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A Comparative Clinical Trial on Role of *Shastra*, *Kshar* and *Agni Karma* on *Vrangranthi*

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ABSTRACT

Keloid/hypertrophic scar is a rare benign, dermal, fibro-proliferative growth characterized by excessive formation of collagen, without any malignant potential. In Ayurveda, *Vrangranthi* disease can be correlated with keloid or hypertrophic scar of modern medicine in its symptomatology. Keloids are one of the most challenging conditions to treat due to their high reoccurrence rate. *Kshar* and *agnikarma* are the potential therapies mentioned in *Ayurveda* for such conditions. *Shastra karma* is for excision, while use of *agnikarma* and *kshar tail* after excision is considered to be effective in avoiding the relapse in condition of benign outgrowth such as keloid/ hypertrophic scars. In the present study 30 patients divided in three groups were studied. Group A was intra-keloidal corticosteroid injection; n=10, Group B was application of *kshar tail* on keloid/ hypertrophic scar; n=10, Group C was combination of *Shastra karma*, *agnikarma* and *kshar tail* application; n=10. Friedman's test and kruskal wallis test were applied to see the efficacy of which group was better & to see the reduction in relapse of keloid. Finally study concluded that Group A is better than Group B and Group C, as it was standard group and between group B and Group C, Group C was better in efficacy and in relapse rate.

KEYWORDS

Vrangranthi, *Shastra karma*, *Kshar karma*, *Agnikarma*, *Keloid/Hypertrophic scar*



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INTRODUCTION

In surgery the main focus always remain in the healing of a wound. However, it is very difficult to determine the healing process of each person, since there are various factors that influence this process. The process of cicatrisation depends on various interrelated factors - both endogenous (site specific & systemic) and exogenous (environment). Changes in any of these factors may lead to pathological or unacceptable cicatrisation; in some cases, they may lead to the formation of Keloid scars, which affects the quality of life of the patients at a personal and social level. Although pathological scarring was first mentioned in the Edwin Smith Papyrus written in around 1700 B.C., it was only described in the 1770s by Retz and in 1802 by Alibert¹. The condition has been known for a long time, but its treatment remains controversial. So in the present study, our aim is to describe the protocol for the treatments of keloid or hypertrophic scars. Keloid and hypertrophic scar are two types of excessive scarring observed clinically that require different therapeutic approaches. As the name suggest, there is hypertrophy of mature fibroblasts in hypertrophic scars. Blood vessels are minimal in this condition. However, in keloid, proliferation of immature

fibroblasts with immature blood vessels is found. A keloid is a tough heaped up, irregularly shaped scar that rises quite abruptly above the rest of skin and tends to enlarge progressively².

In *Ayurveda* numerous therapeutic modalities have been advocated by our *Acharyas* in the management of each and every disease, but their efficacy needs re-establishment by means of thorough and intensive researches. In *Vrihatrayee Acharya Vagbhatt* has given detailed description of the “*Vrangranthi*”^{3,4}. *Acharya Sushruta* and *Acharya Charka* has described the disease *granthi* but did not give its type as *Vrangranthi*^{5,6}. Whereas in *Laghutrayee, Acharya Sharangdher* has also provided the description of *Vrangranthi* under subheadings of *granthi*⁷. The word *grantis* is derived from word *granthitha* which literally means knotted. The etiological factors constitute the vitiated doshas which in turn affect the blood, muscular tissue & fatty tissue. *Kaphadosha* is mainly responsible for formation of a round, elevated and slightly nodular swelling which is known as *granthi*. *Granthi* is categorized to be of nine kinds by *Acharya Vagbhatt*. There is one created by each *dosha* and six categorized by the tissue that is vitiated. These tissues are: *rakta, mamsa, medas, asthi, sira*, and *vran*. *Kapha* plays the predominant role as

it enters the affected *dhatus*. The most common *dhatus* affected are *medas*, *mamsa* and *rakta*. The result is slow growing swelling of benign nature. So *Vrangranthi* is a type of *granthi* or it refers to tumors which form of the dried blood surrounding a wound or ulcer under the following conditions: - the patient with an ulcer does not follow the recommendation and restriction of diet, if ulcer start discharging secretions for a long time, if the ulcer is not treated properly, if the injury occurs at the site of ulcer. The patient suffers from itching & burning at the site of *Vrangranthi*.

The nature of the study was entirely clinical, and importance was given on the relief of sign and symptoms. The patients were selected on the basis of a fixed criteria from the O.P.D. and I.P.D. of Shalya Tantra Department Rishikul Campus Haridwar. The duration of the study was fixed as 3 months.

AIMS & OBJECTIVES

- 1) To find out the effects of *Agni-karma*, *Shastra-karma* and *kshar tail* in the management of *Vrangranthi*.
- 2) To study the literature with regards to disease *Vrangranthi* & Keloid from *Ayurvedic* & Modern point of view, respectively.

3) To note the adverse effect of the *Agnikarma* and *Shastra karma* during the management of *Vrangranthi*^{8,9}.

4) To find the adverse effects of *kshar tail* during the trail, if any.

5) To establish the economical and effective herbal formulation for *Vrangranthi* (keloid or hypertrophic scar).

My ethical committee approval number is UAU/IEC/2016-17/12

MATERIALS & METHODS

Present clinical study was carried out in the Shalya tantra department of Rishikul Campus Haridwar. Patients were selected randomly, fulfilling the selection & eligibility criteria & informed written consent was taken. The consent form was prepared in accordance with guideline of WHO Research Ethics Committee (REC). Approval number of REC is UAU/C/IEC/2016-17/12. Total 30 patients were selected for the study.

Group A: 10 (Corticosteroid injection, standard group)

Group B: 10 (*Kshar tail*)¹⁰

Group C: 10 (*Shastra karma*, *Agnikarma* and *Kshar tail*)

Study Completed by 27 Patients, (7 Patients in group A, 10 patients in group B & 10 in group C)

Laboratory Investigation

1. Complete blood count
2. Urine Routine & microscopic
3. Histopathological examination- if required

Inclusion criteria

- 1) Patients suffering from non-healing, tough, elevated and irregularly shaped swelling diagnosed as *Vrangranthi* will be selected for this study.
- 2) Established cases of *Vrangranthi* based on objective and subjective criteria.
- 3) Both male/ female patients of all age shall be included.
- 4) Patients who wanted to undergo trial.

Exclusion of criteria

- 1) Large sized keloid (above 10 cm.).
- 2) Infected keloids.
- 3) Patient with known systemic disorder like HTN, DM, Malignancy etc.
- 4) Hepatitis B, HIV, and VDRL positive cases.
- 5) Patient not willing to undergo trial.

Period of Study: 90 Days

Follow up: Another 90 Days.

CRITERIA FOR ASSESSMENT

SUBJECTIVE CRITERIA

Assessed by VSS (Vancouver Scar Scale)

1-Pain:

- G₀ – No pain
- G₁- Occasional
- G₂- Required medication

2-Itching: Assessed by VSS (Vancouver Scar Scale).

- G₀ – No itching
- G₁- Occasional
- G₂- Required medication

OBJECTIVE CRITERIA

Assessed by VSS (Vancouver Scar Scale)

1- Vascularity

- G₀- Normal
- G₁- Pink
- G₂- Red
- G₃- Purple

2- Pigmentation

- G₀- Normal
- G₁- Hypopigmentation
- G₂- Hyperpigmentation

3- Pliability

- G₀- Normal
- G₁- Supple
- G₂- Yielding
- G₃- Firm
- G₄- Banding
- G₅- Contracture

4- Height (mm)²

- G₀- Normal (flat)
- G₁- >0 and <2 mm
- G₂- ≥2 and <5
- G₃- >5

Assessment of total effect of therapy: -The overall assessment was calculated on the basis of average improvement in terms of percentage relief of scores.

1. Complete remission - 100%
2. Marked improvement - 76% to 100%
3. Improvement - 51% to 75%
4. Mild improvement - 25% to 50%
5. Unchanged - Below 25%

DISCUSSION

Discussion on Clinical Features of *Vrana Granthi*

In the present study 100% patients complained of hard growth or swelling, 100% patients have itching in the growth, and 76% patients complained of pain or tenderness in the growth. Increased numbers of mast cells have been reported during the active period of hypertrophic and keloid scar formation. Mast cells are an additional leukocyte subset present in the skin, and they are an important source of a variety of pro-inflammatory mediators that can promote inflammation and vascular change. Clinically, the release of histamine by these cells likely contributes to the common patient complaint of itchiness. In addition, the vasodilatory effect of histamine may promote erythema and leakage of plasma proteins into the regional tissues (*Table No.1*).

Table 1 Clinical features of keloid found in 30 patients

S.N.	Sign and symptoms	No. of patients	% of patients
1.	Hard growth/swelling	30	100
2.	Itching	30	100
3.	Pain or tenderness	23	76.67

Discussion on Grading of Vancouver Scar Scale parameters in Table 2-

1. **Vascularity**- Maximum number of patients were having red vascularity i.e. 43%, while 23% patients had pink and again 23% was having purple vascularity.
2. **Pigmentation**- 53% showed hyperpigmentation in keloids while 47% showed hypopigmentation. Hyperpigmentation is darkening of skin from inflammation which occurs after trauma to the skin, such as cut, scrape or severe acne etc.
3. **Pliability**- Maximum number of patients i.e. 57% were having firm pliability followed by 23% yielding and then 10% banding.
4. **Height**- Maximum number of patients i.e., 53% has height in between 2 and <5 mm followed by 27% having height >5mm.
5. **Pruritus**- 100% patients were having pruritus
6. **Pain**- 77% patients also complained of pain in the keloid scar.

Effect of Therapy

We have used Friedman's test to test the efficacy in Group A, Group B and Group C at each follow up and after treatment

1. Effect on Vascularity

From **table no.3** we found that percentage effect in group A was 70.8%, in group B 29.8 % and in group C 61.4%. In group A

Table 2 Grading of Vancouver Scar Scale parameters

Parameters	No. of Patients	Percentage%
Vascularity	Normal	03
	Pink	07
	Red	13
	Purple	07
Pigmentation	Normal	00
	Hypopigmentation	14
	Hyperpigmentation	16
Pliability	Normal	00
	Supple	02
	Yielding	07
	Firm	17
	Banding	03
	Contracture	01
Height	Normal(flat)	00
	>0 and <2mm	06
	2 and <5mm	16
	>5mm	08
Pruritus	Absent	00
	Present	30
Pain	Absent	07
	Present	23

initial score was 6.36 which was reduced to 1.86, in group B initial score was 4.7 which was reduced to 3.3, in group C initial score was 6.35 which was reduced to 2.45 and we can observe that P-value for Group A, Group B and Group C are less than 0.05. Hence we conclude that effect observed in all three groups are significant.

2. Effect on Pigmentation

Statistically we found that percentage effect in group A was 46.7%, in group B 36.5 % and in group C 52.4%. In group A initial score was 5.36 which was reduced to 2.86, in group B initial score was 4.8 which was reduced to 3.05, in group C initial score was 6.2 which was reduced to 2.95 and we can observe that P-value for Group A, Group B and Group C are less than 0.05. So we

conclude that effect observed in all three groups are significant (**Table No.3**).

3. Effect on Pliability

Statistically we found that percentage effect in group A was 74.4%, in group B 59.8 % and in group C 47.1%. In group A initial score was 6.43 which was reduced to 1.64, in group B initial score was 5.85 which was reduced to 2.35, in group C initial score was 6.8 which was reduced to 3.6 and we can observe that P-value for Group A, Group B and Group C are less than 0.05. Hence we conclude that effect observed in all three groups are significant. (**Table No.3**)

4. Effect on Height

Statistically we found that percentage effect in group A was 70.8%, in group B 30.4 % and in group C 47.8%. In group A initial

Table 3 Effect Therapy on Subjective Parameters

S.NO.	SYMPTOMS	GROUP	MEAN SCORE		N	FRIEDMAN'S TEST	P-VALUE	% EFFECT
			BT	AT				
1.	VASCULARITY	A	6.36	1.86	7	38.60	0.000	70.8
		B	4.70	3.30	10	21.00	0.002	29.8
		C	6.35	2.45	10	47.21	0.000	61.4
2.	PIGMENTATION	A	5.36	2.86	7	24.20	0.000	46.7
		B	4.80	3.05	10	27.60	0.000	36.5
		C	6.20	2.95	10	31.03	0.000	52.4
3.	PLIABILITY	A	6.43	1.64	7	40.63	0.000	74.4
		B	5.85	2.35	10	50.34	0.000	59.8
		C	6.80	3.60	10	27.88	0.000	47.1
4.	HEIGHT	A	6.36	1.86	7	39.20	0.000	70.8
		B	4.60	3.20	10	24.00	0.001	30.4
		C	6.90	3.60	10	28.81	0.000	47.8
5.	PRURITUS	A	5.14	2.93	7	21.44	0.002	55.2
		B	6.40	2.15	10	52.50	0.000	72.5
		C	6.15	3.05	10	39.48	0.000	68.4
6.	PAIN	A	4.79	3.95	7	16.00	0.014	31.3
		B	5.40	2.95	10	42.00	0.000	45.4
		C	5.15	3.05	10	33.50	0.000	40.8
TOTAL SCORE		A	7.57	2.05	7	48.30	0.000	67.0
		B	6.45	2.70	10	58.86	0.000	59.2
		C	6.95	2.50	10	39.43	0.000	61.2

score was 6.36 which was reduced to 1.86, in group B initial score was 4. which was reduced to 3.2, in group C initial score was 6.9 which was reduced to 3.6 and we can observe that P-value for Group A, Group B and Group C are less than 0.05. So we conclude that effect observed in all three groups are significant. **(Table No.3)**

5. Effect on Pruritus

Statistically we found that percentage effect in group A was 55.2%, in group B 72.5 % and in group C 68.4%. In group A initial score was 5.14 which was reduced to 2.93, in group B initial score was 6.40 which was reduced to 2.15, in group C initial score was 6.15 which was reduced to 3.05 and we can observe that P-value for Group A, Group B

and Group C are less than 0.05. hence we conclude that effect observed in all three groups are significant. **(Table No.3)**

6. Effect on Pain

Statistically we found that percentage effect in group A was 31.3%, in group B 45.4 % and in group C 40.8%. In group A initial score was 4.79 which was reduced to 3.29, in group B initial score was 5.4 which was reduced to 2.95, in group C initial score was 5.15 which was reduced to 3.05 and we can observe that P-value for Group A, Group B and Group C are less than 0.05. hence we conclude that effect observed in all three groups are significant. **(Table No.3).**

Comparison among Group A, Group B and Group C (Table No.4)

Table 4 Comparison among Group A, Group B & Group C

	Group	N	Mean Rank	Kruskall Wallis	P-Value	Result
VASCULARITY	Group A	7	21.50	17.304	0.000	HS
	Group B	10	6.70			
	Group C	10	16.05			
	Total	27				
PIGMENTATION	Group A	7	13.79	4.434	0.109	NS
	Group B	10	11.00			
	Group C	10	17.15			
	Total	27				
PLIABILITY	Group A	7	20.36	18.705	0.000	HS
	Group B	10	6.00			
	Group C	10	17.55			
	Total	27				
HEIGHT	Group A	7	19.71	7.845	0.010	Sig
	Group B	10	6.10			
	Group C	10	17.90			
	Total	27				
PRURITUS	Group A	7	10.43	16.591	0.000	HS
	Group B	10	15.80			
	Group C	10	14.70			
	Total	27				
PAIN	Group A	7	11.79	8.213	0.025	Sig
	Group B	10	15.45			
	Group C	10	14.10			
	Total	27				
TOTAL SCORE	Group A	7	19.93	16.333	0.000	HS
	Group B	10	6.1			
	Group C	10	17.75			
	Total	27				

As the present study was comparative study and for comparison of all the three groups, to find out which group was best we have used another test Kruskal Wallis test. Following results were found in overall comparison: -

1. Vascularity- statistically highly significant results (p value<0.05) were found in overall comparison of three groups.
2. Pigmentation- statistically non-significant results (p value=0.109) were found in overall comparison of three groups.
3. Pliability- statistically highly significant results (p value<0.05) were found in overall comparison of three groups.
4. Height- statistically significant results (p value=0.010) were found in overall comparison of three groups.
5. Pruritus- statistically highly significant results (p value<0.05) were found in overall comparison of three groups.
6. Pain- statistically significant results (p value=0.025) were found in overall comparison of three groups.
7. Total score was found Highly significant (p value<0.05)

Further we can observe that mean rank for group A is 19.93, Mean rank of group B is 6.10 and mean rank of group C is 17.75 so we conclude that:

- Effect observed in Group A is more than Group B and Group C.
- Between group B and group C mean rank for Group C is greater than group B, so we conclude that Group C is more effective than Group B.

Probable mode of action of formulation along with other procedures:

The probable mode of action of formulation is discussed as mentioned below based on the result of therapy and its interpretation by *Ayurvedic* as well as modern pharmacology. While selecting the formulation, a hypothesis was made that as per etio-pathogenesis of *Vrana Granthi* described in *Ayurvedic* classics and equivalent pathology described in modern texts for keloid or hypertrophic scars, there is deranged function of *vayu*, particularly *vyana vayu* which is the prime causative factor and this perturbed *vata* with *kapha* manifest a hard growth like swelling along with itching and sometimes pain. and as per our *Ayurvedic* texts patient also complained of burning sensation in the growth so *pitta dosha* is also involved in pathogenesis of *Vrana granthi*. So, the drugs which have *vata-pitta-kaphahara* properties like *shothghn*, *kandughn*, *vednashamka* and

dahshamaka were selected, and the procedures which can help to erode the hard growth and prevents recurrence were selected., these properties help to crack the *samprapti* of *Vrana Granthi* as well as pathophysiology of keloid or hypertrophic scars.

Mode of action of *Kshar Tail*:

Among all the *Shastra* and *Anushastra*, *kshar* is said to be the best¹¹. It performs many functions including *Chedana*, *Bhedana*, *lekhana* and has also *tridoshashaamak* properties. These properties of *Kshara* are very helpful in *Samprativighatna* of *Vrana Granthi*. The *kshar* present in *kshar tail* also performs chemical curettage due to corrosive properties of *kshar*. Moreover *Kshara* invades the cells of keloid lesion & performs tissue destruction by *ksharan guna* or corrosive property of *kshara*.

Kshara is simultaneous combination of incision, excision, debridement, scrapping along with haemostatic, antiseptic and healing. This should leave to removal of keloid mass.

DISCUSSION

Drug action

Shukti has *katu*, *madhur*, *sheet* and *pittashamak* properties work as *shoolprashman*, *shothhar*, *dahshaman*. It

contains calcium carbonate, phosphate, oxide of iron etc. Which have anti-inflammatory, insecticidal, analgesic and antimicrobial activity¹².

Sankha possess *kasaya, katu, laghu* and *sheet* properties, *tridosha shamaka*, helps in cessation of bleeding, used in swellings, diseases of eye etc. It contains calcium carbonate having antiinflammatory, antioxidant, anti microbial actions¹³.

Shambook possess *kasaya, laghu, ruksha* and *sheet* properties. It is *pitta kapha shamak*. It is also called as small conch and has same properties as that of sankha¹⁴.

Shyonak possess *madhur, kasaya, tikt, laghu, ruksha, ushna* and *kaphavata shamka* properties as mentioned in *shothahar mahakasaya* by Acharya Charak. It contains baicalein, flavonoids, caprylic, lauric, sitosterol which have anti-inflammatory, spasmogenic, anti-tumour, antifungal properties respectively. It is helpful in *vranropna, shothahara* and *vednasthapana*¹⁵.

Patala has *tikt, kasaya, laghu, ruksha* and *tridosha shamka* properties. It is also mentioned in *shothahara gana* by Acharya Charaka. It is helpful in *vednasthapan, vranropan, sothhara, ruchivardhak*. It contains lapachol, stereolin, dehydrodectol, palmitic and stearic acids having anti inflammatory, anti cancer, analgesic, anti viral properties¹⁶.

Sarshapa tail possess *katu, laghu, ushna* and *vata kapha shamka* properties. It is useful in *shothahara, vranaropna, vednasthapna, vatahara*. It contains carbon sulphide, sinapinic acid, crino sterol etc which has analgesic, anti inflammatory, anti-microbial, antiprurient activities. It is useful in growths, swellings, skin diseases, digestion and induction of vomiting¹⁷.

Khar mutra possess *katu, tikshana, ushna* and *vata kapha shamka* properties. It contains bilirubin, nitrite, ketones bodies, urea etc. It is effective antibacterial, anti fungal and anti viral. *khar mutra* is useful in digestion, epilepsy, seizures and various diseases caused by worms¹⁸.

Mode of action of Agnikarma:

Skin is one of the place of Vayu, Agnikarma is perform to release the *Sangha* (obstruction) of *vayu* which is main factor for the formation of *Vrana granthi*. It works deep in tissue because of its power of penetration to deep tissue by virtue of *laghu, sukshma & teekshan guna*¹⁹.

Agnikarma probably arrests the mechanism that causes excessive proliferation of collagen and which leads to formation of keloid. *Agnikarma* done after removal of keloid reduces the risk of reoccurrence of Keloids²⁰.

TOTAL EFFECT OF THERAPY: (Table No.5)

Table 5 Overall Effect of Therapy

Result on effect therapy	Effect of therapy (Group-A)	
	No. of pt.	%
Complete cured	0	0
Marked Improvement	05	71.20%
Moderate Improvement	02	29%
Mild Improvement	0	0
Unchanged	0	0

1. **GROUP B** of *Kshar tail* has 72.5%

Effect of therapy (Group-B)	Effect of therapy (Group-C)	
	No. of pt.	%
worked best over the itching of the keloid.	0	0
GROUP C results were most encouraging. It has given complete eradication in small sized keloid especially	0	0
	3	30%
	5	50%
	2	20%

Mainly symptomatic criteria was adopted to assess the total effect of the therapy.

In present study in Group A of corticosteroid injection, 71.2% patients were marked improved, 28.6% patient were moderate improved while no case was in mild and unchanged category.

In Group B of single *Kshar tail* application, 30% patients were moderate improved, 50% patient were mild improved and 20% were having no change while no case was in marked improved category.

In Group C of *Shastra*, *Agni* and *Kshar tail* application, 50% patients were marked improved, 20% patient were moderate improved and 30% were mild improved while no case was in no change category.

Thus we can conclude that the overall effect of Group A was best followed by Group C and Group B.

CONCLUSION

The best modality of keloid is still a challenge in medical fraternity. Accepting this challenge, the above study was planned and the results were as below.

those situated over the ear.

Result:

- Finally, we have concluded that role of *Agnikarma* and *Kshar tail* has the most encouraging results in the outcome of *Vrana granthi* or keloid/ hypertrophic scar.
- Simply application of *Kshar tail* over keloid gives promising results in itching which is an important irritating factor in the patients of *Vrana granthi*.

Recommendation and suggestions:

Though the study has been conducted in small number of patients, the duration needs to be increased to understand the incidence of recurrence and percentage of cure.

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