

An open-label pilot study to identify the usefulness of adjuvant homoeopathic medicines in the treatment of cerebral stroke patients

Aslam Abbas¹, Md Shahid Ali¹, Hima Bindu Ponnamp^{1*}, Divya Taneja², Anil Khurana², Chaturbhuj Nayak³, Anil Santapur¹

¹Extension Homoeopathic Clinical Research Unit of CCRH, Princess Durru Shehvar Children's and General Hospital, Hyderabad, Telangana, ²Central Council for Research in Homoeopathy (CCRH), New Delhi, ³Homoeopathy University, Jaipur, Rajasthan, India

Abstract

Background: Stroke, the third leading cause for neurological morbidity and mortality has a global annual incidence of 0.2–2.5/1000 population. The clinical sequelae of stroke are often devastating with hemiparesis, depression, walking difficulties and aphasia. It is essential to take measures halting the progression of stroke. Homoeopathic literature mentions many medicines for stroke. Till a pilot study was undertaken to study the usefulness of Homoeopathy as an adjuvant therapy to standard conventional care in stroke patients. **Materials and Methods:** An open-label pilot study was conducted at Princess Durru Shehvar Children's and General Hospital, Hyderabad, in coordination with Extension Clinical Research Unit of Central Council for Research in Homoeopathy. Fifty patients presenting with episodes of cerebral stroke of the different period were assessed by the National Institute of Health Stroke Scale (NIHSS) Score, prior homoeopathic treatment and after 6 months of treatment. **Results:** Of 50 patients, 10 patients had stroke more than 1 year and suffering with sequelae, 27 patients had stroke episode between 1 month and 1 year and 13 patients had a stroke episode within 4 weeks. The reduction in NIHSS score after 6 months of treatment was statistically significant in all three groups. The useful medicines found were *Causticum* ($n = 11$), *Arnica montana* ($n = 7$), *Nux vomica* ($n = 6$), *Lycopodium* ($n = 6$) and *Lachesis* ($n = 3$). Neither patient had worsening signs nor any new infarcts during the study. **Conclusion:** This pilot study showed encouraging results. Further randomised control trials are suggested to evaluate the efficacy of homoeopathic medicines in stroke.

Keywords: Adjuvant therapy, Arnica, Causticum, Cerebral infarct, Homoeopathy, National Institute of Health Stroke Scale, Pilot study

INTRODUCTION

Stroke is a phenomenon of rapidly developing clinical symptoms and/or signs of focal disturbance of cerebral function, with symptoms lasting for more than 24 h or leading to death. Stroke continues to remain a common neurologic problem in India constituting an important cause of death and hazardous long-term disability. The ageing of our population will undoubtedly result in an increased incidence of stroke and a rapid rise in health-care economic burden. Thus, the reduction of the incidence of stroke is a high priority objective for India. About 80% of strokes are ischaemic, 10% are intracerebral haemorrhage and 5% are subarachnoid haemorrhage.^[1] Clinically, stroke can be classified as follows: (a) transient, if the deficit recovers within 24 h, (b) complete if the focal deficit is persistent and not worsening and (c) evolving, if the focal deficit continues to worsen after about 6 h

from onset. The risk factors for stroke are classified into Irreversible (age, gender, race, heredity and previous vascular event) and modifiable (hypertension, heart disease, diabetes, hyperlipidaemia, smoking, excess alcohol consumption, polycythaemia and oral contraceptives).^[2]

The clinical sequelae of stroke survivors are often devastating with one half having hemiparesis, one-third clinically depressed, approximately one-third unable to walk and

***Address for correspondence:** Dr. Hima Bindu Ponnamp, Scientist II, Extension Clinical Research Unit of CCRH, Princess Durru Shehvar Children's and General Hospital, Purani Haveli, Hyderabad - 500 002, Telangana, India.
E-mail: drbindu_hima@yahoo.com

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one-sixth aphasic. It is essential to take rapid measures that can halt the progression of the cerebrovascular disease to prevent complications.^[3] In homoeopathic literature, a number of medicines are mentioned for the management of stroke and its related symptomatology.^[4] However, no systematic studies could be identified in Homoeopathy for the treatment of stroke and related symptomatology. As such, a pilot study was undertaken to identify the usefulness of homoeopathic medicines adjuvant to the conventional care in patients affected with cerebral stroke where all the patients were assessed for clinical status by using the National Institute of Health Stroke Scale (NIHSS).^[5]

MATERIALS AND METHODS

Study setting

Princess Durru Shehvar Children's and General Hospital, Hyderabad, Telangana, is a tertiary care hospital with inpatient and outpatient services. The extension clinical research unit of the Central Council for Research in Homoeopathy (CCRH) is located in the hospital premises wherein the outpatient homoeopathic treatment is provided. The study was conducted in the Neurology department of the hospital in collaboration with the Extension Clinical Research Unit of the CCRH. Three conventional medicine doctors including a neurologist and physician along with three Homoeopathy experts were involved in the study.

Study duration

Total study duration was 3 years (2006–2009) with two and a half year's enrollment period. Each case was followed for 6 months.

Study design

This was an open-label observational pilot study to evaluate the usefulness of homoeopathic medicines as adjuvant to conventional care in treating patients affected with cerebral stroke.

Selection of patients

Patients presenting with stroke-related sequelae reporting in the neurology department of the hospital were screened for inclusion in the study as per the following inclusion/exclusion criteria:

Inclusion criteria

- Patients aged between 30 and 65 years, of both the sexes, suffering from post-stroke sequelae and patients of stroke not improved after conventional treatment
- Patients that were conclusively diagnosed by investigations such as CT scan, of having cerebral infarcts as an eventuality after a stroke with score <20 on NIHSS.

Exclusion criteria

- Patients with uncontrolled hypertension leading to haemorrhagic stroke, and patients with uncontrolled diabetes which are on insulin therapy for the maintenance
- Patients of stroke presenting with seizures
- Patients that need continuous administration of drugs such as tissue plasminogen activator (TPA), anticoagulants and clot-busters

- Patients with polycythaemia/uncontrolled hyperlipidaemia which were attributed as risk factors for the stroke
- Patients with infections such as HIV and other systemic disorders like malignancies
- Patients with evolving pattern of stroke and also which were of <3 h duration showing signs of worsening
- Patients with severe stroke manifestations i.e., where the NIHSS score is more than 20.

Enrolment procedure

Initially, all patients were screened for cerebral infarct clinically and by computed tomographic scan of the brain and further evaluated through certain essential clinical laboratory tests (haematology, blood chemistry including glucose, lipid profile, electrolytes, renal function tests and electrocardiography) for enrolment into the study as per the inclusion criteria. All the patients were required to give voluntary consent, by signing the Informed Consent Format, for participation in the study. A detailed case history of each patient was recorded in a predesigned case taking proforma.

Intervention

Each case was analysed, evaluated and totality of symptoms was built on. The symptoms were repertorised using the Complete Repertory in Homopath Version 8 Classic software (Jawahar Shah, 2005, Mind Technologies, Mumbai). However, the final selection of the remedy was done using the *Materia Medica*.^[6,7] The Homoeopathic medicine was prescribed adjuvant to the standard conventional care (TPA and anticoagulants). The patients were asked to continue their regular oral hypoglycaemic drugs, antihypertensives and lipid-lowering medicines as per their routine schedule. The selected Homoeopathic medicine was initially prescribed in 6C potency and repeated doses. Subsequently, the potency was raised in sequential manner if the case showed amelioration with one potency and then got stand still with no further improvement.^[8]

Data collection and assessment

Patients were assessed clinically at 7 days, 14 days, 1 month after starting the treatment and then at monthly intervals up to 6 months. NIHSS score was taken at baseline and subsequently at the completion of 6-month treatment. CT scan of the brain was also done at baseline and after completion of 6 months of treatment. Improvement assessment by a neurologist based on the NIHSS score reduction (more than 75% reduction in score was considered as marked improvement, 50%–75% reduction as moderate improvement, 25%–50% reduction as mild improvement, increase in score as worse and no change as static). Clinically, all the patients were assessed by a neurologist basing on the NIHSS Score. This scale (NIHSS) was developed by the investigators at the University of Cincinnati Stroke Center to quantify neurologic status in stroke patients. The NIHSS is a 24-point scale (11 items – level of consciousness, gaze, visual fields, facial palsy, motor arm, motor leg, ataxia, sensory, language, dysarthria and extinction), with zero being a normal score and the maximum possible score is 42. Patients

receive points depending on different areas of deficit. The test takes approximately 5 min to administer and another 5 min to record the proper scores.^[5]

Statistical analysis

Statistical analysis was done using Statistical Package for the Social Sciences Software (IBM SPSS 20.0 version, India). Mean values of NIHSS score before and after treatment were compared using paired *t*-test. All values were expressed as n (%), mean \pm standard deviation, and $P < 0.05$ was considered statistically significant.

Table 1: Baseline characteristics of enrolled cerebral stroke patients

Variable	Number of patients <i>n</i> =50	Percentage
Gender		
Male	35	70
Female	15	30
Age		
<40 years	06	12
41-50 years	08	16
51-60 years	17	34
61-70 years	19	38
Duration of stroke		
<1 month	13	26
1 month to 1 year	27	54
>1 year	10	20
Location of lesion		
Left middle cerebral artery	23	46
Right middle cerebral artery	18	36
Both	09	18
Onset		
Sudden	17	34
Gradual	33	66
Risk factors		
Hypertension	49	98
Family history of hypertension	40	80
Irregular medication taken for hypertension	30	60
Diabetes	18	36
Family history of diabetes	19	38
Irregular medication taken for diabetes	11	22
Family history of CVA	25	50
Hyperlipidaemia	15	30
Tobacco smoking	20	40
Alcohol intake	22	44

Table 2: Change in NIHSS score from baseline to 6 months after treatment

	<i>n</i>	NIHSS score at baseline	Score after 6 months of treatment	Test statistic (value of <i>t</i> statistic)	Significance
Stroke less than 1 month	13	4.62+2.364	2.69+1.932	6.218	0.0001
Stroke episode more than 1 month to 1 year	27	4.78+1.948	3.04+1.808	8.006	0.0001
Stroke episode since more than 1 year	10	5.10+1.853	3.90+1.663	3.674	0.005

$P < 0.05$ is significant

Ethical approval

Necessary ethical approval has been obtained from the Institutional Ethical Committee of the hospital where the study has been conducted.

RESULTS

During the 3-year study, 118 patients with cerebral infarct were screened, out of whom 31 were excluded, 87 patients were enrolled out of whom 27 patients dropped out and 10 patients were withdrawn. Data of 50 patients have been analysed. Of these 50 patients, 10 patients had stroke episodes more than 1 year back, 27 patients had stroke episode for more than 1 month but <1 year back while 13 patients had stroke episodes <1 month. The data of these three groups have been analysed separately as shown in Table 1.

Of 50 patients, whose data were analysed, 36 (72%) of the patients were above the age of 50 years, whereas 14 (28%) patients were 30–50 years old. Twenty-three (46%) of patients presented with the involvement of left cerebral artery lesion, 18 (36%) with right cerebral artery lesion and 9 (18%) showed both cerebral arteries involvement as given in Table 1. Seventeen (34%) patients showed a sudden onset of symptoms and 33 (66%) showed a gradual onset of symptoms as shown in Table 1.

Thirty-six (72%) patients presented with a duration of more than 3 weeks of illness (chronic) and among them 27 (75%) patients showed signs of improvement. Eight (16%) patients were with a duration of 3 days–3 weeks (subacute) of illness, and among them, 5 (62.5%) patients showed signs of improvement. Five (10%) patients were with a duration of 6 h–3 days (acute) of illness and among them 5 (100%) patients showed signs of improvement and only 1 case (2%)

Table 3: Symptoms frequency at baseline and 6 months

Symptoms	No. of cases	
	Baseline	6 months
Weakness	48	46
Numbness	3	4
Difficult Speech	32	30
Vertigo	4	0
Higher Mental Functions (memory, thinking, attention, perception)	10	3
Irritability	13	4
Anxiety	10	4

Table 4: Assessment of initiation of improvement

Initiation of Improvement	No. of cases of stroke duration <1 month	No. of cases of stroke duration 1 month - 1 year	No. of cases of stroke duration >1 year
Within 1 month	13	20	-
1 to 2 months	-	6	-
2 to 3 months	-	1	9
3 to 4 months	-	-	1

Table 5: Medicines prescribed and outcomes

Medicine	No. of cases prescribed	No. of cases improved
<i>Arnica</i>	9	8
<i>Arsenic album</i>	1	-
<i>Baryta carb</i>	1	1
<i>Bothrops</i>	1	1
<i>Calc. carb.</i>	1	-
<i>Causticum</i>	14	11
<i>Conium</i>	1	1
<i>Ignatia</i>	1	-
<i>Lachesis</i>	4	3
<i>Lycopodium</i>	7	6
<i>Nux vomica</i>	9	6
<i>Phosphorus</i>	1	1

was enrolled with a duration of <6 h of illness and showed signs of improvement, when symptomatically assessed. Various risk factors identified in stroke patients such as smoking, alcohol, family history of hypertension and diabetes are given in Table 1. Among those, eight patients reported both smoking and alcohol intake. Significant reduction in NIHSS score was seen in all three groups of patients as given in Table 2. The changes in individual symptomatology and the time of initiation of improvement [Figure 1] are given in Tables 3 and 4, respectively.

Eleven homoeopathic medicines which were used as adjuvant to the conventional care (which included medicines such as blood thinners and TPA) showed no drug interactions or adverse events during the treatment period. *Causticum* (n = 14, 28%) was the most frequently used medicine followed by *Arnica montana* (n = 9, 18%), *Nux vomica* (n = 9, 18%), *Lycopodium* (n = 7, 14%) and *Lachesis* (n = 4, 8%). Other medicines used were *Conium maculatum* (n = 1, 2%), *Arsenic album* (n = 1, 2%), *Baryta carb* (n = 1, 2%), *Bothrops* (n = 1, 2%), *Calcarea carbonica* (n = 1, 2%), *Phosphorus* (n = 1, 2%) and *Ignatia* (n = 1, 2%) as given in Table 5. The characteristic indications of the medicines found useful in four or more patients are given in Table 6.

DISCUSSION

The present open-label pilot study was conducted to explore the usefulness of homoeopathic medicines in the treatment of stroke-related symptoms and stroke sequelae given adjuvant to conventional care in a hospital setting. Among 50 patients, who fulfilled the study protocol, 38 patients showed a marked

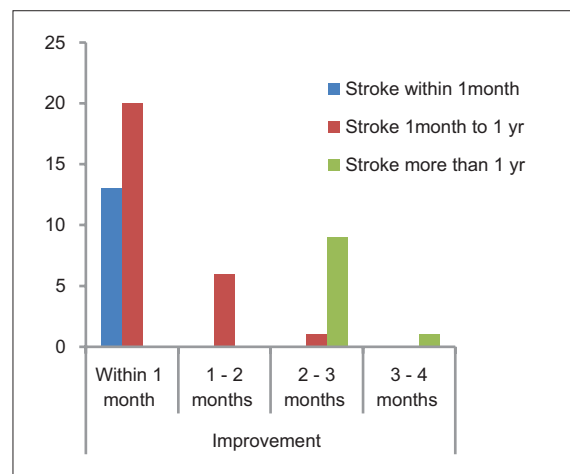


Figure 1: Initiation of improvement in stroke patients with different duration of onset

reduction in the NIHSS score^[9] showing various stages of improvement as marked, moderate and mild, whereas in the remaining 12 patients the overall score remained the same.

Most of the patients (n = 23, 46%) in this study showed lesion in the left middle cerebral artery which corroborates with the classical presentation of stroke,^[10] 18 (36%) patients showed lesions in right cerebral artery, 9 (18%) patients showed lesions in both right and left cerebral artery. The onset of complaints in 17 (34%) patients was found to be of sudden nature, whereas 33 (66%) patients showed a gradual onset.

Forty-nine out of 50 (98%) patients presented with a history of hypertension, 80% (n = 40) with a family history of hypertension and 60% (n = 30) of patients were having irregular treatment for hypertension. Previous studies established that uncontrolled hypertension plays a major role in stroke manifestation,^[11] which corroborates with the patients enrolled in the present study. Twenty-two (44%) patients presented with a habit of smoking and 8 (16%) patients presented with a combination of alcohol and smoking habits.

No change in these risk factors was observed during the study. The effect of these factors on change in the NIHSS score could not be ascertained in this pilot study.

The medicines found useful in this observational study were *Arnica*, *Causticum*, *Lachesis*, *Lycopodium*, *Nux vomica*. The results were found to be encouraging. In spite of many controversial statements on the efficacy of *Arnica*^[12] in the treatment of cerebral stroke patients, it was found beneficial

Table 6: Characteristic indications of frequently used medicines

Medicine	Symptoms		
	Mental	Physical General	Particular/Common
<i>Arnica</i>	Dreams of drowning	Paralytic affections after apoplexy, head hot and body cold, main nervous system and motor functions involved.	Hypertension
<i>Causticum</i>	Anxiety, despondent, complaints from grief, tearful, melancholic, sympathetic, hopeless.	Paralytic affection with progressive loss of muscular strength, paralysis of voluntary & involuntary muscles, hypertension.	Local paralysis of face & extremities, speech difficult & slurring speech, vertigo.
<i>Lachesis</i>	Loquacious, suspicious	Paralysis after apoplexy, left sided complaints, constipation.	Weakness in upper and lower limbs, hypertension
<i>Lycopodium</i>	Suspicious, confused, weak memory	Right sided complaints, ailments developed gradually.	Weakness and numbness in right upper & lower limbs, hypertension.
<i>Nux vomica</i>	Irritable, hypersensitive to noise and odor, obstinate, addicted to stimulants.	Partial paralysis, vertigo, constipation, sensitive to cold air, desire for highly seasoned food, left sided complaints.	Loss of power of arms & legs, hypertension, diabetes mellitus.

in this study showing positive results. The positive role of *Arnica* has been ascertained in middle cerebral artery occlusion in rat model in a previous study.^[13] Our study also emphasises the same clinically. Further, the symptoms given in the homoeopathic literature for the above medicines have been clinically verified albeit in a small number of patients highlighting the importance of the holistic approach.

The homoeopathic medicines were used adjuvant to the conventional care (which included medicines such as blood thinners and TPA). No drug interactions or adverse events were reported during the study.

The computed tomography of the brain was conducted for all the cerebral infarct patients at screening level, and the same was repeated for the patients complying the protocol at the end of the study. In a few patients, where the duration of illness was within 4 weeks, it was observed that the infarct size markedly reduced showing good clinical improvement, which corroborates with the findings of a previous study.^[14] Another significant observation of our study was that no new infarcts appeared during the trial period.

The strength of this study is that it represents a pragmatic setting of homoeopathic practice which reflects the day-to-day clinical practice. However, the study did not have any control group, randomisation and blinding. For authentication of findings, the diffuse weighted image scan^[15] of the brain could not be conducted. These were the limitations of this study.

CONCLUSION

This was an open-label pilot study where a marked reduction in the NIHSS score with good recovery was found after adjuvant homoeopathic treatment in 76% patients. The NIHSS score predicts the patient's recovery after stroke. The results of the study emphasise a positive impact of homoeopathic treatment in stroke-affected patients. For further validation of the results, the following suggestions are given:

- i. Multicentric study with a bigger sample size
- ii. The study to be based on randomised control trial study design

- iii. Diffuse weighted imaging scan to be conducted for the patients for authentication of findings which gives exact size and involvement of the lesion
- iv. To ascertain effects of the risk factors on NIHSS score.

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Conflicts of interest

There are no conflicts of interest.

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मस्तिष्क आघात से ग्रस्त रोगियों के उपचार में सहायक होम्योपैथिक औषधियों की उपयोगिता की पहचान करने के लिए एक खुले स्तर का प्रारंभिक अध्ययन

पृष्ठभूमि: आघात, स्नायु-विज्ञान विषयक रूग्णता और मृत्यु दर का तीसरा प्रमुख कारण है जो विश्व की कुल जनसंख्या में 0.2–2.5/1000 है। 1/2 हैमिपेरेसिस, 1/3 नैदानिक रूप से अवनत, 1/3 चलने में असमर्थ और 1/6 वाक्यरोध संबंधी मामलों के साथ आघात के रोगोत्तर लक्षण अक्सर विनाशकारी होते हैं। आघात की प्रगति को रोकने के उपाय करना आवश्यक है। होम्योपैथिक चिकित्सा साहित्य में आघात के उपचार हेतु कई औषधियों का वर्णन है। होम्योपैथी में आघात रोगियों पर आज तक कोई अध्ययन नहीं किया गया है। इस प्रकार, आघात रोगियों में मानक पारंपरिक देखभाल के साथ सहायक चिकित्सा के रूप में होम्योपैथी की उपयोगिता का अध्ययन करने के लिए एक पायलट अध्ययन किया गया।

सामग्री और विधि: केन्द्रीय होम्योपैथी अनुसंधान परिषद् की विस्तारित नैदानिक अनुसंधान इकाई के साथ समन्वय करके प्रिंसेस दुरू शहवर बाल एवं सामान्य अस्पताल, हैदराबाद में एक खुले स्तर का प्राथमिक अध्ययन आयोजित किया गया। पूर्व होम्योपैथिक उपचार और 6 महीने के उपचार के बाद, विभिन्न अवधि के मस्तिष्क आघात के प्रकरण वाले पचास रोगियों का मूल्यांकन नेशनल इंस्टीट्यूट ऑफ हेल्थ स्ट्रोक स्केल स्कोर द्वारा किया गया।

परिणाम: 50 रोगियों में, 10 रोगियों को 1 वर्ष से अधिक समय से आघात था और वे रोगोत्तर लक्षणों से ग्रस्त थे, 27 रोगियों में 1 महीने से 1 वर्ष के बीच आघात का प्रकरण था और 13 रोगियों में 4 सप्ताह के भीतर आघात का प्रकरण था। 6 महीने के उपचार के बाद एनआईएचएसएस स्कोर में कमी, सभी तीन समूहों में सांख्यिकीय रूप से महत्वपूर्ण थी। 50 रोगियों में, 5 रोगियों (10 प्रतिशत) ने उल्लेखनीय सुधार दिखाया, 17 (34 प्रतिशत) ने मध्यम, 16 (32 प्रतिशत) ने मामूली सुधार दर्शाया और 12 (12 प्रतिशत) स्थिर थे। उपयोगी पाई गई औषधियाँ थी, कॉस्टिकम (एन=11), आर्निका मोंटाना (एन=7), नक्स वोमिका (एन=6), लाइकोपोडियम (एन=6) और लेकेसिस (एन=3)। अध्ययन के दौरान न तो रोगी में कोई दुष्प्रभाव देखने को मिला और न ही किसी प्रकार का कोई संक्रमण।

निष्कर्ष: इस प्रारंभिक अध्ययन ने उत्साहजनक परिणाम दिखाए। आगे यादृच्छिक नियंत्रण परीक्षणों से आघात में होम्योपैथी औषधियों की प्रभावकारिता का मूल्यांकन करने का सुझाव दिया गया है।

Une étude pilote ouverte pour identifier l'utilité des médicaments homéopathiques adjuvants dans le traitement des patients ayant subi un AVC

Contexte: L'AVC, la troisième cause principale de morbidité et de mortalité neurologiques, a une incidence annuelle mondiale de 0,2 à 2,5 personnes/1000. Les séquelles cliniques des accidents vasculaires cérébraux sont souvent dévastatrices pour les patients, avec la moitié parmi eux atteints d'hémiplégie, un tiers cliniquement déprimés, un tiers incapables de marcher et un sixième atteints d'aphasie. Il est essentiel de prendre des mesures pour arrêter la progression de l'AVC. La documentation homéopathique mentionne de nombreux médicaments pour le traitement des accidents vasculaires cérébraux. Jusqu'à ce jour, aucune étude n'a été menée dans l'homéopathie chez les patients ayant subi un AVC. Ainsi, une étude pilote a été entreprise pour étudier l'utilité de l'homéopathie en tant que traitement adjuvant aux soins classiques standards chez les patients ayant subi un AVC. **Matériels et méthodes:** Une étude pilote ouverte a été menée à l'hôpital Princess Durru Shehvar Children's and General Hospital à Hyderabad, en coordination avec l'unité de recherche clinique prolongée du Conseil central pour la recherche en homéopathie. Cinquante patients présentant des épisodes d'AVC cérébral datant de périodes différentes ont été évalués selon le score NIHSS (National Institute of Health Stroke Scale) avant le traitement homéopathique et après 6 mois de traitement. **Résultats:** Sur les 50 patients, 10 patients avaient subi un AVC plus d'un an auparavant et souffraient de séquelles, 27 patients avaient eu un AVC entre 1 mois et 1 an auparavant et 13 patients avaient eu un AVC dans les 4 semaines précédentes. La réduction du score NIHSS après 6 mois de traitement était statistiquement significative dans les trois groupes. Parmi les 50 patients, 5 patients (10 %) ont présenté une amélioration nette, 17 patients (34 %) ont montré une amélioration modérée, 16 patients (32 %) ont présenté une légère amélioration et l'état de 12 patients (24 %) était stationnaire. Les médicaments qui se sont avérés utiles étaient *Causticum* (n = 11), *Arnica Montana* (n = 7), *Nux vomica* (n = 6), *Lycopodium* (n = 6) et *Lachesis* (n = 3). Les patients n'ont ni présenté de signes d'aggravation ni subi de nouveaux infarctus cérébraux pendant l'étude. **Conclusion:** Cette étude pilote a montré des résultats encourageants. D'autres essais cliniques contrôlés randomisés sont suggérés pour évaluer l'efficacité des médicaments homéopathiques dans les accidents vasculaires cérébraux.

Estudio piloto de diseño abierto para identificar la utilidad de los medicamentos homeopáticos coadyuvantes en el tratamiento de pacientes con ictus cerebral

Fundamentos: El ictus, la tercera causa principal de morbilidad y mortalidad neurológica, presenta una incidencia anual global de 0,2–2,5/1.000 población. A menudo, las secuelas clínicas del ictus son devastadoras. Se observa hemiparesia en la 1/2 de los pacientes, depresión clínica en 1/3, incapacidad de marcha en un 1/3, y afasia en 1/6. Es esencial tomar medidas para frenar la progresión del ictus. La bibliografía homeopática menciona numerosos medicamentos para el ictus. Hasta la fecha, no se ha realizado ningún estudio sobre la utilidad de la homeopatía como terapia coadyuvante de la atención convencional estándar en los pacientes con ictus.

Materiales y métodos: Se efectuó un estudio piloto de diseño abierto en el *Princess Durru Shehvar Children's and General Hospital* (Hospital pediátrico y general de la Princesa Durru Shehvar), Hyderabad, en coordinación con la *Extension Clinical Research Unit* (Unidad de Extensión de Investigación Clínica) del CCRH (*Central Council for Research in Homoeopathy*). Se evaluaron 50 pacientes con episodios de ictus cerebral en diferentes periodos mediante el índice *National Institute of Health Stroke Scale* (NIHSS) antes del tratamiento homeopático y seis meses después del mismo.

Resultados: Diez de los 50 pacientes habían tenido un ictus más de un año y sufrían secuelas; 27 pacientes habían sufrido un episodio de ictus entre 1 mes y 1 año y 13 pacientes, un episodio de ictus en 4 semanas. La reducción del índice NIHSS tras seis meses de tratamiento fue estadísticamente significativa en los tres grupos. Entre los 50 pacientes, 5 (10%) mostraron mejoras pronunciadas, mientras que en 17 (34%) eran moderadas, en 16 (32%) leves y en 12 (24%) la situación se había mantenido estable. Los medicamentos útiles fueron *Causticum* (n = 11), *Arnica Montana* (n = 7), *Nuxvomica* (n = 6), *Lycopodium* (n = 6) y *Lachesis* (n = 3). Ninguno de los pacientes mostró signos de empeoramiento, ni infartos nuevos durante el estudio.

Conclusiones: Este estudio piloto mostró resultados alentadores. Se precisan más ensayos de control aleatorizados para evaluar la eficacia de los medicamentos homeopáticos en el ictus.

Eine Open-Label-Pilotstudie zur Ermittlung des Nutzens adjuvanter homöopathischer Arzneimittel bei der Behandlung von Schlaganfallpatienten

Hintergrund: Der Schlaganfall ist die dritthäufigste Ursache für eine neurologische Morbidität und Mortalität und hat ein jährliches Vorkommen von 0,2–2,5 / 1000. Die klinischen Folgen eines Schlaganfalls sind oft verheerend mit 1/2 Hemiparese, 1/3 klinisch depressiv, 1/3 Unfähigkeit zu gehen und 1/6 aphasisch. Es ist wichtig, Maßnahmen zu ergreifen, damit das Fortschreiten des Schlaganfalls gestoppt wird. Die homöopathische Literatur erwähnt viele Medikamente gegen Schlaganfälle. Bis heute wurde keine Studie zu Schlaganfallpatienten in der Homöopathie durchgeführt. Daher wurde eine Pilotstudie durchgeführt, um den Nutzen der Homöopathie als adjuvante Therapie für die konventionelle Standardversorgung bei Schlaganfallpatienten zu untersuchen.

Material und Methoden: Eine Open-Label-Pilotstudie wurde am “Princess Durru Shehvar” Kinder- und Allgemeinkrankenhaus in Hyderabad in Abstimmung mit dem “Extension Clinical Research Unit” des “Central Council for Research in Homoeopathy” durchgeführt. Fünfzig Patienten mit Episoden eines Schlaganfalls im Gehirn während unterschiedlicher Zeiträume wurden durch den NIHSS-Score (“National Institute of Health Stroke Scale”) vor und nach einer sechsmonatigen homöopathischen Behandlung untersucht.

Ergebnisse: Von 50 Patienten hatten zehn Patienten einen Schlaganfall vorüber einem Jahr und litten an Folgeerkrankungen; 27 Patienten hatten einen Schlaganfall vor einem Monat und bis zu einem Jahr, und 13 Patienten vor vier Wochen. Die Reduktion des NIHSS-Scores nach sechsmonatiger Behandlung war in allen drei Gruppen statistisch signifikant. Von 50 Patienten zeigten 5 (10%) Patienten eine deutliche Besserung, 17 (34%) eine mäßige, 16 (32%) eine leichte Besserung und 12 (24%) stagnierten. Die verwendeten Arzneimittel waren Causticum (n = 11), Arnica Montana (n = 7), Nux vomica (n = 6), Lycopodium (n = 6) und Lachesis (n = 3). Keiner der Patienten zeigte während der Studie eine Verschlechterung oder erlitt einen neuen Infarkt.

Schlussfolgerung: Diese Pilotstudie zeigte ermutigende Ergebnisse. Es werden weitere randomisierte Kontrollstudien vorgeschlagen, um die Wirksamkeit homöopathischer Arzneimittel bei Schlaganfällen zu demonstrieren.

公開標籤的先導研究，在腦中風病人的治療中加入順勢療法藥劑的有用性

背景：中風是神經系統發病率和死亡率第三大原因，全球每年發病率為每1,000人有0.2~2.5人。中風的臨床後遺症通常是破壞性的，1/2人有輕偏癱，1/3人有臨床抑鬱症，1/3人不能走路和1/6人有失語症。必須採取措施去停止中風的發展。順勢療法文獻提到許多處理中風的藥物。到目前為止，還沒有關於中風病人使用順勢療法的研究。因此，開展了先導研究，以研究中風病人在標準常規護理中加入順勢療法作輔助治療的有用性。

材料和方法：在海德拉巴（Hyderabad）的杜魯·謝瓦公主兒童綜合醫院（Princess DurruShehvar Children’s and General Hospital），與印度政府順勢療法研究中央委員會（CCRH）的延伸臨床研究單位合作，開展公開標籤性先導研究。在順勢療法治療之前和治療6個月之後，使用美國國立衛生研究院中風量表（NIHSS）對50名呈現不同階段的腦中風病人評分。

結果：50位病者中，10人已中風超過一年，並遭受後遺症；27人在1個月至1年之間中風發作；13人在4周內中風。治療後6個月，所有三組NIHSS評分均在統計學上有明顯減少。50位病者中，5人（10%）明顯好轉，17人（34%）中度好轉，16人（32%）輕度好轉，12人（24%）不變。發現有用的藥劑是苛性鉀（Causticum）（n=11）、山金車（Arnica Montana）（n=7）、馬錢子（Nux vomica）（n=6）、石松（Lycopodium）（n=6）和南美蛇毒（Lachesis）（n=3）。研究期間，所有病者都沒惡化跡象，也沒有任何新的梗塞。

結論：本先導研究取得了令人鼓舞的結果。建議進一步進行隨機對照試驗來評估順勢療法藥劑對中風的療效。