



CLINICAL STUDY

VARIATION OF BLOOD PRESSURE DURING NASYA KARMA IN VISVAACI W.S.R.TO SNEHAPAAKA—A RANDOMIZED DOUBLE BLIND CLINICAL TRIAL

MANOJKUMAR A K¹ DEVI R NAIR²

ABSTRACT:

Background: Marsha nasya (nasal instillation of medicine) has immense impact on brain and circulatory system owing to its absorptive and stimulatory effects. Many a time, observation of vital parameters was not properly monitored leading to life-threatening complications especially when the patient is hypertensive. Whether the snehapaaka (critical end point) used for marsha nasya karma has any relation with variation of blood pressure has not been studied yet. So, a clinical documentation has been planned and done in this angle to ensure safety aspect of the process. **Objective :** To study the variation of Blood Pressure during Nasya karma with kaarpaasaasthyaaditaila nasya in Vis'vaaci (cervical radiculopathy) w.s.r to snehapaaka **Setting :** Panchakarma OPD, VPSV Ayurveda College Hospital, Kottakkal, Kerala; R & D Division, Oushadhi Pharmacy [GMP Certified Company], Thrissur, Kerala. **Design :** Randomized Double Blind Clinical Trial **Materials and Methods:** Ninety three participants were divided randomly into three groups using Random Number Table. Marsha nasya was given with mr'du (mild), madhyama (medium) and khara paaka (scorched) of Kaarpaasaasthyaadi taila. Variation in Blood Pressure was measured just before and just after procedure. **Statistical analysis used :** Paired t- test was done to find out whether the change observed was statistically significant. One-way ANOVA and Tukey-kramer multiple comparison test was used to study the change between the groups. **Results:** The change in Blood Pressure observed during nasya karma in all the three groups was found to be statistically highly significant ($p < 0.001$). The variation is highly significant ($p < 0.001$) in khara paaka group when compared to mr'du and madhayama paaka. **Conclusion:** The present study concludes that there will be a transient increase in Blood Pressure during marsha nasya procedure and is more in khara paaka

KEY WORDS – Marsha nasya, Blood Pressure, Kaarpaasaasthyaadi taila

¹Professor, ²Project Medical Officer, Department of Panchakarma, VPSV Ayurveda College Kottakkal Kerala India.

Corresponding Email id: drdevinair87@gmail.com

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INTRODUCTION:

All the *Panchakarma* procedures bring out immense changes in the vital parameters of the human body including Blood Pressure. *Marsha nasya* has immense impact on brain and circulatory system owing to its absorptive and stimulatory effects. Many a time, this variation is only a transient one and came back to normal level without internal medications. This transient change, may sometimes result in clinical emergencies and life-threatening complications especially when the patient is hypertensive. Whether the *snehapaaka* (critical end point) used for *marsha nasya karma* has any relation with variation of blood pressure has not been studied yet. So, a clinical documentation has been planned and done in this angle to ensure safety aspect of the process.

Trial Drug Details-

Ingredients of *Kaarpaasaathyaadi taila*^[3]

Contents	Proportion
Kashaaya	16 part
Kalka	1 part
Taila	4 part
Goat's milk	4 part

Contents of *kashaaya* used for preparing *Kaarpaasaathyaadi taila*

Sanskrit name	Latin name	Family name
Kaarpaasaasthi	Gossypium herbaceum	Malvaceae
Bala	Sida cordifolia	Malvaceae

To study the variation in Blood Pressure during *nasya karma, vis'vaaci*^[1], a pathology which uses absorptive and stimulatory action of *nasya karma* has been selected.

OBJECTIVE: To study the variation of Blood Pressure during *nasya karma* with *Kaarpaasaasthyaaditaila nasya* in *vis'vaaci* w.s.r to *snehapaaka*.

MATERIALS AND METHODS:

Study Design: Randomised Double Blind Clinical Trial and the blinding was done by coding method.

Materials used in the study was *Kaarpaasaasthyaadi taila* in three *paaka* (critical end point) –*mr'du*^[2], *madhyama*^[2] and *khara*^[2]. Case record form, information sheet, consent form, 93 participants presenting with *vis'vaaci* and sphygmomanometer.

Maasha	Teramnus labialis	Fabaceae
Kulatha	Dolichos biflorus	fabaceae

Contents of *kalka* used for preparing *Kaarpaasaathyaadi taila*:

Sanskrit name	Latin name	Family name
Devadaaru	Cedrus deodara	Pinaceae
Bala	Sida cordifolia	Malvaceae
Rasna	Alpinia officinarum	Zingiberaceae
Kushta	Saussuria lappa	Asteraceae
Sarshapa	Brassica canpestris	Cruciferae
Nagara	Zingiber officinale	Scitaminae
Sathaahva	Anethum sowa	Umbelliferae
Pippalimoola	Piper longum	Piperaceae
Cavya	Piper chaba	Piperaceae
Sigru	Moringa pterigosperma	Moringaceae
Punarnava	Boerhavia diffusa	Nyctaginaceae

Kaarpaasaasthyaaditaila was prepared in three *paaka*, *mr`du*, *madhyama* and *khara* from Oushadhi, Thrissur, Kerala (GMP Certified Company) [Batch no:143, 12/01/2014].

Ethics Committee approval details: The whole plan of study was approved by Institutional Ethics Committee (IEC) of Vaidyaratnam P S Varier Ayurveda College Kottakkal prior to the starting of work.(IEC NO. IEC/CL/15/13 dated 22/04/2013)

Study Population : participants with *visvaaci* who satisfy inclusion and diagnostic criteria

Sample Size : 91

Study Setting: The setting was the OPD of Panchakarma, VPSV Ayurveda College

Kottakkal. Ninety three participants who satisfied diagnostic criteria of *visvaaci* were selected from the OPD of Panchakarma, VPSV Ayurveda College Kottakkal. Investigations prior to the trial were carried out and their details were recorded in case record form.

Diagnostic criteria: Pain in the neck radiating to upper limb minimum upto shoulder blades/pain

in the shoulder blades radiating to upper arm or forearm or fingers and limitation of movement of upper limb.

Inclusion Criteria: Participants between the age 20-50 years with no discrimination of sex

with dosha predominance as *Vaatakapha* was selected. The participants should also satisfy strictly the diagnostic criteria mentioned below and should be willing to give written informed consent

Exclusion criteria: Participants with

1. Uncontrolled Hypertension
2. Diabetes mellitus
3. Pregnant, lactating and menstruating women
4. Recent fracture of cervical spine or upper limbs, recent history of trauma to neck or shoulder joint
5. Diagnosed cases of TB or malignancies
6. Clinically diagnosed Rheumatologic disorders and infectious diseases
7. Recent history of Upper respiratory tract infection, nasal polyps
8. Any condition which the guide thought may jeopardize the study.

Grouping: They were divided into groups A, B and C, thirty one in each group following Random Number Table. Group A had given *marsh`a nasya* with *Kaarpaasaasthyaaditaila mr`du paaka*, group B with *madhyama paaka* and group C with *khara paaka*. *Marsha nasya* was given for a maximum of seven days or upto *samyaknasyalakshana*, *vyaadhi shamana*^[4](complete subsidence of pain). The dose given was in the range of 6-10 *bindu* 3-5 ml. To arrive at a better conclusion, analysis of

paaka has also been studied in detail by analysis of physico- chemical parameters.

Procedure:

Poorva karma:

Participants were educated about the procedure and written informed consent were taken. Vitals were recorded and were asked to satisfy natural urges. Food was restricted 3hours before the procedure. Local *abhyanga* was done with plain *tila taila* on head, neck and shoulders and local *naadi sweda* was done in the above mentioned regions. Participants were asked to lie straight in a slanting table of 15 degree angle with head at the lower end and nostrils facing towards the ceiling. *Swedana* was repeatedly done by continuously rubbing forehead and sinus areas.

Pradhaana karma:

Kaarpaasasthyaadi taila was taken in the above mentioned dose range by using a syringe was made luke warm by taking it in *gokarna* and placing it in hot water. Half of the *taila* was taken in *gokarna* . The tip of the nose was raised by middle finger of left hand and closed the left nostril with ring finger and *taila* was continuously poured into right nostril as a *dhaara*. The participant was then asked to inhale slowly. Similarly remaining half of *taila* was poured into left nostril by closing right nostril with index finger of left hand and asked to inhale slowly and deeply. The participant was asked to hawk to either sides. Rubbing of

palms, soles, forehead and sinus areas were repeatedly done during the time of inhalation. *Naadi sweda* was again done and participant was advised to hawk till the taste of medicine completely disappears from the mouth.

Paschaath karma:

The participant will be given *dhoomapaana* and *kabala* with luke warm water. The participant was advised to avoid head bath, travelling, exposure to cold and wind, cold drinks and frozen foods.

Assessment criteria: Assessment of Blood Pressure was done by a sphygmomanometer just before the *poorvakarma*^[5] and just after the *paschaath karma*^[6] of *nasya* procedure

Statistical analysis: Analysis was done with SPSS software version 16 and Graph pad Instat. Paired t– test was done to find out whether the variation observed was statistically significant within the group. One-way ANOVA and Tukey-kramer multiple comparison test were used to study the change between the groups.

RESULTS:

Analysis of variation in BP in *Mr'du paaka*:

Table 1 :Assessment on Systolic BP:

	MEAN	SD	%	t-VALUE	P VALUE
BT	124.64	8.20	3.89	-9.05	0.00
AT	129.68	9.22			

Table 2 :Assessment on diastolic BP:

	MEAN	SD	%	t-VALUE	P VALUE
BT	83.59	7.82	6.82	-9.34	0.00
AT	89.71	7.98			

Analysis of variation in BP in *Madhyama paaka*:

Table 3 :Assessment on Systolic BP:

	MEAN	SD	%	t-VALUE	P VALUE
BT	123.71	5.00	4.19	-16.24	0.00
AT	129.13	5.06			

Table 4 :Assessment on diastolic BP:

	MEAN	SD	%	t-VALUE	P VALUE
BT	84.14	4.43	5.10	-11.80	0.00
AT	88.67	3.84			

Analysis of variation in BP in *Khara paaka*:

Table 5 :Assessment on Systolic BP:

	MEAN	SD	%	t-VALUE	P VALUE
BT	123.60	5.59	3.58	-15.26	0.00
AT	128.19	4.78			

Table 6 :Assessment on diastolic BP:

	MEAN	SD	%	t-VALUE	P VALUE
BT	83.69	5.09	5.16	-14.29	0.00
AT	88.24	4.49			

Figure 1 :Variation of systolic BP during *mar`sa nasya* in 93 participants :

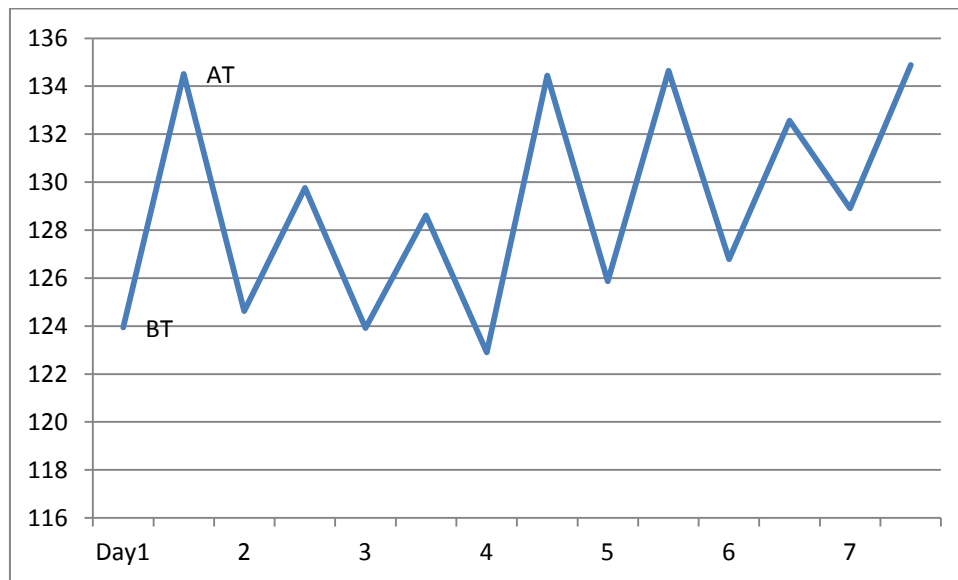


Figure 2 :Variation of diastolic BP during *mar`sa nasya* in 93 participants

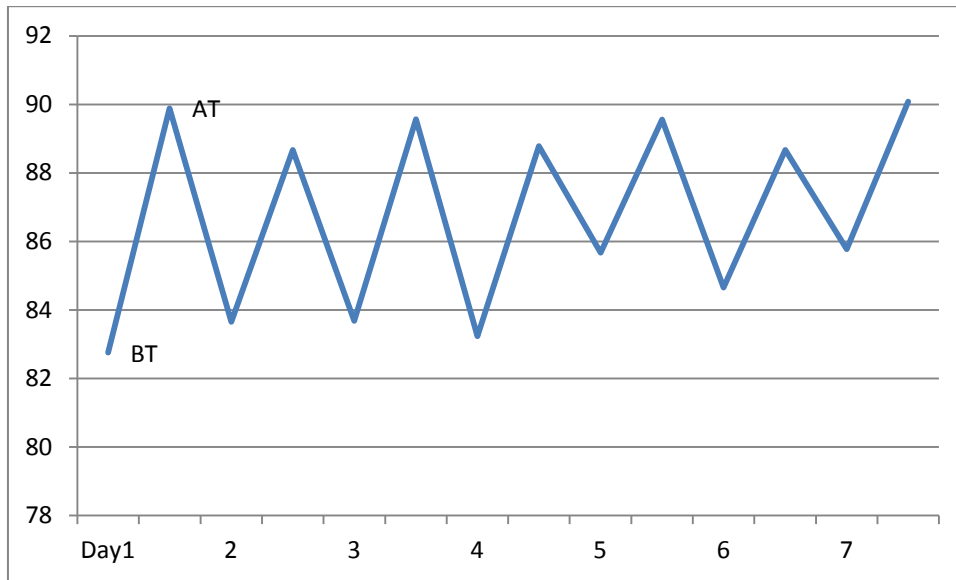


Table 7: Statistical analysis of systolic BP between groups w.s.r.to snehapaaka:

Group	Mean	F- value	p-value
<i>Mr'du</i>	134.97	16.921	P<0.001
<i>Madhyama</i>	136.29		
<i>Khara</i>	128.32		

Since, p-value is highly significant, post-hoc test had been done.

Table 8: Statistical analysis of systolic BP w.s.r.to snehapaaka using Tukey-Kramer Multiple Comparisons Test:

	q-value	p-value
<i>Mr'du Vs Madhyama</i>	1.274	p>0.05
<i>Mr'du Vs Khara</i>	6.402	p<0.001
<i>Madhyama Vs Khara</i>	7.968	p<0.001

Since, p-value is highly significant, post-hoc test has been done.

Table 9 : Statistical analysis of diastolic BP between groups w.s.r.to snehapaaka:

Group	Mean	F- value	p-value
<i>Mr'du</i>	96.32	28.855	P<0.001
<i>Madhyama</i>	93.67		
<i>Khara</i>	88.45		

Table 10: Statistical analysis of diastolic BP w.s.r.to *snehapaaka* using Tukey-Kramer Multiple

Comparisons Test:

	q-value	p-value
<i>Mr'du Vs Madhyama</i>	3.547	P<0.05
<i>Mr'du Vs Khara</i>	10.556	p<0.001
<i>Madhyama Vs Khara</i>	7.008	p<0.001

Table 11 :Physico-Chemical Analysis of *paaka* of *Karpaasaasthyaadi taila*

Parameter	<i>Mr'du</i>	<i>Madhyama</i>	<i>Khara</i>
Refractive Index	1.462	1.463	1.463
Specific Gravity	0.923	0.922	0.921
Acid Value	6.39	6.45	6.50
Saponification Value	194.03	193.12	191.05
Iodine Value	105.48	103.37	102.69
Peroxide value	0.58	0.54	0.51

DISCUSSION:

Blood pressure has been shown transient increase upto 1-2 hours after *nasya karma* and returned to normal without any medical intervention.

Marsha nasya is having direct impact at cerebral level due to the believed existence of a patent nasal – brain pathway. The variation in Blood Pressure observed during the procedure may be a result of a cascade of events taking place in circulatory system of the body to maintain the integrity of Blood – Brain – Barrier. All the steps during *nasya karma* contribute to above mentioned changes.

Swedana done prior to *nasya* in *uttamaanga* leads to vaso-dilatation and

decrease of Blood Pressure at cerebral level and to maintain balance, there will be systemic increase in Blood Pressure. This fluctuation in Blood Pressure accompany throughout the procedure including positioning^[7], inhaling and hawking of medicine, *paschath swedana* etc.

During positioning, due to the head extended position, Blood Pressure at cerebral level may have undergone an increase due to pooling of blood in cerebral vessels in that position and in the forthcoming *hasthasweda* in *uttamaanga* just before instillation, Blood Pressure again decreases, leading to increase in systemic Blood Pressure. During *pradhaana karma*, in instillation and during hawking of

medicine, again the Blood Pressure may undergo an increase leading to decrease in systemic Blood Pressure. But, during *paschaath swedanakarma*, Blood Pressure again decreases in cerebral level due to vasodilation and systemic Blood Pressure increases.

This transient changes in Blood Pressure during the process may be attributed to body's homeostasis mechanism to maintain integrity of Blood – Brain – Barrier. Eventhough, the variations are transient, it can badly affect a patient who is hypertensive leading to life threatening complications if not properly monitored.

In physico- chemical analysis of *snehapaaka*, *mr'du paaka* shows increased saponification value compared to others. Since the saponification value is directly proportional to the low- molecular fatty acids in each *paaka*, *khara paaka* may have least penetration co-efficient than other *paaka*. Refractive index can be directly interpreted as the measure of active ingredients in *taila*. Since, the moisture content is least in *khara paaka*, the amount of active ingredients is more. The more amount of active ingredients with least penetration co-efficient may have resulted in comparatively higher transient variation in Blood Pressure compared to other *paaka*.

Eventhough, *khara paaka* is not recommended in classics for *nasya karma*, many *taila* available today in market is in *khara paaka* and if used for *nasya karma* can seriously affect the safety of the process. So, the present study recommends only *mr'du* or *madhayama paaka* for *nasya karma* considering its safety aspects.

Increase in Blood pressure according to *Ayurveda* can be viewed as combined *vyaana* and *udaana vaayu dushti*. Both modalities of *nasya karma*, *sodhana* and *samana nasya* causes a range of *vaata dushti* of which *sodhana nasya* assumed to cause more *vaata kopa* due to expulsion of *dosha*. So, transient changes in Blood pressure will be more in *sodhana nasya* especially with *khara paaka*.

The power of the study is calculated as 33% only. So, the major limitation of the study is its low sample size. The study was conducted in an OPD setting in which participants get exposed to a multitude of physical and emotional circumstances which may act as a confounding factor in the analysis of variation of Blood Pressure.

The study may be repeated in a larger sample with calculated sample size of 138 in each group to achieve a power of 80%. Also, the study should have been repeated in an IPD setting to avoid the presence of any confounding factors intervening into the study conducted in an OPD setting.

CONCLUSION:

The present study concludes that there is significant transient increase in Blood Pressure after *nasya karma* with *Karpaasaasthyaadi taila* more in *kharapaaka*.

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