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MAKING STRIDES IN WOMEN'S' HEALTH IN GHANA, CREATING SOLUTIONS: THE PROTECTIVE EFFECT OF 'BIOENERGIZED' HIBISCUS SABDARIFA AND ZINGIBER OFFICINALE FORMULA

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ABSTRACT

The rising incidence of breast cancer in Ghana calls for urgent national intervention to ensure prevention and treatment. There is therefore the need for actionable research in Ghana to find preventive remedies to reduce the rate. The Breast being the priciest assets of women also benefits men if it is in good health. This paper examines the development of a natural product that has undergone clinical trials at the Kwame Nkrumah University of Science and Technology (KNUST) at Kumasi-Ashanti region in Ghana. Animal model was employed for the clinical trials. The product formulated by Dr. Raphael Nyarkotey Obu and Manufactured by RNG Medicine Research Laboratory in Ghana contains the Hibiscus Sabdarifa and Zingiber officinale as the ingredients. The product has the brand name 'Women's Formula Tea' with batch number 01D19 for breast health, weight loss, low libido and general wellbeing support. RNG introduced bioenergization into the plant to increase its shelf life, reduce microbial loads and improve its efficacy.

The Faculty of Pharmacy and Pharmaceutical Sciences of the University employed three diverse trials for the product (in a tea form of thirty (30) bags) conducted through Department of Pharmaceutics to assess the microbial loads, the Department of Pharmacology to assess the efficacy, acute and Sub chronic Toxicity test and the Department of Pharmacognosy also assess the phytochemical and Physicochemical properties of the formulation. These are the protocols needed and if passed, to be sent to the Food and Drug Authority for certification. The formulator's dosage is three bags three times for those with breast disorders and one daily for maintenance of breast health.

The result revealed that Women's Formula Herbal Tea has antioxidant activity and hence detoxifying ability and kidney protective function. The OAEL is greater than three times the stated daily dosage indicated by the manufacturer. The recommended dose is thus within acceptable margin of safety.

KEYWORDS

Breast Health, Low Libido, UTI, Hibiscus sabdarifa, Zingiber officinale and General Wellbeing.

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INTRODUCTION

Women's Health is an important subject that needs special attention. In Ghana; cancers such as breast and other gynecological cancers are killing lots of our women. There is therefore the need for evidence based preventive remedies to stop these cancers before they strike. With diverse conventional

remedies available in Ghana and the world for breast cancer including tamoxifen and other selective estrogen receptor modulators, to fight breast cancer, it still remains the most common type of cancer and the leading cause of death among women. Furthermore, despite an initial response to chemotherapy, breast cancer cells often survive and form resistance to treatment. About 40% of women treated with tamoxifen and almost all patients with metastatic disease experience relapse that leads to death.

According to the World Health Organization (WHO) 2,000 Ghanaian women were diagnosed with breast cancer in the year 2012, and out of the number, about 1,000 representing 50 per cent of the cases, died. The report was made by the Daily Graphic newspaper. On cervical cancer, the Ghana Human Papilloma virus and Related Cancers fact Sheet (2017) estimates that every year 3052 women are diagnosed with cervical cancer and 1556 die from the disease. Cervical cancer ranks as the 1st most frequent cancer among women in Ghana and the 1st most frequent cancer among women between 15 and 44 years of age¹.

METHODOLOGY

DEPARTMENT OF PHARMACOLOGY

Test Conducted: efficacy, acute and Sub-Chronic Toxicity Test

Total Phenol determination

Various concentrations (0.3, 1, 3mgml⁻¹) of an extract of women's Formula Herbal Tea were mixed with the Folin-Ciocalteu phenol reagent (1ml, diluted water). This mixture was incubated at room temperature (28°C) for 5min. NaCO₃ (2%w/v, 1ml) was added and incubated for 2h. It was then centrifuged (650g for 10min) to get a clear solution, and the absorbance measured at 760nm using spectrophotometer. Tannic acid was used as reference and the total phenols in Women's Formula Herbal Tea expressed as milligrams per milliliter of tannic acid equivalents (TAEs).

Reducing Power

Various concentrations of an extract of Women's Formula Herbal Tea (0.1, 0.3, 1.3mgml⁻¹, in methanol) was mixed with 2.5 ml of 0.2 M sodium

phosphate buffer (pH 6.6) and 2.5ml 1% potassium ferricyanide solution in a test tube. The mixture was incubated at 50°C for 20 min. Trichloroacetic acid (10%, 1.5ml) was then added to the mixture and centrifuged at 650g for 10 minutes. Two and a half milliliters (2.5ml) of the supernatant was mixed with 2.5 ml distilled water and 0.5ml of 0.1% ferric chloride solution. The absorbance was then measured at 700 nm using the spectrophotometer. Blank samples were prepared as follows: 1ml distilled water was added to 2.5 ml sodium phosphate buffer and 2.5ml potassium ferricyanide and the mixture processed as above. Vitamin E (0.1, 0.3, 1, 3 mg ml⁻¹, in methanol) was used as standard antioxidant. Each test was done in triplicate. The greater the reducing power, the higher the absorbance. Data was presented as concentration – absorbance curves and the EC₅₀ (concentration that gives 50% of maximal of response) computed.

RESULTS

Total Phenols

The phenol content of tannic acid increased with increasing concentration ($r^2=0.95$). Women's Formula Herbal Tea (0.3-3mgml⁻¹) also showed a concentration-dependent increase in phenolic content (0.009±0.003-0.258±0.003) expressed as tannic acid equivalent.

Reducing Power

Women's Formula Herbal Tea (0.1-3mgml⁻¹) and the standard antioxidant-tocopherol (0.1-3mg ml⁻¹) dose-dependently reduced Fe³⁺ to Fe²⁺ as indicated by dose-dependent increase in absorbance. From EC₅₀ (in mg ml⁻¹) obtained for kidney care (10.4 ± 1.42) and tocopherol (18.18 ± 4.29).

REMARKS

Women's Formula Herbal Tea has antioxidant activity and hence detoxifying ability and kidney protective function. The OAEL is greater than three times the stated daily dosage indicated by the manufacturer. The recommended dose is thus within acceptable margin of safety.

DEPARTMENT OF PHARMACEUTICS

Test conducted: Microbial Analysis

MICROBIAL TEST PROTOCOL-(BP Level of Microbial Contamination)

1. Assessment of total viable count of aerobic bacteria and fungi
2. Test for specific harmful organisms.

REMARKS

The bacterial load obtained for the aerobic viable count was within the acceptable limit. The fungal load was within the acceptable limit (BP 2015). No harmful microorganisms were detected

DEPARTMENT OF PHARMACOGNOSY PHYTOCHEMICAL AND PHYSICOCHEMICAL ANALYSIS OF WOMEN'S FORMULA HERBAL TEA

Organoleptic properties

Form- Tea bag

Colour- Wine

Taste- Acidic

Odour- Characteristic.

Physicochemical properties

PH (1% cold aqueous ext.) - 2.5

Total alcohol-soluble extractive - not less than 47%

Total water – soluble extractive - not less than 37%

Moisture Content - not more than 13%

Chromatographic profile

Stationary phase: silica gel

Detecting reagent: Anisaldehyde

Sample used: Chloroformic extract

Mobile phase: chloroform Petether

9: 1

RESULTS

Five (5) spots

Two (2) purple spots (R_f s= 0.25 and 0.37)

Three (3) violet spot (R_f s=0.56, 0.81 and 0.89)

DISCUSSION

Ghana Herbal industry has recently gained widespread recognition by indigenes and on a global scale. In Ayurveda principles, medicines are derived from plants, whether in the modest form of raw plant materials or in the refined form of crude

extracts, mixtures and so on. But research into these plants is underfunded with no private facility dedicated to researching plant medicine. We have therefore decided to establish the RNG Medicine Research Lab to research into plant medicine in Ghana. Our facility employs bioenergization of its plant products, and it is the first of its kind in the country. Bioenergetics is a biochemical process that is used now in many natural healing modalities such as naturopathy and homeopathy, and even has become its own emerging field called bioenergetic medicine. The basic theory (in a nutshell) is that universal life energy (chi, prana, qi, ki, etc.), which exists in every living organism on the planet, can now be harnessed and infused into ingredients for therapeutic products. By doing so, the ingredients become highly concentrated and their beneficial properties become more effective. The sourced raw materials are also washed with bioenergized water. Plant medicine formulations have become well-known in Ghana and it is used mainly in the case of diseases not cooperative to treatment by modern method. Diverse plants have been recognized as an alternative for the treatment of breast cancer. The author of this paper infused these two plants together to bring the body of evidence using the formulation in the management of breast diseases and general women's health.

Ghana has diverse plants with good kinetic energy compared to the same plant in other countries. This is partly because of the abundant of the sunlight that also gives the plant its energy. Ghana therefore stands an opportunity to produce evidence based natural products from the abundance of these plants in the fight against diseases.

The product Women's Formula contains two ingredients: Hibiscus sabdariffa and Zingiber officinale. These are widely available in Ghana and highly consumed. The two plants were combined for better efficacy in the management of women's health. In Ghana, researches are not been done on the efficacies of these plants for potential health and economic benefits. Most of these health benefits are hearsay medicine and as diverse dietary factors exert anti-cancer activities, cancer chomoprevention with dietary factors has received attention as the most

effective approach to fight against of these cancers in Ghana and also to reduce the mortality rate. Ginger is used as a dietary factor as a vegetable, tea and the herbal medicine. Yet, the pharmacological actions of ginger root have not been studied. I have for the first time and with the establishment of the RNG Medicine Research Lab, evaluated the anti-cancer activity of ginger root and its potential mechanism. This study, for the first time, reports that ginger officinale combined with Hibiscus sabdariffa showed an anti-cancer activity associated and effective for women's health. The pharmacological properties of the leaves are still also poorly understood².

Another study also revealed that Ginger may act as an anti-cancer and anti-inflammatory agent by inactivating NFκB through the suppression of the pro-inflammatory TNF-α³. Ginger contains active phenolic compounds such as gingerol, paradol and shogoal that have antioxidant⁴, anticancer⁵, anti-inflammatory⁶ anti-angiogenesis⁷ and anti-atherosclerotic⁸. Another 2012 study which focuses on terpenoids from ginger revealed that it should be further investigated as agents for the treatment of endometrial cancer⁹.

One of the benefits of using natural or dietary compounds as an anti-cancer remedy is that they seem to have low toxicity and show very few adverse side effects. Recently, some plant products have been studied for their possible action as inhibitors of the NFκB pathway. Ginger (Zingiber officinale) is widely used all over the world as a spice and condiment in daily cooking.

On the case of hibiscus sabdariffa; over twenty years ago, water extracts of hibiscus flowers were reported to have a relaxation effect on the uterus and to lower the blood pressure.

Studies in both animal and human models have demonstrated that extracts or infusions affect atherosclerosis mechanisms, blood sugar, lipids and blood pressure^{10,11}. In 2009¹², 60 Type 2 diabetics, mostly women, were given either Hibiscus tea from Saudi Arabia or black tea, 1 cup twice per day. Seven individuals withdrew from the study and after one month, mean HDL cholesterol increased significantly (48.2 mg/dL to 56.1 mg/dL) whereas apolipoprotein A1 and lipoprotein (a) were not significant. There was also a significant decrease in the mean of total cholesterol (236.2 to 218.6), LDL cholesterol (137.5 to 128.5), triglycerides (246.1 to 209.2) and Apo-B100 (80.0 to 77.3) in the Hibiscus group. Only HDLc showed a significant change in the black tea group (46.2 to 52.01). Something as simple as Hibiscus tea in a diabetic is a welcomed intervention. Achieving a 7.6% decrease in total cholesterol, an 8.0% decrease in LDLc, a 14.9% decrease in triglycerides, a 3.4% decrease in Apo-B100, a 4.2% increase in Apo-A1 and a 16.7% increase in HDLc is no small accomplishment with merely two cups of tea per day.

The principal investigator of this paper have shown here that ginger extract combined with Hibiscus Sabdariffa was able to support breast health and general well-being of cats in the laboratory. In addition, to his knowledge, this is the first study reporting the anti-cancer effect exhibited by the two ingredients in Ghana. Interestingly, the result revealed that Women's Formula Herbal Tea also has kidney protective function with no side effect during the course of the investigation Table No.1.

Toxicity Test

Table No.1: NOAEL: No-Observable –Adverse-Effect Level

S.No	Species And strain	No. of animals Sex/group	Route of Administration	Formulations And Dosage	Time of Deaths and Period of observation	NOAL	Symptoms
1	Sprague-Dawley rats	25 males 5 groups (N-5)	Oral	Decoction 10, 30, 100, 300, 1000mg/kg	No death occurred during the period of observation: 24h and 30 days	>100mg/kg	Nil

Test results

Table No.2: Level of microbial contamination

1. The total aerobic viable count of sample (BP 2015 Specification $\leq 1 \times 10^5$ cfu/ml)	4.30x10 ¹ cfu/mL
2. Test for <i>Escherichia coli</i> -MAC/37°C/48hrs (BP 2015 Specification-Nil/MI)	None detected
3. Test for <i>Staphylococcus aureus</i> -MSA/37°C/48hrs (BP 2015 Specification-Nil/mL)	None detected
4. Test for <i>Salmonella</i> spp.BSA/37°C/48hrs (BP 2015 Specification-Nil/mL)	None detected
5. Test for <i>Pseudomonas aeruginosa</i> /PCA/37°C/48hrs (BP 2015 Specification-Nil/ mL)	None detected
6. Test for Yeast and Moulds-SB/25°C/5days (BP 2015 Specification $\leq 1.0 \times 10^5$ cfu/mL)	3.00x10 ¹ cfu/mL

Table No.3: Phytochemical Properties

Reducing sugars	Positive
Saponins	Positive
Tannins	Positive
Alkaloid	Negative
Flavonoid	Positive
Sterols	Negative
Coumarins	Negative



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CONFLICT OF INTEREST

The author reports no conflict of interest for this work.

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