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Making Therapeutic Decisions in IBD: The Role of Patients

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Abstract

Purpose of review—The treatment of inflammatory bowel disease (IBD) is becoming more complex due to the introduction of new medications and evolving treatment algorithms. Data suggest that more aggressive treatment will yield improved clinical results. Although promising, it is not clear if patients will agree to this forceful approach. This review aims to describe what we know about patients' perceptions of risks and benefits of treatment, how much risk IBD patients are willing to accept, and to introduce ideas to facilitate better patient communication.

Recent findings—Patients and parents of children with IBD appear to be willing to accept the known risks associated with IBD therapies, but demand substantial treatment benefit to make this tradeoff. Since patients with IBD have misperceptions about the risks and benefits of treatment, it is important to develop better methods of communicating medical information.

Summary—There are now more treatment options for patients with IBD. To increase patients' participation in medical decisions, it is critical to fairly present the tradeoffs of risks versus benefits of treatment. Tools are being developed to more clearly present clinical trial data, risks of medication side effects and for calculating individualized risks of disease complications and response to therapy.

Keywords

Inflammatory bowel disease; shared decision making; preference; risk; communication

Introduction

Historically, until recently there were not many choices for patients to make in the treatment of inflammatory bowel disease (IBD). The standard approach at diagnosis was to initiate "mild" medications such as 5-aminosalicylates (5-ASAs) with or without prednisone, and then only after a convincing failure of these measures would patients be offered immunomodulators such as 6-mercaptopurine (6MP), azathioprine or methotrexate. When active disease persisted, biologic agents such as anti-tumor necrosis factor (TNF) drugs were added. If all of these measures failed, surgery was a last resort. This rational "step-up" approach made sense to physicians and patients such that it saved the "stronger" medications until they were justified.

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Recent studies have led us to challenge this treatment paradigm, and in doing so have introduced a number of difficult decisions for patients and providers. The D'Haens et al. study of early combination immunosuppression showed that the use of immunomodulators and anti-TNF agents can be more effective if used earlier in the course of the disease (1). The SONIC trial, predominantly studying patients with recent onset disease, showed that the combination of anti-TNFs plus immunomodulators was superior to either drug used alone (2). Researchers at the University of Pittsburgh demonstrated that the use of infliximab immediately after surgery dramatically decreased the post-operative recurrence rate. The pediatric literature is also consistent with the message that aggressive treatment earlier in the course of illness is more effective than when used later (3,4). Although the data are accumulating that an early aggressive treatment algorithm is superior and will likely alter the natural history of Crohn's disease, an important next question is whether patients will agree to this approach.

There has been a lot of work studying patient decision making in other disciplines such as oncology, cardiology, critical care and orthopedics (5-9). This type of work is beginning to permeate into IBD and treatment decisions are becoming more complex. The goal of this review is to discuss new knowledge about patient perceptions and decision making for the treatment in IBD, to introduce ideas on how to facilitate better patient-centered decisions, and finally to offer advice on how to better communicate our medical data in a format more comprehensible to patients.

Preference-sensitive decisions

It has always been important to involve patients in medical decisions but, because of the shifting treatment approach as described above, it has become even more critical. We are moving from a time when the standard of care appeared to have been providing safe and effective treatment, to an era where maximizing treatment response may be possible, but will require patients to make preference-sensitive decisions. A preference-sensitive decision means that there is more than one appropriate treatment choice, and patients will agree on what is right for them based on how they value benefits versus harms (10). Their choice for treatment will depend upon their optimism of response, aversion to risk, severity of illness, tolerance of symptoms and, importantly, what they learn about these treatments from doctors, friends, advertising and the internet. The use of antibiotics to treat pneumonia is not a preference-sensitive decision; neither is repairing a broken bone. The early use of combination therapy for Crohn's disease is a preference-sensitive decision, as is a choice to use infliximab for ulcerative colitis as opposed to colectomy. There are a number of preference-sensitive decisions for IBD that require input from patients before a treatment modality is prescribed (Table 1).

Risk perception and decision making

People accept risk at different levels depending on a variety of factors. Classic work in risk perception by Slovic describes two major factors that control how people perceive risk (11). First, the "dread" associated with an event relates to the possible consequences of a bad outcome. Second is the "unknown", suggesting that new risks, or uncertainty about risk increases worry. Slovic uses the nuclear accident at Three Mile Island in 1979 as an example of how rare but unfortunate events can impact risk perception. Although not a single person died as a result of this event, the high level of dread and uncertainty associated with nuclear leaks changed the way people think about the safety of nuclear power. On a much smaller scale but using the same premise, high profile warnings for pharmaceuticals can have a substantial impact on the use of medications. Consider the level of dread and uncertainty associated with hepatosplenic T-cell lymphoma (HSTCL) or progressive multifocal lymphadenopathy (PML) (12,13). Although both of these events are exceedingly rare, the fear associated with these unfamiliar and dreadful events have changed the way we treat patients.

A survey study of patients with Crohn's disease aimed to determine how much risk patients are willing to take for certain adverse events associated with biologic therapy (14). Patients were presented a series of conjoint trade-off tasks comparing hypothetical scenarios with varying levels of treatment efficacy and chance of dying from serious side effects (PML, lymphoma and sepsis). With this technique, the maximum acceptable risk that patients were willing to tolerate was calculated. As might be expected, patients were willing to take higher risks of adverse events for greater anticipated treatment benefit (Figure 1). Otherwise stated, patients were less willing to accept risk in the setting of less severe disease or smaller clinical improvement. This directly impacts the idea of early aggressive therapy. With the goal of treating disease before complications develop, we will have to effectively communicate to patients the added value of beginning biologic therapy before they have typically felt that it is warranted. Importantly, in this study, patients were overall willing to take higher risks of these three adverse events than have been seen in clinical practice. This leads us to believe that although patients are fearful of the occurrence of these side effects, in general it will not stop them from taking the appropriate medications.

These same trade-off tasks were also performed with parents of children with Crohn's disease (15). Parents were also willing to accept higher risks for treatment with increased disease severity. For children with severely active disease, parents were willing to take even higher risks of adverse events than the adult patients; however, when children were less sick, they were more risk averse than the adults choosing therapy for themselves. This too may impact the idea of early aggressive and combination therapy, as parents may be more hesitant to accept risks such as HSTCL for their kids who have not yet failed more conservative treatment. For both the adult and parent studies, although the occurrence of PML, lymphoma and sepsis were all described as leading to death, patients consistently were more willing to tolerate the risk of lymphoma or sepsis than PML. This is perhaps due to Slovic's reasoning about dread and uncertainty, and may be contributing to the slow integration of natalizumab into clinical practice.

Other work has also shown that Crohn's disease patients are willing to accept risks of therapy in exchange for meaningful treatment benefit. Kennedy et al. explored patient preferences regarding post-operative prophylaxis after an ileal resection (16). Using a threshold technique, they presented clinical scenarios and systematically altered the treatment benefit of a specific medication until it was high enough for a patient to accept the risks of that treatment. Patients were asked if they would prefer to take 5-ASAs or azathioprine to prevent the recurrence of Crohn's disease after surgery. If both of these medications had equal efficacy for maintaining remission after surgery, only 10% of patients would chose azathioprine over 5-ASAs. When the efficacy of azathioprine was increased to a 5% higher chance of remission than with 5-ASAs, 51% of patients would chose azathioprine; if azathioprine was 6%-10% more effective than 5-ASAs, 88% of patients preferred azathioprine. Rising treatment benefit led to increased tolerance of possible side effects.

Is decision making different for Crohn's disease and ulcerative colitis?

Patients with ulcerative colitis have another level of complexity involved in their treatment decisions. Although the medications used to treat Crohn's disease and ulcerative colitis are almost identical, the option of colectomy for ulcerative colitis introduces another consideration for patients. Most patients prefer to reserve colectomy until they have been refractory to all medical treatments. For others, colectomy might be preferable earlier in the disease course. A publication by Arsenualt et al. studied patients' preferences for surgery as opposed to receiving infliximab or cyclosporine for steroid-refractory ulcerative colitis (17). Patients were interviewed by researchers to develop utility scores for certain disease states and outcomes of treatment (e.g., ileostomy, J-pouch, medically induced remission). These scores were then used

as inputs for a Markov decision analysis. The authors showed that although two-thirds of patients preferred medical therapy (specifically infliximab) over surgery for steroid-refractory ulcerative colitis, one-third preferred immediate colectomy (without a trial of infliximab or cyclosporine). In the Markov model overall quality of life was highest for those in the medical therapy group. However, if the response rate to infliximab was less than 60% (just about the initial response seen in the ACT 1 and 2 trials) (18), then quality of life scores tipped in favor of colectomy. Since long-term remission rates of infliximab for the treatment of steroid-refractory ulcerative colitis are probably substantially lower than 60%, these results raise the question of how many ulcerative colitis patients would really prefer medical therapy over surgery if they understood their chances of long-term treatment success.

Shared decision making

Shared decision making is defined as the process of interacting with patients who wish to be involved with their health care providers in making medical decisions. It is most relevant in the setting of preference-sensitive decisions as described above. Although not all patients want to be involved in medical decisions (19,20), the majority will want some part in this process, especially when the consequences are significant (e.g., infliximab versus colectomy for ulcerative colitis). A crucial component of shared decision making is properly educating patients about the risks and benefits of treatment options.

A survey study explored patients' perceptions about the risks and benefits of infliximab (21). Patients and parents of patients with IBD were asked about expected remission rates for infliximab and how often side effects such as lymphoma might occur. The majority (59%) of respondents expected a one-year remission rate of greater than 50%, and nearly 20% of patients expected a one year remission rate of at least 70%. This is substantially higher than data from controlled trials (22). Furthermore, respondents underestimated the risk of lymphoma associated with anti-TNF treatment. Similar results were reproduced in a population from the Netherlands (23). These results demonstrate that before engaging patients in the decision making process, proper education about treatment options is required.

There are a number of methods that can be used to help educate patients about the risks and benefits of treatments. One such technique is the use of a decision aid. Decision aids are interventions developed for preparing patients for decision making about a specific treatment choice (24). The goal is to objectively present evidence-based data in a clear and balanced manner so that patients can decide for themselves the value of the risks versus the benefits. Decision aids have been developed using various media, ranging from simple pamphlets to elaborate web-based videos. Successfully developed decision aids include: Treatment options for atrial fibrillation (7), management of breast cancer (8) and prostate cancer (25), and treatment choices for coronary artery disease (26). There is one decision aid for patients considering surgery for ulcerative colitis (27), but the complexities of the tradeoffs comparing medical therapy (e.g., immunomodulators, biologics) to surgery are not fully explored. Decision aids have now been studied extensively and data are accumulating in favor of their efficacy. A Cochrane analysis identified over 200 patient decision aids, of which 30 were evaluated in randomized controlled trials (28). The authors of the Cochrane analysis concluded that decision aids were effective in improving patient knowledge, realistic expectations, and improving agreement between individual patient values and their choice of therapy.

Another patient communication tool is the "drug facts box," which is a simple table of side-to-side comparisons displaying outcomes of medical interventions. The drug facts box was recently studied in two randomized trials (29). Compared to a control group who received direct-to-consumer advertisements, the drug facts box improved knowledge of prescription drug benefits and side effects. Conceivably, a drug facts box could be developed for every

medication to more accurately (and clearly) communicate the existing medical literature to patients.

Improving patient communication in IBD

Decision aids and other tools are being developed to better educate patients with IBD. They will follow some general principles to improve patient communication (Table 2) (30,31). First, beware of framing. Framing relates to the presentation of statistically identical data in different ways. Malenka et al. demonstrated this nicely showing that patients clearly preferred a medication that resulted in a 34% (relative risk) reduction as opposed to an absolute risk reduction of 1.4%, although they were statistically identical (32). Others have shown similar results and a meta-analysis on this topic has been published (33). Relative risks, odds ratios and number needed to treat are typically difficult to understand and oftentimes misleading. Absolute risk is the easiest to comprehend and most fair format of presenting data.

Second, remember the limitations of numeracy. In one study, half of patients who were surveyed were unable to convert 1% to 10 per 1000, and the majority had difficulty converting 1 per 1000 to 0.1% (34). The interpretation of small numbers is difficult, which is particularly important for discussions about the risk of rare adverse events. As opposed to quoting percentages < 1.0%, presentation of these data as X out of 1,000 or 10,000 is likely to be better understood. In addition, keeping the denominator consistent when making comparisons (e.g., event per 10,000) will also improve clarity.

When possible, individualizing data and increasing active participation in the discussion may allow patients to better use information for proper decision making (35). Risk prediction tools can use available data to provide estimates on individual patient outcomes. One such tool has been developed for pediatric patients with Crohn's disease. This model has the ability to take into account patient characteristics, disease phenotype, serologic anti-microbial markers and genetic information to develop a prediction for the risk of experiencing a complication of Crohn's disease (36). The goal of this model is to allow physicians to show patients their chance of having a complication of Crohn's disease, and how this could be modified by medical treatment. It uses a simple graphical display to communicate the complex interactions between variables into a probability of developing a disease complication over a five year period. The incorporation of this model into a decision aid, which includes the clear display of treatment risks, will be a big step towards improving patient communication.

Conclusion

Due to the increasing complexity of choices for the treatment of IBD, it has become critically important to involve patients in their medical decisions. Improving mechanisms for communicating the risks versus benefits of treatment to patients will allow them to make better decisions based on their personal preferences. Decision aids and other tools are being developed to help in this process. Facilitating shared decision making is becoming an important part of health care delivery, and the care of IBD patients should be no exception.

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Figure 1.

Maximum acceptable annual risk for adverse events depending on the level of the benefit of Crohn's disease treatment. Patients were willing to accept a higher risk of adverse events in exchange for greater treatment benefit (14).

MAR = maximum acceptable risk; PML = progressive multifocal lymphadenopathy; Mild, moderate, severe relate to severity of Crohn's disease symptoms.

This figure is reproduced from Siegel CA. Communicating the risks of inflammatory bowel disease medications to patients. *Inflamm Bowel Dis Monit*;2008(3):78-83.

Table 1

Examples of preference-sensitive decisions in IBD

Preference-sensitive decisions in IBD
Early aggressive <i>versus</i> standard “step-up” treatment
Anti-TNF monotherapy <i>versus</i> combination anti-TNF + immunomodulator therapy
Infliximab <i>versus</i> adalimumab <i>versus</i> certolizumab pegol
Natalizumab <i>versus</i> 2 nd or 3 rd anti-TNF agent
Medical <i>versus</i> surgical management of limited ileal disease
Anti-TNF treatment <i>versus</i> cyclosporine for ulcerative colitis
Anti-TNF treatment or cyclosporine <i>versus</i> surgery for ulcerative colitis
Ileal pouch anal anastomosis (J-pouch) <i>versus</i> ileostomy
Colectomy for low-grade dysplasia <i>versus</i> continued surveillance

Table 2

Recommendations for the clear communication of medical data to patients

Communicating Medical Data to Patients
Beware of framing
Reports results as absolute risk
Avoid relative risks, odds ratios and number needed to treat
Report percentage < 1.0% as a fraction (0.6% = 6 per 1,000)
Present comparison data with consistent denominators (out of 1,000 or 10,000)
Individualize data when possible