, Headache is a common adverse effect in the manufacturer's fact-sheet though

Table 4 — *Relationship of AEFI with gender, age, previous history of COVID-19 and different co-morbidities (logistic regression analysis)*

| AEFI | Adverse effect after first dose of vaccination | Systemic adverse effect after first dose of vaccination | Adverse effect after second dose of vaccination | Systemic adverse effect after second dose of vaccination | Total AEFI | Total systemic AEFI |
|---|---|---|---|---|---|---|
| Sex(male) | 0.862 | 0.129 | 0.572 | 0.253 | 0.538 | 0.052 |
| Age >40 years | 0.017* | 0.081 | 0.950 | 0.849 | 0.259 | 0.249 |
| Previous history of COVID-19 | 0.180 | 0.171 | 0.037* | 0.136 | 0.075 | 0.145 |
| Co-morbidities | 0.010* | 0.005* | 0.378 | 0.561 | 0.396 | 0.395 |
| Arthritis | 0.286 | 0.244 | 1.000 | 1.000 | 1.000 | 1.000 |
| Thyroid disease | 0.960 | 0.900 | 0.701 | 0.383 | 0.401 | 0.136 |
| Hyper-lipoproteinemia | 0.286 | 0.727 | 0.386 | 0.777 | 0.224 | 0.663 |
| Asthma and COPD | 0.144 | 0.483 | 0.683 | 0.980 | 0.254 | 0.576 |
| Hypertension | <0.001* | <0.001* | 0.097 | 0.100 | 0.037* | 0.056 |
| Diabetes mellitus | 0.016* | 0.002* | 0.340 | 0.161 | 0.128 | 0.078 |
| Allergy | 0.130 | 0.002* | 0.999 | 0.072 | 0.079 | 0.020* |
| Liver disease | 0.999 | 0.929 | 0.999 | 0.704 | 0.999 | 0.992 |
| Chronic kidney disease | 0.643 | 0.302 | 0.999 | 0.999 | 0.999 | 0.999 |
| Concomitant medication | 0.424 | 0.079 | 0.786 | 0.990 | 0.952 | 0.958 |

*-p value<0.05,significant

not observed in our study. Tiredness is a common side effect of Covaxin observed after both first and second doses of vaccination in our study though not mentioned as a side effect in the manufacturer's fact-sheet. Other side effects, ie, Cough, Sneezing, Diarrhoea, Urinary difficulty, Changes in Appetite and Sleep, though few in number, are observed in our study, which are inconsistent with the manufacturer's fact-sheet. Side effects were noticeably more after the second dose. Over half of the reactions were mild in nature. Covaxin had a higher number of moderate adverse reactions after both doses. Adults with age >40 years, co-morbidities, Hypertension and Diabetes had a smaller number of adverse effects following the first dose of vaccination. According to Zare, younger adults are associated with more side effects which is consistent with our study[7]. On the contrary, people with previous COVID-19 infection have noticeably less adverse effects after second dose of vaccination. People with previous COVID-19 infections had noticeably fewer side effects after the second dose. Allergic adults were associated with more systemic adverse effects, whereas hypertensive adults had less total AEFI.

Small number of participants and short duration of follow-up were the limitations of the study. However, being the first real world study on the adverse event profiles of Covaxin and Sputnik vaccine in Eastern India this study adds to the evolving safety profile of COVID-19 vaccines in the country.

To conclude, both vaccines had a favorable safety profile and can be used for mass vaccination in India.

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