

Integrated Approaches for Reversing the Progression of Type-2 Diabetes in Advanced Diabetic and Prediabetic Individuals

Roopa Lakshmi¹, Rama Mishra², Shashi Kumar², Kaveri Kuttappa², Nivedita², Deepika² and Gundu HR Rao^{3*}

¹Founder, Director, Wellbeing, Multi-speciality and Integrated Health Centre (IHC), India

²Staff Physicians and Researchers at IHC, India

³Emeritus Professor, Laboratory Medicine and Pathology, University of Minnesota, USA and Founder CEO, Institute for Integrative Medicine (IIM), India

***Corresponding Author:** Gundu HR Rao, Emeritus Professor, Laboratory Medicine and Pathology, University of Minnesota, USA and Founder CEO, Institute for Integrative Medicine (IIM), India.

Received: June 11, 2020; **Published:** July 31, 2020

Abstract

Metabolic diseases have rapidly progressed to epidemic proportions worldwide. In the last four decades, obesity has increased by four-fold and type-2 diabetes by two-fold. Vascular diseases (VDs) have remained the number one killer and have retained this status for over a century. Despite some decline in the morbidity and premature mortality related to VDs, in industrialized nations, these diseases have not been under control worldwide, and we see no hopes of reducing, reversing or preventing metabolic diseases in the near future. Modern medicine has failed to address the prevention of these chronic diseases. Even though it is assumed that modern medicine has wiped out the infectious diseases, occasional pandemics (current Corona Virus Pandemic) demonstrates, how ill prepared we are, when it comes to containment or prevention of diseases. According to a Centre for Disease Control (CDC), USA, more than 700,000 people contract infection in the so-called modern hospitals of the USA in a given year and 70,000 die of such hospital acquired infections. There is an increasing interest in the development of Integrative Medicine, to address the need to reduce, reverse, or prevent the increase in the incidence and prevalence of metabolic diseases. In a preliminary study at the Institute for Integrative Therapies, Bengaluru, India, we subjected known diabetic individuals to a structured diabetes prevention protocol, which included complementary therapies, such as Naturopathy, Ayurveda, Yoga and Allopathy. In this retrospective study, although original cohort had more than three hundred subjects, we selected 56 subjects, for whom we had complete data for presentation in this report. Of the 56 individuals followed with Diabetes Reversal Protocol, 21.4% discontinued medication within 100 days, 50% reduced the medication needed to maintain the HbA1c within 90 days. Whereas 18% reduced medication after 140 days and 10% attained lower HbA1c levels with medication. We have designed future studies, to explore the mechanisms by which one or more of the individual components of this intervention protocol, influences the metabolic risks related to this disease, by using an array of non-invasive diagnostic tools, such as Abbott Free Style Libre-14 day, ambulatory glucose monitor (AMG), LD-diagnostic tools for monitoring a variety of metabolic risks as well as wellness index. We strongly believe that traditional medicine approach of developing complementary therapies, will be a 'game changer' in the way future preventive medicine will be delivered.

Keywords: Ambulatory Glucose Monitor (AMG); Type-2 Diabetes (T2D); Vascular Diseases (VDs)

Introduction

Cardiometabolic diseases such as hypertension, excess weight, obesity, type-2 diabetes (T2D) and vascular diseases, have rapidly increased in the prevalence and incidence, in the past three decades, to epidemic proportions worldwide [1-20]. According to a recent report by the CDC, USA, 50% of the adults in the USA are prediabetic (84 million). Prediabetes is a high-risk state and prevalence of prediabetes is increasing worldwide, in an alarming rate and will reach half a billion by 2030 [21]. For prediabetic individuals, lifestyle modification seems to be the cornerstone of diabetes prevention, with evidence of a 40-70% relative-risk reduction. In view of the fact, both the genetic and environmental factors contribute to T2D progression, it has been proposed that Asian ethnicities have been unable to adapt to food and lifestyle related to Western diet pattern. This increased risk for T2D has been reported for both northern (Chinese) and southern (Indian) Asians [21]. The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. The global prevalence of diabetes among young adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014. Diabetes prevalence has been rising more rapidly in middle- and low-income countries. The age of onset of type-2 diabetes is falling, - not uncommon in those aged less than 30 years, including children, adolescents and young adults, and early onset of T2D has been reported with different ethnic and cultural backgrounds. Available evidence suggests, that early-onset T2D, is a more aggressive disease phenotype than later onset cohort and develops CVD complications with more adverse CVD risk profile and relatively higher risk of myocardial infarction and death [22].

In a retrospective study called NEWSTART (Nutrition, Exercise, Water, Sunlight, Temperance etc.) the interventions reversed systolic and diastolic blood pressure rapidly, and two thirds of the subjects were no longer hypertensives within 18 days [23]. The authors of this study, concluded, that the interventions with whole-foods, vegan diet containing moderate levels of fat and salt, are effective as a first line treatment of hypertension, as recommended by the evidence-base guideline for adults, reported by the V111 joint National Committee (JNC8). Based on 2003 - 2004 NHANES studies, approximately 66 million American adults are obese, and additional 74 million are overweight. According to the experts, -reaching Healthy People 2010 goals of 15% prevalence of obesity in adults, and 5% prevalence in children, may be beyond our reach for several decades to come [24]. According to Professor Roy Taylor of Newcastle University, UK, the primary care-based Diabetes Remission Clinical Trial (DiRECT) showed, that 46% of people with type-2 diabetes, could achieve remission at 12 months and 36% at 24 months, mediated by weight loss [25]. The emphasis on robust management of modifiable risk factors has resulted in the decrease of CVD-related mortality in high-income countries, and diabetes mortality on the other hand, has increased in these countries [26]. No country has reduced, or reversed, metabolic diseases like hypertension, obesity and diabetes at the population level.

Harvard HEALTHbeat dated January 25th 2020 reports “that 90% of all doctor visits are linked to stress-related problems. Yoga can be perfect remedy. It has been shown that Yoga can lower the need for diabetes medications by as much as 40%”. At one of a kind, Vivekananda Yoga University (www.svaysa.edu), Jigni, Bengaluru, Dr Nagendra and associates have been advocating the Yoga-based lifestyle for managing type-2 diabetes [27]. A bilateral project with the US researchers (Prof Frederick Hecht, Osher Center of Integrative Medicine, UCSF), demonstrated that an 8-week yoga intervention resulted in greater weight loss and reduction in waist circumference, when compared to a walking control [28]. In this study, a total of 41 patients with elevated fasting glucose were randomized, to either yoga (n = 21) or a walking control (n = 20). According to the authors of this study, yoga participants had significantly greater reduction in weight, waist circumference, and Body Mass Index (BMI) versus control. Furthermore, they concluded, “that in Indian subjects with elevated fasting glucose, participation in an 8-week yoga intervention was feasible and resulted in greater weight loss and reduction in waist circumference, when compared to a walking control. Yoga offers a promising lifestyle intervention for decreasing weight-related type-2 diabetes risk factors and potentially increasing psychological well-being. Contrary to this relatively short time intervention, it took over 9 months of Yoga based lifestyle modification program to reduce medication score and lipid profile in type-2 diabetes subjects, in another randomized control study [29]. The same group from Yoga University in Bengaluru, India, in a separate study demonstrated, that Diabetic Yoga Protocol reduced HbA1c and stress levels in prediabetic subjects [30].

China and India with large diabetic populations, have a great opportunity to develop a robust traditional medicine approach, to the prevention of chronic metabolic diseases like hypertension, obesity and diabetes. Traditional Medicine System of Asia is a system of heal-

ing, that originated thousands of years ago. Indian Traditional Medicine System uses Ayurveda, Yoga, Unani, Siddha, Homeopathy as well as Tibetan Medicine. Whereas, Traditional Chinese Medicine (TCM) system employs acupuncture/moxibustion (a form of heat therapy), Chinese herbal medicine, diet therapy, mind/body exercises. Covington in an overview on TCM, concludes, that TCM does not offer a cure for diabetes, but instead aims to optimize the body's ability to function normally [31]. Similarly, in the ancient system of Ayurveda, the metabolic alterations are defined as "Doshas" and the aim of the Ayurvedic Vaidya is to restore the balance of Dosha by appropriate lifestyle changes including, diet, yoga, naturopathy and the use of herbal concoctions.

In view of the galloping rate the CMDs are increasing worldwide, Millennium Development Goals (MDGs) and the commitments made on the NCDs at the United Nations General Assembly in 2011 and 2014 and in the 2030, 'Agenda for Sustainable Development' recommend, NCD targets for halt in the rise of the twin epidemics of obesity and type-2 diabetes by 2025. Without any positive action, 1.9 million people worldwide will remain at risk, from the poor health outcomes associated with overweight, obesity and diabetes. Our goal at WELLBEEING, Bengaluru, India, is an honest attempt, to align with the goals of WHO in scaling up prevention, strengthen care, increase awareness, and enhance surveillance of Diabetes, through Diabetes Reversal Protocol (DRP). The Integrated Medicine approach to healthcare, can come as a great rescue in the development of future preventive strategies. The fundamental principal of an integrative and functional medicine is to bring the strength of all traditional medicine systems together, with the hope of promoting healthy lifestyles and reducing the ill effects of excessive medication. We feel strongly that this method of integrated approach to healthcare, is better for developing preventive strategies for reducing, reversing, or preventing the growing menace of chronic cardiometabolic diseases. In this study, we have looked at the effect of a 90-days health management program namely, Diabetic Reversal Programme (DRP) incorporating best of all the Indian traditional medicine approach in a systematic manner, designed in a specific way, integrating interventions from Allopathy, Ayurveda, Naturopathy, Yoga, Diet, and Emotion Freedom Technique (EFT) to address stress and induce relaxation.

Objective of the Study

To assess the effect of DRP on the Fasting Blood Sugar (FBS), Post Prandial Blood Sugars (PPBS) and HbA1c among patients with type-2 Diabetes, attending the Wellbeing center in the year 2016 to 2019.

Methodology

A retrospective study was conducted, where the secondary data were extracted from the files of 300 patients. The data were from the type-2 DM patients, who consented and got enrolled in to the 90-days health management program from the year 2016 - 2019. The program was designed by the team of Allopathic, Ayurveda, Yoga therapists and Naturopaths, at the Wellbeing centre (centre for integrated management of chronic diseases) located in North Bengaluru, India. The program was structured and implemented in such a way, that the patients undergoing our systematically designed protocol, had learned to use it as a daily routine. The programme used an integrated approach, combining Allopathy, dietary modifications, external Ayurveda treatments, pancreas stimulation treatments like hip bath and spinal spray, therapeutic yoga, massage and stress relieving techniques. Weekly fasting and postprandial blood glucose were monitored, while glycosylated haemoglobin (HbA1C) was measured at 0 and 90 days. The progress was monitored and evaluated regularly.

A fully Integrated Therapy Protocol of 'Diabetes Reversal Program' included four interventions (Food, yoga (diabetic yoga) and Non-invasive Ayurveda-Naturopathy therapies and mind therapy (visualization-lymphatic tapping - which influences BEP¹ (Breaking the emotional pattern through visualization, meridian cleansing (Naadi shodana) and EFT (emotional freedom technique)) along with regular monitoring of bio markers, and consultation with the diabetologist. The Indian traditional therapies included were, Udvarthana (powder massage), Shirodhara, Hydrotherapies (hip bath and spinal spray), Abhyanga (oil massage +steam) and GH pack (gastro-hepatic pack). Even though the files had data on the risk factors assessment, Ayurveda profiling, Diet consultation and other parameters, for this study, the investigators looked at only FBS, PPBS and HbA1c levels at initiation and after the completion of the DRP. A total of 300 patients were

enrolled in the program. Since it was a retrospective analysis, we have used the data for only 56 subjects, who had complete records to meet the requirements for the data analysis.

The investigators defined diabetes reversal if: a) An individual patient has reduced the medicines and reduced the HbA1C levels at the end of DRP. b) An individual patient has reduced the medicines and maintained the same level HbA1C levels at the end of DRP. c) An individual patient has maintained the same medicines and reduced the HbA1C levels at the end of DRP. The duration of DM among patients varied from 3 months to 20 years. The mean duration of DM among 56 patients was 7.1 years, whereas around 48% of them had DM for 5 - 10 years.

Results

A total of 56 patient files had complete data pertaining to the parameters studied. Out of 56 patients 39 (%) were males and 17 (%) were females. The mean age of the study population was 50.7 years where around 66% (37) were more than 45 years of age (Table 1). The mean age of male and female was 48.5 and 53.7 respectively.

Gender	FBS (SD) in mg/dl		PPBS Mean (SD) in mg/dl		Glycosylated Hb% Mean (SD)	
	Before the programme	After 3 months in to DRP	Before the programme	After 3 months in to DRP	Before the programme	After 3 months in to DRP
Male	272.3 (99.6)	182 (63.4)	170.2 (52.2)	125.1 (39.1)	9.4 (1.8)	7.3 (1.3)
Female	245.2 (97.6)	182 (72)	174.3 (58.1)	136.2 (43.2)	9.3 (2)	7.6 (1.2)
Total	128.5	182	171.4	264.1	9.34	7.4

Table 1: Gender wise distribution of Mean FBS, PPBS and HbA1C values before and after diabetes reversal protocol.

The mean FBS, PPBS and HbA1C levels at the starting of the program was 182 mg/dl, 264 mg/dl and 9.34% respectively and mean FBS, PPBS and HbA1C levels at the end of DRP was 128.5 mg/dl, 171.4 mg/dl and 7.4% respectively (Table 1).

When the individual group of diabetic patients were classified based on their initial HbA1C levels as just at the risk level (slightly altered metabolism) 6 - 6.99%, Low risk: 7 - 7.99%, Moderate risk: 8 - 8.99%, High risk: 9 to 9.9% and higher risk: 10 and above 10% the outcome was studied (Table 2).

6 to 6.9%	2	116.5 (16.7)	107.5 (41.6)	161.0 (43.8)	136.8 (32.7)	6.68 (0.2)	5.98 (0.6)
7 to 7.9%	11	113.3 (31.4)	101.6 (20)	181.8 (63.0)	142.1 (36.0)	7.41 (0.3)	6.92 (0.65)
8 to 8.9%	11	162.7 (34.9)	133.2 (37.2)	217.2 (42.0)	170 (48.3)	8.89 (4.37)	7.36 (0.55)
9 to 9.9%	6	195.0 (46.3)	131.2 (37.4)	297.0 (65.4)	176.5 (64.0)	9.40 (0.2)	7.20 (1.2)
10 /> 10%	24	231.3 (55.6)	141.5 (45.6)	331.1 (93.5)	188.4 (59.2)	11.23 (1.1)	8.08 (1.5)

Table 2: HbA1c levels at various risk levels (>7 low, 8 and > moderate, (and > high risk).

When the results were compared among the patient’s duration of diabetes, it was seen that while the low risk patients easily showed the reversal process in a short duration, the high risk patients showed equally or better reversal process reducing the progression of the disease by showing reduction in HbA1C. Of the 56 individuals followed with Diabetes Reversal Protocol, 21.4% discontinued medication within 100 days, 50% reduced the medication needed to maintain the HbA1c within 90 days. Whereas 18% reduced medication after 140 days and 10% reduce HbA1c with medication (Table 3).

Reduction on the dependency of the medication	No of patients (Nos.)
Stopped medication within 90 - 100 days	12
Reduced medication within 90 - 100 days	28
Reduced medication after 90 days (within 140 days)	10
Reduced HbA1c without reducing the medication dosage in 90 days	6
Total	56

Table 3: Chart showing the cessation of medication and reduction of medication.

Discussion

The integrative approach for Diabetes Reversal Protocol involved a model, that screens diabetic people, educates them, on the science behind diabetes reversal process, counsels them to get committed to adhering to the protocol administered. The model had 3 components: 1) Screening and risk analysis 2) Lifestyle modification program that involved correction in food/diet, non-invasive therapies of Ayurveda, fitness (diabetic yoga), stress management techniques, and follow up of the same protocol for ninety days. 3) Titration of medication and gradual tapering down of the dosage. All these protocols were administered, and studies were conducted under the supervision of the respective medical experts. Of the 56 individuals followed with Diabetes Reversal Protocol, 21.4% discontinued medication within 100 days, 50% reduced the medication needed to maintain the HbA1c within 90 days. Whereas 18% reduced medication after 140 days and 10% reduce HbA1c with medication. Despite these encouraging results, we are not sure as to what specific component of the DRP, was effective in lowering the glycemic load in these individuals, as there were multiple components in the overall protocol. We have initiated further studies, to validate the effect of individual components of DRP as well as, combination interventions on glycemic load of diabetic and pre-diabetic individuals.

Future directions for validating our integrated therapy protocol

We will use Abbott Freestyle Libre 14-day ambulatory glucose monitor (AGM), to monitor interstitial glucose levels of all patients. Shown in the figure 1 and 2 are data for a typical diabetic patient. The patient studied is an 82-year old male, a long-term diabetic (> 20 years), who is on following medication: Metformin 1 gm/twice/daily), Glipizide (10 mg/twice/daily), Januvia (50 mg/twice/daily), carvedilol (6.25 mg twice/daily), Lisinopril (20 mg/twice/daily). Notice that in the daily mean levels presented in figure 2, there are no great variations in the mean values for interstitial glucose. However, the fasting glucose is fairly high, yet the HbA1c levels are modest (7.2%) considering his age. We would use prediabetic as well as diabetic individuals, to validate the effect of various components of the DRP on interstitial glucose levels.

For monitoring various metabolic risks, we will use noninvasive diagnostic platform developed by LD-Technologies (www.ldteck.com) of Miami, Florida. This diagnostic platform uses a novel approach, to compute a variety of metabolic risks. Since we are reviewing novel approaches, for the early diagnosis of metabolic risks in ‘at risk’ population, it is worth discussing the advantage or otherwise of this novel methodology. We can extend screening for metabolic risks as wells as clusters of risks, using this novel platform called, TM-Oxi, Sudo-Path and ES Complex systems. Basically, this noninvasive system comprises of an oximeter, blood pressure monitor, and a galvanic skin response monitor (Figure 3 and 4). TM-Oxi system detects diabetic or cardiac autonomic neuropathy and endothelial dysfunction; Sudo-Path system detects, early stages of peripheral autonomic neuropathy and alterations in microcirculation, whereas ES-Complex system, focuses on diabetes management and detection of diabetes-related complications. Since it is noninvasive, cost effective, one can use this system, to obtain information on a variety of early metabolic risks, as well as cluster of risks and develop risk scores [36-40].

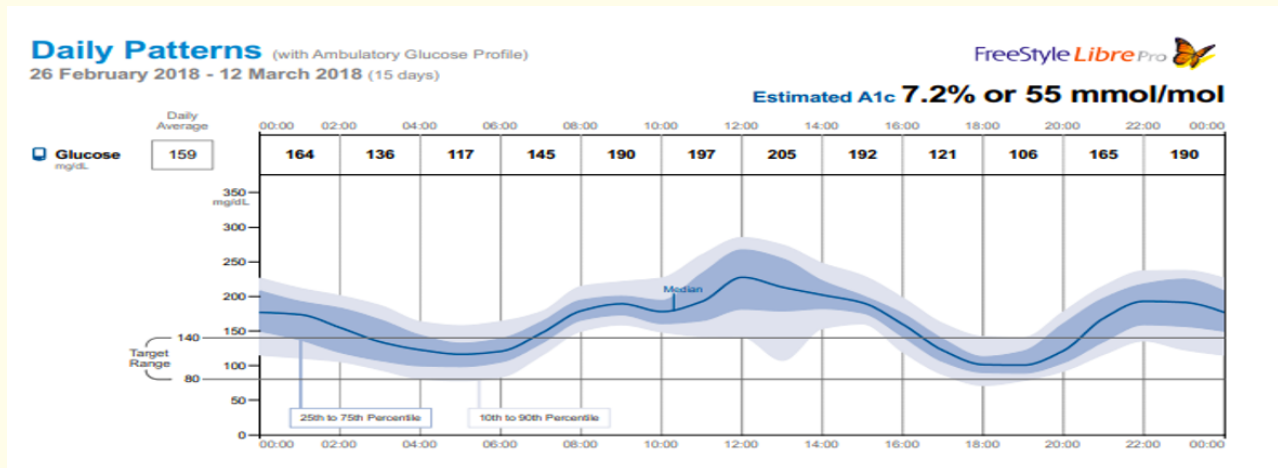


Figure 1: Daily patterns of interstitial glucose profile (Personal Data).

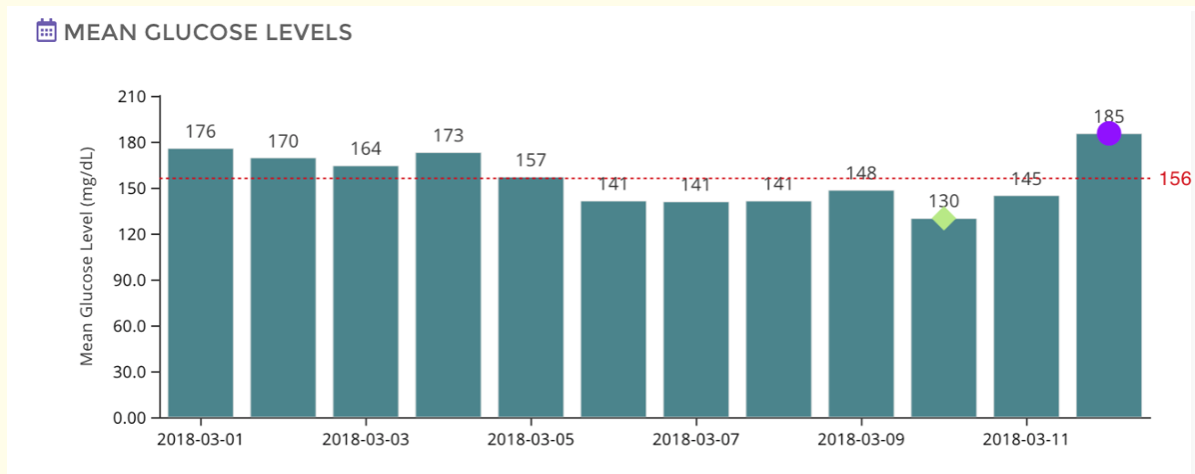


Figure 2: Mean daily interstitial glucose levels for 12-day period (Personal data).

Yoga originated in India over 4,000 years ago, as a traditional form of mind-body training, seems to unite the individual self with transcendental self [34]. Several trials have shown, that yoga can reduce fasting blood glucose, and glycosylated hemoglobin A1c, as well as lipid levels, and improve the quality of life of type-2 diabetes patients [41-46]. Although exact mechanism by which yoga alters the glucose metabolism is not well understood, there are speculations, that the benefits of integrated yoga therapy may be due, to stress reduction and relaxation. In our earlier studies, we have demonstrated the beneficial effects of a structured lifestyle education on metabolic risk reduction, using a noninvasive wellness screening platform developed by LD-Technologies [49,50] which computes wellness index using the risk scores for Life Score, Cardio metabolic score, Autonomic risk score and Vascular risk score (Figure 5).

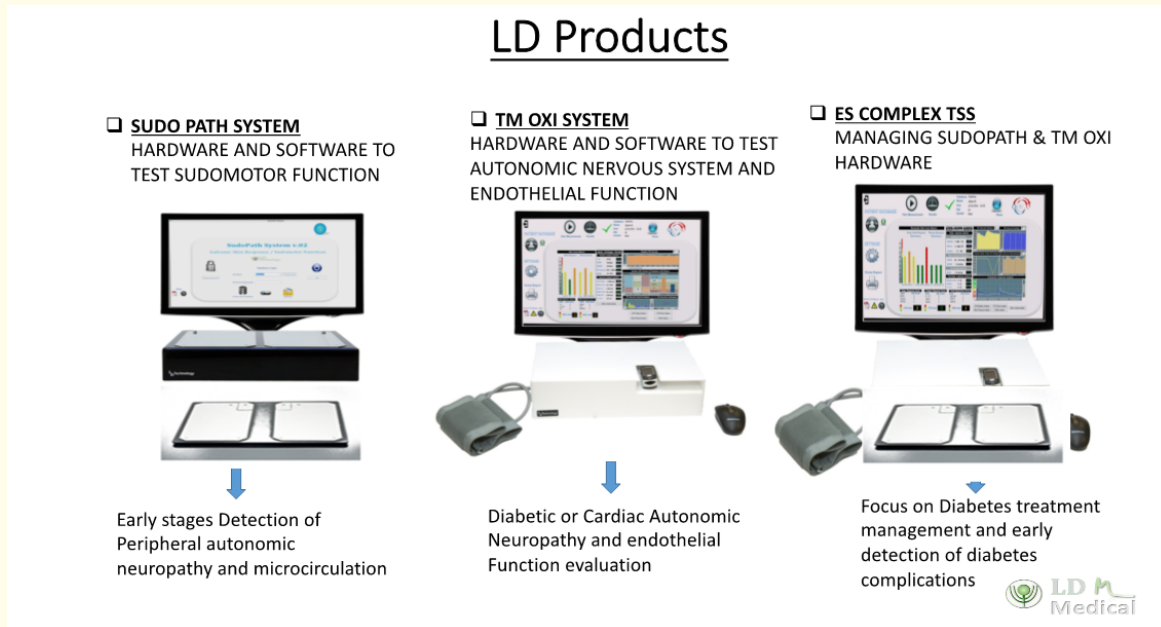


Figure 3: LD-products: SudoPathSystem, TM Oxi and ES complex systems (Courtesy: Dr Albert Maarek, LD Technologies, Miami, Florida).

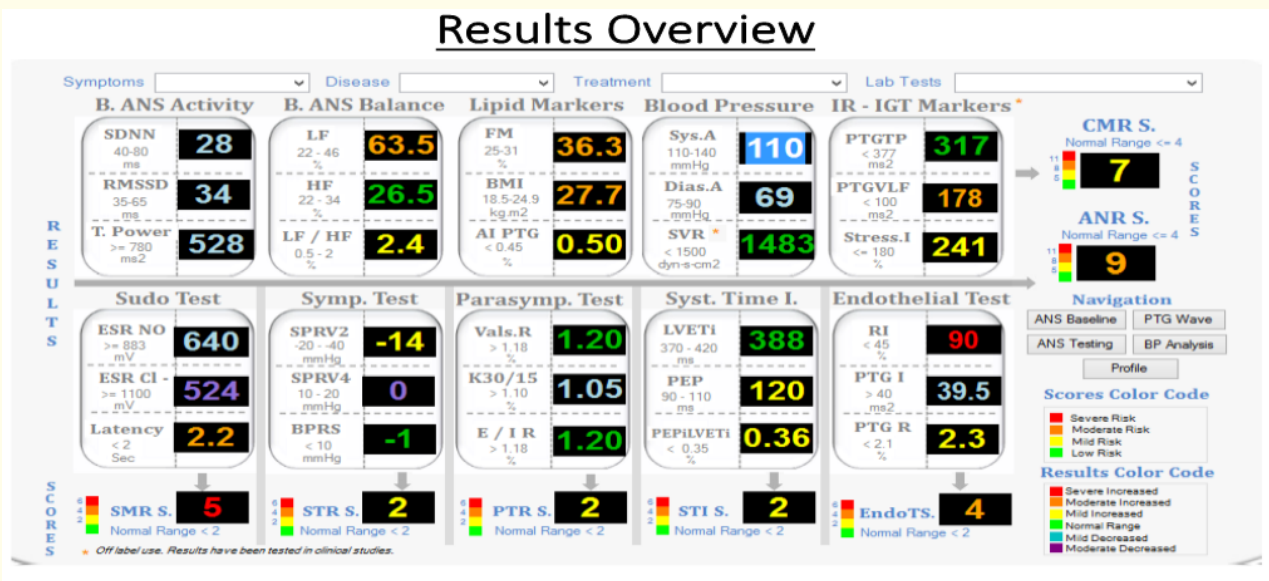


Figure 4: Metabolic risks, color coded and computed as risk scores (LD-technologies).

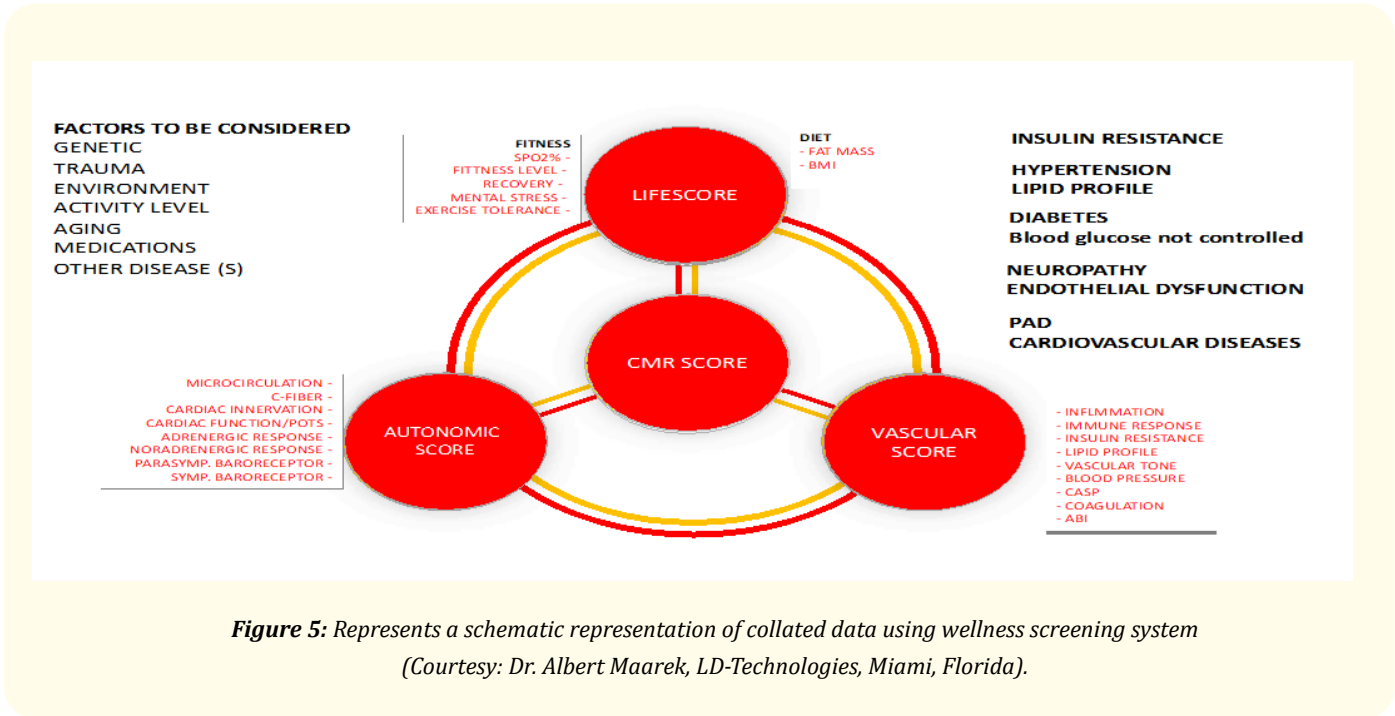


Figure 5: Represents a schematic representation of collated data using wellness screening system (Courtesy: Dr. Albert Maarek, LD-Technologies, Miami, Florida).

A typical wellness score report includes, information on microvascular and autonomic assessments, Sudo motor tests, nitric oxide peaks (representing vasodilation), C-fiber activity. Results of parasympathetic tests, sympathetic reflex tests, lower artery markers, which include right and left leg artery stiffness, vascular and endothelial homeostatic markers are also reported. Figure 5 shows a collective summary of tests and data in a diagrammatic way, to illustrate various risk scores, such as autonomic score (AN Score), vascular score, cardiometabolic score, and life score (diet and fitness score). Data for computing AN Score comes from following tests; microcirculation functions, C-fiber density and activity, cardiac innervation, cardiac function, adrenergic response, noradrenergic response, parasympathetic response, sympathetic response. Vascular Score is computed from data including: inflammation, immune responses, insulin resistance, lipid profile, vascular tone, blood pressure, coagulation, and arterial brachial index.

A fully Integrated Therapy Protocol used in our studies for ‘Diabetes Reversal Protocol’ included four interventions; Food, yoga (diabetic yoga), Non-invasive Ayurveda-Naturopathy therapies, and mind therapy (visualization-lymphatic tapping - which influences BEP¹ (Breaking the emotional pattern through visualization, meridian cleansing (Naadi shodana) and EFT (emotional freedom technique)) along with regular monitoring of bio markers, and consultation with the diabetologist. The Indian traditional therapies included were Udvarthana (powder massage), Shirodhara, Hydrotherapies (hip bath and spinal spray), Abhyanga (oil massage +steam) and GH pack (gastro-hepatic pack). Of the 56 individuals followed with Diabetes Reversal Protocol, 21.4% discontinued medication within 100 days, 50% reduced the medication needed to maintain the HbA1c within 90 days. Whereas 18% reduced medication after 140 days and 10% reduce HbA1c with medication. Despite the remarkable improvements seen in this study, it is not clear as to what components of this integrated therapy exerted the observed beneficial effects.

Review of literature shows, relatively little information on the effects of naturopathy, Ayurveda treatments and the mind therapy, on the glucose metabolism in diabetic subjects. Systematic reviews on Ayurvedic treatments, have pointed out to methodological weakness and have emphasized the need for testing Ayurveda as a whole system, or at least test multiple modalities at the same time [47]. Natu-

ropathy on the other hand, is an alternative medicine philosophy based on pre-scientific principles. The central belief of naturopathy is “vitalism.” Naturopathic treatments are all grounded in the idea of restoring this “energy”, similar to the Ayurvedic “Dosha System of Classification”, which emphasizes the normalization of the ‘altered doshas’ for achieving a healthy living. As we have mentioned earlier, modern science and modern medicine, have not answered all questions, nor they have addressed the prevention of metabolic diseases in any major way. In view of these observations, we would like to recommend development of complementary medicine approach, to the future healthcare in countries like China and India, where there is robust use of alternative and complementary therapies. We also feel strongly that the Traditional Medicine approach, if used wisely and scientifically, will play a very important role in the reduction, reversal, or prevention of metabolic diseases.

Chronic metabolic diseases are lifestyle diseases. Both genetic and lifestyle factors contribute to the promotion of metabolic diseases. Khera and associates at Harvard University, found that across four studies involving 55,685 participants, genetic and lifestyle factors were independently associated with susceptibility to coronary artery disease. Among participants at high genetic risk, a favorable lifestyle was associated with a nearly 50% lower relative risk for coronary artery disease, than was an unfavorable lifestyle [48]. The prevalence of obesity has increased eight-fold since 1975 [49]. In the last four decades childhood and adolescent obesity has increased ten-fold according to a study conducted by WHO, and the Imperial College of London [50]. Furthermore, in just about every country, there is greater number of prediabetics than diabetics. This huge ‘cohort’ of individuals with excess weight, children and adolescents with a tendency to become obese, and the growing number of pre-diabetics, should be the main target for the recruitment of subjects for preventive integrative therapy. These are likely to be most successful when targeting the young, and indeed will require a combination of approaches across health, local government, public health institutions, - to target families, schools and ‘at risk population, to facilitate behavior changes, which influence this cohort’s eating behaviors and physical activity. Yet another area of great interest for the Asian community is the need to address “Barker Hypothesis”, that advocates prenatal interventions and nutritional needs of the would be mother and the growing fetus.

Using the newly developed noninvasive wellness screening platform, we have demonstrated the beneficial effects of a structured wellness education on wellness index [51,52]. We also are developing a robust community healthcare program, as well as an awareness drive, to encourage adaptation of healthy lifestyle and increased physical activity. Our preliminary studies using an integrative approach, have given us a great hope for developing a robust integrative holistic approach, to the treatment and management of diabetes. With this approach, our team will take a personal approach, -a whole person approach, that may include a prescription or recommendation for changes in the diet, exercise habits, stress reduction, and other lifestyle considerations. The concept of whole-person medicine is gathering increasing support in the nutrition and dietetic profession. Equipped by robust scientific evidence-base, the integrative and functional medicine is primarily based on two principles; Each individual has a unique genetic make-up (as well as Prakriti or Dosha) and each individual functions with an internal and external factors that influence interactions with genes, gene expressions, which intern are influenced by the gut microbiome, the mind, body and the spirit.

Conclusion

Cardiometabolic disease like, hypertension, excess weight, obesity, type-2 diabetes and vascular diseases have reached a pandemic state worldwide. No country has reduced, reversed, or prevented these chronic metabolic diseases. By and large, these metabolic diseases are lifestyle diseases. Known metabolic risks include, oxidative stress, chronic inflammation, altered blood flow, increased blood pressure, insulin resistance, increased blood glucose, hardening of the arteries, endothelial dysfunction and subclinical atherosclerosis. Thousands of subjects have been studied worldwide, to validate the effect of complementary therapies on glycemic control, lipid profiles and other diabetes-related complications. Although meta-analysis of these studies uncovered clinically improved effects of yoga intervention on glycemic control, lipid profiles and some of the diabetes related parameters, not much is known about the various other components of the integrated therapies such as Naturopathy, Ayurveda, Integrated Yoga and their combined effects. In this preliminary study, we have explored the effect of a Diabetes Reversal Protocol, using such a combination therapy. Of the 56 individuals followed with Diabetes Re-

versal Protocol, 21.4% discontinued medication within 100 days, 50% reduced the medication needed to maintain the HbA1c within 90 days. Whereas 18% reduced medication after 140 days and 10% reduce HbA1c with medication. The results of these studies, although are very encouraging, do not provide conclusive information on what component of this protocol is effective, in reducing the glycemic load or the mechanism by which this observed improvements occur. Future studies will employ a battery of noninvasive technologies, such as Abbott Freestyle Libre 14-day ambulatory glucose monitor, LD-technologies metabolic profiler, as well as thermal imaging to identify the specificity and accuracy of this diabetes reversal protocol.

Bibliography

1. Rao GHR and Kakkar VV. "Coronary Artery Disease in South Asians: Epidemiology, Risk Factors, and Prevention". JP Medical Publishers, New Delhi, India (2001).
2. NCD Risk Factor Collaboration (NCD-RisC). "Worldwide trends in blood pressure from 1975 to 2015: a pooled analysis of 1479 population-based measurement studies with 19.1 million participants". *Lancet* 389 (2017): P37-P55.
3. Global Burden of Metabolic Risk Factors for Chronic Disease Collaboration. "Cardiovascular disease, chronic kidney disease, and diabetes mortality burden of cardiometabolic risk factors from 1980 to 2010: a comparative risk assessment". *The Lancet Diabetes and Endocrinology* 2 (2014): 634-647.
4. NCD Risk Factor Collaboration. "Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants". *Lancet* 387 (2016): 1513-1530.
5. Kearney PM., *et al.* "Global burden of hypertension: analysis of worldwide data". *Lancet* 365 (2005): 217-223.
6. Evans A., *et al.* "Trends in coronary artery disease risk factors in the WHO MONICA project". *International Journal of Epidemiology* 30 (2001): S35-S40.
7. Juonala M., *et al.* "The 21-year follow up of the cardiovascular risk in young Finns Study: risk factor levels, secular trends and east-west difference". *Journal of Internal Medicine* 255 (2004): 457-468.
8. Reilly JJ., *et al.* "Determining the worldwide prevalence of obesity". *Lancet* 391 (2018): 1773-1774.
9. NCD Risk Factor Collaboration (NCD-RisC). "Worldwide trends in body mass-index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128.9 million children, adolescents, and adults". *Lancet* 390 (2017): 2627-2642.
10. NCD Risk Factor Collaboration (NCD-RisC). "Trends in adult body-mass index in 200 countries from 1975 to 2014: a pooled analysis of 1968 population-based measurement studies with 19.2 million participants". *Lancet* 387 (2016): 1377-1396.
11. The Global Burden of Metabolic Risk Factors for Chronic Diseases Collaboration (BMI Mediate Effects). "Metabolic mediators of the effects of body-mass index, overweight, and obesity on coronary artery disease and stroke: a pooled analysis of 97 prospective cohorts with 1.8 million participants". *Lancet* 383 (2014): 970-983.
12. WHO. "Global action plan for the prevention and control of non-communicable diseases 2013-2020". World Health Organization, Geneva, Switzerland (2013).
13. Kontis V., *et al.* "Contribution of six risk factors to achieving the 25 x25 non-communicable disease mortality reduction target: a modeling study". *Lancet* 384 (2014): 427-437.

14. Ng M., *et al.* "Global, regional and national prevalence of overweight and obesity in children and adults during 1980-2013: a systematic analysis for the Global Burden of Disease Study 2013". *Lancet* 384 (2014): 766-781.
15. NCD Risk Factor Collaboration (NCD-RisC). "Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants". *Lancet* 387 (2016): 1513-1530.
16. Seuring T., *et al.* "The economic costs of type-2 diabetes: a global systematic review". *Pharmacoeconomics* 33 (2015): 811-831.
17. Danaei G., *et al.* "National, regional, and global trends in fasting glucose and diabetes prevalence since 1980: systematic analysis of health examination surveys and epidemiological studies with 370 country-years and 2.7 million participants". *Lancet* 378 (2011): 31-40.
18. Beagley J., *et al.* "Global estimates of undiagnosed diabetes in adults". *Diabetes Research and Clinical Practice* 103 (2014): 150-160.
19. Gakidou E., *et al.* "Management of diabetes and associated cardiovascular risk factors in seven countries: a comparison of data from national health surveys". *Bulletin of the World Health Organization* 89 (2011): 172-183.
20. Shen X., *et al.* "The diabetes epidemic in China: An integrated review of national surveys". *Endocrine Practice* 22.9 (2016): 1119-1129.
21. Yip WCY., *et al.* "Prevalence of Prediabetes across ethnicities: A review of Impaired Fasting Glucose (IFG) and Impaired Glucose tolerance (IGT) for classification of Dysglycemia". *Nutrients* 9 (2017): 1273.
22. Song SH and Hardisty CA. "Early-onset type- diabetes mellitus: an increasing phenomenon of elevated cardiovascular risk". *Expert Review of Cardiovascular Therapy* 6.3 (2014): 315-322.
23. Krueger A., *et al.* "Dietary and Lifestyle changes reverses hypertension rapidly". *Current Developments in Nutrition* 3.1 (2019): 16-20.
24. Kumayika SK., *et al.* "Population-based Prevention of Obesity: The need for comprehensive promotion of healthful eating, physical activity, and energy balance: A scientific statement from American Heart Association Council on Epidemiology and Prevention, Interdisciplinary committee for Prevention (Formerly the Expert Panel on Population and Prevention Science)". *CUTS Institute for Regulation and Competition* 118 (2008): 428-464.
25. Taylor R., *et al.* "Understanding the mechanism of reversal of type-2 diabetes. Personal View". *The Lancet Diabetes and Endocrinology* 7.9 (2019): 726-736.
26. Di Cesare M., *et al.* "The Contributions of risk factor trends to cardiometabolic mortality decline in 26 industrialized countries". *International Journal of Epidemiology* 42.3 (2013): 838-848.
27. Raghuram N., *et al.* "A Yoga based lifestyle for type-2 diabetes: need for a nation-wide movement to control type 2 diabetes". *Journal of Diabetes Research* 5.5 (2018): 188-193.
28. McDermott KA., *et al.* "A yoga intervention for type-2 diabetes risk reduction: a pilot randomized controlled trial". *BMC Complementary and Alternative Medicine* 14 (2014): 212.
29. Nagarathna R., *et al.* "Efficacy of yoga life style modification program on medication score and lipid profile in type-2 diabetes- a randomized control study". *International Journal of Diabetes in Developing* 33.3 (2012):122-130.
30. Singh AK., *et al.* "Partitioning of radiological , stress and biochemical changes in pre-diabetic women subjected to Diabetic Yoga Protocol". *Diabetes, Metabolic Syndrome Clinical Research Revenue* 13 (2019): 2705-2713.

31. Covington MB. "Traditional Chinese Medicine in the Treatment of Diabetes". *Diabetes Spectrum* 14.3 (2001):154-159.
32. Chimodke SM., et al. "Effect of Yoga on Blood Glucose Levels in Patients with Type 2 Diabetes Mellitus". *Journal of Clinical and Diagnostic Research* 9.4 (2015): CC01-CC03.
33. Aljasir B., et al. "Yoga Practice for the Management of Type II Diabetes Mellitus in Adults: A systematic review". *Evidence-Based Complementary and Alternative Medicine* 7.4 (2010): 399-408.
34. Cui J., et al. "Effects of yoga in adults with type-2 diabetes mellitus: A meta-analysis". *Journal of Diabetes Investigation* 8.2 (2017): 201-209.
35. Ramamoorthi R., et al. "The effect of yoga practice on glycemic control and other health parameters in the prediabetic state: A systematic review and meta-analysis". *PLoS One* 14.10 (2019): e0221067.
36. Gandhi PG and Rao GHR. "The Spectral Analysis of Photoplethysmography to Evaluate an Independent Cardiovascular Risk Factor". *International Journal of General Medicine* 7 (2014): 39-47.
37. Gandhi PG Rao. "Detection of Neuropathy Using SudoMotor Tests in Type-2 Diabetes". *Degenerative Neurological and Neuromuscular Diseases* 5 (2015): 1-7.
38. Maarek A., et al. "Identifying autonomic neuropathy and endothelial dysfunction in Type 11 diabetic patients". *EC Neurology* 22 (2015): 63-78.
39. Rao GHR and Gandhi PG. "Need for a non-invasive diagnostic platform for early detection and management of cardiometabolic disorders". *European Journal of Preventive Cardiology* 3.3 (2014): 93-98.
40. Obi Uzomba and Rao GHR. "Management of diabetes, metabolic syndrome and cardiovascular complications using a novel diagnostic platform". *Interventions in Obesity and Diabetes* 2.3 (2018).
41. Singh S., et al. "Influence of pranayamas and yoga-asanas on serum insulin, blood glucose and lipid profile in type 2 diabetes". *Indian Journal of Clinical Biochemistry* 23 (2008): 365-368.
42. Kyizom T., et al. "Effect of pranayama and yoga-asana on cognitive brain functions in type 2 diabetes-P3 event related evoked potential (ERP)". *Indian Journal of Medical Research* 131 (2010): 636-640.
43. Popli U., et al. "Research letter-the role of yoga as a lifestyle modification in treatment of diabetes mellitus: results of a pilot study". *Alternative Therapies in Health and Medicine* 20 (2014): 24-26.
44. Jyotsna VP., et al. "Completion report: Effect of Comprehensive Yogic Breathing program on type 2 diabetes: A randomized control trial". *Indian Journal of Endocrinology and Metabolism* 18 (2014): 582-584.
45. Skoro-Kondza L., et al. "Community based yoga classes for type 2 diabetes: an exploratory randomized controlled trial". *BMC Health Services Research* 9 (2009): 33.
46. Shantakumari N., et al. "Effects of a yoga intervention on lipid profiles of diabetes patients with dyslipidemia". *Indian Heart Journal* 65 (2003): 127-131.
47. Sridharan K., et al. "Ayurvedic treatments for diabetes mellitus". *The Cochrane Database of Systematic Reviews*.

48. Khera AV, *et al.* "Genetic Risk, Adherence to a Healthy Lifestyle, and Coronary Disease". *The New England Journal of Medicine* 375 (2016): 2349-2358.
49. Gregory JW. "Prevention of Obesity and Metabolic Syndrome in Children". *Frontiers in Endocrinology* (2019).
50. Di Cesare M., *et al.* "The epidemiological burden of obesity in childhood: a worldwide epidemic requiring urgent action". *BMC Medicine* 17.212 (2019).
51. Malmefeldt E and Rao GHR. "Changing concepts of healthcare: Physical activity, Fitness and Wellness. EC Endocrinol". *Metabolism Research* 4.6 (2019): 238-250.
52. Malmefeldt E and Rao GHR. "Non-invasive Diagnostic Tools: Cardiometabolic Risk Assessment and Prediction". *Journal of Clinical Cardiology and Diagnostics* 2.1 (2019): 1-10.

Volume 3 Issue 8 August 2020

©All rights reserved by Gundu HR Rao., *et al.*