SUMMARY

INTRODUCTION

Incidence and prevalence of Type 2 Diabetes Mellitus (T2DM) is increasing and affecting millions of people worldwide. According to International diabetes federation (IDF) 381.8 million people had diabetes in 2013 and this number is projected to increase up to 591.9 million by 2035 (IDF, 2013). Asian Indians manifest insulin resistance and metabolic syndrome at a young age and at a higher magnitude than any other ethnic group (Misra et al., 2008). Further since T2DM will soon reach epidemic proportions, the cost of treatment of the disease as well as the cost of treating complications will place immense burden on the world’s healthcare resources (WHO, 2011). The primary driver of the epidemic of diabetes is the rapid epidemiological transition associated with changes in dietary patterns and decreased physical activity as evident from the higher prevalence of diabetes in the urban population. (Mohan et al., 2007).

Numerous clinical trials and cohort studies have provided strong evidences in supporting the value of physical activity in reducing the incidence of T2DM (Sigal et al., 2004). Aerobic exercise is a generally accepted therapeutic strategy for T2DM because its beneficial effects are not only limited to glycaemic profile but also play a major role in reducing metabolic risk factors for cardiovascular disease including insulin resistance (Yokoyama et al., 2004). Walking is currently the most popular physical activity for adults as benefits are similar to other forms of exercises but walking is a low impact activity, requires no equipment, easy to perform and therefore the most common and most acceptable form of physical activity (Hancock, 2012). In a structured exercise, programmed level of physical activity can be closely monitored, however self directed walking is the most common and acceptable form of physical activity to people with type 2 diabetes (Jhonson et al., 2009). Pedometers which measure walking activity in the form of daily step counts while also serving as a motivator, have become popular components of physical activity intervention (Croteau et al., 2007). Tudor-Locke et al. 2001 showed that approximately >9000 steps/day were
associated with body composition benefits and suggested that approximately <5000 steps/day were indicative of an index of sedentarism related to unhealthy body composition, though they recommended caution when applying their cut off points. Arazia et al. 2006 have also demonstrated the effectiveness of pedometer in increasing the number of steps walked as well as the improvements in the parameters of glycemic control. However, there is a relative paucity of literature regarding the efficacy of supervised pedometer based walking programs, as well as the notion that walking a minimum number of steps per day may be as effective as walking at prescribed intensity. Therefore, this study aims to bridge the lacuna in literature by documenting the relative efficacy of walking with pedometer in changing the key parameters of diabetes control.

**METHODOLOGY**

A total of 102 T2DM outpatients (28 women, 74 men) were recruited from Amritsar. Informed consent and baseline measurements were taken before randomization. The study was given approval by Institutional ethical committee of Guru Nanak Dev University, Amritsar. Subjects were recruited after explaining the protocol and getting a clearance from physician. Demographic information and health history were obtained from all the participants. Men and women between the ages of 40 to 70 years were included in the study. The inclusion criteria were as follows (i) ≥ 1 year diagnosis of T2DM (ii) not taking insulin (iii) no physical activity limitation (iv) were not enrolled in any other physical activity program previously or simultaneously. Exclusion criteria were disease or condition (e.g. any evidence of CAD, uncontrolled hypertension, diabetic complications) and moderate–severe orthopedic/ cardiovascular/ respiratory condition that would interfere with physical activity (Shenoy et al., 2010).

Subjects were randomly allocated into one of the three groups by random lottery approach: supervised exercise group with pedometer (Group A), self reported exercise group with pedometer (Group B) and a control group (Group C). Subjects were advised to eat 1-2 hrs before exercise to avoid hypoglycaemia and maintain their hydration levels. No dietary modifications were advised. Baseline readings of all the parameters were recorded before randomization.
Analysis - Paired t-test was used within the groups to compare Mean±SD for the parameters at baseline, 8 weeks and 16 weeks. Differences between the groups were compared using analysis of variance (ANOVA). Statistical difference was further analyzed by Post hoc analysis using Bonferroni method. STATA 11.0 statistical software was used for data analysis. In this study p-value less than 0.05 has been considered as statistically significant.

RESULTS

Overall 88% of participants (90 of 102) completed the study. Subjects in Group A and Group B showed a significant decrease in FBG and glycosylated haemoglobin values whereas Group C showed no significant improvement. Repeated measures ANOVA showed no significant difference in between the groups after 8th week and 16th week of intervention for FBG and HbA1c. In terms of percentage there was significantly little decrease in cholesterol level among Group A and Group B by 11.3% and 6.4 % respectively. Control group showed statistically non significant decrease in cholesterol by 21.4%. Triglycerides levels was decreased by 11.3% in Group A and 6.5% in Group B. HDL-C was significantly increase in both the interventional groups (Group A- 36.9±11 mg/dl to 44.3±6.9 mg/dl, Group B- 34.5±9.4 mg/dl to 39.4±6.9 mg/dl). RHR was significantly decreased in Group A and Group B by 14% and 3.4 % respectively after 16 weeks. SBP and DBP showed significant decrease in both the intervention groups after 16 weeks (p=0.001). Repeated measures ANOVA have shown significant results after 16 week training among all the cardiovascular variables. Broadly, we found that Group A and Group B showed statistically significant reduction in negative impact of ‘quality of life domains’ after16 weeks of supervised and self reported training program. In Group A significant improvement was noted in all domains of quality of life except long distance journey (p<0.05). In Group B participant’s experienced significant improvement in all domains except long distance journey, sex life and living condition.

DISCUSSION

102 T2DM outpatients participated in the current study recruited from Amritsar. In this study we aimed at achieving around 4000 steps/30-40 minutes in Group A as a
Summary

mode of supervised program. Subjects exercising thus safely moved out of their sedentary zone and could derive benefits from being physically active. In Group A after 16 weeks intervention, an increment of approximately 900 -1000 steps was found in 30 -40 minutes of walking session. Subjects in this group progressively increased their capacity for walking from 3012±194 to 3934±207 steps/30-40 minutes after completion of 16 weeks. In Group B i.e. self reported group, participants averaged about 5000 – 6000 steps/day at baseline and progressively increased their physical activity up-to 9000 -10000 steps/day at completion of 16 weeks period. On an average, participants in Group B started with ‘low active range’ and improved to reach ‘somewhat active range’ by the end of 16 weeks. This improvement in their physical activity level might reduce the prospects of future complication imposed due to high ranged values. Approx > 9000 steps/day were associated with body composition benefits and suggested that approx < 5000 steps/day were indicative of an index of sedentarism related to unhealthy body composition, though Tudor Locke (2004) , recommended caution when applying these cut off points.

HbA1c is an important indicator to determine blood glucose and risk of complications in diabetic patients. In the present study, subjects in Group A, Group B and Group C showed mean plasma glycosylated haemoglobin levels of 8.2±1.6, 8.19±1.9, 6.92±0.88 respectively. Values higher that 7 is indicative of high risk complications in diabetes. Compared to control group, subjects enrolled in intervention group, whether supervised or self reported, experienced a favourable decrease in the level of HbA1C. Drops in cholesterol level were higher in Group A i.e. 11.3% than in Group B which was 6.4%. Triglycerides were also lowered by 11.3 % in Group A and 6.5 % in Group B In this study, we observed significant increase in HDL-C by 20 % in Group A and 14.2% in Group B. LDL and VLDL were also significantly reduced in both the interventional groups. Experimental groups (Supervised group and self reported group) showed significant reduction in RHR, SBP and DBP after 16 weeks. RHR, SBP and DBP among all the subjects in the supervised Group A decrease after 8th week and also the decrease was faster in comparison to Group B. Drops in the cholesterol level and triglycerides were higher in Group A than in Group B. Supervised interventions with pedometer have shown slightly better cardiovascular benefits as

119
compared to self reported intervention with pedometer. We believe that even if patients will derive any improvement in physiological status because of psychological influence it should not be ignored and they should be given that advantage. The quality of life questionnaire was introduced with an objective to assess the changes in the quality of life of patients in the study population. In the current study it was found that all the domains in the questionnaire were affected by diabetes.

Results of present study reported highly significant changes in leisure activity, working life, do physically, physical appearance, self confidence, motivation, living condition and all variables of wellbeing in the supervised group (p<0.001). Participants in Group A and Group B experienced a significant improvement in “do physically” item by 45% in Group A and 22.5% in Group B, while control group experienced insignificant decline in “do physically” domain by 5.7%. The magnitude of improvement in quality of life domains was higher in Group A than in Group B. Overall results of the study showed highly significant improvement in glycaemic, metabolic, cardiovascular and psychological parameters in both exercise groups at the end of 16 weeks of the intervention.

CONCLUSION

The study brings out that walking with pedometer may encourage people in increasing their physical activity and results in significant improvement in glycaemic control, metabolic profile, cardiovascular indices and quality of life. Setting a step goal with a pedometer was effective in increasing physical activity levels in T2DM. This study demonstrates that a programme for individuals with T2DM who targets an increase in the total number of steps for 16 weeks at moderate intensity leads to better cardiovascular improvement than the individuals who accumulated steps irrespective of intensity. Thus, though increasing physical activity in terms of step count definitely improves physiological and psychological test parameters focussing on the intensity of the program leads to greater improvement.