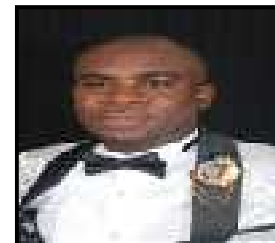




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FINDING SOLUTIONS FOR THE RISING CASES OF PROSTATIC DISORDERS IN GHANA: THE WAIT IS OVER AS NATURAL EVIDENCE BASED TREATMENT ARRIVES

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ABSTRACT

Very often you find elderly men in Ghana above 40 years complaining of a feeble urinary stream, urgency, incomplete voiding et al. These observations are on the increase with no preventive measures to reverse the trend. Prostatic diseases have become a huge national burden and affecting the quality of life in men. It is in line with this that the researcher formulated this novel breakthrough prostate product in Ghana to deal with the rising cases. This paper therefore examines the development of a natural prostatic diseases product that has undergone clinical trials at the Kwame Nkrumah University of Science and Technology (KNUST) in 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, is in two phases: the first stage contains two plants; Hibiscus sabdariffa and Croton Membranaceus. The second phase which is the most important stage contains twelve (12) plants based ingredients for RNG Holistic Hospital and Prostate Research Lab which is currently undergoing clinical trials at the same facility. This paper therefore focuses on the first phase of the trials with Hibiscus sabdariffa and Croton membranaceus which have passed the clinical trials. The product has the brand name 'Men's Formula Herbal Tea' with batch number 01D19 for the management of prostatic disorders and promoting healthy prostate support. The product is developed with three models of attack: promoting urinary health, balancing prostate hormones and improving quality of life (QOL) of the prostate patient with superior science. The plants are organ specific, bioenergized and locally grown. The Faculty of Pharmacy and Pharmaceutical Sciences of the University employed three diverse trials for the product which comes as a tea with content in thirty tea-bags (30). The trials were conducted through the Department of Pharmaceutics to assess the microbial loads, the Department of Pharmacology to assess the efficacy, acute and Sub chronic Toxicity test. Lastly, the Department of Pharmacognosy also assessed the phytochemical and Physicochemical properties of the formulation. These are the protocols needed and if successful, to be sent to the Food and Drug Authority for certification. The formulator's dosage is two bags x 3 daily for prostatic disorders and one daily for reducing risk of prostate disease or maintaining its health. The result revealed that, on total antioxidant activity; the product-Men's Formula Herbal Tea (0.3-10.0mg/ml), showed an increase in total antioxidant capacity expressed as ascorbic acid equivalent. The total antioxidant capacity of ascorbic (0.01-0.3mg/ml) increased with increasing concentration ($r^2=0.9922$). On reducing power, Men's Formula Herbal Tea (0.1-3mg ml⁻¹) and the standard antioxidant-tocopherol (0.1-3mlmg⁻¹) dose dependently reduced Fe³⁺ to Fe²⁺ as indicated by a dose-dependent increase in absorbance. From EC₅₀(in mg ml⁻¹) obtained for Men's Formula Herbal Tea (10.4 ± 1.42) and tocopherol (18.18 ± 4.29). The remarks states that, as per the findings, men's formula Herbal Tea has antioxidant activity and hence would be of significantly relevant in prostate disorders. The No-Observable-Adverse-Effect level (OAEL) is greater than three times the stated daily dosage (7.0ml/kg) indicated by the manufacturer. The recommended daily dose is thus within the acceptable margin of safety.

KEYWORDS

Prostatic disorders, Men's formula, Antioxidant activity, urinary health and Quality of life (QOL).

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INTRODUCTION

Every man has a prostate, but every prostate doesn't have to make every man's life miserable. The prostate; though a small gland has a huge repercussions on the quality of life of a man if allowed to wayward. Yet, men do not pay much attention to this very important gland. It is really my hope that men would not keep ignoring their prostate

glands and realize what they stand to gain from it if it is in a good health.

Incidentally, women have done extensive awareness on breast cancer partly because it is a superficial organ that can easily be seen, unlike the prostate which is difficult to be seen by the naked eyes. So obviously, out of sight is out of mind. But it has become a bothersome gland and the source of a lot of grief for men as they age. But there are diverse steps that can be taken to help it last a lifetime and it is the researcher's major mission. Prostate problems are common in men over 50 years of age. They can affect your daily routine adversely. A person who has good prostate health has a hundred goals; a person who doesn't have good prostate health has but one goal. No one is immune or protected from prostate diseases, no matter how well they decide to eat or exercise.

The prostate's job is to produce some of the fluids that protects and nourishes sperm cells in semen, making the semen more liquid. Just behind the prostate are glands called seminal vesicles that make most of the fluids for semen. The urethra- the tube that carries urine and semen out of the body through the penis, goes through the center of the prostate. The prostate is a gland found only in males, and it is located below the urinary bladder and in front of the rectum. It is the gland I codenamed 'the Powerhouse of Men'. The size of the prostate changes with age. It's about the size of a walnut in younger men, but it can grow to be much larger in older men - and this can become problematic. So there is the need to keep it in a healthy state as men age.

The prostate starts to develop before birth, and is fueled by male hormones called androgens. It nurtures quickly throughout puberty. The main androgen, testosterone, is made in the testicles. The enzyme 5-alpha reductase transforms testosterone into DHT. DHT is the main hormone that signals the prostate to grow. Hence, there is the need for an evidence based product to prevent rapid conversion of Testosterone to Dihydrotestosterone by blocking the rapid signaling of enzyme 5-alpha reductase so that the prostate do not grow rapidly. This is the mission of the researcher's interest; Stopping prostate disorders before they strike.

The prostate would remain approximately the same size as boys grow into men if preventive measures are employed. It however tends to grows slowly in adults, as long as male hormones are present. It's when the prostate becomes enlarged that men begin experiencing symptoms from BPH and lower urinary tract issues. Studies show that over 80% of patients with age related prostate health concerns are taking or are looking to purchase natural supplementation whether or not it is discussed with/recommended by their primary physician. Men's Health Formula is therefore a well formulated tea containing the strongest combination of research based ingredients supported scientifically to satisfy these needs of ageing men.

The second phase of the ongoing trials is well-formulated with twelve (12) key evidence based ingredients that have been proven and backed by research showing it supports men's prostate health. The plants are locally and organically grown. Men's Formula is from Ghanaian plants termed as Phytomedicine. This will be the first Ghanaian Prostate formula that contains (12) active plants ingredients for medical Prostate conditions. The term Phytomedicine is the scientific investigation of the medicinal properties of plants or specific plant extracts for the evaluation and use of herbal medicines on pharmacological principles. It can also be define as an herbal preparation tested and used within conventional pharmacology. This is the foundation of the first herbal medicine product for prostate conditions.

Phytomedicines are becoming more popular all over the world. Prostate cancer patients and those with benign prostatic hyperplasia are increasingly exploring the use of complementary alternative medicine especially due to the risk of mortality and long-term morbidity associated with surgical procedures. The incidence of prostate diseases are continually rising and the effect of phytomedicines already tested does provide relief, and are well comparable with that of traditional forms of treatment.

Men's Formula Phytomedicine solution helps in treating sign / symptoms of prostate related concerns in a natural way. It reduces the size of the prostate,

reduces the Prostate Specific Antigen level which is a key marker use in the management of prostate cancer. Most of the products on the market for prostate conditions contain just a single ingredient with less strength and are marketed as supplement. This is ineffective as you need amalgamation of research backed ingredients to work. In treating prostate conditions; three key areas are very important; the urinary health, hormonal balance and quality of life. Most products fail this test. Making our product unique on the Ghanaian, Africa and World market now.

It is also formulated as a preventive medicine for those concerned about their prostate health. We at RNG Medicine Research Lab want to improve and bring science into our local plants. This will improve the economy and the health of the people, and consequently reduce the need to import packaged traditional medicine products from China, India and others. This is because the Kinetic energy from the abundant sunlight in Ghanaian herbal-plants is high and extremely potent and more efficacious than the foreign plant-based remedies imported into Ghana. Sunlight is a powerful natural medicine.

The second trial which contains Hibiscus Sabdariffa, Saw palmetto, Azadirachtaindica, Willow Herb, Carica papaya, graviola, Stingy Nettle, Xylopiaaethiopica, cyperusesculentus, Pepitas, Zanthoxylumzanthoxyloids and Altsonai Boonei will be made available to the research community soon. It will harness the synergistic power of twelve (12) Ghanaian medicinal plants. It has been developed using high technology for faster and higher bioavailability. It has been formulated to maintain prostate health by reducing prostate inflammation, bladder irritability, urinary urgency, leaking and nocturia. It uses plant based extracts to offer safe and long term solution for prostate health and functions, especially for men nearing their midlife (above the age of 40).

METHODOLOGY

DEPARTMENT OF PHARMACOLOGY

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

Total Antioxidant Capacity Assay

The Department of Pharmacology of the Kwame Nkrumah University of Science and Technology conducted the efficacy, acute and sub chronic toxicity test on the product. Men's Formula Herbal Tea extract (10mg) was combined with 3ml of reagent solution (0.6M sulfuric acid, 28mM Sodium Phosphate and 4mM ammonium molybdate). The tubes containing the reaction solution were incubated at 95°C for 90 minutes. The absorbance of the supernatant was then determined at 695nm against blank after cooling to room temperature. Distilled water (0.3ml) is processed as the extract and used as the blank. All measurements were done in triplicates. Data obtained for the ascorbic acid was analyzed as linear regression of the absorbance against concentration from which ascorbic acid equivalents were obtained and data obtained expressed graphically as column graphs of concentration against ascorbic acid equivalents (Total antioxidants capacity).

Reducing power

Various concentrations of an extract of Men's Formula Herbal Tea(0.1, 0.3mg ml⁻¹, in methanol) was mixed with 2.5ml 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, Trichloroaceticacid (10%; 1.5ml) was then added to the mixture and centrifuged at 650g for 10minutes. Two and a half milliliters (2.5ml) of the supernatant was mixed with 2.5ml distilled water and 0.5ml of 0.1% ferric chloride solution. The absorbance was then measured at 700nm using the spectrophotometer. Blank samples were prepared as follows: 1 ml distilled water was added to 2.5ml sodium phosphate buffer and 2.5ml potassium ferricyanide and the mixture processed as above. Vitamin E (0.1, 0.3, 1.3mgml⁻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 response) computed.

RESULTS

Total antioxidant capacity

Men's Formula Herbal Tea (0.3-10.0mg/ml) also showed an increase in total antioxidant capacity expressed as ascorbic acid equivalent. The total antioxidant capacity of ascorbic acid (0.01-0.3mg/ml) increased with increasing concentration ($r^2=0.9922$).

Reducing power

Men's Formula Herbal Tea ($0.1-3\text{mg ml}^{-1}$) and the standard antioxidant-tocopherol ($0.1-3\text{mg ml}^{-1}$) dose-dependently reduced Fe^{3+} to Fe^{2+} as indicated by a dose-dependent increase in absorbance. From EC_{50} (in mg ml^{-1}) obtained for Men's Formula Herbal Tea (10.4 ± 1.42) and tocopherol (18.8 ± 4.29).

Remarks

The result revealed that Men's Formula Herbal Tea has antioxidant and hence would be of significant relevance in prostate disorders. 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 pharmaceuticals

Microbial analysis test conducted

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 findings revealed that 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

RESULTS

Seven (7) spots were observed after

Spraying with the detecting reagent and gently warming

Three (3) purple spots (Rfs=0.025, 0.37 and 0.49)

Two (2) violet spots (Rfs= 0.56 and 0.89)

Two (2) pink spot (Rfs=0.63 and 0.84).

PREPARATION STAGE FROM RNG MEDICINE RESEARCH LAB

Raw materials were sourced from Ghanaian local communities outside Accra. The Research center employed notable herbalist and distributors of Ghanaian herbal products. The raw materials from the farms were washed and dried. Water for washing raw materials was bio-energized. Our tea bagging machine was procured from China. Each box of the product contains 30 bags before sending to the Kwame Nkrumah University of Science and Technology for the final analysis. The product box contains the composition, indication, Name, Date of manufacture, Expiry date and address of the manufacturer.

DISCUSSION

RNG Medicine Research Laboratory becomes the first bio-energized natural product developer in Ghana. Herbal and traditional plant medicines emerged as many of the highest antioxidant-containing products. The initiator of 'Men's Formula Herbal Tea' estimates that the high inherent antioxidant property of many plants is an important contributor to the tea's medicinal qualities⁴. Though teas are not well-consumed in Ghana; they are one of the best sources of antioxidant to aid in the fight against prostate cancer. Hence, the author decisions to formulate the first synergistic prostate product in a tea form to help the fight in Ghana. Teas are important antioxidant sources in many diets. Diverse types of compounds contribute to teas antioxidant content, e.g., caffeine, polyphenols, volatile aroma compounds and heterocyclic compounds⁷⁻⁹. Most of them are powerfully absorbed, and plasma antioxidants increase after tea intake¹⁰. In green tea, the major flavonoids present are the monomer catechins, epigallocatechin gallate, epigallocatechin, epicatechingallate and epicatechin.

The most important thing about the hibiscus sabdariffa in tea form is that it is one of the richest sources of antioxidants to be used in a beverage. This was revealed in a study published in *Nutrition Journal* where the investigators elucidated how they developed a comprehensive food database that listed the antioxidant content of more than 3,100 foods, spices, beverages, herbs, and supplements. After analyzing 283 different beverages, hibiscus tea beat matcha green tea when it came to antioxidant content. While green tea is still a very good beverage choice for antioxidants, hibiscus tea tops the list⁴. Hence, the author's combination of *Croton membranaceus* and *Hibiscus Sabdariffa* formulation is the first of its kind in Ghana.

The researcher and formulator of this prostate formula in Ghana also understand and recognized that Bioavailability differs greatly from one phytochemical to another^{5,6} hence the combination formula of these two plants for better bioavailability as antioxidant levels also varies in plants.

Just as the components of any food constituent, the researcher and formulator of this product understand that the antioxidant values will differ for a wide array of reasons, such as growing conditions, seasonal changes and genetically different cultivars^{11,12}, storage conditions^{13,14} and differences in manufacturing procedures and processing^{15,16}. This is the major reason why the researcher of this product employed the technology of Bioenergization to bring back all the constituents lost during any of the procedures in the product development pathway. This was found in one research where the investigators realized the differences in unprocessed and processed plant food samples were processed berry products like jam and syrup have approximately half the antioxidant capacity of fresh berries⁴. On the other hand, processing may also enhance foods potential as a good antioxidant source by increasing the amount of antioxidants released from the food matrix which otherwise would be less or not at all available for absorption¹⁷. Processing of tomato is one such example where lycopene from heat-processed tomato sauce is more bioavailable than unprocessed tomato¹⁸.

A 2012 study¹ which examined the anticancer properties of *H. sabdariffa* L. leaf extracts (HLE) showed that among three kinds of human prostate cancer (CaP) cells, androgen-dependent LNCaP cells were the most susceptible to HLE. Molecular data showed the effect of HLE in LNCaP cells might be mediated via both intrinsic and extrinsic apoptotic pathways. The result finally revealed that, HLE inhibited the growth of LNCaP cells in xenograft tumour studies. As a result, their data presented the first evidence of HLE as an apoptosis inducer in LNCaP cells, and these findings may open interesting perspectives to the strategy in human CaP treatment.

Another 2014 study² investigate antioxidant, anti-inflammatory and cytotoxic activities of *Hibiscus sabdariffa* leave extracts from different extraction methods. Fresh and dry *Hibiscus sabdariffa* leaves were extracted by various methods such as maceration with 95% and 50% ethanol, squeeze, and boiling with water or decoction. All extracts were tested for antioxidant activity by using DPPH radical scavenging assay, anti-inflammatory activity by determination on inhibitory effect of nitric oxide production on RAW264. 7 cell. Cytotoxic activity also tested against human prostate cancer cell line (PC-3) by using sulforhodamine B (SRB) assay. Total phenolic content determined by the Folin-Ciocalteu colorimetric method. The results found that the 95% ethanolic extract of *Hibiscus sabdariffa* dried leaves (HSDE95) showed the highest antioxidant activity with an EC₅₀ of 34.51±2.62 µg/ml and had the highest phenolic content (57.00±3.73 mg GAE/g). HSDE95 also showed potent cytotoxicity against prostate cancer cell line with an IC₅₀ of 8.58±0.68 µg/ml whereas HSDE95 and all of extracts of *Hibiscus sabdariffa* leaves had no anti-inflammatory activity. The obtained results revealed that HSDE95 extract showed potent cytotoxic activity against prostate cancer cells but low antioxidant and anti-inflammatory activities.

A similar 2015 study³ which also examined the anti-invasive potential of HLE findings suggested that the inhibition of MMP-9 expression by HLE may act through the suppression of the Akt/NF-κB signaling pathway, which in turn led to the reduced

invasiveness of the cancer cells. A 2017 study¹⁹ examined whether Ca/Mg imbalance exists in BPH patients and the effect of a phytotherapeutic drug on the Ca/Mg ratio revealed that Ca/Mg ratio imbalance is associated with BPH. This has previously not been demonstrated. The imbalance was significantly corrected after treatment with the phytotherapeutic drug.

Another study²⁰ to determine if *Croton membranaceus* aqueous root extract (CMARE) could attenuate the development of BPH in an animal model; Fifty (50) adult male Sprague-Dawley rats weighing 200-250g were randomly divided into 5 groups. Group 1 served as the control and received normal saline p.o. Groups 2-5 were castrated and injected with 5mg/kg b.wt. testosterone propionate subcutaneously for 28 days. Group 2 (model group) had no further treatment. Group 3 was simultaneously given 0.5mg/kg b.wt. finasteride p.o. throughout. Groups 4 and 5 received 30mg/kg b.wt. [low dose (LD)] and 300mg/kg b.wt. [high dose (HD)] CMARE, respectively, for 28 days. Rats were sacrificed at the end of the study and all prostate organs harvested. Wet weights, volumes and prostatic index (PI) were determined. Tissues were histologically examined. Serum prostate specific antigen (PSA) and dihydrotestosterone (DHT) levels

were determined. The researchers revealed in their findings that Prostate volume of the control group was $0.67 \pm 0.23 \text{ cm}^3$. The model, finasteride, CMARE LD and HD groups had the following volumes: 0.92 ± 0.12 , 0.84 ± 0.16 , 0.79 ± 0.16 and $0.80 \pm 0.19 \text{ cm}^3$, respectively. Only the model group showed significant statistical differences with the control ($p=0.007$). PI for control, model, finasteride, LD and HD groups was as follows: 0.19 ± 0.04 , 0.30 ± 0.04 , 0.25 ± 0.04 , 0.21 ± 0.05 and 0.22 ± 0.05 . No statistical differences between the control PI and the CMARE treated groups were observed. Histologically, the model group had massive growth of columnar stromal and epithelial cells. CMARE and finasteride attenuated this growth with a resultant thin layer of stromal and epithelial cells similar to the control. PSA levels were significantly lower in the treatment groups.

A similar study²¹ also proved that *C. membranaceus* shrinks the prostate and improves Quality of life (QoL). In conclusion the product Men's Formula Herbal Tea has demonstrate its antioxidant activity and would be of great relevance in the management of prostatic disorders. This is the first Ghanaian product formulated for prostatic disorders backed by superior science and bioenergized.

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

The total aerobic viable count of sample(BP 2015 Specification - $\leq 1 \times 10^5 \text{ cfu/mL}$)	$1.81 \times 10^1 \text{ cfu/mL}$
Test for <i>Escherichia coli</i> -MAC/37°C/48hrs (BP 2015 Specification- Nil/MI)	None detected
Test for <i>Staphylococcus aureus</i> -MSA/37°C/48hrs(BP 2015 Specification- Nil/mL)	None detected
Test for <i>Salmonella</i> spp.BSA/37°C/48hrs(BP 2015 Specification- Nil/ mL)	None detected
Test for <i>Pseudomonas aeruginosa</i> /PCA/37°C/48hrs(BP 2015 Specification- Nil/ mL)	None detected
Test for Yeast and Moulds-SB/25°C/5days(BP 2015 Specification- $\leq 1 \times 10^5 \text{ cfu/mL}$)	$9.30 \times 10^1 \text{ cfu/mL}$

Table No.3: Organoleptic Properties

S.No	Form	Tea bag
1	Colour	Brown
2	Taste	Acidic
3	Odour	Characteristic

Table No.4: Physicochemical Properties

PH(1% warm aqueous ext.)	2.6
Total alcohol-soluble extractive	not less than 50%
Total water –soluble extractive	not less than 50%
Moisture Content	not more than 10%

Table No.5: Phytochemical Properties

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

Table No.6: Chromatographic Profile

Stationary phase	silica gel
Detecting reagent	Anisaldehyde
Sample used	Chloroformic extract
Mobile phase	chloroform Pet ether 9: 1



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CONFLICT OF INTEREST

The author reports no conflict of interest for this work.

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