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EXPLORATIVE STUDY ON EFFICACY OF AYURVEDIC THERAPY AND AN AYURVEDIC COMPOUND PREPARATION IN THE MANAGEMENT OF EPILEPSY

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ABSTRACT

Epilepsy is the most common presentation in a neurological setting and stands next to stroke and dementia in its prevalence. Epilepsy is the paroxysmal, transitory disturbance of brain function. The aim of this study was to assess the efficacy of the Panchagavya Ghrita administered after Virechana Karma in the management of Apasmara (epilepsy) with special reference to frequency, duration and severity of attack. This study was a single arm interventional study with pre and post test design at outpatient and inpatient level in a tertiary Ayurveda hospital attached to teaching institute located in district headquarters in Southern India. 30 patients of epilepsy were selected from the OPD and IPD of SDM College of Ayurveda and Hospital, Hassan, Karnataka, India fulfilling the inclusion criteria underwent Virechana after the attainment of Nirama Lakshana followed by Samyak Snigdha Lakshana with Panchagavya Ghrita. Thereafter Samsarjana karma was followed according to the Shuddhi. For Shamana 15 ml of Panchagavya Ghrita twice a day with warm water before food was administered for 2 months. The effectiveness of the treatment was considered positive based on the studies and observations. Virechana showed significant relief in frequency, duration and severity of attack. After Shamana, sustained relief was seen in the patients. The result proved the efficacy of Panchagavya Ghrita and Virechana Karma in the management of Apasmara.

Keywords: Apasmara, Panchagavya Ghrita, Virechana Karma, Epilepsy

INTRODUCTION

Epilepsy is a group of long-term neurological disorders characterized by epileptic seizures.[1] These seizures are episodes that can vary from brief and nearly undetectable to long periods of vigorous shaking.[2] The prevalence of epilepsy in India is 5.5/1000.[3] Epilepsy can occur at any age but the incidence is highest at the extremes of life. Incidence rates vary in an age-specific way, between approximately 20 and 70 per 100000 per year.[4] The cumulative incidence of epilepsy by the age of 70 may be as high as 2-3 % of the population.[5] Apasmara (Epilepsy) is defined as vibhatsa-cheshta (sudden abhorrent bodily activities) accompanied by tamapravesha (momentary blackouts or loss of consciousness) owing to disturbance in mental faculties of dhi (intelligence), dhriti (retention) and smriti (memory).[6] It is Vata and Rajo Dosha predominant disease. Apasmara can be treated in two stages, viz., and Vegakaala (period of disease attack) and Vegaantara kala (period between two stages of disease attack).[7] In Vegaantara Chikitsa both Shodhana and Shamana methods are indicated for treatment. Though Shodhana has been mentioned as the first line of treatment in Apasmara however very few research works have been conducted to see the efficacy of Shodhana therapies. Hence in this study Virechana was selected as the Shodhana method followed by Shamana. As Virechana makes Vatanulomana,[8] Pitta rechana,[9-10] it eliminates Kapha[11] which is situated in Pitta Sthana and also because of its practical feasibility; Virechana was planned for the study. Apasmara which has become chronic and difficult for Chikitsa should be managed with Rasayana.[12] The drug Panchagavya Ghrita, comprising of cow's ghee, urine, cow faeces, curd and milk, has been indicated in Apasmara by authoritative Ayurvedic texts.[13-17] Cow's milk[18] is said to be Rasayana,[19] increasing the Ojas,[20] best Jeevaniya drug.[21] Cow's urine is Medhya,[22] Agni Deepaka and Kapha Vatahara. Faeces of cow are Tridosha Shamaka. Curd[23] made out of cow's milk is known to be Vataghna, Deepana, Snehana and Bala Vardhaka. Go Ghrita (cow's ghee) is Pitta Vatahara.[24] Thus a single group observational study was undertaken to assess the efficacy of Panchagavya Ghrita with Virechana Karma in Apasmara.

MATERIALS AND METHODS

Objective

To assess the efficacy of the Panchagavya Ghrita[25] administered after Virechana Karma in the management of Apasmara (epilepsy) with special reference to severity, duration and frequency of attack.

Source of Data

Patients of Apasmara (epilepsy) attending the outpatient and inpatient department of the department Manasa Roga, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India were taken for the study. Institutional

Ethical clearance was obtained from Institutional Ethic committee of SDM College of Ayurveda and Hospital, Hassan, Karnataka, India (IEC No. SDMAH/IEC/73/11-12 dated 01-04-2012).

Diagnostic criteria
As per the clinical features mentioned in Ayurvedic texts and of Epilepsy by International League against Epilepsy (ILAE)

Inclusion Criteria
Patients of 16 to 40 years of age, who were on irregular medications with frequency of attack less than 3 months and were not benefitted by taking other medicines, have been included without disturbing their regular medicines.

Exclusion Criteria
Patients with diabetes mellitus, hypertension, congenital abnormalities, mental retardation, infectious diseases of brain, vascular causes, toxic causes and metabolic causes of seizures and also those contraindicated for Virechana procedure.

Study Design
30 patients of Apasmara who fulfill the inclusion and exclusion criteria were treated in a single group.

Treatment Plan
Initially the patients were administered Panchakola Phanta in the dose of 30 ml three times a day for 3 days before food or till the attainment of Niraama Lakshanas. Panchagavya Ghrita was given to the patients in Aarohana Maatra till the attainment of Samyaka Snigdha Lakshanas reached maximum for 7 days. During Vishrama Kala, Abhyanga with Moorchita Taila and Nadi Svedana was given for two days. On the third day, Virechana was performed with Trivruta leha 60 g as per classical method. Samsarjana karma was followed according to the type of Shuddhi achieved. After Samsarjana Karma, Panchagavya ghrita was administered in dose of 15 ml before food, twice a day with hot water for 2 months.

Assessment Criteria
- Samanya Lakshana of Apasmara
- Severity of attack
- Frequency of attack
- Duration of attack
- Octal features

Patients were assessed before the treatment, after virechana and after the Shamana treatment.[26]

Statistical Analysis
Friedman's test was used to analyze the significance of change in subjective parameters. Wilcoxon signed rank test was done on parameters which show significance in Friedman's test, to interpret the time of significant change.

OBSERVATIONS
Age wise distribution showed that more patients were found in the fourth decade 43.3 % (n = 13). 60.0 % (n = 18) patients were male. Majority of the subjects in the study were Hindus i.e. 83.3 % (n = 25). Maximum numbers of patients were farmers i.e. 30.0 % (n = 9), 16.7 % (n = 5) were housewives and 13.3 % (n = 4) students. 63.3 % (n = 19) were from poor socioeconomic status. Greater number of patients were married i.e. 56.7 % (n = 17) while 43.3 % (n = 13) were single. Majority of patients i.e. 80.0 % (n = 24) of this series belonged to rural regions. 20.0 % (n = 6) of patients had positive history of consanguineous marriage. 33.33 % (n = 10) of patient had positive history of epilepsy in the family. 6.7 % (n = 2) of patients did not start treatment, 50.0 % (n = 15) had started treatment, but discontinued due to various reasons, whereas 43.33 % (n = 13) were still on antiepileptic drugs. 53.3 % (n = 16) were addicted to tea/coffee while 6.7 % (n = 2) have shown addiction to alcohol. Majority of the patients had emotional disturbances i.e. 26.7 % (n = 8), followed by sleep deprivation i.e. 13.33 % (n = 4) as major precipitating factors. Majority of patients had Shoka, Chinta, Bhaya i.e. 60.0 % (n = 18) as Manasika Nidana. 36.7 % (n = 11) experienced seizures only during day time. 60 % (n = 18) of the patients in the study were observed to be non vegetarians. 43.3 % (n = 13) patients in the study had sound sleep followed by 36.7 % (n = 11) were experiencing nightmares and dreams. 60 % (n = 18) of the subjects in the study were working for 6-10 hours per day. 66.7 % (n = 20) patients in the study consumed snehapana for four days. 36.7 % (n = 11) patients in the study attained 17-20 virechana vegas.

RESULTS
Friedman signed-rank test showed a statistically significant reduction in loss of consciousness in 30 patients of Apasmara ($X_2 = 30.960$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.366$) was observed. Friedman signed-rank test showed a statistically significant reduction in the symptom self regaining of consciousness in 30 patients of Apasmara ($X_2 = 16.692$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p = 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.366$) was seen. Fried Man signed-rank test showed a statistically significant reduction in the symptom convulsive movements in 30 patients of Apasmara ($X_2 = 30.621$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.527$) was seen. Fried Man signed-rank test showed a statistically significant reduction in the symptom of fall in 30 patients of Apasmara ($X_2 = 42.538$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.655$)

was observed. Fried Man signed-rank test showed a statistically significant reduction in the symptom epileptic cry in 30 patients of Apasmara ($X_2 = 28.353$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.564$) was seen. Fried Man signed-rank test showed a statistically significant reduction in the symptom of frothing from mouth in 30 patients of Apasmara ($X_2 = 46.500$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.655$) was observed. Fried Man signed-rank test showed a statistically significant reduction in the symptom of chattering of teeth in 30 patients of Apasmara ($X_2 = 38.583$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.655$) was seen. Fried Man signed-rank test showed a statistically significant reduction in the symptom of hallucination in 30 patients of Apasmara ($X_2 = 16.545$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p = 0.007$), but no statistically significant change between Virechana and Post treatment ($p = 0.317$) was seen. Fried Man signed-rank test showed a statistically significant reduction in the symptom frequency in 30 patients of Apasmara ($X_2 = 48.667$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change was seen between Virechana and Post treatment ($p = 0.083$). Fried Man signed-rank test showed a statistically significant reduction in the symptom of duration in 30 patients of Apasmara ($X_2 = 53.020$, $p < 0.001$). The results from running Wilcoxon's test show that level of significance was statistically significant between pre-treatment and Virechana ($p < 0.001$), but no statistically significant change between Virechana and Post treatment ($p = 0.658$) was seen. Friedman signed-rank test on level of consciousness, self regaining of consciousness, convulsive movements, fall, epileptic cry, frothing from mouth, chattering of teeth, hallucination, frequency, duration has been detailed in Table 1. Wilcoxon's test on level of consciousness, self regaining of consciousness, convulsive movements, fall, epileptic cry, frothing from mouth, chattering of teeth, hallucination, frequency, duration has been detailed in Tables 2 to 11.

Table 1: Friedman signed-rank test on all the parameters

S. No.	Parameter	X^2 value	P value	Remark
1.	Loss of consciousness	30.960	0.001	S
2.	Self regaining of consciousness	16.692	0.000	S
3.	Convulsive movements	30.621	0.000	S
4.	Fall	42.538	0.000	S
5.	Epileptic cry	28.353	0.000	S
6.	Frothing from mouth	46.500	0.000	S
7.	Chattering of teeth	38.583	0.000	S
8.	Hallucination	16.545	0.000	S
9.	Frequency	48.667	0.000	S
10.	Duration	53.020	0.000	S

S – Significant

Table 2: Wilcoxon's test on level of consciousness (LOC)

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
LOC (BT-VIR)	0	0.00	0.00	21	11	231	9	30	-4.583	0.000	S
LOC (VIR-AT)	7	6.00	42.00	4	6.00	24.00	19	30	-0.905	0.366	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 3: Wilcoxon's test on self regaining of consciousness

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Self regaining of consciousness (BT-VIR)	3	11.50	34.50	19	11.50	218.50	8	30	-3.411	0.001	S
Self regaining of consciousness (VIR-AT)	7	6.00	42.00	4	6.00	24.00	19	30	-0.905	0.366	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 4: Wilcoxon's test on convulsive movements

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Convulsive movements (BT-VIR)	1	12.50	12.50	23	12.50	287.50	6	30	-4.899	0.000	S
Convulsive movements (VIR-AT)	6	5.50	33.00	4	5.50	22.00	20	30	-0.632	0.527	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 5: Wilcoxon's test on fall

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Fall (BT-VIR)	0	0.00	0.00	24	12.50	300.00	6	30	-4.899	0.000	S
Fall (VIR-AT)	3	3.00	9.00	2	3.00	6.00	25	30	-0.447	0.655	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 6: Wilcoxon's test on epileptic cry

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Epileptic cry (BT-VIR)	0	0.00	0.00	16	8.50	136.00	14	30	-4.000	0.000	S
Epileptic cry (VIR-AT)	2	2.00	4.00	1	2.00	2.00	27	30	-0.577	0.564	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 7: Wilcoxon's test on frothing from mouth

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Frothing from mouth (BT-VIR)	0	0.00	0.00	25	13	325.00	5	30	-5.000	0.000	S
Frothing from mouth (VIR-AT)	2	3.00	6.00	3	3.00	9.00	25	30	-0.447	0.655	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 8: Wilcoxon's test on chattering of teeth

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Chattering of teeth (BT-VIR)	0	0.00	0.00	21	11.00	231.00	9	30	-4.583	0.000	S
Chattering of teeth (VIR-AT)	2	3.00	6.00	3	3.00	9.00	25	30	-0.447	0.655	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 9: Wilcoxon's test on hallucination

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Hallucination (BT-VIR)	1	6.00	6.00	10	6.00	60.00	19	30	-2.714	0.007	S
Hallucination (VIR-AT)	0	0.00	0.00	1	1.00	1.00	29	30	-1.000	0.317	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 10: Wilcoxon's test on frequency

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Frequency (BT-VIR)	27	14.00	378.00	0	0.00	0.00	3	30	-4.747	0.000	S
Frequency (VIR-AT)	0	0.00	0.00	3	2.00	6.00	27	30	-1.732	0.083	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

Table 11: Wilcoxon's test on duration

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Duration (BT-VIR)	30	15.50	465.00	0	0.00	0.00	0	30	-4.839	0.000	S
Duration (VIR-AT)	5	8.90	44.50	7	4.79	33.50	18	30	-0.443	0.658	NS

BT-before treatment; VIR-virechana; AT-after treatment; S-significant; NS-not significant

DISCUSSION

Apasmara is a disease in which mainly Manas afflicted and the major Dosha involvement is of Vata Dosha.[27] All kinds of Cheshta are caused due to Vata. In Apasmara, mainly Bhibhatsa Cheshta, Vikrta Cheshta, Kampa, Vakranga, etc kind of Cheshta is observed. The drug was administered in the form of Sneha. Manda Guna in Sneha has the ability to pacify the Dosha especially Vata. This might be the probable reason that helped in Shamana Karya by reducing the severity, duration and frequency of attack. The distribution of drug in blood is chiefly influenced by its lipid solubility. Water soluble drug is usually distributed in the extracellular spaces and it may not readily diffuse in to CSF and other body cavities, while the lipid soluble drugs are rapidly distributed throughout the intra and extra cellular spaces. The lipid soluble molecules also have the capacity to cross the Blood Brain Barrier thus increasing the availability of active principles in the brain even more.[28] This might be the probable reason that the medicine worked so effectively in a short span of time. While administering Sneha during Snehapana, particular diet which was less in carbohydrates was followed. Even the studies on ketogenic diet by David Goldenberg, specified that it reduced seizure activity.[29] Hence it was better in reducing the severity of seizure attack. In the patients of Apasmara, Pitta and Kapha were vitiated excessively and they remain lying in the body. Virechana has the quality to eliminate both Pitta and Kapha. By the elimination of Kapha and Pitta, obstructions are removed (Avarana), which are caused to the path of Vata.[30-32] At the same time, the elimination of Kapha also alleviates the vitiated Kapha

Vargiya Dushyas. In this way, the Virechana therapy reduced the vitiation of Dosha and the Dushyas. In this study, Shamana therapy was given after the Virechana. When the Shamana drug was given to the patients whose vitiated Doshas were already eliminated by the Virechana therapy, it ultimately provided better relief. The above-mentioned facts are evident from the results of this study. The Virechana Karma clears the Margavarodha (obstruction), eliminates the morbid Doshas from Rasa, Rakta, and regulates the activity and movement of Vata.[33] Thus, it controls Apasmara. According to the modern point of view, during Virechana process, the inflammation of intestinal mucosa leads to hyperemia and exudation resulting into increased passage of protein-rich fluids through vessel walls to intestinal lumen. Increase in fluid volume also results in the dilution of toxic material. Evacuation of the fluid from Rasa-Rakta by Virechana is the direct process that leads to evacuation of toxins. Few studies correlated acetylcholine with Vata, catecholamine with Pitta, and histamine with Kapha.[33] It has been observed that after Virechana, there was reduction in the plasma catecholamine contents of the patients to a statistically significant level. Virechana evacuates all morbid Doshas from all micro to macro Dhatu channels and regulates Vata, thus decreasing all symptoms of Vata, Pitta, and Kapha on Srotas level. Virechana is less stressful procedure than Vamana, has less possibility of complications and could be done easily. Even though Virechana is the best line of treatment for Pitta Dosha, it also helps in cleansing other Dosha in the body. It also helps in Indriya Shuddhi and Mana Prasada. When the Manasika Dosha aggravates and influences the Vata Dosha, it results in repeated attack. As Panchagavya Ghrita controls the Manasika Dosha, hence in long term use of this Ghrita it has proven effective. Panchagavya Ghrita is a combination of five drugs. Most of the ingredients have known anti convulsion property. They are also good antioxidants. According to recent researches increased level of free radicals were reported during seizure. The drug 'Panchagavya Ghrta' has Tridosha Shamana property and is predominantly Vata Shamaka. It is also Agni Deepaka and Sroto Shodhaka. Some of its ingredients have Anulomana property, which also acts on Vata. The drug as a whole is Medhya, Ojasya and Rasayana. Considering all these properties, the drug can act on the mind. The abnormalities like convulsive movements and other abnormal features are greatly Vata predominant and were treated by the Vata Shamaka action of the drug. The Srotoshodhaka action of the drug helps to act deeply on the mind destructing the Aavarana of Tamas. Panchagavya ghrita is a unique preparation having both water based (colloidal milk without fat portion, urine, curd and dung) and fat based (ghee, milk with fat particles) products. It is likely to provide both polar and non-polar natural antioxidants. The data of the antioxidant study revealed uncommon activity limiting behavior. The probability of its higher activity in low concentration at cellular level cannot be ruled out but requires detail study. Since both water and lipid soluble antioxidants are needed by the body for intra and extracellular clearance of the oxidative stress and Panchagavya contains both water based and lipid based products, it has advantage as potential antioxidant. Panchagavya Ghrita contains cow milk, cow ghee, cow urine, cow dung, and curd milk. Out of these five contents cow milk and the cow urine are extensively analyzed. Cow's milk contains carbohydrate, calcium, phosphorus, iron, vitamins A and riboflavin etc. on the other hand cow urine contains sulphur, ammonia, copper, iron urea, uric acid, sodium potassium, Magnesium, Calcium, vitamins A, B, C, D, E; lactose enzymes and creatine. Out of these which component is responsible for its action is really difficult to comment upon. Cow products especially Cow's urine is rich in volatile free acids which are very potent antioxidant agents.[34-35] Also there are enough evidences to suggest the role of oxidants in the causation of epilepsy. If these two facts are considered together then it can be said that Panchagavya Ghrita offers protection in convulsions by virtue of its antioxidant action. Panchagavya Ghrita appears to be possessing anti convulsant properties but the degree of protection might not be sufficient to use it as single antiepileptic agent. This action of Panchagavya Ghrita appears to be not mediated through GABA receptors.

CONCLUSION

Panchagavya Ghrita as Arohana Matra Sneha followed by Virechana provided significant and better relief in most of the symptoms of epilepsy. Moreover, as Arohana Matra Sneha was administered in empty stomach in higher dose, when the patient had good appetite, the absorption and assimilation of Ghrita were faster thereby showing better results, after Virechana. The reason may be that the effect of Ghrita lasts longer as compared to other form of medicine. This being a time bound study; the duration of medicines depending on the response of the patient could not be altered. The Shamana form of administration, appears to be in the form of Rasayana, should also be given for longer period of time.

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