



Clinical Study

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Evaluation of Habb-e-Suranjan in Management of Primary Gout (Niqras)

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ABSTRACT

Gout (*Niqras*) involves many aspects of a person's life namely somatic, psychological, and social. The increasing prevalence of gout placing a huge burden on families, society health care providers, and ultimately on Nations health. The objective of study was to validate and to evaluate the efficacy and safety of Unani pharmacopoeial formulation Habb-e-Suranjan on primary gouty patients. This was an 18 months, randomized open-label trial, carried out on 30 patients and improvements in subjective parameters were assessed weekly and in objective parameter at the baseline, 15 days and 30 days. The subjective parameters were graded arbitrarily from 0- 3 according to severity. There was a significant improvement in subjective and objective parameters and no adverse effects were observed during and after trial. Thus, it can be concluded that Habb-e-suranjan was significantly effective in resolving the symptoms and signs of gouty arthritis and have significant effect on reducing serum uric acid level..

Keywords: Arthritis, Gout, *Niqras*, Suranjan, Uric acid.

1. INTRODUCTION

Gouty arthritis is among the earliest diseases that have been recognized as a clinical entity. It is first identified by Egyptian in 2600 BC, as Podagra (foot pain), or gouty arthritis typically of the big toe, and at present understood as uric acid arthropathy^[1, 2]. Later, recognized by Hippocrates (*Buqrat*, 460- 377 B.C) in fifth century BC, who referred to it as " the unwalkable disease" ^[1, 2, 3].

It affects up to 1-2% of men in Western countries and causes mainly disability and poorer quality of life^[4]. Men are 10 time more likely to have gout than women. The fact that men have higher level of uric acid may explain their increased risk^[3]. The incidence & prevalence of gout increase with age in men and women. Gout rarely occur under the age of thirty^[3, 5, 6]. The incidence of gout, after the age of 60, between men & women is almost equal, and after the age of 80, women seem to predominate^[7, 8]. *Ghulam Jeelani* in "Makhzanul-Ilaj" and *Samarqandi* in "Asbab wa Aalamat" described that *the incidence of Niqris mainly occur after 40 years*^[9, 10].

Gout is a disorder of purine metabolism characterized by formation of monosodium urate (MSU) crystals in the synovial fluid of joints and in other tissues^[11]. It is one of the most common inflammatory joint diseases in men, present as an episodic acute and chronic/recurrent attack. The single most important risk factor for developing gout is a raised level of serum uric acid (hyperuricaemia), with supersaturation of uric acid in the extracellular fluid resulting in the precipitation of urate crytals^[12]. The first metatarsophalangeal joint (podagra) is the initial joint implicated in about one-half of the patients. When a person has had untreated gout for a long period, other joints may also be involved including ankle, heels, knees, Achilles tendon, wrists, fingers, and elbows^[13, 14].

Hyperuricemia is a result of multifactor interaction including gender, age, genetic, and environmental factors. Diet also plays a role in the development of gout^[15]. Sustained hyperuricemia predisposes some individuals to develop clinical manifestations including gouty arthritis, urolithiasis, and renal dysfunction^[11, 13]. Ultimate control of gout requires adjustment of the basic primary defect: the hyperuracaemia. Normalizing serum uric acid to < 300-360 mol/L (5.0-6.0 mg/dL) is the initial footstep to avoid recurrent attacks, and eliminate tophaceous deposits^[13].

According to *Ibn-Hubal* (1122 – 1233 A.D, the word *Niqras* is derived from the term '*Naqoroos*' which means "the joint of the great toe". because this disease typically affects the first metatarsophalangeal joint, hence the name "*Niqras*"^[16, 17]. *Ali Bin Abbas Majoosi* (930-994 A.D) has asserted that Arthritis (*Waja-ul-Mafasil*) when present in great toe is called *Niqras* (Gout) or in other words, *Niqras* is the pain & inflammation of great toe^[16]. *Ibn-Hubal* also state that gout affects those persons more who have excess of

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Akhlat (humor) and body is unable to excrete, then due to retention, it reaches towards joints and other tissues of body [18].

In acute gout, the mainstay of treatment is the administration of anti-inflammatory drugs such as non-steroidal anti-inflammatory drugs (NSAIDs), Colchicines, or Glucocorticoids. Both Colchicines and NSAIDs may be poorly tolerated and dangerous in the elderly and in the presence of renal insufficiency, and gastrointestinal disorders [13]. For the treatment of gout a lot of new drugs were discovered between 1980 & 1990. But all of them, the xanthine-oxidase inhibitors, allopurinol is the most commonly used anti-hyperuricaemic drug yet [1]. Though, it may cause gastric irritation, diarrhea, skin rashes, fever, hepatic and renal dysfunction, eosinophilia, jaundice and severe liver necrosis, with 20-25% mortality [5, 19].

Because of the known side effects of the modern medicines, the Unani drugs and its compound formulations can be used as excellent alternative for treatment of the disease. Unani drugs have long history of efficiency in management of *niqras* without causing any side effect on the human body. Almost all ancient Unani physicians have recommended *Habb-e-Suranjan* in slowing the advancement and relieving the symptoms of *Niqras* [20]. As of all the above factors the classical pharmacopoeial formulations of Unani system of medicine i. e. *Habb-e-Suranjan* is tested in present study for its efficacy in halting the progress and relieving the symptoms of gouty arthritis.

2. MATERIAL AND METHODS

This was an 18 months, randomized open-label trial, approved by Institutional Ethical Committee, carried out on 30 patients of primary gout visiting the OPD/IPD of Ajmal Khan Tibbiya College and Hospital, Aligarh Muslim University, Aligarh during the period of 2015-2016. Patients fulfilling the inclusion criteria were given the information sheet containing particulars regarding the nature of study, drug to be used, and methods of treatment and if they were agreed, included in the study and asked to sign the informed consent form. The patients were selected on the basis of history, physical examinations, and investigations. A relevant history of each patient was recorded with regard to their chief complaints with duration, name, age; sex, religion, occupation, marital status, food habits and history of use of alcohol were noted down. Other points like family history of gout, history of trauma, renal stone, acute monoarticular arthritis, history of thiazide group diuretics use, and NSAIDs were also meticulously noted down at the commencement of the study. To assess the involvement of other system of the body, all patients were interrogated about the presence of dyspnoea, nausea, vomiting, diarrhea, burning micturition, haematuria, proteinuria, frequency of micturition etc. at the beginning of the study (0 day) and thereafter repeatedly during the follow-up. General physical, systemic, and joints examination of all the patients were recorded regularly in the Performa designed for the study. The joint involved were examined for signs of inflammation, active and passive movements and presence of swelling at the beginning of the study (0 day) and thereafter regularly during the follow up i.e. 7th day, 14th day, 21st day, 30th day. The patients were examined for the presence of any tophi too. The hematological assessment of all cases was done at regular intervals. Rheumatoid Arthritis Test (RA-factor) & C - reactive protein (CRP) was carried out at the beginning of the study (0 day) to rule out the presence of rheumatoid disease and LFT, RFT, BSR (random blood sugar), haemogramme (TLC, DLC, ESR, Hb%) were carried out twice at the beginning of the study (0 day) and then at the end (30 day) to establish

the safety & observe the effect (if any) of our drug on renal and liver function and blood glucose level. The estimation of serum uric acid was carried out at the beginning of the study (0 day) and then regularly during the follow up at 15th day and 30th day. Temperament of each patient was assessed on the basis of different parameters mentioned in the classical Unani literature and treatment period was fixed to 30 days. Diagnosis was made on the basis of ACR criteria (American College of Rheumatology Criteria, satisfying any six of the twelve criteria as recommended).

All the findings were recorded on the case report form designed for the study. A total of 30 patients were randomly allocated for the trial, by simple randomization using lottery method. All the observations were tabulated and statistically analyzed with the help of biostatistician to ascertain the efficacy of drug on signs and symptoms and in reducing the serum uric acid level. The patients who did not fulfill the inclusion criteria were excluded from the study.

2.1 Criteria for selection of patients

Inclusion criteria:

- Patients with increased serum uric acid level associated with clinical features of primary gout.
- Age group of 30- 60 years.
- Patients of both sexes.
- Patients who were willing to discontinue NSAIDs or allopurinol, for joint pain and sign the informed consent form.

Exclusion criteria:

- Serious dysfunctions of Renal, Cardiac, Liver & Pulmonary.
- Pregnant and lactating women.
- Secondary gout.
- Patients below 30 years and above 60 years.

Withdrawal criteria:

- Failure to consume the drug.
- Failure to come for follow up.
- Any undesirable drug reaction.

2.2 Method of assessment of the disease

Subjective parameters:

- Pain.
- Swelling.
- Tenderness
- Redness over the joints.
- Increased local temperature.
- Painful joints movement.

Objective parameters:

- Serum uric acid level rose beyond the normal limit i.e., more than 7 mg/100 ml in males and more than 6 mg/100 ml in case of females.

2.3 Dosage schedule and mode of administration of test drug

Habb-e-suranjan is a well known Unani pharmacopoeial preparation

taken from the *Biyaz-e-Kabeer* (Dehli ke Murakkabat) Part II Published by Idara Kitabus shifa New Dehli. This Unani pharmacopoeial formulation is registered in country for use in gouty arthritis patients and selected on the basis of conventional Unani principles of treatment (*Usool-e-Ilaj*) of gout. This formulation has been used by the renowned Greek Physicians for the treatment of gouty arthritis for thousands of years without any significant side effects. The ingredients of this pill were procured from Dawakhana Tibbiya College AMU, Aligarh, before preparing the formulation, all the ingredients of the drug i.e. *Aloe barbadensis* (Liliaceae; Sibr Saqootri), *Terminalia chebula* (Combretaceae; Post Halela Zard), *Colchicum autumnale* (Liliaceae; Suranjan Sheerin), was accurately identified by an expert to ascertain its originality & purity. Later, all the ingredients of drugs were cleaned, taken in equal weight & ground to fine powder to form the pills. Root of *Colchicum autumnale*, Bark of *Terminalia chebula* & dried juice of *Aloe barbadensis* leaves were use in this formulation. Habb-e-surjan is given to each patient in the dosage of 4 pills (each pills weighing 500 mg) thrice a day orally on empty stomach (6gm/day) irrespective of age, sex, and severity of disease. Any adverse reactions reported by the patients during the study were recorded in the CRF (*Case Report Form*) and severe cases were withdrawn from the study. Clinician choosing the *Habb-e-Suranjan* to treat the gout was trained, licensed & had been practicing medicine for an average of 10 years; and had attended continuing medical education lectures on evidence-based herbal medicine interventions.

2.4 Follow up

Follow up of all the cases were carried out at the baseline, 15 days and 30 days for investigation and weekly for symptomatic relief i.e., at 0,7,14,21, and 30 days.

3. OBSERVATION AND RESULTS

3.1 Demographic data

During the entire course of study, it was observed that the occurrence of disease was higher in Muslims (63%) & female patients (57%) between the age group of 50-60 years (47%). Maximum numbers of patients were married (87%) of middle income group (60%) and had mixed dietary habits (73%), Balghami mizaj (57%) and belonged to housewives group (50%) followed by businessmen 5 cases (17%), laborers 4 cases (13%), farmer 3 cases (10%), servicemen 2 cases (7%), and student 1 cases (3%). Family history, history of attack of monoarticular arthritis, and alcohol addiction was present in 27%, 40% & 3% cases respectively. It was also observed that great toe or first metatarsophalangeal joint was involved in maximum number of cases (40%), while in 33% cases involvement of joints was polyarticular and knee joint & ankle joint were involved in 17% & 10% cases.

3.2 Effect of drugs on subjective parameters

3.2.1 Painful joints movement

During the study it was observed that painful joints movements were present in the entire patient and 63.33% improvement was noticed at the end of trial. Baseline and 30 day comparison was found to be statically significant ($P<0.01$). This shows that the efficacy of test drugs is significant on painful joint movement. (Tab. & Fig. 1)

3.2.2 Swelling

It was observed that out of 30 patients, 21 patients suffered from swelling and there was improvement in the swelling is 61.90% at the end of study. Baseline and 30 day comparison was found to be statically significant ($P<0.01$). This shows that test drug (Habb-e-surjan) have significant effect in the management of swelling. (Tab. & Fig. 1)

3.2.3 Tenderness

Out of 30 patients, 24 suffered from swelling and there was an overall improvement in the tenderness is 66.66% at the end of protocol therapy. Baseline and 30 day comparison was found to be statically significant ($P<0.01$). This shows that the effect of test drugs is significant on tenderness. (Tab. & Fig. 1)

3.2.4 Increased local temperature

Out of 30 patients in study group, 6 patients had complaint of increased local temperature. There was an overall improvement in the increased local temperature is 50% at the end of study. Baseline and 30 day comparison was found to be statically significant ($P<0.01$). This shows that the test drug is significantly effective in reducing symptom of increased local temperature. (Tab. & Fig. 1)

3.2.5 Pain in joint

All the patients of study group had complaint of joint pain. The incidence of which gradually cut down to 10 and showing an improvement of 66.66% at the end. Baseline and 30 day comparison were found to be statically significant ($P<0.01$). This shows that the test drug is significantly effective in reducing symptom of pain in joints. (Tab. & Fig. 1)

3.3 Effect of drug on objective parameter

The Mean \pm SD of serum uric acid before starting the treatment was 8.32 ± 0.96 and it got reduced to 7.4 ± 1.01 after treatment. On applying paired 't' test to the observations recorded before and after 30 days of treatment ($t= 11.50$, $p= 0.01$). The p value indicates that the effect of test drug in reducing elevated serum uric acid is significant. (Tab. & Fig. 2)

4. DISCUSSION

This clinical study was conducted on 30 patients to evaluate the efficacy of Unani pharmacopoeia formulation in the management of Primary Gout. The disease is predominantly observed in female i.e. 57% and between the age group of 40-60 years, i.e. 70%. It shows that the gout has an association with sex and a particular age group. Our observations are in accordance with the old description mentioned in classical Unani literature and modern medical text i.e. Gout rarely occurs under the age of thirty and the incidence and prevalence of gout increase with age in men and women [3, 5, 6]. The incidence of gout higher in men than women before menopause and this is due to uricosuric effect of estrogen that promote renal excretion of uric acid in premenopausal women [3, 13, 16, 21].

In our study incidence of disease was higher in Muslim and it is because of that disease has a connection with the intake of high purine-diet (meat and meat products) which is generally consumed by the Muslims.

According to Unani scholars and recent literature mentioned in classical modern text book, purine-rich diet (meat), used by the non-vegetarian, augmented the risk of gout. We observed that 27% cases belonged to the vegetarian's diet group and 73% cases belonged to the non-vegetarians diet group, which is similar to recent literatures and description mentioned in classical Unani text [3, 13, 17, 20, 22, 23, 24]. In this study out of 30 patients enrolled 87% cases were married and only 13% cases were unmarried. This is accordance with *Buqrat's* saying i.e. "A young man does not take gout unless he indulges in coitus". Excessive sexual activity, especially after a meal is recognized as a high risk factor for gout in males [1, 2, 13, 20]. Further studies are needed in this regard. *Avicenna*, *Rhazes* and *Allama Qarshi* have clearly associated phlegm with the pathogenesis of gout. In our observation the phlegmatic temperament were more in numbers (57%), which is parallel to description mentioned in classical Unani text [24]. It is very clearly mentioned in the classical text book that the disease is related with leisure and rich peoples are commonly affected [3, 16, 17, 23, 24] and it was observed that the middle income group particularly of business and housewife class were outnumbered i.e. 60 % and in higher income group it was 13 %. But it is pertinent to mention here that the visitors of our hospital are mainly belonging to lower and middle class, therefore the findings are incoherent. But it is every possibility of trend shift of disease involving more and more to higher middle class and middle class.

Hippocrates recognized the gout as a familial disorder more than 2000 years ago. This assertion is equally relevant even today. Our study included 27% cases having a positive family history, which is consistent with the descriptions given in Oxford Textbook of Rheumatology and Boyd's Pathology.

In the present study only 3% patients had the habit of alcohol consumption, whereas the remaining 97% did not give any such history. This does not coincide with the findings of Choi and colleagues who reported that alcohol consumption is a major triggering factor for gout. This difference can be attributed to two factors. Firstly, the tiny sample size and secondly the higher number of patients included in our study were Muslim. It was observed that 40% cases had the classical presentation of only great toe which is consistent with the description given in standard medical text [3, 13, 21, 22]. This observation may also be a validation for the Unani nomenclature (*Niqras*: derived from *Naqaroos* meaning great toe joint) of this disease [24].

To assess the effect of test drug on subjective parameters the patients were assessed for various sign and symptoms e.g. painful joints movement, tenderness, increased local temperature, swelling, redness, and pain. The severity was rated as severe, moderate, mild, and absent and graded as 3, 2, 1, and 0, respectively based on arbitrary grading system. There was significant but gradual improvement observed on each visit of the patient and about 63.33% of patients felt the improvement in painful joint movement on the 30th day. Similarly, 61.90% of patients felt improvement in swelling while 66.66% improvement in tenderness, 50% improvement in increased in local temperature, and 66.66% improvement in pain in joints was felt by patients at the end of protocol duration.

Test drugs was found to be significance in relieving the symptoms of painful joints movement, tenderness, swelling, increased local temperature, and pain (using paired 't' test, $p < 0.01$).

These clinical improvements are mainly because of composition of our drug. The analgesic activities of *Aloe* [25, 26], *Colchicum* [27, 28], and sedative (*Musakkin*) activity of *T. chebula* [29], are responsible for relief in pain. The anti-inflammatory action of *Colchicum* also play a crucial role on joint pain and painful joints movement along with reduction in swelling and tenderness and may also be responsible for the response in patients. The resolving and analgesic action of *Colchicum* is enough to explain the mechanism through which the gradual improvements happened [27, 28, 30].

Colchicum leads to failure of deposition monosodium urate crystals around the joints and cause kicking out of humors causing the disease [27, 28]. *Colchicum* consists of Colchicines which slow down the aggregation of inflammatory mediators and cytokines on inflammatory sites particularly of synovium and synovial membrane [31].

Aloe due to its strong purgative and mild diuretic properties, *T. chebula* due to its mild diuretic and purgative properties, and *Colchicum* due to its phlegmagogue and mild diuretic properties, smooth the progress of the expulsion of uric acid through the intestine and kidney [20, 23, 24, 25, 26]. Therefore, in under-excretors, this drug plays a wonderful job. Astringent action as well as tonic action on stomach and intestine of *T. chebula* makes the formulation least toxic [32, 33].

Colchicum is effective in all inflammatory joint situation, but due to its excretory action on uric acid, it is mainly prescribed for hyperuricaemia and gouty arthritis, but its purgative action on intestine, astringent and resolving action on joints makes the drug magnificent. This is why the expulsion of uric acid takes place through intestine [30, 3].

Table 2 showing the only objective parameter which was serum uric acid level and it was estimated at 15th day interval, the baseline serum uric acid level was 8.32 ± 0.96 and on the 30th day it was 7.4 ± 1.01 ($t = 11.50$ $p < 0.005$), indicating that test drugs had a very significant action on reducing serum uric acid level.

The well known action of *Colchicum* i.e. the expulsion of Monosodium urate from the blood and urate crystals from joint affected make the formulation very effective to expel out urate crystals and uric acid through intestine. It is therefore the findings are very much encouraging in the reduction of serum uric acid level. During the study the patients were advised to avoid purine rich diets, encourage taking plenty of water along with our medication.

It was found that drug has no apparent adverse effect on hematological and biochemical parameters during the study and at the end of the study. (Fig. 3)

Table 1: Effect of drugs on subjective parameters

Features	0 day	7 day	14 day	21 day	30 day
	No. of patients	No. of patients improved & %	No. of patients improved & %	No. of patients improved & %	No. of patients improved & %
	T	T	T	T	T
Painful joints movement	30	5 (16.66)	9 (30)	17 (56.66)	19 (63.33)
Swelling	21	4 (19)	7 (33.33)	12 (57.14)	13 (61.90)
Tenderness	24	5 (20.83)	8 (33.33)	10 (41.66)	16 (66.66)
Increased local temperature	6	1 (16.66)	2 33.33)	2 (33.33)	3 (50)
Pain	30	6 (20)	10 (33.33)	16 (53.33)	20 (66.66)

p < 0.05 (Paired 't' test applied between zero and 30th day)

T= Test drug (Habb-e-Suranjan)

Table 2: Effect of drugs on serum uric acid

	Test drug		
	Before Treatment	After Treatment	
Follow up in days	0 day	15 th days	30 th days
Mean Serum uric acid ± S.D. (mg/dl)	8.32±0.96	7.8±1.04	7.4±1.01
	t= 11.50 p=0.01		

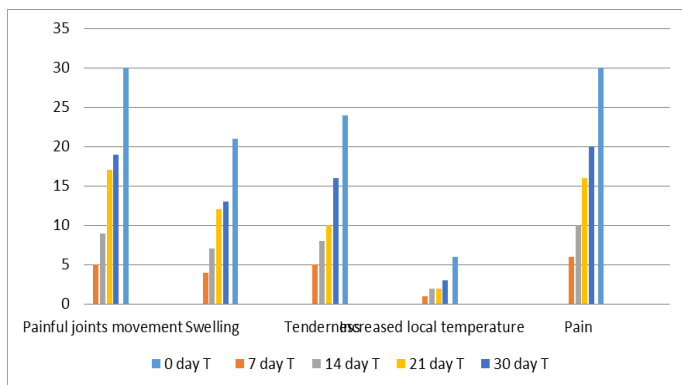
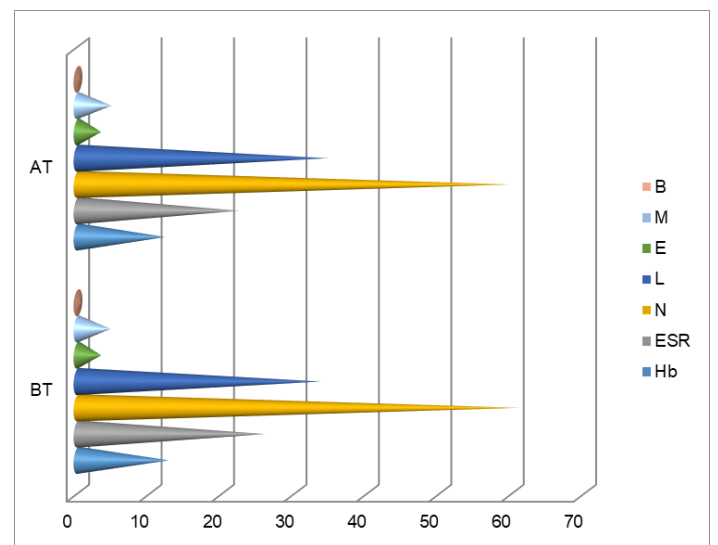
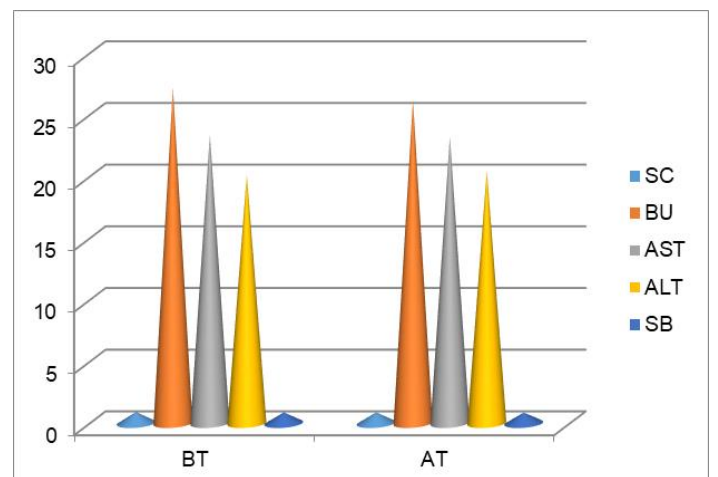


Figure 1: Showing the effect of test drugs on subjective parameters.



BT=before treatment, AT=after treatment, B=Basophil, M=Monocyte, E=Eosinophil, L=Lymphocyte, N=Neutrophil, ESR=Erythrocyte sedimentation rate, Hb= Hemoglobin

Figure 3: (a) showing the effect of test drugs on safety parameters (Hematological Parameters).



SC=Serum creatinine, BU=Blood urea, AST=Aspartate aminotransferase, ALT=Alanine aminotransferase, SB=Serum bilirubin, BT=before treatment, AT=after treatment

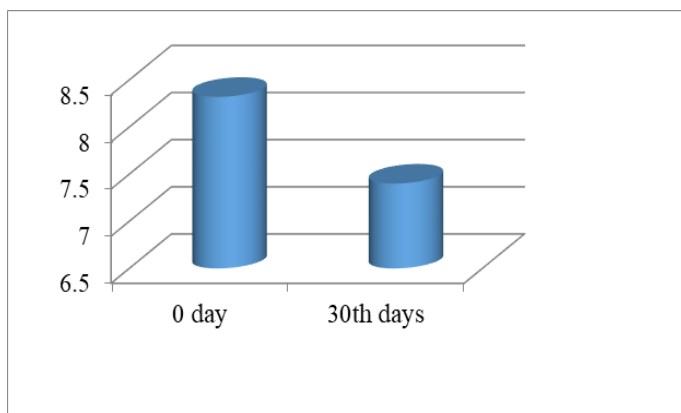
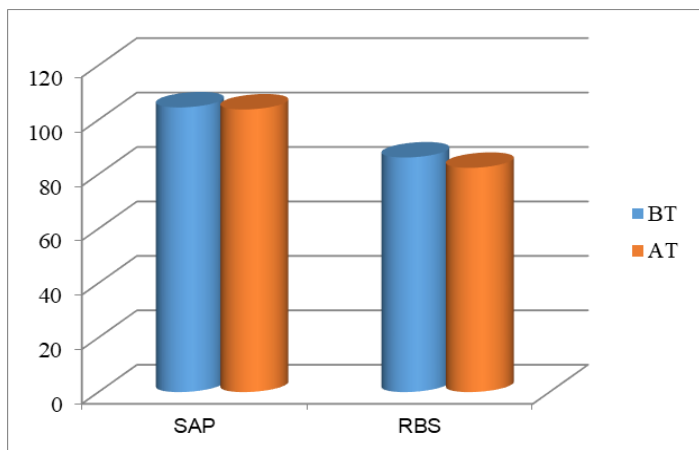


Figure 2: Showing the effect of test drugs on serum uric acid.



BT=before treatment, AT=after treatment, SAP=Serum alkaline phosphatase, RBS=Random blood sugar

Figure 3: (b) Showing the effect of test drugs on Biochemical Parameters

5. CONCLUSION

It was concluded that Habb-e-surjan is significantly effective in resolving the symptoms and signs of gouty arthritis and has significant effect on reducing serum uric acid level as well as has no any adverse effects on safety parameters. Therefore, test drug is safe to use in case of gouty arthritis.

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