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A comparison of various potencies of Arnica montana as an adjunct therapy in hospitalised/ comatose patients with hemorrhagic stroke: An observational study

Abstract

Introduction: Hemorrhagic stroke contributes to 10-20% of stroke cases annually. The incidence is more common in men and increases with age is higher in low and middle-income countries and is increasing, predominantly in African and Asian countries. The case fatality rate is 25% to 30% in high-income countries, while it is 30% to 48% in low- to middle-income countries.

Arnica montana is one of the earliest medicines introduced in homeopathic literature for haemorrhagic phenomenon. Henry Clay Allen's Keynotes mentions, "*Apoplexy, ... in acute attack, controls haemorrhage and aids absorption; should be repeated and allowed to act for days or weeks unless symptoms call for another remedy*." Published research studies have also highlighted the antihemorrhagic properties of this remedy.

Primary Objective: To observe and compare the effects of daily doses of different potencies of Arnica montana, namely 3x, LM1 and 200CH, in hospitalised/ comatose patients, with haemorrhagic stroke, as an adjunct therapy.

Secondary Objective: To record the residual neurological deficits after recovery.

Methodology: On the basis of pre-determined criteria, between 1st January 2010 and 31st May 2023, 30 patients admitted to intensive care units in various hospitals of Delhi received adjunct Arnica montana in 3x (Group A, n=10), LM1 (Group B, n=10) and 200C (Group C, n=10) potencies. Clinical recovery was estimated through changes in the Glasgow Coma Scale (GCS) score daily over a period of 15 days. Clinical recovery time was assessed using Kaplan-Meier survival curves.

Results: A total of 30 patients were included for data analysis in this study [Males = 19; and Females=11]. The median age of the patients was 60 years [SD±7.2 years]. The clinical recovery (GCS 15) appeared much earlier in Group A than B & C. The residual neurological deficits were also lesser in Group A.

Conclusion: The 3x potency of Arnica montana may have a significant beneficial effect as an adjunct therapy in hemorrhagic stroke patients manifesting its concomitant features in comparison to LM1 and 200C, with milder and lesser number of residual neurological deficits. Further clinical studies may validate the preliminary observations of this study.

Keywords: hemorrhagic stroke, homeopathy, Arnica montana, potency, Glasgow coma scale, residual neurological deficits

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Introduction

Hemorrhagic stroke is due to bleeding into the brain by the rupture of a blood vessel. It may be further subdivided into intracerebral haemorrhage (ICH) and subarachnoid hemorrhage (SAH) and contributes to 10-20% of stroke cases annually. The incidence is more common in men and increases with age is higher in low and middle-income countries and is increasing, predominantly in African and Asian countries. Hemorrhagic stroke is associated with severe morbidity and high mortality and its progression is associated with worse outcomes. The case fatality rate is 25% to 30% in high-income countries, while it is 30% to 48% in low- to middle-income countries. Hence, early diagnosis and treatment are vital in view of the usual rapid expansion of hemorrhage, causing sudden deterioration of consciousness and neurological dysfunction.[1, 2]

Hypertension is the single most important cause of ICH, others being cerebral amyloid angiopathy, family history, chronic liver disease, diabetes mellitus, cerebral tumors, lifestyle factors viz. smoking, alcohol and substance abuse etc. On the other hand, the usual causes of spontaneous SAH are ruptured aneurysm of a cerebral artery, arteriovenous malformation, vasculitis, cerebral artery dissection, dural sinus thrombosis etc. and the enhancing risk factors include hypertension, oral contraceptive pills, substance abuse, and pregnancy.[1–3]

The primary injury is due to the compression by the hematoma and an increase in the intracranial pressure. Secondary injury is contributed by inflammation, disruption of the blood-brain barrier, edema, over-production of free radicals such as reactive oxygen species and release of hemoglobin and iron from the clot, which all contribute to peri-

lesional hypoperfusion. Usually, the hematoma enlarges in 3 hours to 12 hours. The enlargement of hematoma occurs in 3 hours in one-third of cases. The peri-hematomal edema increases in 24 hours, peaks around 5–6 days, and lasts up to 14 days.[4]

The clinical presentation of hemorrhagic stroke is usually acute onset headache, vomiting, neck stiffness, increase in blood pressure and progressing/ rapidly developing neurological signs viz. aphasia, hemiparesis, facial palsy, sensorimotor deficits etc. Coma occurs with the pontine and brainstem involvement, which occurs in about 10-20% of ICH cases.[1–3]

There are many different opinions on the treatment of hemorrhagic stroke since it requires a super-speciality (cardio-vascular, neurological, pulmonological, urological and surgical specialists, to name a few) care set-up with emergency medical care, nursing services and rehabilitation department. Conventional treatment includes managing blood pressure and raised intracranial pressure, hemostatic and anti-epileptic therapy, ensuring cerebro-protection and providing surgical treatment when required.[2,5,6]

In homeopathy, diseases are considered a dynamic derangement which presents itself as a psycho-neuro-physical phenomenon, and a 'tout ensemble' of these multitude of signs and symptoms determines the basis of selection of individualized homeopathic medicines.[7] After initial assessment and emergency management, computed tomography and various mandatory serological investigations, a more detailed clinical history, which needs to be anamnestic, with a detailed psychosomatic and lifestyle profiling is required to determine the tout ensemble which is then compared with pathogenesis of different remedies (homeopathic materia medica) to determine the most similar as the adjunct individualized homeopathic medication. One of the most important factors qualifying the sign or symptom as a part of this tout ensemble is their unique synchronicity with another clinically unrelated 'symptom complex' in usual circumstances/ clinical condition.

More than 100 years ago a homeopathic clinical repertory mentioned the following 31 remedies under the rubric 'Apoplexy': Acon., Apis, Arn., Aster., Bar. c., Bell., Cact., Camph., Caust., Chenop., Cinch., Croc., Crotal., Cupr. m., Formica, Glon., Hydroc. ac., Hyos., Junip. v., Kali br., Kali iod., Lach., Laur., Nux v., Op., Phos., Sep., Stram., Sul., Ver. a., Ver. v.[8]

Out of the above, Arnica montana is the most reputed remedy for treating the haemorrhagic phenomenon. Hahnemann published a proving of 150 symptoms of this remedy for the first time in 'Fragmenta de viribus medicamentorum: positivis sive in sano corpore humano observatis' in the year 1805. Henry Clay Allen's Keynotes mentions, *"Apoplexy;... in acute attack, controls haemorrhage and aids absorption; should be repeated and allowed to act for days or weeks unless symptoms call for another remedy."*[9] Published research studies have also highlighted the antihemorrhagic properties of this remedy.[10,11]

In individualised therapeutics like homeopathy, it is difficult to test the efficacy of any single remedy in a clinical condition. In this observational study, for instance, only those cased of ICH were considered, which manifested simultaneously the aforesaid clinical phenomenon along with the unique signs of Arnica montana, as mentioned in the inclusion criteria below.

But guided by the above stated efficacy of Arnica montana to a condition like hemorrhagic stroke, it was decided to observe the effect in such cases and determine its most efficacious potency- decimal, 50 millesimal or centesimal, and record the residual neurological deficits.

Primary objective

To observe and evaluate the effects of daily doses of different potencies of Arnica montana, namely 3x, LM1 and 200CH, in hospitalised/ comatose patients with haemorrhagic stroke, as an adjunct therapy.

Secondary objective

To record the residual neurological deficits after recovery in these patients

Methods

Setting

On 1st January 2010, while the author was employed with the Department of Ayush, Government of Delhi as a Senior Medical Officer (Homeopathy), he was called to consult for a below-poverty line comatose case of 49 years old male who had extensive ICH and was admitted to the ICU of a Government hospital in Delhi, with a grim outcome. On the insistence of family/ attendants and with the approval of treating doctors (obtained by them), after recording anamnestic psycho-somatic case profiling as per the guidelines of homeopathy, and observing the characteristic indications, he was prescribed Arnica montana 3X, 5 drops on tongue every 8 hours. A favorable response to the adjunct homeopathic treatment, paved the way to its application in various private and Government owned hospitals in Delhi, referred mostly by gracious patients/ attendants and a few even by nursing staff who observed the favorable effects of this adjunct therapy. The study was continued even when the author resigned from Government service and established his personal Holistic Homoeopathic Clinic and Research Center in Delhi on 1st August 2016. The last patient for this observational study was recruited on 25th April 2023.

On the basis of pre-determined criteria, between 1st January 2010 and 31st May 2023, 30 patients admitted to intensive care units in various hospitals of Delhi received adjunct Arnica montana in 3x (Group A, n=10), LM1 (Group B, n=10) and 200C (Group C, n=10) potencies.

The family/ attendants also signed an informed consent form for subsequent data analysis and publication with anonymity and confidentiality of the patients being maintained.

Inclusion/ Exclusion criteria

Only those patients were included in the study:

a. comatose and diagnosed with spontaneous ICH form of hemorrhagic stroke

b. displayed/ manifested any of these four objective signs conforming with the pathogenesis of Arnica montana- warm forehead with cold nose and extremities; heat of upper body and coldness of lower; the face or head and face alone is hot, the body cool; deathly coldness of forearms

Post-traumatic cases were not included in the study.

Variables

These comprised of demographic details and comorbidities of the ICH patients.

Homeopathic treatment protocol

All the enrolled patients received Arnica montana in decimal, 50 millesimal or centesimal potencies, after the insistence of their family/ attendants and with the approval of treating doctors (obtained by them). Each patient was assessed initially and clinical recovery was

estimated through changes in the Glasgow Coma Scale (GCS) score daily over a period of 15 days by the author.

The patients were also followed up post recovery for a period of 8 weeks to record the residual neurological deficits, and those who manifested were continued on the same potency.

Decimal potency- 3x (Reckeweg manufacturing) was administered as 5 drops on the tongue every 8 hours.

50 Millesimal potency - LM1 (Homoeopathy International manufacturing) was prepared by dissolving one globule in 15 ml of water to which 8 drops of dispensing alcohol were added and 5 drops to be administered on the tongue every 8 hours, after succusing 10 times.

Centesimal potency- 200 CH (Reckeweg manufacturing) was prepared by dissolving one drop in 15 ml of water to which 8 drops of dispensing alcohol were added and 5 drops to be administered on the tongue every 8 hours.

Data analysis

The patient data was anonymized by removing direct identifier variables for the analysis. Demographic data and coexisting morbidities were obtained from the patient's recorded history. The response to the adjunct homeopathic treatment was also assessed daily using GCS. IBM SPSS Statistics 21.0 was used for data analysis. Clinical recovery time was compared using Kaplan-Meier survival curves. Demographic details were expressed using descriptive statistics.

Results

The 30 patients included for data analysis in this study [Males = 19; and Females = 11] and their demography and comorbidities can be seen in Table 1.

Table 1 Baseline characteristics and Comorbidities of ICH patients

Variables	Group A	Group B	Group C
Age (mean, in years)	60	60.7	61.5
Gender			
Males	6	6	7
Females	4	4	3
Coexisting conditions/ Comorbidities			
Bronchial asthma	1		
Substance abuse	1		
Diabetes mellitus	5	4	3
Hypertension	6	5	6
Coronary artery disease	3	1	1
Breast cancer	1		
Dyslipidemia		4	1
Migraine		1	1
HRT (Post menopause)		1	
Rheumatoid arthritis			1
Recurrent Respiratory tract infections with fever			1
Rheumatoid heart disease (RHD), Valvuloplasty			1

We observed that time taken for all the Group A (S. No 1-10) patients to reach GCS 15 was 9 days (Conventional therapy + Arnica Montana 3X) , as compared to 12 days in all of the Group B (S. No 11-20) (Conventional therapy + Arnica Montana LM1) and 13 days in all of the Group C (S. No 21-30) (Conventional therapy + Arnica montana 200 CH) (Table 2).

Table 3 Residual neurological deficits in all the three groups

Patient no	Group	Residual neurological effects
1	A	Nil
2		Nil
3		Nil
4		Dysphagia for 7 days
5		Nil
6		Nil
7		Nil
8		Nil
9		Nil
10		Left hemiparesis, lasted for 20 days, required physiotherapy/ occupational therapy
11	B	Sensory loss on face, with loss of taste, lasted for 6 weeks
12		Nil
13		Nil
14		Nil
15		Nil
16		Nil
17		Nil
18		Wallenberg's syndrome x 15 days
19		Right hemiparesis lasting for 6 weeks
20		Vertigo episodes on and off x 1 month

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Table 3 Continued...

Patient no	Group	Residual neurological effects
21	C	Nil
22		Dysphagia x 10 days
23		Nil
24		Nil
25		Vertigo x 1 month
26		Left hemiparesis lasting for 8 weeks
27		Sensations diminished left half of body x 4 weeks
28		Nil
29		Nil
30		Nil

The clinical recovery (GCS 15) appeared much earlier in Group A, followed by B & then C as can be visualised in the Kaplan-Meier survival curves below (Figure 1).

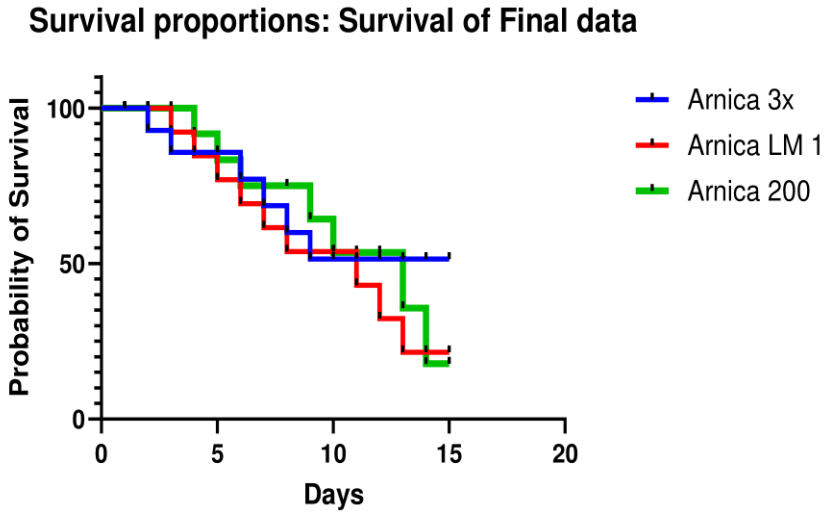

Figure 1 Kaplan-Meier survival curves.

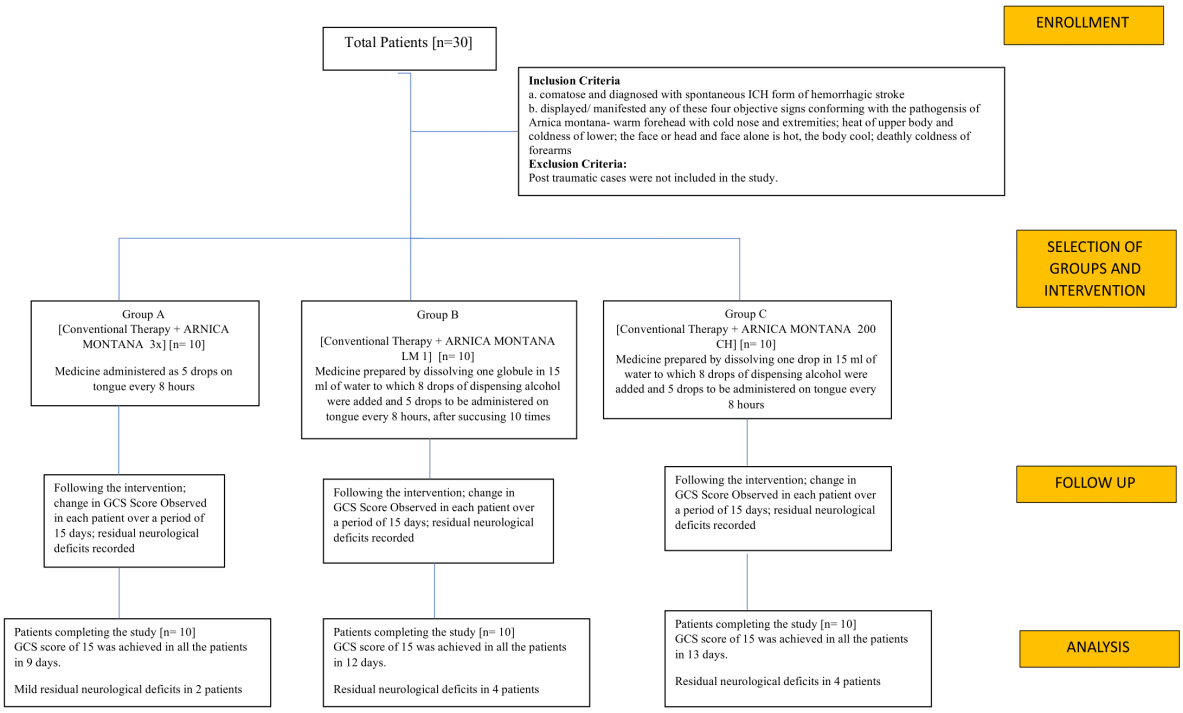

Figure 2 Consort diagram.

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Discussion

Biomedicine is human-centric and incognisant of our relationship and deep connection with nature and the planet. The current dominance of biomedicine in the health systems of countries like India, which are home to the long-standing traditional medicine (TM) systems, is rooted in their colonial histories. The Indian health system respects and honours pluralism and the different perspectives and insights into health as provided by indigenous communities through their knowledge of life, health, balance, and nature.[12] According to the World Health Organization (WHO), 88 per cent of all countries are estimated to use traditional medicine and about 40 per cent of existing pharmaceutical formulations are based on natural products.[13]

The biggest advantages of practicing homeopathy in India is that the Indian health system respects and honours pluralism and its inclusive approach renders the possibility of amalgaming the conventional and traditional and complementary medicines under one roof. Most Government operated OPDs, PHCs and hospitals and quite a few private ones are offering integrated health care services. This has created the possibility of evaluating the effect of a homeopathic medicine in the super-speciality set-ups.

To document and evaluate the effect of a 'single homeopathic remedy' in 'one clinical condition' can be quite a daunting task, as I learned while conducting this study. While I was consulted for a number of stroke patients in this long drawn recruiting period of 161 months, many of them were diagnosed as ischemic strokes, others presented as SDH, a few were post-traumatic cases, some others were non-comatose ICH etc., and I had to wait patiently to recruit just spontaneous comatose ICH cases for this study. Also, what added to the challenge was identifying the indications, before administering the chosen remedy, in this study Arnica montana, since comatose patients display only a few signs which can be compared with pathogenesy of the remedy in materia medica. Few cases of comatose ICH patients during this interval displayed indications/ signs of other homeopathic remedies.

Figure 3 The plant of Arnica montana.[14]

While I had the opportunity to follow-up these patients and record their progress in improving GCS scores, I could not document the serological markers nor could I document the recovery in the CT scans, as that was not permitted.

Numerous published research papers and case studies highlight the therapeutic effect of homeopathic medication Arnica montana in patients with extravasation of blood, even though the underlying mechanisms of its action remain a subject of deliberation and warrants further exploration to gain a deeper understanding of the physiological and molecular processes at play.[10,11,15]

Further, while establishing the plausibility of the therapeutic efficacy of homeopathic medicines, it is also imperative to evaluate the impact of various available potencies of same medicine in identical diagnostic condition. A few studies in this dimension have already been published.[16,17]

Out of the 30 patients recruited for the study, we find that the most common comorbidity was HT found in 17, followed by DM documented in 12.

While the number of patients recruited for the study might seem small, but the results are certainly instructive. Since all the patients in the study recovered and achieved the GCS score 15, it shows that Arnica montana 3x may have a superior therapeutic effect in ICH cases, provided the patient manifests its signs, as in its pathogenesy (materia medica).

The residual neurological deficits were comparatively milder and observed in two patients of Group A compared to four each in Groups B & C.

Conclusion

The 3x potency of Arnica montana may have a significant beneficial effect as an adjunct therapy in hemorrhagic stroke patients manifesting its concomitant objective signs in comparison to LM1 and 200C with lesser residual neurological deficits. Despite the limited number of study subjects, homeopathy showed some promising results. Further well planned controlled clinical studies may validate the preliminary observations of this study.

Study limitations

The limitation of this study was that the findings are only representative of a small group of patient's family members/ attendants who opted and consulted for adjunct homeopathic treatment and cannot be generalized for the entire population set due to the limited sample size. And of course, there is a lack of control group in this study. Another limitation was the lack of necessary permissions due to which the CT scans and serological markers could not be included.

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None.

Conflicts of interest

The author declares that there are no conflicts of interest.

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