Effect of Panchatikta Ghrita Guggulu (PTK-G) on Hematological and Biochemical parameters after long term use in Eczematized patients of Bangladesh

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ABSTRACT:

Ayurveda is one the oldest healing system in the world originated from the India and also native to Bangladesh, and more than 500 compound formulations are available commercially in Bangladesh. Panchatikta Ghrita Guggulu (PTK-G) is one of the leading products in Bangladesh used for skin disease as well as many other ailments though the safety data are lacking due to a few studies on it especially in Bangladesh. The aim of the study was to find out the effect of PTK-G on hematological and biochemical parameters after long term use of the drug in eczematized patient of Bangladesh. Quantitative experimental Pre-test and post-test study was designed and carried out among 20 patients aged between 12 years to 60 years. Patients were selected by guasi-random sampling method. PTK-G is manufactured as per Bangladesh National Ayurvedic Formulary. Each patent was administered 500 mg capsule orally three times a day after meal for 6 weeks without taking any other drug concomitantly. The Pre and Post treatment blood samples were collected to investigate the CBC, Total Protein, S. albumin, S. globulin, Albumin-Globulin ratio, Liver function test and Kidney function test as hematological and biochemical parameters. In this study there was a decrease of hemoglobin level, total count of WBC and ESR which were not statistically significant. A noticeable decrease of ESR (44.12%, p=0.096) content was noted. Eosionophil count was decreased very significantly (p-0.015). Other biochemical test especially Kidney function, liver function, total proteins were within normal limit after long term administration of PTK-G. All the effects of PTK-G were not clearly visible, because of the unavailability of the necessary facilities to run such a large number of experiments. The actual causes of the above mentioned effects were not clear at present, which need further extensive studies to draw a better conclusion in future. But we may summarize that PTK-G is safe to use within recommended therapeutic dose and able to improve the eczema.

Key words: Ayurveda, PTK-G, Hematological, Biochemical parameters

INTRODUCTION

Bangladesh is one of fastest growing developing country in South Asia. Bangladesh as well as a significant part of South Asia believes on medical pluralism. Medical pluralism can be defined as the employment of more than one medical system or the use of both conventional and complementary and alternative medicine (CAM) for health and illness. ^{[1],[2],[3],[4]} (Rashid, 2017; Misra, 2010; Leslie, 1980 and Sujatha 2003). Multiple medical systems such as Biomedicine i.e allopathic medicine, Ayurvedic, Unani and Homoeopathy are officially recognized in Bangladesh health system. Ayurveda is one of the leading medical systems in India due to origin and cultural belief. In Bangladesh it belongs to the second position and lots of people takes Ayurvedic treatment from the Ayurvedic physician. Ayurvedic medicine have attained a significant importance in the treatment of diseases and also in maintenance of optimal health for humans [5] (Badole and Kotwal, 2015).

Panchatikta Ghrita Guggulu (PTK-G) is one of the leading products in Bangladesh used for skin disease as well as many other ailments like bone and joint diseases and inflammatory disorders that help fight infection, calms the tridoshas, and purifies the blood. Panchatikta Ghrita Guggulu (PTK-G) is an ancient Ayurvedic medication prepared from 5 bitter herbs like Neem (*Azadirachta indica*), Guduchi (*Tinospora cordifolia*), Vasaka (*Adhatoda Vasaka*), Patola (Trichosanthes dioica), and Kantakari (*Solanum xanthocarpum*) with Guggulu (*Commiphora wightii*) and consisting of 24 more herbs as per Bangladesh National Ayurvedic Formulary ^[6] (Anonymous 1992) blended in ghee. The Ayurvedic Physician prescribes this drug empirically in skin disease for long time. Its role in the treatment of skin diseases has been implicated but the efficacy and safety data are lacking specially in Bangladesh perspective.

Taking into consideration, there is need to and lot of scope to find out the safety profile after long term using of PTK-G in Bangladesh. One cannot emphasize enough the need for establishing without safety profiles of Ayurvedic drugs. Keeping in mind, the study on Ayurvedic formulation, **Panchatikta Ghrita Guggulu** (PTK-G) was intended to investigate effect of PTK-G on hematological and biochemical parameter after long term using of the drug in eczematized patient of Bangladesh. The aim was to have a better understanding of the possible efficacy and safety profile of the drug under clinical study and to some extent, to decide how reasonable the use of this drug is under the stated circumstances.

MATERIAL AND METHODS

Quantitative experimental Pre-test and post-test study was designed and carried out among 20 patients aged between 12 years to 60 years. Patients were selected by quasi-random sampling method. A health camp was arranged at Kaliagore, Gazipur, Bangladesh and patients were selected after getting written consent. Patients suffering from acute illness, known serious chronic disease and chronic renal failure, severely ill persons, malignancy and drugs taken by the patients which might be influenced the study result were excluded from the study. The drug PTK-G was manufactured in Pharmacology Laboratory of Pharmacy department, Jahangir Nagar University, Savar, Dhaka and 500 mg powders were filled on '0' Size capsule shell using automatic pharmaceutical technology with the help of SQUARE Pharmaceutical Ltd. Each patent was administered 500 mg capsule orally three times a day after meal for 6 weeks without taking any other drug concomitantly. Paid local volunteers were employed to monitor the patient to confirm the drug supply and taking regularly. Experiment was carried out in both male and female human subjects to observe the hematological and biochemical pattern after chronic administration of PTK-G with a dose of 500 mg three times a day. The Pre and Post treatment blood samples were collected to investigate the CBC, Total Protein, S. albumin, S. globulin, Albumin-Globulin ratio, Liver function test and Kidney function test as hematological and biochemical parameters.

RESULTS AND DISCUSSION

After experiment, the following changes were noted in male-female average value.

Table 1: Effect on Complete Blood Count on both male and female patient

Parameter	Pre-test	Post-test	t/p	Incr/dec%
Hemoglobin	12.785±0.336	12.135±0.692	0.844/0.404	↓5.08%
ESR	20.850±5.117	11.650±1.304	1.742/0.096	↓4.12%
WBC Total Count	8.635±0.403	7.475±0.463	1.888/0.067	↓13.43%
Neutrophils	52.70±1.954	55.550±3.713	2.894/1.355	↑5.41%
Lymphocyte	33.20±1.548	31.20±2.190	0.746/0.461	↓6.02%
Monocyte	4.05±0.343	3.950±0.276	0.227/0.822	↓ 2.47%

Eosinophil	9.85±1.275	6.10±0.695	2.581/0.015	↓38.07%
Platelet count	301500±13059.08	267150±18473.06	1.518/0.138	↓11.39%
Nata: *** 0.05 ***	0.04 ****			

Note: *p<0.05, **p<0.01, ***p<0.001

In study there was a decrease (5.08%) in the hemoglobin which statistically was not significant (p=0.404) in comparison with control group. There was a decrease in the Total WBC count (13.43%) and this decrease was not statistically significant but it was noticeable (p=0.067). This may be the result of interaction with autoimmune disorders. As immunoglobulin especially IgE response is higher in ECZEMA, it indicates efficacy of PTK-G against ECZEMA by lowering high WBC count. On the other hand a little bit pre-caution can be taken in immune compromised patients. A noticeable decrease in the ESR (44.12%) content was noted, though it was not statistically significant (p=0.096). It depicts that PTK-G has the ability to lowers the skin inflammation.

Neutrophil and Lymphocyte reflect inflammatory response and disease severity in Eczema patients. Elevated levels of systemic inflammatory markers (Neutrophil and Lymphocyte) are associated with severity of many diseases, such as cancer, psoriasis, systemic lupus erythematosus, and atopic dermatitis.^[7] (Jiang, Y., & Ma, W. 2017).

The Neutrophil count was high (^{5.41%}), which was statistically insignificant (p-1.355) and it was within normal value. On the other hand Lymphocyte and Monocyte count were decreased at 6.02% and 2.47%, which were high before treatment. Lowering tendency of Lymphocyte and monocyte depicts antiinflammatory effect, though Lymphocyte and monocyte were not decreased significantly.

Eosinophilic skin diseases such as allergic drug eruption, urticaria, allergic contact dermatitis, atopic dermatitis, and eczema are characterized by eosinophil infiltration and/or degranulation in skin lesions.^[8] (Long H. et. al. 2016)

From the table 1 it was seen that Eosionophil count was decreased very significantly (p-0.015). It depicts that PTK-G improves the itching and oozing by lowering eosinophil count and improves the inflammation by normalization of WBC count.

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Group	STP mg/dL	S.Alb mg/dL	Globulin mg/dL	A/G ratio %
Pre-test	70.96	41.32	29.54	1.40
Post-test	74.96	43.76	30.84	1.41
Increase or decrease	↑5.129%	15.905%	↑4.40%	↑0.714%
P- value	0.746	0.774	0.839	0.956

Table 2: Effect on Total protein	, albumin, globulir	and A/G on both	male and female patient
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Note: *p<0.05, **p<0.01, ***p<0.001

From the table 2, it was found that the protein content was increased, which was not statistically significantly in comparison with pre-test result. It might be assumed that PTK-G did not alter the protein level in human when taken at therapeutic dose after long term administration.

Table 3: Effect on Lipid profile on both male and female patient

Croup	Cholesterol	HDL	LDL	TG
Group	mg/dL	mg/dL	mg/dL	mg/dL

Control group	145.6	40.75	66.57	163.45	
PTKG group	126.6	39.81	56.505	138.02	
Decr/Incre %	↓13.05%	↓2.31%	↓15.12%	↓15.56%	
p - value	0.100	0.754	0.177	0.237	

Note: *p<0.05, **p<0.01, ***p<0.001

Total cholesterol was decreased (\downarrow 13.05%), which was not significant but it was noticeable (p- 0.100). From the study result it might be assumed that PTK-G might inhibit cholesterol synthesis or cholesterol absorption. So it can be potentiated the activity of cholesterol lowering drug.

Table 4: Effect on Liver and Kidney	function on both male and female patient

Parameter	Pre-test	Post-test	t/p	Incr/dec%	
Liver Function test result					
Bilirubin	0.459±0.052	0.481±0.052	0.386/1.875	↑4.79%	
SGOT	23.335±1.805	20.70±1.868	1.014/0.317	↓ 11.29%	
SGPT	23.750±4.501	20.10±3.051	0.671/0.506	↓15.37%	
ALP	250.70±24.256	216.450±23.520	1.014/0.317	↓13.66%	
Kidney Function test result					
S. Creatinine	0.888±0.063	0.729±0.088	1.463/0.152	↓17.85%	
B.Urea	28.320±3.086	23.820±3.258	1.003/0.322	↓15.89%	
Uric Acid	4.182±0.231	3.479±0.294	1.878/0.068	↓16.82%	
Note: *p<0.05, **p<0.01, ***p<0.001					

From the table 4 it was observed that there was increased Bilirubin (\uparrow 4.79%) and decreased SGOT (\downarrow 11.29%), SGPT (\downarrow 15.37%) and Alkaline phosphatase (\downarrow 13.66%), which were not statistically significant. From these parameters it may be assumed that lowering of sGOT sGPT and ALP reveal lack of Hepatotoxicity. Bilirubin level may conflict the result. But from the table 1, we found that Hemoglobin level was decreased. So, it may be assumed that decreasing tendency of hemoglogin and Bilirubin might have link with haemolytic diseases. So, it should better to take caution in Blood related disease, especially hemolytic disease.

From the table 4, it was observed that B. Urea and Creatinine were decreased insignificantly (p=0.322, & 0.152). The pathological finding denotes that PTK-G does not impair the kidney function badly. But precaution should be taken in kidney patients. A noticeable (p=0.068) decrease was noted in Uric acid. In ayurvedic system of medicine, PTK-G is used in Gout. Decreasing tendency of uric acid indicates the possible action against gout and psoriasis. But large scale study is required to confirm the efficacy.

CONCLUSION

One of the components of the routine physical examination is the Complete Blood Count (CBC) blood test, which provides a lot of information to the physician regarding the state of a person's health. In this study there was a decrease of hemoglobin level, total count of WBC and ESR which were not statistically significant. A noticeable decrease of ESR (44.12%, p=0.096) content was noted. It depicts that PTK-G has the ability to lowers the skin inflammation. Eosionophil count was decreased very significantly (p-

0.015). It depicts that PTK-G improves the itching and oozing by lowering eosinophil count and improves the inflammation by normalization of WBC count. Other biochemical test especially Kidney function, liver function, total proteins were within normal limit. A significant change was noted in lipid profile test where triglyceride was decreased significantly. And a noticeable decrease was noted in total cholesterol and LDL cholesterol. From the study result it may conclude that PTK-G has lipid lowering effect that may potentiate the activity of conventional lipid lowering agent or herbs during concomitant use or may impede the absorption of fat. All the effects of PTK-G were not clearly visible, because of the unavailability of the necessary facilities to run such a large number of experiments. The actual causes of the above mentioned effects were not clear at present, which need further extensive studies to draw a better conclusion in future. But we may summarize that PTK-G is safe to use within recommended therapeutic dose and able to improve the eczema.

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COMPETING INTERESTS

There is no competing interest.

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