



TO COMPARE THE EFFICACY, TOLERABILITY AND PATIENT ACCEPTABILITY OF ALLOPURINOL AND FEBUXOSTAT IN HYPERURICEMIC PATIENTS.

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Article received on:

22/07/2019

Accepted for publication:

15/10/2019

INTRODUCTION

Since last 40-years there is continuous rise in the incidence of hyperuricemia population around the world.¹ Recent data have shown that hyperuricemia and gout are increasing worldwide.² The international prevalence rate of hyperuricemia is 0.3% with a 90% male predominance, while 10 to 20% of patients exhibit a family history.³

Hyperuricemia is presented with raised serum urate concentration above 6.8 mg/dL⁴ at which crystal retain, that appear in gout, considered severe damages to the joint structures and associated with poor kidney and cardiovascular outcomes.⁵

Uric acid has been derived from degradation of

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ABSTRACT... Objectives: To assess the improvement, safety and tolerability of Allopurinol 300mg/daily & Febuxostat 80mg/daily in hyperuricemic patients. **Study Design:** Clinical Interventional Study. **Setting:** Medical OPD, Dr. Ruth K M Pfau Civil Hospital Karachi. **Period:** September 2018 to March 2019. **Material & Methods:** The designed interventional study from the Department of Pharmacology Hamdard College of Medicine & Dentistry, approved by BASR & Ethical Review Board of Hamdard University Karachi. Initially 70 enrolled patients, 60-patients of sUA > 6.8 mg/dl were registered, after fulfilled the inclusion and exclusion criteria and written consent, detail history on pro forma and biochemical assessments (sUA, S. Creatinine, Alkaline Phosphate, SGPT, Cholesterol, HDL, LDL and Blood sugar were measured at day 0), repeated at day 30, 60 and 90, keep in case record file, on follow up visits for final analysis. Group A, (Allopurinol) & B (Febuxostat) results data were compared of sUA, S. Creatinine and biochemical assessments, to estimate the improvement, safety and tolerability of the drugs. **Results:** Group-A baseline uric acid were, mean 8.79 ± 0.98 to mean 6.40 ± 0.86 with percentage change was 26%. Group-B treated sUA were changed mean 8.85 ± 0.97 to 5.96 ± 0.68 with percentage change was 33%. Overall improvement in mean was statistically highly significant. Mean difference \pm SD for change of serum uric acid in Group-A is 2.39 ± 1.15 with Group-B mean change is 2.90 ± 0.87 . Drug safety was determined by adverse effects and blood assay of follow up at day-90 from baseline. **Conclusion:** Improvement reported by mean of reduced uric acid & no serious adverse effects, results are highly significant.

Key words: Allopurinol, Febuxostat, Serum Creatinine, Uric Acid.

Article Citation: Hussain T, Turab M, Sultana M, Shaikh F, Hasan SS, Khalid S. To compare the efficacy, tolerability and patient acceptability of Allopurinol and Febuxostat in Hyperuricemic Patients. Professional Med J 2020; 27(4):796-806. DOI: 10.29309/TPMJ/2020.27.04.3844

purines by xanthine oxidase, in the liver, intestine & muscles from intrinsic source,⁶ while extrinsic sources are fatty meat, organ meat, and seafood, responsible for uric acid synthesis.⁷

Daily production of urate, approximately 70% is eliminated by the kidneys, and the remaining expel in the feces. However, the gastrointestinal passage of urate, to overcome the reduced excretion by the kidneys during renal failure.⁸

Allopurinol is a xanthine oxidase inhibitor, given orally and commonly applied drug in hyperuricemia treatment, owing to its efficacy and good tolerability.⁹ Twelve years after Allopurinol introduction in 1966, in this intervening period studied its origin, mechanism of action, general pharmacological properties, and therapeutic

applications, later first Phase-I human studies were carried out, following several years of laboratory studies.¹⁰

Allopurinol, xanthine oxidase inhibitor treatment, generate hypoxanthine plus xanthine concentration generally in the domain of 0.3 to 0.4 mg/dL, compared to a normal level of approximately 0.15 mg/dl.¹¹

Allopurinol dosing guidelines are considerably contrary and FDA approved up to 800 mg daily in hyperuricemia with gout patient, British Society of Rheumatology guidelines recommended an ultimate dose of 900 mg/daily.¹²

At occasion Allopurinol titrated, starting from 100 to 200 mg/day and followed by increasing the dosage steadily by 100 mg/day at intervals of 1 week or 2–4 weeks' duration, but not exceeding Allopurinol recommended dose guidelines from, the FDA and European League against Rheumatism (EULAR).¹³

Currently introduce Febuxostat is a XO inhibitor and is a selective, non-purine, approved by the FDA in 2009, for prolong duration action. Its efficacy in hyperuricemia and gout with potent urate lowering properties, but not for asymptomatic hyperuricemia.¹⁴

Febuxostat metabolized by microsomal enzyme system in the liver either active oxidized and inactive acylglucuronide metabolites.¹⁵ Kidney excrete more or less 50% of the administered Febuxostat and only 10% as unchanged form of drug.¹⁶

MATERIAL & METHODS

The study was approved from the BASR and permission from Ethical Committee of Hamdard University, conducted at Medical OPD, Civil Hospital Karachi.

Diagnosed patients of either sex, ages varying from 38 to 69 years, with consent were registered after applying inclusion and exclusion criteria and serum uric acid concentration >6.8 mg/dL¹⁷. Initially 70 patients from Medical OPD, interviewed

and examined, all information about the patients in design pro forma. They were divided into two groups, A & B, each having 30 patients, during the period of Six month from Sept 2018 to March 2019.

During follow up, 10 patients dropped out due to irregularity in visits and poor adherence to the study drugs. Registered 60-patients completed the study duration of 90-days. Drugs used in study: Allopurinol and Febuxostat.

Group-A, were treated by Allopurinol (Zyloric) 300 mg once daily for 90 days.

Group-B, were treated by Febuxostat (Go-Uric) 80 mg daily for 90 days.

Patient details, along with baseline serum uric acid. Patient's safety profile of serum creatinine, serum cholesterol, HDL, LDL, blood sugar, SGPT and serum alkaline phosphate, monitored from baseline (day-0) to completion of treatment(90-days). Investigator collected all the data of schedule visits in case recording file (CRF) for final statistical analysis.

RESULTS

Patients of both groups were discussion in detail about the disease, its prognosis and directed to reported any adverse reaction, at schedule visit or inform the investigator. On follow up days, investigator keep case record to enter the data for final evaluation of study outcome.

Group-A registered thirty patients completed study duration of Allopurinol treatment for 90-days, with the following baseline characteristics; male 22 (73.3%) with mean age of 57.60+6.11 years (range 45 to 68 years). Mean body weight 63.27+5.74, and 16 (53.3%) were smokers. Patients mean serum uric acid of 8.79+0.98 (mg/dL), serum creatinine of 1.54+0.39 (mg/dL). Table-I

Group-B registered thirty patients, have baseline characteristics; 21 (70%) male mean age 54.30+8.66 years (range 40 years to 69 years), 13 (43.3%) smokers with body weight mean 65.03+7.22. Baseline serum uric acid & creatinine

parameters showed a mean 8.85 ± 0.97 , & 1.48 ± 0.40 . Table-I.

Evaluation of serum uric acid with safety profile by blood analysis of S. Creatinine S. Alkaline phosphatase, SGPT, Cholesterol, HDL, LDL and Blood sugar in both groups were carried out for the study duration of 90-days.

Group-A & B drugs belong to same class of xanthine oxidase inhibitors with different sources. Allopurinol, is a purine derivative, inhibits the conversion of xanthine into uric acid, and prevents the production of uric acid.

Group-A

(Allopurinol 300 mg/daily): The changes of serum uric acid from day-0 to day-90 was mean 8.70 ± 0.98 to 6.40 ± 0.86 , with percentage change was 27%, serum creatinine mean 1.54 ± 0.39 to 1.42 ± 0.30 , percentage change was 8%. Table-II.

Group-B

(Treated with Febuxostat 80 mg/daily orally for 90-days):

The change from day-0 to day-90 was of mean serum uric acid 8.85 ± 0.97 to 5.96 ± 0.68 , percentage change was 33%, statistically results are highly significant with p-value >0.001 , serum creatinine mean 1.48 ± 0.40 to 1.45 ± 0.31 , and percentage change was 2%. Table-II.

Mean difference \pm SD for change of serum uric acid in Group-A is 2.39 ± 1.15 with Group-B mean change in serum uric acid is 2.90 ± 0.87 . Regarding decreasing the uric acid level, there was no significant difference between Allopurinol (alone) & Febuxostat (alone). The results are statistically non-significant with p-value 0.061. Mean difference \pm SD, for change of serum Creatinine in Group-A is 0.11 ± 0.25 . & in Group-B, is 0.03 ± 0.15 . There was no significant difference between Allopurinol (alone) & Febuxostat (alone)

are statistically non-significant with p-value 0.144 shown in Table-III

Allopurinol hypersensitivity syndrome (AHS) is a rare but potentially serious risk for 2–8% of patients¹⁸. Adverse reactions in the study were reported 9 out of 30 patients of Group-A and 4 out of 30 patients in Group-B. Table-IV

Group-A, do not show any significant difference in the serum alkaline phosphatase, SGPT & blood sugar values, but cholesterol have significant mean difference of -2.90 ± 4.10 resulting significantly decreases with p-value >0.001 in group-A, HDL mean difference 0.20 ± 0.587 significantly increases and LDL mean difference -2.53 ± 6.97 significantly decreases with p-value <0.001 at day-90. Table-VI & VII.

In group-B treated patient's, blood parameters do not show any significant difference in the serum alkaline phosphatase, SGPT & blood sugar values but have significant difference on cholesterol mean 12.43 ± 20.76 significantly decreases with p-value >0.001 , HDL mean difference -7.50 ± 2.58 significantly increases and LDL mean difference 4.63 ± 5.05 , decreases significantly with p-value <0.001 at day-90. Group-B drugs can safely be given in hyperlipidemia, along with some beneficial effects. Table-VI & VII.

Blood sugar concentration change in group-A from day-0 117 ± 14 to 109 ± 14 at day-90 and in Group-B, 122 ± 12 to 111 ± 13 showed statistically highly significant p-value >0.001 but clinically within limit. Compare group A & B for Change in Fasting Blood Sugar, mean difference \pm SD at Day-0 and Day-90 was 08.60 ± 7.18 to 10.73 ± 7.09 . There was no significant difference between Allopurinol (alone) & Febuxostat (alone). Table-VIII

	GROUP-A n=30	GROUP-B n=30
GENDER		
• Female	8(26.7%)	9 (30%)
• Male	22(73.3%)	21 (70%)
Age in years (Mean+SD)	57.60±6.11	54.30±8.66
Smokers	16 (53.3%)	13 (43.3%)
Non-Smokers	14 (46.7%)	17 (56.7%)
Body Weight Kg	63.27±5.74	65.03±7.22
Serum Uric Acid	8.79 ± 0.98	8.85 ± 0.97
Serum Creatinine	1.54 ± 0.39	1.48 ± 0.40

Table-I. Comparison of baseline characteristics between Group-A & Group-B in hyperuricemia patients.

Group- A: Allopurinol 300 mg once daily

Group-B: Tab Febuxostat 80 mg daily

Group-C: Combination of Allopurinol (300 mg) + Febuxostat (40 mg)

n- Number of Patients

Group A (Allopurinol)	Day	MEAN ± SD	P-value*
Serum Creatinine mg/dl	Base line (Day - 0)	1.54 ± 0.39	0.019**
	After treatment (Day - 90)	1.42 ± 0.30	
	Percentage Change	8%	
Group B (Febuxostat)			
Serum Creatinine mg/dl	Base line (Day - 0)	1.48 ± 0.40	0.258
	After treatment (Day - 90)	1.45 ± 0.31	
	Percentage Change	2%	

* Dependent or Paired t test

** Significant

Group A & B	Mean Difference ± SD	P-value*
Group A	2.39 ± 1.15	0.061
Group B	2.90 ± 0.87	

Table-III. Compare group A & B for Change in Serum Uric Acid level (Day -0 and Day -90).

Compare group A & B for Change in Serum Creatinine level		
Group A & B	Mean Difference ± SD	P-value*
Group A	0.11 ± 0.25	0.144
Group B	0.03 ± 0.15	

n = 60

* Dependent or Paired t test

** Significant

Adverse effect of drugs	Response	Allopurinol (alone)		Febuxostat (alone)	
		No.	%	No.	%
Palpitation	Yes	02	6.7	00	00
	No	28	93.3	30	100
Headache	Yes	00	00	01	3.3
	No	30	100	29	96.7
Numbness	Yes	00	00	01	3.3
	No	30	100	29	96.7
Abdominal pain	Yes	03	10	00	00
	No	27	90	30	100
Hematuria	Yes	02	6.7	01	3.3
	No	28	93.3	29	96.7
Hypersensitivity	Yes	02	6.7	00	00
	No	28	93.3	30	100
Vomiting	Yes	00	00	01	3.3
	No	30	100	29	96.7
Fever	Yes	00	00	00	00
	No	30	100	30	100
Fatigue	Yes	00	00	00	00
	No	30	100	30	100

Table-IV. Tolerability / safety of the drugs. (Allopurinol 300 mg & Febuxostat 80 mg).

Group A (Allopurinol)	Day	MEAN \pm SD	P-value*
Serum Cholesterol mg/dl	Base line (Day – 0)	195 \pm 30	0.001**
	After treatment (Day – 90)	198 \pm 31	
Group B (Febuxostat)			
Serum Cholesterol mg/dl	Base line (Day – 0)	176 \pm 36	0.003**
	After treatment (Day – 90)	164 \pm 25	

Table-V. Serum Cholesterol in Group A & B (Day -0 and Day -90).

Serum HDL level in group A & B (Day-0 and Day-90)			
Group A (Allopurinol)	Day	MEAN \pm SD	P-value*
Serum HDL mg/dl	Base line (Day – 0)	31 \pm 07	0.853
	After treatment (Day – 90)	31 \pm 06	
Group B (Febuxostat)			
Serum HDL mg/dl	Base line (Day – 0)	29 \pm 06	< 0.001**
	After treatment (Day – 90)	36 \pm 06	

Serum LDL level in group A & B (Day-0 and Day-90)			
Group A (Allopurinol)	Day	MEAN \pm SD	P-value*
Serum LDL mg/dl	Base line (Day – 0)	135 \pm 20	0.056
	After treatment (Day – 90)	137 \pm 20	
Group B (Febuxostat)			
Serum LDL mg/dl	Base line (Day – 0)	129 \pm 09	< 0.001**
	After treatment (Day – 90)	124 \pm 09	

* Dependent or Paired t test

** Significant

Group A & B	Mean Difference \pm SD	P-value*
Group A	-2.90 \pm 4.10	< 0.001**
Group B	12.43 \pm 20.76	

Table-VI. Compare Mean Difference \pm SD in Serum Cholesterol level (Day-0 to -90).

Compare Mean Difference \pm SD in Serum HDL level (Day-0 and Day -90)		
Group A & B	Mean Difference \pm SD	P-value*
Group A	0.20 \pm 05.87	< 0.001**
Group B	-7.50 \pm 2.58	

Compare Mean Difference \pm SD in Serum LDL level (Day-0 and Day -90).		
Group A & B	Mean Difference \pm SD	P-value*
Group A	-2.53 \pm 6.97	< 0.001**
Group B	4.63 \pm 5.05	

- Febuxostat (alone) was significantly decreased the Cholesterol level than Allopurinol (alone)
- Febuxostat (alone) was significantly increased the HDL level than Allopurinol (alone)
- Febuxostat (alone) was significantly decreased LDL level than Allopurinol (alone)

Group A (Allopurinol)	Day	MEAN \pm SD	P-value*
S. Alkaline Phosphate mg/dl	Base line (Day – 0)	142 \pm 20	0.156
	After treatment (Day – 90)	143 \pm 20	
Group B (Febuxostat)			
S. Alkaline Phosphate mg/dl	Base line (Day – 0)	157 \pm 13	0.037**
	After treatment (Day – 90)	158 \pm 14	

Serum SGPT level in group A & B (Day -0 and Day -90)			
Group A (Allopurinol)	Day	MEAN \pm SD	P-value*
S. SGPT mg/dl	Base line (Day – 0)	30 \pm 05	0.223
	After treatment (Day – 90)	31 \pm 05	
Group B (Febuxostat)			
S. SGPT mg/dl	Base line (Day – 0)	33 \pm 07	0.005**
	After treatment (Day – 90)	34 \pm 06	

Table-VII. Serum Alkaline Phosphate in Group A & B (Day -0 and Day -90).

Compare Mean Difference \pm SD in Serum Alkaline Phosphate level (Day -0 and Day -90)		
Group A & B	Mean Difference \pm SD	P-value*
Group A	-0.83 \pm 3.13	0.961
Group B	-0.80 \pm 2.0	

Compare Mean Difference \pm SD in Serum Alkaline Phosphate level (Day -0 and Day -90)		
Group A & B	Mean Difference \pm SD	P-value*
Group A	-0.83 \pm 3.13	0.961
Group B	-0.80 \pm 2.0	

Compare Mean Difference \pm SD in Serum SGPT level. (Day -0 and Day -90)		
Group A & B	Mean Difference \pm SD	P-value*
Group A	-0.76 \pm 3.37	0.529
Group B	-1.23 \pm 2.22	

* Dependent or Paired t test

** Significant

- Regarding the Alkaline Phosphate level, there was no significant difference between Allopurinol (alone) & Febuxostat (alone).
- Regarding the SGPT, there was no significant difference between Allopurinol (alone) & Febuxostat (alone).

Group A (Allopurinol)	Day	MEAN \pm SD	P-value*
Fasting Blood Sugar mg/dl	Base line (Day – 0)	117 \pm 14	< 0.001**
	After treatment (Day – 90)	109 \pm 14	
Group B (Febuxostat)			
Fasting Blood Sugar mg/dl	Base line (Day – 0)	122 \pm 12	< 0.001**
	After treatment (Day – 90)	111 \pm 13	

Table-VIII. Serum Fasting Blood Sugar level in Group A & B (Day -0 and Day -90).

* Dependent or Paired t test ** Significant

Group A & B	Mean Difference \pm SD	P-value*
Group A	08.60 \pm 7.18	0.252
Group B	10.73 \pm 7.09	

Compare group A & B for Change in Fasting Blood Sugar level. (Day -0 and Day -90).

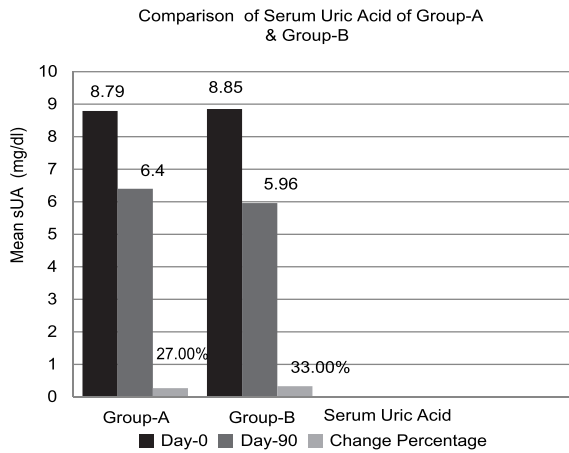


Figure-1

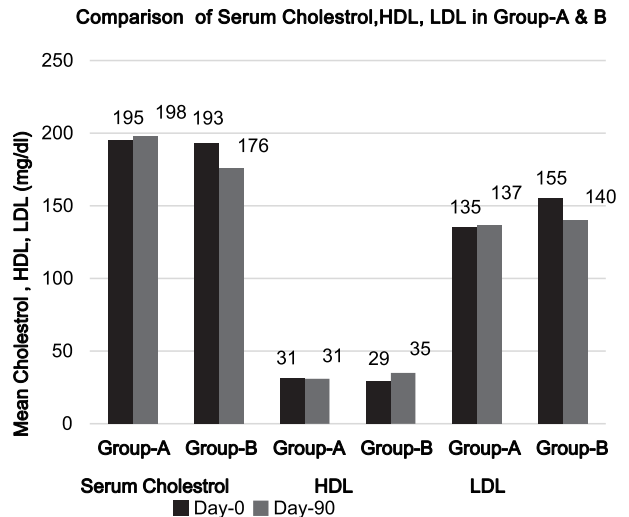


Figure-4. Comparison of Serum Cholesterol, HDL, LDL in Group-A & B.

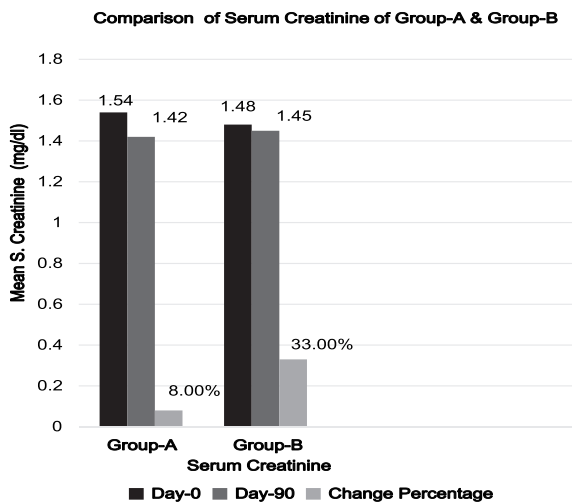


Figure-2

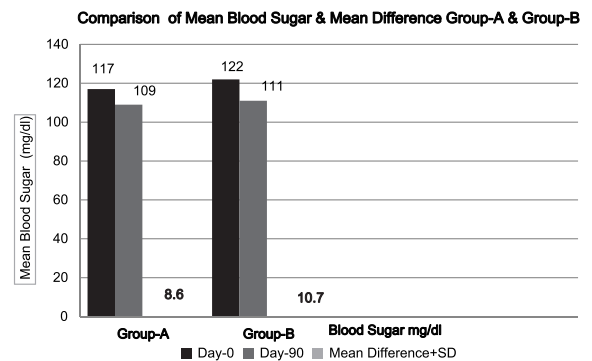


Figure-5: Comparison of Mean Blood Sugar & Mean Difference + SD Group-A & Group-B.

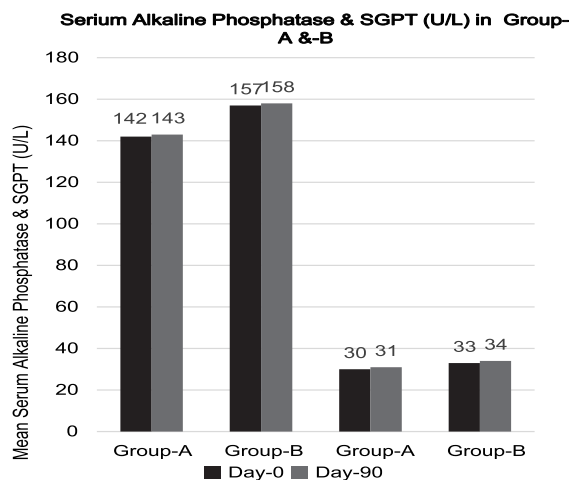


Figure-3 Comparison of Blood parameters of Liver Functions Comparison of serum Alkaline Phosphate & SGPT. Group-A & Group-B

DISCUSSION

Hyperuricemia prevalence not only reported in developed countries but evidence come up in the low and middle-income countries, that incidences are also ascending.¹⁹

The prevalence of hyperuricemia is 1–4%. In European countries, male predominance 3–6% than female 1–2%, as the age advances prevalence rises 10% & 6% respectively in both sex. Yearly incidence is 2.68 per 1000 persons, in male 2–6 folds more than female.²⁰

Hyperuricemia pathophysiology is not clearly known, imbalance of breakdown of purines and uric acid excretion is answerable to its action. Most cases of hyperuricemia clinically reported

because of faulty urate excretion. Elevated sUA is now established as a potential risk factor for developing number of diseases like, insulin resistance, increased blood pressure, lipid disturbances and cardiovascular diseases.²¹

Hyperuricemia in the initial days recognized as gout, but now consider a separate entity and responsible for numbers of metabolic and hemodynamic abnormalities.²²

In our study, the aim of therapy is to treat hyperuricemia with the minimum therapeutic dose and hence minimize the risk of adverse effects, efforts to suppress serum uric acid over long term and prevent relapse. The allopurinol a standard treatment in hyperuricemia since long compare with newly FDA approved drug Febuxostat, in addition to assess the tolerability/safety.

The present study findings with Allopurinol treatment, the serum uric acid reduced from 8.79 ± 0.98 day-0 to 6.40 ± 0.86 on day 90, total percentage change was 27%. Statistically highly significant <0.001 and findings are in agreement with the study conducted by Becker, 2005.¹¹

In renal dysfunctions, better option to start with the minimum dose, a reduced initial target dosage in renal impairment is still defend, but studies support that when unable to obtained desire effects, the dosage may be increased above the present guidelines. In our study, the renal function assessment are within normal limit and allopurinol therapy does not influenced the serum Creatinine level, results agree with (Day, 2007).²³

Our study does not agree with (Wei Li, 2005),²⁴ in which a significant limitation of allopurinol therapy in reducing the serum uric acid, in less than 50% of patients receiving standard dose of 300mg daily.

Study conducted by (Perez-Ruiz, 2000)²⁵ validated, that higher doses of allopurinol are more effective in decreasing concentration of uric acid, but Allopurinol 300 mg in recommended dosage are similarly adequate in decreasing uric acid concentration without influencing the renal

functions, results matched with our study.

Our results agree with (Gerald 1975),²⁶ study, with single 300-mg of Allopurinol per day appears to be beneficial in individuals with hyperuricemia.

Febuxostat, non-purine potent xanthine oxidative inhibitor, used as an alternative to allopurinol Grassi, 2014²⁷ established logical and well-established outcomes, for short period of 1 to 6 months duration use of Febuxostat significantly reduces the serum uric acid concentrations. Our study of 90-day treatment with Febuxostat, supported the study.

Becker, 2005,¹¹ clinical trial of 52 weeks duration, in which sUA was reduced to 6.0 mg/dL, during 3-month study, Febuxostat with Allopurinol, matched with our results in the reduction of serum uric acid at day 90 in the duration of therapy, results more marked with Febuxostat than Allopurinol.

Our study also agrees with (Borghini, 2016)²⁸ reported, that in hyperuricemia, Febuxostat is a suitable option and considered as first line drug, provided safe and efficient in number of clinical studies.

A study of 28 weeks by Schumacher,²⁹ conducted in 2008, of different doses, Febuxostat more adequately reduces and maintained serum urate levels <6.0 mg/dl than allopurinol, at doses (300 or 100 mg) or placebo in hyperuricemic patients and gout, with mild to moderately renal dysfunction. In our study, does of 300 mg of Allopurinol & Febuxostat of 80 mg productively decreased sUA, without any disturbances of renal function and better effects reported with Febuxostat group of patients.

In our study Febuxostat 80 mg, daily dose were more effectively reduces the sUA concentration 39% than allopurinol at daily dose of 300 mg in which showed 27% reduction of sUA, results agrees with Michael,³⁰ clinical study in 2005, in hyperuricemia and gout patients. Prompt and persistent reduction in sUA, less than 6.0 mg/dL more marked in patients treated with daily 80 mg

Febuxostat than 300mg.

Becker 2005¹¹ controlled trial of Febuxostat versus Allopurinol of 52 week randomized, randomized 760 patients to 1 of 3 study groups of Febuxostat 80 mg, Febuxostat 120 mg and allopurinol 300 mg/day and compared the safety and efficacy. During the study measured sUA, laboratory tests, assessed renal function, at each of the last 3 monthly visits. Our study of Febuxostat 80 mg & Allopurinol 300 mg daily for 90-days, the reduction of serum uric acid achieved the desired results.

In a study conducted in 2011 by Kamatani³¹ of comparative study of Allopurinol & Febuxostat in doses 200 mg & 40 mg/d respectively for the period of 44 days showed Febuxostat at 40 mg/daily demonstrated more potent hypouricemic effects than allopurinol at 200 mg/d, in our study Febuxostat 80mg/d & Allopurinol 300mg/d for 90 days demonstrated that Febuxostat is more potent than allopurinol in hyperuricemia.

In another trial, (CONFIRMS trial) conducted in 2010 by Becker,³² our study showed similar efficacy in a 6-month study of 2269 patients of serum urate levels ≥ 8.0 mg/dL and compared Febuxostat proved significant reduction of uric acid levels in patients with normal renal function. Frampton³³ pointed that earlier studies have identified cardiovascular toxicities with Febuxostat, ongoing trials are in progress to identify the cardiovascular safety of Febuxostat versus allopurinol. In our study of ninety hyperuricemia patients for 90-days therapy monitoring drug safety, no adverse events except palpitation self-control, reported in 4% of patients.

Laboratory data of liver function assay (Alkaline Phosphate & SGOT) Table-VII & Figure-3 and blood sugar results in both groups were insignificant Table-VIII & Figure-5.

Study showed decreasing Cholesterol & LDL but showed increased HDL values, beneficial in hyperlipidemia. Table-V & Figure-4.

We observed no serious adverse events, related to drugs used during the study period.

There was no significant difference between Allopurinol (alone) & Febuxostat (alone).

- Group-A: Allopurinol treated 300mg/d
- Group:-B Febuxostat treated 80mg/d
- sUA: Serum Uric Acid
- Day-0: Baseline mean value
- Day-90: Completion of study mean value
- Mg/dl: Milligram per Deciliter
- Group-A: Allopurinol treated 300mg/d
- Group:-B Febuxostat treated 80mg/d
- Day-0: Baseline mean value
- Day-90: Completion of study mean value
- Mg/dl: Milligram per Decilitre

Group-A: Allopurinol (300 mg) treated Patients

Group-B: Febuxostat (80mg) treated Patients

n: Total number of Patients

Group-A: Allopurinol (300 mg) treated Patients

Group-B: Febuxostat (80mg) treated Patients

n: Total number of Patients

Group-A: Allopurinol (300 mg) treated Patients

Group-B: Febuxostat (80mg) treated Patients

n: Total number of Patients

CONCLUSIONS

This clinical study, conducted in patients with hyperuricemia, and treatment with Febuxostat, Allopurinol with regard to safety and urate-lowering efficacy. Administration of Febuxostat 80 mg, Allopurinol 300mg for 90-days resulted in prompt and persistent reduction in serum urate concentration.

In this study, the overall incidences of treatment-related adverse events were similar for all treatment groups, and were mild in severity.

For many years, allopurinol were used for lowering serum urate in patients, which reduced uric acid production through competitive inhibition of xanthine oxidase. There was moderate-quality evidence of little or no difference in the proportion of participants achieving target serum urate when allopurinol was compared with Febuxostat. However, Febuxostat seemed more successful than allopurinol in achieving a target serum urate level (6 mg/dL or less).






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