Research

Feasibility of Establishing a Comprehensive Yoga Program and its Dose-Effect Relationship on Cardiovascular Risk Factors and Wellness Parameters: A Pilot Study

Kavitha M. Chinnaiyan, MD, FACC, Ann M. DePetris, RN, MSA, Judith A. Boura, BS, Korana Stakich-Alpirez, BS, Scott S, Billecke, PhD
William Beaumont Hospitals, Royal Oak, MI

Correspondence: kchinnaiyan@beaumont.edu

Abstract

Background: We sought to study the feasibility of establishing a comprehensive, mostly self-directed yoga program in a hospital and its dose-effect relationship on cardiovascular risk factors and quality of life (QoL) measures over six months.
Methods: Yoga-based techniques (Advanced Yoga Practices; AYP; advancedyogapractices.com) were taught in 12 biweekly group sessions and self-directed practice at home was emphasized. Cardiovascular risk factors were elucidated by interview and review of medical history. Quality of life (QoL) outcomes included the SF-36, the Cohen Perceived Stress Scale (CPSS), and the Hospital Anxiety and Depression Scale (HADS). Risk factors and QoL measures were compared in participants at baseline and six months, as well as between those practicing ≥ 7 times versus < 7 times per week.
Results: A total of 22 individuals (19 women, mean age 59 ± 8.7 years) completed the study. At six months, changes were noted in the Mental Component Scale (MCS) of the SF-36 (p=0.0004) and the CPSS (p = 0.022). A greater improvement in CPSS was noted in those practicing ≥ 7 times versus < 7 times a week (p=0.045). No changes were noted in cardiovascular risk factors.
Conclusions: The prescription of a self-directed yoga program was feasible in a hospital setting and resulted in improvement in QoL measures at six months. Practicing more than seven times per week correlated with greater improvement in the perception of stress. Thus, at least a once-daily dose of AYP techniques for a significant improvement in perceived stress is an appropriate dose to employ and study in hospital settings.

Introduction

Yoga is an ancient Eastern Indian discipline that has evolved and expanded into several medical applications over the last three decades (Jayasinghe, 2004; Nayak & Shankar, 2004; Yogendra et al., 2004). Traditional teachings of yoga are based on mindfulness and body awareness with several complementary techniques such as meditation, postures and physical exercises, breath regulation (pranayama), and deep relaxation playing important roles in achieving overall wellbeing, a sense of connectedness, improved health, and positive change in other related parameters (Nayak & Shankar, 2004). Research studies have shown that yoga has a favorable impact on the progression of coronary artery disease (CAD) as well as on related conventional risk factors such as hypertension, diabetes, and dyslipidemia (Innes, Bourguignon, & Taylor, 2005; Jayasinghe, 2004).

There is growing evidence that CAD is precipitated and exacerbated by stress, anxiety, anger, depression, and hostility (Bunker et al., 2003; Denollet, Vaes, & Brutsaert, 2000; Todaro, Shen, Niaura, Spiro, & Ward, 2003). With its simultaneous impact on mind and body, yoga may result in measurable improvements in physical conditioning as well as enhanced mind-body awareness, resulting in diminished psychophysiological stress and enhanced mood, wellbeing, and quality of life (Ornish et al., 1983; Yogendra et al., 2004). However, the benefit of yoga is largely proportional to compliance, which is dependent upon the motivation of individual practitioners. Thus, although multiple studies have demonstrated the benefits of yoga for modification of CAD (Lakkireddy et al., 2012; Siu, Yu, Benzie, & Woo, 2015; Yadav, Singh, Singh, & Pai, 2015), it has not been consistently reproducible in larger trials (Brook, et al.). Although many motivated individuals practice yoga, the feasibility of introducing and sustaining such a program in a patient population and fostering ongoing self-directed

practice between scheduled group sessions is potentially challenging. Additionally, the correlation between practice intensity and health benefits, if any, is not well described.

The purpose of this research was to study the feasibility of establishing a comprehensive, mostly self-directed yoga program in a hospital and its dose-effect relationship on cardiovascular risk factors and quality of life (QoL) measures over six months.

Methods

Objectives

The primary objective of the study was to evaluate the feasibility of establishing a self-directed yoga program in a hospital setting. The secondary objective was to evaluate the dose-effect correlation between yoga practice and cardiovascular risk factors and QoL measures.

Study Population

Participants were recruited via referrals from outpatient clinics and hospital-wide advertising. Inclusion criteria were age 18 years or older and willingness to participate in all group sessions and to practice at home as instructed (preferably twice daily, or at a minimum, once daily). Exclusion criteria were inability to participate in group sessions and inability to comprehend instructions, as stated by potential participants during the screening process. No participant was excluded due to pre-existing medical conditions, including CAD, because the objectives were to evaluate adherence to the program and document a dose-effect relationship rather than cardiac events. The study was approved by the Institutional Review Board and all participants provided informed consent. At the time of enrollment, prospective participants were assured that they could drop out of the study without repercussions and yet could continue to participate in the program if they wished. A detailed medical history as well as baseline laboratory panels (blood cholesterol, blood sugars, hemoglobin A1c [HbA1C], c-reactive protein) and blood pressures (both arms) were obtained.

Yoga Intervention

All participants were strongly advised to attend all group meetings, which occurred on a biweekly basis for a total of 12 sessions, where the principal investigator (KC, a certified yoga instructor) provided all instructions and evaluated each patient individually for suitability of yoga postures. Postures were modified to accommodate any recent cardiac events and/or physical limitations. All yogic practices were derived from the Advanced Yoga Practices (AYP) methods (www.aypsite.com) and were taught in a stepwise fashion. Deep meditation was introduced first, with the addition of a new technique at every fourth session: pranayama (alternate nostril breathing), yoga postures, and finally, samyama (an advanced yoga tool to receive deeper knowledge of qualities of an object). These methods were developed by an anonymous American spiritual scientist (Yogani), with emphasis on self-directed practice for spiritual awareness and overall wellbeing. These techniques were developed over his four decades of practice and teaching. Participants of the program were strongly encouraged to practice twice daily as prescribed and to log their practice. The complete practice routine consisted of the following: yoga postures for 20–30 minutes, 5–10 minutes of pranayama (alternate nostril breathing), 15–20 minutes of deep meditation, 5 minutes of samyama, and 10 minutes of rest. All participants were given a DVD of the relevant yoga postures and audio-visual recordings of group sessions were encouraged for later perusal and assistance with practice. Deep meditation was emphasized to be the primary practice that would take precedence over other practices in the event of time constraints.

Quality of Life Questionnaires

All participants completed the following questionnaires at baseline and six months:

1. SF-36v2 Health Survey—The SF-36 is a generic health survey used across ages (18 and older), disease, and treatment groups and was developed during the Medical Outcomes Study (Ware & Sherbourne, 1992). It examines eight health concepts (physical functioning [PF], role-physical [RP], bodily pain [BP], general health [GH], vitality [VT], social functioning [SF], role-emotional [RE], and mental health [MH]) and results in two broad component scales: physical [PCS] and mental [MCS]. The eight health concepts are measured on a scale of 0 to 100. The concepts of PF, RP, BP, SF, and RE define health status as the absence of limitation or disability. The measures of GH, VT, and MH measure a wide range of negative and positive health states. For these scales, a score in the mid-range indicates no limitation or disability, and a score of 100 indicates favorable health states. The PCS and MCS have a mean score of 50 ± 10 in the general US population. This questionnaire has been validated for measuring heart-related quality of life (Morrin, Black, & Reid, 2000).

2. Cohen Perceived Stress Scale (CPSS)—The Perceived Stress Scale (CPSS) is used for measuring an individual's perception of the degree of stress caused by life situations. The questionnaire assesses the respondent's perception of how unpredictable or overwhelming they find their lives to be, along with questions relating to current levels of experienced stress (Cohen, Kamarck, & Mermelstein, 1983).

3. The Hospital Anxiety and Depression Scale (HADS)—The Hospital Anxiety and Depression Scale is a self-administered scale that assesses the contribution of mood disorders to underlying medical conditions. This scale has been validated when used in the community and in primary care medical practice (Snaith, 2003).

Follow-Up Data

Objective outcome measures including blood pressure, cholesterol, and other laboratory values were measured at baseline and at six months. Participants were surveyed on adherence to the practices as prescribed at every group session and by personal phone calls at six months.

Statistical Analysis

Sample size was chosen based on estimates of feasibility of recruiting the proposed number of patients over the study period. Since this was designed as a pilot and proof-of-concept study, no power analyses were performed. Paired *t*-tests or Wilcoxon sign tests were used to examine the differences from baseline to six months, dependent on the normality of the differences. In order to determine the potential relationship between frequency of practice and effects, we compared individuals that practiced more than once a day (> 7 days a week) to those that practiced once a day (7 days a week). This cut-off was chosen because, while the participants were instructed to practice twice a day, the investigators determined that an average of once-daily engagement in the practice was a reasonable expectation based on the variability of each individual's schedule. Categorical variables were examined using Pearson's Chi-square or Fisher's Exact tests (where expected frequency < 5) and are reported as counts and % frequencies. Continuous variables were examined using non-parametric Wilcoxon rank tests or t-tests, depending on the distribution of the data; these variables are reported as means ± SD or medians where appropriate. A p-value < 0.05 was considered statistically significant. All tests were two-sided.

Spearman correlations were performed to evaluate the relationship between the outcome measures and the intensity of practices. All statistical analyses were performed using SAS® software (Version 9.1.3, Service Park 4, Cary, NC).

Results

Study Group Characteristics

Of 35 individuals that entered the study and provided consent (32 women, 3 men), a total of 22 (19 women, mean age 59 ± 8.7 years) completed the study requirements (Figure 1). Of these, 6 (27.3%) had known history of CAD, 3 (13.6%) were diabetic, 9 (41%) were hypertensive, and

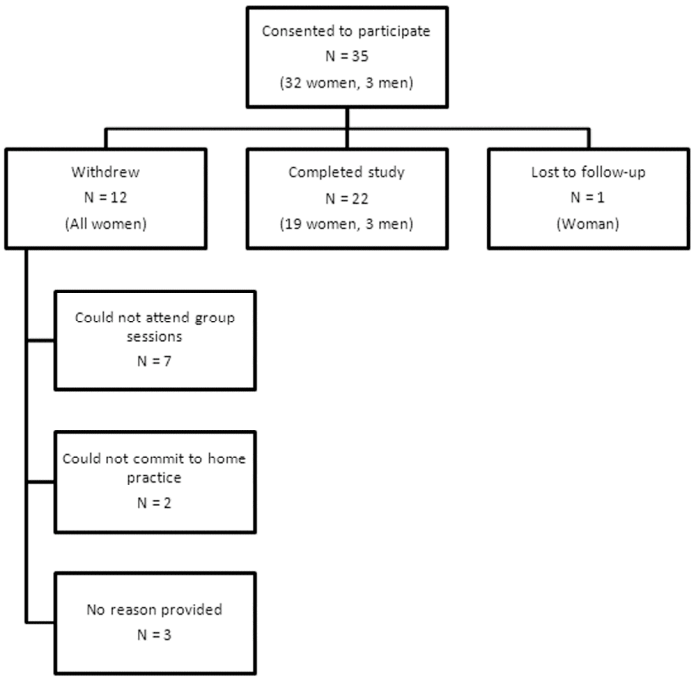

Figure 1. Flowchart of enrollment in the study.

10 (45.5%) were dyslipidemic; these conditions were based on patient-provided history as well as query of medical records (Table 1). Known CAD was defined as previous myocardial infarction or revascularization (percutaneous and/or surgical). Diabetes mellitus, hypertension, and dyslipidemia were determined by history and medical records either as diagnoses made by a physician and/or participants being on corresponding medications.

Age (years)	59 ± 8.7
Female (%)	19 (86.4%)
Race/Ethnicity	
Caucasian	15 (68.1%)
African American	5 (22.7%)
Other	2 (9%)
Known CAD	6 (27.3%)
Prior MI	1 (4.5%)
Prior PCI	2 (9.1%)
Prior CABG	0
Family history of premature CAD	12 (54.5%)
Diabetes mellitus	3 (13.6%)
Hypertension	9 (41%)
Hyperlipidemia	10 (45.5%)
Atrial fibrillation	1 (4.5%)
Valvular heart disease	2 (9.1%)

Table 1. Patient characteristics (n = 22).

CAD = Coronary artery disease, MI = Myocardial Infarction, PCI = Percutaneous Coronary Intervention, CABG = coronary artery bypass grafting

	Baseline Mean	6 Month Mean	*P*-value
Total Cholesterol	175.5 ± 31	170.3 ± 24	0.524
Triglycerides	116.9 ± 62	109.9 ± 56	0.603
High Density Lipoprotein	51.9 ± 12	52.4 ± 12	0.662
Low Density Lipoprotein	100.3 ± 28	96.1 ± 22	0.568
Systolic Blood Pressure	122.0 ± 11	121.6 ± 13	0.899
Diastolic Blood Pressure	75.4 ± 6.9	74.4 ± 8.9	0.503
Fasting Glucose	97.5 ± 24	97.7 ± 33	0.955
Hemoglobin A1C	5.62 ± 0.5	5.65 ± 0.5	0.450
SF-36 PCS	51.7 ± 9.2	47.2 ± 12.5	0.080
SF-36 MCS	43.6 ± 12.2	49.7 ± 11.2	0.0004
SF-36 Physical Functioning	52.4 ± 5.2	50.6 ± 9.4	0.52
SF-36 Role Physical	46.7 ± 12.2	46.7 ± 10.6	0.76
SF-36 Bodily Pain	50.8 ± 9.1	48.1 ± 10.5	0.26
SF-36 General Health	51.1 ± 6.9	50.2 ± 10.6	0.5
SF-36 Vitality	47.8 ± 9.3	49.1 ± 11.5	0.06
SF-36 Social Functioning	47.1 ± 9.7	51.2 ± 9.1	0.08
SF-36 Role Emotional	40.6 ± 13.8	47.9 ± 10.9	0.0007
SF-36 Mental Health	47.4 ± 9.6	49.2 ± 10.5	0.06
CPSS	17.7 ± 7.6	13.9 ± 7.2	0.022
HADS	5.5 ± 3.9	5.5 ± 5.2	0.69

Table 2. Changes from Baseline to 6 months.

SF-36 = Short Form (36) Health Survey version 2, PCS = Physical Component Score, MCS = Mental Component Score, PSS = Cohen Perceived Stress Scale, HADS = Hospital Anxiety and Depression Scale.

Adherence to Practices

Adherence to practice was emphasized at every group session and was determined by a directed interview at follow-up intervals, with evaluation of frequency of practice as well as adherence to the various components of the practice (i.e., asanas, pranayama, deep meditation, and samyama). At six months, adherence to the practice of various aspects of the program was as follows: deep meditation, 17 (77.3%); pranayama, 3 (13.6%); asanas, 2 (9%); and samyama, 2 (9%). By the end of the follow-up period, 10 (45.5%) participants practiced ≥ 7 times a week while 11 (50%) practiced < 7 times a week. One participant reported not practicing at all.

Six-Month Follow-up Data

At six months, no significant changes were noted in lipid profiles, blood glucose, HbA1C, and recorded blood pressure values (Table 2). Among the various components of the SF-36, a significant change was noted in the Mental Component Scale (MCS) (p = 0.0004), specifically within the Emotional Role Functioning category (p = 0.022) (Figure 1). A trend toward improvement was noted in the categories of Mental Health (p = 0.06), Vitality (p = 0.06), and Social Role Functioning (p = 0.08). A significant improvement was noted in CPSS (p = 0.022). No changes were noted in the HADS.

Correlation Between Questionnaire Scoring and Compliance

The results of the various quality of life questionnaire scores among those practicing 7 times versus < 7 times per week are presented in Table 3. Values represent a total change in score; an increase in score indicates improvement in SF-36 outcomes while a decrease in total score represents an improvement in the other measures. Thus, the only significant change in scores was noted in CPSS at six months, with a greater improvement in those practicing ≥ 7 times a week (median change in value of -8.5) compared to those practicing < 7 times a week (median change in value of 1.0), p = 0.045. No other statistically significant changes were noted.

	Practice Intensity < 7 days/week, *n* = 11	Practice Intensity ≥ 7 days/week, *n* = 10	*P*-value
SF-36 PCS, baseline to 6 months	-0.3 (-4.0, 0.4)	-3.3 (-8.6, 1.2)	0.66
SF-36 MCS, baseline to 6 months	5.8 (-0.6, 11.7)	5.9 (5.4, 17.9)0.53	
CPSS, baseline to 6 months	1.0 (-5.0, 4.0)	-8.5 (-10.5, -5.0)	0.045
HADS baseline to 6 months	1.0 (-1.0, 2.0)	0 (-4.0, 1.0)	0.22

Table 3. Comparison in outcomes based on practice intensity.

SF-36 = Short Form (36) Health Survey version 2, PCS = Physical Component Score, MCS = Mental Component Score, CPSS = Perceived Stress Scale, HADS = Hospital Anxiety and Depression Scale.

	***r*-value days/week (minutes/week)**	***P*-value days/week (minutes/week)**
Change in SF-36 PCS	-0.19 (-0.14)	0.49 (0.61)
Change in SF-36 MCS	0.36 (0.48)	0.17 (0.06)
Change in CPSS	-0.51 (-0.59)	0.036 (0.013)
Change in HADS	-0.41 (-0.69)	0.11 (0.002)

Table 4. Spearman Correlation Between Quality of Life Parameter and Practice Frequency and Intensity.

SF-36 = Short Form (36) Health Survey version 2, PCS = Physical Component Score, MCS = Mental Component Score, CPSS = Perceived Stress Scale, HADS = Hospital Anxiety and Depression Scale.

We analyzed the data further to evaluate potential linear correlations between the intensity of practice with improvements in outcomes (Table 4). There was a positive correlation noted between improvement in CPSS with greater number of days in the week of practices (R = 0.51, $p = 0.036$) as well as total number of minutes spent practicing each week (R = 0.59, $p = 0.013$). A similar positive correlation was noted with change in HADS with respect to the number of minutes of practice (R = 0.69, $p = 0.002$).

Discussion

The results of this pilot study demonstrate the feasibility of establishing a largely self-directed yoga program in a hospital setting and the effects of such an initiative on various aspects of overall health and wellbeing, including improvement in perceived stress and mood states over a follow-up period of six months. Additionally, increasing intensity of yoga practices correlated positively with improved mood and perception of stress. Although no changes were noted in cardiovascular risk factors, at least once-daily dose of AYP techniques did result in improvement of stress perception. Furthermore, since most participants practiced only once a day, further studies must be designed to study the effect of this dose over the long term on cardiovascular risk factors and outcomes.

While the study did not specifically recruit patients with known CAD, most patients had the risk factors of hypertension and hyperlipidemia. While the explicit causes of low-level functioning were not elicited, the results of this pilot study are concordant with previous studies demonstrating beneficial effects of yoga in stress reduction and mood enhancement, especially in individuals with lower levels of functioning (Michalsen, et al., 2005; Michalsen et al., 2012).

Optimal Dose of Practices for Sustained Quality of Life Benefit

With respect to quality of life, this study reveals that adoption of yogic practices resulted in significant improvement in perceived stress, mood states, and overall mental health within six months. Although these data suggest that greater intensity of practice is associated with slightly greater improvement in CPSS, the statistical difference between the two groups based on practice intensity (once vs. twice a day) was not strong. Thus, these preliminary data suggest that yoga practices performed at least once daily for six months can result in reducing stress perception.

The various techniques of AYP (and other yoga schools) are designed to transcend thought and to recognize awareness to be the ground of one's identity. It is important to note that many are drawn to yogic practices for this spiritual aspect, wishing to transcend suffering and to become established as this awareness. However, individuals participating in a medical setting are motivated to try yoga primarily for freedom from physical discomfort, lowering of medication dosages, and/or improvement of a disease state. Therefore, the motivation to keep up practices also differed between the two groups. In the present study, group sessions were only offered on a biweekly basis, a much lower frequency than in previous studies (Lakkireddy et al., 2013; Ornish, 1998; Ornish et al., 1983). This frequency was specifically chosen to evaluate the feasibility of offering yoga without the infrastructure of a formal program involving multiple instructors and personnel. Additionally, the program was structured to study the benefits, if any, of a largely self-directed practice along with regular instruction and inspiration. Dedicated programs requiring staffing and infrastructure may not be practical in an average hospital or healthcare system; the costs saved through thoughtful and comprehensive lifestyle changes may offset the costs of maintaining such a program.

Although a twice-daily practice routine was emphasized, most participants practiced less frequently. While the whole practice routine was taught and performed at every group session (deep meditation, pranayama, asanas, and samyama), the majority of the study group practiced only deep meditation at home, most likely due to the added time required for the other practices. As with other lifestyle changes adopting a consistent yoga practice requires motivation and dedication. Most participants voiced their inability to keep up the practices in the context of their already busy lives. Thus, it is unlikely that a prescription of self-directed twice-daily intensive yoga practices can be adhered to over the long term among patients interested in reduction of risk for cardiovascular disease. These results suggest that to implement a program for patients in a medical setting, the optimal dose for yogic practices to demonstrate an improvement in mood and perceived stress is at least once a day, 7 days a week. Future studies are needed to determine the optimal dose for improvement in cardiovascular risk factors and outcomes.

No changes in cardiovascular risk factors were noted in this pilot study. It is likely that improvements in risk factors such as hypertension, diabetes mellitus, and hyperlipidemia require greater intensity of practices and longer follow-up duration.

Importantly, such data are required to bring forth a paradigm shift in the approach to disease and wellness, wherein hospital systems may routinely support programs that address the relationship between the mind and body.

Limitations

Several limitations of this study must be considered. First, this was a pilot study with a very small sample size, which limits the conclusions that may be justifiably drawn. It is not possible to determine the extent to which these effects were the results of the participants' beliefs about the benefits of the yoga approach, social interactions within the group, or the setting of the program.(Moerman & Jonas, 2002) Second, the sample being comprised of self-referred individuals necessarily introduced selection bias. This bias was evident in that only those that were motivated to practice at home and attend the group sessions continued to participate while the rest withdrew from the study. Moreover, although the objective of the study was to evaluate the effects of a comprehensive AYP program, most participants adhered only to deep meditation; thus, incremental effects of pranayama, asana, and samyama practice could not be elucidated. Additionally, the principal investigator provided the intervention, which introduced the possibility of a lack of objectivity. Among those participants that discontinued practices, data regarding reasons for cessation were not collected. At the intensity described herein, these practices resulted in reduced perceived stress and improvements on the mental health components of the SF-36. Future long-term studies are required to examine their effectiveness in reducing cardiovascular risk, morbidity, and mortality.

Conclusions

The results of this pilot study suggest that AYP techniques result in improvement in perceived stress, mood states, and various mental/emotional components of overall health over six months. At least once-a-day self-directed yoga practice is an appropriate dose that can be employed and studied in hospital settings. Further studies are needed to examine the effects of this approach on cardiovascular risk factor modification.

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