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EMPIRICAL CONTRIBUTIONS

Effectiveness of Biofeedback and Relaxation Training in Reducing the Side Effects of Cancer Chemotherapy

Thomas G. Burish and Richard A. Jenkins
Vanderbilt University

Assessed the effectiveness of electromyographic (EMG) and skin-temperature (ST) biofeedback and relaxation training (RT) in reducing the aversiveness of cancer chemotherapy. Eighty-one cancer patients, equated on several individual-difference variables, were randomized to one of six groups formed by a 3 (EMG Biofeedback, ST Biofeedback, No Biofeedback) × 2 (RT, No RT) factorial design. Outcome was assessed with physiological, patient-reported, and nurse-reported indices taken over five consecutive chemotherapy treatments. RT patients showed decreases in nausea and anxiety during chemotherapy and physiological arousal after chemotherapy. EMG and ST biofeedback reduced some indices of physiological arousal but had no other effects on chemotherapy side effects. These findings suggest that RT can be effective in reducing the adverse consequences of chemotherapy and that the positive effects found for biofeedback in prior research were due to the RT that was given with the biofeedback, not to the biofeedback alone.

Key words: conditioned side effects, antiemetics, chemotherapy, EMG biofeedback, skin-temperature biofeedback, relaxation training

The side effects of cancer chemotherapy can be so aversive that some patients regard them as worse than the cancer itself and are noncompliant with their treatment or reject further treatment altogether (e.g., Wilcox, Fetting, Nettesheim, & Abeloff, 1982). These symptoms can include hair loss, fatigue, loss of appetite, and intense gastrointestinal symptoms such as nausea and vomiting. In addition to experiencing these pharmacologically induced symptoms, approximately one in three chemotherapy patients also suffers from conditioned side effects such as nausea, vomiting, and increased negative affect (Carey & Burish, 1988). Conditioned symptoms usually develop after an association has been established between the side effects caused by chemotherapy and various stimuli (e.g., smelling the drugs or seeing the chemotherapy nurse) that are associated with the administration of the drugs. Conditioned side effects can occur before chemotherapy is administered, in which case they are called *anticipatory* side effects, or during and after chemotherapy, in which case they may occur in combination with pharmacological side effects.

The treatment of conditioned symptoms by antiemetic drugs has not been completely effective (Laszlo, 1983), in part because once these symptoms develop, they can continue even if the antiemetics block the pharmacologically induced side effects. Moreover, even when such medications are effective, they often produce side effects (e.g., sedation) or administration demands (e.g., need for hospitalization) that limit their usefulness or acceptance among patients. These limitations have prompted researchers to recommend the use of various behavioral methods of antiemetic control, including at least two types of biofeedback training—electromyographic (EMG) and skin-temperature (ST) biofeedback.

Both EMG and ST biofeedback involve providing information to patients about moment-to-moment changes in a specific physiological response to allow patients to learn to control that response. Moreover, both can serve as cognitive distractors, helping patients to direct their attention away from stimuli (e.g., the sight of the drugs) that might elicit negative responses and onto the feedback tone or the physiological changes it signals (Carey & Burish, 1988). However, the rationale for providing such feedback to reduce the aversiveness of cancer chemotherapy differs considerably for the two procedures. EMG biofeedback is aimed at teaching people to produce deep muscular relaxation, which is presumed to lead to a generalized relaxation response (Danskin & Crow, 1981; Stoyva & Budzynski, 1974). It has been suggested that such relaxation reduces the side effects of chemotherapy by reducing generalized physiological arousal, reducing muscular contractions in the gastrointestinal tract, or increasing the threshold (i.e., decreasing the sensitivity) of the chemoreceptor trigger zone, which is believed to coordinate the vomiting response (Carey & Burish, 1988). In contrast, ST biofeedback is aimed at helping people to control peripheral blood flow and has been shown to lead to improvements in circulatory and vascular disorders (e.g., Raynaud's disease; Freedman, Ianni, & Wenig, 1983). Morrow (1990) demonstrated that a patient's ST drops several degrees immediately before vomiting—often leading to reports of coldness by chemotherapy patients. By teaching patients to increase or at least prevent a decrease in ST, ST biofeedback might interfere with conditioned vomiting as well as the nausea that usually precedes it.

Although there has been much speculation as to the effectiveness of biofeedback for reducing the conditioned side effects of cancer chemotherapy (e.g., Redd et al., 1991), to date only two published studies have explored this issue—both of which were pilot projects. The first study (Burish, Shartner, & Lyles, 1981) used a single-subject design to examine the combination of EMG biofeedback and progressive muscle RT with guided relaxation imagery in reducing autonomic arousal and conditioned nausea and anxiety. Results indicated that, during the training and follow-up sessions (as com-

Requests for reprints should be sent to Thomas G. Burish, 221 Kirkland Hall, Vanderbilt University, Nashville, TN 37240.

pared to the baseline session), the patient generally reported feeling less anxious and nauseated during chemotherapy and exhibited less physiological arousal both before and after chemotherapy. The second study (Shartner, Burish, & Carey, 1985) involved the assignment of 12 chemotherapy patients to groups that received EMG biofeedback plus RT, ST biofeedback plus RT, or no behavioral treatment. Results indicated that both treatments were more effective than no treatment in reducing conditioned side effects in some patients.

Both studies indicated that the use of biofeedback was related to improved outcome, but, in each design, biofeedback training was confounded with RT. RT alone is effective in reducing the side effects of cancer chemotherapy (Burish, Carey, Krozely, & Greco, 1987; Burish & Lyles, 1981; Carey & Burish, 1987; Lyles, Burish, Krozely, & Oldham, 1982) and shares several of the presumed mechanisms through which EMG biofeedback and, to a lesser extent, ST biofeedback exert their effects. For example, like EMG biofeedback, RT is presumed to produce a general relaxation effect and to direct patients' attention away from stimuli in the treatment setting and onto relaxing feelings and imagery (see Carey & Burish, 1988). It may be that the treatment effects in the biofeedback studies were due to RT rather than to the biofeedback procedures or their interaction.

The purpose of this study was to provide the first rigorous test of the effectiveness of biofeedback in reducing the conditioned side effects of cancer chemotherapy. To determine whether the results of prior research were due to the effects of EMG or ST biofeedback, the effects of RT, or their interaction, a 3 (EMG Biofeedback, ST Biofeedback, No Biofeedback) × 2 (RT, No RT) factorial design was used. In accordance with prior research that has suggested that feedback from multiple sites is more effective than feedback from a single site (e.g., Shirley, Burish, & Rowe, 1982), and to replicate the type of feedback used in prior research with cancer patients, multiple-site EMG biofeedback and ST biofeedback were used in the present study. Outcome was assessed with a variety of measures that included physiological, patient-reported, and nurse-reported indices taken over multiple chemotherapy sessions. We predicted that RT, alone or in combination with either biofeedback procedure, would significantly reduce the adverse reactions to chemotherapy. In the absence of any research assessing the isolated effects of EMG or ST biofeedback on chemotherapy patients, specific predictions were not made regarding the effectiveness of the biofeedback procedures. However, we hypothesized that, should the biofeedback procedures prove effective, the combination of RT and ST biofeedback would be the most effective treatment because the two procedures were likely to provide supplementary rather than overlapping mechanisms of action. That is, RT, like EMG biofeedback, is presumed to produce a general relaxation response, whereas ST biofeedback is presumed to interfere with the temperature changes that normally accompany the vomiting response.

METHOD

Patients and Experimental Design

Eighty-one (27 male, 54 female) adult, ambulatory patients with histologically confirmed cancer who were receiving intravenous outpatient chemotherapy at Vanderbilt University Medical Center participated in the study. Patients were referred from consecutive admissions, had at least two prior chemotherapy treatments (M = 5.28, median = 4, SD = 4.21), and (a) had reported pretreatment conditioned anxiety and nausea before and/or (b) were receiving a chemotherapy protocol that was likely to produce postchemotherapy nausea and vomiting.[1] The patients ranged in age from 18 to 75 years (M = 49.0 years) and had a median education of 12.0 years. The primary sites of cancer were breast (n = 21), leukemia and related diseases (n = 20), ovarian (n = 13), and lung (n = 8). The majority of patients (n = 57) received antiemetic medication—prochlorperazine, droperidol, or promethazine hydrochloride—that was held constant during the study.

Patients were assigned to one of six groups formed by a 3 (EMG Biofeedback, ST Biofeedback, No Biofeedback) × 2 (RT, No RT) factorial design according to a stratified random assignment procedure that equated patients in conditions as close as possible on site of cancer, chemotherapy emetogenicity,[2] and antiemetic medication. The EMG-biofeedback group had 17 patients, the ST-biofeedback group had 12 patients, the RT group had 13 patients, the EMG-biofeedback-plus-RT group had 12 patients, the ST-biofeedback-plus-RT group had 12 patients, and the no-treatment control group had 15 patients.

Outcome Measures

Physiological measures. Systolic blood pressure (SBP), diastolic blood pressure (DBP), and pulse rate were obtained before and immediately after each chemotherapy infusion. SBP and DBP were measured at the brachial artery by the auscultatory method; pulse rate was obtained by manually palpating the radial artery.

EMG and ST data were monitored in all patients, whether or not they received biofeedback, and were scored for three periods: (a) the minute before chemotherapy was begun, (b) the middle minute of the chemotherapy infusion, and (c) the first minute after the chemotherapy infusion was completed.

EMG activity was recorded on a J & J M-55 electromyograph with the frequency bandpass set at 100 to 200 Hz and displayed in microvolts on a J & J LGS digital scorekeeper. EMG activity was monitored from the frontal, masseter, neck (sternomastoid), and forearm flexor areas using silver/silver chloride cup electrodes filled with Hewlett Packard Redux paste, using the standard placements suggested by Lippold (1967). The EMG level from each site was input into separate J & J preamplifiers, and the amplified output was averaged across sites to produce one integrated feedback signal. EMG-biofeedback patients received the feedback by means of a tone that increased in pitch as their integrated EMG level increased and decreased in pitch as their EMG level decreased.

ST was monitored with two J & J T-67 thermistors attached to the volar surface of the distal phalange of the index and little fingers

[1] The first 102 consecutive patients who met the selection criteria were approached to participate in the study. Eleven declined to participate, and 2 were not included after the initial interview indicated that they had previously received biofeedback or RT. Of the remaining 89 patients, 81 (91%) completed the study and are included in the analyses. Six patients dropped out after one session, and 2 patients dropped out after two or more sessions; 2 of the dropouts declined to receive additional chemotherapy, and the other 6 dropouts continued chemotherapy but declined to participate any further in the study.

[2] Emetic potencies of chemotherapy drugs and protocols were rated by clinic physicians and nurses on a scale ranging from *no nausea and vomiting* (1) to *intense nausea and vomiting* (5), and the mean of these ratings was used as the emetic potential score. Data indicate that emetogenicity is related to the development of conditioned nausea and vomiting (e.g., Morrow, 1984).

of the arm that was not being used for the chemotherapy infusion. Mean ST across both sites was recorded (in °F) on an Autogenic Systems 5600 or J & J LGS-100 and was fed back to patients in the ST-biofeedback condition by means of a pulsating tone that increased in pitch as ST increased and decreased in pitch as ST decreased. Thermal home training was accomplished with a Bio-Temp Products Biotic-Band, which uses thermochromic liquid crystals to monitor finger temperature to 0.5 °F resolution.

Patient reports. Several different scales were completed by patients. A shortened version of the Multiple Affect Adjective Check List (MAACL; Zuckerman, Lubin, Vogel, & Valerius, 1964) was administered immediately before the prechemotherapy physiological measures were taken and after the postchemotherapy measures were taken. The MAACL yields self-report indices of anxiety, depression, and hostility. On completing chemotherapy, patients were asked to rate, on separate 7-point scales ranging from *not at all* (1) to *extremely* (7), the extent to which they felt anxious and nauseated during the chemotherapy treatment.

Nurse reports. Nurses who administered the chemotherapy were asked to rate, on separate 7-point scales ranging from *not at all* (1) to *extremely* (7), the extent to which the patient appeared anxious and nauseated during the chemotherapy treatment. Nurses also recorded the frequency of vomiting during the chemotherapy session. Nurses were unaware of the ratings made by the patients and of the patients' physiological data.

Procedure

All patients were first told the general purpose of the study and were given specific information about the condition to which they had been assigned. They were then asked to read and sign an informed-consent form. Patients participated in four training and one follow-up session held in conjunction with five sequential chemotherapy treatments. The average length of time between treatments was 15 days. Each session began approximately 45 min before the chemotherapy was scheduled to begin. Patients were escorted to the treatment room and seated in the treatment chair, and the SBP, DBP, pulse rate, and patients' self-reports were collected. The procedures then differed for patients in each condition.

Biofeedback-alone conditions. After the prechemotherapy-dependent measures were collected, the therapist described in detail the purpose and nature of EMG or ST-biofeedback training. Patients were told that the purpose of the training was to help them become as relaxed and comfortable as possible, thereby reducing the unpleasantness of the chemotherapy and the likelihood of some side effects. After giving a description of the biofeedback procedure, the therapist attached the EMG electrodes and ST thermistors to the appropriate sites and demonstrated the relationship between the feedback tone and either muscle tension or ST, depending on the experimental condition. Patients were given suggestions on how to control the tone. For example, EMG-biofeedback patients were told that they might find it helpful to imagine relaxing and letting go of any muscle tension in their body. ST-biofeedback patients were told that they might find it helpful to relax and to imagine that their fingers and hands were very warm and comfortable. All patients were told that biofeedback is a skill that requires active participation and frequent practice. The feedback was then begun, with patients being given feedback for 10-min periods separated by 2-min no-feedback periods. Approximately 5 min into the second feedback period, the nurse entered the room and began the chemotherapy infusion.

Approximately 2 min after the infusion was completed, the feedback tone was turned off, and the postchemotherapy measures were collected. The physiological recording equipment was then removed, and patients were instructed to practice reducing their EMG levels or raising their ST levels daily at home. ST-biofeedback patients were given a small temperature band that indicated changes in finger temperature to aid them in their home practice. EMG-biofeedback patients were told to focus on their feelings of relaxation during the home practice and to try to produce the types of feelings they noticed when the feedback tone indicated low EMG levels.

Procedures during the second, third, and fourth training sessions were similar to those of the first session except that the therapist began by answering any questions the patient may have had and by inquiring about the home practice rather than giving an overview of biofeedback.

The fifth chemotherapy session was a follow-up session during which patients were not given the biofeedback equipment but were asked to relax and reduce their muscle tension or increase their ST on their own.

RT condition. RT patients were treated similar to those in the biofeedback conditions except that they were instructed in and received progressive muscle RT and guided relaxation imagery instead of biofeedback. Patients were told that the goal of RT was to enable them to become as relaxed and calm as possible, thereby making chemotherapy less unpleasant and reducing the severity of the side effects. As with the biofeedback patients, it was emphasized that relaxation is a skill requiring participation and practice. Patients were instructed in the progressive muscle RT procedure recommended by Bernstein and Borkovec (1973). The therapist then suggested that further relaxation was possible with imagery. Patients identified imagery that would be especially relaxing. The actual RT procedure then began. Approximately 20 min later, the nurse began the chemotherapy treatment. Two minutes after the infusion was ended, the RT was discontinued, and the postchemotherapy-dependent variables were collected. Patients were told to practice RT daily at home and were given a tape of the first session as an aid. Similar procedures were followed during the second, third, and fourth training sessions.

As with the biofeedback patients, the fifth chemotherapy treatment was a follow-up session during which patients were instructed to relax on their own by using the procedures they had learned during prior sessions and during their home practice between sessions. In other respects, the session was similar to the training sessions.

Biofeedback-plus-RT conditions. EMG-biofeedback-plus-RT patients and ST-biofeedback-plus-RT patients received a rationale emphasizing that biofeedback and RT together would help the patient to relax and to reduce the unpleasantness of chemotherapy and the severity of the side effects. Patients received RT first and then biofeedback training. At the end of the session, patients were instructed to practice the RT and biofeedback procedures at home and were given the relaxation tape and, if in the ST-biofeedback condition, the ST band.

No-intervention control condition. After patients were seated in the treatment chair, and the prechemotherapy-dependent measures were collected, they were told that, to become as relaxed and comfortable as possible, they should lay back in the chair and relax until the chemotherapy began. They were told that previous research had indicated that, if a patient was relaxed before and during chemotherapy, the experience of chemotherapy was less unpleasant, and the severity of side effects was lessened. About 20 min later, the nurse entered the room and administered the chemotherapy according to routine clinical procedures. The same procedures were followed during each of the subsequent chemotherapy treatments.

RESULTS

Analysis of Demographic and Baseline Session Data

To determine whether there were any differences among conditions on individual-difference variables, patients were first compared with respect to age, sex, education, number of prior chemotherapy treatments, site of cancer, emetogenicity of their chemotherapy medications, and antiemetic medications using either 3 (EMG Biofeedback, ST Biofeedback, No Biofeedback) × 2 (RT, No RT) factorial analyses of variance (ANOVAs) or chi-square analyses, as appropriate. The analyses revealed that there were no significant differences among conditions on any of these variables.

Next, similar 3 × 2 ANOVAs were conducted to determine whether there were any baseline differences among conditions on the presession-dependent variables collected before the first chemotherapy treatment. The analyses revealed no significant effects on any measure, suggesting that the groups were equivalent at the baseline time on the various outcome measures.

Analysis of Biofeedback and Relaxation Manipulations

Before determining whether biofeedback and RT were effective in reducing the distress of chemotherapy, it was necessary to determine whether patients actually learned to reduce their EMG or ST levels. Therefore, 6 (Group) × 5 (Session) × 3 (Measurement Block Within Session) ANOVAs were conducted on the EMG and ST data. The analyses revealed a significant main effect for group on the EMG data, $F(5, 71) = 2.74$, $p < .03$.[3] Subsequent multiple comparisons revealed the expected differences: EMG-biofeedback-plus-RT patients had the lowest EMG levels ($M = 50.3$), followed by ST-biofeedback-plus-RT patients ($M = 54.4$), RT-alone patients ($M = 56.8$), and EMG-biofeedback–alone patients ($M = 55.1$). The EMG levels of each of these groups were significantly lower than those of the control group ($M = 71.6$), with ST-biofeedback–alone patients ($M = 60.2$) falling among these groups and not significantly different from any of them. These data indicate that the EMG-biofeedback and RT interventions were effective in teaching patients to alter the targeted muscle tension response.

The analyses of the ST data revealed a Group × Session interaction that approached significance, $F(20, 300) = 1.50$, $p < .08$. Subsequent multiple-comparison tests indicated that ST-biofeedback–alone patients during the first three sessions ($Ms = 91.2$ to 92.1) and RT-alone patients during the first five sessions ($Ms = 92.0$ to 93.2) had significantly higher ST levels (indicating less autonomic arousal) than EMG-biofeedback patients did (session $Ms = 84.5$ to 85.9). Patients in the other conditions had ST levels that were intermediate and not significantly different from these extremes. These data suggest that ST biofeedback was somewhat effective in increasing ST levels but that RT was even more effective.

Analyses of Outcome Measures

To determine whether there were differences among conditions as a result of the treatment interventions, separate 3 (EMG Biofeedback, ST Biofeedback, No Biofeedback) × 2 (RT, No RT) × 5 (Session) between–within multivariate ANOVAs (MANOVAs) were initially conducted on conceptually related dependent measures.[4] Prechemotherapy and postchemotherapy measurements were analyzed separately because they represented different psychological and physiological processes (prechemotherapy measurements reflected side effects largely or exclusively influenced by associative learning, whereas postchemotherapy side effects reflected both learned and pharmacological factors). Significant MANOVAs were followed with univariate analyses of specific dependent measures; those that involved repeated measures included the Greenhouse–Geisser adjustment to the degrees of freedom. Significant univariate analyses were further probed with Duncan multiple-range tests. Finally, effect sizes for significant MANOVAs were calculated with the Pillai–Bartlett procedure (ηPB^2) recommended by Serlin (1982); effect sizes for significant univariate analyses were calculated with the omega-square statistic.

Nausea and vomiting. The MANOVA on patient and nurse ratings of nausea and nurse records of patient vomiting generated a main effect for RT, $F(2, 63) = 2.88$, $p < .06$, $\omega^2 = .09$, and an RT × Biofeedback interaction, $F(4, 126) = 2.51$, $p < .05$, $\eta PB^2 = .15$. Further inspection of the data with univariate analyses revealed only a significant RT × Session interaction for both patient-rated nausea, $F(4, 324) = 2.58$, $p < .04$, $\omega^2 = .10$, and nurse-rated nausea, $F(4, 324) = 3.44$, $p < .01$, $\omega^2 = .06$. These data are shown in Figure 1. Multiple-comparison tests revealed that RT patients during the first two sessions reported similar levels of nausea compared to no-RT patients. However, RT patients during the last three sessions reported significantly ($p < .05$) lower levels of nausea than no-RT patients. Also, no-RT patients showed a significant rise in nausea with successive chemotherapy treatments, perhaps indicating a con-

[3] All F values not reported were not statistically significant or were not of theoretical interest (e.g., involved only a within-subject effect). Degrees of freedom reflect the use of orthogonal polynomials to detect linear trends. This results in degrees of freedom that vary between analyses, despite constancies in the number of patients and the number of variables. Although MANOVA uses a linear model, significant changes may actually have a curvilinear shape. Orthogonal polynomials test for more equivalence in change over time, as reflected by a more "straight line" shape to the data plot (Marascuilo & Levin, 1983).

[4] Because EMG- and ST-biofeedback procedures differ, both procedurally and in the a priori hypothesized mechanism by which they might reduce the distress of chemotherapy, analyses that assess their independent effects are presented in detail. However, for the sake of completeness, additional 2 (Biofeedback, No Biofeedback) × 2 (RT, No RT) × 5 (Session) analyses were also conducted to assess whether different results would be generated by collapsing across biofeedback conditions. These analyses revealed that combining the biofeedback interventions into a single group produced no new effects for biofeedback compared to analyzing the biofeedback groups separately.

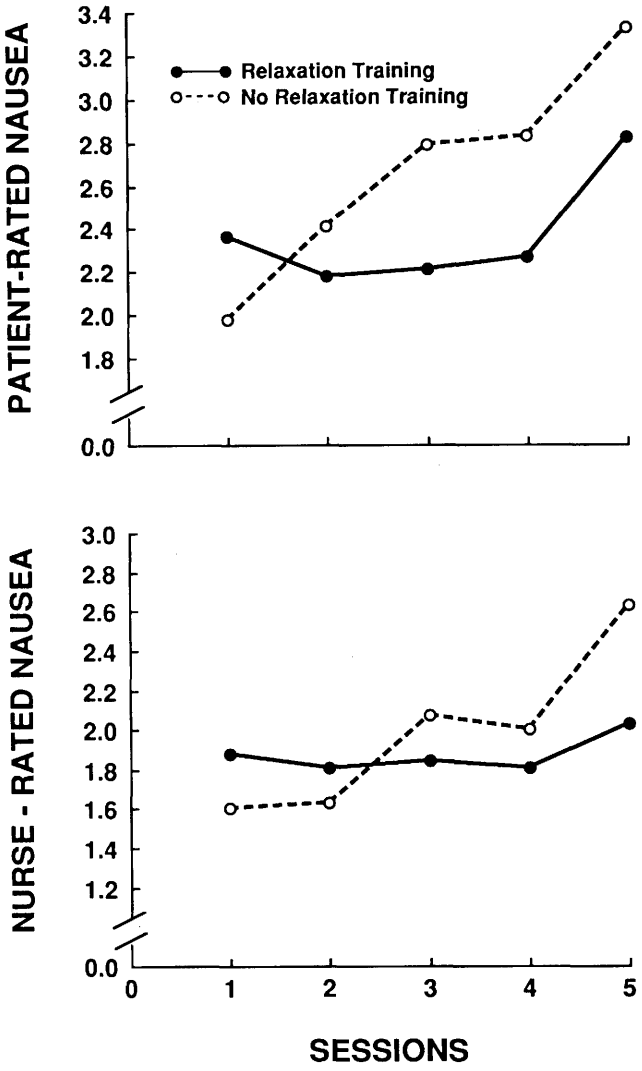

FIGURE 1 Mean patient-rated and nurse-rated nausea levels across sessions for RT and no-RT patients.

ditioning effect over time. In contrast, RT patients showed relatively stable levels of nausea until the fifth session, when they were to practice RT on their own rather than with the help of a therapist. However, even with the significant rise in nausea during the fifth session, RT patients' nausea was still significantly lower than that of no-RT patients. The nurse ratings of nausea are corroborative; although there were no differences between groups in the early sessions, RT patients were rated as having less nausea during the third, fourth, and fifth sessions than no-RT patients, although the difference reached significance ($p < .05$) only at the fifth session. These data suggest that, after several training sessions, RT is effective in controlling chemotherapy-related nausea but biofeedback is not.

Analysis of the vomiting data revealed no significant effects, probably due to a floor effect reflecting low levels of vomiting in each group (all *M*s for all groups at all sessions < 1.0).

TABLE 1
Postchemotherapy SBP for Patients in Each Condition

	Condition					
SBP	*RT*	*EMG*	*ST*	*RT-EMG*	*RT-ST*	*Control*
M	122.7	123.5	128.7	136.7	133.7	129.7
SD	18.1	12.9	15.3	12.5	11.5	16.4

Physiological indices. The MANOVA on prechemotherapy physiological indices did not reveal any significant effects. In contrast, the MANOVA on postchemotherapy physiological indices generated an RT × Session interaction, $F(8, 438) = 1.94$, $p < .05$, $\eta PB^2 = .22$, and an RT × Biofeedback interaction, $F(4, 108) = 2.37$, $p < .06$, $\eta PB^2 = .16$. Subsequent univariate tests revealed a significant RT × Biofeedback interaction for postchemotherapy SBP, $F(1, 55) = 3.72$, $p < .03$, $\omega^2 = .04$. These data are presented in Table 1. Multiple-comparison tests revealed that RT-alone patients and EMG-biofeedback–alone patients had significantly ($p < .05$) lower SBP across all sessions than patients in all other conditions.

Univariate tests also revealed significant RT × Biofeedback, $F(4, 47) = 3.17$, $p < .05$, $\omega^2 = .01$, and Biofeedback × Session, $F(8, 96) = 2.09$, $p < .03$, $\omega^2 = .29$, interactions for pulse rate.[5] These data are shown in Table 2. Further analysis of the RT × Biofeedback interaction with multiple-comparison tests revealed that ST-biofeedback–alone patients had significantly ($p < .05$) lower pulse rates than RT-alone patients and that patients in both these groups had significantly lower pulse rates than patients in the other conditions, which in turn did not differ from one another. Analysis of the Biofeedback × Session interaction indicated that, among biofeed-

[5]Due to a coding error, postchemotherapy pulse rate scores had to be discarded for 18 patients. Hence, pulse rate was analyzed through separate univariate and multiple-comparison tests and was not included in the overall MANOVA on postchemotherapy physiological data.

TABLE 2
Postchemotherapy Pulse Rate by Experimental Condition and Session

	Condition											
	RT		*EMG*		*ST*		*RT-EMG*		*RT-ST*		*Control*	
Session	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
1	74.6	11.6	81.6	9.9	77.1	8.7	77.2	14.7	81.1	12.6	82.8	13.2
2	85.6	16.6	79.2	7.6	73.8	5.3	77.3	11.4	82.9	12.6	82.4	13.6
3	77.6	8.8	84.4	11.9	72.5	8.8	83.7	8.9	79.6	12.2	83.0	14.5
4	76.0	9.2	78.7	9.8	76.2	10.1	85.7	7.7	83.4	11.9	80.6	11.5
5	79.2	10.2	80.5	7.4	76.7	9.9	84.0	6.8	80.3	7.6	83.1	10.1

back conditions, EMG-biofeedback patients (i.e., EMG-biofeedback-plus-RT patients and EMG-biofeedback–alone patients) showed an increase in pulse rate from the first to the fifth session, whereas ST-biofeedback patients and no-biofeedback patients showed more stability across sessions.

Overall, the data suggest that RT and, to a lesser extent, EMG and ST biofeedback, when used alone, were effective in reducing physiological arousal after the administration of chemotherapy.

Affect. The MANOVA on the affect data generated Biofeedback × Session, $F(16, 520) = 1.85$, $p < .02$, $\eta PB^2 = .10$, and RT × Session, $F(16, 518) = 1.74$, $p < .05$, $\eta PB^2 = .05$, interactions. Subsequent univariate tests revealed only a significant RT × Session interaction for nurse ratings of patient anxiety, $F(4, 272) = 2.57$, $p < .04$, $\omega^2 = 10$. These data are shown in Table 3. Multiple-comparison tests indicated that RT patients during the first four sessions were rated as having similar levels of anxiety as no-RT patients. However, by the fifth session, RT patients were rated as having significantly ($p < .05$) less anxiety than no-RT patients.

DISCUSSION

The results of this study support two major conclusions. First, the data indicate that progressive muscle RT with guided relaxation imagery can be a highly effective adjunctive treatment to antiemetic medication in reducing the side effects of cancer chemotherapy. Specifically, RT patients reported less nausea during chemotherapy and had lower levels of autonomic arousal after chemotherapy than control patients. The nurses who administered the chemotherapy rated RT patients as less nauseated and less anxious during chemotherapy—specifically during the last session of the study. Overall, therefore, RT was shown to be effective by patient reports, nurse observations, and physiological measures. These data are consistent with those of several previous studies (e.g., Burish et al., 1987; Burish & Lyles, 1981; Carey & Burish, 1987; Lyles et al., 1982) and suggest that RT can be highly effective in reducing the aversiveness of cancer chemotherapy.

It is important to note that the effects of RT tended to be strongest during the later sessions, especially the fourth and fifth sessions. Inspection of the data suggests that in large part no-RT patients tended to show greater symptoms during later sessions—consistent with the observation that conditioned symptoms are likely to increase with repeated chemotherapy treatments. In contrast, RT patients generally did not evince large increases in symptoms over time—suggesting that RT helped to prevent the development or exacerbation of conditioned symptoms. The data also suggest that patients were able to apply the relaxation procedure on their own during the fifth session, after having been trained by a therapist during the three preceding sessions. This finding suggests that patients learned self-control skills in relaxation. Although such a finding has important practical implications, future research should include an extended follow-up period to determine whether such self-control skills are maintained by cancer chemotherapy patients over longer periods of time.

TABLE 3
Nurse Ratings of Patient Anxiety During Chemotherapy for Patients in the RT and No-RT Conditions for Each Session

	Session				
Condition	*1*	*2*	*3*	*4*	*5*
RT					
M	2.91	2.84	2.78	2.88	2.56
SD	1.03	1.35	1.50	1.43	1.29
No RT					
M	2.91	2.95	2.95	2.74	3.21
SD	1.19	1.38	1.46	1.08	1.66

Besides determining whether RT produced statistically significant effects, it is important to determine whether RT produced clinically meaningful effects. Although it is difficult to precisely define clinical significance, two observations suggest that RT did have a clinical impact. First, in addition to affecting physiological indices and observed anxiety levels, RT had a major impact on one of the most distressing of the side effects of cancer chemotherapy—gastrointestinal distress: RT patients reported significantly less nausea than no-RT patients. Moreover, that the majority of patients in this study were receiving antiemetic medications suggests that RT added something beyond what was achieved by medication alone. These findings suggest that RT can be a useful adjunctive treatment in the care of chemotherapy patients. Second, it should be noted that all the effect sizes for the relevant multivariate and univariate tests for patient- and nurse-reported nausea ranged from .06 to .15, indicating effects of moderate to large size (Cohen, 1977). These data, combined with several patients' and nurses' anecdotal reports that RT produced clear clinical differences, suggest that, although the mean difference in nausea levels may not appear large (see Figure 1), they were noticeable and meaningful to many patients.

The second conclusion is that neither EMG feedback nor ST biofeedback by itself was effective in reducing the aversiveness of chemotherapy. The only effects found for the biofeedback procedures were reductions in measures of physiological arousal. Regrettably, although these changes suggest that the biofeedback procedures were effective in reducing targeted and highly specific indices of outcome, their impact did not generalize to other and, from a patient's viewpoint, subjectively more critical indices of distress. These data suggest that the positive findings of prior research using biofeedback with cancer patients (e.g., Burish et al., 1981; Shartner et al., 1985) were probably due to the fact that the biofeedback interventions also included RT and that the effects of RT lead to the reductions in reported side effects.

From this study, it is difficult to determine why biofeedback was not more effective, although several suggestions and observations can be made. First, in some cases patients found it difficult to concentrate on the biofeedback tone due to the considerable activity that takes place in a cancer clinic. For at least some patients, it was apparently easier to focus on a therapist who was giving specific instructions than to attend exclusively to a changing tone. Second, the biofeedback procedure proved to be cumbersome and inconvenient for some patients. For example, when a patient needed to use the bathroom facilities, he or she had to be unwired and rewired to the biofeedback equipment. Likewise, when a patient made sudden movements—for example, those associated with retching or vomiting—the biofeedback wires could be restrictive and uncomfortable. Third, it is possible that the relative lack of effectiveness of the biofeedback procedures was due in part to the nature of the training procedures used. The specific training procedures chosen were similar to those used in prior research on the effectiveness of biofeedback and RT with cancer patients. Perhaps these procedures are adequate for RT but not for biofeedback. It may be that longer

training periods, additional training sessions held outside the chemotherapy clinic in a relaxed setting, or more tightly monitored home practice sessions would have led to biofeedback-produced changes. Thus, although the data on the effectiveness of biofeedback generated in this study are not encouraging, these findings should not be generalized to the potential impact of other biofeedback training regimens.

Despite limited results in some areas, biofeedback did result in reductions in physiological arousal. This suggests that, in the end, it may be that the greatest limitation of biofeedback is that it leads to relatively specific changes in the targeted symptoms—namely, indices of physiological arousal. This finding is consistent with prior research (e.g., Alexander & Smith, 1979; Glaus & Kotses, 1979) and suggests that biofeedback should be used primarily for specific physiological or psychophysiological problems associated with targeted biological responses.

In summary, the data suggest that progressive muscle RT with guided relaxation imagery can be an effective adjunctive treatment for the conditioned side effects of cancer chemotherapy. In contrast, the EMG- and ST-biofeedback procedures used in this study do not appear to be useful procedures in the context of cancer chemotherapy. That prior research supported the use of biofeedback appears to be due to the fact that RT was also given to biofeedback patients, and it alone accounted for the treatment effects.

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