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Management of Gout through Unani medicine

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ABSTRACT

The Unani medicines have proven its own importance regarding its affectivity, cost and minimal side effects for many illnesses. The general treatment of Gout in Unani system of medicine (USM) comprises of moderating the alter humours (*akhlat*), excretion of excessive & altered humours, correction of digestion & regulation of metabolism and subside the local inflammation. For this purpose, the medicines having properties like, demulcent (*mulattif*), concoctive (*munzij*), diuretic (*mudir-e-boul*), digestive tonic (*muqawwi-e-meda*) and anti-inflammatory (*muhallil-e-auram*) are used. There are so many drugs to treat Gout without causing any side effect but most of these drugs have not been studied on modern scientific parameters, so keeping the fact in mind the formulation comprises of drugs *Chobchini* (*Smilax china*), *Surinjan Shirin* (*Colchicum latium*), *Sibr* (*Aloe barbadensis*) has been tested for gout treatment. It is an open clinical trial; conducted on 60 patients for duration of 60 days. Findings were recorded on a specially designed chart and inference was made by appropriate statistical analysis (Paired 't' test). This result suggesting the effect of test drug is very effective in lowering the serum uric acid. Findings of trial were recorded on a specially designed chart and inference was made by appropriate statistical analysis.

Keywords: *Gout; muhallil; Mudir; Niqris; Arthritis; Mizaj.*

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INTRODUCTION

Gout is common inflammatory condition of joint which has been recognized since antiquity. It is caused by deposition of monosodium urate crystals within joints after the chronic hyperuricaemia. The most typical site of involvement is the first metatarsophalangeal joints of the big toe¹. Nowadays, gout is probably the best understood and most manageable of all common systemic rheumatic diseases.² frequently. Gout is a disorder of purine metabolism and result from urate crystal deposition in and around the joints caused by long standing hyperuricaemia.²



Figure: Acute Gout

Acute arthritis is the most frequent early clinical manifestation of gout. Usually only one joint is affected initially but polyarticular acute gout can occur in subsequent episodes. The metatarsophalangeal joint of the first toe is often involved, but tarsal joints, ankles and knees are also commonly affected. Especially in elderly patients or in advanced disease, finger joints may be involved. The first episode of acute gouty arthritis frequently begins at night with dramatic joint pain and swelling. Joints rapidly become warm, red, and tender, with a clinical appearance that often mimics cellulitis. After many acute mono- or polyarticular attacks, a proportion of gouty patients may present with a chronic nonsymmetric synovitis.^{1,3,4,5}



Figure: Tophaceous gout

Hyperuricemia is defined as a serum or plasma urate concentration greater than two standard from the mean 7.0 mg/dl (0.42 mmol/l)¹ for adult male and 6.0 mg/dl(0.36 mmol/l) in females.^{3,4,5,6,7} Prolonged hyperuricemia is necessary, but is alone not sufficient, for development of gout.⁴

Prevalence of hyperuricemia varies according to the age, sex, race geographical conditions and association with other diseases.⁸ Gout becomes commoner with increasing age. In men the reported prevalence ranges from <0.5% in those aged under 35 to >7% in those aged over 75. It is rare in premenopausal women but increases to 2.5 – 3.0% in those aged over 75. The later age of onset in women may relate to the uricosuric effects of oestrogens.⁹

There is some allopathic medicine like, NSAID, allopurinol, probenecid etc. being used as drug of choice for gout, but these drugs are failed to treat gout permanently also have many side effects. In Unani System of medicine also described many single and compound drugs are also described like, zajabil, Muqil, Darchini, Badyaan, Majoon surijan, Habb-e-Asgandh, Majoon Chobchini, Safoof-e-Auja etc. to treat gout without causing any side effect but most of these drugs have not been studied on scientific parameters, so keeping the fact in mind a step will be taken evaluate efficacy and safety of compound Unani formulation prepared by *Chobchini (Smilax china)*, *Suranjan Shirin (Colchicum latium)*, *Sibr (Aloe barbadensis)* in the management of gout.

MATERIALS AND METHOD

The present clinical study entitled as “Clinical efficacy of compound Unani formulation of *Surinjan shirin, sibr and chobchini* in cash of gout (*Niqris*)”, was conducted at hospital under department of *Moalajat*. Before starting the clinical trial, the proposal was kept before ethical committee of medical college. Once the ethical clearance was sought, clinical study was started by enrolling eligible patients for open clinical trial.

In present study all 60 patients of gout were screened and selected for clinical trial and studied to asses clinical efficacy of Unani formulation comprises of *surinjan shirin, sibr and chobchini* in case of Gout. All 60 patients of Gout were selected on the basis of complete physical examinations family history, clinical symptoms and laboratory investigation, their social and dietary habits were also inquired and included in the clinical study. Details about the disease and treatment were recorder in case report form. Patients were treated with the Unani compound drug (*suranjan shirin, sibr, chobchini*).

Criteria for the selection of cases:

Inclusion criteria:

- Patients come to college’s hospital OPD were selected.
- Both sexes of patient between age group of 20 to 60 years have been selected.

- Acute Gout
- Inter critical gout
- Clinically stable Patient

Exclusion criteria:

- Gout with Diabetic Mellitus.
- Chronic tophaceous gout
- Urolithiasis
- Patient below 20 and above 60 years.
- Patient with organ failure.
- Pregnant women and lactating mother
- Patient with active cardiac diseases and major diseases of heart.
- Patient with severe neurological disorders.

Sample Size: The sample size was 60.

Study design: This is an open level phase II clinical trial

Duration of Study: The treatment period was 60days

Investigations:

Following investigations were done in each and every case, before and after study; Hb%, TLC, DLC (specially Neutrophils, Lymphocytes, Eosinophils and Monocytes) and ESR. Serum uric acid, urine routine and microscopic- specially urine uric acid crystals are examined at every visit. RBS (Random Blood Sugar) was investigated before study only.

Efficacy assessment:

The assessment of efficacy in the patients was based on the following two types of parameters.

1. Subjective parameters.
2. Objective parameters.

The subjective parameters include symptoms like pain, swelling etc. while objective parameters include laboratory investigations of patient suffering from gout. An arbitrary grading of subjective and objective parameters was design for appropriate assessment and statistically evaluation of various symptoms to evaluate the efficacy of test drug. Basal symptoms were recorder in case report form according to their grades. After 60 days of the treatment, the pre and post values of different parameters were analysed grade wise and subjected to comparison and analysis statistically to evaluate the efficacy of treatment.

Objective Parameters:

1. Pain

2. Tenderness
3. Swelling
4. Redness
5. Temperature of affected joints.
6. Movement of affected joints
7. Deformity of joints.

These seven different symptoms were rated with a different grading scale in which the patient can rate some of their symptoms themselves. And the same way the clinician also rated some symptoms according to the patient's presentation. These ratings were done before treatment (zero day); rating was also taken during the treatment on 30th day and after treatment (60 days).

Subjective parameters:

Pain: scored by Visual Analogue scale (VAS).^{10,11,12} Patient is asked to put a mark on the scale at every visit from 0-10, indicating their pain intensity. The distance between that mark and the origin is measured to obtain the patient's pain score.

Tenderness:

0 = No tenderness

1 = mild: Patient allows pressure without any resistance.

2 = moderate: Patient allows pressure with little resistance

3 = Severe: Patient holds hand and does not allow further pressure

Swelling:¹³

0= None

1= mild-swelling

2= moderate – swelling +redness

3= severe- swelling + redness + pain

Redness:¹³

0= Mild

1= Moderate

2= Severe

Temperature of effected joint:

0= Absent

1=Present

Movement of effected joint:

0 = Normal

1 = Partial restricted

2 = fully restricted

Deformity: ¹³

0 = None

1 = slightly narrowing of joint space

2 = Moderate loss of sphericity of joint space

3 = Severe narrowing or obliteration of the joints.

Objective Parameters:

The grading was done on the basis of reports of the lab investigations of the patients before and after the treatment.

1. Haemoglobin
2. TLC
3. Neutrophils
4. Lymphocytes
5. Eosinophil
6. ESR
7. Serum uric acid
8. Urine: Routine and microscopic especially for uric acid crystals

Criteria for the selection of drugs:

For the rational and effective treatment of gout the Unani drug was required all those properties which could revert this pathologic condition towards normal to restore physiologic functions. So, by careful literature review of Unani classics the descent Unani single drugs were found out, and a compound formulation was prepared containing following *mufarrad advia* (single drugs): *chobchini* (*Smiles china*), *suranjan shirin* (*Cholchicum luteum*), *sibr* (*Aloe barbadensis*).

Methods of preparing Dosage and method of administration of test drug:

The compound Unani formulation authenticated, standardized and prepared by GMP certified manufacturing unit. The drug will be kept away from direct heat, sunlight in airtight jar, in the dark, dry and cool place. All the three single drugs were pounded to make fine powder. Mixture of all three powers were made in the proportion of 2:2:1 (*chobchini*, *sibr*, *surinjan shirin*). This mixture of powder was filled in capsule in the quantity of 500 mg/capsule. A dose of two capsule in thrice a day after meal for a period of 60 days were given to all patient gout.

Ingredients: Each 100gm contains:

Unani Names

Botanical names

Weight (in gram/gm).

Chobchini	<i>Smilex china</i> Linn	40 gm
Surannashirim	<i>Cholchicum luteum</i> Baker	40 gm
Sibr	<i>Aloe barbadensis</i> Mill	20 gm

Follow up during treatment:

60 days study was divided in to two follow ups which were made at the interval of 30 days. At every visit the patient were asked about the progression and regression of their subjective symptoms. All objective parameters(investigations) were done before and after the study.

Withdrawal criteria:

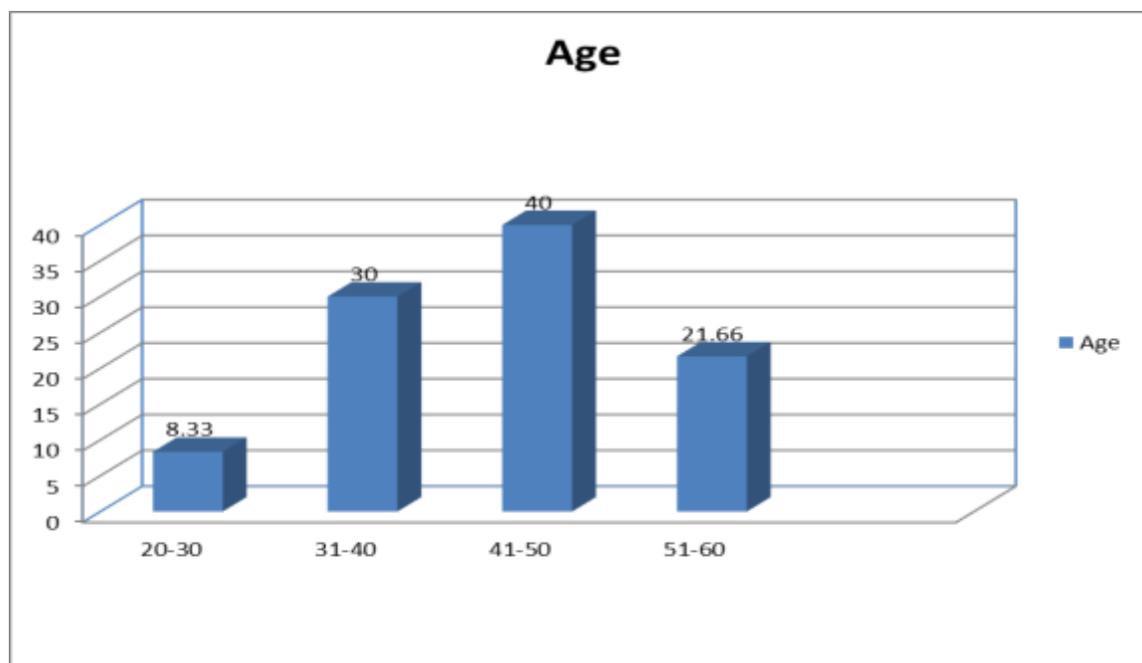
- Failure to follow the protocol.
- Any adverse reaction or advice event.
- Any Idiosyncratic reaction.
- Any life-threatening systemic disorder or pregnancy is revealed during study.

Methods:

GCP (Good Clinical Practice) was strictly followed throughout complete duration of study.

Statistics:

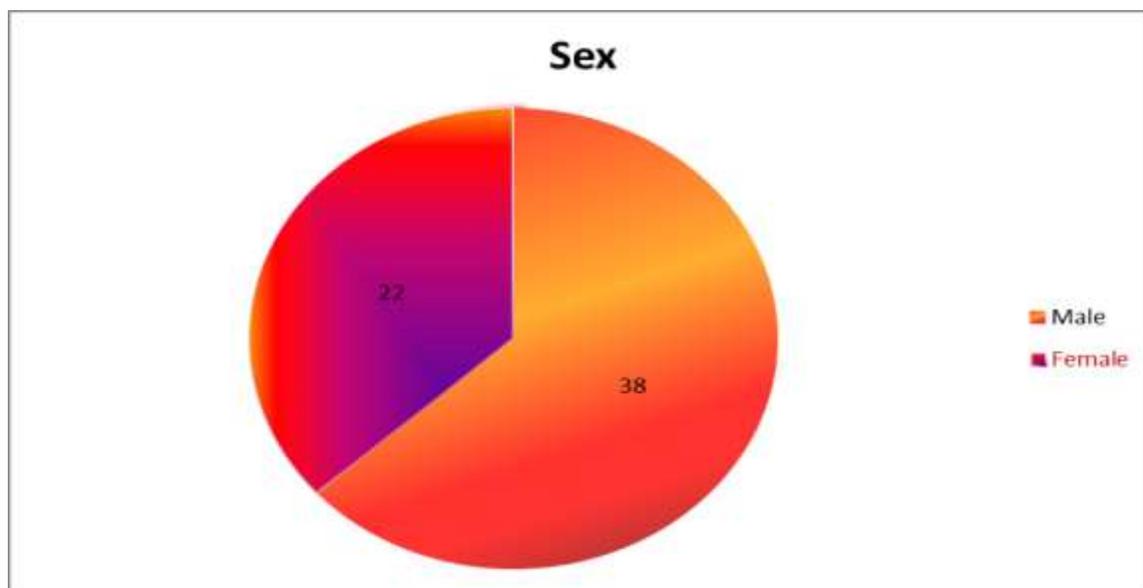
Paired 't' test was applied to evaluate the efficacy of the drug.

RESULTS AND INTERPRETATION

Graph 1: Distribution of subjects according to Age

Interpretation:

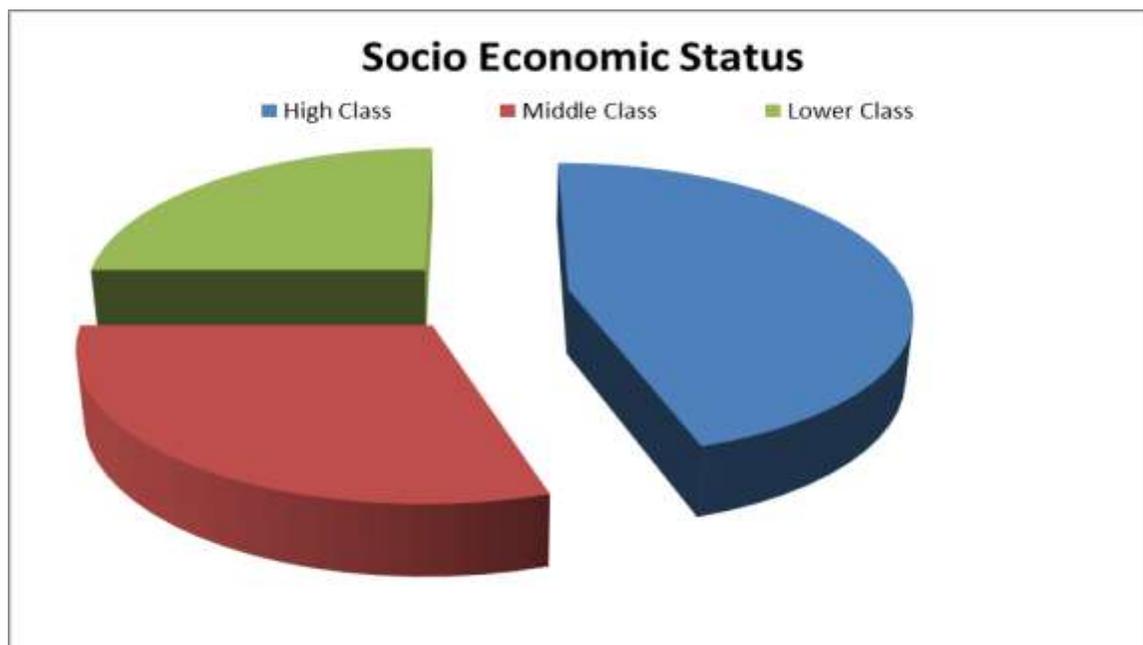
During study all the patient, divided into four age group i.e. 20-30, 31-40, 41-50, 51-60 years. It was observed that maximum no of cases belongs to 41-50 (40%) age group, where as 30% belong to age group 31 to 40, fell in the age group of 51 to 60years. 5 patients (8.33%) were in the age group 20 to 30 years of age.



Graph 2: Distribution of subjects according to Sex

Interpretation:

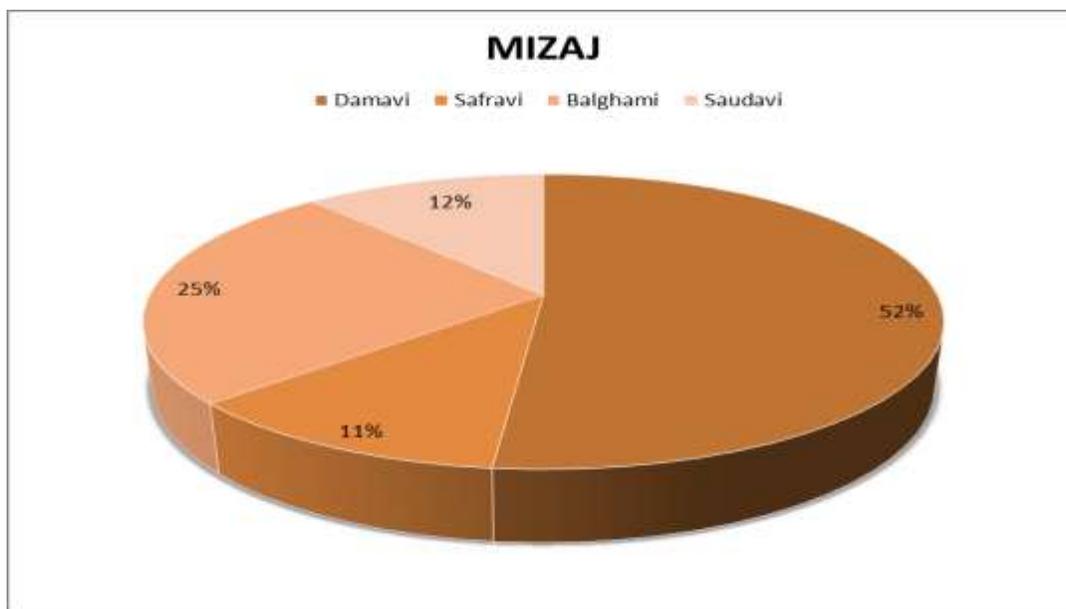
During study it was observed that in total 60 patients. 38 patients (63%) were male and 22(37%) were female.



Graph 3: Distribution of subjects according to Socio economic status

Interpretation:

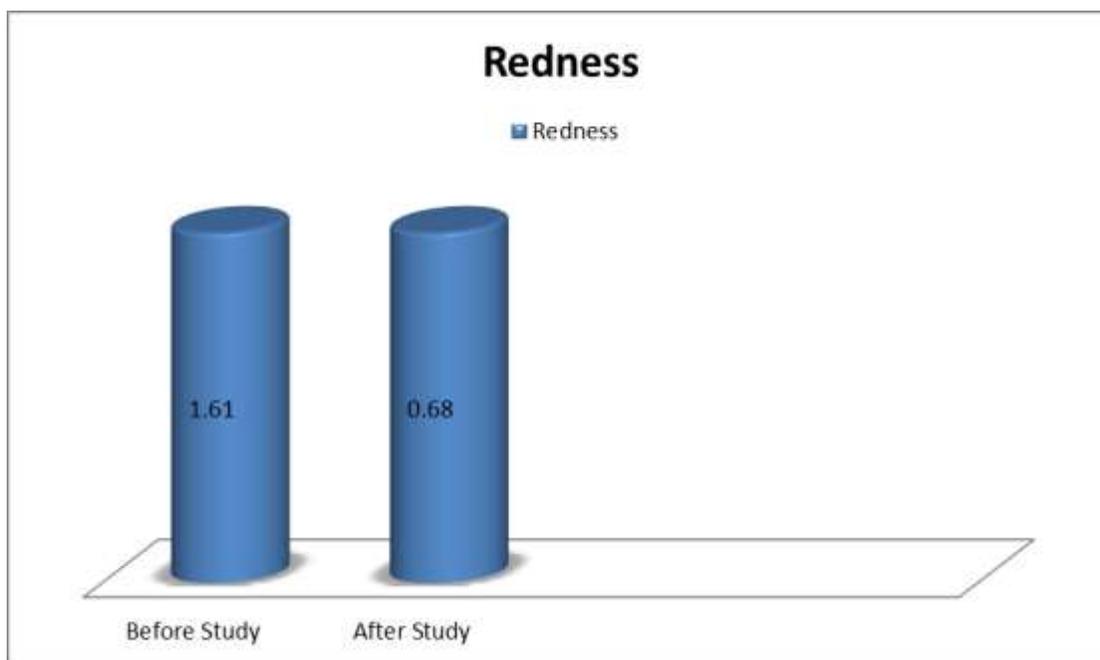
Duration study it was observed that in total 60 patient (45%) were of high class and 18 patients (30%) were belong to middle class and last 15 patient (25%) were lower class.



Graph 4: Distribution of subjects according to Mizaj

Interpretation:

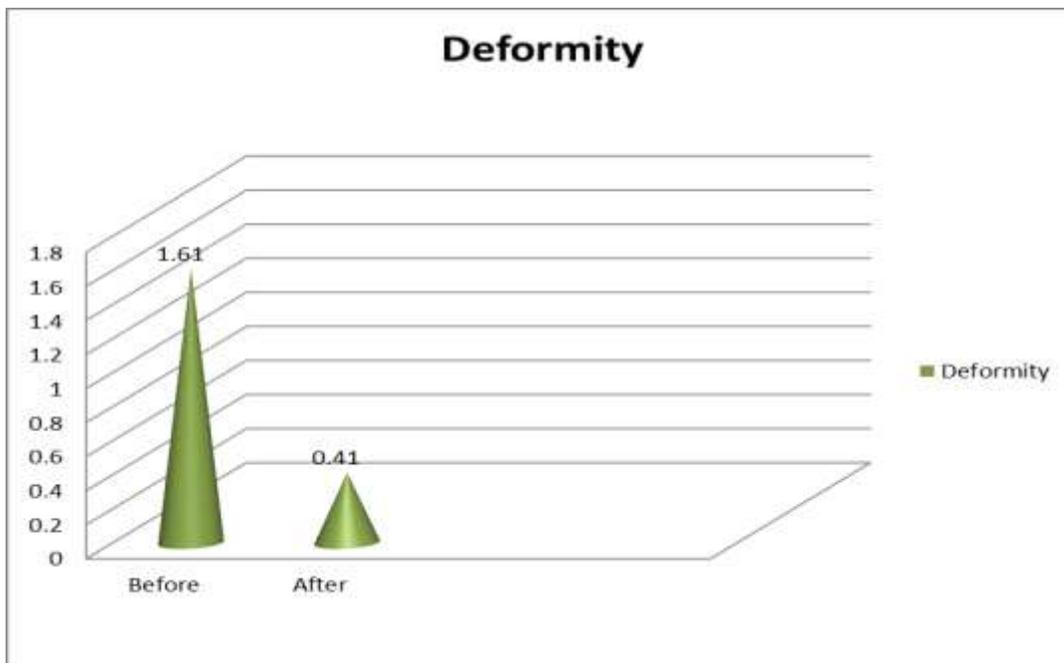
In study it was observed that out of 60 patients 31 patients (51%) had Damavi Mizaj and 15 patients (25%) had Balghami Mizaj and 7 patients (12%) had Safravi Mizaj, and 7 patients (12%) had Soudavi Mizaj. In this study maximum no of patients belongs to Damvi Mizaj.



Graph 5: Comparison of Redness before and after study

Interpretation:

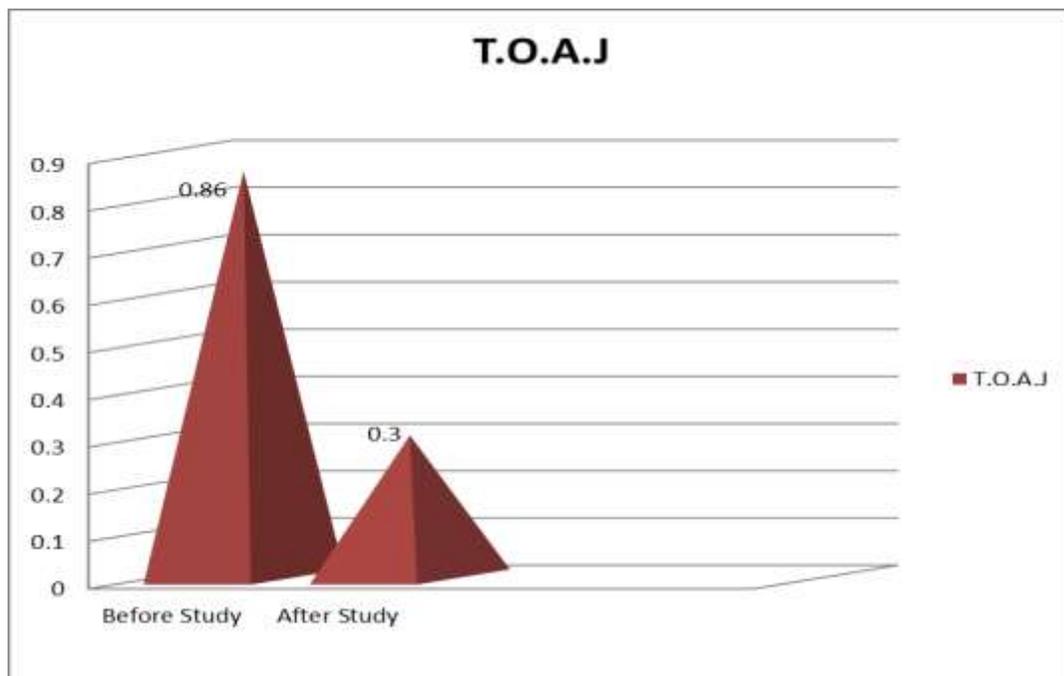
While analyzing the patients according to redness of the joints before and after study their 't' value was found as 13.139, and 'p' value was calculated as 0.001 that is highly significant.



Graph 6: Comparison of Deformity before and After

Interpretation:

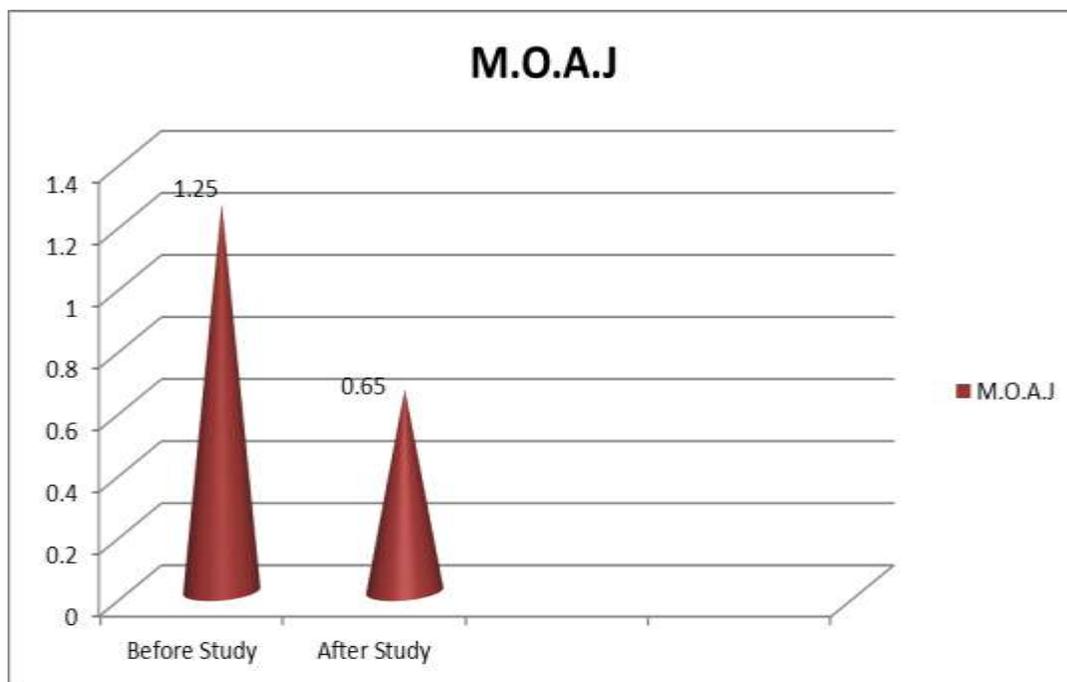
While analyzing the patients according to joint deformity before and after study their 't' value was calculated as 8.16, with highly significant 'p' value 0.001



Graph 7: Comparison of temperature of affected joint (T.O.A.J) before & after Study.

Interpretation:

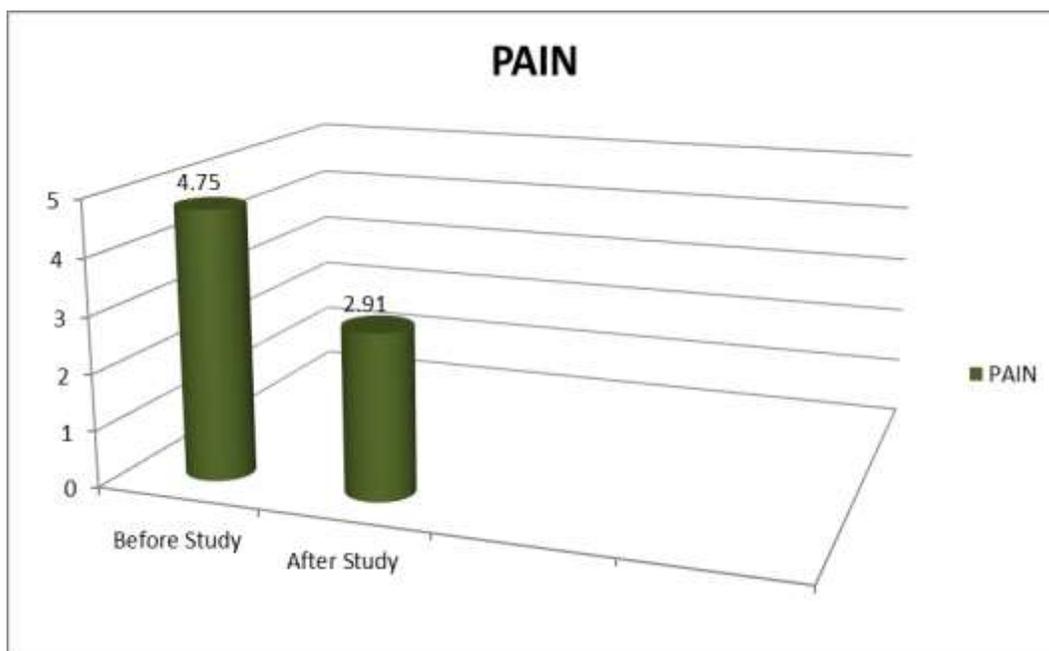
While analyzing of the patients according to temperature of affected joint before and after study 't' value was found as 8.14 and 'p' value was calculated 0.001 which is highly significant.



Graph 8: Comparison of movement of affected joint (M.O.A.J) before & after study.

Interpretation:

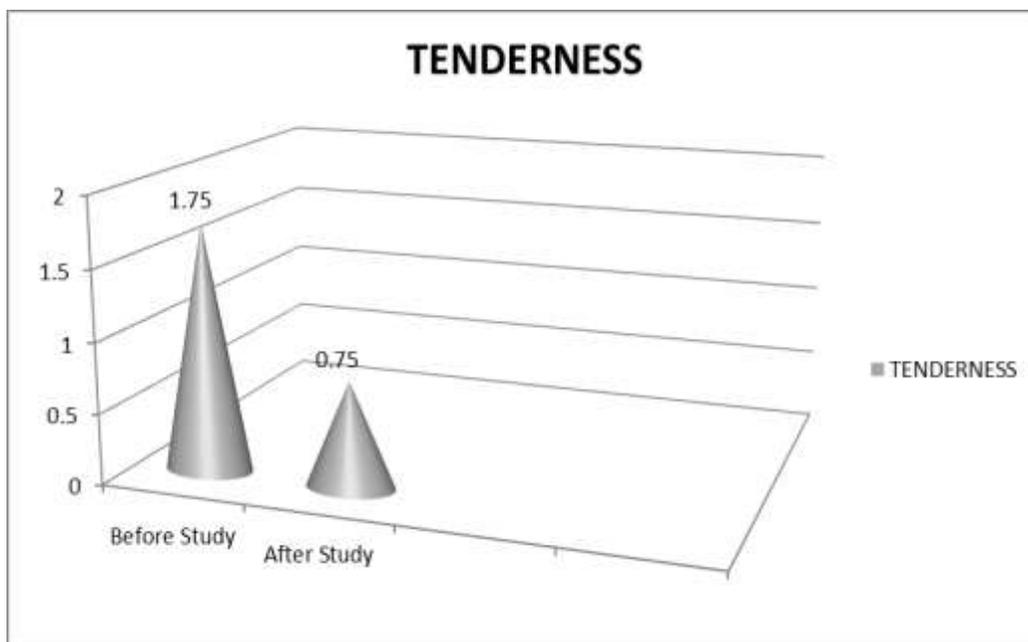
Analyzing patient according to movement of affected joint before and after study their 't' value was calculated as 7.542, with a highly significant 'p' value 0.001.



Graph 9: Comparison of Pain before and after study

Interpretation:

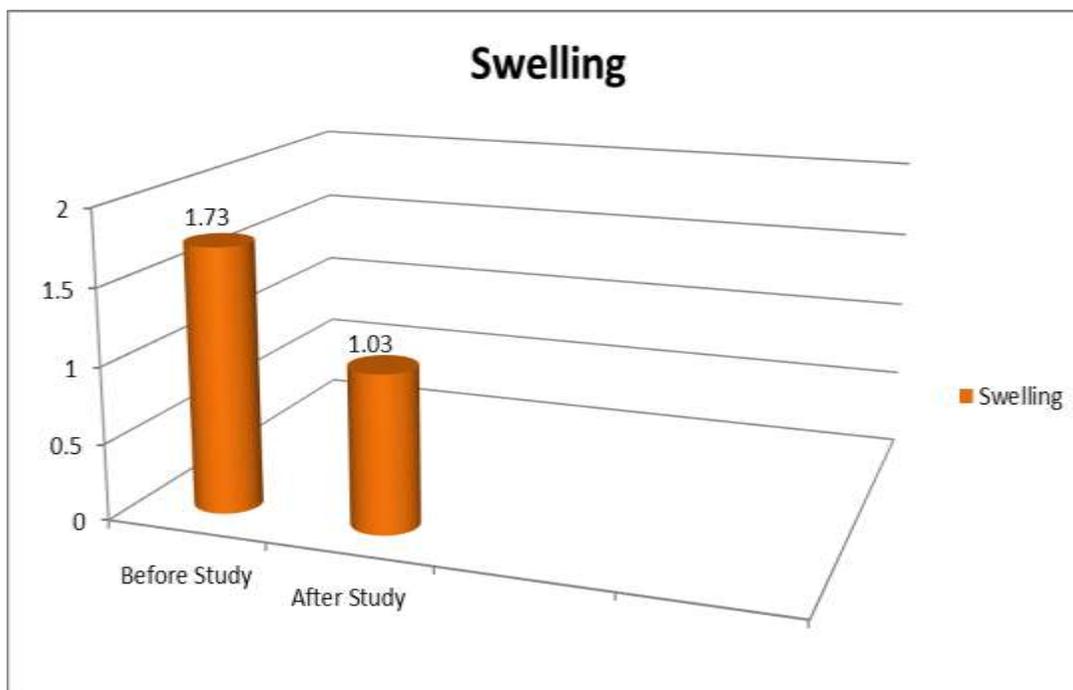
While analyzing of the patient according to pain before and after study 't' value was 14.2 and 'p' value was 0.001 which is highly significant.



Graph 10: Comparison of Tenderness before & after study

Interpretation:

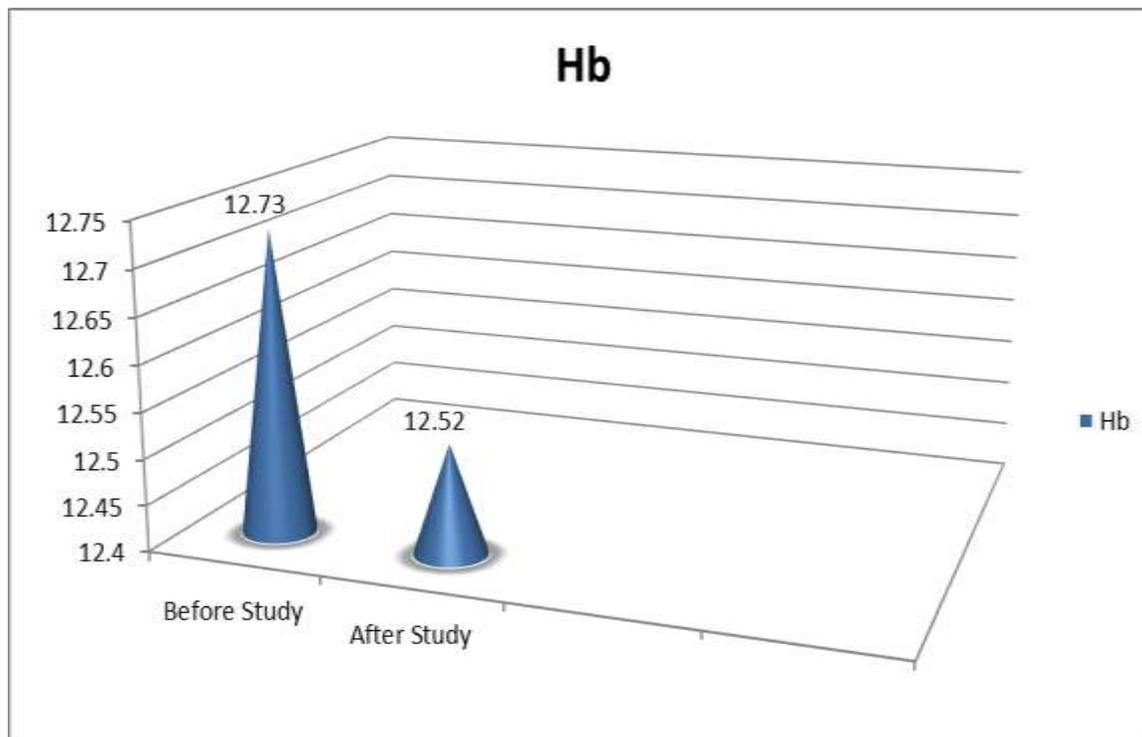
While analyzing the patients according to tenderness before and after study their 't' value was found 12.68 with 'P' value is 0.0001 which is highly significant.



Graph 11: Comparison of Swelling before and after study.

Interpretation:

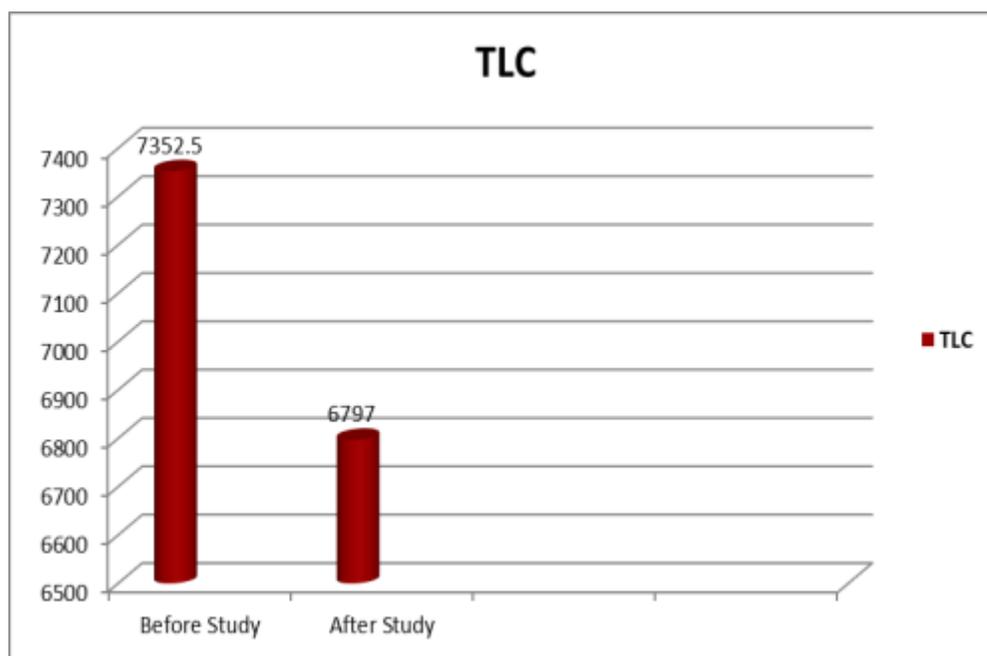
While analyzing of the patients according to swelling of the joint and t value and 'p' value were found to be 8.397 and 0.001 which is highly significant.



Graph 12: Comparison of Hemoglobin (Hb) percentage before and after study.

Interpretation:

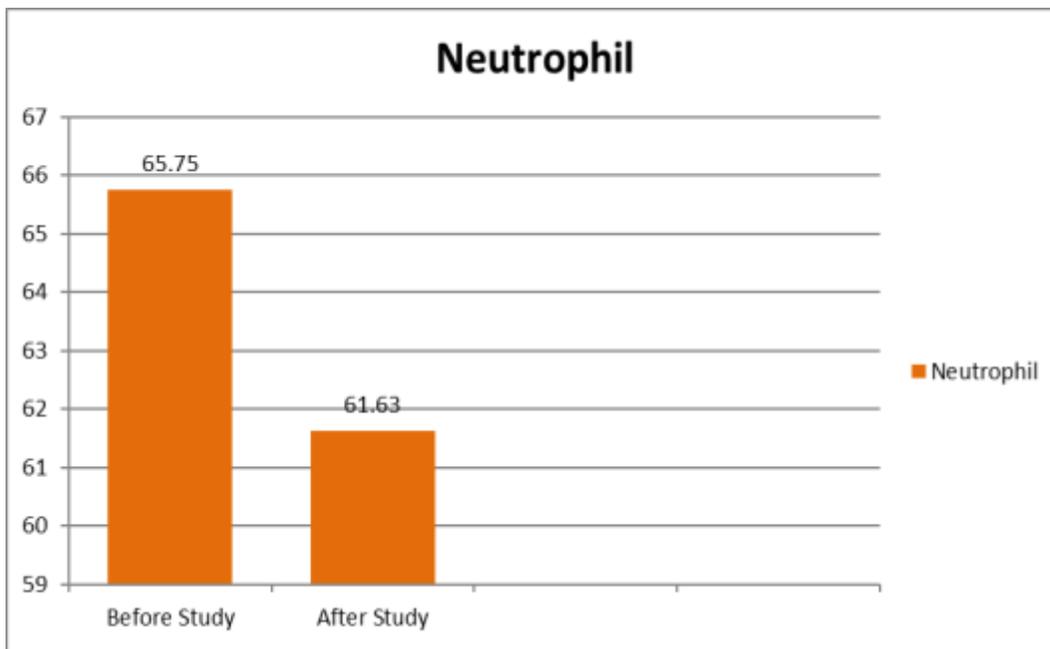
Analyzing of patients according to Hemoglobin percentage their t value was found as 1.94 and p



Graph 13: Comparison of TLC count before and after study.

Interpretation:

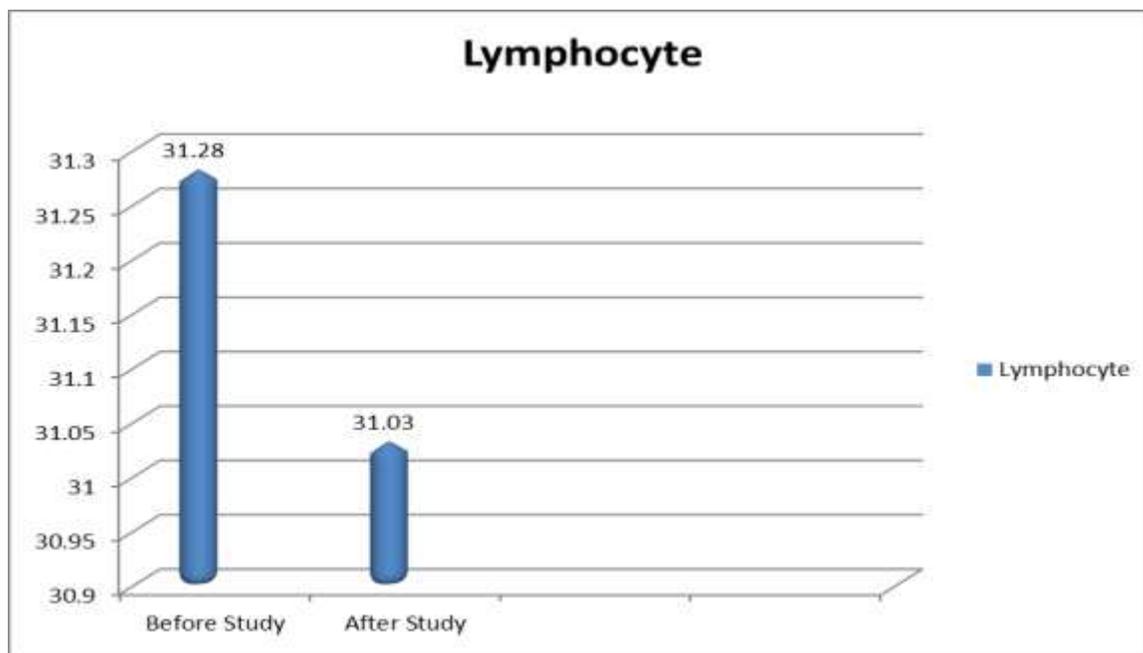
Before and after study of the TLC the calculated t value was 3.29 and p value was 0.001 (Highly significant) after analysis the observation of TLC before and after study.



Graph 14: Comparison of Neutrophil count before and after study.

Interpretation:

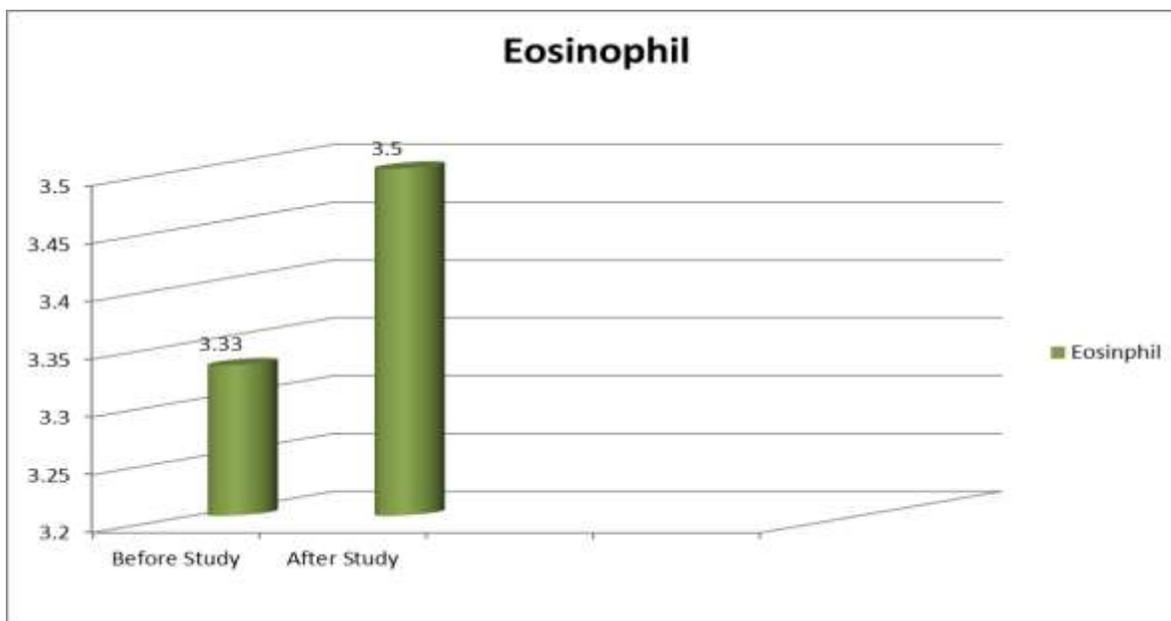
On analysis of the patients according to Neutrophil count 't' value was found as 7.07 and 'p' value was 0.001 which is highly significant.



Graph 15: Comparison of Lymphocytes count before and after study.

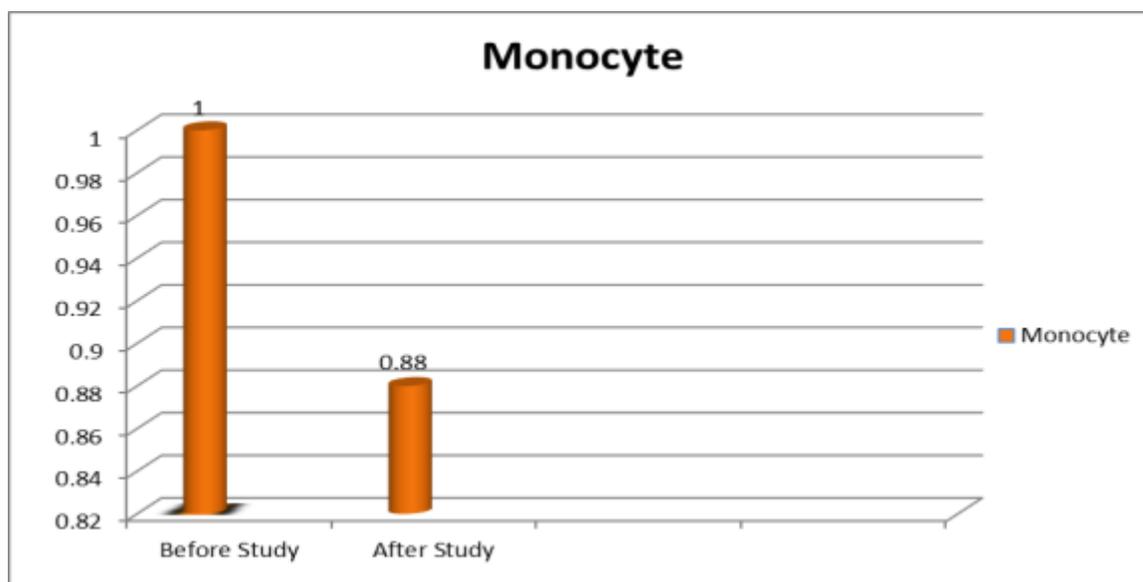
Interpretation:

T value and p value of lymphocyte count was calculated as 0.3 and 0.1 respectively which is not significant.



Graph 16: Comparison of Eosinophil count before study and after study.

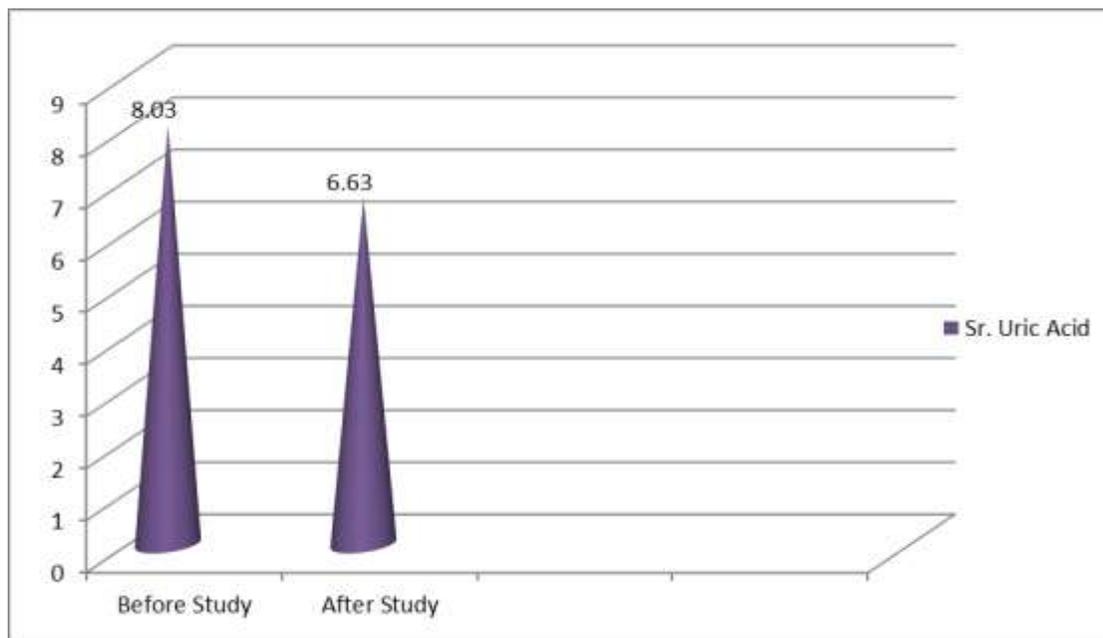
Interpretation: While analyzing patients before and after study t value and p value of Eosinophil count was found 0.662 and 0.1(not significant) respectively.



Graph 17: Comparison of Monocytes before and after study.

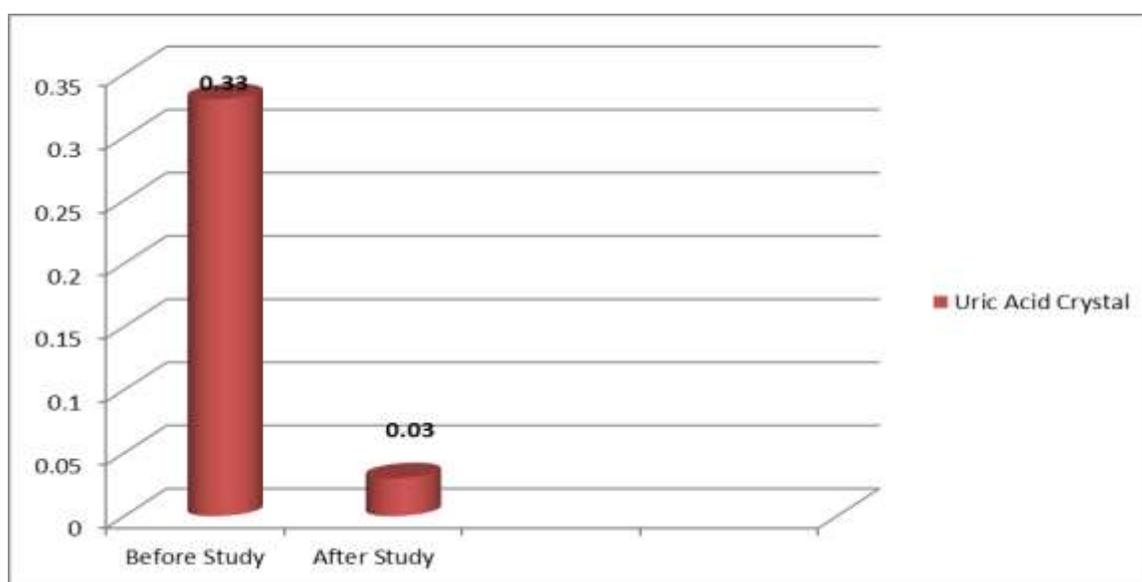
Interpretation:

Analyzing the patients according to monocytes count before and after study t value is found as 0.68 and p value is 0.1 which is not significant.



Graph 18: Comparison of serum uric acid before and after study.

Interpretation: While analyzing the patients according to serum uric acid their t value was calculated as 13.34, and p value was 0.001 (highly significant).



Graph 19: Comparison of Urin routine (uric acid crystals) before and after study.

Interpretation:

It was observed that t value of uric acid crystal in urine calculated as 5.028 and p value as 0.001. This is highly significant.

SUMMARY

Ismail Jurjani have defined the gout as morbid humours which gets accumulate in the small joints

space, if it causes pain and inflammation in small joints. It is called as gout. It occurs mainly in greater toe. Ankle joint and the joint of toes may be involved.

Gout is one of the most painful forms of arthritis. It is a metabolic disease and that form of arthritis which is caused by high level of uric acid in blood stream. The uric acid collects in crystalline form around joints causing pain and inflammation. It is also known as gouty arthritis. In almost all cases of gout, a single distal joint is first affected, which is in most of cases metatarsophalangeal joint of the first toe. Other commonly affected joints are ankle, mid foot, knee, wrist, elbow and small joints of hands. The first episode of acute gouty arthritis frequently begins at night with dramatic joint pain and swelling. Joints rapidly become warm, red and tender. After many acute mono- or oligoarticular attacks, a proportion of gouty patients may present with a chronic non symmetric synovitis.

A research using the UK primary care database reported the incidence of gout per 1000 person per years to be 2.68(4.42 in men and 1.32 in women) for the years 2000-2007. The prevalence increased with age.¹⁴ The male to female ratio is 9:1.¹⁵ The prevalence increases in women after the menopause although this is partly reduced hormone replacement therapy.¹⁶

Majority of ancient physician accepted that *balgam-e-mirra* is the main cause of *madda-e-Niqris* and then it can be Pure *Balgham, Dam, Safra* respectively. Rarely the cause of *madda-e-Niqris* can be *Sauda*.

Present study has been designed to study the efficacy of an Unani compound formulation in the management of gout. It is an open clinical trial. The study was conducted on 60 patients. The drug was administered to the patients orally in a dose of two capsules of 500 mgs thrice a day after meal for a period of 60days. The efficacy of this drug has been evaluated on the basis of standard parameters which are based on subjective and objective parameters. Finding of effectiveness of test were recorded on a specially designed chart and the inference was made by appropriate statistical analysis.

The incidence of Gout is seen more 40% in the age group of 41 years to 50 years. Gout was not found the people below 20 years. The incidence of Gout was found more in male (38, 63.33%) in compression to female which is 22(31.7%). It was observed that Gout found in female which is 22(31.7%). It was observed that gout found in female only after menopause. According to socio economic class people are 27 patients (45%) likewise middle socio-economic class have 18 numbers of patients (30%) and lower economic class have 15 patients (25). The incidence of Gout according to *Mizaj* the *Damavi mizaj* 31 patients (51.6%) patient were more affected. While following the incidence of Gout according to *Mizaj*, it was observed that people having *Damavi mizaj* are a more prone (51.6%) 31 patients in compression to other of *Mizaj*.

The result of the study pain revealed that the standard deviation of pre and post test score is 1.283 and 1.197 respectively. Rating pain with their t value is 14.2 and p value is 0.001. It is inferred that there is a highly significant difference between the pre and post test scores of pain rating. According to the study of tenderness the mean of before and after treatment is 1.75 and 0.75 respectively. Rating tenderness with their t value is 12.68 and p value is 0.001. It is inferred that there is a highly significant difference in between pre and post test and remarkable reduction in the tenderness after treatment. The mean scores of swelling before and after treatment is 1.73 and 1.03 respectively and p value is 0.001. It is inferred that there is a significant difference in between pre and post test and remarkable reduction in the swelling after treatment. It was observed that the mean of score of redness before and after treatment is 1.61 and 0.68 respectively and p value is 0.001. It is inferred that there is a highly significant difference in between pre and post test and remarkable reduction in the redness after treatment. According to study of temperature of joint affected the mean of before and after treatment is 0.86 and 0.3 respectively and p value is 0.001. It is inferred that there is a significant difference in between pre and post test and remarkable reduction in the temperature of joint affected after treatment. According to study of movement of affected joint the mean of before and after treatment is 1.25 and 0.65 respectively and p value is 0.001. It is inferred that there is a remarkable reduction in the restriction of movement of affected joint after treatment. According to study of deformity of joint the mean of before and after treatment is 1.61 and 0.41 respectively and p value is 0.001. It is inferred that there is a significant difference in between pre and posttest and remarkable reduction in the deformity of joints affected after treatment. This study with objective parameters indicates that the treatment with the test formulation was highly effective in all observed symptoms of the gout patient.

The study objective and analyses the pathological investigations also. according to the study of effect on hemoglobin the mean of before and after treatment is 12.73 and 12.52 respectively and p value is 0.1. It is observed that there is no significant difference in between pre and post-test and no changes in the hemoglobin after treatment. According to study of TLC the mean of score before and after treatment is 7352.5 and 6797.6 respectively and p value is 0.001. Its study shows that there is a highly significant difference in between pre and post-test and remarkable reduction in TLC after treatment. According to study of Differential leukocyte count the mean of before and after treatment neutrophils, Lymphocyte, Eosinophil, and Monocyte are 65.75 and 61.63, 31.28 and 31.03, 3.33 and 3.5, 1 and 0.88 respectively p value is 0.001 for Neutrophils count which highly significant. In case of Eosinophils, Lymphocytes and monocytes the p value is 0.1. So, it is inferred that there is a no significant difference before and after treatment in their count. Difference in between pre and post-

test of DLC is significant. And come normal percentage after treatment. According to study of Serum Uric Acid the mean of before and after treatment is 8.03 and 6.63 respectively and p value is 0.001. It is inferred that there is significant difference in between pre and post-test and remarkable reduction in the serum uric acid after treatment. According to study of the uric acid crystals the mean of before and after treatment is 0.33 and 0.03 respectively and p value is 0.001. It is inferred that there is a significant difference in between pre and post-test and reduction in the urine uric acid crystals after treatment. This study with pathological investigation indicates that the treatment with the powder under trail was highly effective to reduce the no. of TLC and neutrophils. However, it was proved to be non- effected against Lymphocyte, Eosinophil and Monocyte observed investigation of the gout patients.

Thus, this study concludes that compound Unani formulation consist of *Suranja shirin*, *Chobchini* and *Sibr* was very much effective in the patients of gout by relieving symptoms as well as correcting of factors that contributes to gout.

CONCLUSION

Gout is one of the most painful forms of arthritis. This study is focused on to relieve the signs and symptoms along with identification and correction of factors that contribute to the gout. In the light of the above-mentioned results, it can be concluded that the trial drug is very effective to relive symptoms of gout for at least 60days after the treatment significantly. The study also concludes that the test drug powder has statistically significant effect for the improvement of movement and reduction in serum uric acid level, WBC, and overall involvement of joints. But this study was carried out for short duration and long-term safety and efficacy of the trial drug can be not highlighted. Hence, the long-term study of the trial drug is further needed to prove its efficacy and safety to gout.

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