



RESEARCH ARTICLE

EFFICACY OF POLY HERBO-MINERAL FORMULATION T-AYU-HM™ ON SICKLE CELL DISEASES FROM AYURVEDA

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ARTICLE INFO

Article History:

Received 19th January, 2016
Received in revised form
26th February, 2016
Accepted 18th March, 2016
Published online 26th April, 2016

Key words:

Ayurveda,
Herbs,
Mineral,
Sickle Cell,
Standardization.

ABSTRACT

Sickle Cell Anaemia is a genetic blood disorder caused by abnormal hemoglobin that damages and deforms red blood cells. The abnormal red cells break down, causing anemia, and obstruct blood vessels, leading to recurrent episodes of severe pain and multiorgan ischemic damage. The Indian System of Medicine Ayurveda has valuable information about herbs and mineral for human uses. T-AYU-HM™ is an extract of eight Indian origin herbal plants and three purified minerals. In laboratory studies it strongly inhibits sickling of red cells in patients with sickle cell diseases and it has been shown in initial clinical evaluation in state of Gujarat, India. Preparations and standardizations are as FDA standard. The Antisickling activity of T-AYU-HM™ was evaluated *in vitro* using Emmel test. The poly Herbo-Mineral formulations exhibited attractive antisickling activity, thus, supporting the claims of the traditional healers and suggesting a possible correlation between the chemical composition of Herbo-Mineral and its uses in traditional medicine.

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Citation: Dr. Atul Desai and Dr. Kavita Desai, 2016. "Efficacy of poly herbo-mineral formulation T-AYU-HM™ on sickle cell diseases from Ayurveda", *International Journal of Current Research*, 8, (04), 29829-29831.

INTRODUCTION

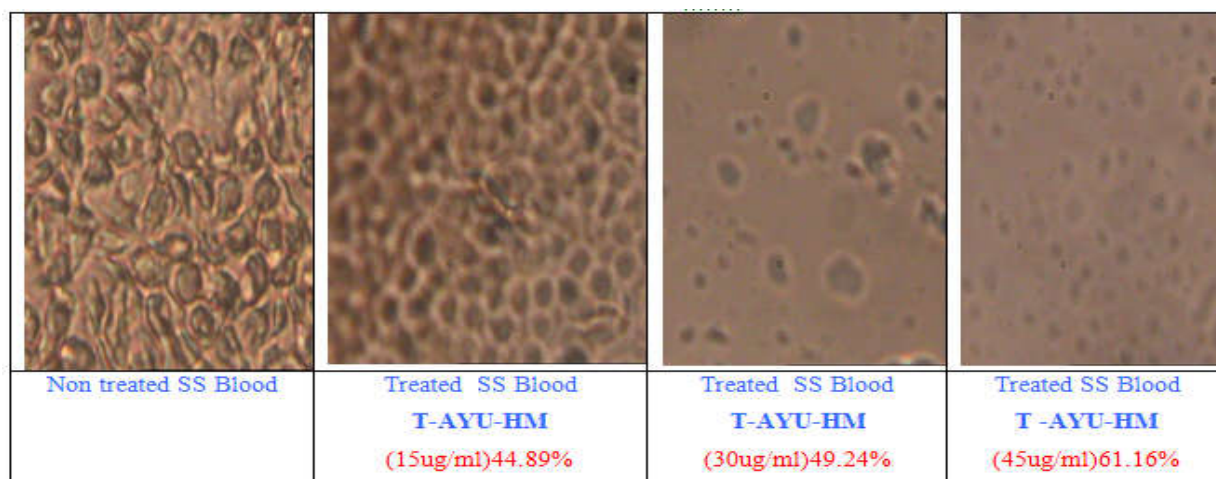
Referring to a recent survey, the sickle cell disease was detected among 1.5 per cent of the total tribal population of South Gujarat and in India more than 2, 00, 00,000 people affected due to Sickle cell. We are from South Gujarat zone and having more than 3000 patients of Sickle cell anemia at our center. The survey of Gujarat state Sickle cell disease programme that prevalence of sickle cell genes has been found to be 31 per cent among the Dodia Patel tribe, 28 per cent in Chaudhary, 31 per cent in Gamit, 27 per cent in Vasava, 28 per cent in Rathwa, 29 per cent in Bhils, 27 per cent among Tadvi, 31 per cent among Naika, 28 per cent among Baria, 20 per cent among Dhanaka, and seven per cent among Kolacha, Kotavadia and Kathodi. Ayurveda remains one of the most ancient and yet living traditions practiced widely in India, Sri Lanka and other countries and has a sound philosophical and experiential basis. *Atharvaveda* (around 1200 BC), *Charak Samhita* and *Sushrut Samhita* (1000–500 BC) are the main classics that give a detailed description of over 700 herbs.

Currently, with over 400,000 registered Ayurveda practitioners, the Government of India has formal strictures AYUSH to regulate issues related to quality, safety, efficacy and practice of herbal medicine. With unique holistic approach, Ayurvedic medicines are usually customized to an individual constitution. Considerable research on pharmacognosy, chemistry, pharmacology and clinical therapeutics has been carried out on Ayurvedic medicinal plants.

Traditional Medicine (TM) is attracting increasing attention within the context of health care provision and health sector reform. The World Health Organization offers the most comprehensive definition. Majority of the population in most developing countries continue to use traditional medicine for their common health needs. Prime issues of concern for attention are: endorsement of TM, validation of efficacy, regulation of safety, standardization of materials and harmonization of practices, professionals' training. This makes new approaches such as Reverse Pharmacology and Systems Biology more attractive, which provide innovation opportunities based on experiential wisdom and holistic viewpoint of TM.

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Morphology of drepanocytes (pretreatment & post treatment with (t ayu-hm) using emmel's test (viewed under 45x magnification)

The working principal involved in the T-AYU-HM™.

- Reduce the pains of Sickle cell Diseases.
- Maintain the Hemoglobin level as per SCA patients' need.
- Reduce crisis episode
- Protect spleen, heart, liver and kidney.
- Promote health and enhance the quality of life.

Preparation and Standardization

T-AYU-HM™ is concave shape tablet of eight Indian origin herbs extract and three purified mineral for use in the pre-clinical evaluation according to traditional practice but with modern techniques. Author has been studying various aspects of T-AYU-HM™ that is requires approval from the Indian Food and Drug Administration. Toxicity studies in animal conducted at Indian Drug Research Association, Pune and the Source of animals are from National Toxicology Centre, Pune. The results shows on mice with the doses used ranging from 1gm/kg to 5.062gm/kg. No mortality was observed up to a dose 5.062gm/kg. Maximum non lethal dose in mice is 5.062 gm/kg. Corresponding non lethal dose in a man of 70kg is 38.7 gm, which suggests a remarkably non-toxic medicine.

Laboratory Studies of T-AYU-HM™

In *Vitro* antisickling effect of T-AYU-HM™ were evaluated at the THE BOMBAY COLLEGE OF PHARMACY KALINA, MUMBAI. The results showed that T-AYU-HM™ s potent antisickling effects on sickle erythrocytes obtained from patients with SCD. The antisickling effect of T-AYU-HM™ is marked. In the absences of T-AYU-HM™, the majority of red blood cells underwent sickling, while in the presents of T-AYU-HM™, sickling of cells are significantly inhibited. The drepanocytary activity of the Herbo-mineral formulation (T AYU-HM™) was 44.89%, 49.24% and 61.16% at concentrations of 15µg/ml, 30µg/ml and 45µg/ml respectively.

Evaluation of T-AYU-HM™

Initial evaluation in randomly selected and a small number of sickle cell disease patients showed no toxicity and the dose

was set as 6-8 mg/kg one BD daily orally in concave tablet. Evaluation was completed on 50 patients[age range 1-50] It demonstrated efficacy including mean decrease in painful crisis [90% during two months] decrease in report of sever pain[90% during two months] Laboratory data showed increasing Hb[38%], maintain Hb[36%]Weight gain was reported and no significant liver or kidney toxicity. In summary, these studies suggest that T-AYU-HM™ appears to be a remarkably effective antisickling drug, well tolerated and non toxic. With T-AYU-HM™, the study showed that clinical manifestations like episode of painful crisis were reduced but also not completely eliminated [similar to hydroxyurea] In spite, the preliminary findings of T-AYU-HM™ suggest that it is potentially a better antisickling agent.

DISCUSSION

Ayurveda, the “science of life,” or longevity, is the holistic alternative science from India, and is more than 5,000 years old.

It is believed to be the oldest healing science in existence, forming the foundation of all others. A constant search is going on to find a substance which can stop sickling of RBCs or which can at least offer lasting symptomatic relief to a patient with sickle cell disease. This multi-ingredient poly herbo-mineral formulation T-AYU-HM™ can be given by multiple routes but preferably by oral route. The formulation when given by Oral route to patients suffering from sickle cell disease provides excellent results; drastically reduces all the symptoms and complications of sickle disease. The need for blood transfusions is also considerably reduced. Increases in the hemoglobin levels were observed when the patients were given this medicine orally.

The novel herbo-mineral formulation described above drastically reduces painful episodes in the sickle cell patients and also protects the vital organs. The formulation has been found to be safe and well tolerated in all the patients. Hence the present invention fills the void in the treatment of sickle cell disease and enhances quality of life of these patients.

Extracts

Herbal powdered extracts along with or instead of plain herb powders have become the industry standard. Extracts can offer a guaranteed potency of more than 3 to 6 times the power of plain herbs. There are 2 approaches to extraction. The common method is to take the active ingredients out of the whole herb. Newer methods to extract the whole plant yet guaranteed potency levels have been developed. This approach is more in line with Ayurvedic thinking because it uses the entire herb. In this method, one receives the properties of whole herb as mother nature has intended. By only using so-called "active ingredients," we are assuming that the other ingredients play no role in the healing process when they may actually prevent side effects or direct the healing effects of the herb to its appropriate site. Thus, the whole plant extract retains the integrity of the herb, ensuring safety and efficacy.

Minerals and Metals (Rasas)

Ayurveda uses many metals in therapeutics. It includes certain *Shodhan* (purification or detoxification) processes to take care of putative toxicity of such heavy metals. Such traditional metal preparations (generally called *Bhasma*) must have the following properties: they should be ultra-fine particles that float on water and one should be unable to recover the metal back from such preparations⁴. A traditional process called *Nirutha* indicates that there should be no elemental forms of metal in the final formulation. Such descriptions in traditional knowledge support the hypotheses that although heavy metals are used in *Bhasma* preparations, the known toxic forms may not remain in the final formulation that qualifies their use for therapeutic purposes

Self-Healing & Self-Realization

The main theme of Ayurveda is that people can adequately educate themselves to take control of their own health. This is achieved by monitoring and balancing ones nutritional and lifestyle habits to heal, prevent illness, and develop longevity. Ayurveda teaches that people are their own best healers. One's intuition is better at discerning subtle health imbalances than relying on another person. All that is needed is some basic guidelines offered by the Ayurvedic practitioner.

Conclusion

- Laboratory studies have confirmed the traditional claim of antisickling effects of T-AYU-HM™ on basis of marked antisickling activity in vitro.

- Laboratory studies have identified that twice a day dosing and increased dose would be expected to improve the clinical efficacy and would be non-toxic.
- Clinical trials have shown preliminary confirmation of the traditional claim of efficacy in reducing sickle cell pain and disability.
- As herbs-mineral complexes are more stable and more interactive as compared to plain herbal (primary or secondary) metabolites, they lead to faster therapeutic action and have a longer shelf life.
- Clinical improvement and the marked antisickling effects in vitro suggest, if confirmed in large trials, that
- T-AYU-HM™ could possibly become a major therapeutic advance for sickle cell disease.

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