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Randomized Control Study to Evaluate the Effect of Rajyoga Meditation on Metabolic and Psychological Correlates of Health in Patients of Surgical Repair for Congenital Heart Disease

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ABSTRACT

Objectives: Congenital heart diseases (CHDs) and their operative management are a source of emotional and financial stress to the patient and family. Rajyoga meditation (RYM) is a specific art and science of meditation that encompasses but is not limited to mind-body medicine theories, inculcation of values in life, and development of life skills for complete physical, mental, and spiritual well-being. The role of RYM has never been studied in CHD patients, especially children. This study aimed to evaluate the efficacy of the RYM program on resting metabolic rate (RMR) and post-hospitalization behavior questionnaire (PHBQ) immediately after the program and after 1 and 3 months.

Material and Methods: It was a single-blind, randomized controlled study. Subjects operated for CHD, in the age group of 8–19 years, were included in the study. Subjects in Group A received cardiac rehabilitation and RYM (Experimental group), whereas subjects in Group B received conventional cardiac rehabilitation (Control group).

Result: At one-month follow-up, the experimental group showed a 14.18% reduction in RMR compared to baseline, whereas Group B showed 8.96% elevated RMR from baseline. Group A showed a more significant reduction in RMR at one-month follow-up from baseline as compared to group B ($P < 0.05$). The patients who underwent RYM training had higher PHBQ (−9.0 [−15.6, −2.5], $P < 0.05$) in comparison to the control group.

Conclusion: The result of this study suggests that the inclusion of RYM along with conventionally given cardiac rehabilitation enhanced metabolic resilience with lowered resting metabolism and enhanced recovery post-surgery in children operated on for CHD. There was an improvement in the psychological adjustment and behavior of adolescents.

Keywords: Rajyoga meditation, Cardiac rehabilitation, Congenital heart disease, Stress management, Resting metabolic rate (RMR)

INTRODUCTION

The abnormalities that occur in the structure of the heart while the fetus is developing in the uterus during pregnancy are defined as congenital heart diseases (CHDs). At All India Institute

of Medical Sciences (AIIMS), around 2000 surgeries for children are being done for the repair of CHD every year. The age group involved ranges from neonates to adults.[1] With a believed incidence rate of 8/1000 live births, nearly 180,000 children are born with CHD each year in India. Of these, nearly 60,000–90,000 suffer from critical CHD requiring early intervention.[2] CHDs and their operative management are a source of emotional and financial stress to the patient and family. The high morbidity and mortality rates and the need for further surgeries for complete correction of heart defects usually create anxiety, apprehension, and distress among both children and their parents.[3] Residual defects also further deteriorate the quality of life and add to the continued stress and suffering.[4] The resting metabolic rate (RMR) can be defined as the amount of energy needed by the body when it is at rest. It is an indicator of the physiological and psychological state of the body and is reported to increase after trauma by as much as 25%, depending on illness and type of surgery performed. Increased resting metabolism is believed to be one of the major factors that limit not only physical growth but also motor and cognitive development in children with CHD.[5] Elevated basal metabolic rate is an important factor in the observed failure to thrive in at least a proportion of children with CHD. A high level of anxiety and stress is also reported among patients undergoing major cardiac surgery, which may be due to fear or discomfort of surgery and can negatively affect the coping capabilities of the patients in the post-surgery phase.

Physical exercise has always been a part of cardiac rehabilitation programs and has proven effects in maintaining the metabolic rate and exercise capacity of patients. Cardiac rehabilitation is defined as a methodology used to make the patient with heart disease to be more active and making a lifestyle that can lead to a stronger heart, better health, and exercise capacity with a better quality of life and will to survive.[6] Rajyoga meditation (RYM) is a specific art and science of meditation that encompasses but is not limited to mind-body medicine theories, inculcation of values in life and development, and practice of life skills for complete physical, mental, and spiritual well-being.[7] Researchers have demonstrated meditation techniques to be effective in reducing oxygen consumption at rest, heart, and respiratory rate due to meditation-induced reduction in muscular activity, mental relaxation, and decreased state of arousal.[8] It does not require any mantras and can be done at any time and any place. RYM focuses on the union of the soul with God. Its role is acknowledged in patients with coronary artery diseases for boosting the health of the cardiac system as one of the measures of lifestyle modification. Its other effects include lowering of blood pressure, cholesterol, and glucose levels.[9] This study, inclusion of RYM for patients born with heart disease undergoing surgical repair, was a pioneering work at the apex institute of super-specialty tertiary care center at AIIMS. As science and technological advancement are taking leaps and bounds, the management of the patient as a whole, his perception of pain, emotion, and the child's normal growth and development is overlooked. Although RYM has proven beneficial effects on stress and autonomic activity, its role has not been clinically studied in patients of CHD, especially children. This study aims to train patients and caretakers on the holistic approach of RYM and to evaluate the effect of mind-body-based intervention in the form of RYM on RMR in patients of surgical repair for CHD. A secondary objective was to evaluate the new behavioral changes in children following hospitalization and surgery using the Post-Hospitalization Behavior Questionnaire (PHBQ).

MATERIAL AND METHODS

Study design and work plan

The study design was randomized controlled trial. It was conducted at the Cardiothoracic Vascular Unit (Cardiothoracic and Vascular Surgery), AIIMS, New Delhi. Ethical approval before starting the study was taken from the Institute's Ethical committee. In accordance with the Declaration of Helsinki, each subject was free to withdraw from the study at any time without any prejudice to further treatment.

All patients admitted to the hospital (AIIMS) for CHD surgery from January 16–September 16 were screened for the study. The work plan constituted the selection of subjects, evaluation of the criteria, randomization, and intervention as defined in the protocol. The whole process of allotment of the subjects into two groups was for nine months so that the last subject may be followed up for three months, and the study was completed in 12 months. The time allotted for the review of data was six months. The next six months were for the analysis of data and writing the project report and research paper. The schedule of activities during the study is shown in Table 1.

Sample selection

All patients admitted to the hospital for CHD surgery from the day of initiation until nine months were screened for the study. Subjects were enrolled in the study only after ascertaining that the subject had met all inclusion criteria and that written informed consent was obtained.

Inclusion and exclusion criteria

The criteria for subject selection were as follows – Subjects ready to give informed written consent for the enrollment into the study. Subjects between 8 and 18 years of age, operated for CHD between January 2016 and September 2016,

Table 1: All the study measurements.

Tests and procedures	Baseline (before surgery)	After surgery when patient is ambulatory	After 1 month	After 3 months
Informed consent	X			
Inclusion/exclusion criteria	X			
Physical examination	X	X	X	X
Vital signs	X	X	X	X
Medical history	X			
Concomitant medications	X	X	X	X
Routine clinical laboratory tests	X			
Disease status	X	X	X	X
Treatment/surgery details		X	X	X
RMR	X		X	X
Biochemical testing	X		X	X

RMR: Resting metabolic rate, X: Activity performed.

ready to give their consent for enrollment into the study, and willing for follow-up till three months after the intervention were included. Subjects with a history of or current neurological or psychiatric impairment or cognitive dysfunction that could compromise data collection, with severe respiratory or cardiac compromise, severely deranged renal or hepatic function, or active infection, were excluded from the study.

Justification for the higher limit of age as 18 years as inclusion criteria

Patients with CHD having atrial septal defects and small-size ventricular septal defects are usually asymptomatic and have normal growth and development, thereby usually present for surgery in the adolescent age group. In our practice at AIIMS, we have seen that this age group is the most anxious. Furthermore, another group of patients with complex cardiac disease requires multi-stage corrective operations (1st within five years; 2nd at 6 to 12 years; and by the time they come for 3rd stage, which is completion of Fontan surgery, usually they attain an age group of 13-18 years). This age group is very apprehensive and anxious and needs Rajyoga practice.

Randomization

Eligible study subjects were randomly divided into two groups – Group A and Group B by computer-generated randomization sheet.

Intervention

Subjects in Group A underwent cardiac rehabilitation (cardiac rehabilitation + RYM).

Subjects in Group B underwent cardiac rehabilitation (conventional treatment).

An almost equal number of patients were enrolled in both arms

- $n = 36$, Group A
- $n = 40$, Group B

Treatment plan for Group A

In addition to the treatment received by Group A, this group received Rajyoga meditation with the help of audio-visual aids provided by trained RYM teachers of Brahma Kumaris Spiritual University with audio-visual aids in a special, dim lighted, and RYM room CT-5 ward.[8] The caretakers of the patients were also given the same training and they were advised certain instructions to be followed. A dimly lighted room was selected for the intervention, which was provided in three sessions as per the standard technique of Brahma Kumaris Spiritual University. The training sessions included

- 1st session – Concept of self-actualization and self-reliance by means of positive thinking.
- 2nd session – Encouraging self by Supreme power
- 3rd session – Constructive and purposeful outlook, self-worth, and self-sufficiency
- The patients were advised to practice RYM in three short sessions of half an hour each. They were instructed to meditate three times a day before breakfast, before lunch, and before dinner at least for 10 min each.
- Rest intervals of 10–20 s between exercises and 45–60 s between sets of exercises were given to the patient.

Treatment plan for Group B

This group was given the conventional protocol of the hospital for physical exercises in which the training for the post-operative physical exercise is given before the surgery. Once a patient was ambulatory after the surgery, the physiotherapist provided assisted exercises of both upper and lower limbs. This exercise training by the physiotherapist

provides relaxation of the muscles of the chest and back, thereby correcting the posture of the patient. Breathing exercises were also taught to the subjects.[10,11]

Assessment

Resting metabolism was assessed using FitMate MED. The FitMate MED is a new, small (20 × 24 cm) metabolic analyzer designed for the measurement of oxygen consumption and energy expenditure during rest and exercise.[12] The subjects were asked not to take any medications for 12 hours and were fasting for a minimum of 8 hours. They were asked to wear loose, comfortable clothes. Testing was done during morning hours between 8 and 10 am. All the subjects were explained about the procedure. They were asked to lie in a supine lying position. A mask to measure RMR was worn by them. An initial 5 min was given for habituation, followed by 15 min of continuous measurement. RMR was measured using the standard equation, that is, RMR = (5.675 × VO_2+1.593 XVCO_2–21.7). VO_2 represents the maximum volume of oxygen consumed per kilogram per minute, and VCO_2 is the output of CO_2 in mL per minute. VO_2 maximum and VCO_2 were measured by FitMate MED.

Data analysis

Statistical analysis was done using STATA software version 14. The normalcy of the data was checked using the Shapiro–Wilk Test. Mean RMR was compared using an independent sample *t*-test between the groups. $P < 0.05$ was considered significant.

RESULTS

Table 1 shows all the study measurements at different points of time. Table 2 shows demographic details of the Subjects. Table 3 shows that there was no significant difference between the groups on the baseline for RMR, indicating that both groups were homogenous. Between-group comparisons showed a significant difference in RMR at the 1st-month follow-up, with a statistically more significant reduction seen in Group A, that is, the group that received RYM along with cardiac rehabilitation. There was a significant reduction in the difference of RMR from 1 month to pre-operative in the RYM group as compared to the control group ($P < 0.05$). No significant difference between both groups was seen at the 3rd month follow-up ($P > 0.05$). Figure 1 shows that the patients who underwent RYM training had higher PHBQ (−9.0 [−15.6, −2.5], $P < 0.05$) in comparison to the control group.

Table 2: Demographic details of subjects.

	Control group	Experimental group
Age (years)	13±2.5	13±2.3
Males (%)	76.7	70
Height (cm)	144.44	139.75
Weight (kg)	34.39	32.62
BMI (kg/m^2)	16.5	16.7
Type of surgery *n* (%)		
TOF	24 (60)	20 (55.6)
Fontan	07 (18)	06 (16.7)
VSD	05 (13)	06 (16.7)
PS	04(10)	04 (11.1)

TOF: Tetralogy of fallot, VSD: Ventricular septal defect, PS: Pulmonary stenosis.

Table 3: Between group comparison of RMR on baseline, and 1st and 3rd month follow-up.

Variable	RY: RMR *n*=36	CT-RMR *n*=40	*P*-value
Pre-operative	1584±339	1403±305	0.01
1 month	1442±399	1602±303	0.24
3 months	1604±449	1389±414	0.18
Difference between pre-operative to 1 month	−195±404	164±120	0.0055*
Difference between pre-operative to 3 months	−53±237	−1.8±464	0.76^{ns}

*Significant, ns: Non-significant, RMR: Resting metabolic rate, RY: Rajyoga, CT: Control.

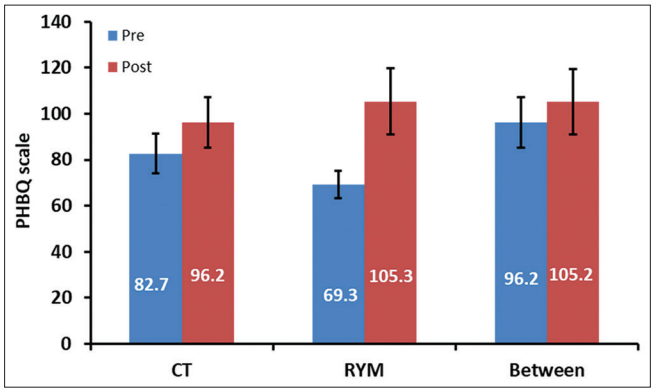

Figure 1: The patients who underwent Rajyoga meditation training had higher post-hospitalization behavior questionnaire (PHBQ) (−9.0 [−15.6, −2.5], $P < 0.05$) in comparison to the control group, CT: Control, RYM: Rajyoga meditation.

DISCUSSION

The present study was conducted on 76 operated children for various CHDs. Results of the present study demonstrated the role of RYM in improving autonomic functions in children and adolescents undergoing surgery for CHD. Acute episodes of illness or chronic diseases can lead to elevated metabolic rate disturbed energy balance, hence, slowed growth and impaired cognitive and neuromotor development of an

individual. Children with CHD have elevated basal metabolic rates due to increased energy demands of hypertrophic cardiac and respiratory muscles.[13] Advanced surgical techniques have resulted in the increased survival rate of children with CHD, but various comorbidities like slowed growth following surgery for CHD have been observed depending on factors such as the severity of the disease, feeding dysfunction, and elevated basal metabolic rate.[14] Growth failure has also been found to be associated with impairments in cognitive and neurodevelopment, affecting the maturation and academic performance of children. It is also recommended that timely intervention and recognition can prevent these complications and improve health outcomes. The stress of undergoing surgery creates distress and apprehension among children. Furthermore, it is believed to place a metabolic burden on the body's homeostasis and increase sympathetic activity and expenditure of energy.[3]

Effect on RMR

The inclusion of RYM along with conventional cardiac rehabilitation helped in decreasing the RMR of post-operative CHD patients after one-month follow-up ($P < 0.05$). It illustrates the fact that even children and adolescents are receptive to learning and practicing meditation. The value of RMR for Group A was 1403 ± 305 at baseline and 1602 ± 303 at 1st-month follow-up. RMR for group B was 1584 ± 339 at baseline and 1442 ± 399 at follow-up. Group A showed a 14.18% reduction in RMR compared to baseline, whereas Group B showed an 8.96% reduction in RMR from baseline. Group A showed a more significant reduction in RMR at one-month follow-up from baseline as compared to group B ($P < 0.05$). However, there were no significant differences between both groups at 3rd month follow-up.

The results of this study suggest that the inclusion of RYM, along with conventionally given cardiac rehabilitation enhanced metabolic resilience with lowered resting metabolism and enhanced recovery post-surgery in children operated for CHD's. RYM is a type of meditation that is practiced by Braham Kumaris Spiritual University. It is an easy and simple technique that is done with open eyes. It focuses on spiritual awareness and enhances the capability of an individual to choose between positive and negative thinking.[15]

These results are consistent with other studies that report that regular yoga practice improves metabolic function.[16] The results of this study are in obedience to the findings of studies by other researchers. A study objectively measured and found meditation and yogic practices to be effective not only in reducing stress levels boosting psychological and emotional well-being but also reducing post-surgery hypermetabolic state that corresponds with mind-body coherence and reduced levels of stress.[17] A study by Chaya *et al*. showed that a combination of different yoga and meditation practices among healthy individuals resulted in a lowered basal metabolic rate by 13% compared to the non-yoga group, which they suggested could be due to reduced arousal of the body.[16] Another study by Usha Kiran *et al*. found RYM to be effective in improving metabolic control in patients with type 2 diabetes compared to the control group.[17]

The results of this study highlight the possible advantages of using RYM in addition to cardiac rehabilitation. The RYM group's continuous decrease in RMR difference from 1 month to the pre-operative phase indicates a long-lasting effect that extends beyond the initial intervention period.

Effect on PHBQ

It demonstrated the role of RYM in improving psychological behavior in children and adolescents undergoing surgery for CHD. It may indicate a beneficial effect on psychological well-being and add another aspect to the advantages beyond physiological results. It also depicts the fact that even children and adolescents are receptive to learning and practicing meditation. These findings demand more investigation into the processes underlying the effects that have been seen and long-term research to determine the viability and wider ramifications of integrating meditation techniques into cardiac rehabilitation programs.

Future scope

Researchers recommend the inclusion of RYM to encourage large prospective randomized clinical trials for evaluating the efficacy of RYM in children suffering from other chronic debilitating diseases affecting their quality of life.

CONCLUSION

As pediatric cardiac care is still in its infancy in India, a study on CHD patients that comprises complete cardiac rehabilitation and inclusion of spiritual RYM at the apex institute of our country is a landmark in itself. Results showed improvement in basal metabolic rate in the group that practiced RYM along with cardiac rehabilitation hence recommending the inclusion of meditation practice in the rehabilitation protocol of patients with CHD's as a medium of holistic health care approach.

Author's contributions

RN: Conceptualization, investigation, data curation, writing-original draft, writing-reviewing, and editing. NM: Conceptualization, supervision, visualization, validation, writing-reviewing, and editing. VD: Conceptualization, supervision, validation, data curation, resources, writing-reviewing, and editing. PR: Conceptualization, formal analysis, methodology, writing-reviewing, and editing.

NK: Conceptualization, project administration, writing-reviewing, and editing. SKS- Methodology, writing-reviewing, and editing. UK: Conceptualization, investigation, data curation, writing-original draft, writing-reviewing, and editing. SK: Writing-original draft, writing-reviewing, and editing. SP: Writing-reviewing and editing. All the authors approved the final version of the manuscript for submission.

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Ethical approval

Ethical approval for the study was obtained from Ethics committee of AIIMS vide Reference no IEC-246/05.05.2017.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

Dr. Usha Kiran is on the Editorial board of the Journal.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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