# BIOFEEDBACK TRAINING IN THE TREATMENT OF NAUSEA AND VOMITING AMONG PEDIATRIC CANCER PATIENTS

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# CHAPTER I

## INTRODUCTION

Pediatric cancer patients undergoing chemotherapy encounter various side effects depending upon the chemotherapeutic agent chosen (Burish & Lyles, 1980; Holland, 1977; Lyles, Burish, Krozely, & Oldham, 1982; Maule & Perry, 1982; Morrow, 1982; Nesse, Carli, Curtis, & Kleinman, 1980). Several chemotherapeutic agents, particularly Cisplatin, produce nausea and vomiting (Morrow, 1982). The pharmacological use of antiemetics may lead to partial alleviation of these symptoms (Drapkin, 1982; Laszlo & Lucas, 1981; Maule & Perry, 1982; Sallan, Cronin, Zelen, & Zinberg, 1980).

In addition, the literature reports many cases of nausea and vomiting occurring prior to chemotherapy treatment (Burish & Lyles, 1979; Burish & Lyles, 1982; Morrow 1982; Morrow, Arseneau, & Asbury, 1982; Morrow & Morrell, 1982; Nesse et al., 1980; Whitehead, Renault, & Goldiamond, 1975). This anticipatory nausea and vomiting generally begins after treatment has been in effect for several months (Nesse et al., 1980). Anticipatory nausea and vomiting is thought to be the result of classical

conditioning in which cancer patients associate various stimuli of the chemotherapy setting with chemotherapy-induced nausea and vomiting (Kutz, Borysenko, Come, & Benson, 1980; Nesse et al., 1980). The chemotherapeutic agent is an unconditioned stimulus. The chemotherapy-induced nausea and vomiting are unconditioned responses. Environmental cues become associated with chemotherapy and become conditioned stimuli. Anticipatory nausea and vomiting become conditioned responses. The pediatric cancer patient then develops anticipatory nausea and vomiting when environmental cues associated with chemotherapy are presented.

The use of operant conditioning in the alleviation of symptoms involving the autonomic nervous system was thought to be impossible until the late 1950's (Gatchel & Price, 1979; Lisini, 1958). It was assumed that the autonomic nervous system could not be brought under voluntary control (Gardner, 1976). Research has demonstrated the success of voluntary human manipulation of various aspects of the autonomic nervous system (DiCara & Miller, 1968; Lapides, 1957; Miller, 1969; Miller, 1978; Miller & Banuazizi, 1968; Miller & DiCara, 1967; Miller & DiCara, 1968).

Several studies have suggested self-regulation strategies including progressive muscle relaxation training and guided imagery (Burish & Lyles, 1979; Burish & Lyles, 1981; Burish, Shartner, & Lyles, 1981), systematic desensitization (Morrow & Morrell, 1982), and hypnosis

(Dempster, Balson, & Whalen, 1976; Labaw, Holton, Tewell, & Eccles, 1975; Redd, Andreson, & Minagawa, 1982) in the treatment of chemotherapy-related nausea and vomiting. These self-regulation strategies have met with success in the alleviation of anticipatory nausea and vomiting.

Biofeedback training has been successfully used in the treatment of tension-related disorders of the autonomic nervous system as cited in the literature (Basmajian, 1977; Brown, 1977; Latimer, 1981; Olton & Noonberg, 1980). Although biofeedback training has been utilized only once in the treatment of nausea and vomiting disorders (Burish et al., 1981) , several gastrointestinal disorders have been successfully treated through its use (Basmajian, 1977; Brown, 1977; Latimer, 1981; Olton & Noonberg, 1980). In addition, biofeedback training has several advantages including its relative low cost and provision of constant, quantifiable feedback which is easily understood (Brown, 1977).

In this study, pediatric cancer patients who were experiencing chemotherapy-related nausea and vomiting were taught to relax the Rectus Abdominus muscles of the abdomen through biofeedback training. Electromyograph recordings and the frequency, severity, and duration of vomiting behavior provided objective indices of the efficacy of biofeedback training in the treatment of nausea and vomiting among patients undergoing chemotherapy. Subjective indices

including patients' self-report of nausea and a variety of tension-related negative affects associated with the chemotherapy process were obtained.

# CHAPTER II

## REVIEW OF THE LITERATURE

This chapter will begin with a presentation of the general problem of the side effects associated with cancer chemotherapy and more specifically chemotherapy-induced nausea and vomiting. Some attention will be given to antiemetic agents used to treat these side effects.

The problem of chemotherapy-induced nausea and vomiting becomes particularly complex and difficult to treat as patients develop nausea and vomiting prior to chemotherapy treatments. This is a medical problem that appears to be dealt with in a less than satisfactory manner through the use of antiemetics. The literature supports the view that anticipatory nausea and vomiting is psychological in origin and is a result of classical conditioning.

The literature offers several behavioral interventions, including progressive muscle relaxation training, systematic desensitization, and hypnosis. The use of these interventions in the treatment of gastrointestinal disorders, in general, and nausea and vomiting, in particular, will be discussed. Finally, biofeedback training appears to be a useful intervention in the treatment of gastrointestinal disorders and this literature will be reviewed.

## Chemotherapy-Induced Side Effects

Side effects of chemotherapy occur as each cell in the body is affected. The effect of chemotherapy on normal tissue involves various side effects. These include decreased immunity, changes in liver enzymes, hair loss, loss of appetite, stomatitus, nausea, vomiting, temporary or permanent frigidity or impotence and psychological side effects such as anxiety and depression (Lyles et al., 1982). Other side effects reported include anemia, diarrhea and anorexia (Burish & Lyles, 1980).

Side effects reportedly vary with the chemotherapeutic agent used. Corticosteriods can cause moon face, acne, overactivity, obesity and insomnia. Use of the steriods may lead to lability of emotions, hypomania early in the course of treatment, depression, and steroid-induced psychosis (Holland, 1977). These symptoms may require psychiatric attention. Several chemotherapeutic agents exert side effects on the central nervous system. Confusion, delirium, slowing and depression may occur. Other chemotherapeutic agents can cause autonomic effects such as constipation, gastrointestinal cramps, and impotence. Effects may also include seizures, altered mental functions, and cranial nerve palsy (Holland, 1977).

The administration of several chemotherapeutic agents leads to nausea and vomiting. Nausea and vomiting after injection of many anticancer chemotherapy drugs may begin after one or two hours and may persist for up to twenty-four

hours (Nesse et al., 1980). This leads to many other medical problems such as the prevention of adequate hydration and nutrition and resultant electrolyte imbalance. Vomiting has also led to vertical compression fractures and Mallory-Weiss tears of the esophageal-gastric mucosa (Maule & Perry, 1982). Nausea and vomiting is also associated with postoperative wound dehiscence and psychological depression (Morrow, 1982).

In addition to these side effects, the lives of patients are disrupted in many ways. Patients may experience nausea and vomiting for at least one day after a chemotherapy treatment. This seriously interferes with work, school and other life activities to which the patient may need to attend. The patient's social life may be seriously disrupted. Perhaps one of the most important disruptions involves significant relationships. Finally, the patient who is receiving chemotherapy treatments already has enough adjustments to make in accepting his or her disease process. Nausea and vomiting are additional stresses which are very uncomfortable.

## Anticipatory Nausea and Vomiting

Patients not only experience nausea and vomiting after the chemotherapy treatments, but they also frequently become nauseous before and during the treatments. Anticipatory nausea and vomiting has been experienced by approximately one in four patients receiving chemotherapy treatments

(Morrow & Morrell, 1982). Anticipatory nausea was reported by 24% and anticipatory emesis was found in 9% of these patients. Anticipatory nausea started, on the average, 17.1 + 3.3 hours before treatment. Anticipatory emesis started approximately 11.4 + 3.8 hours before treatment (Morrow et al., 1982). Pharmacological side effects of chemotherapy, specifically nausea and vomiting, promote many patients to develop negative conditioned responses to treatment. Any stimuli associated with the chemotherapy processes may elicit nausea and vomiting. This may include sights, smells, and even thoughts associated with chemotherapy (Burish & Lyles, 1982). Nesse et al. (1980) reported that patients become nauseous as soon as they entered the clinic building and noticed its "chemical odor," while opening up an alcohol swab as it reminded the patient of chemotherapy, and in a patient's father's car as this was how she arrived at the clinic. One patient recalls becoming nauseous at the sight of a nurse from the clinic at a drugstore (Lyles et al., 1982).

Whitehead et al. (1975) report that,

> ...After one more course (of chemotherapy), patients may begin to vomit in the morning of their treatment, or upon arrival at the physician's office, in anticipation of the injection, attesting to the abhorrence with which they regard the treatment. They confess to feeling ill for three weeks or more out of every four and may become deeply depressed and even suicidal (p. 149).

Morrow (1982) conducted a study of the demographic and clinical characteristics of patients experiencing

anticipatory nausea and vomiting. These patients reported more severe posttreatment emesis, described their most severe posttreatment emesis as occurring relatively late after treatment, and were more likely to be receiving Cisplatin treatments. Morrow (1982) further reported that 75% of patients experiencing anticipatory nausea and vomiting, when asked their opinion as to the origin of these symptoms, answered with psychological reasons rather than treatment-related or other reasons. These patients gave responses such as "anxious," "nervous," "tension," "in my mind," "dread," and "no controls." No consistent physiologic bases for the development of anticipatory nausea and vomiting were found.

Nesse et al. (1980) found that anticipatory nausea and vomiting is common among patients who have received more than six months of chemotherapy treatments. The pattern appears to be as follows: anticipatory nausea and vomiting develops gradually and is frequently precipitated by stimuli generally associated with chemotherapy treatments but in a different location. The patient then experiences nausea and vomiting upon subsequent visits to the clinic in which chemotherapy treatments occur.

These conditioned negative responses may occur at any time but are most prevalent during the treatment sessions. A chemotherapeutic treatment may have to be interrupted several times due to patient discomfort (Burish & Lyles, 1979). This not only makes chemotherapy more uncomfortable

for the patient than it has to be but it is costly in terms of time and medical attention. One of the greatest concerns related to anticipatory nausea and vomiting is the risk of a patient's noncompliance with chemotherapy (Morrow, 1982). Without chemotherapy, the patient will eventually die.

Kutz et al. (1980) and Nesse et al. (1980) view anticipatory nausea and vomiting as a result of classical Pavlovian conditioning. The chemotherapeutic agent is viewed as the unconditioned stimulus to which chemotherapy-induced nausea and vomiting are unconditioned responses. Environmental cues which are associated with chemotherapeutic treatments become conditioned stimuli. There are two cases reported of an antiemetic agent becoming a conditioned stimuli producing nausea and vomiting (Kutz et al., 1980). Anticipatory nausea and vomiting was seen to continue for several clinic visits after chemotherapy treatments had been discontinued (Nesse et al., 1980).

## Treatment of Chemotherapy-Induced Nausea and Vomiting

Pharmacological interventions have included the use of antiemetics such as the antihistamines/anticholinergics, phenothiazines, substituted buterophenones, cannabinoids, Metoclorpramide, and the corticosteroids (Maule & Perry, 1982). Hypnotics and sedatives have also been used in the treatment of chemotherapy-induced nausea and vomiting (Drapkin, 1982).

The rationale behind the use of anticholinergic agents is that they block the transmission of dopamine in the chemoreceptor trigger zone and the vomiting center. Cholinergic receptors and histamine receptors are thought to be involved in nausea and vomiting induced by motion sickness, and small bowel and gastric irritation (Drapkin, 1982). The antihistamines and anticholinergic agents have been effective in relieving motion sickness and nausea but used alone are no more effective than placebo in relieving chemotherapy-induced nausea and vomiting (Laszlo & Lucas, 1981; Maule & Perry, 1982).

The phenothiazines also act as dopamine inhibitors in the chemoreceptor trigger zone and some phenothiazines have additional sites in the vomiting center (Drapkin, 1982). Phenothiazines have been used widely in the treatment of chemotherapy-induced nausea and vomiting. These agents have been found to be more effective than placebo in controlling the emesis that accompanies many chemotherapy agents (Maule & Perry, 1982). Unfortunately, phenothiazines provide little effect in the treatment of chemotherapy-induced nausea and vomiting when potent chemotherapeutic agents such as Cisplatin or high doses of Cyclophosphamide are used (Laszlo & Lucas, 1981). Prolonged use of the phenothiazines is associated with extrapyramidal side effects including parkinsonism with akinesia, akathesia; acute dystonia with facial grimacing, torticollis and oculogyric crisis; tardive dyskinesia and perioral crisis. Other side effects of

phenothiazines include sedation, hypotension, jaundice, photosensitivity, elevation of prolactin levels and blood dyscrasis.

Substituted buterophenones are perhaps the strongest inhibitors of dopamine in the chemoreceptor trigger zone. Side effects, as in the use of the phenothiazines, include sedation and extrapyramidal reactions. They have been found useful in the treatment of chemotherapy-induced nausea and vomiting in patients taking Cisplatin for gynecologic malignancies (Maule & Perry, 1982).

Extensive research has been conducted on the use of the cannabinoids in the treatment of chemotherapy-induced nausea and vomiting (Drapkin, 1982; Laszlo & Lucas, 1981; Maule & Perry, 1982; Sallan et al., 1980). The use of Marijuana was known before the Marijuana Tax Act of 1937 and has regained attention since 1975 when it was used in several controlled studies (Maule & Perry, 1982). The mode of action of the active ingredient of Marijuana, delta-9-THC, THC, is presently unknown. Two derivations are currently being tested for clinical effectiveness in the treatment of chemotherapy-induced nausea and vomiting. THC has been found to be more effective than placebo or Prochloroperazine (Sallan et al., 1980) in the treatment of chemotherapy-induced nausea and vomiting. In younger patients, there appear to be few side effects other than somnolence. In older patients, toxic reactions have included ataxia, hypotension, visual hallucinations and dysphoria (Drapkin,

1982). THC has been found to be especially effective among patients who are taking Methotrexate or high-dose Nitrosourea but has been found to have little value with chemotherapy-induced nausea and vomiting related to the use of Cisplatin or high doses of Cyclophosphamide (Laszlo & Lucas, 1981).

Metoclopramide inhibits the transmission of dopamine and serves to block the chemoreceptor trigger zone. As Metoclopramide acts similarly to a cholinergic agent in the upper gastrointestinal tract, it increases gastric tone, peristalsis and the resting tone of the lower esophageal sphincter (Maule & Perry, 1982). This agent acts to accelerate the emptying of the stomach and directly opposes the process of vomiting (Drapkin, 1982). It has been thought to be an ideal antiemetic in the use of Cisplatin, and research has found it to be more effective than placebo or Prochloroperazine in treating nausea and vomiting associated with the use of Cisplatin (Maule & Perry, 1982). Metoclopramide has been found to be an effective antidote to chemotherapy-induced nausea and vomiting associated with the use of Cisplatin (Maule & Perry, 1982). It has been found to be an effective antidote to chemotherapy-induced nausea and vomiting in Cisplatin use if administered in high doses. Metoclopramide, when effective, is well tolerated and has fewer side effects than those found in high doses of the cannabinoids and phenothiazines (Laszlo & Lucas, 1981). Side effects of the

use of Metocloropramide include sedation and dystonic reactions. The uses of high doses of Metocloropramide may lead to the serious side effect of drug-induced Lupus Erythematosus (Maule & Perry, 1982).

The mode of action of the corticosteroids is conjectural. They are thought to suppress progestaglandin synthesis and since progestaglandins are known to effect emesis, the corticosteroids are considered to be powerful antiemetics for use with the most nauseating chemotherapeutic agents (Drapkin, 1982). Corticosteroids have been tried in combination with the phenothiazines and the combination has resulted in lowered chemotherapy-induced nausea and vomiting. The prolonged use of the phenothiazines, however, is associated with many side effects as previously mentioned. Also of concern is the immunosuppressive effects of steroid use in cancer patients. Despite this, no data has of yet suggested an adverse effect clinically. More research has to be done in order to determine the mode of action and possible side effects of the use of corticosteroids in chemotherapy-induced nausea and vomiting.

Drapkin (1982) mentions the value of the use of hypnotics and sedatives in the treatment of chemotherapy-induced nausea and vomiting. Hypnotics and sedatives, specifically the benzodiazepines and barbituates, act at the synapse level to depress neurotransmission. This depresses

the entire central nervous system. The result is sedation and antiemesis.

It might be argued that the antiemetics are the treatment of choice for chemotherapy-induced nausea and vomiting. All of the antiemetics have potential side effects (Drapkin, 1982). Few of the antiemetics have been found to be more effective than placebo in treatment of chemotherapy-induced nausea and vomiting. Those seeming most effective often have serious side effects. Some of the antiemetics are not found to be useful with certain very powerful or high dose chemotherapeutic agents. While antiemetics may be useful in the treatment of some chemotherapy-induced nausea and emesis, it still does not address the issue of anticipatory nausea and vomiting and chemotherapy-related psychogenic nausea and vomiting. Some self-regulation strategies have been successful in alleviating psychogenic anticipatory and chemotherapy-related nausea and vomiting.

## Self-Regulation Strategies in the Treatment of Chemotherapy-Related Nausea and Vomiting

The use of pharmacological agents in the treatment of chemotherapy-induced nausea and vomiting is associated with side effects which cause discomfort and life disruptions to the patient. While nausea and vomiting are very uncomfortable to the patient and disturbing to his/her family, sedation also affects the quality of life and

relationships. Furthermore, these agents do not seem to prevent anticipatory nausea and vomiting which is thought to be a psychological origin and to be a negatively conditioned response. In order to avoid the life disruptions that antiemetic agents cause in a patient's life and to help control psychogenic anticipatory nausea and vomiting, a number of self-regulation strategies have been studied and found to be effective. Self-regulation strategies have included the use or progressive muscle relaxation training, systematic desensitization, and hypnosis. Self-regulation strategies have been used to treat a wide range of gastrointestinal disorders other than chemotherapy-related nausea and vomiting. The treatment of gastrointestinal disorders has played a prominent part in the development of behavior therapy, biofeedback, psychophysiology, and psychosomatics (Latimer, 1981).

## Progressive Muscle Relaxation Training

Progressive muscle relaxation training has been used in the treatment of "spastic esophagus" and "mucous colitis" (Jacobson, 1927). Research pointed to the efficacy of this method in reducing physiological arousal and self-reported anxiety under stressful conditions (Davidson & Hiebert, 1971). Burish and Lyles (1979) cite several reasons for the use of progressive muscle relaxation training in the alleviation of nausea and vomiting among cancer chemotherapy patients. Relaxation training serves to distract the

patient from aversive stimuli to which they have developed the negative conditioned response of anxiety, nausea and vomiting. Progressive muscle relaxation training is not costly, is easily learned and has negligible side effects (Lader & Matthews, 1970). Finally, Burish and Lyles (1979) state that progressive muscle relaxation training is useful to patients in other stressful situations and thus has the advantage of generalizability.

Burish and Lyles (1979) used progressive muscle relaxation training and guided imagery with a cancer patient both before and during her chemotherapy treatments to alleviate anticipatory nausea and vomiting. The patient reported less anxiety, depression, and nausea than when in a baseline chemotherapy treatment. Postchemotherapy pulse rate and blood pressure were also lower. Burish et al. (1981) combined progressive muscle relaxation training with a patient undergoing chemotherapy. The patient showed less physiological arousal and reported less anxiety and nausea in comparison with baseline chemotherapy sessions. While these results are encouraging, they should be regarded cautiously due to small sample size and inadequate control procedures.

Burish and Lyles (1981) compared a group of fourteen cancer patients receiving progressive muscle relaxation training and guided imagery with a group of patients receiving no treatment. Results indicate that patients receiving progressive muscle relaxation training and guided

imagery showed a lower level of physiological arousal and report less anxiety and nausea both during training and in the follow-up sessions than patients who had received no training. These results suggest that relaxation training can provide an effective adjunct treatment to the control of chemotherapy-related nausea and vomiting, arousal and negative affect.

In a larger study utilizing fifty patients, Lyles et al. (1982) studied the effects of the use of progressive muscle relaxation training and guided imagery in comparison to the use of a therapist and to no treatment. Results indicated that the patients who had received progressive muscle relaxation training and guided imagery, in comparison to patients who were seen by a therapist or who had received no treatment, showed significantly less physiological arousal, measured by pulse rate and systolic blood pressure. Patients who received progressive muscle relaxation training and guided imagery also reported feeling significantly less anxiety and nausea at home following chemotherapy treatments than patients in either of the other two conditions. The differences between conditions generally remained significant during patients' next clinic visit. The combination of progressive muscle relaxation training and guided imagery appears to be effective in preventing anticipatory nausea and vomiting among cancer chemotherapy patients. The reduction of nausea after chemotherapy treatments also appears to be related to the

use of progressive muscle relaxation training and guided imagery. Results suggest that relaxation training is effective for cancer patients who are attempting to cope with the adverse effects of their chemotherapy treatments.

In summary, progressive muscle relaxation training has several advantages. It distracts the patient from adverse stimuli. Its cost is low. It is simple to learn. It has negligible side effects. It is generalizable to other stressful situations, however, progressive muscle relaxation training does make some requirements of the subject (Kroger & Fezler, 1976). It requires that the individual develop the capacity for "passive concentration" and for the performance of simple exercises on specific muscle groups. It requires that the patient notice how his/her body feels without the assistance of further feedback from additional devices.

## Systematic Desensitization

Systematic desensitization, in which patients are taught to relax in anticipation of stimuli to which they have developed stress-related symptoms, has also been used for years in the treatment of gastrointestinal disorders. Latimer (1981) cites several early reports of the use of systematic desensitization for these purposes. Studies involved the use of systematic desensitization in the treatment of "nervous diarrhea" (Cohen & Reed, 1968), mucous colitis (Youell & McCoullough, 1975), chronic gagging

behavior, (Altamura & Chitwood, 1974) and bulimia (Lang, 1965).

Systematic desensitization involves the progressive exposure to feared situations to reduce maladaptive responses. The procedure is planned in advance and is performed in gradual steps. The patient practices relaxing while imagining situations that preceed nausea and vomiting. Progressive muscle relaxation training is sometimes used as an introduction to systematic desensitization (Morrow, 1982). Progressive muscle relaxation training has been used without systematic desensitization but anticipatory side effects were not decreased (Morrow, 1982). This is in contrast to other findings of the efficacy of progressive muscle relaxation training (Burish & Lyles, 1981; Burish et al., 1981; Lyles et al., 1982).

Application of systematic desensitization to anticipatory nausea and vomiting among cancer patients undergoing chemotherapy is reported in only one study at present (Morrow & Morrell, 1982). Twenty chemotherapy patients with anticipatory nausea and vomiting were trained in systematic desensitization and were compared to twenty chemotherapy patients who received counseling and to twenty chemotherapy patients who had received no additional assistance. Significantly more patients who had received systematic desensitization reported that nausea was less severe and of shorter duration than patients in either of

the other two groups. A less consistent result was found with anticipatory vomiting than with anticipatory nausea. This was attributed to the relatively small number of patients who experienced anticipatory vomiting. It was suggested that this study be replicated among larger populations to lend support to these results. It was concluded that the use of systematic desensitization with cancer chemotherapy patients experiencing anticipatory nausea has antiemetic effects and should be considered a useful technique in the management of the symptoms.

Morrow (1982) discusses the advantages and disadvantages of systematic desensitization. This self-regulation strategy is widely used and there are not reported complications. It can be used by a variety of levels of staff with minimal supervision. One disadvantage is that the amount of professional time used makes systematic desensitization not as cost effective as progressive muscle relaxation training which can be administered by an audiotape and with groups of patients.

Hypnosis

The use of hypnosis with chemotherapy patients who were experiencing nausea and vomiting has been reported by several authors (Dempster et al., 1976; Labaw et al., 1975; Redd et al., 1982). Hypnotherapy was reported to be successful in the treatment of a woman with Hodgkin's Disease in reducing her anxiety, nausea and vomiting

(Dempster et al., 1976). The authors' observations and the patients' self-report indicated that hypnosis was successful in decreasing the patients' anxiety, nausea and vomiting. Labaw et al. (1975) hypnotized 27 children with cancer, which resulted in less anticipatory anxiety, nausea and vomiting. Unfortunately, these studies did not give quantifiable indexes of nausea and vomiting, detailed descriptions of training and induction procedures or replication across patients (Redd et al., 1982). Individual hypnosis training prior to and during chemotherapy was given to six female cancer patients, which reduced patient ratings of nausea and stopped all anticipatory vomiting (Redd et al., 1982). When patients stopped receiving hypnosis, however, the anticipatory nausea and vomiting returned. It is possible that if patients are taught self-hypnosis techniques they may be able to control their own anticipatory and psychogenic chemotherapy-relation nausea and vomiting. Other techniques such as the use of an audiotape or the therapist's progressive absence might also be useful (Redd et al., 1982).

Hypnosis, similar to progressive muscle relaxation training, is one in which the patient learns to evoke the physiological condition of relaxation and distraction from the disturbing stimuli. This relaxed state is incompatible with the physiological state of emesis. Emesis can not occur as long as the patient remains in this state. Hypnosis as a means of treating nausea and vomiting has

several advantages. There are no undesirable side effects. It requires no special equipment. It requires little physical effort and training (Redd et al., 1982). Similar to systematic desensitization, it has one drawback. Depending upon the amount of professional time it requires, it may not be cost-effective.

Redd et al. (1982) discuss three crucial components of the induction process: deep muscle relaxation, distraction, and social demand. It was interesting to note that in this study progressive muscle relaxation training was paired with systematic desensitization as in Morrow's (1982) study. Redd et al. (1982) include progressive muscle relaxation training, imagery, and systematic desensitization in their hypnosis process. In hypnosis, progressive muscle relaxation training serves the same purpose as it does in systematic desensitization. It serves to inhibit muscle activity, including the muscle activity needed for emesis.

The differentiation between hypnosis and systematic desensitization is more difficult. During the last session of systematic desensitization, the patient is taken into the environment that elicits nausea and vomiting (Redd et al., 1982). A patient who has been successfully treated with systematic desensitization should be free of anticipatory nausea and vomiting. In order for systematic desensitization to have successfully occurred in conjunction with hypnosis in Redd et al.'s study (1982), patients would have had to be free of anticipatory nausea and vomiting.

This was not the case. Patients experienced anticipatory nausea and vomiting until their hypnotic induction session and then resumed the anticipatory nausea and vomiting after hypnosis was discontinued. This implies that either systematic desensitization was never successfully completed or that hypnosis is only effective during sessions in which it is intentionally employed.

## Biofeedback Training

### Development of Biofeedback in the Control of the Autonomic Nervous System

The autonomic nervous system supplies organs containing cardiac muscle fibers, smooth muscles and glands. These organs include the heart, stomach, small intestine, large intestine, pancreas, bladder, eyes, and salivary glands (Gardner, 1976). It was presumed until fairly recently that the autonomic nervous system could not be brought under voluntary control.

It was argued that since the autonomic nervous system could not be brought under voluntary control, that operant conditioning methods could not be employed. The autonomic nervous system was assumed to be accessible only through classical conditioning. The central nervous system was known to be accessible through operant conditioning (Gatchel & Price, 1979).

A history of the research involving the voluntary control of various autonomic functions is presented by

Gatchel and Price (1979). These findings have led to the development of biofeedback as a clinical intervention in the treatment of many disorders of the autonomic nervous system. These studies signal the beginning of voluntary control over stress disorders.

The first demonstration of the successful use of operant conditioning of an autonomic function is attributable to a Russian psychologist, Lisini (1958), who trained human subjects to constrict and dilate blood vessels by allowing them to monitor their own progress on a recording device. This was followed by many studies involving voluntary control of various aspects of the autonomic nervous system. Success appears to have been the result of using some sort of feedback about the physiological processes that were being conditioned. Early studies involved the voluntary control of heart rate through auditory (Shearn, 1962) and visual (Hniatow & Lang, 1962) types of feedback. Subjects were taught to relax through feedback of alpha rhythms in brain wave activities (Kamiya, 1969; Kamiya, 1977). Several studies demonstrated subjects' voluntary control over skin resistance through reinforcement with light and odors (Fowler & Kimmel, 1962; Kimmel & Hill, 1960; Kimmel & Kimmel, 1963). Early studies were also responsible for the discovery of the voluntary control of blood pressure through auditory biofeedback devices (Schwartz, 1972; Shapiro, Tursky, Gershon, & Stern, 1969).

Upon examination of these initial studies, it was still unclear as to whether results were due to voluntary control of the autonomic nervous system or to voluntary control of the skeletal muscle responses. Studies by Miller (1969, 1978) involved the use of Curare to block acetycholine, which is responsible for chemical transmission to the skeletal muscles, thus blocking skeletal mediation of responses. Several experiments were performed with laboratory animals in which control of the autonomic functions was achieved through reinforcing stimulation of the "pleasure center," the medical forebrain bundle of the hypothalamus (DiCara & Miller, 1968; Miller & DiCara, 1967). In this series of studies, it was demonstrated that heart rate could be instrumentally conditioned through direct stimulation of the brain reward centers. Results were also claimed for blood pressure (DiCara & Miller, 1968), renal blood flow (Miller & DiCara, 1968), and contraction of intestines (Miller & Banuazizi, 1968). Experimentation with human subjects also appears to support the contention that autonomic functions can be brought under voluntary control. Lapides (1957) used Curare to paralyze human subjects and found that they could demonstrate control over urination even though skeletal muscles of the abdomen and bladder had been temporarily paralyzed. This was thought to demonstrate human ability to control a visceral event.

## Theoretical Issues in Biofeedback Training

Biofeedback has been defined (Basmajian, 1979) as a technique in which equipment, generally electronic, is employed to inform humans as to their physiological processes, normal and abnormal, so that they may teach themselves to alter these physiological processes by manipulating the visual and auditory cues given. Most people have difficulty perceiving their own visceral responses, particularly those involving the atonomic nervous system. Learning to lower EMG levels provides a reinforcer. When EMG levels, for example, gravitate in an undesirable direction, this is fed back to the subject, which serves as a mild punishment. Feedback that EMG levels are in the desired direction serves to reinforce the behavior leading to this feedback. Once subjects are able to correctly perceive their own visceral responses, the biofeedback equipment is no longer needed. Responses which individuals have learned to manipulate include alpha and theta EEG, blood pressure, heart rate, muscle tension, salivation, urinary formation, gastric motility, blood flow and skin temperature (Wickramasera, 1976).

There are some theoretical concerns in the use of biofeedback training as a learning device. Biofeedback training is a form of instrumental learning or operant conditioning in which an appetative stimulus is contingently administered upon emission of some response, increasing the

probability that the response will be repeated. Using a broader definition of reinforcement, as opposed to the use of reinforcement in classical conditioning, stimuli are found that increase the probability of the desired behavior occurring and decrease the probability of the undesired behavior occurring. Reinforcement is generally in the form of change in the instrumental display that indicates to the subject that his/her behavior has changed in a desired direction.

One of the theoretical issues in the literature regarding the use of reinforcers in biofeedback, according to Yates (1980), is that reinforcers, generally in the form of feedback about behavioral change, have never been paired with primary reinforcers such as food, water, or sex when deprived. Therefore it is difficult to say that true secondary reinforcers, defined as neutral stimuli which acquire reinforcing properties as a result of being repeatedly paired with a primary reinforcer, are used. Desirable behavior, reinforced by secondary reinforcers, would eventually extinguish if not occasionally paired with a primary reinforcer. Because secondary reinforcement could not adequately explain the maintenance of desired behavior, the distinction between primary and secondary reinforcers was dropped in regards to biofeedback (Yates, 1980). It was decided the role of reinforcement in biofeedback is generally one of increasing motivation for learning rather than directly affecting the learning of responses (Yates, 1980).

Another complex issue involves the ability to differentiate between the informational and the reinforcing aspects of biofeedback training. It is questionnable whether information alone can motivate a subject to learn or whether another motivator such as a reinforcer should be used to encourage the individual to use the information presented (Yates, 1980). Finley (1983) suggests the use of reinforcers in biofeedback training with children. In working with children between the ages of four and ten, he suggests the use of toys, tokens, money, coupons, and candy as reinforcers. In children over the age of ten years, he suggests the use of coupons for privileges, candy, and money. Reinforcers can be placed on trays and earned individually through producing the desired behavior. After initial training, some of the trays can be left empty to provide a variable-ratio intermittent reinforcement schedule. This may reduce the likelihood of extinguishing the acquired response. Shaping may also be used by requiring that the child produce progressively more desirable behavior in order to earn a reward. In children over ten years of age, Finley (1983) considers the use of reinforcers to be optional. Children over the age of ten can be treated more as an adult and may benefit from the informational aspects of the instrumental display without the reinforcement.

Another theoretical concern involves the interplay between skeletal muscles and autonomic functioning. An

individual may learn to relax muscles surrounding an autonomic area of concern but this does not necessarily mean that he/she has gained control of autonomic processes. The question is whether or not the skeletal muscles will indirectly affect the autonomic function. In the case of autonomic control of the gastrointestinal functions, there has been little work in instrumental control. This may be due to the technical difficulty in working for voluntary control of the gastrointestinal system. The best way to measure actual gastrointestinal motility is to have the subject swallow an electrode which reports changes in pH activity (Whitehead et al., 1975). As this is a very invasive means of gaining information and one which subjects are not likely to consent to, the indirect method of controlling autonomic functions in the gastrointestinal system through measuring abdominal EMG is perhaps best.

Another issue which affects biofeedback training but is not measured involves the subjects' cognitive mediation and emotional states. Several studies indicate that a subject's thoughts can change autonomic functioning such as heart rate. Boulougouris, Ravavilas, and Stefanis (1977) found that when obsessive-compulsive patients engaged in fantasies related to their obsessions, heart rate was significantly increased. May (1977) found that heart rate was elevated among snake phobics who were required to think about snakes. The results in regard to somatic variables other than increased heart rate are less clear (Yates, 1980).

Imagery has been coupled with biofeedback and these results are also rather unclear. Dugan and Sheridan (1976) asked subjects to imagine their hands in warm water. Results showed a small, mean increase in hand temperature. Blizard, Cowings, and Miller (1975) found significant increases in heart rate and respiration when subjects were taught to image coolness and lightness in their hands. These results were not found when subjects were taught to image heaviness and warmth in their hands.

## Biofeedback in the Control of Gastrointestinal Disorders

Biofeedback has been utilized in the treatment of several gastrointestinal disorders, including Irritable Bowel Syndrome, fecal incontinence, functional diarrhea, urinary retention and incontinence, gastric acid secretion, esophageal disorders, and vomiting (Basmajian, 1979; Brown, 1977; Latimer, 1981; Olton & Noonberg, 1980).

Irritable Bowel Syndrome has been treated with biofeedback procedures since 1973. Furman (1973) used an electronic stethoscope to amplify bowel sounds in order to teach patients to increase and decrease these sounds. There have been at least two reports in which trial of this technique has been ineffective (O'Connell & Russ, 1976; Weinstock, 1976). Bueno-Miranda, Cerulli, and Schuster (1976) used an intraluminal balloon in the sigmoid colon of patients with Irritable Bowel Syndrome to report pressure

changes. Two-thirds of patients using this form of biofeedback were able to decrease the frequency, amplitude, and duration of contractions and were able to distend more in order to produce contractions.

Biofeedback training has been able to help patients to regain fecal continence when it has been lost due to surgery, degenerative neural diseases and accidents (Olton & Noonberg, 1980). Engel, Nikoomanesh, and Schuster (1974) used a similar method by giving rectosphincteric responses to patients through use of a balloon inflated in the rectum. Patients were then shown responses of continent patients and they attempted to approximate the normal responses.

Success was reported by Engel et al. (1974) and by others who replicated this or similar processes. Kohlenberg (1973) trained a boy who had been incontinent all of his life through biofeedback involving the insertion of a tube containing water into the rectum. Cerulli, Nikoomanesh, and Schuster (1979) used the triple balloon system in the biofeedback training of 50 patients with fecal incontinence. Thirty-six of the 50 patients reduced their fecal incontinence by 90%. Seventy-five percent of these patients needed only one training session.

One study utilized biofeedback training in the treatment of functional diarrhea. Furman (1973), in treating five female patients, recorded peristaltic activity from the gastrointestinal tract and gave feedback to

patients through a tone. Within five sessions, all patients had some control of intestinal motility.

The management of urinary retention and incontinence through biofeedback training is reported by Pearne, Zigelbaum, and Peyser (1977). Biofeedback training was indirect, involving the teaching of a female to relax her frontalis muscles. Feedback involved auditory frontal EMG signals. Major problems of incontinence were solved within two weeks. Several months later, the woman was aware of bladder fullness, could void voluntarily, and was having having no incidents of urinary incontinence.

Brown (1977) discussed several experiments in which biofeedback was used to control the secretion of gastric acid. Welgan (1974) used a biofeedback technique in which patients swallowed a pH electrode that gave feedback as to acid secretion. Positive changes were reported. Whitehead et al. (1975) neutralized gastric acid through the use of sodium bicarbonate injected through a nasogastric tube to which a pH meter had been attached. The amount of sodium bicarbonate used was the indication of gastric acid secretion. Subjects could increase gastric acid secretion, but could not reliably reduce it, when money was used as a reinforcement. If the reinforcement was given on a temporal basis regardless of changes in gastric acid secretion, subjects could reduce the increased levels to baseline values.

Few studies have reported success in using behavioral interventions in the treatment of esophageal disorders. Jacobson (1927) used progressive muscle relaxation training in the treatment of "spastic esophagus." Latimer (1981) attempted to use biofeedback of esophageal motility to aid a patient with weight loss and chest pain due to diffuse esophageal spasms. Biofeedback was unsuccessful, but the patient learned to effectively normalize her esophageal motility through swallowing behavior. Biofeedback training has been used in the treatment of reflux esophagitis by Schuster (1979). Esophageal reflux appears to be a function of lower esophageal sphincter pressure which can be lowered when the patient is given appropriate feedback.

Although biofeedback has been used in the treatment of several gastrointestinal disorders, there is only one study involving the use of biofeedback training in the treatment of nausea and vomiting. As previously cited, Burish et al. (1981) employed a combination of progressive muscle relaxation training with EMG feedback in the treatment of one patient with anticipatory nausea and vomiting. This chemotherapy patient showed less physiological arousal and reported less nausea and anxiety in comparison to the patient's baseline levels.

Successful behavioral treatment of chronic vomiting behavior, however, has been reported frequently. Chronic vomiting is potentially life-threatening and for this reason response-contingent punishment is often used. This

generally involves the use of electrical shock used either at the onset of vomiting or with the occurence of some pre-vomiting behavior. This type of behavioral intervention is generally used with infants with ruminative vomiting and with mentally retarded patients (Latimer, 1981).

Latimer (1981) describes the treatment of adult patients with vomiting disorders. There appear to be two subgroups of adults with vomiting disorders, each involving different behavioral interventions. The first subgroup develops vomiting behavior through operant conditioning involving attention from significant others or the avoidance of anxiety-producing situations. Treatment involves the elimination of reinforcement for vomiting and replacement with reinforcement of adaptive behavior. The second subgroup of adults vomited in response to unpleasant internal sensations such as nausea, pain, and anxiety associated with eating. Vomiting involves the avoidance of these internal sensations. Treatment generally involves the gradual exposure of these patients to the anxiety or fear-producing stimuli.

## Advantages of the Use of Biofeedback Training

Brown (1977) discussed several advantages of using biofeedback in the management of physiological processes. There is some advantage in giving an individual direct information about his/her internal functioning. This is

seldom the practice in the field of medicine. This gives more responsibility to the individual in changing his/her physiological state. The locus of control is shifted from external to internal as the individual learns to progressively rely upon his/her own resources rather than remaining dependent upon medication or professional attention. This is in contrast to the traditional reliance upon an external change agent. Furthermore, biofeedback signals are easily understood by most people. This is in contrast to the complex summarization of information generally found in professional treatment. Biofeedback gives continuous information which is likely to be more useful than the customary practice of giving the patient intermittent progress reports.

There are several advantages in using a form of operant conditioning on a problem that has been classically conditioned (Morgan & King, 1971). Classically conditioned responses are fixed while operantly conditioned responses can be tailored to meet environmental needs. In classical conditioning, the conditioned stimulus is specific. In operant conditioning, the conditioned stimulus is a situation. This allows the individual to learn at his/her own rate. In classical conditioning, the unconditioned stimulus is paired with the conditioned stimulus no matter what the individual does. In operant conditioning, reinforcement is contingent upon the individual's behavior. This encourages the individual to take an active

role in his/her learning and to take responsibility for his/her behavior. In classical conditioning, learning appears to be outside of the individual's control and stems from the environment. Operant conditioning can give the individual a sense of power over the course of his/her problems. This may lessen feelings of helplessness, dependency, and depression. In classical conditioning, reinforcement involves pairing the conditioned stimulus with the unconditioned stimulus. In operant conditioning, reinforcement may be anything that strengthens the desired response, which allows for a wide range of reinforcers. Since reinforcers may be tailored to meet the individual needs of the subjects, more effective learning may result.

## Summary

Nausea and vomiting are commonly reported side effects of cancer chemotherapy treatment and are particularly associated with some chemotherapeutic agents, such as Cisplatin. Antiemetics have shown partial success in the remission of chemotherapy-induced nausea and vomiting. Some nausea and vomiting, however, appears to be psychologically induced. The literature cites examples of nausea and vomiting occurring prior to chemotherapy treatments. This anticipatory nausea and vomiting is thought to be a result of classical conditioning. Stimuli associated with chemotherapy treatments begin to elicit nausea and vomiting,

whereas previously the nausea and vomiting only occurred after the administration of the chemotherapeutic agent.

Nausea and vomiting pose additional difficulties for patients undergoing cancer chemotherapy. Not only does it pose potentially severe medical problems involving dehydration and malnutrition but it is quite uncomfortable and produces negative affect in patients and in family members who are in frequent contact with them.

A variety of self-regulation strategies have been utilized in the treatment of nausea and vomiting. These include the use of progressive muscle relaxation training, guided imagery, systematic desensitization, and hypnosis. The literature cites only one study in which biofeedback training has been utilized in the treatment of chemotherapy-related nausea and vomiting.

Biofeedback training involves operant conditioning as a patient's response is followed by either a reward or punishment. In this study the desired response is the relaxation of muscles in the Rectus Abdominus region and the reward or punishment involves feedback of abdominal muscle tension. The goal is acquisition of self-regulation of muscles in the Rectus Abdominus region. This may be associated with a decrease in self-reported nausea and state anxiety and in the incidence of retching. The primary advantage of using an operant mode in the treatment of what appears to be a classically conditioned symptom is that it offers the individual a chance to take responsibility for an

aspect of his/her treatment. Methods employing operant conditioning offer means which may be manipulated by either the patient or the professional to induce faster, more efficient learning. Biofeedback training offers the patient immediate, constant, and objective information about his/her attempts at relaxation. This information may be readily understood by adults as well as children and adolescents. Objective data provided by an EMG monitor provides the professional with constant information as to the patient's progress in learning to relax. The professional may then intervene to make relaxation training more efficient for the patient. Finally, objective data offered by EMG biofeedback equipment lends itself to more systematic and quantifiable data than interventions that rely solely on patients' self-report.

# CHAPTER III

## SCOPE OF STUDY AND HYPOTHESES

Nausea and vomiting are commonly reported side effects of cancer chemotherapy treatment (Maule & Perry, 1982; Morrow, 1982; Nesse et al., 1980) and are particularly associated with some chemotherapeutic agents, such as Cisplatin (Morrow, 1982). Antiemetics have shown partial success in the remission of chemotherapy-induced nausea and vomiting (Drapkin, 1982; Laszlo & Lucas, 1981; Maule & Perry, 1982; Sallan et al., 1980). Some nausea and vomiting, however, appears to be psychologically induced. The literature cites examples of nausea and vomiting occurring prior to chemotherapy treatments (Burish & Lyles, 1979; Burish & Lyles, 1982; Morrow, 1982; Morrow et al., 1982; Morrow & Morrell, 1982; Nesse et al., 1980; Whitehead et al., 1975). This anticipatory nausea and vomiting is thought to be a result of classical conditioning (Kutz et al., 1980; Nesse et al., 1980). Stimuli associated with chemotherapy treatments begin to elicit nausea and vomiting, whereas previously the nausea and vomiting only occurred after the administration of the chemotherapeutic agent.

Nausea and vomiting pose additional difficulties for patients undergoing cancer chemotherapy. Not only does it

pose potentially severe medical problems involving dehydration and malnutrition (Maule & Perry, 1982) but it is quite uncomfortable and produces negative affect in patients and in family members who are in frequent contact with them.

A variety of self-regulation strategies have been utilized in the treatment of nausea and vomiting (Burish & Lyles, 1979; Burish & Lyles, 1981; Burish et al., 1981; Dempster et al., 1976; Labaw et al., 1975; Lyles et al., 1982; Morrow & Morrell, 1982; Redd et al., 1982). These include the use of progressive muscle relaxation training and guided imagery (Burish & Lyles, 1979; Burish & Lyles, 1981; Burish et al., 1981), systematic desensitization (Morrow & Morrell, 1982), and hypnosis (Dempster et al., 1976; Labaw et al., 1975; Redd et al., 1982). The literature cites only one study in which biofeedback training has been utilized in the treatment of chemotherapy-related nausea and vomiting (Burish et al., 1981). Biofeedback training involves operant conditioning as a patient's response is followed by either a reward or punishment. In this study the desired response is the relaxation of muscles in the Rectus Abdominus region and the reward or punishment involves feedback of abdominal muscle tension. The goal is acquisition of self-regulation of muscles in the Rectus Abdominus region. This may be associated with a decrease in self-reported nausea and state anxiety and in the incidence of retching. The primary advantage of using an operant mode in the treatment of what

appears to be a classically conditioned symptom is that it offers the individual a chance to take responsibility for an aspect of his/her treatment (Brown, 1977; Morgan & King, 1971). Methods employing operant conditioning offer means which may be manipulated by either the patient or the professional to induce faster, more efficient learning. Biofeedback training offers the patient immediate, constant, and objective information about his/her attempts at relaxation. This information may be readily understood by adults as well as children and adolescents. Objective data provided by an EMG monitor provides the professional with constant information as to the patient's progress in learning to relax. The professional may then intervene to make relaxation training more efficient for the patient. Finally, objective data offered by EMG biofeedback equipment lends itself to more systematic and quantifiable data than interventions that rely solely on patients' self-report.

In response to the needs of patients on the Hematology/Oncology Unit of the Oklahoma Childrens' Memorial Hospital, who were experiencing chemotherapy-related nausea and vomiting, this research has attempted to demonstrate the efficacy of biofeedback training in the alleviation of these symptoms. Objective measures included patients' EMG measurements from the Rectus Abdominus region and the frequency of retching. Subjective measures included self-reported nausea, state anxiety, and affective state.

It was hypothesized that:

1. Pediatric cancer patients would demonstrate a significantly lower EMG level in the Rectus Abdominus muscle region during biofeedback training than during baseline sessions.
2. Pediatric cancer patients would demonstrate a significantly lower amount of self-reported state anxiety after biofeedback training sessions than after baseline sessions.
3. Pediatric cancer patients would demonstrate a significantly lower level of self-reported nausea after biofeedback training sessions than after baseline sessions.
4. Pediatric cancer patients would show a significantly lower occurrence of retching behavior during biofeedback sessions than during baseline sessions.

# CHAPTER IV

# METHOD

## Subjects

Subjects were four female pediatric cancer patients undergoing cancer chemotherapy treatment on the Hematology/Oncology Service of the Oklahoma Childrens' Memorial Hospital. The age range of subjects was from 12 to 18 years. The physician and nursing staff were consulted to determine which patients on the Hematology/ Oncology Service were experiencing nausea and vomiting and would be appropriate for biofeedback training to alleviate these symptoms. Subjects were selected according to age and stability in their chemotherapy regimen.

## Dependent Variables

The dependent variables were abdominal muscle tension, self-reported nausea, self-reported state anxiety, and observed incidence of retching. Abdominal muscle tension was measured through standard EMG measurement procedures (Gardner & Montgomery, 1977). Electrodes were placed on the subject's Rectus Abdominus muscle region. Averaged EMG recordings were sampled at one-minute intervals (EMG Recording Sheet is shown in Appendix A). Self-reported

nausea was quantified through the Nausea and Vomiting Questionnaire (see Appendix A), which was administered both before and after baseline and biofeedback training sessions.

Subjects' self-report of state anxiety was elicited through the use of the "How-I-Feel Questionnaire," Form C-1 of the State-Trait Anxiety Inventory for Children (STAIC) as developed by Spielberger et al. (1970). The Form C-1 addresses state anxiety in children. This questionnaire was administered to subjects prior to and following each baseline or biofeedback training session. Retching behavior was operationally defined as spasmodic behavior in which the subject's mouth was open, posture was stooped, and belching noises were emitted. At times there was emesis during the retching episode. Episodes were separated from one another by intervals of approximately one minute to be counted as separate. The experimenter informed the attending parent of the operational definition of retching behavior and requested assistance in recording the number of times the subject retched.

## Design

A multiple baseline across subjects design was utilized (Hersen & Barlow, 1976). Each of the four subjects had a different length of baseline and received biofeedback training at a different point in the process of experimentation. The purpose of varying the baseline among subjects was to provide a comparison between baseline and

biofeedback training measures of the dependent variables. Treatment effects are frequently demonstrated with small sample sizes utilizing such designs (Hersen & Barlow, 1976). (An illustration of the multiple baseline across subjects design is included in Appendix B.)

The advantages of this design include: (1) the ability to demonstrate treatment effects with small subject samples making these designs ideal for clinically-based research, (2) a consideration of clinically-significant as well as statistically-significant changes in the dependent variables, (3) all subjects receive all treatment conditions, and (4) carryover effects between sessions may be accommodated by this design (Hersen & Barlow, 1976).

## Procedure

The purpose and procedure in this study was explained to both selected pediatric cancer patients and their parent(s). Consent for participation in this study was obtained from both subjects and the attending parent or guardian. (The Consent Form is presented in Appendix A). Prior to the onset of experimentation, subjects were randomly assigned to their position in the study. This ensured that prior to experimentation the number of baseline and biofeedback sessions for each subject was determined (Hersen & Barlow, 1976). All subjects were measured for at least three sessions to determine baseline dependent variable levels. One subject was then placed in the

biofeedback training condition as planned. After the three remaining subjects had received two more baseline sessions, the second randomly chosen subject was placed in the biofeedback training condition. After the two remaining subjects had received two more baseline sessions, the third randomly chosen subject was placed in the biofeedback training condition. After the one remaining subject had received two more baseline sessions, she was placed in the biofeedback training condition as the fourth randomly chosen subject. No subject received more than nine baseline sessions before beginning biofeedback training.

All subjects, whether in the baseline or biofeedback training sessions, were administered the Nausea and Vomiting Questionnaire to obtain information about the subjective and behavioral presence of nausea and vomiting. All subjects were administered the "How-I-Feel Questionnaire," Form C-1 of the State-Trait Anxiety Inventory for Children (STAIC), before all baseline and biofeedback training sessions to determine subjective state anxiety level prior to chemotherapy treatments.

All subjects were measured for five one-minute intervals prior to the administration of cancer chemotherapy to obtain abdominal EMG recordings. Surface electrodes were attached to the region adjacent to the patient's Rectus Abdominus muscles. Measurement of abdominal EMG, in conjunction with the Nausea and Vomiting Questionnaire and the STAIC Form C-1 administered prior to the session,

provided a measure of anticipatory nausea and vomiting. All subjects received baseline and biofeedback training after chemotherapy had been administered. All sessions were of forty-three minute duration. Measurement of abdominal EMG activity occurred at one-minute intervals in both baseline and biofeedback training sessions.

Once the EMG and ground electrodes were attached, subjects undergoing measurement, whether as a baseline or a biofeedback training session, were given a ten-minute period of adaptation. Following this, the five-minute recording of pre-chemotherapy abdominal muscle tension was taken. Abdominal EMG was then recorded at the onset of chemotherapy. All subjects then received another ten-minute adaptation period. Following this, another five-minute period of EMG measurement occurred to determine abdominal muscle tension post-chemotherapy but prior to any biofeedback training. Subjects undergoing biofeedback training were given short verbal instructions about biofeedback training (See Appendix A for verbal instructions for baseline and biofeedback sessions). Subjects in the biofeedback training condition had five five-minute biofeedback training periods separated by one-minute periods. Subjects in the biofeedback training condition were then instructed to relax normally in order to gain a posttraining abdominal EMG recording over a five-minute period. Subjects in the baseline sessions were given no verbal instructions regarding biofeedback training or any

feedback about abdominal muscle tension. They were, however, measured at the intervals used in the biofeedback training sessions. During all sessions, both the experimenter and the attending parent observed behavioral episodes of retching. Subjects then completed the Nausea and Vomiting Questionnaire and the "How-I-Feel Questionnaire" STAIC Form C-1 again at the conclusion of all sessions.

## Analyses

This study employed a multiple baseline design across four subjects. The Rn Statistic (Revusky, 1967) was utilized to determine the statistical significance of biofeedback training in altering nausea and vomiting that accompanies chemotherapy. This is a statistical method which is particularly suited to situations in which treatment effects are irreversible and in which multiple baseline design data is collected across individuals (Hersen & Barlow, 1976).

Treatment in this design was introduced to subjects one at a time in a manner determined randomly and prior to experimentation. The performance of each subject as she was assigned to the biofeedback training condition was compared to the performance of all subjects who had not yet received biofeedback training but who had completed the same number of sessions. This subexperiment produced a rank for the subject who had begun receiving biofeedback training.

Subjects who had previously received biofeedback training were not included in subsequent rankings in the individual subexperiments. This ranking procedure was repeated all as if the subjects received biofeedback training. The Rn Statistic is composed of the sum of the ranks for the individual subexperiments across the experiment. This is repeated for each dependent variable. An underlying assumption of the Rn Statistic is that, since treatment is introduced to subjects in a random manner, the ranks of subjects at the point of intervention are equally likely. In order for statistical significance to be demonstrated, the introduction of the treatment intervention would have to consistently demonstrate the lowest ranking of the dependent variable in question. A one-tailed statistical significance was associated with the Rn Statistic (Hersen & Barlow, 1976; Revusky, 1967).

The Rn Statistic was utilized for the statistical analysis of all dependent variables. In order to provide a more stable estimate of actual performance, the mean of the first two biofeedback sessions was used in all rankings. To maintain consistency, subjects' baseline dependent variable values, used in any ranking process, were also a mean between two sessions (Hersen & Barlow, 1976). For purposes of providing additional useful information, graphic representations and means of the dependent variables were provided for individual subjects and for the group.

# CHAPTER V

## RESULTS

Results of the Rn Statistic are presented for each dependent variable. EMG data is presented for the transformed pre- and postchemotherapy five-minute baseline measures (See Appendix K, Figures 1 and 2) and for the nontransformed pre- and postchemotherapy five-minute baseline measures (See Appendix K, Figures 3 and 4). Figure 5 presents the transformed means of the five postchemotherapy practice or baseline periods per session. Figure 6 presents the nontransformed means of the five postchemotherapy practice or baseline periods per session. The State-Trait Anxiety Inventory for Children (STAIC FORM C-1) data is presented for the periods before and after chemotherapy (See Appendix K, Figures 7 and 8). Self-reported nausea, derived from the two scales on the Nausea and Vomiting Questionnaire, are also presented for the time periods before (See Appendix K, Figures 9 and 10) and after (See Appendix K, Figures 11 and 12) chemotherapy and biofeedback training. The incidence of retching behavior before (See Appendix K, Figure 13) and after (See Appendix K, Figure 14) chemotherapy is presented. Issues of clinical

significance of the data are presented in Chapter VI, Discussion.

## Pre- and Postchemotherapy EMG Recordings

The Rn Statistic was performed on abdominal EMG data for three separate time periods (See Appendix A for Data Recording Sheet). The first two time periods analyzed were the five-minute baseline sessions which occurred before and after chemotherapy was begun. The third time period in which abdominal EMG values were analyzed involved the mean of the five postchemotherapy baseline or biofeedback periods per session (See Appendix D for abdominal EMG data for all three time periods). A posttraining abdominal EMG five-minute baseline period was also to be analyzed through use of the Rn Statistic. Inconsistency among experimenters in the use of the headphones during the posttraining five-minute baseline periods was discovered while analyzing this data. This required that a large portion of the posttraining abdominal EMG data not be used in the analysis to avoid contamination of results. As a result there was not enough data available to perform an Rn Statistic on this time period. It was noted, however, that experimenter inconsistency in the auditory presentation of abdominal EMG feedback may not have unduly influenced results in the posttraining baseline sessions as subjects were able to detect visual cues due to design of the EMG equipment,

placement of the equipment in the room, and exposure to feedback cues earlier in the same session.

There was considerable variability in abdominal EMG values between subjects during baseline sessions. Baseline abdominal EMG values varied enough to obscure directional changes in performance when biofeedback was introduced. In order to avoid unwanted influence on the Rn Statistic, all abdominal EMG data was transformed as suggested by Hersen and Barlow (1976). The transformation involved subtraction of the mean abdominal EMG baseline value from the actual session's abdominal EMG value. The result was then divided by the mean abdominal EMG baseline value.

Prechemotherapy Baseline

Figure 1 presents the transformed prechemotherapy five-minute baseline abdominal EMG data for all subjects. The second subject showed an increase in abdominal EMG value in the sessions in which she was to receive biofeedback training later. All other subjects showed no appreciable change in abdominal EMG value in sessions in which they were to receive biofeedback training at a later point (See Appendix K, Figure 1). Results of the Rn Statistic performed on the transformed prechemotherapy five-minute baseline abdominal EMG data indicate that there is no significant decrease in prechemotherapy abdominal EMG value during sessions in which biofeedback training was later introduced ($Rn = 6$, $p. > .05$).

Postchemotherapy Baseline

Figure 2 presents the transformed postchemotherapy five-minute baseline abdominal EMG data for each session. All subjects showed no appreciable change in abdominal EMG value in sessions in which biofeedback training was later introduced (See Appendix K, Figure 2). Visual comparison between pre- and postchemotherapy abdominal EMG data reveals little difference in abdominal EMG value (See Appendix K, Figures 3 and 4). This appears to refute the presence of anticipatory abdominal muscle tension. Results of the Rn Statistic performed on postchemotherapy abdominal EMG values indicates that there is no significant decrease in abdominal EMG value during sessions in which biofeedback is later introduced ($Rn = 9$, $p. > .05$).

Biofeedback Training Sessions

Biofeedback training was introduced only during the five practice periods per session. Figure 5 presents the transformed EMG data for the biofeedback training or baseline periods for each subject. Visual inspection of the transformed abdominal EMG data shows a difference of less than 1.5 microvolts in abdominal EMG tension with the introduction of biofeedback training (See Appendix K, Figure 5). Visual inspection of the actual abdominal EMG data for the biofeedback training periods per session is presented in Figure 6 and is consistent with these findings. Results of the Rn Statistic indicates that there was no significant

decrease in mean transformed abdominal EMG value with the introduction of biofeedback training (Rn = 8, p. > .05).

It is of interest that the mean transformed abdominal EMG for baseline sessions is somewhat higher than the mean for biofeedback training sessions. The mean transformed abdominal EMG data for five-minute baseline sessions is -0.01 while the mean transformed abdominal EMG data for biofeedback training sessions is -0.17. A students' t-test performed on the transformed abdominal EMG means for baseline and biofeedback training sessions was nonsignificant (t = .44, df = 3, p.> .05, one-tailed).

In summary, graphical depiction of abdominal EMG values for each of the three time periods shows no appreciable change in abdominal EMG tension when biofeedback training is introduced (See Appendix K, Figures 1, 2, and 5). Results of the Rn Statistic, performed on pre- and postchemotherapy abdominal EMG values and on Abdominal EMG values during the biofeedback practice periods, also indicated that there is no significant decrease in abdominal EMG value when biofeedback training was introduced. Results do not appear to demonstrate that acquisition of self-regulation of the Rectus Abdominus muscle region was achieved (all transformed abdominal EMG data is presented in Appendix D).

## State-Trait Anxiety Inventory for Children (STAIC Form C-1)

Each item on the State-Trait Anxiety Inventory for Children, STAIC Form C-1, is a three-point rating scale. Each alternative is assigned a value of one, two, or three points. The maximum total score for the STAIC Form C-1 is 60. The minimum total score for the STAIC Form C-1 is 30.

### Pretraining STAIC Data

Figure 7 presents pretraining STAIC state anxiety data for each subject. Subjects show no appreciable change in state anxiety in sessions in which biofeedback training is later introduced (See Appendix K, Figure 7). Results of the Rn Statistic indicate that there is no significant decrease in state anxiety among patients for whom biofeedback training is later introduced ($Rn = 7$, $p. > .05$).

### Posttraining STAIC Data

Figure 8 shows posttraining STAIC data for all subjects. All subjects show no appreciable change in state anxiety in sessions in which biofeedback training is introduced (See Appendix K, Figure 8). Results of the Rn Statistic indicate that there is no significant decrease in state anxiety among patients who have received biofeedback training ($Rn = 7$, $p. > .05$).

In summary, graphic presentation of both pre- and posttraining STAIC data reveals no appreciable change in

state anxiety in sessions in which biofeedback training is introduced (See Appendix K, Figures 7 and 8). Results of the Rn Statistics performed on pre- and posttraining STAIC data shows no significant decrease in state anxiety in sessions in which biofeedback training is introduced (all STAIC scores are presented in Appendix E).

## Self-Report Nausea

A Rn Statistic was performed on both pre- and postchemotherapy data for each of the two scales on the Nausea and Vomiting Questionnaire. Recall that these five-point scales asked subjects to indicate the extent to which they felt sick to the stomach and felt like vomiting. Subjects' mean self-reported nausea varied considerably. It was thought that the differences among subjects' mean self-reported nausea would obscure results of the Rn Statistic. For this reason, a transformation similar to the one used on the abdominal EMG date, was utilized.

### Pretraining Self-Reported Nausea

Figure 9 shows transformed prechemotherapy self-reported nausea data prior to biofeedback training for the extent to which subjects felt sick to the stomach. Visual inspection reveals no appreciable change in self-report nausea among subjects who are later introduced to biofeedback training (See Appendix K, Figure 9). The Rn Statistic performed on this data suggests that there is no

significant decrease in self-reported nausea during sessions in which biofeedback training is later introduced (Rn = 6, p. > .05).

Figure 10 presents transformed prechemotherapy self-reported nausea data prior to biofeedback training for the extent to which patients felt like vomiting. Subjects show no appreciable change in self-reported nausea in sessions in which biofeedback is later introduced (See Appendix K, Figure 10). The Rn Statistic performed on this data suggests that there is no significant decrease in self-reported nausea during sessions in which biofeedback training is later introduced (Rn = 4.5, p.> .05).

Posttraining Self-Reported Nausea

Figure 11 shows transformed postchemotherapy nausea data after biofeedback training for the extent to which subjects felt sick to the stomach. Visual inspection reveals that the second subject reported more feelings of nausea in sessions in which biofeedback training had been introduced (See Appendix K, Figure 11). The three other subjects showed no appreciable difference in self-reported nausea in sessions in which biofeedback training had been introduced. The Rn Statistic suggests that there is no significant decrease in self-reported nausea during sessions in which biofeedback training was introduced (Rn = 7, p.> .05).

Figure 12 presents transformed postchemotherapy self-reported nausea data after biofeedback training for the extent to which subjects felt like vomiting. Visual inspection suggests that the second subject experienced an increase in posttraining feelings of nausea (See Appendix K, Figure 12). All other subjects showed no appreciable difference in posttraining self-reported nausea. Results of the Rn Statistic suggests that there is no significant decrease in self-reported nausea during sessions in which biofeedback training was introduced (Rn = 8, $p. > .05$).

In summary, both the Rn Statistic and visual inspection of the data on pre- and posttraining self-reported nausea suggest that there is no appreciable change when biofeedback training is introduced (data and figures for self-reported nausea are shown in Appendix G).

## Actual Retching Behavior

### Prechemotherapy Retching Behavior

Figure 13 shows subjects' actual retching behavior before chemotherapy was administered. Visual inspection suggests that little actual prechemotherapy retching behavior was reported overall (See Appendix K, Figure 13). Results of the Rn Statistic suggests that there is no significant decrease in retching during sessions in which biofeedback training is later introduced (Rn = 6.5, $p. > .05$).

Postchemotherapy Retching Behavior

Figure 14 shows subjects' actual retching behavior after chemotherapy was begun. Visual inspection reveals that little actual retching took place after biofeedback training was introduced (See Appendix K, Figure 14). The Rn Statistic performed on this data indicates that there is no significant decrease in retching behavior after biofeedback training has been introduced ($Rn = 6$, $p. > .05$). (Data for actual retching behavior is shown in Appendix I.)

# CHAPTER VI

# DISCUSSION

As the acquisition of self-regulation of the muscle tension in the Rectus Abdominus region could not be demonstrated, hypotheses could be neither confirmed nor refuted. No statistically significant statements can be made on the basis of the results of this study about the efficacy of biofeedback training on abdominal EMG, self-report state anxiety, self-report nausea, or the occurrence of retching behavior among pediatric cancer patients experiencing chemotherapy-related nausea and vomiting.

While the literature reports that nausea and vomiting are problematic for pediatric cancer patients undergoing chemotherapy and while these subjects were selected for their complaints of nausea and vomiting, very little actual retching behavior was noted during the course of the study. Vomiting tended to occur either the night before the treatment or several hours after the treatment by subjective report. Pre- and postchemotherapy measures of the dependent variables were compared to demonstrate the presence of anticipatory nausea and vomiting. Although subjects frequently reported clinically that they had experienced

nausea and vomiting the night before a treatment, this study did not demonstrate any noticeable statistically significant presence of anticipatory nausea and vomiting. The low self-reported incidence of anticipatory and postchemotherapy baseline nausea and vomiting makes the demonstration of a treatment effect less likely.

Acquisition of self-regulation of abdominal muscles through biofeedback training involves a secondary reinforcer, namely feedback of bodily functions. Classical conditioning is thought to function through the use of primary reinforcers such as food and water. It is possible that the reinforcers in this study, auditory and visual feedback of tension in the Rectus Abdominus muscles, simply were not effective enough to provide a treatment effect (Yates, 1980). More of a treatment effect might have been demonstrated had biofeedback training been coupled with additional reinforcers.

Finley (1983) particularly stresses the importance of using additional reinforcers in biofeedback training with children. He also suggests that children may require more frequent and varied practice sessions in order to demonstrate a treatment effect. Implementation of differential reinforcers however, would have involved biofeedback training with various reinforcers and in various settings which would have overly complicated the research design. Finley (1983) states that children over the age of ten can generally be treated more as adults and may not

require the use of additional reinforcers. As all of the subjects were between the ages of 12 and 18, the use of additional reinforcers may not have been a useful addition to the procedure in producing a treatment effect.

Lack of adequate demonstration of self-regulation of abdominal muscles, statistically or clinically, may have been in part due to measurement procedures. Abdominal EMG levels appeared quite low throughout the study. Although the Rectus Abdominus muscle region appeared to the experimenters to be a logical place to measure, some other placement may have been more useful. To choose another electrode site, such as the frequently used frontalis (Gardner & Montgomery, 1977), might have provided a more generalized index of muscle tension. The frontalis is generally chosen when the goal is lower arousal or relaxation. It has the advantages of being a direct expressor of stress in the musculoskeletal system, of being readily accessible for instrumentation and of not necessitating postural changes in the subject (Gardner & Montgomery, 1977). It was questionnable, however, whether acquisition of self-regulation of frontalis muscles would be useful in decreasing the clinical incidence of nausea and vomiting. This is due to the necessity of tension within the abdominal muscles for the process of vomiting to occur. The retching phase occurs when there is negative pressure in the thorax, which causes food to move within the gut. Vomiting occurs when the positive pressure in the

abdomen is transmitted to the thorax in an upward shift of the diaphragm (Maule & Perry, 1983). Other muscle sites are frequently chosen for relaxation training depending on the problem (Gardner & Montgomery, 1977). It was thought that a more specific muscle site, such as the Rectus Abdominus muscles, might produce better results. Individual differences in fat and muscle composition further complicate results obtained through electrodes.

Results were further complicated by factors in the clinical setting which were beyond the experimenter's control. All subjects who completed this study were female, although both male and female subjects were recruited and selected. There is, therefore, some question about the statistical generalizability to male pediatric cancer patients had the hypotheses been supported. Individual sessions varied a great deal. Individual sessions, even for the same subject, frequently occurred at different times of the day. The chemotherapy regimens required that different chemotherapeutic agents be administered at varying intervals. The time interval between chemotherapy treatments varied both between and within subjects. An antiemetic was given to the subject during many, but not all, of the sessions. Different types and doses of antiemetics were administered at various times during the chemotherapy sessions. Subjects frequently took antiemetics at home before they came to the clinic for chemotherapy. The administration of the chemotherapeutic agent was

different from subject to subject and from session to session. Subjects were administered chemotherapeutic agents through an IV push, an IV drip, shots, or by mouth. Aside from factors within the clinical setting, there were session-to-session differences in subjects' moods and other personal factors. Outside influences from home and school were present. These affected how the adolescent felt on any given day about receiving treatment. Parental attitudes, often conveyed nonverbally, may have influenced results. The length of time between sessions may be a factor in working with children who may lose some of the benefits of training with time and lack of practice.

Most of the children had the expectation that biofeedback training would help them to decrease their nausea and vomiting. This may have influenced both statistical and clinical results. Subjects became accustomed to being measured after two or three sessions, and any erratic results ceased after some experience with the experimental procedure. Although not a statistically significant result, several of the subjects seemed to clinically experience a slightly lowered EMG level during practice sessions and lower incidence of retching after the introduction of biofeedback training.

Adolescents' subjective accounts of their experiences with biofeedback training may shed some light on the clinical efficacy of biofeedback training in the treatment of chemotherapy-related nausea and vomiting. One of the

subjects reported that throughout her life she had responded to stress through nausea and vomiting. She would become nauseous before a test. She became car sick easily on trips. When she began to receive cancer chemotherapy treatments, this tendency to respond with nausea heightened. She reported, although it was not evident from statistical results, that clinically biofeedback training had helped her in becoming less nauseous. She reported that not only did biofeedback training help her to relax during chemotherapy, but she was able to apply it to upsetting situations outside of the chemotherapy regimen. Her response may have been partially due to the fact that she had received the maximum number of biofeedback training sessions in this study.

Subjects demonstrated interest in the biofeedback equipment. Their interest in the equipment may have taken their attention away from the chemotherapy regimen long enough to allow for some relaxation. The relaxation may have been beneficial in clinically reducing nausea and vomiting. Most of the subjects, if nothing else, seemed to enjoy the extra attention and the relationship that can build through sharing an experience of this sort. This study required that the experimenter be with the subject throughout the session.

Although hypotheses were not statistically supported, clinical observation suggests that the acquisition of self-regulation of the Rectus Abdominus muscles is useful in the

alleviation of nausea and vomiting among pediatric cancer patients. Patients appeared to relax after attempting to lower muscle tension. They frequently fell asleep while doing so. At times, they reported less nausea. Some of them stated that they generally felt better after attempting to relax. Parents reported that when the patient practiced biofeedback at home, she was more relaxed and less nauseous. This was not demonstrated on the "How-I-Feel Questionnaire" (STAIC) or on the Nausea and Vomiting Questionnaire. In many cases they had not reported feeling nauseous or emotionally upset before the session began. It is suspected that lack of reporting nausea or vomiting is due to the lack of sensitivity in the questionnaires used. When asked, patients demonstrated that they could raise and lower their EMG levels in the Rectus Abdominus muscle region. The difference between the relaxed and tensed abdominal EMG levels, however, appeared very small. The range was approximately one microvolt, and the acquisition of self-regulation of the Rectus Abdominus muscles was not demonstrated. Perhaps if the extent of nausea, negative affect, and the acquisition of self-regulation of Rectus Abdominus muscles could have been recorded in a more precise and sensitive manner, there could have been a statistical difference demonstrated.

Further research addressing the acquisition of self-regulation of the Rectus Abdominus muscles is demonstrated may provide a better indication of the efficacy of

biofeedback training in the alleviation of nausea and vomiting among pediatric cancer patients. Replication of the single subject design across two or more groups of pediatric cancer patients experiencing nausea and vomiting may assist in providing a demonstration of the acquisition of self-regulation of the Rectus Abdominus muscles. Another EMG measurement site, such as the frontalis, may prove to be more sensitive to muscle tension among pediatric cancer patients. The Nausea and Vomiting Questionnaire utilized in this study may be revised to provide a better indication of subjective nausea and vomiting among pediatric cancer patients. One revision of the questionnaire would include the expansion of the range of available responses and through the development of questions more specific to the symptoms of chemotherapy-related nausea and vomiting. Where feasible, the number of experimenters should be limited to control for discrepancies in measurement and experimental procedure and to provide for consistency in factors involving the development of a therapeutic relationship. Further control of factors inherent to the clinical setting may also assist in providing a demonstration of the acquisition of self-regulation of muscle tension. Clinical controls could involve the limitation or postponement of the administration of antiemetics and the selection of pediatric cancer patients with a more similar diagnosis and chemotherapy regimen.

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# APPENDIXES

# APPENDIX A

## DESCRIPTION OF INSTRUMENTS

Table A-1

EMG Recording Sheet

Session Number Subject's Session Number:

Subject Name:
Date:
Time:
Observer(s):

Administer questionnaire:

10 minute adaptation period EMG:

Baseline 5-minute EMG: 1.
2.
(Prechemotherapy) 3.
4.
5.

Injection or other form of chemotherapy (Type: )

Chemotherapy administration EMG:

10 minute adaptation period EMG:

Baseline 5-minute EMG: 1.
2.
3.
4.
5.

| | Practice Sessions or Baseline | | | |
|---|---|---|---|---|
| Time One | Time Two | Time Three | Time Four | Time Five |
| 1. | 1. | 1. | 1. | 1. |
| 2. | 2. | 2. | 2. | 2. |
| 3. | 3. | 3. | 3. | 3. |
| 4. | 4. | 4. | 4. | 4. |
| 5. | 5. | 5. | 5. | 5. |

Rest Period

1.
2.
3.
4.
5.

Administer questionnaires.

Table A-2

Nausea and Vomiting Questionnaire

Please place a mark (X) on the place on each scale that describes how you are feeling right now.

| | | |
|---|---|---|
| I don't feel sick to my stomach | 1 2 3 4 5 | I feel very sick to my stomach |
| I don't feel like vomiting | 1 2 3 4 5 | I feel very much like vomiting |

Did you vomit: Yes _____ No _____

If you vomited, when did you do so? _____

How many times did you vomit? _____

How much time did it take? _____

Did you vomit - A great deal? _____
Only a little? _____

Instructions for the Baseline and the Biofeedback Training Sessions

Introduction to the baseline session:

> "During this session, I will be measuring your muscle tension around your stomach. I will be placing these electrodes on your stomach so that I can measure how tense your stomach muscles are. I will also be asking you some questions before and after our session about how you are feeling."

Introduction to the biofeedback training session:

> "During this session, I am going to work with you on biofeedback training. When your muscles are tense, you are more likely to feel sick to your stomach. If you can learn to relax your stomach muscles, you might feel better and you might be less likely to get sick.
>
> As you recall, these electrodes that I placed on your stomach measure your muscle tension in that area. The message that your muscle sends through the electrodes is registered in this machine. When it is time for you to receive biofeedback training, you will be able to hear how tense your stomach muscles are."

Instructions immediately preceding biofeedback training:

> "Now it is time for you to learn about biofeedback training. This machine will help you to see and hear how tense your muscles around your stomach are.
>
> If you look at this dial you can see how tense your muscles are. If you are very relaxed, the needle will be towards the left side of the dial where the lower numbers are. The more tense you are, the more the needle will go to the right side of the dial where the higher numbers are. Your goal will be to get the needle as far to the left side as possible so that the muscles around your stomach will be more relaxed.
>
> It may help you right now to get the feel of how this machine works by tensing and relaxing your stomach muscles a few times before we begin. Then you can see how you feel and what happens to the dial.
>
> Biofeedback training also allows you to hear how tense your muscles are. When we begin, I will put these earphones on your head. You will hear electronic noises through them. In general, the more relaxed the muscles around your stomach are, the less noise you will hear. If your muscles get tenser, the machine will make more noises. Your goal will be to slow down the noise as much as possible so that the muscles around your stomach will be more relaxed. You may find that your stomach feels better this way."

Allow subject to listen briefly to noises and to select from three available electrical noise patterns.

"Now that you have found the noise pattern that you like the best, you might want to try tensing and relaxing your stomach muscles again for a few moments so that you know what you are aiming for. Recall that you want to slow down the noises as much as possible. Don't forget that the dial also gives you an indication of how tense the muscles around your stomach are."

During the biofeedback training practice session:

"Now I want you to try for the next five minutes to relax your stomach muscles. Try to get the needle on the dial as far to the left as possible. Try to slow down the noise as much as you can so that you can be more relaxed."

At the end of the five minute period:

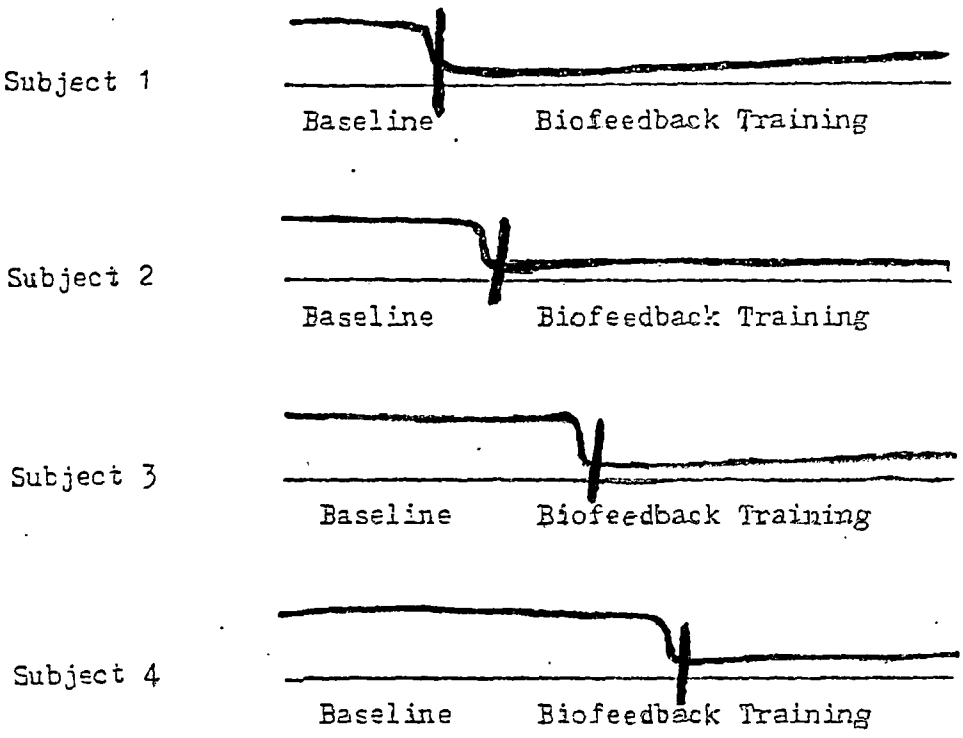
"OK, just relax normally."

# APPENDIX B

# ILLUSTRATION OF DESIGN

Table B-1

Illustration of Design




Multiple Baseline Across Subjects Design - Baseline Sessions and Biofeedback Training Sessions

# APPENDIX C

## CONSENT FORMS

Table C-1

## Participant Consent Form

Participant Consent Form

I, _____, voluntarily consent to participate in the study entitled, "Biofeedback Training in the Treatment of Anticipatory Nausea and Vomiting Among Pediatric Cancer Patients." I, _____, agree to allow my child, _____, to participate.

I understand the following:

1. Purpose: The purpose of this study is to show the usefulness of biofeedback training in the treatment of nausea and vomiting before chemotherapy treatments among pediatric cancer patients.
2. Status of Investigational Drug or Procedure: No investigational drug or procedure is used.
3. Description of Study: Subjects will be pediatric cancer patients undergoing chemotherapy treatments on the Hematology/Oncology Clinic of Oklahoma Children's Memorial Hospital. Subjects will participate in baseline sessions in which muscle tension in the abdominal region will be measured. Subjects will also participate in biofeedback training sessions in an attempt to stop nausea and vomiting before chemotherapy sessions. Parents will be asked to assist in counting the number of times the child retches. All sessions will be of approximately 43 minutes duration and will place little restriction on patients' activities. Subjects will be asked to complete two short questionnaires prior to and after each session about their feelings and the presence of nausea and vomiting. A comparison for each pediatric cancer patient will be made between baseline and biofeedback training sessions to determine differences in abdominal muscle tension, nausea, retching behavior, and feelings.
4. Benefits: This study will help to show the effects of biofeedback training in the treatment of anticipatory nausea and vomiting among pediatric cancer patients. Subjects may experience less muscle tension, nausea and vomiting before, during and after chemotherapy treatments.
5. Risks: There are no known risks to patients or their parents/guardians as a result of their participation in this study.
6. Subject's Assurance: Whereas no assurance can be made concerning results that may be obtained (since results from investigational studies cannot be predicted) the investigators will take every precaution consistent with the best medical and psychological practice. By signing this consent form I have not waived any of my legal rights or released this institution from liability for negligence. I may revoke my consent and withdraw from this study at any time. Should any problems arise during this study, I may take them to the Director of Research Administration, Room 362, Biomedical Sciences Building, Phone (405) 271-2090.

| | |
|---|---|
| _____ | _____ |
| Parent or Guardian's name | Parent or Guardian's name |
| _____ | _____ |
| Parent or Guardian's signature | Parent or Guardian's signature |
| _____ | _____ |
| Child's signature | Signature of Principal Investigator |
| Mary Ann Constable, M.S.<br>Michael Funk, Ph.D.<br>H. Stephen Caldwell, Ph.D. | _____ |
| _____ | Date |
| Investigators | |

Table C-2

# Institutional Review Board Application

UNIVERSITY OF OKLAHOMA HEALTH SERVICES CENTER
INSTITUTIONAL REVIEW BOARD

APPLICATION

I. New Research Grant and Contract Applications (SIGNED ORIGINAL AND SIX COPIES)
Submit a signed original and six (6) copies of your application (this form, protocol, and consent form) to the Chair of the Institutional Review Board, Room 115, MSC Library Building. For training grants, career awards, fellowships or scholarships, submit only ONE copy.

A. Research Proposal

1. Title of Study Biofeedback Training in the Treatment of Anticipatory Nausea and Vomiting Among Pediatric Cancer Patients

2. Sponsoring Agency and Agency ID Number Hematology/ Oncology Service, OCMH

3. Principal Investigator Mary Ann Constable, M.S. (student), OSU

University Appointment: ☒ Yes; ☐ No. If NO, identify institutional employer:

Department Pediatrics, Psychiatry & Behavioral Sciences College Medicine

Building OCMH Room 2B265 Telephone Extension 5311

4. Collaborating Investigator(s)/Department(s)/ College(s) Michael Funk, Ph.D., Pediatrics, Psychiatry & Behavioral Sciences, OUHSC, H. Stephen Caldwell, Ph.D., Professor of Psychology, Oklahoma State University

5. Site(s) of study: ☒ OCMH; ☐ OMH; ☐ VAMC; ☐ Other (identify)

B. Description of Subjects

1. Age(s): 12-18

2. Sex: ☐ Females Only; ☐ Males Only; ☒ Both

3. Special Qualification: patients undergoing chemotherapy on Hematology/ Oncology Service who are experiencing anticipatory nausea and vomiting.

4. Source: OCMH Hematology/ Oncology Service

5. Specify the number of subjects needed for this study: Patients 4 ; Healthy Volunteers: 0

6. Identify any conditions under which subjects will be terminated from the study before its completion:

7. Identify any groups of subjects who will be excluded from the study: none

C. Additionally Protected Groups: Please identify any or all of the following groups involved in this research protocol:

| | | |
|---|---|---|
| ☐ Pregnant Women | ☐ Abortuses | ☐ Mentally Disabled |
| ☐ Prisoners | ☐ Fetuses | ☐ Mentally Retarded |
| ☒ Children | | |

If children are involved, are they wards of the State? ☐ Yes; ☒ No.

D. Ethical Considerations

1. Informed consent will be obtained from any human subjects (patients or normal volunteers) participating in this study: ☒ Yes; ☐ No. If NO, explain why:

2. Informed consent will be obtained for administration of any investigational drug: ☐ Yes; ☒ No. If NO, explain why:
Not applicable

3. Informed consent will be obtained for biopsy, other surgical procedures, or other unusual procedure: ☐ Yes; ☒ No. If NO, explain why:

Not applicable

4. Identify the benefits to the subject or to others to be obtained from the study:

This is an investigational study to assess the effectiveness of biofeedback training in the treatment of anticipatory nausea and vomiting among pediatric cancer patients. Subjects may experience a reduction in nausea, retching and vomiting behavior as well as a reduction in muscle tension.

5. Identify the risks to the subject:

There are no known risks involved.

6. Is there a risk of physical injury to subjects? ☒ No; ☐ Yes. If YES, the subjects must be informed about the availability of compensation and medical treatment. Check with your institutional official about policy governing such compensation and medical treatment.

a. Will medical treatment be provided? ☐ No; ☐ Yes.

If YES, will be be provided free ☐ or at a reasonable fee ☐ ?

b. Will compensation be provided? ☐ No; ☐ Yes. If YES, how will it be provided?

7. Identify on incentives or rewards that will be offered to the subjects.

Not applicable

8. Identify the safety precautions that will be taken to protect the health of subjects and/or the personnel participating in this study.

Not applicable

E. Informed Consent

1. If a written consent document is used, SEVEN (7) copies of the form are to be included with the application The consent form should include all elements of informed consent as described in the Institutional Assurance.

   (See Page 4 for a sample consent form.)

2. If oral consent is used, the exact wording of the statement read to the subject is required. The statement should contain all elements of informed consent as outlined in the Institutional Assurance. A separate document is required in addition to the oral consent statement. The separate document must be signed by the subjec or the subject's legal guardian, the investigator and a third party who witnessed the oral presentation.

3. If children are to be involved as subjects:

   - The consent of both parents is required by federal regulation unless one parent is decreased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
   - The assent of the children is required by federal regulation, if the child is capable o providing such assent.

F. Exempted Review

There are several cases which may "exempt" your protocol fro full IRB review. (See Page 5 for a list of exemptions.) If you request an exemption, you need to submit ONE copy of the application (this form, protocol, and consent form) and identify the exemption by encircling its numbers:

1 2 3 4 5

G. Expedited Review

Expedited review is provided for research which involves no more than minimal risk or for review of minor changes in previously approved research protocols. In order to approve research covered by the regulation, the IRB will determine that all of the following requirements are satisfied (The list below is utilized for all projects under IRB review):

- risks to subjects are minimized;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the
- knowledge that may reasonably be expected to result;
- selection of subjects is equitable;
- informed consent will be sought from each prospective subject or the subject's legally authorized representative;
- informed consent will be appropriately documented;
- when appropriate, the research plan takes adequate provision for monitoring data collected to ensure saftey of subjects; and
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

If you request expedited review, you need to submit ONE copy of the application (this form, protocol, and consent form) and identify the reason for expedited review by encircling its number below. The categories for "Expedited Review" are found on Page 5.

1 2 3 4 5 6 7 8 9 10

H. Annual Review of Studies Involving Research with Human Subjects

The terms of our Institutional Assurance for the protection of human subjects require that the principal investi- gator prepare an annual progress report for review by the IRB. The Office of Research Administration will notify investigators when reports are due. The annual progress report is an important requisite for annual review. If a progress report is not returned by the date requested, the IRB will place the project on inactive status, precluding any further research.

I. Certification

The principal investigator agrees to the above requirements and statements, and has received approval from all persons named as collaborating investigators.

6-19-92
Date

Signature

# APPENDIX D

## EMG DATA

Table D-1

EMG Data for Prechemotherapy Five-Minute Baseline

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1.2 | 1.3 | 1.2 | 1.1 | 0.9 | 1.4 | 1.4 | 1.9 | 2.2 | 0.6 | 0.7 | 0.5 |
| 2 | 0.6 | 0.7 | - | 0.8 | 0.8 | 1.9 | 2.6 | - | - | - | - | - |
| 3 | 3.5 | 0.8 | 0.8 | 2.6 | 0.9 | 0.6 | 0.9 | 1.1 | 0.7 | 0.5 | 0.8 | 0.4 |
| 4 | 1.6 | 2.3 | 2.1 | 1.5 | 0.7 | 1.4 | 1.4 | 0.9 | 2.4 | 0.9 | 0.8 | 2.8 |

Note. - = Missing data.

Table D-2

EMG Data for Postchemotherapy Five-Minute Baseline

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1.0 | 0.9 | 0.7 | 1.1 | 0.8 | 0.8 | 0.9 | 1.0 | 1.3 | 0.7 | 0.7 | 0.5 |
| 2 | 0.7 | 0.6 | 0.9 | 0.6 | 0.9 | 1.2 | 2.0 | - | - | - | - | - |
| 3 | 1.9 | 0.6 | 0.8 | 2.7 | 1.3 | 0.5 | 0.8 | 2.3 | 1.2 | 0.5 | 1.6 | 0.6 |
| 4 | 3.0 | 2.4 | 1.7 | 2.0 | 1.1 | 2.1 | 1.3 | 0.8 | 1.0 | 0.8 | 1.0 | 0.7 |

Note. - = Missing data.

Table D-3

EMG Data for Mean of Five Biofeedback Training Practice Periods

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1.1 | 0.7 | 0.7 | 0.8 | 0.6 | 0.7 | 0.6 | 0.9 | 0.9 | 0.5 | 0.4 | 0.5 |
| 2 | 0.5 | 0.6 | 1.9 | 0.5 | - | 0.7 | 1.7 | - | - | - | - | - |
| 3 | 3.1 | 0.7 | 0.8 | 2.5 | 0.8 | 0.5 | 0.8 | 0.3 | 0.5 | 0.4 | 0.4 | 0.5 |
| 4 | 5.0 | 2.7 | 1.3 | 1.5 | 0.9 | 1.4 | 1.0 | 0.7 | 0.8 | 0.7 | 0.5 | 0.6 |

Note. - = Missing data.

# APPENDIX E

## TRANSFORMED EMG DATA

Table E-1

Rn Statistic on Transformed Prechemotherapy EMG Five-Minute Baseline

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | -0.0 | 0.1 | -0.0 | -0.1 | -0.2 | 0.2 | 0.1 | 0.6 | 0.8 | -0.2 | -0.5 | -0.6 |
| 2 | -0.2 | -0.1 | - | 0.1 | 0.2 | 1.6 | 2.5 | - | - | - | - | - |
| 3 | 1.4 | -0.4 | -0.4 | 0.8 | -0.4 | -0.6 | -0.4 | -0.3 | -0.5 | -0.6 | -0.5 | -0.7 |
| 4 | 0.0 | 0.5 | 0.3 | -0.1 | -0.6 | -0.1 | -0.1 | -0.5 | 0.5 | -0.5 | -0.5 | 0.8 |
| Ranks | | | | | 1 | | 3 | | 1 | | 1 | |

Rn Statistic = 6

Note. - = Missing data.

Table E-2

Rn Statistic on Transformed Postchemotherapy EMG Five-Minute Baseline

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 0.2 | 0.0 | -0.2 | 0.3 | -0.0 | -0.1 | 0.1 | 0.2 | 0.6 | -0.2 | -0.2 | -0.4 |
| 2 | -0.1 | -0.2 | 0.2 | -0.2 | 0.2 | 0.6 | 1.8 | - | - | - | - | - |
| 3 | 0.5 | -0.5 | -0.3 | 1.2 | 0.1 | -0.6 | -0.3 | 0.9 | -0.0 | -0.6 | 0.3 | -0.5 |
| 4 | 0.8 | 0.4 | -0.0 | 0.2 | -0.3 | 0.2 | -0.3 | -0.5 | -0.4 | -0.5 | -0.4 | -0.6 |
| Ranks | | | | 3 | | 3 | | 2 | | 1 | | |

Rn Statistic = 9

Note. - = Missing data.

Table E-3

Rn Statistic on Transformed Postchemotherapy EMG Biofeedback Training Period Means

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | -0.3 | -0.2 | -0.2 | -0.1 | -0.3 | -0.2 | -0.3 | 0.1 | 0.1 | -0.4 | -0.5 | -0.5 |
| 2 | -0.3 | -0.3 | 0.9 | -0.1 | -0.2 | 0.1 | 0.2 | - | - | - | - | - |
| 3 | 0.6 | -0.1 | -0.1 | 1.5 | 0.0 | -0.3 | 0.0 | -0.2 | -0.4 | -0.5 | -0.3 | -0.3 |
| 4 | 0.4 | 0.8 | 0.4 | 0.1 | -0.5 | -0.0 | -0.3 | -0.5 | -0.6 | -0.6 | -0.6 | 0.7 |
| Ranks | | | | 2 | | 3 | | 2 | | 1 | | |

Rn Statistic = 8

Note. - = Missing data.

# APPENDIX F

## STAIC STATE ANXIETY DATA

Table F-1

Rn Statistic on Prechemotherapy STAIC Scores

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 27 | 32 | 20 | 20 | 30 | 22 | 24 | 39 | 20 | 22 | 31 | 30 |
| 2 | 38 | 31 | 31 | 40 | 30 | 33 | 35 | - | - | - | - | - |
| 3 | 32 | 31 | 31 | 30 | 29 | 31 | 31 | 29 | 33 | 31 | 32 | 36 |
| 4 | 28 | 31 | 31 | 30 | 32 | 30 | 30 | 30 | 30 | 30 | 32 | 30 |
| Ranks | | | | | 1 | | 3 | | 2 | | 1 | |

Rn Statistic = 7

Note. - = Missing data.

Table F-2

Rn Statistic on Postchemotherapy STAIC Scores

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 21 | 29 | 20 | 21 | 20 | 29 | 20 | 26 | 20 | 20 | 30 | - |
| 2 | 30 | 29 | 37 | 29 | 28 | 33 | 30 | - | - | - | - | - |
| 3 | 29 | 31 | 30 | 29 | 29 | 26 | 29 | 30 | 31 | 31 | 34 | 35 |
| 4 | 33 | 33 | 31 | 31 | 32 | 30 | 32 | 30 | 30 | 30 | 31 | 31 |
| Ranks | | | | 2 | | 3 | | 2 | | 1 | | |

Rn Statistic = 7

Note. - = Missing data.

Table F-3

Prechemotherapy Self-Report: Feeling Sick to Stomach

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 3 | 2 | 1 | 1 | 2 | 1 | 1 | 3 | 1 | - | 2 | 2 |
| 2 | 2 | 2 | 2 | 3 | 2 | 1 | 5 | - | - | - | - | - |
| 3 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - |
| 4 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

Note. 1 = Does not feel sick to stomach. 5 = Feels very sick to stomach.

- = Missing data.

Table F-4

Prechemotherapy Self-Report: Feeling Like Vomiting

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 3 | 1 | - |
| 2 | 2 | 1 | 1 | 2 | 1 | 1 | 2 | - | - | - | - | - |
| 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | - | - |
| 4 | 4 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

Note. 1 = Does not feel like vomiting. 5 = Feels very much like vomiting.

- = Missing data.

# APPENDIX G

## SELF-REPORT DATA

Table G-2

Postchemotherapy Self-Report: Feelings Like Vomiting

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | - |
| 2 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | - | - | - | - | - |
| 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| 4 | 4 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

Note. 1 = Does not feel like vomiting. 5 = Feels very much like vomiting.

- = Missing data.

Table G-1

Postchemotherapy Self-Report: Feeling Sick to Stomach

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | - |
| 2 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | - | - | - | - | - |
| 3 | 1 | 1 | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 4 | 5 | 3 | 3 | 1 | 1 | 1 | 1 | 3 | 2 | 1 | 1 | 1 |

Note. 1 = Does not feel sick to stomach. 5 = Feels very sick to stomach.

- = Missing data.

Figure G-1. Pretraining self-report: Feeling sick to stomach.

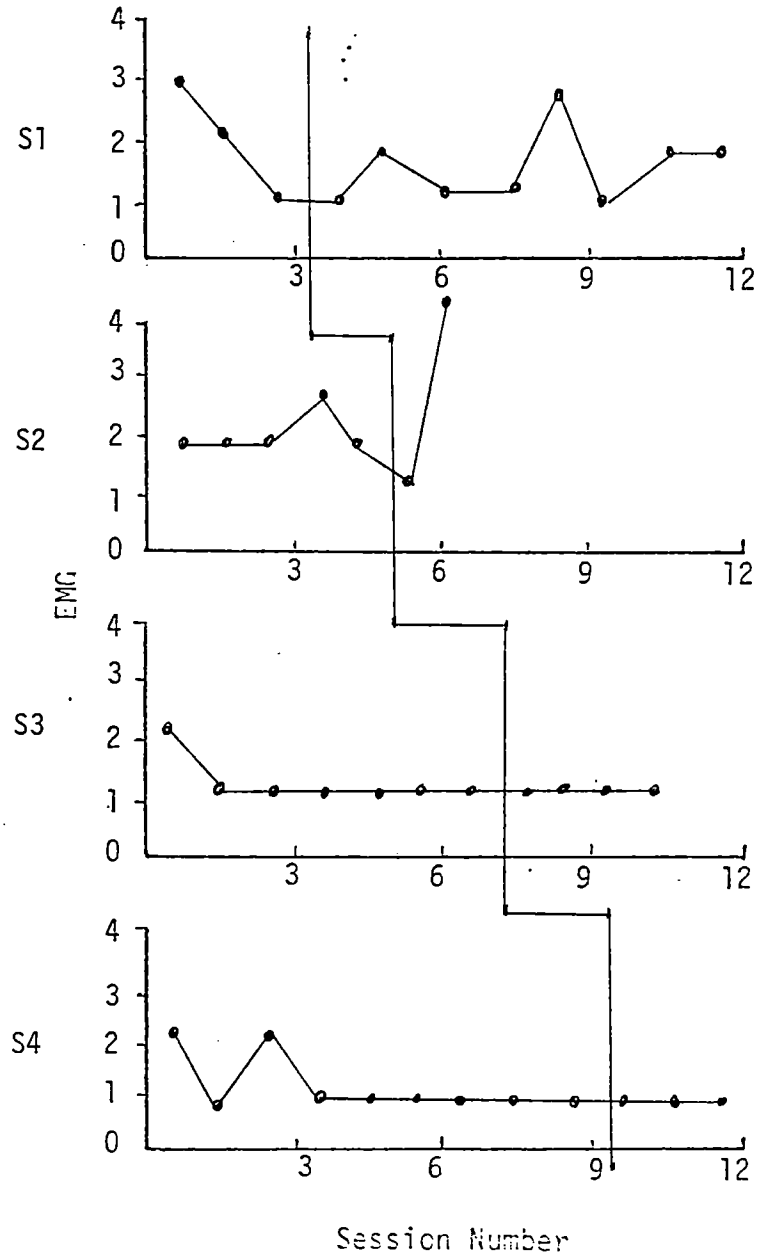

S1
S2
S3
S4
EMG
0
1
2
3
4
3
6
9
12
Session Number

Figure G-2. Pretraining self-report: Feeling like vomiting.

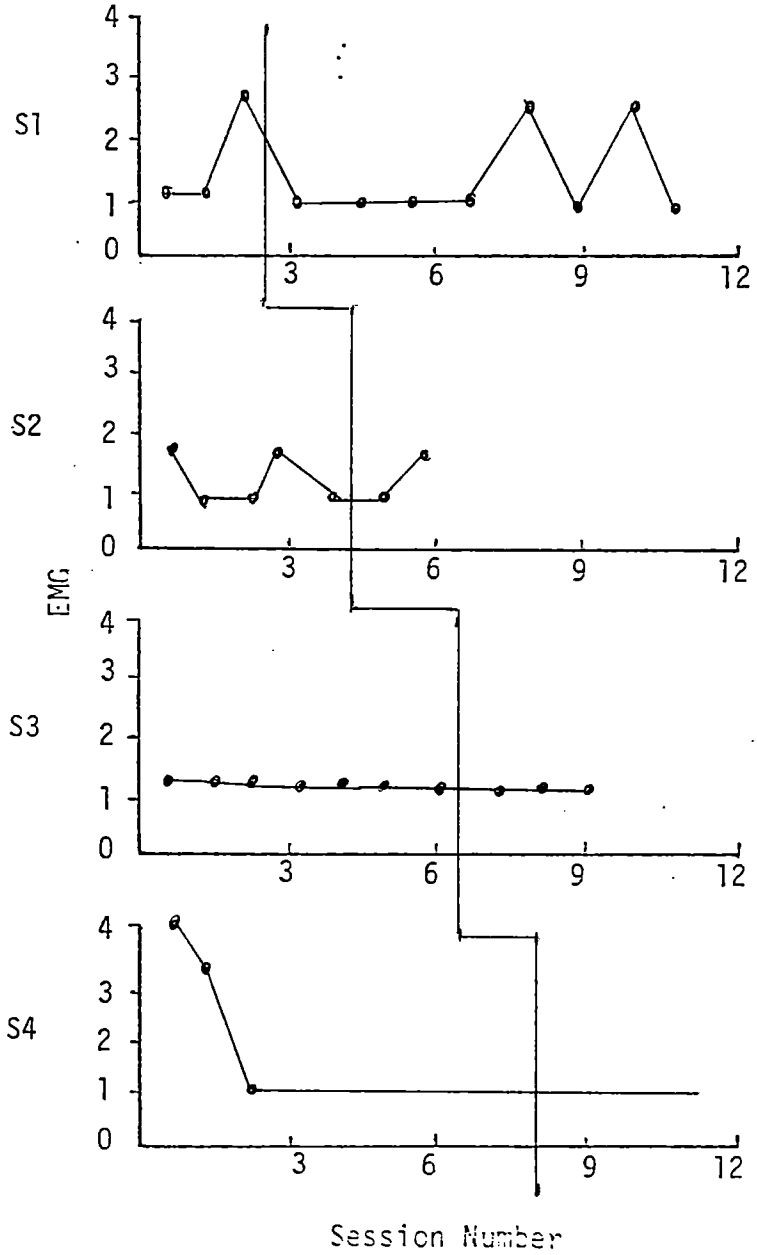

S1
S2
S3
S4
EMG
4
3
2
1
0
3
6
9
12
Session Number

Figure G-3. Posttraining self-report: Feeling sick to stomach.

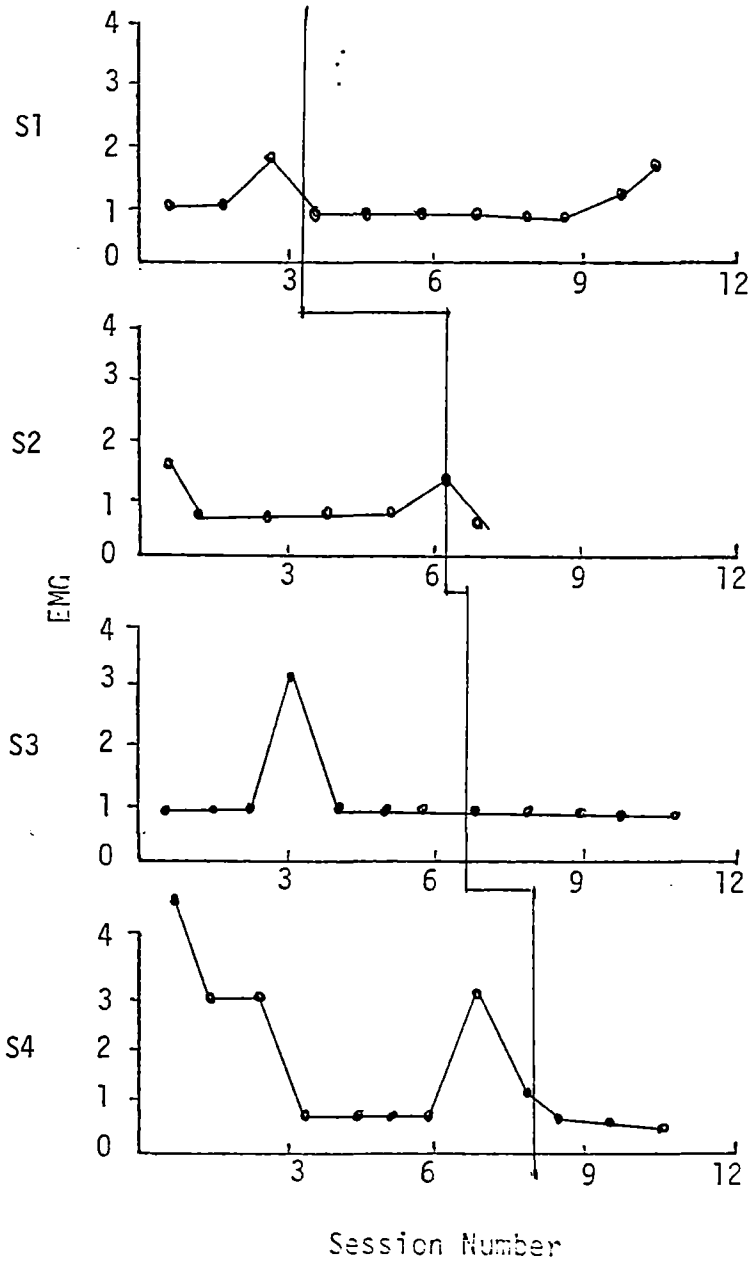
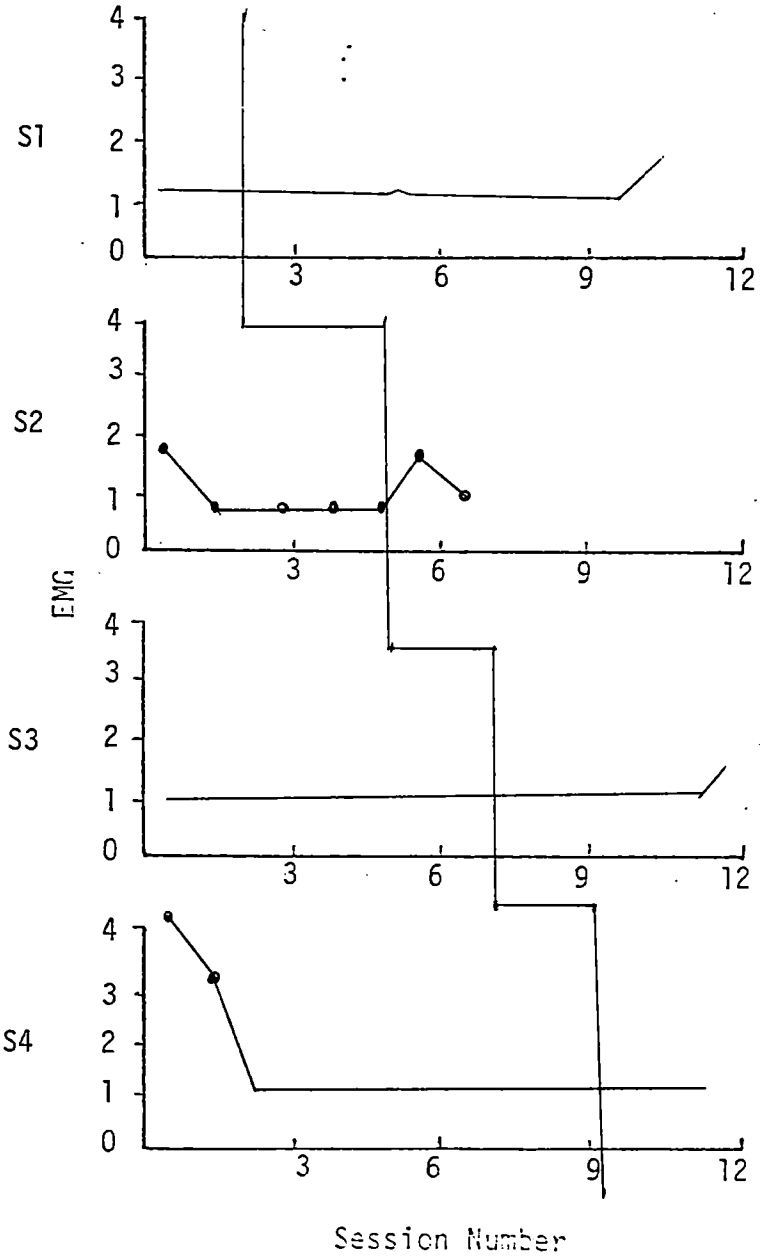

S1
S2
S3
S4
EMG
0
1
2
3
4
3
6
9
12
Session Number

Figure G-4. Posttraining self-report: Feeling like vomiting.


S1
S2
S3
S4
EMG
4
3
2
1
0
3
6
9
12
Session Number

# APPENDIX H

## TRANSFORMED SELF-REPORT DATA

Table H-1

Rn Statistic on Prechemotherapy Transformed Self-Report: Feeling Sick to Stomach

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 0.5 | 0.0 | -1.0 | -1.0 | 0.0 | -1.0 | -1.0 | 0.5 | -1.0 | - | 0.0 | 0.0 |
| 2 | -0.1 | -0.1 | -0.1 | 0.4 | -0.1 | -0.6 | 1.3 | - | - | - | - | - |
| 3 | 0.8 | -0.1 | -0.1 | 0.4 | -0.1 | -0.6 | 1.3 | - | - | - | - | - |
| 4 | 0.6 | -0.2 | 0.6 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 |
| Ranks | | | | 1 | | | 3 | | 1 | | 1 | |

Rn Statistic = 6

Note. - = Missing data.

Table H-2

Rn Statistic on Prechemotherapy Transformed Self-Report: Feeling Like Vomiting

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | -0.4 | 0.8 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 | 0.8 | -0.9 | 0.8 | -0.8 | - |
| 2 | 0.4 | -0.3 | -0.3 | 0.4 | -0.3 | 0.4 | - | - | - | - | - | - |
| 3 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | - | - |
| 4 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | - | - |
| Rank | | | | 1 | | 1 | | 1.5 | | 1 | | |

Rn Statistic = 4.5

Note. - = Missing data.

Table H-3

Rn Statistic on Transformed Postchemotherapy Self-Report: Feeling Sick to Stomach

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | -0.3 | 0.5 | -0.3 | -0.3 | -0.3 | -0.3 | -0.3 | -0.3 | -0.3 | -0.3 | -0.5 | - |
| 2 | 0.7 | -0.2 | -0.2 | -0.2 | -0.2 | 0.7 | -0.2 | - | - | - | - | - |
| 3 | -0.2 | -0.2 | -0.2 | 1.3 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 | -0.2 |
| 4 | 1.3 | 0.4 | 0.4 | -0.6 | -0.6 | -0.6 | -0.6 | 0.4 | -0.1 | -0.6 | -0.6 | -0.6 |
| Ranks | | | | | 2 | | 3 | | 1 | | 1 | |

Rn Statistic = 7

Note. - = Missing data.

Table H-4

Rn Statistic on Transformed Postchemotherapy Self-Report: Feeling Like Vomiting

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 2.0 | - |
| 2 | 0.7 | -0.2 | -0.2 | -0.2 | -0.2 | 0.7 | -0.2 | - | - | - | - | - |
| 3 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 2.0 |
| 4 | 1.6 | 0.9 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 | -0.4 |
| Ranks | | | | | 3 | | 2 | | 2 | | 1 | |

Rn Statistic = 8

Note. - = Missing data.

# APPENDIX I

## ACTUAL RETCHING BEHAVIOR

Table I-1

Prechemotherapy Actual Retching Behavior

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | - | 0 | 2 | 0 | 0 | - | - | - | - | - |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ranks | | | | 2.0 | | 2.0 | | 1.5 | | 1.0 | | |

Rn Statistics = 6.5

Note. - = Missing data.

Table I-2

Postchemotherapy Actual Retching Behavior

| | Session Number | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Subject | | | | | | | | | | | | |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 1 | 1 | 0 | 1 | - | 0 | 0 | - | - | - | - | - |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 7 | 2 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ranks | | | | 1.5 | | 2.0 | | 1.5 | | 1.0 | | |

Rn Statistic = 6.0

Note. - = Missing data.

# APPENDIX J

## MEANS EMG FOR INDIVIDUALS AND GROUP

Table J-1

Mean EMG for Individuals and Group

| | Subject | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | Group |
| Mean EMG | | | | | |
| Prechemotherapy | | | | | |
| 5" Baseline | 1.19 | 1.22 | 1.13 | 1.56 | 1.27 |
| Postchemotherapy | | | | | |
| 5" Baseline | 0.86 | 0.98 | 1.24 | 1.49 | 1.14 |
| Practice Sessions | | | | | |
| Baseline | 0.85 | 0.90 | 1.14 | 1.61 | 1.12 |
| Biofeedback | 0.66 | 1.01 | 1.78 | 0.60 | 0.76 |
| Individual | 0.89 | 1.03 | 1.07 | 1.32 | |

# APPENDIX K

## NARRATIVE FIGURES

Figure 1. Transformed prechemotherapy EMG five-minute baseline.

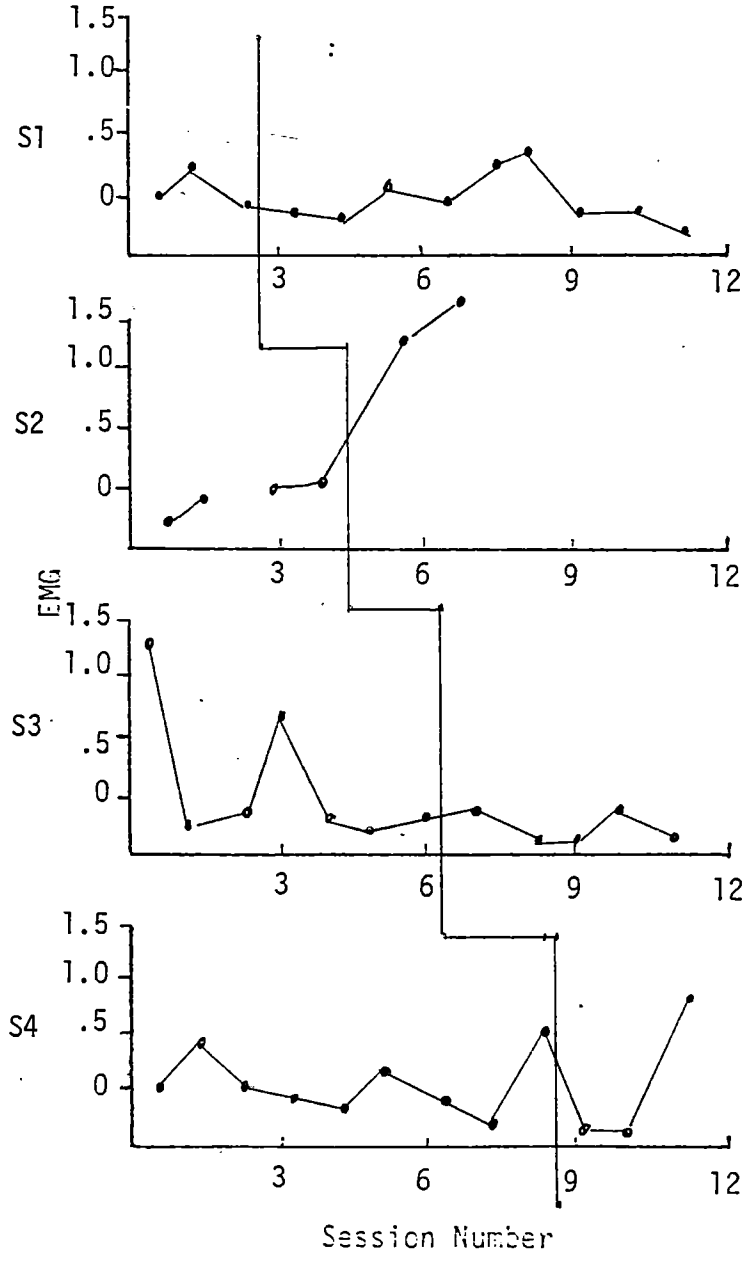

1.5
1.0
.5
0
S1
3
6
9
12
S2
EMG
S3
S4
Session Number

Figure 2. Transformed postchemotherapy EMG five-minute baseline.

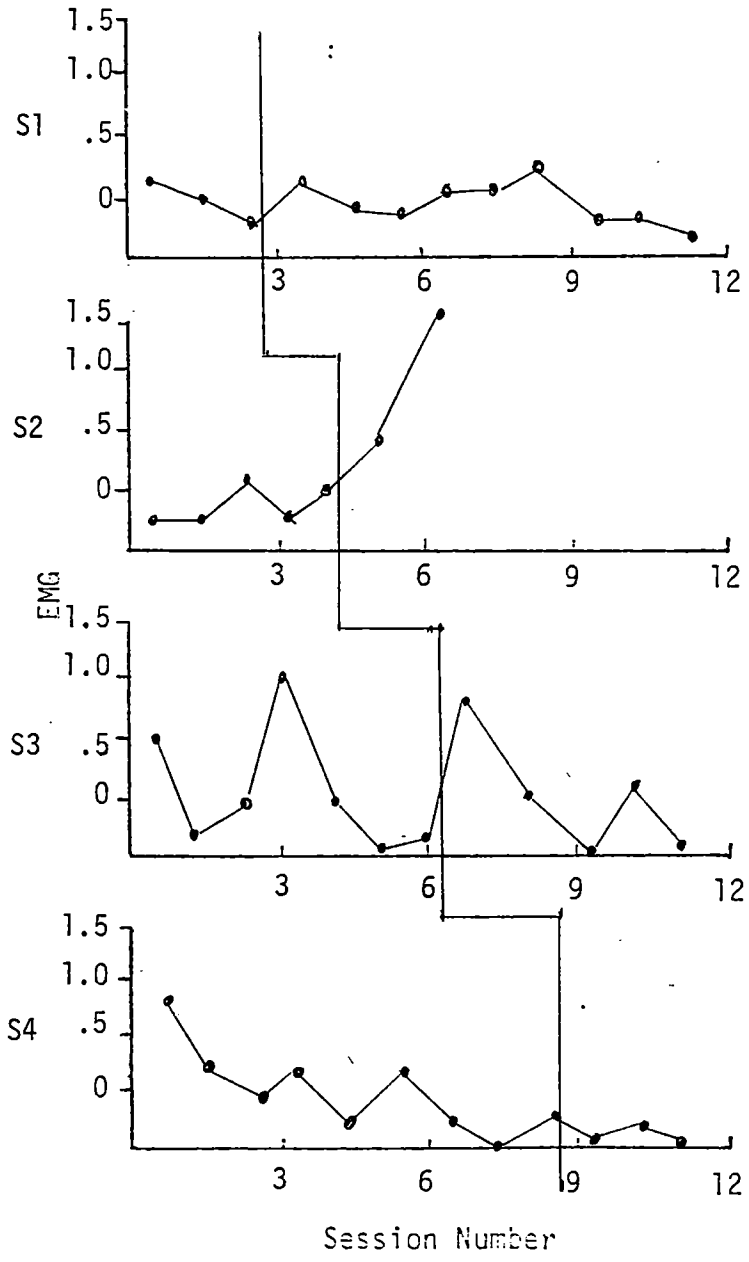

1.5
1.0
.5
0
S1
3
6
9
12
S2
EMG
S3
S4
Session Number

Figure 3. Prechemotherapy EMG five-minute baseline.

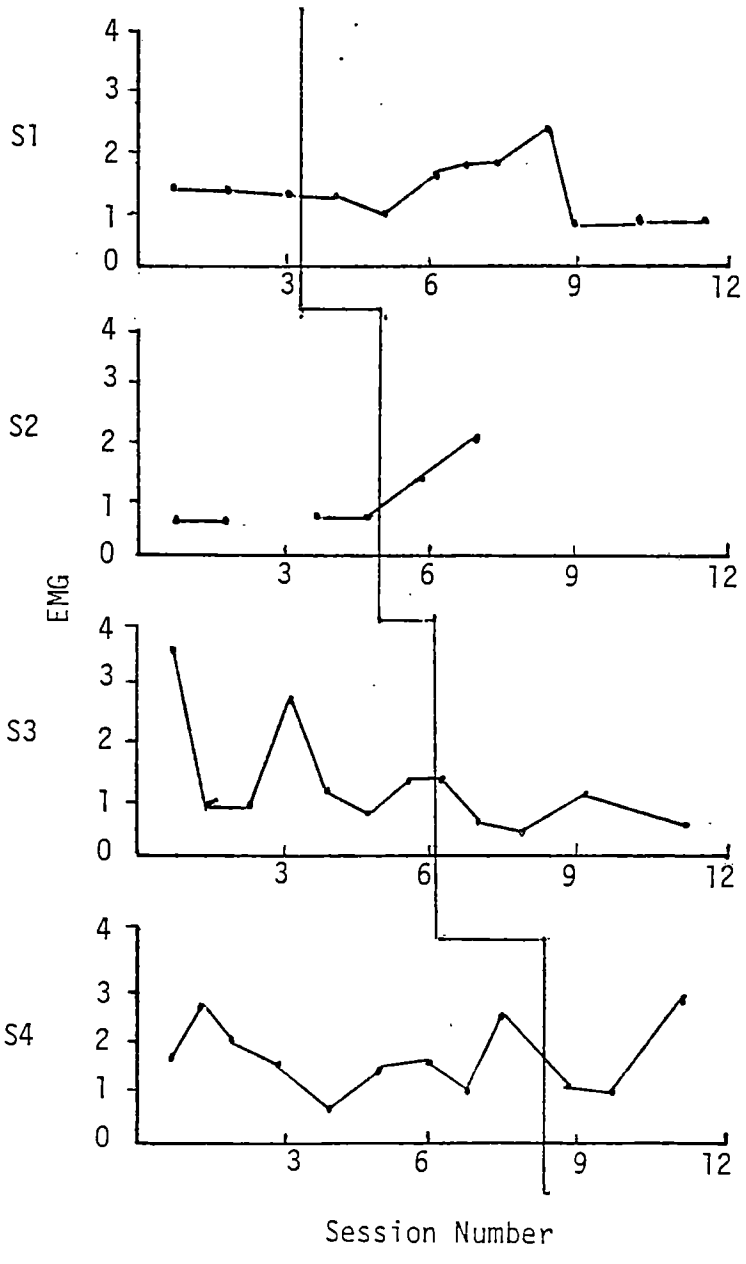

S1
S2
S3
S4
EMG
0
1
2
3
4
3
6
9
12
Session Number

Figure 4. Postchemotherapy EMG five-minute baseline.

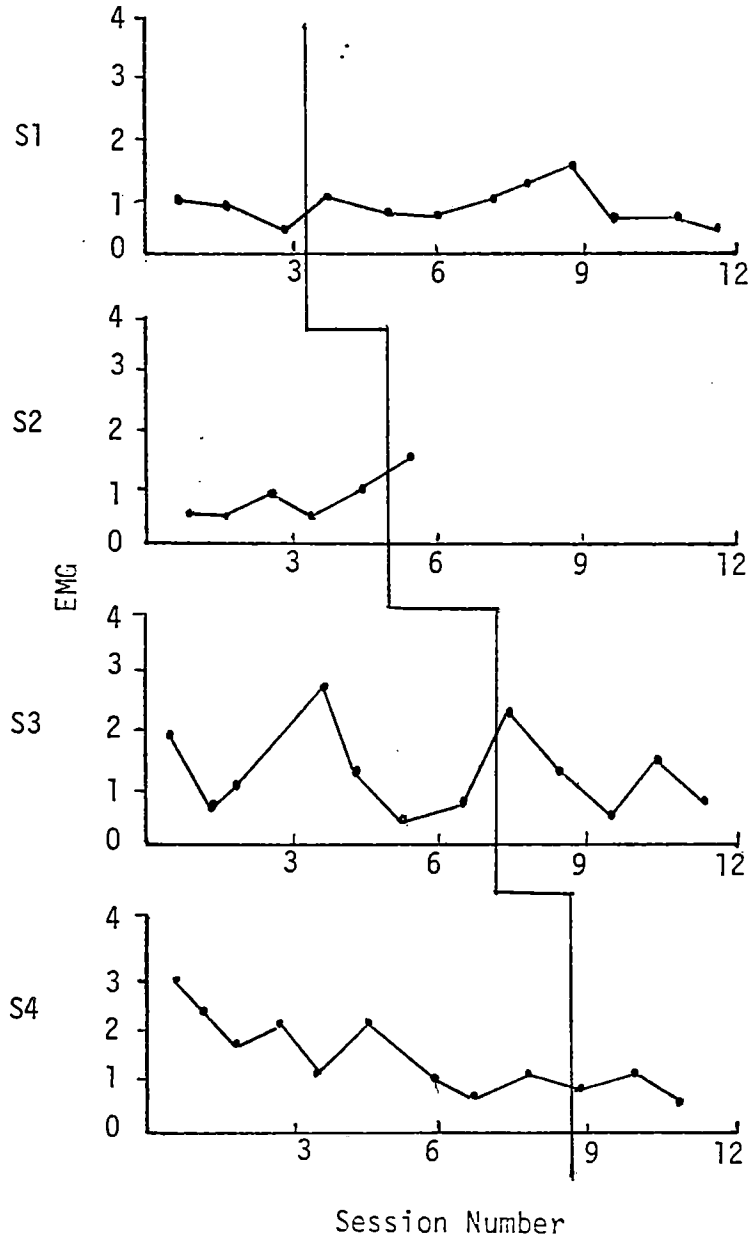

S1
S2
S3
S4
EMG
4
3
2
1
0
3
6
9
12
Session Number

Figure 5. Transformed postchemotherapy EMG practice session means.

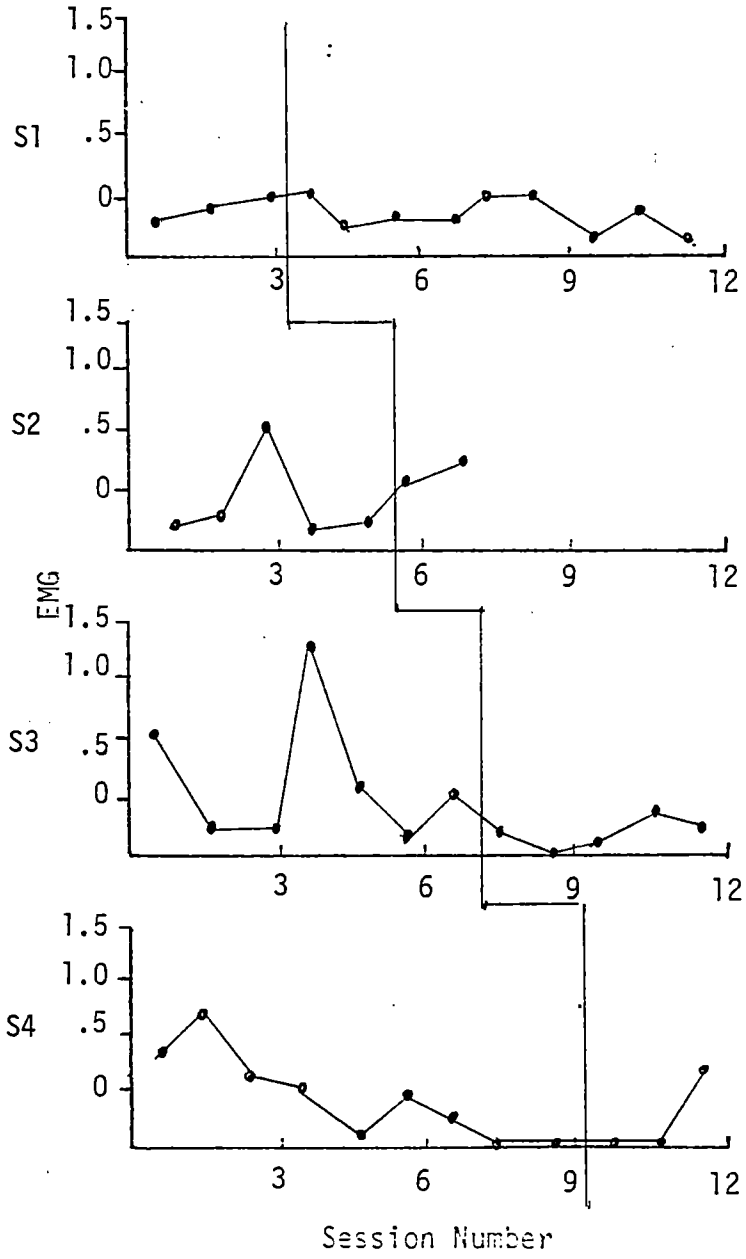

1.5
1.0
.5
0
S1
3
6
9
12
S2
EMG
S3
S4
Session Number

Figure 6. Postchemotherapy EMG practice session means.

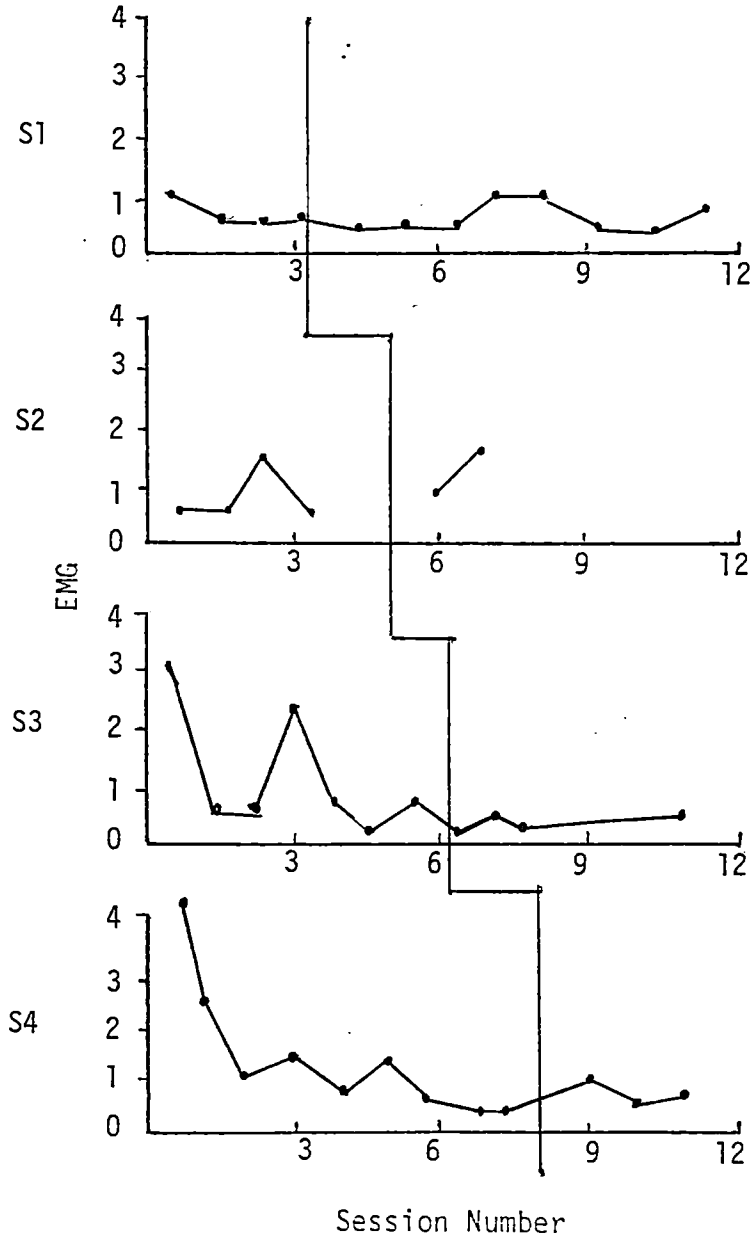

S1
S2
S3
S4
EMG
0
1
2
3
4
3
6
9
12
Session Number

Figure 7. Prechemotherapy STAIC scores.

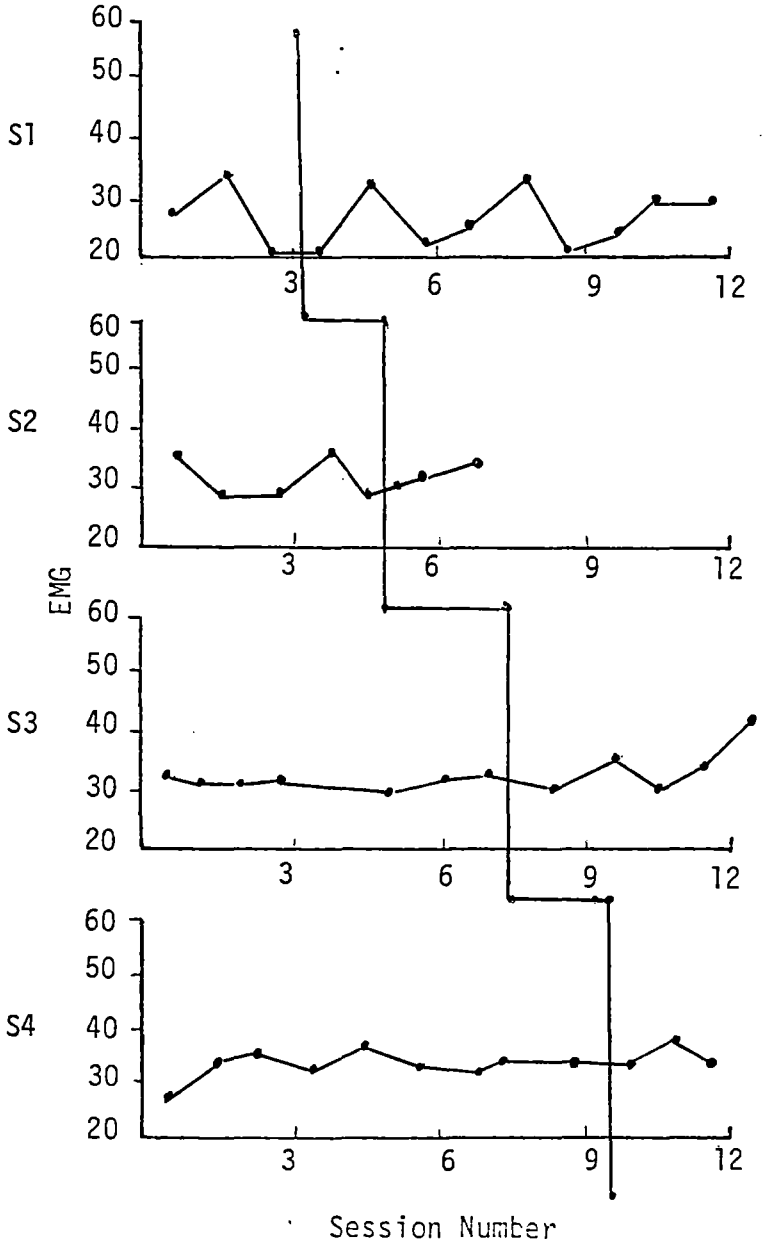

S1
S2
S3
S4
EMG
60
50
40
30
20
3
6
9
12
Session Number

Figure 8. Postchemotherapy STAIC scores.

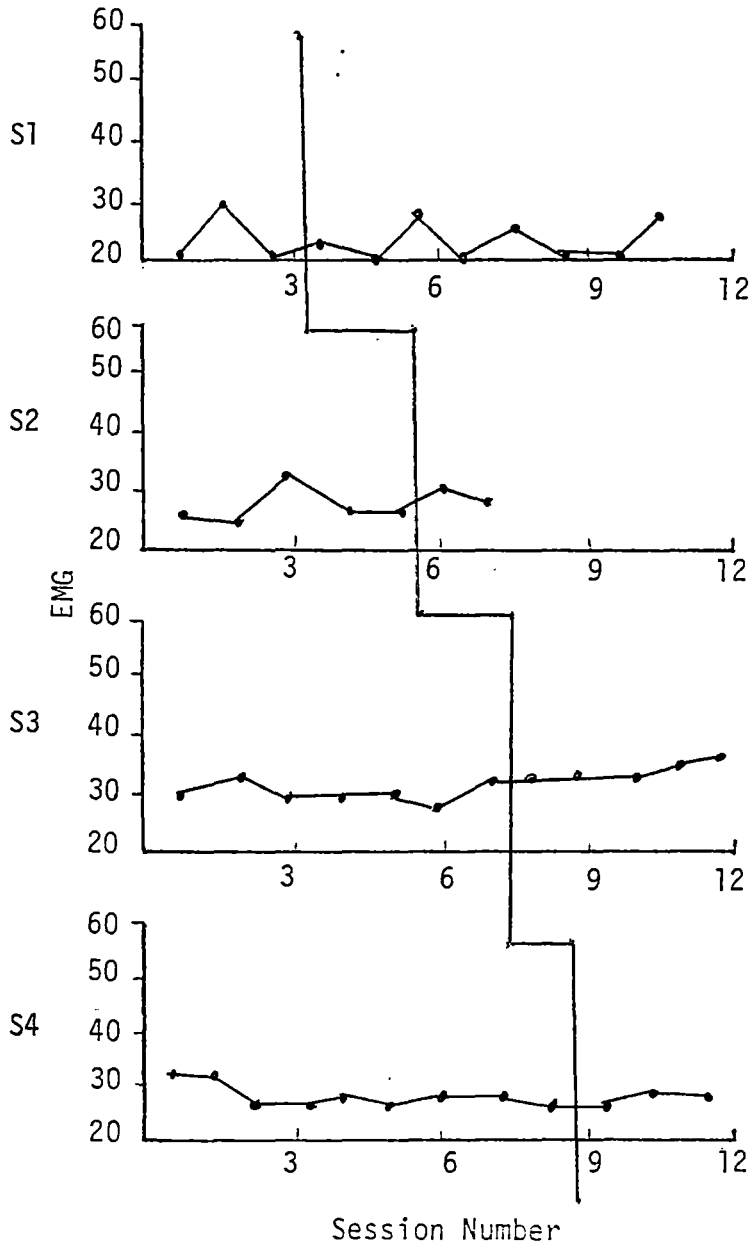

S1
S2
S3
S4
EMG
60
50
40
30
20
3
6
9
12
Session Number

Figure 9. Pretraining transformed self-report: Feeling sick to stomach.

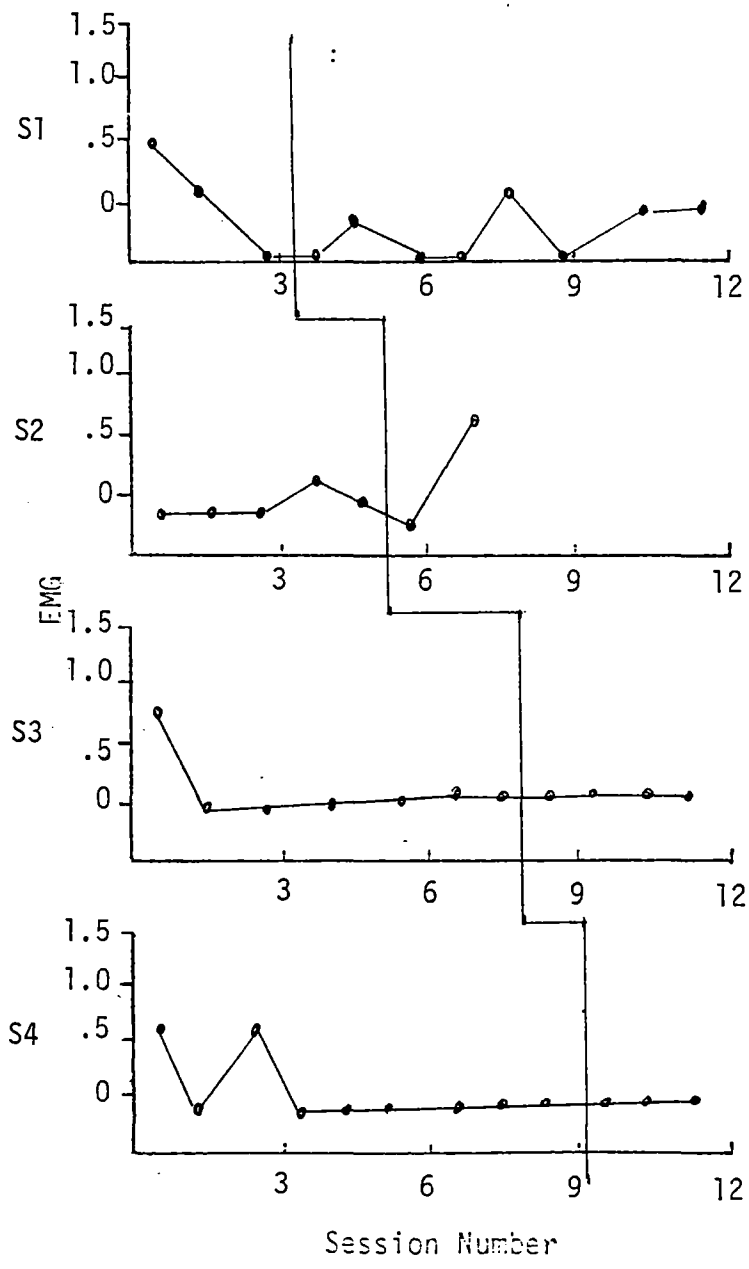

1.5
1.0
.5
0
S1
3
6
9
12
S2
S3
S4
EMG
Session Number

Figure 10. Pretraining transformed self-report: Feeling like vomiting.

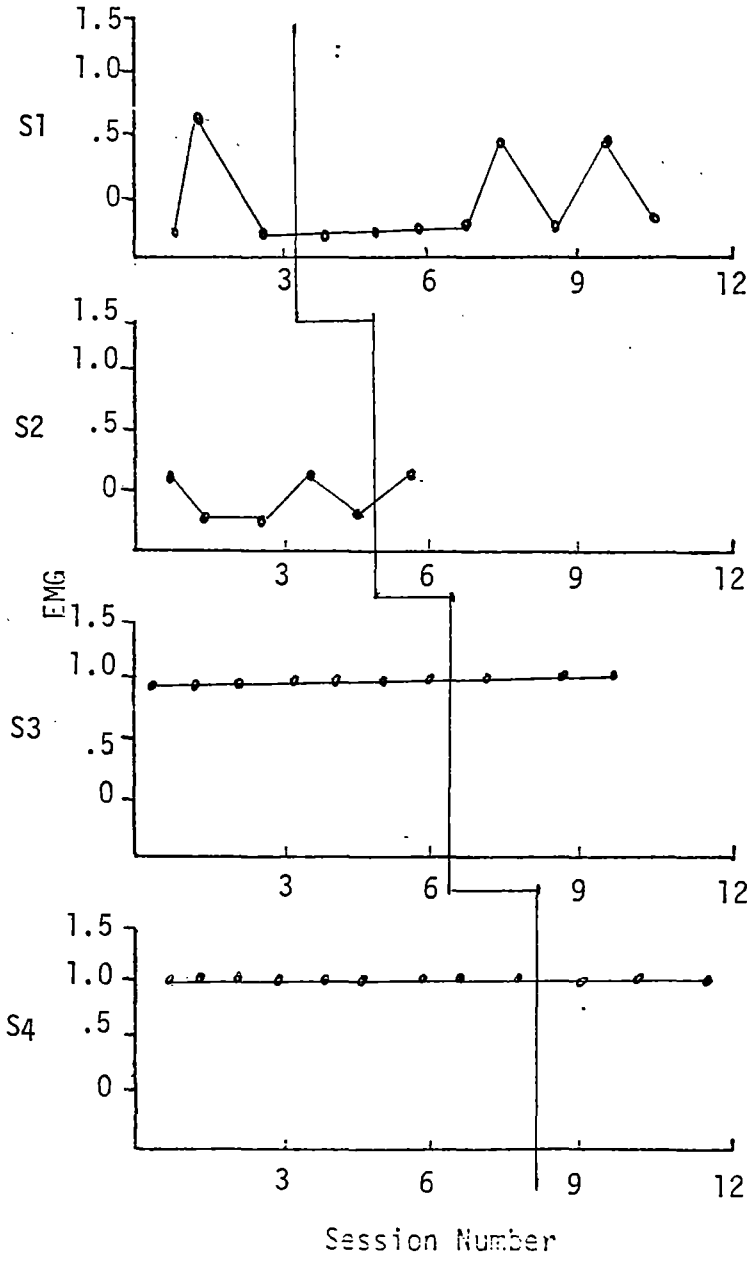

1.5
1.0
S1
.5
0
3
6
9
12
1.5
1.0
S2
.5
0
3
6
9
12
EMG
1.5
1.0
S3
.5
0
3
6
9
12
1.5
1.0
S4
.5
0
3
6
9
12
Session Number

Figure 11. Posttraining transformed self-report: Feeling sick to stomach.

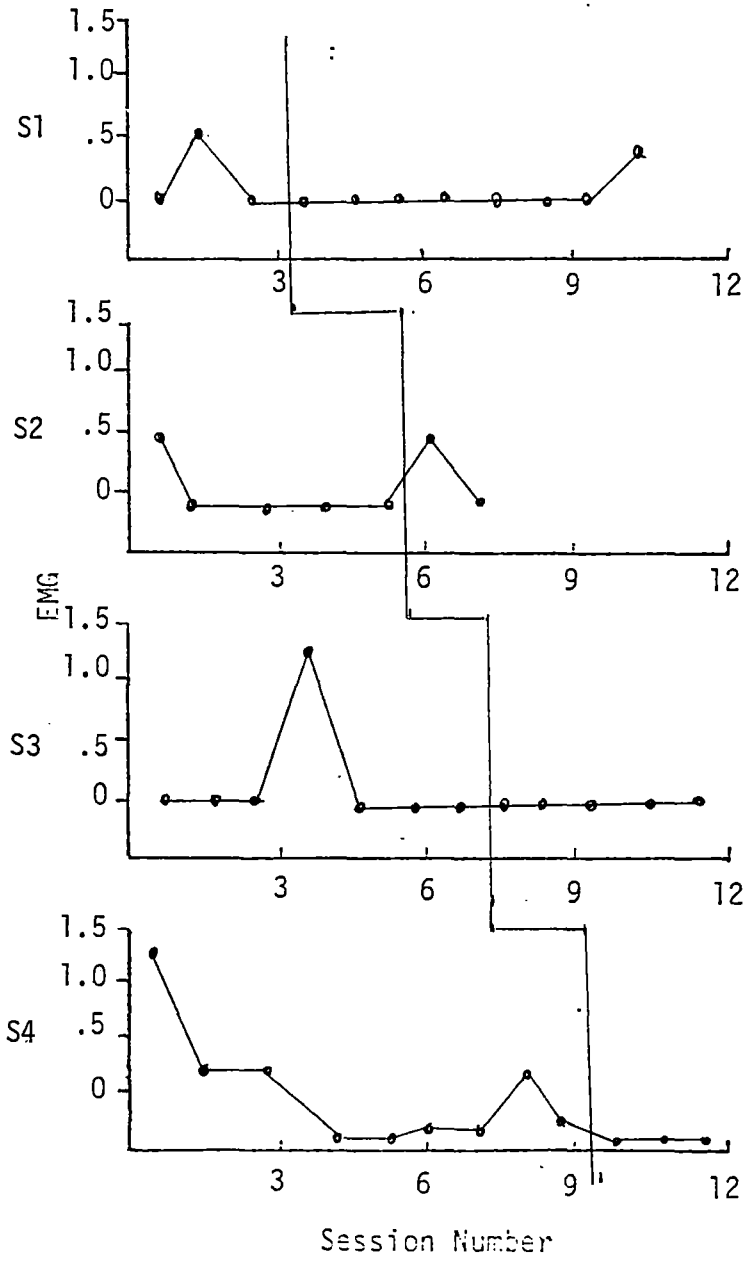

S1
S2
S3
S4
EMG
1.5
1.0
.5
0
3
6
9
12
Session Number

Figure 12. Posttraining transformed self-report: Feeling like vomiting.

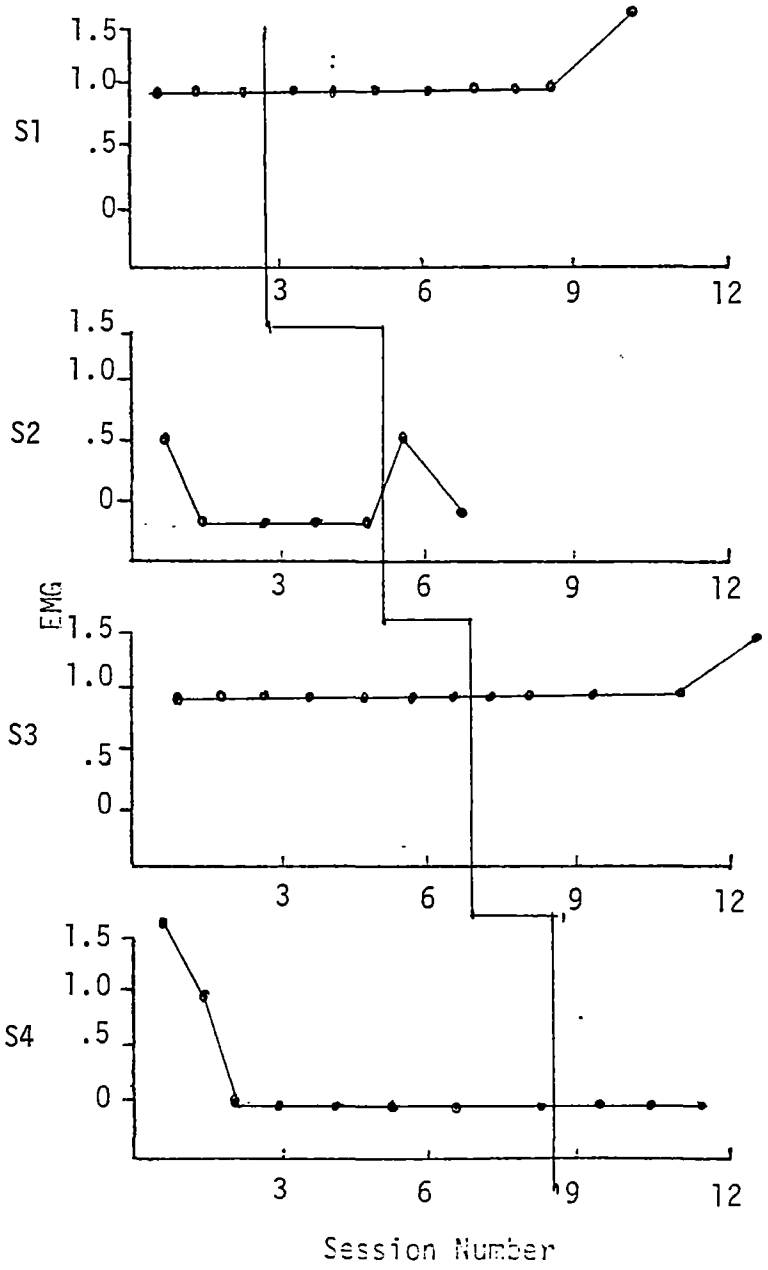

S1
S2
S3
S4
EMG
1.5
1.0
.5
0
3
6
9
12
Session Number

Figure 13. Prechemotherapy actual retching behavior.

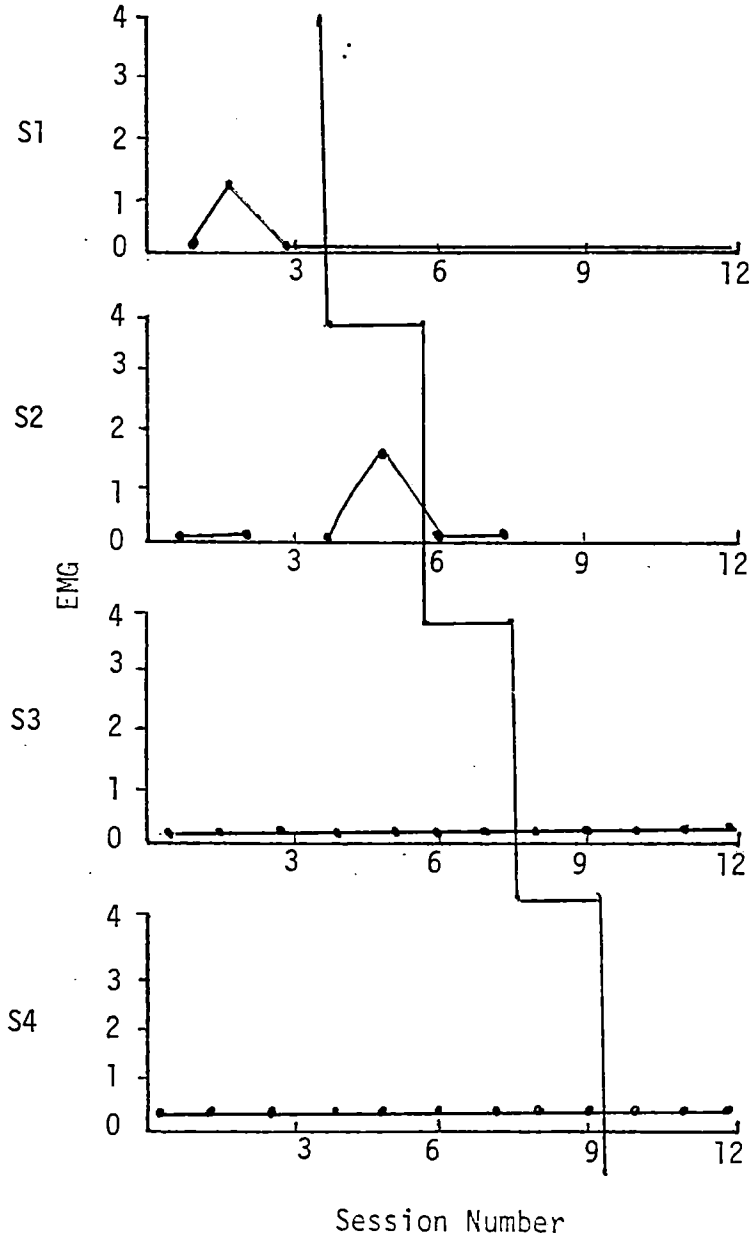
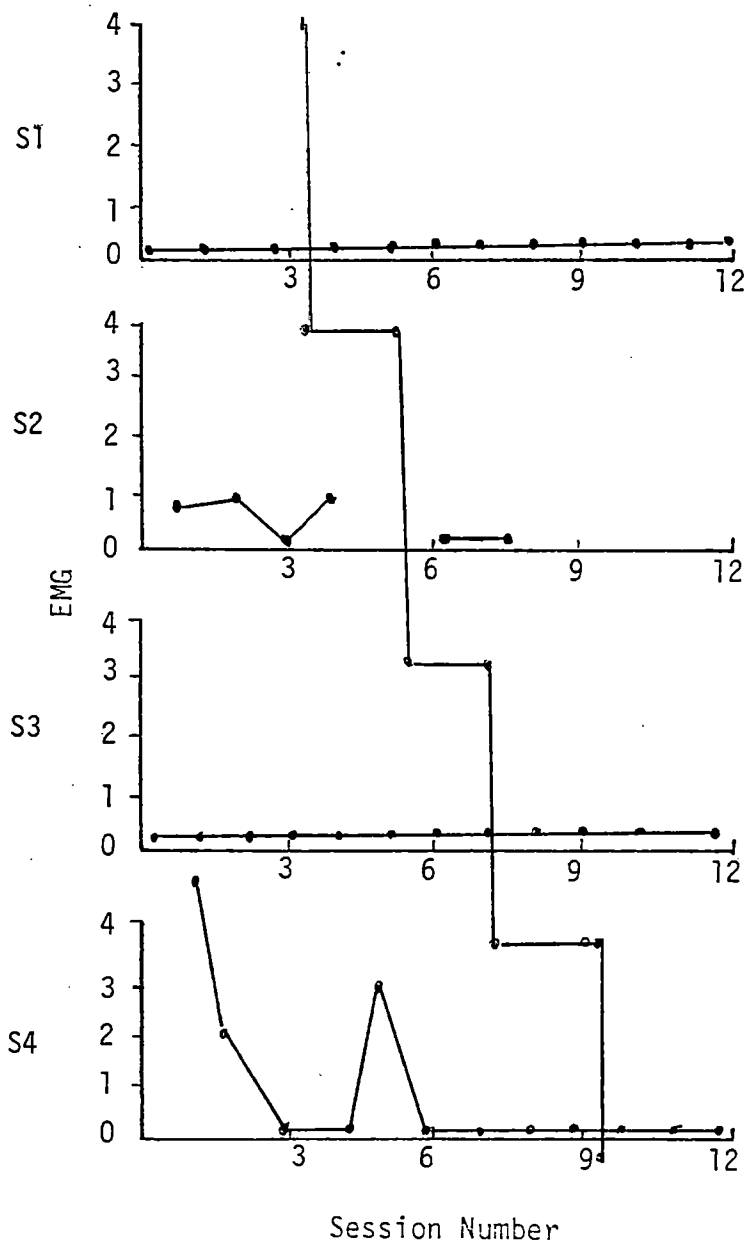

S1
S2
S3
S4
EMG
4
3
2
1
0
3
6
9
12
Session Number

Figure 14. Postchemotherapy actual retching behavior.


S1
S2
S3
S4
EMG
4
3
2
1
0
3
6
9
12
Session Number

2

VITA

Mary Ann Guttman

Candidate for the Degree of

Doctor of Philosophy

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Professional Experience: Research assistant, Laboratory for Clinical Physiology, Chicago, Illinois, 1975-76; research assistant and mental health assistant, Massachusetts Mental Health Center, 1976-78; graduate research assistant, Department of Psychology, Oklahoma State University, 1978-80; mental health assistant, Stillwater Medical Center, 1978-79; psychological associate, Psychological Services Center, Oklahoma State University, 1979-80, 81; graduate teaching assistant, Department of Psychology, Oklahoma

State University, 1980; psychological associate, Larimer County Mental Health Center, Fort Collins, Colorado, 1980; clinical traineeship, Central State Hospital, Norman, Oklahoma, 1981-82; psychological associate, Marital and Family Counseling Services, Oklahoma State University, 1981-83; clinical traineeship, Lloyd E. Rader Diagnostic and Evaluation Center and Intensive Treatment Center, Sand Springs, Oklahoma, 1982-83; internship in Clinical Psychology, Veterans Administration Medical Center, St. Louis, Missouri, 1983-84; psychological assistant, Intermediate Mental Health Center, Joseph Harp Correctional Center, Lexington, Oklahoma, 1984-86.