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Symptomatic distress due to benign prostatic hypertrophy

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SYMPTOMATIC DISTRESS DUE TO
BENIGN PROSTATIC HYPERTROPHY

A Thesis

Presented to

The Faculty of the Department of Nursing
San Jose State University

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

By

Christine Johanna Gilmore

May, 1991

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APPROVED FOR THE UNIVERSITY

ABSTRACT

SYMPTOMATIC DISTRESS DUE TO BENIGN PROSTATIC HYPERTROPHY

by Christine J. Gilmore

This ex-post-facto study was conducted to determine if there is a relationship between degree of distress and other parameters that are characteristic of benign prostate hypertrophy (BPH). The sample consisted of 20 subjects who were diagnosed in a prescreening procedure as having BPH. The data collection instruments, Symptomatic Distress Questionnaire and the Objective Findings Analysis, were used to collect and record subjective and objective information.

Correlational analysis was used to support the hypotheses: (a) there is a statistically significant positive relationship ($p = .001$) between degree of distress and severity of symptoms, and (b) there is no statistically significant relationship between degree of distress and urinary peak flow rate, urinary post-void residual volume, and gram weight of resected tissue.

The study concluded with recommendations that degree of distress should be part of the BPH assessment criteria. The information can be used by nurses to prioritize patient care and provide patient teaching to men with prostate symptoms.

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Chapter 1

INTRODUCTION

Below the bladder and surrounding the urethra is an essential organ of the male reproductive system called the prostate. This chestnut-shaped gland produces alkaline semen that aids in the transportation of sperm. The prostate claims importance not so much for its function as for its trouble-making. In men over 50, the most common urological problem is prostate enlargement, referred to as benign prostate hypertrophy (BPH). BPH has caused untold aggravation, misery, and anxiety for millions of unfortunate men (Miller, 1988).

In all men, the prostate enlarges from puberty until the approximate age of 50. At that time the prostate starts to degenerate, being replaced by fibroadenomatous tissue (Guyton, 1981). While some men never have problems as a result of this normal prostate development, others experience mild to severe impairment of urinary function.

Some symptoms of BPH in men tend to be less important diagnostically, because they commonly occur with increased age. Then too, older patients frequently use medications that cause side effects that mimic a variety of urologic disorders, or have other illnesses that cause urological symptoms. As a consequence, medical providers spend much time and effort in an attempt to determine whether the complaint voiced by the patient is a side effect of a drug, a symptom of a disease, or a prostatic problem.

The Problem and Research Questions

The purpose of this study was to determine if there is a relationship between degree of distress experienced by men with prostate symptoms and other parameters that are characteristic of benign prostate hypertrophy (BPH). More specifically, this study explored the relationship between degree of distress experienced by men with BPH and: (a) severity of symptoms, (b) urinary peak flow rate, (c) urinary post-void residual volume, and (d) gram weight of resected prostatic tissue. The research questions were:

1. In men diagnosed with BPH, is there a relationship between severity of symptoms and degree of distress?
2. In men diagnosed with BPH, is there a relationship between urinary peak flow rate and degree of distress?
3. In men diagnosed with BPH, is there a relationship between urinary post-void residual volume and degree of distress?
4. In men diagnosed with BPH, is there a relationship between prostatic weight and degree of distress?

Justification of the Problem

Diagnosis and treatment of BPH has been based largely on the patient's symptoms (Herbison, Fraunborfer, & Walton, 1988). Some investigators have stated that severity of symptoms is of little clinical value (Abrams & Feneley, 1978; Andersen, Nordling, & Walter, 1979) while others claim symptoms are a crucial factor (Bruskewitz, Jensen, & Iversen, 1983; Frimodt-Moller et al., 1984). Urinary peak

flow rates, urinary post-void residual volume, and prostatic size have been found to correlate with symptoms, but have proven to be unreliable for use as a preoperative assessment criteria (Graversen, Gasser, Wasson, Hinman Jr., & Bruskewitz, 1989).

The patient's perception of distress, as a preoperative assessment criterion, has not been documented. Knowledge of the patient's perception of distress may be helpful to nurse practitioners and nurses working in clinics by providing them with a more accurate gauge of the severity of the client's problems. It can assist nurses with the prioritizing of medical care and the making of referral consultations. The patient may also benefit in that those with higher degrees of distress would receive more rapid and appropriate care. Ultimately, the patient's relief of symptoms and associated distress is the primary goal of nursing care.

Assumptions

This study rests on the following assumptions:

1. Patients having symptoms of BPH are able to identify a degree of distress associated with each symptom.
2. Urinary obstructive symptoms are routinely used by physicians as part of the assessment criteria for the diagnosis of BPH.
3. Decreased urinary peak flow rates and increased urinary post-void residual volumes are objective signs presented in BPH.

4. Prostate enlargement is associated with advanced age in men.

Definition of Terms

For the purposes of this study, the following definitions of terms were used:

Subjective Data: are prostatic complaints expressed by patients, defined by the researcher as symptoms, severity of symptoms, and degree of distress associated with BPH symptoms.

Objective Findings: are any observations of the patient's body or its functions, identified by the researcher as urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue (Thomas, 1977).

Degree of Distress: is the patient's perceptions of degree of discomfort associated with prostatic symptoms determined as being unpleasant or troublesome (Selye, 1974).

Symptom Profile: is a point score system with weighted values that assesses severity of symptoms related to prostatic symptoms (Madsen & Iverson, 1983).

Older Men: for the purpose of this study, are males, 50 years or older.

Benign Prostate Hypertrophy (BPH): is a condition of an enlarged prostate gland that obstructs the urethra (Guyton, 1981).

Urinary Peak Flow Rate: is the highest strength of urinary stream measured by a uroflowmeter.

Urinary Post-Void Residual Volume: is urine left in the bladder after urination, measured by catheterization after voiding.

Transurethral Resection of the Prostate: is a surgical procedure involving removal of prostatic tissue obstructing the urethra, often referred to as transurethral prostatectomy.

Gram Weight of Resected Prostatic Tissue: is the weight of prostatic tissue removed after a transurethral resection of the prostate.

Health Provider: is a physician, medical resident, or nurse practitioner authorized to diagnose and treat health problems.

Hypotheses

The following hypotheses were generated for this study:

1. In men diagnosed with BPH, there is a relationship between degree of distress and severity of symptoms.
2. In men diagnosed with BPH, there is no relationship between degree of distress and urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue.

Setting and Sample Population

The study was conducted in the San Francisco Bay Area of Northern California. The subjects were obtained from the Veterans Administration (VA) Medical Center. The VA Medical Center is the San Francisco Bay Area's largest health care facility and one of the largest medical centers in the

United States. The mission of the VA Medical Center is to provide medical care to America's veterans of war (Veterans Administration, 1989).

The subjects represent a convenience sample selected on the basis of having BPH, identified in a prescreening procedure by a urology medical doctor at the Palo Alto Veteran's Urological Department. The sample consisted of 20 male volunteers who were eligible for treatment at the VA. Restrictive criteria of male patients included: (a) males over 50 years old, (b) presence of prostatic symptoms, (c) candidates for a transurethral resection of the prostate, and (d) written consent for surgery prior to enrollment in the study group.

The rights of the patient participants were protected in the following manner: (a) human subjects' approval was obtained from the Veterans Administration Medical Center, Stanford University, and San Jose State University (Appendix A); (b) after a brief description of the study, the patients were given the opportunity to volunteer or refuse to participate in the study; (c) the patients were given a consent form, and only those signing the consent form were eligible to participate in the study (Appendix B); (d) each patient was informed of his right to withdraw from the study at any time without jeopardy to care; (e) each participant was assured privacy and complete anonymity; (f) participants were informed that results of the study would be made available upon request.

Research Design

This study used an ex post facto correlational design. The independent variables of symptom severity, urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue occurred in the natural course of events (Polit & Hungler, 1983). The dependent variable, degree of distress, was the variable of interest and the prime focus of the investigation (Polit & Hungler, 1983).

In this study the sample consisted of a self-selected group based on their presentation at the Urology Outpatient Clinic with prostate symptoms. The independent variables were not manipulated nor was there random assignment of the subjects into a control or experimental group. A BPH Symptomatic Distress Questionnaire and an Objective Findings Analysis were used as data collection instruments.

The Symptomatic Distress Questionnaire (Appendix D) was used to collect subjective data. The Symptomatic Distress Questionnaire contained two columns entitled "Symptom Profile" and "Degree of Distress." Symptom Profile, an instrument developed and approved for use in this study by Madson and Iverson (1983), listed 8 prostate symptoms with associated degrees of severity. Symptom Profile was used with permission from Dr. Madson who developed the rating scale (Appendix C). Degree of Distress, an instrument developed by the researcher, contained assessment statements of the degree of distress associated with prostate symptoms.

No attempt was made to determine the validity of these instruments.

Symptom severity analysis has been used in numerous studies (Frimodt-Moller et al., 1984; Kelly, Roskamp, & Leach, 1989; Lepor & Rigaud, 1990). Likewise, degree of distress has been proposed as a BPH symptom measurement (Barry, 1990; Fowler et al., 1988). Therefore, based on the experience and expertise of specialists in BPH, both instruments were assumed to be valid. Reliability of the instruments was difficult to determine as BPH symptoms can vary in clients over time, depending upon the progression of the disease. The Objective Findings Analysis (Appendix E), an instrument developed by the researcher, reported urinary peak flow rates, urinary post-void residual volumes, weight of resected prostatic tissue, urine culture results, confirmation of the diagnosis of BPH, and the presence of the patient's consent for surgery. The objective findings are standard measures used in the diagnosis and treatment of BPH (Castro, Griffiths, & Shackman, 1969).

Scope and Limitations

The study was limited to a small selected sample. The data obtained from the sample were at risk for erroneous conclusions due to lack of representativeness and the small size of the sample (Polit & Hungler, 1983). The external validity of this study is limited because the sample was obtained from one particular hospital in Northern California; however, comparison may be made to similar VA

hospitals. This study has implications for delivery of health care by nurses to patients with BPH. The BPH assessment can be used as a means of prioritizing patient care, providing a basis for patient teaching and counseling, and establishing validity of requests for urology referral consultations.

Chapter 2

CONCEPTUAL FRAMEWORK AND RELATED LITERATURE

This chapter presents the conceptual framework of the study, which is based on a stress and distress theory, and reviews the literature on the problem under investigation.

Stress and Distress Theory

The theory chosen for the conceptual framework of this study is the General Adaptation Syndrome (Selye, 1974). Selye (1974) defined stress as the nonspecific response of the body to any demand made on it. Selye (1974) categorized the stress response as eustress and distress. Eustress is an agreeable and healthy experience in which, as stress increases, health and performance also increase. Distress is a disagreeable and pathogenic state in which, as stress increases, health and performance decrease. Stress overload is considered to be the cause of distress.

According to Selye (1974), the optimal stress level for any individual is the point on the stress continuum where performance and health are maximized. Selye (1974) proposed that eustress and distress are not qualitatively different; they are only quantitatively different.

Internal and external manifestations of stress are referred to as the General Adaptation Syndrome (GAS) or the "fight or flight" response. The GAS is characterized over time by three stages. The first stage of alarm reaction is the "fight or flight" response that occurs when an organism is subjected to a stressor. The body first shows an alarm

reaction such as increased vital signs, sleep disturbance, fatigue, or muscle tension. The second stage, state of resistance, is the body's attempt to use its resources to keep its physiology on a normal course during stress. The third stage, state of exhaustion, is bodily exhaustion whereby structural changes occur in the organ system that can ultimately lead to death.

The major concepts of Selye's theory (1974) of internal and external stress can be applied to BPH in the following manner: Internal or external stress can be said to create BPH symptoms and prostate structural changes. Prostate symptomatology has been associated with the physiology of aging (internal stress) and with psychologic dissension (external stress).

Selye (1974) determined that internal stress manifests itself as a syndrome. This theoretical statement of internal stress correlates with the normal physiology of elderly men who develop a benign prostate adenoma, a syndrome of BPH (Guyton, 1981). Men with BPH develop urinary obstructive symptoms of decreased force of stream, hesitancy, intermittency of stream, incomplete bladder emptying, post-void dribbling, nocturia, urgency, and daytime frequency (Abrams, 1979; Jorgensen et al., 1986).

Selye (1974) proposed that the body responds to internal stress by stimulation of an alarm reaction. Miller (1988) attributed this alarm reaction to stress adrenergic end plates located within an organ itself, that in turn

affects the autonomic nervous system. According to Miller (1988), the prostate has the same autonomic end plates as other organs (stomach, colon, and bronchi) and vessels that have been identified as stress adrenergic. Adrenergic, cholinergic, and VIPergic (vasoactive intestinal peptide) fibers have been found in the prostate. Miller (1988) determined neurologists know when the autonomic nervous system is stimulated by stress; the body responds with a cascade effect wherein all organs, including the prostate, are affected.

Selye (1974) also stated that psychologic stress can create physiologic symptoms. Studies support this proposition of the association in organ symptomatology to external stress and physiologic responses.

Four studies of naval populations presented data on physical symptoms with relation to stress (Rahe, 1974). Subjects' recent life changes were gathered by the use of the Schedule of Recent Experience Questionnaire (Hawking, Davies, & Holmes, 1957). Body symptom recognition was estimated by the use of the Health Opinion Survey (MacMillan, 1957). The studies revealed a significant correlation between the perceptions of severity in recent life event changes and an increase in manifestations of physical symptomatology.

Miller (1988) described a study of 218 men complaining of various prostate symptoms. An exam was conducted in a urologic office. In the summing-up portion of the visit, a

description of the actions of stress was given to the patient (specifically describing the expected normal physiologic behavior of the prostate in response to stress) along with a program for stress reduction. No other treatment, tests, or prescriptions were given to the patients. In six months, 134 patients returned for a follow-up visit. Of the 134 patients, 86 percent indicated they were better or cured. The study's findings suggest that stress was a potent factor in the development, prolongation, and perpetuation of symptoms in the condition known generally as chronic prostatitis (Miller, 1988).

Selye (1974) determined that if stress persists, distress will result, causing structural organ damage. Isaacs (1990) and Guyton (1981) described prostate structural damage in BPH as pathologic prostate hyperplasia and degeneration of the prostate gland.

Selye (1956, p. 55) claimed that "stress is a state manifested by a syndrome" and that psychological and physiological sources can combine to produce stress. The internal stress of an enlarged prostate progresses into distress, described by Selye (1974) as the General Adaptation Syndrome. Research studies have concentrated on severity of symptoms of BPH rather than distress; according to Selye (1974) distress precedes prostate symptomatology.

Related Literature

While many studies describe findings of physiological symptomatology, no studies were found that assessed a

patient's degree of distress associated with prostate symptoms. The purpose of this review is to summarize the relevant literature concerning other parameters characteristic of benign prostate hypertrophy (BPH).

Symptoms

Madsen and Iversen (1983) described symptoms of BPH as: decreased quality of stream, straining, urge incontinence, hesitancy, intermittency, bladder retention, nocturia, frequency, and terminal dribbling. Fridmodt-Moller et al. (1984) conducted a study using severity of symptoms as a measurement of improvement after a transurethral prostatectomy. Eighty-five percent of the 84 patients had improved severity of symptom scores, although the preoperative scores did not quantitatively correlate with postoperative severity of symptom scores.

The studies of Abrams and Feneley (1978); Brooks, Hanani, and Braf (1983); and Castro, Griffiths, and Shackman (1969) were unable to substantiate the relationship of symptomatology to BPH. In a survey involving 471 patients, Fowler et al. (1988) found improvement in 93 percent of severely and 79 percent of moderately symptomatic patients after a transurethral prostatectomy. The patients were asked to discriminate by "none," "little," "some," and "a lot" within parameters of incomplete bladder emptying, intermittency of stream, post-void dribbling, and dysuria. Fowler et al. (1988) recommended the decision to operate primarily should depend on the patient's quality of life

values as related to symptoms and not on medical evaluation and opinion.

Uroflowmeter Analysis

Lepor and Rigaud (1990) studied 32 men with moderate symptoms of BPH defined as urinary peak flow rates from 4 to 15 ml. per second. After a transurethral prostatectomy, the mean urinary peak flow rate improved 108 percent (Lepor & Rigaud (1990). Ball, Feneley, and Abrams (1981) also concluded that a decreased urinary flow rate was an indication of urinary obstruction caused from BPH.

In contrast, a study of 200 males (Jorgensen, Jensen, Bille-Brahe, & Morgensen, 1986) found uroflowmeter screening ineffective to confirm a clinical impression of BPH. Dorflinger, Bruskewitz, Jensen, Iversen, and Madsen's (1986) data suggested that improvement in urinary peak flow rate occurred in 40 percent of BPH patients without treatment. Brooks et al. (1983) had similar conclusions. In 50 percent of the cases, general screening procedures with qualitative flowmeter analysis did not add much information for the diagnosis of BPH (Brooks et al., 1983).

Herbison, Fraundorfer, and Walton (1988) studied 128 men between the ages of 49 and 89 for symptoms of poor flow, post-micturition dribbling, hesitancy, nocturia, and urgency. Each symptom was classified as either being not present, occasionally, or frequently a problem. The results were that poor urinary flow rate, followed by

post-micturition dribbling, nocturia, and bladder hesitancy were the most common complaints. Abnormal flowmeter results corresponded to symptoms of poor stream, hesitancy, and nocturia, indicating prostatic involvement. Herbison et al. (1988) determined that symptoms and uroflowmeter results were not significantly related for accurate selection of patients as candidates for surgical intervention. Iversen, Bruskewitz, Jensen, and Madsen (1983) reached similar conclusions following a prospective study. No role could be identified for uroflowmetry as a screening test; however, measurement of urinary flow rate might be justified in patients with vague symptoms of BPH (Iversen, et al., 1983).

Urinary Post-Void Residual Volume

Bruskewitz, Iversen, and Madsen (1982) studied 49 adult males with BPH. The subjects were prescreened using symptom analysis, rectal examination, urinary post-void residual volumes, excretory urography, and cystoscopy. While residual urine was significantly reduced after a transurethral resection of the prostate, the researchers could find no correlation between preoperative residual urine and postoperative outcome.

Abrams and Griffiths (1979) and Turner-Warwick et al. (1973) believed that elevated residual urine reflects bladder dysfunction rather than prostate obstruction. Although other studies (Lepor & Rigaud, 1990) confirm post-void residual urine is present in men with BPH, there

is no research disputing that residual urine determination probably reflects bladder dysfunction.

Symptoms and Prostate Weight

A study of 68 patients, conducted at the University of Wisconsin School of Medicine, examined prostatic weight compared to preoperative and postoperative symptoms (Jensen, Bruskewitz, Iversen, & Madsen (1983). The findings revealed smaller prostates caused more obstructive symptoms. The study concluded that prostatic weight had only a modest influence on symptomatology, not significant enough to predict the outcome of a transurethral resection of the prostate.

According to the study of Frimodt-Moller et al. (1984), there was no evidence to substantiate a clinical value in using prostatic gram weight as a preoperative assessment criteria. In contrast, Castro et al. (1969) and Turner-Warwick et al. (1973) reported there appeared to be a direct relation between prostate size and the degree of prostate obstruction. Castro et al. (1969) recommended that the size of the prostate be measured radiologically as part of the standard assessment of patients under consideration for a transurethral prostatectomy.

Summary

While certain symptoms and objective findings may be helpful to establish a differential diagnosis, neither is entirely accurate to be used as a tool in diagnosing BPH (Graversen et al., 1989). Most often, prostatic surgical

intervention is considered to be the treatment of choice for BPH symptomatology because statistical evidence indicates that BPH is the most common cause of urinary problems in men over 50 years old. Furthermore, surgical intervention provides relief of symptoms for a large proportion of the population. Graversen et al. (1989) and Fowler et al. (1988) recommended that health providers inform patients of the potential complications associated with surgery such as postoperative mortality, morbidity, and disabilities. Given this information, patients may weigh the quality of life in nontreatment versus surgical intervention.

Chapter 3

RESEARCH METHODOLOGY

This chapter describes the research methodology used in this study within the following sections: (a) research design, (b) research procedures, (c) sample selection, (d) data collection instruments, (e) instrument reliability and validity, (f) data collection procedures, (g) data analysis, and (h) strengths and limitations of the study.

Research Design

The design chosen for this study was an ex post facto correlational design. The purpose of this study was to determine if there is a relationship between degree of distress and other parameters that are characteristic of BPH. The independent variables of symptom severity, urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue occurred in the natural course of events. The independent variables were not manipulated nor was there random assignment of the subjects into a control or experimental group. The dependent variable, degree of distress, was the variable under investigation.

Research Procedures

The study was conducted in the following manner. The subjects were prescreened by a urology physician who adhered to the Urological Department's standardized workup for BPH. The BPH preoperative workup required that the following information be obtained and documented on the patient's

chart: medical history, physical examination, urinalysis, urine culture, uroflowmeter analysis, and urinary post-void residual volume. After the patient had been diagnosed with BPH and had agreed to surgical intervention as recommended by the urologist, the physician advised the researcher that the patient was a candidate for the research study. The researcher then asked the patient if he was willing to participate in the study.

The patient was given a brief explanation of the study and told his refusal would have no bearing on the medical care he would receive. If the patient volunteered to participate in the study, he was asked to sign a voluntary consent form. Then a BPH Symptomatic Distress Questionnaire and an Objective Findings Analysis were coded for identification purposes by using the first initial of the patient's last name and the last four digits of his Social Security number.

The researcher interviewed the patient in an exam room to ensure confidentiality. Initially, demographic data was collected on the patient's socioeconomic status, age, race, marital status, and illness history. The patient's responses to his perceived severity and distress associated with BPH symptoms were recorded on the subjective questionnaire. After obtaining the subjective information from the client, the researcher transferred objective findings from the medical record to the data collection form entitled Objective Findings Analysis. The Objective

Findings Analysis form gathered six types of information:

(a) urinary peak flow rate, (b) urinary post-void residual volume, (c) urine culture results, (d) confirmation of BPH by the medical provider, (e) validation that the patient's consent for surgery had been obtained, and (f) gram weight of resected prostatic tissue, obtained postoperatively from the pathology report.

The duration of the entire study was two months with approximately one hour or less devoted to gathering subjective information from each patient. Postoperative follow-up visits are routine protocol for all patients undergoing a transurethral resection of the prostate; however, postsurgical assessment information was not included in this study. Withdrawal of the subjects from the study was based upon advice from the attending physician or lack of consent from the patient for surgical intervention. Data collection for this research project did not interfere with appropriate medical interventions during or after the conclusion of the study. The study terminated after 20 subjects had a BPH subjective and objective evaluation.

Sample Selection

A nonprobability quota sampling approach was used to select the subjects. The sample consisted of 20 men, 50 years and older, who self-selected themselves into the study based on presentation to the VA Urology Outpatient Clinic with prostate symptoms and who consented to a BPH prescreening procedure by a urology physician. The subjects

were qualified to receive medical care at the VA Medical Center. The study was reviewed and approved by the Research Committees for the Protection of Human Subjects at San Jose State University, Department of Veterans Affairs, and Stanford University (Appendix A). Each subject voluntarily agreed to participate in the study by signing a consent form (Appendix B).

Data Collection Instruments

Two data collection instruments were used to collect data pertinent to benign prostate hypertrophy. The Symptomatic Distress Questionnaire (Appendix D) gathered subjective information from subjects. The Objective Findings Analysis (Appendix E) was the fact-finding method used to collect objective information. The data collection instruments are described as follows.

The Symptomatic Distress Questionnaire collected data regarding the current date, the patient's age and identification number, and Madsen and Iversen's (1983) Symptom Profile Score. The Symptom Profile (Madsen & Iversen, 1983) is a list of eight prostate symptoms with a five-point weighted scale to indicate severity of symptoms. A degree of distress rating scale was added by the researcher to match each category of symptoms. This five-point weighted scale gathered information regarding the patient's perceived discomfort associated with each prostate symptom. Degree of distress was rated on a scale broken down into levels of none, mild, moderate, high, and extreme.

The Objective Findings Analysis gathered six types of information: (a) urinary peak flow rate, (b) urinary post-void residual volume, (c) urine culture results, (d) confirmation of BPH by the medical provider, (e) validation that the patient's consent for surgery had been obtained, and (f) gram weight of resected prostatic tissue, obtained from the pathology report. The urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue were rated measurements. Urinary peak flow rates were measured in milliliters per second by a uroflowmeter; urinary post-void residual volumes were measured in milliliters. Weights of resected prostatic tissue were measured in grams on a scale in the pathology laboratory. Affirmative/negative medical provider response boxes were provided to: (a) confirm the patient's problem as BPH, (b) assure the nonexistence of a urinary or prostate infection, and (c) validate the patient's consent for surgery.

Instrument Reliability and Validity

Reliability and validity of the Symptom Profile Score (Madsen & Iverson, 1983) has not been determined; however, the scoring system has been used in ongoing clinical trials by the Veterans Administration (Barry, 1990). Degree of distress, a measurement of the patient's perceptions of BPH discomfort, was susceptible to errors in measurement (Polit & Hungler, 1983, p. 394). The problem in defining stress is that not all situations produce the same degree of stress

for all individuals (Beck, 1983). In addition, reliability in degree of distress, expressed by the patient, cannot be established as perceptual values tend to fluctuate according to time, circumstance, and experience (Selye, 1974).

Content validity of symptoms, symptom severity, urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue have been established as indicators of BPH in previous studies (Fridmondt-Moller et al., 1984; Lepor & Rigaud, 1990; Madsen & Iversen, 1983). The homogeneousness of the instrument measuring degrees of distress from low to high strengthens construct validity (Beck, 1983).

Reliability of the uroflowmeter to measure urinary peak flow rates, the urinary post-void residual volume obtained by catheterization, and the scale used to weigh resected prostatic tissue was based on consistency, as the same units of measurement are routinely used at the VA Medical Center (Polit & Hungler, 1983). The uroflowmeter and scales were calibrated by the VA's biomedical department prior to beginning the study. Urine cultures were processed in the VA's laboratory, staffed by licensed laboratory personnel.

Data Collection Procedures

Data collection consisted of completing a Symptomatic Distress Questionnaire and an Objective Findings Analysis. The Symptomatic Distress Questionnaire gathered subjective information by interviewing subjects in an exam room at the VA Medical Center in the Urology Outpatient Clinic. The

interview was conducted by the researcher. The Objective Findings Analysis documented objective findings that were transferred by the researcher from the subject's medical record to the Objective Findings Analysis. The values described as objective findings were collected as follows: (a) the urinary peak flow rate was collected and measured by a urinary flowmeter that was located in the bathroom in the Urology Clinic; (b) a staff nurse collected the urinary post-void residual volume by catheterization in an examining room; the residual urine was recorded and sent to the laboratory for culture examination; and (c) the prostatic tissue was removed during surgery by a urologist surgeon and weighed in the pathology laboratory on a scale by a pathologist.

The data were collected between August 1990 and October 1990. A total of 20 Subjective Questionnaires and 20 Objective Findings Analysis forms were matched and assembled according to each patient's identification code for preparation of statistical analysis.

Data Analysis

This was a non-experimental, correlational study of patients with BPH symptoms. Data from a Symptomatic Distress Questionnaire and Objective Findings Analysis were used to analyze the existence and relationships between the variables. Descriptive analysis and Pearson r correlational analysis were used in the statistical computations.

Socioeconomic status, age, race, marital status, illness history were not information for control; however, questions regarding the above demographic variables were included in the interview. These data offered a detailed description of this study's sample population for the purpose of comparison to other research samples.

The Symptomatic Distress Questionnaire yielded scores for the variables severity of symptoms and degree of distress. These data provided a weighted value score profile that described the patient's perceived discomfort from BPH symptoms. The Objective Findings Analysis yielded measured parameters on urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue. These data provided a measured value profile that described objective findings in patients diagnosed with BPH. Descriptive statistics (mean, median, and standard deviation) were computed in order to describe the distribution of values for the dependent and independent variables.

In compiling the data, a frequency index was used to describe patients' degree of distress associated with prostate symptoms. Polit and Hungler (1983) described frequency distribution as "a systematic array of numerical values from the lowest to the highest, together with a count of the number of times each value was obtained" (pg. 614). The degree of distress weighted rating scale was none, mild, moderate, high, and extreme. The high score indicated a

high degree of distress, and a low score indicated a low degree of distress.

Relationships between the variables were analyzed using the Pearson r correlational statistic. This statistical computation was used to determine the relationship between degree of distress and: (a) severity of symptoms, (b) urinary peak flow rate, (c) urinary post-void residual volume, and (d) gram weight of resected tissue.

Urine culture results, confirmation of BPH, and validation of the subjects' consent for surgery were not collected for examination, but were used as a control over conditions that might affect the dependent variable under investigation. All calculations were done by computer analysis.

Strengths and Limitations

In choosing an ex post facto design, it was important to identify the strengths and limitations of the study. The strengths of the study were as follows:

1. This type of design was considered to be feasible and within ethical restraints. Patients accepted into the study self-selected themselves based on presentation of prostate symptoms.

2. The design was practical in that it could be implemented in a short period of time, thereby reducing the risk of changes in behavior or environmental influences that might have jeopardized the internal validity of the study.

3. The interview method used to collect subjective information was beneficial because a medical provider interviewer was available to clarify terminology, thereby decreasing the threat to internal validity of the study.

4. Affirmative/negative medical provider response boxes were provided on the Objective Findings Analysis to:

(a) confirm the patient's problem as BPH, (b) assure of the nonexistence of urinary or prostate infections, and (c) validate the patient's consent for surgery. The purpose of this information was to enhance the validity of the study by maintaining control of conditions that might affect the dependent variable under investigation.

The limitations of the study were identified as follows:

1. There was a risk of mortality due to patients changing their minds and declining surgical intervention, a threat to internal validity of the study.

2. The patients may have felt obligated to please the medical provider, either exaggerating or minimizing prostate symptoms and degree of distress, a threat to external validity of the study.

3. Inability to manipulate the independent variables, the lack of randomization of subjects, and a small sample size restricted the ability of the researcher to generalize the findings beyond the participating sample.

4. Validity and reliability of the instruments have not been established.

Chapter 4

FINDINGS

This chapter presents a description of the sample and the study's findings that answer the following four research questions:

1. In men diagnosed with BPH, is there a relationship between severity of symptoms and degree of distress?

2. In men diagnosed with BPH, is there a relationship between urinary peak flow rate and degree of distress?

3. In men diagnosed with BPH, is there a relationship between urinary post-void residual volume and degree of distress?

4. In men diagnosed with BPH, is there a relationship between prostatic weight and degree of distress?

The findings are reported within the value profile and correlation profile sections. The chapter concludes with a summary of the findings.

Description of the Sample

The sample of 20 participants was obtained from the outpatient clinic at a Veterans Administration Medical Center in Northern California. The mean age of the participants was 69.6. The mean educational level for this sample was 12.3 years of schooling, slightly above the level of a high school graduate.

Eleven participants were married, three were widowers, five were divorced, and one was separated. The ethnic composition of the sample included seventeen Caucasians

and three Hispanics.

Income levels reported among the sample included fifteen under \$10,000 annually, three between \$10,000-\$20,000 annually, and two between \$20,000-\$30,000 annually. Thirteen of the participants were voluntarily retired, three were retired due to disability, and four were currently working. Participants' occupations, presently working and retired, included ten blue-collar workers, five white-collar workers, three professionals, and one military career professional.

None of the 20 participants reported radiation or Agent Orange exposure during their military careers. Six participants had no health problems other than BPH. Nine participants cited health problems such as: hypertension, arthritis, arteriosclerosis, kidney stones, depression, asthma, emphysema, and thyroid problems. Three participants had a history of heart problems.

Value Profile

Value Profile reflects the basic information used to measure the variables. It is the basis from which the relationship between the variables was later determined. The Value Profile includes the subjective scores derived from the Symptomatic Distress Questionnaire and the objective values derived from the Objective Findings Analysis. Subjective findings are discussed under subtopic sections entitled: severity of symptoms, degree of distress, and frequency profile. Objective findings are discussed

under subtopic sections entitled: urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue. This section concludes with a subscale analysis that outlines the mean, median, and standard deviation of the variables.

Subjective Findings

The Symptomatic Distress Questionnaires (Appendix D) asked questions regarding the participants' perceptions of the severity of symptoms (entitled Symptom Profile) and degree of distress (entitled Degree of Distress) associated with each prostate symptom. Symptom Profile (Madson & Iverson, 1983) contained a list of 8 prostate symptoms identified as: (a) decreased force of stream, (b) hesitancy of initiation, (c) intermittency of stream, (d) incomplete bladder emptying, (e) post-void dribbling, (f) urgency, (g) nocturia, and (h) daytime urinary frequency.

Severity of Symptoms

Participants were asked to rate their perceptions of the severity of symptoms associated with each prostate symptom. Since the purpose of this portion of the research process was to determine the relationship between severity of symptoms and degree of distress, each symptom was broken down into categories and a score for each category was obtained in the following manner. Each prostate symptom was rated from 0 to 4. If a participant stated that a symptom was nonexistent or "none," that response was given a rating of 0 by the researcher. A response of "occasional" was

given a rating of 1, "moderate" response was given a rating of 2, "frequent" response was given a rating of 3, and an "always" response was given a rating of 4. The higher the score the more severe the symptom. The scores were then totaled for a category score. For each prostate symptom category, there was a possible score of 80. This score represents the total score of a symptom category if all 20 participants rated it as severe (20×4). A high score for a symptom category was considered to be a score of 50 and above. A low score was considered to be a score of 35 and below.

Table 1, presents the weighted scores for severity of symptoms obtained by totaling participants' responses to each symptom category. The weighted score values for each symptom were: (a) decreased force of stream (50), (b) hesitancy of initiation (34), (c) intermittency of stream (42), (d) incomplete bladder emptying (39), (e) post-void dribbling (41), (f) urgency (40), (g) nocturia (57), and (h) daytime frequency (40). The symptoms receiving the highest scores in terms of severity of symptoms were nocturia (57) and decreased force of stream (50). The symptom receiving the lowest score was hesitancy of initiation (34).

Table 1 also presents a rank ordering of the prostate symptom by score. The rank order was established by placing the scores obtained for each symptom category in order from the highest to the lowest score. The most severe symptom

was ranked as number one; the least severe symptom was ranked as number eight.

Table 1

Participants' Perceptions of the Severity of Each
Prostate Symptom (N = 20)

Prostate Symptoms	Weighted Scores for Severity	Rank Order By Severity
Decreased Force of Stream	50	2
Hesitancy of Initiation	34	8
Intermittency of Stream	42	3
Incomplete Bladder Emptying	39	5
Post-void Dribbling	41	4
Urgency	40	5
Nocturia	57	1
Daytime Frequency	40	5

Degree of Distress

The column on the Symptomatic Distress form entitled Degree of Distress was provided for the participant to rate the degree of distress associated with each prostate symptom. Since the purpose of this research was to determine the relationship between severity of symptoms and degree of distress, each symptom was broken down into categories and a score for each category was obtained in the

following manner. Each prostate symptom was rated from 0-4. If a participant stated that a symptom was nonexistent or "none," that response was given a rating of 0 by the researcher. A response of "mild" was given a rating of 1, "moderate" response was given a rating of 2, "high" response was given a rating of 3, and an "extreme" response was given a rating of 4. The more unpleasant or troublesome the prostate symptom, the higher the rating. For each prostate symptom category, there was a possible total score of 80. This score represents the score of a symptom category if all 20 participants rated it as extreme (20×4). A high score for a symptom category was considered to be a score of 35 and above. A low score was considered to be a score of 25 and below.

Table 2, presents the weighted scores for degree of distress obtained by totaling participants' responses to each symptom category. The weighted scores obtained for each symptom were: (a) decreased force of stream (32), (b) hesitancy of initiation (24), (c) intermittency of stream (27), (d) incomplete bladder emptying (37), (e) post-void dribbling (33), (f) urgency (33), (g) nocturia (40), and (h) daytime frequency (23). The symptoms receiving the highest scores were nocturia (40) and incomplete bladder emptying (37). The symptoms receiving the lowest scores were daytime frequency (23) and hesitancy of initiation (24).

Table 2 also presents the rank ordering of the prostate symptoms by score. The rank order was established by placing the scores obtained for each symptom category in order from the highest to the lowest score. The most distressing symptom was ranked as number one; the least distressing symptom was ranked as number eight. The rank order of symptoms, in terms of degree of distress, was: nocturia (1), incomplete bladder emptying (2), post-void dribbling (3), urgency (3), decreased force of stream (5),

Table 2

Participants' Perceptions of Distress for Each Prostate Symptom (N = 20)

Prostate Symptoms	Weighted Scores for Distress	Rank Order By Distress
Decreased Force of Stream	32	5
Hesitancy of Initiation	24	7
Intermittency of Stream	27	6
Incomplete Bladder Emptying	37	2
Post-void Dribbling	33	3
Urgency	33	3
Nocturia	40	1
Daytime Frequency	23	

intermittency of stream (6), hesitancy of initiation (7), and daytime frequency (8).

Frequency Profile

Table 3, the Frequency Profile represents the frequency with which a response to degree of distress (none, mild, moderate, high, and extreme) was noted by participants for each symptom. Since there were eight prostate symptom categories and 20 participants, the total number of possible responses was 160. The frequency with which a distress rating was noted are as follows: the response "none" was rated 37 times, "mild" 33 times, "moderate" 60 times, "high" 24 times, and "extreme" 6 times.

Table 3

Rating Frequency of Responses in Degree of Distress (N = 20)

Degree of Distress Rating Scale	Number of Times Each Rating was Checked	(%) of Responses for Each Rating Category
None	37	23.125
Mild	33	20.625
Moderate	60	37.500
High	24	15.000
Extreme	6	3.750

Table 3 also presents the percentage of participants' rating each response category (none, mild, moderate, high, and extreme). The percentage was obtained by dividing the frequency of each response category by the total possible response (160). Therefore, as summarized in Table 3, 37.5% of the participants indicated that prostate symptoms caused an overall moderate degree of distress; 15% indicated high distress, and 3.75% indicated extreme distress.

Objective Findings

The Objective Findings Analysis (Appendix E) recorded the urinary peak flow rate, urinary post-void residual volume, and gram weight of resected tissue. The following section reviews the findings for these variables.

Urinary Peak Flow Rate

Participants were found to have a range of urinary peak flow rates varying from 3.7 ml/sec. to 24.6 ml/sec. Fourteen of the twenty participants had peak flow rates of 15 ml/sec. or less. Generally, current opinion holds that urinary peak flow rates under 15 ml/sec. are a sign of urinary obstruction (Iversen et al., 1983).

Urinary Post-Void Residual Volume

Participants' urinary post-void residual volumes were obtained by catheterization. The volume of urine collected ranged from 20 ml. to 300 ml. Eighteen of the participants had urinary post-void residuals of 50 ml. or higher. Abrams (1977) determined that a residual urine of 50 ml. or more was an indication of urinary obstruction.

Gram Weight of Resected Prostatic Tissue

The participants' prostate specimens were removed during surgery. The gram weight of resected prostatic tissue ranged from 6 to 60 grams. Ten of the participants had specimens weighing over 18 grams. Generally, current opinion holds that there is no standard of gram weight that is a sign of urinary obstruction (Frimodt-Moller et al., 1984; Sarmina & Resnick, 1989).

Subscale Analysis

Table 4 presents the mean, median, and standard deviation that were derived from the scores and values obtained for each of the five variables used in the study. The variables were: (a) severity of symptoms, (b) degree of distress, (c) urinary peak flow rate, (d) urinary post-void residual volume, and (e) gram weight of resected tissue.

The severity of symptom mean (17.15) and median (16.20) for participant's individual scores were similar to findings obtained in other studies. For example, Lepor and Rigaud (1990) reported a mean of 15.3 and Frimodt-Moller et al. (1984) reported a median of 16.

The urinary peak flow rate mean (11.60) and median (9.65) was slightly higher than those reported in similar studies. For example, Abrams (1977) reported a mean of 8.0 and Frimodt-Moller et al. (1984) reported a median of 9.5.

The urinary post-void residual volume mean (155.75) and median (152.50) was significantly higher than those reported in similar studies. For example, Gerstenberg et al. (1982)

reported a mean of 40 and Bruskewitz et al. (1982) reported a median of 55.

Table 4

Median, Mean, and Standard Deviation for Each of the
Five Variables (N = 20)

Variables	Median	Mean	Standard Deviation
<hr/>			
Severity of			
Symptoms	16.20	17.15	4.88
Degree of			
Distress	13.00	12.45	6.20
PFR	9.65	11.60	5.85
PVR	152.50	155.75	88.63
GM.WT.	16.00	21.85	15.04

The gram weight of resected prostate tissue mean (21.85) and median (16.00) approximated to those reported in similar studies. For example, Lepor and Rigaud (1989) reported a mean of 16.5 and Frimodt-Moller et al. (1984) reported a median of 20.

Correlation Profile

The correlation profile stands for the findings in terms of the relationships between variables. The following section reviews statistical findings regarding those

relationships. Table 5 presents the findings regarding the relationship between degree of distress and the independent variables identified as: (a) severity of symptoms,, (b) urinary peak flow rate, (c) urinary post-void residual volume, and (d) gram weight of resected prostatic tissue.

Pearson product movement correlation coefficient, symbolized by the letter r was used to determine the degree of relationship between the variables. The level of significance was set at $p = <.05$.

Table 5

Correlations Between Degree of Distress and the Independent Variables (N = 20)

Independent Variables	Degree of Distress	p Value
Severity of Symptoms	$r = .642$	.001*
Urinary Peak Flow Rate	$r = -.208$	.189
Post-Void Residual Volume	$r = -.044$	.427
Gram Weight of Resected Tissue	$r = -.262$	.126

Note: * = $p <.05$

The first research hypothesis was: "In men diagnosed with BPH, there is a positive relationship between severity of symptoms and degree of distress." Degree of distress

showed a positive relationship with severity of symptoms reaching a statistically significant level of $r = .642$, $p = .001$. Therefore, the first hypothesis was accepted. It indicated that the higher the perceived severity of symptoms, the higher the degree of distress.

The second hypothesis was: "In men diagnosed with BPH, there is no statistically significant relationship between degree of distress and urinary peak flow rate, urinary post-void residual volume, or gram weight of resected prostatic tissue. The correlations between these variables and degree of distress did not reach a level of statistical significance as indicated in Table 5. A negative correlation means, the lower the urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue, the higher the degree of distress. There is no apparent trend in these negative correlations. On the basis of the statistical findings, the second hypothesis was accepted.

Summary

Approximately one-third of the participants (37.5%) perceived they had a moderate degree of distress from prostate symptoms. Nocturia was ranked as being the most severe and distressing prostate symptom.

The most significant finding of this study was that degree of distress was determined to be statistically correlated with severity of symptom ($p = .001$ level). The relationship between degree of distress and urinary peak

flow rate, urinary post-void residual volume, or gram weight of resected prostatic tissue were associated negatively, but the difference did not attain a level of significance.

Chapter 5

SUMMARY OF STUDY

This chapter summarizes the study with the sections: summary, findings, and significance of findings. It ends with a section called "Conclusion and Implications."

Summary

The researcher conducted this study to examine the degree of distress experienced by men with prostate symptoms and to compare these degrees of distress to other parameters that are characteristic of benign prostate hypertrophy (BPH). The purpose of the study was to identify the patient's perception of degree of distress associated with BPH.

This ex post facto research study was conducted at a Veterans Administrative Medical Center in a large metropolitan area in Northwestern California. The research problem under study was to determine the relationship between degree of distress and: (a) severity of symptoms, (b) urinary peak flow rate, (c) urinary post-void residual volume, and (d) gram weight of resected prostatic tissue in men with BPH symptoms.

Selye's Stress and Distress Theory (1974) was selected as the conceptual guide that gave direction to the research study. The operational variable, degree of distress, was derived from the theory's concept that distress preceeds physiologic symptomology.

Degrees of distress were integrated into a Subjective Questionnaire using a rating scale format. The degree of distress scale matched each category of prostate symptoms and corresponded with Madsen and Iverson's (1983) severity of symptoms scoring method. Prostate symptoms with associated severity of symptoms and objective findings (urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue), were shown as parameters of BPH based on the literature review. The Objective Finding's Analysis was developed to gather the objective data: (a) urinary peak flow rate, (c) urinary post-void residual volume, and (d) gram weight of resected prostatic tissue. In this study, the Objective Findings Analysis included documentation of urine culture results, confirmation of BPH, and validation of the subject's consent for surgery to enhance internal validity of the study.

Twenty subjects volunteered to participate in the study with the following restrictive eligibility requirements: (a) males 50 years and older, (b) identified prostate symptoms, (c) candidates for a transurethral resection of the prostate determined by a prescreening procedure, and (d) a signed consent for surgical intervention. A Symptomatic Distress Questionnaire and Objective Findings Analysis were the instruments used to collect subjective and objective data. Each patient was interviewed by the researcher who recorded the patient's responses on the Subjective Questionnaire. Data obtained for the Objective

Finding's Analysis was collected from patients' medical records.

Upon completion of the data collection phase of the study, data were analyzed using descriptive and correlational statistics. The relationships between degree of distress and: severity of symptoms, urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue were analyzed.

Findings

The study's findings were derived from a sample of 20 participants. All of the participants qualified for health care at the Veterans Administration Medical Center. Six participants reported no health problems other than BPH. The mean age of the participants was 60.6. The following review of the findings of this study will be discussed under the separate categories of descriptive findings and correlational findings.

Descriptive Findings

On the Symptomatic Distress Questionnaire, the participants rated their perceptions of the severity of prostate symptoms on a weighted rating scale. The participants responded that nocturia and decreased force of stream were the most severe symptoms. These findings and the severity of symptom's mean and median were similar to the findings of other studies.

Participants also rated their perceptions of the degree of distress of prostate symptoms on a weighted rating scale.

The participants responded that nocturia and incomplete bladder emptying were the most distressing symptoms. In determining the degree of distress, 37.5% of the participants perceived that prostate symptoms caused an overall moderate degree of distress.

On the Objective Findings Analysis, the participants' urinary peak flow rates, urinary post-void residual volumes, and gram weight of resected prostatic tissue were recorded in measured values. In this study, the objective findings were: (a) urinary peak flow rates' mean and median were slightly higher than those reported in similar studies, (b) urinary post-void residual volumes' mean and median were significantly higher than those reported in similar studies, and (c) gram weight of resected prostatic tissues' mean and median were similar to those reported in similar studies.

Correlational Findings

Pearson r correlation analysis was used to determine the degree of relationship between severity of symptoms and degree of distress. The analysis identified a statistically significant positive correlation ($p = .001$) between degree of distress and severity of symptoms.

Pearson r correlation analysis was used to determine the relationship between degree of distress and: urinary peak flow rates, urinary post-void residual volume, and gram weight of resected prostatic tissue. The analysis did not identify a statistically significant relationship between degree of distress and the independent variables. However,

the values of this study's sample is consistent with values for other samples reported by Graversen et al. (1989).

Significance of Findings

This study explored the relationship between degree of distress and: severity of symptoms, urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue. Findings indicate: (a) there is a significant relationship between degree of distress and severity of symptoms, and (b) there is no significant relationship between degree of distress and: urinary peak flow rate, urinary post-void residual volume, or gram weight of resected prostatic tissue.

Findings indicate a relationship between severity of symptoms and the degree of distress to which patients are bothered by BPH symptoms. However, a clear majority of patients who were symptomatic reported only moderate discomfort from BPH symptoms. It is reasonable to infer that patients who are not severely bothered by their symptoms would agree favorably to nonsurgical treatment interventions.

The failure to produce a significant relationship between subjective and objective parameters (urinary peak flow rate, urinary post-void residual volume, and gram weight of resected prostatic tissue) has also been reported in other research studies. It is reasonable to question the need for routine uroflowmeter testing and invasive catheterization on men with BPH symptoms.

Conclusions and Implications

This study implies that severity of symptoms should not be the total consideration in management of BPH. Degree of distress is shown to closely correlate to severity of symptoms and should be included as part of the assessment criteria. Since other parameters have not been found to be reliable in the assessment of BPH, degree of distress and severity of symptoms may be the only assessment criteria that should be considered as indicators for surgical intervention.

Nurses need to be aware that patients with acute bladder obstruction from BPH have a serious and life-threatening problem that requires immediate attention and referral for medical intervention. Patients with BPH should be advised to have periodic assessments for secondary anatomic changes that could compromise bladder and kidney function. Nurses should be knowledgeable about the optimal treatment strategies available for symptoms that interfere with a patient's life-style. With mild degrees of distress associated with BPH symptoms, nurses can teach patients coping strategies, thereby enabling them to function effectively without having surgical intervention.

Further studies are needed to determine the long-term risks of untreated BPH in respect to bladder or renal damage and to examine the relationship between degrees of distress and prostate cancer. In addition, research studies using a

larger sample are needed to establish validity of using degree of distress as a BPH assessment criteria.

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APPENDIX A

Human Subjects Research Committee Approval

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

Project/Program Title: Symptomatic Distress Due to BPH

Principal Investigator: Christine J. Gilmore, FNP

Review Date: August 7, 1990

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills.
2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances.
3. Every effort has been made to decrease risk to subjects.

RECOMMENDATION: APPROVED

Signature of Chairman

Jeffrey M. Baden, M.D.

STANFORD UNIVERSITY

SUBJECT: CERTIFICATION OF HUMAN SUBJECTS APPROVAL

DATE: August 7, 1990

TO: C.J. Gilmore, FNP

FROM: Chairman, Medical Committee for the Protection of
Human Subjects in Research

PROTOCOL ENTITLED: Symptomatic Distress Due to BPH

The Panel approved human subject involvement in your
research project on August 7, 1990.

The expiration date of this approval is August 6, 1991.
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.

David Oakes, M.D., Chairman

SAN JOSE STATE UNIVERSITY

To: Christine J. Gilmore

From: Charles R. Bolz

Office of Graduate Studies and Research

Date: October 24, 1990

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

"Symptomatic Distress Due to BPH"

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 _____ immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

APPENDIX B
Request for Participation

SYMPTOMATIC DISTRESS DUE TO BPH

INFORMED CONSENT

You are invited to participate in a study of symptomatic distress due to benign prostate hypertrophy (BPH). BPH is an enlargement of the prostate gland caused from hormone changes that occurs in most middle-aged men. As the prostate gland enlarges, symptoms can be bothersome to each man differently in his ability to function physically and socially. We hope to learn the degree of annoyance men experience in connection with BPH. This information may be beneficial as an assessment criteria and be useful in determining future medical management of this disorder.

You were selected as a possible participant in this study because you are having prostate symptoms and have agreed to surgical intervention by a transurethral resection of the prostate that may help to relieve your symptoms.

If you decide to participate, Nurse Practitioner Christine Gilmore will ask you questions concerning your symptoms and associated distress with these symptoms. The purpose is for you to describe how bothersome prostate symptoms have become in your daily life. The questionnaire will take approximately one hour of your time on this initial clinic appointment. Other procedures or surgical interventions, if indicated, are to be considered as management of your care in the _____. The risks of harm expected in the proposed research are not greater than those

ordinarily encountered in daily life or during routine physical or psychological examinations or tests. The expected inconvenience is the additional time involved in collecting your description of the degree of annoyance you experience in connection with prostate symptoms. The benefit to you, as a patient, will be that the medical provider will be better able to evaluate your condition, before and after treatment, and determine the appropriate medical management that would help to relieve your symptoms. We cannot and do not guarantee or promise that you will receive any benefits from this study.

Any data that may be published in scientific journals will not reveal the identity of the subjects. In the interest of public safety, patient information will be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, has the right to inspect research records and, therefore, could learn your identity if you are involved in any study performed under FDA supervision. Your identity and health information will be released to the Veterans Administration's Urological Medical Providers, if information is disclosed that would be pertinent to your medical care.

No payment will be provided for this project. There will be no additional cost to you for participation in this study.

There is no institution or company involved in the study through funding, cooperative research, or by providing study drugs or equipment.

There is no financial relationship with any sponsoring organization in this research.

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.

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 researcher will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs.

In the unlikely event you are injured as a result of participation in this study, the _____ will furnish humanitarian emergency medical care (for non-veteran 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 Claim Act (for non-veteran participants). For further information, contact the VA District Counsel at _____.

You do not waive any liability rights for personal injury by signing this form.

For further information, please call, or write the Administrative Panel on Human Subjects in Medical Research at _____.

In addition, if you are not satisfied with the manner in which this study is being conducted 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.

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.

Participant's Signature & Date

Signature of Investigator

APPENDIX C

Permission to Use Symptom Profile Score

DEPARTMENT OF VETERANS AFFAIRS

Date: October 23, 1990

Dear Ms. Gilmore:

I am gald to give you permission to use my symptoms score system as published in the testbook BENIGN PROSTATIC HYPERTROPHY by F. Hinman, Jr. and S. Boyarsky, 1983 pp. 763-765. I like your modification and believe it represents some improvement in the practical application of the scoring system. There are many variations published on my scoring system and making up a perfect scoring system would probably be a good subject for your thesis alone.

I wish you good luck with your thesis.

Sincerely yours,

Paul O. Madsen, M.D., PH.D.

Professor of Urology

APPENDIX D
Symptomatic Distress Questionnaire

ID#: _____

AGE:

BPH SYMPTOMATIC DISTRESS

SYMPTOM SCALE: 0-None (absence of symptoms)
 1-Occasional (less than 20% of time)
 2-Moderate (occurs 20-50% of the time)
 3-Frequent (occurs over 50% of the time)
 4-Always (always present)

DEGREE OF DISTRESS: To what degree have these symptoms become unpleasant or troublesome to you in your daily activities.

SYMPTOM PROFILEDEGREE OF DISTRESS

A. Decrease Force of Stream:

0-none	0-none
1-occasionally reduced	1-mild
2-moderately reduced	2-moderate
3-frequently weak	3-high
4-always; with dribbling	4-extreme

B. Hesitancy of Initiation:

0-none	0-none
1-occasional	1-mild
2-moderate	2-moderate
3-frequent; up to 1 minute	3-high
4-always; lasts over 1 minute	4-severe

C. Intermittency of Stream:

0-none	0-none
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1-occasional	1-mild
2-moderate	2-moderate
3-frequent	3-high
4-always	4-severe

D. Incomplete Bladder Emptying:

0-complete bladder emptying	0-none
1-occasional retention	1-mild
2-moderate retention	2-moderate
3-frequent retention	3-high
4-always some retention	4-severe

E. Post-void Dribbling:

0-none	0-none
1-occasional	1-mild
2-moderate	2-moderate
3-frequent	3-high
4-always	4-extreme

F. Urgency:

0-none	0-none
1-occasional	1-mild
2-moderate	2-moderate
3-frequent	3-high
4-always	4-extreme

G. Nocturia:

0-none	0-none
1-once a night	1-mild
2-one to two times per night	2-moderate
3-three to four times per night	3-high

4-four or more times per night 4-extreme

H. Daytime Frequency

0-every three hours or more 0-none

1-every two to three hours 1-mild

2-every one to two hours 2-moderate

3-every hour 3-high

4-every 30 minutes or more 4-extreme

Total Score_____

Total Score_____

APPENDIX E
Objective Findings Analysis

ID#_____

OBJECTIVE FINDINGS ANALYSIS

Peak Urinary Flow Rate_____cc/sec.

Post-Void Residual Volume_____ml.

Resected Prostatic Tissue_____grams

Urine Culture:

☐ Positive☐ Negative

Benign Prostate Hypertrophy:

☐ Yes☐ NoPatient's Consent for a Transurethral Resection of the
Prostate:☐ Yes☐ No