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A clinical study to assess the efficacy of *Manjistadi Kshara Basti* in the management of *Vatarakta* w.s.r. to Peripheral Vascular Disease

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ABSTRACT

Among the diseases which may not be life threatening but hampers the quality of life, peripheral vascular diseases are one. Present lifestyle, food, stress, occupations are predisposing factors. *Vatarakta,* a set of clinical manifestations develop due to the same reasons where there is involvement of *Vata, Rakra* with or without *Avarana*. In such conditions, a *Basti* formulated in the form of *Kaphaghna Basti* with drugs acting on *Vatarakta* like *Laghu Manjistadi Kashaya* is the best choice. With this thought, a single blind clinical study with pre and post test design was conducted on 30 patients who were treated with three *Manjistadi Kshara Basti* (600ml) on 2nd, 4th and 6th day in the morning, empty stomach with five *Matra Basti* with *Dashamoola Taila* (35ml) on 1st, 3rd, 5th, 7th and 8th day in the afternoon, immediately after food. Patient were evaluated based on lipid profile, ANA, serum cytokine, Doppler study before and after (after 30 days of follow up) the study. The study showed statistically significant improvement in pain, swelling and discolouration. There was no significant improvement in all other parameters selected for the study.

Key words: *Vatarakta, Avarana, Laghu Manjistadi Kashaya, Dashamoola Taila, Ayurveda.*

INTRODUCTION

Among diseases caused by life style and as secondary to other diseases, lower limb vascular disease is one which affect the quality of later life of a person. If not treated, it may cause severe disability to that of fatal complications.

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Present increasing incidence of the disease and its impact on the quality of life, disability and severity of complications alarms the need of an energetic treatment.

Literature highlights one of the consequences of life style is *Vatarakta* where there will be involvement of *Kapha* and *Medas* causing *Avarana* to *Vata* and *Rakta* in *Raktavaha Srotas*. Another possibility is *Avarana* of *Vata* or *Rakta* by themselves.[1] Literature highlights *Basti Chikitsa* as best line of management in *Vatarakta.*[2] In such pathogenesis, the prime line of treatment suggested was *Kshara Basti.*[3] The *Vata* involved in the *Samprapti* will be managed with *Basti Chikitsa. Kshara* property of the drug helps in reducing *Kapha* and *Medas* with reliving *Avarana. Ushna* and *Teekshna* nature of medicine may cause vitiation of *Rakta*. Hence, drugs which possess *Rakta Prasadana* effect with indication in *Vatarakta* are to be selected for the *Kashaya* and *Kalka Dravya*. With this idea in

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literature, present study on *Vatarakta* was selected. *Laghu Manjistadi Kashaya*[4] was selected as *Kashaya* and *Kalka Dravya* as it is having *Rakta Prasadana* effect and beneficial in *Vatarakta* was selected for the study based on its indication in *Vatarakta.* A *Taila* having effect over *Vatarakta* as *Dashamoola Taila* was selected for the *Matra Basti.*

Another vascular pathology due to present life style involving venous system of lower limb is varicosities causing stasis of blood and many other complications. As *Vata, Rakta* is involved and same *Samprapti* with or without *Avarana* is identified here too, venous diseases are also included in the study.

As increased/altered level of lipids in the blood is one of the risk factor for vascular pathologies, the estimation of lipid level in the blood was also included. ANA and serum cytokines are used as inflammatory markers which help in identifying minute changes after the *Basti Chikitsa*. Doppler study is one of the best evidence to highlight the gross ongoing process in the vascular level. Hence, it was included for the study.

Objectives of the Study

1. To evaluate the efficacy of *Manjistadi Kshara Basti* in *Vatarakta*/ peripheral vascular diseases
2. To evaluate the efficacy of *Manjistadi Kshara Basti* on cholesterol levels, ANA and serum cytokine.
3. To evaluate the efficacy of *Manjistadi Kshara Basti* on arterial and venous Doppler

Materials and Methods

Sample source

Patient suffering from *Vatarakta* / peripheral vascular disease (PVD) was selected from OPD & IPD of the hospital.

Medicine source

Manjistadi Kshara Basti drugs and *Dashamoola Taila* was prepared in SDM Ayurveda Pharmacy, Udupi.

Method of collection of data

Study Design: Single blind clinical study with pre and post test design

Sample Size: Minimum of 30 patients suffering from *Vatarakta* /PVD of lower limb was selected.

Diagnostic criteria

- Patients with the signs and symptoms of *Vatarakta*/ PVD of lower limb
- Patients with the confirmation of PVD by Doppler study

Inclusion criteria

- Patents fulfilling the diagnostic criteria
- Patients between the age group of 16-70 Yrs
- Patients who are fit for *Basti Chikitsa*

Exclusion criteria

- Patients with the symptoms of *asadhya Vatarakta*
- Patients with the complication of PVD (Toxicity, gangrene)
- Spasmodic PVD
- Patients with blockage in upper limb and in Lymphatic system
- Patients with the other systemic illness interfering with the treatment

Duration of treatment: 8 days

Duration of follow up: 30 days

Total duration of study: 38 days (8 days of intervention and 30 days of follow up)

Investigations

- Routine haematological investigations (Hb%, TC, DC, ESR, RBS, Platelet count)
- Lipid profile
- ANA
- Serum cytokine estimation
- Doppler study

Intervention

In selected patients, information sheet related to the study was given. Once they are interested to participate, consent form was given to sign. A detailed

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history and clinical examination were done and recorded in the case proforma prepared for the study. 5ml of blood was drawn for different haematological and biochemical parameter analysis before the treatment.

Manjistadi Kshara Basti was administered in a *Yoga Basti* course, where in three *Manjistadi Kshara Basti* (600ml) was administered on 2nd, 4th and 6th day in the morning, empty stomach along with five *Matra Basti* with *Dashamoola Taila* (35ml) which was administered on 1st, 3rd, 5th, 7th and 8th day in the afternoon, immediately after food. Specific standard diet and regimen for *Basti Chikitsa* was advised for all patients.

Patients were evaluated based on standard subjective, objective parameters before the treatment, on 8th day and after the follow-up. Investigational parameters like lipid profile, ANA, serum cytokine and Doppler was done before treatment and after the follow-up.

***Laghu Manjistadi Kshara Basti* drugs:** (Total 600ml)

- Honey: 120ml
- *Saindhava*: 10 gms
- *Dashamoola Taila*: 80ml
- *Kalka (Laghu Manjistadi Kashaya Choorna)*: 40gms
- *Laghu Manjistadi Kashaya*: 320ml
- *Gomutra*- 40 ml

Observations and Results

No. of patients registered for the study - 48

No. of patients completed the study - 30

No. of dropout - 18

Reason for dropout

Due to lockdown and inter district travel restrictions during Covid 19 surges and waves, all these patients were not registered for the follow up. Even though they came for follow up after these episodes, they were not included for the study as the follow up period of 1 month was exceeded.

Other Observations

As per the proforma, observations were made regarding the incidence of Age, sex, occupation, religion, socio-economic status, marital status, habitat etc.

Table 1: Distribution of 30 patients according to different criteria.

Parameters	Observation	Maximum number of patients	%
Age	51-60	10	33.3
Gender	Male	20	66.6
Marital status	Married	30	100
Occupation	Housewife	9	30
Habits	Nil	20	66.6

Table 2: Disease related observations

Parameters	Observation	Maximum number of patients	%
Main c/	Pain	23	76.6
Associated c/	Swelling	30	100
Vascular system	Venous	29	96.7
Limb involved	both	24	80
Nature of pain	Dragging	28	93.3

About the *Basti*

Retention of *Manjistadi Kshara Basti*

Maximum time - 13 min.

Minimum time - 1 min.

Retention of *Matra Basti*

Maximum time - 13 Hrs 25 min

Minimum time - 4 hours 23 min.

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RESULTS

Clinical Study: Clinical study was conducted at SDM Ayurveda Hospital, Udupi. Among 48 patients registered for the study, 30 patients who completed the study were assessed before the treatment (BT), on 8th day (AT) and after 30 days of follow up on the 38th day (AF). Different parameters were assessed based on the grading given to those symptoms. They were recorded in the case proforma (Annexure 1). Then finally, relevant statistical tests were applied to check the significance. Wilcoxon signed rank test is used to assess BT, AT and AF values of the individual group as the data is categorical (ordinal). The numerical data was tested using paired 't' test. The analysis is done statistically using Sigma stat version 4 software.

Different symptoms, investigations assessed in the patients and their results are as follows;

Table 3: Effect of treatment on different assessment parameters are.

Parameters	n	Mean			Diff. in mean	median	%	Sign rank test			
		BT	Follow up					S.D.	S.E.M	'Z'	P
Pain	30	1.633	AT	1.233	0.4	1.000	24	0.568	0.104	2.755	= 0.004
			AF	0.467	1.166	0.000	71	0.507	0.092	5.014	<0.001
Discolouration	30	0.767	AT	0.621	0.146	0.000	19	0.775	0.144	-2.236	0.063
			AF	0.333	0.434	0.000	56.5	0.479	0.0875	-3.606	<0.001
Swelling	30	1.767	AT	1.000	0.767	1.000	43.4	0.643	0.117	-4.796	<0.001
			AF	0.367	1.4	0.000	79.2	0.490	0.0895	-4.949	<0.001

Over lipid profile

Lipid profile was checked in the blood before the treatment and after the follow up of 30 days on 38th day. The result was analyzed using paired 't' test as the data is numerical. The result is as follows;

Table 4: Effect of treatment on lipid profile

Parameters	Mean			Difference in mean	%	Paired 't' Test			
	BT	Follow up				S.D.	S.E.M	't'	P
Serum cholesterol	190.267	AT	187.167	3.1	1.6	46.700	8.526	0.278	0.782
Sr tyglycerides	187.633	AT	173.600	14.033	7.47	99.664	18.196	0.586	0.560
HDL	44.133	AT	48.267	-4.134	9.36	11.095	2.026	-1.658	0.103
LDL	113.967	AT	111.000	2.967	2.6	27.162	4.959	0.428	0.670

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VLDL	39.600	AT	33.870	5.73	14.4	20.880	3.812	1.032	0.306
Ratio	4.370	AT	3.873	0.497	11.3	0.773	0.141	2.314	0.0242

Effect on Serum Cytokine and ANA

Serum cytokine: Before treatment the mean serum cytokine value was 31.192 which was reduced 24.021. The difference in the mean values is not great enough to reject the possibility that the difference is due to random sampling variability.

ANA: Before treatment the mean ANA was 0.253 which was reduced 0.256 after the treatment. The difference in the mean values is not great enough to reject the possibility that the difference is due to random sampling variability. There is not a statistically significant difference between the input groups (P = 0.930). There is no statistically significant difference between the input groups (P = 0.369). The details of the same is given below in the table.

Table 5: Effect on Serum cytokine and ANA

Parameter	Mean			Difference in mean	%	Paired 't' Test			
	BT	Follow up				S.D.	S.E.M	't'	P
Serum cytokine	31.192	AT	24.021	7.171	22.9	25.469	4.650	0.905	0.369
ANA	0.253	AT	0.256	-0.003	-1.18	0.145	0.0264	0.0878	0.930

Result based on Doppler study

In all the selected patients, Vascular Doppler of either one affected limb or both affected limb was done before the treatment and after 30 days of follow up on 38th day. As the report obtained is descriptive one, the result is depicted in descriptive form only. The result of treatment on Doppler report is as follows:

- No much difference was observed in any of the after-treatment reports compared to before treatment report
- In 29 patients, deep vein was patent. In one patient, there was deep vein thrombosis which was resolved after the treatment. One patient had chronic deep vein thrombosis of popliteal vein which was resolved after the treatment. One patient had chronic deep venous thrombosis with near complete recanalization involving superficial femoral vein and popliteal vein. In two patients, upper one third of right leg showed echogenic thrombus within suggestive of superficial venous thrombosis.
- In 29 patients venous Doppler there was Dilated superficial veins and Varicosity of long Saphenous system in affected limb which remained same after the treatment
- Sapheno-femoral or sapheno-popliteal junction which was incompetent in some of the patients remained the same after treatment report
- Few dilated incompetent perforators are noted in few reports after the treatment which was not present before treatment.
- Bilateral subcutaneous edema which was seen before the treatment was significantly resolved after the treatment.
- Thrombophebiltis of short Sephanous vein was observed in one report which was resolved after the treatment.

Out of 30 patients given with the *Manjistadi Kshara Basti*, overall effect on the scored parameters none had the complete remission, marked improvement, Moderate improvement. All the 30 patients had mild improvement in the symptoms.

Discussion

The present study was intended to assess the effect of *Manjistadi Kshara Basti* in different parameters of *Vatarakta* including clinical symptoms, haematological and radiological assessment. In clinical symptoms: 29

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patients out of 30 were having venous system pathologies. Hence, stasis of blood in the varicose veins were observed in the patients. So, dragging pain, swelling and discolorations were maximum. The *Basti Chikitsa* with *Teekshna* and *Rakta Prasadana* drugs helped in reliving the stasis of blood thus, reducing the swelling and discolouration gradually. The pain due to *Vata* is controlled well by *Basti Chikitsa*. Symptoms like claudication, reduced oxygen saturation were not observed in any patients as the arterial system was patent in them.

As altered lipid levels will be the associated or predisposing factors in vascular pathologies, in the present study this was not altered in all the patients as may be due to the reason that they were having venous pathologies. Hence, no significant changes were observed in the lipid profile. But it is interesting to observe that, the *Kshara* property of the *Basti* has not reduced the level of lipids less than their normal levels. This is evidence that, the properly planned treatments in Ayurveda will help in attaining *Dhatu Samyata* and does not lead to *Dhatu Kshaya*. The elevated levels of triglycerides, total cholesterol may be due to, the *Kshara Basti* has brought the *Dusta Kapha* and *Medas* in the *Dhatu* level to *Rakta Dhatu* from where it needs to be eliminated. As the give course of *Basti* is *Mrudu* and not enough to eliminate all the detached *Dosha*, the levels of these lipids in the blood might have increased. Hence, *Kshara Basti* in *Karma* or *Kala* pattern may be required in such situations to tackle the condition. The ANA and serum cytokines are even though sensitive inflammatory markers, the duration of the treatment and follow-up was very minimum to elicit the changes in these parameters. In some of the patients, the levels are reduced which may be an evidence of target specificity of the treatment and it also indicates that the recovery has started in the minute levels. In some patients, the levels are increased which may be due to, as these vascular pathogenesis are chronic, deep seated, and there is involvement of *Bahudoshavastha,* single course of *Kshara Basti* in the form of *Yoga Basti* may not be sufficient to take care of ongoing pathogenesis. Hence, repeated course of *Kshara Basti* with *Karma* or *Kala* *Basti* pattern may prove beneficial. The changes in the vascular level through the Doppler study may need long duration as the changes observed through this are a very gross level change. Minimum of 5-6 months may be needed during which repeated course of *Basti* may prove effective. The evidences like reduction in subcutaneous level edema, resolved thrombophlebitis are evidences of early changes after the treatment. The observations like Dilated superficial veins and Varicosity of long saphenous system, incompetent Sapheno-femoral or sapheno-popliteal junction which remained the same after treatment shows that either these structural changes are irreversible and needs long term repeated treatment with life style modifications.

CONCLUSION

Clinical study: *Manjistadi Kshara Basti* administered in *Yoga Basti* course using *Laghu Manjistadi Kashaya* is proved to be effective in the management of PVD specially in pain, discoloration and swelling.

Lipid profile: Even though, there was reduction in the bad cholesterol and increase in HDL cholesterol in some of the patient, there was insignificant difference in lipid profile after the treatment except in the ratio where the result was statistically significant.

ANA and Serum Cytokine: There were no statistically significant changes in ANA and serum cytokine levels after the treatment. When assessed individually, there was marked reduction in these two levels after the treatment in some patients and I some, there was drastic increase in the levels.

Doppler report: Doppler report showed no major changes in varicosities, dilated superficial, long and short saphenous veins. The perforators were formed which remained patent. Deep vein thrombosis in one patient was resolved completely. Chronic deep vein thrombosis observed on 2 patients, resolved completely in one patient and complete recanalization was observed in one report. Deep veins were patent in 27 reports. Subcutaneous oedema which was seen before the treatment was significantly resolved after the treatment.

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SCOPE FOR FUTURE WORK

- As this study included both arterial and venous pathogenesis, it is difficult to conclude in which *Vatarakta*, this *Basti* is beneficial?. Hence in future study, 2 separate groups may be made to assess the difference of this *Basti* over arterial and venous pathogenesis.
- In this study, *Basti* was administered in yoga *Basti* course. As the disease is *Gambheera Dhatu Gata*, as there is involvement of *Avarana, Kapha* and *Medas*, there is *Bahudoshavastha*, either *Karma* or *Kala Basti* course may be adopted for better and fast relief.
- In spite of clinical benefits, changes in Doppler needs long duration observation. Hence, the follow up period may be extended up to 3 months to 6 months in future studies.
- As these types of diseases needs combined treatments for cumulative benefits, *Bahir Parimarjana Chikitsa* and *Shamanaushadhi* may be added in future studies.

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