



International Journal of Herbal Medicine

Available online at www.florajournal.com

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International
Journal
of
Herbal
Medicine

E- ISSN: 2321-2187
P- ISSN: 2394-0514
IJHM 2015; 2 (5): 43-45
Received: 13-12-2014
Accepted: 15-01-2015

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A Retrospective Clinical Study on the Effectiveness of the Aqueous Leaf Extract of *Bredelia ferruginea* (Benth) in the Management of Diabetes Mellitus

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Abstract

The increasing preference of diabetic patients for herbal medicines calls for the screening of candidate products to examine the risk to benefit ratio for users. In this study, one of such products Bridelia Tea from the Centre for Plant Medicine Research (CPMR) was evaluated. The product is prepared from the dried leaves of *Bredelia ferruginea*. Data from patients visiting the clinic of the CPMR between May 2012 and May 2013 were retrieved for analysis. Twenty-two (22) patient records which satisfied the selection criteria indicated that Bridelia tea caused a mean reduction in Fasting Blood Sugar (FBS) of 1.886 from a baseline FBS of 13.55 (± 4.79). The decline in fasting blood sugar was concluded to be clinically and statistically insignificant after analysis and hence there is the need to review the product.

Keywords: *Bredelia ferruginea*, Diabetes Mellitus, Herbal medicine, Retrospective clinical study

1. Introduction

Diabetes mellitus (DM) is a metabolic disorder characterised by chronic hyperglycaemia resulting from relative insulin deficiency, insulin resistance or both. The condition may be classified as type I (insulin dependent) and type II (non-insulin dependent) [1]. Gradually diabetes is also assuming the level of an epidemic just like hypertension and other lifestyle related diseases [2-3]. The use of medicinal plants for the treatment of diabetes is not new as numerous plants have been documented as having anti-diabetic properties [4].

Bredelia ferruginea (family: Euphorbiaceae) is known in the local Akan language of Ghana as *opam fufuo*. The plant has diverse traditional uses some of which have been verified scientifically: the anti-inflammatory effect [5] and the antipyretic and analgesic effects [5-6]. *Bredelia* has also been shown to have an immunomodulatory effect and antimicrobial potential against both gram negative and gram positive bacteria [7]. The traditional use of the infusion of the leaves as an anti-diabetic agent was also confirmed by evaluating 12 patients diagnosed with diabetes [8].

The leaves of *Bredelia ferruginea* has been used at the Centre for Plant Medicine Research (CPMR), Mampong-Akwapim as an anti-diabetic product for over 20 years. It is dispensed under the trade name Bridelia Tea. Diabetics who visit the clinic are counselled to prepare an aqueous infusion from the dried leaves which is then taken at a dose of 100mls three times daily. The dry weight of the *B. ferruginea* in this infusion is approximately 0.97(± 0.20)g.

Previously documented case studies from physicians at the CPMR recorded an inconsistent effect of *Bredelia* on the glucose levels of diabetic patients. The physicians involved reported that patients had mixed results when they were treated with the product [9]. The current study was undertaken to analyze retrospective clinical data on the product. The results from this study are expected to influence a decision on the continuous use of the product at its current dosage and in the dosage form delivered to patients.

2. Materials and Methods

2.1 Ethical Clearance

The study was approved by Ethics Committee for Human Research of the CPMR. Patient confidentiality was ensured at all times during the study.

2.2 Study design and Analysis

A retrospective study was conducted using data for patients who visited the clinic of the CPMR over a one year period, between May 2012 and May 2013. All the folders for

diabetics seen at the clinic for the period were retrieved from the records department. Inclusion criteria comprised data from patients who reported for review twice over a period of 1 month and had not been on any other anti-diabetic product for at least a month prior to their first visit. The fasting blood sugar (FBS) readings during the first four (4) weeks of treatment were recorded for analysis.

The expected outcome was that *Bridelia* tea exerted a decrease in the fasting blood sugar of participants during the first four (4) weeks of treatment. In quantifying this effect, a paired *t*-test was used to compare the difference between fasting blood sugar at the first time of reporting (baseline) and after four weeks of treatment (end of the study). An α -level of 5% was set for the detection of significance of the results obtained.

3. Results and Discussion

3.1 Demographics

Data on the participant demographics are reported in Table 1.0. The mean age of participants was 59.50 (± 14.47) with an equal distribution of male and females.

Table 1.0: Demographical data of participants in the study

Mean Age (SD)	59.50 (± 14.47)
Sex	
Males (%)	11 (50)
Females (%)	11 (50)

3.2 Treatment Efficacy

The mean change in fasting blood sugar (FBS) observed for the patients treated for the study period was -1.886 (Table 2.0). Mean FBS at the baseline was 13.55 (± 4.79) and 11.67 (± 5.51) at the end of the study.

Table 1.0: Summary of the results obtained for the participants on the *Bridelia* Tea

	Baseline	After 4 weeks of treatment
Mean FBS (SD)	13.55 (4.79)	11.67 (5.51)
Change in FBS		-1.886
<i>p</i>-value		0.318
Confidence Interval(CI)		(-5.676 to 1.903)

This decline in FBS over the period was not significant after statistical testing (CI -5.676 to 1.903) and this confirms previous reports from the CSRPM stating that *Bridelia* may not be beneficial when used as a monotherapy^[10]. A graphical summary of participant FBS over the four (4) week period for users of the product is presented as Figure 1.0 showing very marginal and non-significant decline in mean FBS during the second and third visits.

Although the study design makes it very difficult to draw definite conclusions from the results due to the limitations of retrospective clinical studies in the provision of evidence, as such studies allow too much bias, there is the need to undertake a review of the product as an anti-diabetic agent^[11]. This suggestion is made in view of the other reports that have shown the plant to possess some activity in the treatment of diabetes^[8] with others like Ampofo (1977) and Malcolm and Soforowa (1969) also identifying rutin a chemical isolate from the plant as having some hypoglycaemic effects^[12].

The need for a review of the product becomes even more imperative when the complications associated with uncontrolled blood sugar are considered. In addition, the current dosage form, the administered dosage and very

importantly issues about standardisation of the product need to be addressed.

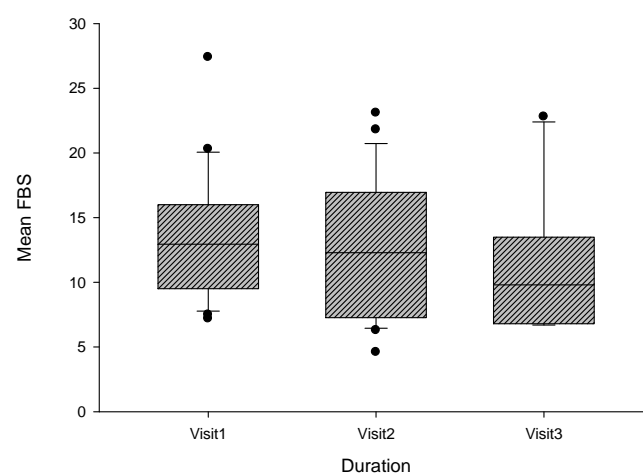


Fig 1.0: Change in FBS of participants at the baseline, week 2 and week 4. Data is presented as mean (SD) (n = 22). The lower and upper margins of the boxes represent the 25th and 75th percentiles, with the extended arms representing the 10th and 90th percentiles respectively. The median is shown as the horizontal line within the box.

4. Conclusion

The results from the study emphasises the need for the clinical appraisal of herbal products to establish their effectiveness. In line with this suggestion and the report from Okine and colleagues^[10], a follow up study has been initiated to look into the benefits of using the product as an adjuvant to the current orthodox anti diabetic treatments and explore the benefit of increasing the treatment dosage.

5. Acknowledgement

Authors wish to thank the staff of the record's unit of CPMR clinic department.

5.1 Conflict of interest

Authors have no conflict of interest

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