

An Observational Clinical Study on the Effectiveness of the Aqueous Leaf Extract of *Lippia multiflora* (Mold) as an Antihypertensive Agent

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Abstract

Hypertension is an issue of public health concern due to its impact on society hence the need to find new treatment options. The leaves of *Lippia multiflora* (Mold) has traditionally been used in the management of hypertension and stress for more than four decades in Ghana. This study reports on an observational clinical study conducted using twenty-eight (28) hypertensive patients visiting the clinic of the Centre for Scientific Research into Plant Medicine (CSRPM). Participants were asked to prepare an infusion of *L. multiflora* by boiling 30 g of the plant material in 250 mls of water for four minutes and then filter. The treatment was to be administered twice daily for a period of four (4) weeks. Results showed a significant decline in both systolic blood pressure (SBP) and diastolic blood pressure (DBP) over the period with the difference in mean SBP of 11.6 mmHg and that of the mean DBP recording a 6.43 mmHg decline from the baseline. The aqueous leaf extract of the plant thus holds some prospects for use as an anti-hypertensive agent.

Keywords: diastolic BP, hypertension, herbal medicine, *Lippia multiflora*, observational clinical study, systolic BP

1. Introduction

Hypertension is gradually attaining the status of an epidemic in Ghana. Figures from some prevalence studies indicated that as many as 48 % of some adult populations studied were hypertensive (Owusu, 2007). The increase in the incidence of cardiovascular diseases and most especially hypertension means a lot more effort has to be applied at finding treatment options that will ensure patients maintain an optimum blood pressure to reduce complications. One of these options involves the use of herbal medicines.

Lippia multiflora (Mold) belongs to the family Verbanaceae. The plant is a stout woody, perennial and aromatic shrub mainly distributed throughout tropical Africa, South and Central American countries (Pascual *et al.*, 2001). It occurs in a wide ecological range throughout West Africa. In undisturbed sites, the plant can grow to a height from 2.7 to 4.0 m bearing large oblong-lanceolate and green leaves. The plant usually flowers from September to November and then fruits in January (Ameyaw, 2009).

Traditionally, *Lippia multiflora* is used as a febrifuge, laxative, sudorific, antimicrobial and anti-inflammatory agent. The plant is also well known for its anti-malarial, stress-relieving, sedative and hypotensive effects (Terblanche and Kornelius, 1996; Mshana *et al.*, 2000). The dried leaves of the plant have been used clinically by the Centre for Scientific Research into Plant Medicine (CSRPM), Mampong-Akwapem for the management of hypertension. This paper reports on an observational study to assess the effectiveness of the product involving patients visiting the clinic of the CSRPM.

2. Materials and Methods

2.1 Ethical Clearance

The trial documents and all related procedures were reviewed and approved by the institution's committee for human research. The trial was also performed in accordance with the Declaration of Helsinki and Good Clinical Practice.

2.2 Study Design

Known hypertensive's with an average systolic blood pressure (SBP) between 130 - 160 mmHg and an average diastolic blood pressure (DBP) between 80 - 100 mmHg for three separate readings over a period of two (2) weeks and who were not on any form of treatment or had defaulted in taking their conventional anti-hypertensive medications for more than a month were recruited for the study. The details of the study were explained to them after which an informed consent was obtained. Participants were then given the necessary advice about their diet and lifestyle and assigned to receive the coarsely comminuted dried leaves of *Lippia multiflora* to be prepared as a hot infusion.

Participants were asked to prepare the infusion by boiling 30 g of the plant material in 250 mls of water for four

minutes and then filter. The resulting filtrate was to be taken as the treatment. This treatment was to be administered twice daily for the duration of the trial. Individuals who had any underlying end organ damage such as kidney, liver and cardiac abnormalities were excluded from the study.

Participants were followed up for a period of four (4) weeks during which they were expected to report for monitoring on week two (2) and week four (4). At the start and during each of these visits, the blood pressure of each participant was measured using a manual mercury sphygmomanometer. The average of these readings was recorded as the blood pressure for the day.

2.3 Statistical Analysis

A paired *t*-test was used to quantify the effect of *Lippia multiflora* on the blood pressure of participants at the end of the study. Results were considered significant if the mean reduction in either systolic or diastolic blood pressure reading produced a *p*-value of ≤ 0.05 .

3. Results and Discussion

3.1 Participant Demographics

A total of thirty-seven (37) participants were included in the study. Twenty eight (28) were able to complete the study giving a dropout rate of 24.32 % (n=9). The mean age of the participants in the study was 54.09 (± 13.93), with the distribution according to sex being twenty (20) females and seventeen (17) males. The demographical data of participants is reported in table 1.0.

3.2 Clinical Effectiveness

The study showed the plant had some effect in pre-hypertensives and stage I hypertensives with 71.43 % of participants recording a decline in SBP and DBP. Another 17.86 % (n=5) and 21.43 % (n=6) recorded an increase in their SBP and DBP respectively compared to their baseline reading. The number of participants not recording any change in their SBP and DBP was 10.72 % (n=3) and 7.14 % (n=2) respectively.

The mean reduction in SBP was 11.6 mmHg over the four week study period. The DBP also had a mean reduction of 6.43 mmHg in the same period. At the baseline (Week 0), mean SBP was $146.0 \pm (10.1)$ mmHg. This reading declined to $134.0 \pm (13.5)$ mmHg at the end of the study (Week 4) (Table 2.0). The change in DBP was also from an initial of $92.14 \pm (7.38)$ mmHg to $85.71 \pm (9.97)$ at week 4.

The antihypertensive effect produced by *Lippia multiflora* can be attributed to its diuretic, sedative, smooth muscle relaxant and lipid lowering effects; properties that play a very important role in the blood pressure modulation (Noamesi *et al.*, 1985; Mwangi *et al.*, 1992; Kanco *et al.*, 2004). Also, verbascoside one of the major constituent in the plant is also reported to play a role in the antihypertensive activity by the inhibition of thromboxane synthesis (Chanh *et al.*, 1988).

Though the study duration was for only four (4) weeks, the continuous decline in both systolic and diastolic blood pressure readings over the period could serve as a basis for a more extensive clinical trial. There is also the possibility of obtaining a higher therapeutic effect if the dosage is increased or its form modified.

The reduction in blood pressure reported in this study increases the prospects for the widespread use of the product as an antihypertensive agent especially for the numerous individuals who are disturbed by the undesirable effect of conventional treatments.

4. Conclusion

The results gathered from the study further confirm the traditional usage and prospects of the plant as an antihypertensive agent.

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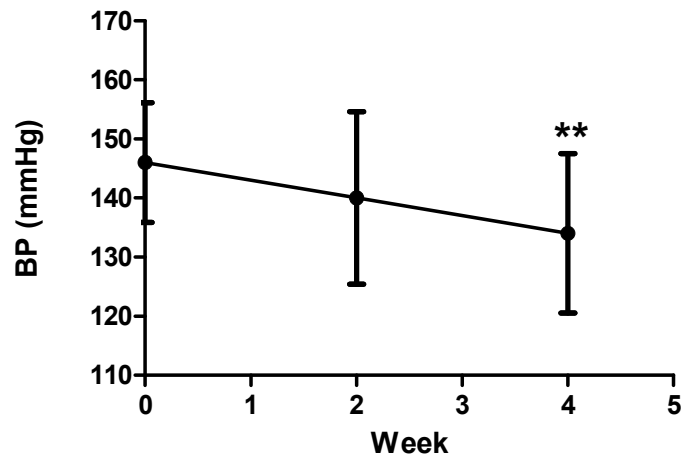


Figure 1.0: Change in the mean systolic blood pressure of participants over the study period;
** - p -value ≤ 0.01 compared to the baseline at week 4.

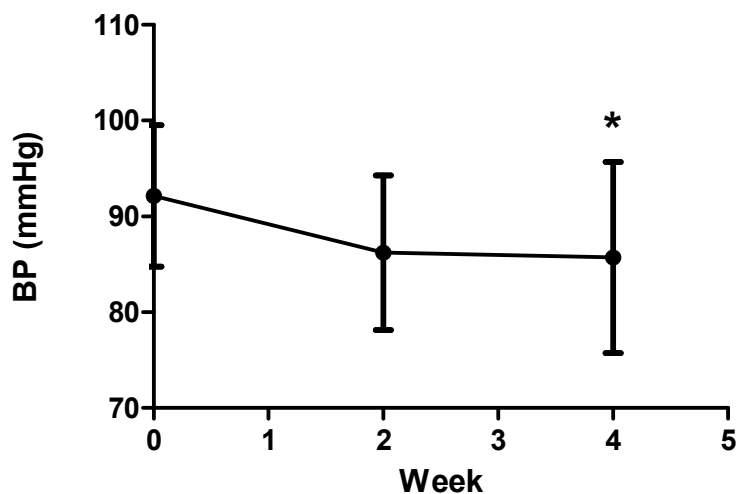


Figure 2.0: Change in mean in diastolic blood pressure of participants over the study period;
* - p -value ≤ 0.05 compared to the baseline at week 4.

Table 1.0 Demographical data of participants in the study

Mean Age (SD)	54.03 (\pm 13.93)
Females	20
Males	17

Table 2.0 Mean blood pressure readings of participants during the study period.

	Week 0	Week 2	Week 4
Mean systolic BP (SD)	146.0 \pm (10.1)	140.0 \pm (14.6)	134.0 \pm (13.5)
Mean diastolic BP (SD)	92.14 \pm (7.38)	86.21 \pm (8.06)	85.71 \pm (9.97)

Table 3.0 Confidence intervals and *p*-values of blood pressure readings at the end of study.

	<i>p</i> -value	Confidence Interval
Systolic BP	0.002**	2.13 – 21.80
Diastolic BP	0.015*	1.34 - 11.51

(* - $p \leq 0.05$) (** - $p \leq 0.01$)

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