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A COMPARITIVE STUDY OF AGNIKARMA AND KSHAR KARMA IN THE MANAGEMENT OF VRANGRANTHI

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ABSTRACT

The patient of ulcer who indulges in all the tastes (all types of foods indiscriminately) when the ulcer has not healed or is in the process of healing or when it is still moist (exudative) or when not bandaged or when the body is hit by stones etc. then vata getting aggravated dries up the vitiated blood which has not flown out, and the ulcer give rise to a tumor, having burning sensation and itching. This is known as vrana granthi. The keloid is referred to as vrana ganthi in Auyrveda, Keloid is a result of an overgrowth of granulation tissue at the site of a healed skin injury which is then slowly replaced by collagen fibers.

KEYWORDS: Agnikarma, Kshar Karma, Kshar injection, Vrangranthi.

INTRODUCTION

Shalya Tantra is a branch of Aayurveda which deals with surgical as well as Para surgical procedures like Kshara karma, Agnikarma & Raktamokshana, but gives equal emphasis on Bhaishajya Chikitsaa also. Shalya tantra is one of an important branch of Ayurveda; shalya karma is a quick acting and result oriented by using different types of Yantra, Shastra, Kshara, *Agni* etc. as different modalities of treatment.

The most valuable and very important chapter no. 5 of Sushrut Samhita (Sutrasthan) is a Treasury of ethical and systemic practice of surgery. In this chapter God dhanvantri has clearly indicated that vranupchar (Management of vrana) is the prime responsibility of surgeon and proper management is always followed by every expert of surgeon otherwise there will be occurrence major complications.

For examples-Acharya Sushrut has guided that tiryak chedan (Horizontal incision) must be done at the bhru (eye brows), ganda(Cheeks), sankha (Temporal region), lalata (Forehead), akshiput (eyelids), ostha(lip), dantavestak (gums), kaccha(axilla), kucchi (abdomen), vankshan (groin), further chandra mandal chedan (moon/circular incision) is indicated in paanipaad (hand and feet), ardha chandrakar chedan (semi- circular) is to be given guda and medhra (Anus&Penis), at the same time as a warning, dhanvantri has clearly mentioned that any mistake or improper incision will lead to sirachedan (excision of the veins/vessels), snayu chedan (excision of the tendons/ligaments), Atimatra vedna (excessive pain), development of chronicity and delay healing of wound.

Further it is a matter of proud of us that in our classical literature it is clearly mentioned that there will be formation of mansakandi due to wrong practice of chedan karma. This pathology is symptomatically very similar to modern clinical entity keloid. The nomenclature, sign and symptoms, aetiology of the disease and prognosis of the disease is very similar to manskandi and keloid. Acharya Dalhan has further explained that there will be formation of manskandi which is very resembled to rhizome or kanda. Practically this condition is commonly found in keloid.

The patient of ulcer who indulges in all the tastes (all types of foods indiscriminately) when the ulcer has not healed or is in the process of healing or when it is still moist (exudative) or when not bandaged or when the body is hit by stones etc. then vata getting aggravated dries up the vitiated blood which has not flown out, and the ulcer give rise to a tumor, having burning sensation and itching. This is known as vrana granthi. Vrana granthi is mentioned in Uttartantra Astang sangrha in 34 Chapter.

Chikitsha

- I want to specify one quotation of Acharya Sarangdhar, one of the prestigious Acharya of laghutraye has mentioned an experience based indication regarding the use of kshar in case of vrangranthi. This contribution of Acharya Sarangdher is till followed by almost all the surgeons in modify way to inhibit the growth of keloid.
- That which has not become ripe, inspite of all these should be cut (excised) and when bleeding stops it should be burnt by fire (thermal cautery) leaving no residue/remnant because such a residue/remnant is sure to develop again into a tumour. Both mansha granthi and vrana granthi should also treat in the same way.
- The keloid is referred to as vrana ganthi in Auyrveda .Keloid is a result of an overgrowth of granulation tissue at the site of a healed skin injury which is then slowly replaced by collagen fibers. Normal collagen bundles are absent. Keloid continues to grow even after 6 months, may be for many years. Keloid expand in claw like growth over normal skin .it is brownish black/ pinkish black in color, painful, tender and sometimes hyper aesthetic, spreads and causes itching. common site of keloid is sternum. Other common sites are upper arm, chest wall, and lower neck in front.

Agnikarma

Agnikarma is combination of two words Agni (Heat) and Karma (procedure).In this procedure heat is transferred in to the body by various Dravyas. The procedure performed by using the agni to cure the various disorders is known as Agnikarma. The therapeutic use of agni is described as Agnikarma, In sushrut samhita sutra sthan chapter 12.

Ksharkarma

Kshara is a caustic, alkaline in nature obtained from the ashes of medical plants. It is a milder procedure compared to surgery and thermal cautery. It is the superior most among the sharp and subsidiary instruments because of performing excision, incision and scraping. It is versatile, because even such places that are difficult in approach by ordinary measures can be treated by kshar karma. Kshar karma is useful as the substitute of surgical instruments, because they can be used safely on the patients who are afraid of surgery. The therapeutic use of kshar is described as kshar karma, in Sushrut samhita sutrasthan chapter 11.

Need of Study

- The surgical advancement and conservative management in modern sciences is not possible to treat vran ganthi effectively.
- In modern science, steroid injection is injected at regular intervals, may be once in 7-10 days, of 6-8 injections. excision is also performed for vran granthi. Even after using these injections and surgical procedures, is not effective at all, the vrangranthi reappears again.
- The ayurvedic texts mention kshar karma and Agnikarma which prevents the recurrence granthi (medo granthi, vrana granthi etc.)

Granthi

The word grant is derived from word granthitha which literally means knotted. The etiological factors constitute the vitiated doshas which in turn affect the blood, muscular tissue and fatty tissue. Kapha slowly accumulates at the site where muscular and fatty tissue are vitiated and gives rise to round , elevated and slightly nodular swelling which is termed as granthi.

Shushrut samhita describes

- Vataj
- Pittaj
- Kphaj
- Medaj
- Siraj.

According to ashtang sangraha, there are four additional granthis

- Mansa granthi
- Rakta granthi
- Asthi grnathi
- Vran granthi

Ayurvedic Literature Review

Vrangranthi is described as a disease of *Manswaha Srotasa* in *Aayurveda*. To understand the pathogenesis of *vrangranthi* it is necessary to know the anatomy & physiology of *Manswaha Srotasa.*

Description of Tvacha

The union of sukra (spermatozoon) and sonata (ovum) while being cooked (processed by heat) give rise to the formation of seven layers of tvaca (skin).just like formation of cream when milk is boiled.

S. N.	Tvacha	Vrihi praman	Adhisthaan
1	Avabhasini	1/18	Sidhma, padmakantak
2	Lohita	1/16	Tilkalk, nyaccha, vyanga
3	Sveta	1/12	Charmadal, ajagallika, masak
4	Tamra	1/8	Kustha, Visarpa
5	vedini	1/5	Kustha, Kilash
6	Rohini	1 vrihi	Granthi, apchi, arbud,
7	Mansdhara	2 virhi	Arsha, bhagander, vidradhi

Skin

The human skin is out covering of body and is the largest organ of integumentary system; the skin has up to seven layers of ectodermal tissue and guards the underlying muscles, bones, ligaments and internal organs. Severely damaged skin will try to heal by forming scar tissue. This is often discoloured and depigmented.

Functions

Skin plays as important immunity role in protecting the body against pathogens and excessive water loss. Its other functions are Insulation, Temperature regulation, sensation, synthesis of vitamin D, and the protection of vitamin B.

Skin is composed of three primary layers

Epidermis –'epi' coming from the Greek meaning 'over' or 'upon', is the outermost layer of skin. It forms the water proof, protective wrap over the body's surface which also serves as a barrier to infection and is made up of stratified squamous epithelium with an underlying basal lamina.

The epidermis contains no blood vessels, and cells in the deepest layers are nourished almost exclusively by diffuse oxygen from the surrounding air. The main types of cell which make up the epidermis are;

- Keratinocytes
- Melanocytes
- Langerhans cells
- Merkel cell

The epidermis can be further subdivided into the following

- Stratum cornium
- Stratum lucidum
- Stratum granulosum
- Stratum spinosum
- Stratum basale

Dermis

Dermis is a layer of skin between the epidermis and subcutaneous tissue. The dermis is tightly connected to the epidermis through a basement membrane.

Structural component of the dermis are collagen, elastic fibres, and extrafibrillar matrix. It also contains mechanoreceptors that provide the sense of touch and thermo receptors that provide the sense of the heat. In addition, hair follicles, sweat glands, sebaceous gland, apocrine gland lymphatic vessels, nerves and blood vessels are present in the dermis. The dermis is composed of 3 major types of cells; fibroblasts, macrophages and adipocytes.

It is divided into two layers-

Papillary dermis – The papillary dermis is the upper most layer of dermis. The papillary region is composed of loose areolar connective tissue. This is named for its finger like projection called papillae, that extend toward the epidermis and contain either terminal networks of blood capillaries.

Reticular dermis- The reticular dermis is the lower layer of the dermis, found under the papillary dermis, composed of dense irregular connective tissue featuring densely packed collagen fibres. The reticular region is usually much thicker than the overlying papillary dermis; It receives its name from the dense concentration of collagenous, elastic, and reticular fibres that weave throughout it.

The orientation of collagen fibres within the reticular dermis creates lines of tension called Langer's line, which are of some relevance in surgery and wound healing. Histopathologically keloid is over abundance of dermal collagen.

Hypodermis- The hypodermis is beneath dermis which is beneath epidermis. It is used mainly for fat storage. It is lower most layer of the integumentary system in vertebrates. The types of cells found in the hypodermis are fibroblasts, adipose cell, and macrophages.

Skin layers described by Susruta and by modern anatomists can be correlated as follows-

Avabhashini - Stratum corneum/ Stratum lucidum
Lohita - Stratum granulosum Sveta- Stratum spinosum
Tamra- Stratum basale Vedini- Papillary dermis Rohini- Reticular dermis Mansdhra- Hypodermis

SCAR

Scar is defined as formation of final relaxed, randomly arrayed collagen bundles (type1) with formation of mature scar. 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 Alibert. 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 treatment of keloid and 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.

Initially immature scar is formed during remodeling phase; this scar is disorganized and contains type 3 collagen. Such scar is raised, itchy, hard, and pink in colour.

Other the span of 12 months scar gets matured fully wherein disorganized collagen gets aligned along the stress lines and there is formation of more type 1 collagen. This mature scar is soft, supple, pale, and flat without any itch. Hypertrophic scar and Keloid persists to have more type 3collagen than type 1 collagen unlike the mature scar.

Types of scar

1. *A mature scar* – It is paler, acellular, softer, flat, with reduced blood vessels and fibroblast, without itching.
2. *An atrophic scar*- It is pale, flat and stretched.
3. *A Hypertrophic scar* – It is excess scar but will not extend beyond the margin of the scar of the original wound; there is prolonged inflammatory phase of wound healing.it develops in 1 to 3 months after trauma. It improves spontaneously.
4. **Keloid**- It is persistent excessive growth of scar beyond its margin into the adjacent skin, occurs in a triangular area between two shoulder point and xiphisternum. It develops 3 months to years after the trauma, progressive. presternal area is the commonest site.

Keloid

Keloids were described by Egyptian surgeons around 1700 BCE, recorded in the Smith papyrus, regarding surgical techniques**.** Baron jeans-louis Alibert (1768–1837) identified the keloid as an entity in 1806. He called them *Cancroide*, later changing the name to cheloide to avoid confusion with cancer. The word is derived from the Greek *chele*, meaning hoof, here in the sense of crab pincers and the suffix *-oid*, meaning "like.

Keloid, also known as keloid disorder and keloidal scar, is the formation of type of scar which depending on its maturity, is composed mainly of either type III (early) or type I (late) collagen. It is a result of an overgrowth of granulation tissue (collagen type 3) at the site of a healed skin injury which is then slowly replaced by collagen type 1. Keloids are firm, rubbery lesions or shiny, fibrous nodules, and can vary from pink to the color of the person's skin or red to dark brown in color. A keloid scar is benign and not contagious, but sometimes accompanied by severe itchiness, pain and changes in texture. In severe cases, it can affect movement of skin.

1. Keloid is common in blacks. Common in females.
2. Genetically predisposed. Often familial. Very rare in Caucasians.
3. There is defect in maturation and stabilization of collagen fibrils. Normal collagen bundles are absent.
4. Keloid continues to grow even after 6 months, may be for many years. It extends into adjacent normal skin. It brownish black/pinkish black (due to vascularity) in colour, pain full, tender and sometimes hyper aesthetic, spreads and causes itching.
5. Keloid may be associated with Ehlers-Danlos syndrome or scleroderma.
6. When keloid occurs following an unnoticed trauma without scar formation is called as spontaneous keloid, commonly seen in dark skinned people.
7. Some keloid occasionally becomes non progressive after initial growth.
8. Pathologically keloid contains proliferating immature fibroblasts, proliferating immature blood vessels and type thick collagen stroma.

Sign and Symptoms

Keloids expand in claw-like growths over normal skin, it is brownish black/ pinkish black in color, painful, tender and sometimes hyper aesthetic, spreads and causes itching .common site of keloid is sternum. Other common sites are upper arm, chest wall, and lower neck in front.

They have the capability to hurt with a needle-like pain or to itch, the degree of sensation varying from person to person.

If the keloid becomes infected, it may ulcerate. Removing the scar is one treatment option; however, it may result in more severe consequences: the probability that the resulting surgery scar will also become a keloid is high, usually greater than 50%. Laser treatment has also been used with varying degrees of success.

Keloids form within scar tissue, collagen used in wound repair, tends to overgrow in this area, sometimes producing a lump many times larger than that of the original scar. They can also range in colour from pink to red. Although they usually occur at the site of an injury, keloids can also arise spontaneously. They can occur at the site of a piercing and even from something as simple as a pimple or scratch. They can occur as a result of severe acne or chicken pox scarring, infection at a wound site, repeated trauma to an area, excessive skin tension during wound closure or a foreign body in a wound. Keloids can sometimes be sensitive to chlorine. Keloid scars can grow, if they appear at a younger age, because the body is still growing.

Locations

Keloids can develop in any place where skin trauma has occurred. They can be the result of pimples, insect bites, scratching, burns, or other skin injury. Keloid scars can develop after surgery. They are more common in some sites, such as over the sternum, back and shoulders (usually resulting from acne), and the ear lobes (from ear piercings). They can also occur on body piercings. The most common spots are earlobes, arms, pelvic region,

and over the collar bone.

Causes
Most skin injury types can contribute to scarring. This includes burn, acne, scars, chicken pox, scars, ear piercing, scratches, surgical incisions, and vaccination sites.

Pathogenisis
A result of an overactive inflammatory response and fibroblast proliferation

A result of an abnormal collagen deposition in healing skin wounds

Skin wound tension is a contributing factor in keloid formation

Individuals with an inflammatory or infectious element are at a predisposition

Treatment
The best treatment is prevention in patients with a known predisposition. This includes preventing unnecessary trauma or surgery (including ear piercing, elective mole removal), whenever possible. Any skin problems in predisposed individuals (e.g., acne, infections) should be treated as early as possible to minimize areas of inflammation. Treatment of a keloid scar is age dependent. Radiotherapy, anti- metabolites and corticoids would not be recommended to be used in children, in order to avoid harmful side effects, like growth abnormalities.

Surgical excision is currently still the most common treatment for a significant amount of keloid lesions. However, when used as the solitary form of treatment there is a large recurrence rate of between 70 and 100%. It has also been known to cause a larger lesion formation on recurrence. While not always successful alone, surgical excision when combined with other therapies dramatically decreases the recurrence rate. Examples of these therapies include but are not limited to radiation therapy, pressure therapy and laser ablation. Pressure therapy following surgical excision has shown promising results, especially in keloids of the ear and earlobe. The mechanism of how exactly pressure therapy works is unknown at present but many patients with keloid scars and lesions have benefited from it.

1. Steroid injection-intra keloidal triamcinolone, is injected at regular intervals, may be once in 7-10 days, of 6-8 injections. Triamcinolone reduces the fibroblast proliferation and collagen.
2. Steroid injection-excision-steroid injection.
3. Methotrexate, vitamin A and C therapy into the keloid.
4. Silicone gel sheeting, topical retinoids.
5. Laser therapy—Nd-YAG Laser.
6. Vitamin E/palm oil massage.
7. Intralesional excision retaining the scar margin may prevent recurrence. It is ideal and better than just excision.
8. Excision and irradiation or irradiation alone.
9. Excision and skin grafting may be done.

MATERIAL AND METHOD
Selection of patients-All the patients were randomly selected on the basis of inclusion and exclusion criteria.

Inclusion criteria
- Keloid scarring patient.
- Able to understand and give informed consent.
- Patient with a strong familial pedigree of keloid scar formation.
- Patient age (21-60).
- Recurrent keloid patient who has previous surgery or had undergone any other modality of treatment.

Exclusion criteria
- Open wound at or proximity of the lesion infected lesion.
- Those who suffer from immunodeficiency disorder.
- Atrophic scar
- vran granthi over the marmasthan (vital parts)
- Inflammation all over the body
- Diabetic patient

Criteria for Withdrawal
1. Patients who did not follow the advice and instruction.
2. Patients who have any allergic reaction.
3. Any other difficulties.

Investigations
1. Routine hematological investigations of Hb%, CBC, ESR
2. HIV
3. HBSAG
4. VDRL
5. Urine Examination -Routine& Microscopic

a. Biochemical Examination-Blood sugar, serum creatinine, Serum calcium, Uric acid

Research Design – Open randomized clinical trial.

Grouping and Administration of Drug

GP	No of patients	Formulation- /Method	Route	Dose	Time
A	15	Agnikarma	Locally	According to literature	weekly
B	15	Kshar injection	Intra-lesional	According to size	weekly

Duration of Study- 28 Days.

Assessment -Assessment was conduct at the time of continuation of Trail drug therapy at weekly interval. (7^{th}, 14^{th}, 21^{th}, 28^{th} days.)

Follow up after Treatment- upto the end of 6 months.

Assessment Criteria
Assessment was done on the basis of relief in sign, symptoms on the basis of of pre decided protocol through the scoring pattern.

Subjective Criteria
1. Severe itching is present
2. Pain

S.N.	Pain criteria	Score
1	No Pain	0
2	Mild Pain	1
3	Moderate Pain	2
4	Severe Pain	3

S. N.	Itching Criteria	Score
1	No itching	0
2	Mild Itching (Occasional) does not disturb routine	1
3	Moderate itching (frequent itching, disturbs routine activity but not sleep)	2
4	Severe itching(Disturbed both routine and sleep)	3

Objective Criteria
Pigmentation

1.	Normal	0
2.	Hypopigmentation	1
3	Hyperpigmentation	2

Tenderness

1	Normal	0
2	Mild	1
3	Moderate	2
4	Severe	3

Height (mm)

1	Normal	0
2	> 0 and < 2 mm	1
3	2 and < 5	2
4	> 5	3

Criteria for Result
For the assessment of the total effect of the therapy following four categories will be taken into considerations.

Complete relief	100% Relief
Marked Improvement	More than 75% relief
Moderate Improvement	51-75% relief
Mild Improvement	25-50% relief
No Improvement	No relief or below 25% relief

Preparation and Packing of the Trials Drugs
The traditional use of kshar is very reactive and inconveniences especially in case of this type such challenging disorder keloid. The use of modern pharmacological technology (manufacture of the medicines) in hence then promotes the efficacy of drug further it limit the side effect of the therapeutic preparations.

The presentations of medicines in capsule, syrup, injection are such very popular and smart mode of drug administration in the body. In this way it is decided to introduce a kshar injection to aiming the minimize dosha (side effects), for the same purpose University authority have a approach to well repotted pharmacy college of jodhpur to prepared a modified kshar presentation in the form of injection. The experts of modern pharmacy have adapted a stander procedure of injection.

To prepare 100ml Kshar injection 5gm Apamarg kshar and 0.5 gm HPMC was taken. This material has been transferred to pestle mortar and with the help of gaumutra they have prepared paste followed by triturate procedure, after proper trituration to prepare slurry more

amount of gaumutra was added in this slurry. This slurry has been transferred to a measuring cylinder to make the volume upto 100 ml with gaumutra. This prepared solution was packed and presented in sterile vial and all the indications of microbe free steps work strictly followed from beginning to the last stage of preparation, presentation and use.

Procedure-Intralesional kshar injection has been injected direct into the site of lesion using a 26 bore needle after proper cleaning the area with antiseptic solution. The initial dose per injection was varied depending on lesion size, site, shape, chronicity, clinical features and other considerable factors being treated. Generally, 0.1-0.2 ml is injected per square centimeter of involved skin.

Probable Action of Drug

In Ayurveda, the action of a drug is understood by properties of its basic physico- chemical factors. The factors are Ras, Guna, Virya, Vipaka and prabhava of the drug; these primarily affect the doshas and determine their dosha shamaka activity; this inturn correct the vitiated doshas and thus, maintain the doshic equilibrium. This is the basic principle of the treatment.

As widely described by Acharya Sushruta, The Kshar possessing, pachan, vilyan, and sodhan karma as per the priority of properties, and this Vilyan means is dissolving the swelling by destroying the unwanted tissue growth. When unwanted tissues have dissolved the affected part becomes healthy (Sudha vran) and this stage lesion is accelerated by ropan karma of selected kshar. Here in my study the fine way of kshar application in the tissue gives targeted result with in due time without any unwanted complication of open ksharpatan. The Additional properties of kshar like sodhan, stambbhan, again helpful for treating the symptoms of keloid like pain, itching, Discharge. Finally kshar is well known for removing the Aama doshas and in this keloid disorder Aama is considered as a route cause of this disease.

These all properties and modalities are just opposite to the samprapti of disease keloid and mansa dusti, Avarana, Vata vradhi and similarly kapha and meda are also corrected by it pharmacological action. Shrotodusti are removed and purified by sodhan and lekhan properties. Hence on the basis of above Synergetic properties, vyadhi pratyaneek action can be explained and discuss from the Ayurved view.

Agnikarma - As per the indication and guidelines directed by Acharya Sushruta, I have followed by the procedure and applied the Agnikarma in selected patients of keloid. Being a Mansgat vyadhi radical removal is the final treatment and it is clearly written that. (मांसजानांतु सांशुद्धौ शस्त्रक्षाराग्निकर्मम च च.सू.**28/25**).

So, for the purpose of comparative study, Agnikarma procedure adapted as per the below description.

Hence I have strictly applied and used the instruments, pre and post procedure management and dietary requirement. By following the classical indication (A.S.su40) medicated oil i.e. Jatayadi oil was used for mansh dah/Deranged mansa dhatu/keloid. This procedure was adopted during all over the year except sarad and grishma ritu, but in some cases this procedure was done in grishma ritu due to urgency and need of study. As pre Agnikarma protocol pichhil anna was given and after local cleaning and followed all disinfection procedure like covering the area with sterilized gauze piece after irrigation of sodhan qwath.

Patient was sifted in procedure room and patient was advised to sit comfortable with the position of clear visibility of the affected side. Jatayadi oil was heated upto the evaporation by fumes. A small bud of cotton was dipped inside this oil, again catches with mosquito forceps and immediately touched the site of disease keloid. The same procedure was done after 1 week. After the Agnikarma Madhu Sarpi application was done as per the classical indication.

Probable Mode of Action of Agnikarma

Agnikarma pacifies vata and kapha dosha, by virtue of the properties that agni possesses viz. Ushna, Tikshna, Sukshma, Ashukari Guna. Here the heat which is transferred to twak dhatu may act as; it removes the obstruction in the Srotas and increase the blood circulation flushes away the inflammation and pain producing substance and patient gets relief from symptoms. The therapeutic heat also increases the Dhatvagni, which cause local Ama pachana. Sneha is said to percolate into Sukshma marga and hence pass to deeper parts.

OBSERVATIONS AND RESULTS

Status of Patients (n= 30)

Status	No. of Patients		Total
	Group A	Group B	
Registered	16	17	33
Completed	15	15	30
Discontinued	01	02	03

Total 33 patients were registered, out of them 16 were in group A and 17 in group B. Total 15 patients in group A and 15 patients in group B were completed the treatment. Only 01 patient in group A and only 2 patients in group B were discontinued the treatment against medical advice.

Clinical Assessment & Result

The data collected were transferred on master chart and the analysis of data was done using **stastistical softwere Graph Pad In Stat 3.10 (Trial version).** All the results were calculated by using software: **"Graph Pad In Stat 3.1 software (Trial version)''**

For nonparametric data **Wilcoxon matched-pairs signed ranks test** was used.

For calculating the inter group comparison **Mann-Whitney Test& Unpaired t test** was used.

The result calculated were interpreting as below:- Not Significant (NS): P>0.05
Significant (S): P<0.05
Highly Significant (HS): P<0.01, P<0.001 Extremely Significant (ES): <0.0001

Showing effect of therapy on Clinical sign & symptoms of Vrngranthi (groupA).

Variable	N	Mean B.T.	Mean A.T.	Mean Diff.	Mean%	S.D.	S.E.	P value	S
Pain	15	2.267	1.000	1.267	55.88%	0.5936	0.1533	<0.0001	ES
Height	15	2.533	1.133	1.400	55.27%	0.6399	0.1652	<0.0001	ES
Itching	15	2.067	1.000	1.067	51%	0.8837	0.2282	0.0002	ES
Pigmentation	15	1.667	0.8667	0.8000	47.99%	0.4880	0.1260	0.0005	ES
Tenderness	15	2.333	1.133	1.200	51%	0.7237	0.1869	0.0002	ES

Showing effect of therapy on Clinical sign & symptoms of Vrngranthi (groupB).

Variable	N	Mean B.T.	Mean A.T.	Mean%	S.D.	S.E.	P value	S
Pain	15	2.133	1.333	62.49%	0.7432	0.1919	<0.0001	ES
Height	15	2.600	1.533	58.96%	0.5071	0.1309	<0.0001	ES
Itching	15	2.133	1.133	53.11%	0.7432	0.1919	<0.0001	ES
Pigmentation	15	1.467	0.800	54%	0.5164	0.4880	0.0002	ES
Tenderness	15	2.333	1.333	57%	0.6172	0.1594	<0.0001	ES

Effect of Therapy on pain Score in Both Groups

- In Group A the mean Score before treatment was 2.267 which lowered down to 1.000 after treatment with SD 0.5936 giving a relief 55.88% which is statistically Extremely significant (p<0.0001).
- In Group B the mean Score before treatment was 2.133which lowered down to 1.333 after treatment with SD 0.7432 giving a relief 2.49% which is statistically Extremely significant (p<0.0001).

Effect of Therapy on Height Score in Both Groups

- In Group A the mean Score before treatment was 2.533 which lowered down to 1.333 after treatment with SD 0.6399 giving a relief 55.27% which is statistically Extremely significant (p<0.0001).
- In Group B the mean Score before treatment was 2.600 which lowered down to 1.533 after treatment with SD 0.5071 giving a relief 58.96% which is statistically Extremely significant (p<0.0001).

Effect of Therapy on Itching Score in Both Groups

- In Group A the mean Score before treatment was 2.067 which lowered down to 1.000 after treatment with SD 0.8837 giving a relief 51% which is statistically Extremely significant (p<0.0002).
- In Group B the mean Score before treatment was 2.133 which lowered down to 1.133 after treatment with SD 0.7432 giving a relief 53.11% which is statistically Extremely significant (p<0.0001).

Effect of Therapy on pigmentation Score in Both Groups

- In Group A the mean Score before treatment was 1.667 which lowered down to 0.866 after treatment with SD 0.4880 giving a relief 47.99% which is statistically Extremely significant (p<0.0005).
- In Group B the mean Score before treatment was 1.467 which lowered down to 0.800 after treatment with SD 0.5164 giving a relief 54% which is statistically Extremely significant (p<0.0001).

Effect of Therapy on pliability Score in Both Groups

- In Group A the mean Score before treatment was 2.333which lowered down to 1.333 after treatment with SD 0.7237 giving a relief 51% which is statistically Extremely significant (p<0.0002).
- In Group B the mean Score before treatment was 2.333 which lowered down to 1.333 after

treatment with SD 0.6172 giving a relief 57% which is statistically Extremely significant (p<0.0001).

Showing Inter-group Comparison of Group A& Group B of Vrangranthi for subjective and objective parameters: (Mann-Whitney Test).

Variables	Day	Gp	Mean	S.D.	S.E.	P value	S
Pain	D 0	A	2.267	0.5936	0.1533	0.6615	NS
		B	2.133	0.7432	0.1919		
	D 28	A	1.0000	0.09759	0.09759	0.0886	NS
		B	0.8000	0.1253	0.1253		
Height	D 0	A	2.067	0.8837	0.2282	0.9645	NS
		B	2.1333	0.7432	0.1919		
	D 28	A	1.0000	0.5345	0.1380	0.9787	NS
		B	1.0000	0.5345	0.1380		
Itching	D 0	A	1.667	0.4880	0.1260	0.2880	NS
		B	1.467	0.5164	0.1333		
	D 28	A	0.8667	0.3519	0.09085	0.2132	NS
		B	0.6667	0.4880	0.1260		
Tenderness	D 0	A	2.333	0.7237	0.1869	0.9269	NS
		B	2.333	0.6172	0.1333		
	D 28	A	1.000	0.3780	0.09759	0.4218	NS
		B	1.1333	0.5164	0.1309		
Pigmentation	D 0	A	2.333	0.7237	0.1869	0.3372	NS
		B	2.600	0.5071	0.1309		
	D 28	A	1.133	0.63999	0.1652	0.7185	NS
		B	1.067	0.4577	0.1182		

(Gp-Group, S-Significant, NS- Non significant)

Difference in Effect of Therapy on pain in Both Groups

- The p>0.05(0.6615) before treatment at Day 0 which is statistically non-significant which shows that there is no statistically difference in the mean of pain in both the groups before treatment.
- The p>0.05(0.0886) After treatment at Day 28 Which is statistically non-significant which shows that there is no statistically difference in efficacy of Therapy of both groups on pain.

Difference in Effect of Therapy on Height in Both Groups

- The p>0.05(0.9645) before treatment at Day 0 which is statistically non-significant which shows that there is no statistically difference in the mean of pain in both the groups before treatment.
- The p>0.05(0.9787) After treatment at Day 28 Which is statistically non-significant which shows that there is no statistically difference in efficacy of Therapy of both groups on pain.

Difference in Effect of Therapy on itching in Both Groups

- The p>0.05(0.2880) before treatment at Day 0 which is statistically non-significant which shows that there is no statistically difference in the mean of pain in both the groups before treatment.
- The p>0.05(0.2132) After treatment at Day 28 Which is statistically non-significant which shows that there is no statistically difference in efficacy of Therapy of both groups on pain.

Difference in Effect of Therapy on pliability in Both Groups

- The p>0.05(0.9269) before treatment at Day 0 which is statistically non-significant which shows that there is no statistically difference in the mean of pain in both the groups before treatment.
- The p>0.05(0.4218) After treatment at Day 28 Which is statistically non-significant which shows that there is no statistically difference in efficacy of Therapy of both groups on pain.

Difference in Effect of Therapy on pigmentation in Both Groups

- The p>0.05(0.3372) before treatment at Day 0 which is statistically non-significant which shows that there is no statistically difference in the mean of pain in both the groups before treatment.
- The p>0.05(0.7185) After treatment at Day 28 Which is statistically non-significant which shows that there is no statistically difference in efficacy of Therapy of both groups on pain.

Group A

In group A, mean percentage improvement of therapy on subjective & objective parameter was 51%. It is moderate improvement.

Group B
In group B, mean percentage improvement of therapy on subjective and objective parameter was 57%. It is moderate improvement.

By Comparing the overall effect of treatment in this trial, it can be deduced that group B is better than group A.

CONCLUSION

- In group A statistically extremely significant results were observed in pain, Tenderness, Itching and pigmentation, because of Agnikarma pacifies vata and kapha dosha, by virtue of the properties that Agni possesses viz. Ushna, Tikshna, Sukshma, Ashukari Guna. Here the heat which is transferred to twak dhatu may act as; it removes the obstruction in the Srotas and increase the blood circulation flushes away the inflammation and pain producing substance and patient gets relief from symptoms.
- In group B statistically extremely significant results were observed in pain, Tenderness and Itching and pigmentation, because of The Kshar possessing, pachan, vilyan, and sodhan karma as per the priority of properties, and this Vilyan means is dissolving the swelling by destroying the unwanted tissue growth. The Additional properties of kshar like sodhan, stambbhan, again helpful for treating the symptoms of keloid like pain, itching, Discharge. Finally kshar is well known for removing the Aama doshas and in this keloid disorder Aama is considered as a route cause of this disease.
- On comparison of results of pain, Itching, tenderness, pigmentation in both groups, the result in group-A was statistically extremely significant and in group- B was also statistically extremely significant, but percentage relief was more in group B than group A.
- Overall assessment of results shows that there statistically extremely significant observed in effects of both groups. Where Group B was showed better improvement rate than group A.

CONCLUSION ABOUT KSHAR INJECTION

- Root of drug administration enhances the efficacy of the medicine as observed in study
- Kshar application in the tissue gives targeted result with in due time without any unwanted complication of open ksharpatan.
- From the present clinical study it is concluded that the Kshar injection procedure and is unparalleled and explanatory management in the way of Vrangranthi managment for qualitative and potential results point of view.
- For the instant and total effectiveness this route can be used on the priority.
- It is my humble observation on the basis of my three years clinical trial that this Kshar application was ideal upkarma in the hands of our great acharyas during ancient time, presently the traditional use of kshar is very reactive and inconveniences especially in case of this type such challenging disorder keloid. The use of modern pharmacological technology (manufacture of the medicines) in hence then promotes the efficacy of drug further it limit the side effect of the therapeutic preparation's. The presentations of medicines in capsule, syrup, injection are such very popular and smart mode of drug administration in the body. In this way it is decided to introduce a kshar injection to aiming the minimize dosha.
- On the principles/ theories and concepts regarding Vrangranthi management is reestablished with my thesis work and in the last I concluded that this management may be trail at multi centric level to observe the efficacy in the therapeutic way.
- The overall result the present study is definitely encouraging and has opened up a new vista for the research workers in this specific field.

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