



## A retrospective clinical study of the safety and efficacy of AFA mixture, an herbal antihypertensive product

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### ABSTRACT

**Background & Aim:** Hypertension is an incurable disease which has become a common major risk factor for many cardiovascular diseases worldwide. Besides increasing the risk of heart diseases and stroke, hypertension can also lead to other health conditions such as renal disease and diabetes. The prolong use of orthodox antihypertensive are usually associated with many side effects coupled with the millions of dollars spent annually for the treatment and detection of heart diseases. However, herbal products with antihypertensive properties offer an alternative and effective way to decrease the rising number of people with hypertension. AFA Mixture is a bi-herbal antihypertensive product on the essential herbal medicine list of the Ministry Of Health of Ghana, used at the pilot centers by Medical Herbalists for about eight years, for the management of hypertension. It is composed of the aqueous stem back extract of *Rauwolfia vomitoria* and *Alstonia boonei*.

**Experimental:** This study reports on the retrospective clinical study of AFA Mixture, for hypertensive patients reporting at Tafo Government Hospital, Herbal Medicine Unit. Data on two hundred (200) patients who were diagnosed of hypertension from January 2018 to June 2018 were assessed.

**Results:** The results indicated a decline in both systolic and diastolic blood pressure, with a mean systolic pressure of 130 mmHg from an initial reading of 160mmHg and a mean diastolic pressure of 90 mmHg from an initial reading of 110mmHg. Kidney and liver function tests were within normal range at the end of the study.

**Recommended applications/industries:** It was concluded that AFA Mixture could be safe and effective in the management of hypertension in motivated clients.

### 1. Introduction

Hypertension, also known as high blood pressure, is a long term medical condition in which the blood pressure in the arteries is persistently elevated (Naish *et*

*al.*, 2014). For most adults, normal blood pressure at rest is within the range of 90-130 millimeters of mercury (mmHg) systolic and 60-80 mmHg diastolic. For most adults, high blood pressure is persistently

above 130/80 or 140/90 mmHg (Whelton *et al.*, 2017). Elevated blood pressure usually does not cause symptoms (CDC, 2015). Long-term high blood pressure, however, is a major risk factor for coronary artery disease, stroke, heart failure, atrial fibrillation, chronic renal disease and vision loss (Lackland, 2015). According to the World Health Organization (WHO), raised blood pressure affects about 1.13 billion people worldwide, and it is predicted that about 23.6 million people will die of cardiovascular diseases by 2030 (WHO, 2017).

Even though there is the availability of several classes of anti-hypertensive medications, the condition is poorly controlled worldwide mostly due to non adherence to therapy by clients as a result of the unfavourable side effects of these medications. Conventional antihypertensive agents, for example *Atenolol*, may cause erectile dysfunction and diabetes mellitus, while *Nifedipine* and *Amlodipine* can cause heart failure ([www.cpsedu.com.au](http://www.cpsedu.com.au)).

Since the integration of herbal medicine practice into the mainstream health care delivery system of Ghana, Medical Herbalists were provided with selected herbal products on the essential herbal medicines list to prescribe from.

AFA Mixture is a bi-herbal product containing *Rauwolfia vomitoria* and *Alstonia boonei* has been developed as an herbal product for the management of hypertension. However, there is no clinical data to validate its safety and efficacy. This has necessitated the need to evaluate the clinical potentials on *AFA Mixture* which is on the essential herbal medicines list in the treatment of hypertension.

## 2. Materials and Methods

### 2.1 Study Design

A retrospective clinical study was conducted using data from two hundred (200) patients who visited the Tafo Government Hospital Herbal Medicine Unit, and were diagnosed of Hypertension, from January 2018 to June 2018. Patients medical records were retrieved from the records department of the hospital and analyzed based on the selection criteria. Two hundred patients qualified for the study during the period. Inclusion criteria comprised of data from patients who reported for review for at least 4 clinic visits, over the period of study, had been diagnosed of having

persistently elevated blood pressure over 130/80 mmHg with at least 2 cardinal signs and symptoms and had not been on any other antihypertensive medication for at least a month prior to their first visit. Their Blood pressure, consisting of Systolic and Diastolic readings, were measured for 4 consecutive visits to the herbal medicine unit of the hospital and analyzed after the administration of AFA Mixture. Graphs were plotted to establish the efficacy of AFA Mixture within the study period.

### 2.2 Treatment and Duration of Study

A decoction of AFA Mixture is dispensed in a dose of 60ml three times daily after meals for a period of thirty days.

## 3. Results and discussion

### 3.1 Participant's Demographics

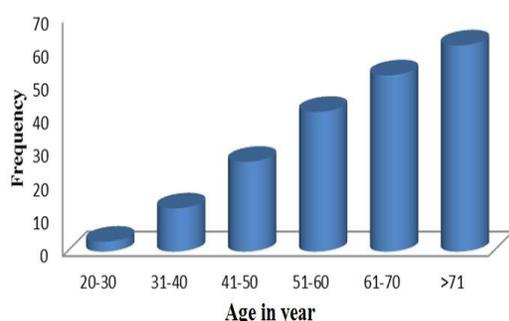
A total of two hundred participants were included in the study. The mean age of participants was 59.65, with the distribution of sex being, 133 males (66.5%) and 67 females (33.5%). The study revealed that more males were diagnosed of hypertension as compared to females who visit the herbal medicine unit of the Tafo Government Hospital. Aging process causes a decrease in the elasticity and increase in stiffness of the arterial system. It could be realized from Figure 1 that, the ages from seventy-one years and above which making 31 per cent of all the participants are significantly affected with hypertension, followed by the age group of sixty-one to seventy consisting of 26.5 percent. The age group from fifty-one to sixty also makes 21 percent of participants having hypertension, followed by 13.5 percent in the age group from forty-one to fifty, then from age group thirty-one to forty makes 6.5 percent of participants having hypertension with the least age been twenty to thirty-one comprising 1.5 percent of total participants. This is as presented in Table 1 and Figure 1, respectively.

The study showed a significant decline in participant's blood pressure from first day of visit to the fourth visit. The mean systolic pressure after the fourth visit was 130mmHg with the mean diastolic pressure after the fourth visit being 90 mmHg. At the start of the therapy (Week 0), the initial mean systolic blood pressure was 160 mmHg. This reading reduced to 130mmHg at the end of the fourth visit (Figure 2). There was a corresponding reduction in diastolic blood

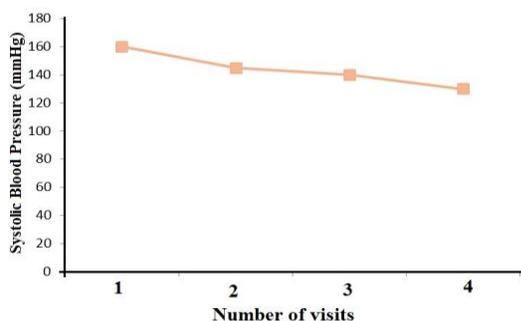
pressure from an initial 110 mmHg to 90 mmHg. This is as shown in Figure 3.

**Table 1.** Age distribution of participants.

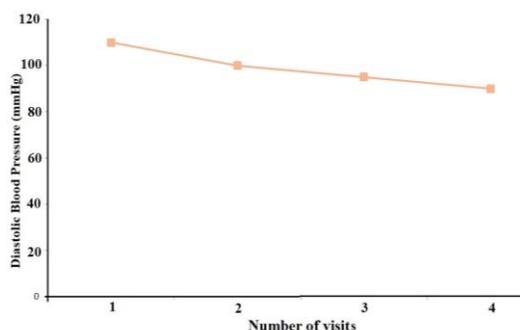
Age	Frequency	%
20-30	3	1.5
31-40	13	6.5
41-50	27	13.5
51-60	42	21
61-70	53	26.5
>71	62	31



**Figure 1.** Age distribution of participants.



**Figure 2.** Clinical effectiveness of AFA Mixture on systolic blood pressure.



**Figure 3.** Clinical effectiveness of AFA Mixture on diastolic blood pressure.

The results of safety on the kidneys and liver showed no effect an indication that the product may be relatively safe. Tables 2 and 3 show the effect of AFA mixture on participants' kidney and livers, respectively. Kidney and liver function tests were within normal range at the end of the study. The anti-hypertensive property of AFA Mixture could be attributed to the diuretic and hypotensive properties of *echitamine* and *echitamidine*, potent constituents of *Alstonia boonei*, which have earlier been reported (Kucera *et al*, 1972; Maurice, 1993).

**Table 2:** Assessment of safety of AFA Mixture on renal function

Tests	Reference range	Initial visit	Visit 2	Visit 3	Visit 4
Potassium	3.5-5.5	4.36	4.22	4.38	4.12
Sodium	135-155	140.25	139.28	141.16	142.10
Chloride	96-110	97.6	98.8	99.12	97.90
Urea	2.1-7.1	5.65	6.7	7.3	6.42
Creatinine	M=61.88-123.8 F=61.88-106.1	98.76	101.14	96.65	98.44

**Table 3.** Assessment of safety of AFA Mixture on liver function

Test	Reference range	Mean of initial test	Mean of final test
AST	0-40 (IU/L)	36	37.1
ALT	0-40 (IU/L)	38	37.9
ALP	64-306 (U/L)	163.6	162.8
GGT	9-61 (U/L)	52.2	53.1
Bilirubin Total	0-18.8 umol/L	20.1	18.5
Bilirubin Direct	0-4.3 umol/L	3.8	3.5
Bilirubin Indirect	0.5-14.5 umol/L	7.7	7.5
Total Protein	66-87 g/L	74	76.4
Albumin	38-51 g/L	41.5	43
Globulin	28-36 g/L	32.5	33.4

The major effects of *echitamine* included: lowering of systemic arterial blood, inductions of negative chronotropic and inotropic responses in isolated atrial muscle strips, relaxation of isolated vascular and extra-vascular smooth muscles, inhibition of electrically-provoked and agonist-induced contractions or relaxations of isolated smooth muscle, and induction of diuresis (Ojewole, 1984). Alkaloid fraction of *Alstonia boonei* has also been reported to possess antilipidemic properties as it improve lipid profile, leptin sensitivity, and decreased body weight (Anyanwu *et al*, 2018). This help to decrease high blood pressure.

*Reserpine* an alkaloid present in *Rauwolfia vomitoria* has been reported to have been used to treat

hypertension (Jerie, 2007). The antihypertensive properties of reserpine are as a result of its ability to deplete catecholamines from peripheral sympathetic nerve endings. These substances are normally involved in controlling heart rate, force of cardiac contraction and peripheral vascular resistance which in turn decrease high blood pressure (Forney and Barbara 2002).

#### 4. Conclusion

The results from the data generated establish the usefulness of AFA Mixture as a potential anti-hypertensive agent in motivated clients. In conclusion, combination antihypertensive herbal therapy with *Alstonia boonei* and *Rauwolfia vomitoria* effectively lowers BP without particular safety problems. There was no incidence of adverse reactions, and there were no severe adverse reactions which hampered the continuation of combination therapy. Therefore, AFA mixture may be safe and effective for the management of hypertension in human.

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