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Surveillance Of Adverse Events Following Immunization (AEFI) After First Dose Of Covid-19 Vaccination Program: A Short Audit.

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ABSTRACT

Adverse Events Following Immunization (AEFI) may occur following vaccinations which may range from mild to severe. A new vaccination program for Covid-19 was started in Malaysia and thus the presentation of persons to the emergency response clinic with AEFI after the first dose of covid-19 vaccination program was studied. The objectives of this study were to use collected daily data of persons presenting to the Emergency Response Clinic with AEFI following the first dose of covid-19 vaccination to know the incidence of AEFI, its presentation and severity. An audit was performed throughout the first dose of Covid-19 vaccination program in a single tertiary center observing patients presenting to the Emergency Response Clinic who turn out to have symptoms post vaccination. The results showed that AEFI incidence was low among those vaccinated and out of these, majority had mild symptoms and only a few had moderate side effects with no one developing severe effects post vaccination. These results show that the vaccine is considered safe because the percentage who had seek treatment was low, and mostly had only mild symptoms. The establishment of an Emergency Response Team will ensure better recognition, monitoring, treatment and referral process for a COVID-19 vaccination program which will identify early and improve the outcomes in patients post vaccination.

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INTRODUCTION

After the world had been hit with the Covid-19 pandemic, we have now followed up with the introduction of vaccines. The role of the vaccine is to immunize a large number of people also called as herd immunity. Increased immunity among the global community would therefore reduce not only the spread of covid-19 but also its morbidity and mortality. Herd immunity with broaden immunological protection against covid-19 and is required to protect the most vulnerable people depending on their biological and environmental factors[1].

Malaysia similar to other countries have acquired the covid-19 vaccines to start the vaccination program in the country. Malaysia aims to vaccinate at least 80 percent of its population within a year of starting the immunization program. The front lines have been selected to be among the first in the country to receive the vaccination and kick start the vaccination program. This National Covid-19 vaccination program is the largest vaccination program ever in the country[2].

Vaccines are known to cause side effects or adverse effects which are generally caused by the body mounting an immune response against the vaccine stimulating a protective immune response from the host. The adverse events can range from mild to severe and varies in its presentation. A collective term Adverse events following immunization (AEFI) has been in use. Anaphylaxis post vaccination is uncommon however has been reported in a few occurrences and should be kept in mind when dealing with cases of AEFI[3].

Safety surveillance of the covid-19 vaccinated persons is an important mitigation plan and should not be taken lightly. Early recognition of signs and symptoms of adverse effects of the vaccine is important to be able to manage the patients well and prevent worsening of symptoms that may lead to life threatening conditions. Safety surveillance includes background of the patients and risk factors, to observation post vaccination and proper disposition planning[4].

METHODS

Data

The data for this audit was collected using daily reports from the Emergency Response Team that had been stationed at the vaccination areas of the hospital. The data was collected for first dose vaccination from the first day 8th of March 2021 until the last day 12th of March 2021. The Emergency Response Team is a team that had been set up by the Emergency Department lead by an Emergency Physician and comprises all levels of emergency department staffs.

Definition of operational terms used in this study

- Mild AEFI- mild reaction not requiring treatment and discharged from ERT site
- Moderate AEFI- had to be sent to the Emergency Department for further treatment
- Severe AEFI- requiring airway and hemodynamic support

Results

Table 1: Total cases that developed AEFI after first dose vaccination

Date	Age	Occupation	Complaint	Treatment
8/3/2021	26		Dysphagia	Monitor v/s
8/3/2021	46		Neck Pain	Monitor v/s IVD 1 pint @12.40
8/3/2021	36		Palpitation	Monitor v/s
8/3/2021	30		Palpitation BP 117/69, HR 111 SPO2 100%	Monitor v/s
8/3/2021	39		Giddiness BP 177/92, HR 98 SPO2 100	Monitor v/s
8/3/2021			SOB BP 150/79, HR 71 SPO2 98%	Monitor v/s
8/3/2021			Giddiness BP 150/96, HR 86 SPO2 100%	Monitor v/s
9/3/2021 @ 9.50 am	31		Giddiness BP 102/82, HR 86 SPO2 100%, Dxt 5.9	Monitor v/s
9/3/2021 @ 10.20 am			Vomiting, nausea BP 121/75, HR 121 SPO2 100%	Monitor v/s - IV Maxolon - IV Ranitidine - IV Drip NS
9/3/2021 @ 10.30 am			Blurry vision BP 118/80, HR 79 SPO2 100%, Dxt 5.5	Monitor v/s
9/3/2021 @ 10.30am			Giddiness BP 138/92, HR 95 SPO2 100%	Monitor v/s
9/3/2021 @ 10.35am			Headache, HPT BP 210/133, HR 110 Dxt 6.6, SPO2 100%	Monitor v/s T. Captopril 25mg stat
9/3/2021 @ 10.40 am			Nausea, vomiting, Headache BP 124/79, HR 90, SPO2 100%, Dxt 5.3	Monitor v/s - IV Maxolon - IV Drip NS

9/3/2021 @ 10.45 am			Headache BP 146/93, HR 86 bpm SPO2 100%, Dxt 5.4		Monitor v/s
9/3/2021 @ 11.26 am			Giddiness BP 106/55, HR 84 SPO2 100%, Dxt 4.9		Monitor v/s
9/3/2021 @ 11.55am			Headache BP 129/80, HR 80 bpm SPO2 100%, Dxt 6.5		Monitor v/s
9/3/2021 @ 12.05pm			Nausea, Vomiting BP 133/80, HR 106 SPO2 100%, Dxt 5.9		monitor v/s
9/3/2021 @ 2.48pm			Dizziness BP 170/88, HR 95 SPO2 100%, Dxt 8.7		monitor v/s
9/3/2021 @ 3.51pm			Allergy reaction BP 156/88, HR 85 SPO2 100%		Monitor v/s
10/3/2021@9.55am	56	HCW	Giddiness	Monitor v/s	Discharged
10/3/2021@10.09am	43	HCW	Tingling sensation over the left hand BP- 153/81mmhg PR- 106/min	monitor v/s	Discharge at 10.35am
10/3/2021@11.19am	29	HCW	Nausea, shaking and chest discomfort pain 5/10 BP- 162/105mmhg PR- 109/min DXT- 7.5	Monitor v/s	Transfer to ED RnR@11.30am
10/3/2021@11.28am	53	HCW	Left finger tingling sensation and dizziness BP- 119/75 mmhg PR- 67/min DXT- 7.5	Monitor v/s	Discharged
10/3/2021@1.10pm	38	HCW	Nausea BP- 116/76mmhg PR- 79/min	Monitor v/s	Discharged
10/3/2021@2.45pm	59	HCW	Giddiness BP- 187/98Mmhg	Monitor v/s	Discharged at 3.18pm BP post- 158/85 mmhg
10/3/2021@2.50pm	34	HCW	Nausea, dizziness BP- 125/74MMHG	Monitor v/s	Discharged at 3.21pm BP post- 128/62mmhg
10/3/2021@3.25pm	40	HCW	Giddiness BP- 165/84MMHG PR- 66/min Spo2- 100%	Monitor v/s	Discharged at 3.55pm BP post- 149/85 mmhg
10/3/2021@3.55pm	26	HCW	Nausea DXT- 5.7	Monitor v/s	Discharged at 4.10pm BP post- 139/53 MMHG

			BP- 126/81Mmhg PR- 85/min		
Date	Age	Occupation	Complaint	Treatment	Remark
11/3/2021@9.28am	33	HCW	Dizziness and tingling sensation over the left hand BP-137/87mmhg PR- 71/min	Monitor v/s	Discharged
11/3/2021@9.36am	32	HCW	No sx post vaccination HX of multiple allergic reaction BP-126/82 PR-84/min Spo2-100%	monitor v/s	Discharge @ 10.20am
11/3/2021@9.40am	29	HCW	Dizziness and light headache BP- 137/81Mmhg PR- 65/min DXT- 5.2	Monitor v/s	Discharge @10.15am Post BP- 124/76Mmhg
11/3/2021@9.55am	46	HCW	Dizziness and mild headache BP- 114/68MmHg PR- 75/min Spo2-100%	Monitor v/s	Discharged
11/3/2021@10.12am	50	HCW	Giddiness BP-122/71mmhg PR-100/ming	Monitor v/s	Discharged
11/3/2021@10.12am	59	HCW	Dizziness Bp- 122/60MmHg Pr-75/min DXT- 5.9 Spo2- 100%	Given T PCM 1G stat Monitor	sx persist associated with headache and unstable gait Transfer to yellow non respi
11/3/2021@10.18am	29	HCW	Mild dizziness Bp- 138/71Mmhg Pr- 84/min Spo2- 98%	Monitor v/s	Discharged
11/3/2021@10.31am	37	HCW	Dizziness Bp-133/91Mmhg Pr- 90/min DXT- 7.3	Monitor v/s	Discharged @ 10.40am Post BP-120/76 mmhg
11/3/2021@10.45am	29	HCW	Dizziness BP-105/67mmHg PR-80/min Spo2-99%	Monitor v/s	Discharged @11.10am
11/3/2021@11.40am	43	HCW	U/L DM vomiting and dizziness Bp-183/100mmhg	Monitor v/s Iv drip 1pint run fast Iv hydrocortisone	Transfered to yellow non respi Repeated DXT- 22.7

			Pr-85/min DXT- 19	200 IV Piriton 10mg stat	
11/3/2021@12.17pm	42	HCW	Dizziness Bp-145/87mmhg Pr- 95/min	Monitor v/s	Discharged
11/3/2021@12.25pm	32	HCW	Dizziness, and mild headache BP- 128/88 mmhg Pr-80/min Dxt- 7.6	Monitor v/s	Discharged Post BP- 105/77 mmhg
11/3/2021@12.32pm	30	HCW	Headache Bp- 137/89 mmhg PR- 95/min DXT- 5.8	Given T PCM 1G stat Monitor v/s	Discharged BP post- 113/71 mmhg
11/3/2021@12.45pm	42	HCW	mild dizziness Bp- 142/ 87 Mmhg Pr- 76/min Spo2- 100	Monitor v/s	Discharge BP post - 135/76 mmhg
11/3/2021@12.45pm	40	HCW	Mild dizziness BP-140/89 mmhg Pr-79/min DXT- 6.5 Spo2-98%	Noted post observatio 30 min - patient developed itchines over the bilateral cubical , palm face	Bp- 149/ 98 mmhg Pr- 78/min Spo2- 98% Lungs- clear Given Iv hydrocortisone 200mg stat Iv piriton 10mg stat transfer to yellow non respi
	31	HCW	nausea and vomiting DXT- 6.8 BP- 138/74mmhg	monitor v/s	Discharged
Date	Age	Occupation	Complaint	Treatment	Remark
12/3/2021@10.35am	33	HCW	Headache BP-142/86 MMHG PR-98	Monitor v/s Given T PCM 1G stat	Discharged Post BP-131/62mmhg
12/3/2021@10.36am	38	HCW	Dizziness BP-188/119mmhg PR- 80/min Spo2-99% Lungs- clear	monitor v/s	Discharge BP post- 149/96 MMHG
12/3/2021@10.47am	41	HCW	Dizziness and palpitation BP-151/87mmhg Pr-97/min Spo2-99%	Monitor v/s	Discharge
12/3/2021@11.32am	52	HCW	Dizziness and mild headache BP- 114/68MmHg PR- 75/min	Monitor v/s	Discharged

			Spo2-100%		
12/3/2021@11.42am	36	HCW	Giddiness Bp- 151/79 mmhg Pr- 90/min Spo2- 98	Monitor v/s	Discharged Post BP-125/80mmhg
12/3/2021@11.39am	37	HCW	Dizziness Bp- 122/60MmHg Pr-75/min DXT- 5.9 Spo2- 100%	Monitor v/s	Discharged
12/3/2021@12.25pm	31	HCW	Nausea and giddiness BP-123/85mmhg Pr- 90/min	Monitor v/s	Discharged
12/3/2021@12.35pm	41	HCW	Allergic to tramadol and voltaren Generalised itchiness Scratch mark over the left neck	BP- 116/68Mmhg Pr- 64/min Spo2- 100% Lungs- clear	Iv hydrocortisone 200mg stat Iv piriton 10mg stat Iv Ranitidine 50mg stat Transfer to yellow non respi
12/3/2021@3.54pm	37	HCW	U/l - HPT- skipped meds Dizziness post vaccination BP- 220/115mmhg PR- 100/min Spo2- 98%	Monitor v/s For T captopril 25mg stat	Repeated BP at 4.15pm Bp- 190/115 MmHg Transfer to ED for HPT urgency
12/3/2021 @4.39pm	37	HCW	Allergic to PCM , ranitidine Generalised itchiness Scratch mark no urticaria rashes No sob	Bp- 150/100mmhg Pr- 100/min Spo2- 98% Lungs- clear	Iv hydrocortisone 200mg stat Iv piriton 10mg stat Send to yellow non respi

Table 2: Severity percentage among the patients who developed AEFI

AEFI severity	Percentage
Mild	81.13 %
Moderate	18.86 %
Severe	0

DISCUSSION

The results showed that the total number of persons vaccinated through this first dose vaccination program in the time frame of the study was 3007 total. This comprises of all levels of staff in the hospitals who had been approved to receive the vaccine.

AEFI consists of signs and symptoms related to adverse events following immunization or vaccination. However, a standardized definition is not easy because of low resource context, limited diagnostic capability and high patient load.[5] Therefore, in this study, operational terms used as described in methods above were used based on the limited resources and capability of the investigating center.

Definition of operational terms used in this study

Mild AEFI- mild reaction not requiring treatment and discharged from ERT site
Moderate AEFI- had to be sent to the Emergency Department for further treatment
Severe AEFI- requiring airway and hemodynamic support

Out of this 3007 vaccinated people, 53 patients had developed AEFI. (1.76 percent of the total persons vaccinated developed AEFI). Out of the 53 persons who developed AEFI, 43 patients were discharged and were considered to have mild AEFI (81.13 %). Out of the 53 persons who developed AEFI, 10 patients were transferred to the Emergency department for further care and were considered to have moderate AEFI. (18.86 percent of all AEFI are of moderate severity). None of the patients were intubated or needed ICU care thus no patients were categorized as severe AEFI. (0%)

STRENGTHS AND LIMITATIONS

The data for this audit was collected from the Emergency Response team covering the vaccination site from the time of start of vaccination in the day until the end of the vaccination for the respective day. Thus, some patients who presented to the Emergency department or to other hospitals or health facility after the vaccination period may have been missed during the duration of the study.

This audit only studied the patients after the first dose of the vaccine. The complete dose is 2 doses 21 days apart. Thus, the AEFI after the second dose was not studied. This could have led to a different data interpretation if the second dose was included.

CONCLUSION AND IMPLICATIONS

The appearance of the vaccine has definitely been a positive factor in development of prevention of covid-19. Malaysia like most other countries have acquired the vaccines and started on the National immunization program against covid-19. There has been reported cases of AEFI following vaccinations and thus education and methods to recognize and treat AEFI has been implemented by many hospitals. Emergency response teams have been prepared to handle AEFI cases and provide a safe environment for vaccinated persons. This data on AEFI has showed that out of all the patients vaccinated, a very small percentage of patients developed AEFI and majority of these AEFI cases were mild and none severe. Thus, an early implication is that the vaccine is relatively safe and should be encouraged to prevent the covid-19 pandemic.

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