EDITORIAL

The Economic Burden of Inflammatory Bowel Disease: Clear Problem, Unclear Solution

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Caring for and treating inflammatory bowel disease (IBD) patients may represent the most challenging aspect of a gastroenterologist's clinical practice. One must properly assess the disease severity, make appropriate therapeutic recommendations, induce a sustained remission, and pay attention to many details during monitoring of care, all the while trying to keep up with a rapidly changing field that will soon introduce a host of new medications. As if this weren't enough, we should also be mindful of the cost of IBD care. In our busy day-to-day practices, we likely do not appreciate how our clinical decision-making impacts the patient personally through their pocket book and affects the insurance system on which they depend. The article by Gunnarsson et al. [1] published in this issue of *Digestive* Diseases and Science highlights the economic burden of caring for Crohn's disease (CD) and ulcerative colitis (UC) patients. The results are sobering. IBD care is expensive, and in this era of cost containment and health care reform, we as gastroenterologists need to prepare ourselves and take action to combat this growing problem.

The article by Gunnarsson et al. [1] differs from prior cost analyses because the authors used data derived from the Medical Expenditure Panel Survey (MEPS), a national survey sample of families, individuals, medical providers and employers across the country. Every year, the US government surveys a sample of households representing 15,000 adult individuals, then follows them for 2 years with in-person interviews. As a result, the data represents a broader scope of the US population and offers perhaps the most comprehensive information on the specific health

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services that Americans use, the cost of these services, and how they pay for them, including out-of-pocket expenses. The authors used statistical modeling to estimate costs for services, including hospital costs, medications, physician payments, outpatient services, and diagnostic testing. They compared adult IBD to non-IBD patients using data from 1996–2009 and results were adjusted to 2010 US dollars.

Of the total sample size (>207,000 individuals), the study identified 358 patients with CD and 198 with UC. These numbers provide a prevalence that is within the range expected based upon published prevalence rates for IBD in the US. However, the rate for CD is disproportionately high given that most estimates have found the ratio of CD to UC to be closer to 1:1 [2]. Nevertheless, and not surprisingly, having CD or UC greatly increased the odds of having medical expenditures and out-of-pocket costs compared to those without IBD. When the data were extrapolated to the general US population, the total estimated expenditures, per year, for CD and UC were \$2.29 billion and \$0.61 billion, respectively (total \$2.8 billion). This is much lower than the overall expense of treating diabetes (128 billion) and coronary artery disease (\$92 billion), as calculated using the same methodology in this report, but this is explained by the fact that these conditions have a much higher prevalence. Importantly, the perpatient yearly expenditures were \$6,482 for CD and \$3,059 for UC. Not only was CD twice as expensive as UC but it was more costly per-patient on a yearly basis than diabetes, coronary artery disease, stroke, and chronic obstructive pulmonary disease.

The cost estimates from this study are actually lower than those found in other reports. Kappelman et al. [3] for example, using insurance claims data from 2003 to 2004, found CD and UC mean total costs per-patient to be \$10,952 and \$7948 per year, respectively, and the

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estimated total cost for the general population was \$6.3 billion. Discrepancies among cost studies are common due to differences in data source and methodologies. Still, there is sufficient consistency among studies to conclude that IBD is among the top five most expensive GI disorders (along with e.g., reflux disease, colorectal cancer, and gallbladder disease), despite having the lowest prevalence among them [4, 5].

So what are we to do with these startling results? Given the increasing focus on the cost of medical delivery in the US, within the scope of gastroenterology practice and in light of these findings, we should expect IBD to be one of the main targets for cost containment, and in order to lower costs of IBD care, we need to dig deeper into what primarily drives the expense. What's missing from the report by Gunnarsson et al. [1] is a specific breakdown of the costs. Previous studies have shown that the majority of the IBD-related healthcare expenditures are due to pharmaceutical claims, hospitalization, and surgery [3, 6, 7], therefore efforts at reducing expenditures need to address these three key areas.

The challenge lies in that these three aspects of care are closely interrelated. Hospitalization and surgery-which add tens of thousands to dollars in expense to an individual's clinical IBD course-can only be avoided by effective management using pharmaceuticals, which themselves can be very costly. The solution to this Catch-22 hinges on optimal usage of the most effective drugs but at the lowest possible cost. Drug efficacy equates to the ability to induce and maintain remission for the long term. In our current era of IBD therapeutics, the use of biologic agents is commonplace, particularly for CD. The future appears to be even more biologically based, as most of the drugs that are expected to receive FDA approval for IBD in the next few years are monoclonal antibodies, as are many other drugs in the pipeline. Despite the fact that our current approach to medical management is becoming more and more biologically based, to date we still do not have conclusive evidence that biologics are cost effective in the treatment of IBD. Studies examining the impact of biologics have been mixed, with some reporting increased cost and others reporting a cost savings [8, 9]. Numerous factors can significantly affect the cost of biologic agents. These include absolute differences in price among different biologics, mode of administration, duration of use, and whether dose escalation is necessary. The high direct costs of anti-TNF α agents may, however, be offset by their ability to lower the indirect costs of IBD treatment via reductions in the need for hospitalization and surgery as well as improvement in overall quality of life [10, 11]. Future long-term costanalysis studies should help reveal how and when to use biologics so that the balance of these opposing factors is tipped toward cost savings for the largest number of patients.

Unfortunately, another difficulty with regard to reducing expense is that our understanding of the effective use of biologics in IBD continues to be in a state of flux. The promise of biologics lowering the cost of care is contingent on the assumption that they are administered correctly. Amazingly, 14 years since the advent of infliximab therapy, we are still scratching our collective heads trying to understand how to optimize its use. The same holds true for the newer injectable anti-TNF α agents. Optimization of these expensive drugs requires recognizing the moderate to severe patient, starting the biologic at the right time, and maximizing its ability to induce and maintain remission. If a CD patient is not identified as requiring aggressive therapy early in the disease course, he may receive a biologic too late-an all too common occurrence-and will be unable to avoid surgery. Thus, any potential savings from the use of a biologic is lost. Add to this the fact that many patients harbor an understandable fear of immunosuppressants in general or may still consider biologic agents a last ditch effort before surgery. In short, many obstacles lie in the path of the biologic drugs in their quest to control disease and save dollars.

So what, if any, solutions can we foresee in the future? We have thus far witnessed the emergence of quality indicators for IBD [12]. All of us as gastroenterologists are or will be judged, rewarded, or even penalized in the future based upon our ability to properly care for IBD patients. These metrics for quality, however, do not directly address the cost of achieving high-quality IBD care. In order for quality measures to succeed in lowering cost, they need to focus on treatment uniformity and the primary goal of achieving remission using the most cost-effective strategy. Optimal use of biologics is not the only solution. Many aspects of IBD care add to cost. In 2008, for example, the seemingly innocuous drug mesalamine was reported to be the costliest and most frequently prescribed medication for CD [5], this, despite the paucity of evidence for its effectiveness in all but the mildest CD cases. Clearly, it makes economic and clinical sense to withdraw medications that, during the course of CD, have failed to be effective rather than continue them because they "won't hurt". Furthermore, like most conditions, IBD patients exhibit a wide range of medical costs with a subset of perhaps 1-5 % of patients-those with most severe disease-incurring the greatest expense, which tends to skew expenditure data to the right. Therefore, we can potentially defray the cost by means of early identification of these most challenging patients and steering them to experienced IBD centers where the chances of achieving a long-term remission tend to be higher.

Of course, getting patients into remission is easier said than done. If we as gastroenterologists are unable to achieve this in the majority of patients, including the most severe ones, then we will likely continue to struggle to contain the cost of managing IBD. Ultimately, it seems that successful medical treatment that prevents hospitalization and surgery is the most essential element of reducing cost. Future research should continue to provide more specifics on how to best use our available medications. Most critically, the drive for improved quality in IBD management holds the promise of raising the bar for what constitutes excellence in clinical outcomes. Hopefully, we will eventually discover the ideal compromise between the expense of our medical therapies and the consequence of not using them effectively.

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