

An International Journal of Research in AYUSH and Allied Systems

Research Article

RANDOMIZED CLINICAL TRIAL TO STUDY THE EFFECT OF *KUNJAL KRIYA* AND *GUDUCHYADI KWATH* IN *MANDAL KUSHTHA* (PSORIASIS)

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Article info

ABSTRACT

Article History: Received: 19-11-2024 Accepted: 02-12-2024 Published: 15-01-2025

KEYWORDS:

Kunjal, Mandal Kushtha, PASI Score, Guduchyadi Kwath, Psoriasis.

The skin diseases, in Ayurveda, have been described under the umbrella of Kushtha which is further divided into Maha Kushtha and Kshudra Kushtha, All Kushtha have Tridosha involvement. Mandal Kushtha is Kapha predominant disease. Swetarakta (faint reddish white), Utsannamandalam (raised patches), Sthiram (stable), Snigdham (unctuous), Annyonyasansaktam (patches joined with each other) are important clinical features of Mandal Kushtha. Since characteristic features of psoriasis are much closer to Mandal Kushtha hence Mandal Kushtha is compared with psoriasis. Aim and Objectives: The aim of this study was to evaluate the effect of Kunjal Kriya and Guduchyadi Kwath in Mandal Kushtha. Materials and Methods: The study was conducted on the subjects of Mandal Kushtha registered in OPD and IPD of NIA Hospital, Jaipur. The 30 subjects who fulfilled the inclusion criteria of the study were randomly selected by clinical and systematic examination; divided into two groups with 15 each, Group A: Kunjal Kriya (empty stomach in the morning) followed by Panchanimba Churna (orally 3 gm, twice daily, after meal with milk) was given for 2 months) & Group B: Guduchyadi Kwath 20 ml (empty stomach in the morning) followed by Panchanimba Churna (orally 3 gm, twice daily, after meal with milk) was given for 2 months. Results: On comparing both groups on subjective parameters, overall relief was seen more in Group A compared to Group B. Relief % in Varna- In Group A showed 42.42% whereas in Group B showed 24.14%. Kandu - In Group A showed 68.75% whereas in Group B showed 43.33%. Akriti- In Group A showed 16.28 % whereas in Group B showed 12.50%. Daha -In Group A showed 47.22 % whereas in Group B showed 28.13%. Texture of lesions - In Group A showed 76.19% whereas in Group B showed 62.50 %. Distribution of patches – In Group A showed 11.63 % whereas in Group B showed 14.29%. PASI Score - In Group A showed 59.69% whereas in Group B showed 38.14%. Discussion: Contents of Guduchyadi Kwath have potent anti-inflammatory, immuno-modulatory and antioxidant properties thereby playing a key role in reducing inflammation. While Kunjal Kriya facilitated the expulsion of morbid material which generally don't get excreted out through the mucosa of gut and also probably helped in the regulation of Autonomic Nervous System as well as gene expression Conclusion: Kunjal Kriya is more effective than Guduchyadi Kwath in the management of Mandal Kushtha with special reference to psoriasis.

INTRODUCTION

In Ayurveda, the skin diseases have been described under the umbrella of "*Kushtha*" which is further divided into *Maha Kushtha* and *Kshudra Kushtha*.^[1] All *Kushtha* have *Tridosha* involvement.^[2] *Mandal Kushtha* is *Kapha* predominant disease^[3].

The aetiology of *Mandal Kushtha* can be understood on the basis of general aetiology of *Kushtha. Swetarakta* (faint reddish white), *Utsannamandalam* (raised patches), *Sthiram* (stable), *Snigdham* (unctuous), *Annyonyasansaktam* (patches joined with each other) are important clinical features of *Mandal Kushtha*^[4]. Since characteristics features of

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Psoriasis are much closer to Mandal Kushtha hence Mandal Kushtha can be compared with psoriasis.

Psoriasis is a chronic, genetically determined inflammatorv disease that is triggered bv environmental factors characterized by raised areas of abnormal skin^[5]. These areas are red and may be purple in some people with darker skin and are dry, itchy, and scaly. It varies in severity from small, localized patches to complete body coverage. Its prevalence is 0.44-2.8% in India^[6] with global range between 0.09% to 11.43% [7].

Kunial^[8] is one of the subtypes of Dhauti ^[9] (one of the six cleansing techniques of Shodhan in Hatha Yoga). Amashava is the seat of Kapha and Pitta so *Kunial Kriva* evacuates the vitiated *Kapha* and *Pitta*. This action directly affects the pathology of *Kushtha* as mentioned in Hatha Yoga classics. It is a mild procedure therefore it can be practiced daily.

Kwath^[10] Guduchvadi mentioned in Yogaratnakara, containing *Guduchi* along with Triphala, Daruharidra and Guggulu, is indicated in skin diseases, injury and swelling. Guggulu has antiinflammatory properties. Triphala has Tridoshshamak properties. Daruharidra has Tikta and Kashava Rasa and has Kapha and Pittahara properties.

Churna^[11] Panchanimba mentioned in Yogaratnakara, containing Nimba, Pippali, Maricha, Bhallataka, Aragwadh, Khadira, Bhringraj, Haridra, Gokshuru, Avalguj, Vidanga. Vijavsara, Shunthi, Chakramard, Lauh-bhasama, Chitraka, and Sharkara is indicated in skin diseases, Mahakshava and longevity. SHD

NEED OF THE STUDY

Mandal Kushtha or psoriasis is a difficult to cure disease as per Avurveda as well as modern means of treatment. Kushtha or skin diseases are chronic and Kashtasadhya. It affects cosmetically which disturbs the patient from psychological point of view. Treatments and procedures in modern medicine are very costly and fraught with excessive adverse effects to liver, kidney, bone marrow and skin itself. Modern drugs basically involve steroids which are known for their long-term side effects and withdrawal effects. Moreover, after spending years and money, satisfactory results are not obtained. Natural and nontoxic treatment approach is a good way to bring skin back to normalcy without above mentioned adverse effects. Regular Sanshodhana is indicated in Kushtha. Kunjal is a non-bothersome Yogic Kriya and could be done at home, once taught under proper supervision and could prove to be a milestone in treating psoriasis.

MATERIALS AND METHODS

Ethical consideration

• After thorough discussion on ethical aspects related to present study, it was approved by IEC, National Institute of Avurveda, Jaipur vides letter number IEC/ACA/2021/02-48: dated 01-09-2021 and CTRI registration was achieved with Number CTRI/2022/07/043831.

Selection of cases

The study was conducted in the subjects of Mandal Kushtha registered in OPD and IPD of NIA Hospital, Jaipur, who fulfilled the inclusion criteria of the study and were randomly selected, irrespective of religion, occupation & socio-economic status by clinical and systematic examination. Details of trial were explained to all subjects and written consent of each subject was taken on prescribed proforma.

 30 subjects were selected from OPD and IPD of NIA Hospital, Jaipur, and divided into 2 groups namely, Group A and Group B. Each group had 15 subjects.

Inclusion Criteria

- Subjects between 18 to 60 years of age.
- Subjects with the classical features of Mandal • Kushtha.

Exclusion Criteria

- Pregnant, menstruating women and lactating mothers.
- Subjects who suffered from other systemic or skin disorders.
- Subjects who were taking any other medicine for Mandal Kushtha.
- Especially for Kunjal; abdominal hernia, recent abdominal surgeries, glaucoma, hypertension, abdominal tumour.

Sample size

• Sample size of 30 was selected for the present study, with 15 subjects in each of the 2 groups.

Randomization

Randomization was done using computer generated randomization method. Randomization plan was generated on www.randomization.com. Simple Random Sampling (SRS) was adopted for selection of inclusion of subjects.

Blinding and Allocation concealment

It was an open label study and no blinding was done. Allocation concealment was done with the help of sequentially numbered, opaque, sealed envelopes. Randomization sequence generated was sealed in opaque envelopes by an independent person not involved in the study. The envelopes were then sequentially numbered and cases were enrolled following the number.

Consent of patients

Details of trial were explained to all subjects and written consent of each subject was taken on prescribed proforma.

Grouping

30 subjects of *Mandal Kushtha* registered in OPD and IPD of NIA Hospital, Jaipur, who fulfilled the inclusion criteria of the study were randomly selected, irrespective of religion, occupation & socio-economic status by clinical and systematic examination

Group A: 15 clinically diagnosed patients of *Mandal Kushtha* (psoriasis) were treated with. *Kunjal Kriya* (Empty stomach in the morning) followed by **Trial Drugs and Intervention** *Panchanimba Churna* (orally 3gm, twice daily, after meal with milk) was given for 2 months. **Group B:** 15 clinically diagnosed patients of *Mandal Kushtha* (psoriasis) were treated with *Guduchyadi Kwath* (orally, 20ml, twice daily, before meal with lukewarm water) followed by *Panchanimba Churna* (orally 3gm, twice daily, after meal with milk) was given for 2 months.

Table 1: Guduchyadi Kwath Ingredients							
S.No.	Name	Botanical Name	Part Used	Quantity			
1	Haritaki	Terminalia chebula Retz	Fruit pulp	1 Part			
2	Vibhitaki	Terminalia bellirica Linn	Fruit pulp	1 Part			
3	Amalaki	Emblica officinalis Gertn	Fruit pulp	1 Part			
4	Amruta	Tinospora cordifolia Willd	Stem	1 Part			
5	Daruharidra	Berberis aristata DC	Stem	1 Part			
6	Guggulu	Commiphora wightii Arnott	Resin	3g/100 ml			

Kunjal-Kriya- After emptying the bowel in the morning, subjects were advised to sit in *Kaagasana* or similar sitting posture followed by drinking of 1 to 1.5 litre of saline lukewarm water (concentration of 1 tsf of epsom salt in 1 litre potable water). After that subjects were advised to stand up and lean forward with gentle tickling of uvula or the back of the tongue with the help of middle and index fingers (nails properly trimmed), this helped them to vomit the saline water which had been drunk. Three to four attempts were required to clear most of the water from the bowel. They were advised not to eat anything for 30 minutes after the *Kriya*. The *Kriya* was advised on daily basis except for women during their menstruation.

Outcomes

• Primary Outcome

Changes in PASI Scores.

• Secondary Outcome

Changes in classical sign and symptoms- Kandu, Daha, Vaivarnya.

Criteria for Assessment

Subjective criteria

• Assessment was done on the basis of classical signs and symptoms and PASI scores before treatment, after treatment and on the last follow up.

Subjective parameters were framed to assess the clinical response in the subjects.

Subjective parameters

Varna (Colour) of patches; Rating Scale

- 0 Normal color
- 1 Shwetabh (Whitish)

2 - *Shwet-Raktabh* (Reddish-white)

3 - Raktabh (Reddish)

Kandu (Itching); Rating Scale

0 - No Itching

1 - Mild itching comes occasionally, duration- 2 to 3 min.

2 - Moderate itching occurs frequently, 3-4 times in a day, duration-3 to 10 min.

3 - Severe itching occurs frequently, more than 4 times in a day, each episode lasting more than 10 min.

Daha (Burning); Rating scale

- 0- No burning
- 1- Mild burning, no intervention required

2- Moderate burning, 3 to 4 times in a day; cream or emollients soothes burning.

3- Severe burning, more than 4 times in a day; cream or emollients required many times to soothe burning.

Akriti (Shape); Rating Scale-based on size and number.

- 0 No Mandal
- 1 2 to 4 *Mandal*, smaller than a rupee coin.
- 3 2 to 4 *Mandal*, larger than a rupee coin.
- 4 ->4 *Mandal*, bigger than a rupee coin.

Texture of Lesion

- 0 Normal
- 1 Erythematous patch
- 2 Plaques covered with scales
- 3 Erythematous plaques covered with scales

Psoriasis Area and Severity index – PASI Score

The Psoriasis Area and Severity Index is quantitative score for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

1. Psoriasis Area and Severity Index (PASI) Score Investigation for Screening

- SGOT, SGPT
- Blood urea, serum creatinine

Routine examination and assessment

The full details of history and physical examination of patient were recorded as per the **OBSERVATIONS AND RESULTS**

proforma. Clinical and physiological assessment was done before treatment and at the end of the treatment and the results were analysed with appropriate statistical tests.

Statistical Analysis

Results were calculated by using Software: In Stat Graph Pad 3 (version 3.10).

For Non-parametric Data Wilcoxon matched-pairs signed rank test was used for the calculation of results in each group.

Inter group comparison; Mann-Whitney Test was used.

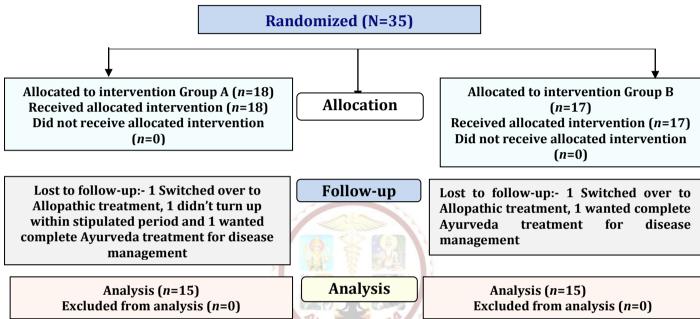


Chart 1: CONSORT flow diagram

Assessment of therapy: Among 35 patients registered for the present clinical trial, 30 patients completed the total trial duration, while 05 patients dropped out during the study. Hence result had been calculated from 30 patients. The effectiveness of therapy was assessed in two steps using statistical methods. The first step was to evaluate each group separately before and after treatment. In the second step, the inter-group or between-group evaluations of both therapies were performed.

5					
P Value	Wording	Summary			
<0.0001 to 0.001	Extremely Significant	ES			
0.001 to 0.01	Very Significant	VS			
0.01 to 0.05	Significant	S			
>0.05	Non-Significant	NS			

Table 3: Intragroup comparison of therapy's effect on Subjective Parameters- Grp A

Group- A									
Symptome	NT	Mean		D:f	% of	SD	CE	D	р
Symptoms	N	BT	AT	Dif.	Change	3D	SE	Р	R
Varna (color) of patches	15	2.20	1.27	0.93	42.42	0.46	0.12	0.0002	ES
Kandu (Itching)	15	2.13	0.67	1.47	68.75	0.74	0.19	0.0001	ES
Akriti (Shape)	15	2.87	2.40	0.47	16.28	0.74	0.19	0.0625	NS

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Texture of lesion	15	2.40	1.27	1.13	47.22	0.74	0.19	0.0002	ES
Daha (Burning sensation)	15	1.40	0.33	1.07	76.19	0.59	0.15	0.0002	ES
Distribution of patches	15	2.87	2.53	0.33	11.63	0.72	0.19	0.2500	NS
PASI Score	15	14.14	5.70	8.44	59.69	5.38	1.39	< 0.0001	ES

Table 4: Intragroup comparison of therapy's Effect on Subjective Parameters Grp-B

Group- B									
с .	NT	Ме	Mean		% of	CD	CE	D	D
Symptoms	Ν	BT	AT	Dif.	Change	SD	SE	Р	R
Varna (color) of patches	15	1.93	1.47	0.47	24.14	0.64	0.17	0.039	S
Kandu (Itching)	15	2.00	1.13	0.87	43.33	0.35	0.09	0.0002	ES
Akriti (Shape)	15	2.67	2.33	0.33	12.50	0.72	0.19	0.2500	NS
Texture of lesion	15	2.13	1.53	0.60	28.13	0.74	0.19	0.0156	S
Daha (Burning sensation)	15	1.07	0.40	0.67	62.50	0.62	0.16	0.0039	VS
Distribution of patches	15	2.80	2.40	0.40	14.29	0.83	0.21	0.2500	NS
PASI Score	15	11.41	7.06	4.35	38.14	4.95	1.28	< 0.0001	ES

Table 5: Intragroup comparison of therapy's effect on Subjective Parameters

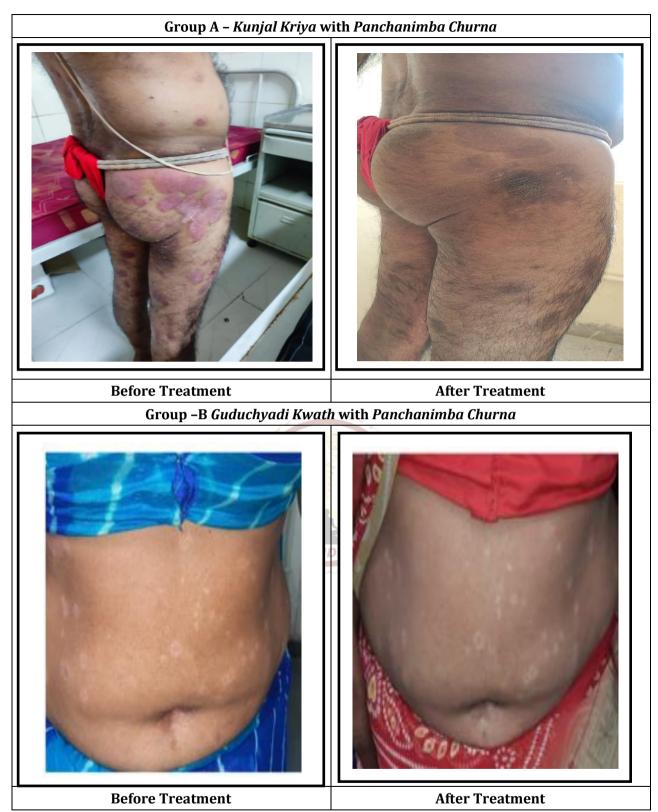
Variables	Mean Diff. Grp A diff - Grp B diff. Diff	SD± Grp A diff - Grp B diff. Diff	SE± Grp A diff - Grp B diff. Diff	U	Р	R
Varna (color) of patches	0.47	0.18	0.05	155.0	0.03	S
Kandu (Itching)	0.60	0.39	0.10	165.5	0.009	VS
Akriti (Shape)	0.14	0.02	0.00	125.5	0.50	NS
Texture of lesion	0.53	0.00	0.00	156.0	0.05	NS
Daha (Burning sensation)	0.40	0.03 AR	0.01	149.5	0.08	NS
Distribution of patches	0.07	0.11	0.02	114.0	0.95	NS
PASI Score	4.07	0.42	0.11	179.5	0.0058	VS

Intergroup Comparison on Subjective Parameters of Both Groups

Table 6: Showing the % age of relief in both the groups in Subjective Parameters							
Subjective Parameters	% Relief in Grp A	% Relief in Grp B					
Varna	42.42	24.14					
Kandu	68.75	43.33					
Akriti	16.28	12.50					
Daha	47.22	28.13					
Texture of lesion	76.19	62.50					
Distribution of patches	11.63	14.29					
PASI Score	59.69	38.14					

Table 7: Extent of Relief according to percentage in 2 groups

% of relief	Category of relief	Group A	Group B
Less than 25%	No relief	2	8
25 to 50%	Mild relief	10	5
50 to 75%	Moderate relief	3	2
More than 75%	Complete relief	0	0



DISCUSSION Mechanism of *Kunjal*

Treating gastric mucosa with saline enhances blood flow (also due to warm water, causing vasodilation), mucous secretion, mucosal proliferation and reduced acid secretion.^[12] Thus helping to increase the surface area for absorption of nutritive contents of further feeds and reducing damage to the GIT mucosa. This explains the improvement in digestive fire or *Jathragni. Kunjal* therapeutically created mild inflammation which helped in quick absorption of the saline in initial phase. *Kunjal*, thereby facilitated the

expulsion of the morbid materials, which generally do not get excreted out through the mucosa of gut.

Multiple neurological centers participate in the complex autonomic reflex of vomiting. The main regulator of vomiting is Vagus Nerve with coordination of Nucleus Tractus Solitarius (NTS) with brainstem vestibular centers, sensory and emotional areas, area postrema and several other areas of the brain. Vagus Nerve orchestrates the Vomiting Reflex.

Intramuscular array (IMA) and intra-ganglionic laminar ending (IGLE) are the two vagal afferent mechanoreceptors from the stomach that respond to smooth muscle contractions and distension along with functioning as tension receptors^[13].

Through; Nodose and jugular ganglion, the mechanical information is carried by the vagal afferents from stomach to the Nucleus Tractus Soltarius.^[14] The NTS is connected with stomach through vagal afferent mechanoreceptors. It has neurological connections with the corresponding areas for control of respiration^[15] as well as for the sensory and emotional areas of brain, and the brainstem vestibular centers^[16].

NTS is also connected with area postrema that serves as the chemo-sensor, which detects any chemical change in the blood. NTS sends signals to the Vagal dorsal motor nucleus after distension of the stomach to initiate vomiting. Acid production is reduced and there is relaxation of gastric wall tone due to decline in neuronal firing of afferents ^[17,18].

NTS, through its monosynaptic connections with the caudal and ventral respiratory group, signals to increase the functions of diaphragm^[19]. NTS signals vasculature of lungs, smooth muscles of respiration and sub-mucous glands, concurrently^[20] to aid in improving expiration, mucosal clearance, diffusion of oxygen into the vasculature and easing of airway resistance, through nucleus ambiguous^[21]. Improved oxygenation reduces and clears free radicals which are a major cause of disease aggravation and relapse.

Thus regular *Kunjal* could help in emotional stability, improving gustatory perception and satiety and thereby reducing excessive *Kapha* and sentimental disturbances which are reasons for relapses and aggravation of the disease^[22]. Yogic practices have proved to be beneficially effective in regulation of the autonomic nervous system as well as gene expressions. As psoriasis is a genetic disease with 9 loci, PSOR1 to PSOR 9 being responsible for the pathogenesis of the disease, *Kunjal* may play an important role in regulating the disease expressing genes^[23].

Probable mode of action of trial interventions based on Ayurvedic principles

Guduchyadi Kwath: Guduchyadi Kwath, described by Yogaratnakara includes 6 ingredients, namely: Guduchi, Haritaki, Vibhitaki, Amalaki, Daruharidra, and Guggulu.

1) Effect on Dosha

- 83.33% have *Tikta-Kashaya* and 50% drugs have *Katu Rasa* dominancy which are *Kaphashamaka*.
- 83.33% drugs have Ushna Virya and 66.66% of drugs have Katu Vipaka which is also Kaphahara.
- According to Dosha Shamana property, 50% drugs have Tridoshaghna property and 33.33% drugs have Kaphapittahara, 16.33% have Pittakaphahara and Kaphavatahara property. Taking into account Tridoshik nature of Kushtha and the above properties of the drugs, the symptomatic relief in Kandu and Rukshata was achieved. So, this medicine is effective on Tridosha.

2) Effect on Dushya

- Guduchyadi Kwath has 83.33% Ruksha and 66.66% Laghu Guna through which it would have acted as Kaphashamaka, 16.66% have Vishada Guna that acts by reducing Pichchhila Guna of Kapha. Tikshna Guna was 16.66% which helped in eradicating disease from deeper Dhatu and 16.33% have Sheet Guna. Thus, it could have helped in Dahaprashamana. 33.33% have Guru Guna which would have a counter-productive function keeping in mind the Kaphaja nature of the disease.
- This formulation also contains *Triphala* which acts as *Pitta Virechaka* helping in *Daah* and also acts as *Rakta Shodhaka* which is one among *7 Dushya*.
- In this Kwath, 83.33% of drugs are having Tikta-Kashaya Rasa and 50% have Katu Rasa which do Lekhana of Pravriddha Mamsa Dhatu.

3) Effect on Srotas

 In this formulation, many components have a quality of *Srotomukha Sodhana* so they removed *Sanga* type of *Srotodusti* and purifies the channels.

4) Effect on Aama

 Most of drugs have Dipana, Pachana, Laghu, Ruksha and Tikshna properties which are helpful in removing the free radicals and enhance the Aamapachana process.

5) Effect on Vyadhi

 Many drugs are *Kushthaghna* and *Kandughna*, so, they have effect on *Mandal Kushtha* symptoms and aetiology.

- Krimi is mentioned as causative factor of Kushtha.
 So, Krimighna Dravya of this medicine have effect on Krimi.
- Most of drugs have Katu-Tikta- Kashaya Rasa; Laghu, Ruksha and Tikshna Guna in nature. So, they have effect on Mandal Kustha
- In Guduchyadi Kwath few drugs i.e., Haritaki, Amalaki, Guduchi are considered Rasayana, thus opening channels and performing Dhatuposhana. Haridra is considered a very potent antiinflammatory and Guggulu has anti-inflammatory as well as Lekhaniya Karma. Guduchi through its Medhya property helps in relieving psychosomatic component of the disease as well being an immunomodulator, it helps in remission and symptomatic relief in a subject suffering from a chronic disease.

Guduchyadi Kwath- It is made from six components viz. *Guduchi, Guggulu, Daruharidra, Amalaki, Haritaki* and *Vibhitaki* which has specific pharmacological properties. By these properties probable mode of action is described below:

- 1. *Guduchi-* It has anti-inflammatory, anti-oxidant, anti-allergic, anti-leprotic, hepatoprotective and immune-modulatory activities.
- 2. *Guggulu* It has anti-inflammatory, anti-oxidant, anti-allergic and anti-septic activities. It is also very effective in regulation of disturbed lipids.
- Daruharidra- Berberine, an isoquinoline alkaloid, has an anti-inflammatory action mediated via COX-2 (this enzyme plays a critical role in prostaglandin synthesis, which is enhanced in inflammation), regulation. The plant's berberine component has pharmacological activity and is employed as an antibacterial, anti-inflammatory, hepatoprotective, immunomodulatory, and anti-depressant agent in many medical systems.
 3.
- 4. *Amalaki –Amalaki* has immunomodulator activity, anti-inflammatory, anti-bacterial and anti-oxidant activity.
- 5. *Vibhitaki* It has an anti-microbial activity.
- 6. *Haritaki- Haritaki* has wound healing activity, anti-oxidant activity, anti- allergic activity and anti-inflammatory activity.

Although many diseases have features similar to psoriasis but the maximum resemblance of major features closely co-relate with *Mandal Kushtha*.

CONCLUSION

Mental stress and psychological condition play a vital role in the production, relapse and aggravation of the disease. Plaque psoriasis was most commonly found in the study group. This disease aggravated in winter season in most of the cases. *Kunjal Kriya* proved way ahead of *Guduchyadi Kwath* in the management of *Mandal Kushtha* i.e., psoriasis in this case. On comparison of improvement in the both the groups, it was observed during the studies that the percentage of relief was much higher and significant in Group A (*Kunjal Kriya* along with *Panchnimba Churna*) as compared to Group B (*Guduchyadi Kwath* along with *Panchnimba Churna*). No untoward adverse effects were observed during and after the research trial. Therefore it can be categorically stated that *Kunjal Kriya* is very effective in the management of *Mandal Kushtha* (psoriasis) and provides a safe, cost effective and side effect free mode of therapy.

Financial support and sponsorship

This study was financially supported by National Institute of Ayurveda, Deemed to be University (*De novo*), Jaipur, Rajasthan, India.

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Cite this article as: Pankaj Rai, Chhaju Ram Yadav, Durgawati Devi. Randomized Clinical Trial to Study the Effect of Kunjal Kriya and Guduchyadi Kwath in Mandal Kushtha

(Psoriasis). AYUSHDHARA, 2024;11(6):8-16.

https://doi.org/10.47070/ayushdhara.v11i6.1838 Source of support: Nil, Conflict of interest: None Declared *Address for correspondence Dr. Pankaj Rai Medical Officer Department of Ayurvedic and Unani Services, Govt. of Uttarakhand. Email: drpankajrai@gmail.com

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