

Evaluation of Poly Herbal Formulation in the Management of Acne and Melasma

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Abstract

Acne vulgaris (Acne) one of the most common skin disorders described by non-inflammatory comedones or inflammatory papules, pustules and nodules. Although Acne does not create serious threat to health, it is one kind of socially distressing condition especially for adolescents. Another serious visual problem in human beings is skin darkening of different shapes and at different locations, known as Melasma. It occurs exclusively in sun-exposed areas which results increase of pigmentation. It is brownish to dark in colour, and UV exposure, pregnancy hormonal change; use of oral contraceptives and certain anti-epilepsy drugs aggravate the condition. The conventional therapy for Acne and Melasma includes prolonged use of synthetic chemicals, antibiotics and anti-inflammatory agents that are identified to cause many side effects. Therefore, traditional or herbal formulations are preferred in recent days. In this present study, 60 patients (17 for Acne, 13 for Melasma and 30 for placebo) were taken under a randomized double blind clinical control trial by a polyherbal formulation named MSP-R. After one month of treatment, significant improvement was observed for both cases. So this medicinal plant formulation may be considered as an effective approach to treat Acne and Melasma and its associated complications.

Keywords

Poly herbal formulation, Medicinal plant, Acne, Melasma, MSP-R



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INTRODUCTION

The objectives of this study were to assessment of efficacy of MSP-R formulation in external use by a double-blind placebo controlled study for treatment of Melasma and Acne. As skin is the most exposed organ in the body, it can be exposed to bacteria and plenty of germs that may cause skin disorders. Acne vulgaris is the most common skin disorder, which generally characterized by formation of inflammatory lesions, which results seborrhea, comedones, and presence of certain bacteria in the follicular canal¹. It mainly affects adolescents, though it may present at any age². There are three types of *Acne vulgaris*: non-inflamed lesions, inflamed lesions and scars³. In more severe Acne, nodules and cysts may occur that can cause scarring and psychological distress⁴. Patients are reported to be depressed and have low self-esteem with this disorder⁵. Though the exact cause of Acne is not known, hormonal, bacterial and inflammatory disturbances could be the main factor. Some common over the counter topical medications for Acne are, benzoyl peroxide, salicylic acid, sulfur and resorcinol. Some prescribed topical medications are Clindamycin, Erytromycin,

Tetracycline, Benzoyl peroxide, Retinoids, Alpha Hydroxy Acid, Azelaic acid, Nicotinamide, and Kera-tolytic soaps¹⁰.

Another serious visual problem in human beings is the darkening of skin, which is more prevalent in middle aged and elderly individuals known as Melasma⁶. Melasma is a common acquired pigmentary disorder that occurs usually in women (more than 90% of cases) of all racial and ethnic groups⁹. The main causes of skin darkening (skin hyper pigmentation) are auto immune conditions, sun damage such as UV radiation and ionizing radiation, drug reactions (chemicals), hormonal changes, genetic factors, medications, hormonal therapy or birth control pills resulting in the hyper secretion of melanin from melanocytes^{6,7}. The management of Melasma demands a continuing treatment plan, in addition to avoid the aggravating factors like oral pills and UV exposure along with topical therapy has been considered as the stronghold of treatment. Common side effects of using chemicals to treat these kinds of skin diseases include a mild to moderate sun burning sensation. Persistent redness may also occur and can last for months¹¹. There is a chance of reactivation of herpes simplex

infection in patients with a history of fever blisters^{12, 13}. As the skin becomes fragile, it is important to avoid over exposure to the sun immediately after taking a chemical peel¹⁴⁻¹⁷. Although salicylic acid appears to be one of the wonderful cosmetic ingredients since 1990s, there are genuine safety concerns associated with its extended use¹⁶.

The search for safer alternative in the treatment of Acne and Melasma has given rise to the development of many newer agents, several of them from natural sources. In this present study, MSP-R is a polyherbal formulation is recommended for the treatment of Acne vulgaris and Melasma. Ayurvedic viewpoint encourages the use of multiple herbs in a particular ratio to get better efficacy. The use of multiple herbs in the specific combination also greatly reduces the toxicity of individual herbs. With this view, MSP-R was manufactured at Ichiban Lifetech Solutions LTD, a registered ayurvedic company in Bangladesh. Out of 60 patients who met the entry criteria were randomly assigned to MSP-R (N=30) treatment and other (N=30) considered as placebo. Satisfactory to good results were observed which establishes MSP-R, as a safer and newer addition to treat Melasma

and Acne. This may open up a new era in traditional medicinal system.

MATERIALS AND METHODS

Study design: This study was a randomized, double blind, placebo-controlled clinical trial conducted on the patients suffering from either Acne vulgaris or Melasma, selected from various locations of Dhaka city, as per the ethical guidelines supports from September to October 2010. Ethical approval was taken from the Scientific Research Committee of Govt. Unani Ayurvedic Medical College Dhaka. First, the nature and target of this study were explained for each patient and formal permission was taken from each patient before starting of the therapy, after full explanation about the nature of the disease, course of the treatment with whole procedure, follow up study, prognosis and the need for pre and post treatment photographs. Photographic evaluation was carried out by highly sensitive Sony-Digital, 16.1 megapixels, five times optical zoom camera. Patients were photographed with the same camera, lighting and location after 15 and 30 days of treatment. The whole study was continuously monitored and was under the strict supervision of respective

supervisors. At the end of the Days 30, the overall performance of the MSP-R was evaluated.

Formulation: MSP-R is a polyherbal formulation recommended for the treatment of *Acne vulgaris* and Melasma. It is formulated as per Ayurvedic philosophy and manufactured at Ichiban Lifetech Solutions Ltd, a registered Ayurvedic manufacturer in Bangladesh. For the study, MSP-R is made available in powder form, packaged in highly durable pharmaceutical plastic jar and it contains no artificial colour and

flavour. Each jar contains 40 grams of MSP-R herbal powder. Good agricultural and collection practice (GACP) was followed during the collecting, manufacturing, processing and packaging of the herbal formulation to ensure appropriate and steady quality of medicinal substances. Botanical identification and Ayurvedic criterion of the desired quality were in agreement with the guidelines of Pharmacopeia Standards of Ayurvedic Formulations. **(For composition see Table 1)**

Table 1 Composition of MSP-R

Bengali Name	Botanical Name	Quantity (%)
Botch	<i>Acorus calamus</i>	20%
Lodhbark	<i>Symplocosra cemosa</i>	15%
Kur	<i>Saussure alappa</i>	15%
Shimul	<i>Bombaxmala baricum</i>	10%
Pipul	<i>Piper longum</i>	10%
Saindhablaban	-	15%
Shankha Powder	-	12%
Pearlash	-	3%

Table 2 Patients with Acne treated by MSP-R

Reduction Status	No. of Patients (acne)	Percentage (acne)	No. of Patients (control)	Percentage (control)
No change	0	0%	11	68.75%
Mild Reduction 1%-25%	0	0%	4	31.25%
Moderate Reduction 26% - 50%	2	11.11%	0	0%
Marked Reduction 51% - 75%	4	22.22%	0	0%
Excellent Reduction 75% - 100%	12	66.67%	0	0%
Total	18	100%	15	100%

Table 3 Patients with Melasma treated by MSP-R

Reduction Status	No. of Patients	Percentage	No. of Patients	Percentage
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	(melasma)	(melasma)	(control)	(control)
No change	0	%	14	93.33%
Mild Reduction 1%-25%	2	16.67%	1	6.67%
Moderate Reduction 26% - 50%	3	25%	0	0%
Marked Reduction 51% - 75%	7	58.33%	0	0%
Excellent Reduction 75% - 100%	0	0%	0	0%
Total	12	100%	15	100%

Procedure: After screening, patients were randomly assigned to either MSP-R or placebo in a 1:1 ratio by sequential allocation of randomization number. All the patients were advised to mix one gram of MSP-R powder with adequate volume of water to make a paste and then apply that on the affected area by gentle massaging once daily, during night, before going to bed for a period of 30 days. The subjective improvement evaluation was done by global grading system.

The severity of Acne and Melasma was graded using the following scores:

Score 0 = 0% No change or baseline. (“No improvement”)

Score 1 = 1% - 25% Mild reductions. (“Fair improvement”)

Score 2 = 26% - 50% Moderate reductions. (“Good improvement”)

Score 3 = 51% - 75% Marked reductions. (“Very good improvement”)

Score 4 > 75% - 100% brilliant reductions (“Outstanding improvement”)

All the patients were asked to adhere to “MSP-R” only as the treatment for Melasma

and *Acne vulgaris*, and no other medicated topical application was allowed. Female patients with irregular menstruation were asked to call on a physician and to take prescribed medication to treat the problem before starting to use MSP-R. To minimize the drop out number from the trial, all the patients were followed up for a period of 30 days and they were evaluated on Days 1(1st visit), 15 (2nd visit) and 30 (3rd visit) for subjective improvement in the disappearance of pigmentation lesions (in case of Melasma) and also observed the reduction of blackheads and whiteheads, inflamed pustule areas and overall inflammation (in case of Acne).MSP-R treatment stopped when the improvement has been observed. At each follow-up visit, patients were frequently asked about the frequency of the application. Clinical assessment of pigmentation lesions (in case of Melasma) and reduction of blackheads and whiteheads, inflamed areas and overall evaluations were done subjectively (by the patients).

Figure 1 Acne treated with MSP-R after 15 days and 30 days**Figure 2** Melasma treated with MSP-R after 15 days and 30 days

RESULTS AND DISCUSSION

Out of 18 patients with Acne, 12(66.677%) got outstanding improvement, 4(22.22%) got very good improvement, and 2 (11.11%) got good improvement after treatment, In case of control for Acne, out of 15 patient, 4(31.25%) got fair improvement, while

11(68.75%) got no improvement at all (See **table 2, figure 1**). Out of 12 patients with Melasma, 7(58.33%) got very good improvement, 3(25%) got good improvement, while 2 (16.67%) got fair improvement after treatment. In case of control, out 15 patient, 1(6.67%) got good

improvement, while 14(93.33%) got no improvement at all (See Table 3, figure2)

For Acne, main line of treatment persists on systemic antibiotics and of them tetracycline remains the first choice. The adverse effects include GIT disturbance, hepatotoxicity, photosensitivity and staining of teeth are fairly common²⁰. Melasma is found mostly on the cheeks, forehead, and nose and these patches are irregularly shaped generally. Topical medications transform different stages of melanogenesis. The most common mechanism of action includes inhibition of the enzyme, tyrosinase. Amalgamation therapy is the preferred mode of treatment for the reduction of unpleasant effects. The most popular combination consists of 2% hydroquinone (HQ), a topical steroid, and retinoic acid. Prolonged HQ usage may guide to unpleasant effects like depigmentation and exogenous ochronosis. Tretinoin can be effective in reducing Melasma, it naturally takes at least 24 weeks to see clinical improvement²¹. It may also increase secondary pigmentation which may cause erythema and peeling²¹. Pruritus, mild erythema, scaling, and burning are the mainstay adverse effects of azelaic acid²³. Since the therapy for Melasma and Acne has limitations in recent medicine;

herbal remedies can suggest an alternative therapy for *Acne vulgaris* and Melasma.

The purpose of Ayurvedic herbs is to clean skin and eradicate vitiated *Tridoshas* (Vitiated Humor) from the body as they are mainly responsible for skin disorders and other diseases³². In Ayurveda *Acoruscalamus* is known as *vachaand*, publically known as sweet flag or Bacha. *Acoruscalamus rhizome* contains α and β -asarone, which possess a wide range of pharmacological activities. β -asarone is demonstrated to have antibacterial activity^{25,27}. *A. calamus* rhizomes are measured as to possess aromatic, stimulant, bitter tonic, emetic, expectorant, aphrodisiac, laxative, diuretic, antispasmodic, carminative, and anthelmintic properties²⁸. It also contains anti secretory agents which gives protection to ulcerogenic activity, protective against cytotoxic agents and also has analgesic activity²⁴. It maintains flexibility and youthfulness of the skin and prevents the skin from becoming dry. *Acoruscalamus rhizome* gave high effectiveness in inhibiting the growth of Acne inducing bacteria²⁹. *Symplocosracemosa* is an evergreen Ayurvedic plant, is used for centuries as a menstrual regulator, the

bark is astringent, expectorant, anti-inflammatory, febrifuge, haemostatic, stomachic, constipating and suppurative³¹. It is useful in skin diseases, Acne and pimples³¹, as the antibacterial effect of *Symlococosracemoca* extracts against Acne producing bacteria is successfully analyzed³⁰. *Lodhra* nourishes the skin by decreasing wrinkles which benefits in Acne, and fruitful for other health issues related with skin; because *Lodhra* is an important element in Ayurveda skin packs. It contains antibacterial ingredients; give balmy and soothing effect on the skin and thereby help in healing skin disorders, therefore, is applied to various skin problems like Acne, scalp dandruff, eczema, sunburn, skin blackheads, blemish marks, pigmentation & dark circles. A paste of *Vacha*(*Acoruscalamus*), *Lodhra* (*Symplocosracemosa*) and *Sendha* (Rock-salt) was used from the ancient time in *Kshudrarogachikitsa*(treatment of minor disease) specially for *Yauvana Pidika* (pimples/Acne)³². *Piper longum* showed outstanding antimicrobial properties against *Propionibacterium Acnes*¹⁹. Pearl ash and shankha powder are used as cleansing agent in skin³³.

This study observed significant reduction of

blackheads and whiteheads, in the number of inflamed areas and overall inflammation (in case of Acne) and very good improvement in the disappearance of dark brown or gray patches (in case of Melasma). Similarly, there was enhanced moisturizing and soothing effect along with noteworthy improvement in healing without scratch mark formation. These positive benefits seen in this study might be due to the synergistic action of the constituents of “MSP-R”.

CONCLUSION

Plant-based preparations have stood the test of time for their safety, efficacy, lesser side effects and cultural acceptability. They contain the chemical components which are a part of the physiological functions of living flora and hence they are supposed to have better harmony with the human body. In the recent past, there has been a fabulous increase in the use of herbal health products in developed along with developing countries resulting in an exponential growth of herbal products globally. With the multiple treatment options and the rapidly expanding newer technologies available to researchers, scientists, industrialists, cosmeticians and dermatologists it is important to be aware of gathering

knowledge regarding herbs and their active role in management of such kind of vital skin diseases. Numerous herbs and other natural raw materials have been formulated into cosmetics products and these pure natural cosmetics are devoid of all sorts of artificial agents. Therefore, they are not only free from side effects but also equally effective in comparison to their modern counterparts. The use of natural ingredients in cosmetics manipulates biological functions of skin and provides necessary nutrients for the healthy skin. In conclusion, the present study clearly shows the effectiveness of MSP-R in treatment of Acne and Melasma. This study also reveals the safety and cost-effectiveness of this Ayurvedic poly herbal formulation named MSP-R.

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DISCLOSURES

None

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