Time Trends in Therapies and Outcomes for Adult Inflammatory Bowel Disease, Northern California, 1998–2005

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BACKGROUND & AIMS: The management of inflammatory bowel disease (IBD) has become increasingly complicated, and it is unknown whether poor outcomes (prolonged steroid use, hospitalizations, and surgery) have declined in the general population. **METHODS:** This multilevel study used computerized clinical data. The study comprised 2892 adults with Crohn's disease (CD) and 5895 with ulcerative colitis (UC) who received care at 16 medical centers within an integrated care organization in Northern California between 1998 and 2005. **RESULTS:** Time trends included (1) a shift in gastroenterology-related visits from the gastroenterology division to primary care; (2) increased use of IBD-related drugs, except for a 7% decline in use of 5-aminosalicylate in CD and no change in steroid use for CD; (3) for the prevalence of prolonged steroid exposure (120 days of continuous use), a 36% decline for CD with a 27% increase for UC; (4) declines in the hospitalization rates of 33% for CD and 29% for UC; and (5) for the surgery rate, no significant change for CD with a 50% decline for UC. **CONCLUSIONS:** Declines in prolonged steroid exposure and the hospitalization rate for CD and in the hospitalization and surgery rate for UC are encouraging; however, the increase in prolonged steroid exposure for UC merits concern and further investigation. The variability in care patterns observed in this study suggests lack of standardization of care and the opportunity to identify targets for quality improvement. These findings should stimulate research to quantify the effect of current trends in IBD management.**

Treatment of inflammatory bowel disease (IBD) is increasingly complicated.[1–3] Immunomodulators are encouraged to minimize long-term steroid exposure.[4]

Infliximab and ileal-release budesonide were recently approved.[2,5,6] Some have questioned the efficacy of 5-aminosalicylates (5-ASA) for maintenance of remission of Crohn's disease (CD),[7,8] whereas evidence for its effectiveness in ulcerative colitis (UC) has increased.[3,9] The body of randomized trials of therapeutic effectiveness has grown,[10] and safety issues have been recognized.[1,10] Physicians are challenged to stay abreast of changing treatment strategies, evidence-based guidelines, and side effects profiles. Importantly, the increasing complexity of the evidence base could lead to variation in the delivery of IBD care.

We explored variation in IBD practice patterns and outcomes over time and across medical centers in an integrated health plan to gain clues about variation in treatment stemming from physician culture and organizational differences across time and location. When variation results in underuse, overuse, or inappropriate use of therapy, it may be possible to improve outcomes by improving the process of care.

Materials and Methods

Setting

This multilevel study was conducted among 3.2 million members of Kaiser Permanente, Northern California. Kaiser Permanente is unlike most other health care providers in the United States in that care is prepaid, comprehensive, and integrated, without intermediating insurance companies. Physicians are partners or employees of The Permanente Medical Group. A medical center campus includes a hospital, outpatient clinics, a laboratory, diagnostic services, and pharmacies. Each medical center has its own division of gastroenterology. Five of

the 16 medical centers examined for this study have a colorectal surgeon on staff. The membership has been well characterized for research studies. Members receive care at ≥ 1 of the medical centers of their choosing, generally those nearest their home and work. Referral to gastroenterology is through the primary care provider. Patients typically are hospitalized at the same medical center at which they receive their usual care, although they may be referred across medical centers if, for example, a colorectal surgeon is needed. Specialty IBD clinics do not exist, and no practice guideline for IBD has been promoted. No referral systems are in place for IBD. The pharmacy directors and not clinicians interact with pharmacy representatives, as laid out in contract provisions enforced through financial penalties. According to the health plan's rules, only specialists and not primary care providers can prescribe infliximab. The other drugs used to treat IBD can be prescribed, and their regimens modified, by primary care providers. We are not aware of any other pressures on treatment decision making that are relevant to this study.

Study Design and Population

For the multilevel study, time period and medical center were treated cross sectionally at the higher level, and patient-level variables were treated longitudinally at the lower level.

CD was defined as ≥ 2 diagnoses for CD (International Classification of Diseases Version 9[ICD-9] CM 555) and no diagnosis for UC (ICD-9 CM 556) in computerized inpatient and outpatient data during 1996–2005; the converse definition was used for UC. Patients were identified on the date of the first computerized diagnosis. Patients aged 18–89 years on January 1, 1996, were included. Twelve or more months of membership during 1996–2005 were required. For UC, we further excluded the 2% (n = 128) of patients with a colectomy before the start of follow-up. From a previous validation study using chart review, we determined the positive predictive value of this case definition to be 95% (95% confidence interval [CI], 94%–96%) for any IBD, 88% (96% CI, 86%–90%) for CD specifically, and 95% (95% CI, 94%–96%) for UC specifically. Although patients were identified starting on January 1, 1996, observation began on January 1, 1998. The 2-year run-in period (1996–1997) was necessary to identify patients with mild disease; without this requirement, sicker patients would have been overrepresented in the earliest years of the study.

Data Collection

Patient-level information was obtained from computerized clinical databases to estimate proportions and rates across four 2-year time windows (1998–1999, 2000–2001, 2002–2003, and 2004–2005) and 16 medical centers.

Independent variables. Age, sex, and enrollment history were obtained from membership files. The health plan does not ask potential members for their race or ethnicity; however, this information is available from the health plan's satisfaction surveys, 2 large-scale self-administered surveys, mortality data, and hospitalization data. We used these sources in this order so that self-reported information was given precedence over provider-recorded information. We adjusted our analyses for comorbidity with the use of the Charlson comorbidity index, Deyo et al[11] modification, being diagnoses recorded during the 12-month period preceding the first recorded IBD diagnosis. Age was recomputed for each 2-year time window.

For a previous study, chart review had been performed for random subsets of 491 patients with CD and 935 patients with UC,[12] for whom maximal extent of disease and disease behavior (for CD) were ascertained as of December 31, 2002.

The health plan assigns each patient to a home medical center based on the location of their primary care visits or, if there are none, on their residential address. However, patients face no barrier in using whichever medical center they choose. For this study, we linked patients to their home medical center in each 2-year window, so that patients could change medical center from one 2-year period to the next. We defined outmigration as the proportion of patients at each home medical center who received their IBD care at another medical center; in-migration was defined as the proportion of patients at each medical center who were treated for IBD at that medical center but whose home center was elsewhere.

We ascertained all outpatient visits to primary care for which the primary reason for the visit was coded as CD (ICD-9 code 555) or UC (ICD-9 code 556). We ascertained all outpatient visits to gastroenterology for which the primary reason for the visit was CD or UC (81%), noninfectious gastroenteritis and colitis (ICD-9 code 558; 7%), abdominal symptoms (ICD-9 code 789; 3%), symptoms involving the digestive system (ICD-9 code 787; 2%), other disorders of the intestine (ICD-9 code 569; 2%), functional digestive disorders (ICD-9 code 564; 2%), and other diseases of the gastrointestinal system (ICD-9 codes 520–579; 3%). The visit rate was computed as the number of visits in the 2-year window divided by the patients' enrollment time during that window. For subanalyses, we dichotomized visits to gastroenterology as any versus none, and we ascertained all outpatient visits to primary care for any reason. Reason-for-visit information was recorded by the provider at the time of the visit with the use of a diagnosis code, with 1.3% of visits to gastroenterology not having a reason for visit; these visits were excluded.

For each medical center and 2-year time window, we estimated from computerized pharmacy data the days-