



ICA Professional Perspectives

Spring 2006

A Newsletter for Healthcare Professionals

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

The Interstitial Cystitis Association / Patients, Researchers, Caregivers ~ *Putting the Pieces Together*

NIDDK International PBS/IC Symposium Dates Announced

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) recently announced that its international conference, *Frontiers in Painful Bladder Syndrome and Interstitial Cystitis Symposium 2006* will be held in the fall of 2006.

- ◆ **Date:** Thursday, October 26 - Friday, October 27, 2006
- ◆ **Location:** Bethesda Marriott (Pooks Hill) in Bethesda, Maryland, just outside of downtown Washington, DC

Don't miss this outstanding opportunity to hear presentations about the latest IC research developments, network, and meet others working in IC research and clinical practice. An unmoderated poster session is being planned.



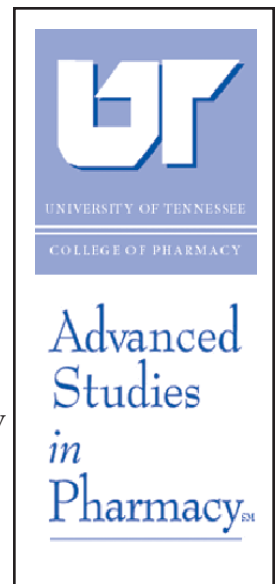
The ICA's **12th National Meeting** will be held at the same location following the NIDDK's Symposium and will take place on the following dates:

- ◆ Opening Reception: Friday, October 27 (evening)
- ◆ Day-long presentations and break-out sessions: Saturday, October 28
- ◆ Half-day "Grand Rounds" featuring group sessions with top IC experts: Sunday, October 29

Watch for more information coming this summer about both of these meetings at www.ichelp.org.

Pharmacists Receive IC Education Through Online CME Course

Advanced Studies in Pharmacy at the University of Tennessee has developed an educational program on IC for community pharmacists entitled *Is It Really Another UTI: Interstitial Cystitis and the Pharmacist's Role in Identifying the Patient At Risk* that has been very well received. The program resides at www.utasip.com (click on CPE Programs and then Urology), is fully accredited by the Accreditation Council for Pharmacy Education (ACPE), and is free to access.



The program features three in-depth, up-to-date articles by three IC educators: Jeffrey R. Dell, MD, Director, Institute for Female Pelvic Medicine, Knoxville, Tennessee; Robert J. Evans, MD, The Urology Center, Greensboro, North Carolina; and Mary Lee, PharmD, BCPS, FCCP, Dean and Professor Midwestern University Chicago College of Pharmacy, Downers Grove, Illinois.

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IC Research Has Momentum, 2006 AUA Annual Meeting Shows



The numerous posters, presentations, and courses on IC at the annual meeting of the American Urological Association (AUA) in Atlanta shows that IC is now a top clinical concern and a hot research topic in urology. So many sessions include basic research and clinical studies on what's now being termed painful bladder syndrome (PBS)/IC that it's impossible to take them all – at least 30 studies – in. The research being presented in those sessions is pointing to new oral drugs, bladder therapies, and neuromodulation techniques on the horizon and is challenging some current concepts in the field.

So much new and important research on PBS/IC is being presented at this meeting that the AUA is holding a briefing on it for the press. That briefing is being chaired by PBS/IC researcher and advocate Kristene Whitmore, MD. Because urologists, too, want to hear about the highlights of this plentiful research, Robert Moldwin, MD, will be putting it in perspective for them in a review the following morning. In addition, urologists have two opportunities to take courses on IC/PBS to learn about the latest advances and approaches to treatment from well-versed experts.

Similar to research presented last year, studies on the prevalence of PBS/IC show that it is more common than many have thought. But, in addition, the research shows that PBS/IC doesn't discriminate – there is no difference in prevalence among ethnic groups. The data also show that IC is still under-diagnosed because a careful survey asking about symptoms shows that there are more people who likely have PBS/IC than in studies based on doctors' diagnoses.

Following up on the studies showing that PBS/IC patients shoulder a heavy financial burden is more research showing how high that cost is – two to three times more in medical expenses than the average person without PBS/IC – and that the higher medical costs are mainly because of pharmacy expenses and doctor visits. That highlights the tremendous need for truly effective treatment.

Many of the potential new therapies target pain. IP 751, a relative of marijuana that eases pain without any "high" is in human trials for neuropathic pain, but animal studies are still being done to learn how to use this drug for PBS/IC. The latest studies being presented here have a new twist. Dr. Michael Chancellor's research shows how a therapy could be delivered in a new way. It's being packaged in tiny liposomes and instilled into the bladder. But even the

instilled liposomes by themselves, researchers are finding, can calm down bladder spasms. Also in early stages of research are: a formulation of St. John's Wort, a relative of vitamin D, and a sodium channel blocker and an ATP-sensitive potassium channel opener that target pathways involved in bladder overactivity and pain.

Two potential immune system approaches are also being talked about at the meeting. They both target cytokines, chemicals involved in the inflammatory process. Right now, those ideas are at the laboratory stage but could lead to drugs that block urinary tract inflammation or prevent damage to the bladder lining. New approaches to neuromodulation are also being researched, especially stimulation of the pudendal nerve. That approach may actually increase bladder capacity and may also help relieve symptoms, even if sacral nerve stimulation has failed.

Another potential treatment for both pain and urinary symptoms in IC is hyperbaric oxygen. IC researcher Arndt van Ophoven, MD, and his colleagues in Germany started research on this treatment in a pilot study funded by a Fishbein Family IC Research Foundation grant, and now they have put the treatment to a more rigorous test with encouraging results.

The idea that IC patients' bladders are more permeable or "leaky" than normal bladders has prevailed for a long time, with treatments and research based on that premise. But now, research being presented here is challenging that idea, even indicating that IC bladders are less leaky than normal bladders. That's a matter of debate, but the idea could lead researchers to more fruitful treatment approaches.

Some have doubted that certain foods and beverages can produce symptoms for PBS/IC patients because no published research has supported that conclusion, and some research has even called it into doubt. But now, for the first time at an AUA meeting, researchers are showing that food and drink do affect symptoms for a significant share of PBS/IC patients.

A medical anthropologist is also detailing the devastating effect IC can have on women's and men's sexual lives, bringing much needed attention to that problem and highlighting the need for pain management and other therapies that can improve this important aspect of patients' lives.

All of these studies and all of this awareness should produce results for patients. First, this professional focus on PBS/IC shows that the days are gone when anyone can doubt that the problem is real and that doctors need to treat pain more effectively and help patients improve their quality of life. In addition, new, more effective treatments are in closer view and should become available for patients in the not-too-distant future.

New Webcast Presenting Information on Interstitial Cystitis and Painful Bladder Syndromes

The Center of Urology Research Excellence-Interstitial Cystitis(CURE-IC) at the University of Pittsburgh has published a webcast entitled *Awareness and Hope for Interstitial Cystitis*, targeted to people experiencing painful bladder symptoms including IC. This webcast discusses treatments, symptom management, and research directions for IC and other painful bladder symptoms while helping to raise awareness of these conditions. The ICA joined the University of Pittsburgh to promote the webcast.

Leading experts present the latest research findings and disease management techniques in a user-friendly format including Michael Chancellor, MD, Professor of Urology, University of Pittsburgh Medical Center and Director of CURE-IC and Vicki Ratner, MD, Founder and President of the ICA. Additional presenters include Colleen Dunwoody, MS, RN, Past President of the American Society of Pain Management Nurses, and current member of the Board of Directors of the American Chronic Pain Association, Susan George, MS, PT, Director Women's Rehab, Center for Rehab Services, and Margie O'Leary, MSN, RN, Director of Research and Education in the Department of Neuro-Urology at the University of Pittsburgh.

Awareness and Hope for Interstitial Cystitis can be viewed by logging on to the following address:
<http://mediasite.cidde.pitt.edu>

Once you are on the site, look to the left-hand side to see listed webcasts and click on *Awareness and Hope for IC*. No log-in information is required. The entire program will take approximately 40 minutes to view. Each section may be viewed individually. The webcast was launched on April 1, 2006 and will remain posted on the website through June 2006.

Healthy Body, Healthy Mind Airing on PBS Network

The series *Healthy Body, Healthy Mind*, on the PBS network, includes a segment on IC being aired this spring in selected areas across the country. The segment was produced by the Information Television Network (ITV).

The show features interviews with ICA Founder and President, Vicki Ratner, MD; ICA Medical Advisory Board member, Robert Moldwin, MD; C. Lowell Parsons, MD; Matt Rosenberg, MD; actress Melody Thomas Scott (*The Young and the Restless*); and Interstitial Cystitis Network Medical Publishing Company Founder Jill Osborne. The *Healthy Body Healthy Mind* show is hosted by Dr. Perry Krichmar. To view this program go to: www.itvisus.com and click on *Healthy Body, Healthy Mind*.

UroToday Provides Quick Access to the Latest IC Research

www.UroToday.com is a website developed by world-class leaders in the field of urology who are committed to delivering translational science into the realities of medical practice. According to their site, their vision is to create a quality, global online publication providing accurate and timely education that is clinically relevant in the practice of urology. UroToday's goal is to provide unique, original content written by global urology key opinion leaders actively engaged in clinical practice.

ICA Medical Advisory Board Co-chairs Alan Wein, MD and Philip Hanno, MD, MPH, are playing major roles in ensuring that the latest in IC research news is included on the site. Dr. Wein is on UroToday's Editorial Board and Dr. Hanno is a Contributing Editor whose synopses of recent urological research are often featured on the site.

Here are headlines of some of UroToday's latest IC research summaries:

Do Symptoms Correlate With Cystoscopic Findings In Newly Diagnosed PBS/IC?

In patients with untreated and newly diagnosed PBS/IC, can one find a correlation between symptoms and cystoscopic findings?

Saccharide Complexes Improve Binding Of Pentosanpolysulfate and Heparin To Bladder Epithelium

Modifying pentosanpolysulphate (PPS) and heparin with saccharide complexes enhances both medications' ability to bind to human or rabbit bladder epithelium.

IC Average Cost In First Year After Diagnosis \$3000 Or More
Wu and colleagues studied data for patients under age 65 with at least one diagnosis of IC from a de-identified administrative database of 2 million beneficiaries that included medical, drug and disability claims for 1999-2002.

DMSO Still Worthwhile Treatment For PBS/IC

Ever since Bruce Stewart popularized the use of intravesical dimethylsulfoxide (DMSO) for the treatment of PBS/IC 40 years ago, it has been a valuable tool for healthcare providers treating this frustrating condition.

To view *UroToday's* entire IC section, please visit www.urotoday.com



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.

Urology Times Focuses on Chronic Pelvic Pain

Urology Times has outdone itself again with a spectacular March 1, 2006, issue that covers in detail the shift in thinking regarding the origins and treatments, in particular treatment with opioid pain medication, of painful bladder syndromes such as IC and chronic prostatitis.

The articles, based on the recent NIDDK-sponsored Chronic Pelvic Pain/Chronic Prostatitis Scientific Workshop held in Baltimore, Maryland, tackle all sides of the debate regarding chronic pelvic pain including the differences between acute and chronic pain, the origin(s) of chronic pain, and visceral pain versus neuropathic pain.

All of the following articles are available online, free-of-charge (no registration is required). Simply type in the title of the article in the search box located on the *Urology Times* site (www.urologytimes.com) or click on the March 1 issue on the site.

- ◆ Chronic pain: It's time to think outside the box
- ◆ Clinicians urged to adopt new model of chronic pain
- ◆ Opiate use in nonmalignant pain: Not a simple dichotomy
- ◆ Genetics could explain chronic pelvic pain
- ◆ Data suggest sources of chronic, acute pain differ
- ◆ Neurophysiologic tests for CP/CPPS show promise
- ◆ New names for pelvic pain could advance treatments
- ◆ Psychological therapies may benefit CP/CPPS patients
- ◆ Pelvic pain shows range of effects on sexual function

All of these articles were written by freelance medical journalist Penny Allen, who is also the ICA's staff medical writer.

Pelvic Pain Pioneer Joins ICA Medical Advisory Board



Fred Howard, MD

The ICA welcomes Fred M. Howard, MD to its Medical Advisory Board. An internationally recognized expert on chronic pelvic pain in women, Dr. Howard is Associate Chair of Obstetrics and Gynecology, Director of the Division of Obstetric/Gynecologic Specialties, and Professor of Obstetrics and Gynecology at the University of Rochester Medical Center in Rochester, New York. He is an expert in endometriosis and laparoscopic surgery, but he also treats IC and started doing so at a time when few gynecologists recognized the disorder.

"I developed my intense interest while I was in private practice in Greenville, South Carolina, in the early 1980s," Dr. Howard told the ICA. "I quickly realized that, not only was my own knowledge inadequate to provide quality care to women with chronic pelvic pain, but also knowledge within

gynecology was inadequate. I started educating myself with everything I could find. Early researchers in pelvic pain who really influenced me were gynecologists John Slocumb, MD, Andrea Rapkin, MD, and John Steege, MD. Also, my patients provided amazing education for me as I expanded my interest in their pain and other disorders."

IC was part of Dr. Howard's focus on pelvic pain in women very early in his career. He explained why this way: "You just can't provide comprehensive care to women with chronic pelvic pain without learning about IC diagnosis and treatment. It is too common a condition in chronic pelvic pain."

His dedication to raising awareness of and finding the best treatments for pelvic pain in women led Dr. Howard, Paul Perry, MD, and Jim Carter, MD, to found the International Pelvic Pain Society in 1996. Dr. Howard has served on the society's board since it was founded, and served as president. This visionary society of pelvic pain experts began focusing on researching and treating pelvic pain at a time when many women found their problems were dismissed. With similar forward thinking, the society has now broadened its focus to include pelvic pain in men.

His research, writing, and awards testify to Dr. Howard's dedication and expertise in pelvic pain: He is senior editor of the textbook *Pelvic Pain: Diagnosis and Management*; the author of numerous scientific papers on pelvic pain, endometriosis, and laparoscopic surgery; and the winner of numerous honors and awards for excellence in teaching. We're grateful that Dr. Howard will be putting his knowledge, energies, and teaching skills to work for us.

The Latest IC Treatments in Development

There are several new IC therapies in development. From oral medications, bladder instillations and injections, to neuromodulation devices, companies are developing new products and clinical trials are underway.

Here are the latest developments in the IC treatment pipeline:

Oral Medications

Amitriptyline (Elavil)

Low doses of amitriptyline (Elavil—a tricyclic antidepressant) have been found to be a helpful treatment for IC pain and urinary frequency/urgency. This medication, one of the first tricyclic antidepressants ever developed (in the 1930s), has been used "off label" to treat IC for many years with just a handful of small studies that have indicated its value. It has unique properties that are unlike those of the newer antidepressants that are currently on the market, such as the selective serotonin reuptake inhibitors (SSRIs) and the selective norepinephrine reuptake inhibitors (SNRIs), as well as several other novel variations.

It was only recently that, for the first time ever, a double-blind, placebo-controlled study was conducted using amitriptyline to treat IC. This study from Germany used the medication to treat IC in 50 patients, and the study was reported on in the August 2004 issue of the *Journal of Urology* (van Ophoven et al).

Now, a new study is testing amitriptyline to confirm its potential to alleviate bladder pain for which there is no known cause and no uniformly effective therapy. Thousands, if not millions, of patients may benefit. The study is funded by the National Institutes of Health (NIH).

For more information:
www.niddk.nih.gov/patient/iccrn/iccrn.htm

MN-001

MediciNova, Inc. is conducting a national clinical trial to test a new medication for its potential use as a treatment for IC. The experimental medication, MN-001, has been shown in previous medical studies to be useful in treating the inflammatory response in asthma. Since IC is also thought to involve an inflammatory component, MediciNova is conducting a phase II (human study with 100-300 participants), randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of two dosing regimens of MN-001 in patients with interstitial cystitis.

For more information: www.bladderpainstudy.com OR
www.medicinova.com/mn001_ic.html

IP 751

Indevus is developing IP 751, a novel anti-inflammatory and analgesic compound for specialty disease states, including interstitial cystitis, with additional applications in the treatment of pain and inflammation. IP 751 is a non-psychoactive synthetic cannabinoid that appears to suppress inflammatory cytokines. The compound has significant activity in multiple pre-clinical models of pain and inflammation and, most recently, IC. Unlike most available NSAIDs, in pre-clinical studies IP 751 did not appear to produce gastrointestinal ulceration.

For more information: www.indevus.com

Suplatast tosilate

The oral drug, suplatast tosilate (Astellas), is already on the Japanese market and is indicated for asthma and allergies. Phase II trials for IC are planned for the United States.

This medication acts somewhat earlier in the allergic process than histamine or leukotriene blockers do by affecting IgE. Suplatast tosilate actually helps suppress the production of IgE. The drug also helps to block production of cytokines. In addition, suplatast tosilate suppresses allergy-related eosinophils.

For more information:
www.astellas.com/global/about/news/yamanouchi/03012

3.html

ERB-041

Wyeth is beginning testing of ERB-041, which is an orally active estrogen receptor beta agonist with potent anti-inflammatory activity. In addition to being studied as a potential IC therapy, it is also being studied for use in the treatment of endometriosis and rheumatoid arthritis. The ERB-041 IC study is a multicenter, randomized, double-blind, placebo-controlled, parallel-design, exploratory study of orally administered ERB-041 in subjects with active IC. The primary objectives of this study are to investigate ERB-041's activity on levels of urinary APF, explore the gene expression response in peripheral blood mononuclear cells (PBMC), and evaluate the safety of ERB-041 in women with active IC.

For more information:
www.clinicaltrials.gov/ct/gui/show/NCT00275379

Bladder Instillations

U101

Vancouver-based Urigen Inc. announced in October 2005 that the FDA has accepted the company's investigational new drug (IND) application to initiate a Phase IIb clinical trial with its lead product, U101. U101 is a proprietary intravesical formulation of FDA-approved components that has been demonstrated to provide near-immediate relief of symptoms associated with IC.

Urigen's Phase IIb clinical trial is a prospective, randomized, double-blind, placebo-controlled Phase II study of U101 in adult subjects with chronic pelvic pain and urgency of bladder origin. The objective of the study is to evaluate the safety and efficacy of U101 in a multicenter trial.

For more information: www.urigen.com

Bladder Injections

Botulinum Toxin Type A

Allergan's Botulinum toxin type A (BTX-A or Botox) is being used to treat many conditions of the bladder, including IC. BTX-A is thought to work by blocking the sensory nerves in the bladder that transmit pain, spasticity and inflammation. At this time BTX-A requires direct needle injections into the bladder.

While BTX-A is not FDA-approved for the treatment of IC, it is being used at various institutions throughout the United States as a potential IC treatment when other standard therapies have failed. The University of Washington is currently recruiting participants for a randomized, double-blind, placebo-controlled efficacy study of BTX-A.

For more information:
www.clinicaltrials.gov/ct/show/NCT00194610?order=1

New Frontier for ICA's National IC Awareness and Education Campaign

We've reached a very exciting and promising point in the ICA's National IC Awareness and Education Campaign. In partnership with the Centers for Disease Control and Prevention (CDC), our dedicated team has laid a foundation of thoughtful research, compelling findings, and broadening support. These efforts have positioned the ICA to execute an effective and meaningful campaign.

With input collected from current IC patients, undiagnosed urological patients and healthcare providers from across the country, we've been able to better understand how our campaign can help alleviate some common frustrations and best support these communities. We've determined what information means the most and will have the most impact in raising awareness and educating patients and providers.

Another critical source of information and guidance has been from our ICA Advisory Council (ICAAC). This group represents a cross-section of patients, healthcare providers, related organizations and foundations, government agencies, and ICA leadership. Our spring meeting yielded unprecedented commitments from our partners to disseminate our materials, educate their peers, provide additional research, and broaden our campaign's reach overall.

The ICAAC gave us added insight into our messages, ways to leverage what we have, and new outlets for getting the message out. We gained consensus on where to focus our efforts in both the patient and provider communities to get the most out of our investment in this important effort. One of the most powerful tools we have to educate people about IC is our website. With the research, feedback, and technical support in line, we'll have an even more dynamic, user-friendly, and content-rich website by late spring 2006. In the next year, the site will be enhanced to be more even more interactive and personalized for those visiting the site.

According to Dr. Vicki Ratner, "This is a phenomenal opportunity for the ICA to extend its educational reach to both healthcare professionals and people with IC, or people who suspect that they may have it. We are exploring every avenue to ensure the broadest possible IC educational outreach."

With the foundation laid and the unwavering commitment of our team and partners, we are equipped to begin the next phase in this journey toward the launch of the campaign. In the next phase, we will be developing new materials, including conference and media outreach materials and updates to our existing materials. We will then proactively and aggressively place our materials through various outlets, including magazines, journals, conferences, partners, radio, and television when possible.

Electrostimulation/Neuromodulation

MiniatURO I Implantable System

A new form of neuromodulation, the MiniatURO I Implantable System (BioControl Medical), is being tested throughout Europe and other parts of the world for use in several bladder conditions including overactive bladder, incontinence, and IC. It is currently undergoing trials for female patients suffering from pelvic pain and/or urinary frequency associated with IC. The MiniatURO I is a minimally invasive implantable device for patients who have failed to respond to conservative treatment.

Urgent PC Neuromodulation System

In October, the FDA approved pre-market clearance of Uroplasty's Urgent PC Neuromodulation System [formerly known as the Stoller Afferent Nerve Stimulator (SANS) and as Post-Tibial Nerve Stimulation (PTNS)]. Urgent PC is a minimally invasive nerve stimulator designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency with or without pain. Uroplasty is planning to market the device in the United States, Europe, and Canada by the end of 2005.

Through the use of a very thin needle placed in the ankle/tibia region, Urgent PC delivers low frequency electrical stimulation (neuromodulation). This process is thought to recondition the misfiring nerves that affect bladder function. The tibial nerve carries the signal to the portion of the spine that controls bladder function.

For more information: www.uroplasty.com

Bion

Bion (Advanced Bionics Corporation) is an implantable matchstick-size device that calms overactive bladder by stimulating the pudendal nerve. This nerve carries sensations from the sacral nerves to external genitals and the lower rectum.

Currently, clinical trials are underway to study the use of the Bion device for overactive bladder and incontinence. Though not yet FDA-approved for use in IC, some researchers and clinicians are hopeful that Bion will also be effective in the treatment of IC.

For more information: www.advancedbionics.com

In addition, the team will produce toolkits for the Ambassador Program, which could include brochures, posters, testimonials, fact sheets, referral response cards, tabletop displays, and other point-of-care awareness materials. The Ambassador Program will identify specific individuals and organizations that can advocate on behalf of the awareness campaign and further spread our message.

We look forward to continuing our partnership with the Centers for Disease Control and Prevention to launch the nation's first IC Awareness and Education campaign. Stay tuned for more updates in the coming issues.

The Latest Published IC Research

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*The ICA does not engage in the practice of medicine.
It is not a medical authority nor does it claim to have
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