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Original Article

Preliminary Outcomes on the Use of an Antioxidant Dietary Supplement for Patients with or at Risk of Heart Disease

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ABSTRACT

Aims: To report initial feasibility outcomes from a pilot study on the use of a potent antioxidant dietary supplement on several parameters in persons with or at risk of heart disease. **Methods and Material:** In this uncontrolled longitudinal pilot study, sixty-six participants received a dietary supplement consisting of Moringa oleifera, Bryophyllum pinnatum and vitamin C. Participants were instructed to consume one capsule daily for a period of six months. Once a month, blood work and a quality of life questionnaire were completed and the data recorded. Feasibility was based on the researcher's observations and collected data. **Statistical analysis used:** Due to the nature of the study no statistical packages were used. Excel spreadsheets and measures of location were used to analyze the data. **Results:** Recruitment and retention data was indicative of feasibility. With 37.9% of the registered participants being lost to follow-up. A 3.26% change in diastolic blood pressure was noted among female participants one month after their initial blood pressure was recorded. Blood glucose levels decreased among participants by 1.81% after three months of supplement use. High Density Lipoprotein (HDL) cholesterol levels increased for both groups, with the males experiencing a 9.25% increase in their HDL levels. On the other hand, Low Density Lipoprotein cholesterol levels among female participants decreased by 5.6%. **Conclusions:** The pilot data is supportive of the implementation of a randomized, long-term evidence-based intervention.

Key words: Heart Disease, *Bryophyllum pinnatum, Moringa oleifera,* Diabetes, Cholesterol, Hypertension.

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INTRODUCTION

Risk factors for heart disease continue to remain alarmingly high.[1] *Moringa oleifera*, *Bryophyllum pinnatum* and vitamin C have been shown to regulate several health factors associated with heart disease. Studies identified *Moringa* and *Bryophyllum pinnatum* as antioxidants sources, with antioxidant activity as high as 66.8% in *Moringa.*[2-5] Both herbs also exhibit hypotensive effects.[6-10] In addition, vitamin C provides protection against oxidative changes in LDL and may prevent endothelial dysfunction.[11-15] It is on the basis of this research that the effects of the "*Life*" supplement were investigated.

MATERIALS AND METHODS

Sixty-six (n=66) participants were enrolled in the study; 31 females and 35 males. Participants ranging from 23 to 83 years of age progressed through the study. All participants were required to complete an informed consent document (Appendix A) and blood work up prior to commencing the supplement.

Following the receipt of the initial lab results participants were instructed to take one capsule once daily at bedtime for six months. Each capsule contained 25mg of *Moringa oleifera*, 25mg of *Bryophyllum pinnatum* and 700mg of vitamin C.

Each participant was required to report once a month for a fasting blood test and blood pressure checks. Weight was also assessed during registration and again three months later. In this longitudinal study participants were monitored and data recorded for a period of six months, following the commencement of the "*Life*" supplement.

Inclusion and Exclusion Criteria

The study consisted of participants who presented with heart disease or two or more risk factors for heart disease; which included elevated total cholesterol levels (≥ 5.2mmol/L) and/or elevated LDL cholesterol levels (4.13mmol/L or higher), high blood pressure (≥ 140/90mmHg), a sedentary lifestyle (<2 days a week of physical activity apart from Activities of Daily Living), a body mass index (BMI) greater than 30kg/m^2 and/or a history of diabetes (Diagnosed more than a year prior to the study and a 126mg/dL or higher fasting plasma glucose) or prediabetes (100mg/dL to 125mg/dL fasting plasma glucose on three or more occasions.).

Patients with kidney disease, renal insufficiency, critically ill patients, patients with a family history of heart disease but no other risk factors, as outlined in the inclusion criteria and those who did not complete the consent document were excluded from the study.

Measures

Weight was assessed using a digital scale. A calibrated Reflotron machine was used to analyze each blood sample provided by the participants during Stages two and three of the study. Each blood sample was analyzed to determine the total cholesterol level, HDL cholesterol, LDL cholesterol, triglyceride level, fasting blood glucose level, HbA1c and hemoglobin. A point-of-care Reflotron machine was used to analyze the samples.

Quality of Life Questionnaire

A 22 item questionnaire was used to record changes regarding various aspects of the participants' health and wellbeing including sleep, appetite, libido, male sexual function (where applicable), energy levels, state of wellbeing, mental state, gastrointestinal condition and physical changes. The questionnaire was completed during each follow-up and an electronic record of all answers was maintained. All data was recorded using a spreadsheet.

RESULTS

In this study consisting of 31 females and 35 males (n=66) ranging from 23 to 83 years of age, several changes of varying degrees were observed. Twenty-five (25) participants discontinued their follow-ups due to commencement of other therapies, surgical procedures, inability to comply

with the follow-up schedule and relocation. No adverse clinical side-effects were reported.

In Stage two of the study it was noted that 22.86% of the male participants presented with a healthy body weight (BMI 18.9kg/m^2 to 24.9kg/m^2), 48.57% were overweight (BMI 25 kg/m^2 to 29.9kg/m^2) and 28.57% were obese (BMI ≥ 30kg/m^2). Of the female participants 25.81% presented with a healthy body weight (BMI 18.9kg/m^2 to 24.9kg/m^2), 38.71% were overweight (BMI 25 kg/m^2 to 29.9kg/m^2) and 35.48% were obese (BMI ≥ 30kg/m^2).

Based on the data collected during Stage two the average weight among male participants was 188.5 pounds and the average weight among female participants was 172.4 pounds. In Stage three no significant change in the participants' weight was observed.

The average blood pressure among female and male participants during Stage two of the study was 132/80mmHg and 130/80mmHg respectively. A 3.26% change in diastolic blood pressure was noted among female participants one month after their initial blood pressure was recorded.

The average initial blood glucose level for test subjects was 5.33mmol/L (95.94mg/dL). Blood glucose levels decreased among participants by 1.81% after three months of supplement use. The highest blood glucose recorded for a male participant was 12.9mmol/L (232.2mg/dL). After seven testing occasions the participant's blood glucose level decreased by 61%.

A history of high cholesterol was reported by 31% of the participants, however during Stage 2 of the study only 20% of the participants presented with a total cholesterol level ≥ 5.2mmol/L.

Female participants presented with an average initial HDL cholesterol which was higher than that of the male participants, 1.17mmol/L and 1.03mmol/L respectively. After three months of using the "*Life*" supplement HDL cholesterol levels increased for both groups, with the males experiencing a 9.25% increase in the HDL levels. The average initial LDL levels for females were also higher than those of the male participants, 3.11mmol/L and 2.48mmol/L respectively. It was observed that after three testing sessions, LDL cholesterol levels among the male participants remained unchanged. On the other hand, LDL cholesterol levels among female participants decreased by 5.6%.

Participants were asked to use a scale from 0 to 3 to describe their level of fatigue. That is, "zero (0)" being no fatigue and "three (3)" being severe. It was noted during Stage 2 that 35.7% of the female participants reported that they were experiencing mild fatigue. After two to four months of taking the "*Life*" supplement 40% of the female participants showed an improvement from mild levels of fatigue to no fatigue. No female participants reported being moderately or severely fatigued. Of the male participants 14.3% reported being either mildly fatigued or moderately fatigued.

After two to four months of taking the "*Life*" supplement 100% of the males who reported experiencing fatigue were no longer doing so.

In Stage two of the study, 48.6% of the male participants reported that they experienced erectile dysfunction (ED). Using "The Erection Hardness Score" self-assessment tool we were able to identify the appropriate stage for each participant.

Of the participants who highlighted they were experiencing some form of ED, only one participant indicated that he was completely incapable of having an erection. Some of the participants reported an improvement in their ability to become erect after commencing the "*Life*" supplement. However, no change was noted by the participant who indicated a score of "1" during his initial assessment and registration.

Figure 1: Blood Glucose Readings Recorded for a Male Participant (Original).

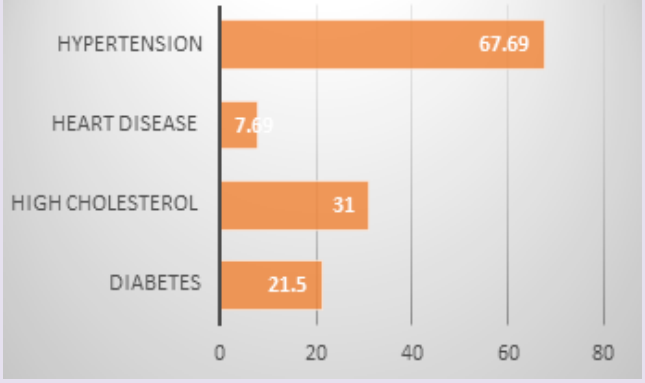

Figure 2: Disease Profiles of Participants (Original).

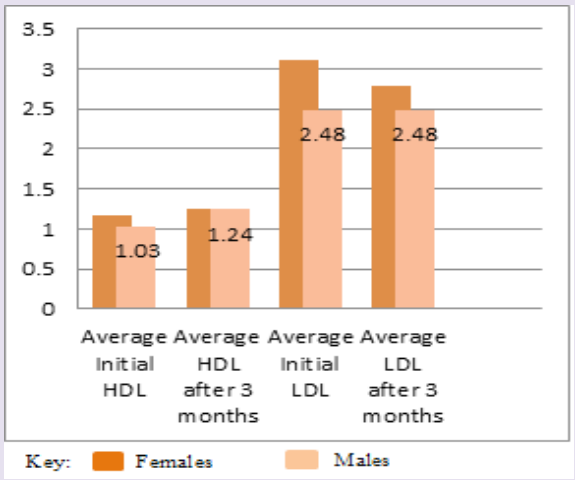

Figure 3: Comparison of HDL Cholesterol and LDL Cholesterol Levels Among Female and Male Participants (Original).

DISCUSSION

A thoroughly researched and evidence-based intervention using a potent antioxidant dietary supplement could assist patients with or at risks of heart disease in the management of their risk factors. These risk factors include high blood pressure, elevated cholesterol levels and blood glucose levels.

There continues to be a plethora of biological and biochemical research which is supportive of the theory that a significant relationship exist be-

tween free radicals, antioxidants and cardiovascular disease. Where free radical formation contributes, via a number of mechanisms, to the pathology of cardiovascular disease. In a 2011 article Bhattacharya, Ahmed and Chakraborty highlighted the involvement of Reactive Oxygen Species (ROS) in cardiovascular disease.[16]

In conducting this study the intent was to examine the feasibility and the validity of the study.

The data collected and observations made suggest that the intervention has validity. However, the internal validity was reduced due to the absence of a control group.

Despite reduced internal validity, the current protocol provides a suitable treatment model.

A retention rate of 62.1% was recorded. Of the 66 participants initially enrolled in the study two (2) were deemed ineligible and twenty-five (25) participants were lost to follow-up. The remaining participants attended the follow-up sessions as scheduled and reported no clinically relevant side effects. Absence of data from the participants who were lost to follow-up had no bearing on the findings. No significant differences in initial measurements (blood pressure, blood tests etc.) were noted between those participants who did not complete the study and those who remained.

The main outcome measures included body weight, blood pressure control, blood glucose levels, total cholesterol levels, HDL cholesterol and LDL cholesterol levels. Information bias was avoided by using identical methods to collect information from each participant.

The questionnaire was not pretested, however, the patient reported outcome scoring tool for erection hardness was previously evaluated and provided good test-retest reliability.[17]

Results for the study were as anticipated. In Ojewole's research (2002) it was observed that *Bryophyllum pinnatum* exhibited hypotensive activity. Although the specific mechanism was not clearly determined. The results suggested that the ability of this herb to reduce blood pressure may be as a result of vasodilation and cardiodepression.[10]

Diabetes is an established risk factor for cardiovascular diseases.[18] As mentioned in the results, a 1.81% reduction in average blood glucose levels was noted after three months. Antihyperglycemic activity of *Bryophyllum pinnatum* was observed in rats in a 2005 study. Blood glucose levels in rats with induced diabetes were tested after a 24 hour period following the oral administration of aqueous *Bryophyllum pinnatum* extracts. It was observed that the blood glucose levels decreased to baseline.[19]

Based on the previous research and the results of this pilot study it may be speculated that the chemical constituents including the polyphenols and flavonoids, found in the individual herbs, and by extension the "*Life*" supplement, after consistent use, may induce antihypertensive effects, antihyperglycemic effects and cholesterol reducing effects. It has been established by way of previous research that the consumption of flavonoids is inversely correlated to cholesterol levels and LDL cholesterol levels.[20]

The results are promising, however further long-term and double-blind evaluation should be carried out in order to establish clinical relevance, before we are able to make inferences regarding the degree of the therapeutic effect which results from continued use of the "*Life*" supplement. Based on our data, the "*Life*" supplement increases HDL cholesterol levels and decreases LDL cholesterol levels and blood glucose levels in both males and females.

This pilot study presents rationale to propose the "*Life*" supplement in the management of risk factors for heart disease.

CONCLUSION

After consistent use of the "Life" supplement of which polyphenols and flavonoids are chemical constituents, persons with or at risk of heart disease are expected to experience antihypertensive, antihyperglycemic and cholesterol reducing effects, as well as reduced fatigue.

ACKNOWLEDGMENT

I would like to thank Kimberlee Thompson MSc. for her assistance and contributions to this research..

CONFLICT OF INTEREST

I have patented the formula in the United States of American and have had the supplement manufactured.

ABBREVIATIONS

BMI: Body Mass Index; **ED:** Erectile Dysfunction; **HDL**: High Density Lipoprotein; **LDL**: Low Density Lipoprotein.

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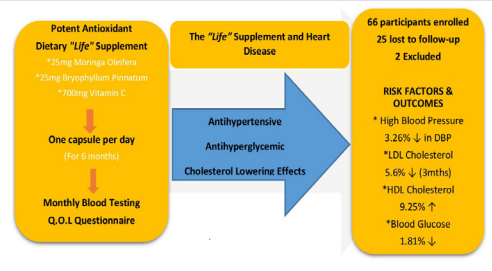
PICTORIAL ABSTRACT



SUMMARY

- Sixty-six (66) participants, twenty-five of whom were lost to follow-up, were asked to take the "Life" supplement (25mg Moringa oleifera, 25mg Bryophyllum pinnatum, 700mg vitamin C) for a period of six months.
- Parameters examined include blood pressure, blood glucose levels, cholesterol levels and fatigue.
- Results confirmed the antihypertensive, antihyperglycemic and cholesterol reducing effects of the "Life" supplement.

ABOUT AUTHORS

Dr. Alfred Sparman: Is an interventional cardiologist and pioneer of angioplasty in Barbados. After earning his medical degree from the New York Medical College and completing his internship, residency in internal medicine and cardiology fellowship, his interest in research continued. He is the author of two publications; "The Initiation of Coronary Angioplasty and Stenting in a Single Outpatient Centre in Barbados (2008) and "Manchineel Poisoning Bradyarrhythmia. A Possible Association" (2009), which have both been published in the West Indian Medical Journal. Dr. Sparman is currently the CEO of the The Sparman Clinic and 4H Hospital, a state-of-the-art cardiovascular and general medicine hospital which offers their services to the citizens of Barbados and the wider Caribbean.