



Formulation And Evaluation of Fenugreek Seeds For Management Of Dysmenorrhea (Menstrual Cramp) Disease.

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Abstract

Legumes like fenugreek (*Trigonella foenum-graecum*) have been used as spices to improve food's sensory qualities for thousands of years. It is well-known for its therapeutic properties, which include immunological, hypo-cholesterolemic, anti-diabetic, and anti-carcinogenic effects. In addition to its therapeutic uses, it is employed as an emulsifier, glue, and food stabilizer in a variety of food product developments. Primary dysmenorrhea is a common illness that negatively impacts the quality of life for a large number of individuals worldwide. This double-blind, randomized, placebo-controlled trial was carried out in response to some evidence about the qualities of fenugreek as a medicinal plant with anti-inflammatory and analgesic activities. The major goal of the research was to assess how fenugreek seeds affected students' primary dysmenorrhea symptoms. An annual plant native to southern Europe and Asia, it has firm, angular, yellowish-brown seeds and white blooms. In addition to its medical uses, it has long been valued for its nutritional content. Gum, fiber, alkaloids, flavonoids, saponin, and volatile content are all abundant in fenugreek seeds.

Keywords: Fenugreek , dysmenorrhea , seeds, menstrual cramps.

Introduction : The terms "menstrual pain" and "dysmenorrhea," which are thought to be interchangeable in clinical literature, refer to an uncomfortable menstrual cycle that usually lasts two to three days. It is brought on by the hormone prostaglandin produced by the uterus or by uterine contractions, which are known to cause cramping in the thighs, lower abdomen, or back. The Greek word dysmenorrhea means difficult, strange, or painful days; meno means month; and rhea means flow. Menarche is one of the most significant physiological

changes that occur in adolescent girls and is frequently linked to issues with dysmenorrhea, heavy bleeding, and irregular menstruation. Among these, dysmenorrhea is a prevalent issue that many teenage girls face.

The annual plant, *Trigonella foenum graecum*, is a member of the Leguminosae family. It is a well-known spice used in human cuisine. Fenugreek has long been employed in medicine and food preparation; its green leaves and seeds are used for both purposes. It has been used to improve the color and flavor of food ingredients as well as change their texture. It is often recognized that including medicinal herbs in one's diet is essential for upholding a healthy lifestyle and preventing a number of food-related illnesses, such as diabetes, cancer, hypertension, inflammation, and cardiovascular diseases.

Adolescence is a time of transition from childhood to adulthood marked by a rapid increase in physical, hormonal, emotional, and cerebral development, as well as a shift from total dependency to a degree of relative independence. For a girl, adolescence is a time of physical and mental preparation for being a safe mother. Adolescent girls' health affects not only their personal health but also the health of the next generation because they are the direct progenitors of future generations. Girls under the age of twenty make up over 25% of India's population.

Menarche is one of the most significant physiological changes that occur in adolescent girls and is frequently linked to issues with dysmenorrhea, heavy bleeding, and irregular menstruation. Among these, dysmenorrhea is a prevalent issue that many teenage girls face. Nag (1982) observed a 33.5% frequency of dysmenorrhea among Indian teenage girls. Over half of all women who menstruate feel some discomfort, according to a Swedish study. Additionally, a prominent obstetrician has revealed that between 5 and 10% of late-teen girls experience severe spasmodic dysmenorrhea, which interferes with their social and academic lives.

In India, the actual frequency and occurrence of dysmenorrhea remain unclear. Recently, George and Bhaduri came to the conclusion that dysmenorrhea (87.87%) is a prevalent issue in India. There was a >2-4% prevalence in Sweden. Similar results with married rural women in Andhra Pradesh have been reported by Jayashree and Jayalakshmi. According to estimates, dysmenorrhea is the leading cause of missed work and school days in the US.

The seriousness of the issue could be demonstrated by a study on the prevalence of dysmenorrhea and the symptoms that go along with it. The study's objectives were to ascertain the prevalence of dysmenorrhea and its typical symptoms, as well as the correlation between the condition and a number of physiological parameters, including body surface area and overall health. Additionally, the study aimed to identify the relationship between the condition and pain intensity, as well as the physiological symptoms. symptoms before menstruation There are two types of premenstrual syndrome (PMS) symptoms: psychological and physical. Physical symptoms included nausea, cramping in the legs, lightheadedness, exhaustion, abdomen discomfort, and breast pain; psychological symptoms included worry, anger, and emotional instability.

Premenstrual syndrome (PMS) is typically linked to dysmenorrhea; however, in this study, the majority of girls (91%) reported having PMS even in the absence of dysmenorrhea, with only 9% reporting no such symptoms. Since most of these 91% of girls (64.2%) have reported more than one symptom, the overall percentage does not equal 100. The study population's obvious presentation of PMS symptoms is shown in Table 2. A woman's menstrual pattern can reveal information about her health. Menstruation typically happens at regular intervals.

Premenstrual syndrome (PMS), dysmenorrhea, amenorrhea, and menstrual disorders (MDs) are examples of menstrual diseases (MDs). Numerous factors, such as diet, lifestyle, cultural expectations and behaviors, and individual constitutions, may mediate the expression of this biological event, as evidenced by the significant variations in symptoms experienced by women with MDs living in different locales, according to ethnographic and epidemiological studies. In contemporary medicine, hormone therapy is the primary treatment for MDs. Nonetheless, a growing number of women are choosing to rely on herbal remedies based on their own traditional or national medicine due to the negative consequences of contemporary medicine.

Prevention

People can also try certain lifestyle measures to reduce cramping. These include:

- exercising regularly
- trying to reduce stress — for example, practicing meditation, mindfulness, or yoga
- quitting smoking, if a smoker, or avoiding secondhand smoke.

SYMPTOMS:

- cramping or pain in the lower abdomen,
- low back pain,
- pain spreading down the legs,
- nausea,
- vomiting,
- diarrhea,
- fatigue,
- weakness,
- fainting,
- or headaches.



Uses & Effectiveness

- Diabetes. Individuals with diabetes appear to have reduced blood sugar levels when fenugreek seed is taken orally.
- dysmenorrhea, or painful menstruation. Oral fenugreek seed powder may lessen unpleasant menstrual cycles.
- A greater reactivity to sexual stimuli in individuals in good health. Male sex interest and ability seem to improve when a certain fenugreek seed extract (Testofen, Gencor Pacific Ltd.) is taken orally.
- Sexual issues that impede one's ability to feel satisfied during sex. For younger, healthy girls with low sex drive, taking a specific fenugreek seed extract by mouth (Libifem, Gencor Pacific Ltd.) appears to boost interest in sex.

ETIOLOGY:

Numerous theories have been put forth to explain the genesis of dysmenorrhea since the 1960s. These hypotheses include etiologies that are psychological, biological, and anatomical. The anatomical theory highlights anomalies in the length or form of the cervix as well as improper uterine position. In their research, Zebitay et al. suggested a favorable relationship between the volume and severity of dysmenorrhea and cervical length. Several other investigations have found that the biochemical explanation provides the strongest supporting data.

Associated risk factors for dysmenorrhea include the following:

- Age (commonly) up to 30 years
- Smoking
- Attempts to lose weight
- Higher or lower than normal body mass index
- Depression/anxiety
- Longer menstrual cycles
- Younger age at menarche
- Nulliparity
- History of sexual assault

- Previous cesarean section with incomplete uterine scar healing (uterine niche)
- Longer and heavier menstrual flow
- Family history of dysmenorrhea
- Disruption of social networks

Primary Dysmenorrhea:

Dysmenorrhea is believed to be primarily caused by prostaglandins (PGs). Menstrual fluid and endometrial tissue from women with dysmenorrhea have been found to contain higher concentrations of PGs. The menstrual cycle's declining hormone levels are what trigger the start of endometrial shedding. PGs are released by endometrial cells during the period of endometrial shedding at the onset of menstruation. The amount of PG released correlates with the severity of uterine contractions, which are caused by PGs. Tension in the uterus results in tissue hypoxia and ischemia, which in turn produce pain and occasionally accompany diarrhea.

Secondary Dysmenorrhea:

Menstrual pain brought on by an underlying illness, condition, or structural anomaly inside or outside the uterus is known as secondary dysmenorrhea. Women may experience it at any point following menarche. For women in their 30s or 40s, it may be their first-time symptom. Different pain levels and occasionally additional symptoms like dyspareunia, menorrhagia, intermenstrual bleeding, and postcoital hemorrhage might be linked to secondary dysmenorrhea. Secondary dysmenorrhea can be caused by a variety of common conditions, such as endometriosis, adenomyosis, big cesarean scar niche, fibroids, endometrial polyps, pelvic inflammatory disease, and possibly the use of an intrauterine contraceptive method. The prevalence of endometriosis in women with dysmenorrhea may reach 29%. Up to 35% of patients with NSAID-resistant dysmenorrhea may also have endometriosis. Another prevalent underlying condition that is connected to

AIM : To formulation and development Fenugreek Powder to treatment of Dysmenorrhea (menstrual cramps)

OBJECTIVES:

- Identify the etiology of primary and secondary dysmenorrhea.
- Apply an evaluation process for primary and secondary dysmenorrhea.

- To general approach to menstrual disorders.
- The menstrual cycle prepares your body for pregnancy.

MATERIAL AND METHOD :

Method :

The raw material such as powders of Fenugreek Seeds, Clove Buds, Ginger, Turmeric , Peppermint Leaves were used for the formulation . The raw material used for this formulation were purchased from market and authenticated in laboratory . The authentication carried out based on the microscopic characteristics of powdered drug .

Sr.no	Ingredients	Quantity Taken (for 100gm)	Uses
1.	Fenugreek seeds	40gm	Emollient
2.	Clove buds	20gm	Analgesic
3.	Ginger	10gm	Antioxidant
4.	Turmeric	15gm	Antiseptic
5.	Peppermint leaves	15gm	Prevent or reduce vomiting

Table no:01

BASIC INFORMATION AND PROPERTIES OF SELECTED DRUGS :

Fenugreek Seeds:

Family: Fabaceae

Biological Source: Dried seeds of *Trigonella foenum*

Chemical Constituents: The alkaloid and volatile compound present are the two main chemical constituents that cause the bitter taste and the odour of the seeds.

Distribution: Fenugreek is a native of South Eastern Europe and West Asia, now cultivated in India, Argentina, Egypt and Mediterranean countries (Southern France, Morocco and Lebanon). In India it is grown extensively in Rajasthan, Gujarat, Madhya Pradesh, Uttar Pradesh, Maharashtra and Punjab.

Uses:

- Diabetes. Taking fenugreek seed by mouth seems to lower blood sugar levels in people with diabetes.
- Menstrual cramps (dysmenorrhea).
- Increasing response to sexual stimuli in healthy people.
- Sexual problems that prevent satisfaction during sexual activity.



Fig.no.01

Ginger:

Family: Zingiberaceae

Biological Source: Ginger (*Zingiber officinale* Rosc.) is a major rhizome spice and medicinal crop and belongs to the family Zingiberaceae.

Chemical Constituents: Ginger is abundant in active constituents, such as phenolic and terpene compounds [13]. The phenolic compounds in ginger are mainly gingerols, shogaols, and paradols.

Distribution: Ginger (*Zingiber officinale* Rosc.), originated in the Indo-Malayan region, is now widely distributed across the tropics of Asia, Africa, America and Australia. It was domesticated in India and China, which represent the centre of origin of the species.

Uses: It is Used as a food flavoring and medicine.

- Better Digestion.
- Improves Immunity. 7
- Alleviates PMS Symptoms.

- Relieves Nausea and Upset Stomach.
- May Help With Cancer.
- Reduces Pain.
- Healthier Skin.
- Weight Loss Aid



Fig no.02

Clove Bud:

Family: Myrtaceae

Biological Source: Cloves consist of dried flower buds of *Eugenia caryophyllus*.

Chemical Constituents: Roughly, 89% of the clove essential oil is eugenol and 5% to 15% is eugenol acetate and β -cariofileno[7]. Another important compound found in the essential oil of clove in concentrations up to 2.1% is α -humulen.

Distribution: Clove is native of Indonesia but nowadays is cultured in several parts of the world including Brazil in the state of Bahia.

Uses:

- Preventing cancer.
- Decreasing pain.
- Repelling mosquitos and other insects.
- Stimulating sexual desire.
- Treating bad breath.
- Promoting optimal digestion.

- Speeding-up wound healing.



Fig no.03

Turmeric:

Family: Zingiberaceae

Biological Source:

Turmeric (*Curcuma longa*) is used as spice, preservative, colouring matter and has wide range of medicinal and pharmacological applications. It exhibits anti-inflammatory, anti-HIV, anti-bacterial, antioxidant, nematocidal, antiparasitic, antispasmodic and anticarcinogenic activities.

Chemical Constituents:

The pharmacological activity of turmeric has been attributed mainly to curcuminoids consists of curcumin (CUR) and two related compounds demethoxy curcumin (DMC) and bisdemethoxycurcumin (BDMC).

Distribution:

India is a leading producer and exporter of turmeric in the world. Andhra Pradesh, Tamil Nadu, Orissa, Karnataka, West Bengal, Gujarat, Meghalaya, Maharashtra, Assam are some of the important states cultivates turmeric, of which, Andhra Pradesh alone occupies 35.0% of area and 47.0% of production.

Uses:

- Inflammation.
- Degenerative eye conditions.
- Metabolic syndrome.
- Arthritis.
- Hyperlipidemia (cholesterol in the blood)
- Anxiety.
- Muscle soreness after exercise.

- Kidney health.



Fig no.04

Peppermint Leaves:

Family: Labiatae.

Biological Source:

Oil obtained by steam distillation-fresh flowering tops- plants *Mentha piperit*

Chemical constituents:

The main ingredient in peppermint essential oil, menthol, is primarily responsible for the agent's anti-spasmodic properties. Limonene (1.0–5.0%), cineole (3.5–14.0%), menthone (14.0–32.0%), menthofuran (1.0–9.0%), isomenthone (1.5–10.0%), menthyl acetate (2.8–10.0%), isopulegol (0.2%), menthol (55.0%), pulegone (4.0%), and carvone (max. 1.0%) are some of the components in peppermint oil.

Distribution: Originally native to Europe and the Middle East, the plant is now widely grown around the world. Occasionally, it can be seen in the wild alongside its parent species.

Uses:

- irritable bowel syndrome (IBS).
- It is also used for indigestion,
- bed sores,
- tension headache,
- anxiety,

- insomnia, memory.



Fig no 05

Method:

- The drug & other ingredients which are used for preparation churna are dried separately.
- Then made fine powdered of each.
- Then passed through (sieved no-80) to get uniform particle size.
- Then these drug powdered are mixed with each other accurately to get a uniform powder.



Fig no; 06 Churna preparation

EVALUATION OF PHYSICAL PARAMETERS:

1) Determination of pH

With the use of an Elico pH meter, the pH of a 1% solution of the churna formulation was measured.

2) Calculating the Moisture Content

Mettler Toledo halogen moisture determination equipment was used to determine the moisture content of the churna.

3) Calculating Ash Values

I. Value of All Ash: In a silicon crucible that had been previously burned and tarred, two grams of churna were precisely weighed. After that, the substance was ignited by progressively raising the heat to 500–600 °CC until it turned white, signifying the lack of carbon. After cooling in a desiccator, the amount of total ash in milligrams per gram of air-dried material is computed.

II. Value of Acid-Insoluble Ash:

After adding 25 milliliters of distilled water and letting it slowly boil for five minutes, roughly 5 milliliters of hot water were added, and the crucible was then filled with total ash. An ashless filter paper was used to gather the insoluble material. After that, the filter paper and the insoluble material were placed in a crucible and burned to a constant weight. The filtrate was then cleaned with hot water until letting the residue cool, it was weighed. it became neutral. After letting the residue cool, it was weigh

4) Determination of Extractive Values

I. Water Soluble Extractive Value :5gms of churna was accurately weighed and placed inside a glass stoppered conical flask. It is then macerated with 100 ml of chloroform water for 18 hours. It was then filtered and about 25ml of filtrate was transferred into a china dish and was evaporated to dryness on a water bath. It was then dried to 105°C for 6 hours, cooled and finally weighed.

II. Alcohol Soluble Extractive Values Ethanol was used as solvent in place of chloroform water and remaining procedure was the same as that of water soluble extractive value.

5) Determination Of Crude Fibre Content 2gms of accurately weighed churna was placed in a round bottom flask and then 100ml of 0.128 M sulphuric acid was added and refluxed for 1 hour then filtered through ashless

filter paper and the residue was washed with water until filtrate becomes neutral. The residue was then weighed (a), ignited to ash and finally the weight of ash (b) was determined.

The difference between a and b represented the crude fibre content and was calculated on dry weight basis.

6) Determination of Heavy Metal Contamination

I. Arsenic Content

Preparation of Standard Solution (10PPM) 0.33gms of arsenic trioxide was dissolved in 5ml of 2M Sodium hydroxide solution and then diluted to 250ml with water. One volume of this was then diluted to 100 volume with water.

PREPARATION OF SAMPLE

Preparation of Churna solution

The churna solution was prepared by means of diluting 1gm of churna to 100ml using distilled water. This is used to carryout limit test for iron and lead and also to perform qualitative test for mercury. 10ml of churna solution was pipetted out into a flask and about 10ml of concentrated nitric acid was added and evaporated to dryness on a waterbath. The residue was then dried at 130° C for 30minutes then about 10ml of hydrazine molybdate reagent was added and refluxed for 20minutes. The solution was then cooled and absorbance of both standard and test solution was measured at 800nm using Perkin Elmer UV spectrophotometer.

II. Limit test for Iron

Preparation of Standard Solution (20 PPM) One volume of 0.1726% w/v solution of ferric ammonium sulphate solution was diluted in 0.05 M sulphuric acid to ten volume using distilled water.

Procedure

Limit test was performed in Nessler's cylinder. 2ml of test and standard solutions were taken in separate cylinders and then 2ml of 20% solution of citric acid and 0.1 ml thioglycollic acid were added. The solution was then mixed and made alkaline with iron free ammonia, diluted to 50ml with distilled water. It was then allowed to stand for 5minutes and colour obtained in sample was compared with that of standard colour. If the colour produced in test is more when compared to that of standard solution then the sample was said to fail the limit test and said to pass the test if vice versa occurs.

III. Limit Test For Lead

Preparation of Standard (20 PPM) 0.4 gm of lead nitrate was dissolved in water containing 2ml of nitric acid and sufficient water to produce 250ml. About 1 volume of above solution was diluted to 10 volume using distilled water.

Procedure

Limit test was performed in Nessler's cylinder. 1ml of standard lead solution and test solution were taken in separate cylinders and were diluted to 25ml using distilled water.

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and then pH was adjusted to value 3-4 by adding dilute acetic acid or dilute ammonia solution and then diluted to 35ml using distilled water. To both the solutions 10ml freshly prepared hydrogen sulphide solution was added, mixed and diluted with water to 50ml. It was then allowed to stand for 5minutes and viewed downwards over white surface. The colour produced in test solution should not be more intense than that of standard solution, if so then the sample is said to pass the limit test for lead.

IV. Test for Mercury

To 10 drops of test solution 6M HCl was added to get a white precipitate. The precipitate was then treated with 6M ammonia solution. If the colour of precipitate changes to grey or black colour then it indicates the presence of mercury.

7) DETERMINATION OF MICROBIAL CONTENT

1gm of churna was dissolved in lactose broth and volume adjusted to 100ml with the same medium. About 10ml of sample was transferred into 100ml of Macconkey broth and incubated for 18-24 hours at 43-45°

C. A subculture was prepared on a plate with Macconkey agar and incubated

at 43-45° C for 18-24 hours. The growth of red, generally non-mucoid colonies of gram negative rods appearing as reddish zones indicates the presence of E.coli if not then it indicates the absence of E.coli.

Determination of Digestive Property

Preparation of Extract

About 100mg of accurately weighed quantity of churna was extracted with 20% aqueous glycerol and phosphate buffer (pH7.8) in 1:4 ratio and filtered and the filtrate was used as enzyme source. The standard sample was prepared similar to the test sample.

Physical Parameters :

1) Angle of repose:

Weighing the reasonable angle at which the minute particles in the air surface detracted toward the level surface was a prerequisite for estimating the angle of repose. Initially, the 100.00 g granules were loaded and fled some what into a channel that was created to go along with a lower tier closure. The lid was previously removed, allowing the granules to fall onto the lowermost portion of the pictorial paper surface. Weighing the altitude (h) and distance (d) of the formed granules allowed us to determine the repose angle (α), and the wealth of liquid balancing was used to carefully consider adding the principles into the final seed's equating content.

$$\theta = \tan^{-1}(h/r)$$

2) Bulk density:

1. Take the 5gm sample powder of known volume (cm³).
2. Add into 25 ml Measuring cylinder.
3. Measure the volume of sample in measuring cylinder.
4. Notify the both mass and volume of the powder.
5. Calculate the bulk density.

$$\text{Bulk density} = \text{Mass} / \text{Bulk volume} \times 100$$

3) Tapped density:

The granules were judged by equating the most and pumped capacities of the freed granules as well as the rates when they were full below. The principle got was delimited as the portion of uninterrupted book, as premeditated in this manner:

Tapped Density = Weight taken / Tapped volume

4) Compressibility / Carrs index :

Carrs index = Tapped density – Bulk density / Tapped density ×100

5) Hausners ratio :

Hausners Ratio = Tapped density / Bulk density

Observation table of physical parameters

Sr. No.	Parameters Observations
1 Angle of Repose (θ)	33 degree
2 Bulk Density (g/ml)	1.70
3 Tapped Density (g/ml)	2.50
4 Carrs index (%)	38.3
5 Hausners ratio	1.15

Table no:02

EVALUATION OF PHYSICAL PARAMETERS OF CHURNA

Name	Physical Parameters Values
1 pH	5.357
2 Moisture content	10.8 % w/w
3 Ash Values	
I. Total ash	10% w/w
II. Acid insoluble ash	5% w/w
4 Extractive values	
I. Water soluble extractive	0.12% w/w
II. Alcohol soluble extractive	2% w/w
5 Crude fibre content	75% w/w

Table no:03

Results and Discussion :

After being purchased, the churna's organoleptic, physical, and physiochemical parameters were assessed. Every outcome that was attained has been totaled. Churn also demonstrates strong patient adherence.

CONCLUSION:

The main causes of primary dysmenorrhea include leading an unhealthy lifestyle, eating erratically, consuming junk food, and not exercising. Both groups demonstrated a notable reduction in pain. This study set out to determine how well various herbal medicines affected the severity of primary dysmenorrhea. The majority of credible research has looked at dietary and natural remedies. Only one study has been done on certain herbs, like fenugreek seeds, clove buds, ginger, turmeric, and peppermint leaves. There isn't enough research in this field, despite the fact that the results show that these plants are beneficial for lowering dysmenorrhea.

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