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Changes in the quality of diabetes care in Japan between 2007 and 2015: A repeated cross-sectional study using claims data

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ABSTRACT

Aim: To assess the temporal changes in the quality indicators pertaining to the process measures of diabetes care during a recent decade in Japan.

Methods: A five-fold repeated cross-sectional study was conducted using health insurance claims data provided by the Japan Medical Data Center between April 2006 and March 2016. We identified 46,631 outpatients with antidiabetic medication who regularly visited hospitals or clinics at least every three months. We evaluated the quality indicators pertaining to glycemic control monitoring, lipid profile monitoring, retinopathy screening, nephropathy screening, and appropriate medication choice. The proportions of patients who received appropriate examinations/prescriptions, by observation period and either the type of antidiabetic medication or facility type were estimated using generalized estimating equation (GEE) models with multiple covariate adjustments.

Results: The quality indicator values for appropriate medication choice and nephropathy screening improved between 2007 and 2015, whereas those for glycemic control monitoring and retinopathy screening remained suboptimal. Patients prescribed medications in larger hospitals were likelier to undergo the recommended examinations (e.g. retinopathy screening: 36.1% (95% CI: 35.4–36.7%) for clinic, 40.6% (95% CI: 39.1–42.2%) for smaller hospital, and 46.0% (95% CI: 44.8–47.2%) for larger hospital in 2015).

Conclusions: Several process measures of diabetes care remained suboptimal in Japan.

1. Introduction

The increasing prevalence of diabetes and the resulting economic burden pose a great challenge to public health and healthcare systems, worldwide [1]. The provision of a high quality of care and regular physician consultations may reduce the risk of microvascular and macrovascular complications and mortality [2–4]. Therefore, improving the quality

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of diabetes care, including the maintenance of favorable glycemic control and regular monitoring of the associated complications, is vital.

According to Donabedian, the quality of healthcare can be assessed based on structure, process, and outcomes [5]. The quality of diabetes care is often measured through process measures and intermediate outcome measures in addition to outcome measures [6]. Process measures (quality indicators on process aspects) include clinical practices such as glycemic control monitoring, lipid profile monitoring, retinopathy screening, nephropathy screening, and appropriate medication choice. Clinical guidelines provide tools for the evaluation of the process measures of diabetes care [7–9]. Various studies in the United States (US) [10–13], European countries [14–19], South Korea [20], and other countries [21,22] have reported on the quality of diabetes care. Those studies demonstrated the temporal improvements in the quality measures observed; however, patients with diabetes received lower-quality diabetes care in some healthcare settings, with some previous studies demonstrating that patient characteristics and the presence of comorbidities affect the quality of diabetes care [23,24].

In Japan, where the prevalence rate of diabetes was 12.1% (16.3% for men and 9.3% for women) among adults in 2016, there is a need to improve the quality of diabetes care [25]. A few studies focusing on the quality of diabetes care have been performed in Japan; while some of those studies indicated the steady performance of glycemic control monitoring, it was observed that retinopathy screening and nephropathy screening were less frequently performed than the optimum even under universal health coverage [26,27]. In addition, our group previously reported that insulin prescription and attending follow-ups in larger facilities were associated with a higher quality of diabetes care [26]. However, as those studies were conducted separately, their findings are not necessarily comparable; temporal changes in the quality of diabetes care in Japan have not been documented in a comprehensive manner to date. Further study is necessary to gain clarity on the progress in diabetes care through clinical development initiatives (e.g. the Japanese Clinical Guideline for diabetes care was firstly published in 2004, and since then revised every three years.) [7].

In this context, the present study aimed to assess the temporal changes in the quality indicators pertaining to the process of diabetes care especially in terms of appropriate examination and prescription, with consistent data and design, during a recent decade in Japan.

2. Subjects, materials and methods

2.1. Research design

We conducted a five-fold repeated cross-sectional study using health insurance claims data in Japan, collected and processed by the Japan Medical Data Center (JMDC). The JMDC Claims Database comprises a series of claims data from several health insurance societies for employees of large companies and their families, collected securely under the contract between the JMDC and these societies. The collected data were processed in terms of anonymization and code standardization [28]. The JMDC Claims Database began collecting claims data in 2005 and the number of beneficiaries has increased gradually in the past decade (248,552 beneficiaries in 2005 and 2,448,581 beneficiaries in 2015). The validity of claim-based patient identification using this database has been reported with regard to diabetes, hypertension, and dyslipidemia [29].

We observed 10 fiscal years that were divided into five periods; (1) April 2006 to March 2008, (2) April 2008 to March 2010, (3) April 2010 to March 2012, (4) April 2012 to March 2014, and (5) April 2014 to March 2016. In total, the JMDC Claims Database contains data on 3,740,239 beneficiaries (2,042,548 men and 1,697,691 women) who were covered by health insurance societies between April 2006 and March 2016. For each 2-year period, we defined the former fiscal year (April to March) as the subject-identification year, within which we identified patients with antidiabetic medication who had regularly visited hospitals or clinics. Subsequently, we defined the latter fiscal year as the quality-reporting year, within which we assessed quality indicators among outpatients in whom follow-up visits were accomplished without any hospitalization.

In the present study, we included patients aged 20–69 years who had visited hospitals/clinics at least every three months and used antidiabetic medication during the subject-identification year. In our claims database, more than 95% of oral hypoglycemic agents were prescribed for 90 days or less per prescription. For the calculation of each quality indicator, we excluded (1) those in whom regular hospitals/clinics visits were not accomplished during the quality-reporting year and (2) those who were hospitalized during the quality-reporting year. In addition, we excluded (3) those whose medical practices may not have been captured by claims data due to the comprehensive payment system. In addition, we excluded patients in whom the examinations and/or prescriptions were no longer recommended due to the presence of a particular comorbidity. Particularly with regards to [3], all detailed criteria are described below. A flow diagram of patients' identification is presented in Fig. 1 (see also Appendix 1 regarding the RECORD statement) [30].

2.2. Identification of patients with antidiabetic medication

We identified patients with a diagnosis of diabetes based on whether their claims data included the diagnosis of diabetes, as determined by International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) codes E10-E14 during the subject-identification year; we did not consider "suspected" diabetes as the presence of diabetes. We identified patients with antidiabetic medication based on at least one prescription during the subject-identification year. We finally identified patients with diabetes using a combination of the diagnosis of diabetes and prescription of antidiabetic medication to increase the specificity of case detection at the expense of sensitivity [26,29].

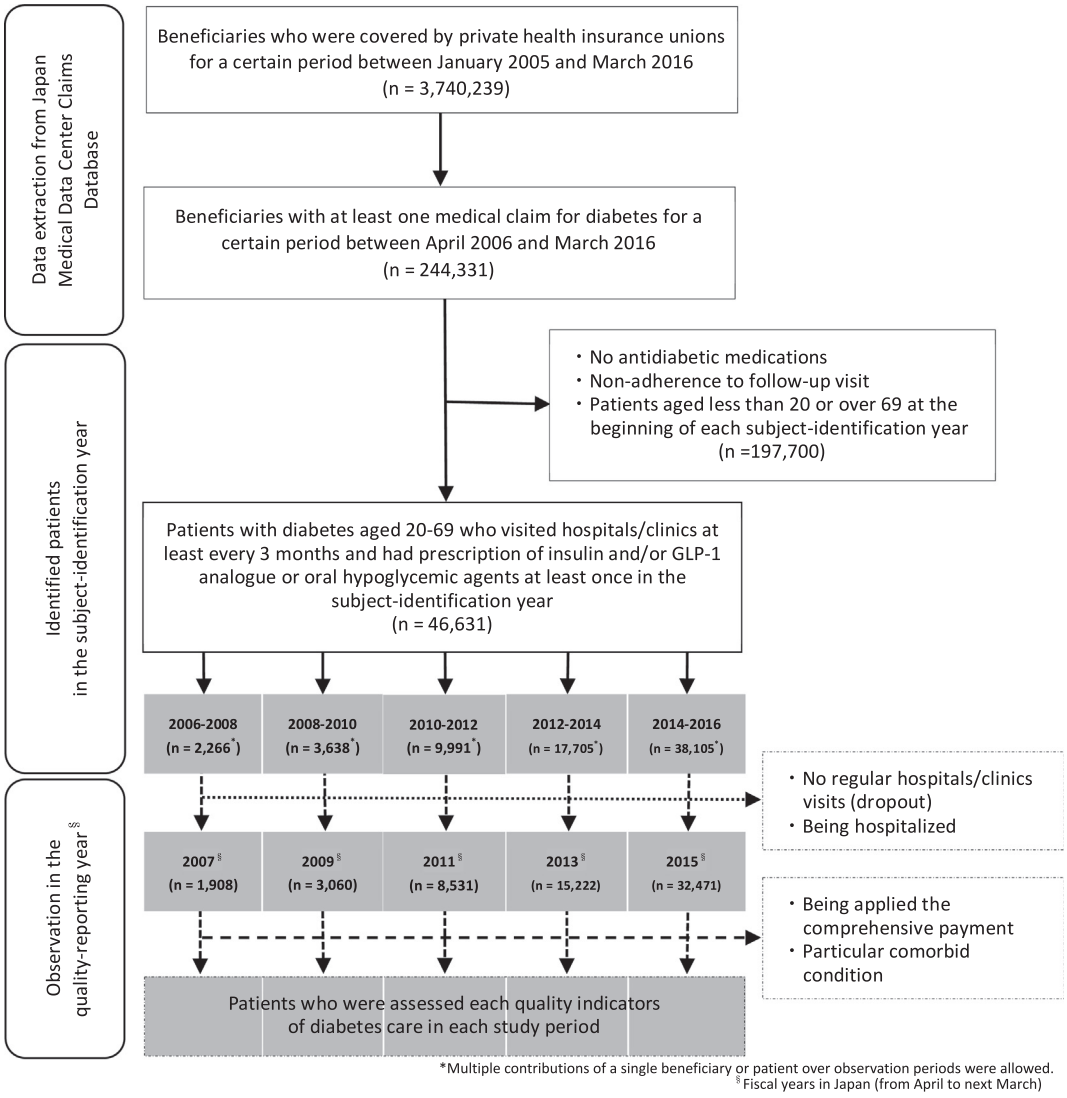


Fig. 1 – Flow diagram of the identification of patients with antidiabetic medication.

2.3. *Characteristics of patients with antidiabetic medication*

2.3.1. *Patient characteristics*

We categorized the patients' ages into five groups: 20–29, 30–39, 40–49, 50–59, and 60–69 years, by sex. As for the type of diabetes, if patients had at least one diagnosis of insulin-dependent diabetes mellitus (IDDM, ICD-10: E10) on medical claim, we classified them as having a diagnosis of IDDM. Among the remaining patients, those who had at least one diagnosis of non-insulin dependent diabetes mellitus (NIDDM), other types of diabetes, and diabetes type that was unknown (ICD-10: E11-14) were classified as those with a diagnosis of NIDDM or other types of diabetes (NIDDM/others). We identified patients with hypertension (I10-15) and those with a diagnosis of dyslipidemia (E78), except pure hypertriglyceridemia, hyperchylomicronemia, and lipoprotein deficiency (E78.1, E78.3, and E78.6) during the quality-reporting year.

2.3.2. *Types of antidiabetic medication*

Insulin and/or GLP-1 analogues were defined by the prescription of "A10C", "A10D", and "A10S" in the Anatomical Therapeutic Chemical (ATC) Classification System managed by the European Pharmaceutical Market Research Association (Appendix 2) [31]. Oral hypoglycemic agents were included as "A10H", "A10J", "A10K", "A10L", "A10M", "A10N", "A10P", and "A10X" in the ATC Classification System. We excluded "Voglibose, 0.2 mg" (A10BF03) and "Epalrestat" (A10XA) prescriptions because they were covered for the prevention of type 2 diabetes and diabetic neuropathy, respectively.

2.3.3. *Medical facility in which antidiabetic medication was prescribed*

We also identified the medical facility in which the antidiabetic medication was last prescribed for each patient in the subject-identification year; we then grouped the facilities into the following three categories: hospital with ≥200 beds (larger hospital), hospital with 20–199 beds (smaller hospital), and clinic (without beds or with fewer than 20 beds).

2.4. Dropout and hospitalization

We defined "dropout" as the absence of hospital/clinic visits for three or more consecutive months during the quality-reporting year. After dropout patients were excluded, we also excluded those who had a history of admission during the quality-reporting year based on the presence of hospitalization in the claims data.

2.5. Quality indicators

2.5.1. Steady performance of recommended examinations

As for examinations, we measured the following aspects of diabetes care: (1) glycemic control monitoring, (2) lipid profile monitoring, (3) retinopathy screening, and (4) nephropathy screening.

(1) For glycemic control monitoring, an HbA1c test at a pace of $\geq$1 per three months was considered standard based on the clinical guideline and previous studies [26,32]. (2) For lipid profile monitoring, serum lipid tests (any three tests from among total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglyceride tests) conducted at least once a year were considered appropriate. (3) Annual eye examinations included one complete fundus examination or more, pan-vitreoretinal examinations, or the use of fundus cameras. (4) For nephropathy screening, the performance of one or both of the following tests was considered appropriate: urine protein quantitative test or urine albumin quantitative test. For the urine protein test, we excluded patients on dialysis and/or with a diagnosis of end-stage renal disease, for whom these tests were no longer recommended. In addition, the results of serum creatinine tests in a year were assessed.

2.5.2. Appropriate medication choice for patients with hyperlipidemia and/or hypertension

Statin use and the disease name of hyperlipidemia were identified for the assessment of appropriate statin prescription among patients with hyperlipidemia. Statin prescription was detected from the prescription of "C10A1" and "C11A1" in the ATC Classification System [31].

We also considered angiotensin-converting-enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) use among patients with hypertension as appropriate. Antihypertensive drugs were identified using the same drug list as that used in a previous study [33]. ACE inhibitor or ARB prescription was detected from the prescription of "C9A", "C9B", "C9C", and "C9D" in the ATC Classification System [31].

2.6. Statistical analysis

After we identified the patients with antidiabetic medication in each subject-identification year, the sex-specific and age-specific proportions of patients with diabetes were calculated. We then computed the proportions of dropouts and hospitalization in the quality-reporting year. From this point forward, those who dropped out, those who were hospitalized, and those whose examinations/prescriptions may not have been captured due to comprehensive payment were excluded, although such cases were an exception (the numbers are mentioned elsewhere in the article). We calculated the proportion of crude examinations/prescriptions and temporal changes (*P* for trend).

In order to estimate quality indicators by patient and facility characteristics, we constructed generalized estimating equation (GEE) models with the logit link function and an exchangeable correlation structure with independent variables as follows. We used the type of antidiabetic medication (insulin and/or GLP-1 analogue group or oral hypoglycemic agent group) and type of medical facility (larger hospital, smaller hospital, and clinic) as the main predictors. We adjusted for age (10-year age interval), sex, type of antidiabetic medication and facility. We also included the observation period (categorical) in the regression model to address secular changes. In addition, in order to estimate the adjusted percentages of the quality indicators, we included an interaction term between the observation period (categorical) and type of antidiabetic medication (categorical) in the model (Model 1), and observation period and type of facility (Model 2). We did not include the variable of IDDM diagnosis in the model to avoid multicollinearity with the type of antidiabetic medication. Finally, using these models, we calculated the adjusted percentages by antidiabetic medication and facility type, respectively. Changes in the quality indicators were assessed by comparing the values between the first and last quality-reporting years (2007 and 2015). All GEE models addressed the possibly underestimated variance of proportions by including the same individual patients in different observation periods by designating the personal identification variable as a cluster. We used Stata version 15.0 (Stata Corp, College Station, TX, USA) for the statistical analysis and data management. A p value lower than 0.05 was considered statistically significant.

Additional methodology information, for the definition of patients with diabetes and quality indicator assessment, is provided in supplementary file (Appendix 3).

3. Results

3.1. Patient characteristics

Table 1 shows the patients' characteristics. The proportions of patients with antidiabetic medication among all beneficiaries aged 60–69 years were 11.5% for men and 7.4% for women in April 2014. The average age had increased during the decade (49.6 to 53.0 in men, 52.7 to 54.1 in women, 2006–2014). The percentages of patients in whom the antidiabetic medication prescribed was insulin and/or GLP-1 analogues plateaued at approximately 19%. In 2014, 66.9% of patients with antidiabetic medications received their prescriptions at clinics.

3.2. Dropout and hospitalization

While approximately 5–6% of the patients had dropped out, about 10% were hospitalized in the quality-reporting year during each study period (Table 1). These trends were stable during this observation period. After the exclusion of those who dropped out and those who were hospitalized, the propor-

Table 1 – Patients' characteristics in each observation period[$] and number of dropouts and hospitalizations in the quality-reporting year.

	April 2006 to March 2008			April 2008 to March 2010			April 2010 to March 2012			April 2012 to March 2014			April 2014 to March 2016			χ^2 test (P value)
	Number of patients (%)		Proportion of patients[*]	Number of patients (%)		Proportion of patients[*]	Number of patients (%)		Proportion of patients[*]	Number of patients (%)		Proportion of patients[*]	Number of patients (%)		Proportion of patients[*]	
Total																
Observed patients	2266		1.0	3638		1.1	9991		1.2	17,705		1.4	38,105		1.7	
Patients characteristics																
Age (years old)																
Men																
Average age, Mean ± SD	49.6 ± 8.32			50.9 ± 8.58			51.4 ± 8.38			51.9 ± 8.35			53.0 ± 8.34			
Total	1567		1.5	2569		1.8	7120		2.0	12,921		2.5	28,050		3.0	
20–29	24	(1.5)	0.1	29	(1.1)	0.1	73	(1.0)	0.1	134	(1.0)	0.1	261	(0.9)	0.1	
30–39	193	(12.3)	0.6	231	(9.0)	0.5	583	(8.2)	0.6	880	(6.8)	0.6	1441	(5.1)	0.6	
40–49	459	(29.3)	1.8	769	(29.9)	2.0	2069	(29.1)	2.1	3749	(29.0)	2.5	7051	(25.1)	2.6	<0.01
50–59	799	(51.0)	4.9	1202	(46.8)	5.2	3166	(44.5)	5.5	5592	(43.3)	6.2	12,565	(44.8)	6.7	
60–69	92	(5.9)	6.8	338	(13.2)	8.1	1229	(17.3)	8.6	2566	(19.9)	10.5	6732	(24.0)	11.5	
Women																
Average age, Mean ± SD	52.7 ± 9.61			52.5 ± 9.65			53.1 ± 9.59			53.3 ± 9.50			54.1 ± 9.24			
Total	699		1.1	1069		1.2	2871		1.2	4784		1.3	10,055		1.6	
20–29	8	(0.5)	0.1	13	(0.5)	0.1	46	(0.6)	0.1	79	(0.6)	0.1	134	(0.5)	0.1	
30–39	67	(4.3)	0.3	115	(4.5)	0.4	230	(3.2)	0.3	343	(2.7)	0.3	541	(1.9)	0.3	
40–49	146	(9.3)	0.9	231	(9.0)	0.9	652	(9.2)	0.9	1130	(8.7)	1.0	2232	(8.0)	1.1	<0.01
50–59	316	(20.2)	3.4	477	(18.6)	3.4	1148	(16.1)	3.0	1835	(14.2)	3.2	3936	(14.0)	3.2	
60–69	162	(10.3)	8.7	233	(9.1)	6.3	795	(11.2)	7.0	1397	(10.8)	7.4	3212	(11.5)	7.4	
Type of diabetes																
Insulin dependent diabetes (E10)	125	(5.5)		176	(4.8)		483	(4.8)		756	(4.3)		1524	(4.0)		<0.01
Non-insulin dependent diabetes and others (E11-14)	2141	(94.5)		3462	(95.2)		9508	(95.2)		16,949	(95.7)		36,581	(96.0)		
Comorbid conditions (ICD-10)																
Hyperlipidemia (E78, excluding hypertriglyceridemia or other conditions for which statin is not applied)	1290	(56.9)		2309	(63.5)		6601	(66.1)		12,006	(67.8)		26,481	(69.5)		<0.01
Hypertension (I10-15)	1047	(46.2)		1874	(51.5)		5575	(55.8)		10,301	(58.2)		22,868	(60.0)		<0.01
Features of antidiabetic prescription																
Type of antidiabetic medication																
Insulin and/or GLP-1 analogue	445	(19.6)		722	(19.8)		1940	(19.4)		3239	(18.3)		6825	(17.9)		<0.01
Oral antihyperglycemic agents only	1821	(80.4)		2916	(80.2)		8051	(80.6)		14,466	(81.7)		31,280	(82.1)		
Type of medical facility																
Hospital (≧200 beds)	779	(34.4)		1052	(28.9)		2398	(24.0)		4059	(22.9)		8114	(21.3)		<0.01
Hospital (20–199 beds)	187	(8.3)		354	(9.7)		1028	(10.3)		1734	(9.8)		4480	(11.8)		
Clinic (0–19 beds)	1300	(57.4)		2232	(61.4)		6565	(65.7)		11,912	(67.3)		25,511	(66.9)		
Dropouts and hospitalizations in the quality-reporting year																
Dropouts	141	(6.2)		204	(5.6)		490	(4.9)		892	(5.0)		1882	(4.9)		0.04
Hospitalization[†]	217	(10.2)		374	(10.9)		970	(10.2)		1591	(9.5)		3752	(10.4)		0.01

SD, standard deviation.

ICD-10: International Statistical Classification of Diseases and Related Health Problems, 10th Revision.

[$] All patients had regularly visited clinics or hospitals at least every three months in the subject-identification year (the first fiscal year).

[*] Proportion of patients among all beneficiaries = (Number of patients with diabetic medication within the stratum)/(Number of all beneficiaries within the stratum) * 100.

[†] After dropout patients were excluded, we identified patients who had a history of admission during the quality-reporting year.

tions of patients were 1908, 3060, 8531, 15,222, and 32,471 in 2007, 2009, 2011, 2013, and 2015, respectively.

3.3. Crude quality indicators

Table 2 shows the numbers of patients with antidiabetic medication in whom the quality indicators during each study period and crude quality indicators in the quality-reporting year were finally assessed. Patients whose examinations/prescriptions may not have been captured due to comprehensive payment were excluded. For instance, 49, 56, 181, 318, and 685 patients were excluded due to comprehensive payment with regards to the HbA1c test in 2007, 2009, 2011, 2013, and 2015, respectively. Regarding the urine protein test, 77 patients (in total) on dialysis and/or with a diagnosis of end-stage renal disease were excluded, and all patients who received their prescriptions in larger hospitals (≥200 beds) were also excluded due to comprehensive payment.

The crude quality indicators were as follows: 68.2% (n = 1859) and 68.9% (n = 31,786) for the HbA1c test (≥1 per three months, P for trend < 0.01), and 42.0% (n = 1865) and 38.7% (n = 31,920) for eye examinations (P for trend < 0.01), in 2007 and 2015, respectively. Regarding nephropathy screening, about 73% of the patients underwent any one of the urine tests in the study period (P for trend = 0.51), but the proportions of those who underwent a quantitative urine protein test were 14.0% (n = 913) and 24.2% (n = 20,022) in 2007 and 2015, respectively (P for trend < 0.01).

3.4. Time trends in the quality indicators

3.4.1. Quality indicators by antidiabetic medication type

Fig. 2 shows the time trends in the quality indicators by antidiabetic medication type after adjustment for covariates (Model 1). The quality indicator values in the insulin and/or GLP-1 analogue group were higher than those in the oral hypoglycemic agent group (for instance, HbA1c test (≥1 per three months), eye examinations, urine protein test, and ACE inhibitor or ARB). Between 2007 and 2015, the proportion of eye examinations was stable (insignificant changes), ranging from 33.7% (95% CI: 31.6–35.7) in 2007 to 35.5% (95% CI: 34.9–36.0) in 2015 in the oral hypoglycemic agent group, and 57.2% (95% CI: 52.7–61.6) to 53.8% (95% CI: 52.6–55.1) in the insulin and/or GLP-1 analogue group. The proportion of patients who underwent a quantitative urine protein test remained 22.2% (95% CI: 21.6–22.8) in the oral hypoglycemic agent group and 39.1% (95% CI: 37.3–40.8) in the insulin and/or GLP-1 analogue group in 2015. The differences in the proportions between the prescription groups were eliminated with regards to serum lipid tests and statin prescription among the hyperlipidemia cases in 2015. Regarding ACE inhibitor or ARB prescription, the proportions of patients in the insulin and/or GLP-1 analogue group were significantly higher than those of patients in the oral hypoglycemic agent group during 2007–2015.

3.4.2. Quality indicators by the type of medical facility

Fig. 3 shows the time trends in the quality indicators by the type of medical facility after adjustment for covariates (Model 2). The quality indicator values in the larger hospital group were generally higher than that in the clinic group, with the value for the smaller hospital group positioned in the middle in most cases. The proportions of patients who received an HbA1c test (≥1 per three months) was 75.7% (95% CI: 74.2–76.3) in the larger hospital group and 77.3% (95% CI: 76.0–78.6) in the smaller hospital group, but remained at 65.8% (95% CI: 65.2–66.4) in the clinic group in 2015. A comparison of the proportions between 2007 and 2015 showed no or suboptimal improvement in the condition of patients with antidiabetic medication who were receiving annual eye examinations: with values ranging from 47.6% (95% CI: 44.3–51.0) to 46.0% (95% CI: 44.8–47.2) in the larger hospital group and from 34.9% (95% CI: 32.5–37.4) to 36.1% (95% CI: 35.4–36.7) in the clinic group; however, the value significantly increased from 32.2% (95% CI: 25.5–38.9) to 40.6% (95% CI: 39.1–42.2) in the smaller hospital group. The proportions of those who underwent a quantitative urine protein test did not increase significantly, ranging from 20.4% (95% CI: 15.2–25.6) in 2007 to 26.0% (95% CI: 24.5–27.4) in 2015 in the smaller hospital group, but significantly increased from 13.9% (95% CI: 12.1–15.7) to 24.0% (95% CI: 23.4–24.6) in the clinic group. A significant increase was observed in the proportions of patients who received a statin prescription: from 59.6% (95% CI: 56.3–62.8) in 2007 to 67.3% (95% CI: 66.1–68.6) in 2015 in the larger hospital group, from 53.8% (95% CI: 46.8–60.7) to 64.1% (95% CI: 62.4–65.9) in the smaller hospital group, and from 58.6% (95% CI: 56.2–61.1) to 62.1% (95% CI: 61.4–62.8) in the clinic group.

4. Discussion

4.1. Main findings

This study identified several important issues pertaining to diabetes care in Japan in the period between 2007 and 2015. First, although the quality indicators for lipid profile monitoring, nephropathy screening, and medication choice among Japanese patients with antidiabetic medications substantially but incrementally improved over the decade, there were no significant changes in the indicators for glycemic control monitoring and retinopathy screening in the observed period. Our findings, therefore, suggest that while the quality indicators for the process of diabetes care were still suboptimal in Japan, the medication choice practices for patients with hyperlipidemia and/or hypertension had substantially improved. Second, with regards to patient characteristics, those treated with insulin and/or GLP-1 analogues had a higher chance of receiving a better quality of care than those treated with oral hypoglycemic agents. We also observed higher quality indicator values among patients who were prescribed antidiabetic medications at larger hospitals than among those who received their prescription at clinics in most cases. These results may provide useful benchmarks for the improvement of the quality of diabetes care in Japan.

4.2. Interpretation

The proportions of indicators on both annual nephropathy and retinopathy screening were still lower than those of the other quality indicators, as also observed in previous studies

Table 2 – Crude quality indicators in the quality-reporting year: fiscal year (April to March) (%).

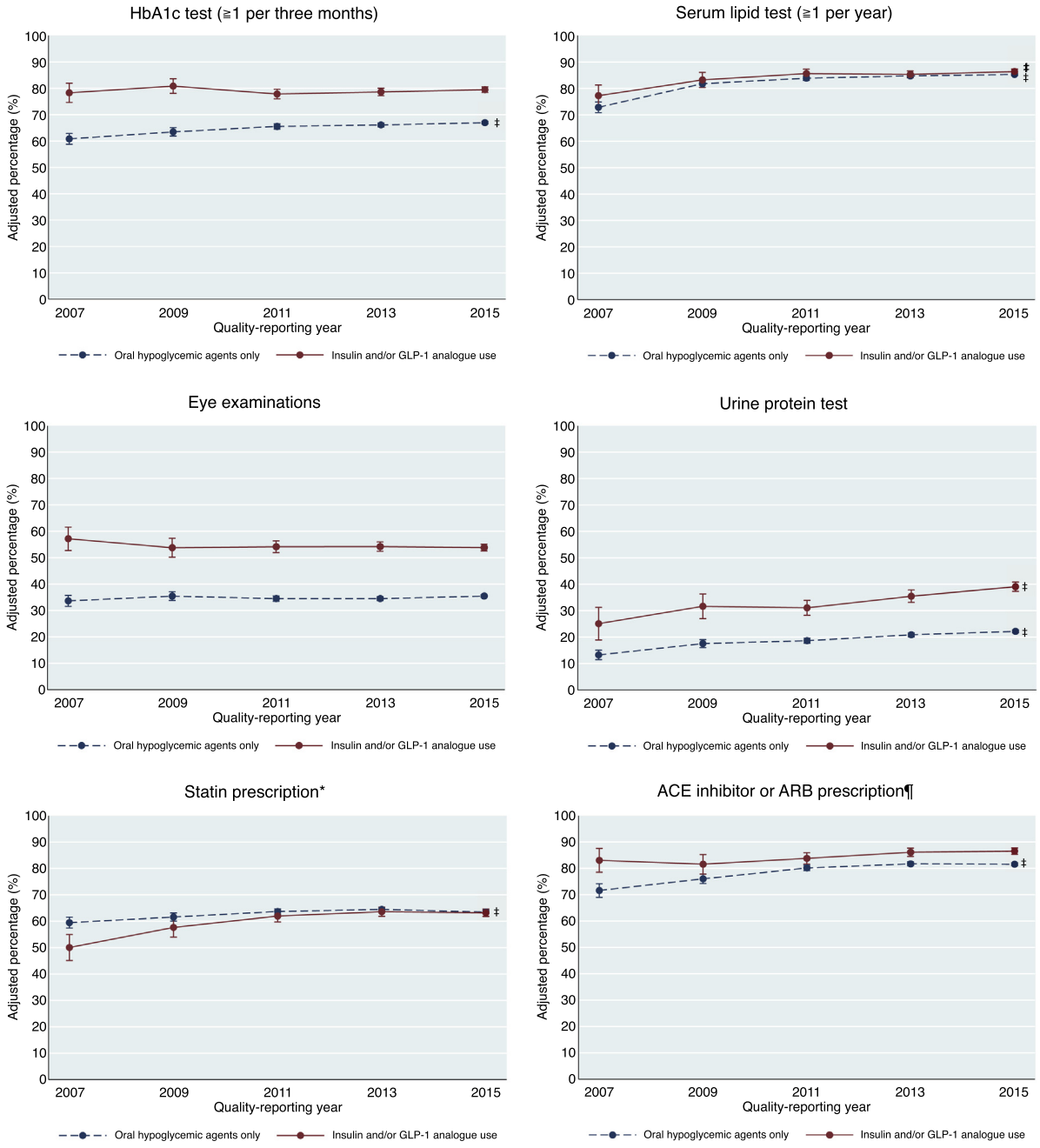
	2007 (n = 1908)	2009 (n = 3060)	2011 (n = 8531)	2013 (n = 15,222)	2015 (n = 32,471)	P for trend
Glycemic control monitoring						
(n = observed patients)*	(n = 1859)	(n = 3004)	(n = 8350)	(n = 14,904)	(n = 31,786)	
HbA1c test (≥1 per year)	93.7	95.5	95.8	95.8	95.9	0.16
HbA1c test (≥1 per three months)	68.2	69.3	69.2	68.3	68.9	<0.01
Lipid profile monitoring						
(n = observed patients)*	(n = 1856)	(n = 2990)	(n = 8322)	(n = 14,846)	(n = 31,293)	
Serum lipid test (≥1 per year)	75.5	83.3	84.9	84.9	85.4	<0.01
Retinopathy screening						
(n = observed patients)*	(n = 1865)	(n = 3018)	(n = 8384)	(n = 14,960)	(n = 31,920)	
Eye examinations (≥1 per year)	42.0	40.3	38.5	37.8	38.7	<0.01
Nephropathy screening						
(n = observed patients without dialysis and/or with diagnosis of end-stage renal disease)*	(n = 913)	(n = 1622)	(n = 5082)	(n = 9137)	(n = 20,022)	
Urine test (≥1 per year)	74.5	72.3	74.4	72.2	72.6	0.51
Urine protein test*,¶ (≥1 per year)	14.0	20.3	21.5	23.3	24.2	<0.01
(n = observed patients)*	(n = 1855)	(n = 2989)	(n = 8319)	(n = 14,833)	(n = 31,260)	
Serum creatinine test (≥1 per year)	88.0	88.2	88.2	88.3	88.6	<0.01
Appropriate medication choice						
(n = observed patients)*	(n = 1867)	(n = 3022)	(n = 8417)	(n = 15,010)	(n = 32,052)	
Statin prescription	37.5	43.0	44.3	45.8	45.6	<0.01
ACE inhibitor or ARB prescription	34.1	38.4	43.5	45.6	45.4	<0.01
(n = observed patients with hyperlipidemia§)*	(n = 1077)	(n = 1917)	(n = 5585)	(n = 10,204)	(n = 22,302)	
Statin prescription	61.7	64.3	64.5	65.0	64.1	<0.01
(n = observed patients with hypertension and prescription of hypertensive drug)*	(n = 768)	(n = 1382)	(n = 4234)	(n = 7924)	(n = 17,281)	
ACE inhibitor or ARB prescription	77.0	78.9	82.5	83.6	82.0	<0.01

HbA1c; Glycated hemoglobin I, ACE; angiotensin-converting-enzyme; ARB, angiotensin II receptor blocker.

* Number of patients with diabetes in whom the quality indicator values were finally assessed.

¶ Any one or more urine protein test or urine albumin excretion tests.

§ Hyperlipidemia (excluding hypertriglyceridemia or other conditions for which statin is not applied).

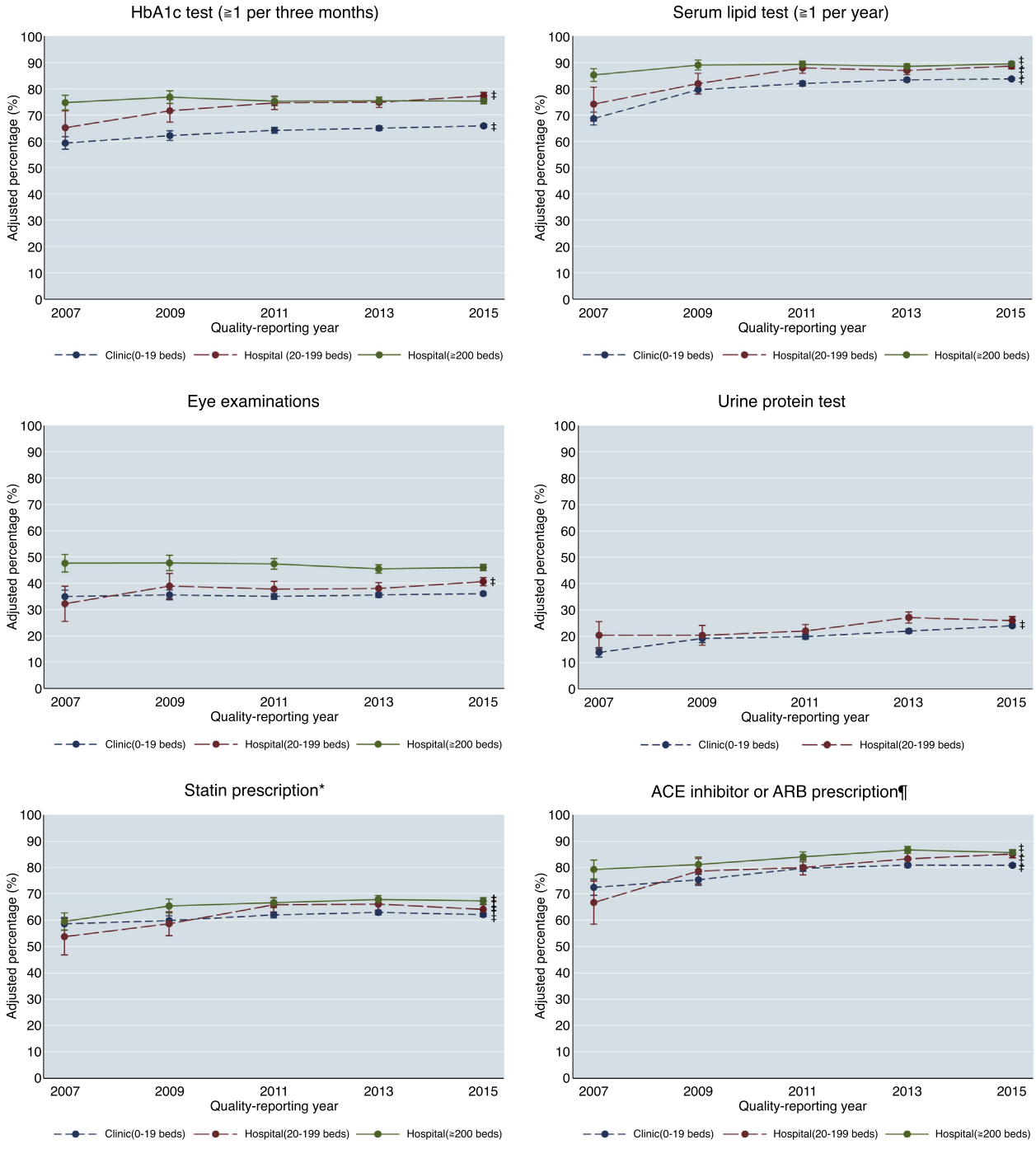


‡ Significant change compared to 2007 ($p<0.05$)

* Among patients with hyperlipidemia, ¶ Among patients with hypertension and prescription of hypertensive drug

Fig. 2 – Changes in the adjusted percentage of quality indicators by the type of antidiabetic medication (Model 1).

[26,27]. The proportion of patients who underwent nephropathy screening at least once a year (microalbuminuria test) was 59.4% in European countries [14]. Compared to the proportions of those who underwent any urine test including a urine qualitative test (about 73%, with an insignificant change during the period), the proportions of those who underwent a urine quantitative protein test were quite small. This finding implies that severe nephropathy may be detected well through urine qualitative tests; however, early nephropathy may not be detected sufficiently due to the lack of a urine quantitative protein test [7]. The quality indicator for retinopathy screening was less optimal than those observed in European countries and the US. For instance, 74.8% and 73.4% of patients with diabetes underwent retinopathy screening in European countries and the US, respectively [10,14]. We suspect that these suboptimal qualities pertain to the physician's attitude, payment systems, and the lack of patients' literacy on diabetes care; however, unfortunately, our analysis could not identify the factors that prevent improvements in the quality of diabetes care. In any case, fur-



‡ Significant change compared to 2007 ($p<0.05$)

* Among patients with hyperlipidemia, ¶ Among patients with hypertension and prescription of hypertensive drug

Fig. 3 – Changes in the adjusted percentage of quality indicators by the type of medical facility in which antidiabetic medication was prescribed (Model 2).

ther study is required to understand why the quality of diabetes care in Japan has not improved sufficiently and is lower than that in the US and European countries.

The result of the present study indicated that the values of the quality indicators, especially those pertaining to glycemic control monitoring and retinopathy screening, were higher among patients using insulin and/or GLP-1 analogues and those who were cared for at a larger medical facility. Together with the suboptimal performances observed worldwide, these differences may be induced by both "patient factors" and "provider factors" [34]. In terms of patient factors, patients with a longer duration of diabetes or difficult glycemic control

(e.g., older patients) are likelier to be prescribed insulin; in these patients, glycemic control and complications may be assessed more intensively in order to titrate prescriptions in response to blood glucose levels and to treat newly detected lesions [35]. As for provider factors, the proportion of specialists (e.g., board-certified diabetologists) who are likely to provide better care for diabetes patients may be higher in larger hospitals [36]. Future studies using datasets with more detailed patient and provider information (e.g., duration of diabetes and distribution of board-certified diabetologists) may enable the investigation of the aforementioned hypothetical relationship.

Even though patient and provider factors are associated with quality indicators, initiatives should be taken to achieve high adherence to the recommended quality of care regardless of the characteristics of patients, physicians, and facilities. For instance, at the facility level, medical facilities with accreditation from organizations such as the Joint Commission International and the Japan Council for Quality Health Care are expected to implement quality management continuously [37,38]; the inclusion of quality indicators for diabetes care as required items may help improve the quality of diabetes care among accredited facilities and facilities seeking accreditation. Another potentially effective strategy could be incentivization through the payment system. In the United Kingdom, physicians are financially incentivized to provide a high quality of care for patients with diabetes in the primary care setting through the Quality and Outcomes Framework [15]. In Japan, although the pay-for-performance framework has not been introduced in the unit of physicians, incentives for quality improvement per facility have already been introduced through the centralized medical fee decision system and nationwide universal health care coverage [39]. From another viewpoint, the implementation of a regular fee-for-service framework may also work in improving the quality of care in Japanese healthcare settings. For instance, the exchange of patients' medical information between physicians and ophthalmologists via special notebooks called "Diabetes Collaboration Notebook" or "Diabetes Eye Notebook", which may also function as personal health records, is widely followed in Japan; the process of referral using these notebooks should be reimbursed as proof of a better process of care.

We found that the medication choice for patients with hyperlipidemia and/or hypertension had improved in the study period, whereas unfavorable signs in the progress of diabetes care were noted. This favorable trend could be attributed to improvements in the adherence to clinical guidelines among Japanese physicians. However, the proportion of statin prescriptions was still lower than 70% in 2015. Further improvements are necessary to ensure appropriate lipid control, so as to prevent hyperlipidemia.

4.3. *Strengths and limitations*

To the best of our knowledge, it is the first study to investigate the temporal changes in diabetes care in Japan. In order to assess the quality indicator values among those in whom diabetes care was a requirement and those in whom the diabetes care was assessable, we carefully identified patients with antidiabetic medication. We also successfully excluded those who dropped out and/or were hospitalized during the observation period. Therefore, we believe that our study provides a meaningful assessment of the recent changes in the diabetes care system in Japan. Moreover, the analytical methods we employed, and the following discussion based on the analyses can be generalizable to any medical system as long as it collects and tabulates healthcare claims data.

The present study has several limitations. First, our study population predominantly included patients with a relatively high socioeconomic status, aged 20–69 years; therefore, the quality of care for elderly patients was beyond the scope of the study. Second, we could not collect data on individual patients' test results (e.g., HbA1c level), because medical claims do not contain clinical test results. Data including both claims and individual test results may facilitate the investigation of the relationship between process and outcome measures with regards to diabetes care. Third, our analysis allowed for patients to be included in several study periods. This may have distorted our analysis in terms of the efficiency of the prediction of the quality indicators; however, we dealt with this problem using cluster terms (patients) in the GEE model. Fourth, differences in patients' characteristics (e.g. average age, types of medical facility where prescribed, and dropouts/hospitalization rates) existed across the five study periods along with substantial changes in the numbers of study participants (Table 1). Although we compensated for the limitation by statistical modelling, residual confounding that can distort our trend analysis, may still remain. Therefore, data shown in Table 2, Figs. 2 and 3 should be interpreted with careful insight.

4.4. *Conclusion*

The quality of diabetes care was overall still suboptimal in Japan as of 2015, especially with regards to diabetic nephropathy and retinopathy screening. However, we observed an improvement in the medication choice for patients with hyperlipidemia and/or hypertension, implying that an increasing number of Japanese physicians are starting to follow clinical guidelines. Future measures in improving diabetes care in Japan should focus both on improving overall quality and reducing quality gaps.

Conflicts of interest

The authors disclose no potential conflicts of interest.

Ethical considerations

The Research Ethics Committee of National Center for Global Health and Medicine, Japan approved this study after due ethical consideration (approval No.: NCGM-G-002096-00).

Acknowledgements

Authors' contributions.

All authors had full access to all the study data and T.S. was responsible for data integrity and the accuracy of the data analysis. H.T., T.S., N.I-S., Y.K., and M.O. were involved in the

study conception and design. T.S. and M.O. took part in data acquisition. H.T., T.S., N.I-S., and M.O. were responsible for the analysis and interpretation of data. H.T., T.S., N.I-S., and M.O. interpreted and analyzed data. H.T., T.S., and N.I-S. drafted the manuscript. H.T. and T.S. conducted statistical analyses. All authors took part in critically revising the manuscript for important intellectual content. M.O. and K.U. obtained funding. Y.K and K.U. provided administrative, technical, and material support. T.S. and M.O. supervised the study.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.02.001.

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