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Author(s)	遠藤, 教子
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博士論文

Factors associated with enrollment and
adherence of outpatient cardiac
rehabilitation in Japan

日本における外来型心臓リハビリテーションの
参加関連要因と継続関連要因についての検討

福島県立医科大学大学院医学研究科医学専攻

疫学・地域保健学分野

遠藤 教子

概要

心臓リハビリテーション（以下心リハ）は、運動耐容能、生活の質（Quality of Life）、そして、生命予後の改善といった効果が示されている。我が国では、心疾患患者への心リハ実施率は諸外国に比較して低い。実施施設においても、参加率並びに継続率は低いことが報告されている。本研究の目的は、外来通院型心リハにおける参加関連要因と、継続関連要因を明らかにすることである。

方法：本研究は症例対照研究で、対象者は一市中病院において、2010年3月から2年間に入院し、心リハを施行された544人である。外来型心リハに参加した患者は78人（参加群）であり、その内3ヶ月外来型心リハを継続できたのは23人（継続群）であった。対照群は、外来型心リハ非参加者から無作為に抽出した179人である。調査項目は患者基本属性、心疾患の詳細、冠危険因子、内服加療内容、心機能関連項目、リハビリ関連項目等であり、電子カルテ、心臓カテテルデータベースから転記した。分析1では、心リハ参加関連要因について解析した。参加群と非参加群を単変量解析にて比較し、有意項目に基本属性を加えて多変量解析を実施した。分析2では、心リハ継続関連要因について解析した。継続群と非継続群の特性を単変量解析にて比較し、有意項目に基本属性を加えて多変量解析を実施した。

結果：分析1では高齢（オッズ比 [以下 OR] , 0.96; 95%信頼区間 [以下 CI] , 0.93-0.98; $p=0.003$ ）、病院までの距離（OR, 0.97; 95% CI, 0.95-0.99; $p=0.014$ ）が有意な参加関連要因であった。分析2では、虚血性心疾患（OR, 6.03; 95% CI, 1.62-22.5; $p=0.007$ ）、安定剤等の内服（OR, 4.14; 95% CI, 1.07-16.0; $p=0.039$ ）が有意な継続関連要因であった。

考察：外来通院型心リハの参加関連要因として、社会的要因（高齢、病院までの距離）が参加阻害因子として挙げられた。継続関連要因としては、身体的要因（虚血性心疾患、安定剤等の内服）が継続促進因子として挙げられた。外来通院型心リハの参加、継続を向上させるためには疾患の詳細だけでなく、患者のセルフマネジメント力や病院へのアクセス、心理的状态を把握し、参加しやすい包括的なシステムを構築することが必要である。

ABBREVIATIONS

CR: cardiac rehabilitation

OCR: outpatient cardiac rehabilitation

AMI: acute myocardial infarction

JCS: the Japanese Circulation Society

ICR: in-hospital cardiac rehabilitation

CABG: coronary artery bypass grafting

IHD: ischemic heart disease

LVEF: left ventricular ejection fraction

$\dot{V}O_2$: cardiopulmonary exercise test results including anaerobic threshold

Peak $\dot{V}O_2$: peak oxygen consumption

$\dot{V}E$: minute ventilation

$\dot{V}CO_2$: carbon dioxide output

INTRODUCTION

Cardiac rehabilitation (CR) is highly effective at increasing exercise tolerance, preventing recurrent events, improving quality of life, and improving long-term prognosis.^{1,2} In Japan, CR is recommended for patients who have undergone open-heart surgery^{2,3,4} or experienced various forms of cardiovascular disease, including acute myocardial infarction (AMI),^{2,5} angina pectoris,^{2,6} chronic heartfailure,^{2,7,8} and peripheral arterydisease.^{2,9} The first nationwide CR survey in 2004 included 526 cardiology training hospitals and reported that in-hospital CR (ICR) was 53% of the hospitals. However, only 9% of those hospitals reported offering outpatient CR (OCR).¹⁰⁻¹² According to the most recent government report by the Ministry of Health, Labor and Welfare's Circulatory Disease Research Commission, the implementation of ICR and OCR had increased to 64% and 21%, respectively.^{10,12}

The above-mentioned increase in the outpatient implementation percentage at the hospital level could be explained in part by the recent shortening of hospital stays, which has followed the latest revision of the treatment guidelines.² In 2004, the mean duration of hospitalization for AMI patients was 19 days, whereas in 2009, it was only 15 days.¹² Nevertheless, the length of hospitalization is much longer in Japan as compared to North America and European countries. In order to achieve further shortening of the hospital stay in Japan, it is necessary to promote wider implementations of outpatient rehabilitation because OCR provides an important opportunity for increased patient follow-up.

In Japan, insurance covers CR for 150 days and the 150-day count starts on the first day of ICR. However, since the length of hospital stay differs for each patient, so does the number of days available for OCR. The JCS guidelines recommend an OCR frequency of 2-3 times a week², but despite increases in the need for OCR and the implementation percentage at the hospital level, it remains difficult to encourage some patients to continue rehabilitation. In addition, no national data are available on enrollment at the individual level and the data available from small-scale studies vary considerably across Japanese hospitals. For example, one hospital reported that only 22% of suitable patients enrolled in OCR and only 52% of those patients continued for 1 month.¹³ But another hospital reported approximately 40% of suitable patients enrolled in OCR.¹⁴ According to a recent report, nearly 17% of OCR patients in the United States dropout before 3 months in the program.¹⁵

Japanese data on the barriers and motivators of OCR enrollment are limited.

Previous studies conducted outside Japan have reported several factors that facilitate OCR enrollment, namely, having social support,¹⁶ male sex,¹⁶ post coronary artery bypass grafting (CABG),¹⁸ and recommendation by a physician.¹⁷ On the other hand, several factors have also been reported to negatively affect OCR enrollment, including living far from the hospital,¹⁹ transportation issues,^{20,21} being employed,^{16,20-22} younger age,²³ and being depressed.²¹ Moreover, it has been reported that having social support facilitates OCR adherence,^{16,24} but that smoking,²⁵ female sex,^{26,27} and being depressed²⁷ negatively effect OCR adherence.

Previous studies in Japan have investigated adherence to OCR. However, no study has yet investigated the background factors related to OCR enrollment in a multifaceted manner. Accordingly, the aims of this study were to investigate the background factors associated with enrollment in OCR (Objective 1) and adherence to OCR (Objective 2). In addition to clinical characteristics, we also considered socioeconomic factors.

METHODS

Study Design

This was a single-hospital, case-controlled study that used data derived from electronic medical charts and a cardiac catheterization database at Ohta-Nishinouchi Hospital in Fukushima Prefecture. Between March 2010 and February 2012, 544 patients were hospitalized for ischemic heart disease (IHD); including AMI and angina pectoris, chronic heart failure or open-heart surgery and were recommended for ICR. We defined patients who participated in OCR at least one time after discharge as “enrollers”, whereas patients were defined as “adherers” if they participated in at least one additional session during the 3 months following the start of OCR; which is equivalent to 60% of the insurance benefit period.

For Objective 1, the 78 patients who participated in OCR were included in our study as enrollers. From the patients who did not participate in the OCR, we randomly selected 179 patients to be included as controls (nonenrollers). On the basis of previous reports in the

literature, the OCR participation rate was expected to be low and so the size of the control group was designed to be 3 times larger than the treatment group. This was done to improve statistical power.²⁸ For Objective 2, 23 of the 78 patients enrolled in OCR met the definition of adherers.

Demographic and Clinical Data

The following information was collected from the hospital database: baseline characteristics (age, sex, employment status, family structure, and distance from the hospital); cardiac diagnosis; IHD status; heart failure status; coronary risk factors (hypertension, dyslipidemia, diabetic mellitus, and smoking history); attending physician's specialty; duration of hospitalization; prescriptions (sleeping pills and/or antidepressants and cardiovascular medications); date the patient started ICR; left ventricular ejection fraction (LVEF) primarily measured by echocardiography; and cardiopulmonary exercise test results including anaerobic threshold ($AT\dot{V}O_2$), peak oxygen uptake ($\dot{V}O_2$), and minute ventilation versus carbon dioxide production ($\dot{V}E$ vs $\dot{V}CO_2$ slope). For the OCR enrollers, medical records were used to determine the starting date, the date of the most recent participation, and the total number of times each patient participated in OCR.

Statistical Analysis

The enroller and non-enroller groups were compared to assess factors associated with enrollment in OCR (Objective 1). The enroller group was divided into patients who were

adherers in OCR for at least 3 months and those who did not (~~non~~adherers”). These 2 groups were compared in order to examine factors associated with adherence to OCR (Objective 2). For both analyses, univariate analyses compared the groups using the Chi-square test for categorical variables and the Mann-Whitney U test for continuous variables. We then performed multivariate logistic regression analyses, adjusted for age and sex, as well as each of the factors that were significant in the univariate analyses. Odds ratios (ORs) with 95% confidence intervals (CIs) and *P* values were calculated from the regression models. Analyses were performed using SPSS statistical software for Windows version 17.0 (IBM SPSS, Inc., Chicago, IL, USA).

Ethical Considerations

The ethics committees of Fukushima Medical University (No. 1465) and Ohta-Nishinouchi Hospital approved our study protocol. All data were collected without using personal health identifiers.

RESULTS

The OCR enrollment percentage was 14% (78/544) among patients who were recommended to start ICR.

Objective 1

A total of 257 patients were included in the analyses, comprising 78 OCR enrollers and 179 non-enrollers. As presented in Table 1, the median age was significantly lower and included a significantly larger proportion of men in the enroller group. Other significant factors in the

univariate analyses included employment, distance from the hospital, history of hypertension, smoking status, and a diagnosis of IHD. In the multivariate analysis, age and distance to the hospital remained significant independent factors (Table 2).

Objective 2

For these analyses, 23 patients were classified as adherers and 55 patients were identified as non-adherers. The following variables were significant in the univariate analyses: IHD and use of sleeping pills and/or antidepressants (Table 3). Multivariate logistic regression analysis was performed including these significant variables, as well as adjusting for age and sex (Table 4). IHD and the use of sleeping pills and/or antidepressants remained significant in the multivariate model.

DISCUSSION

Our results indicate that sociodemographic factors were primarily associated with OCR enrollment whereas clinical factors were associated with OCR adherence. Similarly, a recent meta-analysis reported that social factors, rather than clinical factors, were associated with initiating CR¹⁶ and our results support these previous findings among Japanese patients.

In our study, the OCR enrollment proportion was 14%, which is slightly higher than the average enrollment proportion of cardiology training hospitals reported by Goto et al in a nationwide survey (10.6%).¹¹ However, the enrollment proportion is still low in comparison to North American OCR programs. To improve the CR enrollment proportion, it is also

necessary to consider the methodology used to prescribe OCR. In North America, a previous study reported that a systematic referral system was effective for achieving good adherence.²⁹ In addition, weekly patient group meetings have been demonstrated to effectively reinforce the recognition of the need for OCR.³⁰ These methods may also contribute to improving the enrollment proportion in Japan and should be the focus of future research.

Our results indicated that older age is one of the barriers to starting OCR. Previous studies have described how physical activity declines with age,³¹ which is linked with decreased skills for self-managing diseases.^{32,33} Thus, we recommend more careful monitoring of the physical activity and disease management capacity, especially for older patients.

Consistent with our findings documenting an association between OCR enrollment and the distance between the patient's residence and the hospital, a previous study found that distances ≥ 1 -hour drive decreased CR participation.³⁴ Another study determined that non-drivers were especially likely to be non-participants.²⁶ Accordingly, OCR enrollment at our hospital could perhaps be increased by improving access to the hospital. In the current study, data regarding the means of transportation of the patients was not available and so we analyzed distance. To address this issue, we propose to carefully assess at discharge the available transportation and the time required for travelling to the hospital from home. This will hopefully help us to suggest means to facilitate more frequent visits to OCR. Currently,

there is a shuttle bus service between our hospital and a nearby train station, and we recommend mapping and assessing whether this service covers the areas where most patients of the patients live and whether altered routes may help increase the OCR use.

In addition to the factors significantly associated with OCR enrollment in the multivariate analysis, the fact that we did not observe a significant association between disease severity and OCR enrollment deserves attention. If physicians would make a stronger recommendation for OCR to patients with more severe conditions and if those patients would recognize the need to start and continue OCR, we might likely observe a significant association. Our findings suggest that the severity of the disease and the need for OCR were not effectively communicated to the patients who could benefit the most from OCR.

We found that IHD was one of the motivating factors for OCR adherence among our patients. A previous randomized controlled trial reported that coronary artery disease patients demonstrated good adherence to CR,³⁵ whereas a review by Jackson and colleagues³⁶ stated that there were no clear predictors associated with the long-term behavioral changes in these patients. These authors also found that patients with percutaneous trans luminal coronary angioplasty, angina, or coronary artery bypass grafting were referred more often to CR, suggesting different levels of physician endorsement of the program depending on the patient's condition.³⁶ To encourage enrollment in OCR, we recommend conducting automated computerized referrals, as suggested by Grace et al,²⁹ and performing subsequent monitoring

of enrollment and adherence status. Additional adherence factors were found to include perception of the severity of the heart disease.²⁷ Hence, for patients with chronic diseases such as IHD, it is beneficial to be competent at self-management of their medical treatment in the long-term,³⁷ and we recommend careful monitoring the patients' comprehension of self-management.

In this study, patients using sleeping pills and/or antidepressants were typically adherers to rehabilitation. With respect to the mental health of the patients, it has been reported that anxiety and depression are significant factors for OCR non-enrollment and non-adherence.²⁷ Although it may seem that our results are inconsistent with this previous finding, Bauer and colleagues reported that patients with anxiety have high levels of health behavior.³⁸ We speculate that the use of sleeping pills and/or antidepressants by patients could evidence a greater degree of motivation to improve their health status, thereby resulting in better OCR adherence. Although mental health assessment and counseling is included in the Japanese guidelines for OCR², our hospital has not yet introduced this assessment, which is why we used the use of anti-depressants or sleeping pills as a proxy indicator. We suggest that there is a need to introduce routine mental health assessment for these patients.

LIMITATIONS

This study had 2 major methodological limitations. First, this was a single hospital study, which included a limited number of cases. Moreover, the number of patients included in the

multivariate analysis for adherence was low; hence, the CIs were quite wide for some of the variables. Second, the database used may not have included some important determinants of enrollment and adherence, resulting in relatively low R^2 values (0.30 for Objective 1 and 0.26 for Objective 2, respectively). In particular, we were unable to include information regarding income or educational level, which is considered highly important information potentially affecting enrollment and adherence and it is not routinely collected at our hospital. In addition, psychological status was not routinely assessed for the patients in this study and, therefore, we used psychiatric medications as an indicator of psychological status. A multicenter study with a larger sample size and data on socioeconomic and psychological factors is necessary to confirm these results. However, despite these limitations, our analysis of typical data available in hospital records has resulted in practical recommendations for improving OCR enrollment and adherence in Japan.

CONCLUSIONS

In conclusion, our results indicated that sociodemographic factors may need to be considered when encouraging patients to initiate OCR and that clinical factors should be considered when encouraging patients to continue attending OCR. Younger age and living closer to a hospital promoted OCR enrollment, whereas a history of IHD and the use of prescription psychiatric medication were associated with improved OCR adherence. We propose systematic prescription of OCR, self-management by the patients, an organized hospital

transportation system, and a mental health assessment to facilitate increasing patient access to OCR services and improving health awareness.

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Table 1. Baseline Characteristics of Study Participants Related to Enrollment (Objective 1)

	n (%) [†] or Median (Range)		<i>P</i> value
	Enrollers (n = 78)	Nonenrollers (n = 179)	
Sociodemographic factors			
Age, yrs	57 (21–84)	73 (18–94)	<0.01
Sex, male	59 (75.6)	103 (64.0)	0.07
Employed	45 (57.7)	37 (23.0)	<0.01
Living alone	8 (10.5)	24 (15.3)	0.32
Distance from home to hospital, km	10.7 (4.9–57.3)	19.8 (12.5–116.6)	<0.01
Clinical factors			
Body mass index, kg/m ²	24.2 (14.4–37.4)	23.7 (14.6–40.0)	0.45
Coronary risk factors			
Hypertension	46 (61.3)	117 (75.0)	0.03
Diabetic mellitus	28 (37.3)	43 (27.0)	0.11
Dyslipidemia	37 (48.1)	58 (37.9)	0.14
Smoking	44 (60.3)	59 (41.3)	<0.01
Major diagnosis at admission			
Ischemic heart disease	41 (53.2)	59 (36.6)	0.015
Heart failure	7 (9.1)	30 (18.6)	0.57
Cardiac function			
Ejection fraction, %	56 (8.5–80)	56 (22.0–85)	0.95

$\dot{A}T\dot{V}O_2$, mL/kg/min	10.9 (6.4–15.7)	10.3 (6.7–13.2)	0.36
\dot{V}_E vs. $\dot{V}CO_2$ slope	31.4 (17.0–48.6)	30.1 (22.4–48.4)	0.80
Prescription sleeping pills and/or antidepressant	19 (24.4)	49 (31.0)	0.29
Length of hospitalization, days	31 (21–193)	32 (24–262)	0.33

Abbreviations: $\dot{A}T\dot{V}O_2$, anaerobic threshold; $\dot{V}CO_2$, carbon dioxide output; \dot{V}_E , minute ventilation.

^aTotals for some variables do not equal the group total because of missing data.

Table 2. Statistically Significant Variables Associated with OCR Enrollment

	Odds ratio ^a	95% CI
Sociodemographic factors		
Age, yrs	0.96	0.93–0.98
Sex, male	1.29	0.55–3.01
Employed	1.90	0.82–4.27
Distance from home to hospital, km	0.97	0.95–0.99
Clinical factors		
Coronary risk factors		
Hypertension	0.83	0.39–1.76
Smoking	1.64	0.79–3.42
Major diagnosis at admission		
Ischemic heart disease	1.90	0.93–3.72

Abbreviations: CI, confidence interval; OCR, outpatient cardiac rehabilitation.

^aOdds ratios were calculated from a multivariable logistic regression analysis that included all factors that were significant in the univariate analyses, as well as sex. The R^2 for the model was 0.30.

Table 3. Baseline Characteristics of OCR Enrollers (Objective 2)

	n (%) ^a or Median (Range)		<i>P</i> value
	Continuers (n = 23)	Dropouts (n = 55)	
Sociodemographic factors			
Age, yrs	60.0 (32–83)	57.0 (21–84)	0.35
Sex, male	16 (78.2)	43 (69.6)	0.42
Employed	11 (47.8)	34 (61.8)	0.25
Living alone	2 (9.5)	6 (10.9)	0.86
Distance from home to hospital, km	4.6 (0.3–43.0)	5.5 (0.8–57.3)	0.6
Body mass index, kg/m ²	23.7 (17.9–34.4)	23.7 (14.4–37.4)	0.76
Coronary risk factors			
Hypertension	11 (55.0)	35 (63.6)	0.94
Diabetic mellitus	8 (38.1)	20 (37.0)	0.93
Dyslipidemia	9 (40.9)	28 (50.9)	0.43
Smoking	11 (55.0)	33 (62.3)	0.57
Major diagnosis at admission			
Ischemic heart disease	17 (73.9)	24 (44.4)	0.018
Heart failure	2 (8.7)	5 (9.3)	0.93
Cardiac function			
Ejection fraction,%	58.0 (8.5–80.0)	55.5 (30.0–74.0)	0.99
AT $\dot{V}O_2$,mL/kg/min	11.1 (7.3–13.3)	10.8 (6.4–15.7)	0.95
\dot{V}_E vs. $\dot{V}CO_2$ slope	33.8 (19.8–48.6)	30.5 (17.0–39.6)	0.33
Prescribed sleeping pills and/or antidepressant	9 (39.1)	10 (18.2)	0.049

Abbreviations: AT $\dot{V}O_2$, anaerobic threshold; OCR, outpatient cardiac rehabilitation; \dot{V}_E , minute ventilation; $\dot{V}CO_2$, carbon dioxide output.

^aTotals for some variables do not equal the group total because of missing data.

Table 4. Variables Associated with Attending OCR

	OR ^a	95% CI
Sociodemographic factors		
Age, yrs	1.01	0.97–1.05
Sex, male	1.88	0.60–3.34
Clinical factors		
Major diagnosis at admission		
Ischemic heart disease	6.03	1.62–22.5
Prescription Sleeping pills and/or antidepressants	4.14	1.07–16.0

Abbreviations: OCR, outpatient cardiac rehabilitation; CI, confidence interval.

^aOdds ratios were calculated from a multivariable logistic regression analysis that included all variables that were significant in the univariate analyses, as well as sex and age. The R² for the model was 0.26.