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Impact of Individualised Homoeopathic Medicines on Thrombocyte Count in Dengue Fever: Single Arm Clinical Study

Shimna K,[1] Suveena V,[2*] Sreenath B, [3] Arun Krishnan P [4]

[1] Medical Officer, Government Homoeopathy Dispensary, Kathirur, Kannur, Kerala, India
[2] Medical Officer, Govt. Homoeopathy Dispensary, Kainakary, Alappuzha, Dept. of Homoeopathy, Govt. of Kerala, India
[3] Assistant Professor, Department of Organon and Philosophy, Govt. Homoeopathic Medical College, Calicut, Kerala, India
[4] Research Officer (H)/S-1, National Homoeopathy Research Institute In Mental Health, Kottayam, Kerala, India

ABSTRACT:

Dengue fever is a vector-borne disease transmitted by the bite of the female Aedes aegypti mosquito. The infectious agent is a virus known as the dengue virus, which has four serotypes: Dengue virus-1, Dengue virus-2, Dengue virus-3, and Dengue virus-4. The dengue fever epidemic has emerged as a serious threat to the health sector over the last few years. Although the full global burden of the disease remains uncertain, its impact on human health and the economy is alarming. The study was carried out to assess the effectiveness of homoeopathic medicines in normalizing thrombocyte count in dengue fever. Design - Experimental study using a one-group before-and-after design. Sample - Purposive sampling. Size - 21 participants diagnosed with Dengue fever. Tools - Dengue Thrombocyte Criteria. Technique - Homoeopathic medicines, *Nux vomica, Arsenic album, Pulsatilla, Eupatorium,* and *Gelsemium* were the most indicated medicines prescribed in appropriate doses and repetitions. Procedure - Cases diagnosed with Dengue fever selected from the Government Homoeopathic Medical College, Kozhikode. Post-tests were done 5 to 7 days after illness. Statistical Analysis - Wilcoxon Signed Ranks test. Results - Significant pre-/and post-test differences were observed. Homoeopathic medicines were found effective in normalizing thrombocyte count in patients with Dengue fever.

KEYWORDS: Dengue fever, Homoeopathy, Homoeopathic medicines, Individualization, Normalizing, Thrombocyte count.

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***Corresponding Author:**
Dr. Suveena V
Medical Officer, Govt. Homoeopathy Dispensary, Kainakary, Alappuzha, Dept. of Homoeopathy, Govt. of Kerala, India
Email: suveenav606@gmail.com

INTRODUCTION:

Dengue is a vector-borne disease transmitted by the bite of the female Aedes aegypti mosquito. The infectious agent is a virus known as the dengue virus, which has four serotypes: DEN-1, DEN-2, DEN-3, and DEN-4. The dengue epidemic has emerged as a serious threat to the health sector over the last few years. The disease's impact on human health and the economy is concerning, despite the fact that its exact worldwide burden is still unknown. The loss to the economy is 264 disability-adjusted life years (DALYs) per million population per year. [1,2]Approximately 1.8 billion (more than 70%) of the population at risk for dengue worldwide live in member states of the WHO South-East Asia Region (SEAR) and Western Pacific Region, which bear nearly 75% of the current global disease burden due to dengue. Of the 11 countries in SEAR, 10 countries, including India, are endemic for dengue.[3]

The dengue virus was isolated in India for the first time in 1945.The first evidence of the occurrence of dengue fever in the country was reported in 1956 from Vellore district in Tamil Nadu.The first dengue Hemorrhagic fever (DHF) outbreak occurred in Calcutta (West Bengal) in 1963.[4,5]

During 1996, one of the most severe outbreaks of Dengue Fever (DF)/DHF occurred in Delhi, with 10,252 cases and 423 deaths being reported (country total being 16517 cases and 545 deaths. In 2006, the nation experienced an outbreak of DF/DHF, resulting in 12,317 cases and 184 fatalities. The prevalence of dengue has escalated in recent years. In 2010, 28,292 instances were reported, escalating to 50,222 in 2012 and reaching 75,808 in 2013, the highest figure since 1991. The case fatality ratio (CFR-deaths per 100 cases) decreased from 3.3% in 1996 to 0.4% in 2010 following the dissemination of national guidelines for the clinical management of DF/DHF/dengue shock syndrome (DSS) in 2007.This further declined to 0.3%in 2013.[5,6]

The ineffective dengue virus vaccines and poor preventive measures have resulted in the emergence of dengue endemic in Kerala, particularly in the Thiruvananthapuram area, since 2010.[7] The deficiencies in the treatment and management of dengue fever can be more effectively addressed using homoeopathic remedies chosen based on individualization. Homeopathic remedies operate on the idea of similia similibus curentur. This theory posits that the therapeutic efficacy of medications depends on their ability to elicit symptoms analogous to the disease, yet more pronounced than the disease itself. Each specific instance of sickness is most effectively, swiftly, and permanently eradicated solely by a remedy that may induce, in the human organism, a comprehensive manifestation of its symptoms, which concurrently surpasses the intensity of the disease itself.[8] Homoeopathic remedies are beneficial in the prevention and treatment of acute infectious illnesses.[8]

Various mechanisms have been proposed to explain the signs and symptoms of dengue fever, including complex immune mechanisms, T-cell-mediated antibodies that cross-react with the vascular endothelium, resulting in the enhancement of complement and its products, as well as antibodies and various soluble mediators, such as cytokines and chemokines. Whatever the mechanisms are, these ultimately target the vascular endothelium, platelets, and various organs, leading to vasculopathy and coagulopathy that are responsible for the development of

haemorrhage and shock.[9] The platelet count was found to decrease from the 3rd day of onset of illness, and the count began to increase gradually from the 8th to 10th day of illness.[10,11,12] The decrease in platelet count was attributed to bone marrow suppression and DEN-V-mediated platelet activation.[13]

The triad of fever, bleeding tendencies, and rash, accompanied by thrombocytopenia and elevated hematocrit, may serve as predictive indicators for the early diagnosis of dengue hemorrhagic fever prior to the availability of specific tests such as NS1 antigen and antibodies.[14]A study conducted by Managoli N et al. showed that there was no significant improvement in the clinical outcome of patients who received platelet transfusion during the course of treatment.[15]Another study, by Kumar CM, et al. reveals that that platelet count can be used to predict complication rates in patients with dengue fever. Thrombocytopenia among dengue patients exhibits no preference for age group or gender.[16] Though leukopenia is seen early in the disease, there is no significant correlation to complication rate.[17]

Although a vaccine against dengue fever is now available, no antiviral agent has yet been found to be effective in treating acute dengue fever.[18] The homoeopathic combination appeared to be a more potent treatment against dengue fever.[19] Homoeopathy is found to be effective not only in the treatment but also prevention of dengue fever.[20]

Sinha M et al. found that *Rhustoxicodendron6c* was effective in increasing cell size and also helps in the organization of midgut cells of *Aedes albopictus* mosquito, thereby reducing the DEN-V invasiveness in these midgut cells.[21] In Rio de Janeiro, Brazil, *Phosphorous 30C*, *Crotallus horridus 30C,* and *Eupatorium perfoliatum 30C* were distributed among asymptomatic patients in early 2007 when there was a dengue epidemic. It was observed that the incidence of the disease in the first three months of 2008 fell by 93%compared to the corresponding period in 2007, whereas in the rest of the state of Rio de Janeiro, there was an increase of 128%.[22] Another statistical study by Anand PR et al. points towards the efficacy of *Eupatorium 200C* as prophylactic during dengue outbreaks.[23] Most of the previous studies were focusing on the preventive action of Homoeopathic Medicines in dengue epidemic. However, no experimental studies were available till date to establish effectiveness of Homoeopathic medicines in treatment of any of the stages of DF. Additionally, in the scenario where no effective antiviral therapy have been developed, there is a need for finding alternative methods for treating DF. The current study aims to find out the role of homoeopathic medicines in normalizing the thrombocyte count in dengue fever so that the majority of the morbidity and complications in dengue fever can be reduced. Homoeopathic treatment, hereby employed, was found to be much superior in terms of the economic background. The medicines employed for treating the dengue cases are much safer in regard to the side effects and complications, too. The objective of the study was to find out the effectiveness of homoeopathic medicines in normalizing thrombocyte count in dengue fever

METHODS

Design

The present study employed a one-group before-and-after design. The study was conducted in patients attending the outpatient and inpatient department units of the Government Homoeopathic Medical

College, Kozhikode, from July 2017 to August 2017. Patients with an NS1 Ag positive test result and a thrombocyte count below 1,50,000 were included in the study. Ethical approval was obtained from the institution. Written informed consent was obtained from the patients prior to their enrollment in the study.

The study was conducted in the following phases:

Phase 1: The patients with NS1 Ag positive and thrombocyte count below 1,50,000 cells/mm^3 on the 3rd day of illness were selected for the study. This thrombocyte count is considered a pretest.

Phase 2: Homoeopathic medicines are administered based on the totality of symptoms.

Phase 3: A follow-up of the case is conducted on the 5th or 7th day after fever onset, and the thrombocyte count is recorded. It is considered a posttest.

Sample

Technique-Purposive sampling

Universe-Government Homoeopathic Medical College, Kozhikode

Population-Patients diagnosed with dengue fever.

Size-21 cases

Inclusion Criteria

1. Patients of any age group and gender diagnosed with dengue fever.
2. Patients with a positive NS1 Ag test and thrombocytopenia (platelet count < 1,50,000 cells/mm^3 on 3rd day of illness.

Exclusion Criteria

1. Cases without proper documentation and follow-ups.
2. Cases taking Allopathic medicines for Coronary Artery Diseases (CAD)
3. Cases with malignancies.

Variables

Dependent: Thrombocyte count

Independent: Homoeopathic medicines

Tool

1. Dengue Thrombocyte Criteria (DTC) for dengue fever.

The tool **(Table 1)** was developed based on the WHO criteria. According to WHO criteria,the normal thrombocyte count ranges from 1.50×10^9 to 4.00×10^9 cells/mm^3.Here, the thrombocyte counts of the patients are categorized into 5 ranges. Each range is assigned a score from 1 to 5, as shown below.

10,000 and below- 1
10,001-49,999 - 2
50,000-99,999 - 3
1,00,00-1,49,999 - 4
1,50,000 and above - 5

The pretest and post-test scores are recorded and then subjected to statistical analysis.

2.Informed consent from each patient has been filled out and received.

Technique

Homoeopathic medicines selected on the basis of individualization have been employed. Here, the cases were thoroughly studied, and totality was erected. Repertorisation was performed based on the totality of the framed symptoms. The final judgement of the medicine was made after referring to the Materia medica. Commonly prescribed medicines included *Arsenic album 200 C*, *Nux vomica 200C*, *Pulsatilla 200C*, *Eupatorium 200C*, *Gelsemium 30C*. Dose and repetition were done based on homoeopathic principles.

PROCEDURE:

The study was done at the outpatient and inpatient departments of the Government Homoeopathic Medical College, Kozhikode. Twenty-one cases of dengue fever presented with thrombocytopenia in the early stages of fever. The platelet count was determined on the third day of illness, which is categorized based on the DTC and was considered the pretest. After homoeopathic case taking, individualized homoeopathic medicines for each case were determined and prescribed. The posttest was conducted 5-7 days after the onset of illness.

Statistical analysis:

Here, the given sample was not in a normal distribution, and the sample size is very small. So, the utility of a parametric test for statistical analysis becomes impossible. Therefore, statistical analysis is done by the Wilcoxon Signed Ranks test (WSR). It is a non-parametric test used to find out the difference between two related samples.

The results were obtained after statistical analysis. **Tables2, 3,** and **4** represent the pretest and posttest DTC scores, respectively. **Table 5** showed that the mean rank of negative ranks is 7.00 and the sum of negative ranks is 14.00. The mean rank of positive ranks is 10.89, and the sum of positive ranks is 196.00. There were 2 ranks having post-test scores less than pretest; 18 ranks having post-test scores greater than pretest, and 1 among them had the same pretest and posttest scores. **Table 6** shows the results of WSR. It denotes that the Z score obtained was -3.561, which was significant at the 0.000 level. WSR is used to find out the difference between two related samples. The pretest scores and posttest scores were compared to find out the difference. The result showed that significant changes had occurred.

RESULTS: The pre and post treatment value of thrombocyte count is mentioned in table-2

Table 1: Dengue Thrombocyte Criteria (DTC) scoring

Code No	**Name of the Patient**	**Age**	**Gender**	**Date**

Thrombocyte Count(In Cells /MM^3)	**10,000 and below (1)**	**10,001-49,999 (2)**	**50,000-99,999 (3)**	**1,00,00-1,49,999 (4)**	**1,50,000 and above (5)**

Table 2: Pretest and Posttest – Thrombocyte count (in cells / mm^3)

Code No	**Pretest (Before Treatment)**	**Posttest (After treatment)**
1	10,000	2,50,000
2	62,000	3,20,000
3	1,49,000	4,82,000
4	1,02,000	2,74,000
5	1,19,000	2,61,000

6	1,05,000	3,75,000
7	32,000	1,07,000
8	1,15,000	2,01,000
9	92,000	1,38,000
10	35,000	2,69,000
11	1,46,000	2,12,000
12	1,41,000	2,87,000
13	1,14,000	1,80,000
14	1,15,000	3,80,000
15	58,000	2,27,000
16	1,34,000	56,000
17	38,000	2,96,000
18	1,48,000	1,94,000
19	1,42,000	69,000
20	67,000	1,51,000
21	82,000	86,000

Table 3: Pretest DTC scores

Code No.	**Thrombocyte Count (In Cells /mm^3)**				
	10,000 and below (1)	10,001-49,999 (2)	50,000-99,999 (3)	1,00,000-1,49,999 (4)	1,50,000 and above (5)
1.	+				
2.			+		
3.				+	
4.				+	
5.				+	
6.				+	
7.		+			
8.				+	
9.			+		
10.		+			
11.				+	
12.				+	
13.				+	

14.				+	
15.			+		
16.				+	
17		+			
18				+	
19.				+	
20.			+		
21.			+		

Table 4: Posttest DTC scores

Code No.	Thrombocyte Count(In Cells /mm^3)				
	10,000 and below (1)	10,001-49,999 (2)	50,000-99,999 (3)	1,00,000-1,49,999 (4)	1,50,000 and above (5)
1.					+
2.					+
3.					+
4.					+
5.					+
6.					+
7.				+	
8.					+
9.				+	
10.					+
11.					+
12.					+
13.					+
14.					+
15.					+

16.			+		
17					+
18					+
19.			+		
20.					+
21.			+		

Table 5: Ranks obtained in pretest and posttest Ranks

		N	Mean Rank	Sum of Ranks
posttest – pretest	Negative Ranks	2[a]	7.00	14.00
	Positive Ranks	18[b]	10.89	196.00
	Ties	1[c]		
	Total	21		

a. posttest < pretest

b. posttest > pretest

c. posttest = pretest

Table 6: Test Statistics based on Wilcoxon Signed Ranks Test (WSR)

Test Statistics[a]

	posttest – pretest
Z	-3.514[b]
Asymp. Sig. (2-tailed)	.000

a. Wilcoxon Signed Ranks Test ,

b. Based on negative ranks.

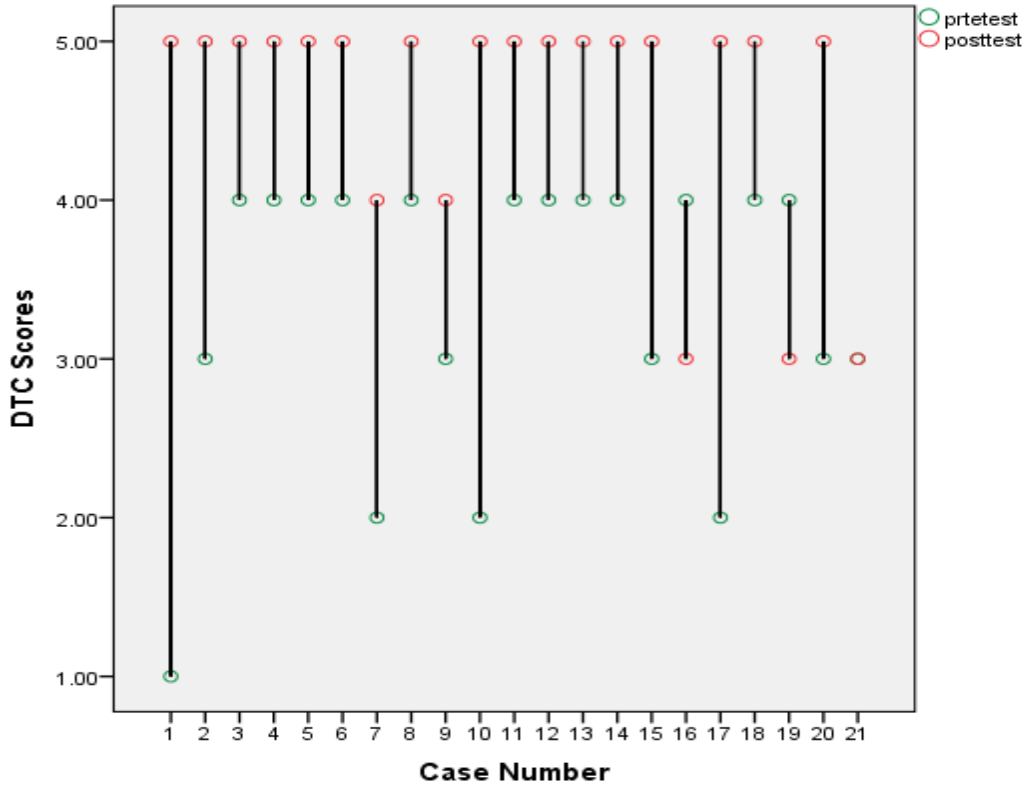

Figure 1: Line Drop graph showing DTC scores of each case during pretest and post test

Figure 1 showed the individual DTC scores of 21 participants. Out of this,5 participants are having posttest scores 4 or below. One sample showed no change in the pretest and posttest.

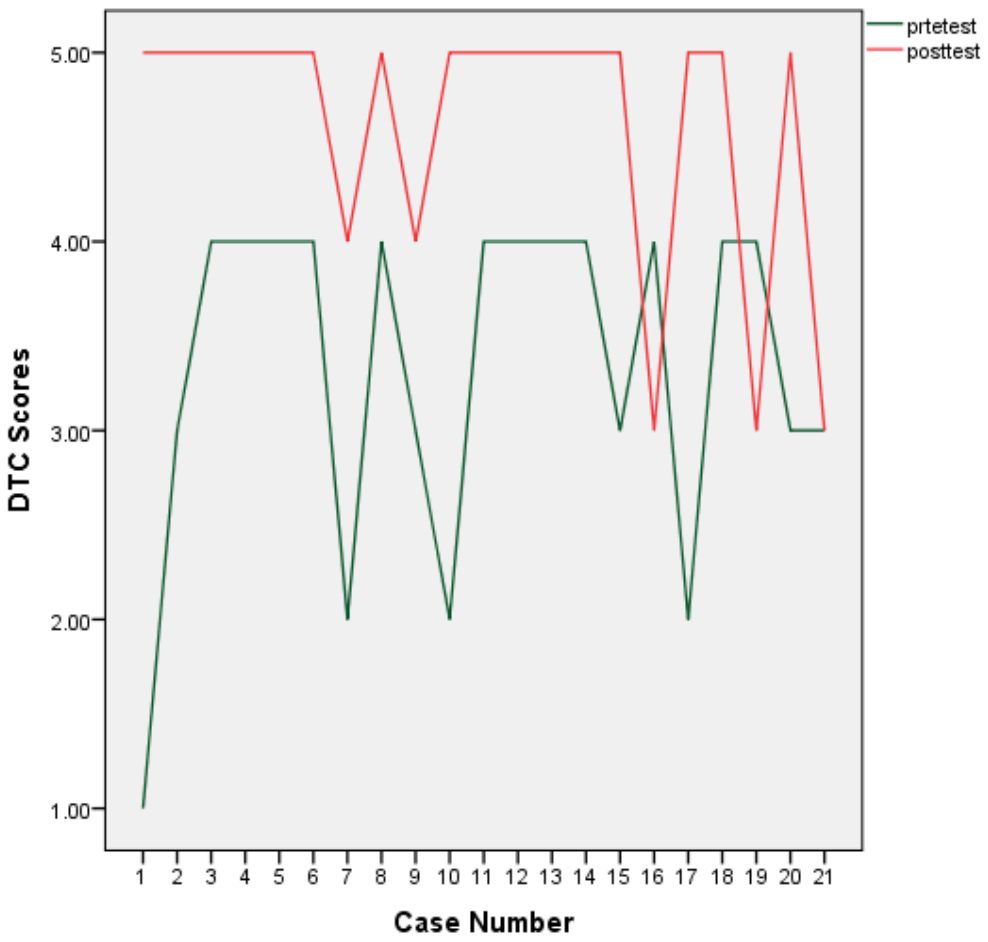

Figure 2: Line graph denoting DTC scores of pretest and

In **Figure 2,** the red line indicates the posttest scores, and the green line indicates the pretest scores. Out of the 21 samples, 16 participants showed a posttest score of 5.Out of the 5 patients having posttest scores at 4 or below, 3 patients have a posttest score of 3.

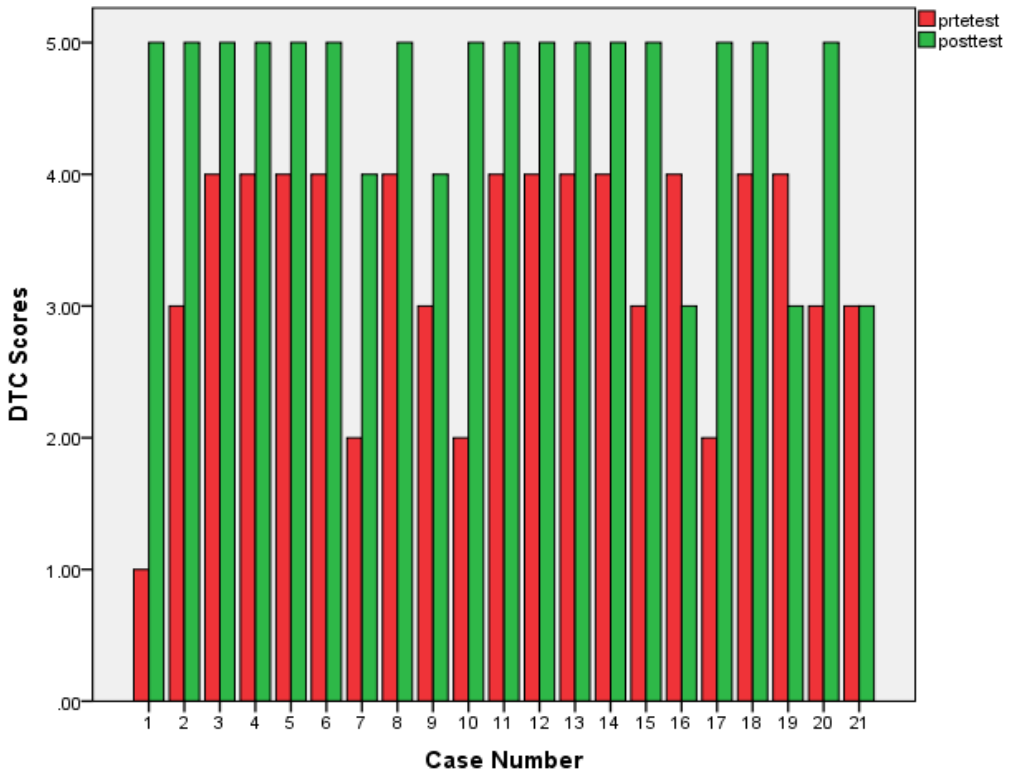

Figure 3: Multiple bar diagram showing individual pretest and posttest DTC scores

Figure 3 showed multiple bar diagram with green bars indicating posttest scores and red bars indicating pretest values. Out of the 16 participants having posttest score of 5,4 patients were having pretest score of 2 or below 2.

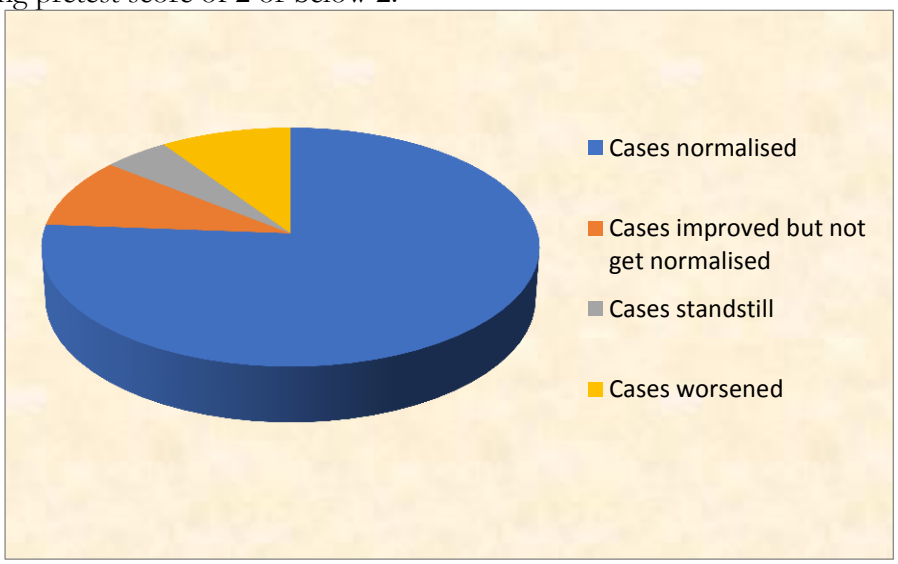

Figure 4: Treatment

In Figure 4, out of 21 cases, 16 cases (76.19%) became normalized, 2 cases (9.52%) improved but did not get normalized, 1 case (4.76%) remained at a standstill, and 2 cases (9.52%)

worsened.

DISCUSSION:

The study was conducted at Government Homoeopathic Medical College, Kozhikode, from July 2017 to August 2017. Out of forty-nine screened cases for DF, twenty-one cases with proper documentation and follow-up took part in the present study. The WSR test showed there was a significant difference. The thrombocyte count was used as the dependent variable. The pretest was assessed using DTC. The criteria were maintained on 5 scoring levels. Thrombocytes below 10,000 were scored as 1 mark, and thrombocyte count between 10,001-49,999 was given 2 marks, and so on. 5 marks were given to thrombocyte count above 1,50,000. The pretest score of all participants was recorded as 4 or below, which means a thrombocyte count of 1,49,999 or below. After the intervention with individualized homoeopathic medicines, the posttest was taken on 5-7 days of illness. The medicines were selected based on symptom similarity rather than specific remedies. Repetition of doses was performed according to the intensity of the symptoms. Out of the 21 participants, 16 had posttest scores of 5. Their posttest scores were found to increase above 1,50,000. Out of the 5 participants with posttest scores of 4 or less, 2 had posttest scores less than pretest scores; only one patient had both pretest and posttest scores of 3. Thus, we see that the posttest DTC scores recorded show a significant change in the thrombocyte count. ~~Hence, the null hypothesis is rejected.~~ These findings undoubtedly stated that individualized homoeopathic medicines were found effective in normalizing the reduced thrombocyte count in dengue fever.

Significant improvement in the symptoms was noted even before the changes in thrombocyte count. In cases of patient weakness and decreased Packed Cell Volume (PCV), intravenous fluids were administered until signs of dehydration subsided. Patients were admitted to a dedicated fever ward, provided with mosquito nets, and their temperature, blood pressure, and pulse rate were monitored every four hours and documented in the fever case records. Among the inpatient cases, none required emergency referral to higher centres, as all were adequately monitored within the hospital. Patients with severe thrombocytopenia and an increase in hematocrit concentration needed accessory management in the form of parenteral fluids. None of the patients needed antipyretics as per the conventional treatment. None of the cases advanced to hemorrhagic complications or Dengue Shock Syndrome.

Nux vomica 200C, Arsenic album 200 C, Pulsatilla 200C, Eupatorium 200C, Gelsemium 30C were the most indicated medicines in the order of frequency. The selection of medicines was made after repertorization and further reference to the Materia medica. Dose and repetition were done based on homoeopathic principles. 33% of the cases received *Nux vomica* as the first prescription. Irritability, burning feeling over the face, chilliness even on uncovering, constipation and severe backache were some of the important symptoms of patients to whom *Nux Vomica* was prescribed.[24] Weakness was present in almost all the patients. *Arsenic album* was prescribed based on the restlessness, chilliness and extreme thirst for warm water in 23% of the patients.[25] Similar patients with thirstlessness were prescribed *Pulsatilla*. Although *Eupatorium* was found to be an effective prophylactic in earlier studies,[26] it was prescribed in only

14% of the cases. The Similarly *Gelsemium* was prescribed only in 14% of the cases and the main presenting complaints were severe weakness with dizziness on trying to move, headache with bursting sensation in the forehead and eyeballs and chilliness.[25] Repetition of the doses was performed hourly when the thrombocyte count was below 50,000. Those with a value above this threshold were prescribed either three times a day or once a day, based on the severity of the symptoms as assessed by the physician. The time taken for the decrease in the thrombocyte count to return to normal ranged from 5 to 7 days after the onset of illness, and in most cases, symptomatic relief occurred even earlier. This finding is consistent with the study by Seema et al. [27]

CONCLUSION:

In this study, homoeopathic medicines were found effective in normalizing the thrombocyte count in dengue fever within 5-7 days of illness. Significant improvement in the symptoms was noted even before the changes in thrombocyte count. None of the cases in this study advanced to hemorrhagic complications and DSS. Commonly prescribed medicines included *Nux vomica 200 C, Arsenic album 200C, Pulsatilla 200 C, Eupatorium 200 C* and *Gelsemium 30 C*. Further studies with large sample size, control groups and time series studies are warranted and it could establish the scope of homoeopathy on rapidly emerging epidemic disease, dengue fever.

Limitations of the study:

a) The study was conducted with a one-group before-and-after design.
b) The sample size was very small.

Suggestions for Further Research

a) The study should be replicated with Time series design.
b) The study should be replicated with an RCT design.
c) Comparative studies with other systems of medicine should be done.

Declaration of patients Consent:

Written informed consent was obtained from the patients for the publication of the case details, including clinical information and images. Confidentiality and anonymity of the patient have been strictly maintained.

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