

A COMPARATIVE CLINICAL TRIAL OF SIDDHA POLY HERBAL FORMULATION THETRAN ILAGAM (INTERNAL) AND YOGAM THERAPY IN THE MANAGEMENT OF AAN MALADU (MALE INFERTILITY)

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ABSTRACT

The siddha system of medicine is rooted in the Dravidian culture of the pre-vedic period. Siddhars are pious, generous and sacred people who guided normal human being to attain motcham. Among the eight limbs of Attanga yogam Iyamam, Niyamam, Pranayamam, Asanam, which comes under bagiranga yogam can be followed for the prevention, treatment and restoration of diseases. During the past decade Siddhar yogam have become topic of global importance. It is a system of self-treatment of diseases, disorders and ailments as a result of faulty ways of living, bad habits, lack of proper knowledge, improper food and malfunctioning of body system. Infertility is the inability of sexually

active, non-contraception couple to achieve pregnancy in one year. Male infertility is global problem in the field of reproductive health. Infertility bears a social stigma, and the incidence is 40% among female's 40% among male's and 20% in both sex .A Clinial trail was conducted to evaluate the effectiveness of Siddhar Yoga, in the treatment of oligospermia (male infertility) at the National Institute of Siddha, Ayothidass pandithar Hospital, Chennai, Tamil Nadu, India. 40 patients diagnosed with idiopathic oligospermia were recruited in this study, Group-1 (20 patients) were administered trail medicine (Thetran Ilagam TI) and

Group-2 (20 patients) were administered trail medicine (TI) along with yogam therapy the patients were followed up every 7 days once for 48 days. The outcome of treatment was assessed using semen analysis and sexual health score. A significant improvement was observed in the yoga group.

KEYWORDS: Siddhar Yogam, Siddha Medicine, Infertility, Thathunattam, Thetranllagam.

INTRODUCTION

Infertility is a common clinical problem and is defined as inability of a couple to conceive naturally after one year of regular unprotected sexual intercourse (Fritz Marc2011) According to the WHO report about 2-10% of couples worldwide are unable to conceive primarily and about 60-80% couples in the world are infertile (WHO, 1992; Cates et al., 1985). According to Siddha System of Medicine Oligospermia can be correlated with *Thathunattam*. Siddhar yogam have become topic of global importance. It is a system of self-treatment of diseases, disorders and ailments as a result of faulty ways of living, bad habits, lack of proper knowledge, improper food and malfunctioning of body system. Siddha system of Medicine [SSM] was started on from Tamil Nadu, a southern state of India. Practiced generally in and around the areas of its foundation. SSM describes the human body is made of five primordial basic elements like space, air, fire, water and earth, which are the building blocks of physical and subtle bodies. The physiological function of the human system is mediated by uyir thathukkal (functional constitution of the body) i) vatham - air (bio energy-movement) ii) pitham-bile (bio energy-fire) iii) Iyyam-phlegm (bio energy-water) which is formed by the combination of the five primordial basic elements. According to Siddha science, Saaram (chyle), senneer (blood), oon (muscle), kozhupu (cholesterol), enbu (bone), moolai (bone marrow), sukkilam/suronitham (semen/ovum) are udal thathukkal (physical constituents) which are identical to the various types of tissues. Siddha scientific principles, has been The present trail was conducted to evaluate the effectiveness of Siddhar Yogam, in the treatment of oligospermia at the National Institute of Siddha, Ayothidass Pandithar Hospital, Chennai, Tamil Nadu, and India.

MATERIALS AND METHOD

Table. 1.

Treatment Protocol	
Study Design	Comparative Clinical Trial The study was approved by Institutional Ethics Committee and the IEC approval no. NIS/IEC/2016/11-13/ 14.10.2016 and the study was registered in CTRI and the registered no. REF/2018/03/018682
Study Place	Ayothidass Panithar Hospital, National Institute of Siddha (Ministry of Ayush), Tambaram Sanatorium ,Chennai,Tamil Nadu
Study period	48 days
Sample size	40 Male Patients
Trail Drug	1. <i>Thetran Ilagam</i> -5gm twice a day with cow's milk
Yoga Thereapy	<i>Sarvangasanam,Machasanam,Dhanurasanam,Pachimottasanam,Mahamudra,Pranayamam,Savasanam</i> (Each Asanams 30 sec to 1minutes 4 times repeat)
Group-I	20 Patients Internal Trial medicine (TI)only
Group-II	20 Patients Internal Trial (TI)medicine with Siddhar Yogam therapy

Tabe: 2.

S. No	Inclusion Criteria	Exclusion criteria
1	Male who doesn't have chance of conception for 1 year after Marriage with frequent unprotected sexual intercourse.	Azoospermia
2	Age :24-50yrs	Diabetic mellitus
3	Sperm count ≤ 20 million/ml & Motility $\leq 50\%$	VD&STD
4	Patient willing to undergo Semen analysis before & after treatment	Inguinal Hernia
5	Patient Willing to participate in trial.	Varicocele
		Renal failure
		Cardiac disease

Tests and Assesments

- I. Clinical assessment
- II. Siddha system assessment
- III. Routine investigations

I. Clinical Assesment: The initial assessment was done before the treatment. The assessment of therapy was made by adopting two parameters.

- Semen Analysis
- Sexual Health Scoring

1. Semen Analysis: As per the recommendations of WHO (1992). [4] Collection of sample Masturbation was advised to all patients for method of collection. The sample was collected between 9-10 a.m. in case of coitus interrupts and it was delivered to laboratory within 20

minutes of the collection of semen.

2. Examination of Semen

3. Volume: Sample was measured by calibrated test tube and volume of semen was noted.

4. pH: pH was measured by comparing the standards pH **paper colour changes**

5. Viscosity: By lifting the glass rod from semen in test tube and on the basis of length of thread formation, the viscosity was scored as 0, 1, 2, 3. (4)

6. Liquefaction time: Liquefaction time (T) = T2 - T1 (T2 = Time observed till semen sample liquefies, T1= Time at the semen collection)

7. Motility: The spermatozoa were scanned systematically for 4 types of motility i.e. rapidly linear progressive, sluggishly linear progressive, nonprogressive and immotile.

8. Viability: For counting viable sperms eosin stain was used in laboratory.

9. Gradation of Sperm count:

Severe Oligozoospermia < 5 mill / ml.

Moderate Oligozoospermia > 5 and < 20 mill / ml

Mild Oligozoospermia > 20 and < 40 mill / ml Normal > 40 mill / ml

10. Morphological evaluation

Abnormal spermatozoa were counted like total abnormal forms and abnormality in head, mid piece, tail and headless spermatozoa.

Sexual Health Scoring

The second objective parameter of assessment is sexual health parameters like sexual desire, erection, rigidity and orgasm. The scoring system developed by Mehra and Singh (1995).

Follow up

A follow-up study was carried out for 12 weeks after completion of treatment.

STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variable and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variable were expressed as Mean \pm Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired “t” test was performed for determining the significance between before and after treatment.

Paired Sample Statistics (Group –I Medicine only) before and after treatment**Table. 3.**

Semen analysis	Mean± SD	t Value	P Value
Before treatment	12.8 ± 7.06064	9.069	< 0.0001
After treatment	38.85±19.46461		

The mean± standard deviation of Group I Patients Semen Analysis at before and after treatment were 12.8 ± 7.0 and 38.85±19.46 respectively which is statistically significant (t=9.069, p=0.0001).

Table. 4.

Sexual Health Score	Mean ± SD	t Value	P Value
Before treatment	6.3± 2.05452	6.8418	< 0.0001
After treatment	8.4±1.729009		

The mean± standard deviation of Group I Patients Sexual Health Score (SHC) at before and after treatment were 6.3± 2.05452 and 8.4±1.729009 respectively which is statistically significant (t=6.8418, p=0.0001).

Paired Sample Statistics (Group –II Medicine along with Yogamtherapy) before and after treatment.**Table: 5.**

Semen analysis	Mean± SD	t Value	p Value
Before treatment	12.8 ±7.06064	5.4025	< 0.0001
After treatment	38.85±19.46461		

The mean± standard deviation of Group II Patients Semen Analysis at before and after treatment were 12.8 ±7.06064 and 8.4±38.85± 19.46461 respectively which is statistically extremely significant (t=5.4025, p=0.0001).

Table: 6.

Sexual Health Score	Mean± SD	t Value	p Value
Before treatment	6.15±1.531253	12.1529	< 0.0001
After treatment	10.7±1.454575		

The mean± standard deviation of Group II Patients Sexual Health Score (SHC) at before and after treatment were 6.15±1.531253 and 8.4±10.7±1.454575 respectively which is statistically extremely significant (t=12.1529, p=0.0001).

Table. 7.

No.of Patients 40	Mean \pm SD	t Value	p Value
Before treatment	13.275 \pm 7.146767	8.9348	<0.0001
After treatment		46.825 \pm 23.22011	

RESULTS AND OBSERVATIONS

The study on Aan maladu was carried out in 40 patients in the Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai-47 attached to Ayothidass Pandithar Hospital during 2016-2018 were analysed. The observation were made and tabulated with following criteria.

Group I (Medicine Only) Opd Patients

Semen Analysis

Table: 8

Sl. No	Result	No of cases 20	Percentage
1	Good	9	45%
2	Moderate	6	30%
3	Poor	5	25%

Observation: Among 20 cases 9cases were good improvement, 6 cases were moderate improvement, 5 cases Poor improvement.

Group II (Medicine Along With Yogam Therapy) Opd Patients

SEMEN ANALYSIS

Table: 9

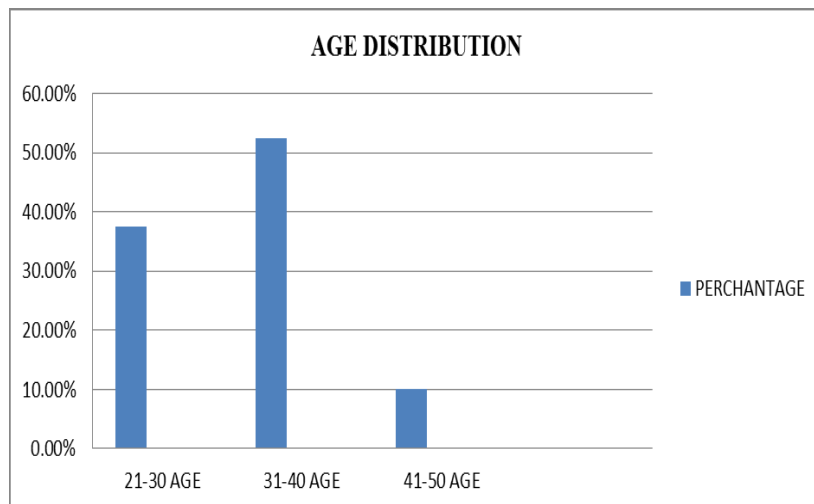
Sl. No	Result	No of cases 20	Percentage
1	Good	14	70%
2	Moderate	3	15%
3	Poor	3	15%

Observation: Among 20 cases 14 cases were good improvement, 3 cases were moderate improvement, 3 cases Poor improvement.

AGE DISTRIBUTION

Table: 10

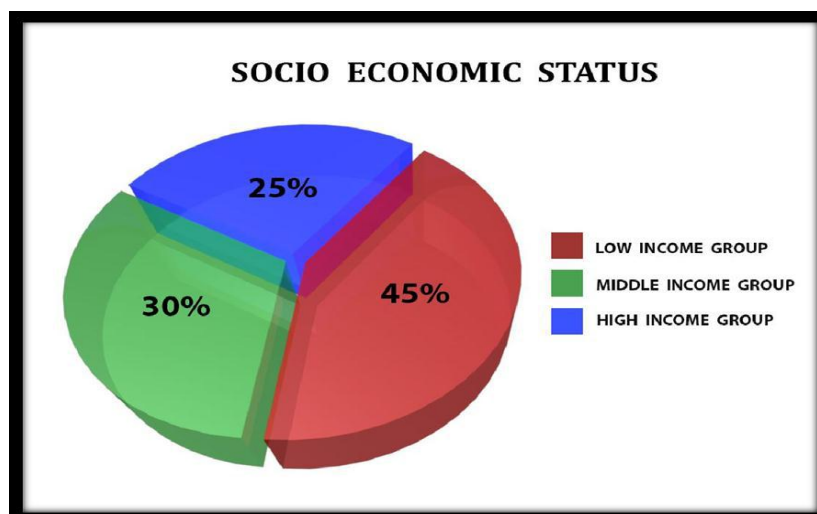
Sl. No	Age	No. of Patients/40	Percentage
1.	21-30	15	37.5%
2.	31-40	21	52.5%

Bar diagram: 1 Age Distribution

Inference: According to the above mentioned data 37.5% of patients were in age group 21-30 years, 52.5% of patients were in age group 31-40 years and 10% of patients were in age group 41-50 years.

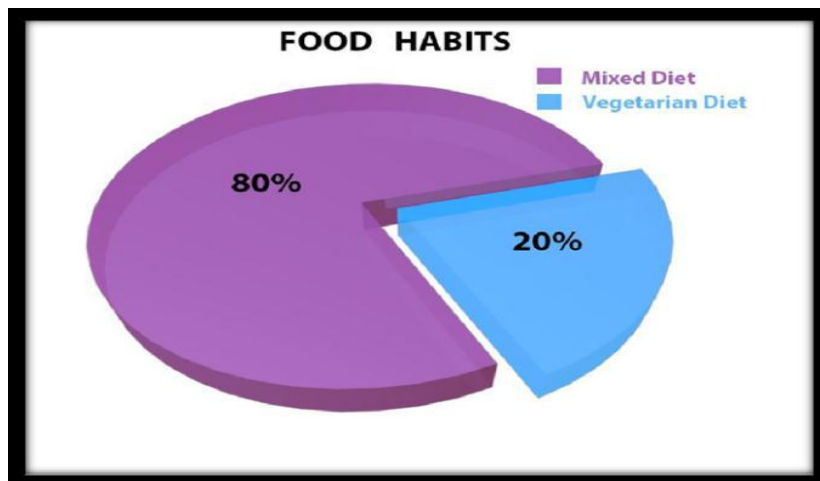
Occupational Status**Table. 11.**

Sl. No	Occupational Status	No. of Patients/40	Percentage
1.	Drivers	16	40%
2.	Labourers	10	25%
3.	Professionals	8	20%
4.	Businessman	6	15%

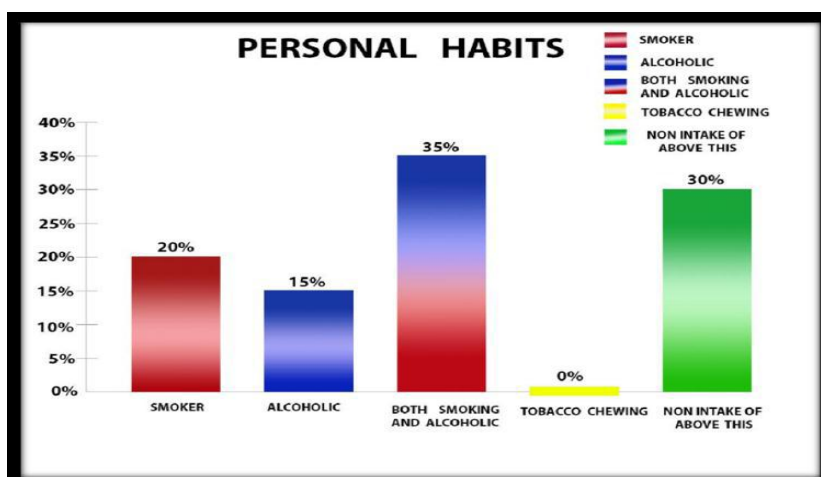
Socio economic status**Bar Diagram 2.**

Inference: 45% of patients belong to low income group, 30% of patients belongs to middle income group and 25% of patients belongs to high income group.

Food habits: Bar diagram 3



Personal habits: Bar diagram 4



Vaatham

Table: 12.

Sl. No	Vaatham	No. of Patients/40	Percentage
1.	Pranan	0	0%
2.	Abanan	20	100%
3.	Vyanan	6	30%
4.	Udhanan	0	0%
5.	Samanan	0	0%
6.	Nagan	0	0%
7.	Koorman	8	40%
8.	Kirukaran	0	0%
9.	Devathathan	14	70%
10.	Dhananjeyan	0	0%

Pitham**Table: 13.**

Sl. No	Pitham	No. of Patients/40	Percentage
1.	Anar Pitham	0	0%
2.	Ranjaga Pitham	10	100%
3.	Sadhaga Pitham	10	100%
4.	Aalosaga Pitham	04	40%
5.	Prasaga Pitham	03	35%

Kapam**Table: 14**

Sl. No	Iyyam	No. of Patients/40	Percentage
1.	Avalambagam	0	0%
2.	Kilethagam	0	0%
3.	Pothagam	0	0%
4.	Tharpagam	8	40%
5.	Sandhigam	5	25%

Udal Kattukal**Table: 15**

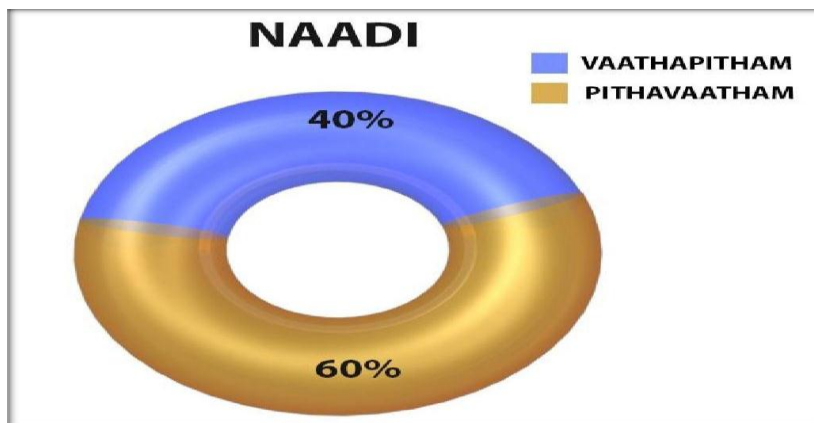
Sl. No	Udal Kattugal	No. of Patients/40	Percentage
1.	Saaram	20	100%
2.	Senner	0	0%
3.	Oon	0	0%
4.	Kozhuppu	0	0%
5.	Enbu	5	25%
6.	Moolai	0	0%
7.	Sukkilam	20	100%

Enn Vagai Thervu**Table: 16.**

Sl. No	Enn Vagai Thervu	No. of Patients/40	Percentage
1.	Naa	0	0%
2.	Niram	0	0%
3.	Mozhi	0	0%
4.	Vizhi	8	40%
5.	Naadi	20	100%
6.	Sparisam	0	0%
7.	Malam	0	0%
8.	Moothiram	0	0%

NAADI

Observation of Bar diagram 5



Neikkuri

Table: 17.

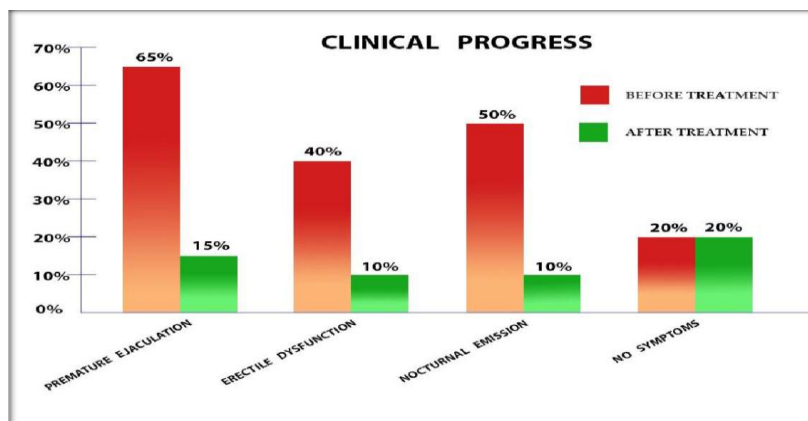
Sl. No	Neikkuri	No. of Patients/40	Percentage
1.	Vali (spreads like snake)	20	50%
2.	Azhal (spreads like ring)	20	50%
3.	Iyyam (spreads like pearl)	0	0%

Clinical Progress

Table: 18.

Sl. No	Symptoms	No. of Patients/40		Percentage	
		BT	AT	BT	AT
1.	Premature Ejaculation	13	3	65%	15%
2.	Erectile Dysfunction	8	2	40%	10%
3.	Nocturnal Emission	10	2	50%	10%
4.	No Symptoms	4	4	20%	20%

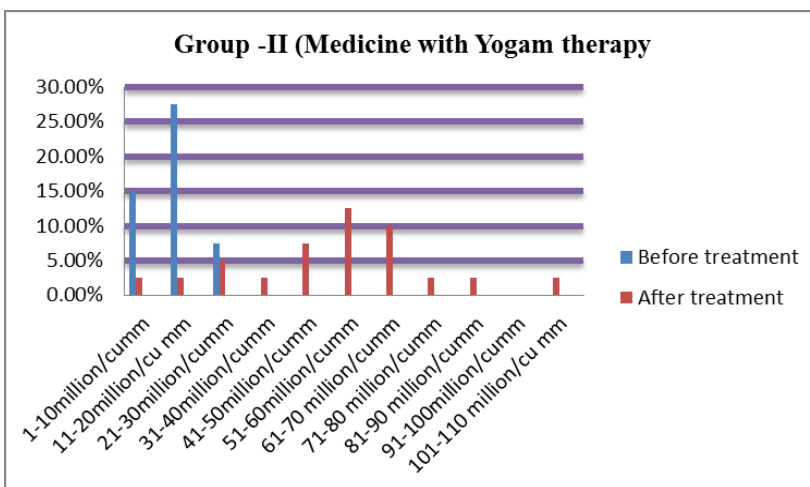
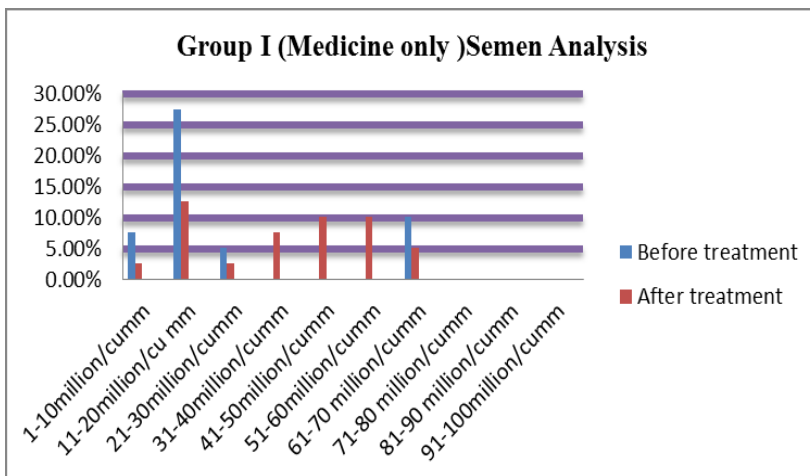
Observation of Bar diagram 6



Inference

Before treatment 65% of cases had Premature Ejaculation, 40% of cases had Erectile Dysfunction and 50% of cases had Nocturnal Emission. After treatment Premature Ejaculation having 15% of cases, Erectile Dysfunction and Nocturnal Emission of cases respectively having 10%.

Semen Analysis Before Treatment and After Treatment



DISCUSSION

One of the Predominant disorders that endanger human species is **INFERTILITY** in Both men and women. The incidence of infertility is comparatively higher in males because of the drastic changes in human life style – irregular food habits, high calorie food items, fast food behavioral changes. Environmental toxins and changed compounds used for dispensing various ailments. It has been suggested that the average sperm count has been decreasing over the past 50 years. *Aan maladu* as stated in yugi vaidya chindhamani has close resemblance with male infertility in Modern Medicine.

In my study 40 patients were treated in outpatient department of Sirappu Maruthuvam department, Ayothidass Pandithar Hospital attached with National Institute of Siddha, Chennai – 47.

All patients were subjected to preliminary investigations which include hematological, urine examination, Semen Analysis, Sexual Health Score before and after Treatment.

Before Treatment purgative was given to all patients to balance the altered three dhosas (vaatha, pitha, kabha).

The Trial Medicine *THETRAN ILAGAM* was administered from the next day onward, course of the Treatment is 45 days.

Age Distribution: According to this study age distribution was 37.5% of patients were in age group 21-30 years, 52.5% of patients were in age group 31-40 years and 10% of patients were in age group 41-50years.

Distribution of Thinai: According to this study 65% of the Patients came from Neithal because Chennai and surrounding areas come under Neithal thinai, and 35% of patients were from Marutham.

Paruvakalam: According to this study 40% of cases came in Koothir kaalam, 20% of cases in Kaar kaalam & Munpani kaalam, 15% of cases came in Elavenil kaalam and 5% cases in Mudhuvenil kaalam. Seasonal incidence is not affected their disease, maleinfertility.

Occupational Status: 40% of the patients were Drivers, 25% of patients were working as Labourers, 15% of patients are Businessman, and 20% of patients are Professionals.

Socio Economic Status: The majority of the Patients affected are from poor socio economic status. Poor hygienic conditions expose to polluted atmosphere and lower immune response made them prone to the disease.

Food Habits: 20% Patients were pure vegetarian, 80% were Mixed Diet (including non-vegetarian). Though a non-vegetarian diet account is not a reason for the occurrence of male infertility.

Personal Habits: In my study 15% of the Patients were using alcohol, 20% were smoker,

35% were having both smoker and alcohol and 30% of the patients were non intake of above this. The observation coincides with the conception that male infertility the disease may be due to smoking, Alcohol consumption.

Symptoms: According to this study 65% of cases came with complaints of Premature Ejaculation, 40% of cases came with complaints of Erectile Dysfunction, and 50% of cases came with complaints of Nocturnal Emission 20% of Cases had No Symptoms.

Classification of Results According To Vali, Azhal and Iyyam:- Vali

- Spermatogenesis, Premature Ejaculation, Nocturnal Emission is due to deranged *AbanaVayu*.
- Erectile dysfunction is due to deranged *viyanan*.
- In 100% patients *abanan* was affected, *viyanan* was affected 40% of patients.
- *Koorman* affected in 40% of cases.
- *And Devathathan* affected in 70% of cases

Azhal: *Ranjaga pitham* and *Sadhaga pitham* were affected in 100% of cases. *Aalosaga Pitham* was affected in 40% of Patients. *Prasaga Pitham* was affected in 35% of patients.

Iyyam: *Tharpagam* may be affected in Patients hot atmosphere. 40% of patients *Tharpagam* were affected. 25 % of Patients *santhigam* was affected & produce Joint Pain.

Udal Kattugal: Both bodily and mental weakness arises when *saaram* was affected. In 100% of patients both the *saaram* and *sukkilam* were affected. In 25% of cases *enbu* was affected.

Envagai Thervu: *Naadi* was affected in 100% of patients and 40% of patients *vizhi* was affected.

Naadi: In 40% of patients *Vaathapitha Naadi* was felt and 60% of patients *Pithavaatha Naadi* were felt.

Neikuri: 50% of cases show *azhal neikuri* (spreads like ring) and 50% of cases show *vali neikuri* (spreads like snake).

Clinical Progress: Before treatment 65% of cases had Premature Ejaculation, 40% of cases had Erectile Dysfunction and 50% of cases had Nocturnal Emission.

Semen Analysis

Before treatment

25% of cases sperm count had 1-10 million/cumm, 50% of cases sperm count had 11-20 million/cumm, 15% cases sperm count had 21-30 million/cumm, 10% of cases sperm count had 61-70 million/cumm (This 10% of cases Active Motility were below normal level).

After treatment: 5% of cases sperm count had 1-10 million/cumm, 10% of cases sperm count had 11-20 million/cumm, 5% cases sperm count had 21-30 million/cumm, 10% of cases sperm count had 31-40 million/cumm, 20% of cases sperm count had 41-50 million/cumm, 25% of cases sperm count had 51-60 million/cumm, 20% of cases sperm count had 61-70 million/cumm, 5% of cases sperm count had 71-80 million/cumm.

Group I Patients: Among 20 cases 9 cases were good improvement, 6 cases were moderate improvement, 5 cases Poor improvement.

Group II Patients: Among 20 cases 14 cases were good improvement, 3 cases were moderate improvement, 3 cases Poor improvement. All the 40 patients among the 23 cases were good improvement, 9 cases were moderate improvement, 8 patients were poor improvement.

CONCLUSION

The present clinical study confirms the efficacy of trial drug *Thetran Ilagam* (Internal medicine) and Yogay therapy. *Thetran Ilagam* is the polyherbal formulation. It was found good resulting on An maladu (Male Infertility) improving clinical sperm count and Clinical process like Erection, Increase the Libido etc. The literature evidence of this drug *Anuboga vaithya navanetham (part-8)* 2nd Edition, pg 143 Publication of Thamarai Noolagam *Thetran Ilagam* exhibited no toxicity on short form administration. The quantitative outcome of Semen Analysis and Sexual Health score shows there is significant improved between at the start and end of treatment i.e the mean and standard deviation is from 13.2 ± 7.14 and 46.8 ± 23.2 . The qualitative outcome shows encouraging results of All the 40 patients among the 23 (57.5%) cases were good improvement, 9 (22.5%) cases were moderate improvement, and 8 (20%) patients were poor improvement. From the above results, the trail drugs "*Thetran Ilagam*" (Internal Medicine) is responded well for the treatment of Aan Maladu Therefore the author concluded that the yogam based intervention in the management of Aan maladu produced better outcome.

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