Journal of Cardiovascular Diseases & Diagnosis

Rohit et al., J Cardiovasc Dis Diagn 2020, 8:2

Research Article Open Access

Impact of Change in Maximum Aerobic Capacity in Patients with Coronary Artery Disease: 36 Months Follow up

Rohit S[1], Rahul M[2*], Dawkhar S[3], Amin G[4] and Ghadigaokar P[5]

[1]*Madhavbaug Clinics and Hospitals, Mumbai, India*

[2]*Head of Research and Development, Madhavbaug Clinics and Hospitals, Mumbai, India*

[3]*Head of Patient Engagement Department, Madhavbaug Clinics and Hospitals, Mumbai, India*

[4]*M.D in Ayurveda, Head of Medical Department, Madhavbaug Clinics and Hospitals, Mumbai, India*

[5]*Head of Medical Operations, Madhavbaug Clinics and Hospitals, Mumbai, India*

[*]**Corresponding author:** Rahul M, Head of Research and Development, Madhavbaug Clinics and Hospitals, Mumbai, India, Tel: +919821014716; E-mail: drrahul@madhavbaug.org

Received: March 23, 2020; **Accepted:** April 01, 2020; **Published:** April 08, 2020

Abstract

Objective: There is a scarcity of literature that documents the results of evidence-based traditional/complementary medicine. Aim of this study was to analyze survival benefit in patients that were treated with ayurvedic therapy called Sampurna Hridaya Shuddhikaran (SHS). Secondary endpoints were to observe a change in demographics and VO2peak.

Methods: This retrospective study analyzed data of CAD patients who received and completed 12-week SHS. Patients whose data was available before and after intervention were enrolled in the study. These patients were then approached via a telephonic call at 36 months to know their survival status and other demographic and clinical parameters.

Results: CAD patients (N=154, males: 127(82)) with a mean age of 63.19 ± 9.91 and LVEF: 50.79 ± 12.57 were enrolled in the study. Peak oxygen uptake (VO2peak) which is an independent predictor of survival benefit was documented to be increased post 12-weeks SHS treatment. At 36 months the all-cause mortality was reported to be 13%. Increase in age, gender (male/female), previous MI history was found to be associated with the mortality rate.

Conclusion: Enhanced survival percentage was observed at 36 months as compared to the documented clinical trials. Therefore, Ayurvedic interventions need to be a strong candidate for better management of CAD and survival benefits.

Keywords: Coronary artery disease; Survival analysis; Ayurveda; VO2 peak

Introduction

Coronary artery disease (CAD) is a growing epidemic across the globe [1]. There is ever-evolving research to decode aetiology, diagnosis, treatment and management of CAD [2-6].

There has been a long debate about the benefit of early PCI or PCI in general or CABG for long term management and survival benefit of CAD patients [7]. Various clinical trials were strategically designed to answer the same. The landmark, COURAGE trial declared no additional benefit of an early PCI on long term survival of CAD patients [7]. ISCHEMIA trial was designed to answer a few questions raised after the results of the COURAGE trial were declared. However, the results of ISCHEMIA supported results of COURAGE although the inclusion and exclusion criteria were far more stringent than that of COURAGE. The ISCHEMIA trial further added that PCI should be used as a choice of treatment based on the patient-doctor discussion of the treatment effects and the patient's health expectations post treatment [8-12]. Other trials explored different aspects that affect survival benefits such as risk factors like diabetes (e.g.: BARI 2D trial), diagnostic tools (e.g.: FAME 2 trial) etc., [13]. As a result of which there is an addition or modification in the treatment/management of CAD guideline every five years or less.

The CAD management approach, medication and treatment administration that has stood the test of time is the one mentioned in ancient Indian scriptures under the umbrella term Ayurveda. The current study was designed with an aim to define efficacy or evidence of an Ayurveda based therapy in the management of CAD with a 36 month follow up.

The Ayurveda therapy is known as Sampurna Hrudaya Shudhikaran (SHS) [14,15] (Combination of Panchakarma and medicinal herb decoctions).

Methodology

Study design

Stable Ischemic Heart Disease patients with age >18 years and all gender were screened. This retrospective study was conducted from January 2017 to March 2017 in Maharashtra, India.

Inclusion Criteria: Known CAD patients who completed SHS therapy with or without a history of earlier MI, PTCA and CABG. All vessel diseases and NYHA class I-III was included. Patients registered for SHS treatment for more than 36 months but less than 40 months before data collection.

Exclusion Criteria: Patients that do not comply with inclusion criteria or those who could not complete therapy.

Treatment modality

SHS therapy (described in detail earlier [14,15]) was administered to the patients. SHS is a panchakarma based therapy administered to the patients in a span of 12 weeks. The data related to study parameters at baseline and at the end of 12 weeks was retrieved from the Institutional Clinic Management Software.

At the end of 36 months, a questionnaire (attached supplementary material (S1)) was used to collect information via a phone call.

Primary endpoints: Long term effect on all-cause mortality at 36 months post-intervention

Secondary endpoints: Effect on weight, blood pressure, heart rate and change in peak oxygen uptake (VO2peak).

Statistical Analysis

Considering the data distribution, continuous variables are represented as Mean ± SD or Median as appropriate. Percentages and frequencies are represented for categorical data. Survival and death percentages were estimated for the overall impact of treatment and effect of factors (past risk history, surgery history etc.) on survival and death probabilities of patients. Relative risk was calculated to see the effect of risk factors on the death rate. Microsoft Excel and R statistical computing (3.6.3) were used for analysing the current dataset.

Results

Baseline characteristics

Based on the study selection criteria, 173 patients that approached Madhavbaug Clinics and hospitals in Maharashtra region were administered treatment in the given inclusion period, 19 patients discontinued in the first 3 months. The remainder 154 were approached for a telephonic interview for primary data collection of the patient.

The patient population had a clinically significant cardiac risk-factor profile at baseline (61% of patients had hypertension, 39% had diabetes, 29% had a prior myocardial infarction, and 30% had undergone prior PCI or coronary artery bypass grafting [CABG] surgery). Demographic details are summarized in Table 1.

	N=154
Age, years Mean ± SD	63.19 ± 9.91
Gender Male, N (%)	127 (82)
Disease History	
HT	93 (61)
Diabetes	60 (39)
MI	44 (29)
Surgery History	
CABG	13(8)
PTCA	45(29)
NYHA Class	
I	26 (17)
II	22 (14)
III	47 (30)
IV	36 (23)
LVEF Mean ± SD	50.79 ± 12.57
Vessel Disease (VD) Status	
Single VD, N (%)	32 (20)
Double VD, N(%)t	33(21)
Triple VD, N (%)	4(2.6)

Note: NYHA: New York Heart Association; LVEF: Left ventricular ejection fraction

Table 1. Demographic and clinical details of the patient population.

Study outcomes

Cardiac Stress testing was done in all patients at baseline and after 12 weeks of treatment. Patients showed notable improvement in VO2peak levels and in resting blood pressure (Table 2).

	Baseline	Post-treatment value	Significance
Body Mass Index	25.12 ± 3.60	24.46 ± 4.51	0.021
Weight	65.90 ± 10.43	64.91 ± 9.93	0.02
Cardiac parameters			
Resting Heart Rate	76.03 ± 13.79	75.74 ± 9.81	0.79
Maximum Heart Rate	119.72 ± 21.30	121.01 ± 10.05	0.47
Resting SBP	129.86 ± 21.32	122.96 ± 15.19	0.0001
Resting DBP	80.76 ± 9.84	77.01 ± 7.53	0.0001
Maximum SBP	157.16 ± 23.62	154.85 ± 15.39	0.22
Maximum DBP	85.77 ± 11.37	84.52 ± 9.44	0.42
VO2peak	15.57 ± 7.54	23.01 ± 9.60	0.0001

Note: SBP: Systolic blood pressure; DBP: diastolic blood pressure; VO2peak: Peak oxygen uptake

Table 2. Treatment effect on baseline characteristics.

Follow up

The follow-up duration for the study was 36 months. The all-cause mortality at the end of 36 months was 13%. The subgroup analysis showed that the surgery history, MI, risk factor positive patients i.e. DM and HTN did affect the survival rate. Age more than 64 and females showed to have more death rates in the current patient population (Table 3).

Subgroup	All patients*
No. of deaths/total no. of patients (%)	
All-cause mortality	20/154 (13)
Surgery history	
PTCA	2/45 (4)
CABG	0/13 (0)
Diabetes	
Yes	12/60 (20)
No	9/94 (10)
Hypertension	
Yes	15/95 (16)
No	6/59 (10)
Myocardial Infarction	
Yes	9/43 (21)
No	12/111 (11)
Age ≥ 64 years	
Yes	18/82 (22)
No	3/72 (4)
Gender	
Male	17/127 (13)
Female	4/27 (15)
Δ Resting heart rate ≥ 0	
Yes	11/89 (12)
No	10/65 (15)
Δ Maximum heart rate ≥ 1	
Yes	14/94 (15)
No	7/60 (12)
↓ Weight >1 kg	
Yes	8/73 (11)
No	13/81 (16)
↓ Body Mass Index >0.35	
Yes	10/77 (13)
No	11/77 (14)
↓ Resting SBP >10	
Yes	11/51 (22)
No	10/103 (10)
Δ Resting DBP ≥ 0	
Yes	8/84 (10)
No	13/70 (19)
Baseline VO2 peak ≥ 16.78	
Yes	10/78 (13)
No	11/76 (14)
Latest VO2 peak ≥ 22.9	
Yes	13/112 (12)
No	8/42 (19)

PTCA: Percutaneous transluminal coronary angioplasty; CABG: Coronary artery bypass grafting; SBP: Systolic blood pressure; DBP: diastolic blood pressure; VO2peak: Peak oxygen uptake

Table 3. Hazard rate among subgroups.

Discussion

In this study, we observed the effect of SHS therapy in patients with CAD as an add-on to standard care or treatment. Primary analysis showed13% all-cause mortality at the end of the 36 months follow up.

While earlier trials such as COURAGE trial reported all-cause mortality at the median follow up of 4.6 years between PCI+OMT group versus the OMT alone group to be 19.0 vs 18.5% of patients; hazard ratio [HR]: 1.05; 95% CI: 0.87-1.27; p=0.62. Additionally, the low-risk SHID patient population enrolled in the ISCHEMIA trial showed cardiac catheterization, PCI vs. MT was associated with reduced 4-year rates of death or MI (16.5% vs. 21.2%; adjusted HR: 1.49; 95% CI: 1.16 to 1.93) [7-13]. Our study shows the lowest mortality in comparison to the above-stated trials and thereby we postulate that this high survival percentage would be attributed to the add-on SHS therapy.

Further, the sub-group analyses helped us identify patients that may be at high risk vs. those with a long-term survival benefit. The subgroup analysis also pinpoints that the median value of VO2 peak increased from baseline to post-treatment (~17 to 23) and this positive change is also translated into the survival rate post-treatment (the patient group with ≥ 23 had 12% deaths and other with ≤23 had 19% deaths).VO2 peak is considered as Independent predictor of long term survival in CHD. Therefore, an increase in VO2 peak ≥ 23 was seen to reduce the risk of death by 5% (RR: 1.25, CI: 0.417-3.794). However, the history of prior MI increases death rate by 11% (RRMI/no MI: 0.363, CI: 0.168-0.787).

Observational data from various registries, numerous clinical trials and meta-analysis are been done to identify the patient sub-group that might have a long-term survival benefit with or without current treatment modalities namely PCI/CABG or both. Additionally, the time of treatment administration, majorly an early PCI is studied in detail to offer the best of care to patients with CAD. But often with varying limitations and mixed patient population the results are not comparable and hence no one answer can be derived from the plethora of literature that is being produced around this topic [12-16].

Limitations and Conclusion

We, therefore, set out to offer an additional solution of an optional add on therapy that holistically helps patient treatment. But this pilot study has its limitation such as the number of sample size, single ethnic group and follow-up of 36 months only. However, through this study, we are trying to document the evidence of complementary medicine and thereby re-introduce traditional therapy that might have promise in the long run.

Funding

Vaidya Sane Ayurved Lab PVT LTD.

Conflicts of Interest

Authors have no conflict of interest to declare.

Acknowledgments

The authors thank Poonam Pawar for writing assistance and editorial support for this manuscript.

References

1. Gaziano TA, Bitton A, Anand S, Abrahams-Gessel S, Murphy A (2010) Growing epidemic of coronary heart disease in low-and middle-income countries. Curr Prob Cardiology 35: 72-115.
2. Nag T, Ghosh A (2013) Cardiovascular disease risk factors in Asian Indian population: A systematic review. J Cardiovasc. Dis. Res 4: 222-228.
3. Hajar R (2017) Risk factors for coronary artery disease: Historical perspectives. Heart views: The official journal of the Gulf Heart Association 18: 109.
4. Fridman D, Makaryus AN, Makaryus JN, Bhanvadia A, Qaja E, et al. (2015) Diabetes 2015 and Coronary Artery Disease-Pathophysiologic Insights and Therapeutic Implications. InCoronary Artery Disease-Assessment, Surgery, Prevention. IntechOpen.
5. Kandaswamy E, Zuo L (2018) Recent advances in treatment of coronary artery disease: Role of science and technology. Int J Mol Sci 19: 424.
6. Garcia M, Mulvagh SL, Bairey Merz CN, Buring JE, Manson JE (2016) Cardiovascular disease in women: Clinical perspectives. Circulation Res 118: 1273-1293.
7. Boden WE (2019) Interpreting the Results of the COURAGE Trial: A Non-Interventionalist Perspective. Rev Cardiovasc Med 10: 34-44.
8. Xie JX, Winchester DE, Phillips LM, Hachamovitch R, Berman DS, et al. (2017) The elusive role of myocardial perfusion imaging in stable ischemic heart disease: Is ISCHEMIA the answer?. J Nucl. Cardiol 24: 1610-1618.
9. P. D. J. Cohen, "ISCHEMIA: Invasive Strategy No Better Than Meds for CV Events," TCTMD.com.
10. Coylewright M, Blumenthal RS, Post W (2008) Placing COURAGE in context: Review of the recent literature on managing stable coronary artery disease. InMayo Clinic Proceedings, Elsevier 83: 799-805.
11. Cheng-Torres KA, Desai KP, Sidhu MS, Maron DJ, Boden WE (2016) Conservative versus invasive stable ischemic heart disease management strategies: What do we plan to learn from the ISCHEMIA trial?. Future Cardiol 12: 35-44.
12. Boden WE, O'Rourke RA, Teo KK, COURAGE Trial Research Group (2007) Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med 356: 1503-1516.
13. Phillips LM, Hachamovitch R, Berman DS, Iskandrian AE, Min JK, et al. Lessons learned from MPI and physiologic testing in randomized trials of stable ischemic heart disease: COURAGE, BARI 2D, FAME, and ISCHEMIA. J Nucl Cardiol 20: 969-975.
14. Sane R, Hanchate M (2014) Effect of the Sampurna Hriday Shuddhikaran (SHS) model in heart failure patients in India: A prospective study. J Adv Med Med Res Title 564-571.
15. Sane RM, Hanchate MS. Sampurna Hriday Shuddhikaran: An Interventional Health Model to Improve Quality of Life in Chronic Heart Failure.
16. Habib RH, Dimitrova KR, Badour SA, Yammine MB, El-Hage-Sleiman AK, Hoffman DM, Geller CM, Schwann TA, Tranbaugh RF. CABG versus PCI: greater benefit in long-term outcomes with multiple arterial bypass grafting. J Am Coll Cardiol 66: 1417-1427.