

Effect of Yoga Lifestyle in Patients with Heart Failure: A Randomized Control Trial

Abstract

Background: In spite of significant advances in the management of heart failure (HF), morbidity and mortality remain high. Therefore, there is a need for additional strategies. We did a randomized clinical trial to study effect of yoga in patients with HF in terms of quality of life (QOL), left ventricle ejection fraction (LVEF), C-reactive protein (CRP), and NTproBNP. **Materials and Methods:** 60 patients with stable HF New York Heart Association Class II with LVEF 30%–40% were randomized into control group (CG) and yoga group (YG). CG received the guideline-based therapy and YG in addition practiced the yoga, one hour daily for 3 months. All patients were assessed for QOL, CRP, NTproBNP, and LVEF at baseline and after 3 months. **Results:** A significant difference was observed in all four parameters in the YG as compared to the CG ($P < 0.01$) after 12 weeks. QOL as assessed by Minnesota living with heart failure questionnaire score improved significantly in YG as compared to CG (10 V/s 14, $P < 0.001$). There was a significant improvement within YG in terms of LVEF (33.4–36.8, $P = 0.001$), and the percentage change in LVEF was significant between the groups (10% V/s 5%, $P = 0.001$). NTproBNP also significantly reduced by 69.8% from 755 to 220 Pmol/l in YG as compared to 39.3% in CG (679–406 Pmol/l). CRP decreased by 49.3% (5.36–2.73 mg/L) in YG and 35.8% (5.39–3.45 mg/L) in CG. **Conclusion:** The result of this pilot study suggests that addition of yoga to guideline-based therapy for HF patients significantly improves QOL, LVEF, and NTproBNP and reduces CRP level. Larger studies are needed to confirm these findings.

Keywords: Heart failure, left ventricle ejection fraction, NTproBNP, yoga

Introduction

Heart failure (HF) is a serious illness with profound clinical and economic impact. The incidence of HF appears to be rising.^[1,2] In India, the exact prevalence of HF is not known, but some studies estimate the prevalence to be 4.5 million patients with annual incidence of 491600–1.8 million.^[3] Although several advances have taken place in the pharmacological and device therapy of HF, morbidity and mortality remain extremely high. Compliance of guideline-based therapy is also poor, especially in developing countries probably because of high cost and side effects of drugs.^[4] Therefore, there is a need for additional cost-effective approaches; yoga may be one such alternative. Yoga is a holistic lifestyle consisting of asanas (postures), breathing exercises (pranayamas), and meditation (dhyana), leading to physical, mental, and spiritual well-being. Yoga has been

shown to have several beneficial effects on quality of life (QOL), stress control, and prevention of lifestyle diseases such as diabetes, hypertension, and cardiovascular diseases.^[5] However, there is a paucity of studies on effect of yoga in HF. Rational of using yoga in HF could be that yoga may correct the pathophysiological abnormalities of HF, namely, neurohormonal and autonomic nervous system disturbances, inflammation, and oxidative stress^[5,6] [Figure 1].

Materials and Methods

Study population

Patients of stable systolic HF.

Inclusion criteria

1. Patients of either sex, 18–65 years of age with New York Heart Association (class I-II)
2. Left ventricle ejection fraction (LVEF) (30%–40%) determined by transthoracic echocardiography

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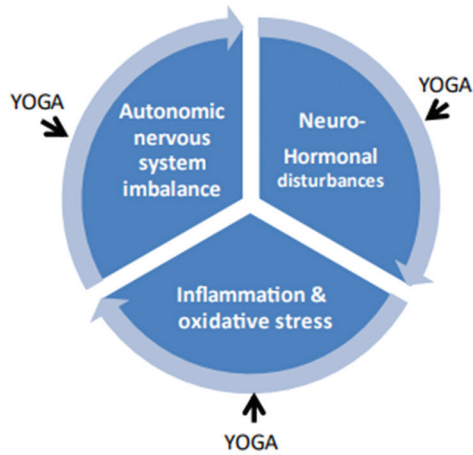


Figure 1: Yoga can affect the main pathophysiological abnormalities of heart failure

3. On stable medical therapy (no change in medical therapy for last 3 months).

Exclusion criteria

1. Suffering from acute coronary syndrome within the last 6 months
2. Patients with other diseases such as chronic obstructive airway disease, liver failure, kidney failure, and malignancy
3. Not able or willing to do yoga.

Study design

We conducted a randomized controlled trial (RCT). All the patients were randomized into two groups using computer method. A computer-generated sequence was prepared and stored in a sealed opaque envelope. The ethical approval was obtained by the ethics committee of our institution.

Methodology

Patients of HF were randomized into two groups: standard medical therapy versus standard medical therapy plus yoga lifestyle. All the patients underwent echocardiography, laboratory tests for biomarkers (NTproBNP and C-reactive protein [CRP]), and filled Minnesota questionnaire for QOL. All Patients were followed for 3 months and echocardiography, laboratory tests for biomarkers, and questionnaire were repeated.

Intervention

Patients randomized in the yoga group (YG) were given yoga training (asana + pranayama + meditation) by a trained yoga instructor for 1 week, after which patients were instructed to continue yoga daily for about 60 min at home. During each class, first 10 min were given to concentrate the thoughts to present-moment for inner-body awareness that was followed by 30 min of asanas and then 20 min of meditation and relaxation which includes breathing exercises (pranayama). The yoga protocol that was followed in the study has been reported earlier.^[7]

Safety measures

We assessed blood pressure, oxygen saturation, and other vital signs before and after each class. Assessment of HF symptoms or history of hospitalization was also analyzed.

Outcome measures

Echocardiography

All patients underwent transthoracic echocardiography. Ejection fraction (EF) was assessed and quantified by biplane method and the modified Simpson's rule and was recorded in percentage. Information regarding the structure and function of both the myocardium and the heart valves were noted including intracardiac pressure, flow, and systolic dysfunctions.

Quality of life assessment

QOL was assessed using Minnesota living with heart failure questionnaire (MLHFQ). This questionnaire is validated and reliable for the assessment of QOL in HF patients. It is composed of 21 questions, which include physical, emotional, and socioeconomic aspects of HF that adversely affects QOL of patients. The response for each question ranges from 0 (no effect on the patient's living) to 5 (item affected the patient's life very much during the past month). The MLHFQ score is obtained by summing the subject's responses. The total score for the 21 items can range from 0 to 105. A lower MLHFQ score indicates less effect of HF on a patient's QOL. A decrease of 5 points in total score after a specific intervention is regarded as clinically significant.^[8]

NTproBNP measurement

Blood was collected through venipuncture, allowed to clot. It was then centrifuged at 3000 RPM at 4°C for 10 min. Serum was separated and stored in a frozen state at -80°C. NTproBNP was measured using a commercially available enzyme-linked immunosorbent assay Kit. Normal range of NTproBNP is <125 pmol/l for <75 years of age and <450 pmol/l for ≥75 years of age.^[9]

C-reactive protein measurement technique

Serum was mixed with intralipid 20% in tris calcium buffer (pH 7.5) after 12 min of incubation at 37°C. CRP phospholipid complexes were measured by nephelometry. Normal range of CRP is under 5 mg/L.^[10]

In addition, all patients were advised to follow healthy lifestyle including a low-fat, low-salt diet, physical activity, stop tobacco, and alcohol use. Patients were asked to visit the yoga center and hospital every month for monitoring and evaluation. Those patients who could not come every month were followed telephonically. The compliance was recorded as reported by the patient and also their spouses.

Statistical methods

Means for the quantitative attributes were estimated along with the confidence interval. For quantitative data, parameters between groups were compared using Unpaired *t*-test and within groups across follow-ups using Paired *t*-test. For qualitative data, comparison between groups was done using Chi-square or Fisher’s exact test depending on whether all cell frequencies were >5 or not.

The baseline characteristics of the patients in both groups were similar [Table 1]. The mean age of the patients was 52 years in both groups and 80% were male and 20% were female in the YG and 70% male and 30% female in the control group (CG). Majority of patients had coronary artery disease (73.33% in YG and 66.67% in CG). The mean LVEF was 33.37 in YG and 33.33 in CG. QOL and biomarkers as well as hypertension and diabetes were not significantly different in both the groups.

Results

LVEF increased significantly by 10.46% (*P* < 0.01) in YG as compared to CG, which showed an insignificant increase of 5.54%. NTProBNP levels decreased significantly in both the groups though the decrease in YG was more (69.83%) as compared to CG (39.36%). The CRP also showed a significant decrease in both the groups (49.3 vs. 35.8).

There was a significant decrease in CRP by 49% in YG (pre: 5.36, post: 2.73, *P* < 0.001) and 36% in CG (pre: 5.39, post: 3.45) at the end of 12 weeks (*P* < 0.01). There was a significant decrease in MLHFQ score in YG from 22 to 10 as compared to CG (21–14) at the end of 12 weeks, suggesting a significant improvement in QOL by yoga lifestyle as compared to controls [Table 2].

Discussion

The present study suggests that 12 weeks of yogic lifestyle has several beneficial effects in patients of stable systolic HF when added to standard guideline-directed medical therapy. There is a significant improvement in LVEF, QOL (assessed by MLHFQ), and reduction in NTproBNP and inflammation as reflected by CRP level after 12 weeks of yogic exercises when compared to CG. There are very few reported studies which have assessed the effect of yoga in HF. Pullen *et al.* in a small randomized study in 19 patients studied the effect of yoga for 8 weeks. They reported an increase in the peak oxygen consumption and treadmill time in the YG as compared to controls. The improvement in peak oxygen consumption and treadmill time correlated with improved QOL score, which is consistent with our results. Actually, our study showed much more improvement in QOL as depicted by 54% decrease in MLHFQ as compared to 26% in their Pullen study.^[11] Another study by Krishna *et al.* also evaluated

Table 1: Baseline clinical characteristics

Total number of patients (n=60)	Yoga group (n=30)	Control group (n=30)
Age (years)	51.9±6.86	52.3±6.58
Men/women (%)	24/6 (80/20)	21/9 (70/30)
Coronary artery disease (%)	22 (73.33)	20 (66.67)
Diabetes mellitus	14 (46.67)	17 (56.67%)
Hypertension (%)	9 (30)	13 (43.33)
Nonischaemic cardiomyopathy (%)	8 (26.67)	10 (33.33)
LVEF (%)	33.37±2.76	33.33±2.54
NTProBNP (pmol/l)	755±272	679±225
CRP (mg/L)	5.36±1.2	5.39±2.02
Quality of life (MLHFQ score)	22.6±4.9	21.03±3.4

LVEF=Left ventricle ejection fraction, CRP=C-reactive protein, MLHFQ=Minnesota Living with Heart Failure Questionnaire, NTproBNP=N-terminal B natriuretic peptide

Table 2: Between groups, within group, mean percentage changes of NTproBNP, left ventricle ejection fraction, C-reactive protein and Minnesota Living with Heart Failure Questionnaire score

Parameter	Baseline	3 months follow up	Percentage change from baseline	<i>P</i> (intergroup)	
LVEF (%)	Yoga	33.37±2.76	36.77±2.99	10.46±7.62	0.001
	Control	33.33±2.54	35.17±2.82	5.54±4.11	
NTproBNP (Pmol/l)	Yoga	755.70±272.75	220.93±81.15	69.83±8.18	<0.001
	Control	679.17±225	406.83±154.86	39.36±13.51	
CRP (mg/L)	Yoga	5.36±1.24	2.73±1.23	49.34±18.89	0.007
	Control	5.39±2.02	3.45±1.74	35.81±22.43	
MLHFQ score	Yoga	22.67±4.97	10.17±2.56	54.22±11.52	<0.001
	Control	21.03±3.49	14.07±3.45	33.21±10.25	

LVEF=Left ventricle ejection fraction, CRP=C-reactive protein, MLHFQ=Minnesota Living with Heart Failure Questionnaire, NTproBNP=N-terminal B natriuretic peptide

the beneficial effects of yoga in 92 patients of HF. After 12 weeks, they observed an increase in LVEF from 38.9% to 53.0% in the YG and from 39.7 to 48.8 in the CG. Our results on the effect of EF are similar to this study though we have a lesser increase in EF in our patients from 33.4% to 36.8%. The reasons for these differences are not clear but may be because our patients had much lower baseline EF (33 vs. 39). Krishna *et al.* also showed a significant decrease in NTproBNP by 63.7%, which is consistent with our results where NTproBNP also decreased by 69.8%.^[12] Our study showing a 49.3% decrease in the inflammatory marker (CRP) is consistent with that of Pullen *et al.* who also observed a significant decrease in hsCRP in the YG at 8 weeks.

We observed that there were no cardiac side effects (shortness of breath, light-headedness, cardiac arrhythmias, or orthopedic injuries, during or in relation to the yoga sessions. Pullen *et al.* also reported that there were no adverse events in their study of 8 weeks of yoga in a chronic HF group.^[13] Our study assessed the safety of the subjects during the yoga training, and blood pressure and vital signs were checked before and after each yoga therapy session. In addition, there were no differences in soreness of the muscle before and after the yoga practice as well as any emergency department visits or hospitalization since the last yoga session.

Thus, all small studies suggest that 8–12 weeks of yoga lifestyle therapy in patients with stable HF leads to significant reduction in NTproBNP, CRP, and improvement in LVEF and QOL. It was easy to incorporate yoga in patients with HF even in those who were unable to do exercise. To the best of our knowledge, no other study has been done in patients who received guideline-based therapy in systolic HF.

The exact mechanisms of benefit of yoga are not clear from our study; however, the following mechanisms may be playing a role.

- a. Meta-analysis of 19 RCTs including 3647 patients of HF showed that exercise training in HF was related to less hospitalizations and mortality and improved QOL. Studies that examined the health-related aspects of yoga found that 8-week yoga training increased muscular strength by 31%, increased muscular endurance by 57%, increased flexibility by 88%, increased oxygen uptake by 7%, and reduced cardiovascular risk in healthy adults^[14]
- b. Improvement in the neurohumoral profile: HF is associated with increase in several neurohormones such as rennin angiotensin, cortisol, and catecholamines. Regular practice of yoga has been reported to decrease levels of catecholamines, cortisol, nitric oxide, arginine, vasopressin, aldosterone, and atrial natriuretic hormone through hypothalamic adrenal pituitary axis^[15]
- c. Improvement in the autonomic nervous system: HF has been shown to be associated with increased sympathetic

activity and yoga has been reported to increase parasympathetic and decrease sympathetic activity, thus balancing the autonomic nervous system. This can improve several symptoms in patients with HF^[5]

- d. Inflammation and oxidative stress: Several studies demonstrate that HF is associated with inflammation and oxidative stress as seen by elevated plasma levels of interleukin-6, CRP, and TNF alpha and leptin. Few studies suggest that yoga could reduce the inflammation and oxidative stress^[16]
- e. Control of stress and depression: Depression may be acting through several mechanisms including neuroendocrine, autonomic imbalance, and inflammation. Several meta-analyses suggest that yoga could be a useful modality to control stress and depression, but no studies are available in HF patients^[17-20]
- f. Yoga may have antiarrhythmic effects, which are beneficial in HF. A few studies have suggested that yoga may reduce episodes of atrial fibrillation, ventricular ectopics, and significant reduction in device-related ventricular events in patients with implanted cardiovascular defibrillator.^[21-23]

Limitations

There are several limitations of our study. It is a single-center study with small number of patients. Follow-up is short and clinical endpoints are not available. By the nature of intervention in YG, the study could not be blinded. Hence, a placebo effect of yoga cannot be excluded. The compliance of yoga was not supervised but informed by the patients and their spouses. However, in spite of these limitations, the variables in two groups appear significant and are likely to be clinically important.

Conclusion

Our small pilot randomized study demonstrates that 3-month practice of yoga with guideline-based medical therapy significantly improves QOL and LVEF and decreases NTproBNP and CRP in stable patients with HF. Yoga is a safe and cost-effective technique, which can be easily incorporated in patients with HF without any side effects. Further larger studies are needed to confirm the findings practices. However, yoga being simple, cost-effective, safe technique could be used as complimentary technique in patients with HF.

Ethical clearance

The study was approved by the institutional Ethics Committee of Sir Ganga Ram hospital, new Delhi Approval no. - EC/07/18/1390.

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Conflicts of interest

There are no conflicts of interest.

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