Guideline Title

Diagnosis and treatment of interstitial cystitis/bladder pain syndrome.

Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


This guideline meets NGC’s 2013 (revised) inclusion criteria.

Scope

Disease/Condition(s)

Interstitial cystitis/bladder pain syndrome (IC/BPS)

Guideline Category

Diagnosis
Management
Treatment

Clinical Specialty

Family Practice
Internal Medicine
Obstetrics and Gynecology
Urology

Intended Users

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

Guideline Objective(s)

• To provide a clinical framework for the diagnosis and treatment of interstitial cystitis/bladder pain syndrome (IC/BPS)
• To provide direction to clinicians and patients regarding how to recognize IC/BPS; conduct a valid diagnostic process; and approach treatment with the goals of maximizing symptom control and patient quality of life while minimizing adverse events and patient burden

Target Population

Patients with interstitial cystitis/bladder pain syndrome (IC/BPS)

Interventions and Practices Considered

Diagnosis

1. Basic assessment, including history, physical examination and laboratory tests
2. Baseline voiding symptoms and pain levels
3. Cystoscopy and/or urodynamics (complex cases only)

Treatment/Management

1. Overall management
   • Use of conservative therapies first
   • Treatment according to symptom severity, clinician judgment, and patient preferences
   • Multiple, simultaneous treatments if appropriate
   • Pain management
   • Discontinuation of ineffective treatments
Methodology

Re-evaluation of interstitial cystitis/bladder pain syndrome (IC/BPS) diagnosis if symptoms do not improve

2. First-line treatments
   - Patient education
   - Self-care practices and behavior modification
   - Stress management

3. Second-line treatments
   - Manual physical therapy techniques
   - Multimodal pain management

   - Oral medications (amitriptyline, cimetidine, hydroxyzine, or pentosan polysulfate)
   - Intravesical treatments (dimethyl sulfoxide [DMSO], heparin, or lidocaine)

4. Third-line treatments
   - Cystoscopy under anesthesia with short-duration, low-pressure hydrodistension
   - Fulguration (with laser or electrocautery) and/or injection of triamcinolone

5. Fourth-line treatments
   - Intradetrusor botulinum toxin A (BTX-A)
   - Neurostimulation

6. Fifth-line treatment (cyclosporine A)

7. Sixth-line treatments (major surgery: substitution cystoplasty, urinary diversion with or without cystectomy)

Note: The following treatments were considered but not recommended: long-term oral antibiotic administration, intravesical instillation of bacillus Calmette-Guerin (BCG) (not recommended outside of investigational study settings), high-pressure/long-duration hydrodistension, systemic (oral) long-term glucocorticoid administration.

Major Outcomes Considered

- Sensitivity and specificity of case definitions for interstitial cystitis/bladder pain syndrome (IC/BPS)
- Patient-rated improvement in symptoms (e.g., ratings on the Interstitial Cystitis Symptom Index [ICSI] or Interstitial Cystitis Problem Index [ICPI], Visual Analog Scale [VAS] for pain, and global response assessment [GRA])
- Urodynamic and voiding parameters
- Patient quality of life
- Adverse events

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

A systematic review was conducted to identify published articles relevant to the diagnosis and treatment of interstitial cystitis/bladder pain syndrome (IC/BPS). Literature searches were performed on English-language publications using the MEDLINE database from January 1, 1983 to July 22, 2009 using the terms "interstitial cystitis," "painful bladder syndrome," "bladder pain syndrome," and "pelvic pain" as well as key words capturing the various diagnostic procedures and treatments known to be used for these syndromes. Studies published after July 22, 2009 were not included as part of the original evidence base considered by the Panel from which evidence-based guideline statements (Standards, Recommendations, Options) were derived. However, the guideline is regularly updated by additional systematic review searches conducted as part of the American Urological Association Education and Research, Inc. (AUA) update literature review process, and the evidence base is regularly updated based on the findings from the update reviews. Preclinical studies (e.g., animal models), pediatric studies, commentary, and editorials were eliminated. Review article references were checked to ensure inclusion of all possibly relevant studies. Studies using treatments not available in the US, herbal or supplement treatments, or studies that reported outcomes information collapsed across multiple interventions also were excluded. Studies on mixed patient groups (i.e., some patients did not have IC/BPS) were retained as long as more than 50% of patients were IC/BPS patients. Multiple reports on the same patient group were carefully examined to ensure inclusion of only nonredundant information. In a few cases, individual studies constituted the only report on a particular treatment. Because sample sizes in individual studies were small, single studies were not considered a sufficient and reliable evidence base from which to construct an evidence-based statement (i.e., a Standard, Recommendation, or Option). These studies were used to support Clinical Principles as appropriate.

The AUA update literature review process, in which an additional systematic review is conducted periodically to maintain guideline currency with newly-published relevant literature, was conducted in July 2013. This review identified an additional 31 articles relevant to treatment. These publications were used to create the majority of the treatment portion of the guideline.

Number of Source Documents

With regard to treatment, a total of 86 articles from the original literature search met the inclusion criteria; an additional 31 relevant studies were retrieved as part of the updated literature review process and also have been incorporated.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted randomized controlled trials (RCTs) or exceptionally strong observational studies

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies
Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data. Because treatment data for this condition are difficult to interpret in the absence of a placebo control, bodies of evidence comprised entirely of studies that lacked placebo control groups (i.e., observational studies) were assigned a strength rating of Grade C.

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) Treatment

With regard to treatment, a total of 86 articles from the original literature searches met the inclusion criteria; an additional 31 relevant studies were retrieved as part of the update literature review process and also have been incorporated. The Panel judged that these were a sufficient evidence base from which to construct the majority of the treatment portion of the algorithm. Data on study type (e.g., randomized controlled trial, randomized crossover trial, observational study), treatment parameters (e.g., dose, administration protocols, follow-up durations), patient characteristics (i.e., age, gender, symptom duration), adverse events (AEs), and primary outcomes (as defined by study authors) were extracted. The primary outcome measure for most studies was some form of patient-rated symptom scales, including the Interstitial Cystitis Symptom Index (ICSI) or Interstitial Cystitis Problem Index (ICPI), Visual Analog Score (VAS) scales, as available. In short supply are objective parameters and placebo controlled trials.

Quality of Individual Studies and Determination of Evidence Strength

Quality of individual studies that were randomized controlled trials (RCTs) or crossover trials was assessed using the Cochrane Risk of Bias tool. Because placebo effects are common in controlled trials conducted with IC/BPS patients, any apparent procedural deviations that could compromise the integrity of randomization or blinding resulted in a rating of increased risk of bias for that particular trial. Because there is no widely agreed upon quality assessment tool for observational studies, the quality of individual observational studies was not assessed.

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design, individual study quality, the consistency of findings across studies, the adequacy of sample sizes, and the generalizability of samples, settings, and treatments for the purposes of the guideline. See the "Rating Scheme for the Strength of the Evidence" field for evidence strength categories.

Limitations of the Literature

The Panel proceeded with full awareness of the limitations of the IC/BPS literature. These limitations include: poorly-defined patient groups or heterogeneous groups; small sample sizes; lack of placebo controls for many studies, resulting in a likely over-estimation of efficacy; short follow-up durations; and use of a variety of outcome measures. With regard to measures, even though the most consistently used measure was some form of patient-rated improvement scale, the scales differed across studies in anchor points, number of gradations, and descriptors. Overall, these difficulties resulted in limited utility for meta-analytic procedures. The single meta-analysis reported here was used to calculate an overall effect size for data from randomized trials that evaluated pentosan polysulfate (PPS). No comparative procedures were undertaken.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The original version of this Interstitial Cystitis/Bladder Pain Syndrome Guideline was created in 2011 by a Panel assembled by the Practice Guidelines Committee (PGC) of the American Urological Association Education and Research, Inc. (AUA). The amended Guideline was drafted in 2014 by the original Guideline Panel. This amendment updates the original guideline document to reflect literature released following the original publication.

The mission of the Panel was to develop clinical guideline recommendations based on an in-depth evidence report of the peer-reviewed literature. The recommendations are based on evidence strength, or where evidence is not available, on Delphi-modification consensus statements.

Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength and the Panel’s judgment regarding the balance between benefits and risks/burdens (see the “Rating Scheme for the Strength of the Recommendations” field).

Rating Scheme for the Strength of the Recommendations

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty and Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A (high quality; high certainty) or B (moderate quality; moderate certainty) evidence

Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C (low quality; low certainty) evidence

Option: Non-directive statement that leaves the decision regarding an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A (high quality; high certainty), B (moderate quality; moderate certainty), or C (low quality; low certainty) evidence.
quality; moderate certainty), or C (low quality; low certainty) evidence

**Clinical Principle**: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

**Expert Opinion**: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Cost Analysis
A cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The updated guideline was approved by the American Urological Association Education and Research, Inc. (AUA) Board of Directors in September 2014.

Recommendations

**Major Recommendations**

Definitions for the body of evidence strength (Grade A, B, or C), the strength of the recommendations (Standard, Recommendation, Option), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

**Diagnosis**

1. The basic assessment should include a careful history, physical examination, and laboratory examination to rule in symptoms that characterize interstitial cystitis/bladder pain syndrome (IC/BPS) and rule out other confusable disorders (see text in the original guideline document for details). ([Clinical Principle])
2. Baseline voiding symptoms and pain levels should be obtained in order to measure subsequent treatment effects. ([Clinical Principle])
3. Cystoscopy and/or urodynamics should be considered as an aid to diagnosis only for complex presentations; these tests are not necessary for making the diagnosis in uncomplicated presentations. ([Expert Opinion])

**Treatment**

**Overall Management**

4. Treatment strategies should proceed using more conservative therapies first, with less conservative therapies employed if symptom control is inadequate for acceptable quality of life; because of their irreversibility, surgical treatments (other than fulguration of Hunner’s lesions) are appropriate only after other treatment alternatives have been exhausted, or at any time in the rare instance when an end-stage small, fibrotic bladder has been confirmed and the patient’s quality of life suggests a positive risk-benefit ratio for major surgery. ([Clinical Principle])
5. Initial treatment type and level should depend on symptom severity, clinician judgment, and patient preferences; appropriate entry points into the treatment portion of the algorithm depend on these factors. ([Clinical Principle])
6. Multiple, simultaneous treatments may be considered if it is in the best interests of the patient; base-line symptom assessment and regular symptom level re-assessment are essential to document efficacy of single and combined treatments. ([Clinical Principle])
7. Ineffective treatments should be stopped once a clinically meaningful interval has elapsed. ([Clinical Principle])
8. Pain management should be continually assessed for effectiveness because of its importance to quality of life. If pain management is inadequate, then consideration should be given to a multidisciplinary approach and the patient referred appropriately. ([Clinical Principle])
9. The IC/BPS diagnosis should be reconsidered if no improvement occurs after multiple treatment approaches. ([Clinical Principle])

**Treatments That May Be Offered**

Treatments that may be offered are divided into first-, second-, third, fourth-, fifth-, and sixth-line groups based on the balance between potential benefits to the patient, potential severity of adverse events and the reversibility of the treatment. See the original guideline document for protocols, study details, and rationales.

**First-Line Treatments**

First-line treatments should be performed on all patients.

10. Patients should be educated about normal bladder function, what is known and not known about IC/BPS, the benefits vs. risks/burdens of the available treatment alternatives, the fact that no single treatment has been found effective for the majority of patients, and the fact that acceptable symptom control may require trials of multiple therapeutic options (including combination therapy) before it is achieved. ([Clinical Principle])
11. Self-care practices and behavioral modifications that can improve symptoms should be discussed and implemented as feasible. ([Clinical Principle])
12. Patients should be encouraged to implement stress management practices to improve coping techniques and manage stress-induced symptom exacerbations. ([Clinical Principle])

**Second-Line Treatments**

13. Appropriate manual physical therapy techniques (e.g., maneuvers that resolve pelvic, abdominal and/or hip muscular trigger points, lengthen muscle contractures, and release painful scars and other connective tissue restrictions), if appropriately trained clinicians are available, should be offered. Pelvic floor strengthening exercises (e.g., Kegel exercises) should be avoided. ([Clinical Principle])
14. Multimodal pain management approaches (e.g., pharmacological, stress management, manual therapy if available) should be initiated. (Expert Opinion)

15. Ameliorative, mitigate, hydromazene, or pentosan polysulfate may be administered as second-line oral medications (listed in alphabetical order; no hierarchy is implied). (Options; Evidence Strength - Grades B, B, C, and B)

16. Dimethyl sulfoxide (DMSO), heparin, or lidocaine may be administered as second-line intravesical treatments (listed in alphabetical order; no hierarchy is implied). (Options; Evidence Strength - Grades C, C, and B)

Third-Line Treatments

17. Cystoscopy under anesthesia with short-duration, low-pressure hydrodistension may be undertaken if first- and second-line treatments have not provided acceptable symptom control and quality of life or if the patient's presenting symptoms suggest a more-invasive approach is appropriate. (Option; Evidence Strength - Grade C)

18. If Hunner's lesions are present, then fulguration (with laser or electrosurgery) and/or injection of triamcinolone should be performed. (Recommendation; Evidence Strength - Grade C)

Fourth-Line Treatment

19. Intradetrusor botulinum toxin A (BTX-A) may be administered if other treatments have not provided adequate symptom control and quality of life or if the clinician and patient agree that symptoms require this approach. Patients must be willing to accept the possibility that post-treatment intermittent self-catheterization may be necessary. (Option; Evidence Strength - Grade C)

20. A trial of neurostimulation may be performed and, if successful, implantation of permanent neurostimulation devices may be undertaken if other treatments have not provided adequate symptom control and quality of life or if the clinician and patient agree that symptoms require this approach. (Option; Evidence Strength - Grade C)

Fifth-Line Treatment

21. Cyclosporine A may be administered as an oral medication if other treatments have not provided adequate symptom control and quality of life or if the clinician and patient agree that symptoms require this approach. (Option; Evidence Strength - Grade C)

Sixth-Line Treatment

22. Major surgery (e.g., substitution cystoplasty, urinary diversion with or without cystectomy) may be undertaken in carefully selected patients for whom all other therapies have failed to provide adequate symptom control and quality of life (see caveat above in guideline statement #9). (Option; Evidence Strength - Grade C)

Treatments That Should Not Be Offered

The treatments below appear to lack efficacy and/or appear to be accompanied by unacceptable adverse event profiles. See the original guideline document for study details and rationales.

23. Long-term oral antibiotic administration should not be offered. (Standard; Evidence Strength - Grade B)

24. Intravesical instillation of bacillus Calmette-Guerin (BCG) should not be offered outside of investigational study settings. (Standard; Evidence Strength - Grade B)

25. High-pressure, long-duration hydrodistension should not be offered. (Recommendation; Evidence Strength - Grade C)

26. Systemic (oral) long-term glucocorticoid administration should not be offered. (Recommendation; Evidence Strength - Grade C)

Definitions:

Body of Evidence Strength

Grade A: Well-conducted randomized controlled trials (RCTs) or exceptionally strong observational studies

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies

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Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Clinical Algorithm(s)
Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for most treatment recommendations (see the “Major Recommendation” field).

Where evidence was lacking, recommendations are supported by expert opinion or consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of interstitial cystitis/bladder pain syndrome (IC/BPS)

Potential Harms

The Panel conceptualized risks/burdens in terms of the invasiveness of the treatment, the duration and severity of potential adverse effects (AEs), and the reversibility of potential AEs. With regard to treatment invasiveness, oral treatments were judged to be less invasive than intravesical treatments and intravesical treatments were judged to be less invasive than surgical treatments. With regard to duration of AEs, some AEs either diminish over time and/or readily cease upon cessation of the treatment (e.g., medication side effects). Some AEs, however, can persist for long periods after the treatment has been discontinued (e.g., need for intermittent self-catheterization in some patients several months after intradetrusor botulinum toxin A [BTX-A] treatment). With regard to the severity of AEs, potential AEs vary in the extent to which they can compromise quality of life. For example, medication side effects can be mild (e.g., pentosan polysulfate) or severe enough to constitute the major reason for study withdrawal (e.g., amitriptyline). Further, some procedures and substances have the potential for rare but life-threatening AEs (e.g., sepsis with intravesical bacillus Calmette-Guérin [BCG] administration). AEs also vary in their reversibility. Most medication side effects cease upon discontinuation of the substance and are completely reversible. Surgical treatments, however, are irreversible.

See the original guideline document for additional information concerning AEs of specific treatments.

Contraindications

Contraindications

- Antibiotic treatment is contraindicated in patients who have previously been administered antibiotics without efficacy and who present with a negative urine culture.
- Intermittent self-catheterization may be necessary post-botulinum toxin A (BTX-A) treatment. This option is not appropriate for patients who cannot tolerate catheterization, and is relatively contraindicated for patients with any evidence of impaired bladder emptying.

Qualifying Statements

Qualifying Statements

- This guideline’s purpose is to provide direction to clinicians and patients regarding how to: recognize interstitial cystitis (IC)/bladder pain syndrome (BPS); conduct a valid diagnostic process; and, approach treatment with the goals of maximizing symptom control and patient quality of life while minimizing adverse events (AEs) and patient burden. The strategies and approaches recommended in this document were derived from evidence-based and consensus-based processes. IC/BPS nomenclature is a controversial issue; for the purpose of clarity the Panel decided to refer to the syndrome as IC/BPS and to consider these terms synonymous. There is a continually expanding literature on IC/BPS; the Panel notes that this document constitutes a clinical strategy and is not intended to be interpreted rigidly. The most effective approach for a particular patient is best determined by the individual clinician and patient. As the science relevant to IC/BPS evolves and improves, the strategies presented here will require amendment to remain consistent with the highest standards of clinical care.
- While these guidelines do not necessarily establish the standard of care, American Urological Association Education and Research, Inc. (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated.
- As medical knowledge expands and technology advances, AUA guidelines are subject to change. Evidence-based guidelines are not absolute mandates but thoroughly considered strategies for best practice under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases. Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Similarly, conformance with any clinical guidelines cannot assure a successful outcome. These guidelines and best practice statements are not intended to provide legal advice.
- The guideline text may include information or recommendations about certain drug or device use (“off label”) that are not approved by the U.S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to understand and carefully follow all available prescribing information about indications, contraindications, precautions and warnings.
- Although guidelines are intended to encourage best practices and to reflect available technologies with sufficient data as of the date of the literature review, guidelines are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies, pharmaceuticals or management practices, including both those that are FDA-approved, or those which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard emerging technologies or management techniques not addressed by this guideline as manifestly experimental or investigational. These emerging technologies or techniques may simply be too new to be included or fully incorporated in the Panel’s evidence-based evaluation at the time the guideline is developed.
Implementation of the Guideline

Description of Implementation Strategy
An implementation strategy was not provided.

Implementation Tools
Clinical Algorithm
Mobile Device Resources
Patient Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need
Getting Better
Living with Illness

IOM Domain
Effectiveness
Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Adaptation
Not applicable: The guideline was not adapted from another source.

Date Released
2011 Jan (revised 2014 Sep)

Guideline Developer(s)
American Urological Association Education and Research, Inc. - Medical Specialty Society

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Interstitial Cystitis/Bladder Pain Syndrome Guidelines Panel

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Financial Disclosures/Conflicts of Interest
Conflict of Interest Disclosures
All panel members completed conflict of interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Consultant or Advisor: Philip M. Hanno, Astellas (C), Lilly (C), Afferent (C); Robert M. Moldwin, Taris (C)

Scientific Study or Trial: Robert M. Moldwin, Taris (C)

Guideline Status
This is the current release of the guideline.

This guideline meets NGC’s 2013 (revised) inclusion criteria.

**Guideline Availability**


**Availability of Companion Documents**


**Patient Resources**

The following is available:


Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline’s content.

**NGC Status**

This NGC summary was completed by ECRI Institute on July 15, 2011. The information was verified by the guideline developer on July 20, 2011. This summary was updated by ECRI Institute on November 25, 2014. The updated information was verified by the guideline developer on January 5, 2015.

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