ABSTRACT

BACKGROUND

Type 2 diabetes mellitus (T2DM) is a highly prevalent public health problem and a significant cause of morbidity and mortality in India. With over 77 million individuals diagnosed with T2DM, the burden of this disease is already huge. But there are two additional dimensions which make the potential public health burden of T2DM even greater: (a) studies indicate that about a third of the cases of diabetes remain undiagnosed and (b) the risk of progression from prediabetes to diabetes, and the pace of this progression, are both much higher among Indians as compared to other populations. Thus, there is urgent need to quantify the scale of the problem – that is, to get a robust estimate of the prevalence of diabetes – so that proper public policy can be shaped. Equally important is to implement preventative protocols for individuals at high-risk of progressing to diabetes. Aiming for prevention at prediabetes stage (which is the stage of increased diabetes risk) may be too late for the Indian population, given the much quicker progression to diabetes from this stage. It is more efficacious to aim preventative protocols at an earlier stage, before prediabetes. This points to the need for a simple, widely implementable, multi-variate risk score for identifying high-risk individuals, potentially even before the stage of prediabetes. The Indian Diabetes Risk Score (IDRS), which is widely used in India, needs to be validated at a nationwide level, and potentially improved to consider better measures of obesity. Once an individual is deemed to be in the high-risk category, there exist several preventative interventions including (but not limited to) Metformin therapy, increased physical activity, and dietary control. Another intervention is the ancient technique of Yoga. In ancient Yoga texts, repeated mention is made of the efficacy of Yogic practices to benefit diabetes risk factors such as reducing obesity, mitigating effects of chronic stress, fostering an active lifestyle and encouraging better dietary choices. This is especially the case with the practices of *Haṭha Yoga,* including techniques that have made Yoga famous the world over:

āsana (physical postures), *ṣaṭ-karma* (purification practices), *prāṅāyāma* (breathing exercises), etc. A thorough examination of *Haṭha Yoga Pradīpika* reveals that these techniques reduce β-cell dysfunction and increase insulin sensitivity via multiple pathways, thereby bringing about diabetes risk reduction and glycemic control. Existing scientific studies provide a preponderance of evidence to back the claims of Yogic texts. Specifically, we find studies reporting that (a) Yoga is effective in mitigating diabetes risk factors such as obesity and stress (b) Yoga effects glycemic control in individuals with diabetes and (c) the mind-body integrative aspect of Yoga fosters behavioral modifications that help one sustain better nutritional habits and a more active lifestyle. These findings hint strongly that a Yoga-based Lifestyle Protocol (YLP) can be a very effective adjunct to both prevention of diabetes and for glycemic control among individuals with diabetes. While YLP has been studied in smaller cohorts and/or in controlled circumstances where it is easier to ensure adherence to the protocol, it has not yet been studied in a large community setting to determine whether it has the necessary characteristics of simplicity, accessibility, and inexpensiveness so that it can be applied as a mitigation to a public health problem (diabetes risk reduction and glycemic control).

AIMS AND OBJECTIVES

The present study seeks to analyze data from *Niyantrita Madhumeha Bharata Abhiyaan 2017* (Diabetes Free India Study 2017, hereinafter simply NMB-2017) to (a) improve the screening characteristics of the Indian Diabetes Risk Score (IDRS) by incorporating a better anthropometric measure of obesity, so that it can be used in the field to identify individuals who have a high risk of developing diabetes (b) test the potency of yoga-based lifestyle protocol (YLP) against diabetes risk reduction among high-risk individuals who are not yet in the

prediabetes stage, in a large community setting and (c) test the efficacy of yoga as an adjunct to standard care for glycemic control among individuals with diabetes.

METHODS

PARTICIPANTS

This study included three separate analyses:

(a) Using a better measure of obesity to increase specificity of IDRS

Using data from a nationwide randomized cluster sample survey (NMB-2017 Phase 2), 7496 adults at high risk for type 2 diabetes (as determined by IDRS ≥ 60) were analyzed. Waist Circumference (WC), Body Mass Index (BMI), and a composite obesity measure combining the two (BMI_{WC}) were evaluated using Odds Ratio (OR), and Classification scores (Sensitivity, Specificity, and Accuracy). These were validated using Indian Diabetes Risk Score (IDRS) by replacing WC with BMI and BMI_{WC}, and calculating Sensitivity, Specificity, and Accuracy.

(b) YLP for diabetes risk reduction

In a cluster randomized trial (NMB-2017 Phase 2) in 80 clusters from India, participants with normal HbA1c (< 5.7%) but screened for diabetes risk (IDRS ≥60) were randomly assigned in a 1:1 ratio to intervention and control groups, n=2316:2134, respectively. The primary outcome was conversion from normoglycemia to diabetes. Absolute and Relative risk reductions were estimated based on marginal probabilities.

(c) YLP for glycemic control

In a cluster randomized trial (NMB-2017 Phase 2) in 80 clusters from India, participants with prior diagnosis of diabetes and/or HbA1c levels in diabetes range (≥ 6.5%) were randomly assigned in a 1:1 ratio to intervention and control groups, n=1820:1572, respectively. Mean

HbA1c reduction was calculated for each group, and independent samples t-test was used to test significance. Heterogeneity of treatment effects were calculated for subgroups with fair and poor glycemic control.

DESIGN

NMB-2017 was a pan-national, two-phased study. Phase 1 was a nationwide cross sectional survey using a multi-level stratified cluster sampling technique with random selection among urban and rural populations, with the objective of collecting data on diabetes status and diabetes risk. Phase 2 was a sub-sample of phase-1 participants who were deemed high-risk (as determined by IDRS $\geq$ 60) or had a previous diagnosis of diabetes. Phase 2 participants went through further assessments in the form of blood tests and more detailed questionnaire.

ASSESSMENTS

i. Anthropometric measures (ordinal): Height (in cm), Weight (in kg), and Waist Circumference (in cm)

ii. Derived measures (ordinal): BMI [Weight(in kg)/Height(in m)^2]

iii. Blood HbA1c levels (in DCCT %) (Ordinal)

iv. Via questionnaire (Categorical): Age, Family history of Diabetes, and levels of physical activity. **Note:** The questionnaire collected more information than detailed here (see Appendix 5), but they were not used in this analysis.

INTERVENTION

Intervention included practice of yoga-based lifestyle modification protocol (YLP) for 9 consecutive days, followed by daily home and weekly supervised practices for 3 months. In the diabetes risk reduction study, the control-cluster received standard of care advice for

diabetes prevention. In the glycemic control study, the control-cluster received standard care for T2DM.

RESULTS

Study 1

BMI_{WC} had higher OR (2·300) compared to WC (1·87) and BMI (2·26). WC, BMI, and BMI_{WC} were all highly Sensitive (0·75, 0·81, 0·70 resp.). But BMI_{WC} had significantly higher Specificity (0.36) when compared to WC and BMI (0.27 each). $IDRS_{WC}$, $IDRS_{BMI}$, and $IDRS_{BMIWC}$ were all highly Sensitive (0·87, 0·88, 0·82 resp.). But $IDRS_{BMIWC}$ had significantly higher Specificity (0·39) compared to $IDRS_{WC}$ and $IDRS_{BMI}$ (0·30, 0·31 resp.).

Study 2

Among individuals at high risk for diabetes (as determined by IDRS $\geq$ 60) but with normal glycemic levels at baseline, the YLP was found to be significantly effective in halting progression to diabetes as compared to standard of care (RRR 68.64%, 95% CI 64.73 – 73.48).

Study 3

Among individuals with diabetes, YLP showed a significantly greater reduction in HbA1c levels (μ=1.31, σ=1.40) compared to control arm (μ=0.45, σ=0.55); $t(\infty) = 22.68$, $p < 0.001$. This effect was even more pronounced in individuals with poor glycemic control at baseline, with the difference in mean reduction of HbA1c levels between yoga and control being significantly higher (μ=1.61, σ=1.29) compared to individuals with fair glycemic control at baseline (μ=0.35, σ=0.83); $t(\infty) = 15.73$, $p < 0.001$.

COLCULSIONS

Both WC and BMI are good predictors of risk for T2DM, but BMI_{WC} is a better predictor, with higher Specificity; this may indicate that Indians with high values of both central (high WC)

and general (BMI> 23) obesity carry higher risk for type 2 diabetes than either one in isolation. Using BMI_{WC} in IDRS improves its performance on Accuracy and Specificity. Substantive influence of yoga-based lifestyle intervention was observed against diabetes risk reduction on the high-risk Indian cohort. Among individuals with diabetes, YLP reduced glycemic levels, with the effect being more significant in people who had poor glycemic control to begin with. This might indicate that YLP can be very valuable clinically as an adjunct to standard treatment for individuals whose serum glucose levels are not responsive to standard care. Overall, our findings point to the efficacy of YLP as an effective strategy to combat the epidemic of diabetes from both preventative and treatment perspectives.