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Original Research Article

A prospective, open label, randomized-controlled study to evaluate the efficacy and safety of MyVir tablets in mildly symptomatic COVID-19 patients

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ABSTRACT

Background: Coronavirus can cause pneumonia, respiratory failure and death. The emergence of novel coronavirus has posed a challenging situation that warrants urgent global attention. Currently there was no effective therapy available for COVID-19 and hence antiviral and immune modulators are most sought after medicines to manage complications of COVID-19.

Methods: In this study involving mild COVID-19 we randomized 42 patients to receive a MyVir tablets twice daily along with standard of care (SOC) or SOC alone in 1:1 ratio for 14 days. We evaluated the benefits of MyVir tablets by assessing clinical outcomes and improvement in immune markers (LDH, CRP, D-dimer, TLC).

Results: At the end of the study the immune markers in MyVir group improved significantly compared to control group. In patients who received MyVir, CRP decreased from 3.3 mg/l to 1.7 mg/l ($p=0.0171$). D-dimer decreased from 0.589 on day 0 to 0.368 on day 14 ($p=0.03$) and LDH decreased from 224 U/l on day 0 to 158 U/l on day 14 in test group ($p=0.05$). TLC showed favorable improvement in study group compared to control group. Early recovery from COVID-19 symptoms was observed in patients on MyVir treated group. Patients treated with MyVir tablets reduced the duration of hospitalization when given along with standard of care.

Conclusions: MyVir accelerated recovery of COVID-19 patients by early improvement in clinical symptoms and immune markers in this study and results clearly indicates that MyVir tablets has antiviral, immune booster activity. Hence this study provides evidence that MyVir has definitive role in the management of mild COVID-19 patients along with standard of care (funded by Mi Lab Life Sciences(P) Ltd. CTRI no. CTRI/2020/05/024967).

Keywords: COVID-19, Complications, Antiviral, Immune booster, MyVir

INTRODUCTION

Coronavirus can cause pneumonia, respiratory failure and death. The pandemic of COVID-19 caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2),

COVID-19 has resulted in death of millions of people. Globally, as on 22 May 2021, there have been 165,772,430 confirmed cases of COVID-19 including 3,437,545 deaths.¹ In India, as on 22 May 2021, there have been 26,289,290 confirmed cases of COVID-19 with 295,525 deaths, reported to WHO.²

The most common findings associated with severe disease are older age, higher inflammatory markers (CRP, D-dimer, LDH) on admission. The most common complications are sepsis, respiratory failure, acute respiratory distress syndrome (ARDS), cardiac injury and acute kidney injury. Although not completely understood, multiple pathophysiological mechanisms have been hypothesized for the cause of mortality in COVID-19. Respiratory failure (ARDS) occurs due to hyperinflammation (cytokine storm). Another plausible mechanism of respiratory failure is occlusion and microthrombosis in small pulmonary vessels. Secondary hemophagocytic lymphohistiocytosis (sHLH) is a hyperinflammatory condition characterized by hypercytokinemia with multi-organ failure. sHLH is usually triggered by viral infections and sepsis. Severe COVID-19 resembles sHLH characterized by cardinal features like fever, cytopenia, hyperferritinemia and increased interleukins. Significantly abnormal coagulation parameters were noted in people who succumbed to COVID-19, with higher levels of D-dimer and fibrin degradation products (FDP) and lower levels of the fibrinogen and AT levels. Increased levels of D-dimer are commonly reported in one third of patients with severe illness. Occlusion and micro-thrombosis formation in pulmonary small vessels in such patients have also been reported. The endothelial cell dysfunction, induced by infection, results in excess thrombin generation and fibrinolysis shutdown in patients with infection. In addition, hypoxia stimulates thrombosis through not only increasing blood viscosity, but also a hypoxia-inducible transcription factor-dependent signaling pathway.^{3,4}

As of now, there is no effective/specific therapy available for COVID-19 although different experimental treatments with antiviral drugs and interferon are being used. Supportive therapy is the only resort to treat complicated COVID-19 cases and hence quest for novel drug continues. In view of this, complementary and alternative medicine (CAM) offers a plethora of interesting possibilities in patients. Herbs exhibit a diverse array of biological activities and can be effectively harnessed for managing pandemic flu. Potentially active herbs can serve as effective antiviral agents. The role of CAM for managing novel COVID-19 and the mode of action of these botanicals is presented here in an evidence-based approach that can be followed to establish their potential use in the management of corona virus pandemics.

MyVir tablets

MyVir tablets is a polyherbal formulation which is a potent combination of antivirals, antibacterials and anti-inflammatory along immune modulating/boosting ingredients. These herbals are used for various infectious ailments from many centuries and with abundant literature evidences. Key herbs in MyVir includes *Andrographis paniculata*, *Azadirachta indica*, *Ocimum sanctum*, *Tinospora cordifolia*, *Allium sativum*, *Carica papaya*, *Curcuma longa*, *Cyperus rotundus*, *Zingiber officinale* and

these are being used in the treatment of viral infections. The active principles in these herb extracts have antiviral and immune boosting activity and enhance the functioning of the immune system by stimulating certain cell types, such as macrophages, lymphocytes, natural killer (NK) cells, dendritic cells and eosinophils by mechanisms including modulation of cytokine secretion, immunoglobulin production, phagocytosis and macrophage activation. These herbs are used from many years for various infections including viral, bacterial and fungal infections in traditional medicine. Hence this clinical trial was conducted to evaluate the safety and efficacy of MyVir tablets in mildly symptomatic COVID-19 patients.

Mechanism of action of MyVir ingredients

Andrographis paniculata

The antiviral activity of the extract was determined by observing its ability on inhibiting virus load in A549 cells transfected with Simian retro virus (SRV) by real time-polymerase chain reaction (RT-PCR) analysis. The immunostimulant activity of extract was determined by its ability to induce lymphocytes cell proliferation using 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay.⁵

Tinospora cordifolia

A variety of active components derived from the plant like alkaloids, steroids, diterpenoid lactones, aliphatics and glycosides have been isolated from the different parts of the plant body including root, stem and whole plant. The plant is of great interest to researchers across the globe because of its reported medicinal properties like anti-inflammatory, antioxidant, anti-allergic, immunomodulatory activities.⁶

Curcuma longa

It has been demonstrated that curcumin as a plant derivative has a wide range of antiviral activity against different viruses. Inosine monophosphate dehydrogenase (IMPDH) enzyme due to rate-limiting activity in the *de novo* synthesis of guanine nucleotides is suggested as a therapeutic target for antiviral and anticancer compounds. Among the 15 different polyphenols, curcumin through inhibitory activity against IMPDH effect in either non-competitive or competitive manner is suggested as a potent antiviral compound via this process.⁷

Azadirachta indica

Rich source of antioxidant and other valuable active compounds such as azadirachtin, nimbolinin, nimbin, nimbidin, nimbidol, salannin and quercetin. It shows antimicrobial role through inhibitory effect on microbial growth/potentiality of cell wall breakdown.⁸

Ocimum sanctum

The chemical composition of tulasi is highly complex containing many nutrients and other biological active compounds. Perhaps best known of many active compounds that have been identified and extracted are eugenol (an essential oil) and ursolic acid. Many scientific studies have indicated that *O. sanctum* has antioxidant, immune modulating, anti-inflammatory, antibacterial, antiviral, antifungal, antipyretic properties.⁹

Zingiber officinale

The aqueous rhizome extract of *Z. officinale* showed anti-inflammatory as well as anti-viral activity.¹⁰

Cyperus rotundus

The extract was tested on three viruses-HSV (herpes simplex-1 virus), polio (poliomyelitis-1 virus) and VSV (vesicular stomatitis virus). *C. rotundus* showed virucidal activity against HSV. Clinical trials and animal research support the use of the plant as an antibacterial, anti-inflammatory, anti-pyretic agent.¹¹

Allium sativum

It was found that garlic extract with a good selectivity index (SI) has inhibitory effect on the virus penetration and proliferation in cell culture. Fresh garlic extract with allicin as the main active component of it has been shown to have antiviral activity *in vitro* and *in vivo*. Its beneficial effects may be due in part to sulfur-containing compounds such as allicine, diallyl disulfide, diallyl trisulfide that react with thiol groups of various enzymes which are critical for microorganism.^{12,13}

Carica papaya

The flavonoid quercetin with highest binding energy against NS2B-NS3 protease which is evident by the formation of six hydrogen bonds with the amino acid residues at the binding site of the receptor. The flavonoids from *C. papaya* have significant anti-viral activities.^{14,15}

Based on the existing information we hypothesized that MyVir supplemented for 14 days would provide a remarkable improvement of Immunity in COVID-19 patients. The purpose of this study is to evaluate the efficacy and tolerability of MyVir in patients with COVID-19. MyVir contains various potential herbs that have been evaluated for their safety and efficacy against flu viruses and hence can prove to be useful to combat the novel COVID-19 pandemic.

METHODS

This prospective, open label, randomized-controlled study was conducted in Bangalore medical college and research institute, Bengaluru, Karnataka, India, after approval from

institutional ethics committee. The trial, which was sponsored by Mi Lab Life Sciences (P) Ltd was conducted in accordance with principles of the ICH-GCP guidelines. The trial has been registered in the clinical trial registry, India (CTRI registration number: CTRI/2020/05/024967).

All the 42 patients had positive results on testing for SARS-CoV-2 and presented with one or more mild symptoms. The investigators reviewed the symptoms, risk factors and other inclusion and exclusion criteria before enrollment. All the patients provided written informed consent. The study was initiated on 30 April 2020 and completed on 31 May 2020. These patients were randomized in 1:1 ratio into test group and control group of 21 each. All subjects completed the study and included in safety and efficacy analysis (N=21 in the test group and N=21 in the control group). Both the groups were managed with the SOC. In addition, the test group received MyVir tablets two times daily for 14 days. Standard of care included paracetamol, antihistamines, glucocorticoids, antibiotics, vitamin C and zinc supplements along with medication for co-morbid conditions like diabetes, hypertension, cardiac, thyroid ailments. The control group received standard of care treatment only. All the subjects were followed up for 14 days or end of treatment whichever is earlier. There was a telephonic visit on day 21 to monitor adverse events if any.

Patients

Inclusion criteria for this study included the age limit of 18-65 years and of either sex, who were willing to give consent to the study. Patients diagnosed with COVID-19 positive mild symptomatic patients (confirmed by RT-PCR) with uncomplicated upper respiratory infection having SpO₂>94% in room air and having no evidence of hypoxaemia or breathlessness and who can take oral medicines were enrolled in this study. Patients with acute hypoxic respiratory failure, requiring intensive care unit (ICU) stay and who need mechanical ventilation were excluded from the study.

Study procedures

All the patients provided written informed consent and entered a 2 day screening period, during which the trial inclusion and exclusion criteria were checked and baseline information gathered including safety and efficacy parameters (LFT, RFT, LDH, CRP, D-dimer and TLC). After this screening, patients were randomly assigned to receive either SOC or SOC+MyVir tablets in 1:1 ratio. Patients were evaluated at day 1, 7 and 14 after randomization, with a focus on assessment of clinical symptoms and adverse events. Repeat assessment of safety and efficacy parameters (LFT, RFT, LDH, CRP, D-dimer and TLC) was done on day 14. Additional visit (telephonic) was scheduled at day 21 for adverse event monitoring. Simple randomization is followed in this study. The principal investigator was provided with the investigational products with the subject's code number.

Outcomes

Efficacy endpoints were improvement in the total leucocyte count (TLC), lactic dehydrogenase (LDH), C-reactive protein (CRP) and D-dimer. Safety endpoints were adverse events (AEs), frequency and severity, number of subjects who discontinue study due to adverse events and changes in vital parameters and safety laboratory parameters. TLC, LDH, CRP, D-dimer and RT-PCR are monitored for improvement on day 0 and day 14. Renal function test (RFT) and liver functions test (LFT) are monitored on day 0 and day 14 for safety assessment. Along with the laboratory parameters patients were also monitored for vitals, physical examination and adverse events for safety in each visit.

Statistical analysis

t test was used separately for within control group (baseline versus visit 4) and within test group (baseline versus visit 4) for safety and efficacy analysis. P value

<0.05 was considered as statistical significance for the study and p value <0.001 was considered as highly significant. Baseline characteristics were summarized as means and standard deviations, medians and interquartile ranges or percentages. Unless otherwise stated, all hypotheses will be tested at a significance level of 0.05 and 95% confidence interval.

RESULTS

All the 42 subjects were distributed equally between the two groups. Total 27 male and 15 female subjects participated in the study. Mean age of participants was 37.5 years (Table 1).

C-reactive protein (CRP)

The CRP marker was found to be significantly increased in the initial phases of the infection for severe COVID-19 patients, also prior to indications of critical findings with CT.

Table 1: Parameters.

Parameters	Test (N=21)	Control (N=21)	P value
Age (in years)			
Mean (SD)	38	37	0.63
Sex, N (%)			
Female	7	8	0.747
Male	14	13	

Table 2: Mean CRP levels in mg/l.

Days	Test	Control	P value*
Day 0	3.3	3.0	0.0171
Day 14	1.7	3.7	

*Data analyzed using Mann Whitney test; p<0.05 is considered statistically significant.

Table 3: Mean LDH levels in U/l.

Days	Test	Control	P value*
Day 0 (baseline)	224	238	0.05
Day 14	158	240	

*Data analyzed using unpaired t test; p<0.05 is considered statistically significant.

Table 4: Mean D-dimer levels per mg/l.

Days	Test	Control	P value*
Day 0	0.589	0.631	0.03
Day 14	0.368	0.796	

*Data analyzed using unpaired t test; p<0.05 is considered statistically significant.

Importantly, CRP has been associated with disease development and is an early predictor for severe COVID-19 (Tan et al 2020). The increased CRP levels were likely due to COVID-19 related acute inflammatory pathogenesis during which multiple cytokines were released and their

amount was associated with disease severity by Huang et al.²² Hence CRP is an important lab parameter in assessing the severity of inflammation. In the present study mean CRP values in control group was 3.0 mg/l on day 0 and 3.7 mg/l on day 14. Mean CRP was 3.3 mg/l in test group on day 0 and 1.7 mg/l on day 14. Mean CRP levels reduced

significantly in test group compared to control group and it was statistically significant. (p=0.0171) (Table 2) (Figure 1).

Lactic dehydrogenase (LDH)

Severe infections may cause cytokine-mediated tissue damage and LDH release. Since LDH is present in lung tissue (isozyme 3), patients with severe COVID-19 infections can be expected to release greater amounts of LDH in the circulation as a severe form of interstitial

pneumonia, often evolving into acute respiratory distress syndrome is the hallmark of the disease. It was also one of the biomarkers most strongly associated with ARDS mortality by Henry et al and Shi et al.^{19,20} Hence LDH is an important laboratory parameter in assessing the severity of tissue injury. In the present study mean LDH values in control group was 238 U/l on day 0 and 240 on day 14. Mean LDH was 224 U/l in test group on day 0 and 158 U/l on day 14. Mean LDH levels reduced significantly in test group compared to control group and it was not statistically significant (p=0.05) (Table 3) (Figure 2).

Table 5: Clinical features.

Sr. No.	Symptoms	Assessments	Test group (MyVir+SOC)					Control group (SOC)				
			Day 0	Day 4	Day 7	Day 10	Day 14	Day 0	Day 4	Day 7	Day 10	Day 14
1.	Fever	Febrile	21	10	5	0	0	21	11	9	3	1
		Afebrile	0	11	16	21	21	0	10	11	18	20
2.	Cough	+ /present	21	12	6	1	0	21	14	11	6	2
		- /absent	0	9	15	20	21	0	7	10	15	19
3.	Sore throat	+ /present	20	10	5	0	0	20	12	8	3	1
		- /absent	0	10	15	20	20	0	8	12	17	19
4.	Mild breathlessness	+ /present	18	5	2	0	0	17	12	10	7	7
		- /absent	2	15	18	20	20	3	8	10	13	13

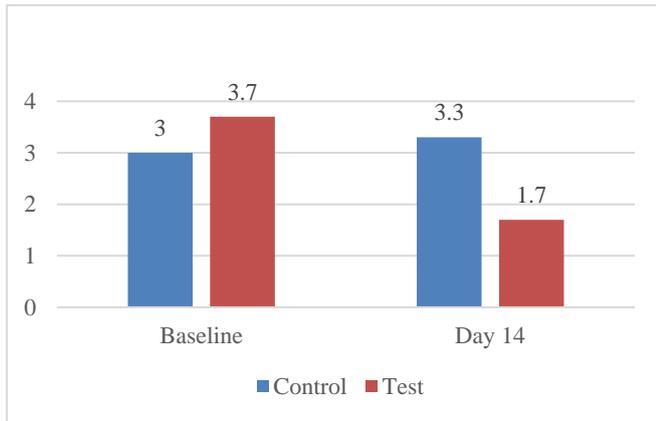


Figure 1: CRP in mg/l.

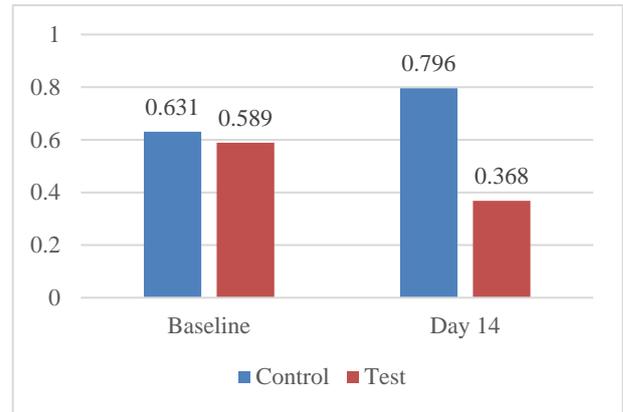


Figure 3: Mean D-dimer levels per mg/l.

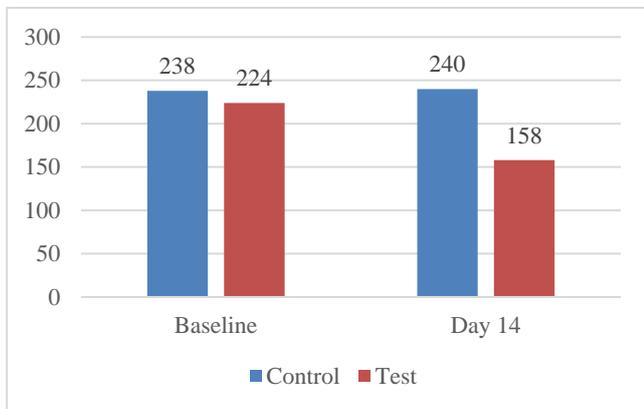


Figure 2: Mean LDH levels in U/l.

D-dimer

D-dimer is a marker of disseminated intravascular coagulation (DIC) and associated with worst prognosis. Recent literature data show that D-dimer values are frequently enhanced in patients with COVID-19, being variably observed in 36 to 43% of positive cases. D-dimer values are even higher in patients with severe COVID-19 than in those with milder forms and therefore, D-dimer measurement may be associated with evolution toward worse clinical picture, though serial measurement would not be easily feasible at present in COVID-19 patients by Lippi et al.²⁷ Notably, Tang et al also recently highlighted that the vast majority of COVID-19 patients who died during hospital stay fulfilled the criteria for diagnosing

disseminated intravascular coagulation (71.6 versus 0.6% in survivors). In the present study in test group mean D-dimer is 0.589 on day 0 and 0.368 on day 14. In control group mean D-dimer is 0.630 on day 0 and 0.796 on day 14. Mean D-dimer values reduced significantly in test group compared to control group at day 14 and it is statistically significant ($p=0.03$) (Table 4) (Figure 3).

Total leucocyte count

Lymphopenia (lymphocyte count $<1.0 \times 10^9 /l$)³ and inflammatory cytokine storm are typical laboratory abnormalities observed during highly pathogenic coronavirus infections such as the SARS-CoV-2 and the Middle East respiratory syndrome coronavirus (MERS-CoV) infections and are believed to be associated with disease severities by Chen et al.²³

Recent studies have also reported decreases in the counts of lymphocytes (e.g. CD4+ T cell, CD8+ T cell) in the peripheral blood and increases in serum inflammatory cytokine levels (e.g. IL-6) in COVID-19 patients by Qin et al, Chen et al and Wang et al.^{23,24,26} Total leucocyte count is a marker to assess the immune response in the viral infections. In the present study there was no lymphopenia in study group however 4 patients in control group had lymphopenia.

Clinical features

MyVir demonstrated significant improvement in clinical symptoms including fever, cough, sore throat, mild breathlessness as early as day 4 and most of the patients were clinically free of symptoms by day 7-10. Early recovery from signs and symptoms was observed in more than 75% of the patients in test group when compared to control group.¹⁵ There was also decrease in the duration of hospitalisation in patients treated with MyVir tablets (Table 5).

Safety results

Vitals including temperature, systolic and diastolic blood pressure, pulse rate, heart rate and respiratory rate measured and recorded at all the visits. The safety laboratory parameters RFT and LFT were within normal limits at screening and on day 14. There was no clinically significant abnormality observed in test and control group subjects inferring the active product is safe for administration. There were 4 adverse events (2 nausea, 1 head ache, 1 stomach upset) observed for four different subjects in test group which were categorized as mild to moderate in severity with none of the events were judged to be related to study product in the investigator's opinion. In control group there were 5 adverse events of mild severity (3 gastritis and 2 nausea) observed. None of the patients discontinued study due to adverse events. All the adverse events were managed clinically by routine measures.

DISCUSSION

In this study we examined safety and efficacy of MyVir in mild COVID-19 patients. Safety assessment was done throughout the study period. Few patients in both groups experienced adverse effects of mild to moderate in severity with none of the events were judged to be related to study product in the Investigator's opinion. None of the patient discontinued the study due to adverse events. Liver function has been identified as an important predictor for COVID-19 patient mortality. A recent study suggested that SARS-CoV-2 may directly bind to ACE2-positive cholangiocytes and therefore, liver abnormalities in COVID-19 patients may be due to cholangiocyte dysfunction and other causes such as drug induced and systemic inflammatory response-induced liver injuries.¹⁶ Regarding the specific and dynamic pattern of liver injury parameters, Lei et al in a wide retrospective multicenter study involving a COVID-19 cohort-derived data set of 5771 patients, reported that AST is strongly associated with mortality risk compared to other parameters, reflecting liver injury.¹⁷ In present study liver function parameters were within normal limits at screening and on day 14. And renal functions were also normal at the end of study period.

Severe infections may cause cytokine-mediated tissue damage and LDH release. Since LDH is present in lung tissue (isozyme 3), patients with severe COVID-19 infections can be expected to release greater amounts of LDH in the circulation as a severe form of interstitial pneumonia, often evolving into ARDS is the hallmark of the disease. It was also one of the biomarkers most strongly associated with ARDS mortality.^{18,19} Hence LDH is an important laboratory parameter in assessing the severity of tissue injury. In the present study mean LDH levels reduced significantly in test group compared to control group and it was statistically significant.

The CRP is an important prognostic marker and found to be significantly increased in the initial phases of the infection for severe COVID-19 patients also prior to indications of critical findings with CT. Importantly, CRP has been associated with disease development and is an early predictor for severe COVID-19.²⁰ The increased CRP levels were likely due to COVID-19 related acute inflammatory pathogenesis during which multiple cytokines were released and their amount was associated with disease severity.²¹ Hence CRP is an important lab parameter in assessing the severity of inflammation. In the present study Mean CRP levels reduced significantly in test group compared to control group from day 0 to day 14 and it was statistically significant.

D-dimer is a marker of DIC and associated with worst prognosis. Recent literature data show that D-dimer values are frequently enhanced in patients with COVID-19, being variably observed in 36 to 43% of positive cases. D-dimer values are even higher in patients with severe COVID-19 than in those with milder forms and therefore, D-dimer

measurement may be associated with evolution toward worse clinical picture in COVID-19 patients.²⁶⁻³⁰ Notably, Tang et al also recently highlighted that the vast majority of COVID-19 patients who died during hospital stay fulfilled the criteria for diagnosing DIC (71.6 versus 0.6% in survivors). In the present study mean D-dimer values reduced significantly in test group compared to control group at the end of therapy (day 14) and it is statistically significant.

Lymphopenia (lymphocyte count $<1.0 \times 10^9 / l$)³ and inflammatory cytokine storm are typical laboratory abnormalities observed during highly pathogenic coronavirus infections such as the SARS-CoV-2 and the MERS-CoV infections and are believed to be associated with disease severities.²² Recent studies have also reported decreases in the counts of lymphocytes (e.g. CD4+ T cell, CD8+ T cell) in the peripheral blood and increases in serum inflammatory cytokine levels (e.g. IL-6) in COVID-19 patients.²³⁻²⁵ Total leucocyte count is a marker to assess the immune response in the viral infections. In the present study none of the patients in test group had low TLC whereas 4 patients in control group had low TLC count.

MyVir demonstrated significant improvement in clinical symptoms including fever, cough, sore throat, mild breathlessness as early as day 4 and most of the patients were clinically free of symptoms by day 7-10. Early recovery from signs and symptoms was observed in more than 75% of the patients in test group when compared to control group.¹⁵ Early clinical resolutions is associated with early clearance of virus and reduce the chances of viral spread among the primary and secondary contacts. There was also decrease in the duration of hospitalisation in patients treated with MyVir tablets.

Impact of COVID-19 complications

COVID-19 patients experience high levels of proinflammatory cytokines and often progress to ARDS and require mechanical ventilation.^{31,32} ARDS may cause permanent scarring of the lung tissue resulting in respiratory problems that persist long after recovery. Between 33 and 75% of patients with COVID-19 require mechanical ventilation, often for weeks at a time. Those on ventilators are more prone to respiratory infections, which, in turn, predispose patients to further harm and risk of permanent lung damage. COVID-19 infection is also associated with high rates of extra-pulmonary complications that may continue to incur morbidity, disability and delayed mortality in survivors. These include cardiac injury, acute ischemic or hemorrhagic stroke, neurological deficits, acute kidney injury including the need for dialysis and liver injury. The thromboembolic complications of COVID-19 such as pulmonary embolism, stroke and other microinfarctions can cause a wide range of permanent organ damage. Independent of ARDS, severe pneumonia has been associated with increased risk of incident heart disease both in the immediate aftermath of the infection and in later years.³³ In hospitalised COVID-

19 patients it was observed that with increasing hospitalization time requiring ICU/ventilator support and managing post covid complications increased the overall cost of COVID-19 management and financial burden to the patient. Effective COVID-19 treatment strategies may lower costs and increase the effectiveness of resource allocation.³⁴

None of the patients in present study progressed to severe COVID-19 at the end of study. MyVir has significantly reduced pro inflammatory markers including CRP, LDH and D-dimer which are known to cause cytokine storm and thromboembolic events leading to post COVID-19 complications. MyVir demonstrated significant improvement in clinical symptoms as early as day 4 and 75% of the patients were clinically free of symptoms by day 7-10 which is significant compared to control group. This early resolution of clinical symptoms correlates with early viral clearance and reduced duration of hospitalization. Thus in this COVID-19 study MyVir improved COVID-19 clinical features and immune markers significantly compared to the control group.

CONCLUSION

The aim of the present study was to evaluate safety and efficacy of MyVir tablets in mildly symptomatic COVID-19 patients. MyVir has demonstrated an excellent safety and efficacy profile in mildly symptomatic COVID-19 patients along with standard of care. MyVir tablets administered patients demonstrated significant improvement in clinical symptoms and early recovery in more than 75% of the patients in test group within 7-10 days when compared to control group. MyVir when administered orally for a period of 14 days in mildly symptomatic COVID-19 patients demonstrated significant antiviral activity and improvement in immune markers including CRP, LDH and D-dimer. This clearly indicates that MyVir tablets when administered orally along with standard of care has definitive role in the management of mildly symptomatic COVID-19 patients.

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Conflict of interest: None declared

Ethical approval: All the study related documents were reviewed by ethics committee-Bangalore medical college and research institute, Bangalore. The study was approved on 18/04/2020 and the study was conducted in compliance with part 56 of title 21 of the code of federal regulations (CFR) and international conference on harmonization (ICH) guidelines. The aforementioned ethics committee was registered under CDSCO with registration number ECR/302/Inst/KA/2013/RR-20

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