"Study in the efficacy of Kushthadi Yoga in Ekakushtha with special reference to Psoriasis-A Comparative Clinical Study"

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Abstract- To evaluate the efficacy of Kushthadi Yoga the management of Ekakushtha with special reference to Psoriasis . In this study,40 patients will be randomly divided into 2 groups(20 in each).In Group A (Control) -Kushthadi Capsule 500 mg will be administered twice a day with lukewarm water after meal for 30 days along with Kushthadi Ointment and Group B (Experimental) –Placebo Capsule 500 mg will be administered twice a day with lukewarm water after meal for 30 days along with Kushthadi Ointment. Assessement will be recorded on 0,30th and 60th day. Changes will be observed in subjective and objective outcomes. Kushthadi Capsule will be more effective than Placebo Capsule

Keyword - Kushtha, Kushthadi Yoga, Psoriasis.

I. Background and rationale

Skin is one of the largest organ in the human body. Subjects with skin disease may experience physical, socioeconomic and psychological embarrassment in the society.^[1]

In Ayurveda all the skin diseases are explained under *Kushtha rogadhikara* and classified as 7 *Mahakushtha* and 11 *Kshudrakushtha*. *Ekakushtha* is one among 11 varieties of *Kshudrakushta*

It is characterized by *Aswedana* (anhydrotic / hypohydratic lesions), *Mahavastu* (covering of large surface area) and *Matsyashakalavat* (scaly lesions) *twacha*. ^[2]Psoriasis is non- contagious, dry, inflammatory and ugly skin disorder which can involve entire system of person. It is an autoimmune disease in which genetic and environmental factors have a significant role. It is mostly inherited and mainly characterized by sharply margined scaly, erythematous plaques that develop in a relatively symmetrical distribution ^[3]. This disease is chronic in nature with a tendency to relapse. Its prevalence is almost equal but it is higher in male (2.4%) than female (0.8%).

Ekakushtha can be co-related with chronic plaque Psoriasis due to similarities of symptoms.

Treatment of Modern medicine for Psoriasis comprises use of Emollients, Tar, Dithranol, Corticosteroid, Vitamin D analogues, Retinoid and Phototherapy. These medicines need long term use and have limitations as they are reported to have associate adverse effects

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In Ayurveda the common treatment principle of Kushtha described by Acharya Charak is administration of Sarpi (Ghrit) in Vata Pradhan Kushtha, Vaman in Kapha Pradhan and Virechan and Raktamokshan in Pitta Pradhan Kushtha A number of study is revealed on this topic Psoriasis in the region of AVBRH and Wardha⁻

AcharyaCharak hasindicated repeated Shodhan and Shaman chikitsa for Kushtha. Shaman chikitsa is used in the form of bahya and abhyantar chikitsa. For bahya chikitsa application of various oils and lepa of kushthaghna dravyas are described whereas for abhyantar chikitsa various formulations are given.

In *Charak Samhita Kushthadi Yoga* is indicated for treatment of *Ekakushtha* which consists of *Chakramarda* (*Cassia tora* Linn), *Aragvadha* (*Cassia fistula* Linn.) and *Vayvidang* (*Embelia ribes* Burm F.).

Trial design :Randomized Standard controlled Double arm Open labeled Study. Interventional study on 2 parallel group having 1:1 ratio.

Methodology :

Study setting : The study will be conducted in academic hospital MGACH & RC, Salod (H), Wardha.

Registration Number: REF/2020/04/033068

Eligibility criteria :Age between 20 yrs to 60 yrs of either sex and any Sharirik Prakruti, Patient Having Cardinal features ok *Ekakushtha* i.e. *Aswedanam* (Loss Of Sweating), *Mahavastu* (covered large area),*Matsyashaklopamam* (fishy Scaling), *Kandu* (Itching) and Mild to Moderate Psoriasis.^[4] Patients of Pregnant and lactating women, Patient , Diagnosed diseases like Diabetes Mellitus, Cancer, AIDS and Tuberculosis, other dermatological infectious conditions, History of any operative conditions and Severe Psoriasis Cases are excluded.

Drug	Dose in	Anupana	Kala	Frequency	Special
	units				Precautions
Group A	500 mg	Water	Prabhakta	Two times a	Avoid Sugar
Kushthadi				day	and sweet
Capsule					products
Kushthadi	QS	-		Two times a	-
Ointment				day	
<u>Group B</u>	500 mg	Water	Prabhakta	Two times a	Avoid Sugar
Placebo Capsule				day	and sweet
					products
Kushthadi	QS	-		Two times a	-
Ointment				day	

Interventions -	-
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Criteria for discontinuing or modifying allocated interventions: Subject will be withdrawn from the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, the subject will be offered free treatment till the problem subsides.We will measure number of tablets for the consumption of

appropriate dose for assessment and to check drug adherence, the patient will be followed up during Treatment 30 days.

Follow up period after treatment : 30th and 60th day

Primary Outcomes and Secondary Outcomes: We will see the effect of interventional drug on the basis of sign and symptoms and PASI Scale.

Statistical analysis : The changes from baseline will be analyze by using Wilcoxon's Signed Rank Test for objective criteria. McNemar's test for Subjective criteria.^[5]

Time duration till follow up : The patient will be followed up during treatment 30 days.

Follow up period–0, 30thand 60thday

Time schedule of enrolment, interventions :Drug will be given from 0 to 30 days and after that follow up on 30th and 60th day.

Recruitment :40 (20 in each group)patient will be recruited by simple random sampling Lottery method, and PI will allocate and enroll the patient

Methods : Data collection, management, and analysis

Data collection methods: Assessment criteria :

Subjective Criteria- Kandu (Purities)

Objective criteria- PASI Scale

The assessement will be done according to the gradations on 0^{th} , 30^{th} day (during treatment) and On 60^{th} day (after treatment).

We will stay in touch with patient by taking contact no. and timely advice them for medication and follow up and data of follow up patient will be stored in documentation with reason.

Expected Result: *Kushthadi Yoga* will reduce Kandu and reduce PASI scale score and give symptomatic and therapeutic relief from Erythema and scaling. Nitya virechan will act on Rukta dushti and due to this pacify the symptoms like erythyma and itching.

Discussion- A number of studies were reviewed ^[6-56]. Kushhadi Yoga contains *Edagaj(Chakvada), vayvidang* and Aragvada. This three drugs act on the Ekakustha due to its properties like

Edagaj has Kushthahara, tridoshahara in karma and due to katu rasa, ushna virya it act on Kushtha.

Vayvidang has Kashay katu rasa, Ushna virya and has Krimighna Kushthahara and tridoshahara karma due to this it acts on reducing the symptoms of Eka kushtha

Aragvada has Sramshan or murudu rechan in karma pitta kaphahara and it act on Vrana, Kushtha, Raktadushthi.Due to Madhur rasa and Guru snighdha Guna it acts on Koshta to act as mrudu virchak. So due to this the vitiated pitta dosha will eliminated from the body and Symptoms will reduced

Data management: The data entry coding will be done by PI

Ethics and dissemination: Research ethics approval ; approval from research ethics committee has taken. No-Ref. No. DMIMS (DU)/IEC/Jun-2019/8025

Consent or assent : The written consent will be taken from the patient before starting the study.

During the study the confidentiality of each patient will be maintained.

Dissemination policy: The data will be disseminated by paper publication.

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Authorship eligibility guidelines and any intended use of professional writers

Informed consent materials: With all the information model consent form and other related documentation will be given to participants.

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