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Efficacy of *Munzij Mushil* and *Zimaad* Therapy in *Sala E Sadi* (*Fibroadenoma* of Breast) - A Randomized Single-Blind Study

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ABSTRACT

Fibroadenoma of the breast is the most common benign tumor of mixed Fibrous and Glandular tissue of the breast, occurring among younger (20-35 years) women. Fibroadenoma accounts for 7-15% of all breast tumors. It assumes that hormones such as Oestrogen may play a part in the growth and development of the tumors. So it is mostly seen in OCP users. Histologically fibroadenomas are comprised of glandular and cystic epithelial structures, surrounded by a cellular stroma. Fibroadenoma often present in adolescence, are recognized most frequently in pre-menopausal women & usually spontaneously involute at menopause. According to Unani Physicians Sula e' saddi is the formation of tumour in the breast. It is formed beneath the skin due to accumulation of phlegm and this phlegm becomes viscid to form the tumor. This tumor has a characteristic that is totally differentiated from the flesh but attached to the skin superiorly. It is mobile and in the initial stages, the tumour is small and resembles the size of a peanut. Objectives: To evaluate the efficacy of Munzij mushil & zimaad therapy in 'Sala e Sadi' (fibroadenoma of the breast) and to minimize the surgical hazards. Methodology: The study was conducted in the Dept of Amraze Niswan wa Qabalat at Govt Nizamia Tibbi College and Hospital, Hyderabad. A total of 30 patients were selected for the study. An inclusion criteria includes women of reproductive age (from 15-50yrs) with a breast lmpu size <5cms. Exclusion criteria were pregnant women, menopausal women, breast lump size >5cms, Carcinoma of breast, and women with serious medical illness were excluded. Munzij, Mushil, and zimaad therapy were the main principles of treatment. Single drugs such as Aslessoos, Parsiyaoshan, Tukhm e Kasoos, Gul e Surkh, Gul e banafsha, Gul e mundi, Sapistan, Tukhm e badiyan, Maveez,AftimoonVilaiti, etc were made as munzij and given for 21 days followed by mushil. Zimaad was prepared by Aarid e jao, Aarid e Hulba, Gul e Banafsha, Chabi e murg, Charbi e Batq. Zimaad is applied locally on the breast for 5 alternative days followed by munzij therapy. Results: In The present study it was observed that among total of 30 patients, 14 patients had less response (<30%), 16 patients showed a good response (>30%) to the study medicine.

Conclusion: *The study proved the efficacy of unani formulation with good results in fibroadenoma of the breast without any side effects.*

Keywords: *Sala e Sadi, Fbroadenoma of Breast, Unani drugs, Cost effective, Munzij Mushil and zimaad therapy.*

Introduction

The breast or mammary gland is the most important structure present in the pectoral region [1]. Breast shape and size depend upon the genetic, racial, and dietary factors and the age, parity, and menopausal status of the individual. Breasts may be hemispherical, conical, variably pendulous, pyriform, or thin and flattened [2]. The Breast is one of the target organs for various hormones, particularly estrogens, progesterone, and Prolactin. As such, many breast-related complaints or diseases are associated with endocrine dysfunction[3]. The ductal epithelium of the mature female breast has some secretory activity, and the secretion is normally reabsorbed [4,5,6]. The diseases of the breasts are usually referred to the gynecologist as the breasts are organs related to reproduction. Changes in the breasts are directly related to the interplay of ovarian hormones.

Examination of breasts is mandatory and should be included as a routine in obstetric and gynecological examination [7]. The common benign breast conditions in women are mastalgia, fibroadenosis, fibroadenoma, cyst of the breast, breast abscess, and discharge from the nipple[7]. The female breast is in the unique position of being a gland that is non-functional except during lactation[4]. Fibro-adenoma presents as a lobulated firm rubbery lump. It moves about very freely in the breast substance, even after the breast has been rendered immobile by traction on the nipple[8]. For this reason, it is called 'Breast mouse [8,9,10,11]' or 'a Floating tumor[12]'. It does not contain fluid on aspiration[10]. It is not considered to be a true tumor, but a disorder of development. The reason is that fibro-adenoma arises from a lobule rather than from a single cell [13,14].

Fibro–Fibr-(L.fibra, fiber)–Fibrous tissue, adeno–from the Greek aden meaning originally "an

acorn" and later "a gland" in the form of an acorn, oma–A tumor or other abnormal growths.

Fibroadenoma is the most common benign tumor of the female breast [9,12,15,16]. Occurs at any age within the reproductive period of life [3,4,10,15,17]. Fibroadenomas are somewhat more common before age 30[13]. They are frequently multiple and bilateral. Young women usually present with a palpable mass and older women with a mammographic density or mammographic calcifications [18]. Unopposed high levels of estrogen and androgens may have a role in both fibrocystic disease of the breast and breast cancer[19].

During pregnancy, fibro-adenomata often enlarge but involute together with the rest of the breast after lactation. This feature is a demonstration of the influence of hormones on neoplasms[8]. A lump may have been detected by the patient herself (usually by chance, e.g. in the shower, although occasionally during self-examination) [10,20,21].

Though malignant change in fibro-adenoma is extremely rare (it changes to a sarcoma rather than to a carcinoma), excision biopsy is always advisable as mistakes in diagnosis could happen. The operative incision should be cosmetic, curvilinear and parallel to the areola, and the tumor is shelled out from within its capsule. Satellite modules should be carefully looked for and excised [18].

In allopathic Medicine the only way to cure the fibroadenoma is through surgery. But for the first time in unani system of medicine an attempt has made to manage the fibroadenoma of breast in non-invasive way by using unani herbs. As it is a tumor, it can be treated by using the unani herbs which can relieve the symptoms as well as the tumor.

Aim and Objectives

To evaluate the Efficacy of munzij wa mushil therapy & zimaad in sala'-e-sadi (fibroadenoma of the breast), to minimize the surgical hazards and to avoid scarring and deformity of the breast.

Unaniliterature

According to Unani Physicians Sala is a type of benign tumor which is formed by the accumulation of putrefied Balgham. According to Janab Abdul Hakeem Khan Saheb (Jamiul Uloom Tibbi), Ibn Hubal Baghdadi (Kitab Al Muqtarat E Fit Tibb) & Majoosi has described in detail about all types of Sala. They also mentioned that sala is formed from viscid phlegm, which is derived from the organ itself. They also stated about the types & sizes of sala & encapsulation. Ismail Jurjani (Zakheera Khwarzam Shahi), Samarqandi (SharahAsbaab) has described in detail about sala, its etiology, types & treatment. They also stated that sala may also be hereditary [22-26].

Salae Sadi

Unani Physicians termed Sala e Sadi for Fibroadenoma of breast. According to ancient Unani physicians, Sala e sadi is an inflammation-like swelling. It is formed due to accumulation of viscid Phlegm beneath the skin of the breast. The tumor has a characteristic that it is differentiated from flesh but it is attached to the skin superiorly. On palpation it is movable on all sides. It is firm in consistency. Generally, it is small in size starting from the size of a pea nut but sometimes it may also increase in size and shows its pressure effects on breast [27,28].

Hakeem Waseem Ahmed Aazmi in his book Amraz e Niswan described that "in breast after so many changes the tumor will occur." First they form a nodule in the breast, later it is converted into tumor. Generally these tumors are benign in nature but sometimes it may also converted to malignant tumor, which may be very fatal[29]. According to Samarqandi Sala e sadi is a fatty or fat like tumors. The color &consistency of sala is like fat & it is formed by viscous Balgham. Which is cold in nature. This is the firm tumor & encapsulated. There is no pain [26].

Classification of Sala E Sadi

Sala e Saalim (Benign Tumors): The structure of these sala are similar to the organ in which they develop. Most of the sala are encapsulated & they do not have liquid in them. They are fleshy or fatty. Recurrence of sala e sadi is common. Usually no pain is present but when they become large, they may cause pressure effect due to which pain & swelling may be present[26].

Saale khabeesa (Malignant Tumours): These are fatal tumors. They may also cause death[26].

Etiopathology of Sala E Sadi: According to ancient unani physicians 3 types of diseases occur in breast. 1. Due to Sue Mizaaj, 2. Due to Sue Tarkeeb, 3. Due to Tafarruqe ittesaal Najeebuddin Samarqandi in his book 'Sharah Asbaab' stated that there is a relation between, reproductive organs & breast through circulating channels. The matter reaches to breast through these channels. Sometimes this matter becomes liquid & viscid. The liquid matter gets dissolved & the remaining morbid matter will accumulate in breast itself & forms a tumour[26]. Abul Hasan Ali Ibn Abbas Majoosi in his book 'Kaamilus Sana' mentioned that "among all the diseases of breast, some are common & some are specific". Common diseases are like all other diseases but specific diseases are caused due to derangement in the temperament of breast. He also mentioned that there is a close relation between the diseases of other reproductive organs with breast[24]. Jurjani in his book 'Zakheera Qhwarzam Shaahi' mentioned that proper food in proper time and required quantity, produces pure & excess blood. When the food we ingest is abnormal & in excess, then it produces impure & less amount of blood & it also changes the temperament of breast. Hence, the tumor occurs due to derangement in the normal temperament of breast. So here the cause of the tumor is sue mizaaj [25].

Hasanul Samarqandi in his book 'Gina Mina' stated that "sometimes the breast may undergo several changes to form a tumor." If the morbid matter is cold in temperament the breast is also cold in touch & white in colour [30].

Material and Methods

Research Design: Clinical Research designed as a randomized single blind study with sample size of 30 was conducted from 2017-2019 in post graduate Dept of Ilmul Qabalat Wa Amraz-e-Niswan, Govt Nizamia Tibbi College and Hospital, Charminar, Hyderabad. Single group is planned for study. Method selected

for Statistical analysis is "Chi-Square test". Ethical clearance is issued by an institutional ethical committee. Single group of 30patients is planned for study.

Duration of Study: 18 Months
Inclusion Criteria: Unmarried and married women of reproductive age i.e; 15-50yrs. women with Symptomatic and asymptomatic fibroadenomas. Mammography reports with fibroadenoma lump size <5cms. Bilateral fibroadenomas. Non pregnant state.

Exclusion Criteria: Menopausal women and women above 50 years. Pregnant women. Women with serious medical illnesses such as cardio vascular diseases, respiratory distress and other systemic diseases. Carcinoma of the breast. Fast-growing and Giant fibroadenomas were excluded

Pharmacognosy: Drugs that are cost effective, easily available in the market, and with the least side effects were selected. Drugs were coded and given in the form of Munzij (concoction), Mushil (purgative), and Zimaad (Local application). A Single group was planned for the study.

Munzij Therapy: Afthimoon Vilaithi, Gul e Banafsha, Maweez Munaqqha, Beekh e Kasini, Tukhm e Baadiyan, Barg e Gaozabaan, Aslessos Mukhasshar, Gul e Gaozabaan, Tukhm e Katan (Alsi), Gul e Surkh, Gul e Mundi, Sapistan, Shaahatra, Tukhm e Kasoos. Soak the above medicine over-night in 400ml of water, and boil it in the morning till it becomes half. Filter it and give 100ml decoction 2 times i.e morning on an empty stomach and night before going to sleep for 21days.

Mushil Therapy: Turbud, Barg e Sana Maki, Turanjabeen, Anjeer. Soak the above medicine along with the medicines of munzij over night in 200ml of water, and boil it till it becomes half. Filter it and give 100ml joshanda in the morning on an empty stomach for 3 alternative days.

Tabreed: Khameera Gav Zubaan Saada is used as Tabreed. 5gms of halwa Morning and night for 3alternative days in between mushil.

Zimaad: Aaride Jao, Aarid e Hulba, Gul e Banafsha, Charbi e Bataq, Charbi e Murg. Both the fats are melted separately. All other medicines are powdered, cleaned, and mixed separately. Now all these medicines are mixed with previously melted fats and a 5gms of wax is added to it as a binding material. Now this zimaad is applied locally on breast for 5 alternative days after Munzij Therapy.

Follow-up: Patients are instructed to start munzij therapy followed by mushil & zimaad for 3 months. Before starting the treatment all the Patients are investigated by Mammography & FNAC to rule out carcinoma. Patients were also enquired about any adverse effects of test drug during the trial.

Subjective Parameters: During the first cycle of treatment, the nature and size of the lump is palpated and History of pain and swelling is also assessed.

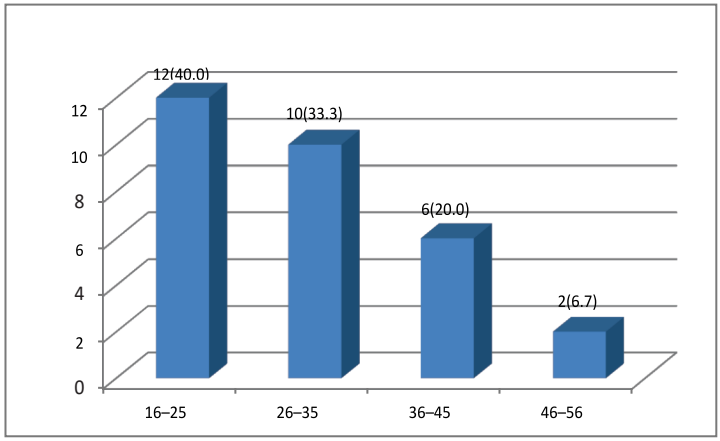
Objective Parameters: Routine Investigations: CBP (Complete Blood Picture), RBS (Random Blood Sugar), BGT (Blood Grouping & Rh Typing), HIV, HBs Ag, VDRL, LFT,RFT, CUE(Complete Urine Examination)

Special Investigations: Sono-Mammography, FNAC (Fine Needle Aspiration Cytology). Before starting the treatment all the Patients are investigated by Mammography & FNAC to rule out carcinoma. Carcinoma of the breast is assessed by BIRRDS score. If any patient is diagnosed with carcinoma, those patients are excluded from the study.

Observation & Results

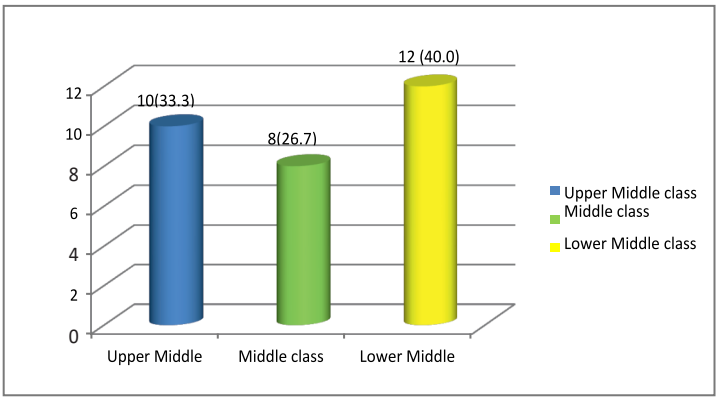
Distribution of patients according to age:

Fig.1: Age wise distribution of patients



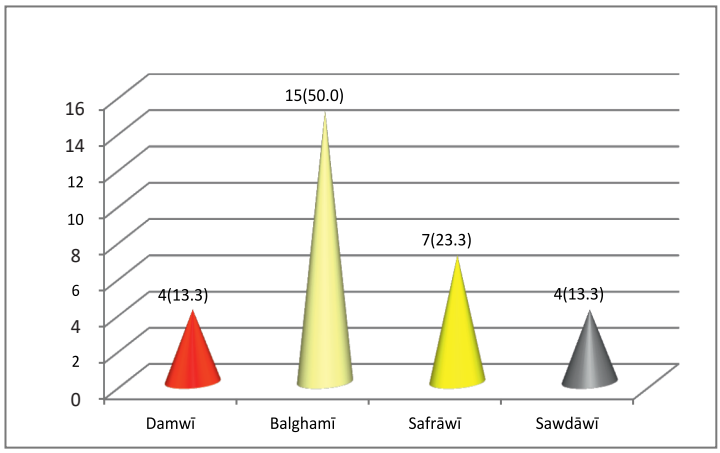
Distribution of subjects according to Socio-Economic status :

Fig.2: showing socio-economic status of patient



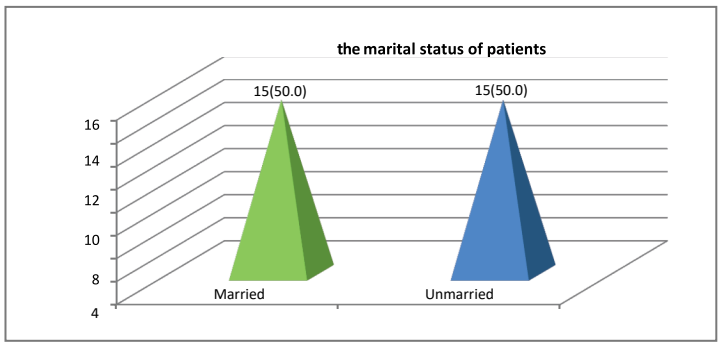
Distribution of subjects according to Mizaj (Temperament):

Fig.3: showing Mizaj (temperament) of patients



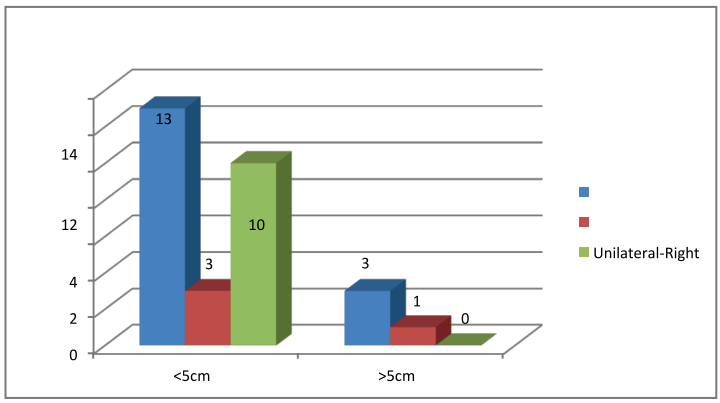
Distribution of subjects according to marital status:

Fig.4: Showing the marital status of patients



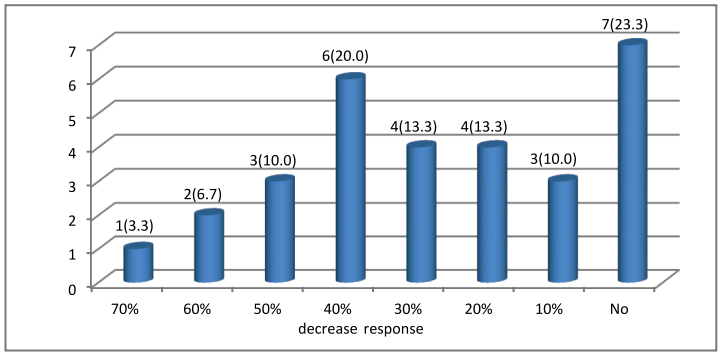
Distribution of subjects according to lump size and Uni/bilateral FA:

Fig.5: Showing fibroadenoma distribution as per size



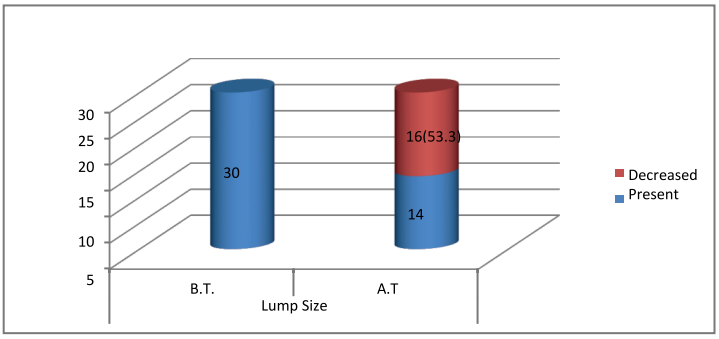
Distribution of subjects according to percentage of decrease in Lump size:

Fig.6: Showing decrease in lump size



Showing decrease in Lump size after treatment:

Fig.7: showing decrease in Lump size after treatment



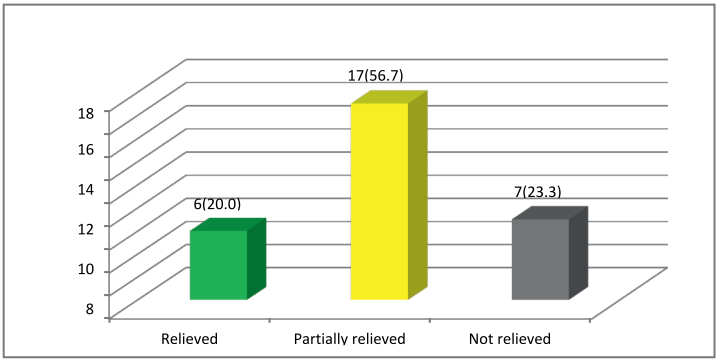
Showing a decrease in Lump size after treatment:

No. of patients			Chi-square test	p-value
Before treatment	After treatment <30% Decrease	After treatment >30% Decrease		
30	14	16	19.176	<0.00001

The Above table shows the response of patients after treatment, among total 30 patients 14patients had <30%decrease in lump size (less response) and 16 patients had >30% decrease in lump size. The p value is <0.00001 which is calculated by using chi-square test 19.176. The p-value is significant.

Therapeutic response of patients:

Fig.8: showing therapeutic response of patients



Therapeutic response of patients

Response	No. of patients	Percentage
Relieved	6	20.0
Partially relieved	17	56.7
Not relieved	7	23.3
Total	30	100.0

From the above table, it is observed that 20% of patients (6) were relieved, 56% of patients (17) partially relieved and 23% of patients (7) were not relieved.

Discussion

The present dissertation is carried out with the title “Efficacy of Munzij wa mushil therapy and Zimaad in “Sala e sadi” - A Randomised single Blind Study, to scientifically evaluate the efficacy of Unani medicine in sala'e sadi. From the current studies it is confirmed that this disease is more common in younger age group (2nd and 3rd decade)[31]. A fibroadenoma can be confused with: Breast Cyst, Breast Carcinoma, Phyllodes tumour, Breast lymphoma, Metastasis to the breast from another Primary site[32]. The only way to treat fibroadenoma in alternative medicine is through surgery. Unani medicine is the famous branch of alternative & complementary medicine that

tries to treat the cause with a change in lifestyle & using medicinal plants.

The present study is carried out for the first time in unani system of medicine to evaluate the efficacy and management of sala e sadi by using unani medicinal plants. In the present study the medicinal plants having the properties of muhallilat, musakkinat, mulattif, carminative, astringent, anti-cancerous properties, purgative, laxative, have been used to treat fibroadenoma. Based on current study, the selected group medicines were proven to be effective in the management of fibroadenoma. The medicinal group have- Aftimoon Vilaithi, Gul E banafsha, Maweez Munaqqha, Beekh e Kasini, Tukhme Baadiyan, Barg e Gaozabaan, Gul e Gaozabaan, Aslessoos Mukhasshar, Tukhm e Katan, Gul e Surkh, Gul e Mundi, Sapistan, Shahatra, Tukhm e Kasoos. These medicines were found to be more effective in current medicinal references. These medicines did not have any side effects & complications in proper dosage with proper duration according to reviewed ancient unani literatures in the present study. Phytochemical studies have shown that flavonoids, alkaloids, phyto sterols, phenolics, glycosides, albuminoids, mono saturated fats, poly unsaturated fats, saturated fats are the main components in the medicinal plants which are responsible for resolving the tumor as well as some of the medicines also have anti cancerous action [33-44].

Fibroadenoma of ectopic breast tissue in the vulva: a case report

Glands located out of the anatomical breast and mimicking breast tissue are ectopic breast tissue with reported incidence of 1-6%. Supernumerary breasts are a known entity. Ectopic breast tissue can occur anywhere along the primitive embryonic milk lines, extending from axilla to groin. Accessory breast tissue is subject to the same benign and / or malignant pathologic processes characteristic of thoracic breast tissue. Vulvar fibroadenoma is rare entity. It has been proposed that the tissue of origin is either ectopic breast tissue or vulvar mammary like glands. Most of the cases in the literature involve malignancies arising from ectopic breast tissues located in the vulva. There are few reports about the benign pathologies of the vulvar mammary glands[45].

Rehana begum et al in her article mentioned that 70-90% of fibroadenomas remain simple, occurrence of giant fibroadenomas is just about 0.5%-2% of all fibroadenomas[46].

Animal-origin medicine like duck fat & hen fat were used in the study. These medicines were used as external application as they have the properties of resolvent, demulcent & astringent, which were helped in resolving the morbid matter from the breast. The resolving; antioxidant, demulcent, anti-inflammatory & anti-cancerous properties of the plants have been proposed to play a key role in regulating oestrogen level, preventing from cancer as well as helped in dissolving the tumors[25,39-44].

Patient Assessment: A total of 40 patients were screened for the study, out of which 3 patients denied participation and 37 were evaluated through investigations. 2 patients were excluded as they doesn't comes under inclusion criteria, and 35 patients were enrolled in the study. Among these 35 patients, 5 patients were dropped out.

In the present study; it was observed that among 30 patients, 14 patients had less response to the medicine & 16 patients have shown good response to the study medicine. The less responsive patients had <30% decrease in lump size after treatment. Good responsive patients have shown >30% decrease in lump size. Among all 30 patients only 1 patient had 70% decrease in lump size. 2 patients out of 30 shown 60% decrease, 3 patients out of 30 showed 50% decrease, 6 patients out of 30 shown 40% decrease, 4 patients out of 30 showed 30% decrease, 4 patients out of 30 showed 20% decrease, 3 patients out of 30 showed 10% decrease. 7 patients had no response to the study drug.

In fig.3 the distribution of patients is purely based on the temperament. In this analysis, majority of patients 50% i.e 15patients with sala e sadi are of Balghami (phlegmatic) Mizaj followed by Safravi 23% i.e 7 patients & Damawi &saudawi are 13.3% in each i.e 4 patients were in damavi & 4patients were in saudavi mizaj. It proves the literature mentioned by Ancient Unani Physicians in pathophysiology of sala e sadi, that it is caused by derangement in temperament of balgham[33] & accumulation of putrified balgham beneath the skin of the breast[27]. It is described in "Kamil us Sana" that sala is formed by the organ in which it is developed[24]. In 'Zakheera e qhwarzamShaahi' also it is mentioned that sala e sadi is a cold swelling that is formed from Phlegm[25]. Ismail Jurjani also described sala as a type of tumor that is formed by viscid Phlegm & the consistency of which is Lahmi. So, the above analysis proves that sala e sadi is more prevalent i.e common among balghami mizaj women[25].

Strength of Research: The efficacy of coded Unani medicine has been proved & for the first time an attempt has made to treat sala‟ e sadi without any surgical hazards. The patients who received treatment have shown gradual relief from symptoms. The main strength of this study was that the patient can overcome their disease without a surgical incision. The Patient is satisfied by the coded medicine and patients have shown more interest in unani medicine comparatively than surgery.

Weakness of Research: Late diagnosis, Patients were not willing to undergo Investigations. Some of the patient refused to take unani medicine. Some patients have undergone surgery even after counselling, because they had a fear of breast cancer. Most of the Patients have complained about the sour taste and coarse texture of test drugs. As the Munzij therapy is of 21 days patients don't want to be admitted in the hospital for a longer duration.

Limitations of the Study: Small sample size (30 patients), Limited duration for research work (18 months). Less prevalence in the Study.

Further Recommendations: Further attempts can be made to treat Sala e sadi with unani medicines on large sample size. Further work can be done by using fewer medicines (can check the efficacy of the single drug in sala”e sadi).

Conclusion

From the present study carried out, it is observed that the patients had good responses to group medicine. Most of the patients were from low socio-economic groups. A good response to study drugs is observed comparatively than modern medicine. A marked decrease was observed after treatment, in patients who had the lump size of 1-2 cm. No side effects of the unani medicines were observed in patients. The selected unani drugs can be used further to treat fibroadenoma of breast (Sala'esadi). Finally, it is concluded that the unani medicines can be used to treat sala'e sadi (fibroadenoma of the breast) rather than the surgical incision.

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