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Research Article

ROLE OF CRITICAL END POINT OF DRUG (PAAKA) IN NASAL INSTILLATION OF MEDICINE (NASYAKARMA) IN CERVICAL RADICULOPATHY - A RANDOMIZED DOUBLE BLIND CLINICAL TRIAL

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ABSTRACT:
Introduction: Ayurveda had given due importance to critical end point of preparation (paaka) to be used for every procedure. The difference in clinical efficacy of nasal instillation of medicine based on critical end point of drug is not documented so far.
Objective: To study the clinical importance of critical end point of drug in nasal instillation of medicine in cervical radiculopathy at Out Patient level.
Methods : Ninety three participants taken for the study was divided randomly into three groups using Random Number Table. The study was conducted as double blind trial in which blinding of medicine was done by coding method. The participants were given nasal instillation of medicine with mild level of critical end point of drug (mr`du) in group A, medium level of critical end point of drug (madhyama) in group B and scorched level of critical end point of drug (khara) in group C. Assessments were done based on Visual Analogue Scale, Oswestry Disability Index and Disability of Arm Shoulder and Hand Index.
Results : The study proved to be effective equally in all the three critical end points clinically on doing one – way ANOVA at p> 0.05 in Visual Analogue Scale, Oswestry Disability Index and Disability of Arm Shoulder and Hand Index. But, the three critical end points differed pharmaceutically.
Discussion: Even though maximum active ingredients are in medium level (madhyama paaka), its concentration is more in scorched level (khara paaka). It can be attributed to the less moisture content present in scorched level (khara paaka) resulted in the more concentration of its active principles.
Key words –Cervical radiculopathy, Critical end point, Nasal instillation of medicine

INTRODUCTION

Ayurveda had given due importance to critical end point of drug to be used for nasal instillation of medicine. Depending upon expected therapeutic effect, different end points were set for preparation of oil (drug).Mild level of critical end point of drug *(Mr'du paaka)* is the stage in which solid portion of drug starts distinguish from the remaining, where as in medium level of critical end point of drug *(Madhyama paaka)*, drug will be non-slimy, non-sticky like bee-wax and in scorched level of critical end point of drug (*Khara paaka)*, drug will become free from moisture[1]. *Ayurveda* classical

literatures had difference in opinion regarding the critical end point of drug to be used for nasal instillation of medicine .Caraka Samhitha[2] and Ashtaanga Hr'daya[3]advocated mild level of critical end point of drug (*mr`dupaaka)* ,but *Sus`ruta* told medium level of critical end point of drug*(madhyama paaka)* for nasal instillation of medicine. But, in the present scenario, in market, oils used for nasal instillation of medicine are available mainly in scorched level. Whether critical end point of drug has got any relevance clinically is not documented so far. So, a clinical trial based on critical end point of drug has been done in this work.

For the clinical trial, a pathology which utilizes the absorptive and stimulatory action of nasal instillation of medicine, cervical radiculopathy, was selected. The drug used, *Kaarpaasaasthyaadi taila[4]* had direct indication and proven effect on neck and shoulder pathologies. So, *Kaarpaasaasthyaadi taila* was taken as the trial drug. The trial drug was prepared in three levels of critical end points to compare the efficacy between the three. The objective of the study was to study the importance of critical end point of drug in nasal instillation of medicine in cervical radiculopathy at Out Patient level**.**

MATERIALS AND METHODS:

Materials used in the study was drug *Kaarpaasaasthyaadi taila* prepared in three levels of critical end points (*paaka),* mild, moderate and scorched *(mr`du ,madhyama* and *khara)*from Oushadhi, Thrissur (GMP Certified Company) [Batch no:143, 12/01/2014], case record form, information sheet, consent form, 93 participants presenting with cervical radiculopathy.

The whole plan of study was approved by Institutional Ethics Committee (IEC) prior to the starting of work.(IEC NO. IEC/CL/15/13 dated 22/04/2013)

The research design used in the study was Randomized Double Blind Clinical Trial and the blinding was done by coding method. The setting was the OPD of Panchakarma, VPSV Ayurveda College Kottakkal, Kerala. Ninety three participants who satisfied diagnostic criteria of cervical radiculopathy were selected from the OPD of Panchakarma, VPSV Ayurveda College Kottakkal, Kerala. Investigations prior to the trial were carried out and their details were recorded in case record form. They were divided into groups A, B and C, thirty one in each group following Random Number Table. Group A had given nasal instillation of medicine *(nasya)* with drug *Kaarpaasaasthyaadi taila* in mild level*(mr`du paaka),* group B with medium level (*madhyama paaka)* and group C with scorched level(*khara paaka)*. Nasal instillation of medicine was given for a maximum of seven days or up to complete subsidence of pain. The dose given was in the range of 3-5 ml.

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

Exclusion criteria:

Participants with uncontrolled Hypertension, Diabetes mellitus, pregnant, lactating and menstruating women, recent fracture of cervical spine or upper limbs, recent history of trauma to neck or shoulder joint, diagnosed cases of TB or malignancies, clinically diagnosed rheumatologic disorders and infectious diseases, recent history of upper respiratory tract infection and nasal polyps.

Assessment criteria:

Assessment was done by Visual Analogue Scale (VAS) [5], Oswestry Disability Index for neck pain (ODI) [6] and Disability of the Arm, Shoulder and Hand Index (DI)[7].

Investigations:

X-ray- cervical spine (AP & Lateral view) to rule out fracture, Fasting Blood Sugar and Blood routine Examination to rule out uncontrolled Diabetes Mellitus and infectious diseases.

Statistical analysis:

Analysis was done with SPSS software version 16. Paired t– test was done to find out efficacy of therapy and one-way ANOVA was done to check which group got better results.

RESULTS:

Table1: Effect of therapy in VAS Scale:

Critical end point of drug *(Paaka)*		**Mean**	**SD**	**t - value**	**P value**
Mild *(Mr'du)*	BT	7.52	0.72	6.003	0.00
	AT	4.25	2.89		
Medium*(Madhyama)*	BT	7.48	0.81	9.31	0.00
	AT	3.90	2.64		
Scorched*(Khara)*	BT	7.51	0.92	9.31	0.00
	AT	3.55	2.59		

Comparison between groups:

ANOVA test (AT vs. AT)

Table 2: Comparison of pain in VAS scale after treatment between the groups

Group	**AT**	**SD**	**F - Value**	**P - value**
A	4.25	2.89	0.53	0.59
B	3.90	2.64		
C	3.55	2.59		

Maximum reduction in pain was observed in group C, followed by group B and A. The difference observed was statistically insignificant ($p>0.05$).

PHARMACOLOGICAL ANALYSIS OF CRITICAL END POINT (*PAAKA*):

HPTLC was performed in three levels of critical end points. Samples 1,2 and 3 represents mild, medium and scorched levels of critical end points respectively.

Figure 1: At 254 nm

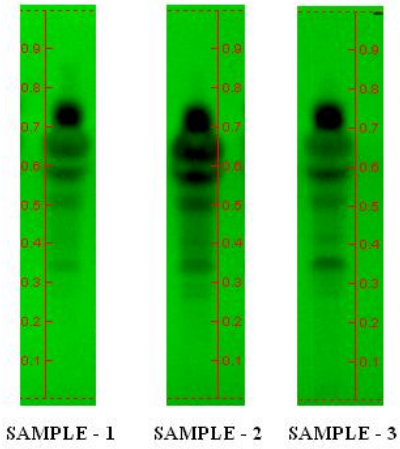

Figure 2: At 366 nm

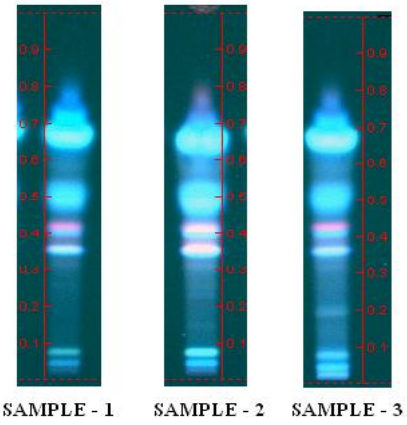

Table 3: Comparison of area and peaks of *Kaarpaasaastyaadi taila* samples at 254nm

MADHYAMA PAAKA **PEAK NO**	***MADHYAMA PAAKA*** **AREA(AU)**	***MR`DU PAAKA*** **PEAK NO**	***MR`DU PAAKA*** **AREA(AU)**	***KHARA PAAKA*** **PEAK NO**	***KHARA PAAKA*** **AREA(AU)**
1	**193.3**	**1**	**531.5**	**1**	**216.6**
2	**220.1**	**2**	**301.2**	**2**	**167.3**
3	**159.7**	**3**	**3163.1**	**3**	**316.8**
4	**2173.1**	**4**	**532.3**	**4**	**5771.7**
5	**844.4**	**5**	**4349.7**	**5**	**1108.3**
6	**3482.6**	**6**	**4235.5**	**6**	**3434.0**
7	**4285.1**	**7**	**4555.6**	**7**	**4824.6**
8	**5065.9**	**8**	**18161.6**	**8**	**3250.1**
9	**13640.2**			**9**	**21381.6**
10	**1693.2**				

A. MEDIUM LEVEL - *MADHYAMA PAAKA*

1. TOTAL PEAK NO – 10
2. TOTAL AREA – 31757.6

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B. MILD LEVEL - *MR`DU PAAKA*

01. TOTAL PEAK NO – 08
02. TOTAL AREA –35830.5

C. SCORCHED LEVEL - *KHARA PAAKA*

01. TOTAL PEAK NO – 09
02. TOTAL AREA -40471

DISCUSSION:

Maximum number peaks are obtained in medium level (*madhyama paaka)*. Number of peaks in HPTLC is directly proportional to amount of active principles in a given *paaka*. This clearly indicates medium level (*madhyama paaka)* has got much more active principles when compared to mild (*mr`du)* and scorched levels (*khara paaka)*.
The area of peak in HPTLC indicates the concentration of active ingredients in each *paaka*. Here, maximum area is obtained in scorched level (*khara paaka)* which indicates even though maximum active ingredients are in medium level(*madhyama paaka),* its concentration is more in scorched level (*khara paaka)*. It can be attributed to the less moisture content present in scorched level (*khara paaka)* resulted in the more concentration of its active principles.

On doing one way ANOVA between the groups after treatment, the test showed statistically insignificant results in VAS scale, ODI, DI .This clearly shows there exists no difference between the efficacy of drug with three levels of critical end points (*paaka)* after treatment. The differences obtained pharmacologically were not elicited clinically.

So, the present study concludes that levels of critical end points of drug has got pharmacological relevance, but can't elicit clinically in the above mentioned setting.

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