Proposed Yoga Protocol Based on Glycemic Control, Insulin Resistance and Anthropometry-specified Parameters: A Retrospective Study on Clinically Euthyroid Type II Diabetics

Manoharan Mangalagowri1, Rajendran Jayanthi2, Abu R Srinivasan3, Ananda B Bhavanani4, Ramanathan Meena5

ABSTRACT

Background and objectives: Inclusion of yoga in the daily routine would favorably moderate glycemic control, alleviate insulin resistance (IR), besides reducing the risk of complications in people with long-standing diabetes and comorbidity. The body mass index (BMI) cut-off criteria are different as per the Asian Indian and WHO standards. Accordingly, overweight range of 23–24.9 in the Asian Indian category will fall under the nonobese category. Obese range of ≥25 BMI in the Asian Indian group will come under the overweight category as per the WHO standards. To devise a unique yoga protocol based on anthropometry and biochemical assessment, has been proposed with reference to specific parameters in insulin-resistant, clinically euthyroid type II diabetics with special reference to Asian Indian and WHO standards.

Materials and methods: A retrospective study was conducted in the Department of Biochemistry with inputs from the diabetic clinic of a tertiary care teaching hospital as well as a designated center for yoga therapy, following acceptance from the research advisory committee. The study subjects were clinically euthyroid type II diabetics (both genders) in the age group 35–70 years who were on diabetic diet and oral hypoglycemic agents (OHAs). Data from clinically euthyroid type II diabetics (n = 101) (adult males and females in the age group 35–70) were utilized for the study. The Pearson correlation coefficient and multivariate analysis were enabled and p < 0.05 was considered significant.

Results: Statistically significant associations were observed between IR (dependent variable) and other independent variables, namely HbA1c, TAG/HDL (surrogate marker of small dense LDL), and thyroid hormones. With reference to BMI, based on Asian Indian standards, TAG/HDL depicted association with homeostasis model assessment-Insulin resistance (HOMA-IR) (p = 0.011) and TSH was negatively associated with HbA1c (p = 0.027) in overweight; HbA1c and TSH exhibited positive association with p = 0.001 and 0.04, respectively, in obese as per the Asian Indian criteria for BMI. Keeping BMI as per the WHO, TAG/HDL (p = 0.008) in nonobese and in overweight HbA1c with p = 0.001 were associated with HOMA-IR. Significant association was not found in the obese subjects, as per the WHO standards.

Conclusion: There is a need for a unique yoga protocol to address clinically euthyroid type II diabetics. Hitherto, such a protocol has not been developed, especially with reference to BMI, as per the Asian Indian and WHO standards. Practicing this proposed yoga protocol on the basis of anthropometry might prove beneficial in glycemic control, alleviating IR, besides reducing complications of type II diabetics in euthyroid population who may later be candidates for frank thyroid comorbidity.

Keywords: Anthropometry, Asian Indian, Euthyroid, Insulin resistance, T2DM, WHO, Yoga.

INTRODUCTION

Diabetes mellitus is a chronic, metabolic disorder that affects glucose utilization by the tissues. Hyperglycemia is a pronounced characteristic feature. The body either does not synthesize adequate insulin or it resists insulin. Statistics received from the International Diabetes Federation (IDF) say that approximately 463 million adults (20–79 years) are living with diabetes; by year 2045, this will rise to 700 million.1 In developed countries, more than half of the people with type II diabetes mellitus are older than 65 years. In developing countries, 75% of diabetic patients are 45 years old and above and 25% of adults with diabetes mellitus are under 44 years.2

Insulin resistance (IR) is defined as the diminished ability of cells to respond to the action of insulin in the transport of glucose from the bloodstream into insulin-responsive tissues. Defective signal transduction or mutations in the insulin receptor that interfere with binding or autoantibodies to the insulin receptor are some of the projected mechanisms for IR.

Insulin resistance is a clinical condition that comprises of a spectrum of disorders that include IR, hypertension, dyslipidemia (decreased HDL and elevated triacylglycerols), central or visceral obesity, type II diabetes or impaired glucose tolerance/impaired fasting glucose, and accelerated cardiovascular diseases. It is to be mentioned that the common comorbidity of T2DM pertains to cardiometabolic risk, besides the characteristic neuropathy, retinopathy, nephropathy, and thyroid disorders.
In the light of the above-mentioned facts, identifying pragmatic lifestyle interventions relevant to the management of T2DM is considered cardinal. Mind–body practices such as yoga refer to the ability of the mind to enhance physical and mental health. In addition, they are ideally suited for objectively addressing multifactorial conditions. It is noteworthy to mention that yoga is a traditional mind–body system that had its roots in the Indian subcontinent over 4,000 years ago. In recent times, the practice of yoga has been on the rise the world over. Yoga therapy as an adjuvant therapy is rapidly emerging as a complimentary medicine. However, evidence-based yoga therapy (comprising of asanas and pranayamas) is a relatively new clinical discipline. Yoga therapy as an adjuvant medicine essentially comprises well-defined body postures (asana) and designated breathing techniques (pranayama). Yoga therapy is generally regarded as safe, easy to learn, and practice with near perfection by even ill, elderly, or disabled individuals. Furthermore, yoga improves psychological conditions to overcome stress and manage emotions. Previous findings point to the fact that yogic practices may help promote significant enhancement in T2DM management, since diabetes mellitus constitutes essentially a broad spectrum in which several glands are implicated appropriately. Asanas that compress and stretch the throat area are regarded as helpful adjuvant modulators. Besides, the pranayama techniques possess a warming effect, which will help individuals whose thyroid imbalance make feel constantly cold. The quantitative determination of insulin, cortisol, triiodothyronine (T3) and thyroxine (T4), and thyroid-stimulating hormone (TSH) is recognized as characteristic of the designated scenario in type II diabetes. However, frequently latent comorbidity of thyroid in T2DM has not been deserving due consideration.

In view of the above-mentioned facts, the present study has proposed a protocol based on yoga therapy. Till date very few protocols are available in the literature on yoga for clinically euthyroid type II diabetic population. Besides, the anthropometric standards of establishing obese and overweight vary with Asian Indian BMI standards, only T3 vs T4 was found significant. Since statistically significant correlation was observed among the anthropometry-specified groups, we had promulgated multiple regressions that form the crux of the results of the present study.

Scope of the Present Investigation
To our surprise, when we had assessed the outpatient register of our hospital and checked with the biochemical profile, we had elicited the fact that despite continuous IR associated with thyroid abnormalities the world over, there was a high percentage of T2DM patients in our hospital who had no previous history or overt clinical manifestation of thyroid disorders.

We also found out that not many references are available citing the significance of the objectified yoga protocol for the special group, namely the clinically euthyroid type II diabetics. Hence, based on the retrospective data that were included in the study and keeping in view the advantage of possessing an exclusive center for administering yoga therapy at our institute that specializes in evidence-based complimentary medicine, we hereby propose a unique protocol of yoga therapy that is purported to have beneficial effects on type II diabetics who are clinically euthyroid. More of prospective studies in future, using this protocol developed by the authors of this paper, are needed. This unique protocol embraces the essence of yoga therapy, as applied to frank T2DM and thyroid disorders.

Materials and Methods
A retrospective study was conducted in the Department of Biochemistry with inputs from the diabetic clinic of a tertiary care teaching hospital as well as a designated center for yoga therapy, following acceptance from the research advisory committee. The study subjects were clinically euthyroid type II diabetics (both genders) in the age group 35–70 years who were on diabetic diet and oral hypoglycemic agents (OHA).

Inclusion Criteria
Data from clinically euthyroid type II diabetics (n = 101) (adult males and females in the age group 35–70) were utilized for the study.

Exclusion Criteria
Data from patients with a well-documented history of thyroid diseases were not considered as also from those with a history of cardiac, liver, endocrine, and muscle diseases.

Biochemical Measurements
All the biochemical measurements were enabled as laid down by the guidelines of the International Federation of Clinical Chemistry (IFCC). The internal QC was achieved with assistance of QC samples provided by M/S Biorad, United States. The external quality assessment was initiated through a collaborative effort with the clinical biochemistry laboratory (accredited by NABL under ISO/IEC 15189), Christian Medical College, Vellore, that is under the aegis of Association of Clinical Biochemistry of India (ACBI). Fasting and postprandial blood glucose were estimated based on the glucose oxidase-peroxidase method. Fasting insulin (venous plasma) was estimated by automated electrochemiluminescence. HbA1c was determined by high-performance liquid chromatography. Insulin resistance was computed by the homeostatic model assessment and computed using the formula. Triacylglycerols and total cholesterol in serum were quantitated by the enzymatic method. High-density lipoprotein (HDL) cholesterol was quantitated by polyanion precipitation. The LDL cholesterol was computed by the Friedewald equation; small dense LDL particles were measured using the surrogate marker (TAG/HDL). Free triiodothyronine (FT3), free thyroxine (FT4), and thyrotropin (TSH) in serum were measured by the automated electrochemiluminescence method.

Statistical Analysis
The Epi Data version 2.2.2.186 and MS Excel were used for statistical analysis for the Pearson correlation coefficient with reference to the study parameters and p < 0.05 was considered statistically significant.

Since statistically significant correlation was observed among the anthropometry-specified groups, we had promulgated multiple regressions that form the crux of the results of the present study.

Results
The Pearson’s coefficient correlation was significant with homeostasis model assessment-insulin resistance (HOMA-IR) that had positively correlated with TAG/HDL (surrogate marker of small dense LDL) and HbA1c vs T3 was negatively associated in nonobese (as per WHO). In overweight category as per WHO standards, both HbA1c vs HOMA-IR and T3 vs T4 depicted strong significance, whereas as per Asian Indian BMI standards, only T3 vs T4 was significant. Obese, as per WHO standards, exhibited significance between HbA1c and T4 (Table 1).
Table 1: Pearson’s correlation coefficient among different parameters in nonobese, overweight, and obese clinically euthyroid type II diabetic patients with Asian Indian and WHO BMI standards

| Parameters | Asian Indian BMI std. | WHO BMI std. |
|-----------|-----------------------|--------------|
|           | r value | p value | r value | p value |
| Nonobese  |          |         |          |         |
| HbA1c vs T3 | -0.941 | 0.059 | -0.666 | 0.001** |
| HOMA-IR vs TAG/HDL | -0.300 | 0.700 | 0.607 | 0.002** |
| Overweight |          |         |          |         |
| HbA1c vs T3 | -0.560 | 0.013 | -0.176 | 0.174 |
| HOMA-IR vs TAG/HDL | 0.657 | 0.002 | 0.019 | 0.884 |
| HbA1c vs HOMA-IR | 0.267 | 0.269 | 0.384 | 0.002** |
| T3 vs T4 | 0.005** | 0.982 | 0.561 | 0.000** |
| Obese     |          |         |          |         |
| HbA1c vs HOMA-IR | 0.325 | 0.004 | 0.081 | 0.756 |
| T3 vs T4 | 0.333 | 0.003 | -0.302 | 0.240 |
| HbA1c vs T4 | 0.085 | 0.457 | 0.537 | 0.026* |

*Correlation is significant at the 0.05 level, **correlation is significant at the 0.01 level

Table 2 represents the multivariate analysis, which depicted that in Asian Indian standard overweight, the p value was significant with TAG/HDL and TSH as 0.011 and 0.027, respectively, when HOMA-IR was taken as a dependent variable.

Table 2A shows multivariate analysis for anthropometry specified (Asian Indian Standard for Obese Type II Diabetics); data from Asian Indian obese type II diabetics depicted the p value that was significant with HbA1c and TSH (0.001 and 0.044, respectively).

Table 2B depicts the multivariate analysis for anthropometry specified (nonobese, as per WHO standards); the p value was significant between HOMA-IR and TAG/HDL (0.008).

Table 2C indicates that in overweight (as per WHO standards), the p value is significant between HOMA-IR and HbA1c (p value 0.001), and there was no significance found between the parameters with HOMA-IR as dependent variable in obese WHO BMI standards.

Discussion

Yoga as a holistic, evidence-based medical science has been in vogue over thousands of years. Physical exercise is a major therapeutic modality in the treatment of type II diabetes mellitus and prevention of complications.13 Hitherto, studies have been focused on yoga exercise in particular reference to glucolutilization.30,31 The intrinsic value of yoga therapy in decreasing fasting and postprandial blood glucose concentrations has been addressed; in addition, the morbidity associated with dyslipidemia as perceived in IR has also been scientifically documented. The role of the counterregulatory hormones in general and cortisol in particular has been the focus of many scientific studies as linked to stress hormones on IR. According to the previous documented research, the favorable changes observed may be attributed to a conglomerate of factors including exercise, metabolism, endocrine influence on insulin, and counterregulatory hormones.32,33 A host of factors, including sociodemography and environment, also play an important role in the progression of T2DM in the genetically vulnerable population. It may be noted that IR dramatically enhances the risk of cardiovascular morbidity.23–25

Several previous studies have shown beneficial effects of yoga in improving conditions associated with IR.26–28 Few studies have, however, reported the effect of yoga therapy on thyroid.29 Several lines of evidence suggest that yoga therapy is beneficial in reducing blood sugar levels pronouncedly following discrete yoga sessions (asanas, pranayama, or both) in the usual routine (mostly for 60 minutes per day, 1–5 days per week) and the duration of intervention ranged from a period of 6 weeks to 6 months. In another study, similar effects were observed in a much shorter period, namely 2 weeks. This suggests if different components of yoga are integrated holistically on the basis of yoga-based lifestyle.30 The impact of exercise points to the glucose transporter, namely GLUT-4. A few mechanisms have been proposed.31

Alterations in the breathing pattern through pranayama can influence to a large extent insulin sensitivity and glycemic status even in healthy individuals and in also such individuals with diabetes. It remains to be clear if insulin sensitivity precedes enhancement in sympathetic outflow, or otherwise.32 This essentially means the depiction of a definite mechanism, which is difficult to project. Though several studies have been conducted as evidenced-based, which project the harmless administration of a therapeutic, adjuvant, and complementary modality, namely Yoga, a greater and well-developed research protocol has to be validated, prior to promulgation.33 It is postulated that direct rejuvenation/regeneration of cells of the pancreas may be taking place, which may increase utilization and metabolism of glucose in the peripheral tissues, liver, and adipose tissues through the enzymatic process.33–35 In one issue, they have demonstrated beneficial effects of the short-term Yoga-based lifestyle intervention program on diabetes risk factors in obese individuals.36

Significant findings were revealed based on our study with reference to the characteristic biochemical profile. Whereas, no significance was observed between IR and the surrogate marker of small dense LDL in the BMI as laid down by Asian Indian standards, a significant association confirmed by the multivariate analysis was exhibited with statistically significant associations between the same parameters (HOMA-IR and TAG/HDL) in the criterion for BMI, as laid down by the WHO. Other interesting findings were differentially observed in the biochemical parameters, namely HbA1c, TAG/HDL and TSH, when evaluated as a function of IR. This is an important finding because there are very few studies oriented toward key biochemical parameters, in the light of different criteria for BMI (Asian Indian, WHO). As a corollary in future, when yoga protocols are established for universal type II diabetic population, care must be taken to follow the BMI criteria strictly with regard to the interpretation of results. For instance, the group designated as obese based on Asian Indian standards would fall into the overweight category, as per WHO standards. We advise that in future, objectified protocols based on yogasanas and pranayama should take into due considerations the aforementioned details for realizing the optimal benefit conferred by yoga on the type II diabetic population in general and clinically euthyroid type II diabetics, in particular. A study group showed a significant weight loss, reduction in waist circumference, and an improvement in psychological well-being.37 Hitherto, yoga protocols have been established with a view to augmenting the evidence-based considerations, as determined by previous workers. However, it must be said that despite the fact that the IR inherent in metabolic...
syndrome (MetS) can be controlled by pranayama and yogasanas, not many reports from the Indian subcontinent are available in this scenario.

Yet another feature is that the anthropometric measures such as BMI, waist circumference (WC), and waist hip ratio (WHR) are differently underlined with reference to IR. This is because IR is directly linked to central adiposity, which will be best described by WC. If BMI is taken as an anthropometry benchmark, then the differences would be observed in the categorization of obese and nonobese. This causes confusion that is partly explained by the WHO and Asian Indian criteria for delineating obese, overweight, and nonobese. This is also revealed in conflicting report as exemplified by the published literature. However, 8-week yoga therapy did not have any effect. Another study reports that yogic

### Table 2: Multivariate analysis for anthropometry-specified (Asian Indian Standard for Overweight based on BMI) type II diabetics

| Model       | Unstandardized coefficients | Standardized coefficients | t  | p value |
|-------------|-----------------------------|---------------------------|----|---------|
|             | B                           | Std. error                | Beta|         |
| HbA1c       | 0.773                       | 0.715                     | 0.242| 1.081  | 0.303 |
| TAG/HDL     | 1.577                       | 0.516                     | 0.613| 3.057  | 0.011 |
| T3          | 6.366                       | 3.587                     | 0.380| 1.774  | 0.104 |
| T4          | -13.414                     | 7.061                     | -0.322| -1.900 | 0.084 |
| TSH         | -2.452                      | 0.961                     | -0.620| -2.552 | 0.027 |
| Cortisol    | 0.385                       | 0.232                     | 0.297| 1.656  | 0.126 |
| TC/LDL      | 6.482                       | 3.406                     | 0.570| 1.903  | 0.084 |

Dependent variable—HOMA-IR
*Correlation is significant at the 0.05 level
HbA1c, glycated hemoglobin; T3, triiodothyronine; T4, thyroxine; TC, total cholesterol; TAG, triacylglycerol; HDL, high-density lipoprotein; LDL, low-density lipoprotein

### Table 2A: Multivariate analysis for anthropometry-specified (Asian Indian Standard for Obese based on BMI) type II diabetics

| Model       | Unstandardized coefficients | Standardized coefficients | t  | p value |
|-------------|-----------------------------|---------------------------|----|---------|
|             | B                           | Std. error                | Beta|         |
| HbA1c       | 0.644                       | 0.189                     | 0.417| 3.400  | 0.001 |
| TAG/HDL     | 0.179                       | 0.168                     | 0.150| 1.070  | 0.288 |
| T3          | 1.262                       | 1.002                     | 0.179| 1.259  | 0.212 |
| T4          | -0.946                      | 2.066                     | -0.057| -0.458 | 0.648 |
| TSH         | 0.535                       | 0.261                     | 0.223| 2.050  | 0.044 |
| Cortisol    | -0.103                      | 0.080                     | -0.172| -1.290 | 0.201 |
| TC/LDL      | -0.937                      | 0.931                     | -0.145| -1.006 | 0.318 |

Dependent variable—HOMA-IR
*Correlation is significant at the 0.05 level
HbA1c, glycated hemoglobin; T3, triiodothyronine; T4, thyroxine; TC, total cholesterol; TAG, triacylglycerol; HDL, high-density lipoprotein; LDL, low-density lipoprotein

### Table 2B: Multivariate analysis for anthropometry-specified (WHO standard for Nonobese based on BMI) type II diabetics

| Model       | Unstandardized coefficients | Standardized coefficients | t  | p value |
|-------------|-----------------------------|---------------------------|----|---------|
|             | B                           | Std. error                | Beta|         |
| HbA1c       | 0.182                       | 0.885                     | 0.060| 0.206  | 0.839 |
| TAG/HDL     | 1.941                       | 0.632                     | 0.716| 3.069  | 0.008 |
| T3          | 1.508                       | 4.419                     | 0.097| 0.341  | 0.738 |
| T4          | -6.274                      | 8.118                     | -0.150| -0.773 | 0.452 |
| TSH         | -0.965                      | 1.128                     | -0.235| -0.855 | 0.406 |
| Cortisol    | 0.197                       | 0.296                     | 0.145| 0.666  | 0.516 |
| TC/LDL      | -0.303                      | 3.874                     | -0.025| -0.078 | 0.939 |

Dependent variable—HOMA-IR
*Correlation is significant at the 0.05 level
HbA1c, glycated hemoglobin; T3, triiodothyronine; T4, thyroxine; TC, total cholesterol; TAG, triacylglycerol; HDL, high-density lipoprotein; LDL, low-density lipoprotein
training modulates the thyrotropin-thyroid hormone release. Researchers who had studied influence of yoga on T2DM or MetS or thyroid disorders have cited isolated evidences. In our laboratory while we were looking to the retrospective data acquired over a period of 6 months, we found out that the type II diabetics under focus had no gross evidences of thyroid disorders. This led to the present study, wherein we had laid due emphasis on elaborating a protocol that is unique to this study population, namely the combination of pranayama technique and yogasanas to address clinically euthyroid T2DM. At our sister center, a dedicated center for yoga therapy has prepared a protocol that is a conglomerate of yoga therapy administered for addressing disorders such as metabolic syndrome, T2DM, hypothyroid, and hyperthyroidism. We aim to administer this protocol on this special study population at different centers, following due approval that would open newer vistas in alleviating IR besides restoring euthyroid status. Several studies have found an association of thyroid function with BMI and IR associated with (latent) thyroid comorbidity, but only after a definite yoga therapy protocol can be promulgated for this special group (T2DM clinically euthyroid).

Yoga has been shown to be effective in reducing the WC, blood pressure, and improving the lipid and glycemic profiles in metabolic syndrome. This is important as the potential use of yoga as lifestyle modification in elderly individuals with MetS will result in significant reduction of the prevalence of cardiovascular disease and diabetes. Both weight reduction and maintenance of a lower weight are best accomplished by a mix of decreased caloric administration and expanded physical action and the utilization of standards of lifestyle change.

We propose a distinct yoga therapy protocol for the clinically euthyroid type II diabetics. This is depicted in Table 3.

**Conclusion**

Yoga therapy is an important adjuvant modality in evidence-based modern medicine. Among various comorbid states in T2DM, mention must be made of thyroid disorders. Hitherto, research on yoga therapy has been studied in isolation with respect to T2DM, hypothyroid, and hyperthyroid status. For the first time in this part of India, we have established a purported yoga therapy protocol that would be apparently used to effect us address T2DM patients who are clinically euthyroid. However, we strongly opine and conclude that prospective research work on the proposed yoga therapy protocol be undertaken by physiologists, biochemists, and internal medicine and endocrine specialists with special interest in adjuvant complementary medicine such as yoga therapy.

**Points of Consideration Related to Our Study**

- The proposed protocol for clinically euthyroid type II diabetics takes into account yoga therapy, a noninvasive tool for effective management of endocrine disorders.
- Since hitherto studies based on yoga therapy for T2DM (clinically euthyroid) have not been documented well in the literature, we had embarked on projecting a proposed yoga therapy protocol for implementation on a wider scale and based on the future studies by the present authors and other research workers; a definite yoga therapy protocol can be promulgated for this special group (T2DM clinically euthyroid).
- Instead of aiming at the pharmacological management of T2DM alone (with or without comorbidity), yoga therapy could be administered as an adjuvant therapeutic modality, as it is noninvasive, nonexpensive, reliable, and could be followed irrespective of age and gender.
- In recent years, the use of a novel therapeutic procedure has been linked with IR and thyroid status, which pertain to be use of thyroid hormone analogs for alleviating IR and restoring the thyroid status. The present protocol based on yoga therapy could also be studied from the perspective of the hypothalamus-anterior pituitary-thyroid axis with special reference to IR, independent of glycemic control. Thyroid hormone agonists or mimetics are considered an emerging therapeutic class with a potential utility in a number of metabolic disorders and it would be worthwhile to accede the suggested yoga therapy protocol to the armamentarium of modalities available to effectively address IR associated with (latent) thyroid comorbidity, but only after a comprehensive validation is enabled in this direction, through evidence-based scientific research.

**Clinical Significance of Yoga Therapy Protocol in the Post-COVID-19 Era**

The COVID-19 pandemic has virtually brought the global focus onto health and well-being, especially in the context of comorbidities. Thus, there is an immediate need for basic and clinical endocrinologists to advocate endocrine hygiene, besides recommending lifestyle modifications and self-care for the diabetics, in general and for such of those diabetics who are...
apparently euthyroid, in particular. Furthermore, the euthyroid sick syndrome is yet another clinical condition that is observed in diabetics, which could be largely attenuated by prophesying appropriate lifestyle modifications. Thus, our protocol might acquire special relevance and significance in the light of the fact that hitherto, protocols based on yoga therapy are available for diabetes and thyroid disorders in isolation, but not for the special group, namely clinically euthyroid type II diabetics. Moreover, the authors of this paper would like to elicit evidence-based information on the administration of this protocol to clinically euthyroid type II diabetics in a prospective manner.

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