Comparative Study of Efficacy of *Hemidesmus Indicus* (L.) R. Br. and *Decalepis Hamiltonii* Wight & Arn. in Acne Vulgaris (*Mukhadushika*)

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Abstract

Hemidesmus indicus (L.) R. Br. (*Sariva*) commonly known as *Anantmool* with its unique attributes is used in therapeutics in Ayurveda. From few decades due to heavy demand and extreme commercial collection from natural habitat of this plant its natural population is decreasing with higher rate and has resulted in extinction of population. In various Ayurvedic raw drug market and in the leading Ayurvedic pharmacies, the roots of *Decalepis hamiltonii* which is considered as *Sariva* species is used in place of the roots of *H. indicus* (*Sariva*) in Ayurvedic formulations. *H. indicus* though is cultivated by special method, still it is very time consuming and expensive process. *D. hamiltonii* is easily cultivated with high yield and less expensive as compared to *H. indicus*. The present study was undertaken to compare the efficacy of *Hemidesmus indicus* (L.) R. Br. and *Decalepis hamiltonii* Wight & Arn. In Acne vulgaris (*Mukhadushika)*and compare its efficacy. On the basis of the observation obtained both drugs relieved symptoms burning sensation (*Daha),* pain *(Vedana),* itching *(Kandu),*erythema*(Lalima)* and Global acne grading scale (GAGS) of Acne vulgaris significantly. As per study it is concluded that tablet (*Ghana Vati*) and Gel of *Hemidesmus indicus* and *Decalepis hamiltonii* are equally effective in the management of Acne vulgaris. Hence *D. hamiltonii* can be used as substitute drug of *Hemidesmus indicus* in the management of Acne vulgaris.

Keywords: *Acne vulgaris, Decalepis hamiltonii, Hemidesmus indicus, Mukhadushika, substitute.*

Introduction

Sariva- Hemidesmus indicus (L.) R. Br. commonly known as *Anantmool*, belonging to family Asclepiadaceae, is a slender, twining or prostrate perennial shrub with cylindrical stems and aromatic roots[1]. They are common in the open deciduous and scrub forest hedges and on degraded sites all over India and Srilanka[2]. The root and root bark are considered as *raktashodhak* (blood purifying), *shothahar* (demulcent), *rasayana* (tonic) and *mutrajanana* (diuretic)[3]. It is used in various skin diseases and in several well known Ayurvedic formulations[4]. *Acharya Charaka* described *Sariva* in six (6) *mahakashayas*. This plant is in heavy demand and natural population is decreasing with higher rate due to extreme commercial collection from natural habitat[5]. *H. indicus* propagation is usually practiced through seeds and has tedious method of collection of root, expensive harvesting and very low yield inspite of adopting special method of cultivation in Bamboo[6].

Decalepis hamiltonii Wight & Arn. belonging to Apocynaceae family, is a climbing shrub with jointed

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branches and cylindrical, fleshy, aromatic roots, found in peninsular India up to an elevation of 1400 m; common in the forests of Western Ghats[7]. The aromatic roots of *D. hamiltonii* are highly prized for their role in preparation of natural cold drinks and Ayurvedic drugs [8]. The *D. hamiltonii* shows the presence of bioactive compounds such as Alkaloids Flavonoids, Phenols, Tannins, Terpenoids and Glycosides[9].

In various Ayurvedic raw drug market *Sariva* species *D. hamiltonii* is sold as *Sariva* instead of *H. indicus*[10]. Nayar and others gathered that in the leading Ayurvedic pharmacies in South India, the roots of *D. hamiltonii* which is considered as *Sariva* species is used in place of the roots of *H. indicus* (*Sariva*) in Ayurvedic formulations[11]. Though *H. indicus* is cultivated by special method, still it is very time consuming and expensive process, *D. hamiltonii* is easily cultivated with high yield and less expensive as compared to *H. indicus*. The essential oil of these two herbs showed a great similarity with chemical components and the actions [12].

Acne is prevalent disease to affect 9.4% of the global population and commonest disease distressing humanity having significant impact on quality of life[13].

In *Ayurveda*, acne has been elaborated as *Mukhadushika* one of the *Kshudra Rogas* (minor ailments) in various texts. Ayurved texts quote that due to vitiation of *Vata* and *Kapha Doshas* and vitiation of *Rakta Dhatu*, *Tarunyapitikas* or *Mukhadooshikas* are produced[14]. Ayurvedic text described *Mukhadushika* with *Saruja* (pain), *Ghan* (firm on touch), *Medogarbha* (filled with oil/sebum) and it has shape like *Shalmali Kantaka* (thorn of *Salmalia malabarica*)[15]. Acharya Sushruta quoted that *Mukhadushika* must be treated by *Vamana (emesis)* and *Lepana*[16].

As per modern science the main causes for acne vulgaris are hormone, bacillary interference and allergic manifestation which directly affect the skin or the pilosebaceous unit so as to produces excess amount of sebum[17]. Most common skin disorder of pilosebaceous unit is Acne vulgaris, which is caused by bacteria *Propionibacterium acnes*, *Staphylococcus epidermis* and *Malassezia furfue*[18].

The roots of *H. indicus* showed strong inhibitory effect on *P. acne* and *S. epidermis* in a study conducted by Kumar and coworkers[19].

Due to the similarity in the chemical components, actions and Ayurvedic properties and the non-availability of the roots of *H. indicus* in large quantity, the roots of *D. hamiltonii* are used in South India as a substitute for the roots of *H. indicus*[20]. Today it is the need to evaluate efficacy of these substitute drugs in clinical trial and use the substitute to get evidences in the Ayurvedic therapeutics. In view of these facts the present study was undertaken to compare the efficacy of *H. indicus* and *D. hamiltonii* on *Mukhadushika* (Acne vulgaris) in view to research in further direction to generate clinical evidences and use it practically in the emerging market.

Methodology

Collection of Field Samples: Field samples of roots of *Hemidesmus indicus* (L.) R. Br. and roots of *Decalepis hamiltonii Wight* & Arn. were collected.

Identification and Authentication of Plant: The field samples collected were identified and authenticated from FRLHT (Foundation of Revitalization of local Health traditions), Bangalore, Karnataka.

Pharmaceutical preparation of drug: The root of *H. indicus* and *D. hamiltonii* was used to prepare *Ghana Vati* (Tablet) and Gel.

Ethics committee approval: After approval from institutional ethics committee (reference no. DMIMS (DU)/IEC/2017-18/6368) on dated 30th March 2017 informed consent was taken from each patient participated in the study.

Clinical Source: The Patients were randomly selected from Kayachikitsa OPD & IPD, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha

Study Design: Single blind interventional study.

Sample Size: Sixty (60) patients.

Materials and Method

Collection of Field Samples: Roots of *Hemidesmus indicus*(L.) R. Br. was collected on from Dapoli, Ratnagiri, Maharashtra and Roots of *Decalepis hamiltonii Wight* & Arn. was collected from Agasti Agroved farms, Sarola Kasar, Ahmednagar, Maharashtra.

Identification and Authentication of Plant: Sample A was identified and authenticated as *Hemidesmus indicus* (L.) R. Br. (Voucher specimen no.-FRLH COL. No. 123401), Sample B as *Decalepis*

hamiltonii Wight & Arn. (Voucher specimen no.-FRLH COL. No. 123403).

[Plate no. 2 & 3]

Pharmaceutical preparation of Drug:

Preparation of Bharad: Field samplecollected of root of *H. indicus* and *D. hamiltonii.* Washed under tap water to remove its physical impurities and dried under the shade. Cut into small pieces and pulverized under no. 10 sieve. *Bharad* (coarse powder) obtained and stored in air tight containers.

Preparation of Ghana Vati (Tablet): Coarse powder of the crude drug was soaked in 8 parts of water overnight. Then heated continuously on low flame until it was reduced to one fourth of its initial quantity. The *Kwatha* (decoction) was filtered through single folded cotton cloth and collected in a separate vessel. Then, the decoction was boiled again over low flame, till a semisolid consistency was obtained. The viscosity of the extract increases, as the water evaporates, resulting in *Ghana* (solid mass).the *Ghana* was mixed with the powder of *Sariva* (up to 10% of *ghana*) further forming a solid mass and it was dried. After drying, the solid mass (*Ghana*) was crushed and granules were prepared and dried in a hot air drier at 40°C. The dried granules were sifted through a no. 20 sieve. Gum acacia (binding agent) and talc powder (lubricant)was used. The formulation was later compressed in a 16 STN single rotor punch tablet press with a target weight of 500mg.

Preparation of Gel:

Phase I: Extraction-The *bharad(coarse powder)* of the crude drug were soaked overnight in sufficient amount of water and extracted by continuous hot extraction method using water (100%).Required quantity of extract was achieved and required amount of sodium benzonate, propyl paraben and methyl paraben were later added. Phase II: Required quantity of Carbomer 934 was soaked in some amount of distilled water for 2 to 3 hrs.

Phase I and II were mixed and adjusted to a pH of 6.8 to 7 with drop wise addition of triethanolamine. The remaining quantity of distilled water was added to make up the final 2000g weight. The formulation was stirred with mechanical stirrer to homogenize and stored in well closed air tight tubes as containers and kept in cool place. (Waghmare N *et al*, 2011).

Inclusion criteria:

1. Patients fulfilling the diagnostic criteria of *Mukhadushika*- Acne vulgaris (facial acne) in 15 to 40 year age group of either sex.

Exclusion criteria:

1. Patients having other dermatological or any other medical problem such as, Rosacea, Folliculitis and boils, Sycosisbarbae, Milia, Peri-oral dermatitis, Acneiform eruption.
2. Patients using any topical acne treatment, topical retinoid, topical and systemic antibiotics, topical any systemic steroids, medicated facial cleansers from 2 weeks prior to the baseline visit and throughout the duration of the study.
3. Patients using facial cosmetic producers (such as laser resurfacing, chemical peel, dermabrasion, etc.) from 6 months prior to the baseline visit and throughout the duration of the study.
4. Patients with any immune compromised disease, uncontrolled diabetes, any systemic illness and structural deformities.

Study Duration: 60 days. Including follow-up period. Assessment of patient was done on the day of Enrollment i.e. 0 day.

Follow Up: On 10^{th}, 20^{th}, 30^{th} day during treatment and on 45^{th} and 60^{th} day after completion of treatment.

Screening Investigation:

1. HB %
2. RBS

Clinical Methodology: The Patients attended Kayachikitsa OPD & IPD, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha with clinical features of *Mukhadushika* were selected for the study. The patients were grouped by simple random sampling method irrespective of their sex, religion and occupation. The informed consent was obtained from each patient before participation in the study. Total 64 patients were registered as per the inclusion criteria and randomly divided into group A and group B by lottery method. Total 60 Patients completed the study, one (01) patient from Group A and three (03) patients from group B withdrawn during study as these patients were not attending regular follow up of scheduled treatment.

Diagnostic Criteria: The parameters for diagnosis of patient include symptoms like *Burning sensation (Daha), Pain (Vedana),* Itching *(Kandu),* erythema *(Lalima)*were selected for the study. Overall Acne (*Pidika*) were assessed by GAGS (Global Acne Grading Scale)[21]. A special proforma was prepared and patients were examined on the basis of available sign and symptoms.

Criteria of Assesment: The patients were assessed on the basis of Subjective and Objective parameters. Severity of disease was assessed by gradation of each criterion. Gradation was done as follows -

Subjective Parameters:

Gradation: 0-None, 1-Mild, 2-Moderate, 3-Severe

1. ***Daha*** **(Burning sensation)**
2. ***Vedana*** **(Pain)**
3. ***Kandu*** **(Itching)**
4. ***Lalima*** **(Erythema)**

Objective Parameter:

Overall rating of Acne was done by GAGS (Global Acne Grading Scale)

Each type of lesion is given a value depending on severity:

No lesions = 0, comedomes = 1, papules = 2, pustules = 3 and nodules = 4.

The score for each area (Local score) is calculated using the formula:

Local Score = Factor x Grade (0-4)

The global score is the sum of local scores and acne severity was graded using the global score. A score of 1-18 is considered mild; 19-30 – moderate, 31-38 – severe and >39 – very severe.

Note: As acne on chest and upper back was not included in the study the local score of the region was not calculated and considered.

Assessment of Results: The assessment of progress was observed after 60 days, after completion of the course of treatment. An assessment scale was framed to assess the rate of improvement. At the end of treatment, the percentage of relief was calculated and classified under the following headings:

1. **Maximum improvement:** More than 75% improvement of the subjective and objective criteria.
2. **Moderate improvement:** 50-75% improvement of the mentioned subjective and objective criteria.
3. **Mild Improvement:** 25-50% improvement of the mentioned subjective and objective criteria.
4. **No Improvement:** 0-25% improvement of the mentioned subjective and objective criteria.

Table No. 1: Intervention for Group A & B

Group	**Group A (Standard Control Group)**	**Group B (Experimental Group)**
Sample Size	30 patients	30 patients
Intervention	Internally Tablet (*Ghanavati)* of *H. indicus* (Hi)	Internally Tablet (*Ghanavati)* of *D. hamiltonii* (Dh)
	Externally *Sariva* Gel of *H. indicus* (GHi)	Externally *Sariva* Gel of *D. hamiltonii* (GDh)
Dose	Tablet (*Ghanvati*)-500mg BD after meal Gel- q.s. local application on infected area at bed time	Tablet (*Ghanvati*)-500mg BD after meal Gel- q.s. local application on infected area at bed time
Duration	30 Days	30 Days
Follow up period	On 10^{th}, 20^{th}, 30^{th} day (During treatment) On 45^{th} and 60^{th} day (After treatment)	On 10^{th}, 20^{th}, 30^{th} day (During treatment) On 45^{th} and 60^{th} day (After treatment)
Total Duration	60 days	60 days

Results

In this study 60 patients who fulfilled inclusion criteria were randomly selected from Kayachikitsa, OPD & IPD of Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha, Maharashtra. The selected patients were categorized in two Groups of 30 patients each. As per proforma prepared, observations were made and statistically presented as follows.

Comparative efficacy of drug on subjective parameters of patients:

Table No. 2 Comparative efficacy of drug on *Daha* (Burning Sensation) of patients:

Daha	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	1	0	-3.782[a]	0.000	91.4	Significant
Group B	1	0	-3.568[a]	0.000	88.6	Significant

Table No. 3 Comparative efficacy of drug on *Vedana* (Pain) of patients:

Vedana	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	2	0	-4.761[a]	0.000	92.2	Significant
Group B	2	0	-4.565[a]	0.000	90.6	Significant

Table No. 4: Comparative efficacy of drug on Kandu (Itching) of patients:

Kandu	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	1.5	0	-3.999[a]	0.000	90.0	Significant
Group B	1.5	0	-3.808[a]	0.000	90.0	Significant

Table No. 5: Comparative efficacy of drug on *Lalima* (erythema) of patients:

Lalima	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	2	1	-4.388[a]	0.000	60.0	Significant
Group B	1.5	1	-4.099[a]	0.000	56.5	Significant

Comparative efficacy of drug on Global Acne Grading Scale (GAGS) Score of patients:

Table No. 6: Comparative efficacy of drug on Global Acne Grading Scale (GAGS) Score of patients:

GAGS Score	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	12.5	4	-4.794[a]	0.000	70.3	Significant
Group B	13	4	-4.791[a]	0.000	66.9	Significant

Discussion

Comparatively in all subjective and objective parameters there was no significant difference between group A and B. (Table No. 4 to 9).

Comparative overall effect of drug in 60 *Mukhadushika* patients, a majority of 51.7% patients were having marked improvement in *Mukhadushika*. While 40% patients benefited moderate improvement and 8.3% had mild improvement in *Mukhadushika*. The entire enrolled patients were benefited with improvement in *Mukhadushika*(Graph no. 1). This shows a strong effectiveness of both the drugs in *Mukhadushika*.

Probable mode of action of drug on Acne vulgaris (Mukhadushika): *Sariva is* having *madhura* (sweet taste), *tikta rasa* (bitter taste), *guru and snigdha guna, sheeta veerya* (cold potency), *madhura vipaka,vata pitta dosha samaka* and t*vakdosahara* (reduce skin disorder), *raktasodhaka* (blood purifier), *varnya* (improving the complexion), *dahaprasamana karma* (reduce burning sensation).

Sushruta explained, *Rakta dhatu Dushti* (blood impurities) is one of the main pathogenic factors of acne formation with other local and systemic pathogenic components related to sexual changes during adolescence.[22] Many authors elaborated that vitiation of *kapha, vata* and *raktadhatu* are main pathophysiological components in the development of *Mukhadushika* (acne). The primary site for acne formation is *Twaka* (skin) so it is included in '*Twagdosha*'.[23]

*Madhura rasa, sheeta veerya, madhura vipaka a*nd *guru - snigdha guna* of *sariva* balances the vitiated *vata dosha.* These attributes helps to minimize the burning sensation andpain in acnes. *Tikta Rasa* acts upon the *pitta dosha* and *rakta dhatu* by performing *raktasodhaka karma* and *twakdosahara karma* which reducesitching over the acnes and helps to detoxify the skin. Though it is *sheeta veeryatmak,* it does not elevate the *kapha dosha*. The *varnya karma* helps to diminisherythma over the acnes. These unique properties present in *sariva* helps in breakdown of pathophysiology of acne vulgaris.

In a study conducted by Kumar and coworkers, the roots of *H. indicus* showed strong inhibitory effect on P.acne and S.epidermis organisms responsible for acne vulgaris.

This clinical study evaluated similar effectiveness of both drugs which is needed to prove *D. hamiltonii* can be used as substitute to *H.indicus*.

Conclusions

The concept of substitute prevailed ages back and in Ayurveda there is need of analysis of this concept with the present trend of substitution so that we can adopt the proper substitute. In case of *Hemidesmus indicus*, comes under the category of substitution of different species, though it is abundantly available naturally in specific region of India, its root collection method is very tedious, time consuming and having low yield, leads to the scarcity of root of *Hemidesmus indicus* in raw herbal market and ultimately use of *Decalepis hamiltonii* which can be easily cultivated having high yield as compare to *Hemidesmus indicus*.

The most essential criteria for substitute is the pharmacological activity rather than morphological. Substitution of herbs achieves many goals through basic idea to provide similar, easily available, cost effective, most appropriate for the clinical condition. In our study *Decalepis hamiltonii* is appropriate drug used as a substitute of *Hemidemus indicus*.

On the basis of study both drugs relieved symptoms burning sensation (*Daha),* pain *(Vedana),* itching *(Kandu),* erythema *(Lalima)* and Global acne grading scale (GAGS) of Acne vulgaris significantly.

As per all observations it is concluded that *Ghana Vati* and Gel of *Hemidesmus indicus* and *Decalepis hamiltonii* are equally effective in the management of *Mukhadushika* (Acne vulgaris). So we can use *D. hamiltonii* as substitute drug of *Hemidesmus indicus* in the management of Acne vulgaris.

Ethical Clearance: Taken from institutional ethics committee.

Source of Funding: Self.

Conflict of Interest: Nil.

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