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A Comparative Clinical Study To Evaluate The Effectivness Of Manjishtadi Kshara Basti Followed By Jaloukavacharana In Comparision With Manjishtadi Kshara Basti In Vatarakta With Special Reference To Thrombo Angitis Obliterans – A Case Series

Dr. Nagaraja .K[1], Dr. Srinivas Masalekar[2]
[1] *Post Graduate Scholar, Department of Shalya Tantra, Government Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, India.*
[2] *Professor & HOD, Department of Shalya Tantra, Government Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, India*

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ABSTRACT
Thrombo angitis obliterans (TAO) is one of the Peripheral vascular disease (PVD) which presents with progressive occlusion of peripheral distal arteries resulting in ischaemia. Patients present with clinical features like intermittent claudication pain, burning sensation, blackish discolouration, gangrene. This condition has striking similarities with "Gambhiravatarakta" which is characterised by similar symptomatology viz., burning sensation, severe pain, suppuration (Mamsa kotha) and tenderness. In this regard for the management of the condition, a comprehensive treatment protocol was planned based on the classical references. A 40 patients of TAO w.s.r.Vatarakta fulfilling the criteria were randomly selected from OPD and IPD of Shalya tantra, Sri Jayachamarajendra Government Ayurveda and Unani Hospital, Bengaluru. the consented patients were devided into two groups viz .., Group A and Group B comprising of 20 patients each. In Group A – Manjishtadi kshara basti followed by Jaloukavacharana , and in Group B – Manjishtadi kshara basti administered. On the basis of assessment criteria and on the overall result of treatment, in both group A and group B has been able to reduce claudication Pain, Tenderness, Burning sensation, improved blood circulation and local colour changes in skin.
Keywords: Peripheral Arterial Disease, Vatarakta, Manjishthadi KsharBasti ,Thrombo angitis obliterans, Jaloukavacharana.

I. INTRODUCTION

Thrombo-angitis obliterans or Buerger's disease is basically caused by tobacco use. It is a non-atherosclerotic, segmental inflammatory occlusive vascular disorder involving medium and small sized distal arteries with the involvement of the neighboring vein and nerve, terminating in thrombosis of the artery.

TAO affects exclusively the males of young age group between 20 and 40 years. It is uncommon in women who constitute only 5% to 10% of all the patients with Buerger's disease.

The features of TAO can be correlated with the Vatarakta. Vatarakta is a syndrome produced by vitiation of both Vata and Rakta. Here there is obstruction to the normal flow of Vata by vitiated Rakta manifesting many clinical symptoms which starts mainly in Pada and Hasta, like, Karshnata(blackish discolouration), Sparshaghnatwa(paraesthesia), Kshate Atiruk(tenderness), Supti'(Numbness), Sheethalata(coldness in limbs), Daha(Burning sensatation), Khangathawa(lamness), Dhamani anguli sandhi sankocha(Constriction of vessels and fingers), Sheetha pradwesha(Aversion towards cold), Prashosha(atrophy), mamsakotha(gangrene), There is a huge resemblance in the features of Vatarakta mentioned in Ayurvedic literature with that of TAO.

In the management of TAO various drugs like Analgesics, Vasodilators, Anticoagulants have been tried with questionable value which have drawbacks like bleeding tendencies, systemic adverse effects and most of the times the disease ends up with major or minor amputations. And several surgical treatments like lumbar sympathectomy, omentoplasty, profundaplasty, ilzarov method with poor success rate,high cost and high reccurence rate.

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As the need of the hour, for the management of TAO, a holistic, comprehensive treatment is required.

Even though Vatarakta management encompasses wide range of treatment modalities like Alepa, Seka, Upanaha, Abhyanga, Raktamokshana, Virechana, Basti. Raktamokshana and Basti are most exemplified. Because of there specific actions on sampraptivighatana and Doshavasechana in TAO. Raktamokshana is indicated as foremost treatment considering its immediate result. Basti is explained as Supreme remedy for expelling the doshas and malas (inflammatory markers, tobacco induced endotoxins etc.) in Vatarakta. the core pathology of TAO lies in series of events triggered by tobacco use like, certain immune reaction sets in followed by concurrent chronic inflammatory process with endothelial damage in artery resulting in thrombosis and occlusion of peripheral vessels eventually. In this respect increased viscosity & hypercoagulability of blood are instrumental in rendering the pathology. Hence Raktamokshana which aims at Dustaraktadhatu nirharana is adopted which is one of the ideal choice in relieving pathology influenced by blood. Among Raktamokshana modalities Jaloukavacharana (ashastrakrita raktamokshana) is selected for the present study considering its therapeutic effect is not only because of loss of blood sucked by Jalouka, but also by its salivary secretions having actions like anticoagulant, local vasodilatation, local anesthesia etc which the leech emits in to the lesion as established by previous study.

And Basti karma as it is well supported in classics by saying "न हि बस्तिसमं किञ्चिद्वातरक्तविकित्सितम् that means no other therapeutics superior than Basti in the management of Vatarakta. Basti treatment has got generalized cleansing as well as rejuvenating action. Also Basti is indicated in Shaakha gata, Marmagata diseases (as evidenced in TAO) and it is the best treatment to control all the types of diseases influenced by Vayu. Aptly it is quoted as Ardha chikitsa for the above reasons.

Considering these facts, here an attempt was made to study the efficacy of Jaloukavacharana and Manjishtadi kshara Basti in the management of TAO.

AIMS AND OBJECTIVES
Objectives of the study:

- To evaluate the efficacy of Manjishtadi Kshara Basti followed by Jaloukavacharana in the management of TAO.
- To evaluate the efficacy of manjishtadi kshara basti in the management of TAO
- To know the added effect of Jaloukavacharana in the management of TAO

Null hypothesis;
- Manjishtadi kshara basti followed by Jaloukavacharana is not effective in the management of TAO.
- Manjishtadi kshara basti is not effective in the management of TAO.
- Jaloukavacharana is not effective in the management of TAO.

Alternate hypothesis;
- Manjishtadi kshara basti followed by Jaloukavacharana is effective in the management of TAO.
- Manjishtadi kshara basti is effective in the management of TAO.
- Jaloukavacharana is effective in the management of TAO.

METHODOLOGY;
Source of Data;
Patient suffering from clinical featers of TAO was selected from OPD and IPD of sri jayachamarajendra govt ayurveda and unani hospital bengaluru and Medical camps conducted by dept of P.G studies in shalya tantra GAMC Bengaluru .
The study was conducted between Sept 2022 – Aug 2023.
Method of Collection of Data;
A total of 40 cases with clinical features of TAO was selected for the present study

- **INCLUSION CRITERIA;**

The Patients of TAO with features of-
- Claudication pain of grade 1 & 2
- Feeble peripheral arterial pulsation (of Posterior tibial &dorsalis pedis artery)
- Tenderness grade 1,2&3.
- Burning sensation grade 1.
- Buergers postural angle > 30 degree
- The cases which are not heading for gangrenous condition
- The cases which do not require amputation
- Age between 20-70years

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- **EXCLUSION CRITERIA;**
- Patients with atherosclerosis, diabetes mellitus and peripheral neuropathy
- Bleeding disorders
- Complete occlusion of artery
- Complete Absence of pulse
- Grade 3 & Grade 4 claudication (rest pain)
- Buergers postural angel< 30 degree
- Tenderness grade 4.
- Burning sensation grade 2.
- Basti ayogya
- Age below 20 years and above 70 years.
- Patients with conditions like malignancy, tuberculosis, leprosy, syphilis, HIV, HbSAg, And other uncontrolled severe systemic diseases.

- **STUDY DESIGN;**

A total of 40 cases of thrombo angitis obliterans, fulfilling the criteria shall be included for study.
The 40 cases included will be randomly selected and allotted into 2 groups namely group - A & Group–B, consisting 20 patients each

Group A- manjishtadi kshara basti followed by jaloukavacharana
Group B- manjishtadi kshara basti
Treatment duration in group A – 30 days
Group B – 15 days.

- **Materials**

Group A- Yoga Basti

- Guduchi Ghrita-Q. S.
- Manjishtadi khwatha choorna – Q.S.
- Yashtimadhu kalka Q. S.
- Gomutra - Q. S.
- Madhu - Q. S.
- Saindhava lavana - Q. S.
- Khalwa yantra-01
- Enema can-01
- 100 ml syringe-01
- Red Rubber Catheter No. 8
- Measuring jar
- Panchakarma Droni
- Gas Stove
- Sterile glove- No.7
- Matchbox

Group B -Jaloukavacharana

- Jalouka- Sufficient number
- Haridra churna-Q.S.
- Saindhava lavana –Q.S.
- Sterile straight needle No.21 gauze
- Plastic containers to store Jalouka
- kidney trays -02
- Water –Q.S.
- Sterile Glove- No. 7
- Bandage material-Q.S

METHODOLOGY OF GROUP –A

Manjishtadi kshara basti in yogabasti pattern.
Niruha with- manjishtadi kahara basti- 585ml
Anuvasana with- guduchi ghrita- 60ml
Jaloukavacharana is done once in 5 days for 4 sittings, after parihara kala of basti.

PROCEDURE;

Table no 01- shows yoga basti pattern for group A

	1st day	2nd day	3rd day	4th day	5th day
Morning (8:00AM)	Anuvasana	Niruha	Niruha	Niruha	Anuvasana
Afternoon (2:00PM)		Anuvasana	Anuvasana	Anuvasana	

YOGA BASTI
PURVAKARMA:

Procedure will be explained to patients in advance and written consent will be taken.
Prior to Anuvasana basti Laghu Bhojana will be advised

Preparation of manjishtadi kshara basti: The different components of basti will be mixed in following pattern : Madhu 80ml + Saindhava lavana 5gm + Guduchighritha 60ml + kalka of yashtimadhu 40gm + manjishtadi kwatha 300ml + gomutra arka 100ml. all ingredients are thoroughly mixed and a preparation in the form of emulsion will be obtained, this will be made Sukhoshna by keeping it inside the ushna jala .

PRADHANAKARMA:

Anuvasana Basti – patients will be subjected to mridu abhyanga with lukewarm taila and nadi sweda locally over abdomen, buttocks and on the thighs. Patients after abhyanga & Sweda will be advised to have laghu bojana. Patients will be asked to lie on the droni in vama parshwa (left lateral position with right leg flexed) and asked to take deep breath. Sukoshna anuvasana dravya

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will be administered slowly with the help of basti syringe.

Niruha Basti --Patients will be advised to come in empty stomach , after confirming digestion of previously taken food and before developing hunger mridu abhyanga with lukewarm tila taila and nadi sweda locally will be done over abdomen, buttocks and on thighs. Patients will be asked to lie on droni in vama parshwa (left lateral position with right leg flexed)and asked to take deep breath; sukoshna basti dravya will be administered slowly with the help of enema can fitted with a rubber catheter.

Extreme care will be taken to avoid all the possible basti vyapat.

PASCHAT KARMA

Patient will be asked to lie in supine position and to defecate on developing the urge.

The time of administration, the time of retention, pratyagamana kala & any complications if present will be recorded and dealt with adequate care.

JALOUKAVACHARANA;

Purva karma: For initial 10-15 min, leeches will be placed in a kidney tray containing Haridra jala and then transferred to a kidney tray containing plain water. After it regained the natural vivacity and freshness, it will be taken and applied to the affected part.

Pradhana karma: One or two leeches will be applied depending upon clinically presenting features over the distal dorsum part of the affected limb. The patient will be made to lie down in supine position or sit comfortably in a chair. Then Jalouka will be brought into contact with the affected area (i.e. over the dorsum of the affected limb). The biting & sucking of blood by the Jalouka will be confirmed by the posture i.e., at the neck the leech resembled a horse shoe shape, raised & arched. In cases where the Jalouka will not bite, the affected area will be pricked with a sterile needle to bring about oozing of a drop of blood, thus facilitating biting. It will then be covered with sterile gauze dipped in plain water which will be moistened at intervals till the end of the procedure. During the procedure the patient will be observed for any untoward effects and the same will be dealt suitably. The procedure will be continued till the Jalouka is dropped off by itself or removed by applying Saindhava lavana to its mouth after 45 mins.

Paschat karma:

Management of the patient- The spot of bite will be wiped thoroughly clearing the secretions & blood from the area. The area will be smeared with Haridra and sterile absorbent pressure dressing will be applied. The patient will be observed for soakage of thedressing with blood.

Management of the Jalouka – The Jalouka which dropped off / those removed will be subjected to vamana karma. The mouth of the Jalouka will be smeared with Haridra repeatedly with simultaneous gentle massage of the Jalouka from the tail towards the mouth so as to expel the sucked blood. After confirming the complete expulsion of the blood, it will be transferred to Haridra water to cleanse and activate it. Once the Jalouka begins to actively move around it is transferred in to clean water and then into the container which is appropriately closed and labeled with the name of the patient and the date of procedure.

The procedure will be repeated after 5 days for 4 sittings in total 15 days duration.

Observations will be made before the treatment and on the 15^{th} , 20^{th} ,25th & 30th day of the treatment for the changes in the signs and symptoms & the same will be recorded in the proforma of the case sheet prepared for the study.

METHODOLOGY OF GROUP – B

Manjishtadi kshara basti in yogabasti pattern .
Niruha with- manjishtadi kshara basti- 585ml
Anuvasana with- guduchi ghrita- 60ml

PROCEDURE; **YOGA BAST;**

Table no 02; showing yoga basti pattern in group B

	1st day	2nd day	3rd day	4th day	5th day
Morning (8:00AM)	Anuvasana	Niruha	Niruha	Niruha	Anuvasana
Afternoon(2:00PM)		Anuvasana	Anuvasana	Anuvasana	

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PURVAKARMA:
Procedure will be explained to patients in advance and written consent will be taken.
Prior to Anuvasana basti Laghu Bhojana will be advised
Preparation of manjishtadi kshara basti: The different components of basti will be mixed in following pattern : Madhu 80ml + Saindhava lavana 5gm + Guduchighritha 60ml + kalka of yashtimadhu 40gm + manjishtadi kwatha 300ml + gomutra arka 100ml. all ingredients are thoroughly mixed and a preparation in the form of emulsion will be obtained, this will be made Sukhoshna by keeping it inside the ushna jala .

PRADHANAKARMA:
Anuvasana Basti – patients will be subjected to mridu abhyanga with lukewarm taila and nadi sweda locally over abdomen, buttocks and on the thighs.Patients after abhyanga & Sweda will be advised to have laghu bojana. Patients will be asked to lie on the droni in vama parshwa (left lateral position with right leg flexed) and asked to take deep breath. Sukoshna anuvasana dravya will be administered slowly with the help of basti syringe.

Niruha Basti --Patients will be advised to come in empty stomach , after confirming digestion of previously taken food and before developing hunger mridu abhyanga with lukewarm tila taila and nadi sweda locally will be done over abdomen, buttocks and on thighs. Patients will be asked to lie on droni in vama parshwa (left lateral position with right leg flexed)and asked to take deep breath; sukoshna basti dravya will be administered slowly with the help of enema can fitted with a rubber catheter.
Extreme care will be taken to avoid all the basti vyapat

Paschat karma
Patient will be asked to lie in supine position and to defecate on developing urge.
The time of administration, the time of retention, pratyagamana kala & any complications if present will be recorded and dealt with adequate care.
Observations will be made before the treatment and on the 15th day of the treatment for the changes in the signs and symptoms & the same were recorded in the proforma of the case sheet prepared for the study

FOLLOW UP AND OBSERVATIONAL PERIOD;
In cases where total reliefs will be obtained, duration of 2 months will be fixed to observe possibility of reoccurrence in such cases.

ASSESSMENT CRITERIA;
The changes in the following parameters will be considered for the assessment of results and graded as follows:
Subjective parameter;
Pain
- Claudication pain: (According to Boyd's classification)
- Grade 0-no pain on walking
- Grade 1-pain on walking but disappears after continued walking
- Grade 2-pain continues, but patient can still walk with effort
- Grade 3-patient has to take rest to relieve the pain
- Grade 4-rest pain

Burning sensation
- Grade 0 –No burning sensation
- Grade 1 –Tolerabale burning sensation
- Grade 2 – Intolerable burning sensation

Objective parameter;
Buerger's postural test:
Grade 0- no pallor on elevation of the limb at 90 degrees for 60 seconds
Grade 1- pallor on elevation of the limb at 90 degrees for 60 seconds
Grade 2- pallor on elevation of the limb at 60 degrees for 60 seconds
Grade 3- pallor on elevation of the limb at 30 degrees for 60 seconds

Pulse :
- Grade 0-full bounding/normal compared to the other normal artery pulsation in the same patient.
- Grade 1- feeble
- Grade 2- absent.

Tenderness :
- Grade 0- No Tenderness
- Grade 1-Patient feels Tenderness
- Grade 2-Patient winces on touch
- Grade 3-Winces & withdraws the affected part
- Grade 4-Patient does not allow to touch

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Assessment of results-

- The total effect of the therapy was assessed based on the following criteria.
- Marked improvement -Relief >75% relief in the features.
- Moderate improvement - Relief >50% and <75%.
- Mild improvement - Relief >25% and <50%.
- Poor response - Relief <25%

Intervention schedule

Study was intervened by certain instructions given to the patients.

- Patients were advised to drink hot water, to avoid sexual intercourse, suppression of natural urges, exercise, excessive speech, uneven sitting and lying postures, exposure to wind, cold, heat, dust, anger and grief.
- To rest as much as possible.
- Complete cessation of smoking & tobacco use.
- Use of well fitting & protective shoes.

II. RESULTS

Within-group comparison of Group-A

When the data were compared between pre and post there was a significant change was seen in claudication pain ($p < 0.001$) with average improvement of 97%, Buergers test ($p = 0.006$) 78.9%, tenderness (<0.001) with average improvement in 68%, burning sensation ($p = 0.01$) with average improvement of 70.83% .

This study shows that after giving Manjishtadi kshara basti followed by Jaloukavacharana intervention for 30 days it reduces the claudication pain, tenderness, outcomes of buergers test, also with reducing burning sensation.

Table 03: Within-group comparison of Group A

Variables	Pre	Post	p-value
Claudication pain	1.7±0.47	1.65±0.48	<0.001
Buergers test	1.9±0.44	1.5±0.51	0.006
Tenderness	2.35±0.48	1.6±0.59	<0.001
Burning sensation	1.2±0.52	0.85±0.36	0.01

RM-ANOVA of within-group comparison with pre, post-1 and post-2

There was a significant difference was observed over period by comparing with baseline, day-15 and day-30 with claudication pain ($F = 35.8$, $\eta^2 = 0.36$, $p = <0.001$), Buergers test ($F = 62.2$, $\eta^2 = 0.49$, $p = <0.001$), pulse (DPA) ($F = 3.35$, $\eta^2 = 0.1$, $P = 0.04$), Pulse (PTA) ($F = 3.35$, $\eta^2 = 0.1$, $P = 0.04$), Tenderness ($F = 153$, $\eta^2 = 0.1$, 0.04), Burning sensation ($F = 38.9$, $\eta^2 = 0.48$, $p = <0.001$) as shown in **(Table 03).**

When the data were assessed at baseline, after 15 days and after 30 days of intervention the trend of change in the outcome variables was shown in decrease in claudication pain, with improvement in buergers test, with change in Pulse (DPA) and (PTA), with decreasing tenderness along with burning sensation.

Table 04: RM-ANOVA of within-group comparison in Group A

Variables	Pre	Post 1	Post 2	F	Effect size	p-value
Claudication pain	1.7±0.47	1.65±0.48	1±0.32	35.8	0.36	<0.001
Buergers test	1.9±0.44	1.5±0.51	0.85±0.36	62.2	0.49	<0.001
Pulse (DPA)	1(0)	1(0)	0.85(0.36)	3.35	0.1	0.04
Pulse (PTA)	1(0)	1(0)	0.85(0.36)	3.35	0.1	0.04
Tenderness	2.35±0.48	1.6±0.59	0.6±0.5	153	0.65	<0.001
Burning sensation	1.2±0.52	0.85±0.36	0.2±0.41	38.9	0.48	<0.001

Within-group comparison of Group-B

When the data were compared between pre and post there was a significant change was seen in claudication pain ($p <0.04$) with average improvement of 51%, buergers test ($p <0.001$) with average improvement of 51%, Tenderness (0.05) with average improvement of 24% and Burning sensation (0.01) with average improvement of 9.5% but not in Pulse (PTA) (0.1) and Pulse (DPA) (0.34) as shown in **(Table 04**).

After giving 15 days of Manjishtadi kshara basti intervention shows slight decrease in claudication

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pain, buergers test only but not much change was seen in pulse (DPA) and (PTA), tenderness and burning sensation.

Table 05: Within group comparison of Group B

variables	Pre	Post	p-value
Claudication pain	1.65±0.48	0.85±0.36	0.04
Buergers test	1.65±0.48	0.85±0.36	<0.001
Pulse (DPA)	1(0)	0.9(0.3)	0.34
Pulse (PTA)	1(0)	0.85(0.36)	0.1
Tenderness	1.25±0.55	0.3±0.57	0.05
Burning sensation	1.05±0.22	0.1±0.3	0.01

Between-group comparison between Group-A and Group-B

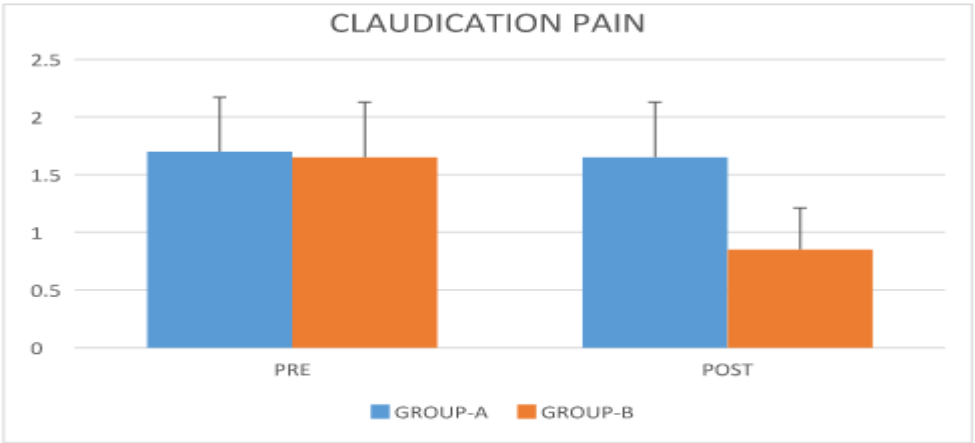
When the data were compared between post values of Group-A and Group-B shows a significant difference in claudication pain (<0.001), buergers test (<0.001), Pulse (DPA) (p = 0.1), Tenderness (p <0.001) and burning sensation (<0.001) but not in Pulse (PTA) (0.08) as shown in **(Table 05).**

When both the group were compared after the intervention there was a huge decrease in claudication pain, improvement in pulse (DPA) and (PTA), remarkable decrease in tenderness with huge decrease in burning sensation was evident in Group A when compared to Group B. These changes were not markedly noticed in Group B.

Table 06: Comparison of between groups of Group A and Group B

variables	**Group A**	**Group B**	**p-value**
Claudication pain	1.65±0.48	0.85±0.36	<0.001
Buergers test	1.5±0.51	0.85±0.36	<0.001
Pulse (DPA)	1(0)	0.9(0.3)	0.1
Pulse (PTA)	1(0)	0.85(0.36)	0.08
Tenderness	1.6±0.59	0.3±0.57	<0.001
Burning sensation	0.85±0.36	0.1±0.3	<0.001

Graph;01–Shows effect on Claudication pain



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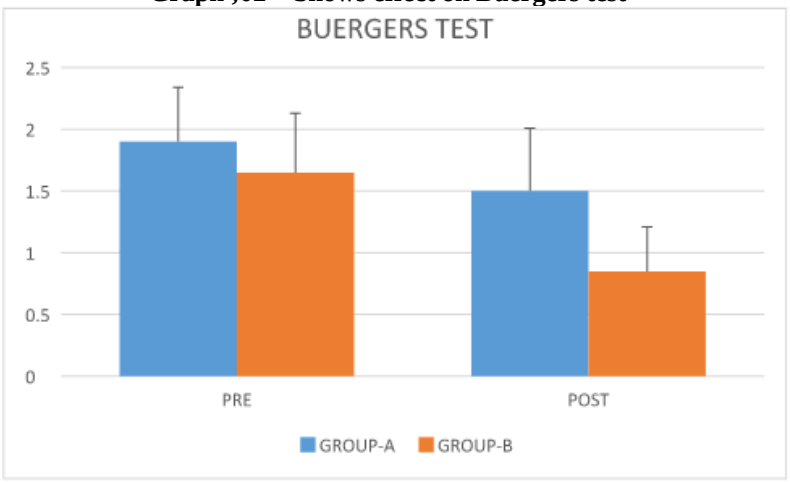
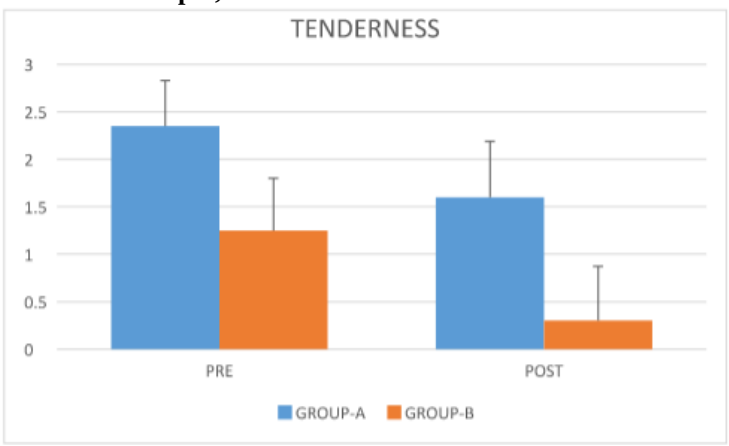
Graph ;02 – Shows effect on Buergers test



Graph ;03 – Shows effect on Tenderness



Graph ;04 – Shows effect on Burning sensation

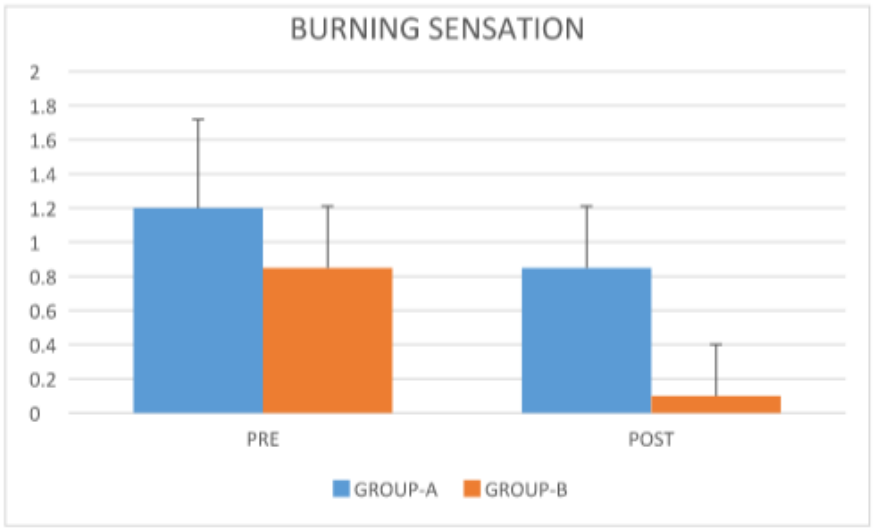


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Table No.07; Showing Overall assessment of all parameters after the treatment in both groups .

	Group A		Group B	
Overall response	**No**	**%**	**No**	**%**
Poor response	0	0	0	0
Mild Response	8	40	10	50
Moderate response	12	60	10	50
Marked response	0	0	0	0
Total	20	100	20	100
Inference	Moderate response is more in Group A (60%) compared to Group B(50%) but not statistically significant with P=0.870			

In Group A:

- No patient had poor response.
- Mild response was seen in 8(40%) cases.
- Moderate response was seen in 12(60%) cases.
- There was no marked response seen in any of the cases.

In Group B:

- No patient had poor response.
- Mild response was seen in 10(50%) cases.
- Moderate response was seen in 10(50%) cases.
- There was no marked response seen in any of the cases.

III. DISCUSSION

Discussion part includes the following sections.

- Discussion on concept of Vatarakta and TAO
- Probable mode of action of Jaloukavacharana and Basti
- Discussion on results

Discussion on concept of Vatarakta and T.A.O

Vatarakta as the name itself suggests that it is a disease produced by the vitiation of **Vata** & Rakta. In Ayurvedic literature, a separate chapter is dedicated to it. in Charaka Samhita & in Sushruta Samhita, it is included under Vatavyadhi chapter. Sushrutacharya has mentioned 3 pathological conditions of Vata i.e., Kevala vata, Doshayukta vata and Avrita vata.

Coming to Avrita vata, the term Avarana refers ‘to cover’ or ‘to obstruct’ gati, being the unique feature of Vata, whenever gati is disturbed due to Avarana, vitiation of Vata occurs. This is the central idea of Avrita vata. Avarana of vata is a distinct pathological condition, where obstruction to its movement occurs due to etiological factors other than its own, leading to its vitiation and prakopa, resulting into various Avarana types of Vatavyadhis.

Similar series of events occur in the etiopathogenesis and manifestation of Vatarakta.

Dalhanacharya comments that Raktavritavata when not treated further gets vitiated and continues as Vatarakta.

Coming to the types of Vatarakta, regarding the Utthana and Gambheera avastha (or classification) of the disease, in fact it is the site of dosha-dooshya sammurchana and sthana samshraya. Eventhough, Sushrutacharya says that there are no two types of Vatarakta, by saying Utthana continues as gambheeravastha, Chakrapani says and makes it clear that its not a rule that all conditions of Vatarakta should start as Utthana, some may start as Utthana and some Gambheera, but one which has started as Utthana, if not taken proper measures will progress into Gambheera Vatarakta.

According to the involvement of the other doshas, these Utthana and Gambheera again can be divided into Vatadhika, Pittadhika, Kaphadhika, Raktadhika, Vatapittadhika, Pittakaphadhika, Vatakaphadhika types.

Vatarakta can be taken as a wide pathological entity which results in many clinical manifestations each of which 2 having their own specific features.

In Garuda Purana, it is mentioned that, there are 36 types of Vatarakta manifestations. Chakrapani says by doing permutation and combination of doshic involvement there are 54 types of manifestations. This gives a clue that the pathological process of Vatarakta leads to many clinical manifestations just like that of Peripheral vascular disease process. Due to different causes the pathology leads to different clinical manifestations like Atherosclerotic vasculopathy, Diabetic vasculopathy, Raynauds disease, TAO so on.

By observing all the above facts, it is foundd that there is a much similarity between general principles of the pathological entity of

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Vatarakta and also the general principles of the pathological process of peripheral vascular diseases.

As the science is getting advanced, so also the newer inventions and techniques, it is becoming easier for us to understand the human body and science (Ayurveda) which was explained by Acharyas in sutra form which is difficult to understand. It is told in Vatarakta lakshanas that Dhamanyanguli sandhinam sankochaha and sirayaama etc. which were not understood clearly. It is understood that, it is nothing but digital arteriolar constriction and dilatation of veins with the help of Doppler technique.

Tobacco in Ayurveda:

Tobacco (Nicotiana tabacum) is mentioned in Yogaratnakar Textbook in the name of 'Thamakhu'. It is having Tikta, Katu rasa; Laghu, Teekshna, Vyavavi, Vikasi guna; Ushna veerya; Katu vipaka and Madaka prabhava with kaphahara and vatapittakaraproperties.

Even though Tobacco is not mentioned directly among the etiological factors of Raktadushti, the qualities of tobacco contribute for the same. It impairs the Preenana and Jeevana karma of Rakta and leads to impaired nourishment.

Tobacco contains nicotine and others toxins. Nicotine is a powerful vasoconstrictor. It is postulated that tobacco use damages the endothelial lining and leads to hypercoagulability and thrombosis and also enhances the inflammatory changes in vessels. as the disease is mainly caused by Vata & Rakta, in modern parlance, this obviously a disease concerned with blood & its movement, i.e. Hemodynamics.

Alteration in the Hemodynamics impairs blood flow to cell or tissue. & is referred to as ischaemia. Ischemia can occur anywhere in the body including blood vessels. And were named as peripheral vascular disorders or peripheral ischeamic disorders. The peripheral vascular disorders include TAO (Thrombo-angitis obliterans),Raynauds' disease, Atherosclerosis etc.

For the present study TAO or Buerger's disease is considered under purview of Vatarakta, more specifically vatarakta

Table no: 08- showing striking similarities between TAO and Vatarakta:

TAO	Vatarakta
Etiopathogenesis: ↓ Smoking & tobacco use Chronic inflammatory process in artey with endothelial damage & hypercoagulability, Thrombosis & obliteration of the vessel ↓ Features of vascular insufficiency i.e. ischeamia in the lower or rarely inupper limbs.	Vata & Rakta vitiating factors. (Use of Tamakhu-indirect cause) ↓ Avaranajanya samprapti results in Vatarakta ↓ Disease process starts from Pada or Hasta

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Clinical features: Intermittent claudication Postural colour changes Ischaemic ulcers Hyperaesthesia Rest pain etc.	Vataja Vatarakta features: Sirayama(dilated venous plexus) Shoola, toda, sphurana (varities of pain) Shothasya karshnya & roukshya (blackish discoloured local swelling with roughness) Shyavata vriddhi haanayaha (Pallor
	on elevation of limb & rubor ondependency) Dhamanyanguli samkocha (digital arteriolar constriction) Atiruk (Excruciating pain) Sheeta pradwesha (aversiontowards cold exposure) Sparshodwighna (hyperaesthesia) Angagraha, swapa (stiffness of the affected part & numbness) etc.
Complications: Gangrene	**Upadrava:** Paaka (Inflammation orsuppuration) Mamsakshaya(muscle atrophy), Marmagraha, Pangulya (paralysis of the local part results in deformify), Angulivakrata (loss of subcutaneous fat leads to finger deformity), Mamsakotha (putrifaction organgrene), pranakskaya (loss of vitality) etc.
Management: Complete cessation of smoking & tobacco use Foot care: Avoid Trauma, Buerger's exercise, proper footwear. Conservative: Analgesics, Vasodilators, Anti-thrombotic agents Surgery: -sympathectomy -Omental graft -Amputation if other measures fail	**Chikitsa:** Nidana parivarjana Bahiparimarjana: lepa, seka, sneha,upanaha etc. Anthahparimarjana: Shodhana measures like vamana, virechana, repeated use of Basti , Raktamokshana with various modalities like Jalouka etc. Shamanoushadhies like various kashayas, ghritas, tailas, guggulukalpas etc.

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Discussion on Probable mode of action of Jaloukavacharana & Basti:Jaloukavacharana:

Raktamokshana using Jalouka is adopted in presence of Grathitha Rakta (Clotted blood) and also in the conditions where Raktadushana is avagaadha (deep seated).

Purpose of Raktamokshana in Vatarakta is to overcome the avarana of Dushitavata by Dushitarakta and to eliminate this Dushitarakta from the body so that the avyahata gati of Vata and also the Prakritarakta is maintained achieving Uparama of Vyadhi.

Jalouka is said to suck only impure blood from blood just like that of Hamsa which drinks ksheera only from ksheerodaka. It is also said that a Jalouka sucks blood of an area equal to Hasta pramana. So it can be applied where there is localized symptomatology.

Vaatarakta is definite indication for Jaloukavacharana even though the other methods of Raktamokshana have also been explained. Since the disease Vatarakta starts from Pada or Hasta, showing the localized symptomatology involving Rakta and Vata both, with features of Ruk, Raga, Toda, Daha etc, Jaloukavacharana would help to overcome the disease as explained above.

Hypercoagulability & increased viscosity of blood (can be considered as Raktadushti) are responsible for regional haemostasis & thrombosis which worsen the disease process. Such being the case, Jaloukavacharana definitely helps in draining the regional haemostasis and inducing thrombolysis by thrombolytic enzymes and also improves local circulation thereby modifying better endocellular exchange of nutrients within the tissues and finally enhancing the effects of local neovascularisation.

It is established by the various researches that a medicinal leech is a small “factory”to manufacture biologically active substances which help in

- Normalization and improvement of capillary circulation
- Expressed anti-inflammatory effect
- Immune stimulating and immune modulatory effects
- Anaesthetic effect
- Anti-coagulant
- Antibacterial effect
- Blood purification by expelling out the vitiated blood
- Positive haemopoetic effect
- Reduces the high blood pressure and blood viscosity
- Early wound healing effect.

These effects are achieved by the cluster of enzymes present in salivary secretion ofthe leech which are released into the blood stream simultaneously when the leech is sucking the blood.

These facts leave no doubt regarding the usefulness of leech application in the disease Thrombo-angitis Obliterans.

Basti:

Vatarakta is considered as Avaranjanya vatavyadhi. Due to properties like Sukshmatva and Saratwa of vayu, Dravatwa and Saratwa of Rakta, they spread all over the body. The spreading is facilitated by VyanaVayu. In this respect Basti is the sole treatment which can control the movement of Vayu and at the same time, can relieve the Avarana.

The Snehabasti by its Snigdha guna counters the rukshatva in pakwashaya & does anulomana of Vatadosha. The Kashayabasti by its Ruksha & Teekshna guna, cleanses the channels (srotas) and relieves the obstruction.

According to Vagbhata the Veerya of drugs used in Basti is absorbed through the siras & reaches all over the body and brings the vitiated doshas from their site into pakwashaya, just like sun absorbs water from the earth, and then does alodhana of sanchita doshas (dislodgement of accumulated doshas) & remove the doshas completely from the body. Thus chemical reaction sequence originated in

pakwashaya passes from cell-to-cell, ultimately in the entire body.

Hence the enhanced systemic effect of Basti influences generalized cleansing action on the body thus relieving the ill-effects of tobacco and does nourishment of the body in this disease particularly.

Sushruta while dealing about number enemas he explained, the enema applied first nourishes the pelvis & inguinal region. There Dalhana clarifies pelvis & inguinal region implies inferior extremity as well.

In the context of Vatarakta chikitsa, both Acharya Charaka & Vagbhata have explained as, the vitiated doshas along with mala should be expelled out by the administration of basti & there is no other therapeutic measure comparable to basti in the management of this disease. The present Basti treatment has Srothoshodhana, Vatanulomana, Rakthaprasadana and more over rectification of Avarana properties.

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In a nutshell, the present Yoga Basti inspite of its procedural effect, it consists of potent drugs like Manjishta (Raktashodaka and Raktaprasadaka), Yastimadhu (phytosteroid),Daruharidra(antiinflammatory,immunebooster),Guduchi(Immunomodulator),Amalaki(antioxidant),hareetaki(Vatanulomana),Bibhitaki(vatanulomana),Nimba(Raktashodhaka), Katuki(Lekhaniya), vacha(Lekhaniya)), Saindhava (electrolyte) etc. which are aptly synergized with Ghrita and gomutra to form holistic action to relieve TAO.

These observations suggest that this therapy not only produces symptomatic relief but also control the disease process and may cause extended relief.

- **Discussion on results**

Effect of treatment on cludication Pain:

In **Group A**, the treatment had a highly significant effect on claudication Pain ($p<0.001$) with an average improvement of 97%. In **Group B**, the treatment had a significant effect on Pain ($p<0.04$) with an average improvement of 51%. The comparative analysis of the treatment's effect on claudication Pain between Group A and Group B resulted in a p-value > 0.001, suggesting a statistically highly significant difference. Hence the result in the effect of treatment on Pain in group A was comparatively better than group B.

Comparatively group A shows more improvement in claudication pain than in group B .in group A and B manjishtadi kshara basti was commonly used which is having the drugs like manjishta known for its vasodilation property and gomutra known for it lekhana property which helps in improving the blood circulation and reduces the obstruction in blood vessels simultaneously ,there by reduces the pain , and moreover the basti which was prime treatment for pain ,told by acharyas , But in group A along with manjishtadi kshara basti , jaloukavacharana was administer directly to the affected part ,which was known for its analgesic , anti coagulant , vasodilation property. And as per classics raktamokshana which is removing the aggravated doshas , removing the avarana of rakta and vata there by sampraptivighatana done, and reduces the pain

Therefore in group A added effect of joloukavacharana, results in more improvement in group A than in group B was seen.

Effect of treatment on buergers test:

In Group A, the treatment had a highly significant effect on buergers test ($p<0.001$) with an average improvement of 76.9%. In Group B, the treatment had a highly significant effect on buergers test ($p<0.006$) with an average improvement of 51%. The comparative analysis of the treatment's effect on buergers test between Group A and Group B resulted in a p-value < 0.001, suggesting a statistically significant difference. Hence the result in the effect of treatment on buergers test in group A was comparatively better than group B. Grade of Improvement was better i.e. 25% more in Group A than Group B.

Buerger's test reflects colour change (pallor) because of vascular insufficiency which was better responded in Group A with Jaloukavacharana as this procedure improved local circulation and relieved local congestion.

Effect of treatment on tenderness:

In **Group A**, the treatment had a highly significant effect on **tenderness** ($p<0.001$) with an average improvement of 68%. In **Group B**, the treatment had a significant effect on **tenderness** ($p<0.05$) with an average improvement of 24%. The comparative analysis of the treatment's effect **tenderness** between Group A and Group B resulted in a p-value > 0.001, suggesting a statistically highly significant difference. . Hence the result in the effect of treatment on **tenderness** in group A was comparatively better than group B. Grade of Improvement was better i.e. 42% more in Group A than Group B.

This may due to added effect of analgesic, anti-inflammatory, anaesthetic effect of salivary contents of leech in group B. And in Group B also good percent of clinical outcome was observed which may be due to actions like Vatashamana, Vedanastapana, Shrothoshodhana, & Raktaprasadana properties of Basti**.**

Effect of treatment on Burning sensation:

In Group A, the treatment had a highly significant effect on burning sensation ($p=0.01$) with an average improvement of 70.3%. In Group B, the treatment had a highly significant effect on burning sensation ($p<0.01$) with an average improvement of 9.5%. The comparative analysis of the treatment's effect on burning sensation between Group A and Group B resulted in a p-value < 0.001, suggesting a statistically significant difference. Hence the result in the effect of

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treatment on burning sensation in group A was comparatively better than group B.

This may be due to local congestion (intermediate metabolites, P substances, Lactic acid etc.) drained by leech, followed by improved microcirculation and systemically basti act as generalized cleansing action along with rejuvenative properties incorporated by Basti and its Dravyas.

Pulse of Dorsalis pedis Artery

Feeble pulse was the significant feature in all the patients. If the pulse becomes feeble from complete absence of pulse is a sign of significant improvement. Occasionally pulse becomes normal or regular due to treatment, but it was not sustained.

So there was no comparative significant statistical change in both the groups with P- value 0.514, but clinically overall improvement of 20% outcome was observed in Group A than Group B (15% outcome).

Grade of improvement was similar in both the groups

Pulse of Posterior tibial Artery

Comparatively there was no significant statistical change in both the groups , but clinically better i.e. 15% of outcome was observed in Group A when compared to Group B (10%).

Grade of improvement was 5% more in Group A when compared to Group B.

So in both the groups encouraging results were observed, this may be due overall Srothoshodhaka, Raktaprasadaka and general Karmukatha of Basti in Group B, whereas in Group A along with basti the good outcome may be attributed to improved local circulation followed by leech application in addition to its thrombolytic and vasodilatation properties.

Discussion on Other Clinical observations

Pain: Pain either due to intermittent claudication (discussed earlier), ischemic neuritis, thrombophlebitis was invariably present in all the patients which they explained vaguely as they suffered with pain in legs**.**

Patients suffering with ischemic neuritis complained pain with burning sensation. It was better relieved in Group A.

Patients suffering with thrombophlebitis complained pain with sudden, irregular onset & migratory in nature over the affected limb. It was better relieved in Group A treated with leech because of its local thrombolytic, anti-inflammatory, analgesic actions of salivary secretion.

In severe ischemic conditions, patients complained of rest pain which was continuous, not subsidable with any measures and was usually observed during night times. There was mild clinical response in such cases in both the groups which may be due to advanced stage of disease condition.

Parasthesia: In both the groups about 52.5% of patients complained of Parasthesia. It was observed that Group A patients treated with Jaloukavacharana responded well than the Group B. This may be due to local congestion (intermediate metabolites, P substances, Lactic acid etc.) drained by leech, followed by improved microcirculation.

Local colour changes- this reflects the vascular insufficiency and also chronicity of the disease. About 80% of patients presented with local skin colour changes. In both the groups, minimal changes were observed which were not appreciable during treatment period, but in follow up period better in Group A. This may be due to improvement of underlying local circulation which was evident by appreciable improved local temperature gradually.

It was also observed that in Group B there was improvement in and all-round general health of the patient because of the Basti.

Overall effect of - Group A

Out of 20 patients of Group A 60% of patients got moderate improvement and 40% of patients got mild improvement.

Overall effect of - Group B

Out of 20 patients of Group B 50% of patients got moderate improvement, 50% of patients got mild improvement.

Interpretation of Statistical analysis:

In Group B with Basti, there was gradual sustained relief with overall moderate response of 50% observed. It may be due to combined synergistic action of manjishtadi drugs and general karmukatha of Basti.

In Group A basti and Jaloukavacharana, there was overall marked response of 60% observed,it may be due to systemic effect of basti and local invasive nature of leech when it bites and sucks the blood simultaneously injecting the salivary enzymes locally and also into the blood

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stream thus enable to exert relief in the disease features.

IV. CONCLUSION

- This dissertation work entitled "A comparative clinical study to evaluate the effectivness of manjishtadi kshara basti followed by jaloukavacharana in comparision with manjishtadi kshara basti in vatarakta with special reference to thrombo angitis obliterans"
- Based on Symptomatology, TAO can be correlated with Vatarakta, more specifically vatarakta.
- Jaloukavacharana is statistically and clinically effective in relieving tenderness, claudication pain, improving Buerger's test and the pulses of dorsalis pedis artery and posterior tibial artery pulse due to its enhanced drainage of local congestion, improved microcirculation, induced thombolytic action through the cluster ofenzymes present in saliva.
- Basti is statistically and clinically effective in relieving claudication pain, tenderness, improving Buerger's test and the pulse of dorsalis pedis artery due to combination of Manjishtadi kshara basti and anuvasana with guduchi ghrita which helped in enhancing generalized cleansing action, followed by improved circulation, and increased tissue vitality.
- In both groups Basti given commonly, where as in group A along with basti, jaloukavacharana done , and in statistics shows more marked improvement , hence there is a significant added effect of jaloukavacharana can be seen.
- Statistically both the groups are insignificant on comparing because of near equivalent results in both the groups with P value 0.870. But clinically both the groups have significant results. Group A has better i.e. 60% of moderte response when compared to 50% of moderate response of Group B. So Group A has performed better than Group B.
- No untoward effects were observed in any of the cases in both the methods of management namely, Jaloukavacharana and Basti.
- Even though complete cure of the disease was not achieved, but progression of the disease process was arrested effectively with better life quality assurance by combination jaloukavacharana and manjishtadi kshara basti modalities of treatments than only in manjishtadi kshara basti.

Figure 01; Photographs showing procedures in GroupA (Manjishtadi kshara Basti)

Figure 02; Procedure of Jaloukavacharana

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REFERENCE

[1]. Sushruta. Sushruta samhita- with English translation of text and Dalhana's commentary along with critical notes edited and translated by P.V.Sharma, Reprint. Varanasi: Chowkhambha Vishwabharathi publications; 2005. 695pp. vol 2.

[2]. Agnivesha. Charaka Samhita- Text with English translation and critical exposition based on Chakrapanidatta's Ayurdipika by Ramkaran Sharma and Vaidya Bhagwan Das, Reprint, Varanasi: Chowkhambha Sanskrit Series Office; 2005. 221pp. Vol

[3]. Bhavamishra. Bhava Prakasha- with Vidyotini Hindi Commentary, edited in Hindi by SriBramha Shankara Mishra and Sri Rupalalaji Vaisya, 11th ed. Varanasi: Chaukhambha Sanskrit Sansthan; 2004. 836pp. Part 2

[4]. Sharangadhara. Sharangadhara Samhita- translated in English by Prof. K. R. Srikanthamurthy, 5th ed. Varanasi: Chaukhambha Orientalia; 2003. 335pp.

[5]. Sriram Bhat M. SRB's Manual of Surgery- Reprint, New Delhi: Jaypee Brothers Medical Publishers; 2010. 1198pp

[6]. S. Das. A Concise Textbook of Surgery- 5th ed. Calcutta: Published by Dr. S. Das; March2008. 1346pp.

[7]. Harshmohan. Textbook of Pathology- Reprint, New Delhi: Jaypee Brothers MedicalPublishers; 2008, 977pp.