

A randomised comparative study to evaluate the efficacy of Homoeopathic treatment -vs- standard allopathy treatment for acute adenolymphangitis due to lymphatic filariasis

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Abstract

Objective: The primary objective of the study was to compare the effectiveness of homoeopathic treatment with standard allopathic regimen in acute ADL and secondary objective was to assess the reduction in frequency, duration and intensity of subsequent attacks, improvement of the quality of life of patients. **Methods:** The study was designed as a comparative randomized trial conducted from October 2012 to April 2014, on 112 patients at Regional Research Institute, Puri, Odisha. The ADL patients enrolled were randomized to receive either homoeopathic treatment or standard allopathic treatment for a period of six months. The outcome parameters used were ADL score and WHO QOL Bref. **Results:** 112 Patients were considered for primary outcome analysis as per the Intention to treat principle. (Homoeopathy= 55 and Allopathy= 57) and were analysed on 11th day of treatment. Both the treatments produced equal improvement in ADL scores. However, during the six months study period, the frequency, duration and intensity of attacks were better in Homoeopathy group compared to allopathy group. There was statistically significant improvement in Homoeopathy for Domain 4 of WHOQOL ($P = 0.004$) as compared to allopathy group. Medicines like *Apismellifica* ($n = 23$), *Rhus toxicodendron* ($n = 20$), *Pulsatilla* ($n = 8$), *Arsenic album* ($n = 1$), *Bryonia alba* ($n = 1$), *Silicea* ($n = 1$) and *Hepar sulph* ($n = 1$) were found most useful in the acute attacks. **Conclusion:** This study provides evidence to support the fact that individualized homoeopathy treatment is equally effective for ADL as the standard allopathy treatment in the management of ADL.

Keywords: Adenolymphangitis, Allopathy, Homoeopathy, Lymphatic filariasis, Randomised controlled trial

INTRODUCTION

Lymphatic filariasis (LF) is a vector-borne disease of the tropical and subtropical countries caused by parasite; the nematode species include mostly *Wuchereria bancrofti* (90%), to a lesser extent, *Brugia malayi* (10%) and *Brugia timori* to a very small extent. The genera of mosquitoes transmitting these parasites include Culex, Anopheles, Aedes or Mansonia. Globally, around 120 million people in around 83 countries are affected; it is ranked as the second most common cause of physical disability.^[1]

In endemic countries, it is the most common cause of lymphoedema, which mostly affects the lower limbs, sometimes the arms, less commonly male genitalia and rarely breasts and female genitals. Several studies have documented the physical, social, psychological, sexual and economic problems resulting

not only from the deformities caused by LF but also from the acute febrile episodes associated with this disease.^[1]

Human LF caused by *W. bancrofti* is highly prevalent in India. Even though this disease does not prove to be fatal, it causes considerable morbidity in the affected community.^[2]

LF is associated with a wide range of clinical signs, symptoms and sequelae, which are influenced by a variety of factors related to host and parasite. Acute episodes of

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adenolymphangitis (ADL) is one of the symptoms, which is characterised by recurrent attacks of fever associated with inflammation of the lymph nodes and or lymph vessels.^[3] It is characterised by the sudden onset of high fever, lymphangitis, lymphadenitis and transient local oedema. Generalised symptoms include fever along with headache, chills, nausea, vomiting and loss of appetite. The lymphangitis is retrograde, extending peripherally from the lymph node draining the area where the adult parasites reside. This nature of filaria-induced lymphangitis distinguishes it from bacteria-induced one. Generalised symptoms include fever along with headache, chills, nausea, vomiting and loss of appetite. Regional lymph nodes are enlarged, and the entire lymphatic channel can become indurated and inflamed. Acute attacks can occur in people with or without detectable microfilaraemia and are common in people with chronic disease. These episodes interrupt normal activities, often confining them to bed.^[4,5]

The importance of acute clinical manifestations, i.e. ADL, in natural progression of the disease, particularly the development of chronic disease has been recognised by filariologists. Although the need of systematic epidemiological studies on acute LF or ADL is recognised, a few studies have been undertaken in different endemic areas.^[3]

In a study conducted to measure physical and psychological burden caused by LF, it was found that even though lymphoedema and hydrocele caused severe and permanent disabilities to the patients, the severity of disabilities caused by ADL was greatest. Pain and discomfort interfered with all activities. Physical incapacitation in the most productive stage of life, financial problems, dependency on others and inability to lead a normal life gradually affects the mental health of the individual and leads to anxiety and depression.^[6-9]

Till date, antifilarial drug like *Diethylcarbamazine* (DEC) is the standard treatment of choice for filaria, but administration of this drug can lead to some short-term adverse reactions such as fever, headache, myalgia, vomiting and even asthma.^[10] With Homoeopathy, this kind of distress can be prevented.

According to the WHO, LF exerts a heavy social burden because of the specific attributes of the disease, particularly since chronic complications are often hidden and are considered shameful. For men, genital damage is a severe handicap leading to physical limitations and social stigmatisation. For women, shame and taboos are also associated with the disease. When affected by lymphoedema, they are considered undesirable, and when their lower limbs and genital parts are enlarged, they are severely stigmatised; marriage, in many situations, an essential source of security, is often impossible.

Gyapong *et al.*^[11] reasoned that many ADL patients might not have found available treatment options very useful, and most knew that episodes would be over in a week or less. Non-treatment of ADL episodes may result in chronic LF, with its concomitant social and economic burdens and functional impairment and disability.

Central Council for Research in Homoeopathy (CCRH) undertook a multicentric open clinical trial for evaluating usefulness of homoeopathic medicines in filariasis between 1980 and 2003. However, the study lacked the currently available diagnostic tests and a proper valid scoring scale. It was, therefore, necessary to carry out a randomised open controlled clinical trial of predefined homoeopathic medicines on ADL due to LF on a set protocol with clear outcome parameters.

The primary objective of the study was to assess the effectiveness of homoeopathic medicines in acute ADL attack, as compared to standard allopathic medicines, as evident from the ADL scoring scale, assessed at baseline on day 1 to 11th day of treatment [Annexure 1].

The secondary objective was to study the reduction in frequency, duration and intensity of subsequent attacks, if any [Annexure 2], and improvement of the quality of life (QOL) of patients as evident from the WHOQOL-BREF, QOL scale.

MATERIALS AND METHODS

Study design

This was a randomised open label comparative trial conducted at Regional Research Institute (H), Puri, Odisha, from October 2012 to April 2014. The Ethical Committee of CCRH approved the study protocol. Written informed consent was obtained from all the patients. The investigator engaged in the study collected all the data as per the protocol designed for this study by CCRH. Consultant Medicine specialist was engaged at the centre to assess the cases of both the intervention groups. The study had been registered in Clinical Trial Registry of India vide registration number CTRI/2011/12/002268.

All the above medicines were prescribed in consultation with the modern medicine specialist, as per the requirement of the case.

Study population

Both males and females in the age group of 15–60 years with the presence of local signs and symptoms such as pain, tenderness, local swelling and warmth in the groin with or without associated constitutional symptoms such as fever, nausea and vomiting reporting within 72 h of attack either with previous history of ADL attacks or reporting for the first time from the endemic areas were included in the study. In known cases of LF, having acute ADL, only the cases with Grade 1 and 2 lymphoedema were included in the study population [Figure 1].

Patients with any of the following criteria were excluded:

- Acute attacks of ADL with Grade III and IV lymphoedema and chronic hydrocele cases
- Lymphangitis due to
 - Thrombophlebitis
 - Infection (ascending lymphangitis)
 - Trauma.

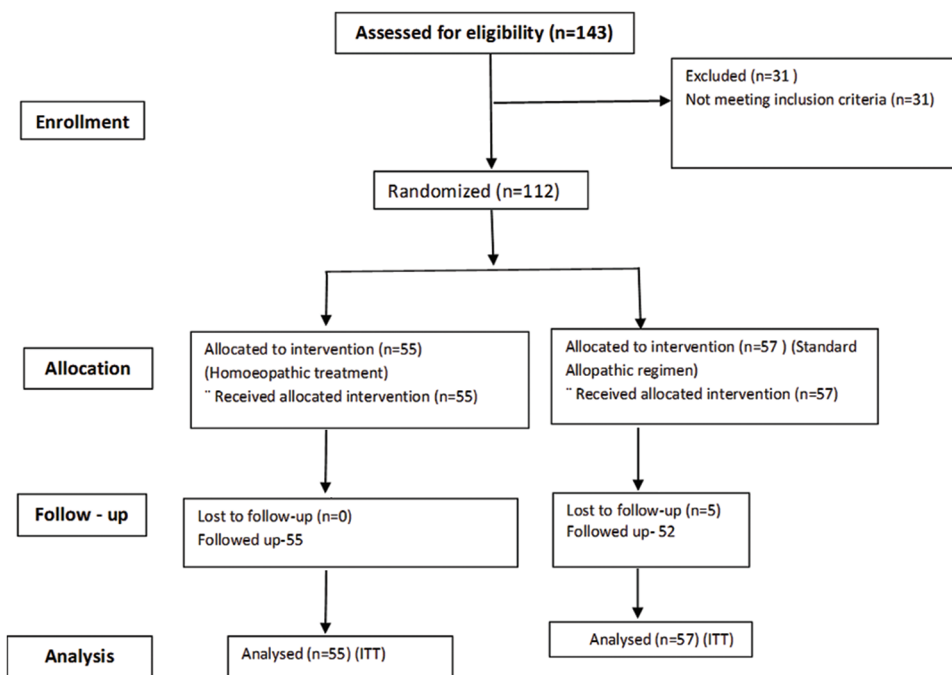


Figure 1: Study flow chart

Patients suffering from diabetes mellitus, severe systemic illness, congestive cardiac failure,

- Nephrotic syndrome, malignancy and congenital lymphatic system abnormality
- Patients coming after taking any treatment for the present ADL attack
- Patients deemed unfit for participation in the study
- Patients not willing to sign the written informed consent.

Examinations and investigations

The study participants were physically examined to elicit, lymphoedema and/or local swelling, local tenderness and inflammation of the lymph nodes and lymph vessels. Inguinal, axillary or epitrochlear lymph nodes were palpated. Examinations for pitting/non-pitting oedema, skin texture, etc., and measurement of lymphoedema of the limbs at the following pre-defined points were measured.^[4]

- Upper extremity
 - Upper arm
 - Elbow
 - Forearm
 - Wrist
 - Hand.
- Lower extremity
 - Below knee
 - Calf
 - Ankle
 - Midfoot.
- Routine blood examination for haemogram including erythrocyte sedimentation rate was done at baseline and on the 11th day of follow-up.

- Night blood examination of peripheral blood for detection of circulating microfilaria was done in all the cases at entry. Immunochromatographic test for filarial antigen was done at entry.
- Routine examination of stool and urine was done.

Study interventions

Based on the outcome of the previous studies,^[10-14] the following homoeopathic medicines had been shortlisted for the homoeopathic arm in the study.

Aconite, Apis mellifica, Arnica montana, Arsenicum album, Belladonna, Bryonia alba, Calcarea carbonica, Graphites, Hepar sulphuris, Lycopodium, Medorrhinum, Merc solubilis, Natrum muriaticum., Pulsatilla, Rhus toxicodendron, Silicea, Sulphur, Thuja occidentalis and Tuberculinum.

The patients in the allopathic arm received the medicines as follows as per the requirement of the case:

1. Antibiotics *Cefixime/Cefadroxil* for 5 days
2. Anti-inflammatory drug *Brufen* and *Paracetamol* for 5 days
3. Antiallergic drugs *Levocetirizine* for 5 days
4. Antifilarial drug DEC, 1 tablet, TDS for 21 days.

The period of trial was of 18 months, including follow-up period of 6 months.

The homoeopathic medicine was prescribed based on totality of symptoms out of the pre-defined medicines.

Study outcomes

The primary outcome : Change in ADL scores before and after treatment at baseline and on 11th day. The secondary outcome was assessed as observed from reduction in frequency, duration

and intensity of subsequent attacks as per the prescribed follow-up form. QOL assessment was done using the WHOQOL-BREF QOL questionnaire in local language (Odia (http://www.who.int/mental_health/media/en/76.pdf). It was done at entry, 11 days and at completion of 6 months' treatment to assess the change in QOL of patients. Clinically improved patients were put on periodic observation till they completed 6-month follow-up for final assessment.

Randomisation

Each patient was assigned for either allopathic or homoeopathic medicine as intervention through random numbers obtained from www.randomizer.org.

Sample size and statistical analysis

All the analysis was done on intention to treat principle (ITT). The sample size of 112 patients including 10% drop out was finalised with assumption of effect size as 0.6 and power = 85% with 5% level of significance was recruited in the study. The sample was subjected to statistical analysis using (IBM SPSS version 20, USA). Group differences were tested using the independent *t*-test. Paired *t*-test was used to compare the results at different time points in the same group. *Z*-test was also used to compare two proportions.

RESULTS

A total of 112 patients, between 15 and 60 years, presenting with local signs and symptoms of acute ADL were enrolled in the study and given either homoeopathic (n = 55) or conventional treatment (n = 57). Baseline characteristics of the ADL patients enrolled in both the groups were statistically insignificant. The mean age was 41.1 ± 11.1 (mean ± standard deviation [SD]) in Homoeopathy group and 40.19 ± 13.1 (mean ± SD) in allopathy group, and the majority (52%) of the study patients were female. Four patients were lost to follow-up during the 6-month study period. One patient was referred due to other

serious illness in between the study period. These patients were considered for analysis through ITT. Data presented in the form of *n* (%), mean ± SD and *P* value with independent sample *t*-test for both the groups at baseline treatment [Table 1].

Primary outcome

The baseline ADL scores were compared between the 1st day and 11th day of treatment for both Homoeopathy and standard allopathic intervention group. Improvement rate (pre and post treatment) was above 90% in both groups. But when both groups were compared, for the difference in ADL scores, it did not show much difference and hence the result was statistically insignificant, and both the groups were equally effective. [Table 2 and Figure 2]. The mean ADL score during baseline to 11 days has been reduced from 11.91±2.99 (mean±sd) to 1.11±0.98 in Homoeopathy group and from 12.26±3.13 to 1.33±1.41(mean±SD) in Allopathy group [Table 2] [Figure 2a].

Apart from the above parameter, another important aspect of the study, i.e. lymphoedema was also measured for comparison between both the groups and establishing the effectiveness of homoeopathic medicines. In the homoeopathic group, 13 out of 25 cases of Grade I lymphoedema and 21 out of 29 cases of Grade II lymphoedema improved after treatment. Twelve out of 30 cases in Grade 1 lymphoedema and 17 out of 26 cases in Grade II lymphoedema improved in allopathy group [Figure 3].

Secondary outcome

Over the follow-up period of 6 months, patients reported a total of 34 ADL episodes (16 [47.06%] –in Homoeopathy and 18 [52.94%] in – allopathy group). Intensity of attacks during 6-month period was of mild to moderate intensity in both the groups.[Table 2].

During 6 months period, In Homoeopathy group, ten (10) patients had one attack. One patient each had 2 and 4 attacks respectively. In Allopathy group, fourteen (14) patients had one attack and two patients had 2 attacks each for 6 months period.

During six months period, forty three (43) patients did not have any further episode of ADL in homoeopathy group, whereas forty one (41) patients did not have any episode of ADL in allopathy group.

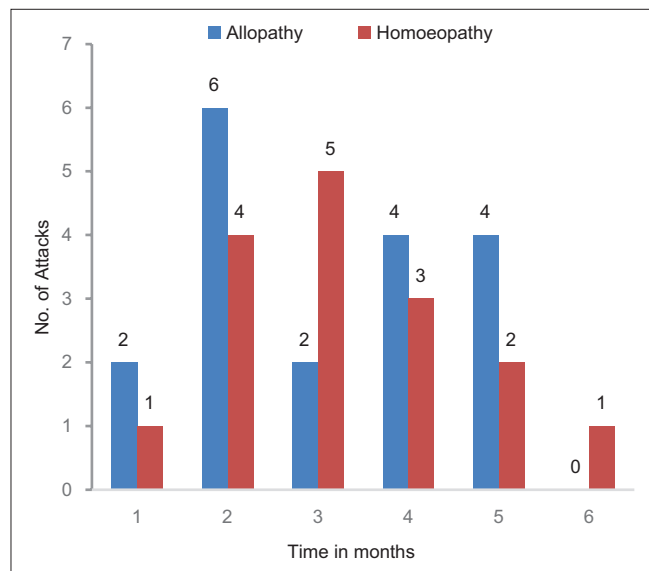


Figure 2: Adenolymphangitis attacks during 6-month treatment

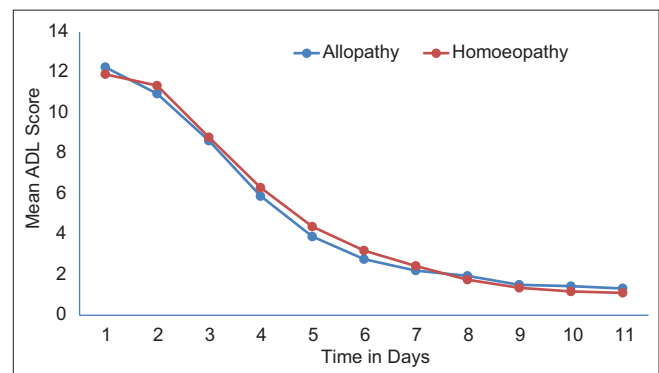


Figure 2a: Comparison of two groups for ADL scores

Table 1: Baseline demographic characteristics

Baseline demographic characteristics	Allopathy (n=57), n (%)	Homoeopathy (n=55), n (%)	P*
Sex			
Male	29 (50.9)	24 (43.6)	
Female	28 (49.1)	31 (56.4)	
Age	40.19±13.1	41.1±11.1	0.69
BMI	22.1±2.02	22.0±2.06	0.86
History of attacks past 1 year	4.91±5.20	4.38±4.80	0.58
History of number of attacks as per the ADL intensity at baseline			
Mild (1-9)	11 (19.3%); 2.73±2.65	11 (20.0%); 2.82±2.32	0.34
Moderate (10-18)	45 (78.9%); 5.51±5.57	42 (76.4%); 4.93±5.24	0.42
Severe (19-28)	1 (1.8%); 2.00±0.00	2 (3.6%); 1.50±0.71	0.39
ADL total score	12.26±3.13	11.91±2.99	0.54
ADL symptoms			
Local pain	2.75±0.51	2.82±0.38	0.46
Local tenderness	2.70±0.53	2.78±0.42	0.38
Erythema	0.75±0.43	0.82±0.39	0.42
Lymphedema	1.44±0.54	1.51±0.54	0.49
Swollen lymph node	0.84±0.37	0.71±0.46	0.93
Fever	0.89±0.72	0.65±0.70	0.77
Myalgia	1.44±0.80	1.36±0.73	0.61
Fatigue	0.82±0.66	0.73±0.65	0.43
Anorexia	0.19±0.44	0.25±0.51	0.49
Nausea	0.07±0.26	0.02±0.14	0.18
Headache	0.35±0.74	0.22±0.63	0.31
Intensity of ADL score at baseline			
Mild (1-9)	11 (19.3%); 7.55±1.37	11 (20.0%); 8.09±0.94	0.81
Moderate (10-18)	45 (78.9%); 13.27±2.10	42 (76.4%); 12.52±2.01	0.50
Severe (19-28)	1 (1.8%); 19.00±0.00	2 (3.6%); 20.00±0.00	0.08
VAS scores			
Pain	7.46±1.27	7.65±0.99	0.36
Myalgia	3.74±2.31	3.44±1.95	0.46
Fatigue	1.81±1.78	1.47±1.57	0.30
Headache	0.89±2.04	0.51±1.57	0.27
WHOQOL			
Domain 1	30.00±6.24	31.38±7.46	0.29
Domain 2	31.56±9.20	30.55±5.46	0.48
Domain 3	33.44±10.65	33.40±13.46	0.99
Domain 4	36.09±8.22	34.44±6.74	0.25
Investigations			
Hb	13.00±1.81	13.07±1.29	0.80
TLC	8884.21±1595.51	8912.96±1984.76	0.93
Neutrophils	59.63±10.29	61.04±8.68	0.44
Eosinophils	7.67±4.13	7.51±4.51	0.85
Lymphocytes	31.96±8.87	31.71±7.72	0.87
ESR	62.11±28.48	69.64±31.79	0.19
Fasting blood sugar	88.11±10.61	89.71±21.46	0.62

*Data presented in form of n (%); mean±SD and P with independent sample t-test for both the groups at baseline treatment. ADL: Adenolymphangitis; SD: Standard deviation; ESR: Erythrocyte sedimentation rate; Hb: Haemoglobin; TLC: Total leucocyte count; WHOQOL: World Health Organization quality of life; VAS: Visual Analogue Scale

Duration of the subsequent attacks were almost equal in both the groups. [Table 2].

Mean ADL score was apparently highest in cases prescribed with *Apis mellifica*. The prescribing indications of the medicines are given in Table 3.

After the acute attack subsided, patients were prescribed constitutional medicines based on totality of symptoms. It was seen that seven constitutional medicines were found indicated in all. [Table 3]. Out of 23 cases of *Apis mellifica*, 9 cases were follow up by *Natrum muriaticum*, 5 by *Lycopodium* and 2

by *Sulphur*, out of 20 cases of *Rhus toxicodendron*, 7 cases required follow up by *Sulphur* whereas 5 cases were followed up with *Lycopodium*.

All four allopathy medicines, as per standard allopathic treatment mentioned above, were used for all allopathy group cases, as prescribed by allopathic consultant.

Secondary objective was to study the reduction in frequency, duration and intensity of subsequent attacks, if any [Annexure 2], and to assess the QOL of the patients before and after treatment. It was assessed using the WHOQOL-BREF, QOL scale questionnaire. It was used at the date of enrolment at the 11th day and at the end of 6 months of treatment to assess the change in QOL of the patients. It consists of raw score and transformed scores on a 4–20 scale and 0–100 scale, respectively. At 6 months of study, improvement in Homoeopathy group was more in Domain 4 of QOL, as compared to the allopathy group, which is also statistically significant ($P = 0.004$) [Table 2].

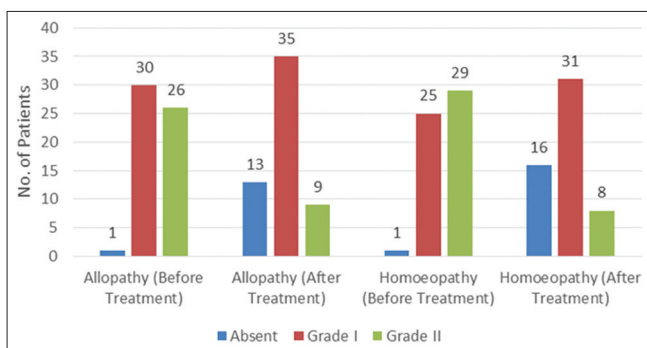


Figure 3: Status of lymphoedema during 6-month treatment

DISCUSSION

The most distressing aspect of LF is the acute attacks of ADL, which prevent the patient from attending his daily activities. Affected individuals are estimated to lose approximately 103 million working days because of episodes of ADL and 1098 million working days because of chronic disease. Most of this time lost is in males (91%), while time loss in females is in domestic activity (83%).^[15,16] This results in considerable economic loss and deterioration of QOL of the affected population.

In a study conducted in rural Odisha on treatment costs and work time loss due to episodic ADL in LF patients, it was found that patients spent INR 92/- on an average (approximately US \$1.85) on each episode. The ADL episodes curtailed the productive activity of patients. Patients (88%) were unable to attend to any economic activity compared with 47% of controls who had no history of disease. Similarly, during 55% of episodes, females (vs. 8% of controls) could not attend to any domestic work. The mean number of hours spent on economic or domestic activities was significantly lower among patients. Disease status and sex had considerable influence on total absenteeism from gainful employment, and similarly, age, family type and disease status influenced total domestic work hours among women.^[17]

Hence, prompt treatment and prevention of ADL are of paramount importance.^[15]

Bontha *et al.*^[3] assessed duration of the episode which varies from 1 to 11 days with mean duration of 3.93 (1.94 SD) days.^[3] Therefore, in this study, an 11-day study of the ADL attack was planned in the protocol.

Table 2: Comparing the two groups for their efficacy at 11th Day & at 6 months

Variable	Allopathic group (n=57)	Homoeopathic group (n=55)	95% CI	P
Primary outcome (changes from baseline)				
ADL Scores at Day 11	1.33±1.41	1.11±0.98	-0.23 to 0.68	0.33
Secondary outcome				
WHOQL (changes from baseline) [#]				
Domain 1 at Day 11	24.56±10.23	22.78±11.69	-2.33 to 5.89	0.39
Domain 2 at Day 11	22.61±7.63	22.07±8.95	-2.57 to 3.65	0.73
Domain 3 at Day 11	15.39±9.27	15.55±11.50	-4.10 to 3.75	0.94
Domain 4 at Day 11	14.86±8.18	17.22±9.58	-5.69 to 0.97	0.16
Domain 1 at 6 th Month	45.26±13.64	42.36±17.79	-3.02 to 8.82	0.33
Domain 2 at 6 th Month	40.68±11.67	40.87±11.08	-4.45 to 4.08	0.93
Domain 3 at 6 th Month	27.47±13.21	29.80±14.16	-7.45 to 2.80	0.37
Domain 4 at 6 th Month	28.53±8.48	32.82±6.75	-7.17 to -1.42	0.004
Total no. of attacks during 6 months treatment period*	18 (52.94%)	16 (47.06%)		
Intensity of attacks in category				
Mild	18 (52.94%)	14 (41.18%)	2.0	0.157
Moderate	0 (0.00%)	02 (5.88%)		
Duration of attacks in category				
1 to 3 days	17 (50.00%)	15 (44.12%)	2.0	0.157
4 to 6 days	01 (2.94%)	01 (2.94%)		

[#]Independent *t* test, Sample *t*-test and ^{*}Chi-square test have been applied to compare both the Groups. (It is no. of attacks and may not be confused with no. of patients)

Table 3: Indications of useful medicines observed in the study

Name of medicine	Number of patients prescribed	Number of patients relieved	Indications
<i>Apis mellifica</i>	23	23	Affected part looked inflamed, red and glossy, shiny, sensitive and sore Acute inflammation with oedema Severe burning, itching, redness and heat of the part, relieved by cold application
<i>Rhus toxicodendron</i>	20	20	Acute lymphangitis with heat, redness, burning, itching and severe pain in the affected part Painful swollen inguinal glands Patient extremely restless due to pain Relieved Group I and early Group II lymphoedema (The humid climate of Puri (coastal region) favoured the action of <i>Rhus toxicodendron</i>)
<i>Pulsatilla</i>	8	8	Pain aggravated by keeping the leg in hanging position; elevating the affected limb relieves pain Thirstlessness with dryness of mouth Amelioration by cold application and desire for open air Used both as an acute and chronic prescription
<i>Arsenic album</i>	1	1	Extreme prostration with chilliness Thirst for small quantity at short intervals Night aggravation of complaints. Amelioration by warmth in general
<i>Bryonia alba</i>	1	1	Patient remained quiet and dull Complaints worse from slightest movement Intense thirst with dryness of mouth, bitter taste and vomiting
<i>Hepar sulph</i>	1	1	Lymphatic abscess, prone to suppuration Very painful and sensitive chilliness with hypersensitiveness
<i>Silicea</i>	1	1	Helped in healing lymphatic abscess area after drainage Chilly patient, relieved by warmth Profuse offensive Sweat

Based on the outcome of the previous studies of CCRH, a group of pre-identified medicines was taken for the homoeopathic arm in the study.^[11]

This randomised controlled trial was first of its kind in the field of acute ADL to study the effect of homoeopathic treatment on it as compared to the modern medicine.

Comparing the baseline scores of the individual groups before and after treatment, the result were much significant. All the cases showed significant improvement in acute attacks at the 11th day of follow-up which is statistically significant, whereas when the two groups were compared with each other and statistically analysed comparing the difference in ADL scores before and after treatment, it was observed that homoeopathic medicines are equally effective as the standard modern medicines.

Another similar study^[10] to observe the role of homoeopathic treatment in controlling the recurrent attacks of ADL, in LF, showed improvement in 70.70% patients; 276 had Grade I lymphoedema out of which total disappearance was observed in 101 patients, and in 81 patients, lymphoedema was reduced; 161 had Grade II lymphoedema which disappeared in 32 patients, and in another 63, it reduced. The results of our study also corroborate with this study.

Individualised homoeopathic medicines were used in this study revealing an equal effect as of allopathy medicines on acute ADL. The medicines prescribed during the acute attacks

were based on their characteristic indications. *Apis mellifica* and *Rhus toxicodendron*, followed by *Pulsatilla* were the most common medicines used in the acute attacks whereas the earlier studies^[11] showed *Rhus toxicodendron*, *Bryonia alba*, *Apis mellifica* and *Arsenic album* to be the most useful medicines. It was observed that *Rhus toxicodendron* was more suitable for ADL patients ($n = 20$) in Puri district of Odisha perhaps due to the coastal climatic conditions, which is also one of the causative modalities of this medicine.

No statistically significant difference was found between the effect of Homoeopathy and allopathy treatment on ADL. However, this study yielded a positive outcome through Homoeopathy. It is proved that Homoeopathy medicines are equally effective in ADL attacks as allopathy medicines.

ADL attacks were controlled and lymphoedema disappeared or reduced. This is in conformation with the findings in the earlier studies.^[18]

But to get a more significant and better result, a multicentric research with larger samples is essential with different approach, i.e. immunological studies on filariasis so that the scientificity of Homoeopathy can be established.

CONCLUSION

Despite all the differences, the overall conclusion from the above study can be drawn that Homoeopathy is equally effective as conventional therapy in the treatment of acute ADL. This

work has certainly contributed to the growing evidence that Homoeopathy is a safe and better treatment strategy and is at par with standard allopathic therapy in the above condition. This work has made our study hypothesis true that when prescribed upon totality of symptoms, Homoeopathy is equally useful in relieving the symptoms of ADL when compared to conventional allopathic therapy. But to get a more significant result, a multicentric research with larger samples is essential with different approach, i.e. immunological studies on filariasis so that the scientificity of Homoeopathy can be established. Future researches exploring the effect of homoeopathic medicines on the filarial antigens using Og4C3 ELISA test (highly specific and sensitive for the diagnosis of filariasis) or lymphoscintigraphy (which helps to access the structural and functional changes in the lymphatics) should be performed to validate the results.

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Conflicts of interest

None declared.

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Annexure 1: ADL scoring scale as devised by CCRH**ADL scoring scale**

Date _____

Serial number	Symptoms	Presence of symptoms and grading according to their intensity			
1	Local pain	0 absent (0)	1 mild (1-3)	2 moderate (4-6)	3 severe (7-10)
2	Local tenderness	0 absent (0)	1 mild (Grade I)	2 moderate (Grade II and III)	3 severe (Grade IV)
3	Erythema or red streaks along the course of affected lymphatics	0 absent (0)	1 present		
4	Lymphoedema	0 absent (0)	1 (Grade I)	2 (Grade II)	
5	Swollen lymph node	0 absent (0)	1 present at one or more site (s)		
6	Fever	0 absent (0)	1 mild (99°F-100°F)	2 moderate (101°F-103°F)	3 severe >103o
7	Myalgias	0 absent (0)	1 mild (1-3)	2 moderate (4-6)	3 severe (7-10)
8	Fatigue	0 absent (0)	1 mild (1-3)	2 moderate (4-6)	3 severe (7-10)
9	Anorexia	0 absent (0)	1 mild (Grade I)	2 moderate (Grade II)	
10	Nausea	0 absent (0)	1 mild (Grade I)	2 moderate (Grade II)	
11	Vomiting	0 absent (0)	1 mild (Grade I)	2 moderate (Grade II)	
12	Headache	0 absent (0)	1 mild (1-3)	2 moderate (4-6)	3 severe (7-10)
Total score					
Mild		<9			
Moderate		10-18			
Severe		19-28			

ADL: Adenolymphangitis

Annexure 2: Assessment form for ADL attacks**Assessment at each monthly visit (form M₁ to M₆)**

Date _____

Name of the patient _____ Sex: Male/female _____ Age _____

Tel No. _____ E-mail _____

Circle relevant number under each heading

Number of ADL attacks in previous month	0 no attack	1 One	2 Twice	3 Thrice
Duration of the entire episode of Acute ADL		1 (1-3 days)	2 (4-6 days)	3 (>6 days)
Intensity at baseline*		1 mild	2 moderate	3 severe

*Intensity at the baseline of each attack as per Annexure 8. ADL: Adenolymphangitis

Signature of consultant.

Signature of investigator

लिम्फैटिक फिलीरियासिस में तीव्र एडेनोलिम्फैंगिटिस के मानक एलोपैथी उपचार के साथ होम्योपैथी की प्रभावकारिता का मूल्यांकन करने के लिए एक यादृच्छिक तुलनात्मक अध्ययन

उद्देश्य: इस अध्ययन का प्राथमिक उद्देश्य तीव्र एडेनोलिम्फैंगिटिस में मानक एलोपैथी उपचार के साथ होम्योपैथिक उपचार की प्रभावकारिता की तुलना करना था और सहायक उद्देश्य आघातों की तीव्रता, अवधि और आवृत्ति में कमी, रोगियों के जीवन की गुणवत्ता में सुधार का आकलन करना था।

विधि: क्षेत्रीय अनुसंधान संस्थान, पुरी, ओडिशा में अक्टूबर 2012 से अप्रैल 2014 तक 112 रोगियों पर यह अध्ययन एक तुलनात्मक यादृच्छिक नैदानिक परीक्षण के रूप में डिजाइन किया गया था। एडीएल रोगियों को नामांकित किया गया और उन्हें यादृच्छिक रूप से छह माह की अवधि के लिए होम्योपैथिक उपचार या मानक एलोपैथिक उपचार दिया गया।

परिणाम: प्राथमिक परिणामों के लिए 112 रोगियों को देखा गया (होम्योपैथी=55 व एलोपैथी=57) और 11वें दिन इनका विश्लेषण किया गया। हालांकि एडीएल स्कोर में सुधार दोनों तरह के उपचारों का प्रभाव समान था, यद्यपि अध्ययन के छह माह के दौरान एलोपैथी समूह की तुलना में होम्योपैथी समूह में आघात की आवृत्ति, अवधि और तीव्रता में सुधार था। एलोपैथिक समूह से तुलना में डब्ल्यूएचओ क्यूओएल के डोमेल 4 में होम्योपैथिक समूह में सांख्यिकीय रूप से महत्वपूर्ण सुधार था (पी=0.004)। होम्योपैथिक औषधि एपिस मेलिफिका (एन = 23), रक्स टोक्सीकोडैन्ड्रोन (एन = 20) और पल्साटिला (एन = 8), आर्सेनिक एल्बम (एन=1), ब्रायोनिआ अल्बा (एन=1), सिलिसिया (एन=1), और हेपर सल्फ (एन=1), जैसी औषधियाँ तीव्र आघातों में सबसे उपयोगी पाई गईं।

निष्कर्ष: यह अध्ययन इस तथ्य के समर्थन में साक्ष्य प्रदान करता है कि एडीएल के लिए व्यक्तिगत होम्योपैथिक उपचार मानक एलोपैथी उपचार के समान ही एडीएल के प्रबंधन में प्रभावी है।

Une étude comparative randomisée pour évaluer l'efficacité d'un traitement homéopathique par rapport à un traitement allopathique lors d'épisodes d'adénolymphangite aiguë dans les cas de filariose lymphatique

Objectif: L'objectif primaire de l'étude était de comparer l'efficacité d'un traitement homéopathique à celle d'un traitement allopathique standard lors d'une adénolymphangite aiguë et l'objectif secondaire était d'évaluer la baisse en termes de fréquence, durée et intensité des crises ultérieures et l'amélioration de la qualité de vie des patients.

Méthodes: L'étude a été conçue comme un essai comparatif randomisé qui a été conduit d'octobre 2012 à avril 2014 sur 112 patients au Regional Research Institute à Puri en Odisha. Les patients inscrits souffrant d'adénolymphangite ont été randomisés pour bénéficier d'un traitement soit homéopathique soit allopathique standard sur une période de six mois.

Résultats: 112 patients ont été examinés pour un premier résultat (homéopathie = 55 et allopathie = 57) et des analyses ont été faites le 11^e jour. Les deux traitements ont apporté la même amélioration dans le traitement de l'adénolymphangite. Cependant, au cours de la période d'étude de six mois, les résultats concernant la fréquence, la durée et l'intensité des crises étaient meilleurs pour le groupe « homéopathie » que pour le groupe « allopathie ». Une amélioration sensible a été statistiquement constatée dans le groupe « homéopathie » dans le Domaine 4 du WHOQOL (questionnaire de l'OMS sur la qualité de vie) (P=0,004) par rapport au groupe « allopathie ». Il a été constaté que des médicaments tels que *Apis mellifica* (n=23), *Rhus toxicodendron* (n=20), *Pulsatilla* (n=8), *Arsenic album* (n=1), *Bryonia alba* (n=1), *Silicea* (n=1) et *Hepar sulph* (n=1) étaient particulièrement efficaces lors de crises aiguës.

Conclusion: Cette étude a établi l'existence d'éléments prouvant qu'un traitement homéopathique individualisé est aussi efficace qu'un traitement allopathique standard pour la gestion de l'adénolymphangite.

Estudio comparativo aleatorizado para evaluar la eficacia de la homeopatía y el tratamiento alopatóico estándar en la adenolinfangitis (ADL) aguda en la filariasis linfática

abstract

Objetivos: El objetivo principal del estudio fue comparar la efectividad del tratamiento homeopático con el régimen alopatóico estándar en la ADL aguda y el objetivo secundario fue evaluar la reducción en la frecuencia, duración e intensidad de los ataques posteriores, la mejora de la calidad de vida de los pacientes.

Métodos El estudio se diseñó como un ensayo comparativo aleatorizado realizado desde de octubre de 2012 a abril de 2014 en 112 pacientes del Regional Research Institute, Puri, Odisha. Se incluyeron pacientes con ADL que se aleatorizaron para recibir el tratamiento homeopático o el tratamiento alopatóico estándar durante un periodo de seis meses.

Resultados: Se consideraron 112 pacientes para el resultado primario (Homeopatía = 55 y Alopátía = 57) y se analizaron en el día 11. Ambos tratamientos producen igual para la mejora en los puntajes ADL. Sin embargo, durante el período de estudio de seis meses, la frecuencia, duración e intensidad de los ataques fueron mejores en el grupo de Homeopatía en comparación con el grupo de alopatía. Hubo una mejoría estadísticamente significativa en Homeopatía en el dominio 4 de WHOQOL (p = 0,004) en comparación con el grupo de alopatía. Medicamentos como *Apis mellifica* (n = 23), *Rhustoxicodendron* (n = 20), *Pulsatilla* (n = 8), *álbum de arsénico* (n = 1), *Bryonia alba* (n = 1), *Silicea* (n = 1) y *Heparsulph* (n = 1) fueron los más útiles en los ataques agudos.

Conclusiones: Este estudio proporciona evidencias que corroboran el hecho de que el tratamiento homeopático individualizado es eficaz en la ADL igual que el tratamiento alopatóico estándar.

Eine zufällig Vergleichsstudie zur Bewertung der Wirksamkeit der Homöopathie gegen die allopathische Behandlung bei akuter Adenolymphangitis bei lymphatischer Filariose

Abstrakt

Ziel: Das primäre Ziel der Studie war es, die Wirksamkeit der homöopathischen Behandlung mit Standard allopathischen Regime in akuten ADL und sekundären Ziel zu vergleichen, um die Verringerung der Häufigkeit, Dauer und Intensität der nachfolgenden Angriffe, die Verbesserung der Lebensqualität der Patienten zu beurteilen.

Methoden: Die Studie wurde als vergleichende randomisierte Studie von Oktober 2012 bis April 2014 an 112 Patienten des Regional Research Institute, Puri, Odisha, durchgeführt. Die ADL-Patienten wurden randomisiert und erhielten entweder eine homöopathische Behandlung oder eine allopathische Standardbehandlung über einen Zeitraum von sechs Monaten.

Ergebnisse: 112 Patienten wurden für den primären Endpunkt (Homöopathie = 55 und Allopathie = 57) berücksichtigt und am 11. Tag analysiert. Beide Behandlungen führten zu einer gleichmäßigen Verbesserung der ADL-Werte. Es gab eine statistisch signifikante Verbesserung der Homöopathie in Domäne 4 von WHOQOL ($P = 0,004$) im Vergleich zur Allopathie-Gruppe. Arzneimittel wie *Apis mellifica* ($n = 23$), *Rhus toxicodendron* ($n = 20$), *Pulsatilla* ($n = 8$), *Arsenalbum* ($n = 1$), *Bryonia alba* ($n = 1$), *Silicea* ($n = 1$) und *Hepar sulph* ($n = 1$) wurden bei akuten Attacken am nützlichsten gefunden.

Schlussfolgerung: Diese Studie belegt, dass die individualisierte homöopathische Behandlung für die ADL ebenso wirksam ist wie die allopathische Standardbehandlung bei der Behandlung von ADL.

