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MediYoga as a part of a self-management programme among patients with paroxysmal atrial fibrillation – a randomised study

Maria Wahlström[1], Mårten Rosenqvist[2], Jörgen Medin[3], Ulla Walfridsson[4,5] and Monica Rydell-Karlsson[2,6]

Abstract

Background: Paroxysmal atrial fibrillation is associated with impaired health-related quality of life. Yoga has been suggested to improve health-related quality of life among patients with heart failure and hypertension.

Aim: The aim of the study was to evaluate the effects of MediYoga, in respect of health-related quality of life, blood pressure, heart rate, as well as N-terminal pro b-type natriuretic peptide, among patients with symptomatic paroxysmal atrial fibrillation, compared with standard therapy or relaxation.

Methods: Patients with symptomatic paroxysmal atrial fibrillation, *n*=132, were stratified for gender and randomised to MediYoga, a relaxation group or a control group, 44 patients per group with a 12-week follow-up. Health-related quality of life, blood pressure, heart rate and N-terminal pro b-type natriuretic peptide were assessed.

Results: After 12 weeks, there were no differences in health-related quality of life between the groups. There were improvements in Short-Form Health Survey bodily pain, general health, social function, mental health and mental component summary scores within the MediYoga group (p=0.014, p=0.037, p=0.029, p=0.030, p=0.019, respectively). No change was seen in the relaxation and control groups. Systolic blood pressure decreased in the MediYoga group (134±18 to 127±13) compared with the control group (126±17 to 127±15, p=0.041); no difference compared with the relaxation group (131±17 to 125±12). Diastolic blood pressure decreased in the MediYoga group (79±9 to 74 ±9) compared with the control group (76±9 to 79±8, p=0.005); no difference compared with the relaxation group (76±9 to 77±8). There were no differences in heart rate and N-terminal pro b-type natriuretic peptide between the groups after 12 weeks.

Conclusions: MediYoga improves health-related quality of life and decreases blood pressure in patients with paroxysmal atrial fibrillation. MediYoga may be used as a part of a self-management programme among patients with paroxysmal atrial fibrillation.

Keywords

Paroxysmal atrial fibrillation, yoga, health-related quality of life, blood pressure, heart rate, N-terminal pro b-type natriuretic peptide

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Introduction

Paroxysmal atrial fibrillation (PAF) is associated with reduced health-related quality of life (HRQoL).[1–3] Symptoms of atrial fibrillation (AF) have an impact on patients' social situation,[4] working habits and mental health.[5] Moreover, patients describe how stress may increase the numbers of AF episodes.[6] Feelings of anxiety and worry are often present in patients with PAF,[3] and there is a need for practical 'tools', such as

[1]Sophiahemmet University, Sweden
[2]Department of Clinical Sciences, Karolinska Institutet, Sweden
[3]The Red Cross University College, Sweden
[4]Department of Cardiology, Linköping University Hospital, Sweden
[5]Department of Medical and Health Sciences, Linköping University, Sweden
[6]Ersta Sköndal Bräcke University College, Sweden

Corresponding author:
Maria Wahlström, Sophiahemmet Högskola, Box 5605, Stockholm, Sverige 114 86, Sweden.
Email: maria.wahlstrom@shh.se

self-management, to manage those emotions and symptoms related to episodic AF.[7]

Treatment, with medications, cardioversion and ablation, focuses on relief of symptoms.[8] Ablation has recently been suggested to be an effective method, in patients with PAF, to reduce symtoms and improve HRQoL.[9] In addition, alternative approaches should be examined, for example, changes in lifestyle factors,[10,11] such as reducing intake of alcohol[12] as well as weight reduction in patients with high BMI.[13] Cognitive behaviour therapy (CBT)[14] and mindfulness-based CBT[15] have also been suggested as ways to reduce symptoms and improve HRQoL among patients with PAF.

Yoga practice consists of various physical exercises (asanas) in combination with breathing techniques (pranayama) and meditation (dhyana).[16] Yoga is supposed to improve the balance of the parasympathetic and sympathetic nervous systems.[17] In addition, yoga has been shown to lower heart rate (HR),[18,19] and blood pressure in patients with hypertension[20] as well as N-terminal pro b-type natriuretic peptide (NT-proBNP) in heart failure.[21] Lakkireddy et al., in a prospective study, found that yoga reduced both symptoms of depression and the number of AF episodes.[22] A similar pilot study conducted by our research group also found that yoga improved HRQoL.[23]

Patients with PAF seek complementary regimes[24] and yoga is suggested as an alternative self-care programme.[25] A Cochrane review noted that the effects of yoga are under debate as most studies are small and nonrandomised.[26] It is therefore important to evaluate MediYoga (MY) as a complementary self-management regime, in patients with PAF.

Aim

The aim of this three-armed study was to evaluate the effects of MY, in respect of HRQoL, blood pressure, HR, as well as NT-proBNP, among patients with symptomatic PAF, compared with standard therapy or relaxation.

Methods

This prospective randomised study, with stratification for gender, was conducted at the Karolinska Institutet, Danderyd University Hospital, Stockholm, Sweden, between 2014–2017. The inclusion criterion was a diagnosis of symptomatic PAF, verified by at least one episode of electrocardiogram with AF during the past six months, necessitating pharmacological treatment. The patients could have a previous or new diagnosis of PAF and should have been receiving pharmacological treatment for at least the past three months. Patients with a diagnosis of diabetes mellitus and with untreated hyperthyroidism were excluded. Patients with difficulties understanding the Swedish language, patients with multiple concurrent medical conditions (i.e. advanced cancer, heart failure and renal failure) and/or cognitive dysfunction and considered to have difficulties in performing yoga in a group session were excluded.

A total of 1532 patients with a PAF diagnosis were screened using medical records, at the arrhythmia department's out-patient clinic (at the hospital). Some were referred from one other arrhythmia department. The principal author (PA) sent information about the study to 152 patients who fulfilled the inclusion criteria. A follow-up telephone call was made by PA after one to two weeks, asking the patients if they wanted to participate in the study, with 132/152 (87%) agreeing to participate (Figure 1). The participants made two visits to the PA at the cardiological clinic, at baseline and after 12 weeks (visit window+2 weeks) after having completed the intervention. At the end of the baseline visit the participants were randomised to blocks of six[27] to the MY group (n=44), the relaxation group (n=44) or a control group (n=44). Randomization was performed by a computer program (www.sealedenevelope.com). The results were placed in a sealed envelope by an independent person. The PA was not aware of which group the participant was randomised to, before opening the envelope.

Various parameters (i.e. demographics (such as sleeping habits, alcohol use, employment, exercise habits, life events), HRQoL questionnaires, haemodynamic and venous blood samples) were collected at both visits. Medication was noted from the medical records and confirmed by information from the participants at the end of study. The participants were encouraged to document their symptomatic episodes of palpitations during the study. The same environment was used for all visits and there were no changes over time.

Ethics

All participants provided verbal and written informed consent. The study was approved by the Ethics Committee of Stockholm, Sweden (DNR 2013/953-31/4), ClinicalTrials.gov identifier: NCT01789372. The investigation conforms to the principles outlined in the Declaration of Helsinki (https://www.wma.net).

Study groups

In this study, we used a therapeutic yoga form, MY (http://mediyoga.com), evolved from Kundalini yoga, which is based on deep breathing, slow movements and meditation. The programme has been shown to stretch the musculature in the chest to achieve a better breathing technique and to balance the autonomous nervous system. The programme consists of five movements together with deep breathing, relaxation and meditation (Supplementary Material 1). The MY group met for a one-hour session, once a week, for 12 weeks (and received standard treatment) at the hospital. All sessions were conducted by a trained MY therapist. The

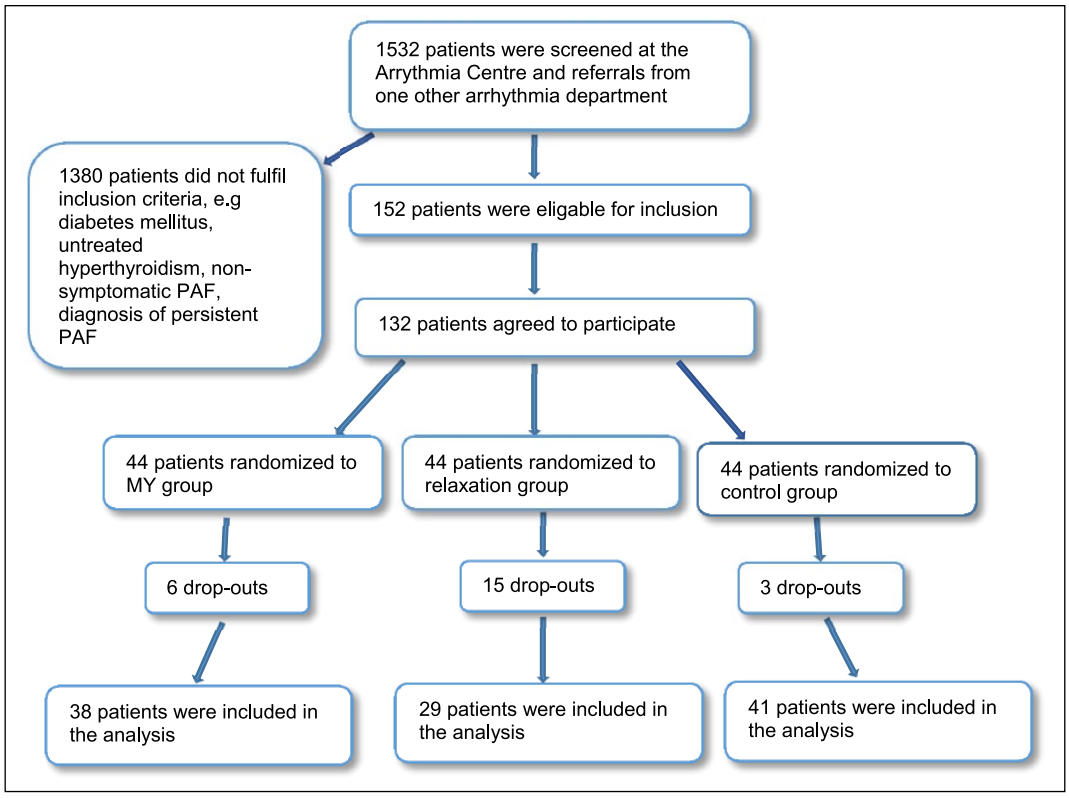

Figure 1. Randomization flow and drop-outs in the study.

MY group also received a CD with the yoga programme and were encouraged to perform MY at home. The relaxation group listened to relaxing music, in group sessions, for half an hour, once a week for 12 weeks (and received standard treatment) at the hospital. The relaxing music is specifically used in stress relief programmes,[28] (www.musicure.com). The control group received standard treatment only. At the first visit, the relaxation and control groups were informed that they would be welcome to participate in the MY programme after the completion of the study.

Assessment of HRQoL, haemodynamic parameters and biomarkers

One generic HRQoL questionnaire, the Short-Form Health Survey (SF-36), and one disease-specific questionnaire, Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA), were used to evaluate HRQoL.

SF-36, is a generic, validated and reliable HRQoL questionnaire comprising 36 questions.[29,30] The questions can be divided into eight subscales; physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), mental health (MH) and two domains named the Physical Component Summary (PCS) and Mental Component Summary (MCS). The scores are coded 0–100, with 100 representing the highest level to estimate HRQoL.

The disease-specific questionnaire, ASTA, is a validated questionnaire consisting of three parts.[31,32] Part I evaluates the latest episode of arrhythmia and current medication. Part II assesses symptom burden, including a nine-item symptom scale (ASTA symptom scale) with a four-point response scale. There are also questions regarding the frequency and the duration of an arrhythmia episode, experience of near syncope, syncope and palpitations in connection with arrhythmia. Part III assesses HRQoL using a 13-item scale (ASTA HRQoL scale), with the same four-point response scale as for the symptom scale. The ASTA HRQoL scale is further divided into a physical and a mental subscale. The values range from 0–100, with higher scores reflecting a higher symptom burden and a worse effect on HRQoL due to the arrhythmia.

Blood pressure (in mm Hg), and HR were measured, after the participant had a resting period of five minutes,[33] with Omron HEM-711DLXCAN.[33] NT-proBNP was analysed with Roche h232.

Endpoints

The primary endpoint was the difference in HRQoL assessments between, and within, the groups from baseline to the end of the study. Secondary endpoints were differences in blood pressure, HR and NT-proBNP between, and within, the groups from baseline to the end of the study.

Statistical analysis

The variables in this study have been processed statistically using the data analysis program, IBM SPSS statistics version 24 (IBM SPSS Statistics, IBM Corporation, Armonk, New York, USA). Categorical variables are presented in terms of median (range) or percentage, and continuous variables as mean (standard deviation, (SD)). Comparisons between the three groups were performed with chi-square tests for proportions, and one-way analysis of variance (ANOVA) for analysis of SF-36 (subscales and domains), ASTA (all four scales), BP, HR as well as NT-proBNP and, when necessary, Sidak was used as a post-hoc test. Student's *t*-test was used for within-group analyses. Analysis of covariance (ANCOVA) was used if a statistically significant relationship was demonstrated between the groups regarding demographic data. To detect an eight-point mean difference[34] in the scales of SF-36 between the groups, using an alpha of 0.016 and a power of 0.80, 44 patients were required in each group, including 20% of drop-outs. A significance level of $p<0.05$ was chosen, within groups, with an eight-point difference in all of the scales of SF-36.[34]

Results

There were six dropouts in the MY group (16%: four men and two women), 15 drop-outs in the relaxation group (34%: eight women and seven men) and four drop-outs in the control group (9%: three men and one woman), Figure 1. The reasons for dropping out in the MY group were infections and change of work schedules, whilst one participant did not offer a reason. In the relaxation group the reasons were an overall lack of interest in participating and one person acquired an infection. The reason for dropping out in the control group was lack of time, Figure 1. There were no differences in clinical characteristics between dropouts and those who completed the study at baseline. There was no difference between the groups in SF-36 (subscales and domains), ASTA (all three parts), blood pressure, HR and NT-proBNP when adjusted for hypertension. With respect to documented episodes of AF (yoga 13.6±8, control 9±8, relaxation 7.6±6), and when adjusted for outliers in the end of study, there were no differences between the groups. The attendance rate at the MY group showed a median of nine (7–11) and for the relaxation group the median was six (3–12). No adverse events were reported by the MY group or relaxation group during the study. Clinical characteristics are shown in Table 1.

HRQoL

There were no differences in SF-36 subscales and domains between the groups at the end of the study. However, there were significant improvements within the MY group in subscales BP (p=0.019), GH (p=0.037), SF (p=0.029), MH (p=0.030) and MCS (p=0.019). There were no differences within relaxation or control groups in the subscales and domains of SF-36, over time, Table 2. Moreover, there were no differences in ASTA, all three parts, between the groups at the end of the study. There was a significant improvement in the HRQoL subscale MH (p=0.035) within the control group but no differences were seen within the yoga or relaxation groups, Table 2.

Blood pressure

Systolic blood pressure decreased significantly within the MY group during the study (134±18 mm Hg to 127±13 mm Hg) compared with the control group (126±17 mm Hg to 127±15 mm Hg, p=0.041), but no difference was seen in comparison with the relaxation group (131±17 mm Hg to 125±12 mm Hg). There was a significant difference within the MY (p=0.008) and the relaxation group (p=0.025), over time. Moreover, diastolic blood pressure decreased significantly in the MY group (79±9 mm Hg to 74±9 mm Hg) compared with the control group (76±9 mm Hg to 79±8 mm Hg, p=0.005), but no difference was seen in comparison with the relaxation group (76±9 mm Hg to 77±8 mm Hg), Figure 2(a) and (b). There was also a significant difference in diastolic blood pressure within the MY group (p=0.002).

HR and NT-proBNP

There were significant differences in NT-proBNP between the MY and relaxation groups at baseline (p=0.015) and between patients in the control and /relaxation groups (p=0.012). There were no differences in HR between the groups; MY/control (p=0.999), MY /relaxation (p=0.993) and control/relaxation (p=0.976) or NT-proBNP between the groups; MY/control (p=0.860), MY/relaxation (p=0.364) and control/relaxation (p=0.777) at the end of study, Figures 3 and 4. There were no differences within any of the groups regarding HR and NT-proBNP.

Discussion

This randomised study suggests that MY improves HRQoL among patients with symptomatic PAF. In addition, MY also has a positive impact on systolic and diastolic blood pressure.

HRQoL

In previous studies, patients with PAF have described impaired HRQoL,[2,3] which is related to symptoms such as palpitations,[35] and mental health, such as anxiety and worry.[5,6] A few studies have evaluated self-management

Table 1. Clinical characteristics.

	Yoga *n*=38	Control *n*=41	Relaxation *n*=29
Age	65±9	63±10	64±15
Female gender	20 (53)	21 (51)	14 (48)
BMI (kg/m²)	26.5±3.4	25.4±6.1	28.2±12.1
Employment	16 (42)	20 (49)	20 (69)
Good sleep	34 (89)	34 (83)	20 (69)
High-intensity training	8 (21)	7 (17)	7 (24)
Life events	8 (21)	15 (37)	10 (35)
Alcohol glasses/week	3.1 (0–15)	3.1 (0–14)	3.8 (0–18)
Medical history			
Hypertension	22 (58)[a]	11 (27)	6 (21)
Stroke	1 (3)	-	-
MI	-	2 (5)	-
Heart failure	-	-	1 (3)
Sleep apnoea	4 (11)	5 (12)	4 (14)
CHA_2DS_s VASc	2 (0–4)	1 (0–4)	1 (0–4)
Medications			
Beta blockers	25 (66)	28 (68)	20 (69)
Antiarrhythmics	16 (42)	19 (46)	8 (28)
Calcium antagonist	7 (18)	4 (10)	3 (10)
DOAC	18 (47)	16 (39)	14 (48)
Warfarin	11 (29)	10 (24)	1(3)
ASA (aspirin)	2 (5)	2 (5)	2 (7)

ASA: acetylsalicylic acid; BMI: body mass index; CHA2DS2VASc; C; Congestive Heart Failure, H; Hypertension, A2; Age ≥75 år, D; Diabetes mellitus S; Earlier stroke/TIA/tromboembolism, V; Vascular disease, A; Age 65-74 år, S; Female gender; DOAC: direct oral anticoagulant; MI: myocardial infarction; SD: standard deviation.
Values are *n* (%) and mean±SD. CHA_2DS_2VASc is described as median (range).
[a]Statistically significant with a *p*-value <0.05.

Table 2. Health-related quality of life (HRQoL) questionnaires.

	MY n=38 Baseline	*MY n=38 End of study*	*Control n=41 Baseline*	*Control n=41 End of study*	*Relaxation n=29 Baseline*	*Relaxation n=29 End of study*	*Between groups yoga/control/ relaxation End of study p-value*	*Within MY End of study p-value*	*Within control End of study p-value*	*Within relaxation End of study p-value*
Type of score SF-36										
PF	83±18	86±14	87±13	85±14	84±14	82±12	0.559	0.485	0.565	0.564
RP	61±43	68±40	72±37	58±43	59±42	47±44	0.234	0.485	0.100	0.316
BP	70±27	83±19	80±24	76±23	75±24	69±24	0.041	0.019[a]	0.448	0.389
GH	61±18	70±17	65±22	65±21	62±19	61±20	0.240	0.037[a]	0.924	0.389
VT	53±18	61±17	55±22	57±16	56±17	53±18	0.244	0.076	0.553	0.570
SF	75±28	88±18	81±23	83±19	75±28	75±30	0.295	0.029[a]	0.631	0.962
RE	60±43	77±35	74±36	66±40	58±39	56±47	0.131	0.058	0.372	0.918
MH	64±16	72±16	67±16	67±13	65±16	66±16	0.335	0.030[a]	0.905	0.836
PCS	48±9	50±8	50±9	48±8	49±8	46±8	0.176	0.337	0.266	0.156
MCS	40±11	46±9	43±12	43±9	40±12	41±14	0.266	0.019[a]	0.266	0.849
Type of score ASTA										
Symptom scale	26 ±15	27±18	33±18	30±16	34±16	30±17	0.093	0.556	0.051	0.052
HRQoL scale	22±14	21±17	29±21	25±18	23±20	29±25	0.363	0.440	0.067	0.425
HRQoL subscale physical	21±16	21±19	30±23	26±21	28±24	28±26	0.330	0.951	0.152	0.941
HRQoL subscale mental	23±16	20±17	29±20	23±16	32±25	29±25	0.606	0.096	0.035[a]	0.107

ASTA: Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia; BP: bodily pain; GH: general health; MCS: Mental Components Summary; MH: mental health; MY: MediYoga; PCS: Physical Components Summary; PF: physical functioning; RE: role emotional; RP: role physical; SD: standard deviation; SF: social functioning; VT: vitality.
Values are mean and SD. PF, RP, BP, GH, VT, SF, RE are subscales of SF-36, MCS and PCS are dimensions of SF-36.
[a]Statistically significant with a *p*-value <0.05.

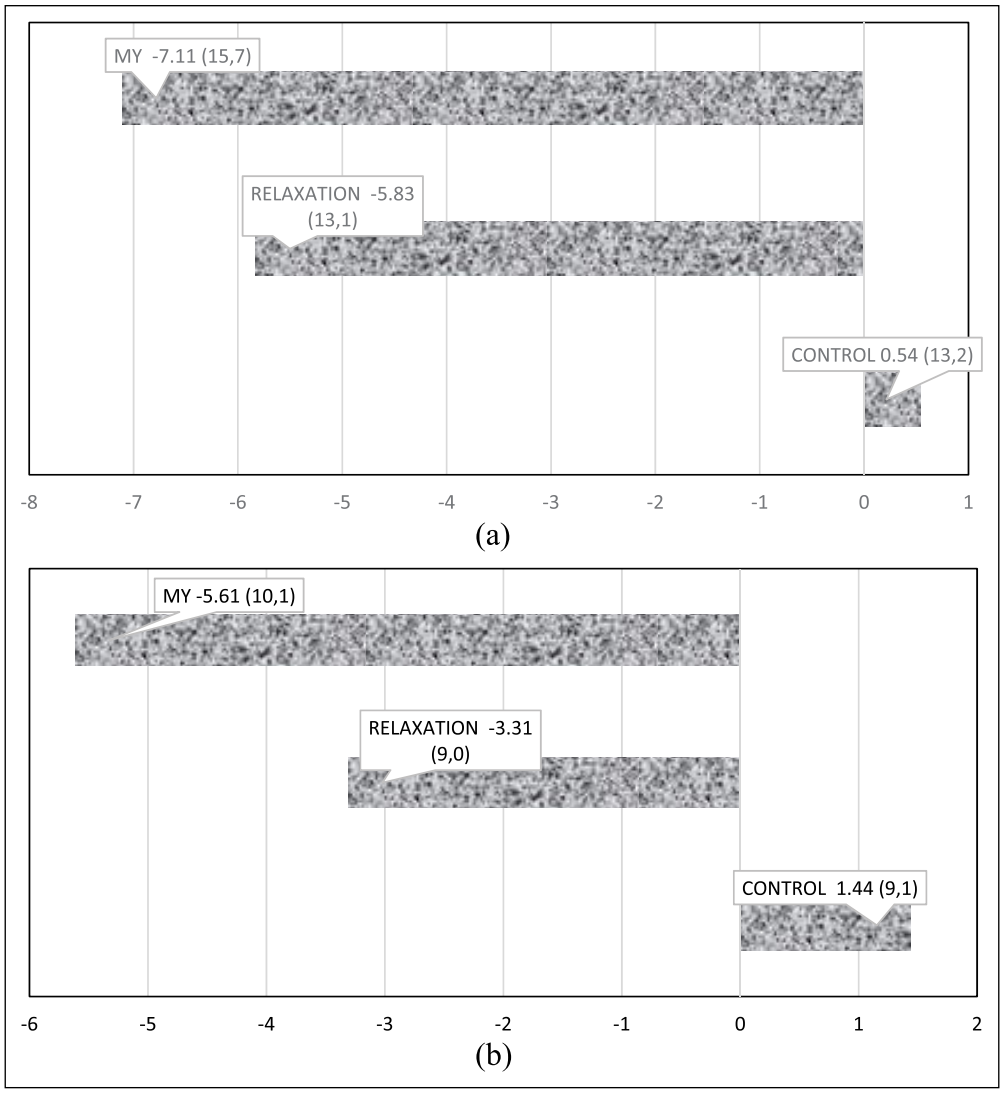

Figure 2. Mean differences (standard deviation (SD)) within MediYoga (MY), relaxation and control groups after 12 weeks. (a) Changes in systolic blood pressure within groups over time. (b) Changes in diastolic blood pressure within groups over time.

programmes aimed at improving HRQoL for patients with PAF. To our knowledge, MY has only been evaluated as a self-management programme for patients with stress-related symptoms.[36] In the present study, data showed a positive effect of MY in the SF-36 subscales, GH and MH, and the MCS domain. Changes in GH, MH as well as the MCS domain, have also been described in one other study of MY.[23] Similar effects have also been found using a different kind of yoga with PAF[22] as well as employing yoga treatment in heart failure.[21,37] Consequently, yoga seems to have a positive impact on mental health when dealing with symptoms, such as anxiety and worry. There was also an improvement in BP in the MY group. This may be related to the movements in the MY programme that contribute to enhancing bodily functions. Patients with PAF often have a deteriorated social life,[4] thus the results of our study, with increased social function, may improve their social situation.

Furthermore, HRQoL improved in the MY group, thus supporting the suggestion that yoga may be used as a self-management programme to reduce symptoms and improve HRQoL.[25]

Blood pressure, HR and NT-proBNP

There was no difference in HR and NT-proBNP in any of the three groups, which might indicate that the changes we detected in HRQoL were not reflected in parasympathetic tonus or in biomarkers reflecting AF attacks.[38] On the other hand, decreased HR has been validated in our recently published study of MY and patients with PAF,[23] as well as in other studies with yoga.[18,19] This may

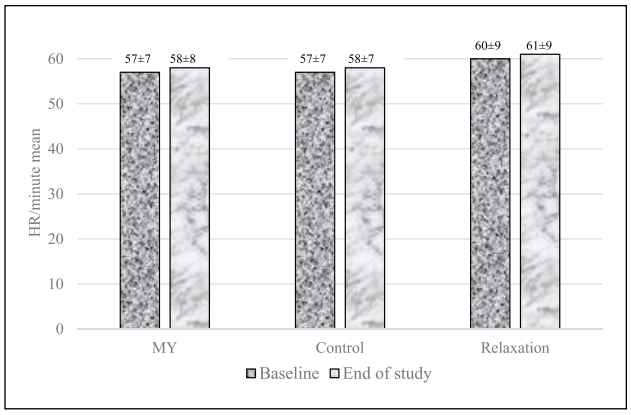

Figure 3. Heart rate (HR) within groups over time. Mean (standard deviation (SD)) in heart rate within MediYoga (MY), relaxation and control groups after 12 weeks.

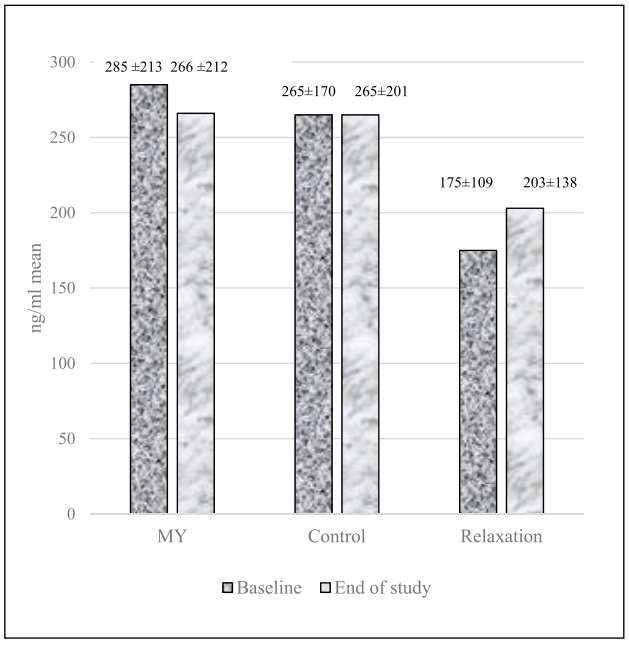

Figure 4. N-terminal pro b-type natriuretic peptide (NT-proBNP) within groups over time. Mean (standard deviation (SD)) in NT-proBNP within MediYoga (MY), relaxation and control group after 12 weeks.

indicate that yoga influences the parasympathetic tonus. Also, our finding of a significant decrease in systolic, as well as diastolic, blood pressure in the MY group indicates that yoga may have affected parasympathetic tonus. This result was also observed in our recently published study[23] as well as in other studies using yoga.[17,39]

Hypertension is an important risk factor in causing cardiovascular events[40] and also the development of PAF and recurrent AF.[41] In our study, participants in the MY group had greater hypertension than those in the relaxation and control groups. According to the literature, patients with hypertension have impaired HRQoL.[42] However, in the present study, this did not influence the HRQoL assessments when adjusted for hypertension.

As both yoga and diabetes mellitus are described as having a role in modifying the autonomic nervous system,[17,43] patients with a diagnosis of diabetes mellitus were excluded.

The main reason for selecting a third group, in this study we selected a relaxation group with music, was to avoid the possible bias of group therapy, as the latter could increase HRQoL.[44]

Furthermore, MY compared with relaxation involves a certain amount of physical exercise. It has been suggested in several studies that physical exercise improves HRQoL in patients with AF.[45,46] Whether yoga has any advantages compared with physical exercise is a question outside the design of this study. Thus, including a fourth group, with physical exercise as an intervention, would have been valuable. However, this was not done for logistical reasons.

Yoga seems to have beneficial effects on HRQoL and may thus be an alternative when looking for a tool in a self-management programme.

Limitations

To the best of the authors' knowledge, this is the largest, randomised study using yoga among patients with PAF.

The episodes of palpitations documented by the participants may not have been caused by AF. The correlation between symptoms of AF and an actual arrhythmia is low[47] and it would thus have been useful to have recorded the ECG during symptoms.

The high number of patients who were screened in the study was explained by incorrect diagnoses (persistent AF instead of PAF), diabetes mellitus, not adjusted thyroid-stimulating hormone (TSH) values and not symptomatic PAF. Another search path of screening the patients could be considered and therefore limit the number of screened patients.

The number of group sessions differed within the groups. Reasons given by the participants were lack of time and illness. There were more dropouts in the relaxation group, due to lack of interest, although the three-arm design strengthens the validity, reliability and results of the study.

Conclusion

MY improved HRQoL parameters and decreased systolic as well as diastolic blood pressure among patients with symptomatic PAF. MY may be adapted as a part of self-management programme, combined with standard treatment, to improve mental health related to the episodes of AF, as well as to reduce blood pressure in this patient group.

Implications for practice

- MediYoga improved mental components in health-related quality of life (HRQoL), which may contribute to an increased feeling of security and therefore a better social situation.
- MediYoga did not improve the physical component summary score in HRQoL, although, this yoga programme is not developed to include movements to increase the exercise capacity and improvement of the physical component.
- In the MediYoga group, blood pressure decreased which may reduce the risk for cardiovascular events.
- The MediYoga programme may be adapted as a self-management programme to complement standard treatment.

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Conflict of interest

The authors declare that there is no conflict of interest.

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