

## Journal of Pharmaceutical Research International

33(60B): 131-141, 2021; Article no.JPRI.80869

ISSN: 2456-9119

(Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919,

NLM ID: 101631759)

# Documentation, Clinical Validation, Safety Assessment and Efficacy of Siddha Treatment in COVID 19 SARS-CoV-2: A Case Series

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#### Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

#### Article Information

DOI: 10.9734/JPRI/2021/v33i60B34595

#### **Open Peer Review History:**

This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here:

<a href="https://www.sdiarticle5.com/review-history/80869">https://www.sdiarticle5.com/review-history/80869</a>

Case Study

Received 15 November 2021 Accepted 20 December 2021 Published 21 December 2021

#### **ABSTRACT**

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

**Presentation of the Case:** Open labelled, interventional, prospective cohort study conducted in Covid ward, Kokila Siddha Hospital and Research Centre, Madurai between June and Aug 2021. Among 22 registered in the trial 5 (22.72%) developed breathing difficulty, treated with oxygen support, 10 (45.5%) were male, 12 (54.5%) were female. At the time of admission, maximum 9 (40.9%) 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-2DM 5 (23%), and 2 (9%) had hypertension as comorbidity. Hematology, LFT, RFT, D-Dimer, PTT, CRP were taken before and after 5 days of treatment.

**Discussion:** The mean hospital stay was 7 days and discharged on a minimum of 4th day and a maximum of 16<sup>th</sup> day. The mean hospital stay for hypoxic patients was 10 days. Paired sample test

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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 first day of admission, depending on the stage and severity of the infection. Patients were provided with appropriate food, exercise, therapy in conjunction with medications and found the patient's condition has not deteriorated further. It is reasonable to conclude that the treatment of COVID-19 with selective Siddha medications stopped the disease progress more critical.

Keywords: Siddha medications; Kabasuram; Kabasurakudineer; hypoxia; Vazhalaivaanguthal; inhalation.

# 1. INTRODUCTION

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 However, the majority worldwide [1]. individuals with COVID19 experience mild to moderate symptoms, and only approximately 10-15 percent develop severe illness [2,3]. There are currently no medications available due to the virus's novelty and broad clinical reach. In the 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 [5]. 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 [6,7].

Siddha literatures describe 64 types of fever under *Suram* (pyrexia/fever). 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*" [8]. *Suram* is characterised according to the impacted *Mukkuttram* (*Vatham, Pitham,* and *Kabam*), 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 [9,10]. Its clinical implications have been described in a few publications, including karisal. Theran 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 Kabam that happens in between Karthigai and Masi (November to February) [11].

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 percent of COVID-19 cases have minor symptoms that could include nonpneumonia 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) [12]. 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 [13]. Diarrhoea arises as a result of a weakened protective immune response, allowing infection to enter, particularly organs with high Angiotensin-converting enzyme 2 genes (ACE2) expression. This induces diarrhoea by causing inflammation in the digestive tract [14]. 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. This stage is similar to the symptoms of an increase in Kabam in the chest area causing Moochu thinaral (Dyspnoea), kollaamai Mael moochu. Oon (loss of Thookkaminmai (Insomnia), appetite). 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 [15]. Hypercapnia can cause a reduction in carbon diffusion, resulting dioxide in increased perspiration and vasodilation [16]. Pallor of the tongue and face, as indicated in Siddha writings, caused be by ARDS. which 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 [17].

# 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 [18]. Symptoms as Naachuvai ariyaamai (loss 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 RT-PCR positive for COVID-19 came for admission in Covid ward, Kokila Siddha hospital and research centre, Madurai 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 COVID-19 based on the World Health Organization (WHO) guidelines those who had an influenza-like illness and were SARS-CoV-2 Reverse transcriptionpolymerase 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 take Siddha medication

# 3.6 Exclusion Criteria

- Patients with high-grade (103°F (39.4°C) or above) 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 [18]. It is done 1-3 times a day for three days. The phleam that has gathered is prevent and spit out to remove development. For the first three days, it is usually done here early in the morning. 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 [19]. 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) contains the diet and drug followed in the In-Patient ward, Kokila Siddha Hospital to the covid patients during the hospital stay.

### 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 bairayam 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).

# 5. CONDITION ON DISCHARGE FROM HOSPITAL

# 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.

# 6. OBSERVATION

In this case study, research carried to evaluate clinical validation, safety assessment and

efficacy of Siddha line of treatment in COVID-19 patients. 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.

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	

Table 2. List of primary drugs

Туре	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

Туре	Name	Formula	Dose & Anupanam
Chenduram	Poorna chandirodayam	Therayar karisal 300	50 mg, twice in a day after food
Tablet	Gorojanai mathirai	Agasthiyar Ratna	100 mg, twice in a day after
		churukkam	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	The Indian Medicine Practitioners,
	Cinammomum verum	Co-operative Pharmacy & Stores
	Elettaria cardamomum	Ltd., Thiruvanmiyur, Chennai-
	Zingiber officinale	600041
	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	
Nialvembu Kudineer	Andrographis paniculata	Raja Sidhaa Marundagam, 3/1A,
	Vetiveria zizanioides	Tharumathupatti, Kappalur,
	Plectranthus vettiveroides	Madurai-625008
	Cyperus rotundus	
	Santalum album	
	Zingiber officinale	
	Piper nigrum	
	Trichosanthes cucumerina	
	Mollugo cerviana	
Vasantha	Purified mercuric sulphide	The Indian Medicine Practitioners,
kusumakaram	Purified borax	Co-operative Pharmacy & Stores
Nusumakaram		•
	Purified sulphur	Ltd., Thiruvanmiyur, Chennai- 600041
	Piper longum	600041
	Saussurea costus	
	Anacyclus pyrethrum	
	Glycyrrhiza glabra	
	Acacia Arabica gum	
	Cinnamomum camphora	
	Crocus sativus	
	Ginger juice	
Brahmananda	Purified sulphur	The Indian Medicine Practitioners,
bairavam	Purified red orpiment	Co-operative Pharmacy & Stores
	Purified yellow orpiment	Ltd., Thiruvanmiyur, Chennai-
	Aconitum Ferox Rt.	600041
	Zingiber offcinale Rz	

	Purified borax	
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

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).

Hematology, LFT, RFT, D-Dimer, PTT, CRP were taken before and after 5 days of treatment. The mean hospital stay was 7 days. The patients were discharged on a minimum of 4th day and a maximum of 16<sup>th</sup> 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.

This study revealed that 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.

#### 7. 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.



Fig. 1. Pictorial representation of Gender participated in the study Table 5. List of ingredients in secondary drugs

Name	Ingredients	Manufacturer
Poorna chandrodhayam	Purified gold	The Indian Medicine
	Purified mercury	Practitioners, Co-operative
	Purified sulphur	Pharmacy & Stores Ltd.,
	Gossypium arboreum flower juice	Thiruvanmiyur, Chennai-600041
	Musa paradisiaca stem juice	
Gorochanai mathirai	Bezoar of cow	The Indian Medicine
	Crocus sativus stamens	Practitioners, Co-operative
	Cinnamomum camphora	Pharmacy & Stores Ltd.,
	Myristica fragrans nut	Thiruvanmiyur, Chennai-600041
	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	
Thayir chundi	Sodium chloride impura	The Indian Medicine
chooranam	Glass salt	Practitioners, Co-operative
	Alkaline Earth salt	Pharmacy & Stores Ltd.,
	Sodium chloride	Thiruvanmiyur, Chennai-600041
	Sochal salt	·
	Dried Zingiber officinale	
	Cow's curd sour	
Madhulai manappagu	Punica granatum	The Indian Medicine
	rose damascene	Practitioners, Co-operative
	Honey	Pharmacy & Stores Ltd.,
	Saccharum officinarum	Thiruvanmiyur, Chennai-600041
Naga parpam	Purified zinc	The Indian Medicine
	Wedelia calendulacea leaf juice	Practitioners, Co-operative
	Aloe vera pulp	Pharmacy & Stores Ltd.,
		Thiruvanmiyur, Chennai-600041

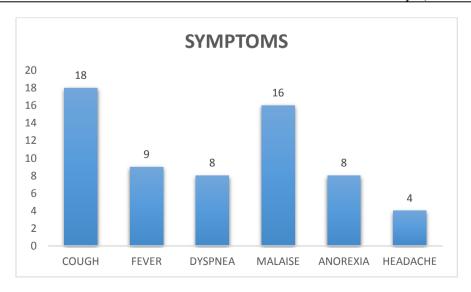
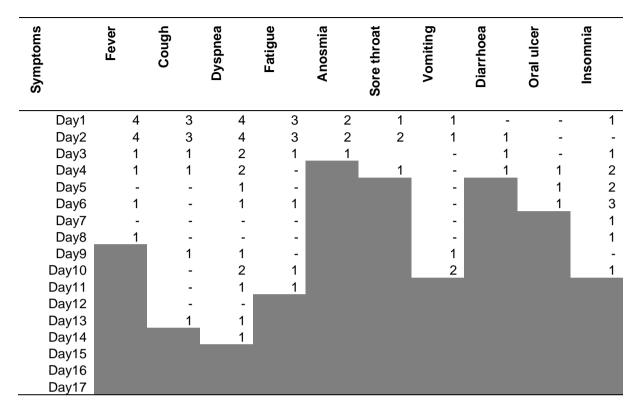


Fig. 2. Symptoms present during the time of admission Table 6. Day wise symptom tracker



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

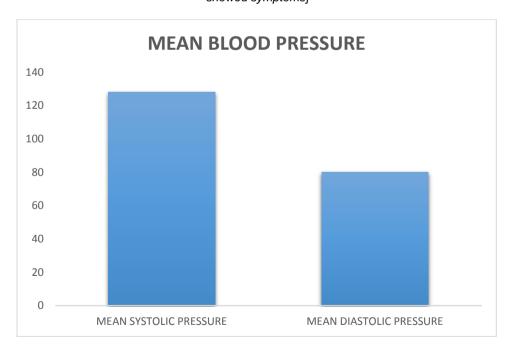


Fig. 3. Mean systolic and diastolic pressure during the time of admission

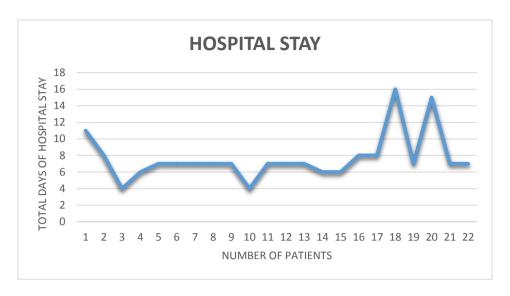


Fig. 4. Total number of hospital stays

# 8. CONCLUSION

The pathology of Kaba suram has been described stage by stage in this study, in accordance with the Siddha literature, and the results that have been previously published. The illness has been traced back to its source (Noi mudhal naadal) and the infection diagnosis. has been made of the infection. The medications have been carefully chosen and administered to patients in the first day of admission, depending on the stage and severity of the infection. Patients were 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. Without using synthetic steroids and with optimum oxygen support, this case report emphasises the therapeutic success of administering herbal and herbomineral Siddha formulations as a supplementary when required in the early inflammatory phase of COVID-19 infection and hypoxic situation. As a result, it is reasonable to conclude that the treatment of COVID-19 Siddha with the medications prescribed stopped the disease from progressing to a more critical stage. Even though with patient who had a severe cough and a fever higher than 39.1 ° Celsius, the patient did not worsen or become breathless. India utilises 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 and also further investigations are needed to provide more scientific evidence.

#### **DISCLAIMER**

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.

# CONSENT

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.

## **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.

#### **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**

Authors have declared that no competing interests exist.

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