

“A CLINICAL STUDY TO EVALUATE THE EFFICACY OF PSORIA-4 Ointment (HYPOTHETICAL) IN THE MANAGEMENT OF MANDAL KUSTHA W.S.R. TO PSORIASIS”

Dr. KOMAL RATHORE^{*1} , Dr. RAVI SHARMA ^{*2} , Dr. JYOTI GANGWAL^{*3}

Assistant Professor, Dept of kayachikitsa, Jayoti vidhyapeet women's university, Jaipur.

HOD & Professor, Dept of kayachikitsa, M.M.M govt Ayurved College Udaipur.

Assistant Professor, Dept of Rachna Sharir, Jayoti vidhyapeet women's university, Jaipur.

Corresponding author:- Dr Komal Rathore

BAMS, MD (kayachikitsa)

Assistant professor at Jayoti vidhyapeet womens's University jaipur

Mob. No:- 8769996494

Mail id.-komalhukam@gmail.com

ABSTRACT

Psoriasis is a proliferative autoimmune skin disease which is affecting 2% of worldwide population. It is characterized by itching, skin rashes and red scalps with white scales on the skin. Though, different types are reported, common existing form of psoriasis is plaque psoriasis. The epidemiology of disease seems to be remains unknown, but the incidence varies, surrounded by the different countries. The samprapti of Mandal kustha (psoriasis) of the disease appears as drastic cellular changes occur both in epidermis and dermis which narrates to keratinocyte hyperproliferation. so the treatment should be aimed at vata and kapha shamk Raktasodhak, varnaya. So in the present study, 30 clinically diagnosed patients from OPD Of kaya Chikitsa Dept. At Anusandhan Kendra hospital udaipur were selected along with consideration of inclusion and exclusion criteria. 30 patient of a group was given PSORIA -4(hypothetical) for locally application 2 month and given MAHATIKTA ghrit(25ml) Daily with milk .the study reveal better result in all parameters and its effectiveness in controlling the psoriasis.

Keywords:-Plaque psoriasis, mandal kustha, keratinocyte, Varnya, Rakta sodhak.

INTRODUCTION

The aim of Ayurvedic system of medicine is not only to cure the disease but also to maintain the health. It is best among all the health sciences because of its basic Sidhantas e.g. *Tridoshas*, *Panchmahabhootas*, *Dincharya*, *Ritucharya*, *Sadvrita*. *Acharya Susruta* define health and healthy person¹ WHO definition of health- as “A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”². Now a day's due to western culture, it is very difficult to follow the schedules as *Dincharya*, *Ritucharya* & *Aahar vidhi vidhan*. Then disturbed life style so many physical and mental diseases are increasing. In the day-to-day life style fast food habits and irregular living schedules are very common, as a result of which “*Viruddha Aahara Janya Vayadhi*” is increasing. Due to this reason a big population is suffering from skin diseases. In Ayurveda our Aacharyas include all the dermatological conditions are grouped under broad term *Kustha* which again have two divisions Mahakustha & Kshudrakustha on the basis of their symptoms, severity & involvement of deeper Dhatus. It includes description of lakshan of disease depends upon *DOSHA-DUSHYA sammurchna* & it affects on strotas & predominance of *DOSHA-DUSHYA*. *Kushtha roga* is said to be consequence of unmanaged dietary habits and lifestyle. Also the negligence towards the timely purification of the increase *DOSHAS* of the body is regarded to be a cause of *kushtha*. All *kushthas* are *tridoshaj* but including that *Mandal Kushtha* is predominantly *kafaj*. Though it has been described under

maha kushtha in Ayurvedic texts & also mentioned as a curable disease yet the relapsing nature of this disease makes it more painful & troublesome for physician. Psoriasis is common, chronic, disfiguring, inflammatory and proliferative condition of the skin, in which both genetic and environmental influences have a critical role. The most characteristic lesions consist of red, scaly, sharply demarcated, indurated plaques, present particularly over extensor surfaces and scalp.[7] In Ayurvedic classics skin disorders are described under one broad term called *Kushtha Roga*. Careful study shows that there is resemblance in symptoms of *Mandal Kushtha* and *psoriasis*. Shwetam, Raktam, Sthiram, Styanam, Utsannamandal [8] & Bahukandu (A.H.Ni 14/17) of *Mandal Kushtha* can be correlated with erythematous silver scaly papule/plaque and itching which are diagnostic symptoms of psoriasis.

Aims & Objectives:-

1. Conceptual & clinical study on psoriasis according to ayurveda as well as Modern science on various scientific parameter.
2. To find out a simplified, effective, economic and safe management of Psoriasis.
3. To ascertain if administration of selected management was associated with any side effect or not.
4. To study the effect of PSORIA-4 ointment. (hypothetical) management of PSORIASIS.

Material & methods:

1. Selection of patient:
2. The study will be conducted on 30 clinically diagnosed & confirmed cases of *MANDAL KUSHTHA* from OPD of associated group of hospital of M.M.M. GOVT. AYURVEDIC COLLEGE UDAIPUR- RAJKIYA CHIKITSALAY & ANUSANDHAN KENDRA (Udaipur) irrespective of their age, sex, religion, occupation etc. Detailed history was taken and a special research proforma was prepared for the study incorporating all the relevant points from both Ayurvedic and Modern views.
3. Written consent was taken from the patient before starting the trial.

PLAN OF STUDY-

1. Criteria for Selection of Patient:

The main criteria of diagnosis of patients were based on the cardinal and associated signs and symptoms of the disease based on the Ayurvedic and modern texts. These have been depicted in detail

Inclusion Criteria:-

1. Aare willing for trial.
2. Patients in the age group of 15 – 60 years.
3. Patients of *Mandal Kushtha* diagnosed by Ayurvedic classics and psoriasis diagnosed by Modern classics.

Exclusion criteria:-

1. Patients with age below 15 & above 60 yrs.
2. Pregnant women's & lactating mothers.
3. Patients suffering from serious systemic disorders like Diabetes Mellitus, Cardiac & Renal Disorders, Malignant disease, Major liver disorders etc.

Withdrawal Criteria:-

- During the course of trial if any serious condition occurs that require urgent treatment.
- Patient who willingly wants to withdrawal from the clinical the trial.
- Irregular follow up.

Table no:-1. SELECTION OF TRIAL DRUGS:- PHARMACODYNAMICS OF PSORIA-4 OINTMENT:-

S.N O	DRUG	RASA	GUNA	VEERYA	VIPA KA	DOSHAGHNATA	PHARMACOLOGICAL ACTION
1	SHEW AT KUTAJ	TIKTA KASHYA,	LAGHU RUKSHA	SHEETA	KATU	KAPHAPITTA- SHAMAK	KUSHTGHNA,KANDUGHAN,DAHAP RASHMAN,RAKTSHODHAKA,KRIMI GHNA,LEKHAN
2	AARAG VADH	MADHUR	GURU SINGDHA MRIDU	SHEETA	MAD HUR	VATAPITTA SHAMAK,KAPHAP ITTA SHODHAK	RAKTASHODHAK MRUDU VIRECHANA, JWARAGHNA
3	MANJI STHA	MADHUR, TIKTA	GURU, RUKSHA	USHNA	KATU	KAPHAPITTA SHAMAKA	Shothahara, Vranaropana, Kushthaghna, Deepana, Pachana,
4	TUVRA K	TIKTA,MA DHUR,KAS YA	SNIGDHA,TI KSHNA	USHNA	KATU	VATAKAPHAHAR, UBHYATOBHAGH ARA,RASAYAN	KRAMIGHNA, KUSHTHGNA, SOTHGNA,DEEPAN PACHAN
5	COCON UT OIL						Antiviral, CNS depressant, antibacterial, anticancer, antifungal, hypolipidaemic, diuretic, antibiotic, immunologic, anticonvulsant, antitubercular.

Adhara Dravya- Coconut oil and Wax Above drugs will be taken in above described proportion and the **Tablet** will be prepared in M.M.M. Govt. Ayu. College pharmacy.

MAHATIKTAKA GHrita:-The preparation of Ayurvedic ghee requires mainly three essential components viz. Drava (a liquid which may be one or more as Kashaya, Svarasa, Dugdha, Mastu, etc., Kalka (a fine paste of the drug(s)) and Sneha dravya (Ghee). For preparing medicated ghee, the decoction, kalkas (paste of drugs) of herbs are boiled in ghee according to formula. The processing is done for absorbing the therapeutic principle absorption in ghee.

Here is given more about Mahatiktaka Ghrita such as indication/therapeutic uses, composition, and dosage.Key Ingredients of Mahatiktaka Ghrita

Below is given complete list of ingredients.

- Saptacchada (Saptaparna) Alstonia scholaris (St. Bk.) 6 g
- Prativisha (Ativisha) Aconitum heterophyllum (Rt. Tr.) 6 g
- Sampaka (Aragvadha) Cassia fistula (Fr. P.) 6 g
- Tiktatohini (Katuka) Picrorhiza kurroa (Rt./Rz.) 6 g
- Patha Cissampelos pariera (Rt.) 6 g
- Musta Cyperus rotundus (Rz.) 6 g
- Ushira Vetiveria zizanioides (Rt.) 6 g
- Haritaki (P.) 6 g
- Bibhitaka (P.) 6 g
- Amalaki (P.) 6 g
- Patola Trichosanthes dioica (Lf./Pl.) 6 g
- Picumarda (Neem) (St. Bk.) 6 g
- Parpatata (Parpata) Fumaria indica (Pl.) 6 g
- Dhanvayasa Alhagi pseudalhagi (Pl.) 6 g

- Chandana (sveta chandana) (Ht. Wd.) 6 g
 - Pippali (Fr.) 6 g
 - Gajapippali Piper chaba (Fr.) 6 g
 - Padmaka Prunus poddum (Ht. Wd.) 6 g
 - Haridra Haldi (Rz.) 6 g
 - Daruharidra Daruhaldi (St.) 6 g
 - Vaca Acorus calamus (Rz.) 6 g
 - Vishala (rakta indravaruni) (Fr.) 6 g
 - Satavari (Rt. Tr.) 6 g
 - Sveta Sariva (Rt.) 6 g
 - Krishna Sariva (Rt.) 6 g
 - Vatsaka bija (Kutaja) (Sd.) 6 g
 - Vasa (Rt.) 6 g
 - Murva Marsdenia tinescsima (Rt.) 6 g
 - Amrita giloy (St.) 6 g
 - Kiratatikta Swertia chiraita (Pl.) 6 g
 - Yashtybhava Licorice (Rt.) 6 g
 - Trayamana Gentiana kurroa (Pl.) 6 g
 - Water 6.144 l
 - Amrita phala rasa (Amalaki) (P.) 1.536 l
- Ghrita (Goghrita) 768 g
 Kalka Dravya: Above given herbs from 1 to 32.
 Sneha Dravya: Ghrita
 Drava Dravya: Jal/water, Amalaki ras

2. INVESTIGATION

CRITERIA OF ASSESSMENT:-

During the trial patients will be assessed on these following parameters

1. Subjective parameters
2. Objective parameters

Table no:-2. 1. SUBJECTIVE PARAMETERS: PASI SCORE

S. NO.	EXTENT ERYTHEMA IN REGION	EXTENT INFILTRATION IN REGION	EXTENT DESQUAMATION IN REGION	EXTENT OF BODY REGION AFFECTED
1.	Erythema head	Infiltration head	Desquamation head	Extent of head affected
2.	Erythema trunk	Infiltration trunk	Desquamation trunk	Extent of trunk affected
3.	Erythema upper extremities	Infiltration Upper extremities	Desquamation upper extremities	Extent of upper extremities affected
4.	Erythema lower extremities	Infiltration lower extremities	Desquamation lower extremities	Extent of lower extremities affected

5. PASI score treatment:-

Table no. 3:- Showing PASI score before treatment:

SKIN	SEVERITY SCORE/ TOTAL	AREA SCORE	% OF SKIN	TOTAL
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SECTION			SECTION	
Head	(E-Head+I-Head+D-Head)	x A- Head	X 0.1	= Total Head
Arms	(E-arms+I-Arms=D-Arms)	x A- Arms	X 0.2	= Total Arms
Trunk	(E-Truk+I-Trunk+D-Trunk)	x A- Trunk	X 0.3	= Total Trunk
Legs	(E-Legs+I-Legs+D-Legs)	x A- Legs	X 0.4	= Total Legs

PASI TOTAL (BT) = Total-Head + Total-Arms + Total Trunk + Total Legs =

Table no:-4. GRADING OF SUBJECTIVE PARAMETERS:-

S.NO.	SYMPTOM	GRADING	OBSERVATION
1.	SHWET RAKTA VARNA	0	Absent
		1	Mild
		2	Moderate
		3	Severe
2.	KANDU	0	Absent
		1	Mild
		2	Moderate
		3	Severe
3	UTSANA MANDAL	0	Absent
		1	Mild
		2	Moderate
		3	Severe
4	4.ANANONYA SANSATAT MANDAL	0	Absent
		1	Mild
		2	Moderate
		3	Severe

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2. Objective parameters

1. Complete medical history.
2. Hematological Test : Hb%, TLC, DLC, ESR.
3. Biochemical Investigation : Blood sugar (RBS)
4. Renal Function Test (Blood urea, Sr. Creatinine), if required.
5. Liver Function Test (SGOT, SGPT), if required

RESULT:- RESULTS

The present clinical trial was done on 30 clinically diagnosed patients of psoriasis. Total 40 patients were screen out & 30 patients were selected for the trial that fulfills the inclusion criteria. All selected patients successfully completed the trial. Obtained observations were analyzed statistically with the help of INSTAT GRAPHPAD 3 & the obtained results are as follows:

Effect on Subjective parameters:

Table No 5: Showing effect of Therapy in Subjective Parametres.

(paired "T" test)

(HS: Highly Significant S: Significant NS: Non Significant)

Variable	Group	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
PASI Score	1	8.150	1.813	6.337	77.75	4.519	0.8251	7.679	0.0039	S

PASI Score was the main criteria of assessment in present trial. The PASI Score includes 3 symptoms Erythema; Indurations & Desquamation the obtained data was analyze stastically & results obtained are as follows.

Table No 6:- Showing effect of Therapy in Subjective Parametres.

(paired "T" test)

Variable	Groups	Mean diff.	SD±	SE±	% relief	T	P	S
SHEWT RAKT VARNA	1	1.700	0.702	0.128	79.69	13.260	0.0384 <0.0001	S
KANDU	1	1.467	0.5713	0.1043	77.21	14.060	0.0118	S
UTSAN MANDAL	1	1.367	0.5567	0.1015	90	13.462	0.0296	S
ANONYSANSAKTA	1	1.200	0.6103	0.1114	78.27	10.770	0.0349	S

(paired "T" test)

(HS: Highly Significant

S : Significant

NS: Non Significant)

DISCUSSION:-

PSORIA-4 ointment:

PSORIA-4 ointment was selected for the bhaya *Snehan*. Patients were advised for external application of it on the patches.

- It contains *Shewet kutaj, Manjistha, Aaragvadh, tuvrak*.
- All these drugs have *Tikta rasa, Kandughna & kushagna* property.
- It is specially indicated by *Acharyas* for management of *Kustha*.

- *Shewetkutaj*:- Kushtghana, Kandughan, Dahprashaman, Raktashodhaka, Dipana,

Kustha is a Raktapradoshaj vikar mentioned by Acharya charak. So while treating it specific consideration of Rakta dhatu is essential. In ayurvedic classics *Manjistha* is well known for its Raktashodhan & Raktaparasadan property.

- *Manjistha* which have *Varnya, Vishagna, Antioxidant, Antibacterial, Anti-inflammatory, Antiviral, Wound healing effect, Haemostatic, Hypoglycemic* properties.

Manjistha act as potent anti-proliferative property against the HaCa T cells which plays key role in pathogenesis of psoriasis. *Manjistha* it also has potent role in inhibiting Keratinocytes proliferation⁹. This helps in reducing the rapid shading of epithelium in psoriasis.

Variables	AT	BT	Diff	% imp	SD±	SE±	t	P	S
Hb%	14.4	14.59	0.343	2.41	0.53	0.097	3.508	<0.0001	S
TLC	6786.6	6766.6	20	0.29	174.2	44.93	0.44	<0.1	NS
Neutrophill	64.06	62.2	1.86	2.91	3.15	0.81	2.28	>0.05	NS
Lymphocyte	35.26	34.8	0.46	1.32	1.18	0.30	1.52	<0.1	NS
Eosinophill	1.33	1.26	0.06	5	0.45	0.11	0.56	<0.1	NS
Monocytes	2.2	1.9	0.26	12.12	0.88	0.22	1.16	<0.1	NS
Basophill	0.33	0.26	0.06	20	0.45	0.11	0.56	<0.1	NS
ESR	34.73	20.4	14.33	41.26	13.35	3.44	4.15	<0.001	HS

- *Aaragvadh* is the ingredient of *PSORIA-4 ointment* which is the one of the best medicine having property of easily torn and painful pruritic erosin, Anti-itching *Anti-oxidant, anti inflammatory anti bacterial, antifungal*.
- *Tuvrak:-kandughna, kaphvata -roghara, kushtaghn, Raktvikar roghara.*
 - The patches of Psoriasis are dry & Scaly. The *PSORIA-4 ointment* provides proper moisture to it resulting in slowing of rapid turn over of epithelium. As dryness reduces some sort of soothing analgesic effect is experienced by the patient. Commonly itching experienced by the psoriatic patients is due to excessive dryness of lesions so local application of *PSORIA-4 ointment* shows beneficial results to patients.
 - When scales of psoriasis are removed tiny bleeding points (Auzpits sign) are observed. As *Tikta rasa* has potent *vranshodahan & Vranropan* property is well known for its healing action results in proper early healing of lesions of Psoriasis.
 - According to Dermal drug delivery system of modern science skin shows the better absorption of lipid & lipid soluble substances than water soluble molecules. So according to this theory *PSORIA-4 ointment* shows better penetration in skin with carrying properties of Drugs added to it ⁽¹¹⁾
 - *PSORIA-4 ointment drugs* is mentioned as *Kapha pitta shamaka, varnaprasadan, Kusthagna, Kandughna, Varnya, Kaphapittashamak Rasayan* properties along with anti-inflammatory, Analgesic, Antioxidant properties can shows synergistic effect & ultimately results in early recovery of patients.

Conclusions:

On the basis of the study, following conclusions can be drawn:

- Mandal kushtha being a Mahakushtha Kustha has Kapha dominance & even involvement of tridosha can be evident from its signs & symptoms.
- Mandal kushtha in modern parlance has similarity with Psoriasis.
- Most of the patients were reported in the chronic stage of Psoriasis. Negligence in early stage and recurrence of psoriasis is common phenomenon.
- Maximum patients had the history of Virrudhaahara and Mandagni which clearly shows the role of Ama formation in pathogenesis of Kushtha.
- Chinta is mansika nidana which leads to vataprakopa which was observed in maximum number of patients. Also maximum patients were found tense and anxious. This observation clearly shows the psychosomatic nature of the disease.
- Excessive intake of madhur, Amla, Lavana and Katu rasa are common causative factors for mandal kushtha.
- Family history was supporting in many patients which suggests that the disease is hereditary.
- The disease used to aggravate during winter season and in dry weather.
- Maximum number of patients had the chronicity of 1-5 years and had previously undergone allopathic treatment. It clearly shows the relapsing nature of the disease. It suggests that, long term intensive therapy is necessary for eradication of the disease.
- Rasa, Rakta, Mamsa and Swedavaha Srotodushti were found chiefly and Kapha and Vata were main Dosha who vitiated these Dhatu and Srotasa.
- Due to very wide range of clinical manifestations we have to conclude that no single disease in Ayurveda can be exactly co-related as Psoriasis. According to Symptoms of disease & Concepts of Ayurveda to some extent we can consider Mandal Kustha as Psoriasis. As maximum Patients registered in trial also shows symptoms of Mandal Kustha so we can finally conclude that Mandal Kustha can be taken as Psoriasis.
- Ayurvedic trial drug shows significant results (77.75%) which reducing PASI Score cannot be neglected.
- Both the groups show considerable efficacy which is significant clinically as well as statistically ($P < 0.001$).
- Significant reduction in ESR which is supposed to be an inflammatory mediator proves potent Anti inflammatory action of Ayurvedic Trial drug.
- In overall assessment of therapy better results by Ayurvedic trial drug were observed over other group.

- No toxic effects were observed in any of the patients treated with Ayurvedic formulation during the trial period.
 - The present trial is done on small sample size & is of short duration so to reach at significant conclusion study with large sample size & of longer duration is required
 - There fore the present study was aimed to establish clinically the effect of a new combination drug in the management of Mandal Kushtha.
 - All the drugs chosen in Psoria-4 ointment (locally application) for the study are having sheet&Ushna Virya, Deepana-Pachana and Kapha pitta shamaka, varnaprasadan, & Dahaprashma, with anti-inflammatory, Analgesic, Antioxidant properties. So by their virtue, they help in dissolving the Samprapti of Mandal Kushtha.
 - Present study reveals that the selected management has potential effect on *Mandal kushtha* with the added advantage of being free from side effects.
 - As per my observation this drug is very effective on *Mandal kushtha*.
 - The present study was a humble try in search of a cure of this disorder and it is fulfilled up to some extent. The results of present study were really fruitful.
- Patient pics.







