The Interstitial Cystitis Data Base (ICDB Cohort) Study

Introduction

Interstitial Cystitis (IC) is a chronic syndrome characterized by a constellation of urinary symptoms of frequency, urgency, and/or pain, in the absence of any identifiable cause, such as bacterial infection, obstruction, or carcinoma. IC pain, when present, may be pelvic, suprapubic, or perineal, and these urinary symptoms may involve both motor and/or sensory bladder dysfunction. The diagnosis of IC is made based on symptomatology, cystoscopy, and exclusion of other bladder disease.

To better understand the diagnosis and natural treated history of IC, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established the Interstitial Cystitis Data Base (ICDB) Cohort Study in 1993, as the first multicenter national prospective cohort study of IC patients. The participating sites and ICDB Study personnel are listed subsequently in this document.

The ICDB served as a centralized, standardized registry containing data and biopsy specimens on a large group of patients with symptomatology consistent with IC. The ICDB Cohort Study was an observational, longitudinal cohort of 637 IC patients treated by their physicians according to usual clinical care, in the absence of protocol-specific treatment intervention. Patient accrual began in May 1993 and continued through January 1997.

The scientific objectives of the ICDB Cohort Study were to (1) characterize the epidemiology of patients with symptomatology consistent with IC; (2) investigate baseline associations among patient characteristics and IC symptoms; (3) determine the longitudinal treated course of IC for selected subgroups; (4) investigate the association between histopathology features and IC symptoms.

Study entry criteria were based on the diagnosis of IC, but were broader than the research criteria developed at the NIDDK from 1987 to 1988. All patients had symptoms of urinary urgency, frequency, or pelvic pain/discomfort for at least six months before study entry. Unlike the NIDDK criteria, the ICDB Cohort Study did not require a baseline cystoscopy at the time of enrollment to confirm the presence of a Hunner's ulcer or glomerulations, provided that the patient had been diagnosed with IC previously. These broader inclusion criteria allowed the inclusion of patients who would be considered to have IC by experienced clinicians, even if they did not meet the strict NIDDK criteria. Although obtaining bladder biopsies was not a protocol requirement at baseline screening, 226 patients did undergo a cystoscopy under anesthesia, of which 211 provided bladder biopsies, either at baseline screening or at the 1-month follow-up visit.

The data from the ICDB Cohort Study provide an essential foundation for further analytic investigations in the diagnosis and treatment of IC.

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