ISSN (P) : 2589-9120 / (O) : 2589-9139
PubMed-National Library of Medicine - ID: 101773527

International Journal of Medical Science and Applied Research (IJMSAR)

Available Online at: https://www.ijmsar.com

Volume – 5, Issue – 4, August – 2022, Page No. : 56 – 63

Effect of Paracetamolas A Prophylactic in Covishield Vaccine

[1]Miss Raveena Rajesh, [2]Ashley Ann Varghese, [3]Aswathy Anna Dilip, [4]Jacob M Cherian, [5]Dr.Elssey Abraham, [6]Dr. Sofy Binu

[1,2,3,4,5]6th Year Pharma D Students, Nazareth College of Pharmacy, Othera, Thiruvalla, Kerala, India

[6]Assistant Professors, Department of Pharmacy Practice, Nazareth College of Pharmacy, Othera, Thiruvalla, Kerala, India

Citation of this Article: Raveena Rajesh, Ashley Ann Varghese, Aswathy Anna Dilip, Jacob M Cherian, Dr. Elssey Abraham, Dr. Sofy Binu, "Effect of Paracetamolas A Prophylactic in Covishield Vaccine,'' IJMSAR – August – 2022, Vol. – 5, Issue - 4, Page No. 56-63.

Corresponding Author: Miss. Raveena Rajesh, Pharma D Intern, Nazareth College of Pharmacy, Othera, Thiruvalla, Kerala, India

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Corona Virus disease 2019 (COVID 19) is a contagious disease caused by Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2). The disease has since spread worldwide, leading to an ongoing pandemic. Risk for severe illness with COVID 19 increases with age, with older adults at highest risk. Studies have shown that this virus causes worse outcomes and a higher mortality rate in older adults and those with comorbidities such as Hypertension, Cardiovascular disease, Diabetes, Chronic Respiratory Disease and Chronic Kidney Disease. A significant percentage of elderly have these diseases, putting them at a higher risk of infection. Vaccines are a critical new tool in the battle against COVID 19.The aim of our study was to evaluate the effect of Paracetamol in Covishiled vaccination. This descriptive study was conducted among 500 people in the vaccination center in tertiary care Hospital from February 2021 to July 2021. Among those people who administered Paracetamol at the time of vaccination affects less adverse events.CDC and WHO recommends Paracetamol for subsiding the adverse events of the vaccine.

Keywords

Covid 19, adverse events, Covishield vaccine, SARS-COV-2 Paracetamol.

Introduction

COVID-19 is an infectious disease caused by a newly discovered virus, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) which

suddenly became a global pandemic On December 31, 2019, National Health Commission of China confirmed the information that the first appearance of COVID-19 in pneumonia patients appeared in Wuhan, a city in the Hubei province of China and it was attributed to a new strain of HCoV. The World Health Organization (WHO) initially named it as 2019-nCoV and later renamed to SARS-CoV-2 by the International Committee on Taxonomy of Viruses Initially, pneumonia patients expressed the normal respiratory infection which rapidly transformed into acute respiratory syndrome.. Most cases of COVID-19 cause mild to moderate illness, but some cases it become severe and leading to death. Common symptoms includes Fever, Breathlessness, Cough, New loss of taste or smell, Headache ,Fatigue, Sore Throat, Chills, Congestion or runny nose, Nausea or vomiting, Diarrhea. Although 80% of the COVID-19 cases are asymptomatic or causes mild upper respiratory tract symptoms, 20% of the patients have pneumonia along with fever, cough, dyspnea and fatigue.

Covid -19 Vaccines

A COVID-19 vaccine is a vaccine which provides immunity against SARS-CoV-2. As of July 2021, 322 vaccine candidates have been proposed, 99 are in clinical testing, 25 have reached Phase III efficacy studies and 18 have received some form of approval for use. A few of these new vaccines are being approved for emergency use. Due to the short development time and novelty of the technologies adopted, these vaccines will be deployed with several unresolved issues that only the passage of time will permit to clarify. Vaccines can be based on whole viruses (live-attenuated or inactivated), viral vectors, nanoparticles or virus-like particles, subunit components, proteins/peptides, RNA, DNA or live cells. Some of the COVID-19 vaccines and its most commonly reported AEFIs.

Covid-19 Vaccines	Vaccine Type	Commonly Reported AEFIs
Covishield	Adenovirus vectored vaccine	Tenderness at the injection site, Fatigue
Johnson & Johnson	Adenovirus vectored vaccine	Fatigue, Pain at the injection site
Sputnik V	Adenovirus vectored vaccine	Flu like illness, Injection site redness
Pfizer	mRNA vaccine	Fatigue, Headache, Pain at the injection site
Moderna	mRNA vaccine	Fatigue, Pain at the injection site
Sinopharm	Inactivated vaccine	Pain at the injection site, Fever

Materials and Methods

- **Study Design:** Descriptive study
- **Study Site:** The study was conducted at tertiary care Hospital, Thiruvalla in the Community Medicine Department.
- **Study Period:** 6 months (January 2021 to July 2021)
- **Study Criteria:** The study was carried out by considering the following criteria:

Inclusion Criteria

1. People with an age group of 45 years and above
2. People who received COVISHIELD VACCINE

Exclusion Criteria

1. People who received other COVID-19 vaccines

- **Sample Size:** The estimated sample size was 500 among the people who receive COVISHIELD vaccine during the study period without further sampling.
- **Sources of data:** All relevant and necessary data was collected from the patient using predesigned data collection proforma.
- **Study Procedure:** Effect of Paracetamol as a prophylactic in Covishield vaccine were identified through a follow-up study of 6 months of duration. All patients satisfying the study criteria were enrolled in the study after obtaining a written informed consent printed in patient's understandable language from the patient or care-giver, in case of the patient being unable to give the consent. All relevant and necessary patient related information has been collected at the time of vaccination and information related to AEFI has been collected after 72 hours by telephone.

Results

Distribution of Gender

Table 1:

S. No	Gender	Frequency	Percentage
1.	Male	235	47
2.	Female	265	53
		500	**100**

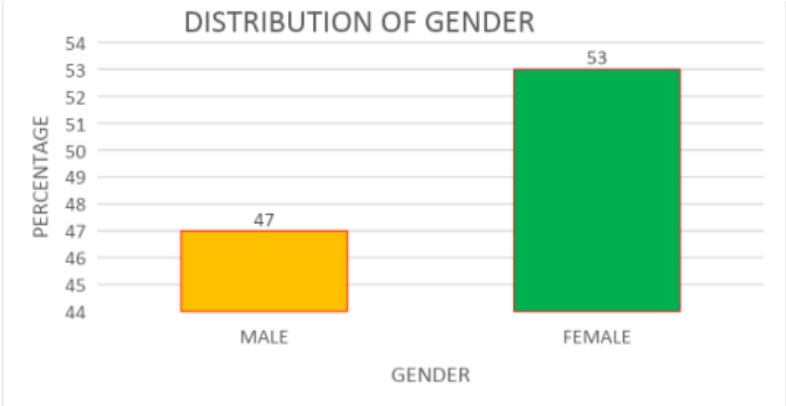

Fig. 1

From the total population distribution of females is 53% and that of male is found to be as 47%

Distribution of People Who Had Paracetamol after First and Second Dose of Vaccination

Table – 2:

S. No	Gender	Frequency	Percentage
	Paracetamol Dose	First Dose (N=500)	Second Dose (N=500)
1.	500mg	350(70%)	299(59.80%)
2.	650mg	150(30%)	201(40.20%)

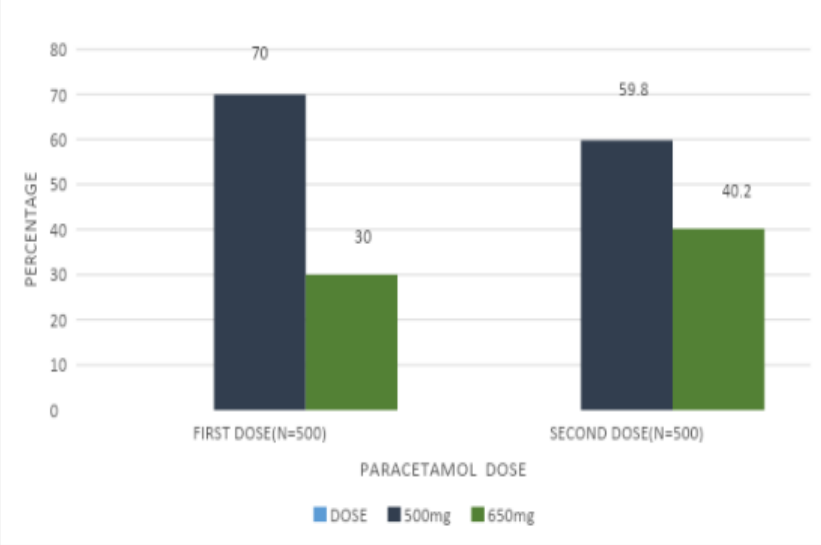

Figure – 2

Among the total population people who took 500 mg Paracetamol in first dose is 70% and in the second dose it is 59.8% .In case of 650 mg Paracetamol people who took in first dose were 30% and in second dose it become 40.2% which shows an increased use of 650 mg Paracetamol as prophylactic among the population.

Distribution of Dose of Paracetamol Before, At the Time of Vaccination and After Vaccination

Table - 3:

S. No.	Response	First Dose(N=500)		Second Dose(N=500)	
		500mg(n=350)	650mg(n=150)	500mg(n=299)	650mg(n=201)
1.	Before Vaccination	65(18.57%)	35(23.33%)	39(13.05%)	45(22%)
2.	At The Time Of Vaccination	165(47.14%)	75(50%)	142(47.49%)	86(43%)
3.	After Vaccination	120(34.29%)	40(26.67%)	118(39.46%)	70(35%)

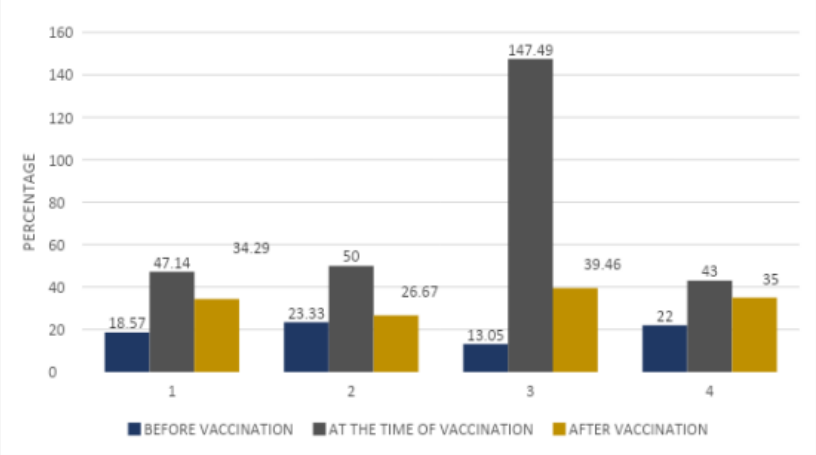

Figure - 3

From the above table people who took 500 mg Paracetamol before first and second doses are 65% and 35% and incase of 650 mg Paracetamol before vaccination in first and second doses are 23.33 % and 22 %.People who took 500 mg Paracetamol at the time of vaccination are 47.14% and 47.49% and in case of 650 mg Paracetamol in first and second dose of vaccination are 50 % and 43%.People who took 500 mg Paracetamol after vaccination in first and second doses are 34.29% and 39.46% and in case of 650 mg in first and second dose of vaccination were 26.67% and 35 %.

Distribution of AEFI in People Who Took Both Doses of Paracetamol as Prophylactic

Table – 4:

Dose	AEFI	First Dose	Second Dose
500mg	Body Pain	45	49
	Fatigue	34	48
	Fever	30	45
	Rashes	10	4
	Chills	12	18
	Pain at the site of injection	70	56
	Insomnia	23	37
	Redness at the site of injection	34	29
	Back Pain	55	23
	Decreased Appetite	15	10
	Headache	60	30
650mg	Body Pain	21	19
	Fatigue	26	14
	Fever	40	30
	Rashes	2	6
	Chills	15	17
	Pain at the site of injection	12	9
	Insomnia	9	4
	Redness at the site of injection	19	7
	Back Pain	11	18
	Decreased Appetite	4	2
	Headache	22	30

From the total population, in the first dose people who had take 500 mg Paracetamol suffered the major adverse event after vaccination is body pain which is about 45 and in the second dose it was found to be as 39.In 650 mg Paracetamol during the first dose the number of people who suffered body pain were 21 and in the second dose it was found to be 19.

Discussion

People aged 45 years or older and especially those with underlying chronic conditions have an increased risk of severe illness and death from COVID-19 compared with other age group. Moreover, the response to vaccines is usually reduced in older adults because of immunosenescence. This implies that the efficacy could be low in the elderly. Adverse Events Following Immunization (AEFI)defined as any untoward medical event that follows immunization and which does not necessarily have a causal relationship with the usage of vaccine .The COVID-19 vaccine can cause adverse effects after the first or second doses, including pain, redness or swelling at the site of vaccine shot, fever, fatigue, headache, muscle pain, chills, anxiety, dizziness, giddiness, nausea, vomiting, itching, joint pain and can also rarely cause anaphylactic shock. Most of these reported AEFIs are mild to moderate and are self- limiting. The Covishield vaccine is currently being used in India. According to the citizens who have been given this vaccine, now their body is more capable of fighting diseases than before. The vaccine checks the Coronavirus and prevents it from entering the body. If the virus penetrates into the body, the vaccine creates antibodies and exits the body. The safety of vaccines is also expected to be different in this population. This follow up study was conducted to observe COVID-19 vaccine adverse events following immunization in elderly population ina Tertiary care hospital . 500 samples were taken over a period of six months. The data of patients were collected by personal interviews and then the data entered into a predesigned data collection proforma.

- In the study the rate of people who had administered 500 mg Paracetamol in the first dose is 70% and in the second dose it was found be as 59.8%.In case of 650mg Paracetamol ,in first dose it was found be 30% and in the second dose it was increased to 40.2%.That is people who were taken 500mg Paracetamol when compared to first dose were decreased and in case of 650 mg Paracetamol during the second dose it was found to be increased to when compared to the first dose.
- In the study regarding Effect of Paracetamol as a prophylactic in Covishield vaccination, people who had taken Paracetamol at the time of vaccination is more when compared to people who had taken Paracetamol before and after vaccination .Also rate of people who were taken 650mg Paracetamol were increased when compared to the first dose of vaccination in before vaccination, at the time of vaccination and after vaccination. That is rate of people who had taken 500mg Paracetamol got decreased when coming to the second dose.
- The number people who had occurred body pain as one of the most adverse events in both the doses of vaccination .People who had occurred body pain after taking 500mg Paracetamol in the first dose is 45 and in second dose is 39.In case of people who had taken 650 mg Paracetamol body pain were found among in 21 people and in second dose it is 19.When compared to both doses

the number of adverse events in people who had administered 650 mg Paracetamol is less when compared to people who had take 500 mg Paracetamol.

Conclusion

The people who had taken Paracetamol as a prophylactic had less adverse events when compared to people who didn't taken Paracetamol, also amon the people who taken Paracetamol as a prophylactic at the time of vaccination had less adverse events after vaccination. The people who had taken 650 mg Paracetamol as prophylactic were found to be had less adverse events when compared to people who had taken 500 mg Paracetamol.

Limitations

- This study doesn't include people who had taken other Covid vaccines
- This study was conducted only in one location over short period of time which restricts the generalizability of the findings.
- This study doesn't include age group below 45.

References

1. Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR, Voysey M, Aley PK, Angus B, Babbage G, Belij-Rammerstorfer S. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomized, controlled, phase 2/3 trial. The Lancet. 2020 Dec 19;396(10267):1979-93.
2. Chatterjee S, Chatterjee S. COVID-19 Diagnosis, Treatments and Prevention: A Review. Journal of Advances in Medicine and Medical Research. 2020 Sep 23:17-34.
3. Aw D, Silva AB, Palmer DB. Immunosenescence: emerging challenges for an ageing population. Immunology. 2007 Apr;120(4):435-46.
4. Kaur SP, Gupta V. COVID-19 Vaccine: A comprehensive status report. Virus research. 2020 Aug 13:198114.
5. https://vaccine-safety-training.org/classification-of aefis.
6. Anerson EJ, Rouphael NG, Widge AT, Jackson LA, Roberts PC, Makhene M, Chappell JD, Denison MR, Stevens LJ, Pruijssers AJ, McDermott AB. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. New England Journal of Medicine. 2020 Dec 17;383(25):2427-38.
7. WHO. Coronavirus disease (COVID-2019) situation reports. 2020.https:// www.who.int/ emergencies/diseases/novel-
8. coronavirus-2019/situation-reports (accessed May 5, 2020).6 Cowling BJ, Ali ST, Ng TWY, et al. Impact assessment of non-pharmaceutical interventions against coronavirus disease 2019 and influenza in Hong Kong: an observational study,Lancet Public Health 2020; 5: e279–88.
9. Amanat F, Krammer F. SARS-CoV-2 vaccines: status report.Immunity 2020; 52: 583–89.
10. Shrestha S, Devbhandari RP, Shrestha A, Aryal S, Rajbhandari P, Shakya B, Pandey P, Shrestha RK, Gupta M, Regmi A. Adverse events following the first dose of ChAdOx1 nCoV-19 (COVISHIELD) vaccine in the first phase of vaccine roll out in Nepal. Journal of Patan Academy of Health Sciences. 2021 May 15;8(1):9-17.
11. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P, Sudre CH, Nguyen LH, Drew DA, Merino J, Hu C. Vaccine side-effects and SARS-

CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. The Lancet Infectious Diseases. 2021 Apr 27.

12. Knoll MD, Wonodi C. Oxford–AstraZeneca COVID-19 vaccine efficacy. The Lancet. 2021 Jan 9;397(10269):72-4. ● Folegatti PM, Ewer KJ, Aley PK, Angus B, Becker S, Belyj-Rammerstorfer S, Bellamy D, Bibi S, Bittaye M, Clutterbuck EA, Dold C. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomized controlled trial. The Lancet. 2020 Aug 15;396(10249):467-78.
13. CLINICAL MANAGEMENT PROTOCOL: COVID-19 Government of India Ministry of Health and Family Welfare Directorate General of Health Services (EMR Division) Version 3 13.06.20