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EFFICACY OF A PERSONALIZED FOOD AVOIDANCE DIETARY APPROACH FOR THE CONTROL OF ESSENTIAL HYPERTENSION

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ABSTRACT

Essential Hypertension (EH) is the leading cause of global morbidity and mortality. Ongoing clinical trials of a Personalized Food Avoidance Dietary Approach to Stop Hypertension (PFADASH) implicate some dietary constituents in the phenotypic expression of EH. The aim of this study was to evaluate the adjunctive efficacy of a PFADASH on the control of EH. This was part of an open controlled clinical trial of a PFADASH approved by the University of Nigeria Teaching Hospital (UNTH) Ethics Committee. Study was carried out at Medical Outpatient Clinics UNTH and Chiolive International Medical Research Organization, Tran-Ekulu Enugu from 2015 to 2019. Seven Study Participants (SPs) met the inclusion/exclusion criteria of being on at least two antihypertensive drugs, adult and literate. Dietary Compliance (DC) to a PFADASH which excludes food additives and hydrogenated fats, Blood Pressure (BP), antihypertensive drug requirements and echocardiography assessments was done for SPs by collaborating dieticians, pharmacists and physicians. Study adopted a longitudinal prospective study design. Analysis of variance (ANOVA), Spearman correlation coefficient and Pearson test were used for inferential statistics. Drug treatment parameters: prescribed treatment (Rx), actual adherence (Adh), adherence score (AdhRx), Antihypertensive Drug Treatment Requirement score (ADTR), blood pressure and echocardiographic parameters did not show positive association with DC ($P>0.05$) although ADTR and average BP scores was lower in SPs with good DC without significant impact from potential confounders like sleep and exercise habits. Study participants with good DC to a PFADASH had lower BP scores with slight improvements in the echocardiographic parameter: Left Ventricular Ejection Fraction (LVEF). These observations should be pivotal in demonstrating the role of some dietary constituents in the aetiopathogenesis of EH.

Keywords: Adjunct, Blood Pressure, Efficacy, Hypertension.

INTRODUCTION

Essential Hypertension (EH) is defined as elevated systolic blood pressure of greater than or equal to 140 mm Hg or diastolic blood pressure greater than or equal to 90 mm Hg (WHO, 2023). It is a classic paradigm of a non-communicable immune mediated inflammatory disease (IMID). Being a leading cause of global morbidity and mortality, it accounts for 30% of myocardial infarctions claims 92 million disability- adjusted life years per annum and affects over 1 billion people globally and is a major risk factor for myocardial infarction, kidney disease and stroke (Practice guidelines, 2021)

Effect of diet on blood pressure is a subject of public health importance (Mrowietz and

Elder 2006). Dietary approaches to stop hypertension (DASH) menus were conceived to attain beneficial levels of fiber and elements like potassium and magnesium for blood pressure reduction (Sacks *et al* 2001, Teresa *et al* 2010). A personalized food avoidance dietary approach to stop hypertension (PFADASH) a modification of DASH was conceived to address primary and secondary intolerance to immune unfamiliar and egregious food substances to abate immune dysfunction underlying IMIDs like hypertension (Chijioke *et al* 2016). Western diet is laden with egregious substances for taste enhancement and is also characterized by overabundance of macronutrients; all of which underscore pathogenesis of EH.

Epidemiological association of IMIDs like hypertension, psoriasis and metabolic syndrome associated disorders suggest that to some extent, they share common genetic, environmental and inflammatory dysfunctional pathways. Moreover, same drugs are effective in managing a variety of IMIDs (Shirinsky, 2007). An anti-psoriatic diet has been shown to have side benefits on blood pressure control (Chijioke *et al* 2012). Open and randomized controlled trials of a personalized food avoidance dietary approach to stop hypertension have shown that study participants with good dietary compliance have shown reduced antihypertensive drug treatment while maintaining or improving their blood pressure control (Chijioke *et al* 2012, Chijioke *et al* 2016, Chijioke *et al* 2018).

Clarion calls have been made for expansion of therapeutics to take account of immunotoxins and immune dysfunctional processes underlying IMIDs. In so doing, drug prescriptions and proscriptions for IMID management aligns with rational drug use for disease management (Okafor *et al* 2023, Okafor 2024). Not relying solely on anti-hypertensive drugs for management of EH will give room for decreased side effects of drugs. Furthermore, recalcitrant hypertension amenable to invasive procedures like surgical ablation of nerves may not be necessary with appropriate dietary strategies to stop hypertension. Hence the aim of this study is to determine the efficacy of a PFADASH for the control of essential hypertension by evaluating its adjunctive therapeutic effect on BP, drug requirements and heart function tests like echocardiography.

METHODS

This was a longitudinal interventional study and part of an ongoing open controlled clinical trial of a Personalized Food Avoidance Dietary Approach to Stop Hypertension.

The study was carried out at Medical Outpatient Unit/Department, University of Nigeria Teaching Hospital and Chiolive International Medical Research Organization (CIMRO), Trans-Ekulu Enugu from 2015 to 2019.

The protocol for the open controlled clinical trial of PFADASH was approved by the University of Nigeria Teaching Hospital ethics committee (certificate no. NHREC/05/01/2008B-FWA00002458-IRB00002323).

Inclusion criteria:

Average automated office BP exceeds 140/90 but below 160/100mm Hg (or exceeds 130/80 if additional vascular risk) regardless of treatment or drug adherence.

On one or two antihypertensive drugs (good adherence, on less than three antihypertensives), regardless of whether BP controlled (exceeding 160/100 however)

Study participants are adults (age above 17 years, not pregnant), sufficiently literate to follow detailed dietary instructions, have freely given full consent, and undertaken their normal daily activities and attended the outpatient clinic without difficulty.

Exclusion criteria:

Disabling complications of hypertension such as secondary hypertension.

e.g. diabetes, chronic kidney disease, sickle cell disease, history of heart attack, stroke, transient ischemic attack (TIA), heart failure.

Manual, home and automated office BP measurements were used to monitor BP control in study participants. Manual and automated office BP measurements were done at least once a month per visit.

Average Home BP recordings of study participants was collated monthly from their home BP record books.

For the PFADASH intervention, Dietary Compliance Scoring was based on exposure to:

A) Primary culprits: amphiphilic fat and oils, glutamatergic flavor enhancers, non-sugar sweetners

B) Secondary (facultative) culprits [food dislikes, autacoids, modest flavourant, or sweetener content, preservatives, unduly frequent/high dose consumption of normally tolerated foods]

GOOD dietary compliance means that there is established MAJOR (category A) dietary indiscretion less than once a month [OR minor (category B) indiscretion less than once a fortnight]. POOR dietary compliance means that there is established MAJOR dietary indiscretion once a month or more frequently [OR minor indiscretion once a fortnight or more frequently].

Rx: Unitary daily dosage of anti-hypertensive drugs was defined as follows: hydrochlorothiazide 25 mg, amlodipine 5 mg, atenolol 25 mg, prazosin 1 mg, lisinopril 5 mg, enalapril 5 mg, ramipril 2.5 mg, losartan 25 mg, telmisartan 20 mg, frusemide 20 mg, methyldopa 250 mg, valsartan 80 mg.

ADTR score was determined by adding or subtracting 0.1 to Actual treatment score for every mmHg that average systolic automated office blood pressure or average systolic home blood pressure get higher or lower than 120 and 100 mmHg respectively.

Echocardiogram indices (diastolic function, interventricular septum thickness and left ventricular ejection fraction) for heart function was assessed at baseline and 6-month intervals.

Exercise assessments were done at baseline and 3monthly to evaluate usual exercise habits and maximum exercise tolerance. Usual exercise habits were evaluated using the international physical assessment questionnaire. Maximal exercise tolerance on a treadmill was evaluated with regard to the following indices: Max oxygen consumption: VO2 max (ml/kg/min), Exercise metabolic equivalent (Kcal/kg/hr.)

Sleep deprivation index (SDI) was scored based on hours of sleep. 0 SDI indicate greater than 8 hours sleep per night, 1 SDI indicate 6 to 8 hours sleep while 2 SDI indicate less than 6 hours sleep per night.

Data was analyzed using Statistical Package for Social Sciences version 25 and Microsoft Excel.

Intervention and control subjects were compared at three monthly time points.

RESULTS

Table 1: Comparison between baseline and last BP scores of study participants with good and poor dietary compliance to a PFADASH.

	Baseline	Last	Mean difference	t	p-value
Good dietary compliance (n = 3)					
HOBP	132.00±5.29	119.33±3.79	12.67	2.448	.134
AOBP	114.33±5.69	115.67±19.14	-1.33	-.111	.922
Poor dietary compliance (n = 4)					
HOBP	130.50±15.95	128.75±20.22	1.75	.418	.704
AOBP	134.25±13.84	131.50±9.88	2.75	.291	.790

HOBP: Home Office Blood Pressure
AOBP: Automated Office Blood Pressure

Table 2: Relationship between Dietary Compliance and Home/Automated office Blood Pressure

SP Code		HOBP	AOBP
2UG (Good DC)	Pearson Correlation	-.466	.194
	p-value	.292	.677
	N	7	7
5UN (Poor DC)	Spearman Correlation	.040	-.289
	p-value	.870	.296
	N	19	15
12AN (Good DC)	Pearson Correlation	-.444*	-.422
	p-value	.038	.051
	N	22	22
3AF (Good DC)	Pearson Correlation	-.715*	-.338
	p-value	.002	.237
	N	16	14
23OU (Poor DC)	Spearman Correlation	-.664*	-.382
	p-value	.018	.220
	N	12	12
24OP (Poor DC)	Spearman Correlation	.664	-.674
	p-value	.150	.097
	N	6	7
35NB (Poor DC)	Spearman Correlation	-.225	-.102
	p-value	.506	.752
	N	11	12

**** significant relationship exist***

Table 3: Test of Normality Result of AdhRX Score and ADTR Score Using Shapiro-Wilk Statistic

AdhRX Score	Statistic	df	p-value
1st Quarter 2016- 1st	.872	8	.156*
1st Quarter 2016- last	.807	8	.034+
2nd Quarter 2016- 1st	.950	9	.691*
2nd Quarter 2016- last	.907	9	.299*
3rd Quarter 2016- 1st	.881	7	.232*
3rd Quarter 2016- last	.888	7	.263*
4th Quarter 2016- 1st	.891	8	.237*
4th Quarter 2016- last	.863	8	.130*
1st Quarter 2017- 1st	.830	6	.107*
1st Quarter 2017- last	.747	6	.019+
2nd Quarter 2017- 1st	.924	6	.536*
2nd Quarter 2017- last	.726	6	.011+
3rd Quarter 2017- 1st	.954	4	.740*
3rd Quarter 2017- last	.855	4	.242*
4th Quarter 2017- 1st	.979	4	.896*
4th Quarter 2017- last	.975	4	.872*
ADTR Score			
1st Quarter 2016- 1st	.842	8	.079*
1st Quarter 2016- last	.835	8	.067*
2nd Quarter 2016- 1st	.933	9	.513*
2nd Quarter 2016- last	.876	9	.141*
3rd Quarter 2016- 1st	.960	7	.816*
3rd Quarter 2016- last	.932	7	.568*
4th Quarter 2016- 1st	.842	8	.078*
4th Quarter 2016- last	.780	8	.017+
1st Quarter 2017- 1st	.815	6	.080*
1st Quarter 2017- last	.764	6	.027+
2nd Quarter 2017- 1st	.865	6	.206*
2nd Quarter 2017- last	.694	6	.0054
3rd Quarter 2017- 1st	.930	4	.595*
3rd Quarter 2017- last	.843	4	.203*
4th Quarter 2017- 1st	.888	4	.375*
4th Quarter 2017- last	.917	4	.523*

**** Score is normally distributed at 5% level of significance; + Score is normally distributed at 1% level of significance***

Table 4: Comparison of ADTR Score between Participants with Good and Poor Dietary Compliance for the open trial.

Dietary Compliance	N	M±SD	Mean difference	t	Point-Biserial Correlation	p-value
Last ADTR score						
Good	3	0.87±0.81	-2.43	-1.667	.598	.156
Poor	4	3.30±2.38				
Penultimate ADTR score						
Good	3	1.28±0.93	-3.05	-1.241	.485	.270
Poor	4	4.33±4.08				
Mean (last and penultimate)						
Good	3	1.07±0.82	-2.74	-1.438	.541	.210
Poor	4	3.81±3.15				

Table 5: Relationship between Dietary Compliance and ADTR Score

Study Participant	Statistic	N (no of time points for assessments)	Correlation Coefficient	p-value
2UG	Point-Biserial	6	-.714	.111
5UN	Spearman	12	-.174	.590
12AN	Point-Biserial	19	-.623	.004
3AF	Point-Biserial	14	-.631	.016
23OU	Spearman	10	.000	1.000
35NB	-	-	-	-
24OP	Spearman	9	.718	.029

Table 6: Comparison of VO2max and LVEF between study participants with good and poor dietary compliance.

	Poor M±SD	Good M±SD	t	p-value
VO2max				
- Endpoint score	41.00±7.07	38.73±8.81	-.300	.784
- Average score	37.38±12.20	32.80±13.85	-.376	.732
LVEF				
- Endpoint score	79.00±1.41	69.00±12.12	-1.103	.351
- Average score	76.75±1.06	69.00±11.53	-.900	.435

Table 7: Comparison between baseline and endpoint VO2max and LVEF

	Baseline	Endpoint	Mean Increase	t	p-value
Good dietary compliance (n = 3)					
- VO2max	20.13±8.63	38.73±8.81	18.60	2.535	.127
- LVEF	55.00±13.89	69.00±12.12	14.00	2.542	.126
Poor dietary compliance (n = 2)					
- VO2max	34.60±14.28	41.00±7.07	6.40	1.255	.428
- LVEF	62.00±4.24	79.00±1.41	17.00	8.500	.075

Table 8: Social isolation/ Sleep Deprivation Index scores

SP CODE	SOCIAL ISOLATION INDEX	SLEEP DEPRIVATION INDEX	SOCIAL STATUS
PHT2UG	1	0	MIDDLE CLASS
PHT3AF	0.5	1	UPPER CLASS
PHT5UN	0.5	0	UPPER CLASS
PHT23OU	0.5	0	MIDDLE CLASS
PHT35NB	1	1	MIDDLE CLASS
PHT24OP	0.5	0	MIDDLE CLASS
PHT12AN	1	0	MIDDLE CLASS

DISCUSSION

With increasing prevalence, morbidity and mortality from essential hypertension globally, there is urgent need to optimize the immune system to stem the tide of immune mediated inflammatory diseases of which EH fall in the spectrum. A PFADASH is perceived to address primary and secondary immune intolerances of different individuals to different foods as well as exposures to toxic food substances suspected to drive adverse gene expressions.

Blood pressure of study participants with poor dietary compliance had higher BP scores with higher variability compared to those with good dietary compliance that abstained from a PFADASH incompatible food substances like food additives and hydrogenated fats, although the difference between the scores was not significant, lower BP scores and variability suggest better BP control in study participants with good dietary compliance. Moreover, there is a significant relationship between dietary compliance of some of the SPs with the BP scores.

Study participants remained on the already prescribed antihypertensive medication they required for control of their blood pressure. This was an ethical requirement insofar as we expected variable efficacy of the PFADASH depending on the degree and durability of compliance by the study participants. Even with good dietary compliance, we expected a delay of a few weeks to a few months for full reversibility of diseases pathogenesis to become apparent.

For AdhRX and ADTR scores all sets of data were normally distributed. Both scores

showed more than 80% likelihood of being normally distributed at 5% significance level. Means of AdhRx and ADTR scores of study participants with good dietary compliance was associated with lower scores than those with poor compliance, although the difference in each was not significant and may be due to sample size. Although seven study participants who met the inclusion/exclusion criteria of the study were included, repeated measures of the evaluated parameters would correspondingly reduce the number of participants required.

There was a slight improvement echocardiographic parameter: Left Ventricular Ejection Fraction (LVEF) of SPs with good DC which suggest that a PFADASH may have positive effects on cardiac functions.

Although VO2 max was not different in the two groups, SPs with good DC had better exercise tolerance. Sleep Deprivation Index Assessment of SPs showed that they had similar sleep patterns. Therefore, there was no confounding impact of exercise and sleep habits of SPs in respect to the efficacy of a PFADASH for the control of EH.

A high-performance liquid chromatography was not used to ascertain drug metabolites in serum or urine of study participants and be correlated to ADTR and AdhRx scores. This is a limitation of this study. Furthermore, arterial stiffness parameters to ascertain indices like pulse wave velocity was not done. This is another limitation to this study. Improvement of pulse wave velocity in study participants with good dietary compliance may indicate immune optimization and lesser arterial thickening/ infiltration of dysfunctional T lymphocytes which may mediate pathogenesis of EH (Okafor 2024).

CONCLUSION

A PFADASH may be effective in abating the phenotypic expression of hypertension. Compliance to the dietary principles of a PFADASH is fastidious as it excludes most of modern food menus and may not be of benefit or serve as a therapeutic adjunct to those that lack the will or determination to adhere to the dietary regimen. However, study participants evaluated on this diet have shown reduced antihypertensive drug treatment requirements while maintaining good blood pressure control.

These observations have demonstrated some therapeutic effects a PFADASH and should be of great importance in demonstrating the actual aethiopathogenic mechanism, of the interaction between our diet and our genome, in the aethiopathogenesis of essential hypertension.

Informed consent

All study participants consented to the study.

Availability of Research data

Available on request to the corresponding author

Declaration of Helsinki

We declare that the study was conducted in accordance with the principles of Helsinki declaration.

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Nil.

Conflicts of Interest

There are no conflicts of interest.

References

Chijioke CP, Chijioke OU, Okolo T. (2012). Personalized diet for psoriasis: side benefit on

blood pressure and metabolic parameters. Presented at 24th meeting of the International Society of Hypertension, Sydney, Australia. J Hypertension 2012b; 30: e-suppl 1, poster 158.

Chioli Chijioke , Chika Ndiokwelu , Nnamdi Nwosu , Michael Okafor , Imelda Nubila , Nnenna Chigbo , Raphael Anakwue , Chijioke Okoli , Nwanneka Gbenimachor , Nwokolo Bridget , Christopher Amah. (2016). Open clinical trial of a personalized food avoidance dietary counselling for the control of essential hypertension. Journal of hypertension. E-suppl. (34): e295.

Chijioke Pascal Chijioke , Michael Okafor , Imelda Nubila , Ifeoma Onah , Nnenna Chigbo , Raphael Anakwue , Ignatius Maduka , Iniekong Udoh , Nwanneka Gbenimachor , Nkeiru Mbadiwe , Chikere Anusiem , Christopher Amah , Nnamdi Nwosu , Angela Muobike , Bridget Nwokolo , Ifeoma Udorah , Josiah Nnadozie , Patience Nwonu , Chinyere Okwara , Lovette Orji , Kenneth Nwadike , Uzoamaka Okoli , Raymond Offiah , Ifeyinwa Uami , Clara Eleazar , Ngozi Ironkwe , Esther Ekwe , Udumma Chijioke , Ebele Aniagor , Aron Okpe , Nkiru Onwuka-Kalu. (2018) Controlled clinical trial of personalized food avoidance dietary approach to stop hypertension (PFADASH): 2 YEARS FOLLOW-UP REPORT. Vol 36 e-supplement October.

Mrowietz U, Elder JT, Barker J. (2006). The importance of disease associations and concomitant therapy for the long-term management of psoriasis patients. Arch Dermatol Res 2006; 298: 309-319.

Michael T. Okafor, Queenet C. Onyebuchukwu, Germaine A. Okafor, Samuel C. Niteh, Chikere A. Anusiem. (2024) Immune Optimization as a Preventive and Therapeutic Adjunct for the Management of Renin-Angiotensin-Aldosterone System Dysfunction Diseases: A Review. International Journal of Medicine and Health Development; 29:161-9.

Okafor MT, Onyebuchukwu QC, Mbah AU. (2023) Immune Optimization as a preventive and therapeutic adjunct for management of metabolic syndrome associated disorders: a review of the literature. Afr J Endocrinol Metab; 13: 1-7.

Okafor MT. (2024) Putative Mechanisms of Immune Dysfunction in the Pathogenesis of Type 1 Diabetes Mellitus: A Scoping Review. Niger J Paediatr. Vol 51, Issue No. 4.

Practice guidelines. American family Physician. 2021;103(12):763-765

Sacks FM, et al. (2001) Effects on blood pressure of reduced dietary sodium and the dietary approaches to stop hypertension (DASH) diet. N Engl J Med;344(1):3-10

Teresa TF, Frank HU, Kana WU, Stephanie EC, Charles SF, Edward G. (2010) The Mediterranean and dietary approaches to stop hypertension (DASH) diets and colorectal cancer. Am J Clin Nutr; 92(6): 1429-1435

Shirinsky IV, Shirinsky VS. (2007) Efficacy of simvastatin in plaque psoriasis: a pilot study. J Am Acad Dermatol; 57: 529–31

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