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Evaluating diagnostic and treatment modalities in the management of benign prostatic hyperplasia in the Veterans Administration population

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EVALUATING DIAGNOSTIC AND TREATMENT MODALITIES IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA IN THE VETERANS ADMINISTRATION POPULATION

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**Thesis submitted to the
School of Pharmacy
at West Virginia University
in partial fulfillment of the requirements for the degree of**

**Master of Science
in
Pharmaceutical Systems and Policy**

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ABSTRACT

**Evaluating Diagnostic and Treatment Modalities in the Management of Benign
Prostatic Hyperplasia in the Veterans Administration Population**

Ancilla W. Fernandes

Benign prostatic hyperplasia (BPH), a common prostatic condition among aging males
significantly affects quality of life. Though clinical practice guidelines for BPH
management have been established, little research has been done to determine adherence
to such guidelines. To assess adherence to such guidelines, this study evaluated
diagnostic and treatment modalities in BPH management in the VA population (a
population with a high percentage of elderly males). A survey, containing simulated
BPH patient cases, was mailed to 292 VA urologists, of which 114 (39%) responded.
Urologists showed good adherence to the recommended diagnostic tests but preferences
varied for the optional tests depending upon severity of the patient case. Preferences for
treatment also showed considerable variation for the patient cases with different degrees
of symptom severity. The treatment failure rate for initiation therapy was determined to
be 42%. Study results need to be validated by tracking BPH patients using VA claims
data.

For Mummy and Daddy

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CHAPTER ONE

INTRODUCTION

Benign prostatic hyperplasia (BPH), a non cancerous enlargement of the prostate gland, occurs as part of the aging process in most men and results in obstruction of the flow of urine from the bladder. Approximately 50 percent of men over the age of 60 have symptomatic BPH and by age 80, one in four men in the US will require treatment for the relief of symptoms associated with BPH (Barry 1990,1991). In the US, more than 1 million men present annually with BPH (McIntyre & Grady, 1996). The high prevalence of symptomatic benign prostatic hyperplasia (BPH) in elderly males is evidenced by the fact that in 1989 transurethral prostactomy (TURP) was performed on over a million males worldwide (Kirby & Christmas, 1993). Moreover, after cataract extraction, TURP was the second most common operation performed on males over the age of 65 years (Kirby & Christmas, 1993). According to 1993 estimates, due to longevity of males in both the developing and the developed world, approximately 30 percent of males with BPH would require prostactomy unless equally effective alternative treatments are developed (Kirby & Christmas, 1993). Autopsy studies have indicated foci of histological BPH in the prostates of approximately 10 percent of males aged 40 years and an increase in incidence with age upto almost 90 percent in males over the age of 80 years (Berry, Coffey, Walsh & Ewing, 1984; Moore, 1943). Direct costs of treatment for BPH range from $1,162 to $12,788 (Medicare) per person in the first year depending upon the treatment strategy utilized (AHCPR, 1994). Also, depending upon

the primary treatment, the costs for the second year range for $69 to $640. Thus, the condition impacts a significant portion of the health care budget (Baum, 1997).

Accurate data on BPH as a primary cause of death are currently not available for most countries in the world. The reported rate for the United States is 1.8 per 100,000 (AHCPR,1994). However, the lack of uniformity in criteria for attributing deaths to BPH limits the usefulness of such figures. Although mortality from BPH is extremely rare, the condition significantly impacts the quality of life in aging males by producing bothersome urinary symptoms (Roehrborn, 1994). The patients seeking medical attention do so due to the symptoms. The symptoms interrupt normal daytime activities and/or sleep, create anxiety and reduce general perception of health. This reduces the quality of life of the patient significantly (AHCPR, 1994). The symptoms of BPH are implications of a complex interaction between the prostate and the bladder (McConnell, 1991). This interaction gives rise to both irritative and obstructive symptoms. Obstructive symptoms include decreased urinary stream force, sensation of incomplete emptying, difficulty initiating the stream (hesitancy), and interruption of the stream (intermittency), while irritative symptoms primarily include increased frequency, urgency, and nocturia.

Enlargement of the prostate causes increase in urethral resistance and this decreases the bladder's ability to generate pressure in order to maintain flow (Roehrborn, 1994). Elevated detrusor pressures are achieved by hypertrophy, which is a compensatory mechanism of the smooth muscle within the bladder wall. Although this adaptive mechanism maintains relatively normal flow during the initial phases of the disease, the detrusor smooth muscle is not necessarily functioning in an entirely normal way. This obstruction-induced detrusor instability gives rise to the irritative symptoms of

urinary frequency and urgency. Obstruction may also affect bladder sensory pathways resulting in sensation of a full bladder, even at low volumes. Frequency and urgency associated with urination may continue after bedtime, giving rise to nocturia. Many of the symptoms of BPH may be aggravated because of age-related abnormalities in bladder function (Roehrborn, 1994).

Little is known about the ultimate complications and morbidity associated with untreated BPH, however sometimes it may lead to more serious symptomatic complications (AHCPR,1994; Mebust, Howltgrewe, Cockett and Peters, 1989). Obstruction of outlet may progress to development of acute urinary retention, i.e. the sudden inability to urinate. Worldwide, 20 to 50 percent of patients are in urinary retention when they undergo prostate surgery (AHCPR, 1994). Also, the likelihood that a patient with a given symptom complex will go into complete urinary retention over a given timespan is not well defined. Sometimes, uninhibited bladder contractions may result in urinary incontinence. Patients with bladder outlet obstruction from any cause may develop bladder calculi secondary to urinary stasis or a failure to pass stones formed in the kidney through the lower urinary tract (Roehrborn, 1994). Urinary tract infection can also cause complications. The probability of urinary tract infection increases as residual urine increases usually, but this has not been observed with BPH. However, if infection does occur, the patient may develop typical symptoms of dysuria, as well as acute exacerbation of urinary frequency and urgency (Roehrborn, 1994). Some cases may result in detrusor failure. However, the probability of this has not yet been well established. In a minority of patients, bladder wall may be extensively damaged. Patients may develop bladder diverticula which may impair bladder emptying. Thus,

progression of symptoms in some patients may actually be due to progression of detrusor

dysfunction rather than due to progression of the anatomic obstruction. Uncommonly,

patients may show a significant decline in renal function (Mukamel, Nissenkorn, Boner,

& Servadio, 1979). Rarely, large veins in the prostate may rupture leading to gross

hematuria in patients with BPH. However, these are some of the less commonly

observed complications of the disease (Roehrborn, 1994).

Guidelines for Management of BPH

In 1994, recommendations for the diagnosis and treatment of BPH were

developed by a multidisciplinary panel of experts, under the sponsorship of the Agency

for Healthcare Research and Quality (AHRQ), (formerly the Agency for Health Care

Policy and Research-AHCPR)(AHCPR, 1994) (see Appendix Figure B). The AHRQ

(formerly AHCPR) was established to enhance the quality, appropriateness and

effectiveness of health care services and access to these services. It carries out its

mission by conducting and supporting general health services research, including medical

effectiveness research, facilitating development of clinical practice guidelines, and

disseminating research findings and guidelines to health care providers, policy makers

and the public. Guidelines assist practitioners and patients make appropriate decisions

for different clinical conditions. One of the major reasons for the development of

guidelines for BPH was the significant geographic variation in treatment patterns. This

was because of lack of sufficient understanding of etiology of the disease at that time and

the lack of long-term outcomes data regarding its natural history, treatment and indicators

to aid in the proper timing of treatment. The guidelines for BPH make specific

recommendations to identify both the most effective methods for diagnosing BPH and the most appropriate treatments for BPH based on patient preferences and clinical need.

Symptom Assessment and Diagnosis

Diagnosis commonly includes four steps: medical history, physical exam, urinalysis and serum creatinine. Medical history is important to determine the presence and severity of BPH. This is because most patients seeking treatment for BPH do so because of bothersome symptoms. Symptoms of BPH are quantified using the AUA symptom score, developed by the American Urological Association (Roberts, 1994). The AUA symptom scoring system is an easy to use patient's self-administered questionnaire for measuring symptom level (see Appendix C). It consists of seven questions relating to symptoms of BPH also called as prostatism. Each question on the AUA symptom index can yield 0 to 5 points, producing a total symptom score with a range from 0 to 35. This is used to categorize patients as having mild (a score of 0 to 7), moderate (a score of 8 to 19), and severe BPH (a score of 20 to 35). This tool has been tested, validated and found to be most reliable instrument to quantify BPH related symptoms (Barry, Fowler, O'Leary & Bruskewitz, 1992). Hence, it should be used in treatment planning and periodically in follow-up, at least annually.

In addition to quantification of symptoms, an adequate medical history focusing on the urinary tract, previous surgical procedures, general health issues, and fitness for possible treatment procedures should also be obtained (Roehrborn, 1994). Specific areas which need to be discussed include a history of hematuria, urinary tract infection, diabetes, nervous system disease (Parkinson's disease or stroke), urethral stricture

disease, urinary retention and aggravation of symptoms by cold or sinus and current medication information to determine if the patient is taking drugs that impair bladder contractility (anticholinergics) or that increase outflow resistance (alpha sympathomimetics).

Physical examination is in the form of a digital rectal examination (DRE) and a focused neurological examination (Roehrborn, 1994). These are done primarily to detect prostate or rectal malignancy, evaluate anal sphincter tone and rule out neurological problems that may cause BPH like symptoms. Also, DRE establishes the approximate size of the prostate gland, which is important for patients who choose invasive therapy (McConnell, 1996). DRE provides a sufficiently accurate measurement in most cases. However, the prostate size should not be considered in deciding whether active treatment is required. This is because prostate size does not correlate with severity of symptoms, degree of urodynamic obstruction or treatment outcomes (Roehrborn, Chinn & Fulgham, 1986; Simonsen, Moller-Madsen, & Dorflinger, 1987; Donkervoort, Zinner, & Sterling, 1975; Bissada, Finkbeiner, & Radman, 1976; Meyhoff, Ingemann, Nordling, & Hald, 1981).

Urinalysis is performed either by the dipstick method or by examining the spun sediment (Roehrborn, 1994). This is done to rule out urinary tract infection and haematuria. There is insufficient evidence about urinalysis being an effective screening procedure (Preventive Task Force, 1989). This is because serious urinary tract disorders are relatively uncommon, giving a low positive predictive value. However, in older men with higher prevalence of these disorders the benefit of this innocuous test outweighs the harm. Also, this test is necessary because a pathological finding will appropriately

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prompt tests such as renal imaging or endoscopy. If a dipstick test is utilized, a test that includes fields for leukocyte esterase and nitric tests for the detection of bacteria and urinary tract infection should be utilized (Roehrborn, 1994).

Serum creatinine is a tool used to measure renal dysfunction (Roehrborn, 1994). There are many reasons for obtaining this test. First, to determine the percentage of BPH patients who may have renal insufficiency. Renal insufficiency has been mentioned in seven studies, which analyzed BPH treatments.   In these, the percentage of patients with renal insufficiency was between 0.3 to 30 percent, and the mean was 13.6 percent (McConnell, Barry & Bruskewitz, 1994). The second important reason is that patients with renal insufficiency have an increased risk for post-operative complications (Roehrborn, 1994). The risk is 25 percent for patients with renal insufficiency compared to 17 percent for patients without the condition (Mebust, Howltgrewe, & Crockett, 1989). Also, patients with renal insufficiency have up to a six-fold increase in mortality rate when surgically treated (Holtgrewe & Valk, 1962, Melchoir, Valk, Foret, & Mebust, 1974). An elevated serum creatinine guides the physician to recommend appropriate imaging studies to evaluate the upper urinary tract in these patients (McConnell, 1996). It is implicitly understood that if any other measure of renal function has been used, then there is no need for laboratory investigation (Roehrborn, 1994).

In addition to the tests described above, there are some other tests which are used for diagnosing BPH, but are not part of recommended guidelines and are left to the discretion of the physician and patient. These include measurement of prostate specific antigen (PSA) levels, uroflowmetry, pressure flow/max flow, measurement of post voidal

residual volume, filling cystometry, urethrocystoscopy and imaging of urinary tract (McConnell, 1996).

Measurement of prostate-specific antigen (PSA) is an optional test in AHRQ's guidelines. This test in combination with a DRE, increases the detection rate of prostate cancer over DRE alone (McConnell, 1996). However, making this test mandatory would be controversial because (a) there is a significant overlap of PSA values between men with BPH and men with organ defined cancer, (b) there is lack of consensus concerning the optimal evaluation of minimally elevated PSA values, and (c) there is no evidence that shows that PSA testing reduces mortality or morbidity of men with prostatic disease. Also, comparison of serum PSA values of men with BPH and organ defined prostate cancer has not shown statistical difference (Partin, Carter & Chan, 1990). Another important factor is the value of early prostate cancer detection itself. No data is available to establish that earlier diagnosis of cancer leads to decrease in morbidity and mortality (McConnell, 1996).

Urologists typically use measurements of peak urinary flow rate. Uroflowmetry as it is called, involves electronic recording of the urinary flow rate throughout the course of micturition (McConnell, 1996). It is a non-invasive urodynamic test used to evaluate patients presenting with symptoms of bladder outlet obstruction. An abnormally low rate may be due to an obstruction (hyperplastic prostate, urethral stricture, meatal stenosis or other obstruction) or due to weakness of the detrusor muscle.

Post voidal residual (PVR) volume, is the volume of fluid remaining in the bladder immediately after completion of micturition (McConnell, 1996). Normal residual volume ranges from 0.09 to 2.24 ml, with a mean of 0.53 ml (Hinnman & Cox, 1967).

About 78 percent of normal men have residual volumes of less than 5 ml, and 100 percent have volumes of less than 12 ml (DiMare, Fish, Harper & Politano, 1963). PVR measurement can be done both by non-invasive and invasive methods. The most common method is urethral in-and-out catherization (McConnell, 1996). This method is accurate if performed correctly but carries a small risk of discomfort, urethral injury, urinary tract infection and transient bacteraemia. Ultrasonography is the non-invasive method. Traditionally, urologists have assumed that increasing amounts of PVR denote BPH progression and are thus an indication for surgery. However, data is lacking to support the predictive value of PVR (McConnell, 1996).

Pressure flow studies should be proposed to patients if an invasive treatment is considered (McConnell, 1996). Pressure flow studies differentiate between patients with a low Q_{max} secondary to obstruction and those whose low Q_{max} is caused by a decompensated or neurogenic bladder. They may also identify high-pressure obstruction in symptomatic men with normal flow rates. Pressure flow studies should be performed when distinction between urethral obstruction and impaired detrusor contractility will affect therapeutic decisions. These studies have been developed to fill a diagnostic gap. Another point to remember is that though pressure flow plots are generally recognized to be more informative, interpretation of these plots has not been standardized (McConnell, 1996).

Filling cystometry is an invasive urodynamic study, which provides information on bladder capacity, presence and threshold of uninhibited detrusor contractions (UDCs) and bladder compliance (McConnell, 1996). UDCs are present in about 60 percent of men with prostatism and correlate strongly with irritative voiding symptoms. Filling

cystometry may be considered for men in urinary retention for those who cannot urinate for a pressure flow study.

Urethrocystoscopy is a test recommended for men with prostatism who have a history of haematuria, urethral stricture disease, bladder cancer, or prior lower urinary tract surgery (McConnell, 1996). It helps the surgeon determine the most appropriate technical approach for men with moderate to severe symptoms, who have chosen surgical or other invasive therapy. Urethrocystoscopy provides visual documentation of the appearance of the prostatic urethra and bladder in men with BPH. Historically, urologists believed that the visual appearance of the lower urinary tract defines the severity of disease or predicts the outcome of treatment. However, this procedure has been poorly studied (McConnell, 1996). It is associated with certain benefits and harms. Potential benefits include ability to demonstrate enlargement of prostate and visual obstruction of the urethra and the bladder neck, identification of specific anatomical abnormalities that alter clinical decision making, identification of bladder stones, trabeculation, cellules and diverticular, measurement of PVR, and ruling out unrelated bladder and urethral pathology. Potential harms are patient discomfort, anaesthetic or sedative risk, urinary tract infection, bleeding and retention of urine. The probabilities of these harms is uncertain and except for discomfort their occurrence is likely to be infrequent. However, the endoscopic appearance of the bladder and prostate is often felt to be helpful in the decision to treat i.e. it helps to select specific techniques, not determine the need for treatment (McConnell, 1996).

Upper urinary tract imaging is another process not recommended unless the patient also has one or more of the following: haematuria, urinary tract infection, renal

insufficiency, history of urolithiasis, history of urinary tract surgery. It can be performed

either by intravenous urography (IVU) or by ultrasonography (McConnell, 1996). IVU is

associated with a 0.1 percent incidence of significant adverse events, whereas no direct

adverse events are known to be associated with ultrasonography.

Treatment of BPH

        AHRQ guidelines recommend four treatment options for managing BPH:

watchful waiting, surgery, drug therapy and balloon dilation. Watchful waiting is used

mainly for patients with mild symptoms. A mild symptomatic patient (AUA score less

than 7) is advised to watch his symptoms and to return in one year for a repeat evaluation

unless a change directs him to return sooner. A man with moderate or severe symptoms

(AUA score greater than 8) is required to be counseled on all four treatment approaches.

The treatment decision is to be made by the patient with guidance from the health care

provider.

         Surgical options include open surgery, transurethral resection of the prostate

(TURP), and transurethral incision of the prostate (TUIP). These are used most of the

times. Other surgical procedures which may be used but not recommended in the

guidelines are trans-vesical prostactomy, retropubic prostactomy, transurethral laser

incision of the prostate, transurethral microwave therapy and transurethral needle ablation

(Kirby & Christmas, 1993). Surgery is recommended for the following types of patients:

(a) those with refractory urinary retention who have shown failure with at least one

attempt at catheter removal, and (b) those who have shown to have recurrent urinary tract

infections, recurrent gross haematuria, bladder stones or renal insufficiency clearly due to BPH (McConnell, 1996).

Open surgery involves surgical removal of the inner portion of the prostate via a suprapubic or retropubic incision in the lower abdominal area. The procedure is rarely done through the perineum. Open prostactomy requires a longer hospital stay compared to other surgical procedures (McConnell, 1996). Open surgery as a treatment for BPH is now mainly indicated for large prostate weighing in excess of 80-100 grams. Only 5-10 percent fall into this category. It is also recommended for patients with osteoarthritis and severe urethral stricture disease (Kirby & Christmas, 1993).

TURP is one of the most common procedures for benign prostates. It has mortality rates of below 0.5 percent in the best medical centers (Holtgrewe, 1989). It is the most common active treatment for symptomatic BPH and usually requires a hospital stay (McConnell, 1996). The most common problem associated with TURP is Transurethral (TUR) syndrome (Kirby & Christmas, 1993). The syndrome is characterized by neurological symptoms such as confusion, coma, bradycardia, shortness of breadth, cyanosis, oliguria and either an elevation or a decrease in blood pressure. This is however uncommon with an incidence of less than 0.5 percent. It is more likely to occur after lengthy resections.

TUIP is a procedure which decreases symptom scores equivalent to TURP but with fewer complications. This procedure requires shorter hospitalization than TURP and is associated with a lower incidence of bladder neck stenosis (Kirby & Christmas, 1993). Some of the other complications that may be associated with surgical prostactomy are hemorrhage, incontinence, sexual dysfunction and urethral stricture. Because of the

significant incidence of complication from prostactomy, a number of physical means of relieving infravesical obstruction have been developed (Kirby & Christmas, 1993). Balloon dilatation (dilation) is one such procedure.

There are two types of prostate balloon dilatation systems that are currently available: one type utilizes a disposable endoscopic system to ensure correct positioning of the balloon so that distal spincter is not dilated (Kirby & Christmas, 1993). The other device employs a location balloon inflate in the bulbar urethra, and a collar on the prostate balloon, which is palpable per rectum, to ensure that the device is correctly sited. The results achieved with these devices have been somewhat mixed (Kirby & Christmas, 1993). Also, it is now beginning to emerge from a number of studies that balloon dilation is likely to be effective in smaller prostates and in those patients who do not have severe obstruction or prominent middle lobe enlargement. It is of no benefit in those patients with either acute or chronic retention, in whom a TURP will yield far better results. Also 80 percent of cases require re-treatment within four years (Kirby & Christmas, 1993).

The non-invasive treatment approach for BPH is drug therapy. It primarily involves use of alpha-1 adrenergic antagonists or 5-alpha reductase inhibitors (Kirby & Christmas, 1993). Alpha-blockers act by inhibiting alpha-adrenergic mediated contraction of prostatic smooth muscles (McConnell, 1996). The main disadvantage of using these drugs is its effect on blood pressure. It requires caution when used in hypertensive patients (Jardin, 1994). The most commonly used alpha-blockers are terazosin, doxazosin and prazosin. 5-alpha reductase inhibitors act by blocking the conversion of dihydroxytestosterone to testosterone. Finasteride is the most investigated 5-alpha reductase inhibitor at the present time. Early clinical studies suggested a

reduction of prostate volume of 18 percent within three months using doses of 5mg/day, as well as modest improvements in symptom score and uroflow (Stoner, 1992). In a six-month study the prostatic shrinkage was 28 percent (Stoner, 1990). The drug appears well tolerated in all reported studies and the only adverse effects that occurred more commonly were impotence, decreased libido and ejaculatory disturbances (Kirby & Christmas, 1993). However, this has been observed in less than 4 percent of patients and is reversible on stopping medications (Kirby & Christmas, 1993). A new medical agent that has been introduced is tamsulosin, which is a prostate specific alpha-blocker, thus associated with fewer hypotensive effects (Beduschi, Beduschi & Ricardo, 1998). Another drug under clinical investigation is episteride, a 5-alpha reductase inhibitor (McConnell, 1996).

In addition to all these approaches, there is an alternative therapy method that has shown an increase in recent times. This includes use of phytotherapeutic preparations like hemlock, ergot, strychnine, pumpkinseeds, rye pollen, hypoxis rooperus etc, cholesterol lowering agents, amino acid complexes, and organic extracts (Fritzpatrick, Dreikorn, Habib, Mebust, Perin, & Shultz, 1994). Their mechanisms of action have not been documented. Also, a critical analysis of data available suggests that the effects of phytotherapy and others are no better than those of placebo treatment (Dreikorn & Schonhofer, 1995)

Adherence to Guidelines

Since the inception of the guidelines in 1994, two studies have been done to evaluate practice trends of practitioners. A national survey of urologists in 1995,

revealed practices consistent with the published guidelines in terms of examinations and

tests for men with suspected BPH (Barry, Fowler, Bin & Oesterling, 1997). The AUA

symptom index demonstrated routine use with a majority of the respondents and the use

of the optional tests varied. Also, alpha-blockers were reported to be prescribed four

times as often as finasteride and TURP was the most common surgical procedure.

Another study determined adherence rates to guidelines by reviewing inpatient records

(Hood, Burgess, Holtgrewe, Fleming, Mebust & Connolly, 1997). This study however,

also concluded that adherence to the guidelines recommendations is documented

infrequently in the medical records. The literature failed to identify any studies assessing

practice patterns of VA urologists for management of BPH, a gap that the proposed study

will aim to fill.

The Veterans Administration Program

In the U.S., the Veterans Administration (VA) program is designed to provide

health care services to retired, disabled, and otherwise deserving veterans of various U.S.

military conflicts. As of July 1, 1997, the VA population in the United States was

estimated at 25.6 million (VA Fact Sheet, 1998). Almost one-third of the nation's

population-- approximately 70 million persons who are veterans, dependents and

survivors of deceased veterans -- are potentially eligible for VA benefits and services.

VA's fiscal year 1998 appropriation was $40.4 billion of which $17.4 billion was for

medical programs. The Veterans Administration's health care system has grown from 54

hospitals in 1930 to 173 medical centers, with at least one in each of the 48 contiguous

states, Puerto Rico and District of Columbia (VA Fact Sheet, 1998). In recent years, VA

has restructured its medical system into 22 integrated networks of care called Veterans Integrated Services Network (VISN's). See Appendix A for a listing of the twenty -two VISNs. These are focused on pooling and aligning resources to best meet local needs in the most cost-effective manner and provide greater access to care. The VA program treats nearly a million patients annually in VA hospitals, 82,400 in nursing homes and 25,000 in domicilaries. VA's outpatient clinics register approximately 29.3 million visits a year. An estimated 3 million individuals receive care annually (VA Fact Sheet, 1998).

Problem Statement

There are about 25 million male veterans living in the U. S. and its territories with the average age being 57 years (VA fact sheet, 1998). Of these, more than 44 percent are over the age of 60. Also, almost 18 percent of them are between 50 and 59 years old and hence in the next decade upon reaching 60 would be at 50 percent risk of developing BPH. With an increase in the life expectancy, the cases of BPH among this population is expected to continue to increase. This probably will result in increased utilization of healthcare resources and increased costs for managing this condition. With increasing healthcare costs, sincere attempts must be made to ensure appropriate utilization of diagnostic procedures and treatment alternatives in the management of BPH while producing optimum outcomes in terms of relief of symptoms. Unnecessary procedures and duplicative therapy if avoided can greatly reduce health care costs for the Veterans Administration program. Since the inception of AHRQ guidelines in 1994, not much research has been conducted to determine its implementation in actual practice. Also, there has been no study conducted with regard to management of BPH in the VA

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population. Thus, an increasing elderly population, increasing prevalence of the disease, and increasing health care costs in the VA program warrant greater attention to appropriate management of BPH in this population.

Study Goals, Objectives and Research Questions

Even though clinical practice guidelines for the diagnosis and treatment of BPH have been established, little research has been conducted to determine its effect on urologists' practices in the VA population. Hence, the overall goal of this study is to evaluate preferences of VA urologists in the use of diagnostic and treatment modalities in the management of BPH. To accomplish this goal the following objectives and research questions will be addressed:

Objective 1: To compare the preferences of VA urologists for diagnosing BPH with established guidelines.

Research Question 1:

How do the preferences of the urologists practicing in the VA health care system compare to established guidelines, for diagnostic evaluation of patients with benign prostatic hyperplasia?

The available studies have assessed national urologists and patient data to measure adherence to guidelines. However, VA urologists have not been studied. Thus these urologists would be surveyed to determine similarities and differences in their preferences of diagnostic tests with the guidelines. Also, effect of severity level on the preference of these tests by respondents will be assessed.

Objective 2: To compare the preferences of VA urologists for treating BPH with expert opinion/established guidelines.

Research Question 2:

How do the preferences of VA urologists compare with the guidelines/ expert opinion while selecting appropriate treatment option(s) for patients with benign prostatic hyperplasia?

Here again there are no studies which have assessed management of symptoms with preferences of urologist in the VA system. Also, the effect of severity levels on treatment preferences has not been studied. The instrument used in this study includes simulated patients with all three levels of severity (mild, moderate, severe). The preferences of the respondents will be compared with the guidelines/ expert panel in an attempt to address the above research question.

Objective 3: To determine the effect of demographic and practice characteristics on preferences of VA urologists for diagnosing and treating BPH.

Research Question 3:

Do the demographic and practice characteristics of VA urologists have any effect on their preferences for diagnostic and therapeutic management of patients with benign prostatic hyperplasia?

This research question is proposed because the study with national urologists indicated that older urologist ordered use of certain optional diagnostic tests more often than younger urologists (Barry, Fowler, Bin & Oesterling, 1997). Also, younger urologists preferred alpha-blockers compared to older urologists for management of BPH

symptoms. Thus, it is necessary to determine if similar effects are observed among VA urologists. Also, effects of other practice characteristics such as years of practice and patient load on practice preferences will be assessed.

Objective 4: To assess the level of agreement among VA urologists on the use of diagnostic tests and procedures for patients presenting with BPH symptoms.

Research Question 4:

Do VA urologists demonstrate agreement among themselves for diagnostic evaluation of patients with BPH symptoms?

This research question is proposed because a study with international urologists indicated disagreement for management of lower urinary tract symptoms (LUTS) (Hansen & Zdanowski, 1997). The study concluded that this might result in increased medical costs. Also, it demonstrated that LUTS from BPH seemed to be managed with the poorest agreement. Exploring this research question will help identify if a similar situation exists in the VA system for diagnostic evaluation of BPH.

Objective 5: To assess the level of agreement among VA urologists on the use of treatment modalities for patients diagnosed with BPH.

Research Question 5:

Do VA urologists demonstrate agreement among themselves for selection of treatment option for patients diagnosed with BPH?

Similar to the previous research question, this one intends to explore agreement among VA urologists in their preferences for selection of treatment options for BPH.

Objective 6: To determine the treatment failure rate for BPH in the VA population and the types of treatment switches commonly made followed failed initiation therapy.

Research Question 6:

What is the treatment failure rate for initiation therapy among VA urologists and what are the common treatment switches utilized?

Here an estimate of the failure rate of initial therapy for BPH among VA urologists will be assessed. Also, the common switches among therapeutic options will be obtained. This will help identify what initiation treatments result in the most switches, and this when combined with treatment preferences will help justify if practice patterns are appropriate.

Objective 7: To estimate the cost of diagnosing BPH in the VA population based on the preferences of VA urologists.

Research Question 7:

What is the cost of diagnosing BPH patients in the VA system based on preferences of VA urologists?

The intent is to determine average costs associated with the diagnostic evaluation of BPH in the VA. Average charges for these tests will be used for this purpose. This will help determine the burden or impact that the utilization of diagnostic tests has on the VA health care system.

Research Significance

The results of this study will help us better understand the preferences of urologists for management of benign prostatic hyperplasia in the Veterans Administration population. These preferences will be compared to the clinical guidelines available for BPH. The practice guidelines aim to manage BPH in the most cost-effective manner with optimum outcomes. This comparison of preferences of urologists with the guidelines will help identify inappropriate patterns, if any. If inappropriate practice patterns are identified, these can be further studied by the Veteran Administration Medical Centers (VAMC). The VAMC's can then target urologists not conforming to practice guidelines, with educational programs which increase awareness and improve compliance. Costs associated with management of BPH depends on the severity of the disease and the appropriate course of treatment. Increasing the awareness and use of appropriate practice patterns may help curb unnecessary dollars spent on this condition. Thus, the VAMC's will be able to reduce expenditures due to duplicative and or unnecessary processes. Currently there are no economic studies that estimate the economic burden of BPH to the US health care system (Kortt & Bootman, 1996). However, it has been estimated that BPH, affects approximately 14 million older men and costs $4 billion annually (McConnell, Barry, & Bruskewitz, 1994; Tsang & Garraway, 1994). Though we do not aim to measure the economic burden of BPH to the US health care system, we will be able to estimate burden to the VA system for diagnosis of BPH, based on preferences of urologists. These results may not be generalizable to other healthcare settings. But the lessons learned would definitely help management of BPH in other healthcare settings. Also, the results of this exploratory study will serve as a springboard for similar studies

that assess adherence to published guidelines for different types of disease conditions in different healthcare settings.

In this chapter, the prevalence and burden of BPH, the different procedures available for diagnosing and treating BPH and the need and significance of the study were presented. The next chapter will present a review of the existing literature associated with BPH management.

CHAPTER TWO

LITERATURE REVIEW

This chapter summarizes the results of an extensive review of the available literature with regards to published practice guidelines for the management of BPH, comparison of diagnostic and treatment modalities available for BPH, use of simulated patients in assessing practice patterns and studies involving management of BPH by urologists and other health care providers.

Benign Prostatic Hyperplasia: Diagnostic and Treatment

Clinical Practice Guidelines

The AHRQ (formerly, AHCPR) BPH guideline panel worked for 3 years to develop recommendations for practice (AHCPR, 1994). Literature associated with BPH diagnosis and treatment was reviewed and critiqued by a panel of experts before making the recommendations. Draft guidelines were then extensively peer reviewed by experts and practitioners. Input was also obtained from men affected by BPH before the publication of the final report. This report had two sections; diagnostic evaluation and treatment recommendations.

Diagnostic Evaluation

The following procedures were recommended in the initial evaluation of all patients presenting with prostatism, with the exception of testing of PSA (which is optional) (AHCPR, 1994)

-Detailed medical history focusing on the urinary tract, previous surgical procedures, general health issues and fitness for possible surgical procedures, in order to detect other causes of voiding dysfunction and comorbities that may complicate treatment. In case of some patients a voiding diary is considered to be helpful to determine the frequency of complaint.

-Physical examination which included a digital rectal examination and a focused neurological examination.

-Urinalysis done by microscopic examination of sediment.

-Measurement of serum creatinine for assessment of renal function

Measurement of PSA is optional. This test increases the detection of prostate cancer at an earlier stage. But it does not distinguish well between patients with symptomatic BPH and cancer patients. Also, there was no evidence that it would decrease mortality and morbidity associated from cancer

Symptom assessment- Symptoms are to be quantified by means of a self-administered AUA symptom index. It has 7 questions relative to symptom of BPH or prostatism. In this scoring system, symptoms are classified as mild (0 to 7), moderate (8 to 19), or severe (20 to 35). This index is to be used in assessing degree of bothersomeness, treatment planning and follow-up. However, AUA symptom index is not meant to be the sole means of diagnosing, BPH, because the symptoms are not specific for BPH.

Additional diagnostics tests- Several additional diagnostic tests are available to assess patients with BPH. However, due to insufficient data, their value in diagnosing BPH and predicting the results of treatment were not confirmed. Moreover, the differences between normal and abnormal values were uncertain.   Results of these tests could not

define BPH and their use was not considered as mandatory. However, they could be useful for patients with uncertain diagnosis. The tests that are considered optional after initial evaluation are: a) Uroflowmetry, helps identify those, whose maximum flow rate is not diminished and are less likely to benefit from therapy. b) PVR, is poorly reproducible for a given patient. However, it could be used during the course of the disease to detect worsening of bladder function. c) Pressure flow studies, are helpful in patients with previous bladder dysfunction as the cause of lower urinary tract symptoms. However, their usefulness in work-up of patient is thought to be questionable. In addition to these optional tests, there are tests which are not recommended in routine cases. These include imaging of upper urinary tract, filling cystometry, and urethrocystoscopy, particularly when symptoms are associated with hematuria and/or irritation.

Treatment Recommendations

The AHRQ- BPH guideline panel made the following recommendations for treatment of patients with BPH (McDonnell, Barry, Bruskewitz et al, 1994):

Patients with mild symptoms – these included patients with an AUA score of less than 7. The strategy for these patients is watchful waiting. The patient is to be monitored, usually annually and instructed on behavioral techniques to reduce symptoms, such as limiting fluid intake and avoiding decongestants. If patient's symptoms progress to moderate and severe levels then symptoms have to be reassessed and other treatment options be offered to him.

Patients with moderate and severe symptoms - these patients have to be provided with information about benefits and harms of watchful waiting, alpha-blocker therapy,

finasteride therapy and surgery. The guidelines require the patient to be informed of all available treatment options applicable to his condition with related risks and benefits. This information is to be given in an unbiased format with probabilities of benefits and uncertainties associated with the probabilities. The physician is required to act as a communicator and present outcomes data to let patient decide the best treatment. Depending on the treatment patients select, appropriate follow-up needs to be determined. These guidelines are summarized in Appendix B.

The key decisions in the evaluative process involve assessment of patient symptoms. Following a detailed focussed history, physical examination and laboratory evaluation to identify other causes of urinary problems and comorbities that may complicate treatment, the guidelines suggest quantification of symptoms by self-administration of the AUA symptom index. Men with symptoms of 0 to 7 are to be allocated to watchful waiting with periodic assessment. Men with moderate to severe symptoms i.e. scores of 8 or higher are to be directed to optional diagnostic tests, treatment or watchful waiting based on clinical judgement of patient and physician.

Comparison of Diagnostic and Treatment Modalities:

Among the different BPH diagnostic tests, the ones that have been most studied and presented in the literature include the assessment of symptoms by the use of the AUA symptom index (AUA- si) and the prostate specific antigen (PSA) levels. This maybe due to the fact that both these diagnostic measures do not differentiate very well patients with BPH from those with other lower urinary tract symptoms (for AUA symptom score) and from prostate cancer (for PSA levels). Chancellor, Rivas et al (1994) carried out a

study to compare the specificity of the American Urological association (AUA) symptom index for BPH versus other urodynamically verified micturitional dysfunction in men. Results indicated that the AUA symptom index does not specifically identify BPH or bladder outlet obstruction. The scores were similar between men with voiding symptoms secondary to bladder dysfunction and bladder outlet obstruction. Another study administered this index to women and found that women with voiding dysfunction gave similar scores (Chancellor & Rivas, 1993). However, it has been emphasized that the purpose of the AUA symptom index is not to distinguish patients with BPH but to quantify the symptoms. Also, validation studies have been done which show that the symptom index captures clinically important changes in patients' condition (Barry, O'Leary, Bruskewitz, Howltegrewe et al, 1992).

A test that measures prostate specific antigen levels also has been extensively studied. This test provides insufficient discrimination between BPH and organ confined prostate cancer (Wolff, Boeckmann, Borchers, Handt, Reineke & Jaske, 1996). However, recent studies have shown that the ratio of the free prostate specific antigen to the total PSA in serum, calculated as a percent of free PSA is lower in patients with prostate carcinoma than in patients with benign prostatic hyperplasia (Meyer, Jung, Lein, Rudolph, Schnorr & Loening, 1997). Thus, this parameter is of help and facilitates discrimination between the two groups of patients.

Among the treatment modalities, watchful waiting and transurethral resection of the prostate (TURP) were options most commonly used. Until the late 1980s, TURP was the standard treatment for BPH when watchful waiting failed (Bruskewitz, 1992). Inspite of the fact that surgery provided far greater improvement in symptoms and urodynamic

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parameters than pharmacotherapy, pharmacotherapy for BPH began to be reported in medical literature between 1988 and 1990 (Guess, Jacobsen & Girman 1995; Lowe, McDaniel, Chmiel & Hillman, 1995). This is due to the morbidity associated with surgery (Eri & Tveter, 1997). Surgery involves loss of work time, need for hospitalization, performance of invasive procedures with well-described set of complications.

Drug therapy for BPH involves two classes of drugs, alpha-blockers and 5 alpha reductase inhibitors. Alpha-blockers include prazosin, terazosin, doxazosin and tamsulosin, whereas 5 alpha reductase inhibitors include finasteride. Both these classes of drugs are well-tolerated and effective in patients with BPH (Eri & Tveter, 1995).   The various alpha-blockers are similar in efficacy and adverse effect profiles and act by reducing the smooth muscle tone of the prostate and the bladder neck. Finasteride on the other hand shrinks the prostate by blocking conversion of dihydrotestosterone to testosterone. A meta-analysis of placebo controlled studies with alpha-blockers showed that these drugs decrease symptom score and improve urinary flow rate (Eri & Tveter, 1995). Their effect was usually seen within the first two weeks and reached maximum clinical effect after 4 to 8 weeks. Finasteride, on the other hand is known to act slowly. Its effect is seen only after 6 months of therapy. But long-term results have shown that its efficacy increases over time. Studies have been reported comparing these two classes of drug therapies. In a Veterans Administration Cooperative study, terazosin, finasteride and a combination of the two were compared (Lepor, Wilford, Barry, Brawker, Dixon, Gormley, Haakenson, Machi, Narayan & Padley, 1996). The investigators concluded that terazosin was effective whereas finasteride was not. Also, the combination was no

more effective than terazosin. This was because finasteride performs best in men with

large prostates (at least 40 grams) while the average size of prostate in this study was 37

grams. Efficacy of finasteride was confirmed in a meta-analysis of six studies using

finasteride (Boyle, Gould, & Roehrborn, 1996). The alpha-blockers are associated with

adverse effects of dizziness, orthostatic hypotension and asthenia in 5 to 29 percent of the

patients. However, tamsulosin, an alpha1A blocker, is prostate selective giving a more

prostate specific action and fewer adverse effects (Eri & Tveter, 1995). Finasteride on

the other hand, is known to impair erectile function in 2 to 7 percent of patients, but this

is reversible on discontinuation of therapy.

Surgical management of benign prostatic hyperplasia has also gone through an

emerging phase (Jepsen & Bruskewitz, 1998). Open prostatectomy is the oldest and most

invasive procedure but it is the most efficient in relieving symptoms and improving flow.

It is recommended in patients with prostates greater than 50 grams. Compared to

transurethral resection of prostate (TURP) it has lower peri-operative mortality.

However, TURP has become the gold standard for treatment of BPH because the

procedure is less invasive, less expensive, and associated with less morbidity. A variety

of less invasive procedures have been introduced and these well-established procedures

are being reassessed. Some of the newer procedures include transurethral incision of the

prostate (TUIP), visually assisted laser prostactomy (VLAP), interstitial coagulation

(ILC), transurethral microwave thermotherapy (TUMT) and transurethral needle ablation

(TUNA). Transurethral electrovaporization of the prostate (TVP), another method is a

modification of TURP. TURP is an inpatient procedure performed under general or

spinal anesthesia. In a trial of watchful waiting versus surgery, TURP showed less

morbidity than previous studies (Wassan, Reda, Bruskewitz, Elinson, Kelley & Henderson, 1995). Also, it indicated that compared to watchful waiting it was not associated with increased impotence or urinary incontinence. However, it does portray the risk of reduced or absent ejaculation and should not be performed in men who want to stay fertile. TVP is a modification of TURP using a roller-ball electrode with high current that vaporizes the tissue. Results of this procedure are comparable to TURP. Also, it is known to prevent TURP syndrome. In addition to this, it appears to be more effective in reducing the number of catherizations and hospitalizations, proving to be more cost effective (Thomas, Coraby, Hammadeh, Philp & Mathew, 1997).

Among the other surgical methods, TUIP is more than 30 years old, is well-documented and a safe procedure that is less expensive than other surgical procedures (Jepsen & Bruskewitz, 1998). It can be performed on an out-patient basis and is indicated in men with prostates less than 50 or 60 grams. It causes less morbidity than TURP and its re-treatment rate is approximately equal to that noted with TURP. VLAP and ILC are techniques which use laser therapy. Laser therapy can be divided into procedures which result in either coagulation or vaporization of tissue. Both VLAP and ILC involve coagulation. ILC technique produces less improvement than VLAP. VLAP is a shorter procedure, produces lower morbidity, and thus appears to be viable and safe alternative to standard TURP. However, a study showed that it does not result in as complete a removal of prostatic tissue as TURP (Cowles, Kabalin, Childs, Lepor, Dixon, Stein & Zabbo, 1995).

TUMT with urethral cooling, another method causes a delayed interstitial ablation of the prostate. A study comparing the outcomes of TUMT with TURP concluded that

inspite of improvement in symptoms it did not alleviate obstruction in patients with BPH (Bell, Ward & Watson, 1997). But it is minimally invasive with no absolute contraindications. The cost is difficult to estimate due to lack of long term data. TUNA, the last of mentioned methods, utilizes low-level energy by radiofrequency (Jepsen & Bruskewitz, 1998). The improvements in symptoms are less compared to TURP, but better when compared with TUMT. Treatment failure rates of TUNA are comparable to TUMT. A clinical and urodynamic evaluation concluded that it is a safe and effective procedure when performed as an outpatient procedure. However, long term costs and outcomes have yet to be assessed (Campo, Bergamaschi, Corrada & Ordesi, 1997).

The cost of TURP in the US ranged from $6000 to $7000 per patient in 1993 (Eri & Tveter, 1997). When we compare this with drug therapy, annual cost of finasteride was $600 and alpha-blockers ranged from $300 to $400, both in 1993 dollars. Cost of TURP corresponds to approximately 8 years treatment with finasteride or 13 years treatment with alpha blockers provided the annual follow-up is around $200 per patient and there is no follow up after surgery. Thus, it is important to decide what therapy should be used for a particular patient. An economic model compared the costs of treatment for a period of two years with finasteride, terazosin and TURP with men who had at least moderate symptoms (Lowe, McDaniel, Chmeil & Hillman, 1995). Results indicated that surgery had the highest probability of success but was the most expensive and resulted in maximum loss of activity days. This study concluded that pharmacotherapy was less expensive over the initial two years of therapy when used as a primary intervention over surgery. Another pharmacoeconomic analysis compared finasteride with doxazosin, prazosin and terazosin (Cockrum, Finder, Ries & Potyk,

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1997). This assessed economic outcomes for a period of three years. It concluded that

alpha-blockers were more cost effective than finasteride and of the three alpha-blockers

included in the study, prazosin was most cost-effective followed by terazosin and

doxazosin. Some other studies which have looked at economics of BPH treatment

options include cost-effectiveness between finasteride to TURP and watchful waiting,

comparing enucleation (prostactomy) with TURP using cost-utility analysis, assessing

cost-of-illness of BPH and measurements of lifetime costs for synthetic cohorts of BPH

patients (Baladi, Menon & Otten, 1996; Woodward, Boyarsky & Barnett; 1983,

Drummond, McGuire & Black NA, 1993; Chiriko & Sanford, 1996). The first study

indicated that when duration of therapy was 3 years or less, finasteride was the preferred

option for patients with moderate symptoms. However, when the therapy was for more

than 4 years, finasteride was a weaker option for patients with severe symptoms. It

concluded that finasteride can improve quality of life for patients with moderate

symptoms (finasteride therapy for more than 4 years) and patients with severe symptoms

(finasteride therapy for less than 3 years) but would cost approximately $ 97,000

(Canadian dollars) per incremental QALY (quality adjusted life years). The second study

concluded that enucleation was more cost-effective than TURP. In 1990, the economic

burden of BPH was estimated in the United Kingdom, and was found to be between 62 to

91 million pounds. The study that assessed synthetic cohorts (groups) reported that cost

of each type of BPH therapy depended on age of the patient. It indicated that surgical

intervention had a cost advantage at younger patient ages, while drug management had

cost advantage at older ages.

Use of Simulated Patients in Assessing Practice Patterns

Measurement of practitioners' performance has been stimulated by two needs: 1) to ensure quality of care; and 2) to examine effectiveness of educational programs (Norman, Neufiled, Walsh, Woodward & McConver, 1985). The most common method to measure practitioner performance is by retrospective audit of medical charts. But this suffers from the possibility of having patient charts with missing critical information. An alternative approach to assess quality of care and performance is using standardized or simulated patients. A simulated patient in literature is "a person who has been trained to simulate all aspects of a disease". (Barrows, 1971). The term standardized is used for both healthy individuals and patients who are trained to present clinical problems consistently and repeatedly. This method has been used for educational purpose in evaluation of undergraduates and residents (Norman, Tugwell & Feightner, 1982). The validity of using simulated patients for this purpose has been established. This methodology also demonstrated feasibility when used to assess physicians' performance and quality of care (Norman, Neufiled, Walsh, Woodward & McConver, 1985). Rethens and Boven (1987) showed that simulated patients could produce reliable and valid data about the performance of doctors in actual practice. They conducted a study in which they used three simulated patients with symptomatic urinary tract infections to assess quality of care provided by 48 general practitioners. This study used patient simulation in two ways a) having simulated patients visiting the practitioners; and b) sending a written patient case to the practitioners. The overall score for both the methods did not show any substantial differences. This study encouraged the use of simulated patient method as a basis for assessing the actual performance patterns of practitioners. Another

study which utilized simulated patients was done to measure level of agreement among randomly selected international urologists in the management of men with lower urinary tract symptoms (LUTS) (Hansen & Zdanowski, 1997). This study utilized computer simulation to provide unbiased format of simulated cases to individual urologists. It indicated considerable disagreement among urologists about management of men with LUTS, which included both the choices of diagnostic tests and the criteria for offering therapy to patients. This study concluded that this disagreement might result in unnecessary medical costs for these patients.

Previous Studies Assessing Practice Patterns in the Management of BPH

The prevalence of BPH has been increasing due to the aging population. Approximately, 50 percent of men over the age of 60 have symptomatic BPH and by age 80, one in four men in the US will require treatment for the relief of symptoms associated with BPH (Barry 1990,1991). Traditionally specialists have referred patients with BPH to urologists for diagnosis and management. However, there has been an increasing trend to involve primary care practitioners in the diagnosis and management of this disorder. This can be through the concept of shared care. This enables medical services to deal with increasing numbers of men seeking advice for BPH and also reduces the wait for patients who need assessment by urologists (Morris, Pogson & Shearer, 1995). Thus, studies on the management of BPH have looked at both primary care practitioners and urologists. The literature yielded two studies that have assessed practice trends of primary care practitioners. One was conducted among delegates attending scientific meetings on prostate disease (Fawzy, Fontenot, Guthrie, & Baudier, 1997). Results indicated that

about one-third of the respondents used AUA symptom index for diagnosing BPH and long acting alpha-blockers was the most preferred mode of treatment. However, these physicians included a cohort with a particular interest in prostate disorders and the results are not representative for all primary care practitioners. The second study, however was a mail survey of primary care practitioners in Brooklyn, New York (Plawker, Fleisher, Nitti & Macchia, 1996). This study showed that 66.5 percent of primary care practitioners were not familiar with the AUA symptom index. Also, less than 50 percent attempted pharmacotherapy with finasteride or terazosin or both and about 15 percent of these were not aware of the mechanisms of action of these drugs. This study concluded that primary care practitioners needed further education in regard to use of diagnostics tests and pharmacotherapy for men with voiding dysfunction.

Additionally, studies have been conducted to evaluate the practice trends of urologists. A nationwide survey of urologists on management of BPH was conducted by Barry et al (Barry, Fowler, Bin & Oesterling, 1997). This study indicated that older urologists tend to perform TURP more often than younger urologists. Also, they tend to obtain diagnostic tests not recommended by the guidelines more often than younger urologists do. Younger urologists prescribed alpha-blockers more often. In general, alpha-blockers were reported to be prescribed more than 4 times as often as finasteride. This study concluded that respondents were fairly consistent with published BPH practice guidelines. When a comparison was made between practices of primary care practitioners and urologists (McNaughton, Barry, Roberts, Oesterling & Fowler, 1997), diagnostic evaluations of primary care practitioners varied from the recommendations of national guidelines and urologists practices. This study also showed that urologists'

diagnostic evaluation would also deviate at times from guidelines. Another observation was that both classes of practitioners used alpha-blockers more often that finasteride. However, increasing awareness and better compliance with guidelines by primary practitioners was stressed even in this study.

A gallop organization in Princeton was commissioned to assess practice patterns of urologists in 1992 (Gee, Holtgrewe, Albertsen, Liwin, Albertsen, Manyak, O'Leary, & Painter, 1995). This showed that 99 percent of the respondents were aware of and used the AUA symptom index, and that 21 percent of the respondents had altered their strategies of diagnosis and management because of this instrument. This study concluded that therapeutic recommendations of respondents based on AUA symptom index paralleled the practice guidelines. When patient records with principle diagnosis of BPH were extracted from a random four-state sample to measure adherence to practice guidelines, different results were observed (Hood, Burgess, Holtegrewe, Fleming, Mebust & Connolly, 1997). These were patients who had undergone TURP, but their records did not show adequate peri-operative evaluation of patients undergoing TURP. The study concluded that guideline recommendations are documented infrequently in medical records.

The various studies, which have assessed compliance with guidelines, demonstrate inconsistency in results and conclusions made. Also, all these studies suffer from the major drawback of recall bias since the survey instruments used intended the respondent to report about his/her practice over several months. Another point to consider is that the guidelines recommend different therapy for patients with different levels of severity. However, none of the above studies looked at the practice patterns

based on severity of symptoms. Hence, one cannot conclude if the practitioners were consistent with guidelines based on different levels of severity. In addition to all these factors, these studies have assessed practitioners in general all over the country. However, none of them have assessed practice patterns of urologists serving the VA population. These urologists form a different cohort practicing in a different healthcare structure. Thus, our study aims to assess practice patterns of this cohort of urologists. Additionally, to exclude the effect of recall bias simulated patient cases with different severity levels will be employed for this study. The validity of using written simulated patients has been demonstrated in literature (Rethens & Bovens, 1987). This would not only help identify compliance of therapeutic recommendations for patients with different severity levels, but also help detect differences, if any, in management of patients with different severity levels. Also, important factor is by using simulated patient cases, all respondents would have the same case and thus we would enable measurement of the degree of agreement among practitioners.

There have been new and emerging methods for management of symptoms of the disease. However, these were not included in the original guidelines due to inadequacy of data. Hence, these new techniques have not been studied extensively in literature with regards to urologists' practice. This study aims to include all such modalities which have shown some degree of effectiveness and which the expert panel used for identifying the patient cases considered to be necessary.

Thus, this chapter presented a review of the literature relevant to the problem being investigated in this study. It included the published guidelines for management of BPH, comparison of diagnostic and treatment modalities available for BPH, use of

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simulated patients in assessing practice patterns, and studies involving management of

BPH by urologists and other health care practitioners.   The next chapter will discuss the

methodology employed to accomplish goals and objectives of this study.

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CHAPTER THREE

RESEARCH METHODOLGY

The intent of this study was to assess VA urologists' preferences in the management of benign prostatic hyperplasia with regards to severity of the symptoms, demographics and practice characteristics. Specific objectives were (i) to compare the preferences of VA urologists for diagnosing BPH with established guidelines, (ii) to compare the preferences of VA urologists for treating BPH with expert opinion/established guidelines, (iii) to determine the effect of demographic and practice characteristics on preferences of VA urologists for diagnosing and treating BPH, (iv) to assess the level of agreement among VA urologists on the use of diagnostic tests and procedures for patients presenting with BPH symptoms, (v) to assess the level of agreement among VA urologists on the use of treatment modalities for patients diagnosed with BPH, (vi) to determine the treatment failure rate for BPH in the VA population and the types of treatment switches commonly made followed failed initiation therapy, and (vii) to estimate the cost of diagnosing BPH in the VA population based on preferences of urologists.

This chapter presents methods employed to achieve the preceding objectives including study population, sampling, instrument content and development, survey implementation, and data analysis.

Study Population

The population of interest in this study was, urologists practicing in the Veterans Administration Medical Centers (approximately 173) all over the United States. However, working within budget and time constraints made it impossible to reach out to every eligible person. Consequently the study population was defined as urologists practicing in those VAMC's whose center was listed on the VA web-site. The web-site had a listing of 149 such centers.

Sampling

Due to difficulty in observing the entire study population, a sample, which is a portion representative of the study population, was drawn for this study. The logic behind sampling draws on the ability of making inferences about the population based on the data collected from the sample. This section will deal with the issue of sample selection and screening.

Although the population of the study was clearly defined, an appropriate sampling frame consisting of all eligible urologists from whom the actual sample was to be drawn (exclusive list of urologists practicing in the VAMC's) was not readily available. The use of telephone directory as a sampling frame was ruled out due to the potential bias that could be introduced by excluding those urologists whose numbers are not listed. Assuming that each VAMC has 2-4 urologists would result in a population ranging from 248 to 596. Due to the small population size, it was decided to include as many urologists as possible in the study. This could help enhance response rate and make the results more representative of the population selected. Also, personalizing the cover

letter to be sent with the survey would also serve to enhance the response rate. Efforts were made to get a directory exclusive to the VA, which had telephone numbers and other details of healthcare professionals practicing in the VA. However, since this directory did not have the urologist specifically listed, it could not be used.

Hence, a different approach was taken to obtain names of urologists. Telephone numbers of all the VAMC's listed on the web-site were first identified. Each VAMC was then called and the Department of Urology was requested. The secretary or nurses in these departments were the contact persons. They were given information about the survey that was to be conducted among urologists as part of this study, for which names of urologists practicing at their center would be required. The mailing addresses of these centers were obtained from the VA web-site that had links to each center's homepage. Some of the centers did not list their phone numbers but had a fax number. Also, some of the nurses/ secretaries refused to disclose the names of the urologists, citing reasons of confidentiality. Some of the centers could not be reached because of busy telephone lines. Two additional attempts were made to reach these centers by telephone. Those that could not be reached after three calls were not included. Some of the centers did not have a practicing urologist since the center was small or because there was another center in the city with a full-capacity urology department. Another important observation was that in some states, the same urologists practiced at multiple centers. For two of the centers, the contact persons refused to divulge the names of the urologist but did provide the number of urologists practicing. Completion of the telephone calls to obtain names of urologists resulted in a list of 233 urologists practicing at 88 centers of the 149 centers identified. To increase the study sample size, a single survey was sent to chief urologists

at the remaining 61 centers. Thus, the sample selection procedure resulted in 233 usable names from 88 centers, and 61 chief urologists (unidentified by names) from 61 centers, resulting in a total sample of 294 urologists.

Instrument Content and Development

A self-administered mail survey was used for this study. Mail surveys offer many advantages such as ability to collect data from a larger geographical area at a relatively low cost, greater versatility, the absence of interviewer bias and successful use of a small staff. For the respondents, it offers the flexibility of replying at their convenience and offers respondent anonymity.

In developing the survey instrument, considerable attention should be given to the kind of information needed to measure both the independent and dependent variables of interest, length of questionnaire, cost, comprehension level of prospective respondents, complexity of the questionnaire and the time required to complete it (Dillon, 1978). All these factors collectively can have a significant impact on the kind of data collected and the response rate.

This survey intended to measure preferences of urologists in diagnosing and treating BPH. Consensus was reached among the researchers that the best way to do so would be to provide simulated patient cases in the survey. To do so, a search of the literature was conducted to determine if there were any standard patient cases with BPH. The book selected was Applied Therapeutics: The Clinical Use of Drugs (6th edition) by Young and Koda Kimble (1995). This book is used to educate clinical pharmacists about management of different conditions, BPH being one of them. The patient case obtained

from this source depicted the symptoms, which a typical BPH patient presents with, some laboratory tests used to diagnose the case and the treatment options available to control the symptoms. It provided a detailed description of all the tests and treatment options suitable. This case was taken as a template and modified to obtain the required cases for the survey instrument. The survey instrument had four sections. Section one was designed to measure association of the use of diagnostic tests with bothersome symptom level. It was decided to include three cases with different levels (low, medium and high) of bothersome symptoms. Expert opinion from urologists practicing at West Virginia University, School of Medicine was utilized for this purpose. A list of symptoms to be included for each patient case with different levels of bothersome symptoms was obtained. This procedure resulted in three patient cases with different bothersome symptom levels, typical of BPH. The response options included all the diagnostic tests, which are part of AHCPR's guidelines and some others that were cited in the literature. To avoid respondent bias, the cases were arranged randomly such that case 1 depicted medium symptoms, case 2 depicted low symptoms and case 3 depicted high bothersome symptoms.

Section two was designed to include patient cases for the treatment section of the survey. For this, symptoms similar to the diagnosis (Section I) were taken. This was supplemented with information of results of certain diagnostic tests and laboratory values. The laboratory values and other information was utilized such that it would distinguish between patients with mild, moderate and severe symptoms (the typical classification system used for BPH). The information about results of diagnostic tests and laboratory values was obtained from expert opinion. This resulted in three patient

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cases- mild, moderate, and severe. Urologists were asked to recommend the best treatment option(s) for each case from a list of commonly recommended and less frequently used treatment alternatives. To avoid bias, these three cases were also arranged randomly and not in increasing order of severity. Thus, case 4 was severe, case 5 was moderate and case 6 was mild.

One of the objectives of the study was to estimate the initial treatment failure rate and common switches utilized. Thus, Section three contained a list of possible treatment switches that was obtained with help from experts. This section was different from the previous two in that it did not involve preferences for simulated patients but, sought information about practice characteristics in real settings. The respondents were required to recall the last five BPH patients they had treated. The number was limited to five to avoid recall bias and failure of recall. The respondents were inquired as to the number of patients among these last five, who had to be switched to other treatment options due to failure of initiation therapy. It also sought information about the type of switch, if any.

Section four of the instrument pertained to respondents demographic and practice characteristics. These included variables such as age, gender, years of practice, number of new BPH patients seen per month, presence or absence of a formulary, the different BPH drugs available on the formulary, and number of urologists at practicing center. These variables were selected to determine if there was some association between them and the diagnostic tests used and the treatment options selected. Demographic factors were measured using either a dichotomous scale or an interval scale. Open-ended questions were primarily used to obtain information about practice characteristics except for the question associated with the drug formulary.

Instrument Pretest

The survey instrument was pre-tested to assess clarity, readability, face validity, reliability and time for completion. For the pretest, the preliminary questionnaire was administered to a convenient sample of eight, resident urologists at West Virginia University, School of Medicine. Of this four questionnaires were retrieved, to yield a response rate of 50 percent. In addition to assessing the clarity and readability of the instrument, the residents were asked to classify the patient cases in section two (selection of treatment option) as mild, moderate and severe. The result of this is summarized in table 3.1. All four residents classified the moderate and the severe case correctly. The mild case was identified correctly by 3 of the 4 residents, 1 classified the case as moderate. Thus, there was 100 percent agreement for the moderate and severe case and 75 percent agreement for the mild case. A kappa statistic was calculated to measure this agreement using the method for multiple raters (Woolson, 1987). This gave a value of 0.745 with standard deviation of 0.089. The Z value was 8.37, thus the kappa statistic was significant. A kappa of 0.745 is interpreted to demonstrate substantial agreement among raters (Landis and Koch, 1977). Thus, validity of the cases was established with regards to patient severity.

Instrument Validity

The clarity and face validity of the instrument was assessed using the pilot survey results. The face validity of the instrument was also assessed by the experts. Experts in health services research from the Department of Pharmaceutical Systems and Policy, and urologists from the School of Medicine reviewed the instrument to determine its clarity and appropriateness. Content validity is defined as "the extent to which test exercises

Table 3.1: Classification of patient cases in section two of survey.

Patient case	Mild	Moderate	Severe	Percent classified correctly
Case 4*	-	-	4	100.00
Case 5*	-	4	-	100.00
Case 6*	3	1	-	75.00

*__Patient # 4:__ A.D., a 75-year-old African-American male comes with the problem of urinary incontinence. He also gives a history of difficulty initiating urination, midstream stoppage and terminal dribbling. Rectal examination reveals an enlarged prostate of 50-55 gms. A.D. gives a history of nocturia approximately 4-5 times a night, daytime urinary frequency of 8-10 times a day and he reports of blood in urine. Laboratory findings are as follows: PSA -4.1, AUA ss -28, serum creatinine -1.2, residual volume -300ml, flow rate -7ml/sec.

__Patient # 5:__ R.C., a 68-year-old Hispanic man, comes to your clinic with severe abdominal discomfort. He reports a history of increased difficulty initiating urination, midstream stoppage and terminal dribbling. R.C. complains of nocturia of 3-4 times/night. DRE reveals an enlarged prostate of approximately 25-30 gms and firm. Laboratory findings are as follow: PSA-2.8, AUA ss - 15, serum creatinine -0.8, residual volume -150ml, flow rate -13ml/sec.

__Patient # 6:__ G.M., a 60-year-old male, presents to your clinic with lower abdominal discomfort. He gives a history of increased difficulty initiating urination, a significant decrease in the force of his urinary stream, occasional midstream stoppage, and post void dribbling. Upon digital rectal examination, the prostate is 20-25 gms and benign. Laboratory findings are as follows: PSA -1.2, AUA ss-6, serum creatinine -0.5, flow rate -20 ml/sec, residual volume -80ml.

reflect and fully cover the curriculum which the test was designed to measure." (Mussio, 1987). The process used for instrument development, the pretest and expert panel input helped cover all the domains and response options which the instrument purported to measure. Feedback from the pilot survey and the experts indicated that the instrument was adequate by itself and did not need any additions or deletions. The final instrument is presented in Appendix D.

Expert Opinion

One of the objectives of the study was to compare the preference of the urologists for selection of treatment option with the guidelines. However, the guidelines do not give specific treatment strategies for patients with moderate and severe symptoms. Hence to obtain a recommended treatment option for the moderate (case5) and severe (case 4) cases, expert opinions were sought. There were three experts in the panel. For the moderate case, two of them suggested the use of alpha-blockers, whereas one suggested the use of finasteride. Thus, it was decided that the appropriate treatment strategy for this case would be drug therapy either in the form of alpha-blockers or finasteride. For the severe case, all three experts suggested TURP as the treatment option, hence it was decided that TURP would be the appropriate treatment option for this case. This information is tabulated in table 3.2.

Survey Implementation

The survey was mailed to 294 VA urologists, 233 of whose names and practice centers were available and 61 chief urologists whose names were not available but center

Table 3.2: Expert opinion for use of appropriate treatment strategies for case 4 & 5.

Patient case	Expert 1	Expert 2	Expert3	Appropriate treatment
Case 4 (severe)	TURP	TURP	TURP	TURP
Case 5 (moderate)	alpha-blocker	finasteride	alpha-blocker	drug therapy (alpha– blocker &/or finasteride)

address was available. The mailing consisted of the questionnaire and a cover letter that explained the purpose of the study. Respondents were asked to return the completed questionnaire in the self-addressed business reply envelope provided in the package. In order to motivate respondents to complete and return the survey, the package also contained a raffle ticket. This required the respondents to write their name, address and phone numbers. This would include them in a raffle drawing which had a first prize of $100, second prize of $75 and two third prizes of $50. All the surveys sent in this mailing were coded for follow–up purposes. All completed and returned questionnaires were checked off from the mailing list.

The second mailing was sent about five weeks later. It consisted of the questionnaire, the cover letter, the self-addressed business reply envelope and the raffle ticket. The second mailing was sent to only those urologists who did not respond to the first mailing. This was possible due to the coding procedure utilized during the first mailing. The second cover letter was designed to stress the importance for the respondents to participate in the study and reminded them of the raffle drawing. Appendix E and F include copies of cover letters used in both mailings. Approximately two weeks after the second mailing, 50 randomly selected non-respondents were called. This was done to enhance the response rate. After a week of reminder calls, 103 urologists who had not responded and also who had not been contacted by phone calls were identified. A non- response survey was developed and mailed to these urologists. This non-response survey included a section which asked respondents to indicate the reasons for not responding, a section on demographic information and a patient case to asses the preferences of these urologists in the use of diagnostic tests for a severely

symptomatic BPH patient. This non-response survey along with a personalized cover

letter and a self-addressed business reply envelope was mailed to the 103 identified non-

respondents. This was done to determine if differences existed between the respondents

and non-respondents. The non-response survey and the cover letter used along with it is

available in Appendix G and H, respectively.

Out of the 294 mailings, 2 questionnaires were returned as undeliverable because

of wrong or incomplete addresses. Thus, 292 surveys were assumed to reach

respondents. Of these, 114 (39.04 %) were completed and returned. For the non-

response survey of the 103 mailings, 8 had to be disregarded either due to wrong

addresses or because response to original survey was subsequently received. Thus, 95

were assumed to reach the targeted individuals. Of these, 24 completed responses were

received, thus giving a response rate of 25.27 percent for the non-response survey.

Data Handling

Each questionnaire that was returned was checked for completeness. The two

mailings finally resulted in 114 usable responses. The Statistical Package for Social

Sciences® (SPSS) version 9 was used for data entry and statistical analysis. The data file

contained 114 cases that represented the usable responses. The data file was

meticulously checked to assure that data was free of errors.

Data Analysis

The data was checked to ensure appropriate data entry. Response analysis was

conducted to estimate the response rate for both the survey instrument and the non-

response survey.   This was followed by descriptive statistics to describe the respondents and the non-respondents.   A non-response bias analysis was conducted to determine if differences existed between respondents and non-respondents for demographic and practice characteristics, and preferences for selection of diagnostic tests.   The following sections deal with the analytical methods used to accomplish each of the study objectives.

Analytical Methods for Objective One: The objective was to compare the preferences of the VA urologists with established guidelines for diagnostic management of BPH for different levels of bothersome symptoms. To meet this objective three scores were calculated for each of the three cases in section one of the survey instrument. The first was the total score- which was a summation of all the diagnostic tests used for each case in the instrument. The second was the recommended score, this was a summation of the five tests recommended by the guidelines, which include medical history, DRE, serum creatinine, urinalysis and AUA symptom index. The third was the optional score, this was a summation of tests which were not recommended by the guidelines, but were optional. This includes PSA, cystoscopy, pressure flow, uroflowmetry, intravenous pyelogram, post voidal residual volume and others. Multiple t-tests were conducted to determine if the three scores differed from each other for the three cases. In addition to this, descriptive statistics were obtained for the tests and test scores for each case.

 Analytical Methods for Objective Two: The objective was to compare the preferences of the VA urologists for treating BPH with expert opinion/ established guidelines. Descriptive statistics were obtained for all treatment options for each case. Additionally,

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percent adherence and non-adherence were calculated for each case to compare it with the appropriate treatment option provided in the guidelines for the mild case and obtained from experts for the moderate and severe cases.

Analytical Methods for Objective Three: This objective was to determine the effect of demographic and practice characteristics on preferences of VA urologists for diagnosing and treating BPH. This objective was divided in two sections, one was to assess effect of demographics on selection of diagnostic tests and the other to assess the effect of demographics on selection of treatment strategy. The first part was accomplished by assessing correlations between performance of tests and number of tests performed with demographics. The second part was accomplished by estimating chi-square statistics for selected treatment options for each case with demographics.

Analytical Methods for Objectives Four and Five: These objectives aimed to assess the level of agreement among VA urologists on their use of diagnostic tests/ procedures and treatment modalities for patients presenting with BPH symptoms. To meet this objective kappa statistic was calculated for each case in section one and two of the survey instrument. The Z-value for this kappa statistic was estimated and its significance was assessed using standardized tables. The kappa statistics obtained were then compared with standard kappa values for level of agreement.

Analytical Methods for Objective Six: The objective was to determine the treatment failure rate for BPH in the VA population and the types of switches commonly made. To

meet this objective, descriptive statistics were performed on the third section of the instrument. Also rate of switch, average switch and ranks for the types of switches were determined.

Analytical Methods for Objective Seven: The objective was to estimate the cost of diagnosing BPH in the VA population. Standard charges for the diagnostic tests, using CPT4 codes, were obtained from a VA center. Descriptive statistics were obtained to determine average cost of diagnosis and range of costs for each case in section one. Also, these costs were projected to get cost of diagnosis for BPH for all the VA centers.

Study Limitations

Limitations that could affect the generalizabiliy of the study findings may be attributed to the following factors: (i) Confounding, (ii) Sampling (iii) Non response bias, and (iv) The use of mail survey for data collection. Following is a discussion of the possible influence of each of these factors on limiting the generalizability of the study.

Confounding Factors

The findings of the study might have been confounded by two factors. First, it is possible that each center has established their own practice patterns for the management of BPH. This may affect the preferences of the respondents. Second, it is possible that preferences may differ from actual practice due to reasons not controlled by the respondents. These may include availability of resources, time constraints, patient variations etc.

Sampling Procedure

Due to unavailability of an appropriate sample frame (list of urologists working in all the Veteran Administration Medical Center's in the United States), a convenient sample which was obtained after telephone calls to various centers was used. Those centers which could not be reached were omitted from the study. Thus, it is possible that the sample used may impose limitations to generalizability of the study results to those who could not be reached and those, whose names were not listed in the mailing list used for the study.

Non-response Bias

The survey was sent to 294 urologists in the VA, 2 were wrong addresses. Thus the survey was assumed to reach 292 urologists. However, the final completed questionnaire was returned by 114 urologists. Thus, bias could have been introduced in the study, as respondents may be significantly different from the non-respondents with respect to preferences in the use of diagnostic and treatment modalities for BPH management. Also, they may be different with respect to demographic and practice characteristics. Previous studies have demonstrated that age affects practice patterns of urologists (Barry et al, 1997). Younger urologists prefer drug therapy and order fewer non-recommended tests compared to older urologists. Hence, to minimize non-response bias, non-response analysis was conducted to test for any possible differences.

A mail questionnaire was used to collect data for respondents. This kind of survey instrument has many disadvantages that may introduce biases in the results of the study. These include low response rate and lack of control over item non-response. Also mail surveys are insensitive to substitution of respondents and may fail to provide standardized understanding of survey questions among respondents. However, financial and time constraints directed the use of mail survey. The questionnaire was pre-tested for validity, readability and time consideration. This indicated that the survey had good clarity and readability and required about 5 minutes for completion.

This chapter provided a detailed description of the methodology employed for the selection of the sample for the study, the development of the survey instrument and the implementation of the study. In the next chapter, the results of the analysis conducted for accomplishing the goal and objectives of the study will be presented.

CHAPTER FOUR

RESULTS AND DISCUSSION

This chapter will present the analytical tools employed to accomplish the study goal and objectives, and the results obtained from such analysis, and provide a discussion of the study results. The Statistical Package for the Social Sciences (SPSS®) was employed for data entry, data coding and data analysis. Prior to presenting the results for the study objectives, survey response analysis including response rate estimation and non-response bias assessment will be presented.

Survey Response Analysis

Survey response analysis involves determination of response rate and estimation of any non-response bias. The following section describes the procedure used to determine the survey response rate and methods employed to estimate the non-response bias for this study.

Response Rate

Response rate analysis involves an estimation of the number of subjects of the total sample who responded and were used in the analysis and interpretation of the study results. Response rate was determined using the procedure in Table 4.1. The survey was mailed to 294 urologists practicing in Veterans Administration Medical Centers (VAMC) all over the United States. Of these, 2 questionnaires were returned because of incomplete or wrong addresses. Thus, 292 surveys were assumed to have reached the

Table 4.1: Response rate calculations

Total sample population selected = 294

Wrong addresses = 2

Effective population reached = 292

Responses received = 114

Response rate = (114/292)*100 = 39.04 %

respondents. A total of 114 completed responses were received yielding a response rate of approximately 39 percent. Although a higher response rate is always desirable, the response in this study was considered adequate for analytical purposes and was comparable to other studies surveying urologists (Barry et al, 1997; Oh, Colberg, Ornstein, Johnson, Chan & Virgo, 1999).

Additionally, the data was reviewed to assess response rate from the states and the 22 Veterans Integrated Systems Network (VISN's). The results of this analysis are presented in Tables 4.2 and 4.3. Responses were obtained from 21 of the 22 VISN's. The only VISN that was not represented was VISN 5 (VA Capitol Network). The 114 responses that were obtained covered 42 States in the U.S. No responses were obtained from the states of Colorado, Hawaii, Idaho, Maryland, Nevada, Wyoming, Washington DC, and Puerto Rico. The state of Maine and the territories of Guam, and Virgin Islands were not represented in the study sample. Also, responses were obtained from 80 of the 149 centers that were part of the study sample.

Non-Response Bias Assessment

The non-response survey (Appendix G) was mailed to 103 urologists who did not respond to the first two mailings. However, since 4 of these replied after the mailing of the non-response survey and 4 were returned due to wrong addresses, the final number of non-response surveys were assumed to be 95. A total of 24 completed surveys were returned, thus giving a response rate of approximately 25 percent. Table 4.4 depicts the reasons the respondents gave for not responding to the main survey. The most common reasons were lack of time (26.15) followed by "don't like to respond to surveys" (17.4%)

Table 4.2: Response rate analysis based on VISN's represented

VISN number	Responses received	Surveys sent	Response rate (%)
1	7	18	38.89
2	2	8	25.00
3	10	22	45.45
4	5	11	45.45
5	0	8	0.00
6	4	12	33.33
7	7	13	53.85
8	8	16	50.00
9	11	18	61.11
10	4	16	25.00
11	4	9	44.44
12	3	10	30.00
13	4	4	100.00
14	2	12	16.67
15	8	18	44.44
16	11	27	40.74
17	6	10	60.00
18	5	12	41.67
19	3	5	60.00
20	3	8	37.50
21	2	6	33.33
22	5	29	17.24
Total	114	292	39.04

Table 4.3: Response rate analysis based on state represented

State	Responses received	Surveys sent	Response rate (%)
Alabama	1	1	100.00
Arkansas	4	10	40.00
Arizona	3	7	42.86
California	8	32	25.00
Connecticut	1	2	50.00
Delaware	2	4	50.00
Florida	8	15	53.33
Georgia	3	5	60.00
Illinois	4	6	66.67
Indiana	1	1	100.00
Iowa	1	6	16.67
Kansas	2	4	50.00
Kentucky	4	8	50.00
Louisiana	2	3	66.67
Massachusetts	2	12	16.67
Michigan	1	8	12.50
Minnesota	2	2	100.00
Mississippi	1	8	12.50
Missouri	6	13	46.15
Montana	1	1	100.00
Nebraska	1	6	16.67
New Hampshire	1	1	100.00
New Jersey	2	3	66.67
New Mexico	2	5	40.00
New York	10	27	37.04
North Carolina	2	7	28.57
North Dakota	1	1	100.00
Ohio	4	17	23.53
Oklahoma	2	4	50.00
Oregon	2	2	100.00
Pennsylvania	2	9	22.22
Rhode Island	2	3	66.67
South Carolina	3	6	50.00
South Dakota	1	1	100.00
Tennessee	6	10	60.00
Texas	8	9	88.89
Utah	2	2	100.00
Vermont	1	1	100.00
Virginia	2	4	50.00
Washington	1	3	33.33
West Virginia	2	4	50.00
Wisconsin	1	4	25.00

Table 4.4: Reasons for not responding to the main survey (N=24)

Reason	N	Percent (%)
Not enough time to complete survey	6	26.1
Don't like to respond to surveys	4	17.4
Not enough incentive to complete survey	3	13.0
Survey was misplaced	2	8.7
Not interested in such studies	2	8.7
Did not receive the survey	2	8.7
Survey was too long	2	8.7
Forgot about survey	1	4.3
Topic was irrelevant	0	0.0
Not enough information about study	0	0.0
Other (not a urologist, vacation, conference)	4	17.4

and the lack of enough incentive to complete the survey (13%). Among the other reasons, 8.7% reported misplacing the survey, not being interested, not receiving the survey and length of the survey as a problem. Also, a small number of individuals (4.3%) reported forgetting about the survey.

Table 4.5 presents demographic and practice characteristics of the respondents to the non-response survey. Of the 18 respondents who responded to the question, 16 (88.89%) were males and 2 (11.12%) were females. Also, 45 percent were less than 40 years of age, 35 percent were between 40-49, 20 percent were 60 or older. All the urologists reported practicing in a center that used a formulary. The average number of urologists at each center was almost 4. The number of new BPH patients visiting each center every month ranged from 2 to 100 with a mean of 40.67 patients. Each urologist was in practice for an average of 88 months (7.33 years).

The respondents and non-respondents were compared for the demographic variables and practice characteristics to determine if they significantly differed from each other. The variables included for analysis were age, gender, number of urologists at the center of practice, years of practice at current center and number of new BPH patients visiting the center per month. Presence of formulary status could not be used for non-response analysis as all urologists reported presence of a formulary at their center. Chi-squares were used for comparison of age and gender whereas ANOVA's were used for comparison of the other variables. The result of this analysis is reported in Table 4.6. Results indicate no significant differences between the two groups of respondents and non-respondents on any of these variables.

The two groups were also compared for their preferences of utilization of

Table 4.5: Demographic and practice characteristics of respondents of non-response survey.

Characteristics	N	Percent (%)
Gender		
Male	16	88.89
Female	2	11.11
Total	18	100.00
Age		
Less than 40 years	9	45.00
40-49 years	7	35.00
50-59 years	0	0.00
60 years or older	4	20.00
Total	20	100.00
Presence of formulary		
Yes	21	100.00
No	0	0.00
Total	21	100.00

	Range	Mean$\pm$Std.Dev
Number of urologists practicing at VAMC	1 - 7	3.63 ± 1.63
Months in practice at present VAMC	24 - 308	88.00 ± 66.85
Number of new BPH patients visiting the VAMC per month	2 - 100	40.67 ± 28.02

Table 4.6: Analysis of non-response bias for demographic and practice characteristics

Characteristics	Respondents	Non-respondents	Test Statistics	Significance
Demographics				
Gender			$X^2 = 1.235$	0.266
Male	95.4%	88.9%		
Female	4.6%	11.1%		
Age			$X^2 = 7.043$	0.071
> 40 years	29.1%	45%		
40 – 49 years	23.6%	35%		
50 – 59 years	23.6%	0%		
60 years or older	23.6%	20%		
Practice Characteristics				
Number of urologists at VAMC	3.18+1.66	3.63+1.63	F = 1.260	0.263
Years of practice at present center	90.49+88.69	88.00+66.85	F = 0.014	0.905
Number of new BPH patients per month	36.09+39.48	40.67+287.07	F = 0.176	0.676

Statistically significant ($p \leq .05$)

diagnostic tests for one of the patient case on the main survey which was also included as a part of the non-response survey. The results of this analysis are summarized in Table 4.7. Chi-squares were used compare the preferences of diagnostic tests between the two groups. Results indicate that the two groups did not differ significantly in their preferences for medical history, serum creatinine, AUA, pressure flow, uroflowmetry, post voidal residual volume and other tests. However, the two groups differed significantly in their preference for digital rectal examination ($\underline{X}^2 = 6.936$, $\underline{p} = 0.058$), urinalysis ($\underline{X}^2 = 4.954$, $\underline{p} = 0.026$), PSA ($\underline{X}^2 = 9.427$, $\underline{p} = 0.006$), cystoscopy ($\underline{X}^2 = 6.407$, $\underline{p} = 0.011$), and intravenous pyelogram ($\underline{X}^2 = 4.221$, $\underline{p} = 0.040$). Also, the respondents included a cohort of urologists who preferred these tests more than the non-respondents. Of these, DRE and urinalysis were tests recommended by the guidelines while the other three, PSA, cystoscopy, and intravenous pyelogram were optional tests.

Thus, the results of the study demonstrate non-response bias, such that the non-respondents prefer fewer number of optional tests compared to respondents for diagnosis of a severely symptomatic BPH patient compared to the respondents. Also, the non-respondents included a group of urologists who may prefer some of the recommended tests, especially DRE and urinalysis, to a lesser extent than the respondents. Thus, this imposes limitations on the generalizability of results to the entire group of VA urologists. Hence, readers are cautioned in their interpretation of the study results.

Table 4.7: Analysis of non-response bias for preference of diagnostic tests for Case 3 (high degree of bothersome symptoms)

Characteristics	Respondents	Non-respondents	Test Statistics	Significance
Medical history			$X^2 = 3.589$	0.058
Yes	96.5%	87.0%		
No	3.5%	13.0%		
Digital rectal examination			$X^2 = 6.936$	0.008[*]
Yes	98.2%	87.0%		
No	1.8%	13.0%		
Urinalysis			$X^2 = 4.954$	0.026[*]
Yes	97.4%	87.0%		
No	2.6%	13.0%		
Serum creatinine			$X^2 = 2.332$	0.127
Yes	79.8%	65.2%		
No	20.2%	34.8%		
PSA			$X^2 = 9.427$	0.006[*]
Yes	92.1%	69.9%		
No	7.9%	30.4%		
AUA symptom score			$X^2 = 0.004$	0.948
Yes	74.6%	73.9%		
No	25.4%	26.1%		
Cystoscopy			$X^2 = 6.407$	0.011[*]
Yes	86.8%	65.2%		
No	13.2%	34.8%		
Pressure flow			$X^2 = 1.348$	0.246
Yes	6.1%	13.0%		
No	84.3%	87.0%		
Uroflowmetry			$X^2 = 3.617$	0.057
Yes	43.0%	21.7%		
No	57.0%	78.3%		
Intravenous Pyelogram			$X^2 = 4.221$	0.040[*]
Yes	77.2%	56.5%		
No	22.8%	43.5%		
Post voidal residual volume			$X^2 = 0.865$	0.352
Yes	66.7%	56.5%		
No	33.3%	43.5%		
Others			$X^2 = 0.328$	0.567
Yes	22.8%	17.4%		
No	77.2%	82.6%		

[*]Statistically significant (p ≤ .05)

Demographic and Practice Characteristics

Demographic and practice characteristics of the respondents are presented in Table 4.8. Of the respondents, 103 were male (95.37%) and 5 (4.63%) were female. Also, 32 (29.09%) were less than 40 years of age, 26 (23.64%) were between 40 to 49, 26 (23.64%) were between 50 to 59 and 26 (23.64%) were 60 or older. All urologists reported practicing in a VAMC that used a formulary. Of these, 103 (90.4%) reported having terazosin on their formulary, 15 (13.2%) having doxazosin, 34 (29.8%) having prazosin and 73 (64.9%) having finasteride.

Respondents were asked to indicate the number of urologists practicing at their center. The number of urologists at each VAMC ranged from 0 to 8 with an average of 3.19 urologists at each center. The respondents indicated that an average of 36 new BPH patients visited their center per month. For the purpose of data analysis, the number of years of practice was converted into months. Thus, months of practice ranged from 1 to 360 with an average of 90.50 months (7.54 years).

Objective One Results

The first objective of this study was to compare preferences of VA urologists for diagnosing BPH with AHRQ (formerly AHCPR) guidelines. Table 4.9 indicates frequencies and percentages for diagnostic tests preferred by respondents for each BPH case of Section I of the survey. Almost 97 percent of the respondents preferred use of medical history, while 98 percent preferred use of digital rectal examination for all the three cases. Preference for urinalysis increased from 93 to almost 97 percent as degree of bothersome symptoms increased from low to medium to high. Preferences for serum

Table 4.8: Demographic and practice characteristics of respondents

Characteristics	N	Percent (%)
Gender		
Male	103	95.37
Female	5	4.63
Total	108	100.00
Age		
Less than 40	32	29.09
40-49	26	23.64
50-59	26	23.64
60 or older	26	23.64
Total	110	100.00
Presence of formulary		
Yes	113	100.00
No	0	0.00
Total	113	100.00
Drugs on formulary		
Terazosin	103	90.40
oxazosin	15	13.20
Prazosin	34	29.80
Finasteride	73	64.90

	Range	Mean±Std.Dev
Number of urologists practicing at VAMC	0 - 8	3.19±1.66
Months in practice at present VAMC	1 - 360	90.50±88.69
Number of new BPH patients visiting the VAMC per month	0 - 200	36.09±39.48

Table 4.9: Preferences of urologists for diagnostic tests in BPH patients

Diagnostics tests	Degree of bothersome symptoms					
	Low (Patient # 2[*])		Medium (Patient # 1[*])		High (Patient # 3[*])	
	N	%	N	%	N	%
AHRQ recommended tests						
Medical history	110	96.5	110	96.5	110	96.5
Digital rectal exam	112	98.2	112	98.2	112	98.2
Urinalysis	106	93.0	110	96.5	111	97.4
Serum creatinine	63	55.3	65	57.0	91	79.8
AUA symptom score	87	76.3	88	77.2	85	74.6
AHRQ optional tests						
PSA	109	95.6	106	93.0	105	92.1
Cystoscopy	24	21.1	19	16.7	99	86.8
Pressure flow	8	7.0	7	6.1	7	6.1
Uroflowmetry	54	47.4	58	50.9	49	43.0
Intravenous pyelogram	7	6.1	8	7.0	87	77.2
Post voidal residual volume	80	70.2	83	72.8	76	66.7
Others **	15	13.2	18	15.8	26	22.8

[*]**Patient # 1:** B.T., a 66-year-old white male comes to your clinic with bothersome urinary symptoms. He complains of increased frequency, incomplete bladder emptying and occasional burning sensation. He denies any hematuria. He also reports occasional post void dribbling and nocturia of about 3-4 times a night.

Patient # 2: J.J., a 54-year-old African-American man, presents to your office with lower abdominal discomfort. He reports occasional difficulty initiating urination, midstream stoppage and post void dribbling. He also complains of nocturia of about 2 times a night.

Patient # 3: M.J., a 72-year-old white man presents to you with history of blood in the urine. He gives also a history of increasing difficulty initiating urination, frequent midstream stoppage, frequent burning on urination, and post void dribbling. He also reports a decrease in the force and caliber of his urinary stream as well as incomplete bladder emptying and complains of nocturia of more than 4 times/night and daytime frequency of more than 10 times/day.

**Other tests for patient #1 included; cytology, pelvic ultra scan, bladder ultrasound, CDB, and CBC, for patient #2 included; pelvic ultra scan, CBD, and bladder scan, and for patient #3 included CTS, pelvic ultra scan, CBD, CBC, urine cytology, urine culture, renal sonography, and bladder scan

creatinine increased from 55 to 57 percent as degree of bothersome symptoms increased

from low to medium and increased to almost 80 percent as degree of bothersome

symptoms increased to high. More than three fourths of the respondent urologists

preferred to use the AUA symptom index irrespective of the degree of bothersome

symptoms. These were all the tests recommended by the guidelines. Of the optional

tests, PSA was highly preferred for all three cases (92 to 96 %), whereas pressure flow

was least preferred (6 to 7%). Uroflowmetry and measurement of post voidal residual

volume had moderate preference with the range of preference being 43 to 50 percent and

66 to 70 percent, respectively.   Both the invasive procedures of cystoscopy and

intravenous pyelogram were less preferred for the cases with low and medium degrees of

bothersome symptoms but their preference increased substantially for the case with high

level of bothersome symptoms.   Almost 87 percent of the urologists recommended the

use of cystoscopy while 78 percent recommended the use of intravenous pyelogram for

the patient with high degree of bothersome symptoms.

To compare the preferences of the VA urologists with guidelines, three scores

were calculated for each case.   The first score was a total score obtained as a result of

summation of all the diagnostic tests preferred by the respondents for each of the three

cases. The second score was the recommended score, obtained as a sum of the tests

recommended by guidelines which included medical history, DRE, serum creatinine,

urinalysis and AUA symptom index. The remaining tests were summed to obtain the

third score called the optional score. The mean and range for these scores for each of the

case is presented in Table 4.10. The average number of tests for the cases with low and

medium bothersome symptoms was approximately 7 while it was 8 for the case with high

Table 4.10: Comparison of preferences of VA urologists for diagnostic tests for BPH with guidelines

Cases	Range	Mean±Std.Dev
Total test scores		
Low (patient case 2)	0 - 10	6.798 ± 1.705
Medium (patient case 1)	0 - 10	6.877 ± 1.745
High (patient case 3)	0 - 12	8.412 ± 1.818
Recommended test scores		
Low (patient case 2)	0 - 5	4.193 ± 1.012
Medium (patient case 1)	0 - 5	4.254 ± 0.976
High (patient case 3)	0 - 5	4.464 ± 0.904
Optional test scores		
Low (patient case 2)	0 - 5	2.605 ± 1.027
Medium (patient case 1)	0 - 5	2.623 ± 1.108
High (patient case 3)	0 - 7	3.947 ± 1.174

degree of bothersome symptoms. The recommended test scores ranged between 4 and 5 and increased in number with increasing degree of bothersome symptoms. The optional test scores were almost the same for the cases with low and medium bothersome symptoms (mean =2.6) but increased for the case with high bothersome symptoms (mean=3.9).

T-tests were conducted to determine whether urologists' preference for diagnostic tests differed for the three cases based on the number of tests preferred. The results of this analysis are summarized in Table 4.11. The case with high degree of bothersome symptoms (case 3) significantly differed for all the three computed scores - total, recommended and optional- from the cases with low (case 2) (t = -14.00, t =-5.25, t =-13.48) and medium (case1) (t =-13.50, t =-4.44, t =-13.13) degree of bothersome symptoms, respectively.

Discussion for Objective One Results

The guidelines recommend use of four tests for initial evaluation of a patient presenting with BPH symptoms. These include medical history, digital rectal examination, urinalysis and serum creatinine. It also recommends the use of the AUA symptom score for quantification of symptoms. Almost all the respondents preferred the use of the first three tests for diagnosis of the patient cases. However, serum creatinine was less preferred compared to the first three. This test was preferred more by respondents for case 3, which presented high bothersome symptoms compared to the first two cases. No definite explanation can be provided for such preferences. AUA symptom index was also preferred less compared to the first three tests with a range of 85 to 88

Table 4.11: Comparison of preferences of VA urologists for diagnostic tests for BPH with guidelines based on severity levels.

Pairs	Mean±S.D.	Test Statistics	Significance
Total test scores			
Low (patient #2)	6.798±1.705	t = +0.824	0.412
Medium (patient #1)	6.877±1.745		
Low (patient #2)	6.798±1.705	t = -14.008	0.000[*]
High (patient #3)	8.412±1.818		
Medium (patient #1)	6.877±1.745	t = -13.508	0.000[*]
High (patient #3)	8.412±1.818		
Recommended test scores			
Low (patient #2)	4.193±1.012	t = +1.617	0.109
Medium (patient #1)	4.254±0.976		
Low (patient #2)	4.193±1.012	t = -5.249	0.000[*]
High (patient #3)	4.464±0.904		
Medium (patient #1)	4.254±0.976	t = -4.441	0.000[*]
High (patient #3)	4.464±0.904		
Optional test scores			
Low (patient #2)	2.605±1.027	t = +0.220	0.826
Medium (patient #1)	2.623±1.108		
Low (patient #2)	2.605±1.027	t = -13.482	0.000[*]
High (patient #3)	3.947±1.174		
Medium (patient #1)	2.623±1.108	t = -13.135	0.000[*]
High (patient #3)	3.947±1.174		

Statistically significant ($p \leq .05$)

percent for the three cases. This is an important index, which is utilized for classification of the severity of the patient symptoms. Depending on this classification appropriate treatment option(s) can be selected. This tool has been tested, validated and found to be the most reliable instrument to quantify BPH related symptoms (Barry, Fowler, O'Leary, Bruskewitz, Holtgrewe et al, 1992). Also, there have been studies which show that it captures clinically important changes in patients' condition (Barry, Fowler, O'Leary, Bruskewitz, Holtgrewe et al, 1992). Thus, lower preference for this index could result in utilization of inappropriate treatment strategy, and thereby result in inefficient use of resources. Measurement of PSA level is an optional test in the guidelines. However, higher preference was shown for this test among respondents, with a range of 92 to 95 percent for the three cases. Though this is an optional test, it is used extensively for screening of prostate cancer. Thus, it is likely that higher preference for this test was shown by respondents since they may want to rule out the possibility of prostate cancer. Among the other optional tests like pressure flow, uroflowmetry and post-voidal residual volume (PVRV), pressure flow was least preferred followed by uroflowmetry and finally PVRV. The two invasive optional procedures, cystoscopy and intravenous pyelogram, were less preferred for case one and two (medium and low degree of bothersome symptoms). However, for case three (high degree of bothersome symptoms) both tests were more preferred. This may be due to the fact that the guidelines recommend the use of cystoscopy only if invasive treatment procedures are to be utilized (AHCPR, 1994).

The patient cases were formulated such that case two presented a patient with low bothersome symptoms, case one with medium symptoms and case three with high symptoms. The average number of both recommended and optional tests increased as the

degree of bothersome symptoms of the patient increased. The number of tests preferred

was not significantly different between case one and two, but were significantly different

from case three where the degree of bothersome symptoms were high. Thus, the

preferences of VA urologists demonstrate adherence to the guidelines for the

recommended tests. However, the number of tests preferred increased with increasing

severity of symptoms. Also, the number of tests performed on a patient with high degree

of bothersome symptoms is significantly higher compared to patients with low to medium

degree of symptoms. The results of this study are comparable to the results of the

national urologists' study (Barry et al, 1997) and the study conducted by Gee, Holtgrewe

et al (1995). Both studies reported practices consistent with BPH guidelines in terms of

examination and tests for men with suspected BPH. Thus, this study further establishes

conformation to guidelines by urologists for diagnostic management of BPH, especially

in the VA population.

Objective Two Results

The second objective of the study was to compare preferences of VA urologists

for treating BPH with guidelines/expert opinion. Table 4.12 summarizes the treatment

preferences of the urologists for the three cases. For the mild case, 77 (67.5%) preferred

alpha-blockers, 36 (31.6%) preferred watchful waiting, 2 (1.8%) preferred finasteride, 2

(1.8%) preferred TUIP and 19 (16.7%) preferred other options not listed. For the

moderate case (patient 5), 101 (88.6%) preferred alpha-blockers, 13 (11.4%) preferred

TURP, 4 (3.5%) preferred finasteride, , 4 (3.5) preferred TUIP, 2 (1.8%) preferred

TUVP, 1 (0.9%) preferred laser prostactomy, 1 (0.9%) preferred watchful waiting, and 27

Table 4.12: Preferences of urologists for treatment options used in BPH patients

Treatment option	Severity of BPH					
	Mild (Patient # 6)[*]		Moderate (Patient # 5)[*]		Severe (Patient # 4)[*]	
	N	%	N	%	N	%
Watchful waiting	36	31.6	1	0.9	0	0.0
Alpha-blockers	77	67.5	101	88.6	72	63.2
Finasteride	2	1.8	4	3.5	33	28.9
Balloon Dilation	0	0.0	0	0.0	0	0.0
TURP	0	0.0	13	11.4	54	47.4
TUIP	2	1.8	4	3.5	0	0.0
Open Prostactomy	0	0.0	0	0.0	2	1.8
Laser Prostactomy	0	0.0	1	0.9	3	2.6
TUVP	0	0.0	2	1.8	4	3.5
Other	19	16.7	27	23.7	30	26.3

[*]**Patient # 4:** A.D., a 75-year-old African-American male comes with the problem of urinary incontinence. He also gives a history of difficulty initiating urination, midstream stoppage and terminal dribbling. Rectal examination reveals an enlarged prostate of 50-55 gms. A.D. gives a history of nocturia approximately 4-5 times a night, daytime urinary frequency of 8-10 times a day and he reports of blood in urine. Laboratory findings are as follows: PSA -4.1, AUA ss -28, serum creatinine -1.2, residual volume -300ml, flow rate - 7ml/sec.

Patient # 5: R.C., a 68-year-old Hispanic man, comes to your clinic with severe abdominal discomfort. He reports a history of increased difficulty initiating urination, midstream stoppage and terminal dribbling. R.C. complains of nocturia of 3-4 times/night. DRE reveals an enlarged prostate of approximately 25-30 gms and firm. Laboratory findings are as follow: PSA-2.8, AUA ss - 15, serum creatinine -0.8, residual volume -150ml, flow rate -13ml/sec.

Patient # 6: G.M., a 60-year-old male, presents to your clinic with lower abdominal discomfort. He gives a history of increased difficulty initiating urination, a significant decrease in the force of his urinary stream, occasional midstream stoppage, and post void dribbling. Upon digital rectal examination, the prostate is 20-25 gms and benign. Laboratory findings are as follows: PSA -1.2, AUA ss-6, serum creatinine -0.5, flow rate -20 ml/sec, residual volume -80ml.

(23.7%) preferred use of other options not listed in the questionnaire. Similarly, for the

severe case (patient 4) 72 (63.2%) respondents preferred alpha-blockers, 54 (47.4%)

preferred TURP (surgery), 33 (28.9%) preferred finasteride, 4 (3.5%) preferred TUVP, 3

(2.6%) preferred laser prostactomy, 2 (1.8%) preferred open prostactomy, and 30 (26.3%)

preferred the use of other options. The other options for all three cases primarily

consisted of additional diagnostic tests like cystoscopy, intravenous pyelogram,

ultrasound etc.

The above responses were compared with the guidelines and to expert opinion to

determine adherence. The recommended option for the mild case was watchful waiting

(from guidelines) whereas for the moderate case it was drug therapy (from expert

opinion) and for the severe case it was TURP (expert opinion). For the moderate and

severe cases the guidelines did not recommend specific treatment options. Hence, expert

opinion was used to compare respondent's preferences. Of the 114 respondents, 36

(31.6%) favored watchful waiting for the mild case, while 78 (68.4%) respondents

preferred other options. For the moderate case, 101 (88.6%) respondents preferred the

use of alpha-blocker to control symptoms and 5 preferred the use of finasteride.

However, since the questionnaire allowed selection of multiple options, close study of the

data indicated that the 5 respondents who preferred use of finasteride also preferred use

of alpha-blockers. Hence, 101 respondents preferred use of drug therapy for controlling

symptoms. Thus, the percent adherence for the moderate case was 88.60. Similarly for

the severe case, of the 114, 54 preferred TURP. Thus, the percent adherence was 47.4

(see Table 4.13).

Table 4.13: Comparison of preferences of VA urologists for treatment of BPH with guidelines/expert opinion

Cases	Recommended treatment option	Percent Adherence	Percent Non-adherence
Mild (patient # 6)	Watchful waiting	31.60	68.42
Moderate (patient #5)	Drug therapy[*]	88.60	11.40
Severe (patient #4)	TURP[*]	47.40	52.60

[*]These cases were compared with expert opinion, as guidelines did not recommend specific treatment options.

Discussion for Objective Two Results

The guidelines recommend watchful waiting as the strategy of choice for patients with mild symptoms. However, only about 32 percent of the urologists preferred this option for case 6, a patient with mild symptoms. Majority of the respondents (68 percent) preferred use of alpha-blockers for this case. This may result in inappropriate utilization of resources. For moderate and severe cases the guidelines do not recommend any particular treatment option. Hence for these two patient cases urologists' preferences were compared with expert opinion. The experts preferred drug therapy (alpha-blockers and/or finasteride) for the patient with moderate symptoms (case 5) and TURP for the patient with severe symptoms (case 4). Among the respondent urologists approximately 89 percent of respondents preferred drug therapy for the moderate case, whereas approximately 48 percent of the respondents preferred TURP for the severe case. Also, a large percentage of the respondents preferred the use of drug therapy either in the form of alpha-blockers or finasteride for the severe case, with alpha-blockers being preferred to a greater extent. None of the respondents showed preference for use of balloon dilation in any of the cases. Thus the respondents preferred the use of alpha-blockers for all the cases, irrespective of the symptom severity. In other words, alpha-blockers are being recommended when pharmacological therapy is not required and also when surgery is a better alternative for managing the symptoms. This result is not congruent with that shown by Gee et al (1997). Gee et al (1997) found watchful waiting to be the most preferred first line of therapy for patients with mild symptoms, alpha-blockers for moderate symptoms and TURP as the preferred first line therapy for severe symptoms. However, the results show some consistency with the national survey of urologists which

demonstrated use of pharmacological therapy when not required (Barry et al, 1997).

Also, it shows some consistency with findings of Bruskewtiz (1999) who demonstrated

that alpha-blockers was employed most of the time for patients with severe symptoms.

But, Bruskewitz also demonstrated that watchful waiting was used 77% of the time for

men with mild symptoms. Thus though VA urologists do not conform too well with

guidelines and expert opinion in their preferences for therapeutic management of BPH

symptoms, their preferences support previous findings reported in literature.

Objective Three Results

The third objective of the study was to determine the effect of demographic and

practice characteristics on the preferences of VA urologists for diagnosing and treating

BPH. This analysis was divided into two sections, the first assessed the effect of

demographic characteristics on the preferences of VA urologists for diagnostic tests, and

the second assessed their effects on preferences for treatment options. Correlations were

conducted for the first section. This was conducted in two ways. A sum score was

computed for each diagnostic test depending on whether it was recommended for all the

three cases in Section I of the survey. Thus, if a test was recommended for all the three

cases it would have a score of three but if it was not recommended for any, it would have

a score of zero. Correlations were obtained between the computed scores for every

diagnostic test and the demographic and practice characteristics. The demographic and

practice characteristics used included number of urologists, years of practice, number of

new BPH patients visiting per month, and age of urologist. The results of this analysis

are presented in Tables 4.14 to 4.24. Additionally, correlations were conducted between

Table 4.14: Correlation matrix for test score of medical history

Variables	Medical history	Number of urologists	Years of practice	Number of BPH patients	Age
Medical history	1.000				
Number of Urologists	-.081	1.000			
Years of practice	-.100	-.051	1.000		
Number of BPH patients	.012	.128	.089	1.000	
Age	-.189[*]	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant (p ≤ .05)

Table 4.15: Correlation matrix for test score of digital rectal examination (DRE)

Variables	DRE	Number of urologists	Years of practice	Number of BPH patients	Age
DRE	1.000				
Number of Urologists	-.147	1.000			
Years of practice	-.109	-.051	1.000		
Number of BPH patients	-.005	.128	.089	1.000	
Age	-.133	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.16: Correlation matrix for test score of urinalysis

Variables	Urinalysis	Number of urologists	Years of practice	Number of BPH patients	Age
Urinalysis	1.000				
Number of Urologists	-.229[*]	1.000			
Years of practice	.027	-.051	1.000		
Number of BPH patients	-.003	.128	.089	1.000	
Age	.017	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.17: Correlation matrix for test score of serum creatinine

Variables	Serum creatinine	Number of urologists	Years of practice	Number of BPH patients	Age
Serum creatinine	1.000				
Number of Urologists	-.204[*]	1.000			
Years of practice	-.012	-.051	1.000		
Number of BPH patients	.072	.128	.089	1.000	
Age	-.218[*]	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.18: Correlation matrix for test score of prostate specific antigen level (PSA)

Variables	PSA	Number of urologists	Years of practice	Number of BPH patients	Age
PSA	1.000				
Number of Urologists	-.011	1.000			
Years of practice	-.032	-.051	1.000		
Number of BPH patients	.069	.128	.089	1.000	
Age	-.112	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.19: Correlation matrix for test score of AUA symptom index

Variables	AUA	Number of urologists	Years of practice	Number of BPH patients	Age
AUA	1.000				
Number of Urologists	-.108	1.000			
Years of practice	.024	-.051	1.000		
Number of BPH patients	.066	.128	.089	1.000	
Age	-.104	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.20: Correlation matrix for test score of cystoscopy

Variables	Cystoscopy	Number of urologists	Years of practice	Number of BPH patients	Age
Cystoscopy	1.000				
Number of Urologists	.064	1.000			
Years of practice	.039	-.051	1.000		
Number of BPH patients	-.063	.128	.089	1.000	
Age	-.079	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant (p ≤ .05)

Table 4.21: Correlation matrix for test score of pressure flow studies

Variables	Pressure flow	Number of urologists	Years of practice	Number of BPH patients	Age
Pressure flow	1.000				
Number of Urologists	.039	1.000			
Years of practice	-.090	-.051	1.000		
Number of BPH patients	-.023	.128	.089	1.000	
Age	.093	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant (p ≤ .05)

Table 4.22: Correlation matrix for test score of uroflowmetry

Variables	Uroflow-metry	Number of urologists	Years of practice	Number of BPH patients	Age
Uroflowmetry	1.000				
Number of Urologists	.031	1.000			
Years of practice	-.073	-.051	1.000		
Number of BPH patients	.034	.128	.089	1.000	
Age	-.148	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.23: Correlation matrix for test score of intravenous pyelogram (IVP)

Variables	IVP	Number of urologists	Years of practice	Number of BPH patients	Age
IVP	1.000				
Number of Urologists	-.051	1.000			
Years of practice	-.004	-.051	1.000		
Number of BPH patients	-.108	.128	.089	1.000	
Age	.155	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

Table 4.24: Correlation matrix for test score of post voidal residual volume (PVRV)

Variables	PVRV	Number of urologists	Years of practice	Number of BPH patients	Age
PVRV	1.000				
Number of Urologists	-.152	1.000			
Years of practice	-.136	-.051	1.000		
Number of BPH patients	-.075	.128	.089	1.000	
Age	-.183	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

the recommended, optional and total score and the demographic and practice characteristics. The details of how these scores were computed is explained in section for objective one of Results chapter (Chapter 4, page 70). The results of these correlations are presented in Tables 4.25 to 4.33.

The correlations which showed significant associations were: age was negatively associated with medical history test score (r = -.189), and positively associated with serum creatinine test score (r =.218), number of urologists was negatively associated with urinalysis test score (r =-.229) and serum creatinine test score (r =-.204). Also, number of urologists was negatively associated with recommended score for case1(r = -.250), recommended score for case 2 (r =-.266), total score for case 1 (r =-.211) and total score for case 2 (r =-.259). Additionally, age was negatively associated with optional score for case 3 (r =-.268) and total score for case 3 (r =-.208).

To assess the effects of demographics and practice characteristics on preferences for treatment options, chi-squares statistics were conducted. To do so, the variables of years of practice at present center and number of new BPH patients seen per month were re-coded to get categorical variables. Thus, years of practice was divided into 5 categories: less than 2 years, 2 to less than 4 years, 4 to less than 7 years, 7 to less than 10 years and 10 years and above. Similarly number of new BPH patients seen per month was divided into 4 categories: less than 10, 11 to 20, 21 to 40 and greater than 40. Chi-squares were conducted for each case in section two, i.e. case 4, case 5, and case 6. Preferences for some of the treatment options were low. Hence they were not included in the chi-squares analysis, since they would result in a greater percentage of empty cells. Thus, chi-square tests were conducted for the treatment options of finasteride, alpha-

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Table 4.25: Correlation matrix for recommended test score for case 1

Variables	Recommended test score 1	Number of urologists	Years of practice	Number of BPH patients	Age
Recommended** test score 1	1.000				
Number of Urologists	-.250*	1.000			
Years of practice	.006	-.051	1.000		
Number of BPH patients	.096	.128	.089	1.000	
Age	.033	-.294*	.421*	.012	1.000

*Statistically significant ($p \leq .05$)

**Recommended test score 1= Medical History + DRE +Serum creatinine + Urinalysis + AUA symptom score (use of these tests for case 1)

Table 4.26: Correlation matrix for recommended test score for case 2

Variables	Recommended test score 2	Number of urologists	Years of practice	Number of BPH patients	Age
Recommended ** test score 2	1.000				
Number of Urologists	-.266*	1.000			
Years of practice	-.020	-.051	1.000		
Number of BPH patients	.014	.128	.089	1.000	
Age	.045	-.294*	.421*	.012	1.000

*Statistically significant (p $\leq$ .05)

**Recommended test score 2= Medical History + DRE +Serum creatinine + Urinalysis + AUA symptom score (use of these tests for case 2)

Table 4.27: Correlation matrix for recommended test score for case 3

Variables	Recommended test score 3	Number of urologists	Years of practice	Number of BPH patients	Age
Recommended ** test score 3	1.000				
Number of Urologists	-.107	1.000			
Years of practice	-.052	-.051	1.000		
Number of BPH patients	.069	.128	.089	1.000	
Age	-.054	-.294*	.421*	.012	1.000

*Statistically significant (p $\leq$ .05)

**Recommended test score 3= Medical History + DRE +Serum creatinine + Urinalysis + AUA symptom score (use of these tests for case 3)

Table 4.28: Correlation matrix for optional test score for case 1

Variables	Optional test score 1	Number of urologists	Years of practice	Number of BPH patients	Age
Optional ** test score 1	1.000				
Number of Urologists	-.113	1.000			
Years of practice	-.094	-.051	1.000		
Number of BPH patients	-.132	.128	.089	1.000	
Age	.008	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

**Optional test score 1=PSA + Cystoscopy + Pressure flow + Uroflowmetry + Intravenous pyelogram + Post voidal residual volume + others   (use of these tests for case 1)

Table 4.29: Correlation matrix for optional test score for case 2

Variables	Optional test score 2	Number of urologists	Years of practice	Number of BPH patients	Age
Optional ** test score 2	1.000				
Number of Urologists	-.163	1.000			
Years of practice	-.089	-.051	1.000		
Number of BPH patients	-.080	.128	.089	1.000	
Age	.005	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

**Optional test score 2=PSA + Cystoscopy + Pressure flow + Uroflowmetry + Intravenous pyelogram + Post voidal residual volume + others (use of these tests for case 2)

Table 4.30: Correlation matrix for optional test score for case 3

Variables	Optional test score 3	Number of urologists	Years of practice	Number of BPH patients	Age
Optional ** test score 3	1.000				
Number of Urologists	.036	1.000			
Years of practice	-.101	-.051	1.000		
Number of BPH patients	-.042	.128	.089	1.000	
Age	-.268[*]	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

**Optional test score 3=PSA + Cystoscopy + Pressure flow + Uroflowmetry + Intravenous pyelogram + Post voidal residual volume + others (use of these tests for case 3)

Table 4.31: Correlation matrix for total test score for case 1

Variables	Total test score 1	Number of urologists	Years of practice	Number of BPH patients	Age
Total ** test score 1	1.000				
Number of Urologists	-.211[*]	1.000			
Years of practice	-.056	-.051	1.000		
Number of BPH patients	-.031	.128	.089	1.000	
Age	.023	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant ($p \leq .05$)

**Total test score 1= Medical history + DRE + Serum creatinine + Urinalysis +AUA + PSA + Cystoscopy + Pressure flow + Uroflowmetry + Intravenous pyelogram + Post voidal residual volume + others (use of these tests for case 1)

Table 4.32: Correlation matrix for total test score for case 2

Variables	Total test score 2	Number of urologists	Years of practice	Number of BPH patients	Age
Total ** test score 2	1.000				
Number of Urologists	-.259[*]	1.000			
Years of practice	-.066	-.051	1.000		
Number of BPH patients	-.039	.128	.089	1.000	
Age	.030	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant (p ≤ .05)

**Total test score 2= Medical history + DRE + Serum creatinine + Urinalysis +AUA + PSA + Cystoscopy + Pressure flow + Uroflowmetry + Intravenous pyelogram + Post voidal residual volume + others (use of these tests for case 2)

Table 4.33: Correlation matrix for total test score for case 3

Variables	Total test score 3	Number of urologists	Years of practice	Number of BPH patients	Age
Total ** test score 1	1.000				
Number of Urologists	-.030	1.000			
Years of practice	-.091	-.051	1.000		
Number of BPH patients	.008	.128	.089	1.000	
Age	-.208[*]	-.294[*]	.421[*]	.012	1.000

[*]Statistically significant (p ≤ .05)

**Total test score 3= Medical history + DRE + Serum creatinine + Urinalysis +AUA + PSA + Cystoscopy + Pressure flow + Uroflowmetry + Intravenous pyelogram + Post voidal residual volume + others (use of these tests for case 3)

blockers and TURP for case 4, alpha-blockers for case 5, and alpha-blockers and watchful waiting for case 6. The results of this analysis are presented in Tables 4.34 to 4.41. The selection of treatment options for the three cases did not demonstrate any significant difference based on the demographic and practice characteristics used.

Discussion for Objective Three Results

The only variables which demonstrated some effect on preferences for diagnostic tests were age and number of urologists. Age was negatively associated with the performance of medical history and positively associated with the performance of serum creatinine tests. Thus, younger urologists preferred not to perform medical history and older urologists preferred to perform serum creatinine tests more often. Also, as the number of urologists practicing in the center increased, their preference for performance of urinalysis and serum creatinine decreased. The analysis also revealed that as number of urologists increases the number of recommended tests and total tests done for the case with low and medium bothersome symptoms, decreases. Also, age was negatively associated with the number of optional tests and total tests performed for the case with high bothersome symptoms. This is contrary to the results of national survey of urologists. The study with national urologists had older urologists recommending more optional tests compared to younger urologists (Barry et al, 1997). Also, none of the demographic and practice characteristics demonstrated any association with the preferences for selection of treatment options. The national urologists' study had demonstrated a non-significant trend for younger urologists to prescribe alpha-blockers

Table 4.34: Analysis of effect of demographic and practice characteristics on selection of alpha- blockers for case 4 (severe)

Characteristics	Yes (%)	No (%)	Test Statistics	Significance
Age			$X^2 = 0.136$	0.987
>40 years	62.5	37.5		
40 – 49 years	61.5	38.5		
50 – 59 years	65.4	34.6		
60 years or older	65.4	34.6		
Years of practice			$X^2 = 0.958$	0.916
at present center				
> 2 years	70.4	29.6		
2 – 4 years	58.3	41.7		
4 – 7 years	61.9	38.1		
7 – 10 years	66.7	33.3		
10 years & above	61.5	38.5		
Number of new BPH			$X^2 = 2.098$	0.552
patients per month				
>10	75.0	25.0		
11-20	55.9	44.1		
21-40	63.6	36.4		
> 40	66.7	33.3		

Statistically significant ($p \leq .05$)

Table 4.35: Analysis of effect of demographic and practice characteristics on selection of finasteride for case 4 (severe)

Characteristics	Yes (%)	No (%)	Test Statistics	Significance
Age			$X^2 = 0.891$	0.828
>40 years	28.1	71.9		
40 – 49 years	30.8	69.2		
50 – 59 years	23.1	76.9		
60 years or older	34.6	65.4		
Years of practice			$X^2 = 5.215$	0.266
at present center				
> 2 years	33.3	66.7		
2 – 4 years	41.7	58.3		
4 – 7 years	33.3	66.7		
7 – 10 years	20.0	80.0		
10 years & above	15.4	84.6		
Number of new BPH			$X^2 = 3.919$	0.270
patients per month				
>10	40.0	60.0		
11-20	29.4	70.6		
21-40	13.6	86.4		
> 40	33.3	66.7		

Statistically significant ($p \leq .05$)

Table 4.36: Analysis of effect of demographic and practice characteristics on selection of TURP for case 4 (severe)

Characteristics	Yes (%)	No (%)	Test Statistics	Significance
Age			$X^2 = 1.628$	0.653
>40 years	53.1	46.9		
40 – 49 years	50.0	50.0		
50 – 59 years	53.8	46.2		
60 years or older	38.5	61.5		
Years of practice			$X^2 = 4.513$	0.341
at present center				
> 2 years	37.0	63.0		
2 – 4 years	62.5	37.5		
4 – 7 years	38.1	61.9		
7 – 10 years	46.7	53.3		
10 years & above	53.8	46.2		
Number of new BPH			$X^2 = 1.795$	0.616
patients per month				
>10	35.0	65.0		
11-20	50.0	50.0		
21-40	54.5	45.5		
> 40	45.8	54.2		

Statistically significant ($p \leq .05$)

Table 4.37: Analysis of effect of demographic and practice characteristics on selection of alpha- blockers for case 5 (moderate)

Characteristics	Yes (%)	No (%)	Test Statistics	Significance
Age			$X^2 = 0.304$	0.959
>40 years	90.6	9.4		
40 – 49 years	88.5	11.5		
50 – 59 years	88.5	1.5		
60 years or older	92.3	7.7		
Years of practice at present center			$X^2 = 4.887$	0.299
> 2 years	92.6	7.4		
2 – 4 years	95.6	4.2		
4 – 7 years	76.2	23.8		
7 – 10 years	86.7	13.3		
10 years & above	88.5	11.5		
Number of new BPH patients per month			$X^2 = 4.148$	0.246
>10	85.0	15.0		
11-20	97.1	2.9		
21-40	81.8	18.2		
> 40	91.7	8.3		

Statistically significant ($p \leq .05$)

Table 4.38: Analysis of effect of demographic and practice characteristics on selection of watchful waiting for case 6 (mild)

Characteristics	Yes (%)	No (%)	Test Statistics	Significance
Age			$X^2 = 0.136$	0.987
>40 years	37.5	62.5		
40 – 49 years	42.3	57.7		
50 – 59 years	23.1	76.9		
60 years or older	26.9	73.1		
Years of practice at present center			$X^2 = 5.662$	0.226
> 2 years	25.9	74.1		
2 – 4 years	45.8	54.2		
4 – 7 years	23.8	76.2		
7 – 10 years	46.7	53.3		
10 years & above	23.1	76.9		
Number of new BPH patients per month			$X^2 = 2.913$	0.405
>10	25.0	75.0		
11-20	32.4	67.6		
21-40	40.9	59.1		
> 40	29.2	70.8		

Statistically significant ($p \leq .05$)

Table 4.39: Analysis of effect of demographic and practice characteristics on selection of alpha- blockers for case 6 (mild)

Characteristics	Yes (%)	No (%)	Test Statistics	Significance
Age			$X^2 = 2.385$	0.496
>40 years	75.0	25.0		
40 – 49 years	57.7	42.3		
50 – 59 years	73.1	26.9		
60 years or older	65.4	34.6		
Years of practice			$X^2 = 2.890$	0.576
at present center				
> 2 years	77.8	22.2		
2 – 4 years	66.7	33.3		
4 – 7 years	71.4	28.6		
7 – 10 years	53.3	46.7		
10 years & above	65.4	34.6		
Number of new BPH			$X^2 = 4.780$	0.189
patients per month				
>10	75.0	25.0		
11-20	73.5	26.5		
21-40	50.0	50.0		
> 40	75.0	25.0		

Statistically significant ($p \leq .05$)

more often than older urologists and older urologists to perform TURP more often than younger urologists. No definite explanations can be provided for this observation.

Objectives Four and Five Results

Objective four aimed to assess the level of agreement among VA urologists on the use of diagnostic tests and procedures for patients presenting with BPH symptoms. The null hypothesis stated no agreement among urologists for selection of diagnostic tests, while adjusting for chance agreement.

The following procedure was followed to meet this objective. The probability that a certain test was preferred in a particular patient, P (test) was calculated for each of the three cases. The use of a diagnostic test in any of the cases was a dichotomous choice, either it was preferred by the urologist or not preferred. The degree of inter-individual agreement in the use of one diagnostic test in a particular case was defined as the probability that two urologists would agree on whether or not a diagnostic test should be used, i.e. the relative measure of agreement RMA (test) (Coughlin, Pickle, Goodman, & Wilkens, 1992). This relative measure of agreement was obtained as follows:

$$RMA \text{ (test)} = P(\text{test})^2 + [1-P(\text{test})]^2$$

P (test) is the probability that the test was used by the urologist and 1-P(test) is the probability that it was not used. This value varies between 0.5 and 1.0. It is a minimum of 0.5 when P(test) is 0.5 and maximum of 1 when P(test) is either 1 or 0. The mean RMA (test) for all the tests in a certain case were calculated and was called RMA (case). It was used to compare the degree of agreement in the diagnostic management of the

three cases. This was then used to calculate the generalized kappa statistic for each case (Woolson, 1987).

$$K_G = [RMA(\text{case}) - P_e]/(1-P_e)$$

P_e is the expected agreement by chance, which in this case is 0.5 as the number of possible categories is two. The study had three cases (N) which had to be classified in two categories by 114 (K) urologists. The variance (Woolson, 1987) for the generalized kappa statistic in each case was obtained as follows:

$$\sigma^2_{KG} = \frac{2}{NK(K-1)} \quad \frac{P(T)^2 + P(T^*)^2 - (2K-3)[P(T)^2 + P(T^*)^2] + 2(K-2)[P(T)^3 + P(T^*)^3]}{\{1 - [P(T)^2 + P(T^*)^2]\}^2}$$

Where, P(T) is the mean value of all the P(test) for one case and P(T*) is the mean value of not performing a test. The significance of agreement on the preference for diagnostic tests in one case was evaluated by the Z-value obtained as follows:

$$Z = K_G/S_{KG}$$

This was done for all the three cases. The results of this analysis are summarized in Table 4.40. The kappa statistic for the case with low degree of bothersome symptoms was 0.517, was 0.529 for the case with medium degree of bothersome symptoms, and was 0.501 for the case with high degree of bothersome symptoms. The Z values for all the three cases demonstrated significance. Thus, the null hypothesis was rejected and conclusion drawn about VA urologists' demonstrating significant inter-rater agreement in their preferences for diagnostic management of BPH.

Objective five aimed to assess the level of agreement among VA urologists on the use of treatment options for management of BPH patients. The null hypothesis for this stated no agreement among urologists for selection of the treatment options, while adjusting for chance agreement.

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Table 4.40: Measurement of inter-rater agreement of VA urologists in diagnostic management of BPH

Case	kappa	SD	Z	p
Low (Case 2)	0.517	0.008	63.85	<.0001[*]
Medium (Case 1)	0.529	0.009	60.33	<.0001[*]
High (Case 3)	0.501	0.024	20.96	<.0001[*]

[*]kappa is significantly different from zero when $p < 0.05$

For this, probability that a certain treatment option was preferred in a particular patient, P(trt) was calculated for each of the three cases. The RMA(trt) was calculated for each case in a similar manner as diagnostic tests. Similarly generalized kappa, standard deviation and Z values were calculated for cases 4, 5 and 6. The results of this analysis are summarized in Table 4.41. The kappa statistic for the mild case was 0.757, was 0.806 for moderate case and 0.617 for the severe case. The Z values for all the three cases demonstrated significance. Thus, the null hypothesis was rejected and conclusion drawn about VA urologists' demonstrating significant inter-rater agreement in their preferences of treatment options for management of BPH.

Discussion for Objectives Four and Five Results

The study demonstrated significant kappa statistics among the respondents for utilization of both diagnostic tests and treatment options. The values of kappa ranged from 0.501 to 0.529 for diagnostic management, while for selection of treatment options it ranged from 0.61 for the severe case to 0.80 for the moderate case. The interpretation of kappa values is given as follows: <0 – no agreement, 0-0.19 –poor agreement, 0.20 to 0.39 -fair agreement, 0.40 to 0.59 -moderate agreement, 0.60 to 0.79 -substantial agreement, and 0.80 to 1.00 -almost perfect agreement (Landis & Koch, 1977). Thus, VA urologists demonstrate moderate agreement for preference of diagnostic tests, while for preferences of therapeutic options they demonstrate substantial agreement with almost perfect agreement for the moderate case. A study conducted by Hansen and Zdanowski (1997), had shown different results. It showed disagreement among urologists for

Table 4.41: Measurement of inter-rater agreement of VA urologists in management of symptoms of BPH

Case	kappa	SD	Z	p
Mild (case 6)	0.757	0.070	10.86	<.0001[*]
Moderate (case 5)	0.806	0.064	12.65	<.0001[*]
Severe(case 4)	0.617	0.051	12.05	<.0001[*]

[*]kappa is significantly different from zero when p <0.05

management of men with lower urinary tract symptoms. However, that study included a group of international urologists, a different cohort of individuals compared to this study.

Theoretically, to solve a certain problem there must be adequate information on the basis of which decisions can be made. When different diagnostic tests are utilized there is a likelihood that therapeutic decisions may differ as they are based on the results of these diagnostic tests.   Also, even if there is agreement about use of diagnostic tests, there may be disagreement about the criteria for subsequent therapy. Thus, disagreement for both diagnostic management and selection of therapy can result in higher costs for management of a condition. However, the respondents in this study demonstrated agreement not only for diagnostic evaluation but also for selection of therapeutic options.

Objective Six Results

This objective aimed to determine the treatment failure rate for BPH in the VA population and the types of treatment switches commonly made following failed initiation therapy. Section three of the questionnaire was utilized for analysis pertaining to this objective. The survey required the respondents to recall treatments for their last five patients, and inquired about the number from these five, who had to be switched due to failure of initiation therapy. The type of switch made was also requested. The number of respondents, who answered this question was 106. Thus total number of patients whose therapy was ascertained was calculated as 106*5, i.e. 530. The total number of switches reported was 218. This resulted in a treatment failure rate of 41.13 %. Results of this analysis are presented in Table 4.42. A total of 26 (24.5%) urologists reported switching 1 patient, 36 (34.0%) switching 2 patients, 26 (24.5%) switching 3 patients, 3

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Table 4.42: Estimation of treatment failure rate for BPH management among respondents

Number of last five patients switched to other treatment options	N	Percent (%)
None	9	7.90
1	26	24.50
2	36	34.50
3	26	24.50
4	3	2.80
5	6	5.70
Total	106	100.00

Total number of patient treated = Number of respondents answering the question * 5

$$= 106 * 5 = 530$$

Total number of patients switched = 0 (9) + 1 (26) +2 (36) + 3 (26) + 4 (12) + 5 (6) = 218

Treatment switch rate = (218/530) *100 = 41.13%

(2.8%) switching 4 patients and 6 (5.7%) reported switching 5 patients. The remaining 9 (8.5%) respondents did not report any switches.

The most common switch reported was from alpha-blockers to surgery, with 103 (47.25%) patients being switched. The next most common switch reported was single to combination drug therapy, done on 33 (15.14%) patients. Around 11 percent of patients were switched from watchful waiting to drug therapy, 10 percent were switched from combination drug therapy to surgery, 6 percent were switched from alpha-blockers to finasteride, 3 percent were switched both from finasteride to alpha-blockers and to surgery, and 1 percent was from watchful waiting to surgery. The remaining switches, which were reported for less than 1 percent of patients were from one alpha blocker to a different alpha-blocker and combination drug therapy to balloon dilation. Also, none of the respondents reported switching patients from watchful waiting to balloon dilation, alpha-blocker to balloon dilation, finasteride to balloon dilation and balloon dilation to surgery (See Table 4.43).

Additionally, analysis was conducted to determine the types of switches made when the first line therapies were alpha-blockers, finasteride and watchful waiting. A total of 27 (12.39 %) patients who started on watchful waiting, 115 (52.75%), who started on alpha-blockers, and 12 (5.50%) who started on finasteride as the first line of therapy had to be switched to other treatment options due to failure of initiation therapy. Also, almost 89 percent of switches from watchful waiting were for drug therapy and 11 percent were for surgery. When alpha-blockers was the first line of therapy, 89.56 percent of switches made were for surgery while 10.43 percent were for finasteride. In

Table 4.43: Summary of type of switch made for failure of initiation therapy

Type of switch	N	%
Alpha-blockers to surgery	103	47.25
Single to combination drug therapy	33	15.14
Watchful waiting to drug therapy	24	11.01
Combination therapy to surgery	21	9.63
Alpha-blockers to finasteride	12	5.51
Finasteride to alpha-blockers	6	2.75
Finasteride to surgery	6	2.75
Watchful waiting to surgery	3	1.38
Other (alpha to different alpha)	2	0.01
Combination drugs to balloon dilation	1	0.01
Watchful waiting to balloon dilation	0	0.00
Alpha to balloon dilation	0	0.00
Finasteride to balloon dilation	0	0.00
Balloon dilation to surgery	0	0.00
Total	218	100.00

case of finasteride, 50 percent of the switches were for surgery and 50 for alpha- blockers (see Tables 4.44 to 4.46).

Discussion for Objective Six Results

The study demonstrated an almost 42 percent treatment failure rate for initiation therapy. Among the switches, alpha-blockers to surgery was the most common. This could be due to the fact that a large percentage of the respondents preferred alpha-blockers as first line of therapy for patients with severe symptoms. The second major switch was from single drug therapy to combination therapy. A study comparing terazosin (an alpha-blocker), finasteride and its combination indicated that combination therapy is no more effective than terazosin (Lepor et al, 1996). Also, there has been no other evidence in the literature which indicates use of combination therapy to be effective. Thus, combination therapy may result in increased use of resources, without better outcomes. Alpha-blockers appear to be the most commonly employed first line of therapy, but almost 53 percent of the patients had to be switched, of which almost 90 percent had to be to switched to surgery. This again substantiates the fact that surgery is underutilized as first line of therapy for severely symptomatic BPH patients, with alpha-blockers being used instead. This results in a high percentage of switches from alpha-blockers to surgery. Almost 13 percent of the patients on watchful waiting had to be switched, of which almost 89 percent had to be switched to drug therapy. This may be one of the reasons why watchful waiting is an underutilized procedure with this cohort of urologists. Switching from finasteride to another option was observed for approximately

Table 4.44: Switching summary for watchful waiting

	N	Percent (%)
Total switches	27	12.39
Type of switch		
Watchful waiting to drug therapy	24	88.88
Watchful waiting to surgery	3	11.12
Watchful waiting to balloon dilation	0	0.00

Table 4.45: Switching summary for alpha-blockers

	N	Percent (%)
Total switches	115	52.57
Type of switch		
Alpha-blockers to surgery	103	89.56
Alpha-blockers to finasteride	12	10.43
Alpha to balloon dilation	0	0.00

Table 4.46: Switching summary for finasteride

	N	Percent (%)
Total switches	12	5.50
Type of switch		
Finasteride to alpha-blockers	6	50.00
Finasteride to surgery	6	50.00
Finasteride to balloon dilation	0	0.00

6 percent of the patients. Thus, it appears to be a good therapeutic option with a lower

switch rate. However, it was not one of the preferred first line of therapy as observed in

the treatment options section. It was preferred more often for patients with severe

symptoms. This is consistent with the findings in literature, about finasteride being more

effective for men with larger prostates (greater than 40 grams) (Boyle, Gould &

Roehrborn, 1996). The severe case in this study included a patient with a prostate greater

than 50 grams. Additionally, finasteride has been shown to be more economical than

other treatments in men with larger prostates (Albertsen, Pellissier, Lowe, Girman, &

Roehrborn, 1999).

Objective Seven Results

This objective aimed to estimate the cost of diagnosing new BPH patients in the

VA population. For fulfillment of this objective, standard charges for all the diagnostic

tests were obtained from the VA center at West Virginia (Clarksburg). For, those

procedures which are preformed during a physician visit such as medical history, DRE

and AUA symptom index , the average urologists' consultation fees was used. This was

obtained from the same center. All charges used are listed in Table 4.47. These charges

were utilized to compute total cost of diagnosis for each of the cases in section one of the

survey i.e. case1, 2 and 3. The physicians' fee was taken as a base to which charges for

other tests were added depending on whether they were preferred by the urologists or not.

The mean total cost for diagnosing each case was obtained. This is summarized in Table

4.48. Thus average cost for diagnosis for the case with low symptoms was $237.37,

medium symptoms was $237.04 and high symptoms was $340.14. The charges for

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Table 4.47: Standard charges for diagnostic tests.

Tests	Charges
Recommended tests	
Physicians fee {Medical history, DRE, AUA symptom index}	$80.00
Urinalysis	$4.52
Serum creatinine	$7.31
Optional tests	
PSA	$26.27
Cystoscopy	$94.34
Pressure flow	$87.45
Uroflowmetry	$46.06
Intravenous pyelogram	$78.46
Post voidal residual volume	$101.72

Table 4.48: Cost of diagnosis per patient

Case	Range ($)	Mean ($)
Low bothersome symptoms	80 – 431.37	237.04
Medium bothersome symptoms	80 – 447.67	237.37
High bothersome symptoms	80 – 526.13	340.14

performance of the recommended tests only were calculated to be $91.83. These charges

were used to project the total costs for diagnosing new BPH patients for the VA

population. The average number of new BPH patients visiting each VAMC per month

was 36. This was multiplied by 12 to obtain the number of patients per year and by 173

to obtain the total number of new BPH patients that are expected to visit VAMCs

nationwide. Thus, the total number of new BPH patients visiting all the VAMCs

annually would be 74,736. Four cost projections were made based on four assumptions:

a) all patients visiting the centers would have low levels of bothersome symptoms, b) all

patients have medium level of symptoms c) all patients have high level of symptoms, and

d) an equal distribution of patients with low, medium and high levels of bothersome

symptoms. These assumptions were made due to the absence of any population data in

literature on distribution of the trend of bothersome symptoms. Thus, the cost of

diagnosis ranged from $17.7 million to $25.4 million depending on the assumption made.

Also, the total cost of diagnosis when only the recommended tests were used was $6.8

million (see Table 4.49).

Discussion for Objective Seven Results

The average cost of diagnosis for BPH ranged from $237.04 to $340.14 per

patient basis. Though the average number of tests for the medium case was higher than

the low case, the average cost was slightly lower. This may be due to the fact that the

respondents had demonstrated higher preference for a more expensive test like

cystoscopy for the low case compared to the medium case. On projecting these values to

the entire VA system, the cost of diagnosis ranged from $17.7 million to $25.4 million.

Table 4.49: Cost of diagnosis for the VA

Assumed level of symptoms	Total costs ($)
100 % Low	17,740,084.32
100 % Medium	17,715,421.44
100 % High	25,420,900.00
Equal case mix (low, medium, high)	20,292,144.34
{Recommended tests	6,863,006.88}

The total cost for the recommended tests was $6.8 million. Thus, depending on the level of bothersome symptoms of the patient the optional tests can cost the VA $10.9 to $18.6 million. Currently, there are no empiric studies assessing the economic impact of BPH in the U.S. or in a specific population such as VA. Totally there have been three cost of illness studies in literature, one in UK, one in Sweden and one in New Zealand (Scott & Scott, 1993; Drummond, Mcguire, Black, Petticrew & McPherson, 1993; Ahlstrand, Carlsson & Jonsson, 1995). However, only one of these studies estimated the cost of diagnosis for BPH (in New Zealand). It estimated total annual cost of diagnosis for BPH to be 330,000 New Zealand dollars. When converted to US dollars it is equivalent 166,500 US dollars. However, investigators of this study indicated that the diagnostic tests and procedures were under-reported and hence the cost of diagnosis may be higher. It is important to caution readers that the charges used in this study may not include full cost of performing tests and procedures. They may include institutional costs such as cost of monitoring lab, cost of maintaining instruments, etc. Also, it is important to remember that adjustment factor for locality (state to state, rural vs. urban, etc) and the perspective used to compute costs may give different results.

This chapter presented the results of the analysis performed for accomplishing the goals and objectives of this study and provided brief discussion of various findings. The next chapter will provide conclusions made based on these findings and give limitations and present implications of the study.

CHAPTER FIVE

SUMMARY AND CONCLUSIONS

This chapter presents a review of this study, draws conclusions, provides recommendations for future research, presents research implications and enlists limitations of the study.

Review of the Study

Benign prostatic hyperplasia is a highly prevalent condition in elderly males (Kirby & Christmas, 1993). In most cases it is not a fatal disease but does affect the quality of life of patients and impacts a significant portion of the health care budget (Baum, 1997). The VA system provides an excellent population in which this condition can be studied, since the average age of a VA recipient is 57 years (VA fact sheet, 1998). Guidelines have been established by AHRQ (formerly AHCPR) for the diagnostic and therapeutic management of BPH. However, there has been little research done to study the adherence of practitioners, including urologists, to these guidelines. Also, very little is known about factors which affect adherence to guidelines, and inter-rater agreement on tests used to diagnose and therapies used to manage BPH.

The goal of this study was to evaluate the diagnostic and treatment modalities for management of BPH in the VA population. To do so, the preferences of VA urologists were assessed to determine their adherence to guideline recommendations, effect of demographic and practice characteristics on adherence and level of agreement among urologists for selection of diagnostic tests and treatment options.

Conclusions

The conclusions of the study are presented based on the objectives of the study;

<u>Objective One: Comparison of Diagnostic Tests with Guidelines</u>

The objective aimed to compare the preference for performance of diagnostic tests and procedures with guidelines. The study demonstrated good adherence to guidelines for the recommended tests and procedures. The preferences for the optional tests varied among the respondents. The number of optional tests increased with increasing level of bothersome symptoms. Also, the numbers of tests preferred for diagnosis of a patient with high symptom level was significantly greater than a patient with low or medium symptom levels.

<u>Objective Two: Comparison of Treatment Option with Guidelines</u>

The objective aimed to compare management of BPH symptoms with guidelines and expert opinion. The recommended treatment strategy was watchful waiting for mild symptoms, drug therapy for moderate symptoms and TURP for severe symptoms. However, the respondents preferred the use of alpha-blockers for all the cases, irrespective of the symptom severity. In other words, alpha-blockers are being recommended when pharmacological therapy is not required and also when surgery is a better alternative for managing the symptoms. Thus, it appears that VA urologists do not conform too well with guidelines and expert opinion in their preferences for therapeutic management of BPH symptoms.

<u>Objective Three: Effect of Demographic and Practice Characteristics on Preferences</u>

This objective aimed to assess the effect of demographic and practice characteristics on preferences of urologists for diagnostic procedures and selection of treatment options. Age and number of urologists were the only two variables which demonstrated some effect on preference for diagnostic tests. Age was negatively associated with the performance of medical history and positively associated with the performance of serum creatinine tests. Thus, we can conclude that younger urologists preferred not to perform medical history and older urologists preferred to perform serum creatinine tests more often. Also, as the number of urologists practicing in the center increased, their preference for performance of urinalysis and serum creatinine decreased. The analysis also revealed that as number of urologists increases the number of recommended tests and total tests done for the case with low and medium bothersome symptoms, decreases. Also, age was negatively associated with the number of optional tests and total tests performed for the case with high bothersome symptoms. However, the correlation coefficient for all these observations was less than 0.3. Also, none of the demographic and practice characteristics demonstrated any association with the preferences for selection of treatment options. Thus, no valid conclusions can be made from the study about the effect of demographic and practice characteristics on respondents' preferences.

<u>Objectives Four and Five: Estimation of Levels of Agreement Among Respondents</u>

These objectives were designed to measure the level of agreement among VA urologists for assessment and management of BPH symptoms. The VA urologists

demonstrate moderate agreement for preference of diagnostic tests, while for preferences of therapeutic options they demonstrate substantial agreement to almost perfect agreement depending upon the severity of the patient case.

Objective Six: Estimation of Failure of Initiation Therapy

The objective aimed to assess treatment failure rate and determine the common switches employed for failed initiation therapy. The study demonstrated an almost 42 percent treatment failure rate for initiation therapy. Among the types of switches, alpha-blockers to surgery was most common. The second major switch was from single drug therapy to combination drug therapy. Also, among the therapeutic options, alpha-blockers demonstrated the highest switch rate followed by watchful waiting and finasteride.

Objective Seven: Estimation of Cost of Diagnosis

The objective aimed to estimate cost of diagnosis for BPH based on the preferences of the VA urologists. The cost of diagnosis per patient ranged from $237.04 to $340.14 depending on the level of bothersome symptoms. Also, the total projected cost of diagnosis for BPH for all the VAMCs ranged from 17.7 million dollars to 25.4 million dollars.

Directions for Future Research

This study can serve as a springboard for several future studies on management of BPH. First, adherence to guidelines needs to be assessed by tracking BPH patients in the VA data to determine the diagnostic and treatment options undertaken. This would help

validate the results of this study and also control for the effect of patient characteristics such as age, co-morbidities, etc.

With the emergence of managed care, the role of primary providers in managing BPH has been increasing. Thus, comparing the practice patterns of primary care providers with the guidelines would make another interesting study. Also, management of BPH in other health care settings, like Medicaid, Medicare (includes individuals over the age of 65) needs to be studied. These programs have a tremendous impact on the U.S. health care system. Hence appropriate management of this condition in these health systems is important.

Kortt and Bootman (1996) reviewed the literature to identify and evaluate studies that had addressed the economic burden of BPH or costs associated with alternative BPH therapies. This search yielded only 14 research studies associated with some economic analysis of BPH or therapies used in its management, of which only 2 studies performed a cost of illness evaluation. Both these have been conducted in countries outside the U.S. i.e. New Zealand and United Kingdom. Subsequent to Kortt and Bootman's literature review only one additional study was found in literature, and this was also conducted outside the U. S. (in Sweden). Thus, there is a need to assess economic impact of BPH in the U.S. or in a specific population such as the VA, Medicaid, or Medicare.

Finally, there is a need to study patient outcomes associated with BPH. This may include quality of life assessments of patients with BPH, estimation of indirect costs and pharmacoeconomic studies comparing various drug therapy and surgical options currently used to treat this disease.

Research Implications

This study was undertaken to evaluate the diagnostic and treatment modalities in the management of BPH in the Veterans Administration population. To do so, preferences of the VA urologists were compared with published clinical guidelines. The findings of this study should be useful to the Veterans Administration program in their effort to encourage appropriate practice patterns and thereby produce better patient outcomes. The study also has implications for patients and policy makers. These implications are described in the following sections.

Implications to the Veterans Administration Program

The results of this study demonstrated that VA urologists showed good adherence to practice guidelines for diagnosis of BPH. However, the same is not true for treatment strategies. They prefer use of alpha-blockers for management of symptoms, regardless of symptom severity. This may not be the most appropriate way of managing this condition, since it has high economic implications. Also, the study demonstrated substantial to almost perfect agreement for selection of treatment options to manage BPH. Hence, there is a need to validate study results by following BPH patients or by tracking them in the VA database. If similar results are obtained one can conclude that VA urologists' practice patterns are not consistent with clinical guidelines. Thus, there may be a need to increase awareness among urologists for appropriate use of therapeutic options. Prescribing pharmacological therapy for patients who do not require active treatment or require surgical intervention may lead to increased expenditures. The VA program can develop and implement educational programs to increase the use of watchful waiting and

TURP for patients with mild and severe symptoms, respectively.   This could result in better use of resources through avoidance of unnecessary procedures and therapeutic options. Additionally, appropriate management of BPH would result in better patient outcomes, as this would result in better quality of care, fewer switches in therapeutic options, better control of symptoms and improvement in quality of life of patients.

Implications to Patients

The findings of the study are also relevant for patients. BPH is a condition that affects quality of life. Inappropriate diagnosis and treatment patterns would only exacerbate the quality of life of BPH patients. Hence, study results could aid in encouraging urologists to adhere to appropriate practice patterns. Since the guidelines were established to provide optimum outcomes, adhering to them will provide better relief of symptoms and thus improve quality of life of BPH patients.

Implications to Policy Makers

The guidelines were established by the AHRQ (AHCPR) in 1994. The guidelines did not include specific treatment recommendations for the management of BPH patients with moderate and severe symptoms. This makes it difficult to assess appropriate practice patterns for such cases. Also, newer non-invasive therapies like TUNA, TUMT, stents, etc. have been emerging in recent times. These were not part of the guidelines due to lack of data on their effectiveness. Thus, there may be a need to re-visit the guidelines so as to make them more effective and contemporary.

Study Limitations

The study included a sample of 292 urologists practicing in the VA population.

Of these, 114 urologists responded to the survey. Of the 22 VISNs, 21 were represented

in the study. Also, urologists from 42 states were represented among the respondents.

Thus, there appeared to be an adequate representation of the population. The non-

response bias analysis demonstrated no significant difference between respondents and

non-respondents for demographic and practice characteristics. However, it did

demonstrate difference in urologists' preferences for the utilization of five of the

diagnostic tests compared to respondents. Thus, non-response bias limits the

generalizability of the study results to the entire VA urologist population.

Another limitation of the study was the use of simulated patients. It can be argued

that a simulated patient does not adequately represent a real patient in clinical practice.

However, the information from each patient is reproducible and ensures that every doctor

obtains the same information from each patient. Thus, the method should be regarded as

an instrument with which the preferences of the urologists can be analyzed. Another

argument is the selection of cases for the instrument. Since BPH is a common condition

among elderly males, it is likely to co-exist with other health-related problems. However,

the cases selected in the instrument did not include any other health-related problems, (or

co-morbidities) which an elderly male may have. Since the utilization of diagnostic

procedures and therapeutic options may be influenced by co-morbidities, the cases in the

instrument used in the study may not be most representative of the patient population.

In addition to the above limitations, the study also suffers from another drawback-

the absence of patient preferences. The guidelines for BPH management stress the

importance of patient preferences. It is reasonable to believe that patients' preferences would strongly influence management of the condition. However, time and budget constraints did not permit exploration of this aspect.

Finally, the limitations of using a self-administered mail questionnaire for collection of data would apply for this study. Although mail questionnaire possess the advantages of being relatively inexpensive to administer, provides larger possible samples, offers greater assurance of anonymity, ensures standardized wording and elimination of interviewer bias, there are substantial limitations to use of self-administered questionnaires. Measurement errors could have occurred and may have caused: (1) the respondent failing to understand the instructions or items; (2) the respondent answering in a way he/she thinks is desirable to the researcher; and (3) the intended person not completing the questionnaire.

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APPENDICES

Appendix A: Veterans Integrated Service Networks

VISN1: VA New England Healthcare System

VISN2: VA Healthcare Network Upstate New York

VISN3: Veterans Integrated Service Network

VISN4: VA Stars and Stripes Healthcare Network

VISN5: VA Capitol Network

VISN6: The Mid-Atlantic Network

VISN7: The Atlanta Network

VISN8: VA Sunshine Healthcare Network

VISN9: Mid South Veterans Healthcare Network

VISN10: VA Healthcare System of Ohio

VISN11: Veterans Integrated Service Network

VISN12: The Great Lakes Health Care System 13

VISN13: VA Upper Midwest Health Care Network

VISN14: Central Plains Network

VISN15: VA Heartland Network

VISN16: Veterans Integrated Service Network

VISN17: VA Heart of Texas Health Care Network

VISN18: Southwest Network

VISN19: Rocky Mountain Network

VISN20: Northwest Network

VISN21: Sierra Pacific Network

VISN22: Desert Pacific Healthcare Network

Appendix B: AHRQ Decision Diagram

Initial Evaluation
- History
- Physical examination and DRE
- Urinalysis
- Creatinine
- PSA (optional)

Presence of Refractory retention
Any of the following, clearly secondary to BPH:
- Recurrent urinary tract infection
- Recurrent or persistent gross hematuria
- Bladder stones
- Renal insufficiency

Surgery

Quantitative symptom assessment

Mild

Moderate to severe

Optional diagnostic tests based on physician and patient preferences

Offer treatment alternatives

- Flowrate
- Residual urine
- Pressure flow

Watchful waiting

Surgery: TUIP, TURP, open

Balloon dilation

Medical Therapy

Yes

Compatible with obstruction?

No

Option for urethroscopy or sonography if important in planning operative approach

Non-BPH problem identified and

Appendix C: American Urological Association Symptom Index for Benign Prostatic

Hyperplasia

	Not at All	Less Than 20% of the Time	Less Than Half the Time	About Half the Time	More Than Half the Time	Almost Always
1. Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	O	O	O	O	O	O
2. Over the past month or so, how often have you had to urinate again less than 2 hours after you have finished?	O	O	O	O	O	O
3. Over the past month or so, how often have you found you stopped and started several times when you urinated?	O	O	O	O	O	O
4. Over the past month or so, how often have you found it difficult to postpone urination?	O	O	O	O	O	O
5. Over the past month or so, how often have you had a weak urinary stream?	O	O	O	O	O	O
6. Over the past month or so, how often have you had to push or strain to begin urination?	O	O	O	O	O	O

7. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until you got up in the morning?

    O None   O Once   O Twice   O 3 Times   O 4 Times   O 5 Times or more

Appendix D: Survey Instrument
UROLOGISTS' PREFERENCES IN THE MANAGEMENT OF
BENIGN POSTATIC HYPERPLASIA (BPH)
SECTION I

The following section is designed to determine your preferences for the diagnostic tests and procedures commonly used by you in diagnosing BPH in your patients. For each of the following patient profiles indicate the diagnostic tests you would have performed on the patient (check all that apply).

Patient Number 1: B.T., a 66-year-old white male comes to your clinic with bothersome urinary symptoms. He complains of increased frequency, incomplete bladder emptying and occasional burning sensation. He denies any hematuria. He also reports occasional post void dribbling and nocturia of about 3-4 times a night.

❑	Medical History	❑	Cystoscopy
❑	Digital Rectal Exam	❑	Pressure Flow
❑	Urinalysis	❑	Uroflowmetry
❑	Serum Creatinine	❑	Intravenous Pyelogram
❑	PSA .	❑	Post Void Residual Volume
❑	AUA Symptom Score	❑	Other (please describe)_____

_____

Patient Number 2: J.J., a 54-year-old African-American man, presents to your office with lower abdominal discomfort. He reports occasional difficulty initiating urination, midstream stoppage and post void dribbling. He also complains of nocturia of about 2 times a night.

❑	Medical History	❑	Cystoscopy
❑	Digital Rectal Exam	❑	Pressure Flow
❑	Urinalysis	❑	Uroflowmetry
❑	Serum Creatinine	❑	Intravenous Pyelogram
❑	PSA .	❑	Post Void Residual Volume
❑	AUA Symptom Score	❑	Other (please describe)_____

_____

Patient Number 3: M.J., a 72-year-old white man presents to you with history of blood in the urine. He gives also a history of increasing difficulty initiating urination, frequent midstream stoppage, frequent burning on urination, and post void dribbling. He also reports a decrease in the force and caliber of his urinary stream as well as incomplete bladder emptying and complains of nocturia of more than 4 times/night and daytime frequency of more than 10 times/day.

❑	Medical History	❑	Cystoscopy
❑	Digital Rectal Exam	❑	Pressure Flow
❑	Urinalysis	❑	Uroflowmetry
❑	Serum Creatinine	❑	Intravenous Pyelogram
❑	PSA .	❑	Post Void Residual Volume
❑	AUA Symptom Score	❑	Other (please describe)_____

_____

SECTION II

Now, we would like to know your preferences with regard to treating or managing BPH in your patients. Again for each of the following patient profiles indicate the treatment you would prefer to initiate.

Patient Number 4: A.D., a 75-year-old African-American male comes with the problem of urinary incontinence. He also gives a history of difficulty initiating urination, midstream stoppage and terminal dribbling. Rectal examination reveals an enlarged prostate of 50-55 gms. A.D. gives a history of nocturia approximately 4-5 times a night, daytime urinary frequency of 8-10 times a day and he reports of blood in urine. Laboratory findings are as follows: PSA -4.1, AUA ss -28, serum creatinine -1.2, residual volume -300ml, flow rate -7ml/sec.

❑ Watchful Waiting   ❑ TUIP
❑ Alpha Blockers   ❑ Open Prostactomy
❑ Finasteride   ❑ Laser Prostactomy
❑ Balloon Dilation   ❑ TUVP
❑ TURP   ❑ Other_____

Patient Number 5: R.C., a 68-year-old Hispanic man, comes to your clinic with severe abdominal discomfort. He reports a history of increased difficulty initiating urination, midstream stoppage and terminal dribbling. R.C. complains of nocturia of 3-4 times/night. DRE reveals an enlarged prostate of approximately 25-30 gms and firm. Laboratory findings are as follow:
PSA-2.8, AUA ss - 15, serum creatinine -0.8, residual volume -150ml, flow rate - 13ml/sec.

❑ Watchful Waiting   ❑ TUIP
❑ Alpha Blockers   ❑ Open Prostactomy
❑ Finasteride   ❑ Laser Prostactomy
❑ Balloon Dilation   ❑ TUVP
❑ TURP   ❑ Other_____

Patient Number 6: G.M., a 60-year-old male, presents to your clinic with lower abdominal discomfort. He gives a history of increased difficulty initiating urination, a significant decrease in the force of his urinary stream, occasional midstream stoppage, and post void dribbling. Upon digital rectal examination, the prostate is 20-25 gms and benign. Laboratory findings are as follows: PSA -1.2, AUA ss-6, serum creatinine -0.5, flow rate -20 ml/sec, residual volume -80ml.

❑ Watchful Waiting   ❑ TUIP
❑ Alpha Blockers   ❑ Open Prostactomy
❑ Finasteride   ❑ Laser Prostactomy
❑ Balloon Dilation   ❑ TUVP
❑ TURP   ❑ Other_____

SECTION III

Often times therapy initiated for managing BPH does not improve the symptoms of BPH. In such situations it becomes necessary to select or switch other treatment options. We would like to know how often it has become necessary for you to move to another treatment option during management of BPH in your patients.

Think of the last **five (5)** patients of yours that were diagnosed with having BPH. Please indicate for how many of these five patients you found it necessary to switch to another treatment option.

<div align="center">

All 5   4   3   2   1   none

</div>

If you have marked "none" above please move on to Section IV.

For the patients for whom you switched or selected another therapy option (as indicated above) please indicate the type of switch that was made.

# of patients

watchful waiting to drug therapy	____
watchful waiting to balloon dilation	____
watchful waiting to surgery	____
alpha blockers to finasteride	____
alpha blockers to balloon dilation	____
alpha blockers to surgery	____
finasteride to alpha blockers	____
finasteride to balloon dilation	____
finasteride to surgery	____
single drug therapy to combination therapy	____
combination therapy to balloon dilation	____
combination therapy to surgery	____
balloon dilation to surgery	____

Total   ____   (should equal the number circled above)

SECTION IV

Finally, a few questions about you and your VAMC:

1. Does your VAMC have a formulary?   ❑   Yes   ❑   No

2. If yes to Q1, then which of the following drugs are on the formulary?

   ❑   Terazosin   ❑   Doxazosin   ❑   Prazosin   ❑   Finasteride

3. Your VAMC is located in :   State _____   Town _____

4. Number of urologists practicing at your VAMC: _____

5. Years of practice for you at current VAMC: _____ years   ____ months

6. Number of **<u>new</u>** BPH patients visiting your center per month are: _____

7. Your age: ❑   Less than 40   ❑   40-49   ❑   50-59   ❑   60 or older

8. Your gender: ❑   Male   ❑   Female

COMMENTS:

Is there anything else you would like to tell us about your preferences or experiences with managing BPH? If so, please use this space to provide your comments.

THANKYOU

Please return the completed survey in the enclosed business reply envelope.

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Appendix E: Cover Letter for First Mailing

December 10, 1999

Dear Urologist:

As you may be aware, in the U.S., more than 1 million men present annually with symptoms associated with benign prostatic hyperplasia (BPH). The quality of life of BPH patients can decline significantly since symptoms may interrupt normal daytime activities or sleep, create anxiety, or reduce perception of general health. The median age of 57 years in the Veterans Administration (VA) population makes BPH a common condition among men in this population. With an increase in life expectancy, the cases of BPH among this population are expected to continue to increase.

There are several diagnostic tests and treatment options available for the management of BPH. We at West Virginia University School of Pharmacy are interested in determining the preferences of urologists in the management of BPH. Your name was randomly selected from a national list of urologists serving the VA population as someone who could provide valuable information. We would appreciate it if you could take a few minutes to complete the enclosed survey.

Your participation in this study is voluntary. You do not need to answer all questions even though we would prefer that you do. However, since this survey is part of a Master's thesis project, complete responses are vital for the study results to be meaningful. We are interested in your opinion, and you may be assured of complete confidentiality. Your individual responses to this survey will be known only to researchers at West Virginia University. The survey has been coded only for follow-up purposes.

As our way of saying thank you for participating in this study, you may also enter your name in a raffle drawing. One prize of $100, one of $75 and two of $50 will be awarded to four individuals whose names will be randomly drawn from the raffle tickets received. If you are the lucky winner of any of these prizes you will be notified. For this purpose, we would appreciate it if you would provide your name, telephone number and address on the raffle ticket provided. You may return this ticket with the completed survey.

Kindly return the completed questionnaire in the enclosed, postage-paid envelope. Thank you very much for your time, effort and promptness in providing this valuable information. If you have any questions, please do not hesitate to call us at (304) 293-6991 (or 0228).

Sincerely,

Ancilla Fernandes   Mayur M. Amonkar, Ph.D.
Graduate Student   Assistant Professor (Pharmacy)

Unyime O. Nseyo, M.D.   Suresh Madhavan, MBA, Ph.D.
Professor (Urology)   Associate Professor (Pharmacy)

Appendix F: Cover Letter for Second Mailing

January 20, 2000

Dear Dr. "Name of the Urologists"

Several weeks ago, a questionnaire regarding your preferences in the management of benign prostatic hyperplasia was sent to you. I realize that you have been very busy. However, I would personally like to request your help in completing the questionnaire for this important clinical study. If you have responded, please disregard this letter and accept our gratitude for time and effort.

Your participation in this study is voluntary. You do not need to answer all questions. However since this survey is part of a Master's thesis project, complete responses are vital for the studies results to be meaningful. I am interested only in your opinion, and you may be assured of complete confidentiality. Only researchers at West Virginia University will know your individual responses to this survey and all the analysis will be done in aggregate form.

As a way of saying thank you for participating in this study, you may also enter your name in a raffle drawing. One prize of $100, one of $75 and two of $50 will be awarded to four individuals whose names will be randomly drawn from the raffle tickets received. If you are the lucky winner of any of these prizes you will be notified. For this purpose, please provide your name, telephone number, and address on the raffle ticket provided and return this ticket with the completed survey.

Kindly return the completed questionnaire in the enclosed, postage-paid envelope. Thank you very much for your time, effort and promptness in providing this valuable information. If you have any questions do not hesitate to call me at (304) 293-6991.

Sincerely,

Ancilla Fernandes,
Graduate student.

Appendix G: Non-response Survey

BENIGN PROSTATIC HYPERPLASIA MANAGEMENT SURVEY

Q1. Mentioned below are some of the possible reasons that might have prevented you from responding to the "Urologists' Preferences in the Management of Benign Prostatic Hyperplasia (BPH)" survey sent to you earlier. Please check the one that most applies to you.

❑ did not have enough time to complete the survey   ❑ did not receive the survey at all

❑ forgot about the survey   ❑ survey was too long

❑ survey was misplaced   ❑ don't like to respond to surveys

❑ did not have enough incentive to complete the survey   ❑ do not have enough information a about benefits of the study

❑ not interested in such studies   ❑ topic was irrelevant

❑ other _____

Q2. For the following patient profile indicate the diagnostic test(s) you would have performed on the patient (check all that apply):

M.J., a 72-year-old white man presents to you with history of blood in the urine. He also gives a history of increasing difficulty initiating urination, frequent midstream stoppage, frequent burning on urination, and post void dribbling. He also reports a decrease in the force and caliber of his urinary stream as well as incomplete bladder emptying and complains of nocturne of more than 4 times/night and daytime frequency of more than 10 times/day.

❑ Medical History   ❑ Cystoscopy

❑ Digital Rectal Exam   ❑ Pressure Flow

❑ Urinalysis   ❑ Uroflowmetry

❑ Serum Creatinine   ❑ Intravenous Pyelogram

❑ PSA .   ❑ Post Void Residual Volume

❑ AUA Symptom Score   ❑ Other (please describe) _____

Q3. A few questions about yourself...

Does your VAMC have a formulary?   ❑ Yes   ❑ No

Your VAMC is located in : State _____   Town _____

Number of urologists practicing at your VAMC: _____

Years of practice for you at current VAMC: _____ years _____ months

Number of **new** BPH patients visiting your center per month are: _____

Your age: ❑ Less than 40   ❑ 40-49   ❑ 50-59   ❑ 60 or older

Your gender: ❑ Male   ❑ Female

Appendix H: Cover Letter for Non-response Survey

February 27, 2000

Dear Urologist,

During the past two months you may have received two mailings of a questionnaire regarding your preferences in the management of benign prostatic hyperplasia. I realize that you have been very busy and have chosen not to answer or were not able to answer. We would appreciate it if you could please take a couple of minutes to answer a few questions on the attached sheet.

All responses will be kept completely confidential. Please complete and return it, in the enclosed postage-paid envelope at your earliest convenience. If you have already responded to the previous questionnaire, please disregard this letter and accept our gratitude for your time and effort. If you have any questions, please do not hesitate to call us at (304) 293-6991

Sincerely,

Ancilla Fernandes
Graduate student