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Clinical study and efficacy of Unani treatment in acute cystitis (Warm – E – Masana Haad)

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Abstract

Acute cystitis is an infection and inflammation of the urinary Bladder wall, most commonly due to the coli form bacteria; especially E. coli. The route of infection is typically ascending from the urethra such as instrumentation or by spread of infection from upper urinary tract. Symptoms include irritative voiding symptoms like burning micturition, frequency, urgency, dysuria and suprapubic pain are common. Urine appears hazy and may be offensive. Women may experience gross haematuria. There is no pyrexia. Cystitis found more frequently in women than in men. It is estimated that one third of the women population has at least one episode of cystitis in their lifetime. Of these many will have recurrent cystitis. The incidence of cystitis is higher in sexually active women than post- menopausal women. Other reason for the higher Prevalence of cystitis in women is shorter and straighter urethra. There is a high incidence of cystitis in immune compromised, elderly, diabetic and individuals with indwelling catheters. Acute uncomplicated bacterial cystitis is common in general practice. Cystitis is at the second raw of antibiotic treatment indications. Females are commonly affected with cystitis than males. The Female to male ratio is 4:1. Common age group is 18 – 39 years. According to Unani concept, the inflammation of urinary bladder wall is due to abnormal Bilious and Sanguineous matter, And sometimes in combination of both humours. The symptoms of warm-e-haar- masana are pain, fever, dysuria, local inflammation. The study is carried out to assess the efficacy and therapeutic response of Unani drugs in acute cystitis. In the Pg Dept. of Moalejat, at Govt. Nizamia tibbi College and hospital, Hyderabad, 60 patients are registered and 40 patients are selected for the trial. These 40 patients are divided into two groups with 20 patients in each group. Informed consent form is taken after explaining the nature and purpose of the study.

Keywords: Warm-e-haar-masana, cystitis, hematuria, dysuria, lower abdominal pain

Introduction

Acute cystitis is an infection and inflammation of the urinary Bladder wall, most commonly due to the coli form bacteria; especially E. coli. The route of infection is typically ascending from the urethra such as instrumentation or by spread of infection from upper urinary tract. Symptoms include irritative voiding symptoms like burning micturition, frequency, urgency, dysuria and suprapubic pain are common. Urine appears hazy and may be offensive. Women may experience gross haematuria. There is no pyrexia. Cystitis found more frequently in women than in men. It is estimated that one third of the women population has at least one episode of cystitis in their lifetime. Of these many will have recurrent cystitis. The incidence of cystitis is higher in sexually active women than post- menopausal women. Other reason for the higher Prevalence of cystitis in women is shorter and straighter urethra. There is a high incidence of cystitis in immune compromised, elderly, diabetic and individuals with indwelling catheters. Acute uncomplicated bacterial cystitis is common in general practice. Cystitis is at the second raw of antibiotic treatment indications. Females are commonly affected with cystitis than males. The Female to male ratio is 4:1. Common age group is 18 – 39 years. According to Unani concept, the inflammation of urinary bladder wall is due to abnormal Bilious and Sanguineous matter, And sometimes in combination of both humours. The symptoms of warm-e-haar- masana are pain, fever, dysuria, local inflammation. The study is carried out to assess the efficacy and therapeutic response of Unani drugs in Acute cystitis.

Material and Methods

The clinical study was carried out to assess the efficacy and therapeutic response of unani drugs in management of acute cystitis at outpatient department (O.P.D) of Govt. Nizamia General Hospital, Charminar, Hyderabad during the period 2016-2017 under the guidance of Dr. MD. Sirajul Haq, MD and supervision of Dr. Mohammed Ahsan Farooqui, MD, H.O.D of Pg department of Moalejat, Govt Nizamia Tibbi College, Hyderabad. The study was conducted on patients from both sexes who has attended the outpatient department of Govt. Nizamia General Hospital, Charminar, Hyderabad. Total 60 patients from outpatient were registered out of which 40 patients are selected for the study and divided into two groups i.e., Group 'A' and Group 'B' each group allotted 20 patients randomly. The study was conducted for 8 weeks (60 days) with regular follow up once in 15 days, clinical manifestation of these patients were recorded in specially designed proforma. The consent is taken after counseling and explanation. Patients are selected according to inclusion and exclusion criteria

Aims and Objectives

The present study of acute cystitis is designed with the following aim and objectives.

To evaluate the efficacy of Unani drugs in treatment of warm-e-masana haad (Acute cystitis).

1. To determine safe, easily available drugs used in acute cystitis.
2. To prevent the people from harmful effect of medicines.

Review Literature

According to Unani physicians, warm-e-masana haad (Acute cystitis) occurs due to abnormal Damvi (sanguinous), or abnormal safravi (bilious) and sometimes in combination of both abnormal (gair tabayi) humours.

1. Hippocrates believed that disease was caused by alteration in kamiyat (quantity) aur kaifiyat (quality) of Akhlath, i.e. Alteration in Mizaj (temperament) of Akhlath of any organ. This holds good to infections as well as metabolic diseases. Warm- e-masana Haad is caused by gair Tabayyi safravi and damvi madda. This abnormal madda leads to Hiddath. And Hiddath leads to infection.
2. Desquidus (100 A. D) in his famous book "KITAB-AL-HASHAYASH" stated that, "The douching of butter and milk cream is beneficial in case of warm-e-masana haad (acute cystitis).
3. Ali Bin SahlRabban Al Tabri, (810 A.D), mentioned "warm-e-masana" in his famous text "Firdous-ul-hikmat".According to him, the symptoms of Warm-e-Haar are pain, fever, dysuria, local inflammation.
4. Rhazes (865-925 A.D), explained it uder the heading of "Auram Gurda-va-masana" in "Kitab al havi". He also gives emphasis over the efficacy of maul jabn to reduce the acidity and burning during micturition.
5. In "Kamil-us-sana", Ali Ibn-e-Abbas Majusi (930 A.D) describes underthe heading of "Warm-e-masana". He has given vivid description about etiology, clinical features etc. According to him "Warm-e-masana "is due to weakness of excretory function and inflammation of neck of urinary bladder. First line of treatment in Acute cystitis is venesection of basilica vein. Orally, Magz-e-tukhm khayarein, Tukhm Kharpaza (cucumis melo),

Tukhm Kaddu, Tukhm khatmi, Parsiya oshan (Adiantum capillis) etc are very beneficial.

6. Ibn-e-sina (980-1030 A.D), in "Canon of Medicine" has given an ample space under the heading of "Warm-e-masana".
7. Hakeem Akbar Arzani (1134 A.D) has also discussed it in detail in his famous book (Tibb-e Akbar), "Mizan e tib".
8. Ismail Jurjani (1140-1236 A.D) in "Zakhera-e-Khwazamshahi "described the disease as "Warm-e-garam masana".Here he clearly described that the infection and hot inflammation is due to abnormal Sanguinous and Biliious humours and sometimes in combination of both.
9. The famous indian Unani scholar Hakim Azam Khan (1813-1902 A.D), in his book Akseer-e-Azam has described the disease as "Warm-e-masana-e-har" and given a wide coverage regarding its etiopathogenesis, clinical features and management.
10. The modern Unani physicians like, Hakeem Ajmal Khan (1868-1927 A.D) has given the description of disease as "Waja-ul-masana" in his book "Haziq" with its etiopathogenesis, clinical features and management."Asbab-e-Alamat", the most popular among Unani scholars, translated by Hakeem Kabiruddin as "Sharah-e-asbaab va alamat", (original author Najimuddinsamarqandi), covers the almost entire aspects of disease and its management under the heading of "Warm-e-masana har" which is very similar to the description available in modern books of medicine.
11. Abu Marwan Ibn Zohr in his book "Kitab-al-Taisir", mentioned about the disease under the heading "Warm-e-Gurda-wa- Masana".
12. Mahzabuddin Abdul Hasan AliBin Ahmed Bin Bogdadi in his text "Kitab Al Muqatarat fi tib"described under the heading "Inflammation of urinary bladder and Injuries", He states that the cause of Hot inflammation in urinary bladder is due to Biliious and Sanguinous matter.
13. In "Moajiz AL Khanoon", Kouserchandpuri described the disease as "warm-e-masana", here the author describes that Inflammation is due to abnormal biliious or sanguinous matter or sometimes in combination of both humours.

Etiology

The cause of disease is not only microbial but also disturbance in Asbab-e- sittah zaruriah (six essentials factors) and weakening of Tabiyat mudabbir –ul- badan. Alteration in kamiyat (quantity) and kaifiyat (quality) of Akhlath i.e., Sue mizaj, Thus when the alteration of akhlath takes place it provides favourable culture media for the microorganisms and therefore, it invites the infection. So the causes of infection are not the microorganisms alone but disturbance in asbab-e-sittah zaruriah and therefore alteration of Akhlath with respect to their quanlity.

According to Unani Concepts the following conditions cause Warm-e-Masana Haad (Acute Cystitis).

Acute and Hot Humour (Akhlat – e- Haadahya Harrah). Deranged hot Temperament of urinary bladder (Sue mizajhaar masana).Person having biliious temperament (mizaj-e- safravi).

Modern Etiology

Many microorganisms can infect the urinary tract, but by far the more common agents are the gram-negative bacilli. *Escherichia coli* causes approximately 80% of acute infection (both cystitis and pyelonephritis) in patients without catheter, urologic abnormalities, or calculi, other gram-negative rods, especially *Proteus*, *Klebsiella* species. Infection associated with urologic manipulation, calculi or obstruction

Pathogenesis – Unani Perspective

The basic of infection which was postulated and hypothesized by renowned ancient scholars of unani medicine, are based on two factors. i.e., Quwat-e-istedad (Favourable condition) and Quwat-e- mudabbir-e-badan (immunity), of the host for infection. As long as Quwat-e- mudabbir-ae-badan (immunity) is strong and Quwwat-e- Istedad (susceptibility) is low, infection does not occur and vice versa.

In Unani system of medicine, it is very much clear that only the Quwwat-e- istedad (susceptibility) and Quwwat-e- mudabbir-e-badan (immunity) are the main factors that can be elaborated as the microorganisms did not do anything, rather these favourable conditions are created inside the human body, tissue and organs by alteration in the original temperament of the concerned organ or body system.

Quwwat-e- mudabbir-e-badan (immunity) also maintains the four humours, in their specific proportion and maintains health while disproportion leading to manifestation of various pathological states and diseases.

According to Unani concept, when human body is attacked by the microorganisms, Quwwat-e-istedad (favourable condition) and Quwwat-e- mudabbir- e-badan (immunity) is altered again in following ways.

1. Good Humours (Akhlath mahmooda) are eaten up by the microorganisms.
2. Their toxins are added to the Akhlath.
3. Owing to these toxins certain other organs are also affected and therefore, mizaj and Akhlath are again altered to the determinant of the body.
4. However, if the tabiyat is strong enough, a good and healthy sign is seen and that is the production of specific humours (immunoglobulins) against the microorganisms to get rid of the infection.

Modern Pathogenesis

Cystitis may be Acute or Chronic, In the Acute form, which is likely due to pyogenic cocci, the mucous membrane is swollen, red, and hemorrhagic.

Small ulcers develop, the surface is covered with shreds of epithelium and small clear cysts are formed on the trigone. Microscopically there is congestion of the submucosa and infiltration with inflammatory cells, the superficial layers of mucosa may be desquamated, but the main substance of the wall is intact.

Clinical Features

According to Unani Literature, the concept of four humours (Akhlath-e- arbah) forms the basis of health and disease in unani system.

It has been already stated that the noxious matter (maddah) responsible for causing Acute cystitis (Warm-e- masana

Haad) may be one of the four humours or their may be combination of more than one Humour, depending upon the factor responsible, following types are recognized with distinct features.

When causative matter is Sanguinous and Bilious (Damvi and safravi), pain, tenderness, swelling in supra pubic and loin region, difficulty in micturition, dribbling of urine, High grade fever, constipation, cold hands and feet, bluishness of tongue and periphery are present.

In Safravi type (bilious), vomiting, polydipsia, pain and burning micturition is more marked. In both of the cases the calorific measures (Haar Tadabeer) will aggravate the condition while refrigerant measures (Barid Tadabeer) will bring about some relief in the clinical features.

The common symptoms of Acute cystitis (Warm-e- masana haad) are the following:

Supra Pubic Pain

Supra pubic pain usually occurs due to lower urinary tract infection, cystitis or urethritis. Symptoms include Dysuria, Frequency or strangury. In men the pain may be associated with extreme perineal or rectal discomfort, here prostatitis is suggested.

Dysuria

The specific form of discomfort arising from the urinary tract in which there is pain before, during and after micturition. Urine is often Burning and associated with frequency of micturition and decreased bladder capacity. Infection and Neoplasia in the bladder or urethra are important causes.

Frequency of Micturition

It results from irritation of Bladder by infection, stone, tumour or from a reduction in capacity of bladder by fibrotic contraction or pressure from pelvic tumour. The patients sleep is disturbed by need to micturate (nocturia).

Urgency

It is the loss of the normal ability to postpone micturition beyond the time when the desire to pass urine is initially perceived

Burning Micturition

Urine often becomes grossly cloudy and Malodorous and it is rarely bloody

Fever rarely exceeds

Examination of urine (Unani Review)

Diagnosis of diseases depends on observation of three important factors in unani system of medicine i.e., Pulse, Urine and Stool. Examination of urine is not only important in clinical practice but also the backbone of diagnosis for nearly all diseases in unani system of medicine.

Conditions for Examination of Urine: (Shariyat-E- Moaina-E-Baul)

According to Sheikh the following conditions should be kept in mind while examining the urine.

1. Urine should be collected early in the morning.
2. Urine should not be retained for too long in urinary bladder.

The whole urine should be collected**Before the collection of urine no food or drink should be taken**

1. Those substances should not be applied to the skin and nails which may give colour to urine. For example henna.
2. Specific diuretic drugs (i.e., diuretic of phlegm and bile etc) help in excretion of specific materials or humours. Such drugs should not be taken.
3. Certain substances should not be taken which may give colour to the urine for example –Saffron changes the urine colour red or yellow, purging cassia vegetables makes the urine green, Almuri which makes the urine dark black and wine which imparts its own colour.
4. Undue physical and mental exercises should be avoided these too colour the urine e.g. fasting, lack of sleep, fatigue, hunger and outbursts of anger make the urine red or yellow.
5. Urine sample should be protected from exposure of heat or cold. Exposure of sun (heat) tends to produce fermentation and cold air makes the urine so dense that it fails to yield even the usual deposit appearing after normal digestion and metabolism.
6. The glass should be clear, colourless, wide mouthed and must be thoroughly washed before use.
7. Examination should not be carried at once but after the urine have been allowed to settle for some time.
8. For culture and sensitivity test, urine must be collected in sterile container and it should be the midstream urine.
9. The specimen of urine should be examined from both close and distance.

Urine looks clear if viewed from distance and dense when viewed from close range.

Urine should be examined in good light.

Urine according to growing age

The infant's urine is white due to milk feeding and moisture in their temperament. The children urine is thick, viscid but at maturity it is to be yellowish or orange due to digestion and dominance of biliary temperament.

In middle age it is pale and watery and in old age the urine is pale, watery and low density and it may develop calculus of bladder or kidney.

Laboratory Assessment of Urine

The urine should be tested as a part of general medical examination this should not be confined to patients with known Renal or Urinary tract disease.

Collection of Urine Sample

1. Urine sample should be passed in a clean container without additives.
2. Testing should normally be conducted as soon as possible and if delayed more than 2 hours the urine should be refrigerated (not frozen) and returned to room temperature before testing.
3. A mid-stream sample is essential for microbiological assessment and desirable for microscopic examination.
4. During collection of the sample in female patients vaginal discharge should be avoided.
5. In some cases patients should be catheterized due to some reasons e.g., urinary obstruction.

Routine examination of urine**It consists of**

1. Physical examination
2. Chemical examination
3. Microscopic examination

Physical examination

Quantity: Normal adults in temperate climates usually pass between 750 ml to 2500 ml of urine in 24 hours. The minimum urine output compatible with normal renal excretory function varies from person to person and also with other factors such as diet. Abnormal low urine output (oliguria or Anuria) implies that the flow rate is below the minimum quantity.

Colour: Normally it is Light to dark amber (yellow). The presence of hemoglobin will give the urine brown to red colour.

Clarity: Freshly voided urine is clear and transparent. Cloudiness in freshly voided urine may indicate the presence of pus, blood or bacteria from urinary tract infections.

pH: Normal urine: 4.8 to 7.5 depending primarily on dietary intake. The acidity of urine increases in acidosis and during fever. Alkaline urine may be produced by letting it stand or by storing it in urinary bladder due to conversion of urea to ammonia, excessive dietary intake of certain foods (e.g. fruits), ingestion of alkaline substances (e.g. Sodium bicarbonate), various states of alkalosis.

Specific gravity: Normal range: 1.010 to 1.030.

Higher values during fever and thirst, and in patients with diabetes mellitus. Lower values: Tends to be low in diabetes insipidus and after excessive quantities of water have been taken.

Odour: Freshly passed urine has a characteristic aromatic odour due to volatile organic acids.

Chemical Examination**Glucose: Normal: negative.**

When glucose in plasma exceeds 180 mg/dl, the transport capacity is exceeded and glucose begins to appear in urine.

Ketones: Normal: negative.

Excessive metabolism of fats due to a high dietary intake of fat or a dependence of the cells on lipid metabolism to produce energy because of fasting, results in the presence of large amounts of ketones in urine.

Protein: Normal: negative

Excess protein in the urine reflects an abnormal leakiness or severe damage of the glomerular membrane or both. Various types of nephrosis and nephritis due to infection, vascular degeneration and other causes may result in proteinuria.

Microscopic: The microscopic examination may include some or all of the following:

1. **White blood cells (WBC):** WBC's in Urine usually indicate inflammation or infection of the urinary tract.
2. **Red blood cells (RBC's):** RBC's in urine can be

caused by inflammation or injury to kidneys or urinary tract.

3. **Epithelial cells:** High concentration of epithelial cells is typically caused by infection or inflammation of urinary tract.
4. **Crystals:** Crystals may be formed by various particles which are dissolved in urine. Crystal formation may be due to abnormal pH balance or a higher than normal concentration of particles. Crystals formed in the kidney may lead to development of kidney stones.
5. **Casts:** Casts are the cylindrical particles formed from the proteins secreted by kidneys.
6. **Mucus:** Mucus in the urine may be the results of a urinary tract infection or condition affecting the digestive system.
7. **Bacteria:** Bacteria in urine is usually indicative of a urinary tract infection

Diagnosis

Diagnosis of Acute cystitis comprises of Detailed History taking, Physical examination of patient, Physical examination of urine, Laboratory investigation and specific investigation.

History taking

Careful history taking is important. The predisposing and precipitating factors must be considered for diagnosis.

Physical Examination of the patient:

Pain or tenderness over supra pubic area are helpful in diagnosis.

Occasionally it may be possible to palpate the bladder when it is fully distended. Physical examination of urine:

Laboratory Investigation:

Routine investigations like CBP, ESR and RBS are required to find out other possible diseases. However, the most specific investigations for Acute cystitis are complete urine examination (CUE) and Urine Culture test. The presence of bacteria in urine is a firm evidence of infection but its absence does not exclude the diagnosis.

Urine culture test is performed to grow and identify organisms, mainly bacteria and fungi that may cause infection in Urinary tract. While in urinary bladder, urine normally sterile and free from any organisms.

Special Investigations

Ultra sonography

Ultra sonography is important to exclude secondary causes of cystitis, such as outlet obstruction, bladder calculi. To look for associated kidney diseases, it is also a good modality for measuring bladder capacity which may be a major concern in cases of cystitis.

Other common features are bladder wall, mucosal thickening, irregularity and mucosal ulceration of varying intensity.

Differential diagnosis

Differential diagnosis is necessary because majority of the abdominal diseases produce the similar manifestations of Acute cystitis. Diagnosis should be accurate.

Acute cystitis should be differentiated with Pyelonephritis,

Vaginitis, Interstitial cystitis, Chlamydia urethritis, Prostatitis.

1. **Pyelonephritis:** In this disease fever, nausea and vomiting are present. On physical examination, flank tenderness is considered pathognomic for pyelonephritis. Elevated WBC and positive blood cultures are observed.
2. **Vaginitis:** Vaginitis is common vaginal infection that is caused by a fungus or bacteria. Occasionally the infection causes frequent urination, mimicking cystitis. Significant pruritis and vaginal discharge are typical symptoms.
3. **Interstitial cystitis:** Here negative urine cultures are observed. Symptoms are more similar to cystitis but no bacteria are present.
4. **Urethritis:** Negative urine culture and positive PCR test for Chlamydia are observed.
5. **Prostatitis:** Prostatitis often causes painful or difficult urination.

Complications and Prognosis

When treated promptly and properly, bladder infections are rarely lead to complications. But left untreated, they can become something more serious.

Complications included are

Kidney infection: An untreated bladder infection can lead to kidney infection, also called pyelonephritis.

Young children and older adults are at greater risk of kidney damage from bladder infections because their symptoms are often overlooked or mistaken for other conditions.

Prognosis

Prognosis after treatment is excellent. As this condition is common many patients will eventually have a recurrence.

USOOL-E-ILAJ

The first line of treatment is to treat the cause.

To do venesection of basilic vein.

Anti-inflammatory drugs, Diuretics and Analgesics are used. Accordingly.

Prevention of acute cystitis

Following preventive measures are recommended for repeated bladder infections.

Drink plenty of liquids especially water.

Urinate frequently, if there is an urge to urinate, don't delay.

Patients are selected according to inclusion and exclusion criteria (Table.1)

1. Good personal hygiene is important. Wipe from front to back after a bowel movement, this prevents bacteria in the anal region from spreading to vagina and urethra.
2. Take shower rather than tub baths.
3. Gently wash the skin around the vagina and anus; don't use harsh soaps and wash vigorously. The delicate skin around these areas become irritated.
4. Urinate before and after intercourse.
5. Wear cotton under wear, avoid wearing tight clothing.
6. Avoid using deodorant sprays or feminine products in genital area. These products can irritate bladder and urethra.

Table 1: Shows the Inclusion Criteria and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Patients with burning micturition with or without fever.	Patient with pregnancy and lactation.
Patients with dysuria	Patient with renal calculi
Patients with urgency of urine.	Patients with Diabetic mellitus.
Patients with frequency of micturition.	Patients with Hypertensive
Age limits 18-60 years.	Patients with systemic diseases.
Sex- both sexes.	
Non or Controlled Diabetic	Trauma
Non Hypertensive	

Investigations Done

Routine Investigations

1. Complete urine examination
2. Urine culture
3. Random blood sugar

Special Investigations

USG – Abdomen

Assessment Criteria

Each patient was overall assessed at every 15 days after the onset of treatment. Relevant data was collected and documented on the detailed case proforma. Assessment of the condition is done on the base of relief in the sign and the symptoms of the disease Acute cystitis, for this purpose standad scoring scale is used.

Efficacy Assessment

The Efficacy of treatment of both groups was assessed on the basis of subjective and objective parameters (table. 2).

Table 2: Shows the Subjective Parameters Like and Objective Parameters Like

Subjective Parameters Like	Objective Parameters Like
Urgency	CUE
Frequency	Urine culture
Dysuria	USG Abdomen
Dribbling	
Supra pubic pain	
Urgency	
Arbitrary scale was adopted for this assessment	

Study Design: Randomized single blind parallel clinical trial.

Sample Size: Sample size was determined as 40 patients

Allocation of Patient into Groups: A total of 60 patients are registered, of which 40 patients were randomly allocated in to two groups A and B with 20 patients in each group.

Duration of Treatment Protocol

The duration of protocol is 60 days (2 months) for group A and B

Selection of Drugs for Clinical Trial Pharmacognosy of Drugs

Drugs which are selected for the trial were finalized on the basis of efficacy in management of warm-e-masana haad (Acute cystitis) and their pharmacological effects, easy availability with least side effects in both groups, Group A and Group B. Drugs used in the present study are having

following pharmacological effects.

- Muhallil-e-Auram (Anti-inflammatory),
- DaafeTaafun (Anti septic)
- Mudir e baul (Diuretic),
- Musakkin- e- hararat
- Musakkin (Analgesic)
- DaafeBukhar (Anti pyretic)

Results and Discussion

In the daily clinical practice, Acute cystitis is detected from routine USG; (or with a symptom of Burning micturition) Patients with cystitis usually complain of dysuria, urinary frequency and urinary urgency. Burning throughout the course of micturition may help differentiate cystitis from urethritis where pain is classically at the beginning of micturition. Patients usually have no fever or constitutional symptoms and are comfortable except during micturition. There is no costoverteloral tenderness. Mild Supra pubic pain is elicited. Cystitis is very common in adult females who are sexually active. Atleast 30% of women experience atleast one episode of cystitis in their life time. Those most at risk are sexually active young women. Their propensity to develop cystitis has been explained on the basis of Anatomy (especially a short urethra) and certain behavioural factors, including delays in micturition, sexually activity, and the use of diaphragms and spermicides. In contrast, cystitis is very rare in men. This is thought due to be secondary to the presence of longer urethra making the ascension of bacteria more difficult and also due to the bacteriostatic nature of prostatic secretions. Ancient physicians viz. Hippocrates, Galen, Rabban Tabni, Rhazes, Ali Ibn Abbas Majoosi etc has described Acute cystitis under the heading of “WARM-E-MASANA”. It is caused due to the gair tabayyi safravi or damvi matter and sometimes in combination of both humours and also concluded its effective treatment in their respective books.

The present study entitled “Clinical study and efficiency of unani treatment in warm-e-masana haad” (auto cystitis) was designed as a Randomized single blind comparative clinical trial with a sample size of 40 pts who are randomly allocated by lottery method into two groups A&B with 20 patients in each group.

The drugs selected for the study in Group-A was a capsule of Kaknaj (Physalis alkengi) and Parsiyaoshan (Adiantum officinalis) and the drug in Group-B was capsule ofTukhm khatmi (Althea officinalis) &Tukhm kharpaza (cucumis melo).

The duration of treatment is 60 days. The disease Acute cystitis was assessed based on clinical symptoms, signs and standard method of scoring viz. Arbitrary scale; here the grading is based on severity of the symptoms are;no symptom, mild, moderate, and severe as (0, 1, 2, 3). The

common complaints were closely observed on 0, 15th, 30th, 45th, 60th days and arbitrary grading were recorded for each pt in before treatment (0 day) and after treatment (60 day). At every visit patients were asked about the progression or regression in their symptoms and arbitrary scale was calculated before and after treatment subjected to assess the clinical findings. The observations and results concerning demography, clinical symptoms and signs and Arbitrary grading obtained from the trial have been illustrated in tables and graphs. They are discussed in the following paragraphs consecutively to draw presumption and to turn up at a conclusion.

The highest no of pts observed in the age group of 21-30 (Table no-1, figure-1), i.e., cases (25%) and secondly the age group observed are from 31-40 & 51-60 years of age group. 15 cases respectively in both groups A&B. The disease was more prevalent in sexually active and immunosuppressed pts.

The maximum no of pts as per the evidence of (table no-2, figure no-2) were females 24 (60%) who are sexually active & followed by males 16 (40%), which correlates with the finding of Davidson's principles and practice of medicine.

As shown in above result, all pts were divided into 4 groups according to their temperament. The temperament of the pts was accessed on the basis of specially modified /prestructured questionnaire based on Ajnas-e-Ashra (Ammexure-III) and it was recorded that minimum no of pts i.e., 19 (47.5%) cases were of Biliious temperament, followed by 16 (40%) cases are of Sanguinous temperament, 3 (7.5%) Phlegmatic temperament and 2 (5%) Melancholic temperament. (Table no-3, figure no-3)

In the light of above observation, it can be concluded that subjects with Damvi and Safravi temperament are more prone to Hot and Acute inflammation. This observation is conformity with the finding described by Rabban Tabri, Abbas Majoosi, Rhazes.

The pathogenesis of most of the diseases in unani medicine is described in term of alterations of humour quality & quantity and most of the unani physians have clearly associated pathoganess of warm-e-masana haad., Supports the description made by the unani physicians, Ibn sina, Ismail jurjani, HK Ajmal Khan, Rhazes, Rabban Tabri as Damvi & Safravi matter are usual cause of " warm-e-haar-haad".

In present study most of the cases were from Biliious & sanguinous temperament and thus the data observed in this study is in the favour of the description. As it is evident from (Table no-4, figure no-4) that highest prevalence of Acute cystitis was seen in married patients 30 (75%) and the remaining 10 (25%) in unmarried cases. In (table-5&figure-5), the highest prevalence of Acute cystitis was seen in pts 16 (40%) was belongs to middle class, followed by 12 (30%) upper class & 12 (30%) lower class. High prevalence is seen in middle class pts. According to religion, the study shows more prevalence in muslim pts 38 (95%) comparing to non-muslim category 2 (5%). Out of 40 pts, 18 (45%) pts are Housewives, 10 (25%) pts are unskilled workers, 7 (17.5%) are professionals and 5 (12.5%) are skilled workers. In this study Acute cystitis is more common in Housewives followed by unskilled workers, professionals and skilled workers.

It was found that out of 40 pts, 23 (100%) patients has supra

pubic pain, 24 (60%) pts relieved of burning micturition, 27 (67.5%) pts relieved of frequency, 29 (72.5%) pts relieved of dysuria, 14 (35%) pts relieved of dribbling 30 (75%) pts relieved of urgency.

The efficiency of group-A and Group-B drugs were accessed on the basis of improvements in typical clinical symptoms and signa of Acute cystitis. At the end of the study, there was (highly significant improvements in these symptoms in both Group-A and Group-B. In Group-A the supra pubic pain was reduced in 10 cases (100%) ($p<0.0001$), Burning micturition was reduced in about 12 cases i.e., 60% (P value= 0.0001), frequency was reduced in 15 cases i.e., 75% ($p<0.0001$), dysuria was reduced in 16 cases; 88% ($p<0.0001$) dribbling was reduced in 9 cases 90% (P 0.0003). Urgency was reduced in about 16 cases 84% ($p<0.0001$).

Where as in Group-B, the supra pubic pain was reduced in 13 cases i.e., 100% ($p<0.0001$), Burning micturition was reduced in 12 cases i.e. 60% ($P=0.0001$), frequency was reduced in 12 cases i.e. 60% ($P=0.0001$), Dysuria was reduced in 13 cases i.e., 76% ($P=0.0001$), Dribbling was reduced in 5 cases i.e., 62% ($P=0.0311$), urgency was reduced in about 14 cases, i.e. 73.6% ($p<0.0001$). It is evident that the all clinical symptoms and signs were highly significant in both groups A and B. Compare to the baseline reading of each group (Table no 8, 9; figure no-8, 9).

It was found that, out of 20 patients, in Group – A, the mean of objective parameter before treatment is 10.50 ± 4.89 and after treatment is 3.70 ± 3.93 and the p value calculated is significant. Similarly in Group – B, the mean of objective parameter before treatment is 12.80 ± 3.54 and after treatment is 5.30 ± 4.05 and the mean calculated is significant.

It was observed that usg done in Group-A, chi square test calculated is 16.200 and p value is significant, where as in Group- B, chi square test calculated is 6.250 and p value is 0.0124.

The response of treatment was defined as Good response, Satisfactory response, No response. Therapeutic response of Group-A showed that out of 20 patients, 12 (60%) patients got good response, 5 (25%) patients got satisfactory response, 3 (15%) patients got no response. Where as in Group- B showed that out of 20 patients 9 (45%) patients got good response, 6 (30%) patients got satisfactory response, 5 (25%) patients got no response.

It is evident from above described observations that, Group A medicines are more effective than Group B. Acute cystitis signs and symptoms were improved in both the groups. At the end of the study, statistically significance of result was noted. It was concluded that, efficacy of unani formulations on Acute cystitis was found clinically & statistically significant & both the Groups are safe & effective.

Group A consists of Capsule

Formula of Capsule

Table 3: Total 1 Gram in 2 divided doses i.e., 500mg in each dose for two months, after meals with luke warm water

S. No.	Name of the drug	Dosage in grams
1.	Kaknaj (Physalis alkekengi)	250 mg
2.	Parsiyaoshan (Adiantum capillus)	250 mg

Group B consists of capsule

Table 4: Total 1 Gram in 2 divided doses i.e., 500 mg in each dose for two months, after meals with luke warm water

S. No.	Name of the drug	Dosage in grams
1.	Tukhm E Kharpaza (Cucumis melo)	250 mg
2.	Tukhm-E-Khatmi (Althea officinalis)	250 mg

Follow UP During Treatment

Duration of treatment of 60 days were divided in to 4 visits of follow up at an interval of 15 days at every visit, patients

were asked about the progression are regression in their symptoms and subjected to assess the clinical findings.

Table 5: Comparative Distribution of Patients According To Age in Group-A and Group-B

S. No.	Age	Group-A		Group-B	
		No. of PTS	%	No. of PTS	%
1	11-20	0	0.0	4	20.0
2	21-30	5	25.0	5	25.0
3	31-40	5	25.0	4	20.0
4	41-50	4	20.0	4	20.0
5	51-60	6	30.0	3	15.0
	Total	20	100.0	20	100.0

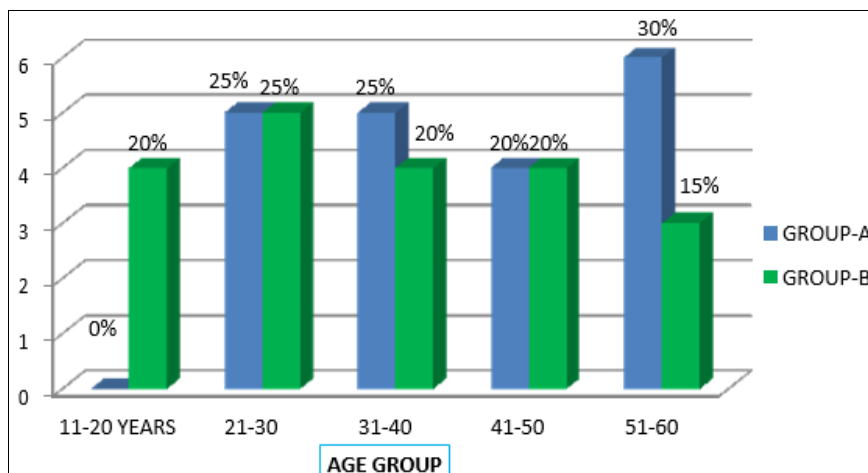


Fig 1: Comparative Distribution of Patients According to Age in Group-A & Group-B (n=20)

Table 6: Comparative Distribution of Patients According To Gender in Group-A and Group-B

S. No.	Gender	Group-A		Group-B	
		No. of PTS	%	No. of PTS	%
1	Male	11	55.0	5	25.0
2	Female	9	45.0	15	75.0
	Total	20	100.0	20	100.0

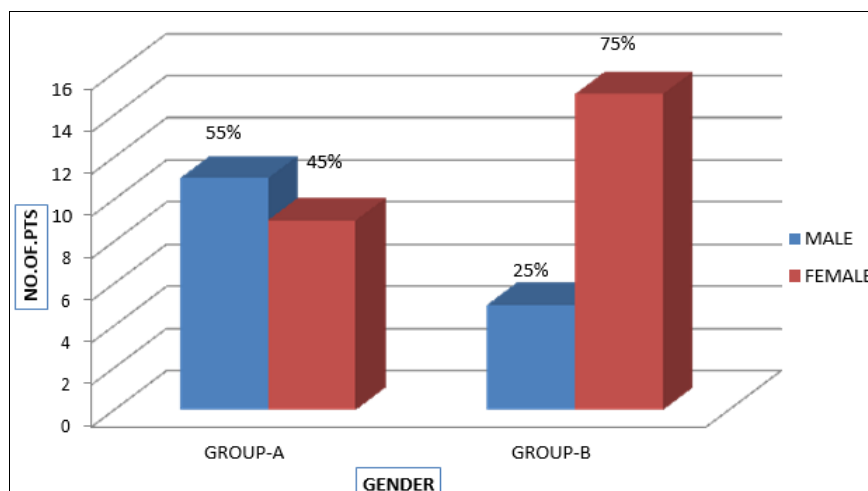


Fig 2: Comparative Distribution OF Patients According To Age in Group-A & Group-B (n=20)

Group-A consists of 11 male cases and 9 female cases, the age of the patients varied from 18 to 60 years. Group-B consists

of 5 male cases and 15 female cases and age of the patients varied from 18 to 60 years.

Table 7: Comparative Distribution of Patients According To Temperment in Group-A and Group-B

S. No.	Temperment	Group-A		Group-B	
		No. of PTS	%	No. of PTS	%
1	DAMVI	9	45.0	7	35.0
2	SAFRAVI	10	50.0	9	45.0
3	BALGAMI	1	5.0	2	10.0
4	SAUDAVID	0	0.0	2	10.0
	TOTAL	20	100.0	20	100.0

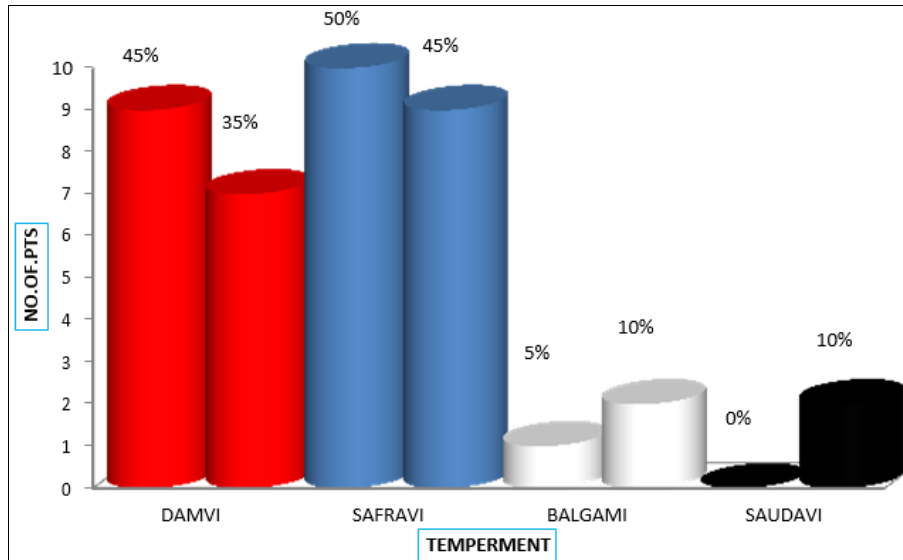


Fig 3: Comparative Distribution of Patients According to TEMPERMENT in Group-A & Group-B (n=20)

The dominant humour of all cases were assessed according to the symptoms and signs described in Unani classics. The present study shows that Auto cystitis is most commonly seen in Safravi (19) and Damvi (16) mizaj. Figure no-3

Table 8: Comparative Distribution of Patients According

S. No.	Marital Status	Group-A		Group-B	
		No. of PTS	%	No. of PTS	%
1	Married	16	80.0	14	70.0
2	Unmarried	4	20.0	6	30.0
	Total	20	100.0	20	100.0

Marital Status in Group –A and Group-B

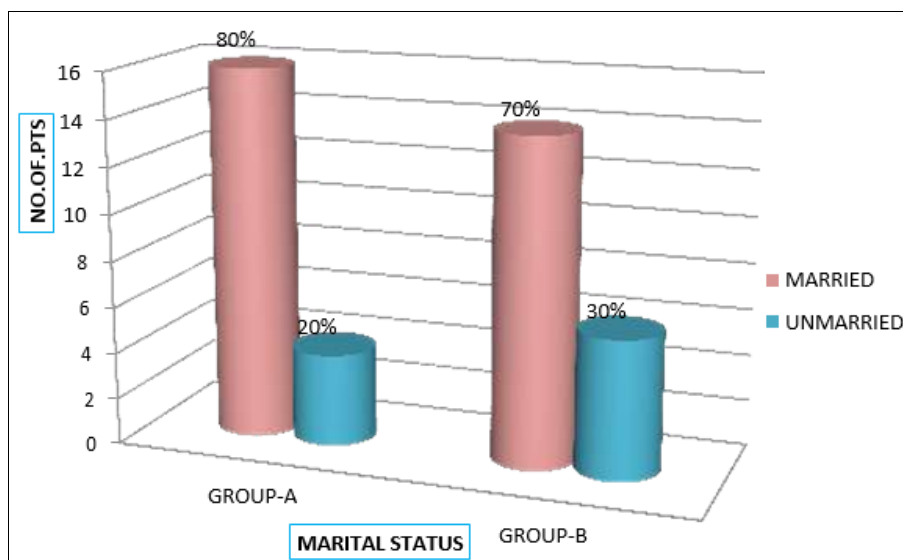


Fig 4: Comparative Distribution OF Patients According To Marital Status in Group-A & Group-B (n=20)

The present study shows that this disease is common in married (30) then unmarried (10) and more common in female than males. Figure no- 4

Table 9: Comparative Distribution of Patients According Socio- Economic Status in Group –A and Group-B

S. No.	Socio Economic Status	Group-A		Group-B	
		No. of PTS	%	No. of PTS	%
1	Upper Class	7	35.0	5	25.0
2	Middle Class	8	40.0	8	40.0
3	Lower Class	5	25.0	7	35.0
	Total	20	100.0	20	100.0

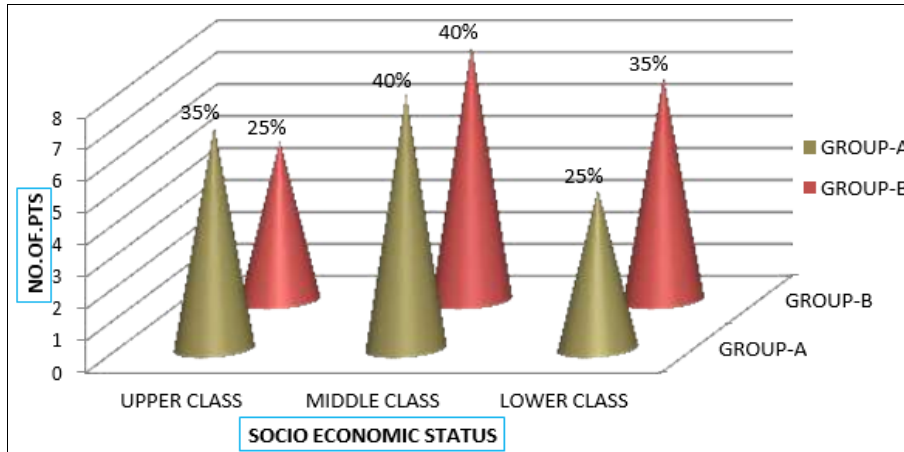


Fig 5: Comparative Distribution of Patients According to Socio-Economic STATUS in Group-A & Group-B (n=20)

The present study shows that this disease is common in middle class patients 16 cases figure no-5

Table 10: Comparative Distribution of Patients According Religion in Group –A and Group-B

S. No.	Religion	Group-A		Group-B	
		No. of PTS	%	No. of PTS	%
1	Muslim	19	95.0	19	95.0
2	Non-Muslim	1	5.0	1	5.0
	Total	20	100.0	20	100.0

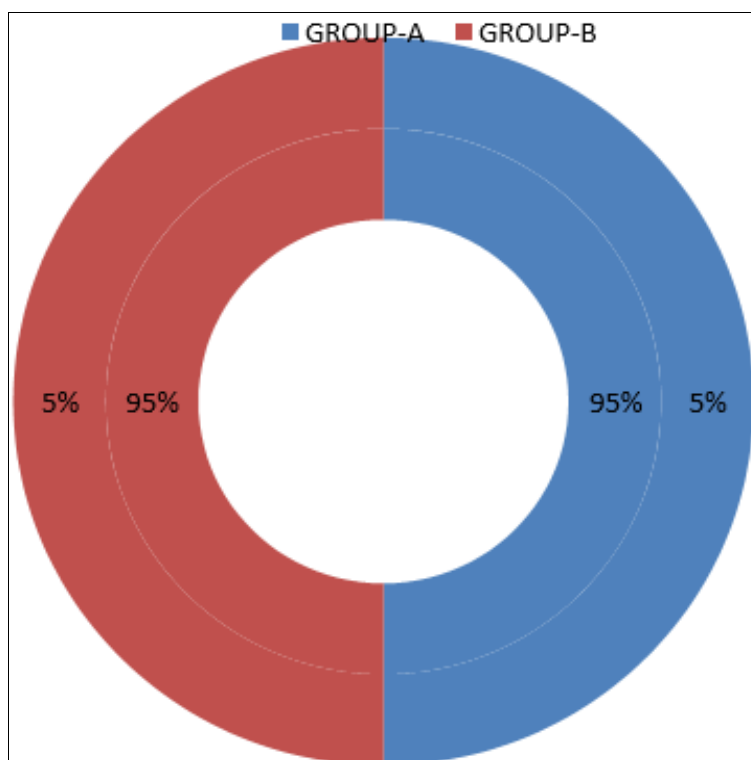


Fig 6: Comparative Distribution OF Patients According To Religion

The present study shows that this disease is most commonly effected in muslim religionpatients 38 cases. figure no-6

Table 11: Comparative Distribution of Patients According Occupation in Group –A and Group-B

S. No.	Occupation	Group-A		Group-B	
		No. of. PTS	%	No. of. PTS	%
1	Skilled Worker	5	25.0	0	0.0
2	Unskilled Worker	6	30.0	4	20.0
3	House Wife	8	40.0	10	50.0
4	Businessman	0	0.0	0	0.0
5	Professional	1	5.0	6	30.0
	Total	20	100.0	20	100.0

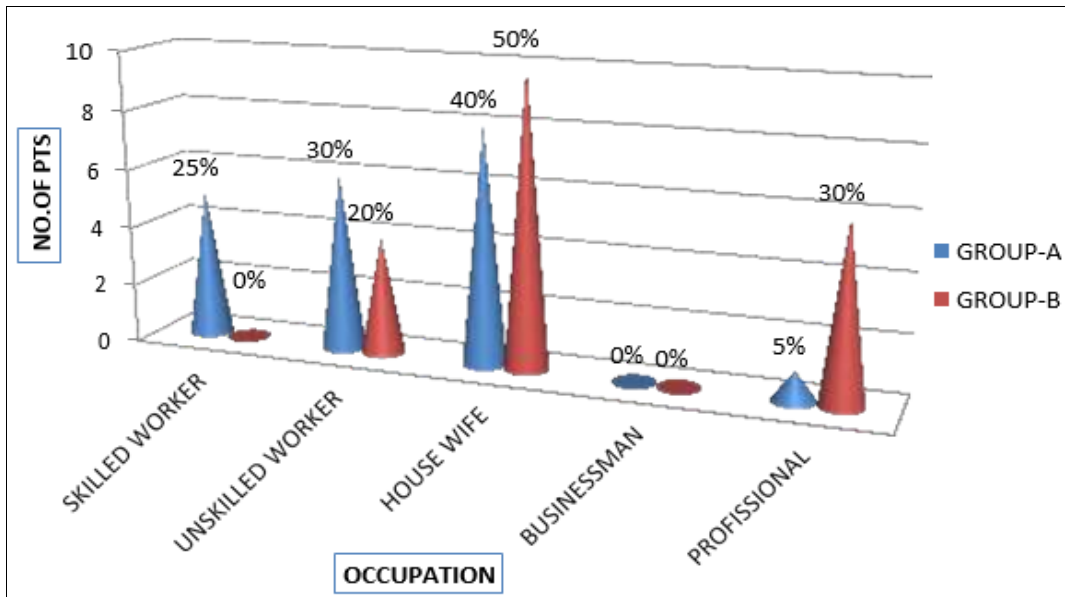


Fig 7: Comparative Distribution of Patients According to Occupation in Group-A & Group-B (n=20)

The present study shows that this diseases most common in Housewives 18 casesfigureno-7

Table 12: Comparative Distribution of Patients According the Subjective Parameters Before and After Treatment in Group-A

S. No.	Clinical Symptoms	Before Treatment	After Treatment	Subsided	Chi Square Test	P Value
		No. of PTS	No. of. PTS			
1	Supra Pubic Pain	10	0	10 (100%)	16.200	<0.0001
2	Burning Micturation	20	8	12 (60%)	14.405	=0.0001
3	Frequency	20	5	15 (75%)	20.907	<0.0001
4	Dysuria	18	2	16 (88%)	25.313	<0.0001
5	Dribbling	10	1	9 (90%)	12.929	0.0003
6	Urgency	19	3	16 (84%)	24.290	<0.0001

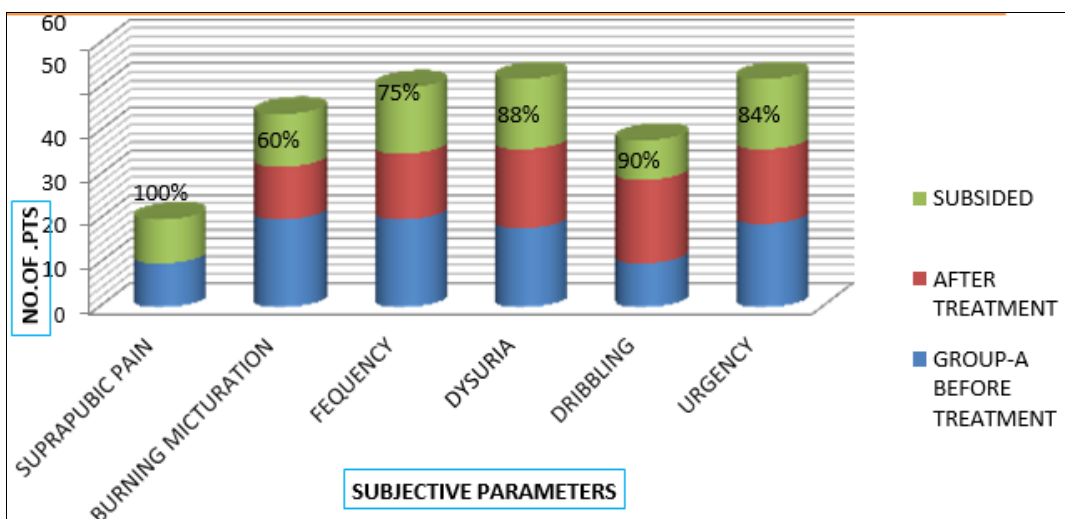


Fig 8: Comparative Distribution OF Patients According To Subjective Parameters Before & After Treatment in Group-A (n=20)

The present study shows the difference in subjective parameters before and after treatment with group-a. Before treatment in group-A 10 (100%) pts were of subrapubic pain, 20 (100%) pts were of burning micturation, 20 (100%) were of frequency, 18 (100%) pts were of dysuria, 10 (100%) pts of dribbling, 19 (100%) pts were of urgency.

After treatment in group-A 10 (100%) pts relieved of suprapubic pain, 12 (60%) pts relieved of burning micturition, 15 (75%) pts relived of frequency, 16 (88%) pts relieved of dysuria, 9 (90%) pts relieved of dribbling 16(84%)pts relieved of urgency,figureno-8

Table 13: Comparative Distribution of Patients According the Subjective Parameters Before and After Treatment in Group-B

S. No.	Clinical Symptoms	Before Treatment	After Treatment	Subsided	Chi Quare Test	P Value <0.0001
		No. of PTS	No. of. PTS			
1	Supra Pubic Pain	13	0	13 (100%)	22.154	<0.0001
2	Burning Micturation	20	8	12 (60%)	14.405	=0.0001
3	Frequency	20	8	12 (60%)	14.405	=0.0001
4	Dysuria	17	4	13 (76%)	17.93	=0.0001
5	Dribbling	8	3	5 (62%)	4.65	=0.0311
6	Urgency	19	5	14 (73.6%)	19.113	<0.0001

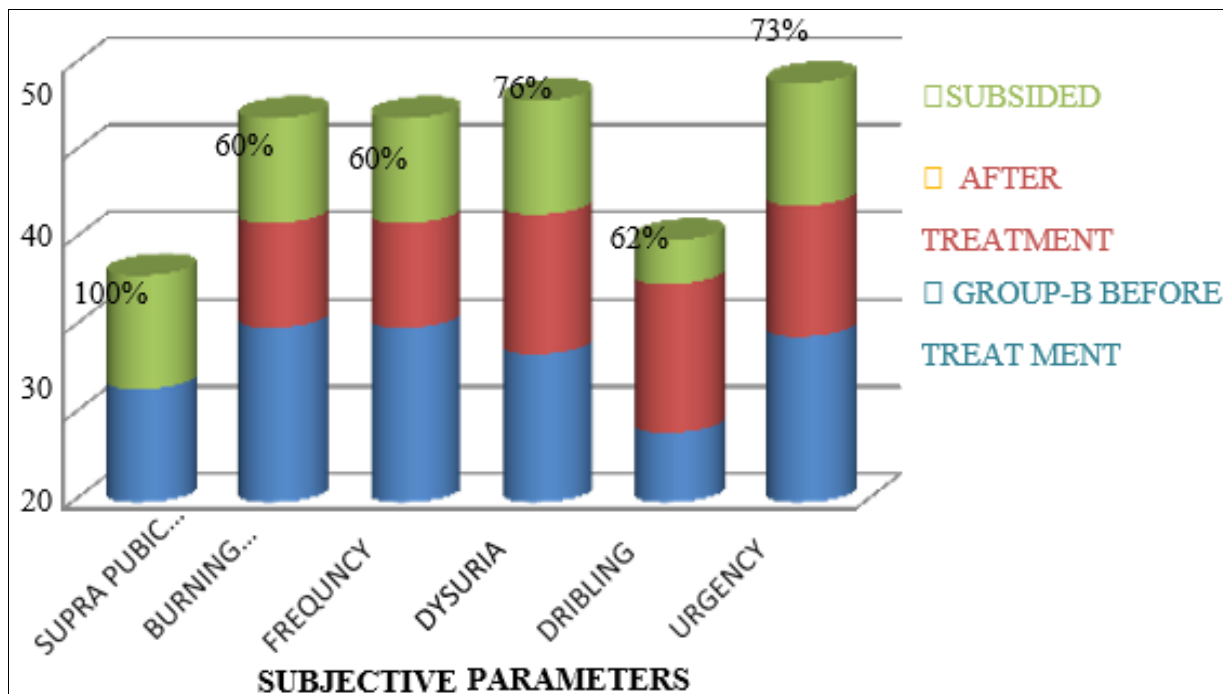


Fig 9: Comparative Distribution OF Patients According To Subjective Parameters Before & After Treatment in Group-B (n=20)

The present study shows the difference in subjective parameters before and after treatment with group-B. Before treatment in group-B 13 (100%) pts were of subrapubic pain, 20 (100%) pts were of burning micturation, 20 (100%) were of frequency, 17 (100%) pts were of dysuria, 8 (100%) pts of dribbling, 19 (100%) pts were of urgency. After

treatment in group-B, 13 (100%) pts relieved of suprapubic pain, 12 (60%) pts relieved of burning micturition, 12 (60%) pts relived of frequency, 13 (76%) pts relieved of dysuria, 5 (62%) pts relieved of dribbling 14 (73.6%) pts relieved of urgency, figure no-9

Table 14: Showing Respons of Patients with Treatment of Group – A Medicine

S. No.	Grading of Response	No. of. PTS	%	Male	%	Female	%
1	Good	12	60.0	5	25.0	7	35.0
2	Satisfactory	5	25.0	3	15.0	2	10.0
3	Noresponses	3	15.0	2	10.0	1	5.0
	Total	20	100.0	10	50.0	10	50.0

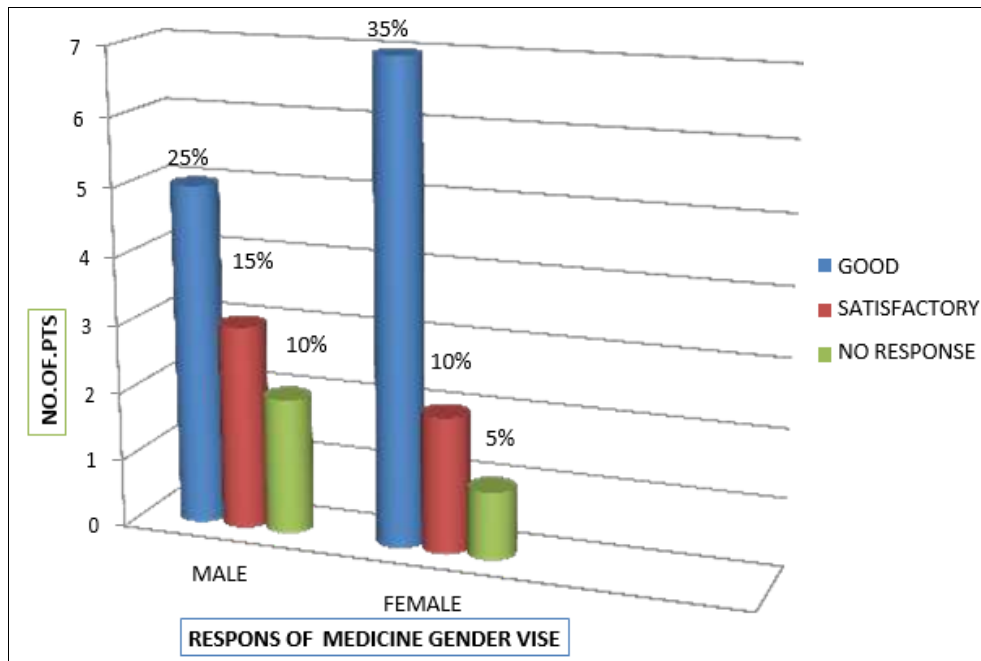


Fig 10: Showing Respons of Patients with Group-A Medicine

The preset study shows that Group-A medicine having 60% good response, 25% satisfactory and 15% no response out of which 25% are male cases good response, 15% male cases satisfactory & 2% males showed no response. And 35% are

female patients cases good response, 10% female cases satisfactory response and 5% female patients showed no response figure no-10

Table 15: Showing Respons of Patients with Treatment of Group – B Medicine

S. No.	Grading of Response	No. of. PTS	%	Male	%	Female	%
1	Good	9	45.0	1	5.0	8	40.0
2	Satisfactory	6	30.0	0	0.0	6	30.0
3	No Response	5	25.0	4	20.0	1	5.0
	Total	20	100.0	5	25.0	15	75.0

study shows that Group-B medicine having 45% good response, 30% satisfactory and 25% no response, out of which 5% male observed good response, 0% male satisfactory and 20% male observed no response and 40%

female observed good response, 30% female observed satisfactory response and about 15% female had a result of no response. Figure no-11.

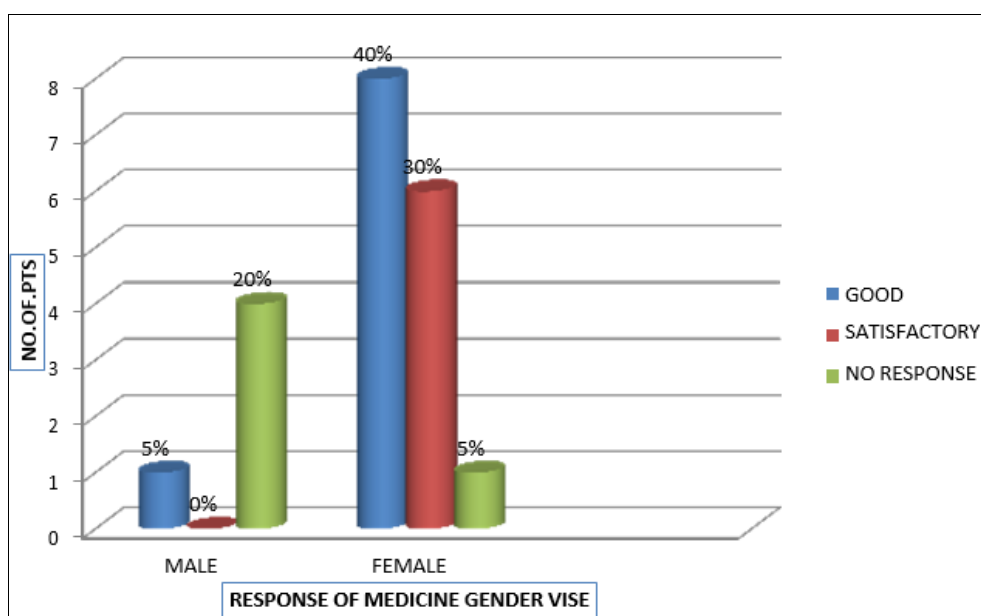


Fig 11: Showing Respons of Patients with Group-A Medicine

Statistical Analysis

observations and results are shown in the tables and figures with the help of statistics all the data were presented as Mean, Median and standard deviation (SD). The level of significance was set at 5% ($p=0.05$) and results were

considered statistically significant at $p<0.05$. The results were analyzed statistically by the Student 't' test and two groups were compared regarding relief of symptoms by X^2 test.

Table 16: Showing Chnges in Laboratory Investigation after Treatmnt in Group-A Patients

S. No.	Parameter	No. of. Patients	Base Line (Mean \pm SD)	After Treatment (Mean \pm SD)	$p<0.05$
1	Pus Ells	20	10.50 \pm 4.89	3.70 \pm 3.93	Significant

Table 17: Showing Chnges in Laboratory Investigation after Treatmnt in Group-B Patients

S. No.	Parameter	No. of. Patients	Base Line (Mean \pm SD)	After Treatment (Mean \pm SD)	$p<0.05$
1	Pus Cells	20	12.80 \pm 3.54	5.30 \pm 4.05	Significant

Table 18: Comparitive Evaluation of Cystitis in U.S.G - Group-A and Group-B

USG	B.T	A.T	Subsided	Chi Square Test	P Value
Group-A	10	0	10(100%)	16.200	SIG
Group-B	9	3	6(64.7%)	6.250	0.0124

Conclusion

In modern system of medicine, treatment is available for Acute cystitis, but recurrent infection occurs and has many draw backs. On the other side the unani drugs are less costlier, safe, mostly effective. Keeping all these things in view a single blind randomized parallel study was carried out during the year 2015 to 2018 at Govt. Nizamia General Hospital after ethical clearance with prior informed consent of the patients. 40 patients were selected and randomly assigned 20 in each Group-A and Group-B. The drugs selected for the study in Group-A were, Kaknaj (Physalis alkekengi), Parsiyaoshan (Adiantum capillus) used orally in capsule form. The drugs selected in Group-B are Tukhm-e-khatmi (Althea officinalis), Tukhm-e-Kharpaza (cucumis melo) used orally in capsule form. In Group-A patients were treated with anti-inflammatory drugs in a capsule form for 60 days with follow up of once in 15 day. Dosage of drug is 1gm twice a day. In Group-B patients were treated with anti-inflammatory drugs in a capsule form for 60 days with follow up of once in 15 days. Dosage of drug is 1gm twice a day, after meals with luke warm water. The total duration of the study was 60 days, All the patients were kept under strict observation and assessment of the efficiency of treatment of both the groups were carried out on the basis of change in the clinical symptoms and signs from the baseline and after the treatment. The protocol for ethical clearance was approved by the institutional ethical committee. Cases were selected on the basis of inclusion, exclusion and diagnostic criteria in the research protocol. The duration of the protocol was 60 days. Total 40 patients were randomly divided into two groups A & B. Summary of Demographic data effect of treatment of Group-A and Group-B are as follows Demographic data following observations were drawn from the study: 1. Maximum no. Of pts was belonging to 21-30 years of age group i.e., 10 cases (25%) 2. Maximum no. Of pts were females 24 cases (60%). 3. Maximum no. Of pts were of Damvi 16(40%) cases and Safravi 19 (47.5%) cases Mizaj. 4. Maximum no. Of pts were married 30 cases (75%) 5. Highest prevalence of Acute cystitis was seen in middle class pts 16 (40%). 6. According to occupation, maximum no of pts observed were Housewives i.e., 18 (45%) 7. Maximum of pts had (a) Supra Pubic Pain (b) Burning Mictrition (c) Frequency of

mictrition (d) Dysuria (e) Dribbling of urine (f) Urgency 8. Investigation were conducted in almost all cases. Common pathogen found in urine culture is E.coli. 9. Most of the pts have pus cells in urine and positive bacterial culture & positive ultrasonography. 10. No adverse (effect) reaction were noted during treatment and follow up period.

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