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RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE THE STUDY OF PATOLADI OINTMENT ON DUSHTA VRANA WITH SPECIAL REFERENCE TO VARICOSE ULCER

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ABSTRACT

Varicose ulcer is often compared with Dushta vrana from Ayurvedic texts due to its similarities in clinical features. The incidence varies in population from 0.3% to 1.33% with overall prevalence 0.12% to 1.69% per 1000. Besides that Varicose ulcers are scarcely disabling but need higher amount of medical attention. Varicose ulcers cause deprivation of valuable work hours and significant financial burden on the family. Although wound healing is a natural process being a chronic ulcer, varicose ulcers, take prolong time to heal. Thus, this study is conducted to reduce time of healing & the progression of disease so as to improve quality of life. In this study 40 patients were selected randomly and divided 20 in each group. In trial group wound was treated with the Patoladi oinrment and in control group with Betadine ointment for 21 days. Observations were done on subjective and objective parameters and analysis was done statistically. When statistical tests were applied to the observed data it was found that Patoladi Ointment was found more effective than Betadine ointment for venous ulcer.

KEYWORDS:- *Patoladi Ointment, Betadine Ointment, Venous Ulcer, etc.*

INTRODUCTION

The condition in which venous wall/venous valves in the veins of legs are not working effectively, making it difficult for blood to return to the heart, is called as ‘’venous insufficiency’’.[1] This causes blood to collect into the veins & this pooling of blood is known as ‘’stasis’’. The most common causes of venous insufficiency are varicose veins. Varicose veins is a disease in which patients develop dilated, tortuous & elongated veins of the lower limb. Most of the clinical feature of the varicose veins are similar to the clinical features of the disease called Siraj Granthi[3] explained in Ayurvedic texts. Sushruta has described Siraj Granthi as a Krichhsadhya vyadhi i.e. disease which is difficult to treat. The pathology of this disease manifests with an elevated, quickly developing, round swelling of veins with dull aching pain.

Symptoms of Varicose veins include aching or discomfort in legs, appearance of dilated veins in the affected leg, swelling over ankle, Redness, dryness, and itchiness of areas of skin, venous eczema, Muscle cramps, etc. Being a long standing disease varicose veins has some complications which includes varicose ulcer or Venous Ulcer.[4]

Varicose ulcer[5] is the wound on the lower limb or ankle caused due to varicose veins or DVT as a complication. It is also known as ‘’Stasis ulcer’’/’’Venous ulcer’’. Venous stasis caused by varicose veins causeschronic venous hypertension around ankle & deposition of hemosiderin in the subcutaneous plane from lysed RBCs. Thus, causing eczema & dermatitis leading to lipodermato-sclerosis. This in turn causes fibrosis of the local tissue & anoxia, ultimately resulting into Ulceration.[6] Varicose ulcers are scarcely disabling but need higher amount of medical attention. Varicose ulcers cause deprivation of valuable work hours and significant financial burden on the family.

Conventional treatment of varicose ulcer includes cleaning and dressing with betadine, hydrogen peroxide or eusol, crepe bandage/stockings, leg elevation, etc. Recent advancement like collagen granules has also been developed for the treatment of venous ulcer. Although wound healing is a natural process being a chronic ulcer, varicose ulcers, take prolong time to heal.

Ayurvedic Acharyas like Charak, Sushruta, Vagbhata, etc. have described Vrana in details in their Samhitas along with wound healing procedures & various kalpa for the treatment of vrana. There measures have been proven to be significant and have been published in various journals.

Patoladi ointment is the Ayurvedic formulation containing Raktapachak kwatha[7], having Patol (Trichosanthesdioica), Sariva (Hemidesmus indicus), Musta (Cyprus rotendus), Patha (Cissampelospareira), Katurohini (Picrorhizakurroa) in equal proportions. Raktapachak kwatha has been traditionally used by clinical practitioners for many years in the treatment of Rakta dhatu gata awastha of Vishamjwara with promising results. We are using it locally in varicose ulcer (Dushtavrana) because of their properties like Tiktaras, Ushna vipaka, etc. which help in the reduction of kleda, dushtasravapresent locally at wound site and also increase local dhatvagni.

Drugs in Raktapachak Kwatha are raktaprasadak & raktashodhak & have shothhar, vedanasthapan, vishaghna, vranashodhan, vranaropan properties. These drugs have been proven to have astringent as well as antioxidant properties.[8] Drug Patol is known to have an anti-inflammatory properties.[9] Musta is proven to have the wound healing properties.[10] Patha is found to have Antinociceptive activity.[11] Whereas Sariwa have Antihistaminic properties& Katuraohini has been proven to have Collagen synthesis-promoting and collagenase inhibitory activities.[12]

Aim & Objective of the research work

Aim

Evaluation of the efficacy of Patoladi Ointment in the treatment of Dushtavrana with special reference to Varicose ulcer.

Objectives

1) To study the efficacy of Patoladi Ointment in the treatment of varicose ulcer.
2) To assess the treatment duration of varicose ulcer using study drug topically.
3) To study the effect of study drug in varicose ulcer using BATES & JENSEN ulcer assessment tool.
4) To assess the effect of study drug in varicose ulcer with special reference to pain using VAS.
5) To assess the effect of study drug in varicose ulcer with special reference to itching.

6) To find a local medication from the texts of Ayurveda.

Place of study:

Post Graduate (P.G.) department of *Shalyatantra* of Ayurved Seva Sangh, Arogyashala Rugnalaya, Panchavati, Nashik.

MATERIAL AND METHODS

The present study was Simple randomized controlled clinical study. The study was conducted on 40 patients of Varicose ulcers selected from OPD and IPD of Shalyatantra Department, Arogyashala Rugnalaya, Nashik.

Criteria of diagnosis

Patients with clinically diagnosed varicose ulcers were selected and as per inclusive criteria they were included in the study.

Inclusion criteria

- Patients willing to participate in the study.
- Patients with diagnosed varicose ulcer (Dushta vrana) with its clinical features.
- Irrespective of sex.
- Age group 20 years to 70 years.
- Ulcer less than or equal to 10 cm2 of area.
- Ulcer with depth = muscle deep.

Exclusion criteria

- Systemic diseases like CKD, Malnutrition, Severe Anemia, Liver diseases.
- Patient with uncontrolled Diabetes mellitus.
- Patient with coagulopathy or bleeding diseases.
- Varicose ulcer with complications like deep vein thrombosis, calcification, etc.
- Tubercular ulcer, malignant ulcer, Ischemic ulcer, Osteomylitis.

Method of study

40 patients fulfilling the inclusive & exclusive criteria were selected randomly selected for the proposed study from the OPD & IPD of Shalyatantra Department of Arogyashala Rugnalaya, The selected patients were then subjected for screening of the proposed study.

These patients were further divided into 2 groups using Computer Generated Randomization Sheet.

Group A (Clinical trial group): Total 20 patients were selected and registered. They were treated with Patoladi ointment daily for 21 days

Group B (Control group): Total 20 patients were selected and registered. They were treated with Betadine ointment daily for 21 days.

Follow up: 0,5th, 10th, 15th, 21st day.

Properties of drugs in patoladi ointment

Table No – 1

Drug	Latin Name	Family	Ras	Virya	Vipak	Ingredients
Patol	T. Dioica	Cucurbitaceae	Tikta	Ushna	Katu	Alkaloids, flavonoids, Vit-A Vit-C, tannins, phenols, etc.
Sariva	H. Indicus	Asclepiadaceae	Madhur, tikta	Sheet	Madhur	P-Methoxy salicylic aldehyde, B-sitosterol, lupeol, B-amyrins, tetracyclic triterpene alcohols.
Musta	C. Rotendus	Cyperaceae	Tikta, Katu, Kashay	Sheet	Katu	cyperenone, mustakone, cyperol, sugenol, cyperolone, eugenol, sugetriol triacetate, copadiene, rotundone, cyperenol, cyperone, isocyperol, Sesquiterpene, etc.
Patha	C. Pareira	Menispermaceae	Tikta	Ushna	Katu	Pelosine, Saponin, lavonol quarternary, and sterol.
Kutaki	P. Kurroa	Scrophulariaceae	Tikta	Sheet	Katu	Picrorhizin, Kutkin, apocynin, D-mannitol, Bainilic acid, Kutkiole, Kutki-sterol, picrosides, etc.

Preparation of medicine

Patoladi ointment:

Raw material i.e. standardized Churna of Patol, Sariva, Musta, Patha & Katurohini were purchased from the authorized dealer. Then Patoladi Ointment was manufactured according to the standard protocols in Rasashastra department under the supervision & guidelines of HOD of Rasashastra department in following steps;

1. Preparation of kwatha

These churna in equal proportions i.e.200gm each were taken & mixed. 1000gm of this churna was then mixed with 16 Liters of water. Then the mixture was heated & boiled to evaporate the water contents until about 2 liters kwatha was remained. This procedure was repeated to get total of 4 liters of kwatha. It was then filtered.

2. Preparation of siddha taila

Then Kalka was prepared from the 250gms of mixture of all the churnas by adding water. Then the kalka was mixed with 1 liter of Tila taila i.e. 4 times the Kalka. This mixture was then added with the 4 liters of Kwatha i.e. 4 times tila taila & heated until Samyak Tail siddhi lakshana are seen.

3. Preparation of ointment

Into this siddha taila, Sikta was mixed in appropriate amount and Patoladi Ointment was prepared.

Criteria for assessment:

Criteria for assessment were designed on the basis of relief in the signs and symptoms of the disease Vatarakta.

A. Objective criteria – BATES-JENSEN ulcer assessment tool

1. Size
2. Depth
3. Edges
4. Undermining
5. Necrotic tissue type
6. Necrotic tissue amount
7. Exudate type

8. Exudate amount
9. Skin colour surrounding wound
10. Peripheral tissue edema
11. Peripheral tissue induration
12. Granulation tissue
13. Epithelialization.

B. Subjective criteria

1. Pain
2. Itching.

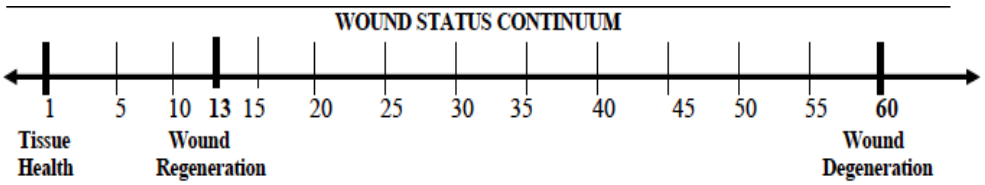
A. Objective criteria – BATES-JENSEN ulcer assessment tool

Table No – 2

Sr. No.	Crteria	Score
1.	Size	Use ruler to measure the longest and widest aspect of the wound surface in centimeters; multiply length x width.
2.	Depth	1 = tissues damaged but no break in skin surface. 2 = superficial, abrasion, blister or shallow crater. Even with, &/or elevated above skin surface (e.g., hyperplasia). 3 = deep crater with or without undermining of adjacent tissue. 4 = visualization of tissue layers not possible due to necrosis. 5 = supporting structures include tendon, joint capsule.
3.	Edges	1= Indistinct, diffuse, none clearly visible. 2= Distinct, outline clearly visible, attached, even with wound base. 3= Well-defined, not attached to wound base. 4= Well-defined, not attached to base, rolled under. 5= Well defined, fibrotic, scarred, or hyper-keratonic.
4.	Undermining	1= Non present. 2= Undermining < 2cm in any area. 3= Undermining 2-4cm involving <50% Wound margins. 4= Undermining 2-4cm involving >50% Wound margins. 5= Undermining >4cm or Tunneling in any area.
5.	Necrotic tissue type	1= None-visible. 2= White/grey non-viable tissue &/or non-adherent yellow slough. 3= Loosely adherent yellow slough. 4= Adherent, soft, black eschar. 5= Firmly adherent, hard, black eschar.
6.	Necrotic tissue amount	1= None-visible. 2= <25% of wound bed covered. 3= 25% to 50% of wound covered.

		4= >50% but <75% of wound covered. 5= 75% to 100% wound covered.
7.	Exudate type	1= None. 2= Bloody. 3= Serosanguineous: thin, watery, pale red/yellow. 4= Serous: thin, watery, clear. 5= Purulent: thin/thick, opaque, tan/yellow, with/without odor.
8.	Exudate amount	1= None, dry wound. 2= Scant, wound moist but no observable exudate. 3= Small. 4= Moderate. 5= Large.
9.	Skin colour surrounding wound	1= Pink/normal for ethnic group. 2= Bright red &/or blanches to touch. 3= White/grey pallor/hypopigmented. 4= Dark red/purple &/or non-blanchable. 5= Black/hyperpigmnted.
10.	Peripheral tissue edema	1= No swelling/edema. 2= Non-pitting edema extends 4cm around wound. 3= Non-pitting edema extends > 4cm around wound. 4= Non-pitting edema extends < 4cm around wound. 5= Crepitus &/or Non-pitting edema extends < 4cm around.
11.	Peripheral tissue induration	1= None present. 2= Induration < 2cm around wound. 3= Induration 2-4cm extending <50% around wound. 4= Induration 2-4cm extending >50% around wound. 5= Induration > 4cm in any area around wound.
12.	Granulation tissue	1= Skin intact/partial thickness wound. 2= Bright, beefy red; 75%-100% of wound filled &/or tissue overgrowth. 3= Bright, beefy red; <75% &>25% of wound filled 4= Pink, &/or dull, dusky red &/or fills <25% of wound. 5= No granulation tissue present.
13.	Epithelialization	1= 100% wound covered, surface intact. 2= 75% to <100% ulcer covered &/or epithelial tissue extends >0.5cm into ulcer bed. 3= 50% <75% ulcer covered &/or epithelial tissue extends >0.5cm into ulcer bed. 4= 25% to 50% wound covered. 5= <25% wound covered.
	Total score	60

Wound status continuum – Total score will be plotted on the Wound Status Continuum by putting an "X" on the line and the date beneath the line. Multiple scores will be plotted with their dates to see-at-a-glance regeneration or degeneration of the wound.



B. Objective criteria

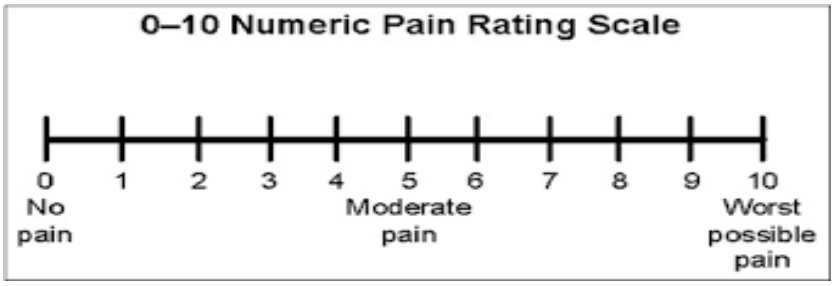
1. **Pain scale - visual analogue scale**VAS is a simple, objective and reproducible method of quantifying pain. For VAS a 10 mm line is drawn with verbal anchors at one end Zero (0) on it denotes no pain while 10 on the other end denotes most excruciating pain.

Further grading of pain is done as;

a) 1mm-3 mm: Mild pain

b) 4mm-6 mm: Moderate

c) 7mm-10 mm: Severe pain



Data Collection and statistical analysis:

To evaluate the efficacy of trial treatment, the data were collected on the basis of demographic findings and patients clinical finding as follows;

Status of registered patients

Table No. 3

Status of patients	No. of Patients		Total	%
	Group A	Group B		
Total Enrolled Patients	20	20	40	100%
Dropped out	00	00	00	00
Complete	20	20	40	40

A. Analysis of demographic data:

1. Age wise distribution:

Table no. 4

Age (In Years)	Experimental Group A		Control Group B	
	No.of Patients	Percentage	No. of patients	Percentage
31-40	1	5	1	5
41-50	8	40	8	40
51-60	5	25	5	25
61-70	6	30	6	30

2. Prakriti wise distribution:

Table no. 5

Prakriti	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
VP	13	65	15	75
KP	3	15	1	5
VK	4	20	4	20

3. Sex wise distribution:

Table no. 6

Sex	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
Male	14	70	13	65
Female	6	30	7	35

4. Diet wise distribution:

Table no. 7

Diet	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
Veg	6	30	12	60
Mixed	14	70	8	40

5. Occupation wise distribution:

Table no. 8

Occupation	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
Houswife	6	30	7	35
Barber	2	10	0	0
Retired	3	15	1	5
Stall	3	15	1	5
Labour	4	20	5	25
Farmer	1	5	1	5
Hotel/Shop	1	5	5	25

6. Distribution According to Extremities involved:

Table no. 9

Extr.inolved	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
Right	13	65	12	60
Left	7	35	8	40

7. Residence wise distribution:

Table no. 10

Residence	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
Urban	17	85	16	80
Rural	3	15	4	20

8. Distribution according to addiction habits:

Table no. 11

Habbits	Experimental Group A		Control Group B	
	No. of patients	Percentage	No. of patients	Percentage
Tobacco	6	30	3	15
Alcohol	3	15	3	15
NO	11	55	14	70

Statistical analysis

In both groups A and B, sample size is 20. On each sample 3 parameters are measured which are ordinal (qualitative) in nature.

All parameters are measured before and after treatment.

According to type of parameter the appropriate statistical tests is as follows**:**

Type of variable	What is going to check	Appropriate test
Ordinal	Before and after treatment results	Wilcoxon signed rank test

This test is applied in SPSS software the results are as follows:

Group A: Experimental group

1) **Bates & Jenson:** Result of before and after treatment by Wilcoxon signed rank test as follows:

Bates & Jenson	N	Test statistic	P value
Negative Ranks	20	-3.926	<0.001
Positive Ranks	0		
Ties	0		
Total	20		

Interpretation: As p value < 0.05, there is significant difference in grades of 'Bates & Jenson's after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. As in all patients it gets reduced, treatment is effective to reduce grades of 'Bates & Jenson'.

2) **Pain:** Result of before and after treatment by Wilcoxon signed rank test as follows:

Pain	N	Test statistic	P value
Negative Ranks	19	-3.862	<0.001
Positive Ranks	0		
Ties	1		
Total	20		

Interpretation: As p value < 0.05, there is significant difference in grades of 'Pain' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. As in almost all patients it gets reduced, treatment is effective to reduce grades of 'Pain'.

3) **Itching:** Result of before and after treatment by Wilcoxon signed rank test as follows:

Itching	N	Test statistic	P value
Negative Ranks	15	-3.499	<0.001
Positive Ranks	0		
Ties	5		
Total	20		

Interpretation: As p value < 0.05, there is significant difference in grades of 'Itching' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. As in most of the patients it gets reduced, treatment is effective to reduce grades of 'Itching'.

Group B: Control Group

1) **Bates & Jenson:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Bates & Jenson'	N	Test statistic	P value
Negative Ranks	20	-3.923	<0.001
Positive Ranks	0		
Ties	0		
Total	20		

Interpretation: As p value < 0.05, there is significant difference in grades of 'Bates & Jenson'after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. As in all patients it gets reduced, treatment is effective to reduce grades of 'Bates & Jenson'

2) **Pain:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Pain	N	Test statistic	P value
Negative Ranks	19	-3.839	<0.001
Positive Ranks	0		
Ties	1		
Total	20		

Interpretation: As p value < 0.05, there is significant difference in grades of 'Pain' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. As in almost all patients it gets reduced, treatment is effective to reduce grades of 'Pain'.

3) **Itching:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Itching	N	Test statistic	P value
Negative Ranks	11	-1.721	0.035
Positive Ranks	2		
Ties	7		
Total	20		

Interpretation: As p value < 0.05, there is significant difference in grades of 'Itching' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. As in most of the patients it gets reduced, treatment is effective to reduce grades of 'Itching'.

Comparison between Experimental Group and Controll Group

According to type of variable the appropriate statistical test for comparison is as follows:

Type of variable	Appropriate test
Qualitative (Ordinal)	Mann Whitney U test

Above test are applied in SPSS software the results are as follows:

1) **Bates and Jenson:** Result of Mann Whitney U test is as follows:

Bates & Jenson	Mean Rank	Test statistic	P value
Group A	16.78	125.500	<0.001
Group B	24.22		

Interpretation: Mean rank of grades of 'Bates & Jenson' is less in Experimental GroupthanControll Group. As p value < 0.05, there is significant difference between both groups for 'Bates & Jenson'. Group A is more effective to reduce grades of Bates & Jenson.

2) **Pain:** Result of Mann Whitney U test is as follows:

Pain	Mean Rank	Test statistic	P value
Group A	18.32	156.500	0.242
Group B	22.68		

Interpretation: Mean rank of grades of 'Pain' is less in Experimental GroupthanControll Group, but as p value > 0.05, there is no significant difference between both groups for 'Pain'. Both groups are equally effective to reduce grades of Pain.

3) Itching: Result of Mann Whitney U test is as follows:

Itching	Mean Rank	Test statistic	P value
Group A	16.88	127.500	0.049
Group B	24.12		

Interpretation: Mean rank of grades of 'Itching' is less inExperimental GroupthanControll Group, and as p value < 0.05, there is significant difference between both groups for 'Itching'. Group A is more effective to reduce grades of Itching.

Overall result

As per above result of comparison between both groups, group A shows more effective result in 2 parameters out of three and in one parameter both groups are equally effective. So, group A is more effective.

Overall effect:

Overall effect	Experimental Group	Controll Group
Marked improvement	14	8
Moderate improvement	4	8
Mild improvement	2	3
No improvement	0	1

Interpretation: Above table and graph reveals that, 70% patients in Experimental Groupand 40% patients in Controll Groupshowed marked improvement. Approximately 40% patients inControll Groupand 20% patients in Experimental Groupshowed moderate improvement. Approximately 15% patients in Controll Groupand 10% patients in Experimental Group showed mild improvement. Only one patient in group B with no improvement. All patients in group A gets relief.

Changes in parameters Before and After treatment

After statistical analysis it was observed that,

- Experimental Group than is more effective to reduce grades of Bates & Jenson thanControll Group.
- Both the groups are equally effective to reduce grades of Pain.

- Experimental Group is more effective to reduce grades of Itching.

  It suggests that,
- Patoladi ointment has more efficacy to reduce grades of Bates & Jenson than Betadine ointment.
- Patoladi ointment is equally efective as that of Betadine ointment to reduce the grades of pain.
- Patoladi ointment is more effective to reduce grades of Itching than Betadine ointment.
- Patoladi ointment is more effective to reduce treatment duration of varicose ulcer.

Before treatment

After treatment

DISCUSSION

The present study was Randomized clinical Trial, entitled as; **"A Randomized, Controlled Clinical study to evaluate the efficacy of Patoladi Ointment on Dushta Vranawith special reference to varicose ulcer."**

Treating a varicose ulcer has been a big task in the area of the surgery. cleaning and dressing with betadine, hydrogen peroxide or eusol or collagen granules, crepe bandage/stockings, leg elevation, etc. has also been the conventional treatment of venous ulcer with their respective side effects. Being a chronic ulcer, varicose ulcers, take prolong time to heal. In the management of chronic venous ulcers Ayurvedic preparation may prove their efficacy. Management of chronic and non-healing wounds like varicose ulcer has been a major question to confront comprehensively. Contents of the Patoladi ointment; Patol, Sariwa, Musta, Patha, Katurohini have raktaprasadak, raktashodhak, shothhar, vedanasthapan, vishaghna, vranashodhan, vranaropan properties. These drugs have been proven to have properties like astringent, antioxidant& anti-inflammatory. Musta is proven to have the wound healing properties. These drugs are also found to have Antinociceptive activity, Antihistaminic, Collagen synthesis-promoting and collagenase inhibitory activities.

Having a local pathology in varicose ulcer, local application of the ointment is far much better treatment modality. Thus Patoladi ointment has more compliance. Besides that it decreases local itching, inflammation & dryness.

Probable mechanism of action of patoladi ointment

In ayurvedic point of veiw

Dravya's Patol, Musta, patha & Kutaki are tikta rasatmaka & have katu & Kashaya uparasa with Katu vipaka & Ruksha, Laghu guna. Tikta rasa helps in Kleda & Puya shoshana & also help in reducing kandu. Katu rasa inhibits vitiated kapha & helps in Vrana Avasadana. Whereas Kashaya rasa also helps in kleda shoshana. By reducing the kleda, these dravyas causes reduction in the vrana srava.

Sariwa is Madhur rasatmaka, Madhur vipaki & Sheet virya dravya having guru guna ultimately inhibiting vitiated vata dosha. As vata is the main cause for ruja, it ultimately inhibits ruja.

Laghu & ruksha guna are essential for lekhana karma thus it can be said that Patoladi ointment causes lekhana of dushta vrana.

According to Ayurvedic Acharyas these drugs are raktaprasadak and raktashodhak. Thus applying Patoladi Ointment locally on varicose ulcer causes purification of local raktadhatu subsequently initiating production of pure Mans dhatu & thereby enhancing wound healing. These drugs according to Acharyas have shothahar, vedanasthapan, vranshodhan & vranropan properties thus reduce local shotha, vedana & enhance wound healing.

In modern point of veiw

Contents of the Patoladi ointment; Patol, Sariwa, Musta, Patha, Katurohini have astringent, anti-oxidant & anti-inflammatory properties.

Drugs having astringent property helps to contract the wound. Thus application of Patoladi ointment helps in wound healing by wound contraction, increased rate of epithelialization at the stage of granulation formation and scar remodeling phase.

Overexposure to oxidative stress leads to impaired wound healing. Normal wound healing requires low levels of reactive oxygen species and oxidative stress. Antioxidant property of Patoladi ointment thus helps in controling wound oxidative stress and thereby accelerate wound healing.

Anti-inflammatory action of Patoladi ointment reduces the local release of pain and thereby reducing pain and further inflammation.

An aquous extract of Sariwa has been proven to have wound healing property. Hence, Patoladi ointment helps in wound healing. It has also been found that Sariwa has antihistaminic activity & helps to reduce itching in patients with varicose uler.

Active principles of Musta; terpenes, flavonol, glycoside & β-sitosterol are proven to have the wound healing property. Thus accelerating wound healing process.

Active principles such as cyperene I, II and cyperol present in musta have shown anti-bacterial activity against a number of organisms. Hence inhibiting bacterial infection of the wound.

Active principles present in kutki such as, acylated iridoid glycosides, picrosides I, II, III, and IV and 6-feruloylcatalpol, phenylethanoid glycosides, triterpene glycosides, cucurbitacin B 2-O-β-D-glucopyranoside and 25-acetoxy-2-β-D-glucopyranosyloxy-3,16,20-trihydroxy-9-methyl-19-norlanosta-5-en-22-one , and an acetophenone glycoside, picein, significantly promoted collagen synthesis. Furthermore, acylated phenylethanoid glycosides, calceolarioside A, plantamajoside, isoplantamajoside, and scroside, exhibited collagenase inhibitory activity. Thus, patoladi ointment helps in wound healing.

Limitation of the study

1. The present study was conducted on limited number of patients.
2. Limited period of assessment up to 30 days. To notice late complication long term follow up is necessary.

Side effect of drug

During trial in the follow up period no adverse effects of the medicine was noted.

CONCLUSION

It may be concluded from the present research work that

- Patoladi ointment has more efficacy to reduce grades of Bates & Jenson than Betadine ointment.
- Patoladi ointment is equally efective as that of Betadine ointment to reduce the grades of pain.
- Patoladi ointment is more effective to reduce grades of Itching than Betadine ointment.
- Patoladi ointment is more effective to reduce treatment duration of varicose ulcer.
- Patients with Vata-pittaj or Pitta-vataj prakruti people are found more prone for developing varicose ulcer.
- The trial is found to be safe in every patient. No side effects were seen during the conduction of the trial.
- Trial group have shown good results and control group have shown moderate results.
- Hence the drug in trial group shown more significant effect than the control group.
  Thus use of patoladi Ointment for 21 days is more efficient for managing Dushta vrana than Betadine ointment given for 21 days.

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