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Retrospectivestudy on Mist Diodia as an Antihypertensive

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Abstract
Hypertension is one of the leading causes of Health problems in Ghana.It may lead to many other health conditions;such as Stroke, Heart attack (Myocardial infarction), Heart failure, Diabetes, just to mention a few. In view of this, there is a need to review other alternative treatment options. Mist Diodia is an herbal-based therapy used at Centre for Plant Medicine Research (CPMR), Mampong- Akuapem for more than two decades, for the management of Hypertension. It is composed of aqueous leaf extract of *Diodia scandens*. This paper reports on the retrospective study of Mist Diodia, forhypertensive patients reporting at CPMR clinic.Data of two hundred and sixty-five (265) patients who were diagnosed of hypertension from January 2015 to December 2015 was retrieved. The results after the retrospective study indicated a decline in both systolic blood pressure and diastolic blood pressure, with a mean systolic pressure of 163.9 mmHg from a baseline of 174 mmHgand a mean diastolic pressure of 96.1 mmHg from a baseline of 99.5 mmHg. It was concluded that Mist Diodia could be effective in the management of hypertension.
Keywords: Retrospective clinical study,*Diodia scandens,* Herbal medicine, Systolic blood pressure, diastolic blood pressure.

1. Introduction

Hypertension (High blood pressure) is a cardiovascular disease condition characterized by persistent elevation of blood pressure of more than 140/80 mmHg and presence of at least one cardinal signs; palpitations, easy fatigability, dyspnea, insomnia and numbness of extremities (Keith, 2005). Hypertension worldwide, is a major health concern since it is the leading risk factor of cardiovascular diseases; the world's number one killer (WHO, 2009). In 2004, 30% of global deaths were attributed to cardiovascular diseases; of which 82% of these deaths occurred in low to middle income countries (WHO, 2009). The World Health Organization predicts that 23.6 million people will die of cardiovascular diseases by 2030. Management modalities include pharmacological and non -pharmacological agents.

Despite the availability of several classes of anti-hypertensive agents, the condition is poorly controlled worldwide. Some of the standard anti-hypertensive agents used in the management of hypertensionhave serious side effects. For example, some diuretics may cause hypokalemia and hypercalcemia (Keith, 2005). Anti-hypertensive agents, for example atenolol, may cause impotence and depression, while a combined therapy involving beta-blockers and vasodilators may cause severe bradycardia, heart blockade or pump dysfunction (Keith, 2005). The limitations of some of the standard anti-hypertensive agents together with other factors such as cost have necessitated the search for alternatives which includes herbal medicines. At CPMR, Mist*Diodia* has been developed as an herbal alternative for the management of hypertension. *Diodia scandens* (family: Rubiaceae) is known in the local Akan language of Ghana as apraprayam. Traditionally,*Diodia scandens*is used as a diuretic, antifungal, anti-inflammatory, hemostatic and for wound healing(Etukudo, 2003).The dried leaves of the plant have been used clinicallyby CPMR for the managementof hypertension. This paper reports on retrospective study to assess the effectiveness of the product as an anti-hypertensive.

2. MATERIALS AND METHODS

2.1 Ethical Clearance

The study was approved by the Ethics Committee for Human Research of the Centre for Plant Medicine Research (CPMR), Mampong-Akuapem.

2.2 Study design

A retrospective study was conducted using data from over two thousand (2000) patients who visited the Centre for Plant Medicine Research (CPMR) clinic, and were diagnosed of Hypertension, from January to December 2015. Patients medical records were retrieved from the records department of the institution and analyzed based on the satisfaction of the selection criteria. Two hundred and sixty-five (265) patients qualified for the study during that period. Inclusion criteria comprised of data from patients who reported for review for at least three (3) clinic visits, over the period of study, had been diagnosed of having persistently elevated Blood pressure over 140/80 mmHg with at least two (2) cardinal signs and symptoms and had not been on any other anti-hypertensive product for at least a month prior to their first visit.

Their Blood pressure, consisting of Systolic and Diastolic readings, were measured for three (3) consecutive clinic visits and analyzed after the administration of Mist Diodia.

Graphs were plotted to ascertain the efficacy of the product, Mist Diodia, as an anti-hypertensive agent.

3. RESULTS AND DISCUSSIONS

3.1 Participant's Demographics

A total of two hundred and sixty-five (265) participants were included in the study. The mean age of participants was 58.32, with the distribution of sex being, 172 males (64.9%) and 93 females (35.1%). The demographical data of participants is recorded in table 1.0 and Figure 1.0 below respectively.

Table 1.0 Demographical data of participants

Mean Age	58.32
Males (%)	172 (64.9)
Females (%)	93 ((35.1)

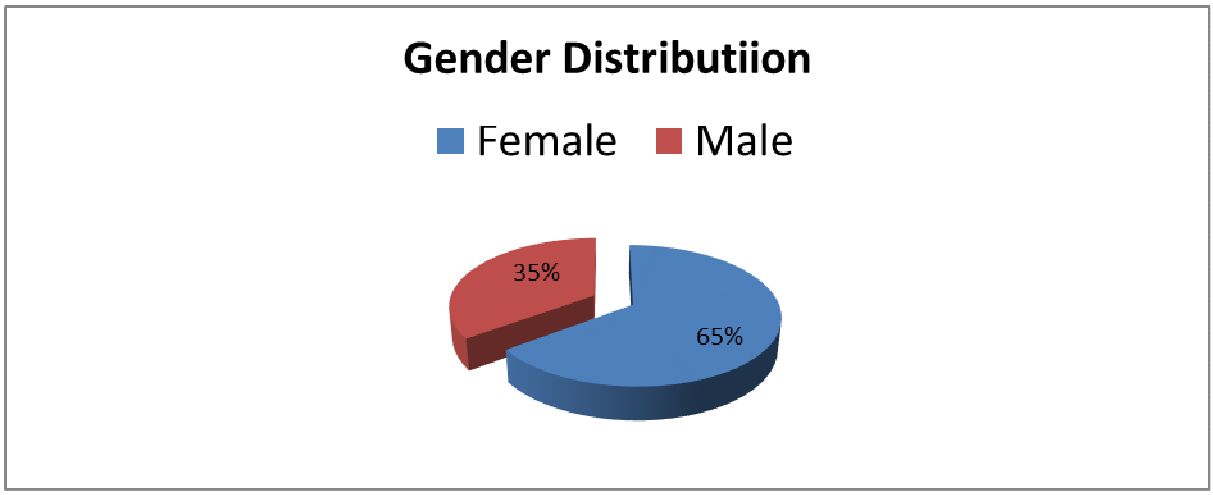

Figure 1.0

The study revealed that more females were diagnosed of hypertension as compared to males who visit CPMR clinic.

Aging is one of the major risk factors in the cause of hypertension. Figure 2 below illustrate it.

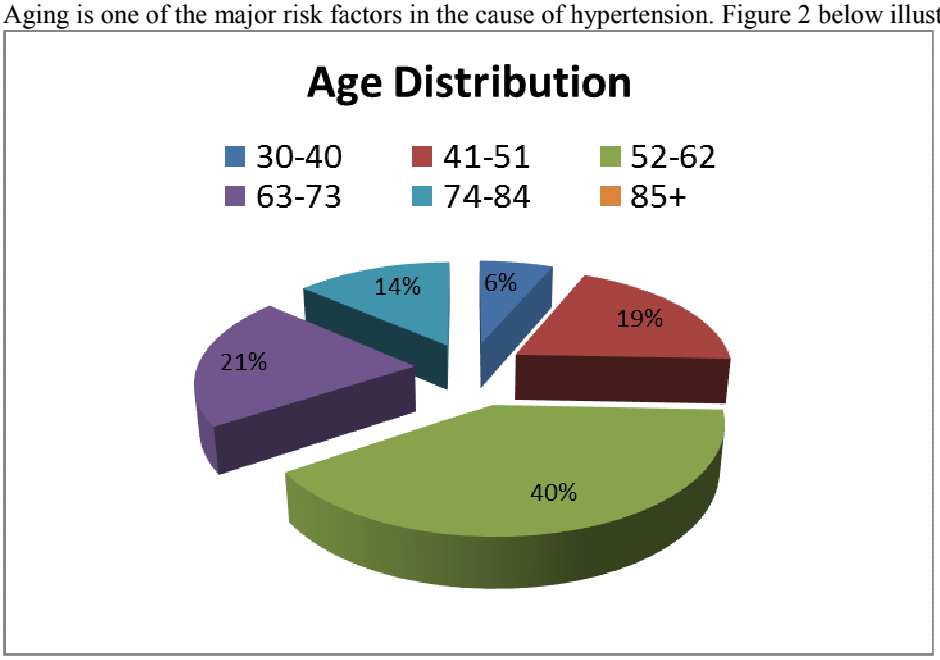

Figure 2

Aging affect the heart, blood vessels and blood. It could be noticed that, the ages from fifty-two (52) to sixty-two (62) making 40% of all the participants are affected with Hypertension the more, followed by the age range of sixty-three (63) to seventy-three(73) making about 21% ,with the least age been thirty(30) to Forty(40) years occupying 6% of total participants. Aging causes thickening and stiffness of the heart and Blood vessel.

This will in turn make the heart work harder, which may lead to high blood pressure in the elderly. This means that, aging affect one's ability to be hypertensive. (Kaplan and Keil 1993)

One's occupation affects Hypertension in many diverse ways. Work stress, lack of physical activity and poverty or low income earners tends to be major factors linking one's occupation to the risk of developing cardiovascular-related disease conditions (Kaplan and Keil, 1993). Figure 3 below shows a graphical representation of the occupation distribution for participants.

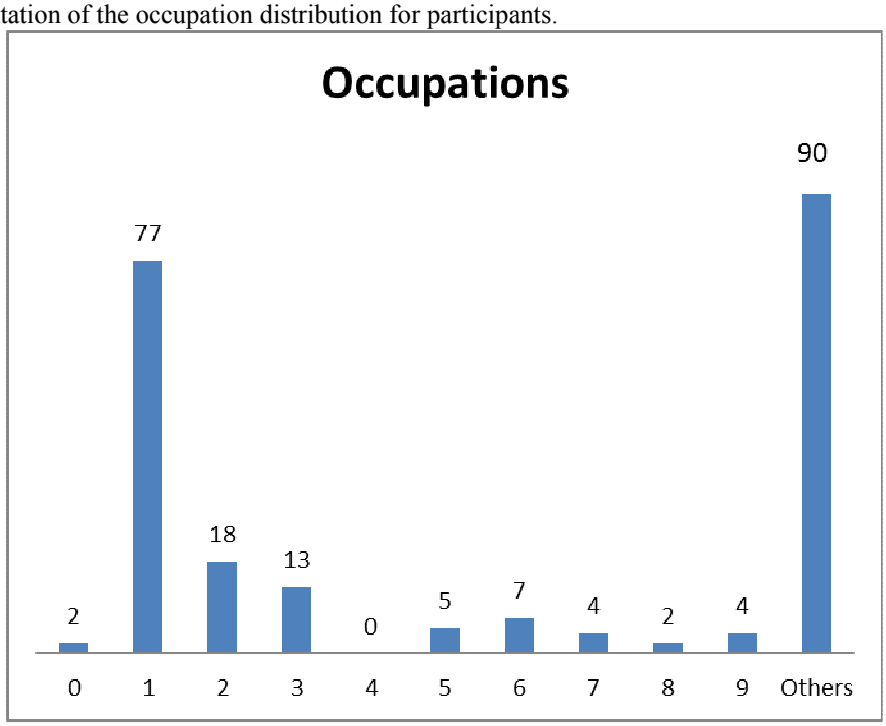

Figure 4

In accordance with the Ghana International Standard Classification of Occupation, the participants were grouped accordingly as follows; 0 represent work relating to the armed forces(examples: army, private security personnel, navy and the police), 1 represent Managers, 2 represent Professionals(examples; Doctors, Nurses and etc.), 3 represent Technicians and associate professionals, 4 represent Clerical support workers, 5 represent Service and sales workers(examples; waiters, hairdressers etc.), 6 represent Skilled Agricultural, forestry and fishery workers(example; farmers), 7 represent Craft and related trade workers(example; painters), 8 represent Plant and machinery operators assemblers(example;miners), 9 represent Elementary occupation(examples; cleaners, car washers etc.) and Others representing, Students, pensioners and unemployed.

It could be inferred from the figure above that; other occupations representing, the aged and pensioners was affected the most with hypertension. This was followed by Managers with the least affected occupation of participants been the work related to the Armed forces (examples; Army, Navy, private security personnel's and the police). This could be due to the fact that, people who are poor, have low levels of education, or are socially isolated therefore are more likely to engage in a wide array of risk-related behaviors and less likely to engage in health-promoting ones (Adler et al., 1994; Matthews et al,. 1989). Exposure to cumulative job strain in white collar workers revealed modest increases in blood pressure as well as fatigue and sleep deprivation which are correlated to mandatory and voluntary overtime, thereby increasing one's risk of developing Hypertension and cardiovascular-related diseases.

It can be observed from the figure above that; Class 0 representing the Armed forces (Army, police, Navy and private security personnel's) had a lower risk of developing hypertension. This could be due to increased physical activity, routine check-ups and health awareness and management.

3.2 Clinical effectiveness

The study showed a significant decline in participant's Blood pressure from first day of clinic visit to third clinic visit. The mean systolic pressure was (163.9mmHg) with the mean diastolic pressure been (96.1 mmHg).At the baseline (Week 0) of study, mean Systolic Blood pressure was 174 mmHg.This reading declined to 156.6mmHg at the end of the study (Third consecutive clinic visit). The change in diastolic blood pressure was also from an initial 99.5 mmHg to 92.9mmHg.These changes occurred after the administration of Mist Diodia.

The anti-hypertensive effect of Mist Diodia could be attributed to its diuretic properties.

According to WHO guidelines (WHO, 2004) in the management of Hypertension, the first-line

medications given are Thiazide diuretics (example: Tablet Bendrofluazide 5mg daily x 30 days). Diuretics in general have the potential of reducing the fluid loadon the heart by their mechanism of action which tends to acton the Kidneys thereby: increasing Sodium (Na+) and water excretion, which will lead to the reduction of blood volume. Finally, there will be a decrease in blood pressure. Hence, Mist Diodiamay be working by this mechanism of action.The decline in blood pressure could also be associated with cardiac glycosides; one of the active constituents found in *Diodia scandens*. Cardiac glycosides are known to be effective in the treatment of heart related diseases (Trease and Evans 2002).

The graphical representations of the average systolic and diastolic blood pressure are labeled in figure 5 and figure 6 respectively.

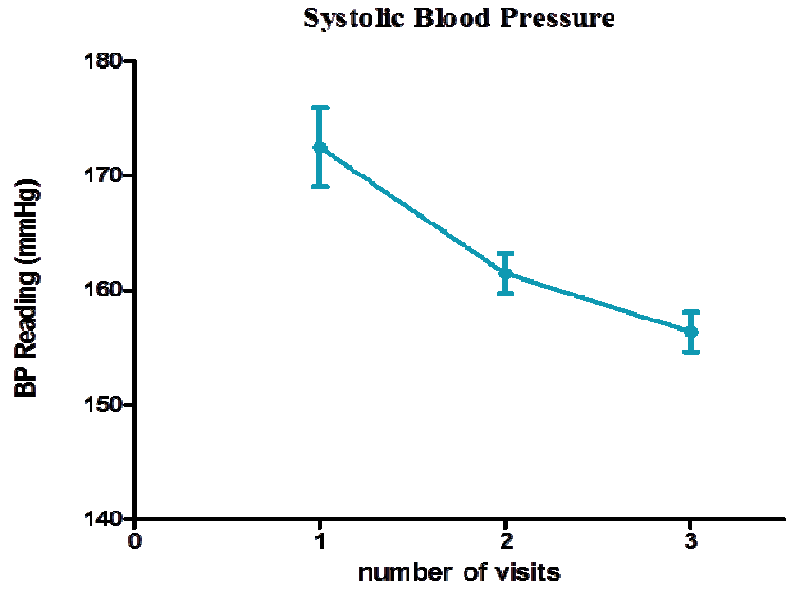

Figure 5

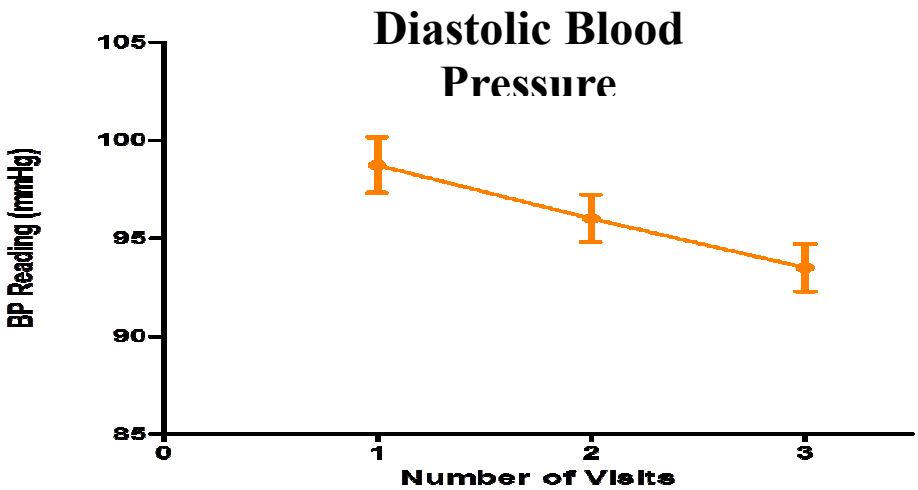

Figure 6

3.3 Assessment of Safety

In reference to medications, safety is the likelihood of not causing harm under the proposed conditions of use. Many supporters of herbal medicines argue that products with a long history of popular use are generally safe when used properly at common therapeutic doses (Fong, 2002).However, there are case reports of adverse events after administration of herbal products. Sometimes, the toxicity is attributed to contaminants and adulteration.Assessment of safety of herbal products, therefore, is the first priority in herbal research.Safety was assessed by comparing the baseline symptoms,vital/physical signs and the routine Laboratory investigations (BUE & Cr, LFT, Lipid Profile and FBC) after subsequent follow-ups.

The following results were deduced from the studies and they're tabulated in Table 2 below.

TABLE 2 SAFETY ASSESSMENT

LAB INVESTIGATION	NO. OF PARTICIPANTS	RESULTS
BUE&Cr	19	Urea:3.64 Creatinine: 111.72.- normal range
LFT	14	T. Bil- 5.89 D. Bil- 1.50 T. Prot-77.78 Albumin- 31.71 AST- 21.51 ALT-20.86 ALP- 155.43- normal range
Lipid Profile	8	T. chol- 5.53 HDL- 0.86 TRIG- 2.03 LDL- 5.26- elevated
FBC	10	WBC- 4.7 RBC- 4.49 HGB- 11.34 (L) HCT- 35.15 (L) PLT- 266.7

It could be deduced from the table that, after subsequent follow-ups and laboratory investigations; Blood Urea Electrolyte and Creatinine (BUE&Cr), Liver Function Test (LFT) and Full Blood Count (FBC) had normal ranges of values for participants who were screened. It could be due to the fact that, Mist Diodia may not contain contaminants/adulterants that may give undesirable effects for human use. It could also be due to the fact that, product went through the preliminary pre-clinical trialsbefore it use as an antihypertensive agent.

It could be observed that, the Lipid profile had the following parameters in normal range; (Total Cholesterol, Triglycerides and High-density lipoprotein Cholesterol) but had the Low-density Lipoprotein Cholesterol elevated. It could be due to the fact that, the product may not work on high Bad Cholesterol levels in a hypertensive patient and the patient might need another drug for lowering the Cholesterol levels. This could be due to the drug's mechanism of action as a diuretic.

On the whole, it could be inferred that Mist Diodia, an antihypertensive agent could be safe for human consumption.

4. CONCLUSION

The results gathered after the study, affirm the usefulness of Mist Diodia as an anti-hypertensive agent.
Hence, Mist Diodia could be effective for the management of Hypertension.

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