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Original Article

Feasibility analysis of medication therapy management in atherosclerosis patients

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Abstract: Objective: This study aimed to investigate the feasibility of medication therapy management (MTM) in atherosclerosis patients. Methods: A total of 92 atherosclerosis patients treated in our hospital were divided into the Study Group (SG, n=46, MTM) and the Control Group (CG, n=46, conventional medication intervention and management) by Random Number Table. Morisky scores indicating medication adherence at 7 d, 30 d, 60 d and 90 d after treatment, IL-6 and hs-CRP levels before and at 90 d after treatment, incidences of medication deviation and adverse reactions at 90 d were compared between the two groups. Results: Compared with the CG, the SG demonstrated higher Morisky scores at 30 d, 60 d and 90 d during follow-up ($P<0.05$), lower IL-6 and hs-CRP levels at 90 d after treatment ($P<0.05$), lower incidences of medication deviation and adverse reactions at 90 d ($P<0.05$). Conclusion: MTM significantly consolidated the medication adherence, improved the inflammatory state, and reduced the incidences of medication errors and adverse reaction in atherosclerosis patients.

Keywords: Atherosclerosis, MTM, feasibility analysis

Introduction

With the rapid society development in recent years, clear changes are taking place in the lifestyle and dietary structure of Chinese people who show a dominant aging tendency and are challenged by annual increases in the incidence of various cardiovascular and cerebrovascular diseases as a result of harmful habits. Pathologically, atherosclerosis is a disease based on lipodystrophy and characterized by lipids, composite glucides or thrombosis with endometrial artery involvement; which further leads to fibroplastic proliferation and calcareous deposits accompanied by the metamorphosis and calcification of the middle cerebral artery. Eventually, pathological changes such as arterial wall thickening and hardening, and vascular stenosis show up [1-3]. In most cases, atherosclerosis involves the large- and medium-sized muscular arteries, or even the lumen of the arteries, resulting in artery insufficiency, ischemia or necrosis of the recipient organs or tissues [4, 5]. Atherosclerosis patients may have various clinical symptoms presenting according to the degree of vascular lesions and ischemia in the involved organs. For example, patients with coronary atherosclerosis may experience angina pectoris, myocardial infarction, and arrhythmia; while some have cerebral atherosclerosis, cerebral ischemia and encephalanalosis, as well as renal atherosclerosis which manifests as enuresis nocturna, refractory hypertension, and renal insufficiency. The onset mechanism of atherosclerosis is very complicated, and its specific causes are not explained clearly. Current clinical practice suggests taking intervention therapy as early as possible for better prognosis [6, 7].

Therapies for atherosclerosis are integrated, medication-based or surgical. Medication is more frequently adopted in the clinic and guarantees treatment quality if conducted on a long-term and regular basis. However, some studies reported that when subject to subjective or objective factors, diversified errors are possible for some atherosclerosis patients during medication treatment, including drug/dose missing, overdose or changing the dose, etc., which can affect clinical treatment, and raised the incidence of adverse reactions and medical burdens [8, 9]. Medication therapy management (MTM) has emerged in recent years, and

it relies on a series of professional services provide by physicians for patients based on their expertise in pharmacy, involving medication education, consultancy and guidance, so as to raise patients' medication adherence and reduce the incidence of medication errors [10]. The concept was first put forward in the United States in the 1990s, and then recognized and popularized by the United States Government in clinical medicine after years of development. In practice, MTM plays an active role in reducing the incidence of adverse reactions and medical burden on patients, and improves their medication adherence [11]. However, MTM is still in the initial stages with a slow speed and less clinical studies in China. In recent years, the Chinese National Government is paying more and more attention to the rational clinical medication that MTM is gradually introducing to the treatment of chronic diseases and some achievements have been made. This study aims to analyze MTM feasibility in atherosclerosis patients and explore its effects in improving the clinical efficacy of atherosclerosis patients, in order to provide more reliable medication guidelines for them.

Materials and methods

General materials

A total of 92 atherosclerosis patients treated in our hospital in 2019 were divided into the study group (SG, n=46) and the control group (CG, n=46) by a Random Number Table.

Inclusion criteria: (1) Clinically diagnosed with atherosclerosis; (2) Clear conciseness to cooperate with the study; (3) Capable of self-care; (4) Highly understanding and compliant with the intervention; (5) Approval by the Ethics Committee of the Taizhou People's Hospital, The Fifth Affiliated Hospital of Nantong University; (6) Informed consents was given from the included patients.

Exclusion criteria: patients complicated with mental diseases, malignant tumors, severe chronic diseases, autoimmune diseases, immunodeficiency, severe liver/kidney/heart insufficiency or chronic infectious diseases, patients with poor understanding and self-care abilities, and patients who were unable to guarantee follow-up were excluded.

Withdrawal criteria: patients who were lost in follow-up, died or who were required to be removed during the study were withdrawn.

Methods

Both groups were conventionally treated, including vital sign monitoring, dietary and exercise guidance. In addition to medication taken according to the physicians' advice upon visit, patients in the CG were regularly followed up by the nurses who performed no special interventions but only recorded their drug use state and informed them the importance of taking medication regularly.

In addition to the treatment given to the CG, the SG patients were additionally given MTM therapy according to following steps: (1) A MTM group was established and trained to make clear the core elements of MTM, which included MTR, PMR, MAP, intervention or proposal of references suggestions, documentation and follow-up. (2) The element MTR consisted of systematic collection of patients' information, covering medication treatment, problems therein, list of drugs the patients had taken before, and plans for a solution. This step was on the one hand to make sure the pharmacist fully mastered the information related to the medication provided for patients, and on the other hand, improve patients' stress level to medical treatment and laid a foundation for self-medication management. (3) The element PMR mainly focused on listing out the names, indications, usage and dose, methods of taking and contradictions of drugs used in treatment by the pharmacist who informed the patients by writing to ensure patients understand the ways and methods of medication and to facilitate the later-stage medication guides. (4) The element MAP principally consisted of information of patients, their family members, and the pharmacist. This step was to build a bridge between patients and the pharmacist for medication monitoring and consultation. (5) Intervention or proposal of reference suggestions were carried out based on the specific conditions of patients in the SG, and carried out on a daily basis to track hospitalized patients, or by phone calls or WeChat or through social hospitals in case of patients not being hospitalized. (6) Documentation and follow up were mostly associated with registration of medication information to form records of a uniform format, facilitating exchange with other medical staff and improving the consistency of treatment.

Observation indices and interventions

Intergroup comparison of medication adherence after intervention: Morisky scale was

used to assess both groups' medication adherence at 7 d, 30 d, 60 d and 90 d after intervention. The Morisky scale consists of 8 questions and has a full score of 8. For questions 1 to 7, the answers are "Yes" or "No" and for question 8, the answers include "never", "occasionally", "from time to time", "often" and "always". Patients with a total score under 6 were recognized as poorly adherent, patients with a score between 6 and 7 were moderately adherent, and patients with a score of 8 were well adherent [12].

Intergroup comparison of IL-6 and hs-CRP before and at 90 d after intervention: In the morning, 5 ml of fasting venous blood was drawn from all patients before and at 90 d after treatment, and then centrifuged. The serum was reserved and stored at -80°C. All samples were collected and tested by ELISA kits sourced from Beijing Solarbio Science & Technology Co., Ltd. for IL-6, and BS-380 automatic biochemistry analyzer produced by Minray for hs-CRP. Instructions on the kits were strictly complied with, and the average of three measurements was taken as the final value.

Intergroup comparison of medication deviations at 90 d after treatment: By follow-up or return visits, the incidences of medication deviations at 90 d after treatment, including unauthorized adjustment of times or doses of medication, missing a dose/drug, drug rejection due to adverse reactions, and taking over-the-counter drugs, were recorded and compared between the two groups for the difference.

Intergroup comparison of incidence of adverse reactions at 90 d after treatment: By follow-up or return visits, the incidences of adverse reactions within 90 d after treatment began; including itchy skin, nausea and vomiting, constipation and diarrhea, gingival hemorrhaging or liver/kidney dysfunction, were recorded and compared between the two groups for the difference.

Statistical analysis

Statistical analysis was performed with SPSS 22.0. In case of numerical data it was expressed as Mean ± Standard Deviation, comparison studies were carried out through Student's t test. In case of nominal data expressed as [n (%)], comparison studies were carried out through chi-squared test. Student's t test was used to analyze the differences of continuous variables between groups. For all statistical comparisons, significance was defined as $P<0.05$ [13].

Results

Intergroup comparison of general clinical materials

According to statistics and comparisons, the SG was not statistically different from but was comparable with the CG, in general clinical data such as gender, average age, educational background, medical history and marital status ($P>0.05$) (**Table 1**).

Intergroup comparison of medication adherence after intervention

Referring to the Morisky scale, SG and CG showed no clear difference at 7 d ($P>0.05$). At 30 d, 60 d and 90 d, the SG experienced significant increases ($P<0.05$) and its scores accordingly were significantly higher than the CG's ($P<0.05$) (**Table 2** and **Figure 1**).

Intergroup comparison of IL-6 and hs-CRP levels before and at 90 d after intervention

After testing, the two groups were not statistically different in IL-6 and hs-CRP levels before intervention ($P>0.05$). At 90 d after intervention, the two indices decreased significantly in both groups ($P<0.05$) and were lower in the SG ($P<0.05$) (**Table 3** and **Figure 2**).

Intergroup comparison of medication deviation at 90 d after treatment

According to follow-up records, 6 (13.04%) and 23 (50.00%) cases of medication deviations were observed in the SG and the CG respectively, at 90 d after intervention ($P<0.05$) (**Table 4**).

Intergroup comparison of incidences of adverse reactions within 90 d after treatment began

Through follow-up comparison, the adverse cases, including itchy skin, nausea and vomiting, constipation and diarrhea, totaled up to 6 (13.04%) in the SG, and 15 (32.61%) in the CG,

Table 1. Intergroup comparison of general clinical materials ($\bar{x} \pm s$)/[n (%)]

General clinical materials		SG (n=46)	CG (n=46)	t/X^2	*P*
Gender	Male	27	28	0.045	0.832
	Female	19	18		
Average age (y)		56.98±3.44	57.03±3.22	0.072	0.943
Course of disease (y)	<1	5	4	0.224	0.644
	1≤ y <2	16	17		
	2< y ≤5	20	21		
	>5	5	4		
Educational background	Illiteracy	3	4	0.341	0.581
	Elementary school	7	8		
	Junior middle school	20	19		
	Senior high school and college	16	15		
Marital status	Married	44	43	0.211	0.646
	Unmarried	2	3		
History of hypertension	Y	26	27	0.045	0.833
	N	20	19		
History of diabetes	Y	27	28	0.045	0.832
	N	19	18		

Table 2. Intergroup comparison of medication adherence score after intervention ($\bar{x} \pm s$)

Group	n	7 d after intervention	30 d after intervention	60 d after intervention	90 d after intervention
SG	46	4.71±0.32	5.77±0.41	7.53±0.44	7.71±0.22
CG	46	4.73±0.29	4.89±0.51	5.21±0.45	5.67±0.39
t	-	0.314	9.121	25.001	30.9
P	-	0.754	<0.001	<0.001	<0.001

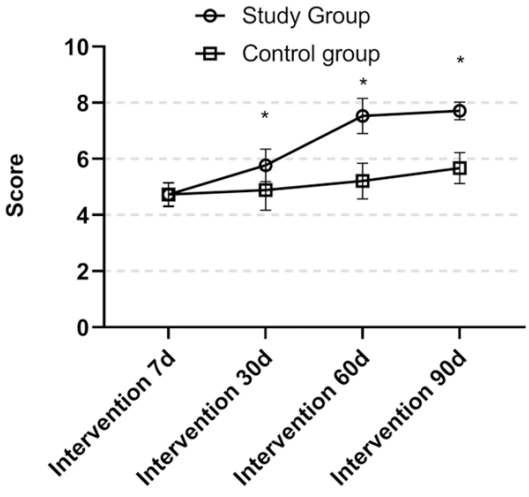

Figure 1. Intergroup Comparison of Medication Adherence Scores after Intervention. SG and CG showed no clear difference in Morisky score at 7 d (P>0.05) after intervention; at 30 d, 60 d and 90 d, the Morisky score of SG was significantly higher than the CG's (P<0.05); *P<0.05 vs the CG for the same index at the same time point.

within 90 d after treatment began (P<0.05) (**Table 5**).

Discussion

Atherosclerosis is a disease with pathological changes mainly including reduced arterial elasticity, narrowed arterial lumen, thickening and hardening of the arterial wall. Clinical studies have pointed out that atherosclerosis constitutes the major pathological foundation of most cardiovascular and cerebrovascular diseases.

Currently, conservative intervention, medication and surgery are the major means to treat patients with atherosclerosis. Patients who are mildly affected are mainly treated conservatively by drugs, and in severe cases, multiple measures are taken at the same time [14-16]. Medication is more recommended in the clinic based on its convenience, non-invasiveness, and little pain to patients. Regular drug taking is an important premise to guarantee the effectiveness and safety of clinical treatment. However, according to some investigation data, most atherosclerosis patients are in a senior age with poor adherence to regular drug taking due to work, life and individual factors. An investigation into 433 atherosclerosis patients for medication adherence pointed out that only 46.42% of the subjects managed to comply

Table 3. Intergroup comparison of IL-6 and hs-CRP levels before and at 90 d after intervention ($\bar{x} \pm s$)

Group	n	IL-6 (pg/mL)		hs-CRP (mg/L)	
		Before intervention	90 d after intervention	Before intervention	90 d after intervention
SG	46	49.29±6.31	22.12±3.21	207.19±20.39	55.12±8.28
CG	46	49.77±6.22	33.18±3.31	210.28±18.28	79.21±7.29
t	-	0.367	16.269	0.765	14.81
P	-	0.714	<0.001	0.446	<0.001

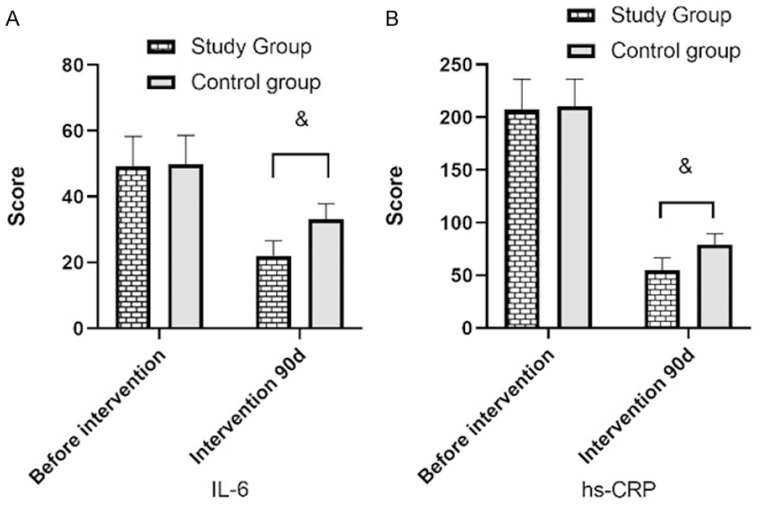

Figure 2. Intergroup Comparison of IL-6 and hs-CRP Levels before and after Intervention. Before intervention, no significant difference between the SG and CG was found in IL-6 and hs-CRP levels (P>0.05); at 90 d after intervention, the IL-6 and hs-CRP levels in the SG were significantly lower than the CG's (P<0.05); &P<0.05 vs the CG for the same index at the same time point.

with doctor's advice, 29.10% often missed doses, 15.01% distrusted the prescription, and 74.60% worried about the adverse reactions therefrom. A further investigation revealed that 95.15% of the patients expected more specific and detailed instructions on how to take drugs [17, 18]. Another long-term follow-up study of 80 atherosclerosis patients demonstrated that, 49 patients who took drugs regularly had an incidence of 10.20% only for various cardiovascular events in 2 years, including arrhythmia and myocardial infarction, while the rest (n=40) who failed to take drugs had a 2-year incidence of cardiovascular events up to 40% (P<0.05) [19]. According to those data, atherosclerosis patients have problems with consistent drug taking, whereas regular drug taking plays an active role in improving prognosis. Therefore, it is urgently required to provide a practical and feasible medication guide for atherosclerosis patients.

MTM includes a series of professional services provided by pharmacists with technical strengths in medicine, including medication education, consultancy and guidance. It is developed to improve patients' medication adherence and clinical treatment effects, reduce the incidence of medication deviation and unreasonable medical burdens on patients [20]. This model was first developed in the United States on the basis of the CDTM proposed by ACCP. According to the model, doctors have an agreement with qualified pharmacists to authorize the latter in a written form to provide patients with medication treatment and services, including evaluation of patients' conditions and adverse reactions, medication treatment related tests, monitoring and adjustment of the medication program. In 2004, the pharmaceutical organization of 11 countries (including the United States) officially put forward the MTM deviating from CDTM. Sharing the same core concept with CDTM, MTM requires instructions from professional medical staff to provide patients with professional medication services in order to optimize the treatment effects and reduce adverse reactions [21]. MTM has achieved rapid development in foreign countries. According to a number of studies, drug involvement in clinical treatment is negatively associated with the incidence of adverse reactions, and a questionnaire survey of patients also indicated that MTM improved patients' satisfaction to medical services, and even extended their survival [22]. At present, there are few studies focusing on MTM in China, and it is still in the initial stages. Many an investigations have shown the high demand of patients with chronic diseases on medication guidelines. In a multi-center and cross-section-

Table 4. Intergroup Comparison of Medication Deviation within 90 d after the Treatment Began [n (%)]

Group	n	Unauthorized adjustment of times or doses of medication	Dose/drug missing,	Drug rejection due to adverse reactions	Taking over-the-counter drugs	Total incidence
SG	46	2 (4.35)	3 (6.52)	0 (0.00)	1 (2.17)	6 (13.04)
CG	46	5 (10.87)	8 (17.29)	6 (13.04)	4 (8.70)	23 (50.00)
t	-	-	-	-	-	14.553
P	-	-	-	-	-	<0.001

Table 5. Intergroup comparison of incidence of adverse reactions within 90 d after treatment began [n (%)]

Group	n	Itchy skin	Nausea and vomiting	Constipation and diarrhea	Gingival hamorrhage	Liver/kidney dysfunction	Total incidence
SG	46	2 (4.35)	2 (4.35)	1 (2.17)	1 (2.17)	0 (0.00)	6 (13.04)
CG	46	3 (6.52)	4 (8.70)	2 (4.35)	3 (6.52)	3 (6.52)	15 (32.61)
t	-	-	-	-	-	-	4.998
P	-	-	-	-	-	-	0.025

al anonymous study, 60% of the patients never heard of MTM, 80% never received any medication review service, 78% never recorded the drugs they took, and 86% never participated in any activity or plan related to drug management. However, 56% of them believed that medication service was of great importance, and 70% found the active role of one-on-one medication guidance to improving their conditions [23].

This study analyzed the feasibility of MTM in atherosclerosis patients by setting up two groups. According to its results, at 7 d after intervention, SG and CG showed no significant difference in the scores of medication adherence, but at 30 d, 60 d and 90 d, the score of the SG was significantly higher than the CG's. Previous studies have figured out that MTM improves patients' medication adherence from medication guide and self-management. Compared with simple health education, MTM incorporated patients' subjective factors to raise their subjective initiative, which means that they can actively participate in their medication, and the effects were outstanding [24]. In this study, traditional atherosclerosis medication management model was made simple by reminding patients to take drugs regularly through phone calls or return visits, and explain to them the consequences of irregular medication and the advantages of regular medication on prognosis. In MTM, medication management was carried out through collecting patients' information, recording the treatment conditions, establishing medication records and cooperating with community medical services, which provided doctors more detailed treatment references to markedly elevate the treatment effects, evidenced by the lower IL-6 and hs-CRP levels in the SG. This can be attributed to the fact that IL-6 and hs-CRP are inflammatory factors widely used as indicators in the clinic, and their levels directly reflect the inflammatory state of the body. Atherosclerosis is a type of inflammatory disease. Through MTM intervention, the clinical symptoms of patients were improved, and the inflammation state was also significantly alleviated, which is reflected in the reduction of IL-6 and hs-CRP levels in laboratory tests. Patients' understanding of their conditions, the importance of regular medication and the medical program was enhanced. Imperceptibly, they were be more willing to participate in the treatment and actively maintained their optimism in treatment. Consequently, medication adherence was significantly raised.

Besides, atherosclerosis patients' medication deviation and treatment-related adverse reactions in MTM were also studied. According to the results, after MTM, patients in the SG had an incidence of medication deviation of only 13.04%, and for patients in the CG, it was 50.00%. The incidence of adverse reactions was 13.04% in the SG and 32.61% in the CG. Those data prove that MTM is capable of signifi-

cantly reducing the incidence of medication deviation and adverse reactions. By analysis, the major factors affecting medication deviation were subjective, such as worries about adverse reactions, no faith in the treatment program, and missing dose, etc. Actually, patients' low involvement principally accounted for the medication deviation, while MTM could improve it by health education, medication records/consultancy, and measures against problems in medication treatment. Eventually, patients established good self-drug management behaviors and consciousness, and the incidences of medication deviation and adverse reactions were reduced as the advantages of MTM.

In conclusion, MTM significantly consolidated the medication adherence, improved the inflammatory state, and reduced the incidences of medication errors and adverse reaction in atherosclerosis patients. However, this study was defective in following aspects: (1) Limited number of samples, resulting in incomprehensive conclusions. (2) Failure in long-term follow-up and insufficient exploration of MTM's shaping effects of patients' self medication management consciousness. Future studies shall be based on a larger sample size and a longer duration, in order to provide atherosclerosis patients with more accurate and detailed theoretical basis of medication treatment.

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Disclosure of conflict of interest

None.

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