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Original Article

Study profile: protocol outline and study perspectives of the cohort by the National Institute of Occupational Safety and Health, Japan (JNIOSH cohort)

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Abstract: How work burden affects physical and mental health has already been studied extensively; however, many issues have remained unexamined. In 2017, we commenced a prospective cohort study of workers at companies in Japan, with a follow-up period of 5–10 years, in order to investigate the current situation of overwork-related health outcomes. From 2017 to 2020, a target population of 150,000 workers across 8 companies was identified. Of these, almost 40,000 workers agreed to participate in the baseline survey. Data on working hours, medical check-up measurements, occupational stress levels, and lifestyle habits were collected. The average age of the participants at baseline was 39.2 ± 11.7 years; 73.1% were men, and 87.7% were regular employees. The most common working hours by self-reported was 41–50 hours per week during normal season, and it increased to more than 50 hours during busy season. Furthermore, more than half of the participants reportedly experienced a form of sleep problem, and the percentage of those who experienced nonrestorative sleep was particularly high.

Key words: Occupational cohort, Working hours, Health check-ups, Job stress, Health outcome

Introduction

The prevention of brain and heart diseases, mental disorders from psychological stress, and suicide as a result of overwork are among the top priorities for ensuring a safe, healthy, productive, and prosperous working life for people in Japan. The Act of Promoting Measures to Prevent Death and Injury from Overwork was enacted in 2014, and then activities to prevent overwork have been steadily promoted. Despite this initiative, the number of cases of brain and heart disease due to overwork has not decreased dramatically, and there are signs of an increase in the number of cases of mental disorders due to the heavy psychological burden of work[1–4]. The association between long working hours and cardiovascular disease risk has been reported

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worldwide, with data from a large European-American meta-analysis showing increased stroke risk and Japanese studies suggesting an association between overwork and acute myocardial infarction[5–10]. Differences in terms of social and biological background and other underlying factors might exist in the international comparison. Working hours is one of the important exposure factors related to health outcomes in occupational cohorts. A well-known, representative, large-scale, Japanese epidemiological study[10] assessed working hours only through self-reporting; thus, its veracity has not yet been sufficiently examined. In recent years, the Japanese government has been promoting a new working style. Thus, new, up-to-date evidence on the health effects of long working hours specific to the Japanese population is necessary. Therefore, in this study, we began a large-scale, prospective, occupational cohort study of Japanese workers entitled the National Institute of Occupational Safety and Health Japan (JNIOSH) cohort study. The aim of this baseline cohort study was to identify and evaluate the effects of working hours and other environmental factors related to working and living that might contribute to the risk of developing overwork-related diseases (brain, cardiovascular, and mental diseases). Our study could also provide useful evidence for assessing working hours because we collected information on both self-reported and objective working hours.

The longitudinal analysis of comparing work style at baseline with physical and mental health outcomes could provide useful information for Japanese workers as well as complement the limitations of retrospective case analyses of overwork and other industrial accidents.

Methods

Study settings and participants

The participants were recruited through collaboration with companies and workplaces in Japan, and they were provided a health management system by Advantage Risk Management, Inc. The target population was all workers who take a stress check in the companies and workplaces that expressed willingness to participate in this survey. The category divisions of these companies were construction (Japan Standard Industrial Classification [Rev. 13, October 2013][11], code D), transport and postal activities (code H), real estate and goods rental and leasing (code K), and living-related and personal services and amusement services (code N).

Initially, we had a target cohort size of 200,000 person-years, and this sample size was set based on information from previous literature[12].

Recruitment began in November 2017. In total, eight companies/workplaces participated in this study, four began their participation in 2017–2018, and the last four were included in 2019. From the four companies/workplaces that commenced participation in 2017–2018, 12,563 of 16,623 workers agreed to participate (agreement rate: 75.6%) in the 2017–2018 survey, while 12,677 out of 16,703 workers agreed to participate in the 2019 survey (agreement rate: 75.9%). The number of participants varies each year because there were new participants, retirees, and withdrawals. In the companies/workplaces that participated from 2019, 31,549 out of the 136,308 workers agreed to participate (agreement rate: 23.1%). Overall, we obtained consent from 44,226 of the 153,011 workers by 2019.

This study had an annual recruitment and consent process for all workers, including those who agreed to participate in a past survey. We used a dynamic cohort design because of its flexibility which ensured that those who were eligible for the survey in 2017–2018 but did not agree to participate at that time and newly employed workers can participate in a future survey.

Data collection

The study data included working conditions recorded by the companies (working hours and days of work), physical conditions from the results of regular medical health check-ups, occupational stress, self-reported occupational background, working hours and sleep habits reported via additional questionnaire. We have continuously performed the same data collection once a year with the same participants. Moreover, we continued to recruit new participants into this study.

Recorded working conditions

The working conditions provided by the companies and workplaces were as follows: monthly number of working days, vacation days, absent days, scheduled working hours, actual working hours, overtime working hours, and midnight working hours.

Medical check-ups

The data from the medical check-up included sex, age, height, weight, body mass index (BMI), waist circumference, systolic and diastolic blood pressure, medication use, past history of disease, and blood test results. The blood test investigations were total cholesterol (mg/dL), high-density lipoprotein cholesterol (mg/dL), low-density lipoprotein (LDL) cholesterol (mg/dL), triglycerides (mg/dL),

fasting blood glucose (mg/dL), hemoglobin (Hb) A1c (%), aspartate aminotransferase (AST) (IU/L), alanine aminotransferase (ALT) (IU/L), γ-glutamyl transpeptidase (γ-GTP) (IU/L), creatinine, and uric acid. We used the results of the regular medical check-ups at the company and workplace to evaluate the participants' physical condition.

Occupational stress

Occupational stress was assessed by self-reporting using a web-based system provided by Advantage Risk Management, Inc. The contents were composed of 57 items developed with reference to the original Brief Job Stress Questionnaire (BJSQ), which was developed by the Ministry of Health, Labour and Welfare, Japan[13]. Assessment of job-related psychological stress for workers has been legally required since 2015 in Japan, and the original BJSQ or modified BJSQ has been widely used in the workplace. The occupational stress questionnaire in this study consisted of three components, that is, "work stressors", "mental and physical stress reactions" and "support from others" which are required by law to be included in the occupational stress check.

Additional questionnaire items

The self-reported questionnaire included employment background (employment status, work schedule, job category), working hours (regular working hours per week, outside working hours per week, working hours per week during the busy season), and sleep habits (average hours of sleep per day, difficulty initiating sleep, difficulty maintaining sleep, early morning awakening, nonrestorative sleep, and excessive sleepiness on the job). Detailed questions about working hours were as follows: (1) How many hours did you work per week in the last month? (2) How many hours did you work per week in the last month including non-office hours? (3) In the past year, how many hours did you work per week including non-office hours during busy seasons? (4) How many months per year did you have a busy schedule? The following questions were asked about sleep habits in the past month (in the case of respondents who work in shifts, we asked them to answer as if they were on the day shift): (1) On the average, how much sleep per day do you usually take at night? (2) How long does it usually take you to fall asleep in bed? (3) How often do you have difficulty staying asleep? (4) How often do you wake up too early and can't fall asleep again? (5) How often do you feel tired after waking in the morning? (6) How often do you feel sleepy during work that makes you almost fall asleep? These questions were developed with reference to previous studies[14–16].

Ethics

This survey was conducted according to the Ethical Guidelines for Epidemiological Studies established by the Japanese government[17], and it was approved by the Ethics Committee of JNIOSH (No. H2812 and H2919). We obtained informed consent from all participants via online or via a written form.

Statistical Analyses

For the univariate analysis, we reported the frequencies and percentages of blood test results, medical check-ups, self-reported working hours, and sleep problems by sex. We then compared proportions using the chi-squared test. All analyses were conducted using IBM SPSS Statistics (Version 26).

Results

Table 1 shows the summary of the participants' backgrounds at baseline in the preliminary data. The data included 111,313 participants, with a mean of age of 39.2 ± 11.7. Majority of the participants were men (73.1%), and their mean age was 40.1 ± 11.5 years, while 26.9% were women, with a mean age of 36.3 ± 11.2 years. The majority (87.7%) of the participants were regular employees, and most (93.3%) of the male participants were regular employees. Among women, the majority (72.5%) were regular employees, followed by part-time employees (15.4%) and contract workers (6.1%). Regarding job category, 19.9% were managers (25.8% of the men and 3.9% of the women). With respect to the non-managerial positions, men worked in sales and marketing (21.6%), followed by construction (15.1%) and professional occupations (13.8%). Among women, 34.6% were office workers, 16.8% worked in sales and marketing, and 16.5% were service workers. The most common working hours were 41–50 hours/week (48.6% in total, 50.8% of the men and 42.5% of the women), followed by 51–60 hours/week for men (17.5%) and 35–40 hours/week for women (28.6%). The result for the total working hours in the busy season including outside the workplace showed that working hours were higher than usual during the busy season. In particular, the percentage of those working 51–60 hours/week increased by 10% compared to the normal season.

Table 2 shows the participant's sleep status and sleep problems at baseline in the preliminary data. The percent-

Table 1. Chracteristics and occupational background by self-administered questionnaire among participants in preliminary data

	Total (n=11,313)		Men (n=8,273)		Women (n=3,040)		*p*-value*
	n	(%)	n	(%)	n	(%)	
Age group							
under 30 yrs	2,769	(24.5)	1,676	(20.3)	1,093	(36.0)	<0.001
30–39 yrs	3,630	(32.1)	2,756	(33.3)	874	(28.8)	
40–49 yrs	2,543	(22.5)	1,938	(23.4)	605	(19.9)	
50–59 yrs	1,669	(14.8)	1,306	(15.8)	363	(11.9)	
≥60 yrs	702	(6.2)	597	(7.2)	105	(3.5)	
Employment type							
Regular employee	9,920	(87.7)	7,716	(93.3)	2,204	(72.5)	<0.001
Contracted employee	383	(3.4)	197	(2.4)	186	(6.1)	
Fixed-term employee	134	(1.2)	119	(1.4)	15	(0.5)	
Temporary staff	7	(0.1)	4	(0.0)	3	(0.1)	
Part-time	640	(5.7)	172	(2.1)	468	(15.4)	
Other	229	(2.0)	65	(0.8)	164	(5.4)	
Work schedule							
Fixed time system	6,156	(54.4)	4,298	(52.0)	1,858	(61.1)	<0.001
Variable working hours system	1,543	(13.6)	1,027	(12.4)	516	(17.0)	
Flextime system	3,049	(27.0)	2,606	(31.5)	443	(14.6)	
Discretionary labor system	57	(0.5)	49	(0.6)	8	(0.3)	
Two-shift system (with night shifts)	190	(1.7)	131	(1.6)	59	(1.9)	
Two-shift system (without night shift)	70	(0.6)	39	(0.5)	31	(1.0)	
Three-shift system	73	(0.6)	35	(0.4)	38	(1.3)	
Only swing shift	20	(0.2)	9	(0.1)	11	(0.4)	
Only night shift	30	(0.3)	17	(0.2)	13	(0.4)	
Other	125	(1.1)	62	(0.7)	63	(2.1)	
Job categories							
Manager	2,255	(19.9)	2,137	(25.8)	118	(3.9)	<0.001
Professional, technical and research jobs	1,595	(14.1)	1,142	(13.8)	453	(14.9)	
Office work	1,980	(17.5)	928	(11.2)	1,052	(34.6)	
Product sales	9	(0.1)	8	(0.1)	1	(0.0)	
Sales and Marketing	2,293	(20.3)	1,783	(21.6)	510	(16.8)	
Services	1,156	(10.2)	654	(7.9)	502	(16.5)	
Transport	41	(0.4)	36	(0.4)	5	(0.2)	
Construction	1,322	(11.7)	1,249	(15.1)	73	(2.4)	
Manufacturing	48	(0.4)	41	(0.5)	7	(0.2)	
Other	614	(5.4)	295	(3.6)	319	(10.5)	

Table 1. Continued

	Total (n=11,313)		Men (n=8,273)		Women (n=3,040)		*p*-value*
	n	(%)	n	(%)	n	(%)	
Working hours/week, at workplace							
1–34h	1,372	(12.1)	763	(9.2)	609	(20.0)	<0.001
35–40h	2,170	(19.2)	1,301	(15.7)	869	(28.6)	
41–50h	5,498	(48.6)	4,205	(50.8)	1,293	(42.5)	
51–60h	1,647	(14.6)	1,448	(17.5)	199	(6.5)	
61–65h	325	(2.9)	295	(3.6)	30	(1.0)	
66–70h	146	(1.3)	134	(1.6)	12	(0.4)	
≥71h	155	(1.4)	127	(1.5)	28	(0.9)	
Working hours/week during busy term, including outside of workplace							
1–34h	1,916	(16.9)	1,083	(13.1)	833	(27.4)	<0.001
35–40h	1,354	(12.0)	793	(9.6)	561	(18.5)	
41–50h	3,172	(28.0)	2,266	(27.4)	906	(29.8)	
51–60h	2,877	(25.4)	2,364	(28.6)	513	(16.9)	
61–65h	1,012	(8.9)	879	(10.6)	133	(4.4)	
66–70h	492	(4.3)	444	(5.4)	48	(1.6)	
≥71h	490	(4.3)	444	(5.4)	46	(1.5)	

* Test of the difference between the proportions of men and women (chi-squared test)

age of people who had some type of sleep problem at least once a month (the sum of the percentage "1 or more times/month", "1–2 times/week", "3 or more times/week", and "almost every day") was calculated. The most common sleep problem was "nonrestorative sleep" (67.7%), which was noted to be higher among women (71.8%) than men (66.5%). Other common sleep problems were "excessive sleepiness on the job" (44.5%), difficulty maintaining sleep (37.8%), and early morning awakening (30.3%).

Table 3 shows the baseline health status of the participants among 9,549 participants, including 7,254 men (76%) and 2,293 women (24%). The total number of participants with available and missing medical check-up data was different for each item, as shown in the Appendix Table. The coverage of medical check-up data among 11,313 participants (8,273 men and 3,040 women) with fixed background data was 84.4%, with 87.7% in men and 75.4% in women. The items with the highest rate of abnormalities in total were LDL (42.3%), HbA1c (31.5%), and BMI (28.3%). Moreover, around 20% of the participants, which was one in five of the participants, have above normal level of triglyceride, ALT, and γ-GTP. The percentage of participants with abnormal values was significantly higher in men than in women for all items ($p<0.001$). The percentage of participants with a BMI of 25 or more, i.e., overweight was 33.4% for men, which is almost three times higher than women (12.3%).

Discussion

The JNIOSH cohort study is one of the occupational cohorts in Japan that could provide a comprehensive analysis of the relationship between working hours and health outcomes. An important goal of this cohort is to examine intermediate indicators like overwork that are likely to be associated with health outcomes using a cross-sectional and longitudinal data set to determine the contribution and multiple effects. Given that the results presented in this paper were based on preliminary data, only a superficial outline can be shown. The results showed a difference in the distri-

Table 2. Sleep status and sleep problems among participants in preliminary data

	Total (n=11,313)		Men (n=8,273)		Women (n=3,040)		*p*-value*
	n	(%)	n	(%)	n	(%)	
Difficulty maintaining sleep							
Almost never	5,107	(45.1)	3,655	(44.2)	1,452	(47.8)	<0.001
A few times a year (occasionally)	1,927	(17.0)	1,428	(17.3)	499	(16.4)	
1 or more times/month	1,718	(15.2)	1,306	(15.8)	412	(13.6)	
1–2 times/week	1,430	(12.6)	1,058	(12.8)	372	(12.2)	
3 or more times/week	623	(5.5)	471	(5.7)	152	(5.0)	
Almost every day	508	(4.5)	355	(4.3)	153	(5.0)	
Early morning awakening							
Almost never	6,227	(55.0)	4,327	(52.3)	1,900	(62.5)	<0.001
A few times a year (occasionally)	1,647	(14.6)	1,244	(15.0)	403	(13.3)	
1 or more times/month	1,464	(12.9)	1,173	(14.2)	291	(9.6)	
1–2 times/week	1,158	(10.2)	888	(10.7)	270	(8.9)	
3 or more times/week	478	(4.2)	398	(4.8)	80	(2.6)	
Almost every day	339	(3.0)	243	(2.9)	96	(3.2)	
Nonrestorative sleep							
Almost never	2,078	(18.4)	1,577	(19.1)	501	(16.5)	<0.001
A few times a year (occasionally)	1,541	(13.6)	1,184	(14.3)	357	(11.7)	
1 or more times/month	1,934	(17.1)	1,451	(17.5)	483	(15.9)	
1–2 times/week	2,529	(22.4)	1,845	(22.3)	684	(22.5)	
3 or more times/week	1,469	(13.0)	1,079	(13.0)	390	(12.8)	
Almost every day	1,762	(15.6)	1,137	(13.7)	625	(20.6)	
Excessive sleepiness on the job							
Almost never	3,933	(34.8)	2,706	(32.7)	1,227	(40.4)	<0.001
A few times a year (occasionally)	2,354	(20.8)	1,777	(21.5)	577	(19.0)	
1 or more times/month	2,292	(20.3)	1,723	(20.8)	569	(18.7)	
1–2 times/week	1,743	(15.4)	1,324	(16.0)	419	(13.8)	
3 or more times/week	644	(5.7)	497	(6.0)	147	(4.8)	
Almost every day	347	(3.1)	246	(3.0)	101	(3.3)	

* Test of the difference between the proportions of men and women (chi-squared test)

bution of working hours between men and women. This difference might be attributed to the differences in terms of the background of working conditions, such as employment type, work schedule, and job category. Moreover, the results of the baseline blood tests by medical check-up showed differences in men and women; hence, biological differences and differences in working backgrounds could be complicated in this cohort population. Adjustments for lifestyle, medication use, and medical history could also lead to more reliable results. This information will be accumulated and completed accordingly.

The unique points of this cohort study were that it included a wide range of industries and multiple companies and two types of methods were used to assess working

Table 3. Health status according to medical check-ups among participants in preliminary data

Measured item		Total		Men		Women		*p*-value*
		n	(%)	n	(%)	n	(%)	
Body mass index	<25 kg/m^2	6,822	(71.7)	4,813	(66.6)	2,009	(87.7)	<0.001
	≥25 kg/m^2	2,692	(28.3)	2,409	(33.4)	283	(12.3)	
Systolic blood pressure	<140 mm Hg	8,684	(91.0)	6,464	(89.1)	2,220	(96.8)	<0.001
	≥140 mm Hg	862	(9.0)	789	(10.9)	73	(3.2)	
Diastolic blood pressure	<90 mm Hg	8,702	(91.2)	6,478	(89.3)	2,224	(97.0)	<0.001
	≥90 mm Hg	844	(8.8)	775	(10.7)	69	(3.0)	
HDL cholesterol	≥40 mg/dL	8,850	(93.2)	6,593	(91.4)	2,257	(98.9)	<0.001
	<40 mg/dL	647	(6.8)	621	(8.6)	26	(1.1)	
LDL cholesterol	<120 mg/dL	5,477	(57.7)	3,791	(52.6)	1,686	(73.9)	<0.001
	≥120 mg/dL	4,012	(42.3)	3,415	(47.4)	597	(26.1)	
Triglycerides	<150 mg/dL	7,583	(79.8)	5,426	(75.1)	2,157	(94.4)	<0.001
	≥150 mg/dL	1,923	(20.2)	1,796	(24.9)	127	(5.6)	
Fasting blood glucose	<100mg/dL	6,277	(82.5)	4,530	(79.4)	1,747	(92.0)	<0.001
	≥100mg/dL	1,327	(17.5)	1,176	(20.6)	151	(8.0)	
HbA1c	<5.6 %	4,795	(68.5)	3,758	(67.0)	1,037	(74.8)	<0.001
	≥5.6 %	2,204	(31.5)	1,854	(33.0)	350	(25.2)	
AST	<30 IU/L	8,329	(87.6)	6,114	(84.6)	2,215	(97.0)	<0.001
	≥30 IU/L	1,178	(12.4)	1,110	(15.4)	68	(3.0)	
ALT	<30 IU/L	7,250	(76.3)	5,075	(70.3)	2,175	(95.3)	<0.001
	≥30 IU/L	2,257	(23.7)	2,149	(29.7)	108	(4.7)	
γ-GTP	<50 IU/L	7,461	(78.5)	5,263	(72.9)	2,198	(96.3)	<0.001
	≥50 IU/L	2,044	(21.5)	1,960	(27.1)	84	(3.7)	

* Test of the difference between the proportions of men and women (chi-squared test)

The measurements were divided by general standard criteria. The number of participants differs for each test item due to the lack of measured values. The numbers used in the tabulations are shown in the appendix table.

Abbreviations; HDL cholesterol: high density lipoprotein cholesterol; LDL cholesterol: low density lipoprotein cholesterol; HbA1c: hemoglobin A1c; AST: aspartate aminotransferase; ALT: alanine aminotransferase; γ-GTP: γ-glutamyl transpeptidase.

hours. In this study, both self-reporting of working hours and objective working data (i.e., work-time data managed and automatically recorded by the companies/workplaces) were collected. The precision between self-reported working hours and company-recorded working hours has not been sufficiently examined thus far[18]. A preliminary assessment in a sub-population of the study cohort showed that the difference between actual working hours and self-reported working hours tended to be greater for those who worked longer hours[19]. The identification of individual and workplace factors that strongly influence the under- and overestimation of working hours will provide important evidence to guide appropriate management of working hours. This study has some limitations regarding subject bias. The participating companies are not representative of all type of industries and occupations. And in the recruiting process, workers who were subject to stress checks conducted at companies/workplaces were the primary participants. Therefore, some workers in the same companies/workplaces not taking the stress check for whatever reason might have been missed during the recruitment. This type of selection bias might be more likely to occur in an occupational cohort. In addition, it was impossible to follow up workers who have participated in a survey once but have since left the company. In the longitudinal analysis, we will consider the magnitude of the lost-to-follow-up effects, and we will apply a survival time analysis of panel data and other appropriate analysis methods.

Herein, we have described the background and design of the JNIOSH cohort study and presented a summary of the baseline data. Until 2019, almost 40,000 workers participated in this study, with cooperation from 8 companies of various sectors. We have obtained important information related to work and health status, such as data on working hours, medical check-ups, and stress check scores. We will continue the study to provide valuable epidemiological evidence and aggregate findings for the prevention of diseases caused by overwork.

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Conflict of Interest Statement

None declared.

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Appendix Table. Measured item at medical check-ups, the number of participants with available and missing data

Measured item	Total (n=9,549)				Men (n=7,256)				Women (n=2,293)			
	Measured		Unmeasured or Missing		Measured		Unmeasured or Missing		Measured		Unmeasured or Missing	
	n	%	n	%	n	%	n	%	n	%	n	%
Body mass index	9,514	(99.63)	35	(0.37)	7,222	(99.53)	34	(0.47)	2,292	(99.96)	1	(0.04)
Blood pressure	9,546	(99.97)	3	(0.03)	7,253	(99.96)	3	(0.04)	2,293	(100.00)	0	(0.00)
HDL cholesterol	9,497	(99.46)	52	(0.54)	7,214	(99.42)	42	(0.58)	2,283	(99.56)	10	(0.44)
LDL cholesterol	9,489	(99.37)	60	(0.63)	7,206	(99.31)	50	(0.69)	2,283	(99.56)	10	(0.44)
Triglycerides	9,506	(99.55)	43	(0.45)	7,222	(99.53)	34	(0.47)	2,284	(99.61)	9	(0.39)
Fasting blood glucose	7,604	(79.63)	1,945	(20.37)	5,706	(78.64)	1,550	(21.36)	1,898	(82.77)	395	(17.23)
HbA1c	6,999	(73.30)	2,550	(26.70)	5,612	(77.34)	1,644	(22.66)	1,387	(60.49)	906	(39.51)
AST	9,507	(99.56)	42	(0.44)	7,224	(99.56)	32	(0.44)	2,283	(99.56)	10	(0.44)
ALT	9,507	(99.56)	42	(0.44)	7,224	(99.56)	32	(0.44)	2,283	(99.56)	10	(0.44)
γ-GTP	9,505	(99.54)	44	(0.46)	7,223	(99.55)	33	(0.45)	2,282	(99.52)	11	(0.48)

Abbreviations; HDL cholesterol: high density lipoprotein cholesterol; LDL cholesterol: low density lipoprotein cholesterol; HbA1c: hemoglobin A1c; AST: aspartate aminotransferase; ALT: alanine aminotransferase; γ-GTP: γ-glutamyl transpeptidase.