E-ISSN 2250-0944

ISSN 2250-1150

doi: 10.48047/ijprt/15.02.403

Research Article

Pilot Study on the Efficacy of Siddha Formulation Vithuvagai Chooranam in the Management of Aan Maladu (Oligospermia)

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ABSTRACT

Male infertility, primarily due to low sperm count (oligospermia) is a common and distressing condition that affects many couples worldwide. Although modern treatments are available, they are not always easy to get and come with possible side effects. Some traditional systems such as Siddha medicine also suggest the alternative approaches through time-tested herbal remedies. Vithuvagai chooranam (VVC) — classical formulation Vithuvagai Chooranam is one of the such classical herbal medicine which has seen to be beneficial in reproductive health of males. The present pilot study investigated the effectiveness and safety of such a therapy in real-life patients. A total of ten men suffering from oligospermia were enrolled in the study at GSMC, Chennai. They were treated with VVC (twice a day) for 90 days. Semen and blood

tests, along with Siddha-based assessments, were done before and after treatment. The results were encouraging-most participants showed noticeable improvements in sperm count, motility, semen volume, and overall seminal quality. Pus cell levels in semen also reduced, suggesting an anti-inflammatory effect. Importantly, no adverse effects were reported during the treatment. These early findings point to the potential of VVC as a safe and promising option for men struggling with infertility. Although the sample size was small, the results provide a strong foundation for conducting larger studies in the future to confirm its role in improving male fertility in a holistic, natural way.

Keywords: Aan Maladu, oligospermia, male infertility, Siddha medicine, *Vithuvagai Chooranam*, pilot study

INTRODUCTION

Infertility is a widespread health challenge that impacts millions of individuals across the globe. It stands as a crucial concern in the realm of reproductive health and plays a significant role in the gradual decline of birth rates in many regions. Medically, infertility is diagnosed when a couple fails to conceive after engaging in regular, unprotected intercourse for a year or longer. In men, the condition is frequently linked to issues such as problems with ejaculation, low sperm count, or abnormalities in sperm shape and movement. The World Health Organization (WHO) estimates that approximately 60 to 80 million couples worldwide are struggling with infertility. While societal perceptions often place the blame on women, data reveal that male factors contribute to 20% to 40% of infertility cases, whereas female factors are responsible for around 15% to 20%. One multicentric study conducted by WHO reported that 45% of infertile men were found to have either Oligozoospermia (low sperm count) or azoospermia (absence of sperm) (1, 2).

As per the WHO's 2010 reference standards, healthy semen should meet the following criteria: a volume of at least 1.5 ml per ejaculation, a minimum sperm concentration of 15 million per ml, a total sperm counts of 39 million or more, with at least 58% of sperm being alive, 40% motile, and 30% showing normal structure. When sperm concentration falls below 15 million/ml, the condition is termed oligospermia (3, 4).

Sexual function in males is a highly intricate physiological process, requiring the harmonious interplay of the nervous, cardiovascular, hormonal, and reproductive systems. When this coordination is disrupted, it can lead to sexual dysfunction (SD), which includes challenges related to sexual desire, erection, intercourse, or ejaculation (5,6). These problems can stem from both physical and psychological origins (7).

A study from Massachusetts states, over 52% men between 40 and 70 experience some form of ED. Globally, 15% couples have issues in sexual response cycle in which men related issues accounts for 40-50%. The sexual response in men is of 3 stages viz, Sexual desire (libido), erection and the act of intercourse. Many health and lifestyle conditions can disrupt this cycle. These include low testosterone levels, mental health issues like anxiety or depression, chronic conditions like diabetes and hypertension, neurological conditions like stroke or brain injuries, and the side effects of certain medications like antidepressants or blood pressure meds. Unhealthy lifestyle choices like smoking, excessive alcohol and obesity and penile conditions like phimosis or Peyronie's disease are also contributing factors (9-12). Aphrodisiacs are defined as substances, whether food or medicine, that enhance sexual desire, arousal, and performance. They may also support reproductive functions by increasing semen volume, boosting sperm production, improving semen quality, enhancing ejaculation, and delaying premature ejaculation (12-15). Although modern medicine offers synthetic drugs to manage sexual dysfunction, their usage is often limited due to high costs, surgical risks, mechanical

complications, and potential side effects. These challenges have sparked a growing interest in exploring natural and safer alternatives.

For centuries herbal remedies have played a major role in supporting male sexual health. Many plant-based compounds have proven benefits including aphrodisiac effects, antioxidant action and sperm health (16,17). In the Siddha system of medicine which is one of the oldest traditional systems of medicine in India many formulations are available to address male reproductive issues. These are gaining popularity for their therapeutic value and less side effects. According to Siddhar Theraiyar vindhu (sperm) is the foundation of life as it combines with nadham (ovum) to conceive. The concept of Thathuviruthi in Siddha is same as modern understanding of spermatogenesis and reproductive enhancement (18). A well-known Siddha formulation called Vithu Vagai Chooranam (VVC) is mentioned in the classical text Noigaluku Siddha Parigaram (Part 1, Page 325) by Dr. M. Shanmugavelu. Traditionally VVC is used to treat conditions like Neerchurukku (less urine), Thathuviruthi (sperm enhancement) and Vellai (leucorrhea) (19). Many of the herbs in VVC have been scientifically studied and found to have aphrodisiac, spermatogenic, antioxidant and anti-infertility properties. Considering this background the current study is designed as a non-randomized clinical trial to evaluate the efficacy of VVC in male patients. The objective is to see how this traditional Siddha herbal formulation can support male reproductive health and help in the treatment of infertility.

MATERIALS AND METHODS

The study conducted by getting IEC approval and registration of the study in the Clinical Trial Registry of India. IEC No: (GSMC-CH-1243/ME-2/010/2023) CTRI No: (CTRI/2024/05/068164).

2.1 Study Design

Pilot study

2.2 Study Place

The study was undertaken at the Postgraduate Department of Pothu Maruthuvam, GSMC, Chennai, involving outpatients from AAGHIM

2.3 Sample size

10 Patients

Total study period

3 months.

2.4 Participants

Inclusion Criteria:

To participate in the study, male subjects had to be between 21 and 50 years old and must have received a clinical diagnosis of oligospermia, specifically evidenced by a sperm count under 15 million per milliliter. Candidates needed to agree to undergo both semen analysis and relevant blood tests according to the examination protocol. Each participant is required to sign the informed consent prior to the study.

Exclusion Criteria:

Exclusion criteria were azoospermia or teratospermia, presence of hydrocele and varicocele. Those with systemic diseases such as diabetes mellitus were also excluded. Importantly, men with known genetic causes of infertility (such as Klinefelter syndrome) were excluded from participation in this study.

2.5 Intervention

Participants were given Vithuvagai Chooranam orally for 90 consecutive days

2.6 Outcome Measures

The study's prespecified endpoint was an increase in sperm concentration and motility. Secondary endpoints were changes in ejaculate parameters such as seminal volume, sperm count, morphology and viscosity. Safety of treatment was assessed with extensive monitoring of adverse events and surveillance for the duration of the study to ensure no unanticipated toxicity occurred.

2.7 Assessment Tools

The study will be assessed by both Siddha and modern parameters. Siddha evaluation methods include, Mukkutram, Udal Thathukkal, and Envagai Thervu. Modern evaluation methods follow Who guidelines 2010, semen analysis, Anti-sperm Antibody, Urine routine and Hematological parameters including hemoglobin (Hb), Total Count (TC), Differential Count (DC), Erythrocyte Sedimentation Rate (ESR), Blood Sugar, and Serum Testosterone levels.

Source of Raw Drug

The required raw drugs will be procured from a well reputed indigenous raw drug shop. The raw drugs taken for study will be authenticated by the Gunapadam department of Government Siddha medical college, Chennai. (Certificate No: GD/2024/05/39)

Ingredients of *Vithuvagai Chooranam*

The ingredients of the VVC are listed in Table 1**.**

Table: 1The ingredients of the VVC

S. No	The vernacular name of the ingredients	Botanical name	Quantity
1.	Ulundhu maavu	*Vigna mungo*	35 g

2.	Ellu podi	*Sesamum indicum*	35 g
3.	Poonaikaali vithu podi	*Mucuna pruriens*	35 g
4.	Neermulli vithu podi	*Hygrophila auriculata*	35 g
5.	Nilapanaikizhangu podi	*Curculigo orchioides*	35 g
6.	Thaneervitaan kizhangu chooranam	*Asparagus racemosus*	35 g
7.	Chukku podi	*Zingiber offcinale*	17.5 g
8.	Milagu podi	*Piper nigrum*	17.5 g
9.	Thippili podi	*Piper longum*	17.5 g
10.	White sugar	*Saccharum officinarum* L	262.5 g

Preparation of Vithuvagai chooranam

The purified ingredients numbered 1 to 6 were taken in the specified quantities and powdered well separately using a mortar. Similarly, the purified ingredients numbered 7 to 9 were roasted and then powdered well separately. All the individual powders were then mixed together thoroughly. The resulting mixture was sieved using a fine cloth to ensure uniformity. Purified sugar, taken in the mentioned quantity, was powdered and mixed thoroughly with the previously obtained powder. Finally, the prepared product was stored in an airtight container to maintain its stability and efficacy.

Dosage: *Mooviral alavu* - (800-1000mg) [BD]

Adjuvant: Honey/Ghee/Milk/Tender coconut

OBSERVATION AND RESULTS

Table: 2 Descriptive Statistics of Age of Participants (n = 10)

Parameter	Minimum (Years)	Maximum (Years)	Mean ± SD
Age	25.00	31.00	28.10 ± 2.13

Table: 3 Comparison of Semen Parameters Before and After Intervention

Parameter	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Mean Difference	*p*-value	Statistical Significance
Semen Volume (ml)	1.71 ± 0.33	2.70 ± 0.51	+0.99	0.000	Significant
Semen pH	8.33 ± 0.35	9.04 ± 0.23	+0.71	0.000	Significant
Liquefaction Time (min)	34.00 ± 3.16	26.00 ± 5.68	–8.00	0.003	Significant
Total Sperm Count (million/ml)	23.90 ± 5.69	33.30 ± 4.92	+9.40	0.000	Significant
Active Motile Sperm (%)	19.50 ± 4.97	30.50 ± 4.38	+11.00	0.000	Significant
Sluggish Motile Sperm (%)	41.00 ± 8.43	38.50 ± 7.09	–2.50	0.299	Not Significant
Non-Motile Sperm (%)	39.50 ± 8.64	31.00 ± 8.10	–8.50	0.000	Significant

Table: 4 Other Observations on Pus Cell Count in Semen

Observation	Before Treatment	After Treatment
Pus Cells in Semen	>5 pus cells (100%)	<5 pus cells (100%)

DISCUSSION

The results of the present study provide compelling evidence supporting the therapeutic potential of *Vithuvagai Chooranam* (VVC), a classical Siddha formulation, in improving male reproductive parameters, particularly in individuals diagnosed with oligospermia. The observed enhancements in semen volume, sperm concentration, motility, pH, and reduced liquefaction time reflect a comprehensive improvement in seminal quality and functionality. Notably, the significant increase in actively motile sperm and the decrease in non-motile sperm post-treatment indicate an improvement in sperm vitality, which is essential for successful fertilization. The decline in liquefaction time may point to improved seminal plasma composition, possibly influenced by enhanced prostatic or enzymatic activity facilitated by the herbal constituents in VVC. Moreover, the consistent reduction in pus cells across participants suggests the presence of anti-inflammatory or antimicrobial activity, which may aid in managing subclinical infections of the male reproductive tract-conditions often overlooked but impactful on fertility outcomes.

These therapeutic benefits align with the pharmacological attributes of VVC's ingredients, which include *Mucuna pruriens*, *Asparagus racemosus*, *Curculigo orchioides*, *Vigna mungo*, Hygrophila auriculata, and Sesamum indicum. Many of these herbs have been extensively documented for their aphrodisiac, antioxidant, immunostimulatory, and spermatogenic properties. Sahoo et al. reported similar findings where a polyherbal formulation (PHF) containing comparable ingredients improved male sexual competence in rats, evidenced by

reduced mount and intromission latencies, using sildenafil citrate as a reference standard (20). In preclinical studies, *C. orchioides* enhanced sexual behavior parameters such as penile erection, mounting frequency, and latency, attributed to its high flavonoid and polyphenol content (21). Likewise, *H. auriculata* reversed cyproterone acetate-induced reproductive damage in rats, restoring sperm quality and testosterone levels (22). V. mungo seed extracts, at 500 mg/kg, significantly enhanced libido and mating behavior in male rats (23,24), while A. racemosus demonstrated improved sexual activity at higher doses, supported by its rich saponin and mucilage content. Clinical evidence also supports the efficacy of *M. pruriens* in improving sperm parameters and alleviating oxidative stress in oligospermic men, with additional benefits observed in animal models at 75 mg/kg dosing (24,25). Apart, from this, it contains flavonoids, alkaloids and phenolic compounds presentation in S. indicum (26). The overall beneficial effect in semen quality observed in this study may be interpreted as a result of the synergistic activities from these herbs. Crucially, there were no reported adverse events during the 90-day trial indicating that VVC is safe and well tolerated as an adjunctive treatment. While these are all very exciting results there may also be some constraints as well. The study is limited by its small sample size, lack of a placebo-controlled or blinded design, and short duration. Hence, larger future RCTs with prolonged follow-up are warranted to confirm this effect, and examine the general and reproductive health associated benefits of VVC.

CONCLUSION

This study shows Vithuvagai Chooranam, a classical Siddha medicine has potential to improve semen parameters in oligospermia. The increase in sperm count, motility, volume and decrease in pus cells indicates multiple benefits due to the combination of its herbal ingredients. The medicine was well tolerated with no side effects during the study period. This study supports VVC as an adjunct therapy for male infertility. But larger controlled clinical trials are needed to confirm its efficacy and to extend its use in reproductive health care.

ACKNOWLEDGEMENT

We sincerely acknowledge The Principal, Government Siddha medical College, Chennai, for providing the opportunity and necessary facilities. We extend our heartfelt thanks to the Head of the Department, faculty members, for their continuous encouragement throughout the study. We are especially grateful to the patients who consented and cooperated during the course of treatment. We also thank all others who directly or indirectly contributed to the successful completion of this study.

PATIENT PERSPECTIVES

Participants in the study reported a positive experience with *Vithuvagai Chooranam* throughout the treatment period. Many expressed satisfactions with the ease of administration, absence of side effects, and the noticeable improvements in their overall health and well-being. Several participants shared that, beyond improvements in semen parameters, they experienced enhanced vitality, confidence, and reduced anxiety related to fertility. The use of a traditional, natural remedy also resonated with their cultural beliefs, which contributed to better compliance and trust in the treatment process. Overall, the intervention was well-received and offered both physical and emotional reassurance for individuals struggling with infertility.

INFORMED CONSENT

Written informed consent was obtained from the patients. The patients had given their consent for their images and other clinical information to be reported in the journal. The patients understood that their names and initials would not be published, and due efforts would be made to conceal their identity, but anonymity cannot be guaranteed.

FUNDING

The author(s) received no financial support for the research, authorship and/or publication of this article

ETHICAL APPROVAL

The study was approved by the Institutional Ethical Committee (IEC), Government Siddha Medical College, Chennai – 600106 (IEC No: GSMC-CH-1243/ME-2/010/2023). It was registered with the Clinical Trial Registry of India (CTRI No: CTRI/2024/05/068164), and initiated only after obtaining CTRI registration.

CONFLICT OF INTEREST

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

AUTHOR CONTRIBUTION

Conceptualization: SV; Data collection and compilation: SV, MM; Manuscript Writing: SV, MM; Proofreading and editing: SV, MM, RM, KSP

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