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Efficacy of Herbal Decoction in *Sala-e-Raham* (Uterine Fibroid) a control Drug Research & Clinical Trial at Govt. Nizamia Tibbi College & Hospital Hyderabad: A Research Article

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Abstract

Uterine fibroids are common reproductive-age benign tumors that contribute to severe morbidity and infertility. Cumulative incidence is 4 times higher in African-Americans compared to Caucasians and constitutes a major health disparity challenge. Fibroids are the leading indication for hysterectomy and their management averages $21 billion annually in the US. No long term minimally invasive therapies exist. Thus, promising drug therapies, their chemistry, pharmacology, and clinical efficacy, focusing first on innovative drug delivery approaches, are reviewed. Uterine fibroid is the commonest benign and solid tumor in female during reproductive life. Approximately 15-25 million of Indian women have affected from fibroid uterus. Histologically itis composed of smooth muscle and fibrous connective tissue of varying proportional. It is considered as Sul'ah (tumor) in Unani classic litretures, as Ali Ibn-e-Abbas Majusi (930-994 AD) defined it under the topic of Warm-e-Balghami; as it is a swelling filled with viscid phlegm (Balgham-e-Ghaleez). Present paper deals with a reports of a 30 years old female having uterine fibroids measuring 2.6 cm× 3.1 cm, 2.6 cm× 3.6 cm, with left ovarian cyst of 3.1 cm × 4 cm. Patient was treated with herbal formulations Like Herbal Decoction containing Afteemoon Wilayati , Gulebanafsha ,Gauzaban , Gule-surkh, Tuqme kasoos, Tuqme kharpaza, Badyan, Mundi, Shahitra , Parsiooshan by orally.

Keywords: Uterine fibroids, Herbal decoction,

I. Introduction of Uterine fibroids

Uterine fibroids are the most common benign pelvic tumor in women with a 70–80% cumulative incidence during childbearing years. African-Americans develop fibroids at younger ages than Caucasians and they tend to persist to menopause. Fibroids tend to regress in size before menopause in Caucasian women. The etiology remains elusive although progress has been made. Previously reported similarities between fibroids and keloids corroborate with recent findings. Fibroids cells secret high levels of collagen and resist apoptosis. Ranging in location and size, growth is influenced by female gonadal steroids by apocrine and paracrine mechanisms. Sub-serosal or intramural fibroids can negatively impact fertility.

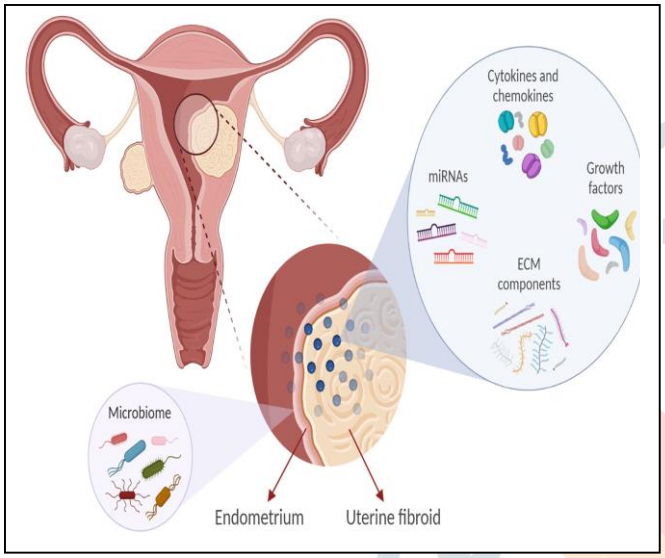


Fig. 1 Anatomy Physiology of Uterine fibroids

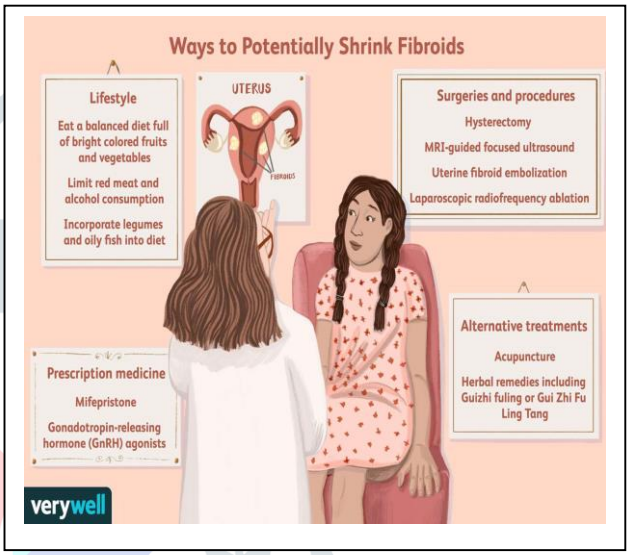


Fig. 2 Uterine fibroids- A common Problem in female

UAE is an angiographic technique that treats the whole uterus by causing ischemic fibroid necrosis. This therapy, like hysterectomy, is considered a standard treatment for women with no desire for future fertility. Alternatively, MRg FUS provides noninvasive fibroid-specific therapy utilizing high-intensity ultrasonography through the abdominal wall to cause coagulate necrosis in specific fibroids. Guidance and thermal monitoring is provided by dynamic real-time magnetic resonance imaging. However, fibroid regrowth after treatment in some cases may necessitate follow up therapies for both UAE and MRg FUS. Current studies are evaluating the long term outcomes of these procedures. Thus, fibroids are a major public health challenge. US treatment costs (~$21 billion annually) contribute more to healthcare expenditures than breast, colon or ovarian cancer. As researchers develop next generation therapies, innovative approaches to drug delivery should be considered.

Uterine fibroid known as leiomyoma, myoma or fibromyoma, is the commonest benign and solid tumor in female. It has been estimated that at least 20 percent of women at age of 30 have got fibroid in their wombs. The prevalence is highest between 35-45 years of age. [1] Approximately 15-25 million women in India have affected from fibroid uterus. [2] Histologically it is composed of smooth muscle and fibrous

connective tissue of varying proportional. Originally it consist of only muscle element but later on fibrous tissues intermingle with the muscle bundle. It arises from the single smooth muscle cell of myometrium. [1] Chromosomal abnormality particularly the chromosome six or seven (rearrangement, deletion) and somatic mutations in myometrial cells may cause uncontrolled cell proliferation. Epidermal growth factor, insulin like growth factor-1, transforming growth factor, stimulates the growth of leiomyoma directly or via estrogen.[1] Nulliparity, obesity, hyperestroegenic state and black women are implicated to be high risk factors for uterine fibroid. It has various types such as interstitial or intramural (75%), subperitoneal or subserous (15%) and submucous (5%), are located in the body of uterus, and fibroid in cervix of uterus is rare (1-2%).[1] Clinically it represented as usually asymptomatic (75%) however can reflects pelvic pain, pelvic lump, infertility, menstrual abnormality; menorrhagia, metrorrhagia, dysmenorrhea, recurrent pregnancy loss; miscarriage, preterm labor, pelvic pressure; urinary frequency, urinary incontinency, dysuria, constipation.[2] Ultrasonography is a non-invasive useful diagnostic tool to confirm the size, number and location of Uterine fibroid.[1]

Fig. 3 life style changes to Help Manage living with uterine fibroids

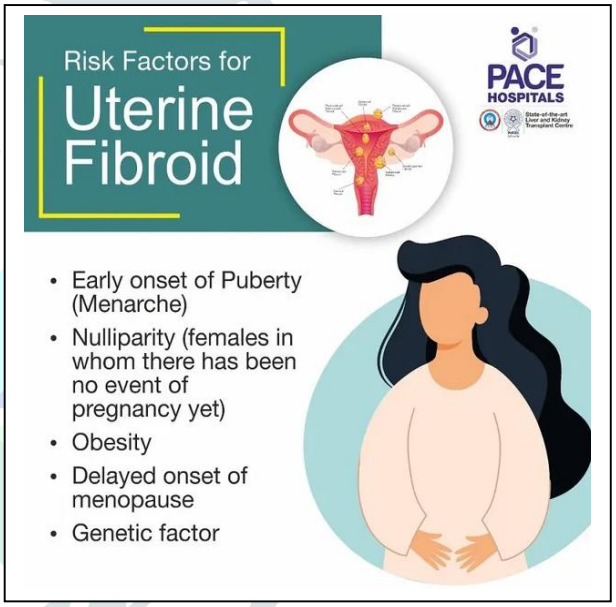


Fig. 4 Risk factor for uterine fibroids- A common Problem in female

According to Unani medicine uterine fibroids considered as Sul'ah (tumor), may be defined as viscid phlegmatic inflammation, enveloped by a sac of membranous tissue. [3] Razi (860-925) has advocated that Sul'ah is a phlegmatic tumor consisting of putrefied phlegm. Its sizes vary from Bengal gram to water melon.[4]

Ali Ibn-e-Abbas Majusi (930-994 AD) mentioned it under the heading of Warm-e-Balghami; as it is a swelling filled with viscid phlegm (Balgham-e-Ghaleez). It is classified into 4 types; Shahmiyah (fat like), Asliyah (honey like), Ard'haliyah (flour like), Sheeraziyah (milk like). It is treated by adopting of concoction and expulsion of the abnormal phlegm (Nuzj-o-Tanqiyah-e-Balgham-e-GhairTab'yiah) along with anti-inflammatory drugs (Muhallil-e-Warm Advia) orally as well as topically in the form of zamad (paste) and Marham (ointment). If it is failed then surgical removal is the treatment of choice. [5] Ibn-e-Sina (980-

1037AD) described it under the topic of Sul'ah (tumor); known as Dunbula-e-Balghami, characterized by a lump filled with abnormal phlegm (Ghair Tab'yi Khilth-e-Balgham), which may be bloody or honey like viscid. [6]

Although the definite treatment of uterine fibroid is surgical removal in both Modern and Unani medicines, but keeping in view of Unani concept regarding etiopathogenesis of Sul'ah (tumor), it is treated medically by herbal drugs having Dafey-e-Sul'ah (antitumor) Munzij-e-Balgham (concoctive of phlegm), Mus'hil-e-Balgham (purgative of phlegm) and Muhallil-e-Warm (anti-inflammatory) properties.

Treatment options for fibroids vary severity of the symptoms, size and location of the fibroid lesions, the patient's desire to maintain fertility with the ultimate goal of therapy being relief of the symptoms. As we learn more about the impact of fibroids on fertility, it becomes important for patients and their physicians to have a toolbox of therapeutic options with viable drug therapies being one of those tools. To this end, promising drug therapies, their chemistry, mechanism of action, pharmacology, clinical efficacy and side effects, focusing first on innovative drug delivery approaches, will be highlighted.

A. Methodology;-

The Study entitled Efficacy of Munzij Mushil therapy in the management of uterine fibroid was conducted in the Dept. of Ilmul-Qabalat wa Amraz Niswan Govt. Nizamia general Hospital Hyderabad during October 2015-June-2017.

B. Study Design'

Randomized single blind trial with pre and post Test evaluation

The patients will be selected on the basis of clinical screening and ultra sound Smaging

C. Duration of Study: 18 months

D. Sample Size: 40 patients.

E. Ethical clearance: The study protocol was approved by institutional ethical committee, GNTC HYDERABAD after which the study was started.

F. Method of Collections of Data

- Clinical Interview
- Laboratory investigation.

G. Criteria for the Selection Of Subject:

The patients were enrolled in the study after filling the following criteria. Inclusion Criteria.

- Age women of reproduction age with age group of 20 years-50 yrs.
- Married women in non-pregnant state.
- Infertility.
- Symptomatic fibroids i.e., menorrhagia and pressure symptoms.
- Asymptomatic fibroid causing pressure on the ureter i.e., Broad ligament fibroid.
- Ultra sound reports with myoma size of > 6cm

H. Exclusion criteria:

- Myoma of < 6 cm size
- Menopausel women and women above 50 years.

- Myoma complicating pregnancy.
- Malignancy of Genito urinary system.
- Systemic disorders, cardio vascular disorders, acute renal failure.

Informed consent.

Patents fulfilling the inclusion criteria mentioned above were given the information sheet having details regarding the nature of study, the drug to be used and method of treatment, patients were given enough time to go through the study details mentioned in the information sheet. They were given the opportunity to ask any question and if they agree to participate in the study were asked to sign the informed consent.

I. Subject Allocation:

20 patients were randomly allocated by attending outpatient and inpatient of Govt. Nizamia General Hospital in to single group in standard control group.

J. Procedure of the Study:

Pellet fulfilling inclusion criteria were enrolled in the study after obtaining Informed consent in each patient a detailed history was evaluated with basic information duration of pain, pressure of menorrgia and the other associated symptoms are enquired, menstrual characterize regarding length or cycle, days of bleeding, amount of bleeding was calculated participant underwent a complete physical examination, including height, weight, BMI, And measurement of vitals. A pelvic examination was done as patient were sexually active. All the information was recorded in the case record from designed for the study were advised for necessary investigations.

K. Investigation:-

Routine, investigation: CBP (complete blood picture), blood sugar, CUE (Complete urine examination), LFT (Liver Function Test), HIV, Hbs Ag. USG ultra sono-graphy a myoma show specific features of a well define rounded tumor, hypoecoic lesion.

Duration of treatment: 3-6 cycles.

The primary outcome were decreased in the size of fibroid measured with well validated ultra sono graphy and safety of test drugs evaluated by clinical examination and laboratory investigations. The secondary outcome variable was associated symptoms (menorrhagia, amenorrhea, white discharge paint the lower abdomen), subject assessment were done before the trail and after the trail on the basis of pain in lower abdomen), subjective assessment were done before and after the trail on the basis ultrasonography report.

L. Assessment and Follow Up During Study Period

The efficacy of munzij mushily therapy were passed by observing in the rating score of subjective and objective parameters. At every visit after menstruation for their consecutive months of treatment and one month of follow up the objects were asked about the improvement or worsening in their symptoms which were recorded in the case record form. After completion of the trial, the pre and post treatment values were statistically analyzed and compared to evaluate the efficacy and safety of the treatment.

M. Adverse Effects Documentation:-

Adverse drug reaction were submitted to the department after completion of study. Withdrawal criteria: The statistical software namely SAS 9.2, SPSS 15.0, State 10.0 medcaci 9.01, systat 12.0 and R environment

Ver. 2.11, were used for the analysis of the data and Microsoft oral and excel has been used to generate, graphs, tables, etc..

N. Statistical Analysis:

Descriptive statistical analysis has been carried in the present study. Results on continuous measurements are presented on mean +or –SD (min-max) and result on categorical measurements are presented.

Criteria for Selection of Drugs:-

In Unani literature, munzij drugs the humours balgam and sauda.

Test Drugs: orally

- Afteemoon wilayati.
- Gulebanafsha
- Gauzaban
- Gule surkh.
- Tuqme kasoos
- Tuqm e kharpaza Badyan
- Mundi
- Shahitra
- Parsiooshan

These drugs are obtained from local market of Hyderabad.

II. Method of Preparation of Trial Drugs Formula:-

The trail drug formula of contains oral decoction and local outmen applied over lower abandonment

Decoction:-

Ingredients:-

- Afteemoon wilayati (Cuscuta reflexa) 10 gm
- Badyaan (*Foeniculum vulgare)* 10 gm
- Gul e surkh (Rosa damascena Mil) 10 gm
- Gul-e- banafsha (Viola odorata) 10 gm
- Pursiaoosahn (Adiantum capillus-veneris) 10 gm

A. Tuqm e kassos (Cuscuta reflexa) 10 gm

- Mundi (Sphaeranthus indicus) 10 mg
- Tuqm e kharpaza (Cucumis melo) 10 mg
- Shahitra (Asparagus racemosus) 10 gm
- Gauzubaan (Borago officinalis) 10 gm

Method of Preparation:

Remove all kinds of impurities:

Take the bowel containing 250ml of water and soak the above medicine leaving afteemoon wilayati and tuqme-kasoos which should be separately added later boil other rest of medicine in water till it becomes half them take afternoon and tuqme-kasoos in small cotton cloth tie in it and lean this two ingredients' in the boiled medicine leave it for 2 hrs. Then separate the decoction from raw drugs collect it in a cup.

Route of administration-oral

Dosage and timing: 60 ml 2 hr. before breakfast and dinner from D5- D25 of menstrual cycle.

III. Herbal drugs Ingredients Description.

B. Cuscuta chinensis

Cuscuta chinensis Lam. is a stem holoparasite vine in the family Convolvulaceae. It produces glomerulate to dense paniculiform inflorescences composed of white-cream 5-merous flowers that are very small, have two styles with capitate stigmata, and produce 3–4 obovoid seeds per capsule. Its pollen grains are small, colporate, and covered by a finely reticulate ektexine. It is found throughout western Asia, tropical Asia, eastern Asia, and Australasia at latitudes between 20° N and 50° N. Specimens of Cuscuta campestris are occasionally mislabeled as C. chinensis; the two species can be differed by C. chinensis's carinate calyx lobes, incurved but not inflexed corolla lobes, and dehiscent seed capsule.

Fig. 5 Cuscuta chinensis

Fig. 6 Fennel (Foeniculum vulgare)

C. Fennel (Foeniculum vulgare)

Fennel (Foeniculum vulgare) is a flowering plant species in the carrot family. It is a hardy, perennial herb with yellow flowers and feathery leaves. It is indigenous to the shores of the Mediterranean but has become widely naturalized in many parts of the world, especially on dry soils near the sea-coast and on riverbanks. It is a highly flavorful herb used in cooking and, along with the similar-tasting anise, is one of the primary ingredients of absinthe. Florence fennel or finocchio is a selection with a swollen, bulb-like stem base that is used as a vegetable. Foeniculum vulgare is a perennial herb.

D. Cuscuta reflexa (Afteemoon wilayati)

Cuscuta reflexa, the giant, is one of 100-170 species in the genus Cuscuta, and is common in the Indian subcontinent and the Greater Himalayas and as far south as Malaysia and Indonesia. This parasitic plant species is a leafless twined sprawling thin vine that grows over a host plant, including large trees with garlands hanging down from the canopy as much as 10 meters (33 fit). Flowers are small, bell shaped and white in colour with yellow filaments. Fruits and seeds are produced from the flower.

Fig. 7 Cuscuta reflexa (Afteemoon)

Fig. 8 Tuqme kharpaza (Cucumis)

E. Tuqme kharpaza (Cucumis melo)

Cucumis melo, also known as melon, is a species of Cucumis that has been developed into many cultivated varieties. The fruit is a pepo. The flesh is either sweet or bland, with or without a musky aroma, and the rind can be smooth, ribbed (such as European cantaloupe), wrinkled (such as casaba melon), or netted (such as muskmelon). In North America, the sweet-flesh varieties are often collectively called muskmelon, including the musky netted-rind varieties and the inodorous smooth-rind varieties, and cantaloupe usually means the former type. However, muskmelon in a narrow sense only refers to the musky netted-rind type, while the true cantaloupe is the European type with ribbed and often warty rind that is seldom grown in North America. The origin of melons is not known. Research has revealed that seeds and rootstocks were among the goods traded along the caravan routes of the Ancient World. Some botanists consider melons native to the Levant and Egypt, while others place their origin in Iran, India or Central Asia.

F. Borage (Gauzuban)

Borage (Borago officinalis), also known as starflower, is an annual herb in the flowering plant family Boraginaceae. It is native to the Mediterranean region, and has naturalized in many other locales. It grows satisfactorily in gardens in most of Europe, such as Denmark, France, Germany, the United Kingdom, and Ireland, remaining in the garden from year to year by self-seeding. The leaves are edible and the plant is grown in gardens for that purpose in some parts of Europe. The plant is also commercially cultivated for borage seed oil extracted from its seeds. The plant contains pyrrolizidine alkaloids, some of which are hepatotoxic, mutagenic, and carcinogenic.

Fig. 9 Borage (*Borago officinalis*)

Fig. 10 Gule Banafsha (Viola odorata)

G. Gule Banafsha (Viola odorata)

Viola odorata is a species of flowering plant in the genus Viola, native to Europe and Asia. This small hardy herbaceous perennial is commonly known as wood violet, sweet violet, English violet, common violet, florist's violet, or garden violet. It has been introduced into North America and Australia. The sweet scent of this flower has proved popular, particularly in the late Victorian period, and has consequently been used in the production of many cosmetic fragrances and perfumes. The French are also known for their violet syrup, most commonly made from an extract of violets. In the United States, this French violet syrup is used to make violet scones and marshmallows. The scent of violet flowers is distinctive with only a few other flowers having a remotely similar odor.

H. Rose (Gule Surkh)

A rose is either a woody perennial flowering plant of the genus Rosa, in the family Rosaceae , or the flower it bears. There are over three hundred species and tens of thousands of cultivars. They form a group of plants that can be erect shrubs, climbing, or trailing, with stems that are often armed with sharp prickles. Their flowers vary in size and shape and are usually large and showy, in colours ranging from white through yellows and reds. Most species are native to Asia, with smaller numbers native to Europe, North America, and northwestern Africa. Species, cultivars and hybrids are all widely grown for their beauty and often are fragrant. Roses have acquired cultural significance in many societies. Rose plants range in size from compact, miniature roses, to climbers that can reach seven meters in height. Different species hybridize easily, and this has been used in the development of the wide range of garden roses.

Fig. 11 Rose family Rosaceae

Fig. 12 Gule Mundi-Sphaeranthus

I. Gule Mudi (Sphaeranthus indicus)

Sphaeranthus indicus, the East Indian globe thistle, is a flowering plant of the genus Sphaeranthus. It is distributed from Northern Australia throughout Indomalaya. The plant has been studied for its potential health-promoting properties, primarily as an anti-inflammatory. Sphaeranthus indicus Linn. (Asteraceae) is widely used in the Ayurvedic system of medicine in various conditions like epilepsy, mental illness, hemicrania, jaundice, hepatopathy, diabetes, leprosy, fever, pectoralgia, cough, gastropathy, hernia, hemorrhoids, helminthiasis, dyspepsia and skin diseases. In different parts of its range Sphaeranthus indicus is known by different common names.

Results and Tables

Table No. 1 Table showing the distribution of Patient according to age

No.	Age in Year	Number of Patient	Percentage
1	21-30 Year	12	30 %
2	31-40 Year	23	57.5 %
3	41-50 Year	5	12.5 %
	Total	40	100 %

Graph No. 1 Showing the distribution of Patient according to age

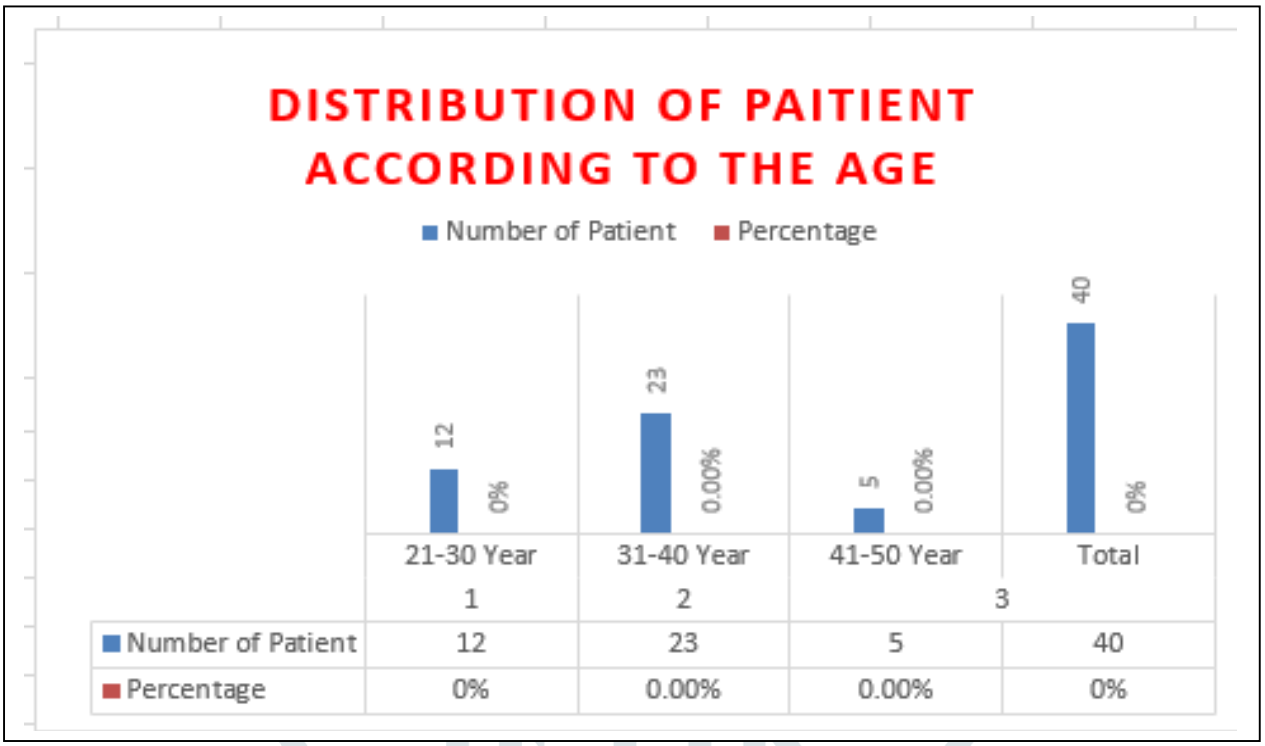


Table No. 2 Table showing the distribution of Patient according to Socio Economic status

No.	Socio Economic Status	Number of Patient	Percentage
1	Class I	1	4 %
2	Class II	19	46 %
3	Class III	20	50 %
	Total	40	100 %

Graph No. 2 Showing the distribution of Patient according to Socio Economic status

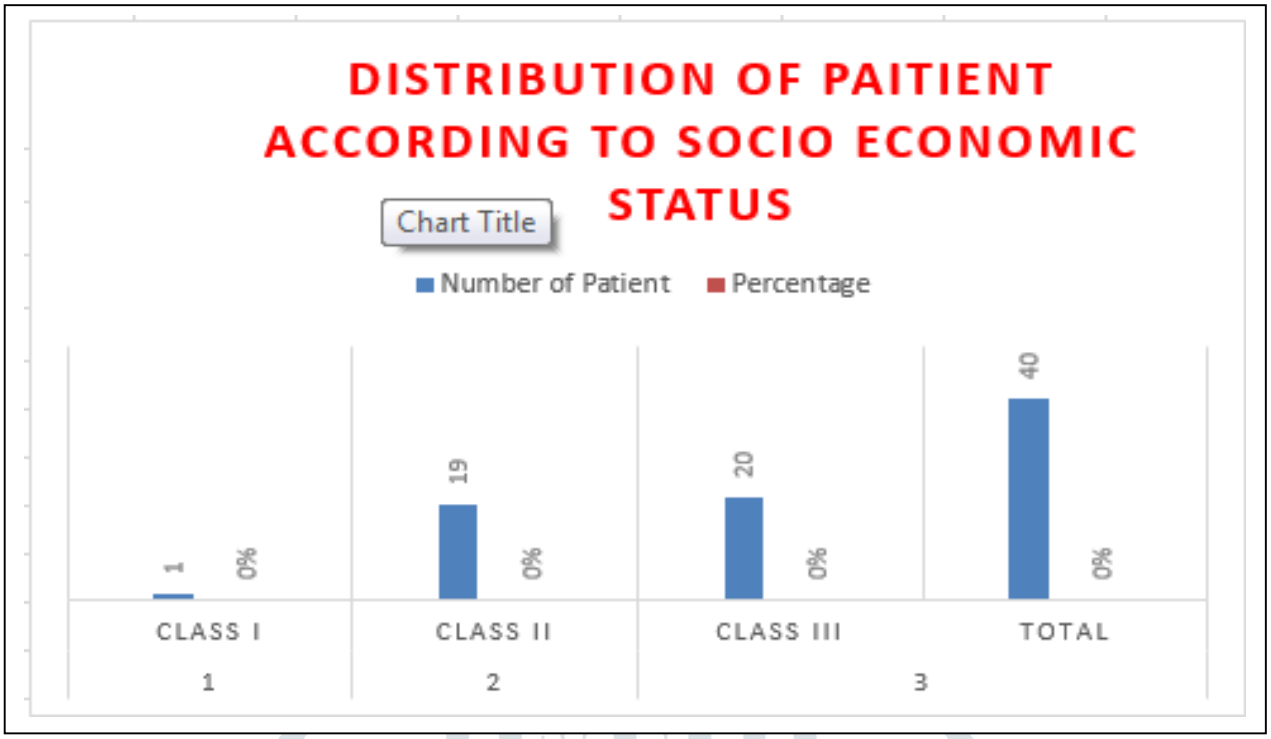


Table No. 3 Table showing the distribution of Patient according to Occupation

No.	Occupation	Number of Patient	Percentage
1	House Wife	36	90 %
2	Labor	04	10 %
	Total	40	100 %

Graph No. 3 Showing the distribution of Patient according to Occupation

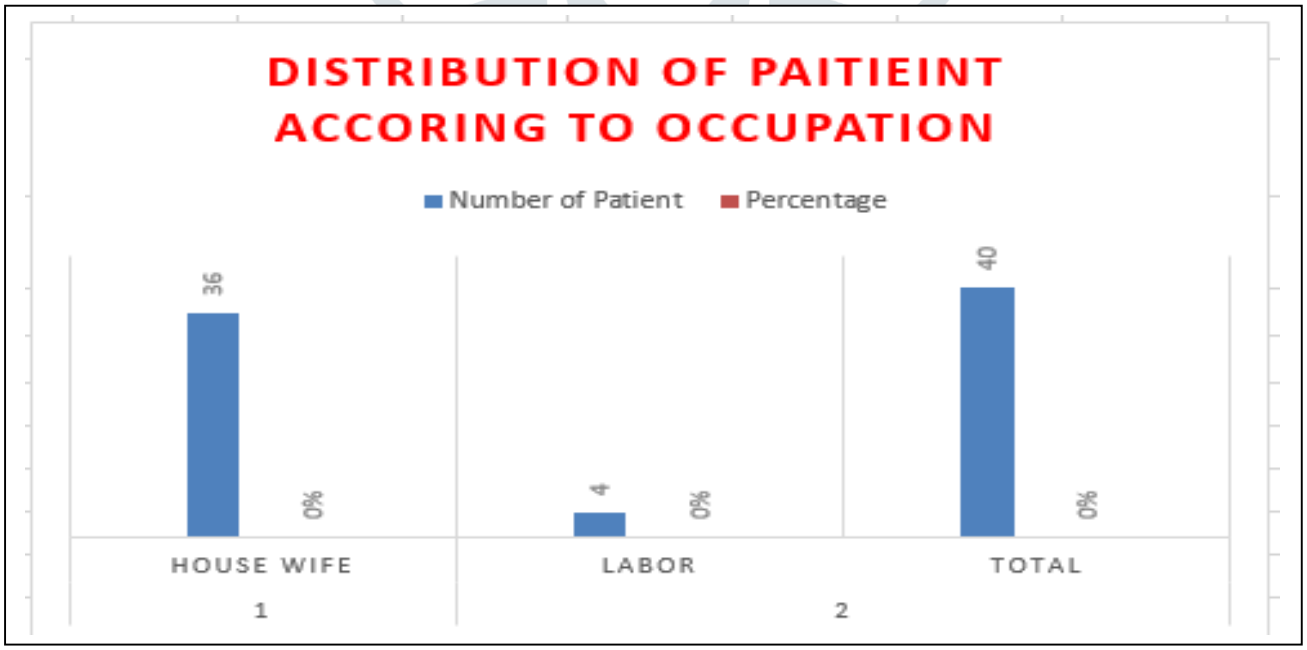


Table No. 4 Table showing the distribution of Patient according to BMI

No.	BMI	Number of Patient	Percentage	Mean + - SD
1	>18.5 (Under Weight)	01	2.5 %	18.0 + - 0
2	18.5 to 24.9 (Normal weight)	15	37.5 %	22.7 + -1.7
3	25.0 to 29.9 (Over Weight)	14	35.0 %	27.0 + - 1.4
4	>29.9 (Obese)	10	25.0 %	38.9 + - 4.2
	Total	40	100	27.4 + - 5.9

Graph No. 4 Showing the distribution of Patient according to BMI

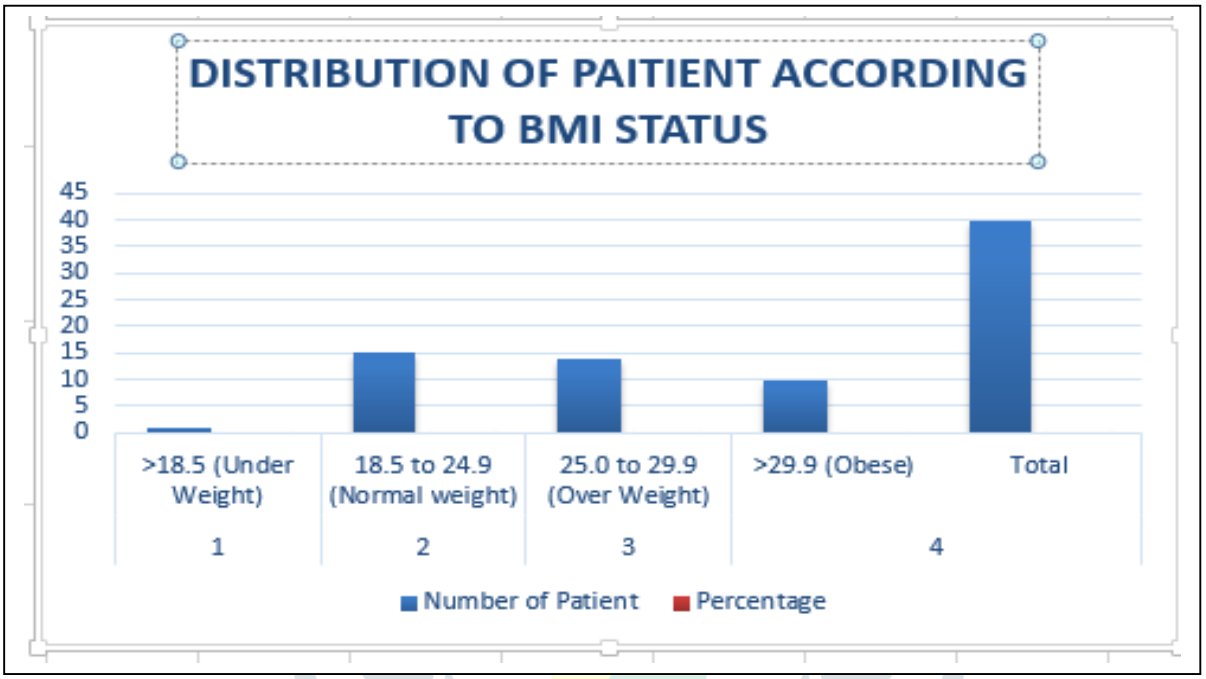


Table No. 5 Table showing the distribution of Patient according to Nutritional Status

No.	Nutritional status	Number of Patient	Percentage
1	Well Nourished	12	30 %
2	Average Nourished	27	67.5 %
3	Mal Nourished	01	2.5 %
	Total	40	100

Graph No. 5 Showing the distribution of Patient according to Nutritional Status

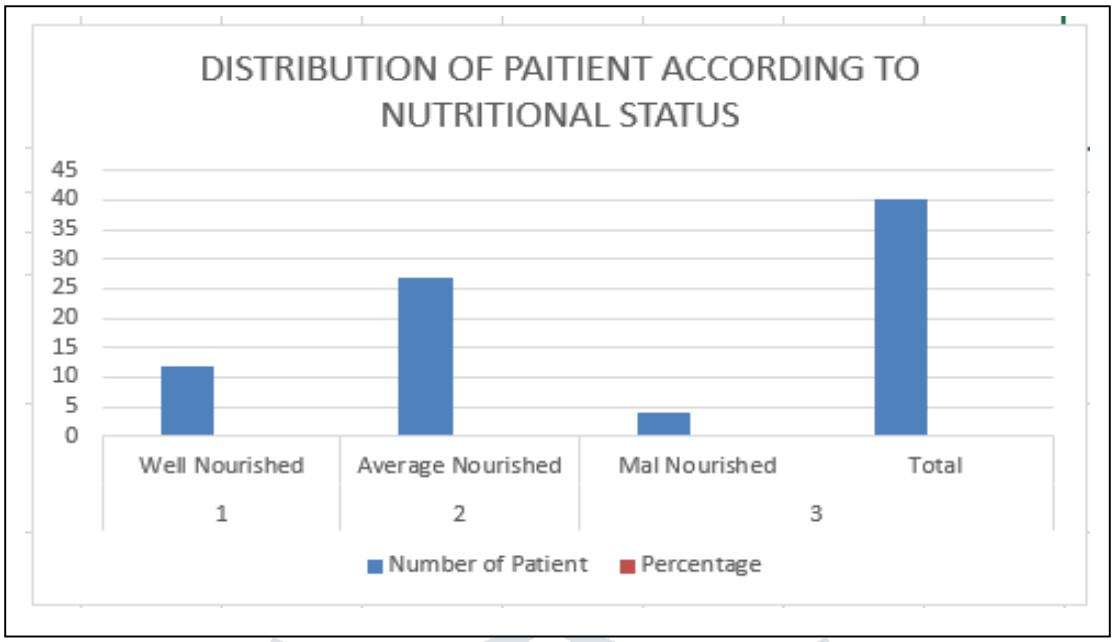


Table No. 6 Table showing the distribution of Patient according to Mizaj (Temperament)

No.	Mizaj or Temperament	Number of Patient	Percentage
1	Damavi	0	0 %
2	Balghami	38	95 %
3	Sufravi	0	0 %
4	Saudavi	02	5 %
	Total	40	100

Graph No. 6 Showing the distribution of Patient according to Mizaj (Temperament)

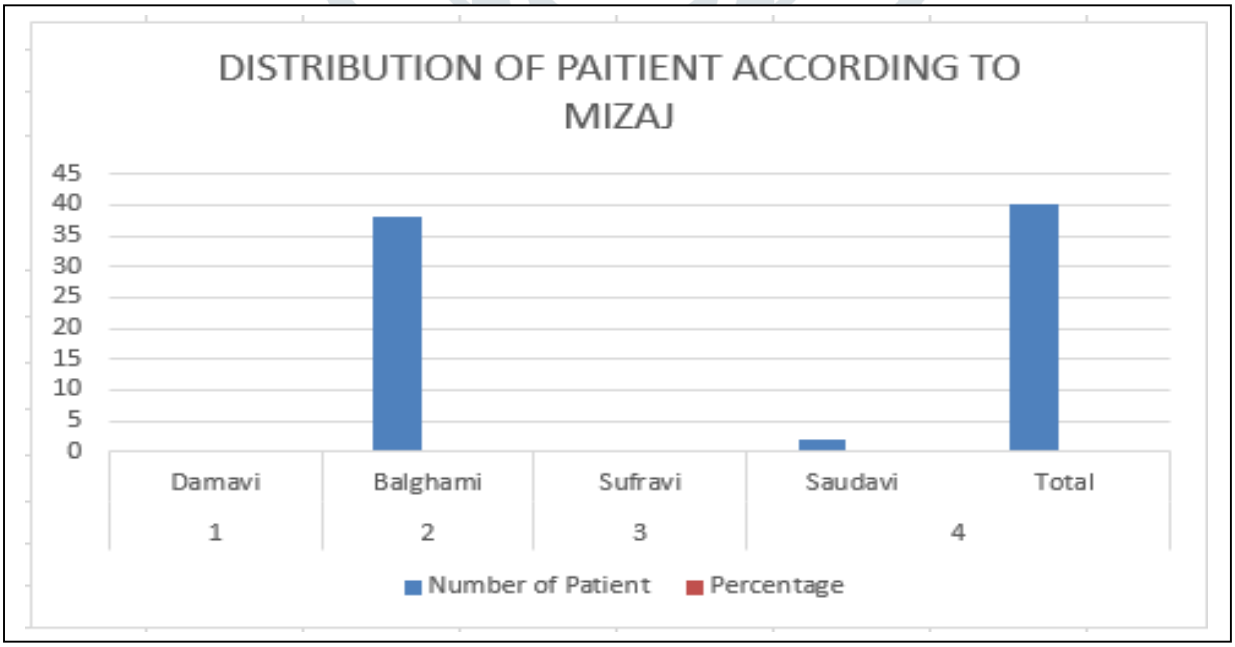


Table No. 7 Table showing the distribution of Patient according to Parity

No.	Parity	Number of Patient	Percentage
1	Nallipara	9	22.5 %
2	P1-P3	21	52.5 %
3	P4-P6	8	20 %
4	P7-P9	2	5 %
	Total	40	100

Graph No. 7 Showing the distribution of Patient according to Parity

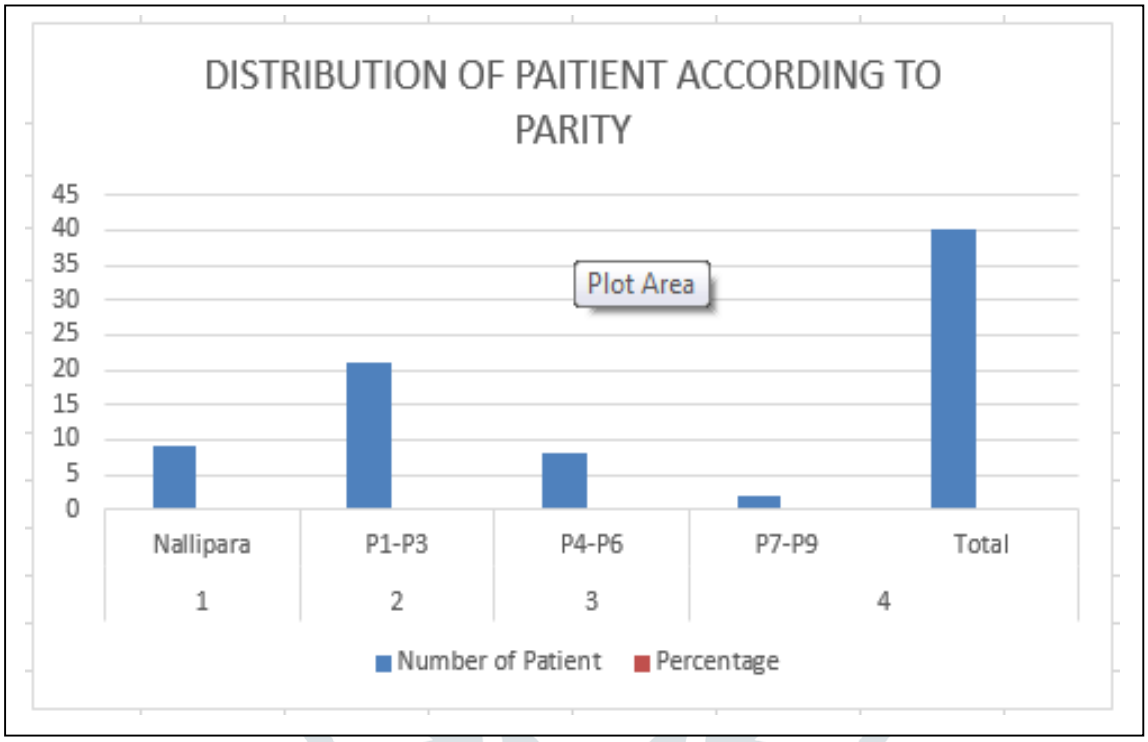


Table No. 8 Patient according to remission of Symptom Before and after treatment

No.	Symptoms	Number of Patient				
		B.T	A.T.	Remission (%)	χ^2 Test	P-Value
1	Menorrhagia	11	0	11(100.0)	18.182	0.00002
2	Poly-menorrhea	4	0	4(100.0)	4.50	0.0339
3	Metrorrhargia	3	0	3(100.0)	2.667	0.1024
4	Infertility	12	11	1(100.0)	0.0	1.0000
5	Pain	21	0	21(100.0)	38.095	<0.00001
6	Anemia	12	0	12(100.0)	20.167	<0.00001
7	Abdominal Lump	0	0	0(100.0)	-	-

Graph No. 8 Patient according to remission of Symptom Before and after treatment

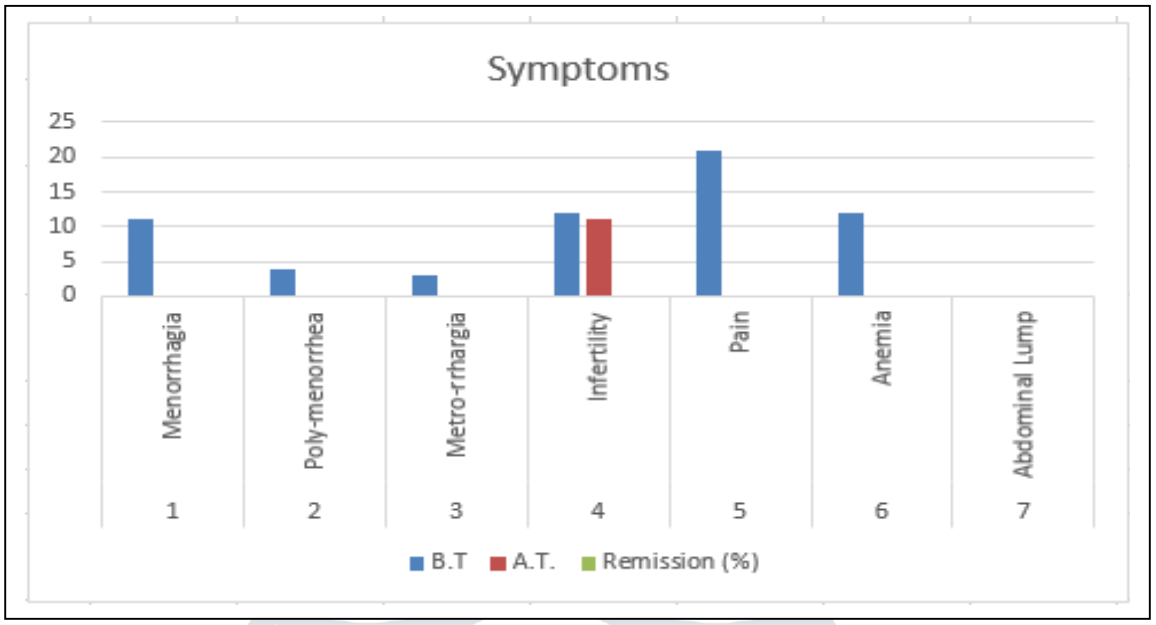


Table No. 9 Table showing the Therapeutic response of coding

No.	Response	Number of Patient	Percentage
1	Cured	14	35.00
2	Not Cured	26	65.00
3	Relived	0	0.00
	Total	40	100

Graph No. 9 Showing the Therapeutic response of coding

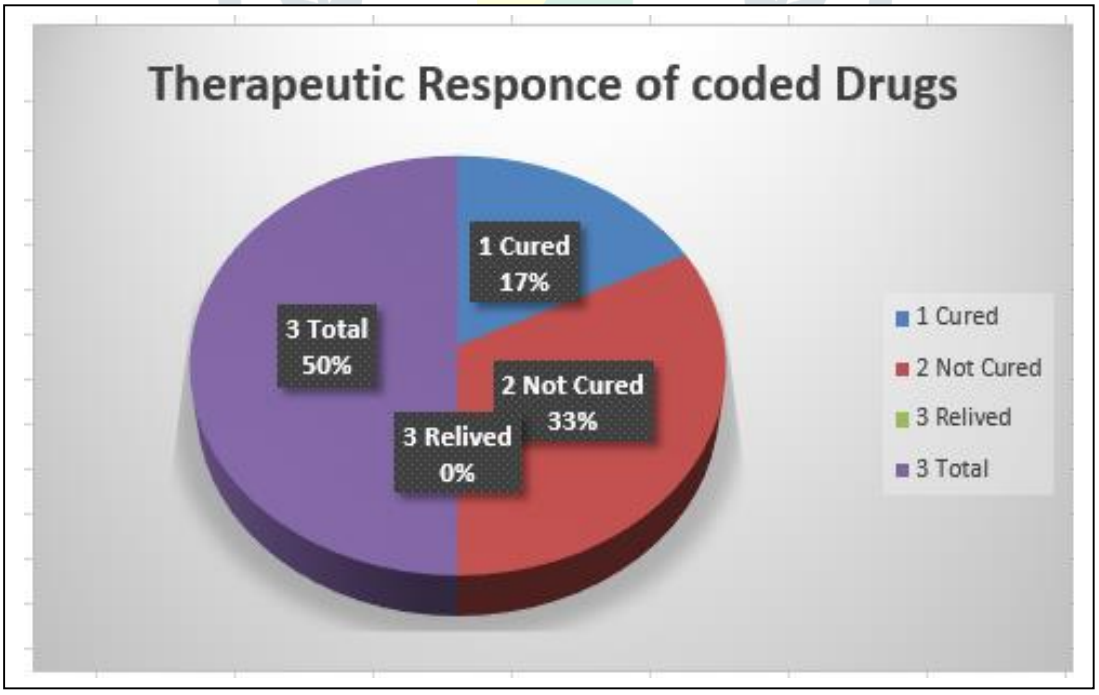
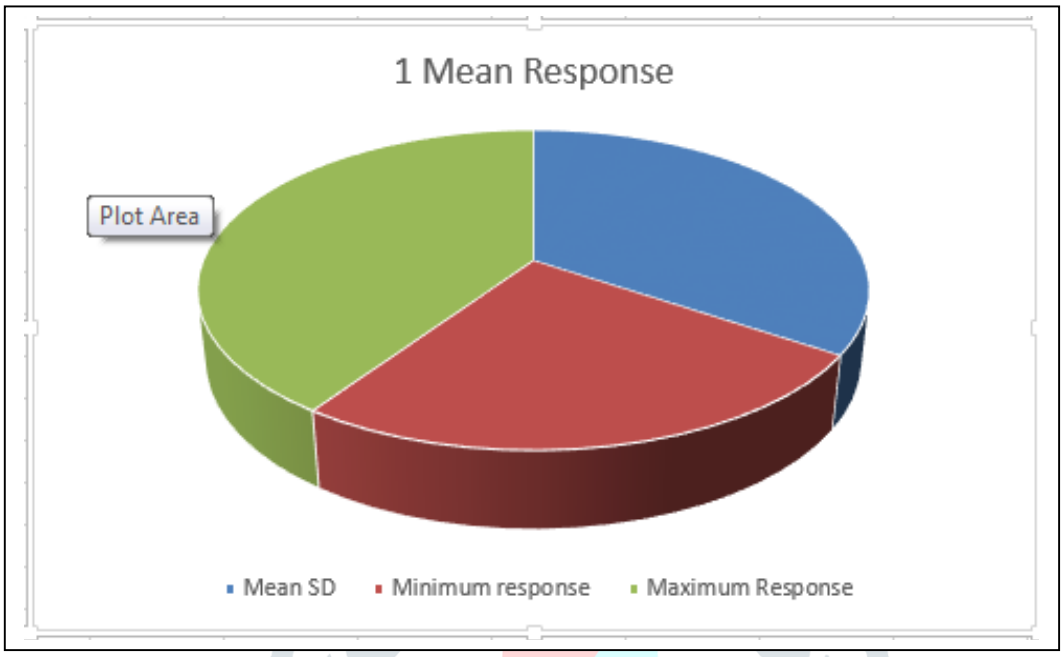


Table No. 9 Table showing the mean + - SD Percentage response and range of Response

No.	Response	Mean SD	Minimum response	Maximum Response
1	Mean Response	84.9 + - 12.4	62.5	100

Graph No. 9 Showing the mean + - SD Percentage response and range of Response



Discussion

The present randomized single blind study was conducted on 40 patients, as a single group was planned for the study to get the best results according to the Unani literature. To, date there is no study documented on Munzij-Mushil therapy in patients with uterine fibroid. Hence the present study was carried out to know the effect of Munzij-e-Balgham wa Sauda adviya in the treatment of uterine fibroid. Thus reducing the surgical interventions for uterine fibroid. Uterine fibroid is the most common benign neoplasm of uterus. Grossly fibroids are discrete nodular tumor that vary in size and number. They may be microscopic or huge, they are very common in fertile age especially between 20 - 50 years of age, and common concern for infertility. Asymptomatic fibroids may be present in 40- 60% of women older than 35yrs of age. Studies have suggested that each fibroid anses from a single neoplastic cell within the smooth muscle of the myometrium. They appears to be an increased familial incidence, and they may be more common in women who are obese. Uterine fibroids can cause multiple bleeding and pain symptoms which might have a negative impact on women's life, influencing their sexual, social and work life. Estrogen growth hormone possibly human placental lactogen have been implicated in the growth of myomas. The evidence in support of estrogen dependence for their growth is impressive myoma are rarely found before puberty and ceases to grow after menopause.

Unani system of medicine is blessed with the treasure of both single and compound drugs for preventing pain and bleeding some of the drugs are found to be more effective in fibroid uteri. According to unani physicians decoction of munzij is most effective in Sala'e-raham. Hence, in present study munzij and mushil

therapy was preferred to evaluate its efficacy in the management of uterine fibroid. A total of 40 married women age between 20-50 years of uterine fibroid were screened. All the patients included in the study were have single to multiple fibroids with 2 different menstrual abnormalities like Menorrhagia, Metrorrhagia, Poly-menorrhea, and dysmenorrhea. In association with abdominal pain, infertility, and heaviness in the abdomen.

The observations from the trial have been put in tables and graphs in order to draw inference and to arrive on conclusion.

A. Age:

The percentage of uterine fibroid according to different age groups was between 21-30 years is 30.0%, 31-40 years is 57.5%, and at the age of 41-50 years i.e. 12.5% respectively. The study have reported that the incidence of uterine fibroid will decrease with increasing in age due to association of uterine fibroid with hyper oestrogenism. Thus in present study it was observed that the incidence of uterine fibroid was more in the reproductive age group (Table-1), which has matched with previous different studies carried out at different places. Uterine fibroid occur in as many as one half of all women older than age 35 years and most the common tumor of the genital tract[1].2. One study of a randomly selected population estimated a cumulative prevalence of greater than 80% in black women and nearly 70% in white women 3. Fibroid are estimated to be clinically significant in at least 25% of women of reproductive age in United States. They are more common in African- American women than white women and have been associated with obesity [1]. [4-6]

B. Socioeconomic status:

In the current study, socioeconomic status was assessed by Kuppuswamy's scale. majority of patients belongs to upper middle and lower middle class, and only one patient was with high class, so according to percentage calculation 1(4%) was of high class, 39(49%) belongs to upper middle class, 40(50%) belongs to lower middle class. low socioeconomic status may be associated with nutritional deficiency. (Table-2).

C. Diet:

In present study maximum number of patients are having mixed diet the patients taking non vegetarian diet and high protein diet gain weight more tt 3 results in decreased sex hormone binding globulin concentration (androgenic effect)and thus reduces serum estradiol value to early follicular phase levels(anti-estrogenic effect), reduces mean LH levels, and obliterate LH and FSH surge (anti-gonadotrophic effect), causes increase secretion estrogen, more amount of fat deposition so, it may be due life style factor

D. BMI:

The mean BMI of patients are described, underweight 18.0(2.5), normal weight 22.7+/-1.7,over weight patients are27.0+/-1.4, and obese patients 35.9+/- 4.2, rest of the patients were average weight. There is controversy about association of BMI with fibroid. Some studies reported incidence of uterine fibroid positively correlates with increased BMI. A French study reported that BMI >25 as a risk factor for more incidence of developing fibroid.

E. Mizaj:

The Mizaj was assessed by using tempermental scale (on the basis of Alamate ajnase ashra) as described by ancient Unani physicians. Majority had Balghami mizaj i.e., 95%. This indicates that "Sal'e Rahm" is likely to be dominated by balghami mizaj. Some of the patients were belongs to saudavi mizaj. These findings were in accordance with our famous ancient physicians like Ibn sina, hakeem jurjani, and hakeem ajmal khan who have coated that khilte balgham and sauda are the causes of fibroid. Thus in present study Munzij-e-balgham wa Sauda adviya has been selecte to confirm the claims of Unani Physicians.

F. Pain abdomen:

The findings in this study suggest that apart from uterine bleeding symptoms, women with uterine fibroids suffer more frequently from multiple gynecological pain symptoms than women without a diagnosis of uterine fibroids. Pain symptoms reported more frequently in women with uterine fibroids were: pressure on the bladder, chronic pelvic pain and pain at different time points during the menstrue 4 cycle. In addition, women with myomas more often suffer from painful sexual intercourse. Even after adjusting for age and co-morbidities women with uterine fibroids reported more often multiple pain symptoms compared to women without a diagnosis. The literature examining the relation of uterine myomas and gynecologic pain symptoms in a population-based study is very limited. An Italian study found that in a non-care-seeking population women with uterine fibroids were more likely to report moderate or severe dyspareunia and moderate or severe non-cyclic pelvic pain than women without uterine fibroids, but not moderate to severe dysmenorrhea 45.The research studies on pain during sexual intercourse are inconsistent: A study from Ferrero et al. (2006) demonstrated that women with uterine fibroids do not have an increased prevalence or severity of deep dyspareunia, whereas Ertunc et al. (2009) found that a potential impairment, mainly because of pain during sexual intercourse, exists in women with myomas47.48. The results of this study suggest that uterine fibroids can cause multiple bleeding and pain symptoms, which may have a negative impact on the sexual life of women, their relationship and family as well as work. Nevertheless further research on the symptoms and their impact on life is needed.

Dysmenorrhea:

About 10% of adult women are incapacitated for up to 3 days per month as a result of dysmenorrhea. Dysmenorrhea can be treated with non-steroidal anti-inflammatory agents used alone or in combination with oral contraceptives or other hormone agents to reduce or ablate mentural flow. In present study the single drugs used were having effect of "Musakkin-e-dard", like Afteemon, Badiyan, and Gul-e-Surkh,

CONCLUSION

This prospective single centre open labelled, simple randomized pre and post evaluation trial was conducted on forty subjects to prove the efficacy and safety of munzij mushil therapy over-all improvement was also observed in associated symptoms. The subjects in the controlled group has not reported any adverse effects. The biochemical and safety parameters were within the normal range before and after trial, proving that study group was safe majority of subjects had balgami mizaj in this study. The presence of abnormal khilte balgami the uterus is responsible for producing warm -e- sulb. This confirms the claims of unani

physician that sala'e raham is caused by sue mizaj and ghalba e khilt. The prevalence of sala'e raham in this study was observed in reproductive age between 20- 30 yrs. It was observed that munzij mushil therapy was effective even after completion of the trial. In this study, munzij was found to be efficacious because of its muhallil, mulattif and mudir properties. It is pharmacologically proved for its anti-inflammatory analgesic, diuretic and immuno modulatory activities. Therefore, munzij wa mushil therapy was effective in relieving pain decreases in size of fibroid and associated symptoms specially menorrhagia. Hence further it is recommended average size fibroid >6cms large duration with scientific validation by estimation of size of fibroid in scan report.

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