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Management of *Vranashopha* by *Bibhitaki Phala Majja Lepa* and Thrombophob ointment- A comparative clinical study

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Abstract

Introduction: *Vranashopha* (inflammation) is one of the commonest clinical entity is characterized by *Vedana* (pain), *Shopha* (swelling), *Sthanikaushma* (raise in local temperature) and *Vivarnata* (redness). The disease has three different stages as *Amawastha* (early inflammatary stage), *Pachyamanawastha* (true inflammatory stage) and *Pakwawastha* (suppurative stage). *Vranashopha* (inflammation) should be managed in early stage to avoid further suppuration.

Objectives The present study has primarily aimed at to compare the efficacy of *Bibhitaki Phala Majja Lepa* over Thrombophob ointment in the management of *Vranashopha* with special reference to Phlebitis.

Methods: Clinically diagnosed 30 patients of *Vranashopha* were randomly divided into two groups, each group consist of 15 patients. Group-A is treated by Thrombophob ointment and Group-B is treated by *Bibhitaki Phala Majja Lepa* for 5 days.

Results: On the basis of assessment criteria and on overall result of treatment, the patients of *Bibhitaki Phala Majja Lepa* group showed better relief when compared Thrombophob ointment.

Conclusion: *Bibhitaki Phala Majja Lepa* has provided better relief in maximum sign and symptoms of the patients of *Vranashopha* in comparison to Thrombophob ointment.

Key words: *Vranashopha*, Inflammation, Phlebitis, *Bibhitaki Phala Majja Lepa* and Thrombophob ointment.

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Introduction

Shotha, Shvayathu and *Shopha* are three terms that denote an unnatural elevation of a part or whole of the body and it is preliminary stage of *Vrana*. Detailed description of *Shotha* along with classification, symptomatology, complication and management is traceable to *Charaka Samhita*.[1] The surgical aspect about

Shopha and *Vrana* drew more attention by *Acharya Sushruta*.[2]

Acharya Sushruta has defined *Shopha* as localized swelling in a part of body involving the skin and underlying flesh which may be even or uneven, massive and knotty in consistency. Again *Acharya* cautions that differentiation should be made from other clinical entities as glandular enlargements, abscess etc. which are also associated with a swelling.[3]

Vranashopha has 3 progressive stages *Amavastha* (early inflammatory stage), *Pachyamanavastha* (true inflammatory stage) and *Pakwavastha* (suppurative stage) respectively.[4] *Amavastha* (early inflammatory stage) *Lakshanas* (clinical features) mentioned in *Sushruta Samhita*[5] and *Bhavaprakash Nighantu*[6] are *Mandoshamata* (minimal raise in local temperature), *Twaksavarna* (skin colour), *Sheetashopha* (cold swelling), *Sthairya* (stable), *Mandavedana* (mild pain) and *Alpashopha* (minimal swelling). Phlebitis is characterized by edema, heat, swelling, tenderness, itching, pain at the affected area of the skin and redness along the path of the vein.[7,8] *Amavastha* resembles to inflammatory swelling like Phlebitis.

Samprapti: Vitiated *Vatadosha* (Humors) comes in contact with vitiated *Pitta* and *Kaphadosha*, it brings them to periphery then *Srotas* (channels) get obstructed to develop *Shopha* in and around the skin and the flesh.[9]

The basic principle of *Vranashopha* management is to prevent onset of *Paka* (suppuration). To achieve this principle of management *Ayurveda* advocated important treatment procedure is *Lepa-upakrama* (application of paste) here is *Saptopakrama* (seven treatment modalities) to prevent *Paka*[10](suppuration), progression of disease into next stage and excess loss of tissue.

Lepa (local application) therapy posses the qualities like *Vedanashamaka* (analgesic), *Dahashamaka* (reduce burning sensation) and *Shophahara* (reduce swelling). These qualities of *Lepa* will bring the beneficial effect in the *Vranashopha* particularly in the *Amavastha* of *Vranashopha*. Hence *Lepa* (local application) therapy in the form of *Bibhitaki Phala Majja Lepa* is selected in the present study.[11]

Thrombophob ointment is used in allied science as topical agent in the

management of Phlebitis,[12] it is taken as standard drug.

Objectives: The present study thus aimed to evaluate the efficacy *of Bibhitaki Phala Majja Lepa* over Thrombophob ointment in the management of *Vranashopha* with special reference to Phlebitis.

Materials and Methods

All diagnosed 30 case of Phlebitis was the sample of present clinical trial. Sampling unit source list were selected from out-patient and in-patient departments of BVVS Ayurved Hospital, Bagalkot. and subjected to clinical trial, after taking informed consent. The methodology of clinical trial and observations are as follows.

Methodology – collection of data

Patients of *Vranashopha* (Phlebitis) in the age group of 18-60 years are selected randomly and subjected to clinical trial.

Patients were divided into 2 groups with 15 patients in each group by computerized random technique (www.randomnumbers.com).

Group A: Standard group- Thrombophob ointment.

Application : External

Setting : twice a day (morning and evening)

Duration : 5 days

Group B: Study group- *Bibhitaki Phalamajja Lepa*

Application : External

Setting : twice a day (morning and evening)

Duration : 5 days

Sign and Symptoms were recorded in the proforma designed specially for this study.

Inclusion criteria:

1. Patient suffering from *Amavastha of Vranashopha* caused by Intravenous trauma to vein.
2. Length of Shopha ranging between 2-10cm, in Upper limb.
3. Patient of either sex between age group of 18-60 years.

Exclusion criteria:

1. Phlebitis caused by Malignancy, Septicaemia, deep vein thrombosis or with pus formation.
2. Patient suffering from diabetes mellitus (DM), chronic renal failure (CRF).

Investigation Criteria

1. Complete blood count (CBC)
2. Retroviral disease (RVD)
3. Hepatitis B surface antigen test (HBsAg)

Assessment Criteria:

The result of the treatment was assessed on the basis of subjective and objective criteria at pre treatment and 4 days post treatment (i.e on 9th day) by a suitable score/grading to each parameter.

Subjective Parameter:

1. *Vedana* (Pain)
2. *Sthanika* Daha (Local raise of temperature)
3. Tenderness

Objective Parameter:

1. *Shopha* (Edema)
2. *Vivarna* (Erythema)

Statistical Analysis:

Data were collected and statistically analyzed by applying students paired and unpaired 't'tests.

Follow-Up:

After completion of treatment patients were asked to report for follow-up study on 9th day.

Observations and Results:

Table 01: Pre and post outcome measures summary (Mean ±SE, n=15) of patients treated with Thrombophob ointment.

Symptom	Pre treatment	Post treatment	Mean ±SE	T value	p value
Vedana	1.80	0.07	1.73+0.07	13.75	0.0001
Shopha	2.40	0.53	1.87+0.17	7.40	0.0001
Vivarna	0.27	0.07	0.20+0.07	14.73	0.052
Daha	0.73	0.00	0.73+0.00	6.20	0.0001
Tenderness	2.40	0.20	2.2+0.11	15.1	0.0001

To compare the mean effect of parameters after treatment, statistical analysis done by using paired t-test by assuming that the mean effect of all the parameters are same in Group-A.

Here parameters like *Vedana* , *Shopha* , *Daha* and Tenderness has shown highly significant as $p<0.0001$. The parameter *Vivarna* showed significant as $p<0.05$.

Table 02: Pre and post outcome measures summary (Mean ±SE, n=15) of patients treated with *Bibhitaki Phala Majja Lepa*.

Symptom	Pre treatment	Post treatment	Mean ±SE	T value	p value
Vedana	1.80	0.07	1.73+0.07	13.75	0.0001
Shopha	1.90	0.00	1.90+0.00	12.6	0.0001
Vivarna	0.47	0.00	0.47+0.00	3.50	0.0001
Daha	0.80	0.00	0.80+0.00	7.48	0.0001
Tenderness	2.13	0.35	1.78+0.35	11.83	0.0001

To compare the mean effect of parameters after treatment, statistical analysis done by using paired t-test by assuming that the mean effect of all the parameters are same in Group-B.Here all parameters like *Vedana*, *Shopha*, *Vivarna*, *Daha* and Tenderness has shown highly significant as $p<0.0001$.

Discusssion

Bibhitaki Phala Majja Lepa is single drug preparation having *Kashaya Rasa* (pungent taste), *Laghu* (light), *Rukshaguna* (dry in nature), *Ushnaveerya* (hot potency), *Sheeta sparsha* (cold touch) and *Madhuravipaka* (sweet end product), *Shothahara* (anti-inflammatory), *Dahashamaka* (reduce temperature), *Vedanashamaka* (analgesic) and *Krimighna* (antibacterial) property.

Probable mode of action

The probable mode of action of *Bibhitaki Phala Majja Lepa* can be described below,when a *Bibhitaki Phala Majja Lepa* is applied over surface of skin opposite to the direction of hairs, through a water base, the active principle of the *Bibhitaki Phala Majja Lepa* is released into water after that this combination enters the *Romakupa* (hair follicles) and further gets absorbed through the *Swedavahasrotas* (sweat glands) and *Siramukha* (venules).

Thereafter the absorbed material is subjected for *Pachana* (metabolism) by *Brajakapitta* (heat of skin) situated in *Twacha* (skin) and some new metabolites might be forming which pacifies the vitiated *Dosha* (humors) locally and thus breaks the pathogenesis cycle leading to the alleviation in the symptoms.

Sheeta sparsha, *Madhura vipaka*, action of *Brajakapitta* thus reduce the local temperature and redness. Its

Ushna veeryaa does vasodilatation and improves the circulation and reduce the swelling and pain.

Thrombophob ointment:

Thrombophob ointment is composed of heparin sodium equivalent to heparin 50 i.u. per 20g. in addition to this it composed of benzyl nicotinate 2mg.

Probable mode of action

Pharmacological action of Thrombophob ointment is a novel form of heparin therapy for topical application it inhibits the thrombin formation, promotes fibrinolysis and helps absorption of more superficial microthrombi. Benzyl nicotinate by vasodilatation and enhances local heparin absorption.

The ointment is distinguished in particular, by its ability to penetrate pathologically altered tissue immediately upon application without leaving residues or degreasing the skin.

The properties and mode of action of natural heparin offer all the prerequisites necessary for effective therapy of superficial inflammation and thrombophlebitis occurring close to the skin. Heparin assists in strengthening and supporting the connective tissue. Scar tissue becomes soft and regains elasticity and strength.

Heparin also has an antiphlogistic and antiexudative effect, thus alleviating pain and promoting tissue metabolism and the process of healing. It is indicated for circulatory disorders, superficial phlebitis, thrombophlebitis and varicose veins.

Conclusion

Bibhitaki Phalamajja Lepa reduces all cardinal features of inflammation as pain, swelling erythema, temperature and tenderness in patients of phlebitis. Thus it can be proven as potent anti-inflammatory medicine compared to Thrombophob ointment. No adverse reaction was found after topical application of *Bibhitaki Phalamajja Lepa*, hence it is proven safe and to be applied in patients.

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Case No.1:

Before treatment During treatment After treatment

Case No. 2:

Before treatment During treatment After treatment

Case No. 3:

Before treatment During treatment After treatment

Case No. 4:

Before treatment During treatment After treatment

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