

Chapter – 7
DISCUSSION



7 DISCUSSION

In the current study, both per-protocol and ITT analysis demonstrated a significant group*time interaction effect for HbA1c at the end of 6 months as well as at the end of 1 year favouring the YBL group. There was also a significant group*time interaction effects for PPBS and depression scores at the end of 1 year favouring the YBL group. ITT analysis showed the significant group*time interaction effects for BMI, T2DM medication scores and blood pressure levels favouring the YBL group. Whereas, Per-protocol analysis demonstrated the significant group*time interaction effects for FBS and stress scores at the end of 6 months favouring the YBL group. A total of 29 thermal imaging variables showed significant negative correlations with the HbA1c level.

Eight thermal imaging variables which have stronger correlation with HbA1c showed a significant increase in temperature in the YBL group as compared to PHE group after intervention. A total of 11 EPI variables showed significant correlations with HbA1c. There was a significant negative correlation between the energy balance of body organs and HbA1c. Whereas, the EPI Stress variable showed a significant positive correlation with HbA1c. Out of 11 EPI variables showing correlation with HbA1c, 7 variables improved significantly in the YBL group as compared to PHE group after intervention.

In the current study, the estimated reduction of mean HbA1c in the YBL group was 0.80 at 6 months and 1.25 at 1 year as compared to the PHE group. The HbA1c reduced by 18.52% at the end of 1 year within YBL group as compared to the baseline. An earlier study demonstrated a reduction in HbA1c by 14.17% in the yoga group after nine months of intervention with no significant between-group difference between the yoga and exercise groups (Nagarathna et al., 2012). The higher reduction HbA1c and the significant group*time interaction effect for HbA1c in our study may be due to longer duration of intervention and the regular supervised

tele-yoga sessions for 11 months after initial supervised direct sessions of 1 month. In the present study, we were able to demonstrate that tele-yoga is a feasible and effective option to maintain the accuracy of yoga intervention, leading to better results. The PHE group also showed a trend of reduction in HbA1c but it could not reach the statistical significance level.

Earlier studies comparing yoga and physical exercise have either demonstrated a trend of better reduction in FBS and PPBS in the yoga group as compared to physical exercise group (Nagarathna et al., 2012) or better results favouring the yoga group (Gordon, et al. 2008). In the current study, both ITT and per-protocol analysis demonstrated a significant reduction in PPBS in the YBL group as compared to PHE group at 1 year. However, only per-protocol analysis demonstrated a significant group*time interaction effect for FBS favouring the YBL group at the end of six months as well as the end of 1 year. One of the earlier studies demonstrated that PPBS reduced significantly by 14.6% within yoga group after 9 months of intervention with significant between-group differences (Nagarathna et al., 2012). Whereas, the present study showed the significant reduction 15.75% in PPBS within YBL group after 1 year of yoga intervention with significant group*time interaction effect. The earlier similar study also demonstrated that the FBS reduced significantly by 7.20 % within yoga group at the end of 9 months (Nagarathna et al., 2012). However, the current study demonstrated a significant reduction of 19.42% in FBS within YBL group after 1 year of yoga intervention. The better reduction in PPBS and FBS in present study confirms the greater effectiveness of regular, supervised and long term yoga intervention.

In the present study, there was a reduction in waist-hip ratio in both the groups without any between group differences. The similar reduction on both groups may be due to the effect of physical component which is common to both yoga and physical exercise Intervention. However, ITT analysis showed that there was a better reduction in BMI in YBL group as compared to the PHE group at the end of 1 year but not at the end of 6 months. The results

suggest that a regular sustained practice of yoga for more than 6 months may be more effective than physical exercise in reducing bodyweight. Further, ITT analysis showed the significant group*time interaction effects for systolic and diastolic blood pressure levels favouring the YBL group at the end of 6 months as well as at the end of 1 year.

The ITT analysis demonstrated a significant reduction in T2DM medication scores in the YBL group as compared to the PHE group at the end of the 1 year. The estimated decrease in mean medication score in the YBL group was 0.87 at the end of 12 months as compared to the PHE exercise group. The medication scores reduced by 56.24% within yoga group compared to baseline at the end of 1 year. All the participants in the study were monitored by the endocrinologists who evaluated the subjects clinically at each visit and titrated the dosage of hypoglycaemic oral drugs or insulin based on blood glycaemic indices and clinical reports. The greater reduction in T2DM medication scores in YBL group compared to PHE group may be due to comparatively greater improvement in blood glycaemic indices at each visit. Only ITT analysis showed the significant group*time interaction effects for blood pressure levels (systolic and diastolic) favoring the YBL group. Per protocol analysis did not demonstrate any significant group*time interaction effects for blood pressure levels. However, mean systolic and diastolic blood pressure levels in both groups are in normal range. An Insignificant increase in mean systolic and diastolic blood pressure levels in PHE group was observed, however, the changes were found to be directed towards the midline of the normal ranges.

Results of the present study also demonstrated a significant group*time interaction effect for depression scores favouring the YBL group at 1 year. The estimated decrease in mean depression score in the YBL group was 1.45 at 1 year as compared to the PHE group. The depression scores reduced by 56.24% within yoga group at the end of 1 year compared to baseline. We did not found any significant time interaction effect or significant group*time interaction effect for Anxiety Scores at 6 months as well as at 1 year. Moreover, per-protocol

analysis demonstrated the significant group*time interaction effect for stress scores favouring the YBL group at the end of 6 months but not at the end of 1 year. The increase in stress scores in last 6 months of the intervention may be due to the stress related to COVID-9 pandemic.

This is the first study which tried to investigate the effect of 1 year yoga-based lifestyle intervention on thermal imaging and electro-photonic imaging variables in patients suffering from type 2 diabetes mellitus. The present study also tried to see the correlations between HbA1c and thermal imaging variables as well as the correlation between HbA1c and electro-photonic imaging variables. All the 59 thermal imaging variables which were selected for the study showed a clear trend towards negative correlation with HbA1C level. However, only 29 thermal imaging variables showed the statistically significant negative correlation with the HbA1c. Especially the temperature of eyes, ears, centre of eyebrows, knees, ankles and shins showed stronger negative correlation with HbA1c. The finding suggests that the body temperature reduces with the increased HbA1c level. Interestingly, we also observed that the body temperature of the patients suffering from T2DM is lower than the normal temperature range of human body. The mean temperature values for the different part of the body in patients with T2DM were less than 35° Celsius at baseline. The decreased skin temperature at certain body regions could be due to the impaired body metabolism and poor blood circulation. When the metabolism decreases, the core body temperature also decreases, which was demonstrable as temperature reduction in the tympani of ears, inner canthi of eyes and centre of eyebrows in particular (Sivanandam et al., 2017). Increased glucose levels injure the endothelial lining of the vessels leading to vascular stiffness and reduction in the luminal blood flow, contributing to peripheral vascular resistance. Increased vascular resistance in turn may lead to compromise in the microvascular circulation in the extremities in particular. This phenomena manifests as reduction in the surface skin temperatures of the extremities such as shin, hands and feet. Interestingly, in our study, thermal imaging variables showed an increase in temperature in

YBL group as compared to PHE group in patients with T2DM which is in correspondence with greater reduction of HbA1C levels in the YBL group. All the 29 thermal imaging variables which were correlated with HbA1c showed the trend towards increase in temperature after the intervention. However, only eyes, centre of eyebrows, knees, ankles and shins showed significant Group*time interaction effects favouring YBL group at the end of 1 year.

Out of 89 EPI variables selected for the study, 11 variables showed correlation with HbA1C. Especially energy balance in the organs (overall balance, organs balance right, organs balance left, kidneys balance, digestive system balance, adrenals balance, cerebral zone vessels balance, cerebral zone cortex balance, liver balance and lumber spine balance) showed significant negative correlation and EPI stress variable showed strong positive correlation with HbA1C. The above findings suggest that the energy balance in different regions of the body deviates with the severity of T2DM. It also suggest the strong association between stress and T2DM. In our study, out of 11 EPI variables showing correlation with HbA1c, 7 variables (EPI stress, balance, organs balance right, organs balance left, digestive system balance, adrenals balance, and cerebral zone cortex balance) showed significant group*time interaction effects favouring YBL group. The balance, organs balance right, organs balance left, digestive system balance, adrenals balance, and cerebral zone cortex balance increased, and EPI stress decreased significantly in YBL group as compared to PHE group at the end of 1 year.

Most of the variables (including HbA1c, FBS, PPBS, depression scores, thermal imaging and electro-photonic variables) showed the trend of improvement within physical exercise group, however, few variables reached to the level of significance. 4 electro-photonic imaging variables out of 11 and 14 thermal imaging variables out of 29 showed significant time interaction effects within PHE group after the intervention of 1 year. Studies show that physical exercises bring beneficial effects in the management of T2DM but we did not find much improvement by tele-exercise intervention as compared to tele-yoga intervention. Probably,

the reason is that in the current study, the major part of the intervention was given through online mode and participants would have found tele-yoga session to be more interesting than tele-exercise as the tele-yoga session included various components involving mind, body and breath. There was more interest and demand for tele-yoga from the participants during the COVID-19 pandemic. In the present study, we observed that 6 subjects who were practicing tele-exercise requested for shifting them to the tele-yoga program in the middle of the study and they were considered as drop outs. We also observed that the rate of improvement in most of the variables reduced in both groups in last 6 months of the intervention as compared to the first half that may be due to the direct or indirect effect of COVID-19 pandemic. The reduction in improvement rate was less in YBL group as compare to PHE group in last 6 months of the intervention that may be because of the additional components of yoga including breath regulation, mindfulness and relaxation to cope with stressful situation.

In the current study, we observed a higher attrition rate as compared to similar studies conducted before. The attrition rate was 52.5 % at 6 months and 65% at 1 year in the YBL group whereas for the PHE group, it was 55% at 6 months and 71.25% at 1 year. In an earlier similar study, there was an attrition rate of around 37.5 % for both yoga and physical exercise groups at the end of 9 months (Nagarathna et al., 2012). The attrition rate of the earlier study is much lesser than what we observed in the current study. It is important to note that earlier studies were conducted in the COVID free scenario and those studies were devoid of tele-interventions. Those studies also did not exclude subjects who have less than 50% attendance for the sessions. In our study, many of the participants dropped out because they adopted different systems of medicine such as Ayurveda and Homeopathy as preventive and treatment options during the COVID-9 pandemic. Similarly, a large number of participants were not able to attend up to 50% of the sessions or reported time constraints to continue in the study due to the direct or indirect effect of COVID-19 pandemic. A number of subjects actually reported

cough, fever or other minor symptoms (although they did not want to reveal their COVID status, possibly due to stigma) in both the groups and these participants were also considered as drop-outs if their yoga practice was affected.

Yoga based lifestyle intervention appeared to be more effective than physical exercise intervention which may be because of various aspects of yoga other than the physical one. The yoga based lifestyle involves the components of mindfulness, relaxation, breath regulation and notional corrections. These components would have enhanced the mood and ability of the participants to be calm and relaxed (Balasubramaniam et al., 2013; Prathikanti et al., 2017). Whereas subjects physical exercise group would have done so more mechanically. This would have led to the benefits at the body level only. Further, yoga based interventions are traditionally more acceptable than exercise based interventions in Indian society (Mishra et al., 2020).

The mechanism through which yoga works may be through down-regulation of the sympathetic nervous system (SNS) and the hypothalamic-pituitary-adrenal (HPA) axis (Ross & Thomas, 2010). Which may lead to the improvement in psychological health, quality of sleep, autonomic balance and lifestyle, and reduction insulin resistance. The components such as mindfulness and relaxation presented in yogic practices may be the major contributors to the down-regulation of HPA and SNS. Further, pranayama (breath regulation) also has the capacity to bring the mind in the present moment and to reduce the stress level (Brown & Gerbarg, 2009). The reduction of stress level may result in better glycaemic control in patients suffering from T2DM as the stress has strong effects on metabolic activity by stimulating different hormones which may result in elevated blood glucose levels in the patients (Surwit et al., 1992). The reduction in depression may further motivate the person to engage in yoga practices more enthusiastically, which may in turn enhance compliance with the lifestyle regimen and thus result in better glycaemic control in patients with T2DM (Surwit et al., 1992).