Establishment of a Population–based Registry of Inflammatory Bowel Diseases in Fars Province, Iran

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ABSTRACT

BACKGROUND

Inflammatory bowel diseases (IBD) are debilitating diseases that lead to a variety of problems in a patient's daily life and are a huge burden for the health care system. Since this group of diseases are multifactorial and complex, long-term longitudinal studies are clearly needed to understand them better. A population–based registry (IBD-FaR) has been established in Fars, a southern Iranian province, with the intent to create a reliable data source. This registry will be of considerable help in future planning of health care resources necessary to deal with IBD and to enable investigators to test their theories on the origin and/or treatment of IBD.

METHODS

This registry is managed by both the Gastroenterohepatology Research Center and Health Policy Research Center at Shiraz University of Medical Sciences. A governing committee is responsible for decisions regarding budget allocations and use of data. The designed questionnaire includes a consent form, basic history data, risk factors, related procedures, medical therapy, and follow-up data. The establishment process has two parallel phases: in the first phase, data is collected from numerous sources, including annual hospital discharge data, referral from university affiliated physicians and private practices, pathologic reports, death certificates, self-referral, and insurance system data. In the interview, the questionnaire is completed and blood samples are taken. The gathered data are entered in a custom-designed, computerized data base. In the second phase, annual follow up interviews will be conducted. New IBD patients are also being registered. This phase will continue indefinitely, in order to include new incident cases.

RESULTS

Briefly, from May 2011 until December 2011, there were 188 patients [94 (50%) females and 94 (50%) males] diagnosed with IBD who were registered in IBD-FaR. Patients' age range was between 15 and 80 years. A total of 164 (87.2%) patients out of 188 were registered as diagnosed with ulcerative colitis (UC) and 23 (12.2%) were registered as having Crohn's disease (CD). Most patients 164 (87.2%) had negative family histories of IBD.

CONCLUSION

By retrospective and prospective data collection methods, this central database of IBD cases can determine the incidence, prevalence, and demographic characters of IBD in a defined population. It can facilitate future research to identify etiology, disease process, new treatment options, factors affecting prognosis, recurrences, optimal health care, morbidity and mortality of IBD, and at last but not least, provide educational and social support for patients by educational materials and organizing nongovermental organizations (NGOs).

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Received: 10 Jan. 2012
Accepted: 29 Feb. 2012

KEYWORDS

Inflammatory bowel disease; Registry; Population-based.

Please cite this paper as:
Taghavi SA, Bagheri Lankarani K, Moini M, Hamidpour L, Ardebili M, Mansoorabadi Z. Establishment of a Population–based Registry of Inflammatory Bowel Diseases in Fars Province, Iran. *Middle East J Dig Dis* 2012;4:97-101.

INTRODUCTION

Inflammatory bowel diseases (IBD) are chronic, debilitating diseases divided into two major entities, namely Crohn's disease (CD) and ulcerative colitis (UC).[1] Patients whose diagnoses are neither CD nor UC, are classified as indeterminate colitis.[2]

The peak appearances of CD and UC are between 15 and 40 years of age.[2,3] The natural history and etiology of CD and UC are still unknown.[1] Recent research indicates that immunology, genetics, and environment are factors which contribute to the etiology of IBD. Of lesser importance are dietary, immunologic, nervous system, and circulatory factors.[2,4]

Although the true epidemiologic profile of IBD in Iran is still unknown it is not as rare as previously thought. Dramatic increase in incidence of IBD over time in Iran and other developing countries is attributed to gradual transition to a western diet and lifestyle.[5,6]

IBD patients frequently need continuous medical care and often require surgical management. These patients are a large, increasing burden for the health care system. Therefore, a reliable database is of considerable help for future planning of the extent of the health care resources necessary to deal with these diseases. Accordingly, the Gastroenterohepatology Research Center and Health Policy Research Center, both affiliated with Shiraz University of Medical Sciences have initiated an IBD population-based registry (IBD-FaR) to establish a central database with the intent to examine the incidence and prevalence of IBD in Fars Province and to facilitate future research for a better understanding of the etiology, new treatment options and factors affecting prognosis, recurrences, development of complications, quality of life, and mortality in IBD patients.

This manuscript presents the IBD-FaR. It is also an effort for cross-linking similar registries across provinces in Iran and worldwide.

MATERIALS AND METHODS

Definition of a population–based registry

A population registry is a registry that intends to cover all residents in a given geographic area within a given time period.[7]

People who live outside the geographical area covered by the population-based registry would not be counted, even if they receive medical care at a facility within the area.

It should be emphasized that intention, rather than performance, defines the term. In other words, a population-based registry uses every possible way to include all affected individuals in the defined geographical area although the end result usually will not be complete.

A population-based disease registry aims at including all diagnosed cases with the disease in the population, be it self-reported, clinically diagnosed, or detected at screening.[7]

IBD-FaR

IBD-FaR is a population-based census in Fars Province that has been established to gather baseline IBD epidemiological data in order to facilitate future research. The intent of IBD-FaR is to maximize scientific benefit to patients and the community.[8] This population-based registry began gathering data in April 2011 and is used for capturing, managing, and organizing specific information for all IBD patients who live in Fars Province.

Completeness, accuracy and accessibility of the data will be assessed as quality measures for IBD-FaR.[9]

Governing body

The registry is jointly managed by the Gastroenterohepatology Research Center (GEHRC) and Health policy Research Center at Shiraz University of Medical Sciences. A governing committee that consists of a head, two faculty members, and appointed manager of the registry are responsible for decisions regarding budget allocations, hiring of new personnel, and use of the data for research or other purposes.

Any research proposal should be reviewed and approved by the governing committee before any access or use of data is allowed. A yearly plan is developed by the registry's governing committee to apply for an annual budget.

Eligibility

Diagnosis of IBD is established based on the combination of clinical, endoscopic, histological and radiological (if applicable) data. Potential enrollees should be residents of Fars Province. People who live outside Fars will not be counted, even they receive medical care at a facility within the area. There is no age or sex limitation.

Data from hospital charts will be included in this registry if a diagnosis of IBD can be certified based upon available data.

Ethical considerations

All patients' data are considered confidential. Access to data is restricted to the authorized personnel. Any use or access to the data will be allowed only after approval of the governing committee.

Before starting the first interview, a consent form is completed by the patient which enables them to join the registry and authorizes release of medical information.

Questionnaire

A questionnaire written by James et al. has been adapted to the Iranian population, particularly with regards to demographic data. The questionnaire includes a consent form and patient data form(s) that can easily be transformed from a paper version into a computerized data file.[3]

The questionnaire will be revised every two years.

In addition to the consent form, the questionnaire also includes the following data: social, educational, and economic, basic history, information determining the date of onset of symptoms, family history of IBD, clinical manifestations, complications, current drug use, response to steroid and immunosuppressive therapies, laboratory and radiological data, any relapses, and major life events. Also included are potential risk factors such as history of surgery, pregnancy, oral contraceptive pills(OCP), hospital admissions, smoking history, breast feeding, radiotherapy and nutritional status. The follow up interview focuses on questions regarding current problems, any surgical procedures or complications during the previous year, the latest laboratory data, endoscopy and biopsy, and radiological data after the last interview.

Data collection methods

The IBD-FaR project has been divided into two phases. In the first phase, the registry office retrospectively completes the modified questionnaire for all IBD hospital admissions in Fars Province and prospectively arranges interviews with IBD patients.

IBD-FaR must collect data from multiple sources in order to ensure that the maximum numbers of IBD cases within the community are accounted for. Sources of data for population-based registries are: annual discharge data from hospitals, university-affiliated physicians and private practice referrals, pathology reports, death certificates, encouragement of self-referrals by the use of local media (TV, radio, newspaper, internet), and insurance system data.

In order to optimize participation, patients are not required to provide answers to all of the questions in the questionnaire or to provide blood samples.

As a part of the patient referral system, the registry office contacts all gastroenterologists, internists, and colorectal surgeons in Fars Province by mail and phone with the intent to outline the purpose of this population-based registry. Physicians are asked to refer patients by either encouraging them to contact the registry or to provide the registry office with the patient's contact phone number, which is then used by data collectors to contact patients.

The registry office sends pre-designed referral forms to contacted physicians to facilitate the referral process. Every 3 months, contacted physicians receive a letter from the IBD registry office that includes the number of IBD patients physicians have personally referred to the IBD registry.

All efforts are made to reassure patients that their information will remain confidential and to reassure physicians that the registry is not involved in clinical follow-up or decision making about their patients. All IBD patients will have access to a phone number so they can ask questions about their medical conditions.

An important step is to link all records pertaining to an individual to avoid duplicate registration. Personal identification numbers (national identification number) are ideal for this purpose; but, in practice, name, sex, date of birth or age, and place of residence are also used for linkage purposes.

During the first patient interview an informed consent is obtained. Registry objectives are outlined, and the questionnaire completed by a trained staff registry person.

The questionnaire and signed consent form are then returned to the registry office for data screening, data entry, and filing. All endoscopy, histology and radiologic data are recorded.

The data gathered during the first interview is reviewed by one of the faculty members to confirm the diagnosis of IBD prior to inclusion in the registry. Follow up interviews are collected by phone or in person on an annual basis.

For the patient's family, efforts are made to directly contact all affected first degree relatives (parents, siblings, and children) regarding their IBD status. Consent is obtained from the proband in order to contact family members. The proband then furnishes the registry personnel with names, addresses, and phone numbers of the first degree relatives. Each affected first degree relative would be contacted by phone.

In the second phase, follow up of all IBD patients will be continued annually. At 6 month intervals, each patient will receive a brochure that contains an update on the etiology, diagnosis and treatment of IBD. This phase will continue indefinitely as to include new incident cases of IBD. Recruitment of new cases will be facilitated as follows: reminders to all referring physicians, annual reviews of hospital discharge data, pathology lab data, and pharmacy data, as well as the use of local media to encourage the self-referral system.

Database development and maintenance

The data entry system and data base is designed by an expert software engineer. All gathered data is entered to the computer system.

Capture–recapture analysis will be used to assess completeness of the data collection.

The data is kept on designated computers with no direct web connection to maintain confidentiality and safety of the data. All entered data will be reviewed every 3 months for completeness and accuracy by the appointed registrar.

Blood sampling

Blood samples are taken from all patients after signing an informed consent. DNA will be extracted and kept at -70°C. In addition, another serum sample will be kept at -20°C for future research.

RESULTS

This registry will continue to register as many patients as possible as mandated .On May 2012, complete results will be reported. Briefly, from May until December 2011,188 patients diagnosed with IBD, of which 94 (50%) were female and 94 (50%) were male were registered in IBD-FaR. Age range was between 15 years and 80 years.

A total of 164 (87.2%) patients out of 188 were registered as having ulcerative colitis (UC) and 23 (12.2%) were registered as diagnosed with Crohn's disease (CD).

Most patients 164 (87.2%) had no family history of IBD. UC was detected in brothers of 3 (1.6%) patients, sisters of 2 (1.6%), aunts of 3 (1.6%), and in a cousin of 1 (0.5%) patient. CD was detected in the brother of 1 (0.5%) patient, a sister of 1 (0.5%) patient, the aunt of 1 (0.5%), the grandmother of 1 (0.5%), and in the cousin of 1 (0.5%) patient.

DISCUSSION

Patients with IBD have a multitude of problems in their daily lives, such as health-, social- emotional-, familial-economic- and work-related problems. All tend to worsen quality of life.

These patients often require continued medical therapy, frequently need hospitalization, and many require multiple surgeries. IBD are complex diseases with wide variation in clinical practice.[8] The mortality rate is relatively low, so that the IBD patients must live for years with their diseases. In general, IBD affects every aspect of the patient's life.[1] Thus, major challenges remain in the prevention and cure of IBD.[1]

The goals of IBD-FaR are to actively identify and recruit newly diagnosed cases of IBD, calculate the burden of disease in order to provide optimal health care for IBD patients, identify if the incidence of IBD is equal in all geographic areas, determine if the incidence of IBD changes over time, monitor the disease course, and investigate its natural course in an effort to better understand IBD. In addition, IBD-FaR aims to identify possible familial clustering of IBD, provide educational and social support for IBD patients by giving them educational materials and organizing NGOs which can advocate for patients in decision-making situations, empower patients to take an active role in their treatment, track the progress of high-risk patients, and directly assess the region's entire population.

Hopefully, any meaningful research about the etiology, quality of life, treatment and prognosis of IBD is possible with the presence of this reliable population-based data which can be obtained through this well-kept registry.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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