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COVID-19 infection or vaccination and development of symptoms of GB syndrome: A descriptive retrospective cohort study

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Abstract

Background: A pilot study on “COVID-19 vaccination and its impact on general health of population in the age group of 20-60 years” was conducted at Shaikh Homoeopathic Medical College, Belagavi, Karnataka. The study was conducted in the month of January 2021. Based on the results of a pilot study aimed at establishing rates of Guillain-Barré syndrome (GBS) in individuals with a history of COVID infection and vaccination, body function, activity, health-related quality of life and the Hughes GBS Disability Score. Present a retrospective analysis of every GBS affected patient in Belagavi. The link between GBS cases and exposure to COVID-19 infection and vaccination history is identified through a survey using a data template that includes information on COVID-19 infection, vaccination history and the Hughes GBS Disability Score.

Aims & Objectives

1. To describe how people with a history of COVID-19 and vaccination may be affected by Guillain-Barré syndrome, in terms of physical function, activity and health-related quality of life.
2. To establish rates of Guillain-Barré syndrome (GBS) through GBS disability score among vaccine receivers.

Methodology: Pilot study & Descriptive Retrospective Cohort study.

Results: A pilot study conducted in January 2021 categorized the effects of COVID-19 vaccination into immediate, intermediate, and late effects. Immediate effects, occurring within 24 hours, included fever and severe myalgias in 230 out of 313 vaccinated individuals. Intermediate effects, between 24 hours and 15 days, involved the return of old symptoms such as allergic rhinitis, irregular menses, and joint pains in 210 individuals. Late effects, observed from 16 to 36 days post-vaccination, included marked weakness in both lower limbs and severe backache in 160 patients, affecting their daily activities. Additionally, seven cases of Guillain-Barré Syndrome (GBS) were diagnosed within a month of vaccination at the KLE Institute in Belagavi. Subsequent descriptive retrospective cohort analysis aimed to investigate the association between COVID-19 vaccination, infection, and GBS.

Keywords: Guillain-Barré Syndrome (GBS), COVID-19, vaccination, homoeopathy, belagavi

Introduction

Guillain-Barre syndrome is a group of autoimmune syndromes consisting of demyelinating and acute axonal degenerating forms of the disease. Guillain-Barré Syndrome usually is associated with an antecedent infection by one of several known pathogens. Cross-reactivity between the pathogen and the nerve tissue sets up the autoimmune response [1].

Patients with Guillain-Barré syndrome typically present with notable weakness and tingling dysesthesias in their extremities, with a preference for proximal muscles, particularly affecting the legs over the arms. Paraesthesia's, or abnormal sensations, often spread proximally but rarely extend beyond the wrists and ankles. Within the first few days of symptom onset, deep tendon reflexes vanish. The progressive phase of the syndrome varies in duration, lasting from a few days to up to four weeks. Around 73 percent of patients reach their lowest point in terms of clinical function within one week, and this figure rises to 98 percent at four weeks. Following the progressive phase, there's a plateau phase characterized by persistent, unchanging symptoms, with improvement typically beginning within days. The time it takes for symptoms to fully resolve can vary among patients. In some cases, cranial nerve involvement may impact functions such as airway maintenance, facial muscles, eye movements, and swallowing, necessitating hospitalization for observation. About 30 percent of patients may require ventilatory assistance at some point during the illness.

Poor outcomes are primarily associated with the increasing severity of the disease, with a mortality rate of up to 20 percent, mainly occurring in patients requiring mechanical ventilation. Pain is another common feature of Guillain-Barré syndrome, affecting approximately half of all patients and often described as severe, triggered by even minor movements. This pain tends to be most intense in the shoulder girdle, back, and posterior thighs ^[2].

The diagnostic criteria for typical Guillain-Barré Syndrome (GBS) include

Features Supporting Diagnosis

- **Progressive Weakness:** Patients exhibit progressive weakness in both arms and legs, with areflexia (absence of reflexes), which strongly supports the diagnosis.
- **Progression:** Symptoms progress over days to up to four weeks, with a relative symmetry of symptoms observed.
- **Mild Sensory Symptoms:** Mild sensory symptoms or signs may be present.
- **Cranial Nerve Involvement:** Cranial nerve involvement, particularly bilateral weakness of facial muscles, can be a characteristic feature.
- **Recovery Onset:** Recovery typically begins two to four weeks after the progression of symptoms ceases.
- **Autonomic Dysfunction:** Autonomic dysfunction may be present.
- **Absence of Fever:** There is an absence of fever at the onset of symptoms.
- **Cerebrospinal Fluid Findings:** Cerebrospinal fluid analysis reveals a high concentration of protein with fewer than 10 cells per cubic millimeter.
- **Electrodiagnostic Features:** Typical electrodiagnostic features are often seen in GBS.

Features Excluding Diagnosis

Other Diagnoses: Diagnosis of conditions such as botulism, myasthenia gravis, poliomyelitis, or toxic neuropathy may exclude the diagnosis of GBS.

- **Abnormal Porphyrin Metabolism:** Abnormalities in porphyrin metabolism can also exclude the diagnosis.
- **Recent Diphtheria:** Recent diphtheria infection may present with a purely sensory syndrome without weakness and should be considered as an exclusionary factor.
- These diagnostic criteria help clinicians differentiate typical GBS from other conditions with similar clinical presentations and guide appropriate management and treatment decisions for patients with GBS.

Prevalence

Prevalence in the month of January 2021 to August 2021 was 19.4% of COVID-19 positive reported patient in Belagavi district ^[3].

A comprehensive population-based study conducted in England, alongside a multicentre surveillance study across various UK hospitals, aimed to investigate the potential association between COVID-19 vaccination and Guillain-Barré Syndrome (GBS). GBS is a rare neurological disorder, and concerns had been raised about whether COVID-19 vaccines might increase the risk of its occurrence.

The study utilized National Health Service data and the National Immunoglobulin Database to retrospectively

identify GBS cases and link them with the dates of COVID-19 vaccine administration, as recorded in the National Immunization Management System in England. The researchers focused on GBS cases that occurred within a 6-week period following any COVID-19 vaccination, considering multiple vaccine types.

Between January 2021 and October 2021, a total of 996 GBS cases were reported in the National Immunoglobulin Database. Notably, there was an increase in GBS cases observed in March 2021, exceeding the average number of cases reported during the years 2016 to 2020. This increase raised concerns and prompted further investigation.

Within the specified 6-week risk window following the first dose of COVID-19 vaccination, 198 GBS cases were reported in England. The incidence rate was relatively low, at 0.618 cases per 100,000 vaccinated individuals. These cases were associated with various COVID-19 vaccines, with 176 cases linked to ChAdOx1 nCoV-19 (AstraZeneca), 21 cases tozinameran (Pfizer), and 123 cases to Moderna. Interestingly, the peak in GBS cases occurred at around 24 days post-vaccination, with ChAdOx1 nCoV-19 accounting for the majority of cases. Importantly, no significant excess of GBS cases was observed following the second dose of vaccination.

In conclusion, while the study identified a temporal association between COVID-19 vaccination, particularly the first dose of ChAdOx1 nCoV-19, and Guillain-Barré Syndrome within the 6-week risk window, the overall incidence of GBS following vaccination remained relatively low. It's crucial to note that the absolute risk of GBS associated with COVID-19 vaccination was quite small compared to the potential benefits of vaccination in preventing COVID-19 and its severe complications. Further research and monitoring are essential to better understand the underlying mechanisms and potential risk factors associated with GBS following COVID-19 vaccination ^[4].

New-onset autoimmune events following COVID-19 vaccination, such as immune thrombotic thrombocytopenia, autoimmune liver diseases, Guillain-Barré syndrome, IgA nephropathy, gout, and systemic lupus erythematosus, have been reported. Mechanisms like molecular mimicry, the production of specific autoantibodies, and the influence of vaccine adjuvants appear to play a role. However, the nature of the relationship between COVID-19 vaccines and autoimmune manifestations, whether coincidental or causal, remains a subject of ongoing research and investigation ^[5].

The Israeli Ministry of Health and National Immunization Guidelines have not identified a history of Guillain-Barré Syndrome (GBS) as a precaution or contraindication to receiving the COVID-19 vaccine. Extensive research and studies conducted by these health authorities have supported this stance, reassuring individuals with a history of GBS that they can safely receive the COVID-19 vaccine as recommended. This aligns with the broader consensus among healthcare experts worldwide, emphasizing the importance of widespread vaccination to combat the spread of the virus ^[6].

A systematic review of multi-institutional studies and literature reports in Taiwan has identified 39 cases of classic Guillain-Barré Syndrome (GBS) occurring within two weeks of coronavirus disease vaccination. This finding underscores the importance of continued monitoring and research into potential vaccine-related adverse events, although it's essential to note that the overall risk of GBS

after vaccination remains relatively low [7]. The report's objective is to emphasize the importance of considering vaccination as a relevant factor in evaluating Guillain-Barré Syndrome (GBS) cases, particularly amidst the ongoing pandemic vaccination efforts. It highlights a case study involving a 62-year-old woman who developed paresthesia and progressive weakness in her lower limbs within three days. Importantly, she had no recent history of gastrointestinal or respiratory infections but had received her first dose of the AstraZeneca COVID-19 vaccine just 11 days prior to her presentation. This case underscores the need for healthcare professionals to remain vigilant in monitoring potential vaccine-related adverse events in GBS evaluations during the current vaccination program [8]. An article reported on 220 patients who developed Guillain-Barré Syndrome (GBS) after contracting COVID-19. Among them, five cases exhibited GBS concurrently with evidence of SARS-CoV-2's neuroinvasive potential. This observation has led to a hypothesis that cerebrospinal fluid (CSF) testing should be considered in all patients suspected of having COVID-19-related GBS. Such an approach aims to shed light on alternative pathogenic mechanisms underlying GBS in the context of COVID-19 infection, enhancing our understanding of this complex neurological condition.9

Pilot study

We at Shaikh Homoeopathic Medical College, Hospital & PG Research centre, Belagavi, Karnataka did a Pilot study on "COVID-19 vaccination and its effect on General Health of population of age group 20-60 yrs". This study was done in the month of Jan 2021 and we found the results wherein

we categorized the effect under immediate, intermediate, and late effect. Effect within 24 hrs considered as immediate effect. Effects after 24 hrs till 15 days as intermediate effect. Effects from 16 days till 36 days as late effect. From the Pilot study it was deduced that out of 313 vaccinated individual 230 had fever and severe myalgias as immediate effect. 210 developed their old symptoms coming back like allergic rhinitis, irregular menses, joint pains. 160 patients developed marked weakness especially of both lower limbs with severe backache that interfered with their daily activity shown in (Fig 1, Fig 2, Fig 3) below. There was 07 diagnosed case of GBS within a month of vaccination that was reported at KLE institute at Belagavi. Based on the results of the Pilot study it was intended to take up a Descriptive Retrospective Cohort study to explore how individuals with history of COVID infection and vaccination may be affected by Guillain-Barré Syndrome (GBS), in terms of body function, activity, and health-related quality of life and establish rates of Guillain-Barré Syndrome (GBS) through Hughes GBS disability score. Our intent is to present our current understanding of autoimmune manifestations linked to COVID-19 vaccines. It's important to emphasize that we do not undermine the crucial benefits of mass COVID-19 vaccination in preventing illness and saving lives. Rather, our aim is to provide data-driven recommendations and appropriate care guidelines for healthcare professionals to address and manage potential autoimmune responses associated with vaccination, ensuring the continued safety and efficacy of vaccination campaigns. Immunization program with respect to age, gender and past illnesses of patients. As mentioned above the results are given below in the graph.

Total No of patient	No of male patient	No of female patient	Vaccines taken	Percentage
198	110	88	168	84.8%

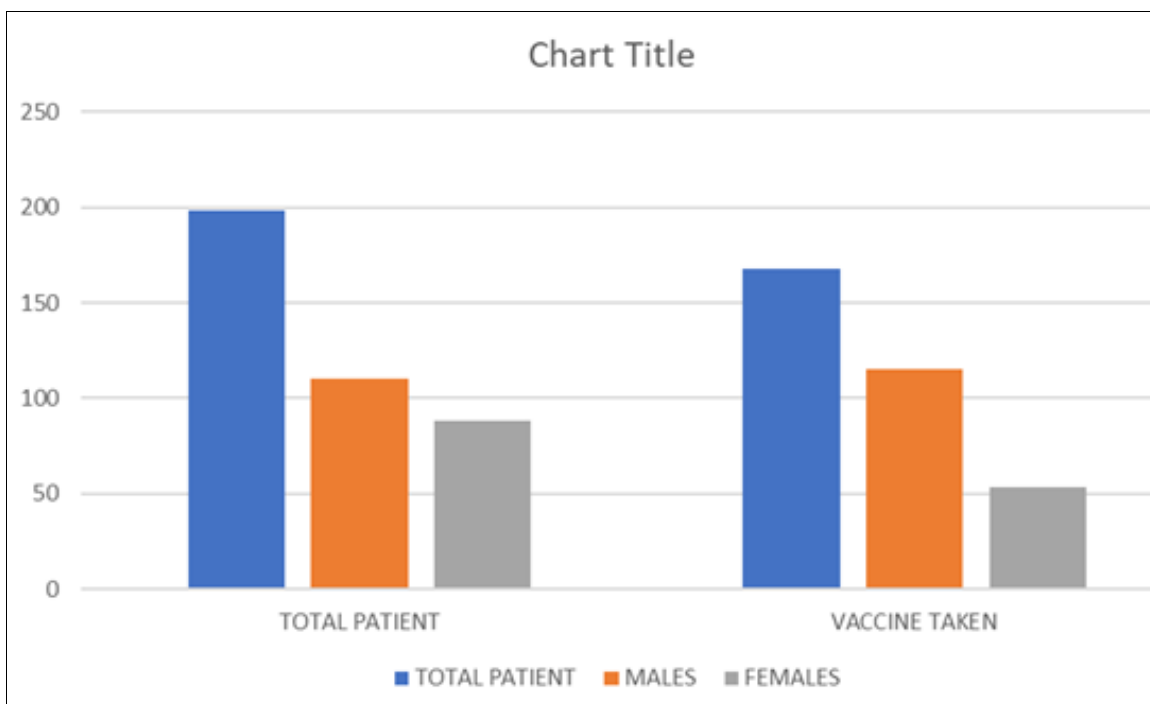


Fig 1: Show chart title total patient and vaccine taken

Total No of patient	Males	Females	Effect of GB syndrome	Indolent of parts	After how many days post vaccination	Percentage
198	110	88	128	Upper/ Lower Limbs	After 1 Months	64%
				Generalised Weakness	After 2 Days	

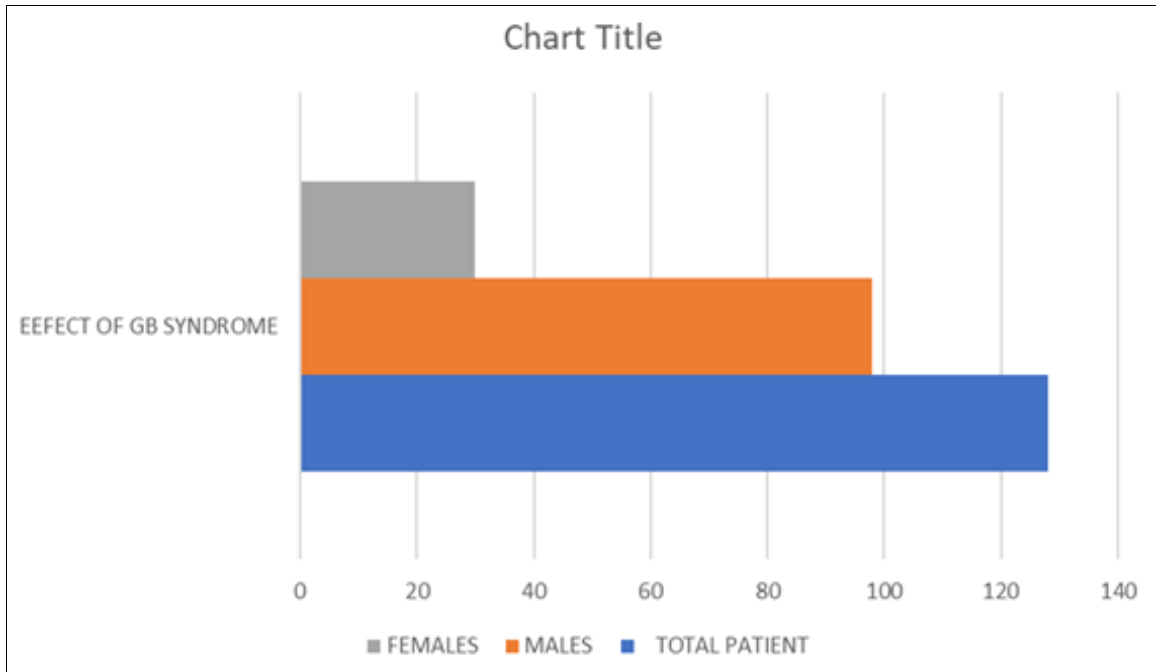


Fig 2: Show chart title effect of GB syndrome

Total no of patient	Males	Females	Effect of vaccine	Symptoms	Percentage
198	110	88	168	1. General Weakness 2. Upper limbs nerve weakness 3. Mild hemiplegia	84.8%

Symptoms	No of patients affected	After how many days after vaccine shot	Percentage
General Weakness	88	After 2 days	44.44%
Upper limbs nerve weakness	105	After 1 week	53.03%
Mild hemiplegia	05	After 1 month	2.52%
Total	198		100%

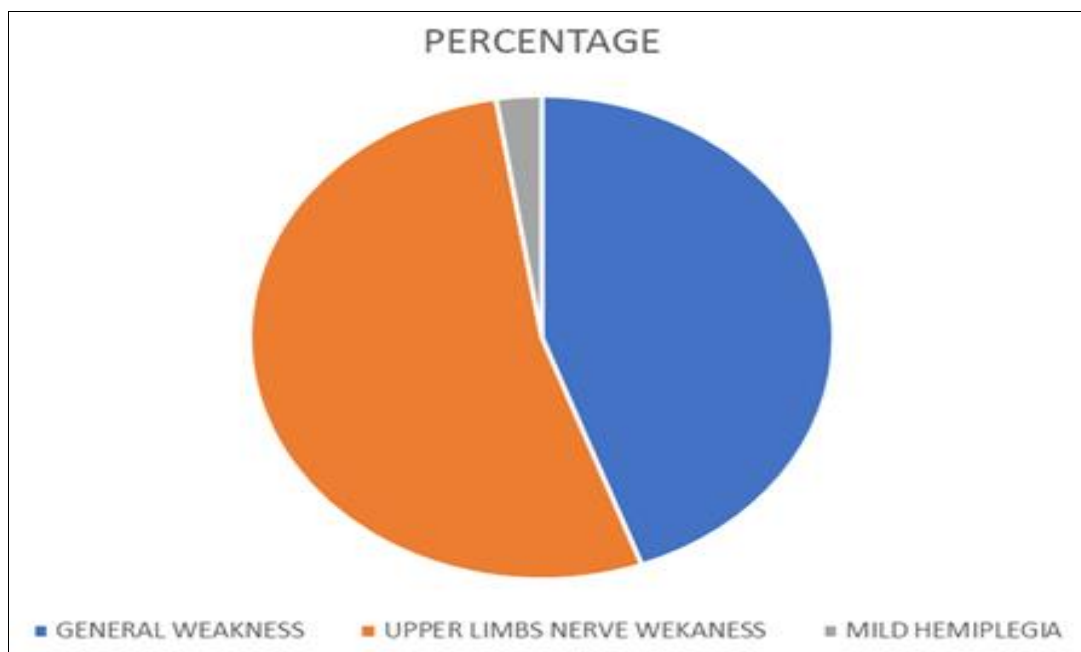


Fig 3: Show percentage general weakness, upper limbs nerve weakness and mild hemiplegia

Aims & Objectives

1. To describe how people with a history of COVID-19 and vaccination may be affected by Guillain-Barré Syndrome in terms of physical function, activity and health-related quality of life.
2. To establish rates of Guillain-Barré Syndrome (GBS)

through GBS disability score among vaccine receivers.

Materials and Methods

Study design: Descriptive Retrospective Cohort study of patients with clinical symptoms of Guillain-Barré Syndrome with COVID-19 infection and vaccination.

Sample

1. Patients with COVID-19 infection diagnosed clinically and with RT-PCR positive report and vaccinated for COVID-19 at Belagavi.
2. Patients with history of vaccination without history of COVID-19 infection at Belagavi from Jan 2021 to June 2021 6 months period shall be enrolled in the study.
3. All cases shall be assessed by the Hughes Guillain-Barré Syndrome Disability Score. (Fig 4).
4. A multicenter surveillance study from hospitals in Belgaum to investigate the association between COVID-19 infection or vaccination and GBS.

Guillain-Barre syndrome disability scale: Tick (✓)

Score	Description
0	A healthy state
1	Minor symptoms and capable of running
2	Able to walk 10m or more without assistance but unable to run
3	Able to walk 10m across an open space with help
4	Bedridden or chairbound
5	Requiring assisted ventilation for at least part of the day
6	Dead

Materials

We present a retrospective analysis of every Guillain-Barré Syndrome affected patient in Belagavi. The link between Guillain-Barré Syndrome cases and exposure to COVID-19 infection and vaccination history is identified through surveys using a data template that includes COVID-19 infection, vaccination history and the Hughes GBS Disability Score.

Data collection sheet and consent form. (Fig 5).

The diagnosis of Guillain-Barre syndrome should be based on the typical clinical features of Guillain-Barré Syndrome. A Guillain-Barré Syndrome -affected person with H/O vaccination and a 6-week risk window for any COVID-19 vaccine will be identified.

Collection of data

Field procedures shall be followed to collect data in Belagavi city. Details of data collection mentioned below in (Fig 6a, 6b, 6c, respectively).

1. Data collected shall be between Jan 2021 and June 2021.
2. The subjects shall be selected from clinics, hospital and GBS affected population at Belagavi.
3. Data collection and recording performed by authors.

COVID-19 DATA COLLECTION

INFORMED CONSENT FORM

PURPOSE OF RESEARCH:

It is survey study to know efficacy of conventional treatment alone and with homeopathic medicine for covid-19 infected individual and also to know post-vaccination [G.B Syndrome symptoms]

STUDY PROCEDURES:

The participant for the study should be tested positive for COVID-19 infection and procedure should be

i have read the foregoing information, or it has been read to me. i have had the opportunity to ask questions about it and any questions that i have asked have been answered to my satisfaction. i consent voluntarily to participate as participant in this research.

NAME OF PARTICIPANT:

SIGNATURE:

I confirm that the participant was given an opportunity to ask question about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. i confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily

CONTACT PERSON:

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Fig 4: Show COVID-19 data collection and recording performed by authors

COVID-19 DATA COLLECTION

TYPE OF CONSENT TAKEN: WRITTEN/ VERBAL

DATE: _____ **RT-PCR:** _____ **SPO2:** _____
CORADS: _____ **SEVERITY:** _____

FIRST NAME		SURNAME	
ADDRESS		AGE	
		SEX	
		OCCUPATION	
		MOB NO	

VACCINATION:

1ST DOSE WITH DATE: _____ **2ND DOSE WITH DATE:** _____

CLINICAL INFORMATION [TICK (✓) THE APPLICABLE]:

<p>MILD SYMPTOMS</p> <ol style="list-style-type: none"> 1. LOW GRADE FEVER <input type="checkbox"/> 2. COUGH <input type="checkbox"/> 3. SHORTNESS OF BREATH <input type="checkbox"/> 4. SORE THROAT <input type="checkbox"/> 5. RUNNY NOSE <input type="checkbox"/> 6. HEADACHE OR BODYACHE <input type="checkbox"/> 7. CONGESTION <input type="checkbox"/> 8. FATIGUE <input type="checkbox"/> 9. SPO2>97% <input type="checkbox"/> 	<p>MODERATE SYMPTOMS</p> <ol style="list-style-type: none"> 1. HIGH GRADE FEVER <input type="checkbox"/> 2. COUGH <input type="checkbox"/> 3. SHORTNESS OF BREATH <input type="checkbox"/> 4. SORE THROAT <input type="checkbox"/> 5. DIARRHEA <input type="checkbox"/> 6. HEADACHE OR BODYACHE <input type="checkbox"/> 7. RESP RATE >24/MIN <input type="checkbox"/> 8. FATIGUE <input type="checkbox"/> 9. SPO2<94% <input type="checkbox"/>
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ANY OTHER SYMPTOMS: _____

Fig 5: Show COVID-19 data collection sheet and consent form

COVID-19 DATA COLLECTION

IF SYMPTOMATIC [TICK(✓)] YES NO

HOSPITALIZATION [ADMITTED] : _____
TREATMENT TAKEN : _____

CONVENTIONAL MEDICATION TAKEN (DAYS) _____
 INJECTIONS (DAYS) _____
 CONVENTIONAL WITH HOMOEOPATHIC MEDICATION (DAYS) _____

DETAILS OF HOMOEOPATHIC TREATMENT :

Indicated symptoms observed in the patient	
Remedy prescribed with potency/ days	

DETAILS OF CONVENTIONAL TREATMENT:

Symptoms observed in patient	
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COVID-19 DATA COLLECTION

Medicine prescribed:	
Asymptomatic	
Symptomatic	
Treated with TICK [✓] THE APPROPRIATE	
1. ONLY MEDICINE <input type="checkbox"/>	
2. MEDICINE WITH OXYGEN <input type="checkbox"/> D VENTILATOR	

FOLLOW UPS:

TREATMENT TAKEN [CONVENTIONAL]	TREATMENT TAKEN ALONG WITH HOMOEOPATHIC
15 DAYS:	15 DAYS:
15 DAYS:	15 DAYS:
15 DAYS:	15 DAYS:
15 DAYS:	15 DAYS:

OUTCOME: TICK (✓) THE APPROPRIATE

CONVENTIONAL	HOMOEOPATHIC
IMPROVED	IMPROVED
NOT IMPROVED	NOT IMPROVED
TIME TAKEN FOR IMPROVEMENT	TIME TAKEN FOR IMPROVEMENT

COVID-19 DATA COLLECTION

DOES THE SYMPTOMS REPEATED : YES NO

AFTER TREATMENT [CONVENTIONAL] : WEAKNESS

BREATHLESSNESS

REPEATED INFECTION

ANY OTHER SYMPTOMS :

AFTER TREATMENT ALONG WITH HOMEOPATHIC : WEAKNESS

BREATHLESSNESS

REPEATED INFECTION

ANY OTHER SYMPTOMS :

Fig 6: Show Details of data collection mentioned below in 6a, 6b, 6c respectively

Statistical treatment of the data

Descriptive data reported as means, ranges, frequencies, and percentages.

Results

An experimental study was done in the month of January 2021 and we got the results in which we classified the effect under immediate, intermediate and late effect. Effects within 24 hours are considered immediate effects. Effect up to 15 days after 24 hours as an intermediate effect. Effect from 16 days to 36 days as late effect. It was estimated from the pilot study that 230 of 313 vaccinated individuals had fever and severe myalgia immediately after exposure. In 210 her old symptoms like allergic rhinitis, irregular menstruation, joint pain started returning. 160 patients developed significant weakness with severe back pain particularly in the lower extremities that interfered with their daily activities. Within one month of vaccination there were 07 diagnosed cases of Guillain-Barré Syndrome reported at KLE Institute at Belagavi. Based on this pilot study a further descriptive retrospective cohort was conducted to clarify the association between COVID-19 infection and vaccination and Guillain-Barré Syndrome.

Discussion

A retrospective analysis of each Guillain-Barré Syndrome patient and contact link to COVID-19 infection and

vaccination history were identified through a survey using a data template that included information on COVID-19 infection, vaccination history and assessment of cases by the Hughes GBS Disability Score.

The diagnosis of Guillain-Barré Syndrome is based on typical clinical features of GBS or clinically diagnosed cases and association with vaccination within the 6-week risk window of any COVID-19 vaccine identified. In the month of January 2021 to August 2021, prevalence in Belagavi district was 19.4% of the registered patients who were COVID-19 positive. In "new-onset autoimmune events after COVID-19 vaccination" it has been reported to increase immune thrombotic thrombocytopenia, autoimmune liver diseases, Guillain-Barré Syndrome, IgA nephropathy, gout, and systemic lupus erythematosus. Molecular mimicry, the production of specific autoantibodies and the role of specific vaccine adjuvants appear to be significant contributors to autoimmune phenomena. A pilot study conducted also showed that 230 out of 313 vaccinated individuals had fever and severe myalgias immediately after exposure. In 210 her old symptoms like allergic rhinitis, irregular menstruation, joint pain started returning. 160 patients developed significant weakness with severe back pain particularly in the lower extremities that interfered with their daily activities. There were 07 diagnosed cases of Guillain-Barré Syndrome within one month of vaccination.

Conclusion

Vaccination against the virus is rarely associated with Guillain-Barré Syndrome. The association of the infection with the COVID-19 virus and the vaccine is unknown. However, whether the association between the COVID-19 vaccine and autoimmune manifestations is coincidental or causal remains to be elucidated. Based on the above pilot study leading to a descriptive retrospective cohort study, it was concluded that there is a causal and causal association between COVID-19 vaccination and Guillain-Barré Syndrome in terms of body function, activity, health-related quality of life.

Conflict of Interest: Not available

Financial Support: Not available

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