Clinical evaluation of Chocoherb Granules in Human Immunodeficiency Virus Infected teenagers

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Abstract:
The relationship between nutrition and human immunodeficiency virus (HIV) is a vicious cycle. HIV compromises nutritional status, and poor nutrition further weakens the immune system, increasing susceptibility to opportunistic infections. The study has been planned with aim to provide sufficient nutrition to malnourished HIV infected children via safe, effective, curative herbs which ensure well nourishments, boosts immunity, increases intellectual and restores the sickness to health and to evaluate the efficacy of Chocoherb granules in malnourished HIV infected children.

The Ayurvedic herbal product named Chocoherb is administered to HIV infected teenagers of age group between 11 to 18 years for 3 months under Civil Hospital - Rajkot Gujarat living with HIV. Chocoherb (Chocolate flavored granules with herbal extract in 10 gms. Individual sachet) twice daily with plain water. In present study, total 20 HIV infected teenagers of age group between 11 to 18 years were observed for weight improvement 1.45 % (p < 0.05), height improvement 0.28 % (p < 0.05), improvement in BMI 1.16% (p < 0.01) and in CD4 count -0.18 % (p > 0.05). The overall therapy shows improving in general health status of malnourished HIV infected teenagers.

Key words: Ayurvedic granules, BMI, Herbal product, HIV infection

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Introduction:
The World Bank estimates that India is one of the highest ranking countries in the world for the number of children suffering from malnutrition. The prevalence of underweight children in India is among the highest in the world.[1] Food is any nutritious substance that people or animals eat or drink, or that plants absorb, in order to maintain life and growth. Without adequate nutrition the human body does not function optimally, and severe nutritional inadequacy can lead to disease. Good nutrition provides a mechanism to promote health and prevent disease.

It is estimated that over 23 million people worldwide are having HIV infection and of which over 8.1 million people have developed acquired immunodeficiency syndrome (AIDS). The situation is going to be worse in coming years. India is having largest number of HIV infected cases in South Asia.[2] Good nutrition is very essential for patients with HIV infection. HIV effects patient’s appetites, make food taste bad, or make it harder for your body to absorb nutrients. Symptoms like nausea and mouth sores can make eating unpleasant. These all lead weight loss and decrease body mass index (BMI) of individual. Malnutrition is upshot progression of HIV disease and a consequence of HIV infection and as well it’s also associated with reduced T-cell proliferative responses. Nutrients play important roles in maintaining immune function especially when immunocompromised patients like HIV infection.

Nowadays Ayurveda recommended at every aspect, Ayurvedic medicines have given effect to HIV infection patients[3], here we also introduced an ayurvedic product for immunocompromised patients like HIV infection. In this study we have approach to HIV infected teenagers for ayurvedic herbal product chocoherb at the civil hospital, Rajkot.

Chocoherb is an ayurvedic preparation with herbal drugs like, Ashwagandha, Shatavari, Vidarikanda, Bramhi, etc. as per mentioned in Table No 1 with chocolate flavour. It’s a classical reference for this preparation taken from Aryabhisaka.[4]

The study has been planned with aim to provide sufficient nutrition to malnourished HIV infected children via safe, effective, curative herbs which ensure well nourishments, boosts immunity, increases intellectual and restores the sickness to health and to evaluate the efficacy of Chocoherb granules in malnourished HIV infected children.

Materials and methods:
Selection of the Patients:
Total voluntary 20 children who have HIV infection are selected for open randomized study at Civil Hospital, Rajkot, Gujarat (Gujarat State AIDS Control Society) and Gujarat State Network of people living with HIV (GSNP) from July 2019 to Sept 2019.

Inclusion:
HIV infected children without symptoms and diagnosed since birth as either parents are infected from HIV; Underweight according to standard BMI measurement, and age between 11 to 18 years irrespective of caste, religion, sex etc.

Exclusion:
Major illness like insulin-dependent diabetes mellitus (IDDM), Tuberculosis (TB), Malignancy etc., congenital
anomaly, age below 11 years and above 18 years were excluded and patient unwilling to participate in the study was excluded from study.

**Anthropometric measurement:**
BMI (Body Mass Index) = Weight in kilograms/height in meter square patient measuring BMI < 18.5 should be taken as underweight (according to WHO). The height (in meter) and weight (in kilograms) are taken with the person standing upright, with arms hanging down loosely.

**Laboratory:**
Before treatment complete blood count, urine routine & micro, and stool routine & micro examinations were carried out in all patients to rule out any illness except HIV infection. Before and after treatment CD4 count Test was conducted.

**Use of Drug:**
Chocoherbs granules – an Ayurvedic formulation (Table 1), prepared at Jishan Herbal, a Good manufacturing practices (GMP) certified ayurvedic manufacturing unit, Rajkot.

**Dosage and Duration of Drug:**
Chocoherb - Chocolate flavored granules 10 gm, twice a day by orally dosage for a period of 90 days along twice daily after meal with plain water. During the study allopathic treatment was continued for HIV as advised by physician according to guidelines of Gujarat State AIDS Control Society.

**Follow Up:** After each 30 days for a period of 3 months.

**Observation and results:**
A total of 20 HIV infected children in the age-group of 11–18 years were registered for this study designed to evaluate the effect of Chocoherb granules. All of them completed their treatment. In this present study, total 50% patients are male and remaining female. Among them 85% are Hindu and remaining are from other casts. The result of this preliminary study observed for weight improvement 1.45 % (p < 0.05 significant), height improvement 0.28 % (p < 0.05 significant), and improvement in BMI 1.16% (P< 0.01 significant). Non-significant (p > 0.05 non–significant) difference was found in CD4 count (-0.18 %) (Table 2).

**Table 1: Ingredients of Chocoherbs granules – an Ayurvedic formulation.**

<table>
<thead>
<tr>
<th>Herbal ingredients</th>
<th>Botanical Name</th>
<th>Used part</th>
<th>Karma-Pharmacological Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aswagandha Ext.</td>
<td>Withania somnifera Linn. Dunal</td>
<td>Root</td>
<td>Balya, Rasayan,</td>
</tr>
<tr>
<td>Satavari Ext.</td>
<td>Asparagus racemosus Willd</td>
<td>Root</td>
<td>Rasayan, Medhya, Balya</td>
</tr>
<tr>
<td>Vidarikanda Ext.</td>
<td>Pueraria tuberosa DC.</td>
<td>Tuber root</td>
<td>Brihman, Dahhara, Balya</td>
</tr>
<tr>
<td>Brahmi Ext.</td>
<td>Bacopa monneri (Linn.) Pennell</td>
<td>Whole plant</td>
<td>Medhya, Rasayana,</td>
</tr>
<tr>
<td>Vaca</td>
<td>Acorus calamus Linn.</td>
<td>Rhizome</td>
<td>Dipan, Pacana, Medhya,</td>
</tr>
<tr>
<td>Jyotismati</td>
<td>Celastrus paniculatus Willd</td>
<td>Seed</td>
<td>Medya, Buddhi-Vardhaka, Swedajanana, Balya, Dipana</td>
</tr>
</tbody>
</table>
Shankhapuspi Ext.    Convolvulus pluricaulis Chois.  Whole plant  Rasayan, Medhya, Smritivardhaka, Balya
Bhringaraja    Eclipta alba Hassk.  Whole plant  Kesya, Krimighna, Rasayan, Balya
Kumari Ext.    Aloe vera Tourn. ex. Linn  Leaves  Rasayan, Balya
Punarnava Ext.    Boerhavia diffusa Linn.  Root  Dipana, Sophahara, Sulahara
Gokshur Ext.    Tribulus terrestris Linn.  Fruits  Dipana, Balya
Tulasi    Ocimum sanctum Linn.  Whole plant  Dipana, Balya
Pippali,    Piper longum Linn.  Fruits  Dipana, Visaghna
Maricha    Piper nigrum Linn.  Fruits  Dipana, Rasayana, Swashara, Kasahara
Dakshini Thor    Opuntia dilenil (Ker-Gawl.) Haw.  Fruits  Dipana, Balya
Gajar    Daucus carota Subps. sativus  Tuber root  Dipana, Krimighna
Bhoi Mug    Arachis hypogaea L.  De-oiled seeds  Balya, Bruhaniya

Excipients
Chocolate Flavor

| Table 2: Statistical analysis: |
|-----------------|-----------------|-----------------|-----------|----------------|
| Parameters      | Mean BT (n=20)  | Mean AT (n=20)  | Relief %  | SD        | SE   | P Value | Significance |
| Weight          | 32.67           | 33.15           | 1.45 %    | 1.125     | 0.252| <0.05  | significant |
| Height          | 142.75          | 143.15          | 0.28 %    | 0.681     | 0.152| <0.05  | significant |
| BMI             | 17.64           | 17.84           | 1.16%     | 0.611     | 0.137| <0.01  | significant |
| CD4 Count       | 876.50          | 874.95          | -0.18 %   | 148.2     | 33.14| >0.05  | non – significant |

Discussion:
Generally, HIV patients eat less food due to secondary opportunistic infections that reduce their appetite and result in weight loss. Inadequate food intake is one of the causes of malnutrition and this status is strongly associated with progression to HIV-infected patients. Malnutrition & HIV infection both show weight loss and make the condition worst thus, malnourished HIV infected children requires greater attention and care for
these patients. In such conditions, Chocoherb granules have such properties to give proper nutrition, strength, immunity buster which helps to restore health. Ayurvedic medicinal plants/herbs are natural sources of medicines which provide good health and immune system. Preparation of Chocoherb granules are presence of various herbal drugs. Each drug works as per its properties like, Rasa, Guna, Virya, Vipaka, Prabhava, Karma etc.

Shatavri, Vidarikanda, Gokshura, Bhoimug etc. have Madhura Rasa, Guru-Shingdha Guna, Madhur Vipaka properties which give Balya (boost immunity) & Bruhaniya (well nutrient) effects. Ashvagandha have Tikta-Kashya Rasa, Madhur Vipaka, Ushna Virya with Rasayana (restores health), Balya (boost immunity), Bruhaniya (well nutrient) effects as well. Pippai, Marich, Tulsi have Katu Rasa, Laghu Guna so its gives Dipana-Pachana effects which cares for digestive system effectively. Bramhi, Sankhapushpi, Vacha etc have Tikta-Kashaya Rasa, Madhur Virya, Sheeta Vipaka with Medhya (increase intellectual) effect; Jyotishmati have Katu-Tikta Rasa, Laghu Guna Ushna Virya although it gives Medhya (increase intellectual) effects.

Chocoherb granules are predominately of Madhur Rasa, Madhur Vipaka, Anushnasheet Virya which provide actions like, Ashvagandha\(^5\), Shatavari\(^6\), Vidarikanda, Jyotishmati, Sankhpushpi, Bringeraj, Kumari, Gajar have are given effect as Balya (increase immunity). Ashvagandha and Vidarikanda have Bruhaniya (well nutrient) effects also. Some herbal drugs are work as Medhya (increase intellectual) like Bramhi, Jyotishmati, Shatavari and Sankhpushpi. Tulsi, Pippai, Pippali mool, Maricha etc are given Dipana – Pachana effects that helps for good digestion and nutrition. Rasayana (restore health) effects given by herbal drugs like Ashvgandha, Shatavri, bramhi, Bringeraj, Kumari etc.\(^7\) (Table 1) Sweet taste is more compatible for children thus granules are prepared with chocolate flavor.

**Conclusion:**
This preliminary study shows improvement in Weight, Height and BMI as well. The overall therapy shows improvement in general health status of malnourished HIV infected teenagers. Chocoherb granules are Combination of herbal drugs which gives effect as Balya (boost immunity), Bruhaniya (well nutrient), Rasayana (restores health), and Medya (increase intellectual) as well. We are still continuing the study with large number of cases along with parameters like CD4 count.

**Limitation of study:**
The sample size is small, and also duration of treatment may be advised for 6 month or more.

**Consent of patients:**
Informed written consent of parents in local language was taken prior study.

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