



Impact of a patient-support program on mesalamine adherence in patients with ulcerative colitis — A prospective study[☆]

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KEYWORDS

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Abstract

Background: Patient adherence to medications, particularly mesalamine, is reported to be low in patients with ulcerative colitis. We sought to determine whether a nurse-delivered patient-support program could improve medication adherence in these patients.

Methods: Patients prescribed mesalamine for ulcerative colitis prospectively received either a 23 week, nurse-delivered, patient support program (PSP) by phone, or standard care (SC). Medication adherence and quality of life were measured before and at 3 and 6 months after the program started.

Results: Eighty-one patients completed the study; 60 who received standard care, and 21 who received the PSP. Patients were in remission (mean SCAI score 3) at enrollment. Mean % of prescribed mesalamine refilled was 71% and 74% in the SC and PSP groups at 3 months ($p=0.7$), and 73% and 84% at 6 months ($p=0.4$). The proportion of adherent patients at 3 months (39% vs 44%, $p=0.7$) and 6 months (50% vs 67%, $p=0.3$) were similar between the SC and PSP groups. There was no association between use of the PSP and adherence at 3 (OR 1.2, 95% CI 0.4 to 3.8) or 6 months (OR 2, 95% CI 0.6 to 7). The change from baseline in SIBDQ scores were similar between SC and PSP groups at 3 months (+0.3 vs +0.2, $p=0.8$), and 6 months (+0.6 vs +0.2, $p=0.2$).

Conclusions: This nurse-delivered patient-support program did not significantly improve medication adherence or quality-of-life beyond standard care at short and medium-term time-points. Simply discussing and measuring adherence improved mesalamine adherence in both groups in this study.

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Abbreviations: PSP, Patient-Support Program; SC, Standard Care; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; SCAI, Simple Colitis Activity Index.

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1. Background

Ulcerative colitis (UC) is a chronic disease of the colon characterized by periods of disease relapse and remission, and thus requires life-long treatment. Mesalamine is an effective medication for induction and maintenance of remission in this condition, and is a standard first-line agent.¹ Despite this, a significant proportion of patients do not adhere to the prescribed interval and dose regimen of mesalamine, especially those whose disease is inactive.² Most patients report that the reasons for their non-adherence are involuntary e.g. they forget to take the pills, rather than intentional.³ Other factors that have been associated with non-adherence include male gender, full-time employment, and multiple dosing schedules.^{2,4,5} It is unclear whether newer single daily dosing formulations of mesalamine will improve adherence rates.⁶

Non-adherence to mesalamine has negative implications for patients and the healthcare system. The risk of disease recurrence is 5 times higher in patients who are non-adherent to maintenance mesalamine compared to adherent patients.³ Since chronic inflammation is a risk factor for colorectal cancer development, this may also influence cancer risk. The crude proportions of patients developing colorectal cancer are 10-fold higher in patients deemed to be non-adherent with sulfasalazine, when compared to patients adherent to maintenance therapy.⁷ Finally, patients who are non-adherent with 5-aminosalicylic acid agents (5-ASAs) have higher healthcare costs than adherent patients for in-patient, out-patient and office visit services.⁸

Strategies to improve patient adherence, such as behavioral interventions and monitoring and feedback, have been studied in other chronic illnesses with mixed results.⁹ Individualized care by telephone was shown to significantly improve medication adherence in a large cohort of diabetics.¹⁰ However, phone calls from store-based pharmacists was not shown to improve persistence of prescription refills for chronic diseases beyond standard care.¹¹

There are few published data on interventions to improve mesalamine adherence in UC. An interventional strategy to minimize mesalamine dosing schedules did not significantly improve 6-month adherence rates in a small study of 22 patients.⁶ Whether behavioral interventions can improve mesalamine adherence in these patients is unknown. Monitoring and feedback interventions have not been studied in mesalamine adherence to date. The objective of this study was to determine whether a patient-support program over 23 weeks would improve mesalamine adherence at 3 and 6 months in patients with ulcerative colitis.

2. Methods

2.1. Patient enrollment

Patients with ulcerative colitis in remission (for at least 2 months) who were prescribed delayed-release mesalamine (Asacol, Proctor & Gamble, Ohio) were eligible for enrollment. Informed consent was obtained according to a study protocol approved by the local Committee on Clinical Investigations (BIDMC Protocol 2007P000083). Patient demographics and disease geography and pharmacy contact details were obtained after enrollment. A baseline Short Inflammation

tory Bowel Disease Questionnaire (SIBDQ) score, and Simple Colitis Activity Index score (SCAI) were obtained. Both scoring systems have been developed for patients with ulcerative colitis.^{12,13}

2.2. Interventions

The first 44 patients were randomized by computer-generated random numbers to receive the PSP or SC during a period of 6 months. After the PSP was discontinued by the sponsor, a further 37 patients were sequentially enrolled into the SC arm. Patients in the standard care group (SC) continued to receive standard follow-up and medication refills as was their physicians' practice. All patients received information about the purpose of the study from the study coordinator, and signed a consent form. Patients in the Patient Support Program (PSP) group were enrolled in *ScriptAssist* (CenCorp Health Solutions, St Louis, MO) an independent treatment adherence program that provides disease-specific information and promotion of medication adherence to patients. Each patient in the PSP group received phone calls from a nurse at 24 h, 3 weeks, 7 weeks, 15 weeks and 23 weeks after enrollment (5 calls in total). The nurses are trained to assess patient risk for noncompliance and intervene with psychological techniques that improve patient medication persistence. A log of each phone conversation was faxed to the treating physician to ensure completion of planned interactions. The nurses involved were blinded to the fact that these patients were enrolled in a study to assess adherence. All patients were enrolled from the clinics of 3 physicians (AM, KF, AC) with an interest in IBD, with similar patient management practices.

2.3. Outcomes

Each patient enrolled had their SCAI and SIBDQ measured at enrollment. At 3 and 6 months SIBDQ, medication adherence, number of hospitalizations, and number of disease flares were recorded. Medication adherence was calculated based on refill data from pharmacies according to Steiner's formula.¹⁴ Only patients with adherence >80% of the time at 3 and 6 months were considered to be "adherent", as defined in prior studies of mesalamine adherence.² This method is considered to provide superior adherence information than patient reporting. "Number of hospitalizations" was based on discharge summaries for ulcerative colitis diagnoses. "Number of disease flares" was based on reports in electronic medical records of treatment intensification or adjustment due to clinical symptoms of active ulcerative colitis. All follow-up outcomes were recorded and analyzed by an investigator blinded to the intervention group.

2.4. Statistical analysis

In total, 21 patients took part on the PSP, and formed the PSP cohort. A further 60 patients were prospectively enrolled who received SC over the same 6 month timeline.

In order to determine the power of the study with these numbers, the average adherence effect size for "reminder and support" interventions was found to be $r=0.3$ from prior studies.^{15,16} Power analysis revealed that with 21 patients in

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