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The initial experience of COVID-19 vaccination from a tertiary care centre of India

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To the Editor

Drugs Controller General of India (DCGI) has approved the Bharat biotech vaccine against COVID-19, which is a locally manufactured inactivated vaccine named "COVAXIN" in

collaboration with the Indian council of medical research (ICMR) on 3rd January 2021 for emergency use along with the "Covishield" Oxford-AstraZeneca vaccine manufactured locally by the Serum Institute of India [1]. The phase 1 vaccine trial of Covaxin, which evaluated 375 patients in 4 groups and found pain at the injection site (5 %), headache (3 %), fatigue (3 %), fever (2 %), and nausea or vomiting (2 %) to be the most common adverse events following immunization (AEFI) All AEFI were mild (69%) or moderate (19 [31%]) and were more common after the first dose [2]. Thus, tolerable safety outcomes along with efficacy for the vaccine were suggested requiring further large-scale data. The phase 2 data revealed a favourable safety data [3] while the phase 3 trial data have not been published or made available yet [4]. The Government of India (GOI) launched a nationwide vaccination drive in a phased manner based on 16th January 2021 for health care workers initially and subsequently extending to frontline workers, and the higher-risk population at designated sites in two doses 28 days apart [5].

The enrolment of beneficiaries was electronic and involved Co-WIN (COVID 19 Vaccine Intelligence Network), a cloud-based IT solution to prepare, implement, track, and evaluate COVID-19 vaccination in India extension of the existing electronic Vaccine Intelligence Network (eVIN) module. The system currently allows registration of beneficiaries (bulk upload), facilities/planning unit, and session sites accompanied by planning and scheduling sessions at the district level [6]. A list of 100 health care workers in the first week were released at each site which was stepped up to 500 in the fourth week. However, the turnaround was only around 50%, and hence walk-in vaccination was also started from 2nd week.

Till 16th February 2021 i.e. one month after initiation, 1322 beneficiaries including doctors, nurses, support staff, and other health care workers, were vaccinated at our centre. It was a predominantly young population (mean age 42.78 years ±10. 2 years). One hundred twenty (9%) of these had comorbidities, with diabetes mellitus and hypertension being the predominant ones.

AEFI reported were minor and scanty, gradually the acceptance for vaccines increased and turnaround also [5]..An AEFI is defined as any untoward medical occurrence that follows immunization, which does not necessarily have a causal relationship with the vaccine's usage. AEFI is categorically reported as minor, severe, or serious [7], Minor AEFI are minor reactions which are common, self-limiting e.g., pain & swelling at injection site, fever, irritability, malaise, etc. Severe AEFI are non-hospitalized cases with increased severity that do not lead to long-term problems but can be disabling. Examples: non-hospitalized cases of anaphylaxis that have recovered, high fever (>102-degree F), hypotonic hyporesponsive episodes, sepsis,

etc. Serious AEFI includes deaths, hospitalizations, clusters, disability, media reports/ community/parental concern following vaccination. The vaccination centre followed guidelines as per the protocol issued by GOI. The site is monitored by a multidisciplinary AEFI team; anaphylaxis kits, essential injectable drugs, defibrillator, ventilator, oxygen support and advanced vital monitors in the AEFI room. A 24-hour ambulance along with a reserved bed in the Intensive care unit has also been earmarked.

At authors current centre, only 15 subjects developed an AEFI in one month duration. These AEFI were all after the first dose of vaccine as the second dose was started after this study period. The initial profile of the vaccinated people and the adverse events following immunization (AEFI) revealed a relatively safe vaccine (Table 1). Out of 15 reported AEFI, 8 were males. 12 of the 15 AEFI were reported on day 1 after vaccination, while 3 were reported on day 2 after vaccination. All 15 minor reported AEFI were treated with tab paracetamol for fever, tab diclofenac for pain and reassurance.

To conclude, our initial experience is that COVAXIN is a safe and tolerable vaccine with minimal and minor side effect profile. There is need to build confidence and trust among the eligible beneficiaries so as to extend the benefit of vaccination to control the current pandemic. The efficacy of COVAXIN can only be determined with a long-term follow-up and after the subjects receive a second dose of the vaccine.

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Table 1. Adverse events following immunization after COVAXIN.

S.no	Age	Sex	Adverse effects	Day of onset	AEFI category	Treatment
1	30	Male	Fever for 2 days	1	Minor	Tab Paracetamol
2	35	Female	Chest pain for 1 day	1	Minor	Tab Diclofenac
3	35	Female	Local swelling of arm	1	Minor	Tab Paracetamol
4	35	Female	Palpitation	1	Minor	Reassurance
5	41	Male	Headache for 1 day	1	Minor	Tab Paracetamol
6	32	Male	Pain at injection site for 3 days	1	Minor	Tab Paracetamol
7	60	Male	Myalgia/ Arthralgia for 3 days	2	Minor	Tab Paracetamol
8	44	Male	Fever for 2 days	1	Minor	Tab Paracetamol
9	41	Male	Headache, dizziness and vertigo for 1 day	2	Minor	Tab Paracetamol
10	54	Female	Pain radiating to hand for 3 days	1	Minor	Tab Diclofenac
11	48	Female	Vertigo for 2 days	1	Minor	Tab Paracetamol
12	61	Female	Myalgia for 2 days	2	Minor	Tab Paracetamol
13	64	Male	Fever for 1 day	1	Minor	Tab Paracetamol
14	26	Female	Fever & rash on arm with itching for 3 days	1	Minor	Tab Paracetamol Tab pheniramine
15	55	Male	Fever for 3 days	1	Minor	Tab Paracetamol