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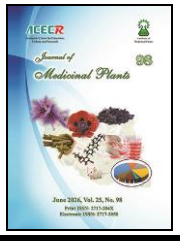

Research Article

Efficacy of Laboob-e Morakab Electuary, a traditional Persian formulation, in idiopathic male infertility: a quasi-experimental pilot study

Maryam Taghavi Shirazi[1], Fataneh Hashem-Dabaghian[1], Farnaz Sohrabvand[2], Soodabeh Bioos[2], Amirhossein Jamshidi[1], Atefe Talebian[2], Somaye Mahroozade[1,*]

[1]*Institute for Studies in Medical History, Persian and Complementary Medicine, School of Persian Medicine, Iran University of Medical Sciences, Tehran, Iran*

[2]*Tehran University of Medical Sciences, Tehran, Iran*

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ABSTRACT

Background: Male factor infertility accounts for 40-50 % of overall infertility cases. Despite medical advances, effective therapeutic options for idiopathic male infertility remain limited. **Objective:** This study aims to evaluate the clinical efficacy and safety of Laboob-e Morakab electuary (LME) - a traditional Persian polyherbal formulation - in improving semen parameters in men with idiopathic infertility. **Methods:** In a single-arm, quasi-experimental pilot study, 40 men with idiopathic male infertility received 5 g of LME orally twice daily for 3 months. Primary outcomes included sperm count, motility, morphology, and ejaculate volume, evaluated according to WHO (4th edition) guidelines at baseline and post-treatment. Statistical comparisons were performed using paired t-tests or Wilcoxon signed-rank tests. **Results:** Forty participants completed the 3-month intervention. LME administration significantly improved total sperm count, percentage of normal sperm morphology, and progressive motility ($P < 0.001$). Mean ejaculate volume increased significantly from baseline, and an improvement in libido was reported by 60 % ($n = 24$) of participants. No serious adverse events were observed. **Conclusion:** Laboob-e Morakab electuary demonstrated preliminary efficacy and safety in improving semen quality in idiopathic male infertility. Randomized, double-blind, placebo-controlled trials are warranted to confirm these findings.

1. Introduction

Primary infertility is an illness defined as the failure of a successful pregnancy after twelve months or more of intercourse without protection [1, 2]. Over 186 million people have infertility worldwide, with the majority living in developing countries [3]. The overall prevalence of infertility in Iran was reported at 7.88 %, which is slowly increasing [4]. In general, 40-50 % of total infertility is related to male factors [2, 5].

Male infertility can be caused by congenital or acquired anomalies of the urogenital system, infections of the genitourinary system, endocrine disorders, genetic abnormalities,

Abbreviations: LME, Laboob-e Morakab electuary; PM, Persian medicine; BMI, body mass index; IQR, Interquartile range

*Corresponding author: mahroozade.s@iums.ac.ir

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immune factors, lifestyle aspects, systemic diseases, changes in temperature of the scrotum (as a consequence of varicocele), erectile dysfunction, and incorrect intercourse habits [6]. However, 30-50 % of infertile men have idiopathic or unknown reasons. Most of these cases have poor semen parameters [2].

Recently, many advances have been made in the treatment of infertility. Although medical therapy and assisted reproductive technology such as surgical testicular sperm extraction, intracytoplasmic sperm injection, intrauterine insemination, and in vitro fertilization have been successful, most of them are invasive and cost a lot for individuals. Also, their efficacies in idiopathic male infertility are uncertain [2, 7].

Regarding the limitations in managing male infertility, further research is needed to find appropriate and effective treatments. Based on several studies, the frequency of use of complementary and alternative medicines in infertility is increasing worldwide [2, 8-11].

As a holistic medicine, Persian Medicine (PM) believes that human body organs are always interdependent [12, 13]. Accordingly, the function of the main organs, such as the heart, brain, liver, and reproductive system, plays essential roles in male fertility [14-18].

Laboob-e Morakab or *Lobub -e Morakkab* Electuary (LME) is a nutraceutical PM polyherbal formula well documented in traditional Iranian medical books for its effectiveness in male infertility, strengthening kidneys, sexual organs, and semen parameters [16, 19, 20].

In a case series, it has been shown that the administration of Majoon-e Loboob or Skink electuary, a PM formulation that has the same purpose as LME, can significantly increase the chance of pregnancy in patients with idiopathic oligoasthenospermia [9]. Another case study reported the remarkable role of Loboob, a similar PM product to LME, in improving the sperm parameters of an infertile man [21]. However, a larger-scale and high-quality trial on the efficacy of this PM formula on semen quality and male infertility has never been conducted. Therefore, this pilot study was designed to assess the potential effect of LME on semen analysis parameters in men with idiopathic infertility.

2. Materials and methods

2.1. Study design and setting

A quasi-experimental study was conducted from September 2015 to May 2016 in participants referred to the Persian medicine clinics in Imam Khomeini Hospital Complex under the supervision of the Tehran University of Medical Science with a previous diagnosis of idiopathic male infertility based on a specialist opinion.

The inclusion criteria were age between 20-45 years, a history of primary infertility for at least one year, and unexplained oligoasthenospermia according to the 4th edition of World Heritage Organization (WHO) criteria as follows [22]:

1- Sperm concentration lower than 20 million/ml

2-Motile sperm lower than 50 %

3- The normal morphology is less than 30 %

Participants were also excluded if they had a history of using chemotherapy intake, corticosteroid, anticoagulation, testosterone, or antiandrogen; the incidence of severe cases of oligospermia (sperm concentration less than one million per milliliter); infections, genital anatomical abnormalities, chromosomal abnormalities, or a history of surgery on the genital tract, exposure to toxins; alcohol or drug abuse and systemic diseases (cancer, thyroid,

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liver and gall bladder diseases, renal failure, etc.); unwillingness to continue treatment or development of adverse effects during the study.

2.2. Sample size calculation

Considering $\alpha = 0.05$ and a study power of 80 %, and based on varying values of σ and d for sperm count, volume, morphology, and motility, the required sample size was assessed to be 43 participants [9].

This study did not include a control group, as it was designed as a pilot trial to assess the potential efficacy of LME preliminarily. The study's exploratory nature and limited resources did not allow for the inclusion of a comparison arm. Finally, forty participants were enrolled and completed the study.

2.3. LME formula preparations:

Laboob-e Morakab Electuary (LME) was prepared and packaged by "*Talaye Sabze Touba*" Company (Tehran, Iran). It obtained the license number S -94-0361 of the Iranian Food and Drug Organization with registration number 462264 under the Iranian Ministry of Health standards.

This electuary consists of various medicinal herbs, with the main ingredients including *Pistacia vera*, *Cocos nucifera*, *Corylus avellana*, *Pinus gerardiana*, *Prunus amygdalus*, *Sesamum indicum*, *Myristica fragrans*, *Lepidium sativum*, *Medicago sativa*, *Zingiber officinale*, *Boswellia carteri*, *Alyssum minus*, and *Urtica dioica*, combined with sugar and honey as carriers. The specific proportions of each component are detailed in Table 1.

2.4. Intervention

At the beginning of the study, participants underwent a semen analysis test after 3-5 days of sexual abstinence. Participants were recommended to collect the semen, preferably by self-stimulation or with a non-spermicidal condom, into a clean glass or plastic container. Because sperm motility decreases after ejaculation, the samples were analyzed within 1 hour at most of the procurement [10, 22].

5 gr of LME with a cup of warm milk twice a day (before breakfast and at bedtime) for 3 months was prescribed to individuals who met the inclusion criteria. After 12 weeks, an additional semen analysis was performed.

All participants were advised to maintain a regular diet and lifestyle and refrain from taking any antioxidant supplements during the intervention. Also, medication compliance was evaluated weekly via phone call or text message.

To evaluate semen analysis, all participants were sent to a specific Lab (*Danesh* Pathobiology Laboratory) in Tehran for the results to be compared before and after the intervention and to reduce bias in the research.

Table 1. *Lobub -e Morakkab* Electuary ingredients

No.	The scientific name of the ingredients	Common name	Ratio (unit)
1	*Prunus amygdalus*	Almond	10
2	*Sesamum indicum*	Sesame	10
3	*Alyssum minus*	Alyssum	6
4	*Pistacia vera*	Pistachio	5
5	*Cocos nucifera*	Coconut	5
6	*Corylus avellana*	Hazelnut	5
7	*Pinus gerardiana*	Chilgoza pine	5
8	*Zingiber Officinalis*	Ginger	2
9	*Boswellia carteri*	Oliban	2
10	*Myristica fragrans*	Nutmeg	1
11	*Lepidium sativum*	Cress seeds	1
12	*Medicago sativa*	Alfalfa	1
13	*Urtica dioica*	Nettle	1
14	Sugar	Sugar	10
15	Honey	Honey	140

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2.5. Outcome measures

Throughout the study, the semen parameters, including volume, motility, concentration, and morphology, were evaluated objectively by microscopic examination and analyzed according to WHO criteria [23] by technicians under the supervision of an andrologist as primary outcomes.

The minimal standards of Adequacy for semen analyses are listed below:

- Ejaculate volume: 1.5-5.5 ml
- Sperm concentration > 20×10^6 sperm/ml
- Motility ≥ 40 %
- Morphology > 30 % WHO normal forms (> 4 % Kruger normal forms) [22]

The results were determined by comparing the difference between the monitoring and the reference values. The pregnancy rate in men's wives was considered a secondary outcome during the study. In addition, self-reported libido changes and any side effects were recorded through structured interviews at the beginning and end of the study.

2.6. Ethical consideration

The study protocol was approved by the Ethics Committee of Tehran University of Medical Sciences (Code: IR.TUMS.REC.1394.847) and registered at the Iranian Registry for Clinical Trials IRCT2015100624377N1 (updated on 2023-02-14).

All participants signed informed consent. During this period, participants could contact the researcher to ask questions or report possible side effects.

2.7. Statistical analysis

The data were analyzed using SPSS software (version 17, SPSS Inc., Chicago, III., USA). Quantitative variables were described by mean and standard deviation. The before-after comparisons were made using a paired t-test or Wilcoxon Signed Ranks Test. Qualitative data were described by frequency and percentage. A $P < 0.05$ was considered as the significance level.

3. Results

Of the 100 men evaluated for eligibility, 43 who fulfilled WHO criteria for sperm impairment entered the study. Finally, 40 of them completed the trial. One of the infertile men was excluded due to itching after 5 days of use, and two participants entered another fertility treatment after 1 month and left the study (Figure 1).

Table 2 presents the basic characteristics of the participants. Their mean age was 34.03 ± 4.9 yrs. The duration of marriage was 2-19 yrs, and the mean duration of deciding to have a baby was 5.05 ± 3. 74. 75 % of participants had prior assisted reproductive technology experience. Eighteen men had a history of failing one or two times intrauterine insemination in their spouses. Moreover, 12 women of sterile men suffered an unsuccessful in vitro fertilization. Most of the participants had primary infertility.

3.1. Primary study outcomes

After 3 months, the results show a statistically significant increase for all four variables in sperm analysis in the LME group ($P < 0.001$). In this way, sperm count improved by more than 40 %, and sperm volume improved by almost double. In addition, the mean percentage of spermatozoa with normal morphology increased by 21.9 %, and sperm motility improved by 29.9 % (Table 3). Moreover, 24 (60 %) men reported an enhancement in libido, and 6 (15 %) reported improved premature ejaculation.

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3.2. Secondary study outcomes

No pregnancies occurred during the intervention, and the participants reported no major adverse effects. Only one man withdrew from the study because of itching.

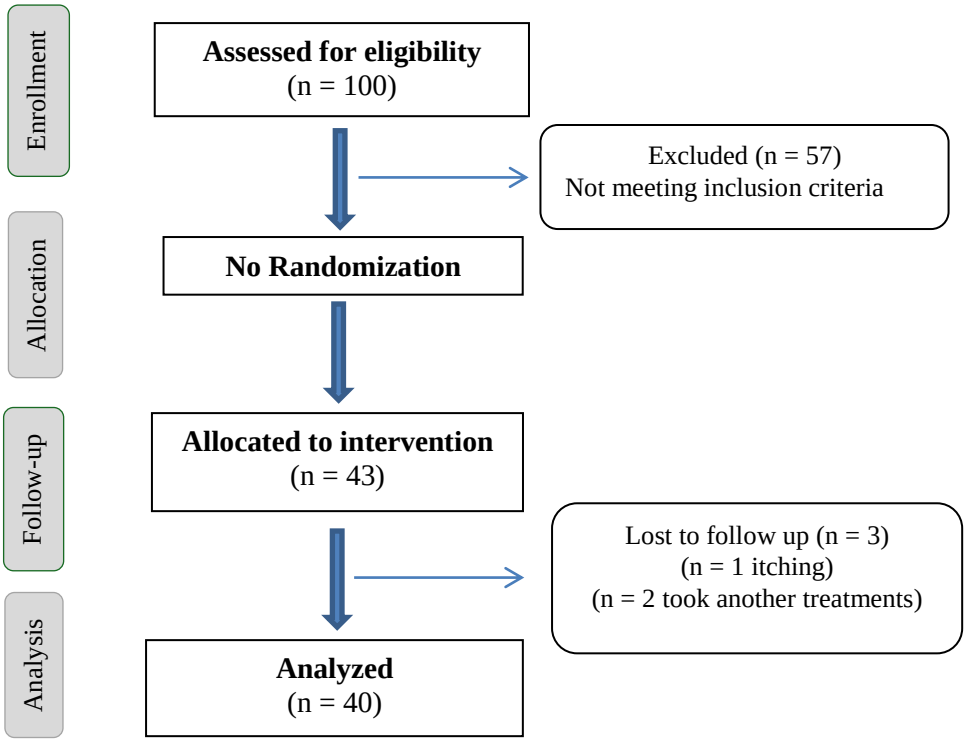

Fig. 1. CONSORT diagram showing patient flow

Table 2. The baseline characteristics of participants enrolled in the study

Variables		Baseline
Age (yr) (mean ± SD)*		34.03 ± 4.9
BMI*		25.53 ± 2.4
Education, n (%)**	Diploma	16 (40)
	More than a diploma	24 (60)
Duration of marriage*		7.07 ± 4.21
Duration of deciding to have a baby (yr)*		5.05 ± 3.74
Intercourse per week*		2.12 ± 0.72
Concurrent positive female factor**		18 (45)
History of using fertilization methods**		30 (75)

* Data presented as mean±SD. ** Data presented as n (%), BMI: body mass index

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Table 3. Semen analysis before and after the intervention

Variables	Before intervention	After intervention	P-value	95% CI	Change (%)
Semen volume (ml) *	2.58 ± 0.6	3.63 ± 0.8	< 0.001	-1.3_ -0.75	**49.72 ± 52.32**
Sperm count ** (m/ml)	10 (23.8)	17.75 (21)	< 0.001a		**40.65 (198.83)**
Normal sperm motility *	25.48 ± 14.6	47.45 ± 17.3	< 0.001	-17.23_ -9.4	**21.96 ± 14.74**
Normal sperm shape*	23.61 ± 22.5	53.55 ± 17.5	< 0.001	-23.89_ -10	**29.93 ± 8.87**

* Data presented as mean ± SD. ** Data presented as median (IQR). IQR: interquartile range, a**:** Wilcoxon Signed Ranks Test.

4. Discussion

The results of the present quasi-experimental trial demonstrated that LME significantly improved the main parameters of sperm analysis in men with idiopathic infertility. This finding aligns with previous observations and traditional knowledge regarding LME's potential in male reproductive health.

Before this study, the authors reported a case report on the efficacy of this PM formula in a man suffering from severe oligoasthenoteratozoospermia. After six years of infertility and multiple unsuccessful ICSI procedures, he took the *Loboob* for 3 months. A remarkable improvement in his sperm parameters was reported at the end of the intervention, leading to the formation of eight embryos in the next ICSI cycle [21].

Also, in another case series, 13 Iranian men with idiopathic infertility were treated with 10 g *Majoon-e Loboob* twice daily. The study concluded that in eleven (84.6 %) cases, their wives became pregnant 4.8 ± 2.0 months after taking the formula. However, participants with severe oligoasthenospermia (< 0.1×10^6/ml) report no changes in their sperm analysis. It is important to note that this was an observational study (not a trial), and product ingredients differed slightly from LME in the present trial [9].

According to the literature on PM, the brain, heart, stomach, kidney, and liver, as well as sexual organs, have essential roles in productivity. In this respect, any dysfunction of these systems can lead to infertility [14, 15].

PM scholars believed the LME had a high potency to increase libido and semen production [18, 19]. In addition, LME ingredients, rich in nutritious components, have fundamental roles in strengthening the reproductive system and major-related organs [24-27] (Table 4).

Modern research corroborates some of these traditional perspectives, particularly regarding the role of antioxidants in male fertility. Oxidative stress is a significant contributor to male infertility, and elevated levels of reactive oxygen species can compromise semen quality. Antioxidant-rich substances are therefore considered beneficial for male fertility parameters [28]. Many components found in LME, such as honey, sesame, and sweet almonds, are known for their antioxidant properties. They have been investigated for their positive effects on semen parameters and male fertility [29-32]. For instance, studies have shown honey's diverse biological properties, including antioxidant effects on reproductive systems [29, 30]. Sesame has demonstrated efficacy in improving semen parameters in both animal and human studies [31, 33, 34]. At the same time, sweet almonds have shown antioxidant activity and the potential to reduce abnormal sperm morphology in animal studies [35, 36]. Other ingredients like pistachio, coconut, hazelnut, and ginger have also been reported to benefit male fertility and sperm parameters [37-40].

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Table 4. The characteristic of *Lobub -e Morakkab Electuary* ingredients in reproduction

ML Ingredients	Part used	Brain	Heart	Kidney	Liver	Stomach	Libido	Sperm production
Alyssum minus **(Alyssum)**	seeds						+	
Boswellia carteri **(Oliban)**	resin	+	+				+	+
Cocos nucifera **(Coconut)**	fruit			+			+	
Corylus avellana **(Hazelnut)**	seeds	+					+	
Lepidium sativum **(Cress seed)**	seeds						+	+
Medicago sativa **(Alfalfa)**	seeds						+	+
Myristica fragrans **(Nutmeg)**	seeds					+	+	
Pinus gerardiana **(Chilgoza pine)**	seeds	+					+	
Pistacia vera **(Pistachio)**	seeds	+			+	+	+	
Prunus amygdalus **(Almond)**	seeds	+	+	+			+	+
Sesamum indicum **(Sesame)**	seeds						+	+
Urtica dioica **(Nettle)**	seeds							
Zingiber officinalis **(Ginger)**	root				+	+	+	+

LME: Lobub -e Morakkab Electuary

Despite these capable findings, the present study as a quasi-experimental trial has some limitations warrant consideration. The lack of a control group limits the ability to attribute the observed improvements to LME. Additionally, the small sample size further confines the generalizability of the findings.

The absence of blinding also introduces potential bias, and crucially, the study did not include long-term follow-up, preventing the assessment of LME's sustained effects on sperm parameters and pregnancy rates. As a result, only a limited statistical analysis was possible.

Hence, future studies should employ larger, randomized, double-blind, placebo-controlled trials with long-term follow-up to confirm LME's efficacy, sustained benefits, and impact on live birth rates.

5. Conclusion

According to the study findings, Laboob-e Morakab Electuary (LME), a nutraceutical herbal formulation derived from Persian Medicine, holds promise for improving sperm parameters without apparent adverse effects.

While these initial findings are encouraging, it's essential to acknowledge the limitations of this quasi-experimental trial. Future research is needed to validate these observations and fully understand LME's clinical impact on male fertility.

Author contributions

M.TSH and S. M. were the guarantors of the integrity of the entire study and contributed to the study concepts and design; F.HD, F.S. S.B, A.J, and A.T contributed to the design, analysis,

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and interpretation of data; all the authors contributed to the manuscript preparation, and approved the final version to be published.

Conflicts of interest

The authors declare that they have no conflict of interest.

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