

1. Introduction

In the face of rapidly ageing populations in the twenty-first century, high political stakes have triggered debates regarding the efficient allocation and financing of healthcare delivery in developed countries, including Japan. As of 2006, approximately 20% of the Japanese population was at least 65 years of age and accounted for over US\$ 137 billion in healthcare costs, or nearly 4.5% of the gross national product [1]. In recognition of these conditions, several articles have reported on the impact of ageing on healthcare expenditures for acute and long-term care [2–4]. At the same time, new medical technologies, such as percutaneous intra-coronary intervention (PCI), off-pump coronary artery bypass surgery, and laparoscopic surgery, are increasingly in use and have enhanced the quality of life of the elderly [5–8]. Furthermore, a novel drug-eluting stent system involving costly pharmaceutical agents is rapidly becoming the prime method of treating ischemic heart disease (IHD) [9,10], which may have a significant impact on healthcare expenditures.

Although several economic evaluations of these medical advancements have been published with mixed results [11–16], the most likely outcome is that the combined impact of population ageing and medical innovations will burden the economy. In fact, in 2002, 120,400 PCI procedures and 306,000 coronary artery bypass graft (CABG) surgeries were performed in the United States alone. Direct healthcare costs associated with coronary revascularization in the United States were estimated to range between US\$ 12 and 20 billion each year [16]. When determining the efficient allocation of limited resources, policy makers need to take into consideration the impact of population ageing and medical advancements on healthcare spending. If population ageing is expected to have a significant impact on the economy, effective financing for the elderly should be established. At the same time, if medical innovation is expected to spur the rise of expenditure, economic evaluations and monitoring of the appropriateness of their use must be executed without delay.

Cancer, ischemic heart disease, and cerebrovascular disease are the leading chronic illnesses that are often highlighted in public health. As such, these diseases are frequently the targets of disease management and control interventions. The mortality and incident rates

of IHD have recently been on the decline, although IHD is still the second leading cause of death in most industrialized countries, including Japan [17,18]. Furthermore, IHD continues to have a significant burden not only on the affected individual and their family, but also on the healthcare insurance system. In fact, the estimated societal costs of medical care and lost earnings and productivity attributed to coronary heart disease was US\$ 90 billion in 1997 [17]. In Japan, the healthcare expenditure for IHD was estimated to be US\$ 21.7 billion in 2004, of which 70% was attributed to those 65 years or older [1].

One of the common procedures in the treatment of IHD is PCI, including percutaneous balloon angioplasty, coronary stent implantation, and arterectomy, which have all prevailed and have been advocated for use among high-risk patients including the elderly [16,19]. The Survey of National Medical Care Insurance Services, published by the Ministry of Health, Welfare and Labor, demonstrated that the use of PCI procedures has been increasing in Japan, from approximately 70,000 procedures in 1998 to 96,000 in 2003 [20,21]. However, given that the probability of receiving these procedures is higher in patients admitted to teaching or academic hospitals, which are readily equipped with PCI facilities, studies need to take into account variations in practice when estimating the effect of ageing and procedure on resource use [6,22,23].

In 2002, the Japanese administrative database was reformed to reflect a new case-mix classification system. This system is used to profile hospital performance and to assess per diem payment among all 82 academic hospitals (80 university hospitals, the National Cancer Center, and the National Cardiovascular Center) and 92 voluntary community hospitals. These hospitals are scattered throughout Japan and play a leading role in providing acute care medicine, with academic hospitals in a special position to advance medical research. The database is derived from this case-mix system and contains both discharge summaries and claims data. Accordingly, it provides information that can be used to determine the amount of healthcare expenditures spent on the elderly and the types of surgical procedures performed. Furthermore, the database contains information that can be used to investigate differences in costs and outcomes of acute care medicine, after controlling for age, severity of principal diagnosis,

comorbidity or complication, and regional or hospital variation.

This study focused on patients admitted for treatment of IHD and compared the descriptive statistics, healthcare resource use, and outliers of resource consumption by age group. The study included multivariate regression analyses to measure the independent effect of ageing by controlling severity of illness, comorbidity, procedures, and hospital function.

2. Materials and methods

This is a secondary data analysis conducted as part of a government sponsored research project on the development of a case-mix classification system. Anonymous claims and clinical data were provided through a research contract with the Ministry of Health, Labor and Welfare (MHLW). Clinical information and claims data were gathered from 82 specialty hospitals

Table 1
Demographics, clinical characteristics, and outcomes by age group

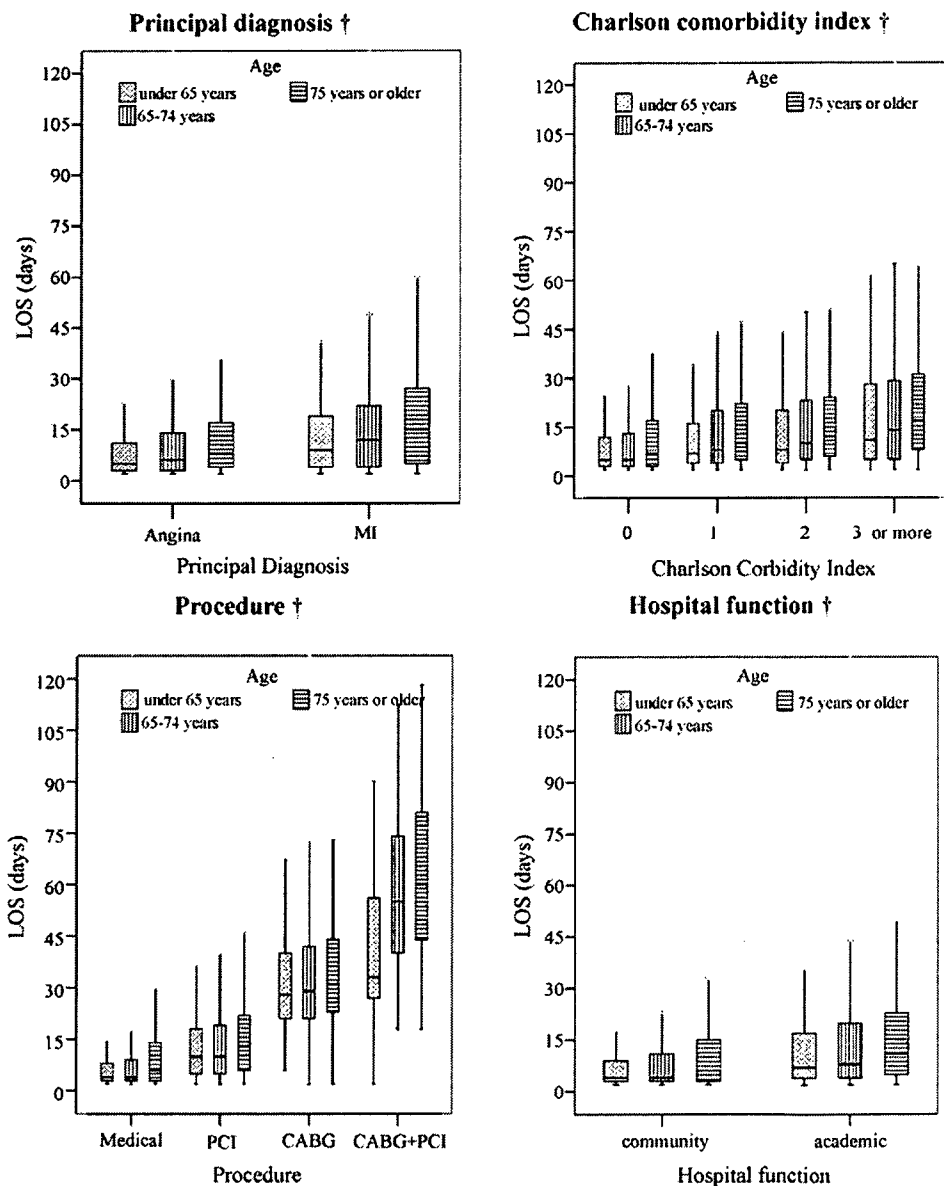
	Age group			P
	Under 65 years	65–74 years	75 years or older	
Overall	7863	7181	4830	
Gender (%)				<0.001
Male	80.4	72.0	60.6	
Ambulance (%)				<0.001
Used	12.6	11.7	17.6	
Principal disease (%)				<0.001
Angina	72.0	75.0	71.4	
MI	28.0	25.0	28.6	
Charlson comorbidity index (%)				<0.001
0	61.7	56.3	56.0	
1	24.5	28.0	25.4	
2	10.4	11.2	12.4	
3 or more	3.4	4.5	6.2	
Procedure (%)				<0.001
Medical	62.7	59.1	61.1	
PCI	30.7	31.7	31.2	
CABG	6.3	8.7	7.3	
PCI + CABG	0.3	0.5	0.4	
IABP (%)				0.069
Used	1.8	2.2	2.4	
Hemodialysis (%)				0.811
Used	4.5	4.7	4.5	
Hospital (%)				<0.001
Community	38.1	36.8	40.7	
Academic	61.9	63.2	59.3	
Outcome (%)				<0.001
In-hospital mortality	0.7	1.0	3.0	<0.001
Mean LOS (days) [S.D.]	10.90 [13.04]	12.88 [15.56]	15.11 [16.5]	<0.001
Mean TC (US\$) [S.D.]	9316 [11,206]	10,584 [12,287]	11,024 [12,950]	<0.001
Outlier (%)				
LOS	3.5	5.4	7.7	<0.001
Total charge	3.8	5.7	5.9	<0.001

MI, myocardial infarction; PCI, percutaneous intracoronary intervention; CABG, coronary aortic bypass graft; IABP, intra-aortic balloon pumping; S.D., standard deviation.

and 92 community hospitals. The data were gathered by the MHLW and merged into a standardized electronic format for 441,142 patients discharged between July 1 and October 31, 2003. From this initial dataset, we selected patients who had been treated for IHD, but excluded those who died within 24 h of admission (134 cases, 0.7%).

2.1. Study variables

Independent study variables included age, gender, principal diagnosis, use of an ambulance, weighted comorbidity, type of procedure, outcome at discharge, use of intra-aortic balloon pumping (IABP), hemodialysis as supportive care, and type of affiliation (academic

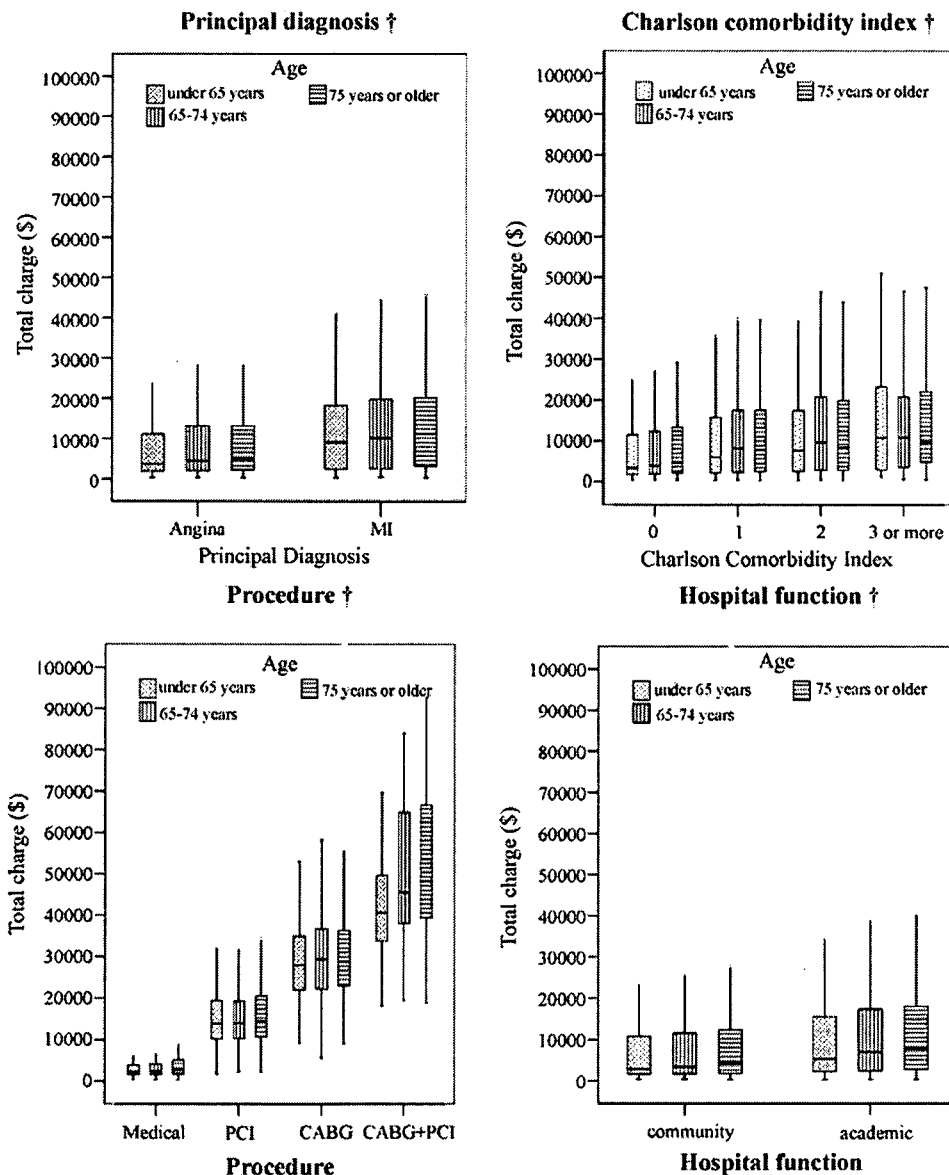


†: statistically significant ($p < 0.001$) at every age group.

Fig. 1. LOS and principal diagnosis, Charlson comorbidity index, procedures, and hospital function, by age group.

or community hospital). Age was stratified into three categories—under 65 years, 65–74 years, and 75 years or older [24]. Emergency admission was defined as transport by an ambulance. The principal diagnosis of IHD was recorded using the International Classification of Diseases, Tenth Revision (ICD-10) code and categorized into angina and myocardial infarction (angina: I20\$,I24\$,I250-1,I255-9; myocardial infar-

ction: I21\$,I22\$,I23\$,I24\$,I252-4). A maximum of four comorbidities were captured in the database. Weighted comorbid conditions were calculated using the Charlson comorbidity index (CCI) [25]. The database also captured a maximum of five operative procedures for each hospitalization. The procedures for IHD patients analyzed in this study included percutaneous intra-coronary procedure as PCI (e.g.



†: statistically significant ($p < 0.001$) at every age group.

Fig. 2. Total charge (US\$) and principal diagnosis, Charlson comorbidity index, procedures, and hospital function, by age group.

percutaneous plain balloon angioplasty, thrombolysis, stenting implantation, atherectomy) and coronary artery bypass graft surgery (CABG). Patients treated for great vessel aneurysm or valve insufficiency were not included in this study.

The dependent variable was length of hospital stay (LOS; days) and total hospital charge (TC; US\$ 1 = ¥120) billed during admission as proxy for cost. In Japan, hospital charges are determined by a standardized fee-for-service payment system known as the nationally uniform fee table. In this study, TC included physician fees, instrument costs, laboratory or imaging test costs, and administration fees. We also examined the presence of longer LOS and costly hospitalizations as indicators of high outliers in LOS or TC, if either exceeded the 95th percentile in overall patient LOS or TC.

2.2. Statistical analysis

All categorical and continuous data were compared across age groups using the Fisher's exact test and analysis of variance (ANOVA). Distributions of LOS and TC were presented using a box chart by age category, principal diagnosis, CCI, procedure and hospital function. Significant differences in principal diagnosis, CCI, procedure, and hospital function among the age groups were tested using ANOVA.

We used a multiple logistic regression analysis to explore the association of age with procedures. In this analysis, a dependent variable was the use of procedures including PCI, CABG or PCI+CABG while independent variables were age, sex, transfer by ambulance car, presence of comorbidity defined in calculation of CCI, and type of affiliation. Use of IABP or hemodialysis was not included because it was not examined whether its use was from the beginning of admission or the result of complication during hospital stay. Next, multiple linear regression analysis was performed to estimate the individual effect of age and procedures on LOS and TC by two types of model: in Model 1, only age and procedures were included, and all study variables were in Model 2. LOS and TC were log-transformed because the distribution of these dependent variables was skewed to the right. Factors associated with high outliers of LOS or TC were also examined using multivariate logistic regression. Statistical analyses were performed using

SPSS version 14.0. All reported *P*-values are two-tailed and the level of significance was set at less than 0.05.

3. Results

We identified 19,847 IHD patients eligible across 174 hospitals (82 specialty and 92 community hospitals). Of these patients, 277 (1.4%) died beyond 24 h of admission. 7181 were 65–74 years of age (36.1%), and 4830 were 75 years or older (24.3%). The number of males varied significantly across age groups, with 80.4% of patients under 65 years of age, 72% between 65 and 74 years of age, and 60.6% at least 75 years old. The proportion of ambulance use, principal disease and CCI were significantly different by age. Overall, the majority of patients (81.4%) were not treated with any procedures previously described, while PCI was performed on a large number of patients (30.7% in under 65 years, 31.7% in 65–74 years, 31.2% in 75 years or older). As for the use of supportive care, there were no significant differences in IABP or hemodialysis. The proportion of patients treated in academic hospitals was statistically different (61.9% in under 65 years, 63.2% in 65–74 years, 59.3% in 75 years or older). Mean LOS,

Table 2
Logistic regression analysis of factors associated with procedures

Independent variables	Odd ratio	[95% CI]	<i>P</i>
Age			
Under 65 years	1.000		
65–74 years	1.191	[1.113–1.274]	0.000
75 years or more	1.081	[1.001–1.168]	0.048
Sex			
Female	1.000		
Male	1.515	[1.415–1.622]	0.000
Ambulance car			
Not used	1.000		
Used	2.726	[2.505–2.968]	0.000
Comorbidity			
Absent	1.000	[1.490–1.680]	0.000
Present	1.582		
Hospitals			
Community	1.000		
Academic	1.282	[1.205–1.364]	0.000

Hosmer Lemeshow goodness for fit; *P*=0.207. MI, myocardial infarction; PCI, percutaneous intracoronary intervention; CABG, coronary aortic bypass graft; IABP, intra-aortic balloon pumping.

mean TC, and the proportion of high outliers in LOS or TC were significantly different across age groups (Table 1).

Figs. 1 and 2 show the comparisons of LOS and TC for all categorical variables. For each age group, both LOS and TC were much higher in patients of MI than of angina, higher in patients with CABG than with medical or PCI only, and also higher in patients treated in academic than in community hospitals. However, LOS and TC were not as high as was for CCI. Furthermore, LOS and TC were significantly different across age groups for these categories.

Table 2 shows the association of age with the use of study procedures. This result revealed that use of ambulance car, presence of CC, male and academic affiliation were significantly more likely to receive pro-

cedures than patients of 65–74 years or 75 years or more.

After adjusting for the potential confounding effects of demographic and clinical variables, LOS and TC were significantly associated with patients aged between 65 and 74 years and those 75 years or older ($P < 0.001$ in Models 1 and 2). Procedures stood significant in predicting LOS and TC ($P < 0.001$ in Models 1 and 2). They were significantly higher estimators among study variables, where estimation of CABG or CABG plus PCI was 1.660 or 2.101 in Model 1, and 1.534 or 1.850 in Model 2, respectively (Tables 3 and 4). CABG and CABG plus PCI were also more significantly associated with high outliers of TC (odd ratio [95% CI]; 67.577 [52.320–87.28] and 496.96 [259.98–949.94], respectively). Age remained

Table 3
Linear regression analysis of factors associated with length of stay (days)

Independent variables	LOS [log LOS]					
	Model 1			Model 2		
	Estimation	S.E.	P	Estimation	S.E.	P
Intercept	1.64	0.01	0.000	1.434	0.015	0.000
Age (for under 65 years)						
65–74 years	0.082	0.013	0.000	0.071	0.012	0.000
75 years or older	0.281	0.015	0.000	0.223	0.014	0.000
Male	***	***	***	–0.165	0.012	0.000
Ambulance car used	***	***	***	0.472	0.016	0.000
Principal diagnosis (for angina)						
MI	***	***	***	0.238	0.013	0.000
Charlson comorbidity index (for zero)						
1	***	***	***	0.100	0.013	0.000
2	***	***	***	0.200	0.018	0.000
3 or more	***	***	***	0.368	0.027	0.000
Procedure (reference; medical)						
PCI	0.603	0.012	0.000	0.481	0.012	0.000
CABG	1.660	0.022	0.000	1.534	0.021	0.000
PCI + CABG	2.101	0.089	0.000	1.850	0.083	0.000
IABP	***	***	***	0.135	0.039	0.001
Hemodialysis	***	***	***	0.144	0.027	0.000
Hospital (reference; community)						
Academic	***	***	***	0.317	0.011	0.000
Outcome						
In-hospital mortality	***	***	***	–0.212	0.047	0.000

F-test for the model. Model 1: $P < 0.001$; Model 2: $P < 0.001$. Coefficient of determination, Model 1: 0.279; Model 2: 0.381. S.E.: standard error; MI: myocardial infarction; PCI: percutaneous intracoronary intervention; CABG: coronary aortic bypass graft; IABP: intra-aortic balloon pumping.

*** Variables not included in Model 1.

Table 4
Linear regression analysis of factors associated with total charge (US\$)

Independent variables	TC [log TC]					
	Model 1			Model 2		
	Estimation	S.E.	P	Estimation	S.E.	P
Intercept	7.924	0.008	0.000	7.748	0.012	0.000
Age (for under 65 years)						
65–74 years	0.039	0.011	0.000	0.036	0.010	0.000
75 years or older	0.136	0.012	0.000	0.095	0.011	0.000
Male	***	***	***	–0.043	0.010	0.000
Ambulance car used	***	***	***	0.322	0.014	0.000
Principal diagnosis (for angina)						
MI	***	***	***	0.156	0.010	0.000
Charlson comorbidity index (for zero)						
1	***	***	***	0.051	0.010	0.000
2	***	***	***	0.115	0.015	0.000
3 or more	***	***	***	0.227	0.022	0.000
Procedure (reference; medical)						
PCI	1.596	0.010	0.000	1.496	0.010	0.000
CABG	2.303	0.018	0.000	2.171	0.017	0.000
PCI+CABG	2.780	0.073	0.000	2.504	0.069	0.000
IABP	***	***	***	0.412	0.032	0.000
Hemodialysis	***	***	***	0.251	0.022	0.000
Hospital (reference; community)						
Academic	***	***	***	0.182	0.009	0.000
Outcome						
In-hospital mortality	***	***	***	0.467	0.038	0.000

F-test for the model. Model 1: $P < 0.001$; Model 2: $P < 0.001$. Coefficient of determination, Model 1: 0.642; Model 2: 0.686. S.E.: standard error; MI: myocardial infarction; PCI: percutaneous intracoronary intervention; CABG: coronary aortic bypass graft; IABP: intra-aortic balloon pumping.

*** Variables not included in Model 1.

significant, but to a lesser extent than procedures (Table 5).

4. Discussion

This study described the characteristics of IHD patients and identified the independent impact of age and procedure type on LOS, TC, and the high outliers of LOS and TC. Age had a statistically significant but weaker association with procedures, compared with other study variables. Patients between 65 and 74 years of age and those 75 years or older were likely to have a modest effect on LOS and TC, while PCI and CABG had a greater impact on LOS and TC. Study findings, after controlling for comorbidity, use of supportive

care, and hospital function, suggested that the type of procedure performed in acute care hospitals has a greater influence on healthcare resource utilization than the age of the patient.

There are several limitations to this study. First, information was gathered from discharged patients during a 4-month time period in 2003. This limits the generalizability of the results. Claims data are now being collected throughout the year and this expanding database will eventually allow researchers to identify the independent effects of various factors on LOS and TC. Second, this study lacked analyses of procedure-related outcomes, such as post-procedure stroke or uneventful cardiovascular attack [26]. However, this database includes complications coded using the ICD-10, such that future investigation of the effect

Table 5
Logistic regression analysis of factors associated with LOS and TC high outlier

Independent variables	LOS		TC	
	Odd	Ratio [95% CI]	Odd	Ratio [95% CI]
Age				
Under 65 years	1.000		1.000	
65–74 years	1.362	[1.146–1.618]	1.291	[1.071–1.557]
75 years or more	2.101	[1.757–2.514]	1.395	[1.132–1.719]
Sex				
Female	1.000		1.000	
Male	0.625	[0.538–0.726]	0.848	[0.707–1.017]
Ambulance car				
Not used	1.000		1.000	
Transferred	1.377	[1.151–1.648]	1.921	[1.575–2.344]
Principal diagnosis				
Angina	1.000		1.000	
MI	2.759	[2.348–3.241]	2.593	[2.121–3.17]
Charlson comorbidity index				
0	1.000		1.000	
1	1.467	[1.242–1.732]	1.132	[0.936–1.369]
2	2.008	[1.646–2.451]	1.630	[1.300–2.043]
3 or more	2.747	[2.125–3.552]	1.910	[1.410–2.586]
Procedure				
Medical	1.000		1.000	
PCI	1.461	[1.224–1.743]	4.176	[3.253–5.360]
CABG	15.760	[13.129–18.917]	67.577	[52.320–87.284]
PCI + CABG	64.619	[38.923–107.279]	496.959	[259.982–949.942]
IABP				
Not used	1.000		1.000	
Used	1.162	[0.874–1.544]	6.137	[4.717–7.985]
Hemodialysis				
Not used	1.000		1.000	
Used	2.200	[1.727–2.803]	3.448	[2.648–4.491]
Hospitals				
Community	1.000		1.000	
Academic	1.688	[1.425–1.998]	1.294	[1.070–1.565]
Outcome				
Alive	1.000		1.000	
In-hospital mortality	1.219	[0.837–1.777]	4.174	[2.881–6.046]

CI: confidence interval. Hosmer Lemeshow goodness for fit; $P=0.020$ and 0.361 , respectively; MI: myocardial infarction; PCI: percutaneous intracoronary intervention; CABG: coronary aortic bypass graft; IABP: intra-aortic balloon pumping.

of procedure-related complications on resource use is possible. Third, the number of stents implanted or use of drug-eluting stents was not surveyed. The database is now collecting information on detailed materials consumed for PCI, so that the impact of using costly pharmaceutical agents on TC can be assessed in future studies. Fourth, though this study was based on

both medical charts and claims data, coding accuracy might be one of concerns. In Japan, coding guidelines and coder training have been promoted by the Japanese Society of Medical Record Administration in collaboration with the Japanese Hospital Association, which have voluntarily engaged in this administrative database.

From both an administrative and a clinical viewpoint, analyzing the effect of age on resource utilization will have policy implications regarding the financing of acute care medicine for the elderly, a matter which remains controversial in Japan. Levinsky et al. analyzed Medicare expenditures for the elderly and demonstrated that spending decreases in the last years of life, particularly among those aged 85 years or older, due in part to the less frequent use of aggressive treatments, such as dialysis and ventilation [24]. Although this study did not specifically focus on patients 85 years or older, age had a smaller impact on total charge in comparison to the type of procedures performed.

These findings have several implications. First, age should not be deemed as a priority of concern in IHD, despite the growing number of elderly populations. According to Kuwabara et al. [27], surgical procedures explain most of the incremental variation in resource use and, therefore, should be monitored in regulating healthcare spending. Economic assessments of medical procedures should include justification for the use of costly innovative technologies, such as intra-coronary drug-eluting stent implantation. Second, the same methodology used in this study may be adopted to survey other common diseases, in which age is thought to be a significant predictor of resource use. These analyses will most likely have positive implications in presenting models of economic evaluation and in helping to make appropriate decisions regarding the global budget, thus contributing to health policy.

In Japan, the LOS for all hospital admissions is generally two to three times longer than in Western countries [28]. One explanation is that Japanese acute care hospitals provide care for wound management and for nursing home service, in addition to rehabilitation for acute medical care. These longer lengths of stay are thought to lessen the burden on family members after discharge. It is also thought that these longer hospital stays mitigate patient anxiety about full recovery to normal life and lessen early readmission for procedure-related complications [29]. Given this background, the information captured by the database may reflect the true burden on the healthcare system because it includes hospitalization, supportive and residential care, and rehabilitation, which might be a strength of this study.

Since medical innovations are quickly reshaping healthcare, it will be increasingly important to inves-

tigate the length of hospital stays, medical costs, and outcomes, including quality of life, through technology assessment and monitoring of practices patterns. Most developed countries have focused their efforts on enhancing the quality of care and, at the same time, attempting to tighten fiscal policy for healthcare delivery. Both healthcare providers and health policy makers need to consider which factors have the greatest impact on quality of care and healthcare spending. Otherwise, the healthcare insurance system and medical care will be unsustainable, and social welfare will be compromised.

In conclusion, this study used data from an administrative database to describe the characteristics of IHD patients, including total costs by age and type of procedures performed in acute care hospitals of Japan. Analysis of the independent effect of age on LOS and TC revealed that age was not as significant of a factor as procedure type. Procedure management needs to be a major focus of technology assessment and monitoring of medical innovation so that policy makers can make appropriate and informed decisions regarding healthcare insurance coverage.

Conflict of interest

Authors have no financial interests to declare regarding this study.

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The effect of age and procedure on resource use for patients with cerebrovascular disease

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Objective: Many studies have described the impact of population ageing on health care expenditures, but few have assessed its impact on specific diseases adjusted for severity and procedure. This study examined the relationship between an ageing population and resource use in patients with cerebrovascular disease (CVD).

Methods: A total of 13,856 CVD patients were treated in 82 academic and 92 community hospitals. Demographic variables, clinical variables, length of stay (LOS) and total charges were analysed by age group (under 65 years, 65–74 years and 75 years or older). The independent effects of age on LOS and total charge were determined using multivariate analysis.

Results: There were 5172 (37%) patients under 65 years of age, 4096 (30%) 65–74 years and 4588 (33%) 75 years or older. Intracranial infarction or ischaemia was diagnosed in 69% of the patients, haemorrhage in 23% and subarachnoid haemorrhage in 9%. The overall mortality was 6% (5% in under 65 years, 5% in 65–74 years and 9% in 75 years or older; $P < 0.001$). There were significant differences in the proportion of procedures performed in each age category. Age and procedure were significantly associated with LOS, particularly the latter. Age had no significant association with total charge, but procedure was highly associated.

Conclusions: Ageing has no significant impact on total charge. Instead policy-makers should acknowledge the effect of procedures on health care costs, conduct economic evaluations and monitor use of procedures.

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Introduction

The ageing of the population in Japan and other developed countries in the 21st century has initiated much political debate regarding the efficient allocation and financing of health care delivery. Approximately 20% of the Japanese population is at least 65 years old and, in 2006, they accounted for over US\$137 billion in health care expenditure or nearly 4.5% of gross national product.¹ In response to these circumstances, several articles have reported the impact of ageing on health care expenditures for acute and long-term care.^{2,3} At the same time, new, less evasive medical technologies, such as percutaneous endovascular or laparoscopic

surgery, are increasingly being employed and have enhanced the quality of life of the elderly through less postoperative pain and earlier mobilization.^{4,5} Although many economic evaluations of these novel procedures have been published, and both proponents and critics of these articles abound,^{6–8} the combination of population ageing and medical advances will most likely burden the economy.

Cancer, cardiovascular disease and cerebrovascular disease (CVD) comprise the largest portion of the chronic illnesses highlighted in public health. As such, these diseases are often the target of disease management. Although the mortality and incident rates of CVD (intracranial infarction, transient ischaemic attack, intracranial haemorrhage and subarachnoid haemorrhage [SAH]) have been on the decline for the past few decades, CVD is still the third cause of death in most industrialized countries, including Japan.^{9–11} CVD also continues to be a significant burden not only on affected individuals and their families but also on the health care system. In fact, it has been estimated that the societal cost of stroke exceeded US\$40 billion in 1997.¹² In Japan, health care expenditure for CVD was

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estimated to be US\$15.4 billion, of which 78% were attributed to those aged 65 years or older.¹

In the treatment of CVD, several innovative procedures, such as endovascular aneurysm occlusion and percutaneous carotid artery stenting, have been advocated, especially for the elderly.¹³ The Survey of National Medical Care Insurance Services, published by the Ministry of Health, Welfare and Labour, demonstrated that the use of percutaneous endovascular surgery has been increasing in Japan. Endovascular occlusion for intracranial aneurysm increased from approximately 500 procedures in 1998 to 4200 in 2003.^{14,15}

In 2002, a new case-mix classification system was introduced in Japan. This system is used to profile hospital performance and to assess per diem payment among all 82 specialty hospitals (80 academic university hospitals, the National Cancer Centre and the National Cardiovascular Centre) and 92 voluntary community hospitals. These hospitals are scattered throughout Japan and play a leading role in providing acute care medicine, advancing medical research and educating students and residents. This national administrative database contains both discharge summaries and claims data. Therefore, it provides information that can be used to investigate differences in charges and outcomes of care, taking into account patients' age, severity of principal diagnosis, co-morbidity or complications and regional variation. The aim of this study was to provide a profile of CVD patients and to assess the independent effect of age and use of innovative procedures on their health care resource use while controlling for severity of illness, co-morbidity and procedure.

Methods

This is a secondary data analysis conducted as part of a government-sponsored project on the development of the case-mix classification system. Anonymous claims and clinical data were provided through a contract with the Ministry of Health, Labour and Welfare (MHLW). Clinical information and claims data were gathered from 82 specialty hospitals and 92 community hospitals. The data were gathered by the MHLW and merged into a standardized electronic format for 441,142 patients discharged between 1 July 2003 and 31 October 2003. From this initial data-set, we selected patients treated for CVD, but excluded those who had died within 24 h of admission.

Study variables

Independent study variables included age, gender, principal diagnosis, use of an ambulance, consciousness level at admission, weighted co-morbidity, type of procedure, in-hospital mortality, use of ventilation or haemodialysis as a proxy for severity of co-morbidity or complication and rehabilitation provided for CVD patients in acute care wards. Age was stratified into three categories: under 65 years, 65–74 years and 75 years or older. Emergency admission was defined as transport by ambulance. The dependent variables were

length of hospital stay (LOS; days) and total hospital charges (TCs; US\$1 = ¥120). TC was the charges billed during hospitalization and was used as a proxy for the cost of acute care (i.e. hospital administration, equipment costs, ancillary and nursing services, and physician's time). Study variables except age and procedure were considered as covariates. In Japan, hospital charges are determined by a standardized fee-for-service payment system known as the nationally uniform fee table.

Consciousness level at admission (alert, disoriented, semi-coma and coma) was used to evaluate disease severity. The principal diagnosis of CVD was recorded using the International Classification of Diseases, 10th Revision (ICD-10) code and categorized into intracranial infarction or ischaemic attack (ischaemia) (G45\$, G46\$, I63\$, I65\$, I66\$, I67\$, I693), intracranial haemorrhage (I61\$, I62\$) and SAH (I60\$). Unruptured aneurysm was not included in this study. A maximum of four co-morbidities were captured in the database. Co-morbid conditions were assessed using the Charlson Co-morbidity Index (CCI).¹⁶ The database also captured a maximum of five operative procedures for each hospitalization. Procedures for CVD patients analysed in this study included interventional percutaneous endovascular procedures (e.g. aneurysm occlusion for SAH, percutaneous stenting for carotid artery stenosis), carotid endarterectomy or bypass surgery for vascular reconstruction, burr-hole drainage, decompression or evacuation of haematoma under craniotomy and clipping or wrapping for ruptured aneurysm. Use of ventilation, haemodialysis and rehabilitation as supportive care was also analysed.

Statistical analysis

The proportions for all categorical data were reported for every age category and compared using the Fisher's exact test. Distributions of LOS and TC were presented using a box chart by age category, consciousness level, CCI, principal diagnosis and procedure type. Differences between consciousness level, CCI, principal diagnosis or procedure type were tested for significance for each age category, using analysis of variance. We used multiple linear regression models to determine the individual effect of age and procedures on LOS and TC. Procedures were put into this model, instead of principal diagnosis because they were used as a proxy for disease. Statistical analyses were performed using SPSS version 14.0. All reported *P* values are two-tailed and the level of significance was set at *P* < 0.05.

Results

We identified 13,856 CVD patients across 174 hospitals (82 specialty and 92 community hospitals). Of this study population, 872 died (6%), 4096 were 65–74 years of age (30%) and 4588 were 75 years or older (33%). Female patients comprised 35% of patients under 65 years of age, 35% of patients 65–74 years of age and 49% of patients at least 75 years old. The proportion

of ambulance use, consciousness level, principal disease and CCI were significantly different by age. Overall, the majority of patients (81%) were treated without any of the procedures previously described and only a small number of patients received intervention in any of the age categories (4% under 65 years, 4% 65–74 years and 2% 75 years or older). As for the use of supportive care, there were significant differences in ventilation or rehabilitation, but not in haemodialysis (Table 1). Figures 1 and 2 show the comparisons of LOS and TC for all categorical variables. Both LOS and TC were much higher in patients in semi-coma, those with SAH or those treated with interventions such as craniotomy and clipping. LOS was higher in patients with a CCI of three or more. LOS and TC were significantly different in every age category.

After adjusting for the potential confounding effects of demographic and clinical variables, LOS was significantly associated with patients aged between 65 and 74 years (1.67 days; 95% confidence interval [CI] 0.83–

2.51) and those 75 years or older (3.64 days; 95% CI 2.80–4.48), but neither were associated with TC. Vascular reconstruction (16.31 days; 95% CI 14.15–18.46), clipping surgery (17.23 days; 95% CI 15.47–18.98) and rehabilitation as supportive care (18.28 days; 95% CI 17.55–19.01) were the most significant factors among all variables in predicting LOS (Table 2). Table 3 shows that intervention (\$15,429; 95% CI 14,751–16,107), clipping or wrapping (\$21,674; 95% CI 21,055–22,292), and craniotomy and decompression (\$9688; 95% CI 8976–10,400) were the most significant factors in predicting TC.

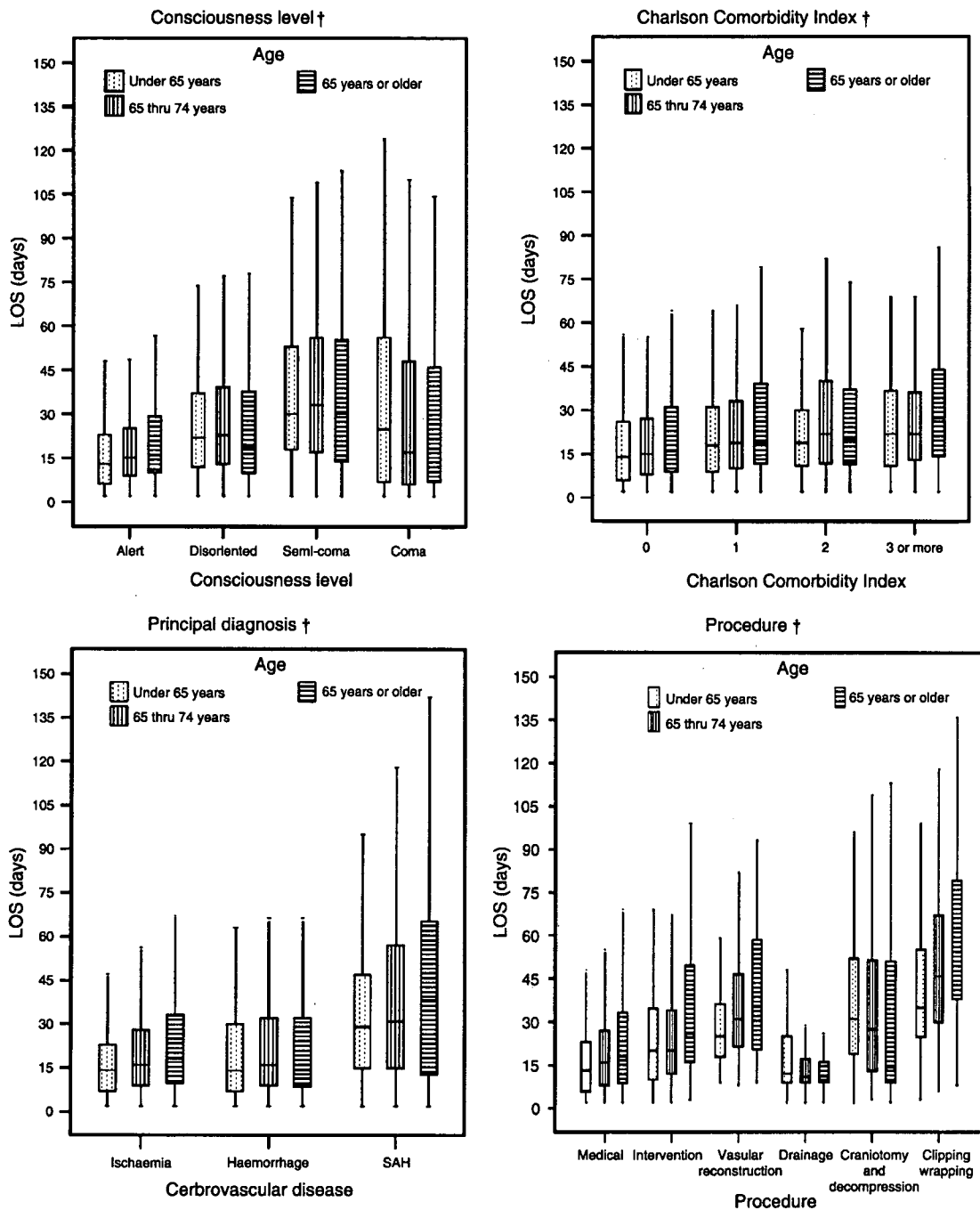
Discussion

This study used an administrative database to describe the characteristics of CVD patients and identify the independent effects of age and procedure type on LOS and TC. After adjusting for severity of CVD, co-morbidity and use of supportive care, patients

Table 1 Patient characteristics, clinical information, procedure and resource use by age categories (%)

Age category	All ages	Under 65 years	65–74 years	75 years or older	P value
Overall (n)	13,856	5172	4096	4588	
<i>Outcome</i>					
Dead	6.3	5.1	4.9	8.9	<0.001
<i>Gender</i>					<0.001
Women	39.9	35.4	35.0	49.4	
Men	60.1	64.6	65.0	50.6	
<i>Ambulance</i>					<0.001
Used	36.2	33.4	34.1	41.3	
<i>Consciousness level</i>					<0.001
Alert	68.3	71.4	71.6	62.0	
Disoriented	16.8	14.0	16.0	20.8	
Semi-coma	7.2	6.7	6.3	8.5	
Coma	7.6	8.0	6.0	8.7	
<i>Primary disease</i>					<0.001
Ischaemia	68.5	60.9	72.4	73.5	
Haemorrhage	23.0	25.6	21.5	21.5	
SAH	8.5	13.5	6.1	5.0	
<i>Charlson Co-morbidity Index</i>					<0.001
0	65.7	68.6	62.5	65.3	
1	22.0	20.9	24.1	21.3	
2	9.0	7.9	9.4	9.8	
3 or more	3.3	2.6	3.9	3.7	
<i>Procedure</i>					<0.001
Medical	81.4	76.6	82.3	86.0	
Intervention	3.3	3.8	3.5	2.4	
Vascular reconstruction	2.6	3.8	3.0	1.0	
Drainage	5.1	3.8	4.9	6.8	
Craniotomy and decompression	3.1	4.1	3.0	2.0	
Clipping or wrapping	4.5	8.0	3.2	1.8	
<i>Supportive care</i>					
Ventilation	7.7	9.7	7.0	6.0	<0.001
Haemodialysis	1.1	1.3	1.1	0.9	0.207
Rehabilitation	38.9	32.5	40.0	45.2	<0.001
<i>Resource use</i>					
LOS (days) (SD)	23.98 (24.02)	22.03 (22.78)	23.89 (23.32)	26.26 (25.74)	<0.001
Total charge (\$) (SD)	9064.97 (10,430.59)	9789.38 (11,905.12)	8828.15 (10,082.69)	8459.78 (8779.51)	<0.001

SAH, subarachnoid haemorrhage; LOS, length of stay; SD, standard deviation



†statistically significant ($p < 0.001$) at every age category

Figure 1 Length of stay (LOS) and age category by consciousness level, Charlson Co-morbidity Index, principal diagnosis and procedure. SAH, subarachnoid haemorrhage

65–74 years of age and those 75 years or older were determined to have a modest effect on LOS and TC. However, several procedures had a greater impact on LOS and TC than age. These findings are consistent with Dormont *et al.*¹⁷ who demonstrated that the rise in health care expenditures caused by demographic change was relatively small compared with the effects of practice changes. Similarly, Levinsky *et al.*¹⁸ analysed US Medicare expenditures for the elderly and demonstrated that spending decreased in the last years of life,

particularly among those aged 85 years or older, due in part to the less frequent use of aggressive treatments, such as dialysis and ventilation.

However, there are several limitations to this study. First, information was gathered from discharged patients during a four-month time period in 2003. This limits the generalizability of the results. Claims data as well as clinical information are now being collected annually from more community hospitals. This growing database will eventually allow researchers to diminish any selection

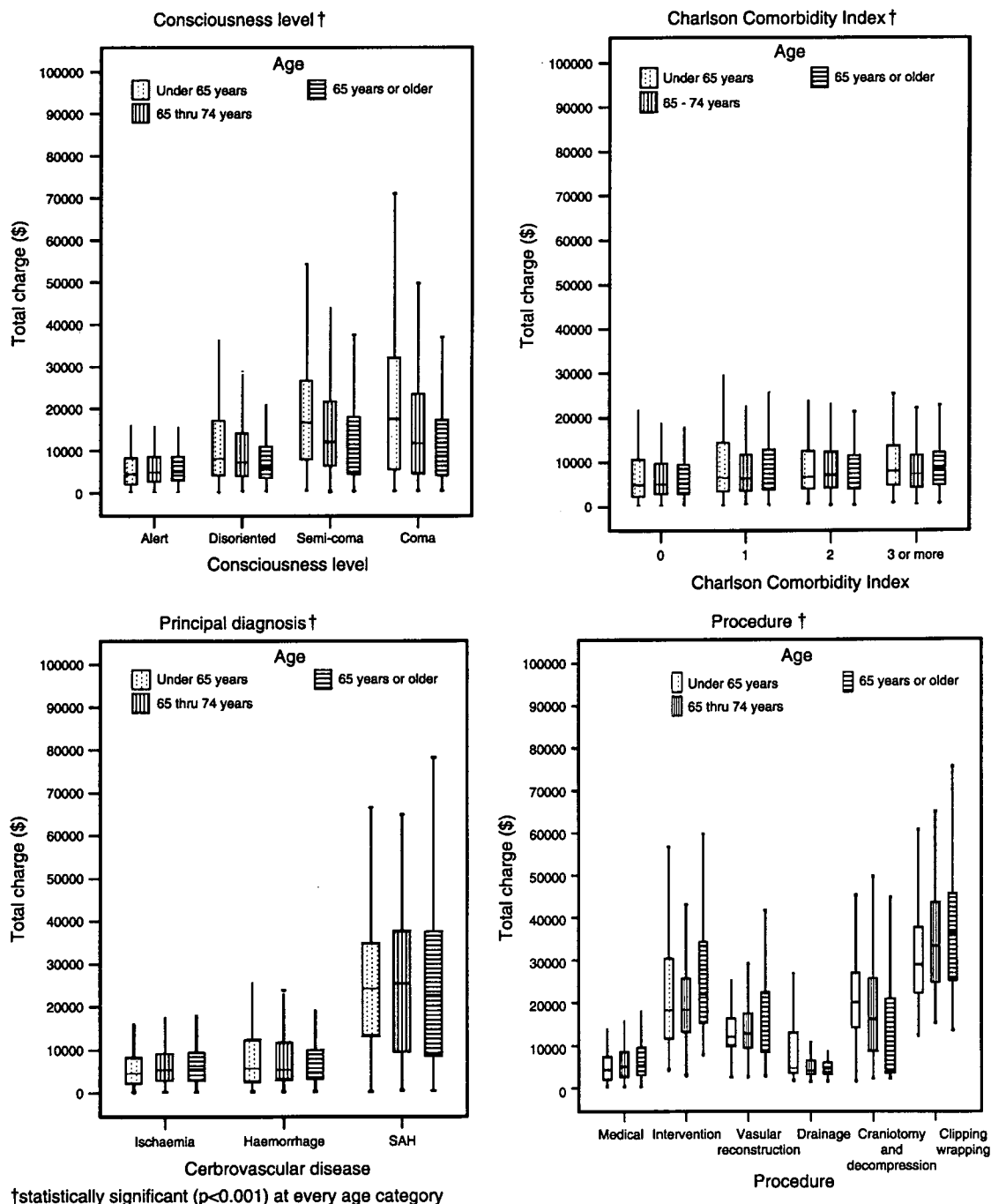


Figure 2 Total charge (\$) and age category by consciousness level, Charlson Co-morbidity Index, principal diagnosis and procedure. SAH, subarachnoid haemorrhage

bias and to identify the interaction effect of age and procedure as well as the independent effects of various factors on LOS and TC exhaustively. Second, this study lacked analyses of procedure-related outcomes, such as post-procedure stroke or uneventful cardiovascular attack. However, the database includes complications coded using the ICD-10, such that future investigation of the effect of procedure-related complications on resource use is possible.¹⁹

Third, though the proportion of patients aged 75 years or more (33%) in this study was comparable with

that of other developed countries, in-hospital mortality (6.3%) was lower,^{11,20,21} suggesting that Japan's patient population may not be fully generalizable to Western countries. A strength of the study is that the measure of TC is closer to the true cost of stroke than would be the case in other countries. This is because, in Japan, LOS for all hospital admissions is generally 2–4 times longer than in Western countries since Japanese hospitals provide wound care, nursing home services and rehabilitation following acute medical care.²² It should be possible in time to link hospital and ambulatory

Table 2 Linear regression analysis of factors associated with length of stay (days)

Independent variables	Unstandardized coefficient	95% CI	Standardized coefficient	P
<i>Intercept</i>	9.82	(8.98–10.66)		0.000
<i>Age (reference; under 65 years)</i>				
65–74 years	1.67	(0.83–2.51)	0.030	0.000
75 years or older	3.64	(2.8–4.48)	0.070	0.000
<i>Men</i>	–0.05	(–0.76 to 0.65)	0.000	0.890
<i>Ambulance car used</i>	3.38	(2.58–4.18)	0.070	0.000
<i>Consciousness level (reference; alert)</i>				
Disoriented	3.19	(2.24–4.15)	0.050	0.000
Semi-coma	9.55	(8.12–10.98)	0.100	0.000
Coma	9.00	(7.39–10.62)	0.100	0.000
<i>Charlson Co-morbidity Index (reference; zero)</i>				
1	1.93	(1.09–2.77)	0.030	0.000
2	1.93	(0.71–3.16)	0.020	0.000
3 or more	5.94	(4.02–7.86)	0.040	0.000
<i>Procedure (reference; medical)</i>				
Intervention	7.30	(5.37–9.22)	0.050	0.000
Vascular reconstruction	16.31	(14.15–18.46)	0.110	0.000
Drainage	–0.94	(–2.49 to 0.61)	–0.010	0.240
Craniotomy and decompression	8.72	(6.7–10.74)	0.060	0.000
Clipping or wrapping	17.23	(15.47–18.98)	0.150	0.000
<i>Ventilation</i>	7.50	(5.91–9.09)	0.080	0.000
<i>Haemodialysis</i>	–1.73	(–5.01 to 1.55)	–0.010	0.300
<i>Rehabilitation</i>	18.28	(17.55–19.01)	0.370	0.000
<i>Outcome (reference; alive)</i>	–12.17	(–13.84 to –10.51)	–0.120	0.000

F test for the model; $P < 0.001$; $R^2 = 0.289$

Table 3 Linear regression analysis of factors associated with total charge (\$)

Independent variables	Unstandardized coefficient	95% CI	Standardized coefficient	P
<i>Intercept</i>	2969.62	(2673.12–3266.11)	0.000	0.000
<i>Age (reference; under 65 years)</i>				
65–74 years	68.98	(–227.25 to 365.21)	0.000	0.650
75 years or older	145.16	(–151.12 to 441.44)	0.010	0.340
<i>Men</i>	180.08	(–68.82 to 428.98)	0.010	0.160
<i>Ambulance car used</i>	1306.02	(1023.91–1588.13)	0.060	0.000
<i>Consciousness level (reference; alert)</i>				
Disoriented	971.45	(634.08–1308.82)	0.030	0.000
Lethargy to stupor	3272.93	(2769.76–3776.10)	0.080	0.000
Coma	3748.61	(3178.09–4319.13)	0.100	0.000
<i>Charlson Co-morbidity Index (reference; zero)</i>				
1	776.81	(481.10–1072.52)	0.030	0.000
2	711.86	(279.07–1144.64)	0.020	0.000
3 or more	1199.17	(521.57–1876.78)	0.020	0.000
<i>Procedure (reference; medical)</i>				
Intervention	15,429.00	(14,750.55–16,107.45)	0.260	0.000
Vascular reconstruction	9116.29	(8356.71–9875.87)	0.140	0.000
Drainage	675.66	(127.16–1224.16)	0.010	0.020
Craniotomy and decompression	9688.45	(8976.42–10,400.48)	0.160	0.000
Clipping or wrapping	21,673.50	(21,055.21–22,291.8)	0.430	0.000
<i>Ventilation</i>	7279.45	(6718.93–7839.97)	0.190	0.000
<i>Haemodialysis</i>	2788.66	(1630.94–3946.38)	0.030	0.000
<i>Rehabilitation</i>	5326.29	(5068.22–5584.37)	0.250	0.000
<i>Outcome (reference; alive)</i>	–3671.79	(–4258.50 to 3085.09)	–0.090	0.000

F test for the model; $P < 0.001$; $R^2 = 0.530$

care databases to obtain an even fuller account of the total costs of stroke by age and pattern of treatment.

The findings of the current study have several policy implications. First, age *per se* should not be a priority of concern in CVD, despite the growing number of elderly people. According to our previous research, the type of procedure explains most of the variation in resource use and, therefore, should be monitored as part of regulating health care spending.²³ Economic evaluation of medical procedures should include justification for the use of costly innovative technologies. Second, the same method used in this study may be adopted to analyse other common diseases in which age is assumed to be a significant factor such that less invasive but more expensive procedures are developed for older patients. Such analyses should help in making appropriate decisions regarding the efficient allocation of a global health budget.

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The association of the number of comorbidities and complications with length of stay, hospital mortality and LOS high outlier, based on administrative data

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Abstract

Objectives With greater concern for efficient resource allocation and profiling of medical care, a case-mix classification was applied for the per-diem payment system in Japan. Many questions remain, one of which is the role of comorbidity and complication (CC) in grouping logic. We examined the association of the number of CC with the length of hospital stay (LOS) and hospital mortality as well as the proportion of LOS high outliers in 19 major diagnostic categories (MDCs).

Methods This study was a secondary data analysis embedded in a government research project, including anonymous claims and clinical data during a 4-month period from July 2002. Every 19 MDC, LOS, hospital mortality or proportion of LOS high outliers was compared by the number of CC and presence of any procedures.

Results From 82 special function hospitals, 241,268 patients were enrolled in this study. Among all patients, 50.5% were identified without any CCs, 32.4% with one or two, 13.4% with three or four, and 3.7% with over five CCs. The overall mean LOS was 22.15 days and hospital mortality 26.05 cases per 1,000 admissions. In any MDC, LOS and the proportion of outliers increased as the number of CC rose. The mortality rate increased prominently in the respiratory system and the hematology system.

Conclusions This study demonstrated that the occurrence of more CC caused longer LOS and higher mortality in some major disease categories. Further study will clarify the association of the weighted CC with resource use through controlling procedures specific for MDC.

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Introduction

The role of comorbidities and complications (CC) in inpatient medicine has been an intense area of investigation, due to their impact on resource use, mortality, functional status, quality of life, and delivery of health care in Western societies [1–6]. Research on the impact of CC on healthcare utilization and quality of medical care is needed, as this is important to hospital payment systems and medical outcome studies [7, 8]. Many

health-related problems increase with age, especially with respect to the number of chronic conditions [1]. As the proportion of chronic conditions increases across populations, practice behaviors will change that will impact hospital costs. Meanwhile, innovative procedures have been advocated for the elderly [9, 10]. Under these circumstances, the impact of CC or age on hospital resource utilization has been examined for diseases such as diabetes mellitus or for hospitalizations of trauma patients [11, 12].

In response to increasing costs associated with the rapid evolution of healthcare technology, cost containment policies and case-mix classification systems have advanced worldwide over the past 20 years [7, 8]. However, problems have emerged in situations where some patients are under-reimbursed if they have more CCs and have consumed more hospital resources than those with fewer CCs. Munoz et al. [13] reported major inequities in Diagnosis-Related Group (DRG) prospective payment systems for pediatric patients. Jencks et al. [14] showed that the number of recorded diagnoses was no higher for patients who died than for those who survived. These studies focused on selected conditions, such as pediatric illnesses, cardiovascular disease, and pneumonia.

In this study, our goal was to demonstrate the association of CCs with resource use and outcome by major diagnostic category (MDC) and treatment group (medical or surgical) using a large administrative database developed for the Japanese case-mix classification system (Diagnosis Procedure Combination; DPC). This type of systematic research has never been performed on this scale, and the results may have some important policy implications, in which MDC CCs may be considered in prior risk adjustment for payment or outcomes, such as resource use or mortality. The aims of this study were to generate descriptive statistics of CCs and to profile the association of length of stay (LOS) and hospital mortality with the number of CCs through the stratification of MDCs and treatments. Furthermore, we identified the relationship between the proportion of LOS high outliers and the number of CCs for each MDC.

Materials and methods

We conducted a secondary data analysis of a government research project on DPC development. Anonymous claims information and clinical data were provided by the Ministry of Health, Labor and Welfare (MHLW) through a research contract. Clinical data and claims information, merged into a standardized electronic format, were gathered by the MHLW for 266,677 patients who were

discharged from 82 academic hospitals (80 university hospitals, National Cancer Center, and National Cardiovascular Center) between 1 July 2002 and 31 October 2002. The Japanese MHLW permits up to seven CCs (four comorbidities and three complications) to be listed in the DPC dataset. From this original dataset, we selected cases with a LOS of up to 365 days and excluded patients who died within 24 h of admission. A total of 241,268 patients were enrolled in the study. We categorized patients into three groups according to the number of CCs documented (absent, 1 or 2, 3 or 4, and 5 or more), based on a study by Munoz et al. [15].

The DPC system is made up of 16 MDCs. However, the 16th MDC consists of four different clinical entities: injury, poisoning, burns and the toxic effect of drugs; mental diseases and disorders; diseases and disorders of systemic infection; and miscellaneous. We therefore divided the 16th MDC into these four groups and analyzed a total of 19 MDCs (Table 1). The DPC database also allows a maximum of five operative procedures to be listed, for which the definition and pricing are determined from a nationally uniform fee table under the standardized fee-for-service payment system. Patients undergoing at least one surgical procedure, as defined by the Japanese fee table, comprised the “surgical group,” while patients not undergoing any surgical procedure comprised the “medical group.” We then divided patients into these two treatment groups for all 19 MDCs.

Statistical analysis

Patient characteristics were analyzed in terms of gender, age (under 15, 15–64, and 65 years or older), and number of procedures. The association between CC category and each of these patient characteristics was assessed using Fisher’s exact test. The association between these patient characteristics and MDC was also assessed.

The mean age, LOS, and mortality rate per 1,000 admissions were calculated for each CC category and compared using analysis of variance (ANOVA). The mean LOS (days) and mortality rate (per 1,000 cases) were illustrated using spider-radar charts, stratified by treatment group (surgical or medical) and MDC. ANOVA was used to compare the mean LOS and mortality rate by treatment group for each MDC.

To define the proportion of high LOS outliers, we identified the 95th percentile of LOS for each MDC and categorized patients beyond that LOS into eight groups (e.g., four CC groups by two treatment groups). We then calculated the proportion of high LOS outliers (the numerator is the number of LOS outliers and the denominator is the number of all patients in the eight

Table 1 The proportion of comorbidity and complication category by presence of procedure and MDC (%)

Major diagnostic category		Absent	One or two	Three or four	Over five	<i>N</i>
Overall	Medical	47.8	33.8	14.9	3.5	123,895
	Surgical	53.4	30.9	11.8	3.9	117,373
MDC1 Nervous system	Medical	46.2	35.1	15.3	3.4	12,292
	Surgical	44.7	32.2	16.0	7.1	3,810
MDC2 Eye system	Medical	65.9	25.3	7.7	1.1	1,854
	Surgical	54.5	32.9	9.9	2.7	17,974
MDC3 Ear, nose, mouth, and throat system	Medical	62.4	26.8	8.5	2.3	5,881
	Surgical	65.0	26.5	6.4	2.1	8,374
MDC4 Respiratory system	Medical	44.2	36.8	15.4	3.6	14,666
	Surgical	47.0	33.5	13.3	6.2	3,609
MDC5 Cardiovascular system	Medical	32.0	40.2	24.4	3.4	12,264
	Surgical	31.5	37.3	23.7	7.5	10,768
MDC6 Digestive tract, hepatobiliary and pancreas system	Medical	49.3	35.3	12.7	2.6	20,697
	Surgical	48.2	34.2	13.4	4.2	24,383
MDC7 Musculoskeletal and connective tissue system	Medical	51.1	31.2	13.9	3.8	7,671
	Surgical	63.5	24.9	8.8	2.8	11,018
MDC8 Skin and subcutaneous tissue system	Medical	50.3	35.1	11.9	2.7	3,500
	Surgical	69.6	22.8	5.2	2.4	671
MDC9 Breast system	Medical	60.0	27.3	9.9	2.9	1,144
	Surgical	69.7	23.4	5.8	1.1	2,532
MDC10 Endocrine, nutrition and metabolic system	Medical	36.0	36.1	23.7	4.2	8,156
	Surgical	44.0	35.1	15.7	5.2	2,784
MDC11 Kidney, urinary tract and male reproductive system	Medical	51.0	30.7	14.5	3.8	10,031
	Surgical	54.2	29.2	12.3	4.3	7,359
MDC12 Pregnancy, childbirth, puerperium and female reproductive system	Medical	61.1	28.7	7.7	2.5	6,195
	Surgical	59.5	29.6	8.4	2.4	10,951
MDC13 Hematology system	Medical	46.6	29.7	15.7	8.1	4,967
	Surgical	37.5	32.8	17.0	12.7	613
MDC14 Neonate system	Medical	49.6	32.0	12.9	5.5	4,386
	Surgical	66.0	24.0	7.3	2.8	4,202
MDC15 Pediatric system	Medical	64.0	28.8	6.4	0.8	1,916
	Surgical	70.0	20.0	5.0	5.0	20
MDC16 Injury, burns, poisonings and toxic effect of drugs	Medical	53.9	34.1	10.4	1.6	3,580
	Surgical	62.1	26.1	9.0	2.9	6,083
MDC17 Mental health system	Medical	47.1	31.4	16.7	4.8	1,256
	Surgical	0.0	0.0	0.0	0.0	0
MDC18 Systemic infection	Medical	41.9	34.1	16.4	7.6	962
	Surgical	29.2	30.3	17.8	22.7	185
MDC19 Miscellaneous	Medical	46.2	32.9	15.7	5.2	2,477
	Surgical	54.9	29.7	11.3	4.1	2,037

MDC major diagnostic category

groups) and demonstrated it with a broken line for each MDC. Statistical analyses were performed using SPSS version 14. All reported *P* values were two-tailed, and the level of significance was accepted as less than 0.05.

Results

The most frequently documented MDC was the digestive tract, hepatobiliary, and pancreatic diseases (45,080 cases, 18.7% of all study cases) and the least frequently