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Clinical validation of unani pharmacopoeial formulation *Majoon-e-Piyaz* in *Surat-e-Inzal* (Premature ejaculation)

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Abstract
Each participant was well informed about the trial and written consent was obtained before initiation of the study. Demographic data and information on the present disease condition, concomitant disease and therapy was recorded. Thorough general physical and systemic clinical examination was carried out. Signs and Symptoms pertaining to premature ejaculation were recorded in CRF. The vital parameters like blood pressure, heart rate, temperature and respiratory rate were also recorded. Blood sample were collected for the evaluation of laboratory parameters like Haemogram, complete blood picture, kidney function test, liver function test and routine and microscopic examination of urine were done. All clinical and laboratory follow up were done at every 4 weeks.
The study was carried out in a total number of 105 patients of premature ejaculation satisfying the criteria, 80 patients completed the trial. All the patients received treatment with Majoon-e-Piyaz**,** out of 80 subjects 06 patients got complete remission, 47 patients got partially remission, 27 patients showed poor remission and 25 patients dropped out. No hepatotoxic and nephrotoxic side effects noticed during the course of study. The clinical and laboratory findings after treatment have shown that Majoon-e-Piyaz possessed efficacy in the treatment of premature ejaculation.

Keywords: Premature ejaculation, Surat-e-inzal, Unani medicine, Majoon-e-Piyaz, remission

Introduction
According to *Tibb-e-Unani* literature all sexual functions (including generation of semen, sperm and ovum and formation of foetus in the mother's womb) depend on *Al quwa-e-tanasuliyah* (reproductive faculties). This Q*uwa* (Faculty) controls many other functions related to reproduction including male and female functions. Q*uwat-e-Bah* (Faculty of sexual potency and libido) governs sexual functions and is essential for maintenance of sexual functions, Bah caries the meaning of virility, lust venereal passion and generative poser.
The faculty of sexual potency and libido (Q*uwat-e-Bah*) depends on health and proper functioning of vital organs *viz*. brain, heart, liver, whereas the sexual function depends on health and proper functioning of vital and genital organs. Any condition affecting adversely on these organs results in *Surat-e-Inzal* (Premature Ejaculation). (Ishtiyaque 1980) [18]
Surat-e-Inzal (Premature ejaculation) is a condition in which ejaculation of semen takes place earlier than normal. It occurs immediately after insertion of penis or rarely even on friction with clothes.
It is caused by predominance of *Burūdat* (Cold) and *Rutūbat* (Wetness) leading to the weakening of Q*uwwat Māsika* (Retentive power), *Kasrat-i Manī* (Excess of semen), predominace of *Dam* (Sanguine), *Hurqat o Hiddat-i Manī* (Increased motility and acuteness of semen), *Zu'f-i A'zā Ra'īsa* (Weakness of vital organs) and *Ittisā'-i Majārī-i Qazeīb* (Dialatation of passages for semen).[2] Sometimes it is caused by *Sū'-i Mizāj Hār* (Hot morbid temperament) of kidneys and testicles and it may be congenital also. It is characterized by ejaculation of semen during foreplay or shortly after the insertion of penis.
The Second International Consultation on Sexual and Erectile Dysfunction defined PE as '*ejaculation with minimal stimulation and earlier than desired, before or soon after penetration, which causes bother or distress, and over which the sufferer has little or no voluntary control*' (McMahon CG 2004) [26].

The International Society for Sexual Medicine (ISSM) has adopted a completely new definition of PE which is the first evidence-based definition, '*Premature ejaculation is a male sexual dysfunction characterized by ejaculation which always or nearly always occurs prior to or within about one minute of vaginal penetration; and inability to delay ejaculation on all or nearly all vaginal penetrations; and negative personal consequences, such as distress, bother, frustration and/or the avoidance of sexual intimacy*'. It must be noted that this definition is limited to men with lifelong PE who engage in vaginal intercourse since there are insufficient objective data to propose an evidence-based definition for acquired PE (McMahon CG, 2008) [27].

All the definitions have taken into account the time to ejaculation, the inability to control or delay ejaculation, and negative consequences (bother/distress) from PE. However, the major point of debate is quantifying the time to ejaculation, which is usually described by intravaginal ejaculatory latency time (IELT). Several proposals for updating the definition of PE in the forthcoming DSM-V and ICD-11 have been presented (Balon R, 2007, Waldinger MD, 2007 Waldinger MD, 2006) [4, 48, 46].

Premature ejaculation is classified as 'lifelong' (primary) or 'acquired' (secondary) (God pod in off ML. 1989).

Lifelong PE is characterized by onset from the first sexual experience, remains so during life and ejaculation occurs too fast (before vaginal penetration or < 1-2 min after).

Acquired PE is characterized by a gradual or sudden onset following normal ejaculation experiences before onset and time to ejaculation is short (usually not as short as in lifelong PE).Recently, two more PE syndromes have been proposed (Waldinger MD, 2006) [46]:

Natural variable PE' is characterized by inconsistent and irregular early ejaculations, representing a normal variation in sexual performance.

Premature-like ejaculatory dysfunction' is characterized by subjective perception of consistent or inconsistent rapid ejaculation during intercourse, while ejaculation latency time is in the normal range or can even last longer. It should not be regarded as a symptom or manifestation of true medical pathology.

The addition of these new types may aid patient stratification, diagnosis and treatment, but their exact role remains to be defined (Waldinger MD. 2007) [48].

The major problem in assessing the prevalence of PE is the lack of an accurate (validated) definition at the time the surveys were conducted (Waldinger MD. 2002) [51]. However, epidemiological research has consistently shown that PE, at least according to the DSM-IV definition, is the most common male sexual dysfunction, with prevalence rates of 20-30% (Laumann EO 2005, Laumann EO, 1999, Porst H, 2007) [24, 25].

The highest prevalence rate of 31% (men aged 18-59 years) was found by the National Health and Social Life Survey (NHSLS) study in USA (Laumann EO, 1999) [25]. Prevalence rates were 30% (18-29 years), 32% (30-39 years), 28% (40-49 years) and 55% (50-59 years). These high prevalence rates may be a result of the dichotomous scale (yes/ no) in a single question asking if ejaculation occurred too early, as the prevalence rates in European studies have been significantly lower. A British self-completed mailed questionnaire survey estimated that the prevalence rate of PE was between 14% (3 months) and 31% (life-time) (Dunn KM, 1998) [11]. A French telephone survey of men aged 40 to 80 years estimated the prevalence of premature ejaculation at 16% (Buvat J, 2009) [8]. A Swedish interview reported an overall prevalence rate of 9% in men aged 18 to 74 years (Fugl-Meyer AR, 1999) [12], with prevalence by age being 4% (18-24 years), 7% (25-34 years), 8% (35-49 years), 8% (50-65 years) and 14% (66-74 years). A Danish study about sexual problems using a questionnaire (12 questions) and an interview (23 questions) reported the prevalence rate for PE to be 14% in men aged 51 years (Solstad K, 1993) [41] while in another Danish random population survey using a structured personal interview the prevalence rates of PE were 7% in men aged 16-95 years (Christensen BS, 2011, 22) [9]. An Italian questionnaire-based survey in andrological centres recorded a prevalence rate of 21% (Basile Fasolo C, 2005) [6]. In a self-administered questionnaire-based survey in the Netherlands, the prevalence rate was 13% in men aged 50-78 years (Blanker MH, 2001) [7].

The prevalence of PE in the Premature Ejaculation Prevalence and Attitudes (PEPA) survey (a multinational, internet-based survey) was 22.7% (24.0% in the USA, 20.3% in Germany, and 20.0% in Italy). The Global Study of Sexual Attitudes and Behaviours (GSSAB) survey was conducted in men between 40 and 80 years old in 29 different countries using personal and telephone interviews and self-completed mailed questionnaires; it confirmed that the worldwide prevalence of PE was almost 30%. Except for a low reported rate of PE in Middle Eastern countries (10-15%), prevalence was relatively similar throughout the rest of the world. The prevalence rate of PE was 18% in a five-country European Observational study using the IELT and the Premature Ejaculation Profile (PEP), comparable to those obtained in a similarly designed US observational study. Two studies reported on PE prevalence rates based on the Premature Ejaculation Diagnostic Tool (PEDT). A computer-assisted interviewing, online, or in-person survey in nine countries in the Asia-Pacific region reported prevalence rates of 16% (premature ejaculation), 15% (Probable PE) and 13% (self-reported PE). Another study at a primary care clinic in Malaysia reported prevalence rates of 20.3% for PE and 20.3% for probable PE (28). Finally, the only study reporting prevalence of all four proposed classifications of PE was a non-interventional, observational, cross-sectional field survey conducted in Turkey (29). Overall, the prevalence rate of PE was 20%. The prevalence rates were 2.3% (lifelong), 3.9% (acquired PE), 8.5% (natural variable PE) and 5.1% (premature-like ejaculatory dysfunction) (Patrick DL, 2005, Tang WS, 2011 Serefoglu EC, 2011) [33, 43, 39].

Further research is needed on the prevalence of lifelong and acquired PE. Limited data suggests that the prevalence of lifelong PE, defined as IELT < 1-2 min, is about 2-5%. These results are supported by the moderate genetic influence on PE and low prevalence rates of IELT < 1 minute (Jern P, 2007 Waldinger MD, 2005) [19, 45].

Pathophysiology and risk factors the aetiology of PE is unknown, with little data to support suggested biological and psychological hypotheses, including anxiety, penile hypersensitivity, and 5-HT receptor dysfunction (McMahon CG, 2004) [26].

Factors responsible for *Surat-e-Inzal* (Premature ejaculation)

1. Inexperience and ignorance of sexual techniques.

2. *Zakawat-e-Hiss* (Hypersensitivity) of genital organs.
3. *Zofe-e-Quwat-e-Maska* (Decrease retentive power)
4. Increase *Quwat-e-Dafeayah* (Increased power of propulsion)
5. *Kasrat-e-Mani* (Seminal abundance) due to excessive use of *Movallide mani* (Seminopoietic substance and long abstinence from intercourse).
6. *Hiddat-e-Mani* (Seminal pungency).
7. *Riqqat-e-Mani* (Decreased viscosity of semen)
8. *Zofe-e-Aza-e-Raeesa* and *Zof-e-Bah* (Debility of vital organs and sexual debility).
9. *Iltehab Aza-e-Tanasuliyah* (Inflammation of genital organs) e.g. Urethritis and inflammation of seminal vesicle. 3
10. Miscellaneous Causes: Excessive sexual thoughts over indulgence in sexual intercourse, anxiety, guilt associated with masturbation, sodomy, abnormalities in prepuce, dilation of urethra, spermatorrhea, too narrow vagina, Bladder stone, intestinal worms, haemorrhoides etc. (Khan 1769, Kabiruddin 1926, Mobeen 1934 and Basheer 1886) [23, 20, 34, 5].

The aetiology of premature ejaculation is not known. To date, no biological factor has been shown to be causative in the majority of men with PE.

Premature ejaculation is believed to be a psychological problem and does not represent any known organic disease involving the male reproductive tract or any known lesions in the brain or nervous system. The organ systems directly affected by premature ejaculation include the male reproductive tract (i.e. penis, prostate, seminal vesicles, testicles, and their appendages), the portions of the central and peripheral nervous system controlling the male reproductive tract, and the reproductive organ systems of the sexual partner.

Labor questions have been raised regarding possible biochemical factors in premature ejaculation. Testosterone is thought to play a role in the ejaculatory reflex. Higher testosterone (free and total) levels have been demonstrated in men with premature ejaculation than in men without premature ejaculation. (Waldinger MD. 2007) [48]

Research published in a Chinese andrology journal showed that semen from men with premature ejaculation contained significantly less acid phosphatase and alpha-glucosidase than did the semen of controls. These researchers concluded that these biochemical parameters may reflect dysfunction of the prostate and epididymis, possibly contributing to premature ejaculation; however, these have yet to be supported by subsequent studies.

In other biochemical parameters, many men with premature ejaculation have been shown to have low serum levels of prolactin. However, in this same study of prolactin in men with sexual dysfunction, men in the lowest quartile of serum prolactin levels who had premature ejaculation also demonstrated associated metabolic syndrome, erectile dysfunction, and anxiety. In other words, while biochemical markers such as prolactin may contribute to premature ejaculation, organic and psychological associations (*i.e.* anxiety) suggest that biochemical parameters play only a partial role in premature ejaculation.

While other factors may play roles of unknown significance, psychological factors have been found to contribute greatly to premature ejaculation beyond merely the time to ejaculation. While patients with premature ejaculation show significantly lower intravaginal ejaculatory latency time (IELT), the IELT in those who fit the *DSM-IV-TR* criteria for premature ejaculation overlaps with the IELT in patients who do not fit the criteria. However, while a shorter IELT has been the measure of premature ejaculation in many studies, the perception of ejaculation control has been shown to mediate patient and/or partner satisfaction with sexual intercourse and ejaculation-related distress. While premature ejaculation is most likely not a purely psychological disorder, such associations demonstrate a significant psychological role in the disorder.

If the patient has always experienced premature ejaculation from the time he began coitus, then he has primary premature ejaculation. If he had successful coital relationships in the past, yet began experiencing premature ejaculation with the current relationship, then he has secondary premature ejaculation. In most cases, secondary premature ejaculation is easier to treat and has a better prognosis. (Cihan A. *et al* 2009, Vignozzi L *et al* 2005) [10, 44].

Material and Methods

Type of trial: An open level clinical trial.

Research Methodology

Each participant was well informed about the trial and written consent was obtained before initiation of the study. Demographic data and information on the present disease condition, concomitant disease and therapy was recorded. Thorough general physical and systemic clinical examination was carried out. Signs and Symptoms pertaining to Surat-e-Inzal (Premature Ejaculation) were recorded in CRF. The vital parameters like blood pressure, heart rate, temperature and respiratory rate were also recorded and blood samples were collected for the evaluation of laboratory parameters like Haemogram, and confirm inclusion criteria and other laboratory test like complete blood picture, kidney function test, liver function test and routine and microscopic examination of urine were done. All clinical and laboratory follow-up were done at every 4 weeks.

Selection criteria

The patients of *Surat-e-Inzal* (Premature Ejaculation) attending the OPD of respective centres will be selected for the study. A detailed clinical history will be taken and complete physical examination will be carried out to make the clinical diagnosis of *Surat-e-Inzal* (Premature Ejaculation). Patients will be considered eligible for enrolment into this study if they fulfill all of the inclusion criteria and none of the exclusion criteria, as defined below:

Inclusion Criteria

The following criteria will be strictly followed for inclusion of cases in the study.

1. Male patients in the age group of 21 to 65 years.
2. Men with an IELT (Intra-vaginal ejaculatory latency time) of less than 1 minute will be included in the study
3. Men with a PEDT Score >11

Exclusion Criteria

The patients of *Surat-e-Inzal* (Premature ejaculation) with following conditions will be excluded from the study:

1. Patients with Erectile Dysfunction
2. Patients with diseases requiring long term treatment

3. Patients with cognitive impairments
4. History of addiction (smoking, alcohol, drugs)

Subject recruitment
Patients with *Surat-e-Inzal* (Premature Ejaculation) attending the OPD of respective Centers will be assessed for clinical, biochemical, and pathological parameters. If they do not meet the exclusion criteria and fulfill the inclusion criteria, they will be enrolled in the present study. They will be informed about the nature and objectives of the study and details of other study related procedures. Informed consent will be obtained before enrolling into the study. The detailed history will be recorded and the patients will be examined in detail clinically to record the various signs and symptoms of *Surat-e-Inzal* (Premature Ejaculation). The study drug will be dispensed as per the schedule and patients will be instructed to take the medicine as per the protocol.

Sample Size: 80 Completed subjects in all respects.

Duration of protocol therapy
The total duration of treatment will be 2 weeks.

Duration of study
The required number of study subjects will be attainable in the institute's OPD in two years. Hence, the duration of research project will be two years.

Follow up of subject
Patients were followed up at every 15 days to record change in symptoms and signs. Clinical follow up and investigations were performed at the base line, after Munzij-Mushil therapy and every 30 days gap and at the end of study. Follow up of relieved cases were performed after every three months for one year.

Safety assessment: The safety was assessed by monitoring adverse events reported by the patients or elicited by the investigator on clinical as well as laboratory investigations before and after treatment. The laboratory tests included Haematological tests (Hb, TLC, DLC, ESR), Liver function test (Serum bilirubin, SGOT, SGPT and alkaline phosphatise) and Kidney function tests (Blood urea and serum creatinine).

Statistical data recording: Data recording was done on separate case record form for each subject at base line, after M. M. Therapy and at every 15 days up to three months. Active and passive complaints of patients were recorded in grades starting from "+" to "+++" at the time of Base line and at different follow up. Percentage in grading was calculated and results were assessed in terms of complete remission (more than 70%), partially remission (50% to 70%), Poor remission (less than 50%).
Each participant will be well informed about the study and provided a participant information sheet (PIS); a written informed consent will be obtained before initiation of any study related procedure. Demographic data and information on the present disease condition, concomitant disease and therapy will be recorded. Thorough general physical and systemic clinical examination will be carried out. Signs and symptoms pertaining to *Surat-e-Inzal* (Premature Ejaculation) will be recorded in the CRF. Vital signs including blood pressure, heart rate, temperature and respiratory rate will be noted. Blood samples will be collected for the evaluation of laboratory parameters including, Haemogram, LFTs, KFTs, and Fasting Blood Glucose to establish and confirm Inclusion and Exclusion criteria. The follow-up for clinical parameters will be done once in a week during treatment.

Subject recruitment
Patients with *Surat-e-Inzal* (Premature Ejaculation) attending the OPD of respective Centers will be assessed for clinical, biochemical, and pathological parameters. If they do not meet the exclusion criteria and fulfill the inclusion criteria, they will be enrolled in the present study. They will be informed about the nature and objectives of the study and details of other study related procedures. Informed consent will be obtained before enrolling into the study. The detailed history will be recorded and the patients will be examined in detail clinically to record the various signs and symptoms of *Surat-e-Inzal* (Premature Ejaculation). The study drug will be dispensed as per the schedule and patients will be instructed to take the medicine as per the protocol.

Duration of protocol therapy
The total duration of treatment will be 2 weeks.

Duration of study
The required number of study subjects will be attainable in the institute's OPD in two years. Hence, the duration of research project will be two years.

Study drug management
The following Unani pharmacopeial formulation will be used in this study:

S. No.	Study Drug	Dosage Form	Dose	Frequency	Route of Administration	Method of administration
1.	*Majoon-e-Piyaz*	Semi solid	7g	Twice daily	Oral	To be taken with water after meals

Composition of *Majoon -e- Piyaz*

S. No.	Ingredients	Botanical / Chemical Name	Quantity
1.	Tudri Surkh	*Matthiola incana*	35 g
2.	Tudri Safaid		35 g
3.	Salab Misri	*Orchis latifolia*	35g
4.	Behman Surkh	*Salvia haematodes*	35 g
5.	Behman Safaid	*Centaurea behman*	35 g
6.	Zanjabeel	*Zingiber officinale*	35 g
7.	Tukhm-e-Piyaz	*Allium cepa*	35 g
8.	Tukhm-e-Turb	*Raphanus sativus*	35 g
9.	Tukhm-e-Gandana	*Allium ascalonicum*	35 g

10.	Tukhm-e-Shalgham	*Brassica rapa*	35g
11.	Talmakhana	*Asteracantha longifolia*	35g
12.	Musli Safaid	*Chlorophytum arundinaceum*	35g
13.	Musli Siyiah	*Curculigo orchioides*	35g
15.	Aab-e-Piyaz	*Allium cepa* (aqueous Extract)	1.5 litter
16.	Asal/Quand Safaid		1.5kg

(NFUM, Part-I, p. 139)

Laboratory Investigations

Each case of *Surat-e-Inzal* (Premature ejaculation) selected for the study will be subjected to the following pathological and biochemical investigations at baseline and at the end of treatment and the reports received from the laboratory will be attached to the CRF.

Pathological Investigations

- Haemogram: Hb, Ht (PCV), Reticulocyte count, MCV, MCH, MCHC, TLC, DLC, platelet count, ESR
- Urine (Routine and Microscopic Examination)

Biochemical Investigations

- **Liver Function Tests (LFTs):** (Serum Bilirubin, SGOT, SGPT and S Alkaline Phosphatase)
- **Kidney Function Tests (KFTs):** (Serum Creatinine, Serum Urea)
- Fasting Blood Glucose (at baseline only)

Assessment of safety

Safety will be assessed clinically and by laboratory parameters at baseline and end of the study:

Laboratory Parameters

- Haemogram 7
- LFTs: S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase
- KFTs: S. Urea, S. Creatinine, S. Uric Acid
- Urine Examination: Routine & Microscopic

Assessment of efficacy

Patients fulfilling the enrolment criteria will be assessed on the basis of PEDT (Premature Ejaculation Diagnostic Tool) at every follow up and score will be recorded in the Case Record Form. PEDT (Premature Ejaculation Diagnostic Tool) is a questionnaire to help identify men who may have a problem with ejaculating too soon during sexual activity

S. No	PEDT Questionnaire	Not difficult at all	Somewhat difficult	Moderately difficult	Very difficult	Extremely difficult
	How difficult is it for you to delay ejaculation?	0	1	2	3	4
		Almost never or never 0%	Less than half the time 25%	About half the time 50%	More than half the time 75%	Almost always or always 100%
	Do you ejaculate before you wish?	0	1	2	3	4
	Do you ejaculate with very little stimulation?	0	1	2	3	4
		Not at all	Slightly	Moderately	Very	Extremely
	Do you feel frustrated because of ejaculating before you want to?	0	1	2	3	4
	How concerned are you that your time to ejaculation leaves your partner sexually unfulfilled?	0	1	2	3	4

The details on how to calculate the score and the grades are given in Annexure -IV

Assessment of results

On the basis of percentage efficacy obtained by the above mentioned scoring system, there will be the following four grades of results of the study:

S. No.	Percentage efficacy	Result
1.	95 – 100%	Cured
2.	50 – 94%	Relieved
3.	25 – 49%	Partially Relieved
4.	0 – 24%	Not Relieved

Temperament and response

The data shows that out of 80 cases studied maximum 38 cases having Safravi temperament followed by 27 Balghami, 14 cases Saudavi, and 01 Damvi case. As per temperament and response of the formulae concerned, it is more effective in Balghami temperament as out of 27 cases 04 cases got complete remission, 15 cases got partially remission and 08 got poor response. In Saudavi 14 cases, 00 cases got complete remission and 07 cases got partially remission. In Safravi 38 case 01 got complete remission, 25 got poor remission and Damvi temperament only case got complete remission as presented in table-1.

Table 1: Response according to Mizaj (Temperament):

Mizaj (Temperament)	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Balghami	4	15	8	27 (33.75%)
Saudavi	-	7	7	14 (17.5%)
Safravi	1	25	12	38 (47.5%)
Damvi	1	-	-	01 (1.25%)
Total (%)	06 (7.5%)	47 (58.75%)	27 (33.75%)	80 (100%)

Chronicity and response

Study data shows that maximum 55 cases were having chronicity up to 02 years followed by 08 cases 2-4 years, 07 cases 6-8 years, 05 cases 4-6years, 3 cases 8-10 years and above 10 years 02 cases. As chronicity and response of the formulae concerned, it is effective in the cases having chronicity up to 02 years and 55 cases having chronicity up to 2 years 5 case got complete remission, 33 cases got partially remission and 17 case got poor remission. Table-2

Table 2: Response according to chronicity of the disease:

Chronicity	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Up to 02 year	5	33	17	55 (68.75%)
02-04 year	-	5	3	8 (10%)
04-06 year	1	2	2	5 (6.25%)
06-08 year	-	5	2	7 (8.75%)
08-10 year	-	1	2	3 (3.75%)
Above10 year	-	1	1	2 (2.5%)
Total (%)	6 (7.5%)	47 (58.75%)	27 (33.75%)	80 (100%)

Sex and Response

In the table-3, the study shows that this disease is only in males as out of 80 cases studied, As per response concerned, 06 got complete remission, 47 cases got partially remission and 27 cases got poor remission. Table 3

Table 3: Response according to sex of patients:

Sex	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Male	06	47	27	80
Total (%)	06	47	27	80(100%)

Dietary habits and response

Data projected from study shows that it is more common in non-vegetarian and vegetarian approximately; out of 80 cases studied 17 cases were vegetarian and 63 non-vegetarian. As per response concerned, good response recorded in both the types of habits, out of 17 vegetarian cases 01 got complete remission, 09 cases got partial remission and 07 cases got poor remission. Likewise 63 non-vegetarian cases, 05 cases got complete remission, 38 cases got partial remission and 20 cases got poor remissions.Table-4.

Table 4: Response according to dietary habits:

Dietary Habits	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Vegetarian	1	9	7	17 (21.25%)
Non-vegetarian	5	38	20	63 (78.75%)
Total (%)	6 (7.5%)	47 (58.75%)	27 (33.75%)	80 (100%)

Social status and response

Study also shows that out of 80 cases, 04 cases were from lower income group, followed by 60 cases from middle income group and 16 cases from high income group. As per income group and response of the drug concerned, good response recorded in MIG as out of 60 cases, 06 cases got complete remission, 35 cases got partial remission and 19 cases got poor remission. In HIG as out of 16 cases studied no case got complete remission, 09 cases got partial remission and 07 cases got poor remission.Table-5.

Table 5: Response according to social status of patients:

Social Status	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Lower Income Group	00	3	1	04 (5%)
Middle Income Group	6	35	19	60 (75%)
Higher Income Group	-	9	7	16 (20%)
Total (%)	6 (7.5%)	47 (58.75%)	27 (33.75%)	80 (100%)

Age and Response

In the table-6, the study shows that this is very common in the age group of 21 to 40 years as out of 80 cases studied maximum 32 cases were belonging to 31-40 age group, followed by 29 cases in the age group of 21-30 years. 02 cases were 51-60 years age group and only 01 case above 60 years age. As per response is concerned, good response observed in the age group of 21-30 years as out of 29 cases belonging to this group 03 cases got complete remission, 18 cases got partial remission and 08 cases got poor remission. In the age group of 31-40 years 03 cases got complete remission, 15 cases got partial remission and 14 cases got poor remission. Table-6

Table 6: Response according to age group of patients:

Age Group (In years)	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
UP TO - 20	0	0	0	00
21-30	3	18	8	29 (36.25%)
31-40	3	15	14	32 (40%)
41-50	0	11	5	16 (20%)
51-60	0	2	0	02 (2.5%)
Above 60	0	1	0	1 (1.25%)
Total (%)	6 (7.5%)	47 (58.75%)	27 (33.75%)	80 (100%)

Conclusion

The study reveals that result of the Unani coded formulae effective, as out of 55 cases studied 21 cases got complete remission, 25 cases got partial remission and 09 cases got poor remission. The formulae reduced signs and symptoms like pain, tenderness, swelling, loss of functions and morning stiffness in uniform way. During the study blood investigations of each patient for haemogram, liver function test, kidney function test, Rheumatoid factor, C- reactive protein were done at base line, after Munzij- Mushil therapy, every follow up and after completion of study. We found that there was no significant effect of formulae on RA factor after completion of study, however there was slight increased in Hb% and marked decline ESR in well responded cases. No Toxicity and adverse effect of the drugs reported during the study. Blood investigations done to observe any hepatic or renal toxicity at baseline, during follow up and after completion of study. It is observed that drug is safe and has no toxic effect on liver and kidney.

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Conflict of Interest

Not available

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Not available

References

1. Althof S, Rosen R, Symonds T. Development and validation of a new questionnaire to assess sexual satisfaction, control, and distress associated with premature ejaculation. J Sex Med. 2006 May;3(3):465-75. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 4th edn. TextRevision. Washington, DC: American Psychiatric Publishing Inc, 20004. International Classification of Diseases and Related Health Problems. 10th edn. Geneva: World Health Organization; c1994.
2. Anonymous: National Formulary of Unani Medicine, Part-I, CCRUM, Ministry of Health & Family Welfare, (Deptt. Of AYUSH) Govt. of India; c2006. p. 139.
3. Anonymous Standard unani terminolgy, NewDelhi CCRUM; c2012.
4. Balon R, Segraves RT, Clayton A. Issues for DSM-V: sexual dysfunction, disorder, or variation along normal distribution: toward rethinking DSM criteria of sexual dysfunctions. Am J Psychiatry. 2007 Feb;164(2):198-200.
5. Basheer A. Risala-e-Quwar-e-Bah, Munshi Nawal Kishore, Kanpur; c1886.
6. Basile Fasolo C, Mirone V, Gentile V. Andrology Prevention Week centers; Italian Society of Andrology (SIA).Premature ejaculation: prevalence and associated conditions in a sample of 12,558 men attending the andrology prevention week 2001-a study of the Italian Society of Andrology (SIA). J Sex Med. 2005 May;2(3):376-82.
7. Blanker MH, Bosch JL, Groeneveld FP. Erectile and ejaculatory dysfunction in a community based sample of men 50 to 78 years old: prevalence, concern, and relation to sexual activity. Urology. 2001 Apr;57(4):763-8.
8. Buvat J, Glasser D, Neves RC. Sexual problems and associated help-seeking behavior patterns: results of a population-based survey in France. Int. J Urol. 2009 Jul;16(7):632-8.
9. Christensen BS, Gronbaek M, Osler M. Sexual dysfunctions and difficulties in Denmark: prevalence and associated sociodemographic factors. Arch Sex Behav. 2011 Feb;40(1):121-32.
10. Cihan A, Demir O, Demir T, Aslan G, Comlekci A, Esen A. The relationship between premature ejaculation and hyperthyroidism. J Urol. 2009;181:1273-80.
11. Dunn KM, Croft PR, Hackett GI. Sexual problems: a study of the prevalence and need for health care in the general population. Fam Pract. 1998 Dec;15(6):519-24.
12. Fugl-Meyer AR, Sjogren Fugl-Meyer K. Sexual disabilities, problems and satisfaction in 18-74 year old Swedes. Scan J Sexol. 1999;2:79-105.
13. Ghulam H. Kamil-us-Sana (Urdu) Munshi Nawal Kishore Lucknow; c1879.
14. Giuliano F, Patrick DL, Porst H. 3004 Study Group. Premature ejaculation: results from a five country European observational study. Eur Urol. 2008 May;53(5):1048-57.
15. Godpodinoff ML. Premature ejaculation: clinical subgroups and etiology. J Sex Marital Ther. 1989;15(2):130-4, 11.
16. Hameed A Marajul Behrain Vol-II Sheikh Ghulam Hussain & Son's Lahore pp.1-17. Ibn-e-Sina (1930) Al Qanoon Fit tib (Urdu Translation by Ghulam Hassan kantoori, Matba Munshi Nawal Kishore, Lucknow; c1932. p. 107.
17. International Classification of Diseases and Related Health Problems. 10th edn. Geneva: World Health Organization; c1994.
18. Ishtiyaque AS. introduction of Al Umar Al Tabiyah (Principles of Human Physiology in Tibb) Hkm Nuzhat Ishtiyaque Saini Printers Pahari Dhiraj Delhi; c1980. p.

185-187.
19. Jern P, Santtila P, Witting K. Premature and delayed ejaculation: genetic and environmental effects in a population-based sample of Finnish twins. J Sex Med. 2007 Nov;4(6):1739-49.
20. Kabiruddin. Tarjuma Kabeer Shareh-eAsbab (Urdu) Voll-III Hikmat Book Depot Hyderabad; c1926.
21. Khan AM. Muheet-e-Azam (Persian) Matba Nizami Kanpur; c1895. p. 163-164.
22. Khan HM. Tarjuma-e-Zakheera Khuraizum Shahi Munshi Nawal Kishore Lucknow; c1883. p. 1374-1376.
23. Khan MA. Akseer-e-Azam II[nd] Edition Vol-3 Munshi Nawal Kishore Lucknow; c1769. p. 580-595.
24. Laumann EO, Nicolosi A, Glasser DB. GSSAB Investigators' Group. Sexual problems among women and men aged 40-80 y: prevalence and correlates identified in the Global Study of Sexual Attitudes and Behaviors. Int J Impot Res. 2005 Jan-Feb;17(1):39-57.
25. Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the United States: prevalence and predictors. JAMA. 1999 Feb;281(6):537-44.
26. McMahon CG, Abdo C, Incrocci L. Disorders of orgasm and ejaculation in men. J Sex Med. 2004Jul;1(1):58-65.
27. McMahon CG, Althof SE, Waldinger MD. An evidence-based definition of lifelong premature ejaculation: report of the International Society for Sexual Medicine (ISSM) ad hoc committee for the definition of premature ejaculation. J Sex Med. 2008 Jul;5(7):1590-606.
28. McMahon CG, Lee G, Park JK. Premature ejaculation and erectile dysfunction prevalence and attitudes in the Asia-Pacific region. J Sex Med. 2012 Feb;9(2):454-65.
29. McMahon CG. Ejaculatory latency vs. patient-reported outcomes (PROs) as study end points in premature ejaculation clinical trials. Eur Urol. 2007 Aug;52(2):321-3.
30. Mobeen FAM. Qanoon-e Mubashrat, Jama-e-Bakri, New Delhi; c1934.
31. Mohammad G. Mohseni, Seyed Reza Hosseini, Farshid Alizadeh, Nazir Rangzan serum testosterone and gonadotropins levels in patients with premature ejaculation: A comparison with normal men. J Advanced Biomedical Research. 2014;29:1-4.
32. Momeen MM. Tohafat-ul- Momimneen (Persian) Matba Munshi Nawal Kishore; c1704. p. 227-228.
33. Patrick DL, Althof SE, Pryor JL. Premature ejaculation: an observational study of men and their partners. J Sex Med. 2005 May;2(3):358-67.
34. Porst H, Montorsi F, Rosen RC. The Premature Ejaculation Prevalence and Attitudes (PEPA) survey: prevalence, comorbidities, and professional help-seeking. Eur Urol. 2007 Mar;51(5):816-23. Discussion 824.
35. Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March; c2009.
36. Rosen RC, Catania JA, Althof SE. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. Urology. 2007 May;69(5):805-9.
37. Rosenberg MT, Sadovsky R. Identification and diagnosis of premature ejaculation. Int. J Clin Pract. 2007 Jun;61(6):903-8.
38. Serefoglu EC, Yaman O, Cayan S. Prevalence of the complaint of ejaculating prematurely and the four premature ejaculation syndromes: results from the Turkish Society of Andrology Sexual Health Survey. J Sex Med. 2011 Feb;8(2):540-8.
39. Serefoglu EC, Yaman O, Cayan S. The Comparison of Premature Ejaculation Assessment Questionnaires and Their Sensitivity for the Four Premature Ejaculation Syndromes: Results from the Turkish Society of Andrology Sexual Health Survey. J Sex Med. 2011 Apr;8(4):1177-85.
40. Shareef M. Miftaha-ul Hikmat First Edition, Art Press Lahore. 1936;2:5-9.
41. Solstad K, Hertoft P. Frequency of sexual problems and sexual dysfunction in middle-aged Danish men. Arch Sex Behav. 1993 Feb;22(1):51-8.
42. Tabri R. Firdous-ul-Hikmat (Urdu translation by Rasheed Ashraf Nadvi). Nawad Printing Press Karachi; c1981. p. 704-707.
43. Tang WS, Khoo EM. Prevalence and correlates of premature ejaculation in a primary care setting: A preliminary cross-sectional study. J Sex Med. 2011 Jul;8(7):2071-8.
44. Vignozzi L, Corona G, Petrone L, Filippi S, Morelli AM, Forti G, *et al*. Testosterone and sexual activity. J Endocrinol Invest. 2005;28:39-44.
45. Waldinger MD, Quinn P, Dil leen M. A multinational population survey of intravaginal ejaculation latency time. J Sex Med. 2005 Jul;2(4):492-7. 12
46. Waldinger MD, Schweitzer DH. Changing paradigms from a historical DSM-III and DSM-IV view toward an evidence-based definition of premature ejaculation. Part I-validity of DSM-IV-TR. J Sex Med. 2006 Jul;3(4):682-92.
47. Waldinger MD, Schweitzer DH. Changing paradigms from a historical DSM-III and DSM-IV view toward an evidence-based definition of premature ejaculation. Part II-proposals for DSM-V and ICD-11. J Sex Med. 2006 Jul;3(4):693-705.
48. Waldinger MD, Schweitzer DH. The DSM-IV-TR is an inadequate diagnostic tool for premature ejaculation. J Sex Med. 2007 May;4(3):822-3.
49. Waldinger MD, Schweitzer DH. The use of old and recent DSM definitions of premature ejaculation in observational studies: a contribution to the present debate for a new classification of PE in the DSMV. J Sex Med. 2008 May;5(5):1079-87.
50. Waldinger MD. Premature ejaculation: state of the art. Urol Clin North Am. 2007 Nov;34(4):591-9,
51. Waldinger MD. The neurobiological approach to premature ejaculation. J Urol. 2002 Dec;168(6):2359-67.
52. Mc Mohan. Disorders of orgasm and ejaculation in men J Sex Med. 2004 Jul;1(1):58-65.
53. Waldinger. The majority of men with lifelong premature ejaculation prefer daily drug treatment: an observation study in a consecutive group of Dutch men. J Sex Med. 2007 Jul;4(4 Pt 1):1028-37
54. Kim SC. Efficacy and safety of fluoxetine, sertraline

and clomipramine in patients with premature ejaculation: a double-blind, placebo controlled study. J Urol. 1998 Feb;159(2):425-7.

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