CHAPTER 8

APPRAISAL

8.1 STUDY 1: DIABETES SCREENING

8.1.1 Summary of findings

Obesity is a well-established risk-factor for diabetes. Existing evidence clearly indicates that both central fat (WC) and general adiposity (BMI) have predictive power for diabetes. However, the results are not consistent, with some studies showing WC to be superior to BMI, and other showing the opposite effect. This apparent conflict is likely indicative of the fact that neither is a complete reflection of actual relationship between diabetes and obesity. We hypothesized that a more complete measure of obesity might capture diabetes risk better and therefore combined these separate measures into a composite measure called BMI_{WC}. Our results showed that low BMI_{WC} was significantly better that eliminating individuals without diabetes when compared to WC or BMI alone, while high BMI_{WC} was just as good as WC or BMI alone in picking individuals with diabetes. This is reflected in the Sensitivity and Specificity scores in the Table 17 below:

Table 17: Performance of obesity metrics

	Odds Ratio (of lowest to highest categories)	**Classification Analysis**		
		Sensitivity	**Specificity**	**Accuracy**
WC	1.87	0.75	0.27	0.47
BMI	2.26	0.81	0.27	0.49
BMI_{WC}	2.30	0.70	0.36	0.50

We also found that the Odds Ratio – the relative odds of having diabetes between the highest obesity category when compared to the lowest obesity category – was the highest for BMI_{WC} when compared to WC and BMI, which indicates that BMI_{WC} captures diabetes risk better than the other two.

When BMI_{WC} was incorporated into a multivariate risk score (the IDRS), we found similar results for the modified score (which we called $IDRS_{BMIWC}$): it was comparably Sensitive as $IDRS_{WC}$, but was significantly more Specific, as seen in the Table 18 below.

Table 18: Performance of IDRS with different obesity metrics

	Classification Analysis		
	Sensitivity	**Specificity**	**Accuracy**
$IDRS_{WC}$	0·87	0·30	0·53
$IDRS_{BMI}$	0·88	0·31	0·54
$IDRS_{BMIWC}$	0·82	0·39	0·56

8.1.2 Implications

There are two clear implications that we see from our study. First, we can explain the conflicting evidence surrounding BMI and WC as anthropometric measures of obesity for diabetes risk. Past explanations have focused on ethnic differences: that WC is a better measure among Asian Indians while BMI is a better measure among Western Europeans. Our search of available evidence found no study either proving or disproving this. However, our study lays the groundwork for an alternative explanation: the etiology of diabetes as it relates to obesity might be dependent on both central fat and general adiposity. The substantial increase in Specificity of BMI_{WC} (Table 17) leads us to an interesting interpretation: individuals with either high value of BMI or high value of WC have higher diabetes risk, while individuals with low values of both BMI and WC have lowered diabetes risk.

This leads us to the second implication of this study: multivariate screening scores deployed across the world are likely to benefit from incorporating BMI_{WC} rather than either BMI or WC. Most screening tests are already very Sensitive; but many of them lack Specificity leading to a lot of false positives and drain on the public/private coffers, but also the discomfort and trauma of having to undergo additional testing for no reason.

8.1.3 Applications

BMI_{WC} can be easily incorporated into public screening scores. It is an anthropometric score, and therefore there is no need for additional testing or measurement. As long as height, weight, and waist circumference measurements are already available, BMI_{WC} can be computed in a straightforward way.

It also opens the door to standardized screening worldwide. While much work needs to be done before this can be realized, there are obvious benefits of having a worldwide databank on a multivariate diabetes risk score, including (but not limited to): the potential to analyze risk factors across national and ethnic boundaries, understanding implications of varied diets, and studying physical activity patterns as they pertain to diabetes risk.

8.1.4 Strengths

Due to the large number of individuals involved in the study, and because of the nationwide cluster sampling design of the study, the observed effects (increased Specificity of BMI_{WC} and $IDRS_{BMIWC}$) can be reliably assumed to apply to nationwide (India).

The strength of the effect was tested through the use of multiple methodologies: ROC analysis, classification analysis, and risk analysis, with each methodology reaffirming the base conclusion. This increases the confidence level of our assertions.

8.1.5 Limitations

We studied high-risk individuals (40·19% diabetics in the study population). We would expect the risk measures and Specificity to be different in a sample reflective of the general population.

Our study of $IDRS_{BMIWC}$ has established a classification threshold of 70. This threshold may change when future analysis will be done using data on individuals in all risk categories.

8.1.6 Suggestions for future work

We postulated that a proper anthropometric measure of obesity should take into account both central fat and general adiposity and have established that this is true among high-risk Indians. Future work should expand this work by: (a) verifying our conclusion within a population sample which includes both high- and low-risk individuals, and (b) study BMI_{WC} among other ethnic groups.

8.2 STUDIES 2 & 3: DIABETES RISK REDUCTION AND GLYCEMIC CONTROL THROUGH YLP

8.2.1 Summary of findings

We found that a 3-month YLP has significant preventative benefits among population that is at high risk (age, family history, sedentary lifestyle, and obesity) but is normoglycemic. People in the Yoga group had 8.76% less risk of progressing to diabetes on an absolute basis. Relatively speaking, they were 50.23% less likely to progress to diabetes.

The effects of 3 months Yoga program are summarized in the Table 19 below:

Table 19: Effect of YLP Intervention on diabetes risk reduction and glycemic control

	Prevention (Risk of diabetes progression in high risk population)	**Adjunct treatment to standard care** (Glycemic control among diabetes population)
Control	Risk = 17.44%	μ (HbA1c Reduction), % All: 0.45 Fair glycemic control @baseline: 0.59 Poor glycemic control @baseline: 0.24
Yoga	Risk = 8.68%	μ (HbA1c Reduction), % All: 1.31 Fair glycemic control @baseline: 0.94 Poor glycemic control @baseline: 1.85
Effect of Intervention	ARR = 8.76% RRR = 50.23%	μ (HbA1c Reduction), % All: 0.86 Fair glycemic control @baseline: 0.35 Poor glycemic control @baseline: 1.61

When used as an adjunct treatment to standard care among population with diabetes, we found that the Yoga group had significantly higher mean HbA1c reduction – 1.31% compared to 0.45% with a mean reduction of 0.86%. More interestingly, the worse off an individual was in terms of glycemic control at baseline, there more effective Yoga was in reducing HbA1c levels: a mean difference of 1.61% between Yoga and Control groups among individuals with HbA1c $\geq$ 7.6% at baseline.

8.2.2 Implications

A preponderance of available evidence indicates that Yoga has a salutary effect on reducing multiple risk factors that lead to insulin resistance, the first clinical sign of impending diabetes. These factors include obesity, stress, increased (and unbalanced) caloric load, sedentary lifestyle, and reduced insulin sensitivity in skeletal muscle. For individuals that have diabetes, managing these same risk factors are key to maintaining long-term glycemic control. Therefore, it has long been suspected that Yoga can be an effective lifestyle intervention in both preventing progression to diabetes, and as part of diabetes treatment.

There have been many studies (as indicated by our literature review in Chapter 3) that have explored these connections, but they have been done in smaller cohorts. The primary implication of our study is a strong evidence that Yogic intervention can be deployed at a public health scale for achieving both risk reduction and glycemic control, thereby providing a promising new frontier in prevention and treatment of diabetes.

8.2.3 Applications

Yoga is simple to learn; it does not require specialized equipment; and most yoga poses used in this study are no more difficult that exercised taught by physical therapists in rehab type settings. Taken together, these characteristics make Yoga very accessible and cost-effective

intervention. The strength of the effects seen in our study make YLP broadly applicable in both urban and rural areas and has the potential to move the dial in a positive direction in the ongoing battle with the epidemic of diabetes.

8.2.4 Strengths

Due to the large number of individuals involved in the study, and because of the nationwide cluster sampling design of the study, the observed effects (risk reduction and mean HbA1c reductions) can be reliably assumed to apply to nationwide (India).

The study used a yoga protocol that would be accessible to a large percentage of the target population. Thus, we can be confident of the practicability of the studied lifestyle intervention and its potential uptake.

8.2.5 Limitations

A substantial proportion (63.44%) of the eligible individuals declined to participate or could not respond to the study. This selective inclusion of the individuals with pre-existing inclination for yoga-based practices could have biased the study outcome. The substantial attrition observed in the present study with follow up rates of only 76% is not a favorable outcome with respect to diabetes, a long-term disease, necessitating further investigation on attrition in long-term follow-ups. The extent of loss to follow up is a major limitation in this study, however, is negated by an equivalent loss in both the study groups.

8.2.6 Suggestions for future work

While we have been able to show strong effects over the 3 month study period, it needs to be validated by longer-term studies which show that these effects are sustained over a period of several years.