Degree	Year	Name of College & University	Registration number with date of registration	
MBBS	1999	MLBMC JHANSI BUNDELKHAND UNIVERSITY	44145 30/10/2020	UPM
	2006	CSVM Medical College, Kanpur	44145	UPI

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ORIGINAL RESEARCH

To study the effect of Diabetes on inflammatory markers (CRP, D- Dimer, Serum Ferritin) and Mortality in Covid -19

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Abstract

Aims and objectives of this study:

1. To study the effect of Diabetes on inflammatory markers (CRP, D-dimer, Serum Ferritin) in Covid -19
2. To study the effect of Diabetes on Mortality in Covid -19

Material and Method: The study was done on patients with COVID- 19 admitted in second wave of covid 19 in super-speciality block of LLRM Medical College, Meerut. Diabetic (Cases) and non- diabetic (control) covid 19 patients were taken according to inclusion and exclusion criteria and they were followed for 6 months.

Result: The present study states that the levels of inflammatory markers (D-Dimer, C-Reactive Protein , Serum Ferritin) and mortality was more in diabetic Covid -19 patients than the non- diabetic Covid 19 patients.

Conclusion: With this study we can conclude that diabetes increases the severity as well as mortality in patients with covid 19 disease.

Keywords: Covid 19, Diabetes, Inflammatory markers

Introduction

Corona virus disease 2019 (COVID-19) is an infectious disease developed by severe acute respiratory syndrome *coronavirus-2 (SARS-CoV-2).* Adults with some underlying medical conditions, such as cancer, heart conditions, chronic lung diseases, and diabetes, are more likely than others to become severely ill if infected with COVID-19. Among patients hospitalized with severe COVID-19 complications, 39.7% also had diabetes as an underlying medical condition.[2]

Patients with diabetes are known to have an increased risk of infections, which is partly attributed to hyperglycemia causing immune dysfunction, among other effects . On the other hand, severe SARS-CoV-2 infection and its associated hyper inflammation contribute to hyperglycemia through an indirect negative effect on insulin target tissues and a potential direct negative effect on pancreatic β-cells . The resulting hyperglycemia can, in turn, worsen the prognosis of COVID-19The hyperglycemic environment present in diabetes favours immune dysfunction through several pathways. The most important underlying mechanisms are a decreased production of interleukins in response to an infection, reduced chemotaxis and phagocytic activity, and immobilization of polymorphonuclear leukocyte. The China Center for Disease Control and Prevention reported a diabetes prevalence of 5.3% among all

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44,672 COVID-19 cases, but 19.7% among non-survivors, with a case fatality rate of 2.3% vs 7.3%, respectively [3]

Materials and Methodology

It was a comparative study done at LLRM Medical College, Meerut on patients with diabetes mellitus admitted in the second wave of covid 19 disease.

Sample Size

50 Diabetic Covid 19 patients (cases) and 50 Non- Diabetic Covid 19 patients (control)

Inclusion Criteria

1. Patients of type 2 diabetes
2. COVID -19 positive by RTPCR.
3.

Exclusion criteria

1. Immunocompromised patients
2. Malignancy, active immunological diseases.
3. Evidence of clinical cerebrovascular or cardiovascular disease.
4. Age>65 yrs and age <18 yrs,
5. Chronic diseases like chronic obstructive pulmonary disease, chronic liver disease, chronic kidney disease.

Criteria for diagnosis of Diabetics[1]

1. Symptoms of diabetes and casual plasma glucose >200mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia and unexplained weight loss.

OR

2. FPG ≥126mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h

OR

3. 2-h plasma glucose ≥200mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water

OR

4. HBA1C≥6.5%

Observations and Results

Table1: Mean age of patients

Non-diabetic		Diabetic	
Mean	**SD**	**Mean**	**SD**
46.80	10.79	47.48	10.07

As per the table 2. Mean age of patients in non- diabetic group was 46.7 with standard deviation of 10.79 and mean age of patients in diabetic group was 47.5 with a standard deviation of 10.07

Table 2: Sex wise distribution of patients

Sex	Non-diabetic	Non-diabetic (%)	Diabetic	Diabetic (%)	Total
F	20	40.0%	22	44.0%	42
M	30	60.0%	28	56.0%	58
Total	50	100.0%	50	100.0%	100

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From table 2. It can be interpreted that percentage of males in non-diabetic group were 60% and percentage of females in non diabetic group were 40%. . In Diabetic group males were 56% and females were 44 %

Table 3: D-dimer (µg/ml) in Non - diabetic and diabetic patients

Non-diabetic		Diabetic		Z	p-value
Mean	SD	Mean	SD		
0.77	0.41	1.46	1.01	-4.350	0.001

From table 3, it was observed that mean D -dimer (µg/ml) in non – diabetic patients was 0.77 ±0.41 and in diabetic patient was 1.46 ±1.01.
By using Mann Whitney U test we found out that difference between the D-dimer of diabetic and non diabetic group was found to be statistically significant($p<0.05$).

Table 4: C -Reactive protein(mg/dl) in Non diabetic and Diabetic patients

Non-diabetic		Diabetic		Z	p-value
Mean	SD	Mean	SD		
18.38	20.06	26.72	22.25	-2.485	0.013

Table 4 shows that mean C -Reactive protein(mg/dl) in non-diabetic patients was 18.38 ±20.06 and in diabetic patient was 26.72±22.25.
This difference of C- reactive protein was found to be statistically significant by using Mann Whitney U test ($p<0.05$)

Table 5: Serum ferritin (ng/dl) in non-diabetic and diabetic patients

Non-diabetic		Diabetic		Z	p-value
Mean	SD	Mean	SD		
307.52	129.67	637.08	173.38	-10.763	0.001

With the help of table 5 it is seen that in the non-diabetic group mean Serum ferritin(ng/dl) was 307.52 ±129.67 and in diabetic group was 637.08±173.38.
The difference between the Serum Ferritin of both the groups was found to be statistically significant using Mann Whitney U test ($p<0.05$)

Table 6: CT-severity score in non-diabetic and diabetic patients

Non-diabetic		Diabetic		Z	p-value
Mean	SD	Mean	SD		
14.82	4.78	16.58	4.39	-2.505	0.012

Table 6 shows that mean CT-severity score in non- diabetic patients was 14.82 ±4.78 and in diabetic patient was 16.58±4.39.
By using Mann whitney test we found out that difference between the CT-severity score of diabetic and non diabetic group was statistically significant ($p<0.05$)

Table 7: Mortality during Covid-19 in non-diabetic and diabetic patients

Mortality	Non-diabetic	Non-diabetic(%)	Diabetic	Diabetic	Total	p-value
N	46	92.0%	38	76.0%	84	
Y	4	8.0%	12	24.0%	16	
Total	50	100.0%	50	100.0%	100	0.029

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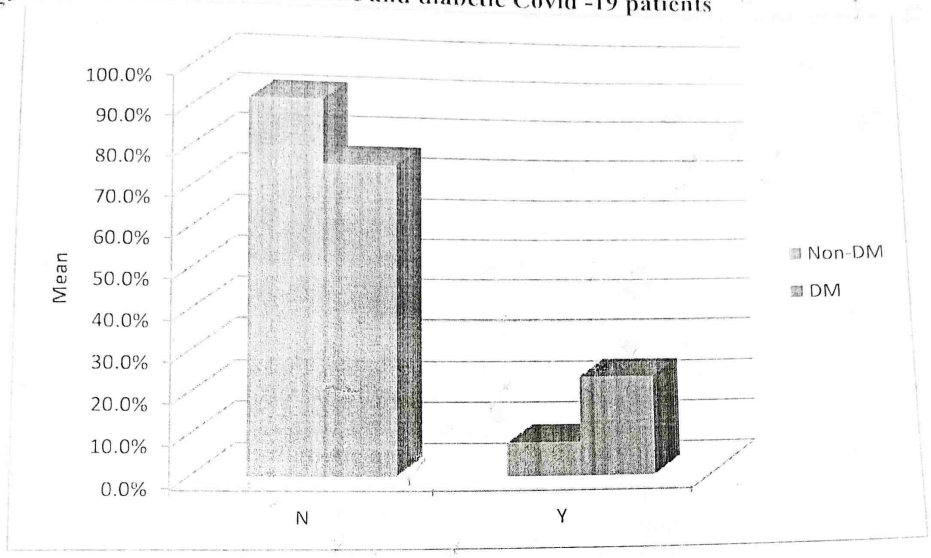
From table 7. It can be observed that mortality in non- diabetic patients was 4 and in diabetic patients was 12.
By using Chi square test test we found out that difference between the Mortality of diabetic and non diabetic group was statistically significant ($p<0.05$)

Figure 1: Mortality in non-diabetic and diabetic Covid -19 patients



Discussion

In our present study, we have compared inflammatory markers like D-Dimer, CRP, Serum. Ferritin, mortality between non diabetic and diabetic Covid 19 positive by real time reverse transcription polymerase chain reaction test. The present study represent that the mean of D-Dimer (ug/dl) in non diabetic group and diabetic group was 0.77 and 1.46 respectively with a p value of 0.001 which was statistically significant. These values were comparable to studies of Yogendra Mishra and Basant Kumar Pathak in which mean D-dimer levels were 1509 in people with diabetes and 515 in patients without diabetes These values are also comparable to studies of Ibrahim Hashim and Ibrahim Elbashir, Yumeng Yao, Chaymae Miri.[4]

Patients with diabetes had higher D-dimer levels which were statistically significant. These values are also comparable to studies of Ibrahim Hashim and Ibrahim Elbashir, Yumeng Yao, Chaymae Miri.[5]

The present study represent that the mean of C-Reactive Protein (md/dl) in non diabetic group and diabetic group was 18.38 and 26.72 respectively with a p value of 0.013 which was statistically significant. These values were comparable to studies of of Hoimonti Debi, Mahmoud Sadeghi-Haddad-Zavarch.[6]

The present study represent that the mean of Serum Ferritin (ng/dl) in non diabetic group and diabetic group was 307.52 and 637.02 respectively with a p value of 0.001 which was statistically significant. These values were comparable to studies of Nerea Pérez-García, Sibtain ahmed, Mukesh Kumar.[7]

The present study also represent that the mortality in non diabetic group and diabetic group was 4 and 12 respectively with a p value of 0.029 which is statistically significant. These values were comparable to studies of Rodrigo Esaki Tamura.[8]

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Conclusion

In this study 50 diabetic and 50 non diabetic COVID -19 positive patients were taken and their inflammatory markers and mortality were compared. The mean age of diabetic patients 47.4 was and mean age of non- diabetic was 46.8

The mean of D- dimer (ug/dl) in non diabetic group and diabetic group was 0.77 and 1.46 respectively with a p value of 0.001, the mean of C-Reactive protein (ug/dl) in non diabetic group and diabetic group was 18.38 and 26.72 respectively with a p value of 0.013 and the mean of C-Reactive protein (ug/dl) in non diabetic group and diabetic group was 18.38 and 26.72 respectively with a p value of 0.013 which were statistically significant. The Mortality in COVID -19 non- diabetic patients was and diabetic patients was 4 and 12 respectively with a p value of 0.029 which was statistically significant.

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ORIGINAL RESEARCH

To Study the Role of Yoga in Physical Wellbeing and COVID Antibody Production in COVID Vaccine Recipients

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Received: 23 March, 2023 Accepted: 28 April, 2023

Abstract

Aim: To study the role of yoga in physical wellbeing and COVID antibody production in COVID vaccine recipients.

Material and Methods: The study was conducted on 186 patients, who were randomly allocated to either Group A (Study group or Yoga group) or Group B (control group) for the purpose of the study. Out of them, a fairly large number of patients (176 patients) completed the study. While in Group A (patients undergoing yoga therapy along with dietary restrictions), out of 93 patients who were enrolled, 89 patients (95%) completed 6 months follow up and the rest were lost to follow up; in the Group B (patients on dietary restrictions only), out of 93 patients, 87 patients (91%) completed 6 months follow up, and the rest were lost to follow up. The patients were followed thoroughly and at the end of three months they were measured again for WHOQOL-BREF score, COVID antibody titres, routine investigations along with Blood Pressure and other parameters.

Results: The difference in mean COVID antibody titres between - Yoga Participants (Study Group) and Non- Yoga Participants (Control Group) one and three month after vaccination is significant (p value= 0.003), and, it is higher in Yoga participants group. Also WHOQOL-BREF is higher in Yoga participants group than in non-Yoga participants group, one and three month after vaccination.

Conclusion: From the present study, we found that Yoga therapy is beneficial in increased production of COVID antibodies and overall sense of physical wellbeing assessed using WHOQOL-BREF score. Yoga did not have significant effect in reducing the side effects of COVID vaccination, however, practicing yoga can significantly increase the tolerance of side effects, i.e. those who practice yoga tolerate the side effects better.

Keywords: COVID, Yoga, WHOQOL-BREF

Introduction

Covid (Coronavirus Disease)

Coronavirus disease 2019 (COVID-19) is defined as illness caused by a novel coronavirus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; formerly called 2019-nCoV), which was first identified amid an outbreak of respiratory illness cases in Wuhan City, Hubei Province, China. It was initially reported to the WHO on December 31, 2019. On January 30, 2020, the WHO declared the COVID-19 outbreak a global health emergency. On

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March 11, 2020, the WHO declared COVID-19 a global pandemic, its first such designation since declaring H1N1 influenza a pandemic in 2009.
The following symptoms may indicate COVID-19.

- Fever or chills (43-45%)
- Cough (63-83%)
- Shortness of breath or difficulty breathing (45.6%)
- Fatigue (63%)
- Muscle or body aches (36-63%)
- Headache (34-70%)
- New loss of taste (54.2%) or smell (70.2%)
- Sore throat (52.9%)
- Congestion (67.8%) or runny nose (60.1%)
- Nausea or vomiting (31.6%)
- Diarrhoea (17.8%)

Yoga

The word "yoga" literally means "yoking," or "joining together" for a harmonious relationship between body, mind and emotions to unite individual human spirit with divine spirit or the True Self. (Prabhupāda, AC, 2001; Stiles M, 2000) Yoga is regarded as a form of mind body medicine or part of complementary and alternative medicine (CAM) (Shannahoff-Khalsa D, 2004)

- It has been suggested that yoga creates inner, physical and emotional balance using postures (Hatha yoga), called asanas, that are combined with breathing techniques or pranayama that are based mainly on isometric muscle contractions. (Williams K et al, 2009)Yoga has diverse clinical and nonclinical applications attributed mainly to the degree of complexity and multi-dimensionality of influences that are apparent in yogic exercises. (Posadzki P et al, 2009)
- The popularity of yoga has grown tremendously in the past several years. In 2007, yoga was the 7th most used CAM therapy. A growing number of research studies have shown that Hatha yoga can improve strength and flexibility, and may help control physiological variables such as blood pressure, lipids, respiration, heart rate and metabolic rate to improve overall exercise capacity. (Dhananjai S et al, 2013) Yoga is also an easy and inexpensive tool requiring little in the way of equipment or professional personnel, with some studies indicating excellent long-term adherence and benefits.

Aims And Objectives

- To study the role of yoga in Physical Wellbeing in COVID-19 Vaccinated individuals.
- To study the role of yoga in antibody production in COVID- 19 vaccinated individuals.

Material And Methods

This study was conducted on patients who are vaccinated for COVID-19 in Lala Lajpat Rai Memorial Medical College, Meerut. Study will be conducted in a total of 200 patients with following inclusion and exclusion criteria.

- Subgroup A - 93 individuals vaccinated for COVID-19 and practicing YOGA.
- Subgroup B - 93 individuals vaccinated for COVID-19 and not practicing YOGA.

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Selection Of Patients

Patients were selected from OPD in Lala Lajpat Rai Memorial Medical College, Meerut.
Patients who came for COVID vaccination in Lala Lajpat Rai Memorial Medical College, Meerut were selected for the study.
A detailed information regarding study was given to the patients using banners, pamphlets and oral explanation of the type of study and their role in the study was explained.
They were motivated to participate in the study using pamphlets and banners.
A detained study proforma and consent form was filled at the time of recruitment which included particulars of the participants, their socio-economic information and detailed physical examination.
A proper informed and explained consent was taken at the time of recruitment.

Sample Size Calculation

Sample Size was calculated using Cochran's Formula for sample size which is as follows-

$$n_0 = \frac{Z^2 pq}{e^2}$$

N_0 = Sample Size,
Z = Z- Score, taken from Z-Score table,
e is the desired level of precision (i.e., the margin of error),
p is the (estimated) proportion of the population which has the attribute in question,
q is 1 – p.
Z-Score for a Confidence Interval of 95% is 1.96.
Prevalence of COVID vaccinated individuals at the time of study was ~65%.
Margin of Error for this study is 10%.
The calculated sample size came out to be 88.
Total no. of patients recruited for the study was 93, keeping a margin of 5% extra individuals who would be lost to follow up.

Inclusion Criteria

1. Patients within one week of history of COVID vaccination.
2. Age 18-60 years.
3. Patients who give written informed consent.
4. Non-Smoker and Non-Alcoholic.
5. Patients willing to perform Yoga.

Exclusion Criteria

1. No history or documentation of COVID Vaccination.
2. Age < 18 Years.
3. Uncooperative/Unable to provide informed written consent.
4. Irregular yoga practice during the intervention.
5. Any physical deformity which prevents them from doing yoga e.g., paralyzed limb.

Tools And Tests For Data Generation

1. Questionnaire.
2. COVID Antibody titre.
3. Detailed Physical Examination.

Study Design

- Subjects will be screened from patient populations visiting COVID vaccination centre in

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LLRM Medical College, Meerut, from January 2021 through June 2021.

- The yoga class was designed by a certified yoga instructor and a physician.
- The program will be carefully illustrated through workshops and subjects will be required to attend at least one yoga class weekly under the supervision of an expert for twenty-four weeks.
- And they will be advised to practice the same yogic practices at home.
- None of the subjects in the yoga group had any earlier exposure to yoga practice. Each yoga session will consist of 10 minutes of dynamic warm-up exercises, 20 minutes of asanas (yogic postures), 10 minutes of pranayamas (breath control exercise), 10 minutes mudra and bandha and 5 minutes of supine relaxation in shavasana (corpse pose).
- Subjects will be given a booklet illustrating the specific pose to help with their independent practice.
- Subjects will also be given a booklet in which they can note dietary compositions, medications taken daily, signs and symptoms, daily blood pressure and information on adherence to yogic practices at home.
- All subjects will be encouraged to see their yoga teacher and investigator regularly.

All patients included in the study will undergo the following evaluation

1. Details of complaints & history.
2. Questionnaire for assessment of physical wellbeing of subjects.
3. Detailed clinical examination.
4. Investigations: COVID antibody titres.

Timings at which assessments would be done

1. Baseline (Day 0).
2. At One month.
3. At Three months.

Results

1. COVID Antibody Titre

Relevant data in terms of mean COVID Antibody Titre, at the baseline, at One month and, at Three months, mean difference and p- value of paired t-test for both groups- Yoga Participants (Study Group) and Non- Yoga Participants (Control Group) is presented in Table 3. This table also presents the p-value of independent t-test at One month and at Three months.

Table 1: Mean COVID Antibody Titre, at the baseline, at One month and, at Three months, mean difference and p- value of paired t-test for both groups- Group- A (Yoga Patients) and **Group- B (Non-Yoga Patients).**

	Yoga patients		**Non-Yoga patients**		**t-test**	**p-value**
	Mean	**SD**	**Mean**	**SD**		
At Baseline COVID Antibody Titre	5.27	2.07	4.92	1.94	1.176	0.241
At One Month COVID Antibody Titre	50.78	13.72	45.49	12.68	1.699	0.002
At Three Month COVID Antibody Titre	137.39	20.30	128.44	20.00	3.028	0.003

It can be observed from Table 1, that COVID Antibody titres increase after First dose and Second dose of vaccine.

Mean COVID antibody titres in yoga participants and non-yoga participants at baseline are

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5.27 and 4.92 (difference = +0.35).
These values when compared using t-test, the value came out to be 1.176 (p-value 0.241), which was statistically not significant, which means the two groups are comparable at the baseline.
One month after First dose of vaccine, there is increase in COVID Antibody Titres in both the groups. The Yoga group has higher mean COVID Antibody Titres (difference = +5.29) and this difference is **statistically significant** (p value = 0.002).
Three months after First dose of vaccine, there is increase in COVID Antibody Titres in both the groups. The Yoga group has higher mean COVID Antibody Titres (difference = +8.95), and, this difference is **statistically significant** (p value = 0.003).

Table 2: Difference in One month and Three months COVID antibody titres when compared with the baseline COVID antibody titres in Yoga Participants (Study Group) and Non- Yoga Participants (Control Group) with p-value.

	Yoga Patients		Non-Yoga Patients		t-test value	p-value
	Mean	SD	Mean	SD		
Difference One Month mean COVID Antibody Titre	47.51	14.16	40.57	13.10	1.472	0.003
Difference Three Month mean COVID Antibody Titre	132.12	20.67	123.52	20.26	2.865	0.005

It can be inferred from Table 2, that the difference in mean COVID antibody titres when compared with the baseline COVID antibody titres between - Yoga Participants (Study Group) and Non- Yoga Participants (Control Group) One month after vaccination is 47.51 and 40.57 respectively (difference = +6.94), and is found to be **statistically significant** (p value = 0.003) and, it is higher in Yoga participants group.
Also, that the difference in mean COVID antibody titres when compared with the baseline COVID antibody titres between - Yoga Participants (Study Group) and Non- Yoga Participants (Control Group) **three months** after vaccination is 132.12 and 123.52 respectively (difference = +8.6), and is found to be **statistically significant** (p value = 0.005), and, it is higher in Yoga participants group.

2. WHOQOL-BREF Score

The WHOQOL is a quality of life assessment developed by the WHOQOL Group with fifteen international field centres, simultaneously, in an attempt to develop a quality of life assessment that would be applicable cross-culturally.
Relevant data in terms of mean WHOQOL-BREF Score, at the baseline, at One month and, at Three months, mean difference and p- value of paired t-test for both groups- Yoga Participants (Study Group) and Non- Yoga Participants (Control Group) is presented in Table 3. This table also presents the p-value of independent t-test at One month and at Three months.

Table 3: Mean WHOQOL-BREF Score, at the baseline, at One month and, at Three months, mean difference and p- value of paired t-test for both groups- Group- A (Yoga Patients) and Group- B (Non-Yoga Patients).

	Yoga patients		Non-Yoga patients		Z	p-value
	Mean	SD	Mean	SD		
At Baseline WHOQOL Score	47.00	5.23	48.00	4.93	-1.342	0.181
At One Month WHOQOL Score	54.00	4.73	47.00	5.23	9.579	0.001
At Three Month WHOQOL Score	59.00	5.53	48.50	4.62	14.046	0.001

It can be observed from Table 3, that WHOQOL-BREF score increase after First dose and

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Efficacy of the BNT162b2 mRNA Covid-19 Vaccine suggested that the side effects of COVID vaccine are similar to other vaccines directed against viral antigens containing mRNA based viral substitutes. The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups.

- The results of our study are consistent with those of the above-mentioned studies. Our study reveals that, there is significant improvement in COVID antibody titre from baseline to 9-fold after one month of vaccination.
- There is significant improvement in COVID antibody titre three months of after vaccination when compared to one month after vaccination. That is, there is 2.85 times increase in COVID antibody titres.
- There is 26-fold increase in COVID antibody titres when compared between at baseline and three months after vaccination.
- There is 2.8-fold increase in COVID antibody titres when compared between one month after vaccination and 3 months after vaccination.
- The above results hold true for both the groups, i.e, study and control groups.
- When compared between Yoga and Non- Yoga groups, baseline COVID antibody titres are almost similar. One month after vaccination, the difference between COVID antibody titres between study and control group is significant. The titres are more in Yoga participants than in non-Yoga participants and differ by 7.39%. This difference is significant.
- Three months after vaccination, the difference between COVID antibody titres between study and control group is significant. The titres are more in Yoga participants than in non-Yoga participants and differ by 10.08%. This difference is significant.
- The physical wellbeing among the participants is assessed using WHOQOL-BREF questionnaire. The baseline WHOQOL-BREF score is comparable between the study and control groups.
- The participants who did not practice yoga did not have any significant variation in their WHOQOL BREF score over time. Their WHOQOL BREF score was comparable over the time when checked for at baseline, one month and three months after starting yoga practice and vaccination.
- The participants who practised yoga had quite a significant improvement in their WHOQOL BREF score over the time when assessed at baseline, one month and three months after starting yoga practice.
- The difference in baseline and one-month WHOQOL-BREF score was 14.8% increase, which was significant.
- The difference between one month and three months WHOQOL-BREF score was 8.4% increase, which was significant.

Conclusion

From the present study, we found that Yoga therapy is beneficial in increased production of COVID antibodies and overall sense of physical wellbeing assessed using WHOQOL-BREF score.

Yoga did not have significant effect in reducing the side effects of COVID vaccination, however, practicing yoga can significantly increase the tolerance of side effects, i.e, those who practice yoga tolerate the side effects better.

Yoga appears to have holistic effect on overall state of health of an individual and will prove as a useful tool in prevention of adverse effects of vaccination, better tolerance of COVID

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symptoms and better management of COVID as a whole. We recommend large scale, multi-centric trials to further authenticate the findings of this study.

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