Outcome of the
Washington, DC, Consensus Meeting on
Interstitial Cystitis/
Painful Bladder Syndrome:

A Multidisciplinary Meeting of Researchers,
Clinicians, and Patients

Washington, DC
Consensus Group on IC/PBS
February 10, 2007
Abstract

A multidisciplinary and multispecialty group convened in Washington, DC, on February 10, 2007 to discuss current issues in Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS) and to develop majority statements. The group successfully developed majority statements concerning the definition and nomenclature of the condition (defined below) and agreed on the need for both updated diagnostic criteria for the research setting and the development of diagnostic criteria for the clinical arena. 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.
Introduction

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. (See Appendix for Participant List.) 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 (ICA), a national education and patient advocacy group dedicated exclusively to IC/PBS.

The meeting was led by a professional facilitator who worked with the sponsoring organizations to develop the meeting agenda and predefined goals and objectives. For the meeting itself, the facilitator used a non-traditional customized meeting format well suited for discussion of potentially contentious topics. It included five rounds of conversations between six to seven participants with individuals changing groups for most rounds.

The meeting was designed to allow for a high degree of interaction between participants, with conversations focused on engaging in dialogue—rather than defending a predetermined opinion—around the questions to be addressed. ARHP and ICA staff recorded key comments and overall conclusions from the small group sessions. The entire group of participants then convened to develop majority statements based on the group discussions and to identify areas requiring future research.

Problem Statement

Impact of IC/PBS

Interstitial cystitis/painful bladder syndrome (IC/PBS) is a chronic debilitating condition characterized by pelvic pain, urinary urgency, and urinary frequency. Experts estimate that the condition affects from 700,000 to one million individuals in the United States, the vast majority of whom are women. However, these figures may significantly underestimate the true prevalence of the condition, because of the lack of diagnostic criteria appropriate for use in the clinical setting. Use of the strict diagnostic criteria developed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for the research setting has been shown to miss 60 percent of cases deemed by researchers to definitely or likely represent IC/PBS.
Patients with IC/PBS suffer from a “silent affliction,” often appearing healthy but experiencing unrelenting pain that requires frequent trips to the bathroom. They may curtail activities due to extreme urinary frequency, both day and night. Sleep deprivation can lead to fatigue and depression. Many are unable to work. Research has shown that patients with IC/PBS score lower on quality of life measures than patients with end-stage renal disease undergoing hemodialysis. In addition to the personal toll IC/PBS exacts, the condition is associated with significant health care costs. It has been estimated that the direct annual costs attributable to IC/PBS in the United States totaled $428 million in 1987. These costs are presumably much higher two decades later.

**Current Gaps in Knowledge**

IC/PBS is a clinical syndrome for which the definition, etiology, diagnosis, natural history, true prevalence, and most effective treatment(s) are uncertain. Indeed, experts in the field are undecided about even the optimal name for the disease. Exacerbating and underlying these gaps in knowledge is a very limited evidence base in the scientific literature regarding the diagnosis, epidemiology, and treatment of IC/PBS. The current gaps in knowledge of IC/PBS directly affect patient care: on average, patients experience a lag time of five to seven years before they receive a diagnosis of IC/PBS.

**Controversy over Nomenclature**

Recent years have been witness to controversy regarding the IC/PBS nomenclature. In March 2003 The International Consultation on Interstitial Cystitis Japan (ICICJ) recommended that the nomenclature for the condition be changed to interstitial cystitis/chronic pelvic pain syndrome (IC/CPPS) to provide a more expansive term. However, in October 2003 the NIDDK held an international scientific symposium on IC and the international researchers decided to change the name from IC to interstitial cystitis/painful bladder syndrome (IC/PBS).

In September 2004, the Multinational Interstitial Cystitis Association facilitated a conference in Rome. The group recommended use of the term “painful bladder syndrome/interstitial cystitis,” to provide nomenclature inclusive of patients without the cystoscopic and histologic features typical of interstitial cystitis. More recently, at the NIDDK Scientific Symposium in October 2006, members of the European Society for the Study of IC/PBS (ESSIC) reported on an earlier meeting at which they agreed to use the name bladder pain syndrome (BPS) without reference to interstitial cystitis. In addition, the group proposed diagnostic criteria based on the results of biopsy and cystoscopy with hydrodistension. The ESSIC group consists of medical professionals with an interest in IC/PBS research or treatment from a number of European countries.

Concerns have been raised by the ICA and other IC-oriented nonprofit organizations around the world about the validity and potential implications of these changes in nomenclature and diagnostic criteria. These concerns include the broadness of the term, the loss of name recognition by patients with the removal of the term “interstitial cystitis,” reliance of the diagnostic criteria on invasive testing not generally used in the US clinical setting, and problems with coding and reimbursement for medical insurance, disability coverage, and prescription medications, which may adversely affect patients. Based on these concerns, along with the known current gaps in knowledge, the ICA joined with ARHP to convene the Washington, DC, Consensus Meeting on Interstitial Cystitis/Painful Bladder Syndrome.
Output of Meeting

Exploratory Discussion

During the large group discussion, participants engaged in an animated discussion about the two key topics of the meeting: the basic definition of IC/PBS and whether a change in the nomenclature of IC/PBS is necessary. The group was able to develop statements to which the vast majority, if not all, participants agreed. Word choice and its implications were carefully considered during the development of these statements.

Majority Statements

1. Definition of IC/PBS

After considerable discussion, the majority of the meeting participants accepted the following as a definition for 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.

Meeting participants debated about the inclusion of the term “urinary frequency” alone and concluded that the addition of “persistent urge to void” helped to distinguish the symptoms of IC/PBS from those of overactive bladder (OAB). In addition, participants discussed whether the definition should specify that urinary frequency is precipitated by or associated with pelvic discomfort. The group decided against this addition based on input from patient members.

The large group also debated whether IC/PBS represents a systemic disease or is localized to the bladder. The group concurred that the condition sometimes appears to be initially localized to the bladder, later evolving into a systemic disease, but in other cases appears to be a systemic disease that affects the bladder. Participants agreed that there is currently a deficiency of evidence-based literature in this area.

Participants also agreed that the results of currently available diagnostic techniques—in particular cystoscopy with hydrodistention under general anesthesia—often do not correlate with the severity of IC/PBS symptoms.

2. Is a Nomenclature Change Needed?

After an in-depth discussion about changing the name of IC/PBS to bladder pain syndrome, the large group quickly arrived at a majority opinion:

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.

It was noted that a change in nomenclature could pose potentially adverse implications for billing and coding, disability insurance claims, pharmaceutical reimbursement, office visit reimbursement to both physician and patient, and name recognition. It also could have a major impact on comparative research.
studies worldwide. For these reasons, the group believes that if nomenclature is changed in the future, the term “interstitial cystitis” should be retained and positioned first.

In addition to the two main topics for consideration at the meeting, participants discussed the currently available diagnostic criteria for IC/PBS. The group agreed that the NIDDK diagnostic criteria, which were developed for research purposes but are used frequently for clinical diagnosis, need to be updated. Participants concluded that two sets of criteria are needed: one set of core criteria for NIDDK research trials and a second set for diagnosis in the clinical setting.

The participants agreed that the criteria should be updated by a multidisciplinary, international group that includes health care providers, researchers, and patients, but excludes participation of industry representatives.

**Identification of Potential Research Topics**

Participants of the Washington, DC, Consensus Meeting on Interstitial Cystitis/Painful Bladder Syndrome concluded the meeting with a discussion of key areas in the field that require additional research. The group identified the following areas:

- Normal voiding patterns, especially related to voiding frequency
- Natural history of IC/PBS
- Long-term (over 20 years) studies of women and men with pelvic pain and urgency symptoms
- Development and validation of the definition of IC/PBS
- Development and testing of supportive criteria for the diagnosis of IC/PBS
- Development of diagnostic criteria and randomized controlled trials using intravesical anesthetics
- Clinical studies evaluating the symptoms, clinical presentations, and physical examination findings of IC/PBS, with follow-up on outcomes
- Identifying new markers of disease, including imaging/CAT scan
- Human studies of IC/PBS using a homogeneous group (e.g., patients with Hunner’s ulcers)
- Development of a comprehensive registry and database of interventions to assess effectiveness
- Clinical studies investigating subgroups, especially regarding symptoms on presentation
- Studies that involve collaboration between researchers and clinicians
- Studies based on reliable tissue banks (blood, serum, etc.) from carefully characterized patients
- Epidemiological studies of co-morbid conditions
Future plans

The ICA and ARHP, along with the members of the Washington, DC, Consensus Meeting on IC/PBS, are planning a number of key action steps as a result of the meeting. The ICA is currently drafting a letter to be sent to NIDDK officials requesting consideration of the need for updated diagnostic criteria for the research setting. The NIDDK is currently planning an international definition meeting for late 2007.

Members of the consensus meeting agreed that a “Best Practices Guide for IC/PBS” for clinicians is sorely lacking and that such a guide should be created by experts in the field. Such a text would provide evidence-based guidance where available and qualitative expert opinion where the evidence base is lacking. ARHP, which has considerable experience in facilitation of expert consensus groups, offered to spearhead project development.

In addition, the ICA, in collaboration with ARHP and guided by an independent expert advisory committee, will develop an array of educational materials for the public and health care providers. These materials include a curriculum on IC/PBS to be utilized at live educational and web-based sessions, a clinical monograph, the Best Practices Guide mentioned above, and patient education brochures in English and Spanish.

Summary

In summary, a multidisciplinary and multispecialty group convened in Washington, DC, on February 10, 2007, to discuss current issues in IC/PBS and to develop majority statements. The group was successful in developing statements concerning the definition and nomenclature of the condition, as well as agreeing on the need for both updated diagnostic criteria for the research setting and the development of diagnostic criteria for the clinical arena.

**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.

The group identified an array of areas in IC/PBS in which future research is needed. Finally, the group has begun a number of action steps as a result of the consensus meeting.
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