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Clinical Efficacy on Treatment of Broad-Spectrum Viral Infections with Topical use of Polyherbal Plant Extract Based Oils

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Abstract

This paper aims to study the efficacy of SAV polyherbal oil blend for the treatment of a range of viral infection based diseases. This study presents scientific, safe, and effective solution for viral infections, which is a natural SAV polyherbal oil-blend and only requires topical application. Gas Chromatography-Mass Spectroscopy was carried out for SAV polyherbal blend and the analysis indicated 13 compounds with anti-viral properties. Two studies have been carried out to assess the efficacy and safety of the polyherbal oil-blend, one with viral infections in humans and second study of viral infection in cattle. Sample consisted of 60 patients who were suffering from different viral infections and three cows with symptoms similar to foot mouth disease. The topical application of the SAV oil helped provide treatment by relieving symptoms of diverse viral infections in 60 patients, and of foot mouth disease in three cows. Therefore, the natural herbal plant extract oils can be safely used as an adjuvant with conventional treatments or as standalone therapy to safeguard human life and animals from various viral infections.

Keywords: Viral infections; Ayurveda; Topical application; Polyherbal; RNA enveloped virus; RNA non-enveloped virus; DNA enveloped virus; DNA non-enveloped virus

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Introduction

Humankind and animals have come across various diseases and infections since time immemorial and there are a number of therapies developed to gain protection and cure for diseases. Specifically, for the treatment of most viral infections, modern medicine follows the route of vaccinations. It has probably been successful in containing several viral strains and hence protect humankind. However, they have their limitations like various side-effects or no complete cure from all symptoms. Further, mutation of viruses at regular intervals may render its challenges. Thus, keeping in consideration the limitations of the current treatments, especially for viral infections/ diseases, there is a need and desire for solutions that are simpler, holistic, safe and effective using natural resources and convenience to use. Over centuries, man has innovated and curated solutions from nature to prevent and treat infections. Literature indicates that herbal solutions are one of the reliable alternative solutions [1].

Several viral infections/diseases are not only a cause of concern but also result in enormous economic and human life burden. For example, within a season of 2019-2020, 105 children lost their lives from the flu (influenza) according to the data from 'US Centers for Disease Control and Prevention (CDC)' [2]. Overall estimates from CDC from Oct 1, 2019 to Feb 15, 2020 indicate **29,000,000–41,000,000 f**lu illnesses, **13,000,000–19,000,000** flu medical visits, **280,000–500,000** flu hospitalizations and **16,000–41,000** flu deaths only in the US [3]. The annual mortality global burden of influenza is estimated to be in the range of 294,000-518,000 [4]. Considering the recent spread of the Novel Corona virus across the world along with regular other flu instances, economic and human life burden will be enormous. Therefore, it will be desirable to have natural, scientific, safe and effective solutions based on complementary therapies for prevention as well as treatment options adjuvant to traditional therapies or as standalone solutions.

The aim of this paper is to assess the effectiveness of a polyherbal oil blend (referred as SAV) against different viral infections. Different cases of RNA/DNA enveloped/non enveloped, according to the broad classification based on the International Committee on the Taxonomy of Viruses (ICTV), were addressed to treatment [5]. This paper presents two studies; one with viral infections in humans and the second study of viral infection in cattle.

SAV was prepared using the plant/herb-extracts/oils of the following: Origanum majorana, Lavandula stoechas, Mentha piperata, Caryophyllus aromaticus, Ocimum basilicum,

Tracyspermum ammi, Citrus medica, Mentha viridis, Origanum vulgare, Thymus serpyllum, Cocos nucifera, Helianthus annuus, Sesamum indicum, Allium sativum, Pimpinella anisum, Brassica campestris. It is prepared using a novel concept referred as Ayurveda Plant Nanocellopathy, based on knowledge presented in Sarangdhar Samhita, that blends therapeutic plant extracts/oils in a form to derive maximum benefit through the synergistic effect of polyherbal composition. Extant literature shares that polyherbal formulations provide more benefits in comparison to single herbal formulations due to the synergistic effect [6]. Gas Chromatography-Mass Spectroscopy (GC-MS) was carried out for SAV polyherbal blend, and the analysis indicated compounds with anti-viral, anti-bacterial, and anti-inflammatory properties. The SAV GC-MS has shown 13 compounds providing anti-viral function **(Table 1)**. The additional benefits of most of these 13 compounds are highly desirable in terms of either anti-microbial or anti-inflammatory or both.

Based on the extant literature, it is studied that SAV will provide viral protection with benzyl alcohol virucidal activity in topical application [7]; with Eugenol [8], Caryophyllene [9], Thymol [10], Anethole [11], Geranial [12], Neral/Citral [13], 1,8-Cineole [14], Cymene [15], Terpinene [16] will prevent fusion of viruses with host cell (attachment with host); with Pinene and Limonene [17] will result in interference in DNA replication by inhibition of DNA polymerase; and with Cinnamaldehyde [18] decreases the apoptosis level; inhibiting the caspase-3, caspase-8, caspase-9 protein expression. Further, it is found that SAV oil blend compounds are effective against Herpes Simplex Virus (HSV), among other kinds of viruses.

The virulence activity of a virus can be due to a number of factors where a virus may infect the cells by growing on mucous membranes, entering in the cell, growing/replicating within the cell, combating the defence mechanism of host cells, or by damaging the host in a number of different manners [19]. Keeping in consideration the compound composition of SAV as well as the synergistic functioning of these compounds, SAV will be able to perform an effective anti-viral activity. The compounds identified in SAV work at the very primary stages to combat the viral activity that is by preventing the virus entry into cells. There are also compounds in the SAV oil blend which inhibit the replication of viruses. In other words, SAV composition is amicable to combat the viral activity from the initial stages itself. Inhibiting replication activity of virus is the next vital support, which will result in preventing any further damage even if virus enters cells and thus neutralizing the virus activity.

Table 1 Retention time and %Peak area of anti-viral compounds in SAV GC-MS.

No.	R Time (minutes)	Name of the compound	% Peak Area
1	7.314	α-Pinene	2.18
2	8.929	β-Pinene	1.22
3	10.547	α-Terpinene	0.16
4	10.967	para-Cymene	2.45
5	11.190	Limonene	3.35
6	11.321	1,8 Cineole	4.86
7	12.133	Benzyl Alcohol	12.29
8	12.472	γ-Terpinene	3.81
9	20.768	Neral	1.95
10	22.247	Geranial	3.23
11	23.192	Anethole	8.59
12	23.707	Thymol	2.71
13	26.098	Eugenol	7.32
14	28.410	Caryophyllene	1.39
15	33.880	Cinnamaldehyde	0.55

Study 1

Study 1 design

A study was carried out by Ayurveda physicians on the patients visiting for the treatment in 2019 at a study centre. With the self-wish and signed consent of the patients, polyherbal blend treatment was administered to the patients. Different cases of RNA/DNA enveloped/non enveloped [5] were provided treatment by using a combination of one generic anti-viral oil blend (SAV) and one specific (to the identified virus family) oil blend of plant-extracts. There were cases representing viral infections from RNA virus family including Common flu, common flu with respiratory discomforts, Chikunguniya, Tonsillitis, Hand Foot Mouth disease, H3N2 (Influenza A), and H1N1 (Swine flu); and cases of Herpes and Human Papilloma Virus (HPV) represented DNA virus family. The demographic details of the patients with symptoms are shared in the results section in **Table 2**. There were 60 patients suffering from different viral infections, including 7 members from a junior cricket team. All patients were observed and followed after oil-treatment upto three months to identify any adverse events or symptoms, which may be due to the use of the oil.

Dosage and administration

Directions for the use of SAV were: topical administration of 3 drops on the back of the head-neck area, 3 drops under each foot and 7 drops on the whole spine. There were also instructions for the second specific oil, only if needed by the patients. All patients were followed at the period of 1 week up to 3 months after oil treatment in order to report adverse effects, if any. The 53 patients have self-administered the oils at home as per the directions given, whereas the junior cricket team has applied oils under their respective doctor guidance.

Results

Out of the 60 patients; 42 patients were suffering from viral infections from RNA Enveloped (RNA E), 2 patients and the 7 members of a school junior cricket team from RNA Non-Enveloped (RNA NE), 8 patients from DNA Enveloped (DNA E), and one patient from DNA Non-Enveloped (DNA NE) virus families. Table 2 presents the age and gender of patients with symptoms and result outcome with topical application of the anti-viral polyherbal oil blend (SAV). The patients did not report any adverse events like allergies, rashes from the use of oil. Therefore, it can be assessed that the oil is safe to use.

In the case of the patient suffering from Human Papilloma Virus (HPV, DNA non-enveloped virus), the Bethesda System of reporting cervical cytology diagnoses was carried out for Pap Smear results before the application of the oil blend. Hybrid

Table 2 Patients' data with symptoms and outcome results after application of SAV.

RNA E, Common Flu	Patients' gender and age	Females of age 53, 38, 45, 35, 40, 42, 16 years + Males of age 40, 20, 65, 13 years {11 Patients}
	Symptoms	High grade fever, severe joint pain, headache, fatigue, muscle pain, body ache, irritability & nausea. Two patients also reported chest congestion and 4 patients reported poor digestion.
	Results after SAV treatment	No Nausea and headache post 4-6 hours of oil application. Temperature started reducing within the first 12 hours. Temperature fell to normal within 24 hours. Considerable relief in joint pain was felt by the 2nd day morning. By the 2nd day evening, the patient felt relief from the body ache. Viral infection treated by the 3rd day. Chest congestion was treated by the 5th day. Digestion became normal as reported by the patients.
RNA E, Flu with respiratory symptoms	Patients' gender and age	Females of age 32, 65, 26, 34, 34, 53, 22, 42, 46, 46, 17, 20, 13, 75 years + Males of age 16, 33, 31, 43, 45, 40 years {20 Patients}
	Symptoms	Fever, blockage of both nostrils, headache, runny nose/ cold, facial pain, irritability. One patient reported blocked ears; one patient reported breathing difficulties and shortness of breath; one reported inflamed sinuses; one patient indicated pressure in ear and head, ear pain.
	Results after SAV + respiratory support oil treatment	Temperatures started reducing within 6-24 hours of oils' application. Temperature reached normal by 2nd morning. Improvement in runny nose by the 3rd day. The patient was treated of viral infection by the 4th day. There was no pain due to sinus by the 3rd evening. Considerable reduction in ear pain felt by the 2nd day morning and viral infection treated by the 3rd day of the oils' application.
RNA E, Chikunguniya	Patients' gender and age	Female of age 35 years + Males of age 50, 8 years {3 Patients}
	Symptoms	Chikunguniya, fever, throat pain, chest congestion and pain in joints, bacterial infection in throat, numbness and stiffness in fingers
	Results after SAV treatment	Temperature started reducing within the first 8-12 hours. By the 2nd day evening, the patient felt considerable relief from the body ache and fever came down to normal. By the 3rd day viral infection was treated and bacterial infection was treated by the 5th day. Fingers were functioning normal without numbness and stiffness.
RNA E, Tonsilitis	Patients' gender and age	Male of age 19 years {1 Patient}
	Symptoms	Tonsilitis, mild fever and throat infection
	Results after SAV treatment	Temperature started to drop and headache stopped within the first 24 hours. By the 2nd afternoon, the patient could easily swallow food. By the 3rd evening the nose wasn't running anymore. By the 4th day the viral infection was treated.
RNA E, Influenza A (H3N2)	Patients' gender and age	Females of age 4, 7 years + Male of age 6 years {3 Patients}
	Symptoms	Influenza A (H3N2), 103 - 104 fever since 2 weeks, severe bouts of cough; also bacterial infection
	Results after SAV treatment	Temperature started reducing within the first 8 hours of treatment and was under control within 24 hours (99.4 F). Long bouts of cough stopped. The patient was treated of H3N2 and flu by the morning of the 3rd day. Infection treated by day 4.
RNA E, Swine Flu - H1N1	Patients' gender and age	Females of age 14, 3, 47 years + Male of age 5 years {4 Patients}
	Symptoms	H1N1, High grade fever, cold and cough, body ache, loss of appetitite
	Results after SAV treatment	Temperature started reducing within the first 8 hours of treatment and was under control within 24 hours. Long bouts of cough stopped. The patient was treated of H1N1 and flu by the morning of the 3rd day. Bacterial Infection treated by day 4.
RNA NE, Hand Foot Mouth disease	Patients' gender and age	Females of age 7, 3 years {2 Patients} + Junior Cricket Team
	Symptoms	Hand foot mouth disease , recurrent fever , rashes on hand , feet , hip and anal region, unable to eat
	Results after SAV treatment + one specific oil	Temperature reduced in first 4-6 hours of application of oils. Fever was normal by the end of 1st day; started eating normal food. By the end of 2nd day, the rashes on the body subsided. By the 3rd – 4th evening, patients were treated of the infection. All the afflicted students in the cricket team were deemed fit by their respective doctors in 18-20 hours with no fever, and no blisters and no sores.
DNA E, Herpes	Patients' gender and age	Females of age 42, 65, 66, 80, 66 years + Males of age 74, 41, 55 years{8 Patients}
	Symptoms	Herpes with high grade fever, painful blisters and burning sensation on the infected area, sores in different areas; very painful
	Results after SAV treatment + one specific oil	Temperature started reducing within the first 8-12 hours. Considerable relief from pain from blisters was felt by the 2nd day morning. The burning sensation in the affected area reduced by 2nd day. Fever and body ache were treated by the 3rd day. Blisters dried by the end of 3rd day with no scars.
DNA NE, HPV	Patient's gender and age	Female of age 65 years {1 Patient}
	Symptoms	HPV- Human Papilloma Virus: Discomfort in cervical region, heart burn, gastric distress, splenomegaly, fatigue
	Results	Temperature started reducing within 48 hours. She got relief from joint pain within 7 days. There was no problem of indigestion. Stiffness over cervical region started easing by the 10th day. HPV DNA Genotyping test results declared HPV negative in the patient.

Capture 2 high-risk HPV DNA test, at Relative Light Units (RLU) cutoff value of 3.01, detected the presence of high-risk HPV type. After the application of the SAV oil blend, the HPV GenoArray DNA test was carried out to detect and for genotyping of 21 types of HPV infection, which might cause cancer. The sample after treatment with the oil blend was found negative for HPV DNA for the 21 different strains, including 15 high risk and 6 low risk strains.

Study 2

A pilot study was carried out to test SAV with one additional polyherbal oil for the safety and efficacy in the management and treatment of symptoms similar to Foot and Mouth Disease in cattle. An outbreak of a disease having symptoms similar to foot-and-mouth disease (FMD) was identified in Mohali, Punjab, which started at the end of December 2018. Three cows were selected for the pilot study, were already vaccinated with FMD vaccine but who had shown severe symptoms similar to FMD.

The common symptoms in all the three cows at the start of the pilot in 2019 were: heavy salivation with thick saliva frequently dropping out of their mouths, and red lesions on their gums and tongue. Cow1 showed signs of laziness with hardly any movement throughout the day. The running body temperature in Cow1 was 102.7 degree Fahrenheit, in Cow2 had 102.5 degree Fahrenheit and in Cow3 had 103 degree Fahrenheit.

Dosage and administration

4 ml of SAV was applied and massaged thoroughly on the spines of the three cows, 3 times a day at the gap of 4-5 hours. Second oil was applied 3 times a day with a gap of 4-5 hours each on the lesions on the exterior of the mouth as well as on the lesions inside the mouth. The oils were applied under the supervision of a veterinary physician.

Result of study2

The topical application of the SAV oil with the second oil was found effective in relieving the symptoms similar to FMD in all the three cows within the first day and were completely treated in 3 days. No adverse events were reported in cows with the use of the oil. Thus, it can be assessed that the polyherbal oil-blend is a safe solution to treat viral infection like FMD in cattle.

Discussion and Conclusion

According to Study1, the application of polyherbal oil blend was found effective in treating broad spectrum of viral infections resulting from RNA Enveloped, RNA Non-enveloped, DNA Enveloped and DNA Non-enveloped. Using the non-metabolized route, they are targeted directly at the area of concern, and hence their response is quick. In most cases, the treatment for the viral infection shows effective results in 1-3 days. Used topically, the solutions were found easy to use, safe and effective. It can be considered that from patients' perspective, there is not only ease of use but also the convenience of use in terms of time, comfort and expenses.

The extant literature indicates that many viral infections do not have complete treatment measures. For example; Chikungunya virus, a mosquito-transmitted alphavirus belonging to the Togaviridae family, has re-emerged in countries around the Indian Ocean due to climatic conditions and causing millions of infections. Additional mortality has been observed with Chikungunya virus outbreaks though death rate is not particularly high. However, there is no specific therapy, and prevention is the key countermeasure, which is avoiding mosquito bites [20]. Similarly, Herpes simplex virus (HSV) infections are among the infections most frequently encountered by humans. However, on occasions, the disease can be life-threatening. Out of more than 80 known herpesviruses, eight are human pathogens. HSV is also a contagious infection with a potential for significant complications in the immunocompromised host [21]. Hand foot mouth disease (HFMD) results in complications with severe neurological sequelae. A number of associated problems need a solution before having adequate prevention from HFMD [22]. Human swine influenza A [H1N1], referred as 'swine flu' is highly transmissible. The emergence of new strains keeps challenges for public health and for the scientific communities for appropriate treatment [23]. In the case of human papillomavirus (HPV), more than 100 different types of HPV exist, including the existence of approximately 30 to 40 strains that infect the human genital tract. It is identified that HPV is the most common sexually transmitted infection in the United States with approximately 80% of women having acquired an infection by the age of 50 [24]. In consideration of the given difficulties, due to the nature of viruses, to provide adequate treatment with traditional medicines; polyherbal blend will be supportive of extending comfort and treatment either standalone or along with traditional treatments.

With respect to Study2, foot and mouth disease (FMD) is a severe, highly contagious viral disease of livestock that has a significant economic impact. Low income and lower-middle income countries spend around 75% of the costs towards prevention and control of FMD. It is identified that the morbidity rate may approach 100% in susceptible cattle populations [25]. Again, in light of the current treatment options and economic burden, the SAV polyherbal oil blend can play an effective treatment for FMD in cattle.

The unique and novel aspect of the approach is the only topical application of natural oil-blends with no ingestion to combat spread and treatment possibilities of different viral infections. However, further research is needed to check efficacy against different viruses. Diverse viruses can be considered to determine efficacy like COVID19 the novel corona (RNA+ enveloped) virus, Ebola (RNA negative single-stranded from filovirus family) and others. The future studies may delve deeper in the different probable mechanisms of action using a polyherbal blend of extracts in fighting different viral infections. Thus, complementary herbal therapies can be considered as standalone solutions or can be used as adjuvant therapy to support and complement other healthcare conventional practices, specially to answer diverse virus-based infections with limited or no available treatment options.

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