



## Review – Pelvic Pain

# Diagnostic Criteria, Classification, and Nomenclature for Painful Bladder Syndrome/Interstitial Cystitis: An ESSIC Proposal

Joop P. van de Merwe<sup>a</sup>, Jørgen Nordling<sup>b,\*</sup>, Pierre Bouchelouche<sup>c</sup>, Kirsten Bouchelouche<sup>c</sup>, Mauro Cervigni<sup>d</sup>, L. Kurosch Daha<sup>e</sup>, Suzy Elneil<sup>f</sup>, Magnus Fall<sup>g</sup>, Gero Hohlbrugger<sup>h</sup>, Paul Irwin<sup>i</sup>, Svend Mortensen<sup>b</sup>, Arndt van Ophoven<sup>j</sup>, John L. Osborne<sup>k</sup>, Ralph Peeker<sup>g</sup>, Benedikte Richter<sup>b</sup>, Claus Riedl<sup>l</sup>, Jukka Sairanen<sup>m</sup>, Martina Tinzl<sup>n</sup>, Jean-Jacques Wyndaele<sup>o</sup>

<sup>a</sup>Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

<sup>b</sup>Herlev Hospital, University of Copenhagen, Herlev, Denmark

<sup>c</sup>Koege Hospital, University of Copenhagen, Copenhagen, Denmark

<sup>d</sup>S. Carlo-IDI Hospital, Rome, Italy

<sup>e</sup>Hospital Hietzing, Vienna, Austria

<sup>f</sup>National Hospital for Neurology and Neurosurgery, London, United Kingdom

<sup>g</sup>Sahlgrenska Academy, Göteborg University, Sweden

<sup>h</sup>University of Innsbruck, Innsbruck, Austria

<sup>i</sup>Leighton Hospital, Crewe, Cheshire, United Kingdom

<sup>j</sup>University of Münster, Münster, Germany

<sup>k</sup>University College Hospital London, United Kingdom

<sup>l</sup>Thermen Klinikum, Baden, Austria

<sup>m</sup>Helsinki University Hospital, Helsinki, Finland

<sup>n</sup>University Hospital Vienna, Vienna, Austria

<sup>o</sup>University of Antwerp, Antwerp, Belgium

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## Abstract

**Objectives:** Because the term “interstitial cystitis” (IC) has different meanings in different centers and different parts of the world, the European Society for the Study of Interstitial Cystitis (ESSIC) has worked to create a consensus on definitions, diagnosis, and classification in an attempt to overcome the lack of international agreement on various aspects of IC.

**Methods:** ESSIC has discussed definitions, diagnostic criteria, and disease classification in four meetings and extended e-mail correspondence.

\* Corresponding author. Department of Urology, Herlev Hospital, DK2730 Herlev, Denmark. Tel. +45 28493658; Fax: +45 44882860.

E-mail address: [jnordling@dadlnet.dk](mailto:jnordling@dadlnet.dk) (J. Nordling).

Confusable disease  
 Diagnostic criteria  
 Frequency  
 Hunner's ulcer  
 Interstitial cystitis  
 Pain  
 Painful bladder syndrome  
 Urgency

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**Results:** It was agreed to name the disease bladder pain syndrome (BPS). BPS would be diagnosed on the basis of chronic pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder accompanied by at least one other urinary symptom such as persistent urge to void or urinary frequency. Confusable diseases as the cause of the symptoms must be excluded. Classification of BPS types might be performed according to findings at cystoscopy with hydrodistention and morphologic findings in bladder biopsies. The presence of other organ symptoms as well as cognitive, behavioral, emotional, and sexual symptoms, should be addressed.

**Conclusions:** The name IC has become misleading and is replaced by BPS. This name is in line with recent nomenclature recommendations by the European Association of Urology and is based on the axial structure of the International Association for the Study of Pain classification. To facilitate the change of the name, ESSIC agreed to include IC in the overall term (BPS/IC) during this transition period.

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## 1. Introduction

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) formulated criteria for a diagnosis of interstitial cystitis (IC) in 1987 and 1988 [1,2]. These criteria were meant for scientific studies. They have worked well in a scientific setting, but were fulfilled by only one third of patients thought to have IC by experts [3]. The International Continence Society (ICS) defined the term “painful bladder syndrome” (PBS) as “the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and nighttime frequency, in the absence of proven urinary infection or other obvious pathology” [4]. The name IC is reserved for PBS with typical cystoscopic and histologic features. Logically IC should include some form of inflammation in the deeper layers of the bladder wall, whereas PBS should include pain in the region of the bladder. At the International Consultation on Interstitial Cystitis in Japan (ICICJ) in 2003, it became clear that the evaluation and diagnosis of patients differed enormously among centers in Europe, North America, and Japan [5] and that a new approach was urgently needed.

Criteria for a diagnosis are needed only if the target disease may be confused with other diseases (confusable diseases) because of overlapping features [6]. For a diagnosis, the target disease has to be recognized in a pool of confusable diseases in one of two ways: by recognition of the specific combination of features of the target disease or by exclusion of confusable diseases. For the diagnosis of bladder pain syndrome (BPS), the name we prefer

for PBS/IC (see below), both methods might be used because:

- Confusable diseases are more common than BPS, so recognition is mandatory because many can be treated.
- Failure to diagnose a confusable disease would automatically incorrectly yield a diagnosis of BPS.
- Patients may have a confusable disease plus BPS.

The diagnosis of BPS is thus made on the basis of exclusion of confusable diseases and confirmation by the recognition of the presence of the specific combination of symptoms and signs of BPS. If the main urinary symptoms are not explained by a single diagnosis (confusable disease or BPS), the presence of a second diagnosis is possible.

Symptoms and signs for use in diagnostic criteria do not need to be specific for the target disease. On the contrary, if a specific symptom or sign existed for the target disease, a diagnosis would only require the presence of the specific feature and diagnostic criteria would not be necessary.

## 2. Methods

The European Society for the Study of Interstitial Cystitis (ESSIC) held meetings in 2003 and 2004 (Copenhagen, Denmark) on standardization of medical history, physical examination, laboratory tests, symptoms evaluation, urodynamics, and the technique and classification of cystoscopic and histologic findings [7]. Briefly, glomerulations represent bleeding at cystoscopy with hydrodistention, with grade 2 being large submucosal bleeding (ecchymosis) and grade 3

diffuse global mucosal bleeding. Detrusor mastocytosis is defined as mast cell counts exceeding 28 mast cells/mm<sup>2</sup> [7]. At ESSIC meetings in 2005 in Baden and 2006 in London, the following approach to the diagnosis of BPS was discussed:

- Selection of patients who need further evaluation for the presence of BPS
- Exclusion of relevant confusable diseases as the main cause of urinary symptoms
- Classification of BPS

### 3. Results

#### 3.1. Name

Consensus was obtained that the name bladder pain syndrome (BPS) better complies with our present knowledge and current nomenclature of other pain syndromes than the name IC or PBS. Omitting the name “interstitial cystitis” might cause serious problems in different health systems by affecting reimbursement, possibility for patients to gain disability benefits, and so forth, and it was therefore decided that the name bladder pain syndrome/

interstitial cystitis (BPS/IC) could be used parallel with BPS for the time being.

#### 3.2. Selection of patients

It was agreed that BPS would be diagnosed on the basis of chronic (> 6 mo [8]) pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder accompanied by at least one other urinary symptom such as persistent urge to void or frequency. Confusable diseases as the cause of the symptoms must be excluded. Further documentation and classification of BPS might be performed according to findings at cystoscopy with hydrodistention and morphologic findings in bladder biopsies.

The presence of other organ symptoms as well as cognitive, behavioral, emotional, and sexual symptoms should be addressed.

#### 3.3. Confusable diseases

Diseases that were discussed and accepted as confusable diseases for BPS are listed in Table 1 with

**Table 1 – Confusable diseases for bladder pain syndrome**

| Confusable disease   | Excluded or diagnosed by <sup>a</sup>  |
|--|--|
| Carcinoma and carcinoma in situ                              | Cystoscopy and biopsy  |
| Infection with   |  |
| Common intestinal bacteria                                   | Routine bacterial culture  |
| <i>Chlamydia trachomatis</i> , <i>Ureaplasma urealyticum</i> | Special cultures   |
| <i>Mycoplasma hominis</i> , <i>Mycoplasma genitalium</i>     |  |
| <i>Corynebacterium urealyticum</i> , <i>Candida</i> species  |  |
| <i>Mycobacterium tuberculosis</i>                            | Dipstick; if “sterile” pyuria culture for <i>M. tuberculosis</i>             |
| Herpes simplex and human papilloma virus                     | Physical examination   |
| Radiation  | Medical history  |
| Chemotherapy, including immunotherapy with cyclophosphamide  | Medical history  |
| Anti-inflammatory therapy with tiaprofenic acid              | Medical history  |
| Bladder-neck obstruction and neurogenic outlet obstruction   | Uroflowmetry and ultrasound  |
| Bladder stone  | Imaging or cystoscopy  |
| Lower ureteric stone   | Medical history and/or hematuria: upper urinary tract imaging such CT or IVP |
| Urethral diverticulum  | Medical history and physical examination                                     |
| Urogenital prolapse  | Medical history and physical examination                                     |
| Endometriosis  | Medical history and physical examination                                     |
| Vaginal candidiasis  | Medical history and physical examination                                     |
| Cervical, uterine, and ovarian cancer                        | Physical examination   |
| Incomplete bladder emptying (retention)                      | Postvoid residual urine volume measured by ultrasound scanning               |
| Overactive bladder   | Medical history and urodynamics  |
| Prostate cancer  | Physical examination and PSA   |
| Benign prostatic obstruction                                 | Uroflowmetry and pressure-flow studies                                       |
| Chronic bacterial prostatitis                                | Medical history, physical examination, culture                               |
| Chronic non-bacterial prostatitis                            | Medical history, physical examination, culture                               |
| Pudendal nerve entrapment                                    | Medical history, physical examination, nerve block may prove diagnosis       |
| Pelvic floor muscle-related pain                             | Medical history, physical examination  |

CT = computed tomography; IVP = intravenous pyelogram; PSA = prostate-specific antigen.

<sup>a</sup> The diagnosis of a confusable disease does not necessarily exclude a diagnosis of BPS.

**Table 2 – Classification of types of bladder pain syndrome on the basis of findings at cystoscopy with hydrodistention and of biopsies**

|                       | Cystoscopy with hydrodistention |        |                             |                              |
|-----------------------|---------------------------------|--------|-----------------------------|------------------------------|
|                       | Not done                        | Normal | Glomerulations <sup>a</sup> | Hunner's lesion <sup>b</sup> |
| Biopsy                |                                 |        |                             |                              |
| Not done              | XX                              | 1X     | 2X                          | 3X                           |
| Normal                | XA                              | 1A     | 2A                          | 3A                           |
| Inconclusive          | XB                              | 1B     | 2B                          | 3B                           |
| Positive <sup>c</sup> | XC                              | 1C     | 2C                          | 3C                           |

<sup>a</sup> Cystoscopy: glomerulations grade 2–3.  
<sup>b</sup> With or without glomerulations.  
<sup>c</sup> Histology showing inflammatory infiltrates and/or detrusor mastocytosis and/or granulation tissue and/or intrafascicular fibrosis.

an indication on how they can be recognized or excluded.

### 3.4. Classification of BPS

Consensus was obtained that for the documentation of positive signs for the diagnosis of BPS, hydrodistention at cystoscopy was a prerequisite and if indicated a biopsy (to document histologic details of BPS). Cystoscopic features that were accepted as positive signs of BPS were glomerulations grade 2–3 or Hunner's lesions or both (see below). Biopsy findings that were accepted as positive signs of BPS were inflammatory infiltrates and/or granulation tissue and/or detrusor mastocytosis and/or intrafascicular fibrosis.

### 3.5. Hunner's lesion

Hunner's "ulcer" is not a chronic ulcer but rather a distinctive inflammatory lesion presenting a characteristic deep rupture through the mucosa and submucosa provoked by bladder distention. The word "ulcer" suggests that it can be seen at cystoscopy without hydrodistention. Consequently, the name Hunner's ulcer was replaced by Hunner's lesion. The following definition by Fall was accepted. "The Hunner's lesion typically presents as a circumscribed, reddened mucosal area with small vessels radiating towards a central scar, with a fibrin deposit or coagulum attached to this area. This site ruptures with increasing bladder distension, with petechial oozing of blood from the lesion and the mucosal margins in a waterfall manner. A rather typical, slightly bullous edema develops post-distension with varying peripheral extension."

### 3.6. Types of BPS

BPS shows large variations among patients in clinical presentation, complaints, quality of life, cystoscopic

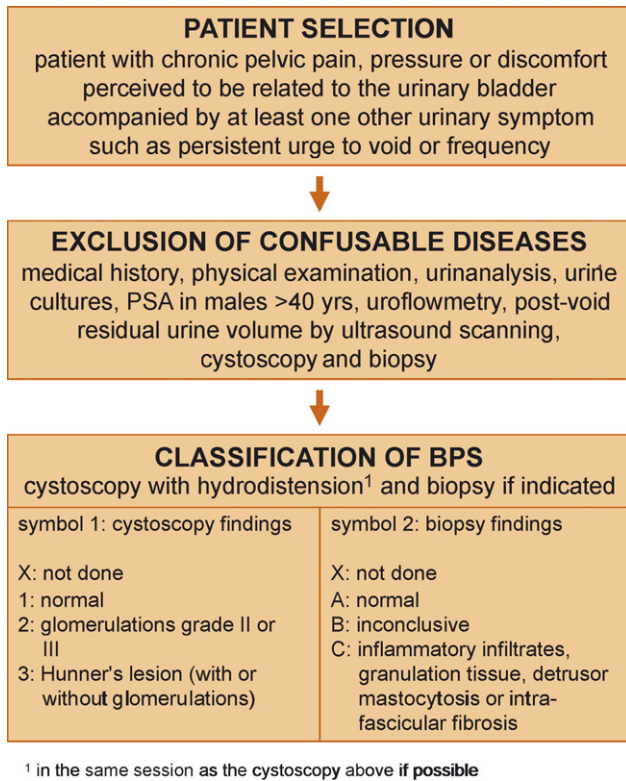
and biopsy findings, response to treatment, clinical course, and prognosis. It was generally appreciated that these characteristics may be correlated only to some extent. Diagnostic criteria and disease classification should facilitate future studies on these relationships. Consequently, types of BPS were defined based on findings used to document positive signs for the diagnosis of BPS. The name BPS will be followed by a type indication that consists of two symbols: symbols 1, 2, or 3 indicate findings at cystoscopy with hydrodistention and symbols A, B or C of biopsy findings. X indicates that no cystoscopy with hydrodistention (first symbol) or no biopsy (second symbol) was done (Table 2). BPS types thus also allow classification of patients with normal findings at cystoscopy with hydrodistention and normal biopsies as long as they fulfill the patient selection criteria and confusable diseases are excluded (BPS type 1A; Fig. 1 and Table 2).

## 4. Discussion

### 4.1. Why do we need new criteria?

The NIDDK criteria for the diagnosis of IC were intended for use in scientific studies. These criteria, however, do not recognize more than one third of patients considered to have IC by experts [3]. Patients under the age of 18 yr are excluded as are those with a bladder capacity of > 350 ml, thus making it difficult to study early stages of the disease. These considerations make the NIDDK criteria less useful in clinical situations and limit their value in scientific studies because the criteria only recognize a biased minority of the patient population. The need for the design of new diagnostic criteria is obvious. To avoid unacceptable discrepancies between scientific studies and clinical practice, it was considered essential that new diagnostic criteria could be used in both situations.





**Fig. 1 – Schematic representation of the proposed approach for the diagnosis of bladder pain syndrome (BPS).**

#### 4.2. Why is pain a prerequisite?

BPS is characterized by urinary bladder pain [9,10]. A recent study, however, demonstrated a correlation between pain bother in the IC problem index (burning, discomfort, pain, or pressure) and the presence of pain in the IC symptom index of only 0.7 [11]. This finding underscores that many patients report a sensation of pressure or discomfort in the bladder/pelvic area and do not report this sensation as pain but rather as urgency (see below). The International Association for the Study of Pain; ([www.iasp-pain.org](http://www.iasp-pain.org); [IASP]) definition of pain is: “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” [12]. Patients having microwave treatment for benign prostatic obstruction producing tissue damage at the bladder neck report the same sensation of pressure and discomfort in the bladder region [13–15]. The sensation is therefore by definition a pain sensation, but not described as such by the patient.

Pain or the equivalent pressure, discomfort perceived to be related to the bladder was, therefore, considered to be a prerequisite for the description of symptoms on the basis of which patients should undergo further investigations for BPS. The increase

of pain on bladder filling was left out of the description because this association is not always present [9,16,17].

#### 4.3. Why is urgency not included in the description of patients who need further evaluation for BPS?

Urgency is defined by the ICS as the complaint of a sudden compelling desire to pass urine, which is difficult to defer [4]. BPS is commonly mistaken for overactive bladder (OAB) because the term “urgency” is used to describe the symptoms of both disorders. For some women, urgency is used to indicate the heightened need to make it to a toilet quickly to avoid getting wet, whereas other women consider urgency to mean a need to void as a way of avoiding intensifying pain, pressure, or discomfort. The first group is most likely to have OAB, and the latter group can be expected to have BPS [9].

Urinary urgency was left out of the description of patients who need further evaluation for the presence of BPS for several reasons. First, urgency is the key symptom of OAB [10,17], a major confusable disease for BPS, that is 10 times more common than is BPS [9]. Second, the clinical aspects of urgency are complex [4,9,17–21]. At a meeting arranged by the Association of Reproductive Health Professionals ([www.arhp.org](http://www.arhp.org)) in the United States in February 2007 involving 33 urologists, gynecologists, and nurses it was proposed to use the term “persistent urge” instead of urgency to avoid confusion with OAB (pers. comm., P. Hanno, 2007). Many patients find the strong, uncomfortable urge to void the most dominant and disabling part of their symptomatology, so patients (and doctors) are often confused because, with the present terminology, a patient is not allowed to use the word urge to describe complaints. In the Oxford *Advanced Learner's Dictionary of Current English* urge is defined as “a strong desire,” whereas urgency is defined as “needing prompt decision or action” [22]. So the words urgency and urge describe very well the difference between the sensation felt by the patient with OAB and the patient with BPS. Persistent urge was therefore included in the definition as a typical symptom, such as frequency. It must be stressed that the presence of these symptoms is not necessary to suspect or diagnose BPS.

#### 4.4. Why should confusable diseases be excluded?

In evidence-based medicine, diagnoses are based on medical history, physical examination, and appropriate clinical investigations to eliminate diseases from the list of differential diagnoses (confusable

diseases) and to confirm the final diagnosis. BPS may occur together with confusable diseases such as chronic or remitting urinary infections or endometriosis. Cystoscopy with hydrodistention and biopsies might in this situation document positive signs of BPS thereby making a double diagnosis more probable. For therapeutic studies it makes sense to exclude patients who also have a confusable disease because symptoms and signs may be caused by BPS, the confusable disease, or by both. For prevalence studies of BPS, on the other hand, all cases with BPS should be included, also those with a confusable disease. This approach eliminates the need for separate diagnostic criteria for clinical practice and scientific studies.

#### 4.5. *Why do we need various BPS types?*

Unravelling the cause of a disease usually begins with grouping patients with similar symptoms and signs. The hypothesis is that these patients have a disease with the same etiopathogenesis that is better recognized in homogeneous than in heterogeneous groups. This has been the reason for dividing BPS patients into subgroups (types) based on positive signs. It is worth noting that the Hunner type of disease stands out as a specific type, not only cystoscopically but also with reference to histopathology, response to treatment, and complications [8,23].

#### 4.6. *Why do we propose to change the name of IC?*

Hanno recently stated that the term IC was not descriptive of the clinical syndrome or the pathologic findings in many cases. Moreover, the term IC is misleading because it directs attention only to the urinary bladder and inflammation [24]. The name IC excludes patients with typical IC symptoms but normal cystoscopic and histologic findings from disease classification in many countries around the world. The inability to classify these patients might have severe negative consequences for the patients, for example, in therapeutic, personal, social, and many other aspects. IC, originally considered a bladder disease, is now considered a chronic pain syndrome [25]. These perceptions have led to the current effort to reconsider the name of the disorder [8,24,26,27]. It is also the contention of the ESSIC that the existing terminology of IC hampers development in this area.

#### 4.7. *Why do we propose to choose BPS as the new name?*

For some time now there has been much work going on in international organizations to create a logical

and workable terminology for chronic (persistent) pain conditions. For background information we refer to the 2007 Guidelines on Chronic Pelvic Pain issued by the European Association of Urology (EAU) [8]. The EAU definitions are in line with recent recommendations for terminology from the ICS [4] and use the axial structure of the IASP classification [12]. This implies a taxonomy-like approach under the umbrella term of chronic pelvic pain syndrome. Further identification is based on the primary organ that appears to be affected on clinical grounds. Urologic pelvic pain syndromes are divided into bladder pain syndrome, urethral pain syndrome, penile pain syndrome, prostate pain syndrome, and others. More specific terminology is based on the identification of, for example, inflammation or infection [27,28]. The classification system of chronic pelvic pain syndromes aims to draw together the expertise of many specialist groups. The impact of the classification of chronic pelvic pain syndromes thus goes far beyond the scope of IC. Another essential feature is that the nomenclature and knowledge of pathophysiologic mechanisms do not conflict with each other. In this context, the name bladder pain syndrome was considered the best new name for IC to date, because the name is in line with the other chronic pelvic pain syndromes and is in balance with the clinical presentation of the syndrome and the level of knowledge of its pathophysiology.

We realize that changing the name of IC into BPS may have emotional implications, understandably for patients, but also for patient organizations with a scope limited to IC and for insurance and reimbursement in different health systems around the world. Considering these consequences, although BPS is the name of choice, ESSIC agrees that including IC in the overall term (BPS/IC) could be used in parallel to BPS during a transition period.

In this context, it is worth remembering that a subgroup of BPS patients (representing the Hunner type of disease) presents interstitial inflammation and is thus fulfilling the requirements of the original term of IC.

#### 4.8. *Next steps*

A worldwide evidence-based consensus is lacking on whether chronic pelvic pain perceived to be related to the bladder is a prerequisite for a diagnosis of BPS and on the value of cystoscopy with hydrodistention and biopsies for the management of patients with BPS. For this reason, ESSIC will start a prospective validation study in which

all patients with symptoms of pain and/or urgency and/or frequency not due to common bacterial urinary infections will be included. The diagnoses using ESSIC criteria will be validated in comparison with expert diagnoses ("gold standard") and diagnoses according to the NIDDK criteria. This will allow the evaluation of individual symptoms that warrant further evaluation for the presence of BPS and the relative contribution of the applied diagnostic procedures, including cystoscopy with hydrodistention and biopsy findings, to distinguish patients with BPS from those without BPS but one of the confusable diseases.

### Conflicts of interest

None of the authors has conflicts of interest in the publication of this paper.

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