



ICA Professional Perspectives

Spring 2007

A Newsletter for Healthcare Professionals

Interested in the Research and Treatment of Interstitial Cystitis / Painful Bladder Syndrome

The Interstitial Cystitis Association ~ *Putting the Pieces Together*

**SPECIAL
DOUBLE ISSUE**

Two New ICCRN Studies Underway

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Interstitial Cystitis Collaborative Research Network (ICCRN) has officially announced the launch of two studies for potential IC treatments: mycophenolate mofetil (CellCept) and physical therapy.

CellCept Study

The CellCept study aims to investigate the safety and effectiveness of this immunosuppressant drug to help IC patients who have severe IC that other treatments haven't helped.

CellCept is currently approved for use in patients who have had organ transplants and is also used for the treatment of severe rheumatoid arthritis.

Researchers aim to test its use (in much lower doses) in patients with severe IC at 11 participating research centers (please see below).

Who can participate?

Patients who have had a diagnosis of painful bladder syndrome (PBS)/IC confirmed sometime in the past and who are considered unresponsive or refractory to previous PBS/IC treatments can participate. Patients should be instructed to contact their closest site for more specific inclusion/exclusion criteria.

CellCept Study Participating Sites

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Clinical Research Coordinator
585-275-0989

University of Maryland, Baltimore, Maryland
Rosanna Dinh, RN, CCRC
Temporary ICCRN Coordinator
410-328-7736

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Mary Eno, RN
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William Beaumont Hospital, Royal Oak, Michigan
Eleanor Anton, RN, Clinical Research Coordinator
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Loyola University Medical Center, Maywood, Illinois
Judith M. Senka, RN, Research Nurse Coordinator
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Joe Downey, MSc CCRP, Research Coordinator
613-548-7832

Stanford University Medical Center, Stanford, California
Debra Clay, RN, Research Coordinator
650-724-1753

University of Washington, Seattle, Washington
Sharon Downing, RN, Research Nurse II
206-598-0850

University of California San Diego, San Diego
Kristen Mangus, Assistant Study Coordinator
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In this Issue of *ICA Professional Perspectives*:

Two New ICCRN Studies Underway	1
Griffin P. Rodgers, MD, Named Director of NIH's NIDDK ..	2
ICA Participates in Recent Japanese Conferences	3
New IC Nurses Online Resource Now Available!	3
Some European Medical Professionals Intend to Change the Name of IC	4
ICA and ARHP Host Washington, DC Consensus Meeting on Interstitial Cystitis/Painful Bladder Syndrome	5
An Interview with Robert D. Mayer, MD	5
IC Clinical Trials Update	7
The Latest IC Published Research Highlights	7

Physical Therapy Study

Physical therapy has potential for treating both PBS/IC and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), so this study is being done jointly by the ICCRN and the Chronic Prostatitis Collaborative Research Network (CPCRN)—the Urological Pelvic Pain Collaborative Research Network (UPPCRN). Few physical therapy studies have been conducted to show its usefulness for these patients, and this small study to include 48 patients aims to do that.

This study will look at two forms of physical therapy as treatments for IC/PBS and CP/CPPS and find out if symptoms improve and if the therapy is safe and tolerable. The study will be conducted at five centers. Both women and men who have not responded to previous therapies for either PBS/IC or CP/CPPS may be eligible. Patients should be instructed to contact individual centers to see if they are eligible to participate.

Physical Therapy Participating Sites

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Stanford University Medical Center, Stanford, California
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William Beaumont Hospital, Royal Oak, Michigan
Eleanor Anton, RN, Clinical Research Coordinator
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Griffin P. Rodgers, MD, Named Director of NIH's NIDDK

Elias A. Zerhouni, MD, director of the NIH, recently announced the appointment of Griffin P. Rodgers, MD, as director of the NIDDK, effective April 1, 2007.

"Griff Rodgers is an outstanding physician-scientist and molecular hematologist. He has made many contributions to the study of globin disorders and is internationally recognized for his contributions to the development of effective therapy for sickle cell anemia and other genetic diseases of hemoglobin. In addition to his research experience, Dr. Rodgers is a dedicated and knowledgeable clinician and a first rate research administrator. He has all the qualities we search for in an Institute Director," said Zerhouni. Dr. Rodgers, who was appointed Deputy Director of

NIDDK in January 2001, was Acting Director of NIDDK and also serves as chief of NIDDK's Clinical and Molecular Hematology Branch, which he has headed since 1998.



Griffin P. Rodgers, MD

As the new Director of the NIDDK, Dr. Rodgers will oversee an annual budget of \$1.8 billion and a staff of 650 scientists, physician-scientists, and administrators. The Institute conducts and supports research on many of the most serious diseases affecting public health including diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition, including obesity; and kidney, urologic, and hematologic diseases.

The NIDDK conducts and supports much of the clinical research on the diseases of internal medicine and related subspecialty fields as well as many basic science disciplines at its research facilities in Bethesda, MD, and Phoenix, AZ, and at research institutions and medical centers throughout the United States. In addition, the NIDDK also supports education programs to translate the results of research to health professionals, patients and the public.

"It is truly an honor to be given the opportunity to lead an organization with a mission as far-reaching and varied as the NIDDK," said Dr. Rodgers. "While NIDDK has a long and distinguished history of accomplishment as an Institute, we must look to the future to capitalize on the opportunities for disease prevention that new technologies and discoveries are giving us. The health problems we face as a Nation are real and the results of research offer substantive promise for solving the difficult questions faced by millions of Americans every day and the health professionals who treat them," he said.

Dr. Rodgers received his undergraduate, graduate and medical degrees from Brown University in Providence, RI. He performed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology/oncology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. In addition to his medical and research training, he earned a master's degree in business administration, with a focus on the business of medicine, from Johns Hopkins University in 2005.

As a research investigator, Dr. Rodgers is widely recognized for his contributions to the development of the first effective—and now FDA approved—therapy for sickle cell anemia. He was a principal investigator in clinical trials to develop therapy for patients with sickle cell disease and also performed basic research that focused on understanding the molecular basis of how certain drugs induce gamma-globin gene expression. He was honored for his research with numerous awards including the 1998 Richard and Hinda

Rosenthal Foundation Award, the 2000 Arthur S. Fleming Award, the Legacy of Leadership Award in 2002 and a Mastership from the American College of Physicians in 2005.

Dr. Rodgers has been an invited professor at medical schools and hospitals in France, Italy, China, Japan, and Korea. He has been honored with many named lectureships at American medical centers and has published over 150 original research articles, reviews, and book chapters and has edited four books and monographs.

Dr. Rodgers served as Governor to the American College of Physicians for the Department of Health and Human Services from 1994 to 1997. He is a member of the American Society of Hematology, the American Society of Clinical Investigation, and the Association of American Physicians, among others. He is the chair of the Hematology Subspecialty Board and is a member of the American Board of Internal Medicine Board of Directors. He is board certified in Internal Medicine, in Emergency Medicine, and in Hematology.

ICA Participates in Recent Japanese Conferences

The ICA was honored to participate in the Second International Consultation on Interstitial Cystitis-Japan (ICICJ), which was held in the ancient city of Kyoto in March. Tomohiro Ueda, MD, PhD, Naoki Yoshimura, MD, Jorgen Nordling, MD, and ICA Medical Advisory Board Co-Chair, Philip Hanno, MD, were the members of the committee that organized this comprehensive three-day event.

IC researchers and clinicians from around the world met to discuss etiology, diagnosis, and treatment and to continue the international dialogue about the nomenclature and definition of IC. Some of the liveliest discussions centered around the name change from IC/PBS (painful bladder syndrome) to BPS (bladder pain syndrome), which was first proposed by a group of European medical professionals (ESSIC) last year. The topic remains under discussion, to be continued at a proposed NIDDK-sponsored meeting in the fall of 2007.

The ICA's Founder and President, Vicki Ratner, MD, and Director of Communications, Ann Moritz Chesnut, represented the ICA in Japan. Dr. Ratner had the opportunity to speak at the scientific meeting and Ann gave an ICA presentation at a concurrent Comfortable Urology Network patient meeting.

These meetings highlighted the emerging involvement of Asian patients and physicians in the IC movement, including patients and healthcare professionals in Taiwan, South Korea, and Japan.

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New IC Nurses Online Resource Now Available!

We are pleased to present the first in a series of online ICA medical education tools to assist healthcare professionals in becoming familiar with all aspects of IC.

This presentation, *Interstitial Cystitis: What Healthcare Providers Need to Know*, is designed to further educate the nursing community about IC and was underwritten by a generous educational grant from The Medtronic Foundation.

A link to the presentation can be found on the ICA's website homepage.



CHECK OUT *CAFÉ ICA* at
www.ichelp.org

Café ICA is your monthly electronic source for the most up-to-date information on IC research, clinical trials, treatments, and other late-breaking news.

A Statement from The Interstitial Cystitis Association Some European Medical Professionals Intend to Change the Name of IC

Release Date: December 15, 2006

During the recent National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) International Bladder Symposium: *Frontiers in Painful Bladder Syndrome and Interstitial Cystitis*, held in Bethesda, Maryland, on October 26 and 27, 2006, the European Society for the Study of IC/PBS (ESSIC) announced that they would be replacing the term "interstitial cystitis" with "bladder pain syndrome" and revamping the current diagnostic criteria.

ESSIC is a non-profit organization for medical professionals that was established in Copenhagen, Denmark, in June of 2004. Its members are scientists and/or medical practitioners with an interest in research into and/or treatment of IC. There are no patient members of ESSIC and we are unaware of any active participants outside of Europe and the UK. There were neither patient organization representatives nor any IC experts from the US at the meetings that developed the ESSIC name change and definition of IC.

In part, ESSIC intends to:

1. Change the name of interstitial cystitis (IC) to bladder pain syndrome (BPS).
2. Establish more rigorous diagnostic testing criteria, including various tests not currently typically used in the diagnosis of IC, relying significantly on cystoscopy with hydrodistention under general anesthesia with a deep-tissue biopsy to confirm the diagnosis.
3. Remove the word "urgency" as a defining symptom of IC.
4. Include only patients who experience pain and urinary frequency. This excludes patients who may only experience urinary urgency, frequency, and/or pelvic pressure.

Some of the ICA's major concerns regarding the terminology change:

1. Bladder Pain Syndrome is too broad a term. For instance, people who are experiencing urinary tract infections, pelvic pain problems, and any other bladder problems that cause pain may feel that they have BPS.
2. Physicians of many specialties, medical students, and residents from urology are now aware of IC (using the term "interstitial cystitis"). This name change could have a very negative impact on their recently acquired recognition, understanding, and ability to treat the condition.
3. A terminology change away from IC at this juncture will also hurt the years that many organizations have spent years working on educating the patient population, legislators, and general public about interstitial cystitis.

4. Consideration must be given to the impact of this terminology change on the US Social Security Administration's recognition and understanding of the disease as well as the ability for people with the condition to gain disability benefits, either from the SSA or privately. The SSA's Ruling was awarded for IC, not BPS.

5. A name change could impact health insurance coding for physician reimbursements, patient coverage, and pharmaceutical coverage.

6. Use of a new name could dilute/confuse or halt research funding programs and opportunities.

7. A terminology change will complicate the process of searching the medical literature on IC. Both healthcare providers and patients will have to contend with multiple terms and descriptions of the disease when they look for the inability to get a full and comprehensive picture of IC research without knowing that multiple terms are required. It is possible that the name change will affect which medical articles are selected for publication by urology journals since editors may reject the term interstitial cystitis and accept only bladder pain syndrome.

8. And, most importantly, the use of a new name will make it more difficult for people suffering from the condition to:

- seek information on the internet & elsewhere
- receive diagnosis and treatment
- find help from organizations such as the ICA
- get validation from friends & family

Concerns regarding ESSIC's definition/diagnostic change:

1. Since it has long been recognized that the NIDDK IC definition/diagnostic criteria were written expressly for the purpose of research studies, we realize that a revision is necessary. The US and other world IC leaders are acutely aware of this problem and have been working on this very important revision for several years.

2. While ESSIC's new name of Bladder Pain Syndrome can be seen as too broad, as stated above, ESSIC's new definition could be seen as too restrictive, excluding patients who may only experience urinary urgency, frequency, and/or pelvic pressure, but not pain, and thus echoing the similarly restrictive NIDDK diagnostic criteria.

3. Unlike many European countries, such as England and the Scandinavian countries, the US healthcare system is not equipped/designed to provide for series of tests. Many people in the US and other parts of the world are underinsured or not insured and could not afford the proposed testing procedures. And many health insurance companies would not reimburse for additional testing.

The problem of excluding urinary urgency:

1. Focusing solely on bladder pain as the main symptom of this condition will exclude patients with urinary urgency and pelvic pressure.

2. While it is recognized that urinary urgency may need to be further refined/defined to describe the unique sensation as it applies to IC patients (as opposed to urge incontinence patients), excluding urgency altogether will not solve this dilemma. Work needs to be done on refining or redefining urinary urgency as it applies to IC. We suggest that the term pelvic pressure be substituted for urgency to avoid confusion with incontinence.

The ICA has a number of concerns with both the process in which ESSIC reached a consensus and the outcome of that consensus. In particular, the ICA believes that any name change or definition change of IC must include the NIDDK and the IC experts from the US as well as the worldwide patient community. Over many years the ICA and the NIDDK have reached out to ESSIC members, as well as the wider international community, and invited them to work collaboratively with both the patient community and US researchers and clinicians. The ICA believes it is critical that there be additional opportunities for thoughtful discussion before ESSIC moves any further ahead and we are committed to taking a leadership role to ensure that this happens. The ICA is confident that ESSIC will see the wisdom in having a larger team of experts review their conclusions and equally importantly, take into serious consideration the very deep concerns of the patients.

ICA and ARHP Host Washington, DC Consensus Meeting on Interstitial Cystitis/Painful Bladder Syndrome

On February 10, 2007, a multidisciplinary group of researchers, clinicians, and patients met in Washington, DC, to exchange ideas and gain majority opinion on several key and potentially controversial issues regarding interstitial cystitis/painful bladder syndrome (IC/PBS).

Specifically, this group convened to discuss whether a nomenclature change is necessary. The group also explored current diagnostic criteria, whether the pathology underlying the condition is systemic or localized to the bladder, and the correlation between patient symptoms and results of currently available diagnostic techniques.

The 23 participants of the Washington, DC, Consensus Meeting on Interstitial Cystitis/Painful Bladder Syndrome offered a range of expertise in the field and included researchers, urologists, obstetrician-gynecologists, pain specialists, nurse practitioners, a registered nurse, and a pharmacist. Three individuals with IC/PBS attended the meeting, offering a patient perspective. The meeting was sponsored by the Association of Reproductive Health Professionals (ARHP), a membership association consisting of experts in reproductive health that provides education

and information about reproductive health science, practice, and policy, and the Interstitial Cystitis Association.

The consensus group also successfully identified an array of areas in IC/PBS in which future research is needed. The group is currently undertaking a number of action steps as a result of the consensus meeting.

Majority Statements:

Definition of IC/PBS: Pelvic pain, pressure, or discomfort related to the bladder, typically associated with persistent urge to void or urinary frequency, in the absence of infection or other pathology.

Nomenclature: The nomenclature of IC/PBS may need to change, but change should not be undertaken now because there is insufficient evidence to support a change. Any change in nomenclature should be evidence-based. This group favors retaining IC in whatever name is considered in the future and positioning it first, as in IC/PBS.

A White Paper has been created to reflect the meeting's findings. The document is available online at the ICA's website homepage (www.ichelp.org) the ARHP's website (www.arhp.org) and at the ICA's AUA Annual Meeting booth (booth # 1766).

In addition, the team will produce toolkits for an Ambassador Program, and will reach out to other non-urologic specialties, such as ob-gyn, urogynecology, and pain medicine, through educational programs, including grand rounds. The group will also identify specific individuals and organizations that can advocate on behalf of the awareness campaign and further spread its message.

An Interview with Robert D. Mayer, MD

Excerpted from the November/December, 2006, issue of the *ICA Update* newsletter.



Robert Mayer, MD

Dr. Mayer is Associate Professor of Urology, Director of Quality Assurance in the Department of Urology at the University of Rochester School of Medicine in Rochester, NY, and an ICCRN principal investigator.

IC experts continue to debate what is required to make a diagnosis of IC or of PBS/IC. How do you diagnose the condition today in your practice?

The diagnosis of IC remains primarily a diagnosis of exclusion. So far, we have no truly reliable, objective diagnostic test that is sensitive enough to pick up IC and specific enough to exclude other problems in all patients.

Although some questionnaires may be used for screening, they are not necessarily diagnostic, and potassium sensitivity testing is known to have limitations. We recently tried another kind of test in an outpatient clinic in which we put a fluorescein dye in IC patients' bladders and then measured how much of the dye was taken up in the blood. We hoped to use this test to gauge how "leaky" a patient's bladder was and to diagnose IC. Unfortunately, that did not work out because the test did not show a difference between IC patients and controls.

The most important aspect of diagnosis is getting a detailed history regarding the patient's complaints and associated symptoms. Generally, IC patients have chronic urinary frequency, urgency, and pelvic discomfort. Their sense of urinary urgency is more about avoiding discomfort rather than a sense that they'll be incontinent if they don't get to the bathroom. They often have coexisting pelvic problems, such as irritable bowel syndrome [IBS], pelvic floor dysfunction, or endometriosis.

For patients with mild symptoms, I do not think that hydrodistention or potassium sensitivity testing would necessarily be required before starting simple steps, such as changing diet and reducing stress. If the history and physical exam are thorough, the findings are consistent with IC, and other tests exclude other treatable conditions, then I start treatment with medications such as amitriptyline [Elavil], antihistamines, and pentosan polysulfate [Elmiron]. I often have patients start pelvic floor physiotherapy as well.

I do discuss the advantages as well as the limitations of diagnostic tests such as potassium sensitivity and hydrodistention with patients. Instead of potassium sensitivity, I personally prefer to instill lidocaine and heparin in the bladder to see whether the patient gets relief. I am not sure that only one instillation is diagnostic, however. Patients who are older—especially those with microscopic blood in the urine—should undergo cystoscopy because they are at higher risk of having other bladder diseases.

Patients should be under anesthesia for cystoscopy and hydrodistention, which allows the urologist to do a biopsy and fulgurate, that is, burn off, any ulcers or lesions. Younger patients who have not responded to initial therapies may get temporary relief from cystoscopy and hydrodistention. I have found that if I see glomerulations or ulcers in the bladder, that gives the patient and family some validation that the patient does have a bladder disease. I have also found that patients have less discomfort after the procedure if I use spinal rather than general anesthesia, especially for patients who have a lot of pain as part of their IC symptoms. Hydrodistention rarely provides a long-term benefit by itself, so it must be combined with additional long-term therapy.

What therapies do you find most effective?

Similar to most physicians treating IC, I find using a number of treatments at the same time rather than one at a time to be the most effective. Although dietary restrictions are extremely helpful in some patients, they don't help every patient. But self-help techniques, whether diet or stress reduction or coping strategies, can help patients gain a sense of some control over their disease. The ICA's website (www.ichelp.org) is very helpful in this regard, and local support groups allow patients to share this kind of information.

With patients, I usually discuss the numerous agents that have been used for this illness and their potential benefits and side effects. Then, I ask patients to tell me which therapies they believe might best suit their needs. Most patients with early disease will opt for oral medications.

In a number of cases, however, multiple oral medications aren't enough. I still occasionally use DMSO, although this has become more expensive for patients, so I use it less frequently.

Other bladder instillations, such as lidocaine with bicarbonate and heparin, can be helpful. For some patients, repeated clinic visits for these instillations can be difficult, especially for those who have to commute long distances. So, for patients who get substantial benefit from this intravesical therapy and are willing to instill the solution themselves at home, I provide instructions and supply prescriptions.

Have you changed your approach to IC therapy in the last 5 to 10 years?

The most significant changes I have made are increasing the use of pelvic floor physical therapy, using sacral nerve root modulation, and continuing to participate in studying new therapies through the NIH.

There are several physical therapists in my town who are extremely skilled in treating patients with pelvic floor dysfunction and have been an outstanding resource in helping a number of my patients. For patients with frequency and urgency that haven't responded to other therapies, sacral nerve root modulation has been quite helpful. I was disappointed, as were many other urologists, with the results of the recent NIH-funded study of intravesical BCG and the results of an industry-sponsored study of resiniferatoxin. These did not provide relief to as many patients as we had hoped when compared to control or placebo therapy.

One of the reasons the results may not have been as good as they could have been was that patients in the studies had longstanding illness. Increasingly, researchers and clinicians in this field think therapy has a better chance of success if we diagnose and treat IC early. My colleagues and I here and at other study sites are continuing to recruit patients with early IC for an ICCRN study to compare a combination of diet, behavioral therapy, and Elavil with diet and behavioral therapy alone.

What research and treatments do you see as having potential in the future for IC?

Today, both the diagnosis and treatment of IC remain challenging. A future urine test for APF or possibly other biomarkers could be extremely helpful for determining whether bladder disease is present. Likely, earlier diagnosis and intervention will be helpful.

Studies of IC treatments often report disappointing results, but this should not detract from the benefit for those who did respond. Whether the poor response rates are related to delays in diagnosis and treatment or to individual intrinsic differences in the disease is unknown. The substantial variability in therapeutic response to a wide variety of agents suggests that IC should be viewed as a symptom complex rather than as a disease with a single, uniform cause.

That is why we need further research so we can better predict the best therapy for a specific patient. That will likely depend on research on the basic science of IC and bladder function. In recent years, researchers have found that the lining of the bladder is much more complex than we thought. The cells can communicate with one another and with the nervous system. I believe that, in the future, these findings will result in substantial improvements in the diagnosis and treatment of IC.

IC Clinical Trials Update

Phase II, multicenter, randomized, double blind, placebo controlled pilot study to determine proof of efficacy, safety, tolerability, and pharmacokinetics of intravesical PSD597 in the symptomatic management of interstitial cystitis/painful bladder syndrome (IC/PBS)

This study sponsored by Plethora Solutions will employ PSD597: 200 mg lidocaine (as 5 ml of 4% lidocaine solution) instilled into an empty bladder followed by 5 ml of 8.4% sodium bicarbonate (alkalinizing agent).

Local anesthetics such as lidocaine are increasingly recognized as having powerful broad-spectrum anti-inflammatory effects, including stabilizing mast cells and blocking histamine release. Theoretically they appear to be ideally suited to suppress the neuroinflammatory cycle occurring in IC/PBS.

For a study sites call: 816-421-6400 ext. 2208. For more information about this study, please visit:
www.controlled-trials.com/ISRCTN56132730

Interstitial Cystitis-A Study to Evaluate the Effectiveness of Acupuncture on Symptoms

Principal Investigator: Larissa Rodríguez, MD
Co-Investigator(s): Shlomo Raz, MD

For more information including an online study application, please visit: www.uclaurology.com/trials/Inter65.cfm

Genetic Study of Painful Bladder Syndrome/Hypersensitive Bladder

At Children's Hospital Boston, the Harvard Urological Diseases Research Center is conducting a research study on the genetic causes of painful bladder syndrome, interstitial cystitis, hypersensitive bladder and chronic pelvic pain syndrome (PBS/IC/HBS/ CPPS).

For more information please contact:

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The Latest Published IC Research

Saban R, D'Andrea MR, Andrade-Gordon P, Derian CK, Dozmorov I, Ihnat MA, Hurst RE, Davis CA, Simpson C, Saban MR. Mandatory role of proteinase-activated receptor 1 in experimental bladder inflammation. *BMC Physiol.* 2007 Mar 30;7(1):4

Macdiarmid SA, Sand PK. Diagnosis of interstitial cystitis/painful bladder syndrome in patients with overactive bladder symptoms. *Rev Urol.* 2007 Winter;9(1):9-16.

Iavazzo C, Athanasiou S, Pitsouni E, Falagas ME. Hyaluronic Acid: An Effective Alternative Treatment of Interstitial Cystitis, Recurrent Urinary Tract Infections, and Hemorrhagic Cystitis? *Eur Urol.* 2007 Mar 20.

McKinlay JB, Link CL. Measuring the Urologic Iceberg: Design and Implementation of The Boston Area Community Health (BACH) Survey. *Eur Urol.* 2007 Mar 19.

Parsons CL, Rajasekaran M, Arsanjani AH, Chenoweth M, Stein P. Role of sialic acid in urinary cytoprotective activity of Tamm-Horsfall protein. *Urology.* 2007 Mar;69(3):577-81.

Steinberg AC, Oyama IA, Whitmore KE. Bilateral S3 stimulator in patients with interstitial cystitis. *Urology.* 2007. Mar;69(3):441-3.

Hanno P. Toward optimal health: Philip Hanno, M.D., M.P.H., discusses improved management of painful bladder syndrome (interstitial cystitis). Interview by Jodi R. Godfrey. *J Womens Health (Larchmt).* 2007 Jan-Feb;16(1):3-8.

Boucher W, Kempuraj D, Cao J, Papaliadis D, Theoharides TC. Intravesical suplatast tosilate (IPD-1151T) inhibits experimental bladder inflammation. *J Urol.* 2007 Mar;177(3):1186-90.

Fenton BW. Limbic associated pelvic pain: A hypothesis to explain the diagnostic relationships and features of patients with chronic pelvic pain. *Med Hypotheses.* 2007 Feb 8.

Bordman R, Jackson B. Below the belt: approach to chronic pelvic pain. *Can Fam Physician.* 2006 Dec;52(12):1556-62.

Sinha D, Karri K, Arunkalaivanan AS. Applications of Botulinum toxin in urogynaecology. Eur J Obstet Gynecol Reprod Biol. 2007 Feb 1.

Diggs C, Meyer WA, Langenberg P, Greenberg P, Horne L, Warren JW. Assessing urgency in interstitial cystitis/painful bladder syndrome. Urology. 2007 Feb;69(2):210-4.

Takahashi S, Yanase M, Inoue R, Ichihara K, Masumori N, Tsukamoto T, Igawa Y, Nishizawa O. [Intravesical instillation of resiniferatoxin for the patients with interstitial cystitis] Hinyokika Kyo. 2006 Dec;52(12):911-3. Japanese.

Erickson DR, Kunselman AR, Bentley CM, Peters KM, Rovner ES, Demers LM, Wheeler MA, Keay SK. Changes in urine markers and symptoms after bladder distention for interstitial cystitis. J Urol. 2007 Feb;177(2):556-60.

van Ophoven A, Hertle L. The dual serotonin and noradrenaline reuptake inhibitor duloxetine for the treatment of interstitial cystitis: results of an observational study. J Urol. 2007 Feb;177(2):552-5.

Bogart LM, Berry SH, Clemens JQ. Symptoms of interstitial cystitis, painful bladder syndrome and similar diseases in women: a systematic review. J Urol. 2007 Feb;177(2):450-6. Review.

Mayer R. Interstitial cystitis pathogenesis and treatment. Curr Opin Infect Dis. 2007 Feb;20(1):77-82.

Peng CH, Kuo HC. Multiple intravesical instillations of low-dose resiniferatoxin in the treatment of refractory interstitial cystitis. Urol Int. 2007;78(1):78-81.

Nordling J. Sensory bladder disorders. Int J Clin Pract Suppl. 2006 Dec;(151):38-42.

Zabihi N, Allee T, Maher MG, Mourtzinou A, Raz S, Payne CK, Rodriguez LV. Bladder

necrosis following hydrodistention in patients with interstitial cystitis. J Urol. 2007 Jan;177(1):149-52; discussion 152.

Leiby BE, Landis JR, Propert KJ, Tomaszewski JE; Interstitial Cystitis Data Base Study Group. Discovery of morphological subgroups that correlate with severity of symptoms in interstitial cystitis: a proposed biopsy classification system. J Urol. 2007 Jan;177(1):142-8.

Erickson DR, Propert KJ. Pregnancy and interstitial cystitis/painful bladder syndrome. Urol Clin North Am. 2007 Feb;34(1):61-9. Review.

Yang Y, Kang J, Mao K, Zhang J. Regression models for mixed Poisson and continuous longitudinal data. Stat Med. 2006 Nov 29.

Inoue R, Takahashi S, Sunaoshi K, Ichihara K, Masumori N, Tsukamoto T. [Hydrodistention of the bladder in patients with interstitial cystitis--clinical efficacy and its association with immunohistochemical findings for bladder tissues] Hinyokika Kyo. 2006 Oct;52(10):765-8. Japanese.

Roth TM. Interstitial cystitis in a woman with systemic mastocytosis. Int Urogynecol J Pelvic Floor Dysfunct. 2006 Nov 24.

Schmitz-Drager BJ, Beiche B, Tirsar LA, Schmitz-Drager C, Bismarck E, Ebert T. Immunocytology in the Assessment of Patients with Asymptomatic Microhaematuria. Eur Urol. 2006 Nov 2.

Sohn MW, Zhang H, Taylor BC, Fischer MJ, Yano EM, Saigal C, Wilt TJ; Urologic Diseases in America Project. Prevalence and trends of selected urologic conditions for VA healthcare users. BMC Urol. 2006 Nov 3;6:30.

Peters KM, Carrico DJ. Frequency, urgency, and pelvic pain: treating the pelvic floor versus the epithelium. Curr Urol Rep. 2006 Nov;7(6):450-5. Review.

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