



Research Article

EFFICACY OF *DHATHU BUSHTI CHOORANAM* IN THE MANAGEMENT OF MALE INFERTILITY
WITH SPECIAL REFERENCE TO OLIGOSPERMIA - AN OPEN PILOT STUDY

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ABSTRACT

Infertility is a common problem of new age couples. It is affecting them psychologically and also affecting the harmony of the family. Among infertility couples, 40% was caused by male partner particularly by oligospermia. Literally oligospermia means insufficient number of spermatozoa in semen, but significantly, it means that oligospermia is a medical condition characterized by the total sperm count less than 20 million/ml of ejaculate. Extensive clinical researches are going on worldwide to treat oligospermia by utilizing various natural sources like plants, mineral and animal origin.

Siddha medicine is having many formulations to treat oligospermia, one among them is *Dhathu bushti chooranam* described in *Noigalukku Siddha Parigaram* –a Sasthiric siddha literature. 10 male partners of infertility couples attending Sool mahalir maruthuvam OPD of the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47 were recruited for this pilot study. All patients were treated with 10 gm of *Dhathu bushti chooranam* twice a day with milk for 90 days. All patients were subjected to complete semenogram on 0th and 90th day of treatment. Results were observed by analyzing the semenogram parameters. The ingredients of *Dhathu bushti chooranam* are *Salamisiri*, *Nilapanai kizhangu*, *Thaneervittan kizhangu*, *Poonikaali vidhai*, *Boomisarkkarai kizhangu* and most of them are having good spermatogenesis and aphrodisiac activities, hence the author selected this drug for this study. The efficacy of the trial drug *Dhathu bushti chooranam* was appreciable and the drug may be taken for clinical trial in large number of population.

KEYWORDS: *Dhathu bushti chooranam*, Siddha medicine, Oligospermia, Infertility.

INTRODUCTION

அமிழ்தினும் ஆற்ற இனிதேதம் மக்கள்
சிறுகை அளாவிய கூழ். - குறள் 64

*Than God's ambrosia sweeter far the food
before men laid, In which the little hands of children of
their own have play'd.*^[2]

குழல்இனிது யாழ்இனிது என்பதம் மக்கள்
மழலைச்சொல் கேளா தவர். - குறள் 66:

*'The pipe is sweet,' 'the lute is sweet,' by them't
will be averred, Who music of their infants' lispings
have never heard.*^[2]

The above verse says about the importance and joy of having a child in a family. Infertility is a common problem of new age couples and also affecting the harmony of their family. It is also creating social stigma to the couple.

The incidence of infertility in couples is one in four (1/4) as per the latest report of WHO survey. Among them 40% of infertility is due to male

partners. Oligospermia is the most prevalent cause of infertility we have seen in the daily clinical practice at the OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai.

Literally oligospermia means insufficient number of spermatozoa in semen, but significantly, it means that oligospermia is a medical condition characterized by the total sperm count less than 20 million/ml of ejaculate. Extensive clinical researches are going on worldwide to treat oligospermia by utilizing various natural sources like plants, mineral and animal origin.

In Siddha system of medicine, saint Yugi explained about four types of *Maladu* (Infertility) in his literature Yugi Vaidhaya Chinthamani. *Aanmaladu* (Male infertility)^[5] is one among them and it may be correlated with oligospermia in modern medical science. Siddhars described innumerable number of formulations for treating male infertility. One such effective Siddha poly herbal formulation is *Dhadhu*

bushti chooranam mentioned in the Sastri text book *Noigalukku Siddha Parigaram*^[1] which is an efficacious and simple formulation.

The ingredients of *Dhathu bushti chooranam* are *Salamisiri*, *Nilapanaikizhangu*, *Thaneervittan kizhangu*, *Poonaiikaali vidhai*, *Boomisarkkarai kizhangu* and most of them are having good spermatogenesis and aphrodisiac activities^[4,6]. Hence the author selected this drug for this study.

Subjects and Methods

This pilot study was conducted in OPD of the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47. The study was conducted in accordance with the good clinical practice guidelines of the Indian Council for Medical Research (ICMR-GCP) and was approved by the Institutional Ethics Committee. (NIS/IEC/10/2016-17/27-20.05.2016).

Subjects

10 male partners from infertile couples who were attending the OPD of Sool and Mahalir maruthuvam (Gynecology OPD) for the treatment of Magavinmai (Infertility) were the subjects for this study. All the 10 patients were screened as per the screening profoma and those meeting the inclusion criteria were included in this study. The patients were treated for 90 days and followed for 12 months including the treatment period. Subjects with Sperm count <20 millions/ml and who had a history of primary or secondary infertility for the period of more than 1 year, and not currently receiving any other treatment from outside, willing to give written consent for this study, and willing to give specimen of semen for the investigation were included. All men had a history of regular sexual intercourse over a one year period with a gynecologically normal female partner with no apparent female organ involvement. Men with Azoospermia were not included. Also men with epididymal cyst, Varicocele, Necrozoospermia patient with history of Mumps, measles, Small pox, Tb, cardiac disease, Men who had trauma to genitalia in last 10 years., any other serious disorder of vital organs, Receiving or having any infertility treatment for past one month were excluded from this study.

Methods

Standard operating procedure for preparation of trial drug.

- The required raw drugs were purchased from – Ramasamy chettiar shop- a well reputed indigenous drug shop at paris, Chennai.
- All the raw drugs were authenticated by Asst.professor of medicinal Botany of NIS, Chennai.

- The raw drugs were purified and the medicine was prepared in Gunapadam Laboratory of National Institute of Siddha, Chennai-47.

Table1: Ingredients of *Dhathu bushti chooranam*

S.No	Tamil name	Botanical name	Action
1	<i>Nilapanai kizhangu</i>	<i>Curculigo Orchiodes</i>	Aphrodisiac
2	<i>Boomisarkkarai kizhangu</i>	<i>Amorphophallus campanulatus</i>	Aphrodisiac
3	<i>Poonaiikaali vidhai</i>	<i>Mucuna Pruriens</i>	Aphrodisiac
4	<i>Thanneervittan kizhangu</i>	<i>Asparagus racemosus</i>	Aphrodisiac
5	<i>Salamisiri</i>	<i>Orchis Latifolia</i>	Aphrodisiac

Preparation of *Dhadhu bushti chooranam*

Ingredients

1. *Nilapanai kizhangu (Curculigo Orchiodes)* -1Kg
2. *Boomisarkkarai kizhangu (Amorphophallus campanulatus)*-1Kg
3. *Poonaiikaali vidhai (Mucuna Pruriens)* -1Kg
4. *Thanneervittan kizhangu (Asparagus racemosus)*-1Kg
5. *Salamisiri (Orchis Latifolia)* -1Kg

All the above ingredients were taken 1Kg each after purification^[8] and powdered well in a stone mortar and then sieved in fine cotton cloth and the prepared drug was stored in a clean and dry air tight glass container.

Dispensing

The medicine was dispensed in ziplock cover with proper labeling during each visit for fifteen days.

Observation

Semenogram is considered to be the direct method of analysis for diagnosis and prognosis of the patient affected with oligospermia, Semen of the each patient was collected and analysed completely after a period of complete abstinence continued for not less than 7 days. These were estimated on day 0 and repeated on day 90 of the trial period. The primary efficacy outcome was obtained from the improvement in the semen parameters after 90 days of therapy.

Safety was assessed based on the adverse events recorded during the study. At the end of the study, the three-point Assessment Scale for Efficacy (Good, Moderate and Poor) was used to assess the efficacy results. Compliance was assessed using the *Chooranam* left in packets and those who consumed over 80% of *Chooranam* were classified as compliant. If the total sperm count >40 million/ml classified on good improvement, >10 million/ml and <40

million/ml was classified as moderate improvement and Poor improvement defined as total sperm count ≤ 10 million/ml.

Study enrollment

Male infertile Patient reporting at the Sool mahalir maruthuvam OPD of the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47 with satisfying inclusion & exclusion criteria were selected for the study. The patients were informed about the study, trial drug, possible outcomes and the objectives of the study in their own language and terms understandable to them and the informed consent was obtained in the consent form.

They were instructed to attend the OPD once in 15 days.

Inclusion Criteria

- Infertile male patients in 20-40 years of age.
- Sperm count below 20 millions sperm / ml.
- History of primary / secondary infertility for the period of more than 1 year
- Not currently receiving any other treatment from outside
- Willing to give consent for the study

- Willing to give specimen of semen for the investigation

Conduct of the study

On the first day patient were advised to take oil bath followed by purgation with *Agasthiyar kulambu* 200mg given with hot water. The trial drug was given by the investigator in the OP department of Sool magalir Maruthuvam, NIS, Chennai. All the patients were asked to attend the OPD once in the 15 days. In every visit the clinical assessment was recorded in the prescribed case report form (CRF) individually. The laboratory investigation done before and after treatment for analyzing the complete semenogram. At the end of the trial (90 days) the patients were advised to come for two more months for further follow-up.

Observation and results

10 patients were recruited for this pilot study. All patients were treated with *Dhathu bushti chooranam* 10gm twice a day with milk for 90 days. All patients were advised for dietary regimen as per Siddha philosophy.

All the 10 patients were subjected to do complete semanogram after 90 days of treatment and the obtained results were tabulated below.

Table 2: Semen analysis report, before and after treatment

S.no	Date	OPD. No	Age	Before treatment		After treatment	
				Count/ Million/ml	Motility	Count/ Million/ml	Motility
1	16/11/2016	I 26757	40	8	50%	66.5	70%
2	30/12/2016	H 12245	27	40	35%	80	30%
3	17/01/2017	I 52029	33	< 1	-	2.34	18.89%
4	03/02/2017	I 58775	32	6	70%	8	70%
5	01/02/2017	H 94668	36	6	30%	100	90%
6	20/03/2017	I 83099	35	7.5	20%	10.5	20%
7	18/02/2017	I 57106	35	14	20%	75	50%
8	21/12/2016	I 77724	29	12	60%	39	80%
9	10/04/2017	I 82476	36	12	10%	30	45%
10	19/03/2017	H 80642	27	< 1	15%	3	10%

From the above results out of 10 patients 4 (40%) patients had good improvement. 3 (30%) patients had moderate improvement. Only 3 (30%) patients responded poorly.

The Note worthy outcome of this study was out of 10 patients 2 of them got their first child during this treatment period.

Table 3: Results of efficacy of Dhathu bushti chooranam

S.NO	Results	Number of patients/10	Percentage
1	Good	4	40%
2	Moderate	3	30%
3	Poor	3	30%

Chart-1. Results of efficacy of Dhathu bushti chooranam

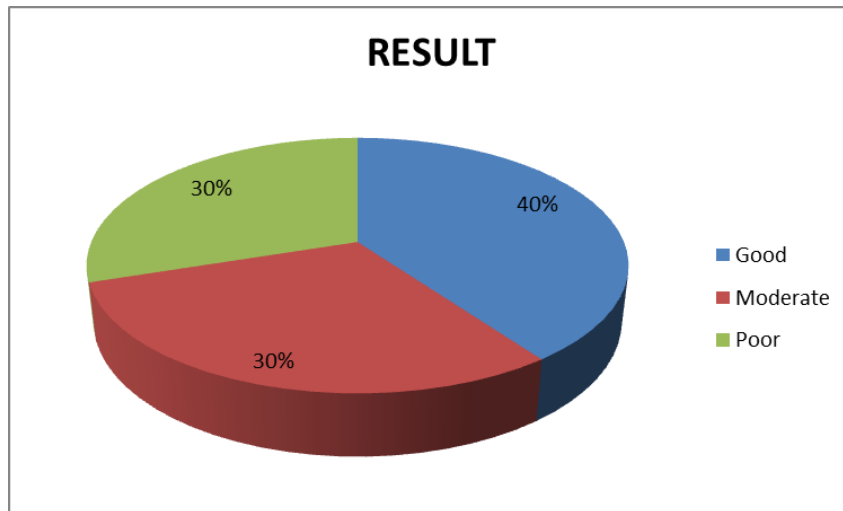


Table 4: Range of sperm count in patients - before and after treatment

S.No	Sperm count Million/ cumm	No. of patients / 10		Percentage	
		BT	AT	BT	AT
1	1-10 million/cumm	6	3	60%	30%
2	11-20 million/cumm	3	1	30%	10%
3	21-30 million/cumm	0	1	0%	10%
4	31-40 million/cumm	1	1	10%	10%
5	41-50 million/cumm	0	0	0%	0%
6	51-60 million/cumm	0	0	0%	0%
7	61-70 million / cumm	0	1	0%	10%
8	71-80 million / cumm	0	2	0%	20%
9	81-90 million/cumm	0	0	0%	0%
10	91-100 million/cumm	0	1	0%	10%

Chart-2. Range of sperm count in patients - before and after treatment

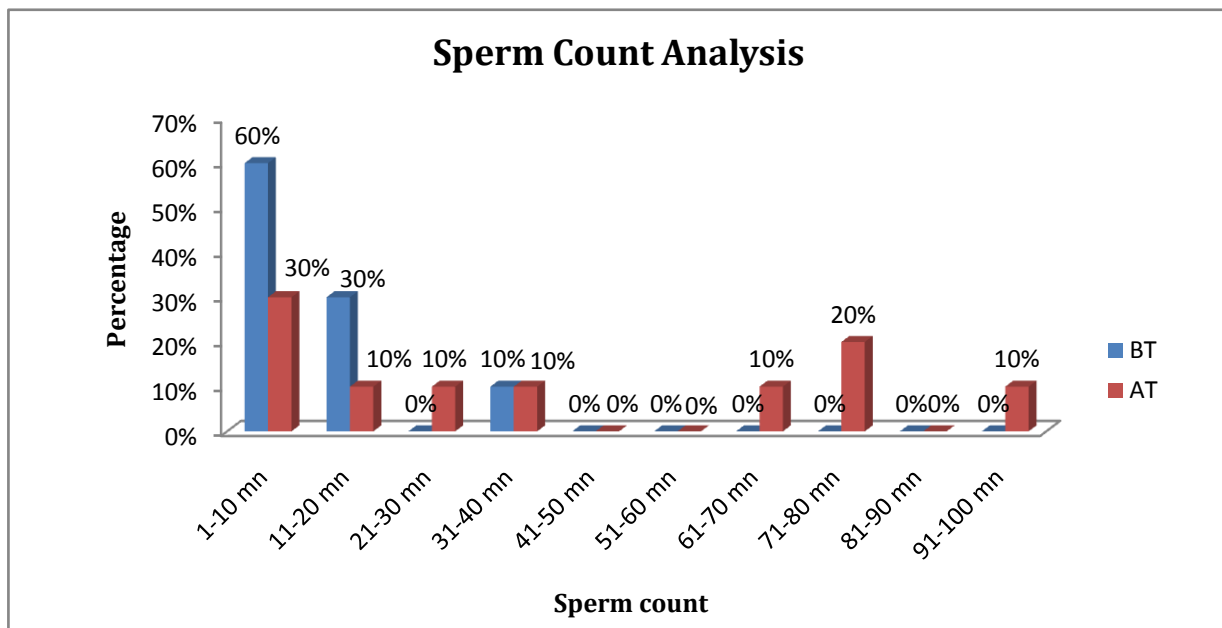
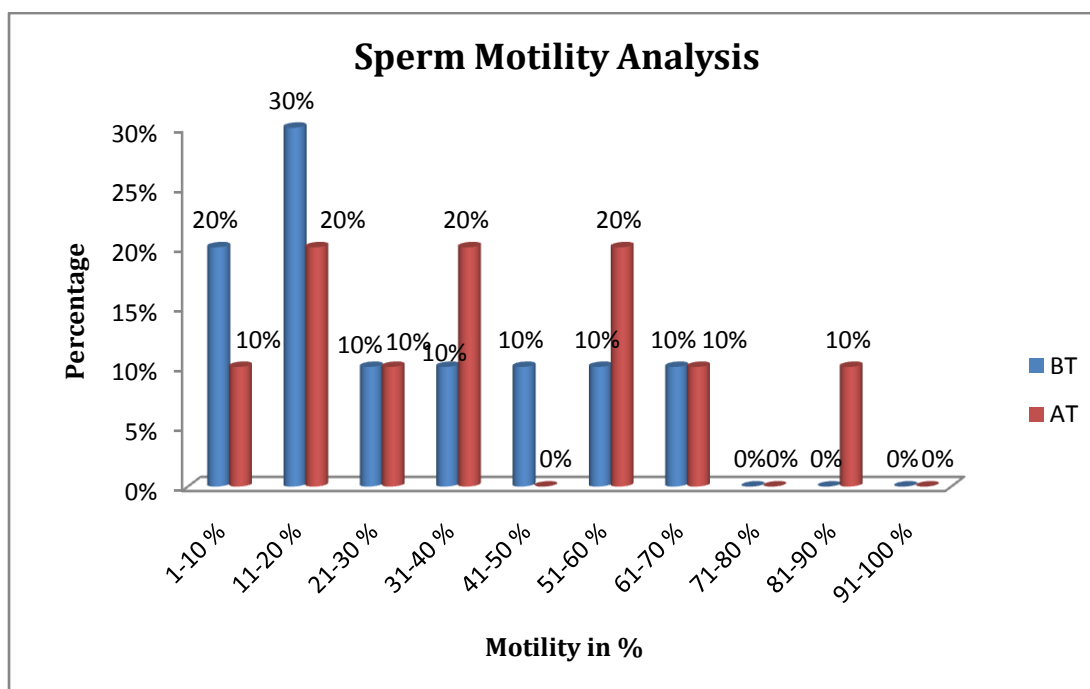


Table 5: Range of sperm motility in patients - before and after treatment

S.No.	Motility	No. of patients / 10		Percentage	
		BT	AT	BT	AT
1	1-10 %	2	1	20%	10%
2	11-20 %	3	2	30%	20%
3	21-30 %	1	1	10%	10%
4	31-40 %	1	2	10%	20%
5	41-50 %	1	0	10%	0%
6	51-60 %	1	2	10%	20%
7	61-70 %	1	1	10%	10%
8	71-80 %	0	0	0%	0%
9	81-90 %	0	1	0%	10%
10	91-100 %	0	0	0%	0%



P Value (2tailed): $p < 0.001$.

Inference

The p value is highly significant ($p < 0.001$). So the treatment was significantly improving the Semen Motility (%).

Inference

Before treatment

60% of cases sperm count had 1 -10 million/ cumm, 30% of cases sperm count had 11-20 million/ cumm, 10% of cases sperm count had 31-40 million/ cumm.

After treatment

30% of cases sperm count had 1-10 million/ cumm, 10% of cases sperm count had 11-20 million/ cumm, 10% of cases sperm count had 21-30 million/ cumm, 10% of cases sperm count had 31-40 million/ cumm, 0% of cases sperm count had 41-50 million/ cumm, 0% of cases sperm count had 51-60 million/ cumm, 10% of cases sperm count had 61-70 million/ cumm. 20% of cases sperm count had 71-80 million/ cumm, 0% of cases sperm count had 81-90 million/ cumm, 10% of cases sperm count had 91-100 million/ cumm.

cumm, 0% of cases sperm count had 81-90 million/ cumm, 10% of cases sperm count had 91-100 million/ cumm.

DISCUSSION

Among infertile couples male infertility (Oligospermia) is contributing 40%. Since more number infertile couples are approaching Sool magalir maruthuvam, OPD of the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47. So the author has decided to conduct this pilot study. The study was conducted in accordance with the good clinical practice guidelines of the Indian Council for Medical Research (ICMR-GCP) and was approved by the Institutional Ethics Committee (NIS/IEC/10/2016-17/27-20.05.2016).

The trial drug *Dhathu bushti chooranam* was prepared as per standard operating procedure by following (GLP) Guidelines.

After getting informed consent 10 patients were recruited for this pilot study those meeting the inclusion and exclusion criteria. All patients were treated with *Dhathu bushti chooranam* at the dose of 10 gm twice a day with milk for 90 days. Before starting the trial complete semenogram was done on 0th day and also on completion of the trial (90th day). Improvement in total sperm count was taken as outcome variable. The results were analysed by comparing the semenogram reports of before and after treatment.

The three point Assessment Scale for Efficacy -(Good>40 million/ml) (Moderate>10 million/ml and <40 million/ml) (Poor ≤10 million/ml) was used to assess the efficacy results. As complete semenogram was used as a major component in this study, the results obtained were given different type of understanding such as improvement in total sperm count in 7 patients and improvement in motility (5/10 patients) 2 patients were had the first child during this treatment. From this pilot study there is no adverse reaction was reported during this entire study period.

CONCLUSION

From this pilot clinical study its observed that *Dhathu bushti chooranam* is having good efficacy in the treatment Male infertility (Oligospermia). *Dhathu bushti chooranam* is easily preparable and cost effective compared with conventional treatment for male infertility. The Noteworthy outcome of this 90 days study was two patients were had their first child

during this treatment. So the author recommended that to conduct this trial in larger number of population for better exploration of this novel drug.

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