

ADVANCES IN IBD

Current Developments in the Treatment of Inflammatory Bowel Disease

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Patient Decision Tools in Inflammatory Bowel Disease



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G&H What are some examples of preference-sensitive decisions for patients with inflammatory bowel disease?

CS Preference-sensitive decisions refer to decisions in which there is more than one appropriate option and in which patients can decide what is right for them based on the balance of benefits and risks. In these cases, a patient's preferences should be incorporated into the decision-making process. An example of what is not a preference-sensitive decision would be the treatment of pneumonia: a patient presents with a lobar pneumonia and is treated with antibiotics. The decision to treat the patient does not require shared decision-making between patient and physician. Consider, on the other hand, a situation in which a decision arises about whether to treat a patient with anti-tumor necrosis factor α (anti-TNF- α) monotherapy or combination therapy for Crohn's disease. Although there are data to support that combination therapy is more effective in some groups of patients, the findings are not completely clear-cut. Because we do not definitively know whether combination therapy is better than anti-TNF- α therapy in inflammatory bowel disease (IBD), clinicians should give relevant information to patients and let them decide whether they want to receive monotherapy or combination therapy.

Not all patients want to be faced with preference-sensitive disease management concerns. Many patients say, "Just get me better." They are less concerned about what it takes to accomplish this. Yet, there are others who are very cautious and give thought to the potential adverse effects (AEs) of recommended medications or else want to be as minimalistic as possible about their treatment.

G&H How are patients most efficiently counseled regarding decisions in the management of their IBD? What is their level of understanding?

CS Patients receive data on a number of different levels. On one level, they hear the specifics of the actual numerical data being presented: the percent chance of treatment response, the statistical significance of the data, and similar information. Although I think patients are very capable of understanding the statistical data, more importantly, I believe they get the gist of what is being related to them. They get the fact that there is some risk in this or that treatment option. They understand that the risk is small and that the medications under discussion can be very helpful.

Most patients can understand the data. A patient does not need to be able to repeat the numerical data back to prove that the data have been understood, but the physician should ascertain whether the patient got the gist of what he or she said. The information needs to be presented in a very straightforward patient-friendly way that provides absolute numbers. That is, the physician should relate that a treatment is associated with, for example, a 30% chance of response vs a 20% chance of response, as opposed to saying that the relative risk is 1.32 or the odds ratio is 3.23.

Some physicians are better than others when it comes to presenting research data to patients to help them make treatment decisions. I think it is a challenging task. The reasons why it is a challenging task are because physicians do not always have the data at their fingertips, they are not perfectly able to predict individual risk in relation to overall risk, and they need significant time resources to properly brief the patient.

Medical students are beginning to be better trained in how to work with patients about treatment decisions. Research, which I am involved in, is also being conducted to develop tools to help doctors with this part of their practice. We in the Dartmouth-Hitchcock IBD Center have developed 2 different tools. One is a Web-based decision aid produced in collaboration with Emmi Solutions, a patient engagement communications company. The program is a 25-minute video that goes through the details, risks, and complications of Crohn's disease. Then, it goes through a careful description of the benefits and risks of all the different medication choices that we have and presents data about monotherapy vs combination therapy. The efficacy data as well as the adverse event data are presented. The video then allows patients to weigh in on what their preferences for treatment are. The video will stop at certain points and ask the patient if he or she is particularly averse to taking shots vs taking pills or has a particular concern or fear about lymphomas, for example. Then, based on the patient's responses, the physician can make certain recommendations so that treatment is matched with the patient's personal preferences.

Unfortunately, the video is not free but is a proprietary program through Emmi Solutions. A deal was recently negotiated with the Crohn's and Colitis Foundation of America (CCFA), though, so any professional member of the CCFA can get access to the video.

G&H Do persons have a different set of values when the patient is their child instead of themselves? How does this impact care?

CS How parents make decisions for their children is a very interesting topic. In studies I have conducted with colleagues, we found that parents were very willing to take high risks regarding AEs—even a 1% risk of lymphoma development—in treatment decisions concerning their children, but only if the child was quite ill. There was a direct relationship between how sick the young patients were and how much risk the parents were willing to take regarding AEs. This is a reasonable response; a parent would be willing to do almost anything to make his or child feel better.

If a child is not that symptomatically ill, then his or her parents are much more risk-averse or protective and often are reluctant to agree to put the child on medication. So, this brings up an interesting problem in relation to IBD care because we are learning that the drugs used to treat it work much better when given earlier in the disease process. That is, the medications should be given before a patient becomes very ill. Therapy needs to begin before complications of IBD develop, not after, but a parent might want to wait until his or her child appears to be "sick enough" to feel that the child now deserves to receive stronger medications.

I think our job, as clinicians, is to help not only pediatric patients and their parents but all adult patients to understand that the medical profession is much better at treating Crohn's disease if treatment begins early on, before major problems occur. It is our job, as physicians, to understand which patients are most at risk for complications so that we can appropriately select those patients who need more early intensive therapy, and we need to be able to adequately explain why to them. The patient needs to be made to understand that it is in his or her best interest to choose therapy because, even though he or she might not feel so sick at the moment, treatment will help prevent more vexing symptoms and disease progression in the future.

Prophylactic or preventative therapy is much more difficult for patients to accept than is responsive therapy when they are very sick, in my opinion. We, as a culture, need to shift our thinking about disease management from being responsive to acute disease to being proactive and preventative about disease.

G&H How best can female patients with IBD be counseled regarding concerns about family planning?

CS There is a misperception that female patients with IBD cannot have children or will have a difficult time having children—or that the medications used for IBD are not compatible with having a successful pregnancy or a healthy child. It is true that patients who are very sick do have more difficulty either getting pregnant or having a healthy baby, and those who are most at risk are those women whose disease is not well controlled when they become pregnant. They are at risk for premature delivery, low birth weight babies, and other complications; however, if their disease is well controlled, they should do quite well during pregnancy.

What is usually required is staying on those medications that resulted in good control of IBD, although the temptation for the patient is to stop all medications for fear of drug exposure to the baby. We are learning, now that we have been using immunomodulators for 40-plus years, that the rate of AEs or any genetic abnormalities in newborns is the same in persons taking and not taking these drugs. As for the anti-TNF- α agents, although a lot of concern had been associated with them, they also are appearing to be very compatible with healthy pregnancies and babies and are considered safe to take right through pregnancy.

The dose can be modified around the time of delivery, but, in general, if women are doing well regarding control of IBD symptoms while on either immunomodulators and/or anti-TNF- α drugs, we tend to keep patients on

those medications throughout pregnancy to keep them well because, as previously stated, the biggest risk factor to the baby is an unhealthy mother.

G&H Are physicians on the same page with patients regarding attitudes about risk-benefit tradeoffs? If not, how does this impact care?

CS I think that they are on the same page in the sense that they both want the most effective therapy with a minimal exposure to AEs but may not be on the same page regarding what their preferences are. I think a disconnect arises because doctors and patients do not talk to each other about their preferences. What the best treatment is might be very clear, according to the medical literature, but if it does not jive with the patient's preferences, it is going to be difficult for the patient to adhere to the therapeutic regimen.

Physicians and patients need to spend time getting on the same page early on. Even if they disagree on what the best treatment is, they should at least formulate a plan for what to do if the initial treatment plan does not work out.

G&H In addition to the Web-based program you described, are there other types of resources for patient decision-making?

CS Yes. We are currently developing another tool that helps predict who will have a severe, complicated disease course vs who will have an easier course. The tool is to be used as a shared decision-making program so that patients do not have to take a physician's word that he or she is at

risk for development of complications of Crohn's disease. Rather, the physician can provide some objective data to show a patient that, based on the individual patient's characteristics, he or she is at high or low risk, and this information can be used in the decision-making process. Information about this tool and the questions it contains were published in a review in *Gut* in March of 2012, and the research was published in the January 2011 issue of *Inflammatory Bowel Diseases*.

Dr Siegel serves as a consultant to AbbVie, Janssen, Takeda, and UCB. Along with Dartmouth-Hitchcock Medical Center, Dr Siegel has a patent pending on the Crohn's Disease Prediction Model. Dr Siegel's work is supported by AHRQ grant #5R01HS021747-02.

Suggested Reading

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