

**Assignment 2 RHSC 501**

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# Benefits and Safety of modified yoga program for heart failure patients

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## CLINICAL SCENARIO:

Patients with heart failure (HF) can have a reduced quality of life and physical function making it difficult to participate in physical activity programs (Bennett et al. 2003). Furthermore, lower exercise tolerance as measured by VO<sub>2</sub>max has been associated with poorer outcomes in heart failure patients (Mancini et al. 1991). Consequently, any intervention that can improve exercise tolerance may have clinical significance for HF patients.

Yoga practice seamlessly combines breathing techniques with flexibility and strength postures that are easily modified for participation by heart failure patients. This may be an ideal way for heart failure patients to increase their physical function. Clinical guidelines for yoga in this population do not exist despite a growing interest in participation.

## FOCUSED CLINICAL QUESTION:

Is yoga practice beneficial and safe for heart failure patients?

## SUMMARY of Search, 'Best' Evidence' Appraised, and Key Findings:

5 articles were found that met the inclusion/exclusion criteria.

- Two were Randomized Controlled Trial's (RCT's) with small sample sizes (Pullen et al, 2010, Pullen et al, 2008) .
- Two were Prospective Cohort studies (Bernardi, 2002; Howie-Esquivel, 2010).
- One was a Systematic Review that contained very limited review of heart failure as a subset of cardiovascular disease (Jayasinghe, 2004).

The benefits of yoga in heart failure population include increased physical

endurance, balance & strength. Quality of Life improvements were not consistent amongst the studies perhaps due to the short-term follow up of this measure.

Markers of inflammation in heart failure patients were improved in two of the studies (Pullen et al, 2010; Pullen et al, 2008) but it was noted that the relevance of this to long-term function remains to be established. More research with longer-term follow up and larger sample size are needed comparing yoga with traditional cardiac rehabilitation to delineate the benefits of yoga.

The article chosen to reflect Best Evidence was one of the RCT's that had the largest sample size and provided the best quality due to blinding of testers. This study was a follow up to one of the other studies done by the same researcher. It offered improvements in sample size and baseline homogeneity of randomized groups (Pullen et al, 2010).

### **CLINICAL BOTTOM LINE:**

Studies reviewed indicate that modified yoga consisting of breathing, relaxation and postures can be safely incorporated into practice by heart failure patients. The benefits of yoga in heart failure population include increased physical endurance, balance & strength.

**Limitation of this CAT:** This critically appraised paper (or topic) was prepared for a graduate course assignment and has /has not been peer-reviewed by one other independent person/an instructor.

### **SEARCH STRATEGY:**

#### **Terms used to guide Search Strategy:**

- **P**atient/Client Group: stable heart failure patients, congestive heart failure, diastolic heart failure, systolic heart failure
- **I**ntervention (or Assessment): yoga practice including breathing, relaxation and/or postures
- **C**omparison: none
- **O**utcome(s): physical function, exercise tolerance, flexibility, balance, strength & quality of life

<b>Databases and Sites Searched</b>	<b>Search Terms</b>	<b>Limits Used</b>
CINAHL (1982-present)  MEDLINE (Ovid SP, combined file)  PUBMED (1947-present)  PEDro  Google Scholar	Heart failure, congestive heart failure, systolic heart failure, diastolic heart failure  AND  Yoga, yoga posture*, asana*  AND  Physical function, exercise tolerance, exercise endurance	English language NO limits for date

## **INCLUSION and EXCLUSION CRITERIA**

- Inclusion:
  - Studies involving systolic and/or diastolic heart failure patients.
    - New York Heart Association (NYHA) Class I-III
  - Studies involving yoga practice incorporating breathing, relaxation and/or postures.
  - Studies measuring outcomes related to heart function, quality of life, physical endurance, balance, flexibility, strength.
- Exclusion:
  - Patients hospitalized < 3months before study.
  - Patients with unstable angina or MI < 6 months before study.
  - Had severe co-morbidities that influenced life expectancy < 6 months.

## RESULTS OF SEARCH

Five relevant studies were located and categorised as shown in Table 1 (\*based on levels of evidence, Centre for Evidence Based Medicine, 1998)

**Table 1:** Summary of Study Designs of Articles Retrieved

Study Design/ Methodology of Articles Retrieved	Level*	Author (Year)
Randomized Controlled Trial	1b	Pullen et al (2010)
Randomized Controlled Trial	1b	Pullen et al (2008)
Prospective Cohort study	2b	Howie-Esquivel et al (2010)
Prospective cohort Study	2b	Bernardi et al(2002)
Systematic Review	1a	Jayasinghe (2004)

## BEST EVIDENCE

The following study/paper by Pullen et al. (2010) was identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting this study were:

- RCT is best evidence for researching an intervention/therapy like yoga
- Largest sample size
- Outcome measures reflected physical endurance
- Yoga intervention included breathing, relaxation and postures
- Testers were blinded to randomized group
- Systematic review was not chosen because it included a very limited review of heart failure as subset of cardiovascular disease.

## SUMMARY OF BEST EVIDENCE

There was much overlap in studies found using the above search terms and databases. Only 5 studies emerged as most relevant. Three of the studies defined modifications to traditional yoga similarly and were consistent in the dose of yoga (2X weekly/one hour sessions/6-8 weeks) making the comparison between studies more relevant.

Two were RCT's and two were cohort studies. One was a systematic review but had limited review of heart failure studies included. The RCT

of Pullen et al. (2010) was chosen for detailed appraisal as this provided the best evidence for the question posed; it was randomized and blinded to assessment, and had the largest sample.

**Table 2:** Description and appraisal of Randomized controlled trial by Pullen et al. (2010)

**Aim/Objective of the Study/Systematic Review:**

**Study Design:** The purpose of the study was to examine the effects of yoga on cardiovascular endurance (VO<sub>2</sub>peak), flexibility, quality of life, inflammatory markers in heart failure patients. Study design was a randomized controlled trial where 21 pts were randomized to yoga intervention group (YG) and 19 in control group (CG). Investigators responsible for pre and post assessment of outcomes were blinded to the treatment assignment giving improved quality to the study. Three from YG, 3 from the CG did not complete the study (85% follow up).

**Setting:** Testing, assessments: Grady Memorial Hospital in Atlanta, Georgia, USA.

Yoga class: Emory University's Vascular Laboratory, Atlanta, Georgia

**Participants:** N=40. Patients recruited prospectively from outpatient cardiology clinic at Grady Memorial Hospital.

They were predominantly from African American descent (2 yoga participants were not, one Asian female and one Caucasian male).

**Inclusion Criteria:** Systolic and diastolic heart failure, NYHA Class I-III, able to walk without assistance, stable medical therapy for HF >3 months before enrolment.

**Exclusion Criteria:** Life expectancy <6 months, unable to walk unassisted, pregnant or breast feeding, unable to attend yoga 2X week, addicted to alcohol or drugs.

Informed consents were obtained. Sample was randomized and research testers were blinded to randomization.

Demographics were comparable at baseline with two exceptions. There was a greater number of patients in YG with systolic dysfunction (17/18) compared to control group (13/16). When left ventricular ejection fraction (LVEF) was compared in only the systolic dysfunction patients in both YG and control group, the mean LVEF was lower in the control group suggesting that the systolic dysfunction patients in the control group were sicker than in the yoga group. This may bias results as response to yoga may vary depending on pathophysiology of heart failure (diastolic vs. systolic). Also the EC-SOD measured at baseline was statistically higher in the control group.

Three patients in each of the groups were lost to follow up and no reasons were given (85% follow up).

## Intervention/Phenomenon Investigated

The yoga intervention was described in enough detail with references provided so that the intervention would be reproducible. Instructors of the Yoga sessions were a Registered Yoga teacher and ACSM certified exercise physiologist. Yoga classes were conducted 2X week, one hours for and 8-10 week period. Yoga group was asked to practice at home for a total of 3 sessions per week. Self reporting of home walking program for both groups and home yoga sessions in YG was done pre and post testing.

## Outcome Measures/Qualitative Methods

Research testers for pre and post testing were blinded to randomization adding to the quality of the study by limiting bias.

Primary outcome measured was:

- 1-min-per-stage ramp protocol treadmill test and peak VO<sub>2</sub> was estimated on basis of workload at peak exertion using ACSM's standard formula for treadmill walking.

Secondary outcomes measured were:

- Inflammatory markers-Interleukin-6(IL-6), C-reactive protein (CRP), and extracellular superoxide dismutase (EC-SOD)
- Flexibility- sit and reach test
- Quality of life- Minnesota Living with Heart Failure Questionnaire (MLWHFQ)-validated assessment of QoL for patients with Heart Failure.
- Other tests included EKG, blood pressure, waist circumference, BMI.

## Main Findings:

### Primary outcomes:

Exercise tolerance as measured by treadmill testing showed that the YG significantly increased both treadmill time ( $p=.002$ ) 95% CI provided and peak VO<sub>2</sub> ( $p=.003$ ) compared to control group. Standard deviations were provided both. Treadmill time increased by 22% in YG compared to 5% in CG. Peak VO<sub>2</sub> in CG values decreased from baseline testing whereas it increased significantly in YG. The mean increase for peak VO<sub>2</sub> was 2.8 (mL/kg/min), which is almost one MET level. This may be a clinically significant improvement for the de-conditioned heart failure patient in terms of their activity of daily living function.

### Secondary outcomes:

Inflammatory markers- There were statistically significant improvements in IL-6 (decreased), CRP(decreased), , and EC-SOD(increased), in yoga group compared to baseline ( $p=.001$ ) Further, there was significant differences for YG improvement compared to changes in CG. ( $p=.001$ ).

QoL- No significant changes were found in differences between YG and CG. There were significant changes in YG compared to baseline in 2 out of 3 of the MLWHFQ subscales (MLWHFQ-T-  $p=.02$ , MLWHFQ-P- $p=.034$ ).

Flexibility- Both a statistically significant change in YG compared to baseline ( $p=.002$ ) and change compared to CG ( $p=.012$ ) were demonstrated.

Other measures were not included in results.

There were no adverse outcomes noted in the YG and the yoga was well tolerated with 85% compliance for yoga sessions and testing appointments.

### **Original Authors' Conclusions**

"The effect of yoga on exercise capacity, inflammatory markers, and QoL in predominantly AA (African American) HF patients indicates that yoga may provide a beneficial adjunctive therapy and may be safely added to standard medical care under similar circumstances". ( Pullen et al, 2010, p. 656)

They point to the need for further larger and longer-term studies that control for physical activity to understand the role of yoga in treatment for heart failure patients.

### **Critical Appraisal:**

#### **Validity**

The methodology (RCT) was the most appropriate to study this intervention. Randomization and blinding of assessors to groups added to the quality/rigour of the study. African American patients were studied almost exclusively due to the cultural make up of the inner city hospital in Atlanta where selection of patients was done. This may impair the transferability of results to other settings where ethnicity is more variable. A confounding variable could be the physical activity that was done outside of the yoga intervention. Patients self reported their walking activity and yoga that they had done at home on pre and post assessments. Error may exist due to subjectivity of self-reporting. Authors do acknowledge this and suggest use of accelerometers or more objective measures for home program would be an improvement in study design.

The primary outcome of exercise tolerance as measured by standardized treadmill test ( $VO_2$ ) does relate to prognosis for heart failure patients so may provide clinical relevance of results.

Secondary outcomes may or may not provide clinical significance for heart failure patients. It is not known if improvement in flexibility and inflammatory markers translates into an improvement in quality of life in

heart failure patients. The authors do state that these endpoints were not the primary focus of the study.

### **Interpretation of Results**

The authors speculate that the improvements noted in exercise capacity in the yoga group may be explained by an attenuation of sympathetic activation leading to a decrease in filling pressures. It is also suggested that improvements may be due to a more effective extraction of oxygen in the stretched peripheral muscles. They state that if yoga improves dysfunction of autonomic nervous system and results in symptom relief then improvements in psychological well being and quality of life would follow. This proposed mechanism of improvement is speculative but follows sound reasoning and is reflective of some of the research cited in the article. The conclusions that were drawn were reflective of the results of this study. There were no adverse events in the modified yoga classes suggesting safety of this type of exercise for HF patients. Some of the conventional forms of aerobic exercise may be too physically demanding for this population and yoga may provide an alternative for activity. Although quality of life measures improved from baseline in the YG there were no differences in improvements between groups. A longer follow up may yield different results regarding quality of life measures. The study is limited by small sample size, short-term follow up and lack of ethnic diversity in population studied.

### **Summary/Conclusion:**

This study demonstrates that participation of African American heart failure patients in a modified yoga program is achievable and safe. Further, yoga intervention enhanced exercise tolerance in this population as compared to standard home walking program. Further research would be needed to establish transferability of results.

## **IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH**

- There is a paucity of research regarding yoga intervention in the heart failure population. Two of the five studies found were conducted by the same author, one building on the other with small improvements of sample size and improved baseline matching of YG and CG.
- It is interesting to note that in this study exercise tolerance improved with participation in a non-aerobic exercise program. Improvements in exercise capacity may be clinically important to heart failure patients in terms of quality of life. Guidelines support the use of symptom limited aerobic exercise in heart failure patients (Stone, Arthur & Suskin, 2009). Continued study of exercise tolerance and program of yoga

compared to aerobic conditioning alone may further define the effect of this therapy.

- Heart failure patients are often limited in their ability to participate in aerobic training due to de-conditioned state and symptoms like shortness of breath. Yoga may provide a bridge to help improve symptoms and tolerance so that aerobic exercise becomes less physically demanding and more achievable. Further research to measure increased participation in physical activity could include more objective monitoring with accelerometers or pedometers.
- As a chronic disease, heart failure has a course marked by gradual physical deterioration, exacerbations, frequent re-hospitalizations, therefore, longer-term studies measuring these outcomes in relation to yoga programs may yield important findings.

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## Addendum

In the search that I performed, I found a paucity of studies that deal with heart failure and yoga. The number of articles would likely expand if my search included a broader scope of heart disease. Heart failure is really just the end stage of many types of heart disease. Results from studies on patients from a broader spectrum of disorders may still be transferable to heart failure patients as they may share some of the same pathophysiology but just at a less advanced stage.

Additionally, by broadening the population studied I may have found studies including a sub group of heart failure patients that would not surface when just searching for this group. The systematic review that I reviewed was an example of this but mention of the sub group heart failure was too limited.

Another limitation could be that I limited my search to English only. I would suspect that South Indian researchers may have added to this area of study as yoga practice is more widespread and entrenched in this culture. I am not aware of databases focusing on South Indian culture but they may exist. Perhaps searching through particular Indian journals individually may have yielded more results.

Although I am most interested in the combination of breathing, relaxation and postures as components together in a yoga program, more articles may be revealed if searching for breathing and relaxation therapies independently. I could also include yoga styles like Iyengar, Bikram, Kundalini, Hatha although I suspect any of these styles would be associated with the word yoga and a broader search would still be better.

In this review I have found that there are several applicable findings for the clinical area I work in. Safety of modified yoga has been demonstrated in the studies that were reviewed and I feel more confident advising heart failure patients in the practice of yoga as an adjunct to more proven therapies. I have a good idea from the studies what modifications to traditional yoga postures are required to make the practice safe for this specific group. I would continue to recommend that aerobic and strength exercise based on current guidelines are the priority for efforts in cardiac rehabilitation for these patients. However, I would now suggest that yoga could be considered as a safe adjunct if desired and may provide benefit of increased endurance.

I look forward to following any future research that will hopefully provide information that is more transferable to the population that I see in our clinic. Studies focusing on long-term outcomes of quality of life, re-hospitalization and physical activity would be valuable additions to the research in this area.