

Clinical Evaluation of *Tinospora Cordifolia* (Giloy) Extract in Patients with Covid-19: An Add on Study in 60 Patients

Kulshrestha Himani¹; Mishra Ankita²; Asthana Shobhit³; Singh Akhand Pratap⁴

1, 2,4, Maharishi University of Information Technology, Lucknow, India

3, School of Engineering and applied sciences, Bennett University, Greater Noida, India

*Corresponding author: Kulshrestha Himani, Department of Biotechnology, Maharishi University of Information Technology, Lucknow, India Email:

himanikul01@gmail.com

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ABSTRACT

*Covid-19 is an epidemic disease and is considered as the major cause of mortality across globe in past 2 years. Covid-19 is originated from China and spread all over the globe. After being experimented with many medicines for covid-19 including vaccination nothing is proved to be permanent cure for this virus, another new variant is now in the air. Now it's time to back to the root of Indian medicine that is ayurveda. We experimented on *Tinospora cordifolia* (Giloy). Leaves and roots of giloy is experimented on 60 patients to cure the symptoms caused by corona virus. Addition of *Tinospora Cordifolia* leaves or root extract in the diet may reduce body pain, fever, loss of smell and other physical characteristics in covid patients. It included the oral administration of giloy leaves or root extract half an -hour before taking meal. We have divided 60 patients in two groups: one group of patients received giloy leaves extract and the other group received giloy root extract. The subjects were assed biochemically for 14 days. As a result, giloy root extract treated group showed significantly ($p < 0.01$) more decrease in body pain, fever and other physical characteristics rather than the other group treated with giloy leaves extract. This giloy preparation founded to be safe in the patients suffering from any other diseases like diabetes, hypertension, asthma or other respiratory problems along with covid infection. As giloy has an immunomodulatory power it can help in fighting any common respiratory issue such as cold and cough, it can also provide relief to asthmatic patient.*

Keywords: *Tinospora, Covid-19, Ayurvedic herb, immunomodulator, Antioxidant*

INTRODUCTION

The pandemic disease coronavirus (COVID-19), originated from the China (Wuhan city), has quickly

spread to different countries, worldwide. Coronavirus 2 (SARS-CoV-2), a severe acute respiratory syndrome, which causes coronavirus disease (COVID-19), was first identified in December 2019.

In Uttar Pradesh nineteen districts are identified as hotspot, and it was followed by fourteen and twelve districts in Maharashtra and Tamil Nadu, respectively (8A) (1). Coronavirus that is responsible for both SARS and COVID-19, affect the respiratory system and causes major disease outbreaks worldwide. SARS is caused by SARS-CoV, whereas COVID-19 is caused by SARS-CoV-2. There is no specific treatment developed to treat COVID-19 or SARS. In the latest search for a COVID-19 cure, some evidence are there that point to SARS-CoV-2 being similar to human coronavirus HKU1 and 229E strains (13, 14A) even though they are of new coronavirus family members. According to these reports, humans do not have immunity to this virus, allowing its rapid spread among human populations through contact with an infected person. SARS-CoV-2 is more transmissible than SARS-CoV. The two possible reasons might be (1.)

Tinospora cordifolia [Giloy] Miers is an immune regulator medicinal drug in Ayurveda which is used to possess properties like antioxidation, immunomodulation, antiviral hyperglycaemic, anti-inflammatory, anti-allergent etc.[1] This herb consists of

compounds like glycosides, alkaloids, steroids, diterpenoid lactones, sesquiterpenoid and aliphatic compound.[2] Scientific researches on *tinospora cordifolia* may provide a new approach as well as insight for prevention, management and development of new beneficial entity to treat COVID-19.

It remove toxins from our body, purifies our blood, fights against bacteria which causes diseases and also combats liver diseases and urinary tract infections [3]. “Giloy is used for the treatment of cardiac problems, and in the treatment of infertility”. [2] The leaf extract of Giloy have the antimicrobial activity against gram-positive and gram-negative bacteria, clinically relevant fungal infections and malarial parasites. The imminent dietary content of Giloy leaves which showed about 51.66% moisture content, 5.90% ash, 3.60% crude fat, 70.6% carbohydrate, 7.2 protein, 6.90% crude fibre and 310.90 Kcal/100g energy value[4].

Ayurvedic uses of Giloy

1. Boosts Immunity: Giloy is an universal Ayurveda herb that helps to boost immunity. It contains a large number of antioxidants which fight against free radicals and keep our cells healthy.
2. Improve vision: Giloy applied to the eyes boost vision .its need to do is boil Giloy powder in water then let it cool down and

- apply over the eyelids. And increase their clear vision.
3. 5. Improve Digestion: Giloy is very beneficial in improving digestion and treating stomach related issues. We can take half a gram of Giloy powder + Amla + jiggery for treating constipation.
 4. 6. Reduces Stress and Anxiety: Giloy used for get rid of toxins boosts of the memory to help for reduce mental stress as well as anxiety and makes for an excellent health tonic with combination of other herbs.
 5. 7. Treatment of Cancer: Giloy might help for the reducing breast cancer because it's found as anti – proliferative property
Tips: Take 2-3 teaspoon of fresh Giloy juice and add same quantity of water and drink it on an empty stomach in the morning. Continuous used of the process at least 2-3 months for better results.
 6. 8. Anti – Inflammatory: Giloy is known as anti – inflammatory properties which provide relief while dealing with inflammatory conditions such as gout and arthritis.

2. MATERIAL AND METHODS

2.1 SUBJECT'S SELECTION

2.1.1 Participants

60 Patients both male (38) 63.33% & female (22) 36.66% patients, age of 18-50 years with a diagnosis of mild

to moderate Covid-19 infection patients. Pregnant and lactating women were not included as the patients. The scientific strategy was to register the clinical history of the patients provide them with standard recommendations and Ayurveda immunity booster [(5mg.2times) Giloy root & (5mg.2times) Giloy Leaves)] to manage the symptoms, monitor the variations in the vital signs and symptoms of the participants, and analyse the effect of the interventions on the clinical outcomes.

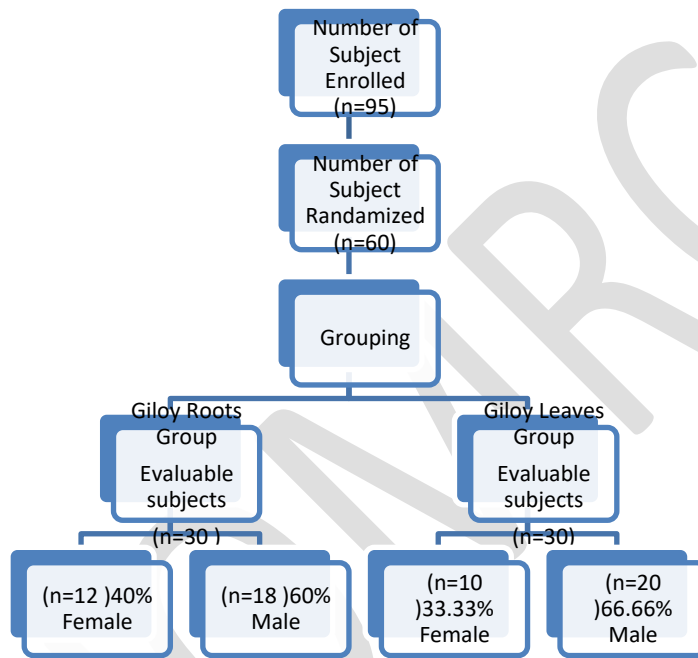
2.2 Study design

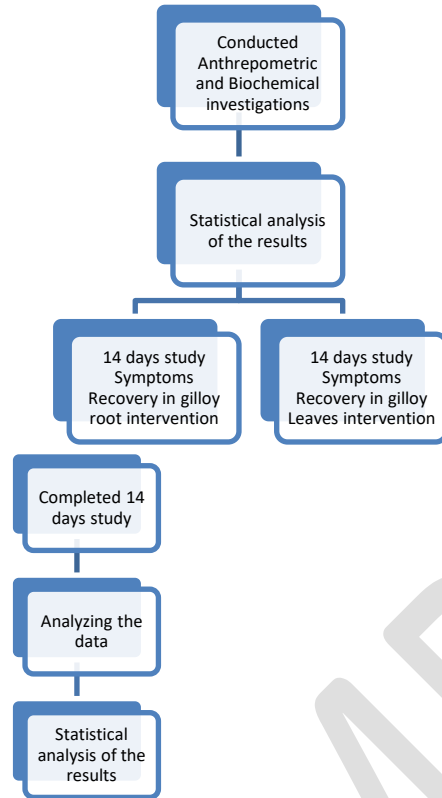
The aims of project were to propose a safe combination of easily available remedies that pose no risk; to improve the self-efficiency in the community participants and to evaluate that the participants who succeed in improving symptoms can reduce the incidences concerning the severity of infections and COVID-19 related complications.

60 Patients both male (38) 63.33% & female (22) 36.66% patients, age of 18-50 years with a diagnosis of mild to moderate Covid-19 infection patients. Pregnant and lactating women were not included as the patients. This trial involved the estimation of the effect of Giloy extract in patients suffering from Covid -19. The fixed dosage of Giloy was administered orally in 60(Number of subjects randomized n=60) patients. As the study was

double-blinded, codes of the groups were opened only after statistical analysis of the two groups. One group (40% Female &60% Male) [The mean age of the patients was 40.73 years] of patients received (5mg.2times) Giloy root and the

other group (33.33% Female & 66.66% Male) [The mean age of the patients was 39.933 years] received (5mg.2times) Giloy Leaves). Patients were randomized as per computer generated randomization code.





2.3 Demographic data

Age of the study population was between 18-50 years. The average age of Giloy **Roots** Group was 40.73 years and that of Giloy **Leaves** Group was 39.93 years. In Giloy **Roots** Group, 60% of the patients were males and 40% of the patients were females. In Giloy **Leaves** Group, 66.66% of the population consisted of male subjects and 33.33% of the population were females. In Giloy **Roots** Group, Total Diabetes, B.P (Blood Pressure) and Respiratory Disease patients was 56.66667 %, 40% and 30% respectively. In Giloy **Leaves** Group, Total Diabetes, B.P (Blood Pressure) and Respiratory Disease

patients was 30%, 30% and 16.66667 % respectively.

Efficacy assessment criteria: After a minimum run-in period of one week (7 days) patients were randomly assigned to 2nd weeks (14 days) of treatment with Giloy **Roots** & Giloy **Leaves**. The study was double-blind. Participants were reviewed every 7 days .The following Anthropometric and Biochemical investigations was performed on each visit of patient.

- Body Pain
- Fever
- Cold
- Loss of smell
- Headache
- Cough
- Fatigue

2.4 Safety analysis

Safety was evaluated by patient's data- Body Pain, Fever, Cold, Loss of smell, Headache, Cough, Fatigue in different levels in all patients who had taken at least one dose of Immunity Booster Giloy leaves and Giloy roots. All adverse effects that were observed during the Anthropometric and Biochemical investigations were recorded. Physical examinations and Anthropometric and Biochemical investigations determinations were

performed upon screening, randomization, and study termination.

Statistical analysis : Data was described as mean \pm SD. The baseline characteristics were compared with outcome on completion of the dosing period as well as with Giloy **Leaves** Group. Appropriate parametric and non-parametric tests were used for analysis of the data.

RESULTS

Efficacy Analysis

TABLE 1
SYMPTOMS RECOVERY IN Giloy ROOT INTERVEUTION

SYMPTOMS	Day 0	Day(7)	Day(14)
Body Pain	17 \pm 2.3	8 \pm 1.1	00 \pm (0.0)
Fever	16 \pm 2.1	2 \pm 0.6	00 \pm (0.0)
Cold	7 \pm 1.9	3 \pm 0.5	00 \pm (0.0)
Loss of smell	7 \pm 1.2	2 \pm 0.7	00 \pm (0.0)
Headache	4 \pm 1.1	1 \pm 0.3	00 \pm (0.0)
Cough	16 \pm 1.7	10 \pm 0.6	00 \pm (0.0)
Fatigue	14 \pm 1.9	11 \pm 1.1	0.5 \pm (0.01)

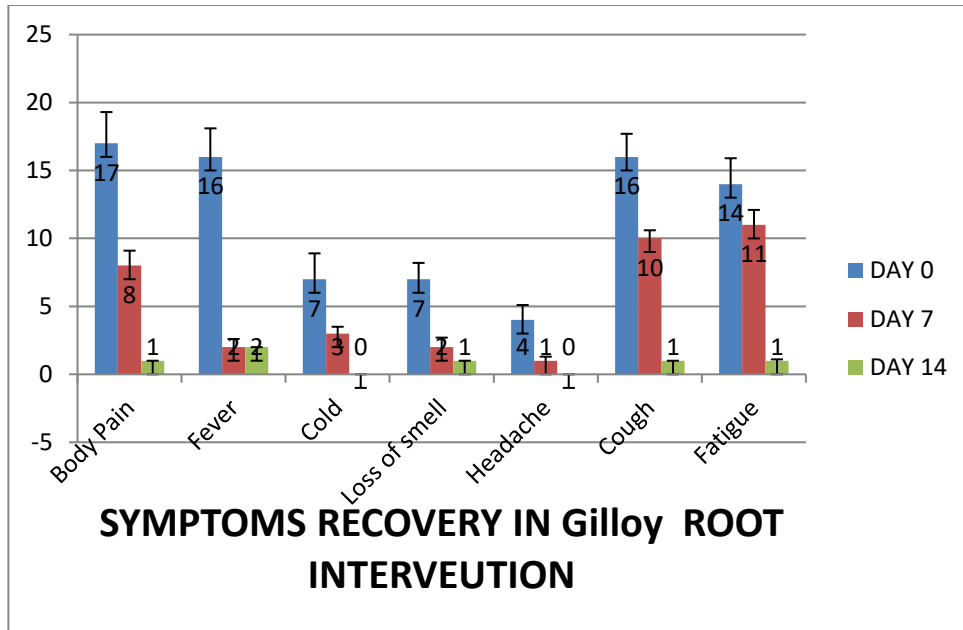


Figure 1

TABLE 2
SYMPTOMS RECOVERY IN Gilloy LEAVES INTERVEUITION

SYMPTOMS	Day 0	Day(7)	Day(14)
Body Pain	14±2.1	10±1.3	01±(0.0)
Fever	12±1.9	4±0.8	02±(0.0)
Cold	7±1.1	4±0.7	00±(0.0)
Loss of smell	9±1.6	3±0.9	01±(0.0)
Headache	2±0.5	1±0.1	00±(0.0)
Cough	17±2.3	11±1.2	01±(0.0)
Fatigue	13±1.7	4±0.5	1±(0.01)

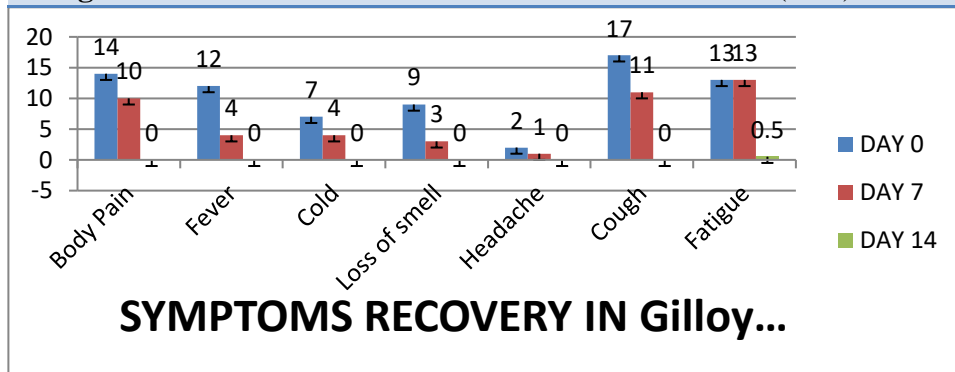


Figure 2

Characteristics	GiLOY root extract (n=30)	GiLOY leaves extract (n=30)
Mean Age,	40.73 years	39.933 years
Gender, (%)	40% Female & 60% Male	33.33% Female & 66.66% Male
Health condition {covid + other disease} (no. Of patient in %)		
Diabetes (%)	56.66667%	30%
Blood pressure (%)	40%	30 %
Respiratory disease (%)	30%	16.66667 %

Table 3

SYMPTOMS	AVERAGE CLINICAL RECOVERY OVER 14 DAYS IN GILOY ROOTS AND GILOY LEAVES GROUP					
	DAY 0		DAY 7		DAY 14	
	MEAN	SD	MEAN	SD	MEAN	SD
Body Pain	15.5	2.2	9	1.2	0.5	0
Fever	14	2	3	0.7	1	0
Cold	7	1.5	3.5	0.6	0	0
Loss of smell	8	1.4	2.5	0.8	0.5	0
Headache	3	0.8	1	0.2	0	0
Cough	16.5	2	10.5	0.9	0.5	0
Fatigue	13.5	1.8	12	0.8	0.75	0.055

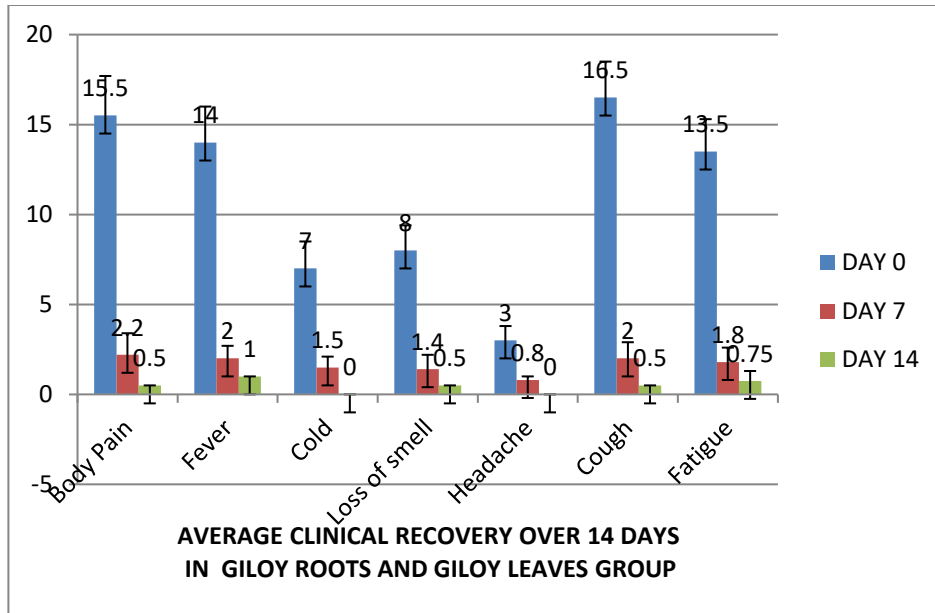


Figure 3

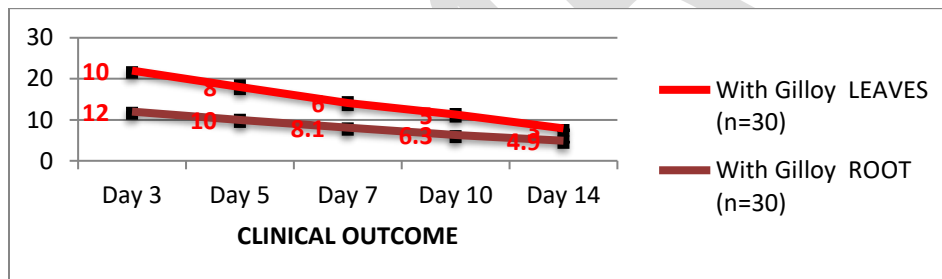


Figure 4

DISCUSSION

Tinospora cordifolia (giloy) belongs to the family Menispermaceae indigenous to tropical region of subcontinent of India. Giloy is believed to be having Immunomodulator ,

Anti-oxidant, Anti-diabetic and hepatoprotective property etc.(9).

In the present study, giloy (leave or root extract) was found to be effective and safe for Covid-19 patients. The treatment with giloy

root extract was compared with giloy leaves extract and it is found that root extract was more effective than leave extract during 14 days of the study(9). With respect to the safety parameters of the study, no side effect or patient death was occurred. We showed here that Ayurveda self-management is efficient in clearing approximately 50% of the viral symptoms of COVID-19 in only seven days, in most of the patients. A significant difference was observed between patients who are supplemented with

giloy leaves extract and giloy root extract within 7 days (11).

Further researches on this set are needed, since such fusions may both act as an antiviral therapy against SARS-CoV-2 and prevent bacterial super-infections. Such conclusions could be encouraging open the opportunity of an international strategy to choice-makers to fight this appearing viral infection in real-time even if other strategies and research including vaccine development could be also effective. We, therefore, recommend that COVID-19 patients should be self-managed who are having mild to moderate symptoms under properly guided Ayurveda care in the community(11).

CONCLUSION

The overall effect of Giloy in reducing symptoms suggests that Giloy (leaves or root extract) is effective in patients with covid 19 infection(9). This benefit is appeared to be clinically significant. Giloy is

well tolerated and safe prescripational medications. Thus, when giloy was given as “an add on” to covid -19 patients , it comes out to be synergistic and effective in better management of the disease.

If we analyse the data of infected persons it is concluded that males are more infected than females. People who are involed in this analysis are already having some other problems like blood pressure problem, diabeties, other respiratory infections etc(10) .

The motive of this study was to improve the impat of covid-19 symptoms ,relief and precautions of severe contaminations of mild to average COVID-19 through giloy . In particular, we report that an Ayurveda intervention, of Giloy can significantly reduce symptoms severity and ultimately prevent the incidence of Covid-19 related complications.

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