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The Impact of Ayurveda-based Ischemia Reversal Program (IRP) and Poly-herbal Medication on Reduction of Resting Myocardial Ischemia'

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aims: To evaluate the 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 Clinics throughout India, between June 2020 and August 2020.
Methodology: Patients with myocardial ischemia were screened using 2D speckle tracking global longitudinal strain (GLS) echocardiography. The selected patients underwent a baseline investigation along with a 6-minute walk test and assessment of the left ventricular ejection fraction, end diastolic volume (EDV), stroke volume and left ventricular 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, 6-minute walk test, left ventricular ejection fraction, EDV, stroke volume and left ventricular mass were measured and compared with the baseline results.
Results: On screening 67 patients, 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 and 7 females aged 63.14 ± 6.40 years. Post IRP treatment and calorie-controlled diet, the GLS score reduced from -10.77% to -12.13%. 6-minute walk test result improved thus indicating the improvement in the functional capacity of the patients. The left ventricular ejection fraction, EDV and stroke volume increased thus improving the cardiac output. Reduction in the left ventricular 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 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. Prognosis of patients having left ventricular diastole dysfunction (LVDD) is worse due to IHD [2]. Statins have proved to reduce the ischemic events [3], however, the use of statins have adverse effects 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 helps to measure the functional capacity of the patients [4]. Distance walked during the 6-minute walk test was indicative of the rates of heart failure and myocardial infarction with the former being inversely proportional to the latter. The 6-minute walk test is a better predictor of cardiovascular events and mortality as compared to traditional risk factors [5]. 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 [6].

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

Panchakarma therapy is an Ayurvedic procedure which boosts immunity, reduces stress, eliminates toxins from the body thereby providing maximum health benefit to the patient. The main focus of the present study was to assess 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.

2. MATERIALS AND METHODS

2.1 Study Design and Population

A retrospective clinical observational study was carried out on patients with known IHD. These patients had approached the various branches of Madhavbaug Clinics throughout India, with a complaint of angina. The GLS score of all the patients were obtained using 2D speckle tracking GLS echocardiography in order to select the study participants. The study inclusion was stable ischemic heart disease patients with GLS ≥15. The study exclusion was unstable angina, GLS ≤15, chronic IHD patients, acute coronary syndrome, and unwillingness to partake in the trial [9].

2.2 Study Evaluation

After selection of the patients for the study, anthropometric measurements consisting of the weight, body mass index and abdominal girth (ABG) were measured. A blood test to measure the lipid profile, glycated hemoglobin (HbA1c) and the ratio of the blood urea nitrogen/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 LVM, stroke volume, end diastolic volume (EDV) and the left ventricular ejection fraction. After the period of 30 days, the anthropometric measurements and the echocardiogram were performed to identify any change from the baseline results. A 6-minute walk test 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 *Panchakarma* treatments twice a day for the period of 7 days. The *Panchakarma* 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 oleation helps to improve cardiac output and vasodilation and reduces inflammation and 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. The daily calorie intake of the study patients was 1000cal/day.

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. Excel 2013 was used to analyze the data.

3. RESULTS

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 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 tests 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)
Total protein	6.38 ± 1.55 g/dL
BUN	16.50 ± 12.97 mg/dL
Serum creatinine	1.216 ± 0.54 mg/dL
BUN/Serum creatinine ratio	35.44 ± 32.24
Cholesterol	127.192 ± 30.86 mg/dL
Triglycerides	129.868 ± 57.07 mg/dL
HDL	43.114 ± 11.40 mg/dL
LDL	58.162 ± 20.67 mg/dL
LDL/HDL ratio	2.11 ± 2.10
HbA1c	7.26 ± 1.97 %

Index: BUN- Blood urea nitrogen; HDL- high density lipids; LDL- low density lipids; HbA1c - glycated hemoglobin

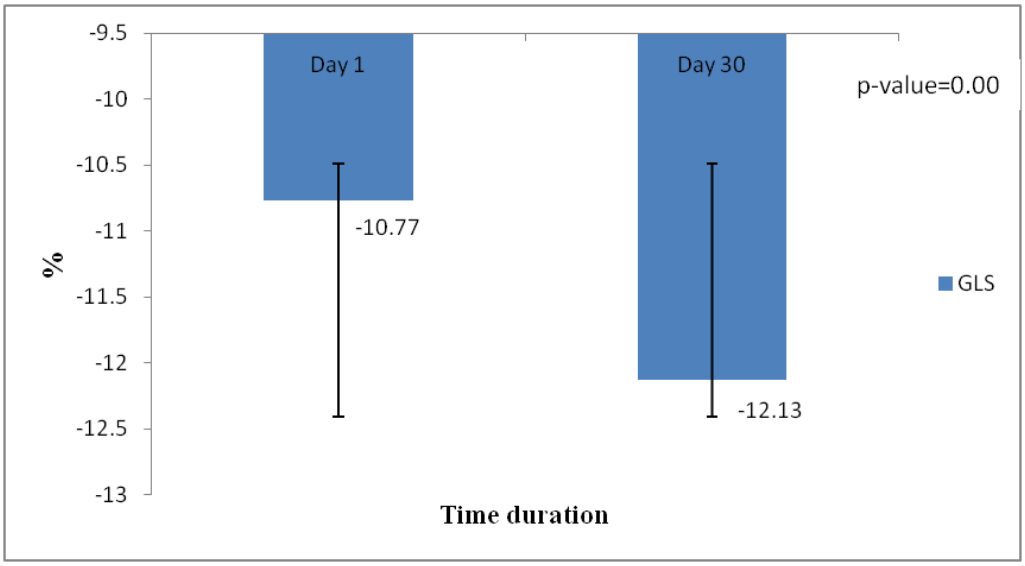

Fig. 1. Comparison of GLS levels before and after 30 days of treatment

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 body mass index (24.85 ± 3.46 kg/m^2 to 23.44 ± 3.05 kg/m^2, 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 left ventricular function was measured using left ventricular ejection fraction 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 procedure. A total of 18 segments were used to calculate the left ventricular 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 (Fig. 1).

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

Test	Day 1 (mean ± SD)	Day 30 (mean ± SD)	p-value
6-minute walk test	293.50 ± 125.79	415.00 ± 84.35	0.000
HR (before 6-minute walk test)	83.15 ± 14.09 bpm	79.35 ± 15.12 bpm	0.220
HR (after 6-minute walk test)	92.35 ± 16.70 bpm	95.60 ± 18.56 bpm	0.440
SBP (before 6-minute walk test)	120.15 ± 18.31 mmHg	119.90 ± 16.90 mmHg	0.960
SBP (after 6-minute walk test)	132.10 ± 27.25	129.45 ± 19.42	0.660
DBP (before 6-minute walk test)	74.20 ± 8.73 mmHg	72.40 ± 10.22 mmHg	0.430
DBP (after 6-minute walk test)	78.15 ± 14.28 bpm	76.65 ± 9.33 bpm	0.620

Index: HR – heart rate, SBP – Systolic blood pressure, DBP – diastolic blood pressure

Table 3. Comparison of the echocardiogram test before and after the treatment

Test	Day 1 (mean ± SD)	Day 30 (mean ± SD)	p-value
LVEF	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
LVM	114.38 ± 36.75 gms	113.88 ± 27.76 gms	0.942979

Index: LVEF- Ejection fraction, EDV- end diastole volume, LVM - left ventricular mass

3.2.4 Minute walk test

Out of the 50 study patients only 20 patients carried out the 6-minute walk test. The rest of the patients showed low left ventricular ejection 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 (Tables 2 and 3).

3.2.5 Echocardiogram test

The left ventricular ejection fraction, EDV and stroke volume increased by after the treatment whereas the LVM reduced details of which is seen in Table 2. The left ventricular ejection fraction improved post treatment, however did not reach the normal range. EDV and stroke volume improved and maintained in the normal range.

4. DISCUSSION

Recent developments in speckle-tracking echocardiography have enabled the quantitative assessment of myocardial function – GLS is one such important technique afforded through this development. This technique enables detection of subtle changes despite normal left ventricular ejection fraction. These detectable changes lead to prediction of cardiovascular events in the general population [12]. Several studies have validated its utility in varying patient populations. The Copenhagen City Heart Study [13] sought to assess the validity of GLS as a parameter to identify individuals at increased risk of future cardiovascular morbidity and mortality. Study findings revealed lower GLS was associated with higher risk of the composite endpoint comprising incident heart failure, acute myocardial infarction, or cardiovascular death. The present study focused on assessing the effect of an Ayurvedic-based IRP and a calorie-controlled diet to treat myocardial ischemia in patients with known chronic heart disease. The primary endpoint was the change in GLS post 30 days of treatment. GLS is considered to be reduced mildly when it falls in the range of -15% and -12.5%, reduced moderately when it falls in the range of -8.1% and -12.5% and reduced severely when it falls below -8.0% [14]. In the present study, GLS reduced from -10.77% to -12.13%. This reflects moderate reduction of systolic function with potential further reduction beyond 30 days. A similar study observed a change from -10.35 ± 3.11% to -11.80 ± 3.48% after 30 days [15]. Another similar study [16] documented a change from −10.26 ± 4.02% to −10.99 ± 3.94% after 7 days.

The secondary endpoints were assessment of left ventricular ejection fraction, EDV, stroke volume and LVM. An increase in the left ventricular ejection fraction, EDV and stroke volume was observed post treatment. The left ventricular ejection fraction 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 LVM is related to diastolic dysfunction. A reduction in the mass will help to improve the diastolic function. The treatment given helped to lower the mean LV mass of the study group thus improving the ischemic condition [17]. Thus, along with improving the GLS score, the IRP treatment and calorie-controlled diet helped to achieve an improvement in the left ventricular ejection fraction, EDV, stroke volume and LVM leading to the reduction in the risk of myocardial ischemia.

5. CONCLUSION

An improvement in the GLS score led to the improvement in the systolic function of the study population. GLS helps to better diagnose chronic heart disease as compare 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.

ETHICAL APPROVAL AND CONSENT

As per international standard or university standard written ethical approval has been collected and preserved by the author(s). Written informed consent with publication of data without disclosure of personal information was obtained from all study patients before commencement of the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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