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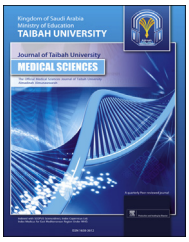

Brief Communication

Can the inflammatory bowel disease biologics registry lead to improved quality of care?

Laith Alrubaiy, MRCP [a,*], Ibtihal Rikaby, MPharm [b], Hayley Anne Hutchings, PhD [a] and John Gordon Williams, FRCP [a]

[a] *Patient and Population Health and Informatics Research, College of Medicine, Swansea University, Swansea, UK*
[b] *Cardiff and Vale University Health Board, UK*

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الملخص

السجل الإلكتروني للأمراض يتضمن جمعا منتظما للبيانات حول مرض أو مجموعة أمراض. هناك رغبة لدى مجتمع المختصين بأمراض الجهاز الهضمي لتطوير السجل الشامل لمرضى داء الأمعاء الالتهابي لسنوات عدة. ومع ذلك لم يكن هناك عمل وطني منسق لتحقيق هذا الهدف. تستعرض هذه المقالة دوافع تأسيس هذا السجل وتقترح طريقة منهجية للعمل وطرق المحافظة على استمراريته.

الكلمات المفتاحية: داء كرون؛ داء الأمعاء الالتهابي؛ التهاب القولون التقرحي

Abstract

A registry is a systematic collection of data about a disease or a group of diseases. For some years there has been a desire amongst the gastroenterology community to develop a comprehensive registry of patients with inflammatory bowel disease (IBD). However, no coordinated national approach has been developed to achieve this objective. This article reviews the possible reasons for establishing an IBD registry and suggests a methodological approach to achieving this goal and strategies to maintain its continuity.

Keywords: Crohn's disease; Inflammatory bowel disease; Ulcerative colitis

Introduction

For some years, there has been a desire amongst the gastroenterology community to develop a comprehensive registry of patients with inflammatory bowel disease (IBD) to monitor patients' responses to treatment.

Review of previous IBD registries worldwide

Several registries of biological therapy in Crohn's disease were commercially funded, including the TREAT Registry for Infliximab® sponsored by Schring-Plough[1] and the Registry Study for Adalimumab® sponsored by Abbott.[2] The problem with commercially funded registries is that they are only run for a period of time as part of the post-marketing phase of clinical trials. To allow for an accurate analysis of treatment response, registries should include patients treated with biologics and those treated conventionally. The Rotherham IBD management software was designed by Prof KD Bradhan to hold a large database on the management of IBD patients. It was been developed and supported by Ferring pharmaceuticals.[3] However, many gastroenterologists found that maintaining the database was too time-consuming and difficult.[3] An Austrian database called the Inflammatory Bowel Disease

* Corresponding address: Room 220, Grove Building, College of Medicine, Swansea University, Swansea SA2 8PP, UK.
E-mail: l.alrubaiy@swansea.ac.uk (L. Alrubaiy)
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Information System (IBDIS)[4] has received growing publicity. The aim of the IBDIS is to recruit patients for clinical trials. However, the IBDIS collects a large number of items for each patient. Therefore, the IBDIS is not suitable for use in day-to-day care of individual patients in busy outpatient clinics. In the Kingdom of Saudi Arabia, a few hospitals have participated in a promising local IBD registry in an attempt to examine the disease distribution and prevalence there.[5,6] The British Society of Paediatric Gastroenterology Hepatology and Nutrition (BSPGHN) established a registry of paediatric IBD in the late 1990s[7]; however, it was only maintained for a few years.

There has been a renewed interest and impetus for the development of an IBD registry since the second round of the UK IBD audit and the launch in Feb 2009 of the National IBD Service Standards,[8] which strongly recommended the establishment of such a registry to monitor the safety and efficacy of biological therapies.[9,10,11]

Another element that encouraged the development of the IBD registry was the licensing of the first anti-tumour necrosis factor α (anti-TNF-α) drug, infliximab, at the beginning of the last decade. The long-term outcomes of patients treated with anti-TNF-α drugs are still unknown, and they have a number of safety issues. Therefore, the National Institute for Health and Clinical Excellence (NICE) in the UK has recommended the establishment of a registry to gather more information about the safety and efficacy of anti-TNF-α drugs in the treatment of IBD.[12,13]

Examples of successful registries for anti-TNF-α drugs have been established in the UK, Sweden, Germany, Spain, Norway, Denmark, the Netherlands and Switzerland.[14,15] The British Society of Rheumatology (BSR) established a highly successful registry of rheumatology patients treated with biological therapies.[16,17] The French developed a registry to identify cases of lymphoma and infection associated with the administration of biological therapies for any condition.[18] Several biological registries were launched to monitor the safety and efficacy of these agents in the treatment of psoriasis.[19–21] The first UK-wide registry for IBD was launched in 2013 to promote an agreed upon, standardised method of data collection and to maintain properly governed access and analysis of that data.

Benefits of the IBD registry;

The IBD registry will accomplish the following:

1. Provide national statistics on IBD patients throughout the UK.
2. Allow local IBD units to compare their performance with other units in the UK.
3. Monitor patient outcomes, safety and adverse events after treatment with immunosuppressive drugs and surgery.
4. Provide a good resource for clinical governance, such as clinical audits, prospective research, performance monitoring, appraisal and revalidation.

Steps in developing an IBD registry:

Developing an IBD registry involves a few steps. The first step is to define the scope and purpose of the registry. This will help define the data required for the registry. The data to be obtained can include both mandatory and optional items. A flexible registry that can adapt to clinicians' needs in daily clinical practice will encourage healthcare professionals to use the registry. The second step of the process is to develop the IT infrastructure for the registry. Participating hospitals can collect and view their data, but data for national collection and analysis will be anonymised and held separately. Local outputs, such as individual history summaries and outpatient letters will provide support for day-to-day patient care. The third step includes implementing the registry at the participating sites and encouraging healthcare professionals to use the registry in their day-to-day care.

There are a few factors that should be considered when implementing an IBD registry to ensure its continuity:

1. Healthcare professionals should be allowed enough time to use the registry and to enter their data. While the value of the IBD registry may be appreciated, entering the data can be "too time consuming".
2. Ideally the registry should be able to link with hospital patient information, including administrative, laboratory, imaging, and endoscopy details. This will avoid duplicate data entries.
3. The registry should be easy to use, "user-friendly", and relevant to patient care with demonstrable benefits to the users.
4. Users prefer a structured format with a minimal need for free text, including, for example, "tick boxes" and "drop down" lists for entering data. This speeds data entry and, thus, aids in prospective data collection.
5. IBD specialist nurses are the most capable of entering patients' details into the registry because of their skills and knowledge. However, the time required for this task should be acknowledged and provided.

Summary

In summary, having a successful IBD registry will ensure efficient patient monitoring and follow-up. It will also support data collection for audit and research purposes. However, any registry should be tailored for individual users' needs to ensure their engagement and participation. A few difficulties associated with establishing a country-wide IBD registry include a lack of clinician participation or interest, costs related to establishing and maintaining the registry, providing sufficient time for clinicians to use the registry and data quality assurance.

Conflict of interest

The authors have no conflict of interest to declare.

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