

A PREVENTIVE CLINICAL STUDY TO ACCESS THE EFFICACY OF *KUMARYADI* CREAM ON *KIKKISA* (STRIAE GRAVIDARUM)**Dr. Hemant Patel^{*1}, Dr. Shilpa Donga², Prof. L. P. Dei³, Dr. Yogesh Manani⁴, Dr. Shrawan Kamble⁵**

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ABSTRACT

Reproduction is an important part of the life of female. Some physiological, hormonal and metabolic modifications occur in mother's body to accommodate and support the fetus throughout pregnancy. Striae gravidarum (SG) is the most common change in connective tissue of pregnant women and may cause cosmetic concerns. Striae gravidarum on women's body symbolizes love and life, it also symbolizes the pain that comes with motherhood. Striae gravidarum do not pose a health risk. However, they are often symptomatic, causing discomfort as well as psychological distress in pregnant women, when severe. Among the common disorders of pregnancy as recognized by various pioneers of Ayurveda, *Kikkisa* is a common ailment which appears on the abdomen during late phase of second trimester. If we look at the etiology of *Kikkisa*, Vitiating 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 as described in modern texts. There is great demand of Ayurveda in the field of cosmetology. Ayurveda has unique concept of beauty and can offer effective, cheaper and long lasting beauty therapy without any side effects. In present study, 17 patient had given *Kumaryadi* cream for local application for 2 months trial period out of them 15 patients completed the course of treatment. Patients were assessed thoroughly for a total period of 3 months including 1 month follow up period. From the above study it has concluded that the drug *Kumaryadi* cream effective to prevent *Kikkisa* (Striae gravidarum) with no apparent evidence of complication.

KEY WORDS: *Kikkisa*, Stretchmark, Striae Gravidarum, *Kumaryadi* cream, Pregnancy.

INTRODUCTION

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]} Almost all pregnant women (75-90%)^[3] of the world are suffering from Striae Gravidarum. 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.^{[4][5]} The condition of Striae Gravidarum 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^[6], Bhela^[7], Vagbhata^{[8][9]}, are of the opinion that growing fetus displaces all the body humors upwards, thus vitiating them. Vitiating 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* which occurs at the late phase of second trimester. Above said causative factors and

symptomatology of *Kikkisa* are having a very close resemblance with striae gravidarum as described in modern texts of obstetrics.^{[10][11]}

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. The cosmetic approach in ayurveda is related to the healthy status of body and mind.^[12] Management of *Kikkisa* with the help of economical Ayurvedic drugs is always desired. So to provide a cheap, safe and effective treatment, *Kumaryadi* cream was hypothesized to be effective. In this study an attempt has been made to understand the ailment according to Ayurvedic ethics on scientific grounds vis-à-vis SG and to evaluate the efficacy of *Kumaryadi* cream in *Kikkisa*.

Drug: contains of *Kumaryadi* cream (Table 1) i.e. *Kumari*, *Haritaki*, *Babul*, *Lodhra*, *Sariva*, *Tila Taila*, and *Madhuchhista* are traditionally used in conditions of *Vrana*, itching, inflammation etc. So *Karviryadi* cream has been selected for local application. Contains of *Kumaryadi* cream having properties like *Kandughna*^[13], *Kushthghna*, *Dahaprashmana*, *Tvachya*, *Varnya*^[14], *Ropana*, *Savarnikarana*^[15], and *Sthirikarana*^[16] (Table 2) which are the requisitions in the present problem-*Kikkisa*.

Aims & Objectives

1. To study the concept of *Kikkisa* and Striae gravidarum.
2. To evaluate clinical efficacy of *Kumaryadi* cream in *Kikkisa* as preventive aspect.
3. To evaluate the occurrence of symptoms in *Kikkisa*.

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 AND METHODS

Patients attending the Outdoor Patients Department of Streeroga & Prasootitantra, I.P.G.T. & R.A. Jamnagar, were incorporated into the study irrespective of caste, religion etc. A suitable research proforma prepared for the assessment of therapy by adopting suitable grading pattern. A written and informed consent was taken from the patient before the commencement of treatment. Total 17 patients were registered, out of them 15 patients completed the course of treatment. *Kumaryadi* taila was prepared in the dept. of Rasashastra & Bhaishajya kalpana, I.P.G.T. & R.A. Jamnagar, with classical method of Taila Siddha Kalpana and then converted in cream as Malhara Kalpana (Rasatarngini).

Study design

Study type: Intervention
 Purpose: Prevention
 Masking: Randomised single blind clinical trial
 Timing: Prospective
 End point: Efficacy and safety
 Routine blood, urine and USG examinations were carried out to rule out any other pathology.

CRITERIA FOR SELECTION OF PATIENTS

Inclusion Criteria

1. Pregnant women of age group between 20 – 40 years.
2. Period of pregnancy from 6th months onwards
3. Primi Gravidae and multi gravidae (Previous H/o 1st trimester of pregnancy)
4. No occurrence or mild occurrence of signs and symptoms of *Kikkisa*.

Exclusion criteria

1. Age below 20 and above 40 years.
2. Multi gravidae & para with previous scar marks.
3. Any type of skin diseases other than *Kikkisa*.
4. Patients having chronic diseases e.g Tuberculosis, Jaundice etc
5. Any malignancy on the affected part was excluded.

Criteria of Assessment

Assessment was done mainly on the basis subjective and objective criteria. These parameters were graded from 0-3 according to severity as given below. Number, color and length were assessed by taking photographs of the affected part.

Subjective parameters: *Kandu*, *Vidaha*^[17]

Objective

Rekhaswaruptwaksankoch(RSTS)^[18], *Twakbheda*, *Vaivarnyata*, *Vairupya*

SCORING PATTERN

Kandu (Itching)

- No Itching : 0
- Mild Itching not disturbing normal activity : 1
- Occasional itching disturbing normal activity : 2
- Itching present continuously & disturbing normal activity : 3

Vidaha (Burning)

- No burning sensation : 0
- Mild Burning not disturbing normal activity: 1
- Occasional burning disturbing normal activity : 2
- Burning present continuously disturbing normal activity: 3

Twakbheda: (Scar on skin)

- Normal : 0
- Mild : 1
- Moderate : 2
- Severe : 3

Vavariniyata (Discoloration)

- Normal skin colour : 0
- Thickening of skin but no criss - cross marking : 1
- Thickening of skin with criss - cross marking : 2
- Severe lichnefication : 3

RekhaswaroopTwaka Sankoch (Texture)

- Not developing : 0
- Mild developing : 1
- Moderate developing : 2
- Severe developing : 3

CRITERIA FOR OVERALL ASSESSMENT OF THERAPY

- No Occurrence - 100% result
- Mild Occurrence - 76 % - 99 % result
- Moderate Occurrence - 51 % - 75% result
- Severe Occurrence - 0 % - 50 % result

COURSE OF TREATMENT

Local Application of *Kumartadi* cream Twice in a day as required (Approx. 10 gram) on the area of abdomen, thigh and breast (where possibilities of *Kikkisa* appears) for duration of 2 months.

Follow Up: Follow up was conducted for one month after completion of the treatment at the interval of 15 days.

OBSERVATION

The observations of the study are presented in Tables 3 & 4

A total of 17 subjects were registered in the present study, out of which 15 patients completed the trial. In this study, maximum no. of patients' i.e.52.94% belonged to 21-25 year age group i.e. reproductive age group - most fertile period should mention here which is very prone to develop the *Kikkisa* in the Primi Gravidae. (TABLE-3) 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 20-28 weeks. The present study shows that maximum number of patients were from lower middle class Even then no relation can be fixed with disease *Kikkisa* in the economic status however good health and *Garbhini Paricharya* is required for the pregnant women to prevent *Kikkisa* in some extent. (TABLE-4)

Table-1: Drug contain.

Content	Latin name	Part used	Ratio	Quantity	Form
<i>Kumari</i>	<i>Aloe barbadensis</i> Mill	<i>Pulp</i>	3.2 part	5.33 kg	<i>Swarasa</i>
<i>Haritaki</i>	<i>Terminalia chebula</i> Retz.	<i>Fruit</i>	3.2 part	5.33 kg	<i>Swarasa</i>
<i>Babul</i>	<i>Acasia arebica</i> Willd.	<i>Bark</i>	3.2 part	5.33 kg	<i>Swarasa</i>
<i>Lodhra</i>	<i>Symplocos racemosa</i> Roxb.	<i>Bark</i>	3.2 part	5.33 kg	<i>Swarasa</i>
<i>Sariva</i>	<i>Hemidesmus indicus</i> R.Br.	<i>Root</i>	3.2 part	5.33 kg	<i>Swarasa</i>
<i>Pashanabhed</i>	<i>Rotula equatica</i> Lour.	<i>Root</i>	3.2 part	5.33 kg	<i>Swarasa</i>
<i>Kumari</i>	<i>Aloe barbadensis</i> Mill	<i>Pulp</i>	1/5 part	333 gm	<i>Kalka</i>
<i>Haritaki</i>	<i>Terminalia chebula</i> Retz.	<i>Fruit</i>	1/5 part	333 gm	<i>Kalka</i>

RESULT AND 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) *Vidah*, *Twakbheda*, *RSTS*, *Vaivarnyata* and *Vairupyata* is mentioned as a symptom. The data regarding cardinal signs & symptoms before and after the treatment was observed that None of the patients developed *Vidah*, *Twakbheda*, *RSTS* and *Vairupyata* while 13.33 % occurrence found in *Kandu* as well as *Vaivarnyata*, which was statistically insignificant ($p>0.05$). (TABLE-5) Whereas 100% of non-occurrence was found in *Vidah*, *Twakbheda*, *RSTS* and *Vairupyata* while 86.67 % occurrence found in *Kandu* as well as *Vaivarnyata*. (TABLE-6) After the treatment with *Kumaryadi* Cream, 13 patients (86.67%) showed no occurrence while 02 patients (13.33%) showed mild occurrence. (TABLE-7) Contains of *Kumaryadi* cream having properties like *Kandughna*, *Kushthghna*, *Dahaprashamana*, *Tvachya*, *Varnya*, *Ropana*, *Savarnikarana*, and *Sthirikarana* which work in the skin health promotion and contributed in the prevention of stretch mark. 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*).

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. *Kumaryadi* cream; 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.

<i>Babul</i>	<i>Acasia arebica</i> Willd.	<i>Bark</i>	<i>1/5 part</i>	<i>333 gm</i>	<i>Kalka</i>
<i>Lodhra</i>	<i>Symplocos racemosa</i> Roxb.	<i>Bark</i>	<i>1/5 part</i>	<i>333 gm</i>	<i>Kalka</i>
<i>Sariva</i>	<i>Hemidesmus indicus</i> R.Br.	<i>Root</i>	<i>1/5 part</i>	<i>333 gm</i>	<i>Kalka</i>
<i>Pashanabhed</i>	<i>Rotula equatica</i> Lour.	<i>Root</i>	<i>1/5 part</i>	<i>333 gm</i>	<i>Kalka</i>
<i>Tila Taila</i>		<i>Oil</i>	<i>4 part</i>	<i>8 kg</i>	<i>Oil</i>
<i>Madhuchhista</i>				<i>1.3 kg</i>	

Table-2: Properties of Karaviryadi cream's Drugs.

RASA	Guna	Drug having this 'Guna'
Madhura	Dahaprashamana, Tvachya, Varnya	Tila Taila, Kumari, Haritaki Sariva
Kashaya	Ropana, Savarnikarana	Tila Taila, Babbula, Haritaki, Lodhra, Pashanabheda
Tikta	Kandughna, Kushthghna, Sthirikarana Dahaprashamana,	Tila Taila, Kumari, Haritaki, Pashanabheda
Katu	Kushthaghna, Kandughna	Haritaki

Table-3: Age Wise Distribution Of Patients.

Age-group (in years)	Number of patients
20-25	09
26-30	05
31-35	03
36-40	00

Table-4: Socio Economic Status Wise Distribution.

Socio economic status	Number of patients
Poor	1
Lower Middle	13
Middle	0
Upper Middle	3
Rich	0

Table-5: Effect Of Therapy On Subjective And Objective Parameters.

Subjective & Objective Parameters	N	Mean		% occurrence	S.D. (±)	S.E. (±)	't'	P	
		B.T.	A.T						
Subjective	<i>Kandu</i>	15	-	0.18	13.33	0.35	0.90	1.46	>0.05
	<i>Vidah</i>	15	-	0	00	00	00	-	-
Objective	<i>Twakbheda</i>	15	-	-	00	00	00	-	-
	<i>RSTS</i>	15	-	-	00	00	00	-	-
	<i>Vaivarnyata</i>	15	-	0.5	13.33	0.35	0.90	1.46	>0.05
	<i>Vairupya</i>	15	-	-	00	00	00	-	-

Table-6: Effect Of Therapy (% of non-occurrence).

Subjective & Objective Parameters		N	BT	AT	Percentage of non-occurrence
Subjective	<i>Kandu</i>	15	00	02	86.67
	<i>Vidah</i>	15	00	00	100
Objective	<i>Twakbheda</i>	15	00	00	100
	<i>RSTS</i>	15	00	00	100
	<i>Vaivarnyata</i>	15	00	02	86.67
	<i>Vairupya</i>	15	00	00	100

Table-7: Effect Of Therapy.

Effect of therapy	Total number of patients	%
No Occurrence - 100% result	13	86.67
Mild Occurrence - 76 % - 99 % result	02	13.33
Moderate Occurrence - 51 % - 75 % result	00	-
Severe Occurrence - 0 % - 50 % result	00	-

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 *Kumaryadi* cream. No adverse action of the *Kumaryadi* cream was seen in this clinical study. Thus *Kumaryadi* cream is a cost effective & safe medicine in the treatment of *Kikkisa* - striae gravidarum.

REFERENCES

1. Sujit K. Chaudhury; Concise medical physiology, New Central Book Agency (P) Ltd.; 2nd Edition.
2. Gyton and Hall, Physiology Review by John E. Hall; Elsevier Publication; 11th Edition 2005.
3. Wiston G.B., Lewis C.W.; Dermatoses of pregnancy, Journal of American Academy of Dermatology; Vol. 6:977, 1982.
4. Dermatology in General Medicine by Fitz Patrick; Mc Grow Hill Company; 7th Edition, 2008.
5. Practice of dermatology by P. N. Behl; CBS Publication New Delhi; 10th edition, 2005.
6. Agnivesha; Charaka samhita Vidyotini Hindi Commentary by Pt. Kashi Nath Shastri and Dr. Gorkha Nath Chaturvedi; Adhaya 8/32, Chaukhamba Bharti Academy-Varanasi; 8th edition, Reprint 2004.
7. Bhela Samhita, by K.H. Krishnamurthy, Adhyaya 8/8; Eastren Book Corp., 1st edition, 2008.
8. Astanga Samgraha by Acharya Vagbhata with Shashilekha commentary of Indu by Kv. Jayotirmitra Acharya; Shareer Sthana Adhyaya 3/9 Choukhambha Sanskrita Series, Office Varanasi; 1st edition, 2006.
9. Ashtang Hridaya by Acharya Vagbhata with Ayurveda Rasayana & Sarvanga Sundara commentary of Hemadri & Arundutta by Krishna RamchandraShastri Navre, ShareeraSthana Adhyaya 1/49; by Pandit Vaidya Lal Chand Shastri; Choukhambha Orientalia Varanasi; 9th edition-2005.
10. Ayurvediya Prasuti tantra avum Stri roga Vol I by Dr. P.V. Tiwari Choukhambha Orientalia Varanasi 1st edition, 1990.
11. Text book of Obstetrics and Neonatology by Prof. C.S. Dawn; Dawn Books; 16th Edition, 2008.
12. Shastri AD. Sushrutsamhita (Purvardha) with ayurveda tatva sandipika hindi commentary, Reprint ed. Varanasi: chaukhambha Sanskrit sanathan 2005 p-56.
13. Charak Samhita Vidyotini Tika, Sutra Sthan-26/43(4) by chaukhambha bharati academy (Reprint 2009).
14. Charak Samhita Vidyotini Tika, Sutra Sthan-26/43 by chaukhambha bharati academy (Reprint 2009).
15. Charak Samhita Vidyotini Tika, Sutra Sthan-26/43(6) by chaukhambha bharati academy (Reprint 2009).
16. Charak Samhita Vidyotini tika, Sutra Sthan-26/43(5) by chaukhambha bharati academy (Reprint 2009).
17. Charak Samhita Vidyotini Tika, Sharir Sthan-8/32 by chaukhambha bharati academy(Reprint 2009).
18. Asthang Samgrah with indu tika 3/9 (tika), chaukhambha prakashan(reprint 2005).