

Moving Towards Universal Health Coverage of India and Management of Chronic Conditions: A Critical Review of Pre and Post Studies Related to Diabetes and Yoga Intervention

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Review Article

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Abstract

The diabetes disease burden in LMICs underlines the need for conducting more research directed towards addressing this disease among the countries that are most affected by it. Several interventional studies have empirically supported the role of yoga in the management of diabetes. We have specifically reviewed the pre and post-interventional studies among diabetics for scrutinizing the methodological rigour of such studies. A comprehensive search of research paper was done using sources such as PubMed, Google scholar and Svyasa digital database. The selected papers were screened by title and abstract while the full text was checked to decide the inclusion. This study review unpacks the methodological rigour of 7 eligible studies that navigate the topic of yoga and its relevance for diabetes under pre and post-study designs. This critical review underlines the methodological areas that need to be strengthened such as the need to standardize the yoga intervention by providing adequate justification for employing certain asanas and pranayama, the sequence in which it is administered, supervision throughout the intervention period etc. Such standardization will help generalize the findings of yoga and enhance its application as an effective intervention to mitigate the health problems resulting from diabetes.

Keywords: Yoga; Diabetes; Type 2 Diabetes; Pre And Post Interventions; Asana; Pranayama

Introduction

Universal health coverage is necessary to improve the quality health care services, mainly for economically

weaker section of the society and to strengthen access to health care for all. Currently, there is an increasing health care costs, resulted in growing inequality between the poor and rich population [1]. The economically weaker

sections of the society are paying high proportion of their income for the health care services. Thus, they are unable to cope with huge health care costs on several health care encounters [2]. India has been attempting to introduce universal health coverage policy to strengthen overall health care services. However, there are serious challenges being faced while addressing chronic medical conditions such as diabetes. The chronic conditions such as diabetes demands constant supervision of physician at regular interval and this can eventually lead to huge financial burden [1]. Furthermore, often the health insurance does not cover such chronic conditions such as diabetes. Moreover, there is dire need of preventive and rehabilitative interventions that are easy to administer and improve quality of life among ageing population in India. Yoga intervention promising to be very effective in preventing and improving quality of life especially in diabetes and other chronic medical conditions [3-5]. In order to achieve and sustain the universal health coverage, introduction of proven cost effective yoga interventions are timely and relevant.

However, there are multiple views shared by different researchers, concerning the yoga interventions for diabetes. While some groups strongly recommend the introduction of Yoga for management of yoga and few question the potential benefits of yoga in diabetes. Thus, in order to promote sustainable universal health coverage cost effective prevention measures such as yoga is crucial. This paper critically reviews the empirical findings related to diabetes.

The Context of Diabetes and Yoga

Diabetes mellitus (DM) is a leading cause of morbidity and mortality worldwide [6-10]. As a result, there are major global health challenges having clinical and economic ramification [4,6,11]. The prevalence of Type II Diabetes Mellitus (T2DM) on a global scale was estimated at 366 million in 2011 and projected to increase to 552 million by 2030 [12]. An estimated 1.5 million deaths were directly caused because of diabetes with more than 80 per cent of them in low- and middle-income (LMIC) countries [13]. The diabetes disease burden in LMICs underlines the need for conducting more research directed towards addressing this disease among the countries that are most affected by it. India is one such country with 60 million diabetic cases in the year 2011. This is projected to increase to 98 million by 2030 [12]. The management of DM requires multi-action drug regimen ranging from endogenous insulin secretion; overcoming resistance; maintaining optimal blood sugar level; restoring the liver glycogen level to producing an

antioxidant effect. The biomedical system does not offer a single drug regimen that is capable of a multi-action modality thus leaving the patient with no option but to consume a plethora of drugs [11].

Apart from a biomedical line of treatment, there are several alternative modalities used for management of diabetes. Lately, there is considerable empirical evidence supporting the effectiveness of complementary therapies in the management of diabetes [14-16]. The National Centre for Complementary and Alternative Medicine defines complementary and alternative medicine (CAM) as a group of varied medical and health care systems, practices and products that are not considered to be part of current conventional medicine. [17]. Few CAM system used for the management of diabetes are acupressure [17-22], acupuncture, massage therapy, hydrotherapy, biofeedback, aromatherapy, Chromotherapy, Tai-chi, Qigong Ayurveda Unani homeopathy [3-8,12,15,17-39].

Of particular interest in this regard is yoga, the benefits of which for the management of diabetes are well documented [3-5]. The physical manifestation of yoga interventions has demonstrated significant fall in the levels of fasting and postprandial blood glucose; haemoglobin A1c; total cholesterol and low-density lipoprotein oxidative stress; blood pressure, body weight to insulin sensitivity [11,12,25,26,37,40-43]. Yogic therapy is believed to rejuvenate the pancreas that is involved in the release of insulin [44]. Evidence also suggests the ability of yoga in addressing co-morbid conditions among diabetes patients such as hypertension, dyslipidemia, cardiovascular function [5,28,34,45]. Lowering of drug requirement is another gain attributed to yoga. Additionally, yoga seems to contribute to a better quality of life, self-efficacy and a cheerful mood that encourages individuals with diabetes to make healthier choices. [4,11,12,37,46,47].

The effectiveness of yoga in the management of diabetes has been researched by varied types of interventional studies. Out of this varied interventional studies, we specifically reviewed the pre and post-interventional studies among diabetics and analyze its outcomes. In order to make the review study more precise, we have excluded studies other than the pre and post research design.

Methodology

The search was limited to 1) English language articles, 2) those published between 1990 and May 2015, 3) those

including adults diagnosed with type 2 Diabetes Mellitus and 4) studies assessing the clinical, physical and psychological effects of yoga. We conducted a comprehensive search of the published literature using PubMed to identify studies focusing on the role of yoga in diabetes. Potentially eligible studies were screened by title and abstract while the full text was checked to decide the inclusion.

The combinations of keywords used for PubMed search were ["diabet*" or "diabet* mellitus" or "type* 2 diabet*" or type* II diabet*] and ["yoga*" or "pranayama*" or "yoga therap*" or "mind-body therap*" or "complementary therap*" or "asana*" or "meditat*" or "exercise*"] and ["pre-post stud*" or "pre-post test*" or "test*, pre-post" or "intervention stud*"].

Additional searches were performed using Google and Google Scholar. The SVYASA (Swami Vivekananda Yoga

Anusandhana Samsthana) database was specifically searched to identify studies of Indian origin. Cross-referencing was done from the reference lists of selected published studies which were screened for additional research papers.

- **Inclusion criteria:** The articles with pre and post-study designs, diagnosed with diabetes along yoga interventions were identified. Full texts were retrieved from Indian Institute of Public Health library source.
- **Exclusion criteria:** The articles which are not pre and post-study designs, no yoga interventions on diabetic cases.

Results

The literature search identified a total of six eligible studies with a pre-post design. The summary details of the pre-post studies included in our review are in Table 1.

S.no	Study title	Type of study	Author and yr of pub	Study objectives	Variable and technique	Intervention	Findings
1	A study of response pattern of non-insulin dependent diabetics to yoga therapy	Sample size: 104	Jain et al 1993 Diabetes Research and Clinical Practice 1993, 19	Evaluate the response pattern to 40 days yoga therapy programme on hospitalized patients of non-insulin dependent diabetes mellitus	Outcome measures- BMI, caloric intake, blood glucose level, glucose tolerance	Shatkriyas, asanas, pranayama	Yoga training resulted in a significant improvement in OGTT and a better blood glucose control, with a decrease in oral hypoglycemic agents There was no significant change in BMI
2	Effect of yoga asanas and pranayama in non-insulin dependent diabetes mellitus	Sample size: 39	Malhotra et al 2014 Indian Journal of Traditional knowledge 2004, 3:2	See the effect of 40 days of yoga asanas on biochemical profile	Outcome measures- blood glucose, lipid profile, glycosylated Hb	Surya namaskar, tadasana, trikonasana, sukhasana, padamasana, bhastrika pranayama, paschimotasana, ardhmatsyendrasana, vajrasana, pawanamuktasana, naukasana, bhujangasana, dhanurasana, shavasana	The statistically significant decrease in FBG, PPG and total cholesterol Lowering of dosage of antidiabetic drugs
3	Effect of yoga therapy on reaction time, biochemical parameters and wellness score of peri	Sample size: 15	Madanmohan et al 2012 Int J Yoga 2012, 5:1	Evaluate the effect of yoga therapy on reaction time, biochemical parameters and wellness score of peri and post-	Conducted as a part of a larger study on the effects of yoga therapy on DMParticipan	Surya namaskar, tadasana, parivrittatrikonasana, padahastasan, ardhkati-chakrasana, vakrasana, paschimotasan,	Significant decrease in fasting and postprandial blood glucose levels, TC, TG, LDL, VLDL Yoga training reduced auditory reaction time from the right as well as

	and post-menopausal diabetic patients			menopausal diabetic patients	ts: female patients aged 36 – 63 years receiving medical treatment for type 2 DM	pawanamuktasan, ardhhalasan, bhujangasan, dhanurasan, viparitakarani, chandranadipranayam, pranavpranayam, nadishuddhi, savitripranayam, kaya kriya, shavasan	left hand, the decrease is statistically significant for ART from the right hand
4	Effect of the holistic module of Yoga and Ayurvedic panchakarma in type 2 diabetes mellitus—A Pilot study	Sample size: 12	Vaibhavi et al 2013 Journal of Endocrine and Metabolic Diseases 2013, 3	Understand the concepts and assess the effect of a combination of Ayurvedic panchakarma and yoga in the management of diabetes	Outcome measures- FBS, PPBS, TC, TG, HbA1c, Oral hypoglycemic agents (OHA) drug score. Statistical technique: Paired t-test	Yoga protocol (Kriyas, pranayama, deep relaxation technique, cyclic meditation, bhajan, mind-sound-resonance technique, trataka) + Ayurveda protocol	Significant reduction in FBG, PPBG, HbA1c, TC and TG along with a reduction in oral hypoglycemic medication and balanced functioning of Agni, ama and kosta after 6 weeks of residential intervention using yoga and Ayurveda
5	Effect of Siddha samadhi yoga camps on health and nutritional status of obese and diabetic subjects	Sample size: 30	Sreedevi et al 2013 International Journal of Scientific and Research Publications 2013, 3:9	Examine the cumulative beneficial effects of Yoga, meditation and changed food habits designed by the Siddha Samadhi Yoga (SSY) camp on obese and non-Insulin-dependent diabetes mellitus (NIDDM) subjects	Outcome measures- postprandial blood glucose, serum cholesterol, serum iron haemoglobin levels, Dietary pattern and intake and personal well being	Siddha Samadhi yoga	A significant difference in pre and postprandial blood glucose level of obese subjects and NIDDM. Per cent reduction in BMI is 7.8 and 4.1 in obese and NIDDM subjects respectively. Serum cholesterol levels among NIDDM subjects reduced by 4.1% and by 3.4% in obese subjects. Serum Iron and haemoglobin levels improved by 1.2% and 14.7% respectively in obese subjects while by 5% and 7.5% respectively in NIDDM subjects.
6	Role of Yoga in Modifying Certain Cardiovascular Functions in Type 2 Diabetic Patients	Sample size: 24	Singh et al 2004 JAPI 2004; 52	To study the effect of 40 days of Yogic exercises on cardiac functions in Type 2 Diabetics and to study the effect of 40 days of Yogic exercises on blood glucose level, glycosylated	Outcome measures: Fasting and postprandial plasma glucose levels, Plasma glycosylated haemoglobin, BP, pulse rate	Surya Namaskar, tadasana, trikonasana, sukhasana, padmasana, bhastrika pranayama, paschimotanasana, ardhmatsyendrasana, Vajrayana, pawanamuktasana, naukasana, bhujangasana,	There was a statistically significant decrease in heart rate, decreases in systolic, and diastolic blood pressure, and corrected QT interval (QTc) after yoga asanas. There was a reduction in both systolic and diastolic blood pressure in hypertensive Type 2

				haemoglobin		dhanurasana, Shavasana	DM subjects after two to three weeks of Yoga practice. This was associated with significant reduction in drug require
7	An investigation into the acute and long-term effects of selected yogic postures on fasting and postprandial glycemia and insulinemia in healthy young subjects	Healthy volunteers	Manjunath et al 2005 Indian J Physiol Pharmacol 2005; 49 (3) : 319-324	to examine the hypothesis that yoga asanas help in the treatment of diabetes mellitus by releasing insulin from the pancreas	Outcome measures- Oral glucose tolerance, serum glucose, serum insulin. Statistical test: Student's t-test	Dhanurasana, Pranayama, Ardhamatsyendrasana, HalasanaVajrasana, Naukasana, Bhujangasana, Setubandhasana, Pavanmuktasana,tadasana	The serum glucose 0.5 h after an oral 75 g-glucose challenge in case of the four sets of asanas was not significantly different from the 0.5 h postprandial plasma glucose level (mean \pm SD, 140.1 \pm 36.7 mg/dL) in the standard OGTT done before the study. The serum insulin levels after the asanas were significantly ($P < 0.05$) lower than those before the asanas.

Table 1: Showing summary of pre and post studies on Yoga interventions in Diabetes Management.

In the following section, we critically review the research on yoga and diabetes with pre and post-study designs. The critical analysis of the article spans around sampling size, sampling procedure, participant recruitment, participant characteristics, assessing

parameter, nature of the intervention, the process of intervention, monitoring of intervention, complementary therapies along with yoga interventions and outcome of yoga intervention. See Table 2 for more details.

Article Number	Sample size adequate* (more than 100 participants)	sample size calculation	Mention of exclusion/inclusion criteria	Subjects diagnosed with diabetes	Yoga intervention	Mention of Sampling technique	Outcome measure clearly defined	Supervision of intervention for the entire study period	Mention of intervention duration	Description of yoga technique	Adequate justification for the intervention
Jain et al (1993)	√	x	x	√	√	x	√	√	√	√	x
Malhotra et al (2004)	x	x	√	√	√	x	√	√	√	√	x
Madanmohan et al (2012)	x	x	√	√	√	√	√	X	√	√	x
Vaibhavi et al (2013)	x	√	√	√	√	x	√	X	√	√	√
Sreedevi et al (2013)	x	x	x	√	√	x	√	X	x	x	x
Singh et al (2004)	x	x	√	√	√	x	√	√	√	√	x

Table 2: Matrix depicting the critical review of pre and post studies on Yoga interventions and Diabetes.

One pre-post study had a sizeable sample at 104 participants [17]. Five out of six studies were limited by a small sample, with 12-60 participants [3,4,18,23,24]. The exclusion and inclusion criteria of participant recruitment

were clearly defined in four studies [4,18,23,24]. Four out of six studies recruited outpatient participants, who were similar in characteristics i.e., 40-70 years, diabetic since 1-10 years, on oral hypoglycemic drugs and not suffering

from diabetes-associated complications [17,18,23,24]. One study recruited the patients from a yoga camp comprising of 30 obese and 30 type 2 diabetes patients [3]. Four out of six studies did not mention sample size calculation [3,17,18,23].

Five out of six studies failed to mention the sampling technique while one of them used accidental sampling [3,4,17,18,23,24]. Parameters such as Body Mass Index, lipid profile, blood glucose level, glucose tolerance, serum insulin and insulin sensitivity were used by several studies for assessing yoga interventions.

In all studies the outcome measures are well-defined and measures of variability presented [3,4,17,18,23,24]. Additionally, two studies have assessed VRT (visual reaction time) and ART (auditory reaction time) among pre and postmenopausal patients [3,23]. Three studies have assessed dietary pattern, intake and personal well-being among the DM2 patients. Three studies had personalized attention and supervision of a yoga expert during yoga sessions [17,18,24]. Four out of six studies supervised the intervention for the entire study duration (approx. 40 days.) [17,18,23,24]. One study supervised the intervention for the initial 6 weeks and relied on home-based therapy for the remaining 12 weeks [4]. Four out of six studies provided an adequate description of the intervention, specifically, asanas, sequence and time duration [17,18,23,24].

Two out of six studies used similar yoga interventions, namely, asanas and pranayama, such as Surya Namaskar, tadasana, trikonasana, sukhasana, padmasana, bhastrika pranayama, paschimotanasana, ardhmatsyendrasana, Vajrayana, pawanamuktasana, naukasana, bhujangasana, dhanurasana, Shavasana [18,24]. One study reported a different combination of asana and pranayama, such as Surya Namaskar, tadasana, parivrittatrikonasana, padahastasan, and Kati-chakras, vakrasan, paschimotasan, pawanamuktasan, ardhhalasan, bhujangasan, dhanurasanviparitakarani, chandranadipranayam, pranavpranayam, nadishuddhi, savitripranayam, kaya kriya [23]. The other three studies differed in terms of using shatkriyas (cleansing procedures) [17], mixed intervention of yoga and Ayurveda & Siddha Samadhi yoga [3,4]. All studies reported a significant decrease in fasting blood glucose with percentage reduction of 17.57% to 25.55% and a significant decrease in postprandial blood glucose with percentage reduction of 8.67% to 27.04%. Three out of six studies reported significant improvement in the lipid profile of the diabetes patients [3,4,23]. Only two out of

six studies reported a reduction in BMI through the changes were insignificant [3,17]. One study reported a significant reduction in blood pressure and heart rate [24].

Discussion

The seven studies with pre-post research design reported improvement in most of the biomarker parameters, such as postprandial blood glucose, lipid profile, BMI, blood pressure and heart rate [3,4,17,18,23-25]. Though limited by small sample size, these studies have well-defined inclusion and exclusion criteria with similar participant background [3,4,18,23,24]. However, the rigour of a study is determined by the methodology adopted which includes a detailed description of the sampling technique. Our observation of the pre-post studies reveal that four out of six studies did not elaborate the calculation sample size and five out of six studies failed to mention the sampling technique, while one of them used accidental sampling [3,4,17,18,23,24]. All pre-post studies have well-defined outcome variable and measure of variability. However, before we study the outcome, it is important to reflect on how the intervention has been executed. Here three points are important; 1) what intervention is selected 2) Based on what evidence has the intervention been selected 3) how has the intervention been executed. The Yoga interventions used by Pre-post studies is a mixed bag; Two used similar yoga intervention, namely, asanas and pranayama; one study used another combination of asana and pranayama; three studies used shatkriyas (cleansing procedures), mixed intervention of yoga and Ayurveda and Siddha Samadhi yoga [3,4,17,18,23,24]. This varied nature of yoga intervention used by pre-post studies might have worked for the patients as demonstrated based on the improvement of biomarkers. However, this variety of intervention is methodologically problematic. In the absence of standardization of yoga intervention, it is difficult to single out the effectiveness of each asana or pranayama on the outcome measures. Again, it is important to understand the justification based on which the yoga asana or pranayama have been chosen by researchers of the pre-post studies for the intervention. The justification for selecting specific yoga asana and pranayama was not given by five of the six studies [4,17,18,23,24]. Only one study justified the use of specific intervention based on their benefits in earlier work [3]. Specifically, argue the review of 16 relevant texts on Ayurveda and yoga to be the basis for intervention choice [4]. However, have not cited those 16 references and have not described the asanas and pranayama used by them.

Hence, in absence of justification for this yoga intervention, we question the rigour of this empirical research. Finally, the quality of intervention process in assessed by the supervision provided during the study period. Half the studies reported personalized attention and supervision of a yoga expert during yoga sessions [17,18,24]. The supervision of intervention for the entire study duration was done in Four out of six studies, for approximately 40 days. One study supervised the intervention for the initial 6 weeks and relied on home-based therapy for the remaining 12 weeks [4,17,18,23,24]. However, compliance to the practice of yoga as part of intervention assessed on the basis of self-reporting is likely to be subjective because it relies on participant's memory and interpretation.

Conclusion

This study review unpacks the methodological rigour of 7 eligible studies that navigate the topic of yoga and its relevance for diabetes under pre and post-study designs. This view on this topic reveals nuances of methodological evidence that has been generated in last twenty-five years. This critical review also underlines the methodological areas that need to be strengthened in future research on this topic. There are several valuable pre-post studies assessing the relevance of yoga for management of diabetes. However, these studies need to standardize the yoga intervention by providing adequate justification for employing certain asanas and pranayama, the sequence in which it is administered, lack of supervision throughout the intervention period etc.

Contributions

First and second authors have searched articles, all the three authors have written the first draft, the third author has critically reviewed the final draft.

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