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# Annual dialysis data report 2019, JSDT Renal Data Registry

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## Abstract

**Background** The Japanese Society for Dialysis Therapy is conducting the survey annually since 1968. The results provide a comprehensive picture of dialysis therapy in Japan. The survey for the year 2019 was performed as of December 2019.

**Methods** Questionnaires were sent to all facilities that provide patients with dialysis therapy in Japan as an Excel file. Data were collected and compiled to form cross-sectional results of dialysis therapy from various aspects.

**Results** At the end of 2019, the annual survey of the Japanese Society for Dialysis Therapy Renal Data Registry (JRDR) was conducted at 4487 dialysis facilities, of which 4411 facilities (98.3%) responded to the facility survey and 4238 facilities (94.5%) responded to the patient survey. The number of chronic dialysis patients in Japan continues to increase every year; it reached 344,640 at the end of 2019, and the prevalence ratio of dialysis patients was 2732 per million population. In the patient survey, the mean age of prevalent dialysis patients was 69.09 years. The most prevalent primary disease among prevalent dialysis patients was diabetic nephropathy (39.1%), followed by chronic glomerulonephritis (25.7%) and nephrosclerosis (11.1%). In 2019, there were 40,885 new patients on dialysis, an increase of 417 over 2018. The average age of incident dialysis patients was 70.42 years, and diabetic nephropathy (41.6%) was the most common cause. The second cause was nephrosclerosis, followed by glomerulonephritis. As 34,642 patients passed away in 2019, the crude mortality rate for the year was 10.1%. Heart failure (22.7%), infectious disease (21.5%), and malignancy (8.7%) were the three leading causes of death. Since 2012, the number of patients treated by hemodiafiltration (HDF) has increased substantially. The figure reached 144,686 by year's end, representing 42.0% of all dialysis patients. In 2019, the number of peritoneal dialysis (PD) patients was 9,920, a small rise from 2017. 19.2% of PD patients also received hemodialysis (HD) or HDF to compensate for the reduction in dialysis dosage or in fluid removal by PD alone (hybrid therapy). At the end of 2019, 760 patients received home HD therapy, an increase of 40 from 2018. In 2019, a detailed survey was conducted on the current status of CKD-MBD treatment, 10 years after the previous survey in 2009. The clinical efficacy of newly released medications during this time period and the impact of the 2012 revisions to the CKD-MBD guidelines require further investigation. These analyses would

The members of the Japanese Society for Dialysis Therapy Renal Data Registry Regional Cooperation Subcommittee are listed in Acknowledgements section.

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serve as the foundation for the next revision of the CKD-MBD guidelines and may reveal deeper therapeutic insights regarding CKD-MBD.

**Conclusions** The results obtained by the survey revealed the comprehensive practice patterns of dialysis therapy and served as a basis for future guidelines.

*Trial registration:* JRDR was approved by the ethics committee of JSDT (approval number 1–5) and registered in the "University hospital Medical Information Network (UMIN) Clinical Trials Registry" on 10th September 2019 with a clinical trial ID of UMIN000018641. [https://upload.umin.ac.jp/cgi-bin/ctr/ctr\\_view\\_reg.cgi?recptno=R000021578](https://upload.umin.ac.jp/cgi-bin/ctr/ctr_view_reg.cgi?recptno=R000021578) (Accessed 20 November 2020).

## Part I JRDR 2019 Annual data report: general remarks

### Introduction

The Japanese Society for Dialysis Therapy (JSDT) has conducted annual surveys of the current status of dialysis therapy in Japan since 1968 (JSDT Renal Data Registry: JRDR). This survey includes the vast majority of dialysis facilities in Japan [1, 2]. While these surveys are performed entirely on a voluntary basis, nearly all facilities answer, ensuring that the survey results accurately reflect the current status of chronic dialysis therapy in Japan.

Since the 2017 survey results, the JRDR annual reports have been printed in full color in the December issue of the Japanese Journal of the Japanese Society for Dialysis Therapy of the following year. The illustrated version of the annual report has been discontinued. Moreover, in 2017, the Japanese Society of Dialysis Therapy created a web-based system (Web-based Analysis of Dialysis Data Archives system: WADDA system) that allows members to set their own parameters and output various tables of their choice [3]. This system has significantly expanded the availability of JRDR survey findings and enabled members of the society to undertake in-depth cross-sectional analysis of the most recent data. The existing CD-ROM edition of "An overview of regular dialysis therapy in Japan" has therefore been replaced by the WADDA system and will no longer be released for society members after 2019.

In 2019, for the first time since 2009, a comprehensive survey on CKD-MBD (Chronic Kidney Disease-Mineral and Bone Disorders) was conducted; detailed analyses of the therapeutic effectiveness of newly developed drugs during this period and related issues, as well as the impact of the revised JSDT CKD-MBD guideline published in 2013, were also performed. These findings will serve as the foundation for the updating of the CKD-MBD guideline, which is anticipated to recommend more effective treatment strategies for everyday clinical practice.

### The ethical basis for the Japanese society of dialysis therapy Renal Data Registry

The JRDR survey is conducted in accordance with the "Ethical Guidelines for Medical and Health Research

Involving Human Subjects" issued by the Ministry of Health, Labour, and Welfare (MHLW) [4] and the Ministry of Education, Culture, Sports, Science, and Technology (MEXT) [4] in December 2014 and revised in February 2017 [5]. The Ethics Committee approved the fundamental plan for the annual survey and compliance with the protection of personal information in March 2015. (Japanese Society of Dialysis Therapy Ethics Committee Approval No. 1).

The 2019 survey revisions were accepted by the Ethics Committee on September 10, 2019, and published on the UMIN clinical trial registration (UMIN-CTR) system. (UMIN000018641). [6]

### Survey method

#### *Sending and collection of survey forms*

The JRDR consists of two questionnaires: a facility questionnaire to investigate the number of dialysis beds, patients, and dialysis fluid quality control status, and a patient questionnaire to investigate the dialysis conditions, laboratory findings, and outcome measures of individual patients at the dialysis facility. In December 2019, all dialysis centers across the country received a universal serial bus (USB) flash drive with a password-encrypted Excel file containing the facility survey and an anonymized version of the 2018 patient survey. The password for the Excel file, unique to each facility, was sent to it on a separate occasion from the Excel file itself. Each dialysis facility used the anonymizing table in a USB stick sent in 2015 to restore real patients' names and then updated data, including outcomes such as deaths, transfers to another facility, and transplantation, as well as the dialysis conditions and laboratory findings as of 2019. After enrolling all patients who had begun dialysis at the facility during the year 2019, the data was anonymized again using the anonymizing program embedded as a Visual Basic for Applications macro in the questionnaire Excel file. Each dialysis center sent only the USB memory stick with the questionnaire to the Secretariat of the Japanese Society for Dialysis Therapy after making sure that all personally identifiable information was removed.

The first deadline for data collection was established for January 31, 2020; after that date, facilities that had not returned questionnaires were asked to do so, and the final collection was completed on June 15 for inclusion in data as of 2019.

### Survey items

The following items were surveyed in the 2019 survey.

#### Facility survey 1. Outline and size of the facility

Facility code, Facility name, Start date of dialysis

Dialysis capacity: number of dialysis machines, number of treatable patients at the same time, maximum number of treatable patients, number of endotoxin-retentive filter-equipped dialysis machines

Number of dialysis staff, initial treatment policy for peritonitis in peritoneal dialysis (PD) patients

#### 2. Patient dynamics

Number of dialysis patients at the end of 2019 (number of patients by treatment method and by either inpatient or outpatient)

Number of patients on dialysis at night in 2019

Number of incident patients in 2019 (including patients started therapies by hemodialysis, hemodiafiltration, and peritoneal dialysis)

Number of patients who deceased in 2019

#### 3. Dialysis fluid quality control status

Frequency of endotoxin concentration measurement of dialysis fluid and its results

Frequency of measurement of viable bacterial count in dialysis fluid and its results

Water supply source for dialysis fluid

Frequency and method of residual chlorine measurement

Recognition of the water quality standards for chemical contaminants issued by the Japanese Society for Dialysis Therapy and the frequency of measuring chemical contaminants

#### Patient survey 1. Patient demographic information

Gender, date of birth, year of introduction, primary disease, prefecture of residence, year of transfer, code of facility before the transfer, outcomes (transfer, death, withdrawal, transplant) and their year and month, code of transferring facility, cause of death, code for change/correction of patient information, treatment modality, the status of the addition of HD/HDF to PD therapy, PD experience, number of previous kidney transplantation(s)

#### 2. Treatment conditions of HD/HDF

Number of dialysis sessions per week, dialysis time per session, blood flow rate

HDF: dilution method, the volume of replacement fluid per session

Height, weight before and after dialysis, systolic and diastolic blood pressure, and pulse rate before dialysis

#### 3. Laboratory findings

Blood urea nitrogen (BUN) and serum creatinine levels before and after dialysis; serum albumin, serum C-reactive protein (CRP), serum calcium, serum phosphorus, serum parathyroid hormone (PTH), hemoglobin, total serum cholesterol, serum high-density lipoprotein cholesterol (HDL-C), serum ferritin, serum iron, TIBC (total iron binding capacity), alkaline phosphatase, and serum magnesium levels all before dialysis sessions; electrocardiograph findings (heart rate and QT interval); methods of PTH measurement (intact PTH, whole PTH); dialysis fluid calcium concentration

#### 4. Outcome-relating factors

Patients with or without antihypertensive medications; smoking status; history of diabetes mellitus, ischemic heart disease, cerebral hemorrhage, stroke, limb amputation, hip fracture, and encapsulating peritoneal sclerosis (EPS); parathyroidectomy or parathyroid-ethanol injection therapy during 2019, CKD-MBD medications including oral vitamin D, intravenous vitamin D, calcimimetics, phosphate binders such as calcium carbonate, lanthanum carbonate, polymers, iron-containing binders, and oral iron (excluding phosphate binders); the presence of atrial fibrillation (Af); history of kidney donation as a donor, and its year

#### 5. Peritoneal dialysis survey

Treatment history: total durations on peritoneal dialysis (PD), months on PD in 2019

Peritoneal function: results of Peritoneal Equilibrium Test (PET), the ratio of creatinine concentration in dialysate to plasma after four hours of PET (the D/P creatinine ratio)

PD prescription: icodextrin dialysate use, dialysate volume per day, urine output per day, average fluid removal volume per day, Kt/V of residual kidney function, peritoneal Kt/V

Dialysis modalities: automated peritoneal dialysis (APD) use, PD dialysate exchange method

Experience of PD-related Infections: number of peritonitis episodes per year, number of exit site infections per year

### Number of facilities that responded to the survey

The 2019 questionnaire was sent to 4,487 facilities across the nation, of which 4,411 (98.3%) answered the facility survey form, an increase of nine facilities, or 0.2%, from

the previous year. 4,238 facilities (or 94.5%) returned patient survey forms.

## Part II 2019 JSDT survey report: results and discussion

### Chapter 1: basic demographics

#### Facility dynamics

Out of the total of 4487 facilities throughout Japan targeted by the 2019 JRDR survey, 4411 facilities (98.3%) responded to the facility-survey questionnaire. Although the number of facilities responding to the facility-survey questionnaire momentarily declined in 2015, it rose again in 2016, and nine more institutions (0.2% more) replied

to the questionnaire in 2019 than in 2018. (Table 1). Of the 4487 facilities, 4238 facilities (94.5%) returned the patient-survey questionnaire. Since 2015, the response rate to the patient-survey questionnaire has dropped from about 96% to about 95%. This could be because paper-based surveys were stopped because a new anonymization method was implemented.

The facility survey showed that there were 141,520 dialysis consoles, simultaneous dialysis capacity for 139,839 patients, and a maximum dialysis treatment capacity of 464,615 patients, representing 1.2%, 1.2%, and 1.3% increases over the previous year, respectively (Table 1).

**Table 1** Summary of chronic dialysis therapy in Japan, 2019

<b>(a) Facility number and dialysis capacity</b>							
Facility number and dialysis capacity		Number	Changes from the previous year (%)				
Surveyed facilities		4487	+ 29 (+ 0.7)				
Responded facilities		4411	+ 9 (+ 0.2)				
Dialysis capacity	Number of bedside machines	141,520	+ 1,633 (+ 1.2)				
	Capacity for simultaneous HD treatments	139,839	+ 1,684 (+ 1.2)				
	Maximum patient capacity	464,615	+ 6,018 (+ 1.3)				
<b>(b) Patient dynamics</b>							
Patient category		Number	Changes from the previous year (%)				
<b>Prevalent patients</b>		<b>344,640</b>	+ 4799 (+ 1.4)				
Prevalence rate (per million of general population)		2731.6	+ 43.9 (+ 1.6)				
Patients in the night shift		32,027	+ 483 (+ 1.5)				
<b>Incident patients</b>		<b>40,885</b>	+ 417 (+ 1.0)				
Started with HD or HDF		38,228	+ 53 (+ 0.1)				
Started with PD		2657	+ 364 (+ 15.9)				
<b>Deceased patients</b>		<b>34,642</b>	+ 779 (2.3)				
<b>(c) Numbers of prevalent dialysis patients by modality</b>							
Modality		Outpatients (%)		Inpatients (%)		Total (%)	
Hemodialysis	HD	163,900	(52.3)	23838	(75.6)	187,738	(54.5)
	HDF	137,552	(43.9)	7134	(22.6)	144,686	(42.0)
	HF	19	(0.0)	12	(0.0)	31	(0.0)
	HAD	1425	(0.5)	80	(0.3)	1505	(0.4)
	Home HD	754	(0.2)	6	(0.0)	760	(0.2)
Peritoneal dialysis (PD)	PD only	7647	(2.4)	370	(1.2)	8017	(2.3)
	PD + HD 1x/week	1620	(0.5)	55	(0.2)	1675	(0.5)
	PD + HD 2x/week	122	(0.0)	6	(0.0)	128	(0.0)
	PD + HD 3x/week	24	(0.0)	6	(0.0)	30	(0.0)
	PD + HD other frequencies	63	(0.0)	7	(0.0)	70	(0.0)
	Subtotal	9476	(3.0)	444	(1.4)	9920	(2.9)
Total	313,126 (100.0)		(31,514) (100.0)		344,640 (100.0)		

PD + HD patients: Patients treated by the combination of PD and HD, HDF, hemoadsorption, or hemofiltration (excluding those who underwent only peritoneal lavage)

HD, hemodialysis; HDF, hemodiafiltration; HF, hemofiltration; HAD, hemoadsorption dialysis; PD, peritoneal dialysis

HAD refers to hemodialysis therapy combined with hemoadsorption using a tandem-connected beta2-microglobulin adsorptive column

\* The data were obtained from the facility survey

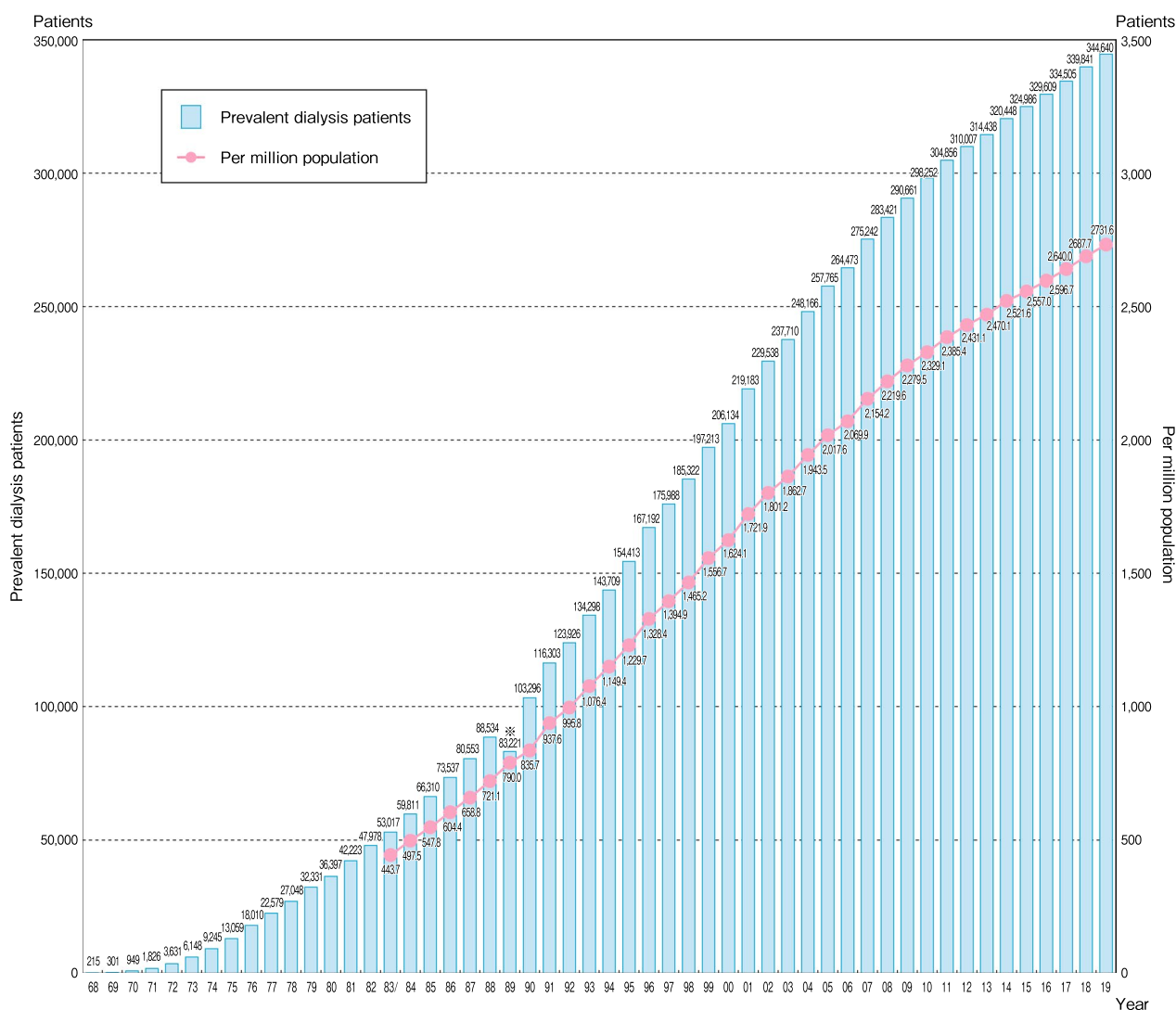
The number of dialysis consoles is also increasing annually (Additional file 1: Table S1).

**Patient dynamics**

According to the facility-survey questionnaire, the total number of patients undergoing chronic maintenance dialysis treatment at the end of 2019 was 344,640. Although the number of dialysis patients grows yearly, the growth rate has slowed in recent years. In 2019, there was an increase of 4,799 patients compared to the previous year (Fig. 1, Additional file 1: Table S1). According to a prediction made by Nakai et al. [7] in 2012, the number of dialysis patients was expected to reach a peak of approximately 349,000 in 2021, to decline thereafter. In 2019, the total number of patients

was below the expected peak. The prevalence rate is indicated by the number of dialysis patients per million population (pmp) (Fig. 1, Additional file 1: Table S1), which has been increasing in recent years. In 2019, the rate was 2731.6 pmp, which means that one in 366.1 Japanese people is a dialysis patient. According to the 2018 United States Renal Data System (USRDS) Annual Data Report, Japan has the second highest rate of dialysis patients in the world, after Taiwan [8].

Although the incidence had been increasing annually until 2008, the number in 2009 dropped as compared with that in 2008. Since 2009, the number has fluctuated, but overall, it has tended to increase. The number of new patients in 2019 was 40,885, representing an increase of 417 (+1.0%) over the number in 2018 (Fig. 2, Additional



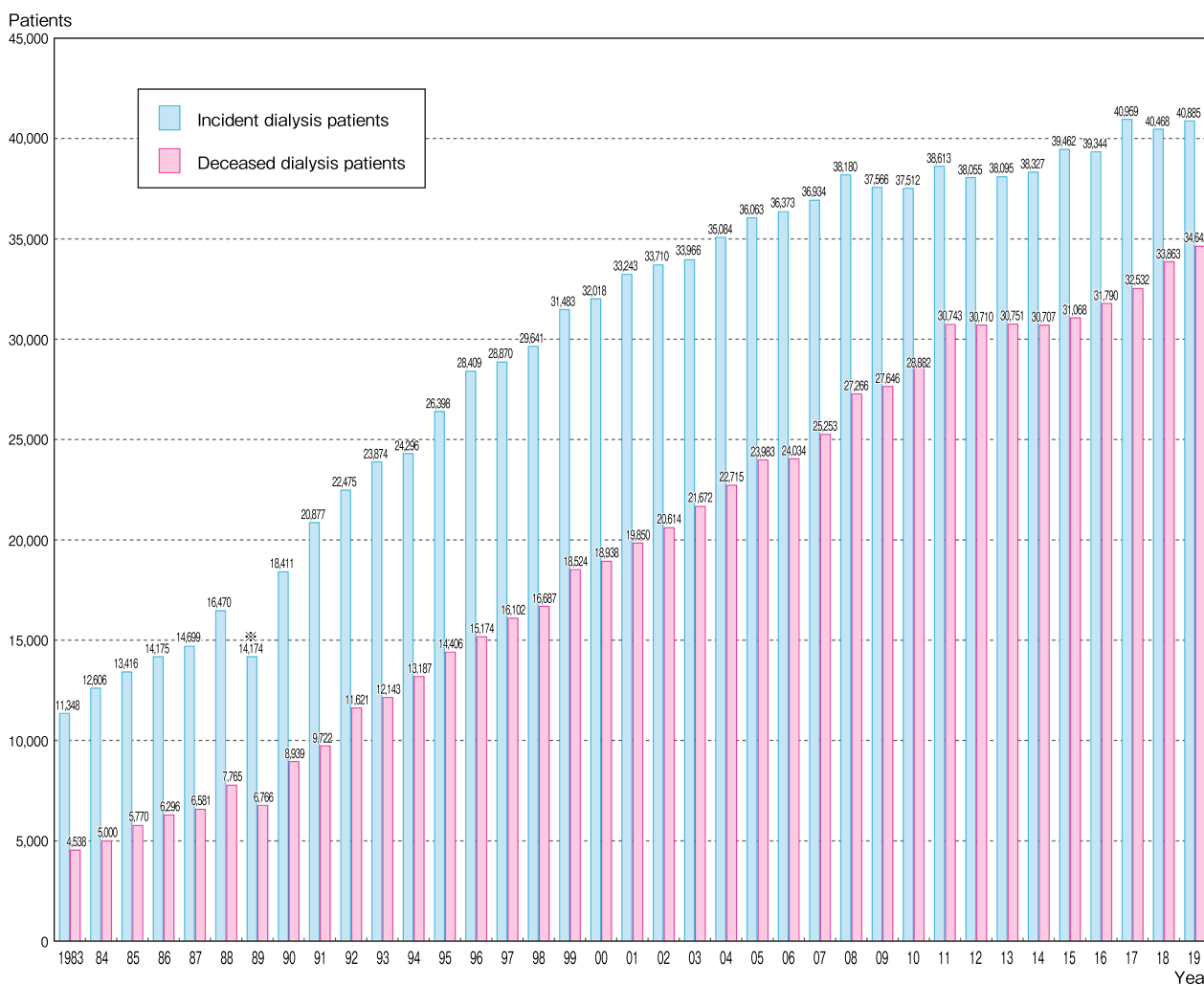
**Fig. 1** Trends in the prevalent dialysis patient count for 1968–2018, and the adjusted prevalent dialysis patient count (pmp) for 1983–2019. *pmp* Per million population

file 1: Table S2). Of these patients, 93.5% received HD/HDF and 6.5% received PD (Table 1). The number of deceased patients has also been increasing annually, though the death rate almost plateaued between 2012 and 2014 temporarily. A total of 34,642 patients deceased in 2019; this number represents an increase of 779 patients (+2.3%) over the number of deaths in 2018 (Fig. 2, Additional file 1: Table S2). In general, the number of patients undergoing dialysis in any given year is calculated by adding the number of incident patients to the number of patients from the previous year and then subtracting the number of deceased patients. However, the number of patients calculated thus did not match the actual number of patients. This may be because the calculated number does not include the number of patients who discontinue dialysis on account of undergoing kidney transplantation, and there is a possibility that the number of new patients is overestimated, and the number of deceased patients is underestimated.

The number of dialysis patients by prefecture is shown in Table 2. The numbers in Table 2 were calculated based on the location of the facility at which the patients underwent treatment, and not on their place of residence. The prevalence rate (number of dialysis patients per million population) differed considerably among prefectures. Since numerous confounding factors are involved in this difference, great caution is needed when interpreting the differences in numbers among prefectures.

**Dialysis modality dynamics over time**

Hemodialysis (HD) accounted for 54.5% of all the dialysis modalities in 2019, followed by hemodiafiltration (HDF; 42.0%), hemofiltration (HF; 0.009%), hemadsorption dialysis (HAD; 0.4%), home hemodialysis (HHD; 0.2%), and peritoneal dialysis (PD; 2.9%) (Table 1). The use of online HDF increased rapidly after a 2012 revision to the medical reimbursement system, and the number



**Fig. 2** Trends in the incident and deceased dialysis patient counts for 1983–2019

**Table 2** Prevalent dialysis patient counts, by modality & prefecture, 2019

Prefecture	Surveyed facilities	Responded facilities	Hemodialysis				Peritoneal dialysis				Total	Prevalence (pmp)		
			HD	HDF	HF	HAD	Home HD	PD only	+HD 1/w	+HD 2/w			+HD 3/w	+HD in other frequencies
Hokkaido	261	259	8460	7,271	0	106	9	434	92	1	1	3	16,377	3,119.4
Aomori	41	41	1,229	2,321	0	3	3	79	12	0	1	0	3648	2,927.8
Iwate	44	43	2267	752	0	14	0	83	11	0	1	0	3128	2,549.3
Miyagi	65	65	3697	2,193	0	12	6	146	17	1	2	2	6076	2,634.9
Akita	43	43	1311	828	0	0	2	53	3	1	0	0	2198	2,275.4
Yamagata	36	36	1648	1,008	0	6	12	53	9	1	2	1	2740	2,541.7
Fukushima	73	69	2431	2,567	0	20	0	57	21	13	1	1	5111	2,768.7
Ibaraki	88	87	5195	3,044	0	56	19	74	12	1	0	0	8401	2,937.4
Tochigi	79	79	3908	2,454	0	27	9	135	15	3	0	1	6552	3,387.8
Gunma	64	64	4011	2,117	0	1	14	56	17	0	0	1	6217	3,201.3
Saitama	197	193	9211	9,486	1	47	80	323	77	5	1	3	19,234	2,616.9
Chiba	159	156	8863	6,627	0	45	13	265	64	4	1	0	15,882	2,537.5
Tokyo	445	435	15,787	15,762	10	127	97	940	293	10	1	12	33,039	2,373.3
Kanagawa	268	263	13,103	8,076	1	92	36	564	104	0	0	3	21,979	2,389.5
Niigata	55	55	3607	1,457	0	19	2	164	24	1	1	1	5276	2,373.4
Toyama	42	41	1774	660	0	14	3	93	12	0	2	0	2558	2,450.2
Ishikawa	40	40	1767	903	0	11	5	58	10	0	0	0	2754	2,420.0
Fukui	26	24	882	779	0	0	3	56	16	0	4	1	1741	2,266.9
Yamanashi	33	33	1069	1,275	0	5	2	19	8	0	0	0	2378	2,932.2
Nagano	72	72	3017	2,288	3	11	15	76	16	3	0	0	5429	2,649.6
Gifu	74	73	3450	1,443	0	19	26	62	15	1	0	1	5017	2,524.9
Shizuoka	127	126	5145	5,981	8	47	24	134	19	6	0	0	11,364	3,118.6
Aichi	197	196	11,014	7,122	0	103	47	640	98	1	0	2	19,027	2,519.5
Mie	56	53	2650	1,342	0	20	7	85	13	0	0	1	4118	2,312.2
Shiga	40	39	1508	1,633	0	33	38	123	18	0	0	0	3353	2,371.3
Kyoto	78	78	3179	3,181	0	68	12	143	61	5	0	6	6655	2,576.5
Osaka	326	318	11,371	12,028	2	178	50	430	94	7	1	6	24,167	2,743.4
Hyogo	202	196	7462	6,602	0	102	75	144	24	4	2	1	14,416	2,637.4
Nara	51	50	1742	1,719	0	29	9	91	35	1	0	0	3626	2,726.3
Wakayama	48	47	2222	702	1	10	27	62	14	0	0	0	3038	3,284.3
Tottori	26	25	604	893	1	3	2	56	7	2	0	0	1568	2,820.1
Shimane	31	31	723	971	0	5	2	55	11	1	0	0	1768	2,623.1
Okayama	66	66	2604	2,473	0	29	6	198	19	5	2	0	5336	2,823.3

**Table 2** (continued)

Prefecture	Surveyed facilities	Responded facilities	Hemodialysis		Peritoneal dialysis				Total	Prevalence (pmp)				
			HD	HDF	HF	HAD	Home HD	PD only			+ HD 1/w	+ HD 2/w	+ HD 3/w	+ HD in other frequencies
Hiroshima	100	99	3924	3,451	2	31	29	243	55	28	4	3	7770	2,771.0
Yamaguchi	61	56	1616	1,779	0	8	1	103	25	3	0	1	3536	2,603.8
Tokushima	40	40	1312	1,364	0	10	5	115	30	4	0	3	2843	3,905.2
Kagawa	49	49	1232	1,370	0	13	7	146	54	1	0	1	2824	2,954.0
Ehime	53	53	1848	2,052	0	12	0	114	37	0	1	9	4073	3,041.8
Kochi	39	39	796	1,770	0	7	0	19	7	2	0	0	2601	3,726.4
Fukuoka	201	196	9515	5,015	1	46	22	697	51	3	1	0	15,351	3,007.6
Saga	36	36	1664	922	0	11	3	18	6	0	0	0	2624	3,219.6
Nagasaki	63	62	2560	1,349	0	28	26	101	13	2	0	0	4079	3,073.9
Kumamoto	90	89	4514	1,857	0	25	4	125	27	2	0	1	6555	3,750.0
Oita	69	67	2867	1,057	0	16	4	94	39	5	0	0	4082	3,596.5
Miyazaki	65	65	2825	1,114	0	7	0	40	9	0	1	2	3998	3,726.0
Kagoshima	95	95	3908	1,440	1	12	2	158	41	1	0	4	5567	3,475.0
Okinawa	73	69	2246	2,188	0	17	2	93	20	0	0	0	4566	3,142.5
Total	4,487	4,411	1,87,738 (54.5)	1,44,686 (42.0)	31 (0.0)	1,505 (0.4)	760 (0.2)	8,017 (2.3)	1,675 (0.5)	128 (0.0)	30 (0.0)	70 (0.0)	3,44,640 (100.0)	2,731.6

HD Hemodialysis, HDF Hemodiafiltration, HF Hemofiltration, HAD hemoadsorption dialysis, PD Peritoneal dialysis; w, week

In columns regarding PD, the title, "+ HD", denotes combination therapy of PD and HD in each frequency

\*The data were obtained from the facility survey

\*\*The numbers of dialysis patients were adjusted as per million population (pmp) by the annual government report. Reference [7]



of HDF patients increased to 144,686 in 2019. The number of patients undergoing PD was 9,920, representing an increase over the corresponding number in the previous year. Of these patients, 19.2% were treated with a combination of PD plus HD/HDF to compensate for the deficit in dialysis dosage or fluid overload caused by PD alone (hybrid therapy). The number of HHD patients was 760, a slight increase over the previous year. The total percentage of patients undergoing home dialysis, the sum of the number of patients undergoing PD and HHD, was 3.1%. This figure is the lowest for home dialysis in the developed world [8]. Although there were regional differences in the dialysis modality data, the differences were related to various regional factors (Table 2).

The number of patients undergoing nighttime dialysis at the end of 2019 was 32,027 (Table 1), which increased by 483 over the number in 2018. Although this number had remained between 41,000 and 42,000 until the 2014 survey, it decreased sharply to 33,370 in 2015. This change is likely to be explained by the addition of the phrase “Dialysis during the time period recognized by the insurance system (starting at 5 PM or later or finishing at 9 PM or later)” to the definition of nighttime dialysis patients in the 2015 survey. Since 2015, the number of patients having nighttime dialysis has continuously decreased, notwithstanding a modest rise in 2019. This decline may be attributable to an increase in elderly dialysis patients who retired and prefer daytime therapy, as well as the preference for healthcare professionals to treat older patients during the day.

**Initial treatment of PD peritonitis (route of antimicrobial administration)**

The 2016 ISPD (International Society for Peritoneal Dialysis) guideline recommends intraperitoneal administration of antimicrobial agents for the initial treatment of PD peritonitis. In this study, we investigated the

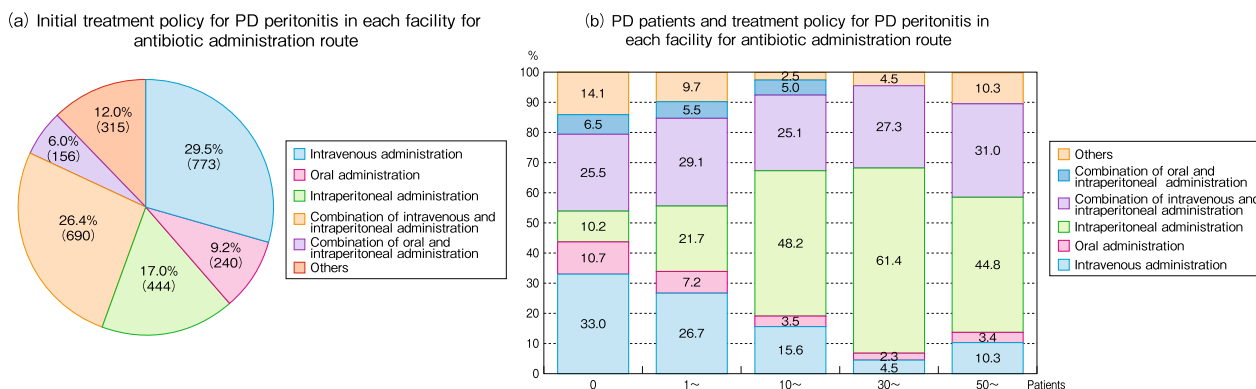
initial treatment strategy (route of antimicrobial administration) for PD peritonitis. Intravenous administration alone was the most common route (29.5%), followed by combined intravenous and transperitoneal administration (26.4%), and transperitoneal administration alone (17.0%) (Fig. 3a, Additional file 1: Table S3). The facilities with more PD patients at the end of the year tended to choose transperitoneal administration according to the ISPD guideline. Facilities with 1–9 PD patients selected combined transvenous and transperitoneal administration (29.1%) or transvenous administration alone (26.7%). In contrast, facilities with 50 or more PD patients were likely to select transperitoneal administration alone (44.8%) and less likely to select the intravenous administration of 10.3% (Fig. 3b, Additional file 1: Table S3).

**Chapter 2: prevalent dialysis patient data at the end of 2019**

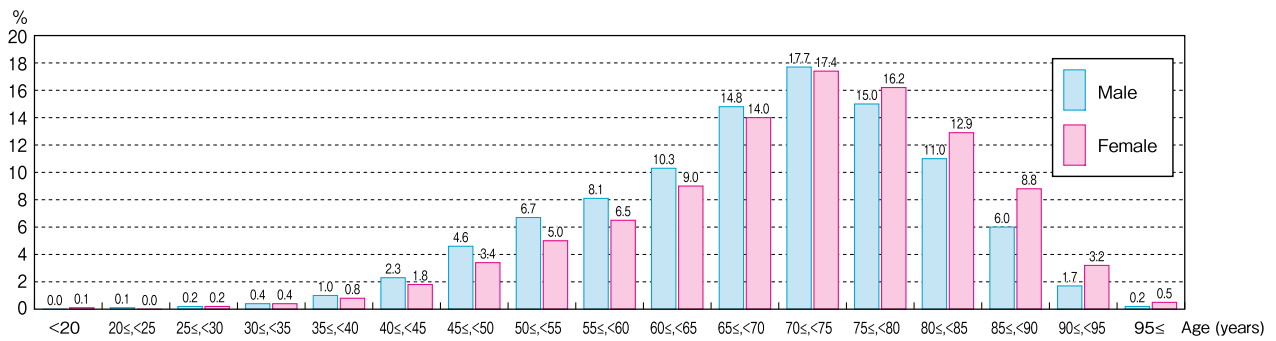
**Clinical background**

In the patient survey, data on age and sex were available for 332,599 patients. Among these patients, 218,552 were male, 114,047 were female, and the mean age was 69.09 (Fig. 4, Additional file 1: Table S4). The mean age has been increasing annually (Fig. 5, Additional file 1: Table S5), and the age group of 70 to 74 years had the highest percentage of males and females among the age groups. The number of patients under 65 and 70 has decreased since 2012 and 2017, respectively. In other words, these results suggest that the rise in the number of people on dialysis in Japan is due to a rise in the number of people aged 70 or older (Fig. 6, Additional file 1: Table S6).

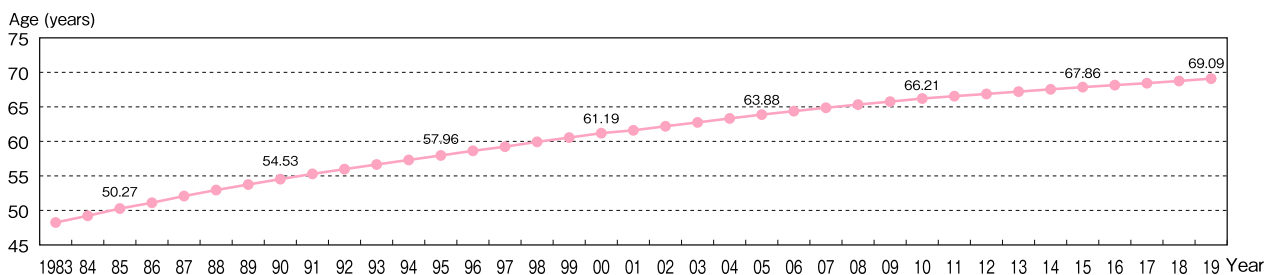
The mean dialysis vintage in chronic dialysis patients as of December 2019 was 6.82 years in males and 8.37 years in females (7.35 years overall). A comparison of the dialysis vintage showed that the dialysis vintage was under five years in 47.6%, 20 years or more in 8.4%, 30 years or more in 2.3%, and 40 years or more in 0.4% of patients (Fig. 7,



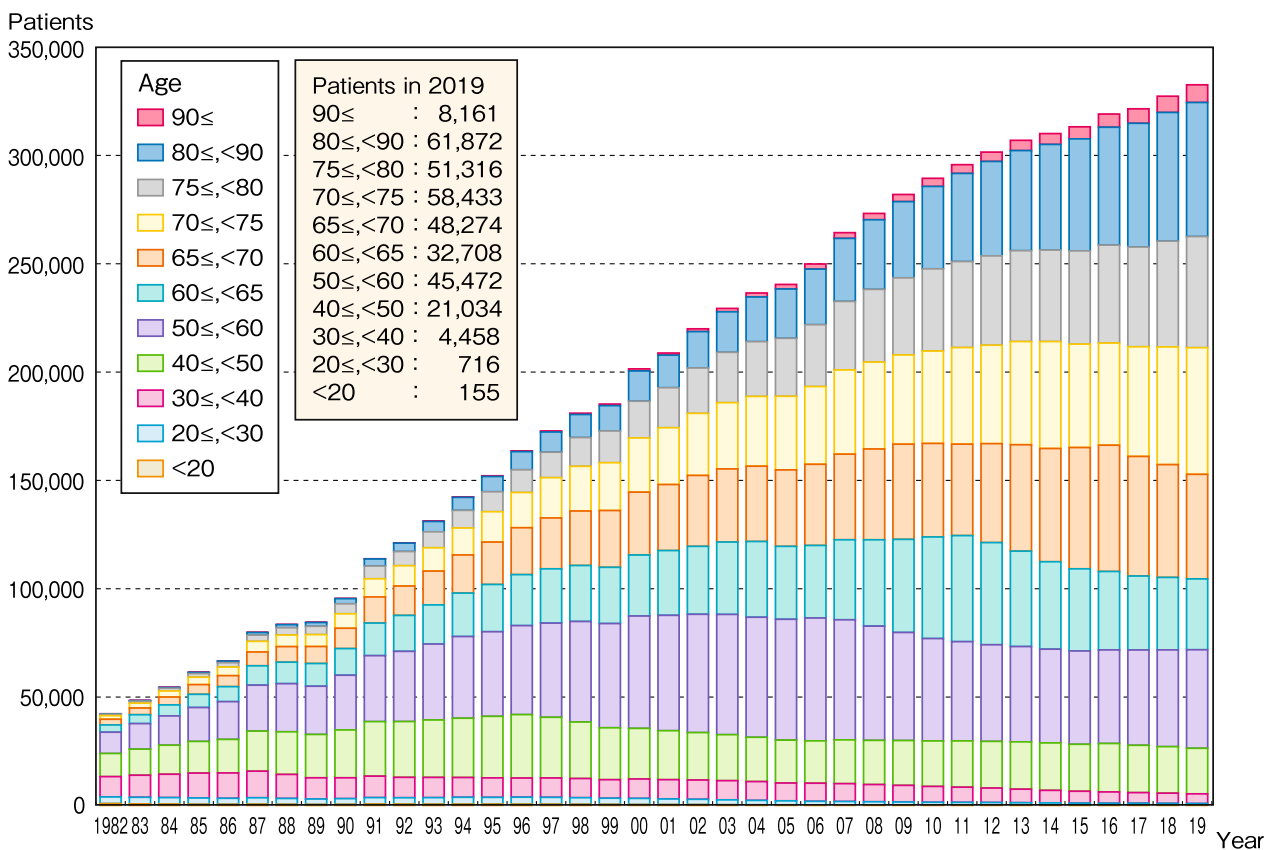
**Fig. 3** Number of PD patients and treatment policy for PD peritonitis in each facility for antibiotic administration route, 2019. *PD* Peritoneal dialysis



**Fig. 4** Prevalent dialysis patient distribution by age and sex for 2019



**Fig. 5** Trend in the average age of the prevalent dialysis patients for 1983–2019



**Fig. 6** Prevalent dialysis patient count by age for 1982–2019

Additional file 1: Table S7). The longest dialysis vintage was 51 years and 4 months. The number of patients with longer dialysis vintages plateaued, with 27.6% of patients having received dialysis for ten or more years. The percentage of patients with a dialysis vintage of 20 years or more, which was less than 1% at the end of 1992, had increased to 8.4% at the end of 2019 (Fig. 8, Additional file 1: Table S8).

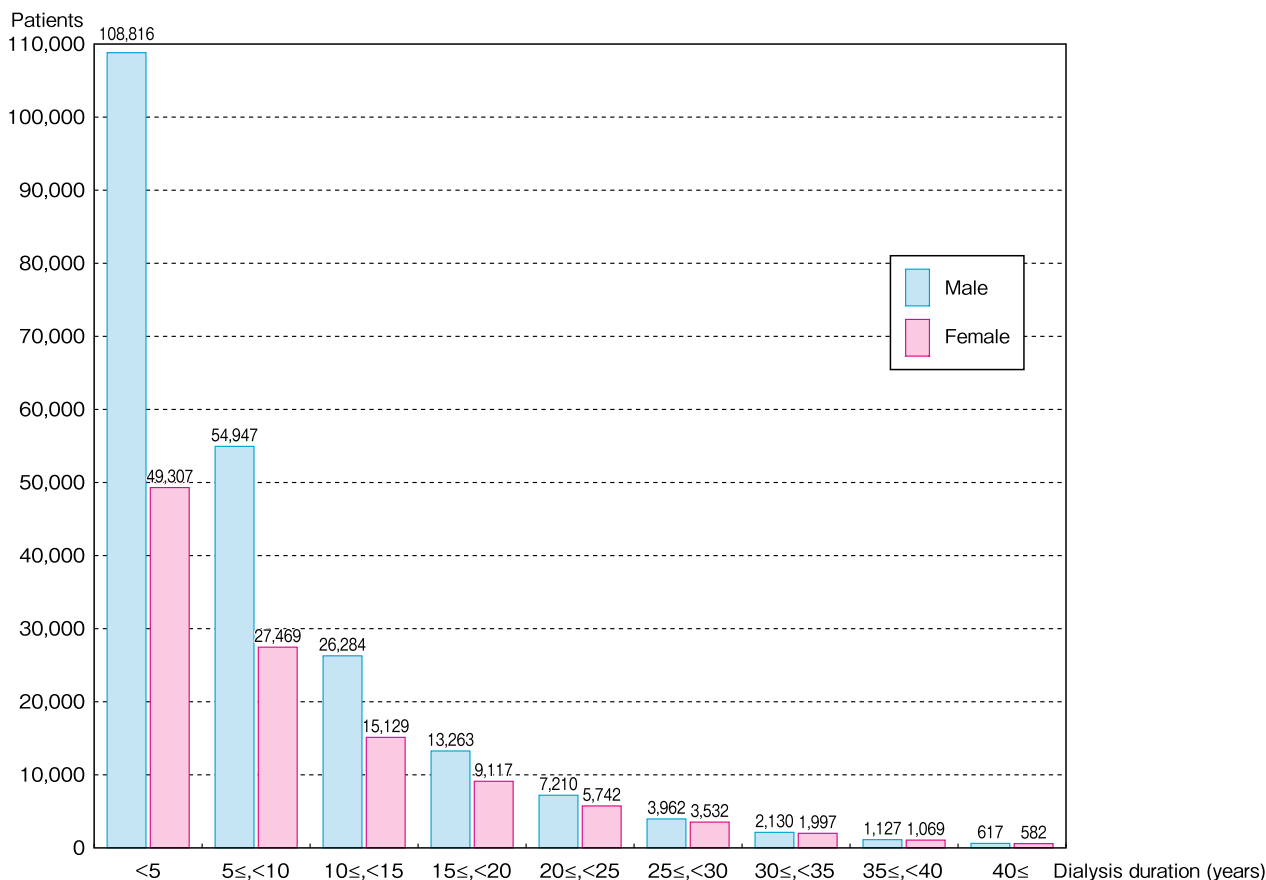
The most common underlying kidney disease in chronic dialysis patients at the end of 2019 was diabetic nephropathy (39.1%), followed by chronic glomerulonephritis (25.7%) and nephrosclerosis (11.4%) (Fig. 9, Additional file 1: Table S9). In 2011, diabetic nephropathy replaced chronic glomerulonephritis as the most common underlying kidney disease. Although the percentage of patients with diabetic nephropathy has continued to increase over time, it seems to reach a plateau. The percentage of patients with chronic glomerulonephritis has steadily declined, while the percentages of patients with nephrosclerosis and “undetermined” have continued to increase (Fig. 10, Additional file 1: Table S10). However, these results need to be interpreted with caution

because the primary disease code has changed since the 2017 survey and the primary disease for each patient is determined mainly by the clinical judgment of the doctor treating the patient.

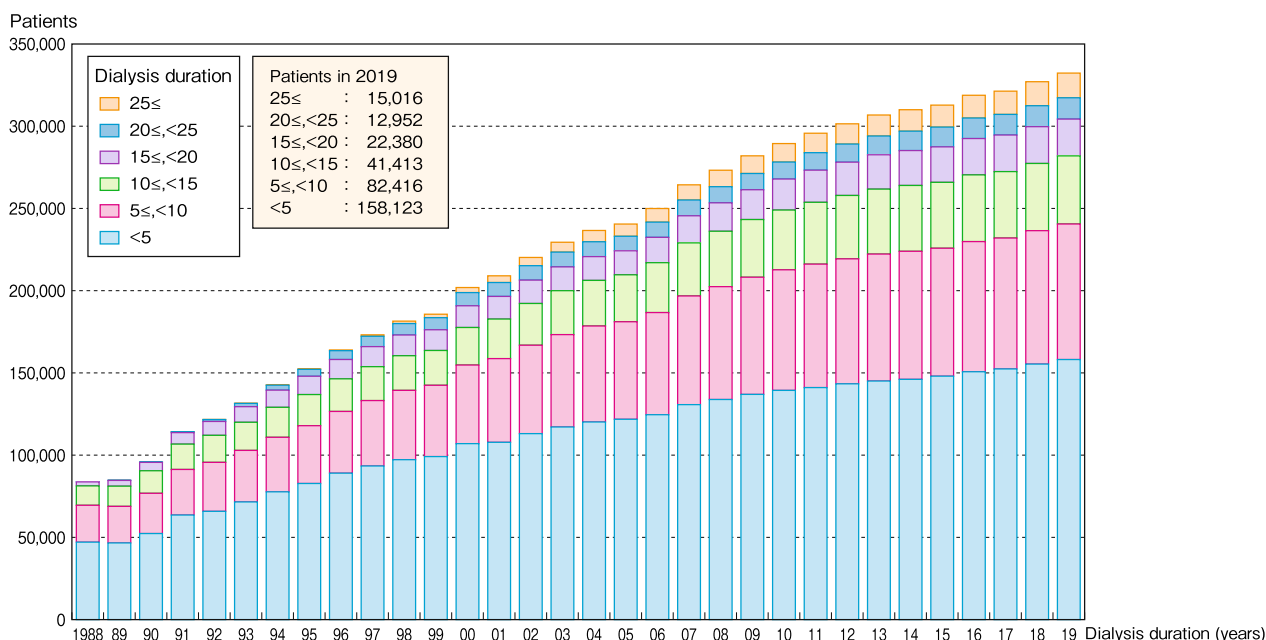
**Causes of death**

Although 34,642 deaths were reported in response to the 2019 facility-survey questionnaire, the number of patients whose cause of death was recorded in the patient-survey questionnaire according to sex was 31,905. The causes of death, in descending order, were heart failure, infectious disease, malignancy, and cerebrovascular disease (22.7%, 21.5%, and 8.7%, respectively). The “Other” category accounted for 11.1% overall. The percentage of patients in the “cardiovascular death” category, which included heart failure, cerebrovascular disease, and myocardial infarction, was 32.3% (Fig. 11, Additional file 1: Table S11).

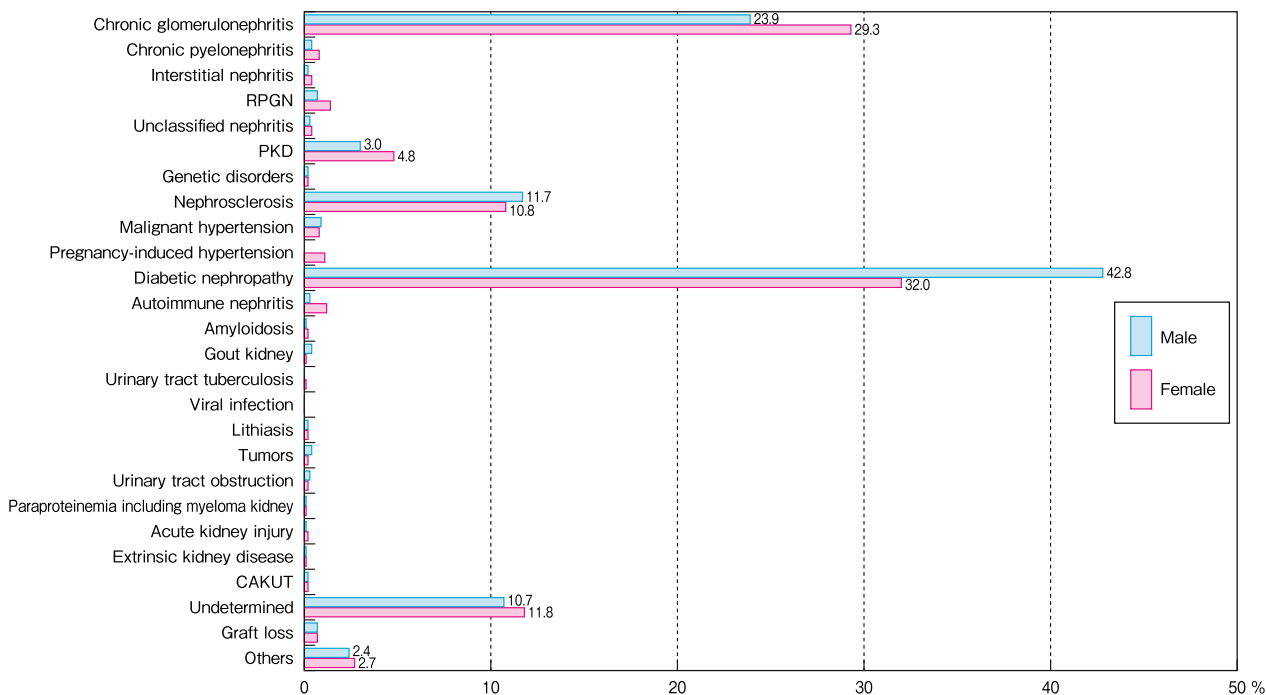
Heart failure has remained the most common cause of death of dialysis patients from 1983 onward, accounting for approximately 25% of all deaths from 1995 onward. On the other hand, deaths caused by infectious diseases



**Fig. 7** Prevalent dialysis patient count by dialysis duration and sex for 2019



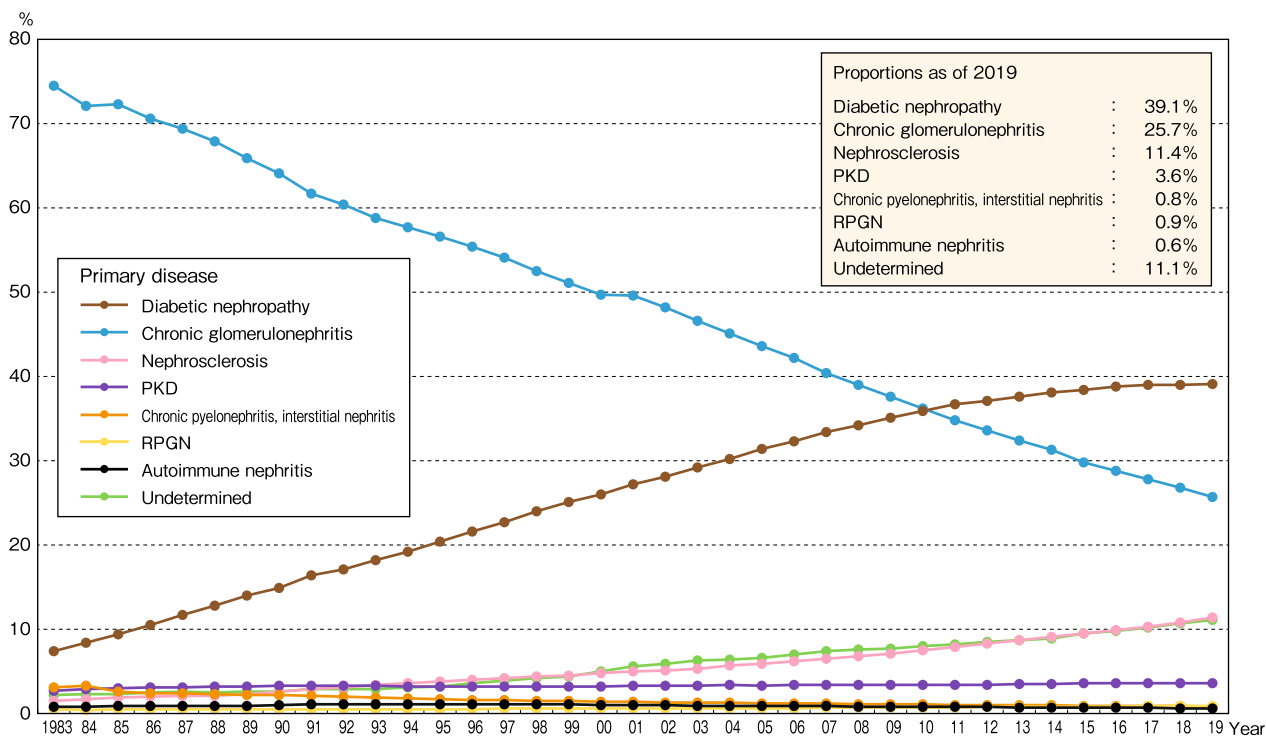
**Fig. 8** Prevalent dialysis patient count by dialysis duration for 1988–2019



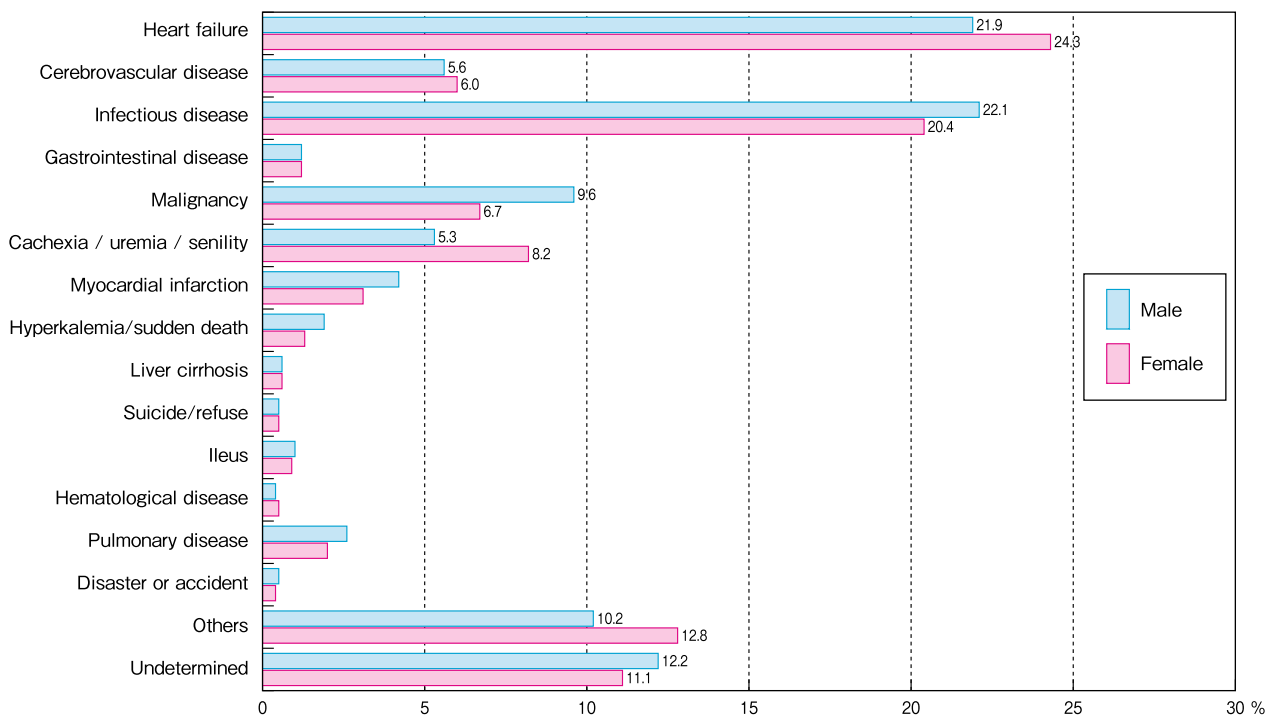
**Fig. 9** Prevalent dialysis patient distribution by primary disease and sex for 2019. *RPGN* Rapidly progressive glomerulonephritis, *PKD* Polycystic kidney disease, *PIH* Pregnancy-induced hypertension, *CAKUT* Congenital anomalies of the kidney and urinary tract

have been increasing since 1993. Deaths from cerebrovascular disease have been gradually decreasing since 1994. After reaching a peak of 8.4% in 1997, the number of deaths from myocardial infarction has been gradually

decreasing. Malignancy-related deaths were at their lowest in 1987 at 5.8%, and although they have increased slightly since then, they have remained at approximately 9.0% since 2004. The percentage of cardiovascular deaths



**Fig. 10** Trends in major primary diseases among prevalent dialysis patients for 1983–2019. PKD Polycystic kidney disease, RPGN Rapidly progressive glomerulonephritis



**Fig. 11** Deceased dialysis patient distribution by cause of death and sex for 2019

mentioned above has consistently decreased after reaching a peak of 54.8% in 1988, and accounted for 32.3% of all deaths in 2019 (Fig. 12, Additional file 1: Table S12). Caution is required when interpreting these statistics, however, as the “cause of death” codes were revised three times: at the end of 2003, at the end of 2010, and at the end of 2017 [9].

**Crude mortality rate**

The annual crude mortality rate was calculated using the patient data reported in the facility survey, as follows.

$$\text{Crude death rate} = \left[ \frac{\text{no. of deaths}}{(\text{no. of patients, previous yr.} + \text{no. of patients, target yr.})/2} \right] \times (\%)$$

The lowest crude mortality rate was 7.9%, observed in 1989 (a year in which the questionnaire recovery rate was low). Generally, however, the rate has fluctuated between

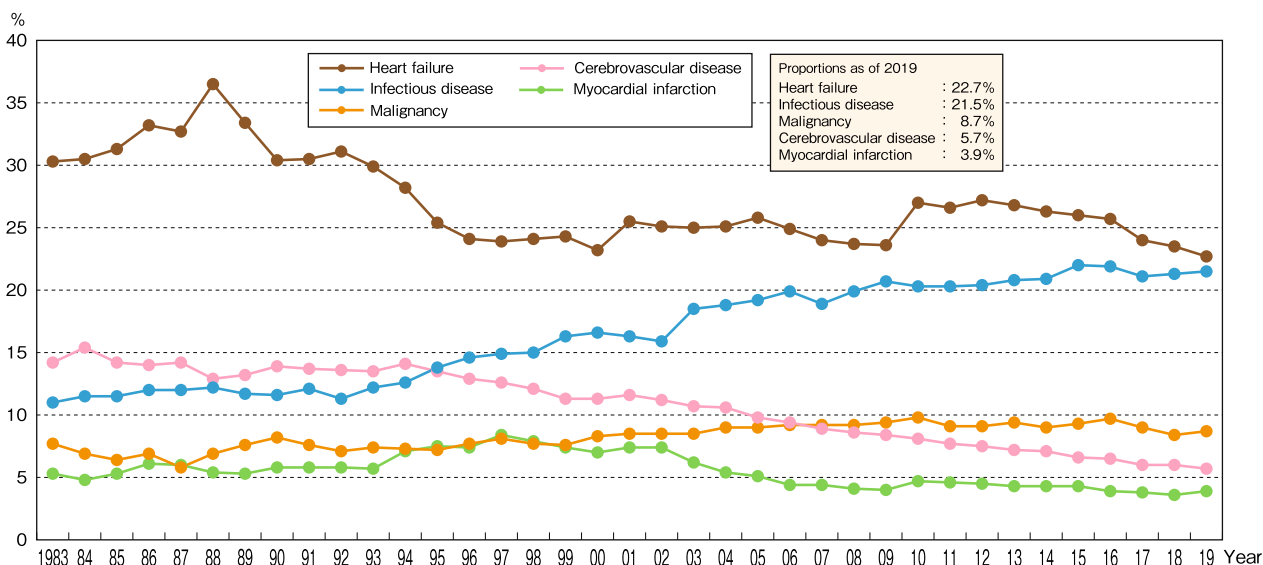
9 and 10%. At the end of 2019, it was 10.1% (Fig. 13, Additional file 1: Table S13).

**Chapter 3. incident dialysis patient data in 2019**

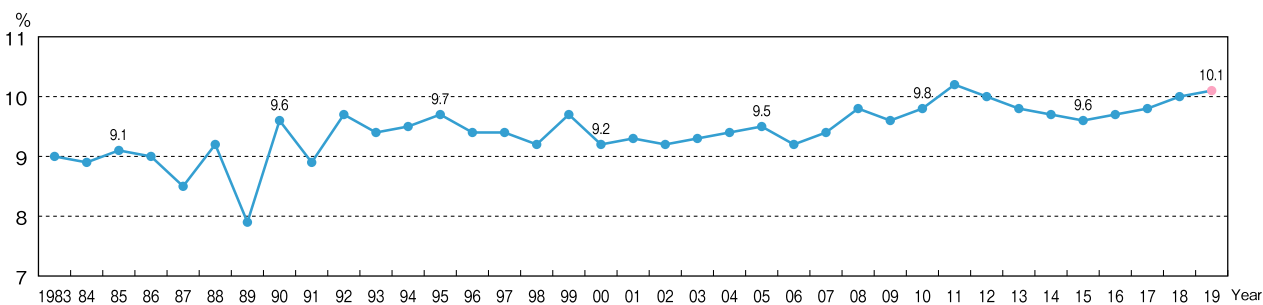
**Clinical background**

Of the 38,556 incident patients whose age and sex data were recorded in the patient survey, 26,731 were male, and 11,825 were female (Fig. 14, Additional file 1: Table S14). The mean age of the incident patients was 70.42 years (males: 69.68 years, females: 72.11 years). The mean age had been increasing annually (Fig. 15,

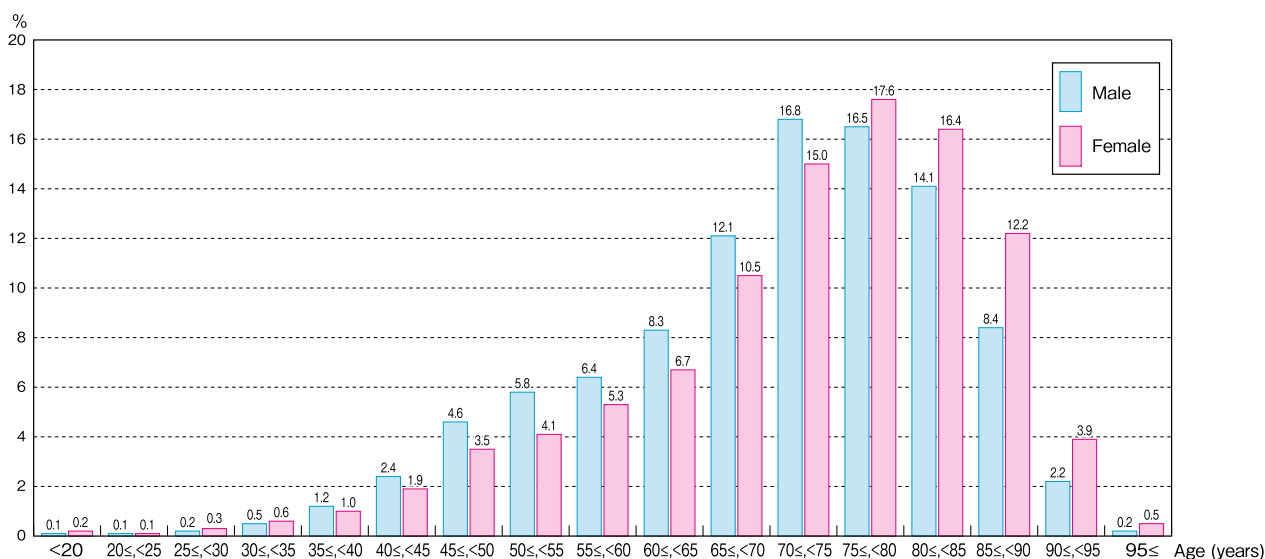
Additional file 1: Table S15). The number of patients categorized into 5-year age groups showed that the highest percentage of males was observed in the 70–74-year



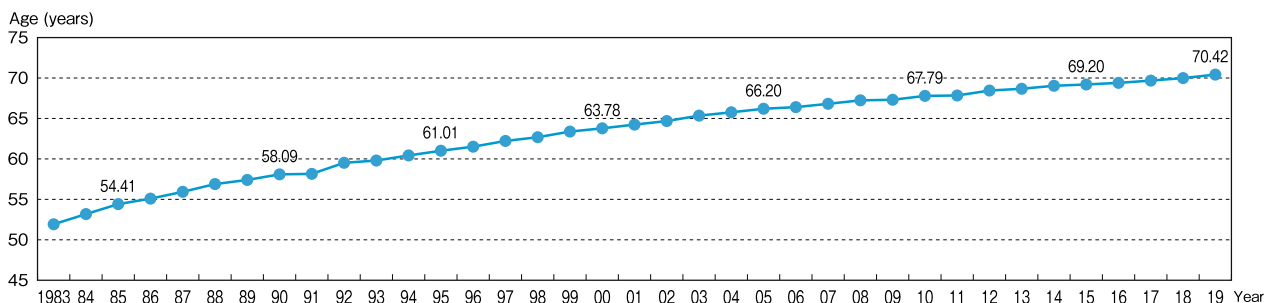
**Fig. 12** Trends in major causes of death for 1983–2019



**Fig. 13** Trend in annual crude death rate for 1983–2019



**Fig. 14** Incident dialysis patient distribution by age and sex for 2019



**Fig. 15** Trend in the average age of incident dialysis patients for 1983–2019

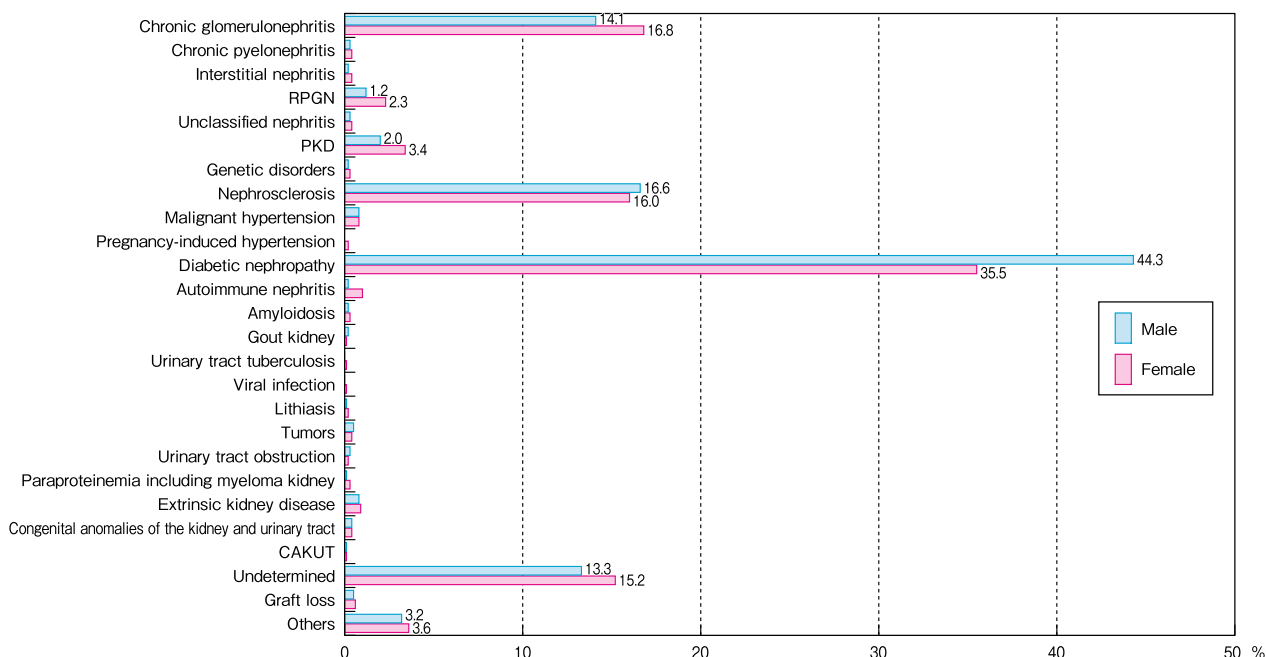
age group, and the highest percentage of females was observed in the 75–79-year age group among all the age groups that were examined.

The most common primary disease among the incident patients in 2019 was diabetic nephropathy (41.6%), followed by nephrosclerosis (16.4%), chronic glomerulonephritis (14.9%), and “undetermined” (13.9%) (Fig. 16, Additional file 1: Table S16). This was the first year when nephrosclerosis replaced chronic glomerulonephritis in the second place. In 1998, diabetic nephropathy replaced chronic glomerulonephritis as the most common primary disease among incident patients. Since then, the percentage of patients with diabetic nephropathy has steadily been increasing, but has stayed almost the same for the past few years. The attenuated increase in diabetic nephropathy may be partly due to the rise in patients with “diabetic kidney disease” with less proteinuria than “classical” diabetic nephropathy. They could be classified into other categories. The percentages of patients

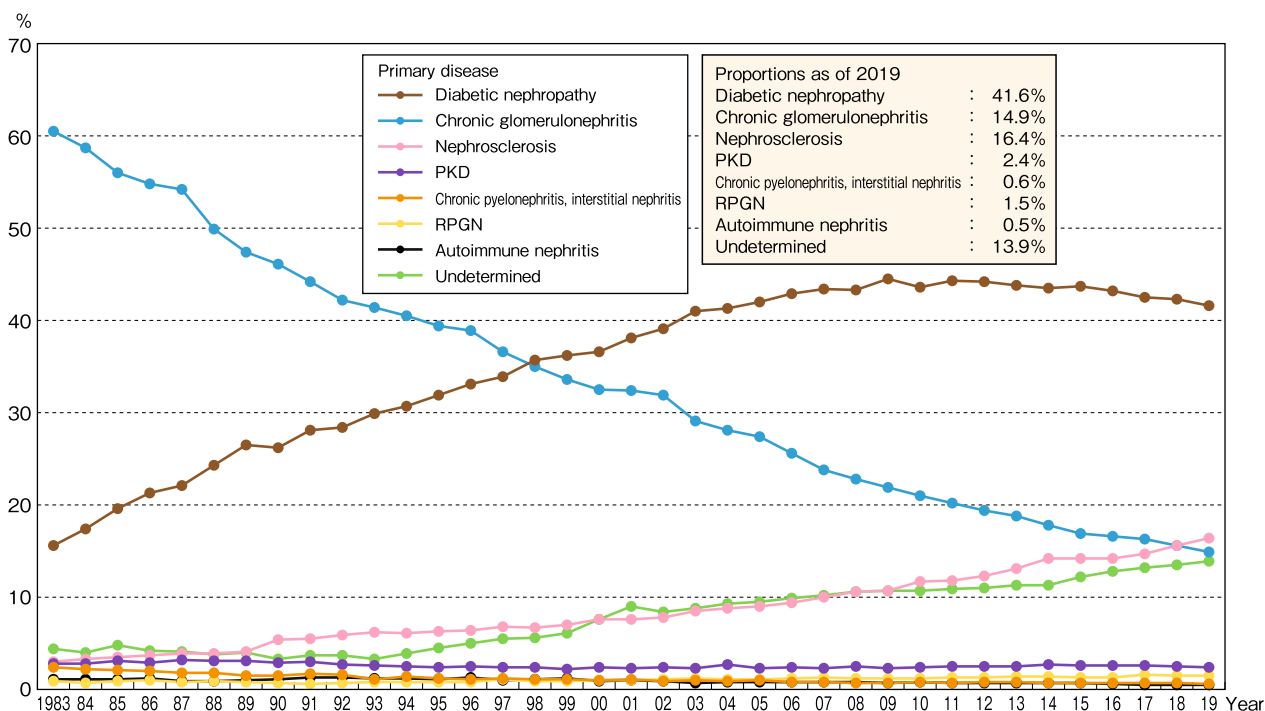
with nephrosclerosis and “undetermined” have increased annually (Fig. 17, Additional file 1: Table S17).

**Causes of death**

In 2019, the most common cause of death among incident patients was infectious disease (24.2%), followed by heart failure (22.0%), malignancy (9.7%), cachexia/uremia/senility (5.6%), cerebrovascular disease (4.7%), pulmonary disease (3.6%), and myocardial infarction (3.1%). The total percentage of cardiovascular deaths was 29.8% (Fig. 18, Additional file 1: Table S18). In the 1990s, heart failure was the most common cause of death during the dialysis incident year. However, the number of infectious diseases slowly increased until they overtook heart failure in 2006. Since then, infectious diseases have remained the leading cause of death among incident patients. The rate of deaths due to malignancy has been increasing, and the percentage exceeded 10% for the first time in 2006. Deaths due to cerebrovascular disease



**Fig. 16** Incident dialysis patient distribution by primary disease and sex for 2019. *RPGN* Rapidly progressive glomerulonephritis, *PKD* Polycystic kidney disease, *PIH* Pregnancy-induced hypertension, *CAKUT* Congenital anomalies of the kidney and urinary tract



**Fig. 17** Trends in major primary diseases of incident dialysis patients for 1983–2019. *PKD* Polycystic kidney disease, *RPGN* Rapidly progressive glomerulonephritis



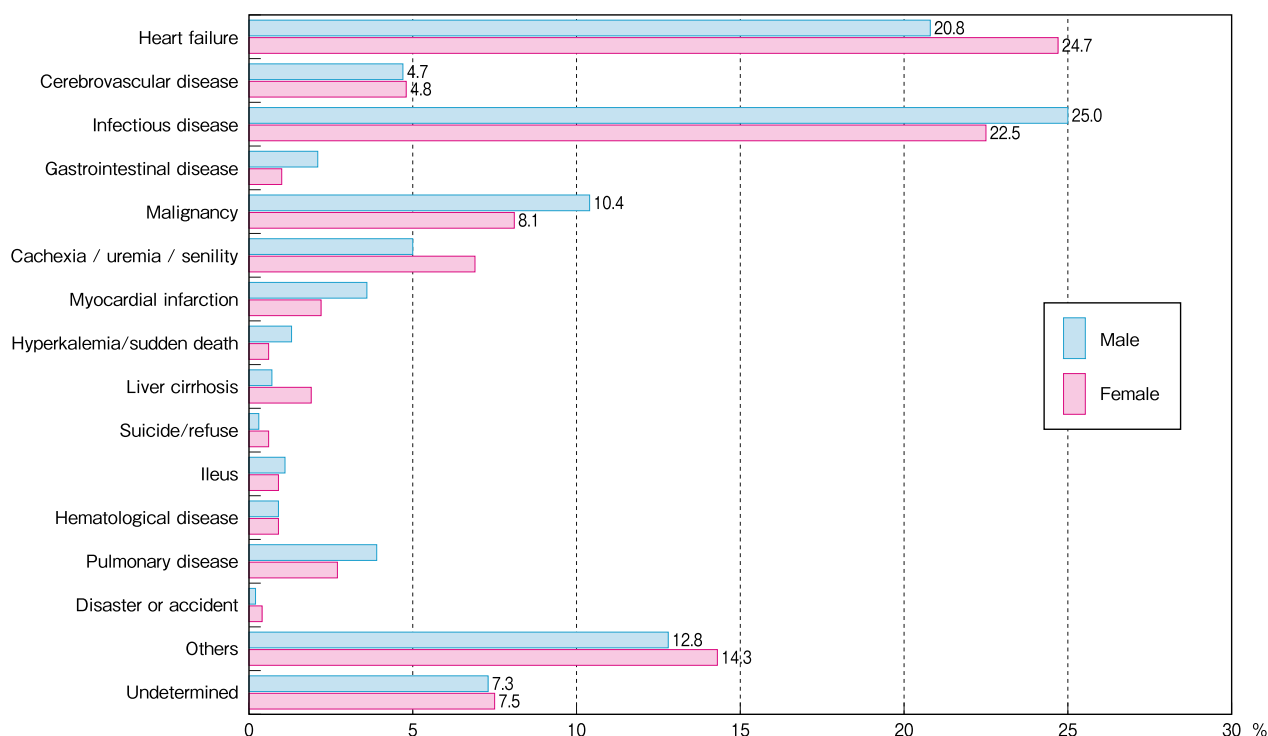


Fig. 18 Incident dialysis patient distribution by cause of death and sex for 2019

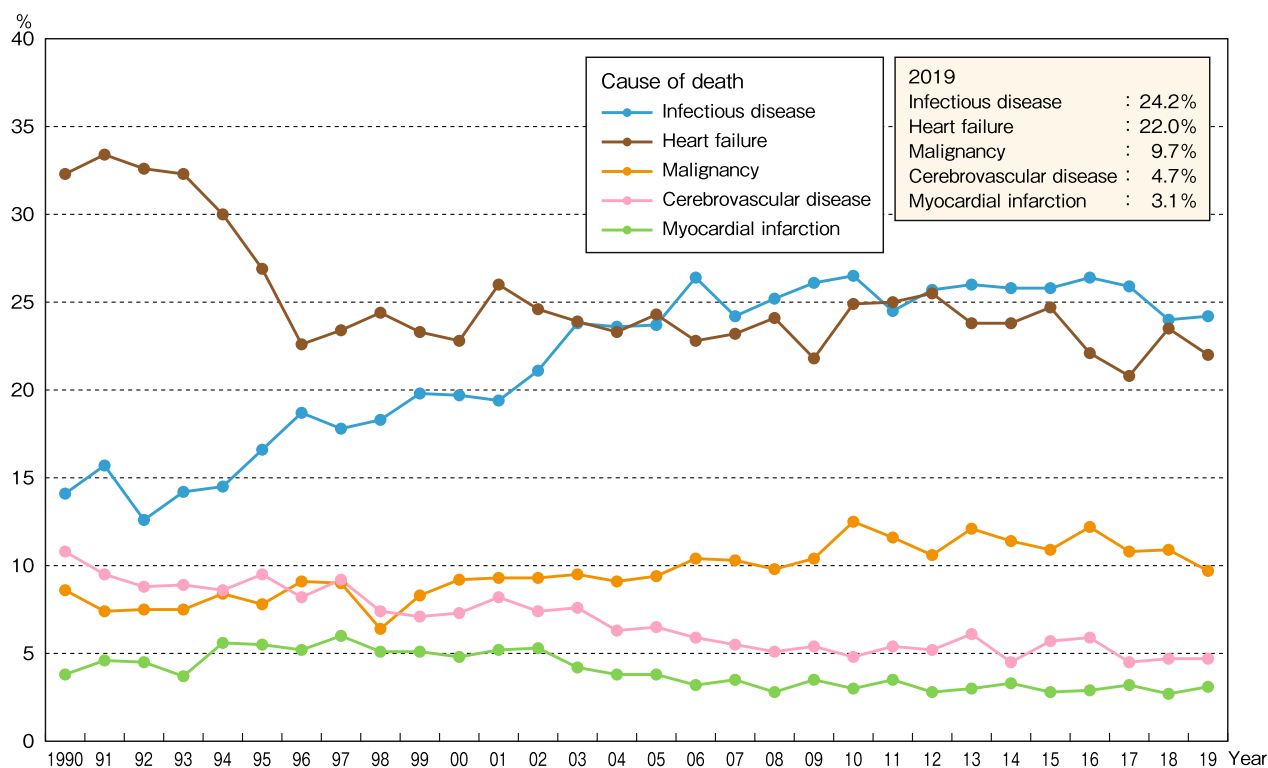


Fig. 19 Trends in major causes of death during the incident year 1990–2019

have been gradually decreasing (Fig. 19, Additional file 1: Table S19).

**Chapter 4: management of dialysis fluid quality**

**Background and subjects**

The 2006 JSDT survey was the first to investigate bacteriological dialysis fluid quality and its management status at dialysis facilities in Japan. Based on the results obtained, the bacteriological standard for dialysis fluid was revised in 2008 [10], and a chemical contamination standard was added in 2016 [11].

Compliance with these standards is assessed by data on measuring the endotoxin (ET) levels and total viable microbial count (TVC) in the dialysis fluid. As per recommendation, both measurements should be conducted at least once a month. At least one dialysis console at each facility should be tested monthly, and all consoles should be tested at least once a year. Standard dialysis fluid must have an ET level of less than 0.05 EU/mL and a TVC level of less than 100 CFU/mL, the minimum standard that must be met for dialysis treatment. Ultrapure dialysis fluid (UPD) is defined as dialysis fluid having an ET level of under 0.001 EU/mL and TVC of under 0.1 CFU/mL. The JSDT standard recommends the use of UPD for all dialysis treatments. Chemical contamination of the dialysis fluid was inquired about for the first time in the 2017 survey. The dialysis fluid standard management status data given in this chapter were derived from data collected from facilities with at least one dialysis machine, 4,396 facilities in the 2019 survey.

**Dialysis fluid ET testing**

The Limulus test is used for the dialysis fluid ET level as a part of the JSDT standard [1, 2]. Unlike in other countries, ET measurement machines are widely used

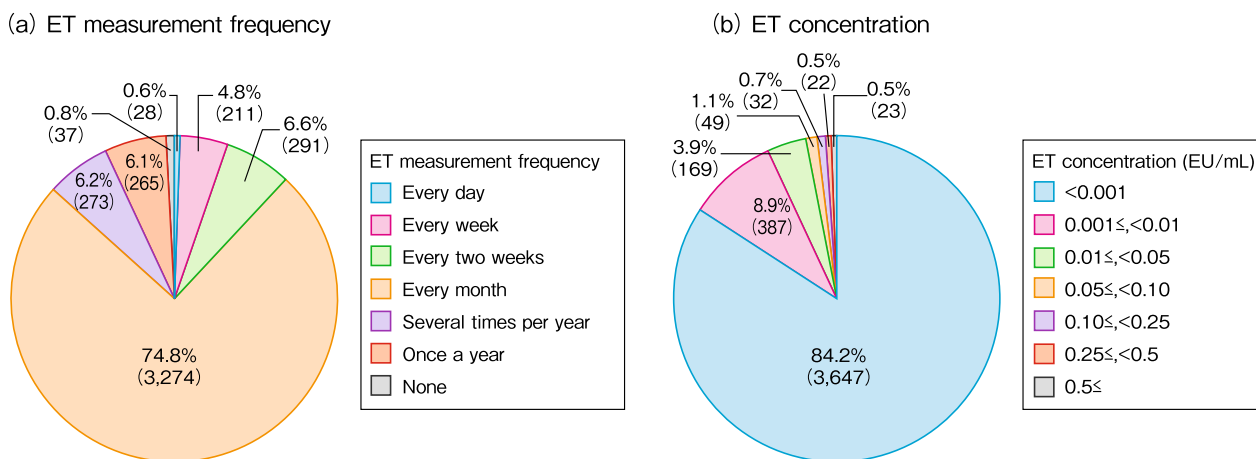
by dialysis facilities in Japan, as several models are relatively inexpensive and available over the counter in our country.

Of the 4,379 facilities which responded to the question concerning the frequency of ET testing, 3,804 (86.9%) indicated that they performed the test and complied with the stipulated frequency of “at least once a month” (Fig. 20a, Additional file 1: Table S20). The dialysis fluid ET test was performed by 33.1% of the facilities in 2008, when the dialysis fluid quality standard was first implemented. This number dramatically increased to 70.6% in 2010, when the reimbursement system started covering the dialysis fluid standard additional fee, and has continued to rise since then (Fig. 21, Additional file 1 Table S21).

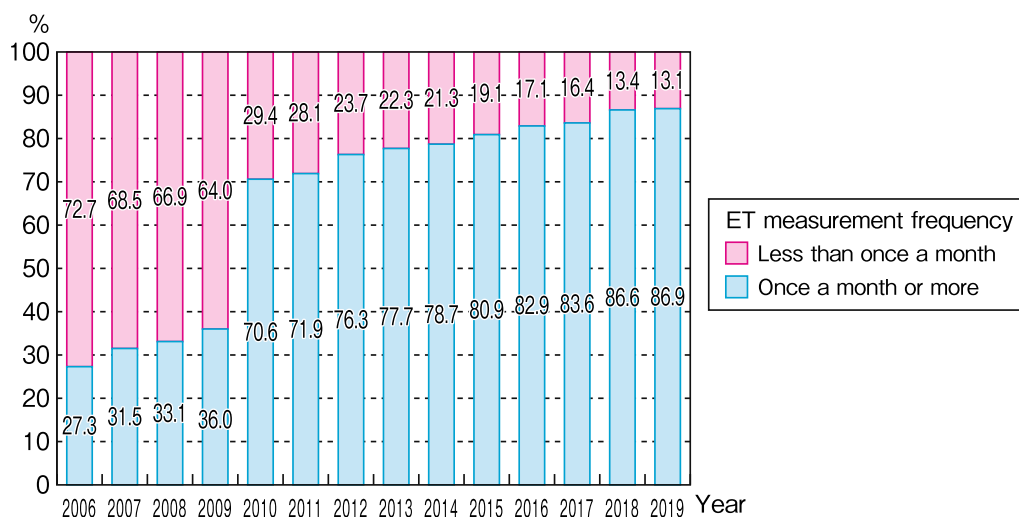
Of the 4,329 facilities that answered the survey regarding dialysis fluid ET levels, 3647 (84.2%) satisfied the UPD standard of less than 0.001 EU/mL, and 4,203 (97.1%) met the standard for standard dialysis fluid of 0.050 EU/mL. (Fig. 20b, Additional file 1: Table S20). The number of facilities fulfilling either dialysis fluid ET standards (less than 0.001 EU/mL or 0.050 EU/mL) is increasing annually (Fig. 22, Additional file 1: Table S22). The data on dialysis fluid ET concentrations in 2008 were omitted because the unit for dialysis fluid ET concentration in the survey was switched from EU/L to EU/mL in the year according to the international rule, which resulted in many incorrect entries.

**Dialysis fluid TVC testing**

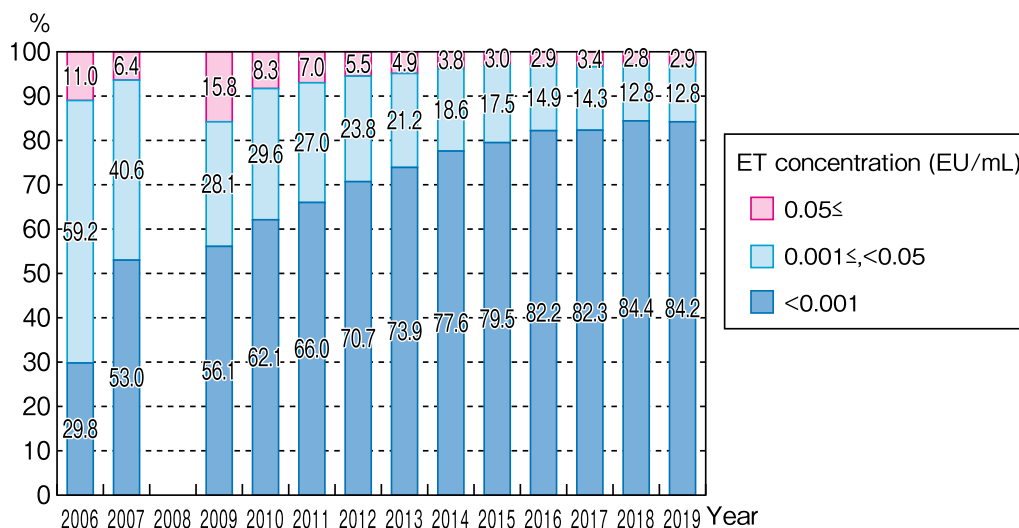
Of the 4,374 facilities which responded to the question regarding the frequency of measuring the dialysis fluid TVC, 3,725 (85.2%) reported measuring at least monthly (Fig. 23a, Additional file 1: Table S23). The frequency of measuring TVC has been increasing annually, and it



**Fig. 20** Facility distribution, by ET measurement frequency and ET concentration in dialysis fluid, 2019. ET Endotoxin, EU Endotoxin unit



**Fig. 21** Trends in dialysis fluid ET measurement frequency, 2006–2019. *ET* Endotoxin



**Fig. 22** Trends in ET concentration in dialysis fluid, 2006–2019. *ET* Endotoxin, *EU* Endotoxin unit

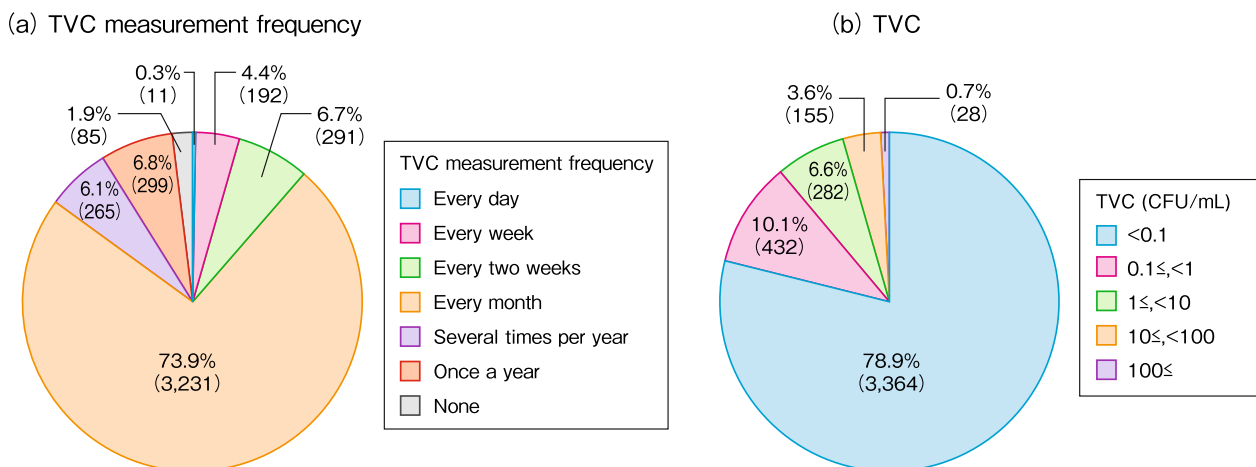
increased significantly in 2010, the same as ET testing. The TVC measurement frequency was slightly lower than the ET-testing frequency in all years (Fig. 24, Additional file 1: Table S24).

Of the 4,261 facilities that responded to the question regarding the dialysis fluid TVC, 3,364 (78.9%) reported meeting the UPD standard of 0.1 CFU/mL, and 4,233 (99.3%) reported meeting the standard dialysis fluid standard of 100 CFU/mL (Fig. 23b, Additional file 1: Table S23). The proportions of facilities meeting either the UPD standard or the standard dialysis

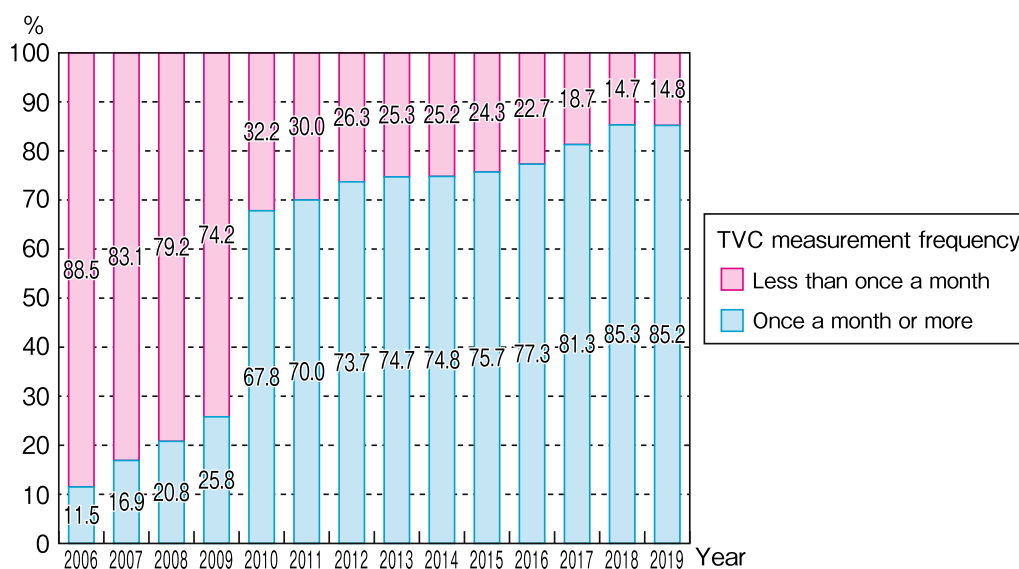
fluid are increasing annually (Fig. 25, Additional file 1: Table S25).

**Achievement quotient of the UPD and standard dialysis fluid standards**

Because the JSdT standard stipulates the bacteriological standard for dialysis fluid (both UPD and standard dialysis fluid standards), the numerical criteria for both dialysis fluid ET concentration and TVC must be met simultaneously [1, 2]. Of the 4258 facilities that responded to both the questions about the dialysis fluid ET level and TVC,



**Fig. 23** Facility distribution by TVC measurement frequency and TVC in dialysis fluid, 2019. TVC Total viable microbial count, CFU Colony-forming unit

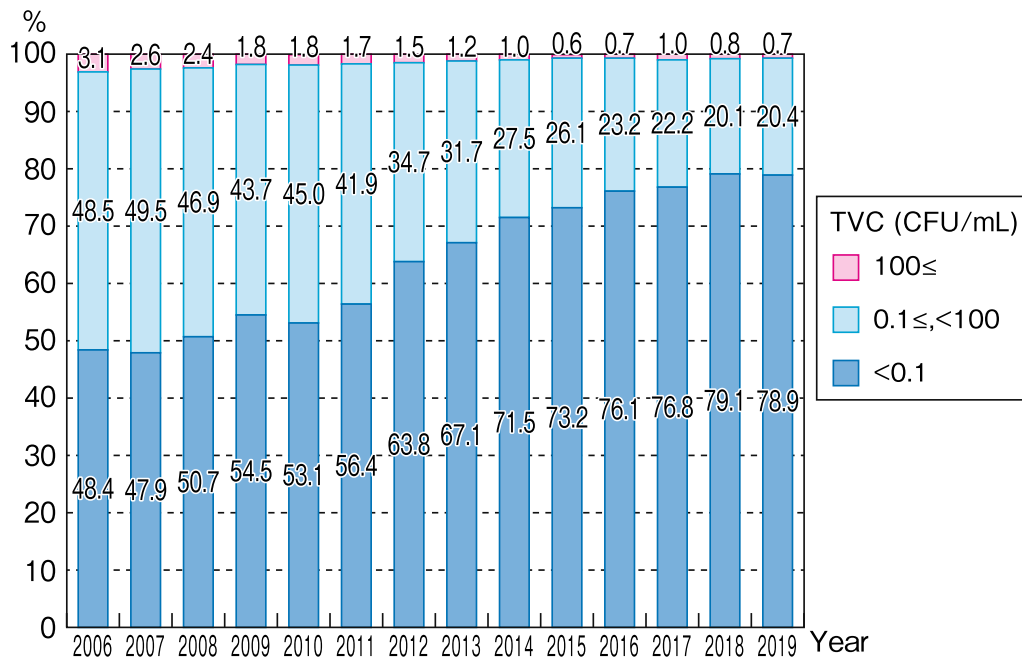


**Fig. 24** Trends in dialysis fluid TVC measurement frequency, 2006–2019. TVC Total viable microbial count

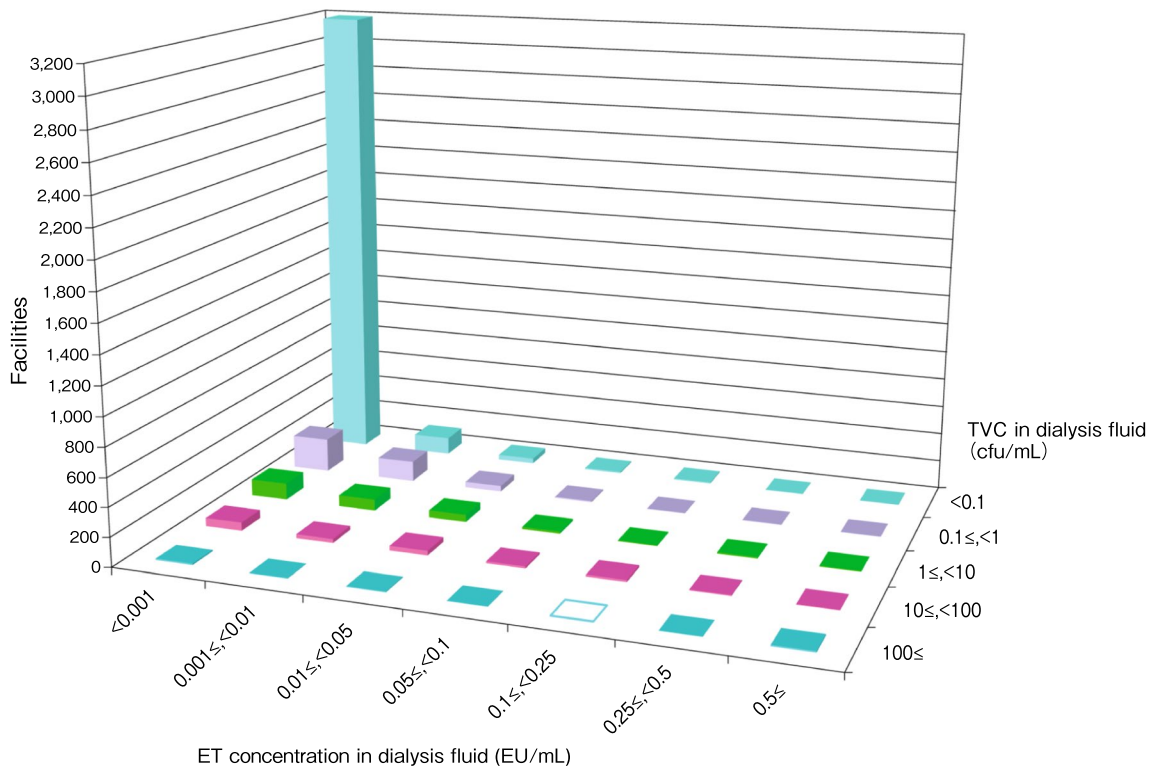
3189 (74.9%) reported meeting the UPD standard (dialysis fluid ET level under 0.001 EU/mL and live bacteria count under 0.1 CFU/mL), and 4125 (96.9%) reported meeting the standard for standard dialysis fluid (dialysis fluid ET level under 0.050 EU/mL and TVC under 100 CFU/mL) (Fig. 26, Additional file 1: Table S26). The achievement quotients of the standards for both UPD and standard dialysis fluid have been increasing over time, indicating that the purity level of dialysis fluid is improving in Japan (Fig. 27, Additional file 1: Table S27).

**Source of dialysis water and chemical contamination preventative measures**

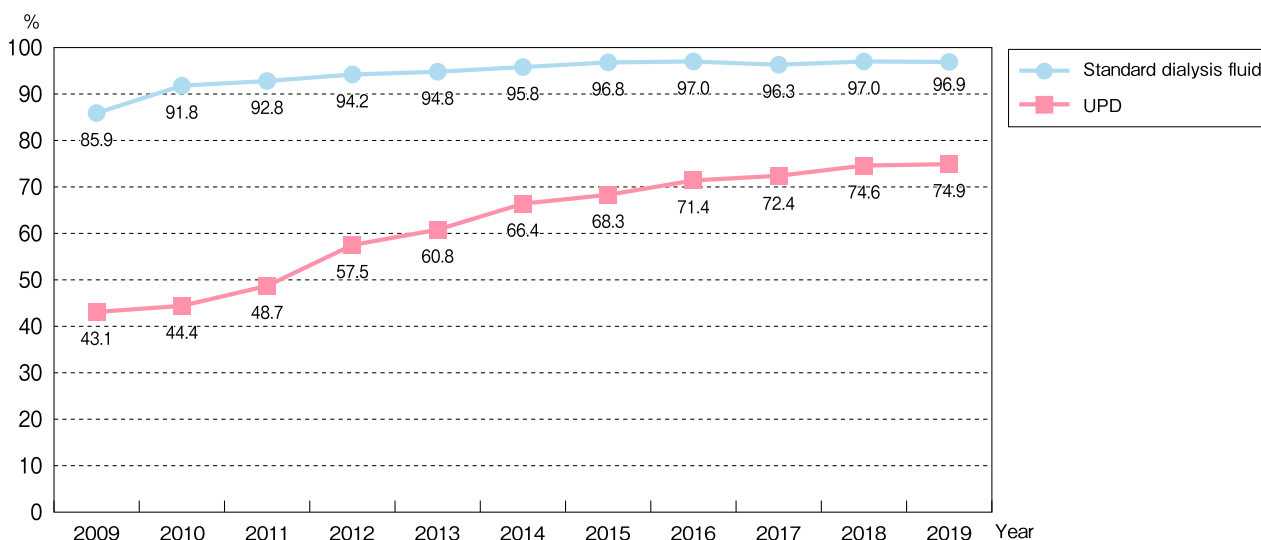
A total of 4,374 facilities responded to the question regarding the source of dialysis water in the 2019 survey. The most commonly indicated source was tap water (3701 facilities, 84.6%), followed by groundwater (365 facilities, 8.3%), and a combination of tap water and groundwater (301 facilities, 6.9%) (Fig. 28 Additional file 1: Table S28), which did not differ significantly from the previous year.



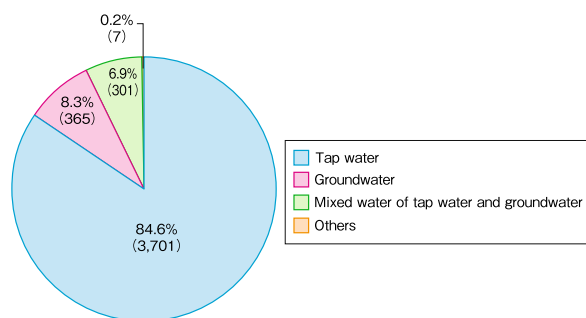
**Fig. 25** Trends in TVC in dialysis fluid, 2006–2019. TVC Total viable microbial count, CFU Colony-forming unit



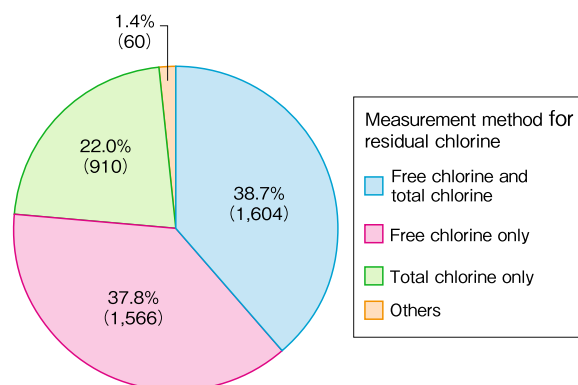
**Fig. 26** Facility distribution by ET concentration and TVC in dialysis fluid, 2019. ET Endotoxin, TVC Total viable microbial count, CFU Colony-forming unit, EU Endotoxin unit



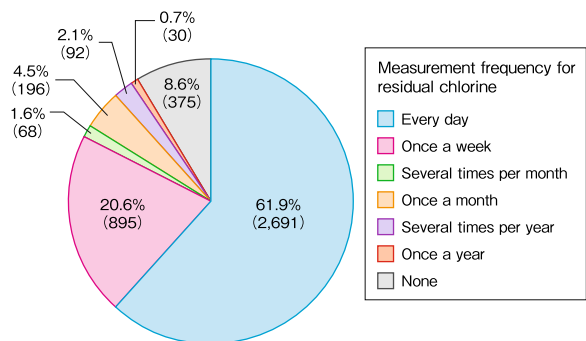
**Fig. 27** Trends in facility distribution for achieving UPD and standard dialysis fluid, 2009–2019. The standard for UPD satisfies both ET < 0.001 EU/ml and TVC < 0.1 CFU/ml. UPD Ultrapure dialysis fluid



**Fig. 28** Facility distribution by the source of dialysis water



**Fig. 30** Facility distribution by measurement method for residual chlorine



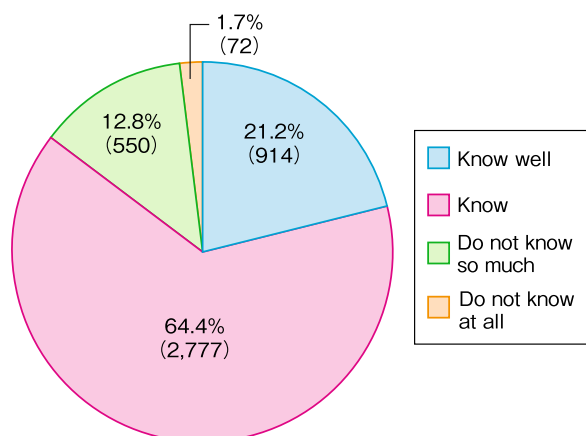
**Fig. 29** Facility distribution by measurement frequency for residual chlorine

A total of 4,347 facilities responded to the frequency of residual chlorine testing in dialysis water before hemodialysis treatment. “Every day” was most common (2,691 facilities, 61.9%), followed by “once a week” (895 facilities, 20.6%), and “once a month” (196 facilities, 4.5%) (Fig. 29,

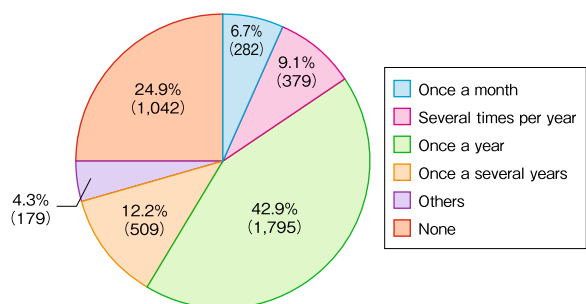
Additional file 1: Table S29). In total, 375 facilities (8.6%) reported that they did not test residual chlorine measurements in the dialysis water before hemodialysis. Routine measurement of residual chlorine should be promoted.

A total of 4,140 facilities responded to the method for residual chlorine measurement. “Both free chlorine and total chlorine” was the method used in most facilities (1604 facilities, 38.7%), followed by “free chlorine only” (1566 facilities, 37.8%). The proportion of facilities that measured the total chlorine, as recommended by the JSDT standard, was 60.7% (Fig. 30, Additional file 1: Table S30).

A total of 4,313 facilities reported being aware of the JSDT chemical contamination standard [2], with 85.6% reporting choosing the response of “very familiar” or “familiar” (Fig. 31, Additional file 1: Table S31). A total of



**Fig. 31** Facility distribution, by awareness of the JSDT standard for chemical contaminants



**Fig. 32** Facility distribution by measurement frequency of the JSDT standard for chemical contaminants

4,186 facilities responded to the question about the frequency of measuring chemical contamination in dialysis fluid stipulated by the standard; 1,795 facilities (42.9%) reported “once a year,” while 1,042 facilities (24.9%) reported not conducting the measurement for chemical contamination at all (Fig. 32, Additional file 1: Table S32). Those figures were 42.6% and 27.0% in the 2018 survey, which means more facilities started measuring chemical contamination in dialysis due to the efforts made by the JSDT. This survey on chemical contamination also has a role in improving awareness and compliance with the JSDT standard on chemical contamination.

**Chapter 5: CKD-MBD**

**Background and objectives**

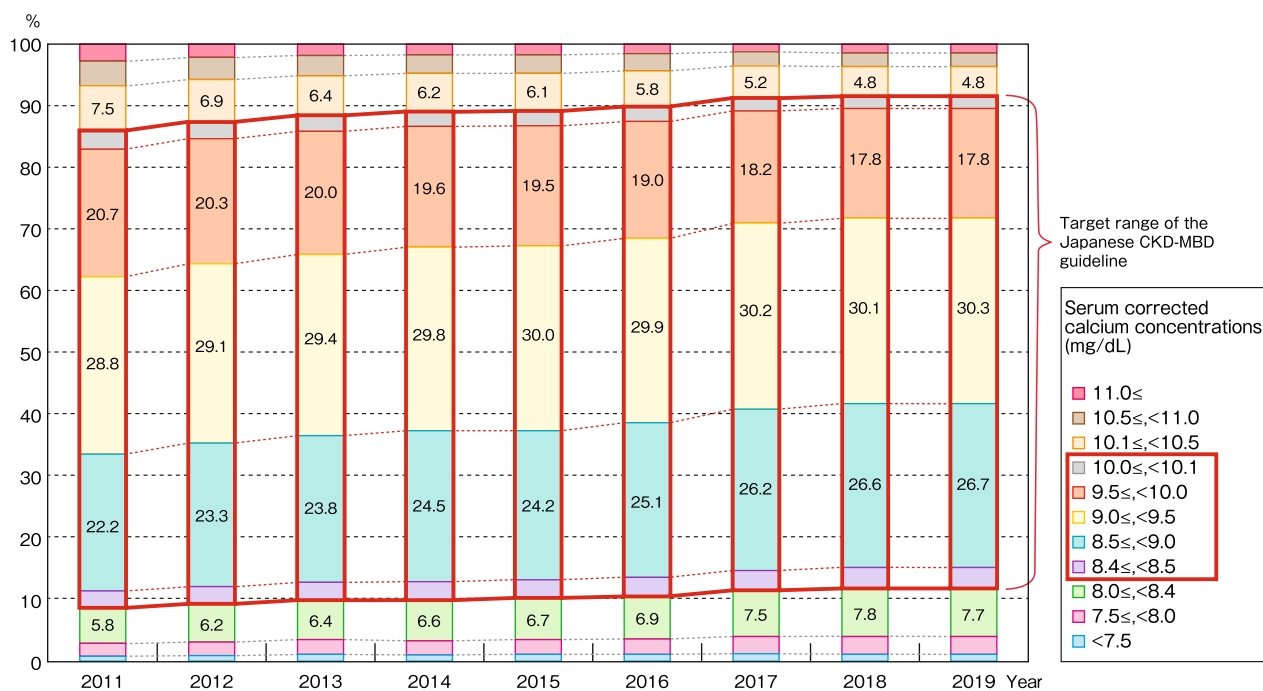
In the present survey, investigations for CKD-MBD (Chronic Kidney Disease-Mineral and Bone Disorder) were carried out for the first time since 2009. The Japanese CKD-MBD Guideline [12], which was revised in 2012 based on the results of the 2009 survey, recommended clinical prioritization of serum phosphate (P) > calcium (Ca) > parathyroid hormone (PTH) levels,

and the target ranges for these markers. The therapeutic strategy for secondary hyperparathyroidism (SHPT) has changed drastically since cinacalcet hydrochloride, a new calcimimetic compound, was launched on the market in 2008. Parathyroidectomy (PTX) and percutaneous ethanol injection therapy (PEIT) had been the treatment mainstays for severe SHPT. The frequencies of these two procedures have declined since 2008 and further decreased after the launch of etelcalcetide, an injectable calcimimetic agent [13]. With these therapeutic changes for SHPT, the goal of CKD-MBD treatment has also changed from the management of the serum PTH to that of Ca/P and prevention of vascular calcification [12]. In terms of P binders, the frequency of use of Ca carbonate has decreased, because it could cause vascular calcification. In place of Ca-containing agents, Ca-free P binders were launched: lanthanum carbonate in 2009 and bixalomer in 2012. Furthermore, iron-based P binders, such as ferric citrate (in 2014) and sucroferric oxyhydroxide (in 2018), which are also effective for countering anemia, were launched one after another.

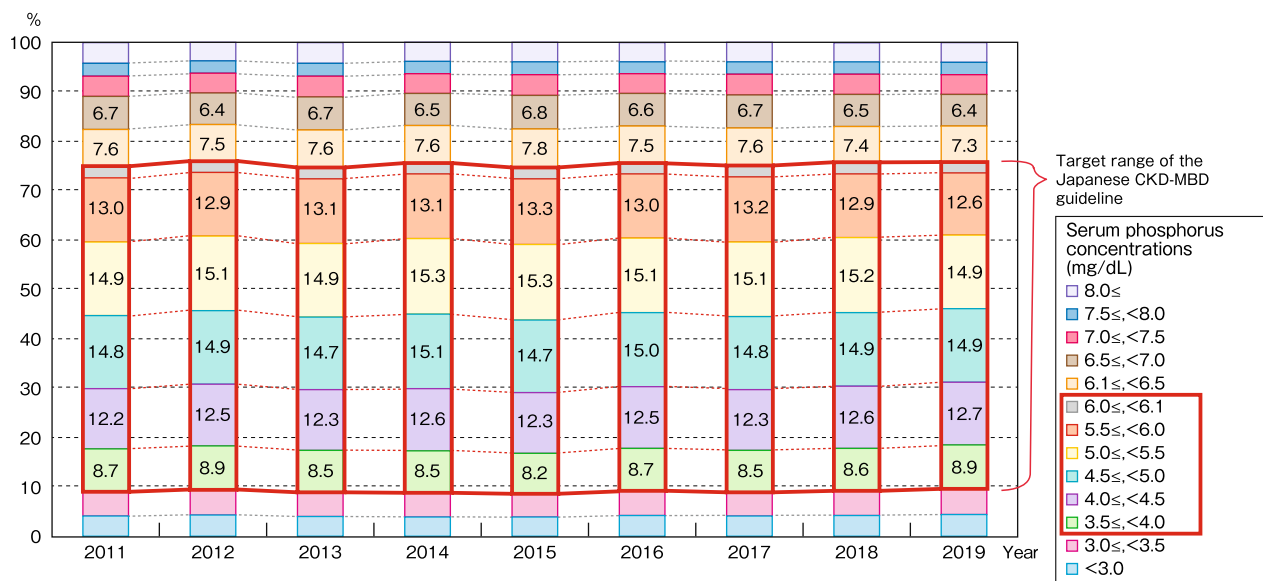
Under these circumstances, the trends in the levels of the serum markers of CKD-MBD during the intervening 10-year period and in the use of treatment agents for CKD-MBD were investigated in the present survey. The aim was to link the data from the present survey to future analyses of mortality or event onset, and design a better practice pattern for CKD-MBD. Although the conversion ratio from whole PTH to intact PTH was described in the JSDT guideline, the ratio may vary by the patient. In this annual data report, only intact PTH data were used for PTH, while the WADDA system allows the analysis of the whole PTH data. The Japanese version of the Annual Data Report included patients with zero values for serum iron, TIBC, serum ferritin, serum alkaline phosphate, or serum magnesium levels in its tables. In this English version, we have updated tables by excluding those patients with zero values. Please note that, therefore, figures in those two versions are different. 2. Trends in serum CKD-MBD-related markers during the period between 2011 and 2019.

The annual changes in the serum-albumin corrected Ca and P levels in all dialysis patients, both hemodialysis and peritoneal dialysis patients, between 2011 and 2019 are shown in Fig. 33 and 34 (Additional file 1: Table S33 and S34). The mean Ca level decreased yearly, from 9.29 ± 0.86 [mean ± SD] mg/dL in 2011 to 9.10 ± 0.73 mg/dL in 2019. The percentage of patients with serum corrected Ca levels within the target range of 8.4–10.0 mg/dL recommended by the Japanese CKD-MBD Guideline was 80.2% in 2019, significantly higher than that of 77.2% in 2011. The WADDA system revealed that patients dialyzed with low-calcium dialysis fluid, non-vitamin D





**Fig. 33** Trends in serum corrected calcium concentrations, 2011–2019. *JSDT* The Japanese Society for Dialysis Therapy

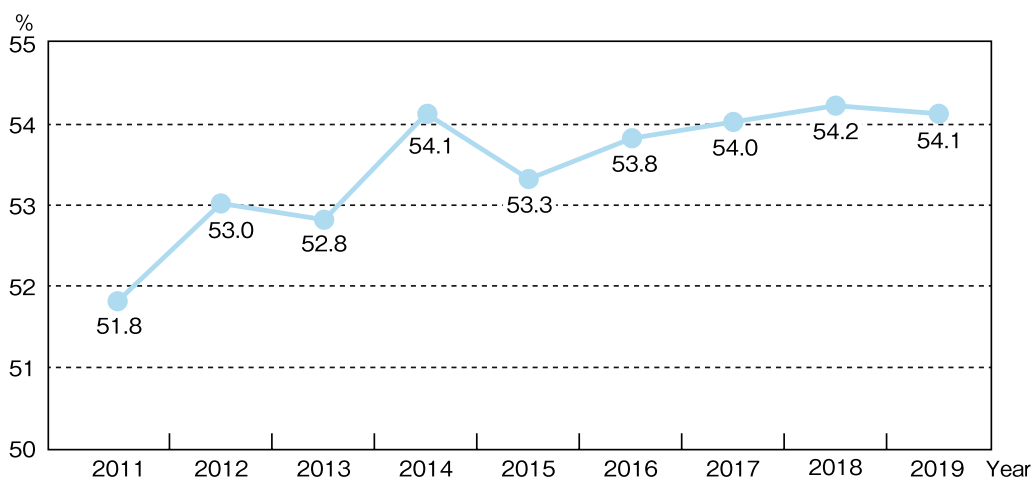


**Fig. 34** Trends in serum phosphorus concentrations, 2011–2019

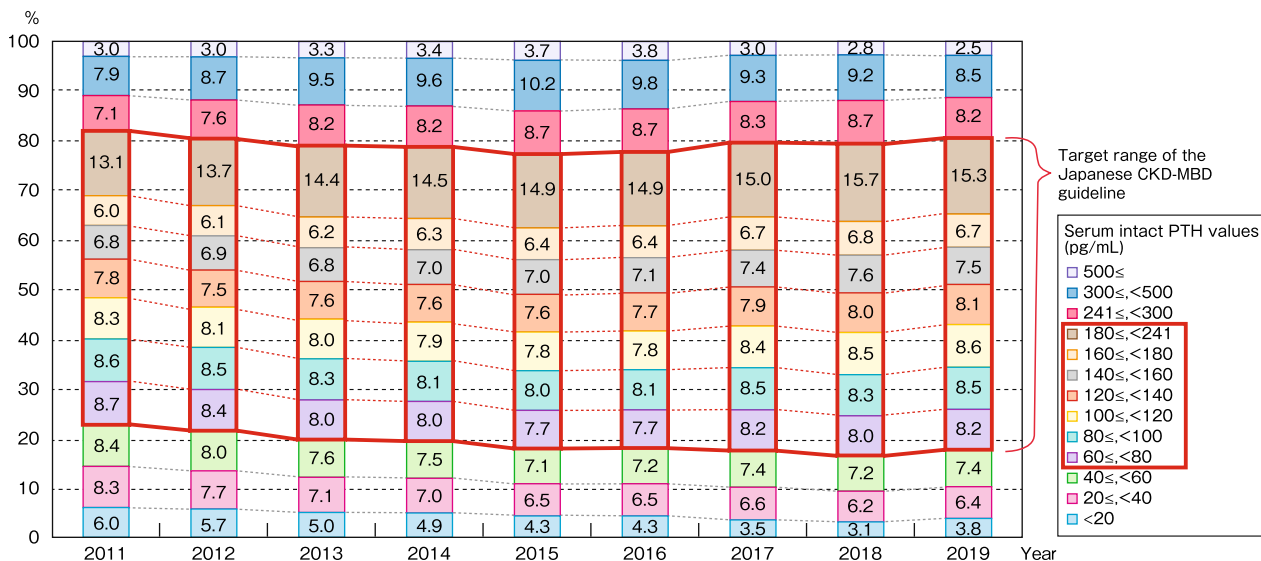
users, and patients on calcimimetics tended to have low serum calcium levels (data not shown). Calcium carbonate users, on the other hand, tended to have low serum calcium levels, most likely due to reverse causality or confounding by indication.

Meanwhile, the mean serum phosphate level remained unchanged between 2011 ( $5.23 \pm 1.46$  mg/dL) and 2019 ( $5.19 \pm 1.46$  mg/dL). The percentage of patients with serum phosphate levels within the target range of 3.5–6.0 mg/dL recommended by the CKD-MBD Guideline





**Fig. 35** Serum corrected calcium and phosphorus concentration guideline attainment status, 2011–2019



**Fig. 36** Trends in serum intact PTH values, 2011–2019. PTH Parathyroid hormone

also remained unchanged during the nine years from 2011 to 2019 (65.8% in 2011 and 66.2% in 2019). The percentage of patients in whom both the target serum Ca and target serum P levels were achieved increased annually from 51.8% in 2011 to 54.1% in 2019 (Fig. 35, Additional file 1: Table S35).

The trends in the serum intact PTH levels are shown in Fig. 36 and Additional file 1: Table S36. The mean serum PTH level increased annually up to 2015, but decreased to 166±147 pg/mL in 2019. The percentage of patients with mean serum PTH levels within the target range of 60–240 pg/mL increased yearly from 59.1% in 2011 to 63.0% in 2019. It is noteworthy that the percentage of patients with

a serum PTH level in excess of 240 pg/mL remained nearly unchanged over the years, while that of patients with levels of less than 60 pg/mL decreased each year.

The serum magnesium (Mg) and alkaline phosphatase (ALP) levels in the 2019 survey were compared with those in the 2009 survey using the WADDA system [3], which can be accessed on the web by members of the JSDT. The mean serum Mg level decreased from 2.60±0.54 mg/dL in 2009 to 2.48±0.51 mg/dL in 2019 (Fig. 37, Additional file 1: Table S37). Notably, the percentage of patients with serum Mg levels of not less than 3.0 mg/dL decreased, while that of patients with levels of under 2.0 mg/dL increased. The mean serum ALP level

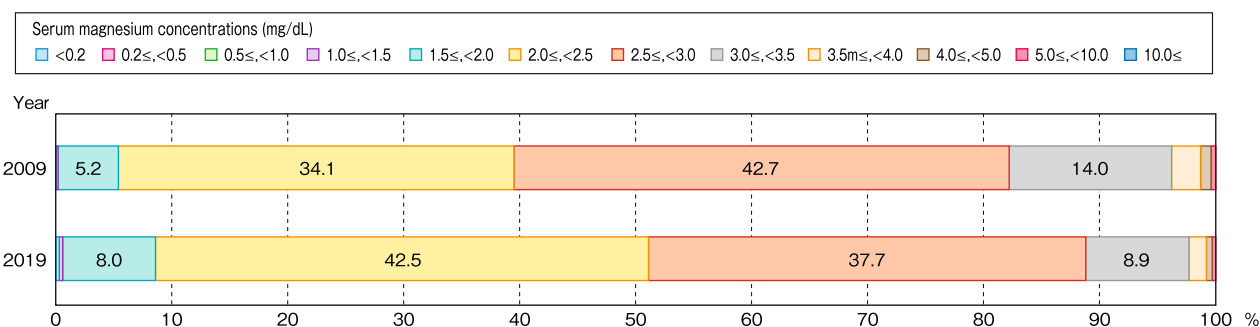


Fig. 37 Trends in serum magnesium concentrations, 2009, 2019

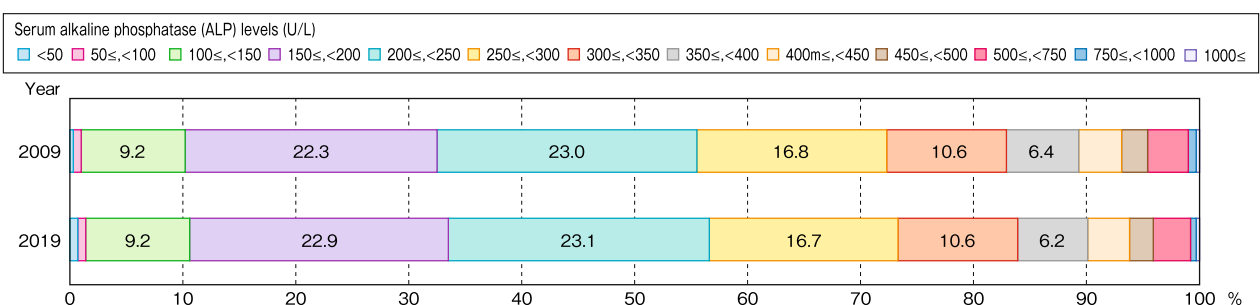


Fig. 38 Trends in serum alkaline phosphatase (ALP) levels, 2009, 2019

Table 3 Implementation of parathyroidectomy (PTx), percutaneous ethanol injection therapy (PEIT) during 2019, 2019

	None (enforced during the year 2019)	With PTx (performed during the year 2019)	With parathyroid PEIT (performed during the year 2019)	With both PTx and PEIT (enforced during the year 2019)	Subtotal	Unspecified	No information available	Total
Number of patients	248,016	637	17	1	248,671	3214	80,714	332,599
(%)	(99.7)	(0.3)	(0.0)	(0.0)	(100.0)			

\* The data were obtained from the patient survey

was 261 ± 134 U/L in 2019, almost the same as that level of 267 ± 148 U/L recorded in 2009 (Fig. 38, Additional file 1: Table S38). There was also no difference in the distribution of the ALP levels between 2009 and 2019.

**PTX and PEIT in 2019**

The number of cases that received PTX and PEIT was investigated in the 2019 survey, and data were obtained for 248,671 patients (Table 3). Of those who responded, 637 had undergone PTX, and 17 had undergone PEIT, corresponding to 0.26% and 0.01% of the respondents, respectively.

**Use of calcimimetics and vitamin D receptor activator (VDRA) agents**

Of the 271,325 patients for whom data pertaining to the use of calcimimetic agents were available, 84,672 (31.2%)

were on these medications (Tables 4 and 5). Among these patients, 14.6%, 11.5%, and 5.1% received evocalcet, etelcalcetide, and cinacalcet, respectively.

Of the 270,116 patients for whom data regarding the use of oral VDRA were available, 93,395 patients (34.6%) took those medications (Table 4). Among the agents, the most commonly prescribed was alfacalcidol (26.3%), followed by calcitriol (6.6%), falecalcitriol (1.0%), and eldelcalcitol (0.6%). Of the 272,645 patients with data on the use of injectable VDRA, 107,227 (39.3%) received those medications (Table 5). Maxacalcitol and calcitriol were the most frequently prescribed medications (28.4% and 10.9%, respectively). The most commonly used combination of calcimimetic and VDRA was etelcalcetide plus maxacalcitol, an injectable vitamin D analog.

**Table 4** Calcimimetics and oral VDRA (vitamin D receptor activator) use, 2019

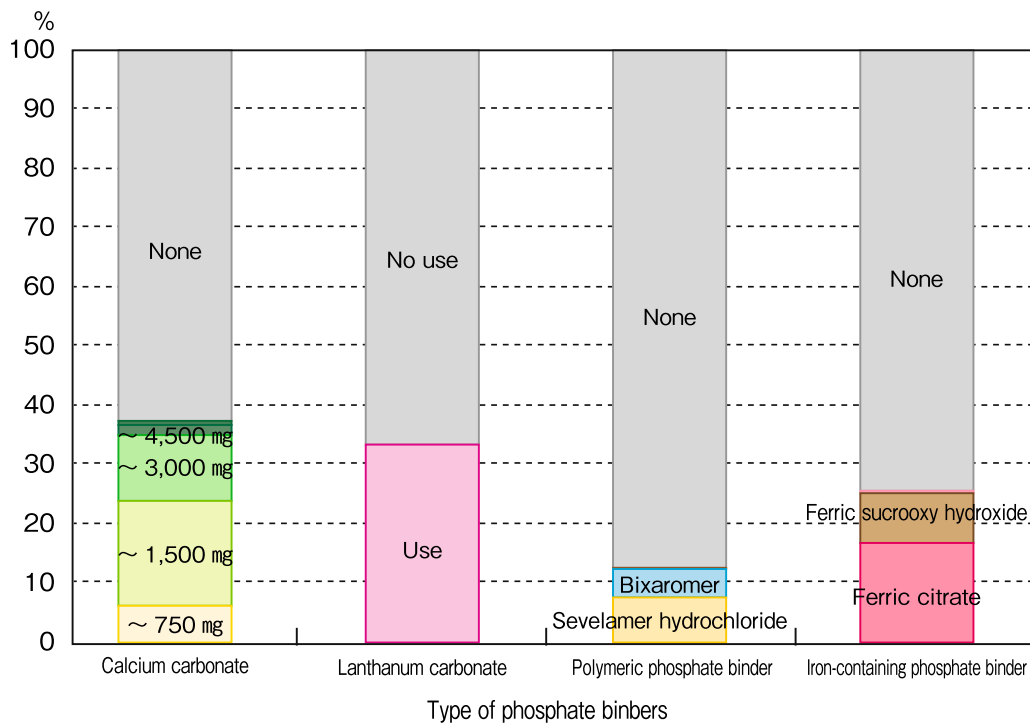
Calcimimetics use	None	Alfacalcidol	Calcitriol	Erdecalcitrol	Farecalcitriol	Others	Subtotal	Unspecified	No information available	Total
None	118,016 (63.8)	51,961 (28.1)	12,190 (6.6)	1,050 (0.6)	1,577 (0.9)	297 (0.2)	185,091 (100.0)	269	1,293	1,86,653
Cinacalcet	8,841 (65.7)	3,468 (25.8)	887 (6.6)	43 (0.3)	190 (1.4)	22 (0.2)	13,451 (100.0)	24	429	13,904
Etercalcetide	23,891 (79.9)	4,143 (13.9)	1,424 (4.8)	185 (0.6)	226 (0.8)	22 (0.1)	29,891 (100.0)	37	1,214	31,142
Evocalcet	25,308 (66.1)	9,137 (23.9)	2,850 (7.4)	304 (0.8)	616 (1.6)	47 (0.1)	38,262 (100.0)	62	1,302	39,626
Subtotal	176,056 (66.0)	68,709 (25.8)	17,351 (6.5)	1,582 (0.6)	2,609 (1.0)	388 (0.1)	266,695 (100.0)	392	4,238	2,71,325
Unspecified	245 (84.8)	40 (13.8)	3 (1.0)		1 (0.3)		289 (100.0)	761	5	1,055
No information available	420 (13.4)	2,179 (69.6)	437 (14.0)	21 (0.7)	57 (1.8)	18 (0.6)	3,132 (100.0)	29	57,058	60,219
Total	1,76,721 (65.4)	70,928 (26.3)	17,791 (6.6)	1,603 (0.6)	2,667 (1.0)	406 (0.2)	2,70,116 (100.0)	1,182	61,301	332,599

\*The data were obtained from the patient survey

**Table 5** Usage of calcimimetics and intravenous VDRA(vitamin D receptor activator), 2019

Calcimimetics use	None	Maxacalcitol	Calcitriol	Subtotal	Unspecified	No information available	Total
None	128,905 (69.3)	41,655 (22.4)	15,535 (8.3)	186,095 (100.0)	118	440	186,653
Cinacalcet	7,047 (52.0)	4,974 (36.7)	1,537 (11.3)	13,558 (100.0)	7	339	13,904
Etercalcetide	9,667 (31.5)	15,346 (50.0)	5,664 (18.5)	30,677 (100.0)	16	449	31,142
Evocalcet	19,013 (49.1)	13,494 (34.9)	6,191 (16.0)	38,698 (100.0)	9	919	39,626
Subtotal	164,632 (61.2)	75,469 (28.1)	28,927 (10.8)	269,028 (100.0)	150	2,147	271,325
Unspecified	161 (45.5)	156 (44.1)	37 (10.5)	354 (100.0)	700	1	1,055
No information available	625 (19.2)	1,862 (57.1)	776 (23.8)	3,263 (100.0)	121	56,835	60,219
Total	1,65,418 (60.7)	77,487 (28.4)	29,740 (10.9)	2,72,645 (100.0)	971	58,983	332,599

\* The data were obtained from the patient survey



**Fig. 39** Phosphate binder use, 2019

**Use of phosphate binders**

The use of phosphate binders and iron agents was examined in the 2019 survey (Fig. 39, Additional file 1: Table S39).

*Ca carbonate* Of the 272,196 patients for whom data were available, 102,080 (37.5%) were receiving calcium carbonate. The dose was also examined, as the use of excessive doses of Ca carbonate had been a clinical issue.

The results revealed that 24.0%, 11.1%, and 2.4% of the total patients with data on Ca carbonate use (i.e., 272,196 patients) were receiving  $\leq 1500$  mg, 1500 to 3000 mg, and  $> 3000$  mg, respectively.

**Lanthanum carbonate** Of the 271,903 patients for whom data were available, 90,881 (33.4%) were receiving lanthanum carbonate.

**Phosphate-binding polymer** Of the 268,814 patients for whom data were available, 20,410 (7.6%) and 12,976 (4.8%) were receiving sevelamer hydrochloride and bixalomer, respectively. Of these, 533 (0.2%) patients were receiving both the drugs concomitantly.

**Iron-based phosphate binders and other iron agents** Of the 270,388 patients for whom data were available, 45,515 (16.8%) and 22,665 (8.4%) were receiving ferric citrate and sucroferric oxyhydroxide, respectively. Of these, 998 (0.4%) patients were receiving both drugs concomitantly. The use of oral and injectable iron agents was also surveyed in order to grasp the usage of iron drugs that were not iron-based phosphate binders (Table 6). Of the 270,111 patients who answered the question, 13,267 (4.9%) and 50,892 (18.8%) were receiving oral and injectable iron preparations, respectively.

#### **Trends in the serum transferrin saturation (TSAT) and ferritin levels**

We examined the serum TSAT and ferritin levels because the iron-based phosphate binders mentioned above were launched on the market in 2014. The percentage of patients with a serum TSAT of  $< 20\%$  was 32.6% in 2019, lower than that recorded in 2012, but higher than the percentages recorded in 2006 and 2007 (Fig. 40, Additional file 1: Table S40). The percentage of patients with serum ferritin levels of  $< 50$  ng/mL was 31.6% in 2019, lower than that recorded in 2012, but higher than the percentages recorded in 2006 and 2007. Meanwhile, the percentage of patients with serum ferritin levels of not less than 300 ng/mL decreased annually, and was 9.1% in 2019 (Fig. 41, Additional file 1: Table S41).

#### **Dialysate Ca concentration**

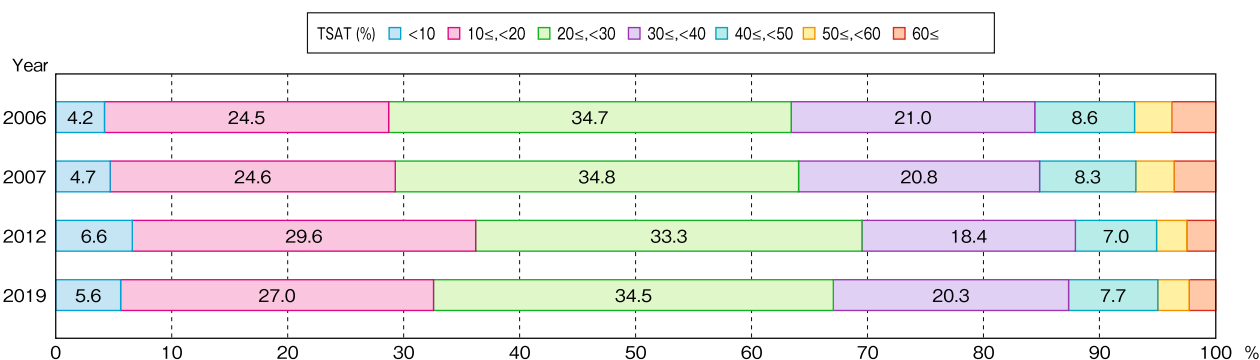
The dialysate Ca concentration was surveyed in all patients receiving extracorporeal dialysis therapy (Fig. 42, Additional file 1: Table S42). Of the 277,652 patients for whom data were available, the dialysate Ca concentration was 2.75, 3.0, and 2.5 mEq/L in 110,339 (39.7%), 79,358 (28.6%), and 53,021 (19.1%) patients, respectively. In the previous survey conducted in 2009, according to data retrieved using the WADDA system, the dialysate Ca concentrations were 3.0 and 2.5 mEq/L in 49.2%

**Table 6** Combined usage of iron-containing phosphate binders and iron preparations (other than as phosphate binders), 2019

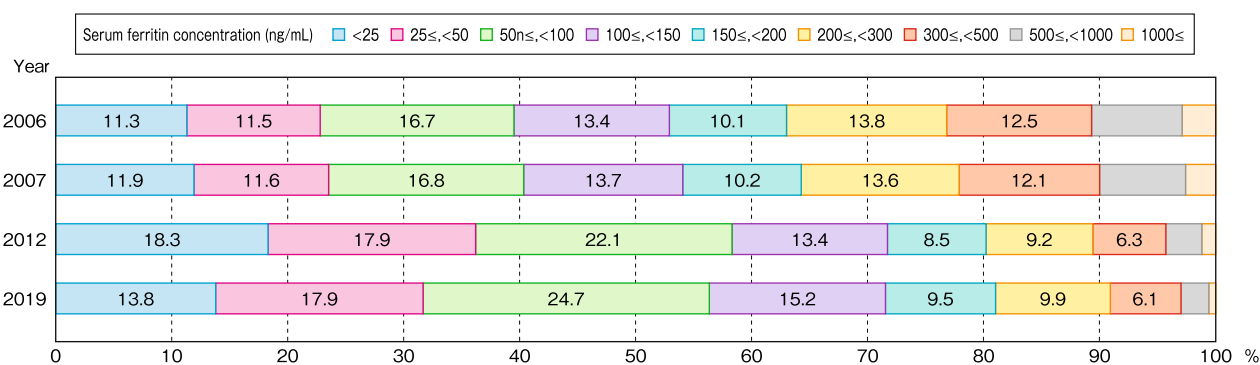
Iron preparations except for phosphate binders	None	Ferric citrate	Sucroferric oxyhydroxide	Concomitant use of two	Subtotal	Unspecified	No information available	Total
None	146,904	38,970	18,699	804	2,05,377	127	448	205,952
(%)	(71.5)	(19.0)	(9.1)	(0.4)	(100.0)			
Oral iron agents	11,152	1,155	534	27	12,868	1	398	13,267
(%)	(86.7)	(9.0)	(4.1)	(0.2)	(100.0)			
IV iron agents	42,380	3,824	2,397	124	48,725	66	2101	50,892
(%)	(87.0)	(7.8)	(4.9)	(0.3)	(100.0)			
Subtotal	200,436	43,949	21,630	955	2,66,970	194	2947	270,111
(%)	(75.1)	(16.5)	(8.1)	(0.4)	(100.0)			
Unspecified	167	40	75	3	285	854	1	1140
(%)	(58.6)	(14.0)	(26.3)	(1.1)	(100.0)			
No information available	607	1,526	960	40	3,133	1	58,214	61,348
(%)	(19.4)	(48.7)	(30.6)	(1.3)	(100.0)			
Total	201,210	45,515	22,665	998	270,388	1049	61,162	332,599
(%)	(74.4)	(16.8)	(8.4)	(0.4)	(100.0)			

Rows represent the status of iron preparation usage; "oral iron agents" means iron-containing medications other than ferric citrate or sucroferric oxyhydroxide. Columns represent the status of iron-containing phosphate binder use, irrespective of the status of iron preparation use other than phosphate binders

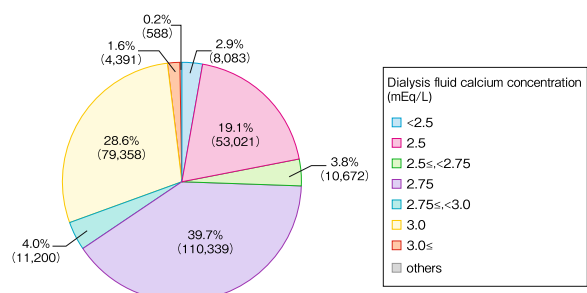
\* The data were obtained from the patient survey



**Fig. 40** Trends in transferrin saturation (TSAT), 2006, 2007, 2012, 2019



**Fig. 41** Trends in serum ferritin concentration, 2006, 2007, 2012, 2019



**Fig. 42** Dialysis fluid calcium concentration (dialysis therapy using extracorporeal circulation except for peritoneal dialysis), 2019

and 35.0%, respectively, and these two concentrations accounted for the majority. However, the 2019 survey showed that a dialysate Ca concentration of 2.75 mEq/L had become mainstream.

### Chapter 6: 12-lead electrocardiogram

#### QT interval

During the last decade, calcimimetics have often been routinely used for the management of secondary hyperparathyroidism and/or mineral bone disorder (MBD) in

patients undergoing dialysis in Japan. Concurrent with this practice, the tendency towards switch of the type of phosphate binder used from a calcium-containing type to a non-calcium-containing type owing to the risk of progression of vascular calcification, which is one of the major concerns related to the use of phosphate binders in patients with MBD. Furthermore, the dialysate Ca concentration is 2.5 mEq/L or less in 25% of Japanese dialysis patients. These management patterns for MBD lead to the pre-dialysis Ca values being low.

Hypocalcemia, hypokalemia, dialysate calcium and potassium concentrations, and fluctuations of these electrolyte levels during hemodialysis strongly affect the risk of QT prolongation in the 12-lead electrocardiogram (ECG) [14]. The QT interval corresponds to the duration of the ventricular action potential. Prolongation of the QT interval, which indicates delayed repolarization after cardiac contraction, is well known as one of the markers of impending polymorphic ventricular tachycardia, such as Torsades de Pointes, and sudden cardiac death. A previous cohort study of Japanese hemodialysis patients revealed that 13% of deaths in hemodialysis patients were due to sudden death [15]. QT prolongation on the ECG

has been reported to have a great impact on the prognosis and risk of sudden death in both HD [16] and PD [17] patients. Moreover, the QT interval, which is evaluated by automatic analysis of a resting 12-lead ECG, has become a useful marker for predicting the prognosis [18]. Therefore, in order to establish more intensive and safe management practices for MBD in dialysis patients, it is important to know the associations of the MBD markers, especially the serum Ca concentration and dialysate Ca concentration, with the QT interval.

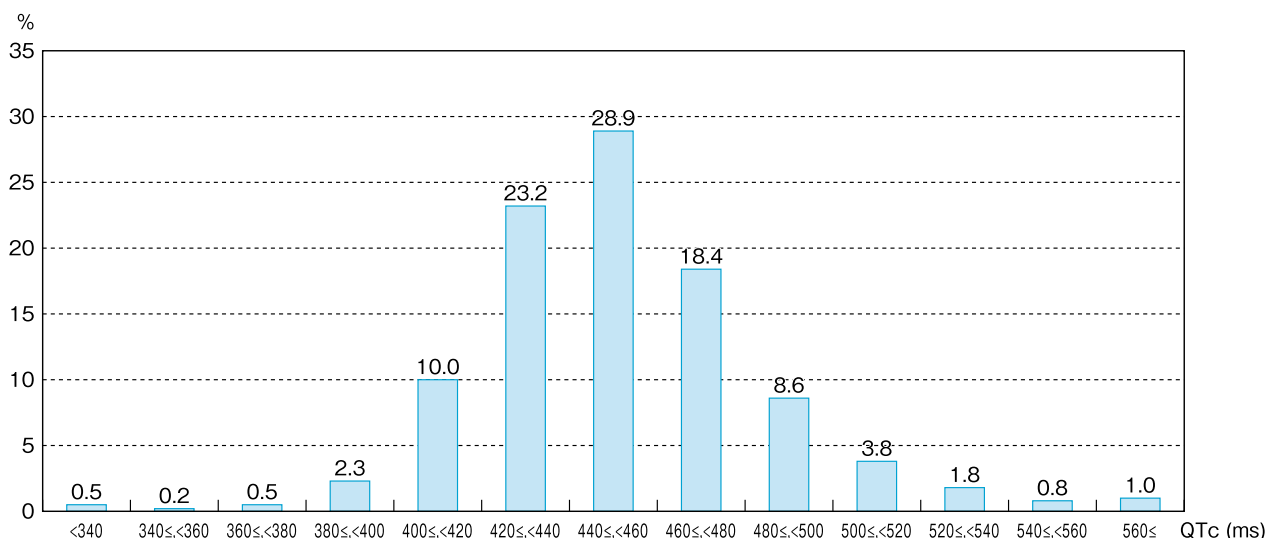
A survey of the QT interval as evaluated by a resting 12-lead ECG in the Japanese renal data registry was performed for the first time in 2019. The QT interval and heart rate automatically measured by each ECG device in the facilities were surveyed. The corrected QT time (QTc) values were calculated using the formula of Bazett ( $QTc = QT \text{ interval} / \sqrt{RR} \text{ interval}$ ). Of the total surveyed population of 332,599 patients, the association of the QTc with the clinical parameters was examined in 229,793 patients without atrial fibrillation.

**Distribution of the QTc** Because data on the QT interval was missing for 9,920 of the 229,793 patients, only the remaining 219,873 patients were included in the final analysis. As shown in Fig. 43 and Additional file 1: Table S43, an almost normal distribution of the QTc was observed, and the mean QTc in the patients was  $451 \pm 37$  ms, which is longer than the upper limit of the standard range of 450 ms for women and 440 ms for men, as calculated using the formula of Bazett. The mean value of QTc in the general population is reported as  $406 \pm 26$  ms [19], which is 50 ms shorter than the aforementioned value in dialy-

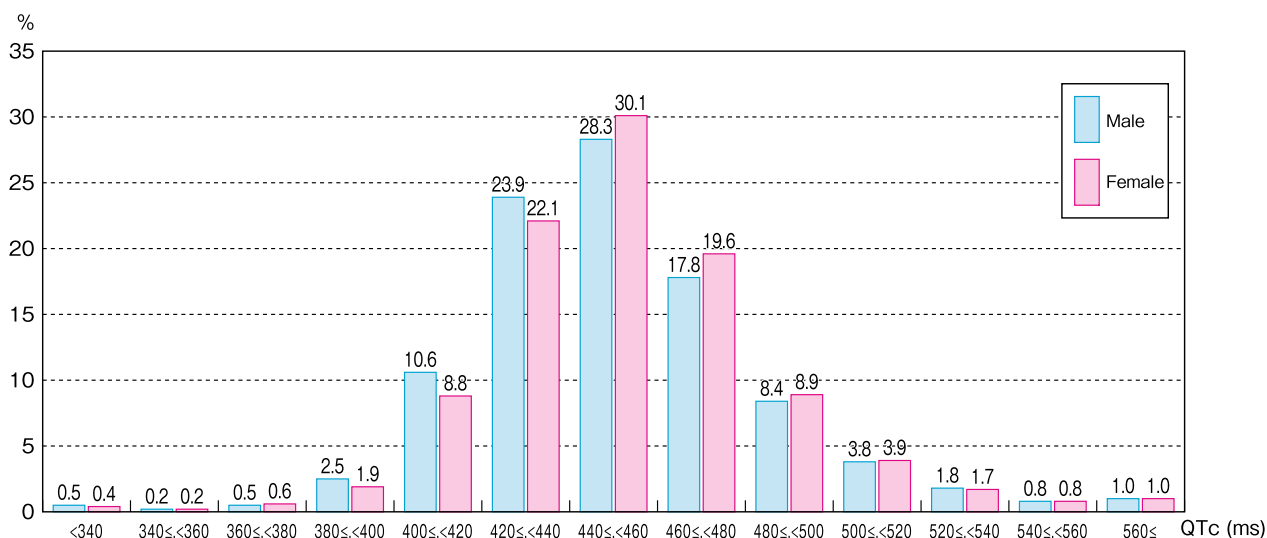
sis patients. According to a recently released guideline for fatal arrhythmias by the Japanese Circulation Society [20], QTc values of over 500 ms are associated with a high clinical risk of the onset of fatal arrhythmias, such as Torsades de Pointes. In this survey, 7.4% of the patients had QTc values of over 500 ms.

**Gender difference** As is clear from the didactically standard value of the Bazett QTc in the general population (360 ms–450 ms in women and 350–440 ms in men), gender differences are known to exist in the QTc. Figure 44 and Additional file 1: Table S44 shows the distributions of the QTc in the men and women included in our survey, which reveals no significant difference in the mean QTc value between the women ( $452 \pm 37$  ms) and men ( $450 \pm 37$  ms). The proportion of  $QTc \geq 500$  ms is also similar (7.4%) in women and men.

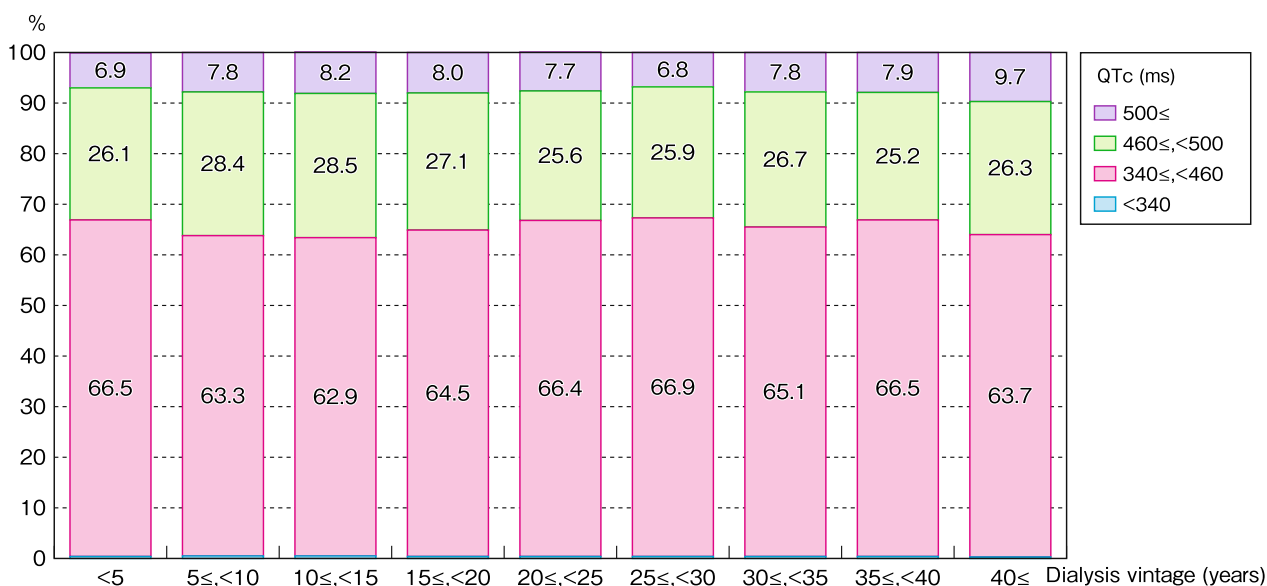
**Association with the dialysis vintage** A previous longitudinal observational study showed that the QTc interval increases as the duration of hemodialysis increases [21]. This survey investigated the association of QTc with the dialysis vintage to confirm this relationship. We compared the proportions of patients in the four QTc categories of < 340 ms, 340–459 ms, 460–499 ms, and  $\geq 500$  ms in 9 dialysis vintage categories. As shown in Fig. 45 and Additional file 1: Table S45, there is no apparent relationship between the QTc and the dialysis vintage. The incidence of patients with  $QTc > 500$  ms was lowest among those with less than five years of dialysis vintage (6.9%), and highest among those on dialysis for 40 years or more (9.7%).



**Fig. 43** QTc in patients without atrial fibrillation, 2019. QTc Corrected QT interval



**Fig. 44** Gender and QTc in patients without atrial fibrillation, 2019. QTc Corrected QT interval



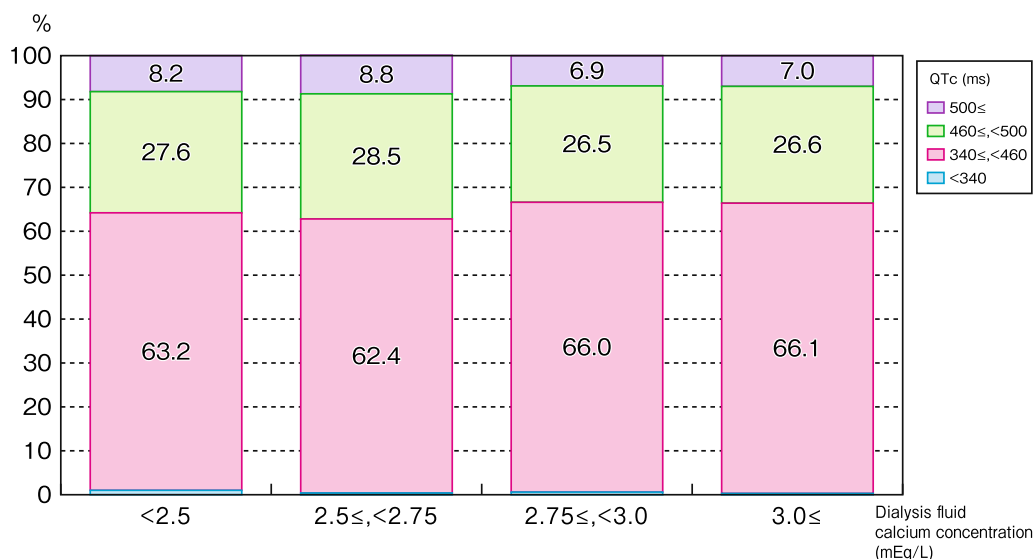
**Fig. 45** Dialysis vintage and QTc in patients without atrial fibrillation, 2019. QTc Corrected QT interval

**Association with the dialysate calcium concentration** It is reported that prolongation of the QTc is seen more often in patients treated using relatively low dialysate Ca concentrations [1]. Figure 46 and Additional file 1: Table S46 depict the proportion of patients in the four QTc categories of 340 ms, 340–459 ms, 460–499 ms, and 500 ms by four dialysate Ca concentration groups (2.5 mEq/L, 2.5–2.75 mEq/L, 2.75–3.0 mEq/L, and > 3.0 mEq/L). The mean QTc (ms) values were 451 ± 38, 453 ± 38, 450 ± 37, and 450 ± 35 ms in the <2.5 mEq/L, 2.5–2.75 mEq/L,

2.75–3.0 mEq/L, and > 3.0 mEq/L dialysate concentration groups, respectively. No significant associations of the mean QTc or proportion of patients in the four QTc categories with the dialysate Ca concentration were found.

**Association with the serum calcium concentration** Based on the serum albumin-corrected Ca concentrations pre-HD, patients with serum Ca concentrations in the range of less than 7.5 mg/dL to 11.5 mg/dL or more were classified into ten groups with an increment of 0.5 mg/dL. The





**Fig. 46** Dialysis fluid calcium concentration and QTc in patients without atrial fibrillation, 2019

serum albumin-corrected calcium concentration was calculated by Payne’s formula. The mean QTc (ms) values were 459 ± 45, 460 ± 35, 455 ± 34, 452 ± 35, 450 ± 36, 448 ± 39, 447 ± 37, 447 ± 40, 447 ± 42, and 447 ± 45 ms, respectively, in the lowest to highest serum Ca concentration groups, showing that the QTc was longer in the lower Ca concentration groups (Fig. 47a and Additional file 1: Table S47). In particular, the QTc interval sharply increased in the patient groups with serum Ca concentrations of less than 8.5 mg/dl, the lower limit of the normal serum Ca concentration range. The proportion of patients with QTc > 500 ms was 12.9% in the patient group with a mean serum Ca concentration of less than 7.5 mg/dL (Fig. 47b and Additional file 1: Table S47).

**Atrial fibrillation (AF)**

Since patients with CKD and ESKD show an accumulation of known risk factors for AF, AF is reported to have a high incidence and prevalence in dialysis patients [22]. AF is well-known as one of the most critical risk factors for the development of ischemic cerebrovascular stroke, which could have a poor prognosis or lead to impaired quality of life. Another problem of AF is tachycardia occurring during a hemodialysis session. It could cause hypotension and necessitate discontinuation of the HD session. The 2019 survey investigated whether the patients had AF as evaluated by a routine resting 12-lead ECG. We received information about the presence or absence of AF for 249,207 patients out of the total survey population of 332,599 patients. The judgment was made on a single measurement of resting 12-lead ECG; a single ECG reading of AF rhythm cannot differentiate between

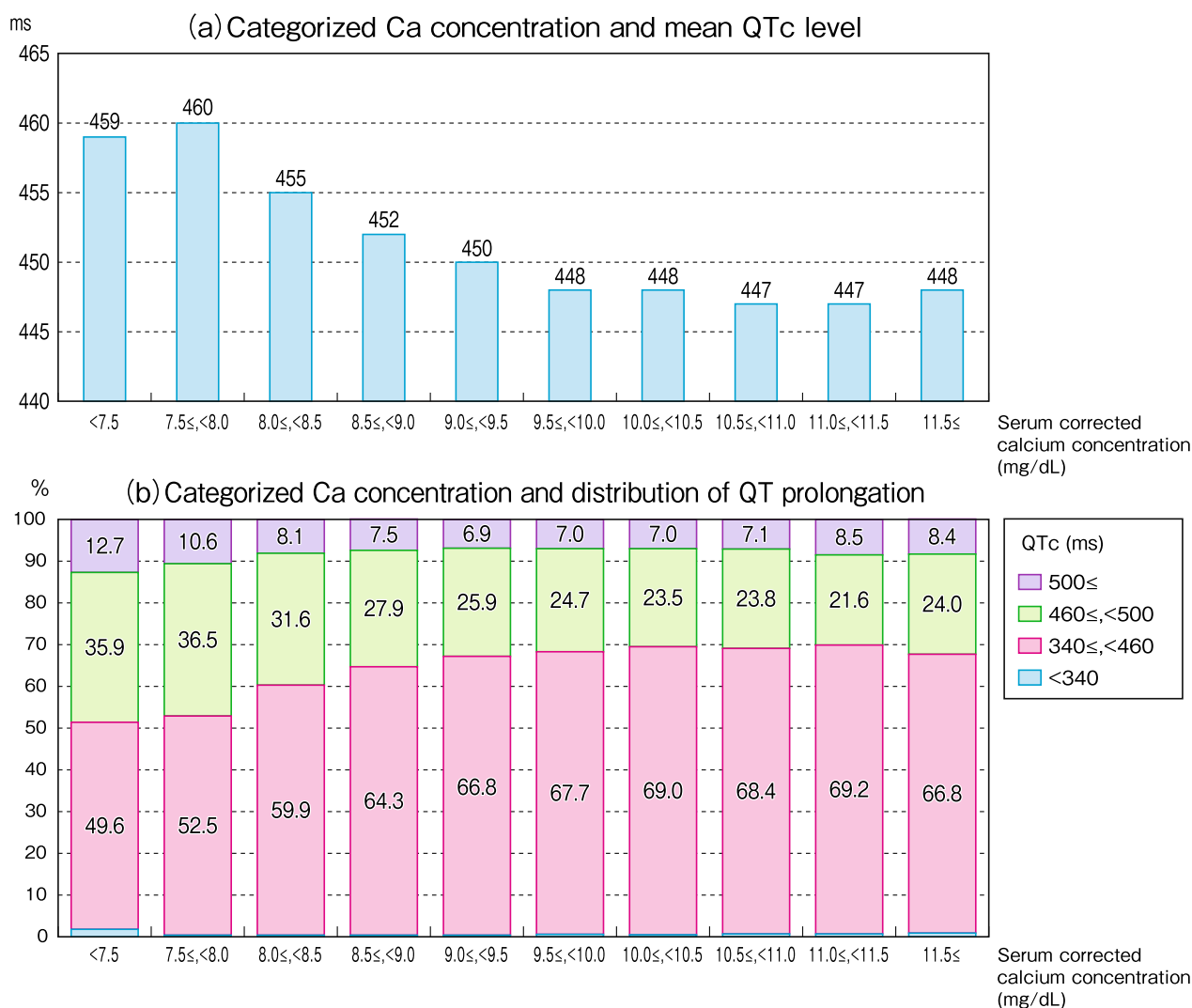
paroxysmal and chronic AF; conversely, a normal rhythm may overlook paroxysmal AF. These are the limitations of our study.

*Association with the age and dialysis vintage* Figure 48 and Additional file 1: Table S48 depicted the prevalence of AF in 15 groups classified by the combination of 5 dialysis vintages and three age groups. A long-dialysis vintage group tended to show a higher prevalence of AF in each age group. About 20% of patients suffered AF in the group with an age of 75 or more and a dialysis vintage of 30 years or more. In contrast, only about 3% of patients had AF in the group with an age of less than 65 and a dialysis vintage of less than five years.

*Association with the dialysis modality* The prevalence of AF by dialysis modality showed 8.0%, 7.6%, and 4.9% of patients on hemodialysis, hemodiafiltration, and peritoneal dialysis, respectively (Fig. 49 and Additional file 1: Table S49). We cannot draw any causal relationship with the dialysis modality because of the cross-sectional nature of the survey.

**Chapter 7: history of kidney donation**

In Japan, 90% of kidney transplantations are living-donor kidney transplantations [23]. Some of the kidneys were transplanted from donors with advanced age, hypertension, or diabetes (expanded criteria donors). Although the safety of living kidney donors is important, the rate of occurrence of end-stage renal disease after a kidney donation in Japan is unclear. According to a report by the Japanese Society for Clinical Renal Transplantation



**Fig. 47** Serum corrected calcium concentration and QTc in patients without atrial fibrillation, 2019

and the Japanese Society for Transplantation, one or two donors were initiated on dialysis during the six-year period after kidney transplantation [23]. However, the problem with this study was that the response rate to the survey on the donor’s prognosis was not sufficiently high. Therefore, in 2019, the survey included a question on the history of kidney donation/year of donation in patients undergoing chronic dialysis treatment; this was the first survey on the history of kidney donation in the annual survey of the JRDR.

A total of 231,140 (69.5%) patients responded to this survey. Among these patients, 181 (0.078%) had a history of kidney donation (Table 7). However, the kidney donation in 21 of these 181 patients was recorded after the initiation of dialysis, possibly erroneous. Of the remaining

160 patients after the exclusion of these 21 patients, 104 patients responded to the question on the year of kidney donation. We calculated the duration from kidney donation to dialysis initiation, assuming June was the month of kidney donation. The mean duration from kidney donation to dialysis initiation was 206 ± 124 months. The duration in 13 patients (12.5%) was under 60 months, and that in 19 patients (18.3%) was from 60 to 120 months (Fig. 50, Additional file 1: Table S50). The number of patients for whom the duration was determined to be under 60 months was different from that reported in a previous paper [23]. However, the history of kidney donation may be interpreted with caution because a considerable number of patients were recorded to donate their kidneys after dialysis initiation.

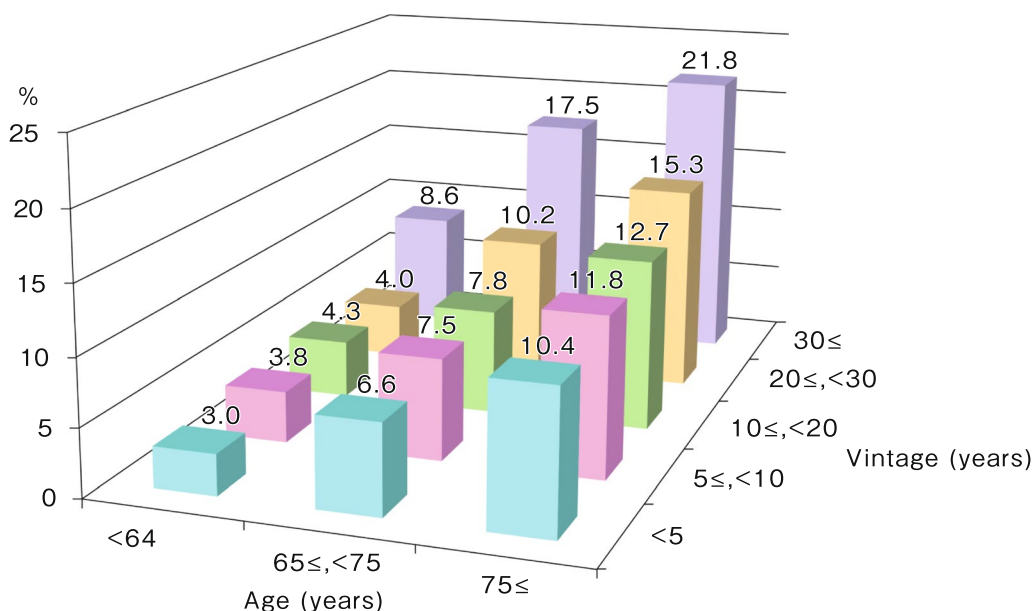


Fig. 48 Prevalence of atrial fibrillation by age, vintage of dialysis,2019

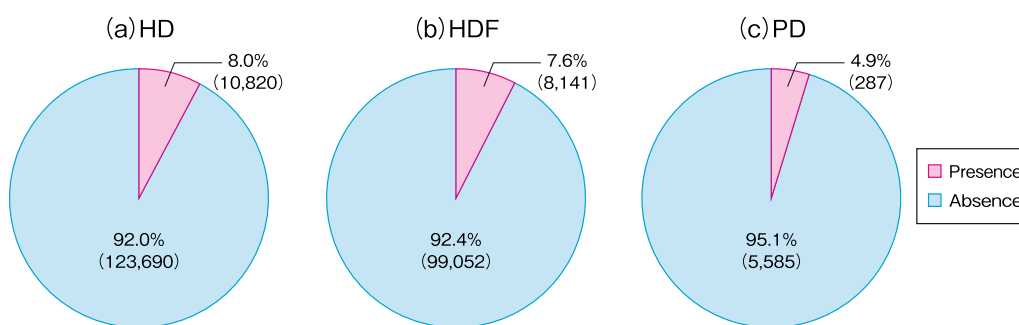


Fig. 49 Treatment modality and presence of atrial fibrillation, 2019

Table 7 Previous kidney donation, 2019

	Without donation	With donation	Subtotal	Unspecified	No information available	Total
Number of patients	230,959	181	231,140	3576	97,883	332,599
(%)	(99.9)	(0.1)	(100.0)			

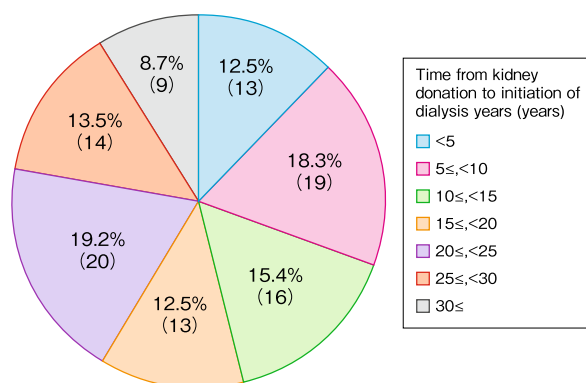
\* The data were obtained from the patient survey

\* Patients with kidney donation includes 21 patients whose kidney donation year was after the year of initiation (initiation year—kidney donation year ≤ 0)

**Conclusion**

According to the 2019 JRDR annual data report shows that the number of patients undergoing chronic maintenance hemodialysis in Japan is continuing to increase (estimated to be 344,640 at present), although at a slower rate. Since it was forecasted in 2012 that the number would reach its peak in 2021, it is necessary to continue

to closely monitor the change in the dialysis population size in the future. The population of the elderly undergoing chronic maintenance hemodialysis in Japan is still growing; the average age of the incident patients in the latest survey was 70.42 years, which exceeded 70 years for the first time, and the average age of the prevalent patients was 69.09 years.



**Fig. 50** Patients with kidney donation, time from kidney donation to initiation of dialysis (year), 2019

The most prevalent primary diagnosis in the incident patients has been diabetes mellitus since 1998, followed by chronic glomerulonephritis from 1998 to 2018. In 2019, nephrosclerosis replaced chronic glomerulonephritis in second place. The proportion of incident patients with diabetic nephropathy has been decreasing in recent years.

The quality of the dialysis fluid used regarding biological contamination was very high in Japan, and a high level of compliance with the JSDT standard has been maintained. Compliance with the JRDR standard for chemical contamination, for which the JRDR started investigations, including measurements of chemical contaminants and residual chlorine, in 2017, is gradually improving. Continuous surveys by the JRDR played a role in raising awareness about the chemical contamination of dialysis fluid.

The continuing increase in the number of patients receiving HDF, PD, and HHD suggests that renal replacement therapy modalities are becoming diverse. The proportion of patients receiving combined PD plus HD, a characteristic form of RRT used in Japan, was about 20%, and has remained stable for the past few years.

The 2019 survey was the first comprehensive survey conducted in 10 years, after 2009, to determine the current treatment status of CKD-MBD. Calcimimetics, which was launched during this interim period, were used in 31.2% of patients. This class of drugs significantly changed the clinical practice patterns for the management of CKD-MBD, with more patients attaining therapeutic goals and fewer patients requiring parathyroidectomy. Hypocalcemia is a possible side effect of calcimimetics, together with non-vitamin D use and dialysis with low-calcium dialysis fluid. It may increase the risks of arrhythmias and sudden death. ECG findings investigated for the first time in the 2019 survey revealed that the QTc interval was longer in dialysis patients, especially

with hypocalcemia. Based on this information, we should make safe clinical practice patterns and guideline recommendations.

The history of kidney donation was investigated for the first time. This study revealed that more patients developed end-stage kidney disease after their kidney donation than in previous studies. More detailed information will provide us with knowledge about the safety of kidney donors.

**Supplementary Information**

The online version contains supplementary material available at <https://doi.org/10.1186/s41100-023-00478-z>.

**Additional file 1:** The detailed data presented in the text as figures are proved in supplementary tables as Additional File 1.

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**Author contributions**

All authors participated in designing this survey about which items should be collected. NH, JH, MT, NJ, and SG wrote the draft version of this article. All authors finalized and approved the manuscript.

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**Availability of data and materials**

Anyone who wants to use the data and materials from the current manuscript WITHOUT modifications can use all data and materials freely only by citing this article and denoting the data obtained from the JRDR. Anyone who wants to use the data and materials from the current manuscript WITH modifications, any re-calculations, or something must state the following sentence in their publication. "The data reported here have been provided by the Japanese Society for Dialysis Therapy (JSDT). The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy or interpretation of the JSDT."

**Declarations**

**Ethics approval and consent to participate**

The ethical committee of JSDT approved the JSDT registry; the approval number is 1. The aims of the JSDT Renal Data Registry (JRDR) were well explained to the participating dialysis patients through the dialysis facilities. It does not

always need to get the documented approval form from the patients because all the collected data had already existed before this survey, and there were no new interventions. The original data had been totally anonymized, so there were no risks of deteriorating the privacy of the dialysis facilities or patients. The data presented in the current manuscript does not contain any images, videos, or voice recordings that might have a risk for identifying an individual.

#### Consent for publication

Not applicable to this article.

#### Competing interests

Prof Masanori Abe MD is the deputy editor of this journal. Prof Norio Hanafusa MD is the associate editor of this journal. Prof Tetsuya Ogawa MD is the editorial board member of this journal.

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