Original Article

Mindfulness-based stress reduction program in coronary heart disease: A randomized control trial

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ABSTRACT

Background: Psychological risk factors such as anxiety and depression have been associated with coronary heart disease (CHD). Stress can have an impact on the risk factors for the disease, such as high blood pressure (BP), physical inactivity and being overweight.

Aims: Examine the effect of the Mindfulness-Based Stress Reduction (MBSR) program on symptoms of anxiety and depression, perceived stress, BP and body mass index (BMI) in patients with CHD.

Settings and Design: Intervention was carried out at an Outpatient clinic. Parallel group – MBSR group; and treatment-as-usual group (TAU) – randomized control design with pre- (baseline), post-intervention and follow-up assessments was adopted.

Materials and Methods: Thirty male patients, age range (30-65 years) with CHD were randomly allocated to either group. The therapeutic program comprised of eight weekly sessions of structured MBSR intervention for the MBSR group and one health education session for the TAU group. Regular medical intervention and monthly consultations with the cardiologist were consistent for both groups. The main outcome measures were: Hospital Anxiety and Depression Scale, Perceived Stress Scale (perceived stress), BP and BMI.

Statistical Analysis: Independent sample *t*-tests, chi square test and paired sample *t*-test were used.

Results: All patients completed intervention in the MBSR group. Significant reduction was observed in symptoms of anxiety and depression, perceived stress, BP and BMI in patients of the MBSR group after the completion of intervention assessment. At 3-month follow-up, therapeutic gains were maintained in patients of the MBSR group.

Conclusion: The MBSR program is effective in reducing symptoms of anxiety and depression, perceived stress, BP and BMI in patients with CHD.

Key words: Anxiety; blood pressure; body mass index; coronary heart disease; depression; mindfulness-based stress reduction; perceived stress.

INTRODUCTION

Coronary heart disease (CHD) is found to be the leading cause of mortality worldwide. It is a condition in which the walls of the coronary arteries (arteries that supply blood to the heart muscle) become narrowed by a gradual build-up of fatty material called atheroma (BHF, 2003). When atheroma affects the coronary arteries, it can cause angina, myocardial infarction (MI) or sudden death. There are certain risk factors that are assumed to have a direct relationship with the origin and course of CHD, such as age (45 or older for men; 55 or older for women), family history of CHD, cigarette smoking, high blood pressure (BP), high blood cholesterol, overweight/obesity, physical inactivity and diabetes.[1] Research indicates that India will bear 60% of the world's heart disease burden by 2010. In addition, researchers have determined that compared with people in other developed countries, the average age of patients with heart disease is lower among the Indian

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people, and Indians are more likely to have types of heart disease that lead to worse outcomes.[2] Research indicates that psychosocial factors such as stress, depression and anxiety significantly contribute to the onset, manifestation and prognosis of CHD. Stress can have unwanted physical and emotional effects, which can affect the heart by releasing certain hormones that increase BP and can encourage clotting in the arteries. The stressors include social isolation, acute chronic life events and work-related stress.[3] Research studies provide strong and consistent evidence that depression is an independent risk factor for CHD and its prognosis.[4] Meta-analytic studies have supported the role of anxiety in the onset of CHD.[5]

Given that psychological factors contribute to the onset, course and recovery in CHD, different psychological interventions have been tried with varying outcome measures. Psychoeducation approaches have also been found to be effective in aiming to modify lifestyles and BP optimization.[6] Cognitive behavioural interventions include techniques such as biofeedback, relaxation training and cognitive restructuring, aiming to reduce anxiety, depression and improve quality of life in patients with CHD.[7] Meditation has been one of the oldest relaxation techniques to treat a wide range of mental and physical health problems.[8] The effects of meditation involve various psychophysiological mechanisms, which include relaxation, stress reduction, decreased heart and respiration rate, increase in brain wave coherence and resonance.[9] Various meditative techniques and yoga have also been part of strategies for management and risk factor reduction in CHD. Transcendental meditation has been found beneficial in improving cardiac status.[10,11]

In the last 25 years, mindfulness meditation and intervention based on it has become the focus of considerable attention for a large community of clinicians and researchers. Mindfulness as a construct has been described as a process of bringing a certain quality of attention to moment-by-moment experience through the practice of mindfulness meditation.[12] Mindfulness in contemporary psychology has been adopted as an approach for increasing awareness and responding skilfully to mental processes that contribute to emotional distress and maladaptive behavior. Much of the interest in the clinical applications of mindfulness has been sparked by the introduction of Mindfulness-Based Stress Reduction (MBSR), a manualized treatment program originally developed for the management of chronic pain.[13]

Mindfulness-based interventions provide potential promise as an effective health care intervention. Research has demonstrated that such interventions alleviate suffering associated with physical, psychosomatic and psychological disorders, and improve quality of life.[14] In addition, its positive effects on health and immunological functioning have also been well documented.[15] Several studies have shown efficacy of mindfulness interventions in problems as varied as anxiety disorders,[16] fibromyalgia,[17] epilepsy,[18] psoriasis,[19] hypertension,[20] breast and prostate cancer,[21] diabetes,[22] human immunodeficiency virus[23] and substance use.[24] Meta-analytic studies and systematic reviews indicate that participation in an MBSR program is likely to result in coping better with symptoms, improved mental health, improved overall well-being and quality of life and enhanced health outcomes for people with chronic medical disease, and mindfulness-based cognitive therapy prevents depressive relapse.[25,26]

There are only two pilot studies that have used mindfulness meditation as the integral therapeutic component in management of CHD.[27,28] Results of these studies are very encouraging. Research on the evaluation of specific effects of MBSR program in patients with CHD is in an initial stage, and there is no published study from India on the effects of MBSR program in patients with CHD. Further, there is a need to develop specific cost-effective intervention programs for patients with CHD that would enhance their self-efficacy in managing stress and in monitoring the risk factors. The present study also attempted to study the impact of MBSR on physical as well as psychological factors, incorporate randomized control design and use individual session format rather than a group format compared with other trials in CHD. Therefore, the present study aimed at examining the effects of MBSR program on symptoms of anxiety and depression, perceived stress, BP and body mass index (BMI) in patients with CHD.

MATERIALS AND METHODS

The sample consisted of 30 male patients with a diagnosis of CHD in the age range of 30-65 years divided into two groups namely, MBSR group (n = 15; mean age = 47.27; SD±12.15) and treatment-as-usual (TAU) group (n = 15; mean age = 50.60; SD±8.21). While carrying out the pilot phase, majority of women declined to participate due to transportation problems, child care and other responsibilities. Therefore, only males were recruited for this study. Patients were recruited from the inpatient and outpatient services of St. Johns Medical College and Hospital, Bangalore. Ethical committee clearance was obtained from the hospital authorities for conducting this study. Patients who had been hospitalized or had had symptoms of heart disease within the last 1 year and their echocardiography test showing ejection fraction >35% with ability to read, write and speak English language were included in the study. Patients with a clinical history suggestive of psychoses, obsessive compulsive disorder, mental retardation, mania, severe depression, neurological or serious medical conditions and those with previous exposure or currently receiving any psychological

intervention were excluded from the study. Informed consent was obtained from the patients, confidentiality was maintained, participation was voluntary and no incentives were offered.

Study design

A randomized control design with pre- (baseline), post-intervention and follow-up assessments was adopted [Figure 1]. Patients were randomly assigned to either groups – MBSR group or TAU group – using computer-generated random tables. Patients were assessed on outcome measures during the week preceding MBSR (pre-assessment), on program completion and at follow-up after 3 months post assessment.

Measures

The Hospital Anxiety and Depression Scale (HADS)[29] was used to assess anxiety and depressive symptoms in patients with CHD. The internal consistency was good – 0.82 (HADS depression subscale) and 0.83 (HADS anxiety subscale) and 0.88 (total HADS). Perceived stress was assessed using the Perceived Stress Scale (PSS). Coefficient alfa reliabilities for the scale were 0.84 to 0.86 in three community samples. Validity was supported in the scale's ability to predict depressive and physical symptoms, and utilization of health services.[30] Physical parameters included measurement of BP and BMI. BP of the patients was measured either by the cardiologist or a physician within 1 week of pre-assessment, post-assessment and at follow-up using sphygmomanometer.

Procedure

Patients were given appointment on an individual basis. Results of the pilot phase of this study carried out earlier indicated that individual program would be feasible in this population. It would allow them flexibility in terms of their time and more individualized focus to address their concerns. A total of eight weekly sessions were held for the MBSR group, including pre-assessment and post-assessment. Sessions were held once a week, with each session lasting for 1–1.5 h. Pre-assessment was carried out for both the groups at least 3 months after the occurrence of a cardiac event such as heart attack or angina, to allow them to stabilize medically in terms of their cardiac status. During the pre-assessment session, patients in both the groups were given health education about CHD and its management. Following that, the MBSR program was carried out with patients in the intervention group spread over 8–10 weeks' duration. Patients in the TAU group did not receive any further sessions after the health education session. For the patients of both groups, routine cardiac care continued, i.e., medical management and once a month follow-up visit with their cardiologist. Post-assessment was carried out for both the groups 8–10 weeks after the pre-assessment and education session. As some participants could not attend scheduled sessions for intervention or post-assessment as per the appointment date, they were given appointment for the alternate week; hence, it took 8–10 weeks to complete sessions and assessments for all. For both the groups, follow-up assessment was attempted for as many patients available after 3 months of completion of the post-assessment.

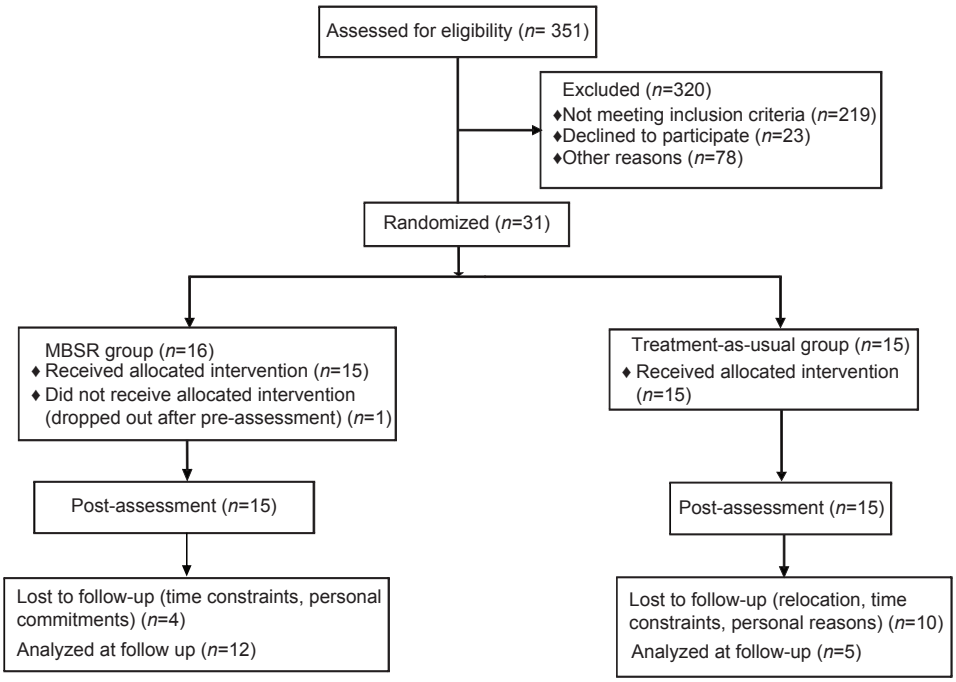

Figure 1: Randomized controlled trial of MBSR v/s TAU

Intervention program

MBSR intervention was based on Kabat–Zinn[12] and Segal *et al*.[31] The therapeutic program included training in different variants of mindfulness meditation such as body scan meditation, sitting meditation, mindful walking, mindful eating, 3-min breathing space, mastery and pleasure activities and cognitive restructuring. Each participant was provided with an audio cassette with recorded instructions of mindfulness meditation and body scan meditation to practice 30 min of meditation at home. All the patients in both the groups followed suggestions from the treating team regarding their health behaviours, i.e. regular exercise for at least 30 min and maintaining the suggested diet.

Statistical analysis

Statistical Package for Social Sciences, Version 15.0 for Windows (SPSS 15.0) was used to analyze the quantitative data. 0.05 level of confidence was used to interpret the significant results of the present study. Results that were significant at 0.01 and 0.001 level have also been specified. Data was found to be normally distributed. Independent sample *t*-test and chi-square tests were used for baseline comparison on sociodemographic variables, clinical characteristics and outcome measures for both groups. Paired sample *t*-tests were used to compare baseline, post-intervention and follow-up means on outcome measures. Data on compliance with practice of meditation at home were collected every week during the intervention.

RESULTS

Table 1 shows that there was a significant difference between the groups on HADS at post-assessment. The scores of MBSR group on anxiety, depression and total score (overall distress) on HADS were significantly lower than the TAU group ($t = -4.6$, $P = 0.001$; $t = -2.9$, $P = 0.01$; and $t = -4.5$, $P = 0.001$, respectively). Within-group analysis indicated that there was a significant reduction in anxiety symptoms ($t = 6.14$, $P < 0.001$), depressive symptoms ($t = 5.13$, $P < 0.001$) and in total score ($t = 7.07$, $P < 0.001$) on HADS from pre- to post-assessment in the MBSR group. There was no significant difference within the TAU group from pre- to post-assessment on HADS.

Perceived stress reduced significantly within patients of the MBSR group, and there was a significant difference between the two groups on this dimension at the end of the intervention. There was no difference in perceived stress in patients of the TAU group (between *t* value $= -2.9$, $P < 0.01$; within *t* value $=7.26$, $P < 0.001$).

Significant decrease in systolic BP within the MBSR group was observed after the completion of intervention (within t value $=4.73$, $P < 0.001$), while there was no significant difference in the within TAU group. Systolic BP was significantly lower in the MBSR group than in the TAU group at post-assessment (between *t* value $= -2.79$, $P < 0.05$).

There was a significant reduction in BMI in the MBSR group ($t = 2.66$, $P < 0.05$), while the BMI of the TAU group did not show any significant change ($t = 1.62$). However, there was no significant difference between the groups on BMI at post-assessment.

Follow-up

Of the 30 patients, there were a total of 17 available at 3-month follow-up (12 in the MBSR and five in the TAU group). For each group, baseline mean scores on outcome measures for patients available for the follow-up were

Table 1: Within- and between-group analysis: Changes in symptoms of anxiety and depression, perceived stress, blood pressure and body mass index at post-assessment in both the groups

Variable	MBSR (*n*=15)			TAU (*n*=15)			Between group *t* value
	Pre Mean (SD)	Post Mean (SD)	Within group *t* value	Pre Mean (SD)	Post Mean (SD)	Within group *t* value	
Anxiety	7.87 (3.31)	3.27 (1.27)	6.14***	7.67 (3.65)	7.53 (3.33)	0.24	−4.63***
Depression	6.13 (2.03)	3.33 (1.59)	5.13***	4.93 (2.49)	5.47 (2.39)	-2.09	−2.9**
Overall distress	14.00 (4.72)	6.00 (2.16)	7.07***	12.60 (5.09)	13.00 (4.94)	-0.64	−4.5***
Perceived stress	30.13 (4.87)	19.60 (3.22)	7.26***	29.87 (7.69)	27.13 (9.39)	1.17	−2.9**
Blood pressure (systolic)	135.67 (13.39)	124.47 (8.97)	4.73***	125.33 (32.47)	135.47 (8.70)	-1.06	−2.79*
Blood pressure (diastolic)	84.16 (5.48)	81.60 (5.19)	1.67	85.47 (5.73)	83.87 (5.26)	0.93	−1.19
Body mass index	24.36 (14.13)	23.77 (13.68)	2.66*	25.61 (13.03)	25.26 (12.30)	1.62	0.42

*$P<0.05$; **$P<0.01$ and ***$P<0.001$; SD=standard deviation; TAU=Treatment-asusual group; MBSR=Mindfulness-based stress reduction

Table 2: Changes in symptoms of anxiety and depression, perceived stress, blood pressure and body mass index post-intervention to 3-month follow-up in both the groups

Measure	MBSR (*n*=12) Post	MBSR (*n*=12) Follow-up		TAU (*n*=5) Post	TAU (*n*=5) Follow-up	
	Mean (SD)	Mean (SD)	*t* value	Mean (SD)	Mean (SD)	*t* value
1. HADS Anxiety	3.17 (1.33)	3.00 (1.13)	0.52	8.00 (4.63)	7.20 (4.96)	2.14
Depression	3.33 (1.72)	3.08 (1.88)	0.89	5.60 (2.30)	5.80 (2.49)	−1.00
Overall distress	6.50 (2.27)	6.17 (2.37)	0.56	13.60 (6.02)	13.00 (6.40)	0.21
2. Perceived stress	19.60 (3.63)	18.33 (4.56)	0.93	31.80 (6.97)	31.20 (7.39)	2.45
3. Physical measures BP (systolic)	124.17 (7.80)	120.83 (8.03)	3.67**	134.80 (4.60)	136.00 (7.07)	−1.00
BP (diastolic)	82.83 (4.47)	81.25 (2.99)	0.91	84.80 (5.02)	86.40 (5.55)	−0.48
BMI	24.27 (1.67)	24.26 (1.96)	0.08	22.46 (2.41)	22.42 (2.41)	1.00

**$P<0.01$; SD=standard deviation; TAU=Treatment-asusual group; MBSR=Mindfulness-based stress reduction

compared with the baseline mean scores of patients who could not come for the follow-up using independent sample *t*-test. The results did not show any significant differences, which indicate that the patients who were available for the follow-up in both the groups were true representatives of their respective groups.

Three-month follow-up mean scores were not significantly different from post-intervention mean scores, except systolic BP mean score for patients in the MBSR group, which showed further improvements. These findings suggest that in the MBSR group, the therapeutic gains were maintained at 3-month follow-up and patients showed further decrease in systolic BP from post-assessment to follow-up assessment [Table 2]. Compliance was also assessed 3 months after the completion of the intervention program. Nine of 12 patients (75%) who completed the follow-up assessment reported practicing mindfulness meditation two to three times per week. Moreover, there were no adverse effects reported by any patient.

DISCUSSION

Results of the present study suggest that the MBSR program was effective in reducing anxiety and depressive symptoms, perceived stress, BP and BMI in patients with CHD. HADS's anxiety and depression sub-scales measure negative affectivity and autonomic arousal, and coherent dimension of depression or anhedonia, respectively.[32] Findings of the present study reveal that mindfulness meditation was effective in decreasing physiological sensations of anxiety by enabling patients to observe these anxiety-laden sensations in a non-judgmental way without avoiding them. Baer[33] has referred this process as exposure. She noted that sustained exposure to anxiety states lead to reductions in autonomic arousal. Reduction in depression symptoms can be explained as a function of mindfulness meditation and cognitive restructuring. Dysfunctional health beliefs were corrected through cognitive restructuring. In addition, mindfulness meditation helped patients in recognizing stress inducing or negative thought patterns and redirecting attention to things that occurred in the present moment. Non-judgmental observation of the bodily sensations and automatic negative thoughts also enhances patients' ability to tolerate negative mood states and leads to reduction in anxiety and depressive symptoms. Teasdale *et al*.[34] have reported that interventions based on mindfulness increases meta-cognitive awareness of the patients. The realization that all thoughts are not facts is one of the key mechanisms of mindfulness. One recent study indicated that mindfulness fully mediated changes in acute anxiety symptoms, and partially mediated changes in worry and trait anxiety.[35] Mindfulness also helps in developing an attitude of acceptance, which might have resulted in reduction in perceived stress as assessed on PSS. Acceptance enables an individual to approach stressful situations "mindfully" instead of automatically reacting to it and resulting in better self-regulation.[36] Patients were also encouraged to involve in activities with a sense of mastery and pleasure, which might have increased their self-efficacy and helped them in combating low mood and anhedonia. Efficacy of mindfulness intervention in reducing anxiety and depression has been shown in many studies.[26,35,37] Meta-analysis and systematic reviews indicate that there is lack of active control groups, and many studies have used TAU or wait list control groups for comparing MBSR interventions.[26,38] Tacon *et al*.[27] in their study have also reported efficacy of MBSR in reducing anxiety, better emotional control and expression of negative feelings and decrease in reactive and impulsive

coping style in women with heart disease. Speca *et al*.[39] in their study on cancer patients reported significant reductions in mood disturbance, subscales of depression, anxiety, anger and confusion and more vigor in treatment group than in the wait list control subjects.

The MBSR program was effective in reducing systolic BP in patients of the MBSR group. This finding is consistent with earlier research, confirming the role of meditation in reducing hypertension. Efficacy of meditative techniques, especially transcendental meditation using randomized controlled trials comparing health education and other active interventions in hypertension has been reported in many studies.[10,11,40] The decrease in systolic BP along with reduction in stress with participation in mindfulness-based interventions has also been reported by Carlson and colleagues in their 1-year follow-up study.[41] Reduction in systolic BP may be understood in terms of mechanisms discussed earlier, contributing to reduction in symptoms of anxiety and depression and overall perceived stress. Furthermore, reduced arousal, stress immunization and relaxation response are known physiological mechanisms of meditation, which may explain reduction in systolic BP.[42,43] Elevated sympathetic activity, which often results in increased fluctuations in BP, also gets inhibited by slow breathing, which is a by-product of meditation.[44,45] Moreover, patients in both the groups were on anti-hypertensive drugs and periodic changes were made in their medications by their cardiologist during the course of this study, which further helped in reducing their BP. In addition to reduction in BP, the mean BMI of patients in the MBSR group also reduced significantly at the end of the intervention. This indicates the benefit of including mindfulness intervention in addition to health education, which increased awareness in participants to exercise regularly and maintain an appropriate diet and healthy lifestyle.

In the participants of the MBSR group, the therapeutic gains were maintained at 3-month follow-up, and the systolic BP decreased further, while participants of the TAU group had not shown any significant improvement from pre-assessment to post-assessment, and from post-assessment to follow-up assessment. Good compliance to mindfulness meditation has been demonstrated by the patients completing the MBSR program. A meta-analytic review of 13 studies reported a mean compliance rate of 85% with mindfulness meditation.[33] The maintenance of therapeutic gains by the patients at 3-month follow-up also reflects good compliance.

Strengths of the present study include randomized control design, structured intervention program that was tailored for Indian clients with session by session focus, assessment on both physical as well as psychological measures, adequate compliance to the MBSR program by the participants and no drop out during the intervention program.

Limitations of the study are in terms of small sample size, lesser number of patients available at follow-up and only male patients included in the sample. For generalizability and to study durability of the effects of MBSR program, patients with different socioeconomic background with large sample size are required. The direct relation of the practice of mindfulness meditation and the change in BP needs further rigorous methodological trial. During the course of the study, there were changes made in medication of patients by their cardiologist. The present study could not control or specifically measure the impact of these changes on outcome measures.

CONCLUSION

Cardiovascular diseases account for a large proportion of all deaths and disability worldwide, and deaths attributable to cardiovascular diseases have increased in parallel to the expanding population in India. The economic and social burden and burden on the health care system due to CHD is increasing. Medical care of heart disease, including surgeries and cardiac rehabilitation programs, are often expensive. Being the first study of its kind in India, the present study provides evidence for the effectiveness of the MBSR program in reducing symptoms of anxiety and depression, perceived stress, BP and BMI in patients with CHD, and offers new insights in the management of patients with CHD.

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