

Relaxation therapy in the background of standard antihypertensive drug treatment is effective in management of moderate to severe essential hypertension

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ABSTRACT

Objective: To evaluate the efficacy of relaxation technique as an adjunctive therapy for control of hypertension.

Methods: From April 2004 to January 2005, with a single blinded randomized controlled design, 220 patients with newly diagnosed essential moderate to severe hypertension who needed drug therapy were included in the study. The study took place in the Hypertension Clinic, Sina Hospital, Tabriz, Iran. Patients were systematically randomized to receive standard plus relaxation therapy, 2 times per week, for 8 weeks, or standard therapy alone. We collected the demographic data, blood pressure measurements, and the data on prescribed drugs.

Results: The mean age of patients was 54 in the case group and 56 years in the control group. The mean blood pressure level (systolic and diastolic) was 192.86/105.16 and 192.09/102.25 mm Hg on admission in the case and the control groups, which decreased to 133.46/81.48 and 146.21/83.57 mm Hg, at the end of study. The difference of blood pressure on admission was not statistically significant, but became significant at the end of the study. Fifty-nine percent in the case group and 36% in the control group had good control of blood pressure.

Conclusion: Relaxation therapy on the background of standard antihypertensive drug treatment results in better control of blood pressure.

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Only 34% of patients with high blood pressure (BP) receive adequate therapy, approximately 50% can lower their BP,¹ and only 27% reach good control of BP.² Hypertension (HTN) is one of the most important risk factors for cardiovascular disease and its treatment is essential for prevention of complications. Like other psychosomatic disorders, non-pharmacologic measures (such as relaxation therapy) are essential for better control of HTN.³⁻⁶ Some kinds of relaxation techniques (RT) have been used for better control of HTN, but results are not uniform in different parts of the world.⁷⁻⁹ Response to biofeedback training as a kind of RT varies greatly, with some patients showing no response and others being able to reduce systolic (SBP) and diastolic blood pressure (DBP), or both by more than 10 mm Hg.^{6,10} Other kinds of RT, particularly, stretch release relaxation (SRR) and progressive muscle relaxation (PMR) therapies were effective in lowering systolic and diastolic blood pressure in Chinese hypertensive patients. The greatest reduction was found in systolic blood pressure.⁷ Progressive muscle relaxation technique should result in treatment of HTN and was reproducible and relatively easy to do by patients at home. Since responses to various types of RT have been non-uniform in different parts of the world, this study addresses whether PMR relaxation therapy as adjunctive to standard therapy is effective in better control of HTN in Iranian hypertensive patients.

Methods. From April 2004 until January 2005, 220 patients with newly diagnosed essential moderate to severe HTN, who needed drug therapy, were included in this single-blinded randomized controlled trial. The exclusion criteria were: 1) acute coronary syndromes, 2) New York Heart Association (NYHA) functional class III or IV of congestive heart failure, 3) chronic renal failure, 4) hypertensive emergencies, 5) pregnancy, 6) patients with musculoskeletal disease who were unable to do relaxation techniques, 7) previous recipients of relaxation techniques, 8) active organ disease elsewhere,

9) significant valvular heart disease, and 10) unwillingness to return for follow-up. Patients were systematically randomized (random allocation) to receive standard plus relaxation therapy, 2 times per week, for 8 weeks (case group), or standard case alone (control group). For patients from case arm (110 patients) group relaxation teaching (groups composed of 2-4 patients) was carried out by a psychiatrist, 2 times per week on the basis of Jacobson's PMR method for at least 30-45 minutes in each session.¹¹ To neutralize the effects of tight control in the case group, the control group had the same attendance schedule but had no relaxation training. On the day of entry, demographic data, clinical and drug history and physical examination findings were collected. Cardiologists checked the diet, drug complications and tolerance and appropriate changes in type and dose of drugs were made, if necessary. Patients of both groups received general instructions for better control of BP, such as salt restriction, weight loss, and regular exercise. In the case group heart rate was measured continually to document a decreased heart rate as a good sign of relaxation technique efficacy.¹² Patients in the case group were asked to practice relaxation techniques at least once a day at home. Blood pressure was measured by a mercurial sphygmomanometer (Kosan Inc.) while the patient was sitting and had been rested for at least 5 minutes. The first reading was discarded and the mean of the next 3 consecutive readings with a coefficient of variation below 15% was used in the study, with additional readings if required.¹³ The cardiologists were unaware of the group allocation of patients. Hypertension was defined as systolic BP (SBP) >140 mm Hg and diastolic BP (DBP) >90 mm Hg. Patients were considered to have HTN if: a) BP >170/110 mm Hg by 3-4 office readings on the same day of visit, b) others who had documented BP \geq 140/90 mm Hg, on several occasions, within the last 2-4 weeks, measured by health personal in their living areas.¹³ All patients

with moderate or severe HTN (SBP \geq 160 or DBP \geq 100 mm Hg) who were candidates for drug therapy,¹⁴ were included in the study. In the current study, we tested the hypothesis that PMR therapy would help in a better control of HTN. Primary end point of the study was an increase in more than 20% of patients achieving good control of HTN in the treatment arm. With the assumption that 30% of hypertensive patients would reach good level of BP in the control group and with primary end point of 20% increase in better BP control among the case group (total = 50%), with 95% confidence and 80% power, 91 patients were required in each group (n=181). By adding 20% loss of follow up in human based studies, 220 patients entered the study at the beginning. Written informed consents were obtained from all patients, and the Local Ethics Committee approved the study.

Statistical analysis. Data were analyzed by the Statistical Package for Social Sciences Version 13 and we used Mantel Haenszel, Chi-square, t-test and mean \pm SD tests. The probability values <0.05 were considered as significant differences.

Results. Among 2578 patients who were visited in our referral outpatient heart clinic, 247 patients had new moderate to severe level of hypertensive that needs drug therapy, and 220 of them were accepted to receive drug plus relaxation therapy (case) or drug therapy alone (control) for treatment of HTN. Each group comprised 110 patients. Ninety-four patients in the case group and 92 in the control group completed their follow up. For better interpretation of results and final analysis, we discarded randomly the data of 3 patients in the case and one patient in the control group. Demographic data of patients are listed in **Table 1**. The levels of HTN¹⁵ in each group of patients are listed in **Table 2**. Blood pressure measurement on admission was used before randomization (methods of measurements described

Table 1 - Demographic data of patients.

Characteristics	Case group (n=91)	Control group (n=91)	Total (n=182)	P-value
Gender (male/female)	44/47	45/46	89/93	0.9
Age (male/female)	54 (54/54)	56 (58/54)	55 (56/54)	0.7
Body mass index (male/female)	28.6/30.5	28.6/30.4	28.6/30.4	NS
Coronary artery disease	5	4	9	NS
Respiratory disease	8	5	13	NS
Gastric disease	4	5	9	NS
Neurologic disease	3	2	5	NS
Hyperlipidemia	7	6	13	NS
Diabetes mellitus	3	5	8	NS
Smoking	11	14	9	NS

Data were expressed as number

earlier). The mean BP (systole/diastole) on admission was 193/105 mm Hg (case group) and 192/102 mm Hg (control group), which decreased to 133/81 (case group) and 146/84 mm Hg (control group) at the end of study. The mean SBP on admission was not statistically different between the groups. Diastolic blood pressure was 3 mm Hg higher in the case group ($p=0.01$). At the end of study control of SBP and DBP was significantly better in the case group ($p<0.001$). If good control of BP means SBP of <140 mm Hg and DBP of <90 mm Hg,¹⁶ 59% and 36% of patients had a good control of BP in the case and the control groups, this difference was statistically significant ($p=0.007$). Drugs needed in each group for control of HTN are shown in **Table 3**. Moderate doses of drugs were prescribed for patients, and diuretics were the most common drugs used in the study. Drugs used in the control group at the end of the study (except for patients who received 4 different classes of drugs) were not statistically different in the case group. No patient in the case group received 4 different classes of drugs for control of HTN, but 10 patients in the control group received 4 drugs, and this difference was statistically significant ($p=0.001$). Loss of follow up to the 16th session (end of study) was 14% and 16% in the case and the control groups (p =not significant).

Discussion. With greater reduction of BP in the case group (12 and 2 mm Hg in systolic and diastolic

BP) at the end of study and the increase in percent of patients who had good control of HTN (59% in the case and 36% in the control group), this study showed that progressive muscle relaxation techniques, in the background of standard drug therapy, may help in controlling BP in hypertensive patients, regardless of their HTN level. Some other studies which used relaxation techniques in adjunctive to drug therapy, reported beneficial results.^{7,11,16,17} Some of these studies applied relaxation therapies for mild HTN only.⁷ Blanchard et al,¹¹ used industry based relaxation techniques for uncontrolled hypertensive patients and, similarly to our findings, reported better control of HTN in the therapy arm of their research. In our study, both groups had the same time schedule for controlling BP, so the difference between patients who achieved good control of BP in the case and the control groups (59% and 36%) was not related to close BP monitoring. More patients in our control group achieved good BP control (36%) than the reported 27% in other studies.² This difference may reflect the effect of close monitoring of patients in our study. Except for 10 patients in the control group, who received 4 different classes of antihypertensive drugs, the numbers of drugs were not different between groups during follow up (p =not significant). It can be assumed that better control of BP in the case group is not related to different drug regimes of patients. Published studies on the effects of relaxation therapy in treatment of HTN have reported different results; some have

Table 2 - The level of hypertension in each group of patients on admission and at the end of follow up. Blood pressure measurement at 16th session of follow up was assumed as end of follow up.

Group	Time severity			
	Case group n (%)		Control group n (%)	
	Admission	End follow-up	Admission	End follow-up
Normal	0	54 (59)	0	33 (36)
Mild hypertension	0	33 (36)	0	37 (40)
Moderate hypertension	25 (27)	4 (4)	28 (31)	19 (21)
Severe hypertension	66 (73)	0	63 (69)	2 (2)
Total	91	91	91	91

Table 3 - Number of drugs used in each group of patients.

Groups	Number of drugs used and the time of study									
	0		1		2		3		4	
	Start	End	Start	End	Start	End	Start	End	Start	End
Case group	0	2	48	11	43	36	0	42	0	0
Control group	0	0	49	8	41	33	1	40	0	10
Total	0	2	97	19	84	69	1	82	0	10
<i>P</i> value			0.88	0.32	0.76	0.75		0.65		0.001

reported positive results,^{7,16,18,19} but others had no clear effects.^{8,20,21} Crowther,²⁰ compared the results of thermal biofeedback training combined with the PMR therapy in their case group and only PMR in their control group for treatment of essential HTN. They concluded that PMR was less effective than combination therapy in lowering BP. This different result may be due to the low sample size and non-existence of a control group without relaxation therapy. In their study, monitoring of BP was less aggressive in the control group. Other studies, with no positive effects of relaxation therapy, either used relaxation techniques as the only treatment strategy, or patients in their control groups had some relaxation trainings. Other studies used multiple kinds of relaxation therapies in their case group.^{8,21} We used relaxation techniques as an adjunctive therapy, so it is different from other studies on the basis of design and follow up. There are several types of relaxation therapies such as SRR, PMR, cognitive imagery relaxation, and some types of meditations. We used PMR because of its better reported results, its simplicity in performance, and its reproducibility by the patient at home.^{22,23} We used office recordings for our BP measurements instead of using out-of-the-office measurements, either with semi-automatic inexpensive devices or with automatic ambulatory recorders. Although this may be a limitation to our study, in the absence of adequate long-term follow-up, evidence of the risks associated with home monitoring, and the limited availability of ambulatory monitoring, office readings will continue to be the basis for diagnosing and management of HTN for most patients.²⁴

In conclusion this study showed that PMR therapy in the background of standard antihypertensive drug treatment is an effective method for better control of HTN.

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References

1. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA* 2003; 289: 2560-2562.
2. Lloyd-Jones DM, Evans JC, Larson MG, Levy D. Treatment and control of hypertension in the community: A prospective analysis. *Hypertension* 2002; 40: 640-646.
3. Kaplan HI, Sadock BJ, editors. Comprehensive text book of psychiatry. Vol 2. 8th ed. Baltimore: Williams & Wilkins; 2005. p. 2142.
4. Fahrion S, Norris P, Green A, Green E, Snarr C. Biobehavioral treatment of essential hypertension: a group outcome study. *Biofeedback Self Regul* 1986; 11: 257-277.
5. Yucha CB, Clark L, Smith M, Uris P, LaFleur B, Duval S. The effect of biofeedback in hypertension. *Appl Nurs Res* 2001; 14: 29-35.
6. Yucha CB, Clark L, Smith M, Uris P, LaFleur B, Duval S. The effect of biofeedback in hypertension. *Appl Nurs Res* 2001; 14: 29-35.
7. Yung P, French P, Leung B. Relaxation training as complementary case for mild hypertension control and the implications of evidence-based medicine. *Complement Ther Nurs Midwifery* 2001; 7: 59-65.
8. McGrady A. Effects of group relaxation training and thermal biofeedback on blood pressure and related physiological and psychological variables in essential hypertension. *Biofeedback Self Regul* 1994; 19: 51-66.
9. Van Montfrans GA, Karemaker JM, Wieling W, Dunning AJ. Relaxation case and continuous ambulatory blood pressure in mild hypertension: a controlled study. *Br Med J* 1990; 300: 1368-1372.
10. Cengiz E, Unalan H, Tugrul A, Ekerbicer H. Biofeedback assisted relaxation in essential hypertension: Short term follow-up of contributing effects to pharmacocase on blood pressure and heart rate. *Yonsei Med J* 1997; 38: 86-90.
11. Blanchard EB, Eisele G, Vollmer A, Payne A, Gordon M, Cornish P, Gilmore L. Controlled evaluation of thermal biofeedback in treatment of elevated blood pressure in unmedicated mild hypertension. *Biofeedback Self Regul* 1996; 21: 167-190.
12. Sultanoff B, Zalaquett C. Relaxation Therapies. In: D Novey ed. Clinician's Complete Reference to Complementary and Alternative Medicine. New York: Mosby; 2000. p. 114-129.
13. Powell TJ, Enright SJ, editors. Anxiety and stress management, Self-help. London: Routledge; 1990. p. 147-149.
14. Kaplan NM, editor. Systemic hypertension, Mechanisms and diagnosis. 7th ed. Philadelphia: Elsevier Saunders; 2005. p. 962-987.
15. The Sixth Report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. *Arch Intern Med* 1997; 157: 2413-446.
16. Smith SC Jr, Allen J, Blair SN, Bonow RO, Brass LM, Fonarow GC, Grundy SM, Hiratzka L, Jones D, Krumholz HM, Mosca L, Pasternak RC, Pearson T, Pfeffer MA, Taubert KA; AHA/ACC; National Heart, Lung, and Blood Institute. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease. *Circulation* 2006; 113: 2363-2372.
17. Patel C, Marmot M. Can general practitioners use training in relaxation and management of stress to reduce mild hypertension? *Br Med J (Clin Res Ed)* 1988; 296: 21-24.
18. Agras WS, Taylor CB, Kraemer HC, Southam MA, Schneider JA. Relaxation training for essential hypertension at the worksite: II. The poorly controlled hypertensive. *Psychosom Med* 1987; 49: 264-273.
19. Davison GC, Williams ME, Nezami E, Bice TL, DeQuattro VL. Relaxation, reduction in angry articulated thoughts, and improvements in borderline hypertension and heart rate. *J Behav Med* 1991; 14: 453-468.
20. Crowther JH. Stress management training and relaxation imagery in the treatment of essential hypertension. *J Behav Med* 1983; 6: 169-187.
21. Hahn YB, Ro YJ, Song HH, Kim NC, Kim HS, Yoo YS. The effect of thermal biofeedback and progressive muscle relaxation training in reducing blood pressure of patients with essential hypertension. *Image J Nurs Sch* 1993; 25: 204-207.
22. Irvine MJ, Logan AG. Relaxation behavior case as sole treatment for mild hypertension. *Psychosom Med* 1991; 53: 587-597.
23. Sheu, Sheila RN, Barbara L. RN, Huey-Shyan L, Chun-Lin M. Effects of Progressive Muscle Relaxation on Blood Pressure and Psychosocial Status for Clients with Essential Hypertension in Taiwan. *Holist Nurs Pract* 2003; 17: 41-47.
24. Lehrer PM. Varieties of relaxation methods and their unique effects. *International Journal of Stress Management* 1996; 3: 1-15.