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Homoeopathic *Genus Epidemicus 'Bryonia alba'* as a prophylactic during an outbreak of Chikungunya in India: A cluster -randomised, double -blind, placebo-controlled trial

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ABSTRACT

Objective: The objective was to assess the usefulness of homoeopathic genus epidemicus (*Bryonia alba* 30C) for the prevention of chikungunya during its epidemic outbreak in the state of Kerala, India.

Materials and Methods: A cluster- randomised, double- blind, placebo -controlled trial was conducted in Kerala for prevention of chikungunya during the epidemic outbreak in August-September 2007 in three panchayats of two districts. *Bryonia alba* 30C/placebo was randomly administered to 167 clusters (*Bryonia alba* 30C = 84 clusters; placebo = 83 clusters) out of which data of 158 clusters was analyzed (*Bryonia alba* 30C = 82 clusters; placebo = 76 clusters) . Healthy participants (absence of fever and arthralgia) were eligible for the study (*Bryonia alba* 30 C *n* = 19750; placebo *n* = 18479). Weekly follow-up was done for 35 days. Infection rate in the study groups was analysed and compared by use of cluster analysis.

Results: The findings showed that 2525 out of 19750 persons of *Bryonia alba* 30 C group suffered from chikungunya, compared to 2919 out of 18479 in placebo group. Cluster analysis showed significant difference between the two groups [rate ratio = 0.76 (95% CI 0.14 - 5.57), *P* value = 0.03]. The result reflects a 19.76% relative risk reduction by *Bryonia alba* 30C as compared to placebo.

Conclusion: *Bryonia alba* 30C as genus epidemicus was better than placebo in decreasing the incidence of chikungunya in Kerala. The efficacy of *genus epidemicus* needs to be replicated in different epidemic settings.

Keywords: Bryonia alba, Chikungunya, Genus epidemicus, Homoeopathy, Prophylactic

INTRODUCTION

Chikungunya is a relatively rare form of viral fever caused by an alpha virus that is spread by bite of *Aedes aegypti* mosquito. The incubation period is usually 2-3 days, with a range of 1-12 days. The word 'Chikungunya' is derived from the Swahili word, meaning 'that which bends up' in reference

to the stooped posture developed as a result of the arthritic symptoms of the disease. It is an acute illness characterised by sudden onset of fever with several of the following symptoms: Joint pain, headache, backache, photophobia, arthralgia and rash.[1] In India, after quiescence of about three decades, an outbreak of chikungunya with sporadic cases of dengue is being reported from different parts of India. Cases of chikungunya like fever were increasingly reported from the state of Andhra Pradesh, Maharashtra, Karnataka since December 2005.[1] During 2007, chikungunya outbreak in India, the worst affected state was Kerala, with 55.8% of the suspected chikungunya fever cases in the country.[2]

According to Shephard,[3] Homoeopathy offers the best solution. Historically, Homoeopathy has had a significant role in the control and management of infectious epidemic diseases, particularly before the advent of modern sanitation, vaccinations and antibiotics. Samuel Hahnemann[4] himself prevented many epidemic diseases like scarlet fever with *Belladonna*. Homoeopathy became particularly popular in the United States and Europe in 19th century, due to its success in the treatment of several epidemics, including typhus, cholera, yellow fever, scarlet fever, small pox, diphtheria, spanish flu, meningitis and polio.[5,6]

The concept of using homoeopathic medicines as '*genus epidemicus*' in epidemic diseases was originally formulated by Samuel Hahnemann[4] who laid the guidelines in Organon of Medicine (§241) as "…each single epidemic is of a peculiar, uniform character common to all the individuals attacked, and when this character is found in the totality of the symptoms common to all, it guides us to the discovery of homoeopathic (specific) remedy suitable for all the cases…"

Kent[7] also affirms that the totality of symptoms of a given epidemic corresponding to the nature of the epidemic disease can be obtained after observing about 20 patients and recording the symptoms of each one. Thus the pathognomonic symptoms of the epidemics are identified. Repertory analysis would guide to a group of six or seven remedies known as *"epidemic remedies"* for that particular epidemic, from which the physician would choose the most suitable after going through the Materia Medica.

A preventive study was carried out by the Central Council for Research in Homoeopathy (CCRH)[8] on Japanese encephalitis in 96 villages in the state of Uttar Pradesh in India during an outbreak of epidemic during 1991. None of 39250 subjects who were given *Belladonna 200C* (*genus epidemicus* during the epidemic) had developed the disease.

A study by Rejikumar *et al.*[9] on 1061 people living in parts of Kerala, most affected by chikungunya epidemic showed that homoeopathic medicine *Eupatorium perfoliatum* 200C, (three doses daily for 5 consecutive days) helped prevent chikungunya in 82.19%.

From (June - August) 2007, there was an outbreak of viral fever with arthralgia in epidemic form in many parts of Kerala. Many of the cases were diagnosed as chikungunya. CCRH undertook a double-blind placebo-controlled trial to assess the efficacy of *genus epidemicus* in containing the spread of this chikungunya.

MATERIALS AND METHODS

Study design

A cluster -randomised, double-blind, placebo-controlled trial was conducted in the two districts of Quilon and Alapuzha covering three panchayats i.e. Yeroor, Alapattu and Aratupuzzha, respectively, during the period August-September 2007, the areas where outbreak of chikungunya had occurred and where no preventive measures were taken either by the Government of Kerala or any private organisations. Ethical clearance was obtained from the Council's Ethical Committee prior to initiation of the study.

Selection of *genus epidemicus*

The selection of the homoeopathic medicine (*genus epidemicus*) to be tried as prophylactic for the chikungunya during the epidemic was done by the standard method of determining the *genus epidemicus* as per the instructions given by Hahnemann[4] in his Organon of Medicine (§101-§102). A total of 205 patients, having fever and severe arthralgia, etc., from the area where laboratory confirmed cases were detected during the epidemic were studied and the totality of symptoms of the prevailing epidemic was constructed [Table 1]. The symptoms were repertorised using Kent's[10] Repertory followed by Synthesis Repertory in Radar version 7.1[11] and thus the *genus epidemicus i.e. Bryonia alba* was selected after common consensus of group of homoeopathic experts, against the epidemic under reference.

Table 1: Symptoms observed during the epidemic

- Pain in joints: worse from motion, during night
- Pain in extremities: worse from motion, during night
- Fever: morning, evening, before mid-night, night with chill; fever with chill; no perspiration
- Headache: forehead, temple; bursting, throbbing; worse from motion, during night
- Coated tongue: white, yellow; dryness of tongue
- Dryness of mouth with: thirst; thirstlessness. Bitter taste in mouth
- Diminished appetite. Nausea
- Thirst: during chill, heat; for large quantity; at long interval; often and extreme
- Complaint worse during motion; feels better while perspiring
- Pain sore, bruised

Before being finalised, the salient symptoms of the *Bryonia alba* was confirmed from the Homoeopathic Materia Medica.[12,13] The medicine/control for the trial were obtained from Sharada Boiron Laboratories (SBL), Pvt. Ltd., Sahibabad.

Study population and procedure

The homoeopathic prophylactic trial was conducted in Yeroor and Alappatu panchayats of Quilon district and Arattupuzha panchayat of Alappuzha district of Kerala. Voluntary Health workers (VHW) were trained on the features of chikungunya, method of administration of medicine and follow-up. A kit containing information sheets, consent forms, survey forms and medicine/placebo were distributed to the VHW's. They (VHW) screened the participants through house visits for healthy state by enquiring about their suffering with fever and arthralgia during the said outbreak. Screened participants who were declared healthy (absence of fever and arthralgia), aged between 1 and 98 years and of both genders were enrolled after obtaining written informed consent. In case of minors, consent of the guardian was taken. Group of families with population around 200 healthy individuals were considered as one cluster. Accordingly estimated sample was divided into 167 clusters and each cluster was kept under observation of one VHW. The clusters were randomly administered *Bryonia alba*/placebo. Out of these, 84 clusters received *Bryonia alba* and 83 clusters received placebo. Computer-generated random numbers were used to randomised the clusters and was sealed until data analysis is completed.

Bryonia alba was distributed in 30C potency. The participants were instructed to take three doses (3 globules of size No. 30) per day for 3 days orally in empty stomach. Similarly placebo was administered to control group but the globules were impregnated with unsuccused non-medicated alcohol. The participants who were under trial were allowed to repeat *Bryonia alba 30 C*/placebo after 15 days in the same dosage schedule provided the prevalence of the epidemic continued in the area. Follow-up visits were made by the VHW's on 8th, 15th, 22nd, 29th and 35th day. Any participant who suffered from fever and arthralgia (characteristic symptoms of chikungunya) during the follow-up period was considered as a case of chikungunya.

Outcome measures

The main outcome measure was to assess number of infected persons as per guidelines of European Centre for Disease Prevention and Control[14] for probable case of chikungunya at the end of 35 days of follow-up.

Sample size

The prevalence of chikungunya was estimated at the initial stage of the epidemic which was 10/1000. To achieve 90% power at level of significance (α) = 0.05 with a prevalence of 5/1000 in *Bryonia alba 30C* group and 10/1000 in placebo the required sample size was 6080 in each arm in a simple random sampling. As cluster sampling was used in this trial it was multiplied by a design effect of 2.5 with additional load of non-response factor which led to total sample sized of 34000 (17000 in each arm).

Statistical analysis

Since this trial used a cluster design, analysis was done with the cluster as the unit. Comparison of rate ratios was done by use of 95% confidence intervals (CIs) of the rate ratios. All the healthy participants were observed for a period of five weeks with a weekly follow-up. Participants infected were not considered for further observation in the study.

The event rate, standard error, standard deviation, intervention effects, difference in event rate and 95% CI of intervention and control group were estimated following the cluster analysis methodology.[15] Independent sample *t*-test was performed to analyze the cluster level event rates. The $P \leq 0.05$ was considered to be significant.

RESULTS

The trial flow diagram is shown in Figure 1. Due to non-compliance of nine VHW (Bryonia = 2; Placebo = 7) data from these clusters could not be

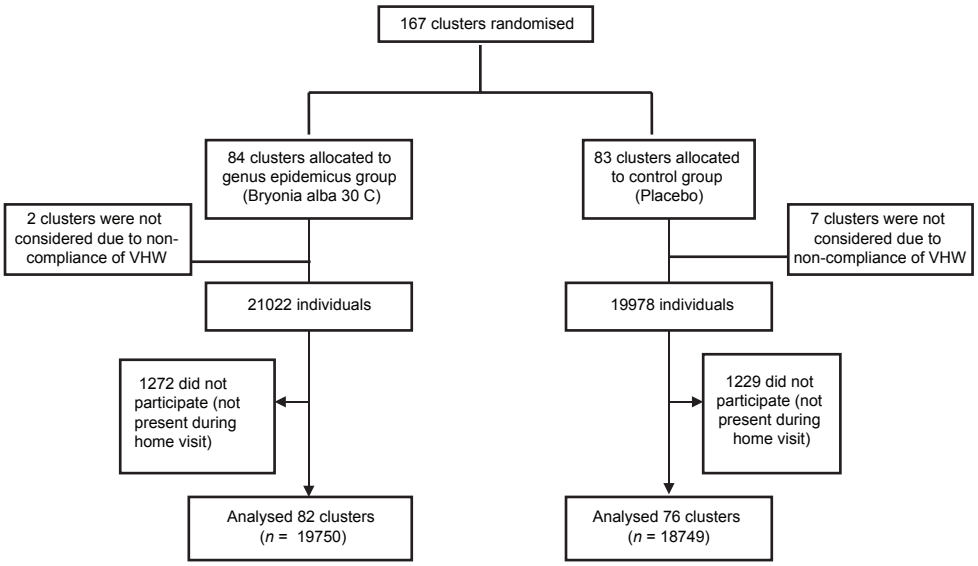

Figure 1: Flow diagram of the progress through the phases of a cluster randomised trial

collected. The number of participants who were not present during the house visit of VHW was similar in both the groups (6.05% and 6.15%, respectively) and therefore not considered for analysis. Prophylactic outcome in intervention group (n = 19750) and placebo group (n = 18749) were analysed.

The study groups were similarly distributed in terms of demographic data (age, sex) at baseline [Table 2]. At the end of follow-ups it was observed that 12.78% (2525 out of 19750) healthy individuals, administered with *Bryonia alba 30 C*, were presented diagnosed as probable case of chikungunya, whereas it was 15.79% (2919 out of 18749) in the placebo group.

Table 3 shows the number of person weeks observation and rate ratio in all eligible participants in both the intervention and control groups. Independent t-test of clusters event rates between the two groups showed significant statistical difference (t-value = 2.19 and P = 0.03). The result reflects a 19.76% relative risk reduction by *Bryonia alba 30C* compared to placebo.

Table 2: Baseline details of participants included in analysis

	Treatment group (*Bryonia alba* 30C)	Control group (placebo)
Number of initially healthy persons (n) considered in analysis	19750	18749
Mean age (years)	32.3±18.9	32.3±18.4
Sex (male: Female)	9633:10117	9018:9731

Table 3: Analysis of chikungunya incidence rates

	Treatment group	Control group	Effect estimates
Number of clusters	82	76	
Total infected	2525	2919	
Total person-weeks	91472	84895	
Analysis based on cluster summaries			
Overall rate	0.027	0.034	
Mean of cluster rates	0.029	0.038	
Rate ratio (95% CI)			0.76 (0.14 to 5.57)
Relative risk (95% CI)			0.80 (0.76 to 0.84)
Relative risk reduction (%, 95% CI)			19.7 (15.4 to 23.8)
P value			0.03

CI: Confidence interval

DISCUSSION

The results of this trial suggests the utility of genus epidemicus *i.e. Bryonia alba* in preventing chikungunya in the said epidemic. *Bryonia alba* 30C acted better than placebo. This argument is appropriate in a situation, when the chikungunya epidemic was prevalent, though there was no laboratory confirmation of the cases. The predictive power of clinical diagnosis will be high during an epidemic because of increased background of prevalence of disease. WHO[16] also categorises such clinical cases, during an epidemic, as probable cases of chikungunya. However, it would be ideal to confirm those cases by laboratory investigations, which could not be done in this study due to resource constraints.

Rejikumar *et al.*[9] in their preventive study on chikungunya selected *Eupatorium perfoliatum* as the genus epidemicus whereas in this trial it was found to be *Bryonia alba*. As stated by Hahnemann[4] that in epidemic diseases the genus epidemicus may not be same, it may vary in two different localities and at two different phases/time of the same epidemic. In their study they selected the *genus epidemicus* by surveying the patients in two different areas (Neyyattinkara and Vizhinjam) which were different from the areas in this trial.

This study was cluster randomised, double-blind, placebo-controlled, where both the groups were similar in their characteristics which is not so in Rejikumar's[9] study and thus in our study bias is minimized. Further their study was not randomised and with unequal groups. The persons who had not taken medicine due to any reason were considered as control is not a true control group to be compared and to give statistical rigour. The merit of our trial is that the genus epidemicus was administered during peak period of epidemic and follow up was continued till there was decline in epidemicity of chikungunya which covered almost all infected cases of the prevailing epidemic whereas in Rejikumar's study the follow-up was only for 10 days. To add further, the strength of our study is that a large number of people of all age groups could be administered the preventive and were followed till decline of epidemic.

Earlier prophylactic studies with homoeopathic medicines showed mixed results. Mroninski *et al.* who conducted a study with meningococcinum involving 89,365 participants concluded statistically significant results in favour of Homoeopathy. The trial showed a protection against meningococcal disease of 95% in 6 months and 91% in a year.[17] However, this study had flaws similar to Rejikumar's study like randomisation, blinding and control group. In another preventive study, *Lathyrus sativus* was found effective in poliomyelitis.[3] In meningitis study the investigators used meningococcinum isopathically, while in poliomyelitis *Lathyrus* was given based on symptomatic affinity irrespective of the symptoms prevailing during the epidemic. Similarly a study by Nunes[18] in prevention of dengue with homoeopathic combination of *Phosphorus* 30C, *Crotalus horridus 30 C* and *Eupatorium perfoliatum* 30C suggests positive results. The incidence of the disease in the first 3 months of 2008 fell by 93% among covered population in comparison to the corresponding period in 2007, whereas in the rest of the State of Rio de Janeiro there was an increase of 128%. These medicines were predefined based on their pathogenesis which is similar to dengue and dengue haemorrhagic fever.

A systemic review of two randomised controlled trials on the use of *Oscillococcinum* (nosode prepared from autolysate of heart and liver of infected wild duck, a vector for aviary influenza virus) as "specific preventive" against flu-like syndromes, ignoring the requirement of similitude between pathogenetic and patients symptoms, showed no significant effect when compared to placebo.[19] In an epidemic conjunctivitis at Hyderabad, a RCT carried out to assess the efficacy of *Euphrasia officinalis* 30CH, chosen on the grounds of the epidemic genius of earlier outbreaks, once again dismissing the symptomatic totality of the ongoing epidemic showed insignificant results.[20]

Thus in the case of epidemics, which owing to the virulence of their etiologic agents awaken symptoms common to most susceptible individuals, individualised remedies (*genus epidemicus*) must exhibit similitude of the sets of symptoms shown by the patients affected in the different stages or phases of each epidemic outbreak which is followed in our trial for the selection of genus epidemicus. The epistemological foundations of Hahnemann's Homoeopathy as preventive medicine has also been vividly discussed by Teixeira[21] and the same has been implemented in this trial which further adds to the merit of this trial.

With emergence of viral epidemic diseases, where the availability of vaccines is meager, costly or no known effective treatments are available, homoeopathic medicines as genus epidemicus can be used as preventive to decrease the incidence at particular epidemic.

CONCLUSIONS

Bryonia alba 30C as genus epidemicus was better than placebo in decreasing the incidence of chikungunya in Kerala. The efficacy of *genus epidemicus* needs to be replicated in different epidemic settings.

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भारत में चिकनगुनिया के महामारी के दौरान रोगनिरोधी जैसे 'ब्रायोनिया अल्बा' होम्योपैथिक जीनस एपिडेमिकसः एक समूह–यादृच्छिक, डबल ब्लाईंड, प्लासिबो नियंत्रित परीक्षण

सारः

उद्देश्यः चिकनगुनिया के दौरान फैली महामारी की रोकथाम के लिए भारत के केरल राज्य, में होम्योपैथिक जीनस एपिडेमिकस (ब्रायोनिया अल्बा 30सी) की उपयोगिता का आकलन करना।

सामग्री एवं विधियाँः केरल के दो जिलों के तीन पंचायतों ने अगस्त–सितम्बर 2007 में चिकनगुनिया के दौरान फैली महामारी की रोकथाम के लिए एक समूह–यादृच्छिक, डबल ब्लाईंड, प्लासिबो नियंत्रित परीक्षण का आयोजन किया। ब्रायोनिया अल्बा 30सी/प्लासिबो को 167 समूहों (ब्रायोनिया अल्बा 30सी=84 समूहः प्लासिबो=83 समूहों) से यादृच्छिकता से प्रशासित किया गया, जिसमें से 158 समूहों (ब्रायोनिया अल्बा 30सी=82 समूहः प्लासिबो=76 समूहों) के आंकडों का विश्लेषण किया गया। अध्ययन के लिए स्वस्थ्य प्रतिभागी (बुखार और जोडों के दर्द से मुक्त) उपयुक्त थे। साप्ताहिक जाँच 35 दिनों के लिए किया गया। अध्ययन समूह में संक्रमण की दर का विश्लेषण किया और समूह विश्लेषण के उपयोग से तुलना की गई।

परिणामः यह पाया गया कि ब्रायोनिया अल्बा 30सी के 19750 में से 2525 व्यक्ति की तुलना में प्लासिबो समूह में 18479 में से 2919 व्यक्ति चिकनगुनिया से पीडित थे। समूह विश्लेषण ने दोनों समूहों के बीच (दर अनुपात=0.76 (95 प्रतिशत सीआई 0.14–5.57), पी मूल्य=0.03) महत्वपूर्ण अन्तर दिखाया। प्लासिबों की तुलना में परिणाम ब्रायनियो अल्बा 30सी 19.76 प्रतिशत संबंधी कम जोखिम दर्शाता है।

निष्कर्षः ब्रायोनिया अल्बा 30सी जीनस एपीडेमिकस के रूप में केरल में चिकनगुनिया की घटनाओं को कम करने में प्लासिबो की तुलना में अधिक बेहतर थी। जीनस एपीडेमिकस की प्रभावकारिता अलग महामारी समायोजन में दोहरायी जानी चाहिए।