# **EDITORIAL**

# Will sustained biological therapy improve long-term outcome in inflammatory bowel disease?

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In this issue of Polish Archives of Internal Medicine, Dr. Piotr Kucha and co-authors present data on the use of advanced therapies for inflammatory bowel disease (IBD), including biologics (anti--tumor necrosis factor [anti-TNF], anti-integrin, and anti-interleukin [IL] 12/23 monoclonal antibodies), as well as the first Janus kinase inhibitor, tofacitinib, available for IBD in Poland between 2012 and 2020.<sup>1</sup> The authors used administrative data and gathered the patients by using a combination of at least 2 assignments of IBD codes (ulcerative colitis [UC] or Crohn disease [CD]) combined with a prescription of more than 1 IBD--related drug and / or intestinal surgery, a method shown to provide an accurate diagnostic yield.<sup>2</sup> IBD is a chronic inflammatory condition often diagnosed during adolescence and requiring continuous medication. The incidence of IBD is increasing worldwide with a prevalence reaching 2.5 to 3 million patients in Europe.<sup>3,4</sup>

Many IBD patients experience progressive disease with complications such as hospitalizations and surgery.<sup>5</sup> Owing to the young age of an average IBD patient, this chronic condition substantially affects work productivity due to sick leave and work disability summing up to half of the total cost of the disease.<sup>6</sup> For CD, the annual health care costs in Europe were EUR 12418 (range, 7681-15780) and for UC they were EUR 7215 (range, 3223–9764).<sup>6</sup> The mean annual cost of absenteeism, presenteeism (being present at the work place for more hours than required), and informal care varied from EUR 1253 (Bulgaria) to EUR 7915 (Spain), from EUR 2149 (Bulgaria) to EUR 14 524 (Belgium), and from EUR 1729 (Poland) to EUR 12063 (Italy), respectively. For patients in the remission, the cost is lower by 54% (presenteeism, P < 0.001) or 75% (absenteeism,

informal care, P < 0.001) according to a Dutch study.<sup>6</sup> In addition to the costs to the health care system and society, the personal implications are considerable. Frequent bowel movements, urgency, soiling, pain, and fatigue are symptoms that often limit social participation. In addition, patients display many IBD-related worries that impair self-perception of their body image, which can cause fear of stigmatization and thereby lead to further social distancing.<sup>7</sup> In this context, the availability of biological therapies when other options are inadequate, may have a significant impact on everyday quality of life of these patients, which can be difficult to assess in terms of costs and savings.

The major impact of biologics has been to prevent disease progression and surgery in patients refractory to corticosteroids, 5-aminosalicylates, and thiopurines. The cost of biologics is considerably higher than of conventional medications, but advanced therapies have been proven to significantly reduce the intestinal inflammation as well as increase the quality of life within the first year of treatment according to randomized controlled trials.<sup>8</sup> In the patients responding to anti-TNF, studies have also demonstrated sustained benefits over several years.<sup>9,10</sup> In a recent Swedish national registry study, the benefit of more than 1 year of anti-TNF therapy as compared with a shorter treatment period was manifested in a lower rate of surgical interventions up to 10 years after introduction of the biologics.<sup>11</sup> The cost of biologics is one of the major reasons for prescribing modern therapeutics with caution. However, the introduction of biosimilars has allowed for a broader and earlier introduction of anti-TNF in patients with inadequate response to conventional options. Indeed, a recent Norwegian national registry study could demonstrate a higher rate of biologic initiation in IBD patients within the first year after diagnosis from 2010 to 2016, coinciding with the approval of biosimilars in 2013.<sup>12</sup>

As Kucha et al<sup>1</sup> discuss in the current publication, the penetrance of biological therapies among Polish IBD patients is quite low in this historic cohort as compared with some other European countries. Not only factors such as limited experience of a newly approved drug and the decentralized health care system play a role. The time-limited reimbursement may also have an impact on the results of the study. The previously mentioned study from Sweden confirmed a clear advantage of prolonged biological therapy lasting over a year regarding the need for surgery.<sup>11</sup> Therefore, it will be interesting to continue to study the use of the biologics, as well as the need for surgery in Poland after implementing a wider therapeutic program without time constraints. The well-established and less expensive biosimilars (anti-TNF and soon also anti-IL12/23) will probably add to the foreseeable increase of biological treatment in Poland similarly to other European countries.

### **ARTICLE INFORMATION**

DISCLAIMER The opinions expressed by the author(s) are not necessarily those of the journal editors, Polish Society of Internal Medicine, or publisher. CONFLICT OF INTEREST None declared.

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