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Evaluation of homoeopathic medicines as add-on to institutional management protocol in Acute Encephalitis Syndrome: An exploratory observational comparative study

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ABSTRACT

Background: Acute Encephalitis Syndrome (AES) treated according to Institutional Management Protocol (IMP) has considerable mortality and morbidity. The study was undertaken to evaluate the effect of homoeopathic treatment (H) as an add-on to IMP (IMP + H) for children affected with AES.

Materials and Methods: This was an exploratory observational study carried out in the IPD setting (epidemic ward) of Baba Rhaghav Das Medical College and Nehru Hospital, Uttar Pradesh (July to November 2012) using convenience sampling. Children whose guardians gave consent were treated with IMP + H and rest remained on IMP only. Glasgow outcome scale was used at discharge for the final outcome.

Results: 151 children (121 in IMP + H and 30 in only IMP) diagnosed with AES (aged 6 months to 18 years) were enrolled. The results showed 12 (9.9%) death out of 121 children administered IMP + H whereas it was 13 (43%) out of 30 children on IMP alone. Proportional odds analysis with covariate adjustment showed added benefit of Homoeopathy in children with AES as compared to IMP alone (adjusted odds ratio, 0.17, 95% confidence interval 0·06–0.45, $P = 0·0001$). The most useful medicines are *Belladonna, Stramonium, Arsenicum album, Helleborus, Bryonia alba, Sulphur, and Cuprum metallicum.*

Conclusion: This exploratory observational study suggests reduction of mortality and morbidity with add-on homoeopathic medicine. Further randomized controlled trial study with comparable groups is desirable. If findings are confirmed by subsequent research, add-on Homoeopathy might have relevant implication for its management.

Keywords: Acute Encephalitis Syndrome, Homoeopathy, India, Institutional management protocol, Morbidity, Mortality, Observational study

INTRODUCTION

Acute Encephalitis Syndrome (AES) is defined as acute onset of fever and changes in mental status (including symptoms such as confusion, disorientation, coma, or inability to talk) and/or new onset of seizures (excluding simple febrile seizures) in a person of any age, at any time of year (World Health Organization).[1] More than 100 different pathogens can cause AES: Viruses, bacteria, mycobacteria, rickettsia, and rarely toxoplasma. Substantial cases are viral in origin; however, exact etiology still remains obscure in 68–75%.[2-5]

In the most robust, prospective studies conducted in western industrialized countries, a minimum incidence of 10.5/100,000 AES cases was reported for children and 2.2/100,000 for adult. The minimum incidence for all ages was 6.34/100,000 in a tropical setting.[6] The National Vector Borne Disease Control Programme Report (2008–13)[7] describes the incidence of AES in 17 regions of India. A total of 36,120 cases were notified in those areas, of which 5,521 died; the highest mortality being from Uttar Pradesh (UP), followed by Assam and Bihar. In UP, the disease affects mainly children; >2000 cases of AES are reported each year since 2006.[2]

The spectrum of brain involvement and the outcome of the disease are dependent on the specific pathogen, the immunological state of the host and a range of environmental factors. Although specific therapy is limited to only several viral agents, correct diagnosis, and supportive and symptomatic treatment (when no specific therapy is available)[8]. The supportive and symptomatic management/Institutional Management Protocol (IMP) includes intravenous (I/V) fluids, correction of blood sugar, suction oxygen, I/V anticonvulsant, use of ambubag if necessary, catheterization, use of mannitol, injection paracetamol, input/output charting, pulse, respiratory rate, temperature and blood pressure monitoring.[8]

A double-blind placebo controlled trial of administration of interferon-α-2a to Vietnamese children indicated no benefit.[9] Similar results were also found with oral Ribavirin for Japanese encephalitis (JE) in children in UP[10] and Dexamethasone in Bangkok.[11] Researchers from the School of Tropical Medicine, Kolkata, in collaboration with the Central Council for Research in Homoeopathy (CCRH) found that homoeopathic medicine *Belladonna* is able to prevent pock formation on the chorioallantoic membrane due to the JE virus.[12] Again, the same investigators tested the preventive role of *Belladonna* in an *(in vivo)* mouse model.[13] Single case reports of managing encephalitis with Homoeopathy suggest beneficial effects.[14,15]

Some studies investigated the effect of adjunctive Homoeopathy in critically ill patients on conditions like severe sepsis[16] and tracheal secretions of critically ill patients.[17] Kent's repertory lists 28 medicines under rubric "inflammation of the brain"[18] but no clinical study has yet been conducted to establish their actual usefulness. Homoeopathy might be used as an adjunct to IMPs in the treatment of children with AES. Keeping this in view, the Council conducted the present study to evaluate homoeopathic treatment (H) as an add-on to IMP in reducing the mortality and disability associated with AES and to detect useful medicines to be included in a future randomized controlled study.

MATERIALS AND METHODS

Study Design

The study was conducted by means of convenience sampling. It was a preliminary exploratory observational study, wherein homoeopathic intervention was given as an add-on to IMP to children with AES whose parents/guardians were willing to administer homoeopathic medicines; the children whose parents/guardians who did not give consent were subjected to IMP alone.

Setting

Clinical Trial Unit (Homoeopathy) at Baba Rhaghav Das (BRD) Medical College and Nehru Hospital, Gorakhpur, UP. The patients admitted in the epidemic ward were approached by the investigators to seek consent. Laboratory investigations were undertaken by the institutional state-of-art reference laboratory. Ethical clearance was obtained from the Ethical Committee of the Council. The investigators were given training on the study protocol before the initiation of the study.

Inclusion criteria

- Children above 6 months and less than 18 years of age at any time of year with the acute onset of fever of ≤15 days and
- a change in mental status (including symptoms such as confusion, disorientation, coma, or inability to talk)
- and/or new onset of seizures
- Written informed consent

Exclusion criteria

- Single generalized convulsion lasting <15 minutes, and who recovers consciousness within 60 minutes of the seizure.

Screening

During the period from July to November 2012 (monsoon or postmonsoon), the children admitted in the epidemic ward of BRD Medical College and Nehru Hospital and diagnosed with AES were screened for the enrolment. The children were assessed for severity at admission using the Modified Glasgow Coma Scale (MGCS), low scores indicating reduced level of consciousness.[19-21]

Intervention

Institutional Management Protocol

All the children were given IMP for managing their symptoms and signs as per presentation, such as fever, focal neurological deficit, cerebral and/or pulmonary edema, anaemia, gastrointestinal haemorrhage, feeding problems, dysnoea, circulatory problems, seizures, renal insufficiency, myocarditis and heart failure, thrombocytopaenia, etc.[8,22]

Homoeopathic intervention

The medicines were procured from Good Manufacturing Practices certified companies in Centesimal potencies Hahmnemannian (CH), which include 6 CH, 30 CH and 200 CH. The investigators themselves administered the first dose of indicated medicine to the children and took care for its compliance for administration of subsequent doses which were given by their guardians. Indicated medicine customized to each patient as per symptoms/signs was given in 30 CH potency in one drop (=0.050 mL) orally. Any clinical change observed after administration (improvement/deterioration) lead to change of potency/repetition/medicine.

Outcome Measures and Follow-up

The Glasgow Outcome Scale (GOS)[23] was to interpret the outcome at discharge from the Hospital. The scale has five levels: Good recovery (normal life), moderate disability (patient independent in daily life), severe disability (patient dependent for daily support), neuro-vegetative stage (patient unresponsive and speechless for weeks or months) and death. The children were assessed at least twice per day or more frequently as per need until discharge.

Note was used also made of the time to resumption of oral feeding and Length Of hospital Stay (LOS). As a rule, the children were discharged from the hospital as soon as they could be fed by mouth and were afebrile. Children whose parents chose to take them home irrespective of the response to treatment were categorized as "Discharge On Patient's/guardians Request" (DOPR). However, some patients did not wait for discharge, but just left the hospital without informing the staff; this condition was referred as "Leaving Against Medical Advice" (LAMA). The patients' functional status at the time of discharge was recorded in terms of ability to comprehend speech, feed orally, speak, and walk.

Sample Size

Being an exploratory study first of its bind in AES, in the IPD settings using homoeopathic intervention in one arm, convenience sampling was performed to enroll the children.

Statistical Methods

All the descriptive statistical analyses were performed using SPSS version 20. Mean and standard deviation were used to express continuous variables. Median, interquartile range and percentages were used to present ordinal variables and proportions. GOS was dichotomized as "good" (i.e., recovery with normal functioning, recovery with disability) or "bad" (death and neuro-vegetative state). The cases of LAMA and DOPR were not considered for analysis. Odds Ratio (OR), Relative Risk (RR), and absolute benefit increase were also calculated. Logistic regression was used to estimate adjusted OR and 95% confidence interval (CI). OR estimate was adjusted for MGCS collected which has baseline differences. $P < 0.05$ was considered significant.

RESULTS

A total of 1,898 children with AES were admitted to BRD Medical College and Nehru Hospital during the study period, however, only 165 were screened for eligibility of inclusion. From these, 14 children were excluded, and 151 children who met the inclusion criteria were enrolled and analyzed. Of these, 121 children were administered IMP + H and 30 IMP alone. The flow chart of patients in the study is depicted in Figure 1. The baseline characteristics of the children are described in Table 1. Although there was difference in the total number of patients between the groups, their baseline characteristics were comparable, except for mean MGCS score (IMP + H: 8 ± 2.8; IMP = 6.6 ± 2.3; $P < 0.05$), disorientation (IMP + H = 68%; IMP = 90%, $P < 0.05$) and speech difficulties (IMP + H = 73%; IMP = 63%, $P < 0.05$).

Overall analysis showed 12 (9.9%) deaths in H + IMP group and 13 (43%) in IMP group (adjusted OR for mGCS score: 0.17, 95% CI = 0·06–0.45, $P = 0·0001$). At discharge, IMP + H group demonstrated a trend toward lower death rate compared to IMP (RR, 0.2; 95% CI: 0.1–0.4; $P = 0.0001$) [Table 2]. Eight children either left against medical advice or were discharged on guardian's request.

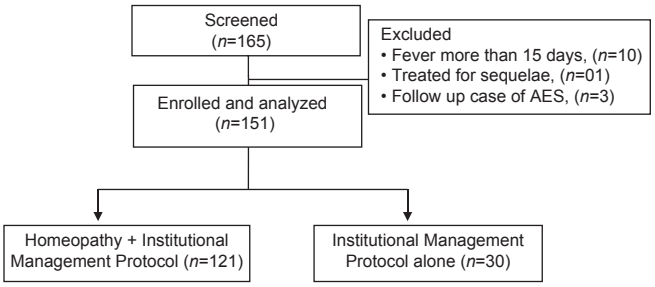

Figure 1: Flow of patients in the study

Table 1: Baseline characteristics of patients

Characteristic	Homoeopathy + IMP (*n*=121)	IMP (*n*=30)	*P*
Demographic characteristics			0.47
Age in years median (IQR)	5 (3-8)	4 (3-8)	
Gender			0.39
Male	58 (47.9)	17 (56.7)	
Female	63 (52.1)	13 (43.3)	
ICU admission	22 (18.3)	15 (50)	
IPD admission	99 (82.7)	15 (50)	
Clinical presentation			
Fever	121 (100)	30 (100)	0.68
Altered sensorium	118 (97.5)	30 (100)	0.38
New onset of seizures	107 (88.4)	25 (80)	0.41
Plum and Posner scale			0.1
Well alert	4 (3.3)	0	
Lethargic	46 (38)	4 (16.7)	
Obtunded	70 (57.8)	23 (76.6)	
Unconscious	01	03	
Modified Glasgow coma scale in children	8.3±2.8	6.6±2.3	0.03
Overall GCS score range			
3-5	13 (10.7)	8 (26.7)	
6-8	55 (45.5)	16 (53.3)	
9-11	29 (24)	4 (13.3)	
12-15	24 (19.8)	2 (6.7)	
AVPU			0.2
Alert	04	00	
Response to voice	26	01	
Response to pain	90	26	
Unresponsive	01	03	
Other symptoms/signs present			
Headache	61 (50)	9 (30)	0.06
Vomiting	82 (68)	23 (77)	0.37
Floppiness	56 (46.3)	15 (50)	0.74
Breathlessness	41 (34)	10 (33)	0.95
Swelling of the body	59 (49)	14 (47)	0.83
Abdominal pain	36 (30)	20 (67)	0.70
Anorexia	59 (49)	18 (60)	0.27
Feeding and swallowing difficulties	80 (66)	25 (83)	0.14
Convulsion with uprolling of eyeball	105 (87)	26 (87)	0.98
Diarrhea	30 (25)	8 (27)	0.83
Disorientation	86 (68.6)	27 (90)	0.01
Meningeal signs	17 (14)	3 (10)	0.55
Generalized seizures	98 (81)	25 (83)	0.76
Gross motor problems	110 (91)	27 (90)	0.40
Speech difficulties	88 (73)	19 (63)	0.03
Cognitive problems	82 (68)	14 (47)	0.96
Behavioral problems	62 (51)	11 (36)	0.51
Laboratory variables blood			
Hemoglobin (g%±SD)	10.2±1.4 [114]	10.3±1.1 [29]	0.98
Mean total leucocyte count, (106/L±SD)	11.6±9.7 [114]	16.5±22.1 [29]	0.06
Mean neutrophil percentage±SD	61±10.2 [114]	62.5±10.4 [29]	0.56

Contd...

Table 1: Contd...

Characteristic	Homeopathy + IMP (*n*=121)	IMP (*n*=30)	*P*
Mean lymphocytes percentage±SD	34.2±10.1 [114]	33.4±12.1 [29]	0.77
SGOT mean U/L	84.9±110.2 [107]	113.4±156 [24]	0.29
SGPT mean U/L	86.5±108.9 [107]	93.1±73.2 [24]	0.77
Serum urea g/dL	39.7±25.9 [83]	45.7±45.3 [20]	0.40
CSF			
Mean CSF cell count/mm^3±SD	54.8±142.6 [99]	34.9±33.8 [22]	0.51
Splenomegaly	17 (14)	4 (13)	0.39
Hepatomegaly	31 (25.6)	8 (26.7)	0.63

Values are presented in *n* (%), mean±SD, median (Q1-Q3), (number of patients). SD: Standard deviation; IQR: Interquartile range; ICU: Intensive Care Unit; IPD: In Patient department; GCS: Glasgow Coma Scale; AVPU: A=Patient Alert, V=Responsive to Voice, P=Responsive to Pain, U=Unresponsive; SGOT: Serum Glutamic-Oxaloacetic Transaminase; SGPT: Serum Glutamic-Pyruvic Transaminase; CSF: Cerebrospinal Fluid

Table 2: Outcome of the adjunctive homoeopathic treatment in children suffering from AES

Outcome	H+IMP (*n*=121)*		IMP (*n*=30)*		RR (95% CI); *P*	ABI (95% CI)	OR (95% CI); *P*	*P*
Overall population								
Effectiveness analysis					0.2 (0.1−0.4); 0.0001		0.17 (0.65-0.45); 0.0001[¥]	
Bad (death)	12 (9.9)		13 (43.3)			33.4 (14.9-51.9)		
Good (recovery with normal functioning)	99 (81.8)	104 (85.8)	7 (23.3)	13 (43.3)		42.6 (23.8-61.4)		
Good (recovered with disability)	5 (4)		6 (20)					
Subgroup analysis								
ICU population	H+IMP (*n*=22)[#]		IMP (*n*=15)[#]					
Effectiveness analysis					0.3 (0.14-0.76); 0.009		0.12 (0.02-0.6); 0.007	
Bad (death)	5 (22.7)		10 (66.7)			43.9 (14.3-73.5)		
Good (recovery with normal functioning)	15 (68.2)	16 (72.7)	3 (20)	4 (26.6)		46 (16.9-75.2)		
Good (recovered with disability)	1 (4.5)		1 (6.6)					
IPD population	H+IMP (*n*=99)[Ψ]		IMP (*n*=15)[Ψ]					
Effectiveness analysis					0.3 (0.08-0.9); 0.04		0.2 (0.05-1.08); 0.06	
Bad (death)	7 (7)		3 (20)			12.9 (7.9-33.7)		
Good (recovery with normal functioning)	84 (84.8)	88 (88.8)	4 (26.6)	9 (59.9)		28.9 (3.3-54.4)		
Good (recovered with disability)	4 (4)		5 (33.3)					
Others	H+IMP (*n*=121)		IMP (*n*=30)					
Resumption of oral feeding in days median (IQR)	3 (2-5) [98]		7.5 (5-13) [8]					0.0001[a]
Hospital stay in days (mean±SD)	10.8±8.4		10.8±8.6					0.99[b]

Values are presented in *n* (%), median (Q1-Q3) [*n*], mean±SD. *LAMA in H+IMP=5, IMP=3; *DOPR: IMP+H=0, IMP=1; [#]LAMA in H+IMP=1, IMP=1; [Ψ]LAMA in H+IMP=4, IMP=2, DOPR: IMP+H=0, IMP=1; [¥]Adjusted OR for GCS. [a]Mann-Whitney U-test, [b]Independent t test. LAMA: Leave Against Medical Advice; DOPR: Discharge on Patient's Request; RR: Relative Risk; ABI: Absolute Benefit Increase; ICU: Intensive Care Unit; IPD: In Patient Department; GCS: Glasgow Coma Scale; SD: Standard Deviation; IMP: Institutional Management Protocol; IQR: Interquartile Range

The outcomes of patients admitted to Intensive Care Unit (ICU) and epidemic ward, were also analyzed separately; the results are described in Table 2. In ICU subgroup, the death rate was 10/15 (66.7%) and 5/22 (22.7%) for IMP and IMP + H, respectively (OR = 0.12, 95% CI: 0·02–0.6, *P* = 0·007). At discharge, group IMP + H demonstrated a trend toward lower death rate relative to IMP. Similarly, among the children who remained in the epidemic ward, 3/15 (20%) and 7/99 (7%) of 99 in IMP and IMP + H groups died, respectively (OR = 0.2, 95% CI: 0·05–1, *P* = 0·06). The response as per mGCS score at admission for the ICU group described in Table 3, which shows no deaths among the children with scores 3–5 in IMP + H group.

There was statistically significant difference (*P* = 0.0001) in resumption of oral feeding. However,

Table 3: Outcome of patients as per mGCS in ICU

mGCS range at baseline/ admission	Total children in H+IMP	Outcome as per GOS			Total children in IMP	Outcome as per GOS		
		Death	Recovered	Recovered with disability		Death	Recovered	Recovered with disability
3-5	3	0	2	1	5	3	0	1
6-8	15	4	11	-	9	6	3	-
9-11	4	1	2	-	1	1	0	0
Total	22	5	15	1	15	10	3	1

ICU: Intensive Care Unit; IMP: Institutional Management Protocol; MGCS: Modified Glasgow Coma Scale; GOS: Glasgow Outcome Scale

no difference was observed in LOS ($P > 0.05$). No adverse events were noted in association with the homoeopathic treatment. The probable causes of death were: Respiratory failure ($n = 4$), aspiration pneumonia ($n = 8$), multi-organ failure ($n = 1$), cardiorespiratory failure ($n = 4$), and others ($n = 8$).

A total of 162 prescriptions were made to 121 children along the study period. The frequency of medicines prescribed is given in Table 4. The most useful medicines were *Belladonna*, *Stramonium*, *Arsenicum album*, *Helleborus*, *Bryonia alba*, *Sulphur* and *Cuprum metallicum*. Homoeopathic medicines were prescribed with a median of 2 doses (range: 1–12 doses) in a median interval of 12 h (1–24 h). The indications of the most frequently prescribed medicines are described in Table 5.

The patients ($n = 10$) suffered from minor disabilities, including: Loss of speech and hearing (H + IMP: 1; IMP: 1), loss of speech only (H + IMP: 1; IMP: 1), loss of vision (H + IMP: 1; IMP: 1), standing, walking, speech and memory problems (H + IMP: 1; IMP: 1), behavioral problem (H + IMP: 1; IMP: 0), and squint (H + IMP: 0; IMP: 1).

DISCUSSION

In India, approximately 70% of the disease burden corresponds to the state of UP, an epicenter for this killer disease. Although the incidence of JE is decreasing, the annual incidence of JE-negative AES remained relatively stable along the period from 2008 to 2012.[24] In 2013 alone, 3,008 patients suffering from AES were admitted to different government hospitals at eastern UP, 640 of whom died.[25] Jain *et al.*[26] conducted a study in North India (UP) including 1578 patients, out of whom 59.4% died from viral AES, including JE, dengue, mumps, measles, varicella-zoster, etc., while 5.9% deaths were due to AES of unknown etiology. Residual neuropsychiatric disability at discharge due to AES of viral and unknown etiology was found in 47.4% and 3.2%, respectively.[26]

Table 4: Medicines prescribed to AES children in IMP+H group

Name of medicine prescribed with potency	no. of patients prescribed	Number of prescriptions in percentage
Belladonna 30	39	24.1
Stramonium 30	17	10.5
Arsenicum album 30	15	9.3
Helleborus niger 30	15	9.3
Bryonia alba 30	13	8.0
Sulphur 30	11	6.8
Cuprum metallicun 30	6	3.7
Nux vomica 30	6	3.7
Cinchona officinalis 30	4	2.5
Causticum 30	3	1.9
Mercurius solubilis 30	3	1.9
Opium 30	3	1.9
Sulphur 200	3	1.9
Arnica 30	2	1.2
Bellodonna 6	2	1.2
Hyoscyamus 30	2	1.2
Phosphorus 30	2	1.2
Pulsaltilla 30	2	1.2
Antimonium tartaricum 30	1	0.6
Apis mellifica 30	1	0.6
Arsenicum album 200	1	0.6
Bryonia alba 200	1	0.6
Calcarea carbonica 200	1	0.6
Calcarea phosphorica 30	1	0.6
Cantharis 30	1	0.6
Chamomilla 30	1	0.6
Lachesis 30	1	0.6
Phosphorus 200	1	0.6
Rhus toxicodendron 30	1	0.6
Stramonium 200	1	0.6
Tarentula 30	1	0.6
Veratrum album 30	1	0.6

In our study, the death rate in IMP group was 43% (out of 30) whereas it was 9.9% (out of 121) in H + IMP group, which points to the benefits of adjunctive homoeopathic treatment in the survival of children. The OR for reduced mortality

Table 5: Indications of prescribed medicine

Medicine	Indications
Apis mellifica	Edema generalized, redness, fever with chill
Arsenicum album	Thirst for a small quantity of water at frequent intervals
	Fever; aggravation: 12-2 am and 12-2 pm
	Restlessness mentally and physically
	Black watery stool and vomiting < eating and drinking after
Arnica	Fever: Upper part of body hot, lower cold
Belladonna	Fever: High, skin dry, red hot, sudden onset, headache congestive, red face, throbbing, violent delirium, disposition to bite, spit, strike and tear things
Bryonia alba	Thirst increased for large quantity of water, mouth and tongue dry, constipation with no desire for stool for several days
Calc. carb	Fever with perspiration on head, vomiting ;less than milk after, staring of eyes, constipation
Causticum	Paralytic weakness of limbs
China	Fever intermittent, loss of appetite, irritable, generalized weakness
Cuprum met	Convulsion beginning in the thumb and fingers, tonic spasm of the body, clenching thumb and fingers
Helleborus	Stupor, interrupted by shrieking, vacant look, stares but does not recognize those around, sensorial depression
Hyosyamus	Delirium with restlessness, talks of imaginary things, makes irrelevant answers, convulsion without consciousness
Lachesis	Protrusion of tongue, *Agg*. evening after sleep, hot patient
Merc sol	Thirst increased with moist mouth and tongue, reproaches others
Nux vomica	Convulsion with consciousness, chilly patient, desire to be covered
Opium	Pupils constricted
Phosphorus	Fever high grade, continuous, burning in body with thirst for cold water
Pulsatilla	Fever without thirst, dry mouth and tongue
Stramonium	Delirium, biting, hitting, picking of clothes
Sulphur	H/O skin eruptions, hot patient, heat of palms and soles, sensation of burning on head

and morbidity also showed some effect in favor of add-on Homoeopathy. The large availability of patients, appropriate coordination between administrative staff, doctors, and nursing staff at BRD Medical College and Nehru Hospital enabled us to conduct the study. The lack of adverse effects and the administration of homoeopathic medicines via the oral route being easy and possible even in ventilated/intubated patients are relevant advantages, which add further strength to the study.

However, as the groups were non-comparable and nonrandomized, definite conclusion cannot be drawn. Bias cannot be ignored, due to the difference in the number of patients in each group and MGCS scores at baseline. These shortcomings might be overcome in a Randomized Controlled Trial (RCT).

The medicines fetching highest prescriptions are given in data label. Whereas the medicines in blue, yellow, rust and light green colors have been prescribed in 1, 2, 3, and 4 patients each, respectively.

CONCLUSION

The present exploratory observational study suggests reduction of mortality and morbidity with add-on homoeopathic medicines. Further RCT studies with comparable groups are desirable. If findings are confirmed by subsequent research, add-on homoeopathy might have relevant implications for the management of AES in children.

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सार

पृष्ठभूमि: संस्थागत प्रबंधन नयाचार (IMP) के अनुसार तीव्र मस्तिष्कशोथ संलक्षण (AES) की चिकित्सा में मृत्यु तथा अस्वस्थता दरें काफी अधिक होती हैं। यह अध्ययन IMP के पूरक के रूप में होम्योपैथिक चिकित्सा (H) का मूल्यांकन करने के लिए किया गया।

विधि: यह समन्वेषी प्रेक्षणमूलक अध्ययन बी. आर. डी. चिकित्सा महाविद्यालय व चिकित्सालय, उत्तर प्रदेश के महामारी वार्ड में (जुलाई 2012-नवंबर 2012) सुविधानुसार प्रतिचयन का उपयोग कर किया गया। जिन बच्चों के अभिभावकों ने सहमति दी, उनकी चिकित्सा IMP+H से की गई। शेष बच्चे केवल IMP पर रहे। छुट्टी के समय अंतिम परिणाम निकालने हेतु ग्लाज्गो परिणाम मापक्रम का उपयोग किया गया।

परिणाम: AES के लक्षण वाले (6 माह से 18 वर्ष की आयु के) एक सौ इक्यावन बच्चों (IMP+H में 121 तथा केवल IMP में 30) का नामांकन किया गया था। परिणामों ने दर्शाया कि IMP +H दिए गए 121 बच्चों में से केवल 12 (9.9%) की मृत्यु हुई जबकि केवल IMP पर रहे 30 बच्चों में से13(43%) की मृत्यु हो गई। नियंत्रण चर समायोजन सहित संयोगानुपातिक विश्लेषण से केवल IMP (समायोजित OR,0.17, 95% CI 0·06–0.45, p=0·0001) की तुलना में AES से ग्रस्त बच्चों में होमियोपैथी के वर्धित लाभ का पता चला। सर्वाधिक उपयोगी दवाएँ हैं– बेलाडोना, स्ट्रैमोनियम, आर्सेनिकम एलबम, हेलेबोरस,ब्रायोनिआल्बा, सल्फर तथा क्यूप्रम मेट।

निष्कर्ष: यह समन्वेषी प्रेक्षणमूलक अध्ययन पूरक होमियोपैथिक दवा से मृत्यु तथा अस्वस्थता दरों में कमी इंगित करता है। तुलनात्मक समूहों पर आगे और RCT अध्ययन वांछित है। यदि परवर्ती अनुसंधानों में इन परिणामों की पुष्टि होती है, तो इसके प्रबंधन में पूरक होम्योपैथी के सुसंगत निहितार्थ हो सकते हैं।

मुख्य शब्द: तीव्र मस्तिष्कशोथ संलक्षण, होम्योपैथी, संस्थागत प्रबंधन नयाचार, अस्वस्थता, मृत्यु, प्रेक्षणमूलक अध्ययन, भारत।