Case study

Documentation, Clinical Validation, Safety Assessment and Efficacy of Siddha treatment in COVID 19 SARS-CoV-2: A case series

ABSTRACT

Aims: To evaluate clinical validation, safety assessment and efficacy of Siddha line of treatment in COVID-19 patients.

Study design: An open labelled, interventional, prospective cohort study

Place and Duration of Study: It was conducted in Covid ward, Kokila Siddha Hospital and Research centre, Madurai between June and Aug 2021.

Methodology: Among 22 patients registered in the trial 5 (22.72%) developed breathing difficulty and were treated with oxygen support, 10 (45.5%) were male, 12 (54.5%) were female. The maximum age of the patient was 77 whereas the minimum age was 25. At the time of admission, maximum 9 (40.9 %) patients had fever, followed by dry cough 18 (81.8%), dyspnea 8 (36.4%), malaise 16 (72.7%), anorexia 8 (36.4%), headache 4 (18.2%), Type - 2 Diabetes Mellitus 5 (23%), and 2 (9%) patients had hypertension as comorbidity. Hematology, LFT, RFT, D-Dimer, PTT, CRP were taken before and after 5 days of treatment.

Results: The mean hospital stay was 7 days. The patients were discharged on a minimum of 4th day and a maximum of 16th day. The mean hospital stay for hypoxic patients was 10 days. Paired sample test analysis has been carried out to find a significant difference in the counts of lymphocytes, ESR, CRP and PTT after the administration of the intervention.

Conclusion: The medications chosen according to the pathology of *Kaba suram* and administered starting on the day of their admission, depending on the stage and severity of the infection. Patients are also provided with appropriate food, exercise and external therapy as needed in conjunction with their medications. It has been seen that the patient's condition has not deteriorated further. As a result, it is reasonable to conclude that the treatment of COVID-19 with the Siddha medications prescribed stopped the disease from progressing to a more critical stage.

Keywords: *Kabasuram**,** Kabasurakudineer**,** Brammanantha bairavam, Vazhalai vaanguthal**,** Vitex negundo*

1. INTRODUCTION

SARS CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2) infection became a global public health threat and had a large economic impact. Since December 2019, when the coronavirus infection 2019 (COVID-19) was found, approximately 100 million confirmed cases and 2 million deaths have been reported worldwide [1]. However, the majority of individuals with COVID19 experience mild to moderate symptoms, and only approximately 10-15 per cent develop severe illness [2,3]. There are currently no medications available due to the virus's novelty and broad clinical reach. In the absence of viable treatments, traditional remedies were used as an integrated treatment for COVID-19, as they had been for other infectious diseases in the past [4].

Traditional Indian medicines include Ayurveda, Yoga, Naturopathy, Unani, Siddha, Sowa-Rigpa, and Homoeopathy (AYUSH). The Siddha system of medicine is largely practised in India's southern states and Tamil-speaking countries around the world. The Ministry of AYUSH of India has provided therapeutic instructions for AYUSH practitioners to prevent and manage COVID-19, including the use of *Kabasura Kudineer* (KSK), a polyherbal Siddha formulation [5,6].

Suram (pyrexia/fever) is one of Siddha literature's 64 types of diseases. According to Siddha philosophy, *Vatham* is responsible for conception and creation, *Pitham* humour is responsible for disease prevention, and *Kabam* is responsible for destruction, as stated in the verses of Siddhar *Theran*: "*Vaathamai padaithu pitha vanniyai kaathu sethuma seethamai thudaithu"* [7]. *Suram* is characterised according to the impacted *Mukkuttram* (*Vatham, Pitham,* and *Kabam*) and the associated unhealthy food and lifestyle. *Kaba Suram* is believed to occur as a result of *kabam's* exacerbated humour being far stronger than normal, creating an ideal habitat for any respiratory infection [8,9]. Its clinical implications have been described in a few publications, including *Theran karisal, Suravagadam,* and *Yugi chinthamani*. *Kabam's* exaggerated nature takes up residence in locations other than its own in the body *(Vaetrunilai Valarchi)*. *Kaba Suram* is mostly a result of *Kabam* variants. *Kabam thannilai sirapurum kaalam* refers to the seasonal aggravation that happens in *Kabam* between *Karthigai* and *Masi* (November to February) [10].

Kaba suram has been classified into three stages,

Stage I (Asymptomatic & Mild cases)
Stage II (Moderate cases with Pneumonia)
Stage III (Critical cases)

1.1 Stage I

Around 81 per cent of COVID-19 cases have minor symptoms that could include non-pneumonia or mild pneumonia. The Tamil linguistic purism of the Siddha literature on *Kaba Suram* classified these symptoms as *Suram* (Fever), *Irumal* (Cough), *Thondai nothal* (Sore throat) and *Kozhai kakkal* (Expectoration). *Suravaagadam's* literature includes *kalaippu* (malaise), *vali* (muscle soreness), and *Vayiru kazhidhal* (diarrhoea) [11]. The increase in *Kaba* humour causes *Thondai nothal* (sore throat), *Irumal* (cough), and *Kozhai kakkal* (expectoration), which are likewise symptoms of COVID-19's basic stage [12]. Diarrhoea arises as a result of a weakened protective immune response, allowing infection to enter, particularly in organs with high Angiotensin-converting enzyme 2 genes (ACE2) expression. This induces diarrhoea by causing inflammation in the digestive tract [13]. This data reinforces the Siddha pathophysiological idea of *kaba* humour aggravation in the colon (*Kudal thannil seetham*), which is the primary cause of fever and disease progression in a stepwise manner. This stage is similar to the symptoms of an increase in *Kabam* in the chest area causing *Moochu thinaral* (Dyspnoea), *Mael moochu*, *Oon kollaamai* (loss of appetite), *Thookkaminmai* (Insomnia), and *Kalaithu pothal* (weariness) as described in the scriptures *Suravaagadam* and *Theran karisal*.

1.2 Stage II

This severe stage of COVID-19 can be well correlated with the persistent severe increase of *Kabam* in the chest area, resulting in *Mael moochu* (Severe dyspnoea), *Naakku mugam veluthal* (Pallor of tongue and face) as indicated in the text *Yugimunivar vaithya chintamani*, *viyarvai* (profuse sweat), *udal veenkuthal* (Anasarca). Due to a high body temperature, *viyarvai* (prolific sweating) can occur [14]. Hypercapnia can cause a reduction in carbon dioxide diffusion, resulting in increased perspiration and vasodilation [15]. Pallor of the tongue and face, as indicated in Siddha writings, could be caused by ARDS, which is characterised by inadequate oxygenation resulting in hypoxia and can also manifest as central or peripheral cyanosis as a result of hypoxia. As indicated in *Theran Karisal*, *udal veenguthal* (Anasarca) can arise as a result of pulmonary oedema, renal dysfunction, and decreased output [16].

1.3 Stage III

Sanni (Delirious stage) has been described in Siddha writings as the final stage of *Kaba suram* (Covid 19) because of the dramatic release of proinflammatory mediators. *Acham*, *Manavetrumai* (Emotional disturbances of fear and depression), *Athatti pesuthal*, *Vaay Kularal* (Irrelevant speech, agitation) and *Thannilai ariyaamai* (Impaired consciousness) are all symptoms of, *kaba suram* which affects the three humours *Vatham, Pitham* and *Kabam*, which are responsible for the well-being of an individual. Even while hiccups (*Vikkal*) appear to be an insignificant symptom, they may be the most common sign of pneumonia [17]. Symptoms such as *Naachuvai ariyaamai* (loss of smell/altered taste), *vaay thuvarthal*, *kadhu iraidhal* and *kadhu kaelamai* (Auditory deficits) are described in detail in the Siddha literature on *Kaba Suram.*

2. AIM AND OBJECTIVE

To evaluate clinical validation, safety assessment and efficacy of Siddha line of treatment in COVID-19 patients.

3. MATERIALS AND METHODS

3.1 Study type

Interventional, prospective cohort study

3.2 Purpose

Treatment

3.3 Masking

Open labelled

3.4 Selection Criteria

The patients experience mild to moderate symptoms such as fever, body ache, dry cough, throat soreness, dizziness, etc. Those who tested positive for COVID-19 and were willing to engage in the study were chosen for the current study.

3.5 Inclusion Criteria

- All patients included in this study were diagnosed for COVID-19 based on the World Health Organization (WHO) guidelines those who had an influenza-like illness and were SARS-CoV-2 Reverse transcription-polymerase chain reaction (RT-PCR) positive in a throat swab.
- Both male and female
- Patients belonging to age 12 years and above
- Patients who are willing to participate in the study

3.6 Exclusion Criteria

- Patients with high-grade fever
- Patients with age below 12 years
- SPO2 < 92%
- Chest pain or discomfort on deep breath
- Difficulty in breathing
- Patients having uncontrolled HT or DM, Bronchial asthma, CKD or liver diseases.
- Patients who require intensive care/ventilator

4. MEDICINE PROTOCOL

4.1. *Vazhalai Vaanguthal* (expectoration)

Vazhalai Vaanguthal (expectoration) can be performed in the morning after brushing the teeth. It is accomplished through the use of *Karisalai Nei*. *Karisalai nei* is made by combining equal amounts of leaf juice from *Manjal karisalai* (*Wedelia calendulacea*) with cow's ghee in a mixing bowl and boiling until smooth. For 12 repetitions or until the phlegm has been expelled, apply 1-2 gram on the thumb finger and insert, smear, and rotate on the upper soft palate, softly touching the uvula. It is done 1-3 times a day for three days. The phlegm that has gathered is spit out to prevent and remove virus development. For the first three days, it is usually done here early in the morning. The administration of this therapy, on the other hand, will be determined following the patient's health status.

4.2 *Vedhu and Otrada pottani* (inhalation and fomentation)

Vedhu is process of steam inhalation after boiling the leaves of the *notchi* plant (*Vitex negundo*). It is done in about 3-5 days. Further the leaves are rolled into an *otrada pottanam* (bundle fomentation) and applied

to the chest and back to relieve chest congestion and prevent it from occurring. It is performed once or twice a day for seven days, depending on the severity of the congestion in the lungs.

4.3 Diet and Drug Regimen

The following table (Table 1) consists of the diet and drug followed in the In-Patient ward, Kokila Siddha Hospital to the covid patients during the hospital stay.

Table 1. Diet and medication chart

Time	Diet and Drug
6.30 am	*Vazhalai Vaanguthal* and Yoga
7.00 am	*vedhu* (steam inhalation) and *otrada pottani* (bundle fomentation) using *Notchi* leaves
7.30 am	*Nilavembu kudineer*
8.00 am	Idiappam or Idli
8.30 pm	*Brammanantha bairava matthirai*, *Adhathodai manapagu*, *Thaleesadhi chooranam*, *Swasakudori mathirai*
10.30 am	Fruit Juice or Salad
12.00 noon	*Chukku* Decoction + *Peyan* or *Sirumalai vazhaipazham* (banana)
1.30 pm	Rice or *Karunkuruvai* or Barley *Kanji* with pepper gravey and pepper *rasam* or *panchamutti kanji* or *chukku mudichu kanji*
2.00 pm	*Vasandhakusumagaram mathirai*
3.00 pm	Vegetable Juice or Soup
5.00 pm	Paruppu sundal (boiled lentils)
6.00 pm	*Kabhasura kudineer*
7.00 pm	Idli or Utthappam (without oil)
7.30 pm	*Brammanantha bairava matthirai*, *Adhathodai manapagu*, *Thaleesadhi chooranam*, *Swasakudori mathirai*, *Kasthuri karuppu*
8.00 pm	*Thiripala churanam* or *Asta churanam* 2 gram with hot water

4.4 Internal medicine

The treatment protocol for the patients includes primary and secondary drugs. The primary drug (Table 2) was used for all the patients suffering from SARS-CoV-2 infection. It includes,

1. *Thaleesadhi chooranam*
2. *Nilavembu kudineer*
3. *Vasandhakusumagaram mathirai*
4. *Brahmanandha bairavam mathirai*
5. *Kasthuri karuppu*
6. *Swasakudori mathirai*
7. *Adathodai manappagu*

The secondary drugs are those used as per the symptoms to patients when necessary. The secondary drug (Table 3) was used for the patients suffering from hypoxia, diarrhoea, vomiting and malaise. It includes,

1. *Poorna chandrodhayam*
2. *Gorochanai mathirai*
3. *Thayir chundi chooranam*
4. *Madhulai manappagu*
5. *Naga parpam*

The ingredients and manufacturer of the drugs those used in the study (Table 4) are as follows,

Table 2. List of primary drugs

Type	Name	Formula	Dose & Anupanam
Churnam	*Thaleesadi churnam*	*Agasthiyar ratnachurukkum*	1 gram with hot water, three times in a day after food

Kudineer	*Nialvembu Kudineer*	*Siddha vaidya thirattu*	60 ml, once in a day, before food
Tablet	*Vasantha kusumakaram*	*Siddha vaidya thirattu*	100 mg, twice in a day after food
Tablet	*Brahmananda bairavam*	*Siddha vaidya thirattu*	100 mg, twice in a day after food
Karuppu	*Kasthuri karuppu*	*Siddha vaidya thirattu*	50 mg, twice in a day after food
Manappagu	*Adathodai manappagu*	*Siddha vaidya thirattu*	10 ml with hot water, twice in day after food
Tablet	*Swasa Kudori*	*Siddha vaidya thirattu*	100 mg, twice in a day after food

Table 3. List of secondary drugs

Type	Name	Formula	Dose & Anupanam
Chenduram	*Poorna chandirodayam*	*Therayar karisal 300*	50 mg, twice in a day after food
Tablet	*Gorojanai mathirai*	*Agasthiyar Ratna churukkam*	100 mg, twice in a day after food
Manappagu	*Maduali manappagu*	*Siddha vaidya thirattu*	10 ml with hot water, twice in a day after food.
Churnam	*Thayirchundi churnam*	*Siddha vaidya thirattu*	2 grams with curd
Parpam	*Naaga parpam*	*Siddha vaidya thirattu*	100 mg, twice in day after food

Table 4. List of ingredients in primary drugs

Name	Ingredients	Manufacturer
Thaleesadi churnam	*Taxus baccata* *Cinammomum verum* *Elettaria cardamomum* *Zingiber officinale* *Glycryrrizha glabra* *Ferula foetida* *Emblica officinalis* *Saussurea lappa* *Piper longum* *Cuminum cyminum* *Nigella sativa* *Anethum sowa* *Piper longum* *Syzygium aromaticum* *Myristica fragrans* Kr *Myristica fragrans* Ar *Pistacia integrimma* *Terminalia chebula* *Terminalia bellerica* *Nardostachys jatamansi* *Piper nigrum* *Cinnamomum wightii* *Michelia champaca* *Embelia ribes* *Cinnamomum tamala* *Trachyspermum ammi* *Corriandrum sativum* Sugar	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041

Nialvembu Kudineer	*Andrographis paniculata* *Vetiveria zizanioides* *Plectranthus vettiveroides* *Cyperus rotundus* *Santalum album* *Zingiber officinale* *Piper nigrum* *Trichosanthes cucumerina* *Mollugo cerviana*	Raja Sidhaa Marundagam, 3/1A, Tharumathupatti, Kappalur, Madurai-625008
Vasantha kusumakaram	Purified mercuric sulphide Purified borax Purified sulphur *Piper longum* *Saussurea costus* *Anacyclus pyrethrum* *Glycyrrhiza glabra* *Acacia Arabica* gum *Cinnamomum camphora* *Crocus sativus* Ginger juice	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041
Brahmananda bairavam	Purified sulphur Purified red orpiment Purified yellow orpiment *Aconitum Ferox* Rt. *Zingiber offcinale* Rz Purified cinnabar Purified borax	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041
Kasthuri karuppu	*Moschus moschiferous* *Cinnamomum camphora* Bos indicus *Crocus sativus* Purified Mercury Purified Suphur Purified Natural Mercuric Sulphide Purified Mercurous Chloride Purified Artificial Mercuric Sulfide Purified Arsenic trisulphide Purified Arsenic disulphide *Piper longum* *Trachyspermum ammi*	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041
Adathodai manappagu	*Adathoda vasika* *Saccharum officinarum*	Raja Sidhaa Marundagam, 3/1A, Tharumathupatti, Kappalur, Madurai-625008
Swasa Kudori	*Calotropis gigantea* flowers *Piper nigrum*	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041

Table 5. List of ingredients in secondary drugs

Name	**Ingredients**	**Manufacturer**
Poorna chandrodhayam	Purified gold Purified mercury Purified sulphur *Gossypium arboreum* flower juice *Musa paradisiaca* stem juice	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041

Gorochanai mathirai	Bezoar of cow *Crocus sativus* stamens *Cinnamomum camphora* *Myristica fragrans* nut *Syzygium aromaticum* flower buds *Elettaria cardamomum* fruits *Saussurea costus* *Anacyclus pyrethrum* Purified mercury chloride Purified mercury sulphide Mica *parpam* *Santalum album* wood decoction *Michelia champaca* flower decoction *Crocus sativus* flower decoction	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041
Thayir chundi chooranam	Sodium chloride impura Glass salt Alkaline Earth salt Sodium chloride Sochal salt Dried *Zingiber officinale* Cow's curd sour	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041
Madhulai manappagu	*Punica granatum* *rose damascene* Honey *Saccharum officinarum*	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041
Naga parpam	Purified zinc *Wedelia calendulacea* leaf juice *Aloe vera* pulp	The Indian Medicine Practitioners, Co-operative Pharmacy & Stores Ltd., Thiruvanmiyur, Chennai-600041

5. CONDITION ON DISCHARGE

5.1 Laboratory investigations

The laboratory investigations like haematology, liver function test, renal function test, D-Dimer, PTT, CRP were taken before discharge to assess the prognosis.

5.2 A 6-minute walk test

A 6-minute walk test is a simple clinical examination that has been used for many years to assess cardiopulmonary exercise tolerance. This test is used to uncover hypoxia that has been concealed. A pulse oximeter is affixed to the patient's finger, and he is instructed to walk about the boundaries of his room for 6 minutes constantly. The slight decrease in saturation below 94 per cent, or an absolute decrease of more than 3 per cent to 5 per cent, or the sensation of being uncomfortable (lightheaded, short of breath) while doing the test or after six minutes are all considered significant findings in this study. These patients are labelled as positive for the 6-minute walk test.

Assessment of general health condition, laboratory investigations, 6-minute walk test are done for all the patients before discharge.

5. OBSERVATION

The study was conducted in Covid ward, Kokila Siddha hospital and research centre, Madurai. Totally 22 patients who were tested covid 19 positive through RT-PCR were included in the study. Out of those all 22 patients completed the trial and were cured successfully whereas 5 patients (3 female and 2 male patients) developed breathing difficulty with low-level SPO2 on the 2nd day of the treatment and were treated with oxygen support.

Out of the registered patients, 10 (45.5%) were male followed by female 12 (54.5%) (Fig.1). The maximum age of the patient was 77 years whereas the minimum age was 25 years. At the time of admission, maximum 9 (40.9 %) patients had fever (average temperature-100 F), followed by dry cough 18 (81.8%) patients, dyspnea 8 (36.4%) patients, malaise 16 (72.7%) patients, anorexia 8 (36.4%) patients and headache 4 (18.2%) patients (Fig. 2). Sore throat, loose motion and nausea, each was found in 1 (4.5%) patient. In these recruited patients 5 (23%) patients had Type - 2 Diabetes Mellitus and 2 (9%) patients had hypertension as comorbidity.

At the time of admission, the mean and median systolic pressure was 128 and 130 respectively which ranges between 90 to 170mg/dl. The mean and median diastolic pressure was 70 and 80 respectively which ranges between 60 to 100mg/dl (Fig. 3).

The mean hospital stay for the patients was 7 days. The patients were discharged on a minimum of 4th day and a maximum of 16th day (Fig. 4). The mean hospital stay for hypoxic patients was 10 days.

The laboratory investigations like haematology, liver function test, renal function test, D-Dimer, PTT, CRP were taken during the time of admission and repeated after 5 days of treatment. Paired sample test analysis has been carried out to find the significance. However, there was a significant difference among patients in the counts of total lymphocytes count, ESR (60min), CRP and Prothrombin time after the administration of the intervention.

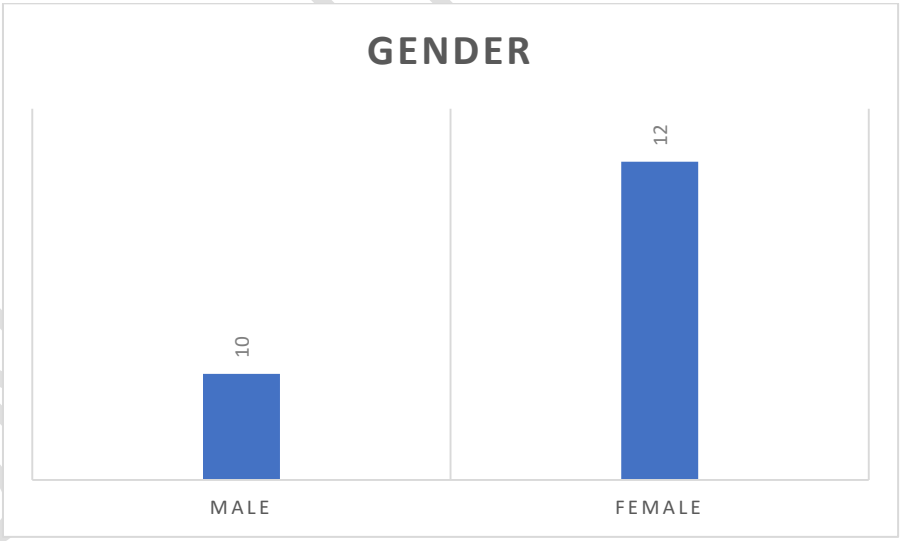

Fig. 1. Pictorial representation of Gender participated in the study

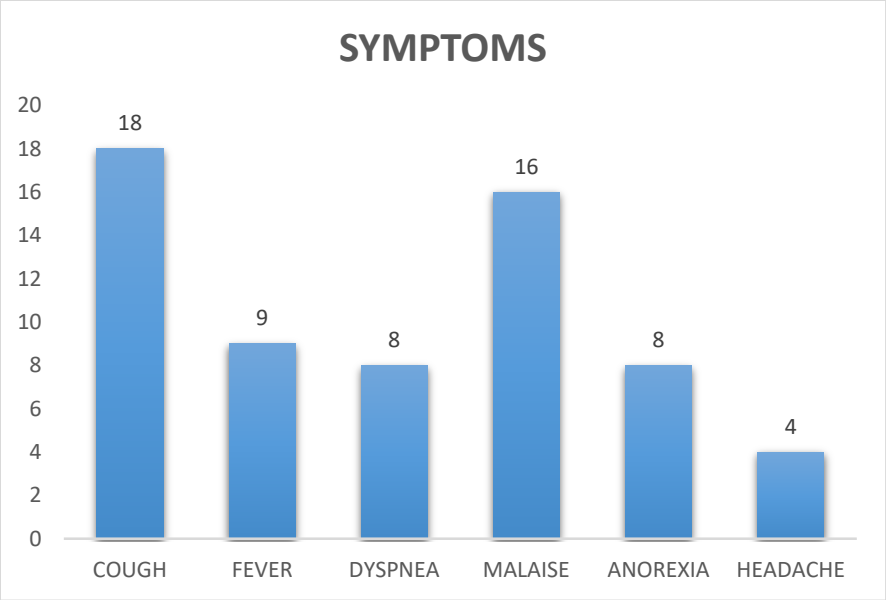

Fig. 2. Symptoms present during the time of admission.

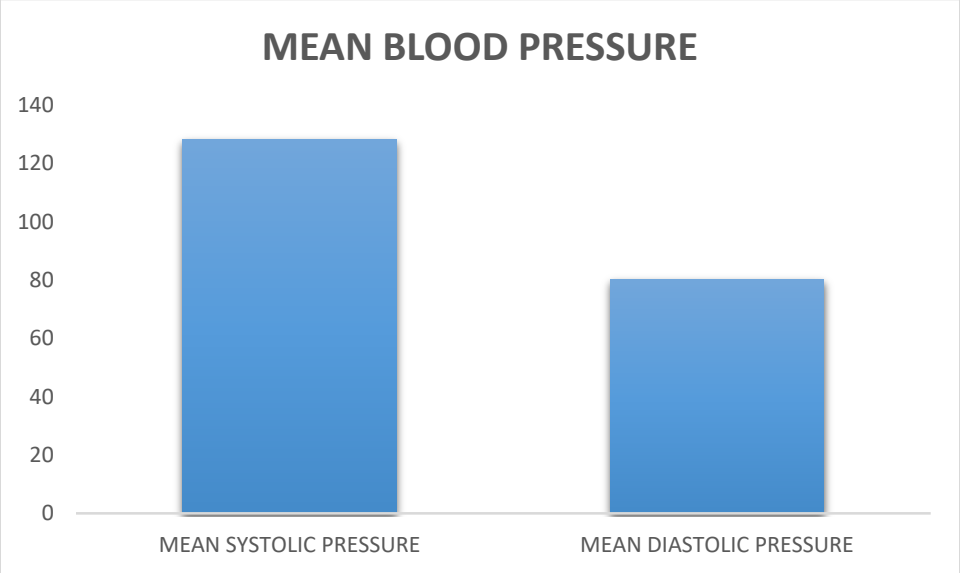

Fig. 3. Mean systolic and diastolic pressure during the time of admission

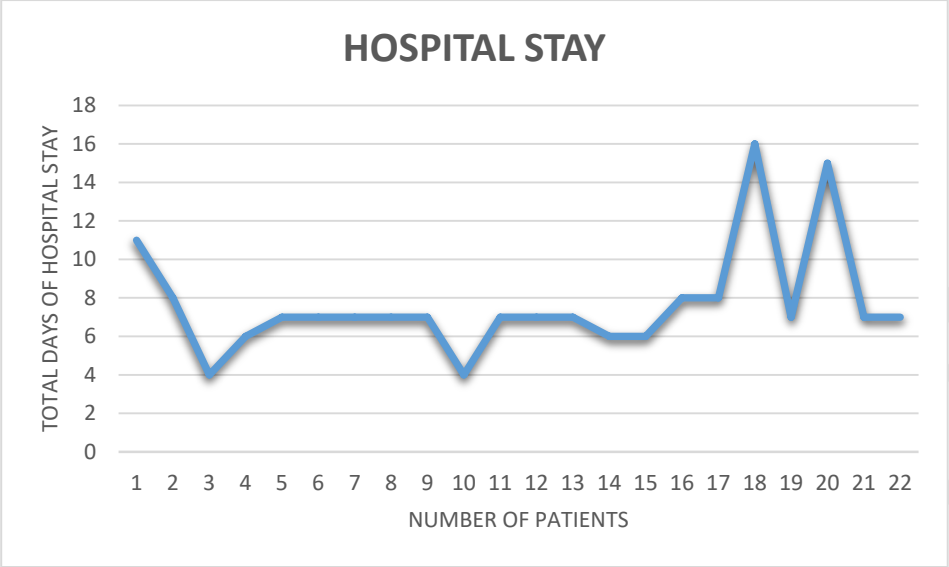

Fig. 4 Total number of hospital stays

Symptoms	Fever	Cough	Dyspnea	Fatigue	Anosmia	Sore throat	Vomiting	Diarrhoea	Oral ulcer	Insomnia
Day1	4	3	4	3	2	1	1	-	-	1
Day2	4	3	4	3	2	2	1	1	-	-
Day3	1	1	2	1	1		-	1	-	1
Day4	1	1	2	-		1	-	1	1	2
Day5	-	-	1	-			-		1	2
Day6	1	-	1	1			-		1	3
Day7	-	-	-	-			-			1
Day8	1	-	-	-			-			1

Day9		1	1	-			1			-
Day10		-	2	1			2			1
Day11		-	1	1						
Day12		-	-							
Day13		1	1							
Day14			1							
Day15										
Day16										
Day17										

***[The black boxes denote the vanish of symptoms and the numbers in the white box denote the number of cases showed symptoms]**

Table 6. Day wise symptom tracker

6. ADVERSE DRUG REACTIONS

No significant adverse reactions were recorded during the hospital stay. None was withdrawn from the treatment due to treatment-related discomfort or any adverse reactions.

7. CONCLUSION

The pathology of *Kaba suram* has been described stage by stage in this study, in accordance with the Siddha literature, and the results have been published. The illness has been traced back to its source (*Noi mudhal naadal*), and a diagnosis has been made of the infection. The medications have been carefully chosen and administered to the patients starting on the day of their admission, depending on the stage and severity of the infection. Patients are also provided with appropriate food, exercise, and external therapy as needed in conjunction with their medications. It has been seen that the patient's condition has not deteriorated further. As a result, it is reasonable to conclude that the treatment of COVID-19 with the Siddha medications prescribed stopped the disease from progressing to a more critical stage. Even though the patient had a severe cough and a fever of more than 39.1 ° Celsius, the patient did not worsen or become breathless. India is in a unique position to utilise the vast amount of knowledge contained within the Indian Systems of Medicine to heal this sickness and bring the epidemic under control. The opportunity to demonstrate the efficacy of Siddha is also extremely valuable at this stage.

8. ETHICAL APROVAL

The trial has received approval from Institutional Ethical Committee of Kokila Siddha Hospital and Research Centre. The trial is registered in Clinical Trial Registry of India and the registration number is CTRI/2021/06/034145. All authors declare that a written informed consent was obtained from the patient

or other approved parties for publication of this case report and accompanying images. A copy of the written consent is available for review.

NOTE:

The study highlights the efficacy of "Siddha" which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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