

SAFETY EVALUATION OF DR IGUEDO GOKO CLEANSER® POLY-HERBAL FORMULATION IN WISTAR ALBINO RATS**Timipa R. Ogoun¹, Odangowei I. Ogidi*² and Frank-Oputu Ayibaene³**

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ABSTRACT

This study was aimed at evaluating the safety of Dr Iguedo Goko Cleanser® poly-herbal formulation in wistar albino rats. Twenty (20) adult albino rats were used for this research. Dr Iguedo Goko Cleanser® treated groups (n=5) was administered to each rat at 5, 10 and 15 mg/kg body weight. Treatment of the animals was done for 14 days after the 7 days acclimatization before sacrificing them through cervical dislocation. Blood was collected by cardiac puncture, using 5ml syringes and 23G needles into blood sample containers for biochemical evaluation using standard biochemical methods. The results obtained in this study indicate that creatinine and ALT levels were observed to be lower when compared with the control group.

Concentrations (10 and 15 mg/kg) of the serum levels of total bilirubin and albumin, ALP (5 and 15mg/kg), AST and total cholesterol (5 and 10mg/kg), total protein (5mg/kg) and urea (5, 10 and 15mg/kg) were observed to be higher when compared with the control. Statistically, there were no significant differences of the evaluated indices at 95% confidence level ($P < 0.05$). In conclusion, Dr Iguedo Goko Cleanser® poly-herbal formulation can serve as an effective blood cleanser by aiding the kidney in excretion of waste products from the body due to low creatinine levels. The herbal formulation also may not cause hepatocellular damage of the liver due to low ALT levels. However, the study has also revealed nephrotoxic potentials, hepatobiliary dysfunctions and cholestatic alteration effects of the poly-herbal

formulation. Therefore, the use of the Dr Iguedo Goko Cleanser® poly-herbal formulation should be under medical supervision and the habitual, higher therapeutic doses and long-term use should be done with utmost caution.

KEYWORD: Dr Iguedo Goko Cleanser®, Safety, Poly-herbal formulation, Biochemical Parameters, Wistar albino rats.

INTRODUCTION

Herbal medicines are traditional preparations or products which contain plant parts or some other plant materials as active ingredients.^[1] Herbal medicine is renowned as the most common form of alternative medicine and is used by about 60% of the world population both in the developing and developed countries.^[2,3] In rural communities, the exclusive use of herbal drugs, prepared and dispensed by herbalists without formal training, for the treatment of diseases is still very common.^[3] Thus, herbal medicines have received greater attention as alternative to clinical therapy in recent times leading to subsequent increase in their demand.^[4]

Presently, self-medication is a common practice in Nigeria and there is an upsurge in the circulation of various kinds of drugs and quasi-drug formulations^[5], many of which are allegedly licensed by the National Agency for Food Drug Administration and Control (NAFDAC). In most countries of the world but predominantly in Africa and Asia, herbal medicines and their derivatives are introduced into the market without any mandatory safety or toxicological evaluation.^[6] These herbal products are continuously made available to consumers without prescription in most cases and the potential hazards in an inferior product are hardly recognized.^[6] Due to failure in standardization, most of these formulations may be contaminated with toxic metals that may put humans at risk. Thus, exposures to them are of serious concern to public health.

Dr. Iguedo Goko Cleanser® herbal mixture is a poly-herbal infusion that is made mainly from aromatics and botanicals, and includes any combination of herbs, roots, barks, leaves or other parts of plants.^[7] Its contents are made of five different plants and a flavouring/colouring agent as shown: *Vernonica amygdalina* (12 %), *Saccharum officinarum* (11.5%), *Allium sativum* (13%), *Cajanus cajan* (11.5%), *Zingiber officinale* (0.5%), and Caramel (1.5%) and it is claimed to cure well over 50 different diseases. The product leaflet states that the herbal mixture “removes harmful toxins from the body systems, thereby reducing accumulated fat

and cholesterol level, regulates monthly menstrual cycle, prevent oedema and numbness. It regulates blood sugar level, pile, waist pain and boosts the immune system. It also prevents malaria and typhoid fever and restores the balance of the cell structure by correcting the metabolic disturbances”.

It is therefore, pertinent that these claims by the manufacturers of this herbal mixture be validated to provide scientific-based findings that will help consumers make evidence-based decisions on the use and quality of the herbal medicine they consume, hence this research, safety evaluation of Dr Iguedo Goko Cleanser[®] poly-herbal formulation in wistar albino rats.

MATERIALS AND METHODS

Materials and chemicals

Syringes and needles, hand Gloves, incubator, glucometer, AucKu check active strip micropipette, stop watch, oven, centrifuge Model 800, cotton wool, HPLC, and GCMS. The chemicals included 10% Chloroform, xylene, hemotoxylin and eosin stains.

Collection of herbal formulation samples

Dr Iguedo Goko Cleanser[®] a Nigerian Herbal formulation was purchased from a registered pharmaceutical shop (Cynflac Pharmacy Yenagoa, Bayelsa State). The product is a combination of several medicinal plants. As an inclusion criterion, the product was ascertained to have been registered with the National Agency for Food, Drug Administration and Control (NAFDAC number: A7-0804L). The manufactured and expiry dates of the product were inspected and all were confirmed to be within the acceptable time frame. The Manufacturer's seal, inspected to ascertain the authenticity of the product was intact in the bottles of the syrup purchased for the analysis and was taken to the Research Laboratory, Department of Pharmacology, Faculty of Basic Medical Sciences, College of Health Sciences, Niger Delta University, Wilberforce Island, Bayelsa State and was stored under room temperature prior to the experiment.



Figure 1: Dr Iguedo Goko Cleanser®

Experimental animals

Animal handling

Twenty (20) adult wistar albino rats used for this study were purchased from the animal house of the Faculty of Basic Medical Sciences, College of Health Sciences, Niger Delta University, Wilberforce Island, Bayelsa State. The animals were kept in standard plastic rat cages in the research laboratory of the Department of Pharmacology, Faculty of Basic Medical Sciences, College of Health Sciences, Niger Delta University, Wilberforce Island, Bayelsa State. The animals were allowed to acclimatize for 7 days under standard laboratory conditions with free access to commercial grower's mash (Delta Feeds), water *ad libitum* and 12 h/ 12 h light/darkness cycle and fresh air prior to the inception of this study. The animal experiment was conducted in accordance with internationally accepted practice for laboratory animals and approved by the Animal Ethics Committee of the Faculty of Basic Medical Sciences, College of Health Sciences, Niger Delta University, Wilberforce Island, Bayelsa State.

Administration of poly-herbal formulation

The herbal formulation was administered using 5 ml syringe, the corresponding dose was given to each rat based at 5, 10 and 15 mg/kg body weight dose of the herbal formulation was selected.

Experimental Design

After the period of acclimatization, the animals were randomly divided into experimental and control groups. The albino rats were grouped and herbal formulation administered as follows;

Group A (n = 5) Control: wistar albino rats received 2ml of distilled water daily within the period of the study before sacrificing.

Group B (n = 5) wistar albino rats were treated with 5 mg/kg body weight of Dr Iguedo Goko Cleanser®

Group C (n = 5) wistar albino rats were treated with 10 mg/kg body weight of Dr Iguedo Goko Cleanser®

Group D (n = 5) wistar albino rats were treated with 15 mg/kg body weight of Dr Iguedo Goko Cleanser®

Blood sample collection

The animals were observed in their cages for clinical symptoms daily and at the end of the 14 days treatment, the rats were sacrificed under chloroform anesthesia and blood was collected by cardiac puncture, using 5ml syringes and 23G needles into blood sample containers. The blood was allowed to stand for 2 hours to coagulate and was centrifuged for 10 minutes at 2000 rpm and the supernatant (Serum) carefully collected for biochemical analysis.

Biochemical indices evaluation

Serum levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT) were determined following the principle described by^[8] while the alkaline phosphates (ALP) were carried out according to the method described by^[9] to assess liver function. Renal function was assessed by measuring plasma creatinine (CREA) levels and blood urea nitrogen (BUN) was assayed following the method of.^[10, 11]

In order to assess the synthetic function of the liver, total serum protein (TP), Total bilirubin and albumin (ALB) concentrations were determined according to the principles based on the Biuret reaction^[12] and bromocresol green reaction^[13] respectively. Total Serum cholesterol (TC) concentrations were estimated following the method described by.^[14]

Statistical analysis of data

All data were expressed as Mean \pm Standard Error of Mean (SEM). Significant differences among the groups were determined by One-Way Analysis of Variance (ANOVA) using the statistical analysis program for social sciences (SPSS 17.0).

RESULTS

Biochemical Indices

The Body Weight of wistar albino rats administered with Dr Iguedo Goko Cleanser® poly-herbal formulation is shown in Table 1. Table 2 shows the effects of Dr Iguedo Goko Cleanser® poly-herbal formulation on biochemical indices of wistar albino rats at 5, 10 and 15 mg/kg doses. The biochemical indices evaluated were creatinine, urea, albumin, total protein, transaminases (AST, ALT), alkaline phosphatase (ALP), total cholesterol and total bilirubin and were compared with the control groups. All mean values of creatinine and ALT were lower when compared with the control group. Concentrations (10 and 15 mg/kg) of the serum levels of total bilirubin and albumin, ALP (5 and 15mg/kg), AST and total cholesterol (5 and 10mg/kg), total protein (5mg/kg) and urea (5, 10 and 15mg/kg) were observed to be higher when compared with the control. Statistically, there were no significant differences of the evaluated indices at 95% confidence level ($P < 0.05$).

Table 1: Body Weight of Animal with Dr Iguedo Goko Cleanser® poly-herbal formulation (Mean \pm SEM, n = 5)

Control	Dr Iguedo Goko Cleanser®		
	5mg/kg	10mg/kg	15mg/kg
113 \pm 1.7	154 \pm 2.3	214 \pm 1.8	211 \pm 1.9

Table 2: Effects of Dr Iguedo Goko Cleanser® poly-herbal formulation on Biochemical Indices of wistar albino rats.

Biochemical indices	Control	Dr Iguedo Goko Cleanser®		
		5mg/kg	10mg/kg	15mg/kg
Total Bilirubin (mg/dl)	0.35 \pm 0.02 ^c	0.34 \pm 0.01 ^a	0.47 \pm 0.02 ^b	0.47 \pm 0.01 ^d
Total Protein (g/dl)	5.4 \pm 0.31 ^a	6.3 \pm 0.21 ^c	5.4 \pm 0.26 ^b	5.4 \pm 0.26 ^d
Albumin (g/dl)	4.2 \pm 0.14 ^d	3.5 \pm 0.2 ^b	5.3 \pm 0.31 ^a	4.5 \pm 0.20 ^c
Creatinine (mg/dl)	0.63 \pm 0.01 ^b	0.53 \pm 0.02 ^d	0.62 \pm 0.03 ^c	0.54 \pm 0.01 ^a
Alkaline phosphatase, ALP (u/l)	71.6 \pm 0.14 ^a	72.7 \pm 0.08 ^b	66.3 \pm 0.27 ^c	74.2 \pm 0.18 ^d
Aspartate aminotransferase, AST (u/l)	56.5 \pm 0.17 ^b	61.2 \pm 0.28 ^d	58.8 \pm 0.15 ^a	52.8 \pm 0.05 ^c
Alanine aminotransferase, ALT (u/l)	26.7 \pm 0.18 ^d	21.3 \pm 0.24 ^c	22.4 \pm 0.20 ^b	26.3 \pm 0.21 ^a
Urea (mg/dl)	17.3 \pm 0.17 ^c	19.3 \pm 0.27 ^d	19.2 \pm 0.15 ^a	17.6 \pm 0.14 ^b
Total Cholesterol (mg/dl)	72.6 \pm 0.24 ^d	76.4 \pm 0.26 ^a	81.3 \pm 0.28 ^c	66.4 \pm 0.26 ^b

(Mean \pm SEM, n = 5), Means of the same superscript alphabets in the same column shows no significant difference at 95% confidence levels ($p < 0.05$)

DISCUSSION

The growing acceptance and use of herbal mixtures such as Dr Iguedo Goko Cleanser® poly-herbal formulation has necessitated the need to evaluate the effect and safety of this

traditional or natural remedy on the body organs vis-à-vis their functions. This study was aimed at evaluating the safety of Dr Iguedo Goko Cleanser[®] poly-herbal formulation in wistar albino rats at 5, 10 and 15 mg/kg body weight.

The basic kidney function indices investigated in this work are creatinine, urea, albumin, total protein. Creatinine is considered to be a good traditional marker for kidney function especially because of the fact that it is not influenced by diet and many other extra renal factors. The observed lower level of creatinine in the experimental rats in all the body weight compared to the control in this study may support the claim of Dr Iguedo Goko Cleanser[®] poly-herbal formulation works as a blood cleanser by aiding the kidney in the excretion of waste products from the body. This finding is in accord with the works of reference.^[15]

However, the increased urea levels in all the dosage (5, 10 and 15mg/kg) observed in the experimental groups may be due to nephrotoxic effect of the herbal formulation, leading to reduced renal function. Urea is formed in the liver, representing the principal waste product of protein catabolism and is excreted by the kidney. This herbal formulation may have probably caused a decrease in glomerular filtration rate, resulting in decreased excretion of urea, which may produce an increase in the concentration of the blood urea as observed in Table 2. This result is in consistent with the works of references.^[16, 17]

Serum protein measurements can reflect nutritional status and may be used to screen for and help diagnose kidney and liver diseases and many other conditions.^[18] The increase in serum total protein at 5mg/kg concentration when compared with the control is an indication that there could be impaired renal function or tissue inflammation. Albumin plays very vital role in many functions including maintaining pressure in the blood vessels and transporting substances such as hormones and medications. Albumin levels below 3.4 grams per deciliter (g/dl) are considered low which can lead to hypoalbuminemia. The increase serum albumin at 10 and 15mg/kg concentrations in rats administered of the poly-herbal formulation can mean that Dr Iguedo Goko Cleanser[®] formulation can play a hepatoprotective role at these doses. However, at 5mg/kg concentrations the serum albumin level was not considered low to cause hypoalbuminemia. Therefore the formulation might not have an indication of impairment in the synthesizing function of the liver. The result is in agreement with the findings of reference.^[19]

The activities of AST, ALT, ALP and Total bilirubin are commonly used as biochemical indicators of liver functions. Structural and functional alterations in the liver result in elevated levels of these enzymes in circulation.^[20] The levels of these aminotransferases (ALT and AST) in serum are elevated in all liver diseases. In fact, very high levels of more than 1000 units can be seen in acute hepatitis.^[21] These enzymes are intracellular, thus their normal blood levels are very low, but when there is hepatocellular damage or necrosis of the liver cells^[22], they leak out into the blood circulation, drastically increasing their levels in blood.^[20]

Therefore, albino rats were tested for ALP, AST and ALT levels to check for hepatic and cardiac toxicity. Therefore the increases observed in AST (5 and 10 mg/kg) and ALP (5 and 15 mg/kg) activities in this study suggest that the administration of Dr Iguedo Goko Cleanser® at the above dosages may provide preliminary evidence of liver impairments as this indicates cholestatic alterations in the liver biliary ducts. The ALP and AST levels are usually elevated as a result of cholestasis or biliary obstructions and this is used as a marker of hepatobiliary dysfunctions.^[21] Our findings are in agreement with reference.^[23,24] However, ALT is a more sensitive marker of hepatocellular damage than AST and ALP. Thus the non-significant differences ($P > 0.05$) in the ALT levels in Dr Iguedo Goko Cleanser® compared to that of the control in this study is an indication that the poly-herbal formulation may not cause any hepatocellular damage to the liver of the albino rats.^[25] This finding is in agreement with the studies of reference.^[15]

Bilirubin is known to be one of the non-enzymatic antioxidants in the body. There was an increase of total bilirubin levels at 10 and 15 mg/kg when compared with the control. However the increase was only observed in the high dosage groups. This increase in serum total bilirubin observed in the high dosage groups may be due to liver impairments. Serum bilirubin is one of the markers of liver impairments, as it tests for hepatic excretory function. Bilirubin is the excretory product formed by the catabolism of heme, which is normally conjugated by the liver to form bilirubin diglucuronide and excreted through the bile, so elevated serum bilirubin is seen when there is liver impairment.^[26] The findings of this study were in agreement with the works of reference.^[27]

The increased levels observed in serum total cholesterol at 5 and 10 mg/kg dosages may be due to the effect of the herbal formulation. Cholesterol may increase due to hepato-biliary disease and protein-losing nephropathy. The increase in the serum levels of total cholesterol may be

attributed to the toxic effect of the formulation, leading to hepatobiliary disorders and impaired cholesterol metabolism. These findings are in accord with reference.^[28]

CONCLUSION

The results obtained in this study indicate that creatinine and ALT levels were observed to be lower when compared with the control group. That explains that Dr Iguedo Goko Cleanser® poly-herbal formulation may be an effective blood cleanser by aiding the kidney in excretion of waste products from the body. The herbal formulation also may not cause hepatocellular damage of the liver due to the lower ALT levels observed in the study. However, contrary to the popular belief that herbal drugs are 100% natural, completely safe and devoid of any toxicity whatsoever, the present study has also revealed the nephrotoxic potentials, hepatobiliary dysfunctions and cholestatic alteration effect of the poly-herbal formulation thereby hindering renal and liver functions. Therefore, the use of the Dr Iguedo Goko Cleanser® poly-herbal formulation should be under medical supervision and the habitual, higher therapeutic doses and long-term use should be done with utmost caution and wherever possible, be avoided.

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