



Pharmaceutico-Analytical Study and Clinical Evaluation of Tiktadi Ghrita Ointment in Kikkisa with special reference to Striae Gravidarum: A Randomized Controlled Trial

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Introduction: Striae gravidarum are formed with extensive stretching and rupture of elastic fibers present in dermis during pregnancy. The prevalence rate of striae gravidarum, varies from 50% to 90% in various studies among pregnant women. Tiktadi Ghrita, a formulation described in Yogaratnakar (Uttarkhand), aids in the treatment of Vrana, promoting wound healing and alleviating skin discoloration. This study aimed to find the effect of this new topical treatment option i.e., Tiktadi Ghrita ointment on Kikkisa in relation to striae gravidarum.

Aim and Objectives: To evaluate the pharmaceutico-analytical study and clinical effect of Tiktadi Ghrita Ointment in Kikkisa with special reference to Striae gravidarum.

Materials and Methods: Tiktadi Ghrita ointment will be prepared as per classical reference. The prepared formulation will be assessed with organoleptic characters and physicochemical parameters. comparative clinical study will be carried out in 2 groups where each group will receive respective drug and will be evaluated for their results on Kikkisa.

Result: The analytical parameters will be assessed to establish pharmaceutical standardization. The result of clinical study will be drawn from the mentioned assessment criteria. Statistical analysis will be done accordingly.

Discussion: If significant positive results are obtained in this work, then it will be a valuable contribution and evidence that the drug Tiktadi Ghrita ointment is equally effective in Striae gravidarum as Karveer Taila.

Keywords: Kikkisa, Pregnancy disorders, Striae gravidarum, Tiktadi Ghrita ointment

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Introduction

Ayurveda is an ancient science of life that focuses on achieving balance and harmony in the body, mind, and spirit to promote overall health and wellbeing. *Ayurveda* offers numerous formulations with beautifying properties to enhance skin health and appearance.[1-3]

Rasashastra and *Bhaishajya Kalpana* are branches of *Ayurveda* that deal with the preparation of medicinal formulations.[4] *Rasashastra* focuses on the use of heavy metals, minerals, and products of animal origin, poisonous substances, etc for therapeutic purposes, while *Bhaishajya Kalpana* involves the preparation of herbal medicines and formulations.[5] These disciplines are integral to Ayurvedic pharmacology and play a significant role in traditional Indian medicine.

Since women are God's created symbol of beauty and have a divine role in *Utpatti*, *Dharan*, and *Poshan* of *Garbha*, it is crucial to improve *Garbhini's* physical and mental health. Our *Acharyas* describe the *Paricharya* for *Garbhini*. Being a mother is a wonderful feeling for every woman, and every woman expects a fruitful pregnancy and delivery. [6,7]

In *Ayurveda* various physiological disorders during pregnancy are mentioned under the heading of *Garbhini Vyapada*, *Kikkisa* is one of them.[8] It occurs mostly in *Saptam Masa* of *Garbhini Kala* (7th month of pregnancy)[9]. As the fetus grows and enlarges the uterus (*Garbhashaya*), it displaces the *Doshas Vata*, *Pitta*, and *Kapha* upwards, causing a burning sensation (*Daha*) and itching (*Kandu*) in the abdomen, breasts, and thighs.

The factors and symptoms of *Kikkisa* are having closely resemblance with *Striae gravidarum*[10]. The prevalence rate of *striae gravidarum*, varies from 50% to 90% in various studies among pregnant women[11,12].

Striae gravidarum (SG) are formed with extensive stretching and rupture of elastic fibers present in dermis. These marks heal and scars formation takes place. These are the atrophic linear scars along natural skin lines due to connective tissue changes during the third trimester of pregnancy[13]. Symptoms such as Itching, burning sensation over abdomen, buttocks and thighs can be seen as pregnancy progresses.[12]

In various Ayurvedic texts for the treatment of *Vran* i.e., scar various *Vran Savarnikaran Yogas* has mentioned, *Tiktadi Ghrita* is one of these preparations[3]. *Tiktadi Ghrita*, a formulation described in *Yogaratanakar (Uttarkhand)*, aids in the treatment of *Vrana*, promoting wound healing and alleviating skin discoloration[14]. *Tikta Rasa* possesses properties such as *Vranaropan*, *Krumighna*, *Puyanashak*, and *Kandunashak*.

Kikkisa

Kikkisa is a skin problem that can occur during pregnancy, as described by various *Acharyas* in pregnancy disorders. *Acharyas* such as *Charaka*, *Vagbhata*, *Harita*, and *Bhela*, along with their commentators like *Chakrapani*, *Arundatta*, *Indu*, *Gangadhar*, and *Jaydev Vidhyalankar*, have discussed *Kikkisa* in the context of pregnancy issues. But, *Acharya Sushruta* did not discuss *Kikkisa* specifically in relation to pregnancy, but he did mention it as one type of *Raktaja Krimi* out of the seven types he described.[15]

Etiology/Hetu

Vataprakopak Hetu: *Katu*, *Tikta* and *Kashay Rasatmak Aahar*, *Ruksha*, *Shita Aahar*, *Vegvidharan*, *Diwaswap*, *Ratrijagaran*, *Langhan*, *Atichankraman* leads to *Vataprakopa*.

Pittaprakopak Hetu: *Ati Ushna-Tikshna-Vidahi Bhojan*, *Katu-Amla-Lavan Rasatmak Bhojan*, *Upwas*, *Atikrodha* leads to *Pittaprakopa*.

Kaphaprakopak Hetu: *Madhur-Amla Rasatmak Aahar*, *Ati Sheeta*, *Snigdha*, *Guru*, *Abhishyandi Aahar* and *Diwaswap* causes *Kaphaprakopa*.

Aahar - Vihar of mother plays important role in the formation of *Kikkisa*.

Etiopathogenesis (Samprapti)

According to women, the growth of a fetus's scalp hair during the seventh month causes an increase in *Vidaha* in the mother, leading to the development of *Kikkisa*.

However, *Atreya* disagrees, stating that as the fetus grows, it pushes the *Doshas* (*Vata*, *Pitta*, and *Kapha*) upward. These *Doshas*, when they reach the *Urah* (breasts, according to *Charaka*) or *Hridaya* (heart, according to *Vagbhata*), cause a burning sensation that results in itching and the formation of *Kikkisa*.

In late second trimester

↓

Growing foetus

↓

Displaces *Dosha* upwards

↓

Rekhaswarupa Twak Sankocha, Charma Vidararva

↓

Kandu, Vidah, Vaivarnya

↓

Kikkisa

According to *Charak Samhita*:

Some Acharyas believe that itching during pregnancy, leading to *Kikkisa*, is caused by the fetus's hair growth in the seventh month causing *Vidaha* in mother. However, *Acharya Atreya* disagrees, suggesting that the growing fetus pushes the *doshas* upward, causing itching in the chest area (*Uras*). This itching, known as *Vidah*, results in *Kikkisa*. [16]

But according to *Chakrapani*, since all organs start developing by the third month, hair growth also starts developing from third month, indicating that it unlikely to be the exclusive cause of itching. He uses the word "*Charma Vidaranam*" for this.

"*Kikkisaccha Charma Vidaranam*" (Ch.Sa.8/32 *Chakrapani Teeka*).

Gangadhar and Chakrapani both agree that "*Kikkisa*" refers to a tear in the skin. Hindi commentator Jayadev Vidhyalankar provides two reasons why hair growth cannot be the cause of itching:

1. Hair development begins in the third month, so if hair were the cause, itching should start earlier.
2. There is no direct connection between fetal hair and uterine wall, as fetus is enclosed within amniotic sac, which is filled with amniotic fluid.

According to *Astanga Hridaya*:

The pressure from the developing fetus pushes the *Doshas* upto the *Hridaya*, causing itching and burning sensations, which leads to *Kikkisa*. [17]

Arundatta provides a detailed description of the disease, mentioning that *Kikkisa* appears as wrinkled or creased markings (*Valivishesha*) in areas like the hips, breasts, and abdomen. These markings resemble linear lines and are called *Kikkisa*. He describes as –

Shooka Kairieva Poornatha. "*Rekhakaara Stakale Prayo Jayante Te Kikkisasamgnaha*" (A.H.Sa.1/58 *Arundatta Teeka*).

In some women, there are long, paddy-like structures (*Shukakriti Purnata*), also known as *Kikkisa*. Burning sensations in the palms and soles are referred to as *Vidaha*.

According to *Astanga Sangraha*:

In *Ashtanga Sangraha*, *Vridhdha Vagbhatta* gives a similar description to *Charaka*, but he uses the word "*Hridaj*" instead of "*Uras*" [18]. Commentator *Indu* suggests that the linear contractions of the skin cause *Kikkisa*.

According to *Bhela Samhita*:

In the seventh month of pregnancy, the pressure from the growing fetus disturbs the *Vata*, *Pitta*, and *Kapha Doshas*, causing them to rise upto the *Ura* and resulting in burning sensations and itching. This condition is known as *Kikkisa*. [19]

According to *Harita Samhita*:

Harita has not described *Kikkisa*, but he has mentioned eight disorders of pregnancy and *Vivarnata* is one of them which is a symptom of *Kikkisa*. [20]

Symptoms:

1. *Kandu* (Itching)
2. *Vidaha* (Burning sensation) 94333401

Signs:

1. *Charamvidarama*: Cracking of the skin between the breasts, abdomen, and thighs.
2. *Rekhaswaroop Twak Sankocha*: Linear line markings and contractions on the abdominal skin.
3. *Valivishesha Rekhakara*: Round, oval, and linear markings on the thighs, breasts, and abdomen.
4. *Shukakriti Purnata*: Paddy seed-like structures on the skin.
5. *Twak Bheda*: Differentiation or splitting of skin.
6. *Vairupya/Vaivarnya*: Discoloration of the skin.

Treatment:

Ayurvedic texts describe two main treatment approaches- *Abhyantar* and *Bahya Chikitsa*. *Abhyantar Chikitsa* involves different *Yogas* (Ayurvedic formulations) for internal consumption whereas *Bahya Chikitsa* comprises local application and irrigation with different medicines.

Treatment of *Kikkisa* is explained only in *Charak Samhita*, *Astang Hridaya*, *Astang Sangraha* and *Bhela Samhita*.

I) *Abhyantar Chikitsa*:

Butter infused with the drugs of *Madhuragana* should be given to pregnant women frequently in the dose of *Panitala Matra* with *Kolodak* (*Sushka Badar Phala Kwath*) as an *Anupan*.^[21]

The butter medicated with decoction of dry fruit of *Badar* and drugs of *Madhuragana* should be given.

II) *Bahya Chikitsa*:

Lepa - Any one of the following rubbed over the abdomen and breasts:

- Paste of *Chandan* and *Mrinala*
- *Chandan* and *Usira*
- Powder of *Sirisha* stem bark, *Dhataki* flowers, *Sarsapa*, and *Madhuyasti*
- Pestled bark of *Kutaja*, seeds of *Arjaka* (*Tulsi*), *Musta*, and *Haridra*
- Pestled leaves of *Nimba*, *Kola*, *Surasa*, and *Manjistha*
- Triphala pestled with blood of deer and rabbit
- Oil prepared with pestled leaves of *Karvir*
- Oil prepared with pestled leaves of *Karanj*

Parisheka - Irrigation of abdomen and breasts should be done by any one of the following:

- Water infused with *Punarnava*, *Malati* flowers, and *Madhuka*.
- Decoction of *Patol*, *Nimba*, *Manjistha*, and *Surasa*.
- Decoction of *Daruharidra* and *Madhuka*.
- For severe itching, apply the mentioned powders or an ointment.
- Bath with *Chandan* to soothe itching with its cooling properties.

Striae Gravidarum:

Striae gravidarum, or stretch marks of pregnancy, are a common cutaneous physiological change occurring during pregnancy.^[22] They are considered the most common connective tissue change of pregnancy^[23] and affect both primipara and multipara women.

Striae gravidarum are slightly depressed linear marks with varying length and breadth. These stretch marks represent the scar tissues within the deeper layers of the skin. They are primarily found on the abdominal wall below the umbilicus and sometimes over the thighs and breasts. Women of all racial groups are at risk (24). Rates of occurrence vary, with reported rates ranging between 50 and 90%.^[25] Striae gravidarum usually first appears around the sixth and seventh month of pregnancy^[26] but has been reported before 24 weeks gestation.^[27]

Etiopathogenesis:

Extensive stretching of the skin

↓

Causes elastic fibers in the dermis to rupture

↓

Microscopic bleeding occurs along with the inflammation of tissue

↓

Leads to reddish-purple appearance of newly formed stretch marks

↓

As the dermis stretches, the epidermis also stretches becomes translucent, revealing reddish-purple stretch marks

↓

These marks heal leading to scar formation

Striae undergoes three different stages of maturation:

1. Acute characterized by red and slightly raised striae (rubra);
2. Subacute characterized by purpuric striae;
3. Chronic characterized by hypopigmented and atrophic striae (alba).

In particular, striae rubra are flattened areas of skin with a pink-red hue that may be itchy and slightly raised. Then, they are prone to increase in length and acquire a darker purple color. Over time, the striae rubra develop into striae alba that appear white, flat, and depressed.^[28] In multiparous women the combination of pinkish and white striae are visible.

Risk factors associated with the development of striae gravidarum are not identified clearly.^[29] Two commonly recognized risk factors are higher weight gains in pregnancy and higher birth weight babies. Other risk factors include a family history,

A personal history of striae and young maternal age.[30] Apart from the mechanical stretching of the skin, increase in aldosterone production during pregnancy are the responsible factors. Estrogen, relaxin, and adrenocortical hormones may decrease the adhesiveness between collagen fibers and increase ground substance thus resulting in SG.

Treatment:

There is no specific treatment

Controlled weight gain during pregnancy and massaging the abdominal wall with lubricants like olive oil may be helpful in reducing their formation.

During Ante Partum-Massage with the lubricants contains tocopherol, fatty acids, hyaluronic acid.

During postpartum- Laser therapy and cosmetic surgery is indicated.

Table 1: Nature of the Knowledge gap identified.

Research Gap Types	Type of research gap used
Knowledge Gap	There is no previous work done on the effectiveness of Tiktadi Ghrita and its ointment on Kikkisa.
Methodological Gap	After an extensive literature search, the research scholar could not find any clinical study of Tiktadi Ghrita and its ointment on Kikkisa w.s.r. to striae gravidarum.
Practical Knowledge Gap	There are conflicting results regarding the pharmaceutical conversion of Ghrita to ointment.
Empirical Knowledge gap	The insufficient literature regarding conceptual, pharmaceutical, analytical, and clinical studies has formed an empirical knowledge Gap.

Aim and Objectives

Aim

To evaluate the pharmaceutico-analytical study and clinical effect of *Tiktadi Ghrita* Ointment in *Kikkisa* with special reference to *Striae gravidarum*.

Objectives

Primary objectives:

1. To study pharmaceutical proce. of *Tiktadi Ghrita*
2. To analyze organoleptic and physico-chemical parameters of *Tiktadi Ghrita*

Secondary objective:

1. To compare the effect of *Tiktadi Ghrita* Ointment and *Karveer Tail* in *Kikkisa* .

Materials and Methods

Present work will be conducted under the following headings.

1) Pharmaceutical Study

In this study, *Tiktadi Ghrita* will be prepared as per classical reference to establish pharmaceutical standardization. This pharmaceutical study will be done according to the following steps.

- A) Selection of Raw material
- B) Procurement of raw drugs - All raw drugs will be collected/procured from the field and authentic reliable sources.
- C) Authentication of raw material - All raw materials will be verified and authenticated.
- D) Raw drugs will be standardized as per API.

Tiktadi Ghrita –

Table 2: *Tiktadi Ghrita* Ingredients

SN	Dravya	Latin name / English name	Parts used
1.	Kutaki	Picrorhiza kurroa	Root
2.	Siktha	Bees wax	-
3.	Nisha	Curcuma longa	Root
4.	Yashtimadhu	Glycyrrhiza glabra	Root
5.	Karanj Patra	Pongamia pinnata	Leaves
6.	Karanj Phal	Pongamia pinnata	Fruit
7.	Malti Patra	Jasminum officinale	Leaves
8.	Patol Patra	Trichosanthus dioica	Leaves
9.	Nimb Patra	Azadiracta indica	Leaves
10.	Goghrita	-	-

Method of preparation of *Tiktadi Ghrita*[31]

1. The above-mentioned *Kwath Dravya* will be made into *Churna* separately and mixed together. It will then be taken into a vessel, and eight times water will be added. The mixture will be kept overnight. The next morning, the contents will be heated over *Mandagni* until the total volume is reduced to one-fourth and then filtered through a clean cloth.
2. All ingredients mentioned in *Kalka Dravya* will be crushed into a fine powder and mixed with water to make a *Kalka*.
3. *Go-ghrita Murcchana* - It will be carried out according to proce. given in Bhaishajya Ratnavali.
4. *Go-ghrita* will be taken in vessel & heated slightly over *Mandagni* until water content evaporates, foam disappears, & characteristic sound from *Ghrita*.

5. Then, the *Kalka* and *Kwath* will be added to the *Ghrita* and heated until it reaches the *Sneha Siddha Lakshanas*. After this, the vessel will be removed from the fire, and after cooling the *Ghrita* will be filtered.

6. The prepared *Ghrita* will be stored in glass containers.

Tiktadi Ghrita Ointment-

Table 3: Tiktadi Ghrita Ointment ingredients

SN	Ingredients	Use/Action	Quantity
1.	Tiktadi Ghrita	Active Ingredients	5 parts
2.	Beeswax	Thickening agent	1 part
3.	Rose water	Perfuming agent	Q.S

Method of preparation of Tiktadi Ghrita Ointment[32-34]

1. The appropriate quantity of beeswax will be taken and gently heated in a suitable vessel until it melts completely.
2. In another vessel, the appropriate quantity of *Tiktadi Ghrita* will be taken and gently heated until it melts completely.
3. The heated *Tiktadi Ghrita* will be slowly added to the vessel containing the melted beeswax.
4. The mixture will be stirred gently until a homogeneous mixture is obtained, and then rose oil will be added.
5. The mixture will be thoroughly mixed to achieve the desired ointment consistency.
6. The mixture will be allowed to cool at room temperature.
7. The prepared ointment will be stored in a wide-mouth container.

2) Analytical Study:

1. Descriptive parameters

Subjective parameters of the finished product (Organoleptic Characters)

- *Shabda* (Sound)
- *Sparsh* (Sensation)
- *Rupa* (Color)
- *Rasa* (Taste)
- *Gandha* (odor)

2. Objective parameters

Objective parameters of the finished product (Physiochemical parameters)

- Ph
- Viscosity
- Acid Value
- Specific gravity
- spread ability
- Rancidity

3. Experimental Study:

1. Assessment for eligibility.
2. Randomization.
3. Allotment of Trial Group A and Control Group B.
4. Trial group-A will receive *Tiktadi Ghrita* Ointment and Control group-B will receive *Karveer Taila*. [35]
5. Individual follows up of Gr-A and Gr-B will be taken every 15 days for 45 days.
6. Final analysis after completion of trials.
7. Conclusion and Result.

Inclusion criteria

Patients willingly participating in the trial and giving consent form.

1. Age group 20-35 years.
2. Selection of patient will be Primigravida only.
3. Women diagnosed with symptoms of *Kikkisa*

A) *Vaivarnya* (Discoloration)

B) *Kandu* (Itching)

C) *Vidaha* (Burning sensation)

D) *Rekha Swarupa Twak Sankocha* (Linear line marking and contractions of the skin in the abdomen).

Exclusion criteria

1. Women suffering from any other skin diseases except *Kikkisa*.
2. Known case of any systemic illness like tuberculosis, HIV, Hepatitis B, Hepatitis C, Diabetes mellitus, Hyperbilirubinemia, etc.
3. Presence of any surgical scar on the abdomen.
4. High-risk pregnancy. (multiple pregnancy, pregnancy induced hypertension, Polyhydramnios, etc.)

Criteria for withdrawal

1. Patient willing to discontinue the trial.
2. Intercurrent illness.
3. If the patient develops any allergy due to the study drug

Sample size: Sample size in present study will be 32 for each group. Thus, total 64 will be estimated sample size for this study

Table 4: Intervention Details

	Group –A	Group –B
No. of patients	32	32
Drug	Tiktadi Ghrita Ointment	Karveer Tail
Dose	QS	QS
Route of Administration	External Application	External Application
Period of Administration	30 Days	30 Days
Duration of study	45 days	45 days
Follow-up	0th, 15th, 30th, 45th day	0th, 15th, 30th, 45thday

Parameters of assessment:

Table 5: Parameters of assessment

SN	Symptoms	0th Day	15th Day	30th Day	45th Day
1.	No. of striations over abdomen				
2.	Itching				
3.	Burning				
4.	Discoloration				

Overall Assessment Criteria:

Table 6: Overall assessment criteria

Poor Improvement	0-25% relief in signs and symptoms
Mild Improvement	26-50% relief in signs and symptoms
Moderate Improvement	51-75% relief in signs and symptoms
Marked Improvement	76-100% relief in signs and symptoms

Statistical analysis: All the statistical analysis will be performed using STATA software. P value < 0.05 will be considered as statistically significant.

Study design:

1. Pharmaceutical, Analytical, Experimental
2. Study period - 18 months study
3. Study centres - Present work will be conducted at the following study centres.

A) Pharmaceutical work will be carried out at the department of Rasashastra & Bhaishajya Kalpana of our Institute.

B) Analytical work will be carried out at certified Analytical laboratory.

C) Experimental study will be carried out in the OPD of Study centre.

D) We will approach other inst. as per need of study

Statistical analysis:

1. Results will be expressed in mean value and standard error of the mean.

2. Statistical analysis will be applied accordingly.

Observations and Results

Stepwise observations will be recorded and presented in the form of tables, charts and pictures, etc.

Discussion

The prevalence rate of striae gravidarum, varies from 50% to 90% in various studies among pregnant women. Pregnancy brings about numerous cosmetic changes that can be distressing for women in today's beauty-conscious era. Hence there is need of study for the treatment of stretchmarks which is cost effective and with minimal side effects.

Many conventional treatments for stretch marks, such as certain topical creams or laser therapies, micro-needling may not be recommended during pregnancy due to potential risks to the fetus. Also, no consistently effective therapies established yet.

There is a need to study Ayurvedic principles for managing stretch marks during pregnancy, as they offer non-invasive alternatives with minimal side effects for pregnant women. Exploring Ayurveda could provide safer, potent, gentle solutions for this unavoidable concern in women's life.

Also, no prior study done on clinical aspects of *Tiktadi Ghrita* ointment on *Kikkisa* in relation to striae gravidarum. Therefore, this study aimed to find the effect of this new topical treatment option for stretchmarks. The ointment formulation of *Ghrita* is develop for the patient compliance, ease of application and stability of product.

Conclusion

The present study is planned to evaluate the effect of *Tiktadi Ghrita* Ointment on *Kikkisa*.

A) The positive outcome of the study will give the evidence of efficiency of *Tiktadi Ghrita* Ointment on *Kikkisa*.

B) With the positive outcome of *Tiktadi Ghrita* ointment, we can study further for its clinical studies for large population.

C) If the conversion method of *Tiktadi Ghrita* ointment preparation proves to be more efficient, then such modified dosage form can be more effective and convenient for the patient.

Consent: Consent form will be signed from the subjects before start of study.

Ethical approval: Ethical approval will be taken from the Institutional Ethical Committee at our Institute.

Competing Interests: No competing interests exist.

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