An alternate approach in the management of COVID – 19 in unvaccinated / vaccine allergic population – A case study.

Abstract:

The COVID-19 vaccines offer protection against the severe acute respiratory syndrome Corona virus 2 (SARS-CoV-2) by developing an immune response to the same. Further, there are mass vaccination programs being conducted across the globe. India administered COVID – 19 vaccines for more than 90 crores of people as on October 2021. However, there are still a bunch of people yet to receive vaccination. Adding to this, very few are found to be allergic to COVID – 19 vaccines. Hence there is a need for an alternative approach till the whole population of the world gets vaccinated. One such approach is prescribing Nilavembu kudineer and Kabha sura kudineer, a polyherbal Siddha medicine formulation of Traditional Indian system of Medicine. This case study highlights the positive effects and importance of the above mentioned polyherbal formulations in the management of mild to moderate COVID-19 patients. Hence, the same can be advised to the individuals who are yet to receive COVID-19 vaccine and persons who are allergic to COVID -19 vaccines.

Key words: Siddha Medicine, SARS-CoV-2 and COVID-19 Vaccine

Introduction:

India administered more than 90 crores of COVID-19 vaccination as of mid October 2021 and it has shown promising effects with decreased morbidity and mortality rate of Coronavirus disease across the country. Similar pattern of reduction in death rate was observed across the globe among the vaccinated populations[1-4]. But, still there are plenty of people around the world are yet to receive vaccination. Additionally, researchers advised to take more precautions against usage of vaccination against patients with severe allergy to any components of COVID-19 vaccines[5-10]. Hence, there is a need for an alternate way for the people with vaccine allergy. Among the available literature it was found that usage of Indian systems of Medicine like Siddha medicine would be a suitable candidate for patients with severe vaccine allergy as well as patients who are waiting to receive the first or second dose of COVID – 19 vaccinations. Among the available Siddha polyhedral drugs, two important preparations namely Nilavembu kudineer and Kabha sura kudineer showed highly positive effects in decreasing the illness of COVID-19 in mild to moderate symptomatic patients[11-15]. In India, above Siddha medicines have been used to treat the dengue and chikungunya virus outbreak and found successful in treating the same[16]. However, very little effort was made to use only Siddha treatment in the management of COIVD-19 patients. In this regard, the author presents this case report (a single case study) of a mild to moderate Coronavirus disease patient in Chennai who was treated totally with Siddha medications and was completely relieved of his symptoms and the test result was negative within five days.

Case presentation

Patient information

The patient aged 41 years is a faculty of a premier college in Chennai, Tamil Nadu India. He is not vaccinated for COVID-19 vaccine. He is normally built with a height of 153 cms and weighing 68 kgs with no comorbidities.

Present medical history

Patient on the first day of illness approached his Siddha Physician, an Indian system of Medicine practitioner in Chennai for a consultation and started taking medication for his complaints. Since he lived in Chennai, he had self-quarantined due to the likelihood of a COVID-19 infection. Presenting symptoms were fever associated with body pain, mild cough from day one and loss of taste and smell from day 2 onwards. Medications like Nilavembu kudineer and Kabhasura Kudineer are clearly recommended for fever in Siddha pharmacopeia and hence the patient management was started as per Siddha's wisdom of Knowledge.

Past medical history

He had been under Siddha treatment (Siddha herbal concoctions) for a period of 1 month for renal calculus and it got dissolved which was confirmed with Ultrasound scan abdomen about 6 months ago.

Therapeutic intervention

Therapeutic intervention consisted of two Siddha poly herbal decoctions namely Nilavembu Kudineer and Kabha sura Kudineer, normal diet and water of 3-4 liters per day. The patient had self-quarantined from the first day of fever. Details of the Siddha medicines are:

- Nilavembu Kudineer 30 ml OD (after noon after meals)
- Kabha sura Kudineer 30 ml BD (morning and night after meals)
  Both the medicines were taken for 1 week and details are given below.

Table 1 Details of the symptoms, duration, and laboratory investigation performed and medicines taken

Day	Date	Symptoms	Test	Siddha Treatment
1	09.08.2020	Severe body ache (Pain scale : 8/10), mild cough and Temp: 100 °F	Not done	Nilavembu Kudineer and Kabhasura Kudineer (Dosageas given above)
2	10.08.2020	Severe body ache (Pain scale: 8/10), mild cough and temperature: 99 - 100 °F. Additionally the patient had loss of taste and smell	RT PCR test done in the Naso-pharyngeal and throat swab. **Detection of SARS-CoV-2** Ct Value: E gene :32.01 RdRp gene 32.32 (Laboratory Report 1)	Same medicines continued
3	11.08.2020	Body ache started decreasing**,** temperature becomes normal, no cough and continued loss of taste and smell	Not done	Same medicines continued
4	12.08.2020	Completely normal except continued loss of taste and smell	Not done	Same medicines continued
5	13.08.2020	Completely normal except continued loss of taste and smell	Not done	Same medicines continued
6	14.08.2020	Completely normal. Taste and smell sensation - Normal	RT PCR test done in the Naso-pharyngeal and throat swab – **No Detection of SARS-CoV-2** (Laboratory Report 2)	Same medicines continued
7	15.08.2020	Completely normal.	Not done	Both the medicines were stopped

Outcome

Initially on day one there was a little high temperature of 100 °F, the symptoms started to subside. From day 3, there were no significant symptoms, except loss of taste and smell. Later, on day 6 there was normalization of his sensation of taste and smell[17-18]. The patient followed all recommended instructions and the symptoms got normalized very quickly and there was no deterioration of the disease. There were no reported adverse effects.

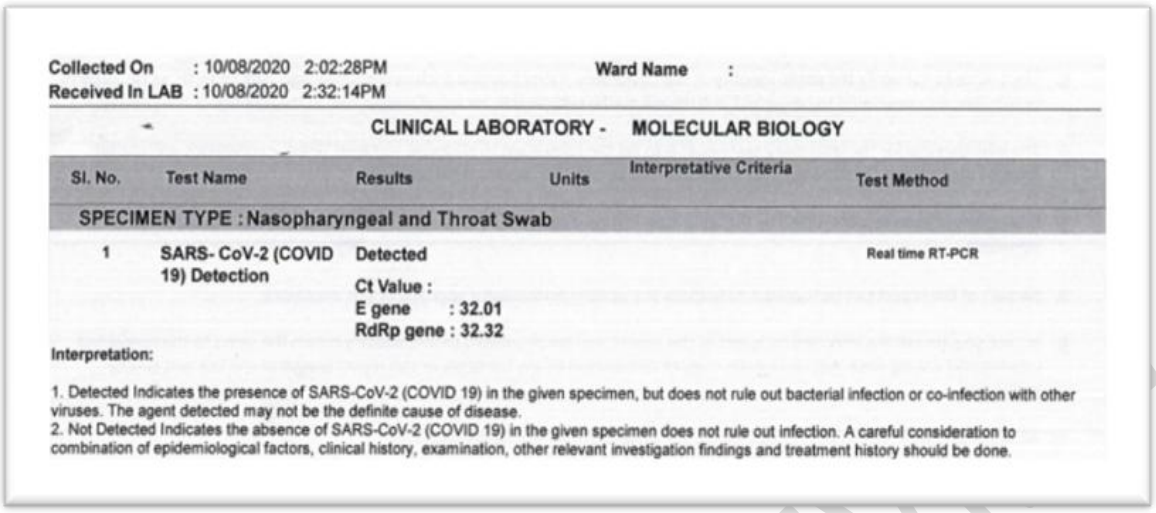
Discussion:

Siddha medicine is one of India's oldest systems of medicine which are being practiced mainly in the southern part of India. The patient's condition has not worsened in the management of COVID – 19 with the above-mentioned Siddha medicines. As a result, it's safe to speculate that treatment with the above prescribed Siddha medicines for COVID-19 which halted the progress of the severity of the disease. In other words, it can be said that the usage of Siddha medicines has stopped the patient from going into a critical condition like breathlessness and loss of consciousness. However, this case belongs to the category of mild to moderate illness of COVID-19. Additionally, the above-mentioned Siddha medicines can be prescribed under a qualified Siddha physician especially for those waiting to receive vaccination and those who are allergic to COVID-19 vaccines. Plenty of literature is in support of our study where thousands of mild to moderate COVID-19 patients are recovered with only Siddha medicines in the quarantine centers, however they have used a different dosage of the abovementioned poly herbal preparations[11-13]. Further, limitations of this study include - Siddha medicines are not generally advised for a critical patient and this study is a single case study; a larger sample must be researched before a standard approach for the treatment of COVID-19 can be developed. Further, impact and hidden problems of COVID-19 false positive or negative has to be considered before therapeutic management in both modern as well as Indian systems of medicine[19-20].

Conclusion:

The Siddha medicines namely Nilavembu and Kabhasura kudineer are found to be highly effective in treating the mild to moderate COVID-19 patients. Even though this case study is done in an unvaccinated patient, it can be extrapolated to the individuals who are allergic to the COVID-19 vaccine. Hence, the same can be advised to the individuals who are yet to receive COVID-19 vaccine and persons who are allergic to COVID -19 vaccines.

Laboratory Report 1: COVID -19 Positive report on Day 2



Collected On : 10/08/2020 2:02:28PM
Received In LAB : 10/08/2020 2:32:14PM
Ward Name :

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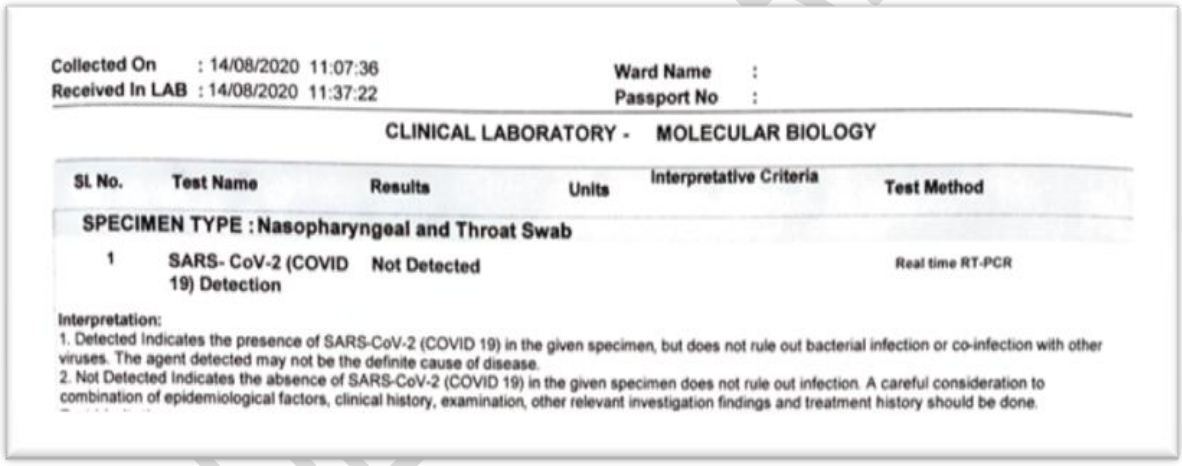
Sl. No.	Test Name	Results	Units	Interpretative Criteria	Test Method
SPECIMEN TYPE : Nasopharyngeal and Throat Swab					
1	SARS- CoV-2 (COVID 19) Detection	Detected Ct Value : E gene : 32.01 RdRp gene : 32.32			Real time RT-PCR

Interpretation:

1. Detected Indicates the presence of SARS-CoV-2 (COVID 19) in the given specimen, but does not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
2. Not Detected Indicates the absence of SARS-CoV-2 (COVID 19) in the given specimen does not rule out infection. A careful consideration to combination of epidemiological factors, clinical history, examination, other relevant investigation findings and treatment history should be done.

The patent naso-phrangeal and throat swab sample showed positive for COVID-19

Laboratory Report 2: COVID -19 negative report on Day 6



Collected On : 14/08/2020 11:07:36
Received In LAB : 14/08/2020 11:37:22
Ward Name :
Passport No :

CLINICAL LABORATORY - MOLECULAR BIOLOGY

Sl. No.	Test Name	Results	Units	Interpretative Criteria	Test Method
SPECIMEN TYPE : Nasopharyngeal and Throat Swab					
1	SARS- CoV-2 (COVID 19) Detection	Not Detected			Real time RT-PCR

Interpretation:

1. Detected Indicates the presence of SARS-CoV-2 (COVID 19) in the given specimen, but does not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
2. Not Detected Indicates the absence of SARS-CoV-2 (COVID 19) in the given specimen does not rule out infection. A careful consideration to combination of epidemiological factors, clinical history, examination, other relevant investigation findings and treatment history should be done.

The patent naso-phrangeal and throat swab sample showed negative for COVID-19

NOTE:

The study highlights the efficacy of "Siddha medicine" 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.

Disclaimer regarding Consent and Ethical Approval:

As per university standard guideline, participant consent and ethical approval have been collected and preserved by the authors

References:

1. Ali I. Impact of COVID-19 on vaccination programs: adverse or positive? Hum VaccinImmunother. 2020 Nov 1;16(11):2594-2600. doi: 10.1080/21645515.2020.1787065. Epub 2020 Sep 22. PMID: 32961081; PMCID: PMC7733893.
2. Foy BH, Wahl B, Mehta K, Shet A, Menon GI, Britto C. Comparing COVID-19 vaccine allocation strategies in India: A mathematical modelling study. Int J Infect Dis. 2021 Feb;103:431-438. doi: 10.1016/j.ijid.2020.12.075. Epub 2020 Dec 31. PMID: 33388436; PMCID: PMC7834611.
3. Dutta AK. Vaccine Against Covid-19 Disease - Present Status of Development. Indian J Pediatr. 2020 Oct;87(10):810-816. doi: 10.1007/s12098-020-03475-w. Epub 2020 Sep 3. PMID: 32880819; PMCID: PMC7468088.
4. Sharma J, Sharma D, Tiwari D, Vishwakarma V. The Challenges and Successes of Dealing with the COVID-19 Pandemic in India. Res Rep Trop Med. 2021 Aug 14;12:205-218. doi: 10.2147/RRTM.S274673. PMID: 34429681; PMCID: PMC8374532.
5. Shimabukuro T, Nair N. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine. JAMA. 2021 Feb 23;325(8):780-781. doi: 10.1001/jama.2021.0600. PMID: 33475702.
6. Cabanillas B, Akdis CA, Novak N. Allergic reactions to the first COVID-19 vaccine: A potential role of polyethylene glycol? Allergy. 2021 Jun;76(6):1617-1618. doi: 10.1111/all.14711. PMID: 33320974.
7. Kleine-Tebbe J, Klimek L, Hamelmann E, Pfaar O, Taube C, Wagenmann M, Werfel T, Worm M. Severe allergic reactions to the COVID-19 vaccine - statement and practical consequences. Allergol Select. 2021 Jan 5;5:26-28. doi: 10.5414/ALX02215E. PMID: 33426427; PMCID: PMC7787363
8. Nilsson L, Csuth Á, Storsaeter J, Garvey LH, Jenmalm MC. Vaccine allergy: evidence to consider for COVID-19 vaccines. Curr Opin Allergy Clin Immunol. 2021 Aug 1;21(4):401-409. doi: 10.1097/ACI.0000000000000762. PMID: 34091550; PMCID: PMC8270228.
9. Turner PJ, Ansotegui IJ, Campbell DE, Cardona V, Ebisawa M, El-Gamal Y, Fineman S, Geller M, Gonzalez-Estrada A, Greenberger PA, Leung ASY, Levin ME, Muraro A, Sánchez Borges M, Senna G, Tanno LK, Yu-Hor Thong B, Worm M; WAO Anaphylaxis Committee. COVID-19 vaccine-associated anaphylaxis: A statement of the World Allergy Organization Anaphylaxis Committee. World Allergy Organ J. 2021 Feb;14(2):100517. doi: 10.1016/j.waojou.2021.100517. Epub 2021 Feb 3. PMID: 33558825; PMCID: PMC7857113.

10. Sellaturay P, Nasser S, Islam S, Gurugama P, Ewan PW. Polyethylene glycol (PEG) is a cause of anaphylaxis to the Pfizer/BioNTech mRNA COVID-19 vaccine. Clin Exp Allergy. 2021 Jun;51(6):861-863. doi: 10.1111/cea.13874. Epub 2021 Apr 9. PMID: 33825239; PMCID: PMC8251011.

11. Srivastava A, Rengaraju M, Srivastava S, Narayanan V, Gupta V, Upadhayay R, Kumar J, Parameswaran S, KanakavalliKadarkarai, AarthiVelmurugan. Efficacy of two siddha polyherbal decoctions, Nilavembu Kudineer and Kaba Sura Kudineer, along with standard allopathy treatment in the management of mild to moderate symptomatic COVID-19 patients-a double-blind, placebo-controlled, clinical trial. Trials. 2021 Aug 28;22(1):570. doi: 10.1186/s13063-021-05478-0. PMID: 34454572; PMCID: PMC8397852.
12. Parthasarathy R, Mathew M, Koshy P, Babu M, Abraham G. Traditional medicines prescribed for prevention of COVID-19: Use with caution. Nephrology (Carlton). 2021 Jul 28:10.1111/nep.13947. doi: 10.1111/nep.13947. Epub ahead of print. PMID: 34322937; PMCID: PMC8420558.
13. Srivastava A, Rengaraju M, Srivastava S, Narayan V, Gupta V, Upadhayay R. A double blinded placebo controlled comparative clinical trial to evaluate the effectiveness of Siddha medicines, Kaba Sura Kudineer (KSK) & Nilavembu Kudineer (NVK) along with standard Allopathy treatment in the management of symptomatic COVID 19 patients - a structured summary of a study protocol for a randomized controlled trial. Trials. 2021 Feb 11;22(1):130. doi: 10.1186/s13063-021-05041-x. PMID: 33573696; PMCID: PMC7876527.
14. Mekala P, Murthy TG. Phytochemical screening and pharmacological update on Kaba Sura Kudineer Choornam and Nilavembu KudineerChoornam. J Pharmacognosy Phytochemistry. 2020;9(3):1031-6.
15. Jose SP, M R, S S, Rajan S, Saji S, Narayanan V, S S. Anti-inflammatory effect of Kaba Sura Kudineer (AYUSH approved COVID-19 drug)-A Siddha poly-herbal formulation against lipopolysaccharide induced inflammatory response in RAW-264.7 macrophages cells. J Ethnopharmacol. 2022 Jan 30;283:114738. doi: 10.1016/j.jep.2021.114738. Epub 2021 Oct 12. PMID: 34653521; PMCID: PMC8507575.
16. Jain J, Kumar A, Narayanan V, Ramaswamy RS, Sathiyarajeswaran P, Shree Devi MS, Kannan M, Sunil S. Antiviral activity of ethanolic extract of Nilavembu Kudineer against dengue and chikungunya virus through in vitro evaluation. J Ayurveda Integr Med. 2020 Jul-Sep;11(3):329-335. doi: 10.1016/j.jaim.2018.05.006. Epub 2019 Jan 23. PMID: 30685096; PMCID: PMC7527801.
17. Inan S, Özer F, Erbek SS, Çaylaklı F, Ödemiş İ, Kurşun E. Olfactory disorders in patients with mild to moderate COVID-19: spontaneous recovery in one-month follow up. B-ENT. 2021 Jan 1;17(1):18-23.
18. Wu D, Rao Q, Zhang W. The natural course of COVID-19 patients without clinical intervention. J Med Virol. 2021 Sep;93(9):5527-5537. doi: 10.1002/jmv.27087. Epub 2021 May 19. PMID: 33990975; PMCID: PMC8242845.
19. Surkova E, Nikolayevskyy V, Drobniewski F. False-positive COVID-19 results: hidden problems and costs. Lancet Respir Med. 2020 Dec;8(12):1167-1168. doi: 10.1016/S2213-2600(20)30453-7. Epub 2020 Sep 29. PMID: 33007240; PMCID: PMC7524437.
20. Healy B, Khan A, Metezai H, Blyth I, Asad H. The impact of false positive COVID-19 results in an area of low prevalence. Clin Med (Lond). 2021 Jan;21(1):e54-e56. doi: 10.7861/clinmed.2020-0839. Epub 2020 Nov 26. PMID: 33243836; PMCID: PMC7850182.