REVIEW ARTICLE

Nonpharmacologic Control of Essential Hypertension in Man: A Critical Review of the Experimental Literature

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Many nonpharmacologic (behavioral) techniques are being proposed for the therapy of essential hypertension. The research in this area is reviewed and divided roughly into two categories: the *biofeedback* and *relaxation* methodologies. While feedback can be used to lower pressures during laboratory training sessions, studies designed to alter basal blood pressure levels with biofeedback have not yet been reported. The absence of evidence for such changes through biofeedback limits the usefulness of this technique in hypertension control. The various relaxation methods, such as yoga, transcendental meditation, progressive muscle relaxation, and others have shown more promise. With varying degrees of experimental vigor, many of these techniques have been associated with long-lasting changes in blood pressure. The strengths and weaknesses of the various authors' research designs, data and conclusions are discussed, and suggestions for further experimentation are offered.

INTRODUCTION

The problem of essential hypertension facing both the medical community and society in general is, by any standard of measurement, overwhelming. The medical profession is acutely aware that 15–20 percent of the adult population suffers from some degree of hypertensive vascular disease. Abundant statistical evidence exists demonstrating an inverse correlation between the level of arterial blood pressure (BP) and the expected length of life. Persons with hypertension are at dramatically increased risk of death from myocardial infarction, congestive heart failure, stroke, dissecting aneurysm, and renal failure. These risks are combined with those changes in morbidity and mortality associated with the accelerated atherosclerosis, and the renal and vascular changes that occur with prolonged hypertension (1, 2).

The landmark Veterans Administration studies (3, 4) have clearly shown that both the morbidity and mortality of hypertensive vascular disease can be reduced by pharmacotherapy when the patient's diastolic pressures are over 104 mm Hg. They do note that "the difference in the incidence of morbid events between control and treated patients was less clear-cut in patients with blood pres-

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sures below these levels (4)." Other authors (2) state this more strongly: "No data exist which show the benefit of reduction of slight pressure elevations (diastolic pressures of 90 to 104 mm Hg)." Consequently, many physicians are reluctant to commit asymptomatic patients with diastolic BPs in this range to long term pharmacotherapy. Even more significantly, patient compliance in this area is notoriously poor (5). Asymptomatic patients with early, minimal essential hypertension cannot easily be convinced or educated to stay on a therapeutic regime. Many of these "mild" or "borderline" hypertensives identified by the burgeoning number of screening programs are then lost to followup. No one would argue the value of having this group of patients normotensive, if one could do so without subjecting them to the risks attendant on a lifetime of drug therapy.

The problems of making therapeutic decisions for this group of patients prompted efforts to reduce blood pressure without drugs. There have been two major approaches to the nonpharmacologic control of BP The first uses the relatively new experimental techniques of *biofeedback* control of physiologic processes. The second class of approaches relies on a mixed bag of ancient and modern methods which have in common the elicitation of some form of the *relaxation response* (e.g., yoga, transcendental meditation, progressive muscle relaxation, hypnosis).

Within the last few years, a large number of articles have been appearing in the medical, psychological, and lay literature dealing with these techniques and their application to various medical problems (6–9). Many patients are becoming aware of this literature and are asking their physicians for advice. Many more are seeking behavioral "treatment" on their own. It is the purpose of this article to critically review the experimental literature in this area; to aid the reader in counseling those who might be seeking such programs; to point out the strengths and weaknesses in previous studies; and, hopefully, to stimulate the research needed to critically evaluate these new treatment modalities.

BIOFEEDBACK AND THE CONTROL OF BLOOD PRESSURE

Definitions and Theoretical Considerations

Biofeedback has been defined as "the translation of visceral and neural responses into a sensory analogue which is provided to the individual as information about his own physiological responses (10)." Laboratory equipment provides ordinarily unavailable information about the body's internal processes to the individual, literally "feeding it back" to him in some form. In order for the subject to acquire *control* over his physiologic functions, information about the state of the variable being measured is often coupled with "rewards" of some kind. Rewards in human experimentation have been as varied as food, money, the opportunity to view slides, and positive verbal statements. For many subjects, knowledge of success, i.e., feedback that they have made the "correct response" has been more than enough to enable learned control of a variety of visceral responses. In many cases it is not even necessary for subjects to know what physiological responses they are controlling, but only whether or not they are "correct." The feedback itself is often a light, tone, or reading on a dial—some sensory stimulus that tells the subject "how he or she is doing." The list of variables so far shown to be modifiable by these methods in man has included electrodermal activity, heart rate, muscle potentials, various electroencephalographic rhythms, skin temperature, salivation, and many others; including blood pressure (11).

The controversies concerning theoretical issues and terminology in this field are considerable and far beyond the scope of this paper. Much of the theoretical, experimental, and clinical literature concerning all aspects of the use of biofeedback techniques has been reprinted in a number of yearly volumes (12–15).

Review of Research

D. Shapiro and G. E. Schwartz and their co-workers at Harvard were the pioneers and most prolific publishers in this field (10, 16–26). One of the major contributions of this group has been their system for automatically monitoring changes in median systolic or diastolic BP, and providing biofeedback and rewards for small changes in these parameters (26). A standard BP cuff is attached to the subject's upper arm and a crystal microphone fastened over the brachial artery to record the Korotkoff sounds (K-sounds) heard whenever cuff pressure is between systolic and diastolic BP. EKG is simultaneously recorded. Median BP was defined as that cuff pressure at which a K-sound coincided with the subject's heart beat (R-wave of the EKG) 50 percent of the time (actual range was 72–28 percent). The cuff would inflate automatically for 50 heart beats and then deflate for a 30-second rest. Subjects training to increase their systolic blood pressure (SBP) would be given feedback (a 100 msec light-tone combination) on every heartbeat on which a K-sound was present, i.e., SBP> cuff pressure. Those subjects trying to decrease their BP received feedback for every beat *without* a K-sound (SBP< cuff pressure). When subjects were successful in changing their BP in the appropriate direction during the one trial, the pressure in the cuff was changed by 2–4 mm Hg to make the task on the next trial more difficult. When the subject obtained feedback on less than 28 percent of the beats in a trial, the task was made easier by changing the BP by 2–4 mm Hg in the other direction. The same technique could be used to track diastolic blood pressure (DBP), except that with DBP the presence of a K-sound signified a successful decrease (pressure in the occluding cuff> DBP).

In addition to biofeedback, "reinforcement" was also given, usually after every 20 "successes." Reinforcement consisted of viewing projected slides (each worth a five-cent bonus) Slides were three-second views of scenery, nude women, and reminders of the amount of money won so far.

Studies of Normotensive Subjects

Shapiro Group. Most of this group's experiments studied normotensive male college students over a single 35-minute conditioning session. Subjects were not told that they were to control BP, but the presence of the automatic blood pressure cuff and EKG leads probably gave them quite a bit more information than the instructions did about the responses in which the experimenters were interested.

When groups given biofeedback and reward for increasing their median SBP were compared with groups trained to decrease their pressure, small but statistically significant differences were found by the end of a 35-trial training period. The maximum decreases below baseline SBP were on the order of 4–6 mm Hg, with BP increases limited to 1–2 mm Hg (17, 20, 24). The absence of control groups (either trying to change BP without feedback, or whose BP was monitored without attempts to change) makes interpretation of these data difficult. Shapiro et al. (25) added control subjects receiving "random" feedback and reinforcement to this basic design. Again, a difference in SBP was noted between the "increase" and "decrease" groups (with a maximum decrease of 4.5 mm Hg). However, neither of these two groups was found to differ significantly from the randomly rewarded controls. Similar results were found when changes in median *diastolic* BP are followed by feedback and reward (23).

Other Investigators. Studies of normotensive subjects by other groups of investigators have employed slightly different procedures, yet produced similar results. Blanchard et al. (27) used closed circuit TV to show two groups of experimental subjects the plotting of their SBP on graph paper once per minute ("proportional feedback"). Another group was given minute-to-minute "binary feedback" to decrease their BP: they were shown the words "correct" or "incorrect" on the TV screen depending on whether or not their SBP was 5 mm Hg less than baseline. A control group was instructed to try and decrease their BP, but was not given any feedback. Subjects in the increase groups gained a maximum of 5 mm Hg over groups without feedback, while decrease groups lost 4 mm Hg. The binary and no-feedback groups showed no SBP change over the 3–4 experimental sessions.

Elder, Leftwich, and Wilkerson (28) compared four groups given feedback for increasing or decreasing either their SBP or DBP. A green light was flashed for a change of 5 mm Hg; a red light meant no change had occurred. Subjects were instructed to "repeat whatever they had done to earn a green light and avoid repeating anything that preceded a flash of the red signal." Differences between increase and decrease groups emerged, with the greatest difference (11 mm Hg) seen for DBP. That 11 mm corresponded to a 7-mm increase and a 4-mm decrease. No controls were included, but measures of DBP in groups trained to change their SBP were found to decline significantly (by about 4 mm Hg) regardless of whether subjects were being trained to increase or decrease SBP. This finding indicates that some tonic changes (habituation) were probably taking place over the three training sessions that were not related to the feedback procedure.

The largest decreases in SBP found using biofeedback in normotensive subjects were noted by Brener and Kleinman (29). In two separate sessions their five experimental subjects watched a manometer measuring SBP from their index finger every 2–3 heartbeats. Subjects also watched an electromechanical counter; the rate and total on the counter for each 50-second trail was proportional to cuff pressure. They were told to decrease their BP by "mental processes only" keeping the manometer and counter as low as possible. Five control subjects were exposed to the same feedback stimuli, but were told to just pay attention to the displays. BPs prior to the start of training were not reported. Over the twenty trials of the first session, SBP in the experimental group declined by 16 mm Hg. BP in the control group subjects did not change. On the second session, BPs for both groups were lower than during the first, without apparent continued decreases by the experimental group. No information is given as to the amount of time separating the two sessions.

Fey and Lindholm (30) have conducted the most complete and controlled study in this area to date. Using an automated apparatus almost identical to that used by Shapiro and his co-workers, they examined four independent groups of five normal subjects. Three groups were told that the experiment had to do with control of BP and that a screen would light up (feedback) if they were successful. They were to keep the screen lit as much as possible. One of these groups received feedback for increasing their SBP, and one was trained to decrease. The third, "random" group received feedback on 50 percent of the trials, randomly selected. Verbal rewards were also given to these three groups: "good," "very good," and "excellent" depending on the percentage of successes on a given trial. The random group got these rewards in a random order. A fourth no-feedback group was told that they were to watch the screen and count the number of times the light came on (equal to the random group) and tell the experimenter, who replied "Okay, that's fine." By the end of the third 25-trial session the decrease group had lowered their SBP by 10 mm Hg, significantly below the increase, random, and no-feedback groups, which did not differ from each other.

Studies of Hypertensive Subjects

In general, experiments applying biofeedback techniques to the control of BP in patients with hypertensive vascular disease have used fewer subjects and a greater number of conditioning trials in attempts to achieve clinical as well as statistical significance with their results.

The tremendous potential benefits from teaching hypertensives to control their BP with biofeedback is nowhere more clearly illustrated than in the single case reported by Miller (31). He describes one hypertensive patient given beat-to-beat feedback for correctly controlling her BP (both increasing and decreasing DBP). After ten weeks of 45-minute training sessions (5 days/week), her *baseline* DBP (measured when feedback was *not* being given) had declined from a mean of 97 mm Hg to a baseline of 76 mm Hg. Concomitantly she went from being on considerable antihypertensive medications to no medication at all. With follow-up and continued training this patient's BP stayed at this low baseline level without medications despite discharge from the hospital and return to an unusually stressful environment. The author freely admits that uncontrolled factors other than biofeedback might well have produced the observed BP decline, e.g., other medications, the fact that the patient was recovering from a stroke. Subsequent work by Miller with this and other patients has been unrewarding. While no case report can ever be much more than illustrative and suggestive, it is the kind of dramatic clinical change that experimental studies have been trying to duplicate.

Benson et al. (16) studied seven patients with essential hypertension. After a stable baseline SBP had been obtained the authors gave biofeedback and reward for SBP reductions, continuing training for each subject until five consecutive sessions had passed without further decreases. Treatment time varied from 8 to 34 conditioning sessions (30 trials/session). The mean decrease in median SBP from the last five baseline sessions to the end of training was 16.5 mm Hg. The authors noted that the decline obtained occurred at a rate of about 5 mm Hg per conditioning session until the eventual leveling-off took place. It is interesting to note that 5 mm Hg is about the average decrease obtained in normotensives in one conditioning session. The absence of controls is partially compensated for by the extreme stability of the preexperimental baseline BPs in this study. It would have been helpful, however, to discontinue treatment in this study and see if BP returned to pretraining levels.

When feedback for *diastolic* BP was studied in hypertensive patients, Schwartz and Shapiro (19) could not find any persistence of within-session BP decreases from one training session to the next. Their seven patients were first asked to "relax" for five sessions without feedback. They were then given ten feedback sessions plus monetary rewards that were directly related to the decrease in median pressure. Within individual conditioning sessions feedback did produce 5 mm Hg declines in DBP similar to those observed with SBP in their earlier study (16). Unfortunately, these intrasession decreases in DBP did not persist into the next sessions, and tonic BP remained unchanged.

Elder et al. (32) studied three groups of six hypertensive patients. They used a "shaping" technique in which the experimenters followed successively larger decreases in DBP with a feedback signal (a red light). When BP had decreased by 5 mm Hg, feedback would be withheld until new lows occurred. No fixed criteria for making the task harder were described. One group received biofeedback alone. A second group had both biofeedback and "verbal reinforcement" ("good," "very good," or "wonderful," depending on the degree of BP decline on each trial). Subjects in both of these groups were told to lower their pressure any way they could, and that when the red light appeared they had been successful in reducing their BP by at least a small amount. A control group received the same instructions and training, except that no mention was made of the light signal's significance (no feedback). By the end of seven training sessions the verbal-reward subjects had decreased their DBP to 80 percent of their baseline levels (a decrease of 21 mm Hg); the group receiving feedback alone had declined to 92 percent of basal DBP (9 mm Hg); while the control group had not changed their BP significantly.

Elder and Eustis (33) found a maximal 9% decrease in DBP (corresponding to 7.5 mm Hg) in hypertensive patients studied over 9–10 training sessions. Basal DBP was the average of the first ten trials of the first session in which BP was measured. Subjects were then given feedback (green light) on subsequent trials any time their DBP fell below that level. A red signal was given whenever their pressure increased or showed no change. One verbal reinforcement was provided during each half of each 20-trial training session. The largest decreases (9 percent) were for the four subjects who received "massed" trials (daily sessions), while the 18 subjects with "spaced" trials (9 sessions spread over 80 days) showed a maximum decrease of 7 percent below basal levels. The Elder and Eustis (33) study is difficult to interpret for several reasons:

1. Basal blood pressure was measured for only ten trials, and further decreases due to habituation were not ruled out with appropriate controls (the strong possibility that the decreases observed may be due to habituation is supported by the fact that SBP also declined by 7 percent over training sessions without specific feedback);
2. No increase in the difficulty of the task over time ("shaping") took place, even though changing the criterion for biofeedback to occur as soon as easier criteria have been mastered is an essential feature of the biofeedback-conditioning paradigm.

Two recent studies (34, 35) have attempted to prolong and extend gains obtained in the laboratory by having subjects practice BP control at home. Kristt and Engel (35) studied five hypertensive subjects who took their own BP at home for 5–7 weeks before feedback training. The subjects were then hospitalized for three weeks and taught (14 sessions /week) to increase their SBP on the first week, decrease it on the second week, and both to increase and to decrease SBP on the third week. The beat-to-beat feedback technique of Tursky et al. (26) was used (but without rewards). During training, subjects successfully increased or decreased their BP by roughly 15 and 12 mm Hg, respectively, by the last four of the week's 14 training sessions (calculated from authors' Fig. 2 (26)). These changes occurred only *within* training sessions, and no changes occurred in resting (baseline) BP measured at the beginning of each training session. Resting BP was the same at the end of the decrease week as it was at the end of the week of increase training. In addition, the subjects were taught to simulate the biofeedback procedure at home: first they measured their SBP with a standard cuff; then they were to try to make the K-sound disappear; after doing so they could determine the new (lower) SBP by deflating the cuff until the sound appeared again. They practiced 4–30 times /day at home after discharge and mailed in daily pressure records. The subjects were retested at one and three months after training. On these followup visits, *baseline* SBP was found to be 3–18 percent below values obtained during feedback training (this corresponds to a maximum decrease of about 16 mm Hg, calculated from the authors' Fig. 5 (26)). Unfortunately, no statistical analyses could be performed on these data. The patients' BP as measured at home went from a mean of 162 /94 before training to 144 /87 three months after training was over. This decrease was statistically significant for SBP in four of four patients followed, and for DBP in two of four (even though training was only for decreasing SBP). While the results of this uncontrolled study of only five patients must be interpreted with caution, the suggestion that at-home training techniques may be effective in lowering baseline (resting) BP levels certainly warrants further controlled investigation.

Goldman et al. (34) gave seven hypertensive subjects the same kind of biofeedback for decreases in systolic BP during nine weekly two-hour sessions (25–30 trials /session). Four hypertensive control subjects had their BP monitored by the same apparatus during three weekly two-hour sessions. Experimental subjects were given a complete explanation of the feedback setup and told that the greater the number of lights they produced, the greater would be the decrease in their BP. They were also encouraged to practice at home for a half-hour /day "however they managed to produce lights and tones in the laboratory." These subjects did not take their own BP. Controls were told to relax (without feedback) as much as possible, both during sessions and at home for 30 minutes /day. As seen in other studies, experimental subjects showed within-session decreases in SBP (Mean = 7 mm Hg) as a result of training, while control subjects did not. More interestingly, resting *diastolic* BP (which was only measured once before each training session began) decreased by 15 mm Hg from the beginning of the first session to the beginning of the last. No similar change in SBP occurred from one session to the next. In control subjects, neither systolic nor diastolic pressures changed from one session to the next. Unfortunately, controls were only tested for three weeks, versus nine weeks for the experimental subjects. Seven subjects in this study were "unable to complete" biofeedback training; more information about them might have revealed some unknown biases in patient selection or self-selection that may have contributed to the results observed.

Not all controlled studies have had positive results. In a recent paper Frankel et al. (36) reported the "clinical ineffectiveness of a combination of psychophysiologic therapies." They randomly assigned their 22 essential hypertensive patients to three groups One group received 20 training sessions utilizing biofeedback (for DBP), EMG training, autogenic exercises, and "other relaxation techniques." Another group got 20 sessions of "pseudo-feedback" (i.e., feedback not contingent on BP changes). Controls had only weekly BP measurements. No group's BPs declined from their preexperimental baselines, although two patients did reduce their BPs with treatment, maintaining their reductions for over a year.

DISCUSSION

Enough studies have been done to make it clear that BP can be significantly reduced during biofeedback training. In normotensive college students, small but statistically significant differences are found between groups trained to change their BP in opposite directions, even within one short training session. Decreases amount to about 5 mm Hg (systolic or diastolic) in one session, with as much as 10 mm Hg noted by Fey and Lindholm over three training sessions (30). Hypertensive subjects given more extensive training have been able to decrease their BP by significantly larger amounts, as much as 16 mm Hg systolic (16) and 21 mm Hg diastolic (31). The differences between hypertensive and normal subjects may be due in part to factors other than the increased amount of training. It may simply be easier to lower "abnormal" BP. In addition, the hypertensive subjects were usually told that it was blood pressure that they were changing; the normal subjects were not given this information. With this knowledge, the motivation of the hypertensive patients may well have been significantly higher.

The importance of individualizing training for each hypertensive patient and continuing until maximal improvement has been reached was well demonstrated by Benson et al. (16). They found a wide range of BP decreases in their seven patients (0–34 mm Hg SBP) and an equally wide range of training times needed for each subject to reach asymptomatic performance (8–34 sessions). The failure of the combination of biofeedback with other techniques noted by Frankel et al. (36) needs to be further explored.

The ultimate usefulness of the biofeedback methodology in treating hypertension cannot be determined until important questions are answered in a number of methodological areas.

CONTROLS Most of the differences obtained in studies of normotensive subjects involved statistically significant groups-by-trials interactions without significant differences between "increase" and "decrease" groups (20, 23, 28). When a "random" control group was included, no differences between it and the other two groups were found (25). Other deficiencies in controls have been noted in the discussion of specific experiments. Appropriate control groups for studies of this type would include (a) a group receiving the same instructions to change BP as the experimental groups, but getting no feedback; (b) a group receiving equal exposure to the feedback stimuli, but without instructions to change BP; and (c) subjects without feedback or instructions. The best controlled of the feedback experiments in normal subjects was by Fey and Lindholm (30). They had control groups comparable to the first two mentioned and found a 10-mm Hg decline in SBP after three daily sessions, without change in the increase, random, or no-feedback groups.

SYSTOLIC VS. DIASTOLIC BP In general, it is felt that reductions in DBP are more clinically significant than SBP changes since DBP more closely reflects the level of peripheral vascular resistance. Decreases in both diastolic and systolic pressures can be obtained with biofeedback. In several studies, training in decreasing SBP (especially when continued at home) has resulted in prolonged reductions of diastolic pressures as well (28, 34, 35). In general, it seems easier to decrease SBP than increase it, the reverse being true for DBP (21, 28).

NATURE OF THE FEEDBACK STIMULI AND METHODS. At some point in the evolution of this research there must be a careful determination of which of the feedback stimuli and methods are most effective. There are important questions to be answered. Is it the light, the tone, or the combination of the two that is needed for optimal training? What is the contribution of the added rewards used in some studies and missing in others? Both beat-to-beat and minute-to-minute feedback have been used successfully; which is the most effective? Should feedback be continuous (e.g., manometer) or "binary" (correct-incorrect)?

CHANGES IN BASELINE (RESTING) BP. While most of the successful studies reported showed within-session changes in BP which sometimes became larger in successive training periods, there are only a few experiments that report measuring baseline BP from one session to the next. (Baselines were usually determined at the start of a day's training, before feedback was instituted.) For any technique to be effective in the clinical reduction of BP, baseline changes must, of course, occur. Most of the studies in normal subjects lasted for only one session. In the studies in which measures were taken over successive sessions no change in baseline BP occurred (25, 29, 30). Appropriate controls to rule out habituation are particularly important for the study of this variable, since Elder et al. (28) found a significant decrease in diastolic pressure from session to session in all normotensive subjects reinforced for changing their *systolic* BP regardless of the direction of SBP change. Similar results were found in hypertensive subjects by Goldman et al. (34). In hypertensives, Schwartz and Shapiro (19) specifically looked for baseline changes in DBP between feedback sessions and did not find any. Similarly, no differences were found by Kristt and Engel (35) between the resting pressures taken at the end of the week on which their hypertensive subjects were successfully trained to increase their BP and pressures after the decrease week. However, Miller's case study showed striking changes in basal DBP over an extended number of sessions (31).

FOLLOWUP. It is most important to determine how long the effects of feedback training persist, with or without home practice. Most experiments that have looked into this have studied the patients' ability to control BP when brought back to the laboratory after varying intervals. An equally important variable to determine at followup is the persistence of changes in basal pressure that may have developed over the training period. Elder et al. (28) found no effect of feedback training on basal pressures in normotensives when they were brought back to the laboratory three weeks after the last of their three days of training. Elder and Eustis (33) gave a standard training trial to their hypertensive subjects thirty days after the end of training. They found (without statistics) that SBP was back to basal levels, but DBP was still decreased. (Their patients had been rewarded for decreases in DBP, but both DBP and SBP had declined during training.) Elder et al. (32) showed that the average decreases they obtained in DBP by their last training session did not disappear over a one week interval, even when the followup session did not provide feedback. Kristt and Engel (35), whose patients used home practice sessions to lower SBP, found a decrease in baseline BP three months after their three formal weeks of training had been completed. Their subjects also demonstrated a continued ability to control BP in the three-month followup session. Unfortunately, none of these followup findings could be analyzed statistically.

"RELAXATION" AND THE CONTROL OF BLOOD PRESSURE

Under the general category of "relaxation" techniques fall a diverse group of ancient and modern religious and secular practices.[1] These can be considered self-induced, nonpharmacologic altered states of consciousness. They include Transcendental Meditation (TM), various forms of Yoga, Progressive Muscle Relaxation, Hypnosis, and Autogenic Training. All of these have been used, either recently or in the past, to control BP and

[1]While Benson and his associates (37) have used the term "relaxation response" to refer often to changes specifically associated with the practice of Transcendental Meditation, "relaxation" is used here to refer to those general physiological and psychological effects common to all of the techniques mentioned.

many other physiological and psychological variables in practitioners. Relaxation techniques are being studied more extensively in the West today than ever before, largely because of their alleged beneficial effects on mental and physical health, and for the overall sense of well being that they are believed to impart to their practitioners.

Benson et al. (37) offer an excellent review of the various techniques. In it they note four basic elements that are common to the various methods, and which are considered necessary to elicit the relaxation response in man: (a) a mental device, a constantly repeated stimulus (sound, word, phrase, fixed gaze at an object) intended to produce a "shift from logical, externally-oriented thought;" (b) a passive attitude, disregarding distracting thoughts; (c) decreased muscle tone; and (d) quiet environment, usually with the eyes closed. Trained instructors are believed to increase the efficiency with which the various methods are learned.

Physiologic changes during the practice of the various techniques include, in part: decreases in oxygen consumption, carbon dioxide elimination, respiratory rate, heart rate, and muscle tension; with increases in skin resistance and EEG alpha-wave activity (38–41). Physiologically, relaxation is believed to be "an integrated hypothalamic response which results in a generalized decreased sympathetic nervous system activity, and perhaps also increased parasympathetic activity (37)." It is believed to be a part of the body's protections against stress, balancing the "flight or fight" defense reactions that mobilize the body's systems for action. Essential hypertension has been seen by many investigators as an imbalance between these two systems with the activating system (increased sympathetic activity) predominating.

EXPERIMENTAL DATA

Transcendental Meditation

Transcendental Meditation (TM) is currently a very widely practiced form of yoga with millions of followers worldwide. As taught by its developer, the Maharishi Mahesh Yogi (42), it is allegedly easily learned in four consecutive daily sessions. The practitioner is instructed in a systematic way of repeating a word or sound (mantra) without specific concentration. Little change in life style is required beyond 15–20 minutes of meditation, twice daily, in a comfortable position, with the eyes closed.

Wallace, Benson, and Wilson (41) measured physiological changes before and during 30–40 minutes of TM in "normal" experienced meditators. Oxygen consumption, carbon dioxide elimination, respiratory rate, minute ventilation, arterial pH and base excess, and blood lactate were all decreased. Skin resistance and EEG alpha and theta activity markedly increased. Respiratory quotient, systolic and diastolic BP, mean arterial pressure, arterial pO_2 and pCO_2, and rectal temperature did not change. These changes are consistent with the authors' description of TM as a "wakeful hypometabolic physiologic state" different from that found in sleep, hypnosis, and autosuggestion. BP (measured intra-arterially) did not change during meditation in these normal subjects. Their average BP, however, was noted to be extremely low, 106 (± 12)/57 (± 6). Their subjects (78 percent male) ranged from 17–41 years of age (mean=24) and had practiced meditation for an average of 30 months. The mean BP in the general population for men 20–24 years old is 123 (±14)/76 (±10) (43).

In a recent study of a "normotensive working population" Peters et al. (44) found lowered systolic and diastolic pressures when "relaxation response breaks" resembling TM (38) were taken during the day. Most significantly, the declines occurred during periods of the day when subjects were *not* practicing relaxation.

Almost all of the studies of the effects of TM on BP in *hypertensive* subjects have been done by Benson and his associates in Boston (45–49). Recruiting their subjects at introductory lectures of the Students International Meditation Society, they offered to pay for the TM sessions of volunteers who "knew they had hypertension," and who were willing to delay their instruction. To be included, they had to have SBP > 140 and/or DBP > 90 on the last of 3–4 measures over a 20-minute period. "Premeditation" (baseline) measures were taken over a 5–6 week period. On a given day measures were made until BP was stable (no change > 5 mm Hg, systolic or diastolic, from previous measure). All readings were taken using a Random-Zero Sphygmomanometer (50) which is designed to eliminate observer bias. Subjects were then given the standard TM course and returned for followup BP measurements at times that were "independent" of their twice-daily meditation periods. Subjects who change medications or diet were discarded from the studies (48).

In general, both systolic and diastolic pressures declined significantly in meditating hypertensive subjects over followup periods ranging from 9 to 63 weeks. This was true in all but one study (reported in 45, 46) in which only SBP declined. Mean decreases in the different studies were on the order of 6–15 mm Hg systolic and 0–6 mm Hg diastolic. It must be re-emphasized that these reduced BPs occurred during "nonmeditation" times of the day.

The lack of a control group whose BP was followed for an equivalent period of time without TM training hampers the interpretation of these studies. However, the relatively long baseline period of stable BP measures before TM training, coupled with the return of BP to premeditation levels in nine subjects who stopped meditating (45), suggests that the effects observed were due to the practice of TM. The fact that nothing was known about the etiology, duration, or natural history of the subjects' hypertension also makes it difficult to evaluate these studies. Subjects with longstanding hypertension accompanied by vascular changes might well be less likely to respond to this form of therapy, as would the 10 percent of patients with definable pathology (secondary hypertension). Self-selection factors after the experiments began may well have altered the results. For example, in one study (48) 50 of 64 original subjects were dropped from the experiment because they had changed their diet or medications. Whether the changes they made were due to beneficial or adverse effects of TM on their disease is unknown. The effects of duration of TM training need to be further studied, since in two studies the greatest changes in BP had occurred by

30 days after TM training with no further declines after that point (47, 48).

A few studies have been conducted outside of Benson's laboratory. Blackwell and his co-workers (51) studied seven medicated hypertensive patients whom they had trained in TM. They measured blood pressures in the clinic and had their patients take their own BPs at home. Significant declines occurred in a majority of their patients, averaging 7.5/6.1 mm Hg at home and 4.2/1.6 in the clinic. At a six month followup visit (with the patients continuing to meditate) home BPs had decreased by 13.0/7.3, while those measured in the clinic were down 2.6/4.0 from baseline levels. Six of seven also showed a decline in a psychological test's measure of "state anxiety." The absence of controls, and the small number of subjects must limit this study's contribution. In addition, the largest changes were in self-measured blood pressure; and such data must be viewed with caution.

In contrast with the preceding studies, Pollack et al. (52) felt that they were *not* successful in lowering BP with TM in their 20 hypertensive patients. Subjects first had baseline pressures established during "multiple measures" for three months before taking the standard TM course. Followed monthly after TM training, their SBP did decline significantly for the first three months (by about 10 mm Hg), but DBPs never differed from baseline measures. In the last three months of the six monthly followup sessions the patients' blood pressures returned to pre-TM levels. Unfortunately, no estimate of patient compliance with the meditation regime was offered. The authors did note that in spite of the failure of TM to control BP, 70 percent of their subjects expressed a "strong desire" to continue meditating.

Muscle Relaxation

Progressive Muscle Relaxation (PMR) is a technique developed by Edmund Jacobson (53, 54) to achieve conscious discriminative control over skeletal muscle groups and to induce a very low level of generalized muscle tonus for the purpose of controlling anxiety states. Jacobson believed that anxiety and muscle relaxation produce opposite physiologic states, and therefore could not coexist (37). During PMR training the subject is placed in a comfortable position in a quiet setting. While maintaining a "passive attitude," instructions are given to systematically tense and relax various muscle groups (54–56). PMR has found its greatest application in the practice of behavior modification, particularly in the therapy of phobias (55, 56). Jacobson, however, made the first reference to the possible relationship between PMR, tension reduction, and BP as long ago as 1920 (57). In 1939, he confirmed a direct correlation of BP with skeletal muscle tension by directly measuring muscle action potentials in normal and hypertensive subjects (58).

The technique has only occasionally been employed in studies of BP reduction in hypertensives. Shoemaker and Tasto (59) compared three groups of hypertensive subjects matched for their pretreatment DBPs. One group had six 80-minute relaxation sessions when they listened to repeated presentations of a tape recording designed to induce PMR. A second group was given biofeedback on the same six sessions: they were told to try and decrease their BP while they watched a physiograph showing their systolic and diastolic BPs every 90 seconds. Control subjects just had their BP measured over the same number of sessions. Statistically significant decreases in BP occurred from the beginning to the end of each separate session for subjects in the relaxation group. Decreases averaged 6.8/7.6 mm Hg. There was no significant change for either the control or biofeedback groups. There was no significant downward trend in BP for any group from one session to the next, indicating that this degree of relaxation training was not likely to influence BP away from the experimental setting. The fact that these patients were not instructed to practice relaxation outside the laboratory may have influenced the results.

Redmond et al. (60) also observed a fall in BP when PMR instructions were given to five hypertensive patients for three five-minute sessions. Within-session decreases averaged 13.8/5.5 mm Hg. When subjects tried to induce PMR themselves (after an unspecified period of practice at home) BP did not fall. Interestingly, Redmond et al. (60) found that when these same subjects were simply told repeatedly to decrease their BP (e.g., "make your heart beat slower and less forcefully;" "make your vessels less resistant to the flow of blood") the changes produced were the same as with experimenter-induced PMR. This study did not examine any between-session BP changes.

Brady, Luborsky, and Kron (61) trained three graduate students with "labile hypertension" in "Metronome Conditioned Relaxation (MCR)." This technique (62) consists of taped instructions to relax muscle groups accompanied by the sound of a 60 beat-per-minute metronome. A long habituation period preceded training (2–4 weeks of daily half-hour control sessions, five days per week) in order to stabilize "baseline" DBP. Training consisted of four weeks of daily half-hour MCR sessions (five days/week). BP was measured "at another time of day" from MCR. Two of their three subjects decreased their DBP significantly below baseline by the end of their training (by 2.8 and 5.9 mm Hg). Discontinuation of MCR was followed by return of these two patients' BPs to baseline. When one resumed practice of MCR at home for six months his DBP again declined (from 95.6 to 82.1 mm Hg). Brady et al. (61) also report data from one additional subject who practiced MCR at home and took his own BP. After 11 weeks his DBP, recorded at a time different from MCR sessions, declined from 85 to 80 mm Hg ($p < .05$). After discontinuing the tapes for three weeks pressures returned to baseline. With reinstitution of daily MCR his DBP declined to an average of 75.4 mm Hg and remained stable over six months, allowing him to discontinue his antihypertensive medications without subsequent change in his BP.

Combined "Yoga and Biofeedback"

Patel (9, 63–68) has developed a relaxation technique which she describes as "psychophysical relaxation exercises based on yogic principles and reinforced by biofeedback instruments (63)." Her method, which has much in common with PMR and TM, involves having the patient lie comfortably on a couch with instructions to "go limp" and systematically relax various parts of the body. Subjects are to concentrate on their breathing and repeat "relaxed" to themselves in a "type of Transcendental Meditation." Biofeedback is not related to BP at all, but serves as an aid to relaxation: subjects were connected to a device which measured skin resistance (in some cases muscle potentials or alpha-waves were used); the device gave off a constant audio signal which decreased in pitch as the patient relaxed.

In the first uncontrolled study of 20 patients who had hypertension of various etiologies and who were taking assorted medications, three months of training (0.5 hour/session, 3 sessions/week) produced dramatic results (65). Mean blood pressures measured at the beginning of each session (*before* relaxation training) decreased from 160/102 on the first session to 134/86 at the last. Five patients were able to stop their medications altogether, while seven others decreased their dosages by 33–60 percent. These changes were maintained by practice at home for at least 3–5 months after formal training had stopped (64).

The absence of controls in that experiment prompted a followup study adding age- and sex-matched hypertensive subjects retrospectively to the first experiment (66). These patients came three times/week for three months, and were asked to rest on the couch for a half-hour without relaxation training. These subjects did not change their BP significantly over this period. Experimental subjects from the earlier study were given no more training, but were seen once a month for a year to have their BP measured. They were encouraged to continue practicing their relaxation and meditation at home. By doing so they maintained their previously established lowered BPs, staying an average of 20 mm Hg systolic (±11) and 14 mm Hg diastolic (±8) below their pretraining levels for the 12 months of followup. BP in controls did not change during their nine-month followup period. One complication of this study, in addition to its retrospective design, is the fact that drug dosages during the study were adjusted to keep BP in the "satisfactory range." Although adjustments were presumably made similarly for both experimental and control subjects, the lack of more information concerning changes in medications raises some doubts about the findings.

In a more tightly controlled prospective study Patel and North (68) randomly assigned 34 patients with hypertension (etiologies not stated) to experimental and control groups. All subjects had DBPs ≥110 mm Hg on two separate days prior to the study. Patients were asked not to change their medications during the experiments, and all BPs were measured "blind" by a practical nurse. Experimental subjects were seen for two half-hour sessions per week for six weeks, and BP was taken at the beginning and at the end of each session. During these times experimental subjects were shown films and slides about hypertension and the physiology of relaxation; biofeedback and self-control were explained; and they were given training in the yoga/biofeedback technique. They also received much verbal encouragement, and were shown their BP records. They were urged to practice their relaxation twice a day, and to incorporate relaxation and meditation in their daily activities by using events such as red lights, telephones, looking at the time, and doorbells as signals to check for tension and to practice relaxation briefly. Controls, who were seen for the same periods, relaxed in a reclining chair or couch without specific instructions or biofeedback.

By the end of the twelve weeks *both* groups had significantly decreased their BP, but the experimental group showed a statistically greater decline than controls (26/9 mm Hg for experimental subjects; 15/4 mm Hg for controls). Experimental subjects maintained their BPs at their new low levels over a 3-month followup period, during which they were encouraged to continue practicing relaxation. Over the same followup period the controls' BPs returned to their prior level. When the controls were given 12 weeks of yoga/biofeedback training, their BP decreased again, this time by 28/15 mm Hg. It is important to note that these lowered BPs were measured at the beginning of each session, and not after the day's relaxation training had taken place. They are thus more likely to represent tonic BP levels that might be expected to persist outside the laboratory. The sustained and significant BP declines in this study, coupled with the presence of appropriate controls make this one of the more significant experiments in the use of relaxation techniques in hypertension.

Patel has also applied her technique to modifying the responses of her hypertensive patients to stress (63). Thirty-two of her patients with essential hypertension first had their pressures measured before and after an "exercise test" (climbing a nine-inch step 25 times), and a "cold pressor test" (their hand in 4°C water for 80 seconds). Then half of the patients (randomly selected) received six weeks of training and home practice in the yoga/biofeedback technique while controls returned only for pressure measurements. The two stress tests were then repeated. While no absolute BP levels are reported, the relaxation-trained group showed significant improvement in both their maximum BP-rise during stress, and the amount of time required for BP to return to pre-stress measures. This was true for both SBP and DBP changes after "cold," and for DBP after "exercise."

In her more recent work, Patel (69, 70) has applied her successful behavioral techniques to the lowering of serum levels of cholesterol, triglycerides, and free fatty acids as well as BP.

Hypnosis and Relaxation

In their 1959 review of the literature on physiological changes associated with hypnosis, Crasilneck and Hall (71) found no evidence that the hypnotic state could affect BP directly. BP could be changed, however, by the induction of relaxation or strong emotions while subjects were hypnotized. Paul (72) combined hypnosis with PMR in normotensive subjects, finding decreases in both "subjective tension and distress" and in "physiologic arousal" (as measured by heart rate, respiration, tonic muscle tension and skin conductance). BP was *not* measured.

The one study of hypertensive subjects was conducted by Deabler et al. (73) using a combination of hypnosis and PMR. They examined 21 hospitalized patients with essential hypertension. Two experimental groups (one taking and one not taking antihypertensive medications) were given 8–9 training sessions at half-day intervals. Each session consisted of a period of PMR followed by hypnosis, with BP measured several times. Around the fourth session patients were given the opportunity to self-relax and self-hypnotize; and practice at home was encouraged. Controls went to seven similarly timed sessions, but only had their BP taken. By the end of the experiment, systolic and diastolic BPs at the end of a training session were 14–20 percent lower than basal pressures taken before the first training session began. (This corresponds roughly to a decline of 25/16 mm Hg by calculation from their data.) In general BPs were lower after hypnosis than after PMR, and significant differences from basal levels appeared earlier in training with the hypnotic suggestions. More importantly, both drug and no-drug groups had managed to reduce their SBP into the normotensive range (<140 mm Hg) by the end of the hypnosis phase of session three and to keep within normal limits during subsequent sessions. Control subjects did not change their BP. Unfortunately, no data are reported to indicate if any between-session decreases in tonic BP levels were occurring in hypertensive experimental subjects to go along with their dramatic within-session changes.

Yoga ("Shavasan")

"Yoga" is a collective term for many variant Hindu techniques of meditation and/or physical exercises involving control of posture and respiration (37). Datey et al. (74) taught "Shavasan," a yogic exercise, to 47 patients with hypertension of mixed etiologies (essential, renal, arteriosclerotic) who practiced it for a half-hour daily. In Shavasan the supine practitioner lies limply in a specified position with eyes closed and adopts slow rhythmic diaphragmatic breathing with regular pauses before and after inspiration. The subject is to attend particularly to his nostrils and the temperature of inspired and expired air. (The authors note (74) that it is "difficult to perform this exercise in the presence of nasal congestion".) Mastering this technique usually took about three weeks of daily sessions, and resulted in a respiratory rate of 4–10/minute (normal = 14–18).

Results depended on the nature of the patients' medication regimen. In subjects taking placebo medications, mean BP declined significantly, from 134 to 107 mm Hg. In patients whose BPs were well controlled on medications (mean BP = 102) the experimenters didn't "try" to decrease BP, but rather hoped to change their patients' drug requirements, which declined by 32 percent. A third group of subjects whose BP was "inadequately controlled in spite of drugs" showed no significant changes in either mean BP or drug requirement. No control groups were employed, nor was it possible to determine exactly when in the session BP was determined (before or after Shavasan). Consequently, the effects of this technique on tonic BP levels could not be assessed.

Psychologic Relaxation

Stone and DeLeo (75) studied 19 newly-diagnosed hypertensive patients. Mean BP was over 105 mm Hg in over 50 percent of 14 pretreatment determinations. Fourteen subjects were treated with "psychologic relaxation" (PR) taught in five 20-minute training sessions, while five control subjects received no training. No medications were given and sodium was not restricted. All subjects returned every month for BP determinations by a nurse "blind" to what treatment group the subjects were in. PR was described as a "technic based on Buddhist meditation exercises designed to elicit a relaxation response." Patients were advised to sit in a comfortable chair in an area free from distraction, to loosen tight clothing and to sit upright and relax their muscles. They then counted their breaths subvocally for 10–15 minutes. This was done twice a day. After six months the experimental subjects had decreased their blood pressures by 9/8 mm Hg supine and 15/10 mm Hg upright. Mean pressure declined by 12 mm Hg in both the supine and erect positions. No change occurred in the controls' BP over the same period. This patient population was significantly younger (mean = 28 years) than that in other studies, and their hypertension was borderline (baseline around 141–144/90); yet this simple technique significantly lowered their BPs when compared with appropriate controls. Since BPs were measured in the office without relation to relaxation periods, the declines may well represent changes in resting (tonic) BP.

Autogenic Training

Autogenic training is a "psychophysiologic form of psychotherapy which the patient carries out himself by using passive concentrations upon certain combinations of psychophysiologically adapted stimuli (76)." It is a technique of medical therapy designed to enable the lower brain centers to activate the relaxation response. Therapy is based on six exercises developed by the German neurologist J. H. Schultz which deal with heaviness of the limbs, cardiac regulation, breathing, feelings of warmth on various parts of the body, and coolness of the forehead. Luthe (76) has reported briefly on a series of cases treated with the standardized autogenic training methods for 6–8 weeks (77): "of 79 cases with primarily 'essential' or 'labile' hypertension, 37 showed no improvement, 19 responded well, and in 29 others some definite improvement, was observed" (76). Klumbies and Eberhardt (78) reported on 26 patients with BPs averaging 165/100 whom they treated with autogenic training. They found statistically significant declines in BP beginning one month after training started. After four months the average BP was 130/80. No further decreases occurred when the patients were followed up to five and a half months. In 22 of their 26 patients the BP had normalized by this time. Unfortunately, no controls were studied in either of these interesting reports.

DISCUSSION

The bulk of the evidence indicates strongly that practicing some of the various relaxation techniques can successfully lower BP in patients with essential hypertension. In contrast with the literature on biofeedback, the data from the relaxation studies provide relatively more information on which to base further investigations.

For example, *control groups* are more prevalent in the relaxation literature, and have taken into account both the patients' medications and the etiology of their hypertension. While the presence or absence of appropriate controls is discussed under the description of each experiment, it is important to note here that some of the most impressive studies have also been particularly well controlled: Deabler et al. (73) (25/16 mm Hg reduction); Patel and North (68) (26/9 mm Hg); and Stone and DeLeo (75) (9–15/8-10 mm Hg). This is in contrast to the biofeedback studies in which the most impressive results were found in the absence of controls (31). On the negative side, of the two studies illustrating failure of relaxation techniques, one had control groups (36) and one did not (52). The Frankel et al. (36) controlled comparison of "a combination of psychophysiologic therapies" (see the discussion of biofeedback techniques) can also be included in this list of failures.

In addition, most studies have emphasized changes *in baseline (tonic) BP*. In fact, this is the most significant facet of the BP declines noted in patients practicing relaxation: lowered BP can be documented at times separate from the practice of the relaxation response. There is no comparable controlled experimental evidence in the biofeedback literature for BP reduction in the absence of biofeedback.

A significant number of these experiments have also provided long-term *followup* of their patients (with statistical analyses of the results). In general, baseline BP declines have persisted for as long as they have been measured in the various successful studies: 9–63 weeks for TM, three months to a year for yoga and biofeedback (66, 68), and six months with psychologic relaxation (75). The importance of followup is illustrated by Pollack et al. (52) who found significant declines in SBP for the first three months of TM practice, declines that disappeared in the next three months of the study.

An essential feature of the successful studies in this area had been daily *home practice* of the relaxation technique. (Home practice of biofeedback also appeared to be of value in at least one study.) It is important to note that the one study in which PMR training that was effective in the laboratory did *not* lead to any basal BP change was the one in which no home relaxation practice occurred (59). With home practice, PMR related techniques *have* shown encouraging BP changes (61).

An extremely important feature of the relaxation methodologies is the *subjective improvement* they seem to offer their practitioners. Brady et al. (61) reported that their subjects slept better and felt more relaxed after PMR. Deabler et al. (73) found that the "vast majority" of their patients, "both medicated and nonmedicated, reported improvement in their hypertensive symptoms as a consequence of using muscle relaxation and hypnosis." Relief included decreases in the frequency and intensity of headaches, decreased anxiety, easier and deeper sleep, and an increased ability to relax. Similar findings were reported by Datey et al. (74) in patients using their "Shavasan" technique, and testimonials to TM are often found in this literature (51, 52). This reported "sense of well being" experienced with these techniques may prove to be an important factor in maintaining the prolonged compliance with the relaxation regime that would be needed to avert the long term morbidity of chronic hypertension.

More research is clearly needed to define the aspects of the various relaxation techniques that contribute most strongly to the reductions in BP observed, and to isolate the technique or modification which will give the maximal benefit. In addition, the possible side effects of relaxation therapy need to be investigated before it can be offered on a large scale. Benson et al. (37) note no side effects with the chronic practice of the relaxation response (TM) for two limited daily periods. They note that more frequent practice has led to "withdrawal from life" and symptoms ranging from insomnia to psychosis. Lazarus (79), however, reports a number of patients with psychiatric problems (including a serious suicidal attempt) associated with the practice of TM.

In general, compared with the experiments conducted to date with biofeedback, the studies of relaxation techniques have gone considerably further towards the eventual possibility of providing practical nonpharmacologic control of BP outside the laboratory. No elaborate apparatus is needed. Patients can practice on their own time. There is some evidence that BP reductions persist throughout the day. Subjective benefits of therapy may aid compliance. Treatment can be extended to the large group of asymptomatic individuals with borderline hypertension whom physicians may be reluctant to treat pharmacologically, and who may be unwilling to accept drug therapy for an indefinite period of time.

SUGGESTIONS FOR FURTHER EXPERIMENTATION

In addition to the experiments and control procedures suggested in the rest of this paper, certain features need to be added to any new studies in this area.

Selection of Subjects

Etiology. Experiments to date have varied greatly in the rigor with which they have substantiated the etiology of their patients' hypertension. For example, Shoemaker and Tasto (59) recruited subjects by sending letters to faculty and staff at Colorado State University requesting "those persons experiencing essential hypertension, not secondary hypertension, to apply for the program." Other studies have not controlled for, or even mentioned etiology. All patients in studies of this type should have a complete workup (2), including whatever specialized studies are needed to diagnose secondary hypertension. Separate studies in patients with hypertension of various known etiologies may prove valuable.

New laboratory techniques may be of value. Recently investigators have demonstrated that serum dopamine beta-hydroxylase (DBH) levels may be useful in discriminating patients with fixed or labile essential hypertension (high DBH) from those with secondary hypertension (low DBH) (75, 80–82). In an extensive review of the role of sympathetic nervous system dysfunction in essential hypertension, DeQuattro and Miura (83) have stressed the importance of distinguishing among patients on the basis of their plasma renin levels and plasma volume.

Duration of Hypertension. Experimental studies in patients with long-standing essential hypertension may be complicated by varying amounts of secondary organ system damage (renal, vascular) which may be very difficult to control for. It is essential for the success of controlled studies in this area that the duration of the subjects' hypertension be known and preferably controlled for. Ideally, patients without retinal evidence of disease should be used in preliminary work.

Race and Sex. Because of the higher incidence of hypertensive vascular disease in males and in Blacks, effect of these variables on nonpharmacologic therapy needs to be measured.

Medications. Studies to date have been extremely variable in the degree of control exerted over medications. Some have discarded subjects who change medications; others have included subjects on none or multiple medications, allowing changes during the experiment. It seems preferable that patients in experiments on the *nonpharmacologic* control of blood pressure should not change their medication regime during their participation in the experiment. Ideally, they should be on no medications. If groups taking antihypertensive drugs must be included, they should have been at stable dosages for a significant period of time prior to the experiment. Using groups of subjects, all taking the same medications may be helpful. Some means of assessing compliance with the drug regimen should be employed. Dietary sodium should be considered in the same category as pharmacologic agents and should either be controlled (with appropriate compliance measures) or unrestricted in all subjects.

Appropriate Control Groups

There is no question that every effort must be made to use controls treated exactly the same as experimental subjects with only the presence or absence of BP training separating the two. They should ideally be matched with respect to initial BP, duration of hypertension, age, sex, race, and medications. The dramatic decline in BP in *control* subjects in the Patel and North (68) experiment underscores the need for such groups as part of the experimental design.

A multitude of placebo effects and experimental biases can influence blood pressure and confound the results of studies in this area (8). Placebo antihypertensive medications are known to significantly lower BP by as much as 56/19 mm Hg (84). Behavioral manipulations can have "beneficial" effects as well: BPs can decline over time even in the absence of treatment (85). Suggestion, even just instructing patients to lower their BP, can have significant effects (60, 86). Carnahan and Nugent (87) have shown that hypertensives using a sphygmomanometer at home can lower BP (as measured by a nurse) in comparison with subjects who don't take their own pressure. The influence of such phenomena can be avoided only by the most stringent adherence to the principles of treating control and experimental groups as identically as possible.

Measurement of BP

The role of subject and experimenter bias in BP measurement is best eliminated by having BP measured by someone "blind" to the subjects' treatment group or by using a device such as the Random-Zero Sphygmomanometer (50). Having the patient take his or her own BP introduces another possible source of "experimenter" bias into the experimental design. From earlier discussion it is clear that there is an absolute necessity for a stable baseline of BP measurements prior to the institution of therapy, coupled with a need to monitor basal BP changes in every patient. (Basal BPs are those measured at times unassociated with practice of the experimental BP-lowering technique under study.) Ideally a series of blood pressure recordings taken at random times of the day during the subject's normal activities and sleep would convey the most information concerning tonic BP levels; both before and after the institution of treatment. Portable, programmed, automatic devices which are worn by the patient have been developed and would be extremely useful in this research (88–93). Although the daily wearing of such a device would be impractical and might actually interfere with BP control, the use of such a system for determining 24-hour basal BP on one or two days both before and after a course of experimental therapy would be of tremendous value in assessing treatment effects outside of the standardized experimental situation or "doctor's-office" setting. For studies of the biofeedback and BP control the Tursky et al. (26) technique has been the most useful and most thoroughly studied. (For more information on BP measurement techniques see Benson (94) and Krausman (95).)

Standardization of Treatment Techniques

It will be difficult for new researchers in this area to replicate or expand on existing work until authors provide more complete descriptions of their methods. Biofeedback methodologies are usually clearly defined. TM (42), PMR (54), and the relaxation response of Beary and Benson (38) are, however, the only relaxation techniques that are well described and likely to be easily replicated. The others, including those used in the successful and well-controlled studies of Patel (9) and Stone and DeLeo (75), could probably not be conducted by other investigators studying their reports. Until such descriptions are made available, new research should concentrate on those successful techniques which are easily replicated. These are the methods, if successful, that could most readily be adopted by the general medical community in the treatment of hypertension.

Nonspecific Psychological Factors

Many of the factors important in nonpharmacologic treatment of hypertension are difficult to quantify or control. Yet, they need to be accounted for in research on this topic. Patel (9, 96) has stressed the combined importance of *all* of the several aspects of her treatment, which consists only in part of yoga/biofeedback training. In addition, her patients receive considerable education about hypertension and biofeedback, coupled with a great deal of encouragement and support to motivate their incorporation of relaxation into their daily lives. The strong doctor-patient relationship established through this close contact appears to be an essential part of therapy. Patel points out that "If doctors refer their hypertensive patients to TM centers or yoga classes, they may be in for a disappointment (96)." This may reflect the well-documented role of support and psychotherapy in the treatment of hypertension [see Shapiro et al. (8)]. These factors, too, need both to be controlled in the studies of other variables, and to be studied in a controlled manner themselves. The absence of these difficult-to-measure factors may account for some of the recent failures of relaxation techniques to alter BP when studied by other investigators (36, 52).

Compliance

Techniques must be devised to determine the level of subject compliance, particularly with paradigms requiring regular home practice. The effectiveness of the patient's self-induced BP-control should be assessed periodically to determine if he or she is performing the technique involved correctly. If relaxation is used, objective evidence of relaxation in each subject at various intervals may be helpful (e.g., measurement of skin conductance, muscle potentials). Such measures would allow for correlation of the success of an individual subject in performing the technique with his success in lowering BP.

Followup

The need for long-term evaluation of the success of these measures is paramount. Particular attention must be paid to the drop-out rate in comparing various methods. Whether or not the ideal can be reached (that is, the prevention of serious hypertension, the prolongation of the eventual need for pharmacologic control, the delay or elimination of the morbidity of progressive disease) can only be assessed by careful long-term followup of patients trained in these techniques.

SUMMARY

In response to the near-epidemic incidence of essential hypertension, a steadily increasing number of nonpharmacologic (behavioral) techniques are being applied to the control of blood pressure (BP). In reviewing this literature, the various methods can be divided into *biofeedback* and *relaxation* methodologies.

Biofeedback refers to the use of electromechanical devices to inform subjects about changes in their BP on a second-by-second or minute-by-minute basis. Subjects attempt to control their BP by mental means and are given "feedback" (information) by means of signals and rewards when they are successful in changing their BP in the desired direction. The data reviewed indicate clearly that the biofeedback technique can lower BP by 5–10 mm Hg in both normal and hypertensive patients during a short training session. However, the application of biofeedback to hypertension-control requires that basal BP be lowered outside of the laboratory. The requirement for sophisticated equipment and the absence of trials intended to demonstrate lowered basal BP must limit the usefulness of biofeedback to experimental settings at this time.

Relaxation methods are represented by such techniques as yoga, transcendental meditation, progressive muscle relaxation, and several others. They are widely practiced, easily learned, and have the advantage of requiring no elaborate equipment and being suitable for daily home practice. Several well-controlled studies have been reported and replicated showing prolonged and significant changes in BP in hypertensive subjects. Studies have shown persistence of beneficial effects for followup periods as long as a year. Importantly, these changes have generally been noted in "basal" BP readings, taken at times of the day when the particular relaxation technique was *not* being practiced. Subjective improvements in patients' anxiety and hypertensive symptoms attributed to these techniques may aid in compliance, a major problem with any antihypertensive therapy.

With further studies, using improved experimental designs, nonpharmacologic techniques may one day be generally available for the treatment of essential hypertension. They may be particularly useful in the many asymptomatic individuals with borderline BP elevations

whom physicians may be reluctant to treat pharmacologically, and who may be reluctant to accept an indefinite course of drug therapy. Nonpharmacologic methods may also be suitable additions to the traditional, staged pharmacologic management of more severe hypertension.

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