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Original Research

Effect of medication therapy management on discharged patient with Ulcerative Colitis with initial stage biotherapy: a randomized study

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Abstract

Purpose: The aim of this study was to explore the effects of medication therapy management in improving perception, medication adherence, and disease control in UC patients with first-stage of biotherapy. Subjects and Methods: A total of 120 patients with UC who received first-stage biotherapy participated in this study. The patients were divided into MTM group and CFU group. Both groups received three times follow-up, which were carried out at first, third, and sixth discharged month, Group A was followed with the MTM method, and Group B received conventional follow-up. MDRKT was used to assess patient perception, adherence to treatment was assessed by MMSA-8, and we also explored disease control and patient satisfaction. Results: A total of 116 patients completed the survey, the MTM group showed a significant improvement in perception, 84.2% of patients can correctly handle ADEs and 82.5% of patients knew what to do when they leak medication, 87.8% of patients in the MTM group had better adherence than 71.2% in the CFU group (P<0.05). The evaluation of disease control showed that 56.1% of patients in the Group A were in remission which was significantly higher than 32.2% in the Group B (P<0.05). Furthermore, the result of the questionnaire survey showed that perception, ADE, self-management, anxiety, and satisfaction were better in the MTM group than in the CFU group (P<0.05). Conclusion: The MTM group was effective in improving medication adherence, perception, and satisfaction in the patient with ulcerative colitis treated with first-stage biotherapy, and the disease control significantly improved.

Keywords: Medication therapy management (MTM); Ulcerative Colitis (UC); first-stage; biotherapy; adherence

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INTRODUCTION

Ulcerative colitis (UC) is a chronic inflammatory bowel disease that affects any aspect of the colon, starting with mucosal inflammation in the rectum and extending proximally continuously.[1] It is one of the two major forms of intestine inflammation that could be classified from mild to severe,[2,3] most cases are treated with medication therapy to induce remission and then maintain corticosteroids-free remission. There are multiple therapeutic drugs, from conventional 5-aminosalycilates, thiopurines, and corticosteroids to a variety of new monoclonal antibody drugs, including targeting tumor necrosis factor, integrins, and small-molecule Janus kinase inhibitors for UC.[4] However, medication adherence for discharged patients remains low with the application of biological agents, especially in the initial stage of biologic

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agent injection,[5,6] a study reported that 14% of recently discharged patients experienced a medication discrepancy,[7] and in another study of discharged medication discrepancies reported that more than 40% of patients experienced at least one unintentional medication discrepancy.[8]

The core elements of Medication Therapy Management (MTM) include review of medication therapy, a personal medication record, a medication-related action plan, intervention or referral, documentation, and follow-up.[9] The MTM service has obvious advantages in reducing the incidence of adverse drug effects and focusing on patient care and cognitive services,[10, 11] and patients could be educated on how to properly use the medicines for their specific ailment. which increase patient adherence and satisfaction,[12,13] MTM interventions have shown improvement in medication adherence and cardiovascular disease (CVD) risk factor controls.[14,15] However, there is no report of whether MTM could help UC patients improve their adherence to medications.

The purpose of this study is to explore that the patient with UC in the initial stage of biotherapy could receive expected therapeutic results from the prescribed medications through the application of MTM, as well as to guide the patient to use the drugs correctly, reduce the occurrence of unexpected events, and improve therapeutic effect by increasing patient cognition, compliance, and satisfaction.

MATERIAL AND METHODS

Material

The participants were between the ages of 18 and 80, a total of 120 UC discharged patients met the inclusion criteria were involved in the study. The inclusion criteria were chosen as we anticipated that patients with mild to moderate remaining symptoms received the first-stage of biologic agent therapy, patients discharged from the hospital and needed to be maintained with medication, patients or their family members have normal communication and understanding ability and can fill out the questionnaire. All eligible subjects who were scheduled in regular medical treatment from April 1, 2022, to June 31, 2022, were consecutively invited to participate. The participants were divided into two groups, Group A was managed with the MTM method and Group B was managed with the CFU method. During the follow up, pharmacist and nurse conducted the intervention, and the research assistant evaluated medication adherence, patient perception, disease control and the satisfaction, the variables were collected from medical records and follow up system, which was a prospective, single-blind study.

Methods

Study design and period

This single-center, single-blind, randomized controlled trial focused on continuous care from the hospital setting to the home setting. Randomization was computer-generated, allocation was concealed by opaque, sequentially numbered sealed envelopes. Study period was from July 1, 2022, to December 31, 2022. The medication history was obtained through the hospital information system, and the current medication therapy management plan was sent through the cloud follow-up system and recorded in the medication treatment files. Both groups were diagnosed and treated by doctors, patients received the first-stage of biotherapy and needed drug administration after discharge. Group A was conducted with MTM service and Group B was conducted with CFU telehealth follow-up after the patient discharged 1 month, 3 months, and 6 months. The effect of the intervention was evaluated after 6 months of biotherapy, a brief questionnaire was completed at each follow up, the types and frequency of interventions were documented within the cloud follow-up system. The study protocol was approved by the Ethics Committee of the Sixth Affiliated Hospital of Sun Yat-sen University.

MTM follow-up

The medication and self-management plan were made and sent through the cloud follow-up system, the pharmacist talked about the curative effect and possible adverse reaction with the patient and discussed with the doctor to provide medical suggestions according to the characteristics of the patient's condition. Pharmacists also popularized the knowledge of UC and diet characteristics during the follow-up period, encouraged the patient to participate in lectures and patient associations, communicated and shared with others. The MTM method was carried out mainly through the cloud follow-up platform by the pharmacist after the patient discharged 1 month, 3 months, and 6 months, and some patients were communicated and informed by phone or wechat.

Conventional follow-up

Conventional follow up was carried out by the responsible nurse, the nurse explained the treatment duration, hospitalization appointment, and therapy attention by telephone after the patient discharged 1 month, 3 months, and 6 months, also explained living habits and dietary precautions, UC Health & Nutrition suggestion, and reminded the patient of the return time.

Study endpoints and other variables

The primary endpoint was the medication adherence. Secondary endpoints included the patient perception, disease control and the satisfaction of patients. Medication adherence to treatment were compared before and after the intervention, MDRKT was used to assess patient perception, and we also explored disease control and patient satisfaction.

Statistical Analysis

SPSS 22.0 software (SPSS Inc., Chicago, IL, USA) was used for data analysis. Normally distributed data are represented as the mean ± standard deviation, and the heterogeneity of the two groups was compared with a T test. The chi-square test was used to evaluate the percentage and difference between the two groups, and the Kruskal–Wallis test was used to compare the categorical data. Values of $p<0.05$ were considered statistically significant.

RESULTS

Demographics of the patients in the study

A total of 136 patients were eligible, 116 patients completed the survey among 120 participants met the inclusion criteria who were discharged from the sixth affiliated hospital of Sun Yat-sen University from July 1, 2022 to December 31, 2022, with 57 participants assigned to Group A (38 men, 19 women) and 59 participants assigned to Group B (33 men, 26 women) (shown in Figure 1). Group A was carried out with the MTM method and Group B was carried out with the CFU method, the patients were volunteered to participate, the mean age of the patients ranged from 34.3±2.7 to 31.2±2.4. There were no significant differences between the two groups in terms of age, education background, marriage, income, and degree of disease (P>0.05; shown in Table 1).

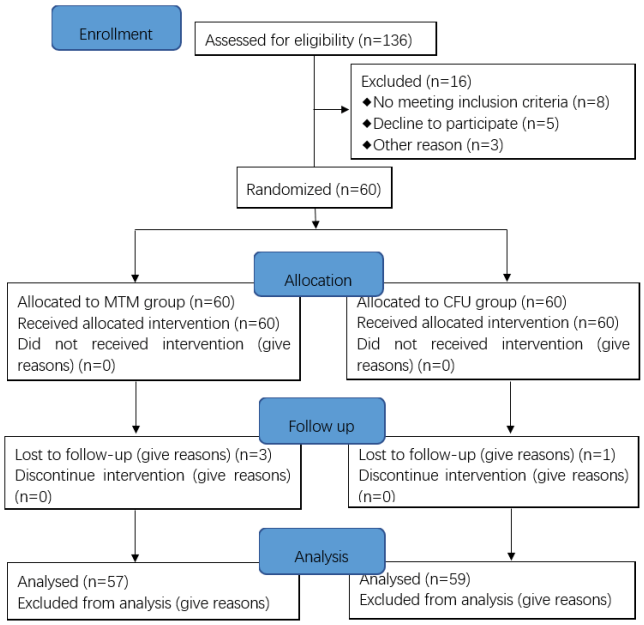

Figure 1. CONSORT 2010 flow diagram

Table 1. Demographics of all the participants

Characteristic	Group A(n=57)	Group B (n=59)	P value
Age (years ± SD)	34.3±2.7	31.2±2.4	0.87
Gender			0.239
Female	38 (66.7%)	33 (55.9%)	
Male	19 (33.3%)	26 (44.1%)	
Education level			0.761
Middle school and below	9 (15.8%)	8 (13.6%)	
Higher vocational education	22 (38.6%)	23 (39.0%)	
Junior college or above	26 (45.6%)	28 (47.4%)	
Marriage			0.476
Unmarried/divorced/ widowed	25 (43.9%)	22 (37.3%)	
Married	32 (56.1%)	37 (62.7%)	
Monthly per capita income (¥, yuan)			0.697
<2,000	1 (1.8%)	3 (5.1%)	
2,000–3,499	22 (38.6%)	18 (30.5%)	
3,500–4,999	11 (19.3%)	19 (32.2%)	
≥5,000	23 (40.3%)	19 (32.2%)	
Degree of disease			0.598
Mild	41 (71.9%)	45 (76.3%)	
Moderate	16 (28.1%)	14 (23.7%)	

a, independent samples t-test; b, Chi-square test.

Comparison of Medication or disease related knowledge test (MDRKT) results between the two Groups

To collect information on UC-related knowledge from participants, the Medication or Disease-Related Knowledge Test (MDRKT) section of the questionnaire was developed based on medication treatment management. Perception of the patient based on diagnostic criteria, therapy session, indication and use of medications, side effects, warning signs, and risk factors. According to the self-report, there were no significant differences between two groups before the intervention, the MTM group had a better feedback compared to the CFU group after the intervention, among which 89.5% of the 57 respondents were clear about diagnostic criteria, therapy session compared to 72.8% in the CFU group, 94.7% understand the purpose of the medication compared to 71.2% in the CFU group, and 93.0% know the proper usage compared to 66.1% in the CFU group. Regarding side effects and warning signs, participants in the MTM group correctly responded with 86.0% and 80.7% compared to 71.2% and 59.3% in the CFU group. If patients in Group A encountered problems with their medication, 84.2% reported that they can correctly handle ADE in their treatment plans, 82.5% reported that they know what to do when they leak medication and 93.0% certain about serious hazards and risk factors, while 54.2% reported that they can correctly handle ADE in their treatment plans, and 44.1% reported that they know what to do when they leak medication, 59.3% certain about serious hazards and risk factors in Group B (P<0.05; shown in Figure 2).

Comparison self-reported adherence between the two groups

The Morisky Medication Adherence Scale (MMAS-8) was used to evaluate the degree of adherence to medications, the survey included an anonymous questionnaire.[16] For our 116 respondents, 36 patients (63.2%) in the MTM group had a high adherence score that was significantly higher than 22 patients (37.3%) in the CFU group, and 12.2% of the patients in the MTM group had a lower adherence score compared to 28.8% of the patients in the CFU group, respectively (t=2.989, P<0.05; shown in Table 2).

Comparison of disease control between the two groups

The Mayo score disease activity index (DAI) was used to assess the degree of UC, which was originally developed in 1987 during a clinical trial by Schroder.[17] There are four elements in the

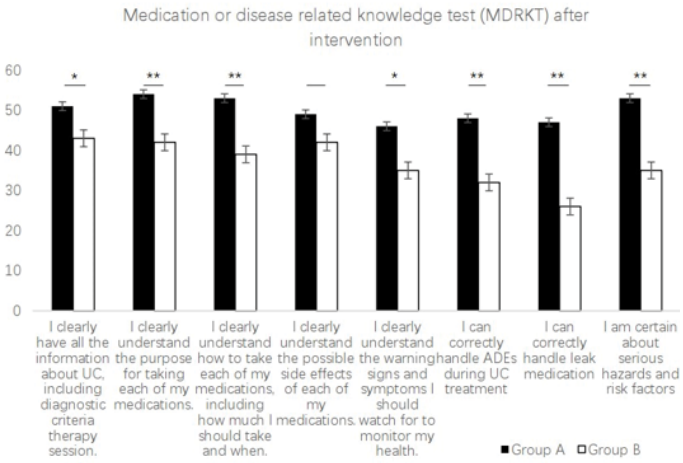

Figure 2. Comparison of medication or disease related knowledge test (MDRKT) after intervention. **P<0.05, **P<0.001, by a t test

score, including stool frequency, rectal bleeding, endoscopic findings, and physician evaluation, each rated from 0 to 3, where 3 means the highest severity. The Mayo score ranges from 0 to 12 with higher scores indicating worse severity. Patients got remission and received first-stage biotherapy and needed drug administration after discharge, we observed that the MTM group had better control compared to the CFU group after intervention, among which 56.1% in the MTM group were in remission compared to 32.2% in the CFU group, 19.3% in the MTM group were in moderate degree compared to 32.2% in the CFU group (P<0.05; shown in Table 3).

The results of the patient questionnaires

A total of 116 questionnaires were sent and returned, and the majority of the patients in the MTM group were satisfied with the instruction of medications and health education. The satisfaction rate and perception in Group A was high at 93.0%

Table 2. Self-reported adherence of subjects as determined by MMAS-8

MMAS-8 (n = 120)	**"Yes" responses n (%)**		**t**	**P value**
	Group A (n=57)	**Group B (n=59)**		
Do you sometimes forget to take your medication?	12 (21.1%)	25 (42.4%)	2.508	0.014
Thinking over the past 2 weeks, were there any days when you forgot to take your medicine?	6 (10.5%)	16 (27.1%)	2.312	0.023
Have you ever cut back or stopped taking your medication because you felt worse when you took it?	6 (10.5%)	13 (22.0%)	1.680	0.096
When you travel or leave home, do you sometimes forget to bring your medication?	7 (12.3%)	17 (28.8%)	2.225	0.028
Did you take your medicine yesterday?	56 (98.2%)	54 (91.5%)	-1.639	0.104
When you feel better, do you sometimes stop taking your medicine?	6 (10.5%)	21 (35.6%)	3.315	0.001
Do you ever feel hassled about sticking to your treatment plan?	18 (31.6%)	25 (42.4%)	1.202	0.232
How often do you have difficulty remembering to take your medicine?			-1.741	0.084
Never/rarely	22 (38.6%)	14 (23.7%)		
Once in a while	18 (31.6%)	18 (30.5%)		
Sometimes	6 (10.5%)	12 (20.3%)		
Usually	7 (12.3%)	8 (13.6%)		
All the time	4 (7.0%)	7 (11.9%)		
Medication Adherence			2.989	0.003
High (8)	36 (63.2%)	22 (37.3%)		
Moderate (6-8)	14 (24.6%)	20 (33.9%)		
Low (<6)	7 (12.2%)	17 (28.8%)		

Table 3. Comparison of disease control between the two groups

UC degree	**Group A (n=57)**	**Group B (n=59)**
Remission (>1)	32 (56.1%)	19 (32.2%)
Mild (3-5)	14 (24.6%)	20 (33.9%)
Moderate (6-10)	11 (19.3%)	19 (32.2%)
Severe (11-12)	0 (0%)	1 (1.7%)
P	0.049 (0.010)	

and the adherence to medications was 87.7% in Group A and 71.2% in Group B. Group A showed better feedback than Group B in knowledge of the disease and ADE (P<0.05), and Group A had a better feedback than Group B in self-management, anxiety, and there were no significant differences between the two groups in terms of self-management, anxiety, satisfaction of the follow-up mode, and desire of the knowledge about drug interactions (P>0.05; shown in Table 4).

DISCUSSION

UC is often associated with abdominal pain, diarrhea, and other intestinal stress syndromes that require long-term use of drugs

Table 4. Feedback on two follow up methods from patients

Questions	Group A	Group B	t	P value
1.This method increases disease knowledge	53 (93.0%)	46 (78.0%)	-2.319	0.022
2.This method improves medication adherence	50 (87.7%)	42 (71.2%)	-2.225	0.028
3.This method reduces ADEs of treatment	52 (91.2%)	45 (76.3%)	-2.203	0.030
4.This method improves self-management	53 (93.0%)	54 (91.5%)	-.291	0.771
5.This method decreases anxiety of the UC	44 (77.2%)	45 (76.3%)	-.116	0.907
6.Are you satisfied with the follow up mode	53 (93.0%)	50 (84.7%)	-1.406	0.163
7.Want to learn knowledge about drug interactions	32 (56.1%)	30 (50.8%)	-.567	0.572

and seriously affects life quality.[18,19] With the development of medical science, biologic agents including TNFα inhibitors, interleukin monoclonal antibodies, and integrin receptor antagonists have fewer adverse effects compared to oral administrations.[20] However, the effectiveness of the biologic agent was overrated in the first-stage treatment; many patients with UC would like to stop the medication at this stage because the biologic agent was considered to control the symptom as soon as it was injected, until discomfort symptoms appear.[21] Actually, the generation of the biologic agent effect requires a certain duration to response, such as vedolizumab takes 14 weeks to generate effect and the response time of ustekinumab could start from 28 weeks after injection, therefore more attention should be paid to discharged patients during the response-free period of the biologic agent,[22] and patients are expected to have a good compliance to conventional drug administration, the replacement opportunity between biologic agent and conventional drug administration must be carefully evaluated by professionals in this process. For our 116 participants, 38 patients (63.2%) in the MTM group had a high adherence score that was significantly higher than that of the control group, 7 patients (12.2%) in the MTM group had a low adherence score that was significantly lower than that of the CFU group.

The purpose of MTM follow-up in this research is to improve patient perception, medication adherence, and reduce adverse effects. In these cases, the cloud follow-up system sent the medication management and self-management education plan to the patient, talked the curative effect and adverse reaction with patient, discussed the possible drug adverse reaction and state of the disease with the doctor according to the characteristics of the patient's condition.[23] Compared to pharmacist-led MTM, the effects of self-management improvement in the CFU group may not be noticeable because nurse educators were not always able to engage participants in the medication aspect. According to the result, the perception of diagnostic criteria, therapy session, purpose of the medication, use, serious risks, and risk factors improved significantly after the intervention. Regarding the handling of side effects and leak medication, 84.2% and 82.5% of participants in the MTM group responded correctly compared to 39.0% and 44.1% of the CFU group.

As the COVID-19 pandemic forced the discontinuation of face-to-face interactions in this setting, comprehensive and convenient follow-up should be adapted with the goal of continuing high-impact patient interactions and keeping everyone involved safe.[24] The cloud follow-up platform consists of follow-up content, follow-up plan and follow-up interaction which provide a variety of functions; discharged UC health issues were managed remotely.[25] The value of the cloud follow-up platform was well presented during individual follow-up.[26] The pharmacist contacted the physician with certain recommendations for patients if they identified treatment-related problems.[27] According to the questionnaire, the satisfaction rate in Group A was high at 93.0% and 91.2% in Group A regarded that ADEs decreased compared to 76.3% in Group B. Group A showed better feedback than Group B in knowledge, self-management, anxiety, and satisfaction with follow-up mode. The percentage of patient in remission in the Group A were higher than in the Group B after the intervention ($p<0.05$).

Furthermore, the results showed that not all patients are suitable to be followed in a telemonitoring program, and some patients are incapable of using mobile phone software to communicate that the information will be sent to other family members. Also, it is important to realize that there are differences in people's desire for information, some patients would like as much information as possible about the threat of the disease, while others try to seek potentially threatening information.

CONCLUSION

This research showed that MTM combined with a cloud follow-up platform intervention can significantly improve patient perception, reduce adverse effect, and improve patient adherence to UC during the first-stage biotherapy, the patients can generally transfer to stable biotherapy. However, the results should be approached with caution due to the small number of participants and the single centered method used in the trial, and more robust studies with more participants are required to confirm the results.

Long-term or even lifelong drug treatment for UC is a huge expense for low-income families. Some patients tend to discontinue the medication plan or pay little attention to remedial measures for missed medications when they appear to be asymptomatic, it is important for the pharmacist to improve patient compliance by medication therapy management.

ABBREVIATIONS

MTM: medication treatment management; CFU: conventional follow-up; UC: Ulcerative Colitis; MDRKT: Medication or Disease Related Knowledge Test; CVD: cardiovascular disease

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Qinbo Wang, Yuan Zhou, and Guozeng Ye contribute equally to this work and share first authorship, Xiaoyan Li and Xia Wu handle the correspondences, including any questions about the methodology and materials. We thank the colleagues of the pharmacy department for MTM support. We also thank all the nurses of Graceland medical center who participated in this study.

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AVAILABILITY OF DATA AND MATERIALS

All data are available upon request from the authors.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This trial follows the Ethical Principles for Medical Research Involving Human Subjects and Good Clinical Practice. It was approved by the Ethics Committee of the Sixth Affiliated Hospital of Sun Yat-sen University under Grant 2022ZSLYEC-264. Written consent was obtained from each of the participants.

DISCLOSURE STATEMENT

The authors report no conflicts of interest.

AUTHOR CONTRIBUTIONS

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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