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 blind randomized controlled design, 220 patients with newly diagnosed moderate to severe hypertension who needed drug therapy, were included in the study. Patients were systematically randomized to receive standard plus relaxation therapy (cases), two times per week, for eight weeks, or standard therapy alone (controls). Demographic data, BP measurements and the data on prescribed drugs were collected.

Results: Mean age of patients was 54 and 56 years in the case and the control groups, respectively. Mean BP level (systolic and diastolic) was 192.86/105.16 and 192.09/102.25 mmHg on admission in the case and the control groups, which decreased to 133.46/81.48 and 146.21/83.57 mmHg, respectively, at the end of study. The difference of BP 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. (Rawal Medical J 2007;32:120-124).

Key Words: Hypertension, Relaxation technique, blood pressure.

INTRODUCTION

Only 34% of patients with high blood pressure (BP) receive adequate therapy, approximately 50% can lower their BP, and only 27% reach good control. 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 (e.g. relaxation therapy) are essential for better control of HTN. Various types of relaxation techniques (RT) have been used for better control of HTN, but results are not uniform in different parts of the world.

Response to biofeedback training as a form 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. Other types of RT, particularly, stretch release relaxation (SR) and progressive muscle relaxation (PMR) therapies were effective in lowering systolic and diastolic blood pressure in Chinese hypertensive patients, where greatest reduction was found in SBP. Since responses to various types of RT have
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been nonuniform in different parts of the world, this study addresses whether PMR therapy as adjunctive to standard therapy is effective in better control of HTN in Iranian hypertensive patients.

MATERIALS AND METHODS

From April 2004 to January 2005, 220 patients with newly diagnosed moderate to severe hypertension, who needed drug therapy, were included in this single blind randomized controlled trial. Patients with acute coronary syndromes, NYHA functional class III or IV of congestive heart failure, chronic renal failure, hypertensive emergency, pregnancy, patients with musculoskeletal disease who were unable to do relaxation techniques, recipients of previous relaxation techniques, active organ disease elsewhere, significant valvular heart disease, and patients unwilling to return for follow-up were excluded from the study. 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 interval and 80% power, 91 patients were required in each group (total = 181 pts). By adding 20% loss of follow up, 220 patients entered the study at the beginning. Written informed consents were obtained from all patients, and the study was approved by our local ethics committee.

Patients were systematically randomized (random allocation) to receive standard plus relaxation therapy, two times per week, for eight weeks (case group), or standard therapy alone (control group). For patients in the case arm (110 patients), group relaxation teaching (groups composed of two to four patients) was done by a psychiatrist (F.R), two times per week on the basis of Jacobson's progressive muscle relaxation (PMR) method for at least 30 to 45 minutes in each session. 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. Diet, drug complications and tolerance were checked by cardiologists (F.A and B.K) 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, like salt restriction, weight loss, and regular exercise. In the case group, heart rate was measured each time to document a decreased heart rate as a good sign of relaxation technique efficacy. Patients in the case group were asked to practice relaxation techniques at least one time per day at home.

Blood pressure was measured by a mercurial sphygmomanometer (Kosan Inc.) in sitting position at least after five minutes rest. The first reading was discarded and the mean of the next three consecutive readings with a coefficient of variation below 15% was used in the study, with additional readings if required. The cardiologists were unaware of group allocation of patients. Hypertension was defined as systolic BP greater than or equal to 140 mm Hg and diastolic BP greater than or equal to 90 mm Hg. Patients were considered to have HTN if: A) BP >170/110 mm Hg by 3 to 4 office readings on the same day of visit, B) patients who had documented BP ≥ 140/90 mmHg, on several occasions, within the last 2-4 weeks, measured by health personal in their living areas. Primary end point of the study was an increase in more than 20% of patients achieving good control of HTN in the treatment arm.
Data were analyzed by SPSS-13 and we used Mantel Haenszel, Chi-square, T-test and Mean ± SD tests. P values equal to or less than 0.05 were considered as significant.

RESULTS
Among 2578 patients who visited our referral outpatient heart clinic, 247 patients were found to have new moderate to severe hypertension who needed drug therapy. Among these, 220 were randomly assigned either to receive drug plus relaxation therapy (case) or drug therapy alone (control) for treatment of HTN. Each group had 110 patients. Ninety four and 92 patients in the case and the control group completed their follow up, respectively. Demographic data of patients are listed in table 1.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group</th>
<th>Case</th>
<th>Control</th>
<th>Total</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td></td>
<td>91</td>
<td>91</td>
<td>182</td>
<td></td>
</tr>
<tr>
<td>Sex (M/F)</td>
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<td>44/47</td>
<td>45/46</td>
<td>89/93</td>
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<tr>
<td>Age (M/F)</td>
<td></td>
<td>54 (54/54)</td>
<td>56 (58/54)</td>
<td>55 (56/54)</td>
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<tr>
<td>Body mass index (M/F)</td>
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<td>28.6/30.4</td>
<td>28.6/30.4</td>
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<td>Coronary artery disease (no.)</td>
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<td>4</td>
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<td>NS</td>
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<tr>
<td>Respiratory disease (no.)</td>
<td></td>
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<td>5</td>
<td>13</td>
<td>NS</td>
</tr>
<tr>
<td>Gastric disease (no.)</td>
<td></td>
<td>4</td>
<td>5</td>
<td>9</td>
<td>NS</td>
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<td>Neurologic disease (no.)</td>
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<td>6</td>
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<tr>
<td>Diabetes Mellitus (no.)</td>
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<td>Smoking (no.)</td>
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</table>

Mean SBP on admission was not statistically different between groups. DBP was 3 mmHg higher in case group (P = 0.01). At the end of study, control of SBP and DBP was significantly better (P=0.001) in the case group (fig.1). Considering SBP of less than 140 mmHg and DBP of less than 90 mmHg as normal, 59% and 36% of patients had good control of BP in the case and the control groups, respectively (P = 0.007).

Moderate doses of drugs were prescribed for patients, and diuretics were the most common drugs used in the study. The number of drugs used in the control group at the end of the study (except for patients who received 4 different classes of drugs) was not different statistically with respect to the case group. No patient in case group received 4 different classes of drugs for control of HTN, but 10 patients in control group received 4 drugs, and this difference was statistically significant (P= 0.001).
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Fig 1. Mean systolic and diastolic blood pressure in each session of follow up in both groups.

![Graph showing mean systolic and diastolic blood pressure over sessions.]

Loss of follow up to the 16th session (end of study) was 14% and 16% (fig. 2) in the case and the control groups, respectively (P= N.S).

Fig 2. Number of patients who completed their follow up in each session.

![Bar chart showing number of patients who completed follow up in each session.]

DISCUSSION

With greater reduction of BP in the case group (12 and 2 mmHg in systolic and diastolic BP, respectively) at the end of study and the increase in number 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 addition to standard drug therapy, may help in better control of blood pressure, in hypertensive patients, regardless of their initial HTN level. Some other studies which used relaxation techniques in addition to drug therapy, reported beneficial results.7,10,13 Some of these studies applied relaxation therapies for mild hypertension only.7 In our study, both groups had the same time schedule for controlling BP, so the difference between patients who achieved good control of blood pressure in the case and the control
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groups (59% and 36% respectively) was not related to close BP monitoring. More patients in our control group achieved good BP control (36%) than 27% reported in other studies.\textsuperscript{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 number of drugs were not different between the two groups during follow up (P= N.S). It can be assumed that better control of BP in the case group is not related to different drug regimes of patients.

Published studies about the effects of relaxation therapy in the treatment of hypertension have reported different results; some have reported positive results\textsuperscript{7,13-15} but others couldn’t show any clear benefit.\textsuperscript{8,16,17} Hahn et al,\textsuperscript{17} 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 hypertension. They concluded that PMR was less effective than combination therapy in lowering blood pressure. But the sample size of the study was small and there was absence of control group. In their study, monitoring of BP was also less aggressive in the control group. Other studies, which couldn't show positive effects of relaxation therapy, either used relaxation techniques as the only treatment strategy, or patients in their control groups had some relaxation trainings. Some studies used multiple types of relaxation therapies in their case group.\textsuperscript{8,17} 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 stretch release relaxation (SRR), progressive muscle relaxation (PMR), cognitive imagery relaxation (COG), 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.\textsuperscript{18,19} We used office recordings for our BP measurements instead of using out-of-the-office measurements, either with semiautomatic 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.\textsuperscript{20} 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


