

個案管理對心臟衰竭患者之成效-以台灣某醫院為例

¹ 蕭伊祐、² 陳嘉民、^{3,4} 陳志暉、⁵ 陳秋媛、⁶ Hanoch Livneh、^{3,7} 林庭光、^{8,9,10*} 蔡宗益

¹ 佛教慈濟醫療財團法人大林慈濟醫院護理部心衰竭個案管理師、² 南華大學自然生物科技學系自然療癒碩士班助理教授、³ 佛教慈濟醫療財團法人大林慈濟醫院心臟內科主治醫師、⁴ 慈濟大學醫學系助理教授、⁵ 南華大學自然生物科技學系自然療癒碩士班副教授、⁶ PhD, Professor, Rehabilitation Counseling Program, Portland State University, Portland, USA、⁷ 慈濟大學醫學系講師、⁸ 佛教慈濟醫療財團法人大林慈濟醫院醫學研究部副研究員、⁹ 慈濟科技大學護理系兼任講師、¹⁰ 國立成功大學醫學院工業衛生學科暨環境醫學研究所博士候選人

摘要

目的：個案管理是一有助於激發慢性病患者行為改變以提升預後之照護模式。但對於台灣心臟衰竭患者之成效仍未趨定論。本文旨在探討個案管理對該組群之成效。**方法：**採單組重複測量研究設計。以立意取樣招募 2011-2012 年至台灣某醫院就醫之 100 位心臟衰竭患者。個案管理介入則包含一系列的衛教課程與電話諮商等服務內容，並利用結構式問卷與病歷回溯等方式收集介入後和介入後六個月的成效指標，再以廣義估計方程式評值成效。**結果：**個案管理介入雖對心臟衰竭患者之血壓與高密度脂蛋白雖無明顯改善效果，但可有助強化個案的生活品質和自我照護行為，亦能降低膽固醇、三酸甘油脂、空腹血糖和低密度脂蛋白等代謝指標($p < .01$)。上述指標於介入後六個月仍具顯著成效。**結論：**個案管理對台灣心臟衰竭患者有顯著成效，可作為改善其疾病調適和臨床預後之照護參考。

關鍵詞：心臟衰竭、個案管理、廣義估計方程式

收文日期：2017 年 08 月 16 日

接受日期 2018 年 01 月 03 日

*通訊作者：蔡宗益 佛教慈濟醫療財團法人大林慈濟醫院醫學研究部 副研究員

聯絡住址：嘉義縣大林鎮民生路 2 號

聯絡電話：886-5-2648000 ext. 3209

電子郵件：dm732024@tzuchi.com.tw

Effects of case management for patients with heart failure: a hospital-based study in Taiwan

I-Yu Hsiao¹, Chia-Min Chen², Chih-Wei Chen^{3,4}, Chiu-Yuan Chen⁵,
Hanoeh Livneh⁶, Tin-Kwang Lin^{3,7}, Tzung-Yi Tsai^{8,9,10*}

¹RN, MSc, Case Manager, Department of Nursing, Dalin Tzuchi Hospital, The Buddhist, Tzuchi Medical Foundation, Chiayi, Taiwan. ²PhD, Assistant Professor, Graduate Institute of Natural Healing Sciences, Nanhua University, Chiayi, Taiwan. ³MD, Department of Cardiology, Dalin Tzuchi Hospital, The Buddhist Tzuchi Medical Foundation, Chiayi, Taiwan. ⁴Assistant Professor, School of Medicine, Tzu Chi University, Hualien, Taiwan. ⁵PhD, Associate Professor, Graduate Institute of Natural Healing Sciences, Nanhua University, Chiayi, Taiwan. ⁶PhD, Professor, Rehabilitation Counseling Program, Portland State University, Portland, USA. ⁷Lecturer, School of Medicine, Tzu Chi University, Hualien, Taiwan. ⁸Associate Researcher, Department of Medical Research, Dalin Tzuchi Hospital, The Buddhist Tzuchi Medical Foundation, Chiayi, Taiwan. ⁹Adjunct Lecturer, Department of Nursing, Tzu Chi University of Science and Technology, Hualien, Taiwan. ¹⁰PhD candidate, Department of Environmental and Occupational Health, College of Medicine, National Cheng Kung University, Tainan, Taiwan.

Abstract

Purpose: Case management (CM) has been recommended as a way of inspiring measurable changes in individual behaviors and improving clinical outcomes for patients with chronic diseases. However, data on its effectiveness for Taiwanese patients with heart failure (HF) are limited and inconclusive. So this study aimed to determine the long-term effectiveness of CM for Taiwanese HF patients. **Methods:** One group repeated measures design with purposive sampling recruited one hundred HF patients from a hospital in Taiwan during 2011-2012. CM program was composed of health education sessions and follow-up telephone consultations over a six-month period. A review of medical records and structured questionnaires yielded data about patient demographics and disease characteristics, and included Chinese version of the SF-36 and the European Heart Failure Self-Care Behavior Scale. A comparison of the long-term effectiveness of the CM program was made using generalized estimating equation. **Results:** Although no significant differences were observed in blood pressure or high density lipoproteins between pre- and post-CM, CM did improve self-care behaviors and quality of life, and reduced the values of patient metabolic parameters such as total cholesterol, triglycerides, fasting blood glucose and low density lipoprotein (all $p < 0.01$). Notably, these parameters remained significantly improved for six months following completion of the CM program. **Conclusion:** This study supported the long-term effectiveness of CM for Taiwanese patients with HF, and may be a reference for healthcare providers in facilitating the provision of appropriate interventions to improve the adaptation processes and clinical outcomes for them.

Keywords: Heart Failure, Case Management, Generalized Estimating Equations

Received: Aug. 16, 2017

Accepted: Jan. 03, 2018

*Corresponding Author

Tzung-Yi Tsai, No. 2, Minsheng Rd., Dalin Township, Chiayi 62247, Taiwan, ROC

Email: dm732024@tzuchi.com.tw

TEL: 886-5-2648000 ext. 3209

FAX: 886-5-2648000 ext. 3241

Background

Aging and changes in lifestyle have caused a remarkable increase in age-related chronic diseases such as heart failure (HF). It is estimated that, worldwide, nearly 30 million people were affected with HF¹, and one million new cases emerge each year². Additionally, the irreversible nature and poor prognosis associated with HF further result in a heavy economic cost. For example, Cook and colleagues estimated that the worldwide direct medical expenditure of treating HF in 2012 was USD \$65 billion, with the total societal costs (the sum of direct costs and indirect costs) estimated to exceed USD \$108 billion³, thus posing a heavy burden on patients with HF, their families and healthcare system.

In response to the increasing threat of HF, effective coordination across healthcare services might be essential in order to reduce symptom distress and improve clinical outcomes for HF patients⁴. Recently, case management (CM) has drawn more attention in medical practice as an approach to such a high-cost and high-risk chronic disease. CM is patient-tailored care that includes assessment, planning, integration, implementation and evaluation of a treatment plan^{5,6}. Thus, the growing body of literature on examining the effectiveness of CM with HF patients has now been gradually aggregated. A recent meta-analysis of 27 studies from 1997 to 2012 established that CM effectively reduced mortality, hospital admissions, and visits to the emergency department by HF patients⁶. One

two-year follow-up work conducted in Italy compared the healthcare costs in a CM program with traditional care and found that the CM program resulted in a meaningful cost saving of euro 982.04 per enrolled HF patient⁷.

Until now, most of former studies concerning the assessment of CM effects were conducted in Western populations⁶⁻⁹. Evidence as to whether CM could improve the performance of HF patients in Taiwan was limited to two reports and both yielded inconclusive findings^{10,11}. Moreover, these studies had small sample sizes (36 and 26 subjects, respectively) and neither evaluated the long-term effects of CM, which made clear conclusion about CM difficult. To narrow this gap in the literature, this study aimed to clarify the long-term effectiveness of CM for HF patients by using generalized estimating equations (GEEs), with the intent that the findings could serve as a reference for providing empirically robust grounds for healthcare providers to formulate CM programs that are culturally appropriate for Chinese HF patients.

Methods

Study design and subjects

A single group repeated measures design with purposive sampling recruited patients from the cardiology clinic at a hospital in Taiwan from June 2011 to March 2012. Eligibility criteria required that patients were: (i) at least 20 years old at the time of recruitment; without cognitive impairment and to have the ability to

express themselves in either Mandarin or Taiwanese; (iii) diagnosed with HF by a physician; and (iv) willing to participate in this study. Before enrollment, all participants received detailed written and verbal information regarding the aims and protocol of the study and signed informed consent. To ensure participants' anonymity, all questionnaires were marked with an encryption code to facilitate data analysis, but without any personal identifiers. The study protocol had been approved by the Ethics Committee of Dalin Tzuchi Hospital (B10002009) prior to patient recruitment.

The CM program

The major content of the CM program was developed by the cardiology team and researchers and was made up of two parts: health education sessions and follow-up telephone consultations. All intervention content was delivered by the nursing case manager who had over 10 years of nursing experience and received more than 20 hours of case management training. At the initial visit, the case manager introduces the case management program and explains the roles of the case manager at a private room in the outpatient unit. If the subject gives consent to participate in the program, the case manager would undertake a face-to-face interview to assess the patient's health needs and problems via a questionnaire designed by the case management program. The questionnaire consists of the following categories:

socioeconomic information, medical information and utilization of healthcare service, knowledge about HF, self-management and health behavior. At the end of this initial visit, the subject's health problems are listed, goals are set by problem lists and a plan of action is established. The case manager would help their self-efficacy in successfully achieving their goals. Thereafter, the subjects received health education for 60 min per session, once a month for six months. The contents of the health education session included information about the physiology of HF, advice on diet and prescription drugs, the design of an individual exercise program, an overview of disease complications and rehabilitation, and the skill of self-care at home. The case manager also offers different interventions according to patients' understanding, demand and family involvement. For the sake of strength of the subjects' knowledge and skills, the corresponding color molds or drawings are used to help them understand the materials in more detail. Therefore, participants of the program receive interventions tailored to their individual needs. Additionally, twice per month follow-up telephone consultations were then implemented to assess the patients' condition, or to contact them if they did not keep scheduled appointments. If necessary, the case manager reinforced counseling via home visits.

Instruments

A set of measures were used for data

collection. These included the 36-Item Short Form Health Survey (SF-36), the European Heart Failure Self-Care Behavior Scale (EHFScBS), and an additional questionnaire that obtained information about demographic and disease characteristics.

Quality of life (QOL) was evaluated with the SF-36, a 36-item questionnaire developed as a brief, multidimensional self-reported instrument to assess the following domains: "Physical functioning", "Role limitation due to physical problems", "Body pain", "General health", "Vitality", "Social functioning", "Role limitation due to emotional problems", and "Mental health", as well as "Reported health transitions". For each subscale, item scores are coded, summed, and scaled from 0 to 100, with higher scores indicating a better perceived health status¹². This scale was translated into Chinese and shown to have good psychometric properties. Lu and colleagues established norms for the Taiwanese version of the SF-36 and found that all subscales passed the tests for item discriminant validity; moreover, the corrected item-total score correlations of this scale were positive and statistically significant, ranging from 0.27 to 0.67¹³.

The EHFScBS, developed by Jaarsma et al¹⁴, was utilized to evaluate the patient's self-care efficacy. It contains 12 questions scored on a 5-point Likert scale, with lower scores indicating more positive self-management level. The instrument has acceptable content and

concurrent validities as it was able to discern the different levels of self-care in patients with and without extra HF education¹⁴. This scale has been translated into Chinese to evaluate the level of self-efficacy among Taiwanese HF patients, and the internal consistency of Cronbach's alpha was reported as 0.81¹⁵.

The third questionnaire gathered information about demographic and disease characteristics which was developed according to clinical experience and literature review^{6,7}. Information included gender, age, marital status, educational level, job status, living status and certain lifestyle factors, containing smoking, alcohol consumption, and exercise habits. Those who answered "currently" or "yes/past" to smoking were classified as smokers. Alcohol consumption was divided into two groups based on if they had consumed alcohol at least two times per week. Those who exercised 3 or more days within one week were defined as having regular exercise habits. The disease characteristics included: New York Heart Association (NYHA) functional classification, disease duration, left ventricular ejection fraction, body mass index (BMI), blood pressure (BP) and the values of total cholesterol, triglycerides, fasting blood glucose, low density lipoprotein (LDL) and high density lipoprotein (HDL). All disease characteristics were obtained by review of the patients' medical records.

Data collection procedure

Prior to the subject beginning the CM program, the questionnaires were administered and collected as the baseline data at the initial visit (T0). Then, the subjects were asked to complete the SF-36 and EHFSBS within one week after completion of all CM sessions (T1). Data regarding disease characteristics were collected by the case manager through review of medical records at three different points: T0, T1 and 6 months following the completion of the CM program (T2).

Statistical analysis

Descriptive and inferential statistical analyses were done according to the study aims and the nature of the variables. Descriptive analysis, including means, standard deviations (SD) and percentages, were used to describe the distributions of the various participant personal and medical data. For inferential analysis, we used the Generalized Estimating Equations (GEEs) method with first-order autoregressive correlation structure to evaluate the long-term effects of the CM program, while taking into account the statistical dependence of the multiple observations over time for each patient and the varying duration of observation of patients. All analyses were conducted with SPSS version 18.0 (SPSS, Inc., Chicago, IL). The $p < 0.05$ was considered statistically significant.

Results

A total of 100 subjects with HF were included for data analysis. Their mean age was

69.65 (± 12.89). The majority were male (74.0%), married (70.0%), with low educational level (below 9th grade) (68.0%), unemployed (65.0%) and cohabitating (80.0%). Most subjects were smokers (64.1%), and approximately half consumed alcohol or exercised (49.0% and 51.0%, respectively). In terms of disease characteristics, most of them had disease duration greater than six years (52.0%). Patients with a stage II or below NYHA classification made up the majority of this group (88.0%), and the left ventricular ejection fraction was less than 40% in most cases (Table 1).

Table 2 presents the multivariate analysis using GEEs with first-order autoregressive structure. It shows that, except for BP and HDL, significant improvements were observed in BMI, total cholesterol, triglycerides, fasting blood glucose, and LDL at both T1 and T2, when compared to T0 (all $p < 0.01$). Additionally, in comparison with T0, the scores on SF-36 and EHFSBS after the CM program were significantly enhanced by 27.43 and 26.36 points, respectively (all $p < 0.01$).

Table I. Demographic data and disease characteristics of subjects. (N=100)

Variables	N(%)
Gender	
Male	74(74.0)
Female	26(26.0)
Educational level	
Low (below 9th grade)	68(68.0)
High (above 9th grade)	32(32.0)
Marital status	
Single	70(70.0)

Married (or divorced)	30(30.0)
Job	
Unemployed	65(65.0)
Employed	35(35.0)
Living status	
Cohabiting	80(80.0)
Living alone	20(20.0)
Cigarette smoking	
No	36(36.0)
Yes	64(64.0)
Alcohol consumption	
Low (≤ 1 times/week)	51(51.0)
High (≥ 2 times/week)	49(49.0)
Regular exercise	
No	49(49.0)
Yes	51(51.0)
Disease duration (years)	
≤ 2	25(25.0)
3-5	23(23.0)
≥ 6	52(52.0)
NYHA grade	
I/II	88(88.0)
III/IV	12(12.0)
Left ventricular ejection fraction	
$> 40\%$	40(40.0)
$\leq 40\%$	60(60.0)

Discussion

This study show that the overall disease characteristics, with the exception of BP and HDL, were significantly improved after the completion of the CM program, and then remained constant throughout the six-month follow-up. To date, no study has been conducted that examined the effects of CM on the metabolic parameters of HF patients, which makes a comparison of results difficult. Despite this concern, when compared with similar reports across groups with chronic diseases^{16,17}, our finding were consistent with those earlier studies and added to the growing body of

knowledge that CM is beneficial in strengthening metabolic controls among patients with chronic diseases. The findings also suggest that CM targeting patient-centered care and including health education sessions with two-way communication, as well as follow-up telephone consultations, do not only change patients' self-care behaviors but also improve clinical outcomes for HF patients.

In this study, CM did not improve the levels of HDL, echoing a previous report which failed to find significant effects of CM on HDL in diabetic patients¹⁶. Yet, due to the paucity of research in this area targeting HF patients, future work with larger sample sizes or longer follow-up periods is suggested in order to clarify if this finding could be replicated in other demographic and geographic groups. With regard to the effect of CM on BP, it was found that CM was associated with lower BP values but with no statistical significance.

Table II. Multivariate analysis of the effectiveness of the CM program by GEEs (N=100)

Variables	Regression coefficient	Standard error	Z	P
BMI				
T1/T0	-0.62	0.22	-2.89	<.001
T2/T0	-0.46	0.90	-5.14	.001
Systolic blood pressure				
T1/T0	-2.13	1.86	-1.14	.32
T2/T0	-2.22	2.23	-0.99	.25
Diastolic blood pressure				
T1/T0	-1.67	1.56	-1.07	.28
T2/T0	-2.53	1.54	-1.64	.15
Total cholesterol				
T1/T0	-53.38	5.75	-9.29	<.001
T2/T0	-41.09	7.19	-5.71	<.001
Triglycerides				
T1/T0	-66.41	14.07	-4.72	<.001
T2/T0	-61.64	14.88	-4.14	<.001
Fasting blood glucose				
T1/T0	-33.77	7.21	-4.68	<.001
T2/T0	-29.76	6.34	-4.69	<.001
HDL				
T1/T0	-2.12	1.59	-1.33	.18
T2/T0	-1.24	2.37	-0.52	.60
LDL				
T1/T0	-34.99	4.28	-8.17	<.001
T2/T0	-48.11	5.93	-8.11	<.001
SF-36				
T1/T0	27.43	1.23	-22.35	<.001
EHFScBS				
T1/T0	-26.36	0.61	-45.21	<.001

Note. Results from GEEs model after adjusting for the baseline variables listed in Table 1.

We speculated that the BP measurements at all three points were within the normal range, so possibly lessening the influence of CM to some extent. In clinical practice, BP levels might also not be too tightly controlled in elderly subjects¹⁸. On the other hand, our results were inconsistent with the former report which revealed that CM could improve the BP level¹⁹. This inconsistency may be associated with the study design and statistical analyses used. In a longitudinal or repeated measures study design,

the utilization of traditional analysis of variance (ANOVA) may fail to specifically ascertain the variation in outcome variables that were derived from intervention programs only, or it may be confounded by the effects of maturation²⁰.

In keeping with previous reports^{8,9,11}, this study also revealed that CM significantly improved the self-care behaviors and QOL of HF patients. It could be inferred that CM have modified the psychophysiological reactions

caused by clinical sequelae via the efficient reinforcement of individual self-care abilities⁶. Our findings, however, did differ from those of Li and colleagues' findings¹⁰. The difference may have been due to the measurement instrument and the statistical analysis employed in both studies, as Li et al. used a self-designed questionnaire to examine self-care behaviors¹⁰, which is different from our scale (EHFScBS). Furthermore, ANOVA was used in their study and it may have been insufficiently robust to reveal the interaction effects that may otherwise result from treatment status or time effects, thus leading to statistically unsupported conclusions.

Our study may have some limitations that are noteworthy. First, the study subjects were recruited from a single hospital, so inferences drawn from the results are restricted in the generalizability. This limitation, however, is not unique to our study. Actually, most studies are limited by such factors as subjects' ethnicity, geographic location, nationality and the nature of the medical data available; nevertheless, the use of larger samples with randomized or stratified sampling to increase the generalization of findings is still warranted. Second, a single group with repeated measures design rather than randomized design may fail to accurately validate the effectiveness of the CM program. However, the data collected by the researchers, prior and following completion of CM, further utilized GEEs to adjust for the potential impact of natural aging and maturation, hence any

possible biases may, in fact, favor the null hypothesis, thus posing a lesser threat to the validity of our findings. Third, this study lacked 6-month follow-up data about patients' QOL and self-care behaviors, thus limiting the long-term effects of CM. Future work should routinely assess these psychological indicators to comprehensively present the long-term effects of CM.

In conclusion, this was the first evidence-based study to investigate the long-term effectiveness of CM among Taiwanese HF patients. It demonstrated that CM could effectively enhance self-care behaviors as well as QOL immediately following its completion, and also reduce metabolic parameters including total cholesterol, triglycerides, fasting blood glucose and LDL, in the long run. It was noteworthy that the improvement in metabolic features remained significant at the end of six months of follow-up. The study provided evidence that CM with patient-centered care might be beneficially integrated into routine disease management to achieve the treatment goals and cost-savings for patients with chronic diseases.

Acknowledgements

We thank the co-investigators in this project and the patients who responded to our survey. IYH and CMC contributed equally to this work. TKL is the co-corresponding author of this paper (shockly@tzuchi.com.tw).

References

1. Ambrosy AP, Fonarow GC, Butler J, et al. The global health and economic burden of hospitalizations for heart failure: lessons learned from hospitalized heart failure registries. *J Am Coll Cardiol.* 2014;63(12):1123-1133.
2. McMurray JJV, Stewart S. The burden of heart failure. *Euro Heart J Suppl.* 2002;4(suppl_D):D50-D58.
3. Cook C, Cole G, Asaria P, Jabbour R, Francis DP. The annual global economic burden of heart failure. *Int J Cardiol.* 2014;171(3):368-376.
4. Annema C, Luttik ML, Jaarsma T. Do patients with heart failure need a case manager? *J Cardiovasc Nurs.* 2009;24(2):127-131.
5. Hisashige A. The effectiveness and efficiency of disease management programs for patients with chronic diseases. *Glob J Health Sci.* 2012;5(2):27-48.
6. Martínez-González NA, Berchtold P, Ullman K, Busato A, Egger M. Integrated care programmes for adults with chronic conditions: a meta-review. *Int J Qual Health Care.* 2014;26(5):561-570.
7. Del Sindaco D, Pulignano G, Minardi G, et al. Two-year outcome of a prospective, controlled study of a disease management programme for elderly patients with heart failure. *J Cardiovasc Med.* 2007;8(5):324-329.
8. Ducharme A, Doyon O, White M, Rouleau JL, Brophy JM. Impact of care at a multidisciplinary congestive heart failure clinic: a randomized trial. *CMAJ.* 2005;173(1):40-45.
9. Peters-Klimm F, Campbell S, Hermann K, et al. Case management for patients with chronic systolic heart failure in primary care: the HICMan exploratory randomised controlled trial. *Trials.* 2010;11:56.
10. Li CY, Lee CY, Chang LSN, Liao WC, Chen YJ. The effectiveness of case management for patients with heart failure. *Macau J Nurs.* 2013;12(1):35-41.
11. Wei CY, Chang SC. The effectiveness of case management model on inpatients with congestive heart failure. *Tzuchi Nurs J.* 2010;9(4):71-83.
12. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care.* 1992;30(6):473-483.
13. Lu JF, Tseng HM, Tsai YJ. Assessment of health-related quality of life in Taiwan (I): development and psychometric testing of SF-36 Taiwan version. *Taiwan J Public Health.* 2002;22(6):501-511.
14. Jaarsma T, Strömberg A, Mårtensson J, Dracup K. Development and testing of the European Heart Failure Self-Care Behaviour Scale. *Eur J Heart Fail.* 2003;5(3):363-370.
15. Yeh HF, Shao JH. A study of dietary self-efficacy and self-management

behaviors in elderlies with heart failure.
Tzuchi Nurs J. 2010;9(4):96-107.

16. Chang HC, Chang YC, Lee SM, et al. The effectiveness of hospital-based diabetes case management: an example from a northern Taiwan regional hospital. *J Nurs Res.* 2007;15(4):296-309.
17. Lu KY, Lin PL, Tzeng LC, Huang KY, Chang LC. Effectiveness of case management for community elderly with hypertension, diabetes mellitus, and hypercholesterolemia in Taiwan: a record review. *Int J Nurs Stud.* 2006;43(8):1001-1010.
18. Vergheze J, Lipton RB, Hall CB, Kuslansky G, Katz MJ. Low blood pressure and the risk of dementia in very old individuals. *Neurology.* 2003;61(12):1667-1672.
19. Gabbay RA, Lendel I, Saleem TM, et al. Nurse case management improves blood pressure, emotional distress and diabetes complication screening. *Diabetes Res Clin Pract.* 2006;71(1):28-35.
20. Ma Y, Mazumdar M, Memtsoudis SG. Beyond repeated-measures analysis of variance: advanced statistical methods for the analysis of longitudinal data in anesthesia research. *Reg Anesth Pain Med.* 2012;37(1):99-105.