

Effectiveness of *Syzygium cumini* (Naval) Root Decoction of on Diabetics Mellitus (*Mathumeaham*)

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Publication Date: 30 December 2016

Article Link: <http://medical.cloud-journals.com/index.php/IJAAPR/article/view/Med-313>



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Abstract This study is Quasi-experimental clinical trial to determine the effectiveness of root decoction of *Syzygium cumini* (Naval) in the management of Diabetics Mellitus (*Mathumeaham*). It also determines the association of Diabetics Mellitus with hereditary, food habits, physical activities and mental disturbances. Diabetics Mellitus disease is a problem of the Pancreas. The researcher administered questionnaire was used to collect the data. Ten (10) patients were selected clinically during the period of May 2015 to June 2015 at the Rural Ayurvedic hospital, Kopalapuram. Patients were treated with root decoction of *Syzygium cumini* (Naval). Evaluation visits were made at baseline, 5th day, 10th day, 20st day, 30th day, and 40th day. Effect of treatment was evaluated on changes in the sign and symptoms. Clinical parameters were analyzed by scores as difference between the visits on first day of treatment and after treatment. Statistically highly significant improvement ($p < 0.004$) in Polyuria, frequency of urine, pain and fasting blood sugar level and statistically not significant ($p < 0.208$) dyspnea, polydipsia and increase appetite. In general it is hoped that the findings of this study would help in the global use of decoction of *Syzygium cumini* for the treatment of Diabetics Mellitus.

Keywords *Syzygium cumini*; *Diabetics Mellitus*; *Decoction*

1. Introduction

This is a single blind comparative clinical trial to determine the internal administration of *Naaval Vear Decoction* in the management of *Mathumeaha* patients. In modern science, *Madhumeha* is correlating with Diabetes mellitus and is one of the cardinal problems in the medical profession because it cannot be cure but some extent controlled. Diabetes mellitus is a clinical syndrome characterized by hyperglycaemia due to absolute or relative deficiency of insulin (Ramchandra, 2002).

Siddha System of Medicine clearly defines Diabetes. Diabetes Mellitus was known to Indian Civilization since Vedic period by the name *Mathumeaham*. Diabetes is also known as *Madhumeham*, is mentioned under the *Vatha* disease (Subramaniyan, 1998). All parts of the body and every cell of human physiology are effected by *Mathumeaha*, It also disturbs 5 sheaths of the body-*Annamayakosha* (Food sheath), *Pranamayakosha* (Energy sheath), *Manomayakosha* (Mind

Sheath), Vijnanamayakosha (Intellectual Sheath) and Anandamayakosha (Bliss Sheath) (www.holycrystals.in is owned by M/s. Holy Crystals, 2015).

Mathumeaham in siddha medicine, there are 20 types of Madhumeham that is 4 types of 6 types of Pitham and 10 types of Kapham according to Yuhimuni. Madhumeha disease is characterized by frequent urination against nature, ants and flies found in the urine, caramelized sugar odour from the urine, and gradual weight loss these characters are compatible with the symptoms of excessive appetite, excessive thirst, frequent urination, weight loss, sleep apnea and syncope (Kuppusamymuthaliyar, 2007).

Diabetes mellitus is of two types:

- (1) Type I– Insulin depended diabetes mellitus (IDDM) or juvenile Diabetes mellitus.
- (2) Type II– Non-insulin depended diabetics mellitus (NIDDM) or adult onset Diabetes mellitus.

Others are gestational Diabetes mellitus and secondary Diabetes mellitus.

WHO estimated that diabetics are 19.4, 16.01, 13.9 millions in India, China, USA in 1995 AD and these increase 57.2, 37.6, 21.9 million respectively in 2025 AD and the global prevalence of type II diabetes will be more than double from 135 million in 1995 to 300 million 2025. Presently it is estimated to affects about 150 – 200 million people Worldwide (Ramchandra, 2002).

There is a wide urban and rural difference in the prevalence of type II diabetes; the prevalence is 2.4% in rural and 11.6% in the urban population. In recent time, high prevalence of impaired glucose tolerance was also report in urban population. WHO estimates that India will have 79.9 million diabetics by 2030. A quarter of the income is devoted to diabetic care for a low-income Indian family that WHO said. Every fifth adult of the world is an Indian, for which India is considered as the Diabetic capital by International Diabetic Federation (Munichoodappa, 2001).

1.1. Background and Justification of the Study

Siddha Medicine means medicine that is perfect. Siddha medicine revitalizes and rejuvenates the organ which is causing disease. This brings back normal functioning of the organs. It also maintains *Vatha*, *Pitha* and *Kapha*, thus maintaining the healthy state of body. Since no artificial chemicals are involved it doesn't cause any side effect (Uthamaroyan, 2005).

Researcher selected *Mathumeham* as the target disorder for this study. In Sri Lanka most of the people are affected by this *Mathumeham* and day to day this is increasing, because the main cause of *Mathumeaham* are lack of exercise and consumption of excess food having *Ushna*, *Snigdha* and *Guru* Nature. Foods that increase *Kapha*, *Medhas* and *Moot-ra* are the major factors for *Mathumeaham*.

The siddha explain this *Naval Vear* Decoction by its theoretical part. But there is no one evaluate by the practical. Hence this study is evaluated by the clinical knowledge and experience. This study helps to standardize *Naval Vear* Decoction for the treatment of *Mathumeaham* for global use.

2. Objective of the Research

To identify the effectiveness of root of *syzygium cumini*.

3. Methodology

This is a Single Blind Comparative Clinical Trial. In this study, Mathumekam patients, according to the inclusive criteria, were selected at the Siddha Rural Hospital, Kopalapuram. The selected patients were divided into two groups and treated with selected drugs for forty days.

3.1. Study Area

This is an institutional based study. The study was conducted at the Rural Ayurveda Hospital, Kopalapuram.

- 1) This hospital has necessary facilities for research work.
- 2) Both indoor and outdoor patients are available
- 3) The number of Out Patient Department (OPD) patients is higher than other Hospitals.
- 4) Accessibility of the rural Ayurveda Hospital, Kopalapuram.

3.2. Study Design

This is a Single Blind Comparative Clinical Trial. *Mathumeka* patients, according to the inclusive criteria, were selected at the Siddha Rural hospital, *Kopalapuram* during (April 29-2015 to June 15 2015). The selected patients were divided into two groups and treated with selected drugs for forty days.

All the selected patients were interviewed by the researcher on their first visit to the OPD. They were assured that all information obtained from them would be strictly confidential.

Treatment allocation depended only on the time sequence in which patients entered the study, thus minimizing selection bias. The drugs selected for this study were prepared by the researcher.

Ten (10) patients were systematically divided into two groups of five each. These patients were selected within the study time frame (April 29-2015 to June 15 2015), using inclusion/exclusion criteria based on the signs, symptoms and investigation *Mathumeaham* in the first phase of the screening procedure. The purpose of the trial was explained to the patients and those who volunteered signed 'informed consent' to enroll in the trial.

3.3. Selection of Mathumeha patients

Patients are age between 35-65. And both sexes presenting with the signs, symptoms and investigation of *Mathumeha* were selected from Outpatients of Rural Hospital of Kopalapuram Nilaveli and were subjected to clinical examination with investigation Dur-ing the period of study (April 29-2015 to June 15 2015), 10 patients were examined by the researcher for *Mathumekam* at the Rural Hospital, Kopalapuram.

First five patients were randomly selected for this study by the sign, symptom and investigation. The researcher found the patient suffered from the *Mathumeham* disease. Those patients who do not take any allopathic treatment.

Other five are patient used allopathic treatment.

All the patient of the researcher is very cooperative for the researcher.

3.3.1. Inclusion criteria

- 1) Age limit 35 - 65 years.
- 2) Sex – both
- 3) Newly detected subjects of type-2 diabetes and were not taking any regular medication. (Fasting blood glucose(FBS) >115 mg/dl)
- 4) Type-2 diabetes mellitus, who were taking modern ant-diabetic medication, but their blood-glucose Level was not controlled to desired level. (Fasting blood glucose(FBS) >115 mg/dl)
- 5) Age limit 35 - 65 years.
- 6) Patient with Cardinal sign & symptoms: - Polyuria, polyphagia, Polydipsia, peripheral neuritis, pain & weight loss.

3.3.2. Exclusion criteria

- 1) Newly detected subjects of type-2 diabetes and were not taking any regular medication. (Fasting
- 2) blood glucose (FBS) < 115 mg/dl)
- 3) Type-2 diabetes mellitus, who were taking modern ant-diabetic medication, but their blood-glucose level was not controlled to desired level.(Fasting blood glucose(FBS) < 115mg/dl)
- 4) Age limit below 35 Above 65 years old.
Other associated diseases such as
 - a. pancreatic diseases
 - b. Stroke patient
 - c. Un controlled diabetic patient
 - d. Ischemic heart disease patients
 - e. And also type 1 diabetes mellitus.
 - f. On medication for any disease also excluded.
 - g. Gestational diabetes.

4. Preparation of Medicine

Plant material (root) was collected and purified by removing sand, small stones, washed with water, boiled in milk and dried in shade. Finally researcher has obtained the purified *naval* root.

The drug was prepared by standard method for decoction (Ramanathan, 2000).

Raw material of root of *Syzygium cumini* – 35g

Water – 625ml

It was heated and reduced into 1/8th (~80ml).

5. Instrument

On the basis of results and findings of this Quasi-experimental clinical trial on root decoction of *Indigofera tinctoria* for Peptic ulcer show remarkable reduction of degree of symptoms with highly significant improvement of the selected symptoms such as heart burn, epigastric pain, indigestion, nausea & vomiting and eructation.

Interviewer administrated questionnaire were used to collect the data (Annexure 1). Questionnaire was formulated based on the specific objective.

5.1. Data Collection

The drugs selected for this study were prepared by the researcher.

Ten (10) patients were systematically divided into two groups of five each. These patients were selected within the study time frame (April 29-2015 to June 15 2015), using inclusion/exclusion criteria based on the signs, symptoms and investigation *Mathumeaham* in the first phase of the screening procedure.

6. Treatment

The ten patients were divided in to two groups.

Group I (Newly Diabetics Mellitus) -treated with *Naval Vear* decoction 60ml twice a day before meals

Group II (Known Diabetics Mellitus) - treated with *Naval Vear* decoction 60ml twice a day before meals

6.1. Side effects

Observed for any side effects after the treatment by the researcher

6.2. Clinical assessment

Evaluation visit made as base line and 1st day, 5th day, 10th day, 20th day, 30th day& end of the day. 56

Effect of treatment evaluated on the basis of changes in the signs &symptoms after the treatment. Such as Polyuria, Frequency of urine, Polydipsia, Increase in appetite, pain, Dyspnea, Weakness, Numbness in palm & foot & measurement of blood sugar considered as clinical parameters and recorded on first day, tenth day and last day three visits.

7. Results and Discussion

7.1. Effect of drug on Polyuria

Table 7.1: Effect of drug on Polyuria

Polyuria	Known (DM Group I)						New DM (Group II)					
	BT		20 th day		40 th day		BT		20 th day		40 th day	
	No	%	No	%	No	%	No	%	No	%	No	%
1-1.5 L/24hrs	-	-	-	-	3	60%	-	-	-	-	2	40%
>1.5-2 L/24 hrs.	2	40%	3	60%	1	20%	2	40%	3	60%	3	60%
>2- 2.5L / 24 hrs.	2	40%	2	40%	1	20%	1	20%	2	40%	-	-
> 2.5-3 L / 24 hrs.	1	20%	-	-	-	-	2	40%	-	-	-	-
> 3L/24 hrs.	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	100%	5	100%	5	100%	5	100%	5	100%	5	100%

Statically highly significant improvement ($p < 0.004$) in polyuria was observed in both groups (Groups I & II). Initial mean values were 2.0 and 1.8 respectively in group I and II. After the treatment of 20th and 40th day it reduced as 1.4 and 0.6 in both groups.

7.2. Effect of drug on frequency of urine

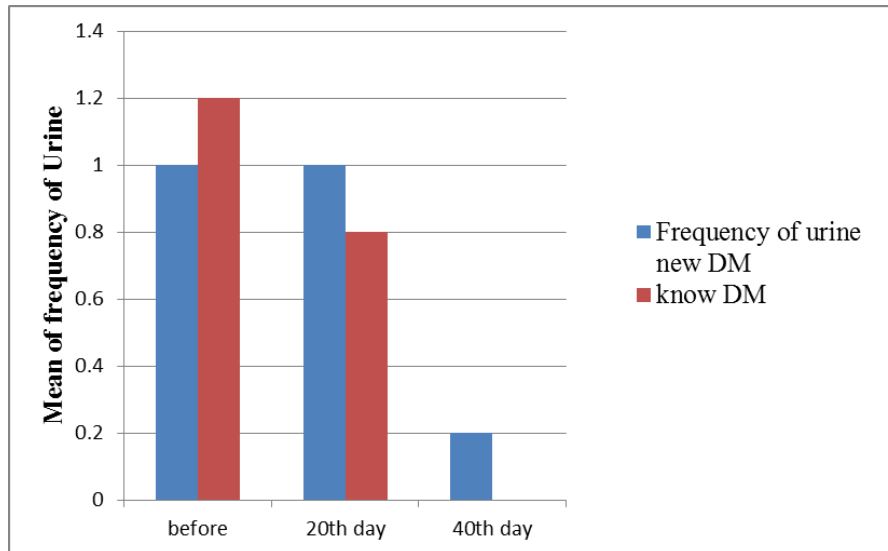


Figure 7.1: Effect of drug on frequency of urine

Statically highly significant improvement ($p < 0.016$) in frequency of urine was observed in group -1, Statically highly significant improvement ($p < 0.004$) in frequency of urine was observed in group-II. Initial mean values were 1.0 and 1.2 respectively in group1 and I. After the treatment of 20th and 40th day it reduced as 1.0 and 0.8 in group-I. After the treatment of 20th and 40th day it reduced as 0.8 and 0.0 in group-II.

7.3. Effect of drug on Polydipsia

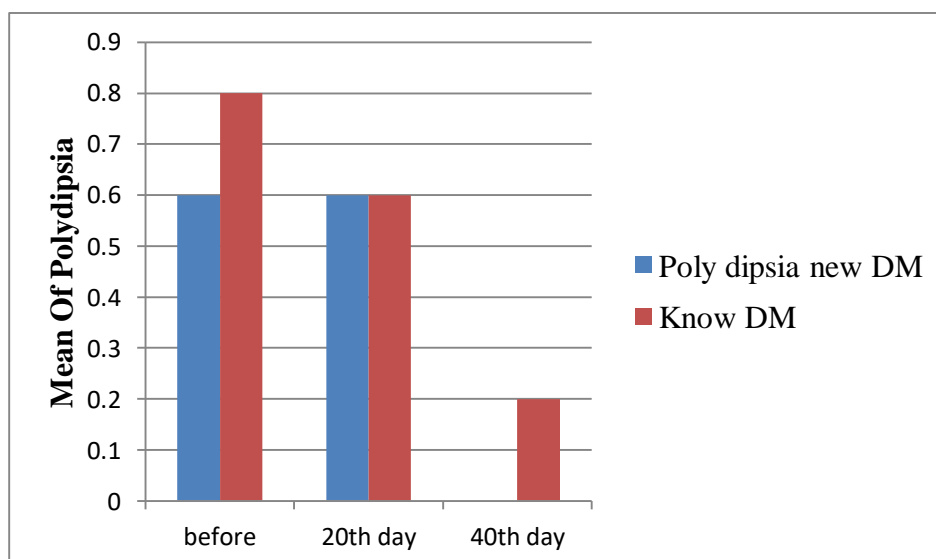


Figure 7.2: Effect of drug on Polydipsia

Statically not significant ($p < 0.208$) in Polydipsia was observed in group -1, statically not significant ($p < 0.070$) in Polydipsia was observed in group-II. Initial mean values were 0.6 and 0.8 respectively in group I and II. There was no reduction in polydipsia at the 20th day of the after the treatment in group- 1.but group II had reduction as 0.6 at same day. And 40th day Polydipsia reduced as 0.0 and 0.6 in group 1 and II respectively.

7.4. Effect of drug on increase in appetite

Table 7.2: Effect of drug on increase in appetite

Increase in appetite.	Known DM						New DM					
	BT		20 th day		40 th day		BT		20 th day		40 th day	
	No	%	No	%	No	%	No	%	No	%	No	%
Asusual/routine(3meal s/day)	3	60%	3	60%	5	100%	2	40%	1	20%	4	80%
Slightly increased (4 meals/day)	1	20%	2	40%	-	-	2	40%	4	80%	1	20%
Moderately increased (5meals/day)	1	20%	-	-	-	-	1	20%	-	-	-	-
Markedly increase (6meals/day)	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	100%	5	100%	5	100%	5	100%	5	100%	5	100%

Statically not significant ($p < 0.305$) in Increase in appetite was observed in group -I, statically not significant ($p < 0.208$) in Increase in appetite was observed in group-II. Initial mean values were 0.8 and 0.6 respectively in group I and II. There was no reduction in polydipsia at the 20th day of the after the treatment in group- I. But group II had reduction as 0.4 at same day. And 40th day Increase in appetite reduced as 0.2 and 0.0 in group I and II respectively.

7.5. Effect of drug on pain

Table 7.3: Effect of drug on pain

Pain	Known DM (Group I)						New DM (Group II)					
	BT		20 th day		40 th day		BT		20 th day		40 th day	
	No	%	No	%	No	%	No	%	No	%	No	%
No pain	-	-	-	-	1	20%	-	-	-	-	1	20%
Pain in joint, routine movements normal.	1	20%	2	40%	4	80%	1	20%	3	60%	4	80%
Pain in joint, slight limitation of Movement.	3	60%	3	60%	-	-	3	60%	1	20%	-	-
Pain in joint, limitation of movements with much reduced activity.	1	20%	-	-	-	-	1	20%	1	20%	-	-
Total	5	100%	5	100%	5	100%	5	100%	5	100%	5	100%

Statically moderate significant improvement ($p < 0.033$) in Pain was observed in group -I, statically highly significant improvement ($p < 0.004$) in Pain was observed in group-II. Before, 20th day and 40th day treatment mean the values of pain were same in both groups 2.00, 1.6 and 0.8.

7.6. Effect of drug on dyspnoea

Table 7.4: Effect of drug on dyspnoea

Dyspnoea	Known DM(Group I)						New DM (Group II)					
	BT		20 th day		40 th day		BT		20 th day		40 th day	
	No	%	No	%	No	%	No	%	No	%	No	%
Dyspnoea after heavy work& walking.	-	-	-	-	2	40%	1	20%	2	40%	4	80%
Dyspnoea after moderate work& walking.	3	60%	4	80%	3	60%	3	60%	3	60%	1	20%
Dyspnoea after mild work.	2	40%	1	20%	-	-	1	20%	-	-	-	-
Dyspnoea even at resting condition.	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	100%	5	100%	5	100%	5	100%	5	100%	5	100%

Statically not significant ($p < 0.099$) in Dyspnea was observed in group -I, statically not significant ($p < 0.160$) in Dyspnea was observed in group-II. Initial mean values were 1.0 and 1.4 respectively in group I and II. After the treatment of 20th and 40th day it reduced as 0.6 and 0.2 in group-I. After the treatment of 20th and 40th day it reduced as 1.2 and 0.6 in group II.

7.7. Effect of drug on weakness

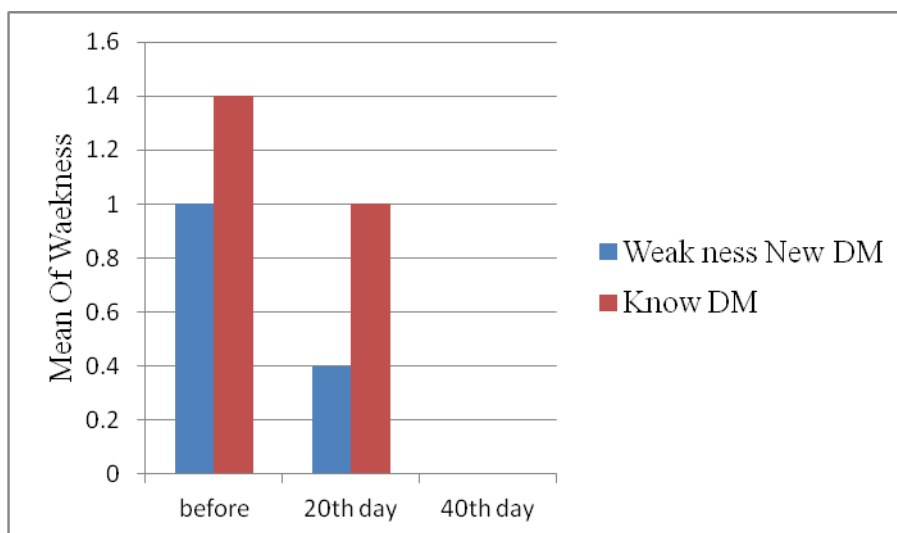


Figure 7.3: Effect of drug on weakness

Statically significant improvement ($p < 0.034$) in Weakness was observed in group I, statically significant improvement ($p < 0.025$) in Weakness was observed in group II. Initial mean values were 2.0 and 1.4 respectively in group I and II. After the treatment of 20th and 40th day it reduced as 0.4 and 0.0 in group I.

After the treatment of 20th and 40th day it reduced as 0.1 and 0.0 in group II.

7.8. Effect of drug on improvement of numbness palm and foot

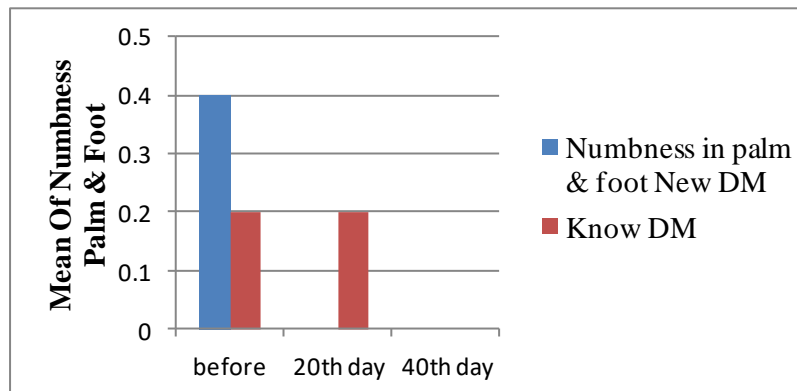
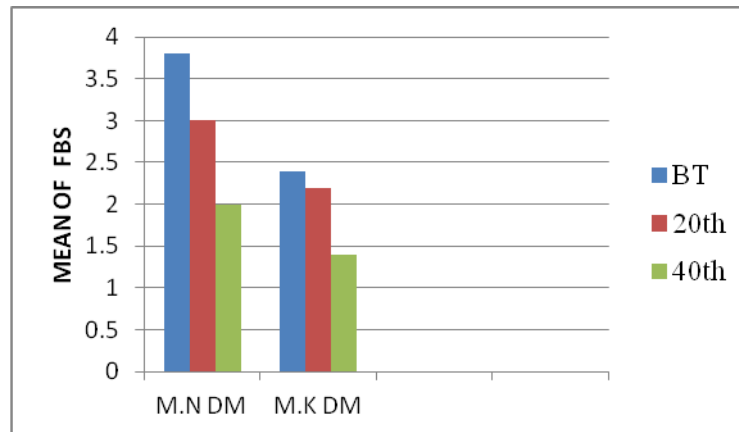


Figure 7.4: Effect of drug on improvement of numbness palm and foot

Statically not significant ($p < 0.374$) in Numbness in palm & foot was observed in both groups (Groups 1&11). Initial mean values were 0.4 and 0.2 respectively in group I and II. After the treatment of 20th and 40th day it reduced in to same values (0.00) in group I.

After the treatment of 20th and 40th day it reduced as 0.2 and 0.0 in group II.

7.9. Effect of drug fasting blood sugar



M.N.DM-mean of newly diabetic's mellitus. M.K.DM-Mean of known diabetic's mellitus

Figure 7.5: Effect of drug fasting blood sugar

Statically highly significant improvement ($p < 0.009$) in Fasting blood sugar level (mg/dl) was observed in group I, statically moderate significant improvement ($p < 0.034$) in Fasting blood sugar level (mg/dl) was observed in group II. Initial mean values were 3.8 and 2.4 respectively in group I and II. After the treatment of 20th and 40th day it reduced as 3.0 and 2.0 in group I.

After the treatment of 20th and 40th day it reduced as 2.2 and 1.4 in group II.

7.10. Side Effect Reported By Patients during the Treatment

Table 7.5: Side Effect Reported By Patients during the Treatment

Other complains	Patients	
	No	%
Drowsiness	05	50%
Mild headache	03	30%
Prolong sleep	02	20%
Excessive appetite	01	10%

Side effect reported by patients during the treatment.

Maximum 50% of complained of drowsiness. Followed by Mild headache (03:30%), Prolong sleep (2:20%). Only one patient's complaint excessive appetite (1:10%).

7.11. Overall effect of treatment

Table 7.6: Overall effect of treatment

Overall	Known DM(Group I)		Newly DM(Group II)	
	No	%	No	%
Poor improvement	0	00	0	00
Mild improvement	0	00%	1	10
Moderate improvement	5	100%	3	60%
Markedly improvement	0	00%	1	10
Complete improvement	0	00	0	00

Overall effect of treatment groups on end of the day (40day).In group I as observed in 40th day (3:60%) had moderate improvement. While (1:20 %) mild improvement and markedly improvement.

In group II as observed in 40th day (5:100%) had moderate improvement.

No patients found poor and complete improvement. In summary, based on the research with these result, it can be said that *Naveal Vear* Decoction serve all the needs which are required for the treatment of *Mathumeaham*.

8. Conclusion

- 1) *Naval Vear* Decoction can be used as a highly effective internal administration for *Mathumeaham*. And no serious side effect was detected.
- 2) Best response was observed in the Group I patients.
- 3) The test drug gives satisfactory recovery of *Mathumeaham* with the added advantage of relatively free from any serious side effects.

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