Psychological Correlates of Sinus Headache

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Psychological correlates of sinus headache

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Western Michigan University, 1991
This dissertation is dedicated to Dr. Kenneth Bullmer
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This dissertation is dedicated to Dr. Kenneth Bullmer, my teacher, my mentor, and my friend during the last six years of this doctoral program. He provided invaluable instruction and guidance, and showed me a great deal of patience. Any student could not have asked for more and I will never forget his kind consideration.

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CHAPTER I

INTRODUCTION

Headache is the most common medical complaint and a universal medical problem. It has been estimated that over half of the people in the world are afflicted with recurring headaches and that over 42 million Americans suffer from recurring headaches of a severe nature (Raskin & Appenzeller, 1980). It is believed that some form of headache will descend upon nearly everyone at some time of their lives.

As the term implies, headache refers to a feeling of pain or discomfort in some part of the head. It can take on quite a wide degree of manifestations: the pain may be either steady or throbbing and it can be mild enough to be ignored or it can be incapacitating (Diamond & Dalessio, 1982). Common descriptions of cephalalgia, or headache, include feelings of dizziness, tension, unusual sensations, or feelings of pressure rather than actual pain.

Headache is a symptom rather than a disease, the different causes of which do not affect the severity of the pain that is perceived (Diamond & Dalessio, 1982). This is to say that mild headaches are often found to accompany quite serious illnesses. Alternatively, a benign medical problem may coincide with headaches which are quite severe.
in intensity; nearly any medical disorder is capable of provoking a headache (e.g., low-blood sugar; fever; allergies; dental, circulatory and glandular disease; as well as alcohol intoxication).

Most headaches do not require professional attention and generally respond to home remedies and mild analgesics. In fact, greater than 50 million pounds of aspirin, in addition to other analgesics, are ingested annually, primarily to relieve headache pain (Diamond & Dalessio, 1982). Headaches can be classified according to their pain-causing mechanism (not the underlying condition, but the immediate cause of the pain). Various physical, neurological and psychological etiologies have been implicated in the cause of pain in different areas of the head.

Clinical Features

Four possible mechanisms exist which mediate headache pain and include: vasodilation, internal traction, inflammation and muscle contraction (Diamond & Dalessio, 1982). In vasodilation, the blood vessels inside or outside the cranium expand, causing the walls of the blood vessels to exert pressure upon the accompanying nerve, resulting in pain. Vasodilation gives rise to the headache phase in vascular-type headache etiologies, which include classic and common migraine, hemiplegic and ophthalmoplegic migraine, cluster, toxic, and hypertensive headaches. Internal
traction is indicative of a foreign presence, such as a tumor, an abscess, swelling or infection which causes pain by pulling on the cranial arteries. Inflammation that accompanies injured or irritated tissues resulting from diseases of the eye, ears, teeth, jaw and sinuses is another mechanism that causes headache. The actual inflammation and swelling of tissues places pressure on the blood vessels and nerves, resulting in the headache pain. A final mechanism of headache pain is muscle contraction of the neck, face and scalp. When muscles are tensed for a prolonged period, pain results in the form of a muscle contraction headache. Frequently, such headaches are viewed as though they are "psychogenic" in nature—that is, caused by excessive worry, anxiety and depression.

There is a popular view, applied regularly to headache, that such pain is associated with emotion (Merskey & Spear, 1967; Sternbach, 1974; Walters, 1961). It has been further suggested (Sternbach, Wolf, Murphy, & Akeson, 1973; and Woodforde & Merskey, 1973) that virtually any pain experienced over a long period of time may produce emotional change, most frequently depression. In a group of 103 patients examined to assess a relationship between persistent headache (not due to significant physical illness) and emotional disturbance, these patients demonstrated slightly more evidence of emotional disturbance than a general practice population but less than psychiatric outpatients.
(Merskey et al., 1985). In a series of 100 headache patients Martin (1972) reported that obvious tension was present in 74% of these cases, depression was noted in 35% and secondary gain was evident in 56%. In these patients the most common psychological problems noted involved issues of dependence, sexuality, and control of urges.

Several studies (e.g., Alvarez, 1947; Harrison, 1975; Henryk-Gutt & Rees, 1973) have also investigated the possible existence of characteristic personality traits in patients with different headache classifications. A primary question addressed in many of these inquiries is whether particular personality types are predisposed to specific kinds of headaches or whether certain personality traits evolve in consequence to such pain syndromes. Dalessio (1981) asserted that distinct personality traits are associated with headache, and that this relationship becomes more pronounced as the chronicity of the headache problem increases.

In what has been considered a "model" study (Blanchard, Andrasik, & Arena, 1984), Kudrow and Sutkus (1979) studied six discernible headache types (e.g., migraine, cluster, chronic muscle contraction, migraine and chronic muscle contraction combined, post-traumatic and conversion), as differentiated by the Minnesota Multiphasic Personality Inventory (MMPI) (Hathaway & McKinley, 1940). Sternbach, Dalessio, Kunzel, and Bowman (1980) obtained similar results.
as Kudrow and Sutkus (1979), who reported elevations in the neurotic triad pattern (i.e., the hypochondriasis, depression, and hysteria scales) of the MMPI for patients characterized as suffering from either migraine, muscle contraction, or combined headache types. Other psychological tests, such as the Beck Depression Inventory (Beck, Ward, Mendolsohn, Mock, & Erbaugh, 1961) the State-Trait Anxiety Inventory (Spielberger, Gorsuch & Lushene, 1970), the Psychosomatic Symptom Checklist (Cox, Freundlich, & Meyer, 1975), and the Autonomic Perception Questionnaire (Mandler, Mandler, & Uviller, 1958), have been utilized in much the same manner as the MMPI in attempts to objectively identify differential personality and psychophysiological parameters in individuals suffering from various types of headache (Blanchard et al., 1984).

Despite the rigor with which investigators have approached this issue, the majority of reports have been contradictory in their attempts to define different personality patterns in patients diagnosed with various headache classifications. In striving to confirm such hypotheses, investigators have only marginally substantiated their conclusions, partly as a consequence of not adhering to a uniform set of diagnostic criteria in determining headache classifications (Ellertsen & Klove, 1987).
Numerous studies have explored the possibility that specific personality patterns underlie and possibly serve as an etiological basis for definable headache classifications. In systematically reviewing the outcomes of these investigations, Blanchard et al. (1984) concluded that although the data do not support the notion of a specific headache personality per se, there is presumably some justification for the speculation about personality factors playing a role in headache activity for some patients. As a group, patients with chronic headache are more psychologically distressed and show more "deviant personality characteristics" than do non-headache sufferers. Whether this is cause or effect remains undetermined. It is conceivable that years of chronic headache could lead to personality changes; conversely, personality deviations could predispose individuals to headache.

Statement of the Problem

Traditional views hold that the personality makeups of individuals with headache are markedly different from individuals without headache and that these differences predispose these individuals to headache. To date, investigations designed to elucidate psychological and personality factors specifically correlated with various types of headache have been limited in scope. Such implications have been studied.
in headache types that are mediated through vasodilation (e.g., migraine), muscle contraction (e.g., tension), or psychogenic (e.g., conversion), but not in headaches believed to be caused by inflammation (e.g., sinus). Consequently, the possibility remains undetermined that sinus headache might entail psychological constituents.

Significance of the Problem

There exists definite clinical utility for assessing the psychological characteristics of headache sufferers; such information could be quite useful in making reasonable predictions about patients' likelihood of obtaining relief from a particular modality of treatment (e.g., biofeedback, psychotherapy, medication, progressive relaxation, etc.). Whereas an individual's psychological state may not account for the entirety of his pain symptomatology, important instances have been identified in which the emotional correlates of headache pain require and, indeed, demand attention. This has often been the case wherein relaxation therapy and biofeedback have successfully been used to alleviate or reduce pain associated with muscle contraction and migraine headache, respectively (Blanchard & Andrasik, 1982). The potential relevance of such methods for the treatment of sinus headache remains unclear because of a virtual absence of research aimed at examining possible emotional concomitants of headaches in which inflammation
is an etiology.

Treatment strategies need to reflect differences which may exist between headache patients, instead of creating simplistic categorizations, such as organic versus psychogenic or psychiatric versus normal. Further examination is required to determine how potential headache subgroups respond to different treatment modalities in order to design effective therapeutic regimens. Because of the complex, intertwining nature of etiologies giving rise to headache pain, consideration for treatment of psychological contributions should be preferred over mere reliance on analgesic or narcotic medications (Sovak, Kunzel, Sternbach, & Dalessio, 1981).

Significance of the Study

This study was significant in several ways. First, in addition to the medical and physiological parameters utilized in making the diagnosis of sinus headache, it provided a complementary set of data for examining the psychological and personality characteristics of sinus headache sufferers. Second, it permitted an analysis of the tendencies of sinus headache sufferers to differentially respond to blinded pharmacologic treatments as a function of particular personality characteristics. Finally, this study served a practical purpose in reinforcing the need for clinicians who treat patients suffering from headache to
take into consideration their patient's personality characteristics when formulating a treatment plan that will serve to reduce the frequency and intensity of the headache pain.

To the extent that psychological processes influence patients' responses to treatment, it is of consequence that such factors be appraised when evaluating the utility of an intervention aimed at alleviating symptoms, or in selecting a treatment modality that is most likely to provide relief.

Limitations of the Study

This study was limited in the following ways:

1. A single headache type was investigated, limiting the extent to which the hypotheses can be tested.

2. A control group was not included, which would have facilitated the possible psychological differentiation between sinus headache patients and patients without headaches, and would have allowed greater control to be exerted over threats to internal and external validity.

3. It was assumed that these patients provided honest and accurate responses to the various psychometric test items and headache assessments. This was not substantiated through behavioral observations or a clinical interview.

Other notable experimental weaknesses of this study will be more fully addressed in Chapter V.
Hypotheses

Within the context of the above, the present study examined the following three null hypotheses:

Null Hypothesis 1: There are no differences between sinus headache patients and individuals on whom the Profile of Mood States questionnaire (Nowlis & Green, 1957) was normed in terms of subjective mood variability.

This hypothesis was based on previous findings that patients suffering from other types of headache are easily hurt, moody, and sensitive to perceived criticism (Gatchel, Deckel, Weinberg, & Smith, 1985), as well as extremely inhibited, susceptible to psychosomatic illness, and predisposed to self-generated tension (Jay, Grove, & Grove, 1987).

Null Hypothesis 2: There are no differences between sinus headache patients and patients on whom the California Psychological Inventory (Gough, 1948) was normed in terms of particular personality characteristics which are endorsed.

This hypothesis was based on previous findings that headache sufferers tended to doubt that their personal reactions to life problems could account for their headache pain, that they were coping poorly with life's problems despite evidence to the contrary (Barnat & Lake, 1983), and that their headaches were psychological rather than somatic in origin (Demjen & Bakal, 1981).
Null Hypothesis 3: There are no differences between sinus headache patients who either succeed or fail to obtain relief from blinded pharmacologic treatments designed to differentially alleviate physiological symptoms in terms of their responses to the Millon Behavioral Health Inventory (Millon et al., 1979).

This hypothesis is based on previous findings which suggested that low scores on the hypochondriasis, depression, and social isolation scales of the MMPI (Hathaway & McKinley, 1940) demonstrated a high correlation with headache patients achieving a positive response to biofeedback treatment (Werder, Sargent, & Coyne, 1981), as well as headache patients scoring low on the Inhibited Style, Sensitive Style, Recent Stress, Premorbid Pessimism, Future Despair, Somatic Anxiety, Allergic Inclination, Gastrointestinal Susceptibility, Life Threat Reactivity, and Emotional Vulnerability scales of the MBHI (Millon, Greene, & Meagher, 1979) evidenced a better response to behavioral treatment (e.g., biofeedback) of their pain (Gatchel et al., 1985).
CHAPTER II

HISTORY OF HEADACHE IN THE LITERATURE

As early as the Neolithic Age, trephining, or drilling holes in the head to allow the evil spirits to escape, was practiced to cure headaches (Diamond & Diamond-Falk, 1982). Over the past 3,000 years references to headache in the literature suggest that it has always been with us and that it remains a common symptom of our time (Friedman, 1972). During the epoch of the Egyptian dynasties, headache was attributed to the possession of evil spirits. The ancient Egyptians called the evil spirit of headache "Tiu" and believed that if one developed this condition, one was a broken person; they likened it to insanity.

The gods were blamed for the headaches of Greek citizens. Approximately 400 B.C., Hippocrates depicted a type of headache that was very similar to that of the migraine syndrome, giving a clear description of the warning, or aura, and the intense pain associated with classical migraine, along with the relief that occurred with vomiting. The ancient Jewish Talmud advised rubbing the head with wine, vinegar, or oil in treating a headache. It is written in the Talmud: "I can tolerate any illness, but not an intestinal disease, any suffering, but not stomach
or [heart] troubles, any pain, but not headache" (quoted in Diamond & Diamond-Falk, 1982, p. 10). Christian doctrine also recognized the headache entity; Chronicles I advised that the healthier physicians of antiquity recommended rubbing the head with wine, vinegar, or simply oil. The universal remedy for any ailment, including headache, was to occupy oneself with the words of God: "they are an ornament of grace unto thy head" (Proverbs 1:9).

Mankind's long experience with headache has provoked much speculation about its nature and management. Plato, in the Charmides, alluded to an apparent link between headache and emotional problems; Shakespeare's Desdemona casually dropped a practical hint about the treatment of migraine. The notion that headache is connected with specific personality characteristics or psychological function can be traced as far back as 250 years ago to the writings of D. Junkerius, who asserted that migraine headaches were caused by anger, tacit and unexpressed (Alvarez, 1947).

Early investigations of psychological factors in headache employed primarily the uncontrolled clinical interview to identify suspected relationships. A number of investigations have subsequently been conducted in attempts to further document and verify these early descriptions of the headache sufferer. Research to date, with limited
exceptions, is remarkably equivocal in terms of facts, owing to several methodological deficiencies (Andrasik et al., 1982; Blanchard et al., 1984).

Epidemiology

Headache is so familiar and general a symptom as to need no detailed definition. Common usage, however, applies the term to discomfort, usually painful, in any portion of the upper half of the head, from the orbits back to the suboccipital area. Recent estimates indicate that 5 to 10% of the population seek intermittent medical treatment for the relief of disabling headache (Raskin & Appenzeller, 1980). It is believed that headache is the chief complaint in more than one half of all patients who seek the attention of a physician (Friedman & Merritt, 1959).

Surveys of the general population gauge the incidence of frequent and/or distressing headache to be about 14% of males and 28% of females, while severe headache occurs in about 31% of males and 44% of females. It is predicted that nearly one in three Americans will suffer from severe headaches at some time during his or her life (Leviton, 1978).
Suspected Etiologies

The etiology and symptomatology underlying the phenomenon of headache pain has been a problem worthy of considerable concern and investigation. In this regard, the most common headache types have only recently been considered a possible manifestation of a lowered biologic threshold to a large variety of stimuli. Prior to the last twenty-five years, the responsible mechanism for the basis of such headaches (e.g., muscle contraction and migraine) was held to be psychologic in nature (Raskin & Appenzeller, 1980).

Several personality and psychological factors have been implicated in the psychogenesis of headache, including: anger, anxiety, conflict, dependency, depression, defense mechanisms, fears, guilt, hysteria, inability to express emotions, obsessive-compulsiveness, psychosis, and sexual problems. A large number of situational and behavioral factors have also been portrayed as precursors to headache, and include: substance use/abuse, conflict, emotional upset, fatigue, relationship problems, secondary gain, and stress. Taken together, these elements comprise what has been termed the "personality theory" of headache (Blanchard et al., 1984). This approach is actually a variant of Alexander's (1950) "emotional specificity hypothesis," which asserted that specific emotional types tend to exhibit
specific psychosomatic/psychophysiological disorders.

Whereas Alexander's (1950) theory stipulated a hereditary "organ weakness" as a requirement for acquisition of a psychosomatic or psychophysiological disorder, the personality theory of headache states that individuals who possess certain personality traits will develop specific types or classifications of headache. This thesis has been examined from a variety of positions, yielding a wide range of conclusions, contradictions and, often, quite compelling evidence that either supported or negated the postulates of this theory (Demjen & Bakal, 1981; Jay et al., 1987; Phillips, 1976). Despite the equivocal validity of this hypothesis, orthodox views maintain that symptoms of anxiety, stress, and worry are frequently associated with many common forms of headache (Raskin & Appenzeller, 1980).

Personality Factors of Headache

Classification According to Personality Characteristics

Traditional views hold that the personality makeups of individuals with headache are markedly different from individuals without headache and that such differences predispose these individuals to headache (Blanchard & Andrasik, 1982). Recent investigations have encountered numerous complications in attempting to effectively sort out
the factors contributing to the etiology of various headache types. Constitutional factors, for instance, may render an individual susceptible to headache, but the factors which trigger the underlying physiological mechanism need to be determined in order to adequately alleviate the headache. For a minority of headache sufferers, these factors might involve such specific events as the consumption of certain foods, alcohol, excessive exercise, bright lights, noise and lack of sleep. Current data suggest, however, that headache sufferers may be little different from each other or from controls when assessed by standard psychophysiological measures (Blanchard & Andrasik, 1982).

Many more headaches are likely precipitated by non-specific psychological stress (Bakal, 1975). Wolff (1937), for example, found that events such as vacations, examinations, increased responsibility, criticism, fear of failure, and fantasies have all been correlated with the onset of headache symptoms. Further, several psychophysiological studies have demonstrated that individuals exhibit idiosyncratic patterns of bodily response to different simple stimuli (Davis, 1957). In this regard, the possibility exists that sensory stimuli may play a direct or facilitative role in the development and manifestation of headache. The necessity of employing a multimodal approach to this problem, obtaining information from behavioral, subjective,
and physiological domains has been suggested by Phillips and Hunter (1981) and Appelbaum, Radnitz, Blanchard, and Prins (1988).

In 1962, the American Medical Association's Ad Hoc Committee on Classification of Headache, on the basis of general consensus, delineated 15 categories of headaches. The categories descriptive of the most frequently experienced headaches are: (a) vascular headache of the migraine type; (b) muscle contraction headache; (c) combined headache (vascular and muscle contraction); (d) headache of nasal vasomotor reaction; and (e) headache of delusional, conversion, or hypochondriacal states. The remaining categories refer to headaches that are symptomatic of some physical disorder, such as cranial inflammation; diseases of ocular, aural, nasal, or neck structures; traction on intracranial structure\(^1\) and cranial neuralgia (i.e., head pain deriving from end-organ stimulation and extending along nerve pathways) (Bakal, 1975).

Muscle contraction headache (frequently described by various authors as "tension" headache) and headache of delusional, conversion, or hypochondriacal states have been referred to as "psychogenic" headaches. That is to say that

\(^1\)The term "traction headache" is used to describe the often nonspecific headache seen with mass lesions of the brain, including tumors, hematomas, abscesses, and brain edema (Diamond & Dalessio, 1982, p.1).
emotional factors are of primary significance in the precipitation of the headache (Diamond & Dalessio, 1982).

Confusion exists among investigators as to what is meant by the term "psychogenic headache." Most authors, however, would agree that pain in the head, like pain anywhere else in the body, is an affective state. Thus, it can be fairly stated that there is likely a psychogenic component to all types of headache. Caution must be exercised, though, in drawing broad conclusions about the psychological origin of headaches. The term "psychogenic headache" should be limited to describing those headaches which do not have a peripheral pain producing mechanism or for which there is no obvious or demonstrable organic cause (Weatherhead, 1980).

Regardless of this caveat, innumerable investigations have sought to examine the psychological and personality attributes of patients from various headache classifications, but primarily those having received a diagnosis of either: (a) migraine headache; (b) muscle contraction headache; or (c) headache due to delusional, conversion, or hypochondriacal states. Following is a synopsis of the findings from investigations of patients having been diagnosed with these headache classifications; there are currently no studies available that have investigated personality attributes in sinus headache patients.
Migraine Headache

Migraine headache is usually unilateral in onset and is episodic in nature. It is often described as throbbing or pulsating pain, and is typically accompanied by nausea and vomiting. The precise cause of migraine is presently unknown, but the wide diversity of factors capable of triggering migraine attacks suggests that there are either subgroups of patients with migraine who have different biologic abnormalities, or that there is a common single mechanism that can be provoked by a wide range of identifiable factors (Raskin & Appenzeller, 1980). During the headache, the patient may exhibit chills, blushing, and other kinds of sensations traditionally believed to be mediated by the autonomic nervous system. The patient frequently complains of being unusually sensitive to light and/or sound. Often there is reported to be a family history of migraine in one or more first-degree relatives. Over 90% of migraine patients indicate that their attacks initiated before the age of 40 years, with between 20 and 35% being under the age of 5 years when their attacks began (Blanchard et al., 1984).

Migraine occurs commonly and is the most extensively studied headache syndrome. It is classified as a vascular type headache, as evidence supports the view that cranial arterial distention and dilatation are frequently implicated
in the painful phase but cause no permanent changes in the involved vessel (Ad Hoc Committee on Classification of Headache, 1962). The best presently available estimates of the annual prevalence of migraine is 20 to 25% of the population. The incidence of migraine does not appreciably differ according to intelligence, social class, or educational or racial background. It is far more common in women, who comprise about 75% of all patients diagnosed with migraine (Raskin & Appenzeller, 1980).

Alvarez (1947) characterized migrainous women as being hypersensitive to light, sounds, and smells, quick of thought and movement, prone to tension, worry, tiring easily, and subject to interrupted sleep. He further described them as perfectionistic, rigid, orderly, compulsive/obsessive, ambitious and preoccupied with success, resentful, insecure, and unable to express aggressive feelings in a constructive manner.

The work of Frieda Fromm-Reichman (1937) best typifies the psychoanalytic position regarding the "migrainous personality." She described migraine as being a physical expression of unconscious hostility against consciously beloved persons, claiming that migraine sufferers turn their hostile activity from other persons against themselves: "the persons introject the beloved and hated person so that injuring themselves means at the same time hurting the
introjected person, and vice versa" (p. 27).

An abundance of well-controlled studies (e.g., Bihldorff, King, & Paines, 1971; Passchier, van der Helm-Hylkema, & Orlebeake, 1984; Pearse, 1977) have recently lent support to clinical observations concerning migraine patients experiencing more stress in their lives than normal because of their personality structures. Henryk-Gutt and Rees (1973) also found that a high percentage of migrainous subjects attributed the cause of their headache to anger, frustration, anxiety, and personal problems. The reported recurrent findings of contained anger and inhibited expression of aggression and hostility in the migraine patient reduce to six general characteristics: (1) migraine patients are more inhibited in expressing feelings of aggression than persons who do not suffer from migraine; (2) migraine patients are more likely to experience anxiety and/or guilt after expressing anger than non-headache patients; (3) migraine patients have fewer outlets for the expression of anger than do persons without chronic headache; (4) migraine patients react with anger to situations which should not necessarily produce anger; (5) migraine patients feel angry for longer periods of time than those not suffering from chronic headaches; and (6) migraine patients were punished for, and/or prevented from, expressing anger when they were children.
Muscle Contraction Headache

A daily, constantly recurring headache, without associated neurologic symptoms or prominent vomiting, represents the clinical features that usually lead to the diagnosis of muscle contraction or "tension" headache. This is the most common form of chronic headache, comprising about 85% to 90% of all headache diagnoses. Head pain is bilateral in about 90% of patients diagnosed as exhibiting muscle contraction headache. Their pain is usually described as dull, pressing or bandlike, waxing or waning in intensity during the day, with no predilection for any particular cranial location. The vast majority of these patients experience head pain daily and constantly, with symptoms dating back as long as 10 to 20 years (Raskin & Appenzeller, 1980).

Although rarely incapacitating, exacerbations of headache occur with a variable frequency and are periodically accompanied by nausea and other symptoms characteristic of the vascular type headaches. Headache is often present upon or shortly after awakening and persists throughout the day, often without any obvious relationship

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2 The terms "muscle contraction" and "tension" headache have been used synonymously for over forty years to describe chronic headaches of a nonspecific type which are not vascular and are not associated with traction and inflammation (Diamond & Dalessio, 1982, p. 99).
to stress and anxiety. About 10% of patients with muscle contraction headache are wakened by a throbbing headache between 1 and 4 a.m. The prevalence of muscle contraction headache in the population at large is not clear; however, as an index of its frequency, over 40% of 1,152 patients referred to an outpatient clinic were diagnosed as having muscle contraction headache (Lance, Curran, & Anthony, 1965). Diamond and Dalessio (1982) reported that muscle contraction headache is evidenced in both men and women, but that women predominate in most accounts of frequency distribution. While the familial incidence data for migraine headache are supportive of an inherited predisposition for this condition, muscle contraction headaches tend to occur in families only because parents with these symptoms may leave the stigma with their children as an example of learned and inappropriate behavior (Diamond & Diamond-Falk, 1982).

Like migraine patients, persons who regularly suffer from muscle contraction headache have been traditionally regarded as worrisome, depressed, anxious, chronically tense, hostile, dependent, histrionic, and psychosexually conflicted. Kolb (1963) found that the family history of these patients typically discloses parents who are nagging, insistent, and sometimes sadistic. The patients reveal that they were disallowed ordinary expression of feelings and
that they were frequently punished for behavior which their parents considered inappropriate.

As a consequence of parental over-control, the developing child was afforded few opportunities to cultivate feelings of personal self-esteem and acquired many doubts about personal adequacy. Kolb (1963) further asserted that these patients repressed all feelings of resentment, as well as socially taboo sexual impulses, resulting in an arrival at adolescence with no preparation or experience in social control over expression of these natural inclinations. Such a person "literally uses the muscles in the back of his head and neck in order to maintain an external appearance of composure while concealing the anxiety aroused in connection with taboo feelings" (p. 36).

The pain associated with muscle contraction headache arises out of a constant tightening of the muscles of the jaw, face, scalp, and neck. Muscle tension is known to accompany mental tension; experiencing stress can cause an individual to tighten muscles of the head and shoulder regions, and prolonged tautness of the muscles can cause pain (Diamond & Diamond-Falk, 1982). Several studies involving patients diagnosed with muscle contraction headache (e.g., Friedman, de Sola Pool, & von Storch, 1953; Kolb, 1963; Martin, Rome, & Swenson, 1967; Martin, 1978) have alleged that emotional factors are of prime importance.
in the causation of muscle contraction headache.

Although no single determinant was found to be productive of muscle contraction headache, multiple conflicts were usually evident in patients diagnosed as having such headaches. Anxiety and depression were frequently noted in patients experiencing chronic muscle contraction headache; patients were, however, usually convinced of the somatic authenticity of their complaints. Authors have repeatedly suggested that anxiety and especially depressive symptoms are converted by these individuals into acceptable (to the patient) physical symptoms (Diamond & Dalessio, 1982).

Recent investigations with muscle contraction headache sufferers have concluded that these patients were more "psychologically distressed" than patients receiving a headache diagnosis under any other classification (Blanchard et al, 1984; Drummond, 1985). Bihldorff et al. (1971) profiled muscle contraction headache patients as being hostile, psychologically disorganized, and prone to guilt feelings and depression. Migraine headache patients, on the other hand, were portrayed as controlling, as inhibiting emotional responses of all kinds, and as exhibiting traits ordinarily associated with a compulsive character structure. Other studies, however, have reported no demonstrable psychological differences between muscle contraction headache or migraine patients (Raskin & Appenzeller, 1980).
Contemporary perspectives submit that the similarities between migraine and muscle contraction headache may be more striking than the differences, and that these headache variants may form opposite poles of a spectrum of "essential headache" rather than comprising discrete clinical entities. There appears to be no compelling evidence to support a biologic mechanism of muscle contraction headache that is qualitatively different from that of migraine. Moreover, there are lines of evidence which suggest that the varying clinical manifestations of recurring headache may include classic migraine at one end, with variations of common migraine and tension-migraine occupying the vast middle ground, and muscle contraction headache at the other end (Drummond, 1985; Raskin & Appenzeller, 1980).

**Headache of Delusional, Conversion, or Hypochondriacal States**

Headache accompanying neurosis (i.e., anxiety disorders), psychosis, or depressive disorders for which no lesion or altered physical state can be determined is considered to be of psychogenic origin. Headache symptoms are typically woven into a pattern of complaints which vary with the particular mental disorder. The main focus of the patient's attention is on the headache, which is believed to represent or symbolize distress relative to head function rather than disease or stress originating within any
specific psychophysiologic mechanisms (Friedman, 1979).

Psychogenic headache patients often describe their pain as encompassing pressure sensations all over the head or pressure behind the eyeballs, giving rise to visual disturbances such as double or triple vision. Their pain may be sharp or dull, localized or generalized, it may migrate or feel like a crawling sensation, or like pins and needles inside the skull or under the scalp (Weatherhead, 1980). These headache patients further characterize their headache as severe, constant, unremitting, and socially and occupationally incapacitating. The pain associated with psychogenic headache is depicted by the patient in flamboyant terms; it is often characterized as an ever-present, excruciating pain or as resembling lightning-like explosions, a spike driven into the head, or a tight band of thorns around the head. One can be reasonably assured that the headache is psychogenic in origin if the patient appears comfortable while describing it (Friedman, 1979); this appears to comprise the belle indifference affective state described first by Pierre Janet (Weatherhead, 1980).

Headaches of purely psychogenic origin are thought to be quite rare, but appear to be equally distributed between males and females. The age of onset of psychogenic headache typically is found to be around twenty or thirty years or occasionally forty, but they are believed to occur at any
age. Accounts given by patients indicate that such headaches are capricious and bizarre and follow no definite pattern as to time, location, duration, or nature of the pain. The coincidence of an acute emotional state and the appearance of headache is frequently indicative of psychogenic precipitation, especially if the connection between the psychological event and the symptom is unrecognized or denied by the patient. A key mechanism in the development of the psychogenic headache may be the patient's identification with symptoms of a person with whom they have a close relationship (Packard, 1980).

It has been reported that psychogenic headache patients frequently grow up in the presence of an ill relative: a parent, an aunt, or a grandparent. Many times these patients will have had a history of a prolonged illness throughout childhood. Such patients have generally been found to be quite suggestible and often react to suggestions made by the examiner. Other symptoms frequently associated with headaches of psychogenic origin include anxiety, reactive depression, insomnia, anorexia, and constipation or diarrhea (Packard, 1979).

Psychogenic headaches are believed to arise in response to external stress or internal conflict or both, with the headaches being symbolically connected with the precipitating stress. Cases of psychogenic headache have reportedly
developed following the suicide of someone close to the patient who had shot him/herself in the head (Rosenblum, 1947).

Headache of psychogenic origin is usually regarded as being a difficult diagnosis to make. It is rarely amenable to differential diagnosis in the initial evaluation because of a vague and sometimes inadequate history, subtle symbolism, and no major abnormalities in the patient's mental status. Such patients may exhibit satisfied indifference, often despite bitter complaining, bizarre or unusual symptoms sometimes described in a dramatic manner, exaggerated complaints of pain, early passive or angry denial of any emotional difficulties, or a headache, sometimes chronic, which has not responded to any medications. A possible precipitating event, not recognized by the patient is also significant, as are the possibilities of secondary gain, and an immature personality (Packard, 1980).

Inasmuch as headache of psychological origin is considered to represent a symbolic attempt by the patient to solve a problem, it may constitute: (a) a method of handling nonspecific stress; (b) a manipulation of family members in an attempt to adapt to an almost intolerable family situation; (c) a means of coping with the threatened breaking loose of rage; (d) body symptoms symbolic of conflict; (e) a forerunner of a pending major life-change
situation, usually unconsciously perceived; (f) a method of dealing with an unchangeable life impasse; (g) a substitute for a major psychological illness as a means of communication to self and the world of a catastrophic life situation; (h) a manifestation of a severe body-image problem; (i) an expression of resentment of authority and an a temptation to rebel against it; (j) a need to inhibit sexual temptations; or (k) delusions of hypochondriacal states associated with disturbances of body image very much like the body-image problem (Friedman, 1979).

Assessment of Various Headache Classifications

Researchers in the area of headache have long been interested in the personality attributes and psychological functioning of headache sufferers. Consequently, there presently exists relatively widespread clinical agreement about the personality characteristics of such individuals. Conventional attitudes maintain that the psychological constituency of persons with chronic headache evidences greater levels of depression and anxiety than that of persons without such headache, and that these attributes predispose such individuals to headache (Phillips, 1976).

Formulations Based on Clinical Impressions

Many of today's insights regarding the psychological
factors related to headache are based on the clinical inferences of early investigators, most of whom were psychiatrically-oriented physicians. Unfortunately, the claims by these authors concerning the psychological etiology of headache are primarily observational in nature; they did not rely on psychological test data but upon other means to render conclusions concerning the relationship between headache and personality. The majority of their assertions were based on both systematic and unsystematic clinical impressions, reviews, case reports, questionnaires, or archival records (Bihldorff et al., 1971; Blanchard et al., 1984).

This substantial body of literature is essentially classified as "clinical lore" and subjective observations on personality and headache. It continues to influence practitioners and is passed along in the informal education of professionals. In this regard, it has served as a fertile source of hypotheses to be studied with more objective measures and improved methodology. Recently, this type of reporting has tended to fade from the professional headache literature in favor of studies employing greater precision (Blanchard et al., 1984).

Psychometric Investigations

Many of the early reports addressing the psychological
and personality aspects related to headache suffer from methodological deficiencies. Considering this dilemma, several recent investigations have endeavored to identify statistically significant attributes between patients diagnosed with various headache classifications and/or control subjects on a number of standard psychometric measures (Arena, Andrasik, & Blanchard, 1985).

As previously stated, the primary assumption underlying this line of investigation is that specific personality factors are, in some way, connected with the etiology of headache pain. A decisive limitation with existing psychometric methodology is the complication of determining whether particular personality characteristics are a precursor to, or a consequence of the experience of living with chronic headache pain. Bakal (1982) has asserted that living with unremitting pain may precipitate increased anxiety, depression, and other coping difficulties, leading to elevations on the clinical scales of psychological test instruments.

Arena et al. (1985) sought to investigate this hypothesis and found no significant differences greater than that expected by chance on several psychological test instruments (e.g., Minnesota Multiphasic Personality Inventory, Hathaway & McKinley, 1940; Beck Depression Inventory, Beck et al., 1961; State-Trait Anxiety Inventory,
Spieberger, et al., 1970; Autonomic Perception Questionnaire, Mandler et al., 1958; Rathus Assertiveness Schedule, Rathus, 1973; Social Readjustment Rating Scale, Holmes & Rahe, 1967; and the Psychosomatic Symptom Checklist, Cox et al., 1975). They concluded that the pathological personality traits so often found in headache sufferers are not differentially affected by duration of pain experience and, therefore, were likely to have been present prior to the onset of the pain problem. Despite the findings that with increasing chronicity there appears to be no significant increase in either sensory or affective components of headache pain experience, Phillips and Jahanshahi (1985) found an increase in behavioral disruption and a stronger bond between pain experience and, both, complaint levels and behavioral avoidance (i.e., withdrawal from social and occupational situations).

Other investigations that employed psychometric testing to evaluate associations between headache and personality have consistently shown that headache patients are distinguishable from other patients (Davis, Wetzel, Kashiwagi, & McClure, 1976; Jay et al., 1987). Similarly, some studies have produced compelling data that personality traits are differentially associated with patients having headaches of varying classifications (Blanchard et al., 1984; Ellertson & Klove, 1987; Harrison, 1975; Kudrow & Sutkus, 1979).
Psychophysiological Assessment

Several investigations have examined the hypothesis that distinct psychophysiological mechanisms may be operative in the development of different types of headache. The predominant view of headache has asserted that migraine arises out of cerebral vasculature lability, while muscle contraction headache results from sustained contraction of the neck, shoulder, scalp, and facial muscles. Researchers have attempted to test these postulates by assessing psychophysiological functioning of headache patients under both resting and contrived or simulated laboratory stress conditions. The bulk of this work has been conducted with migraine and muscle contraction headache patients; reports were not identified wherein similar exploration has been undertaken with patients diagnosed as exhibiting headaches of purely psychogenic origin.

A single psychophysiological investigation of sinus headache was conducted by Hamilton, Haynes, Gannon, & Safranek (1980), using low frequency headache controls and high frequency muscle contraction headache patients as comparison groups. Two cardiovascular and two electromyograph (EMG) measures were recorded across rest, stress, and post-stress adaptation periods. The study results revealed no significant between-group differences in the psychophysiological measures during rest or stress conditions. On
measures of blood volume pulse (BVP), however, there was a
tendency for sinus headache patients to demonstrate a
greater rate of recovery during post-stress adaptation.
This finding implied that sinus headache patients may
demonstrate greater variability in some cardiovascular
responses, but the lack of significant between-group
differences in response to stress makes this inference more
tenuous. Overall, the results of this study suggest that
there were few psychophysiological differences between sinus
headache patients and nonheadache controls, or muscle
contraction headache patients.

Early research by Wolff (1937) and Jacobson (1939)
provided relatively explicit support for the above-stated
pathophysiological basis of headache. Inquiries conducted
during the 1970s (e.g., Bakal & Kaganov, 1977; Friar &
Beatty, 1976; Pozniak-Patewicz, 1976; Sargent, Green, &
Walters, 1973), however, produced somewhat more equivocal
findings. The most recently completed examinations (e.g.,
Anderson & Franks, 1981; Andrasik & Holroyd, 1980; Andrasik
et al., 1982; Gannon, Haynes, Safranek, & Hamilton, 1981)
have extended the findings of studies conducted during the
1970s, and actually dispute a pathophysiological basis for
various types of headache.

Interestingly, but not surprisingly, the empirical
trend toward establishing a reduced psychophysiological
distinction between headaches of different classifications has been paralleled by increases in methodological rigor. In this regard, then, current data suggest that muscle contraction headache sufferers may be little different from migraine headache sufferers, from controls, or from sinus headache patients when assessed by standard psychophysiological measures.

Reliability and Validity of Assessment Methods

Observational Data

Over the last several centuries there has existed substantial conjecture about the psychological and personality influences believed to be contributory in either the genesis or maintenance of headache. The preponderance of these assertions has been based upon uncontrolled or non-standardized clinical observations. Such suppositions provide important clues about possible causal or maintaining factors, but are by no means confirmatory.

Psychometric Assessment

A number of investigators have attempted to study psychological factors in a more systematic fashion by employing standardized psychological tests. A complication here is the instrumentation used in assessing the psychological characteristics of individuals suffering from
chronic headache pain. A majority of headache investigators have relied upon the Minnesota Multiphasic Personality Inventory (MMPI) (Hathaway & McKinley, 1940) in their attempts to identify personality characteristics which correlate to a significant degree with different headache classifications.

A myriad of reports (e.g., Ellertson & Klove, 1987; Harrison, 1975; Kudrow & Sutkus, 1978; Sternbach et al., 1980) have pointed to elevations of the first three clinical scales of (1) hypochondriasis, (2) depression, and (3) hysteria (the "neurotic triad") in patients with chronic somatic complaints as being indicative of psychopathology. This is representative of the so-called conversion-V pattern, wherein the hypochondriasis scale exhibits the greatest elevation, the hysteria scale demonstrates the next highest elevation, and the depression scale is also elevated, but is the lowest of the three.

In accordance with the original intent of the designers of the MMPI, the hypochondriasis scale score represents complaints about the body by patients who are supposed not to have a physical disorder. If, however, a physical disorder truly exists this scale will inevitably be elevated to some degree, even in the absence of a psychological disorder. The hysteria scale score involves some of the items that are included in the hypochondriasis scale
and other items that reflect extroversion. Consequently, if the hypochondriasis scale is elevated, the hysteria scale will, to an extent, exhibit coinciding elevations. Furthermore, the depression scale, which may reflect mood, might also encompass sleep disturbances that could be produced as well by organic illness as by psychological disturbance.

Clearly, the reliability and repeatability of MMPI (Hathaway & McKinley, 1940) results relative to pain are quite high. Unfortunately, interpretation of the associated findings is much less straightforward. Definitive evidence will be required that none of the symptoms can be due to organic disturbance before such findings can be confidently accepted as confirmation of psychological etiology (Merskey et al., 1985).

Psychophysiological Measures

Studies which have sought to delineate distinct psychophysiological mechanisms that predispose individuals to headache of different classifications have largely arrived at conflicting, and for the most part, negative conclusions. As the majority of these investigations examined headache subjects while in a non-headache state, a number of researchers have suggested that studying psychophysiological responding of headache subjects during both headache and headache-free periods may provide more adequate tests of
etiological hypotheses (Arena et al., 1985).

The consensus of investigators conducting psychophysiological research has indicated a greater need for consistency of response measures and enhanced experimental methodology. Specifically, recommendations have taken the form of greater attention being given to patient selection criteria, the matching of controls to headache subjects, incorporation of adequate adaptation periods, the inclusion of subjects with different types of headache, and measurement of vasomotor as well as muscular responding (Blanchard & Andrasik, 1982).

Summary and Conclusions

Discussion of the possible role of personality and psychological factors in chronic headache has a long history. As with many other areas of behavioral medicine, research on the psychological constituents of different headache entities has shown enormous growth over the last several years. In light of the literature summarized herein, attempts to precisely define the concept of a "headache personality" or "headache-prone personality" have been quite enigmatic. Similarly there is relatively no consistent and reliable support for the etiologic theories which propose a generalized psychophysiological dysfunction for headaches of various classifications.
Despite the apparent incapacity to identify the dimensions of a "headache personality," per se, two over-all conclusions appear to have materialized:

1. Patients with chronic headache, as a group, are more psychologically distressed and show more "deviant personality characteristics" than do non-headache sufferers. Whether this is cause or effect has not been clearly established. Extended periods of suffering with chronic headache pain could lead to personality changes, but pre-existing personality deviations could also predispose individuals to headache.

2. There is unequivocal clinical utility in assessing the personality characteristics of headache sufferers because such data can lead to rational and precisely formulated treatment plans, and possibly facilitate patients' response to treatment.

In recognition of the complications involved in attempting to effectively sort out possible factors contributing to the etiology of various headache types, the importance of employing a comprehensive approach to this problem is readily apparent. Obtaining further data through valid and reliable behavioral, psychological, and physiological measurement is clearly in order. Significant clinical importance lies in objectively examining the manner in which patients exhibiting headache of various manifestations
respond to treatment aimed at alleviating their pain.

As previously noted, an abundance of literature has been generated concerning the personality and psychological makeup of headache patients with vascular, tension, and psychogenic etiologies. Dozens of investigations also have focused on identifying or developing a consistent means of predicting such patients' responses to various types of treatment. To date, however, headache believed to be caused by inflammation had not been studied in these terms. Thus, the present study was undertaken in an effort to develop a better understanding of the personality and psychological characteristics of sinus headache patients, as well as to examine the possibility that correlations exist between specific personality attributes of these patients and their responses to various blinded medications designed to alleviate their psychophysiological symptoms.
CHAPTER III

METHOD

Description and Selection of the Experimental Sample

Selection of Patients

Fifty-six patients were recruited from a roster of 115 individuals having previously been screened and diagnosed as suffering from headaches due to sinus congestion and not by any other causes, as determined by: (a) physical examination, emphasizing: blood pressure; head, ears, nose and throat; eye examination, to include visual acuity and optic fundi; and a limited neurologic examination; (b) serum IgE level (i.e., a physiological indicator of immune system function); (c) sinus translumination (i.e., direct visual examination with an illuminating instrument); (d) sinus examination by x-ray; (e) medical history and headache questionnaire substantiating a pattern of headache consistent with the source and character of the pain as being located in the sinuses.

Specific Inclusion Criteria

The following conditions were adhered to in determining the acceptability of patients into this study: (a) female
patients needed not be sterile but had to have a negative pregnancy test just prior to the start of the study; (b) female patients had to be practicing adequate birth control methods to ensure that they did not become pregnant during the study; (c) patients had to be aged between 18 to 70 years inclusive; (d) patients had to be in good physical health as documented by intake history, physical examination and laboratory analysis of blood and urine; (e) patients had to express a willingness to participate in the study for its entire duration and be competent to follow instructions and complete accurate records and examinations.

Specific Exclusion Criteria

The following characteristics were used as a basis for excluding patients from participation in this study: (a) mental status indicators (e.g., psychosis or severe neurosis) which could compromise the validity of historical data; (b) chronic painful disease of other organ or etiology (e.g., malignancy, chronic arthritis, etc.); (c) abuse of alcohol, street drugs, or narcotics; (d) sensitivity to anti-inflammatory drugs such as aspirin or ibuprofen, or alpha-adrenergic agents such as pseudoephedrine; (e) migraine headaches or headaches related to eye problems such as glaucoma, refractive error or other disorder; (f) swelling of the blood vessels of the head, increased pressure attributed to brain swelling, or arthritis of the
back of the neck; (g) chronic or severe gastrointestinal disease, especially gastric or duodenal ulcer; (h) concurrent use of investigational drugs or Monoamine Oxidase Inhibitors (MAO) and sympathomimetic agents; (i) pregnant or nursing women, positive pregnancy test, or women not practicing birth control methods; (j) other serious medical conditions.

Patient Characteristics

Of the 56 patients initially selected for this study, 52 reported that they had experienced a total of four sinus headaches required for completing the study. All patients were caucasian. Of these, 8 patients were male and 44 were female. The males ranged in age between 32 and 47 years with a mean age of 38.88. The females ranged in age between 27 and 55 years with a mean age of 38.16. All of the males in this study were married, while 29 of the women were married, 8 were single, 6 were divorced, and 1 was living with her boyfriend.

Six of the males possessed graduate degrees, while 1 had a college degree and 1 was a high school graduate. Nine of the females held non-degree diplomas (i.e., nursing) or had accumulated some college credits, while 2 possessed post-graduate degrees, 2 had acquired graduate degrees, 13

3 A total of 56 sinus headache patients completed the initial test battery while only 52 of these patients completed the remaining four POMS surveys.
had earned college degrees, 16 had graduated from high school, and 2 had completed grade school.

For males the annual household income ranged from $35,000 to more than $50,000, with the mean income falling between $35,000 and $40,000. For females the annual household income ranged between $10,000 to more than $50,000, with the mean income falling between $35,000 and $40,000.

**Study Design**

This study comprised a double-blind, placebo-controlled trial to evaluate the pharmacological efficacy of ibuprofen when given in combination with pseudoephedrine to 56 patients exhibiting a history of headaches attributable to sinus congestion. This randomized, crossover study was conducted on an outpatient basis and measured patient responses to two doses of medication. Additionally, a psychological test battery was administered to evaluate the possibility that specific personality characteristics might differentiate these patients from individuals on whom the psychological test instruments were normed, as well as to examine the possibility that specific psychological test scales might correlate with patients' differential responses to the pharmacologic treatments described below.
Procedures for Patient Evaluation

Pretreatment Procedures

The Upjohn Company (Kalamazoo, MI) obtained informed consent for the medical aspects of this study, while this investigator obtained separate informed consent for the psychological testing component. A history and physical examination were conducted, along with all specific evaluations for confirming a diagnosis of headache due to sinus congestion. Eligible patients were entered into the study and assigned a patient number which corresponded to the appropriate randomization schedule. Eligible patients were reminded that they could not take any other anti-inflammatory medications, decongestants, bronchodilators, antidepressant or tranquilizing drugs. Physical treatments such as cold/head packs, physical therapy, and biofeedback were also not permitted during the course of this investigation.

Information obtained from patients included: age; sex; marital status; educational level; occupation; income; race; height; weight; blood pressure; and a listing of any special tests that the patient had undergone (e.g., x-rays, ultrasound) which indicated a sinus condition. Patients were also asked to list all drugs currently being used and

4 Appendices A and B, respectively, contain the Informed Consent document that was utilized for the psychological testing and the Western Michigan University Human Subjects Institutional Review Board approval for this study.
refrain from taking those which might interfere with the study.

Psychometric Evaluation

Patients accepted into the study were administered a battery of three psychological test instruments prior to their assignment to a treatment group. This battery was comprised of: (1) The California Psychological Inventory (CPI) (Gough, 1948); (2) The Millon Behavioral Health Inventory (MBHI) (Millon et al., 1979); and (3) The Profile of Mood States Questionnaire (POMS) (Nowlis & Green, 1957). The POMS was also administered at all four follow-up clinic visits, subsequent to each of the patient's headaches.

Instrumentation

The California Psychological Inventory (CPI) (Gough, 1948) is a multipurpose questionnaire designed to assess normal personality characteristics. It is a self-administered test, consisting of 462 items that normally takes from 45 minutes to one hour to complete. This inventory may be given under normal conditions to individuals aged 14 through adult and is designed to provide a measure of an individual's personality based on his or her self-perception rather than the impression he or she may wish to project. Clinically, it can be used for understanding maladjustments and evaluating specific problems, such as abuse, juvenile
delinquency and criminality, vulnerability to physical illness, marital discord, and social immaturity.

The Millon Behavioral Health Inventory (MBHI) (Millon et al., 1979) is a comprehensive psychodiagnostic instrument designed expressly to assess psychological factors related to physical health care. This examination consists of 150 true-false items developed for individuals 17 years of age and older, and can be completed in about 20 minutes. The twenty scales of the MBHI are grouped into four broad categories, including: (1) basic coping styles, which evaluates an individual's likely style of relating to health care personnel, services, and medical regimes (e.g., cooperation, confidence, respect, inhibition, sociability, forcefulness, and sensitivity); (2) psychogenic attitudes, which examines problematic psychosocial attitudes and stressors (e.g., chronic tension, premorbid pessimism, social alienation, recent stress, future despair, and somatic anxiety); (3) psychosomatic correlates, which compares similarities to patients with psychosomatic complications (e.g., allergic inclination, cardiovascular tendency, gastrointestinal susceptibility); and (4) prognostic indexes, which evaluates possible treatment problems or difficulties (e.g., pain treatment responsivity, life threat reactivity, emotional vulnerability).

The Profile of Mood States Questionnaire (POMS) (Nowlis & Green, 1957) measures dimensions of affect or mood, and
has been utilized for assessing individual's responses to various therapeutic approaches, including drug evaluation studies. This instrument consists of 65 adjectives describing feeling and mood to which the individual responds according to a five-point scale, ranging from "Not at all" to "Extremely." This test was designed for outpatients 18 years of age or older, and takes about 3 to 5 minutes to complete. Six dimensions of affect or mood are measured, including: (1) tension-anxiety; (2) depression-dejection; (3) anger-hostility; (4) vigor-activity; (5) fatigue-inertia; and (6) confusion-bewilderment.

**Treatment Assignment**

Patients were randomized to receive all of the following four treatment groups: (1) pseudoephedrine 60 mg (one matching placebo tablet to ibuprofen 400 mg plus one capsule containing two pseudoephedrine 30 mg tablets); (2) ibuprofen 400 mg p.o. (one ibuprofen 400 mg tablet and one matching placebo capsule); (3) ibuprofen 400 mg/pseudoephedrine 60 mg p.o. (one ibuprofen 400 mg tablet and one capsule containing two pseudoephedrine 30 mg tablets); (4) placebo (one matching placebo tablet and one matching placebo capsule). Study medication, supplemental rescue medication, and a report card for the first sinus headache were

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5 Two tablets of acetaminophen 325 mg to be taken by the patient two hours after the second dose of study medication if headache relief was not achieved.
distributed to patients accepted into the study.

**Treatment at the Time of the Headache**

Patients must have experienced headache pain prior to taking the assigned medication. If congestion occurred without headache, medication could not be taken. A headache must have been present for one (1) hour to qualify as significant for this study and be of such nature that the patient would normally have taken medication for it (i.e., definition of moderate or intense pain).

Report card entries were to be made within fifteen (15) minutes before the first dose of medication, and at 1/2, 1, 2, 3, 4, 6, and 8 hours after the first dose. At the specified times, patients were instructed to record their assessments of pain intensity (i.e., none, slight, moderate, intense) and rate the relief of the headache as worse, unchanged, approximately half gone, or completely gone. Patients also assessed the degree of nasal congestion present as none, slight, moderate, or severe, and rate congestion relief as none, fair, good, or complete. Patients were also to describe any new symptoms experienced after taking the study medication (i.e., possible medical events) and the time the new symptom occurred.

Patients recorded their ratings of overall effectiveness of the study medication in relieving the sinus headache (e.g., ineffective, slightly effective, moderately effec-
tive, very effective, completely effective). Patients also recorded whether supplemental medication was taken, the time it was taken, and indicated if and when the supplemental medication relieved the headache. Patients also noted if and when any other non-study medication was taken.

A total of two doses of medication was to be taken for each headache occurrence: the first dose of medication should be taken one hour after the onset of the headache and the second dose should be taken at four hours after the first dose. If headache symptoms were present at two (2) hours after the second dose of study medication had been taken, acetaminophen 10 grains (two 325 mg tablets, as supplied as the supplemental [rescue] medication) were to be taken. If the patient was unable to wait until this time, they were allowed to take the supplemental medication as needed. For purposes of analysis, the patient was considered a treatment failure for that treatment period. A minimum of forty-eight (48) hours must have elapsed between reportable headache occurrences.

**Post-Treatment Efficacy Evaluation**

Patients were to contact the clinic to schedule an appointment after each headache occurrence. At clinic visits, vital signs were taken, report cards reviewed, brief interview conducted, medication counts taken, and a POMS survey was administered. Additional medication and a report
card were distributed until a total of four (4) headaches had occurred per patient. Patients were contacted by the study nurse if they did not contact the clinic within a two week period of time after their previous clinic visit. All patients were paid $110.00 for completing participation in the study.
CHAPTER IV

RESULTS

The purpose of this investigation was to evaluate the responses to the Profile of Mood States (POMS) (Nowlis & Green, 1957), the California Psychological Inventory (CPI) (Gough, 1948), and the Millon Behavioral Health Inventory (MBHI) (Millon et al., 1979) of patients diagnosed with sinus headache: (1) to determine if sinus headache patients evidence greater subjective mood variability than "normal" individuals; (2) to determine if sinus headache patients endorse personality characteristics which differ from "normal" individuals; and (3) to determine if correlations exist between the psychological attributes of sinus headache patients and their ratings of efficacy obtained from blinded pharmacologic treatments designed to differentially alleviate physiological symptoms.

Statistical procedures are presented first, followed by the results specific to each hypothesis tested. A summary of the study findings concludes this chapter.

---

6 Scale descriptions for the POMS, the CPI, and the MBHI are presented in Appendices C-E.

7 Normative data for the POMS, the CPI, and the MBHI are located in the respective test manual referenced for each of these instruments.
Statistical Procedures

Responses to the psychological test battery were computer-scored by the respective test publishers. Funding for this service was provided by The Community Research Fund, courtesy of Bronson Clinical Investigational Unit, Inc., Kalamazoo, MI.

For the POMS questionnaire, \( t \)-values for each subscale were calculated for five periods: (1) baseline, (2) treatment one, (3) treatment two, (4) treatment three, and (5) treatment four. A \( t \)-value was also calculated for each CPI scale for purposes of comparing z-scores between sinus headache patients and normative data for these scales. Finally, \( t \)-tests were performed on each MBHI scale between the sinus headache patients who obtained relief from the blinded study medications and those who did not obtain relief from the study medications.

Hypothesis Testing

Subjective Mood Variability

Null Hypothesis 1: Sinus headache patients will not demonstrate greater subjective mood variability than do individuals on whom the psychological test instruments were normed. A two-tailed \( t \)-test was employed to test this hypothesis. Tables 1-6 present the results of this analysis, displaying time of evaluation, means, standard
deviations, t-values and probability for each POMS scale.

Table 1
Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the Tension-Anxiety Scale of the POMS

<table>
<thead>
<tr>
<th>Time of Evaluation</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHP</td>
<td>Norm</td>
<td>SHP</td>
</tr>
<tr>
<td>Baseline</td>
<td>7.69</td>
<td>20.7</td>
<td>4.87</td>
</tr>
<tr>
<td>Headache #1</td>
<td>5.85</td>
<td>20.7</td>
<td>3.60</td>
</tr>
<tr>
<td>Headache #2</td>
<td>5.46</td>
<td>20.7</td>
<td>3.73</td>
</tr>
<tr>
<td>Headache #3</td>
<td>5.90</td>
<td>20.7</td>
<td>5.42</td>
</tr>
<tr>
<td>Headache #4</td>
<td>5.75</td>
<td>20.7</td>
<td>4.97</td>
</tr>
</tbody>
</table>

*p < .001

Table 2
Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the Depression-Dejection Scale of the POMS

<table>
<thead>
<tr>
<th>Time of Evaluation</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHP</td>
<td>Norm</td>
<td>SHP</td>
</tr>
<tr>
<td>Baseline</td>
<td>5.44</td>
<td>28.0</td>
<td>6.77</td>
</tr>
<tr>
<td>Headache #1</td>
<td>3.25</td>
<td>28.0</td>
<td>4.46</td>
</tr>
<tr>
<td>Headache #2</td>
<td>2.19</td>
<td>28.0</td>
<td>3.38</td>
</tr>
<tr>
<td>Headache #3</td>
<td>2.62</td>
<td>28.0</td>
<td>3.61</td>
</tr>
<tr>
<td>Headache #4</td>
<td>3.10</td>
<td>28.0</td>
<td>4.83</td>
</tr>
</tbody>
</table>

*p < .001

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Table 3

Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the Anger-Hostility Scale of the POMS

<table>
<thead>
<tr>
<th>Time of Evaluation</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHP</td>
<td>Norm</td>
<td>SHP</td>
</tr>
<tr>
<td>Baseline</td>
<td>6.08</td>
<td>14.9</td>
<td>5.90</td>
</tr>
<tr>
<td>Headache #1</td>
<td>4.31</td>
<td>14.9</td>
<td>5.41</td>
</tr>
<tr>
<td>Headache #2</td>
<td>3.17</td>
<td>14.9</td>
<td>3.54</td>
</tr>
<tr>
<td>Headache #3</td>
<td>2.75</td>
<td>14.9</td>
<td>4.53</td>
</tr>
<tr>
<td>Headache #4</td>
<td>3.94</td>
<td>14.9</td>
<td>6.25</td>
</tr>
</tbody>
</table>

*p < .001

Table 4

Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the Vigor-Activity Scale of the POMS

<table>
<thead>
<tr>
<th>Time of Evaluation</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHP</td>
<td>Norm</td>
<td>SHP</td>
</tr>
<tr>
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<td>9.3</td>
<td>5.45</td>
</tr>
<tr>
<td>Headache #1</td>
<td>18.12</td>
<td>9.3</td>
<td>5.75</td>
</tr>
<tr>
<td>Headache #2</td>
<td>17.69</td>
<td>9.3</td>
<td>5.60</td>
</tr>
<tr>
<td>Headache #3</td>
<td>18.50</td>
<td>9.3</td>
<td>5.96</td>
</tr>
<tr>
<td>Headache #4</td>
<td>17.58</td>
<td>9.3</td>
<td>6.37</td>
</tr>
</tbody>
</table>

*p < .001
Table 5

Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the Fatigue-Inertia Scale of the POMS

<table>
<thead>
<tr>
<th>Time of Evaluation</th>
<th>Mean SHP</th>
<th>Norm</th>
<th>Std. Dev. SHP</th>
<th>Norm</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>7.69</td>
<td>13.0</td>
<td>5.70</td>
<td>8.2</td>
<td>-2.93</td>
</tr>
<tr>
<td>Headache #1</td>
<td>6.23</td>
<td>13.0</td>
<td>5.18</td>
<td>8.2</td>
<td>-3.74*</td>
</tr>
<tr>
<td>Headache #2</td>
<td>5.42</td>
<td>13.0</td>
<td>4.09</td>
<td>8.2</td>
<td>-4.95*</td>
</tr>
<tr>
<td>Headache #3</td>
<td>5.40</td>
<td>13.0</td>
<td>4.41</td>
<td>8.2</td>
<td>-4.20*</td>
</tr>
<tr>
<td>Headache #4</td>
<td>4.52</td>
<td>13.0</td>
<td>3.78</td>
<td>8.2</td>
<td>-4.69*</td>
</tr>
</tbody>
</table>

*p < .001

Table 6

Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the Confusion-Bewilderment Scale of the POMS

<table>
<thead>
<tr>
<th>Time of Evaluation</th>
<th>Mean SHP</th>
<th>Norm</th>
<th>Std. Dev. SHP</th>
<th>Norm</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>4.31</td>
<td>13.3</td>
<td>3.43</td>
<td>6.7</td>
<td>-9.61*</td>
</tr>
<tr>
<td>Headache #1</td>
<td>3.88</td>
<td>13.3</td>
<td>3.14</td>
<td>6.7</td>
<td>-10.09*</td>
</tr>
<tr>
<td>Headache #2</td>
<td>3.60</td>
<td>13.3</td>
<td>2.80</td>
<td>6.7</td>
<td>-10.40*</td>
</tr>
<tr>
<td>Headache #3</td>
<td>3.85</td>
<td>13.3</td>
<td>3.85</td>
<td>6.7</td>
<td>-10.09*</td>
</tr>
<tr>
<td>Headache #4</td>
<td>3.88</td>
<td>13.3</td>
<td>3.32</td>
<td>6.7</td>
<td>-10.08*</td>
</tr>
</tbody>
</table>

*p < .001

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Statistically significant differences were evident which were lower at each time of evaluation than the normative values for the Tension-Anxiety, Depression-Dejection, Anger-Hostility, and Confusion-Bewilderment scales of the POMS. The same findings were evident for the Fatigue-Inertia scale, with the exception of the baseline measurement. Statistically significant differences were evident which were higher at each time of evaluation than the normative values for the Vigor-Activity scale of the POMS.

The first null hypothesis was that sinus headache patients would not demonstrate greater subjective mood variability than did individuals on whom the psychological test instruments were normed. Based on the findings of this study, significant differences existed between the responses of sinus headache patients and the normative data for all scales across all evaluation periods (except for the Baseline measurement on the Fatigue-Inertia scale); therefore, the first null hypothesis was rejected. It is noteworthy that while the sinus headache patients' scores were significantly lower than the normative values on all other scales, their responses on the Vigor-Activity scale were significantly higher than the normative value for that scale.

Variance in Interpersonal Functioning

Null Hypothesis 2: Sinus headache sufferers do not
endorse particular personality characteristics which differ from those of individuals on whom the psychological test instruments were normed. A two-tailed t-test was employed to begin testing this hypothesis with CPI data. Table 7 provides an abbreviation key for each of the CPI scales, while Table 8 presents the results of this analysis, displaying means, standard deviations, t-values and probabilities.

Scale elevations for the sinus headache patients were significantly different from the normative values for the Do, Cm, Ac, Ai, Fx, F/M, Wo, Mp, and v.1 scales, with scales F/M and v.1 demonstrating opposite directionality. This indicated that the sinus headache patients scored higher than the normative values on these scales, except for the F/M and v.1 scales, for which they scored lower than the normative values.

The second null hypothesis was that sinus headache sufferers do not endorse particular personality characteristics which differ from those of individuals on whom the psychological test instruments were normed. Based on the analysis of the CPI data, significant differences were identified between the sinus headache patients and normative data; therefore, the second null hypothesis was rejected.

8 For the MBHI, raw scores are transformed into base rate scores rather than standard scores. As such, standardized normative data are presently unavailable for nonparametric analyses.
Table 7
CPI Scale Identification Key

<table>
<thead>
<tr>
<th>Scale Name</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominance</td>
<td>Do</td>
</tr>
<tr>
<td>Capacity for status</td>
<td>Cs</td>
</tr>
<tr>
<td>Sociability</td>
<td>Sy</td>
</tr>
<tr>
<td>Social Presence</td>
<td>Sp</td>
</tr>
<tr>
<td>Self-acceptance</td>
<td>Sa</td>
</tr>
<tr>
<td>Well-being</td>
<td>Wb</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Re</td>
</tr>
<tr>
<td>Socialization</td>
<td>So</td>
</tr>
<tr>
<td>Self-control</td>
<td>Sc</td>
</tr>
<tr>
<td>Tolerance</td>
<td>To</td>
</tr>
<tr>
<td>Good impression</td>
<td>Gi</td>
</tr>
<tr>
<td>Communality</td>
<td>Cm</td>
</tr>
<tr>
<td>Achievement via conformance</td>
<td>Ac</td>
</tr>
<tr>
<td>Achievement via independence</td>
<td>Ai</td>
</tr>
<tr>
<td>Intellectual efficiency</td>
<td>Ie</td>
</tr>
<tr>
<td>Psychological mindedness</td>
<td>Py</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Fx</td>
</tr>
<tr>
<td>Femininity/Masculinity</td>
<td>F/M</td>
</tr>
<tr>
<td>Work orientation</td>
<td>Wo</td>
</tr>
<tr>
<td>Managerial potential</td>
<td>Mp</td>
</tr>
<tr>
<td>v.1</td>
<td>v.1</td>
</tr>
<tr>
<td>v.2</td>
<td>v.2</td>
</tr>
<tr>
<td>v.3</td>
<td>v.3</td>
</tr>
</tbody>
</table>
Table 8

Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients (SHP) and the Normative Data of the CPI

<table>
<thead>
<tr>
<th>CPI Scale</th>
<th>Mean SHP</th>
<th>Mean Norm</th>
<th>Std. Dev. SHP</th>
<th>Std. Dev. Norm</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do</td>
<td>22.39</td>
<td>20.08</td>
<td>6.07</td>
<td>5.00</td>
<td>3.33*</td>
</tr>
<tr>
<td>Cs</td>
<td>17.21</td>
<td>16.59</td>
<td>3.55</td>
<td>4.00</td>
<td>1.14</td>
</tr>
<tr>
<td>Sy</td>
<td>21.98</td>
<td>20.84</td>
<td>4.94</td>
<td>5.13</td>
<td>1.62</td>
</tr>
<tr>
<td>Sp</td>
<td>25.39</td>
<td>24.57</td>
<td>4.80</td>
<td>4.25</td>
<td>1.40</td>
</tr>
<tr>
<td>Sa</td>
<td>18.55</td>
<td>17.54</td>
<td>4.02</td>
<td>3.50</td>
<td>2.09</td>
</tr>
<tr>
<td>In</td>
<td>17.45</td>
<td>15.92</td>
<td>4.68</td>
<td>4.89</td>
<td>2.28**</td>
</tr>
<tr>
<td>Em</td>
<td>21.54</td>
<td>20.77</td>
<td>4.31</td>
<td>4.98</td>
<td>1.28</td>
</tr>
<tr>
<td>Re</td>
<td>26.75</td>
<td>25.96</td>
<td>4.40</td>
<td>5.27</td>
<td>1.10</td>
</tr>
<tr>
<td>So</td>
<td>31.64</td>
<td>31.33</td>
<td>6.23</td>
<td>6.34</td>
<td>0.36</td>
</tr>
<tr>
<td>Sc</td>
<td>22.38</td>
<td>21.04</td>
<td>6.26</td>
<td>6.59</td>
<td>1.48</td>
</tr>
<tr>
<td>Gi</td>
<td>18.63</td>
<td>17.82</td>
<td>5.91</td>
<td>6.42</td>
<td>0.92</td>
</tr>
<tr>
<td>Cm</td>
<td>35.71</td>
<td>34.62</td>
<td>4.51</td>
<td>2.93</td>
<td>2.63**</td>
</tr>
<tr>
<td>Wb</td>
<td>31.98</td>
<td>30.59</td>
<td>5.47</td>
<td>5.46</td>
<td>1.91</td>
</tr>
<tr>
<td>To</td>
<td>22.11</td>
<td>21.08</td>
<td>3.94</td>
<td>5.51</td>
<td>1.38</td>
</tr>
<tr>
<td>Ac</td>
<td>29.71</td>
<td>27.18</td>
<td>4.53</td>
<td>5.92</td>
<td>3.15**</td>
</tr>
<tr>
<td>Ai</td>
<td>24.25</td>
<td>21.88</td>
<td>4.68</td>
<td>6.45</td>
<td>2.71**</td>
</tr>
<tr>
<td>Ie</td>
<td>30.48</td>
<td>29.82</td>
<td>5.10</td>
<td>6.09</td>
<td>0.80</td>
</tr>
<tr>
<td>Py</td>
<td>16.39</td>
<td>15.30</td>
<td>3.20</td>
<td>4.44</td>
<td>1.84</td>
</tr>
<tr>
<td>Fx</td>
<td>12.45</td>
<td>14.16</td>
<td>3.48</td>
<td>4.09</td>
<td>-3.07**</td>
</tr>
<tr>
<td>F/M</td>
<td>17.45</td>
<td>20.00</td>
<td>3.67</td>
<td>3.12</td>
<td>-5.90*</td>
</tr>
<tr>
<td>Wo</td>
<td>31.00</td>
<td>28.46</td>
<td>5.66</td>
<td>6.04</td>
<td>3.07**</td>
</tr>
</tbody>
</table>
Table 8—Continued

<table>
<thead>
<tr>
<th>CPI Scale</th>
<th>Mean SHP</th>
<th>Norm</th>
<th>Std. Dev. SHP</th>
<th>Norm</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mp</td>
<td>22.30</td>
<td>20.26</td>
<td>5.58</td>
<td>6.02</td>
<td>2.48***</td>
</tr>
<tr>
<td>v.1</td>
<td>16.77</td>
<td>18.80</td>
<td>6.14</td>
<td>6.05</td>
<td>-2.44***</td>
</tr>
<tr>
<td>v.2</td>
<td>23.46</td>
<td>22.46</td>
<td>5.11</td>
<td>6.05</td>
<td>-1.32</td>
</tr>
<tr>
<td>v.3</td>
<td>38.75</td>
<td>36.04</td>
<td>8.84</td>
<td>10.56</td>
<td>1.88</td>
</tr>
</tbody>
</table>

*p < .001  
**p < .01  
***p < .02  
****p < .05

Personality Factors and Treatment Response

Although four treatments were rated in this study, efficacy data could be obtained for only the placebo and combined-drug treatments; according to an Upjohn Company statistician (A. Zagar, personal communication, April, 1991), the greatest degree of variance in treatment effects were observed between these two treatments. Exhausting efforts were made in attempting to acquire data from The Upjohn Company for all four treatments evaluated. Unfortunately, their representatives maintained that this constituted "proprietary information concerning a new product concept," and further disclosure of the study findings were withheld from this investigator. Consequently, a full assessment of the sinus headache patients' ratings of the
study medications could not be performed and was limited to their evaluations of the placebo and combined-drug treatments.

Null Hypothesis 3: Correlations do not exist between specific personality characteristics of sinus headache patients and their success or failure in obtaining relief from blinded pharmacologic treatments designed to differentially alleviate physiological symptoms.

Patient evaluations of the placebo and combination drug treatments involved rating the perceived effectiveness of these treatments as either ineffective, slightly effective, moderately effective, very effective, or completely effective. For the purposes of conservative data analysis, the ratings of ineffective and slightly effective were categorized as "ineffective," while moderately effective, very effective, and completely effective were categorized as "effective."

Within this framework, patients' responses to the blinded treatment paradigm could have comprised one of the following four rating combinations: (1) placebo ineffective/combination drug ineffective; (2) placebo ineffective/combination drug effective; (3) placebo effective/combination drug effective; (4) placebo effective/combination drug ineffective.
Table 9
Frequency Distribution of Sinus Headache Patients' Efficacy Ratings of Placebo (P) and Combination Drug (CD)

<table>
<thead>
<tr>
<th>Rating Combination</th>
<th>Weighted Rating</th>
<th># of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>P</td>
</tr>
<tr>
<td>1 Ineffective</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>2 Slightly Effective</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>3 Moderately Effective</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4 Very Effective</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5 Completely Effective</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>1 Ineffective</td>
<td>19</td>
<td>-</td>
</tr>
<tr>
<td>2 Slightly Effective</td>
<td>8</td>
<td>-</td>
</tr>
<tr>
<td>3 Moderately Effective</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>4 Very Effective</td>
<td>-</td>
<td>13</td>
</tr>
<tr>
<td>5 Completely Effective</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>1 Ineffective</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2 Slightly Effective</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3 Moderately Effective</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>4 Very Effective</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>5 Completely Effective</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1 Ineffective</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>2 Slightly Effective</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>3 Moderately Effective</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>4 Very Effective</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>5 Completely Effective</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Table 9 displays the frequency distribution for each of these derived rating combinations and their actual rating breakdown. The largest number of the sinus headache patients (27, 52%) rated the placebo as ineffective and the combination drug as effective. An equal number of patients (10, 19%) rated the placebo as effective and the combination drug as effective, as well as rating the placebo ineffective and the combination drug as ineffective. The smallest group of patients (5, 9.6%) rated the placebo as effective and the combination drug as ineffective.

Table 10 displays the results of a parametric evaluation of the weighted rating values for the placebo and the combination drug treatments.

The results of this analysis demonstrated that the sinus headache patients rated the combination drug as significantly more effective than the placebo. The following analysis was performed to evaluate the MBHI scale scores of the sinus headache patients to determine if significant differences existed between those patients who rated the combined drug as effective and those who rated it as ineffective. Table 11 provides an abbreviation key for each of the MBHI scales, while Table 12 presents the results of this analysis, displaying means, standard deviations, t-values and probabilities.

Parametric analysis of the MBHI scale scores did not show significant differences between the sinus headache
patients who obtained relief from the study medications and those who did not obtain relief.

Table 10

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>52</td>
<td>2.00</td>
<td>1.27</td>
<td>5.17*</td>
</tr>
<tr>
<td>Combined Drug</td>
<td>52</td>
<td>3.28</td>
<td>1.29</td>
<td></td>
</tr>
</tbody>
</table>

*p < .001

In consideration of these findings, the premises comprising the third null hypothesis of this study failed to be rejected. As such, the possibility that specific personality attributes might be used to predict sinus headache patients' response to treatment designed to alleviate physiological symptoms will require further investigation.
<table>
<thead>
<tr>
<th>Scale Name</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introversive Style</td>
<td>Int</td>
</tr>
<tr>
<td>Inhibited Style</td>
<td>Inh</td>
</tr>
<tr>
<td>Cooperative Style</td>
<td>Cop</td>
</tr>
<tr>
<td>Sociable Style</td>
<td>Soc</td>
</tr>
<tr>
<td>Confident Style</td>
<td>Con</td>
</tr>
<tr>
<td>Forceful Style</td>
<td>For</td>
</tr>
<tr>
<td>Respectful Style</td>
<td>Res</td>
</tr>
<tr>
<td>Sensitive Style</td>
<td>Sen</td>
</tr>
<tr>
<td>Chronic Tension</td>
<td>CT</td>
</tr>
<tr>
<td>Recent Stress</td>
<td>RS</td>
</tr>
<tr>
<td>Premorbid Pessimism</td>
<td>PP</td>
</tr>
<tr>
<td>Future Despair</td>
<td>FD</td>
</tr>
<tr>
<td>Social Alienation</td>
<td>SA</td>
</tr>
<tr>
<td>Somatic Anxiety</td>
<td>Som</td>
</tr>
<tr>
<td>Allergic Inclination</td>
<td>AI</td>
</tr>
<tr>
<td>Gastrointestinal Susceptibility</td>
<td>GS</td>
</tr>
<tr>
<td>Cardiovascular Tendency</td>
<td>Car</td>
</tr>
<tr>
<td>Pain Treatment Responsivity</td>
<td>PTR</td>
</tr>
<tr>
<td>Life Threat Reactivity</td>
<td>LTR</td>
</tr>
<tr>
<td>Emotional Vulnerability</td>
<td>EV</td>
</tr>
</tbody>
</table>
Table 12

Parametric Analysis Comparing the z-Scores Between Sinus Headache Patients Rating the Combination Drug as Effective (E) Versus Ineffective (I)*

<table>
<thead>
<tr>
<th>MBHI Scale</th>
<th>Mean E</th>
<th>Mean I</th>
<th>Std. Dev. E</th>
<th>Std. Dev. I</th>
<th>t Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Int</td>
<td>49.36</td>
<td>46.40</td>
<td>26.15</td>
<td>32.42</td>
<td>0.2684</td>
</tr>
<tr>
<td>Inh</td>
<td>34.07</td>
<td>23.70</td>
<td>41.63</td>
<td>33.89</td>
<td>0.4162</td>
</tr>
<tr>
<td>Cop</td>
<td>35.67</td>
<td>33.10</td>
<td>25.45</td>
<td>30.00</td>
<td>0.2500</td>
</tr>
<tr>
<td>Soc</td>
<td>59.05</td>
<td>51.20</td>
<td>27.26</td>
<td>34.09</td>
<td>0.6781</td>
</tr>
<tr>
<td>Con</td>
<td>58.17</td>
<td>61.10</td>
<td>24.52</td>
<td>37.61</td>
<td>0.2350</td>
</tr>
<tr>
<td>For</td>
<td>46.86</td>
<td>46.40</td>
<td>26.79</td>
<td>29.69</td>
<td>0.4680</td>
</tr>
<tr>
<td>Res</td>
<td>48.07</td>
<td>59.00</td>
<td>23.30</td>
<td>24.24</td>
<td>1.3684</td>
</tr>
<tr>
<td>Sen</td>
<td>32.24</td>
<td>33.70</td>
<td>26.98</td>
<td>32.77</td>
<td>1.6000</td>
</tr>
<tr>
<td>CT</td>
<td>44.52</td>
<td>50.20</td>
<td>25.40</td>
<td>28.83</td>
<td>0.5720</td>
</tr>
<tr>
<td>RS</td>
<td>35.81</td>
<td>30.30</td>
<td>25.80</td>
<td>24.33</td>
<td>0.6360</td>
</tr>
<tr>
<td>PP</td>
<td>30.07</td>
<td>22.00</td>
<td>22.02</td>
<td>26.02</td>
<td>1.3028</td>
</tr>
<tr>
<td>FD</td>
<td>27.81</td>
<td>24.00</td>
<td>20.11</td>
<td>22.88</td>
<td>0.4839</td>
</tr>
<tr>
<td>SA</td>
<td>32.50</td>
<td>25.70</td>
<td>21.53</td>
<td>30.04</td>
<td>0.5435</td>
</tr>
<tr>
<td>Som</td>
<td>27.17</td>
<td>29.50</td>
<td>20.26</td>
<td>21.63</td>
<td>0.3103</td>
</tr>
<tr>
<td>AI</td>
<td>39.29</td>
<td>41.10</td>
<td>24.67</td>
<td>26.08</td>
<td>0.2000</td>
</tr>
<tr>
<td>GS</td>
<td>41.81</td>
<td>41.80</td>
<td>20.62</td>
<td>21.04</td>
<td>1.2915</td>
</tr>
<tr>
<td>Car</td>
<td>46.52</td>
<td>46.90</td>
<td>21.72</td>
<td>24.88</td>
<td>0.0440</td>
</tr>
<tr>
<td>PTR</td>
<td>25.86</td>
<td>19.90</td>
<td>17.75</td>
<td>26.19</td>
<td>0.6830</td>
</tr>
<tr>
<td>LTR</td>
<td>35.45</td>
<td>37.40</td>
<td>20.00</td>
<td>24.70</td>
<td>0.2319</td>
</tr>
<tr>
<td>EV</td>
<td>17.38</td>
<td>11.40</td>
<td>24.10</td>
<td>24.83</td>
<td>0.8563</td>
</tr>
</tbody>
</table>

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CHAPTER V

DISCUSSION

The present study sought to examine the psychological and personality attributes of patients diagnosed with sinus headache, and to evaluate the usefulness of particular psychological test scales in predicting these patients' responses to medications designed to relieve the physiological symptoms of their sinus headache. This chapter offers interpretive analysis of the results of the study hypotheses, a general discussion of the results, practical implications concerning treatment of sinus headache patients, limitations of this study, and suggestions for further research.

Discussion of Results by Hypothesis

Subjective Mood Variability

It was hypothesized that significant differences would not be observed in the subjective mood states between sinus headache patients and the normative values from the POMS. The data resulting from the two-tailed t-test employed to test this hypothesis allowed it to be rejected. Significant differences were observed for each of the POMS scales
across each period of measurement, suggesting that the sinus headache patients consistently rated themselves as experiencing less tension and restlessness, less depression, personal inadequacy, futility, emotional isolation, sadness, and guilt, less intense and overt anger, resentment and suspiciousness, less weariness and diminished energy, and less inability to concentrate, confusion, forgetfulness, and uncertainty, along with perceiving themselves as having more energy, cheerfulness, alertness, and feeling more carefree than individuals on whom the POMS was normed.

These findings are similar to those of other studies involving both patients with migraine and those with muscle contraction headaches, in whom suppression of emotions was evident. In those patients, a consistent pattern was identified wherein many of them were not allowed to express emotions of anger or rage as children, and that love and approval could only be won by suppressing their real feelings (Gatchel et al., 1985).

The symptoms of anxiety and depression typically observed in patients with chronic muscle contraction headache were not apparent in the sinus headache patients. Conversely, the Vigor-Activity scale was significantly elevated, implying the possible presence of a hypomanic defense, which serves as a protective mechanism that leaves the person without time for introspection or time to focus
on painful feelings or memories.

It is noteworthy that while the sinus headache patients' responses to the POMS were compared to the normative data for this instrument, an informal parametric comparison to the data comprising a college student normative sample revealed significant differences which paralleled those found between the sinus headache patients and the normative sample. Exceptions, however, were noted for the Vigor-Activity scale, in that the sinus headache patients' mean scores did not vary significantly from the college student normative data for baseline or any of the subsequent evaluation periods. The sinus headache patients' baseline mean score for the Fatigue-Inertia scale also did not differ significantly from the college normative data, although all subsequent mean scores were significantly lower than the college normative data on the Fatigue-Inertia scale.

Variance in Interpersonal Functioning

It was further hypothesized that significant differences in personality dimensions of broad personal and social relevance would not be evident between sinus headache patients and normative data from the CPI. The data resulting from the two-tailed t-test employed to test this hypothesis allowed it to be rejected. Significant differences were observed between sinus headache patients
and normative data from the CPI for the Dominance, Communality, Achievement via Conformance, Achievement via Independence, Flexibility, Femininity/Masculinity, Work orientation, Managerial potential, and v.1 scales. The sinus headache patients' test results demonstrated significantly higher scores over normative data on all of these scales, except for the Femininity/Masculinity and v.1 scales, which were significantly lower than the normative data.

Within this cluster of CPI scales it is possible to discern elements of interpersonal behavior with a focus on being well-organized, action-oriented, decisive, assertive, outgoing, confident, dependable, and somewhat unsympathetic and impatient. Taken together, these personality characteristics support a psychological construct frequently referred to as a "strong work ethic."

Two studies (Hicks & Campbell, 1983; Rappaport, McAnulty, & Brantley, 1989) investigated the relationship between Type A behavior pattern (TABC) and headache occurrence, and have noted strong similarities between descriptions of migraine headache patients and the personality characteristics typically ascribed to the Type A individual. In particular, both of these "personality types" appear to share low thresholds for irritability, competitiveness and preoccupation with achievement, restlessness and impatience, and a tendency for dominating
their environment.

The findings of the present study appear to support a similar cluster of personality attributes in sinus headache patients, suggesting further similarities may exist between these patients and migraine headache patients.

**Personality Factors and Treatment Response**

The third hypothesis of this study postulated that correlations did not exist between identifiable personality characteristics of sinus headache patients and their efficacy ratings of the study medications. The two-tailed t-test utilized to evaluate this hypothesis resulted in a failure to reject this premise.

Not only were significant differences absent between sinus headache patients who obtained relief from the blinded study medications and those who did not, the mean scale values for either group did not exceed a base rate score of 74 for any of the MBHI scales, which is the cut-off score above which scale percentages would correspond to the estimated prevalence rates for "presence" of coping style or psychosomatic correlate tendencies. This suggests that the sinus headache patients, either collectively or categorized as treatment responsive and treatment non-responsive, did not endorse MBHI test items in a manner that revealed the presence of any dominant coping styles, personal feelings and perceptions regarding different
aspects of psychological stress which increase psychosomatic susceptibility or which aggravate the course of a disease. Neither did they exhibit similarities to patients whose illness has been judged as substantially psychosomatic.

Limitations of the Study

Andrasik et al. (1982) identified several criteria to consider when evaluating psychometric investigations of headache. First, as is true when researching any disorder, it is important that key inclusion and exclusion characteristics be used to assure homogeneous patient groups. The present study observed this criterion, utilizing extensive diagnostic procedures to ensure that the sample of patients studied was suffering from recurrent sinus headache, and that their symptoms were not due to other medical factors.

Second, results will be more useful when two or more distinct headache types are investigated concurrently so that the specificity of key psychological constructs can more adequately be tested. Due to the specific nature of the research goals of this study (i.e., to evaluate the efficacy of ibuprofen and pseudoephedrine when given in combination to sinus headache patients) this particular criterion was not met. Although measurement of the same psychological attributes of other headache entities would
have proved useful for the purpose of comparison with sinus headache patients, the type of treatment being evaluated was specifically targeted toward the symptoms of sinus headache. As such, only the first two hypotheses of this study could have been evaluated if patients with other types of headache would have been included, although patients' responses to the MBHI could have been compared.

A third criterion concerns the inclusion of an appropriate control or comparison group, which ideally is matched to the headache group on key demographic variables such as age, gender, and socioeconomic status. Control subjects should, at a minimum, be relatively headache free and screened for the presence of any other type of psycho-physiological disorder. The present study constituted a Phase-II drug efficacy trial and, as such, the only patients enrolled for study were those for whom the treatment was designed. Nonetheless, the normative data for the POMS and the CPI constituted a second best alternative to a matched control group drawn from the same population and tested under the same conditions as the sinus headache patients. Again, however, only the first two study hypotheses, as well as a comparison of MBHI responses, could have been evaluated with the inclusion of a control group. A question concerning a control group's responses to a treatment designed to alleviate sinus headache symptoms would have been irrelevant in an drug
efficacy study.

Further, to increase the information yield, it is desirable to administer tests that assess multiple psychological characteristics and/or to include a number of single-attribute tests. Although three separate instruments were utilized to evaluate the hypotheses in the present study, only one instrument was involved for testing each hypothesis. The addition of other tests, such as the Psychosomatic Symptom Checklist (Cox, et al., 1975), the State-Trait Anxiety Inventory (Spielberger et al., 1970), the Beck Depression Inventory (Beck et al., 1971), the Rathus Assertiveness Scale (Rathus, 1973), or others might have contributed a gauge of the validity and reliability of the findings of the instruments used in this study.

Another primary limitation of this study involved not having all of the study data. As noted earlier, The Upjohn Company would not permit access by this investigator to the sinus headache patients' ratings of the non-combination formulations of ibuprofen and pseudoephedrine. Had this data been available it would have been possible to perform a two-way analysis of variance to determine the relative contributions of each drug to the relief perceived to be obtained by the subjects, as well as the effects derived from possible interactions of the two drugs. Such an analysis would have revealed the necessity (or lack thereof) for combining the two drugs in order to achieve
the degree of relief obtained from the combined formulation. Based on the data provided by The Upjohn Company, however, it was not possible to determine if the combined drug formulation provided a significantly greater degree of relief than either of the individual drugs alone.

A final limitation of the present study was that the majority of subjects (44, 85%) were female. Consequently, the findings of this study cannot be readily extended to a male population of sinus headache patients. A consideration here, however, is that epidemiological data indicates a significantly greater incidence of virtually all types of headache in females than in males, with the exception of cluster headache (Adler et. al., 1987; Kudrow, 1980; Raskin & Appenzeller, 1980). For both migraine and muscle contraction headache, the incidence ratio of females to males is approximately 3:1, while for cluster headache the incidence ratio of males to females is approximately 4:1. In the present study patient sample, the ratio of females to males was 5.5:1, although this should not be taken as an indication that this is the female-to-male incidence ratio of sinus headache in the population.

Treatment Implications

The availability of psychological and personality characteristics about headache patients may allow healthcare providers to rule in or rule out specific therapeutic
modalities early on in the course of treating a patient. The intent here is to enable the patient to obtain a reduction in the severity and frequency of his or her headache pain.

The need for adequate and thorough assessment of headache patient's psychological characteristics belies the larger need for getting to know the patient in order to work with him or her, rather than be at odds with the patient, to achieve a reduction in the intensity and frequency of the pain, and less of a need to rely on medication for pain attenuation.

It is nearly impossible to get to know the patient without spending time with him or her. Obtaining information about their symptoms, the duration and frequency of pain, precipitating circumstances, susceptibility to stress, current and chronic psychosocial stressors, personal remedies that have been effective, past history, psychiatric history, family history, and so on, is all relevant to the process of determining a proper treatment strategy for the headache patient.

Selection of appropriate therapy and treatment provider depend upon the type of problem the patient has and the type of human being the patient is; these can be determined by careful assessment. Both the healthcare provider and the patient need to be attuned to the relevance or reviewing exact details of symptoms and signs that
will facilitate diagnosis. The provider should expect to do this and the patient should expect it of the provider. At the same time, if the patient is interested in developing a good therapeutic alliance, the provider should be quietly, consciously or unconsciously, attempting to evaluate the patient's personality, what it is the patient is seeking, his or her attitude toward his or her illness, and his or her attitude toward its treatment.

In the evaluation and treatment of sinus headache patients, it is important to clarify and address the expectations of the patient. If the provider assumes that a sinus headache patient is merely seeking relief or medication, that may be all that is provided. If, however, the provider begins to recognize features about the patient which suggest the presence of a hypomanic defense or TABP, then the provider must engage careful observation and attentive listening to learn how specific physical, social, and emotional factors intertwine to produce the patient's headaches. Only in this manner can the provider help the patient begin to slowly attune to and understand his or her unproductive and unhealthy patterns of coping with his or her environment.

It may be a waste of both the provider's time and the patient's if the patient will not or cannot discuss the emotional aspects of his or her problem. A patient needs to understand the reasons behind psychological treatment
and have some motivation to participate in it. Despite the prominence of psychological factors in chronic headache, only a small percentage of the 10-20% of the general population who suffer from it are ever seen in a setting which addresses emotional issues therapeutically (Adler, Adler, & Packard, 1987).

Although psychological treatment for headache can be either plain or fancy, if it is to be effective, it is always founded on the basis of the provider's empathetic concern for the patient's discomfort. Following the diagnosis, the most important objective of the first few interviews is the establishment of a good rapport or therapeutic alliance. If this is not secured, the patient will sense it, and be unlikely to profit from therapeutic maneuvers by the provider. If present, it forms the foundation for the therapeutic contract, and allows the physician to better enable the patient to confront self-defeating character traits. Even if other considerations, such as organic contributing factors, require that therapeutic goals be limited, if the provider's empathy is present and the dignity of the patient's struggle is communicated, the benefits derived from treatment will be greater than the sum of medications prescribed.

Directions for Further Headache Research

As with many other areas of behavioral medicine,
research on the psychological assessment and treatment of headache has demonstrated enormous growth in the last twenty years, with hundreds of studies having been conducted. Yet, with headache comprising one of the most troubling and prevalent disorders in the history of medicine, many aspects of headache warrant further investigation. Within the medical profession, drugs are considered the initial treatment of choice for headache disorders (Diamond & Dalessio, 1978). Perhaps it would be advantageous to combine behavioral and pharmacological treatment in order to make a direct, controlled comparison of pharmacotherapy and psychological therapy, or to study the interaction of psychological therapy with drug therapy. Such an approach might produce a means for devising an optimal blend of psychological therapy and drug therapy, such that the extent of drug treatment could be held to a minimum as a result of adding psychological therapy to the total regimen.

Headache is also one of the more frequent complaints in pediatric medicine (Blanchard & Andrasik, 1982). Headache has been reported in children as young as the age of two, although very infrequently, and its prevalence steadily increases through adulthood. Historically, professionals have expressed minimal concern about the headaches of children, largely viewing them as transient (Ryan, 1954). Data from a relatively recent longitudinal
study suggest that this is not so for the majority of children. Bille (1981) followed a group of child migraineurs for a remarkable period of 23 years, at which time all of the subjects turned thirty years of age. It is noteworthy that 60% of the subjects continued to be troubled by migraine as adults. This strongly suggests that more attention needs to be given to treatment of headache in children, which may also help to prevent these children from becoming troubled adult headache sufferers.

Similar to the present investigation, many studies have sought to use psychological tests as predictors of treatment response. With costs for healthcare skyrocketing, it would clearly be advantageous to be able to predict which patients are likely to respond best to which treatments. Thus far, results have been quite complex and frequently contradictory (Blanchard & Andrasik, 1982), but sometimes relatively successful in predicting a priori which patients will most successfully respond to treatment (Blanchard et al., 1984). Clearly, however, these efforts are in need of cross-validation. Moreover, predictors in addition to ones used thus far, such as physiological variables or social-demographic variables, also need to be investigated to determine if prediction can be improved.

With regard to sinus headache sufferer, the apparent psychological characteristics which these patients seem to share with migraine headache patients suggest that an
investigation of alternative treatments, such as biofeedback or psychotherapy, is warranted. Additionally, a study aimed at evaluating sinus headache patients for Type A behavior pattern (TABP) might prove worthwhile. In the exploratory investigation by Rappaport, McAnulty, and Brantley (1988), well over 50% of the migraine patients evaluated were determined to be Type A individuals. The findings of that study support the proposition that the original conceptualization of Type A behavior (i.e., coronary-prone behavior) needs to be broadened to include other vascular dysfunctions (Woods, Morgan, Day, Jefferson, & Harris, 1984).

Future studies are needed to replicate and extend these findings to support the concept of a vascular-prone behavior pattern. The results of that study imply that those individuals who possess Type A features may be at risk for other disorders, particularly vascular, in addition to the coronary problems that have been previously documented. The notion that a behavior pattern can function as a risk factor for a disease process was recently expressed by Friedman & Booth-Kewley (1987). In their meta-analytic review of personality characteristics and disease, they concluded that an individual's pattern of behavior "may function like diet: Imbalances can predispose one to all sorts of diseases" (p. 552).

Whether a person's headaches are psychologic or
somatic in origin, however, is less important than whether there are significant psychologic or physical findings. Abnormalities in either area require treatment intervention in parallel, regardless of causation. The issue of which came first, the psychologic or physical factors, is of theoretical interest but quite probably of less functional importance.
Appendix A
Informed Consent Document
INFORMED CONSENT FORM

I, ______________________, give my consent to The Upjohn Research Clinics-BCIU/Jasper to release to Stanley R. Carlock of Western Michigan University the completed results of my responses to the psychological tests which I will complete during my participation in The Upjohn Research Clinics study BC799. These tests will include: 1) the California Psychological Inventory; 2) the Millon Behavioral Health Inventory; and 3) the Profile of Mood States Questionnaire. The first two tests will be administered one time only, and the Profile of Mood States Questionnaire will be administered at the beginning of the study at each clinic visit, for a total of five times.

To enable the researcher to fully evaluate the results of my responses to these tests, I also authorize The Upjohn Research Clinics to release to Stanley R. Carlock demographic information (i.e., age, educational level, marital status, income level) as specified in the Personal Information form you will be asked to complete as a part of your participation in BC799.

I understand that at all times my anonymity and confidentiality will be protected and that at no time will my identification be disclosed.

I understand that by signing this consent I am only agreeing to allow my psychological test scores and demographic information to be used in the research study being conducted by Stanley R. Carlock.

I understand that I will receive a copy of this consent form, and that no other copy of this document will be made. This document will be placed in my patient chart along with all other study records, which will remain within the Medical Records Department of The Upjohn Research Clinics-BCIU/Jasper. I understand that the researcher will possess no material upon which my name appears.

Participant’s Signature ______________________ Date ______________

Witness’s Signature ______________________ Date ______________

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Appendix B

Human Subjects Institutional Review Board Approval
TO: Stanley R. Carlock
FROM: Ellen Page-Robin, Chair
RE: Research Protocol
DATE: April 6, 1989

This letter will serve as confirmation that your research protocol, "Psychological Correlates of Sinus Headache" has been approved at no more than minimal risk after full review by the HSIRB.

If you have any further questions, please contact me at 387-2647.
Appendix C

Profile of Mood States
Scale Descriptions
Appendix C

Profile Of Mood States
Scale Descriptions

Tension-Anxiety: This scale is defined by adjective scales descriptive of heightened musculoskeletal tension. The defining scales include reports of somatic tension which may not be overtly observable (Tense, On edge), as well as observable psychomotor manifestations (Shaky, Restless).

Depression-Dejection: This scale appears to represent a mood of depression accompanied by a sense of personal inadequacy. It is best defined by scales indicating feelings of personal worthlessness (Unworthy), futility regarding the struggle to adjust (Hopeless, Desperate), and a sense of emotional isolation from others (Blue, Lonely, Helpless, Miserable), sadness (Sad, Unhappy), and guilt (Guilty, Sorry for things done).

Anger-Hostility: This scale appears to represent a mood of anger and antipathy towards others. The principle defining scales (Angry, Furious, Ready to fight) describe feelings of intense, overt anger. "Grouchy" and "Annoyed" describe milder feelings of hostility. "Resentful," "Spiteful," "Deceived," and "Bitter" are items referring to more sullen and suspicious components of hostility.

Vigor-Activity: This scale is defined by adjectives suggesting a mood of vigor, ebullience, and high energy. It is negatively related to the other POMS factors.

Fatigue-Inertia: This scale represents a mood of weariness, inertia, and low energy level.

Confusion-Bewilderment: This scale appears to be characterized by bewilderment and muddleheadedness. This scale may represent a self-report of cognitive efficiency, possibly a by-product of anxiety or related states.

Appendix D

The Twenty Folk Concept Scales of the CPI and Their Intended Meanings
## The Twenty Folk Concept Scales of the CPI and Their Intended Meanings

<table>
<thead>
<tr>
<th>Scale Name</th>
<th>Intended Implications of High and Low Scores</th>
</tr>
</thead>
</table>
| Do (Dominance)      | **High:** confident, assertive, dominant, task-oriented  
                      | **Low:** unassuming, not forceful                                                       |
| Cs (Capacity for Status) | **High:** ambitious, wants to be a success, independent  
                      | **Low:** unsure of self, dislikes direct competition                                      |
| Sy (Sociability)    | **High:** sociable, likes to be with people, friendly  
                      | **Low:** shy, feels uneasy in social situations, prefers to keep in the background       |
| Sp (Social Presence) | **High:** self-assured, spontaneous; a good talker, not easily embarrassed  
                      | **Low:** cautious, hesitant to assert own views or opinions; not sarcastic or sharp-tongued |
| Sa (Self-acceptance) | **High:** has good opinion of self; sees self as talented, and as personally attractive  
                      | **Low:** self-doubting; readily assumes blame when things go wrong; often thinks others are better |
Appendix D—Continued

In (Independence)  
High: self-sufficient, resourceful, detached  
Low: lacks self-confidence, seeks support from others

Em (Empathy)  
High: comfortable with self and well-accepted by others; understands the feelings of others  
Low: ill at ease in many situations; unempathetic

Re (Responsibility)  
High: responsible, reasonable, takes duties seriously  
Low: not overly concerned about duties and obligations; may be careless or lazy

So (Socialization)  
High: comfortably accepts ordinary rules and regulations; finds it easy to conform  
Low: resists rules and regulations; finds it hard to conform; not conventional

Sc (Self-control)  
High: tries to control emotions and temper; takes pride in being self-disciplined  
Low: has strong feelings and emotions, and makes little attempt to hide them; speaks out when angry or annoyed

Gi (Good Impression)  
High: wants to make a good impression; tries to do what will please others
<table>
<thead>
<tr>
<th>Index</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cm (Communality)</strong></td>
<td></td>
</tr>
<tr>
<td>Low:</td>
<td>insists on being himself or herself, even if it causes friction or problems</td>
</tr>
<tr>
<td>High:</td>
<td>fits in easily; sees self as a quite average person</td>
</tr>
<tr>
<td>Low:</td>
<td>sees self as different from others; does not have the same ideas, preferences, etc., as others</td>
</tr>
<tr>
<td><strong>Wb (Well-being)</strong></td>
<td></td>
</tr>
<tr>
<td>High:</td>
<td>feels in good physical and emotional health; optimistic about the future</td>
</tr>
<tr>
<td>Low:</td>
<td>concerned about health and personal problems; worried about the future</td>
</tr>
<tr>
<td><strong>To (Tolerance)</strong></td>
<td></td>
</tr>
<tr>
<td>High:</td>
<td>is tolerant of others' beliefs and values, even when different from or counter to own beliefs</td>
</tr>
<tr>
<td>Low:</td>
<td>not tolerant of others; skeptical about what they say</td>
</tr>
<tr>
<td><strong>Ac (Achievement)</strong></td>
<td></td>
</tr>
<tr>
<td>High:</td>
<td>has strong drive to do (via Conformance) well; likes to work in settings where tasks and expectations are clearly defined</td>
</tr>
<tr>
<td>Low:</td>
<td>has difficulty in doing best work in situations with strict rules and expectations</td>
</tr>
<tr>
<td><strong>Ai (Achievement)</strong></td>
<td></td>
</tr>
<tr>
<td>High:</td>
<td>has strong drive to do (via Independence) well; likes to work in settings</td>
</tr>
</tbody>
</table>
Appendix D—Continued

that encourage freedom and individual initiative

<table>
<thead>
<tr>
<th></th>
<th>Low:</th>
<th>High:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>has difficulty in doing best work in situations that are vague, poorly defined, and lacking in clear-cut methods and standards</td>
<td>efficient use of intellectual abilities; can keep on a task where others might get bored or discouraged</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Low:</th>
<th>High:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>has a hard time getting started on things, and seeing them through to completion</td>
<td>more interested in why people do what they do; good judge of how people feel and what they think about things</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Low:</th>
<th>High:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>more interested in the practical and concrete than the abstract; looks more at what people do than what they feel or think</td>
<td>flexible; likes change and variety; easily bored by routine life and everyday experience; may be impatient, and even erratic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Low:</th>
<th>High:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not changeable; likes a steady pace and well-organized life; may be stubborn and even rigid</td>
<td>more interested in the practical and concrete than the abstract; looks more at what people do than what they feel or think</td>
</tr>
<tr>
<td>F/M (Femininity/ Masculinity)</td>
<td>High: sympathetic, helpful; sensitive to criticism; tends to interpret events from a personal point of view; often feels vulnerable</td>
<td></td>
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<tr>
<td>------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Low: decisive, action-oriented; takes the initiative; not easily subdued; rather unsentimental</td>
<td></td>
<td></td>
</tr>
<tr>
<td>v.1</td>
<td>High: reticent, modest, shy, reserved, moderate, and reluctant to initiate or take decisive social action</td>
<td></td>
</tr>
<tr>
<td>Low: outgoing, confident, talkative, having social poise and presence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>v.2</td>
<td>High: well-organized, conscientious, conventional, dependable, and controlled</td>
<td></td>
</tr>
<tr>
<td>Low: rebellious, pleasure-seeking, restless, and self-indulgent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>v.3</td>
<td>High: relatively free of neurotic trends and conflicts, moderate, mature, optimistic, insightful, and possessing a wide range of interests</td>
<td></td>
</tr>
<tr>
<td>Low: unsure of self, dissatisfied, uncomfortable with uncertainty and complexity, possessing a narrow or reduced range of interests</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix D—Continued

### Special Scales and Indices

<table>
<thead>
<tr>
<th>Scale</th>
<th>High:</th>
<th>Low:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wo (Work orientation)</td>
<td>reliable, reasonable, dependable, and moderate</td>
<td>restless, strong-willed, and self-centered</td>
</tr>
<tr>
<td>Mp (Managerial-potential)</td>
<td>ambitious, well-organized and clear-thinking</td>
<td>dissatisfied, impatient with convention, and inconstant in the pursuit of long-range goals</td>
</tr>
</tbody>
</table>

Note. From California Psychological Inventory administrator's guide (pp. 6-7, 16-20) by H. G. Gough, 1987, Palo Alto, CA: Consulting Psychologists Press. Copyright 1987 by Consulting Psychologists Press. Reproduced by special permission of the Publisher. All rights reserved. Further reproduction is prohibited without the Publisher's written consent.
Appendix E

Summary of MBHI Scales
Appendix E
Summary of MBHI Scales

Introversive Style: High scorers are rather colorless and emotionally flat, tending to be quiet and untalkative. Health care professionals should give clear directions and not expect these patients to take the initiative in following a treatment plan.

Inhibited Style: High scorers tend to be hesitant with others and are often shy and ill-at-ease. However, they do seek understanding and attention; with a sympathetic attitude, one should be able to get them to cooperate.

Cooperative Style: High scorers tend to be eager to attach themselves to a supportive professional and will follow advice closely. These patients become very dependent and may resist when suggestions are made for referral to other doctors or clinic.

Sociable Style: High scorers tend to be outgoing, talkative and charming. However, dependability is likely to be low.

Confident Style: High scorers act in a calm and confident manner. If these patients are impressed with the critical importance on their health of following the medical regimen, they will do so carefully.

Forceful Style: High scorers tend to be somewhat domineering and tough-minded. It will be necessary for the team to work hard to get these patients to follow the prescribed treatment course.

Respectful Style: High scorers are likely to be responsible, conforming and cooperative. They do not like being sick since it signifies weakness and inefficiency.

Sensitive Style: High scorers tend to be unpredictable and moody. Report may be easy on some days but difficult on others.

Chronic Tension: High scorers on this scale are disposed to suffer various psychosomatic and physical ailments, notably in the cardiovascular and digestive system. Where feasible, the thought of reducing tensions and slowing down the rapid pace of life these patients pursue should be discussed.

Recent Stress: High scorers on this scale have an increased susceptibility to serious illness for the year following test administration. Regular and frequent contact with med-
Appendix E—Continued

ical personnel would be advisable during this period so to anticipate and avert the possibility of serious illness.

Premorbid Pessimism: High scorers on this scale are disposed to interpret life as a series of troubles and misfortunes and are likely to intensify the discomforts they experience with real physical and psychological difficulties.

Future Despair: High scorers do not look forward to a productive future life and view medical difficulties as seriously distressing and potentially life threatening.

Social Alienation: High scorers are prone to physical and psychological ailments and a poor adjustment to hospitalization is common.

Somatic Anxiety: High scorers tend to be hypochondriacal and susceptible to various minor illnesses. They experience an abnormal amount of fear concerning bodily functions and are likely to overreact to the discomfort of surgery and hospitalization.

Allergic Inclination: High scorers among patients with allergic disorders—urticaria, dermatitis, asthma—experience emotional factors as significant precipitants of their disease.

Gastrointestinal Susceptibility: High scorers among patients with gastrointestinal disorders—ulcers, colitis, dyspepsia—are likely to react to psychological stress with an increase in the frequency and severity of symptomatology.

Cardiovascular Tendency: High scorers among patients with cardiovascular symptoms—hypertension, angina pectoris—are susceptible to a significant increase in complaint symptomatology under conditions of psychic tension.

Pain Treatment Responsivity: High scorers on this scale are similar in their results to patients whose management with a traditional medical treatment program was less than satisfactory.

Life Threat Reactivity: High scorers who are currently suffering a chronic or progressive life threatening illness are likely to deteriorate more rapidly than is typical among patients with a comparable physical illness.

Emotional Vulnerability: High scorers facing major surgery or other life-dependent treatment programs are vulnerable to severe disorientation, depression, or frank psychosis.
BIBLIOGRAPHY


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