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Original Article

Providing Hospitalized Ulcerative Colitis Patients With Practice Guidelines Improves Patient-Reported Outcomes

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Abstract

Background and aims: Variation in care has been demonstrated among hospitalized patients with ulcerative colitis. Guidelines aim to reduce variation; however, it is known that the uptake of guidelines by physicians is variable. Providing patients with guidelines is a strategy that has not been extensively studied in inflammatory bowel disease (IBD). Our aim was to evaluate the impact of a patient-directed educational intervention that included treatment guidelines among hospitalized ulcerative colitis patients.

Methods: We performed a quality improvement, cluster-randomized trial at seven tertiary IBD centres. Sites were randomized to implement an educational intervention or standard care for a 6-month period between January 2017 and January 2018. The educational intervention consisted of a patient-directed video that provided a summary of inpatient management guidelines for ulcerative colitis. Primary outcome measures included the length of stay and colectomy at discharge and 6 months. Patient-reported outcomes included trust in physician and patient satisfaction at discharge and at 6 months.

Results: Ninety-one patients were enrolled. No statistically significant differences in length of stay or colectomy were noted. Patients who received the intervention had higher trust in physician as measured by Trust in Physician Score at discharge (69.5 vs. 62.6, $P = 0.028$) and at 6 months (77.7 vs. 68, $P = 0.008$). Patient satisfaction as measured by the CACHE questionnaire in the intervention group was higher at discharge (72.8 vs. 67.1, $P = 0.04$); however, this difference was not sustained.

Conclusion: Empowering patients with guidelines through an educational intervention resulted in differences in trust in physician and patient satisfaction. Further studies are needed for evaluating a strategy of engaging IBD patients to take a more active role in their care. (clinicaltrials.gov, NCT02569333).

Keywords: *Compliance/Adherence; Guidelines; Inflammatory bowel disease; Ulcerative colitis*

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INTRODUCTION

The literature has revealed significant variation in care among hospitalized ulcerative colitis (UC) patients (1,2). These patients are at increased risk of a variety of complications, such as infections, venous thrombosis and surgery (3–7). Variation in care is considered a surrogate of suboptimal care delivery with regard to the quality of care in the management of patients with chronic disease (8). The development of practice guidelines aims to help providers improve the quality of care and reduce variation. However, it is well established that the uptake of and adherence to guidelines are variable. Christensen et al. (9) surveyed 53 gastroenterologists regarding knowledge of guidelines. While most surveyed knew guidelines existed, the majority cited forgetfulness on the content of the guidelines or insufficient time to consult the guideline as major barriers toward implementing guidelines. Therefore, there is a need for more innovative ways to disseminate and improve guideline uptake. Engaging patients and providing them with education about best practices is one strategy that may overcome some of these barriers. Moreover, active participation in care has been shown to be important and helpful to individuals with chronic diseases such as inflammatory bowel disease (IBD) (10,11). The impact of patient education interventions has not been extensively evaluated in hospitalized patients with UC. Therefore, we performed a multi-site quality improvement, cluster-randomized control trial evaluating the impact of providing hospitalized UC patients with the practice guidelines for hospitalized patients with UC through an educational intervention.

MATERIALS AND METHODS

Study Population

In this multi-centred quality improvement study, we performed a cluster-randomized trial at seven tertiary IBD centres across Canada who were part of CINERGI (Canadian IBD Network for Research and Growth in Quality Improvement). All patients with a known diagnosis of UC admitted to hospital for an acute disease flare from January 2017 to January 2018 were approached to participate. All hospital admissions were scanned daily on weekdays by research staff to identify potential enrollees, and suitable participants were approached to participate in the study. Patients with Crohn's disease and those unable to provide informed consent were excluded. Only the first UC flare hospitalization during the study period was included for each patient.

Study Design

Sites were cluster randomized to implement either an educational intervention (described below) or standard care (control group) for a 6-month period. Computer-generated randomization was performed centrally. Patients admitted with a UC flare within a specific 6-month time period were allocated to the intervention designated for that time cluster. At the end of the 6-month time period, sites that had been randomized to the intervention group would then return to usual care or vice versa. Therefore, the total duration of the study was 12 months.

Intervention

Within the first 24 hours of admission (or 48 hours if admission occurred over the weekend), subjects in the intervention arm were provided with an iPad containing specific patient-directed educational material regarding the optimal in-hospital management of acute severe UC. The educational material consisted of an original, interactive video that provided a summary of the 2012 Canadian consensus statements on the treatment of hospitalized adult patients with severe UC (12), presented using patient-friendly languages and images. The video included a description of what the patient should expect to occur each hospital day, information on preventable hospital-acquired complications, including venous thrombotic event (VTE), and general information on UC therapies that may be used during the hospitalization, including corticosteroids and biologics. Subjects could access the educational material on demand throughout the hospital admission.

Outcomes of Interest

Overall length of stay, the development of hospital-acquired VTE and the occurrence of colectomy were recorded. We also assessed adherence to quality indicators for patients hospitalized with acute, severe UC including time to initiation of rescue medical therapy (mean ± SD), prescription and administration of VTE prophylaxis, tuberculosis (TB) skin testing at admission, flexible sigmoidoscopy within 72 hours of admission and *Clostridium difficile* testing at admission.

At discharge, all subjects completed questionnaires and again at 6 months after discharge to assess trust in physician as measured by the Trust in Physician Scale (TIPS) (13), patient satisfaction as measured by the CACHE questionnaire (14) and anxiety and depression as measured by the hospital anxiety and depression score (HADS) (15). The TIPS score is a validated scale consisting of 11 items, each scored on a scale of 1 to 5 and then combined for a total score which is divided by 11 and multiplied by 100 to provide a range from 0 to 100 whereby the higher the value, the higher the level in trust. The CACHE questionnaire contains 31 items on a 5-point Likert scale with final scores ranging from 0 to 100 whereby the higher the number, the higher the satisfaction. The HADS scale consists of 14 questions related to anxiety and depression and a total score exceeding 11 is considered anxiety or depression.

Statistical Analysis

Analyses were performed using Stata 14.2 (College Station, Texas). Descriptive baseline characteristics, process measures and

outcomes were compared between intervention and standard of care study groups. Statistical comparisons accounted for clustering at the level of study sites. Continuous variables were compared between study groups using univariable linear regression that was performed with clustered standard errors using Stata's cluster subcommand. The use of this cluster robust variance estimator accounted for correlation of outcomes within clusters; 95% confidence intervals were calculated for continuous variables. Categorical variables were compared between study groups with a cluster-adjusted chi-square test using Stata's clchi2 command. Cluster-adjusted *P* values of <0.05 were considered statistically significant. Intracluster correlation coefficient was calculated for all the outcomes.

Ethical Consideration

The study was approved by Research Ethics at all participating sites. The study protocol was registered prior to initiating the study at clinicaltrials.gov (NCT02569333).

RESULTS

Overall, 91 subjects were enrolled into the study with 46 receiving the educational intervention arm and 45 receiving usual care (Figure 1). Four subjects at one site had incomplete follow-up data and thus full data were available for analysis in 87 subjects.

Table 1 shows the baseline demographic data and clinical characteristics of the two patient groups. There were no important differences among the two groups with regard to demographics, disease severity or medication history.

Clinical Outcomes

Fewer patients in the intervention arm underwent inpatient colectomy or colectomy at 6 months compared with the control arm; however, these differences were not statistically significant (24% vs. 11%, $P = 0.216$, 23% vs. 15% $P = 0.438$). VTE data were available on 86 patients and overall 9 patients developed a new VTE during admission (10.5%). There was no difference in the incidence of VTE between the intervention and control group (13.3% vs. 7.3%, respectively, $P = 0.77$). Mean length of stay was 9.3 (6.7) days in the intervention arm as compared with 11.3 (8.5) days in the control group, a difference that was not statistically significant ($P = 0.164$). Table 2 compares performance among a number of quality-related process measures among the two groups. Overall, there were significantly more patients in the intervention group who received a TB skin test within 48 hours of admission as compared with the control group (43% vs. 26%, $P = 0.013$). This did not defer among type of admitting services (Table 3). There was no difference in time to the initiation of medical rescue therapy, which was an anti-tumor necrosis factor at all sites, between the two groups nor any other process measures.

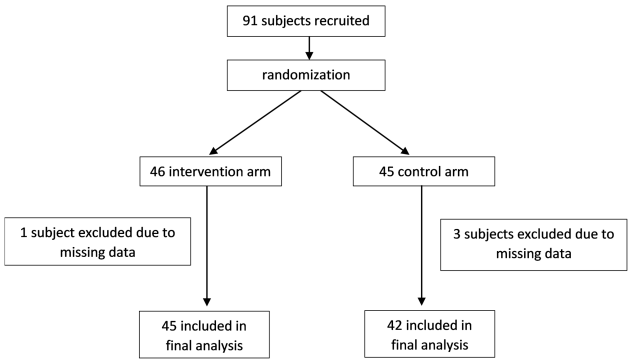

Figure 1. Flow of subjects through study.

Patient-Reported Outcomes

Patients who received the educational intervention reported higher trust in physician at discharge (69.5 vs. 62.6, $P = 0.004$) and

Table 1. Baseline demographics and clinical characteristics

	Standard of care $N = 45$ (%)	Intervention $N = 46$ (%)	*P* value
Age at diagnosis	29.4 (11.8)	26.6 (11.9)	0.41
Age at admission	35.6 (12.6)	32.1 (11.4)	0.33
Male	22 (52)	21 (47)	0.67
Site			0.41
Toronto	24 (53)	20 (43)	
Calgary	8 (18)	12 (26)	
Vancouver	5 (11)	5 (11)	
Other	8 (18)	9 (20)	
Weekend admission	6 (14)	7 (16)	0.94
Admitting service			0.89
Gastroenterology	26 (62)	33 (73)	
Internal medicine	13 (31)	10 (22)	
Surgery	3 (7)	1 (2)	
Other	0 (0)	1 (2)	
Partial Mayo Score	6.6 (1.8)	6.5 (2.0)	0.84
Disease extent			0.91
Proctitis	6 (14)	5 (12)	
Left-sided	16 (38)	18 (42)	
Extensive	20 (48)	20 (47)	
Medical therapy			
5-aminosalicylate	18 (43)	16 (36)	0.49
Steroids	21 (50)	18 (40)	0.45
Thiopurine	7 (17)	3 (7)	0.14
Anti-TNF	16 (38)	12 (27)	0.25
Admission			
Hemoglobin	115 (24)	117 (21)	0.60
Albumin	34.1 (10.8)	32.1 (6.8)	0.27
C-reactive protein	62.5 (65.1)	67.5 (67.7)	0.76

Table 2. Process measures during the study period

	Standard of care ($N = 42$)	Intervention ($N = 45$)	*P* value	Intracluster correlation coefficient
VTE prophylaxis ordered			0.86	0.427
Not done	7 (17)	15 (33)		
Within 48 hr	28 (68)	27 (60)		
48 hr	6 (15)	3 (7)		
VTE prophylaxis administered			0.42	0.000
Not done	1 (3)	0 (0)		
Within 48 hr	27 (79)	27 (90)		
After 48 hr	6 (18)	3 (10)		
C. difficile testing			0.64	0.013
Not done	2 (5)	3 (6)		
Within 48 hr	39 (93)	42 (93)		
After 48 hr	1 (2)	0 (0)		
Flexible sigmoidoscopy			0.41	0.000
Not done	5 (12)	10(22)		
Within 48 hr	31 (74)	28 (62)		
After 48 hr	6 (14)	7 (16)		
Cytomegalovirus biopsies during flexible sigmoidoscopy			0.52	0.158
Not done	2 (5)	0 (0)		
Done	35 (95)	35 (100)		
TB skin testing			0.13	0.000
Not done	18 (43)	22 (50)		
Within 48 hr	11 (26)	19 (43)		
After 48 hr	13 (31)	3 (7)		
Hepatitis B serology			0.44	0.063
Not done	17 (40)	12 (27)		
Within 48 hr	20 (48)	31 (69)		
After 48 hr	5 (12)	2 (4)		

Table 3. TB testing stratified by type of admitting service

	Gastroenterology ($N = 58$)	Medicine ($N = 23$)	*P* value
TB skin testing			0.07
Not done	27 (47)	9 (39)	
Within 48 hr	24 (41)	6 (26)	
After 48 hr	7 (12)	8 (35)	

this was sustained at 6 months (77.7 vs. 68.0, $P = 0.001$) (Table 4). Patient satisfaction in the education intervention group was higher at discharge (72.8 vs. 67.1, $P = 0.018$); however, this difference was not sustained after 6 months of follow-up (69.3 vs. 65.6, $P = 0.212$). No differences were seen in anxiety or depression.

DISCUSSION

In this multi-site quality improvement study, we have demonstrated improvements in patient satisfaction and sustained improvements in trust in physician using an educational intervention based on Canadian guidelines for the hospital management of UC. Improvements in clinical outcomes were also noted, including a higher proportion of patients undergoing TB skin testing within 48 hours of admission. These results suggest that empowering patients to take a more active role in their care through providing educational materials can lead to meaningful improvements in patient outcomes. To our knowledge, this is among the first studies to evaluate providing guidelines to hospitalized patients with UC. However, in the field of infection control, providing patients with education about the importance of hand hygiene and empowering patients with the confidence to ask their health care provider if they washed their hands led to sustained improvements in handwashing behaviours. McGuckin et al. (16) showed that hand hygiene compliance increased by 94% during the intervention period when inpatients were educated on the importance of hand hygiene and told to ask their providers if they washed their hands. Moreover, there was a sustained 40% increase in hand hygiene behaviours 3 months after the completion of the intervention. Similarly, Davis et al. (17) showed that educational

Table 4. Patient-reported outcomes at discharge and 6 months after discharge

	Standard of care	Intervention	*P* value	Difference (95% CI)	Intracluster correlation coefficient
Trust in Physician Scale (SD)					
During admission	62.6 (14.8)	69.5 (15.0)	0.004	6.9 (3.1, 10.8)	0.080
6 months	68.0 (13.9)	77.7 (9.2)	0.001	9.7 (6.2, 13,2)	0.229
Global CACHE score (SD) (Patient satisfaction)					
During admission	67.1 (14.6)	72.8 (11.3)	0.018	5.6 (1.3, 10.0)	0.067
6 months	65.6 (12.0)	69.3 (13.8)	0.212	3,7 (−3.0, 10.5)	<0.001
HADS Scale (SD) (Anxiety and depression)					
During admission	8.5 (4.6)	7.5 (4.3)	0.284	−1.0 (−2.9, 1.0)	0.002
6 months	8.5 (4.6)	8.1 (4.3)	0.638	−0.4 (−2.3, 1.5)	<0.001
Length of stay (days) (SD)	11.3 (8.5)	9.3 (6.7)	0.164	−2.0 (−5.0, 1.0)	0.011
Inpatient colectomy	10 (24)	5 (11)	0.216	n/a	0.022
Colectomy at 6 months	6 (23)	5 (15)	0.438	n/a	<0.001
Readmission at 6 months	8 (31)	11 (38)	0.744	n/a	0.080

patient videos are an effective method to convey patient education materials and promote an attitude toward asking providers about their behaviours and management.

In our study, education and awareness of a guideline-based management strategy may have led to a greater sense of control in management, engagement in the care process and understanding of the overall management plan which translated to the observed improvements in trust in physician and satisfaction. The sustained difference in trust in physician suggests that the education process and awareness of the management plan were impactful on the physician–patient alliance that continued as care transitioned to the ambulatory setting. We also noted improvements in a number of clinical outcomes. There was a trend toward a shorter mean length of hospital stay in the intervention arm by 2 days. While this was not statistically significant, one explanation for this finding is that the implementation of pre-biologic workup early in admission and clear time points to assess the efficacy of intravenous corticosteroids may have contributed to a shorter stay. In fact, we did show a significant difference in the ordering of TB skin testing within 48 hours of admission in the intervention arm. This is required prior to the initiation of rescue medical therapy (e.g., anti-tumor necrosis factor) and requires 48 hours before a result can be obtained. This is often a source of delays in starting therapy as it is often ordered when the decision is made to start infliximab rather than at admission, which can, therefore, contribute to a 48-hour delay. Alternatively, it is also possible that patients had a better understanding of the direction of care and trust in physicians and, therefore, had less concerns about being discharged after partial improvement on corticosteroids to have a close outpatient follow-up to initiate further treatment, thereby contributing to shorter length of stay. Statistical differences may not have been seen in other process measures due to fairly good performance among both groups, for example, *C. difficile* testing.

Our study has several limitations. The study was underpowered to show differences in several outcomes due to the small sample size despite multiple sites enrolling subjects. As this was a quality improvement study, no power calculations were performed and all consecutive patients admitted at participating centres were recruited. There was uneven recruitment among sites with one site recruiting approximately half of the subjects. Moreover, all sites were tertiary IBD centres and community hospitals were not included. Both these may limit the generalizability of the results. Moreover, different hospitals had different admitting processes whereby some patients are cared for by gastroenterology, whereas others by internal medicine. This may have influenced the results as the most responsible physician type has been shown to influence the outcomes (18). Another important limitation to consider is an order effect. It is possible that health care providers who work at a centre that was assigned to the intervention arm first may have contaminated the results in the control phase because they may have learned from the patients as a result of the educational tool. However, the focus of the intervention was the patient and not the provider, and most providers were unaware of the specific content of the educational intervention provided to the patients. Therefore, the impact on health care provider behaviour would not be expected to be significant but certainly may have affected the results and, therefore, is an important limitation to consider. Finally, while we attempted to capture all patients, it is likely that many potentially eligible patients, particularly those admitted on the weekend, were missed.

In summary, in this multi-centred national quality improvement study, empowering patients with practice guidelines about their disease through an educational intervention resulted in important differences in patient-reported outcomes, including trust in physician and patient satisfaction. Studies of post-discharge quality initiatives that build on inpatient efforts will be important to assess if these results can be sustained in the ambulatory setting. Moreover, larger studies that include multiple practice settings including both community and tertiary hospitals are needed to further explore patient empowerment and the impact of patient education on outcomes.

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Authors Contributions

Guarantor of the article: A.V.W.

Specific author contributions: A.V.W. and G.C.N. conceived and designed the study. A.V.W., B.B., C.H.S., W.A., N.M.A., L.T., J.L.J., V.H., S.K.M. and G.C.N. all contributed to data acquisition. A.V.W., G.C.N., D.H.N. and N.M.A. analyzed the data. All authors have been involved in drafting the article and revising it critically for important intellectual content and provided final approval of the version to be submitted. All authors approved the final version of the article, including the authorship list. The manuscript has not previously been previously published and is not under consideration elsewhere.

Conflict of Interest

A.V.W. has served as an advisory board member for Abbvie, Janssen, Takeda, Ferring and as a speaker for Abbvie, Janssen, Takeda, Ferring, Pfizer; B.B. has served as an advisory board member and speaker for Ferring, Janssen, Abbvie, Takeda, Pfizer, Novartis, Merck, an advisory board member for Robarts Clinical Trials, Celgene, Microbiome Insights, Merck, Amgen, Pendopharm, Genentech, BMS, Allergan, Protagonist and has received research support from Janssen, Abbvie, GSK, BMS, Amgen, Genentech, Merck, BI, Qu Biologic, Celgene, Alvine. He owns stock options in Qu Biologic; C.H.S. has served as an advisory board member for Janssen, Abbvie, Takeda, Ferring, Shire, Pfizer and as a speaker for Janssen, Abbvie, Takeda, Ferring, Shire, Pfizer; W.A. has served as an advisory board member for Janssen, Abbvie, Takeda, Merck, Pfizer and has received research support from Theradiag, Prometheus; N.M.A.: none; L.T. has served as an advisory board member for Janssen, Abbvie, Merck, Pfizer, Takeda, Mallinckrodt, as a speaker for Janssen, Takeda and has received research funding from Janssen; D.H.N.: none; J.L.J. has served as an advisory board member for Janssen, Merck, Pfizer, Abbvie, Shire, Takeda and as a speaker for Janssen, Pfizer, Abbvie, Shire, Takeda; V.H.: none; S.K.M. has served as an advisory board member for Takeda, Ferring, Shire, Abbvie and as a speaker for Ferring, Pfizer; G.C.N: none.

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