Research Article

International Research Journal of Ayurveda & Yoga
Vol. 5 (7),102-111, July, 2022
ISSN: 2581-785X;https://irjay.com/
DOI: **10.47223/IRJAY.2022.5712**

A Clinico-Pathological Study on *Vatarakta* w.s.r. to Gout and its Comparative Effect of *Bodhivrikshya Kashaya* and *Bodhivrikshya Ghana Vati.*

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Article Info

Article history:
Received on: 12-06-2022
Accepted on: 22-07-2022
Available online: 31-07-2022

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ABSTRACT:

Vatarakta is the major example of *Vatavyadhi*, caused due to *avarana* pathology. The scenario of *Vatarakta* featuring sign & symptoms which can very well be correlated with Gouty Arthritis. The literature enlists a number of formulation in the management of *Vatarakta*. An additional cavernous revise was indispensable to bring out the precise outcome of these products. Keeping these visions in mind, the particular comparative study was performed with *Bodhivrikshya Kashaya* and *Bodhivrikshya Ghana Vati*, which are explained in the same context. This is a single-blind comparative clinical study with a pre-test and post-test design, wherein a minimum of 30 patients of either sex, suffering from *Vatarakta*, in an age limit of 20 to 50 years with symptoms like *sandhishoola* (joint pain), *sotha* (swelling), *kandu* (itching), *daha* (burning sensation), *twakvaivarna* (discolouration), *sparshaasahatwa* (tenderness), *sphurana*(twitching)and serum uric acid value more than 6.8mg/dl were selected and randomly categorized into two groups. The 15 patients of group A were treated with oral administration of *Bodhivrikshya Kashaya* 25ml twice day and the group B patients with *Bodhivrikshya Ghana Vati* 2tab(1tab-500mg) thrice daily with *anupana* of *Madhu*. The therapeutic effect of the treatment was assessed in both the groups based on specific subjective and objective parameters. The results obtained were analyzed statistically in both the groups and the comparative effect was assessed using the unpaired "t"-test. In both the groups, a statistically significant improvement was observed in all the criteria of assessment. The outcome of the study revealed an identical therapeutic efficacy of *Bodhivrikshya Kashaya* and *Bodhivrikshya Ghana Vati* in *Vatarakta* but *Bodhivrikshya Kashaya* have shown more than *Bodhivrikshya Ghana Vati*. No Adverse effect was noticed during clinical trial in both groups.

Keywords: *Vatarakta*, *Margavarana*, *Raktavahasrotas*, Gout

INTRODUCTION

In *Ayurveda*, *Vatarakta* was mentioned by most of Samhita. The disease occurs when both *vataprokapaka* and *raktadustihetus* are involved. Then *vridhavata* obstructed by *dustarakta dhatu* in turn vitiates the whole *rakta* which manifest as *vatarakta*. It is classified as *Uttana* & *Gambhira*; and *Vataja*, *Pittaja*, *Kaphaja*, *Raktaja*,

Sansargaja & Sannipataja. *Vatarakta* first manifestation occurs either *mula of hastha* or *pada*[1,2]. The peculiarities of *vatarakta* can be related to contemporary disease Gout.Gout is a progressive, painful, debilitating form of inflammatory arthritis ,caused by factors that elevate the concentration of SUA (Serum Uric Acid) i.e. greater than 6.8 mg/dl (404 mol/l) leading to hyperuricemia[3].It priorly affects the metatarsophalangeal joint with extensively painful, red, hot, swollen and very tender joints. In later stage, it may produce large, visible bumps made of urate crystals, tophi[4].

Among various *kalpanas, Kashaya kalpana* and *Ghanavatikalpana* are used more profusely to treat diseases now a days. For the ease of patient suffering from *vatarakta,* a clinical trial of *Bodhivrikshya Kashaya*[1] and *Bodhivrikshya Ghanavati*[1] on 30 patients (divided in two groups) was done for 30 days.

AIMS AND OBJECTIVES

- To evaluate the effect of *Bodhivrikshya Kashaya* and *Bodhivrikshya Ghana Vati* in the management of *vatarakta.*

- To evaluate and establish the reducing level of Uric acid found in *Vatarakta*(Gout).

MATERIALS AND METHODS

IEC Number- 1148/G.A.C & H Dated 20/05/2020

CTRI Ref No-REF/2022/04/053744

Selection of patients

This is a single-blind comparative clinical study with a pre-test and post-test design .The total 30 patients (Group-A 15, Group-B 15) had been selected by a special proforma covering demography alongwith both Subjective and Objective parameters from OPD and IPD of Govt. Ayurvedic College and Hospital, Balangir and Saradeswari Govt. Ayurvedic Hospital Balangir. The consent of patient was also taken before clinical trial.

Diagnosis Criteria

The patient were diagnosed on the basis of subjective and objective parameters for the diagnosis of *Vatarakta i.e. Kandu (itching), Daha (burning sensation), Sphurana (twitching), Sotha (swelling), Sandhishoola (joint pain), Twakvaivarna (discolouration) & Sparsha asahatwa*[1] (tenderness)and TLC, ESR, Serum uric acid &CRP respectively[3].

Inclusion Criteria

1. Presenting with clinical features of Vatarakta.
2. Subjects with chronicity of disease more than 6 months and less than 5 years,
3. Either sex, age between age group of 20-50 yrs.
4. Subjects showing the uric acid level, Male->7.0 mg/dl, Female->6.0 mg/dl.

Exclusion Criteria

1. Patient present with OA, RA, ASO, Filariasis.
2. Subjects with autoimmune disease of joints.
3. Either sex, age below 20yrs and above 50yrs.
4. Uric acid level-Male- <7.0 mg/dl, Female-<6.0 mg/dl.

Selection Of Drugs

Two medicines, *Bodhivrikshya Kashaya* and *Bodhivrikshya Ghana Vati* had been taken for clinical trial. *Bodhivrikshya* was identified by the experts of Dept. of Dravyaguna which was approved by DRC and IEC of Govt. Ayurvedic College & Hospital, Balangir, and Sambalpur University respectively. Medicines were prepared as per GMP certified method in Mini Pharmacy of College under the supervision of expert of *Rashasashtra&Bhaisajya Kalpana*. The sample of research medicines were sent to Quality control Laboratories of ALN Rao Memorial Ayurvedic Medical College & PG Centre Koppa, Dist. Chikmagalur, Karnataka for Analytical study.

Intervention

Group A: Fifteen patients with oral administration of *BodhivrikshyaKashaya* in a dose of 25 ml twice daily after food with *madhu as sahapan.* Group B: Fifteen patients with oral administration of *BodhivrikshyaGhanavati* in a dose of 2 tablet (each tablet = 500 mg) thrice daily after food with *Madhu* as *Anupana* (Table 1)

Assessment Criteria

The subjective and objective parameters were assessed by the grading score from 0 to 3 according to the severity of disease and favourable shift to back. Both parameters were followed up after 10^{th}, 20^{th} and 30^{th} day of medication.

Table No-02: Showing the assessment of subjective and objective parameters of vatarakta.

OBSERVATION & RESULT:

The clinical study period of 30 patients were taken from 11.07.2021 to 09.01.2022.Within aforesaid period the demography (Table No-3) based on Age-Sex-marital status, etc. along with incidence of *Dasavidha Parikshya*(Table No-4) were observed and assessed.

The subjective and objective parameters of both Group-A

and Group-B were observed during clinical study. The percentage of improvement were also assessed after clinical trial. (Table No-05)

After observation of subjective and objective parameters, the statistical analysis of parameters were assessed by the helping statistical method.(Table No-06 and 07) Table No-08: Showing clinical assessment of Result in Group-A and Group-B (n=30):

DISCUSSION

Vatarakta is a *Vatavyadhi Prabheda.* The illness is considered to be the finest illustration of an *Avarana Vyadhi*, as an opening from the etiopathogenesis to the complications, the illness follows the characteristic presentation of *Avarana.* Compared with the other *Vata vyadhi*, *Vatarakta* possesses a special place in the literature, due to its high prevalence in the society, increased incidence as age advances, step-wise succession, and so on. From the overall view of the etiology, it is obvious and unambiguous that the precise etiological factors of *Vata Dosha* as well as *Rakta Dhatu* are accountable for the causation of illness. Whatever be the grounds, an obstruction in the path of *Rakta Dhatu* and *Vata Dosha* is the core pathology of the disease

Discussion on Demography

In this present study the demographic assessment shows maximum number of patients were having *madhyamvaya* i.e. 83.33%. This reveals that most of the patients are middle age group as Hyperurecemia is mostly occurring from 30-60 age group. It also shows that the 63.33 % of males were affected, which implies the increase incidence in the male gender. This may be due to occupational, nature of work, addictions etc, which indicates exposure of males to these *Nidana* are more. The observations reveal that 96.67% of patients belong to the higher-middle class status. Sedentary lifestyle is one of the major cause of the disease. Maximum number of patients i.e. 96.67% were taking mixed diet, who consumes more red meat& pulses. The study reveals maximum number of patients had addiction to the Alcohol 33.33%. Alcoholics are more prone to get the disease Gouty Arthritis and the same has been shown in this study, ingestion of smoking and alcohol results in prompt increase of uric acid. Among 60% of total patients had disturbed sleep this may be due to the pain which is most commonly experienced in night hours, burning sensation and sudden pain during hours of darkness in Gouty Arthritis.

Discussion on *Dasavidha Pariksha*

As regards to the *dasavidhapariksha*, observation shows patients were mostly of *vata-pitta prakruti* i.e. 76.67%. Maximum number of patients were having *madhyamsatwa, sara, samhanan, satmya, pramana, abhyavaran shakti, vyayama shakti* .

Discussion on subjective and objective parameters(Graph 1&2)

***Sandhishoola*:**In Group A the percentage of effect was 81.25 % and in Group B the percentage of effect was 70.97%.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

***Sotha*:** In Group A the percentage of effect was 77.78 % and in Group B the percentage of effect was 67.67%.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

Sparshasahatwa: In Group A the percentage of effect was 80.77% and in Group B the percentage of effect was 70.00%.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

Twakvaivarna:In Group A the percentage of effect was 84.00 % and in Group B the percentage of effect was 68.97%.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

Kandu:In Group A the percentage of effect was 83.33 % and in Group B the percentage of effect was 60.00%.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

Daha: In Group A the percentage of effect was 80.77 % and in Group B the percentage of effect was 66.67 %.The p value for both the groups is <0.05. Hence both the groups are significant but in comparision Group A shows more significant result than Group B.

***Sphurana* :**In Group A the percentage of effect was 85.71 % and in Group B the percentage of effect was 50.00%.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

TLC:In Group A the percentage of effect was 55.00 % and in Group B the percentage of effect was 42.86 %.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

ESR:In Group A the percentage of effect was 76.96 % and

in Group B the percentage of effect was 65.38 %.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

Serum Uric Acid: In Group A the percentage of effect was 79.31 % and in Group B the percentage of effect was 70.00 %.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

CRP:In Group A the percentage of effect was 79.17 % and in Group B the percentage of effect was 62.50 %.The p value for both the groups is <0.05. Hence both the groups are significant but in comparison Group A shows more significant result than Group B.

Probable mode of action

Ayurvedic Point of view:

Ashvattha is a drug which shows *Vichitrapratyarabdhata* properties like *Madhura* and *Kashaya rasa, Guru Rukshaguna, Sheetavirya* and *Katuvipaka*. Among these *Madhura rasa* is responsible for the decrease in *vata* and *pitta doshas* and *Kashaya rasa* is having the properties of *raktaprasadana, amaharatva* and *mutra sangrahaniya* in its *ruksha bhava.* The *Mutra sangrahaniya* property of *kashaya* may be the cause for this action by detaching the uric acid crystals from the tissue and the same was eliminated through urine, which is considered as one of the *malas* according to Ayurveda. *Guru Guna* helps in pacifying *vata* and helps in *dhatu poshana.Ruksha Guna* help in pacifying pitta also it helps in absorbing toxicity of *rakta dhatu*. *Sheetavirya* helps in pacifying *pitta* and helps in relieving symptoms like *Sandhi Shotha, Raga, Daha, Sparshasahatava. The sheetavirya* of the drug have the action to increase the amount of urine and thereby helps to expel the formed uric acid crystals from the body through urine. Due to *Katu rasa Vipaka of Bodhivrikshya* helps in *agnideepana*. also katu rasa has properties like *"shonitasanghatabhinnati", "bandhas chinnati", "marganbibrunati*". So the obstruction of both *rakta* and *vata* gets cleared.

Contemporary science point of View:

The phyto-constituents present in *Ficus religiosa* Linn. such as tannins, alkaloids, terpenoids, glycosides, phenols and flavonoids .Xanthine oxidase inhibitory effect, uricosoric action, anti-inflammatory effect and analgesic effect are the key for the management of gout[12].Flavonoids,alkanoids,phenol,tannin shows the potential of anti gout effect by their xanthine oxidase inhibitory action[11,12,15].Terpenoids,alkaloids,phenol,and flavanoids shows anti inflammatoryeffect[12].Tannines and flavonoids shows uricosoricacion The analgesic effect of the drug is due to its chemical constituents like flavoniods, glycosides, phenol and terpenoids is mediated via inhibition of cyclo-oxygenases leading to the inhibition of prostaglandin synthesis, which reduces the pain significantly.

The overall assessment showed in Table No-08 (Graph 3) revealed that In Group A, 66.67% patients had marked improvement, while 26.67% patients had moderate improvement and in Group B, 40.00% patients had marked improvement while 46.67% patients had moderate improvement.

CONCLUSION

Vatarakta is manifested due to *vata-avarana* and *rakta-dushti*. As mentioned in mode of action, *Bodhivrikshyakashaya* and *Bodhivrikshyaghanavati* clears the *marga-avarana* and reduce *rakta-dushti*. Results show noticeable improvement in the symptoms and signs of *Vatarakta* after the intervention in both the groups. The outcome of the study reveals the identical therapeutic efficacy of *Bodhivrikshyakashaya* and *Bodhivrikshyaghanavati* in *Vatarakta* but *Bodhivrikshyakashaya* shows more efficacy than *Bodhivrikshyaghanavati.*

Acknowledgement: Nil
Financial support: Nil
Conflict of Interest: Nil

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How to cite this article: Chandrakar B, Singh V.C, Panda P.K, Panda S "A Clinico-Pathological Study On *Vatarakta* W.S.R. To Gout And Its Comparative Effect Of *Bodhivrikshya Kashaya* And *Bodhivrikshya Ghana Vati*." IRJAY.[online]2022;5(7); 102-111.
Available from: https://irjay.com
DOI link- https://doi.org/10.47223/IRJAY.2022.5712

Table No-01: Showing the Pharmacodynamics of drugs of *Bodhivrikshya Kashaya* and *Bodhivrikshya Ghana Vati*

Name	***Rasa***	***Guna***	***Veerya***	***Vipaka***	***Doshakarmata&Prabhava***
Bodhivrikshya	*Kashaya, Madhura*	*Guru, Rukshya*	*Sheeta*	*Katu*	*Kaphapittashamaka*

Table No-02: Showing the assessment of subjective and objective parameters of vatarakta.

SUBJECTIVE CRITERIA	**SCORING**
Kandu(**itching*****)***	
Frequently severe itching	3
Moderate itching infrequently	2
Mild itching	1
No itching	0
Daha(**burningsensation)**	
Severe burning sensation not able to sleep	3
Moderate burning sensation with disturbed sleep	2
Mild burning sensation	1
No burning sensation	0
Sphurana(**twitching*****)***	
Severe twitching always felt	3
Moderately twitching felt sometimes	2
Mild twitching felt infrequently	1
No twitching	0
Sotha(**swelling*****)***	
Severe swelling with loss of movements	3
Moderate swelling without loss of movements	2
Mild swelling	1
No Swelling	0
Sandhishoola**(joint pain*****)***	
Moderate pain at rest, severe and intolerable pain while working	3
Mild pain at rest, moderate and tolerable pain while working	2
No pain at rest, mild tolerable pain while working	1
No pain at rest, no pain while working	0
TwakVaivarnya(**discolouration of skin*****)***	
Severe discoloration in large multiple areas	3
Moderate discoloration in multiple areas	2
Mild color changes in one to two region	1
No discoloration	0
SparshaAsahatwva(**tenderness)**	
Patient do not allow to palpate	3
Moderate pain on palpation	2
Mild pain on palpation	1
No pain on palpation	0
OBJECTIVE CRITERIA	**Scoring**
Serum Uric Acid	
12.5-15.5mg/dl	3
9.5-12.5mg/dl	2

7-9.5mg/dl	1
<6.8mg/dl	0
TLC (4000-11000/Cu mm)	
>13500/Cu mm	3
12000-13500/Cu mm	2
10500-12000/Cu mm	1
4500-10500/Cu mm	0
CRP	
>26.1mg/l	3
16.1-26mg/l	2
6.1-16mg/l	1
0-6mg/l	0
ESR	
>75mm/hr	3
51-75mm/hr	2
25-50mm/hr	1
<25mm/hr	0

Table No-03:Demographic incidence of registered patients(n=30)

Criteria	Maximum Percentage	Category
Age	83.33%	*Madhyamavastha*
Sex	63.33%	Male
Religion	96.67%	Hindu
Marital status	90.00%	Married
Socioeconomic status	96.67%	Higher middle class
Education	100.00%	Literate
Desha	100.00%	*Jangala*
Dietary habit	96.67%	Mixed
Addiction	33.33%	Alcohol
Sleeping habit	60.00%	Disturbed
Bowel habit	76.67%	Abnormal

Table No-04:Incidence of *Dasavidha Parikshya* of registered patients

Criteria	**Max. Percentage**	**Category**
Prakriti	76.67%	*Vatapittaja*
Vikriti	100%	*Madhyamvalavyadhi*
Sara	73.33%	*Madhyam sara*
Samhanan	60.00%	*Madhyam*
Pramana	80.00%	*Madhyam*
Satwa	86.67%	*Madhyam*
Satmya	70.00%	*Madhyam*
Ahara Shakti	86.67%	*Madhyam*
Vyayama Shakti	56.67%	*Madhyam, Uttama*
Vaya	83.33%	*Madhyavasta*

Table No-05: Total patients as per disease and percentage of improvement in Group-A and Group-B: (n=30)

Subjective& Objective Parameter	Group A		Group B		Group A	Group B
	N	%	N	%	% Effect	% Effect
***Sandhi shoola(*jointpain)**	15	100.00%	15	100.00%	81.25	70.97
Sotha(*swelling*)	15	100.00%	15	100.00%	77.78	66.67
Sparshaasahatwa(*tenderness*)	15	100.00%	15	100.00%	80.77	70.00
***TwakVaivarna*(discolouration of skin)**	15	100.00%	15	100.00%	84.00	68.97
Kandu(*itching*)	3	20.00%	3	20.00%	83.33	60.00
Daha(*burningsensation*)	15	100.00%	15	100.00%	80.77	66.67
***Sphurana*(twitching)**	5	33.33%	4	26.67%	85.71	50.00
TLC	13	86.67%	11	73.33%	55.00	42.86
ESR	15	100.00%	15	100.00%	76.92	65.38
Serum Uric Acid	15	100.00%	15	100.00%	79.31	70.00
CRP	15	100.00%	15	100.00%	79.17	62.50

Table No-06: Showing the statistical analysis of subjective parameter. (n=30)

Subjective parameter			**Mean**	**Median**	**SD**	**Wilcoxon W**	**P-value**	**% effect**	**Result**
Sandhishoola(*joint pain*)	Group A	BT	2.13	2.00	0.35	-3.578[b]	0.00035	81.25	Sig
		AT	0.40	0.00	0.51				
	Group B	BT	2.07	2.00	0.26	-3.508[b]	0.00045	70.97	Sig
		AT	0.60	1.00	0.51				
Sotha(*swelling*)	Group A	BT	1.80	2.00	0.41	-3.520[b]	0.00043	77.78	Sig
		AT	0.40	0.00	0.51				
	Group B	BT	2.00	2.00	0.00	-3.542[b]	0.00040	67.67	Sig
		AT	0.67	1.00	0.49				
Sparshsasahatwa(*tenderness*)	Group A	BT	1.73	2.00	0.46	-3.520[b]	0.00043	80.77	Sig
		AT	0.33	0.00	0.49				
	Group B	BT	2.00	2.00	0.00	-3.520[b]	0.00043	70.00	Sig
		AT	0.60	1.00	0.51				
Twakvaivarna(*discoloration of skin*)	Group A	BT	1.67	2.00	0.49	-3.520[b]	0.00043	84.00	Sig
		AT	0.27	0.00	0.46				
	Group B	BT	1.93	2.00	0.26	-3.542[b]	0.00040	68.97	Sig
		AT	0.60	1.00	0.51				
Kandu(*itching*)	Group A	BT	0.40	0.00	0.83	-1.633[b]	0.01025	83.33	Sig
		AT	0.07	0.00	0.26				
	Group B	BT	0.33	0.00	0.72	-1.732[b]	0.00833	60.00	Sig
		AT	0.13	0.00	0.35				
Daha(*burningsensation*)	Group A	BT	1.73	2.00	0.46	-3.520[b]	0.00043	80.77	Sig
		AT	0.33	0.00	0.49				
	Group B	BT	2.00	2.00	0.00	-3.542[b]	0.00040	66.67	Sig
		AT	0.67	1.00	0.49				
Sphurana(*twitching*)	Group A	BT	0.47	0.00	0.74	-1.857[b]	0.00633	85.71	Sig
		AT	0.07	0.00	0.26				
	Group B	BT	0.40	0.00	0.74	-1.732[b]	0.00833	50.00	Sig
		AT	0.20	0.00	0.41				

Table No-07: Showing the Statistical Analysis of Objective Parameter:

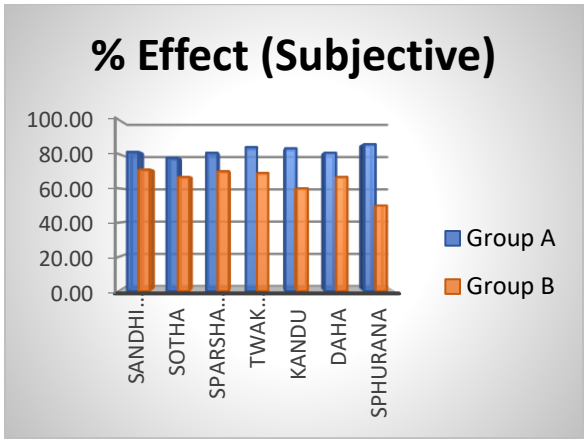
Objective parameter			Mean	SD	T-value	P-Value	% effect	Result
TLC	Group A	BT	1.33	0.82	4.036	0.001	55.00	Sig
		AT	0.60	0.63				
	Group B	BT	0.93	0.70	3.055	0.009	42.86	Sig
		AT	0.53	0.52				
ESR	Group A	BT	1.73	0.46	8.367	0.000	76.92	Sig
		AT	0.40	0.51				
	Group B	BT	1.73	0.46	6.859	0.000	65.38	Sig
		AT	0.60	0.51				
Serum Uric acid	Group A	BT	1.93	0.70	9.280	0.000	79.31	Sig
		AT	0.40	0.51				
	Group B	BT	2.00	0.53	10.693	0.000	70.00	Sig
		AT	0.60	0.51				
CRP	Group A	BT	1.60	0.51	10.717	0.000	79.17	Sig
		AT	0.33	0.49				
	Group B	BT	1.60	0.51	7.246	0.000	62.50	Sig
		AT	0.60	0.51				

(SD=Standard Deviation, SE=Standard Error, t=Test of Significance, P=Probability, <0.05=Significant at 5% level, >0.05 = No Significant at 5% level)

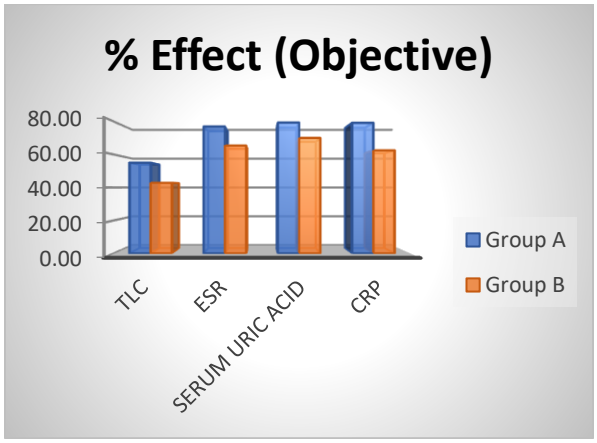
Table No-08: Showing clinical assessment of Result in Group-A and Group-B (n=30):

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	10	66.67%	6	40.00%
Moderate Improvement	4	26.67%	7	46.67%
Mild Improvement	1	6.67%	2	13.33%
No Change	0	0.00%	0	0.00%
TOTAL	15	100.00%	15	100.00%

GRAPH 1



GRAPH 2



GRAPH 3