Pharmaceutico-analytical study and clinical evaluation of *Tiktadi Ghrita* Ointment in *Kikkisa* with special reference to Striae gravidarum: A Randomized Controlled Trial.

Abstract

Background: *Kikkisa* is a pregnancy-associated dermatological condition described in Ayurveda and clinically resembles Striae gravidarum. It is characterised by linear skin changes associated with *Vaivarnya* (discolouration), *Kandu* (itching), *Vidaha* (burning sensation) and *Rekha Swarupa Twak Sankocha* (linear skin markings and contraction). The present study evaluated *Tiktadi Ghrita* Ointment through pharmaceutical, analytical and clinical investigations.

Aim: To evaluate the pharmaceutico-analytical characteristics and clinical efficacy of *Tiktadi Ghrita* Ointment in *Kikkisa* with special reference to Striae gravidarum and to compare its clinical effect with *Karveer Taila*.

Materials and Methods:*Tiktadi Ghrita* was prepared according to the classical principles of *Sneha Kalpana* using authenticated raw materials and subsequently converted into a semisolid ointment using *Siktha* (beeswax). The prepared formulation was evaluated for organoleptic and physicochemical parameters. The clinical study was conducted as a randomised controlled trial in 64 antenatal women diagnosed with *Kikkisa* with special reference to Striae gravidarum. Participants were allocated into two groups; 60 participants (30 in each group) completed the study. Group A received *Tiktadi Ghrita* Ointment and Group B received *Karveer Taila*, applied twice daily for 30 days, with assessments on Days 0, 15, 30 and 45. Clinical outcomes included *Vaivarnya*, *Kandu*, *Vidaha* and *Rekha Swarupa Twak Sankocha*.

Results: The prepared ointment exhibited satisfactory physical characteristics and was easily spreadable. Both groups showed statistically significant improvement in all assessed clinical parameters. Intergroup analysis demonstrated significantly greater improvement with *Tiktadi Ghrita* Ointment in *Vaivarnya* (p=0.002) and *Vidaha* (p=0.040). Differences in *Kandu* (p=0.411) and *Rekha Swarupa Twak Sankocha* (p=0.211) were not statistically significant. Marked improvement was observed in 50.00% of participants in Group A compared with 16.67% in Group B.

Conclusion:*Tiktadi Ghrita* Ointment demonstrated satisfactory pharmaceutical characteristics and a favourable clinical response in *Kikkisa* with special reference to Striae gravidarum. It showed comparative superiority over *Karveer Taila* particularly in reducing *Vaivarnya* and *Vidaha*. Further larger, multicentric studies with longer follow-up and objective dermatological assessment are warranted.

Keywords:*Kikkisa*; Striae gravidarum; *Tiktadi Ghrita*; *Karveer Taila*; Ayurveda

Introduction

Ayurveda is a traditional system of medicine that emphasises maintaining harmony between the body, mind and spirit to promote health and well-being.[1] It describes numerous formulations intended to support skin health and improve its appearance.[2–4] *Rasashastra* and *Bhaishajya Kalpana* are important branches of Ayurveda concerned with the preparation, processing and standardisation of medicinal formulations, thereby contributing to their quality, safety and therapeutic use.[5,6]

Pregnancy is a significant period in a woman's life, accompanied by various physical and psychological changes. Ayurveda places special emphasis on maternal and fetal well-being and describes specific dietary and lifestyle measures under *Garbhini Paricharya*.[7,8] Among the skin changes associated with pregnancy, *Kikkisa* is described as a condition that commonly appears during the later months of gestation. It is characterised by linear changes in skin colour and texture, often accompanied by *Kandu* (itching) and *Daha* (burning sensation), particularly over the abdomen, breasts and thighs.[9,10]

A similar condition recognised in modern dermatology is Striae gravidarum (SG), commonly known as pregnancy-related stretch marks. These are linear, atrophic skin lesions that develop due to changes in the dermal connective tissue and are frequently observed during the later stages of pregnancy.[11,12] Initially, the lesions may appear reddish or violaceous and gradually become pale or silvery-white with time.[13] Although medically harmless, Striae gravidarum can be a significant cosmetic concern and may affect body image, self-esteem and psychological well-being.[14]

The clinical description of *Kikkisa* shares several features with Striae gravidarum, including linear skin changes, discoloration, itching and burning sensation. Based on these similarities, *Kikkisa* may be considered an Ayurvedic correlate of Striae gravidarum, providing a rationale for exploring traditional Ayurvedic approaches in its management.[15,16]

Ayurvedic principles of *Vrana Chikitsa* and *Vrana Savarnikarana* emphasise the restoration of damaged skin and improvement of abnormal skin colour. Classical texts describe the use of local applications, massage and oleation for promoting tissue healing and improving the appearance of affected skin.[17] Formulations containing *Tikta*, *Kashaya* and *Sheeta* drugs are

traditionally considered useful in conditions involving itching, inflammation, impaired healing and discoloration.[18,19]

Tiktadi Ghrita, described in *Yogaratnakara* (*Uttarakhanda*), is a classical formulation indicated for *Dushta Vrana* and certain skin disorders associated with impaired healing and discoloration.[20] Its ingredients are traditionally attributed with *Vranaropana* (wound-healing), *Kandughna* (anti-pruritic), *Krimighna* (antimicrobial) and *Shothahara* (anti-inflammatory) properties. *Ghrita* provides unctuousness and nourishment to the skin and serves as a suitable base for topical application.[21] These properties suggest a possible role of *Tiktadi Ghrita* in addressing the skin changes and associated symptoms of *Kikkisa* (Striae gravidarum).

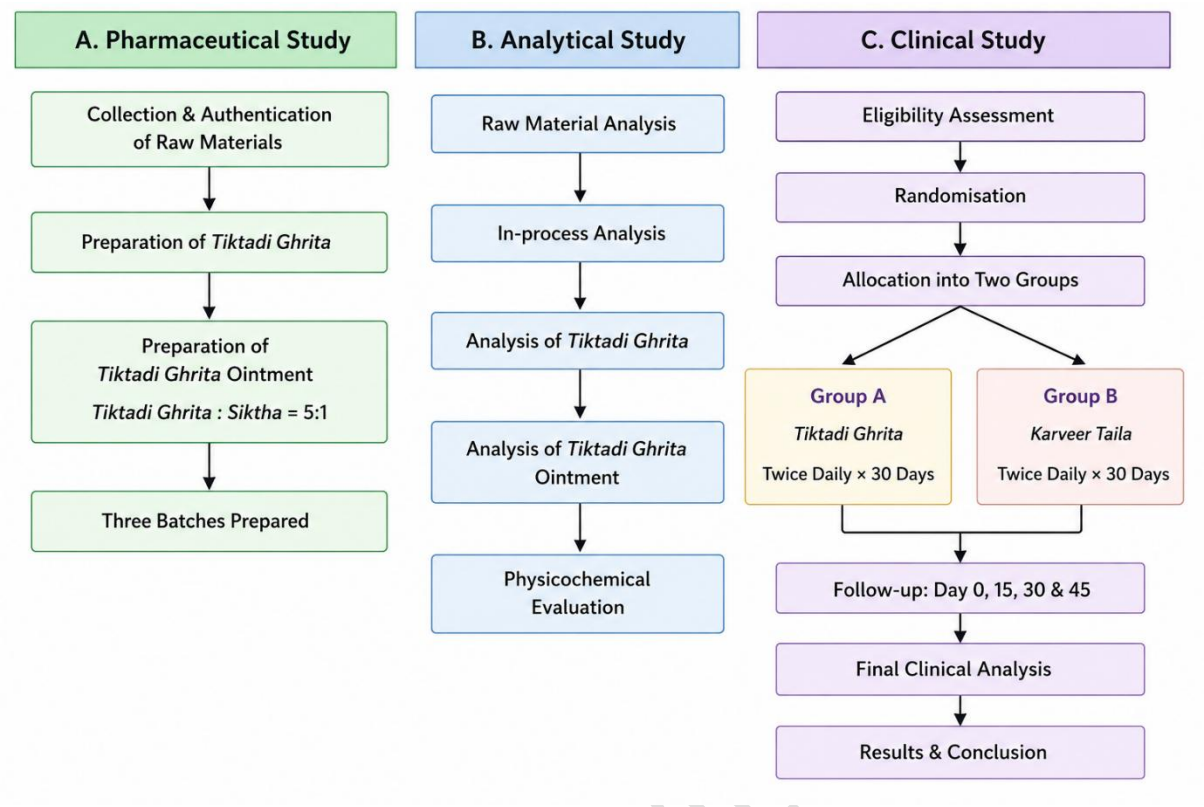
Despite the use of various Ayurvedic topical preparations for Striae gravidarum, evidence regarding *Tiktadi Ghrita*, particularly in ointment form, remains limited. Hence, the present study was undertaken to evaluate *Tiktadi Ghrita Ointment* through pharmaceutical, analytical and clinical assessment in *Kikkisa* (Striae gravidarum).[22]The study aims to assess its quality, standardisation, safety and therapeutic potential and to provide scientific evidence supporting the clinical application of this classical formulation.

Materials and Methods:

Study Design

The present study was designed as an integrated **pharmaceutical, analytical and randomised controlled clinical study** to evaluate the pharmaceutico-analytical characteristics and clinical efficacy of *Tiktadi Ghrita* Ointment in *Kikkisa* with special reference to Striae gravidarum. The study was conducted in three phases: (A) Pharmaceutical Study, (B) Analytical Study and (C) Clinical Study.

Figure 1. Schematic representation of the study design and methodological workflow.



A. Pharmaceutical Study:

The pharmaceutical study was carried out in the following sequential stages:

1. Collection and Authentication of Raw Materials

The raw materials required for the preparation of *Tiktadi Ghrita* and the ointment were procured from reliable sources. The identity and authenticity of the raw drugs were verified and authenticated before use. The raw materials were subsequently subjected to relevant pharmacopoeial quality evaluation.

2. Preparation of *Tiktadi Ghrita*

Tiktadi Ghrita was prepared according to the classical principles of *Sneha Kalpana* as described in the selected classical reference.[23] The preparation involved three principal components: *Sneha Dravya* (*Go-Ghrita*), *Kalka Dravya* and *Drava Dravya* (*Kwatha*). Prior to the preparation of *Tiktadi Ghrita*, *Go-Ghrita Murchhana* was carried out according to the classical procedure.

The *Kwatha Dravya* were processed separately into coarse powder, mixed and subjected to *Kwatha* preparation using the prescribed quantity of water. The mixture was heated over

controlled heat until the desired reduction was achieved and subsequently filtered through clean muslin cloth. The *Kalka Dravya* were finely powdered and processed into *Kalka*.

The *Murchhita Go-Ghrita* was heated under controlled conditions, followed by the addition of *Kalka* and *Kwatha*. The mixture was subjected to controlled heating with continuous stirring until the characteristic *Sneha Siddhi Lakshana* were achieved. The prepared *Tiktadi Ghrita* was then filtered and stored in a suitable container until further processing.

Three batches of the formulation were prepared under standardised processing conditions to assess the reproducibility of the pharmaceutical procedure. The major process variables, including the proportions of ingredients, heating, stirring and processing conditions, were maintained uniformly across batches.

3. Preparation of *Tiktadi Ghrita* Ointment

The prepared *Tiktadi Ghrita* was converted into a semisolid ointment using *Siktha* (beeswax) as the stiffening agent. *Tiktadi Ghrita* and *Siktha* were used in a fixed ratio of **5:1**.

The required quantity of *Siktha* was melted under controlled heating. In a separate vessel, *Tiktadi Ghrita* was liquefied by gentle heating. The liquefied *Ghrita* was gradually incorporated into the melted *Siktha* with continuous stirring to obtain a uniform mixture. The mixture was subsequently allowed to cool with intermittent stirring until a homogeneous semisolid consistency was achieved. The prepared ointment was filled into suitable wide-mouth containers and stored under standardised conditions until further evaluation and clinical use.

Preparation of Kwatha 		

Kalka dravye 	**Preparation of *Kalka*** 	***Murchhita Ghrita*** 
Kalka* was added to the *Ghrita 	***Kwatha* was added to the *Ghrita*** 	
		***TIKTADI GHRITA*** 

Bees wax 		
Tiktadi ghrita 		***Tiktadi Ghrita*ointment** 

B. Analytical Study:

The analytical study was conducted at three levels:

1. Raw Material Analysis

The raw materials used in the formulation were subjected to authentication and relevant pharmacopoeial evaluation. The analytical assessment included appropriate organoleptic and physicochemical parameters for establishing the quality and identity of the raw materials.

2. In-Process Analysis

In-process observations were recorded during the preparation of *Go-Ghrita Murchhana*, *Tiktadi Ghrita* and *Tiktadi Ghrita* Ointment. Relevant process parameters, including temperature, colour, odour, consistency, heating and *Sneha Siddhi Lakshana*, were monitored and documented to ensure uniformity and reproducibility of the manufacturing process.

3. Analysis of Prepared *Tiktadi Ghrita* and *Tiktadi Ghrita* Ointment

The prepared *Tiktadi Ghrita* and final *Tiktadi Ghrita* Ointment were evaluated for organoleptic and physicochemical characteristics. The finished ointment was assessed for colour, odour, appearance, consistency, pH, specific gravity, viscosity, acid value, spreadability and rancidity, as applicable. These parameters were used to establish the preliminary quality profile of the formulation and to assess its suitability as a topical semisolid preparation.

C. Clinical Study:

Study Design and Participants

The clinical component was conducted as a **Randomised controlled clinical study** in antenatal women diagnosed with *Kikkisa* with special reference to Striae gravidarum. A total of 64 participants were enrolled and allocated equally into two groups, with 32 participants in each group. Following completion of the study and follow-up, 60 participants(30 in each group) completed the study and were included in the final clinical analysis.

Participants were screened according to predefined eligibility criteria. The study procedure, potential benefits and responsibilities were explained to eligible participants in an understandable languageand written informed consent was obtained before enrolment. Participant demographic, obstetric and clinical information was documented using a Case Record Form.(CTRI REG NO: CTRI/2024/12/078715)

Randomisation and Group Allocation

After assessment for eligibility, participants were randomly allocated into two treatment groups:

- **Group A (Trial Group):***Tiktadi Ghrita* Ointment
- **Group B (Control Group):***Karveer Taila*

Both interventions were administered by external application **twice daily** for **30 days**. The dose was *Q.S.* for topical application. The total study duration was **45 days**, with clinical assessment and follow-up performed on **Day 0, Day 15, Day 30 and Day 45**.

Intervention

Group	**Intervention**	**Route**	**Frequency**	**Duration of treatment**	**Follow-up**
Group A	*Tiktadi Ghrita* Ointment	External application	Twice daily	30 days	Day 0, 15, 30, 45
Group B	*Karveer Taila*	External application	Twice daily	30 days	Day 0, 15, 30, 45

Clinical Assessment

Clinical assessment was performed at baseline and during scheduled follow-up visits. The clinical outcome measures included the principal manifestations of *Kikkisa* with special reference to Striae gravidarum:

Sr.no	Criteria	Details	Score
1.	No. of striations over Abdomen	Absent	0
		1- 4 striae	1
		5-10 striae	2

		More than 10 striae	3
2.	Itching	No itching	0
		Mild itching without disturbance in normal activity	1
		Moderate itching with disturbance in normal activity	2
		Severe Itching continuously and disturbing sleep	3
3.	Burning	No burning	0
		Mild burning without disturbance in normal activity	1
		Moderate burning with disturbance in normal activity	2
		Severe burning continuously and disturbing sleep	3
4.	Discoloration	Normal – even skin tone	0
		Mild – pinkish in colour	1
		Moderate – Purple in colour	2
		Severe – Whitish or silver in colour	3

The overall therapeutic response was assessed based on the percentage of relief obtained and categorised as follows:

- **Marked improvement:** 76–100% relief
- **Moderate improvement:** 51–75% relief
- **Mild improvement:** 26–50% relief

- **Poor improvement:** 0–25% relief

Statistical Analysis

The data obtained from the clinical study were systematically compiled and analysed statistically. Within-group comparisons of the clinical parameters were performed using the **Wilcoxon signed-rank test**. For intergroup comparison, the **Mann–Whitney U test** was applied to the subjective clinical parameters. The level of statistical significance was set at **$p<0.05$**. The results were expressed using appropriate descriptive and inferential statistical measures.

Study Flow

The overall methodology of the study was conducted sequentially as follows:

RESULTS

Pharmaceutical Study

The pharmaceutical study was completed in three stages: *Murchhana* of *Go-Ghrita*, preparation of *Tiktadi Ghrita* by classical *Sneha Kalpana*and conversion of the prepared *Ghrita* into a semisolid ointment using *Siktha* (beeswax).

During *Murchhana* of *Go-Ghrita*, the initial quantity of 2 kg *Go-Ghrita* yielded 1900 g of *Murchhita Go-Ghrita*, with a total loss of 100 g (5%). During the process, progressive changes in colour, frothing, odour and separation of *Ghrita* from the *Kalka* were observed. At the completion of the process, the *Ghrita* became clear, smooth and homogeneousand the characteristic *Siddhi Lakshana* were observed. No unpleasant or burnt odour was noted.

The prepared *Tiktadi Ghrita* was subsequently converted into a semisolid ointment using *Siktha* as a stiffening agent. Three independent batches of *Tiktadi Ghrita* Ointment were prepared using a fixed ratio of 5:1 (*Tiktadi Ghrita:Siktha*). The melting temperature of *Siktha* was maintained at approximately 65–75°C, while *Tiktadi Ghrita* was liquefied at approximately 60–70°C. The two components were mixed at approximately 65–75°C with continuous stirring for 8–10 minutes, followed by gradual cooling with intermittent stirring.

The final yields of Batch I, Batch II and Batch III were 675 g, 672 g and 674 g, respectively. The variation between the three batches was minimal. All three batches exhibited

comparable physical characteristics, including smooth texture, homogeneous consistency and good spreadability. No visible phase separation, wax precipitation or oil exudation was observed. The results demonstrated satisfactory reproducibility of the manufacturing process at laboratory scale.

Table 1. Pharmaceutical Results of *Tiktadi Ghrita* Ointment

Parameter	**Observation/Result**
Ratio of *Tiktadi Ghrita:Siktha*	5:1
Number of ointment batches	3
Batch I final yield	675 g
Batch II final yield	672 g
Batch III final yield	674 g
Physical appearance	Smooth, homogeneous semisolid
Spreadability	Good
Phase separation	Not observed
Wax precipitation	Not observed
Ghrita exudation	Not observed

The minimal variation in the yield of the three batches and the comparable physical characteristics indicated consistency and reproducibility of the developed manufacturing process.

Analytical Study

The raw materials used in the preparation of *Tiktadi Ghrita* were subjected to pharmacopoeial evaluation. The analytical assessment included organoleptic examination

and physicochemical parameters such as foreign matter, total ash, acid-insoluble ash, water-soluble extractive and alcohol-soluble extractive values.

Table 2. Analytical Results of Raw Materials Used in *Tiktadi Ghrita*

Drug	Foreign matter (%)	Total ash (%)	Acid-insoluble ash (%)	Water-soluble extractive (%)	Alcohol-soluble extractive (%)
Kutaki	0.17	2.0	0.04	25.0	14.6
Nisha	0.17	3.4	0.01	25.0	14.6
Yashtimadhu	—	4.8	0.04	25.0	12.6
Karanj Phala	0.17	2.0	0.00	25.0	28.6
Karanj Patra	0.17	5.8	1.20	18.6	12.6
Malti Patra	0.17	2.0	0.10	26.4	21.6
Nimba Patra	0.13	4.2	0.20	25.0	18.6

The prepared *Tiktadi Ghrita* was evaluated for selected physicochemical and organoleptic parameters. It exhibited a greenish-yellow colour, ghee-like odour and translucent appearance. The refractive index at 40°C was 1.4592. The saponification value was 217.4 KOH/g, acid value was 0.71, iodine value was 37.36 g I_2/100 g and pH was 5.43.

Table 3. Analytical Profile of *Tiktadi Ghrita*

Parameter	Result
Refractive index at 40°C	1.4592

Saponification value	217.4 KOH/g
Acid value	0.71
Iodine value	37.36 g I_2/100 g
pH	5.43
Colour	Greenish-yellow
Odour	Ghee-like
Appearance/Clarity	Translucent

The final *Tiktadi Ghrita* Ointment was evaluated for organoleptic and physicochemical characteristics. The formulation showed a greenish-yellow colour and characteristic ghee-like odour. It was easily spreadable and possessed a homogeneous semisolid consistency. The specific gravity at 40°C was 0.8947, acid value was 0.89 mg KOH/g, pH was 4.34 and viscosity was 39.3 cP. The rancidity test was negative.

Table 4. Analytical Profile of *Tiktadi Ghrita* Ointment

Parameter	**Result**
Specific gravity at 40°C	0.8947
Acid value	0.89 mg KOH/g
pH	4.34
Spreadability	Easily spreadable
Rancidity	Negative
Viscosity	39.3 cP
Colour	Greenish-yellow
Odour	Ghee-like

Overall, the analytical evaluation demonstrated that the prepared *Tiktadi Ghrita* Ointment possessed consistent organoleptic characteristics, suitable spreadability, appropriate semisolid consistency, mildly acidic pH, low acid value and absence of detectable rancidity at the time of evaluation.

Clinical Study

A total of 64 participants fulfilling the predefined inclusion and exclusion criteria were enrolled in the clinical study, with 32 participants allocated to each group. Group A received *Tiktadi Ghrita* Ointment, while Group B received *Karveer Taila*. Four participants were lost to follow-up and excluded from the final analysis. Thus, 60 participants, comprising 30 participants in each group, completed the study and were included in the final clinical analysis.

The interventions were applied externally twice daily for 30 days. The total study duration was 45 days, with assessments conducted on the 0th, 15th, 30th and 45th days. Clinical assessment was based on *Vaivarnya* (discolouration), *Kandu* (itching), *Vidaha* (burning sensation) and *Rekha Swarupa Twak Sankocha* (linear line markings and contractions of the abdominal skin).

Effect of *Tiktadi Ghrita* Ointment

In Group A, all four assessed clinical parameters showed statistically significant improvement following treatment. The mean *Vaivarnya* score decreased from 2.767 before treatment to 1.00 after treatment. The mean *Kandu* score decreased from 2.067 to 0.167, while the mean *Vidaha* score decreased from 1.933 to 0.133. The mean score of *Rekha Swarupa Twak Sankocha* decreased from 2.467 to 1.20. The within-group changes were statistically significant ($p<0.05$).

Effect of *Karveer Taila*

Group B also demonstrated statistically significant improvement in all four clinical parameters. The mean *Vaivarnya* score decreased from 2.367 before treatment to 1.20 after treatment. The mean *Kandu* score decreased from 2.167 to 0.40, *Vidaha* from 2.133 to 0.70 and *Rekha Swarupa Twak Sankocha* from 2.567 to 1.067. The improvement in all parameters was statistically significant ($p<0.05$).

Table 5. Within-Group Clinical Outcomes

Clinical parameter	Group A BT	Group A AT	Group B BT	Group B AT
Vaivarnya	2.767	1.000	2.367	1.200
Kandu	2.067	0.167	2.167	0.400
Vidaha	1.933	0.133	2.133	0.700
Rekha Swarupa Twak Sankocha	2.467	1.200	2.567	1.067

BT: Before treatment; AT: After treatment.

Intergroup Comparison

Intergroup comparison demonstrated a statistically significant difference in favour of *Tiktadi Ghrita* Ointment for *Vaivarnya* and *Vidaha*. For *Vaivarnya*, the mean difference score was 1.767 in Group A compared with 1.167 in Group B, with p=0.002. For *Vidaha*, the mean difference score was 1.800 in Group A and 1.433 in Group B, with p=0.04.

For *Kandu*, the mean difference score was 1.900 in Group A and 1.767 in Group B, with p=0.411, indicating no statistically significant intergroup difference. For *Rekha Swarupa Twak Sankocha*, the mean difference score was 1.267 in Group A and 1.500 in Group B, with p=0.211, also indicating no statistically significant difference between the groups.

Table 6. Intergroup Comparison of Clinical Parameters

Clinical parameter	Mean difference Group A	Mean difference Group B	*p*-value	Result
Vaivarnya	1.767	1.167	0.002	Significant in favour of Group A
Kandu	1.900	1.767	0.411	Not significant
Vidaha	1.800	1.433	0.040	Significant in favour of Group A
Rekha Swarupa	1.267	1.500	0.211	Not significant

Twak Sankocha				

Percentage Relief

The percentage relief was higher in Group A for *Vaivarnya*, *Kandu* and *Vidaha*. The percentage relief in Group A was 63.86% for *Vaivarnya*, 91.94% for *Kandu*, 93.10% for *Vidaha* and 51.35% for *Rekha Swarupa Twak Sankocha*. In Group B, the corresponding values were 49.30%, 81.54%, 67.19% and 58.44%, respectively. Thus, *Tiktadi Ghrita* Ointment demonstrated greater percentage relief in three of the four assessed parameters, while *Karveer Taila* showed greater percentage relief for *Rekha Swarupa Twak Sankocha*. The mean percentage relief was 75.06% in Group A and 64.12% in Group B.

Table 7. Percentage Relief in Clinical Parameters

Clinical parameter	**Group A: *Tiktadi Ghrita* Ointment (%)**	**Group B: *Karveer Taila* (%)**
Vaivarnya	63.86	49.30
Kandu	91.94	81.54
Vidaha	93.10	67.19
Rekha Swarupa Twak Sankocha	51.35	58.44
Mean percentage relief	75.06	64.12

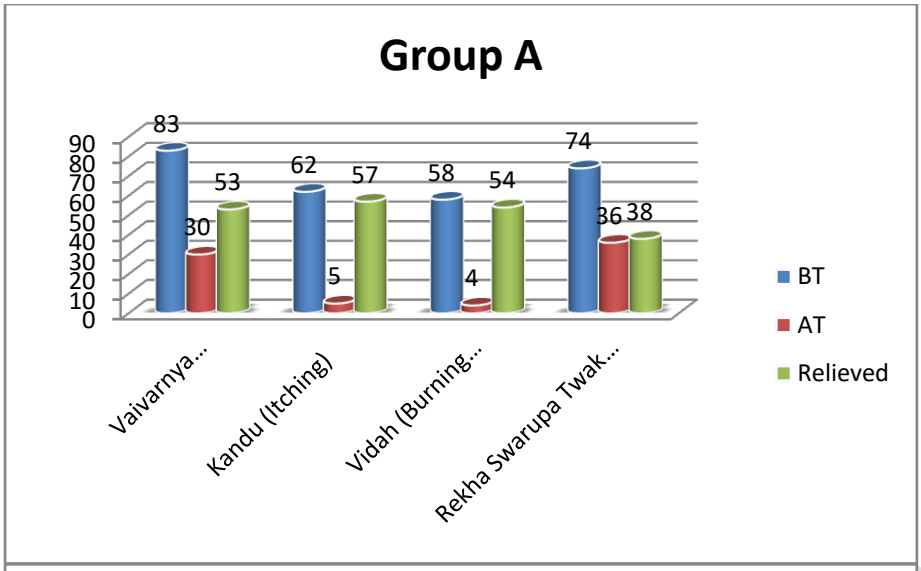
Overall Therapeutic Response

According to the predefined criteria for overall improvement, 15 participants (50.00%) in Group A demonstrated marked improvement, 14 (46.67%) showed moderate improvement and 1 (3.33%) showed mild improvement. No participant showed poor improvement.

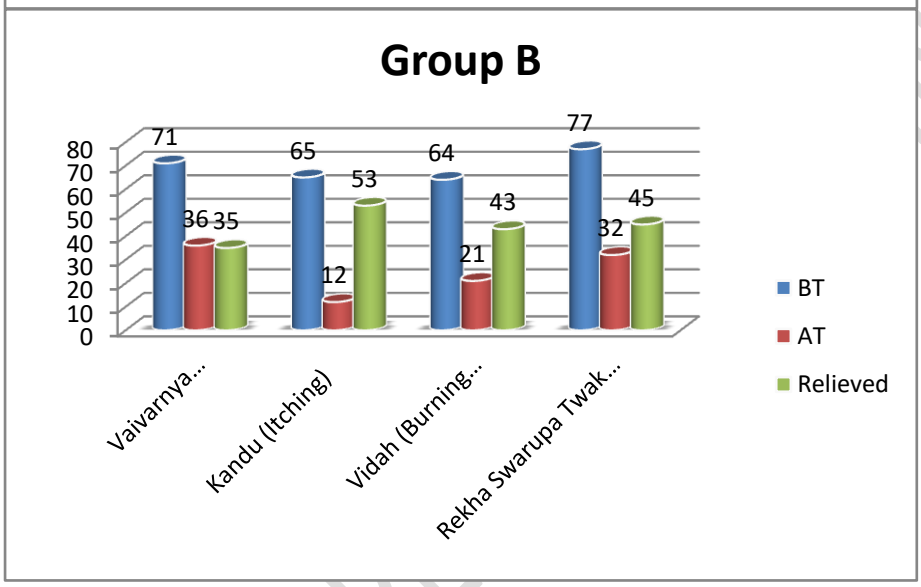
In Group B, 5 participants (16.67%) demonstrated marked improvement, 24 (80.00%) showed moderate improvement and 1 (3.33%) showed mild improvement. No participant showed poor improvement.

Table 8. Overall Therapeutic Response

Therapeutic response	**Group A: *Tiktadi Ghrita* Ointment, n (%)**	**Group B: *Karveer Taila*, n (%)**
Marked improvement (76–100% relief)	15 (50.00)	5 (16.67)
Moderate improvement (51–75% relief)	14 (46.67)	24 (80.00)
Mild improvement (26–50% relief)	1 (3.33)	1 (3.33)
Poor improvement (0–25% relief)	0 (0.00)	0 (0.00)


Group A
90
80
70
60
50
40
30
20
10
0
83
30
53
62
5
57
58
4
54
74
36
38
Vaivarnya...
Kandu (Itching)
Vidah (Burning...
Rekha Swarupa Twak...
BT
AT
Relieved

307


Group B
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77
32
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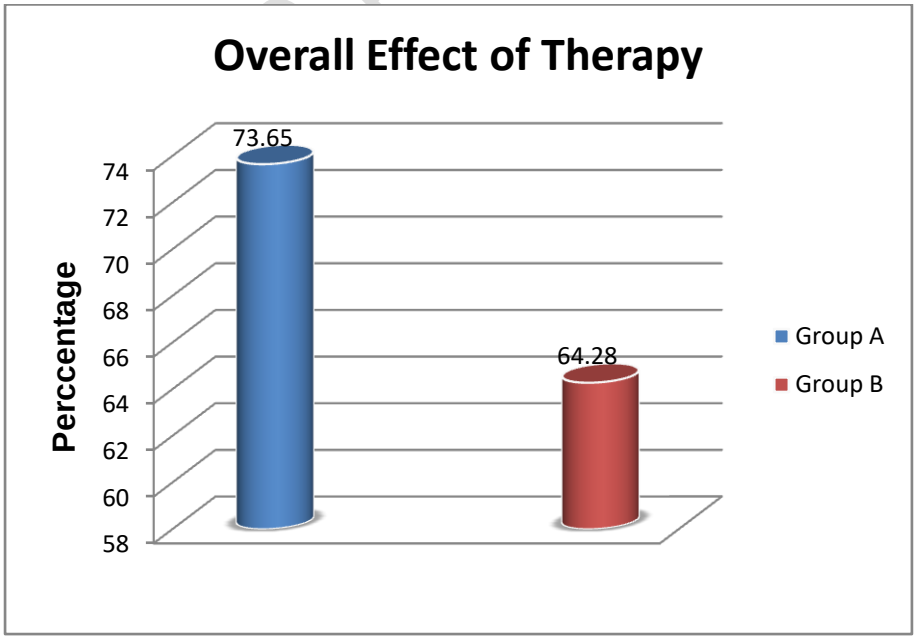
Vaivarnya...
Kandu (Itching)
Vidah (Burning...
Rekha Swarupa Twak...
BT
AT
Relieved

308


Overall Effect of Therapy
Perccentage
74
72
70
68
66
64
62
60
58
73.65
64.28
Group A
Group B

309

Overall Clinical Result

The clinical results demonstrated that both *Tiktadi Ghrita* Ointment and *Karveer Taila* produced statistically significant improvement in all four assessed clinical manifestations of *Kikkisa* with special reference to Striae gravidarum. On intergroup comparison, *Tiktadi Ghrita* Ointment was statistically superior to *Karveer Taila* in reducing *Vaivarnya* and *Vidaha*. The difference between the groups was not statistically significant for *Kandu* and *Rekha Swarupa Twak Sankocha*.

The overall therapeutic response was comparatively better with *Tiktadi Ghrita* Ointment, with 50.00% of participants achieving marked improvement compared with 16.67% in the *Karveer Taila* group. No significant adverse effects or treatment-related complications were reported during the study period and the formulation was reported to be well tolerated.

Overall, the pharmaceutical, analytical and clinical findings indicate that *Tiktadi Ghrita* Ointment was successfully developed as a reproducible semisolid topical formulation with satisfactory physicochemical characteristics. In the clinical study, both interventions were beneficial; however, *Tiktadi Ghrita* Ointment demonstrated a comparatively superior effect on *Vaivarnya* and *Vidaha* and a higher overall therapeutic response than *Karveer Taila*.

Discussion

The present study was undertaken to evaluate *Tiktadi Ghrita* Ointment in *Kikkisa* with special reference to Striae gravidarum through an integrated pharmaceutical, analytical and clinical approach. The rationale for selecting *Kikkisa* was based on its clinical resemblance to Striae gravidarum, particularly the occurrence of linear skin changes associated with *Vaivarnya* (discolouration), *Kandu* (itching), *Vidaha* (burning sensation) and *Rekha Swarupa Twak Sankocha* (linear markings and contraction of the skin). Modern Striae gravidarum is characterised by linear atrophic changes in the skin associated with stretching and alteration of dermal connective tissue. Although the Ayurvedic and modern concepts arise from different theoretical frameworks, their overlapping clinical manifestations provide a reasonable basis for evaluating Ayurvedic interventions in this condition.

The selection of *Tiktadi Ghrita* was based on its classical therapeutic rationale. The formulation is described for *Dushta Vrana* and skin disorders and its constituent drugs

possess traditionally described *Vranaropana*, *Kandughna*, *Shothahara* and *Twachya* properties. The predominance of *Tikta* drugs is considered relevant in conditions involving itching, inflammation and altered skin complexion, while *Ghrita* provides *Snigdhata* and nourishment to the skin. The present study therefore explored the applicability of this classical formulation to *Kikkisa* based on similarity of clinical features and therapeutic principles rather than claiming that Striae gravidarum is identical to *Vrana*.

From a pharmaceutical perspective, the conversion of *Tiktadi Ghrita* into an ointment was intended to provide a convenient and easily applicable topical dosage form. The incorporation of *Siktha* (beeswax) produced a smooth, homogeneous semisolid preparation with satisfactory spreadability. The three prepared batches showed comparable physical characteristics and minimal variation in yield, indicating reproducibility of the adopted manufacturing process. The absence of visible phase separation, wax precipitation and oil exudation during the period of observation further indicated satisfactory physical uniformity of the formulation. These findings are relevant because standardisation of the manufacturing process is essential for ensuring consistency in the quality of traditional formulations adapted to contemporary dosage forms.

The analytical evaluation provided preliminary quality-control parameters for *Tiktadi Ghrita* Ointment. The formulation showed a greenish-yellow colour, characteristic ghee-like odour and homogeneous semisolid consistency. The specific gravity at 40°C was 0.8947, acid value was 0.89 mg KOH/g, pH was 4.34 and viscosity was 39.3 cP. The formulation was easily spreadable and the rancidity test was negative. These findings establish a baseline physicochemical profile that may be useful for future batch-to-batch comparison and standardisation. However, these parameters should be considered preliminary quality specificationsand further stability studies would be required to establish formal shelf-life and long-term stability.

The clinical findings demonstrated significant improvement in all four assessed parameters in both treatment groups. This indicates that both *Tiktadi Ghrita* Ointment and *Karveer Taila* were beneficial in reducing the clinical manifestations of *Kikkisa*. On intergroup comparison, *Tiktadi Ghrita* Ointment demonstrated statistically significant superiority over *Karveer Taila* in reducing *Vaivarnya* and *Vidaha*. The greater improvement in *Vaivarnya* is consistent with the classical rationale for selecting *Tiktadi Ghrita*, particularly its association with

*Vranaropana*and improvement of altered skin colour. Similarly, the greater reduction in *Vidaha* may be interpreted in relation to the traditionally described *Tikta* predominance and *Shothahara* properties of its constituent drugs. These interpretations are based on Ayurvedic pharmacodynamic principles and should not be considered as direct evidence of specific molecular mechanisms.

For *Kandu*, both groups showed substantial improvement, with a numerically higher percentage of relief in the *Tiktadi Ghrita* group; however, the intergroup difference was not statistically significant. This suggests that although *Tiktadi Ghrita* Ointment was effective in reducing itching, its superiority over *Karveer Taila* could not be established statistically. Similarly, the difference between the groups for *Rekha Swarupa Twak Sankocha* was not statistically significant. The structural nature of established striae may partly explain this finding, as visible linear changes in the dermis may require a longer period to demonstrate measurable improvement compared with symptoms such as itching and burning. Therefore, the present findings suggest that the comparative benefit of *Tiktadi Ghrita* was more evident for discolouration and burning sensation than for established linear structural changes.

The overall therapeutic response further supported the favourable clinical effect of *Tiktadi Ghrita* Ointment. A greater proportion of participants in Group A achieved marked improvement compared with Group Band the mean overall percentage relief was also higher in Group A. However, the response was not uniform across all clinical parametersand both groups demonstrated improvement. This indicates that the observed therapeutic effect may involve both formulation-specific properties and the general benefits associated with regular topical application.

The findings are broadly consistent with previous Ayurvedic studies on *Kikkisa* and Striae gravidarum, in which topical *Ghrita*, *Taila*, *Lepa* and other herbal preparations have demonstrated improvement in symptoms such as itching, burning and discolouration. The present study contributes to this body of evidence by evaluating *Tiktadi Ghrita* in a modified ointment dosage form and by combining pharmaceutical standardisation, analytical evaluation and comparative clinical assessment. The study therefore provides preliminary evidence supporting the potential use of *Tiktadi Ghrita* Ointment in the management of *Kikkisa* with special reference to Striae gravidarum.

The principal strengths of the study include the use of a classical formulation, standardised pharmaceutical preparation, analytical characterisation and a comparative clinical design. However, the study was conducted with a relatively limited sample size and short follow-up periodand the clinical assessment was primarily based on clinical scoring. Objective dermatological methods such as dermoscopy, digital image analysis and assessment of skin elasticity were not incorporated. Therefore, larger multicentric studies with longer follow-up and objective outcome measures are required to confirm the findings and determine the long-term effect of the formulation on established striae.

Overall, the findings indicate that *Tiktadi Ghrita* Ointment has a favourable therapeutic potential in *Kikkisa* with special reference to Striae gravidarum, particularly for reducing *Vaivarnya* and *Vidaha*. Its satisfactory pharmaceutical characteristics and preliminary analytical profile, together with the observed clinical response, support further investigation of this formulation as a standardised Ayurvedic topical preparation.

Conclusion

The present study demonstrated that *Tiktadi Ghrita* could be successfully formulated into a homogeneous, easily spreadable semisolid ointment with satisfactory pharmaceutical and physicochemical characteristics. Both *Tiktadi Ghrita* Ointment and *Karveer Taila* produced significant clinical improvement in *Kikkisa* with special reference to Striae gravidarum; however, *Tiktadi Ghrita* Ointment showed statistically superior improvement in *Vaivarnya* and *Vidaha*, while the intergroup differences in *Kandu* and *Rekha Swarupa Twak Sankocha* were not significant. The higher overall therapeutic response observed with *Tiktadi Ghrita* Ointment suggests its potential as a useful topical formulation, particularly for discolouration and burning sensation associated with pregnancy-related striae. The study also provides preliminary pharmaceutical and analytical standards for the formulation. Further large-scale, multicentric clinical studies with longer follow-up, validated objective dermatological assessment and formal stability evaluation are recommended to establish its long-term efficacy, safety and standardisation.

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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