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Clinical Trial

Title of Article

Comparative Clinical Evaluation of Efficacy of *Siddhartadi Lepa* Given In *Sushrut Samhita* V/S 2.5 % Benzoyl Peroxide on Mild to Moderate Acne Vulgaris

¹ Praddyumna Vaidya ² Dr. Shilpa Revale

¹3rd year BAMS ² Prof. Department of Rachana Sharir, S C Mutha Aryangla Vaidyak Mahavidyalaya Shahupuri, Satara.

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Address for Correspondence:

Dr Praddyumna Vaidya, 3rd year BAMS

Email- Praddyumnavaidya6@gmail.com

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ABSTRACT

The study attempts to investigate the efficacy of *Siddhartadi lepa* given in *Sushrut Samhita* on acne vulgaris. Also to compare the efficacy of *Siddhartadi lepa* with standardized drug which is 2.5% benzoyl peroxide. To empower and authorize the medicine given in Samhita, such experimentation needs to be done, that's why we undertook this study. In addition, the study focused on to standardized the contents of *Siddhartadi lepa*. and to evaluate the efficacy of *Siddhartadi lepa*. This study also focused on comparison of efficacy of *Siddhartadi lepa* with standardized drug. To accomplished the objectives and to evaluate the efficacy of *Siddhartadi lepa*, some hypothesis was set. Final results obtained after study was compared with hypothesis and according to the comparison the conclusions were made. The results obtained from the research was detailed discussed with appropriate statistical analysis, which states that the *siddhartadi lepa* is more effective than standardized drug on acne vulgaris.

Keywords: Siddhartadi Lepa, Benzoyl Peroxide, Acne Vulgaris

INTRODUCTION

Acne vulgaris is a severe condition affecting more than 85% of adolescents and two-third of adults aged 18 years and older (1). Acne vulgaris is the common form of acne characterized by a mixed eruption of inflammatory and non-inflammatory skin lesions (2). Acne vulgaris most often affects face; but it can spread to involve neck, chest and back and in very severe condition it can happen on whole body (2). Acne vulgaris is inflammatory disease of pilosebaceous units characterized by seborrhoea,

comedones, papules sometimes pustules and in chronic condition nodules, pseudocysts and scars are also seen.

Despite of its Apparent cosmetic nature acne harms far deeper than surface of skin, and put heavy emotional and psychological burden on patient, and it is worse than its physical effect (3). The drugs described in *Sushrut Samhita* in *Kshudra Roga* are used in many places for external treatment of various ailments. Skin is a large organ present all over the body. Since cosmetics are applied directly on the skin are get quickly absorbed by the skin (4). Therefore, there is a need of time for the

drugs used on the skin to be very safe. *Siddhartadi lepa* containing vacha (*Acorus calamus*), *lodhra* (*Simplocos*). In the study, we compared *Siddhartadi lepa* with standardized drug to evaluate its efficacy on patience of acne vulgaris. References from *samhitas* should be empower, authorized and proved.

For that purpose, we need to do experiments and collect data, this was done by this study. Through this study, evaluation of the effectiveness of *Siddhartadi lepa* is tested. And a safe, easily available and easy to use alternative is created for the use of society. Therefore, we undertook this study to provide good cosmetic health to society.

METHODOLOGY

Collection of drugs of *Siddhartadi lepa* :-

The drugs used in *Siddhartadi lepa* was collected from authentic source, The *Ayurvediya Arkshala* Pharmacy Satara (Fig. 1). Raw drugs collected from authentic source in quantity of 500 grams each. The drugs

racemosa, *siddharthak* (*Sinapis alba*) and *saindhav* (rock salt) is a remedy on acne vulgaris (5,6,7).

submitted to research and development department of *Ayurvediya Arkshala* Pharmacy, Satara for Standardization.

Standardization of drugs of *Siddhartadi lepa* :-

Drugs used in *Siddhartadi lepa* were standardized in Research and development department of *Ayurvediya Arkshala* Pharmacy, Satara. After Standardization we made fine powder of drugs in sterile environment and make *lepa* ready after mixing equal amount of fine powder of drugs. The *Siddhartadi lepa* made ready in quantity of 2 kilograms. They give us certificate of Standardization of drugs as it is safe to use and standardized in sterile environment and it can be used on patients. The *Siddhartadi lepa* was filled in small containers of 25 grams, after making its fine powder through clothing process and named it as medicine 1 (Fig. 2).

Table 1. Details of the drugs used in *Siddhartadi lepa* :-

Name of drug	Ayurvedic name	Latin name	Family	Guna	Rasa	Veeya	Vipak
Sweetflag	Vacha	<i>Acorus calamus</i>	Araceae	Laghu, tikshna, ruksha	Tikta, katu	Ushana	Katu
Lodhra	Lodhra	<i>Symplocos racemosa</i>	Symplocaceae	Laghu, ruksha	Kashay	Shita	Katu
Mustard	Siddarthak	<i>Sinapis alba</i>	Brassicaceae	Laghu, snigdha	Katu, tikta	Ushana	Katu
Rock salt	Saindhav	---	---	Snigdha, tikshna, shlakshna	Lavan	Shita	Madhu r

Collection of Standardized drug: -

A 2.5 % benzoyl peroxide was finalized to use as standardized drug as it is widely used in treatment of acne vulgaris (11). 2.5% benzoyl peroxide is finalized to be used as standardized drug after discussion with local dermatologist in Satara. 2.5% benzoyl peroxide is purchased from local authorized Pharmaceutical Store (Fig. 3). It is filled in small containers of 25 grams and named it as medicine 2 (Fig. 4).

Sample size: -

30 patients fulfilling inclusion criteria were selected randomly for this study.

Method: -

30 patients taken for the study randomly. We give *Siddhartadi lepa* for first patient, standardized drug for second patient like this in alternative manner to 30 patients.

- 1) All patients of odd patient no. were treated with medicine 1, which is grouped under Group A.
- 2) All patients of even patient no. were treated with medicine 2, which is grouped under Group B.

Group A

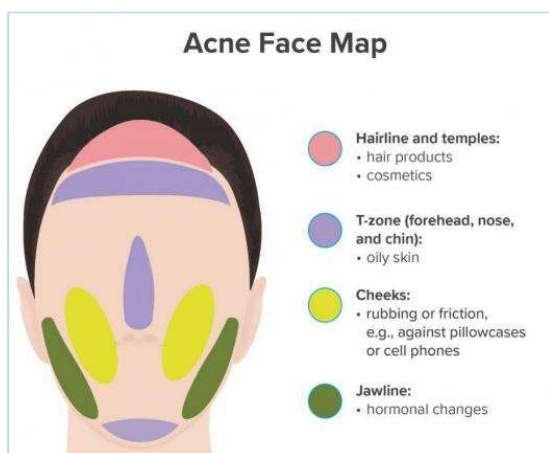
Patients of group A was advised to wash their face with cold water. Take small amount of *lepa* mix it with water and apply at the place of acne on face. Keep *lepa* on face for 15 to 20 minutes. Wash the face with cold water,

After *Prakriti parikshan* of each case taken for study, take photographs of face of patient with proper consent for comparative study. Follow up were taken of the patients of both the groups after every 7 days.

Evaluation scale:

Evaluation of patients were done as follows,

- Mild acne - <20 comedones
<15 inflammatory lesions
Total lesion count <30
- Moderate acne - 20 -100 comedones
15-50 inflammatory lesions
Total lesion count 30-125
- Severe acne - >5 pseudocysts
Total comedo count >100
Total inflammatory count >50
Total lesion count >125



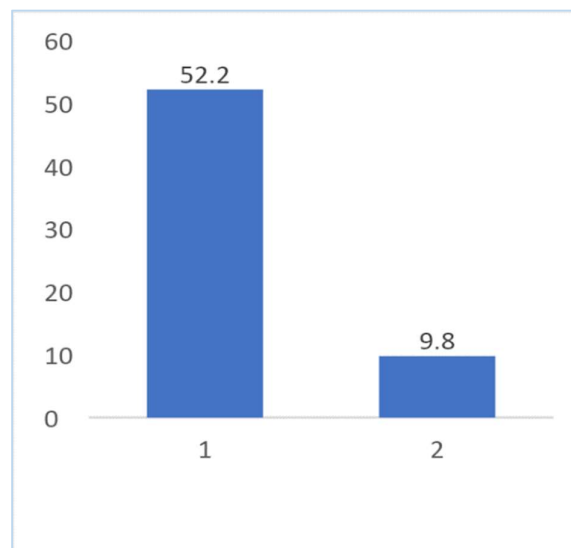
Data collection :-

Data of the experiment was collected on every follow up of patient. Data was collected in patient information sheet. Photographic images of face of patient were taken before treatment and on every follow up for comparative study.

Quality control :-

All drugs were standardized before use. Patients were advised to apply *lepa* on their face with clean hands. The *lepa* given to patient was in sterile container. The study was strictly carried out under the supervision of subject guide. Study was conducted after permission with IEC letter from institutional ethical committee.

Graphical Representation of Before and After treatment of Acne vulgaris with *Siddhartadi lepa* :- Table 3.



X axis:

1 = Mean of Before treatment with *Siddhartadi lepa*.

2 = Mean of after treatment with *Siddhartadi lepa*.

Y axis: No. of total lesions in patient.

Literature review :-

Following literature were concern

Sushrut Samhita: Dr. Ambikadatta shastri

Sarth Bhavprakash: Purushottam nanal vaidya

Bharatbhaishajya Ratnakar: Nagindas chhaganlal shah

Dravyagunavidnyam: Dr. A. P. Deshpande

Astang hrudayam: Vaidya D. P. Gadgil

Charaka samhita: Vaidya Y. G. Joshi

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4318060/>

<https://dermnetnz.org/topics/acne-vulgaris>

<https://www.hmpgloballearningnetwork.com/site/thederm/site/cathlab/event/acne-vulgaristhe-psychosocial-and-psychological-burden-illness>

<https://www.easyayurveda.com/2013/09/30/lodhra-symplocos-racemosa-benefits-usage-dose-side-effects/amp/>

<https://www.easyayurveda.com/2015/03/19/mustard-benefits-types-side-effects-research/amp/>

The contents of *Siddhartadi lepa vacha* (*Acorus calamus*), *lodhra* (*Symplocos racemosa*), *siddharthak* (*Sinapis alba*), and *saindhav* (Rock salt) were standardized in authorized research and development department of *Ayurvediya Arkshala Pharmacy*, Satara

Figure 1 :- sample of raw drugs.



Figure 2 & 3: Prepared medicine 1 (Siddhartadi lepa) and Prepared medicine 2 (standardized drug)



DISCUSSION

The results obtained from study after statistical analysis supports the alternative hypothesis. There is a mark difference in efficacy of *Siddhartadi lepa* and standardized drug on acne vulgaris. We compared the average of total lesion count before treatment and after treatment of acne vulgaris with *Siddhartadi lepa* for analysis.

On an average 52.2 count of total lesions are present before treatment in group A, which is treated with medicine1, and after treatment the total lesion count found is 9.8 only. It states that treatment with *Siddhartadi lepa* cures approximately 82% of acne vulgaris. The results are drawn by graphical representation in table 3. For comparison of treatment of *Siddhartadi lepa* v/s 2.5% benzoyl peroxide, we treated 15 patients of group A with medicine 1, and 15 patients of group B with medicine 2. *Siddhartadi lepa* was found more effective in curing acne vulgaris.

Siddhartadi lepa succeed in curing approximately 82% of acne and standardized drug cured only approximately 21% of acne vulgaris. In 5 cases inflammatory lesions increased after application of benzoyl peroxide, it irritated the skin of patients. We treated patients of acne vulgaris for 2 months with *Siddhartadi lepa* and it cured comedones and inflammatory lesions, but scars on face due to acne are not cured during this period. If *siddhartadi lepa* applied for more days it will definitely cure scars.

It is found that the people having acne vulgaris are mostly between the age group of 18 to 23, which is a period just after the puberty. Out of 30 patients taken for study, 22 patients found were of *pitta* dominating *Prakriti*.

The people having *Prakriti* of dominating *pitta* are facing more problems of acne vulgaris is seen during study. The *Siddhartadi lepa* containing *vacha* (*Acorus calamus*), *lodhra* (*Symplocos racemosa*), *Siddharthak* (*Sinapis alba*) and *saindhav* (rock salt). In which *vacha* suppresses the primary and secondary phase of inflammation significantly (8). So, it can help to reduce inflammation in lesions of acne vulgaris. *Vacha* is a *lekhan dravya* (9). Which helps to cure acne vulgaris and reduces the reoccurrence of acne. *Vacha* is *bhutaghni* (12), so it helps to clear infection in skin. *Vacha* is *ushna* (9), so it can help to clear *avarodh* of *swedvaha strotas* in skin, to reduce inflammation. *Lodhra* is anti-inflammatory drug, which helps to reduce inflammation, charak mentioned *lodhra* in *kushth* treatment, it relieves *Kitibh*, *kandu*, ringworm, pruritis, keloids, *vicharchika* and *eczema* (9). *Lodhra* and help to make glowing skin (10). *Lodhra* is *ruksha* (8), so it helps to put skin dry which reduces the chance of bacterial growth. *Sinapis alba* helps to treat the skin disorders involving itching and pain. *Siddharthak* is *ushna* (12), so it can help to *shaman* of *vata* in skin and relieves from itching and pain. The properties of all drugs used in *Siddhartadi lepa* improves skin texture and reduces acne, so it is best remedy for acne vulgaris.

CONCLUSION

The results obtained from the study supports the hypothesis, that there is a mark difference in before treatment and after treatment of acne vulgaris with *Siddhartadi lepa*, hence *Siddhartadi lepa* is mark effective in acne vulgaris. The average count of total no. of lesions in acne vulgaris is 52.2 before the treatment with *Siddhartadi lepa* and is reduced on an average to 9.8, Hence it is proved that the treatment is mark effective. The results also support the hypothesis that the efficacy of

Siddhartadi lepa is more than standardized drug. *Siddhartadi lepa* cured approximately 82% of acne, whereas standardized drug cured approximately 21% of acne vulgaris.

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