

Efficacy and safety of *Guduchighana Vati* in asymptomatic and mild-to-moderate cases of coronavirus disease-19: A randomized controlled pilot study

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Abstract

Background: Currently, there is no approved treatment for the management of coronavirus disease (COVID-19). Drug repurposing of existing medications could be a possible way to find out a novel therapeutic entity to combat the COVID-19. **Aim:** To determine the clinical efficacy and safety of an Ayurveda intervention (*Guduchighana Vati*) in asymptomatic and mild-to-moderate cases of COVID-19. **Materials and Methods:** This was an open-label randomized controlled pilot study with a sample size of 30 participants (15 in each arm). The participants were asymptomatic or mild to moderate cases of COVID-19. *Guduchighana Vati* 500 mg twice daily for 10 days was administered in the study group and Hydroxychloroquine for 5 days in the control group. Paracetamol, Vitamin C, Multivitamin, and Zinc were also provided in the control group. The main outcome measures were to negative real-time reverse transcription–polymerase chain reaction (RT-PCR) assay for COVID-19, proportion of participants with negative RT-PCR for COVID-19 at 5th and 10th day, proportion of participants with clinical recovery, improvement in laboratory parameters, and incidence of adverse drug reaction/adverse event (ADR/AE). The results of RT-PCR and clinical recovery were compared between groups using Chi-square test. The data related to laboratory parameters were compared within group using paired sample *t*-test/Wilcoxon signed-rank test and between groups using independent sample *t*-test/Mann–Whitney test. **Results:** The proportion of participants with negative RT-PCR for COVID-19 in the *Guduchighana Vati* group (93.3%) was better as compared to the control group (66.6%) till 10th day of the study period. Though, the results are statistically not significant ($P = 0.068$). All the symptomatic patients in the *Guduchighana Vati* group clinically recovered whereas one patient remained symptomatic in the control group on the 5th day. No symptoms of COVID-19 were observed at 10th day in both the groups. No ADR/serious adverse event were observed during the study period in either of the groups. **Conclusion:** In this study on asymptomatic and mild to moderate cases of COVID-19, *Guduchighana Vati* showed numerically better proportion of participants with negative RT-PCR assay for COVID-19 and reduced time to clinical improvement which requires confirmation through studies with larger sample size. Although, the study outcomes are statistically not significant which may be due to small sample size.

Keywords: Coronavirus disease-19, *Guduchi*, *Guduchighana Vati*, severe acute respiratory syndrome coronavirus 2, *Tinospora cordifolia*

Introduction

The pandemic caused by Coronavirus disease (COVID-19), affected more than 181 million people globally with around 3.9 million reported deaths as per the information updated by World Health Organization on June 30, 2021.^[1] The global scale of transmission, considerable morbidity and mortality, and increased risk of complications and death in high-risk individuals have been the major cause of concern related

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to this pandemic.^[2] Till date, there is no proven treatment for the management of COVID-19, although several pharmacological options are being explored as per the clinical condition. Significant numbers of clinical trials are going on in conventional as well as traditional medicine systems to find out a safe and effective treatment of COVID-19. Repurposing of existing medications could be a possible way to overcome the time limitation of research and development required to find out a novel therapeutic entity to combat the COVID-19. It can facilitate prompt clinical decisions at lower costs as compared to new drug development. *Ayurveda* is probably the oldest medicine system having a description of infectious diseases and epidemics and their various modes of transmission.^[3-5] *Ayurveda* has time-tested interventions to improve the immune response which have been further evaluated for their immune-modulator, anti-inflammatory, and anti-viral properties.^[6-17] These interventions may arrest the progression of COVID-19 and helpful in reducing morbidity and mortality associated with this pandemic. Government of India has incorporated *Ayurveda* interventions also in the National clinical management protocol based on *Ayurveda, Yoga* for management of COVID-19.^[18]

Guduchi (*Tinospora cordifolia* [Willd.] Miers) is a widely used medicinal plant in *Ayurveda* indicated for *Jwara* (febrile illness) among other indications.^[19] Several research studies have established the immune-modulatory, anti-inflammatory, and anti-microbial properties exhibited by *T. cordifolia*.^[20-26] *Guduchighana Vati* (formulation prepared from powdered aqueous extract of *T. cordifolia*) has been widely prescribed in the management of febrile illnesses of infective origin. However, there is no evidence to recommend its use in the management of COVID-19. Therefore, the present study was designed to determine the efficacy and safety of *Guduchighana Vati* in the management of asymptomatic and mild-to-moderate cases of COVID-19.

Materials and methods

The study was executed in accordance with the principles of Declaration of Helsinki and the ICMR ethical guidelines for biomedical research on human participants (2017). The study was reviewed and approved by the Institutional Ethics Committee of Pt. Khushilal Sharma Government Ayurveda College and Institute, Bhopal, Madhya Pradesh, India vide letter no. KLSGACI/IEC/2020/06 dated July 24, 2020. The clinical trial was registered prospectively at Clinical Trial Registry of India vide CTRI/2020/07/026840 dated July 27, 2020. The CONSORT guidelines were followed while reporting the study results.

Study design

This was an open-label randomized active-controlled pilot study. No deviation from study protocol occurred after the commencement of the study.

Study setting and participants

The study was conducted at Pt. Khushilal Sharma Government Ayurveda College and Institute, Bhopal, Madhya Pradesh,

India. The study site was a designated COVID care center notified by the State Government of Madhya Pradesh. Real-time reverse transcription–polymerase chain reaction (RT-PCR) for COVID-19 of all the participants included in the study was done at ICMR authorized laboratory.^[27] The participants included in the study were kept in isolation and regular clinical monitoring and check-up were done at the study site. The study was conducted from July 2020 to September 2020.

Inclusion and exclusion criteria

Participants of either sex aged 18 years and above who were RT-PCR positive for COVID-19 and categorized as asymptomatic or mild-to-moderate cases as per the guidelines of Ministry of Health and Family Welfare (MoHFW), Government of India guidelines were included in the study.^[28] Participants with severe COVID-19 as per 8-point ordinal score,^[29] i.e., hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation, participants with comorbidities, participants with severe vomiting which would make oral administration of medicine difficult, with alanine amino transaminase (ALT) or aspartate amino transaminase (AST) more than two times the upper limit of normal, and pregnant or lactating women were excluded from the study.

Among the 32 individuals screened as per the inclusion and exclusion criteria, 30 patients of COVID-19 confirmed by RT-PCR and fulfilling the inclusion criteria were included in the study. The detailed information related to the research study was provided to the study participants and written informed consent in their regional language was taken before enrolling them in the study.

Study intervention

Guduchighana Vati (Batch no.: HTW011; Manufacturing date: April 2020; Expiry date: March 2023) two tablets (250 mg each) twice daily after food with water for 10 days was administered to the participants in the *Guduchighana Vati* group. Hydroxychloroquine (Batch no.: GPD080012BH; Manufacturing date: March 2020; Expiry date: February 2024) was given in the maintenance dose of 800 mg for 1st day followed by 400 mg per day for the next 4 days in divided doses in the control group as per the recommendations of the MoHFW, Madhya Pradesh, India. Paracetamol, Vitamin C, Multivitamin, and Zinc were also provided in the control group whereas Paracetamol only was provided in the *Guduchighana Vati* group as per the clinical condition of the participant if required. All the study participants were also instructed to follow respiratory and hand hygiene measures.

Guduchighana Vati was procured from Pharmanza Herbal Private Limited, Gujarat, India. It is an Ayurvedic classical formulation included in the Ayurvedic Formulary of India.^[30] It is prepared from the powdered aqueous extract of *T. cordifolia* (Willd.) Miers in tablet form. This dosage form has several advantages such as accuracy of dosage, stability, patient palatability, and easy storage.

Outcomes measures

Primary outcome measure

Time to negative RT-PCR for COVID-19 (from the day of trial drug administration) and proportion of participants with negative RT-PCR assay at 5th and 10th day was the primary outcome measure. Two-day continuous real-time RT-PCR test was done on 5th day and 10th day (in case the study participant was found RT-PCR positive on 5th day assessment).

Secondary outcome measures

The proportion of participants with clinical recovery on 5th and 10th day; changes in laboratory parameters (from baseline to 10th day of the study period) such as differential and Total leukocyte count, erythrocyte sedimentation rate, immunoglobulin M and immunoglobulin G (IgM and IgG), inflammatory markers such as interleukin-6 (IL-6), serum ferritin, changes in liver enzymes, renal function parameters, proportion of participants advanced to severe stage of COVID-19 (i.e., participants referred due to onset of complications or required invasive or noninvasive oxygen therapy during the intervention period) and incidence of adverse drug reaction/adverse event (ADR/AE) on 10th day (end of the trial).

Criteria of “clinical recovery”

Normal body temperature ($\leq 36.6^{\circ}\text{C}$ axilla or $\leq 37.2^{\circ}\text{C}$ oral), absence of cough or mild cough, absence of dyspnea on routine activity or respiratory rate < 30 breaths per minute without supplemental oxygen, absence of any other symptom/sign attributed to COVID-19, normal SpO_2 by standard peripheral oximetry (above 93%) and recovery should be sustained for at least 48 h under physician observation.

The study participants who remain RT-PCR negative at the end of the study period were discharged as per the existing MoHFW, Government of India guidelines.^[31]

Safety assessment

The study participants were assessed daily for the presence of ADR/AE till discharge. Laboratory parameters such as aspartate transaminase (AST), alanine amino transaminase (ALT), serum alkaline phosphatase, serum bilirubin, serum creatinine, blood urea, and serum uric acid were assessed on baseline and 10th day of the study period.

Sample size and randomization

A sample size of 30 participants (15 in each group) was taken in a pilot study. Thirty eligible participants were randomized into two parallel arms in the ratio of 1:1. A statistician generated a randomized list using the SPSS 15.0 for Windows, 233 South Wacker Drive, 11th Floor, Chicago, Illinois, U.S.A.

Statistical analysis

The categorical variables (such as results of RT-PCR and clinical recovery) have been represented as number (percentage) and compared using Chi-square test. The continuous data (related to laboratory parameters) has been represented as mean (standard deviation), and median (min-max) for data

not following normal distribution. This continuous data has been compared within group by using paired sample *t*-test/Wilcoxon signed-rank test and between groups analysis has been done using independent sample *t*-test/Mann-Whitney test. A $P < 0.05$ has been considered as statistically significant. Analysis has been done using the Statistical Package for the Social Sciences SPSS 15.0 for Windows, 233 South Wacker Drive, 11th Floor, Chicago, Illinois, U.S.A.

Observation and Results

Patient enrollment

A total of 32 patients were screened as per the inclusion and exclusion criteria of the study from July 28, 2020. Two patients were not willing to provide written consent to participate in the study and thus were excluded from the study. A total of 30 participants were included in the study (15 each in *Guduchighana Vati* group and control group). Outflow of the study participants is shown as CONSORT flow diagram in Figure 1.

Baseline clinical characteristics of study participants

The demographic data of the participants are shown in Table 1. The mean age of participants in the *Guduchighana Vati* group and control group was (30.27 ± 8.83) and (32.27 ± 7.35) years, respectively. The distribution of age of the participants was similar between the two groups ($P = 0.506$). In the present study, 53.3% participants were found symptomatic in each group ($P = 0.991$). At baseline, fever was present in 40%, cough in 26.7%, sore throat in 20%, and body-ache (myalgia) in 33.3% of participants in the *Guduchighana Vati* group whereas it was 20%, 6.7%, 13.3%, and 6.7% respectively in the control group. The demographic and clinical characteristics were comparable between the two groups at baseline.

Efficacy outcomes

In the *Guduchighana Vati* group, 66.6% participants turned RT-PCR negative for COVID-19 on 5th day and 93.3% participants on 10th day from the administration of trial drug. While it was 53.3% and 66.6% on 5th and 10th day in the control group [Table 2]. However, the results were statistically insignificant ($P = 0.068$). The remaining patients with positive RT-PCR assay in both the study groups were asymptomatic at the end of the study period and discharged as per the existing guidelines. On the 5th day of study period, all the symptomatic

Table 1: Baseline clinical characteristics of the study participants

| Variable | Parameters | GVG (n=15) | CG (n=15) | P ^s |
|--------------------------|--------------|-------------|-------------|----------------|
| Age: Mean±SD | - | 30.27±8.836 | 32.27±7.353 | 0.506 |
| Gender, n (%) | Male | 12 (80.0) | 11 (73.3) | 0.666 |
| | Female | 3 (20.0) | 4 (26.7) | |
| Clinical features, n (%) | Asymptomatic | 7 (46.7) | 7 (46.7) | 0.991 |
| | Symptomatic | 8 (53.3) | 8 (53.3) | |

^sCompared using Chi-square test. SD: Standard deviation, GVG: *Guduchighana Vati* Group, CG: Control group

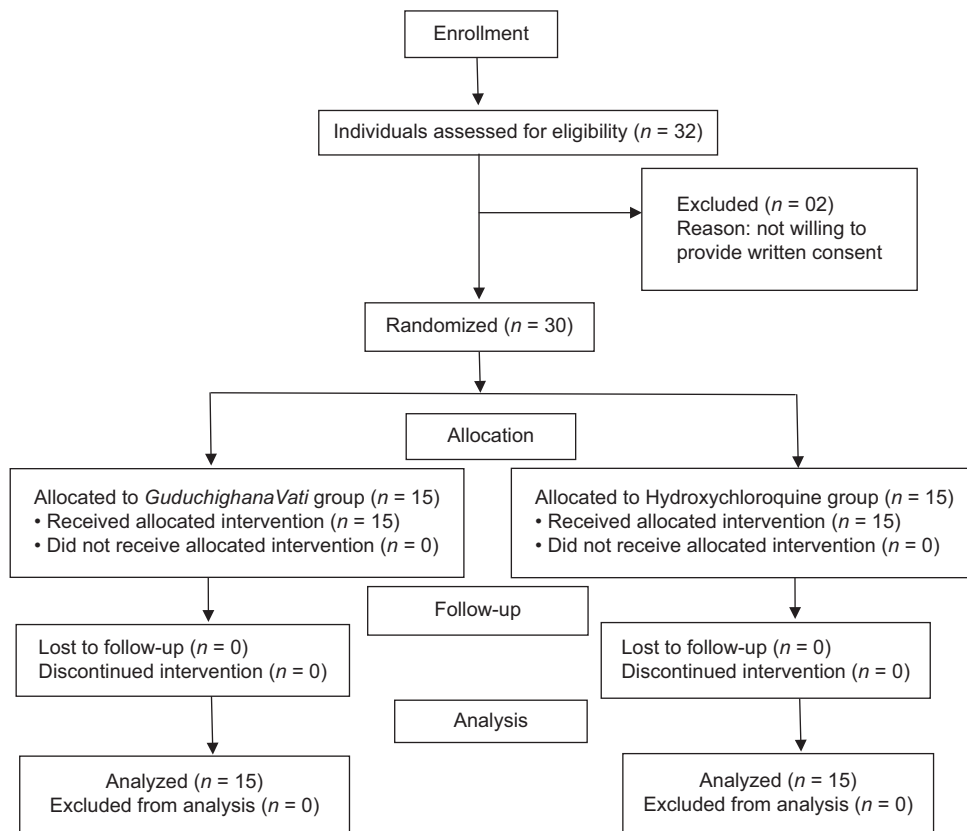


Figure 1: CONSORT flow diagram

Table 2: Result of reverse transcription-polymerase chain reaction assay in *Guduchighana Vati* group and control group

| Day to assess RT-PCR for COVID-19 | GVG (n=15), n (%) | CG (n=15), n (%) | P ^s |
|-----------------------------------|-------------------|------------------|----------------|
| 5 th day | 10 (66.6) | 8 (53.3) | 0.456 |
| 10 th day | 14 (93.3) | 10 (66.6) | 0.068 |

^sCompared using Chi-square test. RT-PCR: Reverse transcription-polymerase chain reaction, COVID-19: Coronavirus disease-2019, GVG: *Guduchighana Vati* Group, CG: Control group

patients in the *Guduchighana Vati* group clinically recovered whereas one patient remained symptomatic in the control group. No symptoms were observed in any of the patients at the end of the study period, i.e., 10th day in both the groups [Table 3].

Vital parameters such as SpO₂, pulse rate, respiratory rate, and blood pressure were within normal limits in both the groups during the study period. No complications such as pneumonia, acute respiratory distress syndrome, sepsis, septic shock, arrhythmia developed in any of the participants during the study period in both the groups. The values of laboratory parameters such as IL-6, IgG, IgM, serum ferritin, and SpO₂ are depicted in Table 4. The reduction in IL-6 levels after the treatment was statistically significant in both the groups. The level of IgG, IgM, Serum Ferritin, and SpO₂ were found within the normal limits during the study period in both the groups. None of the participants enrolled in the

trial required invasive/noninvasive oxygen therapy during the intervention period.

Safety outcomes

ADR/AE was not observed or reported by any of the study participants. Hematological tests, liver function test and kidney function test were found to be within the normal limits throughout the study period in both the groups [Tables 5 and 6].

Discussion

This randomized, active-controlled pilot study evaluated the efficacy and safety of Ayurvedic intervention, *Guduchighana Vati* in asymptomatic and mild to moderate COVID-19. In this study, both the groups were comparable in clinical characteristics and disease severity at baseline. Improvement in terms of better proportion of negative RT-PCR for COVID-19 was observed in the *Guduchighana Vati* group. Although the proportion of participants with negative RT-PCR test was numerically better in the *Guduchighana Vati* group at each scheduled clinical evaluation, however, it was statistically not significant (P = 0.068). It may be attributed to the small sample size for the study. Clinical recovery in terms of fever, cough, sore throat, and body-ache was within 5 days in all the symptomatic participants of *Guduchighana Vati* group whereas one patient remained symptomatic in the control group on 5th day. No symptoms were observed on 10th day in both the groups. Statistically significant reduction in the inflammatory markers such as IL-6 in both

the groups is noteworthy as elevated levels of inflammatory markers can be associated with heightened cytokine release, leading to COVID-19 associated systemic inflammation and hypoxic respiratory failure.^[32,33] The elevated level

Table 3: Chief complaints in Guduchighana Vati group and control group

| Chief complaints | Group | Baseline | 5 th day | 10 th day |
|-----------------------|-------|----------|---------------------|----------------------|
| Fever at evaluation | GVG | 6 (40.0) | 0 | 0 |
| | CG | 3 (20.0) | 0 | 0 |
| <i>P</i> [#] | | 0.232 | - | - |
| Cough | GVG | 4 (26.7) | 0 | 0 |
| | CG | 1 (6.7) | 0 | 0 |
| <i>P</i> [#] | | 0.142 | - | - |
| Sore throat | GVG | 3 (20.0) | 0 | 0 |
| | CG | 2 (13.3) | 1 (6.7) | 0 |
| <i>P</i> [#] | | 0.624 | - | - |
| Bodyache/myalgia | GVG | 5 (33.3) | 0 | 0 |
| | CG | 1 (6.7) | 0 | 0 |
| <i>P</i> [#] | | 0.068 | - | - |
| Anorexia | GVG | 2 (13.3) | 0 | 0 |
| | CG | 1 (6.7) | 0 | 0 |
| <i>P</i> [#] | | 0.543 | - | - |
| Headache | GVG | 7 (46.7) | 0 | 0 |
| | CG | 3 (20.0) | 0 | 0 |
| <i>P</i> [#] | | 0.245 | - | - |

[#]Compared using Chi-square test. GVG: GuduchighanaVatiGroup., CG: Control group

of IL-6 has also been associated with high case fatality from COVID-19.^[34] The level of serum ferritin was within normal range in both the groups. Ferritin is a key mediator of immune system deregulation through pro-inflammatory and immunosuppressive effects. It has been observed that the serum ferritin levels might be influencing the severity of COVID-19.^[35] The level of SpO₂ was within normal range in both the groups indicating no requirement of invasive or noninvasive oxygen therapy during the study period. Notably, oxygen saturation to fraction of inspired oxygen ratio (SpO₂/FiO₂) has been considered a noninvasive prognostic marker of adverse outcome for COVID-19.^[36] Liver Function Test and Kidney function Test were also found within normal limits after the study period and there was absence of any ADR or serious adverse event in both the study groups. Further, *Tinospora cordifolia* (*Guduchi*) has established safety profile as observed in earlier published studies^[37-39] and this study also substantiate the safety of the trial drug. Although no ADR/serious adverse event was observed in the control group also in this study, United States Food and Drug Administration reported that Hydroxychloroquine has certain known side-effects such as cardiac arrhythmia, blood and lymph system disorders, kidney injuries and liver failure.^[40]

Guduchi (*T. cordifolia* [Willd.] Miers) is one of the most popular and important *Ayurvedic Rasayana* (medicines used to improve health and longevity) widely used in practice for a variety of infective ailments.^[41] *T. cordifolia* has established

Table 4: Effect on interleukin-6, immunoglobulin G, immunoglobulin M, serum ferritin and oxygen saturation in Guduchighana Vati group and control group

| Parameters | Mean ± SD | | Between group <i>P</i> [#] |
|---------------------------------------|-------------------------------|-------------------------------|--|
| | GVG (n=15) | CG (n=15) | |
| IL-6 (pg/mL) (0-5.9 pg/mL) | | | |
| Baseline | 6.59 (1.0-19.4) ^a | 4.10 (2.0-12.9) ^a | 0.983 |
| 10 th day | 3.15 (1.20-9.86) ^a | 2.80 (0.20-5.20) ^a | 0.297 |
| <i>P</i> ^s | 0.027* | 0.001* | |
| IgG (g/L) (5.4-18.22 g/L) | | | |
| Baseline | 13.42±1.99 | 11.54±1.64 | 0.009* |
| 10 th day | 13.39±1.94 | 12.28±1.41 | 0.965 ^b |
| <i>P</i> ^s | 0.951 | 0.002* | |
| IgM (g/L) (0.22-2.40 g/L) | | | |
| Baseline | 0.93±0.27 | 1.08±0.38 | 0.235 |
| 10 th day | 1.09±0.28 | 1.10±0.24 | 0.732 |
| <i>P</i> ^s | 0.007* | 0.722 | |
| Serum ferritin (ng/mL) (20-400 ng/mL) | | | |
| Baseline | 83.76±45.08 | 104.89±84.15 | 0.399 |
| 10 th day | 97.16±43.81 | 103.97±72.64 | 0.758 |
| <i>P</i> ^s | 0.395 | 0.929 | |
| SpO ₂ (%) | | | |
| Baseline | 95.82±1.54 | 96.08±1.31 | 0.620 |
| 10 th day | 97.64±0.67 | 96.73±1.38 | 0.029* |
| <i>P</i> ^s | 0.006* | 0.433 | |

**P*<0.05 has been considered as significant, ^sWithin group *P* value, compared using paired sample *t*-test/Wilcoxon signed rank test, [#]Between group *P* value, compared using independent sample *t*-test/Mann-Whitney test, ^aData has been reported as median (minimum-maximum),

^bAdjusted data at baseline through ANCOVA. SD: Standard deviation, IgG: Immunoglobulin G, IgM: Immunoglobulin M, IL-6: Interleukin-6, SpO₂: saturation of peripheral oxygen, GVG: GuduchighanaVatiGroup, CG: Control group

Table 5: Effect on Hematological parameters in *Guduchighana Vati* Group and control group

| Parameters | Mean±SD | | Between group P# |
|--|-----------------|-----------------|---------------------|
| | GVG (n=15) | CG (n=15) | |
| Total leukocyte count (per mm ³) | | | |
| Baseline | 5793.33±1087.24 | 6980.00±1993.63 | 0.053 |
| 10 th day | 7273.33±1447.39 | 7506.67±1582.70 | 0.677 |
| P ^s | 0.001 | 0.375 | - |
| Neutrophils (%) | | | |
| Baseline | 54.07±9.88 | 66.40±9.02 | 0.001 |
| 10 th day | 56.53±8.35 | 63.13±7.28 | -0.74 |
| P ^s | 0.208 | 0.270 | - |
| Eosinophils (%) | | | |
| Baseline | 3.87±1.30 | 4.27±0.96 | 0.347 |
| 10 th day | 4.40±1.35 | 3.60±2.06 | 0.220 |
| P ^s | 0.251 | 0.290 | - |
| Lymphocytes (%) | | | |
| Baseline | 39.20±10.04 | 26.87±8.63 | 0.001 |
| 10 th day | 36.00±8.05 | 30.67±6.58 | 0.057 |
| P ^s | 0.144 | 0.162 | - |
| ESR (mm/1st hour) | | | |
| Baseline | 9.40±2.72 | 10.07±4.32 | 0.617 |
| 10 th day | 8.47±2.85 | 9.67±4.08 | 0.359 |
| P ^s | 0.224 | 0.373 | - |

^sWithin group P value, compared using paired sample t-test, #Between group P value, compared using independent sample t-test, P<0.05 has been considered as significant. SD: Standard deviation, ESR: Erythrocyte sedimentation rate, GVG: *Guduchighana Vati* group, CG: Control group

anti-inflammatory and immunomodulatory properties as observed in several experimental and clinical studies.^[42-45] It modulates the response of CD4+ and CD 8+ T-cells, activates macrophages via TLR6 signaling and nuclear factor kappa B translocation, inhibit lipoygenase, and cyclooxygenase enzymes, inhibit tumor necrosis factor- α and cytokine production and alters the level of enzymes such as catalase to stimulate lymphocytes.^[42-45] *T. cordifolia* also alters the activity of immune system through the dynamic regulation of cytokines.^[46] Furthermore, one of the active compounds of *T. cordifolia*, Tinocordiside is capable of inhibiting the interface between host angiotensin-converting enzyme 2 receptor and Receptor Binding Domain of severe acute respiratory syndrome coronavirus 2 spike protein, which is crucial for virus entry into the host respiratory epithelium.^[47] Research studies also showed significant anti-infective and antipyretic properties of *T. cordifolia*.^[48,49]

Hydroxychloroquine was considered a candidate for COVID-19 prophylaxis and management due to its immunomodulatory property. The immune responses in COVID-19 are different between severe and mild to moderate infected patients. In mild-to-moderate COVID-19, before resolution of symptoms, increase in the activated CD4+ helper T-cells, CD8+ killer T-cells, follicular helper T cells, IgG, and IgM were observed.^[50] Whereas, in severe COVID-19 cases, lymphocytopenia, substantial fall in CD3+ T-cells, CD4+ helper T-cells, CD8+ killer T cells, increase in neutrophil-to-lymphocyte ratio and elevated levels of C-reactive protein, pro-inflammatory cytokines, and

chemokines were observed.^[32,51,52] This hyperactive immune response along with impaired adaptive immune response may trigger complications such as pulmonary injury, sepsis and organ failure, and even death in some patients. Further, lung opacities have been observed as sequelae in asymptomatic COVID-19 patients also.^[53] In such circumstances, *Guduchi* can be considered in the management of asymptomatic and mild to moderate COVID-19 as it may be beneficial in inducing optimum immunomodulation and anti-inflammatory activities which are the key targets to COVID-19 management and aid in preventing long term effects of COVID-19.

Limitations of the study

Since it was a randomized controlled pilot study, it had some limitations which should be considered while interpreting the study results. The small sample size was one of the main limitations. Further, patients with asymptomatic and mild-to-moderate COVID-19 were included in the study, so the findings cannot be extrapolated to patients with severe disease or with co-morbidities.

Conclusion

Guduchighana Vati can be considered as safe and potential therapeutic option in the management of asymptomatic and mild cases of COVID-19. *Guduchighana Vati* also demonstrated the potential in reducing the levels of pro-inflammatory markers such as IL-6. Nevertheless, randomized controlled trials with a sufficient sample size are required to confirm these preliminary findings, and to make conclusions for the efficacy of this

Table 6: Effect on kidney function test and liver function test in Guduchighana Vati group and control group

| Parameters | Mean±SD | | Between group P [#] |
|----------------------------------|--------------|--------------|---------------------------------|
| | GVG (n=15) | CG (n=15) | |
| Blood urea (mg/dl) | | | |
| Baseline | 27.40±4.81 | 28.16±2.91 | 0.605 |
| 10 th day | 27.76±3.13 | 27.43±4.13 | 0.809 |
| P ^s | 0.730 | 0.402 | - |
| Serum uric acid (mg/dl) | | | |
| Baseline | 5.07±0.82 | 5.49±0.67 | 0.136 |
| 10 th day | 5.08±0.49 | 5.41±0.67 | 0.138 |
| P ^s | 0.952 | 0.592 | - |
| Serum creatinine (mg/dl) | | | |
| Baseline | 1.11±1.36 | 0.75±0.13 | 0.326 |
| 10 th day | 0.69±0.23 | 0.64±4.13 | 0.476 |
| P ^s | 0.314 | 0.035* | - |
| AST (IU/L) | | | |
| Baseline | 26.47±4.20 | 28.31±2.29 | 0.146 |
| 10 th day | 26.55±3.98 | 26.24±3.45 | 0.820 |
| P ^s | 0.894 | 0.006* | - |
| ALT (IU/L) | | | |
| Baseline | 33.89±3.22 | 36.25±3.26 | 0.055 |
| 10 th day | 33.38±3.83 | 35.66±3.13 | 0.085 |
| P ^s | 0.716 | 0.555 | - |
| Total protein (g/dl) | | | |
| Baseline | 6.04±0.87 | 6.43±0.75 | 0.204 |
| 10 th day | 5.58±0.72 | 5.88±0.78 | 0.282 |
| P ^s | 0.017* | 0.001* | - |
| Serum albumin (g/dl) | | | |
| Baseline | 4.31±0.54 | 4.44±0.70 | 0.33 |
| 10 th day | 4.26±0.28 | 4.40±0.41 | 0.29 |
| P ^s | 0.735 | 0.804 | - |
| Serum globulin (g/dl) | | | |
| Baseline | 1.73±0.68 | 1.98±0.62 | 0.298 |
| 10 th day | 1.32±0.69 | 1.48±0.58 | 0.498 |
| P ^s | 0.035* | 0.003* | - |
| Conjugated bilirubin (mg/dl) | | | |
| Baseline | 0.11±0.02 | 0.10±0.00 | 0.326 |
| 10 th day | 0.11±0.05 | 0.12±0.10 | 0.643 |
| P ^s | 0.702 | 0.334 | - |
| Unconjugated bilirubin (mg/dl) | | | |
| Baseline | 0.68±0.17 | 0.65±0.14 | 0.563 |
| 10 th day | 0.53±0.17 | 0.51±0.15 | 0.729 |
| P ^s | 0.035* | 0.002* | - |
| Serum alkaline phosphatase (U/L) | | | |
| Baseline | 156.91±34.87 | 169.39±34.39 | 0.332 |
| 10 th day | 158.04±38.15 | 155.01±32.62 | 0.817 |
| P ^s | 0.874 | 0.166 | - |

*P<0.05 has been considered as significant, ^sWithin group P value, compared using paired sample t-test, [#]Between group P value, compared using independent sample t-test. SD: Standard deviation, AST: Aspartate transaminase, ALT: Alanine transaminase, GVG: Guduchighana Vati Group, CG: Control group

Ayurveda intervention in managing the mild to moderate cases of COVID-19.

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Conflicts of interest

There are no conflicts of interest.

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