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Prevalence of tardive dyskinesia in the elderly after 20 years on neuroleptics

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PREVALENCE OF TARDIVE DYSKINESIA
IN THE ELDERLY AFTER 20 YEARS
ON NEUROLEPTICS

A Thesis
Presented to
The Faculty of the School of Nursing
San Jose State University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science

by
Shirlee B. Smith
May, 1996

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ABSTRACT

PREVALENCE OF TARDIVE DYSKINESIA IN THE ELDERLY AFTER 20 YEARS ON NEUROLEPTICS

by Shirlee B. Smith

This thesis examined tardive dyskinesia (TD), an involuntary movement disorder, in a sample of elder outpatient veterans who are followed by a VA outpatient clinic in northern California (M age 68.25 years). Data were gathered by administering the Abnormal Involuntary Movement Scale (AIMS) to a nonrandom sample (N = 20). The AIMS provides an effective means of quickly rating the presence and severity of abnormal movements in seven different regions of the body. In this sample, 14 of the subjects tested positive for TD with a prevalence rate of 70% which is consistent with previous studies. A larger study with a random sample is recommended. The data suggest research questions for the future.

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Chapter 1

INTRODUCTION

The discovery of chlorpromazine in the 1950s along with the civil rights movement changed the treatment for many persons with serious mental illness. Consequently, the doors of the state hospitals were forced open, allowing the hospitalized mentally ill population to be treated in the community in the least restrictive setting. The continued discovery of new drugs that were capable of producing neurologic effects (neuroleptics) followed (Wojcik, Gelenberg, LaBrie, & Mieske, 1980).

The goal of these drugs was to assist people with severe mental illness to return to a less restrictive environment, similar to that which existed before the onset of symptoms of the illness (Bickal, 1987). According to Yassa, Ananth, Cordozo, and Ally (1983), the neuroleptic drugs were a significant positive development on one hand, but on the other hand, their administration resulted in many side effects. One group of side effects is known as extrapyramidal symptoms (EPS) and includes: akathisia, akinesia, drug-induced parkinsonism, dystonia, dyskinesia, neuroleptic malignant syndrome and tardive dyskinesia (TD).

TD is the most serious and underdiagnosed side effect of neuroleptic medication. This study addressed the prevalence of TD in a sample of elder outpatient veterans who were 60 years old and over with a 20-year history of

neuroleptic medication treatment.

Problem and Research Question

Tardive dyskinesia symptoms are frequently observed in many of the elderly clients treated at a Veterans Administration (VA) mental health and rehabilitation outpatient clinic. Because the World War II and Korean War veteran population is aging, a large cohort of this outpatient clinic is elderly veterans.

The median age for the onset of schizophrenia, a major mental illness, is the mid to late 20s. Consequently, many of these elderly clients have been taking neuroleptic medication for 20 years or more to control the symptoms of their illness. These symptoms include delusions, hallucinations, disorganized speech and thinking, and disorganized behavior (American Psychiatric Association, 1994).

The exact cause of TD is unknown. Jeste and Caligiuri (1993) suggest that several neurotransmitter systems in the brain may be affected. Tardive dyskinesia may be associated with increased central dopaminergic and noradrenergic activity and reduced gamma-amino-butyric acid (GABA)ergic and cholinergic activity. The neuroleptic agents block dopamine activity at the post-synaptic level in the brain. Since the syndrome was discussed in the literature more than 30 years ago, advanced age has been the only consistent risk factor confirmed by most authors (Baldessarini, 1985).

Gender differences have been reported by a number of researchers. Yassa and Jeste (1992) reported the prevalence of TD as significantly greater and severity of symptoms higher in women. Several other factors have been considered as predisposing to the development of TD, including: presence of mood disorders, type of neuroleptic, age at first neuroleptic treatment, amount of neuroleptic administered, number of lengthy drug-free periods, and development of early extrapyramidal side effects (Casey, 1987). In the Yale Tardive Dyskinesia study of risk factors among long term outpatients maintained on neuroleptic medications, Morgenstern and Glazer (1993) found the TD rate was positively affected by age, nonwhite ethnicity, and neuroleptic dose. It was not affected by years of previous exposure. Although progress has been made in identifying TD risk factors, research findings are varied, and more research is needed.

Research Question

The research question asked in this study was: What is the prevalence of tardive dyskinesia in persons 60 and over after 20 years of neuroleptic medication?

Purpose and Need

The purpose of this study was to determine the prevalence of tardive dyskinesia movements in a group of elder veterans who were treated with long term neuroleptic medication therapy. These veterans received outpatient

treatment and follow-up at a VA Mental Health and Rehabilitation Center in northern California.

This study examined a serious public health problem. As early as 1979, the American Psychiatric Association Task Force Report on Tardive Dyskinesia declared TD a major public health problem, because increasing numbers of patients are being treated with neuroleptic medications and are developing TD, which interferes with the rehabilitation of the patient living in the community (American Psychiatric Association, 1979).

According to Feltner and Hertzman (1993), the majority of cases of TD are mild, but the disorder can be socially disfiguring. Many cases are persistent, and some may be irreversible. In extreme cases, there can be serious physical impairments associated with TD.

This study will increase the knowledge base of TD within the nursing profession and support the consumer/patient's need for regular assessment of neuroleptic medication side effects. Weiden, Mann, Haas, Mattson, and Frances (1987) found that psychiatrists, registered nurses, nurses aids, and nursing home staff including general medical physicians have a high rate of nonrecognition of extrapyramidal side effects of neuroleptic medications and have an even greater knowledge deficit about TD. As early as 1977, Crane reported clinical evidence that in the future, there will be a large population of geriatric patients with

TD unless it can be detected early and the drug treatment stopped or in some way altered. Weiden et al. (1987) underscore the need for careful supervision of patients and training of providers as well as the importance of the accurate diagnosis of TD. All people receiving neuroleptic drugs need to be routinely assessed for possible side effects and early symptoms of TD. Educating health care providers about TD, baseline screening, and regular follow-up for side effects of these medications is essential to avert long term problems. This study adds to the current body of nursing research by describing TD prevalence in an elder veteran population.

Definition of Terms

1. Athetoid is slow, sinuous, continual involuntary movements (American Psychiatric Association, 1994, p. 749).
2. Choreoathetotic is rapid, jerking, nonrepetitive involuntary movements (American Psychiatric Association, 1994, p. 749).
3. Dyskinesia is a broad term that includes several types of abnormal involuntary movements and generally includes chorea, athetosis, and dystonia. It does not include akathisia, compulsions, continuous partial seizures, mannerisms, myoclonus, stereotypy, tics, or tremors (American Psychiatric Association, 1992, p. 9).
4. Extrapyramidal syndrome is a variety of signs and

symptoms, including muscular rigidity, tremors, drooling, shuffling gate (parkinsonism); restlessness (akathesia); peculiar involuntary postures (dystonia); motor inertia (akinesia) and many other neurologic disturbances (American Psychiatric Association, 1984, p. 40).

5. Neuroleptic is the specific antipsychotic effect of a pharmacologic agent on the nervous system (Campbell, 1989, p. 472).

6. Neuroleptic-induced akathesia is subjective complaints of restlessness accompanied by observed movements (e.g., fidgety movements of the legs, rocking from foot to foot, pacing, or inability to sit or stand still) developing within a few weeks of starting or raising the dose of a neuroleptic medication (or after reducing a medication used to treat extrapyramidal symptoms) (American Psychiatric Association, 1994, p. 679).

7. Neuroleptic-induced akinesia is an extrapyramidal, parkinsonism symptom manifested by a decrease in spontaneous facial expressions, gestures, speech, or body movements (American Psychiatric Association, 1994, p. 738).

8. Neuroleptic-induced dystonia-acute is abnormal positioning or spasm of the muscles of the head, neck, limbs, or trunk developing within a few days of starting or raising the dose of a neuroleptic medication (or after reducing a medication used to treat extrapyramidal symptoms) (American Psychiatric Association, 1994, p. 679).

9. Neuroleptic-induced malignant syndrome is severe muscle rigidity, elevated temperature, and other related findings (e.g., diaphoresis, dysphagia, incontinence, changes in level of consciousness ranging from confusion to coma, mutism, elevated or labile blood pressure, elevated creatinine phosphokinase developing in association with the use of neuroleptic medication (American Psychiatric Association, 1994, p. 679).

10. Neuroleptic-induced parkinsonism is parkinsonian tremor, muscular rigidity, or akinesia developing within a few weeks of starting or raising the dose of neuroleptic medication (or after reducing a medication used to treat extrapyramidal symptoms) (American Psychiatric Association, 1994, p. 679).

11. Neuroleptic-induced tardive dyskinesia is involuntary choreiform, athetoid, or rhythmic movements (lasting at least a few weeks) of the tongue, jaw, or extremities developing in association with the use of neuroleptic medication for at least a few months (may be for a shorter period of time in elderly persons) (American Psychiatric Association, 1994, p. 679).

Research Design

This study employed an exploratory design to determine the prevalence of TD in a selected population. A nonrandom convenience sample was composed of 20 Veterans Administration (VA) outpatient veterans who were 60 years old or older.

Each subject was tested by the researcher using the Abnormal Involuntary Movement Scale (AIMS) (Guy, 1976).

The objective of this study was to determine the prevalence of TD movements in an elder population who had been treated with neuroleptic medication for 20 years or more. Descriptive statistics were used to analyze the data.

Scope and Limitations

Findings from this study are limited by the size of the sample and nonrandom selection of subjects. The veteran population is predominantly male; no female subjects participated in the study. Research by Yassa and Jeste (1992) has shown an increase in TD in elderly women. It was not possible to obtain a neuroleptic drug history for the subjects. Over the years, medication changes and adjustments are common. The aging subjects were unable to provide this information.

Research has shown that tardive dyskinesia movements fluctuate from time to time; consequently, variations in AIMS scoring are possible. As observed in clinical practice, and described by Baldessarini (1985), neuroleptic treatment can "mask" the appearance of dyskinesia, and often when neuroleptics are reduced or discontinued, a temporary worsening of TD is noted. Recent medication changes could then affect the AIMS scores. Anxiety level or discomfort level during the testing can also affect the AIMS scores.

Chapter 2

CONCEPTUAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

Conceptual Framework

The nursing conceptual framework of this study is based on the Newman Health Model because of its broad application and value in psychiatric nursing. Newman's model is abstract and future oriented which offers opportunity for nursing research. In Newman's extensive concept of health, the goal of nursing is not to make people well or prevent their becoming sick, but to assist people to utilize the power that is within them as they evolve toward higher levels of consciousness (Newman, 1986).

In the Newman framework, the nurse enters into a partnership with the client with the mutual goal of participating in an authentic relationship, trusting that in the process of its evolving, both client and nurse will grow and become healthier in the sense of higher levels of consciousness (Newman, 1986). The nurse, using this model, will view clients in relation to their environment and look for patterns of energy exchange. Nurse and clients work together to identify patterns. Pattern identification is a slow process, because the role of the nurse within this paradigm is to help clients recognize their own patterns (Newman, 1987). Newman (1987) refers to this as the burst of insight for nurse and client that occurs when, suddenly, everything fits together and makes sense, and then the

pathway of action opens up. Nursing facilitates the process of pattern identification. The nurse's goal is not to fix the pattern, but to be with clients as they identify concerns and actions they want to pursue (Smith, 1990). The Newman framework is a guide for assessment, a way of viewing person-environment interaction that focuses on the whole (Newman, 1987). The Health Model concepts of movement, time, space, and consciousness are used for assessment guidelines in pattern identification.

Concepts of the Newman Health Model

Movement

Applying the Newman framework for this study, the nurse enters into a partnership with the client to identify patterns of involuntary body movement. According to Newman (1979), individuals convey awareness of self through movement by language, posture, and body movement. Through movement, people communicate and provide an index for pattern recognition (Newman, 1986). In diseases of the brain where there is an imbalance of brain chemicals as in schizophrenia, disorders of thinking can result in external body movement. Tardive dyskinesia, the extrapyramidal side effect of neuroleptic medication, results in involuntary movements of the body. Applying the Newman framework, the nurse helps patients identify and understand their patterns of involuntary body movements.

Space

The concept of space is defined as personal space, inner space, and life space. Tardive dyskinesia movements vary depending on space. Space includes living environment and space as related to daily activities. Tardive dyskinesia movements can be aggravated by stress, anxiety, and tension producing environments (American Psychiatric Association, 1992). The nurse provided a relaxed, friendly environment during the AIMS screening procedure to promote more accurate screening results.

Consciousness

Newman (1990) takes space to another dimension of expanded consciousness. By expanding consciousness, it is possible to transcend the disease state. Consciousness is the information capacity of the person, it is the self-knowledge and ability to communicate with self (Newman, 1983). The nurse participated with the client to identify patterns and increase consciousness about TD, informed consent, and risk factors.

Time

According to Newman (1979), time is the measure of consciousness and is a function of movement. Research by Whall et al. (1989) found that TD movements fluctuate in intensity throughout the hours of the day. Movements also disappear in sleep. The concept of time did affect the AIMS scores in this study, because movements can vary depending

on the time of day. The screening tool measured the patient's awareness of body movements, but not if the movements changed during the day.

Literature Review

Review of the literature revealed extensive research on TD. For this study, the literature review addresses (a) description of TD, (b) prevalence of TD, (c) TD in the elderly, and (d) disability, stigma, and self-esteem.

Description of Tardive Dyskinesia

Tardive dyskinesia is a movement disorder associated with the use of neuroleptic drugs (American Psychiatric Association, 1980). Tardive dyskinesia syndrome is a serious side effect of the medications used to treat psychoses. This involuntary movement disorder can occur at any time during treatment with neuroleptic medications but is usually associated with long term exposure to the drugs (Feltner & Hertzman, 1993). According to Jeste and Caligiuri (1993), many studies have attempted to address the issue of neuroleptic dosage and TD but have been unable to show a definite association between development of TD, drug variables, lifetime dosage, or type of drug. In The Harvard Mental Health Letter, Kane (1992) writes that "higher doses of drugs probably raise the risk of TD" (p. 8).

Tardive dyskinesia consists of involuntary buccolingual movements that may be accompanied by choreoathetotic movements of the limbs. These involuntary movements can

affect the tongue, jaw, lips and other facial muscles, and the limbs and trunk. According to Scrak and Greenstein (1986), TD is a difficult side effect to identify accurately, because spontaneous dyskinetic movements can occur in normal populations, especially in the elderly and particularly in females. According to Cummings and Wirshing (1989), TD is clinically underrecognized, with only 10% of patients with evidence of TD having their movement disorder identified and recorded in the course of clinical care. The Task Force Report of the American Psychiatric Association (1979) states:

The diagnosis of TD should be considered in any patient displaying orofacial dyskinesia, facial grimacing, chorea, athetosis, dystonia, or tic-like disturbances who have been taking phenothiazines, thioxanthenes, butyrophenones, high doses of reserpine, or other neuroleptic/antipsychotic agents for a period of at least several months. (p. 8)

Prevalence of Tardive Dyskinesia

The prevalence of TD in people taking neuroleptic medication has been reported to be between 5% and 65% (American Psychiatric Association, 1980). According to the American Psychiatric Association Task Force (1992), the prevalence range of TD is broad, because diverse procedures are used for data collection and analysis, and various assessment techniques with or without rating scales are used

with a lack of consistent criteria for defining a case of TD. Also, populations studied differ with regard to psychiatric diagnosis, inpatient or outpatient status, and age. Additionally, neuroleptic drugs can mask TD.

Glazer, Morgenstern, and Doucette (1993) studied 362 outpatients with serious and persistent mental illness in a prospective cohort study. Based on 5 years of follow-up on this group, the researchers estimate that more than 50% of all patients treated with neuroleptics for at least 15 years will develop TD. Woerner et al. (1991) studied 2,250 New York subjects from three institutions: a voluntary hospital with a relatively young patient population; a Veterans Affairs medical center with an older, more chronic population; and a state facility with mostly elderly and chronic patients. The findings of this study showed an overall prevalence of 23.4% for TD symptoms. The voluntary hospital patients had the lowest prevalence at 13.1%. The state hospital patients had the highest prevalence of 36.1%. High doses of neuroleptics were negatively associated with covert TD (masked TD).

A ten-year study by Gardos et al. (1994) assessed 122 neuroleptic-treated Hungarian outpatients for TD. In this study, the overall prevalence of TD was quite stable over a span of 10 years. The second 5 years of the follow-up showed no progression of TD in comparison with the first 5 years. The overall prevalence of TD in this group was 30.2% at the

beginning of the study, 36.5% at 5 years, and 31.7% at 10 years. The results of this study suggest that tardive dyskinesia typically shows a benign long term course even when the presence of a psychotic illness dictates the continued use of neuroleptics. Findings support the contention that TD and psychoses can be managed by the judicious and frugal use of neuroleptic medication.

Tardive Dyskinesia in the Elderly

The neuroleptic drugs were developed to treat psychoses in the psychiatric population, but their effective sedative qualities have expanded their use for treatment of behavior problems related to organic brain disorders in the elderly. As a result, they are often overused in long term facilities and with nursing home residents as chemical restraints for behavior problems such as confusion and agitation. According to Avorn, Monane, Everitt, Beers, and Fields (1994), neuroleptics are effective in blunting behavior seen as disruptive by nursing home staff and other caregivers.

Avorn et al. (1994) studied the relationship between neuroleptic drug use and clinical evidence of EPS in a large population of elderly nursing home patients. The researchers found little written about the efficacy of prescribing neuroleptic drugs for the management of behavior problems in nursing home patients. More is known concerning the adverse side effects of these drugs on this age group. The Avorn et al. (1994) research found clinical evidence of

extrapyramidal dysfunction three to six times more common in institutionalized elderly patients than in comparable patients using neuroleptic drugs. Drug-induced parkinsonism was the most common side effect. Clearly, these drugs present many risk factors for a population already at risk, and efficacy issues need to be addressed for prescribing neuroleptic drugs in the absence of true psychoses.

As people age, less of all medication is required because of the physiologic changes taking place in the body (Strome & Howell, 1991). In the elderly, the functions of absorption, metabolism, and elimination of neuroleptics are impaired. Absorption is less impaired than metabolism and elimination; thus, higher blood levels of drugs occur in the elderly. Higher blood drug levels increase the chance of having adverse side effects and adverse drug interactions. For these reasons, special care is needed when prescribing neuroleptic medication for all elderly including those with serious and persistent mental illness. Regular medication assessment with reduction in drug dosage when feasible and routine screening for side effects is essential.

Disability, Stigma, and Self-esteem

According to Feltner and Hertzman (1993), the majority of the cases of TD are mild, but the disorder can be socially disfiguring and adds to the stigma of mental illness. Many cases are persistent, and some may be

irreversible. Disabilities associated with TD are often related to the specific involuntary movements involved. Trunk and limb involvement can cause impairment with mobility. In extreme cases, physical impairment associated with TD may include trauma and hypertrophy of the tongue, swallowing and eating difficulties, dysarthria, irregular respiration and dyspnea, and involuntary retching and vomiting. These disabilities place the elderly at further risk.

Psychosocial factors are also important considerations in people who have TD. A study by Yassa (1989) examined functional impairment associated with TD in 22 patients. Twenty of these patients were aware of and complained of their symptoms to their physicians. All 22 of the patients complained of embarrassment because of their movement disorder. Subjects felt people were looking at them when they were in the community. Two patients in the study discontinued college courses and secluded themselves in their apartments, because they felt neighbors ridiculed them. In this study, Yassa also found that family members reacted negatively to their family member's movements. Even fellow patients excluded patients who ground their teeth. TD movements also interfered with hospital rehabilitation of some of the subjects. Clearly, TD can result in decreased socialization and decreased self-esteem which results in adverse effects on quality of life.

Summary

The theoretical concept used for this study was Newman's Health Model. The Newman framework is a guide for assessment and provides a way of viewing person-environment interaction that focuses on the whole. The Health Model concepts of movement, time, space, and consciousness are used for assessment guidelines in identifying the individual patient's patterns.

Tardive dyskinesia is a movement disorder associated with the use of neuroleptic agents. The medication prescribed as treatment to control the unwanted psychotic symptoms associated with mental illness also causes serious side effects. Prevalence rates for people taking neuroleptic medication is reported to be between 5% and 65%. The elderly require less medication and are more susceptible to medication side effects. Care must be taken in prescribing these potent drugs to this population. Disabilities resulting from TD place the elderly at risk. Involuntary body movements cause psychosocial stress.

Chapter 3

METHODOLOGY

Research Design

An exploratory design was used in this study to determine the prevalence of TD in an elder outpatient population.

Research Question

The research question asked in this study was: What is the prevalence of tardive dyskinesia in persons 60 and over after 20 years of neuroleptic medication?

Setting

The setting was a Department of Veterans Affairs Mental Health and Rehabilitation Outpatient Clinic in northern California. The researcher administered the AIMS to 20 subjects in one of the clinic offices.

Subjects/Sampling

The subjects were a nonrandom, convenience sample of 20 veterans who were 60 years old or older and received psychiatric follow-up treatment in various programs at a northern California VA outpatient clinic. A diagnosis of major mental illness was determined by chart review, along with current neuroleptic medication treatment. Due to the absence of old records, subjects self-reported the number of years taking neuroleptic medication. Those subjects with a 20-year history of neuroleptic use were selected to participate in the study.

Data Collection

On three consecutive Thursday mornings, veterans were approached by the researcher as they waited in the clinic lobby for their monthly appointment and were asked if they would participate in the research. All subjects were able to give informed consent. Nine veterans refused participation. Twenty subjects were recruited over a 3-week period of time. The 20 subjects were cooperative with the research procedures and the administration of the AIMS. The participants were individually escorted to a clinic office where the testing took place. The AIMS procedure was explained, and the subjects were given a consent form to sign, which included a statement of rights for human subjects. During this initial orientation, the researcher attempted to provide a relaxed, comfortable environment for the subject before the administration of the AIMS tool. The researcher screened all subjects using the AIMS tool to determine the presence of involuntary body movements, including tardive dyskinesia.

Instrument

The instrument used to gather the data was the Abnormal Involuntary Movement Scale (AIMS) (see Appendix B). The AIMS examination was developed by the National Institute of Mental Health in 1977 for use in evaluating TD movements and is becoming increasingly popular as a clinical rating instrument of TD. The tool was originally developed for use

in research. Whall et al. (1983) and Wojcik et al. (1980) report that the rating method of the Abnormal Involuntary Movement Scale has been regularly used by many researchers, including nurses who have studied TD. The AIMS provides a useful means of quickly rating the presence and severity of movements in seven different regions of the body (Neehall, 1989).

The AIMS procedure takes approximately 15-30 minutes to administer; the subject performs a series of arm, leg, and facial movements designed to activate TD movements. The instrument, according to Cummings and Wirshing (1989), uses a 0 to 4 scale to rate movements of the muscles of facial expression, lips, and perioral area, jaw, tongue, upper and lower limbs, and truncal musculature (neck, shoulders, hips). A zero rating indicates no abnormal movements; a four indicates severe movements. At least one rating of 2 or higher in any one body region was considered a positive indication of TD.

AIMS Validity and Reliability

The widespread use of the AIMS has resulted in testing of the instrument and, according to Bostrom (1988), interrater and test-retest reliability have been adequate and relatively consistent. According to Whall et al. (1989), the AIMS has an interrater reliability of .867 to .90 when used by trained raters. The researcher was trained in using the AIMS and was tested for interrater reliability using the

tool. Approximately 20 minutes of researcher time was involved in the administration of each AIMS examination. Whall et al. report the validity of the AIMS as compared with a mechanical measurement at .72.

The tool may give an incomplete picture of a person's TD, because a score on any of the global items does not give a specific indication of the actual movements of a person's TD. This makes the scale difficult to use for ongoing clinical assessment and evaluation if the global scores are the primary focus (Bostrom, 1988). In a study on voluntary suppression of TD, Caligiuri and Lohr (1989) found that clinical rating scales are insensitive to voluntary suppression of movements which may lead the examiner to underestimate the severity of TD.

The AIMS tool is widely used by many researchers including nurses who have studied TD and is an adequate measure for rapid assessment for initial prevalence screening. It can also be used in cross-sectional research designs (Bostrom, 1988).

Analysis of the Data

The statistical procedures used to describe and summarize the data include frequency distribution, measures of central tendency, and measure of variability. A description of demographic data includes gender, years on medication, age, dentures, and current problems with teeth. Also discussed are the overall and individual AIMS scores.

Summary

This exploratory study examined 20 elder veterans who were 60 years old or older and who had been taking neuroleptic medication for 20 years or more. Data were gathered by testing the 20 participants for abnormal involuntary movements using the AIMS tool (Guy, 1976) and with brief demographic questions.

Chapter 4

ANALYSIS AND INTERPRETATION OF DATA

The purpose of this exploratory study was to determine the prevalence of TD among a sample of elderly veterans with a 20-year history of neuroleptic medication treatment. The objectives were to describe the characteristics of the sample, to assess the subjects for TD movements using the AIMS, and to determine TD prevalence for this group. Twenty elderly subjects age 60 and above receiving follow-up mental health care at a VA outpatient clinic in northern California were tested using descriptive statistics which provided a demographic profile of the subjects, as well as range and means for age, and number of years on medication. Frequency of AIMS scores were reported.

Analysis of the Data

Setting and Sample

The 20 participants in this study comprise a nonrandom convenience sample of elderly veterans who receive follow-up mental health care at a VA outpatient clinic. The participants visit the outpatient clinic monthly for medication refills and for assessment by clinicians.

Demographics

The subjects, 20 males, ranged in age from 60-79 years; the mean was 68.25 years (see Table 1). The number of years that subjects reported they were treated with neuroleptics ranged from 28-52 years; the mean was 38.40.

Table 1

Demographic Data (N = 20)

Gender	Age	Years on		Current Problems With	
		Neuroleptics	Dentures	Teeth or Dentures	
M (20)	Range 60-79 yrs	Range 28-52 yrs	Yes	Yes	3
	M 68.25 yrs	M 38.40 yrs	No	No	17
	Median 68 yrs	Median 38.5 yrs			

Seven subjects wore dentures, and 3 reported having dental problems, with 7 being edentulous. Of the edentulous subjects, 2 reported problems with dentures, 2 subjects had no dentures, 1 subject had broken dentures, 1 subject lost his dentures, and 1 subject complained of loose fitting dentures.

Abnormal Involuntary Movement Scale

The summary of AIMS scores of the 20 subjects are shown in Table 2. Using the most conservative criterion for the diagnosis of TD, a minimum rating of "mild" (2 or more on the AIMS) of the 20 people screened, 70% (14) were found to have TD. Among these, 20% (4) had an overall rating of mild, 10% (2) moderate, and 40% (8) were rated as severe. Among patients who did not qualify for the diagnosis of TD, 15% (3) had a score of 1 (minimal).

The seven body parts on the AIMS were analyzed individually for frequency of occurrence and are shown in Table 3. In those subjects who tested positive for TD, movements of the tongue were most common, 75% (15), followed by the lips and perioral area, 45% (9), jaw, 30% (6), and upper extremities, 15% (3), muscles of facial expression, 5% (1), lower extremities, 5% (1), neck, shoulders, hip, 5% (1), subjects' awareness of movement scored high with 65% (13) reporting awareness. Incapacitation due to movements occurred in only one subject who scored 4 (severe) on the AIMS and showed severe incapacitation due to involuntary

Table 2

Abnormal Involuntary Movement Scale (AIMS) Scores (N = 20)

Rating	<u>n</u>	%
Mild	4	20
Moderate	2	10
Severe	8	40

Note. Rating of 2 or more = TD.

Table 3

Distribution of Dyskinetic Movement in 20 ClientsDyskinetic Sample (N = 20)

Symptom Category	<u>n</u>	%
Tongue	15	75
Awareness	13	65
Lips and Perioral Area	9	45
Jaw	6	30
Upper Extremities	3	15
Muscles of Facial		
Expression	1	5
Lower Extremities	1	5
Neck, Shoulders, Hip	1	5

movement of the hands.

Interpretation

The American Psychiatric Association (1980) reports the prevalence rates of TD to be 5% to 65% of the patients taking neuroleptic medication. Research predicting the long term risk of TD in outpatients maintained on neuroleptics by Glazer et al. (1993) predicted a risk of persistent TD to be 68% after 25 years of neuroleptic exposure. Consistent, but slightly higher prevalence rates than reported in the literature, this study found prevalence at 70% for this group of elders with long term medication treatment exposure.

The effect of dental status and abnormal movements is not well documented. According to research by Woerner et al. (1991), patients who had dentures, but were not wearing them during the testing, were 3.5 times more likely to be considered positive for TD than patients who did not have dentures. In this study, 7 subjects were edentulous, and all 7 scored positive for TD. Six of the subjects tested positive for oral movements (lips and perioral area, jaw, and tongue). According to Woerner et al. (1991), there is a possibility that TD prevalence rates among the elderly may be overestimated due to edentulousness. Yet research by Brandon, McClelland and Protheroe (1971) suggest an association between edentulousness and orofacial dyskinesia, hypothesizing that patients with oral dyskinesia have

difficulty keeping dentures in their mouths and fail to wear dentures as a result of orofacial dyskinesia. This study supports this hypothesis. The 7 subjects who failed to wear dentures were all positive, scoring 2 or more on the AIMS, for facial and oral involuntary movements.

Summary

This exploratory study examined TD movements in a group of elder veterans with a 20-year history of neuroleptic treatment. The characteristics of the subjects were presented along with the descriptive findings that were obtained using the AIMS. In this sample, 14 of the subjects tested positive for TD with prevalence at 70% for this group which is consistent with previous studies in the literature.

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

The purpose of this exploratory study was to determine the prevalence of TD in an elder outpatient population. The research question asked was: What is the prevalence of tardive dyskinesia in persons 60 and over after 20 years of neuroleptic medication?

The subjects received follow-up mental health care at a northern California VA outpatient clinic. The data were analyzed using descriptive statistics which provided a demographic profile of the sample as well as range and means scores for the overall AIMS.

The prevalence of TD was 70% in this group of elders with serious and persistent mental illness and long term medication treatment. These findings are consistent with those reported in the literature (American Psychiatric Association, 1980; Glazer et al., 1993; Gardos et al. 1994). Seven of those with positive facial oral TD scores were also edentulous and similar to those studies that recorded this factor. The effect of dental status and abnormal buccal oral movements is not well documented.

Limitations

Interpretation of the findings from this study is limited by the small nonrandom sample size. Race was not included in the demographic questions, but research by

Morgenstern and Glazer (1993) found that African-American patients were twice as likely to develop TD as were Caucasian patients. No females were recruited for the study, even though research shows an increased prevalence of TD in elderly women. It was difficult to recruit females because of the military population. Research demonstrates that TD movements fluctuate from time to time, and because of this, variation in the AIMS scores is possible. One limitation in this study was that the assessment was performed one time only. Another limitation, overestimation of oral dyskinesia, may have resulted from subjects not wearing dentures. Seven of the subjects were edentulous and all seven scored positive for facial oral dyskinetic movements. The result may have affected the AIMS scores and increased the overall prevalence. A mouth without teeth may cause more lip and perioral, jaw, and tongue movement especially in the aged. Researchers hypothesize that subjects often do not wear dentures because of TD mouth movements. Also, many of these aging veterans have not had adequate dental care over the years resulting in poor dental status. It is difficult to ascertain the specific etiology of the mouth movements in this study, because the participants were not asked about this.

Recommendations

Based on the findings of this study to determine prevalence of TD in a sample of elder outpatient veterans

with long term neuroleptic exposure, it is recommended that further studies be repeated with a larger randomized sample that (a) includes women, (b) screens subjects at different times of the day to determine fluctuation in TD movements, and that (c) includes race in the demographic questionnaire.

The elderly are a population at risk for psychiatric problems and medication side effects. Additional recommendations include: prescribing neuroleptic medications on an individual basis with (a) the lowest possible dose to obtain the desired effects, (b) ongoing patient assessment and monitoring of abnormal movements for those receiving neuroleptic medication, (c) obtaining drug histories for patients receiving these potent medications, and (d) stressing the importance of patient and staff education.

The Newman Health Model provides a framework for the nurse for viewing person and environment interaction. The concepts of movement, time, space, and consciousness can be used as a guideline for identifying individual patient's pattern of movement. Assessment, monitoring, and education are all in the domain of nursing.

Summary

Tardive dyskinesia is a well-documented side effect of neuroleptic medication treatment, especially in long term therapy. Paradoxically, the drugs that cause TD are the very agents that suppress the psychiatric manifestations of the psychotic disorder. Persons with serious mental illness need

medication treatment to suppress these psychiatric symptoms.

In general, this prevalence survey has identified that persons with serious and persistent mental illness on long term (20 years) neuroleptics are at risk for TD, and that assessments for TD need to start when neuroleptic medication treatment first begins.

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APPENDIX A
Human Subjects' Institutional Review Board
Permission to Conduct Research
and Subject Consent Form

A campus of The California State University

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408/924-2480

TO: Shirlee B. Smith
2854 Forbes Ave.
Santa Clara, CA 95051

FROM: Serena W. Stanford *Serena W. Stanford*
AAVP, Graduate Studies & Research

DATE: March 27, 1995

The Human Subjects-Institutional Review Board has approved your request to use human subjects in the study entitled:

"The Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above With a 20-Year History of Neuroleptic Medication Treatment"

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity when they participate in your research project, and with regard to any and all data that may be collected from the subjects. The Board's approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Dr. Serena Stanford immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised that each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate, or withdrawal, will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact me at (408) 924-2480.

College of Applied Sciences and Arts • School of Nursing • Graduate Program
One Washington Square • San José, California 95192-0057 • 408/924-1321

School of Nursing

Agreement to Participate in Research

Responsible Investigator: Shirlee Bogart Smith RN,C BSN

Title of Protocol: What is the Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above With a 20-Year History of Neuroleptic Medication Treatment

I have been asked to participate in a research study investigating how often tardive dyskinesia involuntary body movements occur in people who have been taking psychiatric medications for 20 years or more.

I will be asked to participate in a 15-minute assessment of my fully clothed body by the nurse researcher. This testing will take place in her office at the San Jose Mental Health and Rehabilitation Clinic.

The nurse will ask me to follow simple directions and move various parts of my body as she examines for involuntary body movements using a tool called the Abnormal Involuntary Movement Scale.

No risks are anticipated as part of this screening.

The results of the study may be published, but no information that could identify me will be included.

There is no compensation for participation.

Questions about the research may be addressed to the principal investigator at (408) 275-7652. Complaints about the research may be presented to the respective Director of Nursing, Dr. Bobbye Gorenberg at (408) 924-3130. Questions or complaints about the research, subjects' rights, or research-related injury may be presented to Serene Stanford, Ph.D., Associate Academic Vice President for Graduate Studies and Research, at (408) 924-2480.

No service of any kind, to which you are otherwise entitled, will be lost or jeopardized if you choose to "not participate" in the study.

Consent is given voluntarily. You may refuse to participate in the study or in any part of the study. If you decide to participate in the study, you are free to withdraw at any time without prejudice to your relations with San Jose State University or any other participating institutions.

You will receive a signed and dated copy of this consent form.

The signature of a subject on this document indicates agreement to participate in the study.

The signature of a researcher on this document indicates agreement to include the above-named subject in the research and attestation that the subject has been fully informed of his or her rights.

Subject's Signature

Date

Investigator's Signature

Date

**Department of
Veterans Affairs**

Memorandum

Date : May 2, 1995
From : Research Administration (151A)
Subj : Approval of Research Proposal
To : Shirlee B. Smith, R.N. (170A4SJ)

1. Your research program entitled, The Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above with a 20-year History of Neuroleptic Medication Treatment was approved at the Research and Development meeting of April 20, 1995. I plan to start work on this project 7/1/95. Please complete and return to (151A). Thank you. (date)

2. The results of this review are as follows:

 X Approved as written
 Approved, pending changes or clarification (you will be contacted on this)
 Tabled for future review (you will be contacted on this)
 Disapproved (you will be contacted on this)

3. BY VA LAW, you must submit an INITIAL, and thereafter, annual PROGRESS reports on all research in which you participate, whether the research is VA-funded, non-VA-funded, or non-funded. Please complete the attached forms and return to (151A). Thank you.

Shirlee B. Smith RN
 PI Signature

5/26/95
 Date

 Evelyn Willcox
 Program Assistant
 x5111

STANFORD UNIVERSITY
Stanford, California 94305
(415) 723-5244

CERTIFICATION OF HUMAN SUBJECTS APPROVAL

DATE: April 4, 1995
TO: S.B. Smith, R.N.
Department of Nursing Research
FROM: Chairman, Administrative Panel on
Human Subjects in Medical Research

PROTOCOL ENTITLED:

The Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above with a 20-Year History of Neuroleptic Medication Treatment.

The Panel approved human subject involvement in your research project on April 4, 1995.

The expiration date of this approval is April 3, 1996. If this project is to continue beyond that date, please submit an updated proposal in advance for the Panel's re-approval. If this proposal is used in conjunction with any other human experimentation or if it is modified in any way, it must be re-approved for these special circumstances. In addition, the Panel requests prompt notification of any complications which may occur during any experimental procedure.

All continuing projects and activities must be reviewed and re-approved at least annually by the Panel. Panel approval of any project is for a maximum period of one year. It is the responsibility of the investigator to resubmit the project to the Panel for annual review.

James Theodore, M.D., Chairman

cc: Sponsored Projects
M. Hays, M.D., VA

Funding Agency: (VA Study)(N)
Period of Time: 04/04/95 through 04/03/96
Investigational New Drugs: N
Investigational New Device: N
Cooperating Institution: N
Expedited Review
Assurance Number: M1272
IRB #01

March 1, 1995

Title of Protocol: The Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above With a 20-year History of Neuroleptic Medication Treatment.

Are you participating in any other research studies? ☐ Yes ☐ No

INFORMED CONSENT

You are invited to participate in a study of tardive dyskinesia. I hope to learn how frequently the involuntary body movement of tardive dyskinesia occurs in people who have been taking neuroleptic medications for 20 years or more. You were selected as a possible participant in this study because you are a veteran age 60 or older and receive your follow-up psychiatric care at San Jose Mental Health and Rehabilitation Clinic.

If you decide to participate, Shirlee Smith RN, C BSN will administer the Abnormal Involuntary Movement Scale, which is a 15-minute test, to observe your fully clothed body for involuntary movements. You will be asked to perform simple body movements of your face, arms, and legs during the test. There is no discomfort associated with this procedure. No risks are anticipated. The benefits are the identification of side effects of your medication. Results of study will be given to your clinic doctor. I CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

While participating in this study, you should not take part in any other research project without approval from all of the investigators. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

Any data that may be published in scientific journals will not reveal the identity of the subjects. Patient information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

No payment will be provided for participation in this project.

There will be no cost to participate in this study.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care.

If you have any questions, I expect you to ask me. If you have other questions or concerns about the study, please feel free to contact my advisor, Dr. Phyllis M. Connolly, at (408) 924-3144 Dr. Serena Stanford, Associate Academic Vice President for Graduate Studies and Research at San Jose State University, (408) 924-2480.

Signature

Date

Signature of Investigator or Witness

Date

March 1, 1995

Title of Protocol: The Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above With a 20-year History of Neuroleptic Medication Treatment.

In the unlikely event you are injured as a result of participation in this study, Palo Alto Veterans Administration Medical Center will furnish humanitarian emergency medical care (for nonveteran participants) or medical care (for veteran participants) as provided by federal statute. Compensation for such injury may be available to you under the provision of the Federal Tort Claims Act and/or 38 U.S.C. section 1151 (formerly section 351) (for veteran participants only). For further information contact the V.A. District Counsel at (415) 744-7676.

All forms of medical diagnosis and treatment--whether routine or experimental--involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment, but this study does not provide financial assistance for additional medical or other costs. [Additionally, Stanford is not responsible for research and medical care by other institution's initiations or personnel participating in this study.] You do not waive any liability rights for personal injury by signing this form. For further information, please call (415) 723-5244 or write the Administrative Panel on Human Subjects in Medical Research at Medical School Office Building, Room x-107, Stanford, CA 94305. In addition, or if you have any questions concerning your rights as a study participant, please contact the Human Subjects Office at the same address and telephone number.

As a human subject, you have the following rights. These rights include, but are not limited to, the subject's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably solvable to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signature

Date

Signature of Investigator or Witness

Date

March 1, 1995

Title of Protocol: The Prevalence of Tardive Dyskinesia in an Outpatient Population of People Age 60 and Above With a 20-year History of Neuroleptic Medication Treatment.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PRINCIPAL INVESTIGATOR AND HIS OR HER STAFF, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature

Date

Signature of Investigator
or Witness

Date

Approval Date _____ Expiration Date _____

APPENDIX B

Abnormal Involuntary Movement Scale (AIMS)

		Abnormal involuntary Movement Scale		AIMS				
Ref.: Department of Health, Education, and Welfare Public Health Service Alcohol, Drug Abuse, and Mental Health Administration National Institute of Mental Health								
Instructions: Complete Examination Procedure before making ratings. Movements ratings: Rate highest severity observed. Rate movements that occur upon activation one less than those observed spontaneously.		0 = None	1 = Minimal, may be extreme normal	2 = Mild	3 = Moderate	4 = Severe		
Facial and oral movements:	1. Muscles of Facial Expression e.g., movements of forehead, eyebrows, periorbital area, cheeks; include frowning, blinking, smiling, grimacing	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
	2. Lips and Perioral Area e.g., puckering, pouting, smacking	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
	3. Jaw e.g., biting, clenching, chewing, mouth opening, lateral movement	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
	4. Tongue Rate only increase in movement both in and out of mouth, NOT inability to sustain movement	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
Extremity movements:	5. Upper (arms, wrists, hands, fingers) Include choreic movements, (i.e., rapid, objectively purposeless, irregular, spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine). Do NOT include tremor (i.e., repetitive, regular, rhythmic)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
	6. Lower (legs, knees, ankles, toes) e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
Trunk movements:	7. Neck, shoulders, hips e.g., rocking, twisting, squirming, pelvic gyrations	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
Global judgments:	8. Severity of abnormal movements	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
	9. Incapacitation due to abnormal movements	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐		
	10. Patient's awareness of abnormal movements Rate only patient's report	0 ☐ No awareness 1 ☐ Aware, no distress 2 ☐ Aware, mild distress 3 ☐ Aware, moderate distress 4 ☐ Aware, severe distress						
Dental status:	11. Current problems with teeth and/or dentures	0 ☐ No 1 ☐ Yes						
	12. Does patient usually wear dentures?	0 ☐ No 1 ☐ Yes						