

Efficacy of the regime PB8-YDBNP with medicated enema treatment in the management of pakshaghata

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Abstract

The objective of this study was to determine the efficacy of concomitant administration of PB8-YDBNP and selected medicated enema in the Management of *Pakshaghata*. PB8-YDBNP was administered to the control group (Group A) for 30 days continuously in contrast to the test group (Group B), which was given PB8-YDBNP for 30 days continuously with Enema treatment for 10 days concomitantly. The effect of treatment in improving the symptoms and functional status of Group B is greater than that of Group A compared to the before treatment ($p < 0.05$). Group B has shown significant improvement in symptoms and functional status compared to the Group A group ($P < 0.05$). Therefore, the study confirms that the concomitant administration of PB8-YDBNP and selected *Maduthailika* enema treatment improves the symptoms as well as the motor functions of paralyzed limbs than the administration of PB8-YDBNP alone.

KEY WORDS: *Pakshaghata*, Enema

Introduction

Pakshaghata (Paralysis of one side of the body) is one of the major health problem in the society characterized by the partial or permanent disability of the body, which is caused by several pathological conditions especially cerebral vascular accident in middle and old aged people. In the context of Ayurveda, *Pakshaghata* is categorized in the section of *Vataroga*, which is manifested as a result of the vitiation of *Vata*, the supreme controller of all the psychic and somatic functions of the body (Ca.Ci.28; As.3.8-9). The *vata* is vitiated due to the aetiological factors such as excessive indulgence in food, which possesses the qualities: *Ruksha*, *Sheeta*, *Laghu*, and being awoken at night, prolonged exercises. *Vitiated vata* affects the *Sira* and *Snayu* of any half of the body causing loosening of its joints, loss of control, inability of functioning, and loss of sensation in the limbs, considered as *Pakshaghata* in Ayurveda. Enema, which is one of the major procedures in *Panchakarma* (As.Su.1.25)¹, gives 50% benefit in the management of *Pakshaghata* (Ca.Si.1.41; Su.Ci.8: 45-46). Ayurvedic practitioners recommend conventionally the administration of decoctions, pills, *arishta*, external application of oils and fomentation in the management of *Pakshaghata*.

Aim and Objectives

Administration of medicated enema (*enema*) has been withdrawn by many of Sri Lankan practitioners even though it has been recommended in authentic texts of Ayurveda. Selected regime (PB8-YDBN) has been used in the management of *Pakshaghata* but the efficacy of concomitant administration of selected regime and medicated enema has not yet been scientifically investigated. The objective of this study was to determine the efficacy of concomitant administration of PB8-YDBN and selected medicated enema in the Management of *Pakshaghata*.

Materials and method:

Design

Randomized positive controlled clinical trial. Two groups (Test and Control) of 30 patients were randomly selected from volunteers for the study with a written consent. The Board of Management of the Institute approved the study.

Selection of Patients

Sixty patients (39 - 76 years) of either sex were selected from the O.P.D. of Gampaha Wickramarachchi Ayurveda Hospital and admitted to the Gampaha Wickramarachchi Ayurveda Hospital. Detailed history of each patient was

taken on the basis of specific profoma prepared according to the method of clinical examination and other information related to the disease mentioned in Ayurvedic authentic texts and modern texts.

Management Procedure

Patients were randomly divided into two groups consisting of 30 patients per each and two regimen of treatment were given. The group A was treated with conventional regimen (PB8-YDBNP) and Group B was treated with PB8-YDBNP and Medicated enema consisting of *Madhuthailika niruha enema* and *Suddhabala sneha enema*². The PB8 - YDBNP includes *Balasaahacaradi Kwata*, *Yogaraja Guggulu*, 1:1 mixture of *Balarishtha & Dasamoolarishta*, external application of *Maha Narayana Thaila* and fomentation with *Patra Pottali*³.

Preparation of Drug

All plant materials and prepared medicines were purchased from the Gampaha Siddhayurveda Pharmaceutical Company Limited and fresh green leaves for fomentation were collected from the herbal garden of the Institute. Decoctions¹, Enema², and fomentation³ were prepared according to the methods and instructions described in authentic texts.

Preparation of Madhuthailika Enema

240 ml of Decoction of *Eranda* (*Resinus communis*, *Euphorbiaceae*) roots; 60 ml of *Tila Thaila* (*Sesame oil*), 60 ml of *bee honey*, 10 g of *Satapushpa* (*Pseuedanum graveolens*) (Roasted & Fine Powdered seeds), 5 g of *Saindhava Lawana* (Rock salt) were used in the preparation of Madhuthailika Enema.

Preparation of decoction (*R. communis* - Root) for enema

The Decoction was prepared according to Ayurvedic texts (*Ashtangahridaya Kaipasthana 4/16*). Required quantity of dried pieces of roots of *Eranda Moola* (120g) was weighted by using a chemical balance and transferred to the clay vessel of required capacity (2L) and 1920ml of water was added to the vessel. The plant materials were boiled under the moderate heat for 2 hours until the 240ml of decoction was obtained. The decoction was filtered using a fine strainer into a clean bowl and kept in the room temperature until later use.

Preparation of Emulsion:

The emulsion was prepared as per the instructions given in the authentic text (*Ashtangahridaya Kalpasthana 4/16*). Required quantities of *Makshika* (*bee - honey*) and *Lawana* (*salt*) were finely ground using a Mortar and a pestle. Required volume of *Tila Thaila* was added little by little while grinding was being continued until the emulsion was formed. Then the required quantity of powder of *Satapushpa* was added while grinding. Finally, previously prepared decoction of *Eranda moola* was added and mixed thoroughly in order to dilute the emulsion and filtered again into a clean bowl. Final preparation was warmed up to the body temperature of the patient using hot water bath before use. This emulsion was freshly prepared for each patient.

Dosage and Administration:

PB8-YDBNP was administered to the Group A group for 30 days continuously in contrast to the Group B, which was given PB8-YDBNP for 30 days continuously with enema treatment for 10 days concomitantly. PB8-YDBNP consists of *Balasaahacaradi Kwata* (60ml two times a day), *Yogaraja Guggulu* (2 pills two times a day), 1:1 mixture of *Balarishtha & Dasamoolarishta* (15 ml two times a day after meals), external application of *Maha Narayana oil* and fomentation with *Patra Pottali*³.

Dosage and Administration of Medicated Enema

Madhuthailika niruha enema and *Suddhabala sneha enema*² were administered alternatively as given in the Table 1 to the Group B in addition to the PB8 - YDBNP. The recommended pre-treatment and post treatment procedures were applied before and after the selected enema treatments (Ca.Si.1.47).

Method of Administration of Enema

After finishing *pre-treatment procedure*, oil was applied over the pelvic region of the patients and fomented with steam by using *Nadiyantra*. This procedure was followed by the administration of each enema dose.

This *Sneha Enema* procedure was performed at 12.30 pm after having a light meal. Disposable plastic syringe with 100ml capacity connected to a rubber catheter (Length x 22Gage - Folley's catheter) was used to administer the enema.

Patient was informed well about the treatment procedure and instructed to lie down on the bed on left lateral position, flexing the right leg from the knee joint and the straightening the left leg steadily. Rubber catheter and anal orifice were lubricated with oil 90ml of warmed *Shuddha Bala* oil was filled into the syringe and lubricated catheter was inserted gently into the anal canal and delivered the enema slowly. Patient was instructed to have a deep breath while delivering the enema. After administrating the enema patient was instructed to lie on supination position and abdominal area was gently massaged. Then the patient was allowed to rest for 15 minutes on the bed.

Previously prepared and warmed *Madhuthailika Enema (1500ml)* was administered slowly under the force of gravity (Table 1) at 11.00 Am on an empty stomach by using enema can (1.5L) fixed with a flexible rubber tube connected to disposable plastic rectal nozzle. Lubrication was applied before the insertion of rectal nozzle into the anal canal. Precautions were taken to prevent entering the air bubbles. Patient was informed about the procedure and instructed to follow the enema position described earlier. The lubricated plastic nozzle was inserted gently and properly into the anal canal and patient was instructed to take deep breath slowly and to count one, two, three etc while delivering the enema. After the procedure was completed, patient was instructed to lie down on

his back and legs were gently raised 3 times and few tapping were given to the lower abdomen and thighs of the patient. Then the patient was instructed to rest on the bed until the urges of evacuation comes.

Post - Treatment procedure

After the enema came out and patient had returned normal condition, they were allowed to take a warm bath. Thereafter ascertaining the *Valadi Dosha* and strength of the patient, a light diet was given with meat soup (*mamsa rasa*). (Su.Ci.37.44)

Instruction Given to the Patients During Procedures

Patient was advised to take bed rest and avoid heavy diets and light vegetarian diet was prescribed for all patients.

Management

Clinical assessment was done daily during the period of trial and all patients were followed up for three months after the completion of protocol.

Criteria for Assessment

Clinical symptoms and functional status were recorded through out the protocol and follow up period. Eight cardinal symptoms were taken to the account for the evaluation and severity of each symptom was rated using five-point scale (0 – Normal, 1 – Mild, 2 – Moderate, 3 – Marked, 4 – Severe).

Table 1: Treatment procedure for the duration of 17 days.

Duration	Administered Time	Treatment Procedures
1 st day to 7 th day		Pre-treatment procedure: External application of oil (Narayana) over whole body and fomentation with steam by using Nadisweda yantra
8 th day	12.30 pm	Administration of Shuddhabala oil enema (90 ml)
9 th day	11.00 am	Administration of Maduthailika enema (Trial drug) (1.5L)
10 th day	12.30 pm	Administration of Shuddhabala oil enema (90 ml)
11 th day	11.00 am	Administration of Maduthailika enema (Trial drug) (90 ml)
12 th day	12.30 pm	Administration of Shuddhabala oil enema (90 ml) and of Maduthailika enema (Trial drug) 1.5L)
13 th day	11.00 am	Administration of Maduthailika enema (Trial drug) (1.5L)
14 th day and 15 th day		Rest
16 th day	12.30 am	Administration of Shuddhabala oil enema (90 ml)
17 th day	12.30 am	Administration of Shuddhabala oil enema (90 ml)

Table – 1: Percentage of recovered patients (Symptoms) for each study group and the comparison of the treatment effects.

Symptom	Group A			Group B			Difference	
	Total	Recov.	%	Total	Recov.	%	B - A	p-value
Loss of Function								
Upper Limb	30	15	50	30	26	86.67	36.67	0.001
Lower Limb	30	18	60	30	29	96.67	36.67	0.000
Face	22	16	72.73	25	22	84.62	11.89	0.156
Difficulty of Pain	25	16	64	24	20	83.33	19.33	0.063
Upper Limb	28	17	60.71	30	29	96.67	35.95	0.000
Lower Limb	29	19	65.52	28	25	89.29	23.77	0.018
Headache	21	21	100	22	22	100	0	0.5
Swelling								
Upper Limb	26	11	42.31	29	28	96.55	54.24	0.000
Lower Limb	25	19	76	27	27	100	24	0.003
Heaviness								
Upper Limb	30	15	50	30	27	90	40	0.000
Lower Limb	30	15	50	30	27	90	40	0.000
Loss of sensation								
Upper Limb	30	28	93.33	30	29	96.67	3.33	0.277
Lower Limb	30	27	90	30	27	90	0	0.5
Dizziness	27	26	96.3	30	29	96.67	0.37	0.47

Assessment of Functional Status

Functional status and the pattern of functional improvement were assessed on the basis of Barthel Index⁴.

- 3 - Unable (Complete loss of function; sensation)
- 2 - Need Major Help (Largely incapacitated and more than some degrees of dependency)
- 1 - Need Minor Help (Limited self care, some assistance)
- 0 - independent (Capable to manage all activities but mild degree of weakness or slowness in performance)

Method of Diagnosis

Diagnosis was done according to the criteria including affected side, loss of function, and loss of sensation, pain, and dysarthria.

Statistical Analysis

Statistical Analysis was done using the Fisher's exact test, Wilcoxon signed rank test and Z-test. The MINITAB statistical package was used for the Analysis.

Results and Discussion

There was no significant difference of male: female ratio ($P > 0.05$), and variation of age, diet, social status, type of onset, duration of illness,

affected parts ($P > 0.05$) in both groups. The habit of chewing beetle and tobacco in test and Group A is 33.33%, and 26.67 % respectively. The frequent alcohol users and smokers are lesser in Group B than the Group A. 60% of patients ($n = 30$) of retained the enema till evening. 20% of patients retained it up until next morning. Rest of the patient had motion after two hours. Five patients evacuated their bowels with the enema after 10 minutes and one patient was unable to retain the enema and it came out immediately. 80% of patients evacuated their bowels with the enema 2 to 3 times. At the end of prescribed term of treatment, both groups have shown significant improvement ($P < 0.05$) compared to the clinical status before treatment (Table 1). 50% and 80% of patients (Group A) recovered from loss of functions of UL and LL respectively compared to that of group B, where 86.67% and 96.67% of patients recovered (Figure 1) and is statistically significant ($P < 0.05$). Although the patients of both groups (Group A - 64%; Group B - 84.62%) have shown significant improvement in the loss of function of face when compare the clinical status of pre-treatment and post-treatment, there is no statistically significant difference (Table 1) between Group A and Test. ($P = 0.15$). Both groups have shown similar improvement in pain, swelling and heaviness of LL and UL (Table 1).

Figure - 1: Percentage distribution of recovered patients (Symptoms) for each study group and the comparison of the treatment effects.

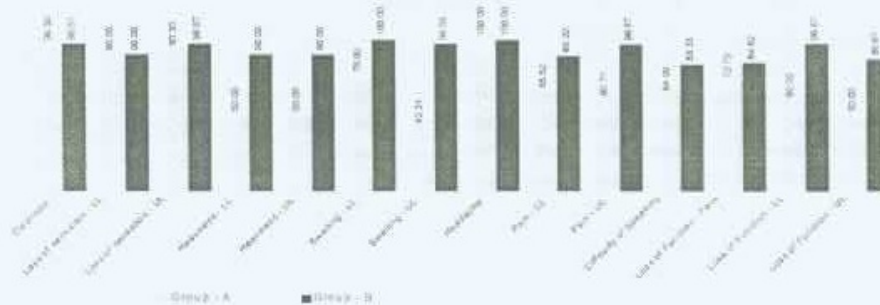


Table - 2: Percentage distribution of recovered patients (Functions) for each study group and the comparison of the treatment effects:

Activity	Group A			Group B			Difference	
	Total	Recov.	%	Total	Recov.	%	B - A	p-value
Feeding	30	19	63.33	30	28	93.33	30	0.002*
Dressing	30	13	43.33	30	27	90	46.67	0.000*
Personal Toile Use	30	16	53.33	30	28	93.33	40	0.000*
Transfer	30	12	40	30	23	76.67	36.67	0.002*
Mobility	30	24	80	30	26	86.67	6.67	0.244

Figure - 2: Percentage distribution of recovered patients (Functions) for each study group and the comparison of the treatment effects.



Percentage of patients of Group B, who achieved the improvement in selected clinical features such as pain, swelling and heaviness of the limbs, is greater than that of Group A (Figure 1). Further, both groups have shown significant improvement in performing activities such as eating, dressing and managing personal hygiene (Table 2).

In conclusion, the Madhuthālikā enema, in addition to the selected conventional regime of treatment PB8 – YDBN, is effective in rehabilitation of motor function of paralyzed limbs. The patients of Group B (93.33%) have shown better improvement in performing that activities compared to the Group A (63.33% - Figure 2).

References

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