

Original Article

Effectiveness of a case management model in newly treated smear-positive pulmonary tuberculosis patientsYanLing Li¹ #, Ying Wang² #, GaiJing Wang³, YiLin Wang⁴, YanQing Tian¹, SiWei Zhu¹, Jiao Chen¹, LiLi Diao¹¹ Department of tuberculosis, Affiliated Hospital of Hebei University, Baoding, Hebei, China² Department of Integrated Traditional Chinese and Western Medicine, Affiliated Hospital of Hebei University, Baoding, Hebei, China³ Department of Gynecology, Affiliated Hospital of Hebei University, Baoding, Hebei, China⁴ Class 1 of the five-year clinical medicine major of grade 2020, School of basic medicine, Shandong University, Jinan, China

Authors contributed equally to this work.

Abstract

Introduction: To investigate the effectiveness of the case management mode on the application of smear-positive pulmonary tuberculosis patients.

Methodology: This was a randomized control trial. A total of 70 newly diagnosed smear-positive pulmonary tuberculosis patients were recruited and been randomly divided into experimental group and control group, with 35 participants in each group. In the experimental group, patients received the tuberculosis case management mode based on the conventional management mode. In the control group, patients received the routine management mode. We compared the knowledge, attitude, and practice score; sputum-negative conversion rate, effective imaging rate of the two groups at the time of initial admission, discharge, and one month after discharge.

Results: The results showed that there was no significant difference in baseline data between the two groups ($p > 0.05$); at the time of discharge and one month after discharge, the knowledge, belief, behavior, sputum-negative conversion rate, and imaging examination effective rate of the experimental group were higher than those of the control group ($p < 0.05$).

Conclusions: The case management mode can improve the knowledge, attitude, and practice level; sputum-negative conversion rate; and imaging efficiency of newly treated smear-positive pulmonary tuberculosis patients.

Key words: Case management; newly diagnosed smear positive pulmonary tuberculosis; KAP level; sputum negative conversion rate; imaging examination.

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Introduction

The prevalence rate of smear-positive tuberculosis among individuals aged 15 years and over was 66/100,000 [1-3]. According to the “2020 global TB report” released by the WHO, 833,000 people were estimated to have been newly infected with tuberculosis in 2019 in China. Among newly diagnosed TB patients in China, 7.1% are drug-resistant/MDR-TB patients, and 23% are relapsing drug-resistant/MDR-TB patients. Tuberculosis is among the top 10 causes of death and represents a serious threat to human health. The diagnosis and successful treatment of tuberculosis can avoid millions of deaths each year and are of great significance in the prevention and control of tuberculosis in China [4,5]. Patients classed as newly diagnosed with smear-positive pulmonary tuberculosis

are individuals who have never received anti-tuberculosis drugs or who have received a positive sputum smear for less than one month. Some studies have shown that the cure rate of newly treated smear-positive pulmonary tuberculosis can exceed 90% under standard treatment conditions (consisting of an intensive phase of 2 months of isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB) followed by a continuation phase of 4 months of INH and RIF) [6]. If there is no standardized treatment and management, the cure rate is greatly reduced, and the untreated patients can become a source of infection, which has adverse consequences on their families and society. Domestic and foreign researchers have engaged in extensive discussion on the management mode of newly treated smear-positive

pulmonary tuberculosis patients. Case management is a cooperative process that includes six stages: evaluation, planning, implementation, coordination, monitoring, and evaluation.

At present, the case management mode has achieved good results in other diseases [7-9] but has been applied less frequently in newly treated smear-positive pulmonary tuberculosis patients [10]. The purpose of the present study is to explore the Effect of case management mode on cure rate of sputum positive TB, Prevention of spread of infection to close contacts, adherence to treatment, early identification of adverse events, patient education, etc.

Methodology

Research subjects

This was a randomized control trial. Between October 2019 and January 2020, 70 newly diagnosed smear-positive pulmonary tuberculosis patients in the tuberculosis department of a tertiary hospital in Hebei Province were randomly divided into experimental group and control group, with 35 participants in each group. The researchers obtained the random number and code through the computer or mobile app login electronic case reporting system. Patients were divided into a control group and an experimental group according to the corresponding number of random numbers. In experimental group, patients receive the tuberculosis case management mode based on the conventional management mode. In control group, patients received the routine management mode. This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of our hospital. All participants had signed the informed consent.

Inclusion and exclusion criteria

Inclusion criteria: (1) informed consent; (2) aged 18–85 years; (3) positive sputum smear or culture positive and chest x-ray showing the presence of active tuberculosis lesions; (4) no anti-tuberculosis treatment received or anti-tuberculosis treatment received for less than one month.

Exclusion criteria: (1) patients with severe complications, severe disability, or after major surgery; (2) previous or current mental illness; (3) severe cognitive impairment; (4) serious communication barriers.

Case management preparation stage

A case management team was established by a case manager, a tuberculosis department director, a head

nurse, a doctor, and five nurses. The case manager establishes case management files of tuberculosis patients, makes case management plans together with the case management team and patients, and the head nurse carries out disease-related health education to relieve patients' tension and anxiety. Health education includes: to observe the adverse reactions of drugs and regular review during treatment period; during the recovery period, attention should be paid to ensure the supplement of nutrition, avoid excessive fatigue, emotional fluctuations and respiratory infection and stimulation, reasonable arrangements for rest, and enhance the ability to resist diseases; pay attention to personal hygiene, don't spit everywhere, give up smoking and drinking. Spend 1-2 hours with each patient through one-to-one instruction. The tuberculosis department director formulated the medication plan and issued the prescription, the doctor sign the informed consent and make ward rounds, the nurse dispenses the medicine and explains the dosage and matters needing attention. In addition, the responsible nurse needs to make a comprehensive assessment of the patient and conduct telephone follow-up. The team established the "Case Management Record Card", and prepared the "Case Management Related knowledge training". The contents of "Case Management Record Card" mainly include the patient's physical condition, psychological condition, disease awareness, living environment, patient needs and family and social support. "Case Management Related Knowledge Training" mainly includes basic theoretical knowledge of tuberculosis, knowledge of disinfection and isolation, knowledge of diet, knowledge of anti-tuberculosis medication, and knowledge of individualization. It is displayed in the form of slides and reviewed and approved by relevant experts.

Evaluation stage of case management implementation

Both the control group and the experimental group were followed up for at least 6 months. The control group was given routine nursing care for newly treated smear-positive pulmonary tuberculosis from admission to one month after discharge, while the experimental group was given the case management mode of newly treated smear-positive pulmonary tuberculosis based on routine nursing. Relevant investigation data were collected at admission, discharge, and one month after discharge.

The case management team was mainly responsible for the case management of patients from admission to one month after discharge. During hospitalization, patients were evaluated; nursing plans were formulated

and implemented; and coordination, monitoring, and evaluation were conducted. Telephone follow-up and outpatient review were conducted after discharge [11]. The specific steps were to (1) write the tuberculosis case management record card; (2) urge patients to take medications according to the doctor's advice; (3) supervise and ensure that the patients returned to the clinic on time and received sputum, chest x-ray, and other relevant examinations; (4) pay attention to the side effects of anti-tuberculosis drugs and refer patients for treatment in a timely manner; (5) check the contacts; (6) offer effective education and guidance to patients and their families; and (7) record patients' latest dynamic information at any time.

The four objectives of the case management plan were as follows: (1) help patients seek regular and timely medical treatment and ensure they take medications according to the doctor's advice; (2) assist patients in stably controlling the disease and turning the sputum from positive to negative as quickly as possible; (3) encourage patients and their families to pay attention to the treatment of sputum and maintain the air circulation at home; and (4) encourage patients' close contacts to be examined as quickly as possible and receive immediate treatment in the event of sickness.

Evaluation tools

General information questionnaire

A general information questionnaire was designed and developed by the researchers based on relevant literature, including patients' general social demographic data, such as age, gender, education level, marital status, and the occurrence of hemoptysis.

Questionnaire on the knowledge, attitudes, and practice of newly treated smear-positive pulmonary tuberculosis patients

The questionnaire [12] was used to investigate the KAP level of newly treated smear-positive pulmonary tuberculosis patients. The 24 items in the questionnaire included knowledge, attitude, and the behavior of tuberculosis. Scoring methods: 1 point for each correct answer and 0 points for incorrect or unknown answers to tuberculosis-related knowledge items; 4, 3, 2, 1, and 0 points for answers to tuberculosis-related attitude items, including "very agree," "agree," "neutral," "disagree," and "very disagree;" 1 point for correct behavior and 0 points for behavior error. The total score was 63 points; scores ≥ 47 points were considered mastery of knowledge, attitude, and practice level of newly treated smear-positive pulmonary tuberculosis patients, while scores < 47 points were considered as

having not reached the standard. Correct rate = correct number of people / total number of people; Error rate = number of errors / total number of people.

Sputum negative conversion

The sputum smear without acid-fast bacilli was negative, which was consistent with the study of Zhang Wenxin. In this study, the sputum smear was negative for two consecutive times (on two consecutive days) and no longer reverted to positive, and the time for the first negative sputum smear was taken as the criterion [13]. Three specimens were used for each time: instant sputum, night sputum, morning sputum, and the sputum smear method was used. The sputum samples were purulent, caseous or purulent mucinous sputum with a volume of 3-5ml. For unqualified sputum, re-examination is required. When qualified specimens are difficult to obtain, sputum culture is performed. Phlegm bacteria and sputum culture are negative for two consecutive times, can be judged as cure.

Chest imaging

There are various forms and types of pulmonary tuberculosis lesions. The various imaging manifestations include nodules and masses, exudations and consolidations, cavities, calcifications, and fibrous lesions. The effective treatment of smear-positive pulmonary tuberculosis was as follows: lesions decreased, pulmonary tuberculosis lesions gradually appeared fibrosis or calcification, cavity lesions closed, etc. Findings must be stable for at least 6 months [14]. Chest films were taken and compared at the beginning of admission, discharge and the end of one month after discharge. The imaging results showed that the scanning range was from the thoracic entrance to the bottom of the lung. When there was a dispute about the imaging opinion of the lesion, three doctors read the film and assessed the change in the lesion according to the principle of the minority obeying the majority.

Data collection methods

Before the intervention, the case manager introduced the research purpose, significance, and research process to the patients. The patients signed the informed consent form. Data before the intervention were collected within 24h of the patients being admitted to the hospital. Sputum Mycobacterium tuberculosis examination and imaging examination were conducted. The general situation questionnaire was conducted, and the knowledge, attitude, and practice level of newly treated smear-positive pulmonary tuberculosis patients were investigated. The questionnaire was collected

within 10 minutes at the time of discharge and on return to the hospital one month after discharge. The questionnaire assessing the knowledge, attitude, and practice level of newly treated smear-positive pulmonary tuberculosis patients was distributed among the research subjects, and sputum Mycobacterium tuberculosis examination and imaging examination were conducted again. Following this, data from after the intervention were collected. The questionnaires were collected immediately after completion.

Statistical methods

Excel software was used for data input, and SPSS 22.0 statistical software was used for the data analysis. When describing the current state of KAP, the continuous variables of normal distribution were expressed as mean \pm standard deviation, the continuous variables of non-normal distribution were expressed as median (interquartile range [IQR]), the categorical variables were expressed as frequency (percentage [%]). The KAP pass rate of the research object is expressed as a ratio. For two comparisons, each value was compared by *t*-test when each datum conformed to normal distribution, while the non-normally distributed continuous data were compared using non-parametric tests. The counting data were tested by chi-square test. A value of $P < 0.05$ was considered statistically significant.

Ethical statement

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of our hospital. All participants had signed the informed consent.

Results

The general characteristics

A total of 70 newly diagnosed smear-positive pulmonary tuberculosis patients were recruited and been randomly divided into experimental group and control group, with 35 participants in each group. In the experimental group, there were 10 female and 25 male, the average age of patients was 47.54 ± 16.31 years old. In the control group, there were 8 female and 17 male, the average age of patients was 48.43 ± 15.73 years old. The results showed that there was no significant difference in age, gender, marital status, education level, and hemoptysis between the two groups, the details were listed in Table 1.

Comparison of KAP between the two groups before and after the intervention

The results revealed no significant difference in scores of knowledge, attitude, and behavior between the two groups at the time of initial admission, discharge, and one month after discharge, respectively ($p > 0.05$). The KAP scores in the experimental group were higher than those in the control group at the time of discharge and one month after discharge, and the difference was statistically significant ($P < 0.05$; see Table 2).

Comparison of the sputum-negative conversion rate between the two groups before and after intervention

The control group and the experimental group were examined for sputum smear and sputum culture of Mycobacterium tuberculosis at the time of discharge and one month after discharge. The results showed that the sputum-negative conversion rate of the experimental group was higher than that of the control group at the time of discharge and one month after

Table 1. Comparison of baseline data between the two groups.

Subjects' characteristics	Group	Control (n = 35)	Experimental (n = 35)	χ^2/t	P-Value (Two-Sided)
Age (Years)		48.43 \pm 15.73	47.54 \pm 16.31	0.308	0.76
Gender	Female	8 (22.9)	10 (28.6)	0.299	0.584
	Male	27 (77.1)	25 (71.4)		
Education	Junior high school and below	12 (31.6)	14 (40.0)	0.245	0.621
	High school and above	23 (65.7)	21 (60.0)		
Marriage	Married	13 (37.1)	15 (42.9)	0.238	0.808
	Unmarried or divorced	22 (62.9)	20 (57.1)		
Hemoptysis	Yes	6 (17.1)	5(14.3)	0.108	0.743
	No	29 (82.9)	30 (85.7)		

Table 2. Comparison of KAP scores between the two groups before and after intervention.

Subjects' characteristics	Control (n = 35)			Experimental (n = 35)			χ^2/t_1	P ₁	χ^2/t_2	P ₂	χ^2/t_3	P ₃
	On initial admission	On discharge	At the end of one month after discharge	On initial admission	On discharge	At the end of one month after discharge						
Knowledge part	0.50 ± 0.50	0.58 ± 0.49	0.62 ± 0.48	0.51 ± 0.50	0.74 ± 0.44	0.77 ± 0.42	-0.355	0.723	-3.384	0.001	-3.149	0.002
Attitude part	2.88 ± 0.75	3.22 ± 0.61	3.28 ± 0.59	2.86 ± 0.84	3.34 ± 0.62	3.37 ± 0.60	-0.398	0.691	-2.962	0.003	-2.217	0.027
Behavioral part	0.50 ± 0.51	0.51 ± 0.50	0.59 ± 0.49	0.51 ± 0.50	0.65 ± 0.47	0.78 ± 0.41	-0.137	0.891	-2.797	0.006	-4.13	0.001
Up to standard	9 (25.7)	20 (57.1)	25 (71.4)	8 (22.9)	28 (80.0)	32 (91.4)						
Not up to standard	26 (74.3)	15 (42.9)	10 (18.6)	27 (77.1)	7 (20.0)	3 (8.6)	0.078	0.78	4.242	0.039	4.629	0.031

$\chi^2 / T_1 P_1$ is the comparison at the time of initial admission; $\chi^2 / T_2 P_2$ is the comparison at the time of discharge; $\chi^2 / T_3 P_3$ is the comparison at the end of one month after discharge. Pp < 0.05 was statistically significant.

discharge, and the difference was statistically significant ($p < 0.05$; Table 3).

Comparison of imaging results between the two groups before and after intervention

The imaging examination results of the two groups were compared at the beginning of admission, time of discharge, and one month after discharge. The results showed that in the control group, 23 patients with imaging examination results were markedly effective; in the experimental group, the imaging examination results of 32 patients were markedly effective. The imaging efficiency of experimental group was higher than that of control group; the difference was statistically significant ($p < 0.05$). The results of the imaging examination one month after discharge were compared with those at the time of initial admission. The results showed that 27 patients in the control group were significantly affected, while 34 patients in the experimental group were significantly affected. The difference was statistically significant ($p < 0.05$; Table 4).

Discussion

The results of the survey showed that the level of KAP in the experimental group was higher than that in

the control group at the time of discharge and one month after discharge, and the difference was statistically significant. In the conventional management mode, there was a lack of effective communication between medical workers and patients due to the busy environment and lack of targeted management, and some patients' questions were not answered correctly and in a timely manner. In this study, the patient-centered case management and the case manager as educators realized the information communication between medical workers and patients, and improved the cognitive level of patients with smear-positive pulmonary tuberculosis on disease-related knowledge. As a coordinator, case manager constantly guides patients in the process of diagnosis and treatment, improves their compliance and corrects their attitude to the disease. As a guide, case manager pays attention to the common decision-making and participation of patients, and timely corrects the unhealthy behavior of patients and their families. Therefore, through the implementation of case management, the case management team could track and master changes in patients' condition at any time, conduct targeted management of patients, and effectively guide patients and their families on disease knowledge, attitude, and related behaviors to improve

Table 3. Comparison of negative conversion rate of sputum bacteria between the two groups after intervention.

Group	Number	On discharge				At the end of one month after discharge			
		Number of sputum negative conversion	Sputum negative conversion rate (%)	χ^2	P	Number of sputum negative conversion	Sputum negative conversion rate (%)	χ^2	P
Control	35	22	62.86	4.786	0.029	26	74.29	7.467	0.013
Intervention	35	30	85.71			34	97.14		
total	70	52	74.29	⊗	⊗	60	85.71	⊗	⊗

p < 0.05 was considered statistically significant.

Table 4. Comparison of the efficiency of imaging examination between the two groups after intervention.

Group	Number	On discharge				At the end of one month after discharge			
		Effective number	Significant efficiency (%)	χ^2	P	Effective number	Significant efficiency (%)	χ^2	P
Control	35	23	62.86	6.873	0.018	26	74.29	6.248	0.028
Intervention	35	32	85.71			34	97.14		
total	70	55	78.57	⊗	⊗	61	87.14	⊗	⊗

p < 0.05 was considered statistically significant.

the knowledge, attitude, and practice level of newly treated smear-positive pulmonary tuberculosis patients. Therefore, in the management of newly treated smear-positive pulmonary tuberculosis patients, attention should be paid to communicating with and effectively guiding patients and their families, as well as improving patient compliance to improve the knowledge, attitude, and practice level of newly treated smear-positive pulmonary tuberculosis patients and promote overall rehabilitation [15,16].

The survey results showed that the sputum-negative conversion rate of the experimental group was higher than that of the control group at the time of discharge and one month after discharge, and the difference was statistically significant. It has been reported that sputum bacteria positive at the end of two and three months after discharge is closely related to the final treatment failure of patients, particularly among those who are still positive at the end of three months, and plays an early warning role in clinical practice. Studies have shown that personalized, comprehensive intervention measures can significantly improve the sputum-negative conversion rate of smear-positive pulmonary tuberculosis patients. In the case management mode of newly treated smear-positive pulmonary tuberculosis patients, the case management team continuously evaluates, treats, and nurses patients; after discharge, the case management team carries out regular telephone and outpatient follow-ups and conducts real-time monitoring and tracking on the follow-ups to improve patients' treatment compliance and the sputum-negative conversion rate of newly treated smear-positive pulmonary tuberculosis patients [17-22].

The survey results showed that the effective rate of imaging examination results of the experimental group was significantly higher than that of the control group at the time of discharge and one month after discharge, and the difference was statistically significant, $p < 0.05$. The results of dynamic contrast imaging examination are helpful in judging the efficacy of treatment for newly treated smear-positive pulmonary tuberculosis. Patients in the experimental group were given systematic health education by case managers during the study period. Patients in the experimental group could master basic disease self-management skills through self-study, consultations with medical staff, and follow-up supervision and guidance by the case management team. At the same time, the experimental group used network resources to communicate with case management team members in a timely and effective manner, which facilitated information exchange between newly treated smear-positive

pulmonary tuberculosis patients, strengthened self-management and supervision of the disease. This promoted the rehabilitation of newly treated smear-positive pulmonary tuberculosis patients and improved the efficiency of imaging examination results.

The results showed that the management level of tuberculosis patients with smear positives and smear-positive cases could be improved. Case management can provide the full range of care services for patients and provide professional help and support for patients in the diagnosis, treatment, and rehabilitation stages to realize the continuity of nursing care for newly diagnosed smear-positive pulmonary tuberculosis patients.

Limitations: There were several limitations in this study. Firstly, this study was only single-center trial, another multiple center trial was still needed in the future. Secondly, the sample size of this study was really limited, another larger trial with more participants was necessary. Thirdly, the intervention time was really short, another study with longer intervention should be conducted in future to clarify the long-term intervention effect of the case management model on newly diagnosed smear-positive pulmonary tuberculosis patients.

Conclusions

The case management mode can improve the knowledge, attitude, and practice level; sputum-negative conversion rate; and imaging efficiency of newly treated smear-positive pulmonary tuberculosis patients. Case management can provide the full range of care services for patients and provide professional help and support in the diagnosis, treatment, and rehabilitation stages to realize the continuity of nursing care for newly treated smear-positive pulmonary tuberculosis patients.

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Corresponding author

YanLing Li, MSc
 Department of tuberculosis,
 Affiliated Hospital of Hebei University,
 No. 648, Dongfeng East Road, Lianchi District,
 Baoding 071000, China
 Tel: +86 13633222248
 Email: yanlinglidr@163.com

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