

ORIGINAL RESEARCH

Physiological Changes Following Thermomechanical Massage in a Population of Hypertensive Patients and/or Type II Diabetics

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ABSTRACT

Introduction: This pilot study presents findings regarding the influence of the Migun HY 5000 thermomechanical massage device[™] on three populations of patients diagnosed respectively with hypertension, type II diabetes, or hypertension and type II diabetes. A previous paper describing thermomechanical massage made a link to chiropractic from the standpoint that thermal and/or mechanical devices have long been used in conjunction with, or as part of, chiropractic care (i.e., Spinalator, Anatomotor, Spinalign, Chattanooga Ergo Wave, Model CBR Massage Table, AME Quest Intersegmental Traction Table ATT-300). A second rationale for investigating this device is associated with the on-going quest to evolve non-medical approaches for overall physiological enhancement.

Purpose: The present pilot study was conducted to achieve an initial impression of the efficacy of the Migun HY 5000 thermomechanical device (bed) on hypertensive and type II diabetic subjects.

Discussion: Hypertensive subjects exhibited significant decreases in systolic, diastolic, and pulse pressures after commencing

ing Migun thermomechanical massage. Type II diabetic subjects exhibited significant decreases in both fasting and 2hrPP blood glucose levels after commencing Migun thermomechanical massage. Hypertensive/type II diabetic subjects exhibited statistically significant reductions in systolic, diastolic, and pulse pressures after commencing Migun thermomechanical massage. A possible mechanism of action is proposed for the pathways affected by Migun thermomechanical massage relative to the hypothalamic-pituitary-adrenal cortex axis.

Conclusion: The pilot study provides only preliminary, limited empirical data. Consequently, while further study is suggested, the results, though high in consistency and magnitude of clinical effect (effect size) and similarity regarding duration of care prior to subjective reporting of initial improvement must be interpreted cautiously.

Key words: Hypertension, Systolic BP, diastolic BP, Pulse Pressure, Type II diabetes, blood glucose, chiropractic, thermal massage, mechanical massage, Migun.

Introduction

The purpose of this pilot study is to present findings regarding the influence of a thermomechanical massage device on three populations of patients, diagnosed respectively with hypertension or type II diabetes or hypertension and type II diabetes. The Migun thermomechanical device,[™] is variously referred to herein as Migun, Migun device, thermomechanical massage Migun device. It is manufactured by Migun Medical Instruments International, Taejeon, Korea.

A previous report¹ provided a general overview of the Migun device drawing upon anecdotal reports of effectiveness. That

study was based on commentary from medical doctors in China and Korea treating 76 patients, pre and post thermomechanical massage with the Migun device. The patients involved presented with problems in the following systems: musculoskeletal, gastrointestinal, nervous, cardiovascular, integumentary, urological and endocrine, and respiratory. An additional 238 patients in Seoul Korea, with similar disorders, were also surveyed for self-reports of effectiveness of the Migun device.

The data from that study led to the suggestion that Migun thermomechanical massage may provide health benefits across

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a wide range of disorders. Recommendations were made for further study, including use of standardized outcome measures, such as the Self-Reported Health and Wellness Survey.² This approach would be in conjunction with controlled clinical trials across a large statistical population of Migun users to evaluate the health benefits of the device.

As the next step in assessing the impact of thermomechanical message on health disorders, limited empirical data derived from the Korean population previously studied has been further evaluated in this pilot study. This study was conducted to determine if evidence could be provided to justify a large-scale clinical trial.

The choice of preliminarily assessing Migun in three populations, respectively exhibiting hypertension, type II diabetes, and both conditions concomitantly, is underpinned by two factors. The first deals with the prevalence of these conditions and their impact on society as a whole. In that regard, the estimated prevalence of diabetes in 1997 was 124 million worldwide, with 97% being type II.³ King et al.,⁴ have made projections from World Health Organization (WHO) data and other demographic information provided through the United Nations. These projections suggest that the number of people with diabetes, worldwide, will be 221 million in 2010 rising to 300 million by 2025. The most pronounced increases in diabetes were expected to occur between 1995 and 2025 in the Americas (30.7 to 63.5 million), the Eastern Mediterranean (13.8 to 42.8 million), Southeast Asia (27.6 to 79.5 million), and the Western Pacific (26.4 to 56 million).

Moreover, the CDC estimates that 6.2% (17 million) of the United States had diabetes in 2000 with 9% being greater than or equal to 20 years of age and 20.1% being 65 or older.⁵

The United Kingdom Prospective Diabetes Study (1997)⁶ found evidence that tight control of blood glucose and blood pressure of less than 144 over less than 82 decreased the risk of the long term complications of diabetes. The study found that those with the best control of blood glucose and blood pressure had a 37% risk decrease for small blood vessel complications, 44% reduced risk of stroke, 56% reduced risk of heart failure and a 32% reduced risk for all diabetes related deaths.

Although hypertension can be present in non-diabetic, type II diabetics often develop hypertension hence linking the two disorders. Jaber and colleagues⁷ found a possible positive correlation between glycemia and blood pressure in black, type II diabetic, hypertensive patients.

Wolz and colleagues⁸ released information from the National High Blood pressure Program based on a definition of hypertension as systolic pressure greater than 140mm Hg, or a diastolic pressure greater than 90, or if the subject was taking medication for hypertension. Based on this information it was estimated that 42.3 million have hypertension.

Lifestyle changes believed to be health promoting (exercise, cessation of smoking, weight loss, low sodium diet, vegetarian/low fat diet and conservative alcohol consumption) could be effective in lowering blood pressure in many cases. However, because of the insidious nature of hypertension these changes are often ignored resulting in stroke or other cardiovascular episodes, too often with debilitating consequences or death. Mehler and colleagues⁹ found that intensive blood pressure control re-

duces the risk of cardiovascular events in patients with peripheral arterial disease and type II diabetes. Hence the importance of lowering and regulating blood pressure is important from the standpoint of both improved health for non-diabetics as well as decreasing the risk of cardiovascular events in type II diabetics with hypertension.

The second underpinning factor is linked to the on-going quest to evolve non-medicinal approaches for overall enhancement. In that regard, a previous paper describing thermomechanical massage,² made a link to chiropractic from the standpoint that thermal and/or mechanical devices have long been used in conjunction with or as part of chiropractic care (i.e., Spinalator, Anatomotor, Spinalign, Chattanooga Ergo Wave, Model CBR Massage Table, AME Quest Intersegmental Traction Table ATT-300). Consequently it is proposed that the thermomechanical message device used in this study may be of further benefit to the chiropractic profession. This second factor in choosing subjects with hypertension and type II diabetes was also linked to outcomes reported in association with chiropractic care. That is, while chiropractic does not have treatment of medical disorders as one of its objectives,¹⁰ the literature does reveal significant findings in relation to the lowering of blood pressure in hypertensive patients while under chiropractic care.¹¹ Moreover, improvement in blood glucose levels in type II diabetics has also been demonstrated.¹² As well, the problems associated with medical (pharmaceutical) management of these conditions are well documented.¹³

Thus, these authors seek a non-pharmaceutical approach to improving health that also has the possibility of benefiting patients with serious conditions. This approach could be provided singularly, or more desirably, coupled with other modes of health care delivery. If the non-pharmaceutical approach demonstrated chiropractic care could be coupled with another form of care that may also ameliorate aberrant physiology, the patient would ultimately be the benefactor through a possible synergistic effect. That is, concomitant care utilizing the two approaches could result in a greater overall effect than either applied alone. Much like the chiropractic practice philosophy the administration of thermomechanical massage via the Migun device is not provided for the cure of any specific disorder. Although positive outcomes have been anecdotally reported for a number of conditions² the application of the Migun Thermomechanical massage is based on acupuncture theory originating in China.¹⁴ This theory proposes that energy circulates throughout the body in well-defined pathways, or meridians linking to the internal organs of the body. The Migun thermomechanical device targets two primary meridians overlying the spinous processes of the vertebrae and the distal parts of their transverse processes. This non-pharmaceutical approach to, believed to stimulate the flow of energy through these meridians may be a useful complement to other non-pharmaceutical approaches such as chiropractic.

To test this hypothesis, the present pilot study has investigated the influence of Migun thermomechanical massage in patients already under medical care. Prior to assessing its effectiveness in combination with other non medical-methods, it was considered prudent to begin the process by first assessing its efficacy in terms of demonstrating if positive outcomes could be achieved beyond those anticipated with medications alone.

Methods and Materials

Subjects

The subject pools for this study were drawn from a population of 238 patients that were being cared for, for a variety of disorders by physicians in South Korea. Patient data was collected from 25 different Migun centers throughout the country. The center were available to all who could access them, as frequently as they pleased, receiving Migun thermomechanical massage free of charge.² One intent of this pilot study was to control for patients that had a variety of serious, possible interacting conditions. Thus, only those subjects that presented with one or two major complaints were included. That delineated and limited the population to hypertension (n=16) and type II diabetes (n=12) and a third group that had both hypertension and type II diabetes (n=19). The hypertension group was composed of 8 females with a mean age of 64 ± 9.9 and 8 males with a mean age of 69 ± 9.0 . The type II diabetic group had 8 females with a mean age of 65 ± 8.8 and 4 males with a mean age of 64 ± 2.8 . The hypertensive/type II diabetic group (n=19) was composed of 7 females age 66 ± 7.8 and 12 males age 69 ± 7.9 .

Blood Pressure Readings

The hypertensive and hypertensive/type II diabetic subjects were under medical treatment, receiving condition specific medication prior to commencing Migun thermomechanical massage and remained under medical supervision while receiving Migun. Blood pressure readings were taken regularly with a sphygmomanometer with the subject seated. The blood pressure readings just prior to commencing Migun sessions are reported in this study as "Before Migun." Although most of the hypertensive patients home monitor their blood pressure, a subsequent blood pressure reading was taken after Migun sessions commenced during the subjects regularly scheduled appointment established by their physician between January and Feb-

ruary of 2003. These data are presented as "After Commencing Migun." The same designations were used for blood glucose determinations.

Blood Glucose Levels

The type II diabetic and type II/hypertensive subjects were under medical treatment, receiving condition specific medication prior to commencing Migun thermomechanical massage and remained under medical supervision after commencing Migun. A fasting and two-hour post prandial (2hrPP) blood glucose level (mg/100 ml) were determined shortly before commencing Migun and reported in this study as "Before Migun." Although subjects home monitored blood sugar levels, this report presents the last fasting and 2hrPP (after eating) that was conducted by their physician after commencing Migun during their regularly scheduled office visit between January and February 2003.

Migun Device

The device used to provide thermomechanical massage to the subjects in this study is a bed (Migun HY-5000) is designed to access two regions of the spine at the same time. It consists of 2 mounted probes each containing 5 helium bulbs that are moved horizontally to massage the back, from occiput to sacrum, with the patient in the recumbent position. Another hand held 5 helium bulb probe was accessible to the subject to be moved over any area of their body at will.

Statistical Treatment of Data

Systolic and Diastolic blood pressure readings "Before Migun" and "After Commencing Migun" were compared by a paired two-tailed Student's T test, $P < 0.05$. Fasting and 2hrPP blood glucose values were also compared in the same manner.

In order to test the strength of the bivariate relationships/magnitude of clinical effect before Migun and after commencing Migun, effect size was determined after the method of

Table 1. Changes in Systolic, Diastolic and Pulse Pressure in Hypertensive Subjects* Before and After Commencing Thermomechanical Massage

	Before Migun	Pulse Pressure	After Commencing Migun	Pulse Pressure
Blood Pressure (mm Hg) (mean \pm s.d.)				
Systolic (n=14)	174 \pm 38.3	67 \pm 22.4	133 \pm 13.9** (P = 0.00)	52.4 \pm 10.4 (P = 0.03)
Diastolic (n=14)	101 \pm 29.9		86 \pm 14.4 (P = 0.00)	

* Patients were diagnosed with essential hypertension in Seoul Korea at varying dates prior to 2003. Subjects received condition specific medication for essential hypertension prior to commencing Thermomechanical massage (Migun) and throughout the duration of Migun sessions. Blood pressure was taken seated with a sphygmomanometer at scheduled appointments. The last blood pressure reading taken, prior to commencing Migun, is

reported in the Table above as before Migun. After commencing Migun Blood pressure was taken between January and February, 2003 during regularly scheduled visits to the physician's office.

** Significant numbers are in bold. Means were compared by a paired two tailed Student's T test with $P < 0.05$.

Table 2. Changes in Systolic and Diastolic Blood Pressure in Hypertensive/Type II Diabetic Subjects* Before and After Commencing Thermomechanical Massage

	Before Migun	Pulse Pressure	After Commencing Migun	Pulse Pressure
Blood Pressure (mm Hg) (mean ± s.d.)				
Systolic (n=14)	163 ± 31.7	66 ± 22.1	138 ± 16.6** (P = 0.00)	53 ± 13.7 (P = 0.02)
Diastolic (n=14)	96 ± 20.8		84 ± 9.5 (P = 0.02)	

* Patients were diagnosed with essential hypertension and type II diabetes in Seoul Korea at varying dates prior to 2003. Subjects received condition specific medication for essential hypertension prior to commencing Migun and throughout the duration of Migun sessions. Blood pressure was taken with a sphygmomanometer at scheduled appointments. The last blood pres-

sure reading taken, prior to commencing Migun is reported in the Table above. After commencing Migun Blood pressure was taken between January and February, 2003 during regularly scheduled visits to the physician's office.

** Significant numbers are in bold. Means were compared by a paired two tailed Student's T test with P < 0.05.

Cohen.¹⁵ The formula applied was $M_2 - M_1/S_1$, where M1 and M2 are the mean values before Migun and after commencing Migun, and S1 is the standard deviation before Migun. Cohen describes the magnitude of clinical effect as being 0.20 (small), 0.50 (moderate), and 0.80 or greater as large.

The difference between systolic and diastolic (pulse pressure) is also presented. It can be seen that in this group the mean value was 67 ± 22.4 mm Hg before Migun and 52 ± 10.4 after commencing Migun, representing a significant decrease (P = 0.03).

Systolic and diastolic blood pressure for the hypertensive/type II diabetic group (n=19) is presented in Table 2. Before Migun the systolic pressure was 163 ± 31.7, exhibiting a significant drop (P = 0.00) to 138 ± 16.6 after commencing Migun.

Significant change in Pulse pressure (P = 0.02) in the group was seen as a decrease from 66 ± 22.1 prior to Migun and 53 ± 13.7 after commencing Migun.

Blood Glucose

Fasting and 2hrPP blood glucose levels before and after commencing Migun are shown in Table 3 for the type II diabetic only group. Fasting blood glucose levels (n=12) decreased significantly (P= 0.00) from 275 ± 132.1 before Migun to 156 ±

Results

Blood Pressure

Changes in systolic and diastolic blood pressures (mm Hg) before and after commencing Migun thermomechanical massage are presented in Table 1 for the hypertensive only group. A significant decrease in Systolic blood pressure (n=14) from 174 ± 38.3 before Migun to 133 ± 13.5 (P= 0.00) after commencing Migun is shown. Diastolic blood pressure (n=14) also decreased from 101 ± 29.9 before Migun to 86 ± 14.4 (P= 0.03) after commencing Migun.

Table 3. Changes in Fasting and Two Hour Post Prandial (2hrPP) Blood Glucose Levels in Type II Diabetic Subjects* Before and After Commencing Migun Thermomechanical Massage.

	Before Migun	After Commencing Migun	P=< 0.05**
Blood Glucose (mg/100ml) (mean ± s.d.)			
Fasting (n=12)	275 ± 132.1	156 ± 60.9	0.00
2hrPP (n=12)	289 ± 130.8	165 ± 14.4	0.00

* Patients were diagnosed with type II diabetes in South Korea at varying dates prior to 2003. Subjects were receiving condition specific medication for type II diabetes prior to commencing Migun and throughout the duration of Migun sessions. Fasting and 2hrPP glucose levels were determined shortly before com-

mencing Migun. The after commencing Migun data represent the last determinations in January or February of 2003.

** Means were compared by a paired two tailed Student's T test with P < 0.05.

Table 4. Effect Size * for Changes in Systolic, Diastolic, and Pulse Pressures, Fasting Blood Glucose and 2hrPP Blood Glucose in Hypertensive, Hypertensive/Type II Diabetes and Type II Diabetes Subjects Before and After Commencing Thermomechanical Massage

Before Migun compared to After Commencing Migun Effect Size *	
Hypertensive Group (n=14)	
Systolic Pressure	1.07
Diastolic Pressure	0.50
Pulse Pressure	0.65
Hypertensive/type II diabetes Group (n=19)	
Systolic Pressure	0.80
Diastolic Pressure	0.57
Pulse Pressure	0.59
Type II Diabetes Group (n=12)	
Fasting Blood Glucose	0.90
2hrPP Blood Glucose	0.95

* Based on description by Cohen¹⁵, clinical effect/magnitude of clinical effect is determined by the formula $M_2 - M_1 / S_1$, where M_2 is the after commencing Migun mean, M_1 is the before Migun mean, and S_1 is the before Migun standard deviation. A value of

0.20 equals a small effect size/magnitude of clinical effect, 0.50 = moderate effect size/magnitude of clinical effect, and 0.80 or higher = large clinical effect/magnitude of clinical effect.

60.9 after commencing Migun. The 2hrPP values (n=12) also decreased from 289 ± 130 (mg/100ml) before Migun to 165 ± 14.4 (P=0.00) after commencing Migun.

Reported data regarding changes in fasting and 2hrPP blood glucose levels was sparse for the hypertensive/type II diabetic group (n=6), and therefore are not presented in tabular form. However, within this small sample fasting blood glucose levels decreased from 189 ± 53.1 prior to Migun to 119 ± 34.3 after starting Migun (P= 0.03). There was no significant change in the 2hr PP glucose levels although a lower mean was reported from 171 ± 109.5 before Migun to 108 ± 26.2 .

Clinical Effect

Effect size/magnitude of clinical effect is shown in Table 4. Effect sizes for the hypertensive only group (n=14) revealed a large clinical effect (1.07) for systolic pressure before Migun compared to after commencing Migun. For the same group, diastolic changes exhibited a moderate clinical effect (0.50)

while pulse pressure change was also moderate (0.65). The magnitude of clinical effect was similar for the hypertensive/type II diabetes group (n=19) with a large clinical effect shown for systolic pressure when comparing before to after commencing Migun (0.80), and a moderate clinical effect for diastolic (0.57) and pulse (0.59) pressure.

In the type II diabetes group (n=12), a large clinical effect (0.90) was observed in regard to fasting blood glucose levels prior to Migun compared to after commencing Migun. A similar clinical effect was observed for 2hrPP glucose levels under the same conditions (0.95).

Duration of Care and Report of Initial Improvement

Duration of care and subjective reports of initial improvement were recorded in months (Table 5) prior to the last data collection of January/February 2003. Hypertensive subjects were under care 19.7 ± 13.5 months, type II diabetic subjects 22.2 ± 15.0 , and hypertensive/type II diabetic subjects $21.4 \pm$

Table 5. Duration of Care* Receiving Migun Thermomechanical Massage and Time of Initial Improvement After Commencing Migun in Hypertensive, Diabetes Type II, and Hypertensive/Type II Diabetic Subjects

	Duration of Care (months) (mean \pm stdev)	Initial Improvement (months) (mean \pm stdev)
Hypertensive Subjects	19.7 ± 13.5	4.7 ± 3.3
Type II Diabetes Subjects	22.2 ± 15.0	4.6 ± 4.2
Hypertensive/Type II diabetes Subjects	21.4 ± 13.2	5.8 ± 5.6

* Months date previous to Jan/Feb 2003.

13.2 months. Initial subjective reports of improvement were 4.7 ± 3.3 for hypertensive subjects, 4.0 ± 4.2 for type II diabetics, and 5.8 ± 5.6 for hypertensive/type II diabetic subjects.

Discussion

A previous paper describing the Migun thermomechanical massage device made reference to considerable subject reported and physician supported anecdotes of improvement in a variety of health related disorders.² These reports suggested that the Migun device might play a role in assisting the body to ameliorate a variety of physiological and functional conditions. Although 238 subjects were involved there was a paucity of empirical data as most of the "field" information was based on subjective reports of improvement and commentary by subjects and physicians. This is not altogether surprising as the Migun device is not touted as a cure for any particular disorder but is rather based on ancient acupuncture theory involving restoration of energy flow through the various somatic meridians.¹⁴

Even with the limitation of empirical data, however, the purpose of this pilot study was to achieve an initial impression of the efficacy of Migun from the standpoint of clinical outcomes. This was viewed as an important next step to determine if a large scale controlled clinical trial would be justified.

In that regard, this study has provided some preliminary evidence that suggests exposure to the Migun HY-5000 positively influences blood pressure as well as blood glucose levels.

Duration of care was similar for the three groups (Table 5). It is of interest that mean subjective reports of initial improvement was also similar, within approximately 5 to 6 months under care. The reports of initial improvement were not quantified as subjects subjectively reported events such as "lower blood pressure" and decreased "fasting blood glucose levels." Other comments included improved energy levels and feeling better in general. The hypertensive/type II diabetic subjects reported near 6 months while the other two groups were closer to 5 months. The slightly longer response time might be explained by the fact that the hypertensive/type II diabetic group perhaps delayed reporting initial improvement until both facets of their primary conditions, i.e., blood pressure and blood glucose levels were recognized. Moreover, the similarity in the relatively short duration of care before noticeable improvement was recognized among the three populations, suggests a consistency in response to possible effects of the thermo-mechanical massage.

Hypertension

The significant decreases in both systolic and diastolic pressures as well as pulse pressure (difference between the two) in patients already receiving medication for hypertension is of interest. Although the number of subjects in this pilot study warrants caution in interpreting the findings, it is noteworthy that among the 14 subjects in the hypertension only group as well as the 19 subjects in the hypertension/type II diabetes (mean age greater than 60 years for both groups), 85% exhibited a decrease in systolic pressure, while 78% exhibited a decrease in pulse pressure. Considering the small n value (33 total), there appeared to be a consistency in terms of pressure reduction. The strength of this relationship is borne out by the effect size, or magnitude of clinical effect (Table 4). Following Cohen's¹⁵

description of effect size, the changes in systolic pressure represented a large clinical effect. As well, effect size values for changes in diastolic pressures within the same two groups were moderate and the effect size for pulse pressures for these two groups was also moderate. This is an important observation due to the implication of these parameters in cardiovascular disease, especially among men over 60 years of age. Sesso et al¹⁶ have reported that either average systolic blood pressure or pulse pressure predicts cardiovascular disease among older men, greater than age 60 years. As well, Benetos, et al¹⁷ state that a wide pulse pressure is an independent significant predictor of all-cause cardiovascular and coronary mortality even among men with relatively low cardiovascular risk.

While these studies focus on men, the low n values in the present study precluded drawing any conclusions comparing men and women, as there was no significant difference in the blood pressure range between the genders in this study.

Type II diabetes

In terms of analyzing the data, the three groups blood glucose levels and blood pressures were not combined as the subjects represented different categories of disorders that could be interacting, thus creating a different response to Migun. However, for sake of discussion, they were combined to test whether the differences before Migun and after commencing Migun would be altered. In both instances the level of significance remained the same or improved to $P = 0.00$ for instances of comparing systolic, diastolic, pulse pressure or fasting and 2hrPP blood glucose values.

In that regard, the significant decrease in both fasting blood sugar levels in the type II diabetes group ($n=12$) receiving concomitant medical care and Migun thermomechanical massage is also of interest. Blood glucose levels were only determined for $n=6$ of the hypertension/type II diabetes group and consequently, when analyzed alone led only to a significant change in the fasting blood levels, but not significant when comparing before and after in regard to the 2hrPP. However, combining the groups for a total number of $n=16$ subjects for whom glucose levels were recorded, 100% demonstrated decreases in fasting blood glucose levels and fifteen of the sixteen (94%) showed decreases in 2hrPP glucose levels. Moreover, the decrease in mean fasting blood glucose represented a 58% drop in both mean fasting glucose and 2hrPP values. This observation, coupled with the large effect size or magnitude of clinical effect for both fasting and 2hrPP values, add strength to a possible positive affect of the Migun device on changes in blood sugar in type II diabetes patients.

The importance of controlling glycemia in diabetes is well documented. Findings from the UK Prospective Diabetes Study (UKPDS) showed that intensive glycemic control significantly reduced microvascular complications.¹⁸

The UK Prospective Diabetes Study (UKPDS) also compared the benefits of intensive glycemic control versus conventional glycemic control in reduction of diabetes-related endpoints. The major benefit was in the reduction of microvascular endpoints. Myocardial infarction was reduced by 16%, but this reduction did not achieve statistical significance. There was no statistically significant reduction in the incidence of stroke

or peripheral vascular disease in the intensively treated group compared with the group treated with conventional glycemic control. UKPDS showed that glycemic control management in the context of a clinical trial did not necessarily result in the reduction of macrovascular events, but primarily reduced microvascular endpoints in patients with diabetes. Similarly, Haffer¹⁹ has reported that both glycemic control and blood pressure control significantly reduced any complication related to diabetes whereas blood pressure control was most effective in stroke. Mehler⁹ has shown that blood pressure control can reduce the risk of cardiovascular complications in patients with existing peripheral arterial disease and type II diabetes.

These findings are further elaborated by the American Academy of family physicians (AAFP), American Diabetic Association in the AAFP Policy Action Statement (1999). The policy statement emphasizes that epidemiologic evidence clearly demonstrates a relationship between elevated blood glucose and microvascular and neuropathic diabetic complications including new (or worsened) retinopathy, nephropathy, and peripheral neuropathy.²⁰

The present pilot study, although preliminary with limited statistical power, suggests that Migun may be exerting an enhancing effect, above that achieved with medications alone, with regard to lowering blood pressure and blood glucose levels. Limited evidence regarding this affect has been provided in subjects that have either hypertension or type II diabetes, with similar findings in subjects with both conditions.

Moreover, the high degree of consistency among subjects with regard to these findings further suggests a relationship between Migun and the observed outcomes.

These authors recommend further study to clarify the outcomes of this pilot study. A clinical trial will control for many of the unknowns characteristic of data obtained from a subjective study based on information gleaned from a variety of sources. It will be important to standardize methodologies, recording and reporting of data. As well, it will be important to identify Migun sessions in relationship to concomitant treatment regimens, as well as other demographic features, including locations of Migun Centers from which data is collected.

In proposing further study, it also becomes important to glean information that impacts on the mechanism through which Migun thermomechanical massage may be exerting positive or ameliorating effects regarding hypertension and/or type II diabetes. While medical treatment for type II diabetes is relatively standardized, relying on diet as well as dose dependent insulin for control, the myriad of medications treating hypertension is exhaustive. These include such agents as diuretics, alpha blockers, beta blockers, calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors, and angiotensin receptor antagonist. Moreover, it is not uncommon for patients to be receiving a combination of these medications. It is difficult to know, in the present pilot study, which of these agents, singularly or in combination, was being taken by the subjects. It is unlikely, however, that all were receiving the same medication or combination thereof. Thus, it begs the question as to how such a similar effect could be observed among a presumed wide spectrum of medicinal applications.

Possible mechanisms of action should, therefore, take into consideration that the proposed effects of Migun thermo-mechanical massage are elicited through pathways that supersede pharmaceutical approaches blocking or stimulating certain metabolic pathways. In considering possible mechanism of action, the following aspects of massage are relevant and well accepted through observation and opinion, though scientific verification is not strong.

Effects of mechanical and thermal massage

There is a considerable body of information that relates to the benefits of mechanical and vibration aspects of massage. From the mechanical standpoint, which is primarily directed at muscle tone, it has been proposed that "effleurage" or light gliding movements over the skin produce sensory reactions, reduces swelling, and helps with venous return. Further, "petrissage" involves pressing and rolling of the muscles. It is believed to increase the local blood supply also increasing venous and lymphatic return. Percussion or "tapotement" is said to create a state of contraction in relaxed muscles or heighten somatic awareness.^{21,22}

Norris²³ cites Bell who has shown that vigorous massage increases blood volume for 40 minutes. Norris also cites Barr and Taslitz who report that blood pressure is reduced following back massage. Other studies following the extent to which the lowering of blood pressure becomes stable do not appear in the literature to these authors knowledge. An increase in blood flow, it is reasoned²⁴ would necessarily be the mechanisms through which toxic substances would be more readily eliminated from tissues. As well, there is evidence using intradermal dye injections²³ that lymph flow improves with massage.

Cafarelli and Flint²⁴ cite Boone et al who suggest that the benefits from mechanical massage may be more psychological than physiological, creating a sense of well being and feeling of relaxation. It seems reasonable that physical relaxation can improve blood flow, reduce muscle tone and tension in soft tissues.²²

Heat or thermal aspects of massage often provide relief from pain, which in turn reduces muscle spasms and accompanying tension. As well, heat can also increase muscle and ligament extensibility, facilitating muscle contractility.²⁵ An interesting thought is that ultrasound, short-wave and microwave diathermy are thought to generate heat, but of course deeper in the tissues.²⁶ That may be of significance, as increasing core temperature also speeds rates of metabolic reactions, which may in turn have positive physiological consequences. It has also been proposed that mechanically or thermally induced vibrations at a variety of frequencies may block the vasoconstrictor mechanism thus lowering blood pressure. In this regard, deep-heating agents such as short-wave diathermy and continuous-wave ultrasound can raise tissue temperatures without overheating the skin at depths of 3-5 cm.²⁶ Heat from the Megan device should penetrate to greater depths since it employs a modified infrared thermal source having a measured wavelength of 0.75 - 1.0 x 10⁻³ M. However, this has not yet been evidenced.²

These aspects of massage are for the most part accepted among those who use them in practice as well as many recipients of massage.²⁷ However, validation of these ideas is prima-

rily theoretical, though logical. Moreover, the probable actions of light, deep, and thermal massage do not alone appear to provide satisfactory information to propose a physiological mechanism that could account for the preliminary patient outcomes observed in this study and the prior descriptive study.²

However, the combination of the physical aspects of thermo mechanical massage accepted as promoting a state of well-being and relaxation, may also promote a reduction in the physiological stress response. Affecting various pathways associated with long-term stress seems a plausible mechanism through which Migun could be producing positive outcomes over a wide range of disorders including hypertension and diabetes.

Possible mechanism of action for Thermomechanical Massage as applied via Migun.

It is well known that long-term exposure to stress promotes a variety of physiological problems that could manifest as hypertension or diabetes. The hypothalamic-pituitary-adrenal cortex (HPA) axis has received substantial attention (REF). Repeated stimuli, especially stressful stimuli, are perceived through the limbic system, including the hypothalamus, via nerves. The neural release of corticotrophin releasing factor (CRF) in turn promotes secretion of a number of hormones, including adrenocorticotropic hormone (ACTH), from the anterior pituitary gland. ACTH further stimulates the adrenal cortex to release glucocorticoids that raise blood glucose level through promoting gluconeogenesis in the liver as well as suppressing the immune system. Glucocorticoids have also been shown to increase blood pressure by vasoconstriction, and sodium retention. Moreover, this class of steroid hormones is antagonistic to insulin binding to cell receptors, thus further raising blood glucose levels. Another component of the stress response involves the adrenal medulla, which releases epinephrine and norepinephrine in response to mental and physical stress. Through binding to transmembrane adrenergic receptors, these endocrines produce several effects. These include an increase in heartbeat rate and strength, thus increasing blood pressure. Glycogenolysis is also promoted which raises the blood glucose level. Moreover, stimulation of the adrenal medulla also promotes increased secretion of ACTH from the anterior pituitary.²⁸⁻³¹

Thus, long-term exposure to stressful stimuli links the HPA axis to both hypertension and elevated blood sugar levels, possibly related to type II diabetes. Interestingly, there is little agreement in the literature concerning the etiology of essential hypertension and or II diabetes.¹³ Should the stress response over the long term be involved in the etiology of either of these conditions, it will be of interest to investigate if the combination of thermal and mechanical massage, applied in a manner as described via the Migun device, can positively modify any of the elements involved in the stress response, thus producing the positive effects on blood pressure and blood glucose levels as cautiously suggested by the limited data of this pilot study.

Summary and Conclusions:

1. The application of Migun thermomechanical massage concomitant with medical treatment exhibits statistically significant outcomes beyond treatment with medications alone.

2. Hypertensive subjects exhibited significant decreases in systolic, diastolic, and pulse pressures after commencing Migun thermomechanical massage.
3. Type II diabetic subjects exhibited significant decreases in both fasting and 2hrPP blood glucose levels after commencing Migun thermomechanical massage
4. Hypertensive/type II diabetic subjects exhibited statistically significant reductions in systolic, diastolic, and pulse pressures after commencing Migun thermomechanical massage.
5. Combining blood pressure and fasting and 2hrPP findings from the hypertensive/type II subjects with the hypertension only and type II only groups did not decrease the level of significance for these parameters.
6. Patients reports of improvement were predominantly supported by their respective physician's clinical findings.
7. The pilot study provides only preliminary, limited empirical data. Consequently, the results, though high in consistency and magnitude of clinical effect (effect size) and similarity regarding duration of care prior to subjective reporting of initial improvement must be interpreted cautiously.
8. It is recommended that further study in the design of a controlled clinical trial be conducted to assess the outcomes of the pilot study and to investigate long term changes in subjects receiving Migun.
9. A review of current theory and clinical observations of the mechanical and thermal benefits of massage in general, do not provide sufficient information to derive a working hypothesis for a mechanism of action for the Migun device.
10. A possible mechanism of action, resulting in the suggested positive outcomes derived through the Migun device, is linked to an abatement of one or more elements of the classic stress response as mediated through the HPA axis.
11. Based on verification of the findings of this pilot study through a controlled clinical trial it would appear that the Migun device could serve as a complement to other disciplines, such as chiropractic, that have also reported positive outcomes with various disorders.

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