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COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *MADHUSNUHI*RASAYANA AND SHIVAGUTIKA IN KITIBHA KUSHTA W.S.R. TO PSORIASIS.

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ABSTRACT:

The reported prevalence of Psoriasis in countries ranges between 0.09% and 11.43% making Psoriasis a serious global problem with at least 100 million individuals affected worldwide. The Unique treatment Modality of Ayurveda provides long lasting results and a better life to patients of Kitibha kushta (Psoriasis) by overcoming social stigmatization through its three basic principles of treatment i.e, Shodhana, Shamana, and Nidana parivarjana through which the disease can be stay at bay for longer duration. From this point of view, the present study was undertaken to evaluate the management of psoriasis from Ayurvedic point of view. Objectives: To assess the clinical efficacy of Madhusnuhi Rasayana and Shiva Gutika in the management of Kitibha Kushta with special reference to Psoriasis. Materials and Methods: An Open labeled, randomized, comparative, interventional clinical study. Forty patients of Kitibha Kushta were selected and randomly assigned into two groups. Results: The Combined Effect of "Madhusnuhi Rasayana and Kutajasuryapaki taila" is more effective than the Combined effect of "Shiva Gutika and Kutajasuryapaki Taila" in the present study. Hence Madhusnuhi Rasayana in group A is more effective than Shiva Gutika in Group B in the present study. Conclusion: Madhusnuhi Rasayana in group A is more effective than Shiva Gutika in Group B in the present study.

Keyword: Kitibha Kushta, Trikatu Choorna, Hareetakyadi Yoga, Madhusnuhi Rasayana, Shiva Gutika, Kutajasuryapaki Taila, Psoriasis, PASI Score Grading.

INTRODUCTION:

In Ayurveda all skin diseases are described under the heading of Kushta. Kitibhakushta comes under Ekadashakshudra kushta as per the classics and the Nidana of kushta is explained in Madhavanidana as - Viruddha annapana sevana, excessive intake of drava, snigdha, and guru ahara, Vegadharana^[1]. According to Charaka Acharya the vitiated Saptadravyas are considered as Sannikrishta hetu for kushta^[2]. The Sapta dravva sanaraha are Tridosha, Twacha, Rakta, Mamsa and Lasika which makes the blackish discoloration of skin. Kitibha kushta is predominantly of vata-kapha dosha as per Acharya Charaka and on the other hand Pitta dosha as per Acharya Sushruta. Tridosha involvement is seen in Kitibhakushta. The lakshanas of Kitibha kushta are Shyavam, Kina khara sparsha, Parusham^[3], ugrakandu, Ghanatwam, Sravi, Vrittam, Krishnam^[4], Snigdham, Prashanthnischa Punarutpadyante^[5] which resembles to Psoriasis in Modern Science.

Psoriasis is a chronic non communicable, painful and disfiguring disease of the skin i.e, disorder of keratinization for which there is no cure and exact etiology is unknown. It is a papulo-squmaous disorder of the skin characterized by sharply defined erythemato-squamous lesions. It is known for its course of remission and exacerbation. It

tends to run in families and is precipitated by climate, streptococcal infections etc. Male and female are equally predisposed and all age groups are affected. Moreover Psoriasis affects mental health and people suffering from the disease experience social Stigma^[6].

The reported prevalence of Psoriasis in countries ranges between 0.09% and 11.43% making Psoriasis a serious global problem with at least 100 million individuals affected worldwide^[7].

The Unique treatment Modality of Ayurveda provides long lasting results and a better life to patients of Psoriasis by overcoming social stigmatization through its three basic principles of treatment i.e, Shodhana, Shamana and Nidana parivarjana.

The drugs selected under this study are Trikatuchoorna [8] (described in Baishaiya Ratnavali Paribhasha prakarana) taken for Amapachana and Agnideepana, Hareetakyadi yoga^[9] (described in *Charaka chikitasthana* Rasayana prathama pada) for Koshta shodhana, Kutajasuryapaki Taila for external Rasavana^[10] application, Madhusnuhi (described in Sahasrayoga Lehyaprakarana 41) and Shivagutika^[11] (described in Baishajya Ratnavali Rasayana) as Shamana yoga in the form of Rasayana. Acharya Harita explained the chikitsa which does the drudikarana of the Deha, Indriya and Danta and that which

eliminates *Vali, Palita, Khalitya* is known as *Rasayana*^[12]. As *Twacha* is one among the *Ekadashaindriya* the effect of *Rasayana* can be expected.

In Madhusnuhi Rasayana, Majority of the drugs are Agnideepana and Tridoshahara. Madhusnuhi is Raktaprasadaka. Amalaki, Hareetaki and Ashwagandha etc drugs acts as Rasayana. The Majority of the ingredients in Shivagutika are Tridosha Shamaka Krimiahna. Shodita Shilaiatu acts as raktaprasadaka as well as Rasayana. The drug selected for external application Kutaiasurvapaki taila-Kutaia acts kushtaghna^[13] and Narikelataila will primarily helps in returning the normal texture and complexion of the skin.

OBJECTIVES:

- ✓ To Evaluate the Combined effect of Madhusnuhi Rasayana and Kutajasuryapaki Taila in Kitibha Kushta with special reference to Psoriasis.
- ✓ To Evaluate the Combined effect of Shiva Gutika and Kutajasuryapaki Taila in Kitibha Kushta with special reference to Psoriasis.

✓ To Evaluate the Comparative effect of Madhusnuhi Rasayana and Shiva Gutika in Kitibha Kushta with special reference to Psoriasis.

MATERIALS AND METHODS:

Study Design: An Open labeled, randomized, comparative, interventional clinical study.

Source of Data:

Literary Source: All the information about the concerned topic collected from Ayurvedic literature, Modern books, Journals, websites about the disease and the Medicine was reviewed and documented for the planned study.

Study Sample The patients were selected from OPD and IPD of DGM Ayurvedic Medical College, hospital and Research centre, Gadag.

Drug Source : Raw drugs required were collected from the GMP approved pharmacy.

 Trikatu choorna, Hareetakyadi yoga and Kutajasuryapaki taila was prepared in Shri D.G.M Ayurvedic Medical College, Department of Rasashastra and Bhaishajya Kalpana Pharmacy, Gadag. All Yogas in the clinical trial were prepared as per the classical

Table No 01: Showing the part used and Proportions of Trikatu Choorna

SI.No	Drug	Botanical Name	Part Used	Proportion
01	Pippali	Piper longum	Phala	1 part
02	Maricha	Piper nigrum	Phala	1 part

03	Shunti	Zingiber officinale	Phala	1 part	
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Table No 02: Showing the part used and proportions of Hareetakyadi Yoga

Sl.No	Drug	Botanical Name	Part Used	Proportion
1.	Hareetaki	Terminalia chebula	Phala	1 part
2.	Saindava lavana	Rock salt	-	1part
3.	Amalaki	Emblica officianalis	Phala	1 part
4.	Guda	jaggery	-	1 part
5.	Vacha	Acorus calamuslinn	Rhizome	1 part
6.	Vidanga	Embelia ribes	Phala	1 part
7.	Rajani	Curcuma longa linn	Rhizome	1 part
8.	Pippali	Piper longum	Phalamoola	1 part
9.	Shunti	Zingiber officinale	Rhizome	1 part

Table No.03: Showing the part used and proportion of Ingredients in Kutajasuryapaki Taila.

SI.No	Drug	Botanical Name	Part Used	Proportion		
1.	Stri Kutaja	Wrightia tinctoria	Patra	1 part		
2.	Narikela Taila	Coccus nucifera	Phala majja	4 part		

Methods of Collection of Data: For the purpose of clinical trial, 40 subjects fulfilling the criteria of diagnosis and inclusion criteria of *Kitibha Kushta* (Psoriasis) and the subjects willing to participate in the clinical trial were selected irrespective of their gender, caste, religion from OPD & IPD of Shri D.G.M. Ayurvedic Medical College and Hospital, Post Graduate Studies and Research Centre Gadag, Bangalore. For diagnosis, detailed medical history was taken and physical examination was done according to both Ayurvedic and

Modern clinical methods. All the patients were studied for their demographic profile including of age, gender, address, occupation, education, socio economic status, marital status, life style, addictions, dietary habits, etc. Evaluation of the patient was done based on the specially prepared case sheet proforma.

Sample Size and Grouping : Forty patients of *Kitibha Kushta* were selected and randomly assigned into two groups.

Group A - 20 patients received *Madhusnuhi Rasayana* and *Kutajasuryapaki Taila*.

Group B - 20 patients received *Shivagutika* and *Kutajasuryapaki Taila*.

All the patients undergone *Ama pachana*, *Agnideepana* and *Koshtashodhana* before intervening the trial medicines.

Criteria for Diagnosis: Diagnosis established by clinical examination of skin, signs and

Table No 04: Showing Criteria For Diagnosis

symptoms of *Kitibha kushta* (Psoriasis) as follows :

According to Ayurveda :	According to Modern Science:
Shyava - Krushna varna of Twacha	Erythema, Induration, Scaling of skin.
Kina kara sparsha of Twacha	Itchy skin.
Parushata of Twacha	Positive Koebner's phenomenon
Kandu in Twacha	Positive Auspitz sign
Ghanatwa of Twacha	Positive Candle grease test.

Inclusion Criteria:

- Patients having the classical symptoms of Kitibha Kushta like Shyavam, Kina khara sparsha, Parusham, Kandu, Ghanatwa etc in Twacha.
- The presence of other signs and symptoms of Psoriasis like dry scaly papules and plaques of varying size (pinhead to palm sized or larger) etc described in modern texts and further diagnosis is confirmed by Auspitz's sign, Koebner's Phenomenon, Candle grease test.

 Patients of age between 20-60 years of either gender below 10 years of chronicity.

Exclusion Criteria:

- Patients with history of systemic illness like
 Diabetic mellitus, Hypertension, Endocrine
 disorder, Cardiac pathology, Cancer,
 Immune deficiency disorders like AIDS.
- Patients having major Medical or Surgical illness.
- Pregnant woman, lactating mother and patients taking modern medication more than 4 weeks.

Investigations: For the purpose of assessing the general condition of the patient and to

exclude other pathology the following investigations were carried out.

Hematological:

- Complete Blood Count (CBC)
- Erythrocyte Sedimentation Rate (E.S.R.)
 (Westergren method) mm/ 1st hour
- Absolute Eosinophil count (AEC)
- Random Blood Sugar (RBS) in mg/dl

Dietary restrictions: The patients were strictly advised to follow the restrictions regarding food habits and life style. They were instructed to avoid the possible causative factors of disease.

Posology, Grouping of the Subjects and Treatment Schedule

Table No.05: Showing the Posology and Duration of Yogas in Group A and Group B

Shamana Yoga	Trikatu	Hareetakyadi	Madhusnuhi	Shiva	Kutaja-
	Choorna	Yoga	Rasayana	Gutika	Suryapaki Taila
GROUP A	√	✓	√	-	√
GROUP B	✓	✓		✓	✓
Yoga form	Choorna	Choorna	Lehya	Gutika	Taila
Single Dose	3 grams	10grams	6 grams	2 grams	Quantity sufficient
Divided dose	Thrice a	At night	Twice in a day	Twice a	Twice a day (Bid
	day (Tid)	(Hs)	(Bid)	day (Bid))
Route of drug	Oral	Oral	Oral	Oral	Parentral Route
Administration					
Anupana	Luke	Luke warm	Luke warm	Luke	After application
	warm	water	water	warm	Exposing the body
	water			water	to early morning
					sunrays and
					evening sunrays.
Duration	3 days	2 days	40 days	40 days	40 days

Subjects assessed on 0th, 15th, 30th, 45th and 60th day i.e at fortnight intervals to the check the status of the psoriasis.

Follow up period: A follow - up was done on 15th day (60th day) after completion of the treatment. (i.e., without medication - to see the sustained effect of trial medicine and to assess the relapsing nature of the disease), if any such aggravation of symptoms noticed by the patient within follow up period, the patient is asked to take immediate consultation.

Total study duration: 60 days.

Assessment criteria:

Assessment of cardinal and associated symptoms of *Kitibha Kushta* (Psoriasis) were done and recorded on the zero day (i.e. one day before administering the trial drugs), Fortnightly till completion of the treatment period (i.e. on 45th day of the treatment) and on the day of follow -up (i.e. on 15th day after completion of treatment). The changes in the signs and symptoms were assessed by adopting suitable scoring method and by using appropriate clinical tools. Assessment was done by considering the base line data of Subjective and Objective Parameters to Before Treatment (BT), After Treatment (AT) and

After Follow up (AF) and they were compared for assessment of results. All the results were analyzed Statistically using Un-paired and paired student 't'-test. Criteria for assessment were kept on the basis of relief in the signs and symptoms of the *Kitibha kushta* (Psoriasis).

Assessment of Results: Overall effect of the treatment assessed in terms of completely cured (76 - 100% relief in the signs and symptoms of *kitibha kushta*psoriasis). moderate improvement (51 – 75% relief), mild improvement (25 - 50% relief) and no improvement (less than 25% relief) by adopting the net effect of Subjective Parameters - Shyava-Krushna varna of Twacha, Parushata of Twacha, Ghanatwa of Twacha, Kandu in Twacha and Objective Parameter (PASI Score Grading) to Before Treatment (BT), After Treatment (AT) and After follow up (AF) Within the Groups and in Between the Groups Group A and Group B were done.

Observation and Results:

Group A

Table No 06: Showing Declaration of the result in Group A

SI.No	Impression	AT	AF
01	Completely cured	04 (20%)	04 (20%)

02	Moderate improvement	09 (45%)	09 (45%)
03	Mild improvement	07 (35%)	07 (35%)
04	No improvement	00 (00%)	00 (00%)

Group A: After Treatment 13(65%) and After Follow up 13(65%) of subjects shown better results in this Group.

BEFORE TREATMENT



AFTER TREATMENT



Figure 04: BT and AT showing reduced Erythema, Induration, Scaling in GROUP A

BEFORE TRATMENT



AFTER TREATMENT



Figure 05: BT and AT showing reduced Erythema, Induration, Scaling in Group A.

Group B

Table No.07: Showing Reduction % in the Group A, Group B and within the groups

Subjective and	Reduction (N%)							
Objective	Group A		Gr	oup B	Between the groups			
Paramerers	AT	AF	AT	AF	AT	AF		
Shyava-	64%	64%	58.5%	56.05%	19%	28%		
krushna varna								
in twacha								
<i>Parushata</i> in	63%	63%	59.5%	59.5%	17%	19%		
twacha								
<i>Ghanatwa</i> in	60%	62%	57.5%	57.5%	23%	26%		
twacha								
<i>Kandu</i> in	72%	61%	60.4%	48.8%	24%	28%		
twacha								
PASI Score	63%	62%	56%	52%	62%	56%		
Grading								

Table No 08: showing Declaration of the result in Group B

SI.No	Impression	AT	AF
01	Completely cured	06 (30%)	05 (25%)
02	Moderate improvement	05 (25%)	04 (20%)
03	Mild improvement	07 (35%)	09 (45%)
04	No improvement	02 (10%)	02 (10%)

Group B: After Treatment 11(55%) of subjects and After Follow up 09 (45%) of subjects shown better results in this Group.

BEFORE TREATMENT

AFTER TREATMENT





Figure 06: BT and AT showing reduced Erythema, Induration, Scaling in Group B

BEFORE TREATMENT







Figure 07: BT and AT showing reduced Erythema, Induration, Scaling in Group B.

Observation on Statistical Analysis:

Statistically all the Subjective and Objective
Parameters have shown highly significance
within the Group A and Group B. Objective
Parameter: PASI Score Grading shown
significant results than subjective parameters
in between the Groups. Comparing P values of
both the groups concerning to their subjective

and objective parameters and over all response, it can be concluded that Group A shown Significant result than Group B.

Observation on investigations: majority of the subjects shown decrease in the AEC and ESR values after treatment in both the Groups, which indicates the good prognosis of psoriasis.

DISCUSSION:

Discussions on the drugs selected in the clinical trial:

- a) *Trikatu Choorna*: It is having *agni deepana* property there by it restores the *agni* and checks the formation of *ama*. It is also having *pachana* property which helps in digesting the ama which is already formed. This helps to attain *niramavastha*, there by facilitating *koshtashodhana* efficiently and it is said to be *kushtanashaka*.
- b) Hareetakyadi Yoga: This yoga having the ingredients which does the vata anulomana and acts as mrudu rechaka. Hence, the vitiated doshas can be expelled out of the body. The main aim is to do the koshta shodhana of subjects before administering the trial drugs so that efficacy of the trial drugs can be achieved.

c) Madhusnuhi Rasayana as shamana yoga :

The reason to choose Madhusnuhi Rasayana is because of its ingredients. It is in the form of Lehya and easily acceptable by patient. In Madhusnuhi Rasayana, Majority of the drugs are Agnideepana and Tridoshahara. Madhusnuhi is Raktaprasadaka. Amalaki, Hareetaki and Ashwagandha etc drugs acts as Rasayana. The majority of the ingredients of the yoga are kushtaghna and kandughna are estimated to relieve the disease. On dosha, the drugs have vata kaphahara

tridoshahara effect so these are interpreted as bringing the doshas to the normal state. The guna of the drugs like musta have got grahee guna in them which are drava shoshaka i.e. in this context it is taken as kledashoshana, rooksha guna present in musta, hareetaki, and daruharidra is said to perform kledashoshana which is present in excess in kushta rogi. The other ingredients like triphala etc. drugs have got vranahara, kapha vatahara. Tripahala are used for virechanartha as stated by Acharya Charaka in first chapter which help in taking the doshas, this effect is of minimal extent but taken in regularly may show the effect of Nitya virechana. Acharya Sushruta says the cumulative effect of triphala kushta and meha hara and vranaropaka. The deepana pachana property of the drugs corrects the dhatu paka so that there is proper nourishment of the twacha and they avoid the excessive kleda formation.

d) Shivagutika as shamana yoga: The reason behind choosing the Shiva Gutika for the present study was its ingredients. The ingredients of the medicines were chiefly having kushtaghna (abhaya, amalaka, saptaparna and aragwada) and kandughna (krutamala, naktamala, kutaja, daruharidra and musta) property which encouraged us to take for the trial as the main complaint of kitibha kushta is ugrakandu. The Majority of

the ingredients in *Shivagutika* are *Tridosha Shamaka* and *Krimighna*. *Shodita Shilajatu* acts as *raktaprasadaka* as well as *Rasayana*. These drugs are well placed in the respective *dashemani gana* as in these *ganas* 10 best and potent drugs are given as examples. The drugs were *kashaya tikta rasa pradhana* which is very important to heal the kina (*vrana*), excess *kleda* and the *kapha dosha* in the *kitibha kushta*. The *laghu rooksha guna* also is helpful for drying the excess amount of *kleda* present in the body. Most of the drugs were having *vata kaphahara* or *tridoshahara* property which suits to the demands in *kushta chikitsa*.

e) Kutajasuryapaki Taila for external application:

The drug selected for external application i.e, Kutajasuryapaki taila- Kutaja acts as kushtaghna and Narikela taila will primarily helps in returning the normal texture and complexion of the skin.

Benefits of Taila application:

This is to maintain the cutaneous hydration so that the active principles present in the *taila* i.e. *Kutaja* which is considered as best *Kushtagna dravya* is well absorbed via the skin. The *taila* applied over the skin directly reaches the site of pathology being skin affected in Psoriasis.

Instructions for *Taila* application : *Kutajasuryapaki taila* was asked to apply by

self or by assisting them in case where patient can not apply by himself like back region . The pressure during the application was avoided as fear of bleeding is always there (Auspitz sign) only gentle pressure is advised. Patient was advised to expose the body to early morning sun rays after application of oil for at least 15-20 min as the penetration of the drug through the dermal route is always great because of hydration when compared to the dry skin. The absorption of the medicine increases with the media of coconut oil.

Mode of action of Kutajasuryapaki taila: The utility of kutajaaditya paka taila is to promote easy absorption through the skin which provides the cutaneous hydration, by this the drug easily comes in contact with the twachasthita bhrajaka pitta after its successful absorption. Once the active ingredient of medicine reaches the level of bhrajakagni, the drug is made sajateeya at this level. This will then bring back the normalcy in the skin. Our Seers have told us to use the vathartha siddha taila for application so the active ingredient of the medicine also gets in to the body through the skin in this manner as it is said already that the drug entry through the skin may be made easy by suspending in the oily media. The drug chiefly of the tikta and kashaya in rasa which have got readily the vrana ropana guna. The quna of these drugs are also opposite to

kapha, the main dosha for kandu to manifest. The dosha karmas of these drugs are told already as kaphavatahara and some as tridoshahara, this taila is estimated to bring down the increased dosha at the site of pathology. The cumulative effect of Kutaja is told as Kushtaghna, this when used in the form of taila may yield the result. The main pathology told in psoriasis is increase in the rate of mitosis of keratinocytes which is interpreted as increased vata guna and karma. Also as swedana is the choice of treatment for the vata, exposing to early morning sun rays after application of Kutajasuryapaki taila is expected to decrease vata by the swedana effect. The taila application along with

exposure to early morning sun rays which acts as mrudu sweda helped to yield better results as the snehana can not alone impart the result if swedana is not followed after. So the swedana effect also plays a major role in kitibha kushta chikitsa. The other pathology of kushta is told as retention of excessive kleda in the body because of swedavaha sroto avarodha, this avarodha can be relieved by swedana as the phalashruthi of sweda is swedakaraka.

Kitibha kushta and Psoriasis: Generally Kushta is a Tridoshaja Vyadhi. Particularly Kitibha kushta with its lakshanas simulates to Psoriasis of modern science and was considered for the convenience of this study.

Table No.09: Showing the similarity between Kitibha Kushta and Psoriasis.

Sl.No	Kitibha Kushta	Psoriasis				
01	Shayava, krushna and aruna varna of twach	Erythema, Induration				
02	Khara sparsha	Dry lesion, scaling				
03	Parushata Dryness and scaling					
04	Srava	Flow of exudates from lesion in early stage of psoriasis 206 (Boyd's pathology)				
05	Vrutta	Rounded plaques (Harrison, vol, 311).				
06	Ghana	Thickness of the lesion. Stable plaque (Harrison, vol, 311).				
07	Ugra kandu	Lesions are variably pruritic (Harrison, vol, 311).				

08	Vartate cha samutpannam /		The disease may aggravate without any									
	Prashantani	cha	punaha	apparent	cause	or	flare	up	of	psoriasis	can	occur
	utpadhyate.		randomly.									

CONCLUSION:

Objective parameters shown highly significant in group A and Group B i.e. p-value < 0.005.

Objective parameter i.e PASI Score Grading shown highly significance in between the groups, After Treatment (AT) and After Follow up (AF). All subjective parameters shown non-significant results in between the groups After Treatment (AT) and After Follow up (AF).

Within the Groups, all the Subjective and

The Combined Effect of "Madhusnuhi Rasayana and Kutajasuryapaki taila" is more effective than the Combined effect of "Shiva Gutika" and Kutajasuryapaki Taila" in the present study. Hence Madhusnuhi Rasayana in group A is more effective than Shiva Gutika in Group B in the present study.

Limitations of the study:

- Sample size was very small to universalize the results.
- Prolonged treatment duration is essential as classical Shodhana was not adopted in this study.
- Application of oil in the form of Bahirparimarjana chikitsa is a must and inevitable in the skin diseases especially like Kitibha Kushta where

there is prabhuta doshas, here Kutaja – Suryapaki taila is opted as it is best kandughna and shown combined effect with Madhusnuhi Rasayana in Group A and Shiva Gutika in Group B. Moreover Kutajasuryapaki Taila efficacy can be assessed without internal medication by adopting another group.

Recommendations for the future study:

- The same study can be taken for the study including large number of samples.
- Ayurveda Rasayana formulations can do neutraceutical qualities, both as preventive and curative. Hence the Rasayana benefits of trial drugs can be assessed by considering the serum IgA, IgM, IgG as objective parameter. Rasayana therapy followed by Shodhana is beneficial and hence can be planned in upcoming studies.
- How we calculate PASI Score by dividing the body into 4 parts, similarly the body can be divided into 6 parts taking the Ayurvedic concept of Shadanga Shareera so that subjective parameters

will also get standardized. This shadanga shareera concept can be utilized in the case sheet proforma to calculate the *Kitibha Kushta* score similar to that of PASI Score.

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Conflict of Interest: None

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