Efficacy of Ischemia Reversal Program in Stable Ischemic Heart Disease Patients to Improve Quality of Life

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Authors' contributions

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

Original Research Article

ABSTRACT

Background: Hypertension is one of the predominant risk factors of ischemic heart disease – appropriate control of blood pressure is key to both primary and secondary ischemic heart disease prevention. Despite comprehensive recommendations for management of ischemic heart disease and hypertension, the rising prevalence of ischemic heart disease remains undeterred. The Ischemia Reversal Program (IRP) combines *panchakarma* with nutrition therapy.
Aim: To assess the impact of IRP on patients diagnosed with ischemic heart disease with hypertension as an underlying comorbidity.
Methods: A retrospective study was conducted at Madhavbaug Clinic, Chandrapur, Maharashtra from March 2018 to December 2021. Patients aged 40–75 years diagnosed with ischemic heart

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disease and hypertension who had completed at least 7 sessions of the IRP program over a 90 (±15) day duration were included in this study. Weight, body mass index, abdominal girth, glycated hemoglobin, systolic and diastolic blood pressure measurements, and duke's treadmill score readings on Day 1 and Day 90 were documented and compared. Patient adherence to pharmacotherapy was also studied.

Results: The mean age of the study population was 55.1 ± 7.35 years. Study findings revealed statistically significant improvements in weight, abdominal girth, glycosylated hemoglobin, body mass index, and diastolic blood pressure at the 90-day follow-up. Duke's treadmill score also showed statistically significant improvement from -1.76 on Day 1 to 6.34 on Day 90.

Conclusion: Study findings reveal noticeable improvement in anthropometric measurements, blood pressure, glycosylated hemoglobin as well as duke's treadmill score. Moreover, patient dependence on pharmacotherapy also decreased. These findings are suggestive of IRP as alternative to conventional therapy advised for ischemic heart disease.

1. INTRODUCTION

Ischemic heart disease is the foremost cause of death and disease burden among adults in India. An estimated 1.5 million deaths were caused by ischemic heart disease in the year 2019 with a mortality rate of 109,23 deaths per 100,000 population. This disease affects patients of all ages but predominantly the working class leading to premature death – this causes a significant socioeconomic impact. Thus, curbing death attributed to ischemic heart disease is mandatory to eradicate premature death and the financial burden imposed by the same [1].

Hypertension is a vastly prevalent risk factor. Epidemiological data is suggestive of 25–30% and 10–20% prevalence of hypertension in urban and rural India, respectively [2]. This risk factor also plays an important role in augmenting the risk of ischemic heart disease as it is associated with a 6-fold increase in the odds of ischemic heart disease mortality [3]. Moreover, the Global Burden of Disease Study has held hypertension accountable for 1.6 million deaths. It has been predicted that reducing hypertension prevalence can circumvent 400,000–500,000 premature deaths in the country. However, although hypertension awareness has increased from less than 30% to an approximated 60%, control status is less than 30% in urban areas and 10–15% in rural areas [2]. Pharmacotherapy alone is the mainstay treatment strategy, however there are a few concerns regarding patient adherence considering the high costs. Lifestyle modification defined by weight control, adherence to a healthy and balanced diet, and a regular exercise regime has been shown to reduce elevated blood levels [4]. Hence, pharmacotherapy along with lifestyle modification can be a more rewarding treatment strategy. The Ischemia Reversal Program (IRP) combines *panchakarma* with nutrition therapy. The current study was designed to assess the effect of IRP on patients diagnosed with ischemic heart disease with hypertension as an underlying comorbidity. Patient adherence to pharmaco-therapy was also studied.

2. MATERIALS AND METHODS

2.1 Study Design and Patient Population

This retrospective cohort study was conducted on ischemic heart disease patients who presented to Madhavbaug Clinic, Chandrapur, Maharashtra from March 2018 to December 2021. Patients aged 40–75 years diagnosed with ischemic heart disease with hypertension as an underlying comorbidity were studied. Patients with history of myocardial infarction 3 weeks prior to admission, unstable angina, severe hepatic or renal insufficiency, acute heart failure, severe aortic stenosis, arrythmia, severe anemia, and pregnant and lactating patients were excluded from the study.

2.2 Procedure

The Ischemia Reversal Program (IRP) is a combination of *panchakarma* and pharmacotherapy. *Panchakarma* is an internal cleansing therapy introduced during the chronic phase of disease. It comprises of 3 techniques: *snehana*, *swedana*, and *basti*. *Snehana* is centripetal oleation using a decoction of oils. It reduces sympathetic over stimulation, myocardial workload, myocardial oxygen demand and

Table 1. Study treatment: Ischemia reversal program

Step of ischemia reversal program	Type of therapy	Herbs used for therapy	Duration of therapy
Snehana	Massage or external oleation (centripetal upper strokes directed towards heart)	100 ml [80% Sesame oil + 20% Lavender oil]	30–35 mins
Swedana	Passive heat therapy	*Dashmoola* (group of 10 herbal roots) with steam at ≤40°C)	10–15 mins +3–4 mins of relaxation after procedure
Basti	Per rectal drug administration using a rectal solution.	100ml luke-warm decoction of Gokshura (*Tribulus terrestris*), Haridra (*Curcuma longa*), and Amalaki (*Emblica officinalis*)	15 mins

improves vascular tone. *Swedana* is passive heat treatment. The patient is positioned in a supine position inside a wooden box with their head protruding outwards. The patient is then exposed to dashmoola steam at ≤40°C. This induces sweat and causes vasodilatation of the microvasculature, reduces systemic vascular resistance, afterload, cardiac workload, and myocardial oxygen demand. *Basti* is rectal administration of medicinal extracts. This decreases oxidative stress and inflammation whilst improving endothelial function and dilating capacity of the blood vessels. It also promotes healthy healing. The techniques were practiced after a light breakfast and each procedure had a duration of 65–75 mins. The details of treatment are given in Table 1 above.

2.3. Duke's Treadmill Score

The formula used to compute Duke treadmill score is as follows [5]:

Duke treadmill score = Met value − [(5 x ST segment deviation (mm)] − (4 x angina index)

Where:

0 indicates no angina
1 indicates non-limiting angina
2 indicates exercise-limiting angina

The duke's treadmill score is typically used for stratifying patients based on their risks and typically ranges from -25 to +15.

2.4 Data Collection

Data were retrospectively collected from hospital records. Patient data such as age, gender, weight, height, glycated hemoglobin levels, systolic and diastolic blood pressure, duke's treadmill score, and adherence to medication were documented. Data for the same variables were collected and documented for Day 90. Data for Day 1 were compared with data from Day 90. Data was only extracted for those patients who had completed at least 7 sessions of the IRP over a duration of 90 ± 15-days. The patient records wherein complete treatment and follow up details were not available or treatment was changes were excluded from analysis. Adherence to medication on Day 1 and Day 90 were also noted and compared at follow-up.

2.5 Statistical Analysis

All patient data were collected and coded in a Microsoft Excel sheet. Software R 3.4.4 was used to analyze data. Continuous data are expressed as the mean ± standard deviation, whereas categorical data are expressed as number (frequency). Paired t-test was used to analyze the difference in various parameters at baseline and 90-day follow-up. A p-value <0.05 was considered as statistically significant.

3. RESULTS

The mean age of the study patients was 55.1 ± 7.35 years. Males comprised 25 (63%) of the study population. Study analysis revealed significant improvement in weight, abdominal girth, glycosylated hemoglobin, body mass index, and diastolic blood pressure at the 90-day follow-up as detailed in Table 2. Mean duke's treadmill score was -1.76 on Day 1 and 6.34 on Day 90 (p=0.001) as shown in Fig. 1. 90% patients ceased adherence to calcium channel

blockers, 84.21% ceased adherence to beta blockers, and 100% patients ceased adherence to vasodilators and nitrates. The medication adherence of the study patients before and after the 90-day follow-up is shown in Table 3.

Table 2. Changes in mean values of various parameters at Day 1 and Day 90 in the study patients

Parameter	Day 1	Day 90	p value
Age, years	55.1 ± 7.35		
Males, n (%)	25 (63%)		
Weight, kg	66.35 ± 8.22	61.68 ± 7.85	0.001
Abdominal girth, cm	94.45 ± 6.77	88.20 ± 6.69	0.001
Heart rate, bpm	80.15 ± 11.04	76.02 ± 9.19	0.08
Glycated hemoglobin , %	9.05 ± 1.81	7.05 ± 1.06	0.001
Body mass index	26.08 ± 2.94	24.29 ± 2.83	0.001
Systolic blood pressure, mmHg	131.18 ± 16.67	122.08 ±15.43	0.01
Diastolic blood pressure, mmHg	80.5 ± 9.50	73.73 ± 8.18	0.001

Table 3. Percentage of patients showing tapering of allopathic medication towards the end of Ischemia Reversal Program. The negative indicates the of medicine tapered as a percentage

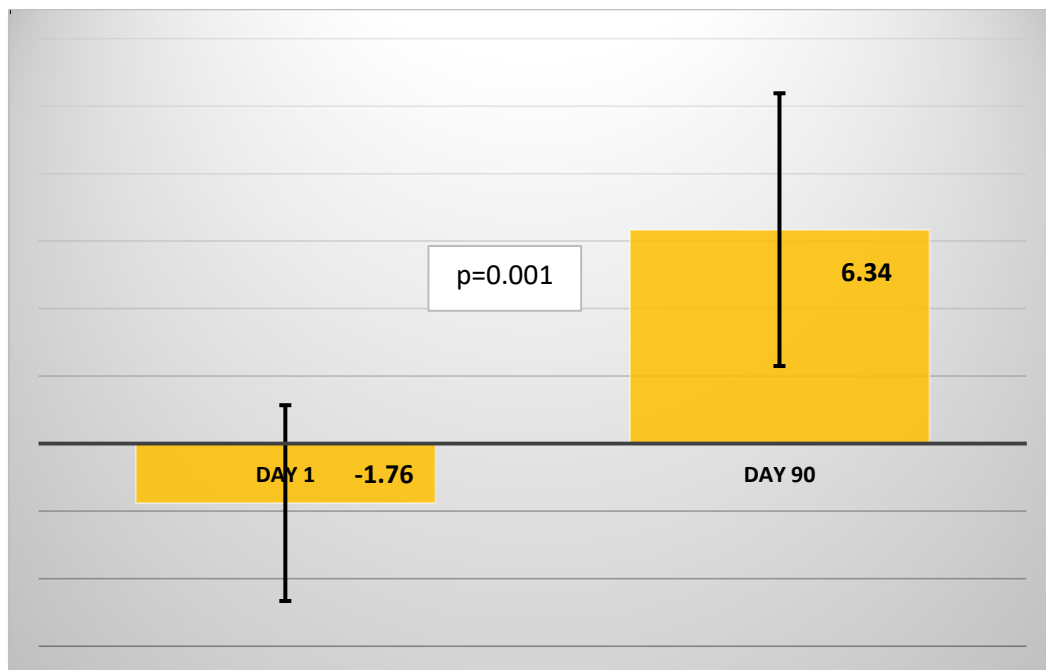| Drug class	Day 1 (n)	Day 90 (n)	Percentage of patients who ceased medicines
Calcium channel blockers, n (%)	10	1	-90
Beta blockers, n (%)	19	3	-84.21
Vasodilators, n (%)	2	0	-100
Diuretics, n (%)	12	5	-58.33
Nitrates, n (%)	25	0	-100

Fig. 1. Mean duke's treadmill score at Day 1 and Day 90 in patients of present study

4. DISCUSSION

Hypertension is a vastly prevalent risk factor of ischemic heart disease. The present study sought to assess the effect of IRP on patients diagnosed with ischemic heart disease with hypertension as an underlying comorbidity. Study findings revealed significant improvement in weight, abdominal girth, glycosylated hemoglobin, body mass index, and diastolic blood pressure at the 90-day follow-up.

High systolic blood pressure is a major risk factor for ischemic heart disease, yet it is a modifiable risk factor. Several studies have evidenced continuous log-linear associations between systolic blood pressure and mortality due to vascular events across a wide spectrum of diverse populations [6-8]. An increase of 20 mmHg in systolic blood pressure doubles the risk of ischemic heart disease mortality [3]. Therefore, reduction in systolic blood pressure is synonymous with a more favourable patient prognosis which can furthermore significantly reduce mortality due to ischemic heart disease. *Swedana* has been known to significantly reduce systolic blood pressure [9] due to which ischemic heart disease patients diagnosed with hypertension had observed reduced in systolic blood pressure from 127.68 ± 13.65 mmHg to 122.74 ± 11.65 mmHg after 90 days [10]. This observation has been fortified by findings of another study in which systolic blood pressure reduced from 133.50 ± 16.36 mmHg to 121.87 ± 11.67 mmH after 90 days in the same patient subset [11]. Study findings from the present study further corroborate this observation.

Duke's treadmill score is used as a diagnostic and prognostic tool study for patients at risk of ischemic heart disease. It has been employed as a risk stratification tool to help predict patient outcome of patients diagnosed with ischemic heart disease [12,13]. The duke's treadmill score improved from -1.76 on Day 1 to 6.34 on Day 90 in the present study.

5. CONCLUSION

After IRP, there was an observed improvement in the duke's treadmill score and diastolic blood pressure among other anthropometric measurements. The patient's dependence on pharmacotherapy was also significantly decreased. Therefore, IRP may be a strong and practical alternative to the pharmacotherapy alone in ischemic heart disease patients.

6. STUDY LIMITATIONS

The study has a few limitations that should be taken into perspective. The first is the retrospective study design. Prospectively designed could provide further insights as well as fortify the existing literature which is predominantly of retrospective design. The second is the relatively small sample size due to which the study outcomes may be generalized. The third is follow-up of longer duration. Studies longer follow-up duration could provide insights into long-term outcomes.

CONSENT

All authors declare that written informed consent was obtained from the patient for publication of this case report and accompanying images.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

ACKNOWLEDGEMENTS

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/96475