

“Real world experience about efficacy and safety of GiloyGomutra (Cow Urine), AsthiChurna and KamdhenuAsava in the management of COVID-19 in Indian setting. (REAL GiloyGomutra, AsthiChurna and KamdhenuAsava Product)”

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ABSTRACT: Globally, as of 12:10pm CEST, 22 September 2020, there have been 31,132,906 confirmed cases of COVID-19, including 962,008 deaths, reported to WHO.ⁱ After the initial description in Wuhan and China, Italy was hit first in Europe and the impact has been immense.ⁱⁱ The virus spread very rapidly such that 2 weeks from the first cases diagnosed 1000 patients tested positive. One week later the number of positive cases exceeded 4600, reaching over 30,000 patients and 2500 deaths on the 18 March 2020.ⁱⁱⁱ The region of Lombardy was the most profoundly affected, with local institutions forced to reset the entire healthcare system to face the challenges, while the all the governments around the world ordered a nationwide lockdown. Rather than this there is no more progression in spreading of Covid-19. This type of circumstances can be overcome with the help of the other interventions like AYUSH System. Ayurveda community had played a major role in defeating the pandemic Covid-19 in preventive and curative way. Panchgavya based medicines are used in this study which have Gaumutra as a main content. The real world experience about these medicines on Covid-19 was observed by this retrospective study.

Materials and Methods: A retrospective, nonrandomized, single group, multicentre clinical study was conducted at Ahmedabad and Surat. A total of 100 patients were enrolled in the study. The real world experience study was conducted in Indian health care centers, having medical records of adult patients who had received treatment with Ayurvedic Drug. Data was collected from medical records authenticated by doctors during care.

Results: Mean of Total Recovery of all the patients in Days is 7.44 Days. Encouraging response about the symptoms rapid recovery was got from all the patients.

Conclusion: All the three combinations GiloyGaumutra Capsules, AsthiChurna and KamdhenuAsava has excellent effect on pandemic Covid-19.

Key-words:

I. INTRODUCTION:

COVID-19 is a constantly changing and evolving condition which has affects the lifestyle in a major way. No specific cure has been found from any intervention. Ayurveda can do the tremendous job in response to the curative and preventive aspects of the epidemic condition like this. Coronaviruses are a large family of viruses which may cause illness in humans. Several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes disease “COVID-19”. Entire mankind across the globe is suffering from its spread. The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Other symptoms that are less common and may affect some patients include aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhoea, loss of taste or smell or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but only have very mild symptoms.

Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 5 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Despite application of precautionary plans like social distancing, lockdown and hygienic measures the cessation of the outbreak of diseases is troublesome. India is the country where the world's oldest living health care system- "Ayurveda" originated and therefore it is being carefully watched by the world community for how it handles the crisis using its own resources. Eventually the world seems to be eager to listen about traditional health care approaches to curb viral epidemics if these are found worthy in handling such situations. Ayurveda is the Science where Janpadodhvas (Death of groups of people) has been described by Acharya Charaka. So, its principles can be used to treat this type of pandemic disease. Using Gaumutra as an important ingredient of the medicines is the base of this study. From this perspective, implementing the suggested intervention plan within AYUSH healthcare facilities by Ayurveda workforce may benefit the nation greatly.

The combination of medicines used in this trial group were Giloy Gaumutra Capsules, Asthi Churna and Kamdhenuasava. All of these having Gaumutra as a content. Which increase the potency of each medicine in Vata kapha pradhana disease and also increases its overall efficacy.

Aim:

To investigate real-world treatment patterns of Ayurvedic Giloy Gaumutra, Asthi Churna and Kamdhenu Asava in Treatment of Covid 19 patients in India.

Study Objective:

The objective is to evaluate the demographic, clinical characteristics, treatment pattern of ayurvedic Giloy Gomutra, Asthi Churna and Kamdhenu Asava on Covid-19 patients.

Overview of Study Design:

The real world experience study was conducted in Indian health care centres having medical records of adult patients who had received treatment with Ayurvedic Drug Data related to demographic characteristics, duration of disease, co-morbidities, and concomitant medications was collected from medical records authenticated by doctors during care.

Discussion of Study Design:

This is a retrospective, non-randomized, non-comparative, multi-centric study to investigate real world experience of Ayurvedic Product in treatment of Covid-19 conducted in approximately 100 sites (houses) in India.

The data was extracted from health facility records and entered into case report forms (CRF).

Materials and methods:

Medical records from various medical centres and homes treating Covid 19 patients were been selected. Approvals from the treating physicians or medical practitioner and independent ethics committee (IEC) or institutional review board (IRB) were been obtained. Post approval from site investigator and IEC/IRB the comprehensive patient-level information on demographic, clinical, and laboratory variables were been collected and entered in paper CRF (case report form). Medication data and co-morbidities were been collected.

Study Population:

Retrospective data of 100 patients diagnosed with Covid-19 who received treatment with Ayurvedic Giloy Gaumutra, Asthi Churna and Kamdhenu Asava Drug.

Subject Eligibility:

Study population consist of Covid-19 patients in India identified by the following inclusion criteria.

Inclusion Criteria:

- Treating physician had to agree to provide information regarding the Patients who have been diagnosed with Covid-19 with mild and moderate symptoms.

Exclusion Criteria:

- Patient having severe symptoms will not be included in the study.
- Any condition that according to the discretion of the investigator indicate that the patient is not suitable for inclusion in the study.

Informed Consent:

It was not applicable. Data were been taken from patient's medical records available at hospital/clinics or homes of the patients.

Ethical Conduct of the Study:

- This study was conducted in compliance with the principles of the Declaration of Helsinki, and the protocol was approved by the Ethics Committee.
- The sponsor/designee had submitted the study protocol including the waiver for Informed

Consent to the responsible IEC/IRB for review.

Data Collection:

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF were been recorded. It is taken on telephone.

Follow up: It has been taken on phone at time of screening and registration of the patient.

SECTION 1: Covid 19 Positive assessment

‘Section to be answered by Subjects and filled by Study Personnel’

This section measures the extent of your illness and the further cure with the help of the medicinestaken during the entire recovery process. Please Tick the box against the appropriate response.

1. Did you test positive to Covid 19?

- a. No
- b. Yes

2. Did you have fever and pain during the illness?

- a. No
- b. Mild
- c. Severe
- d. Extensive

3. Did you have respiratory problems?

- a. No
- b. People say I have it
- c. Yes
- d. Severe
- e. Uncertain

4. Did you lose taste?

- a. Unlikely
- b. Sometimes
- c. Regularly
- d. Always
- e. Unsure

5. Did you feel weak?

- a. Unlikely
- b. Sometimes
- c. Regularly
- d. Always

6. After administration ofdid you started feeling better?

- a. No
- b. People say I have it
- c. Yes
- d. A severe case
- e. Unaware

7. After how many doses did you start feeling better?

- a. One
- b. Two
- c. Three
- d. Four
- e. Did not feel better

8. Did you take additional medicines along with these medicines?

- a. Unlikely
- b. Sometimes
- c. Regularly
- d. Always

9. If yes, which medicines did you take?

- a.
- b.

10. Were any member of your family was infected?

- a. None
- b. Just one relative
- c. A few relatives

11. What happened after you started our medicines?

- a. Nothing
- b. Started feeling better

12. How many days did you take to recover?

- a.

13. After recovery, did you feel weakness?

- a. Unlikely
- b. Occasionally
- c. Regularly
- d. A natural occurrence
- e. Completely recovered

14. Have you tested negative now?

- a. No
- b. Yes

15. Were you tested after recovery?

- a. No
- b. Yes

16. Are you back to your normal life?

- a. No
- b. Yes

17. Have you started your normal diet?

- a. No
- b. Yes

‘Section to be filled by Doctor’

Q: Has the subject been diagnosed to have Covid 19 and recovered? Yes No

Interventions:

Procurement of Raw material:

Sample of Giloy, Parijata, Gaumutra, and Dhataki was collected from BansigirGaushalaAhmedabad Gujarat and Cultivation plots at same place. BansigirGauveda at premises forms No. 25-D bearing Manufacturing License No. GA/1863

Table No.1. Details of Medicines:

Drug No.	Pharmaceutical Products	References
1	GiloyGaumutra Capsules	AyurvedicProprietary medicine
2	AsthiChurna	AyurvedicProprietary medicine
3	KamdhenuAsava	AyurvedicProprietary medicine

Table No. 2. Details of GiloyGaumutra Capsule
(State license authority {Ayurveda} approval dated 2 Aug. 2017, 1 Aug.2022)

GENERIC NAME OF THE PRODUCT	GiloyGaumutra capsules
BATCH SIZE	50,000 Capsules
MANUFACTURING SITE	S.P. Ring Road, Near Shantipura Circle, Hotel Apex Service Road, Ahmedabad, Gujarat- 380058
SHELF LIFE	Maximum 24 months from date of Manufacturing.
PACK SIZE	60 , 90, 120 Capsules

Table No. 3. Composition of GiloyGaumutra Capsule

Sr. No.	Ingredients	Latin Name	Part Used	Quantity	Reference
1	Guduchi	Tinosporacordifolia	Stem	400 mg	Aryabhishak ^{iv}
2	GaumutraGhan	--	--	100 mg	Aryabhishak ^v

Product Class: Capsule

Table No. 4. Details of AsthiChurna

(State license authority {Ayurveda} approval dated 23 Sep. 2019)

GENERIC Name of Product	AsthiChurna
Batch Size:	10 Kg
Packing Size	100 g
Type of Product	Ayurvedic Proprietary Medicine

Table No. 5. Composition of AsthiChurna

Sr. No.	Ingredients	Botanical Name	Form	Part Used	Label Claim %	Reference
1	Parijat	Nyctanthus arbor-tristisLinn.	Powder	Leaves	80 %	BhavprakashNighantu ^{vi}
2	Gaumutra Ghana		Powder	---	20 %	Aryabhishak

Product Class:Churna (Powder)

Table No. 6. Details ofKamdhenuAsava

(State license authority {Ayurveda} approval dated 23 Sept. 2019)

GENERIC NAME OF THE PRODUCT	KamdhenuAsava
BATCH SIZE	100 Lit.
MANUFACTURING SITE	S.P. Ring Road, Near Shantipura Circle, Hotel Apex Service Road, Ahmedabad, Gujarat- 380058
SHELF LIFE	--
PACK SIZE	200 ml

Table No. 7. Composition of Kamdhenu Asava

Sr. No.	Ingredients	Botanical Name	Part Used	Quantity (in each 10 ml)	Reference
1	Gaumutra	--	--	08 ml	BR
2	PuranGud	--	--	02gm	BR
3	DhatkiPushpa	Woodfordiafruticosa	Flower	0.4gm	BR

Product Class: Asava Kalpana

Outcome Measure and Efficacy Evaluation:

The efficacy evaluation of the medicines Giloy Gaumutra Capsule, Asthi Churna and Kamdhenu Asava was done by assessing the symptoms subjective recovery viz. fever, tiredness, dry cough, aches and pains, nasal congestion, runny nose, sore throat and diarrhoea. The evaluation of that patients was done by telephone. It was taken specifically according to the questionnaire described before. The results were analyzed for the total recovery days.

Method of statistical analysis:

Statistical testing were been done using appropriate statistical tests. Demographic characteristics were been summarized with descriptive statistics, including mean and standard deviation (SD) for continuous variables, and frequency and percentages for categorical variables.

II. RESULTS:

Between 10th September 2020 and 16th September 2020, a total of 100 participants were screened and enrolled in the study. All the patients have taken the above mentioned three Ayurveda combinations and observed at the time of enrollment in study on telephonic talk.

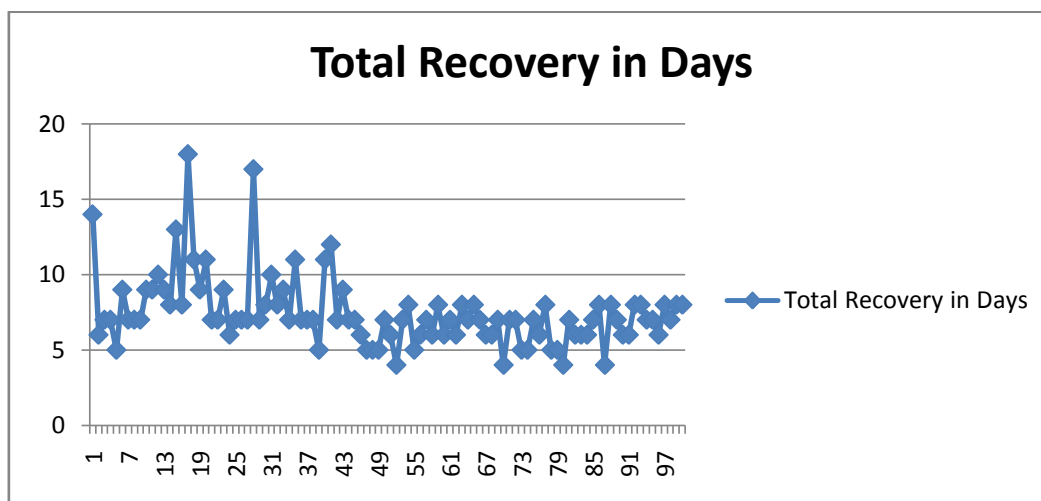
Baseline Data:

- Total 100 patients registered in the study.
- In this study, 25% patients were between age group 31–40 years. 25% patients were between age group 41–50 years and 23% patients were between age group 41–50 years.
- In 69% patients were male.
- Patients who had confirmed their history of Reports were enrolled in the study. It is as below.
- 19% patients were taking some allopathic interventions with this medications.

Test Name	Number of Patients
RT-PCR	22
Rapid Antigen test	02
HRCT	28
Other blood test only	03
Test done but No reports found	37

Outcomes and Estimation:

Mean of Total Recovery of all the patients in Days is 7.44 Days.



III. DISCUSSION:

After analysing the whole data it can be understood that features of COVID-19 exhibits characteristics of sannipatajwara in general. From the etiological perspective, it is of exogenous origin (Aagantuja). All the three drugs of the study having Gaumutra as a main content of the formulation. Gaumutra is one of the dravya from Panchagavya^{vii}. Panchgavya itself is Vishamajwaranashaka (Anti Pyretic property).^{viii}

The first combination GiloyGaumutra Capsule having Guduchi (*Tinosporacordifolia*) as a main content. It is made up after mardan (repeation of churning process) in Gaumutra. The mardan process increase the effect of medicine in respect to its action on disease. The second combination asthiChurna is also prepared by churning in Gaumutra, which is jwaranashaka, shvasa-kasanashaka.^{ix} In asthichurnaParijata is the main content; which is jwaraghna^x It is also effective in Kasa-shvasa.^{xi}

The third drug is KamdhenuAsava; This Asava is the medicated fermented syrup type medicine. The properties of any Asava are same as the beejadravya(main content) used in it. In this asava, Gaumutra is the main content; So this combination is purely having properties of the Gaumutra. The another two medicines of the trial are also having Gaumutra as the main and major content. So, the properties of the Gaumutra are - Katu, Tikshna, Ksharayukta and Vatakaphanashaka. It is also Laghu, Agnidipana, Medhya, and Pittala^{xii}. So, this may directly pacify the Vatakaphapradhana symptoms of Covid-19. All the symptoms of Covid-19 can be compared to SannipatikaVatakaphapradhanajvara. So, the chief

complain fever may be fast recovered due to the AgnidipanaGuna of Gaumutra. Gaumutra is also virechaka^{xiii} (Purgative) and it also observed during the treatment. Gaumutra is having Kasa-shwasanashaka properties.^{xiv} Covid-19 disease mainly affect on Respiratory tract. So, using Gaumutra based drugs in it may be the best choice. The another Chief complain of Covid-19 is Tiredness. Which may compared to Ruja and Shula in Ayurveda; Gaumutra may also effective on it^{xv}. It may reduce aches and pains like bodyache and headache in this type of disease condition.

Limitations of the Study: The limitations of the study are mainly the investigational parameters. As all the patients were symptoms free but we could not have data of the reports of all the patients.

Scope of the further study: We could collect data of more patients from many other sites. Also we can collect this type of retrospective data of the two different interventions and compare it for its effectiveness on pandemic Covid-19.

IV. CONCLUSION:

It can be concluded after completion of the whole study that these panchgavya based ayurvedic medicines may give the best results as treatment of Covid-19. It may provide the successful and fast recovery of mild and moderate symptoms of Covid-19. Cessation of the progression process of the diseases must be the aim of every intervention.

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Ctri Registration No.:CTRI/2020/07/027083
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Ethical Approval: Independent Ethics Committee
(ACEAS) – Approval on 23rd July, 2020.

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