Original Research Article

Impact of Ayurveda based Ischemia Reversal Program (IRP) and Polyherbal Medication on reduction of resting myocardial Ischemia within 4 weeks, studied with speckle tracking Global Longitudinal Strain imaging

ABSTRACT

Aims: To evaluate effect of an ayurvedic based ischemic reversal program (IRP) and a calorie controlled diet to treat myocardial ischemia in patients with known chronic heart disease CHD.

Study design: Single arm prospective study.

Place and Duration of Study: Madhavbaug clinic all over India, between June 2020 and August 2020.

Methodology: Patients with myocardial ischemia were screened using the 2D speckle tracking global longitudinal strain (GLS) echocardiography. The selected patients underwent a baseline investigation along with 6 minute walk test (6MWT) and assessment of the ejection fraction (EF), end diastolic volume (EDV), stroke volume and the LV mass. The study group were administered 14 IRP panchakarma (twice a day) for 7 days and followed a calorie controlled diet for 30 days. Post 30 days of treatment, the GLS score, 6MWT, EF, EDV, stroke volume and LV mass was measured and compared with the baseline results.

Results: On screening 67patients, 50 patients with a GLS score of >-16 were selected for the study. The study population consisted of 43 males aged 59.37 ± 10.45 years (mean± SD) and 7 females aged 63.14 ± 6.40 years. Post IRP treatment and calorie controlled diet, the GLS score and 6MWT result improved thus indicating the improvement in the functional capacity of the patients. The EF, EDV and stroke volume increased thus improving the cardiac output. Reduction in the LV mass was observed which indicates a reduction of the risk of cardiovascular events.

Conclusion: The IRP and calorie controlled diet helped to reduce the myocardial ischemic condition in the study population and the effect of the treatment was evaluated using the speckle tracking global longitudinal strain echocardiography.

Keywords: Myocardial ischemia, Global longitudinal strain, 6 minute walk test, ischemic reversal program, calorie controlled diet, cardiac output

1. INTRODUCTION

Ischemic heart disease (IHD) is characterized by the presence of angina symptoms. Myocardial ischemia results due the interaction between the myocardium and the coronary

vessels. It occurs when myocardial supply and demand of oxygen is not balanced.1 Presence of ischemic conditions is an indicator of a coronary artery disease (CAD) and it is therefore important to prevent ischemic events in CAD patients. The prognosis (Prognosis) of patients having Left Ventricular Diastole Dysfunction (LVDD) is worse due to IHD.2Statins have proved to reduce the ischemic events, 2 however the use of statins have adverse effect on the muscles causing stiffness and cramps thus, reducing the exercise capacity of the patient.

Functional capacity of the heart reduces in ischemic conditions. A 6 minute walk test (6MWT) helps to measure the functional capacity of the patients.4 Distance walked during 6MWT was indicative of the rates of heart failure and myocardial infarction with the former being inversely proportional to the latter. 6MWT is a better predictor of cardiovascular events and mortality as compared to traditional risk factors.5The heart rate and blood pressure should be monitored at the start and at the end of the test. The test can differentiate between mild to moderate to severe CAD.

The functional capacity of the heart is dependent on the ventricular function. Initially the left ventricular function (LVF) was evaluated by measuring the left ventricular ejection fraction (LVEF). Echocardiography was regarded as the best method for evaluating LVF. However in recent studies GLS has been proved to (be) better (to)diagnose acute coronary heart disease as compared to LVEF. The results obtained by LVEF is dependent on the experience of the analyst and therefore interpretation will vary. But in case of GLS the results obtained are fairly accurate irrespective of the experience of the analyst. Thus, GLS can predict the development of the cardiac disease better than LVEF.7,8Along with GLS, left ventricular mass (LVM), Ejection fraction (EF), end diastolic volume (EDV) and stroke volume can also help to predict adverse cardiovascular events.

The main focus of our (the present) study was to assess the effect of the IRP on the improvement of resting myocardial ischemia using 2D speckle tracking echocardiography to measure any change in GLS post 30 days of treatment.]

2. MATERIAL AND METHODS

2.1. STUDY DESIGN AND POPULATION

A retrospective clinical observational study was carried out on patients with a known case of IHD. These patients had approached the various branches of Madhavbaug clinic all over India, with a complaint (complain) of angina. The GLS score of all the patients was (were) obtained using 2D speckle tracking GLS echocardiography in order to select the study participants.

2.2. STUDY EVALUATION

After the patients were selected (After selection of the patients) for the study, their anthropometric measurements consisting of the weight, BMI and abdominal girth (ABG) was (were) measured. A blood test to measure the lipid profile, HbA1c and the ratio of the blood urea nitrogen (BUN)/serum creatinine was carried out as a part of the baseline investigation.

The primary endpoint of the study was considered as a change in the GLS score from the baseline. GLS at day 1 and day 30 of the treatment was measured using 2D speckle tracking echocardiography. For evaluating the secondary endpoints, the patients were studied using an echocardiogram to measure the left ventricular mass (LV mass), stroke volume (SV) end diastolic volume (EDV) and the left ventricular ejection fraction (LVEF). After the period of 30 days, the anthropometric measurements and the echocardiogram

was(were) performed to identify any changes (change) from the baseline results. A 6 minute walk test (6MWT) was also performed before and after the treatment to evaluate the functional capacity of the heart.

2.3. STUDY THERAPY

The patients under study were given a total of 14 panachkarma treatments twice a day for the period of 7 days. The panachkarma treatment consisted of 3 steps- Centripetal Oleation, Thermal vasodilation and per rectal herbal decoction administration details of which is mentioned in previous published papers.10 Centripetal 0oleation helps to improve cardiac output and vasodilation and reduces inflammation, thermal vasodilation causes the loss of excessive salts and water by sweating and per rectal herbal decoction administration reduces lipid, water overload and oxidative stress of the body. The patients were prescribed with Tab GHA 2tb twice a day (BD) before meal and ARJ Kadha 10 ml BD post meal for 30 days. They were also advised a calorie controlled diet for 30 days.

2.4. STATISTICAL ANALYSIS

The data obtained was analyzed using Anova single factor and the mean ±SD was calculated for all the parameters tested. A p-value of <0.05 was considered as significant. A paired two sample t-test was carried out in order to analyze the results for the GLS parameter.

3. RESULTS AND DISCUSSION

3.1. STUDY POPULATION

After screening 67 patients, 50 patients (86% male and 14% female) with a GLS score > -16 and who were ready to take treatment for 7 days with a follow up after 1 month were selected for the study. The males belonged to the age group 59.37±10.45 years (mean ± SD) and females belonged to the age group 63.14 ± 6.40 years. The patients with unstable angina, acute illness and a GLS score of <-16 were excluded from the study.

The study population had co-morbidities of which CAD, hypertension and diabetes mellitus was the major co-morbidity observed in the study population.

3.2. STUDY EVALUATION

3.2.1. Baseline investigations

The patients had to undergo a baseline investigation as shown in table 1, at day 1 of their inclusion in the study group. These test were performed to assess the overall health of the patients. The mean ± SD for each parameter was calculated. On comparing with the results of the study population with the reference range, all the parameters were within the desired range.

Table 1- Day 1 results of the baseline investigations carried on the study population.

Test	Day 1(mean ± SD)	Reference Range
Total protein	6.38 ± 1.55 g/dL	6.0 - 8.3 g/dL

BUN	16.50 ± 12.97 mg/dL	7 – 20 mg/dL
Serum creatinine	1.216 ± 0.54 mg/dL	0.7 – 1.2 mg/dL
BUN/Serum creatinine ratio	35.44 ± 32.24	10 - 20
Cholesterol	127.192 ± 30.86 mg/dL	<200 mg/dL
Triglycerides	129.868 ± 57.07 mg/dL	<150 mg/dL
HDL	43.114 ± 11.40 mg/dL	>40 mg/dL
LDL	58.162 ± 20.67 mg/dL	<100 mg/dL
LDL/HDL ratio	2.11 ± 2.10	<5.1
HbA1c	7.26 ± 1.97 %	6.5%

Index: BUN- Blood urea nitrogen; HDL- high density lipids; LDL- low density lipids

3.2.2. Anthropometric measurements

The IRP helped to reduce the weight (66.76 kgs ± 9.99to 62.98 kgs ± 8.75, p-value=0.05), ABG (94.96 cm ± 9.63 to 90.72 cm ± 8.47, p-value= 0.022791) and the BMI (24.85 kg/m2± 3.46 to 23.44 kg/m2± 3.05, p-value=0.035668) of the study population within 30 days of treatment. All the parameters were observed to be statistically significant.

3.2.3. Global Longitudinal strain (GLS)

GE Healthcare Vivid S6 Ultrasound System (Wauwatosa, USA), an echocardiography machine was used for the study according to American Society of Echocardiography guideline.11 The LV function was measured using EF and 2D speckle tracking to determine the global longitudinal strain. The test was carried out within the span of 24 hours before and after post-percutaneous coronary intervention (PCI) procedure. A total of 18 segments was used to calculate the LV global longitudinal peak strain average (GLPS-Avg). The vertical segments were basal, mid, and apical and horizontal segments were anterior, anteroseptal, inferoseptal, posterolateral, inferior, dan anterolateral. Apical long axis (APLAX) was used to view the anterior and inferior segments, Apical 4-chambers (4-Ch) was used to view anterolateral and inferoseptal segments and Apical 2-chambers (2-Ch) was used to view anteroseptal and posterolateral segments.

The primary endpoint of the study was considered as a change in the GLS from the baseline results. There was an improvement observed in the GLS score post 30 days of treatment. (Figure 1)

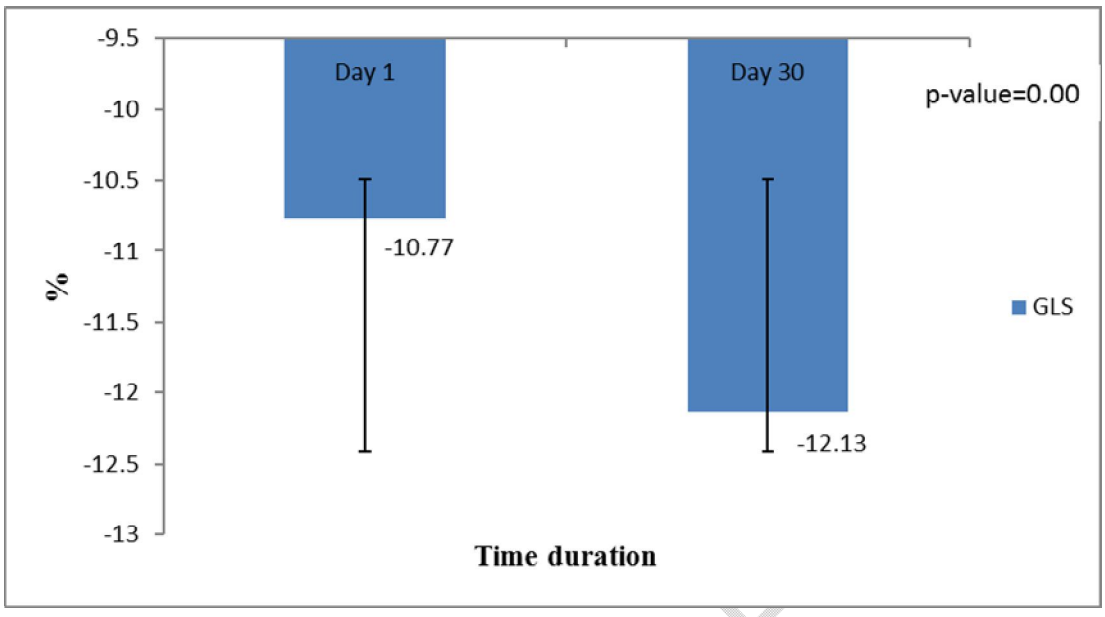

Figure 1- Comparison of GLS levels before and after 30 days of treatment.

3.2.4. 6 minute walk test (6MWT)

Out of the 50 study patients only20 patients carried out the 6 minute walk test. The rest of the patients showed low EF values and were not included in the test. It was observed that after the treatment, the mean distance covered increased by 29.27%. The heart rate and blood pressure was monitored before and after performing the test and the readings were within the desired range. (Figure 2 and Figure 3)

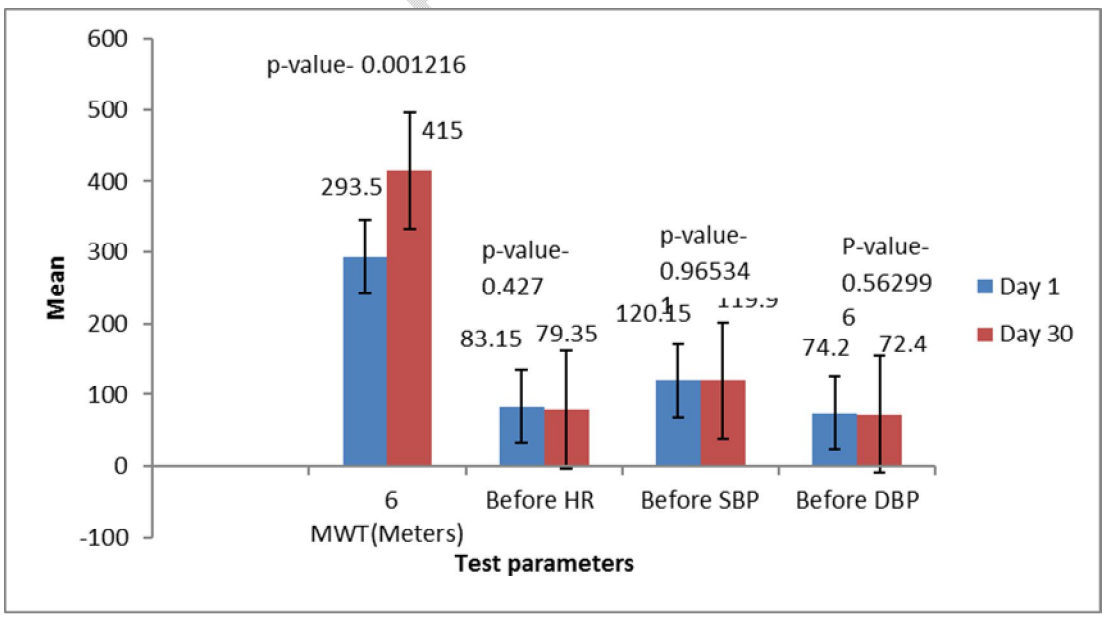

Figure 2: Comparison between 6 minute walk test (6MWT) before and after 30 days of treatment. During the test, heart rate (HR), Systolic blood pressure (SBP) and diastolic blood pressure (DBP) was noted and compared before the start of the 6MWT at day 1 and day 30 of the treatment. HR is measured in beats per minute, SBP and DBP is measured in mm of Hg.

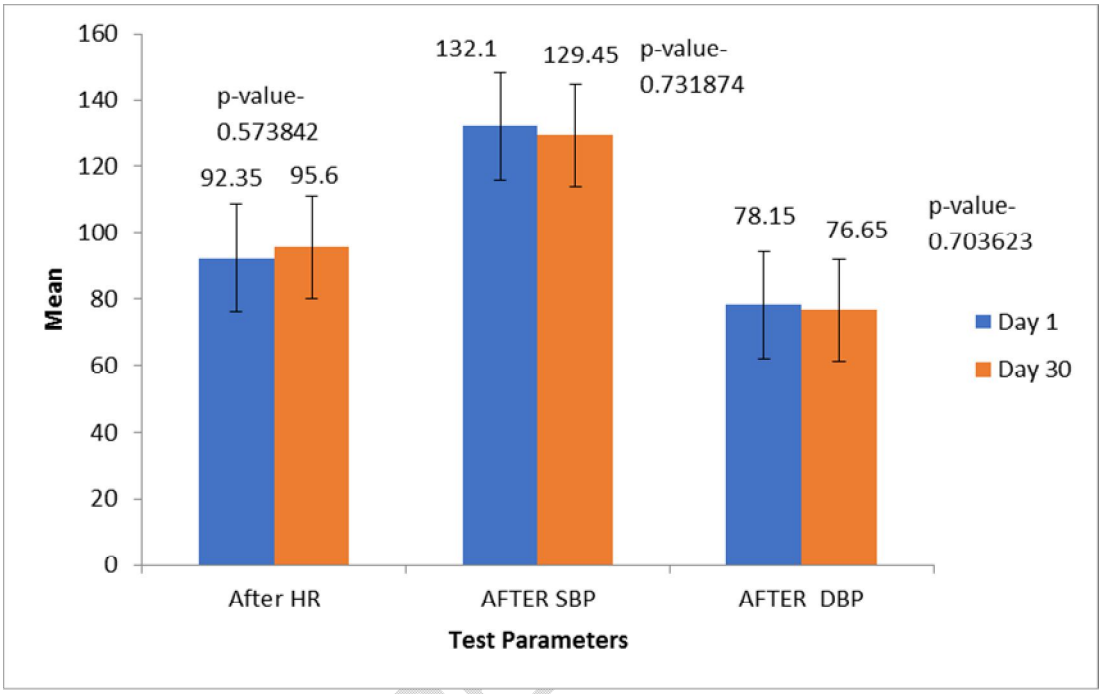

Figure 3: Comparison of the heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) after performing the 6MWT on day 1 and day 30 of the treatment.

HR is measured in beats per minute, SBP and DBP is measured in mm of Hg.

3.2.5. Echocardiogram test

The EF, EDV and stroke volume increased by after the treatment whereas the LV mass reduced details of which is seen in table 2.The EF improved post treatment, however did not reach the normal range. EDV and stroke volume improved and maintained in the normal range.

Table 2: Comparison of the echocardiogram test before and after the treatment.

Test	Day 1	Day 30	p-value
EF	43.6 ± 12.73 %	47.52 ± 11.46 %	0.112411

EDV	130.26 ± 59.22 ml	138.41 ± 49.26 ml	0.479834
Stroke volume	76.86 ± 47.64mL/beat	77.09 ± 43.02 mL/beat	0.981074
LV mass	114.38 ± 36.75 gms	113.88 ± 27.76 gms	0.942979

Index: EF- Ejection fraction, EDV- end diastole volume, LV mass- left ventricular mass

3.3 DISCUSSION

This study was carried out on 50 patients with a GLS score >-16% at baseline and stable angina. The study group consisted of 43 males aged 59.37 ± 10.45 years (mean± SD) and 7 females aged 63.14 ± 6.40 years. The selected patients underwent a baseline blood investigation for lipid levels and renal function which were within the reference range. After the day 1 investigations, the patients underwent 14 IRP panchakarma treatment (twice a day) for 7 days, followed by a calorie controlled diet for 30 days. The anthropometric parameters and GLS was measured at day1 and day 30 and the results were compared using Anova single factor statistical tool.

The IRP treatment was found to be beneficial in reducing the mean weight, ABG and BMI of the study population. Reduction in the BMI led to reducing (reduce) the metabolic burden on the body. As a result the load on the heart reduces thus reducing the ischemic conditions.10,12

GLS was considered as the primary endpoint of the study. The GLS is considered to be reduced mildly when the it falls between -15% and -12.5%, reduced moderately when it falls between -8.1% and -12.5% and reduced severely when it is below -8.0%.13 It was observed that though the mean value of the GLS score at the start and the end of the study period ranged between -8.1% to -12.5 % which denotes moderate reduction of systolic function, there is an improvement observed post 30 days of treatment and with longer treatment the GLS score may improve further.

The IRP improved the results of the 6MWT performed by 20 patients. The distance covered by the study group increased by 29.27%. No abnormal fluctuation was observed in the HR and BP after performing the test. Thus, the functional capacity of the patients improved post treatment.

A change in the EF, EDV, stroke volume and LV mass was considered as the secondary endpoints of the study. An increase in the EF, EDV and stroke volume was observed post treatment. The EF was below the normal range of 50-70% and may increase with further IRP treatment. The EDV and stroke volume though within the normal range at the start of the study, improved by the end of the 30 days period. Increased LV mass is related to diastolic dysfunction. A reduction in the mass will help to improve the diastole (diastolic) function. The treatment given helped to lower the mean LV mass of the study group thus improving the ischemic condition.14 Thus, along with improving the GLS score, the IRP treatment and calorie controlled diet helped to achieve an improvement in the EF, EDV, stroke volume and LV mass leading to the reduction in the risk of myocardial ischemia.

4. CONCLUSION

An improvement in the GLS score led to the improvement in the systolic function of the study population. GLS helps to better diagnose (diagnosis of) chronic heart disease as compare (compared) to LVEF. The myocardial ischemic condition reduced as a result of the IRP and

calorie controlled diet. The treatment also resulted in improving the cardiac output by reducing the LV mass and improving the EF, EDV and stroke volume. The improved 6MWT results proved that the treatment was beneficial in increasing the functional capacity of the patients under the study.

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