A cross-sectional study on the physical activity of selected elderly diabetics

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Abstract

Regular exercise may prevent or delay the development of Type 2 Diabetes Mellitus (T2DM). In addition to moderate-to vigorous-intensity exercise, daily physical activity is also important for the prevention and management of T2D. Elderly diabetics (50-70 years) were selected from the PSG Hospitals - a multi-speciality hospital. A Diabetes Self-Management Questionnaire (DSMQ) was developed to be locally relevant. The validity and reliability was checked before administration of the questionnaire. Data on glycemic control, energy expenditure, and physical activity (MET) were recorded. Physical activity from age 50-60 & 60-70 years were similar as indicated by the 24hr physical activity pattern and MET values. We observed a progression of the metabolic disorder with age as shown by HbA1c values. Physical activity and exercise recommendations, therefore, should be tailored to meet the specific needs of each individual.

Key words: Type 2 Diabetes; Physical Activity; Elderly Diabetics; MET

1. Introduction

T2DM is a primarily self-manageable condition. Healthcare professionals like medical nutrition therapists and diabetologists usually offer education, treatment, and support, but patients themselves are responsible for the daily management of their blood glucose levels. Increasing the effectiveness of self-management support through physical activity and exercise may have a considerable impact on health care, especially for elderly people.

Diabetes self-care includes a range of activities (e.g., self-monitoring of blood glucose, eating a low-saturated-fat diet, record of physical activity and checking one’s feet). Self-care is multidimensional, it is necessary to assess each component separately rather than to combine scores across components [1]. The original Summary of Diabetes Self-Care Activities (SDSCA) measure [2] assessed five aspects of the diabetes regimen: general diet, specific diet, exercise, medication taking, and blood-glucose testing. More recent studies using the scale have also included items on foot care and smoking. Exercise may be considered as the simplest strategy for any person to adopt as a means to control blood glucose levels. It is just that it needs to be incorporated into the daily schedule.

Physical activity includes all movement that increases energy use, whereas exercise is planned, structured physical activity. Certain facts about physical activity and diabetes are well established. The introduction of continuous glucose monitoring (CGM) several years ago enabled researchers to investigate the impact of exercise strategies on 24-hour glycemic control. Such unique information on the gluco-regulatory properties of exercise will ultimately lead to more effective exercise intervention programs to manage and/or prevent and treat T2D [3]. Exercise improves blood glucose control in T2D, reduces cardiovascular risk factors, contributes to weight loss, and improves well-being [4; 5]. Regular exercise may prevent or delay T2DM developments [5]. Physical activity and exercise recommendations, therefore, should be tailored to meet the specific needs of each individual.

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There are several types of exercises and physical activity that can play a role in the management of blood glucose levels. Aerobic exercise involves repeated and continuous movement of large muscle groups [6]. Activities such as walking, cycling, jogging, and swimming rely primarily on aerobic energy-producing systems. Resistance (strength) training includes exercises with free weights, weight machines, body weight, or elastic resistance bands. Flexibility exercises improve range of motion around joints [7]. Balance exercises benefit gait and prevent falls [8].

Aerobic training increases mitochondrial density, insulin sensitivity, oxidative enzymes, compliance and reactivity of blood vessels, lung function, immune function, and cardiac output [9]. Moderate to high volumes of aerobic activity are associated with substantially lower cardiovascular and overall mortality risks in both type 1 and T2DM [10]. Alternatively, high-intensity interval training (HIIT) promotes rapid enhancement of skeletal muscle oxidative capacity, insulin sensitivity, and glycemic control in adults with T2DM [11; 12].

The health benefits of resistance training for all adults include improvements in muscle mass, body composition, strength, physical function, mental health, bone mineral density, insulin sensitivity, blood pressure, lipid profiles, and cardiovascular health [9]. Resistance training benefits for individuals with T2DM include improvements in glycemic control, insulin resistance, fat mass, blood pressure, strength, and lean body mass [13].

World Health Organization (WHO) recommends that adults aged 18–64 years do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week, or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week, or an equivalent combination of moderate- and vigorous-intensity activity. Aerobic activity should be performed in bouts of at least ten minutes duration. For additional health benefits, adults need to increase their moderate-intensity aerobic physical activity to 300 minutes per week, or engage in 150 minutes of vigorous-intensity aerobic physical activity per week, or an equivalent combination of moderate- and vigorous-intensity activity. Muscle-strengthening activities should be done involving major muscle groups on two or more days a week [14].

Getting enough regular physical activity is important for maintaining good health and ensuring good diabetes management [15]. Exercise has been considered a cornerstone of diabetes management, along with diet and medication. Epidemiological studies have suggested that moderate-to-vigorous leisure-time physical activity (LTPA) protects against the development of T2DM [16] as well as the metabolic syndrome which commonly precedes diabetes and cardiovascular disease [17]. The therapeutic benefits of exercise have been studied extensively in middle-aged men and women with T2D, but little is known about the impact of exercise training in older people with this condition.

2. Methodology

2.1. Identification of Study Problem

People with diabetes need on-going clinical, psychosocial and behavioral diabetes self-management support (DSMS). No single strategy or programme focus shows any clear advantage, but interventions that incorporate behavioral and affective components are more effective. In most cases, T2DM treatment begins with weight reduction through diet and exercise. This study was an attempt to reiterate that management of diabetes is a basic problem of the balance between diet and exercise.

2.2. Selection of Subjects and Ethical Clearance

The study was carried out at PSG Hospitals, Coimbatore, Tamil Nadu, India. It is a Multi-Specialty Hospital certified by the National Accreditation Board for Hospitals & Healthcare Providers. It is a patient-centric medical service with more than 1000 beds. The study was conducted in the Endocrinology Department of PSG Institute of Medical Sciences and Research Hospitals, Coimbatore, Tamil Nadu, India, where, the ethical clearance was obtained to do the study among Type 2 Diabetic patients.

The ICMR [18] guidelines were followed to protect the rights of the study participants. Ethical Clearance (15/328, dated 04/12/2015) was obtained from PSG Institute of Medical Sciences and Research Hospitals, Coimbatore, Tamil Nadu, India. The purpose of study was explained by the researcher to the participants and their consent was obtained in the ICMR human ethics consent form.

The participants were selected on the basis of the inclusion and exclusion criteria. The study participants were T2D patients in the age group of 50 to 70 years of both genders. The researcher was permitted to scrutinize the medical records at the Endocrinology Department of PSG IMSR Hospital for selection of the study participants.
In-patients who met inclusion criteria were informed about the possibility to participate in a cross-sectional study of questionnaire evaluation. Patients who consented were assessed with the modified DSMQ (Diabetes self Management Questionnaire) [19]. Additionally, demographic and diabetes-specific characteristics were gained from the electronic patient records (sex, age, BMI, diabetes type, diabetes duration, type of diabetes treatment, late complication status, and current HbA1c). Data collection was carried out as a cross-sectional survey.

2.3. Physical activity

Physical activity is usually classified by its intensity and duration. The metabolic equivalent (MET) is a useful measurement for representing the intensity of physical activity and is defined as the amount of oxygen uptake while sitting at rest. An oxygen uptake of 3.5 mL/kg per minute is equal to the basal resting metabolic rate and is considered to be 1 MET [20]. Ainsworth et al [21] have provided a list of MET values for 821 specific physical activities that vary in their intensity of daily physical activity according to the situation in which they are performed. For example, walking inside is equal to only 2.0 METs (light intensity) whereas walking with children is the equivalent of 4.0 METs (moderate intensity). Therefore, it should be noted that daily physical activity covers a wide range of intensity that at times are the same as structured exercise.

Therefore in our study we recorded physical activity and glycemic control (FBG, PPBG, HbA1c) and statistically established the relationship between the two. The 24hr activity was recorded as per the guidelines given by WHO in the GPAQ. The GPAQ was chosen because it is a widely used global PAQ which has been validated in India [22; 23].

2.4. Statistical analysis

Descriptive analyses were performed considering absolute frequency and relative percentage. Data were described as n (%) for categorical variables and mean ±SD or median for numerical variables. The mean (±SD) glycaemic indicators and their 95% CIs were also calculated. Independent sample t-test for normal distribution continuous variables was used to compare the differences between the physically active group based on their age. The t-test or one-way analysis of variance was used to identify the differences in scores depending on different independent variables.

3. Results and discussion

In this article we report aspects of our study namely, physical activity and glycemic control in relation to physical activity as classified by MET values. We looked at a large study on physical activity among diabetics conducted in the country to make some meaningful comparison. They report the following.

ICMR-INDIAB study assessed the reports on the levels of physical activity and inactivity in India using Global Physical Activity Questionnaire (GPAQ) [24]. Overall, 54.4% of the population were inactive (males: 41.7%), while 31.9% (males: 58.3%) were active and 13.7% (males: 61.3%) were highly active. Subjects were more inactive in urban, compared to rural, areas (65.0% vs. 50.0%) and female subjects were significantly more inactive than their male counterparts. Physical inactivity was highest in Chandigarh (66.8%) followed by Tamilnadu (60.0%), Maharashtra (55.2%) and Jharkhand (34.9%). Absence of recreational activity was reported by 88.4%, 94.8%, 91.3% and 93.1% of the subjects in Chandigarh, Jharkhand, Maharashtra and Tamilnadu respectively. Most of the time spent in moderate to vigorous intensity activity was at the workplace. Even among those who reported recreational physical activity (8.1%), the time spent in moderate to vigorous intensity activity was overall.

3.1. Lifestyle (mean time spent in activities in 24hrs) of the selected Diabetics

Physical activity helps to improve the body’s response to insulin which can lower blood glucose levels, lower blood pressure and cholesterol levels, reducing the risk of heart disease, control weight, reduce the risk of developing diabetes complications. American Diabetes Association (ADA) recommends that individuals with T2DM perform at least 150 min of moderate-intensity aerobic exercise and/or at least 90 min of vigorous aerobic exercise per week [23; 25].

Life style and physical activity data in Table 1 shows the various activities including sleep, leisure, household works, moderate intense activity, physical activity-walking and cycling and hours spent for those activities.
Table 1 Life Style – Physical Activity (mean values) Pattern in Selected Diabetics

<table>
<thead>
<tr>
<th>Activity</th>
<th>50-60 Years (Hours)</th>
<th>60-70 Years(Hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep</td>
<td>8.43(1.77)</td>
<td>8.73(1.69)</td>
</tr>
<tr>
<td>Leisure (sitting activities)</td>
<td>13.27(2.59)</td>
<td>13.00(2.47)</td>
</tr>
<tr>
<td>Household works</td>
<td>1.21(1.63)</td>
<td>1.32(1.96)</td>
</tr>
<tr>
<td>Moderate intense activity</td>
<td>0.76(1.86)</td>
<td>0.50(1.04)</td>
</tr>
<tr>
<td>Physical activity-walking</td>
<td>0.33(0.39)</td>
<td>0.42(0.44)</td>
</tr>
<tr>
<td>Physical activity-cycling</td>
<td>0.00(0.03)</td>
<td>0.03(0.12)</td>
</tr>
<tr>
<td>Total hours</td>
<td>24.00</td>
<td>24.00</td>
</tr>
</tbody>
</table>

From the above Table we concluded that the physical activity of both age group were similar. Physical activity of 50-60 year age group was slightly better than the 60-70 year age group, since they were engaged with some kind of physical activity related to their work while the 60-70 year age group was sedentary, probably because they had retired from professional engagements.

ELSA (English Longitudinal Study of Ageing) is a prospective cohort study of community-dwelling men and women aged 50 years and over to examine whether small amounts of low-intensity physical activity were associated with reduced risk of developing T2DM in a national sample of people aged 50 years and over. The sample comprised 7,466 individuals (55.9% women) free from self-reported doctor-diagnosed diabetes and was prospectively followed for a mean of 45.3 months. Baseline self-reported physical activity was categorized as physical inactivity, low- and vigorous/moderate-intensity physical activity at least once a week. Cox proportional hazard regression was used to model the association between baseline physical activity and incident T2D. Physical activity performed at least once a week was reported in 1966 participants who performed Low intensity activity, 4950 participants performed Vigorous/ moderate intensity activity and 550 performed none [26].

Cohort studies consistently show a marked reduction in the incidence of T2DM among physically active individuals compared with their sedentary peers, and recent investigations provide empirical support for the prescription of 30 min/day of moderate-intensity activity. In these studies, exposure data were derived from self-reported physical activity questionnaires. Among more than 70,000 initially healthy US women aged 40–65 year participating in the Nurses’ Health Study, walking briskly for at least 2.5 h/week (i.e., 30 min/day for 5 days/week) was associated with a 25% reduction in diabetes over 8 year of follow-up among those reporting no vigorous exercise, after adjustment for age, body mass index (BMI), and other risk factors for diabetes [27].

Lifestyle interventions including 150 min/week of physical activity and diet-induced weight loss of 5–7% reduced the risk of progression from impaired glucose tolerance (IGT) to T2DM by 58% [28; 29].

3.2. Physical activity of the selected Diabetics classified according to MET values

One of the easiest methods for recording of the intensity of a physical activity is the Metabolic Equivalent Task (MET) method. The energy cost of many activities has been determined, usually by monitoring the oxygen consumption during the activity, to determine an average oxygen uptake per unit of time. This value is then compared to the resting oxygen uptake. One MET is the energy expended at rest, two METs indicates the energy expended is twice that at rest, three METs is triple the resting energy expenditure, etc [29].

Phase 1 of the ICMR-INDIAB study was conducted in four regions of India (Tamil Nadu, Maharashtra, Jharkhand and Chandigarh representing the south, west, east and north of India respectively) with a combined population of 213 million people. Physical activity was assessed using the Global Physical Activity Questionnaire (GPAQ) in 14227 individuals aged ≥ 20 years [urban- 4,173; rural- 10,054], selected from the above regions using a stratified multistage design. Of the 14227 individuals studied, 54.4% (n = 7737) were inactive (males: 41.7%), while 31.9% (n = 4537) (males: 58.3%) were active and 13.7% (n = 1953) (males: 61.3%) were highly active. Subjects were more inactive in urban, compared to rural, areas (65.0% vs. 50.0%; p < 0.001). Males were significantly more active than females (p < 0.001). Subjects in all four regions spent more active minutes at work than in the commuting and recreation domains. Absence of recreational activity was reported by 88.4%, 94.8%, 91.3% and 93.1% of the subjects in Chandigarh, Jharkhand, Maharashtra and Tamil Nadu respectively. The percentage of individuals with no recreational activity
increased with age (Trend $\chi^2 : 199.1, p < 0.001$). The study shows that a large percentage of people in India are inactive with fewer than 10% engaging in recreational physical activity. Therefore, urgent steps need to be initiated to promote physical activity to stem the twin epidemics of diabetes and obesity in India [24].

Further, Tamilnadu, a significantly greater proportion of urban residents were inactive compared to rural residents (71.0% vs. 55.4%; $p < 0.001$), while a significantly higher proportion of rural subjects were classified as highly active compared to their urban counterparts (13.3% vs. 8.3%; $p < 0.001$). Compared to males, a higher proportion of female subjects were physically inactive in both the urban as well as rural areas. Conversely, a higher proportion of males were found to be highly active as compared to females, in both the urban as well as rural areas [24].

The data from Global Physical activity questionnaire was used to compute the MET of the selected diabetics. The following Table 2 gives the details.

Table 2 Classifications of the Selected Diabetics According to MET Values

<table>
<thead>
<tr>
<th>MET Classification</th>
<th>50 – 60 years</th>
<th>60 – 70 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>MET &lt; 600</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>MET &gt; 600</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>30</td>
</tr>
</tbody>
</table>

Exercise training may improve insulin action via changes in regional adipose tissue (AT) deposition, a recognized predictor of risk for T2DM and cardiovascular disease (Sheehan & Jensen, 2000), and more recent evidence suggests that intramuscular lipid is an early contributor to the pathogenesis of insulin resistance [30].

3.3. Physical Activity and Glycemic Control of Selected T2D

Physical activity and glycemic control of selected T2DM population were computed by Global Physical Activity Questionnaire and indicated in Metabolic Equivalent (MET) which gives the border line of 600MET value which separates physically active (MET ≥600 MET) and physically inactive (MET < 600 MET) participants [31] (Stewart & Kristin 2000). The data on FBG, PPBG and HbA1c from medical records of participants were obtained and consolidated into two groups i.e. physically active and physically inactive persons are compared in the Table 3

Table 3 Physical Activities and Glycemic Control of Selected T2DM subjects (n=100)

<table>
<thead>
<tr>
<th>Indicators Of Glycemic Control</th>
<th>MET &lt; 600</th>
<th>MET ≥ 600</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>FBG (mg/dl)</td>
<td>137.04±39.28</td>
<td>153.08±59.53</td>
</tr>
<tr>
<td>PPBG (mg/dl)</td>
<td>209.17±78.06</td>
<td>233.84±91.6</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>8.16±1.69</td>
<td>9.04±2.41</td>
</tr>
</tbody>
</table>

In our study we found that the glycemic parameters increased in the group with greater physical activity (MET ≥600). Therefore in this study there are other factors responsible for poor glycemic control in spite of physical activity. The most probable factor would be food intake. It may be that total food intake and eating in-between meals could be greater. So, as age increases diet has to be monitored more carefully in addition to physical activity.

According to the table below FBG and PPBG values were significantly different among the males of the two groups of physical activity. HbA1c values were also significantly different in the males but not among the females. As the t value is small (-0.8) we are unable to conclude that the glycemic control among females of the two physical activity group are different.
The Chennai Urban Population Study (CUPS) is an epidemiological study involving two residential areas in Chennai in South India representing the middle and lower socio-economic group. Prevalence of glucose intolerance was significantly higher among subjects who had light grade physical activity (23.2%) compared to moderate (17.5%, p = 0.04) and heavy grade activity (0.1% p < 0.00001). Subjects belonging to higher socio-economic status (SES) and who also had a positive family history of diabetes had five times greater prevalence of glucose intolerance compared to subjects from lower socioeconomic status and no family history (p < 0.0001) [32].

The results of a study by Dunstan et al., (2002) [33], showed that fasting plasma insulin levels remained unchanged throughout the 6-month intervention for both the RT (resistance training) & WL (weight loss) and WL groups. For fasting plasma glucose, no changes were detected in either group after 3 months, but a 1.4-mmol/l decrease (P = 0.06) was observed in the RT & WL group after 6 months. However, there were no differences between the groups for either serum insulin or plasma glucose at any time point. Furthermore, insulin sensitivity (Homeostatic Model Assessment for Insulin Resistance - HOMA) remained unchanged in both groups.

Further the RT & WL program was associated with a significant reduction in HbA1c at both 3 months (0.6 ± 0.7%, P < 0.01) and 6 months (1.2 ± 0.9%, P < 0.01). No detectable changes were observed in HbA1c for the WL group. There was a significant group-by-time interaction (P < 0.05), with the magnitude of the decrease in HbA1c being greater in the RT & WL group than in the WL group. The overall net difference between groups in mean HbA1c from baseline was −0.5% (P < 0.05) at 3 months and −0.8% (P < 0.05) at 6 months. The results remained unchanged after adjustment for age, sex, duration of diabetes, use of oral hypoglycemic medication, medication change, baseline HbA1c levels, and change in waist circumference [33].

This reported study has demonstrated that a supervised progressive high-intensity resistance training program performed 3 days/week for 6 months was safe and well tolerated by older patients with T2D and was effective in improving glycemic control and muscle strength. The combination of resistance training and moderate weight loss was associated with a threefold greater decrease in HbA1c levels after 6 months compared with moderate weight loss without resistance exercise, and this was not mediated by concomitant reductions in body weight, waist circumference, and fat mass. The addition of resistance training also contributed to the maintenance of LBM (lean body mass) despite moderate weight loss [33].

A systematic review of randomized trials found that resistance training improves glycemic control (as reflected by reduced glycated hemoglobin (A1c), decreases insulin resistance and increases muscular strength in adults with type 2 diabetes [34]. Another systematic review and meta-analysis found that supervised programs involving aerobic or resistance exercise improved glycemic control in adults with type 2 diabetes, whether or not they included dietary co-intervention [35]. The Diabetes Aerobic and Resistance Exercise (DARE) study showed that aerobic and resistance exercise training each improved glycaemic control and that a combination of both was superior to either type alone in patients with type 2 diabetes mellitus. Here we report effects on patient-reported health status and well-being in the DARE Trial [36]. Several researchers have argued whether exercise or non-exercise physical activity improves glycemic control. Despite the well-documented benefits of exercise in the prevention and treatment of T2D. Many patients with T2D have difficulties engaging in or adhering to structured exercise intervention programs. The most cited reasons to abstain from regular exercise include lack of time, lack of motivation, lack of joy, physical discomfort during exercise, and resistance against exercise facilities [37]. Therefore, it could be questioned whether engaging in a typical exercise intervention program is the most suitable physical activity intervention for all patients with T2D.

It has been argued that physical activity strategies should focus more on increasing physical activity applicable to patients’ daily life and home environment [37; 38]. In that respect, an increase in unstructured physical activities such as strolling, walking a dog, or performing light gardening or household tasks may represent a promising alternative to

Table 4 Statistical Analyses Comparison of Glycaemic Control and Physical Activity (MET)

<table>
<thead>
<tr>
<th>Indices of Glycemic control</th>
<th>Males t values p value</th>
<th>Females t values p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBG</td>
<td>-11.6</td>
<td>≤0.05</td>
</tr>
<tr>
<td>PPBG</td>
<td>-19.5</td>
<td>≤0.05</td>
</tr>
<tr>
<td>HbA1c</td>
<td>-9.5</td>
<td>≤0.05</td>
</tr>
</tbody>
</table>

*NS – not significant
structured exercise. This view is supported by evidence from epidemiological studies, indicating that nonexercise physical activity is beneficially associated with glucose concentrations independent of moderate to vigorous intensity physical activity [39].

Recent experimental studies have confirmed the benefits of non-exercise physical activity on postprandial blood glucose homeostasis. In this regard, repeated short bouts (2–15 minutes) of light physical activity during the postprandial phase have been shown to reduce postprandial glucose and/or insulin responses in non-diabetic individuals [40]. Thus, resistance training may also be considered in the treatment of insulin resistance, and not only with a view to increasing the muscle mass. Resistance exercise is probably very attractive to the typically overweight type 2 diabetic patient, who may be reluctant to take endurance exercise.

A cluster-randomized trial found that diet alone; exercise alone, and combined diet and exercise were equally effective in reducing the progression from IGT to diabetes [41]. The effect of resistance exercise training on insulin sensitivity may last somewhat longer [42] perhaps because some of its effects are mediated by increases in muscle mass [43].

4. Conclusion

Higher levels of PA were associated with lower mortality risk in individuals with diabetes. Even those undertaking moderate amounts of activity were at appreciably lower risk for early death compared with inactive persons. These findings provide empirical evidence supporting the widely shared view that persons with diabetes should engage in regular PA.

However, the therapeutic benefits of exercise have been studied extensively in middle-aged men and women with type 2 diabetes; little is known about the impact of exercise training in older people with this condition.

Despite the well-documented benefits of exercise in the prevention and treatment of type 2 diabetes, many patients with type 2 diabetes have difficulties engaging in or adhering to structured exercise intervention programs. The most cited reasons to abstain from regular exercise include lack of time, lack of motivation, lack of joy, physical discomfort during exercise, and resistance against exercise facilities. Therefore, it could be questioned whether engaging in a typical exercise intervention program is the most suitable physical activity intervention for all patients with type 2 diabetes.

Compliance with ethical standards

Acknowledgments

The authors are grateful to PSG IMS&R and PSG Hospitals, Coimbatore, TN, India, for approving the study and permitting us to collect data from their T2DM patients.

Disclosure of conflict of interest

There is no conflict of interest between all the three authors

Statement of informed consent

The ICMR [18] guidelines were followed to protect the rights of the study participants. Ethical Clearance (15/328, dated 04/12/2015 was obtained from PSG Institute of Medical Sciences and Research Hospitals, Coimbatore, Tamil Nadu, India. The purpose of study was explained by the researcher to the participants and their consent was obtained in the ICMR human ethics consent form.

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Author’s short Biography

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