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ADD-ON EFFECT OF SELECTED AYURVEDIC TREATMENT PROTOCOL IN FOCAL SEIZURES EVOLVING TO GENERALIZED SEIZURES - A NON-RANDOMIZED CONTROLLED TRIAL

Vidhya M. Sanker [*1] and M, Jithesh [2]

ManoVigyan Avum Manasroga [1], Department of Kayachikitsa [2], VPSV Ayurveda College, Kottakkal - 676501, Kerala India.

Keywords:

Snehapāna, śodhana, Virecana, Apasmāra, Secondary generalized seizures

Correspondence to Author:
Vidhya M. Sanker

P. G. Scholar,
Mano Vigyan Avum Manasroga, V. P. S. V. Ayurveda College, Kottakkal - 676501, Kerala, India.

E-mail: vidhyasanker90@gmail.com

ABSTRACT: Epilepsy is a chronic non-communicable disease that affects 50 million people worldwide. AEDs play a vital role in controlling seizures but are not a permanent solution. For a large percentage of Persons with Epilepsy, seizures happen even with the intake of AEDs. Apasmāra is more or less compared to epilepsy. The majority of studies conducted on Apasmāra were śamana therapies and suggested śodhana therapy for better results. A non-randomized controlled trial on the Add-on effect of Selected Ayurvedic Treatment Protocol in Focal Seizures Evolving to Generalized seizures was conducted to assess and compare the selected protocol's add-on effect, including śodhana and śamana in secondary generalized seizures. In the trial group, 10 diagnosed subjects with secondarily generalized seizures on Anti-Epileptic Drugs were included and given the intervention. In control, group 10 diagnosed subjects with secondarily generalized seizures on Anti-Epileptic Drugs were observed for the same period. The treatment's effect was assessed using the Epilepsy severity assessment chart. Assessments were done on 0th day, 15th day, 30th day, 45th day, 60th day and on 75th day and Quality of life by QOLIE-10p questionnaire before and after treatment. The control group was also assessed, and the results were compared. The selected protocol was found to have a significant add-on effect in reducing severity, frequency, duration, and post-ictal features compared to the control group and improving the Quality of life compared to the control group.

INTRODUCTION: Epilepsy is a chronic non communicable disease that affects 50 million people of all ages worldwide. The global burden report estimates that about 13 million Disability Adjusted Life Years are due to epilepsy each year [1]. Due to the ongoing epidemiological transition from communicable to non-communicable disease, mental and neurological disorders are increasingly indicated as a public health concern [2].

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A person with epilepsy had difficulties in emotional and physical domains that limited their activities and resulted in poor social interactions, decreased energy levels and feelings of social isolation [3]. Presentation of seizures varies from brief lapses of attention or muscle jerks to severe and prolonged convulsions with a varying frequency from less than one per year to several times per day [4].

As per WHO's data, an estimated 25% epilepsy cases are preventable, and up to 70% of people living with epilepsy could become seizure-free with appropriate use of anti-seizure medicines [5]. But for a large percentage of PWE (Person with Epilepsy), seizures do happen even with the intake of AEDs.

The missing dose is reported as a major trigger. Intractable epilepsies may not respond to AEDs. The persistence of these problems highlighted the need for effective management. These conditions are more or less compared to *Apasmāra* in our classics which primarily presented with impairment or alteration in memory [6]. Well explained treatment modalities were included as *Apasmāra pratiṣeda upāyas* in our classics [7]. Though *Śodhanas* are the primary line of treatment in *Samhitas,* studies reported mainly focused on *Samana* and recommended *Śodhana* for better results.

METHODOLOGY:

Aim: To explore the scope of Sodhana therapy in epilepsy.

Objectives:

Primary Objective: To compare the effect of selected Ayurvedic treatment protocol with the control group in focal seizures evolving to generalized seizures.

Secondary Objective: To compare the Quality of life in both groups.

Study Design: Non-Randomized controlled trial.

Settings:

- Control group – OPD, PVS Hospital, Calicut.
- Trial group - IPD, VPSV Ayurveda College Hospital, Kottakkal and IPD, Govt Ayurveda Research Institute for Mental Diseases, Kottakkal

Sample Siz: Considering the dropouts, N is fixed as 10.

Sampling Procedure: Convenience sampling **Inclusion criteria**.

- Age Group: 18 – 50 years.
- Diagnosed cases of focal seizures evolving to generalized seizures.
- Participants on AED (AntiEpileptic Drugs) for the last one year, with at least one seizure in a month, for the previous three months.
- Those who are fit for snehapāna and śodhana.

Participants were willing to give written consent.

Exclusion criteria:

- With a recent history of alcoholism or drug abuse.
- Pregnancy or lactation.
- With symptoms of any other progressive brain disordersorco-morbidpsychiatric disorders.
- Cardio-vascular diseases, chronic hepatic diseases, renal dysfunction, thyroids function and status epilepticus.

MATERIALS:

- Epilepsy Assessment charts [8].
- QOLIE–questionnaire (Quality of Life in Epilepsy-10p) [9].
- Samyak snigdha assessment chart [10]**.**
- Samyakrukṣana assessment chart [11].
- Consent form and Participant information sheets.
- Case record from
- Drugs.
  - ✓ Takra [12]
  - ✓ Vaiśwānaracūṛna[13]
  - ✓ Kūṣmandaswarasaghrita[14]
  - ✓ Dhanvantaram taila[15]

Avipathicūrna [16] (Medicines purchased from a GMP certified company)

Methods of Preparation: Takrapāna– Takra 1.5L+Vaiśvānara Cūrna 5 gm.

Intervention in Trial Group.

Rukṣana:

- Time of intake: intake frequently to the maximum of 1.5 lina day.
- Duration: up to samyakrukṣana lakṣana / 3 days.

- Drugs: Takra and vaiswānara cūrna.
- Dose: 1.5 Ltakra and 5 gm of vaiswānara cūrna.

Snehapāna:

- Time of intake: 6.00 am.
- Duration: up to samyaksnig dhalakṣana / 7days.
- Drug: Kūṣmandaswarasa ghrita.
- Dose: Arohanamatra as per Agni and Koṣta (Starting from 30ml).
- Abhyanga and ushma sweda– Abhyanga with dhanwantharam taila followed by uṣmasweda - 3 days -20 minutes.
- Virecana– Avipathi cūrna -1 day (30gm)-8.00 am.
- Samana Kūṣm and aswarasa ghrita 20 mlin 2 divided doses for one-month.

Control Group-Observation [10]: Participants on AEDs for the last year with at least one seizure in a month for the last three months satisfy the inclusion criteria. Settings: OPD, PVS Hospital, Calicut Outcome measurement. The treatment's effect was assessed using the Epilepsy severity assessment chart –Assessing on the 0th day, 15th day, 30th day, 45th day, 60th day, and on 75th day and Quality of life by QOLIE-10p questionnaire before and after treatment. The control group was also assessed these days, and the results were Compared. Ethical committee clearance. The dissertation work, case record form and consent form were placed before the Institutional Ethical Committee (IEC No: IEC/Cl/14/19, dated 02/05/2019) of VPSV Ayurveda. College, Kottakkal. After the various levels of scrutiny and Subsequent modification, the final acceptance was gained, and ethical clearance was obtained for the dissertation work. CTRI Registration Number: CTRI/2021/01/030168

Observation and Analysis: Each group included ten diagnosed subjects of Focal seizures evolving to generalized seizures. Data collected using case record forms were entered into Microsoft excel spreadsheet2010and the results were represented as Mean + Standard Deviation. As the data failed to follow a normal distribution, Friedman's test was done, followed by Wilcoxon's signed-rank test for multiple comparisons. The effect of treatment between groups was assessed using Mann–the Whitney U test.

The selected protocol has a statistically significant result within the trial group and when compared to the control group in reducing the severity, frequency, duration and post-ictal feature ($p< 0.001$-Friedmans test) and also in improving the Quality of life ($p<0.01$- Wilcoxon signed-rank test). Domains of Mental health, Role functioning, and epilepsy distress show significant changes ($p<0.001$).

TABLE 1: SEVERITY OF SEIZURES

Severity of seizures						
Tests	**Groups**	**BT-AT1**	**BT-AT2**	**BT-AT2**	**BT-AF1**	**BT-AF2**
Friedman test	Control(p)			0.186		
	Trial(p)			0.001		
Wilcoxon signed rank	Control(p)	1.000	.180	.180	.317	.317
	Trial(p)	.016	.016	.010	.011	.017
Mann-Whitney U	(p values)	.003	.022	.002	.001	.006
Frequency of Seizures						
Friedman test	Control(p)			0.363		
	Trial(p)			0.001		
Wilcoxon signed rankt	Control(p)	.157	.564	1.000	.317	.157
	Trial(p)	.009	.009	.010	.010	.015
Mann-Whitney U	(p values)	.003	.022	.002	.001	.000
Duration of Seizures						
Friedman test	Control(p)			0.416		
	Trial(p)			0.001		
Wilcoxon signed rankt	Control(p)	1.000	.317	.317	1.000	1.000
	Trial(p)	.009	.009	.009	.015	.023
Mann-Whitney U	(pvalues)	.001	.006	.004	.003	.013

Post–Ictal features						
Friedman test-	Control(p)	0.629				
	Trial(p)	0.001				
Wilcoxon signed rankt	Control(p)	.317	.655	.655	.317	.317
	Trial(p)	.009	.001	.001	.010	.010
Mann- Whitney U	(p values)	.000	.003	.002	.000	.000
Quality of Life						
Tests	Groups	Mental health	Role functioning	Epilepsy effect	Distress	Total score
Wilcoxon signed rank test	Control(p)	1.000	1.000	1.000	1.000	.180
	Trial(p)	.007	.011	.180	.009	.008
Mann-Whitney U	(p values)	.000	.000	.447	.000	.000

DISCUSSION: The protocol selected for the Study includes rúksana, snehapāna, abhyangauṣ masweda, virecana, and śamana. It's hard to differentiate the role of each therapy in the effect of treatment. Overall, the selected protocol is significantly effective in reducing the symptoms. As purvakarma of snehapana to avoid snehavyāpath, rukṣana [17] is indicated. Rukṣana being pacana [18] may have acted on the Vyādhi directly and it creates a suitable condition for snehapāna. This may be because of its laghuguna (laghava or ropana [19]) along with uṣnaguna (pācanaschaviseṣata [19]) as it corrects the impaired agni. Snehapana provides vātanulomata and agnidīpti [20] which have a negative action on the precipitating factors like indigestion; constipation [21] *etc* and may initiate the koṣtagati of doṣa (vridhiabhishyandanāt [22]). In bahudoṣāvasta, śodhana is the only line of treatment [23] and the choice in apasmara. Virecana being the primary line of treatment in pitta and pittanubhandha dosha [24] its action can be justified in apasmāracikitsa as the involvement of pitta in apasmārasamprapti was explained by Harita [25]. Apasmara being an achronic disease after śodhana, Śamana like therapies are needed. For samanasnehapāna medicated ghee was used, and the medication included will certainly have a role in the action (samskarasyānuvartini [26]) along with the effect of ketogenic diet [27]. The drug used has an evident role in the reduction of seizures. As apasmāra is primarily associated with impairments in memory, the selected formulation acts as medhya 28 and helps reduce the symptoms. A previous experimental study shows that the drug possesses a neuroprotective effect against lithium bicarbonate – pilocarpin induced status epileptic us [29].

CONCLUSION: The selected protocol was found to have a significant add-on effect in reducing the severity, frequency, duration, and post-ictal features when compared to the control group and also have a significant add-on effect in improving the Quality of life when compared to the control group. AEDs do play a vital role in controlling seizures. Still, in this particular study, as per the inclusion criteria, the selected participants had at least one seizure in a month, even after the intake of AEDs. And the selected protocol was found to have a significant add-on effect in reducing the seizures and improving the Quality of life compared to the control.

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