

Clinical efficacy of Kumkumadi Ghrita prepared by Kesar and Nagakesar on Mukhdushika (Acne vulgaris)

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Abstract

Introduction: In spite of large number of treatment options for Mukhdushika (Acne vulgaris), efforts are still carried out by medical society to bring out more effective treatment. Kumkumadi Ghrita (KG) is one of the highly valued formulations among Ayurvedic physicians, commonly recommended in Mukhdushika. Kesar (stigma of *Crocus sativus* Linn) is a prime ingredient in the formulation. Due to high cost and increased adulteration trends in Kesar, another botanical 'Nagakesar' (stigma of *Mesua ferrea* Linn.) is suggested by Ayurvedic experts as a substitute, which have relatively low cost and possess similar therapeutic attributes like Kesar. However, no published work has been available till date on comparative clinical efficacy of KG prepared by Kesar and Nagakesar.

Aims and Objectives: To evaluate the comparative clinical efficacy of Kesaryukta (with Kesar) Kumkumadi Ghrita (KKG) and Nagakesar yukta (with Nagakesar) Kumkumadi Ghrita (NKG).

Materials and Methods: Sixty known patients of Mukhdushika of both genders were selected. Both KKG and NKG were used as external application by Abhyanga (massage) for 15 minutes and keep it for 10 minutes and then wash face by Besan (Gram powder) once in a day, for 4 weeks duration. Suitable diet and lifestyles modifications were advised along with the therapy. The obtained data was analyzed statistically by applying paired 't' test.

Results and conclusion: Both groups of KG were found effective in treatment of Mukhdushika. Though, on signs and symptoms, KKG showed comparatively slightly better effect; on overall comparing the clinical efficacy of both groups, statistically no major difference was found. Since NKG is highly cost effective than KKG, present study warrants the use of Nagakesar in place of Kesar for preparation of KG.

INTRODUCTION

Ayurvedic drugs need clinical trials and quality assurance studies to ascertain and validate their therapeutic potential on modern parameters, and to make them globally acceptable. Mukhdushika (Acne vulgaris) is a well known skin disorder since ancient time and Ayurveda offers wide range of successful formulations (herbal/herbo-mineral) for its management. Kumkumadi Ghrita (KG) is a famous and commonly used Ayurvedic preparation in Mukhdushika.^[1] It is the burning problem of this present era because it causes unattractive look to a permanent disfigurement which may result inferiority complex or sometimes even isolation and its pathology is not fully understood. KG comes under Ghrita Kalpana (medicated ghee preparations), which is one of the commonly used dosage form in Ayurvedic pharmaceuticals, aimed to extract the lipid soluble active principles from the plants and minerals.^[2] The formulation have Kesar, also known as Kumkum (stigma of *Crocus sativus* Linn) as a prime ingredient, which makes the formulation costly. Since Kesar possesses wide range of therapeutic attributes, it is highly demanded and used herb in Ayurvedic medicines. Though it is expensive, its demand far exceeds than the production. Therefore, adulteration of this herb is much common in herbal drug industry and makes challenging task for consumers to find out the original, finest Kesar.^{[3],[4]} Nagakesar (stigma of *Mesua ferrea* Linn.) is another highly recommended herb in Ayurvedic medicines; though, it is costly too, but is comparatively cheaper than Kesar. As per Ayurvedic classics, it can be used as a substitute of Kesar, as it is supposed to possess similar therapeutic qualities.^{[5],[6]} Some texts have also considered Kesar as synonym of Nagakesar.^[7]

Since, KG is one of popular Ghrita based widely used formulation, published information on its efficacy in Mukhdushika is lacking. Taking a note of this, present study has been framed to assess the effect of Kesar yukta (with Kesar) Kumkumadi Ghrita (KKG) and Nagakesar yukta (with Nagakesar) Kumkumadi Ghrita (NKG) in management of Mukhdushika.

MATERIALS AND METHODS

Criteria for selection of patients and Study design

In this open label clinical trial 60 patients of Mukhdushika (males-22 and females-38) attending OPD and IPD of Rasa Shastra and Bhaishajya Kalpana department, IPGT & RA, Gujarat Ayurved University, Jamnagar; who fulfill the inclusion criteria were included. A detailed clinical performa was prepared incorporating selected symptoms. Examination of classical signs and symptoms of Mukhadushika were carried out. Written informed consent was taken as per the Helsinki declaration after offering sufficient explanations about the study and its aims.

Criteria for exclusion

Patients having: Age <14 years and > 40 years, Pidika (papule/pustule) on other part of body except on Mukha (face), Mukhadushika caused due to any systemic disease, and hyper pigmentation due to any other reason except Mukhadushika were excluded from study.

Preparation of KKG and NKG

The formulations under trial were prepared by adopting the guidelines of classical texts of ayurvedic pharmaceuticals.^[8-10]

Groups

The selected patients were randomly divided into two groups –

Group A:

Patients were advised to wash face by Luke warm water and do Abhyanga (massage) with KKG for 15 minutes and keep it for 10 minutes and then wash face by Besan (Gram powder) once in a day.

Group B:

Patients were advised to follow the same procedure with NKG.

Dose, duration and advice:

KG was administered 10-30 g according area involvement for Abhyanga (massage) once/day, for the duration of 4 weeks. Patients were advised to avoid etiological/aggravating factors for Mukhadushika, use of cosmetics etc. Suitable diet and lifestyles modifications (viz avoiding oily, fried, spicy foods, adequate sleep, no addictions, avoid stress, cleanliness etc.) were recommended bring the body physiology to normal.

Criteria for assessment

Assessment criteria adopted were improvement in the signs and symptoms based on clinical parameters. Examination was conducted before and after treatment. The changes observed in the signs and symptoms were assessed by adopting suitable scoring pattern (Table 1). Improvement in all signs and symptoms of disease was encapsulated, while analyzing the overall effect of therapy. The assessment of overall effect of therapy was done through the following gradations: Complete remission: 100% Improvement; Markedly Improved: Improvement between 76% to 99%; Moderately Improved: Improvement between 51% to 75%; Mildly Improved: Improvement between 26% to 50%; Unchanged: No relief/improvement less than 25%.

Statistical Analysis

The obtained data were analyzed statistically. The observed difference was calculated by adopting paired and unpaired student 't' test, where, $P < 0.05$, $P < 0.01$, and $P < 0.001$ were considered as statistically Non significant, and highly significant respectively.

RESULTS AND DISCUSSION

Ayurveda has also given utmost importance to quality of drug, maturity of plant, standard preparation methods, and its mode of clinical usage in logical manner.^{[11],[12],[13],[14]} Of the 60 enrolled patients, 49 completed the study. Eleven patients were found Left Against Medical Advice due to long distance from centre during trail period, whereas 24 and 25 patients in group A and B respectively completed the drug course (Table 2). Statistically obtained results on clinical symptomatology as per scoring pattern and overall effect of therapy have been placed in Figure 1 and 2. Significant relief in all signs and symptoms and glycemc levels was found in both treated groups.

In present study, the disease was found maximum (53.33%) between 14-20 years of age. According to modern science condition of the disease usually starts in adolescence. 68.33% of patients were students in the present study. This may be because these patients were more conscious regarding their looks and are mostly in stressful condition. Total 83.34% of patients were unmarried. This may be because after marriage in midtwenties, hormonal changes play the role in occurrence of this disease.^[15]

Most of the patients (68.33%) had constipation. So before starting Abhyanga of KG, Avipattikara churna or Shivaksharapachana churna was given before meal twice a day for a week or whenever required, to clear the bowels.

Twaka Vaivarnya (skin discolouration) was found in 75% patients and Rukshata (dryness) in 11.67% patients in Twaka Dushya Pariksha (examination of skin) of Ayurveda. Vaivarnya is generated as post marks of pimples/acne which is responsible for unattractive looks and also challenging for treatment. Though Acne vulgaris is produced due to over secretion of sebaceous glands, many patients had complaint of Rukshata in 'V' zone of face.

Most patients (80%) were vegetarian, as majority of Gujarati have vegetarian trend of diet. Maximum patients (56.67%) came in chronic condition (2 to > 6years). 28.33% patients had more than 2 years chronicity. Only 15% patients had less than 6 months chronicity. It can be said that in our society most of the patients start treatment at very late phase.

Total 38.33% of patients had Grishma Kala (summer season) as an aggravating time of disease. 43.34% of patients had more than 21 number of Pidika, 46.67% of patients had 1 to 2 cm of area occupied by Pidika, 53.34% of patients had Srava (discharge) that needs mobbing and 28.34% of patients had over all discoloration. This suggests worse condition of disease.

In KKG group, significant result at $p < 0.01$ were obtained in Number of Pidika, Discolouration of skin, and Pain in lesion. Non significant relief at $P < 0.05$ were found in area occupied by Pidika, Srava from lesion and Itching at the face (Table 3).

In NKG group, Significant result at $p < 0.01$ were obtained in Number of Pidika, Discolouration of skin, and Itching at the face. Non significant relief, at $P < 0.05$ were found in Srava from lesion, Pain in lesion and at $p < 0.1$ in area occupied by Pidika (Table 4).

The comparative results of test drugs on cardinal symptoms reveals that statistically significant reduction in Number of Pidika i.e. 17.50% and 17.91% in group A and group B respectively. In group A, non significant result at $P < 0.05$ was found i.e. 23.34% and in Group B, 20.73% which was also statistically non significant at $P < 0.1$ in area occupied by Pidika and non significant result was found also in Srava from lesion at $P < 0.05$ i.e. 22.85% and 26.82% respectively. Significant decrease was found in symptom Discolouration of skin in both groups i.e. 42.50% and 37.03% in group A and group B respectively. Significant decrease in Itching at the face i.e. 41.65% was only found in group B in comparison to group A while significant reduction in Pain in lesion i.e. 28.12% was only found in group A in comparison to group B.

While comparing the results of both test drugs, statistically non significant result was found by Unpaired 't' test. Means, both Group A (KKG) and Group B (NKG) showed similar result statistically in sign and symptoms (Table 5). Overall, KKG shows slight better result in clinical study than the NKG, this may be due to the 'Varnya' (which improves complexion) property of Kesar. Both Groups of KG showed significant results in Number of Pidika and in Discoloration of skin. Both Groups show no significant results in Area occupied by Pidika and in Srava from lesion. KKG show comparatively significant result in Pain in lesion and NKG showed comparatively significant result in Itching at the face (Table 5, 6 and 7). No major difference is observed in comparative clinical efficacy of both KKG and NKG, therefore, NKG can be preferred over KKG, as NKG is more cost effective than KKG.^[16]

It is suggested that internal medicine is also necessary for complete remission of Mukhadushika. Especially in constipated patients, without treatment of Vibandha (constipation), Abhyanga alone can't show its effect.

CONCLUSION

Both KKG and NKG were found highly effective on cardinal signs and symptoms of Mukhadushika. Though, on signs and symptoms, KKG was found comparatively slightly more therapeutically effective; overall comparison of clinical efficacy of both KKG and NKG on Mukhadushika reveal no major difference statistically. Therefore, NKG, which is more cost effective than KKG, can be preferred for future utilization by physicians. As the disease is associated with multi-factorial etiological factors, along with drug interventions, due importance must be given to cleanliness and to adopt healthier diet and lifestyle modifications, while management of Mukhadushika.

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Tables:

Table 1: Scoring of sign and symptoms

Sign and symptoms	Criteria	Score
Number of Pidika	No	0
	Up to 5	1
	6 to 10	2
	11 to 20	3
	>20	4
Area occupied by the Pidika	No	0
	1 to 2 cm	1
	3 to 4 cm	2
	> 5cm	3
Discolouration of the skin involved	No	0
	At the centre of lesion	1
	Surrounding the lesion	2
	Over all face	3
Srava from lesion	No Srava	0
	Very less need not to mob	1
	Needs mobbing	2
	Profuse	3
Itching at the face	No	0
	Occasional	1
	Frequent	2
	Continuous	3
Pain in lesion	No	0
	On pressure	1
	On simple touch	2
	Without touching	3
Burning in Lesion	No	0
	Occasional	1
	Frequent	2
	Continuous	3

Table 2: Status of the enrolled patients

Patients	Group A	Group B	Total
Treated	24	25	49
LAMA	06	05	11
Total	30	30	60

Table 3: Effect of KKG on cardinal symptoms of Mukhadushika

Criteria for Mukhadushika	n	B.T.	A.T.	Change	% of relief	S.D. ±	S.E. ±	t value	p
Number of Pidika	24	3.33	2.75	0.58	17.50	1.01	0.20	2.80	< 0.01*
Area occupied by Pidika	18	1.50	1.16	0.35	23.34	0.76	0.18	1.85	< 0.05
Discolouration of skin	21	1.90	1.09	0.81	42.63	0.74	0.16	4.94	< 0.01*
Srava from Lesion	19	1.84	1.42	0.42	22.85	0.90	0.20	2.03	< 0.05
Itching at the Face	04	2.25	1.50	0.75	33.33	0.50	0.25	3.00	< 0.05
Pain in lesion	16	2.00	1.44	0.56	28.12	0.80	0.20	2.76	< 0.01*

*= Significant, n= number of patients, B.T.= Before Treatment, A.T.= After Treatment, S.D.= Standard Deviation, S.E.= Standard Error

Table 4: Effect of NKG on cardinal symptoms of Mukhadushika

Criteria for Mukhadushika	n	B.T.	A.T.	Change	% of relief	S.D. ±	S.E. ±	t value	P
Number of Pidika	25	2.68	2.16	0.48	17.91	1.12	0.22	2.13	< 0.01*
Area occupied by Pidika	17	0.82	0.64	0.17	20.73	0.88	0.21	0.82	< 0.1
Discolouration of skin	22	1.22	0.77	0.45	37.03	0.80	0.17	2.66	< 0.01*
Srava from Lesion	24	1.84	1.37	0.47	26.82	1.10	0.22	2.03	< 0.05
Itching at the Face	09	1.33	0.77	0.55	41.65	0.52	0.17	3.16	< 0.01*
Pain in lesion	23	1.65	1.26	0.39	23.68	1.03	0.21	1.81	< 0.05

*= Significant, n= number of patients, B.T.= Before Treatment, A.T.= After Treatment, S.D.= Standard Deviation, S.E.= Standard Error

Table 5: Comparative effect of KKG and NKG on cardinal symptoms of Mukhadushika

Symptom	Groups	n	Change	% of relief	S.D. ±	S.E. ±
Number of Pidika	A	24	0.58	17.50	1.01	0.20
	B	25	0.48	17.91	1.12	0.22
Area occupied by Pidika	A	18	0.35	23.34	0.78	0.19
	B	17	0.17	20.73	0.88	0.21
Discolouration of skin	A	21	0.81	42.63	0.74	0.16
	B	22	0.45	37.03	0.80	0.17
Srava from lesion	A	19	0.42	22.85	0.90	0.20
	B	24	0.47	26.82	1.10	0.22
Itching at the Face	A	04	0.75	33.33	0.50	0.25
	B	09	0.55	41.65	0.7	0.23
Pain in lesion	A	16	0.56	28.12	0.80	0.20
	B	23	0.39	23.68	1.03	0.21

n= number of patients, S.D.= Standard Deviation, S.E.= Standard Error

Table 6: Discoloration and Area involvement wise distribution of 60 patients

Discolouration and Area occupied by Pidika	Group A	Group B	Total	Percentage
No Discolouration	00	08	08	13.33
Discolouration at the centre of lesion	12	09	21	35.00
Discolouration surrounding lesion	10	07	17	28.33
Over all discolouration	08	06	14	23.33
No Involvement of Area	18	08	26	43.34
1 to 2 cm	10	18	28	46.66
1 to 2 cm	02	04	06	10.00

TABLE 7: Overall effect of therapy of both KKG and NKG

Effect of Therapy	Number of Patients			
	Group A	%	Group B	%
Marked Improvement	03	12.00	04	15.38
Moderate Improvement	11	44.00	07	26.92
Mild Improvement	04	16.00	06	23.07
Unchanged	07	28.00	09	34.61