

A Randomized Control Study on Effect of 12 Weeks Yoga Therapy in Type 2 Diabetes Mellitus Patients with Distal Polyneuropathy

Jasmin Parmar^a, Jaydeep D. Kagathara^b, Anand H. Mistry^c, Vilaschandra J. Patel^d

Abstract

Background: Yoga asana practices were documented for therapeutic use in diabetes mellitus Type 2 patients. The progress and complications of diabetes could be reduce by prescribing yoga therapy. **Material and Method:** The randomized control study of Type 2 Diabetes Mellitus patients with polyneuropathy was done by making study and control group. The index tests applied for analysis of distal polyneuropathy were Visual Pain Analogue Score, Diabetic Neuropathy Symptom (DNS) score and Diabetic Neuropathy Examination (DNE) scores. All patients' anthropometric, biochemical, cardiac and index test score data were collected before and after study in both groups. The study group had performed various yoga asanas and Bhastrika pranayama for 60 minutes every alternate day for 12 weeks. The control group was taking regular medication without any yoga therapy. Data were analysed in MedCalc Software by application of student t test. **Results:** The study group DNS & DNE Score before yoga 2.3 ± 1.0 and 3.2 ± 1.9 respectively were significantly improve after yoga intervention to 0.6 ± 1.1 and 1.9 ± 1.7 respectively ($p < 0.0001$). The pain score was also improved after yoga therapy in study group from 5.5 ± 1.7 to 1.4 ± 1.6 ($p < 0.05$). The control group, without yoga intervention did not show any significant change in index score after 12 weeks of regular medication. **Conclusions:** This study showed regular yoga therapy in diabetic prescription can improve pain and neuropathy condition in polyneuropathy patients of Type 2 Diabetes Mellitus.

Keywords: Yoga; Pranayama; Bhastrika; Distal Polyneuropathy; Diabetes Mellitus Type 2; Painful Neuropathy.

Introduction

The yoga word derived from Sanskrit word "yug", meaning was: referring to the discipline of aligning the mind and body for spiritual goals [1]. The yoga practice for healthy life style as alternative medicine was popular in India since long time. Now it was not uncommon that western countries, National Center for Complementary and Integrative Health (NCCIH), also giving identification to yoga as mind and body medicine [2]. The population doing yoga as health prospectus were 300 Million worldwide and out of them 36 Millions in USA [3,4]. The 25% regular yoga practitioners were use yoga asana as alternative medicine during disease condition for treatment [5]. The yoga practice was documented for improvement in audio visual reaction time in health individual [6]. The yoga was also found to promote Hand Grip Strength and Reaction Time during Examination

Stress [7], this parameter suggests yoga was promoting autonomic and somatic nervous system function in healthy individual. The prayanama, breathing yoga practice, were documented for helping respiratory function and cardiovascular parameter with improvement on nerve conduction [8].

India had 2nd largest diabetic population in the world [9]. The modified life style had put on extra stress on individual and they are prone for non communicable disease as diabetes mellitus Type 2 and its associated complications [10]. Presence of symptoms and sign of peripheral nerve dysfunction that occur in diabetes mellitus Type 2 without any other aetiology of peripheral neuropathy is called diabetic neuropathy [11]. Diabetic neuropathy was the most common complication leading to morbidity & mortality [12]. Prevalence of diabetic neuropathy was average 30% in Indian population and out of this 45% patient had symptom of painful neuropathy

Author's Affiliations: ^aAssistant Professor, Department of Physiology, M.P. Shah Medical College, Jamnagar, Gujarat 361008, India. ^bAssistant Professor, ^cAssociate Professor ^dProfessor and Head, Department of Physiology, GCS Medical College, Ahmedabad, Gujarat 380025, India.

Corresponding Author: Jaydeep D. Kagathara, Assistant Professor, Department of Physiology, GCS Medical College, Opp DRM Office, Nr Chamunda Bridge, Naroda Road, Ahmedabad, Gujarat 380025, India.
E-mail: j.kagathara@gmail.com

Received on: June 16, 2017

Accepted on: July 20, 2017

[13]. Distal polyneuropathy was the most common syndrome of diabetes and it was precursor of foot ulceration, 50 to 70% cases out of this polyneuropathy required amputation [14]. The proven disease modifying treatment approach had good glycemic control. Life style modification like diet therapy, aerobic exercise & yoga therapy could help for early glycemic control and less occurrence of morbid complication.

Present study has been done to evaluate effect of addition of 12 weeks yoga therapy to standard medical care in patients of type II DM with distal polyneuropathy on anthropometric parameters, clinical outcome & glycemic control. The screening of all OPD patients of known Diabetes Mellitus with Nerve Conduction Velocity (NCV) was not feasible to perform for analysis of Distal Polyneuropathy. Thus we used index test for analysis polyneuropathy by Diabetic Neuropathy Symptom (DNS) score [15] and Diabetic Neuropathy Examination (DNE) scores [16]. This index score system was fast and sensitive for diagnosis and follow up of diabetes polyneuropathy. The electrodiagnostic studies were not mandatory for clinical diagnosis of diabetic neuropathy [17].

Materials and Methods

The randomized controlled study was executed for 12 weeks, matching-group, pursue in known cases of diabetic distal polyneuropathy adults aged 40-65 years from 2013 to 2015.

The ethical clearance of study had obtained from Ethical Review Board, Gujarat Research and Medical Institute. Total 180 patients from diabetic clinic of medicine department of Rajasthan hospital were randomly selected for study. The application of exclusion, inclusion criteria as following and written consent 76 patients were totally agreed for study.

Inclusion Criteria

Type II Diabetes Mellitus patients with presence of one or more of following signs and symptoms in distal limbs.

- Numbness or feeling of walking on cotton wool.
- Tingling or Pins and needle sensations
- Cramping of calves and foot muscles
- Decrease or absence of ankle jerk
- Decrease or absence of vibration sense at great toe

Exclusion Criteria

- Disabling Polyneuropathy
- Evidence of target organ damage
- Alcoholic or drug induced neuropathy
- Physical condition hindering yoga practice
- Patient doing regular Yoga Exercise

Study Design

The written informed consent was provided by all patients after elucidating whole study design. Seventy six patients were randomly divided in two even groups, Study Group and Control Group. The baseline parameters, as following, were recorded on enrolment of patient in study.

Parameter Studied

- Anthropometry: Body Weight, Height, Waist Circumference
- Biochemical Profile: Fasting Blood Sugar, HbA_{1c}
- Cardiac Profile: Heart Rate, Mean Blood Pressure
- Diabetic Neuropathy Symptom (DNS) score [15] [Annexure – I], Diabetic Neuropathy Examination (DNE) scores [16] [Annexure – II] and Visual Pain Analogue Score [18]

The index test DNS score, DNE Score and Pain score were validated. The DNS score between 1to 4 confirm polyneuropathy and DNE score > 3 confirm clinically polyneuropathy in Type 2 Diabetes Mellitus patients.

The study groups were treated with 12 weeks yoga therapy and standard medication prescribed by physician, where the control group patients prescribed standard medication prescribed by physician and restriction of any yoga practice during study. Method of Yoga therapy session of one hour had (a) 5 minutes of preparatory practices, (b) 20 minutes static posture - Sarvangasana, Halasana, Ardhamatsyendrasana and Paschimottansana following (c) 20 minutes of Bhastrika breathing yoga: 20 cycles of Deep breathing, 20 cycles of normal breathing following 40 cycles of rapid breathing, and (d)15 minutes of Shavasana [19]. The yoga was done with at least two hour fasting before session. The yoga therapy session was done three times in a week for 12 weeks at Rajasthan Hospital at 5 pm to 6 pm. All patients of both groups baseline parameters were repeated after 12 weeks on follow up.

All data were collected and analysed by MedCalc Software (Version 17.6). The significance level was

set at 0.05 for comparison of mean value. The data was evaluated by student's t test.

Results

During 12 weeks on Yoga therapy 13 patients out of 38 from study group had cease for study. The 12 patients of control group not come up to appear for follow-up. The total study group sample size was remaining 25 and for matching control group only 22 patients were kept for data analysis. The patients' characteristic baseline data were mentioned in Table 1. The patient diabetic neuropathy were confirmed by Diabetic Neuropathy Symptom (DNS) score [Annexure – I] and Diabetic Neuropathy Examination (DNE) scores [Annexure – II] with blood profile of Glycated Hemoglobin. The distribution of age,

duration of diabetes mellitus and duration of polyneuropathy were comparable in both groups (Table 1).

The Diabetic Neuropathy Symptom (DNS) score (0.6±1.1) and Pain Score (1.4±1.6) after yoga intervention of study group had significant (p < 0.0001) improvement from yoga. The clinical Diabetic Neuropathy Examination (DNE) scores (1.9±1.7) was also improved significantly due to yoga in study group. Though biochemical parameter Fasting Blood Sugar and HbA1c did not affected significantly by yoga in this study. The cardiology parameters – Heart rate and Mean Blood Pressure were also remaining statistically not significant after yoga study (p > 0.05).

The control group had no significant improvement after only medication of 12 weeks in DNS score, Pain Score and DNE scores (p>0.05). The control group had consumed only standard medication for distal

Table 1: Patient Characteristic

Characteristic	Study Group	Control Group
Sample Size (n)	25	22
Gender (Male : Female)	11:14	10:12
Age (years) (Mean ± SD)	52.2 ± 9.3	52.4 ± 9.1
Duration of Type 2 DM (Mean ± SD)	6.3 ± 4.5	5.9 ± 4.2
Painful Neuropathy (n)	17	18
Polyneuropathy Duration Years (Mean ± SD)	5.5 ± 6.8	6.9 ± 5.9

Table 2: Comparison of mean value of Study group parameters before and after yoga intervention with standard medication.

Parameter	Study Group (n=25)		p value
	Baseline	After 12 weeks	
Body Weight (Kg)	60.3 ± 9.3	60.2 ± 9.5	0.97
Waist Circumference (cm)	88.6 ± 9.5	87.7 ± 9.3	0.73
Fasting Blood Glucose (mg/dl)	128.0 ± 50.8	127.0 ± 46.9	0.94
HbA1c (%)	7.5 ± 2.2	7.8 ± 1.4	0.567
DNS Score	2.3 ± 1.0	0.6 ± 1.1	< 0.0001*
Pain Score	5.5 ± 1.7	1.4 ± 1.6	< 0.0001*
DNE Score	3.2 ± 1.9	1.9 ± 1.7	0.014*
Heart Rate (bpm)	78.48 ± 15.93	74.88 ± 9.49	0.336
Mean Blood Pressure (mmHg)	94.87 ± 10.18	89.70 ± 9.61	0.071

(*p < 0.05, Significant difference in student's t test)

Table 3: Comparison of mean value of control group parameters before and after standard medication without yoga.

Parameter	Control Group (N=22)		P value
	Baseline	After 12 weeks	
Body Weight (Kg)	62.4 ± 10.4	62.7 ± 10.6	0.92
Waist Circumference (cm)	90.0 ± 8.5	90.7 ± 7.3	0.75
Fasting Blood Glucose (mg/dl)	137.5 ± 67.3	156.4 ± 85.0	0.387
HbA1c (%)	7.6 ± 2.6	8.9 ± 2.0	0.053
DNS Score	2.4 ± 0.9	2.1 ± 1.2	0.364
Pain Score	5.4 ± 1.8	5.1 ± 2.3	0.609
DNE Score	4.1 ± 1.9	4.3 ± 2.0	0.718
Heart Rate (bpm)	75.63 ± 12.04	74.58 ± 9.08	0.729
Mean Blood Pressure (mmHg)	93.96 ± 10.7	91.11 ± 7.09	0.272

Annexure - I: DNS score

1. Are you suffering of unsteadiness in walking?
Need for visual control, increase in the dark, walk like a drunk man, lack of contact with floor.
 2. Do you have a burning, aching pain or tenderness at your legs or feet?
Occurring at rest or at night, not related to exercise, exclude claudication intermittens.
 3. Do you have prickling sensations at your legs and feet?
Occurring at rest or at night, distal > proximal, stocking glove distribution
 4. Do you have places of numbness on your legs or feet?
Distal > proximal, stocking glove distribution
- The questions should be answered 'Yes' (positive: 1 point) if a symptom occurred more times a week during the last 2 weeks or 'No' (negative: no point) if it did not

Maximum Score = 4

1-4 = Polyneuropathy (PNP) Present

0 = Polyneuropathy (PNP) Present

Annexure - II: DNE scoring

Muscle strength:

1. Quadriceps femoris: extension of the knee
2. Tibialis anterior: dorsiflexion of the foot

Reflex:

3. Triceps surae (Ankle Jerk)

Sensation: index finger:

4. Sensitivity to pinpricks

Sensation: big toe:

5. Sensitivity to pinpricks,
6. Sensitivity to touch,
7. Vibration perception,
8. Sensitivity to joint position

Only the right leg and foot are tested.

Scoring from 0 to 2:

0 = Normal

1 = Mild/ moderate deficit; Muscle strength: Medical Research Council (MRC) scale 3-4; Reflex: decreased but present; Sensation: decreased but present

2 = severely disturbed/ absent; Muscle strength: MRC scale 0-2; Reflex: absent; Sensation: absent

Maximum score: 16 points

A score of > 3 indicates presence of polyneuropathy.

polyneuropathy, which had no statistically significant ($p > 0.05$) outcome. The poor glycemic control, HbA1c (8.9 ± 2.0) in control group was reflected after 12 weeks.

The anthropometric data body weight and waist

circumference had no significant difference in study ($p > 0.70$) and control ($p > 0.75$) group after 12 weeks regime. The cardiac parameters like mean blood pressure (MBP) and heart rate had also no significant ($p > 0.05$) change after 12 week yoga intervention or medication.

Discussion

The prevalence of type 2 Diabetes Mellitus (NIDDM) with irregular medication or late diagnosis leads to polyneuropathy in patients. The hyperglycaemia induces oxidative stress which leads to endonurial microangiopathy and hypoxia. These changes made genesis of pain, delay nerve conduction and demyelination to degeneration of nerve fibre [20]. The clinical diagnosis of diabetic polyneuropathy was easy and reliable on DNS and DNE score system [15,16]. The reliability of DNS and DNE score leads us to choose this test instead of Neuropathy Symptom Score (NSS) [15]. The San Luis Valley Diabetes Study proved inadequate glycaemic control and insulin insensitivity were autonomously promoting polyneuropathy in chronic NIDDM patients [21]. This study had found no improvement in chronic polyneuropathy and no control of blood sugar level with regular standard medication (Table 2).

Malhotra V (2002) had found yoga asanas improve previously altered nerve conduction velocity in Type 2 Diabetes Mellitus [22]. Malhotra V found that yoga asanas can improve glycemic control by regular yoga practice in diabetes mellitus type 2. The yoga will improve insulin sensitivity and glucose utilization by tissue which reduce extra glysemic load on tissue and reduce generation of free oxidative radicals [23], so neuritis induced polyneuropathy will be improved by yoga.

The six month yoga practice was documented by Chimkode SM (2015) for control of blood sugar level in type 2 Diabetes Mellitus [24], but this study was focused on effect of 12 weeks yoga training on diabetic polyneuropathy patients. The study group did not show any significant change in Blood glucose level or Glycated Hemoglobin (Table 2) after 12 weeks of yoga exercise.

Garfinkel MS (1998) documented role of yoga as alternative medicine to reduce pain due to Median nerve compression in Carpal Tunnel Syndrome [25]. Pain score in this study had also significant improvement after yoga intervention with medication in study group (Table 2) as compared to control group (Table 3). This study support Garfinkel MS (1998) results.

The painful polyneuropathy, developed in 45% patients of diabetes neuropathy, was limiting factor for daily activity of individual as reported by Bansal Dipika (2014) [13]. This morbid condition was corrected by yoga intervention with medication in diabetic patients (Table 2). The pain score was improved in study group from 5.5 ± 1.7 to 1.4 ± 1.6 as

per visual pain analogue scale ($p < 0.0001$). The control group did not show significant change in pain score with only medical intervention (Table 3). The long term use of medication may help in symptomatic relief from pain but if we add yoga therapy in same prescription, it will augment outcome of therapy.

Conclusion

This study had confirmed the role of yoga therapy in diabetes mellitus type 2 patients with distal systemic neuropathy. DNS Score, DNE Score and Pain Score reduce significantly in patients after 12 weeks yoga therapy. This suggests that prescription of yoga therapy as alternative medicine with regular medical therapy had benefit to patient health than only medical therapy.

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