A PROSPECTIVE OPEN LABELLED PHASE- II NON RANDOMIZED CLINICAL TRIAL ON *"KARUNJCHIRAKAM CHOORANAM"* FOR *"RAKTHA SOORAI VAAYU"* (POLY CYSTIC OVARIAN SYNDROME)

Dissertation submitted to

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DEPARTMENT OF POTHU MARUTHUVAM

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI, TIRUNELVELI - 627 002,

TAMIL NADU, INDIA.

OCTOBER 2019

BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"A PROSPECTIVE OPEN LABELLED PHASE-II NON RANDOMIZED CLINICAL TRIAL ON "*KARUNJCHIRAKAM CHOORANAM*" FOR *RAKTHA SOORAI VAAYU* (POLY CYSTIC OVARIAN SYNDROME)" is Bonafide Work** done by **Dr.D.ARIVOLI (Reg.No.321611001)** Govt. Siddha Medical College, Palayamkottai – 627 002 in partial fulfilment of the university rules and regulations for award for **MD (S) POTHU MARUTHUVAM (BRANCH-I)** under my guidance and supervision during the academic year **OCTOBER 2016-2019.**

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DECLARATION

I declare that the dissertation entitled **"A PROSPECTIVE OPEN LABELLED PHASE-II NON RANDOMIZED CLINICAL TRIAL ON "*KARUNJCHIRAKAM CHOORANAM*" FOR *RAKTHA SOORAI VAAYU* (POLY CYSTIC OVARIAN SYNDROME)"** submitted for the degree of MD Siddha Medicine of Government Siddha Medical College, Palayamkottai, Tirunelveli, Tamil Nadu (The Tamil Nadu Dr. M.G.R. Medical University, Chennai) the record of work carried out by me under the supervision of **Prof. Dr. A. MANOHARAN, MD(S), (Ph.D)** Head of the Department of Pothu Maruthuvam, and guided by **Dr.S.JUSTUS ANTONY, M.D(S),** Lecturer Grade II, Govt. Siddha Medical College, Palayamkottai. This work has not formed the basis of award of any degree, diploma, associateship, fellowship or other titles in the university or any other university or institution of higher learning.

Signature of the candidate

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Date :

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CONTENTS

CHAPTER No.	TITLE	Page No.
	LIST OF ABBREVIATIONS	
	ABSTRACT	
I	**INTRODUCTION**	1
II	**AIM AND OBJECTIVES**	4
III	**REVIEW OF LITERATURE**	
	3.1) JOURNAL ASPECTS	5
	3.2)GUNAPADAM ASPECTS	8
	3.3) SIDDHA ASPECTS	9
	3.4) MODERN ASPECTS	23
IV	**MATERIALS AND METHODS**	37
V	**RESULTS AND OBSERVATIONS**	
	5.1) PRE CLINICAL STUDY	43
	5.2) CLINICAL STUDY	66
VI	**DISCUSSION**	112
VII	**SUMMARY**	120
VIII	**CONCLUSION**	122
	BIBLIOGRAPHY	123
	ANNEXURES	

LIST OF TABLES

TABLE No.	TITLE	Page No.
1.	AGE INCIDENCE	68
2.	MARITAL STATUS	69
3.	PARITY	70
4.	RELIGION DISTRIBUTION	71
5.	DISTRIBUTION OF CASES BY PARUVAKAALAM	72
6.	DISTRIBUTION OF CASES BY THINAI	73
7.	DIETARY HABITS	74
8.	DISTRIBUTION OF CASES BASED ON INCIDENCE OF FERTILITY	75
9.	BODY BUILT (BASED ON BMI)	76
10.	OCCUPATIONAL DISTRIBUTION	77
11.	POSITIVE FAMILY HISTORY FOR THE DISEASE	78
12.	CHRONICITY OF ILLNESS	
	a). IRREGULAR MENSTRUATION	79
	b). INFERTILITY	80
13.	TREATMENT HISTORY OTHER THAN SIDDHA TREATMENT	
	a). FOR TREATING INFERTILITY	81
	b). FOR IRREGULAR MENSTRUATION	82
14.	THEGI	83
15.	DERANGEMENT IN MUKKUTRAM	
	a). DERANGEMENT IN VATHAKUTRAM	84
	b). DERANGEMENT IN PITHAKUTRAM	86
	c). DERANGEMENT IN KAPHAKUTRAM	87
16.	GNANENTHRIYAM INVOLVEMENT	88
17.	KANMENTHRIYAM INVOLVEMENT	89
18.	KOSANGAL	90
19.	DISTURBANCE IN UDAL THATHUKKAL	91

TABLE No.	TITLE	Page No.
20.	ENVAGAI THERVU	
	a). NAADI	93
	b). NEIKKURI	94
21.	BEFORE TREATMENT ASSESSMENTS	
	a)INTERMENSTRUAL PERIOD ASSESSMENT SCORE	95
	b). DURATION OF BLEEDING SCORE	96
22.	CLINICAL SYMPTOMS BEFORE TREATMENT	97
23.	OUTCOME MEASUREMENT BEFORE AND AFTER TREATMENT	
	a). INTERMENSTRUAL PERIOD ASSESSMENT SCORE	99
	b). DURATION OF BLEEDING SCORE	100
24.	CLINICAL SYMPTOMS BEFORE AFTER TREATMENT	102
25.	CHANGES IN USG AFTER TREATMENT	104
26.	BIOSTATISTICS BEFORE AND AFTER TREATMENT	105
27.	BMI SCORE BEFORE AND AFTER TREATMENT	106
28.	WAIST HIP RATIO BEFORE AND AFTER TREATMENT	107
29.	CASE SUMMARY OF OUT PATIENTS	108
30.	CASE SUMMARY OF IN PATIENTS	109
31.	LABORATORY INVESTIGATIONS OF OUT PATIENTS	110
32.	LABORATORY INVESTIGATIONS OF IN PATIENTS	111

LIST OF FIGURES

FIGURE No.	TITLE	Page No.
1.	AGE INCIDENCE	68
2.	MARITAL STATUS	69
3.	PARITY	70
4.	RELIGION DISTRIBUTION	71
5.	PARUVAKAALAM	72
6.	THINAI	73
7.	DIET	74
8.	CASE DISTRIBUTION	75
9.	BODY BUILT	76
10.	OCCUPATION	77
11.	FAMILY HISTORY	78
12.	a). CHRONICITY OF ILLNESS	79
	b). YEAR OF INFERTILITY	80
13.	a). FOR TREATING INFERTILITY	81
	b). FOR IRREGULAR MENSTRUATION	82
14.	THEGI	83
15.	a). CLASSIFICATION OF VATHAM	85
	b). CLASSIFICATION OF PITHAM	86
	C). CLASSIFICATION OF KAPHAM	87

FIGURE No.	TITLE	Page No.
16.	GNANENTHRIYAM	88
17.	KANMENTHRIYAM	89
18.	KOSANGAL	91
19.	UDAL THATHUKKAL	92
20.	ENVAGAI THAERVU	
	a). NAADI	93
	b). NEIKKURI	94
21.	a). INTERMENSTRUAL PERIOD SCORE	95
	b). DURATION OF BLEEDING SCORE	96
22.	CLINICAL SYMPTOMS	97
23.	a). INTERMENSTRUAL PERIOD ASSESSMENT SCORE	99
	b). DURATION OF BLEEDING BEFORE AND AFTER TREATMENT	101
24.	CLINICAL SYMPTOMS BEFORE AND AFTER TREATMENT	102
25.	IMPROVEMENT	104

ABBREVIATIONS

BMI	-	Body Mass Index
DBP	-	Diastolic Blood Pressure
DM	-	Diabetes Mellitus
FBS	-	FastingBlood Sugar
FSH	-	Follicle Stimulating Hormone
GnRH	-	Gonadotropin –releasing hormone
HDL	-	High Density Lipo protein
IGF	-	Insulin Like Growth factor
IGT	-	Impaired glucosetolerence
IR	-	Insulin resistance
IGFBP-1	-	Insulin – like growth factor binding protein -1
LDL	-	Low DensityLlipoproteins Levels
LH	-	Luteinizing Hormone
NIH	-	National Institutes of Health
PPBS	-	Post Prandial Blood Sugar
PCOS	-	Polycystic Ovarian Syndrome
TG	-	Triglycerides
TSH	-	Thyroid Stimulating Hormone
VLDL	-	Very Low DensityLipo Protein
WHR	-	Waist Hip Ratio
WBC	-	White Blood Cell
OP	-	Out Patients
IP	-	In patients
TC	-	Total count
DC	-	Differential count
ESR	-	Erythrocyte sedimentation Rate
Hb	-	Hemoglobin
KJC	-	KarunjchirakamChooranam

ABSTRACT

Siddha system of medicine is one among the traditional medical systems originated in India which has its foundations from superior wisdom of Siddhars. They are responsible for the Tamil medicine of the present day and also for many other sciences of public utility.

Raktha soorai vayu mentioned in siddha literatures may be co-related with poly cystic ovarian syndrome in modern medical science. Poly Cystic Ovarian Syndrome (PCOS) is one of the most common reproductive health problems suffering of women .It is considering as a problem of anovulation and infertility along with the symptoms of irregular menses , obesity, insulin resistance, hirsuitism, acne, androgenic alopecia and recurrent miscarriage. Treatment of PCOS may be enhanced in all aspects of syndrome including short term problems like acne & infertility as well as long term problems such as obesity.

Reviewing the modern science and Siddha literatures regarding PCOS, better understanding of symptoms, pathogenesis of PCOS and its proper line of Siddha treatment can be obtained. Various pre – clinical studies such as bio-chemical , phytochemical , anti –microbial, hypoglycemic,hypolipidemic and toxicity studies were carried out for Karunjchirakam Chooranam and relevant results were obtained.

By this study, I planned to identify the PCOS syndrome early so as to encourage young women to seek timely treatment and prevent its long term complications.In most of the cases treated with Karunjchirakam Chooranam, better results were visible. All the concerned results were statistically analysed and found to be significant.

CHAPTER-I

INTRODUCTION

The Siddha medicine is one of the ancient systems of medicine founded by spiritual scientists called 'Siddhars'. They had more evolved consciousness that allowed them to investigate, understand and share the relationship between human and nature. They had already illustrated that the universe and humans were made up of five elements- earth, water, fire, air and space and also told that the three humors (*vatham, pitham* and *kapham)* are made up of five elements. Most of the siddha medicines are formulating from herbal and mineral sources. Siddha medicine is based on *Pancha Bootha* theory.

The ratio between *vatham, pitham* and *kapham* are 4:2:1 respectively. At the onset of disease, one of the humor levels is changed, causing an imbalance. The line of treatment is dictated by which humor is abundant and by how much. The goal of treatment is to restore the perfect balance of the three humors. The exponents of this system emphasize on achievement of this state via medicines and meditation. It was quoted by *Thiruvalluvar* as follows,

"மிகினும் குறையினும் நோய் செய்யும் நூலோர்
வளி முதலா எண்ணிய மூன்று"

\- திருவள்ளுவர்

The treatment aspect involves the neutralization of affected humors.

விரேசனத்தால் வாதம் தாழும்
வமனத்தால்பித்தம் தாழும்
நசிய அஞ்சனத்தால் கபம்தாழும்

-நோய் நாடல் நோய் முதல் நாடல் பாகம் - 1

Vatha kutram is neutralized by *viresanam* (purgative). *Pitham* is neutralized by *vamanam* (emetics). *Kapha kutram* is neutralized by *anjanam* and *nasiyam* (application of medicine in eyes andnose).

According to the siddha medicine, various physiological functions of the body are attributed to the combination of seven basic tissues: They are as follows

1. *ooneer* (plasma) responsible for growth, development and nourishment;
2. *seneer* (blood) responsible for nourishing muscles, imparting colour and improving intellect;
3. *oon* (muscle) responsible for shape of the body;
4. *kozhuppu* (fatty tissue) responsible for oil balance and lubricating joints;
5. *elumbu* (bone) responsible for body structure and posture and movement;
6. *elumbumajjai* (bone marrow) responsible for formation of blood corpuscles ;
7. *sukkilam* (semen) / *sronitham*(ovum) responsible forreproduction.

The siddhars had classified diseases into 4448 in number. There is another concept based on *kuttram* basis (humoural basis) viz 80 *vatha* diseases, 40 *pitha* diseases and 20 *kapha* diseases. In this modernized mechanical world, peoples are suffering from various pattern of diseases. Considerably females are the majority of sufferers due to their role in family as well as society. Since the diseases due to endocrine disorder are unnoticeable due to their ignorance.Usually these disorders leads to moderate as well ascomplications.

Polycystic ovarian syndrome (PCOS) is thought to be the most common endocrine disorder found in women. PCOS impacts women of all races and ethnicities who are of reproductive age. In unspecified populations the prevalence of PCOS has a reported incidence rate of 3-10%. PCOS is a syndrome that is characterized by an imbalance of the sex hormones. Common symptoms include irregular menstrual cycle, polycystic ovaries, and hirsutism. Features of the syndrome may also include fertility, insulin-resistance, impaired glucose tolerance and dyslipidemia due to increased risk factors. The etiology of PCOS is not completely understood and there is no known cause, although a genetic component and diet/lifestyle factors, such as insulin resistance and obesity have been identified .
Giving a patient the diagnosis of PCOS makes the patience aware of possible fertility concerns, dysfunctional bleeding, endometrial cancer, obesity, diabetes, dyslipidemia, hypertension, and the theoretical increased risk of cardiovascular disease. Since PCOS could be genetic, it may bring awareness to family members and future children. It is an important for the field to reach the level of comprehension with PCOS to the extent that diabetes and metabolic syndrome established to improve the quality of life for these women.

In siddha literature ***Yugimuni vaithiya kaviyam***has explained about ***RakthaSoorai Vaayu*** with the symptoms of amenorrhoea, dysfunctional uterine bleeding, oligomenorrhoea, pelvic pain, heaviness of thigh, threatened abortion. All the symptoms and signs can be correlated with Poly Cystic Ovarian Syndrome in modern medicine.

So,I have to chosen the herbal drug ***KARUNJCHIRAKAM CHOORANAM*** in a classical siddha single preparation ***KARUNJCHIRAKAM CHOORANAM*** mentioned in ***Gunapaadam Mooligai Vaguppu- muthal paagam*** **pg no.463** for the treatment of ***RAKTHA SOORAI VAAYU*** (Poly Cystic Ovarian Syndrome).

Rationale:

KARUNJCHIRAKAM CHOORANAM is the herbal siddha formulation taken from the classical siddha literature. The trial medicine is choosen to evaluate the efficacy of treating polycystic ovarian syndrome .It was estimated to be useful for this disease because it possess medicinal activities like anti-hyperlipidemic,emmenagogue, anti –hyperglycemic, analgesic, anthelmitic, anti-microbial, anti-iflammatory, spasmolytic, anti oxidant properties.

According to literature references and existing research work done in this medicine,it was revealed that due to its emmenagogue and anti-spasmodic properties it is convenient and safe for the management of polycystic ovarian syndrome.

Extraction of the seeds showed better recovery of phenolic compounds than HD SFE and proved the occurrence of thermally labile or photosensitive bioactive volatiles of four major quinonic phenol compounds

CHAPTER-II

AIM AND OBJECTIVE

AIM

To clinical document of the efficacy in ***KARUNJCHIRAKAM CHOORANAM*** (Internal Medicine) in the management of ***Raktha Soorai Vaayu*** (Poly Cystic Ovarian Syndrome)

OBJECTIVES

Primary Objective:

To evaluate the therapeutic efficacy of ***KARUNJCHIRAKAM CHOORANAM*** (Internal medicines) in the treatment of ***Raktha Soorai Vaayu***(Poly Cystic Ovarian Syndrome)

Secondary Objective:

- To evaluate the bio-chemical and pharmacological parameters of trial drug
- To evaluate the safety profile of the trial drug in animal models(OECD guidelines).
- To analyse the siddha diagnostic methods (*Envagai thervugal*) in *Raktha soorai vaayu.*
- To have an idea of incidence of the disease with reference to age, occupation, marital status, habitetc.
- To evaluate the infertility ratio among the studypatients.
- To study the changes in USG Pelvis before and aftertreatment.
- To compare the BMI (Body Mass Index) before and aftertreatment.
- To analyse biostatistics approach documentation of clinical evaluation in *Raktha SooraiVaayu*
- To collect both siddha and modern literatureevidences.

Justification of research :

Polycystic ovarian syndrome is a common issue which leads to complications like infertility ,if it ts not properly treated. prevalence of PCOS ranging from 2.2% to 26%.most reports have studied adult women with age ranged from18 to 45 years .Nowdays for the treatment and diagnosis many sophisticated methods are available but it is very expensive and time consuming.

This study aims to asses symptomatic presentations, prognosis of treatment with herbal formulation which is mentioned in valuable literature.

CHAPTER-III

REVIEW OF LITERATURE

3.1 IN JOURNAL

The various journals to collections related to Karunjchirakam (Nigella sativa).

TAXONOMY

Kingdom	–	Plantae-plants
Superdivision spermatophyta	–	Seed plants
Division magnoliophyta	–	Flowering plants
Class magnoliopsida	–	Dicotyledons
Subclass	–	Magnoliidae
Order	–	Ranunculales
Family	–	Ranunculaceae
Genus	–	Nigella
Species	–	Nigella sativa

MACROSCOPIC.

SHAPE : Pear –shaped with slightly curved taperedends. one sideis flat and the other is convex. The surface is slightly and regularly embossed.

COLOR : Black with hints of light grey.

SIZE : Length 4.1cm ,Width 2.0 cm . Transversal cross-section often hexagonal. Longitudinal cross – section is pear shaped.

FLAVOUR AND TASTE EVOLUTION:

Metallic taste when the seed comes into contact with dental enamel. After crushing, taste of lead pencil, followed by sharp,aromatic.

Peppery taste,becoming irritant at the base of the throat and leaving a strongbitternesspersist on the palate.

CRUSHING:

Easy with dissociation of tissues

Microscopic characteristics:

- Brick red external legment consisting of polygonal cells (penta-to heptagonal) with coloured albumen &consisting of thin walled cells with several oil droplets.
- Tissues surrounding are very slightly embossed.
- Grey –the albumen is orangey –brown consisting of a single layer of polygonal cell (square) with are often aligned

Chemical composition of nigella sativa L.seed extracts obtained by supercritical carbon dioxide :

Sureh kumar et al(2010) has studied chemical composition of black cumin (nigella sativa L) seed extracts obtained by supercritical carbon dioxide at two different conditions that result in total extract (28mpa/50 c,SFE1) and major volatile part (12 MPA/40 C ,SFE2)and essential oil optional by hydro distillation of sfe-1(HD SFE) .SFE have been carried out to characterize the compounds and variation of quoins of phenolics .The extract were analysed by GC and GC-MS and the presence of phenolic compound was further confirmed bby 2D HSQCT 1H and 13 C NMR spectroscopy.

Forty seven volatile compound were reported detected where sixteen compound were reported for the first time in the oil of this seed, moreover, thymoquinone(TQ) and thymol (THY) were the major phenolic compounds.

DIABETIC NEPHROPATHY :

Phytochemical analysis Haddad.A .et al (2017)was studied the spectrophotometric evalvation of the antioxidants (fdlavonoids and carotenoid) Showed that nigella sativa seed contains 993.6 mg |100 g dry weight flavonoids and 80.6 mg \100g dry weight carotenoids .whereas propolis contains 4630 mg \100 g dry weight flavonoids and 1.92 mg \100 g dry weight carotenoids

FASTING BLOOD SUGAR (FBS)

Haddad.A .et al(2017) was studied the effect of treating STZ induced diabetic rats 1.the mean values of serum fasting blood sugar (FBS) Were significantly ($p<0.001$) increased in the positive control group .when compared with those of the negative control .however ,treating these rats with methanolic extract of nigella sativa and propolis for 4 weeks significantly (p\0.001) reduced the fasting blood sugar in the serum og both G3 and G4 groups .Respectively although being higher than of the negative control values methnolic extract of propolis in G4 was more effective in reducing fasting blood sugar than of nigella sativa in G3

ANTIOXIDANT AND ANTIMICROBIAL ACTIVITIES

Sunita singh et al(2014) was studied seeds of black cumin seed to possess magical showed and have been worked out extensively revealed that black cumin essential oil and its oleoresins constitute a good alteranate source of essential fatty acids compared with common vegetable oil. The present results showed that essential oil and oleoresins of black cumin exhibited higher antioxidant activity than synthetic antioxidants

ANTIBACTERIAL POTENTIALS OF NIGELLA SATIVA:

Hera Chaudhry et al(2015) was studies plants products are rich sources phytochemicals as is the extract of this study and have been found to possess a variety of biological activites including antioxidant cytotoxic and hapatoprotentials potentials they are excellent reducing agents and reverse oxidation by donating electrons and \or hydrogen ions [49]study was carried out of exploit the potential of n.sativa epicotyl suspension culture of N.sativa under the effective of biotic and abiotic elicitation .results showed that MnCl2 elicitation enhanced the production of thymoquinone and thymol

ANTI INFLAMMATORY AGENT IN ACTION :

Mukhtar Ikhsan et al(2018) was studies Nigella sativa has a broad spectrum of pharmacologicals actions, including antioxidant, antidiabetic anticancer, antitussive, immunomodulator analgesic. antimicrobial, anti-inflammatory, spasmolytic, and bronchodilator.

LIPID LEVELS AND HYPOGLYCEMIC ACTION:

Ahmed Badar et al was(2017) studies thenigella sativa group had a significant decline in TC,LDL.TC\HDL AND LAL-C rations .compared with the respective baseline data and the control group HDL-C was significations elevation in the nigella sativa.Datau EA and Kaatabi et al was studies Type 2diabetic with hypercholesterolemia they recevived 2g n.sativa per day for weeks .this resulted in a signification decrease in TG,TC.LDL-C ;however it indicated that n.sativa has no beneficial effects on fasting blood sugar and HDL-C more over a nonsignificant reduction in lipids has reported in in adults who received powdered n –sativa seeds and men withy central obesity treated with nigella sativa.

3.2GUNAPADAM ASPECT -KARUNJCHIRAKAM

Botanical name : Nigella sativa

Synonyms : Aranam, Upakunjikai

NAMES

Tamil : Karunjeeragam

Hindi : Kulanji ,Kala-Zira

Telugu : Nalla-jilakarra ,Ulli Ginjalu

Karunjeeragam part used : Seeds

Properties :

Suvai (Taste) : Kaippu

Thanmai (Nature) : Veppam

Pirivu (Bio-Transformation) : Kaarppu

ACTIONS:

Carminative

Diuretic

Emmenagogue

Galactogogue

Anthelmintic

Stomachic

Parasiticide

Emollient

Ingredients and medicinal uses of Karunjeeraga chooranam :

TAMIL NAME	Pharmacologigal Actions	THERAPEUTIC USES IN SIDDHA
Karunjeeragam	Antihypertensive Emmenagogue Diuretic Liver tonic Analgesic Anti bacterial Anti diabetic Anti cancer Immunomodulator Bronchodilator Anti oxidant	Soothaga kattu Soothaga soolai Karappan Thalai noi Kan noi Vanthi Kaamalai Irumal

3.3 SIDDHA ASPECT – *RAKTHA SOORAI VAAYU*

Siddha system of medicine has its own treasure regarding gynecological diseases and its management. Siddha literatures clearly states about the concepts of puberty, menarche, menstruation, conception, contraception and pregnancy, labor, sterility and mentioned about disorders of menstruation. Primarily,inflammation infection and neoplasmic changes causes diseases of female urinary tract .

Maan murikiyam quotes menstrual diseases as follows,

பூப்பு நோய்கள்

"பூப்புக் காலை நோவு மிகுதல்
முறைப்படி நாளின் முன்பு பூத்தல்
அந்தா நெல்லை யகன்று பூத்தல்
திங்க ளிருமுறை மும்முறை பூத்தல்
குருதி யருகல் மிகுந்த தோன்றல்
கறுத்தல் வெளிறல் கழுநீர் நிறங்கொளல்
திணிந்து குருதி துணிந்து வீழ்தல்
மிகக்கெடு நாற்றம் வீசல் நுரைத்தல்
ஐந்து நாளின் மிக்கொழ கிடுதல்
சதைத்திரள் தோன்றல் எனுமிவை பிறவும்
கருப்பை வளியினும் பிறவினுந் தோன்றும்
பூப்பு நோய்க ளாமென மொழிப"

-மான்முருகியம்

***POOPU* (Menstruation)**

Definition

It is a normal phenomenon of a female characterized by bleeding through the vagina once in 27 days after attaining puberty. Normally the bleeding occurs for 3 to 5 days.

"பூப்பெனப் படுவது பூவையர் தமக்குக்
கருவுறுப் பிற்படு கழிவுச் செம்புனல்
மதிதோறும் அல்குல் வழிவெளிப் படலே"

From ovaries the ovum is released once in every month alternatively before the ovum reaching the uterus. If got fertilized it is implanted in endometrium of the uterus.

"கருக்கா யிரண்டினு முருக்கொளத் தோன்றிக்
கருப்பை யுட்புகுங் குருதிக் கலப்பால்
கருத்தோல் தோன்றுந் திங்கள் தோறும்
அதுவே கருப்பையி னுட்சுவர் சாரும்
அத்தோல் இயல்பின் அமைந்திடும் பையுள்
கருவிளை முற்றும் காக்கும் பொருட்டை"

If the ovum is not fertilized, it shrinks and the endometrium is disintegrated. Then it is expelled out through the vagina as normal menstrual bleeding.

"கருச்சென்று றமைந்தில தாயின் அத்தோல்
சிதைந்து கழலுந் திங்கள் தோறும்

அத்தோல் சிதைதலின் ஆகிய செந்நீர்
குறிவழி வெளிப்படல் பூப்பென மொழிப்
இயம்பிய நாளோ ரிருபத் தேழே
தோகையர் பூப்புத் தோற்றக் காலம்''

Raktha Soorai Vaayu – a disease comes under *karpa rogam* described in *Yugimuni vaithiya kaviyam.*

DEFINITION OF *RAKTHA SOORAI VAAYU*

Also known as *soothaga vaayu*.It is generally presented with symptom of congestion of the womb due to the accumulation of blood due to the deranged *vaayu.*

The symptoms includes very acute pain of a darting character shooting down the thighs, pain in the lower part of the bowels, pain in the groins, nausea and sometimes vomiting just before or during the menstrual period.
This may even tend to prevent conception.

AETIOLOGY

The text *Agathiyar Kanmakaandam* says the reasons for *Karpa Noiga*l are due toanykindofinfanticide,takingthecow'smilkwithoutforcalf, destroyingthe Youngcrops.

''சுழலாமல் பெண்களுக்குக் கெற்பநோய் தான்
சூழ்ந்து வந்து கருமத்தைச் சொல்லக்கேளு
அழலாலே விந்துவகை யழித்த பாவ
மஞ்சாமற் பாலகனைக் கொன்றபாவம்
குழவியிளம் பிஞ்சு பூப்பறித்த பாவங்
கோவினங்கள் பருகும்பால் குடித்தபாவம்
விளைவான விளம்பயிரை யழித்தபாவ
மேதியினில் மலடான விந்தை தானே''

-அகத்தியர் கன்ம காண்டம்
ப.எண்:36, பாடல் எண்:104

The text *Thanvanthiri vaithiyam*mentioned about the causes of *karpa noi* as the following. Due to toxic substance (Philter), increased sexual desire, accumulated postpartum blood in the womb, derangement of *vatha kutram.*

''வஞ்சனை தன்னினாலும் மருந்தீடு தன்னிலாலும்

மொஞ்சிடு சரீர வேட்கை யுறுதிசெய் தண்டிப்பாலும்
அஞ்சலாம் பிள்ளை பேறி லடங்கிய இரத்தத்தாலும்
மிஞ்சிய வாயுவாலும் கருப்பநோய் மேவுமென்னே''

-தன்வந்திரி வைத்திய பாகம்-1
ப.எண்:251 பாடல் எண்:61

CLASSIFICATION

கெர்ப்பரோகம் வகைகள்:

In *Yugimuni vaithiya kaviyam* six types of diseases are described under the *Karpa noigal*.

- கெர்ப்பரோகம்
- கெர்ப்பவிப்புருதி
- கெர்ப்பவாயு
- சுரோணிதவாயு
- இரத்தசூரைவாயு
- கெர்ப்பசூலை

Athma Rakchamirtham Ennum vaithiya sara sangiraham

Under the topic *karpakol* the following diseases are described.

- இரத்தச்சூலை
- கெர்ப்பவிப்புருதி
- சூதகவாயு

In sarabendra vaithiya muraigal

In *sarabendra vaithiya muraigal – Garpini bala rogasikichai*

The following diseases are described under *KarpaRogam*

- பெரும்பாடு
- மலட்டுரோகம்
- கெர்ப்பவிப்புருதி
- கெர்ப்பவிடரோகம்
- கெர்ப்பச் சூலை
- இரத்த சூலை

In *Mega noi, soothaga nool mattrum arivaiyar chinthamani*

Karpa noigal is classified into six types

- ❖ கெர்ப்பவாயு
- ❖ சுரோணிதவாயு
- ❖ உதிரவாயு
- ❖ இரத்தகுன்மவாயு
- ❖ சூதகவாயு
- ❖ கருக்குழிவாயு

CLINICAL FEATURES

A. In *yugi muni vaithiya kaviyam*

இரத்தச் சூரை வாயுவின் குணம்:

"திரண்டு பிரண்டு கீழ்வயிற்றில் திரமாய்மாதவிடாய் தோறும் அரண்டும்
குருதிமிருந்து விழும் அரையும் துடையும் உளைக்கும் மிக திரண்டு
சிலநாள் சிக்கி நிற்கும் திருவார் கருவைஅழித்து விடும் உருண்ட
இரத்த சூரை என்ற வாய்வென்றுரைத்தார் உணர்ந்தோரே"

- யூகிமுனி வைத்திய காவியம்
பக்க எண்:100, பாடல் எண்:32

The manifestations of ***Raktha soorai vaayu*** are

- ❖ Excessive bleeding(menorrhagia)
- ❖ Pain present in the thighs andgroin
- ❖ Absence of menstruation (Amenorrhoea)
- ❖ Miscarriage

B) Athma Rakchamirtham Ennum Vaithiya Sarasangiraham

1.இரத்தசூலைக் குணம்

The manifestations of *Raktha soolai* are,

- ❖ Painfulmenstruation (Dysmanorrhoea)
- ❖ Abnormal heavy or prolongedmenstruation
- ❖ Miscarriage

"பார்த்திடவே மங்கையர்க்கு ரத்தச்சூலை
பகறுகிறே னடிவயிற்றைப் பற்றி நிற்கும்
கோர்த்திடவே யுதிரமது திரண்டுமே தான்
கொதிப்பெடுத்து மாதவிடாய் காலந்தன்னிற்
சேர்த்திடவே சூதகங்கள் மிகுந்து காணுஞ்
சிறுவழியாய்க் கருவழியும் பிரண்டுளைக்கும்
ஏர்த்திடவே துடையிடுப்பு வுளைச்சலாகும்
இரத்தமாஞ் சூலைகுண மிதுதான் பாரே"

-ஆதமரட்சாமிர்தமென்னும் வைத்திய சாரசங்கிரகம் ப.எண்:48

2. **சூதகவாயு**

The manifestations of *soothaga vaayu* are

- ❖ Derangement of *vaayu* results in painfulmenstruation
- ❖ Headache
- ❖ Central obesity

"கேளுமே சூதகத்தி லக்கினி வாய்வு
கெடுத்துவிடு மாதவிடாய் கட்டிப் போகும்
ஆளுமே கருக்குழியுந் தூந்து தேகம்
அப்பனே யுதிரமது அடிமூலத்தில
நீளுமே சூதகத்தில் வாய்வு தோன்றி
நேரான அடிவயிறு வலிப்புக்காணும்
பாளுமே தலைவலிக்கும் வயிறுளைக்கும்
பக்குவமாய் மருந்துண்ணத் தீருந்தானே"

-ஆத்மரட்சாமிர்தமென்னும் வைத்திய சாரசங்கிரகம்
ப.எண்:50

C. In Dhanvandhri vaithiyam – Muthalbaagam

Under the topic *soorai nithanam*

1. The manifestations of *Raktha soorai*are

- ❖ Infrequent menstruation
- ❖ Giddiness
- ❖ Amenorrhoea
- ❖ Miscarriage

இரத்தசூரை

"திரண்டு புரண்டு கீழ்வயிற்றில் திறமாய் மாதவிடாய் போது
மருண்டு குருதி குறுகிவரும் வாய்நீர் பெருத்து மயங்கிவரும்
திரண்டு சிலநாட் சிக்கி நிற்கும் திறமாங் கருவை யழிப்பிக்கு
முருண்ட விரத்த சூரையென்று முறுக்கு ணங்கண்டுரைபீரே"

-தன்வந்திரி வைத்தியம் முதல் பாகம்
ப.எண்:236, பா.எண்:26

2. The manifestations of *Karba suronitham*are

- ❖ Painful and infrequentmenstruation
- ❖ Nausea

- ❖ Giddiness
- ❖ Amenorrhoea
- ❖ Miscarriage

கர்ப்ப சுரோணிதம்

"திரண்டு புரண்டு கீழ்வயிற்றில் திங்கள் முழுக்கில் வலியுண்டா
மருண்டு குருதி வரும் வாய்நீருறு மயங்கிவருந் திரண்டு
சிலநாட் சிக்கி நிற்கும் திறமாங் கருவை யழிப்பிக்கு
முருண்ட கர்ப்பச் சுரோணித மென்றுரைக்குங் குணங் கண்டறிவீரே"

-தன்வந்திரி வைத்தியம் பாகம்- ஐ
ப.எண்:253 பா.எண்:66

D.* In *Sarabendra vaithiya muraigal – Garpini Bala Rogasikichai

Under the topic *Sthrikalin Rogangal*

The manifestations of *Raktha soolai* are

- ❖ Lower abdominal distension withvomiting
- ❖ Painfulmenstruation
- ❖ Excessive menstrual flow(menorrhagia)
- ❖ Pain in the thighs (a part ofdysmenorrhea)
- ❖ Delayed / irregular menstrualcycle
- ❖ Miscarriage

இரத்தசூலைக் குறிகுணம்

"திரண்டு புரண்டு கீழ் வயிற்றில் திறமாய் மாதவிடாய் பெற்று
உருண்டு குருதி மிகுதிவிழு முறைந்துடையு முளைந்து வரும்
திரண்டு சில நாள் சிக்கி நிற்கும் திறமாய் கருவையழிப் பிக்கும்
உருண்டயிரத்த சூலையென்று உறுதியிவை கொண்டுரையீரே"

-சரபேந்திர வைத்திய முறைகள்
-கர்ப்பிணி பாலரோக சிகிச்சை ப.எண்: 42

E. In silerpana noi mattrum uthara noi thohuthi – Edited byT.Mohanraj

Under the classification of *uthara noi*

The manifestations of *Raktha soolai vaayu* are

- ❖ Acute pain shooting down thethighs
- ❖ Lower abdominal distention withvomiting
- ❖ Pain in the lower part of thebowels
- ❖ Menstrual bleeding inclots
- ❖ Miscarriage

இரத்த சூலைவாய்வு

"திரண்டு புரண்டு அடிவயிற்றில்
திறமாய் இரத்தம் கட்டியதாய்
உருண்டு குருதி திரண்டு வரும் தொடையும்
வயிறும் உளைந்து வரும்
திரண்டு சில நாள் சிக்கி நிற்கும்
திறமாய்க் கருவை அழிப்பிக்கும்
உருண்டு இரத்த சூலைவாய்வு உறுதி
கண்டு உரைத்தோமே"

"பார்த்துடவே மங்கையர்க்கு ரெத்த சூலை
பகருகிறேன் அடிவயிறு கனத்த காணும்
சேர்ந்திடவே உதிரமது திரண்டுமே தான்
கொதிப்புண்டாம் மாதவிடை காலந்தன்னில்
சேர்ந்திடவே சூதகவும் மிகுந்து காணும்
சிறுவழியாய்க் கருவழிக்கும் பிரண்டுளையும்
ஏர்த்திடவே தொடை இடுப்பு உளைச்சல் ஆகும்
இரத்த சூலை வாயுவென சாற்றலாமே"

-சேற்பன நோய் மற்றும் உதர நோய் தொகுதி
ப.எண்:291,பா.எண்:116,117

F*. In Mega noi, *Soothaga nool mattrum arivaiyarchinthamani

The manifestations of *soothaga vaaivu* are

- ❖ Infrequent menstruation
- ❖ Lower abdominalpain
- ❖ Headache
- ❖ Generalized bodypain
- ❖ Loss of appetite

சூதகவாய்வு

"பாதமொடு சூதக வாயுவது தன்மை கேள்
மாதவிடையது குறையுமே
புகழுரிய வயிறு கனமாகி யதி வேதனை
அடிவயிறு புண்போல நோவாம்
போதமுறு சென்னிவலி உச்சியதிலே குத்து
இரு கொங்கையது முளையுமே
மோதியதி தாயிரு கைகால் கிடுக்குமே
கால் மண்ணையது முளையுமே
முதிய நாவானது வழுவழுப்பாயிடும்
அன்னம் குறைந்து வருமே
நீதமுறு மேனியது விளனுமதி சோபமாய்
சொற்பனம் அதிகரிக்கும்
நித்தனருள் பெற்ற முனி சொல்லு
முறையின் படி செந்தமிழா யுரைத்தேன்"

-மேகநோய், சூதகநூல் மற்றும் அரிவையர் சிந்தாமணி
பதிப்பாசிரியர் வு.மோகன்ராஜ்

G. Thiruvalluva Nayanaar –"Gnanavettiyaan-1500"

In *Gnanavettiyaan-1500, Thiruvalluva Nayanaar* wrotes as follows

- Vatham decreases in its place and get increases in pitham and kabamregion
- Vatham gets decreases in ovary resulting in accumulation ofwater
- Kabam gets increases and may results in increased bodyweight

"சூதகத்தில் வாய்வதுபோய்ச் சொக்குங் காலைச்
சுருதியெனும் வன்னிபித்தந் துணையாய்ச் சேரும்
மாதவிடாய் நாகமதும் வஸ்துக் கட்டும்
மாதாந்தம் கட்டினதால் மாதுதேகம
ஊது உடல் சரீரமெல்லாங் கருப்பை துந்து
உதிரநீர் சூசிகா வாய்வுந்த் தோன்றி
வாதனையால் வயிறுடம்பு பெருத்து ஊதி
மகத்தான அடிமூலம் வாதஞ் சேர்ந்தே"

-ஞானவெட்டியான்- 1500

H. Thirumoolar school of thought:

"சூதான மாமிசம் சுழித்திடில் கர்ப்பத்தில்
வாதான மேகத்தால் வழங்கிச் செனிப்பிக்கும்"

-திருமூலர் கருக்கிடை வைத்தியம்

I. Pararasasekeram:

The manifestations of *karbavaayu* are

- Amenorrhoea
- Dysmenorrhoea
- Constipation
- Obesity

கெர்ப்ப வாயுவின் குணம்:

"பொருமு முதரந் தனையடைத்துப் போத மிகவும் வலியுண்டாய்க்
குருதிகழியில் வலிதீருங் கொள்ளுங் கெர்ப்ப முறவலிக்கும்
வருடி யிடுப்புத் துடையுளையு மயக்கு மலத்தை மிகவிறுக்கும்
பெருகப் பணைக்கும் முதரத்திற் பேசும் கெர்ப்ப வாயுவிதே"

முக்குற்ற வேறுபாடு (Pathology)

In siddha system the manifestations of all diseases are due to the derangement of *tridoshas* i.e., *vatham, pitham, kapham*

Vatha kutram:

Vatham in its normal condition, it maintains a state of equilibrium between different humors and the root principles of the body. It also tends to maintain uniform state in the metabolism of the body and helps the organs to discharge their specific function.

வாயு- நரம்பின் வழியாய் வாதநீர் அதிகரித்து அபானத்தில் நரம்பின் வழியாயும் வேறு பற்பல வழியாயும் இறங்கி உண்டாகும் ஓர் வாத நோய்.

-T.V.Sambasivam Pillai Agarathy Vol – V

The following vaayu are affected in *Raktha Soorai Vaayu*

Abanan - Irregularly menstruation, Miscarriage *Viyanan* - Tenderness in the lower abdomen, fatigue.

பிணியறிமுறைமை **(Diagnosis)**

In *piniyari muraimaigal* following principles are followed in Siddha system They are

Poriyaalarithal	-	Inspection
Pulanaalarithal	-	Palpation
Vinaathal	-	Interrogation

Poriyaal arithal:

Porigal is the five sense organs of perception namely nose, tongue, eye, skin, and ear.

Pulanaal arithal:

Pulangal is the fire senses namely smell, sound, taste, sight and sensation. Physicians use their *pori* and *pulan* to examine the *pori* and *pulan* of the patient respectively.

***Vinaathal*:**

Getting informations about the history of the diseases from the patient or from the attenders of him, when the patient is not in a position to speak or if the patient is a child.

***ENVAGAITHERVUGAL*:**

"தரணியுள்ள வியாதி தன்னை யட்டாங்கத்தால்
தானறிய வேண்டுவது யேதோ வென்னில்
திரணியதோர் நாடி கண்கள் சத்தத்தோடு
தேகத்தினது பரிசம் வருணம் நாக்கு
யிரணமல மூத்திரமாமிவை களெட்டும்
யிதம்பட வேதான் பார்த்துக் குறிப்புங் கண்டு
பரனருளால் பெரியோர்கள் பாதம் போற்றிப்
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே"

-குணவாகட நாடி

The prime method adopted to diagnose the disease is by means of "*Envagaithervugal*". The value of *envagaithervugal* is very important for diagnosing purposes, which is the unique and special method describing in Siddha system of

medicine. *Envagai thervugal* are

"நாடிப் பரிசம் நாநிறம் மொழிவழி
மலம் மூத்திரமிவை மருத்துவராயுதம்"

- நோய் நாடல் நோய் முதல் நாடல் திரட்டு
- முதல் பாகம் ப.எண்- 270

"நீடிய விழியினாலும் நின்ற நாக்குறிப்பினாலும்
வாடிய மேனியினாலும் மலமொடு நீரினாலும்
சூடிய வியாதி தன்னைச் சுகம் பெற அறிந்து சொல்லே"

-அகத்தியர்

"மெய்க்குறி நிறத்தொனி விழி நாவிருமலம் கைக்குறி"

-சித்த மருத்துவம் நோய்நாடல

a. *Naadi* (Pulse)
b. *Sparisam*(Palpation)
c. *Naa*(Tongue)
d. *Niram* (Colour of theskin)
e. *Mozhi* (Speech)
f. *Vizhi*(Eyes)
g. *Malam* (Stools)
h. *Moothiram*(Urine)

Naadi

The naadi indicated the state of *udal thathus* whether normal or abnormal.

"நோய்நாடி நோய்முதல் நாடி அதுதணிக்கும்
வாய்நாடி வாய்ப்பச் செயல்"

-திருவள்ளுவர்

In *Ratha Soorai Vaayu* the *vathanaadi* or *vathathonthanaadigal* were seen commonly.

"பாரிய வாய்வு பரிந்து குழுப்புகில்
தாரிக் கழிந்து சதநித்தங் கூப்பிடும்
வாரி உடம்பெலாம் வலிக்கும் இடைநோகும்
ஆரியன் சொன்னான் அறிந்தவர் சித்தரே"

-பதிணென் சித்தர்கள் நாடி சாஸ்திரம்
ப.எண்:95, பா.எண்:90

Vaayu stays in uterus and causes miscarriage and generalized body pain.

"சித்தான கர்ப்பத்தில் சேர்ந்திடும் இரத்தந்தான்
வத்தாம் வுருண்டு வாயு போல் ஓடிடும்
உற்ற பசிபோகும் உழன்றே இரைந்திடும்
வற்றாக் கழிச்சலாம் வன் சூதக வாயுவே"

-பதிணென் சித்தர்கள் நாடி சாஸ்திரம்
ப.எண்:94, பா.எண்: 91

ACCORDING TO SATHAGANADI, Vaayu and blood stagnant in uterus causes *soothagavaayu*.

Sparisam

Tenderness felt over the lower abdomen and mild increase in body temperature.

Naa

Niram

Pallor

Depending on body constitution it may be black (*vatham*), red or yellow (*pitham*), whitish (*kapham*) or mixed colour (*thonthanaadi*)

Mozhi Vizhi

Normal vocal resonance present Conjunctival pallor present, due to menstrual blood loss **(Anemia)**

Malam

Normal bowel habit

Moothiram

Neerkuri

"அருந்துமாறிரதமும் அவிரோதமதாய்
அ.ர்கல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக்கலசத் தாவியே காது பெய்
தொருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

-தேரர் நீர்க்குறி நெய்க்குறி நூல்

Urine analysis is done according to five parameters

1. *Niram*
2. *Manam*
3. *Nurai*
4. *Edai*
5. *Enjal*

In *Raktha Soorai Vaayu,*

Niram : The colour of urine exists in both straw colour & yellow

Manam: No abnormal smell seen

Nurai, Edai, Enjal : All the three parameters were normal *Neikuri*:

In Ratha Soorai Vaayu, neikuri shows mostly *Kaphaneer*, *Pithaneer* and *Vathaneer* are less common in thisdisease.

3.4 MODERN ASPECT

PHYSIOLOGY OF FEMALE REPRODUCTIVE SYSTEM

The Reproductive Cycle

The female reproductive cycle is the process of producing an ovum and readying the uterus to receive a fertilized ovum to begin pregnancy. If an ovum is produced but not fertilized and implanted in the uterine wall, the reproductive cycle resets itself through menstruation. The entire reproductive cycle takes about 28 days on average, but may be as short as 24 days or as long as 36 days for some women.

Oogenesis and Ovulation

Under the influence of follicle stimulating hormone (FSH), and luteinizing hormone (LH), the ovaries produce a mature ovum in a process known as ovulation. By about 14 days into the reproductive cycle, an oocyte reaches maturity and is released as an ovum. Although the ovaries begin to mature many oocytes each month, usually only one ovum per cycle is released.

Fertilization

Once the mature ovum is released from the ovary, the fimbriae catch the egg and direct it down the fallopian tube to the uterus. It takes about a week for the ovum to travel to the uterus. If sperm are able to reach and penetrate the ovum, the ovum becomes a fertilized zygote containing a full complement of DNA. After a two-week period of rapid cell division known as the germinal period of development, the zygote forms an embryo. The embryo will then implant itself into the uterine wall and develop there during pregnancy.

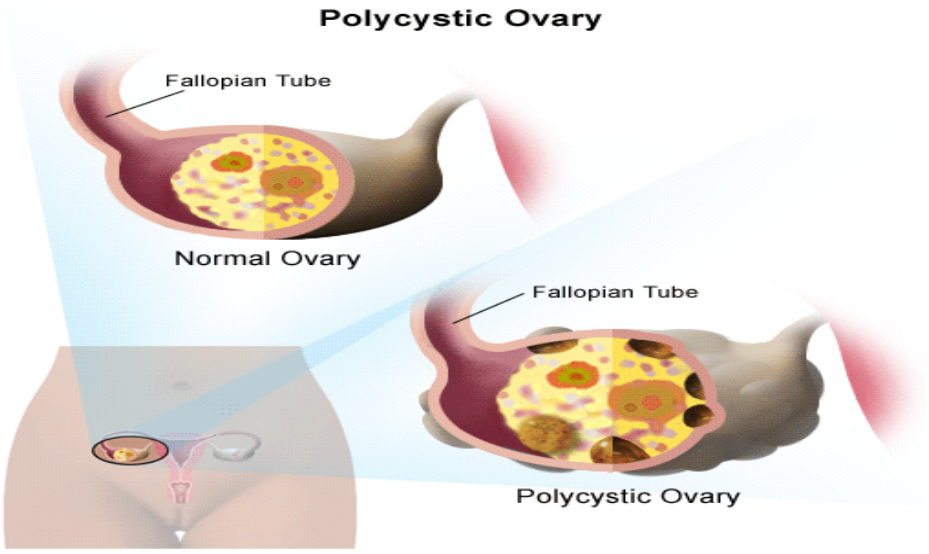
Menstruation

While the ovum matures and travels through the fallopian tube, the endometrium grows and develops in preparation for the embryo. If the ovum is not fertilized in time or if it fails to implant into the endometrium, the arteries of the uterus constrict to cut off blood flow to the endometrium. The lack of blood flow causes cell death in the endometrium and the eventual shedding of tissue in a process known as menstruation. In a normal menstrual cycle, this shedding begins around day

28 and continues into the first few days of the new reproductivecycle.

POLYCYSTIC OVARIAN SYNDROME

Poly Cystic Ovarian Syndrome (PCOS) is the most common endocrine disorder in women of reproductive age group, affecting 5 to 10% of women exhibiting, the full blown syndrome of hyperandrogenism, chronic an ovulation and polycystic ovaries. Chronic anovulation accompanied by hyperandrogenism and clinical manifestations including hirsutism, acne, elevated testosterone and androstenedione, and frequently but not always obesity is seen in PCOS. This disease was discovered by and named as Stein-Leventhal syndrome in 1935.



INCIDENCE

Approximately 75% of anovulatory women of any cause have polycystic ovaries and 20 to 25% of women with normal ovulation demonstrate ultrasound findings typical of polycystic ovaries. Current incidence of PCOS (5-6%) is fast increasing lately due to change in the lifestyle and stress. It is also becoming a common problem amongst adolescents, developing soon after puberty. Amongst infertile women, about 20% is attributed to anovulation caused by PCOS. Some of the women who develop cardiovascular disease, hypertension, endometrial cancer and type 2 diabetes later in life appear to have suffered from PCOS in earlier years

AETIOLOGY

PCOS has been attributed to several causes including change in lifestyle, diet and stress. Initially, the ovaries were thought to set the changes in the endocrine pattern. Genetic and familial environment factors (autosomal dominant inherited factor) were added as aetiological factors in the development of PCOS. The environment factor may function in utero or in early adolescent life, manifesting clinically a few years later as PCOS. CYP_{21} gene mutation has been discovered in this connection. Familial occurrence has also been reported.

PATHOPHYSIOLOGY

When compared with levels found in normal women, patients with persistent anovulation have higher mean concentration of LH, but low or low normal levels of FSH. The elevated LH levels are partly due to increased sensitivity of the pituitary to gonadotropic releasing hormone stimulation. Because the FSH levels are not totally depressed, new follicular growth is continuously stimulated, but not to the point of full maturation and ovulation, and they are in the form of multiple follicular cysts 2 to 10mm in diameter. These follicles are surrounded by hyperplastic theca cells, often luteinized in response to high LH levels. As various follicles undergo atresia, they are immediately replaced by new follicles of similar limited growthpotential.

Poly Cystic Ovarian Syndrome may set in early adolescent life, but clinically manifest in the reproductive age with long-term implication of diabetes, hypertension, hyperlipidaemia and cardiovascular disease, this cluster of disorders is known as, X syndrome.

Endocrinology changes are as follows:

1. Estrone / E_2 levelrises.
2. LH level is raised over 10IU/ml
   FSH level remains normal, but FSH/LH ratio falls.
3. SHBG level falls due tohyperandrogenism
4. Testosterone and epiandrostenedione levels rise.
   Testosterone >2 ng/ml, free T >2.2 pg/ml (normal level 0.2-0.8 ng/ml) Normal androstenedione level is 1.3-1.5 ng/ml.
   DHEA >700 ng/ml suggests adrenal tumor.

5. Prolactin is mildly raised in 15%cases
6. Fasting insulin is more than 10 IU/ml inPCOS
7. Thyroid function tests may be abnormal(hypothyroidism)
8. 17 –α- hydroxyprogesterone in the follicular phase >300 ng/dl suggests adrenal hyperplasia due to 21 hydroxylasedeficiency.

Insulin and the mechanism of anovulation in Poly Cystic Ovarian Syndrome

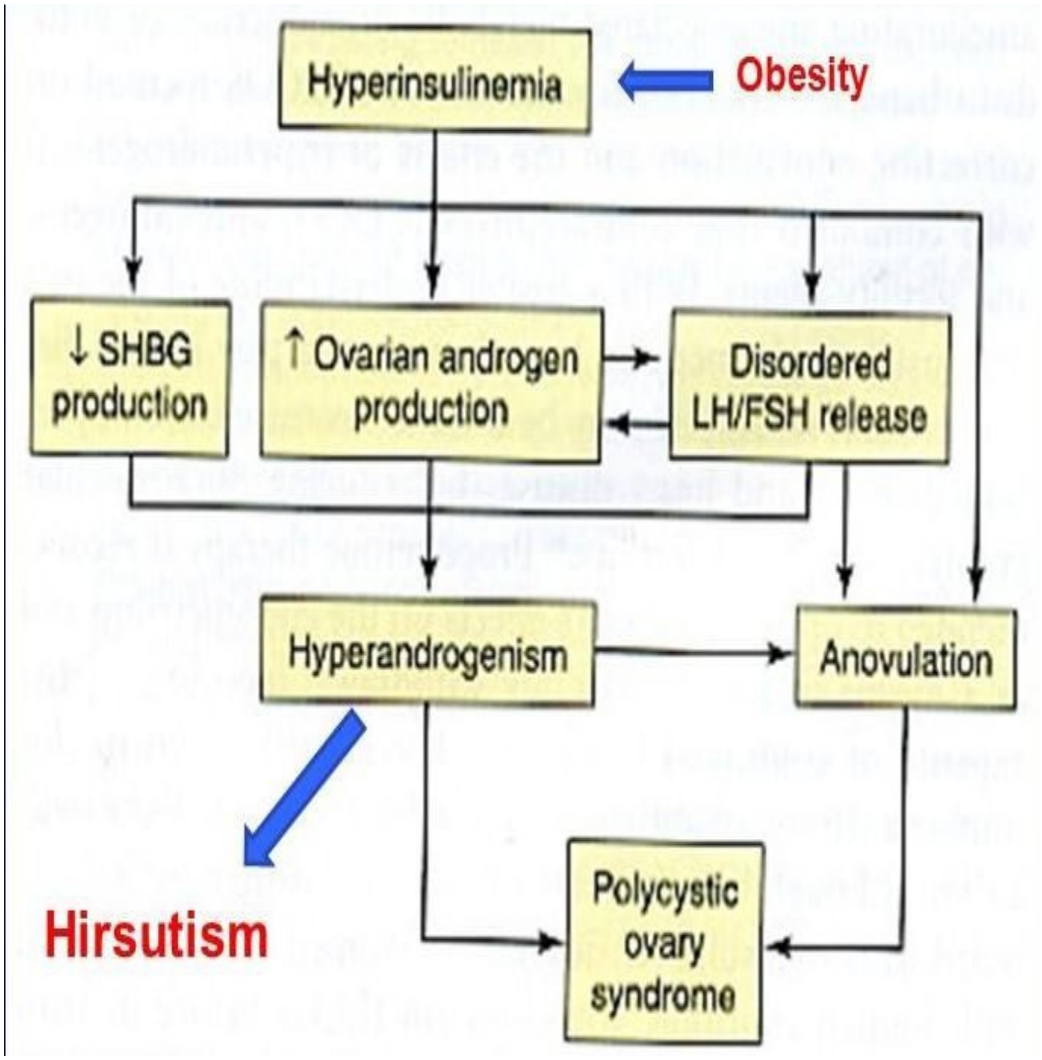
There is growing evidence that hyperinsulinemia may stimulate P 450c 17 enzyme resulting in hyperandrogenism. P 450c 17 is the key enzyme that regulates androgen synthesis.

The characteristic feature of anovulation in PCOS is the arrest of growth of antral follicles after reaching a diameter between 5 and 8 mm. This may be caused by premature activation of LH. It is well known that the syndrome is clustered in families. The sister of the women with PCOS in such a family has a 50% risk of PCOS compared with a population prevalence of only 5 to 10%. There is evidence from family studies to support a genetic predisposition to develop PCOS and insulin resistance that seem to co-exist in thissyndrome.

Role of Hyperinsulinemia in the pathogenesis ofPCOS

Obesity, genetic predisposition and insulin receptor disorders lead to insulin resistance. Insulin resistance leads to abnormal glucose tolerance raising the blood sugar, and hyperinsulinemia. This hyperinsulinemia acts on the liver and reduces SHBG (sex hormone binding globulin) and also increases IGF-1 (insulin like growth factor -1). Reduction of SHBG increases the testosterone, whereas the increased IGF-1 will cause increased androgen production from ovaries. Hyperinsulinemia itself causes the theca cell hyperplasia and increasedandrogens.

Considering these clinical observations and in vivo/in vitro studies, it was proposed that hyperinsulinemia and hyperandrogenism, regardless of which is the primary event, is connected to PCOS.



Hyperandrogenism in PCOS

Androgens are important contributors in the pathophysiology of PCOS. In the ovary the characteristic morphology of PCOS is closely related to serum androgen levels. Recruitment and growth of early follicles is stimulated by androgens, followed by a growth arrest at a diameter between 3 and 5 mm. Elevated intrafollicular androgen concentrations are held responsible for the succeeding follicular atresia. The ability of progesterone to slow down the frequency of the GnRH pulse is reduced in hyperandrogenic patients. An accelerated GnRH pulse increases the secretion of

luteinzing hormone (LH) while reducing the secretion of follicle stimulating hormone. Elevated LH levels stimulate theca-cell-mediated androgen synthesis, further increasing hyper androgenism. In such a state, the aromatase activity is dependent on FSH, which is not sufficient to convert excess androgens into estrogens. Androgen excess has been postulated to be an in vivo environmental factor that contributes to insulin resistance in the adipose cells and skeletal muscle of women with PCOS.

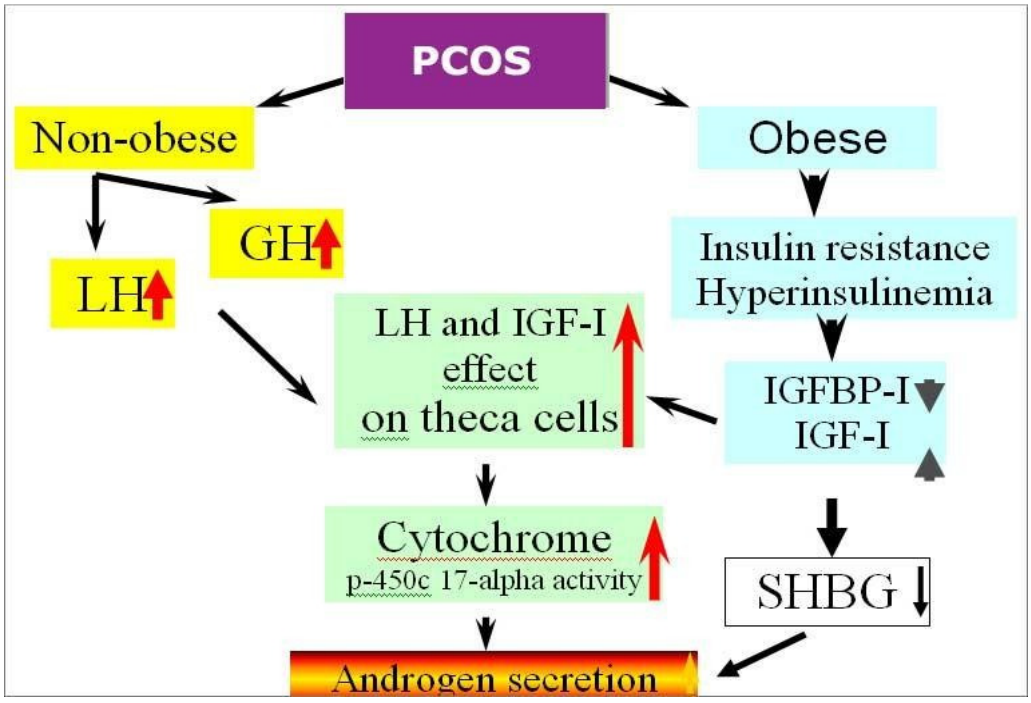
OBESITY AND PCOS

More than 50% of women with PCOS are overweight or obese. In comparison to lean women with PCOS, obese women with PCOS have a higher prevalence of menstrual disorders and infertility. They are more likely to be hirsute, and have lower SHBG levels, leading to higher serum concentrations of free testosterone. They are also less likely to respond to induction of ovulation. Obesity is defined in forms of an increased body mass index (BMI) or an increase waist to hip ratio(WHR).

Weight in Kilogram BMI =Height in m^2

Underweight = < 19.9 Kg/m^2 Normal = 20-24.9 Kg/m^2 Overweight = 25-29.9 Kg/m^2 Obese = > 30 Kg/m^2

If the WHR is more than 0.82 then the patients are considered as obese. Adipose tissue plays an important role in steroid production and metabolism. Hence, it influences the hyperestrogenic state in PCOS and its associated menstrual and reproductivedysfunction.



LEPTIN

Leptin, an important adipose derived hormone plays a key role in regulating energy intake and energy expenditure, appetite, and metabolism. The Ob (Lep) gene (Ob for obese, Lep for leptin) is located on chromosome 7. Leptin binds to the ventromedial nucleus of the hypothalamus, known as the "appetite center". Leptin signals to the brain that the body has had enough to eat (satiety). A very small group of people possess homozygous mutations for the leptin gene, which leads to a constant desire for food, resulting in severe obesity. Although leptin is a circulating signal that reduces appetite, in general, obese individuals have an unusually high circulating concentration of leptin. They are proposed to be resistant to the effects of leptin. The high and sustained concentrations of leptin from the enlarged adipose stores result in leptindesensitization.

GHRELIN

Ghrelin is a hormone produced mainly by P/D1 cells lining the fundus of the stomach and epsilon cells of the pancreas that stimulates appetite. Ghrelin levels increases before meals and decrease after meals. It is considered the counterpart of the hormone leptin, which induces satiation. Women with PCOS are less satiated after a meal compared to normal women. The ghrelin levels of the PCOS patients do not

decline after meals to the same extent as control women.

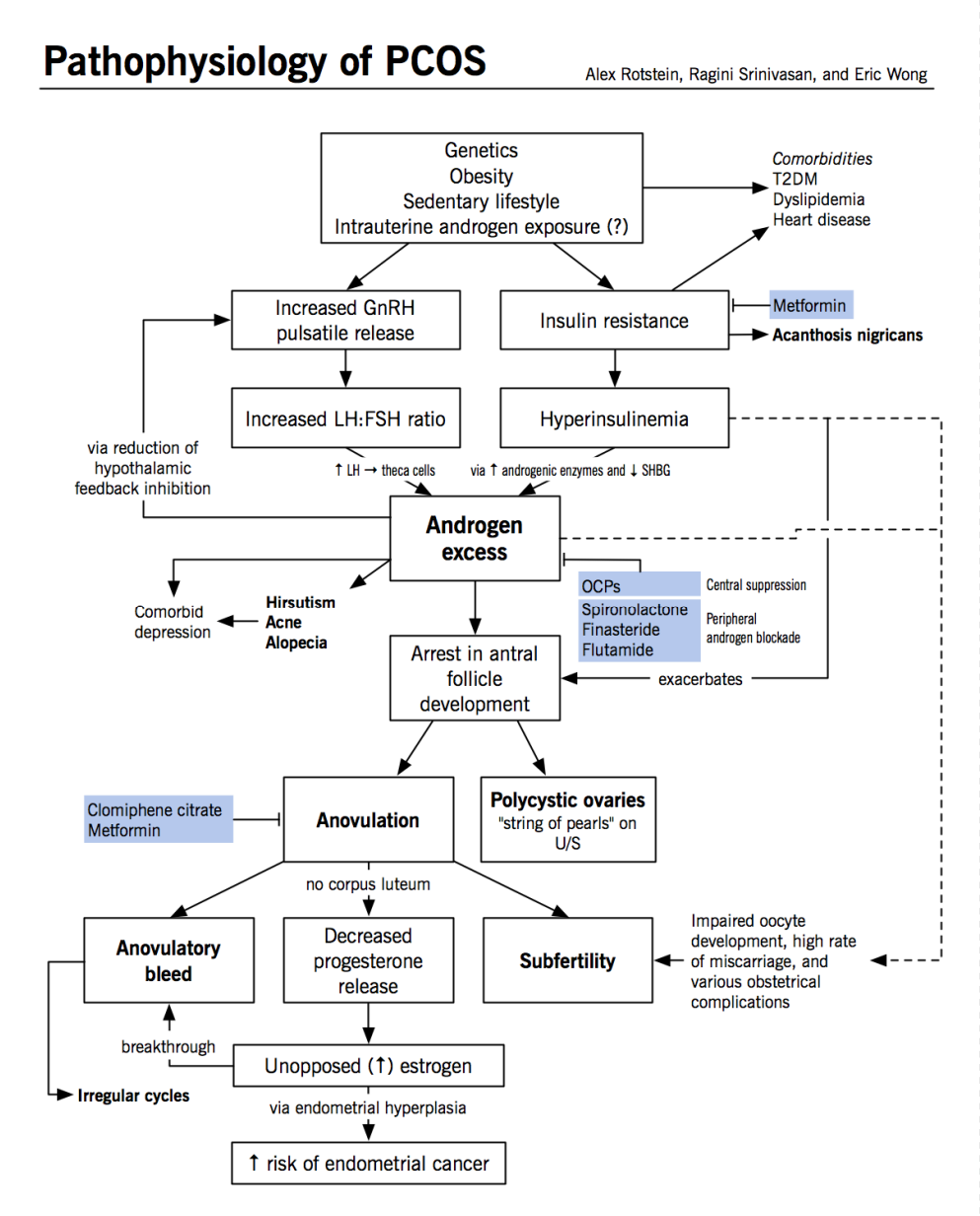
ANTI-MULLERIAN HORMONE (AMH) AND PCOS

Anti-Mullerian hormone (AMH), a member of the transforming growth factor- β superfamily that includes inhibin and activin, is derived specifically from the granulose cells of early developing pre-antral and antral follicles. AMH inhibits the initiation of growth of primordial follicle and is reported to act on the follicle cohort preventing multiple selection of dominant follicles. There is evidence that abnormal, local (follicle-to-follicle) signaling of anti-Mullerian hormone may play a part in disordered folliculogenesis in PCOS. It is postulated that the AMH excess is involved in the lack of FSH-induced aromatase activity, which characterizes the follicular arrest of PCOS. Alternatively, an endocrine action of AMH is suggested since there is a 3-4 fold increase in the circulating AMH levels in PCOS patients compared to normalwomen.

CLINICAL FEATURES

An ovarian follicular cyst is usually asymptomatic and unilocular (simple) and can reach 15 cm in diameter. It usually regresses during the subsequent menstrual cycles. In general, a lutein cyst is apt to be smaller but more firm or even solid in consistency and is more likely to cause pain or signs of peritoneal irritation. Because it may continue to produce progesterone, it is also more likely to cause delayed menses. On occasion, a functional ovarian cyst may undergo torsion or may rupture, which may produce acute lower abdominal pain and tenderness and significant hemoperitoneum.

- Hirsutism
- Oligomenorrhoea
- Obesity
- USG showing - Subscapularcysts



DIAGNOSIS

The diagnosis of PCOS is usually made on the basis of a combination of clinical, ultrasonographic and biochemical criteria. A woman presenting with oligomenorrhoea is likely to have the problem of PCOS if she has one or more of these three features: polycystic ovaries on ultrasound, hirsutism and hyperandrogenemia. Many women have high LH, although normal LH do not rule out thediagnosis.

In its fully developed form, PCOS is characterized by menstrual abnormalities, hirsutism, obesity, hyperandrogenemia, elevated plasma luteinizing hormone (LH) and ultrasonographic evidence of polycystic ovaries. However, thin women can also have the problem. Ultrasonographically, there should be more than 10 cysts 2 to 8 mm indiameter, scattered either around or through an echodense, thickened centralstroma.

Indeed many women with polycystic ovaries detected by sonography do not have symptoms of the PCOS. Ovarian morphology appears to be the most sensitive marker for the PCOS compared with the classic endocrine features of a raised serum LH and / or testosterone concentration.

MANAGEMENT

- To cure a woman with menstrualdisorders
- To treathirsutism
- To treatinfertility
- To prevent long-term effects of X syndrome in laterlife.
- The treatment therefore is catered to the requirement of thewoman.

Weight Loss

Although obesity is not a prerequisite for the diagnosis of PCOS, it is a common feature. Almost 50% of women with PCOS have an android type of phenotype characterized by waist: hip ratio greater than 0.85(9). Obesity may induce hyperandrogenism by increasing the production of androgens, reducing sex hormone binding globulin levels (SHBG), thereby increasing free testosterone levels causing hyperestrogenemia. This causes pulsatile LH secretion and/or insulin resistance and therefore, insulin secretion which could amplify the LH dependent regulatory mechanisms that regulate ovarian androgen secretion.

Increase of LH can cause a vicious cycle of hyperandrogenemia and follicular atresia. Even moderate obesity (BMI > 27 kg/m^2) is associated with a reduced chance of ovulation. Obese women with PCOS (BMI > 30 kg/m^2) should therefore be encouraged profile and a likelihood of ovulation and healthy pregnancy.

Insulin sensitizing agents

Improving the action of insulin is a relatively new concept in therapy. It is demonstrated that reduction of hyperandrogenism in women with PCOS may be achieved by interventions which improve insulin sensitivity and reduce circulating insulin. Such measures might include, but are not limited to weight loss, dietary modifications and insulin sensitizing agents like Metformin.

Diet

Reducing the caloric intake with reduced glycemic load may be beneficial in alleviating hyper-insulinemia and its metabolic consequences. It is recommended that obese women with PCOS should reduce the caloric intake by 500 Kcal/day with less carbohydrate, a diet which will help them to shed 5% of their weight.

Exercise

Insufficient physical activity may contribute to obesity in women with PCOS. Any weight loss regimen should include regular physical activity to maintain weight reduction in the long term.

Life style

Cigarette smoking should be abandoned. It lowers E2 level and raises DHEA and androgen level. Hormones to control menstruation are:

- Oral combined pills(OC)
- OC and cyproterone acetate. Oestrogen suppresses androgens and adrenal hormones (DHEA). It raises the secretion of SHBG in the liver, which binds with testosterone, thus reduces free testosterone. It also suppressesLH.
- Progesterone may be required to induce menstruation in amenorrhoeic woman prior to initiating hormonal cyclicaltherapy.
- OC with cyproterone is prescribed if the woman hashirsutism.

Hirsutism

Anti – androgens are used. Dexamethasone (0.5 mg) at bedtime reduces androgen production, and is used in some infertile women with clomiphene.

Infertility

Clomiphene is the first line of treatment if PCOS woman is to be treated for infertility.

Ovulation Induction

Women with PCOS belong to WHO group II of anovulatory patients and will respond to oral agents such as clomiphene citrate (CC), insulin sensitizers and aromatase inhibitors. A few of them will require ovulation induction with gonadotropins and some may benefit from assisted reproductive technologies.

Surgery

Surgery is reserved for those in whom

- Medical therapyfails
- Hyperstimulationoccurs
- Infertilewomen
- Previous pregnancylosses

Surgery comprises laparoscopic drilling or puncture of not more than four cysts in each ovary either by laser or by unipolar electrocautery.

Prevention

With the knowledge that PCOS has long-term adverse effects (three fold) on health of the woman, such as diabetes, hypertension, cardiovascular disease and hyperlipidaemia, endometrial cancer, it is now suggested that PCOS should be adequately treated at the earliest. This woman should be observed for these ailments in later life. Obesity in adolescents needs to be avoided and corrected. Lifestyle changes should be recommended. It is suggested that in utero malnutrition results in intrauterine growth – retarded baby which develops PCOD and X syndrome in later life. This implies that pregnancy should be managed well to maintain a good health of the individual

.

Exercise

Obesity and irregular periods can be controlled by regular exercises.

Yoga

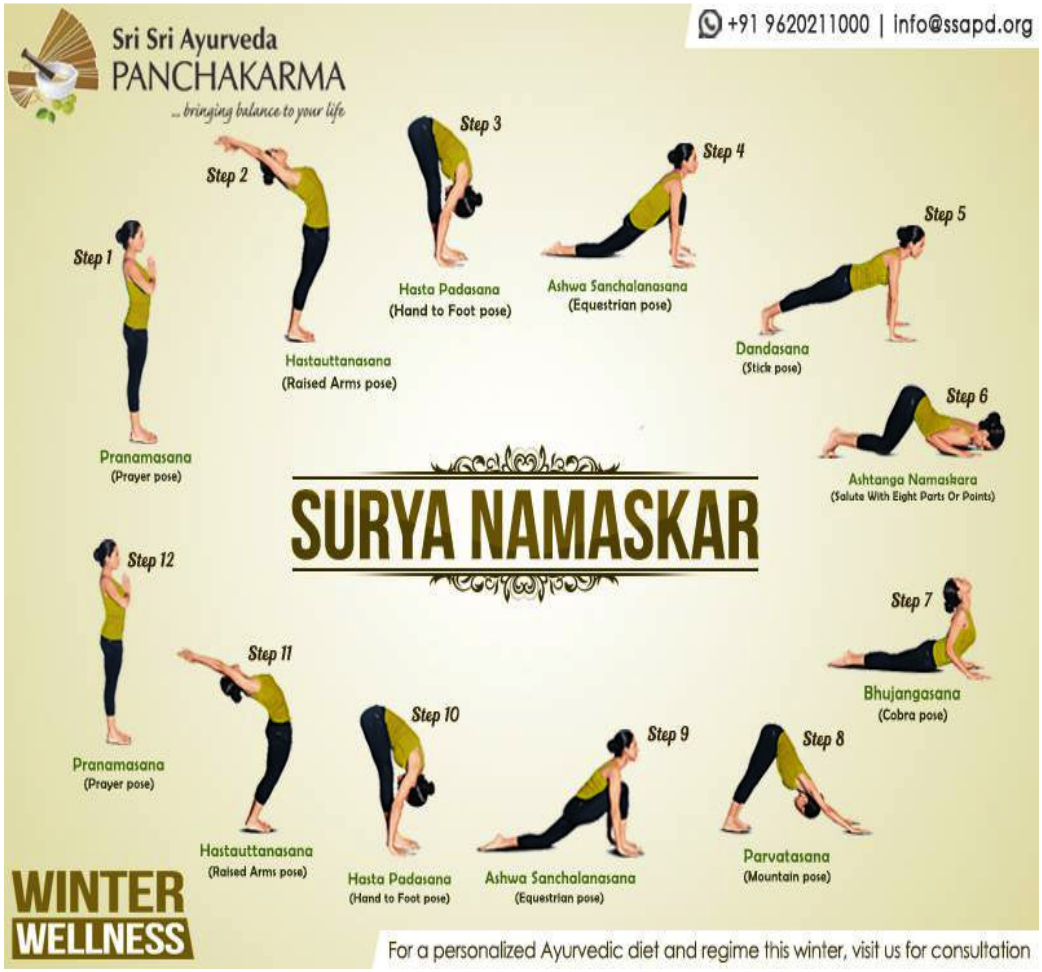
Yogasanas help a lot to keep PCOD symptoms in control. Suryanamaskar is also very helpful.

Pranayam

Pranayam can greatly help in getting the hormones back to normal.

Diet

Include fruits, salads and green leafy vegetables, & reduce intake of refined carbs and dairy products.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SURYA NAMASKAR
Step 1
Pranamasana
(Prayer pose)
Step 2
Hastauttanasana
(Raised Arms pose)
Step 3
Hasta Padasana
(Hand to Foot pose)
Step 4
Ashwa Sanchalanasana
(Equestrian pose)
Step 5
Dandasana
(Stick pose)
Step 6
Ashtanga Namaskara
(Salute With Eight Parts Or Points)
Step 7
Bhujangasana
(Cobra pose)
Step 8
Parvatasana
(Mountain pose)
Step 9
Ashwa Sanchalanasana
(Equestrian pose)
Step 10
Hasta Padasana
(Hand to Foot pose)
Step 11
Hastauttanasana
(Raised Arms pose)
Step 12
Pranamasana
(Prayer pose)
WINTER
WELLNESS
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CHAPTER-IV

MATERIALS & METHODS

STUDY AREA AND SETTING

The study period was covered from June 2017 to July 2019 at the Govt. Siddha Medical College and Hospital, Palayamkottai- 627 002, Tirunelveli, Tamil Nadu. All procedures were carried out before getting the permission from Institutional Ethical Committee.

STUDY DESIGN

The study design is a prospective open labeled non-randomized Phase-II clinical trial of 40 *Raktha soorai vaayu* (Polycystic ovarian syndrome) subjects. The selected subjects were newly diagnosed or already diagnosed as PCOS patients with or without taking treatment. A written informed consent form was recruited in the study. The purpose of the study was explained to the patients before administration of trial drug. The patients' basic information, life style and siddha parameters were recorded before starting the treatment.

The total number of 40 female patients and aged ranging from 18 to 45 were taken for this study. The selected patients were treated with the trial drug for the entire of the study period (60 days).

SELECTION OF PATIENTS

The criteria for selection of patients are given below (3.3.1). Screening is done before starting the treatment.

Detailed personal history, family history, occupation, habits, clinical symptoms, medical history, and the duration of illness were recorded in all patients (proforma annexed).

Inclusion Criteria

The parameters for the selection were insidious,

Age: 18 – 45years

Marital status: Married / Unmarried

Patient having the symptoms of irregular menstruation (*Kuruthi migunthu vizhuthal or Kuruthi veliahathiruthal*)

Oligomenorrhoea (or) Amenorrhoea (or)Dysmenorrhoea

Patient willing to take USG pelvis

Patient willing to undergo routine bloodinvestigation

USG pelvis showing polycystic ovarianchanges

Patient willing to participate in trial and signing in consentform

Increased vathanaadi

Exclusion criteria

H/O systemic hypertension

H/O Type 2 diabetes mellitus

H/O Cardiac diseases

H/O liver diseases

H/O other uterine disorders

Auto Immune disease

Pregnancy and lactation

Known H/O thyroid dysfunction

Hyper prolactinemia

Androgen secretingneoplasms

Other pituitary or adrenal disorders

Sanninilai

Withdrawal Criteria:

Intolerance to the drug and development of adverse reactions during the drug trial.

Poor patient compliance &defaulters

Patients turned unwilling to continue in the course of clinicaltrial

Occurrence of any seriousillness

Evaluation of clinical parameters

Patients are evaluated clinically using following parameters

History taking

Clinical assessment

Investigation of blood andurine

Specific investigation assessments based on siddha system

I. History taking

Age, occupation, previous illness, family history, personal habits were recorded in the proforma of every patients.

II. Clinical assessment

Irregular menstruation

Amenorrhoea

Oligomenorrhoea

Menorrhagia

Weightgain

Infertility

Acanthosis nigricans

Hirsutism

Acne

Androgenichairloss

BMI

Waist hipratio

III. INVESTIGATIONS

Blood

TC

DC

ESR

Hb

Sugar (fasting)

Urea

Creatinine

Serumcholesterol

Urine

Albumin

Sugar

Deposits

IV. Specific investigations

USG – abdomen andpelvis

Diagnosis

The Siddha diagnostic procedures were included this study, which is,

Poriyal Arithal

Pulanal Arithal

Vinathal

Mukkutra nilaigal

Envagai thervugal

Nilam

Kaalam & Udal kattugal

Investigations

Blood - Complete blood analysis TC, DC, Hb, TRBC, ESR,

Routine Urine Analysis - Albumin, Sugar, Deposits,

Stools- for Ova, Cyst and Occult blood were also done.

Biochemical Analysis- Serum Cholesterol, Blood Sugar, Blood urea are carried out before the treatment and at the time of discharge.

The Lab investigations were carried out before and after administration of trial drug.

TREATMENT

Preparation of Trial Medicine (Annexure-I (A) & I (B))

The herbal preparation of ***KARUNJCHIRAKAM CHOORANAM*** was selected from the classical siddha literature,

Reference: "GUNAPADAM MOOLIGAI VAGUPPU PART-I"- Page No:463-464

Author: K.S.MURUGESA MUDHALIYAR

Collection and authentication of Trial Medicine (Annexure-I):

The Nigella sativa Seeds was collected fromthe Nagar kovil based siddha medical shop. It was identified and authenticated by the medicinal botanist **Dr.S.Sutha, Msc., M.Ed.,Ph.D., Associate Professor, Department Of Medicinal Botany** at Government Siddha Medical College and Hospital, Palayamkottai.

Purification of seeds and preparation of the medicine was executed in the P.G Gunapadam Practical lab of Govt. siddha medical college, Palayamkottai.. The specimen sample of the Seeds would be preserved in PG Gunapadam department individually for future reference.

Preclinical Analysis of Trial Medicine

All the preclinical studies of the study drug which includes bio-chemical and pharmacological studies were carried out and results were cross checked before starting the treatment. The bio-chemical analysis was done in Dept. of Biochemistry, GSMCH, Palyamkottai. (Annexure-III).

The pharmacological activities- Anti hyperglycemic, Anti hyperlipidemic activity, Acute and sub-acute toxicity, Phytochemical activitity,hormonal study were carried out in this study. (Annexure-IV) studies were done in K.M. College of Pharmacy, Madurai -625107.

Ethical Review

The study was conducted in accordance with the ethical principles that are consistent with Good Clinical Practice guidelines and obtained prior approvals before start of the trial from the Institutional Ethical Committee of GSMCH, Palayamkottai (**GSMC-IV-IEC/2017/Br-I/01/29.05.2017**) and & Institutional Animal Ethical Committee (IAEC) (approval number is **321611001/KMCP/27/2018).** The study was registered in Clinical Trials Registry.

Study Enrolment

An open labeled non-randomized phase II clinical trial on **"*Raktha Soorai Vaayu*"** was conducted in Government Siddha Medical College and Hospital, Palayamkottai, Tirunelveli. Totally forty cases were selected. 20 patients were treated as OP cases remaining 20 patients as IP cases. The clinical signs and symptoms of **"*Raktha Soorai Vaayu*"**of different ages were selected and studied under the guidance of the professor, reader and lecturer of P.G. Pothu Maruthuvam Department. Participants were informed in Tamil language, regarding the trial, the expected benefits and their right to opt-out of trial at any time without prejudice. Informed written consent was obtained from each participant, prior to her inclusion into the trial.

Patients were advised to withdraw in the conditions such as intolerance to the drug, development of any serious adverse effects during the trial, patients turned unwilling to continue in the course of clinical trial, poor compliance, any other acute illness which needs rescue medication and to follow regular diet schedule.The subjects with history of treatment with other drugs and serious medical or psychological condition are excluded from the study.

During the visit, body weight, blood pressure, cardiovascularand respiratory system were clinically recorded. During the treatment if any adverse reaction or side effects occurs, it was to inform the pharmacovigilence committee. At the end of the study period, all the patients were instructed to follow diet. They were also advised to pursue the further treatment in the PG, Pothu Maruthuvam OP for the follow up study.

Statistical Analysis

All data were analysed using the SPSS 20.0 (IBM). Data were expressed as means and standard deviation. The significance of the difference between the means of the baseline and the final examinations was tested using the paired “t” test. A probability value of <0.05 was considered to be statistically significant.

CHAPTER-V

RESULTS AND OBSERVATIONS

5.1 PRE CLINICAL STUDY

BIO-CHEMICAL ANALYSIS OF *KARUNJCHIRAKAM CHOORANAM*

Preparation of the extract:

5gms of the drug was weighed accurately and placed in a 250ml clean beaker then 50ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100ml volumetric flask and then it is made to 100ml with distilled water. This fluid is taken for analysis.

QUALITATIVE ANALYSIS

S.NO.	EXPERIMENT	OBSERVATION	INFERENCE
1.	**TEST FOR CALCIUM** 2ml of the above prepared extract is taken in a clean test tube. To this add 2ml of 4% Ammonium oxalate solution	A white precipitate is formed	Presence of Calcium
2.	**TEST FOR SULPHATE** 2ml of the extract is added to 5% Barium chloride solution.	A white precipitate is Formed	Presence of Sulphate
3.	**TEST FOR CHLORIDE** The extract is treated with silver nitrate Solution	A white precipitate is Formed	Presence of Chloride
4.	**TEST FOR CARBONATE** The substance is treated with concentrated Hcl.	No brisk effervessence is Formed	Absence of Carbonate
5.	**TEST FOR STARCH** The extract is added with weak iodine Solution	No Blue colour is Formed	Absence of Starch

6.	**TEST FOR FERRIC IRON** The extract is acidified with Glacial acetic acid and potassium ferro cyanide.	No blue colour is Formed	Absence of ferric Iron
7.	**TEST FOR FERROUS IRON** The extract is treated with concentrated Nitric acid and Ammonium thiocyanate Solution	Blood red colour is Formed	Presence of ferrous iron
8.	**TEST FOR PHOSPHATE** The extract is treated with Ammonium Molybdate and concentrated nitric acid	No Yellow precipitate is Formed	Absence of Phosphate
9.	**TEST FOR ALBUMIN** The extract is treated with Esbachs Reagent	No yellow precipitate is formed	Absence of Albumin
10.	**TEST FOR TANNIC ACID** The extract is treated with ferric chloride.	No blue black precipitate is formed	Absence of tannic acid
11.	**TEST FOR UNSATURATION** Potassium permanganate solution is added to the extract	It doesnot get decolourised	Absence of Unsaturated Compound
12.	**TEST FOR THE REDUCING SUGAR** 5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8-10 drops of the extract and again boil it for 2 minutes.	No colour change Occurs	Absence of reducing sugar

13.	**TEST FOR AMINO ACID** One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% Ninhydrin is sprayed over the same and dried it well.	Violet colour is Formed	Presence of amino acid
14.	**TEST FOR ZINC** The extract is treated with Potassium Ferrocyanide.	No white precipitate is formed	Absence of zinc

Inference

Indicates presence of calcium,Sulphate, Cholride,Ferrous iron and Amino acid.

PHYTOCHEMICAL ANALYSIS

Result of Qualitative phytochemical analysis of **KARUNJCHIRAKAM CHOORANAM**

	OBSERVATION	**INFERENCE**
Alkaloids	A white or creamy precipitate indicates that the test as positive	Presence of alkaloids
Carbohydrates	Appearance of brown ring at the junction of 2 layers shows the presence of carbohydrates 37	Presence of carbohydrates
Glycosides	Appearance of pink to red color shows the presence of glycosides and aglyeones	Presence of glycosides
Phytosterols	Appearance OF BLUISH GREEN COLOR SHOWS THE PRESENCE OF PHYTOSTEROLS	Presence of phytosterols

Saponins	Absence of the foam formation shows the devoid of saponins	Absence of saponins
Phenolic compounds and tannins	a)dilute ferric chioride solution (5%)gives a dark green colour. b)10%agulous potassium dicaromate solution gives yellowish brown precipitate .c)10% leads aletate solution gives a white precipitate.	
Protein and free amino acids	A white precipitate indicates the presence of protein. A characteristicnn purple color indicates the presence of amino acids	Presence of protein, free amino acids and free amono acids
Flavanoids	Appearance of magenta color shows the presence of flavanoids	Presence of flavanoids
Lignin	Appearance red color,which shows lignin is present	Presence of lignin
Fixed oils and fats	Soap formation indicates the presence of fats and fixed oils	Absence of fixed oil and fats

The above Table no The qualitative phytochemical analysis was resulted in the presence of Alkaloids ,Carbohydrates ,Glycosides ,Phytosterols ,Flavanoids ,Tannins ,Proteins and Lignin.

ANTI – MICROBIAL ANALYSIS OF KARUNJCHIRAKAM CHOORANAM:

Sample Code	Bacteria Strains Name				
	***Staphylococcus aureus* (G+)**	***Streptococcus mutans* (G+)**	***Bacillus subtilis*(G+)**	***Klebsilla pneumonia* (G-)**	**E – coli (G-)**
KJC	11	8	9	11	14
PC	24	11	24	20	17
NC	-	-	-	-	-

Keys

PC - Positive Control (Streptomycin)
NC - Negative Control
- - No Zone
Mm - Millimetre
G+ - Gram Positive Organism
G- - Gram Negative Organism

Fig.1 Staphylococcus aureus

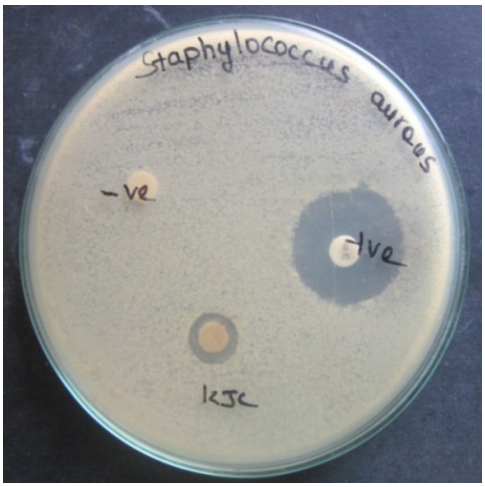


Fig.2 Streptococcus Mutans

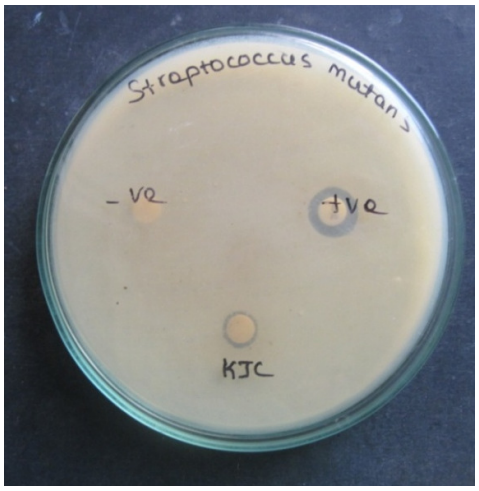


Fig.3 Bacillus Subtilis

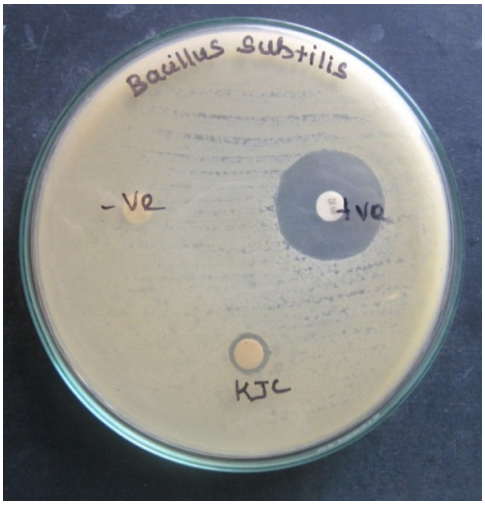
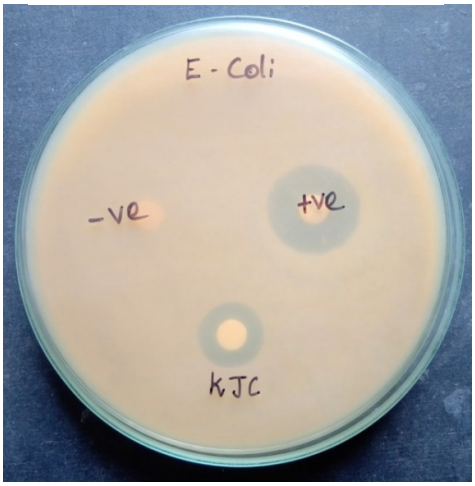


Fig.4 Klebsiella Pnaumoniae

Fig.5 E-Coli



PHARMACOLOGICAL ACTIVITY

Effect of siddha formulation karunjchirakam chooranam on female wistar rats with estradiol valerate induced polycystic ovarian syndrome

Induction of PCOS in the Animals

Thirty adult virgin Wistar rats of approximately 10-12 weeks of age with regular 4-5 day oestruscycles as assessed by vaginal smear, were used for the study(8). Six of the rats were kept as controls, and the others were each given intramuscular injection of 4 mg EV in an oily solution per rat.(9,10)Vaginal smears were examined daily in all animals. Cessation of cyclicity, which was shown by the persistent cornification of vaginal smears, was used as a criterion forselection into the PCOS group.

Treatment Protocol

The rats were allowed to establish PCOS for 30 days.(14) After 30 days, groups in G4 & G5 were dosed orally by gavage for 15 days, whereasrats in the standard group was dosed for 5 days.

- **Group 1** served as the normal control.
- **Group 2** served as the PCOS control. Group 1 and 2 receives normal diet and Water.
- **Group 3** served as the positive control, was treated with injection Clomiphene citrate at 20 mg/kg body weight, Intra peritoneally.(15)
- **Group 4** served as the treatment control, treated with siddha formulation karumjeeraga chooranam at 100 mg/kg body weight, through orally.
- **Group 5** served as treatment control which was treated with siddha formulation karumjeeraga chooranam at 200 mg/kg of body weight, through orally**.**

On 16th day, Six animals from each group (Control and PCO) were randomly selected and anaesthetised with ether. Blood samples were collected by retro orbital puncture, and the serum were used for hormonal assays (FSH, LH, estradiol, progesterone andtestosterone). The ovaries were excised and weighed, and histopathological examination was conducted on the ovaries.

Table no:1 Effect of siddha formulation karunjchirakam chooranamon hormonal level in EV induced PCOS

GROUP	LH	FSH	Estradiol	TSN	PRGSN
G1	6.10±0.25	8.50±0.30	55.05±2.30	0.30±0.04	14.10±0.75
G2	11.70±0.68**a	2.52±0.18**a	14.25±0.85**a	0.40±0.06**a	7.08±0.34**a
G3	5.60±0.30**b	7.28±0.50	45.30±1.78**b	0.32±0.05	12.25±0.40**b
G4	3.95±0.10**b	6.85±0.54**b	38.10±1.38**b	0.36±0.05**b	10.8±0.75**b
G5	4.35±0.18**b	6.35±0.60**b	41.15±1.45**b	0.34±0.04**b	11.74±0.88**b

G_1- Normal, G_2-Toxic, G_3-Standard, G_4-Low dose (karunjchirakam chooranam), G_5-High dose (karunjchirakam chooranam).

All values expressed as means ± SEM for 6 animal in each group.

**a- Values are significantly different from Normal control (G_1) at P<0.001

**b- Values are significantly different from PCOS control (G_2) at P<0.001

*b- Values are significantly different from PCOS control (G_2) at P<0.01

There was statistically significant decrease in estradiol levels with Estradiol valerate(EV) injection after 30 days (p<0.01). Concurrent administration of karunjchirakam chooranam for 15 days showed significant rise in estradiol levels (p<0.01). Animals in Standard group also showed significant rise in estradiol levels. (Table:1)

Toxic control group i.e treated with estradiol valerate had shown significant lowering ofprogesterone. But treatment with karunjchirakam chooranam at both doses (100mg/kg and 200mg/kg) along with EV was able to increase the progesterone levels($p<0.001$)to near normal values significantly. Similar results were also observed in standard group.(Table:1)

There was no significant rise in testosterone levels after exposure of rats to estradiol valerate ($p<0.01$) for 30 days.Treatment with karunjchirakam chooranam at two doses 100mg/kg and 200mg/kg for 15days doesn't show any significant changes in testosterone levels. Similar results were observed after clomiphene treatment.(Table:1)

Effect of siddha formulation karunjchirakam chooranam on ovarian morphology

Table.2 Effect of karunjchirakam chooranam on ovarian morphology of PCOS rats

Dose mg.kg ovarian feature	Normal	Toxic control	Std control	Low dose	High dose
Atretic follicle	0.00±0.00	4.68±0.30	1.15±0.05	3.10±0.20**b	0.06±0.01*b
Cystic follicle	0.00±0.00	10.68±1.40	3.5±0.60	0.00±0.00	0.00±0.00
Cystic follicle diameter	0.00±0.00	86.90±2.38	70.30±2.60	0.00±0.00	0.00±0.00
Cystic follicle thickness	0.00±0.00	42.36±1.90	33.75±2.20	0.00±0.00	0.00±0.00

G_1- Normal, G_2-Toxic, G_3-Standard, G_4-Low dose (karunjchirakam chooranam), G_5-High dose (karunjchirakam chooranam).

All values expressed as means ± SEM for 6 animal in each group.

**b- Values are significantly different from PCOS control(G_2) at P<0.001

*b- Values are significantly different from PCOS control(G_2) at P<0.01

Ovaries of toxic control (Estradiol valerate) group exhibited more cystic follicles compared with other groups but these were not evident in extract control group. Both the 100mg/kg &200mg/kg showed normal follicle at different stage of development.There was evident of arteric follicles present in 100mg/kg.The group that received 200 mg/kg showed numerous healthy developing follicles. (Table:2)

The follicular diameter & thickness of the cysts in PCOS treated group were increased whereas it was reduced in standard & extract treated groups (Table:2).

The ovarian weight of EV control group showed a significant decrease ($p<0.01$), when compared with other groups, whereas in treatment control group 100mg/kg &200mg/kg it was restored to near normal values.

Anti-hyperglycemiuc effect of siddha formulation karunjchirakam chooranam in alloxan induced diabetes rats

MATERIALS AND METHODS

Materials:

Animals	:	Male albino wistar rats (180-220gm)
Drugs	:	siddha formulation Karunjchirakam chooranam
Chemical	:	Alloxan monohydrate (S. D Fine. Chem. Ltd, Mumbai)

INDUCTION OF DIABETES MELLITUS

Diabetes mellitus is induced in wistar rats by single intraperitoneal injection of freshly prepared solution of Alloxan monohydrate (150mg/kg BW) in physiological saline after overnight fasting for 12hrs.[1]

Alloxan is commonly used to produce diabetes mellitus in experimental animals due to its ability to destroy the β-cells of pancreas possibly by generating the excess reactive oxygen species such as H_20_2, 0_2 and $H0^-$. The development of hyperglycemias in rats is confirmed by plasma glucose estimation 72 hrs post alloxan injection. The rats with fasting plasma glucose level of 160-220mg/dl were used for this experiment.

Experimental procedure:

In the experiment a total of 30 rats (24 diabetic surviving rats & 6 normal rats) were used. Diabetes was induced in rats 3 days before starting the experiment. The rats were divided into 5 groups after the induction of alloxan diabetes. In the experiment 6 rats were used in each group.

TREATMENT PROTOCOL

- Group-I: (Normal control) consist of normal rats given with 10ml/Kg of normal saline, orally.
- Group-II: (Toxic control) Diabetic control received 150mg/Kg of Alloxan monohydrate through I.P.
- Group-III:Diabetic control received glipizide at a dose of (10mg/Kg orally) for 28 days.
- Group-IV: Diabetic control received siddha formulation Karunjchirakam chooranam at a dose of (100mg/Kg orally) for 28 days.
- Group-V : Diabetic control received siddha formulation Karunjchirakam chooranam at a dose of (200mg/Kg orally) for 28 days.

METHODOLOGY

Sample collection:

After 28 days of treatment, body weight, blood glucose, haemoglobin, glycosylated haemoglobin, plasma insulin, total cholesterol, triglycerides, HDL-cholesterol and phospholipids were determined. Blood was collected from the eyes (venous pool) by sino-ocularpuncture. [2] in EDTA coating plasma tubes for the estimation of blood parameters.

Table No: 3 Effect of siddha formulation Karunjchirakam chooranamon initial and final body weight and blood glucose in normal and treated animals.

GROUP	Body weight (g)		Blood glucose (mg / 100ml) Initial	Blood glucose (mg / 100ml)
	Initial	Final		Final
G1	228 ± 7.20	240± 7.45	90.60 ± 3.40	92.80 ± 3.85
G2	234 ± 7.35	178 ± 4.55**(a)	91.80 ± 3.60	220.50 ± 6.94**(a)
G3	236 ± 7.38	245 ± 7.50	89.45 ± 4.05	126.40 ± 4.45**(b)
G4	225± 7.15	242 ± 7.40	83.60± 3.60	142.45± 5.30**(b)
G5	235 ± 7.36	246 ± 7.54	95.40 ± 3.80	132.50 ± 4.46**(b)

- Values are expressed as mean **±** SEM.
- Values were compared by using analysis of variance (ANOVA) followed by Newman-Keul's multiple range tests.
- ** (a) Values are significantly different from normal control G1 at P<0.001.
  ** (b) Values are significantly different from Diabetic control G2 at P<0.01.

RESULT

According Table no: 3 illustrates the levels of initial and final blood glucose, and change in body weight , in normal rat, and treatment control animals in each group. The mean body weight of diabetic rats (G2) was significantly decreased as compared to normal control rats. The body weight of diabetic control rats treated with siddha formulation Karunjchirakam chooranam at a dose of 100 and 200mg/kgwas increased the body weight non-significantly as compared to normal control animals.

Fasting blood glucose level was significantly increased 220.50 ± 6.94 in diabetic animals as compared to normal animals. However the level of fasting blood glucose, returned to near normal range indiabetic rats treated with siddha formulation Karunjchirakam chooranam at a dose of 100 and 200mg/kg.

Table no:4-Effect of siddha formulation Karunjchirakam chooranam on plasma insulin, Hemoglobin & Glycosylated hemoglobin in normal and treated animals.

GROUPS	Haemoglobin (gm/100ml)	Glycosylated haemoglobin HbA_1 (%)	Plasma Insulin (µU/ml)
G1	12.90 ± 1.70	0.48 ± 0.07	38.60 ± 2.86
G2	6.30 ± 0.85**(a)	0.96 ±0.20**(a)	13.86 ± 1.88**(a)
G3	14.30 ± 1.44**(b)	0.44 ±0.09**(b)	29.50 ± 2.50**(b)
G4	12.80 ± 0.90**(b)	0.50 ±0.18**(b)	26.80 ±2.46**(b)
G5	11.95 ± 1.24**(b)	0.44±0.07**(b)	28.90± 2.80**(b)

- Values are expressed as mean ± SEM.
- Values were compared by using analysis of variance (ANOVA) followed by Newman-Keul's multiple range tests.
- ** (a) Values are significantly different from normal control G1 at P<0.001.

  ** (b) Values are significantly different from Diabetic control G2 at P<0.01.

RESULT

In table no: 4illustrates the levels oftotal hemoglobin, glycosylated hemoglobin and plasma insulin in normal rat and treatment control animals in each group.

The levels of total hemoglobinand plasma insulin levels were decreased significantly where as glycosylated heamoglobin levels were increased significantly as compared to normal control rats.However the level oftotal hemoglobin, glycosylated hemoglobin and plasma insulin,returned to near normal range indiabetic rats treated with siddha formulation Karujchirakam chooranam at a dose of 100 and 200mg/kg

Table No.5-Serum lipids of Normal and experimental groups.

GROUPS	Total Cholesterol (mg/dl)	Triglyceride (mg/dl)	HDL-C (mg/dl)	Phospholipids (mg/dl)	LDL (mg/dl)
G1	87.65 ± 2.65	94.70 ± 2.70	60.45 ± 1.76	130.70 ± 2.45	14.50± 1.50
G2	232.45 ± 6.85**(a)	162.45 ± 4.60**(a)	31.75 ± 1.35**(a)	219.45 ± 6.40**(a)	37.75 ± 2.48**(a)
G3	122.95 ± 3.40**(b)	98.60 ± 2.62**(b)	47.85 ± 1.40	152.50 ± 3.85	28.25 ± 1.95**(b)
G4	132.65 ± 3.75**(b)	120.85 ± 2.85**(b)	40.35 ± 1.40**(b)	162.55 ± 4.05**(b)	29.15 ± 1.90**(b)
G5	126.45 ± 3.42**(b)	98.60 ± 2.65**(b)	43.70 ± 1.60**(b)	159.35 ± 3.85**(b)	24.35 ± 1.80**(b)

- Values are expressed as mean **±** SEM.
- Values were compared by using analysis of variance (ANOVA) followed by Newman-Keul's multiple range tests.
- ** (a) Values are significantly different from normal control G1 at P<0.001.
  ** (b) Values are significantly different from Diabetic control G2 at P<0.01.

RESULT

Table no: 5 shows the level of serum total cholesterol (TC), triglycerides (TG), high density lipoprotein (HDL),Low density lipoprotein(LDL) and phospholipids of normal and experimental animals in each group.Total cholesterol, triglycerides, high density lipoprotein,Low density lipoprotein(LDL) and phospholipids levels were significantly increased, where as HDL-C level was decreased in alloxan induced diabetic rats as compared to normal rats. Treatment of normal and alloxan induced diabetic rats with siddha formulation Karumjeeraga chooranam at a dose of 100 and 200mg/kg for 28 days resulted in marked decrease in total cholesterol, triglycerides,Low density lipoprotein(LDL) and phospholipids levels and increase in HDL-C levels as compared to alloxan induced diabetic rats.

Hypolipidemic activity of siddha formulation karunjchirakam chooranam in hyperlipidemic models of wistar albino rats

Method

All the animals were weighed and divided into five groups and each group having six rats.

- In group I, rats were normal control.
- In group II, fed the cholesterol to the rats at a dose of 400 mg/kg body weight for 30 days.
- In group III, atorvastatin was fed to rats at a dose of 1mg/kg body weight from day 15 to 30.[3
- In group IV, siddha formulation of karumjeeraga chooranam was fed to rats at a dose of 100 mg/kg from 15 days to 30 days.
- In group V, siddha formulation of karumjeeraga chooranam was fed to rats at a dose of 200mg/kg body weight from days 15 to day 30.

At end of study (30 days) all the rats were sacrificed and the blood was collected and allowed to clot the blood and serum was obtained using centrifuge machine through centrifugation process. The collected serum samples were analysed under biochemical and statistical analysis.

Table 6: Effect of Siddha Formulation KARUNJCHIRAKAM CHOORANAM in lipid Profile.

GROUPS	Total cholesterol (mg/dl)	Triglycerides (mg/dl)	HDL (mg/dl)	LDL (mg/dl)	VLDL (mg/dl)	AI	LDL/HDL
Normal Control	48.65 ± 1.65	58.22± 0.88	27.48 ± 1.21	15.25± 0.78	32.85 ± 1.15	0.86 ± 0.50	0.55 ±
Cholesterol Control	118.45± 1.58**(a)	163.2 ± 1.72**(a)	12.85 ±0.66**(a)	30.95± 1.30**(a)	12.12 ± 0.72**(a)	8.50± 1.33**(a)	2.40 **(a)
Standard Control	73.55± 1.35**(b)	83.25 ± 1.84**(b)	22.4 ± 0.46**(b)	21.15± 0.78**(b)	25.80 ± 0.76**(b)	2.35± 2.33**(b)	0.94 **(b)
Treatment control	93.75 ± 1.20**(b)	115.26 ± 1.92**(b)	18.3 ± 0.52**(b)	24.30± 0.58**(b)	16.80 ± 0.45**(b)	4.40 ± 1.48**(b)	1.32**(b)
Treatment control	84.80 ± 0.92**(b)	95.8± 1.08**(b)	21.35 ± 1.30**(b)	23.26± 0.74**(b)	22.28 ± 0.50**(b)	3.12 ± 0.24**(b)	**(b)

RESULTS AND DISCUSSION

Table 6 showed that the level of Serum cholesterol, Triglycerides, HDL, LDL and VLDL was significantly increased. It was compared to Standard (Group III) and Treatment Control groups (Group IV, V). Rats were feed 100 to 200mg/KJC and atorvastatin 1mg/kg were treated in Standard control groups (Group III) with both doses of siddha formulation and here was significant decrease in cholesterol, The TGs, LDL-C, and VLDL and increases HDL-C when compared with cholesterol control rats. Table 1 showed the changes of Atherogenic Index and LDL-C / HDL-C ratio in control and treated rats. The test results revealed that the cholesterol induction significantly affects the cardio vascular risk markers.

Indeed, AI was statistically increased in cholesterol control group 90% compared with the values found in their normal control group. Besides there were significant further increase of LDL – C / HDL – C ratio appears due to the enhancement of LDL – C catabolism through hepatic receptors. Siddha formulation Karum jeeraga chooranam showed protective action against atherogenesis since an independent inverse relationship between blood HDL – C levels and cardio vascular risk incidence is reported.[5] The possible pharmacological mechanism of this activity may result from the enhancement of lecithin cholesteryl acyl transferase (LCAT) and

inhibition of Hepatic Triglyceride Lipase (HTL) on HDL which may lead to a rapid catabolism of blood lipids through enterohepatic tissues. Siddha formulation Karum jeeraga chooranam significantly suppress the elevated blood concentration of TGs. This result suggests that the product is able to restore the catabolism of TG. The restoration of catabolic mechanism of TGs would be due to an increased stimulation of the lipolytic activity of Plasma Lipoprotein Lipase (LPL).

Administration of siddha formulation Karum jeeraga chooranam provides a beneficial action on rat lipid metabolism with regard to the reduction of AI. Infect, the AI was decreased in all treated groups. Similar results were reported by others when studying the hypolipidemic effects of natural products.[10] The administration of siddha formulation of KARUNJCHIRAKAM CHOORANAM is significantly suppress the higher values of LDL – C / HDL – C ratio showing the beneficial effect of this formulation in preventing atherosclerosis incidence.

TOXICOLOGICAL ANALYSIS

Safety studies of Siddha Medicine *KARUNJCHIRAKAM CHOORANAM* in acute and Subacute toxicity wistar rat models

Materials and Methods

In acute oral toxicity study, *Karunjchirakam chooranam* were administeredorally initially at the dose of 50 mg/kg/body weight which was increasedup to 2000mg/kg/body weight and animals were observed for toxic symptomstill 14 days as per the OECD-423 guidelines.

For sub-acute toxicity study, the *KARUNJCHIRAKAM CHOORANAM*were administeredfor 20 days, with the doses of 50 mg, 100 mg, 200 mg and 400 mg/kg/ body weight for different groups. At the end of 20th day, the animals weresacrificed and toxicity parameters were assessed. Biochemical analysis onblood samples and histo-pathological evaluation of different organs were alsoperformed to assess any toxicity.

Result

In acute toxicity, there was no mortality or morbidity observedin animals through the 14-days period following single oral administration at all selected dose levels of the *Karu**njchirakam** chooranam* (Table-1). The animals did not show any changes in the general appearance during the trial..

	Dose (mg.kg-1)	**Sign of Toxicity (ST.NB-1)**	**Mortality (D.S-1)**
Group I	0	0/3	0/3
Group II	300	0/3	0/3
Group III	2000	0/3	0/3

Table.1**.** Acute toxicity study of *KARUNJCHIRAKAM CHOORANAM* on experimental mice. The acute toxicity of *KARUNJCHIRAKAM CHOORANAM* on experimental rats were tested using OECD-423 guidelines, where ST- sign oftoxicity; NB- normal behavior; D- died; S- survive. Values are expressedas number of animals (n=3).

SUB-ACUTE TOXICITY STUDIES

Effect of Karumjeeraga chooranamon body weight changes in rats

Table.2.The results of body weight changes in rats

Treatment	Day 1	Day 5	Day 10	Day 20
Control	187.16±6.13	187.45±6.20	196.14 ±6.35	196.74±6.24
Karumjeeraga chooranam **50 mg.kg^{-1}**	196.30 ±6.4	194.30±6.30	199.25 ±6.70	199.35±6.72*
Karumjeeraga chooranam **100 mg.kg^{-1}**	187.35 ±5.7	190.30±6.40	197.55±7.10	198.36±6.40*
Karumjeeraga chooranam **200 mg.kg^{-1}**	196.35±7.2	199.15±6.50	199.90±7.20**	207.41±7.22**
Karumjeeraga chooranam **400 mg.kg^{-1}**	189.67±6.05	193.15 ±5.60	196.68±6.35**	208.65±7.38**

- groupIanimals(GPI)weretreatedwithnormalsaline(5ml.kg^{-1})
- groupIIanimals(GPII)with50 mg.kg^{-1} of Karumjeeraga chooranam
- group III animals (GPIII) with 100 mg.kg^{-1} of Karumjeeraga chooranam
- group IV animals (GPIV) with 200 mg.kg^{-1} of Karunjchirakam chooranam
- group V animals (GPV) with 400 mg.kg^{-1} Karunjchirakam chooranam.

The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01*P<0.05.

Effect of Karunjchirakam chooranamon kidney, heart, liver and brain in rats

Table.3Results in Internal organs:

Treatment	Heart (gms)	Kidney (gms)	Liver (gms)	Brain (gms)
Control	0.39 ± 0.07	0.69± 0.06	3.35± 0.08	0.70± 0.08
Karunjchirakam chooranam@ 50 mg.kg^{-1}	0.40± 0.02	0.85± 0.03	3.47± 0.03	0.73± 0.33
Karunjchirakam chooranam@ 100mg.kg^{-1}	0.41± 0.06	0.83± 0.04	3.39±0.06	0.71± 0.22
Karunjchirakam chooranam@ 200mg.kg^{-1}	0.40± 0.08	0.78± 0.06	3.37± 0.07	0.78± 0.08
Karunjchirakam chooranam@ 400 mg.kg^{-1}	0.39± 0.07	0.79± 0.08	3.39± 0.05	0.80± 0.08

Table.3. A study on the effects of Karunjchirakam chooranamon kidney, heart, liver and brain of the rats was tested.

- group I animals (GPI) treated with normal saline (5 ml.kg^{-1})
- group II animals (GPII) with 50 mg.kg^{-1} of Karunjchirakam chooranam
- group III animals (GPIII) with 100 mg.kg^{-1} of Karunjchirakam chooranam
- group IV animals (GPIV) with 200 mg.kg^{-1} of Karunjchirakam chooranam
- group V animals (GPV) with 400 mg.kg^{-1} Karunjchirakam chooranam.

The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01.

Effect of Karunjchirakam chooranamon biochemical profiles of rats

Treatment	Glucose ($mg.dl^{-1}$)	Cholesterol ($mg.dl^{-1}$)	Triglyceride ($mg.dl^{-1}$)	HDL ($mg.dl^{-1}$)	LDL ($mg.dl^{-1}$)
Control	92.65± 0.62	37.62± 0.56	26.25± 0.45	133.25± 0.55	82.15±1.72
Karunjchirakam chooranam@ 50 $mg.kg^{-1}$	90.50± 0.56	23.85± 0.25*	11.22± 0.23*	173.28± 0.65*	69.59±1.28
Karunjchirakam chooranam@ 100 $mg.kg^{-1}$	89.50± 0.42	26.79± 0.28*	15.47± 0.30*	165.82±0.81*	69.89±1.12
Karunjchirakam chooranam@ 200 $mg.kg^{-1}$	90.30± 0.57**	33.23± 0.32	17.89± 0.40*	184.35± 0.83*	42.65±1.60
Karunjchirakam chooranam@ 400 $mg.kg^{-1}$	86.30± 0.47**	32.83± 0.31	17.28± 0.34*	182.7± 0.87*	46.55±0.86

Table.4. A study on the effect of Karunjchirakam chooranamon biochemical parameters such as glucose, cholesterol, triglyceride, HDL and LDL in rats was tested.

- groupI animals(GPI)treatedwithnormalsaline($5ml.kg^{-1}$)
- groupII animals(GPII) with 50 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group III animals (GPIII) with 100 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group IV animals (GPIV) with 200 $mg.kg^{-1}$ ofKarunjchirakam chooranam
- group V animals (GPV)with400$mg.kg^{-1}$of karunjchirakam chooranam.

The values are expressed as mean ±S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01*P<0.05

The effects of Karunjchirakam chooranamon biochemical parameters such as AST, ALT, ALP, TP and Albumin in rats.

The results are shown in Table.5

Treatment	AST ($IU.l^{-1}$)	ALT ($IU.l^{-1}$)	ALP ($IU.l^{-1}$)	TP ($g.l^{-1}$)	ALBUMIN ($g.l^{-1}$)
Control	328.10±12.45	71.10± 3.21	253.58± 8.82	69.90± 3.37	39.20±2.49
Karunjchirakam chooranam@50 $mg.kg^{-1}$	317.0±9.55**	69.5± 2.22**	266.15± 2.77**	70.35± 2.35	36.35±2.67
Karunjchirakam chooranam@ 100 $mg.kg^{-1}$	318.8±7.25**	67.6± 3.20**	260.19± 6.76**	80.20± 2.82	38.35±3.08
Karunjchirakam chooranam@ 200 $mg.kg^{-1}$	331.4±7.97	62.4± 2.96	265.00± 5.22	69.25± 3.34	40.25±2.78
Karunjchirakam chooranam@ 400 $mg.kg^{-1}$	323.2± 8.25	64.3± 3.57	269.40± 4.45	74.05± 2.63	39.48±2.75

Table.5. A study on the effects of **Karunjchirakam chooranam**on biochemical parameters such as AST, ALT, ALP, TP and Albumin rats was tested.

- group I animals (GPI) were treated with normal saline ($5ml.kg^{-1}$)
- group II animals (GPII) with 50 $mg.kg^{-1}$ of HAEBD
- group III animals (GPIII) with 100 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group IV animals (GPIV) with 200 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group V animals (GPV) with 400 $mg.kg^{-1}$ Karunjchirakam chooranam

The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV, and V. The statistical analysis was carried out using one way ANOVA method, where **P<0.01*P<0.05.

Effect of Karunjchirakam chooranamon haematological parameters inrats

Treatment	Haemoglobin ($mg.dl^{-1}$)	RBC ($10^6/mm^3$)	WBC ($10^6/mm^3$)	Calcium ($mg.dl^{-1}$)
Control	15.3± 0.30	11.15± 0.02	13.45± 0.05	11.40 ±0.08
Karunjchirakam chooranam@ 50 $mg.kg^{-1}$	16.55± 0.31*	11.45± 0.06*	11.5± 0.01*	11.21 ±0.03
Karunjchirakam chooranam@ 100 $mg.kg^{-1}$	16.35± 0.15*	11.55± 0.02*	10.3± 0.32*	11.27 ±0.20
Karunjchirakam chooranam@ 200 $mg.kg^{-1}$	14.27± 0.20*	10.32± 0.12*	13.4± 0.03*	11.56 ±0.13
Karunjchirakam chooranam@ 400 $mg.kg^{-1}$	15.5± 0.35*	10.46± 0.45*	12.5± 0.13*	11.70 ±0.02

Table.6.. A study on the effect of **Karunjchirakam chooranam** on haematological parameters such as Hb, RBC, WBC, Calcium in rats was tested.

- group I animals (GPI) treated with normal saline (5 $ml.kg^{1}$)
- group II animals (GPII) with 50 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group III animals (GPIII) with 100 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group IV animals (GPIV) with 200 $mg.kg^{-1}$ of Karunjchirakam chooranam
- group V animals (GPV) with 400 $mg.kg^{-1}$ Karunjchirakam chooranam.

The values are expressed as mean ± S.E.M. n=6. The results of group I were compared with other groups such as II, III, IV and V. The statistical analysis was carried out using one way ANOVA method, where *P<0.0

5.2CLINICAL STUDY

1. Ageincidence
2. Maritalstatus
3. Parity
4. Religiondistribution
5. Distribution of cases byparuvakaalam
6. Distribution of cases bythinai
7. Dietaryhabits
8. Distribution of cases based on incidence ofinfertility
9. Body built (based onBMI)
10. Occupationaldistribution
11. Positive family history for thedisease
12. Chronicity ofillness
    a) Irregularmenstruation
    b) Infertility
13. Treatment history other than siddhatreatment
    a) For treatinginfertility
    b) For irregularmenstruation
14. Thegi
15. Derangement inmukkutram
    a) Derangement in vathakutram
    b) Derangement in pithakutram
    c) Derangement in kapha kutram
16. Gnanenthriyaminvolvement
17. Kanmenthriyaminvolvement
18. Kosangal
19. Disturbance in udalthathukkal
20. Envagaithervu
    a) Naadi
    b) Neikkuri
21. Before treatmentAssessments:
    a) Intermenstrual period assessmentscore
    b) Duration of bleedingscore
22. Clinical symptoms before treatment

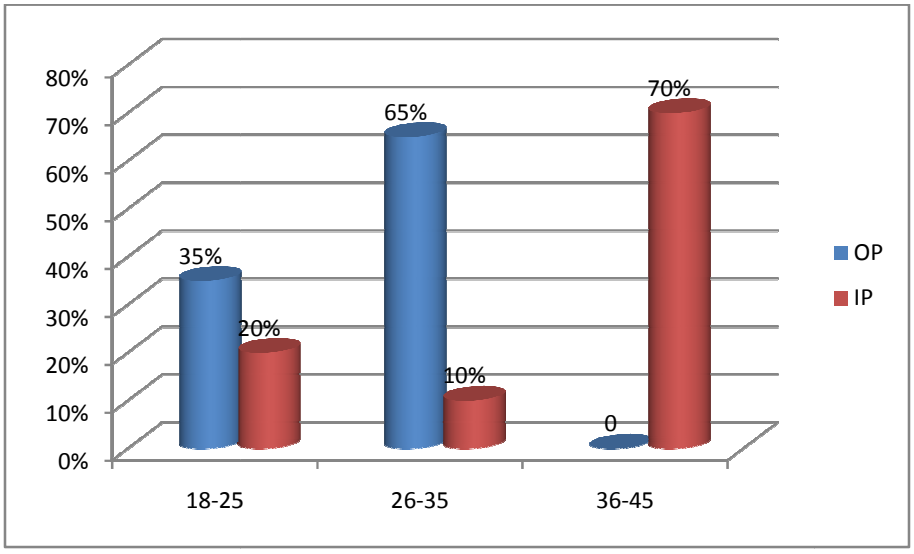
23. Outcome Measurement before and after treatment
    a) Intermenstrual period assessmentscore
    b) Duration of bleedingscore
24. Clinical symptoms before and after treatment
25. Changes in USG aftertreatment
26. Before and after *KARUNJCHIRAKAM CHOORANAM intervention*
27. BMI score before and aftertreatment
28. Waist Hip Ratio Before and AfterTreatment
29. Case Summary of OutPatient
30. Case Summary of InPatient
31. Laboratory Investigations of OutPatients
32. Laboratory Investigations of InPatients

1. AGE INCIDENCE

Table : 1 Illustrate the distribution of age incidence and its percentage

AGE (YEAR)	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO.OF CASES	PERCENTAGE
18-25	7	35%	4	20%
26-35	13	65%	2	10%
36-45	0	0	14	70%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 1(AGE INCIDENCE)



Among 20 OP cases, 7(35%) cases were in the age group of 18-25, 13(65%) cases were between 26-35.

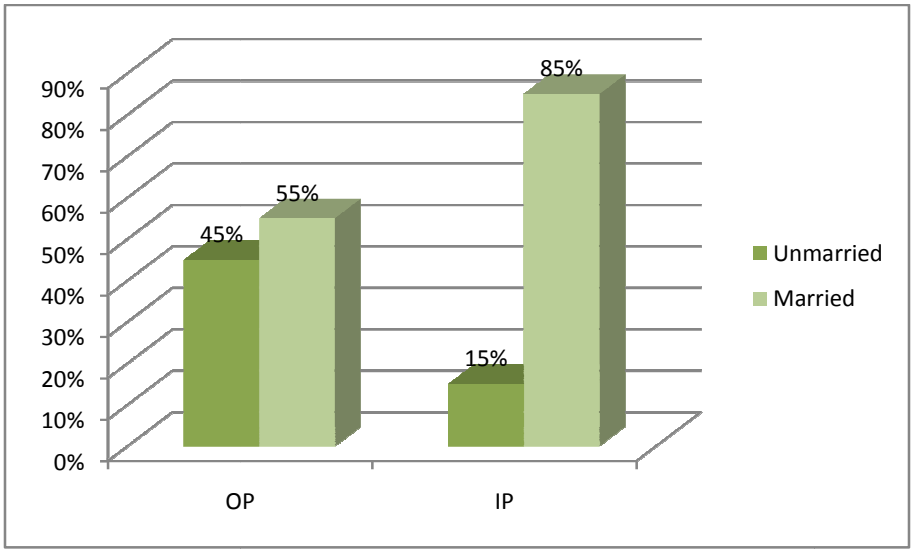
Among 20 IP cases, 4(20%) case was between the age group of 18-25, 2(10%) case were between 26-35, 14(70%) cases were between 36-45.

2. MARITALSTATUS

Table: 2 Illustrates the distribution of marital status

MARITAL STATUS	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Unmarried	9	45%	3	15%
Married	11	55%	17	85%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 2(MARITAL STATUS)



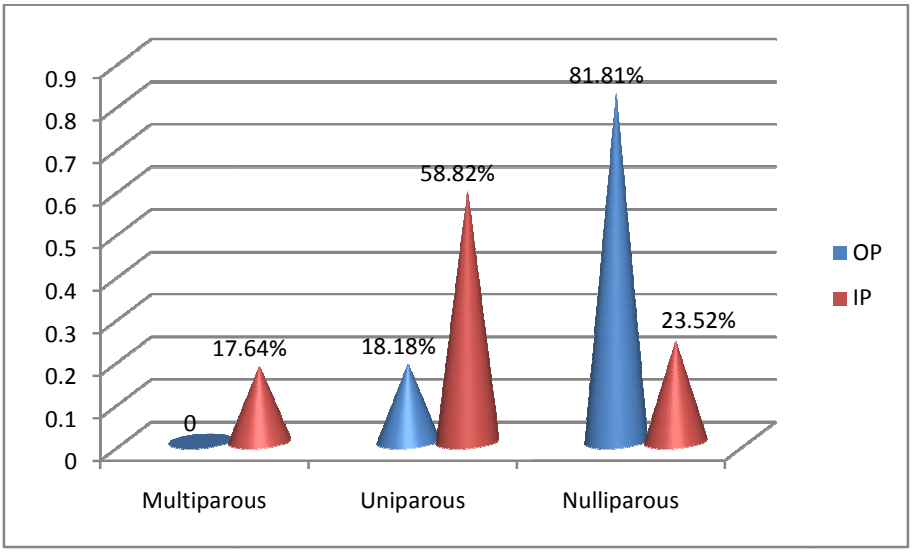
Among 20 OP cases, 9(45%) were unmarried, 11(55%) were married Among 20 IP cases, 3(15%) were unmarried, 17(85%) were married.

3. PARITY

Table: 3:Distribution of parity

PARITY	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Multiparous	-	-	3	17.64%
Uniparous	2	18.18%	10	58.82%
Nulliparous	9	81.81%	4	23.52%
Total	**11**	**100%**	**17**	**100%**

FIGURE – 3(PARITY)



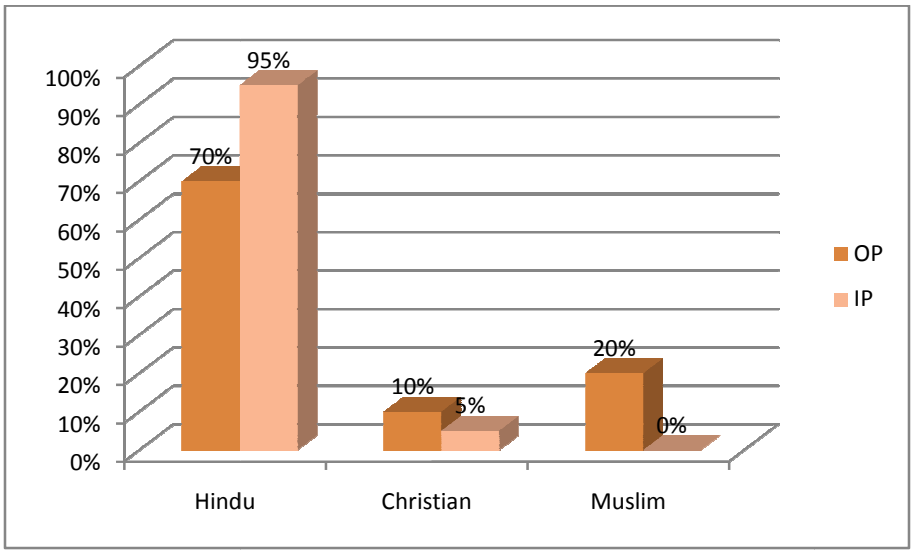
Among in 11 Marrried OP cases, 2(18.18%) were uniparous and 9(81.81%) were nulliparous. Among in17 IP cases, 3(117.64%) were multiparous, 10(58.82%) were uniparous and4(23.52%) were nulliparous.

4. RELIGION DISTRIBUTION

Table: 4: Distribution of religion

RELIGION	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Hindu	14	70%	19	95%
Christian	2	10%	1	5%
Muslim	4	20%	0	0%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 4(RELIGION DISTRIBUTION)



Among 20 OP cases, 14(70%) were Hindus, 2(10%) were Christians, 4(20%) was Muslim.

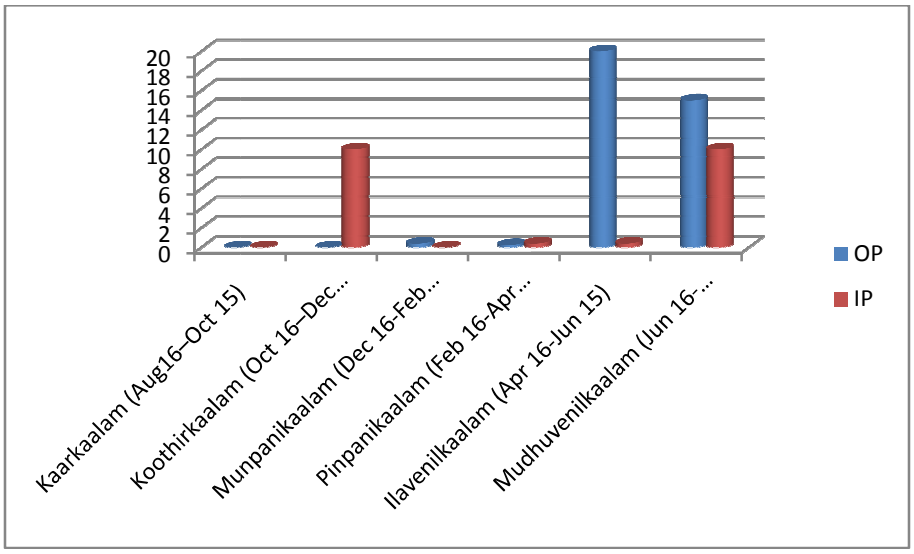
Among 20 IP cases, 19(95%) were Hindus, 1(5%) were Christians, 0(0%) wasMuslim.

5. PARUVA KAALAM (SEASON)

Table: 5: Distribution of paruva kaalam (season)

PARUVAKAALAM	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	%	NO. OF CASES	%
Kaarkaalam (Aug16–Oct 15)	-	0	-	0
Koothirkaalam (Oct 16–Dec 15)	-	0	2	10%
Munpanikaalam (Dec 16-Feb 15)	8	40%	-	0
Pinpanikaalam (Feb 16-Apr 15)	5	25%	8	40%
Ilavenilkaalam (Apr 16-Jun 15)	4	20%	8	40%
Mudhuvenilkaalam (Jun 16-Aug 15)	3	15%	2	10%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 5 (PARUVAKAAALAM)SEASON



Among 20 OP cases, 8(40%) cases the treatment period was munpanikaalam, 5(25%) cases it was pinpanikaalam.4(20) cases it was ilavenilkaalam , 3(15) cases it was Mudhuvenilkaalam.

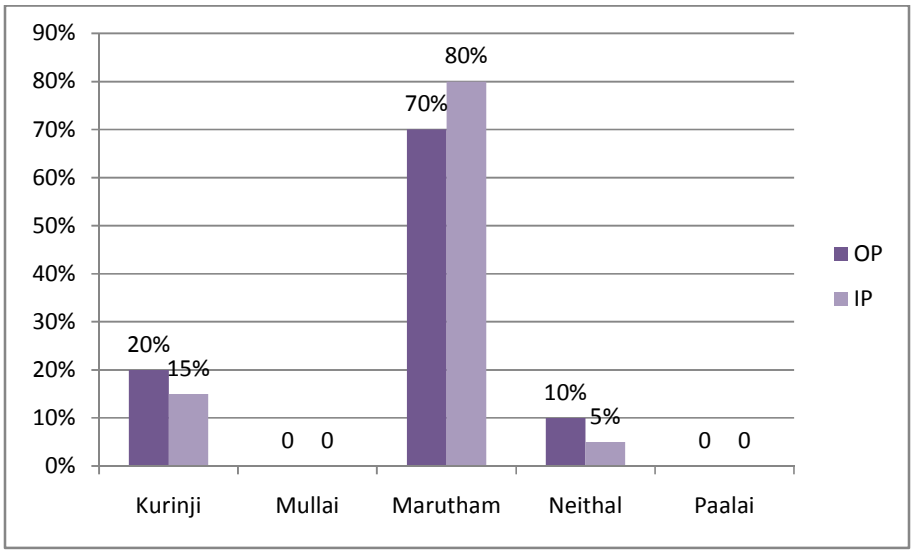
Among 20 IP cases, 2(10%) cases it was Koothirkaalam, 8(40%) cases it was pinpanikaalam, 8(40%) cases it wasilavenilkaalam.2(10) cases it was Mudhuvenilkaalam.

6.THINAI

Table: 6: Distribution of thinai

THINAI	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Kurinji	4	20%	3	15%
Mullai	-	-	-	-
Marutham	14	70%	16	80%
Neithal	2	10%	1	5%
Paalai	-	-	-	-
Total	**20**	**100%**	**20**	**100%**

FIGURE – 6(THINAI)



Among 20 OP cases, 4(20) cases were from the land Kurinji, 14(70%) cases were from the land Marutham, 2(10%) case was from the land Neithal.

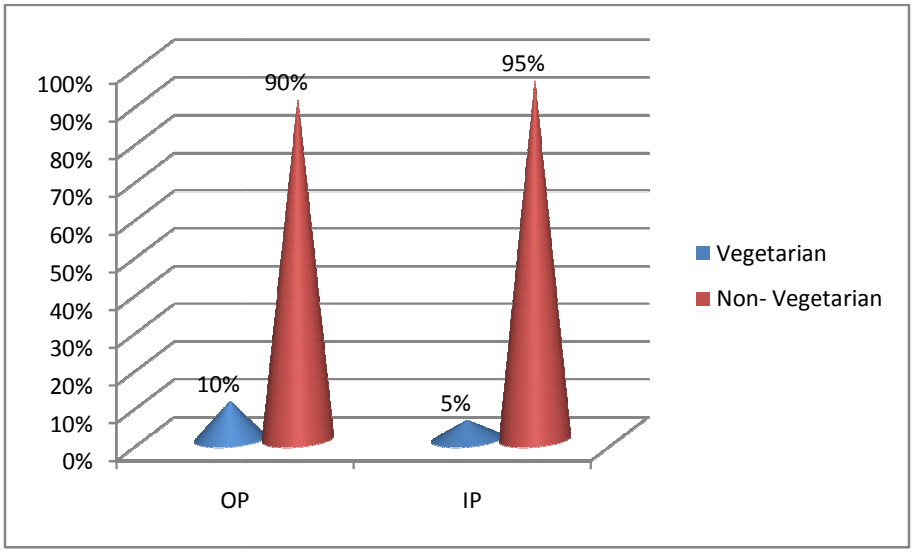
Among 20 IP cases, 3(15%) cases were from the land Kurinji, 16 (80%) were from the land Marutham and 1(5%) were from the land Neithal.

7.DIET

Table: 7: Distribution of Diet

DIET	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Vegetarian	2	10%	1	5%
Non-Vegetarian	18	90%	19	95%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 7(DIET)



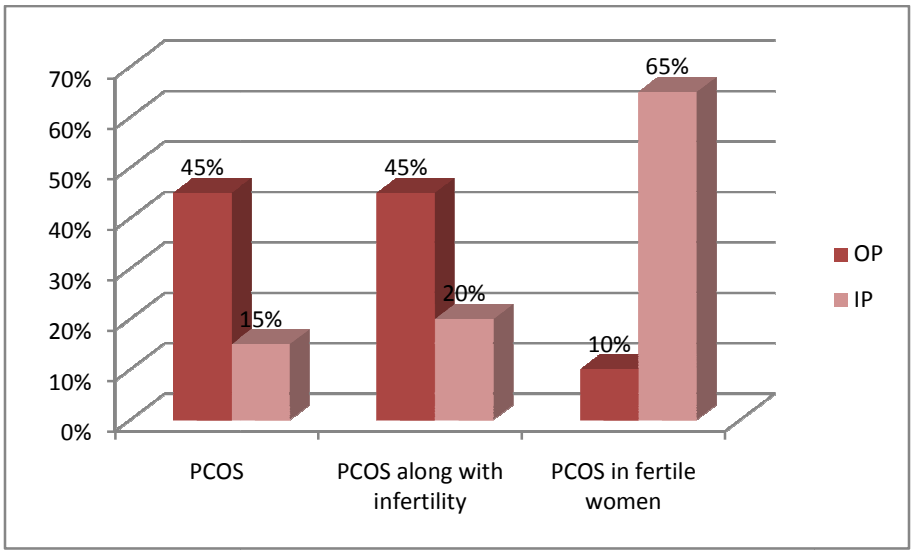
Among 20 OP cases, (10%) were Vegetarian, 18(90%) were Non-vegetarian. Among 20 IP cases, 1(5%) was Vegetarian, 19(95%) were Non-vegetarian.

8. CASE DISTRIBUTION

Table: 8: Distribution of case

CASE DISTRIBUTION	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
PCOS	9	45%	3	15%
PCOS along with infertility	9	45%	4	20%
PCOS in fertile women	2	10%	13	65%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 8 (CASE DISTRIBUTION)



Among 20 OP cases, 9(45%) cases was diagnosed as PCOS, 9(45%) have PCOS along with infertility, 2(10%) cases was fertile with PCOS.

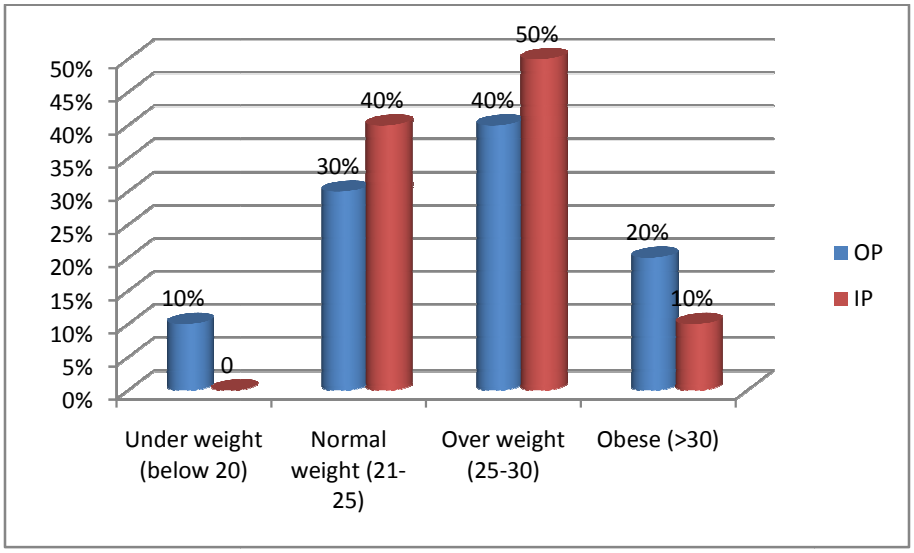
Among 20 IP cases, 3(15%) cases were diagnosed as PCOS, 4(20%) cases had PCOS along with infertility, 13(65%) cases were diagnosed as PCOS in fertile women.

9. BODY BUILT

Table: 9: Distribution of body built

BODY BUILT BASED ON BMI	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Under weight (below 20)	2	10%	-	-
Normal weight (21-25)	6	30%	8	40%
Over weight (25-30)	8	40%	10	50%
Obese (>30)	4	20%	2	10%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 9(BODY BUILT)



Among 20 OP cases, 2(10%) cases were underweight, 6(30%) cases were normal weight, 8(40%) cases were overweight, 4(20%) cases were obese.

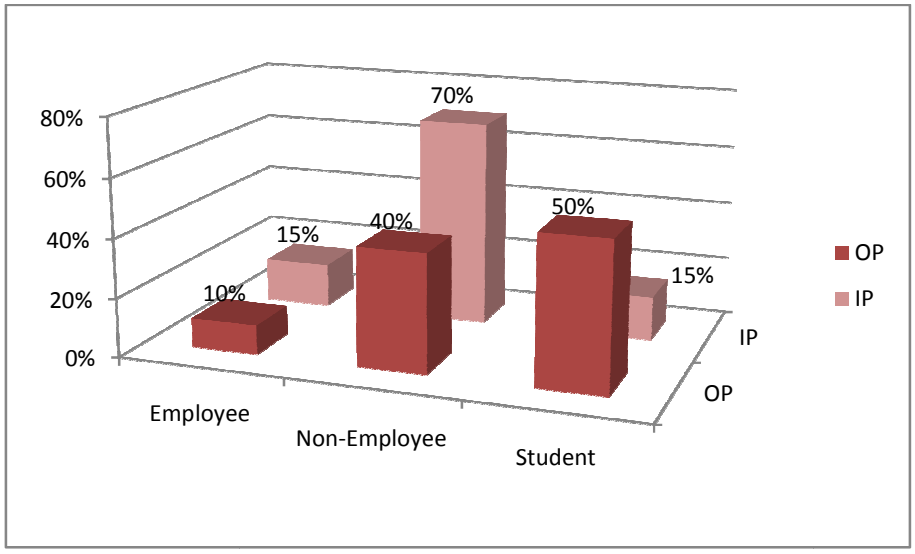
Among 20 IP cases, 8(40%) cases were normal weight, 10(50%) cases were overweight, 2(10%) cases were obese.

10.OCCUPATIONAL DISTRIBUTION

Table: 10; Distribution of occupation

OCCUPATION	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Employee	2	10%	3	15%
Non-Employee	8	40%	14	70%
Student	10	50%	3	15%
Total	**20**	**100%**	**20**	**100%**

FIGURE– 10 (OCCUPATIONAL DISTRIBUTION)



Above 20 OP cases, 2(10%) cases were employee, 8(40%) cases were non-employee, 10(50%) cases were students.

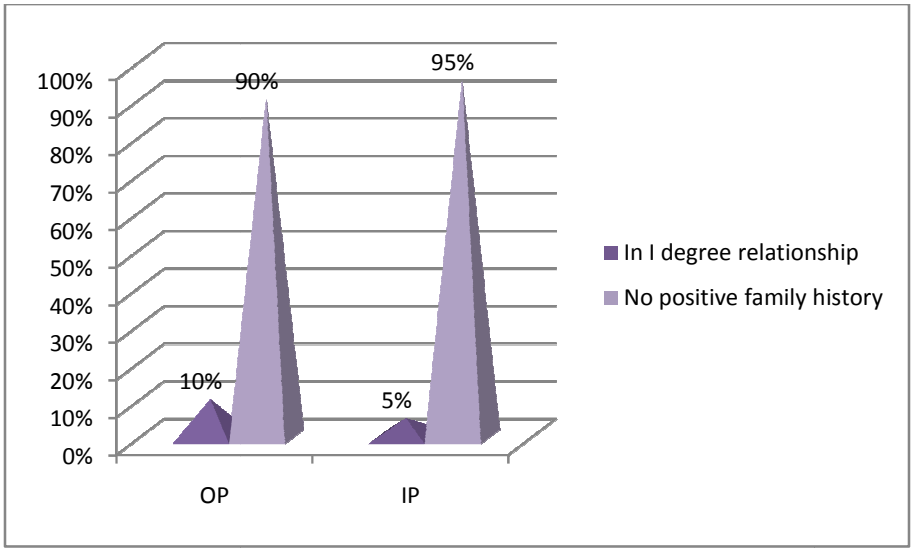
Above 20 IP cases, 3(15%) cases were employee, 14(70%) cases were non-employee, 3(15%) case was students.

11.POSITIVE FAMILY HISTORY FOR THEDISEASE

Table: 11: Distribution positive family history

FAMILY HISTORY FOR THE DISEASE	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
In I degree relationship	2	10%	1	5%
No positive family history	18	90%	19	95%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 11(POSITIVE FAMILY HISTORY)



Among 20 OP cases, 2(10%) cases have positive family history, 18(90%) cases have no relevant familyhistory.

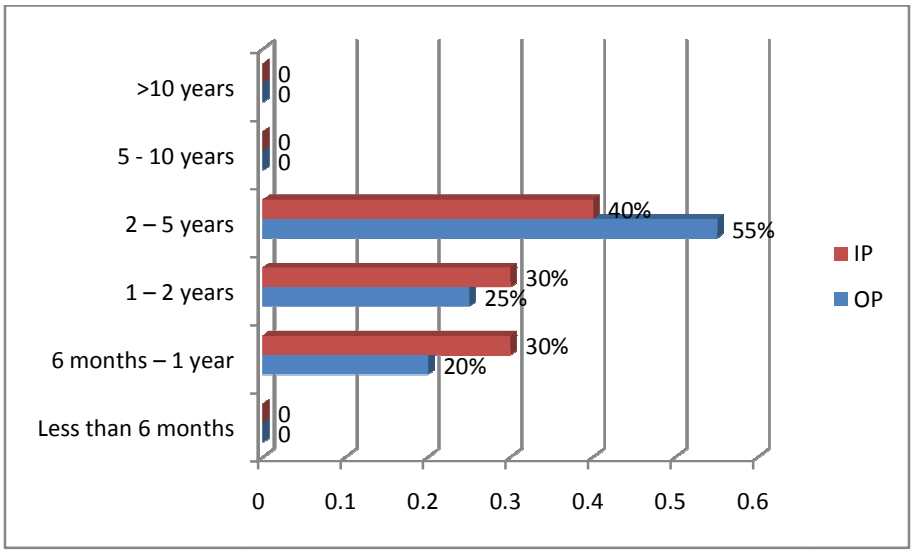
Among 20 IP cases, 19(95%) cases have no positive family history and 1(5%) case had positive family history.

12. CHRONICITY OF ILLNESS

Table:12 (a) Irregular Menstruation

CHRONICITY OF ILLNESS	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	%	NO. OF CASES	%
Less than 6 months	-	-	-	-
6 months – 1 year	4	20%	6	30%
1 – 2 years	5	25%	6	30%
2 – 5 years	11	55%	8	40%
5 - 10 years	-	-	-	-
>10 years	-	-	-	-
Total	**20**	**100%**	**20**	**100%**

FIGURE – 12(a)(IRREGULAR MENSTRUATION)



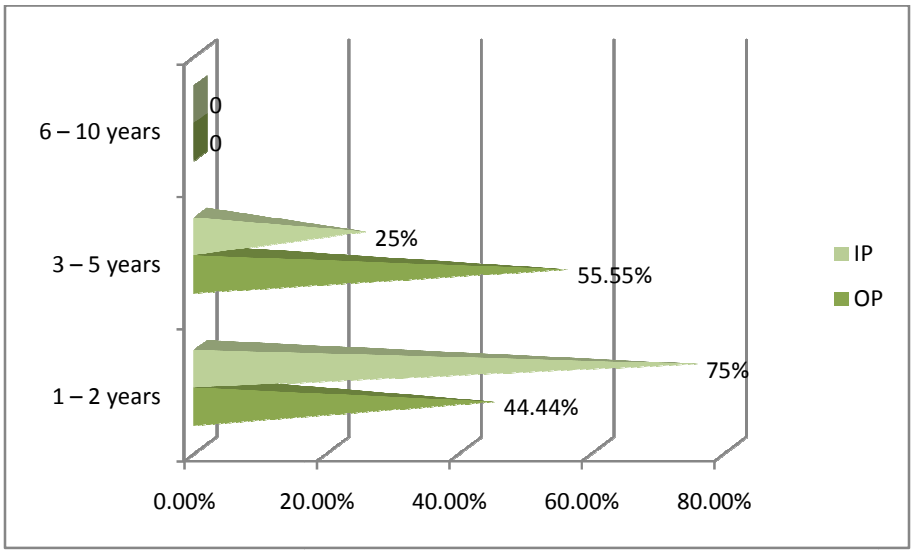
Among 20 OP cases, 4(20%) cases were between six months – 1 year, 5(25%) cases were between 1- 2 years, 11(55%) cases were between 2 – 5 years.

Among 20 IP cases, 6(30%) cases were between 6 months–1year, 6 (30%) cases were between 1–2 year, 8(40%) cases were between 2–5 years.

Table: 12 (b) Nulliparous

YEAR OF INFERTILITY	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
1 – 2 years	4	44.44%	3	75%
3 – 5 years	5	55.55%	1	25%
6 – 10 years	-	-	-	-
Total	**9**	**100%**	**4**	**100%**

FIGURE – 12(b) (NULLIPAROUS)



Among 9 OP cases, 4(44.44%) case was nulliparous for 1-2 years, 5(55.55%) cases were for 3-5 years..

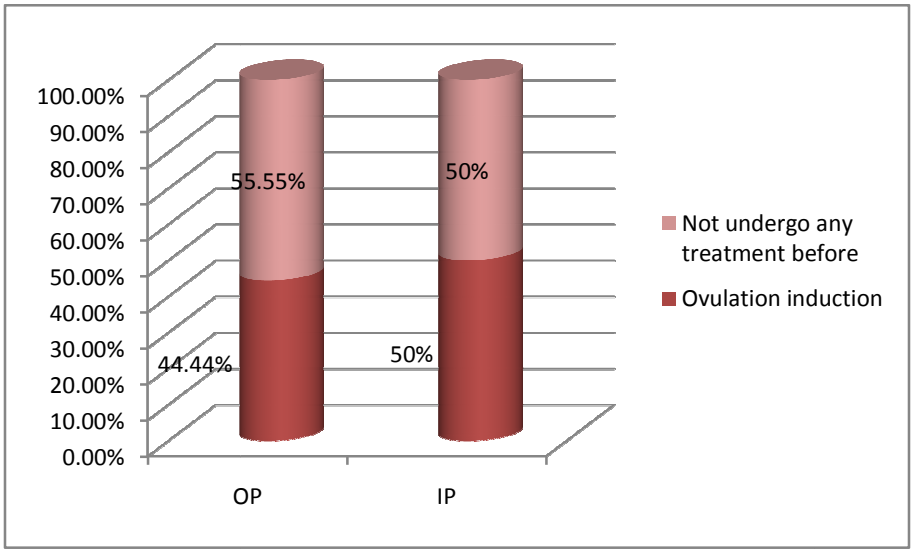
Among 4 IP cases, 3(75%) case was nulliparous for 1 – 2 years and 1(25%) cases were for 3-5 years.

13. TREATING FOR INFERTILITY

Table:13 (a) For treating infertility

VARIOUS TREATMENTAL HISTORY	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Ovulation induction	4	44.44%	2	50%
Not undergo any treatment before	5	55.55%	2	50%
Total	**9**	**100%**	**4**	**100%**

FIGURE – 13(a) FOR TREATING INFERTILITY



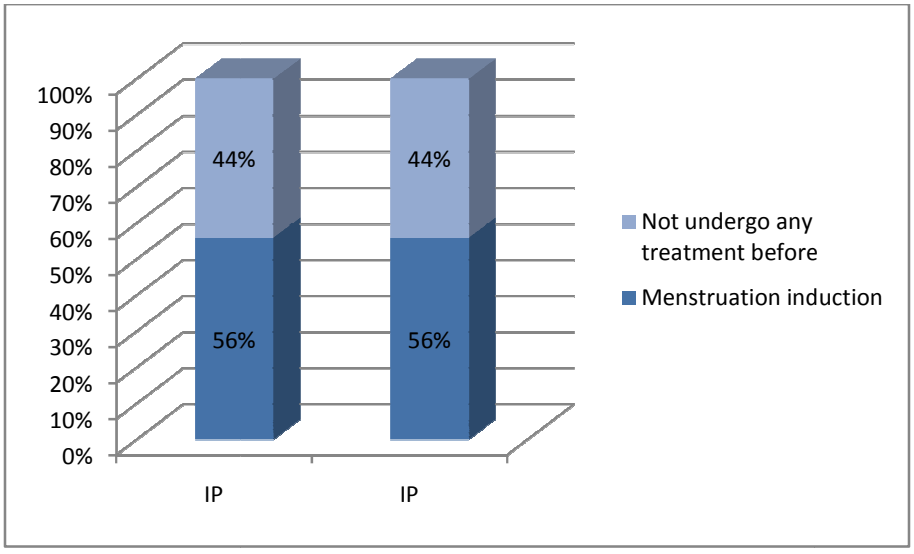
Among 9 OP cases, (44.44%) cases had undergone ovulation induction treatment, 5(55.55%) case had not undergone anytreatment.

Among 4 OP cases, 2(50%) cases had undergone ovulation induction treatment, 2(50%) case had not undergone anytreatment.

Table: 13 (b) FOR IRREGULAR MENSTRUATION

VARIOUS TREATMENTAL HISTORY	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Menstruation induction	5	56%	2	50%
Not undergo any treatment before	4	44%	2	50%
Total	**9**	**100%**	**4**	**100%**

FIGURE – 13(b)FOR IRREGULAR MENSTRUATION



Among 9 op cases, 5(56%) cases had undergone treatment for menstruation induction and 4(44%) cases had undergone any treatment before.

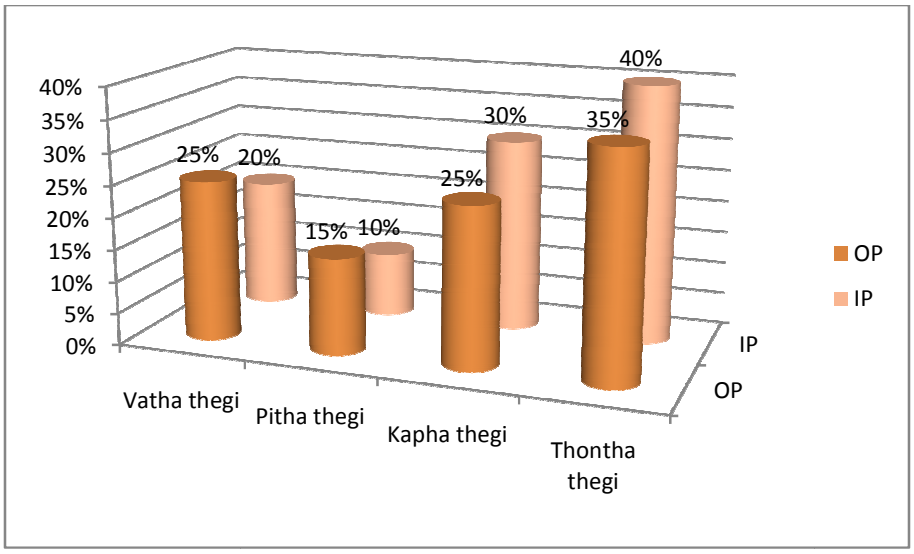
Among 4 IP cases,2 (50%) had undergone treatment for menstruation induction and 2(50%) had not underwent any treatment before.

14. THEGI

Table: 14: Distribution of thegi

	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	**PERCENTAGE**	**NO. OF CASES**	**PERCENTAGE**
Vatha thegi	5	25%	4	20%
Pitha thegi	3	15%	2	10%
Kapha thegi	5	25%	6	30%
Thontha thegi	7	35%	8	40%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 14(THEGI)



Among 20 OP cases, 5(25%) were vatha thegi, 3(15%) were pitha thegi, 5(25%) were kapha thegi and 7(35%) were thontha thegi.

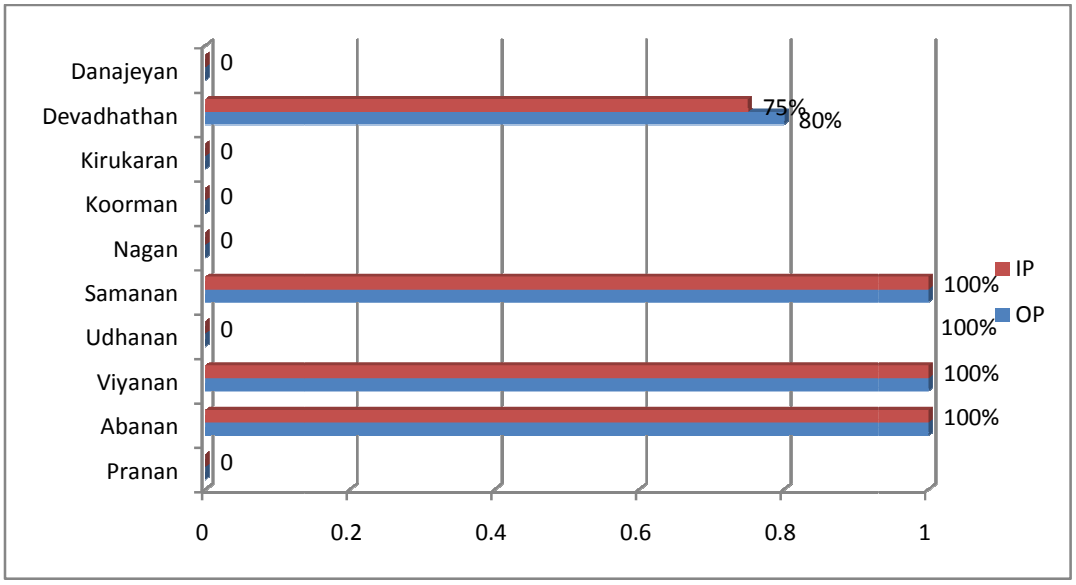
Among 20 IP cases, 4(20%) were vatha thegi, 2(10%) was pitha thegi, 6(30%) were kapha thegi and 8(40%) were thontha thegi.

15.DERANGEMENT IN VATHAM

Table: 15 (a) Distribution of vatham

CLASSIFICATION OF VALI	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Pranan	-	0	-	O
Abanan	20	100%	20	100%
Viyanan	20	100%	20	100%
Udhanan	-	0	-	0
Samanan	20	100%	20	100%
Nagan	-	0	-	0
Koorman	-	0	-	0
Kirukaran	-	0	-	0
Devadhathan	16	80%	15	75%
Danajeyan	-	0	-	0

FIGURE – 15 (a) (DEARRENGEMENT IN VATHAM)



In OP study Abanan was affected in 20 (100%) cases, Viyanan was affected in 20(100%) cases, Samanan was affected in 20(100%) cases, and Devadhathan was affected in 16 (80%) cases.

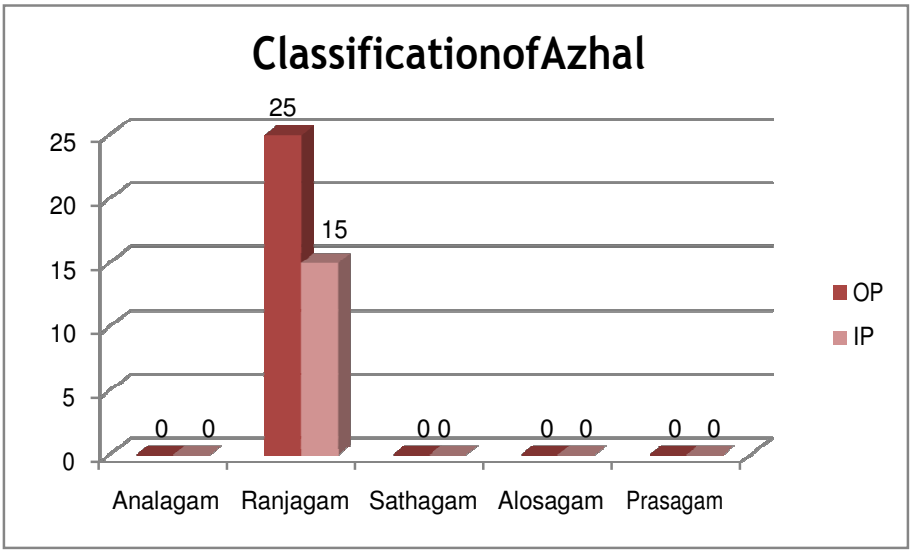
In IP study Abanan was affected in 20(100%) cases, Viyanan was affected in 20(100%) cases, Samanan was affected in 20(100%) cases and Devadhathan was affected in 15(75%) cases.

15. DERANGEMENT IN PITHA KUTRAM

Table: 15 (b): Distribution of pitha kutram

CLASSIFICATION OF AZHAL	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Analagam	-	-	-	-
Ranjagam	5	25%	3	15%
Sathagam	-	-	-	-
Alosagam	-	-	-	-
Prasagam	-	-	-	-

FIGURE – 15 (b) (DEARRANGEMENT IN PITHA KUTRAM)



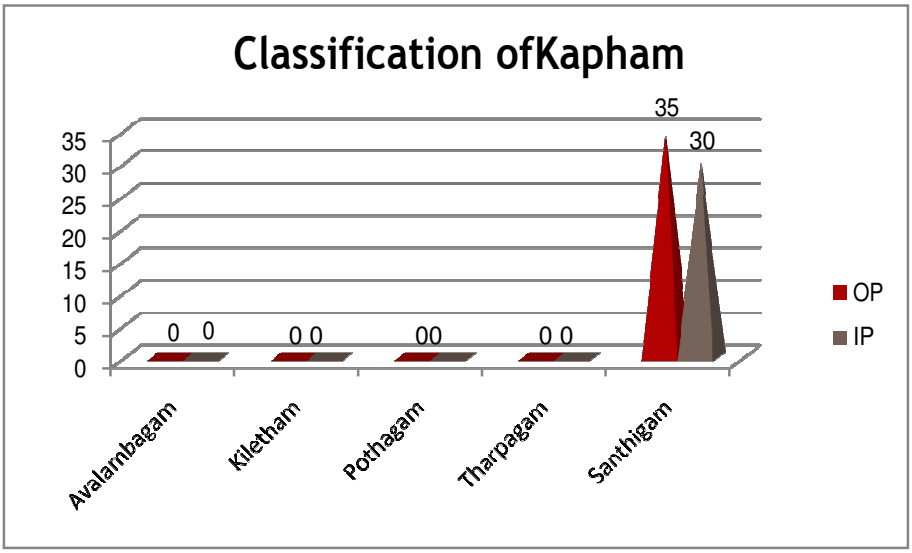
In OP study, ranjagam was affected in 5 (25%) cases. In IP study, ranjagam was affected in 3(15%) cases.

15.DERANGEMENTS IN KAPHA KUTRAM

Table: 15 (c): Distribution of kapha kutram

CLASSIFICATION OF KAPHAM	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Avalambagam	-	0	-	0
Kiletham	-	0	-	0
Pothagam	-	0	-	0
Tharpagam	-	0	-	0
Santhigam	7	35%	6	30%

FIGURE – 15(c)(DERANGEMENT IN KAPHA KUTRAM)



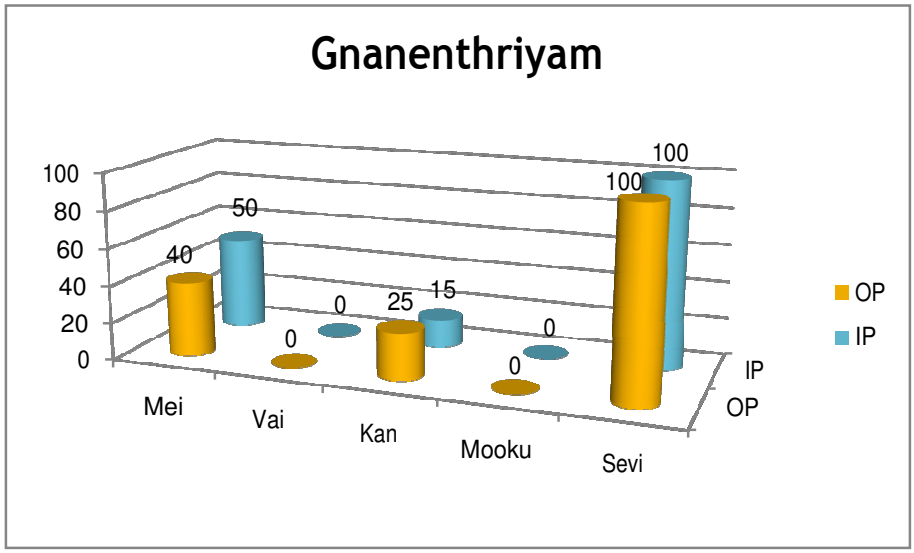
In OP study santhigam was affected in 7(35%) cases. In IP study santhigam was affected in 6(30%) cases.

16.DISTRIBUTION IN GNANENTHRIYAM

Table: 16: Distribution of gnanenthiriyam

GNANENDRIYAM	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Mei	8	40%	10	50%
Vai	-	-	-	-
Kan	5	25%	3	15%
Mooku	-	-	-	-
Sevi	-	-	-	-

FIGURE – 16 (DISTURBANCES IN GNANENTHRIYAM)



In OP study kan was affected in 5(25%) cases and mei was affected in 8(40%) cases.

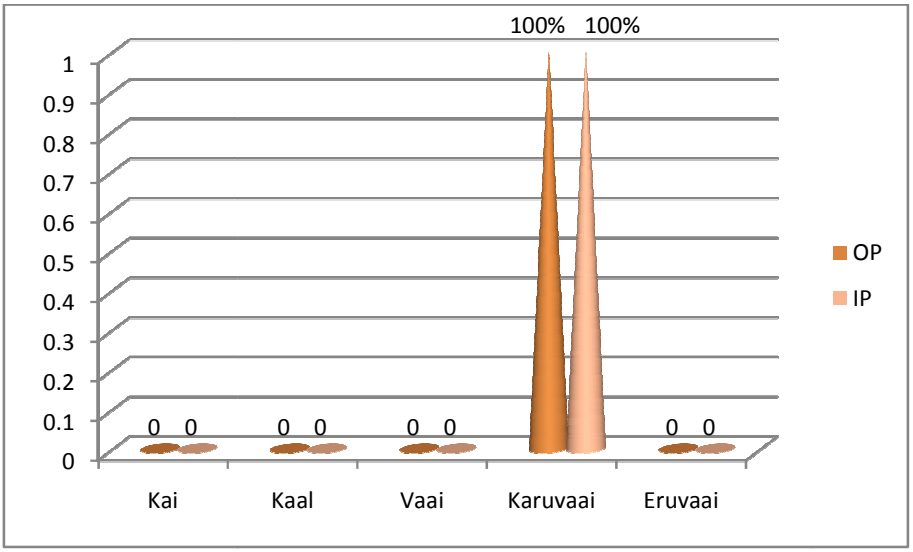
In IP study kan was affected in 5(15%) cases and mei was affected in 10(50%) cases

17. KANMENTHRIYAM INVOLVEMENT

Table: 17: Distribution of kanmenthriyam

KANMENTHRIYAM	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Kai	-	0	-	0
Kaal	-	0	-	0
Vaai	-	0	-	0
Karuvaai	20	100%	20	100%
Eruvaai	-	0		0

FIGURE- 17 KANMENTHRIYAM INVOLVEMENT



In OP study, Karuvaai was affected in 20(100%) cases.

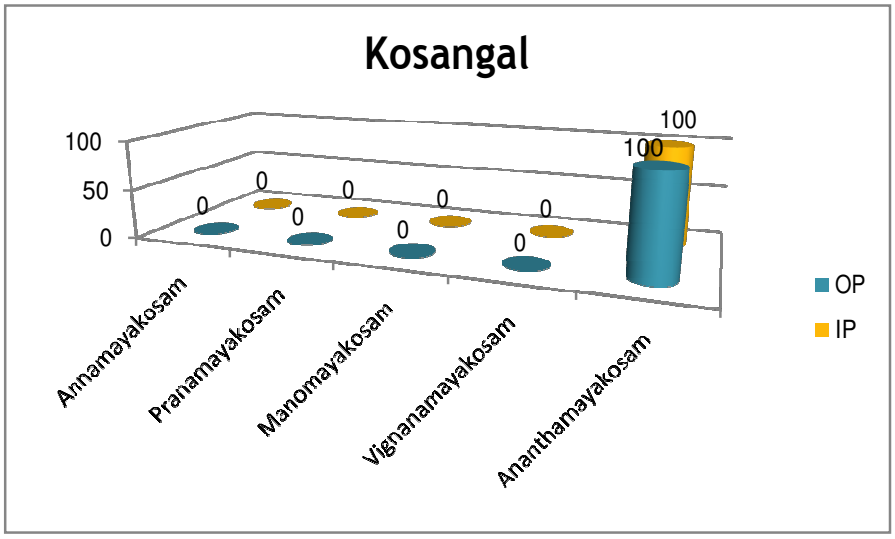
In IP study, Karuvaai was affected in 20(100%) cases

18. KOSANGAL

Table: 18. Distribution of kosangal

KOSANGAL	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Annamayakosam	-	-	-	-
Pranamayakosam	-	-	-	-
Manomayakosam	-	-	-	-
Vignanamayakosam	-	-	-	-
Ananthamayakosam	20	100%	20%	100%

FIGURE – 18 KOSANGAL



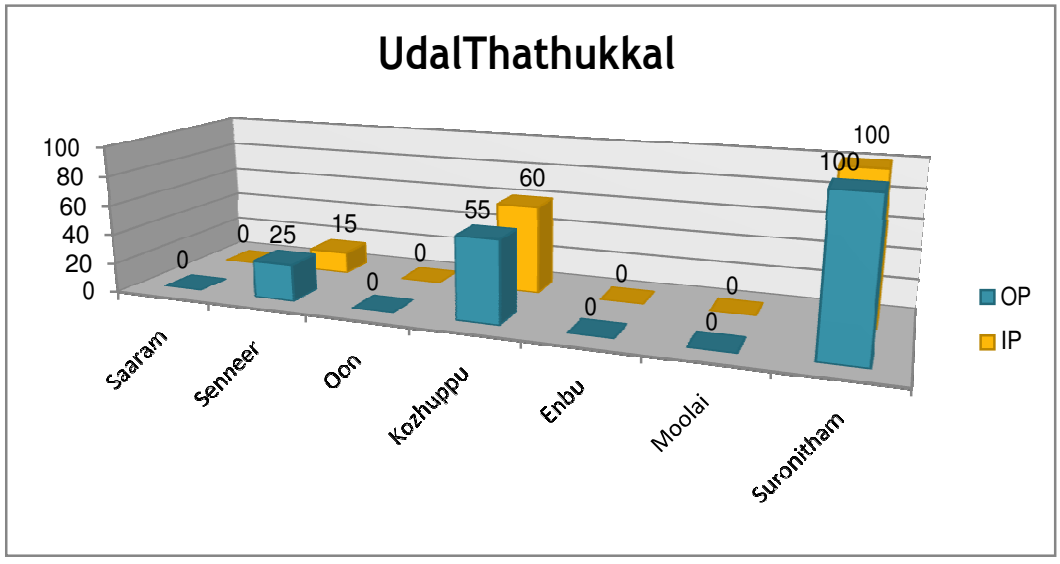
In OP study Ananthamaya kosam was affected in 20(100%) cases. In IP study Ananthamaya kosam was affected in 20(100%) cases.

19. DISTURBANCE IN UDALTHATHUKKAL

Table: 19. Distribution of Udal Thathukkal

UDAL THATHUKKAL	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Saaram	-	-	-	-
Senneer	5	25%	3	15%
Oon	-	-		-
Kozhuppu	11	55%	12	60%
Enbu	-	-	-	-
Moolai	-	-	-	-
Suronitham	20	100%	20	100%

FIGURE – 19 UDAL THATHUKKAL



In OP study, Senneer got affected in 5(25%) cases, Kozhuppu got affected in 11(55%) cases, and Suronitham got affected in 20 (100%) cases.

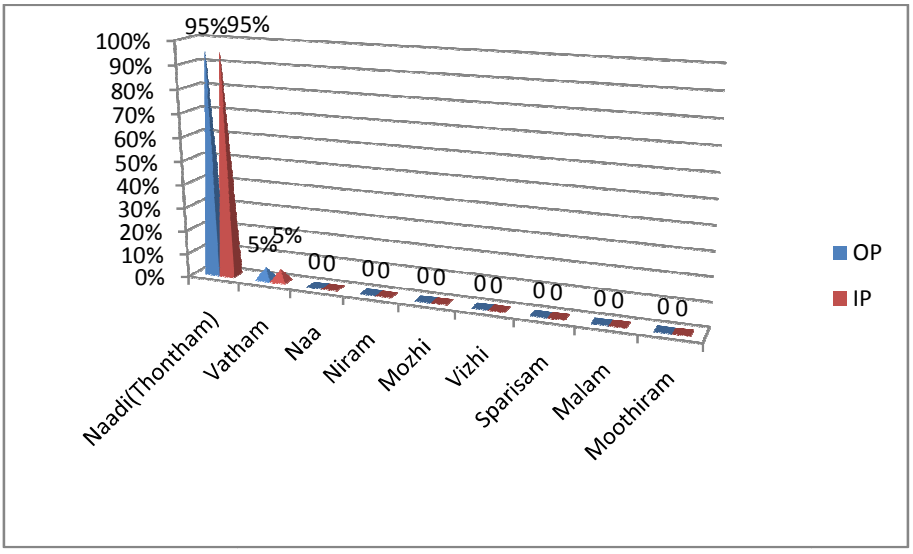
In IP study, Senneer got affected in 3(15%) cases, Kozhuppu got affected in 12(60%) cases and Suronitham got affected in 20(100%) cases.

20. ENVAGAI THERVUGAL (EIGHT DIAGNOSTIC METHODS)

Table:20: Distribution of envagai thervugal

ENVAGAI THERVU	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Naadi (Thontham)	19	95%	19	95%
Vatham	1	5%	1	5%
Naa	-	-	-	-
Niram	-	-	-	-
Mozhi	-	-	-	-
Vizhi	-	-	-	-
Sparisam	-	-	-	-
Malam	-	-	-	-
Moothiram	-	-	-	-

FIGURE – 20 ENVAGAI THERVUGAL



In OP study, Thondhanaadi was seen in 19(95%) cases, vathanaadi was seen in 1(5%) case

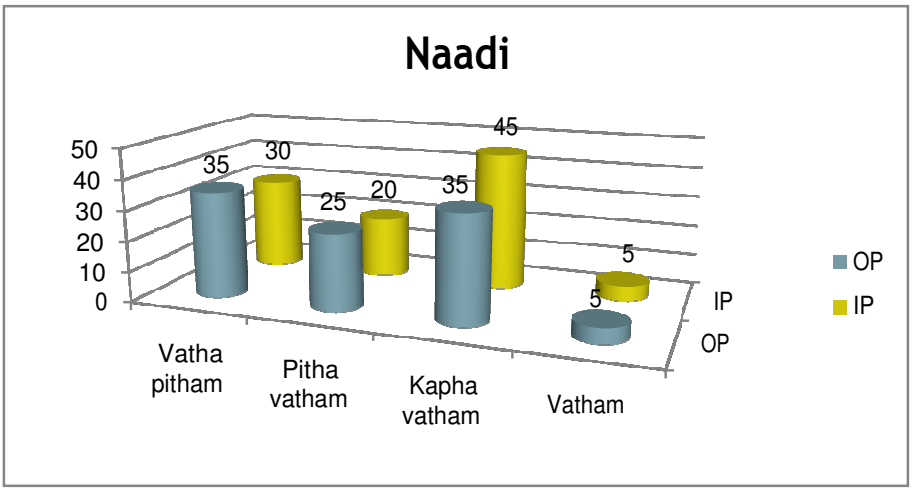
In IP study, Thonthanaadi was seen in 19(95%) cases, vathanaadi was seen in 1(5%) case

20. (a) NAADI

Table: 20 (a): Distribution of Naadi

NAADI	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Vatha pitham	7	35%	6	30%
Pitha vatham	5	25%	4	20%
Kapha vatham	7	35%	9	45%
vatham	1	5%	1	5%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 20(a) NAADI



In OP study, 7(35%) cases revealed Vathapitha naadi, 5(25%) cases revealed Pithavatha naadi, 7(35%) cases revealed Kaphavatha naadi and 1(5%) case revealed Vathanaadi.

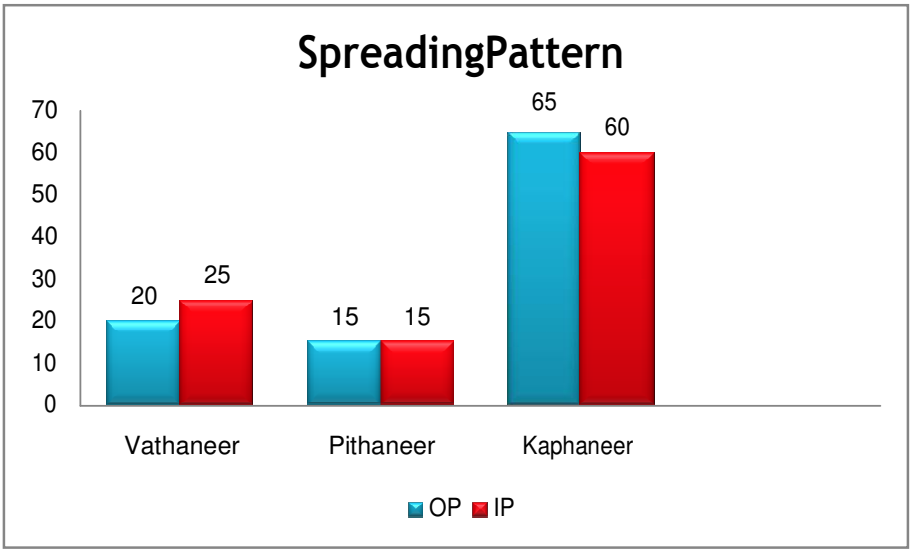
In IP study, 6(30%) cases revealed Vathapitha naadi, 4(20%) cases revealed Pithavatha naadi, 9(45%) cases revealed Kaphavatha naadi and 1(5%) case revealed Vathanaadi.

20.(b)NEIKKURI

Table: 20 (b): Distribution of Neikkuri

SPREADING PATTERN	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Vatha neer	4	20%	5	25%
Pitha neer	3	15%	3	15%
Kapha neer	13	65%	12	60%
Total	**20**	**100%**	**20**	**100%**

FIGURE – 20(b) NEIKKURI



In OP study, 4(20%) cases showed vathaneer pattern, 3(15%) cases showed pithaneer pattern and 13(65%) cases showed kaphaneer pattern.

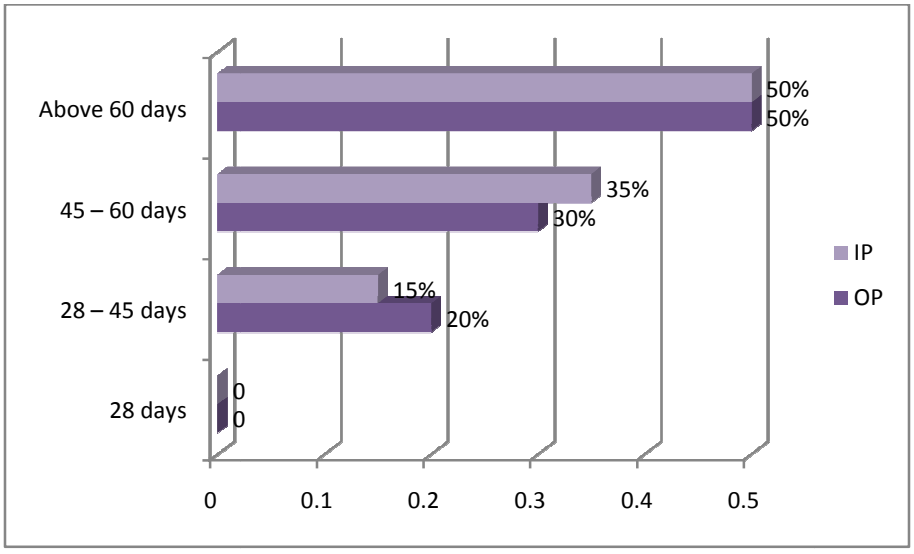
In IP study, 5(25%) cases showed vathaneer pattern, 3(15%) cases showed pithaneer pattern and 12 (60%) cases showed kaphaneer pattern.

20. (a) INTERMENSTRUAL PERIOD ASSESSMENT SCORE

Table.21. (a) Intermenstrual Period Assessment Score

GRADE			BEFORE			
LENGTH OF THE CYCLE			OP PATIENTS		IP PATIENTS	
0	28 days	Nil	0	0	0	0
1	28 – 45 days	Mild	4	20%	3	15%
2	45 – 60 days	Moderate	6	30%	7	35%
3	Above 60 days	Severe	10	50%	10	50%
Total			**20**	**100%**	**20**	**100%**

FIGURE – 21 (INTERMENSTRUAL PERIOD ASSESSMENT SCORE)



Among 20 OP cases, the length of cycle is 28 days cycle in 0(0%) cases, 28-45 days cycle in 4(40%) cases, 45-60 days cycle in 6(30%) cases, above 60 days cycle in 10(50%) cases.

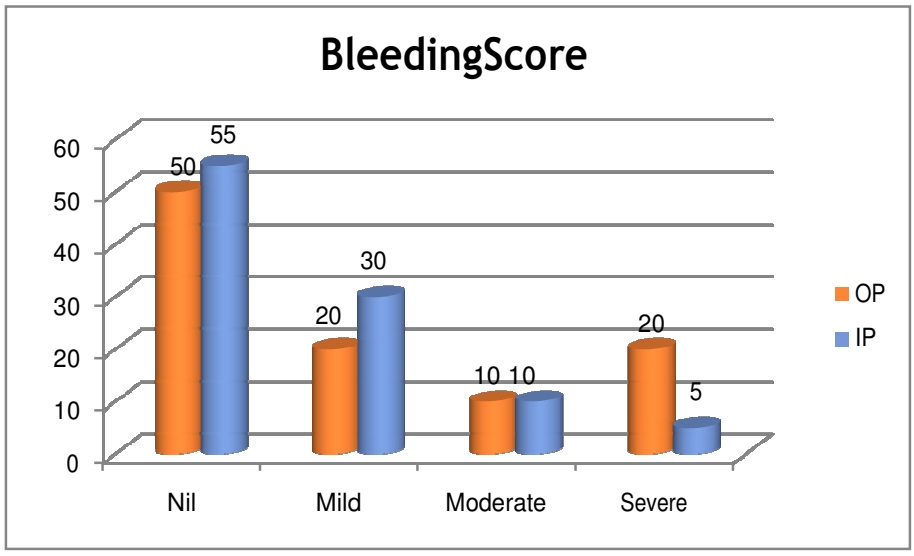
Among 20 IP cases, 28 days cycle in 0(0%)case, 28-45 days cycle in 3(15%) cases, 45-60 days cycle in 7(35%) cases, above 60 days cycle in 10(50%) cases.

21.(b) DURATION OF BLEEDING SCORE

Table: 21 (b): Distribution of bleeding score

GRADE			BEFORE			
LENGTH OF THE CYCLE			OP PATIENTS		IP PATIENTS	
0	3 – 5 days	Nil	10	50%	11	55%
1	1 – 2/6-7 days	Mild	4	20%	6	30%
2	1/8-9days	Moderate	2	10%	2	10%
3	Spotting />9 days	Severe	4	20%	1	5%
Total			**20**	**100%**	**20**	**100%**

FIGURE – 21(b) (DURATION OF BLEEDING SCORE)



Among 20 OP cases, the duration of bleeding is 3-5 days in 10 (50%) cases,1-2/6-7 days in 4(20%) cases,1 / 8-9 days in 2 (10%) cases, spotting / >9 days in 4(20%) cases.

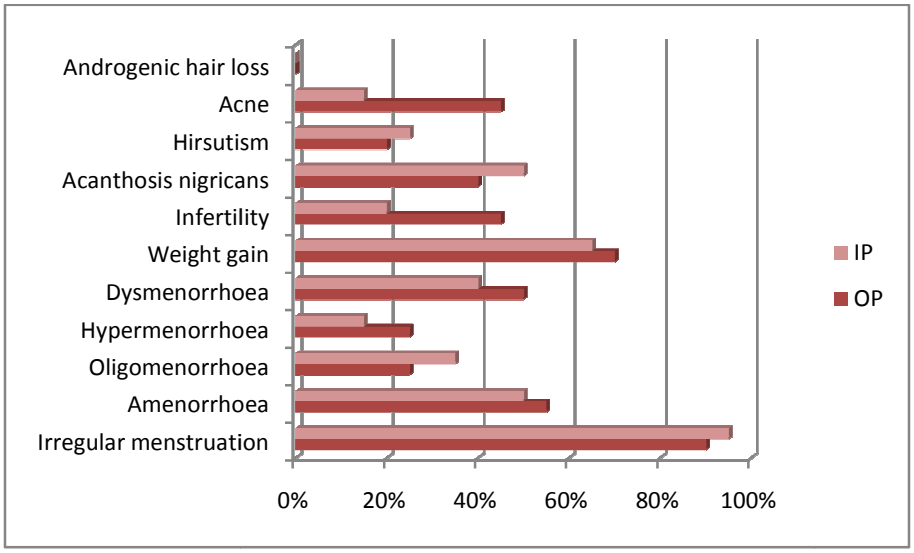
Among 20 IP cases, 3-5 days in 11(55%) cases, 1-2 / 6-7 days in 6 (30%) cases,1 / 8-9 days in 2(10%) cases, spotting / >9 days in 1(5%) case.

22.CLINICAL SYMPTOMS BEFORE TREATMENT

Table: 22: Distribution of clinical symptoms before treatment

CLINICAL FEATURES	OP PATIENTS		IP PATIENTS	
	NO. OF CASES	PERCENTAGE	NO. OF CASES	PERCENTAGE
Irregular menstruation	18	90%	19	95%
Amenorrhoea	11	55%	10	50%
Oligomenorrhoea	5	25%	7	35%
Hypermenorrhoea	5	25%	3	15%
Dysmenorrhoea	10	50%	8	40%
Weight gain	14	70%	13	65%
Infertility	9	45%	4	20%
Acanthosis nigricans	8	40%	10	50%
Hirsutism	4	20%	5	25%
Acne	9	45%	3	15%
Androgenic hair loss	-	-	-	-

FIGURE – 22 CLINICAL SYMPTOMS BEFORE TREATMENT



Among 20 OP cases, irregular menstruation was seen in 18 (90%) cases, amenorrhoea in 11(55%) cases, oligomenorrhoea in 5(25%) cases, hypermenorrhoea in 5(25%) cases, dysmenorrhea in 10(50%) cases, weight gain in 14(70%) cases, infertility in 9(45%) cases, acanthosis nigricans in 8(40%) cases, hirsutism in 4 (20%) cases, acne in 9 (45%)cases.

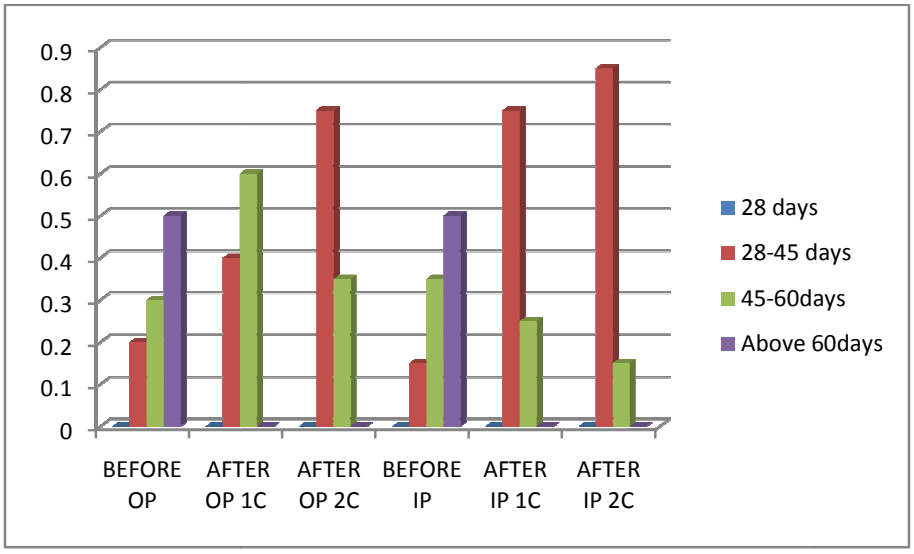
Among 20 IP cases, irregular menstruation was seen in 19 (95%) cases, amennorhoea in 10(50%) cases, oligomenorrhoea in 7(35%) cases, hypermenorrhoea in 3(15%) cases, dysmenorrhea in 8(40%) cases, weight gain in 13(65%) cases, infertility in 4(20%) cases, acanthosis nigricans in 10(50%) cases, hirsutism in 5 (25) acne in 3(15%) cases.

23.(a) INTERMENSTRUAL PERIOD ASSESSMENT SCORE

Table: 23. Distribution of Intermenstrual period assessment score

GRADE			OP PATIENTS						IP PATIENTS					
LENGTH OF THE CYCLE			BEFORE		AFTER				BEFORE		AFTER			
			cases	%	1C	%	2C	%	cases	%	1C	%	2C	%
0	28 days	Nil	0	0	0	0	0	0	0	0	0	0	0	0
1	28-45 days	Mild	4	20%	8	40%	13	75%	3	15%	15	75%	17	85%
2	45-60 days	Moderate	6	30%	12	60%	7	35%	7	35%	5	25%	3	15%
3	Above 60 days	Severe	10	50%	0	0	0	0	10	50%	0	0	0	0
Total			**20**	**100%**	**20**	**100%**	**20**	**100%**	**20**	**100%**	**20**	**100%**	**20**	**100%**

FIGURE – 23(a) INTERMENSTRUAL PERIOD ASSESSMENT SCORE



1 C - First Menstrual Cycle; 2 C - Second Menstrual Cycle

Among 20 OP cases, , 4(200%) cases were mild, 6(35%) cases were moderate and 10(50%) cases were severe, In **first cycle** 0(0%) cases - normal, 8(40%) cases - mild, 12(60%) case - moderate, 0(0%) cases - severe. In **second cycle** 0(0%) case - normal, 13(65%) cases - mild, 7(35%) cases – moderate, 0(0%) cases were severe.

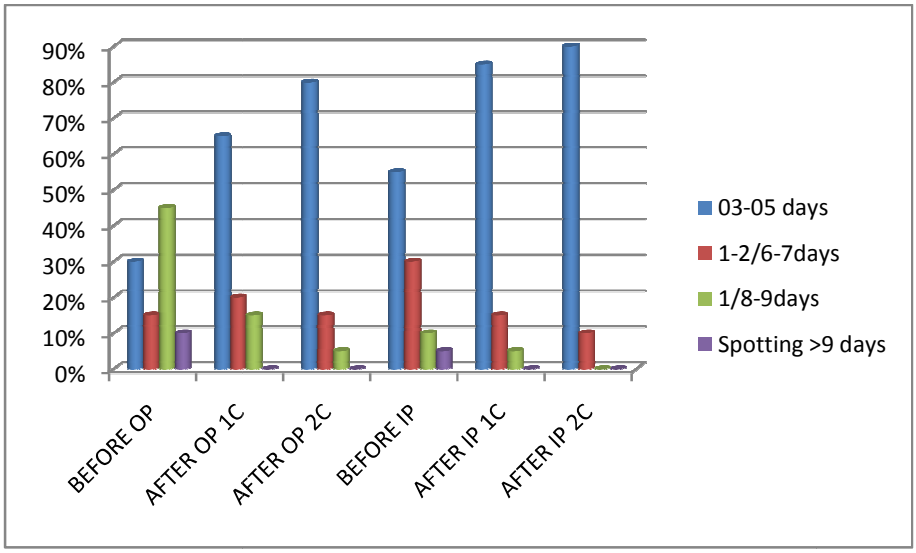
Among 20 IP cases, 0(0%) was normal, 3(15%) were mild, 7(35%) were moderate and 10(50%) cases were severe. In **first cycle** 0(0%) cases - normal, 15(75%) cases - mild, 5(25%) cases - moderate, 0(0%) cases - severe. In **second cycle** 0(0%) cases - normal, 17(85%) cases - mild, 3(15%) case – moderate, 0(0%) cases - severe.

23. (b) DURATION OF BLEEDING

Table: 23 (b) Duration of bleeding

GRADE			OP PATIENTS						IP PATIENTS					
LENGTH OF THE CYCLE			BEFORE		AFTER				BEFORE		AFTER			
			cases	%	1C	%	2C	%	cases	%	1C	%	2C	%
0	3-5 days	Nil	6	30%	13	65%	16	80%	11	55%	16	80%	18	90%
1	1-2/6-7days	Mild	3	15%	4	20%	3	15%	6	30%	3	15%	2	10%
2	1/8-9 days	Moderate	9	45%	3	15%	1	5%	2	10%	1	5%	0	0
3	Spotting >9 days	Severe	2	10%	0	0	0	0	1	5%	0	0	0	0
Total			20	100%	20	100%	20	100%	20	100%	20	100%	20	10%

FIGURE – 23(b) DURATION OF BLEEDING



1 C - First Menstrual Cycle; 2 C - Second Menstrual Cycle

Among 20 OP cases, 6(30%) cases the DOB was normal, 3(15%) cases - mild, 9(45%) cases - moderate and 2(10%) cases - severe. In **first cycle** 13(65%) cases - normal, 4(20%) case - mild, 3(15%) case - moderate, In **second cycle** 16(80%) cases - normal, 3(15%) cases – mild, 1(5%)cases-moderate.

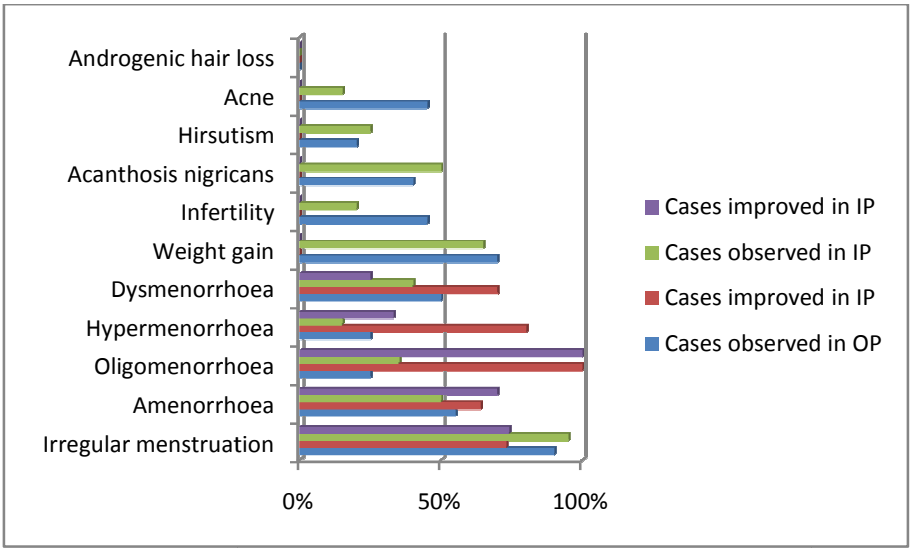
Among 20 IP cases, 11(55%) cases the DOB was normal, 6(30%) cases - mild, 2(10%) cases - moderate, 1(5%) case - severe. In **first cycle** 16(80%) cases - normal, 3(15%) case- mild, 1(5%) case - moderate. In **second cycle** 18(90%) cases - normal, 2(10%) case – mild, 0(0%) case-moderate.

24.CLINICAL SYMPTOMS BEFORE AND AFTERTREATMENT

Table:24: Distribution of clinical symptoms before and after treatment

CLINICAL FEATURES	OP PATIENTS				IP PATIENTS			
	Cases observed	%	Cases improved	%	Cases observed	%	Cases improved	%
Irregular menstruation	18	90%	13	73%	19	95%	14	74%
Amenorrhoea	11	55%	7	64%	10	50%	7	70%
Oligomenorrhoea	5	25%	5	100%	7	35%	7	100%
Hypermenorrhoea	5	25%	4	80%	3	15%	0	33%
Dysmenorrhoea	10	50%	7	70%	8	40%	0	25%
Weight gain	14	70%	-	-	13	65%	-	-
Infertility	9	30%	-	-	4	20%	-	-
Acanthosis nigricans	8	40%	-	-	10	50%	-	-
Hirsutism	4	60%	-	-	5	40%	-	-
Acne	9	20%	-	-	3	10%	-	-
Androgenic hair loss	-	-	-	-	-	-	-	-

FIGURE – 24 CLINICAL SYMPTOMS BEFORE AND AFTER TREATMENT



Out of 20 OP cases, In 18(85%) cases the menstrual cycle was irregular before treatment and improved in 13(74%) cases after treatment, Amenorrhoea 11(55%) were seen in before treatment and improved in 7(64%) cases after treatment, Oligomenorrhoea were seen in 5(25%) cases before treatment and improved in 5(100%) cases after treatment. Hypermenorrhoea were seen in 5(25%) cases before treatment and improved in 4(80%) cases after treatment. Dysmenorrhoea were seen in 10(50%) cases before treatment and improved in 7(70%) cases aftertreatment.

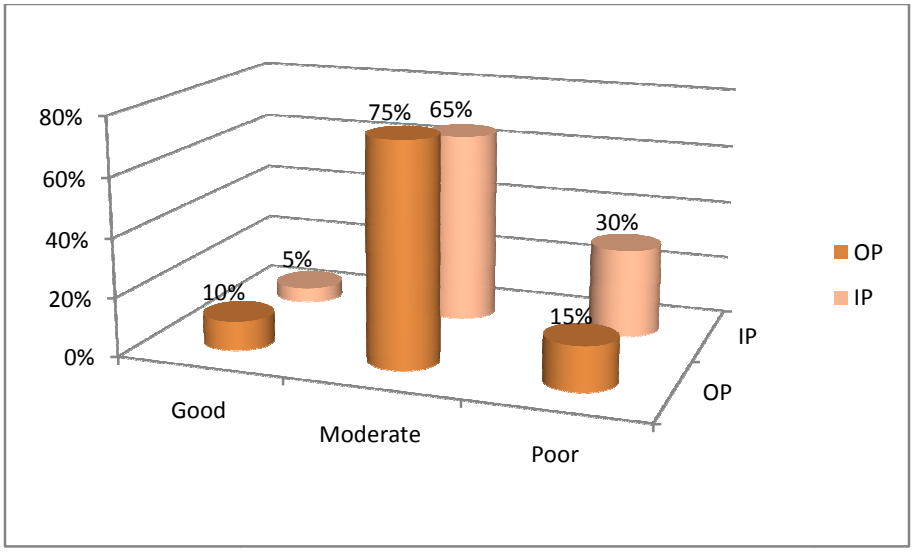
Out of 20 IP cases, irregular menstruation was seen in 19(95%) cases before treatment and improved in 14 (74%) cases after treatment. Amenorrhoea 10(50%) were seen in before treatment and improved in 7(70%) cases after treatment, Oligomenorrhoea were seen in 7(35%) cases before treatment and improved in 7(100%) cases after treatment. Hypermenorrhoea were seen in 3(15%) cases before treatment and improved in 1(33%) cases after treatment. Dysmehorrhoea were seen in 8(40%) cases before treatment and improved in 2(25%) cases after treatment.

25.CHANGES IN USG ABDOMEN AFTERTREATMENT

Table: 25: Distribution of usg abdomen after treatment

IMPROVEMENT	USG Abdomen changes	OP		IP	
		NO. OF CASES	%	NO. OF CASES	%
Good	Complete clearance of the cyst	2	10%	1	5%
Moderate	Changes in the size of the cyst	15	75%	13	65%
Poor	No changes	3	15%	6	30%
	Total	**20**	**100%**	**20**	**100%**

Figure:25 CHANGES IN USG ABDOMEN AFTER TREATMENT



In 20 OP cases, complete clearance of cyst was seen in 2(10%) cases,changes in size of the cyst was seen in 15(75%) cases and no changes observed in 3(15%) cases.

In 20 IP cases, complete clearance of cyst was seen in 1(5%) cases, changes in size of the cyst was seen in 13(65%) cases and no changes observed in 6(30%) cases

Table 26. BIOSTATISTICS BEFORE AND AFTER KARUNJCHIRAKAM CHOORANAM INTERVENTION

VARIABLE	BEFORE TREATMENT Mean ± SD	AFTER TREATMENT Mean ± SD		P VALUE	RESULT
BMI	26.0258 ± 3.7596	25.5190 ± 3.6638		<0.0001	HS
Waist Hip Ratio	0.8665 ± 0.0695	0.8232 ± 0.0731		<0.0001	HS
Size of the cyst BFT	5.925 ± 2.19	4.5875± 2.50		<0.0001	HS
Duration of bleeding	6.3250± 2.36	1C	2C	<0.0001	HS
		4.95 ± 1.72	4.50 ± 1.30		
***HS – HIGHLY SIGNIFICANT** *SD – STANDARD DEVIATION					

1. BMI SCORE BEFORE AND AFTERTREATMENT

S.No	OP No	OP		IP No	IP	
		Before	After		Before	After
1	31084	24	23.56	1938	27.87	27.87
2	33039	24.97	24.56	1939	23.7	22.64
3	32999	23.74	22.83	2786	21.48	20.7
4	33405	27.95	27.9	2928	21.33	20.67
5	44385	22.68	22.44	443	24.34	23.53
6	44938	39	38.53	517	27.39	26.48
7	49374	27.34	28.13	518	24.97	23.73
8	50040	28.51	28.51	538	23.56	22.22
9	52701	22.23	21.51	788	24.97	24.56
10	61282	34.17	33.11	789	30.67	30
11	61349	29.33	29.56	948	25.3	24.88
12	11405	26.35	25.41	949	26.4	25.44
13	12241	30.26	29.36	1326	27.43	26.67
14	14539	24.22	23.44	1404	22.22	22.22
15	15365	19.63	20.9	1405	26.17	25.59
16	15348	27.78	27.39	1408	23.14	22.68
17	16457	25.4	24.86	1393	28.52	27.73
18	16336	25.16	24.61	1495	26.35	25.59
19	16338	21.45	21.64	1496	28.89	28.6
20	17460	21.36	21.79	1497	30.8	28.92

2.WAIST HIP RATIO BEFORE AND AFTERTREATMENT

S.No	OP No	OP		IP No	IP	
		Before	After		Before	After
1	31084	0.90	0.87	1938	1.03	0.91
2	33039	0.75	0.69	1939	0.92	0.88
3	32999	0.93	0.97	2786	0.75	0.71
4	33405	0.92	0.80	2928	0.79	0.79
5	44385	0.82	0.80	443	1.0	0.98
6	44942	0.91	0.74	517	0.75	0.68
7	49374	0.91	0.91	518	0.95	0.90
8	50040	0.78	0.80	538	0.90	0.83
9	52701	0.83	0.83	788	0.91	0.86
10	61282	0.85	0.85	789	0.87	0.82
11	61349	0.76	0.83	948	0.90	80
12	11405	0.80	0.75	949	0.92	0.90
13	12241	0.88	0.82	1326	0.86	0.87
14	14539	0.82	0.78	1404	0.80	0.72
15	15365	0.83	0.82	1405	1.0	0.89
16	15348	0.90	0.87	1408	0.80	0.82
17	16457	0.88	0.85	1393	0.89	0.79
18	16336	0.83	0.80	1495	0.87	0.84
19	16338	0.90	0.90	1496	0.86	0.80
20	17460	0.79	0.65	1497	0.90	0.79

3.CASE SUMMARY OF OUTPATIENTS

S.No	OP No	Name	Age	Sex	Date of admission	Date of discharge	Duration of illness	Treatment with dose	Total no. of days treated
1	31084	Aneesh fathima	24	F	03/04/18	01/06/18	3 years	KARUNJCHIRAKAM CHOORANAM 2gm BD	60 days
2	33039	Balarasheedha	26	F	10/04/18	09/06/18	2 years		60 days
3	32999	Dona	34	F	10/04/18	09/06/18	5 years		60 days
4	33405	Karthika	27	F	13/04/18	12/06/18	5 years		60 days
5	44385	Ramalakshmi	28	F	22/05/18	20/07/18	5 years		60 days
6	44942	Mookkammal	19	F	23/05/18	21/07/18	1year		60 days
7	49374	Feliciya	19	F	09/06/18	07/08/18	2 years		60 days
8	50040	Samyuktha	18	F	12/06/18	10/08/18	1year		60 days
9	52701	Janaki	30	F	21/06/18	19/08/18	3 years		60 days
10	61282	Nilofer	24	F	23/07/18	10/09/18	2 years		60 days
11	61349	Alagurani	25	F	23/07/18	10/09/18	5 years		60 days
12	11405	Subhasree	18	F	10/01/19	10/03/19	1 year		60 days
13	12241	Saranya	26	F	03/02/19	03/04/19	4 years		60 days
14	14539	Subhashini	22	F	08/02/19	09/04/19	2 years		60 days
15	15365	Basariya	27	F	11/02/19	11/04/19	4 years		60 days
16	15348	Suba	19	F	11/02/19	11/04/19	1 year		60 days
17	16457	Pathmavathi	27	F	14/02/19	14/04/19	3 years		60 days
18	17460	Subbulakshmi	29	F	14/02/19	14/04/19	3 years		60 days
19	16336	Nishanthini	28	F	15/02/19	15/04/19	4 years		60 days
20	16338	Subbulakshmi	28	F	16/02/19	16/04/19	2 years		60 ays

4. CASE SUMMARY OF INPATIENTS

S.No	IP No	Name	Age	Sex	Date of admission	Date of discharge	Duration of illness	Treatment with dose	No. of days treated		Total no. of days treated
									IP	Follow	
1	1938	Ananthammal	25	F	30/07/18	13/08/18	3 years	KARUNJCHIRAKAM CHOORANAM -2gm BD	15 days	45 days	60 days
2	1939	Knniyammal	43	F	30/07/18	13/08/18	4 years		15 days	45 days	60 days
3	2786	Ponrani	39	F	15/11/18	12/01/19	1 year		59 days	1 day	60 days
4	2928	Usha	36	F	29/11/18	19/01/19	1 ½ years		52 days	8 days	60 days
5	443	Dhivya	28	F	21/02/19	10/04/19	2 years		49 days	11 days	60 days
6	517	Ramalakshmi	39	F	28/02/19	12/04/19	1 year		44 days	16 days	60 days
7	518	Rajapriya	36	F	28/02/19	07/03/19	4 years		8 days	52 days	60 days
8	538	Abirami	37	F	12/03/19	12/04/19	2years		32 days	28 days	60 days
9	788	Nallammal	41	F	27/03/19	10/05/19	2 years		45 days	15 days	60 days
10	789	Mahalakshmi	35	F	27/03/19	10/05/19	1 year		45 days	15 days	60 days
11	948	Subbulakshmi	39	F	15/04/19	05/05/19	2 years		21 days	39 days	60 days
12	949	Muthulakshmi	41	F	15/04/19	05/05/19	1 year		21 days	39 days	60 days
13	1326	Valli	21	F	02/05/19	29/05/19	1 year		28days	32days	60 days
14	1404	Janaki	39	F	03/05/19	26/06/19	3½ years		54 days	6 days	60 days
15	1405	Sujatha	40	F	03/05/19	14/06/19	3 years		43 days	17 days	60 days
16	1408	Ganthimathi	40	F	03/05/19	22/05/19	2 years		20days	40 days	60 days
17	1393	Gracy	24	F	5/05/19	14/06/19	3 years		45 days	15 days	60 days
18	1495	Sudha	18	F	9/05/19	26/06/19	1 year		49days	11 days	60 days
19	1496	Muthaparanam	39	F	09/05/19	25/06/19	3½ years		48 days	12 days	60 days
20	1497	Subbulakshmi	40	F	09/05/19	26/06/19	3 years		49 days	11 days	60 ays

5.LABORATORY INVESTIGATION OF OUTPATIENTS

S.No	OP No.	HEMATOLOGICAL INVESTIGATIONS													BIOCHEMICAL ANALYSIS						URINE ANALYSIS					
		BT				HB %	AT				HB %	BT		AT		BT			AT			BT			AT		
		TC	DC				TC	DC				ESR mm/hrs				Sug	Ur ea	Ch ole	Sug	Ure a	Chole	Alb	Sug	Dep	Alb	Sug	Dep
			P	L	E			P	L	E		½	1	½	1												
1	31084	8400	61	35	2	8.4	9005	60	32	6	10.4	11	27	19	31	129	25	186	107	23	127	Nil	Nil	NAD	Nil	Nil	NAD
2	33039	7100	62	37	4	8.2	8107	67	34	5	9.7	12	28	3	17	108	17	198	97	24	148	Nil	Nil	NAD	Nil	Nil	NAD
3	32999	8300	60	34	6	9.1	8907	65	35	4	9.6	13	29	5	14	93	15	175	106	27	145	Nil	Nil	NAD	Nil	Nil	NAD
4	33405	7700	66	37	3	8.3	8109	60	38	3	9.7	12	20	6	15	103	13	142	109	18	129	Nil	Nil	1-2pus cells	Nil	Nil	NAD
5	44385	7600	66	26	4	14	7108	66	37	4	11.3	5	19	7	17	114	13	183	108	26	157	Nil	Nil	NAD	Nil	Nil	NAD
6	44942	8600	65	29	9	9.6	8802	62	30	1	10.5	10	26	8	17	85	16	153	98	25	185	Nil	Nil	NAD	Nil	Nil	NAD
7	49374	9200	69	27	7	11.1	8701	53	40	5	10	24	47	15	37	97	14	173	96	29	148	Nil	Nil	NAD	Nil	Nil	NAD
8	50040	9500	43	50	5	10.2	8804	64	36	6	11.5	16	25	23	5	86	25	154	95	16	130	Nil	Nil	NAD	Nil	Nil	NAD
9	52701	8800	57	39	6	8.7	9005	67	38	7	10.4	25	27	5	18	95	27	173	93	29	149	Nil	Nil	NAD	Nil	Nil	NAD
10	61282	8200	58	3	4	8.2	8709	69	36	1	9.6	24	46	16	29	114	15	185	103	26	179	Nil	Nil	NAD	Nil	Nil	NAD
11	61349	8603	66	30	7	9.0	8703	63	39	5	9.8	37	61	14	34	122	19	171	116	23	149	Nil	Nil	NAD	Nil	Nil	NAD
12	11405	9804	55	30	3	10	8704	65	39	6	10.6	9	25	9	15	103	10	152	104	28	147	Nil	Nil	NAD	Nil	Nil	NAD
13	12241	8205	69	30	8	12.7	8109	67	38	8	16	39	66	17	36	74	29	124	88	26	150	Nil	Nil	NAD	Nil	Nil	NAD
14	14539	9004	65	30	5	10.4	8200	69	37	9	10.7	20	47	18	27	116	28	165	107	27	140	Nil	Nil	NAD	Nil	Nil	NAD
15	15365	7804	67	20	7	12.4	8105	60	39	7	10.9	10	40	17	35	68	27	146	84	28	120	Nil	Nil	NAD	Nil	Nil	NAD
16	15348	8805	68	30	6	8.7	8205	67	30	5	9.0	8	10	9	16	99	26	177	87	26	157	Nil	Nil	NAD	Nil	Nil	NAD
17	16457	7906	62	30	9	10.7	8404	60	26	6	11.9	19	28	7	15	89	16	218	85	26	189	Nil	Nil	1-2pus cells	Nil	Nil	NAD
18	17460	7607	63	30	5	9.7	7008	75	26	2	11.7	10	39	15	26	90	25	155	73	27	190	Nil	Nil	NAD	Nil	Nil	NAD
19	16336	9006	57	40	7	8	8209	66	30	8	8.6	9	10	6	5	70	14	129	84	28	116	Nil	Nil	NAD	Nil	Nil	NAD
20	16338	8703	68	29	9	15	8809	50	47	9	13.4	8	19	3	13	92	13	144	105	29	169	Nil	Nil	NAD	Nil	Nil	NAD

6.LABORATORY INVESTIGATION OF INPATIENTS

S.No.	IP No.	HEMATOLOGICAL INVESTIGATIONS														BIOCHEMICAL ANALYSIS						URINE ANALYSIS					
		BT				HB %	AT				HB %	BT			AT	BT			AT			BT			AT		
		TC	DC					DC				ESR mm/hrs															
			P	L	E		TC	P	L	E		½	1	½	1	Sug	Urea	Chole	Sug	Ure a	Chole	Alb	Sug	Dep	Alb	Sug	Dep
1	1938	8004	60	35	5	11.8	8206	61	36	2	13	2	10	9	12	83	14	143	95	12	158	Nil	Nil	NAD	Nil	Nil	NAD
2	1939	8405	62	39	7	8.8	7806	62	38	4	9.4	4	18	7	4	124	16	214	96	13	177	Nil	Nil	NAD	Nil	Nil	NAD
3	2786	6808	62	34	9	10	8906	64	37	7	11.4	15	35	6	25	96	25	215	96	14	188	Nil	Nil	1-2 pus cells	Nil	Nil	NAD
4	2928	7507	54	45	7	11.1	7807	65	38	8	11.5	44	4	5	16	87	16	166	107	15	167	Nil	Nil	NAD	Nil	Nil	NAD
5	443	9508	63	39	8	10.6	8508	56	39	4	10	17	33	17	27	148	15	157	127	14	168	Nil	Nil	NAD	Nil	Nil	NAD
6	517	8406	65	39	9	8	8609	57	30	7	9.5	15	32	13	25	79	16	158	88	16	169	Nil	Nil	NAD	Nil	Nil	NAD
7	518	7808	65	38	4	12.9	8007	57	49	2	10.9	18	22	18	26	90	18	169	107	17	188	Nil	Nil	NAD	Nil	Nil	NAD
8	538	8105	76	29	5	9.9	8808	78	28	4	10.7	14	27	17	26	119	29	239	118	28	208	Nil	Nil	NAD	Nil	Nil	NAD
9	788	7209	69	28	7	8.7	7109	69	38	9	9.6	7	10	6	14	87	18	208	99	17	188	Nil	Nil	1-4 pus cells	Nil	Nil	NAD
10	789	6901	67	38	8	10	7207	60	37	8	17	9	9	7	17	86	27	199	88	28	199	Nil	Nil	NAD	Nil	Nil	NAD
11	948	7502	70	22	3	9.4	8604	54	36	6	10.5	23	56	13	28	84	25	225	112	22	152	Nil	Nil	NAD	Nil	Nil	NAD
12	949	7903	69	33	2	12.8	8306	55	44	4	14	32	70	14	38	75	25	215	94	24	182	Nil	Nil	1-2 pus cells	Nil	Nil	NAD
13	1326	8004	58	34	8	11.5	9007	56	35	5	11	14	37	19	27	126	36	167	102	25	143	Nil	Nil	NAD	Nil	Nil	NAD
14	1404	9004	68	25	7	7.9	8809	67	25	6	3	15	28	10	20	67	15	139	73	14	133	Nil	Nil	NAD	Nil	Nil	NAD
15	1405	8305	66	36	6	10.6	8208	68	36	8	10.5	16	20	14	26	128	25	200	132	27	194	Nil	Nil	NAD	Nil	Nil	NAD
16	1408	8006	65	27	5	9.4	7607	59	37	7	10	17	32	10	25	107	18	183	92	28	165	Nil	Nil	NAD	Nil	Nil	NAD
17	1393	7107	66	37	3	12.7	7505	60	28	8	16	3	6	4	14	138	15	194	123	16	194	Nil	Nil	NAD	Nil	Nil	NAD
18	1495	8600	65	38	5	9.8	7604	64	37	8	13	10	20	6	15	117	16	153	102	28	135	Nil	Nil	1-4 pus cells	Nil	Nil	NAD
19	1496	8207	54	49	4	10.9	8700	73	22	9	10.2	17	39	5	14	134	25	166	100	29	144	Nil	Nil	NAD	Nil	Nil	NAD
20	1497	8508	63	30	5	11.4	8803	65	26	3	10.8	22	44	42	25	125	34	187	102	20	143	Nil	Nil	NAD	Nil	Nil	NAD

CHAPTER - VI

DISCUSSION

- ***Raktha Soorai Vaayu*** is one of the disease ,which it was described in the text ***Yugimuni Vaithiya Kaviyam***. It is characterised by absence or irregular of menstruation, heavy menstrual bleeding, menstrual pain and miscarriage. The symptoms are correlated in modern medicine is **Poly Cystic Ovarian Syndrome.** The clinical study was conducted in 40 cases after screening the patients. 20 cases were studied in Outpatient Department and 20 cases were admitted in Inpatient Department of Govt. Siddha Medical College,Palayamkottai.
- The trial drug ***Karunjchirakam chooranam*** is given twice daily after food for 60days.
- The clinical assessment was recorded for every 15days.
- The observations are summarized below.

1. Distribution of cases by age:

The 20 OP cases the prevalence was found to be higher in 13 cases (65%) in the age group of 26-35 years. 20 IP cases the prevalence was found to be higher in 14 cases (70%) in the age group of 36-45years.

2. Distribution of cases by marital status:

The 20 OP cases the prevalence of disease was found to be higher in unmarried females i.e. 11cases (55%).IP cases the prevalence of disease was found to be higher in married females i.e. 17 cases (85%).

3. Distribution of cases by parity:

Among 11 OP cases, 9 (82%) cases were found to be nulliparous and 2(18%) cases were found to be multiparous. 17 IP cases, 4(23.52%) cases were found to be nulliparous, 10(58.82%) cases were found to be uniparous and 3(17.64%) cases were found to be multiparous.

4. Distribution of cases by Religion:

Among 20 OP cases, 14 (70%) cases were Hindus, 2(10%) cases were Christians and 4(20%) case wasMuslim. 20 IP cases, 19(95%) cases were Hindus and 1(5%) cases were Christians and 0(0%) case was Muslim.

5. Distribution of cases by Paruva kaalam:

The 20 OP cases, for 8(40%) cases the treatment period was Munpanikaalam and 5(25%) cases it was Pinpanikaalam.and 4(20%)cases it was ilavenilkaalam, and 3(15%)cases it was mudhuvenilkaalam. 20 IP cases, for 2(10%) cases the treatment period was koothirkaalam,8(40%), cases it was Pinpanikaalam and 8(40%) cases it was Ilavenilkaalam and 2(10%) cases it was mudhuvenilkaalam

6. Distribution of cases by Thinai:

The 20 OP cases, 4(20%) were from the land Kurinji, 14(70%) were from the land Marutham and 2(10%) was from the landNeithal.The 20 IP cases, 3(15%) were from the land Kurinji, 16(80%) were from the land Marutham and 1(5%) were from the land Mullai.

7. Distribution of cases by Diet:

The 20 OP cases, majority of the cases i.e. 18(90%) were Non-vegetarians.The 20 IP cases, majority of the cases i.e. 19(95%) were Non - vegetarians.

8. Case distribution:

The 20 OP cases 9(45%) cases were diagnosed with PCOS only, 9(45%) cases were PCOS with primary infertility and 2(10%) cases were PCOS seen in fertile women.

The 20 IP cases, 3(15%) cases were diagnosed with PCOS only, 4(20%) cases were PCOS with primary infertility and 13(65%) cases were fertile women with PCOS.

9. Distribution of cases by Body built:

The 20 OP cases, majority of the cases i.e. 8 (40%) cases were overweight and 6 cases (35%) were normal weight.

The 20 IP cases, majority of cases i.e.10 (50%) cases were overweight.

10. Distribution of cases byoccupation:

The 20 OP cases, the incidence was more in students i.e. 10 cases (50%). The 20 IP cases, the incidence was more in non-employee i.e. 14 cases (70%).

11. Distribution of cases by positive familyhistory:

The 20 OP cases, only 2(10%) cases had positive familial history. The 20 IP cases, only 1(5%) case had positive familial history.

12. Distribution of cases by chronicity of illness:

The 20 OP cases (irregularmenstruation)

In 0(0%) case had the duration of illness were less than 6 months,

4 (20%) cases were between 6 months – 1 year,

5 (25%) cases were between 1- 2 years,

11(55%) cases were between 2 – 5 years,

The 20 OP cases, majority of the cases the chronicity of the illness was between 2-5 years

The 20 IP cases,

6(30%) cases were between 6 months – 1 year,

6 (30%) cases were between 1 – 2 years,

8 (40%) cases were between 2 – 5 years,

0 (0%) case was between 5 – 10 years and

Among 20 IP cases, majority of the cases the chronicity of the illness was between 2-5 years.

The chronicity of illness i.e. infertility before recruitment for the study,

In 9 OP study,

In 4 (14.44%) case the chronicity of illness was between 1-2 yrs. In 5 (55.55%) cases the chronicity of illness was between 3-5 years. In 0(0%) case the chronicity of illness was between 6-10 years. In OP study majority of cases were between 3-5 years.

In 4 IP study,

In 3 (75%) case the chronicity of illness was between 1-2 years. In 1 (25%) case the chronicity of illness was between 3-5 years. In IP study majority of cases were between 1-2 years.

13. Treatment history:

In 20 OP cases, among 9 infertility cases, 4(44.44%) cases underwent treatment for ovulation induction, 5 case (55.55%) had not taken anytreatment.

In 20 IP cases, among 4 infertility cases, 2(50%) cases underwent treatment for ovulation induction, 2 case (50%) had not taken anytreatment.

In OP study, among 9 PCOS cases, 5 cases (56%) had undergone treatment for menstrual induction, 4 cases (44%) had not undergone any treatment.

In IP study, among 4 PCOS cases, 2(50%) had undergone treatment for menstrual induction and 2 cases (50%) had not undergone any treatment before.

14. Thegi:

In 20 OP cases,the majority of the cases i.e. 9(45%) were Thonthathegi . In 20 IP cases, the majority of the cases i.e. 8(40%) were Thonthathegi.

15.Mukkutram:

15. a.Derangement in Vathakutram:

The 20 OP cases,

Abanan was affected in 20(100%) cases. Samanan was affected in 20(100%) cases. Viyanan was affected in 20(100%) cases. Devadhathan was affected in 16(80%) cases.

The 20 IP cases,

Abanan was affected in 20(100%) cases. Samanan was affected in 20(100%) cases. Viyanan was affected in 20(100%) cases. Devadhathan was affected in 15(75%) cases.

15 .b. Derangement in Pithakutram:

IN 20 OP cases,

Ranjagam was affected in 5(25%) cases.

IN 20 IP cases,

Ranjagam was affected in 3(15%) cases.

15. c. Derangement in Kapha kutram:

In 20 OP cases, santhigam was affected in 7(35%) cases. In 20 IP cases, santhigam was affected in 6(30%) cases.

16. Distribution of cases by Gnanenthriyam:

The 20 OPcases,

Mei was affected in 8(40%) cases. Kan was affected in 5(25%) cases.

Vaai, mooku and sevi were found to be normal in all cases.

The 20 IP cases,

Mei was affected in 10(50%) cases. Kan was affected in 3(15%) cases.

Vaai, mooku and sevi were found to be normal in all cases.

17. Distribution of cases byKanmenthriyam:

Among 20 OP cases,

Karuvaai was affected in 20(100%) cases.

Kai, kaal , vaai and Eruvaai were found to be normal in all cases.

Among 20 IP cases,

Karuvaai was affected in 20(100%) cases.

Kai, kaal ,vaai , and Eruvaai were normal in all cases.

18. Kosangal:

Among 20 OP cases,

In 20(100%) cases, Ananthamayakosam was affected. Annamayakosam, Pranamayakosam, Vignanamayakosam and Manomayakosam were normal in all cases.

Among 20 IP cases,

In 20(100%) cases Ananthamayakosam was affected. Annamayakosam, Pranamayakosam, Vignanamayakosam and Manomayakosam were normal in all cases.

19. Distribution of cases by UdalThathukkal:

Among 20 OPcases,

Senneer was affected in 5(25%) cases. Kozhuppu was affected in 11(55%) cases. Suronitham was affected in 20(100%) cases.

Saaram, Oon, Enbu and Moolai were not affected in all cases.

Among 20 IP cases,

Senneer was affected in 3(15%) cases. Kozhuppu was affected in 12(60%) cases. Suronitham was affected in 20(100%) cases.

Saaram, Oon, Enbu and Moolai were not affected in all the cases.

20. Distribution of cases by Envagaithervugal:

The 20 OPcases,

All are normal.

The 20 IP cases,

All are normal.

20. a.Distribution of cases by Naadi type:

The 20 OP cases,

Vathapithanaadi and kaphavathanaadi were predominant in 7(35%) cases each.

Pithavatha naadi in 5(25%) cases. Vathanaadi was found in 1(5%) case.

The 20 IP cases,

Kaphavathanaadi was predominant in 9(45%) cases. Vathapithanaadi was found in 6(30%) cases.

Pithavathanaadi was found in 4(20%) case. Vathanaadi was found in 1(5%) case.

20.b. Distribution of cases by Neikuri:

In 20 OPcases,

4(20%) cases had vathaneer pattern. 3(15%) cases had pithaneer pattern. 13(65%) cases had kapha neer pattern.

In 20 IP cases,

5(25%) cases had vathaneer pattern.

3(15%) cases had pithaneer pattern. 12(60%) cases had kapha neer pattern.

21. a. Intermenstrual period assessment before treatment:

The 20 OPcases,

0(0%) cases were in 28 days cycle, 4(20%) cases were in 28-45 days cycle, 6(30%) cases were in 45-60 days cycle and 10(50%) cases were in above 60 dayscycle.

In this study, most of the cases 10(50%) fall under above 60 days cycle.

The 20 IP cases,

0 (0%) case were in 28 days cycle, 3(15%) cases were in 28-45 days cycle, 7(35%) cases were in 45-60 days cycle and 10(50%) cases were in above 60 days cycle.

In this study, most of the cases 10(50%) fall under above 60 days cycle.

21.b.Duration of bleeding phase scoring before treatment:

In 20 OPcases,

In 10(50%) cases the DOB was under grade 0 In 4(20%) cases the DOB was under grade 1 In 2(10%) cases the DOB was under grade 2 In 4(20%) cases the DOB was under grade 3 In OP study 10(50%)cases were under grade0.

In 20 IP cases,

In 11(55%) cases the DOB was under grade 0 In 6(30%) cases the DOB was under grade 1 In 2(10%) cases the DOB was under grade 2 In 1 (5%) cases the DOB was under grade 3 In IP study 11(55%) cases were in grade 0.

22. Clinical symptoms before treatment

Irregular menstruation was seen in 18(90%) cases, amenorrhoea in 11(55%) cases, oligomenorrhoea in 5(25%)cases, hypermenorrhoea in 5(25%) cases, dysmenorrhea in 10(50%) cases, weight gain in 14(70%)cases, infertility in 9(45%) cases, acanthosis nigricans in 8(40%) cases, hirsutism in 4(20%) case, acne in 9(45%) cases were observed in op cases.

Irregular menstruation was seen in 19(95%) cases, amennorhoea in 10(50%) cases, oligomenorrhoea in 7(35%) cases, hypermenorrhoea in 3(15%) cases, dysmenorrhea in 8(40%) cases, weight gain in 13(65%) cases, infertility in 4(20%) cases, acanthosis nigricans in 10(50%) cases,hirsutism in 5(25) , acne in 3(15%) cases were affected in 20 cases of IP.

OUTCOME MEASURES:

PRIMARY OUTCOME OBSERVATIONS:

23. a .INTERMENSTRUAL PERIOD ASSESSMENT SCORE

The 20 OP cases,

In 13(65%)cases there was days cycle. In7(35%) cases there was 45-60 days cycle.

In 0(0%) cases there was above 60 days cycle.

The 20 IP cases,

In17(85%) cases there was 28-45days cycle .In 3(15%) case there was 45-60 days cycle.

In 0(0%) cases there was above 60 days cycle.

23.b. IMPROVEMENT IN DURATION OF BLEEDING SCORE

IN OP cases,

16(80%) cases had improved to grade 0 3(15%) cases had improved to grade 1 1(5%) cases had improved to grade 2

IN IP cases,

18(90%) cases had improved to grade 0.

2 (10%) cases had improved to grade 1

24. IMPROVEMENT IN THE CLINICAL SYMPTOMS:

The 20 OPcases,

Regular menstrual cycle in 13 (73%) cases.

After treatment there was a considerable reduction in the symptoms like oligomenorrhoea,dysmenorrhoea,hypermenorrhoea andamenorrhoea.

The 20 IP cases,

Regular menstrual cycle in 14(74%) cases.

After treatment there was a considerable reduction in the symptoms like oligomenorrhoea, dysmenorrhoea, hypermenorrhoea andamenorrhoea.

In both OP and IP there are no significant changes in the body weight. In both OP and IP Infertility cases had not conceived.

25.ASSESSSMENT THROUGH USG PELVIS:

Out of 20 OPcases,

2(10%) cases showed complete clearance of the cyst. 15(75%) cases showed changes in the size of the cyst. 3(15%) cases showed no changes.

Out of 20 IP cases.

1(5%) cases showed complete clearance of the cyst. 13(65%) cases showed changes in the size of the cyst. 6(30%) cases showed no changes.

26.BMI SCORE

There is a mild improvement showed in after treatment,it was confirmed by the BMI score.

27.WAIST HIPRATIO:

There is a reduced the waist hip ratio.

CHAPTER - VII

SUMMARY

- The aim of the study is to document the efficacy of siddha medicine ***KARUNJCHIRAKAM CHOORANAM***(Internal Medicine) in the treatment of ***RakthaSoorai Vaayu***(Poly Cystic OvarianSyndrome)
- The raw drug was authenticated by the botanist and the trial drug was prepared in the Gunapaadam Department of Government Siddha Medical College, Palayamkottai.
- The medicine was subjected to preclinical studies in K.M.College of pharmacy, Madurai and acute toxicity studies in animal house of Govt. Siddha Medical College,Palayamkottai.
- In preclinical study, biochemical and clinical parameters in a rat model of PCOS reveals that KARUNJCHIRAKAM CHOORANAM had induced recovery from Estradiol valerate (EV) induced PCO state in rats, probability of interaction of the GABA system, regulation of LH surge secretion, increase the size of dominant follicles and in the uterus it causes better endometrial tissue arrangements.
- For the clinical study, 40 cases (20 OP and 20 IP) were recruited for the trial as per the inclusion and exclusion criteria and the informed consent were obtained from thepatients.
- 20 cases were treated in the OP Pothu Maruthuvam and 20 cases were admitted in IP ward of Govt. Siddha Medical College, Palayamkottai. Case sheet proforma was maintained both for OP and IPpatients.
- The trial medicine***KARUNJCHIRAKAM CHOORANAM***was given twice daily after food for sixtydays.
- Laboratory investigations were carried out before and after the treatment and concerned data was recorded in theproforma.
- USG pelvis was done before and after thetreatment.
- Clinical assessments were done once in 15 days for all thepatients.
- During the study period, there was no adverse eventreported.
- In this study out of 40 cases, the improvement in the clinical symptoms were normal menstrual cycle i.e., 28-45 days cycle in 20(50%) cases and duration of menstrual bleeding(3-5days) in 34(85%)cases.
- USG pelvis shows complete clearance of the cyst in 3(15%)cases

- Follicular study was done in 1 case and it shows no follicular development.
- Mild improvement changes showed in the BMI and waist hip ratio before and after the study.
- As per siddha text and recent research articles, the ingredient of the trail drug was found to have properties owing to the disease manifestations.
- In acute toxicity study there was no mortality up to the dose level of 300mg/kg body weight in experimental mice.
- This ensures the safety usage of the drug ***KARUNJCHIRAKAM CHOORANAM*** as per literature.
- Biochemical and ***KARUNJCHIRAKAM CHOORANAM*** showed the presence of Calciam, sulphate, chloride, , ferrous iron, Amino acid.

CHAPTER - VIII CONCLUSION

- Clinical study revealed the therapeutic efficacy of the trial drug by showing normal menstrual cycle i.e., 28 days cycle in 20(50%) cases and duration of bleeding (3-5days) in 34 (85%)cases.
- USG pelvis shows complete clearance of cyst in 3 (15%) cases.
- In Pharmacological studies resultd in a rat model of PCOS reveals that ***KARUNJCHIRAKAM CHOORANAM*** had induced recovery from Estradiol valerate (EV) induced PCO state in rats, probability of interaction of the GABA system, regulation of LH surge secretion, increase the size of dominant follicles and in the uterus it causes better endometrial tissue arrangements.
- Preclinical studies biochemical, phytochemical and anti-microbial are resulted were carried out for the trial medicine of Karunjchirakam Chooranam
- The acute toxicity studies conducted revealed that the trial drug was safe at higher dosage of 200 mg/kg body weight in experimental mice.
- Biochemical analysis of **KARUNJCHIRAKAM CHOORANAM** showed the presence of sulphate, chloride, starch, ferrous iron, phosphate, unsaturated compound and aminoacid.
- No adverse drug reactions were noticed during the course of treatment.
- The trial drug is cost effective and easily preparable.

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ANNEXURE 1

PREPARATION OF KARUNJCHIRAKAM CHOORANAM

Ingredient:

Karunjchirakam - Seeds only.

Purification of raw drug:

Remove the dust particles and soaked it calcium carbonate water. Then allow it to dry in shade light

Methodology:

The *Karunjchirakam* seeds were dried under sunlight and made into fine power. The powder is then filtered in pure white cloth. The prepared drug will be stored in clean and dry air – tight container.

Dosage:

2gm bd twice a day after food.

Reference:

Poem Ref: Gunapaadam mudhal paagam Mooligai Vaguppu – Pg .no: 463-464 Chooranam preparation Ref:Gunapaadam Thathu Seeva vaguppu- paagam 2 & 3- Pg.no: 60, 61.

PROPERTIES OF TRIAL DRUG

The trial drug is *Karunjchirakam* seeds.

கருஞ்சீரகம் *(KARUNJCHIRAKAM)*

1. **Botanical Name** : *Nigella sativa*
2. **Family** : Renunculaceae
3. **Characters** :

சுவை :கைப்பு

தன்மை: வெப்பம்

பிரிவு :கார்ப்பு

கருஞ்சீரகந்தான் கரப்பனொடு புண்ணும்
வருஞ்சிராயப் பீநசமும் மாற்றும்- அருந்தினால்
காய்ச்சல் தலைவலியும் கண்வலியும் போமுலகில்
வாய்ச்ச மருந்தெனவே வை.

-அகத்தியர் குணவாகடம்

4. Chemical constituents:

- Tymoquinone
- Tymohytroquinone
- Ditymoquinone
- P-cymene
- Carvacrol
- 4-terpineol
- T-anethol
- Sesquiterpene
- Longifolene

5. Pharmacological action:

- Anti-diabetic
- Anti-hypertensive
- Liver tonic
- Anti-bacterial
- Diuretic
- Emmenagogue
- Anti-cancer
- Immunomodulator
- Anti-inflammatory
- Anti-oxidant
- Bronchodilator.

Name	Mrs. RAJA PRIYA	26.02.2019
Age/ Sex	36 Y/F	6139 /USG

USG ABDOMEN

Thanks for reference

Liver

Liver is mildly enlarged and measures 17.3cms. Diffuse parenchymal hyperechogenicities seen in liver. No evidence of focal lesion is seen. IHBR are not dilated. Portal vein and its major branches appear normal.

GB:

Gall bladder appears normal. No abnormal echogenecity or evidence of calculus seen. CBD is not dilated.

Pancreas

Pancreatic parenchyma appears normal. Pancreatic duct is not dilated. No evidence of calcification or abnormal echogenecity is seen.

Spleen:

Parenchyma appears normal in size and echogenecity. No evidence of focal lesion is seen.

KIDNEYS:

Right kidney measures 10.5x4.7cms. Left kidney measures 11.0x5.0cms. Parenchymal echoes are normal and CMD is preserved. No evidence of calculus is seen. Pelvicalcyceal system is normal. Ureters are not dilated.

Urinary Bladder:

Bladder appears normal. No evidence of calculus is seen. No significant wall thickening is seen.

Uterus & Ovaries:

Uterus is enlarged in size and measures 9.8x5.3x4.4cms. Endometrium (7mms) and myometrium appears diffuse cystic changes present.

Right ovary appear normal. Right ovary is measuring 2.8x1.1cms and left ovary is measuring 4.8x3.4cms. There is a cyst measuring about 3.2x2.7cms present in left ovary.

Both adnexa appear normal.

No free fluid present in POD.

Retroperitoneal structures appear normal.

No significant inflammatory changes or mass in RIF.

No significant free fluid in abdomen and pelvis.

Note: This imaging modality has its own limitations. Hence it should be correlated with clinical and other parameters.
Patient's identity is not verified.

9-B, Thiruchendur Road. (Near Murugankuruchi Signal)
Palayamkottai, TIRUNELVELI - 627 002. Ph : 0462 - 2583222 email : baraniscans@yahoo.com

Name	Mrs. RAJA PRIYA	26.02.2019
Age/ Sex	36 Y/F	6139 /USG

IMPRESSION:

- **Mild hepatomegaly with diffuse fatty changes.**
- **Bulky uterus with adenomyosis.**
- **Simple left ovarian cyst.**
- **Normal sonographic study of GB, pancreas, spleen, both kidneys and right ovary .**

Dr. R.GUNASEELARAJAN DMRD
CONSULTANT RADIOLOGIST
Ph.No: 9443555342

TYPED:M.N

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Name	**Ms. SUBHASREE**	**25.12.2018**
Age/ Sex	**17 Y/F**	**3712/USG**

USG ABDOMEN

Thanks for reference

Liver

Liver parenchyma shows normal size, echogenecity and morphology. No evidence of focal lesion is seen. IHBR are not dilated. Portal vein and its major branches appear normal.

GB:

Gall bladder appears normal. No abnormal echogenecity or evidence of calculus seen. CBD is not dilated.

Pancreas

Pancreatic parenchyma appears normal. Pancreatic duct is not dilated. No evidence of calcification or abnormal echogenecity is seen.

Spleen:

Parenchyma appears normal in size and echogenecity. No evidence of focal lesion is seen.

KIDNEYS:

Right kidney measures 10.3x4.6cms. Left kidney measures 10.0x5.3cms. Parenchymal echoes are normal and CMD is preserved. No evidence of calculus is seen. Pelvicalcyceal system is normal. Ureters are not dilated.

Urinary Bladder:

Bladder appears normal. No evidence of calculus is seen. No significant wall thickening is seen.

Uterus & Ovaries:

Uterus is normal in size and measures 8.2x4.0x6.1cms. Endometrium (8mms) and myometrium appears normal.

Both ovaries are enlarged with multiple peripherally arranged .small cysts and central echogenic medulla. Right ovary is measuring 3.5x4.3x3.2cms, Vol – 13.9ccs, and left ovary is measuring 4.2x2.5x3.3cms, Vol – 18.3ccs.

Both adnexa appear normal.

Minimal free fluid present in POD.

Retroperitoneal structures appear normal.

No significant inflammatory changes or mass in RIF.

No significant free fluid in abdomen and pelvis.

Note: This imaging modality has its own limitations. Hence it should be correlated with clinical and other parameters.
Patient's identity is not verified.

9-B, Thiruchendur Road, (Near Murugankuruchi Signal)
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Name	Ms. SUBHASREE	25.12.2018
Age/ Sex	17 Y/F	3712/USG

IMPRESSION:

- **Polycystic appearance of both ovaries.**
- **Normal sonographic study of liver, GB, pancreas, spleen, both kidneys, and uterus.**

Dr. A.GOPINATH MD (RD)
CONSULTANT RADIOLOGIST
Ph.No:8870009015

TYPED. M.P.

AARTHI SCANS & LABS

AN ISO 9001 ORGANISATION

Name	DR.BALARASHEEDA. B	Patient ID	AS_VPI_US_12404
Accession No	16_012404_182267	Age/Gender	26Y / Female
Referred By	Dr.GOVT.SIDDHA MEDICAL COLLEGE	Date	06-Mar-2018

USG ABDOMEN

LIVER:

Is normal in size and uniform in echo texture.

Intrahepatic biliary radicles and CBD appear normal. Portal and hepatic veins appear normal.

GALL BLADDER:

Is partially distended. No internal echoes are seen. Wall thickness is normal.

PANCREAS:

Appears normal in size and it shows uniform echo texture.

SPLEEN:

Is normal in size and uniform echogenicity.

KIDNEYS:

RT. Kidney measures 10.1 x 4.4cms. LT.Kidney measures 9.5 x 4.6cms.

Cortico medullary differentiation is maintained on both sides.

Pelvicalyceal system on both sides appears normal.

BLADDER:

Is normal contour. No intra luminal echoes are seen. Urinary bladder wall thickness is normal.

RIF:

Appears normal. No free fluid.

UTERUS:

Measures 6.7 x 3.4cms. Anteverted.

Myometrium shows normal echogenicity. Endometrium is regular and thickness is 6.1mm.

OVARIES:

Right ovary measures 3.9 x 2.3 x 2.2cms. Vol: 10.9cc.

Left ovary measures 3.8 x 2.2 x 2.1cms. Vol: 9.4cc.

Both ovaries show multiple small peripheral arranged follicles of size 2 – 3mm.

P.O.D.:

No free fluid in P.O.D.

IMPRESSION:

- ***Polycystic ovaries.***
- *Normal sonographic study of Liver, GB, Spleen, Pancreas, Both Kidneys, Bladder and Uterus.*

DR.T.ANNIE STALIN

CONSULTANT SONOLOGIST

- TIRUNELVELI : 177, TVM Road, Vannarapettai, Ph: 0462-250 1353, Mobile : 98430 40346
- PALAYAMKOTTAI: Lakshmi Complex, North High Ground Road, Ph: 0462-258 1353
- TUTICORIN :40, Palai Road, Ph: 0461-232.7353, Mobile: 99401 10515
- MADURAI : 4, Dr. Thangaraj Salai, Madural. Ph:0452-2521353, Mobile:99400 80507
- TIANJAVUR : 22/1, Pudukottai Rd, Ph:279914, 279917, Mobile:87544 38504, 99529 69814
- TENKASI : 242, Samba Street, Ph:04633-223211, Mobile:99401 60317
- KOVILPATTI : 14-D, Santhai Pettai Road, Ph:04632-228626, Mobile:99400 72448
- RAJAPALAYAM: 64, Kamaraj Nagar, 2nd Street, Ph.04563-225101, Mobile:99401 10504

Note :This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters

Name	Mrs. RAJA PRIYA	20.05.2019
Age/ Sex	36 Y/F	9316 /USG

USG ABDOMEN

Thanks for reference

Liver

Liver is mildly enlarged and measures 17.3cms. Diffuse parenchymal hyperechogenicities seen in liver. No evidence of focal lesion is seen. IHBR are not dilated. Portal vein and its major branches appear normal.

GB:

Gall bladder appears normal. No abnormal echogenecity or evidence of calculus seen. CBD is not dilated.

Pancreas

Pancreatic parenchyma appears normal. Pancreatic duct is not dilated. No evidence of calcification or abnormal echogenecity is seen.

Spleen:

Parenchyma appears normal in size and echogenecity. No evidence of focal lesion is seen.

KIDNEYS:

Right kidney measures 10.5x4.7cms. Left kidney measures 11.0x5.0cms. Parenchymal echoes are normal and CMD is preserved. No evidence of calculus is seen. Pelvicalcyceal system is normal. Ureters are not dilated.

Urinary Bladder:

Bladder appears normal. No evidence of calculus is seen. No significant wall thickening is seen.

Uterus & Ovaries:

Uterus is enlarged in size and measures 9.8x5.3x4.4cms. Endometrium (7mms) and myometrium appears diffuse cystic changes present.

Both ovaries appear normal. Right ovary is measuring 2.8x1.1cms and left ovary is measuring 3.5x2.3cms.

Both adnexa appear normal.

No free fluid in POD.

Retroperitoneal structures appear normal.

No significant inflammatory changes or mass in RIF.

No significant free fluid in abdomen and pelvis.

Note: This imaging modality has its own limitations. Hence it should be correlated with clinical and other parameters.
Patient's identity is not verified.

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Name	Mrs. RAJA PRIYA	20.05.2019
Age/ Sex	36 Y/F	9316 /USG

IMPRESSION:

- **No free fluid in POD.**
- **Normal sonographic study of GB, pancreas, spleen, both kidneys and both ovaries .**

Dr. R.GUNASEELARAJAN DMRD
CONSULTANT RADIOLOGIST
Ph.No: 9443555342

TYPED:M.N

Note: This imaging modality has its own limitations. Hence it should be correlated with clinical and other parameters.
Patient's identity is not verified.

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BARANI SCANS
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Registered with AERB, Lab Accredited by CMC Vellore

Name	**Ms. SUBHASREE**	**10.04.2019**
Age/ Sex	**17 Y/F**	**7321/USG**

USG ABDOMEN

Thanks for reference

Liver

Liver parenchyma shows normal size, echogenecity and morphology. No evidence of focal lesion is seen. IHBR are not dilated. Portal vein and its major branches appear normal.

GB:

Gall bladder appears normal. No abnormal echogenecity or evidence of calculus seen. CBD is not dilated.

Pancreas

Pancreatic parenchyma appears normal. Pancreatic duct is not dilated. No evidence of calcification or abnormal echogenecity is seen.

Spleen:

Parenchyma appears normal in size and echogenecity. No evidence of focal lesion is seen.

KIDNEYS:

Right kidney measures 10.3x4.6cms. Left kidney measures 10.0x5.3cms. Parenchymal echoes are normal and CMD is preserved. No evidence of calculus is seen. Pelvicalcyceal system is normal. Ureters are not dilated.

Urinary Bladder:

Bladder appears normal. No evidence of calculus is seen. No significant wall thickening is seen.

Uterus & Ovaries:

Uterus is normal in size and measures 8.2x4.0x6.1cms. Endometrium (8mms) and myometrium appears normal.

Both ovaries normal

Right ovary is measuring 3.5x4.3x3.2cms, Vol – 13.9ccs, and left ovary is measuring 3.5 x2.5x1.5cms, Vol – 18.3ccs.

Both adnexa appear normal.

No free fluid in POD.

Retroperitoneal structures appear normal.

No significant inflammatory changes or mass in RIF.

No significant free fluid in abdomen and pelvis.

Note: This imaging modality has its own limitations. Hence it should be correlated with clinical and other parameters.
Patient's identity is not verified.

9-B, Thiruchendur Road, (Near Murugankuruchi Signal)
Palayamkottai, TIRUNELVELI - 627 002. Ph : 0462 - 2583222 email : baraniscans@yahoo.com

Name	Ms. SUBHASREE	10.04.2019
Age/ Sex	17 Y/F	7321/USG

IMPRESSION:

- **No free fluid in POD.**
- **Normal sonographic study of liver, GB, pancreas, spleen, both kidneys, and uterus.**

Dr. A.GOPINATH MD (RD)
CONSULTANT RADIOLOGIST
Ph.No:8870009015

TYPED. M.P.

9-B, Thiruchendur Road, (Near Murugankuruchi Signal)
Palayamkottai, TIRUNELVELI - 627 002. Ph : 0462 - 2583222 email : baraniscans@yahoo.com

AARTHI SCANS & LABS

AN ISO 9001 ORGANISATION

Name	DR.BALARASHEEDA. B	Patient ID	AS_VPI_US_24104
Accession No	16_012404_182267	Age/Gender	26Y / Female
Referred By	Dr.GOVT.SIDDHA MEDICAL COLLEGE	Date	30 - Jun -2018

USG ABDOMEN

LIVER:

Is normal in size and uniform in echo texture.

Intrahepatic biliary radicles and CBD appear normal. Portal and hepatic veins appear normal.

GALL BLADDER:

Is partially distended. No internal echoes are seen. Wall thickness is normal.

PANCREAS:

Appears normal in size and it shows uniform echo texture.

SPLEEN:

Is normal in size and uniform echogenicity.

KIDNEYS:

RT. Kidney measures 10.1 x 4.4cms. LT.Kidney measures 9.5 x 4.6cms.

Cortico medullary differentiation is maintained on both sides.

Pelvicalyceal system on both sides appears normal.

BLADDER:

Is normal contour. No intra luminal echoes are seen. Urinary bladder wall thickness is normal.

RIF:

Appears normal. No free fluid.

UTERUS:

Measures 6.7 x 3.4cms. Anteverted.

Myometrium shows normal echogenicity. Endometrium is regular and thickness is 6.1mm.

OVARIES:

Right ovary measures 3.9 x 2.3 x 2.2cms. Vol: 10.9cc.

Left ovary measures 3.8 x 2.2 x 2.1cms. Vol: 9.4cc.

Both ovaries normal

P.O.D.:

No free fluid in P.O.D.

IMPRESSION:

- *No free fluid in P.O.D.*
- *Normal sonographic study of Liver, GB, Spleen, Pancreas, Both Kidneys, Bladder and Uterus.*

Both ovaries show multiple small peripheral arranged follicles of size 2 – 3mm.

DR.T.ANNIE STALIN

CONSULTANT SONOLOGIST

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- PALAYAMKOTTAI: Lakshmi Complex, North High Ground Road, Ph: 0462-258 1353
- TUTICORIN :40, Palai Road, Ph: 0461-232.7353, Mobile: 99401 10515
- MADURAI : 4, Dr. Thangaraj Salai, Madural. Ph:0452-2521353, Mobile:99400 80507
- THANJAVUR : 22/1, Pudukottai Rd, Ph:279914, 279917, Mobile:87544 38504, 99529 69814
- TENKASI : 242, Samba Street, Ph:04633-223211, Mobile:99401 60317
- KOVILPATTI : 14-D, Santhai Pettai Road, Ph:04632-228626, Mobile:99400 72448
- RAJAPALAYAM: 64, Kamaraj Nagar, 2nd Street, Ph.04563-225101, Mobile:99401 10504

Note :This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters

GOVERNMENT SIDDHA MEDICAL COLLEGE
PALAYAMKOTTAI

SCREENINGCOMMITTEE

Name of the Candidate: **Dr.D.ARIVOLI**

Reg No : _____

Department : POTHU MARUTHUVAM (Branch I)

This is to certify that the dissertation topic **RAKTHA SOORAI VAAYU (Polycysitic ovarian syndrome) with"KARUNJCHIRAKAM CHOORANAM "**has been approved by the screening committee.

Branch	Department	Name	Signature
1	PothuMaruthuvam	Dr.A.Manoharan. MD(S)., Professor	
2	Gunapadam	Dr.A.KingslyMD(S)., Associate Professor	26/5/17
3	SirappuMaruthuvam	Dr.A.S.PoongodikanthimathiMD(S)., Professor	26/5/17
4	KuzhandhaiMaruthuvam	Dr.D.K.Soundararajan. MD(S)., Professor	26/5/17
5	NoiNadal	Dr.S.VictoriaMD(S)., Professor	for 26/5/17
6	NanjuNoolMaruthuvam	Dr.M.Thiruthani. MD(S)., Professor	For 26/5/17

Place:Palayamkottai

Date: 26.05.2017

26/5/17

PRINCIPAL
Govt. Siddha Medical College
Palayamkottai.

INSTITUTIONAL ETHICAL COMMITTEE,
GOVERNMENT SIDDHA MEDICAL COLLEGE,
PALAYAMKOTTAI, TIRUNELVELI- 627002,
TAMIL NADU, INDIA.

Ph: 0462-2572736/2572737/2582010 Fax: 0462-2582010
Email ID: gsmc.palayamkottai@gmail.com

R.No.GSMC/5676/P&D/Res/IEC/2014Date: 29.05.2017

CERTIFICATE OF APPROVAL

Address of Ethical Committee	Government Siddha Medical College, Palayamkottai-627002, Tirunelvelli district.
Principal Investigator	Dr.D.Arivoli M.D(S) First year, Department of PothuMaruthuvam, Reg. No: Not yet registered.
Supervisor	**Prof.Dr.A.Manoharan, M.D$_{(s)}$.,** Head of the Department, Department of PothuMaruthuvam, Government Siddha Medical College and Hospital, Palayamkottai - 627002, Tirunelveli District. drmanoharan25@gmail.com
Guide	**Dr.S.Justus Antony, M.D(s).,** Lecturer Greade II, Department of PothuMaruthuvam Government Siddha Medical College and Hospital, Palayamkottai - 627002, Tirunelveli District. Justusantony71@gmail.com
Dissertation Topic	AProspectiveopen labelled Phase II Non-Randomized Clinical trial on herbal formulation of "***KARUNJCHIRAKAMCHOORNAM***" for the treatment of **RAKTHASOORAIVAAYU** (Polycystic Ovarian Sundrome)
Documents Filed	(1)Protocol (2)Data Collection Forms (3)Patient Information Sheet (4)Consent Form (5)SAE (Pharmacovigilance)
Clinical/Non Clinical Trial Protocol (Others-Specify)	Clinical Trial Protocol-yes
Informed Consent Document	Yes
Any other Document	Case Sheet/Investigation Documents
Date of IEC Approval & its Number	GSMC-IV-IEC/2017/Br-I/01/29.05.2017

We approve the trial to be conducted in its presented form.

The Institutional Ethical Committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study, any changes in the protocol and submission of final report.

Chairman

Prof. Dr.M.MURUGESAN, M.D(S)

Member Secretary

29/5/17

Prof.Dr.R.NEELAVATHY, M.D(S). Ph.D

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI

Certificate of Botanical Authenticity

Certified the following plant drug used in Siddha formulation (Internal) **"KARUNJCHIRAKAM CHOORANAM"** for **RAKTHA SOORAI VAAYU** (POLYCYSTIC OVARIAN SYNDROME) taken up for Post-Graduation Dissertation Studies by Dr.D.ARIVOLI, PG Scholar MD siddha, Department of Pothu Maruthuvam, is correctly identified and authenticated through Visual inspection / Organoleptic Characters / Experience, Education & Training Morphology Microscopically and Taxonomical methods.

Table 1: Ingredients of Karunjchirakam chooranam

S.N	Drug	Botanical Name	Family	Parts Used
01	Karunjchirakam	*Nigella sativa, Linn*	Ranunculaceae	Seeds

Station: Palayamkottai

Date : 12.2.2018.

12/2/2018.

Authorized Signature

Dr. S. SUTHA, M.Sc.,M.Ed.,Ph.D.,
Associate Professor
Dept. of Medicinal Botany
Govt. Siddha Medical College
Palayamkottai, Tirunelveli - 2.

K.M. COLLEGE OF PHARMACY – MADURAI

IAEC – CERTIFICATE

This is to certificate that the project title A PROSPECTIVE PHASE II OPEN LABELLED NON-RANDOMIZED CLINICAL STUDY ON **RAKTHA SOORAI VAAYU (POLYCYSTIC OVARIAN SYNDROME)** AND THE DRUG OF CHOICE IS **KARUNJCHIRAKAM CHOORANAM** (INTERNAL MEDICINE) has been approved by the **IAEC/D. ARIVOLI /TNMGRMU/MD(S)/321611001/KMCP/23/2018.**

Dr. N. CHIDAMBARANATHAN

Name of the Chairman / Member Secretary IAEC:

Signature with Date 1/5/18

I. A. E. C. CHAIRMAN
INSTITUTIONAL ANIMAL ETHICAL COMMITTEE
K. M. COLLEGE OF PHARMACY
MADURAI-625 107.

Dr. P. THIRUPATHY KUMARESAN

Name of the CPCSEA Nominee

1/5/18

CPCSEA NOMINEE
INSTITUTIONAL ANIMAL ETHICS COMMITTEE
K.M. COLLEGE OF PHARMACY
MADURAI-625 107

Chairman / Member Secretary of IAEC **CPCSEA Nominee**

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by office).

The Tamil Nadu Dr. M.G.R. Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This certificate is awarded to Dr/~~Mr/Mrs~~.....D...ARIVOLI.....

for participating as ~~Resource~~ ~~Person~~ / Delegate in the XXIII Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

Organized by the Department of Siddha,

The Tamil Nadu Dr. M.G.R. Medical University from 6th to 10th March 2017.

Dr. N. KABILAN, M.D.(Siddha)
PROF & HEAD
Dept of Siddha

Dr. T.BALASUBRAMANIAN M.S.,D.L.O.,
REGISTRAR

Prof. Dr. S.GEETHALAKSHMI, M.D.,Ph.D.,
VICE CHANCELLOR

GOVERNMENT SIDDHA MEDICAL COLLEGE& HOSPITAL
PALAYAMKOTTAI

CME PROGRAMME

Conducted by
SIRAPPU MARUTHUVAM
DEPARTMENT
GSMCH - PALAYAMKOTTAI

Organised by
ASHTAVAIDYAN THAIKKATTU MOOSS
VAIDYARATNAM

Supported by
PG Student Council

S.No: 153

CERTIFICATE

This Certifies that

Dr. D. Arivoli

has participated in Continuing Medical Education on "**AYUSH External Therapies-II**" held at GSMCH, Palayamkottai on Dec, 4 2018

A.S. Poongodi

Dr. A.S.Poongodi Kanthimathi MD (s).,
Head - Dept. of Sirappu Maruthuvam

Authorised Signatory
VAIDYARATNAM

Dr. R. Neelavathy MD (s), Ph.D.,
Principal

வித்திடு ! கரம் கொடு ! நோயறு !

SEED அறக்கட்டளை

திருநெல்வேலி அண்ணா பல்கலைக்கழகம்

இணைந்து நடத்திய

"சித்த மருத்துவ தொடர்கல்வி பயிற்சி கருத்தரங்கம்" (CME - 2018)

பாராட்டுச்சான்றிதழ்

மருத்துவர் / மாணவர் ..... D. அறிவொளி ..... அவர்கள் செப்டம்பர் 2ஆம் தேதி ஞாயிற்றுக்கிழமை, 2018 அன்று திருநெல்வேலி அண்ணா பல்கலைக்கழகத்தில் நடைபெற்ற சித்த மருத்துவ தொடர்கல்வி பயிற்சி கருத்தரங்கில் (CME - 2018) கலந்து கொண்டு பயிற்சி பெற்றதை பாராட்டி SEED அறக்கட்டளை இச்சான்றிதழை வழங்குகிறது.

மரு. இரா. நீலாவதி M.D(s), PhD.,
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SEED அறக்கட்டளை, 47- A, திருவனந்தபுரம் ரோடு, குலவணிகர்புரம் திருநெல்வேலி – 2, போன்: 0462 - 4000053

International Journal of Reverse Pharmacology & Health Research

INTERNATIONAL JOURNAL OF REVERSE PHARMACOLOGY AND HEALTH RESEARCH

ISSN 2589 - 3343 A Peer Reviewed Interdisciplinary Medical Journal

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The board of "International Journal of Reverse Pharmacology and Health Research"
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Arivoli D

in recognition of the publication of the Research/Review Paper entitled

Safety studies of Siddha Medicine Karunjeeraga chooranam in acute and subacute toxicity on wistar rat models

CODENJ: IJRPHR

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Council of Science Editors

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International Journal of Modern Pharmaceutical Research (IJMPR)

SJIF Impact Factor: 3.498

Date: 29/06/2019

CERTIFICATE FROM EDITOR

It is hereby certified that Article entitled **"HYPOLIPIDEMIC ACTIVITY OF SIDDHA FORMULATION KARUM JEERAGA CHOORANAM IN HYPERLIPIDEMIC MODELS OF WISTAR ALBINO RATS"** Manuscript no. IJMPR/224/3/2019, Author name: **Dr. Arivoli D.* and Manoharan A.,** received for publication in *International Journal of Modern Pharmaceutical Research*(IJMPR), (ISSN No: 2319-5878) and has been published (Volume 3, Issue 3) after getting reviewed by three reviewers.

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Editor in chief

Society for Advance Healthcare Research

IJMPR

URKUND

Urkund Analysis Result

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