International Clinical Study of *Power QuickZap* and *Powertube QuickZap* (TENS) as a New Mode of Therapy In Hypertension and Diabetes

(A Randomized Controlled Trial)

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ABSTRACT

Background:

Trans-cutaneous electrical nerve stimulation (TENS) had been a modality for decades now. Its hypoalgesic, hypotensive and hypoglycemic effects have been published in several literatures. This trial aims to determine the effectiveness of the new machine Power QuickZap and Powertube QuickZap (TENS) in controlling blood pressure and glucose in a randomized controlled clinical trial.

Rationale:

The control of hypertension and diabetes requires multifaceted approach. Patients, despite professional advice seek other forms of therapy that can address their health needs. The use of TENS has been shown to be an alternative and safe modality in alleviating pain and discomfort. This trial will provide baseline information in objective outcomes as blood pressure and glucose levels in addition to patient-based subjective assessment.

Design: Randomized controlled trial

Category: Internal medicine, Alternative & Complementary Medicine, Neurology, Endocrinology, Vascular Medicine

Setting: Malolos San Ildefonso County Hospital

Patients and Methods:

All adult patients ages 19 and above with a primary diagnosis of hypertension using the current JNC VII as well diabetes mellitus using the American Diabetes Association criteria were randomly selected from a community based list of the said morbidities. Systematic sampling resulted into the enrolment of 104 hypertensives and 67 diabetics (total n=171) were subjected to daily TENS using the Power QuickZap and Powerube QuickZap equipment applied to forearm or hand at least 3 minutes daily for 30 days . Outcomes include comparison of mean blood pressure, lipid profile, glucose indices signs and symptoms from baseline until post-intervention.

Results :

A total of 104 hypertensives (61%) were randomly allocated to receive medications plus trans-cutaneous electrical nerve stimulation (TENS-Power QuickZap and Powertube QuickZap) (53 or 51%) and no medications plus TENS (51 or 49%). Among the diabetics subgroup (total n=67), 39 patients were randomized to receive medications plus TENS
(58%) while 28 cases (42%) received only TENS. No drop outs were noted . Those treated with TENS alone showed a mean drop in SBP which was noted during the 10^{th} to the 12^{th} day (SBP mean difference 8 mmHg, p=.036) while DBP dropped during the first week of treatment (DBP mean difference =2.5 mmHg, *p*=.022). No difference in glucose values existed between the two groups.

Conclusion:

TENS using the Power QuickZap and Powertube QuickZap can be an adjunct therapy in the lowering of blood pressure, triglycerides and VLDL among patients with hypertension especially those not currently

taking anti-hypertensive medications. Its effect on glucose levels of diabetics has to be examined in large scale studies. Diabetic neuropathy may benefit from TENS.

Key Words: trans-cutaneous electrical nerve stimulation, hypertension, diabetes

Transcutaneous Electrical Nerve Stimulation (TENS) POWER QUICKZAP and POWERTUBE QUICKZAP:
A New Mode of Therapy in Hypertension and Diabetes

INTRODUCTION:

Type 2 Diabetes is a growing health problem, with the prevalence of the disease set to rise dramatically in Westernized societies. Individuals with diabetes have a life expectancy that can be shortened by as much as 15 years, with up to 75% dying of macrovascular complications.[1] Diabetes mellitus is a leading cause of morbidity and death in the United States. It affects an estimated 16 million Americans, 11 million of whom have both diabetes and hypertension. Type 2 Diabetes mellitus accounts for the majority of affected persons (90% – 95%) and affects older adults particularly those older than 50 years of age.[2] In England around 1.3 million people are currently diagnosed with diabetes and incidence is increasing in all age groups.[3] Most adverse diabetes outcomes are results of vascular complications. These complications are generally classified as microvascular, such as retinopathy, nephropathy, and neuropathy, or macrovascular, such as coronary artery disease, cerebral vascular disease and peripheral vascular disease.[4] In order to prevent or diminish the progression of microvascular and macrovascular complications, recommended diabetes management necessarily encompasses both metabolic control and cardiovascular risk factor control.[5] Another common health problem that comes

without symptoms until the late stages when the first symptom may be a heart attack or stroke is high blood pressure, often called “The Silent Killer”.

An elevated arterial pressure is probably the most important public health problem in developed countries. Heart disease and stroke claim the lives of 17 million people a year worldwide, this means one in 3 deaths globally is due to heart disease and stroke.[6] A higher prevalence has been documented in the nonwhite population. In females the prevalence is clearly related to age, with a substantial increase occurring after age 50, thus the ratio of hypertension frequency in women versus men increase from 0.6 to 0.7 at age 30 to 1.1 to 1.2 at age 65.[7] Hypertension is usually a result of genes, lifestyle factors, disease factors such as diabetes or high blood sugar, high cholesterol, stroke, heart disease. If you have high blood pressure, you are more likely to suffer from: heart attack, stroke, kidney damage and other complication involving your blood vessels, heart and brain. Several classes of drugs are available to treat Hypertension such as: Vasodilators, ACE inhibitors, angiotensin – receptor blockers, and calcium channel blockers. Interventions to delay or prevent type 2 diabetes and hypertension have the potential to improve the health of a population and reduce the burden of healthcare costs. Interventions were either lifestyle, comprising diet and exercise interventions, or pharmacological and herbal.[8] While several studies have the clinical effectiveness of both pharmacological and lifestyle interventions in significantly reducing the risk of type 2 diabetes and hypertension, several issues and controversies remain. Determining the best approach to intervention be it pharmacological or lifestyle

is not yet resolved. For pharmacological interventions adverse effects need to be fully understood to enable potential harms and benefits to be assessed.

Because of the issues of effectiveness and safety of pharmacological interventions in the management of hypertension and diabetes a newly discovered Transcutaneuos Electrical Nerve stimulant appliance called Power QuickZap and Powertube QuickZap can be used as alternative mode of therapy for hypertension and diabetes. The transcutaneous electrical nerve stimulation Power QuickZap and Powertube Quickzap is a battery – operated electronic equipment which can be handled easily to the nerve stimulation. Appropriate points of nerve are stimulated by electronic impulses directly and to know so the body – own energy level to affect. The self treatment is harmless and without side effects.

RATIONALE:

Transcutaneous electrical nerve stimulation (TENS) has been an existing therapeutic modality for pain relief and was previously considered an alternative form of treatment. Certain patients despite professional advice prefer an “all natural form of treatment”. This places the physician in a decision to embark on western medical regimen which is mostly pharmacologic in nature.

OBJECTIVES:

This study aims to *(a)* determine the effect of Power QuickZap and Powertube QuickZap in patients with hypertension and diabetes by lowering blood pressure, blood sugar and cholesterol, *(b)* to compare the effects of Power QuickZap and Powertube QuickZap among patients with hypertension without medications and hypertension with antihypertensive medications based on blood pressure and lipid profile,

(c) to compare the effects of Power QuickZap and Powertube QuickZap among patients with diabetes without medications and diabetes with oral hypoglycemic agents based on fasting blood sugar and hemoglobin A1c, *(d)* to know the effects of Power QuickZap and Powertube QuickZap on constitutional symptoms of hypertension (chest pain, dizziness, nape pain and palpitations) and diabetes (peripheral neuropathy, polydipsia, and polyuria).

METHODOLOGY:

This is a single blind, parallel randomized controlled trial involving TENS in both diabetic and hypertensive subjects. The study took place last March 19 2007 to April 19 2007) involving adult patients ages 18 and above with hypertension and

diabetes, utilizing the transcutaneous electrical nerve stimulator Power QuickZap Powertube Quickzap therapy. An initial sampling frame separate for diabetes and hypertension were assembled. Criteria for diagnosis of hypertension was based on the current JNC VII criteria and diabetes mellitus was based on the American Diabetes Association Criteria for adult onset diabetes (DM Type II). Once informed consent was signed, a simple random sample was obtained using systematic random sampling of every 3rd patient in the list. The sample size requirement was met generating a computed study power of 86% at a type II error of 20% at .05 alpha level of significance. Included in the study were the following hypertensive with and without medications, diabetic with and without medications, male and female , ages 18 years old and above. Excluded in the study were hypertensive and diabetic with co-morbidities, those with severe coronary artery disease or those with implantable electrical devices (cardiac pacemakers, insulin pumps) that can be jolted by TENS. Patients included in the study were categorized as follows: hypertensive without medications, hypertensive with medications, diabetic without medications and diabetic with medications. Randomization was done using simple concealed allocation facilitated by an independent and blinded personnel. A patient selects a sealed envelope containing the group assignment. This was shown to the doctor in-charge where baseline data were gathered using a standardized data collection form.

Demographic profile (age and sex),constitutional symptoms, vital signs (BP& HR), lipid profile (total cholesterol, triglycerides, LDL, HDL, VLDL) for hypertensive and FBS & HgbA1c for diabetics were taken initially before they were subjected to the Power QuickZap and Powertube QuickZap. Patients included in the study were subjected to a 3 minute Power QuickZap and Powertube QuickZap therapy on a daily basis for a 30 - day period. Patient's response were monitored as follows : BP was monitored during daily session, including the symptoms, repeat FBS at the end of the session was taken, repeat of lipid profile and HgbA1c after completion of 30 - day session with Power QuickZap and Powertube Quickzap therapy. Results of the above parameters were compared with the baseline values. ***Statistical Analysis:*** All analyses were done using the intention to treat principle. Descriptive statistics include mean and the standard error of the mean for continuous numerical variables, while percentage frequency distribution for the categorical variables. Tests of homogeneity of sample at baseline was done using Fisher exact test for categorical data and Mann Whitney U test for continuous variables. Comparison of mean blood pressure across days and weeks of observation was done using the general linear model repeated measures analysis of variance. Tests of multiple comparison was done using Tukey's test.

All analyses were performed by a blinded statistician using STATA version 7 with outcomes having statistical *p*-values less than 0.05 were considered statistically significant.

ETHICAL ISSUES:

This clinical trial conforms with the Declaration of Helsinki and the code of Good Medical Practice in the use of humans as research subjects. All patients were informed of the nature of the interventions. Those patients who were not maintained on any medications were asked to renew their decision daily and were ultimately considered drop-outs.

RESULTS:

A total of 171 subjects met the inclusion criteria. A total of 104 hypertensives (61%) were randomly allocated to receive medications plus trans-cutaneous electrical nerve stimulation (TENS-Power QuickZap and Powertube QuickZap) (53 or 51%) and no medications plus TENS (51 or 49%). In the 67 diabetic subgroup (total n=67), 39 patients were randomized to receive medications plus TENS (58%) while 28 cases (42%) received only TENS. At baseline, hypertensive patients randomized to the intervention arm (medications plus TENS) had a statistically higher mean age than the control group (mean 59 versus 56 years, p=.031). However, after adjusting for such variable in the main outcome, no age was not a significant co-variate in the analysis of the final systolic and diastolic blood pressures (p=.08). Sex distribution, initial systolic and diastolic blood pressure, lipid profile and complaints such as chest pain,

dizziness, nape pain and palpitations did not significantly vary at baseline. (all *p*-values were above.05) (Table-1)

In the diabetic subgroup, age, sex, initial fasting glucose levels, glycosylated hemoglobin, and symptoms such as neuropathy, polydipsia did not significantly vary between the two groups (all *p*-values were >.05) Only the percentage of reported polyuria was statistically higher in the treatment rather than the control arm was noted (79% versus 54%, *p*=.033). After adjusting for this co-factor, no significant difference in outcomes was noted (*p*=.076) (Table-2)

Table – 1. **Baseline Demographic and Clinical Profile of Patients with Hypertension**

Characteristic	Power QuickZap Powertube QuickZap with Medications N=53 (%)	Power QuickZap Powertube QuickZap without Medications N=51 (%)	*p*-value*
Age (Years)			
Mean ± SE	59 ± 1.3	56 ± 1.4	***.031†***
Range	37 - 83	37 – 80	
Sex			
Male	14 (27)	12 (24)	.82 (NS)
Female	39 (73)	39 (76)	
Systolic BP (mm Hg)			
Mean ± SE	152 ± 3	152 ± 3	.48 (NS)
Range	120-200	110 -200	
Diastolic BP (mm Hg)			
Mean ± SE	92 ± 2	93 ± 1	.47 (NS)
Range	70-120	80- 110	
Symptoms			
Chest pain	42 (79)	38 (74)	.64 (NS)
Dizziness	40 (75)	36 (70)	.66 (NS)
Nape pain	42 (79)	36 (70)	.29 (NS)
Palpitations	37 (70)	31 (61)	.41 (NS)

Lipid Profile			
Total cholesterol	258 ± 8.8	255 ± 9	.84 (NS)
Triglycerides	162 ± 10	184 ± 9	.12 (NS)
HDL	29 ± 6	31 ± 3	.80 (NS)
LDL	200 ± 10	181 ± 11	.19 (NS)
VLDL	33 ± 3	36 ± 2	.18 (NS)

*Significant difference if p-value is <.05, Fisher Exact Test, ** Mann Whitney U-test
SE –Standard error of the mean, NS –not significant, † -non-significant co-variate by regression

Table – 2. **Baseline Demographic and Clinical Profile of Patients with Diabetes Mellitus type 2**

Characteristic	Power QuickZap Powertube QuickZap with Medications N=39 (%)	Power QuickZap Powertube QuickZap without Medications N=28 (%)	*p*-value*
Age (Years)			
Mean ± SE	59 ± 12	55 ± 13	.12 (NS)**
Range	20-77	30-85	
Sex			
Male	18 (46)	7 (25)	.065 (NS)
Female	21 (54)	21 (75)	
Fasting Blood Sugar			
Mean ± SE	183 ± 10	179 ± 15	.21 (NS)
Range	84 - 338	82 -464	
Hemoglobin A1c			
Mean ± SE	8.3 ± 0.27	8.6 ± 0.28	.28 (NS)
Range	5.1 – 11.8	5.2 -11.2	
Symptoms			
Neuropathy	32 (82)	17 (61)	.92 (NS)
Polydipsia	30 (77)	15 (54)	.065 (NS)
Polyuria	31 (79)	15 (54)	***.033*** †

*Significant difference if p-value is <.05, Fisher Exact Test, ** Mann Whitney U-test
SE –Standard error of the mean, NS –not significant, , † -non-significant co-variate by regression

Comparison of Blood Pressures Among Hypertensives Across Period of Observation

In terms of the systolic blood pressure (SBP), the mean drop was noted statistically from baseline and all throughout the 30-days (4 weeks) of observation in both the TENS without medications group and the TENS plus medications group (*p*=.028 within groups comparison) (See figure-1). Comparing between the two interventions, the mean SBP was statistically lower in the TENS without medications group than those with concomitant medications (red line is under the blue line) (*p*=.010 between groups comparison).

Using Tukey's test, the most observable significant difference was during the 10th to the 12th day of treatment with TENS only. (*p*=.036) (See table-3)

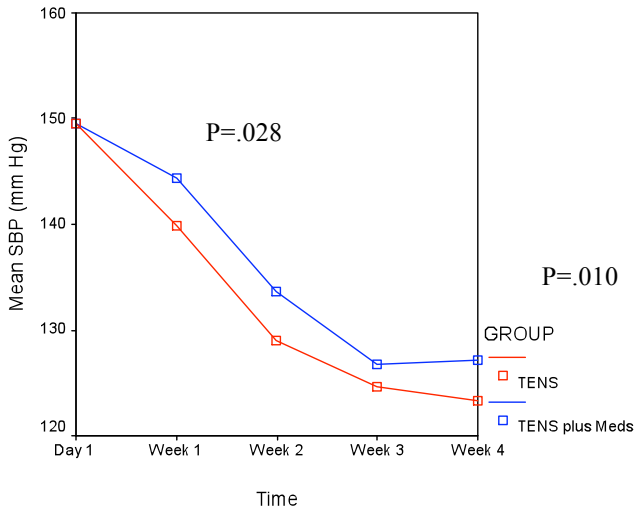

Figure -1. **Comparison of Systolic BP in Hypertension treated with TENS with or without Medications**

In terms of the diastolic blood pressure (DBP), the mean drop was noted statistically from baseline and all throughout the 30-days (4 weeks) of observation in both the TENS without medications group and the TENS plus

medications group (*p*=.018 within groups comparison) (See figure-2). Comparing between the two interventions, the mean SBP was statistically lower in the TENS without medications group than those with concomitant medications (red line is under the blue line) (*p*=.041) using between groups comparison.

Using Tukey's test, the most observable significant difference was during the 4th to the 5th day of treatment with TENS without medications group. (*p*=.022)

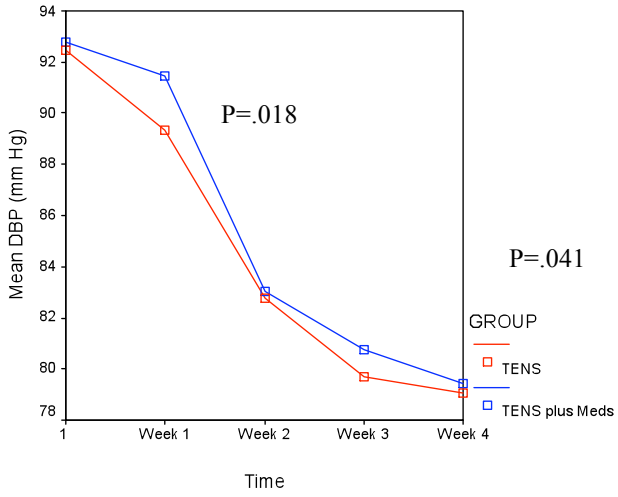

Figure – 2. **Comparison of Systolic BP in Hypertension treated with TENS with or without Medications**

Post Hoc Analysis

Systolic blood pressure levels approached age- adjusted normal values at the 2nd week of treatment (10th -12th days). Using Tukey's test of honestly significant difference, observed statistical lower SBP levels was noted with the TENS without medications group at the 2nd week of therapy . (SBP mean difference 8

mmHg, *p*=.036) while diastolic pressure difference was observed more during the first week of therapy (DBP mean difference= 2.5 mm Hg *p*=.022). (Table- 3)

Table – 3. **Post Hoc Analysis on the Actual Mean Differences in Systolic and Diastolic Blood Pressure**

	Systolic Blood Pressure			
Days of Observation	**TENS plus Medications (mm Hg)**	**TENS Only (mm Hg)**	**Mean Difference**	***p*-value***
Week 1	148 ± 3	140 ± 2	8	.054 (NS)
Week 2	137 ± 4	129 ± 3	8	***.036***
Week 3	129 ± 5	127 ± 1	2	.11 (NS)
Week 4	128 ± 2	122 ± 1	6	.07 (NS)
	Diastolic Blood Pressure			
Week 1	91.7	89.2	2.5	***.022***
Week 2	83.1	83	0.1	.98 (NS)
Week 3	81.2	79.6	1.6	.33 (NS)
Week 4	79.6	79.4	0.2	.31 (NS)

*Significant difference if p-value is <.05, repeated ANOVA

Effect of TENS on Serum Lipids in Hypertensive Individuals:

After 4 weeks of treatment, patients randomized to the TENS only arm had *statistically* lower serum triglycerides (160 versus 189 mg/dL, mean difference= 29 mg/dL) p=.003 and lower VLDL values (32 versus 38 mg/dL, mean difference 6 mg/dL, p=.001). No difference in the total cholesterol, LDL and HDL values were noted. (p-values > .05) (See Table-4)

Table – 4. **Lipid Profile and other Signs and Symptoms After TENS Therapy**

Parameter	TENS plus Medications (mm Hg)	TENS Only (mm Hg)	p-value
Total cholesterol			
Baseline	258 ± 8.8	255 ± 9	.84 (NS)
Post Intervention	196.6 ± 60	205 ± 45	.45 (NS)
Triglycerides			
Baseline	162 ± 10	184 ± 9	.12 (NS)
Post Intervention	189.7 ± 8	160 ± 6	***.003***
HDL			
Baseline	29 ± 6	31 ± 3	.80 (NS)
Post Intervention	58 ± 2	65 ± 10	.51 (NS)
LDL			
Baseline	200 ± 10	181 ± 11	.19 (NS)
Post Intervention	105 ± 7	120 ± 7	.13 (NS)
VLDL			
Baseline	33 ± 3	36 ± 2	.18 (NS)
Post Intervention	38 ± 2	32 ± 1	***.001***

*Significant difference if p-value is <.05, repeated ANOVA

Effect of TENS on Signs and Symptoms of Hypertension

Chest pain was significantly reduced in the 3rd week of treatment. (45% versus 67%, p=.04). Overall percentage reduction in the frequency of signs and symptoms of hypertension did not statistically differ between the two groups across the days of observation. (all p-values were >.05) (Table-5)

Table – 5. **Effect of TENS on Signs and Symptoms of Hypertension**

	Overall Percentage Reduction * in Frequency From Baseline (TENS + Meds versus TENS only)			
Signs & Symptoms	**Week 1 %**	**Week 2 %**	**Week 3 %**	**Week 4 %**
Chest pain	12 / 9 p=.33 (NS)	33 / 57 p=.13	45 / 67 p=.04	72 / 78 p=.11 (NS)
Dizziness	19/ 12 p=.22	32 / 30 p=.11	38 / 32 p=.22	37 / 39 p=.32
Nape pain	28 / 14 p=.23	37/ 35 p=.33	45/48 p=.32	48 / 56 p=.08
Palpitations	26 / 27 p=.33	31 / 39 p=.33	55/67 p=.07	98/89 p=.56

*Percentage reduction = $\frac{\text{frequency at baseline - frequency at end of week}}{\text{frequency at baseline}} \times 100$

*significant difference in proportion if <.05, Z-test for proportions

Subgroup Analysis for Diabetic Subjects

Comparing between groups, glucose levels decreased from baseline in both arms (TENS plus meds, mean difference=4 mg/dL while for TENS without

medications =27 mg/dL) (see table-6) and this drop in levels was statistically significant within each group (p=.03), however comparing between both arms at post intervention, this was not statistically different (p=.07)

No difference was observed with glycosylated hemoglobin post treatment. (*p*=.18)

Table – 6. **Effect of TENS on Fasting Glucose, Glycosylated Hemoglobin and Signs and Symptoms of Diabetes**

Parameter	TENS plus Medications	TENS Only	Mean Difference	p-value* (between groups)
Fasting Glucose (mg/dL)				
Baseline	183 ± 10	179 ± 15	4	.21 (NS)
Post-Intervention	179 ± 11	152 ± 12	27	.07 (NS)
Mean Difference	4	27	--	--
Within groups p-value*	***p*=.03**	***p*=.03**		
Hemoglobin A1c (%)				
Baseline	8.3 ± 0.27	8.6 ± 0.28	- 0.3	.28 (NS)
Post-Intervention	8.2 ± 0.22	8.6 ± 0.27	-0.4	.18 (NS)
Mean difference	0.1	0	--	--
Within groups p-value*	p=.23	p=.23		

*Significant difference if p-value is <.05, repeated ANOVA

Effect of TENS on the Signs and Symptoms of Diabetes

A significant reduction in perceived peripheral neuropathy was observed among those with TENS treatment alone especially noted at the 3rd and 4th week of

therapy. (45% TENS + medications versus 67%-TENS alone, p=.04; 70% versus 88%, p=.016 respectively). (see table-7)

Table -7. **Effect of TENS on Signs and Symptoms of Type 2 Diabetes Mellitus**

	Overall Percentage Reduction * in Frequency From Baseline (TENS + Meds versus TENS only,)			
Signs & Symptoms	**Week 1 %**	**Week 2 %**	**Week 3 %**	**Week 4 %**
Peripheral neuropathy	12 / 13 p=.33 (NS)	33 / 57 p=.13	45 / 67 ***p=.04***	70 / 88 ***p=.016***
Polydipsia	28 / 14 p=.23	37/ 35 p=.33	45/48 p=.32	48 / 56 p=.08
Polyuria	12 / 9 p=.33 (NS)	33 / 57 p=.13	45 / 67 p=.04	72 / 78 p=.11 (NS)

*Percentage reduction = $\frac{\text{frequency at baseline - frequency at end of week}}{\text{frequency at baseline}} \times 100$

*significant difference in proportion if <.05, Z-test for proportions

DISCUSSION:

This trial aims to compare the effectiveness of trans-cutaneous electrical nerve stimulation (TENS) using a simple battery operated portable equipment commonly known as the Power QUICKZAP and Powertube QUICKZAP on blood

pressure and glucose levels of hypertensive and diabetes type 2 patients respectively with and without any maintenance medications. Our parameters of outcome include a 30-day observation of the fluctuations in systolic and diastolic pressures, and the glucose indices of diabetic patients. To our knowledge, our study is the first local trial that utilized TENS in a relatively large sample of hypertensive and diabetic subjects.

Effect of TENS (QuickZap) on Blood Pressure

In this trial, blood pressure has shown to fluctuate significantly during the first 10 to 12 days of therapy. The biomolecular basis for this effect has been a subject debate since the early conclusions of early animal studies utilizing TENS in baroreceptor reflexes. The proposed mechanisms for hypotension include systemic cutaneous vasodilation and stimulation of the central barorecpetor reflex via neuroceptive pathways.[9] The results of these studies suggest that blood pressure changes produced by activation of the central nucleus of the amygdala may be mediated by attenuation of baroreceptor reflexes through a GABAergic mechanism at the level of the nucleus tractus solitarius.[10]

A human clinical study on electrical nerve stimulation involving concomitant BP lowering medications (e.g. nitroglycerin) show a more significant rapid time to achieve the mean arterial blood pressure.[11] The control arm in our study, maintained a statistically lower mean SBP and DBP throughout the first week of

the study in comparison to those randomized to the intervention arm and no significance difference in drop between the two arms was noted thereafter. This finding could be explained by slow pulse-releases of endogenous opioid substances that mediate hypoalgesia- induced relaxation and thus the BP-lowering action according to a clinical trial among healthy men.[12] Conversely, the opposite findings seen among those with medications will only indirectly prove to us that the control of hypertension is not solely addressing peripheral resistance.

Our study did not show statistical difference in terms of the overall reduction in the other symptoms of hypertension except for chest pain. Our findings support a randomized controlled trial involving 14 subjects with effort related angina and resting angina, vagal electrical nerve stimulation abolished chest pain and significantly lowered blood pressure and decreased heart rate. Vagal stimulation reduced sympathetic inflow to the heart, seemingly via an inhibition of norepinephrine release from sympathetic nerves. VNS' sympatholytic/vagotonic action dilated cardiac microcirculatory vessels and improved left ventricular contractility in patients with severe coronary artery disease.[13]

In our study, TENS (Power QUICKZAP and Powertube QUICKZAP) was administered in the forearms to effect stimulation. One study has shown that the sympathetically mediated pressor response to handgrip exercise was blunted when TENS was applied to the ipsilateral hand and forearm, but not when TENS was applied to the contralateral leg. [Hollman, 1997[14]] This must be considered in

patients with hypertension with concomitant peripheral arterial occlusive disease that are candidates for therapy.

In resistant hypertension, TENS can be used. The mean change in both systolic and diastolic BP closely approximates the study of Jacobsson *et.al*. wherein the patients in this trial were treated with TENS at two acupoints on both forearms for 30 minute twice daily during 4 weeks. Twenty-four ambulatory blood pressure monitoring was recorded 1 week before, at start, at the end and finally 1 week after the TENS treatment. Their study results showed that blood pressure did not change significantly during the run-in period. After 4 weeks of TENS, the mean systolic blood pressure decreased by 6.3 mm Hg ($P < 0.05$) and the mean diastolic blood pressure decreased by 3.7 mm Hg ($P < 0.05$). The blood pressure reduction remained unchanged 1 week after treatment.[15]

This trial can only derive conclusions based on the effect of TENS as an adjunct treatment to hypertension and not as a main therapeutic modality for hypertension because all the subjects were treated with TENS to begin with and that maintenance anti-hypertensive medications was absent in the control arm.

The voltage and amperage of electricity administered may be varied from dose to dose. The QuickZap can deliver 9 volts as maximum output using the 3-21 minute program of application. A well designed clinical trial suggests that TENS must utilize low frequency (2 Hz) as the modality of choice.[16]

EFFECTS OF TENS ON BLOOD LIPIDS

In our trial, the QuickZap intervention without medications showed statistically lower VLDL and triglycerides in comparison to total cholesterol, HDL and LDL values.

Human clinical studies on electroacupuncture 30minutes once a day demonstrated a reduction in total cholesterol when compared to conventional low fat diets.[17]

For electrotherapy to be effective other studies recommend that delivery of voltage be prolonged. for triglycerides, frequency AM 50 Hz, needle-retained time 20 minutes, intensity 1 mA, twice each week; for total cholesterol, frequency AM 100 Hz, needle-retained time 30 min, intensity 1 mA, once every other day; for LDL-C, frequency Am 100 Hz, needle-retained time 30 min, intensity tolerable and comfortable, once every other day.[18] However, these two studies that studied TENS on cholesterol had patients with concomitant anti-cholesterol medications extended up to the end of the trials.

EFFECTS OF TENS ON DIABETES MELLITUS

In this trial, statistically significant differences in fasting glucose levels were seen even those without anti-diabetic medications. However the perceived difference was not different between the two arms. This could be explained by the skewed sample distribution. (ie, more patients randomized to the medication group) and

perhaps due to the inherent variability of the glucose levels of these documented diabetics. Even in the absence of medications, subjects randomized to pure TENS had greater glucose fluctuations on a 24-hour basis among obese, non-diabetic women. [19] There is a dearth of both local and foreign clinical trials involving diabetic subjects. In animal models, percutaneous electrical stimulation enhance insulin sensitivity and ultimate sustained hypoglycemia.[20] The exact mechanism in regulated insulin sensitivity and ultimately hypoglycemia is still unknown.

In our trial, diabetic peripheral neuropathy seem to benefit from low frequency TENS. One proposed mechanism for the pain-relieving properties of transcutaneous electrical nerve stimulation (TENS) is gating of impulses carried by group III and IV afferent nerve fibers.[21] Several convincing human trials in the past demonstrate the short term effects of periodic TENS with promising outcomes.[22]

In this trial no adverse events were reported. Although assessed as a safe procedure, TENS has been shown to cause interference to cardiac pacemakers [Crevenna 2003].[23] There are only anecdotal reports that TENS causes gastrointestinal bleeding or exacerbation of neuropathic pain.

Our study is not without limitations. The ideal selection of treatment arms did not include controls for comparison. Placebos are justified in trials which deal with subjective symptoms as outcomes. Second, our trial was not able to account for

other variables that will confound blood pressure control. (e.g. of intake of herbal preparations that produce BP lowering effects, level of activity, dietary requirements). Glucose control is affected by level of activity, and diet which were not adequately addressed in this study.

CONCLUSIONS:

The trans-cutaneous electrical nerve stimulation (TENS) procedure using the Power QuickZap Powertube QiuickZap is able to demonstrate the following effects:

- TENS using the Power QuickZap and Powertube QuickZap can be an adjunct therapy in the lowering of blood pressure among patients with hypertension especially those not currently taking anti-hypertensive medications.

- TENS produces BP lowering effects with the observable during the first 2 weeks of treatment from baseline among those treated with and without maintenance anti-hypertensive medications. Those treated with TENS alone showed a mean drop in SBP which was noted during the 10^{th} to the

12th day (SBP mean difference 8 mmHg, p=.036) while DBP dropped during the first week of treatment (DBP mean difference =2.5 mmHg, *p*=.022)

- Only reported chest pain showed statistically significant reduction during the third week of treatment (45% versus 67%, p=.04).

- Statistically lower serum triglycerides (mean difference=29.7 mg/dL, *p*=.003) and VLDL (mean difference =6 mg/dL, *p*=.001)

- TENS applied to diabetics with and without maintenance diabetes medications showed a statistically significant drop in mean fasting glucose, however comparing between the two groups , no significant difference exists. (mean difference 4 mg/dL versus 27 mg/dL, *p*=.07)

- Patients on TENS alone when compared with those with medications reported lesser painful neuropathy noted at 3 and 4 weeks (45% versus 67%, p=.04 and 70% versus 88%, p=.016).

RECOMMENDATIONS:

With the above findings of this study, we propose the following:

- Repeat the study using a control arm for both diabetics and hypertensives and controlling for the other important confounding variables (diet, level of activity).

- Examine the effect of TENS (Power QuickZap and Powertube QuickZap) at varying voltages and amperage on BP and glucose levels.

- Cost –effectiveness studies on TENS can be undertaken.

REFERENCE:

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- Martin Frischknecht, Engr.- Power QuickZap and Powertube QuickZap, Founder

OTHER READINGS:

- Power QuickZap and Powertube QuickZap, TENS Therapy Equipment (Product Information)

FOOTNOTES:

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