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OPTIMIZATION OF EFFICACY OF CORE STRENGTHENING EXERCISE PROTOCOLS ON PATIENTS SUFFERING FROM DIABETES MELLITUS

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Abstract

Background and Aims: *Lack of physical activity, obesity, eating habits contributes to an increase in metabolic disorders. Patients with diabetes have balance, gait, and proprioceptive impairments which hinder the activity of daily living. Therefore, the main objective of present research was to optimize and to find efficacy of the exercise protocols on gait, balance, proprioception and glycated haemoglobin (HbA1c) levels in patients suffering from Type 2 Diabetes mellitus (T2DM).* ***Material and Methods:*** *Forty individuals with T2DM age between 35 to 60 were recruited and randomly allocated to four groups with 10 subjects per group. Core strengthening exercises were given with duration of twenty or thirty minutes per session and frequency of twice or thrice weekly for six weeks.* ***Results:*** *Design Expert Software version 10.0.6 was used to analyse data Design Expert software. Further duration and frequency of exercises were compares using ful factorial design. Paired sample t test was used at significance level $p<0.05$ to find efficacy of core strengthening exercises. The results showed the roe of duration and frequency along with significant effect of exercises on balance, gait, proprioception and HbA1c.* ***Conclusion:*** *Pilates based core strengthening exercises (PBCS) significantly improved all the parameter selected if exercise protocol was given for 30 minutes and thrice weekly for six weeks. Study has also shown impact of duration and frequency of exercises separately on these parameters.*

key words: *Diabetes, postural stability, Core Strengthening, gait*

Background and Aims

Diabetes Mellitus (DM) is a metabolic disorder that has affected large population both in developing and developed countries like an epidemic. It has been estimated currently there are 415 million [1] patients suffering from DM globally, which is assumed to rise 592 million by year 2035 [2] and 612 million by year 2040 [1]. India has turned out to be capital of diabetes globally, every fifth diabetic in world is Indian. India alone contributes around 41 million patients suffering from DM that may increase to 87 million by year 2028 [2]. DM is often associated with many peripheral neurological complications. During its evolution it may lead to increased postural sway, gait deviations, abnormal neuromuscular control and increased

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reaction time [3]. These complications can lead to increase in falls as these patients have decreased balance [4]. Balance is of paramount importance to carry on routine activity of daily living. Diseases, which lead to poor balance, may result in falls and fall related injuries. Balance is an issue of concern for patients with DM especially with peripheral neuropathy (PN) as this leads to the abnormality in proprioception and tactile information to central nervous system [5]. Decrease in perception of movement at hip and ankle joint can lead to reduced static and dynamic balance which further leads to risk of falls [6]. Patient with DM walk slowly, have shorter steps with wider step time variability on irregular surfaces and improper pressure distribution [7]. These alterations are found in patients of DM with PN. It has been reported that gait deviations may appear in patients well before clinical detection of PN where gait speed and cadence are decreased prior to shortening of stride length in patient with DM without PN [8]. Therefore it can be postulated that patients with DM without PN can also have balance and gait impairments. 30% patients suffering from DM have associated PN and the remaining population may be ignored by clinicians for impairment in balance that is about 70% patient with DM may largely go undetected [3]. The aim of present study was to investigate the efficacy of exercises on patients with DM without overt PN as balance and gait impairments which are generally ignored in them.

Balance is mostly quantified by using balance platform, body wearable sensor technology [5], force plates [8] and balance master system [6]. Similarly, gait is measured using gait analysers which are three dimensional computerized devices that processes time-distance, kinetic and kinematic variables [9]. There are various other methods to measure these variables for example balance can be measured using Berg Balance test [10], Tinetti performance oriented mobility assessment scale [8], timed up and go scale [10] while gait can be evaluated by modified gait abnormality rating scale [11], gait deviation index [12], dynamic gait index [13], Gillette Gait Index (GGI), Gillette Functional Assessment Questionnaire Walking Scale (FAQ), and topographic classifications within the diagnosis of Cerebral Palsy (CP) [14]. In the present study, balance has been evaluated using Modified Fullerton Advanced balance scale which measures both static and dynamic balance and gait has been assessed by measuring spatial and temporal parameters like step length, stride length, and cadence [7,15,16]. Proprioception is a sensory system which receives inputs from various muscles, joint and cutaneous mechanoreceptors. This sensory information from these receptors is sent to central nervous system for controlling to regarding joint position and movement [17]. Chronic hyperglycaemia results in distal symmetrical polyneuropathy which has symmetrical sensory alterations that begin in feet and progress to legs and hands [18]. Patients suffering from DM may have proprioceptive impairment due to development of PN [17]. This implies that HbA1c levels may be directly correlated with neuropathy and thus it can be suggested that control of glucose may slow down progression of such diabetic neuropathy [19].

Pharmacological treatment of T2DM include various drugs aiming to control blood glucose levels like sulphonylureas, glinides, dipeptidyle peptidase-4 inhibitors, glucagon like peptide-1analogues of receptor agonists, sodium glucose cotransporter 2 inhibitors or insulin[19]. Patients are advised to practise physical exercises like aerobic, resistance exercises along with medical management to control glucose levels. Anything that increases physical activity may help in

decreasing the risk of development of the complications related to the disease for example walking for thirty minutes daily helps in regulating blood glucose [2].

Various studies were conducted to evaluate the efficacy of different modes of exercises on balance, gait, proprioception and HbA1c but very little research has been carried out on optimization of various exercise protocols along with efficacy of these protocols. Therefore by having a randomized trial design, to our knowledge, of the present study is the first to evaluate relationships between factors (duration & frequency of exercises) and responses followed by optimization of exercise protocols and also to assess the efficacy of Pilates based core strengthening exercises on gait, balance, proprioception and HbA1c.

Material and methods

Participants

Approval of study protocol was obtained from institutional ethics committee of Department of Physiotherapy, GJUS&T, Hisar, India in its meeting held on 03/11/2015 with letter no PTY/2015/800. The committee was constituted in accordance with Indian Council of Medical Research Guidelines.

The study has a prospective randomized design and was organized in the Department of Physiotherapy, GJUS&T, Hisar, India from March 2016 to July 2017. The patients with T2DM (blood glucose > 7.0 $mmoll^{-1}$ in fasting state and HbA1c > 6%) were recruited from hospitals through referrals, outpatient clinics and who reported directly to health centre and OPD of Physiotherapy Department, GJUS&T. Patients with foot ulcers, musculoskeletal, neurological problems and recent surgeries that can influence outcome measures directly or indirectly. Subjects were explained about the study protocol, risk factors and a written consent was taken from them.

Randomization

40 individuals who met the inclusion criteria were allocated to four groups randomly using chit method by the supervisor. Subjects in all the groups received core strengthening exercises with different duration and frequencies. Exercise duration and frequency of each session for different groups is shown in (Table 1).

Table 1. Exercise Protocol with 6 week study period for Different Groups

Group	Number of patients (n)	Duration in minutes	Frequency sessions /week	study period in weeks
Group 1	10	Twenty	Twice weekly	Six
Group 2	10	Twenty	Thrice weekly	Six
Group 3	10	Thirty	Thrice weekly	Six
Group 4	10	Thirty	Twice weekly	Six

Exercise intervention

The structured Pilates Based core strengthening (PBCS) exercises were conducted in Department of Physiotherapy, GJUS&T. Prior to the start of experimental protocol each patient from all the groups were trained about method of breath controlling and engaging the abdominal muscles. The exercise protocol involved six stages of progression, each stage was introduced weekly. Before commencement of the exercise protocols pre intervention data was collected.

Session started with 5 minutes of warm up on static cycle followed by 30 or 20 minutes of core strengthening exercises with 5 minutes of break. By the end of session cool down exercises which included stretching and relaxation was given This was continued thrice or twice weekly for 6 weeks. Six repetitions were done according to the convenience of the patient. Some exercises were excluded as patients were unable to

perform them. Patients were kept unaware of the hypothesis. After 6 weeks of intervention of exercises patients were encouraged to continue exercise protocol at their own.

Outcome measures

Fullerton advanced balance tests- this scale measures both static and dynamic balance. Another reason to choose this scale was that this is easy, cost effective and less time consuming and is the reliable and valid tool. This scale has ten items and with 0 to 4 points each with maximum of 40 points and minimum of 25 points [20].

Gait assessment: gait was assessed by measuring gait parameters that is stride length, step length, cadence, gait velocity [21].

OptiPlex 3 continuous passive motion (CPM) was used to measure Proprioception. Patients were asked to sit with back supported and dominant leg was placed in CPM. Then patient was supposed to remember the position of the knee joint at three different angles 15, 45 and 60 degree. Patients were asked to mainrtain the position for 5 seconds and then leg was returned to initial position. Then patient was asked to reconstruct the same angles. This procedure was repeated three times and average of reading of joint reposition error was obtained.

High Performance Liquid Chromatography was used to measure HbA1c in the laboratory.

Statistical analysis

Design Expert software version 10.0.6 was used to make experimental design which was 40 trial runs with four groups and ten blocks which wasdata obtained from patients were evaluated for each group. After analysis of all four groups by Design Expert software the equations were generated for effect of factors on different responses in terms of actual factor (Table 2). Further efficacy of exercise protocols was measured using paired t-test performed within group at significance level $p<.05$ (as shown in Table 3).

Table 2. Numerical relationship between factors and responses.

RESPONSES	EQUATION GENERATED (factors #X & #Y)
Balance	3.1+0.3*X+0.45*Y+0.45*XY……(a)
Step length	2.29+0.16*X+0.34*Y-0.09*XY……(b)
Stride length	3.52-0.13*X+0.73*Y-1.02*XY……(c)
Velocity	0.13+0.076*X+0.067*Y+0.06*XY……...(d)
Cadence	2.53+0.57*X+0.68*Y+0.43*XY……(e)
Proprioception	-0.14-1.04*X-0.26*Y-0.53*XY……(f)
HbA1c	-0.36-0.45*X-0.49*Y-0.17*XY……(g)

#X= Duration of exercise, #Y= Frequency of Exercise

Table 3. Comparison within the groups (n=10 per group).

	Groups					
	Group 1			Group 2		
variables	mean±SD 0 week	mean±SD 6 week	Sig	mean±SD 0 week	mean±SD 6 week	Sig
Balance	22.30±3.10	25.10±3.14	.001*	19.0±2.98	21.8±3.76	.002*
Step length	59.60±8.15	61.30±7.74	.000*	48.70±9.88	51.26±9.10	.004*
Stride length	1.14±17.71	1.16±16.89	.002*	89.90±19.12	94.30±17.93	.000*
Velocity	0.88±0.13	0.92±0.10	.077**	0.89±0.11	0.95±0.10	.039*
cadence	1.03±9.41	1.05±8.98	.003*	1.04±3.56	1.06±3.74	.000*
Proprioception	8.77±2.29	9.40±3.05	.187**	10.95±2.71	12.13±4.32	.185**
HbA1c	8.35±1.87	8.75±1.70	.115**	9.11±1.76	8.87±1.73	.278**

Table 3. *Continued.*

	Groups					
	Group 3			Group 4		
variables	mean±SD 0 week	mean±SD 6 week	Sig	mean±SD 0 week	mean±SD 6 week	Sig
Balance	17.90±2.96	22.20±3.32	.000*	20.20±2.82	22.70±3.65	.002*
Step length	47.20±5,94	49.90±5.50	.000*	47.80±7.22	50.00±6.59	.003*
Stride length	91.50±11.47	94.60±11.27	.001*	91.50±16.07	95.17±15.98	.004*
Velocity	0.82±0.09	1.15±0.12	.000*	0.88±0.14	0.96±0.11	.042*
cadence	1.03±5.98	1.07±5.86	.000*	1.03±4.55	1.05±4.76	.000*
Proprioception	8.04±2.40	6.07±2.69	.000*	7.80±1.47	7.41±1.33	.298**
HbA1c	10.56±1.51	9.08±1.03	.002*	8.16±1.02	8.02±1.06	.213**

*Significant, **non- significant

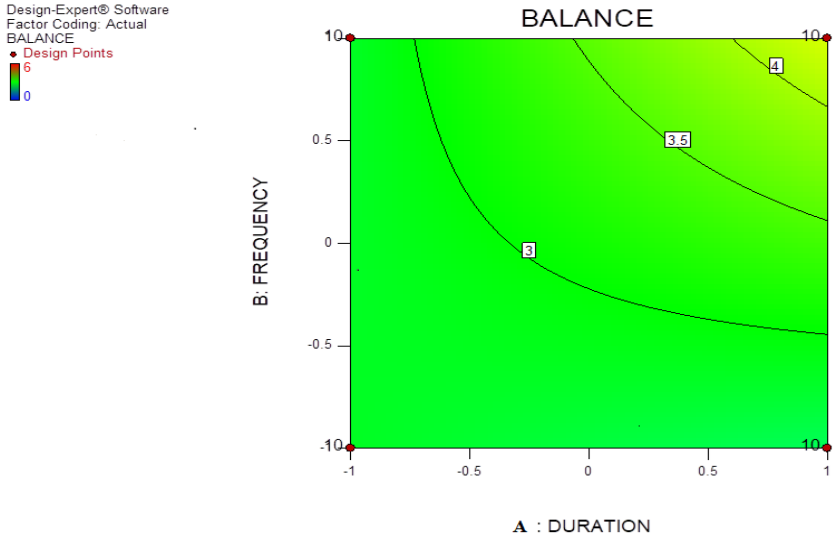

Figure 1. *Effect of duration and frequency of exercises on Balance through contour plot.*

Results

A full factorial design was used to find out efficacy of PBCS on responses that is gait, balance, proprioception and HbA1c by selecting two factors a) duration of PBCS exercises which were given for thirty or twenty minutes with five minutes break in each session and b) frequency of PBCS exercises, which were visits to the session thrice and twice weekly. After analysis the design expert software generated equations for each response (Table 2). Equation a along with contour plot (Figure 1) showed that although duration and frequency of exercises increases, there is noticeable improvement in balance but when both the factors were compared frequency of exercises had greater role in improving balance. Further when within group analysis was done group 3 was found to have extremely significant results with p>.001 which shows that increase in both the factors improves balance (Table 3).

The equation (b & c) depicted that both frequency and duration of exercises resulted in improvement of step length and stride length but frequency of exercises showed significant improvement as compared to duration of exercises. This was also shown by higher factor component of frequency in equation ii & iii. Similar finding can be observed in contour plots (Figures 2 and 3) that frequency is a better factor in improving both step length and stride length.

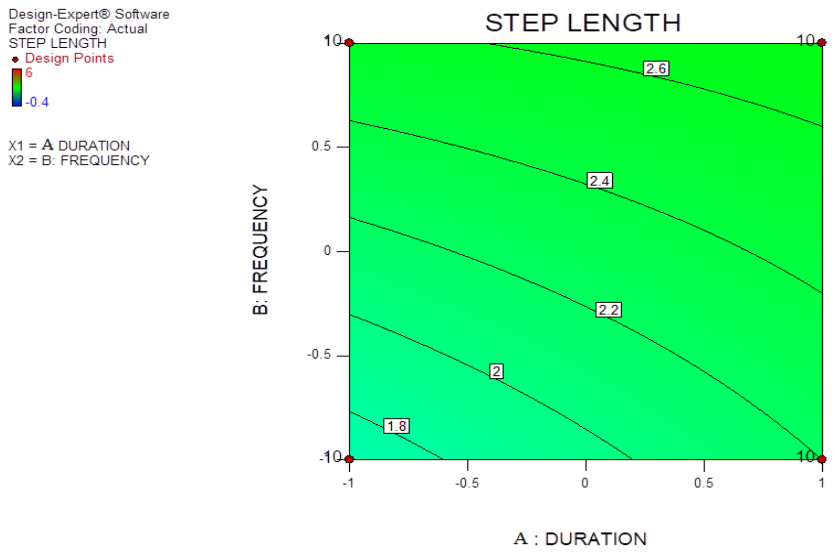

Figure 2. *Effect of duration and frequency of exercises on step length through contour plot.*

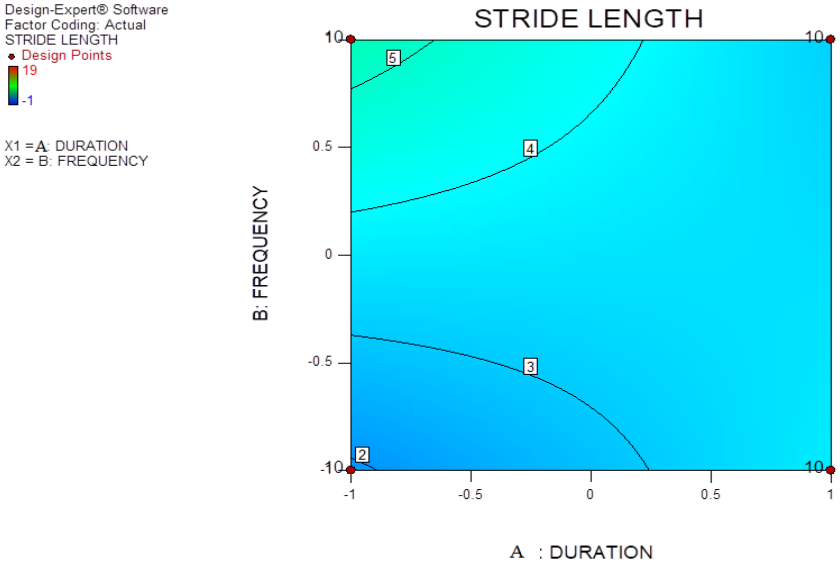

Figure 3. *Effect of duration and frequency of exercises on Stride Length through contour plot.*

The equation (d) for velocity revealed positive effects of both frequency and duration. This means that increase in frequency and duration of exercises resulted in improvement in velocity of patients suffering from DM, which is calculated as distance covered, divided by time taken. Similar results can also be depicted from contour plots (Figure 4), as the frequency and duration values are increasing the velocity are also increasing from value -0.3 to 0.6. But here duration seems to be playing more effective role as compared to frequency. That is if duration of exercises is increased it may help in increasing velocity. Furthermore when equation (e) was analysed similar results were observed for cadence which is number of steps taken per unit time by any individual. Contour plot (Figure 5) also depicted that interaction of frequency and duration increases the velocity where value was ranging between 0-7, but duration plays a little more significant role in improving cadence i.e duration of exercises is directly proportional to improvement in cadence.

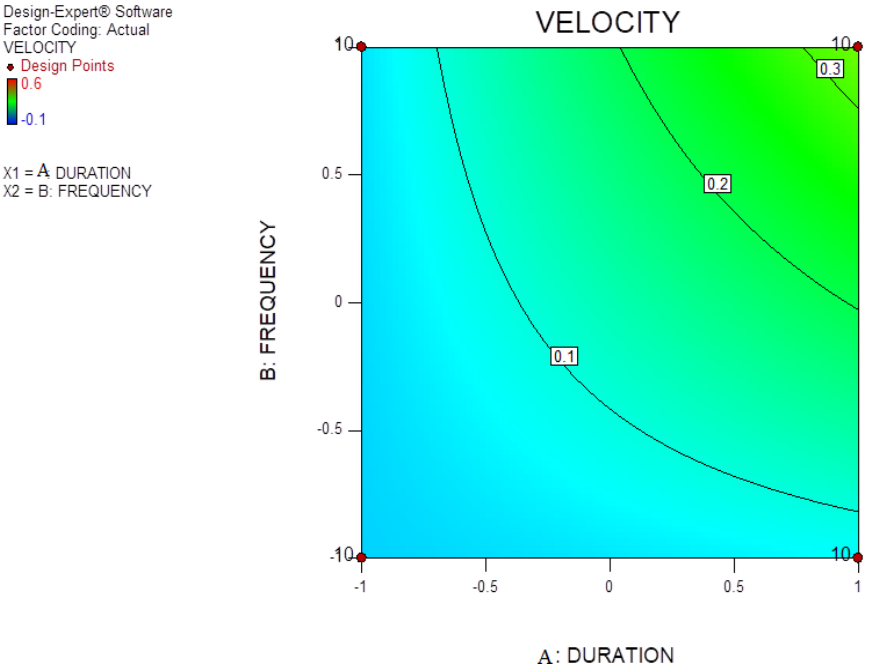

Figure 4. *Effect of duration and frequency of exercises on velocity through contour plot.*

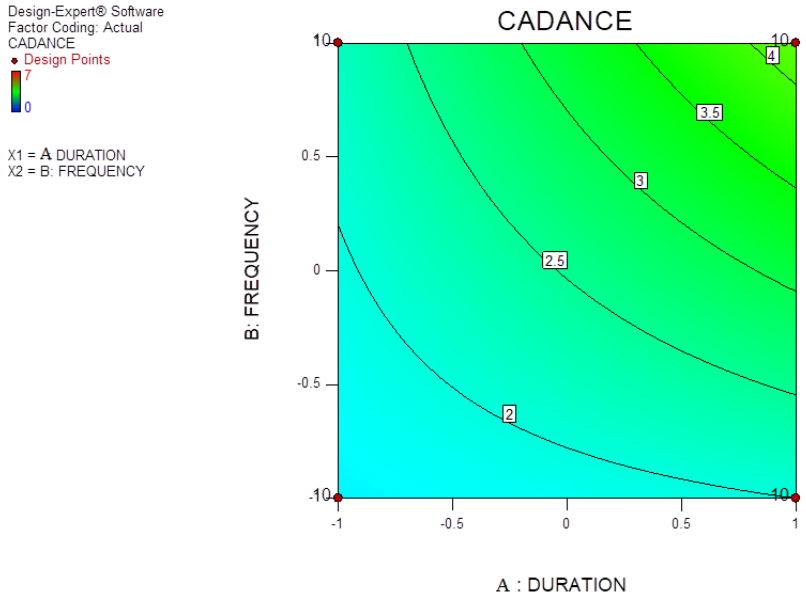

Figure 5. *Effect of duration and frequency of exercises on cadence through contour plot.*

The equation (f) suggests that proprioceptive error decreased significantly in the patients suffering from DM frequency and duration of exercises have significant role in improving proprioceptive error. Further the contour plot (Figure 6) shows although duration and frequency both improves proprioception but duration of exercises has significantly improves proprioception when compared to frequency of exercises. Further calculation of proprioceptive error was done by post intervention minus pre intervention. Therefore the negative value suggests decrease in proprioceptive error.

Equation-g suggests that increase in frequency and duration of exercises results in decrease of HbA1c. this was also observed in contour plot (Figure 7) that as frequency and duration of PBCS exercises was increased the

level of HbA1c falls. Therefore it can be assumed that to decrease levels of HbA1c both the factors need to be increased. As improvement is calculated on post intervention minus pre intervention. Therefore the negative value suggests decrease in HbA1c.

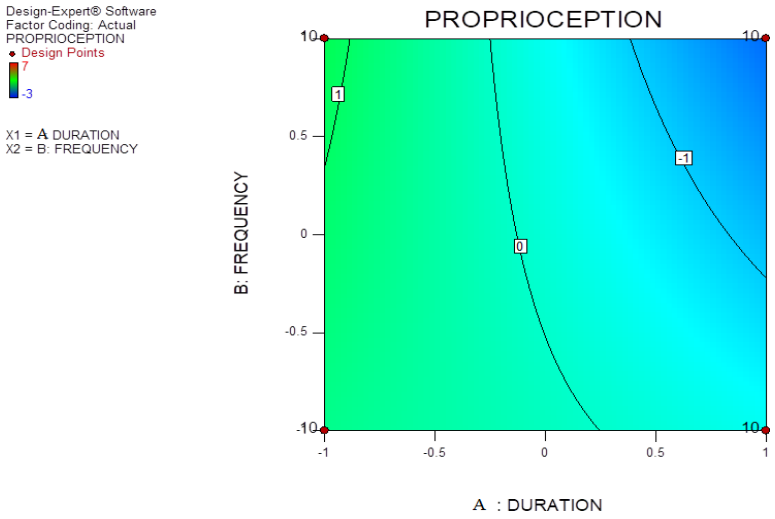

Figure 6. *Effect of duration and frequency of exercises on Proprioception through contour plot*.

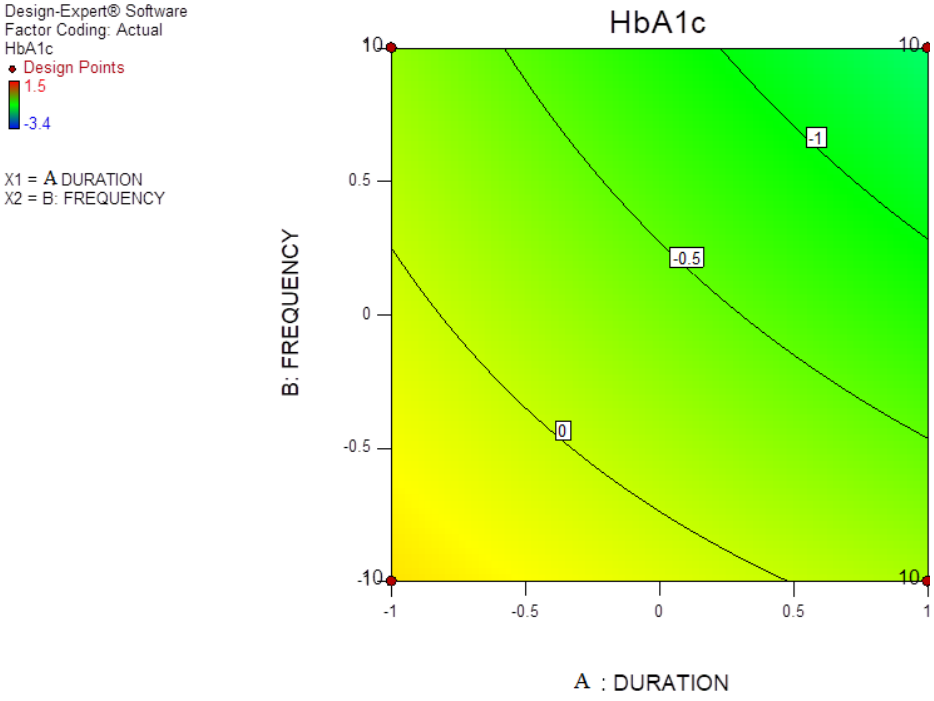

Figure 7. *Effect of duration and frequency of exercises on HbA1c through contour plot*.

The constraints imposed along with goals of optimization are shown in Table 4. The two factors duration and frequency of exercises were kept in range to minimize errors in data. The goal of optimization in present study was to maximize balance with more importance (value 4) and to maximize velocity with less importance (value 3), Step length, stride length , cadence and proprioception were kept in moderate importance (value 3). Whereas maximum importance was assigned to minimization of HbA1c (value 5). The given solution search using design expert software yielded four solutions with different desirability

(Table 5) in order to achieve goals of optimization. Therefore, solution 1 with maximum desirability of 0.688 was selected. This solution (Table 5) indicated that duration and frequency of exercises at level +1 that is duration of 30 minutes and frequency of exercises thrice a week on every consecutive day should yield balance of 4.3, step length 2.7, stride length 3.1, velocity 0.33, cadence 4.2, proprioception -1.97 and HbA1c -1.48 this is an average of data of all responses obtained after intervention. These values match the average of all responses individually in group 3. Further after applying paired t test (Table 3) the results showed significant improvement with $p<0.05$. Although the improvements in some responses were found in all the groups but group 3 showed extremely significant improvements.

Table 4. Goals for Optimization goals of responses.

Name	Goal	Lower Limit	Upper Limit	Importance
Factor X:Duration	is in range	-1	1	3
Factor Y:Frequency	is in range	-1	1	3
Response 1-Balance	maximize	0	6	4
Response 2-Step length	is in range	-0.4	6	3
Response 3-Stride length	is in range	-1	19	3
Response 4-Velocity	maximize	-0.1	0.6	3
Response 5-Cadence	is in range	0	7	3
Response 6-Proprioception	minimize	-3	7	3
Response 7-Hba1c	minimize	-3.4	1.5	5

Table 5. Solutions Suggested by Design Expert version 10.0.6.

S.No	Duration	Frequency	Balance	Step length	Stride length	Velocity	cadence	Proprioception	HbA1c	Desirability
1	1.000	1.000	4.300	2.700	3.100	0.330	4.200	-1.970	-1.480	0.688
2	0.981	1.000	4.286	2.699	3.122	0.327	4.181	-1.940	-1.468	0.685
3	1.000	0.964	4.267	2.691	3.110	0.325	4.160	-1.941	-1.456	0.683
4	0.715	1.000	4.086	2.680	3.428	0.291	3.915	-1.521	-1.303	0.646

Discussion

Present investigation is first of its kind for optimizing treatment protocols with full factorial design in patients suffering from DM. Diabetic patients have neuropathy resulting in decreased Balance, Gait, and Proprioception. Results of present study suggests that Pilates based Core Strengthening exercise, are an effective mode of treatment in improving not only above parameters but can also reduce HbA1c levels. Six weeks of progressive core strengthening exercises resulted in 1) improvement in balance and Gait parameters, improvement in proprioception, 2) decrease in HbA1c levels. Efficacy of exercises were analyzed for different duration (two levels- Thirty minutes and Twenty minutes) and frequencies (twice and thrice weekly). Results of optimization suggest that 30 minutes of core strengthening, thrice weekly were most effective. Isolated effects of both the factors (duration and frequency) were analyzed on outcome measures it was observed that increase in duration resulted in significant improvement of proprioception, gait velocity, cadence. Increase in frequency improved balance, step length, stride length significantly, while HbA1c showed significant improvement with increase in both these factors.

Insulin action has been found to improve with Endurance oriented exercise training in insulin resistant individuals. Exercises also resulted in clinically prolonged insulin action, after 2 weeks of exercises. And this effect was

due to the intensity and weekly exercise schedule done during intervention period. These effects of exercises on insulin action and persistence may provide insight on improvement on HbA1c levels in the present study [22,23]. The HbA1c levels in the present study were also dependent on duration and frequency of exercises.

Many Patients with DM suffer from distressing complications of PN which may adversely affect their balance, however patients with DM without PN also show low medio-lateral stability. A spectrum of neural excitability abnormalities are found in patients suffering from DMand early axonal dysfunction may be present prior to development of neuropathy [6,24]. Therefore, intervention on balance training can prove beneficial to manage balance related complications in patients with DM. Results of present study suggest improvement in balance after core strengthening exercises. Pilates based core strengthening exercises resulted in increased leg endurance and added core strength in subjects with metabolic syndrome [25]. While in elderly females resulted in decrease in postural sway and improved gait parameter [26]. Pilates based mat exercise program was more effective in improving balance as compared to unstable support surface exercises [27]. Results of previous are in concordance with the result of present study that Pilates based core strengthening program improves static and dynamic balance, trunk muscle strength and stability, functional mobility in elderly population [28-31].

Recent studies have reported that patient may show altered gait before any symptom of PN appears [32]. Patients suffering from DM shows slower gait speed, wider step width, step to step variability, spends more time in stance and double support, which can be explained as protective mechanism to avoid falls [7,32-34]. It has been suggest that gait changes that occur in patients suffering from DM may be due to damage to Vestibular, somatic and automatic system which occurs as a result of micro circulation changes that are related to poor glycemic control and not due to peripheral pathology [31]. There is paucity of research on the efficacy of intervention strategies to improve gait parameters. Rosigtitazone, an insulin sensitizer can improve gait by reversing some circulatory impairments in diabetic patients. However, rosiglitazone was implicated for increased risk of myocardial infarction and death associated with cardiovascular incidents [33]. Surgical intervention includes lengthening of Tendo-Achillis, which results in short term deficit in peak plantar flexor torque but follow up for seven months showed improvement in ankle dorsi-flexion range of motion, walking ability among Diabetic patients [34]. Type 2 DMhave robust relationship with muscle power and velocity. Rhonda Orr et all 2006 in a study concluded that muscle contraction velocity was the single characteristic independently associated with poor balance and gait in patients with DM. In their study Tai Chi resulted in modest significant improvement in mobility. Therefore, improvement in muscle contraction velocity may be implicated to improvement in balance and gait parameters in patients with DM or in that case to any population suffering from balance deficits [35]. Core strength training results in a multitude of neural adaptations such as more efficient neural recruitment pattern, faster nervous system activation, improvement in synchronization of motor units, and lowering of neural inhibitory reflexes. A stable core, biomechanically, facilitates the transfer of torques and angular momentum between the lower and upper extremities during the task performance i.e it provides proximal stability for distal mobility. There is evidence that Trunk

muscle activations are organized well ahead in anticipation of movements or perturbation to balance in healthy adults [29]. These biomechanical and neurophysiological changes as a result of exercises can result in improvement of gait and balance parameters in patients suffering from diabetes. Therefore, Pilates exercises can be considered as safest intervention for improving gait as well as balance as compared to medical and surgical interventions. Pilates have significant effect on gait of patients with low back pain, multiple sclerosis but not much work could be found on efficacy of Pilates on gait specifically in patients with DM. Pilates based core strengthening has shown to improve gait. Newell 2012 showed the Pilates exercise have potential to improve gait and sway parameter [26] in older adults. Therefore, the results of the present study are in agreement with the results of previous studies that PBCS exercises have significant effect on gait [29,36-39].

Proprioceptors are responsible for position and movement sense and are very important in maintaining dynamic balance stability and decreasing falls in individuals. Research confirms that knee and ankle proprioception is reduced in diabetic patients. Which may be due to the effect of DM in nervous system including the nerves related to sensation of proprioception [40]. Diabetic neuropathy, a serious complication of DM has a prominent component of sensory neuropathy this may corporates the fact that the pathology of disease significantly affects various sensations including proprioception. Further sensory impairments are correlated with duration of DM [41]. Present study suggests that Pilates based core strengthening exercises resulted in decrease in joint reposition error. Various exercises like strength training, plyometric, balance exercises have shown to improve proprioception in osteoarthritis, ACL surgery and hypermobile joints [40-42]. Pilates based core strengthening exercises nay result in proprioceptive stimulation thus increasing joint position sense and decreasing the threshold of detecting joint movement this may be implicated to decrease in joint reposition error. The proprioception was measured at three angles – 15, 45 and 60 degrees. The angle 15 degree was selected Because this is the angle where proprioception activity is expected and 45 degree because at this angle there is no proprioceptive activity sent to central nervous system by anterior cruciate ligament [39]. Various studies on proprioceptive training have been carried out among patients with DM with PN. But to our knowledge no study has been found which shows effect of Pilates on the proprioception. Therefore, the present study suggests that Pilates can also be considered as one of the treatment options by practitioners and therapists to reduce proprioceptive errors. There is shortage of available literature on effects of exercises on proprioception in diabetic patient not suffering from PN thus, making it difficult to compare the results with other studies. This study has few limitations first that ratio between male and female was not balanced. Secondly duration of DM was not kept constant as patient with DM more than 3years were all included in study. Therefore, future studies need to be done keeping these factors in consideration.

In summary this may be the first trial to optimize duration and frequency as well as to evaluate efficacy of Pilates based core strengthening exercises on balance, gait, proprioception and HbA1c levels in patients with T2DM. Also, if Pilates based core strengthening exercises are given for 30 minutes and thrice weekly can show a significant improvement in these parameters. As due to paucity of literature

on this topic further studies need to be done to evaluate the results of present study.

Conclusion

Pilates based core strengthening exercises are beneficial for improving balance, gait, proprioception and HbA1c in patients with T2DM. Further 30 min of PBCS exercises thrice weekly are sufficient to improve of maintain these variables in patients suffering from DM.

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