Improving Adherence in Inflammatory Bowel Disease

Inflammatory bowel disease (IBD), the broad term encompassing both ulcerative colitis (UC) and Crohn’s disease (CD), represents a chronic inflammatory condition of various elements of the colon, small bowel and, in rare cases, the upper digestive tract. Characterized by episodes of relapse and remission, these diseases are unpredictable in course, debilitating in nature, and generally require lifelong treatment. Continued disease progression over time can lead to an increase in the number and severity of disease-related complications, as well as in increased risk for the development of colorectal cancer. As with other chronic illnesses, patient adherence to a prescribed course of medical treatment is paramount in the successful management of their disease burden. Unfortunately, it has been appropriately stated that “patient noncompliance thrives wherever and whenever medical recommendations are generated” (1). “Adherence” is a term used to describe the extent to which patients follow the advice of healthcare professionals regarding their medication and disease management, and is generally interchangeable with “compliance” (2). If one takes a more analytical perspective, adherence can be considered the sum of compliance (medication consumption as directed) and persistence (the duration of time over which medication is consumed). This distinction becomes important in chronic illnesses such as IBD, particularly given the overall variation in disease severity that occurs over the course of a patient’s lifetime.

Prior to the twentieth century, adherence likely mattered little in the overall efficacy of a multitude of widely accepted treatments of the day. In fact, those who ignored their physician’s recommendations for dangerous treatments such as cupping, purging, trephening, bloodletting, and the ingestion of arsenic likely fared better for their skepticism. In modern times, however, the implications of medication non-adherence are far-reaching, including not only increased morbidity and disease-related complications, but economic and social impacts as well. This is particularly true of IBD, where prolonged periods of dis-
ease remission can lull patients into a false sense of “wellness,” tempting them to disregard adherence to the very therapies that brought them to that point. Medical recommendations, while easy to follow during the short term, can become burdensome when they are part of a lifelong strategy that may or may not prevent disease recurrence.

For at least the past three decades, low rates of patient adherence have been seen as one of the most serious problems facing medical practice (3). Approximately 50% of patients who suffer from chronic illness are not adherent to their prescribed medication regimen, and those afflicted with IBD are no exception (4). As early as 1982 van Hess and van Tongeren demonstrated that a substantial number of patients claiming compliance to sulfasalazine therapy had actually failed to take their medication as prescribed (5). More recent data suggested that only about 40% of patients were adherent with maintenance therapies for UC (6). Although duration of therapy certainly plays a role in medication compliance, adherence issues can be a problem for even short-term courses of treatment (7).

The clinical impact of non-adherence to therapy for UC has been evaluated in a number of studies, the results of which show an increased morbidity with a greater risk of symptomatic relapse, reduced quality of life, and a possible increased risk of colorectal cancer (8). Those patients with quiescent UC who failed to adhere to their prescribed 5-ASA regimen had a 61% chance of relapse, compared with just 11% among those who were compliant (6).

**PREDICTORS OF MEDICATION NON-ADHERENCE**

A number of factors play a role in non-adherence. In UC, non-adherent patients are more likely to be male (67% versus 52% in adherent patients, respectively), single (86% versus 53%), have left-sided disease as opposed to pancolitis (83% vs. 51%), or be taking four or more concomitant medications (60% versus 40%) (9). Alternately, a study examining compliance in patients with CD receiving infliximab showed a much higher compliance rate, with the majority of non-adherent patients being female gender. Other factors, including the approach and attitude of the physician, the perception of that patient, the medication side effects, prescription costs, and quiescent disease have also been linked to non-adherence (10). Furthermore, multiple daily doses of medication, undesirable routes of administration, a lack of education on the importance of maintenance, full-time employment, depression, younger age, new patient status, and shorter disease duration would intuitively seem to adversely affect patient compliance, and this has been demonstrated to hold true (2).

A study by Kane et al showed that persistence with 5-ASA treatment in UC also varied depending upon the time period being considered. A more rapid decline was noted in the acute/active phase of the disease (57% were persistent over 3 months) than in the later, chronic, possibly asymptomatic phase. Interestingly, the increasing practice of mail-order prescription refills had a deleterious effect on compliance with treatment. The authors concluded that this was related to less frequent contact with health care professionals, which has been previously shown to significantly influence persistence with UC treatment (11).

**PATIENT BARRIERS TO ADHERENCE**

Multiple studies have examined the many barriers that serve to reduce patient adherence. Foremost among these is simple forgetfulness, which was cited as a reason for non-adherence (Table 1). Other barriers include disease denial, lack of perceived benefit of treatment, physician interaction style, insufficient support/information, complicated dosing schedule, side effects or fear of side effects, and cost of prescription.
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son for non-adherence by 50% of patients in a study by Kane in 2006 (8). This form of non-compliance can be regarded as a form of illness denial, since multiple daily dosing may make patients acutely aware of their chronic illness status. When asked for other reasons for non-adherence to their prescribed regimen, 30% of patients in this same study cited too many pills while 20% stated they did not think they needed that much medication.

A useful model that has been developed for examining the barriers to patient adherence is to divide these barriers into those that are patient-related, physician related, medication-related, and cost related (Table 1) (2,8). Each of these areas offers a potential point of intervention at which patient compliance can be reinforced or improved.

Finally, it has been hypothesized that low adherence rates in IBD are secondary to a difficult adjustment process to a chronic disease (rather than the consequence), and that psychiatric intervention as a preventive liaison may prove useful (12).

IMPROVING PATIENT ADHERENCE

While achieving optimal adherence can reasonably be considered traditional goal for healthcare providers, national initiatives have mandated this as a priority. The National Quality Forum, a non-profit organization that aims to improve national healthcare, has established improving medication adherence as one of its quality measures. Specifically, this organization recommends that adherence needs to be evaluated as a vital sign, at every patient interaction with a physician or physician extender. Focused questions such as “are you taking the medication,” “how are you taking it,” and “what is the dose” should be routine (13). In addition, the Joint Commission’s Ongoing Professional Practice Evaluation (OPPE) initiative includes patient outcome and adherence data as part of its overall benchmark for credentialing and board re-certification. Finally, the fact that a specific reimbursement code is provided for focused counseling on medication adherence (V58.69 high-risk medication) belies its importance.

As mentioned, there are a variety of factors that play a role in patient adherence. These factors can be grouped into those associated with treatment, with the disease, and with the individual. Each of these areas can be targeted as potential points of intervention in which adherence can be reinforced and, if necessary, improved.

As would be expected, a key strategy for improving adherence is the establishment of a satisfactory therapeutic relationship. This should be conceptualized as a 2-way alliance between the patient and health care provider, where patients play an active role in their treatment, understand their responsibilities, and are informed on how their decisions and actions may affect the long-term course of their disease. Given the unpredictable nature of IBD, it seems reasonable that an approach that focuses on patient empowerment can provide patient’s with a small sense of control over their disease. The benefits of this approach have been demonstrated in subgroup analysis, suggesting that improvements in adherence can be realized through increased support, encouragement, and patient education (6,14).

Integral to any successful therapeutic relationship is the concept of “interval empathy” and how it relates to patient outcomes. Clinician demonstrations of empathy, which in this context can be loosely defined as the ability to understand and identify with a patient’s feelings, perspective, and paradigm, have been associated with improved patient satisfaction and adherence to treatment (15). Despite this, even after years in medical practice, expression of empathy during clinical encounters is frequently lacking, as evidenced in a study of recorded encounters between oncologists and patients during which no empathetic expression was noted in over one third of encounters with patients where it would have been appropriate (16). A more recent study showed even more dismal results, with empathy provided in only 1 out of every 10 instances where it would have otherwise been appropriate (17). By consciously making an effort to increase one’s empathy during each patient visit, patient satisfaction with the communication process and subsequently their overall adherence may be improved.

Patient education about and understanding of their disease process, treatment plan, and management goals is also important in maintaining or improving adherence. Reinforcing therapeutic goals such as increasing the chances of disease regression, decreas-
ing the chances of disease progression and reducing the risk for the development of colorectal cancer are all specific goals that should be discussed with patients early in their treatment. Providing patients with hard evidence of the effects of medication adherence such as improvement in biochemical indices of disease or photographic documentation of mucosal healing can provide tangible evidence of treatment efficacy. One may even find that reviewing such “hard target” goals with patients in advance, combined with a visual tool that pictorially illustrates where their disease lies within the overall IBD spectrum, may be helpful.

In addition to the above, excellent studies have provided specific areas to target in attempting to ensure patient adherence. Simplification of treatment using less intrusive drug delivery systems and more convenient dosing regimens have lead to improved patient adherence in the treatment of a variety of other disorders, and it seems reasonable that similar results would be found in the treatment of IBD. In fact, multiple studies have shown an association between both a lower pill burden and once daily dosing with improved patient adherence (14). Furthermore, improved efficacy, such as that seen in 5-ASA enemas when compared to oral formulations for left-sided UC, may need to be traded for improved adherence to an oral regimen. In a small pilot study of patients in this category, the overall rate of adherence to oral 5-ASA treatment was 97%, versus 87.5% with rectal 5-ASA (18). Simple management changes, such as changing from thrice or twice daily to once daily dosing of mesalamine or changing from a rectal to oral route of administration may provide dramatic results in patient satisfaction, and hence compliance. However, it must be noted that a change to once-daily dosing does carry the potential for an actual decrease in adherence if the patient misses their scheduled dose, as the patient will then miss 24 hours of therapy instead of just 8 to 12 hours had they been taking 2 or 3 doses daily.

As previously discussed, routinely questioning patient’s about their adherence has been suggested. This can be accomplished not only through a simple interview during the patient intake process, through routine pill checks, or by the use of managed care databases, where available. Each of these methods can provide the opportunity to open a dialogue between the physician and patient regarding their adherence, allowing for patient education and identifying any potential barriers that may be interfering with the patient’s ability to comply with their established treatment regimen.

One strategy provides a quick acronym for addressing compliance issues. Known as C.O.P.E., this strategy captures the essence of many of the above concepts. First, Communicate with your patient about the importance of medication adherence at every visit. Establish and nurture a therapeutic alliance based upon a respect for the patient’s beliefs and wishes, without diminishing the physician’s, so that both the physician and patient are able to proceed on the basis of reality, and not of misunderstanding, distrust, or concealment (19). Next, Obtain your patient’s commitment to therapeutic objectives. Furthermore, one should Promote emotional and psychological support. This is where the concept of “interval empathy” finds its place. Finally, Educate the patient and family about their disease process, treatment plan, and management goals. Wide varieties of educational materials are available for this purpose, and should be utilized where appropriate.

In summary, patient adherence to treatment regimens is important in the management of chronic diseases such as IBD. A variety of factors can negatively impact patient adherence, with deleterious consequences in both the short and long term. The development of a therapeutic alliance, use of “interval empathy,” and education of the patient and their family are paramount to ensuring adherence. Specific interventions such as simplification of treatment dosing schedules, altering routes of medication administration, and routinely querying the patient regarding adherence are easy management tools that may prove beneficial. Finally, the C.O.P.E. acronym captures the essence of many important strategies useful in reinforcing and achieving patient compliance.

References
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