

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

How to Help Men with LUTS Help Themselves

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Executive Summary

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Opening Remarks

*Robert Star, M.D., Director, Division of Kidney, Urologic, and Hematologic Diseases (KUH),
NIDDK, National Institutes of Health (NIH)*

Dr. Robert Star welcomed participants and introduced the theme of the meeting. Lower urinary tract symptoms (LUTS) is a condition that affects the physical and mental well-being of a substantial percentage of the male population, especially those in their middle and later years. Although traditional treatments have focused on the association of LUTS with benign prostatic hyperplasia (BPH), newer approaches have begun to embrace more holistic perspectives that recognize the influence of co-occurring disorders and other physiological factors on LUTS. These approaches view LUTS more as a chronic condition to be managed and less as a single disorder with a single therapeutic solution. Because surgery and pharmaceutical treatments for LUTS can have significant side effects and do not always offer a definitive cure, interest is growing in developing additional therapies, including self-management of behavioral and lifestyle interventions, either to supplement traditional therapies or to delay or reduce their use. Other chronic diseases that incorporate lifestyle interventions and preventive strategies into patient care can serve as models for developing a comprehensive treatment strategy for LUTS.

LUTS/BPH—I'm Getting Old!

Ziya Kirkali, M.D., Senior Scientific Advisor, KUH, NIDDK, NIH

Dr. Ziya Kirkali thanked the organizing committee for their support. He stated the three objectives of the conference: to review the various factors that affect LUTS in men; to discuss the current state of knowledge about self-management treatments for LUTS; and to identify potential intervention strategies that could ameliorate the effect of LUTS on the quality of men's lives.

The impact of LUTS is not trivial. Men seeking treatment for LUTS make an estimated 8 million physician office visits per year, at a cost of approximately \$1.1 billion per year (as of 2000) in direct health care expenditures; more difficult to quantify, but no less significant, LUTS reduces the quality of life for the millions of men and their partners who suffer from it. LUTS associated with BPH, is most frequently seen in older age groups, affecting at least 25 percent of men older than age 50 and at least 50 percent of men 80 years and older. LUTS sufferers experience reduced urine flow, increased urination frequency or urgency, and nocturia; also, LUTS often is associated with sexual dysfunction, depression, and other difficulties.

Until the late 20th century, prostate surgery was the only treatment for LUTS; the introduction of pharmaceutical therapies in recent decades has offered medical alternatives to surgery for many LUTS patients. Both surgical and pharmaceutical approaches, however, have potential side effects and therapeutic limitations.

In recent years, health care providers have recognized that enlargement of the prostate is not the only factor contributing to LUTS and that other physiological factors—including overactive bladder, obesity, and diabetes, and such lifestyle factors as diet and fluid intake—also may contribute to urinary symptoms. Despite this clinical knowledge, LUTS research has continued to focus on surgical or pharmaceutical treatment of urinary tract dysfunction. To encourage a broader approach to LUTS research and treatment, the NIDDK has developed a comprehensive conceptual framework for preventing, understanding, and treating LUTS. This framework encompasses numerous biological factors, including genetics and local physiology of the lower urinary tract and neighboring organs; systemic factors, such as cardiovascular health, diabetes, obesity, and depression; the consequences of behavioral patterns, such as diet and exercise; and the effects of psychological functioning and socioeconomic and environmental factors on symptom progression and therapy outcomes.

What's Wrong with Men?

Martin Miner, M.D., Co-director, Men's Health Center, Department of Family Medicine and Urology, The Miriam Hospital, Brown University

Dr. Martin Miner emphasized the relationship of LUTS treatment to the need for an improved system of health care for men. It is a challenge to draw men into a doctor's office for regular care. Adolescents see doctors regularly for routine pediatric checkups and sports physicals. But, barring symptoms or events that might signal the need for medical attention or the intervention of a concerned family member, men tend to avoid the health care system until age 50 or older. In contrast to women, whose regular gynecological visits generally keep them in closer touch with the medical system, men of all racial and socioeconomic groups are 24 percent less likely than women to have visited a doctor in the last year, and 25 percent of men (as of 2011) had no regular source of health care whatsoever. By the time men do resume seeing doctors regularly, they come with a lifelong history of behavioral and dietary habits and environmental exposures and a physiology that reflects that history. Because 50 percent of premature male deaths are preventable, the social costs of these habits are high; the rate of preventable deaths could be lowered if men could retain a continuing connection with health care providers throughout their lives.

Centers devoted to comprehensive care of men's health not only could help maintain a health care connection for men but also could serve as centers for research on men's health; for patient education; and for community outreach on prostate cancer, sexual health, and other issues. They would be particularly well suited to reach underserved populations, such as African American men, and men with such chronic diseases as Parkinson's disease, multiple sclerosis, and chronic obstructive pulmonary disease. A comprehensive approach is particularly important because many male-specific problems are linked to broader health issues. Many symptoms commonly faced by aging men—including LUTS, sexual dysfunction, prostate cancer, cardiovascular disease, testosterone deficiency, obesity, osteoporosis, and sleep disorders—are physiologically interrelated. A comprehensive initial exam can allow providers to raise sensitive issues, such as sexual dysfunction, that men might be reluctant to discuss in other contexts.

Physicians themselves need to be educated on men's health. Wider implementation of a holistic approach to men's health care could be facilitated by developing a defined men's health care curriculum for medical school, including substantive training in men's health in family and internal medicine residencies, and training urologists to recognize the links between urological concerns and broader aspects of men's health.

Male LUTS: What We Know, What We Don't Know, What We Need to Know

*Kevin McVary, M.D., Professor and Chair, Division of Urology, Department of Surgery,
Southern Illinois University School of Medicine*

Dr. Kevin McVary reviewed the current understanding of LUTS risk factors and of the physiological effects of several modes of nonsurgical treatments for LUTS, and proposed some directions for future research.

Age is a well-known risk factor for LUTS, but it is not the only factor associated with LUTS in men. Other known risk factors include a family history of LUTS, high levels of C-reactive protein, obesity, heart disease, and low physical activity. The recent Multinational Survey of the Aging Male (MSAM-7) also has suggested a correlation between erectile dysfunction (ED) and increasing LUTS severity, independent of age. Emerging data suggest that LUTS may be associated with disordered sleep beyond the effects of nocturia on sleep patterns. Other recent studies also indicate that genetic factors may be significant predictors for developing moderate to severe LUTS.

Evidence shows that drug treatments and lifestyle interventions to reduce LUTS can be effective. High prostate volume and high prostate-specific antigen (PSA) levels predict a greater risk for severe LUTS, but treatment with the 5 α -reductase inhibitor finasteride can reduce both prostate size and PSA levels. Treatment of LUTS/BPH with the phosphodiesterase type 5 (PDE5) inhibitor, tadalafil, yields lower International Prostate Symptom Score (IPSS) values. Greater intake of dietary (not supplemental) carotenoids and vitamin C appears to be associated with decreased risk for LUTS. Finally, preliminary data offer the promising suggestion that even 2 weeks on a low-fat diet may decrease the growth of prostate epithelial cells.

There is, however, still much to learn, especially with regard to the causes and symptoms of LUTS in individual patients. Researchers have inadequate knowledge of the correlation between physiological severity of clinical symptoms and patient complaints about symptoms, in part because LUTS symptoms are largely self-reported. LUTS treatment would be enhanced by greater understanding of the multifactorial causes of LUTS and its variable rate of progression in individual patients and by a greater ability to predict the genetic risk of LUTS. Finally, the influence of ethnicity or environmental and cultural factors on the development of LUTS requires more study, including consideration of cultural traditions that might discourage complaints about LUTS as a sign of male weakness.

The trend toward using "watchful waiting" strategies for LUTS patients indicates a need for a systematic investigation of the costs and benefits of delaying medical treatment for LUTS. Some studies suggest that there may be benefits to early surgical or medical intervention. A Veterans Administration trial that compared the outcomes of immediate transurethral resection of the prostate (TURP) surgery with TURP scheduled after 5 years of watchful waiting suggested that patients who delayed surgery never achieved the same level of post-surgery symptom reduction as those who underwent TURP immediately. Similar results were found for pharmaceutical

therapy: Immediate treatment with the 5 α -reductase inhibitor dutasteride reduced symptoms more than treatment after 2 years of watchful waiting.

Discussion

During discussion, a participant observed that the quality of data comparing the effects between early and delayed medical treatment depends crucially on the quality of the self-management protocols, patient adherence to those protocols, and the quality of self-reporting of patient symptoms. Even with type 2 diabetes—for which lifestyle management has long been integrated into patient care—full compliance with self-management guidelines is difficult to achieve. Well-defined self-management guidelines for LUTS patients and a standardized system for self-monitoring and self-reporting of symptoms would be crucial elements for follow-up studies. Another participant raised the possibility that drug treatments or behavioral modifications might mask the actual progression of LUTS and suggested that independent physiological measures of LUTS should be incorporated into future research programs to supplement data based on self-reported symptoms.

Nonurologic Modifiable Factors Contributing to LUTS

Brad Erickson, M.D., Associate Professor, Urology Clinic, University of Iowa Hospitals and Clinics

In his remarks, Dr. Brad Erickson discussed the relationship of LUTS to nonurologic aspects of men's health. Chronic conditions like LUTS have effects on, and are affected by, other chronic conditions elsewhere in the body. It would be helpful to know more about the ways these chronic conditions affect one another and, in particular, whether mitigation of nonurologic conditions also can ameliorate LUTS.

The introduction of alpha blocker and 5 α -reductase inhibitor drug therapies in the late 1980s provided, for the first time, a viable alternative to surgery to alleviate the symptoms of LUTS/BPH. By the beginning of the 21st century, medication was the predominant therapeutic approach, with combination alpha blocker/5 α -reductase inhibitor therapy showing the greatest effectiveness in decreasing progression of BPH.

With time, however, another problem has emerged: decreasing patient compliance with medication prescriptions over time. After 2 years, 60 percent of men have discontinued single-drug therapies, and 40 percent have discontinued combination therapy, in large part because of perceived side effects of the medications. One BPH drug, finasteride, reportedly increases ED. The Prostate Cancer Prevention Trial also raised concerns (whether ultimately confirmed or not) about the risk of increased rates of high-grade cancers in patients taking finasteride. Patients complain of light-headedness with use of alpha blockers, and anticholinergics cause dizziness, which precludes their use in older men.

LUTS treatments also need to take into account the medical histories of individual LUTS patients, especially the several nonurologic, systemic factors that can affect diagnosis, patient symptoms, choice of appropriate treatment, and responses to treatment. The complex interrelationships between LUTS and systemic physiological and psychological processes are striking. Constipation and other gastrointestinal disturbances can be associated with LUTS, and alleviating constipation can improve both LUTS and sexual function in older patients. Type 2 diabetes and poor diet are both predictive of LUTS. Diet has an important and complex relationship with both digestive and urinary health, in part through its effects on oxidative stress,

the sympathetic nervous system, steroid metabolism, obesity, diabetes, inflammation, and the microbiome; diet itself can be affected by socioeconomic status, education, and access to health care. Anxiety can exacerbate LUTS, and LUTS can provoke depression, which can, in turn, affect diet, inflammation, and gastrointestinal health.

LUTS can be seen as a local manifestation of a systemic disease process. The many interacting factors indicate the importance of assembling a medical team and treatment plan that can address the various causes and consequences of urinary tract symptoms. Clinical experience with management of other chronic diseases emphasizes the importance of listening to the patient's account of the problems that bother him most, of personalizing care for each LUTS patient, and of setting achievable goals and realistic expectations for the treatment plan.

LUTS in Men: Treatment and Side Effects

Michael Naslund, M.D., Professor of Surgery and Chief, Division of Urology, University of Maryland School of Medicine

A full understanding of the many factors that affect LUTS and a systematic evaluation of the efficacy of the various LUTS treatments are necessary for developing effective therapies. To that end, Dr. Michael Naslund reviewed the current state of knowledge of the benefits and limitations of commonly used LUTS treatments.

One of the hallmarks of LUTS, nocturia, is an excellent example of the many interacting factors involved in urinary tract complaints. Although nocturia is considered a symptom of BPH, other factors—such as light sleep (which, like prostate enlargement, becomes more prevalent with age), sleep apnea, bladder function, and excessive fluid uptake—may be at least as important as prostate enlargement as contributing factors to LUTS.

Multiple treatment options are available for LUTS. For most men, no single approach is likely to resolve urinary symptoms, and therapy needs are likely to change with time. “Watchful waiting,” commonly the initial approach to LUTS management, is also the least invasive. But its effectiveness is dependent on self-reporting of symptoms and physician attentiveness to the patient's lifestyle habits, such as excessive fluid uptake, that are often overlooked as relevant factors by urologists in initial examinations of patients.

Usually, the second step in LUTS treatment is chemical remediation of urinary symptoms. Despite interest in phytotherapy as an alternative, nonprescription treatment for LUTS, no rigorous, consistent evidence suggests that phytotherapy reduces LUTS any more effectively than a placebo. Prescription drugs include alpha blockers, 5 α -reductase inhibitors, phosphodiesterase (PDE) inhibitors, and antimuscarinic drugs. Each of these drug types addresses different LUTS symptoms, and each drug has therapeutic limitations. Reflecting the multiple factors that contribute to LUTS, combination drug therapies often are more effective than single-drug regimens.

A 2003 controlled clinical trial comparing the long-term effects of placebo medications, an alpha blocker (doxazosin), a 5 α -reductase inhibitor (finasteride), and a combination doxazosin-finasteride regimen showed that all three regimens slowed BPH progression over 5 years compared to the placebo, and the combination regimen was the most effective of all. Those patients on finasteride or combination therapies had the lowest incidence of surgeries and the lowest incidence of acute urinary retention (AUR) after 5 years. The rate of surgery of patients on doxazosin after 5 years was at least as high as that of those on placebo; AUR of doxazosin-treated

patients was higher than those on finasteride or combination therapy, but slightly less than AUR rates in placebo-treated patients. AUR risk increases with prostate volume, which is controlled most effectively by finasteride or combination therapy. In general, symptoms of a slightly enlarged prostate can be relieved by alpha blockers, and more severe BPH can be relieved by combination therapy of alpha blockers with 5 α -reductase inhibitors.

ED and LUTS symptoms seem to be linked, regardless of age. Although PDE inhibitors do not improve urinary flow rates, they do appear to relieve self-reported prostate symptoms; thus, PDE inhibitors can be used to treat both ED and LUTS when there is not a severe reduction in urinary flow. Where overactive bladder is a contributing factor to LUTS, antimuscarinic agents can reduce urinary frequency and urgency; therapies that combine antimuscarinic drugs with alpha blockers seem to be particularly effective. Because antimuscarinic drugs can increase urinary void retention, they should be used with caution where urinary post-void retention (PVR) is a known problem.

Historically, prostatectomy has been the surgical treatment of choice, and TURP remains the surgical gold standard for long-term effectiveness and patient satisfaction. However, TURP also entails risks of side effects on sexual and urinary function. Recent surgical innovations—such as green light laser prostate surgery, thermotherapy, and minimally invasive techniques—have faster recovery times and fewer side effects than standard techniques, but they are not free of risk.

Discussion

Several points were raised during discussion. The effectiveness of drug therapies also can be limited by lack of patient compliance. Men often stop medication because of unwanted side effects, and compliance tends to abate as symptoms abate. Patients who stay on medication the longest tend to be those on combination therapy, in part because combination therapies are indicated for patients with the largest prostates, who also are the patients most likely to feel significant relief of their symptoms after treatment.

Pharmacological studies document improved urinary flow as measures of drug effectiveness, but, as a participant observed, urinary flow is not necessarily the most relevant measure for patients, for whom relief of nocturia is often the main objective. Patient compliance can be improved by participation in peer support groups. Patients are more motivated to participate in support groups when faced with life-threatening conditions, such as cancer, than with conditions such as LUTS, which involve discussion of sensitive topics; strategies to encourage participation in LUTS support groups would be helpful. Discussants with experience managing other chronic diseases affirmed that long-term compliance with self-management programs also is improved by sustained communication between the patient and health care providers, by setting achievable goals related to the patient's complaints, and by addressing the goals one at a time.

Psychosocial Processes in Self-management

William Elwood, Ph.D., Opportunity Network (OppNet) Facilitator and Health Scientist Administrator, Office of Behavioral and Social Science Research, Office of the Director, NIH

As Dr. William Elwood emphasized in his presentation, all diseases are affected by an array of interacting biological, psychological, sociological, and environmental factors. But care for chronic diseases depends crucially on awareness of the roles played by all these factors and on the fact that each of these factors is also bound to change over time.

Effective management of chronic conditions requires, on the one hand, long-term self-management and ownership of the condition by the patient, as well as regular, effective communication between the patient and health care providers. Because chronic disease can affect many aspects of a patient's biological health and overall quality of life, effective health care also demands communication among all of a patient's health care providers and multidisciplinary health care perspectives that transcend the usual specialist boundaries.

Current treatment protocols for type 2 diabetes take into account the multiple dimensions of chronic disease, as well as the roles that the patient, family, friends, peer support groups, and health care providers play in managing that disease. In the case of diabetes, this support can literally be a matter of life or death. Nontraditional health care providers, including certified diabetes educators and patient navigators, also play important support roles in managing diabetes.

In 2015, an expert panel offered NIH a list of research recommendations on self-management of chronic conditions. Among the research needs identified by the panel were facilitation of patient-directed goals in self-management; expansion of research teams to include representatives of business, the insurance and pharmaceutical industries, and other fields; creation of methods for following study participants over their entire lives; identification of data elements common to all chronic conditions; understanding the sociobehavioral processes that affect implementation of self-management behaviors; and incorporation of novel educational methods, such as storytelling, to engage patients in self-management.

Discussion

One participant suggested that self-management of LUTS does not need to be complicated: Communicating information to patients about their condition and about effective self-management techniques does not require a fundamental reconceptualization of the disease. Dr. Elwood replied that after the patient is diagnosed, delivery of initial information on management might be straightforward, but delivering health care to men who may not realize or admit, either to themselves or to their physicians, that they have LUTS remains an educational and clinical challenge. Other participants pointed out that emotional management of chronic disease is a complex and important component of long-term treatment and that the interplay of physiological symptoms with emotional factors in chronic conditions can change in ways that may require a change in self-management strategies over time, as well as collaboration among a variety of health care specialists.

Self-management Is a Viable Option in Chronic Conditions

Shirley M. Moore, Ph.D., R.N., FAAN, Associate Dean for Research, School of Nursing, Case Western Reserve University

Dr. Shirley Moore defined self-management as “the ability of the individual, in conjunction with family, community, and health care professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of chronic illnesses.” It is a philosophy, a process, and a set of tools that can be applied not just to chronic conditions, but also to the recovery process from acute illness. It has been estimated that only 20 percent of health care is professional care; the remaining 80 percent is self-care. This generalization is especially pertinent to patients with chronic diseases, for whom their continued well-being depends on their active, informed participation in managing the disease.

Effective self-management demands collaboration and sustained, two-way communication between patients and health care providers. One challenge in communication is that clinicians and

patients define health problems differently. Clinicians define health problems in terms of diagnosis, poor patient compliance with prescribed treatment, or continuance of unhealthy behaviors. Patients' concerns are focused on pain, symptoms, impaired functioning, emotional distress, fears, and the difficulty of carrying out prescribed treatments. Effective, long-term communication requires sensitivity to patient concerns and multiple approaches to communication—not only traditional discussions during office visits, but also regular communication through electronic mail, telephone calls, and other methods.

Self-management entails not only managing the illness itself, but also managing everyday family life and work life and managing emotional aspects of the disease, including anger, fear, and depression. Depression can affect physical and social functioning more than the physical limitations posed by diabetes, arthritis, and other chronic conditions.

Of the most intensively studied chronic diseases, diabetes, asthma, and osteoarthritis offer some particularly useful lessons for developing self-management therapies. Systematic evaluation of self-management protocols indicates that group-based self-management support is particularly effective for these diseases. Among patients with diabetes and asthma, those with more severe conditions respond best to self-management, perhaps because they are more motivated to improve their condition. Telephone conversations, interactive web communications, and text messaging can be useful adjuncts to in-person clinician-patient communications. Patient log-keeping is an especially effective method to encourage consistent self-monitoring.

Discussion

During the discussion, a participant observed that self-management is most successful when a patient can see and feel the effects of the treatment; because of the varied factors that affect LUTS, goals in self-management must be tailored to individual patients. Research proposals are also most successful when investigators can demonstrate that they will be able to measure an effect. In general, the higher the IPSS score (a measure of symptoms perceived by the patient), the more likely a treatment will provide a meaningful change. If symptoms are severe, however, medical or self-management interventions might be able to deliver a physiologically significant effect, but still not improve symptoms enough to be meaningful to the patient.

Remarks from the Institute Director

Griffin P. Rodgers, M.D., M.A.C.P., Director, NIDDK

Affirming the significance of the conference theme, Dr. Griffin Rodgers stated that LUTS is a very important topic that, unfortunately, has not received enough research attention. Usually associated with BPH, LUTS affects the quality of life both for men and for their life partners. The actual cost of LUTS to patients and insurers exceeds even the 2000 estimate of \$1.1 billion per year because that figure reflects only the direct costs of health care and excludes the costs of prescription drugs. As the population ages, the costs of LUTS also will rise.

In recent years, the NIDDK has been moving away from organ-centric approaches and has been working to develop integrative, collaborative approaches to researching and treating LUTS. To encourage innovative, multidisciplinary, comprehensive research in this field, the NIDDK is sponsoring the Multidisciplinary Approach to Urologic Chronic Pelvic Pain (MAPP) Research Network, Symptoms of Lower Urinary Tract Research Network (LURN), and Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium. Several well-known chronic diseases, such as diabetes and arthritis, can serve as models for developing self-management of

LUTS. To help men find solutions to living with LUTS, researchers need to address the behavioral aspects of LUTS interventions in men.

Self-management in Diabetes

Elizabeth A. Walker, Ph.D., R.N., C.D.E., Professor of Medicine, Department of Medicine and Endocrinology; Director, Center for Diabetes Translation Research, Albert Einstein College of Medicine, Bronx, New York

Dr. Elizabeth Walker outlined the challenges and successes of self-management in diabetes and the useful lessons that the experience of the diabetes community can provide for development of self-management treatment protocols for LUTS. A task for clinical research on any chronic disease is to identify the necessity of self-management and how it fits into the overall treatment of the disease and how health care providers and multi-disciplinary teams can interface with patients to optimize effective self-management.

Components of self-management of diabetes include education (by the health care providers) and support (through family, peers, health care personnel, and technological support). It is apparent that LUTS providers will need ancillary personnel to inform and engage patients in these kinds of programs. Because diabetes is a condition that patients must manage for the rest of their lives, and because mismanagement could have fatal consequences, education carried out by certified educators or other knowledgeable health care professionals is essential. Self-management support can include peers and community health workers, as well as health care providers; peer support works best when it is integrated into the health care system. These people can assist patients with daily maintenance routines and long-term emotional and social support. Whatever the system (group or individual) of self-management support, it is essential that it be carried out person-to-person, using technology as appropriate. Although it can be difficult to persuade men to participate in peer support groups, they will continue to participate in the program if there is a good match between the patient and the peer coach.

Diabetes self-management requirements are integrated into American Diabetes Association guidelines for diabetes care standards:

- Healthy eating (the most difficult to discipline).
- Physical activity and healthy lifestyle habits, which go hand in hand with healthy eating.
- Monitoring of medication, blood glucose, healthy eating, and physical activity. Research has shown that it is particularly difficult to persuade patients to keep logs of these indicators, but new smartphone apps may be helpful for increasing adherence.
- Taking medication. Visits to pharmacists and doctors can be tracked, but self-management skills and good physician-patient communication are needed to ensure adherence to medication protocols.
- Problem solving and goal setting. Patients generally need help defining the problem and setting goals, while assessing the positive and negative consequences of changes in the management plan.

Discussion

Discussants considered the similarities and differences between living with diabetes and living with LUTS. One challenge in developing self-management plans for LUTS is that BPH is managed largely by urologists, who traditionally are surgeons by training. Since the goal of self-management protocols is at least partly to avoid or delay surgery, more holistic treatment plans require a broader view of care and innovative collaboration among urologists, primary care

physicians, and other health care providers, as well as incorporation of peer support into management plans. Good behavioral interventions for LUTS have been developed, but implementation remains a challenge.

Another reason to focus on diabetes as a model is that 50 percent of LUTS patients have diabetes. These patients would be good candidates for pilot studies on LUTS self-management because they may already be experienced with self-management activities. Training diabetes educators on LUTS would make it easier to build on the diabetes management system. Adding to the pertinence of the diabetes model is that risk factors for LUTS have much in common with those of diabetes.

Arthritis: Self-management and Quality of Life

Leigh Callahan, Ph.D., Mary Link Briggs Distinguished Professor of Medicine, Department of Medicine, Thurston Arthritis Research Center, The University of North Carolina at Chapel Hill

Reviewing current practices for self-management of arthritis, Dr. Leigh Callahan stressed that patient education is an important component of treatment for all chronic diseases, and that it is a key element in managing arthritis.

Arthritis refers to approximately 100 different conditions that affect more than 32 million people in the United States, and the costs to the economy are about 1.1 percent of the gross national product, roughly equivalent to the economic impact of a moderate recession. The most common form of arthritis, osteoarthritis (OA), is the most common source of disability in the United States, and its incidence continues to increase. Because it limits physical activity, it can interfere with treatments for diabetes and cardiovascular disease.

Nonmodifiable risk factors for OA include female gender, age, and genetic predisposition. Modifiable factors include obesity, joint injuries, infection, and certain occupations. As with other chronic diseases, OA has multiple physical, emotional, and sociological consequences.

The sequence of OA management has much in common with that of LUTS. First-line approaches include behavioral interventions, such as exercise, weight reduction, and self-management education. Second-line treatments include physical therapy and pharmacological therapies. Surgery, including complete joint replacement, is the treatment of last resort.

A 2003 article by Lorig and Holman noted several common characteristics of chronic disease:

- Its onset is often gradual, and it can take an unpredictable course over time.
- It often has multivariate causation.
- Diagnosis and prognosis can be uncertain.
- There is usually no cure, which makes medical and behavioral intervention essential.
- It can cause emotional distress, as well as social and professional difficulties.
- Patients need to work with physicians to participate in decisions about their health care.
- Patients need to take responsibility for self-management, including proper use of medications, behavioral and lifestyle changes, and self-monitoring and reporting of symptoms.

Patients seek information on diagnosis and treatment; they seek coordination of care, a functional health infrastructure, and emotional and medical support to help them adapt to the disease. In a series of publications, Lorig and her colleagues developed a national program of evidence-based

self-management education to address these needs. Their studies suggested that the process of education was as important as the content, and that patients who felt that they had control over their symptoms tended to improve more than those who felt that there was nothing that could be done.

A number of physical activity and self-management interventions have been developed and established to be appropriate for individuals with or at risk of developing arthritis. These arthritis-appropriate evidence-based interventions are delivered in community-based settings or online. They can be found on the website of the Arthritis Program of the Centers for Disease Control and Prevention.

Discussion

Participants noted that in management of both arthritis and LUTS treatment, there is debate about the consequences of avoiding or delaying medical therapies to allay symptoms. Another shared challenge of care for chronic disease is sustaining patient engagement in self-management programs. Participation is maintained only when programs center on patient-oriented concerns and when patients can link progress to their self-management activities. Even with the robust educational initiatives in place for arthritis care, only a small percentage of OA patients take advantage of the classes and training. Arthritis interventions are successful when goals are manageable and relevant to patient goals and concerns.

Self-management for Men with LUTS—Is It Possible?

Mark Emberton, M.D., Professor of Interventional Oncology, Faculty of Medical Sciences, University College London

Dr. Mark Emberton summarized the results of a clinical trial on LUTS self-management conducted at the University College London (UCL). LUTS is a condition that is defined symptomatically, and successful treatment also is defined symptomatically. The UCL study conducted by Dr. Emberton in collaboration with a clinical epidemiologist and psychologist demonstrates the feasibility of successful self-management programs for LUTS. Shifting responsibility of care from the clinician to the patient empowers the patient to help control symptoms and aligns with the preference of most patients to avoid medical and surgical interventions. The use of simple tools, such as a diary of urinary patterns, can illuminate causative factors for both doctor and patient at the beginning of the diagnostic process, and the rapid benefits achieved from lifestyle and behavioral modifications act as positive reinforcement to encourage continued participation in the program.

Working with colleagues to decide on a series of appropriate lifestyle and behavioral modifications that target the most bothersome patient concerns, Dr. Emberton and his colleagues conducted a multiyear study comparing the progression of LUTS in self-managed patients with those in standard care. Their data demonstrated that self-management improves quality of life and reduces both symptoms and symptom progression, compared to standard pharmacological (dutasteride-tamsulosin) treatment. Pharmacological intervention does not improve IPSS scores unless self-management is included with standard treatment.

Currently, most physicians at UCL use self-management as first-line care; self-management also is used in conjunction with other treatments. Although optimal self-management methods need to be refined, results to date suggest that self-management is a promising and feasible approach to the care of LUTS.

Discussion

One discussant asserted that the results could be seen as a placebo response, because, in the end, all of the patients still were symptomatic. Another participant suggested that LUTS self-management education programs could benefit by the addition of a specialized LUTS educator, similar to a certified diabetes educator, who could train patients in behavioral modifications.

In answer to several questions that sought information on the key elements of the behavioral modifications, Dr. Emberton acknowledged a limitation of the study: because multiple interventions were tried at once, the investigators could not distinguish the relative effectiveness of each self-management technique. Whatever the most effective individual elements of the behavioral modifications might turn out to be, the statistical evidence indicated persuasively that the combined modifications reduced or delayed symptom progression in LUTS patients.

Scalability of Self-management for Men with LUTS

Steven Jacobsen, M.D., Senior Director of Research, Department of Research and Evaluation, Kaiser Permanente Southern California

Dr. Steven Jacobsen and his colleagues applied Dr. Emberton's model on a larger scale for use with a study population composed of LUTS patients at the Kaiser Permanente integrated health care plan in southern California. Their health education program built on several pillars of the Emberton program: fluid management, bladder training, medication management, and a bladder diary (which turned out to be an intervention tool). Although the patient education program in the Emberton study used classic patient education techniques, with experts teaching small groups of study subjects, the large scale of the Kaiser Permanente program, combined with budget considerations, led to the development of a web-based video education program. To create the video, two in-person classes were led by a health educator and assessed formally by a study team to identify the face-to-face dynamics that were important to replicate in the web-based version. A web designer and script writer were enlisted to translate the classes into web-friendly material.

The pilot study established that physician endorsement of the classes is essential to course effectiveness. The goals of the classes should be introduced early in the session, and be meaningful, attainable, and adjustable depending on patient feedback. Patients also requested handouts to supplement the classes so that they could refer to the material at leisure. To be effective as a web-based course, the material has to be clear and engaging. The video version of these classes is narrated by an approachable, ordinary-looking actor in the role of a LUTS patient, and the urological recommendations are presented in simple language, with clear illustrations. The module can be tailored to individual patient concerns, and it is interactive in style to encourage patient contact with his care provider. To encourage continuing involvement, patients receive a certificate of completion upon conclusion of the course.

To be a viable alternative to traditional educational methods, web-based courses require extra initial effort and an independent assessment of their effectiveness. Dr. Jacobsen and his colleagues are considering ways to add apps that would facilitate diary keeping and other self-reporting activities.

Discussion

During the discussion, Dr. Walker observed that self-management offers LUTS patients a real advantage over many patients with chronic conditions because behavioral modifications can

improve their symptoms quickly. This advantage should be exploited in design of self-management programs.

A Holistic Approach to Health: Cognitive, Social, and Emotional Domains

Mary H. Palmer, Ph.D., R.N.C., FAAN, AGSF, Helen W. and Thomas L. Umphlet Distinguished Professor in Aging, School of Nursing, The University of North Carolina at Chapel Hill

Sex differences exist in health behaviors, morbidity, and mortality with men having higher rates of cigarette smoking, obesity, and higher suicide and homicide rates than women. Beyond this generalization, however, variations exist among men on their cognitive and emotional responses to disease and its treatment. Dr. Palmer reviewed the effects of some of these differences on variations in responses to LUTS therapy in men. When faced with serious disease, the most important factor for young men is lower morbidity; the top priority of older men is continued functional independence and social functioning. With regard to self-management, some men are more open than others to complementary and alternative therapies. Some seek sources of emotional support in addition to medical treatment, while some do not. Some men seeking help for LUTS may be motivated initially by anxiety about the possibility of prostate cancer, others may come in hope of mitigating their symptoms, and others may be responding to educational outreach.

Patient education for LUTS is essential, as is acknowledgement of men's dignity and respect for their personal needs. Emotional, social, and cognitive factors will have an effect on almost every aspect of LUTS. In general, men show poor understanding of urinary symptoms, and they tend to delay seeking professional help until the symptoms become unmanageable. Medications used to treat depression can affect urine storage symptoms of LUTS, and LUTS can contribute to depression, making holistic assessment essential. Some men cope with limitations and uncertainty better than others and this information is important in care planning. Among cultural and ethnic barriers, some men are reluctant to seek care because they are hesitant to admit to or complain about issues that might imply lack of masculinity. Differences in work environments can also affect men's needs. Older men who travel for work may be devastated by incontinence, while other men with easier bathroom access may not be. Socioeconomic factors, such as lack of funds for co-pay costs, family caregiving and obligations, or work constraints that do not allow employees to take time off for healthcare appointments, can discourage men from seeking health care.

Self-management Support Implementation

Judith Schaefer, M.P.H., Senior Research Associate, Group Health Research Institute, MacColl Center for Health Care Innovation

Ms. Judith Schaefer stated that effective self-management entails a kind of marriage between the health care system and the community because important elements of self-management occur in both settings. Self-management support is most effectively delivered by a care team, with assessment, information sharing, goal setting and follow up tasks shared among appropriate team members. When first delivering a diagnosis of chronic disease, physicians can encourage their patients by explaining that although their condition may not be curable, the patient can do a great deal to manage the condition with the help of the care team. Other practice team members can work with patients to operationalize treatment goals within the context of their own lives. The self-management plan must reflect each patient's specific needs.

In setting up a self-management action plan with the patient, it is important to have at hand updated clinical data, as well as data from the patient himself, and his experience managing his

condition. The physician and patient - optimally with the support of a health coach, nurse, or navigator—then work collaboratively to set the self-management goals for the action plan. Communication among health care providers, including regular conversations between urologists and primary care providers, is essential for successful implementation of an action plan for self-management in LUTS. That plan should list specific behavioral goals, potential barriers to those goals, and strategies to address those anticipated barriers. The plan should be shared with all of the staff, including social support personnel, involved in the patient’s care. Regular follow-up contact is essential to support ongoing, effective self-management. Provider-patient contact might include a post-visit telephone call with the patient, specialist referrals, office visits, or introduction to community and peer-support resources.

THURSDAY, SEPTEMBER 22, 2016

The Role of Social Media and Technology in LUTS: Does It Matter?

Steve Kaplan, M.D., Professor of Urology, Department of Urology, Icahn School of Medicine at Mount Sinai

Dr. Steve Kaplan emphasized the potentially important role that social media can play in modern medicine. Major social media sites—such as Facebook, Twitter, YouTube, and LinkedIn—have billions of users, and the ubiquity of smartphones has increased the effectiveness of social media even more. More than 40 percent of consumers state that information on social media has affected their approach to their personal health, and almost 20 percent of smartphone owners have at least one health app on their phone. About 40 to 50 percent of the general population seeks information on social media about health topics and doctors; young adult patients (18–24 years old) trust medical information on social media; and about one-third of health care providers use social media themselves for professional networking. Thus far, many health care organizations have used social media cautiously, partly because of privacy and security concerns. But because of heavy use of social media as a source of medical information, health care professionals have an obligation to post clear, engaging, accurate health information to help patients to distinguish information from misinformation. When used insightfully, social media sites can be important tools for electronic communications between patient and health providers; for creation of personalized, interactive web experiences for patients; and for patient education on surgery procedures, self-management protocols, and other therapies.

Social media sites have at least two downsides: First, web-based information is not infallible. Websites and social networks can disseminate misinformation, and even credible information sources are not necessarily up to date. Second, social media cannot substitute for patient-physician communication, a vital part of health care that is compromised when “smartphone-addicted” patients check their devices during doctor visits instead of communicating with their physicians. Nevertheless, technology also provides many exciting opportunities. Web-based resources, such as Medivizor, provide extensive information for physicians, and can personalize and organize cutting-edge health and medical information for patients, allowing them to learn of treatment options, guidelines, research, and clinical trials of clinical relevance. Other innovative apps can monitor and manage stress levels, predict a patient’s risk for particular diseases, and inform the physician’s choice of treatment.

Innovative use of social media and digital technology could be very useful for designing effective, personalized management plans for LUTS patients and could poise the LUTS provider community to take leadership in the application of innovative technology to advance integrative, holistic approaches to health care and research in this field.

Discussion

In response to concerns about the lower level of social media use and computer skills among older patients, Dr. Kaplan noted that his own mother communicates with her grandchildren via Facebook. Although young adults are the best poised to make use of social media and digital technology in their own health care, many older patients are familiar with some of this technology.

Dr. Star observed that not all new technology is as effective as one might think. In one study, people who used FitBits lost less weight than peers who did not. Dr. Kaplan replied that FitBits is a unidirectional app. To be an effective self-management tool, a health app has to be bidirectional.

Breakout Groups

Conference participants divided into three groups, each of which devoted 2 hours of discussion to a single topic:

- Group I: What trials can be done?
- Group II: Outcomes for a self-management program for male LUTS.
- Group III: How can the results be applicable to the broader community?

A summary of each discussion was then presented to the full conference.

Reports from the Breakout Sessions

I. What Trials Can Be Done?

Moderator: Ziya Kirkali, M.D.

Reporter: Steve Kaplan, M.D.

LUTS can affect a patient's quality of life in a number of ways and also can be a harbinger of other diseases, such as depression and cardiovascular disease. Research that investigated the relationship of LUTS to other diseases that are often associated with LUTS, such as depression and diabetes, could be very important for treating both LUTS and those diseases.

Behavioral management of LUTS is challenging regardless of the patient's age. Understanding the neurobiology that enables behavioral change and maintenance of self-management behavior could be very important in devising effective therapies for LUTS. LUTS researchers need to assess the effectiveness of self-management among men of different ages, different degrees of LUTS severity, and different cultural and geographical contexts.

Although it was agreed that organization of the multidisciplinary health care team to monitor care in LUTS patients is important, no single optimal formula for the composition of a LUTS health care team emerged. One candidate for health care "gatekeeper" for LUTS patients could be the primary care provider, who might be best poised to connect patients with resources for lifestyle and behavioral management, preventive care, community resources, medical therapy, and surgical

treatment. Urologists, who eventually play a key role in the care of most LUTS patients, are certainly well suited to manage pharmacological and surgical treatments but perhaps less well suited to supervise other, more holistic aspects of LUTS care.

The factors that encourage men to seek out health care for LUTS symptoms and to engage in self-management programs need to be understood. One predictive factor for men seeking medical help is the presence of a spouse, who is likely to nudge his or her partner to seek health care for bothersome symptoms. Community and educational outreach also help men to seek medical care, but with a condition like LUTS that becomes a significant problem only in middle age and beyond, traditional school programs seem ill-suited to serve this role. Participants debated the relative usefulness of clinic-based, community-based, web-based, and employer-based educational efforts.

A well-designed clinical trial, comparing the effects of traditional medical treatments (whose details also need to be decided), behavioral self-management, and a combination of medical and self-management protocols, could have a major impact on how LUTS is recognized and managed. Research is needed to test the relative effectiveness of various elements of self-management protocols; assist in experimental design of large clinical trials; and probe the relationship between LUTS and other diseases, particularly the interrelationship between LUTS and depression.

Watchful waiting is an active, structured process, not a passive one. Thus, the organizational structure of self-management programs could have a profound effect on the effectiveness of self-management therapy. For this reason, assessment of the most effective structures of self-management programs could be a promising research focus.

II. Outcomes for a Self-management Program for Male LUTS

Moderator: John Kusek, Ph.D., Senior Scientific Advisor, KUH, NIDDK, NIH

Reporter: Steven Jacobsen, M.D.

Among the health outcomes of interest are effects of self-management on urinary flow and retention, as well as the possibility that self-management may reduce or delay a need for medical or surgical therapy. Quality-of-life outcomes include overall health and the effect of self-management on the status of LUTS symptoms that matter most to the patient. A third outcome measure is utilization of office visits and implementation of self-management procedures. Finally, economic outcomes for patients, providers, and insurers are an important factor to consider in developing a sustainable management program.

It would be useful to discern the LUTS populations most likely to benefit from self-management. Two particular candidates for self-management interventions might be early-stage LUTS patients, with an emphasis on the investigation of self-management as a preventive strategy. Another candidate population might be the cohort of men who have undergone a pharmacologic and surgical treatment for LUTS, who might benefit from self-management techniques to control their symptoms post-surgery.

Comorbidity of LUTS with other diseases, such as heart failure and diabetes, can affect the health outcomes of LUTS self-management programs. A large-scale, multicenter pilot study is needed to gain qualitative insight into the interaction of LUTS with co-occurring chronic conditions. Inclusion of physiological samples and DNA samples in such studies could be very informative.

The individual components of bundled interventions need to be disentangled to identify those elements that are the most important in behavioral management of LUTS. Greater understanding of the effect of individual interventions could enable the eventual development of personalized or optimized self-management therapies.

Better measures of the effectiveness of implementation and educational strategies for self-management programs are needed, both for individual patients and for large-scale providers.

III. How Can the Results Be Applicable to the Broader Community?

Moderator: Jenna Norton, M.P.H., Program Manager, KUH, NIDDK, NIH

Reporter: Kevin McVary, M.D.

It would be useful to compare the effectiveness of LUTS self-management programs among different income groups, among different ethnicities, and between men in rural and urban environments. The effects of cultural background also are of potential interest, especially in cases where cultural background might discourage men from seeking care. It was not clear, however, whether cultural differences could be measurable in a study of this sort.

Comparison of the effectiveness of self-management techniques in LUTS patients with differing degrees of symptom severity could be of direct clinical relevance. Studies focusing on men afflicted with severe symptoms could assess whether self-management techniques have any effect at all on symptom relief in severe LUTS. Investigating the effectiveness of LUTS self-management for patients who also have diabetes or a history of previous LUTS surgery could also be useful.

Another relevant question is the effect of family and other social support on the patient's commitment to self-management techniques. The effect of health literacy and such traits as executive function, problem-solving skills, and self-efficacy also should be measured.

Finally, the feasibility and cost of self-management interventions are ultimately measures of effectiveness. One argument for self-management interventions is that they do not entail the same kinds of costs as surgical or pharmaceutical therapies. However, an economic analysis, including the costs of patient education and support, might be warranted.

What Have We Learned?

Robert Star, M.D.

In his concluding remarks, Dr. Star reminded the conference participants that the ultimate goal of this conference is to assess whether LUTS is amenable to self-management and, if so, to determine for individual patients the right self-management approach at the right time. In this conference, experts on other chronic diseases have helped educate urologists on the design and challenges of successful self-management programs in diseases such as diabetes, asthma, and arthritis.

Before a meaningful clinical trial can be conducted to test self-management therapy for LUTS, more information needs to be gathered on LUTS itself. There are several research gaps: It is not known which symptoms are the most bothersome to men and which groups of LUTS patients are most likely to engage in, and respond to, self-management. A list of possible interventions could be compiled, and more needs to be understood about the influence of such associated conditions

as obesity, diabetes, and ED on LUTS outcomes. The effect of family members and social support on participation in health care and self-management programs is also unknown.

Pilot studies might determine which subsets of patients to test (degree of symptom severity, presence or absence of co-occurring conditions), the best institutional setting for the clinical trial, the nature of controls and intervention protocols, and the specific effects and outcomes to be measured. The possibility of economic incentives for study participants also could be considered.

Some technological tools could be developed to assist in implementing interventions, maintaining patient engagement, and monitoring responses.

If interventions can be shown to work, the LUTS community will face the next challenge: how to embed the several nontraditional elements of a self-management program into the current health care system.

Discussion

One participant complimented the NIDDK for recognizing that LUTS is a considerable health burden and noted that it is especially interesting, given the traditional surgical orientation of urologists, that self-management has emerged as a potentially key aspect of LUTS treatment. Dr. Star replied that the NIDDK has played an inadvertent role in the evolution of urology practice.

Another participant observed that there seems to be a need to collect solid qualitative data on patient-centered outcomes. Dr. Star replied that a major focus of LURN is to collect these kinds of patient data. The challenge is to implement those data in a useful way.

One attendee asserted that self-management is effective, but arguably not effective enough. In many practices, “watchful waiting” and “patient self-management” really are synonyms for benign neglect. Clinicians need to understand how self-management interacts with pharmacological and surgical approaches in LUTS treatment. Is self-management always the first line of treatment for LUTS, or do some situations require immediate surgical intervention? Dr. Star agreed on the need to investigate whether self-management treatment can ever be implemented successfully as a substitute for surgical or pharmacological therapy, or whether self-management must always be only a preliminary or supplementary approach to LUTS treatment. Participants emphasized that resolving this question demands a serious, multiyear trial to assess the long-term efficacy of lifestyle interventions before a meaningful comparison of self-management and traditional treatments can be conducted. Serious lifestyle and behavioral interventions must be carefully designed, structured programs in which health care providers are actively involved.