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A Clinical Study to Access the Efficacy of Karaveer Taila on Kikkisa (Striae Gravidarum)

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ABSTRACT : Reproduction is an important part of the life of female. Some physiological, hormonal and metabolic changes occur in mother's body to accommodate and support the fetus throughout pregnancy. In response to these changes some ailments appear during pregnancy. Among the common ailments of pregnancy as recognized by various pioneers of Ayurveda, Kikkisa is a common disorder which appears on the abdomen during seventh month. If we look at the etiology of Kikkisa, it shows that various sages has compiled the same cause i.e. vitiation of tridosha due to the growing fetus which leads to burning sensation and itching as symptoms and stretch marks as a sign. Above said causative factors and symptomatology of Kikkisa has close resemblance with Striae Gravidarum (S.G.) as described in modern texts. In this study an attempt has been made to define Kikkisa, on scientific grounds vis-a-vis S.G. In present study, 30 clinically diagnosed Kikkisa patients were divided into two groups of 15 each and given Karaveer *(Neriun indicum* Mill.) taila for local application for 2 months trial period. Karaveer taila was prepared from leaves of Karaveer and Til oil as per the method of preparation of oil described in classics. Patients were assessed thoroughly for a total period of 3 months including 1 month follow up period. A statistically highly significant ($p<0.001$) decrease was observed in features of itching and colour of Kikkisa. No untoward reactions were observed in both the groups throughout the study period.

Key words : Kikkisa, Striae Gravidarum, Karaveer, Pregnancy.

INTRODUCTION

Healthy female lays the strong foundation of the nation . Emphasizing the importance of this fact Pt. J.L. Nehru said that "To awaken people, it is the woman who must be awakened. Once she is on the move, the family moves, the village moves, the nation moves". A comprehensive concept of health is developed by Ayurveda thousands of years ago which is witnessed by Manu Smriti prescribing rules and regulations for personal health, dietics and hygienic rituals at the time of birth. All the similar ideas can also be traced during most ancient civilization when our great pioneers of Ayurveda have advocated many formulations intended to maintain the reproductive health simultaneously.

Major adaptations in maternal anatomy, physiology, hormones and metabolism are required for a successful pregnancy. These adaptations profoundly affect nearly every organ/ system of the pregnant women[1, 2].

Among various disorders of pregnancy, Kikkisa is a common disorder which occurs at the late phase of second trimester. Almost all pregnant women (75-90%)[3] of the world are suffering from Kikkisa (Striae Gravidarum). The condition of Kikkisa may not be a life threatening illness but it has tendency to effect the daily life and health of a pregnant woman including her social and mental health. If it is very chronic, the person may develop psychiatric illness like uneasiness.

If we look at the aetiopathology of Kikkisa in the literature of Ayurveda, Acharya Charaka (Ch.Sh. 8/32)[4], Bhela (Bh.Sh. 8/8)[5], Vagbhata (As. Sa. Sh. 3/9[6] and As. Hr. Sh.1/49[7]), are of the opinion that growing fetus displaces all the body humors upwards, thus vitiating them. Vitiated Vata dosha leads to twak prasaran (stretching of skin), Pitta dosha causes vidaha and vaivarnyata (burning and pigmentation) and Kapha dosha leads to Kandu (itching), which all together is termed as Kikkisa.

Above said causative factors and symptomatology of Kikkisa are having a very close resemblance with striae gravidarum (S.G.) as described in modern texts of obstetrics[8, 9]. In this study an attempt has been made to define Kikkisa, on scientific grounds vis-à-vis S.G. Striae Gravidarum is defined as scar like lesions, found on the abdomen, breasts, buttocks and thighs during and following pregnancy. It results from over extension of the skin and atrophy of the dermis. Itching of various intensity, burning sensation give a lot of discomfort to the pregnant woman as well as the stretch marks also give a cosmetic concern to the patient[10, 11].

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In modern era only for the last half century, it became the universal subject of human concern to examine the mysteries and mechanisms of Kikkisa. Recent literary research shows that very less clinical work have been conducted on this problem[12]. In comparison to the therapeutic procedure of different system of medicine, Ayurveda literature has a beautiful and detailed description of the local and internal management/ treatment of this clinical problem.

Drug : Karaveer *(Nerium indicum* Mill. of Apocynaceae family), is traditionally used in conditions of itching, inflammation etc. So Karaveer patra sidhha taila which is indicated in the treatment of Kikkisa (Cha.Sha. 8/32) has been selected for local application and is prepared out of leaves of Karaveer and Til taila i.e. Sesame oil. In classics of Ayurveda Karaveer is highlighted for Kapha Vatahara, Kushthaghna (Cures skin diseases) and Kandughna (Anti pruritis)[13, 14, 15, 16] actions which are the requisitions in the present problem- Kikkisa. Sesame oil after processing is also having Tridoshahara property which is also beneficial for treatment of the problem.

Management of Kikkisa with the help of economical Ayurvedic drugs is always desired. So to provide a cheap, safe and effective treatment, Karaveer taila was hypothesized to be effective. Non controversial status of Karaveer, its easy availability & formulation of single drug and easy application were also the main criterion for selection of the drug[14,15].

Thus in view of magnitude of the problem Kikkisa & indication of simple formulation in its treatment , the present study was undertaken with following aims and objectives.

Aims & Objectives :

1. To study Kikkisa and Striae gravidorum conceptually.
2. To access the efficacy of Karaveera taila in the treatment of Kikkisa- Striae gravidarum.
3. To access the toxic/ side effects of Karaveer taila clinically if any.

Purpose : The goals of treatment were either to prevent the disease, or to restore synchrony of the skin, to preserve skin health and to relieve the agony of the patient with the help of a cheap, safe, effective and easily applicable Ayurvedic medicament.

MATERIAL & METHODS

Patients were recruited from the OPD and IPD of R. G. Govt. Ayurvedic hospital , Paprola, Dist. Kangra. (HP) for 3 months study period. Written & informed consent was obtained from all subjects.

Total 32 patients were registered, 2 patients were excluded because they could not complete the trial. Of the remaining 30 patients suffering from Kikkisa were included in the study and after run in period the patients were simply randomized to one of the following 2 groups (15 patients in each group).

1. Preventive group (Having no stretch marks)
2. Curative group (Already having stretch marks)

Karaveer taila was prepared out of Karaveer leaf paste 1/4-parts, Sesamen oil 1 -part and Water 4-parts as per the method described in AFI to prepare taila to the state of Kharapaka(Slightly over heated)[17].

Dose, Duration and Follow up: All patients were advised to use 5ml of Karaveer Taila locally on the abdomen as Abhyanga 2 times a day for a period of 2 months. Clinical re-assessments were performed every 15 days for a total of 6 medical visits over a period of 3 months. (i.e. follow up of 1 month).

Routine blood , urine and USG examinations were carried out to rule out any other pathology.

Inclusion criteria :

1. Age group between 20-40 years.
2. Women having pregnancy between 5-8 months.
3. Patients having classical signs and symptoms of Kikkisa.

Exclusion criteria :

1. Age <20 years and >40 years.
2. Patients having skin disorders.
3. Patients having chronic medical and surgical disorders.
4. Patients having complications of pregnancy.
5. Any malignancy on the affected part.
6. Patients who were not willing for trial.

Criteria of Assessment :

Assessment was done on the basis of subjective and objective criteria. Parameters evaluated were severity of itching, number, color and length of Kikkisa. These parameters were graded from 0-4 according to severity as given below. Number, color and length were assessed by taking photographs of the affected part.

Subjective criteria :

1. Kandu-
   - No Kandu(Normal Activities) - 0
   - Mild Kandu (1-2 times/day) - 1

- Moderate Kandu (3-4 time /day, but not disturbing the routine work) - 2
- Severe Kandu (5-6 times/day, disturbing the routine work) - 3
- Very Severe Kandu (Through out the day, disturbing the routine work and sleep) - 4

Objective criteria :

1. No. of Kikkisa marks present on Lower Abdomen-
   - No Kikkisa - 0
   - 1-10 No. of Kikkisa - 1
   - 11-20 No. of Kikkisa - 2
   - 21-30 No. of Kikkisa - 3
   - >30 No. of Kikkisa - 4
2. Length of Kikkisa in Centimeters-
   - No Kikkisa - 0
   - 1-3 Centimeters - 1
   - 3-6 Centimeters - 2
   - 6-9 Centimeters - 3
   - >9 Centimeters - 4
3. Colour of Kikkisa-
   - Normal Skin Colour - 0
   - Blackish white - 1
   - Yellowish white - 2
   - Pinkish white - 3
   - Silvery white - 4

Overall Assessment of Therapy :

Over all result was assessed in terms of percentage relief obtained in sign/symptoms:-

- Complete Remission - 100%
- Markedly Improved - 75-100%
- Moderately Improved - 50-75%
- Mildly Improved - 25-50%
- Unchanged - <25%

OBSERVATIONS

A total of 32 subjects were registered in the present study, out of which 30 patients completed the trial. In this study, maximum no. of patients i.e.56.25% belonged to 21-25 year age group i.e. reproductive age group. Majority of patients were housewives, educated up to matric or higher secondary, from rural Hindu community. Maximum no. of patients were primigravida with gestational age between 29-36 weeks. Observations showed that kandu was present in maximum 75% of patients because it was present in both the groups whereas Kikkisa was present in 46.87% of patients.

The comparative overall effect of therapy was encouraging (especially in preventive groups) as out of 30 patients 56.66% patients were cured, 6.66% patients were markedly improved, 16.66% were moderately improved and 13.33 patients were mildly improved and 6.66% patients remain unchanged.

TABLE NO. 1 : STATISTICAL ANALYSIS OF EFFECT OF KARAVEER TAILA ON CARDINAL FEATURES OF KIKKISA ON 15 PATIENTS OF PREVENTIVE GROUP (KANDU ONLY) :

Cardinal Sign	n	Mean score		X	% Relief	SD	SE	t	p
		BT	AT						
Kandu	14	3.07	0.28	2.78	90.55	0.97	0.26	10.71	<0.001

TABLE NO. 2 : OVERALL EFFECT OF KARAVEER TAILA ON 15 PATIENTS OF KIKKISA IN PREVENTIVE GROUP :

Effect	No. of Patients	%
Complete Remission	12	80
Marked Improvement	1	06.66
Moderate Improvement	2	13.33
Mild Improvement	0	00
Unchanged	0	00

TABLE NO. 3 : STATISTICAL ANALYSIS OF EFFECT OF KARAVEER TAILA ON CARDINAL SIGNS AND SYMPTOMS OF KIKKISA ON 15 PATIENTS OF CURATIVE GROUP :

Cardinal Signs and symptoms	n	Mean score		X	% Relief	SD	SE	t	p
		BT	AT						
Kandu	8	3.25	0.25	3	92.30	1.06	0.37	8.10	<0.001
Colour of Kikkisa	15	2.53	0.93	1.6	63.24	1.05	0.27	5.92	<0.001
No. of Kikkisa	15	2.26	1.73	0.53	23.45	0.63	0.16	3.33	<0.01
Length of Kikkisa	15	1.80	1.33	0.47	26.11	0.63	0.16	2.91	<0.05

TABLE NO. 4 : OVERALL EFFECT OF KARAVEER TAILA ON 15 PATIENTS OF KIKKISA IN CURATIVE GROUP :

Effect	No. of Patients	%
Complete Remission	5	33.33
Marked Improvement	1	6.66
Moderate Improvement	3	20
Mild Improvement	4	26.66
Unchanged	2	13.33

TABLE NO. 5 : COMPARATIVE OVERALL EFFECT OF KARAVEER TAILA ON 30 PATIENTS OF KIKKISA ON BOTH GROUPS :

Effect	No. of Patients		%
	Preventive	Curative	
Complete Remission	12	5	56.66
Marked Improvement	1	1	06.66
Moderate Improvement	2	3	16.66
Mild Improvement	0	4	13.33
Unchanged	0	2	06.66

DISCUSSION

There is ample description of kikkisa disorder in Ayurvedic literature which on exploration of the modern literature is a similar clinical condition to that of Striae gravidarum. In modern medical system, symptomatic treatment measures to relieve itching sensation are advocated whereas preventive aspect is missing. Ancient scholars of Ayurveda have mentioned many oral medications along with local formulation in the treatment of Kikkisa. Ayurvedic scholars were well aware of the fact that prevention of this disease is possible if it is properly managed during pregnancy, that's why its management has been mentioned during "Garbhini Paricharya" i.e. antenatal care.

In Kikkisa Kandu (Itching) is mentioned as a causative factor and as a symptom. In this clinical trial especially in preventive group encouraging results are seen, where in 90.55% relief was observed in itching. None of the patients of preventive group developed stretch marks. Also 80% patient showed complete remission in the preventive group. Kushthaghna (skin diseases relieving) & Kandughna(Anti-pruritis) actions of Karaveer and skin health promoting action of Sesame oil has contributed in the prevention of stretch marks.

The effect of Ayurvedic formulation in curative group was found to be highly encouraging. 92.30% relief in itching, 63.24% relief in the color if the stretch marks was observed in this group. This gave a sense of relief and satisfaction to the patient from cosmetic view point. Not only this the patients of this group showed approximately 25% reduction in size and number of stretch marks. During course of therapy and after withdrawal no adverse effect was noted. Thus present trial drug is a cost effective, safe and simple treatment of Kikkisa (Striae Gravidarum).

Effect of therapy on various clinical features like Kandu and Colour of Kikkisa showed statistically significant result ($p<0.001$). The statistically significant improvement was probably because of tridoshahara activity, Kandughna, anti inflammatory, varnya properties of the trial drug and by the enhancement of stretching capacity of the skin due to Abhyanga (Local massage).

Although the present clinical study gave satisfactory results which proved our hypothesis yet a few humble recommendations are forwarded in this respect. A study on a larger sample is required; standardization of the tried formulation i.e. Karaveer taila; its chemical characterization to find out the exact mode of action of the drug, along with histo- pathological study of the skin should be done.

CONCLUSION

Kikkisa(striae gravidarum) is a common discomforting problem in the late second trimester of pregnancy which can be prevented by following proper antenatal regimen as described in Ayurvedic literature along with the application of the Karaveer taila. The tried drug also showed its potential in relieving itching as well as changing the colour & reducing the size of stretch marks during pregnancy. No adverse action of the Karaveer taila was seen in this clinical study. Thus Karaveer taila (single drug processed oil) is a cost effective & safe medicine in the treatment of kikkisa-striae gravidarum.

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हिन्दी सारांश

किक्किस (स्ट्राए ग्रेविडरम) पर करवीर तैल के चिकित्सकीय प्रभाव का अध्ययन

कामिनी धीमान, मंजुश्री साहू एवं के. एस. धीमान

गर्भावस्था प्रत्येक महिला के जीवन का एक सुखद अनुभव है। क्रमिक गर्भवृद्धि एवं उदर व ऊरू प्रदेश की त्वचा में तनाव के फलस्वरूप किक्किस रोग की उत्पत्ति होती है, जिसमें कण्डू, दाह व व्रणवस्तु (निशान) होते हैं। कण्डू व दाह रूग्णा को शारीरिक कष्ट व उदर पर बनने वाले निशान असौंदर्यकर व मानसिक कष्ट देते हैं। करवीर तैल का इस रोगावस्था में चिकित्सकीय प्रभाव हेतु अध्ययन किया गया। किक्किस प्रतिषेध वर्ग व चिकित्सकीय वर्ग इन दो वर्गों में रूग्णों को बांटकर करवीर तैल का प्रयोग करवाया गया। प्रतिषेध वर्ग में किक्किस की उत्पत्ति नहीं हुई जबकि चिकित्सकीय वर्ग में कण्डू व व्रणवस्तु में अति अल्पता पायी गई। सारांशतः करवीर तैल किक्किस की चिकित्सा में सस्ती व सुलभ निर्विकार औषधि है।

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